Health, Bioethics and the LAW

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MAURICE N. CAUCHI
KEVIN AQUILINA
BRIDGET ELLUL

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This publication gives the position of the Law as at 31st December 2005.

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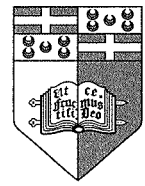

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FOREWARD

This is a necessary book. It comes in the wake of intense public debate and controversy in the local media in Malta, as well as in the Social Affairs Committee of the House of Representatives which has dedicated several sittings to the discussion of bioethics and its manifold socio-legal implications. Indeed the book attempts to inquire into the thorny ethical and legal issues which have cropped up after the modern advances in the medical sciences. It is therefore a pleasure for me to introduce it to the reader; this book is the fruit of joint research carried out by academic members of the University of Malta's Faculties of Law and of Medicine on health, bioethics and the law. It is not intended to be a final word but in reality a reply to the more disquieting issues which have been raised; eventual legislation on the matter will not outdate it as it will serve as a guide to the uninitiated in better understanding such law.

This book sets out the provisions of Maltese Law dealing with health, bioethics and the law in an organised and user-friendly manner. It also discusses the various international and regional contributions which have been made in this delicate field by way of, *inter alia*, international and regional conventions, declarations, recommendations and plans of action which are undoubtedly pertinent to a study of this nature. The relative documents of the European Union on this topic are also dealt with especially now that Malta since 1st May 2004 is a member of the European Union.

This publication demonstrates how complex the law is in this field of human knowledge. It can be seen also that over the last few years there has been an entire overhaul of Maltese law concerning health and the health sector but, this notwithstanding, there are certain areas where Malta is still lagging behind. Foremost amongst these is the complete lack of regulation in relation to assisted reproduction, including regulation relating to in-vitro fertilisation and ante-natal diagnosis. These and other aspects need undoubtedly further deep thought with a view to regulation, for as things stand today, in certain cases much is left to the discretion of the medical practitioner, with no local guidelines provided to act as eye openers for the profession, as to how it should conduct itself in such instances. Yet, where there are *lacunae* in the law, the authors have

directed the reader to foreign sources which may possibly be of assistance to the local authorities in adopting similar codes of practice or guidelines.

Health, Bioethics and the Law is a compendium of legislation – both primary and secondary – on the subject under review. It serves as a ready reckoner for those members of the medical profession who do not have the time to stay researching where to find the pertinent provisions of the law dealing with health issues and, to this extent, it makes life easier for one and all. This *vademecum* is also of interest to the law practitioner, to medical and law students and, generally, to the various professions referred to in this publication itself who have a role to play within the health sector.

One augurs that this publication will be given its due recognition and importance not only by the academic community but also by the legislator who, eventually, will have to enact a law, as several other states have already done, to regulate bioethical issues for the common good of humankind.

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INTRODUCTION

The aim of this book is to discuss the various aspects of Maltese legislation that relate to bioethical issues.

The approach has been to introduce the bioethical issue in question, then to review Maltese legislation that has any bearing (in a wide sense) on the topic. This is followed, where possible, by aspects of relevant international and/or European legislation relating to the topic, emphasizing those which have been adhered to by Malta or have been incorporated within Maltese law.

This publication gives the position of the Law as at 31st December 2005.

Disclaimer: *The information relating to Primary and Subsidiary Legislation provided here is meant only for general guidance. While we have made every effort to ensure accuracy, we disclaim any responsibility for any inaccuracies there may be.*

Chapter 1

Human Dignity, Rights and Freedoms

1. Human Dignity

01.01

Human dignity is not to be taken for granted. A number of philosophers have attacked the concept recently. John Harris, for instance, finds no value whatsoever in the concept of 'dignity of the human person'. Likewise, Peter Singer would not accord human dignity to the embryo or fetus, and grudgingly admits that respect for a human being should begin only some time after birth (a date 28 days after delivery has been suggested!).

It is therefore relevant and important for such concepts to be defined and emphasised. The concept of 'dignity' has had a respectable history in European philosophy, and has been accepted as part of our intellectual heritage, but it seems that these days, it has to be justified rather than accepted automatically.

In general, by dignity we mean that respect owed to a human being by virtue of being human. We believe that anyone deserves respect, irrespective of whether s/he is young or old, healthy or diseased, sane or lacking full mental capacity. We also extend the concept to include embryos and fetuses from the very first moment of conception, although considerable controversy exists in Europe in relation to the amount of dignity due to embryos.

01.02

Related also to human dignity is the question of 'personhood'. In the Catholic tradition, there is no distinction between a human being and a person. In English law as well as in most European countries, there is, however, a clear distinction, with the term

'person' being reserved for those who have rights in law, and the term is therefore applicable only to infants after birth.[1]

01.03

The concept of dignity is well entrenched in international instruments, including the ***Universal Declaration of Human Rights***, which stipulates that: 'All human beings are born free and equal in dignity and rights,'[2] as well as in the European ***Convention on Human Rights and Biomedicine***,[3] which is designed to preserve human dignity, rights and freedoms, through a series of principles and prohibitions against the misuse of biological and medical advances.

01.04

The concept of human dignity is referred to in Maltese legislation but it is not specifically defined. It is not mentioned at all in the ***Constitution of Malta***, which, however, makes several references to rights and freedoms (see below).

Reference to human dignity may be found in the ***Broadcasting Act*** which contains a Code for Advertisements, Teleshopping and Sponsorships[4] and, under general standards, states: 'Advertising and teleshopping shall not prejudice respect for human dignity.'

The ***Malta Communications Authority Act*** establishes the Malta Communications Authority,[5] one of whose functions is 'the protection of morals and respect for the dignity of the human person.'[6]

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[1] Generally constitutional law does not define human beings or persons but persons are granted the right to life. Even if a fetus is accorded rights, these are only realised if the fetus is born alive. For instance, in the UK, a neonate with congenital disability has to live for 48 hours before being able to recover damages for negligence.

In Maltese law, the embryo or fetus is accorded some rights but not on equal terms with living persons, e.g. abortion has a milder penalty at law than homicide and also less than grievous bodily harm to a pregnant woman, which results in a miscarriage.

[2] *Universal Declaration of Human Rights*, 1948, article 1.

[3] *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, Council of Europe, 1997.

[4] *Broadcasting Act*, Third Schedule, paragraph 1(a).

[5] *Malta Communications Authority Act*, article 3.

[6] *Malta Communications Authority Act*, article 4(1)(a)(v).

The ***Press Act*** emphasises the right of reply for any person whose dignity has been attacked in the media. It states that: 'Any person whose actions or intentions have been misrepresented or who has been subjected to an attack on his honour, dignity or reputation, or to an intrusion into his private life by means of, or in a newspaper, or in any broadcast, shall be entitled to demand and to have published forthwith, free of charge, in the same newspaper or on the same broadcasting medium, as the case may require, a statement by way of contradiction or explanation.'[7]

The ***Code of Organisation and Civil Procedure*** refers to the need to treat persons, including debtors, with dignity. In relation to seizure of property from a debtor, it states that 'the debtor may be allowed to use or maintain in possession of such items of the property seized as the court may authorise if it considers that such items are normally required by an average household for decent living to maintain the human dignity of the debtor and his family.'[8]

The ***Criminal Code*** addresses human dignity of the victim. When referring to persons subject to prosecution, it mentions persons committing an offence against a 'protected person', one class of such a person being defined as one who 'is a representative or an official of a State or an official or agent of an international organisation of an intergovernmental character, [who] is entitled under international law to special protection from attack on his person, freedom or dignity.'[9]

It also defines ill treatment of children under twelve to include 'neglecting the child's need for adequate nutrition, clothing, shelter, and protection from harm, persistently offending the child's dignity and self-esteem in a serious manner and persistently imposing upon the child age-inappropriate tasks or hard physical labour.'[10]

The ***Commissioner for Children Act*** sets up a Commissioner, one of whose guiding principles should be 'that all children are to be treated with dignity, respect and fairness.'[11]

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[7] *Press Act*, article 21(1).
[8] *Code of Organisation and Civil Procedure*, article 298(1).
[9] *Criminal Code*, article 5(3)(b).
[10] *Criminal Code*, article 247A(2).
[11] *Commissioner for Children Act*, article 10(b).

These selections highlight the concept of 'dignity' within Maltese legislation and indicate that it should be respected even when the person concerned has in some way broken the law.

2. Discrimination

01.05

Discrimination refers to the process of making distinctions between persons based on physical, mental, ethnic or other characteristics, often resulting in inequities and inequalities of treatment. Although the practice is universally condemned, it is a very frequent human failing and needs to be constantly guarded against.

The expression 'discriminatory' is defined in the ***Constitution of Malta***. An action is discriminatory when it metes out 'different treatment to different persons attributable wholly or mainly to their respective descriptions by race, place of origin, political opinions, colour, creed or sex whereby persons of one such description are subjected to disabilities or restrictions to which persons of another such description are not made subject or are accorded privileges or advantages which are not accorded to persons of another such description.'[12]

The ***Employment and Industrial Relations Act*** defines 'discriminatory treatment' as 'any distinction, exclusion or restriction which is not justifiable in a democratic society including discrimination made on the basis of marital status, pregnancy or potential pregnancy, sex, colour, disability, religious conviction, political opinion or membership in a trade union or in an employers' association.'

The ***European Convention Act***[13] incorporates the ***European Convention for the Protection of Human Rights and Fundamental Freedoms***, and in relation to Article 14, ensures the enjoyment of these rights without 'discrimination on any ground such as sex, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status.'

The following are the major variants of discrimination and the relevant corresponding laws available in Maltese legislation.

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[12] *Constitution of Malta,* article 45(3).

[13] *European Convention Act,* First Schedule, in relation to article 14.

a. Sexual discrimination

01.06

In Maltese legislation we find many instances of injunctions against sexual discrimination. In relation to equal rights of men and women, the ***Constitution of Malta*** states that: 'The State shall promote the equal right of men and women to enjoy all economic, social, cultural, civil and political rights and for this purpose shall take appropriate measures to eliminate all forms of discrimination between the sexes by any person, organisation or enterprise; the State shall in particular aim at ensuring that women workers enjoy equal rights and the same wages for the same work as men.'[14]

The ***Equality for Men and Women Act*** defines discrimination as one that is 'based on sex or because of family responsibilities and includes the treatment of a person in a less favourable manner than other person has been or would be treated on the grounds of sex or because of family responsibilities.'[15]

Discrimination is presumed to be based on sex or because of family responsibilities, when one:

(a) gives less favourable treatment, directly or indirectly, to men and women on the basis of their sex or because of family responsibilities;
(b) treats a woman less favourably for reasons of actual or potential pregnancy or childbirth; and
(c) treats men and women less favourably on the basis of parenthood, family responsibility or for some other reason related to sex.

'Sexual harassment' means the unlawful activities listed in the Act, which defines sexual harassment as follows:

'(a) to subject other persons to an act of physical intimacy; or
(b) to request sexual favours from other persons; or
(c) to subject other persons to any act or conduct with sexual connotations, including spoken words, gestures or the pro-

[14] *Constitution of Malta*, article 14. See also article 45(3) and Chapter 14: Societal Issues.
[15] *Equality for Men and Women Act*, article 2.

duction, display or circulation of any written words, pictures or other material, where the act, words or conduct is unwelcome to the persons to whom they are directed and could reasonably be regarded as offensive, humiliating or intimidating to the persons to whom they are directed; or

(d) the persons so subjected or requested are treated less favourably by reason of such persons' rejection of or submission to such subjection or request, it could reasonably be anticipated that such persons would be so treated.'[16]

These actions are also covered in the ***Employment and Industrial Relations Act***, with regard to the behaviour of the employer or employee. It is unlawful to subject a person to 'any unwelcome act, request or conduct, including spoken words, gestures or the production, display or circulation of written words, pictures or other material, which in respect of that person is based on sexual discrimination and which could reasonably be regarded as offensive, humiliating or intimidating to such person.'[17]

The ***Employment and Industrial Relations Act*** makes it unlawful for any person to discriminate between applicants for a job:[18]

(a) when advertising or offering employment to applicants; and
(b) in regard to conditions of employment for those already employed.

Discriminatory treatment is here meant to include:

(a) employing a less qualified person than a person of the opposite sex;
(b) giving terms of payment or employment conditions less favourable than would otherwise apply for the same work; and
(c) distribution of tasks so that an employee is assigned less favourable status.

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[16] *Equality for Men and Women Act*, article 9.

[17] *Employment and Industrial Relations Act*, article 29. See *Equality for Men and Women Act*, article 9(1)(c).

[18] *Employment and Industrial Relations Act*, article 26.

This Act also deals with victimisation[19] and harassment.[20] It makes it unlawful to victimise a person who:

(a) makes a complaint to the lawful authorities; or
(b) initiates or participates in proceedings for redress on grounds of alleged breach of the provisions of this Act; or
(c) discloses information to a designated public regulating body regarding alleged illegal or corrupt activities committed by his/her employer or in his/her name.

Any person who alleges that an employer is in breach of these conditions may lodge a complaint to the Industrial Tribunal within three months of the alleged breach.[21]

b. Race, place of origin, political opinions, colour, and creed

01.07

The ***Constitution of Malta*** offers protection from discrimination on grounds of race, place of origin, political opinions, colour, creed or sex. It states that 'no law shall make any provision that is discriminatory either of itself or in its effect.'[22] It adds: 'no person shall be treated in a discriminatory manner by any person acting by virtue of any written law or in the performance of the functions of any public office or any public authority.'[23]

One of the main objectives of the Police Force is 'to apply the law without discrimination on any ground such as sex, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status.'[24] The Police Board, established in 2002, has the function 'to inquire and report on any complaint made to it by an officer against treatment which he deems prejudicial or discriminatory, or causes him undue distress.'[25]

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[19] *Employment and Industrial Relations Act*, article 28.
[20] *Employment and Industrial Relations Act*, article 29.
[21] *Employment and Industrial Relations Act*, article 30.
[22] *Constitution of Malta*, article 45(1).
[23] *Constitution of Malta*, article 45(2).
[24] *Police Act*, article 4(c).
[25] *Police Act*, article 49(b).

c. Discrimination and advertising

01.08

Advertising and sponsorship which causes 'discrimination on grounds of race, sex or nationality' is prohibited.[26] The ***Broadcasting Act*** also prohibits discrimination with respect to issuing of licences for broadcasting. It states: 'An applicant whose application has been refused by the Authority and who feels that the Authority has not acted in conformity with the rules of natural justice, or that it has acted in a manner which is grossly unreasonable or with undue discrimination, or whose application has been pending for at least four months, may appeal against such decision or delay to the Court of Appeal.'[27]

d. Communications

01.09

The ***Malta Communications Authority Act*** sets up the Malta Communications Authority, one of whose functions is to 'ensure non-discrimination and equality of treatment in matters related to communications.'[28] The ***Electronic Communications (Regulation) Act*** refers to the development of the internal market by ensuring that 'there is no discrimination in the treatment of undertakings providing electronic communications networks and services and associated facilities.'[29] Also a 'vertically integrated undertaking, over which the Government of Malta or of a Member State has effective control, which provides electronic communications networks and which is in a dominant position shall not discriminate in favour of its own activities.'[30]

e. Employment

01.10

The ***Constitution of Malta***[31] provides that the Employment Commission is 'to ensure that, in respect of employment, no distinction, exclusion, or preference that is not justifiable in a

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[26] *Broadcasting Act*, Third Schedule, paragraph (1)(b).
[27] *Broadcasting Act*, article 11(3).
[28] *Malta Communications Authority Act*, article 4 (1)(b).
[29] *Electronic Communications (Regulation) Act*, article 4(3)(b).
[30] *Electronic Communications (Regulation) Act*, article 21(1).
[31] *Constitution of Malta*, article 120 (8).

democratic society is made or given in favour or against any person by reason of his political opinions.'

In relation to engagement (not made after a public examination) of employees by government and government owned or controlled bodies and companies, the ***Employment and Training Services Act*** states that any person who 'shows favour to, or uses discrimination against, any person for employment with any employer . . . on the grounds of race, colour, sex, creed or on the grounds of his party or other political beliefs or associations . . . shall be guilty of an offence against this Act.'[32]

The ***Tribunal for the Investigation of Injustices Act***[33] provides that the Tribunal has 'the power to hear and determine any written complaint made by any person who claims to have sustained injustice in consequence of any undue distinction, exclusion or preference which has been made or given to his prejudice, or of any disability or restriction to which he has been subjected' regarding appointments, promotions or transfers, recruitment for employment, licences or permits required by law and any other matter approved by the House of Representatives. This applies to public officers or members or employees of any body established by law.[34]

f. Punishment

01.11

The ***Criminal Code*** states that 'any public officer or servant or any other person acting in an official capacity who intentionally inflicts on a person severe pain or suffering, whether physical or mental . . . for any reason based on discrimination of any kind, . . . shall, on conviction, be liable to imprisonment for a term from five to nine years.'[35] One of the reasons mentioned is obtaining information or a confession, an important point as it relates to police practice outside lawful sanctions or measures and which amounts to torture.[36]

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[32] *Employment and Training Services Act*, article 15(6)(b).
[33] *Tribunal for the Investigation of Injustices Act*, article 6(1).
[34] See also *Equality for Men and Women Act*, mentioned above.
[35] *Criminal Code*, article 139A.
[36] See also Chapter 14: Societal Issues.

g. Disability

01.12

Discrimination in relation to disabled persons is dealt with extensively in the ***Equal Opportunities (Persons With Disability) Act*** and the ***Disabled Persons (Employment) Act.*** Discrimination on the basis of disability coupled with the infringement of human rights and fundamental freedoms is incorporated within article 14 of the ***European Convention for the Protection of Human Rights and Fundamental Freedoms,*** which is listed in the First Schedule to the ***European Convention Act***. These are discussed in detail in **Chapter 8: Disability**.

3. Human Rights

01.13

It is stated in the ***Constitution of Malta*** that: 'Malta is a democratic republic founded on work and on respect for the fundamental rights and freedoms of the individual.'[37] 'Human Rights and Fundamental Freedoms' refer to those rights and freedoms which have been itemised in international Conventions as well as in Maltese law.[38]

Article 7 of the ***European Union Act,*** which came into force on 1st May 2004 amended subarticle (1) of article 65 of the ***Constitution of Malta***. The substituted article states: 'Subject to the provisions of this Constitution, Parliament may make laws for the peace, order and good government of Malta in conformity with full respect for human rights, generally accepted principles of international law and Malta's international and regional obligations in particular those assumed by the treaty of accession to the European Union signed in Athens on the 16th April, 2003.'

The fundamental rights and freedoms of the individual are enshrined in the ***Constitution of Malta.***[39] These rights may be

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[37] *Constitution of Malta*, article 1(1).

[38] See *European Convention Act*, 1987, article 2, article 3(1) and the First Schedule. Articles 2 to 18 of the *Convention for the Protection of Human Rights and Fundamental Freedoms* and Articles 1 to 3 of the *First Protocol* to the Convention, Articles 1 to 4 of the *Fourth Protocol*, Articles 1 and 2 of the *Sixth Protocol* and Articles 1 to 5 of the *Seventh Protocol* are reproduced in the First Schedule of the *European Convention Act*.

[39] *Constitution of Malta*, articles 32–46.

considered as 'negative rights' since they are meant to ensure that the individual enjoys liberties which belong to every person within society. They do not necessarily confer 'positive' rights or obligations, apart from the expectation that those in authority will ensure that there will be no interference with the enjoyment of such rights.

01.14

The following rights are guaranteed by the ***Constitution of Malta***:

Article:	**Rights and Freedoms**
32.	Fundamental rights and freedoms of the individual.
33.	Protection of right to life.
34.	Protection from arbitrary arrest or detention.
35.	Protection from forced labour.
36.	Protection from inhuman treatment.
37.	Protection from deprivation of property without compensation.
38.	Protection for privacy of home or other property.
39.	Provisions to secure protection of law.
40.	Protection of freedom of conscience and worship.
41.	Protection of freedom of expression.
42.	Protection of freedom of assembly and association.
43.	Prohibition of deportation.
44.	Protection of freedom of movement.
45.	Protection from discrimination on the grounds of race, etc.

a. Fundamental rights and freedoms of the individual

01.15

The ***Constitution of Malta*** states that 'every person in Malta is entitled to the fundamental rights and freedoms of the individual, that is to say, the right, whatever his race, place of origin, political opinions, colour, creed or sex, but subject to respect for the rights and freedoms of others and for the public interest, to each and all of the following, namely:

(a) life, liberty, security of the person, the enjoyment of property and the protection of the law;
(b) freedom of conscience, of expression and of peaceful assembly and association; and
(c) respect for his private and family life.'[40]

[40] *Constitution of Malta*, article 32.

The three basic freedoms are therefore considered to be: life and liberty, freedom of conscience and expression, and respect for private life. The Constitution also emphasises that these freedoms are conditional to respect for the rights and freedoms of others and to public interests in matters of defence, safety, morality and health.

(a) Right to life

01.16

The right to life is enshrined in the ***Constitution of Malta*** which says: 'No person shall intentionally be deprived of his life save in execution of the sentence of a court in respect of a criminal offence under the law of Malta of which he has been convicted.'[41] It is to be noted that the death sentence has been officially abolished since Malta ratified the ***Thirteenth Protocol*** to the ***Convention for the Protection of Human Rights and Fundamental Freedoms***.[42]

The use of force which results in the death of a person may be justified by law under certain circumstances. The ***Constitution of Malta*** states that 'a person shall not be regarded as having been deprived of his life in contravention of this article if he dies as the result of the use of force to such extent as is reasonably justifiable in the circumstances of the case –

(a) for the defence of any person from violence or for the defence of property;
(b) in order to effect a lawful arrest or to prevent the escape of a person lawfully detained;
(c) for the purpose of suppressing a riot, insurrection or mutiny; or
(d) in order to prevent the commission by that person of a criminal offence,

or if he dies as the result of a lawful act of war.'[43]

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[41] *Constitution of Malta*, article 33(1).

[42] Note that the *Sixth Protocol* to the *Convention for the Protection of Human Rights and Fundamental Freedoms* still reserved the death penalty in case of war. The *Thirteenth Protocol* (which entered into force in Malta in July 2003) abolished the death penalty in all circumstances.

[43] *Constitution of Malta*, article 33(2).

(b) Arbitrary arrest or detention

01.17

Persons are allowed to enjoy their liberty free from the fear of arbitrary arrest or detention.[44] A person may be deprived of his personal liberty as authorised by the law in several circumstances, including:

(a) 'in execution of the sentence or order of a court, whether in Malta or elsewhere, in respect of a criminal offence of which he has been convicted';[45]
(b) 'upon reasonable suspicion of his having committed, or being about to commit, a criminal offence';[46]
(c) 'in the case of a person who has not attained the age of eighteen years, for the purpose of his education or welfare';[47]
(d) 'for the purpose of preventing the spread of an infectious or contagious disease';[48]
(e) 'in the case of a person who is, or is reasonably suspected to be, of unsound mind, addicted to drugs or alcohol, or a vagrant, for the purpose of his care or treatment or the protection of the community';[49]
(f) 'for the purpose of preventing the unlawful entry of that person into Malta, or for the purpose of effecting the expulsion, extradition or other lawful removal of that person from Malta.'[50]

At the time of arrest or detention, a person should be informed of the reasons for his arrest or detention in a language that he can understand.

(c) Protection from forced labour

01.18

No person shall be required to perform forced labour, except under a sentence of a court, or except in a public emergency or when labour is required in pursuance of one's duties.[51]

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[44] *Constitution of Malta*, article 34.
[45] *Constitution of Malta*, article 34(b).
[46] *Constitution of Malta*, article 34(f).
[47] *Constitution of Malta*, article 34(g).
[48] *Constitution of Malta*, article 34(h).
[49] *Constitution of Malta*, article 34(i).
[50] *Constitution of Malta*, article 34(j).
[51] *Constitution of Malta*, article 35.

(d) Protection from inhuman treatment

01.19

No person shall be subjected to inhuman or degrading punishment or treatment. The imposition of collective punishments is unlawful.[52]

(e) Protection of person and property

01.20

In Maltese law, 'every person who is charged with a criminal offence is presumed to be innocent until he is proved or has pleaded guilty.'[53] Personal protection is also ensured and the law guarantees that any person 'charged with a criminal offence, unless the charge is withdrawn, be afforded a fair hearing within a reasonable time by an independent and impartial court established by law.'[54]

Protection of property is ensured under the ***Constitution of Malta.***[55] Where compulsory acquisition is required, adequate compensation must be made.[56] Furthermore, it gives protection for privacy of the home and other property.[57] This includes protection against the search of a person or his property or entry by others on his premises except in certain specified situations (e.g. in the interests of defence, public safety and order, public health, etc.).[58]

(f) Freedom of conscience and worship

01.21

The ***Constitution of Malta*** also provides for the protection of freedom of conscience and worship. It states that: 'All persons in Malta shall have full freedom of conscience and enjoy the free exercise of their respective mode of religious worship.'[59]

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[52] *Constitution of Malta,* article 36(3).
[53] *Constitution of Malta,* article 39(5).
[54] *Constitution of Malta,* article 39(1).
[55] *Constitution of Malta,* article 37.
[56] This is without contravention of laws relating to acquisition of property in execution of court judgements or orders or in satisfaction of any tax, rate or due or because the property is dangerous to health of humans or animals.
[57] *Constitution of Malta,* article 38.
[58] *Constitution of Malta,* article 38.
[59] *Constitution of Malta,* article 40(1).

A person can object to be instructed in religion once he reaches the age of sixteen, and parents or guardians of a child under that age may object to the child under their care receiving any religious instruction.[60]

(g) Protection of freedom of expression

01.22
This is enshrined under article 41 of the ***Constitution of Malta,*** which states: 'No person shall be hindered in the enjoyment of his freedom of expression, including freedom to hold opinions without interference, freedom to receive ideas and information without interference, freedom to communicate ideas and information without interference (whether the communication be to the public generally or to any person or class of persons) and freedom from interference with his correspondence.'

Exceptions include the following: the interests of defence, public safety, public order, public morality or decency and public health; the protection of reputations, rights and freedoms of other persons, including persons concerned in legal proceedings; the prevention of disclosure of information received in confidence; the protection of parliamentary privileges and the protection of means of communication.

(h) Protection of freedom of peaceful assembly and association

01.23
Everyone has the right 'peacefully to assemble freely and associate with other persons and in particular to form or belong to trade or other unions or associations for the protection of his interests.'[61]

(i) Freedom of movement

01.24
This refers to 'the right to move freely throughout Malta, the right to reside in any part of Malta, the right to leave and the right to

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[60] *Constitution of Malta,* article 40(2).
[61] *Constitution of Malta,* article 42(1).

enter Malta.' This is guaranteed under article 44 of the ***Constitution of Malta***. This holds for all Maltese citizens, except in certain circumstances, e.g. under court order for such limitations, including leaving the islands, and restrictions that are reasonably required in the interests of defence, public safety, public order, public morality or decency, or public health.

b. Other rights enshrined in the Constitution

01.25
A number of other justicible and non-justicible rights are referred to, by the ***Constitution of Malta,*** namely:

(a) The right to work: article 7
(b) Equal rights of men and women workers: article 14
(c) Protection from discrimination on the grounds of race: article 45
(d) Protection of pension rights: article 113.

A number of these issues have been discussed above (under 'Discrimination') or will be discussed in the following chapters.[62]

c. Other legislation relating to human rights

(a) The *European Convention Act*

01.26
The ***European Convention Act*** incorporates into Maltese law the relevant articles, which protect human rights and freedoms, which are enshrined in the ***European Convention for the Protection of Human Rights and Fundamental Freedoms*** and in the ***First, Fourth, Sixth, Seventh and Thirteenth Protocols***. These articles are listed in the First Schedule to the Act and the following is a summary of the rights as they appear in the Schedule. Some of these rights are also guaranteed by the ***Constitution of Malta***.

Articles 2 to 14 of the ***Convention for the Protection of Human Rights and Fundamental Freedoms*** refer to the following:

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[62] In so far as articles 7 and 14 are concerned, they are not enforceable in a court of law, according to article 21 of the *Constituton of Malta*. However the principles are applied in ordinary legislation.

Article 2: Protection of right to life.
Article 3: Prohibition of torture or inhuman or degrading treatment or punishment.
Article 4: Prohibition of slavery or forced labour.
Article 5: Right to liberty and security of person.
Article 6: Right to a fair and public hearing of charges brought against one.
Article 7: Prohibition of retrospective liability with respect to criminal offences.
Article 8: Right to respect of private and family life, home and correspondence.
Article 9: Right to freedom of thought, conscience and religion.
Article 10: Right to freedom of expression.
Article 11: Right to freedom of peaceful assembly.
Article 12: Right to marry and found a family.
Article 13: Right for redress in relation to breach of these rights and freedoms.
Article 14: Right to freedom from discrimination on the basis of sex, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status.

01.27

Articles 1 to 3 of the ***First Protocol*** to the ***Convention*** refer to the following:

Article 1: Right of every person to peaceful enjoyment of his possessions.
Article 2: Right to education. It also states that 'the State shall respect the right of parents to ensure such education and teaching in conformity with their own religious and philosophical convictions.'
Article 3: Relates to obligations to hold free elections, at reasonable intervals, by secret ballot.

01.28

Articles 1 to 4 of the ***Fourth Protocol*** to the ***Convention*** refer to:

Article 1: Prohibition of imprisonment for debt.
Article 2: Freedom of movement.
Article 3: Prohibition of expulsion of nationals.
Article 4: Prohibition of collective expulsion of aliens.

01.29
Articles 1 and 2 of the ***Sixth Protocol*** to the ***Convention*** refer to:

Article 1: Abolition of the death penalty.
Article 2: Death penalty in time of war.

01.30
The ***Seventh Protocol*** to the ***Convention*** refers to:

Article 1: Procedural safeguards relating to expulsion of aliens.
Article 2: Right of appeal in criminal matters.
Article 3: Compensation for wrongful conviction.
Article 4: Right not to be tried or punished twice.
Article 5: Equality between spouses.

01.31
Article 1 of the ***Thirteenth Protocol*** to the ***Convention*** refers to the abolition of the death penalty in all circumstances.

(b) Telecommunications and human rights

01.32
The ***Malta Communications Authority Act*** provides for the establishment of an Authority that has the duty to ensure 'the protection of the right to privacy'[63] and 'the protection of the rights and freedoms of others.'[64]

The regulation of telecommunications is governed by the ***Electronic Communications (Regulation) Act.*** Under this Act, the Malta Communications Authority is designated as the Authority[65] whose functions include the regulation of the electronic communications sector on the basis of the fundamental principles of this Act including the promotion of the 'interests of users within the Community' by:

(a) 'ensuring that all users have access to a universal service';
(b) 'contributing to ensuring a high level protection of personal data and privacy';

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[63] *Malta Communications Authority Act,* article 4(1)(a)(i).
[64] *Malta Communications Authority Act,* article 4(1)(a)(vi).
[65] *Electronic Communications (Regulation) Act,* article 3.

(c) 'promoting the provision of clear information'; and
(d) 'addressing the needs of specific social groups, in particular disabled users.'[66]

(c) Rights of refugees

01.33
The rights of refugees for certain basic facilities, including the right to be settled in a safe country, is recognised in the ***Refugees Act***. Article 2 of the Act defines 'a safe country of origin' as one 'of which an applicant is a national or citizen or' where he 'has a right of residence and which, in general terms, is considered as presenting no serious risk of persecution on the basis that a person seeking asylum will be treated in accordance with the following principles in that country:

(a) life and liberty are not threatened on account of race, religion, nationality, membership of a particular group or political opinion; and
(b) the principle of non-*refoulement* in accordance with the Convention[67] is respected; and
(c) the prohibition on removal in breach of the right to freedom from torture and cruel, inhuman or degrading treatment as laid down in international law is respected; and
(d) the possibility exists to request refugee status and, if found to be a refugee, to receive protection in accordance with the Convention.'

A safe third country is, moreover, 'a country of which the applicant is not a national or citizen and where:

(a) the life or freedom of the applicant would not be threatened within the meaning of Article 33 of the Convention; and
(b) the applicant had resided for a meaningful period of time prior to his entry into Malta; and

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[66] *Electronic Communications (Regulation) Act*, article 4(c).

[67] 'Convention' means the United Nations *Convention relating to the Status of Refugees* done at Geneva on 28th July, 1951, to which Malta acceded on 17th June, 1971, and the 1967 *Protocol* relating to the Status of Refugees of 31st January, 1967, to which Malta acceded on 15th September, 1971, subject to the declarations and reservations made by Malta. Article 33 of the Convention deals with prohibition of expelling or returning refugees to countries where life or freedom would be threatened.

(c) the applicant would not be exposed to torture or inhuman or degrading treatment, and would be treated in accordance with basic human rights standards; and
(d) the applicant had either already been granted protection or has had an opportunity, at the border or within the territory of that country, to make contact with that country's authorities in order to seek their protection, before applying for asylum in Malta, or where there is clear evidence of his admissibility to that country; and
(e) the applicant is afforded effective protection against *refoulement* within the meaning of the Convention.'

A safe third country is, moreover, a place where a refugee can hope to be resettled and where 'the applicant would not be exposed to torture or inhuman or degrading treatment, and would be treated in accordance with basic human rights standards.'

(d) Human rights within marriage and family values

01.34
The ***Marriage Act***[68] refers to 'wanting to ensure, in line with fundamental human rights and the values of the family based on marriage, a free choice in matters of marriage.'

(e) Business, economics and human rights

01.35
The ***Malta Membership of the European Bank for Reconstruction and Development Act***[69] reproduces the Agreement establishing the Bank, which states that the contracting parties are 'committed to the fundamental principles of multiparty democracy, the rule of law, respect for human rights and market economics.' Moreover, the Agreement acknowledges the intent of countries 'to further the practical implementation of multiparty democracy,

[68] See Schedule to the *Marriage Act*: Agreement between the Holy See and Malta.
[69] *Malta Membership of the European Bank for Reconstruction and Development Act*, Schedule, (Section 2).

strengthening democratic institutions, the rule of law and respect for human rights.'

(f) The *Data Protection Act*

01.36

Personal data may be processed only if 'necessary for a purpose that concerns a legitimate interest of the controller or of such a third party to whom personal data is provided, except where such interest is overridden by the interest to protect the fundamental rights and freedoms of the data subject and in particular the right to privacy.'[70]

A data subject need not be informed that his/her data is being used for scientific research purposes, except 'where the data is used for taking measures or decisions regarding any particular individual or where there is a risk of breaching the privacy of the data subject.'[71]

4. Privacy

01.37

The concept of privacy refers to the right that everybody has of being left alone without interference, disturbance or intrusion. A number of distinct forms of privacy can be envisaged:

(a) *informational privacy:* privacy of information obtained from the person concerned;
(b) *physical privacy:* relates to the body and the person;
(c) *decisional privacy:* relates to personal decisions and choices;
(d) *proprietary privacy:* which looks on the human person as property; and
(e) *relational or associational privacy:* relating to decisions which also involve family or other intimate relations.[72]

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[70] *Data Protection Act*, article 9(f).

[71] *Data Protection Act*, article 23(2). The rights and freedoms of the data subject are further referred to in articles 29(4) (i) and 34(1) (a).

[72] Beauchamp, T.L. and Childress, J.F., *Principles of Medical Ethics*, Fifth Edition, Oxford University Press, 2001, p. 294.

Justification of the legal concept of privacy has been based on fundamental rights of life, liberty and property. While these concepts were well developed in the Anglo-Celtic world, they have far more recent acceptance in Europe, where many countries (including Malta) do not even have a word which precisely translates the English term 'privacy' (or have only a recently borrowed foreign word).

The concept of privacy also has an 'instrumental' value. By giving or refusing to give rights of privacy on our person, we allow relationships to develop or otherwise. We actively allow a doctor to examine us, or alternatively share our inmost secrets with a friend, or become agitated when information about us is disseminated without our knowledge or permission.

Perhaps the most important justification for the notion of privacy derives from the concept of personal autonomy. We are responsible for our own person, our decisions, etc. It is perhaps significant that acceptance of the concepts of privacy and autonomy seem to run parallel to each other: countries which give high importance to one of these concepts are also likely to give importance to the other, and vice versa.

Particularly relevant is privacy that relates to genetic information ('genetic privacy'). As more and more genetic tests are made available at reasonable prices, to cover more and more medical conditions, the pressure will increase for individuals to become aware of their genetic make-up and their tendency to disease processes. This is likely to be followed by pressure from relevant organisations, and particularly insurance companies, to exclude such persons from insurance policies. Such discriminatory practices would result in encroachment on personal and family privacy.

There may be a conflict between patient privacy and confidentiality on the one hand, and the use of health data by health care providers. Privacy requires access to medical data only by informed consent, whereas health care providers need to disseminate information under specific circumstances for the greater social good.

Reference to privacy in Maltese legislation can be found in the following areas.

a. Broadcasting

01.38

Legislation under the ***Broadcasting Act*** provides protection of privacy during broadcasting. The Authority deals with complaints against 'unjust or unfair treatment in sound or television programmes broadcast by any person providing broadcasting services in Malta'[73] and against 'unwarranted infringement of privacy in, or in connection with the obtaining of material included in, sound or television programmes so broadcast.'[74] For the purpose of this Act, 'unjust or unfair treatment' includes 'treatment which is unjust or unfair because of the way in which material included in a programme had been selected or arranged.'[75]

b. Communications

01.39

The ***Malta Communications Authority Act*** sets up the Malta Communications Authority, one of whose functions is to ensure freedom of communication which is limited only when this is necessary under certain conditions. These include the protection of the right to privacy.[76]

The ***Electronic Communications (Regulation) Act***[77] also refers to the question of privacy, and specifically to the role of the Authority to promote the interests of users by 'contributing to ensuring a high level protection of personal data and privacy.'

Other regulations 'prescribe measures to be taken by any person for the purpose of ensuring the inviolability of the electronic communications transmitted and their confidentiality and the protection of privacy in relation to any electronic communications service including data protection measures in the electronic communications sector and data protection measures related to the use of information obtainable in the electronic communications sector for the purpose of direct marketing.'[78]

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[73] *Broadcasting Act*, article 34(1)(a).
[74] *Broadcasting Act*, article 34(1)(b).
[75] *Broadcasting Act*, article 34(3)(b).
[76] *Malta Communications Authority Act*, article 4(1)(a)(i).
[77] *Electronic Communications (Regulation) Act*, article 4(c)(3).
[78] *Electronic Communications (Regulation) Act*, article 34(1)(k).

The *Data Protection Act* was enacted 'to make provision for the protection of individuals against the violation of their privacy by the processing of personal data and for matters connected therewith or ancillary thereto.'

It states that personal data may be processed if 'necessary for a purpose that concerns a legitimate interest of the Controller or of such a third party to whom personal data is provided, except where such interest is overridden by the interest to protect the fundamental rights and freedoms of the data subject and in particular the right to privacy.'[79]

It also allows transfer of data to a third country without being 'restricted on grounds of protection of privacy' to be approved by the Minister, for the purpose of implementing any international convention to which Malta is a party, or any other international obligation of Malta.[80]

Moreover, it also allows the Commissioner to authorise transfer of personal data to a third country that does not ensure an adequate level of protection, provided that the Controller provides adequate safeguards, 'with respect to the protection of the privacy and fundamental rights and freedoms of individuals and with respect to their exercise.'[81]

c. Patients' privacy

01.40

The *Mental Health Act*[82] deals specifically with privacy in relation to the rights of the administration to examine correspondence of patients. This is dealt with more extensively in **Chapter 9: Mental Health.**

In relation to scientific research, the *Data Protection Act* deals with exemption of informing the data subject (patient in the case of medical research) that his/her data is being used for research purposes provided that this exemption 'shall not apply where the data is used for taking measures or decisions regarding any particular individual or where there is a risk of breaching the privacy of the data subject.'[83]

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[79] *Data Protection Act,* article 9(f).

[80] *Data Protection Act,* article 28(1).

[81] *Data Protection Act,* article 28(3).

[82] *Mental Health Act,* article 22.

[83] *Data Protection Act,* article 23(2). This topic is dealt with further in Chapter 12: Research.

5. Consent

a. Definitions

01.41

The question of consent forms a very important chapter in the relationship of client and provider of services. In the ethical field, consent has been given considerable importance in recent years. The ***Public Health Act*** defines consent as 'approval given by an individual without any force, fraud or threat.'[84] Essential to any process involving consent are the following:

1. *Ability to give consent:* Normally one assumes that an adult person is capable of giving consent unless unable to do so for a reason such as the following:

   (a) mental disability;
   (b) physical disability which (temporarily) clouds consciousness (e.g. coma resulting from disease, trauma, drugs, etc.);
   (c) no legal capacity, which is also applicable to children under a specified age (usually now taken as eighteen years of age[85]), who are not fully capable of giving consent (See **Chapter 7: Children**).

2. *Diminished capacity to give consent:* This is seen in certain categories of persons, who, because of the condition they are in, are not fully free to give consent. This includes prisoners, and others who are detained against their will.

3. *Informed consent:* It is important also to emphasise that no consent can be given unless the required information has been provided in a form that can be digested and acted on. This leads to the concept of 'informed consent'. Consent can be expressed or implied. This distinction is very relevant

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[84] *Public Health Act*, article 2.

[85] See below for validity of contracts by children over 14. Also in the *Criminal Code*, article 350(1), 'appropriate consent' for providing samples in a criminal investigation requires the consent of children from the age of fourteen upwards.

to medical practice where often the doctor relies on implied consent.[86]

In the subsidiary legislation to the ***Medicines Act, Clinical Trials Regulations,***[87] 'informed consent' is defined as 'a decision, which must be written in one of the official languages of Malta or in a language understandable to the clinical trial subject and, or his legal representative, dated and signed, to take part in a clinical trial, taken freely after being duly informed of its nature, significance, implications and risks and appropriately documented, by any person capable of giving consent or, where the person is not capable of giving consent, by his or her legal representative; if such person is unable to write, oral consent may be given in the presence of at least one witness.'

01.42

Legislation in Malta deals primarily with aspects of consent in general and hardly with issues of consent in relation to bioethics.

As mentioned above, consent implies a form of contract. The ***Civil Code*** defines a contract as 'an agreement or an accord between two or more persons by which an obligation is created, regulated, or dissolved.'[88] It distinguishes *bilateral* contracts, when the contracting parties bind themselves mutually to one another, from *unilateral* contracts when only one party is bound by this obligation.[89]

01.43

The ***Civil Code*** defines the requisites of contracts essential to make it valid.[90]

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[86] There is no specific reference to this distinction relating to the health field in Maltese law, except in relation to Clinical Trials. However in the *Data Protection Act*, 'consent' is defined as being freely given, specific and informed, in relation to agreement by a data subject to his personal data being processed. See Chapter 2: Confidentiality and Data Protection.

[87] *Clinical Trials Regulation*, SL 458.43, regulation 3.

[88] *Civil Code*, article 960.

[89] *Civil Code*, article 961.

[90] *Civil Code*, article 966.

These are:

(a) capacity of the parties to contract;
(b) the consent of the party who binds himself/herself;
(c) a certain thing which constitutes the subject-matter of the contract;
(d) a lawful consideration.

01.44

It defines those persons who are incapable of making a contract, namely:[91]

(a) minors, that is persons who have not reached eighteen years of age;[92]
(b) persons interdicted[93] or incapacitated;[94] and
(c) generally, all those to whom the law forbids certain contracts.

In the case of children:

(a) any contract with a minor under the age of seven years is null;[95]
(b) any obligation entered into by a child under the age of fourteen years is also null;[96]
(c) where a child has attained the age of nine but has not yet reached fourteen years, 'the agreement shall be valid in so far as it relates to the obligations entered into by any other person in his favour';[97]
(d) agreement with persons aged fourteen years but who have not reached eighteen shall be valid 'if such person is subject to parental authority, or is provided with a curator, saving always any other provision of law relating to marriage';[98]

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[91] *Civil Code*, article 967(3).
[92] *Civil Code*, article 188(1).
[93] *Civil Code*, article 972.
[94] *Civil Code*, article 968. 'Any contract entered into by a person who has not the use of reason, or is under the age of seven years is null.'
[95] *Civil Code*, article 968.
[96] *Civil Code*, article 969(1).
[97] *Civil Code*, article 969(2).
[98] *Civil Code*, article 970.

(e) a child over sixteen years of age may open and operate a bank account. 'For all purposes of law the child shall with regard to the opening and operation of any such account be considered a major';[99] and

(f) a minor who has attained the age of sixteen years may trade and shall be deemed to be a major with regard to obligations contracted by him for purposes of trade, if authorised to that effect by the parent(s) or in their absence by a judge of the Civil Court.[100]

01.45

The ***Civil Code*** specifies several situations where consent is not valid, namely, where consent has been given by error, or extorted by violence or procured by fraud.[101] The use of violence to obtain consent renders null any agreement. Violence is said to occur when it is such as 'to produce an impression on a reasonable person and to create in such person the fear of having his person or property unjustly exposed to serious injury'[102] bearing in mind the age, sex and the condition of the person concerned. It is pointed out, however, that 'mere reverential fear towards the father, mother or other ascendants or towards the husband, shall not be sufficient to invalidate a contract, if no violence has been used.'[103]

b. Personal and property searches

01.46

The ***Constitution of Malta*** states that 'no person shall be subjected to the search of his person or his property or the entry by others on his premises,' except with his/her own consent.[104]

The exceptions to this rule include instances where this is necessary in the public interest, including:[105]

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[99] *Civil Code,* article 971A.
[100] *Commercial Code,* article 9.
[101] *Civil Code,* articles 974–981.
[102] *Civil Code,* article 978.
[103] *Civil Code,* article 980.
[104] *Constitution of Malta,* article 38(1).
[105] *Constitution of Malta,* article 38(2).

(a) public order, safety, morality or health;
(b) to promote the rights or freedoms of other persons;
(c) for purposes of inspection by authorised persons or bodies, e.g. for tax purposes; and
(d) to enforce a court order.

01.47

In the ***Criminal Code*** 'appropriate consent' is defined as follows:[106]

(a) in relation to a person who has attained the age of 18 years, the consent of that person;
(b) in relation to a person who has not attained the age of 18 years but has attained the age of 14 years, the consent of that person and the consent of his/her parent or guardian;
(c) in relation to a person who has not attained the age of 14 years, the consent of his/her parent or guardian.

01.48

Since late January, 2004,[107] the ***Criminal Code*** distinguishes between intimate and non-intimate samples. Article 350 defines an 'intimate sample' as 'a sample of blood, semen or any other tissue fluid, or pubic hair, and includes a swab taken from a person's body orifice other than the mouth.' A ' non-intimate sample' is defined as:

'(a) a sample of hair other than pubic hair,
(b) a sample taken from a nail or from under a nail,
(c) a swab taken from any part of a person's body including the mouth but not any other body orifice;
(d) urine or saliva;
(e) a footprint or a similar impression of any part of a person's body other than a part of his hand.'

The investigating officer may 'request a Magistrate to authorise the necessary procedure' for taking intimate samples or photographs or video recordings of intimate body parts of the person arrested.[108] However an intimate sample still requires the arrested person's consent[109] but the Magistrate now has to decide whether the request

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[106] *Criminal Code,* article 350.
[107] Legal Notice 273 of 2003.
[108] *Criminal Code,* article 355AV.
[109] *Criminal Code,* article 355AW.

is justified or not.[110] 'Where the Magistrate decides that the request is justified he shall visit the person arrested to request his consent and before asking for his consent he shall explain to him the nature of the request and the reasons thereof.'[111] This article also provides for legal assistance to the person before giving consent but this provision is not yet in force.

The investigating officer requires appropriate consent in writing from the person arrested, to proceed to take non-intimate samples, fingerprints or palm prints or photographs of non-intimate parts of the body.[112]

01.49

The ***Police Act*** states that: 'The investigating officer with the assistance of such competent persons as may be necessary and with the appropriate consent, may:

(a) take fingerprints, palm-prints or other prints from the person arrested;
(b) take photographs of the person arrested or of non-intimate parts of his body;
(c) take non-intimate samples from the person arrested.' [113]

Appropriate consent 'shall have the same meaning assigned to it by article 350 of the ***Criminal Code.***' [114]

Any request from the arrested person to provide any sample must be made in writing[115] while 'samples from a person other than a person arrested may only be taken with that person's prior consent in writing,'[116] provided that for the taking of an intimate sample a Magistrate's authorisation must also be obtained.[117]

An arresting officer who has a reasonable suspicion that the person arrested may have unlawfully concealed any item on his person, 'may request a Magistrate to order an intimate search

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[110] *Criminal Code,* article 355AX(1)
[111] *Criminal Code,* article 355AX(2).
[112] *Criminal Code,* article 355BA(1).
[113] *Police Act,* article 68.
[114] *Police Act,* article 2. See above 01.47.
[115] *Criminal Code,* article 355BA (2) and (3).
[116] *Criminal Code,* article 355BB.
[117] *Criminal Code,* articles 355BA(3) and 355BB.

of the person arrested.'[118] The Magistrate shall not appoint 'an expert for the purpose of carrying out an intimate search on a person of the opposite sex unless the expert is a medical practitioner and the person to be searched consents thereto in writing.'[119] The law does not even authorise non-intimate search of an arrested person by a police officer of the opposite sex, except in urgent cases.[120]

The ***Criminal Code*** states that 'it is the duty of the Police to execute any warrant or order of arrest or search that as prescribed by law, be issued by any other competent authority.'[121] Police officers require a warrant from a Magistrate, to enter a house or any premises to effect a search or arrest a person 'who has committed or is reasonably suspected of having committed or of being about to commit any offence',[122] unless the person is caught committing a crime or it is feared he will escape or the police is trying to prevent commission of crime. Also, after an arrest, the police do not require a warrant to search any premises that are reasonably suspected of harbouring evidence related to the offence.[123]

01.50

Likewise, the ***Occupational Health and Safety Authority Act*** states that: 'An officer shall not enter a work place which is at the time used as a dwelling house without the consent of the occupier, or unless that officer is accompanied by a police officer not below the rank of Inspector.'[124]

01.51

The ***Clean Air Act*** allows authorised officers to enter residences to investigate offences against this Act, only if the occupier is given twenty-four hours notice of the intended entry or if such occupier consents to such entry.[125]

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[118] *Criminal Code*, article 355AP.
[119] *Criminal Code*, article 355AQ(2).
[120] *Criminal Code*, article 353.
[121] *Criminal Code*, article 355AG.
[122] *Criminal Code*, article 355E(1).
[123] *Criminal Code*, article 355L.
[124] *Occupational Health and Safety Authority Act*, article 16(2).
[125] *Clean Air Act*, article 11(1)(a). This Act will be repealed by the *Public Health Act* when article 45 comes into force. Similar provisions exist in the *Public*

c. Medical certificates

01.52

Medical certificates are confidential documents. A medical practitioner 'must not disclose voluntarily without the consent of the patient, preferably written, information, including certification which he has obtained in the course of his professional relationship with the patient. Exception to this rule is made only by the requirements of the law.'[126] Similarly, a dental practitioner 'must not disclose voluntarily, without the consent of the patient, preferably written, information, including certification which he has obtained in the course of his professional relationship with the patient. Exception to this rule is made only by the requirements of the law'.[127]

Restrictions to what may be requested to be put in a medical certificate in the case of a disabled person are discussed further in **Chapter 8: Disability**.

d. Disclosure of statistical data

01.53

Information collected under the ***Malta Statistics Authority Act*** 'shall be used only for the purpose of statistical compilation and analysis.'[128] Information which can be related to an identifiable person or undertaking shall not 'except with the written consent of that person or undertaking, or the personal representative or next-of-kin of that person, if he be deceased, be disseminated, shown or communicated to any person or body.' The exceptions to such disclosure are:

(a) for purposes of prosecution for an offence under this Act; or
(b) to officers of statistics in the course of their duties.[129]

Health Act, article 6(1)(a) which states that 'an authorised officer may, at any reasonable time enter, and inspect any area, premises, body of water or vehicle' and article 6(2)(b) which specifies the need to 'give reasonable notice.'

[126] *Ethics of the Medical Profession Regulations*, SL 94.15, regulation 13(1). Medical practitioners are reminded of article 257 of the *Criminal Code* (disclosure of professional secrets).

[127] *Ethics of the Dental Profession Regulations*, SL 94.14, regulation 5.

[128] *Malta Statistics Authority Act*, article 40.

[129] *Malta Statistics Authority Act*, article 41(1).

The same provisions exist under other legislation, including the ***Census Act, Income Tax Act, Value Added Tax Act,*** etc.

e. Prevention of disease

01.54

The ***Venereal Diseases (Treatment) Act*** makes it a duty of the medical practitioner, responsible for venereal diseases, to notify the Chief Government Medical Officer of certain particulars relating to a patient suffering from venereal disease and the suspected patient source.[130]

Before examining a patient, the doctor must explain to the patient that all information will be treated as strictly confidential, and that information received for the purposes of this Act is exempt from civil or criminal proceedings.[131] The doctor is requested not to send this information to the Chief Government Medical Officer 'before he has obtained the patient's signature or mark to a statement setting out that patient's consent to the proposed transmission of notice.'[132]

The ***Prevention of Disease Ordinance*** gives power to the authorities ('superintendent') to disinfect premises which housed patients with infectious disease. Consent of the owner or occupier may be sought for this purpose,[133] but articles may be cleansed, disinfected or even destroyed without such consent if considered necessary (at the expense of the government). This Ordinance also gives power to remove a person from a house for the purpose of disinfection, and if the person does not give consent, a magistrate may grant a warrant authorising the police to effect such removal.[134] For the purpose of this Act, consent for such purposes may be

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[130] *Venereal Diseases (Treatment) Act*, article 3. This post no longer exists and the relevant officer in this context is the Superintendent of Public Health.

[131] *Venereal Diseases (Treatment) Act*, article 4(1).

[132] *Venereal Diseases (Treatment) Act*, article 4(2).

[133] *Prevention of Disease Ordinance*, article 17(1). This Ordinance will be repealed by the *Public Health Act* when article 45 comes into force. The *Public Health Act*, article 21(2) deals with disinfection but article 23(2) states that failure 'to comply with a requirement of an authorised officer,' is an offence.

[134] *Prevention of Disease Ordinance*, article 19(1). This Ordinance will be repealed by the *Public Health Act* when article 45 comes into force and the article will be replaced by article 29(3) when it comes into force.

given by parents or guardians of a person under the age of eighteen years or of a person 'irresponsible through mental deficiency'.[135]

Removal of an infected person to hospital may be made by order of a magistrate if consent of the patient (or his guardians) is not given.[136]

01.55

In the ***Public Health Act,*** 'consent' is defined as 'approval given by an individual without any force, fraud or threat.'[137] This Act gives widespread powers to the Superintendent of Public Health to ensure public health, including measures to prevent and control infectious disease. Failure to comply with any of the directions amounts to an offence. In the case of the necessity to quarantine an individual, who does not consent, a warrant may be obtained.[138] The Superintendent may cause a person, including his clothing to be cleansed, if s/he 'does not consent or is unable to consent to be cleansed.'[139]

A medical practitioner and a person in charge of the laboratory which provides a positive result, must report a notifiable disease to the Superintendent and they 'shall not require the consent of the person being treated or examined.'[140]

Consent is not required by a doctor in relation to ***Notification of Cancer Act*** where the doctor is obliged by law to disclose information about a patient's diagnosis. Likewise, infection with HIV virus is a notifiable disease in Malta.[141]

f. Termination of employment in the case of injury

01.56

If a worker suffers a personal injury during the course of employment, or suffers from an occupational disease as defined by

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[135] *Prevention of Disease Ordinance,* articles 19(1) and 20(4). This Act will be repealed by the *Public Health Act* when article 45 comes into force.

[136] *Prevention of Disease Ordinance,* article 25. This Ordinance will be repealed by the *Public Health Act* when article 45 comes into force and the article will be replaced by article 29(3) when it comes into force.

[137] *Public Health Act.* Not all articles are in force by 31st December 2005.

[138] *Public Health Act,* article 29. This is not yet in force by 31st December 2005.

[139] *Public Health Act,* article 30. This is not yet in force by 31st December 2005.

[140] *Public Health Act,* article 31. This is not yet in force by 31st December 2005.

[141] *Public Health Act,* article 27(a)(i) and Government Notice No. 75 of 2004 published in the Government Gazette of 27th January 2004 (issue number 17,333, p. 406).

law, then an employer cannot terminate his/her employment, without the consent of the employee. The ***Employment and Industrial Relations Act*** states: 'A contract of service shall not, except with the consent of the employee, be terminated by the employer during any period of incapacity for work of the employee caused by personal injury by accident arising out of and in the course of employment or by any of the occupational diseases specified in the ***Social Security Act*** in each case occurring in the service of that employer.'[142]

g. Data processing

01.57

The ***Data Protection Act*** defines 'consent' in relation to data processing as 'any freely given specific and informed indication of the wishes of the data subject by which he signifies his agreement to personal data relating to him being processed.'

'Personal data' means 'any information relating to an identified or identifiable natural person; an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity.'

Personal data may be processed only if 'the data subject has unambiguously given his consent.'[143]

A data subject has the right to object to processing of personal data for purposes concerned with direct marketing.[144] S/he may also withdraw a previously given consent for 'compelling legitimate grounds'.[145]

01.58

'Sensitive personal data' means personal data that reveals race or ethnic origin, political opinions, religious or philosophical beliefs, membership of a trade union, health, or sex life. Processing of such data is prohibited unless explicit consent is given by the data

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142 *Employment and Industrial Relations Act,* article 36(15).
143 *Data Protection Act,* article 9(a).
144 *Data Protection Act,* article 10(1).
145 *Data Protection Act,* article 11.

subject (or unless he has made such data public).[146] Processing of sensitive data may be necessary under certain conditions such as where the vital interest of the data subject or other person is at stake and the data subject is physically or legally incapable of giving his consent, or where such processing is necessary under any law.[147]

Consent by the data subject is also required where sensitive personal data will be provided to a third party.[148]

Special precautions apply to the processing of the identity card number in the absence of consent. This is allowed only when such processing 'is clearly justified' for the purpose of processing, for secure identification or for any other valid reason.[149]

01.59

Transfer of personal data to a third country that has an adequate level of protection (within the meaning of the Act) is allowed subject to the provisions of this Act[150] while transfer to a third country without an adequate level of protection is only allowed under certain conditions including the proviso that 'the data subject has given his unambiguous consent to the proposed transfer.'[151]

In relation to intellectual data and research data in particular, the ***Criminal Code*** states that it is illegal to forge or alter, without the consent of the owner, the name, mark or any other distinctive device of any intellectual work or any industrial product, or to knowingly make use of any such name, mark or device forged or altered, without the consent of the owner.[152]

h. Marriage

01.60

Consent in relation to marriage is covered by the ***Civil Code*** as follows:

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[146] *Data Protection Act*, article 12.
[147] *Data Protection Act*, article 13.
[148] *Data Protection Act*, article 14.
[149] *Data Protection Act*, article 18.
[150] *Data Protection Act*, article 27(1).
[151] *Data Protection Act*, article 28(2).
[152] *Criminal Code*, article 298(1)(a).

(a) in relation to the matrimonial home, alienation of title may occur by consent of the other spouse;[153]
(b) separation may take place on the demand of one spouse against the other[154] or by mutual consent. 'Personal separation may, subject to the authority of the court, be effected by mutual consent of the spouses, by means of a public deed';[155]
(c) parties may put an end to separation by mutual consent;[156]
(d) a child conceived and born out of wedlock, born to a spouse before or during marriage, and acknowledged during a marriage, may be brought into the matrimonial home only with the consent of the other spouse;[157]
(e) the presumption that a child, of one parent, was conceived or born in wedlock, is allowed only if the other spouse gives his or her consent;[158]
(f) in the situation mentioned in paragraph (e) above, the consent of the child, if of age, must be proved;[159]
(g) an adoption decree shall not be made unless there is the consent of every person who is a parent of the person to be adopted or of the mother in the case of a person conceived and born out of wedlock;[160] and
(h) an adoption decree shall not be made when the person to be adopted has attained the age of fourteen, without his or her consent.[161]

The court may dispense with any consent, required in relation to adoption, when the person who is required to give consent is incapable of giving such consent, in cases of abandonment of the person to be adopted and in special and exceptional circumstances.[162]

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[153] *Civil Code*, article 3A(2).
[154] *Civil Code*, article 36.
[155] *Civil Code*, article 59(1).
[156] *Civil Code*, article 63.
[157] *Civil Code*, article 89.
[158] *Civil Code*, article 107(b).
[159] *Civil Code*, article 107(c).
[160] *Civil Code*, article 115(3)(a) and (b).
[161] *Civil Code*, article 115(3)(d).
[162] *Civil Code*, article 117.

In the case of abduction of a person with intent to abuse or marry, the ***Criminal Code*** states that 'if the offender, after abducting a person, shall marry such person, he shall not be liable to prosecution, except on the complaint of the party whose consent, according to the civil laws, would be required for the marriage.'[163]

i. Criminal action

01.61

Consent is specifically mentioned in relation to certain crimes. Intoxication may be a defence to a criminal charge if it was caused without one's consent by the malicious or negligent act of another person.[164]

Causing abortion is a crime, 'whether the woman be consenting or not'[165] but if she consents or procures her own miscarriage, she is also guilty of the offence and liable to the same punishment.[166]

In the ***Criminal Code,*** there are provisions for protection of the rights of the accused in terms of cases being dealt with summarily[167] and in procedures during a trial. The Attorney General may withdraw the indictment filed, but if the accused had already plead to the issue of 'guilty or not guilty', his/her consent is required.[168]

A person accused in a foreign country, may, at that country's request be heard before a Magistrate in Malta, provided 'that the hearing shall only take place with the consent of the person to be heard.'[169] When a foreign country requests 'the hearing of a witness or expert by telephone conference,' this may occur 'provided that the witness or expert consents to the hearing.'[170]

j. The Council of Europe's Convention on Human Rights and Biomedicine

01.62

While the Maltese government has not to date signed or ratified the Council of Europe's ***Convention on Human Rights and Biomedicine,***

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[163] *Criminal Code,* article 200(2).
[164] *Criminal Code,* article 34(2).
[165] *Criminal Code,* article 241(1).
[166] *Criminal Code,* article 241(2).
[167] *Criminal Code,* article 370(4)(b).
[168] *Criminal Code,* article 600(1).
[169] *Criminal Code,* article 649(12).
[170] *Criminal Code,* article 649(13).

(1997),[171] it is expected to do so in the near future. Informed consent forms the backbone of this Convention. Chapter II of this Convention deals with the topic of consent, with special emphasis on protection of persons who cannot give consent. Extracts from the relevant articles relating to informed consent are given below. The importance of this Convention is considerably enhanced in view of the fact that there is such a dearth of local legislation dealing specifically with informed consent in the medical context.

Article 5 – General rule
An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time.

01.63
Article 6 – Protection of persons not able to consent
1. An intervention may only be carried out on a person who does not have the capacity to consent for his or her direct benefit.
2. Where, according to law, a minor does not have the capacity to consent to an intervention, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law.
   The opinion of the minor shall be taken into consideration as an increasingly determining factor, in proportion to his or her age and degree of maturity.
3. Where, according to law, an adult does not have the capacity to consent to an intervention because of a mental disability, a disease, or for similar reasons, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law.
   The individual concerned shall as far as possible take part in the authorisation procedure.

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[171] *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, Council of Europe, 1997.

4. The representative, the authority, the person or the body mentioned in paragraphs 2 and 3 above shall be given, under the same conditions, the information referred to in Article 5.
5. The authorisation referred to in paragraphs 2 and 3 above may be withdrawn at any time in the best interests of the persons concerned.

01.64

Article 7 – Protection of persons who have a mental disorder

Subject to protective conditions prescribed by law, including supervisory, control and appeal procedures, a person who has a mental disorder of a serious nature may be subjected, without his or her consent, to an intervention aimed at treating his or her mental disorder only where, without such treatment, serious harm is likely to result to his or her health.

01.65

Article 8 – Emergency Situation

When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the individual concerned.

01.66

Article 9 – Previously expressed wishes

The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account.

Chapter 2

Confidentiality and Data Protection

1. Introduction

02.01

One of the most crucial tenets guiding health professionals is the need for confidentiality.[1] It is expected by patients and is normally guaranteed by law. Without this guarantee it would be practically impossible to practice medicine. From the very beginning of medical history we find Codes of Practice that emphasise the need for confidentiality. The Hippocratic Oath itself enjoins the doctor in no uncertain terms: 'Whatsoever I shall see or hear in the course of my profession, as well as outside my profession in my intercourse with men, if it be what should not be published abroad, I will never divulge, holding such things to be holy secrets.' More recent injunctions to the same effect may be found in the World Medical Association's Declaration of Geneva, which imposes 'absolute secrecy'. It states: 'I will respect the secrets which are confided in me, even after the patient has died.' The International Code of Medical Ethics requires that: 'A doctor shall preserve absolute secrecy on all he knows about his patients because of the confidence entrusted in him.'

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[1] The distinction between 'privacy' and 'confidentiality' may not be absolutely clear. A breach of confidentiality occurs when there is failure to protect information given by a person in confidence, that is, without the consent of the person. A breach in a person's right to privacy occurs when information about a person is obtained illegitimately (e.g. through stealing computerised data). See Beauchamp, T.L. and Childress, J.F. *Principles of Biomedical Ethics*. Vth Ed. Oxford, 2001, p. 304.

02.02

Confidentiality is normally justified for the following reasons:[2]

(a) *consequence based arguments*: patients have to trust health professionals otherwise they will find it very difficult to discuss intimate details with them, resulting in inadequate communication and possible misdiagnosis. In other words, without the expectation of confidentiality, the fiduciary relationship between doctor and patient cannot exist;
(b) *autonomy and privacy based arguments*: a patient has a right to confidentiality and privacy. Information (and particularly 'sensitive' information) obtained from a patient is private property and divulging such information conflicts with this concept;
(c) *fidelity based arguments*: the health care professional has a duty to live up to the patient's reasonable expectations, based on the respective code of ethics.

Confidentiality is broken when information about a patient, obtained through verbal communication, or through physical or other examination, obtained under professional conditions, is disclosed to a third party without permission and without the consent of the person to whom it refers. However, it is a well-known fact that medical data (e.g. within a patient's history file) may be handled by a large number of people (calculated by Mark Siegler to be in the region of 75 persons!).[3]

02.03

Moreover, it is accepted that there are several conditions where confidentiality may have to be broken, including:

(a) when required to do so by a court of law;
(b) when required by law in the public interest to report certain diseases, e.g. infectious disease, venereal disease;
(c) where notification of disease is required by law (e. g. cancer);

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[2] Beauchamp T.L. & Childress J.F., *Principles of Biomedical Ethics*. Vth Ed. Oxford, 2001.

[3] Mark Siegler, 'Confidentiality in Medicine - A Decrepit Concept'. *New England Journal of Medicine 307*, 1982, 1518-1521.

(d) when required to report on the condition of a patient by e.g. an insurance company, employer, the military (but see further below);
(e) when a patient's condition or actions may prove a risk to a third party (e.g. epilepsy and driving, child abuse); and
(f) where a genetic (or acquired) condition affects other members of the family.

02.04

One may distinguish between *obligatory* disclosure as opposed to *permissible* disclosure. Obligatory disclosure refers to disclosure demanded under legislation or specifically by a court of law. Permissible disclosure is based on an analysis of the magnitude of the harm envisaged, as well as the probability of such harm ensuing. For instance in the case of infection by HIV (AIDS virus), the doctor may feel justified in informing the spouse of such a patient about the condition, even against the patient's own conviction and consent. On this topic, the American Medical Association advises that a physician who 'knows that a seropositive individual is endangering a third party ... should (1) attempt to persuade the infected patient to cease endangering the third party; (2) if persuasion fails, notify the authorities; and (3) if the authorities take no action, notify the endangered third parties.'[4] In Malta, the transmission, communication and passing on of certain types of diseases is punishable by law.[5]

Nonetheless it has been considered necessary from time to time to enshrine these notions into law, with corresponding penalties for wrongdoers. At both national and international levels we find plenty of guidelines and legislation that enshrine concepts relating to confidentiality and data protection.

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[4] Council on Ethical and Judicial Affairs, 'Ethical Issues Involved in the Growing AIDS Crisis', Journal of the American Medical Association, 259, 1988, 1360-61. In terms of article 27(a)(i) of the *Public Health Act*, HIV infection is a notifiable disease in Malta. [Government Notice No. 75 of 2004 published in the Government Gazette of 27th January 2004.]

[5] *Criminal Code*, article 244A(i).

2. Definitions

02.05

The following definitions are found in the ***Data Protection Act***:

Consent means any freely given specific and informed indication of the wishes of the data subject by which s/he signifies his/her agreement to personal data relating to such subject being processed.

Data subject means a natural person to whom the personal data relates.

Identity card number means the identifying number contained in an identity card as provided in the ***Identity Card Act.***

Personal data means any information relating to an identified or identifiable natural person.

Identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity.

Personal data filing system or 'filing system' means any structured set of personal data, which is accessible according to specific criteria, whether centralised, decentralised or dispersed on a functional or geographical basis.

Processing and 'processing of personal data' mean any operation or set of operations which is taken in regard to personal data, whether or not it occurs by automatic means, and includes the collection, recording, organisation, storage, adaptation, alteration, retrieval, gathering, use, disclosure by transmission, dissemination or otherwise making information available, alignment or combination, blocking, erasure or destruction of such data. Processing of data can be by automated or non-automated means, and includes a filing system.[6]

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[6] *Data Protection Act*, article 3.

Third party means a person other than the data subject, the controller of personal data, the personal data representative, the processor and such persons who under the direct responsibility of the controller of personal data or the processor are authorised to process personal data.

Other relevant definitions are found in the ***Malta Statistics Authority Act*** and the ***Professional Secrecy Act***.

Confidential data is defined for the purpose of the ***Malta Statistics Authority Act***, as 'data obtained by the National Statistics Office for the production of official statistics when such data allows statistical units to be identified directly or indirectly, thereby disclosing individual information.'[7]

Professional secret or 'secret' in the ***Professional Secrecy Act*** refers to information which falls under any of the following categories:

(a) where it is considered secret under a specific provision of any law;
(b) any information passed on to a professional person or official and described as secret by the person communicating it;[8]
(c) information considered secret in view of:
    i. the circumstances in which the information is communicated and received;
    ii. the nature of the information; and
    iii. being received by a person who by nature of his calling is expected to respect such information and if applicable the calling of the person giving the information.[9]

3. Obtaining Information

02.06

Information may be obtained for statistical purposes. The ***Malta Statistics Authority Act*** establishes the Malta Statistics Authority with the aim of collecting, compiling and publishing official statistics.

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[7] *Malta Statistics Authority Act*, article 2.
[8] *Professional Secrecy Act*, article 2(3)(b). See also article 257 of the Criminal Code for an explanation of categories of people involved.
[9] *Professional Secrecy Act*, article 2(3)(c).

The Director General has the authority to prepare forms, questionnaires or other records necessary for the collection of information, as well as the instructions necessary for completing these forms, and to specify dates by which these forms have to be completed.[10]

It is made clear that an individual may be requested to complete the form/questionnaire, answer the questions therein, and provide the information or records requested.[11]

The matters about which statistics may be collected are very wide indeed and consist of a variety of items,[12] including, population, housing, migration, health, accidents, morbidity, social matters (including education, social security, criminal and judicial matters, government), land tenure, environmental issues, employment, services, trade, industry, cost of living and broadcasting.

The Director General, or an 'officer of statistics', has the right to access information relating to matters specified in the First Schedule of the ***Malta Statistics Authority Act***.[13] The Director General or 'officers of statistics' may access any public authority 'to inspect and to take copies of or extracts from any records.'[14] Information thus obtained 'shall be used only for the purpose of statistical compilation and analysis.'[15]

4. Communication of Information and Confidentiality

02.07

The ***Malta Statistics Authority Act*** refers to 'restrictions on use and prohibition on disclosure of information' obtained.[16] Data, which relates to an identifiable person or an undertaking cannot 'be disseminated, shown or communicated to any person or body' except in certain circumstances, namely, for the purposes of prosecution for an offence under this Act, or to officers of statistics in the course of their duty, unless the person consents in writing.

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[10] *Malta Statistics Authority Act*, article 35.
[11] *Malta Statistics Authority Act*, article 36.
[12] *Malta Statistics Authority Act*, First Schedule.
[13] *Malta Statistics Authority Act*, article 38.
[14] *Malta Statistics Authority Act*, article 39(1)(a).
[15] *Malta Statistics Authority Act*, article 40.
[16] *Malta Statistics Authority Act*, article 41.

02.08

Disclosure of information. relating to patients with mental disability is further regulated under the ***Mental Health Act***.

The Minister responsible for justice may make rules with respect to applications to the Mental Health Review Tribunal. These include rules for:

(a) 'regulating the methods by which information relevant to an application may be obtained by or furnished to the Tribunal';[17]

(b) 'making available to any applicant, and to any patient in respect of whom an application is made to the Tribunal, copies of any documents obtained by or furnished to the Tribunal in connection with the application, and a statement of the substance of any oral information so obtained or furnished except where the Tribunal considers it undesirable in the interests of the patient or for other special reasons';[18]

(c) requiring the Tribunal, if so requested in accordance with the rules, 'to furnish such statements of the reason for any decision given by the Tribunal as may be prescribed by the rules, subject to any provision made by the rules for withholding such a statement from a patient or any other person in cases where the Tribunal considers that furnishing it would be undesirable in the interests of the patient or for other special reasons'.[19]

02.09

The ***Malta Communications Authority Act*** refers to 'communications' which include electronic communications, postal services, data protection in electronic communications and electronic commerce.

The Act sets up the Malta Communications Authority, one of whose functions is 'the protection of the right to privacy'[20] and 'contributing to ensuring a high level protection of personal data and privacy.'[21]

The Act also sets up a 'Directorate for Telecommunications' as well as a 'Directorate for Information and Other Systems', which

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[17] *Mental Health Act*, article 41(1)(e).
[18] *Mental Health Act*, article 41(1)(f).
[19] *Mental Health Act*, article 41(1)(g).
[20] *Malta Communications Authority Act*, article 4(1)(a)(i).
[21] *Electronic Communications (Regulation) Act*, article 4(c)(iii).

respectively have the responsibility for the regulation of all matters relating to telecommunications and for electronic commerce as well as information and other systems, as may from time to time be assigned to the Authority. There is also the establishment of a Directorate for Data Protection with responsibility for the regulation of all matters relating to data protection as may from time to time be assigned to the Authority by or under an Act of Parliament.[22]

The ***Electronic Communications (Regulation) Act*** provides for regulations, which may 'prescribe measures to be taken by any person for the purpose of ensuring the inviolability of electronic communications transmitted and their confidentiality and the protection of privacy in relation to any electronic communications service including data protection measures in the electronic communications sector and data protection measures related to the use of information obtainable in the electronic communications sector for the purpose of direct marketing.'[23]

'An undertaking that acquires information from another undertaking before, during or after the process of negotiating access or interconnection arrangements shall use that information solely for the purpose for which the information was supplied and shall respect at all times the confidentiality of information transmitted or stored.' Such acquired information must not be passed on to another party, particularly when it could provide a competitive advantage.[24]

5. The *Data Protection Act*

02.10

The most recent legislation relating to data protection is to be found in the ***Data Protection Act***. Its aim is to 'make provision for the protection of individuals against the violation of their privacy by the processing of personal data and for matters connected therewith or ancillary thereto.'

In relation to journalists and the media, the Commissioner may establish specific measures to protect data subjects,[25] or may

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[22] *Malta Communications Authority Act*, schedule related to article 5(2).
[23] *Electronic Communications (Regulation) Act*, article 34(1)(k).
[24] *Electronic Communications (Regulation) Act*, article 14(5) and (6).
[25] *Data Protection Act*, article 6(3).

'prohibit any person concerned from carrying out any processing, in whole or in part, and order the blocking of data when, having regard to the nature of the data ... there is a serious risk of a relevant damage to one or more data subjects'.[26]

This Act requires that the data is processed under certain specific criteria. The controller has the responsibility of ensuring that personal data is processed 'fairly and lawfully' and in accordance with good practice.[27]

02.11

Importantly, 'personal data is only collected for specific, explicitly stated and legitimate purposes,'[28] and 'personal data is not processed for any purpose that is incompatible with that for which the information is collected.'[29] It is also necessary to ensure that data collected is adequate and relevant to the purposes of the processing,[30] and no more personal data is processed than is necessary.[31] Incomplete or incorrect data has to be removed or erased.[32] Finally, there is a limit to the length of time that data can be kept; personal data is not to be kept for a period longer than is necessary, for the purposes for which it is processed.[33] This important article provides a considerable amount of protection in relation to the type and quality of personal data that are to be collected.

Another important proviso to be found in article 8 is that when data is processed for historical, statistical or scientific purposes, such data 'shall not be regarded as incompatible with the purposes for which the information was collected' provided that it 'shall not be used for any decision concerning a data subject.'[34]

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[26] *Data Protection Act*, article 6(4).
[27] *Data Protection Act*, article 7(a)(b).
[28] *Data Protection Act*, article 7(c).
[29] *Data Protection Act*, article 7(d).
[30] *Data Protection Act*, article 7(e).
[31] *Data Protection Act*, article 7(f).
[32] *Data Protection Act*, article 7(h).
[33] *Data Protection Act*, article 7(i).
[34] *Data Protection Act*, article 8(b).

The *Data Protection (Processing of Personal Data in the Police Sector) Regulations 2004*[35] deal with the collection of personal data 'for police purposes ... as is necessary for the prevention, suppression, investigation, detection and prosecution of specific criminal offences or for the prevention of real danger, or as specified in any law.'[36] This includes collection of personal data by technical surveillance or other automated means.[37]

a. Criteria for processing

02.12
Personal data may be processed only when a number of conditions are satisfied:[38]

(a) when the data subject has given his or her consent;[39] or
(b) when processing is required in the course of performing a contract or other legal obligation, or in the performance of an activity carried out in the public interest, or even 'the vital interests of the data subject.'

Personal data processing for a legitimate interest of the controller or of a third party to whom the data is provided, is allowed except where 'such interest is overridden by the interest to protect the fundamental rights and freedoms of the data subject and in particular the right to privacy.'[40]

'The processing of personal data for police purposes shall as far as possible, be limited' to data necessary 'to allow the public authority exercising police powers to perform their functions according to Law and to fulfil international obligations arising out of any convention, treaty or bilateral agreement relating to police

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[35] Legal Notice 142 of 2004, came into force on 3rd September 2004 by Legal Notice 399 of 2004.
[36] *Data Protection (Processing of Personal Data in the Police Sector) Regulations 2004*, regulation 5(1).
[37] *Data Protection (Processing of Personal Data in the Police Sector) Regulations 2004*, regulation 5(3).
[38] *Data Protection Act*, article 9.
[39] *Data Protection Act*, article 9(a).
[40] *Data Protection Act*, article 9(f).

matters to which Malta is a party.'[41] When such 'personal data has been processed without the knowledge of the person concerned, the data subject should only be informed, where practicable, . . . as soon as the object of police activities is no longer likely to be prejudiced, and if the data are not deleted.'[42]

'The communication of personal data between different bodies exercising police powers shall only be permitted where there exists a legitimate interest for such communication within the framework of the legal powers of such bodies.'[43]

There is provision for transfer of personal data, collected for police purposes, to foreign authorities[44] 'exercising police powers'. This is allowed 'if there exists a legal obligation . . . or an international obligation under a treaty, convention or international agreement on mutual assistance, to which Malta is a party' or if it is 'necessary for the prevention of a serious and imminent danger, or is necessary for the suppression of a serious criminal offence.'

b. Objections to data collection and processing

02.13

The ***Data Protection Act*** seems to imply that direct marketing will be allowed except when the data subject objects to this.[45] Even though the subject is given appropriate information of his/her rights to do so, this article seems to be vague with respect to what 'direct marketing' actually means, and who precisely is going to be the recipient of this personal data.[46]

A data subject has the right to object at any time, to the controller, about the processing of personal data, when there are 'compelling grounds' to do so.[47] He may moreover withdraw his

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[41] *Data Protection (Processing of Personal Data in the Police Sector) Regulations 2004*, regulation 6(1).

[42] *Data Protection (Processing of Personal Data in the Police Sector) Regulations 2004*, regulation 5(2).

[43] *Data Protection (Processing of Personal Data in the Police Sector) Regulations 2004*, regulation 8(1).

[44] *Data Protection (Processing of Personal Data in the Police Sector) Regulations 2004*, regulation 9.

[45] *Data Protection Act*, article 10(1).

[46] *Data Protection Act*, article 10(2).

[47] *Data Protection Act*, article 11(1).

previously given consent, 'for compelling legitimate grounds relating to his particular situation.'[48] Again note that, in contrast with other international documents/instruments (e.g. the *1997* Council of Europe's ***Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine***), the data subject has to have compelling reasons to withdraw from being processed. The onus is thus on the data subject to show that there are such compelling grounds.

c. Processing sensitive personal data

02.14

Sensitive personal data means 'personal data that reveals race or ethnic origin, political opinions, religious or philosophical beliefs, membership of a trade union, health, or sex life.' Such data may not be processed, unless the data subject has given his explicit consent to processing or has made the data public.[49]

Sensitive personal data may however be processed under certain circumstances, including:

(a) when it is in the public interest;[50]
(b) when processing is considered necessary (e.g. to protect vital interests of the data subject or other person, or when legal claims have to be established);[51]
(c) processing of their members, by foundations or any body of persons (other than political, philosophical, religious or trade union entities), provided that data subjects explicitly consent;[52]
(d) processing for health and hospital care purposes, provided that it is necessary for preventive medicine, diagnosis, health care or treatment as well as management of health and hospital care. In this instance, a 'health professional' is a person with a warrant to exercise a profession regulated by the ***Medical and***

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[48] *Data Protection Act*, article 11(2).
[49] *Data Protection Act*, article 12(2). Note absence of reference to genetic data within this category.
[50] *Data Protection Act*, article 12.
[51] *Data Protection Act*, article 13.
[52] *Data Protection Act*, article 14.

Kindred Professions Ordinance and 'any person acting under the personal direction and supervision of such person may process such information';[53]

(e) for research purposes, provided that the research has been approved by the appropriate authority.[54] Here there is a reference to a research ethics committee, of an institution, being recognised by the Commissioner.

Processing of data relating to legal offences, criminal convictions or security measures may be processed only with certain specific provisos:

(a) that they will be under the control of a public authority, or authority given by the Minister to any person for this purpose;
(b) that a complete register of criminal convictions may only be kept under the control of a public authority.[55]

The processing of sensitive personal data for police purposes is allowed if 'this is necessary for the purposes of a particular inquiry.'[56]

02.15

The ***Identity Card Act*** establishes the requirement for all persons over the age of 14 years to have a unique identifier. Article 18 of the ***Data Protection Act*** states that the ID number may be processed only if consent is given. However, the exceptions to this rule include the 'importance of a secure identification' and 'some other valid reason as may be prescribed' which may be interpreted as giving a wide berth to situations requiring ID number processing. It is to be noted that there is considerable objection in countries outside Malta to allowing a single identifier (such as an identity card number) to be used for linking such disparate personal information relating to health, social security, and taxation data. This is considered by many to be an unacceptable intrusion into one's privacy.

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[53] *Data Protection Act*, article 15. Note that the *Medical and Kindred Professions Ordinance* is mostly repealed and replaced by the *Health Care Professions Act.*

[54] *Data Protection Act*, article 16(2).

[55] *Data Protection Act*, article 17.

[56] *Data Protection (Processing of Personal Data in the Police Sector) Regulations 2004*, regulation 5(4).

d. Rights of the data subject

02.16

A data subject has the right to certain information relating to collection of data, including the identity of the controller, and the purpose of data collection. S/he is also entitled to information about who will receive the data including third parties. A subject is entitled also to know whether s/he is obliged to give the information requested. S/he also has to know about the 'existence of the right to access, the right to rectify, and, where applicable, the right to erase the data concerning him.'[57]

The right to access to information is highlighted in the ***Data Protection Act***. A data subject may request information (at no cost, and without excessive delay) as to whether personal data has been processed, and if so, information relating to content, source and purpose of collection and processing, as well as information as 'to which recipients or categories of recipients the information is disclosed.'[58]

The controller[59] is liable to rectify, block or erase any personal data at the request of the data subject, and moreover to notify the third party to whom the data has been disclosed.[60]

Further protective measures relate to particular risks, and in particular, 'processing of personal data that involves particular risks of improper interference with the rights and freedoms of data subjects shall be submitted for prior checking to the Commissioner.'[61]

02.17

The Act provides for the establishment of a Data Protection Commissioner[62] who 'shall act independently and shall not be subject to the direction or control of any other person or authority,'[63]

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[57] *Data Protection Act*, article 19.

[58] *Data Protection Act*, article 21.

[59] The 'controller of personal data' or 'controller' means a person who alone or jointly with others determines the purposes and means of the processing of personal data (*Data Protection Act*, article 2).

[60] *Data Protection Act*, article 22.

[61] *Data Protection Act*, article 34 (1)(a).

[62] *Data Protection Act*, article 36.

[63] *Data Protection Act*, article 37.

who is appointed for a term of five years,[64] and whose functions include:[65]

(a) maintaining a public register of all processing operations;
(b) verifying whether processing is carried out in accordance with the provisions of this Act;
(c) taking remedial action, including legal action, relating to reports of violations of this Act;
(d) encouraging drawing up of suitable codes of conduct by various sectors;
(e) providing information to the general public relating to this Act.

The Commissioner has right of access to personal data, and other relevant documentation relating to processing. S/he has the power to prohibit the controller of personal data from processing personal data in any other manner than by storing them. S/he also 'shall have the same powers to enter and search any premises as are vested in the executive police by any law as may from time to time be in force.'[66]

An Appeals Tribunal is established[67] with powers to hear and decide any appeal made to it.[68]

e. Some comments on the Data Protection Act

02.18
There appears to be lacunae in this Act in relation to health-related information. The main weaknesses are:

(a) the Act seems to be largely oriented to the role and duties of the controller. The role of other data gatherers and processors are not defined. This is particularly relevant in relation to health related data;
(b) lack of distinction between anonymised data and traceable (e.g. coded) data;

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[64] *Data Protection Act*, article 39.
[65] *Data Protection Act*, article 40.
[66] *Data Protection Act*, article 41(5).
[67] *Data Protection Act*, article 48.
[68] *Data Protection Act*, article 50.

(c) lack of distinction between handling data for statistical purposes and that relating to other purposes (Note however that data collected for statistical purposes is dealt with in the ***Malta Statistics Authority Act***);
(d) there is not sufficient emphasis on the need for informed consent by the data subject at all stages of manipulation of data. This holds particularly when third parties become involved;
(e) the Act does not recognise the obvious lacunae in other areas of data processing, including particularly scientific research where there is currently no obligation to obtain permission to initiate any research, or obligation of Ethics Committees to ensure overseeing of outcomes, etc.;[69]
(f) the new field of genomic information has been completely ignored (merely referred to as 'health' data). Various international bodies have made specific instruments dealing with this data (See UNESCO, Council of Europe, WHO, etc.);
(g) use of data for purposes other than those for which they were originally obtained.[70] This is contrary to intentions expressed in recent international Instruments.

02.19
The ***Professional Secrecy Act,*** is meant to cover employees of government, or those employed by any body corporate established by law,[71] as well as to any person acting as a consultant to the Government of Malta or body corporate established by law.[72]

02.20
The ***Code of Organisation and Civil Procedure*** states that: 'Unless by order of the court, no accountant, medical practitioner or social worker, psychologist or marriage counsellor may be questioned on such circumstances as may have been stated by the client to the said person in professional confidence or as may have come to his knowledge in his professional capacity.'[73]

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[69] However there is legislation regarding clinical trials, the *Clinical Trials Regulations,* SL 458.43, which addresses these issues. See also Chapter 12: Research.
[70] *Data Protection Act,* article 13. See also articles 8, 10, 16, 20(4).
[71] *Professional Secrecy Act,* article 2(a)(b).
[72] *Professional Secrecy Act,* article 2(c).
[73] *Code of Organization and Civil Procedure,* article 588(2).

02.21

This is also stated in the ***Criminal Code*** which makes it an offence for 'any person, who by reason of his calling, profession or office, becomes the depositary of any secret confided in him' to disclose such secret 'except when compelled by law to give information to a public authority.'[74] A number of persons are considered to fall within the scope this article by virtue of their calling, profession or office. These are listed in the ***Professional Secrecy Act*** and include members of the medical and healthcare professions, legal professions and financial institutions.[75]

02.22

Other persons are considered to be a 'depository of a secret' by reason of being an employee or employer, practitioner or assistant of a person falling within the scope of article 257 of the ***Criminal Code*** or through obtaining information during the course of employment by the State.[76] Further any 'public officer or servant who communicates or publishes any document or fact, entrusted or known to him by reason of his office, and which is to be kept secret, or who in any manner facilitates the knowledge thereof' is liable to an offence under the said Code,[77] unless the act in question does not constitute a more serious offence as would be e.g. the case under the ***Official Secrets Act***.

6. Disclosure of Secret Information

02.23

This is allowed under certain circumstances:

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[74] *Criminal Code*, article 257.

[75] *Professional Secrecy Act*, article 3(1). These include professions regulated by the *Medical and Kindred Professions Ordinance*, (now *Health Care Professions Act*), advocates, notaries, legal procurators, social workers, psychologists, accountants, auditors, employees and officers of financial and credit institutions, trustees, officers of nominee companies or licensed nominees, persons licensed to provide investment services, licensed stockbrokers, insurers (agents, managers, brokers, sub-agents) and officials and employees of the State.

[76] *Professional Secrecy Act*, articles 4(1) and 4(2).

[77] *Criminal Code*, article 133.

(a) when there is authorisation from the person giving the information;[78]
(b) when such communication is necessary for the performance of services requested by the person who entrusted the information;[79] and
(c) disclosure compelled by law. A person is deemed to be compelled by law to give information to a public authority only when there is an express statutory requirement to that effect.[80] 'A Court may authorise or make an order requiring the disclosure of secret information pursuant to an express provision of law for the specific purposes for which that provision was enacted.'[81] Where the court authorises such disclosure, 'such evidence shall be held *in camera* and shall only be accessible to the court and to the parties.'[82]

It is not an offence to divulge secret information if the information had already entered the public domain legitimately.[83]

It is likewise not an offence 'for a person employed by the State to communicate secret information to another person employed by the same State entity or to the Minister responsible for that entity where such communication is directly necessary for the carrying out of their respective functions.'[84] However, this may be one source of leakage of secret information, through passage within governmental departments and ministries.

7. Electronic Data

02.24

Data held in electronic form is further protected by the ***Criminal Code*** as revised in 2001, which relates to unlawful access or use of information.[85] It states that:

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[78] *Professional Secrecy Act*, article 6(1).
[79] *Professional Secrecy Act*, article 7(1).
[80] *Professional Secrecy Act*, article 8.
[81] *Professional Secrecy Act*, article 9.
[82] *Professional Secrecy Act*, article 9. *Official Secrets Act*, article 11(3).
[83] *Professional Secrecy Act*, article 10. Note that in the *Data Protection Act*, article 12(2)(b), sensitive personal data may only be processed if the subject has given his consent or made the data public.
[84] *Professional Secrecy Act*, article 11(1).
[85] *Criminal Code*, article 337C.

'A person who without authorisation does any of the following acts shall be guilty of an offence against this article:

(a) uses a computer or any other device or equipment to access any data, software or supporting documentation held in that computer or on any other computer, or uses, copies or modifies any such data, software or supporting documentation;
(b) outputs any data, software or supporting documentation from the computer in which it is held, whether by having it displayed or in any other manner whatsoever;
(c) copies any data, software or supporting documentation to any storage medium other than that in which it is held or to a different location in the storage medium in which it is held;
(d) prevents or hinders access to any data, software or supporting documentation;
(e) impairs the operation of any system, software or the integrity or reliability of any data;
(f) takes possession of or makes use of any data, software or supporting documentation;
(g) installs, moves, alters, erases, destroys, varies or adds to any data, software or supporting documentation;
(h) discloses a password or any other means of access, access code or other access information to any unauthorised person;
(i) uses another person's access code, password, user name, electronic mail address or other means of access or identification information in a computer;
(j) discloses any data, software or supporting documentation unless this is required in the course of his duties or by any other law.'

Offences are also described in the ***Electronic Communications (Regulations) Act,*** which states that an employee of any electronic communications network and services is guilty of an offence if s/he:[86]

(a) 'gives any information with regard to any message with which he becomes acquainted by reason of his office to any person not entitled to receive such information;

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[86] *Electronic Communications (Regulation) Act,* article 35(3).

(b) wilfully alters or suppresses any message or the designation of the person to whom it is transmitted or to whom it is addressed, without a good cause;
(c) wilfully omits, delays or obstructs the transmission or delivery of any message or cancels or destroys any message or an application for the transmission of any message without a good cause;
(d) wilfully represents a message as having been sent by a person other than the sender or as being addressed to a person other than the addressee, or an application for the transmission of a message as having been made by a person other than the applicant, without good cause;
(e) wilfully cancels or destroys any message not addressed to him or an application for the transmission of a message, without good cause;
(f) unlawfully withdraws from the control of an undertaking, or of an individual employed or detailed for duty with, or attached to, an undertaking, a message addressed to another person.'

8. Confidentiality and the Press

02.25

The ***Press Act*** stipulates offences that may be committed 'by means of the publication or distribution in Malta of printed matter, from whatsoever place such matter may originate, or by means of any broadcast.'[87] By using such means to divulge any secret matter confided to him or her by reason of his profession or calling, such person 'shall be liable on conviction to imprisonment for a term not exceeding three months or to a fine (multa) or to both such imprisonment and fine.'[88]

Protection of confidentiality of sources is covered and no court shall require any journalist to disclose the source of information contained in a newspaper or broadcast for which he is responsible, 'unless it is established to the satisfaction of the court that such disclosure is necessary in the interests of national security, territorial integrity or public safety, or for the prevention of disorder or crime or for the protection of the interests of justice.'[89]

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[87] *Press Act*, article 3.
[88] *Press Act*, article 8.
[89] *Press Act*, article 46.

9. Confidentiality Relating to Persons with Disability

02.26

The Commission established by the ***Equal Opportunities (Persons with Disability) Act*** is bound to ensure confidentiality relating to information, concerning persons with disability. It states: 'The Commission shall deal with all documents and other information in its possession or under its control, or otherwise coming to its notice, concerning persons with disability, and all matters and things relating to such persons, as confidential and the obligation of confidentiality imposed upon the Commission shall extend to all the members of the Commission, the Executive Director and to all the officials and servants of the Commission.' [90]

Special requirements obtain relating to the confidentiality of medical information obtained from examination of persons with disability for employment purposes. Any information obtained 'regarding the medical condition and history of the applicant in relation to his disability shall be:

(a) collected and maintained on separate forms;
(b) kept in separate medical files; and
(c) treated as a confidential medical record.' [91]

10. Employment and Confidentiality of Health Data

02.27

The ***Occupational Health and Safety Authority Act*** sets up an Authority whose functions include the collation and analysis of 'data and statistics on occupational injuries, ill health and deaths, and on matters ancillary to occupational health and safety.' [92] Such data or information 'shall be deemed to have been given and received under the obligation of confidentiality.'

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[90] *Equal Opportunities (Persons with Disability) Act*, article 26(3).
[91] *Equal Opportunities (Persons with Disability) Act*, article 8(3).
[92] *Occupational Health and Safety Authority Act*, article 9(2)(h).

11. Confidentiality and Infectious (Venereal) Diseases

02.28

A medical practitioner has a specific duty to notify certain particulars, about a patient suffering from venereal disease, to the Health authorities. The practitioner is required to submit such information to the authorities, giving 'particulars as to the patient and the disease from which the patient is suffering and as to the person from whom it is suspected that the disease was contracted.'[93]

The practitioner is required to 'explain to the patient that all information supplied will be treated as strictly confidential and that any communication made in good faith for the purposes of this Act is exempt from civil or criminal proceedings.'[94]

02.29

Issues relating to notifiable diseases are discussed in **Chapter 3: The Healthcare Professions - Medical Issues** and in **Chapter 13: Public Health Issues.** It is worth noting that infection with HIV virus is now also a notifiable disease in Malta.[95]

12. Ethics of the Medical and Dental Professions

02.30

In the subsidiary legislation, ***Ethics of the Medical Profession Regulations*** it is stated that: 'A medical practitioner must not disclose voluntarily without the consent of the patient, preferably written, information, including certification which he has obtained in the course of his professional relationship with the patient. Exception to this rule is made only by the requirements of the law. Medical practitioners are reminded of article 257 of the ***Criminal Code,***'[96] which has been discussed above.

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[93] *Venereal Diseases (Treatment) Act,* article 3. Similar provisions exist for notifiable diseases in the *Public Health Act,* article 31, (not yet in force by 31st December 2005) but there is no mention of confidentiality.

[94] *Venereal Diseases (Treatment) Act,* article 4(1).

[95] Government Notice No. 75 of 2004 published in the Government Gazette of 27th January 2004 in terms of the *Public Health Act,* article 27(a)(i).

[96] *Ethics of the Medical Profession Regulations,* SL 94.15, regulation 13(1).

02.31
Similarly the subsidiary legislation, ***Ethics of the Dental Profession Regulations*** states that: 'A practitioner must not disclose voluntarily, without the consent of the patient, preferably written, information, including certification which he has obtained in the course of his professional relationship with the patient. Exception to this rule is made only by the requirements of the law.'[97]

13. Some International Comparisons

02.32
Directive 95/46/EC[98] issued by the European Parliament in October 1995 is the source directive, which has been transposed comprehensively into the ***Data Protection Act.*** Some of the differences may be highlighted here.

The Directive has a preamble of 72 'recitals' which give a background to the Articles in the Directive. This has been omitted completely from the Maltese ***Data Protection Act.*** This can give rise to some misunderstandings. For instance, Recital 26 refers to the need that the principle of protection should apply to:

(a) information concerning an identified or identifiable person;
(b) for this purpose account should be taken of all the means, likely and reasonably, to be used, either by the controller or by any other person, to identify the said person;
(c) the principles of protection shall not apply to data rendered anonymous in such a way that the data subject is no longer identifiable;
(d) guidance to be provided in relation to ways in which data may be rendered anonymous and retained in a form in which identification of the data subject is no longer possible.

02.33
Reference is also made in Recitals 39-40 to disclosure of data collected, namely:

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[97] *Ethics of the Dental Profession Regulations*, SL 94.14, regulation 5.
[98] *Directive 95/46/EC* of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

(a) the legitimate disclosure of data to a third party, even if the disclosure was not anticipated at the time the data were collected from the data subject. In such a case the data subject should be informed when the data are recorded or at the latest when the data are first disclosed to a third party;
(b) however, there is no obligation for this requirement if the recording or disclosure are expressly provided for by law, or if the provision of information to the data subject proves impossible, or would involve disproportionate efforts, which could be the case where processing is for historical, statistical or scientific purposes.

This exception may become very important particularly with respect to examining and manipulating data which had been collected for one purpose (e.g. medical diagnosis) and retained in archives for several years, and then used for research purposes, for instance. It is one way of escaping from the obligation of informing the data subject (i.e. patient in this case) of the fact that data obtained from him or her several years previously, were being manipulated, albeit anonymously.

02.34

The Council of Europe's ***Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine,*** although not yet law in Malta is expected to become so in the near future. Chapter III of this Convention deals with private life and the right to information. Article 10 states that:

1. Everyone has the right to respect for private life in relation to information about his or her health.
2. Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed.
3. In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraph 2, in the interest of the patient.

02.35

These Articles re-affirm the principles contained in the ***Charter of Fundamental Rights of the European Union,***[99] and the ***Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data.***[100] They establish the patient's right to know as well as the equally important principle of the right not to know. Health professionals are obliged to respect both of these principles.

There are, however, situations where it is considered essential for the patient to know certain facts, irrespective of whether they wish to know or not. Such situations include information relating to predisposition to disease about which they could take active steps regarding prevention, or when there is a particular risk of the patient infecting someone else (e.g. a patient with HIV infection who takes no suitable measure to protect his spouse or partner).

02.36

Restriction of these rights are also highlighted. In the first instance, there could be situations where such information could be harmful to the patient. This could be the case in patients with a mental disorder, from whom information may be withheld for the benefit of the patient. Likewise, there could be a case where restriction of information would be necessary to protect the rights of a third party, namely those which refer to those restrictions 'prescribed by law and are necessary in a democratic society in the interest of public safety, for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others.'[101]

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[99] *Charter of Fundamental Rights of the European Union,* article 8.

[100] *Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data,* article 6.

[101] Council of Europe's *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine,* article 26(1).

02.37

Article 8 of the ***Charter of Fundamental Rights of the European Union***[102] deals with protection of personal data. It states:

1. Everyone has the right to the protection of personal data concerning him or her.
2. Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified.
3. Compliance with these rules shall be subject to control by an independent authority.

[102] This provision has also been incorporated in Part II, Title II, Article II-8 of the Treaty Establishing a Constitution for Europe.

Chapter 3

The Health Care Professions: Medical Issues

1. Introduction

03.01

The new ***Health Care Professions Act,*** integrates and updates several aspects of the ***Medical and Kindred Professions Ordinance,*** and the ***Department of Health (Constitution) Ordinance.*** Several aspects of the older legislation are therefore repealed.

This Act defines the several Councils that are responsible for the various professions, as follows:

(a) Medical Council;[1]
(b) Pharmacy Council;[2]
(c) Council for Nurses and Midwives;[3]
(d) Council for the Professions Complementary to Medicine.[4]

It also defines a 'health care profession' as one which is regulated by this Act; and 'health care professional' as a person who is authorised to practise a health care profession in accordance with the provisions of this Act.[5]

03.02

Medical doctors, dentists, pharmacists and midwives must be in possession of a 'licence', which means an endorsement issued to a

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[1] *Health Care Professions Act,* article 9.
[2] *Health Care Professions Act,* article 15.
[3] *Health Care Professions Act,* article 21.
[4] *Health Care Professions Act,* article 26.
[5] *Health Care Professions Act,* article 2.

health care professional by the President of Malta. A health care professional must be registered as a member of one of the health care professions by the 'relevant Council' that is:

(a) the Medical Council for medical practitioners and dental surgeons;
(b) the Pharmacy Council for pharmacists and pharmacy technicians;
(c) the Council for Nurses and Midwives for nurses and midwives;
(d) the Council for the Professions Complementary to Medicine for the Professions Complementary to Medicine, listed in the Third Schedule.

03.03

The enactment also employs the concept of a 'specialist', which means a health care professional whose name is entered in the appropriate part of the specialist register kept by the relevant Council.[6] 'A "speciality" is such speciality as is listed in the Fifth Schedule of this Act or as may be prescribed.'[7] Specialists are entitled to assume the appropriate professional and academic titles.[8]

The Act deals with the practice of the health care professions. For all the professions mentioned above, a number of conditions are laid down, namely that:

(a) the use of any professional title (including related abbreviations) corresponding to a health care profession, depends on fulfilling the required conditions for pursuing that profession;[9]
(b) one must be a citizen of Malta or a person otherwise legally entitled or authorised to work in Malta;[10]
(c) one may not practice any two or more of the health care professions concurrently,[11] except when the Minister may (exceptionally) approve; and
(d) one is subject to supervision by the relevant Council.[12]

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[6] *Health Care Professions Act*, article 2.
[7] *Health Care Professions Act*, article 30(9)(b). At present, there are specialist registers for medical practitioners and for dental surgeons.
[8] *Health Care Professions Act*, articles 29(2) and (3).
[9] *Health Care Professions Act*, article 3(2).
[10] *Health Care Professions Act*, article 3(3).
[11] *Health Care Professions Act*, article 4.
[12] *Health Care Professions Act*, article 5.

2. The Medical Council

03.04

This Act sets up the Medical Council, consisting of a President, who is a legal practitioner, appointed by the Prime Minister, and several medical and dental practitioners appointed or elected as follows:[13]

(a) one medical practitioner, one dental surgeon and two persons who are not health care professionals appointed by the Prime Minister;
(b) one medical practitioner appointed by the University of Malta;
(c) five medical practitioners, at least one of whom must be a hospital-based specialist and one a general practitioner, elected from and by all medical practitioners;
(d) two dental surgeons elected from and by all dental surgeons.

The functions of the Medical Council include the following:[14]

(a) to recommend to the President of Malta the granting or revoking of licences to medical practitioners and dental surgeons;
(b) to keep the respective registers up to date;[15]
(c) to prescribe and maintain professional and ethical standards for the medical and dental professions;
(d) to set up committees for the purposes of enforcing professional and ethical standards applicable to medical practitioners and dental surgeons;
(e) to investigate allegations of misconduct and take disciplinary action in accordance with article 31 of this Act;
(f) to advise the Minister on any matter affecting the medical and dental professions; and
(g) to set up registration fees and yearly retention fees.

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[13] *Health Care Professions Act*, article 9.

[14] *Health Care Professions Act*, article 10.

[15] These include the Medical Register, the Register of Dental Surgeons and the Specialist Registers according to the Fifth Schedule of the *Health Care Professions Act*.

3. Some Relevant Definitions

03.05

Medical practitioner is not defined in the ***Health Care Professions Act***. However, in the ***Medicines Act*** it refers to a person who is authorised to exercise such profession under the ***Medical and Kindred Professions Ordinance*** or any other law replacing it. Therefore one can draw the conclusion that this term would refer to a health care professional person who possesses a licence granted by the President of Malta to practise the medical profession in Malta and whose name is on the Medical Register kept by the Medical Council.[16]

In fact, in the ***Social Security Act***, a 'medical practitioner' or a 'dental practitioner' means a person who is authorised to exercise such profession under the ***Medical and Kindred Professions Ordinance*** or any other law replacing the same.

Specialist means a medical practitioner or dental surgeon whose name is entered in the appropriate part of the specialist register kept by the Medical Council in accordance with the ***Health Care Professions Act***.

Medical treatment means medical, surgical or rehabilitative treatment including any course or diet or other regimen, and any surgical and pharmaceutical aid.[17]

Disease includes any injury, ailment or adverse condition, whether of body or mind.[18]

Medicinal product means any substance or combination of substances presented for treating or preventing disease in human beings, as well as any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological

[16] *Health Care Professions Act*, article 7.
[17] *Social Security Act*, article 2.
[18] *Medicines Act*, article 2.

functions in human beings.[19] The ***Medicines Act***[20] classifies medicinal products according to whether there is, or not, a need for a prescription.

Practice in respect of any health care professional means the taking up, and/or, pursuit of the respective profession and includes the provision of services.[21]

Good conduct means conduct to the satisfaction of the relevant Council.[22]

Professional and ethical standards include the 'standards relating to the general conduct of a member of a health care profession, including the behaviour of such member towards his client or the patient under his care or being attended by him, during or consequential to the exercise of his profession, and the behaviour of such member towards other members of his profession and towards members of other health care professions and towards society.' [23]

4. Licence to Practice

03.06

To practise medicine or dentistry in Malta, one must hold a licence issued by the President of Malta. To qualify for such a licence, one must:

(a) be a citizen of Malta or of a Member state or is otherwise legally entitled or authorised to work in Malta;
(b) be of good conduct; and
(c) have his/her name entered in the Medical Register or the Register of Dental Surgeons.[24]

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[19] *Medicines Act*, article 2.
[20] *Medicines Act*, article 29.
[21] *Health Care Professions Act*, article 2.
[22] *Health Care Professions Act*, article 2.
[23] *Health Care Professions Act*, article 2. See also *Department of Health (Constitution) Ordinance*, article 2.
[24] *Health Care Professions Act*, articles 7 and 8.

5. Medical and Dental Specialists

03.07

The ***Health Care Professions Act***[25] states that no one shall practise as a specialist unless he is registered in the respective register for specialists, kept by the Medical Council in the case of medical practitioners and dental surgeons. This register includes the name of the doctor or dentist who:

(a) is in possession of a certificate issued by the Specialist Accreditation Committee for the profession, which shows that he has completed the prescribed specialist training for the speciality; or
(b) is in possession of a specialist qualification listed in the Second Schedule;[26] or
(c) is in possession of any specialist qualification recognized by the Specialist Accreditation Committee.

03.08

The Act establishes the Specialist Accreditation Committee (SAC) for each of the professions, including one for medical practitioners and another for dental surgeons.[27]

The SAC is to be composed of the following members:

(a) one member appointed by the relevant Council;
(b) one member, not being a member of the relevant Council, appointed by the Dean of the relevant Faculty or Director of the relevant Institute of the University of Malta;
(c) one member, not being a member of the relevant Council, appointed by the Superintendent of Public Health; and
(d) one member, not being a member of the relevant Council, appointed by each of the relevant professional associations.[28]

The functions of the Specialist Accreditation Committee are:[29]

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[25] *Health Care Professions Act*, article 29(1) and (4).
[26] *Health Care Professions Act*, Second Schedule, Part Ib includes the list of qualifications in specialised medicine in Member States and Part IIb the qualifications in specialised dentistry in Member States.
[27] *Health Care Professions Act*, article 30.
[28] *Health Care Professions Act*, Part II of the Fourth Schedule.
[29] *Health Care Professions Act*, article 30(6)(a).

'(i) to issue certificates of completion of specialist training in the specialities listed in the relevant part of the Fifth Schedule, upon the fulfilment of criteria recommended by the relevant professional associations listed in the Fourth Schedule;
(ii) to advise the Minister and the relevant Council on issues concerning specialist training and registration, and any other matter that may be referred to it;
(iii) to act as the advisory body for training in any of the special areas of practice;
(iv) to accredit post-graduate training programmes;
(v) to levy such fees for accreditation, as may be prescribed.'

6. Consent and the Doctor

03.09

The requirements for informed consent have been discussed in **Chapter 1**. It remains the responsibility of a doctor to ensure that a patient is capable of giving consent and if so, to ensure that all requirements for giving consent have been met.[30] Specifically, a patient must be aware of the following aspects relating to a procedure:

(a) why the procedure is being performed;
(b) whether there are other alternatives to the procedure;
(c) a brief description of what will take place during the procedure;
(d) information about anaesthesia required: local or general;
(e) mention of significant risks and complications; it is always difficult to draw the line between too little emphasis to avoid frightening the patient, and too much, with an aim to reduce chances of future litigation;
(f) prognosis relating to disease with or without the procedure;
(g) requirements prior to, or following procedures (e.g. fasting, bed rest, etc.);
(h) whether another doctor will be performing the procedure, in which case the patient should be told about the possibility of this;

[30] General Medical Council, UK: *Seeking Patient's Consent: the Ethical Considerations,* November, 1998.

(i) patients should be given time to ask questions, both immediately, and some time after having considered the problem. They must be told that they have the right to change their mind prior to the procedure without this in anyway affecting their medical care; and
(j) involvement of other persons, particularly students and trainees, must be discussed and consent given.[31]

03.10
These requirements hold in all cases but in particular in the following situations:

(a) *Intimate examinations*:[32] These involve examination of the rectum, groin, breast, vaginal examinations, and examination of male genitalia. A medical practitioner may be requested by a Magistrate to perform a body search in the case of a person suspected of having unlawful drugs concealed on their persons. In the case of a person of a different sex from the examiner, no search should be made unless 'the expert is a medical practitioner and the person to be searched consents thereto in writing.'[33] Moreover, 'an intimate sample may be taken from a person arrested only if his appropriate consent is given.'[34]
(b) *Examination under anaesthesia*: Where medical students or trainees are expected to carry out such examinations, specific permission must be obtained from the patient beforehand. The number of students and trainees allowed to take part in such examinations should be strictly limited.

03.11
In case of litigation, any or all of the following might be held responsible for failing to obtain the required informed consent from a patient:

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[31] Some of these points have been incorporated in the *Patients' Charter of Rights and Responsibilities* of St. Luke's Hospital.
[32] Department of Health (UK): Reference Guide to Consent for Examination or Treatment, March 2001.
[33] *Criminal Code*, article 355AQ(2).
[34] *Criminal Code*, article 355AW. See Chapter 1 for definitions of 'appropriate consent', 'intimate sample' and for legislation regulating the taking of samples.

(a) the individual performing the examination or procedure;
(b) supervisors in case of students;
(c) the hospital concerned.

Too often, litigation arises from the fact that there was no adequate explanation of procedures and, after the procedure, no attempt is made at admitting that some things might have gone wrong. Admission of errors is often all that is required to prevent relations souring and litigation starting.

7. Confidentiality[35]

03.12

Confidentiality is considered to be one of the most important aspects of a doctor's obligations towards a patient. It is emphasised through several codes of practice, and enshrined within the legislation of Malta, particularly in the ***Criminal Code***. This provides that: 'If any person, who by reason of his calling, profession or office, becomes the depositary of any secret confided in him, shall, except when compelled by law to give information to a public authority, disclose such secret, he shall on conviction be liable to a fine *(multa)* not exceeding twenty thousand liri or to imprisonment for a term not exceeding two years or to both such fine and imprisonment.'[36]

The ***Code of Organisation and Civil Procedure*** when dealing with privileged communications, clearly states that: 'Unless by order of the court, no accountant, medical practitioner or social worker, psychologist or marriage counsellor may be questioned on such circumstances as may have been stated by the client to the said person in professional confidence or as may have come to his knowledge in his professional capacity.'[37]

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[35] The General Medical Council, UK, has issued a useful booklet on this topic: *Confidentiality: Protecting and Providing Information*, April 2004.

[36] *Criminal Code*, article 257.

[37] *Code of Organisation and Civil Procedure*, article 588(2). It is to be noted that the phrase 'unless by order of the court' is not included in article 588(1) which refers to requesting confidential information obtained by an advocate or legal procurator or clergymen obtaining confidential information during confession. In other words, doctors may be requested, by a court, to reveal professionally obtained information, but the legal profession may not.

However article 642 of the ***Criminal Code***[38] implies that medical practitioners may not be compelled to reveal a professional secret, in court. The Code states:

'(1) Advocates and legal procurators may not be compelled to depose with regard to circumstances knowledge whereof is derived from the professional confidence which the parties themselves shall have placed in their assistance or advice.
(2) The same rule shall apply in regard to those persons who are by law bound to secrecy respecting circumstances on which evidence is required.'

03.13

There are situations, however, when a doctor is required to breach confidentiality. This requirement often puts the doctor in a very difficult situation, which needs to be negotiated on its own merit. Situations which require a doctor to reveal confidential information include:

(a) when required to do so by a court of law, doctors may not refuse to answer questions.[39] The court has the power 'to order the production of any expert or other witness who shall appear from the *procès-verbal* to have been examined at the inquest; and for such purpose any such expert or witness shall, in all cases within the jurisdiction of the Criminal Court, be included in the list of the witnesses of the Attorney General, to be, if necessary, examined.'[40]

To note also that a magistrate holding an inquest may 'order the seizure of any papers, effects, and other objects generally, which he may think necessary for the discovery of the truth.'[41] Papers may include medical records.

(b) notifiable diseases (section 8b);
(c) notification of cancer;
(d) incidents of food poisoning;
(e) accidents at work;

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[38] *Criminal Code*, article 642.
[39] As required by article 257 of the *Criminal Code* referred to earlier.
[40] *Criminal Code*, article 550(3).
[41] *Criminal Code*, article 554(1).

(f) births, including still births and abortions;[42]
(g) deaths;[43] and
(h) reporting of drug addicts. The Superintendent of Public Health is required to keep a register with the details of every drug addict. Every medical or dental practitioner must inform the Superintendent (on the prescribed form), of every patient under his care who in his opinion 'is suffering from any form of addiction to or dependence on a drug.'[44] No drug[45] may be prescribed unless the addict has been registered by informing the Superintendent.

One notes also that a person who would otherwise be bound by professional secrecy may divulge information to 'a competent public authority' relating to drug offences under the ***Dangerous Drugs Ordinance*** and the ***Medical and Kindred Professions Ordinance*** but this does not apply to the medical profession.[46] Again, the Commissioner of Police, in terms of case law rather than an explicit provision of the law, is not bound to reveal his/her sources and hence the courts, both in the UK and in Malta, have protected the identity of informers.[47]

It is also normally accepted that a doctor may breach the confidentiality rule in the following circumstances:

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[42] *Civil Code*, article 272. Births are to be reported within five days of a birth at which he attended, in default of the father or anyone else present at the birth, such as the midwife.

[43] *Civil Code*, article 296 and Certificate of Death, Second Schedule, *Medical and Kindred Professions Ordinance.*

[44] *Registration of Drug Addicts Regulations*, SL 31.21, regulation 3(1).

[45] *Registration of Drug Addicts Regulations*, SL 31.2. A 'drug' means a drug or chemical listed in the Third Schedule to the *Medical and Kindred Professions Ordinance* (psychotropic drugs) and any drug to which the *Dangerous Drugs Ordinance* refers.

[46] *Criminal Code*, article 257.

[47] *Ir-Repubblika ta' Malta vs. Andrew sive Andrea Facchetti u Frederick Joseph Attard*, 9th June 1994, Kollezzjoni ta' Decizjonijiet tal-Qrati Superjuri ta' Malta Vol. LXXVIII, 1994, Pt. I, p. 100; and *Ir-Repubblika ta' Malta vs. Meinrad Calleja*, Court of Criminal Appeal, Superior Jurisdiction, Kollezzjoni ta' Decizjonijiet tal-Qrati Superjuri ta' Malta, Vol. LXXXIV, 2000, Pt. IV, 3.5.2000, pp. 8–9.

(a) when the patient has given written consent for this to take place (for instance, for the purposes of research);
(b) when it is considered to be in the patient's best interest. This often poses problems as to how a person's best interests are to be defined when these do not necessarily agree with the judgement of the patient;
(c) in the public interest. The rights of a patient cease when the rights of other persons start. For instance in the case of child abuse, rape or other serious violence, a doctor must take action to protect the injured party;
(d) an Act of Parliament requiring the production of information about patients, e.g. the ***Notification of Cancer Act*** and the ***Data Protection Act***, which refers specifically to 'sensitive data' among which is included data relating to health.[48]

To note also that confidentiality should be maintained even after the patient's death.

8. Duties of Medical Practitioners

03.14
The duties of the medical practitioner were clearly enunciated in the ***Medical and Kindred Professions Ordinance***, but the relevant article 7 has been repealed by the recent ***Health Care Professions Act***. However, we believe it is still worth enumerating these duties,[49] with reference to other existing legislation:

(a) in cases of urgency, whether by day or by night, to 'render his aid and prescribe the necessary remedies';
(b) to notify the Superintendent of Public Health of any facts or circumstances touching public health; this includes notifiable diseases of an infectious nature[50] with the responsibility for notification lying also with the person in charge of a laboratory, which issues a positive result[51] (the registration of drug addicts

[48] *Data Protection Act*, article 12(2).
[49] *Medical and Kindred Professions Ordinance*, article 7, repealed by the *Health Care Professions Act*.
[50] *Public Health Act*, article 31(1) (not yet in force by 31st December 2005) and *Venereal Diseases (Treatment) Act*, article 3.
[51] *Public Health Act*, article 31(2) (not yet in force by 31st December 2005).

to the Superintendent of Public Health is justified as a public health issue);[52]

(c) to notify cases of suspected food poisoning to the Superintendent of Public Health;[53]

(d) to notify the Superintendent of Public Health about cases of disease or incident associated with the patient's employment. A list of diseases, for which compensation is available is set out in the Fourth Schedule to the Social Security Act;

(e) to inform the police of any grievous bodily harm or poisoning or violent death;

(f) in every case of death, to report to the police in writing, indicating the cause thereof, using the form set out in the Second Schedule[54] (Death Certificate);

(g) to report, within five days, to the police any birth at which s/he assisted (unless a midwife was also present), in default of the father. The duty is mainly the father's but anyone present at the birth can, in default of the father, carry that responsibility;[55]

(h) when referring a patient to a government hospital, s/he should give adequate medical particulars concerning the patient, on the proper forms;

(i) to use the specified forms when prescribing medicinals to a patient entitled to medical aid under the ***Social Security Act***; and

(j) to use the correct nomenclature in accordance with the international classification of diseases of the World Health Organisation when writing certificates for patients.

Medical practitioners and dentists are also to notify cases of cancer to the Superintendent of Public Health.[56]

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[52] *Registration of Drug Addicts Regulations*, SL31.21, article 3(1).

[53] Unspecified food-borne illness is one of the notifiable diseases in terms of the *Public Health Act*, article 27(a)(i). Government Notice No. 75 of 2004 was published in the Government Gazette of 27th January 2004.

[54] The Second Schedule is retained in the *Medical and Kindred Professions Ordinance*.

[55] *Civil Code*, article 272.

[56] *Notification of Cancer Act*, article 3.

a. Emergency situations and duty of care

03.15

A doctor is expected to render his or her services in an emergency. The ***Medical and Kindred Professions Ordinance,*** stated that it was the duty of every medical practitioner 'to practise his profession whenever he is so required in cases of urgency, whether by day or by night, and without any wilful delay to render his aid and prescribe the necessary remedies.'[57] However, this article has been repealed by the ***Health Care Professions Act.*** Yet it is still considered as correct responsible practice that no medical practitioner can deny his/her services when called in an emergency. In fact the ***Public Health Act,*** states that in an epidemic, 'medical practitioners exercising their profession within the area affected by the disease, as well as other medical practitioners engaged by the Government, shall not refuse to treat persons suffering from such disease within the area.'[58]

It might be argued that the word 'emergency' has not been adequately defined; what is considered an emergency by a patient is not necessarily considered to be so by a medical practitioner.

Certain countries, e.g. UK, consider that there is no legal obligation to treat people needing medical assistance, such as on an aeroplane or in the street. Assistance in such a situation is a matter for personal decision in the spirit of being a good Samaritan. However, other countries require a doctor to come to the assistance of a patient in an emergency. This is the case for Germany and France, for instance, and includes persons who require such help on one of their airlines. It is worth while pointing out that in such a situation there is always the possibility of litigation if things go wrong, however unlikely this may appear to be.

Maltese law refers only to practice within the Maltese islands, and does not include responsibilities of doctors who happen to be at a scene of an accident when overseas. There is no obligation imposed on medical practitioners in Maltese law that require medical practitioners to render services to patients overseas in case of an emergency.[59]

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[57] *Medical and Kindred Professions Ordinance,* article 7(1), repealed by the *Health Care Professions Act.*

[58] *Public Health Act,* article 35.

[59] This might change for Member States, in line with practice in Europe.

3.16

The concept of 'duty of care' refers to the responsibility that a person or an organisation has towards a client or patient. In the case of a doctor, as mentioned above, one assumes that this duty extends towards a patient under one's care, but does not extend to anything like the same extent to a stranger, (although Maltese law does not make such a distinction). Whether a doctor decides to give help, including first aid, to a total stranger ('Samaritan' effect), is often left to the individual doctor to decide.

In countries such as the UK where a practitioner has a certain specified number of patients registered with the practice, one would assume that such a practice, or group of doctors, have a duty of care towards the registered person who requires their care.

In the case of a hospital, there is obviously a duty of care to patients for the duration of their stay within the hospital, and for the necessary follow-up. Hospitals which have an emergency department have an assumed duty of care to all those who present themselves with an emergency condition requiring attention. This duty starts as soon as a patient sets foot within the hospital.

Those hospitals (public or private) which do not have an emergency department are not obliged to take in patients with an emergency problem. One would expect, however, that they would provide every reasonable facility to ensure prompt help to the extent that they can provide such care.

b. Notification / reporting of cases of disease

03.17

It is the duty of a medical practitioner to report any cases of disease that can be considered a public health risk, even if this conflicts with the right of privacy of the individual patient. The following are specifically mentioned in legislation:

(a) notifiable diseases, including food poisoning - see below;
(b) the ***Notification of Cancer Act*** states that 'every medical practitioner attending on or called in to visit a patient shall forthwith, on becoming aware that the patient is suffering from cancer in any form, send to the Superintendent of Public Health a certificate stating the name, age, occupation and address of the patient and the type of cancer from which, in his opinion,

the patient is suffering as well as the organ, tissue or site which is affected by the disease';[60]

(c) incidents and diseases connected with one's employment, were specifically covered in the ***Medical and Kindred Professions Ordinance***, article 7, which is now repealed. However, the appropriate certificate is still to be found in the First Schedule;[61]

(d) grievous bodily harm, poisoning or violent death, were specifically mentioned in the ***Medical and Kindred Professions Ordinance***, article 7, with a duty to inform the police;[62]

(e) the registration of drug addicts to the Superintendent of Public Health is also justified as a public health issue and is covered by the subsidiary legislation, ***Registration of Drug Addicts Regulations***.[63]

03.18

This issue is dealt mainly by the ***Public Health Act***, which states that a medical practitioner who treats or examines a person for a notifiable disease must report the disease to the Superintendent of Public Health, on the prescribed certificate.[64] 'The person in charge of a laboratory that receives a primary specimen or sample that yields a positive result indicating that the patient who supplied the specimen is suffering from a notifiable disease' also has to report such findings to the Superintendent according to the prescribed manner.[65] The law specifically provides that the reports 'shall not require the consent of the person being treated or examined.'[66]

The Superintendent may require a person to be examined by a medical practitioner if it is suspected that 'such person is suffering from a notifiable disease or if he has an occupation which

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[60] *Notification of Cancer Act*, article 3.

[61] *Medical and Kindred Professions Ordinance*, article 7(1c). The specific form is extant in Part 2 of the First Schedule. See also Fourth Schedule, *Social Security Act*, which contains a list of diseases for which compensation is available, which is more extensive than that in the First Schedule of the *Medical and Kindred Professions Ordinance*.

[62] *Medical and Kindred Professions Ordinance*, article 7(1d), now repealed.

[63] *Registration of Drug Addicts Regulations*, SL 31.21, regulation 3(1).

[64] *Public Health Act*, article 31(1). Not yet in force by 31st December 2005.

[65] *Public Health Act*, article 31(2). Not yet in force by 31st December 2005.

[66] *Public Health Act*, article 31(3). Not yet in force by 31st December 2005.

is considered capable of spreading disease.' The doctor must 'provide the Superintendent with a written report.'[67]

Moreover the Superintendent may require any person to notify him of the presence or occurrence of any notifiable disease, any human pathogenic organisms or any contaminant or even just the suspicion of any of these.[68]

03.19

The list of notifiable diseases is issued by the Superintendent, in terms of article 27.[69] It includes venereal diseases but these receive special consideration in the ***Venereal Diseases (Treatment) Act.*** A doctor is bound to report information received from a patient found to be suffering from a venereal disease. He is expected to 'send a notice in the prescribed form to the Chief Government Medical Officer giving the prescribed particulars as to the patient and the disease from which the patient is suffering and as to the person from whom it is suspected that the disease was contracted.'[70] The doctor must explain to the patient that all the information supplied will be treated as strictly confidential, and that such information will be exempt from civil or criminal proceedings.[71] The doctor must obtain the patient's signature or mark to a statement setting out that patient's consent to the proposed transmission of notice.[72]

03.20

Special precautions and regulations are envisaged in the eventuality of epidemic disease. In fact the ***Public Health Act,*** states that in an epidemic, 'medical practitioners exercising their profession within the area affected by the disease, as well as other medical practitioners engaged by the Government, shall not refuse to treat persons suffering from such disease within the area.'[73]

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[67] *Public Health Act,* article 28. Not yet in force by 31st December 2005.
[68] *Public Health Act,* article 31(4). Not yet in force by 31st December 2005.
[69] *Public Health Act,* article 27(a)(i). The Government Notice was issued on 27th January 2004.
[70] *Venereal Diseases (Treatment) Act,* article 3.
[71] *Venereal Diseases (Treatment) Act,* article 4(1).
[72] *Venereal Diseases (Treatment) Act,* article 4(2).
[73] *Public Health Act,* article 35. Not yet in force by 1st March 2005.

It is clear from this article that it is considered an obligation for the medical practitioner to place oneself at the service of the patient irrespective of the danger that this imposes on oneself or one's family. It is also to be concluded from this article that only medical practitioners 'engaged by the Government to give his services in such district' are expected to be so responsive to patients' needs and not necessarily all medical practitioners not so engaged.

As regards the reporting of cases of food poisoning, previously covered under the ***Medical and Kindred Professions Ordinance,*** article 7, this is now catered for under the ***Public Health Act*** through the list of notifiable diseases in terms of article 27, where, among others, are listed, unspecified foodborne illness and salmonellosis.

c. Death certification

03.21

The doctor in attendance during the last illness has the duty of reporting the death of the person, without delay, on the specific form, containing the following information:[74]

(a) place of death;
(b) cause of death; and
(c) date and time at which death occurred.

This notice is to be delivered to any adult member of the family of the deceased, or transmitted directly to the relevant police officer, drawing up the act of death.

Where a doctor was not attending the person who died, the duty to give notice of such a death devolves on members of the family or other person occupying the house of the deceased or other place where death occurred.[75]

The doctor carries out such a duty by issuing a death certificate and to do so, must be in a position to state the cause of death. The appropriate form of the death certificate is given in the Second Schedule of the ***Medical and Kindred Professions Ordinance.*** It requires the following information:

[74] *Civil Code,* article 296(1) and Form F in Part II of the Schedule.
[75] *Civil Code,* article 297.

(a) details of the dead person (name, age, I.D., residence, etc.);
(b) details relating to date, time and place of death;
(c) disease or condition leading directly to death;
(d) antecedent causes and diseases; and
(e) other factors contributing to the death.

d. Prescribing

03.22
Only medical or dental practitioners and veterinary surgeons 'or other person authorized to prescribe' under any Act, have the right to issue a prescription for medicines. In fact, the ***Medicines Act***[76] states that 'it shall not be lawful for any pharmacist to dispense any medicinal product except on the prescription of a medical or dental practitioner, veterinary surgeon or other person authorized to prescribe under this or any other Act, unless the medicinal product is deemed not to require a medicinal prescription by the Licensing Authority.'

As a minimum a prescription should contain the date, the name and the address of the patient, and the name and dose of each medicine included in the said prescription. It should be written in an 'indelible manner', easily legible, and bearing an indication of the use to be made of it. It is also mandatory that it is signed with the name and surname of the person giving it.[77] 'The Licensing Authority may by rules prescribe the format, content and presentation of a prescription required by or under' the ***Medicines Act.***[78]

This should hold also for prescriptions written in a hospital patient's record. Too often the date is not indicated, or the name of the doctor is illegible or not indicated at all.

03.23
The pharmacist should return the prescription back to the patient or other person on his/her behalf, unless the medication is a psychotropic

[76] *Medicines Act*, article 81(1) and Third Schedule (3).
[77] *Medical and Kindred Professions Ordinance*, articles 11(2) and 12(1)(2), now repealed. See also *Drugs (Control) Regulations*, SL 31.18, articles 7(1) and (2) for specified psychotropic drugs.
[78] *Medicines Act*, articles 29(2), 30(1)(c) and 82.

drug or falls under the provisions of the ***Dangerous Drugs Ordinance***.[79] The hospital pharmacist will also retain prescriptions for free medicinals available under the ***Social Security Act***.[80]

The pharmacist can only dispense the medicine on prescription[81] unless the medicine is exempt[82] or 'he has a justified reason of concern that the prescription is false, that the person is misusing the prescribed medicinal product, or that the medicinal product is not available or if he has professional reasons for not preparing or dispensing the prescription.'[83] Unless the prescriber specifically requests a branded medicine, the pharmacist is allowed to dispense 'an equivalent medicinal product having the same chemical entity, dose, dosage form, formulation and dosage frequency as the medicinal product indicated on the prescription.'[84]

'When, in dispensing any medicinal product, a pharmacist discovers that there are reasons why the medicinal product should not be dispensed to the patient or that the dosage regimen indicated on the prescription goes beyond what can be considered a safe therapeutic dose, the pharmacist is bound to draw the attention thereto of the person prescribing the same and may require such person to write out in ink or in other indelible manner on the prescription a statement assuming responsibility for the prescription.'[85]

(a) Prescribing dangerous drugs, mainly narcotic and psychotropic drugs

03.24

The ***Dangerous Drugs Ordinance***, states that the Minister responsible for Public Health may make regulations for controlling the manufacture, exportation, importation, possession, distribution and sale of drugs considered especially dangerous.[86]

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[79] *Prescription Forms for Free Medicinals Regulations*, SL 458.24, regulation 4, covers retention of prescriptions for a) medicines available free under the *Social Security Act* and b) psychotropic and narcotic drugs.

[80] *Prescription Forms for Free Medicinals Regulations*, SL 458.24, regulation 4.

[81] *Medicines Act*, articles 81 and 80(1).

[82] *Medicines Act*, articles 29(1)(b) and 80(4).

[83] *Medicines Act*, article 80(1).

[84] *Medicines Act*, article 80(2).

[85] *Medicines Act*, article 80(3).

[86] *Dangerous Drugs Ordinance*, articles 3(1), 9(1)(c) and 22(1D)(b).

Part IV of this Ordinance regards cocaine, morphine and those drugs listed in the First Schedule[87] and deals specifically with 'regulating the issue by medical practitioners of prescriptions containing any such drug and the dispensing of any such prescriptions.'[88]

These prescriptions have to be on the prescribed form, the same as that for psychotropic drugs.[89] There is specific subsidiary legislation for prescribing and dispensing methadone.[90] Formulations that only contain specified small amounts of a narcotic or of cocaine are exempt from being dangerous drugs and are listed in the First Schedule, Part III.

Special regulations for distribution of psychotropic drugs, have been enacted with regard to the powers of the Minister to 'make regulations for controlling the manufacture, exportation, importation, possession, distribution and sale of psychotropic drugs,'[91] in particular, in relation to 'prescriptions containing any such drug or chemical product and the dispensing of any such prescription.'[92] These regulations are found in the subsidiary legislation, ***Drugs (Control) Regulations***, where in particular, there is provision for the special prescription form,[93] use of which is only exempted in prescribing to 'ward patients in government hospitals, which prescription shall be controlled by the hospital internal rules.'[94] The regulations also provide for control cards for narcotic and psychotropic drugs[95] and for the maintenance of registers to

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[87] *Dangerous Drugs Ordinance*, article 10(1).

[88] *Dangerous Drugs Ordinance*, article 9(1)(c).

[89] *Drugs (Control) Regulations*, SL 31.18, regulation 7(7) and Seventh Schedule and *Prescription Forms for Free Medicinals Regulations*, SL 458.24, Third Schedule.

[90] *Methadone Rules*, SL 101.06.

[91] *Medical and Kindred Professions Ordinance*, article 40A.

[92] *Medical and Kindred Professions Ordinance*, article 40A(1)(a). A list of psychotropic drugs is included in the Third Schedule of the Ordinance and in the First Schedule of the subsidiary legislation, *Drugs (Control) Regulations*.

[93] *Drugs (Control) Regulations*, SL 31.18, regulation 7(1) and Seventh Schedule. The form is also to be found in the *Prescription Forms for Free Medicinals Regulations*, SL 458.24, Third Schedule.

[94] *Drugs (Control) Regulations*, SL 31.18, regulation 7(11).

[95] *Drugs (Control) Regulations*, SL 31.18, regulation 9(1)(a) and Ninth Schedule.

document any transaction.[96] The rules also set the amount of drugs that can be prescribed for professional use.[97]

e. Assessment of bodily harm

03.25

The doctor is often asked by a court to assess the degree of bodily harm suffered by an individual.

Bodily harm is defined in the ***Criminal Code***: 'Whosoever, without intent to kill or to put the life of any person in manifest jeopardy, shall cause harm to the body or health of another person, or shall cause to such other person a mental derangement, shall be guilty of bodily harm.'[98] To note that this definition includes both physical, as well as, mental harm. It excludes the intention to kill the person or put his life in 'manifest jeopardy'.

It defines bodily harm as either grievous or slight.[99] Grievous bodily harm is defined as such:

'(a) if it can give rise to danger of:
  (i) loss of life; or
  (ii) any permanent debility of the health or permanent functional debility of any organ of the body; or
  (iii) any permanent defect in any part of the physical structure of the body; or
  (iv) any permanent mental infirmity;
(b) if it causes any deformity or disfigurement in the face, neck, or either of the hands of the person injured;
(c) if it is caused by any wound which penetrates into one of the cavities of the body, without producing any of the effects mentioned in article 218;
(d) if it causes any mental or physical infirmity lasting for a period of thirty days or more; or if the party injured is incapacitated, for a like period, from attending to his occupation;
(e) if, being committed on a woman with child, it hastens delivery.'[100]

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[96] *Drugs (Control) Regulations*, SL 31.18, regulation 4.
[97] *Drugs (Control) Regulations*, SL 31.18, regulation 7(3).
[98] *Criminal Code*, article 214.
[99] *Criminal Code*, article 215.
[100] *Criminal Code*, article 216(1).

Naturally more serious injuries also constitute grievous bodily harm, as mentioned in article 218, and more severe punishments are specified for:

(a) permanent debility of the health or permanent functional debility of any organ, or permanent defect in any part of the body, or any permanent mental infirmity;
(b) if it causes any serious and permanent disfigurement of the face, neck, or either of the hands;
(c) if, being committed on a woman with child, it causes miscarriage.

To note that even when debility of health or functional debility or mental infirmity or serious disfigurement are only probably permanent, these are considered to be permanent.[101]

Punishment is increased by one or two degrees when committed on a person of sixty and over or on one with physical or mental infirmity 'in consequence of which he is unable to defend himself adequately.'[102]

03.26

As provided in the ***Social Security Act***, with respect to an injury at work or the development of an industrial disease, if there is 'permanent loss of physical or mental faculty, the person concerned shall be entitled to Injury Grant or Injury Pension.'[103] In assessing any impairment, the 'medical panel or the medical officer appointed by the Minister' has to 'take account of all such bodily or mental impairments (whether or not involving loss of earning power or additional expense) to which the claimant may be expected to be subject as compared with a person of the same age whose physical and mental condition is normal, but excluding any other particular circumstances with regard to his financial means or resources.[104]

The panel must state the degree of 'impairment in the form of a percentage' since less than 20% impairment entitles the injured person to Injury Grant while impairment between 20% and 89%

[101] *Criminal Code*, article 218(2).
[102] *Criminal Code*, article 222A. See also article 276A for theft accompanied by bodily harm.
[103] *Social Security Act*, article 29(1).
[104] *Social Security Act*, article 29(2).

entitles the person to Injury Pension, in accordance with the Third Schedule to this Act. With impairment at 90% or more, the person concerned shall be automatically entitled to the full rate of 'Invalidity Pension or Increased Invalidity Pension or National Minimum Pension, as the case may be, in accordance with the Twelfth Schedule to this Act.'[105]

f. Doctors' duties on Medical Boards

03.27

A doctor is often asked to sit on committees and boards or may even be in the employ of an organisation whose aim is to enforce regulations, which at times may go against the private interests of the patient concerned.

Examples of such situations are the following:

(a) Medical Board to examine 'whether a person who has applied to be registered as a voter or is already registered is disqualified from being so registered in terms of paragraph (a) of article 58 of the Constitution.' The Board is to consist of three doctors, one appointed by the Electoral Commission, and one by each of the political parties.[106]

(b) Medical Board appointed by the Commission for the Administration of Justice.[107]

(c) Doctors employed by Government and other employers and companies to check on a patient's ability to do his or her normal duties. According to the Public Service Management Code, sick leave may be verified and in fact, Heads of Ministries/ Departments are authorised to enter into a contract with private doctors, on an individual or group basis, 'with a view to conducting house visits as and when necessary if this is considered expedient for the better management of their organisation. Sick leave should be verified in suspected cases of abuse and when such leave is excessive or regular.'[108]

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[105] *Social Security Act*, article 29(3) and (4).

[106] *General Elections Act*, article 14(1) and (2).

[107] *Commission for the Administration of Justice Act*, article 10.

[108] *Public Service Management Code*, 6th edition, December 2005, 4.3.2.1.

03.28

The Code also states that 'an officer on sick leave may be visited by a Medical Board or Medical Officer appointed by Government, whenever it is considered expedient, with a view to ascertaining the state of the officer's health.'[109] 'Heads of Department may request examination of officers by a Medical Board if they have any doubts about an officer's behaviour or about any medical certificate submitted by their employees.'[110]

In effect, the specially appointed doctor is asked to check on the veracity of a colleague's certificate relating to a person's state of health. This often leads to the invidious situation of having one doctor checking on the report of another. It is to be emphasised that under no circumstances should clinical details be divulged to an employer, but only whether, in the doctor's opinion, a person is fit to work or otherwise (see above).

Although the ***Ethics of the Medical Profession Regulations*** state that 'when it becomes the duty of a practitioner occupying an official position to see and report upon a case of illness or injury he should communicate with the patient informing him that it is his right to ask his practitioner to be present during the examination,' this is impractical.[111] However the doctor is to comply with the ethical guideline to 'scrupulously avoid interference with, or remarks upon, the treatment or diagnosis that has been adopted.'[112]

g. Writing certificates: what responsibility in law?

03.29

Doctors have a duty to provide patients with a certificate to substantiate a claim for any benefit, pension, allowance or assistance available under the ***Social Security Act***, including Sickness Benefit, Maternity Benefit, Medical Assistance and Disability Pension.[113]

They also have a duty to provide an assessment of the degree of disability, which may have important societal issues, ranging

[109] *Public Service Management Code*, 6th edition, December 2005, 4.3.8.1.

[110] *Public Service Management Code*, 6th edition, December 2005, 4.3.8.2.

[111] *Ethics of the Medical Profession Regulations*, SL 94.15, regulation 12(d).

[112] *Ethics of the Medical Profession Regulations*, SL 94.15, regulation 12(d).

[113] *Social Security Act*. See also above, Section 10a, 'Disability and the Doctor' and Chapter 14: Societal Issues.

from justifying absence from work or school to preventing dangerous driving or ensuring issues of public health. Doctors also draw up certificates for exempting witnesses from attending court.

These duties confer considerable obligations on medical practitioners, which should not be taken lightly. For instance, to certify that one is sick and unable to attend work has considerable implications on the economy of any country. Under no circumstances must doctors be seen to be colluding with employees to deny employers legitimate continuity of work. Often, in these and similar circumstances, the doctor is torn between his duties to the patient, and his duties to society at large.

03.30

Certification of the capacity to drive a vehicle is one such instance. There are a number of conditions which impair the capacity of a driver to be in charge of a vehicle, a situation which could be a source of danger to himself as well as to other members of the public. Such circumstances may include disability resulting from:

(a) old age and associated physical problems, such as poor eyesight and lack of concentration;
(b) visual problems (e.g. monocular vision, diplopia, but not colour blindness);
(c) psychiatric disorders (e.g. schizophrenia);
(d) neurological disorders (e.g. epilepsy); and
(e) systemic disease e.g. diabetes mellitus.[114]

A doctor has a duty to society to ensure that unsafe drivers are kept off the road. A certificate relating to ability to drive can be issued only when one is convinced about the driver's ability to do so. If a driver refuses the advice offered, then the doctor is obliged to inform the licensing authority. A breach of confidentiality in this respect is done for the greater good of the general public.[115]

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[114] *Motor Vehicles (Driving Licences) Regulations*, SL 65.18, regulations 27, 28 and Eight Schedule.

[115] See also: General Medical Council, UK, booklet: *Confidentiality: Protecting and Providing Information*, April 2004.

03.31

Another aspect of certificates is that of the information disclosed. This should be limited to the extent that is needed by the body requesting the certificate. A medical or dental 'practitioner must not disclose voluntarily without the consent of the patient, preferably written, information, including certification which he has obtained in the course of his professional relationship with the patient. Exception to this rule is made only by the requirements of the law.'[116]

These Ethical Regulations expressly lay down that 'untrue certification' constitutes 'professional misconduct' and is liable to disciplinary action by the relevant Council.[117]

h. Autopsy

03.32

Autopsy represents a considerable intrusion into the privacy of an individual, albeit a dead one. Many consider that such a procedure is incompatible with the concept of dignity of the human body after death, and therefore permission to hold a post-mortem on a dear relative is usually given only with reluctance and when a greater good is to be expected (e.g. increased medical knowledge).

As in other countries, consent for legal post-mortems is neither asked for, nor required. There is also no mention of any consultation with next of kin. It is assumed that legal proceedings in such cases pre-empt any consideration of family feelings since the common good is the primary objective. However experiments at joint legal/medical explanatory sessions held with relatives after the autopsy are being studied.

There are two situations where post-mortem examinations are considered necessary:

(a) autopsies undertaken for clinical investigation of difficult or unusual cases, for educational or research purposes; and
(b) in the case of sudden unexplained death, under suspicious or unexpected circumstances. These include suicide, accidents at

[116] *Ethics of the Medical Profession Regulations*, SL 94.15, regulation 13(1) and *Ethics of the Dental Profession Regulations*, SL 94.14, regulation 5.

[117] *Ethics of the Medical Profession Regulations*, SL 94.15, regulation 17(a) and *Ethics of the Dental Profession Regulations*, SL 94.14, regulation 2.

work, deaths in custody (e.g. prisoners) and deaths occurring unexpectedly while in hospital, such as death of a patient under anaesthesia.

03.33

Maltese legislation does not deal with post-mortems performed for scientific or medical reasons. These seem to be neither allowed nor disallowed by law. In former days these were undertaken, if there were no objections from relatives. These days, specific consent must be obtained and post-mortems performed only if relatives do not object. Consent is also required for collection and storage of organs for teaching or research purposes (including pathological archiving), and for use in research projects.

03.34

In cases of sudden or violent or suspicious death or of death whereof the cause is unknown, a report thereof shall be made by the Executive Police to a magistrate; 'the magistrate shall hold an inquest on the body for the purpose of ascertaining the cause of death and shall, for that object, take all such evidence as may be possible for him to procure; after taking all the evidence, the magistrate shall draw up and sign a *procès-verbal* stating his finding as to the cause of death.'[118]

There is further qualification of the type of deaths to be investigated:

(a) when a person dies while he is imprisoned or detained in any place of confinement contemplated in the ***Prisons Act***, or while he is in police custody;[119]
(b) when a person dies in Mount Carmel Hospital while he is kept there under a court order.[120]

The ***Medical and Kindred Professions Ordinance*** bound a doctor to report violent deaths and suspected poisoning; the doctor was 'to inform the Police, without any avoidable delay, of any grievous bodily harm attended to by him and of any case in which

[118] *Criminal Code*, article 551(1).
[119] *Criminal Code*, article 551(2).
[120] *Criminal Code*, article 551(3).

he may have observed in any person signs of poisoning or of violent death.'[121]

The Magistrate is not obliged to establish the precise cause of death in the medical sense but a doctor has, 'in every case of death, to report to the Police the death and the cause thereof in writing' in accordance with the specified form, that is the Death Certificate.[122] So, naturally in any death where the doctor is unable to write a Death Certificate, the death must be reported to the Magistrate, through the local Police.

03.35

In certifying patients as suffering from a disease or injury, or of dying from a disease, a doctor must use nomenclature in accordance with the international classification of diseases of the World Health Organisation.[123]

The ***Criminal Code*** refers to the authority of a magistrate who may 'order the disarticle and the internal examination of the body' where s/he considers this to be necessary.[124] For this purpose s/he may appoint one or more medical experts for 'establishing the identity of the body and to ascertain the cause of death.'[125] They are empowered also to hear evidence on oath for this purpose.

The magistrate may order the exhumation of a body, as long as this poses no danger to public health.[126]

In Malta it has been normal practice to appoint three medical officers, in keeping with the direction of the ***Criminal Code*** in relation to appointment of experts in uneven numbers,[127] although in most other countries overseas, two are considered adequate.

The law makes no comment on the qualifications necessary for a medical expert to be appointed by the magistrate. The ***Criminal Code*** states that: 'In all cases where for the examination of any

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[121] *Medical and Kindred Professions Ordinance*, article 7(d), now repealed.

[122] *Medical and Kindred Professions Ordinance*, article 7, now repealed but the Death Certificate is still extant in the Second Schedule. See Section 8c on Death certification.

[123] *Medical and Kindred Professions Ordinance*, article 7, now repealed.

[124] *Criminal Code*, article 552(1).

[125] *Criminal Code*, article 552(2).

[126] *Criminal Code*, article 553.

[127] *Criminal Code*, article 650(4).

person or thing special knowledge or skill is required, a reference to experts shall be ordered.'[128]

The Council of Europe is currently working on a Protocol to the 1997 Council of Europe's ***Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine,*** dealing with these matters.

9. Professional and Ethical Standards

03.36

As mentioned above, professional and ethical standards refer to 'the standard of the general conduct of the members of a profession, as well as the behaviour of such member towards his client or the patient under his care or being attended by him, during or consequential to the exercise of his profession.'[129]

The Medical Council has the duty 'to prescribe and maintain professional and ethical standards for such professions.' The Medical Council has issued two *Code of Ethics*, one for medical practitioners and one for dental surgeons, which have been published as the subsidiary legislation, ***Ethics of the Medical Profession Regulations*** and ***Ethics of the Dental Profession Regulations***. They include regulations regarding:

(a) Professional Duties and Responsibilities;
(b) Guidance on Professional and Ethical Conduct; and
(c) Forms of Professional Misconduct.

The relevant Council of a health care profession has the power, either on the complaint of any person or of its own motion, to investigate any allegation of professional misconduct or breach of ethics by a health care professional falling under its supervision.[130]

The ***Medicines Act***[131] enjoins the Chief Executive Officer and all other executive officers and employees of the Medicines Authority

[128] *Criminal Code*, article 650(1).
[129] *Department of Health (Constitution) Ordinance*, article 2. See also *Health Care Professions Act*, article 2.
[130] *Health Care Professions Act*, article 31(1).
[131] *Medicines Act*, article 12.

to conform with and abide by any public service values and Code of Ethics that may be in force from time to time in relation to public officers.[132]

a. Unethical conduct

03.37

The Medical Council in such a situation appears to have a fairly wide latitude in interpreting what is meant by 'infamous conduct' or what is failure to abide by the relevant professional and ethical standards.

In relation to drug trafficking, the ***Medical and Kindred Professions Ordinance*** enumerates several offences:[133]

(a) controlling the manufacture, exportation, importation, possession, distribution and sale of psychotropic drugs, including non-compliance with conditions of licence for this purpose;
(b) making any false declaration, or statement for the purpose of obtaining, whether for himself or for any other person, the issue, grant or renewal of any licence, permit or authority;
(c) conspiring with others overseas to commit acts which are illegal in Malta; and
(d) selling or dealing in a drug (whether in Malta or overseas). This holds both for Maltese citizens as well as permanent residents.

Other types of professional misconduct include:[134]

(a) untrue certification or report;
(b) covering an association with unqualified or unlicensed persons;
(c) contravention of the ***Dangerous Drugs Ordinance*** and ***Drugs (Control) Regulations***; and
(d) advertising, canvassing, lectures, broadcasting, etc. not within the guidelines of the Medical Council.

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[132] *Code of Ethics for Employees in the Public Sector*, Cabinet Office, Office of the Prime Minister, Valletta, October 1994.
[133] *Medical and Kindred Professions Ordinance*, article 120A.
[134] *Ethics of the Medical Profession Regulations*, SL 94.15, regulation 17.

b. Negligence and incompetence

03.38

There is a fine distinction between these two terms:

(a) *incompetence* refers to the performance of an act which is considered below the professional standard expected of a professional due to lack of knowledge or competence;
(b) *negligence* refers to harm resulting to a patient because the practitioner failed to take the necessary and expected measures to prevent them, irrespective of his personal competence.

In practice this is often a distinction without a difference.

Specific issues relating to incompetence may be found in Maltese legislation. In cases involving involuntary homicide or bodily harm it states that: 'Whosoever, through imprudence, carelessness, unskilfulness in his art or profession, or non-observance of regulations, causes the death of any person, shall, on conviction, be liable to imprisonment for a term not exceeding four years or to a fine (*multa*) not exceeding five thousand liri.'[135]

Specifically relating to incompetence in connection with pregnancy resulting in 'culpable miscarriage', it states that: 'Whosoever, through imprudence, carelessness, unskilfulness in his art or profession, or non-observance of regulations, causes the miscarriage of a woman with child, shall, on conviction, be liable to imprisonment for a term not exceeding six months or to a fine (*multa*) not exceeding one thousand liri.'[136]

There are two aspects relating to the definition of negligence:

(a) negligence resulting from *commission* of an act which is below accepted professional standards: e.g. wrong diagnosis or treatment; and
(b) negligence resulting from *lack of provision* of adequate treatment, or quite often from not giving adequate information, especially warning of risks associated with procedures and interventions.

[135] *Criminal Code*, article 225.
[136] *Criminal Code*, article 243A.

The burden of proving negligence lies with the patient who takes action against the doctor. He must prove:

(a) that the doctor concerned was in charge of his/her case (i.e. owed him/her a 'duty of care');
(b) that the doctor's standard of care was below what was to be expected from a doctor with comparable training and experience; and
(c) that s/he suffered an injury as a result of the negligence in question.

It is the Medical Council's responsibility to ensure that all practitioners maintain adequate standards, and to take the necessary measures when there is any indication that these have not been maintained, including erasure of the practitioner's name from the register, or suspension for a specified period, determined by the Council.

Erasure from the register can also follow if in the opinion of the Council 'any health care professional is unfit to continue to practise his profession on account of some physical or mental infirmity.'[137]

c. Abortion

03.39

Essentially the ***Criminal Code*** makes it clear that any person who causes the miscarriage of any woman with child by any medicine (among other things) shall be liable on conviction to imprisonment for a term from eighteen months to three years.[138] This injunction holds irrespective of whether the woman consents to the procedure or otherwise. The woman is also guilty if she procures her own abortion or if she consents.[139]

Moreover, if death or grievous bodily harm ensues from the attempt to induce a miscarriage, irrespective of whether miscarriage did actually ensue, the person thus convicted would 'be liable to the punishment applicable to wilful homicide or wilful bodily harm, diminished by one to three degrees.'[140] Also: 'Any physician,

[137] *Health Care Professions Act*, article 38(1).
[138] *Criminal Code*, article 241(1).
[139] *Criminal Code*, article 241(2).
[140] *Criminal Code*, article 242.

surgeon, obstetrician, or apothecary, who shall have knowingly prescribed or administered the means whereby the miscarriage is procured, shall, on conviction, be liable to imprisonment for a term from eighteen months to four years, and to perpetual interdiction from the exercise of his profession.'[141]

This topic is discussed further in **Chapter 6: Pregnancy and the Family**.

d. Administering noxious substances

03.40

The ***Criminal Code*** specifically forbids the administering or causing others to take substances injurious to health. It states: 'Whosoever shall, in any manner, maliciously administer to, or cause to be taken by another person any poisonous or noxious substance capable of causing any harm or injury to health, shall, on conviction, be liable to imprisonment for a term from thirteen months to two years, provided the offence does not in itself constitute the offence of homicide, completed or attempted, or a serious injury to the person.'[142]

It is unlawful to supply an officer or man of the regular force with 'any drug or preparation calculated or likely to render him, or lead to the belief that he is, permanently or temporarily unfit for service, with a view to enabling him to avoid military service, whether permanently or temporarily, shall be liable on summary conviction to a fine (*multa*) not exceeding one hundred liri or to imprisonment for a term not exceeding six months, or to both such fine and imprisonment.'[143]

The administration of noxious substances in relation to abortion is dealt with further in **Chapter 6: Pregnancy and the Family.**

e. Disciplinary procedures against medical practitioners

03.41

One of the duties of the Council is 'to investigate any allegation of professional misconduct or breach of ethics by a health care

[141] *Criminal Code*, article 243.
[142] *Criminal Code*, article 244.
[143] *Malta Armed Forces Act*, article 169.

professional falling under its supervision.'[144] The Council has the power to start such an investigation either following a complaint of any person or on its own initiative.

The Medical Council has the power to discipline medical officers which includes erasure from the register 'on grounds of conviction or infamous conduct' if such a person:

(a) has been convicted by any court in Malta of any crime punishable by imprisonment for a term exceeding one year or of any of the crimes mentioned in articles 198 to 205 or in articles 206 to 209 of the ***Criminal Code***; or
(b) has been guilty of professional or ethical misconduct in any respect; or
(c) in any other manner has failed to abide by the professional and ethical standards applicable to him.'[145]

The sanctions that the Council can impose for these infringements vary from a simple cautioning of the individual concerned, to inflicting a fine, or having one's name taken off the register for a period of time, or to erasure from the register.[146] The Council can also 'order that the health care professional undergoes such period of training or practice of the profession under supervision for such period as the relevant Council may determine.'[147]

'Any inquiry held by a relevant Council shall be without prejudice to any other criminal, civil, administrative or disciplinary proceedings which may be taken against the person concerned under the provisions of any other law.'[148]

The ***Department of Health (Constitution) Ordinance*** sets up an Advisory and Executive Board. One function of this Board is 'to advise the Minister in respect of disciplinary proceedings against medical practitioners in the government service in their capacity as public officers.'[149]

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[144] *Health Care Professions Act*, article 31(1).
[145] *Health Care Professions Act*, article 32.
[146] *Health Care Professions Act*, article 32(1)(i)-(iv).
[147] *Health Care Professions Act*, article 32(1)(v).
[148] *Health Care Professions Act*, article 33.
[149] *Department of Health (Constitution) Ordinance*, article 26(1)(d).

The Prime Minister may make regulations in respect 'of disciplinary proceedings against medical practitioners in government service in their capacity as public officers.' This includes the appointment of a committee to conduct an inquiry, the persons appointed as members, the procedure, the representation of the officer involved, etc.[150] Further proceedings may be taken against the person concerned under the provision of the ***Criminal Code*** or any other legislation.[151]

f. Employment of doctors who break the law

03.42

The Medical Council in Malta has the power to strike off the register any person found guilty of misconduct, as already mentioned above.

Since July 2002, in the UK, all NHS employees are requested to have a re-appointment check. Doctors must declare prior to appointment whether they have been convicted of an offence or received a police caution, reprimand or final warning. Doctors must also declare details relating to criminal offences even when these occurred several years previously.[152] In addition, doctors who deal with patients under the age of 18 years have to declare whether they had been previously dismissed or even investigated by police for reasons of misconduct.

In Maltese legislation we find that no person may practise the medical or dental profession unless 'he is of good conduct'.[153] There is however, no obligation on the part of the practitioner to declare previous convictions prior to applying for an employment position. It is to be noted, however, that any posts advertised by the Department of Health require the candidate to be of good moral character.

It is also proposed that the new Medical and Dental Registers will include a record of any previous disciplinary action taken by the Medical Council.

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[150] *Department of Health (Constitution) Ordinance*, article 27(1).
[151] *Department of Health (Constitution) Ordinance*, article 27(2).
[152] UK: *Rehabilitation of Offenders Act*, 1974.
[153] *Health Care Professions Act*, articles 7(2)(b) and 8(2)(b).

g. The sick or incompetent doctor

03.43

Doctors also get sick and may require treatment like any other patient. They may also become incapable of carrying on their job of caring for their own patients, in which case they should gracefully acknowledge this fact and retire. There are instances however, where this may not occur. For example:

(a) *Doctors and drug abuse*: Doctors, more than any other person are exposed to drugs and some have become addicted to their use. In so far as such an addiction does not diminish their capacity to continue with their work, then this should be a personal problem only, unless a crime is committed, in which case, the doctor also becomes liable to criminal prosecution and disciplinary action by the Medical Council.

(b) *HIV positive doctors and operative procedures*: Doctors may present a considerable risk to patients if they themselves suffer from a serious infectious disease. A surgeon who is HIV positive or suffers from other serious infectious disease should not operate on patients because of the danger of transmission of the disease.[154]

(c) *Alcoholism*: The medical profession is not immune to the dangers of alcoholism. The social habits of an individual are of no concern to others, as long as patients are not put at risk. When, however, the addiction has gone so far that it endangers the health of the patient, then it has far more wide-reaching consequences.

What is the duty of colleagues when faced with someone who is blatantly putting patients at risk? Often it is colleagues who notice that things are beginning to go wrong. Should one try to protect one's colleagues and cover-up for them? It is a professional

[154] The General Medical Council (GMC), UK, defines a communicable disease as 'one that may be transmitted between humans and which may result in death or serious illness' (GMC: *Serious Communicable Diseases*, October 1997). Examples include: HIV, TB, Hepatitis B and C. See also *Public Health Act* and Chapter 13: Public Health Issues for definition of infectious disease in Maltese law.

responsibility that standards should not be allowed to deteriorate. If one is in a condition to ensure that the doctor in question takes remedial action, then that may be all that is required. On the other hand, if such actions do not achieve their desired result, then more drastic action must be taken to ensure that such a doctor does not pose an extra danger to his or her patients.

The ***Health Care Professions Act*** states that if it appears to the Council that any health care professional is unfit to continue to practise his profession on account of some physical or mental infirmity, the respective Council shall direct his name to be erased from the appropriate register.[155] Such a practitioner may, when recovered sufficiently, ask the Council to have his/her name re-instated.[156]

The situation arises from time to time where a colleague is suspected of performing below par. One is often put under pressure on whether to take any form of action to remedy the situation or whether to just shrug one's shoulders, and turn the other way. Unfortunately, too often, the latter is a common mode of reaction in most of our population.

Maltese law has no equivalent to the British 'Public Interest Disclosure Act' (1998). This Act, also called the 'Whistle Blowing Act' is designed to protect anybody who reports to the authorities anyone who is suspected of behaving unethically, or who in any way is performing below the expected level of efficiency. The legislation ensures that such a 'whistle blower' will not be victimised.

Several Codes of Ethics designed for the health professions do, however, emphasise the responsibility that each member of the profession has in ensuring adequate standards among his or her professional colleagues, including, when necessary reporting to the authorities. While this drastic step may not be to everyone's taste, and should certainly not be the first line of action, every professional medical association should ensure that standards are maintained through regular clinical audit, and should actively take an interest when suspicion of malpractice is raised.

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[155] *Health Care Professions Act*, article 38(1).
[156] *Health Care Professions Act*, article 38(3).

10. Treatment Issues

a. Disability and the doctor

03.44

The question of disability as it affects the patient is discussed elsewhere (see **Chapter 8: Disability**). Here we mention only those aspects which relate specifically to the medical practitioner who has to deal with the disabled person.

The ***Persons with Disability (Employment) Act*** defines a person with disability as 'a person, being over compulsory school age, who, by reason of injury, disease, congenital deformity or other physical or mental incapacity, is substantially handicapped in obtaining or keeping employment or in undertaking work on his own account, of a kind which apart from that injury, disease, deformity or incapacity would be suited to his age, experience and qualifications; and the word "disability", in relation to any person, shall be construed accordingly.'

03.45

Medical practitioners who are employed by an employer to examine a person with disability must be careful not to divulge information which is irrelevant to the ability of the person to perform the specific kind of work required of him/her. The ***Equal Opportunities (Persons with Disability) Act*** states that 'an employer shall not conduct or require any medical examination or otherwise make any enquiries of an applicant for employment or of any of his employees as to whether such applicant or employee is a person with a disability or as to the nature or severity of such disability except to ascertain the ability of the applicant to perform job-related functions or to identify the cost involved in any adaptations that may be required as a result of such disability.'[157] In other words, the report on such a person should only state whether the person in question can or cannot perform the work requested by the employer.

On the other hand there are situations where an employer might have a policy of requesting a pre-employment medical examination, e.g. as a baseline in case of future litigation. In such a case, the disabled person is treated in exactly the same way as everybody

[157] *Equal Opportunities (Persons with Disability) Act*, article 8(1).

else, and there is no attempt at discrimination. There is no objection to such a medical examination.[158] However, information obtained in such a case (as well as in the case of the examination of the applicant with disability) has to be treated in a different way from normal procedures, namely, it is:

(a) collected and maintained on separate forms;
(b) kept in separate medical files; and
(c) treated as a confidential medical record.[159]

03.46

However, information relating to special needs of the disabled person, once employed, including special accommodation, restriction on work or duties and information about emergency treatment that might be necessary, may be relayed to supervisors or managers, as required without being in breach of this Act.[160] Voluntary medical examinations for compilation of medical histories for the purpose of a health programme for employees is also allowed, subject to the provisos of special treatment of information and of passing necessary information to supervisors.[161] To note that a medical examination referred to in this article includes both physical as well as psychological assessment.[162]

Doctors may be employed by employers to check on whether their employees are fit for work, and whether they are absenting themselves from work for valid medical reasons. Moreover, doctors are often called to confirm that a person is unable to attend to work or school or other duties because of a physical or psychological disorder. Giving a certificate to this effect has assumed an important part of a family doctor's practice. There is no specific legislation about this in Maltese law.

03.47

With regards to company doctors, the ***Ethics of the Medical Profession Regulations*** state that: 'When it becomes the duty of a practitioner occupying an official position to see and report upon a

[158] *Equal Opportunities (Persons with Disability) Act,* article 8(2).
[159] *Equal Opportunities (Persons with Disability) Act,* article 8(3).
[160] *Equal Opportunities (Persons with Disability) Act,* article 8(4).
[161] *Equal Opportunities (Persons with Disability) Act,* article 8(5).
[162] *Equal Opportunities (Persons with Disability) Act,* article 8(6).

case of illness or injury he should communicate with the patient informing him that it is his right to ask his practitioner to be present during the examination. The practitioner seeing the case officially shall scrupulously avoid interference with, or remarks upon, the treatment or diagnosis that has been adopted.'[163]

In the ***Social Security Act***, a claim for Sickness Benefit, in respect of the fourth and subsequent day of each spell of incapacity for work, must be backed by a medical certificate signed by a medical practitioner, appointed by the Minister for this purpose. The Director of Social Security may consult, on the medical aspects of the claim, one or more medical practitioners appointed by the Minister for this purpose.[164]

There is also mention of Maternity Benefit being payable to a woman upon the submission of a claim on the form provided 'accompanied by a certificate signed by a person holding the warrant to practise the medical profession in Malta.'[165]

b. Who is responsible for incompetent patients?

03.48

In the case of minors under the age of 18 years, parents have the responsibility for their care. Where parents disagree with a decision, which the health care professionals believe is in the vital and best interest of the patient, then it may be necessary to take the case to court for it to decide on the best mode of action. Such a decision is well illustrated with the objections to blood transfusions by persons of the Jehovah Witness persuasion. Such a case has indeed occurred locally and a Maltese court has ordered treatment to be given.[166]

The ***Civil Code*** states that 'the parents jointly represent their children, whether born or to be born, in all civil matters.'[167] Where there is disagreement between parents 'on matters of particular importance, either parent may apply to the court, which after hearing the parents and the child, if over fourteen years, shall make

[163] *Ethics of the Medical Profession Regulations*, SL 94.15, regulation 12(d).
[164] *Social Security Act*, article 106(d).
[165] *Social Security Act*, article 72(1).
[166] Magistrate Dr. Carmelo Farrugia Sacco decreed that blood transfusion was in the interests of a minor on 16th May 1982.
[167] *Civil Code*, articles 135 and 136(3).

suggestions in the best interest of the child and the unity of the family.' The court can authorise the parent whom it considers more suitable, to protect the interest of the child,[168] but it may also 'give such directions as regards the person or the property of a minor as it may deem appropriate in the best interests of the child.'[169]

An incompetent patient over the age of 18 should be treated in his or her best interest. While relatives have no right to impose their view in such a situation, it is normally considered proper to consult with relatives and any other person involved in the care of the patient before taking decisions.

A doctor may examine a minor and prescribe treatment as long as s/he is convinced that that patient is capable of understanding the significance of the procedures and interventions. Maltese Law is generally silent on this subject except for the fact that the ***Mental Health Act*** grants the right of voluntary admission to a mental hospital, for treatment, to a person who has attained the age of sixteen years and who is capable of expressing his/her own wishes, 'notwithstanding any right of custody or control vested by law in his parent or tutor.'[170] This right is not given for entry to other hospitals.

As regards other medical treatment there are usually references to common law cases in the UK, of which the Gillick case is perhaps the most notorious. In that instance, the House of Lords ruled that children under the age of 16 may be mature enough to decide for themselves.[171]

03.49

Prescribing contraceptives for minors has been a bone of contention. In the UK it is an offence to 'cause or encourage the commission of

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[168] *Civil Code*, article 136(5) lays down the provisions of article 131. See articles 131(3) and 131(4).

[169] *Civil Code*, article 149.

[170] *Mental Health Act*, article 3(2).

[171] This is referred to as 'Gillick competence': Mrs Victoria Gillick, mother of four girls under the age of 16, objected to doctors giving contraceptive (and abortion) advice to her daughters without her knowledge and consent. The Court, in 1985 ruled against her, *Gillick v West Norfolk* and *Wisbech AHA* [1984] 1 All ER 365. The Court of Appeal [1986] AC112, [1985] 1 All ER 830 CA ruled in her favour. The House of Lords [1986] AC 112, [1985] 3 All ER 402, HL eventually ruled against, stating that children who were mature enough could make their own decisions.

unlawful sexual intercourse with a girl for whom [the] accused is responsible.' The Lords decided that this does not include a doctor who prescribes contraception. On the other hand, Lord Scarman commented: 'Clearly a doctor who gives contraceptive advice or treatment . . . with the intention of facilitating her having unlawful sexual intercourse may well be guilty of a criminal offence.'[172] In Maltese law, the ***Criminal Code,***[173] refers to anyone who 'instigates, encourages or facilitates the defilement of a minor of either sex,' but it is unlikely that this is ever going to be applied to the case of a doctor who prescribes contraceptive options.

c. 'Best interest'

03.50

The concept of 'best interest' of the patient has been bandied about as a yard-stick to use in the case where a patient is incapable of making an informed decision. At best it is meant to guide the medical practitioner to act in cases of emergency or other situations, which require an intervention to take place, when the patient is incapable of giving consent. On the other hand, it could also smack of paternalism in that it may assume that the 'doctor knows best' and that patients would, as in the past, be only too happy to leave decisions in the hands of their medical practitioner. The British Medical Association has issued guidelines in this respect.[174]

A number of issues need to be considered when taking a decision on behalf of a patient, in the belief that this is in their best interest. These are summarised as follows:[175]

(a) the patient's own wishes and values, including any advance statement;
(b) clinical judgement about the effectiveness of the proposed treatment, particularly in relation to other options;
(c) where there is more than one option, which option is least restrictive of the patient's future choices;

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[172] Gillick case [1986] AC 112, [1985] 3 All ER 402.
[173] *Criminal Code*, article 203A.
[174] British Medical Association, *Consent Tool Kit*, 2001.
[175] Baxer Chloë, Brennan M.G., Coldicott Y.(Ed), *The Practical Guide to Medical Ethics*. Pastest Ltd, 2002.

(d) the likelihood and extent of any degree of improvement in the patient's condition if treatment is provided;
(e) the views of the parents, if the patient is a child;
(f) the views of people close to the patients, especially close relatives, partners, carers or proxy decision makers; and
(g) any knowledge of the patient's religious, cultural and other non-medical views that might have an impact on the patient's wishes.

d. Dealing with relatives of patients

03.51
Maltese law does not pronounce on the issue relating to rights of patients' relatives. However, it is generally accepted that patients' relatives have no special rights in law. They cannot demand that information is filtered through them prior to being given to the patient. This is particularly the case where a patient specifically demands that such information is not passed on to the rest of the family. The only exception to this is the case of patients who are incompetent of giving informed consent (minors and those with mental disability). In the case of an emergency, the doctor should take the necessary action in the best interest of the patient and not wait for deliberation with relatives.

03.52
There are, however, a number of situations where it is considered good practice to involve relatives in discussions relating to decisions taken about a patient. These include:

(a) *Advance Directives*: these indicate the patient's wishes at the time they are made, sometimes years prior to the need for their activation. In such instances the relatives' wishes should also be taken into consideration.
(b) *Organ Donation*: even when a patient carries a donor's card, it is the practice in Malta to take the relatives' views on the matter and not follow the card's directive where there is conflict. This is also the practice in the UK but not in several countries in Europe (e.g. France, Austria and Italy) where the system of 'opting out' exists, namely, that a dead person's organs are taken *unless* the individual has specifically expressed prior objection to this.

(c) *Post mortem Examination for scientific or diagnostic ends (i.e. excluding forensic post mortem examinations)*: in such instances no autopsy should be performed unless relatives give permission for the procedure.

e. Advance Directives

03.53

Advance Directives or so called 'living wills' are directives given by a person to be actuated at a time when s/he would be incapable of taking an active decision. For instance a patient may request that no attempts at resuscitation should be made at any time. It is generally accepted that patients cannot request specific treatment through an Advance Directive. Moreover one cannot refuse treatment when authorised by law or when refusal would constitute a health risk to others.

Maltese Law is silent on this issue. In the UK, in following such directives one should ensure that the intervention would benefit the patient directly, and that one should do only the minimum necessary to achieve this aim, i.e. not include pre-planned or non-urgent treatment. In the UK, the person's right to refuse treatment as expressed in an Advance Directive was tested and accepted.[176] There is however no specific UK legislation to govern Advance Directives.

As mentioned already, it is also wise to take into consideration the views of relatives and others who have an interest in the patient.

f. 'Do Not Attempt Resuscitation' (DNAR) orders

03.54

An area which is often the cause of concern is a notice attached to the patient's notes requesting that no attempt should be made to resuscitate the patient. Such a notice has often caused distress

[176] *Re C* [1994] 1 All ER 819, (1993) 15 BMLR 77. This was the first case making a patient's advance refusal of treatment legally binding under common law in England. It concerned a mental inpatient who refused amputation of his gangrenous leg and the judges ruled that he was competent to refuse treatment then and also later if he became incompetent, thus also establishing the competence test, the Re C test (see below).

when seen by relatives prior to being consulted. Under what situations may a medical practitioner decide that no attempts at resuscitation should be made, and what is the legal status of such a directive?

Clinically it is well accepted that a point is reached when it would not be wise to continue active measures to prolong life, e.g. in the case of a moribund patient with, say, advanced cancer. However, ethically, such issues should be discussed with a competent patient, before a final decision is taken.

Although, as stated above, a patient's Advance Directive should be respected, the case of a person with depression who has requested that no attempts should be made to resuscitate, e.g. in case of an overdose, is less clear cut.

In effect, a doctor's order not to resuscitate may be regarded as an advance directive given, not by the patient but by the doctor. Such a decision should follow consultation with other members of the health care team and assessment of all aspects of the patient's condition. The order should be kept under constant review.

Maltese legislation makes no mention of DNAR orders.

(a) The role of relatives in such decisions

03.55

Relatives have a right to be involved in decisions about a patient if:

(a) the patient is a minor in their care. This right is limited in the case where such a minor is mature enough to understand the implications of treatment or intervention requested;
(b) the patient is incapable of giving consent because of mental disability; and
(c) the patient has given power of Attorney to the relative (or other person) to act on his/her behalf.

In all other instances, a relative has no right to demand that s/he be consulted about the treatment regime involving an adult person. This includes forced feeding, medication and objections to advance directives. Having said that, it is often advisable, in a culture such as ours, to ensure that the relatives are given every opportunity to express their opinion, though it must not be considered binding on the physician.

g. Withdrawal of treatment

03.56

Related to the above is the situation where treatment is discontinued because it is considered no longer justified. Treatment may be stopped under any of these circumstances:

(a) where a patient capable of making an informed decision, requests that this happens; and
(b) where in the opinion of the physician, it is not in the patient's best interest to continue with the treatment.

Maltese legislation is lacking in this respect. Guidelines are however, available in the UK as General Medical Council recommendations.[177] It is advisable to seek the guidance of the courts before withdrawing life-prolonging treatment.

Two cases in the UK illustrate this situation. The first one is the recent case of 'Miss B', a 43-year old woman who requested, and was granted, permission to stop treatment. The ventilator was switched off and she died soon after.[178] It was considered that a patient, who was fully capable of making an informed decision, has every right to object to any treatment.

In another, case, an English football fan, Tony Bland (1989) was in a permanent vegetative state. The House of Lords decided that a treatment can be discontinued where it is not considered to be in the patient's best interest.[179] Most importantly the treatment included artificial feeding and hydration.

These cases are quite different from those related to assisted suicide. This is forbidden by the ***Criminal Code***[180] and more specifically the law clearly indicates that administration of drugs to produce harm is illegal (see above, Section 9d).

A recent case in the UK brought this issue to the forefront. Diane Pretty was a 43 year-old lady suffering from long-standing motor-neurone disease. She was fully mentally competent but could

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[177] General Medical Council, UK, *Withholding and Withdrawing Life-prolonging Treatments: Good Practice in Decision-making*, August, 2002.
[178] *Re B (Adult: Refusal of Medical Treatment)* [2002] 2 All ER 449.
[179] *Airedale NHS Trust v Bland* [1993] 1 All ER 821; AC879.
[180] *Criminal Code*, article 213.

not physically take tablets, and she asked her husband to help her take an overdose. The House of Lords ruled that what she was asking was illegal.[181] The case was taken to the European Court of Human Rights which again ruled against her.[182]

The difference between this case and the previous two is that a patient cannot ask anyone to perform an illegal action. Administering a lethal dose of a drug, at the request of the patient, is legally considered to be assisted suicide (see below) while cessation of a treatment when the patient requests it, or when it is not in the patient's best interest, is not.

h. Refusing treatment

03.57

The above cases also illustrate the situation where a patient refuses treatment. A competent person has every right to refuse treatment. When taking a decision as to whether a patient is competent or not, one must take into account whether the patient can understand:

(a) what the medical treatment proposed involves;
(b) the benefits as well as the risks involved;
(c) the available alternative treatments; and
(d) the consequences of not undertaking the suggested treatment.

The patient must be:

(a) capable of understanding and retaining this information; and
(b) must be able to make the choice without being under pressure.[183]

03.58

Forced feeding is a special case which may be considered as treatment in certain conditions. Where the mental capacity of a patient is

[181] See *R (on the application of Pretty) v Director of Public Prosecutions* [2002] FLR 268.

[182] Case of *Pretty v United Kingdom*, Application no. 00002346/02.

[183] *Re C* [1994] 1 All ER 819, (1993) 15 BMLR 77. This case established such criteria as a competence test - the Re C test. It concerned a mental inpatient who refused amputation of his gangrenous leg and the judges ruled that he was competent to refuse treatment then and also later if he became incompetent

considered not to be impaired, then forced feeding, like any other treatment, may not be imposed on a patient, and no one should be coerced to undertake such treatment against one's wishes. In the case of an emergency situation, the doctor should carry out any interventions and treatment as s/he thinks fit, in the best interest of the patient.

Anorexia nervosa presents a special case. In some countries, (e.g. the UK), anorexia nervosa is considered to be a mental disorder and can be treated as such. This includes forced feeding.[184]

i. Euthanasia[185]

03.59

The definition of euthanasia varies from 'a painless death' to 'the intentional killing of a person to relieve suffering, or mercy killing'; in practice euthanasia involves helping patients to die, at their own request. It may be active, if the doctor actually brings about the death of the patient as for instance through the injection of a lethal dose of a drug, or passive if s/he withholds treatment at the request of the patient. The doctor may also be instrumental in causing death indirectly, if s/he merely provides the wherewithal for the patient to take the final step, as for instance writing a prescription of a lethal dose of a medication, such as barbiturate tablets, to a person about whom there is reason to believe that there is a possibility of suicide. The latter is better called 'physician assisted suicide'.

In Maltese legislation helping a person to commit suicide is a criminal offence The ***Criminal Code*** states that: 'Whosoever shall be guilty of wilful homicide shall be punished with imprisonment for life.'[186] It proceeds to define 'wilful homicide' as follows: 'A person shall be guilty of wilful homicide if, maliciously, with intent to kill another person or to put the life of such other person in manifest jeopardy, he causes the death of such other person.'[187]

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[184] See Chapter 9: Mental Health.
[185] See *Criminal Code* and Chapter 14: Societal Issues.
[186] *Criminal Code*, article 211(1).
[187] *Criminal Code*, article 211(2).

The main issue here is whether there is 'intent' to kill another person. This is usually the case in euthanasia.[188] On the other hand, the word 'maliciously' seems to exclude the concept of 'mercy' killing, since there is generally no 'malicious' intent when helping someone to end a 'miserable existence'.

This is clarified further in article 213 which states: 'Whosoever shall prevail on any person to commit suicide or shall give him any assistance, shall, if the suicide takes place, be liable, on conviction, to imprisonment for a term not exceeding twelve years.' In this article it is made clear that whatever the intention, a person helping anyone to commit suicide is also guilty of an offence.

11. Staff Requirements and Essential Services

03.60

The Schedule to the ***Employment and Industrial Relations Act***[189] lists the number of offices that are required to be manned at all times in order to provide essential health services to the community.

It distinguishes between categories relating to 'on call' which means that 'the person may be contacted by phone, pager or otherwise and is expected to exercise clinical judgement,' and the term 'resident', which means 'present on site in the hospital to deliver emergency services.' Moreover, the term 'by day' is defined as from 8.00 am to 10.30 pm and the term 'by night' from 10.30 pm to 8.00am.

In this respect it is relevant to note that the hours that a doctor was expected to work have traditionally been much too long and even dangerously long, considering the responsibility involved. Moreover, the younger the doctor, the longer was s/he expected to work, often 40 hours or more at a stretch. This cannot be considered to be ethically just to either doctor or patient.

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[188] The administration of high doses of analgesics, such as morphine, for the relief of pain is justifiable as the intention is to relieve the patient's pain, even though the dose might cause respiratory depression and death. Such an action is allowed under the principle of 'double effect'.

[189] *Employment and Industrial Relations Act*, Schedule according to article 64(6).

12. Prison Medical Service

03.61

The presence of medical services inside a prison and for the use of prisoners is a necessary one, and in no way may it be interpreted as collusion of the medical profession with the punitive system of the State.

A medical officer is expected to visit prison on a daily basis and should take as long as is necessary, depending on requirements of the prisoners. Responsibility for the overall service for co-ordination and management devolves on the Prison Medical Officer. Specialised services are to be made available to inmates, including dental and psychiatric, for all physical and mental disorders. In fact the prisoners are regularly referred to the hospital for specialist consultations and dental services.

There should be a properly equipped infirmary and a pharmacist and qualified nursing and paramedical staff should be made available, under the direction of the Medical Officer.[190]

03.62

Sick prisoners requiring hospital treatment outside the prison should be transferred to such an institution. This includes prisoners requiring hospitalised treatment in a mental hospital.[191]

The Medical Officer in charge is responsible for the care of the physical and mental health of the prisoners.[192] S/he is required to report to the Director of the prison whenever he considers that 'a prisoner's physical or mental health has been or will be adversely affected by continued imprisonment or by any condition of imprisonment.'[193] In the case of an infectious disease, this has to be reported to the Director and steps taken to prevent its transmission to others.

Prisoners should be examined on admission, and prior to release, by a medical practitioner.[194]

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[190] *Prisons Regulations*, SL 260.03, regulation 31(5).
[191] *Prisons Regulations*, SL 260.03, regulation 31(6).
[192] *Prisons Regulations*, SL 260.03, regulation 32(1).
[193] *Prisons Regulations*, SL 260.03, regulation 32(3)(a).
[194] *Prisons Regulations*, SL 260.03, regulation 33(1)(a).

The Medical Officer is also expected to advise the Director on general issues relating to health, including quality and quantity of food and water, hygiene and cleanliness, sanitation, heating, lighting and ventilation.[195]

Experimentation using prisoners is forbidden.[196]

The medical services of the prison are required to 'seek to detect and shall treat any physical or mental illness or defect or drug-related condition which may affect a prisoner's well being in prison or which may impede a prisoner's re-settlement after release,' and to provide all necessary services which are normally provided free of charge outside prison.[197]

03.63

In the case of infants of female prisoners, pre-natal care should be provided as well as transfer to hospital for confinement and delivery of the child. Such an infant may be kept in the care of its mother in prison until the child is one year old.[198]

03.64

In the event of the death of any prisoner, the Medical Officer shall, enter into a specialist register, all the necessary details concerning the death, the date, time and nature of any antecedent illness or injury, and the result of the autopsy carried out according to law.[199]

13. Doctors and Resource Managers

03.65

Doctors are rarely trained as managers, and training in economic issues is often non-existent. Yet more and more they need to have a grasp of the issues that underlie the availability of resources. They have to balance their well-intentioned drive to provide their individual patient with the best possible care and therapy, with the overall societal needs, given a specific budget. No doctor can be considered to be acting ethically if s/he squanders resources or does not follow some basic principles relating to prioritisation.

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[195] *Prisons Regulations*, SL 260.03, regulation 34(1).
[196] *Prisons Regulations*, SL 260.03, regulation 36(1).
[197] *Prisons Regulations*, SL 260.03, regulation 37.
[198] *Prisons Regulations*, SL 260.03, regulations 38(1) and 38(2).
[199] *Prisons Regulations*, SL 260.03, regulation 39(3).

In this respect one needs to bear in mind some fundamental theories of justice. These include:

(a) *utilitarian theories*: these propose that one must endeavour to provide the greatest good for the greatest number of people;
(b) *libertarian theories*: these state that there is no special right to healthcare – it is a choice. People are encouraged to provide for healthcare in the same way that they provide for other services. It therefore encourages the development of health insurance cover for most medical and health-related services. Such a system, flourishing particularly in the US, tends to favour those who can afford such insurance, and penalises the poor and those who cannot plan for future needs;
(c) *communitarian theories*: these involve distribution of healthcare services according to the needs and goals of the community. These emphasise the needs of the community as a whole and tend to balance individual needs (e.g. expenditure on provision of heart surgery), against procedures which would benefit society as a whole (e.g. vaccination, public health issues, etc);
(d) *egalitarian theories*: these aim to ensure that everyone has an equal opportunity to succeed in life. 'Each member of the society, irrespective of wealth or position, would have equal access to an adequate, although not maximal, level of healthcare – the exact level of access being contingent on available societal resources and public processes of decision-making.'[200]

14. Business and Financial Interests

03.66

A doctor is not allowed to have a financial interest in a pharmacy. The ***Medicines Act***[201] lists those who may not have a 'direct or indirect' interest in a pharmacy, namely: a medical practitioner, dental surgeon, dentist or veterinary surgeon or the spouse of any such medical practitioner, dental surgeon, dentist or veterinary surgeon. It is also forbidden to enter into any agreement with any pharmacist or any other person for any share in the profits of a

[200] Beauchamp T.L., & Childress J.F., *Principles of Biomedical Ethics*, 5th Edition, Oxford, 2001.
[201] *Medicines Act*, Third Schedule.

pharmacy, or to have any direct or indirect interest of whatever nature in any pharmacy.

The Minister responsible for Public Health may establish a tariff of fees payable in respect of professional services rendered by medical practitioners and dentists and these are published as subsidiary legislation.[202] The fees for operations and other services not included in the tariff, which was last amended in 1983, 'shall be assessed by the Medical Council according to circumstances, provided there has been no previous agreement.'[203]

To operate a private hospital, nursing home for the aged, medical diagnostic laboratory, X-ray department or any other similar institution, a valid licence issued by the Minister responsible for Public Health is required.[204]

With respect to private hospitals, the ***Medical and Kindred Professions Ordinance*** refers to a 'standard of medical care', and states that: 'No licence shall be granted or renewed ... if the premises, equipment and facilities as well as the personnel, whether medical or otherwise, are not such as to provide such standard of medical care or service as the Minister responsible for Public Health deems to be satisfactory.'[205] It is to be noted that no such provision exists in relation to other (public) hospitals.

The Minister has the power to establish a tariff of charges to be charged by establishments and institutions licensed to practice as private hospitals and clinics. And to ensure that these establishments do not charge in excess of such a fee.[206]

Moreover, these establishments are required to 'display, and keep at all times displayed, in a prominent place in the licensed premises and which is easily accessible to the public, the tariff of fees and charges currently applicable.'[207]

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[202] *Tariff of Fees Payable to Medical Practitioners Order*, SL 458.02, Schedule and *Tariff of Fees Payable to Dental Surgeons/Dentists Order*, SL 458.03, Schedule.

[203] *Tariff of Fees Payable to Medical Practitioners Order*, SL 458.02, Schedule, 42 and *Tariff of Fees Payable to Dental Surgeons/Dentists Order*, SL 458.03, Schedule, 26.

[204] *Medical and Kindred Professions Ordinance*, article 98(1).

[205] *Medical and Kindred Professions Ordinance*, article 98(2).

[206] *Medical and Kindred Professions Ordinance*, article 100(1).

[207] *Medical and Kindred Professions Ordinance*, article 100(2). See *Licensing of Private Medical Clinics Regulations*, SL 458.23, regulations 6(4) and 6(5).

15. Advertising

03.67

The ***Medicines Act*** defines 'advertising' in relation to medicinal products to include 'any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products and without prejudice to the generality of the foregoing in particular includes:

(a) the advertising of medicinal products to the general public;
(b) the advertising of medicinal products to persons qualified to prescribe or supply them;
(c) visits by medical or sales representatives to persons qualified to prescribe medicinal products;
(d) the supply of samples;
(e) the provision of inducements to prescribe or supply medicinal products, by way of a gift, offer or promise of any benefit or bonus, whether in money or in kind, except when the intrinsic value of such an inducement is minimal;
(f) sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products;
(g) sponsorship of any scientific congress attended by persons qualified to prescribe or supply medicinal products and in particular where payment of their travelling and accommodation expenses is offered in connection therewith.'

Moreover, medicinal products may only be advertised in accordance with such conditions as may be established by or under the ***Medicines Act***.[208] 'Advertising of certain medicinal products or classes of medicinal products may, by such regulations, be prohibited.'[209] The subsidiary legislation, ***Medicinal Products (Advertising) Regulations*** makes it unlawful to advertise to the general public medicinal products which are available on medical prescription only or which contain narcotic drugs or psychotropic substances.[210]

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[208] *Medicines Act*, article 31. These have been issued as subsidiary legislation, SL 458.32, *Medicinal Products (Advertising) Regulations*.

[209] *Medicines Act*, article 106(g).

[210] *Medicinal Products (Advertising) Regulations*, SL 458.32, regulations 5(1) and 5(2).

03.68

'Medicinal products may be advertised to the general public which, by virtue of their composition and purpose, are intended and designed for use without the intervention of a medical practitioner for diagnostic purposes or for the prescription or monitoring of treatment, with the advice of the pharmacist, if necessary.'[211] However certain criteria[212] must be met and in particular, an advert must not:[213]

(a) give the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by mail, internet or any other means;
(b) lead to erroneous self-diagnosis;
(c) suggest that the effects of the medicine are guaranteed and are unaccompanied by adverse reactions or are better than other treatments;
(d) suggest that health can be enhanced by the medicine or adversely affected by not taking it or refer, in misleading terms, to claims of recovery;
(e) be directed exclusively or principally at children;
(f) refer to a recommendation by scientists, health professionals or persons who because of their celebrity, could encourage the consumption of medicinal products;
(g) suggest that the product is a foodstuff, cosmetic or other consumer product;
(h) suggest that the safety or efficacy of the product is due to the fact that it is natural; and
(i) mention that the medicinal has been granted a marketing authorisation.

'Where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy.'[214]

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[211] *Medicinal Products (Advertising) Regulations*, SL 458.32, regulation 5(5).
[212] *Medicinal Products (Advertising) Regulations*, SL 458.32, regulation 6.
[213] *Medicinal Products (Advertising) Regulations*, SL 458.32, regulation 7.
[214] *Medicinal Products (Advertising) Regulations*, SL 458.32, regulation 10(1).

03.69

The ***Public Health Act***, allows the Superintendent of Public Health to make, vary or revoke orders 'controlling advertisements that may affect public health and in particular:

(i) controlling the visual, audio and written content thereof;
(ii) controlling the layout and sequence of events of the advertisements;
(iii) regulating the persons or class of persons used in the advertisements; (and)
(iv) requiring a written permission from the Superintendent before the publication of an advertisement.'[215]

03.70

The ***Broadcasting Act***, also makes it illegal to advertise particular products. It states: 'Advertising for medicinal products and medical treatments available only on prescription shall be prohibited.' This applies also to teleshopping and prohibition of naming these medicinals by a sponsor.[216]

Advertising of medical and health services is governed by the ***Medical and Kindred Professions Ordinance***, which says: 'No person shall advertise or permit or suffer to be advertised in any manner whatsoever, any medical or health service or treatment, not being a service provided by Government, or any other service or treatment which is or is described as being of a medical, therapeutic or curative value or effect, or in any other way beneficial to health, without the approval of the Council of Health.'[217] This article seems to refer to advertising of a health service even by a non-medical person, and, moreover, that anyone has a responsibility 'not to permit or suffer' advertising of this nature to occur, implying that everybody has the duty to report such activity.[218]

A doctor should not instigate nor condone any advertisement relative to his/her professional status or work.[219]

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[215] *Public Health Act*, article 27(b).

[216] *Broadcasting Act*, Third Schedule, paragraphs 16, 17 and 22.

[217] *Medical and Kindred Professions Ordinance*, article 90A (1).

[218] To note, however, that under company law and free trading, a company may advertise services – unless the advert is falsifying claims as to benefit. See *Medicines Act* article 31 and SL 458.32, *Medicinal Products (Advertising) Regulations.*

03.71

The ***Medicines Act*** sets conditions and criteria for any person to have, or not have, a direct or indirect interest in a pharmacy. In the Third Schedule to this Act, it states that it is not lawful for any pharmacist:

'(a) to carry on the business of a pharmacy on account of, or in partnership with any medical practitioner, dental surgeon, dentist or veterinary surgeon or any other person authorised to issue prescriptions under the ***Medicines Act*** or any other Act;

(b) to enter into any agreement with any medical practitioner, dental surgeon, dentist or veterinary surgeon or any other person authorised to issue prescriptions as aforesaid, for any share in the profits of a pharmacy;

(c) to lend his name in order that the business may be carried out by some other person.'

This is reinforced by the guidelines from the Medical Council that a medical practitioner must not circulate professional cards to chemists or opticians; neither must s/he have any salary or commission or any other arrangement with a chemist or optician; s/he must not have a financial interest either directly or indirectly in a chemist's shop.[220]

[219] *Ethics of the Medical Profession Regulations*, SL 94.15, regulation 8.

[220] *Ethics of the Medical Profession Regulations*, SL 94.15, regulation 16.

Chapter 4

Other Health Care Professions

1. Introduction

04.01

The role of a number of the other professions (apart from medical and dental professions) within the health system is often underrated. It is often, however, the case that patient satisfaction within the health profession as a whole depends at least to the same extent on the related professions as on the medical profession itself. There is often far more contact between patient and nurses, for instance, than with the doctor(s) involved in the particular case.

All these professions are covered by their own specific code of conduct (e.g. Maltese Code of Ethics for Nurses and Midwives, Ethics and the Pharmaceutical Profession, etc.). There is also specific legislation enshrined in Maltese law, originally in the ***Medical and Kindred Professions Ordinance***, and more particularly in the more recent ***Health Care Professions Act***, which deals with the health-related professionals, namely:

(a) Medical Practitioners and Dental Surgeons; [1]
(b) Pharmacists and Pharmacy Technicians;[2]
(c) Nurses and Midwives;[3]
(d) Professions Complementary to Medicine.[4]

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[1] *Health Care Professions Act*, articles 7–12. It is to be noted that the Veterinary Surgeons are now represented by the *Veterinary Services Act*, Part VI, articles 39–47.
[2] *Health Care Professions Act*, articles 13–18.
[3] *Health Care Professions Act*, articles 19–24.
[4] *Health Care Professions Act*, articles, 25–28.

There are also provisions dealing with Specialist Accreditation for all of the above professions.[5]

2. The *Health Care Professions Act:* General Considerations

04.02

The other health care professions, namely, Pharmacists and Pharmacy Technicians, Nurses and Midwives, and Professions Complementary to Medicine, are covered by the ***Health Care Professions Act.*** In addition, these professions are regulated by other laws described below. In this chapter each of these professions is discussed emphasising specific or particular legislation of interest.

As mentioned in the chapter on medical issues, the new ***Health Care Professions Act*** integrates several aspects of the ***Medical and Kindred Professions Ordinance*** and the ***Department of Health (Constitution) Ordinance.*** Several aspects of the older legislation are therefore repealed.

This Act sets up specific Councils responsible for the various professions, as follows:

(a) Pharmacy Council;[6]
(b) Council for Nurses and Midwives;[7] and
(c) Council for the Professions Complementary to Medicine.[8]

It also defines a 'health care profession' as one which is regulated by the relevant Council and a 'health care professional' as a person who is authorised to practise a health care profession in accordance with the provisions of this Act.

04.03

Pharmacists and midwives must be in possession of a 'licence', which means an endorsement issued to a health care professional by the President of Malta, and all pharmacists, pharmacy technicians, midwives, nurses and professionals listed in the Third Schedule to this Act, must be registered as members of their health care profession.

It also introduces the concept of a 'specialist', which means a health care professional whose name is entered in the appropriate

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[5] *Health Care Professions Act,* articles 29–30 and Schedule 5.
[6] *Health Care Professions Act,* article 15.
[7] *Health Care Professions Act,* article 21.
[8] *Health Care Professions Act,* article 26.

part of the specialist register kept by the relevant Council in accordance with this Act, and which covers specialities in all the above health care professions, and their right to assume the appropriate academic or other relevant titles.[9]

04.04

The Act also refers to:

(a) 'good conduct' in terms of conduct to the satisfaction of the relevant Council; and

(b) 'professional and ethical standards', which include the standard of the general conduct of a member of a health care profession, including the behaviour of such member towards his/her client or the patient under his/her care or being attended by him/her, during or consequential to the exercise of his/her profession. It also relates to the behaviour of such member towards other members of his/her profession and towards members of other health care professions and towards society.

To practice any of the professions mentioned above, there are a number of conditions that have to be fulfilled, namely:

(a) no one is permitted to use any professional title (including related abbreviations) corresponding to a health profession, unless s/he fulfils the required conditions for taking up and pursuing that profession.[10] S/he must be a citizen of Malta or a person otherwise legally entitled or authorised to work in Malta;[11]

(b) must not practice any two or more of the health care professions concurrently,[12] except when the Minister may exceptionally approve; and

(c) must be subject to 'special supervision of the relevant Council', which means the supervision, by the relevant Council of 'the professional and ethical standards as prescribed by the relevant Council.'[13]

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[9] *Health Care Professions Act*, article 29. In practice, there are established specialist registers only for medical practitioners and dental surgeons.

[10] *Health Care Professions Act*, article 3(2).

[11] *Health Care Professions Act*, article 3(3).

[12] *Health Care Professions Act*, article 4.

[13] *Health Care Professions Act*, article 5.

3. Authority and Responsibilities of Councils

04.05

The role of the several Councils mentioned above is:

(a) to recommend to the President of Malta the granting, and withdrawal, of licences to practise their profession (for pharmacists and midwives only);
(b) to keep updated registers containing the names of persons who qualify for inclusion, including specialist registers, as may be prescribed, and registers for special areas of practice as determined by the relevant Council;
(c) to prescribe the qualifications required to practice the relevant profession;
(d) to prescribe and maintain professional and ethical standards for the relative profession; and
(e) other functions, including setting up committees and levying fees.

For further details relating to the general issues relating to health care professionals as determined by the ***Health Care Professions Act,*** see **Chapter 3**.

4. Specific Regulations Relating to the Various Professions

a. Pharmacists and pharmacy technicians

04.06

The qualifications required to practice as a pharmacist are as follows:[14]

(a) s/he holds a licence to practice as a pharmacist;
(b) s/he is a citizen of Malta, or of a recognised Member State or is otherwise legally entitled or authorised to work in Malta;
(c) s/he is of good conduct;
(d) his/her name is entered in the Register of Pharmacists; and
(e) s/he possesses qualifications, recognised by the Pharmacy Council, which entitle registration.

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[14] *Health Care Professions Act*, article 13.

The qualifications required to practice as a pharmacy technician are the same as above except that there is no provision for a licence and the relevant Register is called the 'Register of Pharmacy Technicians'.[15]

Again there is provision for future specialist registers as may be prescribed and registers of special areas of practice, as may be determined by the Council.[16]

b. Nurses and midwives

04.07

This Council for Nurses and Midwives has to keep separate registers as follows:

(a) Register of Midwives;[17]
(b) Register of Nurses[18] consisting of the following parts:
    Part I in respect of first level registered nurses;
    Part II in respect of second level registered nurses; and
    Special Parts in respect of nurses trained in the different special areas recognised by the Council for Nurses and Midwives; and
(c) Specialist Registers for midwives and nurses, as may be prescribed.[19]

The Council requires the same qualifications for the practice of midwifery and nursing as indicated with respect to the pharmaceutical profession, with midwives also requiring a licence.

c. Professions complementary to medicine

04.08

Again, this Council for the Professions Complementary to Medicine has the general duties outlined for other Councils, including keeping the Registers of those registered to practice the several aspects of

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[15] *Health Care Professions Act*, article 14.
[16] *Health Care Professions Act*, article 16(c).
[17] *Health Care Professions Act*, article 23.
[18] *Health Care Professions Act*, article 24.
[19] *Health Care Professions Act*, article 22(1)(c).

the profession. The separate Registers to be kept by this Council are for the following professions:[20]

(a) Acupuncturist;
(b) Chiropractor;
(c) Clinical Psychologist;
(d) Dental Hygienist;
(e) Dental Technologist;
(f) Dietician;
(g) Environmental Health Officer;
(h) Medical Laboratory Scientist;
(i) Nutritionist;
(j) Occupational Therapist;
(k) Optometrist;
(l) Orthoptist;
(m) Osteopaths;
(n) Perfusionist;
(o) Physiotherapist;
(p) Psychotherapist;
(q) Podiatrist;
(r) Radiographer; and
(s) Speech Language Pathologist.

The Council requires the same qualifications for the practice of these professions as indicated with respect to the pharmaceutical and nursing professions.

Also there is provision for future specialist registers as may be prescribed and registers of special areas of practice, as may be determined by the Council.[21]

5. Specialisation Within These Professions

04.09

The Health Care Professions Act sets up a Specialist Accreditation Committee in the following areas:[22]

(a) for medical practitioners;
(b) for dental surgeons;

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[20] *Health Care Professions Act*, Third Schedule.
[21] *Health Care Professions Act*, article 27(1)(a).

(c) for pharmacists;
(d) for nurses and midwives; and
(e) for professions complementary to medicine.

Their functions include:[23]

(a) issuing certificates of completion of specialist training in the specialities listed in the relevant part of the Fifth Schedule of the ***Health Care Professions Act,*** upon the fulfilment of criteria recommended by the relevant professional associations listed in the Fourth Schedule;
(b) accrediting post-graduate training programmes; and
(c) carrying out other duties, including advising the Minister, and acting as an advisory body to the relevant Council concerning issues of training.

The Fifth Schedule of the ***Health Care Professions Act*** specifies which specialities will be recognised in each area. While those for the medical and dental professions have been listed in detail, those for the other health care professions have not yet been indicated. Moreover the Fourth Schedule only lists the Malta Chamber of Pharmacists and the Malta Union of Midwives and Nurses as the relevant non-medical (and dental) associations. There is no recognised association for the Professions Complementary to Medicine.

6. Councils and Disciplinary Action

04.10
The Councils also serve as watch-dogs, supervising the activities of registered professionals. In the case of 'conviction or infamous conduct' each Council has the duty to 'investigate any allegation of professional misconduct or breach of ethics by a health care professional falling under its supervision.'[24]

The respective Council may take action against a registered health professional if such a person:[25]

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[22] *Health Care Professions Act,* article 30(1).
[23] *Health Care Professions Act,* article 30(6).
[24] *Health Care Professions Act,* article 31(1).
[25] *Health Care Professions Act,* article 32(1).

(a) has been convicted by any court in Malta of any crime punishable by imprisonment for a term exceeding one year or of any of the crimes mentioned in articles 198 to 205 or in articles 206 to 209 of the ***Criminal Code***; or
(b) has been guilty of professional or ethical misconduct in any respect; or
(c) in any other manner has failed to abide by the professional and ethical standards applicable to him/her.

In such a case the respective Council may direct that:[26]

(a) his/her name be erased from the appropriate register and where appropriate recommend to the President of Malta withdrawal of the licence; or
(b) his/her name be taken off such register for such period of time as the relevant Council may determine and where appropriate recommend to the President of Malta suspension of the licence; or
(c) a fine is inflicted on the health care professional concerned; or
(d) the health care professional concerned is cautioned; or
(e) the health care professional concerned undergoes further training or practice under supervision for such period of time as the relevant Council may determine.

Erasure from the respective register can also occur on the grounds that the 'health care professional is unfit to continue to practise his profession on account of some physical or mental infirmity.'[27]

7. Pharmacists and the Control of Drugs and Chemicals

04.11
The Minister responsible for public health may make regulations relating to 'the manufacture, exportation, importation, possession, distribution and sale of such drugs or chemical products,'[28]

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[26] *Health Care Professions Act*, article 32(1).
[27] *Health Care Professions Act*, article 38.
[28] *Medical and Kindred Professions Ordinance*, article 40.

including psychotropic drugs,[29] if control is required in the public interest and 'for preventing their improper use'. This is also reflected in the ***Dangerous Drugs Ordinance*** which states that: 'For the purpose of preventing the improper use of the drugs to which this Part of this Ordinance applies, the Minister responsible for public health may make rules for controlling the manufacture, sale, possession and distribution of those drugs.'[30]

Regulations may be made in relation to the dispensing of prescriptions for such drugs, their labelling and also regarding the upkeep of adequate documentation of transactions, to be produced for inspection.[31]

The name and address of the apothecary in charge of the dispensary must be affixed to the door of the dispensary so as to be clearly visible from the street at all times.[32]

04.12

The Licensing Authority set up under the ***Medicines Act*** is required to specify which medicinal products[33] are subject to a medicinal prescription, and which are not, and which therefore can be sold or supplied under the supervision of a pharmacist.[34]

The obligations of a holder of a pharmacy licence include the duty to:[35]

(a) 'maintain such records for any transaction in medicinal products as may be established by or under this Act and have such records available for inspection by any authorised officer for such period of time as may be required by or under this Act';

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[29] *Medical and Kindred Professions Ordinance*, article 40A.

[30] *Dangerous Drugs Ordinance*, article 9(1).

[31] *Medical and Kindred Professions Ordinance*, articles 40 and 40A.

[32] *Medical and Kindred Professions Ordinance*, article 49.

[33] 'Medicinal product' means any substance or combination of substances presented for treating or preventing disease in human beings, as well as any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings (*Medicines Act*, article 2). See also *Product Safety Act*, article 2(a) where the term is used to include products that are also used for animals.

[34] *Medicines Act*, article 29(1).

[35] *Medicines Act*, article 74.

(b) 'comply with regulations or Orders relating to good practice in retail sale of medicinal products as may be established by or under this Act'; and
(c) 'dispose of medicinal products as established by or under this Act or any other law.'

04.13
Every pharmacy has to be managed by a 'managing pharmacist' who is expected to:[36]

(a) manage the pharmacy and related premises;
(b) ensure that a pharmacist is present in the pharmacy at all times, supervise sale of medicinal products, and keep adequate records;
(c) 'comply with regulations or rules relating to good practice in the dispensing of medicinal products'; and
(d) dispose of medicinal products as established by law.

The duties of a pharmacist also include[37] dispensing medicinal products. Only a pharmacist (or a pharmacy technician under his/her personal supervision) can prepare or dispense a medicinal product, in accordance with standards as may be established under this or other laws. This is further emphasised in article 79(2) which states that 'a medicinal product shall only be sold from a pharmacy.'

04.14
A pharmacist may only refuse to dispense any medicinal product, on the presentation of a prescription, if:

(a) s/he has reason of concern that the prescription is false;
(b) that the person is misusing the prescribed medicinal product;
(c) the medicinal product is not available; and
(d) s/he has professional reasons for not preparing or dispensing the prescription.[38]

A pharmacist should dispense the particular brand of product if the prescription so demands (i.e. by the words

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[36] *Medicines Act*, article 75.
[37] *Medicines Act*, article 76(1).
[38] *Medicines Act*, article 80(1).

'branded' or '®'). Otherwise, a pharmacist may 'dispense the medicinal product prescribed or an equivalent medicinal product having the same chemical entity, dose, dosage form, formulation and dosage frequency as the medicinal product indicated on the prescription.'[39]

If there is reason to believe that the product should not be dispensed (e.g. suspected wrong dosage), then the pharmacist 'is bound to draw the attention thereto of the person prescribing the same and may require such person to write out in ink or in other indelible manner on the prescription a statement assuming responsibility for the prescription.'[40] This article also states that the pharmacist is responsible for dispensing medicinal products which do not need a prescription.[41]

04.15

No medicinal product shall be dispensed by a pharmacist without the prescription from an authorised person, i.e. a medical or dental practitioner, veterinary surgeon or other authorised person.[42]

The Act states that the preparation of any prescription and 'the pre-packing, reconstitution, dispensing and administration of medicinal products and any other activity related to medicinal products' must be in accordance with established standards.[43] The pharmacist must 'label each medicinal product' dispensed in accordance with such regulations or rules made under this Act.[44]

It is illegal for a managing pharmacist 'to sell, allow the sale, dispensing or supply' of:

(a) 'any imperfect, deteriorated or harmful substance;
(b) any medicinal product bearing an expiry date which has expired; and
(c) food not in accordance with the provisions of the ***Food Safety Act,*** or any regulations made thereunder.'[45]

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[39] *Medicines Act,* article 80(2).
[40] *Medicines Act,* article 80(3).
[41] *Medicines Act,* article 80(4).
[42] *Medicines Act,* article 81(1).
[43] *Medicines Act,* article 87.
[44] *Medicines Act,* article 83.
[45] *Medicines Act,* article 84.

A medicinal product must not be kept in unsuitable conditions and 'which are not such as to protect it from alteration, deterioration or contamination.' It must not 'be kept or stored outside the pharmacy.'[46] It is the duty of the managing pharmacist to 'ensure that the pharmacy has the facilities to ensure that medicinal products are stored in accordance with storage recommendations.'[47]

A pharmacist should not be in partnership with 'any medical practitioner, dental surgeon, dentist or veterinary surgeon or any other person authorised to issue prescriptions under the Medicines Act or any other Act,' or to share with them profits of a pharmacy.[48]

8. The *Medicines Act*

04.16

The recent ***Medicines Act*** sets up a Licensing Authority (in effect it is the Superintendent of Public Health) whose functions include:[49]

'(a) to establish standards to ensure the quality, safety and efficacy of medicinal products;
(b) to establish standards for the operation of pharmacies;
(c) to establish standards for the manufacture, preparation, packaging and labelling of medicinal products or any substance which is used or is intended to be used in such products;
(d) to establish standards for the operation of wholesale distribution;
(e) to establish standards for the testing or analysis of medicinal products or any substance which is used or is intended to be used therein;
(f) to establish standards for the carrying out of clinical trials;
(g) to establish standards for the reporting of adverse reactions, serious adverse reactions or suspected unexpected adverse reactions and make provision for the collection or submission of related information from any person or activity regulated by or under this Act;

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[46] *Medicines Act*, article 85(1).
[47] *Medicines Act*, article 85(2).
[48] *Medicines Act*, article 77 and Third Schedule, article 4(a) and (b).
[49] *Medicines Act*, article 3.

(h) to establish standards in relation to the advertising of medicinal products;
(i) to advise the Minister in the making of regulations in respect of the classification of medicinal products;
(j) to issue, renew, amend, vary, suspend or revoke marketing authorisations for medicinal products;
(k) to withdraw or recall medicinal products from the market in the interest of public health;
(l) to ensure compliance with international obligations entered into by the Government of Malta in relation to any matter regulated by or under this Act;
(m) to issue, renew, amend, vary, suspend or revoke any authorisation or licence that may be required by or under this Act;
(n) to carry out inspections of any activity, service or procedures in relation to medicinal products and to do all such things as may be necessary for the purpose of ensuring compliance with any provisions of this Act, or made thereunder;
(o) to authorise the advertising and promotion of medicinal products;
(p) to carry out any other activity as may be prescribed; and
(q) to advise the Minister on any matter connected with its functions or any other provision of this Act.'

The Licensing Authority may set up rules to delegate the functions to the Medicines Authority and may establish advisory committees to assist it in the proper exercise of its functions.[50]

04.17

This Act also sets up a Medicines Authority,[51] a body corporate, headed by a Chief Executive Officer, with the capability of employing personnel, and with functions which include:[52]

(a) functions related to paragraphs (m), (n) and (o) above, delegated to it by the Licensing Authority;[53]

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[50] *Medicines Act*, article 3(5).
[51] *Medicines Act*, article 4.
[52] *Medicines Act*, article 6.
[53] *Medicines Act*, article 3(3).

(b) assisting and advising the Licensing Authority on any matter related to the regulation of medicinal products;
(c) undertaking activities and projects as necessary for the proper exercise of its functions;
(d) establishing procedures, 'as may be necessary,' for obtaining and assessing information as regards the safety, quality and efficacy of medicinal products to be placed on the market in Malta;
(e) establishing procedures, 'as may be necessary,' for making assessments as regards the safety, quality and efficacy of medicinal products to be placed on the market in Malta;
(f) establishing procedures for monitoring and obtaining reports on the quality, safety or efficacy of medicinal products;
(g) making recommendations to the Licensing Authority in relation to standards and licensing;
(h) advising the Licensing Authority on the precautions or restrictions to which medicinal products may be subjected for their marketing or continued use in Malta; and
(i) furnishing advice or recommendations to the Licensing Authority on any matter connected with its functions, on its own initiative or on request by the Licensing Authority.

To note that article 12 of the ***Medicines Act*** emphasises the need for a Code of Ethics. It states: 'The Chief Executive Officer and all other executive officers and employees of the Authority shall conform with and abide by any public service values and Code of Ethics that may be in force from time to time in relation to public officers.'[54]

9. 'Trades Akin to the Sanitary Professions'

04.18

The ***Medical and Kindred Professions Ordinance,*** Part X, most of which is now repealed, had dealt with various aspects of business related to medicines and medical services, under the title of 'trades akin to the sanitary professions'.

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[54] *Code of Ethics for Employees in the Public Sector,* Cabinet Office, October, 1994.

Legislation prohibits the sale of drugs by any person who is not a pharmacist (or a supervised pharmacy technician) effectively excluding any other tradesman.

The ***Medical and Kindred Professions Ordinance*** prohibits distribution of 'a secret remedy or specific'.[55] This also applies to all additives or colouring matter unless it bears the name or designation of the substance(s) contained therein.

It also forbids all advertising relating to any medical or health service (except a service provided by government) or treatment without approval of the Council of Health.[56] It is important to note that for the purpose of this article, treatment 'shall include any form of advice relating to the treatment or cure of maladies or ailments, or any advice relating to health.'[57] These provisions apply also to apothecaries and pharmacy technicians.[58]

04.19

The ***Medicines Act*** deals with the wholesale distribution of medicinal products in general and with the sale of medicinal products by pharmacists. It prohibits the sale of poisons by any person, who does not possess a licence from the Licensing Authority.[59] This licence may 'only be granted to manufacturers of, and dealers in chemical products, colorists and such other persons as require to make use of poisons in the exercise of their trade or profession.'[60]

Moreover, no one may set up any laboratory of chemical products used in medicine without a licence.[61]

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[55] *Medical and Kindred Professions Ordinance*, article 90.
[56] *Medical and Kindred Professions Ordinance*, article 90A(1).
[57] *Medical and Kindred Professions Ordinance*, article 90A(2).
[58] *Medical and Kindred Professions Ordinance*, article 91.
[59] *Medicines Act*, articles 91–95 and 97–98.
[60] *Medicines Act*, article 92(1).
[61] *Medical and Kindred Professions Ordinance*, article 96.

Chapter 5

The Embryo and Genetic Testing

1. Introduction

05.01

There is a marked surge of interest currently in genetic manipulation of the embryo. This has resulted from the enormous advances in molecular biology in recent years, and has been spurred by the possibility of intervening in the process of gene expression in the embryo and fetus. Marked advances have taken place in the molecular diagnosis of genetic disorders in the fetus, which have led to a considerable reduction of hereditary conditions like thalassaemia, in countries like Cyprus, where there is a very high incidence of the condition (up to 21 percent of the population carry the trait).

More directly, there is the opportunity of actually manipulating the genes of the embryo and fetus in an attempt to replace diseased genes with normal ones. While this appears to be the ultimate solution to genetic problems, it also raises several ethical problems. For instance, the Council of Europe's ***Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine,*** henceforth referred to as the ***Convention on Human Rights and Biomedicine,*** makes it clear that while interventions involving somatic genes are allowed, those involving reproductive genes are banned.[1] The reason for this is that introduction of new or altered genes in the reproductive genome

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[1] Council of Europe, *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine,* article 13.

would be tantamount to changing the human genetic heritage because these genes, once introduced, will spread like ordinary genes. We are still far from clear about the possible outcomes of such procedures.

Interest in embryo research has become an important source of stem cells which promise to provide cell lines capable of producing cells and substances essential for treatment of medical disorders, including replacement of human tissues. Already such cells have been used in patients suffering from myocardial infarction and Parkinson's disease, with promising results.

05.02

The only reference to these issues in Maltese law is contained in article 4 of the ***Patents and Designs Act.*** In effect this Act states that a patent shall not be granted in respect of 'the human body, at the various stages of its formation and development and the simple discovery of one of its elements,' which presumably refers to anatomical, physiological or embryological aspects, 'including the sequence or partial sequence of a gene.'

However, 'an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.'[2]

A patent cannot be granted for 'processes for cloning the human body, processes for modifying the germ line genetic identity of the human body and uses of the human embryo for industrial or commercial purposes'[3] and for 'DNA sequence not containing any technical information and in particular any indication of its function.'[4]

This implies that discovery of substances or elements within the embryo or fetus will not have commercial value, and therefore research in this field is unlikely to be of commercial interest. To be noted that this Act does not by itself prohibit research using these procedures. In fact articles 4(5)(b) and 4(5)(g) seem to condone

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[2] *Patents and Designs Act*, article 4(5)(b).
[3] *Patents and Designs Act*, article 4(5)(c).
[4] *Patents and Designs Act*, article 4(5)(g).

such research. There is no provision in Maltese Law which prohibits such research.

2. Cloning

05.03

Human cloning involves the artificial production of an identical human being, a process which has become technically possible in recent years, and has been actually achieved in the case of animals such as the sheep (cf. 'Dolly', the first sheep produced by this process).

There are various ways in which cloning can be achieved. Nuclear transfer involves the transfer of a nucleus from a donor cell (which can be taken from any part of the body, either from a third party donor or from the mother herself) and this nucleus is transferred to an ovum whose nucleus has been removed. The result is an offspring which is identical genetically with the donor of the nucleus.

Other techniques may be used to produce an identical 'twin': for instance, splitting the zygote or embryo during the first few days of its existence may lead to artificial 'twinning', a variety of cloning. Other researchers have used various methods to stimulate the development of cells in ways other than sexual reproduction.

These processes are referred to more specifically as 'reproductive cloning', to distinguish them from 'therapeutic cloning' which refers to the process of producing embryos for the purpose of extracting stem cells, or other material, useful in the treatment of disease. In effect, therapeutic cloning is of far greater importance, and has assumed far more significance than reproductive cloning. The reason for this is the fact that stem cell extraction from embryos is seen as a potential source of cell lines which could be of enormous commercial value (as mentioned earlier).

05.04

The Council of Europe has banned reproductive cloning.[5] In Maltese legislation, we have reference to cloning in the ***Patents and Designs Act***. It states that patents will not be granted with respect to

[5] Council of Europe, *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, article 13 and the *Additional Protocol on the Prohibition of Cloning of Human Beings*, particularly article 1.

'processes for cloning the human body, processes for modifying the germ line genetic identity of the human body and uses of the human embryo for industrial or commercial purposes.'[6]

As in the previous case, it is not the act of cloning which is prohibited by this provision, but only the process of patenting. There is no legislation that prohibits the practice of cloning as a research procedure within Maltese law.

3. Genetic Manipulation

05.05

The Council of Europe ***Convention on Human Rights and Biomedicine*** states that: 'An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.'[7]

However, there is no mention at all of human non germ line genetic manipulation, in Maltese legislation. It is interesting to note that the ***Patents and Designs Act*** refers specifically to genetic manipulation in animals and plants, but in relation to human beings, it restricts itself only to germ line manipulation.

Moreover, prohibition of genetic manipulations that modify the germ line genetic identity of the human body are not prohibited as such in Maltese legislation. However, patents will not be granted for 'processes for cloning the human body, processes for modifying the germ line genetic identity of the human body and uses of the human embryo for industrial or commercial purposes.'[8] Although the latter does tend to indirectly prohibit genetic research, as the law does not consider it a patentable invention, the provision does not go so far as to outlaw, in unambiguous terms, such research.

The Act states that patents shall not be granted in respect of 'processes and products for modifying the genetic identity of animals which are likely to cause them suffering without any

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[6] *Patents and Designs Act*, article 4(5)(c).

[7] Council of Europe, *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, article 13.

[8] *Patents and Designs Act*, article 5(c).

substantial medical benefits to man or animal,'[9] or 'in respect of animal varieties'.[10]

05.06

It appears that the legislator's concern was more with the prevention of suffering in animals as a result of such genomic modifications (itself a laudable aim), and not at all with the possible genetic effects that such manipulations can engender.

However under the ***Veterinary Services Act,*** the Minister may prescribe rules regarding veterinary medicinal products intended for animals listed in the Sixth Schedule,[11] which include genetically modified organisms (GMOs). Part C of the Sixth Schedule defines genetic modification of an organism as 'an organism in which the genetic material has been altered in a way that does not occur naturally by mating and, or, natural recombination.' The Act goes on to explain which genetic techniques are considered as constituting genetic modification. These at least include:

(a) recombinant DNA techniques using vector systems;
(b) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation;
(c) cell fusion (including protoplast fusion) or hybridization techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

'The techniques which are not considered to result in genetic modification, on condition that they do not involve the use of recombinant DNA molecules or GMOs, are: polyploidy induction, *in vitro* fertilization, conjugation, transduction, transformation or any other natural process.'[12]

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[9] *Patents and Designs Act,* article 4(5)(d).
[10] *Patents and Designs Act,* article 4(5)(e).
[11] *Veterinary Services Act,* article 32.
[12] *Veterinary Services Act,* Sixth Schedule, Part C. In terms of article 32 of the Act, these techniques apply to veterinary medicinal products (defined by article 2), or any medicinal products intended for animals.

4. Genetic Testing

05.07

Genetic tests are considered to be of a different order from most other diagnostic tests. This is because such tests involve, and may throw light, not only on the patient on whom the tests are performed, but also on other members of the family - siblings, cousins and other blood relatives. It may therefore be argued that informed consent, so essential in any investigation, would be required from all those whose privacy could be invaded by such a procedure. In practice this is a very difficult issue and it is often considered adequate if the individual is warned about these issues before the test is actually performed and it is pointed out clearly that it would be expected of him or her to inform relatives if the results of such a test indicate that they may be relevant to relatives.

This also emphasises the view that such tests should be performed only after considerable discussion and counselling by those well qualified for this job and, moreover, that they should not be available to the general public without such counselling, which should address, *inter alia*, medical, psychological and legal implications.

The Council of Europe's ***Convention on Human Rights and Biomedicine***[13] insists on tests being performed 'only for health purposes or scientific research linked to health purposes and subject to appropriate genetic counselling.'

5. The Definition of a Relative

05.08

The ***Civil Code*** defines liability for maintenance in terms of family order,[14] and for the purpose of intestate succession.[15]

05.09

The ***Mental Health Act,*** defines a relative as follows:[16]

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[13] Council of Europe, *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, article 12.

[14] *Civil Code*, article 12.

[15] *Civil Code*, article 789.

[16] *Mental Health Act*, article 30(1).

(a) the husband or wife;
(b) the son or daughter;
(c) the father;
(d) the mother;
(e) the brother or sister;
(f) the grandparent;
(g) the grandchild;
(h) the uncle or aunt;
(i) the nephew or niece.

It also states that 'any relationship of the half-blood shall be treated as a relationship of the whole blood.'[17]

This Act also defines the concept of 'nearest relative' as being the person[18] who is for the time being surviving, relatives of the whole blood being preferred to relatives of the same description of the half-blood and the elder or eldest of two or more relatives, described in any of the paragraphs (a) to (i) above, being preferred to the other or others of those relatives, in any case regardless of sex.[19] This means that the husband or the wife is the nearest relative.

6. Genetic Testing to Confirm Paternity

05.10

Genetic data may be used as evidence in paternity cases. 'The husband can repudiate a child conceived in wedlock . . . if he proves that during the said time the wife had committed adultery or that she had concealed the pregnancy and the birth of the child, and further produces evidence of any other fact (which may also be genetic and other scientific tests and data) that tends to exclude such paternity.'[20]

Genetic and scientific tests may be included as evidence, but do not appear to be mandatory (e.g. in the situation where the wife admits that the father of the child is not her husband but some other person).

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[17] *Mental Health Act*, article 30(2).
[18] First described in paragraphs (a) to (i) of article 30(1) of the *Mental Health Act*.
[19] *Mental Health Act*, article 30(3).
[20] *Civil Code*, article 70(1)(d).

However, the court may 'in an action of disavowal invite all or any of the parties including the child whose filiation is in dispute to submit to the tests necessary to establish the genetic proof that may be relevant to the case. The court shall be entitled to draw such inferences as may be justified by the refusal to submit to such tests. Where the child whose filiation is in dispute is a minor, the court itself shall determine whether the child shall submit to the tests.'[21]

05.11

To note here that genetic tests involving a minor are considered sufficiently significant to require the permission of a court. At least this protects the general interests of the child vis-à-vis parents litigating in a court suit.

In the case of children born out of wedlock, a judicial demand for a declaration of paternity or maternity may also be contested by any interested party.[22] In such a case the court may 'without prejudice to any evidence that may be produced by the parties,' invite them to submit to tests to establish genetic proof, as in article 70(3), and shall draw the same inferences if such tests are refused.[23] The legislation does not mention if the court should determine whether the child, if a minor, shall submit to the tests, but it is likely that if the child is the party contesting filiation, that child is an adult or at least a mature minor.

It is to be noted that amendments to the ***Civil Code***,[24] which came into force on 1st March 2005, are aimed at removing any discriminatory treatment of children born outside marriage.

7. The Rights of the Fetus

a. Right to life and abortion

05.12

In Malta, the right of the fetus not to be interfered with is paramount. As mentioned already, abortion laws are stricter in

[21] *Civil Code*, article 70(3).
[22] *Civil Code*, article 100.
[23] *Civil Code*, article 100A.
[24] These amendments were made by Act No. XVIII of 2004.

Malta than anywhere else in Europe. The ***Criminal Code*** states categorically: 'Whosoever, by any food, drink, medicine, or by violence, or by any other means whatsoever, shall cause the miscarriage of any woman with child, whether the woman be consenting or not, shall, on conviction, be liable to imprisonment for a term from eighteen months to three years.'[25]

Thus one might say that Maltese law provides full protection for the fetus as far as its right to life is concerned, even when this provides a threat to its mother. Most other countries (including some Muslim countries like Morocco) make an exception and allow abortion for medical reasons associated with the health of the mother.

Also in the ***Criminal Code,*** 'a bodily harm is deemed to be grievous and is punishable with imprisonment for a term from three months to three years ... if, being committed on a woman with child, it hastens delivery.'[26] Moreover the punishment rises to imprisonment for a term from nine months to nine years if grievous bodily harm 'committed on a woman with child, ... causes miscarriage.'[27] However the fetus is not accorded the same protection as an adult since death of an adult following grievous bodily harm, carries a harsher sentence, from four to twenty years imprisonment.[28]

The fetus is indirectly protected through regulations about health and safety at work for pregnant females, in particular 'when an employer takes measures to protect the health and safety of an employee who becomes pregnant or starts breastfeeding, to the satisfaction of the Occupational Health and Safety Authority, to prevent the risk of exposure which could jeopardise the health or safety of such an employee, to agents, processes or working conditions to which exposure is prohibited in terms of specific provisions made under the Occupational Health and Safety Authority Act, provided that the employee has duly informed her employer that she is pregnant or breastfeeding.'[29]

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[25] *Criminal Code,* article 241(1).
[26] *Criminal Code,* article 216(1)(e).
[27] *Criminal Code,* article 218(1)(c).
[28] *Criminal Code,* article 220(1).
[29] *Protection of Maternity Employment Regulations* SL 452.91, regulation 4.

The *Commissioner for Children Act* empowers the Commissioner for Children 'to promote special care and protection, including legal protection for children both before and after birth.'[30]

In the *Domestic Violence Act,* 'the child conceived but yet unborn' is afforded protection through inclusion as a 'household member' in the definition of possible victims of domestic violence, which is defined as 'any act of violence, even if only verbal, perpetrated by a household member upon another household member and includes any omission which causes physical or moral harm to the other.'[31]

b. Viability and inheritance

05.13

'(1) Those who are not born viable are incapable of receiving by will. (2) In case of doubt, those who are born alive shall be presumed to be viable.'[32] This could be interpreted as meaning that rights of inheritance begin only at birth, and only when the newborn is sufficiently mature to be considered viable.

Viability as such is not defined by Maltese law. This may be considered as the ability to live outside the womb. The *Civil Code,* article 70, makes an indirect reference to 180 days (over 25 weeks) as the threshold of viability (see below) when it presumes that being born 180 days, after marriage, is the minimum length of gestation, for a child to be presumed to have been conceived in wedlock.

From the medical point of view this is not realistic in view of the fact that the potential for viability has been extended to younger and younger infants, so that even a child born at the age of 24 weeks gestation now has a chance, albeit a slim one, of survival, and therefore would be covered by subarticle (2) of article 601. In fact in the UK, where stillbirths are registered, stillbirths are legally defined as infants born after 24 weeks gestation and have never showed signs of life after being expelled from the mother.[33] Also

[30] *Commissioner for Children Act*, article 9.

[31] *Domestic Violence Act*, article 2.

[32] *Civil Code*, article 601. Note also that article 1747 of the *Civil Code* refers to receiving a donation in the same terms, namely: '(1) Those who are not born viable, are also incapable of receiving by donation. (2) In case of doubt, those who are born alive shall be presumed to be viable.'

[33] *Stillbirth (Definition) Act 1992* and *Stillbirths (Scotland) Act 1938*. Fetuses born dead before 24 weeks are not registered.

in the UK the *Human Fertilisation and Embryology Act (1990)*, sets 24 weeks as the limit up to when legal abortion is permissible.

05.14

In Maltese legislation, stillbirths require an act of birth, and 'the fact of the stillbirth shall be stated in the act'[34] but there is no gestational limit on defining a still birth.

Interestingly 'in case of abortion, an act of birth shall only be drawn up where the fetus shall have completely assumed the human form.'[35] Again there is no attempt to establish a gestational age.

The international mortality statistics for fetal deaths use a classification based on gestation and weight and divide deaths into three groups, without commenting on viability:

> 22 weeks or < 500gm in weight
> 22–27 weeks or 500–999gm in weight
> >28 weeks or >1000gm in weight.

05.15

The ***Trusts Act*** also uses the term 'any person unborn.'[36] It states that the court may approve on behalf of 'any person unborn' . . . any arrangement varying or revoking all or any of the terms of the trust or enlarging the powers of the trustees of managing or administering any of the trust property. The court would approve such an arrangement only when it appears to be for the benefit of that person.[37]

'Any person unborn' means any future child and hence is more extensive in meaning than a fetus. Likewise, the term 'person' used in this context is not necessarily referring to the legal status of an unborn fetus, but to that of the child once born (see further below).

05.16

Curator ad ventrem: If the husband of a pregnant woman dies, 'the court may, upon the demand of any person interested, appoint a

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[34] *Civil Code,* article 283(1).
[35] *Civil Code,* article 283(3).
[36] *Trusts Act,* article 36(1)(c) and article 36(2).
[37] *Trusts Act,* article 36(2).

curator ad ventrem with a view to preventing any supposition of birth, or substitution of child, and administering the property up to the day of the birth, under such directions as the court may deem it proper to give.'[38] It adds that it shall 'be lawful for the court to appoint a female as curatrix, and entrust another person with the administration of the property.'[39]

It is to be noted that such a person is appointed to protect the interests of the new-born rather than of the fetus per se.

8. Is the Fetus a 'Person'?

05.17

Unlike laws in other countries, (e.g. UK), Maltese laws do not make a clear distinction between the concept of a 'human being' and that of a 'person', the first relating to the biological fact, whereas the latter refers to legal issues (particularly legal rights). The ***Trusts Act*** as already mentioned, refers to 'any person unborn' without any attempt at definition. It implies that 'it' has some legal rights (e.g. that a trust can be made on behalf of a fetus). On the other hand the ***Civil Code*** does not confer the rights of inheritance or donation on the fetus, which are the rights of every 'person'.

In a recent court decree relating to a Moroccan woman who was pregnant with the child of (but not married to) a Maltese national, the Judge decided to issue a warrant of prohibitory injunction to prohibit the extradition of such woman because:[40]

The ***Immigration Act*** refers to 'persons', which is taken to refer to those born and have a life independent from their mother.

Article 2 of the ***Immigration Act*** refers to children under the age of 21 years and who thereby are exempted from the extradition provisions. The Court questioned whether any reference to age below 21 years should include those who are not yet born. The Court believed that *prima facie* it would appear that the unborn child has the right to be considered as such a person, to be exempted from extradition under Part II of the ***Immigration Act***.

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[38] *Civil Code*, article 170(1).

[39] *Civil Code*, article 170(2).

[40] The Hon. Mr. Justice Giannino Caruana Demajo, Civil Court, First Hall, Warrant of Prohibitory Injunction No. 2836/2000 *Emilio Persiano vs. Commissioner of Police* decreed on 24th August 2000.

Where there is a danger that a fetus might be aborted if the mother is extradited to a country where this is allowed, extradition has been suppressed. In the case of the Moroccan woman mentioned above, the Civil Court accepted that that there was a real danger that the woman would be obliged to have an abortion if sent to Morocco. The Court argued that extradition would thus impose a real danger to the unborn child. This is difficult to understand in view of the fact that Morocco has strict anti-abortion laws, permitting abortion only in case of serious medical danger to the mother. The Court nevertheless concluded that the mother should not be extradited so that the rights of the unborn child will be protected.

Chapter 6

Pregnancy and the Family

06.01
It is the role of the Law to promote 'the unity and stability of the family.'[1] By this is meant presumably the family as historically understood, i.e., where there exists a *de jure* relationship between man and woman. *De facto* relationships are not recognised by Maltese law, except in extraordinary circumstances such as in legislation concerning social security.

The ***Civil Code*** also emphasises the fact that the spouses have equal rights and equal responsibilities during marriage.[2] Both have the duty 'to maintain each other and to contribute towards the needs of the family.'[3]

1. Marriage

06.02
Maltese law recognises several impediments and restrictions to marriage. These include:

(a) *Age*: The ***Marriage Act*** states that: 'A marriage contracted between persons either of whom is under the age of sixteen shall be void';[4]
(b) *Infirmity of mind*: 'A marriage contracted between persons either of whom is incapable of contracting by reason of infirmity of mind, whether interdicted or not, shall be void';[5]

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[1] *Civil Code*, article 2(1).
[2] *Civil Code*, article 2(2).
[3] *Civil Code*, article 3.
[4] *Marriage Act*, article 3(1).
[5] *Marriage Act*, article 4.

(c) *Close relatives*: Marriage between the following relatives is forbidden:

(a) 'an ascendant and a descendant in the direct line;
(b) a brother and a sister, whether of the full or half blood;
(c) persons related by affinity in the direct line; or
(d) the adopter and the adopted person or a descendant, or the husband or wife, of the adopted person,'

whether the relationships derive from legitimate or illegitimate descent;[6]

(d) *Previous marriage*: 'Marriage contracted between persons either of whom is bound by a previous marriage shall be void.'[7] In fact bigamy is a criminal offence, as stated in the ***Criminal Code***: 'A husband or wife who, during the subsistence of a lawful marriage, contracts a second marriage, shall, on conviction, be liable to imprisonment for a term from thirteen months to four years.'[8]

06.03

a. Formalities to precede marriage

There are a number of formalities required prior to proceeding to marriage. These include:

(a) bans of matrimony,[9] giving details relating to the couple to be married, and including, the name, surname, place of birth and residence, and usually, the name of the father, and name and surname of the mother, as well as the place where they are to be married. These details are to be made available to the public by posting up at the Marriage Registry for a period of not less than eight consecutive days, excluding weekends and public holidays, as well as 'at the place where official acts are usually posted up in the town, village or parish in Malta in which each of the persons to be married resides';[10]

[6] *Marriage Act*, article 5(1).
[7] *Marriage Act*, article 6.
[8] *Criminal Code*, article 196.
[9] *Marriage Act*, article 7(2).
[10] *Marriage Act*, article 7(3).

(b) a marriage contracted before the sixth day from termination of the posting of the banns or after three months from the first day of posting is void;[11]
(c) requirements for publication of bans can be dispensed with in case of danger of death.[12]

One could argue that marriage is a private contract and publications of such details may be seen to conflict with the concept of the right to privacy. It may be pointed out that such requirements are not part of legal requirements in many other places overseas.

b. Nullity of marriage

06.04
Ability to consent to marriage, as well as having the right psychological and physical requirements are at the basis of a successful marriage. In addition to the situations mentioned above, marriage shall also be void under the following circumstances:[13]

(a) when the consent of either of the parties is extorted by violence (physical or moral), by fear, or by fraud;
(b) when there is error on the identity of either party;
(c) a serious psychological anomaly which makes it impossible for the party to fulfil essential obligations of marriage;
(d) when consent is 'vitiated by a serious defect of discretion of judgement on the matrimonial life';
(e) impotence, when antecedent to the marriage;
(f) when, at the time of contracting marriage, either of the parties did not have sufficient powers of intellect or volition to elicit matrimonial consent (even if a temporary condition); and
(g) other conditions, including subjecting consent to marriage to some condition referring to the future.

[11] *Marriage Act*, article 9(1).
[12] *Marriage Act*, article 10.
[13] *Marriage Act*, article 19.

c. Annulment of marriage and divorce

06.05

In Malta, divorce as such is not recognised. However there may be reasons for annulment. An action for annulment of a marriage may be brought after the lapse of three months from the date of the celebration of marriage at the request of one of the spouses on the grounds that the other party has refused to consummate marriage.[14] Any submission to arbitration in regard to any dispute concerning questions of personal status including those relating to separation or annulment of a marriage between husband and wife, is null.[15]

Children from such a marriage are however protected. It is worth noting that 'the effects of a valid marriage shall be deemed to have always existed with reference to the children born or conceived during a marriage declared to be void as well as with reference to children born before such marriage and acknowledged before the judgment declaring the nullity.'[16]

One may note that a court may not compel a person 'specifically to perform or complete any promise of marriage made to another, or any contract or agreement entered into with another for the solemnization of marriage.'[17] However, an action for damages may be brought by an injured party against the guilty party for a breach of promise.[18]

Problems often arise in relation to the status of persons who have had a divorce or annulment accepted overseas, particularly if they desire to proceed to a second marriage in Malta. 'A decision of a foreign court on the status of a married person or affecting such status shall be recognised for all purposes of law in Malta if the decision is given by a competent court of the country in which either of the parties to the proceedings is domiciled or of which either of such parties is a citizen.'[19] Many Maltese migrants now reside in a foreign country, and, moreover,

[14] *Marriage Act*, article 19A(1).
[15] *Code of Organization and Civil Procedure*, article 968(2).
[16] *Marriage Act*, article 20(2).
[17] *Promises of Marriage Law*, article 2.
[18] *Promises of Marriage Law*, article 3.
[19] *Marriage Act*, article 33.

intermarriage with non-Maltese citizens in the second generation is very common. There are, therefore, increasing instances where one person who had obtained divorce overseas seeks marriage under Maltese legislation.

d. Giving evidence against a spouse

A witness may not 'be compelled to answer any question which tends to expose him to any criminal prosecution.'[20] This right is extended to the spouse of the accused or charged person.

In a criminal action, 'the wife or husband of the party charged or accused cannot be admitted to give evidence either in favour of or against such party, except:

(a) in the case of offences committed against the witness, or against his or her ascendants or descendants';
(b) if the offence relates to prostitution where the 'spouse is a person on whom or in respect of whom the offence is committed or is a person on the earnings of whose prostitution the party charged or accused has lived'; and
(c) if the party charged or accused gives evidence, such party may also request the spouse to do so.[21]

Nevertheless, the court has discretion not to compel a witness to give evidence if s/he be unwilling to depose against a person related to him/her.[22] Evidence from a spouse may also be given at the Court of Criminal Appeal on the request of the appellant.[23]

In a civil action, 'the husband or wife of a party to a suit shall be competent and compellable to give evidence in such suit at the request of any of the parties thereto,' provided that: (*a*) they may not be compelled to disclose any communication made to each other during the marriage; and (*b*) that they may not be compelled to answer any question tending to incriminate each other.[24]

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[20] *Criminal Code*, article 643.
[21] *Criminal Code*, article 635.
[22] *Criminal Code*, article 633(2).
[23] *Criminal Code*, article 506.
[24] *Code of Organization and Civil Procedure*, article 566(1).

2. Pregnancy

06.06

Pregnancy is a state full of biological and social implications. From the biological point of view, it is probably the most important function of the human couple, ensuring the perpetuation of the species. While it is a mistake to medicalise the condition of pregnancy, it is none the less a fact that it has, particularly in the past, posed a greater danger, to the young cohort of women who bore the brunt of the dangers associated with pregnancy, than any other individual condition in this age group.

Firstly, the health of the pregnant woman and the child is addressed in the ***Commissioner for Children Act,*** which states that one of the functions of the Commissioner for Children, is 'to promote the highest standards of health and social services for women during pregnancy and to promote special care and protection, including adequate legal protection, for children both before and after birth.'[25]

Secondly, from the social point of view it may be said that pregnancy (and child-bearing) put women at a considerable disadvantage, in that they are put in a position of relative dependency on the husband and society. Moreover, their careers have to be postponed, making pregnancy one of the most important factors of lack of participation in the workforce, which eventually leads to discrimination in obtaining satisfying jobs, particularly at the top of the employment scale. The unacceptably high level of non-participation in the workforce by women in Malta is often blamed on their responsibilities associated with raising a family.

Thirdly and importantly, pregnancy leads to responsibilities vis-à-vis children, whose care is unequally split between parents, with the bulk of the parenting being still regarded as the province of the female. This poses an enormous responsibility on one party, with great impact on the future generation.

In the following summary, Maltese legislation which impinges on pregnancy and child-bearing is discussed.

[25] *Commissioner for Children Act,* article 9(h).

3. Employment, Marriage and Pregnancy

06.07

An employer cannot terminate the employment of a woman on the grounds that the employee contracts marriage, or that an employee is pregnant with child or is absent from work during maternity leave.[26] Moreover, any condition in a contract of service which empowers the employer to terminate the employment of a female employee on her contracting marriage or becoming pregnant with child are considered null and void.[27]

A pregnant woman may not be subjected to discrimination when looking for work or encouraged to resign from her job. Discrimination in this context means any distinction, exclusion or restriction which is not justifiable in a democratic society including discrimination made on the basis of marital status, pregnancy or potential pregnancy, sex, colour, disability, religious conviction, political opinion or membership in a trade union or in an employers' association.

a. Maternity leave

The ***Conditions of Employment (Regulation) Act,*** now repealed, defined 'maternity leave' as 'absence from work because of pregnancy and confinement for an uninterrupted period of not more than thirteen weeks, five of which follow the date of confinement.'[28] 'Confinement' means the birth of a living child or the birth of a child whether living or dead after seven months of pregnancy.'[29]

The subsidiary legislation, ***Protection of Maternity (Employment) Regulations,*** states that the pregnant woman is entitled to 'maternity leave for an uninterrupted period of fourteen weeks,' thirteen with full pay and the last week being unpaid. Six weeks of the maternity leave entitlement have to be taken compulsorily immediately after

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[26] *Employment and Industrial Relations Act,* article 36(14)(c) and (d).

[27] *Employment and Industrial Relations Act,* article 40.

[28] *Conditions of Employment (Regulation) Act,* article 2(1). This is now repealed. See however the *Protection of Maternity (Employment) Regulations,* SL 452.91, regulation 6(2).

[29] *Employment and Industrial Relations Act,* article 2.

the date of confinement and the rest, according to the woman's request.[30]

A pregnant employee who intends to avail herself of her maternity leave entitlement, 'shall notify the employer in writing of the date when she intends to avail herself of such entitlement,' and this should be 'at least four weeks before the maternity leave begins.'[31]

A pregnant employee is 'entitled to time off without loss of pay or any other benefit, in order to attend antenatal examinations, if such examinations have to take place during her hours of work.'[32]

b. Protection of pregnant employee

A number of provisions in Maltese Law protect the woman during pregnancy and early childbearing. With regards to employment, a whole-time female employee 'shall not be dismissed by the employer during the period of her maternity leave or the period of five weeks following the end of such leave in which she is incapable for work owing to a pathological condition arising out of confinement.'[33] She is 'entitled to resume work in the post she occupied on the commencement of her maternity leave, or in an analogous post if at the time when she becomes so entitled the post she formerly occupied is no longer available.'[34]

The employer has to take measures 'to protect the health and safety of an employee who becomes pregnant or starts breastfeeding, to the satisfaction of the Occupational Health and Safety Authority, to prevent the risk of exposure which could jeopardise the health or safety of such an employee, to agents, processes or working conditions to which exposure is prohibited in terms of specific provisions made under the ***Occupational Health and Safety Authority Act.***'[35]

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[30] *Protection of Maternity (Employment) Regulations*, SL 452.91, regulations 6 and 7.

[31] *Protection of Maternity (Employment) Regulations*, SL 452.91, regulation 8.

[32] *Protection of Maternity (Employment) Regulations*, SL 452.91, regulation 9(1).

[33] *Employment and Industrial Relations Act*, article 36(17).

[34] *Employment and Industrial Relations Act*, article 36(19).

[35] *Protection of Maternity (Employment) Regulations*, SL 452.91, regulation 4.

If the employer is unable to ensure a safe working environment, s/he must grant 'special maternity leave', which is defined as 'leave of absence from work granted by the employer to an employee who is pregnant, breastfeeding or has recently given birth,' when, despite the employer taking certain steps, 'there exists or would still exist, a risk that could jeopardise the health or, safety of the employee.'[36] The measures referred to include 'the temporary adjustment of the working environment and, or, the hours of work of the employee concerned' and 'the assignment of the employee to suitable alternative work which is appropriate for her to do in the circumstances.'[37]

During the special maternity leave the employee is paid, for a period of eight weeks, a special allowance equivalent to the rate of sickness benefit payable in terms of the ***Social Security Act.*** Any special maternity leave, extending beyond a cumulative total of eight weeks, shall be unpaid.[38]

c. Maternity benefit

06.08

Maternity benefit is meant to provide financial help to the pregnant woman, who is not eligible for maternity leave, and tide her over that period of time. To qualify for maternity benefit, a woman:

(a) must have entered the eight month of pregnancy. 'A woman who, at any time on or after the 1st day of January, 1981 is pregnant with child and has entered the eighth month of pregnancy shall be entitled to Maternity Benefit under and in accordance with the provisions of this Article';[39]

(b) must be a citizen of Malta or married to a citizen of Malta, and resident in Malta;[40]

(c) must not have availed herself of Maternity Leave to which she was entitled to in accordance with the provisions of the ***Employment and Industrial Relations Act.***[41]

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[36] *Protection of Maternity (Employment) Regulations*, SL 452.91, regulation 2.
[37] *Protection of Maternity (Employment) Regulations*, SL 452.91, regulation 3(3).
[38] *Protection of Maternity (Employment) Regulations*, SL 452.91, regulation 5.
[39] *Social Security Act*, article 71(1).
[40] *Social Security Act*, article 71(2).
[41] *Social Security Act*, article 71(3).

d. Parental leave

06.09

Either one of the spouses can now avail themselves of a period of unpaid leave, entitled parental leave, 'designed to facilitate the reconciliation of parental and professional responsibilities for working parents.'[42]

'It shall be the individual right of both male and female workers to be granted unpaid parental leave on the grounds of birth, adoption or legal custody of a child to enable them to take care of that child for a period of three months until the child has attained the age of eight years.'[43] Parental leave may be taken in periods of one month each. The employer together with the employee may decide whether the leave is to be taken on a fulltime or a part-time basis, in a piecemeal way or in the form of a time credit system.

'When there is still an existing balance of parental leave, an employee shall remain entitled to such leave even if there is a change in the employer or in the employment of the employee.'[44]

An employer may postpone the granting of parental leave for 'justifiable reasons' as listed in the Regulations, including seasonal nature of work, if a replacement cannot be found, when the employee's work is of strategic importance, if the business is a small enterprise employing not more than ten people and when a significant proportion of the workforce applies for parental leave at the same time.[45]

The employee is entitled to return to the same job 'occupied prior to the granting of parental leave, or, where this is no longer possible for any valid reason, to an equivalent or similar job consistent with the original contract of employment of the employee.'[46] Moreover it is not 'lawful for the employer to dismiss an employee solely because an employee takes or applies to take parental leave' and any such dismissal is not a valid reason for termination of employment.[47]

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[42] *Parental Leave Entitlement Regulations*, SL 452.78, regulation 2.
[43] *Parental Leave Entitlement Regulations*, SL 452.78, regulation 4(1).
[44] *Parental Leave Entitlement Regulations*, SL 452.78, regulation 4(3).
[45] *Parental Leave Entitlement Regulations*, SL 452.78, regulation 7(2).
[46] *Parental Leave Entitlement Regulations*, SL 452.78, regulation 8.
[47] *Parental Leave Entitlement Regulations*, SL 452.78, regulation 10.

4. Abortion

06.10

Malta has some of the strictest regulations, in the world, about abortion. No exception is made for any reason, including medical reasons involving the health of the mother or the prevention of serious genetic abnormalities. There is no provision in Maltese law to indicate that the procurement of abortion for medical, including psychological, or social reasons can be tolerated.

The ***Criminal Code*** states categorically: 'Whosoever, by any food, drink, medicine, or by violence, or by any other means whatsoever, shall cause the miscarriage of any woman with child, whether the woman be consenting or not, shall, on conviction, be liable to imprisonment for a term from eighteen months to three years.'[48]

There are no exceptions to this rule, and in particular, the views of the woman herself have no influence on the criminality of the procedure. The same article goes on to add: 'The same punishment shall be awarded against any woman who shall procure her own miscarriage, or who shall have consented to the use of the means by which the miscarriage is procured.'[49] Not only is the woman prohibited from procuring her own miscarriage, but consent to such is itself punishable as if she had actually performed the procedure herself.

In other words, this prohibition relates both to the doctor, midwife or any other third person involved with the procedure, as well as to the woman who either actively produces the miscarriage, or even consents to this procedure.

To what extent these laws are applied varies. In this context, Dr Anthony E. Borg Barthet (former Attorney General, now Judge at the European Court of Justice) had this to say: 'While no change in the statue book has been made in the Maltese law of abortion, one did discern in the past a reluctance to prosecute the mother who has sought abortion, and a milder sentencing policy where she is actually prosecuted.'[50]

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[48] *Criminal Code*, article 241(1).

[49] *Criminal Code*, article 241 (2).

[50] Anthony E. Borg Barthet: *The Legal Position in Bioethical Problems of Life and Death*. In: *Bioethics. Responsibilities and Norms for those involved in Health Care*. A Ministry for Social Policy Publication, 1989, p. 27.

The *Criminal Code* goes on to consider the complications that can arise during and after an attempt at miscarriage, particularly in case death of the woman or serious bodily harm ensues: 'If the means used shall cause the death of the woman, or shall cause a serious injury to her person, whether the miscarriage has taken place or not, the offender shall, on conviction, be liable to the punishment applicable to wilful homicide or wilful bodily harm, diminished by one to three degrees.'[51]

These prohibitions are not directed merely at active and physical involvement in the procurement of miscarriage. A health professional who prescribes the means for procurement of miscarriage is also guilty of a serious offence: 'Any physician, surgeon, obstetrician, or apothecary, who shall have knowingly prescribed or administered the means whereby the miscarriage is procured, shall, on conviction, be liable to imprisonment for a term from eighteen months to four years, and to perpetual interdiction from the exercise of his profession.'[52]

06.11

It is of interest to see how prescribing a drug such as 'the morning-after' pill would be considered in court. Such a drug is prescribed prior to definitive diagnosis of pregnancy, in order to prevent pregnancy. Since the drug interferes with nidation (the settling of the fertilised ovum into the uterus), it is considered in many quarters as producing an abortion in a proportion of women taking the drug. Logically it would appear that in such instances it is abortifacient, and therefore subject to the same prohibitions mentioned above.

06.12

In addition, there is provision for 'culpable miscarriage': 'Whosoever, through imprudence, carelessness, unskilfulness in his art or profession, or non-observance of regulations, causes the miscarriage of a woman with child, shall, on conviction, be liable to imprisonment for a term not exceeding six months or to a fine *(multa)* not exceeding one thousand liri.'[53] In other words,

[51] *Criminal Code*, article 242.
[52] *Criminal Code*, article 243.
[53] *Criminal Code*, article 243A.

miscarriage, which is not intentional but which results from incompetence is punishable by law under this article.

Article 244 of the ***Criminal Code*** is a general article referring to the administration of any substance which can be injurious to health, and therefore one may argue that it includes health of the unborn fetus. However the wording used by the law is to 'cause to be taken by another person,' so this would only apply if the fetus is considered as a person at law. This article specifies a penalty of 13 months to 2 years, as long as this action does not involve homicide or a serious injury to the person.

5. Pre-natal Screening

06.13

Screening of the fetus during pregnancy for genetic abnormalities has been an established procedure overseas for several years. Samples of fetal blood or amniotic fluid can be taken after about the 16th week of pregnancy. Sampling of the placenta (chorionic villus sampling or CVS) can be obtained as early as 8–9 weeks gestation. Several biochemical tests (e.g. alpha-fetoprotein, haemoglobin, bilirubin, coagulation factors, etc.) can be done, and cells may be obtained for chromosome analysis or DNA testing.

Pre-natal testing in early pregnancy (10–16 weeks) is usually undertaken to rule out fetal genetic abnormalities. In pursuing such a goal one must be guided by considerations such as:

(a) *Genetic counselling*: no test should be performed unless there is adequate counselling and plenty of opportunity to discuss possible outcomes. All such procedures must be accompanied by free and informed consent. In Malta, in particular, the absence of the option of abortion makes it even more imperative to determine why such tests are requested in the first place. One argument has been the preparation of the family in case there is an abnormality, as well as of course the peace of mind resulting from exclusion of an abnormality. Even where abortion is an option, it is to be understood, however, that no woman should be induced to terminate pregnancy. Nonetheless, currently, it is estimated that one per cent of pregnancies in Maltese women end as abortions in the UK, and no doubt others may be occurring elsewhere in Europe;

(b) *'Wrongful birth'*: the birth of a child with a genetic abnormality which was left undiagnosed from lack of offering the relevant pre-natal testing might render the doctor liable to damages for distress and expenses involved in bringing up the child. While such actions are not unknown overseas, it is unlikely that they would be countenanced in Maltese courts.[54]

Prenatal testing later on in pregnancy is more usually undertaken to diagnose treatable disorders, e.g. Rhesus incompatibility. Failure to diagnose and treat such conditions may result in severe abnormalities in the newborn, and this may lead to action relating to 'wrongful life'.[55]

6. Sex Selection

06.14

There are no specific regulations relating to selection of the sex of the infant. The ***Convention on Human Rights and Biomedicine*** makes the following recommendations relating to pregnancy and related areas: 'The use of techniques of medically assisted procreation shall not be allowed for the purpose of choosing a future child's sex, except where serious hereditary sex-related disease is to be avoided.'[56]

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[54] Related to 'wrongful birth' one may meet also with the term 'wrongful pregnancy' where an unwanted pregnancy resulted through negligence of the doctor (e.g. in case of inadequate sterilisation procedures). A recent court case in Australia has even awarded damages following the birth of an unwanted but otherwise normal child. On the other hand, a recent case in France has ruled out payment of costs resulting from a child's disability, even when fault was established, and compensation was granted to the parents for distress caused. Whether this is likely to become European practice remains to be seen. See Mason et al., *Law and Medical Ethics,* article 6.54, p. 206, Butterworths, 2002.

[55] Such are the cases from overseas where a mother was sued by her newborn child because of damage occurring *in utero*. See BMJ 1992; 304: 1400 and Lancet 1991; 338: 687.

[56] Council of Europe, *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine,* article 14: Non-selection of sex.

This article prohibits all procedures for selection of the sex of a child except for the purpose of avoiding serious disease. In other words, these techniques cannot be used for instance for the purpose of choosing the sex of the child.

The Convention allows selection of sex of the fetus in those situations where a serious hereditary disease may result. For instance, in the case where a boy is at risk of haemophilia, this article allows for selecting a girl to avoid this risk.

7. Registration of Birth

06.15

Registration of a new born child is compulsory under Maltese Law: 'In the case of every child born, it shall be the duty of the father, and in default of the father, of the physician, surgeon, midwife, or any other person in attendance at the birth, or in whose house the birth has taken place, to give, within five days of such birth, notice thereof to the officer charged with the duty of drawing up the act of birth.'[57]

Normally this responsibility devolves on the head of the family. If the father is not available, then the health professional in attendance has the responsibility of registering the child within a period of five days. This is done in one of several ways:

(a) by sending the certificate of baptism to the relevant officer;[58]
(b) by written notice, by means of a letter signed by the person giving the notice;
(c) verbally, by attending personally before the officer charged with drawing up the act of birth.[59]

Data required to be registered on the act of birth consists in the following:[60]

'(a) the date of the act itself;
(b) the hour, day, month, year, and place of birth;

[57] *Civil Code*, article 272.
[58] *Civil Code*, article 273(1).
[59] *Civil Code*, article 274.
[60] *Civil Code*, article 278.

(c) the sex of the child;
(d) the name given to the child, and, where more names are given, a special indication of the name or names by which the child is to be called;
(e) the name, surname, identification document, age, place of birth and of residence of the father of the child, of the mother, and of the person making the declaration'; and
(f) 'the name and surname of the father of each of the parents of the child, and of the father of the person making the declaration, stating whether he is alive or dead.'

The act of birth also requires the name and surname of a former husband in the case where the mother was a widow prior to her marriage to the father of the child, presumably to make a clear distinction between the rights of the new-born from those of children born from a previous marriage.

8. Still-born Children

06.16

A still-born child still has to be registered. The fact of stillbirth has to be stated in the act of birth.[61] When a child dies soon after birth (technically, therefore, not a still-birth), the act of death is drawn up immediately after the act of birth.[62]

In the case of abortion 'an act of birth shall only be drawn up where the foetus shall have completely assumed the human form.'[63] This has an implied definition of a still-birth - presumably any fetus that has assumed the human form, and is born dead is considered a still-birth for the purpose of this Act. Assessment of assumption of human form is the yardstick in this definition. This is, however, not a hard objective measure. Certainly a fetus has a recognisable human form even at 6-7 weeks, when miscarriages are not uncommon. By this time the fetus has assumed a recognisable human form, distinct from

[61] *Civil Code*, article 283(1).
[62] *Civil Code*, article 283(2). Note that this subarticle is listed under the heading of still-born children, but since the child is born alive, this is not a stillbirth in medical terminology.
[63] *Civil Code*, article 283(3).

other animal fetuses with limbs, eyes and ears and the fetus may be said to have assumed a human form. It is doubtful however that the Act refers to this early assumption of human form.

06.17

It is of interest to compare this age, with that given by other countries, to draw a line prior to which miscarriage can be procured. This is frequently given to be in the range of 20–24 weeks gestation, or around 400 gm weight. Maltese law does not rely on these more objective criteria for the purpose of defining when an act of birth is to be entered.

The following information gives an idea of the diversity of opinion relating to the definition of viability of a fetus:[64]

(a) *UK*: A stillborn child is 'a child which has issued forth from its mother after the 24th week of pregnancy and which did not at any time after being completely expelled from its mother breathe or show any other signs of life';[65]
(b) *US*: A stillbirth is defined as the death of a fetus at any time after the twentieth week of pregnancy. A stillbirth is also referred to as an intrauterine fetal death (IUFD);[66]
(c) *Australia*: A fetus born dead is considered as a stillbirth when over 20 weeks gestation or over 400 gm weight;
(d) *WHO*: The World Health Organisation (WHO) has recommended a definition for compiling national perinatal statistics. This includes infants and fetuses weighing at least 500 gm or having a gestational age of 22 weeks or a crown-heel body length of 25 cm.

9. Concealing the Birth of a Child and Kidnapping

06.18

Disposal of a dead child should take place according to accepted standards. This is in accord with the concept of the dignity of the born child who has to be treated accordingly. 'Any person who,

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[64] See Chapter 5: The Embryo and Genetic Testing, section 7(b).
[65] http://pcpss2.rfc.ucl.ac.uk/socind/content.asp?Event_ID=38&Page=1] *Stillbirth (Definition) Act 1992* and *Stillbirths (Scotland) Act 1938.*
[66] http://www.healthatoz.com/healthatoz/Atoz/ency/stillbirth.jsp

immediately after the delivery of a child, shall, by secretly burying or otherwise disposing of the dead body of the child, endeavour to conceal the birth thereof, shall, on conviction, be liable to imprisonment for a term from four months to one year.'[67]

The ***Criminal Code*** also deals with kidnapping, or concealing of an infant, or of substituting one infant for another and provides relevant penalties. It also mentions 'suppression' of the birth or 'suppositiously representing an infant to have been born of a woman who had not been delivered.'[68] This law is aimed at protecting the proof of the status of a child.

10. Infanticide

06.19

There is a severe penalty for infanticide, i.e. death of a child under the age of twelve months by a woman, when 'the balance of her mind was disturbed by reason of her not having fully recovered from the effects of giving birth to the child or by reason of the effects of lactation consequent upon the birth of the child.'[69] The woman is liable to 'the punishment of imprisonment for a term not exceeding twenty years.' It is fair to say, however, that judges often take into consideration the not unusual circumstance of disturbed balance of mind in such conditions and give an appropriately lighter sentence.

11. Suggestions for Further Legislation Relating to Pregnancy

06.20

The above represents a summary of legislation available in Malta in relation to pregnancy. As is quite apparent, there are wide gaps in the legislation that would be needed to cover the many aspects of pregnancy that have become current practice in recent years. Most blatant is the complete lack of regulation in relation to assisted reproduction, including regulation relating to *in vitro* fertilisation and ante-natal diagnosis.

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[67] *Criminal Code,* article 240.
[68] *Criminal Code,* article 210.
[69] *Criminal Code,* article 245.

The Bioethics Consultative Committee has issued guidelines entitled *'Ethical Considerations Relating to Human Reproductive Technology'*,[70] which makes recommendations in relation to *in vitro* fertilisation, donation of embryos, interventions on embryos, use of embryonic tissue for research and surrogate motherhood. It also makes several recommendations relating to necessary legislation as follows:

(a) accreditation and licensing of clinics where such techniques are carried out;
(b) the creation of an adequate structure for the supervision of facilities and practices carried out in such clinics;
(c) the provision of free, informed, specific and written consent by all persons involved in donation or receipt of gametes in the process of artificial procreation, following adequate counselling;
(d) provision for keeping detailed records of all procedures, to be available for inspection by the competent authorities;
(e) provision of effective and appropriate penal sanctions;
(f) provisions relating to the length of time that gametes can be kept frozen;
(g) provision of adequate legal protection for persons involved in the process of artificial procreation, including the legal status and rights of any offspring resulting from procedures involving gamete donation;
(h) the following procedures to be declared illegal:
    (i) production of embryos specifically for experimental purposes;
    (ii) experimentation on the human embryo;
    (iii) cross-species embryo transfer involving human beings;
    (iv) manipulation of the human germinal genome;
    (v) donation or preservation of human embryos;

[70] *Patients' Rights, Reproductive Technology, Transplantation*, Ed. Maurice N. Cauchi, The Bioethics Consultative Committee, Malta, 2000, Government Press.

(vi) breeding hybrid embryos (chimeras) involving human cells;

(vii) commercialising and profit making from donation of gametes;

(viii) surrogacy;

(ix) induction of post-menopausal pregnancy; and

(x) donation of stored sperm from dead donor (including husband).

Chapter 7

Children

1. Introduction

07.01

There are several ethical issues involving minors. These include questions relating to:

(a) autonomy and competence;
(b) consent to medical interventions;
(c) relationships with parents, particularly issues of confidentiality;
(d) transplantation involving children; and
(e) research involving children.

07.02

The *age of consent* itself has not been a fixed entity and has changed over the years to include younger and younger persons. In fact, this is mirrored in the Maltese legislation where we find that the earlier legislation refers to minors as those under the age of 18 years, (and 21 years in certain instances), whereas the more recent legislation includes those aged 16 years of age.[1] The ***Children and Young Persons (Care Orders) Act***, 1980, and the ***Child Abduction and Custody Act***, 2000, both refer to a child as a person under the age of sixteen years. The ***Mental Health Act*** gives the right of voluntary informal admission to 'a minor who has attained the age of sixteen years and is capable of expressing his own wishes ...

[1] See Chapter 1: Human Dignity, Rights and Freedoms, section 5(a) on consent.

notwithstanding any right of custody or control vested by law in his parent or tutor.'[2]

Moreover, it is generally understood that there is no clear and abrupt watershed defining the capacity of children to become involved in decision making, and most legislation these days assumes that the child's views are taken more and more into consideration as s/he gets older and capable of understanding the issues involved.[3]

It is disconcerting to see within Maltese legislation discrimination still persisting between the sexes with regards to rights, etc. For instance, the ***Widows' and Orphans' Pensions Act*** considers a child to have ceased to be of pensionable age at the age of eighteen years in the case of the male and twenty one years (and has not been married) in the case of a female.[4] This is despite the ***Constitution of Malta,*** article 45(1) stating that 'no law shall make any provision that is discriminatory either of itself or in its effect.'

2. The Rights of the Child

07.03

Malta has no comprehensive specific legislation dealing with the rights of the child, akin to the UK's Children Act. The specific Maltese legislation dealing with children is to be found in the ***Children and Young Persons (Care Orders) Act,*** which deals with the case of children requiring 'care' and the ***Child Abduction and Custody Act,*** which deals with the special case of child abduction (which ratifies two international Conventions relating respectively to the civil aspects of international child abduction and to the recognition and enforcement of custody decisions). More recently, the ***Commissioner for Children Act*** has made provision for the appointment of a Commissioner for Children, with power to investigate any breaches or infringements of the rights of children, including those enshrined in international treaties, conventions or agreements, ratified, or otherwise acceded to, by Malta.

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[2] *Mental Health Act,* article 3(2).

[3] See for instance the UK *Children Act* 1989, and the *Charter of Fundamental Rights of the European Union.*

[4] *Widows' and Orphans' Pensions Act,* article 2.

07.04
Malta has signed the ***Convention on the Rights of the Child*** adopted by the UN General Assembly, 1989 (signed and ratified by Malta in 1990). The following is a summary of some of the relevant articles in this Convention:

Article 6 recognises the inherent right to life of every child, and binds all State Parties to ensure, to the maximum extent possible, the survival and development of the child.

Article 12 refers to the need to assure that a child who is capable of forming his or her own views should be given the right to express those views freely in all matters affecting the child. These views should be given due weight in accordance with the age and maturity of the child. It is therefore required that the child is given an opportunity to be heard in any judicial and administrative proceedings affecting the child, through a representative or appropriate body if necessary.

07.05
Article 13 deals with the child's right to freedom of expression, including freedom to seek, receive and impart information and ideas of all kinds, so long as this does not interfere with the rights or reputations of others, or is a risk to public order, public health or morals.

Article 14 requires that the State shall respect the right of the child to freedom of thought, conscience and religion. Moreover, the State should respect the rights and duties of parents or guardians to provide direction to the child in the exercise of his or her rights. There should be freedom to manifest one's religion or beliefs as long as these do not provide a threat to public safety, order, health, morals or the fundamental rights and freedoms of others.

Article 16 states that a child's privacy, family, home or correspondence should not be interfered with unlawfully. The law should protect the child against such interference, including unlawful attacks on his or her honour and reputation.

07.06

Article 18 emphasises further the role of parents. They have the primary responsibility for the upbringing and development of the child. Both parents have common responsibilities for the upbringing and development of the child. States shall use their best efforts to ensure recognition of these principles. The best interests of the child will be their basic concern. The States should render appropriate assistance to parents and legal guardians in the performance of their child-rearing responsibilities and shall ensure the development of institutions, facilities and services for the care of children. Child-care services and facilities should be provided for working parents who are eligible.

Article 19 deals with protection of the child from all forms of physical or mental violence, injury or abuse, neglect or negligent treatment, maltreatment or exploitation, including sexual abuse, while in the care of parent(s), legal guardian(s) or any other person who has the care of the child. States should provide protective measures, including social programmes to support the child and his/her carers, effective prevention as well as measures to facilitate identification, reporting, referral, investigation, treatment and follow-up of instances of child maltreatment described heretofore, and, as appropriate, for judicial involvement.

07.07

Article 23 deals with disabled children. Mentally or physically disabled children should enjoy a full and decent life, in conditions which ensure dignity, promote self-reliance and facilitate the child's active participation in the community. The disabled child has a right to special care which 'shall be provided free of charge, whenever possible, taking into account the financial resources of the parents or others caring for the child and shall be designed to ensure that the disabled child has effective access to and receives education, training, health care services, rehabilitation services, preparation for employment and recreation opportunities in a manner conducive to the child's achieving the fullest possible social integration and individual development, including his or her cultural and spiritual development.'

07.08

Article 24 refers to the health of the child and the duty that States have of ensuring that the child enjoys the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. No child should be deprived of his or her right of access to such health care services. In this respect all efforts should be made to:

(a) reduce infant and child mortality;
(b) develop primary health care, and provide necessary medical assistance and health care to all children;
(c) combat disease and malnutrition, through available technology and through the provision of adequate nutritious foods and clean drinking-water, taking into consideration the dangers and risks of environmental pollution;
(d) ensure appropriate pre-natal and post-natal health care for mothers;
(e) ensure access to education and support in the use of basic knowledge of child health and nutrition, the advantages of breastfeeding, hygiene and environmental sanitation and the prevention of accidents;
(f) develop preventive health care, guidance for parents and family planning education and services.

Article 25 relates to the child who is placed in care because of his or her physical or mental health. There should be a periodic review of the treatment provided to such a child.

07.09

Article 26 deals with the need of a child for social security and insurance, taking into consideration the resources and the circumstances of the child and persons having responsibility for the maintenance of the child.

Article 27 emphasises the standard of living required to allow physical, mental, spiritual, moral and social development of the child. Parents, or those who have primary responsibility for the child, should ensure this, within their abilities and financial capacities, and with appropriate assistance from the State.

Article 28 refers to education of the child, with a view to ensure this right on the basis of equal opportunity. Primary education should be compulsory and freely available to all. Secondary education should be accessible to every child and be sufficiently varied to include general and vocational education. All measures should be taken to encourage regular attendance at schools and reduce the drop-out rate. Higher education should be accessible to all children on the basis of capacity.

07.10

Article 29 continues with the need for education to develop the child's personality, talents and mental and physical abilities to their fullest potential (and not merely restricted to academic subjects). It should include the development of respect for human rights and fundamental freedoms. It also emphasises the development of respect for the child's parents, his or her own cultural identity, language and values, for the national values of the country in which the child is living, the country from which s/he may originate, and for civilizations different from his or her own. It encourages the preparation of the child for responsible life in a free society, in the spirit of understanding, peace, tolerance, equality of sexes, and friendship among all peoples, ethnic, national and religious groups and persons of indigenous origin. Finally it urges the development of respect for the natural environment.

Article 31 importantly emphasises the right of the child to rest and leisure, to engage in play and recreational activities appropriate to the age of the child and to participate freely in cultural life and the arts. Each State should encourage and promote the right of the child to participate fully in cultural and artistic life and should encourage the provision of appropriate and equal opportunities for cultural, artistic, recreational and leisure activity.

Article 32 deals with the labour performed by a child. Children should be protected from exploitation and from performing any work that is likely to be hazardous or to interfere with the child's education, or to be harmful to the child's health or physical, mental, spiritual, moral or social development. Each State should set the minimum age for employment and the number of hours and conditions of employment and should ensure effective enforcement of such legislation.

Article 33 aims at protecting children from illicit use of narcotic drugs and psychotropic substances and from being used in the illicit production and trafficking of such substances.

07.11

Article 34 deals with the protection of children from all forms of sexual exploitation and sexual abuse. States should take all appropriate measures to prevent:

(a) the inducement or coercion of a child to engage in any unlawful sexual activity;
(b) the exploitative use of children in prostitution or other unlawful sexual practices; and
(c) the exploitative use of children in pornographic performances and materials.

Article 35 prohibits the abduction, sale of, or traffic in children for any purpose or in any form.

Article 36 refers to the need for protection of the child against all other forms of exploitation prejudicial to any aspects of the child's welfare.

Article 37 deals with prevention of torture or other cruel, inhuman or degrading treatment or punishment of a child. In particular, there should be no capital punishment, nor life imprisonment, for offences committed by persons below the age of eighteen years. This article also deals with arbitrary deprivation of liberty, arrest and detention, and with need for respect for the inherent dignity of every human person.

07.12

Article 39 deals with the need for rehabilitation of children who are victims of any form of neglect, exploitation or abuse, torture or any other form of cruel, inhuman or degrading treatment or punishment or armed conflicts.

Article 40 also relates to the need for the penal law to deal with the child, who has committed a crime, in a manner consistent with the promotion of the child's sense of dignity and worth, which reinforces the child's respect for the human rights and fundamental freedoms

of others and which takes into account the child's age and the desirability of promoting the child's reintegration and the child's engagement in a constructive role in society.

It is clear that this Convention should provide a backbone which protects the rights of the child, and against which all other legislation about children should rest.

07.13

The ***Commissioner for Children Act,*** enforces the articles of the above Convention. This Act establishes the post of Commissioner for Children whose functions are:[5]

(a) to promote and advocate for the rights and interests of children;
(b) to ensure that children's opinions are given and considered;
(c) to protect family unity;
(d) to advocate adequate support for parents;
(e) to promote the development of alternative care for children in need;
(f) to ensure that the rights and interests of children are taken into account by governmental and other organisations when decisions on policies affecting children are taken;
(g) to promote protection of children from physical or mental harm, neglect and sexual abuse or exploitation;
(h) to promote the highest standards of health and social services for pregnant women and to promote special care and protection, including legal protection for children both before and after birth;
(i) to promote the highest standards of health, education and social services for children;
(j) to promote the highest standards of leisure, play and recreational facilities for children;
(k) to ensure measures are taken by the relevant authorities to prevent and remedy poverty and social exclusion among children; and
(l) to promote compliance with the United Nations ***Convention on the Rights of the Child,*** as ratified by Malta.

In achieving these functions, the Commissioner should be guided by general principles related to achieving the best interest of children and the family, to ensuring respect and dignity of the

[5] *Commissioner for Children Act,* article 9.

child, with particular emphasis on children with disability or those from disadvantaged families, and to ensuring that children and their families are given an opportunity to participate in decisions that affect them, including the provision of relevant services.[6]

The Commissioner is required to monitor the protection of children's interests, including the observance of legislation and in general ensure that services for children are adequate and relevant. In this respect, s/he is to advise the Government, provide public education and encourage relevant research. The Commissioner has to collect information relating to breaches of the rights of children, and may in fact, if s/he considers it necessary, investigate any such alleged breach, including the death of a child.[7]

This Act also sets up a Council for Children with the specific aim of monitoring compliance with the UN ***Convention on the Rights of the Child***.[8]

07.14

The ***Charter of Fundamental Rights of the European Union***[9] emphasises the rights of the child.[10] It covers several aspects relating to child upbringing:

(a) right to education;[11]
(b) rights of the child, including protection, respect for their views, consideration of the child's best interest, as well as the right to keep in contact with parents;[12] and
(c) prohibition of child labour.[13]

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[6] *Commissioner for Children Act*, article 10.
[7] *Commissioner for Children Act*, article 11.
[8] *Commissioner for Children Act*, article 12.
[9] *Charter of Fundamental Rights of the European Union*. The articles of this Charter have been incorporated in the *Constitution for Europe*, which is still to be finally approved by the European Union Member States.
[10] *Charter of Fundamental Rights of the European Union* (2000/C364/01), article 24 (article 24-II of the *Constitution for Europe*).
[11] *Charter of Fundamental Rights of the European Union*, article 14 (article II-14 of the *Constitution for Europe*).
[12] *Charter of Fundamental Rights of the European Union*, article 24 (article II-24 of the *Constitution for Europe* and a new article, *III*-172, related to rules regarding criminal offences with cross border dimensions, which include sexual exploitation of women and children).
[13] *Charter of Fundamental Rights of the European Union*, article 32 (article II-32 of the *Constitution for Europe).*

07.15
In summary, there are a number of ethical issues relating to rights of the child, and to the relationship of children with adults, whether parents or educational or civil authorities, including:

(a) the right to life and care;
(b) the right to an adequate education to enable them better to become autonomous citizens;
(c) the right to participate in decisions that involve them, to the extent that they are capable of so doing;
(d) older children have also a right to privacy in general and particularly in discussing their medical problems;
(e) protection from exploitation and harm, occasionally even from their parents; and
(f) their own ethical responsibility, associated with decisions which they make, and their capacity to appear in court as witnesses or as litigants.

The aim of this chapter is to give an overview of Maltese legislation that is relevant to ethical issues concerning this period of life.

3. Definitions

07.16
In the older (but still relevant) chapters of Maltese law, a child is defined as one who has not yet attained the *age of 18 years,*[14] as seen in the following:

(a) 'a minor is a person of either sex who has not yet attained the age of eighteen years';[15]
(b) 'majority is fixed at the completion of the eighteenth year of age';[16]

[14] Note that this age limit is also the one set by the 1996 Hague Convention on *Parental Responsibility and Measures for the Protection of Children.* Article 2 states that: 'The Convention applies to children from the moment of their birth until they reach the age of 18 years.'
[15] *Civil Code,* article 157.
[16] *Civil Code,* article188(1).

(c) 'child' means any person under eighteen years of age;[17]
(d) 'parental authority ceases *ipso jure*' when 'the child attains the age of eighteen years';[18]
(e) for the purposes of the ***Maltese Citizenship Act***, a person shall 'be of full age if he has attained the age of eighteen years';[19]
(f) a person must attain the age of eighteen years before s/he qualifies to be a registered as a voter for the election of members of the House of Representatives;[20]
(g) no person shall sell or expose for sale gunpowder or other explosives in any street, nor shall any person sell or give gunpowder or other explosives to any child apparently under the age of eighteen;[21]
(h) 'a child shall be deemed to cease to be of a pensionable age within the meaning of this Act (***Widows' and Orphans' Pensions Act***), if a male, on attaining the age of eighteen years or dying under that age, and if a female, on attaining the age of twenty-one years or marrying or dying under that age';[22] and
(i) where any income is payable to or for the benefit of a child, 'the income shall, if at the commencement of that year the child was unmarried or has not yet reached the age of eighteen years, be treated for the purposes of this Act (***Income Tax Act***) as the income of the disponer for that year and not as the income of the said child.'[23]

In the ***Commissioner for Children Act*** a 'child' means 'any person who has not attained majority'; although this is not defined here, it implies eighteen years as defined in the ***Civil Code***.[24]

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[17] *Prevention of Disease Ordinance*, article 54, in Title III which deals with Immunisation.
[18] *Civil Code*, article 150(b).
[19] *Maltese Citizenship Act*, article 2(3).
[20] *Constitution of Malta*, article 57.
[21] *Explosives Ordinance*, article 19.
[22] *Widows' and Orphans' Pensions Act*, article 2.
[23] *Income Tax Act*, article 51(3). See also below for tax rates for single parents, where the age limit is 16.
[24] *Commissioner for Children Act*, article 2. See *Civil Code*, article 188(1).

07.17

On the other hand, more recent legislation defines a child as one who has not as yet reached the *age of 16 years*:[25]

(a) 'child' means a person under the age of sixteen years;[26]

(b) 'child or young person' means a person who is under the age of sixteen years;[27] 'child' means a person who is under the age of sixteen years and includes a stepchild, an adopted child and a child born out of wedlock[28] although under this Act (***Social Security Act***) most allowances cease on attaining the age of 18 years;

(c) the ***Mental Health Act*** refers to 'a child who is so admitted (to a mental hospital) before having attained the age of sixteen years';[29]

(d) the income tax rates for single parents apply if the parent maintains a child 'not over 16 years of age or, if over that age,' the child is receiving full-time education or serving an apprenticeship or is incapacitated from maintaining himself or herself, and who, was not, in his or her own right, receiving income in excess of Lm1,000';[30] and

(e) a minor, of sixteen years, who is authorized under the ***Commercial Code***, article 9, to perform certain acts of trade, shall, 'in regard to all matters relating to his trade, ... be considered as being of age.'[31]

Other definitions refer to a child *aged 21 years*:

(a) the ***Constitution of Malta*** states that for the purpose of freedom of movement, Maltese citizens include also a 'child under twenty-one years of age,' when the parents of such person

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[25] Note that this age limit is also the one set by the Hague Convention on the *Civil Aspects of International Child Abduction*, signed at The Hague on the 25th October, 1980.

[26] *Child Abduction and Custody Act*, article 2.

[27] *Children and Young Persons (Care Orders) Act*, article 2. However a care order following conviction of an offence ceases to be effective at age 18 - see article 3. *Juvenile Court Act*, article 2.

[28] *Social Security Act*, article 2.

[29] *Mental Health Act*, article 19(3)(b).

[30] *Income Tax Act*, article 56(1)(b)(i).

[31] *Civil Code*, article 156(1).

qualify for citizenship by virtue of birth or descent as provided for in the ***Maltese Citizenship Act***;[32]

(b) in the ***Social Security Act***, Children's Allowance is payable up to 21 years if the child is still undergoing full-time education or training and does not receive any remuneration or allowance and is not registered unemployed;[33]

(c) in the ***Immigration Act***, 'dependant' in relation to another person means 'the child or step-child of such person, if the child or the step-child is under the age of twenty-one years';[34] and

(d) a child shall be deemed to cease to be of a pensionable age within the meaning of this Act, ***(Widows' and Orphans' Pensions Act)*** if a female, on attaining the age of twenty-one years or marrying or dying under that age.[35]

Still other definitions refer to *children aged 14 years:*

(a) the ***Identity Card Act*** establishes the age for possession of a valid identity card at 14 years (previously it was 16 years);[36] and

(b) in the ***Civil Code***, regarding adoption, a child who has attained the age of 14 years has to consent to being adopted, unless incapable of giving his or her consent.[37]

4. Caring for Children

07.18

Every child has the right to be brought up within a nourishing and loving family environment, so s/he can develop her or his inherent capacities. This right is referred to (albeit indirectly) in several aspects of Maltese legislation.

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[32] *Constitution of Malta*, article 44(4)(c) and (d), referring to articles 3(1) and 5(1) of the *Maltese Citizenship Act*.

[33] *Social Security Act*, Part VI.

[34] *Immigration Act*, article 2.

[35] *Widows' and Orphans' Pensions Act*, article 2. Note the sexual discrimination implied here.

[36] *Identity Card Act*, article 3.

[37] *Civil Code*, article 115(3)(d). However this is subject to the Court's jurisdiction. See article 117.

The *Civil Code* states:

'Marriage imposes on both spouses the obligation to look after, maintain, instruct and educate the children of the marriage taking into account the abilities, natural inclinations and aspirations of the children.'[38]

The Commissioner for Children has 'to promote the protection of family unity and to advocate for adequate support to parents for the upbringing of their children.'[39]

As mentioned earlier, even before the child is born, where the father is dead, the child is entitled to protection. The court may appoint a *curator ad ventrem*, whose function is that of 'preventing any supposition of birth, or substitution of child, and administering the property up to the day of the birth.'[40] One of the functions of the Commissioner for Children is 'to promote special care and protection, including adequate legal protection, for children both before and after birth.'[41]

It is an offence to abandon or expose any child under the age of seven years.[42] If a child dies as a result of this, the person responsible will be guilty of wilful homicide.[43]

Everybody has the duty to report finding a newly born child: 'Whosoever, having found a newly born child, shall fail to provide for its immediate safety, or, having assumed the care thereof, shall not, within twenty-four hours, deliver the same, or give information thereof, to the Executive Police, shall, on conviction, be liable, in the first case, to imprisonment for a term from four to six months, and, in the second case, to imprisonment for a term from one to three months.'[44] This article makes it clear that being a good Samaritan is not a matter of choice but something that is demanded by the law.

Likewise, every person is guilty of a contravention if 'meeting in the street any abandoned or stray child, does not convey such

[38] *Civil Code*, article 3B.
[39] *Commissioner for Children Act*, article 9(c) and (d).
[40] *Civil Code*, article 170.
[41] *Commissioner for Children Act*, article 9(h).
[42] *Criminal Code*, article 246.
[43] *Criminal Code*, article 247. This article excludes the crime of infanticide, dealt with in article 245.
[44] *Criminal Code*, article 248.

child or immediately report the fact to the Executive Police, or does not otherwise provide for the safety of the child.'[45]

07.19

Moreover, in the ***Refugees Act*** we find that this right to care is extended to refugee children seeking asylum. It says: 'Any child or young person below the age of eighteen years falling within the scope of this Act who is found under circumstances which clearly indicate that he is a child or young person in need of care, shall be allowed to apply for asylum, and for the purposes of this Act, shall be assisted in terms of the ***Children and Young Persons (Care Orders) Act***, as if he were a child or young person under such Act.'[46]

Parents must also ensure that they themselves are in a fit state to look after their children. It is an offence to be found drunk or incapable of taking care of oneself when in charge of a child under the age of seven years.[47]

07.20

Ill-treatment or neglect of a child (under the age of twelve years) is dealt with in the ***Criminal Code***, which provides that 'whosoever, having the responsibility of any child under twelve years of age, by means of persistent acts of commission or omission ill-treats the child or causes or allows the ill-treatment by similar means of the child shall, unless the fact constitutes a more serious offence under any other provision of this Code, be liable on conviction to imprisonment for a term not exceeding two years.'[48]

Ill-treatment includes 'neglecting the child's need for adequate nutrition, clothing, shelter, and protection from harm, persistently offending the child's dignity and self-esteem in a serious manner and persistently imposing upon the child age-inappropriate tasks or hard physical labour.'[49]

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[45] *Criminal Code*, article 339(k).
[46] *Refugees Act*, article 12.
[47] *Criminal Code*, article 338.
[48] *Criminal Code*, article 247A(1).
[49] *Criminal Code*, article 247A(2).

5. Sexual Abuse

07.21

Defilement of minors of either sex is punishable by a term of imprisonment not exceeding three years.[50] Such an offence is aggravated and attracts a more severe sentence when this act is performed:

(a) on persons who have not attained the age of 12 years;
(b) where violence, threats or deceit are used; and
(c) by a relative or an adopted parent or tutor or a person charged, even temporarily with the care, education, instruction, control or custody of the minor.

Instigation, encouragement or facilitation of defilement of a minor is also an offence.[51]

Inducing a person who is under age to prostitution is prohibited, as is encouragement or facilitation of prostitution or defilement, and punishable by imprisonment for 18 months to four years. Such acts are considered aggravated and punishable by longer periods of imprisonment (2–6 years) if committed:

(a) on a person who has not yet attained the age of twelve years;
(b) by deceit;
(c) by a relative, adoptive parent, tutor or a person in charge of the minor (as mentioned earlier); and
(d) habitually or for gain.[52]

Using violence, threats or deceit, to compel or induce a relative under age or a minor under his tutorship, to prostitution, is liable to imprisonment from three to six years.[53]

It is an offence to traffick any minor for the purpose of exploiting the minor in prostitution or in pornographic performances or in the production of pornographic material.[54] The punishment is increased if the following means are used:

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[50] *Criminal Code*, article 203.
[51] *Criminal Code*, article 203A.
[52] *Criminal Code*, article 204.
[53] *Criminal Code*, article 197.
[54] *Criminal Code*, articles 248D and 248B. Article 248D refers to article 248A which prohibits exploitation in the production of goods or provision of services and to article 248C, which prohibits exploitation in the removal of any organ of the body.

'(a) violence or threats, including abduction;
(b) deceit or fraud;
(c) misuse of authority, influence or pressure;
(d) the giving or receiving of payments or benefits to achieve the consent of the person having control over another person.'[55]

07.22

These practices are also forbidden by the ***White Slave Traffic (Suppression) Ordinance*** which forbids the procurement of a person under the age of twenty-one years for purposes of prostitution overseas, with more severe penalties if a person has not reached the age of twelve years or other aggravating conditions as mentioned earlier.[56]

To note that the ***Child Abduction and Custody Act*** protects the child against abduction. This Act adopts the relevant articles of the ***Convention on the Civil Aspects of International Child Abduction***.[57]

6. Children in Financial Need

07.23

The ***Social Security Act*** provides for assistance where there appears to be a special need within the family, e.g.:

(a) entitlement to Social Assistance where a head of household is a single parent who is unable to take up full employment as he has to take care of his own child; [58]
(b) entitlement to Orphan's Supplementary Allowance for a person who has the care of an orphan child and an Orphan's Supplementary Allowance when the child is between 16 and 21 years and not earning more than the minimum wage;[59]

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[55] *Criminal Code*, article 248A.
[56] *White Slave Traffic (Suppression) Ordinance*, article 3(1).
[57] The *Convention on the Civil Aspects of International Child Abduction* was signed at The Hague on the 25th October, 1980, the relevant articles of which have been adopted by Malta (See Schedules to *Child Abduction and Custody Act*).
[58] *Social Security Act*, article 30(7).
[59] *Social Security Act*, articles 69(1) and (2).

(c) Children's Allowance[60] paid to the head of a household; a similar allowance is due for foster children and children in care;[61] and
(d) subsidies to Day Care Centres.[62]

To note that as regards pensions for children under the ***Widows' and Orphans' Pensions Act,*** 'a child shall be deemed to cease to be of a pensionable age within the meaning of this Act, if a male, on attaining the age of eighteen years or dying under that age, and if a female, on attaining the age of twenty-one years or marrying or dying under that age.'[63]

7. Child Labour

07.24
It has been the traditional role of each member of the family, including children, to help with the chores involved in bringing up younger children and helping in the work involved in the house, farm, etc. In underdeveloped countries in particular, the older child (who may be no more than five years old) is expected to look after the younger children. These traditional chores are not considered exploitation of children.

On the other hand, we find, again particularly in eastern countries, gross exploitation of children who are expected to work for long hours doing tedious and repetitive work, like carpet weaving, to the exclusion of all other childhood activities, and being paid a pittance for this work. It is these Dickensian practices which are particularly to be abhorred. Legislation is meant to enforce the need to protect the child from such exploitation and to ensure that they have a chance for normal development, physically, socially, and intellectually.

07.25
Reference has already been made to the United Nations ***Convention on the Rights of the Child,*** which deals with protection from child exploitation in relation to work performed by children.[64]

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[60] *Social Security Act,* article 76.
[61] *Social Security Act,* article 76A.
[62] *Social Security Act,* article 84A.
[63] *Widows' and Orphans' Pensions Act,* article 2.
[64] *Convention of the Rights of the Child,* article 32.

The ***Constitution of Malta*** refers to safeguarding the labour of minors. It states that the minimum age for paid labour shall be prescribed by law,[65] and moreover, that 'the State shall provide for safeguarding the labour of minors and assure to them the right to equal pay for equal work.'[66] This bare statement does not define minimum hours of work or other conditions necessary with regards to child employment.

The ***Criminal Code***, under the rubric of 'ill-treatment', includes 'persistently imposing upon the child age-inappropriate tasks or hard physical labour.'[67]

07.26

The ***Education Act*** stipulates that persons of compulsory school age may not be employed without written permission of the Minister.[68] 'Compulsory school age' is defined as 'from five years to fifteen years, both inclusive, and accordingly a person shall be deemed to be of compulsory school age if he has attained the age of five years and has not attained the age of sixteen years.'[69]

The Minister will grant such a permission when, following the necessary investigations, 'he is of the opinion that there are sufficient reasons to justify the exemption of the parents of the minor from their duty to ensure the regular attendance of the minor at school and when the Minister is also of the opinion that the employment of the minor would not be of harm to the health or normal development of that minor.'[70] However, approved apprenticeships and training schemes are not deemed to constitute employment for the purpose of this provision of the ***Education Act***.

With regard to apprenticeship training, the ***Employment and Training Services Act*** requires a written agreement between an employer and an apprentice, or trainee, and only with the consent

[65] *Constitution of Malta*, article 15.
[66] *Constitution of Malta*, article 16.
[67] *Criminal Code*, article 247A(2).
[68] *Education Act*, article 43(1). See *Charter of Fundamental Rights of the European Union*, article 32 which states that 'the minimum age of admission to employment may not be lower than the minimum school-leaving age, without prejudice to such rules as may be more favourable to young people and except for limited derogations.'
[69] *Education Act*, article 2.
[70] *Education Act*, article 43(2).

of the minor's parent, or if there are no parents, with the consent of the Director.[71] This article also states that 'a minor who binds himself as an apprentice or trainee' is 'bound by the agreement throughout its currency notwithstanding that he may have in the meantime attained the age of eighteen years.'[72]

8. Filiation and Children's Rights

07.27

The rights of a child have throughout the centuries centred around legitimacy. An illegitimate child had considerably reduced civic rights compared to one born in wedlock. Society nowadays tolerates with much more latitude the concept of family units, which have not been formally so recognised through civil or church marriage, and, moreover, some societies accept the concept of *de facto* relationships much more than others, giving rights to children, born from such unions, equal rights to those born outside it.

Recent amendments to Maltese legislation have substituted the term 'illegitimacy' for 'conceived and born out of wedlock' to remove any discrimination against these children.[73] The recently enacted ***Commissioner for Children Act*** defines a child as 'any person who has not attained majority'[74] and makes no distinction as to whether one has been born in or out of wedlock. The protection afforded by the Commissioner created by the Act is expected to extend to all children.

Civil law is very much concerned with the rights of the child, particularly from the point of view of establishing legitimacy and consequently rights of inheritance. In view of the fact that *mater semper certa est*, it is the relationship of husband to child that needs particularly to be defined by law.

We find in the ***Civil Code*** several references relating to filiation of children conceived or born in wedlock, in particular the law states that 'a child conceived in wedlock is held to be the child of

[71] *Employment and Training Services Act*, article 31(1) and (2).
[72] *Employment and Training Services Act*, article 31(3).
[73] To note also that the European Court of Human Rights has ruled against any such discrimination between children (vide *Marckx v. Belgium* decided on 13 June 1979).
[74] *Commissioner for Children Act*, article 2.

the mother's husband.'[75] 'Where a child is born of a married woman, the name of her husband shall be entered in the act as that of the father, notwithstanding any declaration to the contrary, saving any correction which may subsequently be made upon a judgment in regard to the filiation of the child,' provided the couple were living together up to 300 days before the birth.[76]

07.28

For a child to be presumed to have been conceived in wedlock, s/he has to be born 'not before one hundred and eighty days from the celebration of the marriage, nor after three hundred days from the dissolution or annulment of the marriage.'[77]

A husband may not repudiate a child born before 180 days from marriage if:

(a) he was aware of the pregnancy before marriage;
(b) if he acknowledges himself to be the father of the child and made the necessary declaration for the act of birth; and
(c) if the child is declared non-viable.[78]

It is now difficult to scientifically justify the cut off point of 180 days (six months or over 25 weeks). Premature deliveries prior to this time, although not common, are not inexistent.

07.29

A husband can repudiate a child if he proves that:

(a) he was in the physical impossibility of cohabiting with his wife between the 300th and the 180th day before the birth of the child;
(b) he was separated from his wife *de facto* or legally during this period;
(c) if he was impotent during this time; and
(d) if he can prove that his wife had committed adultery during this time or that she concealed the pregnancy and the birth and further produces evidence (which may also be genetic and scientific tests and data) that tends to exclude such paternity.[79]

[75] *Civil Code*, article 67.
[76] *Civil Code*, article 280(1).
[77] *Civil Code*, article 68.
[78] *Civil Code*, article 69.
[79] *Civil Code*, article 70.

The mother's declaration that the husband is not the father of the child is not sufficient to exclude paternity of the husband.[80]

07.30

Special emphasis is made in the ***Civil Code*** to protect the identity of the father in the case of a child conceived and born out of wedlock, and to make sure that this fact is well documented. Article 279 of the ***Civil Code*** specifically states that the name of the father shall not be stated in the act of birth, except when the person acknowledges himself before the relevant officer drawing up the act that he is the father of the child; even so, there must be joint acknowledgement by both the father and the mother for immediate effect without further judicial intervention.[81]

The court may ask for genetic tests to be provided by all parties, including the child whose filiation is in dispute.[82] Moreover, in case of refusal to submit to such tests, the 'court shall be entitled to draw such inferences as may be justified.' This article continues to add that 'where the child whose filiation is in dispute is a minor, the court itself shall determine whether the child shall submit to the tests.' This important proviso emphasises the need to protect a minor from tests which threaten to disclose its genetic provenance. It would seem to indicate clearly that parents are not at liberty to perform genetic tests on their children, to settle their disputes, without such a court order.

Indeed, in the case of a judicial demand for a declaration of paternity or maternity the court 'may, without prejudice to any evidence that may be produced by the parties according to law, invite the parties to submit to examinations as referred to in sub-article (3) of article 70, and in the same manner and in the same circumstances may, in case of refusal, draw such inferences as mentioned in that subarticle.'[83]

07.31

Other conditions necessary before a husband can bring an action to disown a child include:

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[80] *Civil Code*, article 70(2).
[81] *Civil Code*, article 279(2).
[82] *Civil Code*, article 70(3).
[83] *Civil Code*, article 100A.

(a) action has to be brought within six months of the birth, or if absent for this time, within 6 months of returning to Malta;
(b) within six months of discovering the fraud if the birth was concealed from him;[84] and
(c) the heirs of such a husband can bring an action for disavowal within the stipulated time.[85]

Registration in the Public Registry or the parochial registers is necessary as proof of filiation of children conceived or born in wedlock.[86]

9. Rights of Step-children and Children Conceived and Born out of Wedlock

07.32
Children are especially at risk if they happen to be step-children or orphans, and therefore legislation is considered necessary to protect their rights.

It is to be noted that equal rights of children are protected in the ***Social Security Act,*** where the definition of a 'child' includes a 'stepchild, an adopted child and a child born out of wedlock.'[87]

Also, for the purposes of maintenance of a child, the ***Income Tax Act*** defines a child as the following:

'(a) a stepchild, or an adopted child, or an illegitimate child[88] of the individual or of the individual's spouse; or
(b) a child orphan of or abandoned by either of the parents and living with the individual or the individual's spouse.'[89]

The definition of 'dependant' of a person in the ***Immigration Act*** includes:

(a) 'the child or step-child of such person, if the child or the step-child is under the age of twenty-one years'; and

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[84] *Civil Code,* article 73.
[85] *Civil Code,* article 74.
[86] *Civil Code,* article 78.
[87] *Social Security Act,* article 2.
[88] The *Income Tax Act* has not as yet been amended to remove the reference to illegitimate children.
[89] *Income Tax Act,* article 51(5).

(b) 'an adopted child under the age of twenty-one years, having been adopted by such person in a manner recognised by law.'[90]

07.33

However further legislation is considered necessary to protect the rights of illegitimate children. This can be found in the following legislation.

When there is no question that a person is not biologically the parent of the child, such children can be 'acknowledged' by the respective parent. 'A child conceived or born out of wedlock may be acknowledged by the father and the mother, either jointly or separately' unless the person acknowledging himself to be the father is a minor and provided that the person claiming to be the father has served a judicial letter upon the mother and the child, if of age, stating his intention for registration and both the mother and child, if of age, do not oppose such registration within two months from the date of service of such judicial letter.[91] Such acknowledgement may be made in the act of birth, a public deed made before or after the birth, or in an affiliation suit.[92]

However, when a child, conceived and born out of wedlock, is acknowledged by one of the spouses, the child may be brought into the matrimonial home only with the consent of the other spouse.[93] The parent who has acknowledged such a child has all parental authority, 'other than the legal usufruct.'[94]

When a child, conceived and born out of wedlock, is acknowledged by the father, s/he may assume his surname (to which the mother's surname may be added). Otherwise s/he may use only the mother's surname.[95]

Parents of children conceived and born out of wedlock, 'have in respect to such children and their descendants the same duty to maintain and educate them as they have with regard to children born or conceived in wedlock, and such children shall have in

[90] *Immigration Act*, article 2.
[91] *Civil Code*, article 86.
[92] *Civil Code*, article 87.
[93] *Civil Code*, article 89.
[94] *Civil Code*, article 90.
[95] *Civil Code*, article 92(1).

respect of their ascendants and other relatives the same rights and duties as children born or conceived in wedlock.'[96]

07.34
The rights of children conceived and born out of wedlock with regard to inheritance of property are dealt with in the ***Civil Code***.

A parent, whether he or she has acknowledged the child, may refuse to maintain a child if such a child refuses:

(a) to follow the directions of the parent in regard to his conduct or education;[97] and
(b) to live in the house appointed by the parent.[98]

Where parents of children conceived and born out of wedlock subsequently marry, or where the court of voluntary jurisdiction so decrees, such children shall be deemed *iuris et de iure* to have always been conceived or born in wedlock;[99] provided that the children are acknowledged by both parents.[100] Such children have all the rights of children conceived or born in wedlock as from the day of the celebration of the marriage.[101]

10. Parental Authority

07.35
The rights and obligations of parents towards their children are covered by the ***Civil Code.***[102] A child is subject to the authority of his parents,[103] which normally means 'the common accord of both parents', and after the death of one parent, by the surviving parent.[104] Where there is disagreement between the parents on matters of importance, the court may be required to decide and 'make those

[96] *Civil Code,* article 93.
[97] *Civil Code,* article 96
[98] *Civil Code,* article 97.
[99] *Civil Code,* article 101.
[100] *Civil Code,* article 102.
[101] *Civil Code,* article 103. Aspects of adoption are found in articles 113 *et seq,* and in the *Adoption Regulations,* SL 16.04. These are not dealt with further here. See below 07.38.
[102] *Civil Code,* articles 131 *et seq.*
[103] *Civil Code,* article 131.
[104] *Civil Code,* article 131(2).

suggestions which it deems best in the interest of the child and the unity of the family.' For this purpose, the court will also hear the views of a child aged 14 years. The court may consider one parent to be the more suitable.[105]

A child is expected to obey his parents in all that is permitted by law.[106] It is not lawful for a child to leave the parental house without the consent of the parents,[107] and parents have the right to recall him/her with the help of the police if necessary.[108]

However, the courts may, where there is just cause, authorise the child to leave the parental house.[109] If a child is beyond the control of his/her parents, the court may authorise placement of the child in alternative care at the request of the parents and at their expense.[110]

Failing a request by the parents, a Care Order may be issued in compliance with the ***Children and Young Persons (Care Orders) Act,*** which considers a child 'to be in need of care, protection or control if:

(a) he is beyond the control of his parents or guardian; or
(b) he is not receiving such care, protection and guidance as a good parent may reasonably be expected to give.' [111]

Parents also have the right of jointly representing their children, whether born or yet to be born in all civil matters.[112]

Likewise, parents have the power of jointly administering the property of their children whether born or yet to be born.[113]

Where there are conflicting interests between children or between children and either parent, the court may appoint one or more special curators.[114]

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[105] *Civil Code*, article 131(4).
[106] *Civil Code*, article 132.
[107] *Civil Code*, article 132(2).
[108] *Civil Code*, article 132(3).
[109] *Civil Code*, article 133.
[110] *Civil Code*, article 134(2).
[111] *Children and Young Persons (Care Orders) Act*, article 7.
[112] *Civil Code*, article 135.
[113] *Civil Code*, article 136.
[114] *Civil Code*, article 139.

07.36

Situations where parental authority ceases *ipso jure* include the following:

(a) 'on the death of both parents or of the child;
(b) when the child attains the age of eighteen years;
(c) on the marriage of the child;
(d) if the child, with the consent of the parents, has left the parental home and set up a separate domestic establishment'; and
(e) if the parent fails to honour the legal rights of the child as relates to property. [115]

A parent may be deprived of parental authority by a court in the following circumstances:

(a) ill-treatment of the child, or neglect of his/her education;
(b) conduct which endangers the education of the child;
(c) where the parent is interdicted due to mental infirmity;
(d) if the parent mismanages the property of the child;
(e) failure to look after, maintain, instruct and educate the children of the marriage, taking into account the abilities, natural inclinations and aspirations of the children. [116]

11. Tutorship of a Minor

07.37

A minor in this sense is a person of either sex who has not yet attained the age of eighteen years.[117] The question of tutorship of a minor is dealt with in the ***Civil Code***.[118]

A minor is considered to require tutorship where parents have died or forfeited parental authority and s/he has not married.[119] In such a case, the court may appoint a tutor, taking into account any disposition contained in the will of either of the parents,[120] preference being give to the nearest relative, and in the best interest

[115] *Civil Code*, article 150.
[116] *Civil Code*, article 154.
[117] *Civil Code*, article 157.
[118] *Civil Code*, article 157 *et seq.*
[119] *Civil Code*, article 158.
[120] *Civil Code*, article 159.

of the child.[121] A tutor may also be appointed, in default of parental authority, in the case of a child conceived and born out of wedlock.[122]

The duties of tutor[123] relate to having the care of the person of the minor; and to represent him/her in all civil matters, and administer his/her property as a *bonus paterfamilias*. The court may specify the place in which the minor is to be brought up, the education which it is proper to give him/her, and the expense to be incurred for his/her maintenance and education.[124]

A minor is expected to obey the tutor in all that is permitted by the law.[125]

A curator may also be appointed in the case of a minor whose parents are absent and thus deprived of parental authority.[126]

12. Adoption

07.38

This topic is dealt with in the ***Civil Code,***[127] and includes the adoption of children both in Malta as well as those from overseas. Adoption may take place only with the authority of the court of voluntary jurisdiction and only for 'the welfare of the person to be adopted.'[128]

The following conditions must be met:

(a) an application may be made by the two spouses who have been married for a period of not less than five years and are living together[129] but one spouse may apply if s/he is the natural parent and has the consent of the other spouse;[130]
(b) the applicant must have attained the age of 30 years, but not reached 60 years, and is at least 21 years older than the person

[121] *Civil Code,* article 160.
[122] *Civil Code,* article 91.
[123] *Civil Code,* article 172.
[124] *Civil Code,* article 173.
[125] *Civil Code,* article 175(1).
[126] *Civil Code,* article 233.
[127] *Civil Code,* articles 113–130. See also *Adoption Regulations,* SL 16.04.
[128] *Civil Code,* article 119(b).
[129] *Civil Code,* article 114(2).
[130] *Civil Code,* article 115(3)(c).

to be adopted[131] or else is the mother or father of the person to be adopted and has attained majority;[132]

(c) consent is required from the parents of the child to be adopted or from the mother, if the child is conceived and born out of wedlock, and from the child when s/he is 14 years old;[133]

(d) if the person to be adopted is the natural child of one spouse, consent is required from of the other spouse;[134]

(e) the person to be adopted must not be 18 years old, unless being adopted by a sole applicant who is the person's mother or the father;[135]

(f) a female can only be adopted by a sole male applicant, if the court is satisfied that there are justifiable special circumstances;[136] and

(g) the person to be adopted, must be 'continuously in the care and possession of the applicant for at least three consecutive months immediately preceding the date of the adoption decree' unless being adopted by a parent,[137] that is there is a term of pre adoption fostering.

However, the court may dispense with the need for any consent.[138]

In determining whether an adoption decree will be 'for the welfare of the person to be adopted,' the court considers 'the health of the applicant, supported by a medical certificate,' and also considers 'the wishes of the person to be adopted, having regard to his age and understanding and to the religious persuasion of such person and of his parents.'[139]

The rights and duties of the adopting parents and those of the biological parent are defined.[140] When an adoption is made, the adopted person is considered as the child of the adopter/s, born to the adopter/s in wedlock, and 'as the child of no other person or

[131] *Civil Code*, article 115(1)(a).
[132] *Civil Code*, article 115(1)(b).
[133] *Civil Code*, article 115(3)(a)(b)(d).
[134] *Civil Code*, article 115(3)(c).
[135] *Civil Code*, article 115(2)(a).
[136] *Civil Code*, article 115(2)(b).
[137] *Civil Code*, article 116(1).
[138] *Civil Code*, article 117.
[139] *Civil Code*, article 119(2).
[140] *Civil Code*, article 121.

persons.' The relatives of the adopted person (i.e. the biological relatives) 'shall lose all rights and be freed from all obligations with respect to such person.'[141]

07.39

The adopted person has the right to assume the surname of the adopter. If the adopted child is below the age of four years, the adopter may, with the approval of the court, give the child a new name.[142]

The ***Civil Code*** prohibits payments to be made in respect of the adoption of a person, the granting of any consent required, transfer of care and possession, or the making of any arrangements for the adoption of a person.[143] This excludes payment in respect of maintenance, and professional fees by legal and medical professionals.

With respect to deals for adoptions carried out overseas, the court has the power to determine whether such overseas adoption is to be treated as an adoption in accordance with the law in Malta.[144]

13. The Health of the Child

07.40

The ***Prevention of Disease Ordinance*** deals with several aspects relating to child health and the prevention of transmission of infectious diseases.

a. Child immunisation

Parents have the duty to immunise a child against 'diphtheria, tetanus and poliomyelitis or against any disease as the Minister may prescribe'[145] and this service is provided free of charge at

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[141] *Civil Code*, article 121(b).

[142] *Civil Code*, article 124.

[143] *Civil Code*, article 128.

[144] *Civil Code*, articles 130 and 130A. This is in accordance with the *Convention on Protection of Children and Cooperation in respect of Intercountry Adoption*, The Hague, 29th May 1993, as laid out in the *Overseas Adoption (Definition) Order*, SL 16.05.

[145] *Prevention of Disease Ordinance*, article 57. This Ordinance will in future be repealed when article 45 of the *Public Health Act* comes into force. This Act covers immunisation under articles 27(d), 29(1)(c), 29(2) and 29(3).

specific centres.[146] This immunisation should take place when the child has attained the age of three months, unless the child is unfit for immunisation,[147] in which case the child is immunised when considered fit to be so by the medical practitioner.

On completion of the full basic immunisation course, a certificate is provided by the officer in charge,[148] who is responsible for keeping records regarding the immunisation status of children.[149]

If a child is not immunised, the court may make an order directing the proper immunisation of such a child within such time as the court may prescribe.[150] Neglect to immunise a child may render the person in charge of that child liable to a fine.[151]

There is a prohibition of attendance at school by those children (defined as under 18 years of age) suffering from an infectious disease or who are living in a house where there is such disease.[152] A medical certificate is necessary to certify that such children have become free from disease or infection, and that 'the house and everything therein exposed to infection has been disinfected to the satisfaction of any of the medical officers.' Otherwise, the teachers must not allow the child to attend the school.[153]

b. Children and mental disorders

07.41

A person who has attained the age of 16 years and 'is capable of expressing his own wishes,' may make an application for voluntary admission to a mental institution for treatment, 'notwithstanding any right of custody or control vested by law in his parent or

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146 *Prevention of Disease Ordinance*, article 56.

147 *Prevention of Disease Ordinance*, article 58.

148 *Prevention of Disease Ordinance*, article 60.

149 *Prevention of Disease Ordinance*, article 61.

150 *Prevention of Disease Ordinance*, article 64.

151 *Prevention of Disease Ordinance*, article 102. Note that this article also refers to 'every person of age who shall neglect to cause himself to be vaccinated or revaccinated as provided for in this Ordinance, shall be liable to a fine (ammenda) not exceeding ten liri.'

152 *Prevention of Disease Ordinance*, article 28. This article is to be replaced by article 29(2) of the *Public Health Act* when it comes into force.

153 *Prevention of Disease Ordinance*, article 28. This article is to be replaced by article 29(2) of the *Public Health Act* when it comes into force.

tutor.'[154] Also a person who is an inpatient, admitted under compulsory admission for treatment, on reaching sixteen, 'may apply to the Mental Health Review Tribunal' within six months of turning sixteen years of age.[155]

Moreover when compulsory admissions are reviewed for renewal of detention, once the inpatient turns sixteen, unless the patient is to be discharged, s/he must be informed 'as early as practicable,' so that they may apply to the Mental Health Review Tribunal.[156]

14. Education and the Child

07.42

Education has a very important role in forming the ethical conscience of a child and eventual adult. It might be said that, nowadays, no person can fully participate in the process of obtaining and giving informed consent unless that person has achieved a reasonable level of education, which involves not only literacy, but also familiarity with basic concepts in biology and science in general.

One might also argue that lack of education is very closely associated causally with poverty and these two are prime culprits in perpetuating conditions which we associate with ill-health. Hence the right to education is one which may be linked to the right to enjoy good health, and anyone with an inadequate education is condemned to problems relating to health issues as well.

07.43

The ***Education Act*** affirms that 'it is the right of every citizen of the Republic of Malta to receive education and instruction without any distinction of age, sex, belief or economic means.'[157]

'Compulsory school age' means 'any age from five years to fifteen years, both inclusive, and accordingly a person shall be deemed to be of compulsory school age if he has attained the age of five years and has not attained the age of sixteen years.'[158]

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[154] *Mental Health Act*, article 3(2).
[155] *Mental Health Act*, article 19(3).
[156] *Mental Health Act*, article 21(6).
[157] *Education Act*, article 3.
[158] *Education Act*, article 2.

The duties of the State include:[159]

(a) the promotion of education and instruction through a system of schools and institutions, including their provision where they do not exist; and
(b) ensuring that these are accessible to all Maltese citizens catering for the full development of the whole personality including the ability of every person to work.

To achieve this end, the State has the right to:[160]

(a) establish national minimum conditions and a curriculum of studies for all schools; and
(b) ensure compliance with these.

Parents have the duty to register a minor in a school when s/he reaches compulsory school age, and to ensure the child continues attending school regularly until s/he ceases to be of school age.[161] A parent has the right to give his or her 'decision with regard to any matter concerning the education' of the minor.[162] A parent who fails to do so 'shall be guilty of an offence and is liable on conviction to the punishments established for contraventions and to a fine (ammenda) not exceeding one lira for each day during which the offence continues in the case of a continuing offence.'[163]

15. Research and Services in the Field of Child Development

7.44

An Institute for Child Development at the University of Malta has been set up as an inter-Faculty and inter-agency institution in order to:[164]

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159 *Education Act*, article 4.
160 *Education Act*, article 7.
161 *Education Act*, article 5.
162 *Education Act*, article 6.
163 *Education Act*, article 44(1).
164 *Statute I 16 – Institute for Child Development Statute*, SL 327. 48, article 3. Moreover through the Institute for Child and Parent Learning Support, set up by the *Institute for Child and Parent Learning Support Regulations*, SL 327.191, the Division of Education is committed to enhancing child development through the support of 'preventive and remedial strategies against illiteracy and failure in schools' (regulation 3).

(a) organise multidisciplinary research and services in the field of child development;
(b) organise, provide and research multidisciplinary habilitation / rehabilitation programmes for children with special needs and their families, in co-operation with governmental and non-governmental agencies;
(c) set up certificate, diploma, degree and postgraduate courses in the field of childhood disabilities;
(d) service Faculties and other institutions in the field of child development especially with regard to the area of children with special needs;
(e) organise and promote multidisciplinary workshops seminars and conferences on child development and childhood disabilities;
(f) serve as a resource centre and offer consultative services in the field of child development to individuals, governmental and non-governmental agencies;
(g) undertake any other activities in the field of child development in co-operation with governmental and non-governmental agencies;
(h) promote the role of parents as equal partners with professionals and their empowerment for informed choices regarding their children and families;
(i) promote the principle that every child has the same rights as other members of society to realise his individual capacity for physical, social, emotional and intellectual development; and
(j) promote the rights of all children for integrated services within the community and mainstream systems.

One must note that there is no relevant local legislation relating to the involvement of children in research. This is addressed in **Chapter 12: Research**.

16. Children in Need of Care

07.45
The ***Children and Young Persons (Care Orders) Act*** deals with situations where a child or young person is deemed to be in need of care, protection or control. This occurs if:

(a) 'he is beyond the control of his parents or guardian; or
(b) he is not receiving such care, protection and guidance as a good parent may reasonably be expected to give and:

(i) the child or young person is falling into bad associations or is seriously exposed to moral danger; or
(ii) such lack of care, protection or guidance is likely to cause the child or young person unnecessary suffering or seriously affect his health or proper development.'[165]

This Act establishes that the Minister, responsible for social welfare, when satisfied that a 'child or young person is in need of care, protection or control,' has the duty 'to take such child or young person into his care.' This follows notification of the case by the Department responsible for social welfare.[166] The parents and guardians are to be informed and only if they raise an objection, is the case taken to the Juvenile Court for a decision.[167] Any order will cease to have effect when the child turns eighteen.[168] This provision emphasises the need to ensure that children have adequate supervision and care, and empowers the Minister to act *in loco parentis* when the latter are not providing adequate supervision and care.

It is interesting to note that under such conditions of care the Minister 'shall not cause a child or young person in his care by virtue of an order made under this Act to be brought up in any religious creed other than that in which he would have been brought up apart from the order.'[169]

The duty of the Minister in these situations is to further the child's 'best interests and to afford him opportunity for the proper development of his character and abilities.'[170]

07.46

Thus, development of character is, curiously, included in the duties of the Minister in regard to children in care.

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[165] *Children and Young Persons (Care Orders) Act*, article 7.
[166] *Children and Young Persons (Care Orders) Act*, article 4(1). However note article 5 provides for an interim order for 21 days without involving the department of social welfare.
[167] *Children and Young Persons (Care Orders) Act*, article 4(3)(4).
[168] *Children and Young Persons (Care Orders) Act*, article 4(5).
[169] *Children and Young Persons (Care Orders) Act*, article 8.
[170] *Children and Young Persons (Care Orders) Act*, article 9.

The Minister's duties include the provision of accommodation and maintenance in a residential home or similar institution, provided by the Minister,[171] or boarding out the child with a private institution or with a fit person,[172] including a guardian, relative or friend.[173]

A child taken into care according to this Act is not permitted to 'abscond from the premises.' S/he may be apprehended without warrant by any member of the Police and taken back to such premises.[174] Any person helping him/her to abscond is guilty of an offence, which is punishable with imprisonment for a term not exceeding six months or a fine.[175]

The ***Children and Young Persons (Care Orders) Act,*** establishes a 'Children and Young Persons Advisory Board to advise the Minister' on the best methods of dealing with children and young persons committed to care and to exercise supervision over them and 'to promote their welfare.'[176]

The Minister has the power to regulate procedures of this Board, procedures to be adopted in referring a case to the Juvenile Court, the administration of state homes, hostels and institutions for the care of children, the duties of persons or institutions in charge of children, the arrangements for visiting children and for periodical review of the cases of these children by welfare officers.[177]

17. Fostering

Fostering is aimed at placing children in a family rather than an institution, providing better opportunities for the children to grow.

The term, is used only twice in Maltese main legislation. The Commissioner for Children has to encourage 'the development of alternative care to children who need such care with special reference to fostering and adoption.'[178]

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[171] *Children and Young Persons (Care Orders) Act,* article 10(1)(a).
[172] *Children and Young Persons (Care Orders) Act,* article 10(1)(b).
[173] *Children and Young Persons (Care Orders) Act,* article 10(3).
[174] *Children and Young Persons (Care Orders) Act,* article 12(1).
[175] *Children and Young Persons (Care Orders) Act,* article 12(2).
[176] *Children and Young Persons (Care Orders) Act,* article 11.
[177] *Children and Young Persons (Care Orders) Act,* article 13.
[178] *Commissioner for Children Act,* article 9(e).

The ***Social Security Act***, in terms of a Care Allowance, states that it is the right of every child who is a fostered child, or who is 'under care in an institution, to have an allowance paid out in his respect to the head of the household or the head of the institution.'[179]

However the concept is provided for under the ***Children and Young Persons (Care Orders) Act***, where the Minister provides for a child by 'boarding him out with a fit person, whether a relative or not.'[180] In the related Subsidiary Legislation 285.01, ***Children and Young Persons (Care Orders) Regulations***, regulation 7 refers to foster carers and foster families of children under a care order. Similarly in the case of separation, the court directs to which of the spouses custody of the children is entrusted, and if it considers such measures necessary, directs that the children be placed in the custody of third parties or in alternative forms of care.[181]

The ***Civil Code*** states that a person may make an agreement or arrangement or facilitate arrangements for 'the placing of a minor in the care or possession of any person.'[182] Such placements are regulated by subsidiary legislation.[183]

In effect fostering goes beyond Care Orders, whether with the co-operation of the parents or under a Court Order. It may be of variable length of time according to the needs of the child and family and may include respite care as well as emergency foster care for children who need protection. Foster Care Services are provided by Agenzija Appogg, forming part of the Foundation for Social Welfare Services within the Ministry for the Family and Social Solidarity.

It is also to be noted that the Public Service Management Code entitles foster parents to avail themselves of special unpaid leave for a period not exceeding one year, in order to foster a child.[184]

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[179] *Social Security Act*, article 76A.
[180] *Children and Young Persons (Care Orders) Act*, article 10(1)(b).
[181] *Civil Code*, article 56(1) and (2).
[182] *Civil Code*, article 113(1)(b).
[183] *Placing of Minors Regulations*, SL 16.01.
[184] Public Service Management Code, 6th Edition, 31st December 2005, article 4.8.9.1.

18. Young Offenders

07.47

A child becomes responsible for his or her actions in proportion, among other things, to his or her age:

(a) children under the age of nine years are exempt from criminal responsibility for any act or omission;[185]
(b) children under the age of fourteen years are also exempt from criminal responsibility for any act or omission done 'without mischievous discretion';[186]
(c) in either case, however, a parent or guardian may be bound by a court to watch over the conduct of the minor under penalty or else the court may award the usual punishment (of a fine) against the person charged with the upbringing of the minor, if the fact could have been avoided by his diligence;[187]
(d) a child over 9 years but under the age of 14 years 'acting with mischievous discretion' is liable on conviction to the punishment established for contraventions but the court has more discretion. It may apply measures as outlined in (c) or else, depending on the gravity, the punishment laid down for the offence is decreased by three degrees provided that in no case may the punishment exceed four years imprisonment;[188] and
(e) in the case of minors aged fourteen years but under the age of eighteen years, punishment is diminished 'by one or two degrees.'[189]

Similarly in the ***Civil Code***, 'children under nine years of age, and, unless it is proved that they have acted with a mischievous discretion, children who have not attained the age of fourteen years, shall not be bound to make good the damage caused by them.'[190]

However 'any person having the charge of a minor . . . shall be liable for any damage caused by such minor . . . if he fails to exercise the care of a *bonus paterfamilias* in order to prevent the act.'[191] The

[185] *Criminal Code*, article 35 (1).
[186] *Criminal Code*, article 35 (2).
[187] *Criminal Code*, article 35(4).
[188] *Criminal Code*, article 36.
[189] *Criminal Code*, article 37.
[190] *Civil Code*, article 1035.
[191] *Civil Code*, article 1034.

Court may order damages to be paid out of the property of the minor if the person in charge of the minor is not liable.[192]

A court, on finding a young offender guilty of an offence, may alternatively to any other punishment and due to the fact that the offender 'is in need of care or control,' may 'make an order committing him to the care of the Minister for a period of not less than one year and not more than five years.'[193] Such an order is subject to an appeal as any other sentence. The order ceases to have effect when the child reaches the age of 18 years.

Moreover, the Minister, for social welfare, may in the interest of the education or welfare of a child or young person remove the person from prison to be taken into care (except in the case of imprisonment for wilful homicide).[194] The order lasts till the date when the person would have been released from prison.

The Juvenile Court is a Court of Magistrates with jurisdiction, as a court of criminal judicature and as a court of inquiry, and is set up 'for the purpose of hearing charges against, or other proceedings relating to, a child or young person,'[195] meaning a person who is under the age of sixteen years.[196] The Court cannot 'hear charges against, or other proceedings relating to, a child or young person who is charged jointly with any other person not being a child or young person.'[197]

It consists of a magistrate, assisted by two persons, one of whom must be a woman, who 'have previous experience and special qualifications for dealing with problems of juveniles.'[198]

07.48

Among the special provisions relating to the functioning of the Juvenile Court, we find:

(a) restriction in the number of persons who can attend court hearings to those directly involved but '*bona fide* representatives of newspapers' are allowed;[199] and

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[192] *Civil Code*, article 1036.
[193] *Children and Young Persons (Care Orders) Act*, article 3.
[194] *Children and Young Persons (Care Orders) Act*, article 6.
[195] *Juvenile Court Act*, article 3.
[196] *Juvenile Court Act*, article 2.
[197] *Juvenile Court Act*, article 6(3).
[198] *Juvenile Court Act*, article 4.
[199] *Juvenile Court Act*, article 7.

(b) prohibition of publication of the name, address or school or any other particulars that could lead to the identification of the child or young person concerned in any of the proceedings unless the Court or Minister allows this, in the interest of justice to a child or young person. Otherwise a person publishing such information is considered to be in contempt of court.[200]

When a child or young person is called as a witness in relation to an offence against, or any conduct contrary to, decency or morality, before any court of criminal justice, the court may restrict the number persons attending as mentioned above for Juvenile Court sittings. The court may also hold its sittings with closed doors.[201]

No child or young person is permitted to be present in any court of criminal justice unless accompanied by his/her parent, relative or guardian, and if unaccompanied, is removed by the court unless s/he is the person charged with the offence or a witness.[202]

19. Competence of the Child in Court

07.49

'Every person of sound mind is admissible as witness, unless there are objections to his competency.'[203] 'The court shall explain to the witness the obligation of the oath if, on account of his age or for other reasons, it appears doubtful whether he understands such obligation.'[204]

'No person shall be excluded from giving testimony for want of any particular age; it shall be sufficient that the court be satisfied that the witness, though not of age, understands that it is wrong to give false testimony.'[205]

Any objection because of age 'shall affect only the credibility of the witness, as to which the decision shall lie in the discretion of those who have to judge of the facts, regard being had to the

[200] *Juvenile Court Act*, article 8.
[201] *Juvenile Court Act*, article 9.
[202] *Juvenile Court Act*, article10.
[203] *Criminal Code*, article 629(1).
[204] *Criminal Code*, article 629(2).
[205] *Criminal Code*, article 630.

demeanour, conduct, and character of the witness, to the probability, consistency, and other features of his statement, to the corroboration which may be forthcoming from other testimony, and to all the circumstances of the case.'[206]

The competence of a child 'of tender years' to be examined under oath is also mentioned in the ***Malta Armed Forces Act*** with regard to a court martial. The provision[207] states that 'provided that where any child of tender years called as a witness does not in the opinion of the court understand the nature of an oath, his evidence may be received, though not given upon oath, if in the opinion of the court he is possessed of sufficient intelligence to justify the reception of the evidence and understands the duty of speaking the truth, so however that when the evidence is given on behalf of the prosecution the accused shall not be liable to be convicted unless it is corroborated by some other material evidence in support thereof implicating the accused.'

Generally witnesses are 'examined in court and *viva voce*,'[208] but 'the court may, if it deems it proper so to act, allow for the audio-recording or for the video-recording of any evidence required from a witness.'[209] This has been applied in case of testimony of minors.

20. Legal Capacity

07.50

The capacity of a minor to enter into a contract is covered by the relevant articles in the ***Civil Code***. Minors are incapable of contracting.[210] 'Any contract entered into by a person who has not the use of reason, or is under the age of seven years is null.'[211] 'Any obligation entered into by a child under the age of fourteen years is also null.'[212] This also applies to any person who is over fourteen but not yet eighteen years, if still 'subject to parental authority, or is provided with a curator' unless married.[213]

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[206] *Criminal Code*, article 637.
[207] *Malta Armed Forces Act*, article 99(2).
[208] *Criminal Code*, article 646(1).
[209] *Criminal Code*, article 647A.
[210] *Civil Code*, article 967(3)(a).
[211] *Civil Code*, article 968.
[212] *Civil Code*, article 969(1).
[213] *Civil Code*, article 970.

A minor who has attained the age of fourteen years, and is not subject to parental authority, nor provided with a curator, may enter into certain obligations, but not rescissory actions; there are some exceptions, including in relation to immovable property, which require the authority of the competent court.[214]

An agreement, which is 'expressly declared by law to be null,' is subject to rescission.[215] Minors may demand rescission on the grounds of lesion[216] or liability to litigation or expense,[217] unless such lesion is the effect of a fortuitous and unforeseen event. Rescissory action is allowed even for agreements between two minors.[218] Where the agreement is one under the provisions of the ***Commercial Code,*** or in relation to the minor's trade, for which the minor is considered of age, the minor can exercise rescissory action under the same provisions as an adult.[219]

However any obligation entered into by an adult in favour of a child above nine years is valid.[220]

A child over the age of sixteen years may open and operate a bank account.[221]

A child who has 'not completed the fourteenth year' of age 'is incapable of making wills.'[222] Any will made by a person subject to incapacity is null, even though the incapacity of the testator may have ceased before his death.[223]

Persons 'who have not completed the eighteenth year of their age cannot make by will other than remuneratory dispositions.'[224]

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[214] *Civil Code,* article 971.
[215] *Civil Code,* article 1212.
[216] *Civil Code,* article 1214.
[217] *Civil Code,* article 1215.
[218] *Civil Code,* article 1216.
[219] *Civil Code,* article 1218 applies except for the provisions of articles 1035 and 1036.
[220] *Civil Code,* article 969(2).
[221] *Civil Code,* article 971A.
[222] *Civil Code,* article 597.
[223] *Civil Code,* article 599.
[224] *Civil Code,* article 598(1).

07.51

A minor may not sue or be sued, 'except in the person of the parent exercising paternal authority, or, in the absence of such parent, of a tutor or a curator.'[225] There are, however, exceptions to this rule, including situations where a minor sues his own parents or carries a trade with the consent of his/her parents or guardian or if the parent consents to the child suing or being sued, without his/her assistance.[226] In such cases, the court may appoint a curator *ad litem*, unless the minor is represented by a tutor or curator.[227] If the parent is unable or refuses to appear for the child or refuses to give permission for the child to sue, the court may grant such authority.[228]

A crime perpetrated against a child assumes greater significance before the law. For instance, 'theft is aggravated by the nature of the thing stolen when it is committed on any article of ornament or clothing which, is at the time, on the person of any child under nine years of age.'[229] Also with regard to grievous bodily harm,[230] sexual offences,[231] and the taking of indecent photographs,[232] the fact that the victim 'has not completed the age of nine years', is an aggravating circumstance leading to an increase in the punishment due. Committing sexual offences 'in the presence of, or within hearing distance of a minor'[233] and causing grievous bodily harm to children, as an act of domestic violence,[234] are also aggravating circumstances for these offences. Domestic violence is discussed in **Chapter 14: Social Issues**.

An effort is made also to restrict the quality of merchandise that can be sold to a child. For instance, a shop licensed for the sale

[225] *Code of Organisation and Civil Procedure*, article 781(a).
[226] *Code of Organisation and Civil Procedure*, article 782.
[227] *Code of Organisation and Civil Procedure*, article 783.
[228] *Code of Organisation and Civil Procedure*, articles 784, 785.
[229] *Criminal Code*, article 271(f).
[230] *Criminal Code*, article 222(1)(b).
[231] *Criminal Code*, article 202(g).
[232] *Criminal Code*, article 208A(3).
[233] *Criminal Code*, article 202 (i). This is an amendment established by the *Domestic Violence Act*, article 11.
[234] *Domestic Violence Act*, article 13.

of spirits 'shall not sell any wine, beer or spirituous liquor' to any person 'under the age of sixteen years'.[235] Also selling or giving explosives to a child under the age of eighteen is prohibited.[236]

A person may be arrested for a minor offence, without need of a warrant, if caught committing an offence or if the arrest is necessary to prevent an offence, in respect of which the Police may institute criminal proceedings without the complaint of the injured party, when 'a police officer has reasonable grounds for believing that the arrest is necessary to protect a child or any other vulnerable person.'[237]

A child has a right to citizenship of the country where s/he was born, and/or of the citizenship of his/her parents. With respect to minors, the ***Maltese Citizenship Act*** states that a 'minor child of any citizen of Malta' may be granted a certificate of naturalisation as a citizen of Malta, by the Minister.[238] Moreover 'the Minister may, in such special circumstances as he thinks fit, cause any minor to be granted a certificate of naturalisation as a citizen of Malta.'[239]

[235] *Code of Police Laws*, article 185(1)(b).
[236] *Explosives Ordinance*, article 19.
[237] *Criminal Code*, articles 355Y and 355Z(e)
[238] *Maltese Citizenship Act*, article 11(1).
[239] *Maltese Citizenship Act*, article 11(2).

Chapter 8

Disability

1. Introduction

08.01

Persons with disability are often faced with problems which have been created by society through lack or forethought or through ignoring their special needs. Throughout life, and depending on the degree of disability, there may be a need for special help. This may start from well before birth, as is evidenced by the current spate of techniques developed to diagnose genetic diseases through pre-natal testing and techniques of *in vitro* fertilisation, which allow choice and selection of embryos having specific characteristics. Likewise medical techniques have proliferated to diagnose, and often dispose of, fetuses found to have a severe malformation or prone to some chronically disabling disease (e.g. thalassaemia, spina bifida, etc). After birth, a child with a disability may require medical attention to a varying degree, depending on the type and severity of the condition. As they grow older, children with disability require special education to enable them to cope with the basic necessities of life, including the possibility of participating in the work force. All these topics raise significant bioethical issues relating to the rights of this section of the population. The Bioethics Consultative Committee has published the proceedings of a conference on Bioethics and Disability.[1]

National as well as international governments and organisations have promulgated the rights of persons with disability. The ***Charter of Fundamental Rights of the European Union*** emphasizes the need

[1] *Proceedings of the Conference on Bioethics and Disability*. Ed. M.N.Cauchi. The Bioethics Consultative Committee, in collaboration with the National Commission Persons with Disability, Malta 1999.

for integration of persons with disability, as well as their right to 'benefit from measures designed to ensure their independence, social and occupational integration and participation in the life of the community.'[2]

To mark the Official Opening of the European Year (2003) of Persons with Disability, the National Commission Persons with Disability, (NCPD), issued a Declaration in Favour of Equal Opportunities for Persons with Disability. It was signed by the President of Malta, on behalf of the people of Malta, in November 2002. The Declaration, signed by more than 150 Maltese organisations, recognises that 'persons with disability, for one reason or another, often face various obstacles to accessible physical environment, means of communication and information, educational system, work place, family-life and free time activities. They may also face negative attitudes from certain sectors of society, denying them equal opportunities and full participation in society.'[3] The Public Service is signatory to this declaration and is committed 'to doing all that is reasonably possible in putting in action the principles contained in the Equal Opportunities (Persons with Disability) Act' and the 'UN Standard Regulations of 1993 on Equal Opportunities for Persons with a Disability.'[4]

Maltese legislation deals with various aspects which control and direct several issues of vital interest to this group of citizens. In this chapter we look at this legislation.

2. Definitions

08.02

'*Disability*' means, a physical or mental impairment that substantially limits one or more of the major life activities of a person.[5]

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[2] *Charter of Fundamental Rights of the European Union*, article 26. The articles of this Charter are being proposed to be included in the *Constitution for Europe* if approved by the European Union Member States (article III-26). EN C 364/14 Official Journal of the European Communities, 18.12.2000.

[3] See National Commission Persons with Disability, Disability Year 2003, http://www.knpd.org.mt.

[4] Public Service Management Code, 6th edition, December 2005, paragraph 9.5.1.2.

[5] *Equal Opportunities (Persons with Disability) Act*, article 2 and *Equal Treatment in Employment Regulations*, SL 452.95, regulation 2.

A *'person with disability'* means a person, being over compulsory school age, who, by reason of injury, disease, congenital deformity or other physical or mental incapacity, is substantially handicapped in obtaining or keeping employment or in undertaking work on his own account, of a kind which apart from that injury, disease, deformity or incapacity would be suited to his age, experience and qualifications; and the word 'disability', in relation to any person, shall be construed accordingly.[6]

'Impairment' in the context of disability, means any loss, restriction or abnormality of psychological, physiological, or anatomical structure or function.[7]

A *'blind person'* means a person who has no sight or whose sight is, or is likely to become, so defective that he is unable to obtain or keep any employment, or to undertake any work on his own account, for which sight is essential.[8]

'Perceptual disability' is defined as 'a disability that prevents or inhibits a person from reading or hearing a literary, musical, dramatic or artistic work in its original format, and includes such a disability resulting from:

(a) severe or total impairment of sight or hearing or the inability to focus or move one's eyes;
(b) the inability to hold or manipulate a book; or
(c) an impairment relating to comprehension.'[9]

A *'severely disabled person'* means 'a person who still has a reasonable expectancy of life and who is incapable of supporting himself through full-time employment or self-occupation, or who will be rendered so incapable when of age to do so, owing to a permanent disability arising from' a number of listed diseases and conditions.[10] For the purpose of receiving a Disabled Child

[6] *Persons with Disability (Employment) Act*, article 2.
[7] *Equal Opportunities (Persons with Disability) Act*, article 2.
[8] *Persons with Disability (Employment) Act*, article 2.
[9] *Copyright Act*, article 2.
[10] *Social Security Act*, article 2. These include the following:
(a) total deafmutism; or
(b) achondroplasia, hypopituitarism, osteogenesis imperfecta or other forms of dwarfism; or

Allowance, 'a child shall still be deemed to be a severely disabled person if he is certified to be totally and permanently mute or permanently deaf to a degree of no less than 70 decibel.'[11]

A *'deaf person with speech'* means 'a person who, even with a hearing aid, has little or no useful hearing and whose normal method of communication is by speech and lip reading.'[12] A *'deaf person without speech'* means 'a person who has no useful hearing and whose normal method of communication is by signs, finger spelling or writing.'[13]

'Visually impaired person' means 'a person whose visual acuity has been certified by an ophthalmologist to be so low as to render such person unable to perform any work for which eyesight is essential.'[14]

'Special educational needs' are defined by the ***Education Act.*** 'A minor shall be deemed to have special educational needs when that minor has special difficulties of a physical, mental or psychological nature.'[15]

'Disablement resettlement services' means 'such facilities as are designed to place in suitable employment registered persons.'[16]

'Suitable employment' means 'such employment, or such work on one's own account, as a placement medical officer, having regard

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(c) one of the following diseases, namely: Multiple Sclerosis, Muscular Dystrophy, Spina Bifida, Systemic Lupus Erythematosus, Haemophilia or any other similar permanent disorder of the blood, characterised by chronic or repeated bleeding, Hydrocephalus, Huntington's Chorea, Cystic Fibrosis, TC II Deficiency; or

(d) permanent total paralysis or permanent total severe malfunction or permanent total disease, whether through amputation or otherwise, of both upper or lower limbs; or

(e) epilepsy with a frequency of attacks exceeding four per month, which condition is confirmed by appropriate investigations including an electro-encephalogram and so certified by a Government neurologist or psychiatrist provided that the person concerned is not in possession of a driving licence; or

(f) congenital indifference to pain.

[11] *Social Security Act*, article 77.

[12] *Persons with Disability (Employment) Act*, article 2.

[13] *Persons with Disability (Employment) Act*, article 2.

[14] *Social Security Act*, article 2.

[15] *Education Act*, article 18(2).

[16] *Persons with Disability (Employment) Act*, article 2.

to the age, experience and qualifications of the person with disability, considers suitable for that person.'[17]

08.03

A distinction may be made between 'disability' and 'impairment'.[18] The former refers to the physical or mental defect and is presumably defined medically. The latter refers to the loss of function, which the person with disability suffers as a result of having the specific abnormality. It is worth mentioning also that the impairment may be psychological.

Maltese legislation in this area specifically highlights the following issues:

(a) mental as well as physical defects;
(b) defects of sight and hearing;
(c) the educational needs of children with disability;
(d) special requirement in the employment of these persons;
(e) social security arrangements for those unable to earn a living; and
(f) data protection relating to their disability.

3. Employment and Disability

08.04

There are several services provided for employment of persons with disability, including:

(a) vocational guidance services;
(b) vocational training courses;
(c) industrial rehabilitation courses; and
(d) disablement resettlement services.[19]

The law also includes adequate medical supervision of persons receiving any of these services.[20]

The Employment and Training Corporation set up under the ***Employment and Training Services Act,*** is responsible to maintain

[17] *Persons with Disability (Employment) Act*, article 2.
[18] *Equal Opportunities (Persons with Disability) Act*, article 2.
[19] *Persons with Disability (Employment) Act*, article 3(1).
[20] *Persons with Disability (Employment) Act*, article 3(2).

a register of persons with disability[21] and to provide each person whose name is entered in the register with a certificate of registration.[22] Any registered person may have his/her name removed from the register on making a written application to the Corporation.[23]

Registered persons have the right to employment according to a specified quota.[24] Moreover these registered persons have priority over unregistered persons in being offered employment, so long as the quota is not filled.[25]

08.05

An employer's quota is determined by the Minister (after consultation with the Corporation) and may specify a specific percentage of the working force that should be reserved for persons with disability.[26] Employers must keep a register containing the number and names of all persons employed by him/her as well as the number and names of registered persons in his/her employ.[27] Preference for employment is given to registered persons with a severe disability, as certified by a placement medical officer; although this is not meant to imply that the employer is bound to engage a person submitted to him by the Corporation.[28]

The functions of the Corporation include:

(a) providing persons with disability an equal opportunity for obtaining and keeping employment;
(b) promoting opportunities for obtaining and keeping employment;
(c) overcoming, in respect of training or employment, discrimination against persons with disability;
(d) promoting awareness among employers about work capacities of persons with disability.[29]

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[21] *Persons with Disability (Employment) Act*, article 5.
[22] *Persons with Disability (Employment) Act*, article 6.
[23] *Persons with Disability (Employment) Act*, article 14.
[24] *Persons with Disability (Employment) Act*, article 16.
[25] *Persons with Disability (Employment) Act*, article15 (2).
[26] *Persons with Disability (Employment) Act*, article16.
[27] *Persons with Disability (Employment) Act*, article 20.
[28] *Persons with Disability (Employment) Act*, article 22.
[29] *Persons with Disability (Employment) Act*, article 24.

A Disablement Resettlement Officer is available to monitor conditions of employment and work environment and to investigate any complaints made by persons with disability.[30]

4. Discrimination

08.06

Discrimination is said to occur when a person with disability is treated differently from another person:

(a) because of particular circumstances;[31]
(b) because of some characteristic of the disabled person;[32]
(c) when a disabled person is required to comply with a requirement which is unreasonable considering the circumstances of the case, even though persons who do not have this disability are able to comply;[33]
(d) because of the need for an auxiliary aid (e.g. hearing aid, wheelchair, etc.),[34] or an interpreter, reader, assistant or carer.[35]

08.07

The discrimination by an employer against a qualified disabled person with respect to procedures relating to applications for employment, hiring, promotion, dismissal, compensation, job training and other conditions and privileges, is prohibited.[36]

An employer is considered to be discriminating against a person with disability if any of his/her actions affect adversely a person with disability; such actions include:[37]

(a) limiting, segregating or classifying such a person in a way that adversely affects him/her;
(b) participating in contracts or arrangements, the implementation of which, subjects such persons to discrimination;

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[30] *Persons with Disability (Employment) Act*, article 25.
[31] *Equal Opportunities (Persons with Disability) Act*, article 3 (1)(a).
[32] *Equal Opportunities (Persons with Disability) Act*, article 3 (1)(b).
[33] *Equal Opportunities (Persons with Disability) Act*, article 4.
[34] *Equal Opportunities (Persons with Disability) Act*, article 5.
[35] *Equal Opportunities (Persons with Disability) Act*, article 6.
[36] *Equal Opportunities (Persons with Disability) Act*, article 3 and article 7(1).
[37] *Equal Opportunities (Persons with Disability) Act*, article 7(2).

(c) using standards, criteria or methods of administration, that screen out such persons;
(d) failing to make reasonable accommodation, or denying employment because of absence of such.

Discrimination against a person because of his/her association with a person with disability, by exclusion from employment or by discontinuation of employment, is also considered as discrimination on the grounds of disability.[38] This provides protection to relatives of persons with disability.

An employer is requested to 'make reasonable accommodation' which means:[39]

(a) ensuring that the disabled person can have access to existing facilities used by employees; and
(b) restructuring jobs, modifying time-schedules, including part-time work, modifying equipment, providing adequate training and providing readers or interpreters for the person with disability.

A medical examination can be requested by an employer only 'to ascertain the ability of the applicant to perform job-related functions or to identify the cost involved in any adaptations that may be required as a result of such disability.'[40] It is forbidden to require assessment of the nature or severity of disability as such, if it does not relate to the job.

If a medical examination (and/or psychological assessment) is required by all employees prior to employment, then a person with disability may be requested to submit to such an examination.[41]

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[38] *Equal Opportunities (Persons with Disability) Act*, article 7(3).

[39] *Equal Opportunities (Persons with Disability) Act*, article 7(5). Note also: The publication by the National Commission Persons with Disability, *Design Guidelines: Access to All*, December 2000, ISBN 99909-71-08-0, giving detailed directions relating to building specifications and guidelines relating to exterior and interior arrangements to ensure that disabled persons get maximum benefit. These directives have been incorporated by the Malta Environment and Planning Authority (MEPA) and are found on its webpage: http://www.mepa.org.mt and that of the NCPD, http://www.knpd.org.mt.

[40] *Equal Opportunities (Persons with Disability) Act*, article 8(1).

[41] *Equal Opportunities (Persons with Disability) Act*, article 8(2).

However, any information obtained from such medical examinations, in relation to the disability, has to be collected on separate forms and kept in a separate medical file and treated as a confidential medical record.[42]

Nevertheless, the employer may inform (a) supervisors and managers about necessary accommodations and restrictions on the work and duties of the employee with disability and (b) first aid and safety personnel with regard to special precautions to be taken and possible emergency treatment that might be required.[43]

A disabled person has a right to be registered with a trade union with all ensuing benefits.[44] It is also unlawful for a trade union to discriminate against a person on the grounds of disability of family members.

Employment agencies may not refuse their services to a person on the grounds of his/her disability or disability of a relative.[45]

Regarding employment, a person with disability is also covered by the ***Employment and Industrial Relations Act*** which states that it is unlawful for any person to discriminate:[46]

(a) between applicants, when advertising or offering employment; and
(b) in regards to conditions of employment for those already employed.

Discriminatory treatment is here specifically meant to include:

(a) giving terms of payment or employment conditions less favourable than would apply to another employee doing similar work; and
(b) distribution of tasks so that an employee is assigned a less favourable status.

The ***Employment and Industrial Relations Act*** also deals with victimisation[47] and harassment.[48] It makes it unlawful to victimise a person who:

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[42] *Equal Opportunities (Persons with Disability) Act*, article 8(3).
[43] *Equal Opportunities (Persons with Disability) Act*, article 8(4).
[44] *Equal Opportunities (Persons with Disability) Act*, article 9.
[45] *Equal Opportunities (Persons with Disability) Act*, article 10.
[46] *Employment and Industrial Relations Act*, article 26.
[47] *Employment and Industrial Relations Act*, article 28.
[48] *Employment and Industrial Relations Act*, article 29. Sexual harassment is dealt with in the *Equality For Men and Women Act*, article 9(1).

(a) makes a complaint to the lawful authorities; or
(b) initiates or participates in proceedings for redress on grounds of alleged breach of the provisions of this Act; or
(c) discloses information to a designated public regulating body regarding illegal or corrupt activities committed by his/her employer or in his/her name.

Any person who alleges that an employer is in breach of these conditions may lodge a complaint with the Industrial Tribunal within three months of the alleged breach.[49]

08.08

An educational authority may not refuse admission to a student because of his/her disability,[50] unless this would require services or facilities, the provision of which, would impose unjustifiable hardship on the educational institution or authority concerned.[51] However, the reverse is allowed, i.e. an institution primarily established for students with a particular disability may refuse admission to persons without that particular disability.[52]

08.09

Access to premises must be provided for disabled persons and it is unlawful for any person to prevent access on the grounds of disability.[53] This includes the provision of means of access to such premises and of making such access possible,[54] except where provision of such access 'would impose unjustifiable hardship on whoever is required to provide such an access.'[55]

Persons with disability have a right to provision of goods and services if they qualify for them.[56] This includes rights relating to provision of housing, accommodation in hotels, access to public places, banking, participation in occupational and other schemes,

[49] *Employment and Industrial Relations Act*, article 30.
[50] *Equal Opportunities (Persons with Disability) Act*, article 11.
[51] *Equal Opportunities (Persons with Disability) Act*, article 11(3).
[52] *Equal Opportunities (Persons with Disability) Act*, article 11(2).
[53] *Equal Opportunities (Persons with Disability) Act*, article 12.
[54] *Equal Opportunities (Persons with Disability)* Act, article 12(1)(c).
[55] *Equal Opportunities (Persons with Disability) Act*, article 12(2)(b).
[56] *Equal Opportunities (Persons with Disability) Act*, article 13.

education facilities, sport, travel, services of any profession or trade, membership of associations, etc. Refusal of accommodation to a person because of his/her disability, or disability of any member of his/her family, is forbidden.[57]

08.10

Positive discrimination, i.e. that intended to give special treatment, grants or benefits, etc. to meet the special needs of persons with disability, is not prohibited;[58] neither is any act aimed at encouraging disabled persons 'to take advantage of opportunities for doing a particular work' that 'prevents or compensates for disadvantages linked to' the disability.[59]

08.11

Insurance cover can provide special difficulties to a person with disability. An insurer is not discriminating against a person with disability when offering discriminatory terms or conditions of insurance, as long as these are based on actuarial/statistical data 'relevant to the assessment of the risk insured.'[60]

Factors to be considered in determining if the need for any modifications or actions required to be undertaken do not impose 'unjustifiable hardship',[61] include, the nature and cost of the actions in question, financial resources available to those required to do the changes and alterations, and availability of public funds for the purpose.

08.12

A National Commission Persons with Disability is established and at least one half of the total members 'shall themselves be persons with a physical disability or family members of persons with a mental disability.'[62] The functions[63] of the Commission include:

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[57] *Equal Opportunities (Persons with Disability) Act*, article 14.
[58] *Equal Opportunities (Persons with Disability) Act*, article 15.
[59] *Equal Treatment in Employment Regulations*, SL 452.95, regulation 6.
[60] *Equal Opportunities (Persons with Disability) Act*, article 16.
[61] *Equal Opportunities (Persons with Disability) Act*, article 20.
[62] *Equal Opportunities (Persons with Disability) Act*, article 21.
[63] *Equal Opportunities (Persons with Disability) Act*, article 22.

(a) assessing national policies and reviewing the working of legislation relating to disability, including ensuring that all relevant government programmes are implemented as well as proposing amendments to policies and law and new initiatives;
(b) ensuring co-ordination between government departments and agencies;
(c) identifying needs of persons with disabilities, of their families and of voluntary bodies working in the field of disability; and taking all measures to fulfil such needs;
(d) monitoring provision of services to disabled persons provided by government or other agencies;
(e) working towards the elimination of discrimination;
(f) providing assistance, including legal and financial aid, to persons with disability, in enforcing their rights;
(g) investigating failure to comply with legislation, on the Commission's initiative or on receiving a complaint; and
(h) collating, analysing and publishing relevant statistics.

5. Special Rights of Persons with Disability

08.13

The law provides for certain dispensations and 'privileges' for persons with disability.

Designated classes of employment: The Minister may designate classes of employment which 'appear to afford specially suitable opportunities for the employment of persons with disability.'[64] For instance, the employment in operating and controlling an electrically driven passenger lift is deemed to be a designated class of employment.[65] Moreover the employer must employ a registered disabled person in an employment in a designated class.[66]

The standard percentage of disabled employees to be employed for the purpose of the ***Persons with Disability (Employment) Act,*** is two per cent.[67]

The National Employment Authority set up under the ***Employment and Training Services Act*** has the function to make

[64] *Persons with Disability (Employment) Act,* article 19(1).
[65] *Designated Employment of Persons with Disability Order,* SL 210.03.
[66] *Persons with Disability (Employment) Act,* article 19(2).
[67] *Standard Percentage of Employment of Persons With Disability Order,* SL 210.02, order 2.

rules as regards the provision of 'special consideration to be given to applicants (for employment) who are disabled, infirm or incapacitated or applicants requiring physical or social rehabilitation.'[68]

08.14

Right to vote: A registered person with disability has the right to vote, and moreover, if he is unable to 'claim delivery of his voting document' because he is in a retirement home, or in a hospital, or suffers from a disability or is bed-ridden or is otherwise physically unable to appear at one of the places designated by the Commission, then, it is the duty of the Electoral Commission 'to effect service of such document on the person concerned either through one of the Commissioners or by any person, appointed for the purpose by the Commission, in their stead.'[69]

Exclusion from VAT: Exemption from VAT is available for the importation of artificial limbs and other surgical appliances of a similar nature, including spare parts and accessories for the relief of permanent bodily disablement, provided that 'they are imported for the purpose of making locally artificial limbs or such other appliances and invalid chairs which the Comptroller of Customs is satisfied are for the exclusive use of a person suffering from some permanent physical defect or disability.'[70] This exemption applies also for 'the importation of goods which are specifically designed for the education, employment or social advancement of a person suffering from some permanent physical or mental disability.'[71]

08.15

Free medical aid: The head of a household, where there is a person with a disability, is entitled to 'the supply of such drugs, spectacles, dentures, and other prosthetic aids,'[72] provided that 'on account of bodily or mental impairment, sickness or disease, which does not require treatment in a hospital, he or any member of his household is in need of medical, surgical or pharmaceutical aid.'

Pension entitlements: A disabled person is entitled to an Invalidity Pension or Increased Invalidity Pension or National Minimum

[68] *Employment and Training Services Act*, article 4(1)(d)(ii).
[69] *General Elections Act*, article 46(9).
[70] *Value Added Tax Act*, Fifth Schedule, 3(1).
[71] *Value Added Tax Act*, Fifth Schedule, 3(2).
[72] *Social Security Act*, article 23(1).

Pension at one of the specified rates, provided that 'immediately before his claim he has been continuously in full-time or regular part-time employment or self-occupation for a period of not less than twelve months, and he has been incapable for suitable full-time or regular part-time employment or self occupation by reason of a serious disease or bodily or mental impairment (other than any mild mental disorder or disturbance) for such number of months or part thereof immediately before his claim as the Director may determine in the appropriate circumstances of the case.'[73]

A person who has attained the age of sixteen years and is certified to be suffering from a mental severe sub-normality or to be a severely disabled person 'shall be entitled to a Disability Pension, ... the highest rate of which, ... shall be such in accordance with Part III of the Sixth Schedule.' Also a person who has attained the age of fourteen years and is certified to be suffering from visual impairment qualifies for a Pension for the Visually Impaired.[74]

08.16

Injury grants and injury pensions: In the case of permanent loss of physical or mental faculty, as long as this is not less than 1% of the total disability, a person is entitled to a pension, and the following considerations hold:

(a) the medical officer shall take account of all such bodily and mental impairments to which the claimant may be expected to be subject, as compared to a person of the same age without these injuries;
(b) an impairment less than 20%, entitles a person to an Injury Grant;[75]
(c) an impairment between 20–89% entitles a person to an Injury Pension;[76]
(d) an impairment 90% or more entitles a person to a full rate of Invalidity Pension or Increased Invalidity Pension or National Minimum Pension.[77]

[73] *Social Security Act*, article 26(1). The rates are specified in the Twelfth Schedule.
[74] *Social Security Act*, article 27.
[75] *Social Security Act*, article 29 and Third Schedule, Part II.
[76] *Social Security Act*, article 29 and Third Schedule, Part III.
[77] *Social Security Act*, article 29 and Twelfth Schedule.

Carer's rights: A female who is single (or widowed) and unemployed, who is taking care on a full-time basis of a relative, living in the same household, who is suffering from a severe physical or mental infirmity, is 'entitled to Social Assistance as a separate household . . . but such assistance shall not exceed 75% of the full rate applicable to a household consisting of one person.'[78]

08.17

Pensions for children: A child suffering from cerebral palsy or from a mental severe sub-normality is eligible to a Disabled Child Allowance till s/he qualifies for a Disability Pension at sixteen.[79] Likewise, a severely disabled person or a visually impaired person is also eligible till the age of fourteen.[80]

Copyrights: 'Reproduction, translation, distribution or communication to the public of a work for the benefit of people with a disability, which are directly related to the disability and on a non-commercial nature, to the extent required by the specific disability' have special dispensations with respect to copyright regulations.[81]

08.18

Protection from discrimination in the press: A person who by means of the publication or distribution in Malta of printed matter, from whatsoever place such matter may originate, or by means of any broadcast, threatens, insults or exposes to hatred, persecution or contempt a person or group of persons with disability (among other things) 'shall be liable on conviction to imprisonment for a term not exceeding three months and to a fine (multa).'[82]

Criminal offences: In the ***Criminal Code***, a contravention against a person is committed when one 'annoys, vexes or scoffs at any imbecile, aged, crippled, feeble or deformed person.'[83]

Offences by disabled persons and the law: Deaf-mute persons who at the time of the offence have not reached the age of fourteen years or those who have attained this age but who have acted

[78] *Social Security Act*, article 30(8).
[79] *Social Security Act*, article 77.
[80] *Social Security Act*, article 77.
[81] *Copyright Act*, article 9(1)(i).
[82] *Press Act*, article 6.
[83] *Criminal Code*, article 339(n).

without 'mischievous discretion' shall be exempted from punishment.[84] On the other hand, those who have acted with mischievous discretion are liable to punishment established by law, but diminished, to take into consideration their condition.[85]

6. Limitations of Rights / Activities

08.19

Tourist guides: No licence is granted to a person unless 'he is medically fit and not suffering from any disability which, in the opinion of the Minister, is likely to interfere with the performance of his services as a guide.'[86]

7. Educational Services for the Disabled

08.20

The ***Constitution of Malta*** states that: 'Disabled persons and persons incapable of work are entitled to education and vocational training.'[87]

As mentioned earlier, it is illegal for an educational authority to refuse admission to a student because of his or her disability or that of a relative.[88]

The Minister is required to make arrangements for the provision of training and vocational services, namely:[89]

(a) vocational guidance services;
(b) vocational training courses;
(c) industrial rehabilitation courses; and
(d) disablement resettlement services.

Moreover, the Minister is required to defray or contribute towards the cost incurred in the provision of such courses, including expenses incurred in travelling to and from the place where the course is held, and may also grant other assistance in kind.[90]

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[84] *Criminal Code*, article 39.
[85] *Criminal Code*, article 40.
[86] *Tourist Guide Services Act*, article 5(1)(b).
[87] *Constitution of Malta*, article 17(3).
[88] *The Equal Opportunity (Persons with Disability) Act*, article 11.
[89] *Persons with Disability (Employment) Act*, article 3.
[90] *Persons with Disability (Employment) Act*, article 4.

The ***Education Act*** provides basic legislation for those described as having 'special needs'. 'It is the duty of the State to provide special schools for the children of Maltese citizens being minor children having special educational needs.'[91] These occur when a minor has 'special difficulties of a physical, mental or psychological nature.'[92]

08.21

Regulations relating to admission to University state that a candidate may also be admitted as a regular student of the University if he 'suffers from some severe physical disability which would have made it difficult for him to obtain the required entry qualification and has been judged eligible for admission by the Admissions Board.'[93]

In relation to examinations, the University Examinations Regulations[94] make special provisions 'to assist persons with special needs to be able to sit for its examinations,' provided that such assistance does not give undue advantage to the student. Special exemption regulations exist for particular elements of an examination (e.g. orthography, an oral, or a practical).[95] The certificate obtained will be endorsed as follows: 'Special arrangements were made to enable the candidate to be assessed in this subject. Details may be obtained from the Registrar.'[96] It is to be noted that this could be interpreted as a permanent stigma on such a certificate, giving the impression that the candidate had a special advantage in obtaining such a certificate. However article 7 also states that such certificates shall only be issued as a last resort when ways cannot be found of supporting disabled candidates to satisfy examination requirements.

The Institute For Child Development is set up at the University of Malta as an inter-Faculty and inter-agency institution and one of its aims is 'to organise, provide and research multidisciplinary

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[91] *Education Act*, article 18(1).

[92] *Education Act*, article 18(2).

[93] *Education Act*, Schedule II, B - Regulations and Bye-Laws, RO1 Admission Regulations 1997, regulation 2.2(a)(v) and 2.2(b).

[94] *Education Act*, Schedule II, R02 – University Examinations Regulations, 1997, regulation 7, Special Needs.

[95] *Education Act*, Schedule II, R02 – University Examinations Regulations, 1997, regulation 7.2.

[96] *Education Act*, Schedule II, R02 – University Examinations Regulations, 1997, regulation 7.2.

habilitation/rehabilitation programmes for children with special needs and their families in co-operation with governmental and non-governmental agencies,'[97] and to set up courses and service Faculties and other institutions in the field of child development especially with regard to the area of children with special needs.[98] In fact the University also provides a Diploma in Education for Children with Special Needs, offered by the Faculty of Education.[99]

8. Quality of Life

08.22

The ***Commissioner for Children Act***[100] provides for the creation of the post of Commissioner for Children, one of whose guidelines is to ensure that 'disabled children and children with disadvantaged family or social circumstances should enjoy the same quality of life like all other children.'

The Collective Agreement for public officers (2002–2004) binds the Government to take the necessary initiatives to 'enhance, as far as possible, the status of disabled employees and their opportunities of advancement.'[101]

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[97] *Statute I 16, Institute for Child Development Statute*, SL 327.48, article 3(b).

[98] *Statute I 16, Institute for Child Development Statute*, SL 327.48, article 3(c) and 3(d).

[99] *Education Act*, Schedule II, A – Statutes, Statute 3 – Courses of Studies, Degrees and Distinctions – 3.1 Courses of Studies for Degrees, Diplomas and Certificates.

[100] *Commissioner for Children Act*, article 10(c).

[101] Public Service Management Code, 6th edition, December 2005, *Persons with a Disability, General*, paragraph 9.5.1. See also paragraph 1.1.19, *Special Arrangements for Persons with Disability applying for Posts /Positions in the Public Service.*

Chapter 9

Mental Health

09.01

Why is mental health considered to be such a different aspect of health from a societal, ethical and legal point of view? The reason is partly historical, in that for centuries persons declared to be insane were treated little better than animals, ignored at best, beaten, maltreated and locked up most times.

More relevant from our point of view is the fact that mental health is often associated with loss of autonomy and incapacity to give consent to treatment and care, making one dependent, often completely, on the actions of others. Hence the special role of bioethical and legal considerations relating to mental disorders.

1. Definitions

09.02

Mental disorder means mental illness, arrested or incomplete development of mind, psychopathic disorder, and any other disorder or disability of mind.[1]

Personal injury includes any disease and any impairment of a person's physical or mental condition.[2]

Psychopathic disorder means a persistent disorder or disability of mind (whether or not including subnormality of intelligence), which results in abnormally aggressive or seriously irresponsible conduct on the part of the patient, and requires or is susceptible to medical treatment.[3]

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[1] *Mental Health Act*, article 2(1).
[2] *Employment and Industrial Relations Act*, article 2(1).
[3] *Mental Health Act*, article 2(1).

Subnormality means a state of arrested or incomplete development of mind (not amounting to severe subnormality), which includes subnormality of intelligence and is of a nature or degree, which requires or is susceptible to medical treatment or other special care or training of the patient.[4]

Severe subnormality means a state of arrested or incomplete development of mind, which includes subnormality of intelligence and is of such nature or degree that the patient is incapable of living an independent life or of guarding himself against serious exploitation, or will be so incapable when of an age to do so.[5]

Promiscuity or other immoral conduct is not to be construed as mental disorder.[6]

Hospital for mental diseases: There is only one hospital in Malta for Mental Diseases, namely, Mount Carmel Hospital and one in Gozo, namely, Gozo General Hospital. Any reference to the Hospital for Mental Diseases is to be understood in this way.[7]

2. Admission of Patients to a Mental Hospital

09.03

Admission of patients to a mental hospital can be either voluntary ('informal') or compulsory. Voluntary patients have the rights of any other patients in other (non-mental) hospitals, including the right to refuse any treatment or to leave hospital when they so desire. In the case of involuntary or compulsory admission, there are far more restrictions on the rights of patients and therefore these need strict control and regulation.

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[4] *Mental Health Act*, article 2(1).

[5] *Mental Health Act*, article 2(1). A similar definition is found in article 2 of the *Social Security Act*.

[6] *Mental Health Act*, article 2(2).

[7] *Mental Health Act*, article 2(1) still mentions Chambrai Hospital, though the Act was amended in 2001, whil *Designation of Places as Hospital Order*, SL 262.04, article 2(1) of 2000 mentions Gozo General Hospital. The Act includes mental nursing homes under the definition of hospital and makes provisions for residential homes for mentally disordered persons. Such homes include two wards in Mount Carmel Hospital, as established by article 2(2) of SL 262.04. These are also acute psychiatric wards in St Luke's Hospital and Gozo General Hospital.

a. Informal admission

09.04

Patients may be admitted 'informally' to a mental hospital or mental nursing home. This means that a patient may be admitted for treatment of mental disorder 'without any application, order or direction rendering such patient liable to be detained therein under the ***Mental Health Act.***'[8]

The ***Mental Health Act*** extends this right of voluntary admission to a person who has attained the age of sixteen years and who is capable of expressing his/her own wishes, 'notwithstanding any right of custody or control vested by law in his parent or tutor.'[9] There is no legal provision for such a right with regards to entry to other hospitals.

b. Compulsory admission

09.05

Compulsory admission to a hospital, either for (a) observation or for (b) treatment, represents a serious breach of the patient's rights and therefore needs careful legislative attention. Part III of the ***Mental Health Act*** is devoted to the issue of compulsory admission for observation or for treatment.

For such a compulsory admission, the following grounds are required:[10]

(a) that the individual is suffering from mental disorder of a nature or degree which warrants the detention of the patient in a hospital; and
(b) that it is necessary that s/he be so detained in the interests of his/her own health or safety or with a view to the protection of other persons.

Application for any admission to hospital can be made by the nearest relative or by a mental welfare officer.[11] The application has

[8] *Mental Health Act*, article 3(1).
[9] *Mental Health Act*, article 3(2).
[10] *Mental Health Act*, article 4(2).
[11] *Mental Health Act*, article 16(1).

to be addressed to the manager of the hospital to which admission is sought. The application must specify the qualification of the applicant making the application. An application for admission has to be made by a person who has personally seen the patient within 14 days.[12]

09.06

The nearest relative is defined as (a) the husband or wife; (b) the son or daughter; (c) the father; (d) the mother; (e) the brother or sister; (f) the grandparent; (g) the grandchild; (h) the uncle or aunt; or (i) the nephew or niece.[13]

The nearest relative can object in writing to the mental welfare officer or to the Superintendent of Public Health to an application being made for admission for treatment.[14] In such case, an application cannot be made by a mental welfare officer. Moreover a mental officer must consult the nearest relative before making any application for treatment, except where consultation by the officer would involve considerable delay.[15]

An application for admission must be verified by the written recommendations, on the prescribed form, given either jointly or separately by two medical practitioners, who must specify that the above grounds are satisfied.[16] Also, in the case of an application for admission for treatment, they must give detailed reasons for their opinion and must specify why other treatment methods are not appropriate.[17] They have to examine the patient together or at an interval of not more than three days.[18]

The application is sufficient authority for the applicant, or any person authorised by him/her in writing, to take the patient to the hospital within fourteen days from the date appearing on the medical recommendation last given.[19] The application is sufficient

[12] *Mental Health Act*, article 16(3).
[13] *Mental Health Act*, article 30(1).
[14] *Mental Health Act*, article 16(2).
[15] *Mental Health Act*, article 16(2).
[16] *Mental Health Act*, article 14(3).
[17] *Mental Health Act*, article 14(3).
[18] *Mental Health Act*, article 17(1).
[19] *Mental Health Act*, article 19(1).

authority for the manager to detain the patient in the hospital in accordance with the provisions of this Act.[20]

c. Emergency compulsory admission

09.07

In the case of an emergency,[21] a patient may be admitted for observation and detained, if an emergency application states the urgent necessity, which is verified by the recommendation of just one medical practitioner (preferably by one who has had previous acquaintance with the patient), and also states that compliance with the other provisions of Part III of the ***Mental Health Act*** regulating compulsory admission to hospital would involve undesirable delay.[22] It is worth noting that such an order expires after seventy-two (72) hours unless a second medical recommendation is made and received by the manager within that period and provided that both recommendations comply with article 17 of the enactment under examination.[23]

An applicant can be a relative or mental health officer but they must have personally seen the patient within 3 days.[24]

In the case of a prisoner, an emergency application can be made by the Director of Prisons.[25]

An emergency application is sufficient authority for the applicant, or any person authorised by him/her in writing, to take the patient to the hospital within two days from the date appearing on the medical recommendation.[26] An emergency application can

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[20] *Mental Health Act*, article 19(2).

[21] *Mental Health Act*, article 15(1).

[22] *Mental Health Act*, article 15(2).

[23] *Mental Health Act*, article 15(3)(b).

[24] *Mental Health Act*, article 16(3).

[25] *Mental Health Act*, article 16(1). Compulsory admission may also result following a court-martial. Article 122 of the *Malta Armed Forces Act* states that when a court-martial finds that an accused is unfit to stand trial because of mental health ('by reason of insanity'), the accused shall be kept in custody in Mount Carmel Hospital under conditions stipulated in Part IV of the *Mental Health Act*. If the reviewing authority quashes a finding of not guilty by reason of insanity (but does not substitute another finding), it may still order continued detention if it considers it necessary for the person's health or safety, or that of others.

[26] *Mental Health Act*, article 19(1).

be sufficient authority for the manager to detain the patient in the hospital in accordance with the provisions of the ***Mental Health Act***.[27]

d. Medical recommendations

09.08

Article 17 of the ***Mental Health Act*** refers specifically to medical recommendations. Medical practitioners, as referred to above, have to examine the patient together or at an interval of not more than three days.[28] Of the medical practitioners in question, one must have special experience in diagnosis or treatment of mental diseases and has to be approved for this purpose by the Minister. Previous acquaintance with the patient by one or other of the practitioners (if practicable) is desirable but not essential.[29]

In an emergency, the urgent necessity must be verified by the recommendation of just one medical practitioner (preferably by one who has had previous acquaintance with the patient) but a second medical recommendation must be received by the manager within seventy-two (72) hours.[30]

The doctor giving a medical recommendation, even in an emergency, cannot be: (a) the applicant or the applicant's partner or employee; (b) the spouse or relative or partner or employee of the other doctor giving a recommendation; (c) interested in the payments made on account of the maintenance of the patient; or (d) the spouse or relative, up to the second degree, of the patient.[31]

Moreover a recommendation cannot be made by a doctor if the patient is the husband, wife or relative by consanguinity or affinity up to the second degree.[32]

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[27] *Mental Health Act*, article 19(2).
[28] *Mental Health Act*, article 17(1).
[29] *Mental Health Act*, article 17(2).
[30] *Mental Health Act*, article 15(3).
[31] *Mental Health Act*, article 17(3).
[32] *Mental Health Act*, article 17(3).

e. Change of admission of inpatients[33]

09.09

An application for compulsory admission for observation or treatment may be made with respect to a voluntary inpatient. An application for compulsory admission for treatment may be made with respect to a patient already compulsorily admitted for observation. Compulsory admission starts when the manager receives the application.

In fact, nothing should 'preclude a patient admitted to a hospital in pursuance of an application for (compulsory) admission for observation from receiving such medical treatment as the responsible medical officer considers appropriate.'[34]

However if the doctor in charge of the voluntary patient's treatment sees the need for compulsory admission for observation or for treatment, s/he may furnish a report in writing to the manager to that effect, and the patient may be detained for a period of three days beginning with the day on which the report is so furnished.[35]

f. Compulsory admission by Court Order

09.10

Compulsory detention may be ordered by a court which may 'order the accused to be kept in custody in Mount Carmel Hospital there to remain in custody and detained according to the provisions of Part IV of the ***Mental Health Act***, or any other provision of law or enactment applicable to the case, and those provisions shall apply to the accused accordingly.'[36]

In the case of an allegation of insanity raised before the Court of Magistrates as a Court of Criminal Inquiry, the court first appoints 'one or more experts to examine the accused and the facts relating to the alleged insanity'[37] before ordering compulsory detention. Any allegation of insanity before the Criminal Court must be determined by a jury.[38]

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[33] *Mental Health Act*, article 18.
[34] *Mental Health Act*, article 14(4).
[35] *Mental Health Act*, article 18(4).
[36] *Criminal Code*, article 623(1).
[37] *Criminal Code*, article 402(3).
[38] *Criminal Code*, article 620(1).

The special case of patients involved in criminal proceedings, including those under detention for observation, those charged with criminal offences and those pleading insanity, is dealt with in Part IV of the ***Mental Health Act***.[39] The main ethical issue is not so much the deprivation of persons of their rights but to what extent do such persons have the right to informed consent. While they may be fully capable of deciding on diagnostic tests to be performed and the type and quality of treatment they would want to receive, they obviously have no say in matters relating to compulsory detention.

09.11

'Where in the course of any proceedings on the charge of a criminal offence the question' arises relating to 'the insanity of the accused, whether at the time of the offence or of the proceedings,' the Court has the right to order detention in a mental hospital for the purpose of observation for a period of time determined by the Court.[40]

Upon a finding of insanity, at the time of offence, whether or not insane at the time of criminal proceedings, the Court may direct that the accused be kept in custody in a hospital. In such a case 'the accused shall be conveyed to and detained and kept in custody in that hospital by virtue of the order of the court and shall be treated as if he were a patient liable to be detained in a hospital under Part III of this Act,' but subject to certain provisions, namely that only the Minister for Justice, acting on advice by medical officers, may order leave, transfer and discharge and that there can be no appeal to the Mental Health Tribunal except through the Minister for Justice.[41]

If the accused is detained because of insanity only at the time of the proceedings, and subsequently recovers sufficiently to stand trial, the Minister may remit the accused to prison for the continuation of the proceedings on the charge preferred against him, subject to the application thereafter of the provisions of the ***Criminal Code*** relating to the granting of bail.

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[39] *Mental Health Act*, article 42 *et seq.*
[40] *Mental Health Act* article 42.
[41] *Mental Health Act*, article 43.

09.12

Compulsory detention and appropriate treatment may also be ordered by a court in relation to a drug offender. The ***Probation Act*** states that: 'Where in the opinion of the court the mental condition of the offender is such as requires and as may be susceptible to treatment, but not such as to justify other measures or procedures, or where the court is satisfied that (a) the offender is a drug addict; and (b) that proper arrangements have been or can be made for treatment, a probation order may include a requirement that the offender shall submit to treatment not exceeding the length of the order by or under the directions of a suitably qualified person with a view to the improvement of the offender's mental condition or with a view to freeing the offender from drug addiction.'[42]

The Minister may direct a person serving a sentence of imprisonment to be transferred to a mental hospital, following the report by two medical practitioners,[43] for the length of the sentence imposed on him/her.[44]

g. Correction of application and recommendations

09.13

Provision exists for correction of any application for admission for observation or for treatment, or for any medical recommendation, so long as there is the consent of the manager of the hospital.[45] The correction must be made by the person originally signing, within fourteen (14) days, beginning with the day on which a patient has been admitted to the hospital. It shall then have effect as if it was the original, signed on the original date.

If within 14 days of an application, the manager finds an insufficient medical recommendation, s/he is to inform the applicant and if another recommendation is submitted within those 14 days, that counts as if it was originally sufficient.[46] If both medical recommendations are insufficient to warrant detention of the patient, the manager has also to inform the

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[42] *Probation Act*, article 7(5).
[43] *Mental Health Act*, article 17.
[44] *Mental Health Act*, article 44.
[45] *Mental Health Act*, article 20.
[46] *Mental Health Act*, article 20(2).

applicant but another recommendation must be received within the 14 days. This applies also to errors in an emergency application but the 72 hour interval for the second recommendation must be complied with.[47]

h. Duration of detention

09.14

A patient admitted to hospital in pursuance of an application for admission for observation may be detained in a hospital for a period not exceeding twenty-eight (28) days and shall than be discharged, unless an application for detention for treatment is received in this period.[48]

A patient admitted to hospital in pursuance of an application for admission for treatment may be detained in a hospital for a period not exceeding one year.[49] This may be renewed (for a year and then for two successive year periods) subject to special provisions. If the responsible medical officer, having examined the patient determines that 'in the interests of the patient's health or safety or for the protection of other persons' it is necessary to detain the patient further, s/he has the authority to request such a detention (in writing, and on the prescribed form).[50]

If the patient in question is one who has attained the age of sixteen years, during the detention year, the patient may apply to the Mental Health Review Tribunal.[51]

09.15

'Where in the course of any proceedings on the charge of a criminal offence the question of the insanity of the accused, whether at the time of the offence or of the proceedings, arises,' the Court has the right to order detention in a mental hospital for the purpose of observation for a period of time determined by the Court.[52]

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[47] *Mental Health Act*, article 20(4).
[48] *Mental Health Act*, article 21(1).
[49] *Mental Health Act*, article 21(2).
[50] *Mental Health Act*, article 21(4).
[51] *Mental Health Act*, article 21(6).
[52] *Mental Health Act*, article 42(1).

Only the Minister for Justice, acting on the advice of medical officers, may order leave, transfer and discharge. There can be no appeal in such instance.[53]

If the accused is detained because of insanity only at the time of the proceedings, and subsequently recovers sufficiently to stand trial, the Minister may remit the accused to prison for the continuation of the proceedings on the charge preferred against him/her, subject to the application thereafter of the provisions of the ***Criminal Code*** relating to the granting of bail.

The Minister may direct a person serving a sentence of imprisonment to be transferred to a mental hospital, following the report by two medical practitioners,[54] for the length of the sentence imposed on him/her or if two medical officers are satisfied that s/he does not require detention any more.

3. Correspondence for and by Patients

09.16

The ***Mental Health Act*** restricts the rights of patients to receive correspondence if the responsible medical practitioner believes this to be harmful to the patient.[55] A postal article from a patient can also be withheld by the manager of the hospital if the addressee had given such an instruction, or if the Manager believes that the article might contain defamatory or other offensive material or against the interests of the patient. However, the manager has no right to hold correspondence addressed to the following:

(a) a member of the House of Representatives;
(b) the manager of the hospital;
(c) any other authority or person having the power to discharge the patient; or
(d) the Mental Health Review Tribunal.

Neither the manager nor the responsible medical officer can open any postal article unless the medical officer thinks that the patient's mental disorder is likely to make him/her send such communications.

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[53] *Mental Health Act*, article 43. However the Minister may refer the case of the patient to the Tribunal, for advice.
[54] *Mental Health Act*, article 17, as discussed above.
[55] *Mental Health Act*, article 22(1).

This restriction represents a considerable, albeit necessary, infringement of the patient's rights, softened somewhat by the requirements that correspondence relating specifically to detention in hospital is not restricted in any way.

4. Leave of Absence from Hospital

09.17

Permission may be granted for the patient to leave the hospital for a specified period or on indefinite leave. For this purpose, the responsible medical officer may direct that during his/her absence the patient remains in custody of the nearest relative or other person, designated in writing by the manager, when it is considered that this is in the interests of the patient's health or safety or for the protection of other persons.[56] Leave may be revoked by the medical officer by notice in writing to the patient or to the custodian.

A patient who is absent without leave or who fails to return to hospital from leave, 'may be taken into custody and returned to the hospital or place by any mental welfare officer, by any officer of the staff of the hospital, by any Police officer, or by any person authorised in writing by the manager of the hospital.'[57]

If during absence without leave, a patient ceases to be liable to be detained under this Act, s/he will have to be detained for an additional time.[58]

09.18

An order for discharge following admission for observation may be made by the responsible medical officer or by the manager of the hospital but in the case of admission for treatment this may be made by the responsible medical officer, by the manager of the hospital or by the nearest relative of the patient.[59] The relative's request is conditional on the doctor's assent and must therefore be given in writing to the manager. The doctor is allowed seventy-two (72) hours to advice against discharge. Such a refusal restricts the relative from making a further request within six (6) months.[60]

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[56] *Mental Health Act*, article 24.
[57] *Mental Health Act*, article 25.
[58] *Mental Health Act*, article 26.
[59] *Mental Health Act*, article 28.
[60] *Mental Health Act*, article 29.

The relative may however apply to the Mental Health Review Tribunal in respect of the patient.

With a patient in a mental nursing home in pursuance of an application for admission for observation, or for treatment, an order for his/her discharge may also be made by the Superintendent of Public Health.

5. Review by the Mental Health Review Tribunal

09.19

One of the more significant aspects of the ***Mental Health Act*** is the establishment of a Mental Health Review Tribunal, presided over by a person who holds or has held the office of a judge of the superior courts, two other members, one being a medical officer, and a secretary, all appointed by the Minister. The functions of the Tribunal include dealing with applications made to it, and in particular to determine whether a patient may be discharged because she is not mentally ill, or if s/he is, because s/he is not a danger to him/herself or others. This represents another important safeguard with regards to patient's rights. Moreover it also includes appeal from a previously refused discharge.[61] Applications are received by the secretary in writing, from the patient or in his/her respect, from a person authorised by him/her,[62] or even from the Minister.[63]

The Tribunal may decide:

(a) not to consider another application until a year has passed, but this postponement does not apply if the hospital authority changes in the interval,[64] or if application is made in accordance with article 21[65] and article 29[66] or if the minister applies rule 17(a);[67]

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[61] *Mental Health Act*, article 29(2).

[62] *Mental Health Act*, article 40 and *Mental Health Review Tribunal Rules*, SL 262.03, rule 3.

[63] *Mental Health Act*, article 35.

[64] *Mental Health Review Tribunal Rules*, rule 4(2). The *Mental Health Review Tribunal Rules*, SL 262.03, are not yet in force.

[65] Such an application made under article 21 of the *Mental Health Act* concerns the duration of authority for detention of a patient.

[66] Article 29 of the *Mental Health Act* deals with restrictions on discharge by the nearest relative.

[67] Rule 17(a) of the *Mental Health Review Tribunal Rules* regards references made to it by the Minister responsible for Public Health.

(b) not to hold a hearing, but to allow the person the chance of an interview, in keeping with rule 16(2). This is the procedure when a hearing is not requested by the applicant or when if so requested, the Tribunal decides this would be detrimental to the patient's health.[68] It is also the procedure to deal with an application by the Minister, as provided for in rule 18.

The hearing shall be private unless so requested by the applicant and it is not detrimental to the patient's health. Also the reports or names therein may be prevented from publication.[69] Patients may be represented by someone else.

09.20

Information about a patient must be supplied by the responsible authority to the Mental Health Review Tribunal.[70] The Tribunal 'shall on request make available to the applicant and the responsible authority copies of any other documents obtained by or furnished to the tribunal for the purposes of the application and a statement of the substance of any oral information so obtained or furnished,' except where the Tribunal considers it undesirable in the interests of the patient or for other special reasons.[71]

The Tribunal may authorise one of its members from the medical profession, to examine the patient in private and look at his medical records,[72] and may interview the patient in private or in the presence of any other person.[73] The patient may be represented by another.[74]

The Tribunal's decision is communicated to the applicant, the authority and the patient,[75] and the first two may request reasons for the decision reached by the Tribunal. However the Tribunal may withhold any statement from a patient or any other person and disallow publication of all or part of the decision, if it is not in the interests of the patient or for any other reasons.

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[68] *Mental Health Review Tribunal Rules*, rule 22.
[69] *Mental Health Review Tribunal Rules*, rule 23.
[70] *Mental Health Review Tribunal Rules*, rule 6.
[71] *Mental Health Review Tribunal Rules*, rule 12(1).
[72] *Mental Health Review Tribunal Rules*, rule 10.
[73] *Mental Health Review Tribunal Rules*, rule 11.
[74] *Mental Health Review Tribunal Rules*, rule 9.
[75] *Mental Health Review Tribunal Rules*, rule 26.

09.21

Any medical practitioner authorised by or on behalf of the patient or person entitled to make an application, may 'at any reasonable time, visit, interview and examine the patient in private and, for such purpose, may require the production of and may inspect any documents relating to the detention of the patient and any other medical records relating to the treatment of the said patient.'[76]

The purpose of this examination is related to an application to the Mental Health Review Tribunal and the doctor's examination is:

(a) to advise whether such an application should be made;
(b) furnish information as to the condition of the patient for the application;
(c) advise as to the exercise, by the nearest relative, of the power to order discharge.[77]

6. Safeguards to Patients' Rights

09.22

The ***Mental Health Act*** provides several safeguards meant to ensure that the patient is protected from unlawful detention, namely:

(a) the requirement that there must be two medical practitioners, one of whom must have special qualifications in the subject and be specially selected by the Minister;
(b) other requirements relating to medical practitioners include not being able to make both an application and a recommendation for the same patient;
(c) not being able to make a recommendation in relation to:
    (i) relatives, up to the second degree; or
    (ii) patients for whom they receive maintenance payments; or
    (iii) if they are the partner or employee of the applicant; or
    (iv) if they are relatives, or linked through work or other financial interests, to the other medical doctor;
(d) the establishment of a Mental Health Review Tribunal to which applications for review and objections can be sent. It has many discretionary powers as to what it thinks is detrimental to the patient;

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[76] *Mental Health Act*, article 23.
[77] *Mental Health Act*, article 23.

(e) special regulations relating to those who reach the age of 16 years (in terms of voluntary admission,[78] and in the case of involuntary admission, to appeal to the Mental Health Review Tribunal;[79] and
(f) the right of inspection of documents prior to application to the Mental Health Review Tribunal by the doctor authorised by the patient or applicant.[80]

7. Involvement of Mental Patients in Research Procedures

09.23

Patients with a mental disability may be incapable of giving informed consent. Several measures have been taken to ensure that research involving mental patients is performed only under certain restrictive conditions. The ***Mental Health Act*** does not refer to involvement of such patients in research.

The Council of Europe's ***Convention on Human Rights and Biomedicine*** makes several stipulations relating to research regarding persons not able to consent to research.[81] In addition to the normal requirements for any clinical research, as discussed in **Chapter 12: Research**, the Convention stipulates that such research may be carried out only if:

(a) the results of the research have the potential to produce real and direct benefit to the health of the person taking part in the research;
(b) research of comparable effectiveness cannot be carried out on individuals capable of giving consent;
(c) the necessary authorisation provided for under Article 6[82] has been given specifically and in writing; and
(d) the person concerned does not object.

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[78] *Mental Health Act*, article 3(2).
[79] *Mental Health Act*, articles 19(3)(b) and 21(6).
[80] *Mental Health Act*, article 23.
[81] *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, Council of Europe, 1997, Article 17.
[82] Article 6 of the *Convention on Human Rights and Biomedicine* deals with the protection of persons not able to give their consent.

Moreover, where the research does not have the potential to produce results of direct benefit to the health of the person concerned, such research may be authorised, in exceptional circumstances, where:

(a) the research has the aim of contributing, through significant improvement in the scientific understanding of the individual's condition, disease or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition; or
(b) the research entails only minimal risk and minimal burden for the individual concerned.[83]

8. Representation of the Mentally Disabled on Commissions and Public Bodies

09.24

It is now well accepted that patients should be represented on bodies which regulate their way of life. Patients' representatives should be included in all bodies that are involved in formulating procedures relating to patients' activities and interests, including research procedures. In the case of a mental disability, a relative of a patient with disability is required to be included.

Maltese legislation has some reference to the compulsory representation of patients with mental disability on such public bodies.

(a) The ***Equal Opportunities (Persons with Disability) Act*** states that the Commission set up under this Act is to have at least seven of its 14 members with a physical disability or family members of persons with a mental disability.[84] The Chairman or Deputy Chairman of the Commission appointed by the Prime Minister is himself to be a person with a disability or a family member of a person with a mental disability.[85]

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[83] *Convention on Human Rights and Biomedicine*, Article 17.
[84] *Equal Opportunities (Persons with Disability) Act*, article 21(2). Under this Act, disability means 'a physical or mental impairment that substantially limits one or more of the major life activities of a person.'
[85] *Equal Opportunities (Persons with Disability) Act*, article 21(3).

(b) The Commission may initiate investigations about allegedly unlawful acts,[86] or on receipt of complaints, in writing, from an aggrieved person, or from 'any person who is the parent, or legal curator or family member of a person with a mental disability.'[87]

The Commission has a duty to take reasonable steps to provide appropriate assistance to a person who wishes to make a complaint and requires assistance to formulate the complaint orally and/or in writing.[88]

9. Restriction of Civil Rights for Persons with Mental Disability

09.25

Persons with mental disability often find themselves restricted with regards to what they are free to do. Compulsory detention means loss of freedom of movement. It often also means loss of control of personal activities, communication and intercourse with society in general. It is therefore important to ensure that such limitations are reduced to the absolute minimum compatible with court, medical or other restriction orders, and that they are not retained for longer than absolutely necessary.

The ***Civil Code*** defines the categories of persons who may be interdicted or incapacitated. It states that: 'A major who is in a state of imbecility or other mental infirmity or is prodigal, may be interdicted or incapacitated from doing certain acts.'[89] This applies also to a minor, over 16, who is carrying on a trade.[90] The disability of persons interdicted is either general, in regard to all agreements, or special in regard to certain agreements only.[91]

A demand for interdiction 'in the case of idiocy or other mental infirmity' may be made by the Attorney General, unless the demand had been made by any other person.[92]

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[86] *Equal Opportunities (Persons with Disability) Act*, article 32(1).
[87] *Equal Opportunities (Persons with Disability) Act*, article 32(2)(b).
[88] *Equal Opportunities (Persons with Disability) Act*, article 32(3).
[89] *Civil Code*, article 189(1), which refers to articles 520 to 527, inclusive, of the *Code of Organization and Civil Procedure.*
[90] *Civil Code*, article 156.
[91] *Civil Code*, article 972, which refers to Title IV of Part II of Book Second of the *Code of Organization and Civil Procedure.*
[92] *Code of Organization and Civil Procedure*, article 521(d).

Making a will: A person is deemed incapable of making a will if s/he is interdicted on the ground of insanity or if a person is not of sound mind at the time of the will. Moreover any will made by a person subject to incapacity is null even though the incapacity ceases before his/her death.[93]

09.26

Contracting: The conditions essential to the validity of a contract include:[94]

(a) capacity of the parties to contract; and
(b) the consent of the party who binds himself/herself.

Persons interdicted or incapacitated are incapable of contracting.[95] However, 'persons capable of contracting may not set up the nullity of the contract on the ground of the disability of those with whom they have contracted.'[96]

Capacity to sue or to be sued: A 'lunatic or an insane person,' is excluded from the capacity of suing or being sued.[97]

Competency to serve as a juror: Among the list of persons who are not competent to serve as jurors, we find 'persons who are interdicted or incapacitated' and 'persons who, owing to any notorious physical or mental defect, are reputed to be unfit to serve as jurors.'[98] Moreover, 'a person who has the care of a family or of a person who suffers from any physical or mental infirmity shall also be exempt from serving as a juror.'[99]

Prohibited immigrant: A person is considered to be a prohibited immigrant 'if he is suffering from mental disorder or is a mental defective.'[100] A person can be so considered even if the Principal Immigration Officer had approved landing or if s/he had been granted a residence permit.

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[93] *Civil Code*, article 599.
[94] *Civil Code*, article 966.
[95] *Civil Code*, article 967(3).
[96] *Civil Code*, article 973.
[97] *Code of Organisation and Civil Procedure*, article 781(b).
[98] *Criminal Code*, article 603(4)(a) and(4)(c).
[99] *Criminal Code*, article 604(3).
[100] *Immigration Act*, article (5)(2)(b). However the Act provides for the granting of certain exemptions.

09.27

Standing for elections and voting:

(a) A person is not qualified to stand for local Council elections, or to remain a member thereof if 'he is interdicted or incapacitated for any mental infirmity or for prodigality by a court in Malta, or is otherwise determined to be of unsound mind.'[101]

(b) No person shall be qualified to be elected as a member of the House of Representatives 'if he is interdicted or incapacitated for any mental infirmity or for prodigality by a court in Malta, or is otherwise determined in Malta to be of unsound mind.'[102]

(c) No person shall be qualified to be registered as a voter at a General Election for the election of members of the House of Representatives if 'he is interdicted or incapacitated for any mental infirmity by a court in Malta or is otherwise determined in Malta to be of unsound mind.'[103] The Registrars of the Courts in Malta and Gozo have the duty to prepare a list of persons who have been interdicted for reasons of mental incapacity by a competent court[104] and to forward to the Electoral Commission this information, which is to contain the name, surname, identity card number, if any, and other particulars of each person.[105] The Commission is required to obtain the decision of the Medical Board before refusing to register a person as a voter or before removing his/her name from the Electoral Register.[106] The decision of the Medical Board, that a voter is of unsound mind, has to be unanimous.[107]

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[101] *Local Councils Act*, article 12(g).

[102] *Constitution of Malta*, article 54(1)(e).

[103] *Constitution of Malta*, article 58(a).

[104] *Code of Organization and Civil Procedure*, article 527(3).

[105] *General Elections Act*, article 20(4). This article also requires publication, in the Government Gazette, of persons interdicted or incapacitated. The purpose of publication is to protect innocent third parties who may enter into a contract with an interdicted person or who may end up defrauded.

[106] *General Elections Act*, article 27(1).

[107] *General Elections Act*, article 27(3).

10. Special Rights of Patients with a Mental Disorder

09.28

Maltese legislation specifies particular rights and exemptions enjoyed by persons with a mental disorder.

Right to special education where required: The State has the duty to provide special schools for children of Maltese citizens who have special educational needs, that is, 'when that minor has special difficulties of a physical, mental or psychological nature.'[108]

Right to correspond with the Ombudsman: A person in custody, including 'any patient in any hospital within the meaning of the ***Mental Health Act,***' has the right to have any letter addressed to the Ombudsman to be 'immediately forwarded unopened, to the Ombudsman by the person for the time being in charge of the place or institution where the writer of the letter is detained or of which s/he is a patient. Any letter written by the Ombudsman to a person or patient so described shall be immediately forwarded, unopened, to such person or patient by the person for the time being in charge of the place or institution.'[109]

Exemption from appearing in court because of a mental disability: A number of instances are enumerated relating to the situation where a person cannot appear in court by virtue of having a mental incapacity. In such an instance, the lawful representative is expected to represent the person with the disability. Such instances include:

(a) where a summons is issued to order that a nuisance be abated;[110]
(b) offences relating to the ***Housing Act;***[111]
(c) offences relating to the ***Public Health Act;***[112]
(d) offences relating to the ***Explosives Ordinance.***[113]

Exemption from being sued: Persons with a mental disability cannot be sued.[114]

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[108] *Education Act*, article 18.
[109] *Ombudsman Act*, article 16(2).
[110] *Code of Police Laws*, article 321(3).
[111] *Housing Act*, article 19(1).
[112] *Public Health Act*, article 40(5).
[113] *Explosives Ordinance*, article 48(1).
[114] *Code of Organization and Civil Procedure*, article 781(b).

Offences by persons who (temporarily) do not have full mental capacity: A person is exempt from criminal responsibility if at the time of the act or omission complained of, such person was in a state of insanity.[115] Wilful homicide is excusable 'where it is committed by any person acting under . . . mental excitement in consequence of which he is, in the act of committing the crime, incapable of reflecting.'[116]

Right to refuse to provide a specimen by person involved in a traffic infringement: A person may refuse to provide a specimen for testing in the laboratory (for alcohol, drugs etc.) without being guilty of an offence if s/he can prove that such failure to provide a specimen was due to physical or mental incapacity.[117]

09.29

Tax Exemptions: Tax exemptions are permitted with regard to the importation of goods which are specifically designed for the education, employment or social advancement of a person suffering from some permanent physical or mental disability, provided that the Comptroller of Customs is satisfied that the said goods are imported for the exclusive use of such person.[118]

11. Employment and Persons with Disability

09.30

The ***Equal Opportunities (Persons with Disability) Act*** defines disability as 'a physical or mental impairment that substantially limits one or more of the major life activities of a person.' This Act is concerned with discrimination in general, but significantly, includes mental impairment as one such disability. In relation to employment, it states that no employer shall discriminate on the grounds of disability against a qualified person with a disability in regard to: (a) procedures relative to applications for employment; (b) the hiring, promotion or dismissal of employees; (c) employee compensation; (d) job training; and (e) any other terms, conditions

[115] *Criminal Code*, article 33.
[116] *Criminal Code*, article 227(c).
[117] *Traffic Regulation Ordinance*, article 15E(4).
[118] *Value Added Tax*, Fifth Schedule 3(2).

and privileges related to employment.[119] This topic is dealt with in greater detail in **Chapter 8: Disability**.

The ***Persons with Disability (Employment) Act*** defines a 'person with disability' to mean 'a person, being over compulsory school age, who, by reason of injury, disease, congenital deformity or other physical or mental incapacity, is substantially handicapped in obtaining or keeping employment or in undertaking work on his own account, of a kind which apart from that injury, disease, deformity or incapacity would be suited to his age, experience and qualifications; and the word "disability", in relation to any person, shall be construed accordingly.' A Disablement Resettlement Officer is appointed 'to monitor generally the conditions of employment and the work environment in which persons with disability are gainfully employed.' In carrying out such duties the Disablement Resettlement Officer is expected to 'investigate any complaints he may receive regarding the conditions of employment under which any person with disability is employed, taking into account the physical or mental disability of the person with disability.'[120]

09.31

Sickness benefits are paid for a day taken off work because of incapacity to work, 'by reason of some specific disease or bodily or mental impairment or that he is under treatment or observation for a disease or a bodily or mental impairment.'[121] However, the incapacity referred to here is not meant just for someone who is disabled but for everyone who is ill.

Free medical aid is available for the head of a household, including supply of 'such drugs, spectacles, dentures, and other prosthetic aids as in the opinion of the Chief Government Medical Officer are indicated in his case' and which are required 'on account of bodily or mental impairment' of any member of the household.[122]

A disability pension is available for a person who is certified to be suffering from a mental severe sub-normality or to be a severely disabled person in accordance with the provisions of this Act, or to be suffering from cerebral palsy.[123]

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[119] *Equal Opportunities (Persons with Disability) Act*, article 7.
[120] *Persons With Disability (Employment) Act*, article 25(1) and (2).
[121] *Social Security Act*, article 18(4).
[122] *Social Security Act*, article 23(1).
[123] *Social Security Act*, article 27(1)(b).

An Injury Grant and Injury Pension are paid to a person where an accident or industrial disease results in the permanent loss of physical or mental faculties.[124]

09.32

Assessment of bodily or mental impairment is carried out by the Medical Panel or the medical officer, appointed by the Minister, for this purpose, irrespective of whether there is loss of earning power or additional expenses.[125] Bodily or mental impairment is to be assessed as follows:

(a) at less than 20%, the insured person shall be entitled to an Injury Grant (Part II of Third Schedule of Act);
(b) 20–89% provides entitlement to an Injury Pension (Part III of Third Schedule of Act);
(c) at 90% or more, there is entitlement to the full rate of Invalidity Pension or Increased Invalidity Pension.

Other provisions of the ***Social Security Act*** refer to provision for pensions to a married man being paid at a single rate, for permanent loss of physical or mental faculty arising out of his employment or self occupation,[126] and to a child's entitlement to a Disabled Child Allowance.[127]

12. Protection of Persons with Mental Disability

09.33

A person with mental disability is considered to have a reduced capacity to defend himself or herself. Indecent actions performed against such a person therefore assume greater significance. In relation to abuses involving persons with mental disability, the ***Criminal Code*** states that: 'Unlawful carnal knowledge and any other indecent assault, shall be presumed to be accompanied with violence' when 'the person abused was unable to offer resistance owing to physical or mental infirmity, or for any other cause

[124] *Social Security Act*, article 29(1).
[125] *Social Security Act*, article 29.
[126] *Social Security Act*, article 62.
[127] *Social Security Act*, article 77.

independent of the act of the offender, or in consequence of any fraudulent device used by the offender.'[128]

A bodily harm is deemed to be grievous if it can give rise to danger of any permanent defect in any part of the physical structure of the body; or any permanent mental infirmity; or if it causes any mental or physical infirmity lasting for a period of thirty days or more, or if the party injured is incapacitated, for a like period, from attending to his/her occupation.[129]

The punishment for theft accompanied with attempted homicide or bodily harm is increased by one or two degrees when the 'violence' is directed 'against a person who is suffering from a degree of physical or mental infirmity in consequence of which he is unable to offer adequate resistance.'[130] Similarly the punishment for bodily harm is also increased when the victim is 'a person suffering from a degree of physical or mental infirmity in consequence of which he is unable to defend himself adequately.'[131]

The Police may institute proceedings even without the complaint of the private party, 'in the case of any offence committed against a person who, by reason of physical or mental infirmity, is incapable of instituting criminal proceedings, even though such offence be one in respect of which, if committed against any other person, the complaint of the private party would be requisite.'[132]

A person who 'annoys, vexes or scoffs at any imbecile, aged, crippled, feeble or deformed person'[133] is guilty of a contravention.

13. Consent and the Person with Mental Disability

09.34

To what extent do persons with mental disability lose their capacity to give consent?

Capacity to give consent depends on whether the person is competent to consent, that is, if s/he can understand the information provided, assess it and proceed to take an informed decision.

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[128] *Criminal Code*, article 201.
[129] *Criminal Code*, article 216.
[130] *Criminal Code*, article 276A.
[131] *Criminal Code*, article 222A.
[132] *Criminal Code*, article 543(c).
[133] *Criminal Code*, article 339(n).

It has already been noted in the ***Civil Code*** that the 'disability of persons interdicted is either general in regard to all agreements, or special in regard to certain agreements only,'[134] as provided in the ***Code of Organization and Civil Procedure***. However there is no mention of the ability to give consent with regard to medical interventions.

In the ***Mental Health Act***, there is reference to a patient authorising a medical practitioner, to advise him/her, with respect to the making of an application to the Mental Health Review Tribunal.[135] This implies that such patients are capable of giving consent to being examined by the doctor.

a. Convention on Human Rights and Biomedicine: Mental patients and consent

09.35

Chapter II of the Council of Europe's ***Convention on Human Rights and Biomedicine***[136] deals with consent. This topic has been dealt in detail in **Chapter 1: Human Dignity, Rights and Freedoms.** However, the special needs of those who are not able to give consent because of a mental disability should be emphasised here. The relevant articles are as follows:

Article 6(1): 'An intervention may be carried out on a person who does not have the capacity to consent, for his or her direct benefit.'

Article 6(3): 'Where, according to law, an adult does not have the capacity to consent to an intervention because of a mental disability . . . the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law. The individual concerned shall as far as possible take part in the authorisation procedure.' Article 6(4) specifies that adequate information is to be given to these persons or authorities, as is required, prior to any procedure or intervention.

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[134] *Civil Code*, article 972, which refers also to Title IV of Part II of Book Second of the *Code of Organization and Civil Procedure*.

[135] *Mental Health Act*, article 23.

[136] *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, Council of Europe, 1997.

Moreover, Article 6(5) states that they may withdraw such consent at any time, in the best interests of the person concerned.

Article 7: This deals specifically with the protection of persons who have a mental disorder. It states: 'A person who has a mental disorder of a serious nature may be subjected, without his or her consent, to an intervention aimed at treating his or her mental disorder only where, without such treatment, serious harm is likely to result to his or her health.' This emphasises the fact that it is not merely necessary for the doctor or guardian to believe that the treatment may be of benefit to the patient. Compulsory treatment is acceptable only if, without such treatment, there is a definite risk of harm occurring.

09.36

Another specific aspect of the Convention that concerns patients with mental disability relates to research on these patients. Obviously research in any area of medicine needs to be encouraged, but in the case of those unable to consent, special precautions need to be taken. Article17 of the Convention deals with conditions that must be met for research to be allowed.

(a) In the first instance, all conditions set down for research on patients who can consent need to be followed (see **Chapter 1** which discusses Informed Consent).
(b) 'The results of the research have the potential to produce real and direct benefit to his or her health.' In other words, one cannot involve patients with a mental disorder in research, the results of which have general application and are not specifically relevant to mental disease. If research of comparable effectiveness can be carried out on individuals capable of giving consent, then persons with mental disease should not be used for this purpose.[137]
(c) All necessary authorisation as mentioned above, needs to be obtained in writing.
(d) It is also made clear that while these patients may not be able to give consent, they still may object to participate, in which case that person should be excluded from any research.[138]

[137] *Convention on Human Rights and Biomedicine*, Article 17(1)(iii).
[138] *Convention on Human Rights and Biomedicine*, Article 17(1)(v).

(e) It is accepted that research in mental diseases may not benefit the person taking part in it. In such cases research involving patients with mental disease can be undertaken only if 'the research has the aim of contributing . . . to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons . . . afflicted with the same disease or disorder or having the same condition,' and moreover, that 'the research entails only minimal risk and minimal burden for the individual concerned.'[139] This article has the aim of not inhibiting research in mental disease if the results are not directly beneficial to the subject taking part in the research. It introduces the concept of 'minimum risk and minimum burden' by which is meant minor procedures like taking a blood sample or assessing the blood pressure, or minor inconveniences like overnight fasting, for instance.

14. Involuntary Treatment

09.37

Treatment of patients with a mental disability presents special ethical and legal issues, relating to the various categories of patients and treatment available.

(a) *Voluntary patients*: These should be treated as ordinary patients, and they have every right to refuse any recommended treatment or other intervention.

(b) *Involuntary patients*: Forced (involuntary) treatment should be restricted to those measures necessary to prevent harm to him/herself or to others. The ***Mental Health Act*** does not specify to what extent this should be applied, and what treatments are or are not acceptable. It states that 'in the case of an application for admission for treatment, the two medical practitioners shall give detailed reasons for their opinion and must specify whether other methods of dealing with the patient are available and, if so, why such methods are not appropriate.'[140]

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[139] *Convention on Human Rights and Biomedicine*, Article 17(2).

[140] *Mental Health Act*, article 14(3).

09.38

Moreover, it is further emphasised that: 'Nothing in this article contained shall preclude a patient admitted to a hospital in pursuance of an application for admission for observation from receiving such medical treatment as the responsible medical officer considers appropriate.'[141] There appears therefore to be no limit to what treatment can be applied, so long as the medical officer considers it appropriate.

There has been considerable discussion relating to how appropriate certain treatments can be. These include:

(a) *Forced feeding*: It is generally accepted that no person capable of giving consent should be subjected to forced feeding (e.g. by nasal gastric tube or intravenous drip). In the case of those with mental disability who are unable to give consent, such feeding could be considered as basic care.[142] In the particular case of anorexia nervosa, no specific Maltese legislation exists. However, legal cases in the UK have confirmed that this condition can be considered as a mental disorder under the Mental Health Act (UK).[143]

(b) *Irreversible treatment*: Such treatment, e.g. lobotomy, is not considered under Maltese legislation. However, the Council of Europe recommends that such treatment for mental disorder 'should be exceptional, and should not be used in the context of involuntary placement' and 'should only be carried out if the person concerned has given free, informed and specific consent in writing.' Moreover, an independent second medical opinion should agree that it is appropriate.[144]

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[141] *Mental Health Act*, article 14(4).

[142] In the UK, feeding a patient via a naso-gastric tube can be considered as treatment (*Airedale NHS Trust v Bland* [1993] 1All ER 821, 12BMLR 64).

[143] See:Riverside Health NHS Trust v Fox [1994]1 FLR 614, and B v Croydon HA [199r] 1 All ER 683.

[144] Council of Europe, Committee of Ministers *Recommendation concerning the protection of the human rights and dignity of persons with mental disorder*, Rec(2004)10, Article 28 on Specific Treatments.

(c) *Non-essential treatment*: This is treatment not essential for the mental condition of the patient. Maltese legislation would indicate that it is up to the doctor caring for the patient to determine the best interest of the patient.[145]

[145] The question of sterilisation to prevent pregnancy in a woman with a mental age equivalent to five years was the subject of a case in the UK (*F.v West Berkshire Health Authority* [1989]2 All ER 545, HL). Lord Brandon (House of Lords) ruled that 'a doctor can lawfully operate on, or give other treatment to, adult patients who are incapable, for one reason or another, of consenting to his doing so, provided that the operation or other treatment concerned is in the best interest of the patient.'

Chapter 10

Old Age and Retirement

1. Introduction

10.01

The onset of old age brings with it several health and social issues which have a direct relationship to ethical practice. Malta is one of the few countries that insists on setting the retirement age at the low level of 60/61 years of age (females and males respectively), with the result that the average person spends the best of a third of their life-span in retirement.[1] While some workers look forward to retirement as the time to indulge in activities long delayed, others are invariably thrown on their own resources, which they find wanting, with the result that time hangs on their hands with consequent rapid physical and mental deterioration.

It is also a fact that the current low cut-off point in the definition of ageing and retirement (often taken to be synonymous) does not distinguish between the younger able-bodied person from the older person who requires social and medical assistance. It is also true that financial resources are required increasingly as the person gets older, with the result that the section of the population over the

[1] During the November 2004 budget speech, the Government has published a White Paper proposing that the pensionable age should rise to 65 years. Ministry for the Family and Social Solidarity, White Paper – *Pensions: Adequate and Sustainable Reforms Needed Now To Ensure Adequate and Sustainable Pensions for Future Generations.* White Paper, Valletta, November 2004, available at http://www.mfss.gov.mt/pensions/documents/whitepaper/wp_layout.pdf. Government's proposals on the subject were published through DOI press release no. 307 dated 4th March 2006. A bill to amend pensions legislation is expected to be published in the coming weeks. For further information see: http://www.mfss.gov.mt/pensions.

age of 75–84 takes a considerably greater proportion of the economic resources than any other 10-year cohort of the population. It has been stated that health care resources required for those aged over 65 exceed those required for all the population below that age.

Some of the ethical issues that become increasingly relevant as one gets older include the following.

10.02

Ageism and discrimination: Ageism is a neologism which refers to the discriminatory and denigrating way in which older members of the public are regarded by the rest of the population, including the media, where older people are often portrayed as helpless, demented and a strain on society. Discriminatory policies in relation to work are still rampant within our society.

10.03

Social and economic needs: Pensions are meant to reflect the needs of the ageing person. However, almost invariably, pensions never keep up, in real terms, with the cost of living, with the result that over a longer period of time, pensionable age becomes synonymous with poverty. This is particularly the case where, as in Malta, retirement age is relatively early. It is known that poverty and illness are very closely linked together. Related to these issues are dietary considerations, which in turn lead to deficiency diseases. Increased expenditure on drugs and medication is compounded by the fact that insurance policies often become prohibitive in older age groups; some insurance agencies may even prohibit such facilities for the older person.

10.04

Health and disease: It is also an unfortunate reality that many of the chronic diseases affect the elderly far more than any other age group. Almost by definition old age and chronic disease go hand in hand. Diseases like arthritis, high blood pressure, mental deterioration, culminating in dementia, and cancer are all commoner in older age groups.

10.05

Incapacity: Incapacity is the inability to direct the course of events in one's life. As one gets older one finds that one becomes more and more marginated. In older societies the views of the elderly were taken as wise sayings to be followed by the younger ones. In

today's rapidly moving societies, the views of the elderly very soon become outdated, with the result that older people feel they have nothing to contribute to the running of daily events. This very often includes their own life, where children or carers often take over the day-to-day management of affairs.

10.06

Informed consent and autonomy: A particular issue in bioethics is the capacity to give informed consent for a particular intervention. This concept implies the capacity to understand the reasons and needs for a procedure, and the ability to decide freely and without any pressure from anybody, whether to accept it or otherwise. It is regrettable that very frequently decisions are taken on behalf of the elderly, by members of his or her family, with little regard to what the patient actually wants. Often patients are left in the dark as to the diagnosis and prognosis of their condition. This is more likely to happen the more serious and life-threatening the condition happens to be. It is to be emphasised that the degree of autonomy to be enjoyed by an individual does not cease abruptly on reaching any particular age, but diminishes gradually, depending on the degree of loss of capacity of the individual concerned. The right to know or not to know should be determined by the individual and not by other members of the family, however well-meaning.

10.07

Rationing of resources and the elderly: It is unfortunate that when resources are limited, as they often are, clinicians and other providers of services might decide to give preferential treatment to younger members of the community. This has been the case for instance in kidney transplantation, where over the years there has been a gradual increase in the age limit where such procedures would be considered. The same applies to heart surgery, hip replacement, etc. While discrimination of this kind is always invidious, practical issues relating to availability often take precedence.

10.08

Quality Adjusted Life Years (QALY), Cost-effective analysis and the elderly: Related to the above, the quality of life for a number of years, as measured by this index, has been used to relate to the cost

effectiveness of any procedure. Often this has been the justification for discriminatory treatment of the elderly, seeing, for instance, that they cannot compete, on these parameters, with saving the life of a newborn or young adult. Yet, principles of justice and beneficence would insist that no life is intrinsically inferior to any other and therefore, making decisions, to benefit the one rather than the other, is intrinsically fraught with problems. It is to be noted that both the British Medical Association and the World Medical Association do not consider advanced age as a valid criterion for excluding patients from necessary treatment.

10.09

Research and the elderly: Older people may be especially at risk because of their position of dependency. As in all such situations, research using older people is not justified if the research can be performed on younger persons. It is particularly important to emphasise that unwillingness to participate in research should in no way interfere with the usual care and management of such persons.

10.10

Abuse and neglect of the elderly: Abuse is more likely to happen the greater the dependency and incapacity to respond. Hence the incidence of abuse is greatest in the very young and the very old and incapacitated. These patients require legislation to ensure their protection.

10.11

End of life issues: While issues like euthanasia, resuscitation orders, forced feeding, etc. are not entirely restricted to older people, they obviously tend to involve this age-group more than any other.

The following provides a summary of legislation extant in Malta in relation to the elderly.

2. Pensions and Assistance to the Elderly

10.12

The vast majority of elderly persons depend on their pension to maintain an acceptable standard of living and to ensure that they live with dignity an independent existence. Pensions therefore rate very highly in the scheme of things for this group of people.

The ***Constitution of Malta*** maintains that social assistance and insurance should be available for everyone, including the elderly. Article 17 states:

(1) 'Every citizen incapable of work and unprovided with the resources necessary for subsistence is entitled to maintenance and social assistance'; and
(2) 'Workers are entitled to reasonable insurance on a contributory basis for their requirements in case of accident, illness, disability, old-age and involuntary unemployment.'[2]

'Pension age' means:[3]

(a) in the case of a man, the age of sixty-one years; and
(b) in the case of a woman, the age of sixty years.

a. Sickness Assistance

10.13
The head of a household is entitled to sickness assistance when he or a member of his household fall in any of the following categories:[4]

(a) an unemployed person suffering from a disease mentioned in the Fifth Schedule, with a requirement for a special diet or regimen;
(b) an unemployed person with chronic schizophrenia, certified by a consultant psychiatrist, on treatment for at least 3 years;

provided that the total weekly means of all members of the household fall below the minimum;[5] but receipt of Social Assistance or an Age Pension or a Carer's Pension, 'shall be deemed not to have means exceeding the scale rate for that household.'

However, in the case of old people, on admission to a state-owned old people's home, the right to sickness assistance is

[2] *Constitution of Malta*, article 17(1) and 17(2).
[3] *Social Security Act*, article 2(1).
[4] *Social Security Act*, article 20(1).
[5] *Social Security Act*, article 20(1)(b). As determined by the Seventh Schedule of the *Social Security Act*.

'extinguished from the first day of his admission into such a state-owned institution.'[6]

Elderly persons also qualify for Free Medical Aid, in accordance with article 23 of the *Social Security Act*.

b. Social Assistance

Social Assistance is available to a single or widowed unemployed female who 'is taking care, all by herself, on a full-time basis and regularly, of her parent or brother, sister, grandparent, uncle, aunt, father or mother-in-law or brother or sister-in-law who is living in the same household' and 'who is suffering from a severe physical or mental infirmity' or 'who is aged sixty years or over and is physically or mentally unable to take care of himself and of his day to day needs,' provided the person being taken care of does not have a parent or spouse, in the same household, to look after him/her.[7]

Moreover a single or widowed person taking care on a full-time basis of any relative, as above, living in the same household, and who is bedridden or confined to a wheel-chair, is entitled to a Carer's Pension, provided the applicant satisfies a means test.[8]

An inmate of a state-owned institution for the care and welfare of old people is entitled to receive an allowance, even though he has not yet reached the age of 60 years.[9]

c. Pensions in Respect of Retirement

10.14

'Retirement' means attainment of pension age.[10] In respect of a person over pension age who is disqualified from receiving a pension because of his being in insurable employment or self occupied, retirement means the date on which he ceases to be so disqualified or on which he reaches the age of sixty-five years, whichever is the earlier.

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[6] *Social Security Act*, article 20(3).
[7] *Social Security Act*, article 30(8).
[8] *Social Security Act*, article 68.
[9] *Social Security Act*, article 30(10).
[10] *Social Security Act*, article 2(1).

(a) Early retirement

In Malta the pensionable age is taken to be 60 years for females and 61 for males. As mentioned earlier this is an excessively rigid determination, which moreover is becoming more and more unsustainable in view of the increasing proportion of people reaching this age and the relatively ever reducing base of working population who have to support pensions and retirement schemes. It may be pointed out that in many western countries, the retirement age is 65 and there is increasing pressure to actually increase this cut off point even higher.

The second point of relevance is the fact that optional retirement is not available in most circumstances. One exception was the ***Malta Dockyard Act***, which established an early retirement scheme, whereby workers between the ages or 56 and 61 years may retire voluntarily, and be given a pension on their retirement. A woman may retire at the age of 55 years. This applies also to younger persons suffering from ill-health or injury, irrespective of their age. The provisions concerning early retirement schemes were contained in article 16A of the ***Malta Dockyard Act*** and in article 5(a)(i) of the Second Schedule of the same enactment. Although this law has been repealed by the ***Dockyard and Shipbuilding Yard (Restructuring) Act***, 2003, article 3(1) of the latter enactment provides that the Government of Malta has assumed all liabilities and obligations, instead of the Malta Drydocks Corporation and the Malta Shipbuilding Company, in so far as early retirement schemes are concerned.

Another exception is found in the ***Police Act***, where police officers, may retire 'on or after attaining the age of fifty-five years or' on completion of 'twenty-five years' service in the Force.'[11] 'The service in respect of which a pension may be granted must be unbroken.'[12] Moreover when retirement is necessary because of injury, a police officer 'may be granted an additional pension appropriate to his case,' including severity of injury and years of service.[13]

However although early retirement schemes exist in different EU countries, the Opinion of the EU Economic and Social Committee

[11] *Police Act*, article 123.

[12] *Police Act*, Fifth Schedule, Police Pensions Regulations, regulation 3.

[13] *Police Act*, Fifth Schedule, Police Pensions Regulations, regulation 9.

is to 'make an overall assessment of end-of-career schemes - of which early retirement is one aspect - taking account in particular of the negative impact which they can have on state budgets, of possible alternatives to early retirement schemes, of the impact on labour relations, of the relationship with legislation on pensionable age and of the motives of workers.' 'The objective set at Barcelona[14] of raising the effective pensionable age could be achieved by combining measures to discourage the current trend towards early retirement with measures to encourage workers who reach the legal retirement age to remain at work on a voluntary basis (although not necessarily in the same post or with the same function).'[15] This would also ensure access to life long learning.

(b) Contributory pensions

A number of contributory pensions to which there may be an entitlement are in existence as follows:

(a) Retirement Pension; or
(b) Increased Retirement Pension; or
(c) National Minimum Pension; or
(d) Increased National Minimum Pension;[16] or
(e) Two-Thirds Pension.[17]

Any person commencing work and starting to pay insurance on or after the 16th day of January, 1979, may only 'be entitled to the two-thirds pension.'[18]

Retirement Pension: A person qualifies for a Retirement Pension, once retirement age or pension age is reached. However a person under the age of sixty-five, who is gainfully occupied and earning in excess of a weekly, average equivalent to the National Minimum Wage, is disqualified from receiving a pension under this scheme but 'earnings derived from membership of any Board, committee,

[14] *'Increasing labour force participation and promoting active ageing'*. Council doc. N° 6707 of 8th March 2002, adopted on the basis of COM(2002) 9 final of 24.01.2002.
[15] Opinion of the Economic and Social Committee on *'Options for the reform of pension schemes'* (2002/C 221/14), OJEC C 221/58, 17.9.2002.
[16] *Social Security Act*, article 44, and Twelfth Schedule.
[17] *Social Security Act*, articles 44 and 53 to 57.
[18] *Social Security Act*, article 48.

commission, or council established by or under any law or such classes of earnings as the Minister may declare' are exempt.[19]

Persons are eligible for a contributory pension, if they satisfy the relevant contribution conditions and make a claim within six months of such date; otherwise the pension is payable from the day on which the claim is made.[20] The rate of Retirement Pension depends on the average of contributions paid and on the income earned from gainful occupation in the last ten years prior to retirement.

10.15

Increased Retirement Pension: A person who is entitled to a Service Pension[21] is also entitled to a contributory Retirement Pension and if the two together amount to more than two thirds of the pensionable income, the pensioner is only entitled to the Retirement Pension, while if it amounts to less than two thirds, the pensioner becomes entitled to an Increased Retirement Pension.[22]

Where a pensioner's Service Pension together with the rate of Retirement Pension or Increased Retirement Pension is less than the National Minimum Pension, such a person is entitled to the National Minimum Pension abated by his Service Pension.[23]

National Minimum Pension: A person who does not receive a Service Pension is entitled to a National Minimum Pension. The highest rate of pension is equivalent to four-fifths of the national minimum wage in the case of a married man, who is maintaining his wife, and two-thirds of the national minimum wage in the case of any other person.[24] These pensioners are also entitled to receive, additionally, a National Minimum Pension Additional Allowance in accordance with the Twelfth Schedule to this Act.[25]

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[19] *Social Security Act*, article 45.

[20] *Social Security Act*, articles 44.

[21] 'Service Pension' means 'a pension or other allowance awarded to a person at any time before or after' the 1st day of April, 1978, 'payable by or on behalf of his employer in respect of past services in Malta or abroad' together with net increases for cost of living. See *Social Security Act*, article 2(1).

[22] *Social Security Act*, article 47.

[23] *Social Security Act*, article 51.

[24] *Social Security Act*, article 50.

[25] *Social Security Act*, article 64.

Increased National Minimum Pension: A person entitled to a National Minimum Pension shall, instead, be entitled to an Increased National Minimum Pension 'or to such part thereof, if any, as shall ensure that his rate of such pension does not exceed two-thirds of his pensionable income.'[26]

Two-Thirds Pension: A person is entitled to this pension if such a person:[27]

(a) has been an employed or self-employed or self-occupied person for not less than ten years in the aggregate prior to his retirement; and
(b) has retired on or after the l6th day of January, 1979; and
(c) has paid the proper rate of contribution under the ***Social Security Act*** at any time after the 21st day of January, 1979; and
(d) is not disqualified under section 45 of the ***Social Security Act***.

One is normally entitled to the full rate of the Two-Thirds Pension if one has paid an average of fifty contributions yearly over a period of thirty years, to include the last ten consecutive years preceding the last contribution.[28]

Reduced rates of the Two-Thirds Pension apply in certain instances.[29]

10.16

Pensions when in a residential home: When 'a person is receiving a State Financed Residential Service, such person shall pay to the Government such contribution as may be prescribed under subarticle (2). The Director shall calculate the contribution payable by such resident.'[30]

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[26] *Social Security Act*, article 63(1). Article 2 defines 'pensionable income' as 'the average annual basic wage or salary or the net income, or earnings, calculated in accordance with the Thirteenth Schedule to this Act.' This takes into consideration the average income in the last ten years prior to retirement.

[27] *Social Security Act*, article 52.

[28] *Social Security Act*, article 53.

[29] *Social Security Act*, article 55.

[30] *Social Security Act*, article 93(1). New regulations were published in January 2004 as SL 318.13, *State Financed Residential Services Rates Regulations*, where the amounts deducted from the pension depend on the level of care offered, with a minimum of Lm 10.50 and a maximum of Lm 13.50 per day.

(c) Age Pension – a non contributory pension

There is also a non contributory pension, the Age Pension.[31]

A person who attains the age of sixty years and whose weekly means 'do not exceed the highest rate of Age Pension, which in the case of a married man whose wife also qualifies for a pension in her own right, shall be equivalent to 80%, and in the case of widowed or single persons, up to 60% of the national minimum wage, . . . shall be entitled to an Age Pension.'[32] The weekly rate of pension brings the total weekly means, calculated in accordance with the provisions of the Act, up to the highest rate of pension payable in accordance with Part II of the Sixth Schedule to this Act.

When this pensioner becomes an inmate of a state-owned hospital or institution he shall still be entitled to such pension during the first six months starting from the first day of admission 'unless it is a state-owned institution for the care and welfare of old people as is specified by the Minister,' in which case such a person shall not be entitled to the pension 'but to an allowance in lieu of pension payable in accordance with Part VI of the Sixth Schedule' to the ***Social Security Act*** and, if applicable, to house rent.[33]

(d) Welfare Committee

10.17

The ***Social Security Act*** establishes a Welfare Committee.[34] The functions of this committee are to administer funds entrusted to it by Government, for the benefit of inmates of State Financed Residential Services and state-owned hostels, as specified by the Minister, and to advise the Minister on any matter concerning the care and welfare of the elderly.[35] Funds are also made available to recipients of home-care and home-help services. These services

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[31] *Social Security Act,* article 66.

[32] *Social Security Act,* article 66. This is subject to a Capital Resources Test and a Means Test.

[33] *Social Security Act,* article 66(3).

[34] *Social Security Act,* article 130.

[35] *Social Security Act,* article 131. The institutions are listed in SL 318. 13, *State Financed Residential Services Rates Regulations.*

are provided by Government for the elderly and include 'daily shopping needs and personal errands, bed-making, laundering, drying and ironing of clothes, limited personal attention, such as dressing-up and washing, as may be required in the circumstances of the case, general household cleaning, and, where specifically requested by the recipient of such service, cooking and feeding.'[36] There is also a handyman service.

3. Continuing Education and the Elderly

10.18

The ***Education Act***[37] sets up the Institute of Gerontology within the University of Malta with the aim of:

(a) organising interdisciplinary research concerning ageing and the elderly;
(b) setting up postgraduate courses related to the care of the elderly; and
(c) co-operating with the UN Institute on Ageing, in Malta.

One important function of the Institute of Gerontology is the organisation of a variety of courses within the concept of the University of the Third Age. This has proved to be quite popular with a large number of elderly persons and has provided an opportunity for continued education of this group of people.

To improve the standards and expertise of those who work with older people, the University of Malta offers a course leading to a Postgraduate Diploma and another to a Masters Degree in Gerontology and Geriatrics.[38] These courses are designed for those who hold a degree or other qualification in an appropriate subject or a professional qualification together with adequate working experience with the elderly.

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[36] *Social Security Act*, article 131(1)(a)(iii).

[37] *Statute I 06 - Institute of Gerontology Statute*, SL 327.06.

[38] *Postgraduate Diploma in Gerontology Regulations*, SL 327.11 and *Postgraduate Diploma and Degree of Master of Gerontology and Geriatrics - Dip. Ger. - M.Ger. - Regulations*, SL 327.28.

4. Voting

10.19

The right to vote and elect one's representatives is a fundamental right enshrined in the Council of Europe's ***Convention for the Protection of Human Rights and Fundamental Freedoms***.[39] Often, however, there are impediments which prevent the older person from participating in this important social function, either through waning of general interests, or through lack of facilities for voters. People in retirement homes are particularly at risk of being institutionalised and becoming very dependent on their carers. It is therefore important also to ensure that inmates are allowed to express their views without undue interference.

The ***General Elections Act*** deals with voting in retirement homes, defined as a place for the care of the elderly in which at least fifty voters reside.[40] The Electoral Commission must form a sub-committee, with representatives from each of the political parties, to run the election in all retirement homes,[41] to ensure that no undue pressure is brought to bear on voters and to ensure that adequate arrangements for voting are made in view of the special needs of these voters. Immediate steps should be taken to remove temporarily members of staff, in homes run or administered by the Government, 'suspected to have attempted to influence voters.'[42] The sub-committee must deal with arrangements for distribution of propaganda material and for canvassing by candidates, during visiting hours. It must also deal with any complaints by political parties. 'Members of the staff in retirement homes are expressly prohibited from engaging in propaganda for any political party or candidate and any employee contravening this article shall be guilty of an offence and shall on conviction be liable to the penalty of general interdiction for a period of ten year.'[43]

Voters may choose to go to the polling place by themselves or request the assistance of members of staff or of their family.[44] No

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[39] *Council of Europe's Convention for the Protection of Human Rights and Fundamental Freedoms*, First Protocol, article 3.
[40] *General Elections Act*, article 80.
[41] *General Elections Act*, article 81.
[42] *General Elections Act*, article 81 (3).
[43] *General Elections Act*, article 82 (4).
[44] *General Elections Act*, article 83.

person should accompany the patient if s/he has any objection to this. A medical consultant may issue a medical certificate pointing to any dangers to the health of a particular patient. However a patient has every right to ignore the medical warning and decide to cast his vote.[45]

The ***Local Councils Act*** has a number of provisions which mirror those expressed above, in relation to Local Council elections.[46]

The ***European Parliament Elections Act*** and the ***Referenda Act*** both also apply the provisions of the ***General Elections Act*** to the European Union Parliamentary elections and to voting at referenda respectively.[47]

5. Other Issues Relating to Older Persons

Respect for the older person: With failing powers, elderly persons often find themselves the butt of ridicule. Whoever 'annoys, vexes or scoffs' an aged person (or a person with some other disability) may be found guilty of a contravention.[48]

Representation on official bodies: The ***Malta Council for Economic and Social Development Act*** refers to a standing Civil Society Committee to be consulted by the Council. This Committee should as far as possible be representative of Maltese society and therefore includes *ex officio* among its members, the chairperson of the National Council for the Elderly.[49]

10.20

Court attendance: A witness is excused from being placed in the witness-box in court if, by reason of old age, infirmity or physical condition, this would cause great inconvenience.[50] Moreover: 'If it shall be necessary to examine any person who either through infirmity or old age is unable to appear in court, such person shall

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[45] *General Elections Act*, article 83(3).

[46] *Local Councils Act*, Third Schedule Local Councils (Elections) Regulations, Part VII, regulation 48 *et seq.*

[47] *European Parliament Elections Act*, article 21 and Second Schedule; *Referenda Act*, article 10 and Second Schedule.

[48] *Criminal Code*, article 339(n).

[49] *Malta Council for Economic and Social Development Act*, article 6.

[50] *Criminal Code*, article 530(2)(b).

be examined by the court, or, if the court so orders, by a member of the court, in the place of his or her abode.'[51] The court may delegate the taking of such evidence to a magistrate or to a judicial assistant.

The court may, on application, exempt from serving as a juror, any person over 60 years, 'unless, in some particular case, the court deems otherwise for the ends of justice.'[52]

Extradition: A person's return to a country listed in the ***Extradition (Designated Foreign Countries) Order***[53] is barred by reason of his or her age, if and only if at the time s/he is alleged to have committed the extraditable offence he would have been because of his age exempted from criminal responsibility under the criminal law of Malta on the assumption that:

(a) the conduct constituting the extraditable offence constituted an offence in Malta;
(b) the person carried out the conduct when the extraditable offence was committed or alleged to be committed;
(c) the person carried out the conduct in Malta.

Safe products: The ***Product Safety Act*** emphasises the need for extra care in the preparation and marketing of products for elderly consumers. A safe product is defined as one which 'under normal or reasonably foreseeable conditions of use, including duration, does not present any risk or only the minimum risks, compatible with the product's use, which are considered as acceptable and consistent with a high level of protection for the safety and health of persons, taking into account' particular factors, including 'the categories of consumers at risk when using the product, in particular children, the disabled and the elderly.'[54]

6. Issues Not Adequately Covered by Maltese Legislation

10.21

Abuse and the elderly: A number of elderly, particularly women, tend to find themselves in their old age without any adequate

[51] *Criminal Code*, article 647(1).
[52] *Criminal Code*, article 604(2).
[53] *Extradition (Designated Foreign Countries) Order*, SL 276.05, order 17.
[54] *Product Safety Act*, article 2.

protection. Crimes of violence against older people living alone are becoming more frequent. In fact punishments for offences of bodily harm, are increased by one or two degrees when the victim is over sixty years or is 'suffering from a degree of physical or mental infirmity in consequence of which he is unable to offer adequate resistance.'[55]

However, there seems to be a need for greater incentives to promote assistance and companionship for those living alone. This could be done through establishment of more homes for night rest, as well as the encouragement of schemes which encourage companionship during the night.

10.22

Carers can on occasion take over the life of the individual elderly person. They often replace family members when these are not available. Often they share medical information with the doctor and take decisions on behalf of the older person. There are, moreover, a number of self-appointed carers who take in an elderly person for a couple of years only to send them to a nursing home as soon as they have managed to ensure that they inherit house and other belongings.

In relation to the above, it is often the case that pressure is brought on elderly patients to consent to hospitalisation or to elderly homes against their wishes, to suit their children or carers.

10.23

Driving fitness and the elderly: There is a need to ensure that an elderly person continues to be fit to drive. Driving licences may only be granted or renewed, at 70 years of age and biennially thereafter, if a person produces a medical certificate of physical fitness.[56] The Eight Schedule of the subsidiary legislation, ***Motor Vehicles (Driving Licences) Regulations*** lists the minimum standards of physical and mental fitness for driving and in fact several medical conditions would disqualify an applicant from driving.

Otherwise, except on the first application, there is no mandatory medical assessment relating to capacity to drive one's own vehicle;

[55] *Criminal Code*, articles 222A and 276A.

[56] *Motor Vehicles (Driving Licences) Regulations*, SL 65.18, Part IV, regulation 39.

this appears to have become necessary. This should ensure that patients with incipient dementia, visual impairment, or other medical condition, which makes driving a hazard, be picked up.

The family doctor has a special responsibility in this area. At the very least s/he should try to convince the patient to give up driving voluntarily. When this is refused, there should be some mechanism of bringing this problem to the attention of the health authorities.

However there are more frequent medical assessments required for drivers of public transport vehicles. They must 'produce a medical certificate of physical fitness at the age of fifty, and every five years thereafter until the age of sixty, after which such medical certificate shall be produced annually prior to the renewal of their driving licence.'[57]

10.24

Loneliness: One of the commonest issues involving the 'healthy' elderly is the fear of being left alone, particularly at night time. Special arrangements should be made so that they might have the option of utilising sheltered accommodation for the night, or otherwise providing special carers for this purpose.

7. International and European Instruments Relating to Ageing[58]

a. European Convention of Human Rights

10.25

The Council of Europe's ***Convention for the Protection of Human Rights and Fundamental Freedoms***[59] has been ratified by Malta and is enshrined in the ***European Convention Act.*** It provides protection of human rights and fundamental freedoms for all individuals, (including the ageing), and allows individuals to bring complaints against national governments when these rights are not upheld. These include the right to life, protection of health interests, etc. The following articles may be relevant:

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[57] *Motor Vehicles (Driving Licences) Regulations*, SL 65.18, Part IV, regulation 40.

[58] Extracted from Liz Morrall, 2000, Report to the group of specialists on the improvement of the quality of life of elderly dependent persons (CS-QV).

[59] Accessed at http://conventions.coe.int/Treaty/en/Treaties/html/005.htm.

(a) *Article 5*: Right to liberty and security: Everyone has the right to liberty and security of person. No one shall be deprived of his liberty save in the following cases and in accordance with a procedure prescribed by law. Forced hospitalisation, for instance, would be contrary to this principle, whereas detention of persons of unsound mind, alcoholics, vagrants, alcoholics or drug addicts would not.
(b) *Article 8*: Right to respect for private and family life: Everyone has the right to respect for his private and family life, his home and his correspondence. There shall be no interference by a public authority with the exercise of this right, except such as is in accordance with the law.
(c) *Article 14*: Prohibition of discrimination: The enjoyment of the rights and freedoms set forth in this Convention shall be secured without discrimination on any ground such as sex, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status.
(d) *Protocol 1*: *Article 1*: Protection of property: Every natural or legal person is entitled to the peaceful enjoyment of his possessions. No one shall be deprived of his possessions except in the public interest and subject to the conditions provided for by law and by the general principles of international law.

b. European Social Charter

10.26
The ***Council of Europe's European Social Charter,***[60] which is ratified by Malta, has several articles which can be applied to the elderly, as follows:

(a) *Article 11*: right to health;
(b) *Article 12*: right to social security;
(c) *Article 13*: right to social and medical assistance;
(d) *Article 14*: right to benefit from social welfare services;
(e) *Article 15*: right of persons with disabilities to independence, social integration and participation in the life of the community;
(f) *Article 16*: right of the family to social, legal and economic protection;

[60] Accessed at http://conventions.coe.int/Treaty/en/Treaties/html/035.htm.

(g) *Article 23*: right of elderly persons to social protection; this article encourages older people to remain active members of society for as long as possible, and to 'lead independent lives in their familiar surroundings for as long as they wish and are able.' Those in institutions are guaranteed appropriate support, privacy and participation in decisions affecting them;
(h) *Article 30*: right to protection against poverty and social exclusion; and
(i) *Article 31*: right to decent housing.

c. Convention on Human Rights and Biomedicine

10.27
The Council of Europe's ***Convention on Human Rights and Biomedicine***[61] deals with a number of topics relating to ethical issues, including informed consent, rights to private life, and information, transplantation, medical research, etc.

With respect to elderly persons, the following articles are relevant:

(a) *Article 1*: protection of the dignity and identity of all human beings; respect for their integrity and other rights and fundamental freedoms;
(b) *Article 3*: equitable access to health care;
(c) *Article 6(3)*: protection of persons not able to consent; and
(d) *Article 10*: private life and right to information.

d. UN International Plan of Action on Ageing (1982)

10.28
This Plan of Action[62] addresses various recommendations, a number of which have a bearing on the elderly, including:

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[61] *Convention for the Protection of Human Rights and Dignity of the Human Being, with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine.* It is not yet signed by Malta by December 2005.

[62] The *Vienna International Plan of Action on Ageing* was the first international instrument on ageing, guiding thinking and the formulation of policies and programmes on ageing. It was endorsed by the UN General Assembly in 1982 (resolution 37/51). This plan of action is not a legally binding document. Accessed at http://www.un.org/esa/socdev/ageing/ageipaa.htm.

(a) *Recommendation 2*: Health care should involve the health and social sectors and the family in improving the quality of life of older persons.
(b) *Recommendation 3*: Early diagnosis and appropriate treatment is required, as well as preventive measures, to reduce disabilities and diseases of the ageing.
(c) *Recommendation 4*: Particular attention should be given to providing health care to the very old. This is particularly true when they are suffering from mental disorders or from failure to adapt to the environment.
(d) *Recommendation 8*: This highlights the need to allow ageing people to participate in decisions that affect them.
(e) *Recommendation 11*: The promotion of health and the prevention of disease and the maintaining of functional capacities among elderly persons should be actively pursued.
(f) *Recommendation 13*: This encourages development of home care to provide high quality health and social services for the elderly.
(g) *Recommendation 19*: This relates to housing for the elderly. They should be encouraged to continue to live in their own homes for as long as possible. Housing policies should suit the status and degree of self-sufficiency of the aged themselves, in accordance with local traditions and customs.
(h) *Recommendation 22*: Elderly persons should be encouraged to continue to live in their own environment, with involvement in the community.

e. UN International Plan of Action on Ageing (2002)

10.29
The United Nations Political Declaration and Madrid International Plan of Action on Ageing (2002)[63] is also not binding upon Member States of the United Nations but contains several recommendations, for the adoption by States, which update those previously incorporated in the Vienna International Plan of Action on Ageing.

[63] Available at http://www.unece.org/ead/pau/age/berl/aconf19719e.pdf.

f. UN Principles for Older Persons (Resolution 46/91)

10.30

These principles[64] relate to rights for older persons in relation to:

(a) Independence;
(b) Participation;
(c) Care;
(d) Self-fulfilment; and
(e) Dignity.

See **Appendix D** for further details.

g. UN Universal Declaration of Human Rights

10.31

The ***Universal Declaration of Human Rights*** [65] is not a legally binding document, but has been quite influential in moulding national legislation. The more relevant articles in relation to elderly people are as follows:

(a) *Article 17*: right to own property; no one shall be arbitrarily deprived of his property;
(b) *Article 22*: right to social security and entitlement to social and cultural rights, indispensable to his/her dignity;
(c) *Article 25*: right to a standard of living adequate for the health and well-being of himself and his/her family, including food, clothing, housing and medical care and necessary social services. There is also a right to security, in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood.

h. EU Declaration of Principles (1993)

10.32

This ***Declaration of Principles*** to mark the end of the European Year of the Elderly (1993),[66] though not binding the individual

[64] Accessed at http://www.unac.org/iyop/unquest.html.
[65] Accessed at .ttp://www.un.org/Overview/rights.html
[66] *Declaration of Principles* of the Council of the European Union and the Ministers for Social Affairs, of December 6, 1993, to mark the end of the European Year of the Elderly and of solidarity between generations (1993), Official Journal C 343, 21.12.1993, p. 0001–0003. Also accessed at http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:41993X1221:EN:HTML.

EU states, emphasises objectives relating to old age. These include:

(a) *Housing and mobility*: encouraging flexibility in provision of accommodation for the elderly, independence, privacy, the provision of accessible and safe residential environment and transport; and
(b) *Care and services*: the provision of services, including home care, home help, mobilisation of services, sheltered housing and health services.

i. Charter of Fundamental Rights of the European Union (2000)

10.33
This ***Charter of Fundamental Rights of the European Union***[67] is now incorporated in the EU Constitution as Part II: The Charter of Fundamental Rights of the Union.

(a) *Article 25*: The Union recognises and respects the rights of the elderly to lead a life of dignity and independence and to participate in social and cultural life.
(b) Other relevant articles (though not specific to the elderly) deal with social security (*Article 34*), health care (*Article 35*), access to services of general economic interest (*Article 36*), consumer protection (*Article 38*), citizens' rights (*Articles 39-46*) and justice (*Articles 47–50*).
(c) There are other articles in Part III of the Constitution, which deal with the Policies and Functioning of the Union, that cover topics of citizen's rights, public health, consumer affairs and justice.

[67] These articles in the *Charter of Fundamental Rights of the European Union* are included in the *Constitution for Europe*, signed in October 2004 but still not ratified by member states. Articles 25, 34, 35, 36, 38, 39–46 and 47–50 of the Charter correspond to Articles II–25, II–34, II–35, II-36, II–38, II–39 to 46 and II–47 to 50 of the EU Constitution.

Chapter 11

Laboratories

1. Introduction

Laboratories play a very significant role in the management of patients. It might be said that no patient these days is ever examined without supporting laboratory tests and information. The main ethical issues that revolve around laboratories include the following:

11.01
Confidentiality: It is normal practice for the laboratory to have all the information relating to a patient's identity as well as the results of the tests, which often establish a diagnosis. This information is readily available on data storage systems and is often easily accessible by any member of the laboratory staff. It is therefore incumbent on all staff working in a laboratory to realise the importance of confidentiality of this information and not to divulge it to other than authorised personnel.[1]

11.02
Disposal of body tissues and material: The sheer volume of blood that reaches the average laboratory creates a massive problem of disposal. All bodily fluids and tissues are potentially infective and therefore they have to be treated as such, often by incineration (which itself introduces environmental problems relating to atmospheric

[1] See also *Data Protection Act,* dealt with in Chapter 2.

pollution) or other more or less environmentally friendly procedures.

11.03

Safety: More than any other place in a hospital, the laboratory could be a place where biohazards are present. Staff handle blood and other body fluids as a routine, all of which may be hazardous. It is often the laboratory which first becomes aware of a possible infectious disease. Standard techniques in microbiological laboratories actually result in proliferation of micro-organisms in the process of reaching a conclusive diagnosis. Hence there is need for very strict safety precautions within the laboratory.

11.04

Source of bodily material and tissues: More and more laboratories these days are looked at as a source of material for research. For a long time, histological examination of material has entailed the accumulation of tissues from patients, often over a period of decades, and these make up valuable tissue-banks which may be very useful in the investigation of certain diseases. The recent interest in DNA analysis of specimens from stored tissues makes it mandatory that the use of these tissue-banks are carefully monitored and controlled.

11.05

Preparation of material for transfusion: Transfusion laboratories, in particular, deal with the production of material to be given back to the patient, as well as with specific testing of blood for blood group, etc. Such preparation requires meticulous and rigid application of standardised rules. Major laboratories may be involved in the production of blood products for distribution overseas, therefore international regulation is necessary to control its production. Hence there is a need for international conventions to cover this aspect.

11.06

Private laboratories: These provide the useful role of ensuring that private hospitals, as well as individual private patients, are well covered for diagnostic purposes and ensure choice and availability of care for the patient. Because they are run on a commercial basis,

and for the other reasons mentioned above, special regulations are deemed necessary to cover their daily activities.

Maltese legislation covers some aspects of the topics mentioned above.

2. Authority and Responsibilities

11.07

Laboratory workers fall under the rubric of 'professions complementary to medicine' which are defined as health care professionals whose name is entered in the Registers of Professions Complementary to Medicine referred to in the ***Health Care Professions Act.*** The Council for the Professions Complementary to Medicine set up under this Act[2] is responsible for a number of aspects, namely:[3]

(a) to keep updated registers containing the names of persons who qualify for inclusion; there will be separate registers for each of the professions[4]; there is also provision for specialist registers[5];
(b) to prescribe and maintain professional and ethical standards for the Professions Complementary to Medicine;
(c) other functions, including advising the minister on any matter affecting the professions and appointing a member to sit on the Specialist Accreditation Committee for the Professions Complementary to Medicine.[6]

However at present there is no Specialist Accreditation Committee for these professions since specialities in these professions are not, as yet, recognised by the ***Health Care Professions Act***[7]. The functions of a Specialist Accreditation

[2] *Health Care Professions Act*, article 25.
[3] *Health Care Professions Act*, article 27.
[4] *Health Care Professions Act*, article 28(1).
[5] This is the first mention of a Specialist Register in the category of Professions Complementary to Medicine but as yet no specialities are recognised in the *Health Care Professions Act*, Fifth Schedule.
[6] *Health Care Professions Act*, article 30(2)(a).
[7] *Health Care Professions Act*, Fifth Schedule.

Committee for the Professions Complementary to Medicine set up under this Act[8] would include:[9]

(a) issuing certificates of completion of specialist training in the specialities listed in the relevant part of the Fifth Schedule to this Act, upon the fulfilment of criteria recommended by the relevant professional associations listed in the Fourth Schedule to this Act[10];
(b) accreditation of post-graduate training programmes.

The Council has the right to impose penalties for unethical conduct or other misdemeanour, including a caution, fines, suspension or withdrawal of licence and may culminate in erasure from the Register on grounds of conviction by a court in Malta or infamous conduct.[11] This includes erasure on the grounds that the 'health care professional is unfit to continue to practise his profession on account of some physical or mental infirmity.'[12]

Further details on general issues relating to health care professionals, as determined by the ***Health Care Professions Act,*** are discussed in **Chapter 3: The Health Care Professions - Medical Issues**.

3. Permission to Operate a Laboratory

According to Maltese legislation, a licence is required to operate certain laboratories.

a. Preparation of medicines

11.08
Setting up a 'laboratory of chemical products used in medicine' is not permitted without having a licence from the Superintendent of Public Health.[13] Such a laboratory must be under the management

[8] *Health Care Professions Act*, article 30(1).
[9] *Health Care Professions Act*, article 30(6)(a).
[10] The Professions Complementary to Medicine have no representative associations listed in the Fourth Schedule of the *Health Care Professions Act.*
[11] *Health Care Professions Act*, article 32.
[12] *Health Care Professions Act*, article 38(1).
[13] *Medical and Kindred Professions Ordinance*, article 96(1).

of 'an apothecary or by a person holding a certificate of competency in chemistry.'[14] If this is not the case, the Superintendent of Public Health may close the laboratory.[15]

The ***Medicines Act***[16] forbids the manufacture, assembly or modification of any medicinal product except in accordance with a manufacturer's licence issued for the purpose by the Licensing Authority. To ensure that the premises used are suitable,[17] the Licensing Authority inspects such premises before granting a licence.[18] There has to be a qualified person professionally responsible for the activity of such a laboratory.[19] The minimum qualifications are laid down in regulation 9 of the Subsidiary Legislation 458.36, ***Manufacture of Medicinal Products for Human Use Regulations***. The responsibilities of such a person include ensuring that 'standards of good practice in manufacturing are complied with at all times,' and that 'each batch of medicinal products has been manufactured, tested and complies in all respects with any requirements' established under this Act. It also specifies that the qualified person must be present at the premises at all times when the activity is being carried out.[20]

b. Chemical laboratories

11.09

As discussed above, setting up a laboratory of chemical products used in medicine, without a licence from the Superintendent of Public Health, is illegal.[21] Such a laboratory must be managed by an apothecary or by a person holding a certificate of competency in chemistry.

The ***Ratification of Chemical Weapons Convention Act***[22]

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[14] *Medical and Kindred Professions Ordinance*, article 96(2).
[15] *Medical and Kindred Professions Ordinance*, article 96(3).
[16] *Medicines Act*, article 37.
[17] *Medicines Act*, article 38(1).
[18] *Medicines Act*, article 39(1).
[19] *Medicines Act*, article 38(e).
[20] *Medicines Act*, article 45. See also, *Manufacture of Medicinal Products for Human Use Regulations*, SL 458.36, regulations 11 and 12.
[21] *Medical and Kindred Professions Ordinance*, article 96.
[22] *Ratification of Chemical Weapons Convention Act*, article 12(c).

prohibits the operation of a facility or laboratory which produces or uses certain chemicals (identified in Schedule I of the Act) in quantities greater than 100 grams per year, unless the facility is prescribed. It also prohibits the exports of such chemicals, except to another state party to the Convention, for 'research, medical, pharmaceutical or protective purposes.'[23] The Act also contains references relating to the definition of analytical laboratories for the purpose of analysing chemical weapons.

OECD (Organisation for Economic Co-operation and Development) Member countries have established criteria for the performance of non-clinical health and environmental safety studies for assessment of safety of test items, usually chemicals, contained in pharmaceutical products, pesticide products, cosmetic products, veterinary drugs as well as food additives, feed additives, and industrial chemicals. International harmonisation of test methods led to the establishment in 1981 of the principles of Good Laboratory Practice. The revised protocol is now incorporated in Maltese legislation in the ***The Good Laboratory Practice Regulations, 2004.***[24]

With regards to the principles laid down in the ***Product Safety Act***, 'laboratories carrying out tests on chemical products, in accordance with the ***Dangerous Substances (Notification) Regulations, 2001***'[25] and 'in respect of tests on chemical products to evaluate their safety for man and, or the environment'[26] must comply with the principles laid out in the First Schedule of the ***Good Laboratory Practice Regulations, 2004.***

The National Accreditation Body-Malta Standards Authority is the body responsible for verification of compliance with legislation,

[23] *Ratification of Chemical Weapons Convention Act*, article 12(b).

[24] Legal Notice 371 of 2004, *The Good Laboratory Practice Regulations, 2004*, made under article 39 of the *Product Safety Act*. These regulations implement the provisions of Directive 2004/9/EC of the European Parliament and of the Council and of Directive 2004/10/EC of the European Parliament and of the Council.

[25] Legal Notice 371 of 2004, *The Good Laboratory Practice Regulations, 2004*, regulation 2(1). The *Dangerous Substances (Notification) Regulations, 2001* was issued as LN 318 of 2001.

[26] Legal Notice 371 of 2004, *The Good Laboratory Practice Regulations, 2004*, regulation 2(2).

of any testing laboratory, claiming to use Good Laboratory Practice in the conduct of tests on chemicals.[27] Compliance is to be verified on inspection of the laboratories, using the procedure laid down in the Second Schedule to these regulations.[28]

c. Private diagnostic laboratories

11.10

In order to have a private diagnostic laboratory, a specific licence is required under the ***Medical and Kindred Professions Ordinance***[29] which states that: 'No person shall use any premises as a . . . medical diagnostic laboratory . . . unless there is in respect of such premises a valid licence for the purpose issued by the Minister responsible for public health.' Such a licence may have specific conditions imposed[30] and is renewed on a year by year basis.[31]

The licence is only granted if 'the premises, equipment and facilities as well as the personnel, whether medical or otherwise,' are such as to 'provide a standard of medical care or service as the Minister responsible for public health deems to be satisfactory.'[32]

Supervision of laboratories is further emphasised: 'Every licensee shall ensure that medical laboratory tests are carried out by, or under the professional direction, supervision and responsibility of, a biochemist, microbiologist or other pathologist, or a toxicologist, as the case may be, or a medical practitioner or scientist qualified to assume professional, scientific, consultative, organisational and administrative responsibility for the service.'[33]

d. University laboratories

11.11

The University of Malta has the function and power 'to set up and

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[27] Legal Notice 371 of 2004, *The Good Laboratory Practice Regulations, 2004,* reglation 3(1).

[28] Legal Notice 371 of 2004, *The Good Laboratory Practice Regulations, 2004,* regulation 5(3) and Second Schedule.

[29] *Medical and Kindred Professions Ordinance,* article 98(1).

[30] *Medical and Kindred Professions Ordinance,* article 98(3).

[31] *Medical and Kindred Professions Ordinance,* article 98(5).

[32] *Medical and Kindred Professions Ordinance,* article 98(2).

[33] *Licensing of Private Medical Diagnostic Laboratories Regulations,* SL 458.25, regulation 6.

properly maintain libraries, laboratories and other facilities required for teaching, research, experimentation, or diffusion of knowledge and sciences as well as the establishment of academic audit and quality assurance schemes.'[34]

4. Laboratory Workers: Risks and Safety

11.12

Working in a laboratory exposes workers to special risks. Those whose work involves routine testing of patients' blood are continuously being exposed to the risk of infection inherent in processing of material which is potentially infectious. Often, the first diagnosis and identification of an infectious disease is made by the laboratory worker.

There are strict laboratory procedures on how to handle samples, including the use of gloves, a total ban on sucking pipettes to withdraw fluid from a container, a ban on food and drink in the laboratory and similar common-sense directives.

Legislation in Malta relating to this topic includes the following.

11.13

The ***Social Security Act***[35] itemises various diseases or injuries associated with various occupations, which qualify for Injury Benefit. With regards to laboratory personnel we find specific mention of three diseases associated with laboratory workers, namely:

(a) tuberculosis in 'a laboratory worker, pathologist or person taking part in or assisting at postmortem examinations of human remains where the occupation involves working with material which is a source of tuberculosis infection';
(b) brucellosis in a laboratory worker; or
(c) typhoid in 'a research worker engaged in research in connection with typhoid' or in 'a laboratory worker where the occupation involves working with material which is a source of typhoid infection.'

11.14

The ***Occupational Health and Safety Authority Act*** emphasises

[34] *Education Act*, article 28(g).
[35] *Social Security Act*, Fourth Schedule: Industrial Diseases or Injuries.

the role of both employers and employees in relation to safety within the workplace. With regards to duties of employers, it states that: 'It shall be the duty of an employer to ensure the health and safety at all times of all persons who may be affected by the work being carried out for such employer.' This responsibility remains even when 'an employer enlists competent external services or persons' to oversee safety procedures.[36] Ill-health here includes both physical and psychological aspects. In general, the employer is responsible for taking the necessary measures for:[37]

'(a) the avoidance of risk;
(b) the identification of hazards associated with work;
(c) the evaluation of those risks which cannot be avoided;
(d) the control at source of those risks which cannot be avoided;
(e) the taking of all the necessary measures to reduce risk as much as reasonably practicable, including the replacement of the hazardous by the non-hazardous or by the less hazardous;
(f) giving collective protective measures priority over individual protective measures;
(g) adapting the work to the worker, particularly in so far as the design of work places, the choice of work equipment and the choice of working and production methods are concerned, in particular with a view to alleviating monotonous work and work at a predetermined work-rate, and to reducing their effect on health;
(h) adapting to technical progress in the interest of occupational health and safety; and
(i) development of a coherent overall prevention policy which covers technology, the organisation of work, working conditions, social relationships and the influence of factors related to the working environment.'

An employer is also required 'to provide such information, instruction, training and supervision as is required to ensure occupational health and safety.'[38] Where 'a sufficient number of workers are employed,' an employer must ensure that a designated

[36] *Occupational Health and Safety Authority Act*, article 6(1).
[37] *Occupational Health and Safety Authority Act*, article 6(2). See also *General Provisions for Health and Safety at Work Places Regulations*, SL 424.18, which introduces the concept of health surveillance for employees.
[38] *Occupational Health and Safety Authority Act*, article 6(3).

person is elected or chosen to act as the Workers' Health and Safety Representative, to be consulted by the employer on matters which may affect the occupational health and safety of employees.[39]

With respect to the duties of workers in ensuring their own and their colleagues safety, the Act states that: 'It shall be the duty of every worker to safeguard one's own health and safety and that of other persons who can be affected by reason of the work which is carried out,' and moreover, that it is the duty of every worker to 'co-operate with the employer and with the Health and Safety Representative or Representatives at the work place on all matters relating to health and safety.'[40]

11.15

The ***Occupational Health and Safety Authority Act***[41] establishes an Occupational Health and Safety Authority, whose functions include:

(a) establishing strategies, 'by which the general national policy relating to occupational health and safety, ... may be implemented';[42]
(b) monitoring 'compliance with relevant occupational health and safety legislation' and taking enforcement action;[43]
(c) preparing 'regulations or Codes of Practice required to promote, maintain and protect a high level of occupational health and safety';[44]
(d) promoting 'the dissemination of information regarding occupational health and safety, and the methods required to prevent occupational injury, ill health or death';[45]
(e) promoting 'education and training on occupational health and safety, and emergency and first aid response at work places';[46]
(f) collating and analysing 'data and statistics on occupational injuries, ill health and deaths, and on matters ancillary to

[39] *Occupational Health and Safety Authority Act*, article 6(4).
[40] *Occupational Health and Safety Authority Act*, article 7.
[41] *Occupational Health and Safety Authority Act*, articles 8-14.
[42] *Occupational Health and Safety Authority Act*, article 9 (2)(b).
[43] *Occupational Health and Safety Authority Act*, article 9 (2)(d).
[44] *Occupational Health and Safety Authority Act*, article 9 (2)(e).
[45] *Occupational Health and Safety Authority Act*, article 9 (2)(f).
[46] *Occupational Health and Safety Authority Act*, article 9 (2)(g).
[47] *Occupational Health and Safety Authority Act*, article 9 (2)(h).

occupational health and safety';[47]

(g) keeping 'registers of such plant, installations, equipment, machinery, articles, substances, or chemicals and intended for use at work which in the opinion of the Authority provide a serious occupational health and safety risk';[48]

(h) carrying out 'any investigation on any matter concerning occupational health and safety, including but not limited to the investigation of any accident, injury, disease or death occurring as a result, or by reason of, any association with work, as well as investigations to ascertain the level of occupational health and safety provided at any work place, and the duty of the Authority to secure the enforcement of any provision of this Act shall not be reason to debar the carrying out of such investigations';[49]

(i) promoting and carrying 'out scientific research aimed at better methods of preventing occupational ill health, injury, or death';[50] and

(j) keeping 'registers of persons competent to give advice on matters related to occupational health and safety.'[51]

11.16

This Act also establishes the posts of Occupational Health and Safety Officers.[52] These officers have the authority[53] to enter and inspect, without notice, at any time of day, particular work premises, to question any employer or workers, examine work places and take any object or samples for examination, request certificates relating to safety of any structure or mechanical or electrical installation, and to require the employer to provide, to the medical officer of the Authority, a certificate from a medical practitioner relating to the occupational health of any worker or class or workers. He/she may also request any document, certificate or list of technical specifications in relation to any matter concerning occupational health and safety, the method of handling or use of any plant, installation, equipment, machinery, article, substance or chemical, which is used or intended to be used at work.

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[48] *Occupational Health and Safety Authority Act*, article 9 (2) (i).
[49] *Occupational Health and Safety Authority Act*, article 9 (2) (j).
[50] *Occupational Health and Safety Authority Act*, article 9 (2) (k).
[51] *Occupational Health and Safety Authority Act*, article 9 (2) (l).
[52] *Occupational Health and Safety Authority Act*, article 15.
[53] *Occupational Health and Safety Authority Act*, article 16.

5. Special Provisions for Laboratories

The safety of laboratory equipment and reagents, called medical devices, is controlled by regulations issued under the ***Product Safety Act***.[54] A 'medical device'[55] is 'any instrument, apparatus, appliance, material or other article,' including 'any software necessary for its proper application intended by the manufacturer to be used for human beings' for:

'(a) diagnosis, prevention, monitoring, treatment or alleviation of disease;
(b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
(c) investigation, replacement or modification of the anatomy or of a physiological process; and
(d) control of conception and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.'

Examples include reagents used for *in vitro* diagnostic tests in microbiological and blood transfusion laboratories.[56]

Regulation of the set up and work of Public Health laboratories and of any laboratory, providing a service concerning public health, also falls within the powers of the Superintendent of Public Health.[57]

a. Laboratories to prepare vaccines

11.17
The ***Prevention of Disease Ordinance*** specifies a number of issues relating to the preparation and distribution of vaccines, including:

[54] *Product Safety Act*, articles 38 to 40.
[55] *Medicines Act*, article 2.
[56] *In Vitro Diagnostic Medical Devices Regulations, 2002* (Legal Notice 61 of 2002) and *In Vitro Diagnostic Medical Devices (Amendment) Regulations, 2004* (Legal Notice 30 of 2004).
[57] *Public Health Act*, article 26.

(a) the requirement of a licence by the relevant institute to prepare a vaccine[58] and such an institute must be under the direction of a medical practitioner;[59] and
(b) requirement of a licence for the sale of vaccine or serum.[60]

It is the Licensing Authority set up in the ***Medicines Act***, which 'may prescribe rules regulating the issue or otherwise of a marketing authorisation for immunological medicinal products,' which include vaccines.[61]

b. Manufacture of dangerous drugs

11.18
The ***Dangerous Drugs Ordinance*** empowers the Minister responsible for public health to make rules controlling the manufacture, sale, possession and distribution of drugs such as cocaine, morphine, etc.[62] These include regulations:

(a) prohibiting the manufacture of any of these drugs 'except on premises licensed for the purpose and subject to any conditions specified in the licence'; and
(b) 'prohibiting the manufacture, sale or distribution of any such drug except by persons licensed or otherwise authorised under the rules and subject to any conditions specified in the licence or authority.'

c. Blood transfusion laboratories

11.19
Blood transfusion laboratories are under very severe pressure to provide blood and derivatives from blood, which are very necessary for everyday clinical use, being indispensable for many surgical procedures. On the other hand, these products have to be obtained from individuals, often on a voluntary basis. Added to this, there is

[58] *Prevention of Disease Ordinance*, article 55(1).
[59] *Prevention of Disease Ordinance*, article 55(2).
[60] *Prevention of Disease Ordinance*, article 55(4).
[61] *Medicines Act*, article 35(2).
[62] *Dangerous Drugs Ordinance*, article 9(1).

the problem of ensuring as far as possible that the donors are free from any infectious disease. The result is that on a worldwide basis there is a far greater demand for blood and blood products than can be supplied. Hence the need to ensure that the best use is made of this material at a clinical level, and that the laboratories co-operate as far as possible to provide it to all those who require it, emphasising principles of solidarity and subsidiarity.

The Treaty of the Council of Europe, ***European Agreement on the Exchange of Therapeutic Substances of Human Origin,*** entered into force on 1st January 1985 and Malta is bound by the provisions of this treaty.[63] It aims at co-ordinating the exchange of human blood and its derivatives among the nations of Europe.

Contracting parties undertake 'to make therapeutic substances of human origin available to other Parties who are in urgent need of them and to charge only costs involved in the collection, processing and carriage of such substances,'[64] and subject to the express condition that no profit is made from them.[65]

Contracting Parties must ensure that labelling, packing and dispatch is done properly according to the Protocol to this agreement, and according to international standardisation in this field. The products should be accompanied by a certificate to the effect that they were prepared according to the Protocol.[66]

Part II of the Treaty deals with the preparation of human blood and its derivatives.

(a) In the case of whole blood it is important to ensure that it is not taken from persons with possible infections (syphilis is specifically mentioned). Medical examination, including medical history is the minimum requirement to ensure that the patient is free from disease transmissible by blood transfusion. Details

[63] *European Agreement on the Exchange of Therapeutic Substances of Human Origin,* article 1. http://conventions.coe.int/Treaty/EN/Treaties/Html/026.htm. Text amended following Additional Protocol ETS 109, which entered into force on 1st January 1985.

[64] *European Agreement on the Exchange of Therapeutic Substances of Human Origin,* article 2.

[65] *European Agreement on the Exchange of Therapeutic Substances of Human Origin,* article 3.

[66] *European Agreement on the Exchange of Therapeutic Substances of Human Origin,* article 4.

are given relating to withdrawing of the blood, blood anti-coagulation to be used and techniques of blood grouping, storage and labelling.

(b) With regard to Dried Human Plasma there are details relating to preparation and testing to ensure that there is no bacterial contamination. Labelling procedures are clearly laid out. Similar directions are given for Human Albumin, Human Immunoglobulin and Human Fibrinogen.

Directive 2002/98/EC of the European Parlament and of the Council sets 'standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components.'[67] This Directive amends ***Directive 2001/83/EC***,[68] which only ensured the quality, safety and efficacy of industrially prepared medicinal products derived from human blood or plasma, since it specifically excluded whole blood, plasma and blood cells of human origin intended for transfusion.

In Malta, the ***Medicines Act*** regulates 'the manufacture and assembly of medicinal products derived from human blood and human plasma'[69] including the requirement for a relevant licence.

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[67] *Directive 2002/98/EC*, Official Journal of the European Union, L 33/30, 8.2.2003, done at Brussels on 27th January 2003. As regards certain technical requirements for blood and blood components, it was implemented by *Directive 2004/33/EC* of 22nd March 2004, Official Journal of the European Union, L 91/25, 30.3.2004. It is envisaged to transpose these directives into Maltese legislation as the *Human Blood and Transplants Act, 2006*, which was published as Bill No. 62 in the Government Gazette, No. 17,886, on 28th February 2006. This bill incorporates licensing and controls to ensure adherence to the directives. *Directive 2005/61/EC*, Official Journal of the European Union, L 256/32, 1.10.2005, implements the traceability requirements and the notification of serious adverse reactions and events. *Directive 2005/62/EC*, Official Journal of the European Union, L 256/41, 1.10.2005, implements the standards and specifications relating to a quality system for blood establishments.

[68] *Directive 2001/83/EC* of 6th November 2001 on the Community code relating to medicinal products for human use, Official Journal of the European Union, L 311, 28.11.2001.

[69] *Medicines Act*, article 50, referring to the provisions in articles 37 to 48. See also section 11.08.

d. Private medical diagnostic laboratories

11.20

As mentioned above, a specific licence is required under the ***Medical and Kindred Professions Ordinance***[70] in order to operate a private diagnostic laboratory. Further regulations relating to licensing of private medical diagnostic laboratories are contained in the subsidiary legislation, ***Licensing of Private Medical Diagnostic Laboratories Regulations.***

A laboratory is here defined as 'a private medical diagnostic laboratory, and includes any facility, building or otherwise, used for the purpose of biological, microbiological, serological, chemical, immuno-haematological, haematological, biophysical, cytological, pathological, or other examination of material derived from the human or animal body, or for the purpose of providing information for the diagnosis, prevention or treatment of any disease, condition or impairment of health, or for the assessment of the state of health of a person or animal, but does not include a government laboratory.'[71]

11.21

It refers to '*good laboratory practice*', which 'includes the compliance at all times with the ethical standards and with laws and regulations governing the professions related with laboratory practice, as well as compliance with international standards for procedures, practices and methods used in a laboratory.'[72]

The application for the licence should contain the following information:[73]

(a) 'a comprehensive list of all the tests and other activities carried out or intended to be carried out at such laboratory';
(b) a list of all the staff with details relating to qualifications and duties and responsibilities;
(c) 'a list of equipment that is used, or intended to be used on the premises;

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[70] *Medical and Kindred Professions Ordinance*, article 98(1).
[71] *Licensing of Private Medical Diagnostic Laboratories Regulations*, SL 458.25, regulation 2.
[72] *Licensing of Private Medical Diagnostic Laboratories Regulations*, SL 458.25, regulation 2.
[73] *Licensing of Private Medical Diagnostic Laboratories Regulations*, SL 458.25, regulation 4(2).

(d) a list of animals that are kept or used, or intended to be kept or used for such tests;
(e) the policy and procedures for quality control and safety.'

11.22

The supervision of medical laboratory tests should be under the professional direction and responsibility of 'a biochemist, microbiologist or other pathologist, or a toxicologist, as the case may be, or a medical practitioner or scientist qualified to assume professional, scientific, consultative, organisational and administrative responsibility for the service.'[74] These conditions are not, however, defined or described further.

The range of tests that may be carried out on the premises has to be specified in the licence certificate and no other tests are to be performed on the premises.[75]

The following information has to be kept in a register by the licensee of the laboratory, in relation to tests performed:[76]

'(a) the name and surname, (or initials), identity card number, sex, address and date of birth of the patient;
(b) the name, surname, address and medical registration number of the referring medical practitioner;
(c) the date when the request was received at the laboratory;
(d) the type of test requested by the referring medical practitioner;
(e) the type of test carried out at the laboratory and methods used;
(f) the name of the microbiologist, biochemist or other pathologist, or toxicologist responsible for the test, as well as the technical person who carried out the test;
(g) where practicable, the result of the test.'

'The licensee shall also keep records of reports of all results of tests carried out at his laboratory.'[77]

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[74] *Licensing of Private Medical Diagnostic Laboratories Regulations*, SL 458.25, regulation 6.
[75] *Licensing of Private Medical Diagnostic Laboratories Regulations*, SL 458.25, regulation 7.
[76] *Licensing of Private Medical Diagnostic Laboratories Regulations*, SL 458.25, regulation 8(1).
[77] *Licensing of Private Medical Diagnostic Laboratories Regulations*, SL 458.25, regulation 8(2).

11.23

To note that in the case of human immunodeficiency virus (HIV), special procedures to protect the identity of the patient prevail, and the above requirements relating to patient identification do not hold. Moreover this test is only carried out in a government laboratory. HIV is now a notifiable disease in terms of the ***Public Health Act.***[78]

This article also sets stringent regulations relating to medical staff attendance at the laboratory. The laboratory must have a register to indicate date and time of entering and leaving the laboratory.[79]

The issue of how long should laboratory results be kept has been a problem for a long time. This is regulated by regulation 9 of the ***Licensing of Private Medical Diagnostic Laboratories Regulations.*** It states that all information in the register as well as 'all records, shall be retained by the licensee for a period of not less than two years from the date of the last entry in the register or record.' In the case of histology tests and any forensic or toxicological tests, the results should be kept for a period of twenty-five years. It is also required that results of tests of quality assessment or maintenance shall be kept indefinitely.

While these guidelines are comparable to recommendations of the Royal College of Pathologists, UK,[80] there are no legal requirements for government laboratories.

11.24

A private laboratory has to inform 'the Superintendent of Public Health of any infectious disease diagnosed at the laboratory, notifiable under the ***Prevention of Disease Ordinance,***[81] as well as

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[78] The legal notice was issued as Government Notice No 75 of 2004 published in the Government Gazette of 27th January 2004 (issue number 17,333, p. 406).

[79] *Licensing of Private Medical Diagnostic Laboratories Regulations*, SL 458.25, regulation 8(3a).

[80] *The Retention and Storage of Pathological Records and Archives.* Report of the Working Party of the Royal College of Pathologists and the Institute of Biomedical Science. 2nd edition, 1999, RCPath., UK.

[81] *Prevention of Disease Ordinance,* articles 10 and 11 will be repealed and replaced by any notice in terms of article 27 (a)(i)of the *Public Health Act.* At present the list of notifiable diseases is contained in Government notice No. 75 of 2004.

of all pathological samples confirmed for malignancy.'[82] The following details are required to be given:

(a) name, address and identity card number of the patient;
(b) the name, address and medical registration number of the referring medical practitioner.[83]

It is expected that private laboratories maintain adequate standards relating to facilities and services provided.[84] In particular, they should provide and maintain adequate laboratory facilities in accordance with good laboratory practice and they should take precautions against risks, both physical and biological, including the disposal of infectious material. They should, in addition, have available the following codes of practice:

'(a) the laboratory's policy for quality control on a daily basis, including accreditation of its tests from an authority that is recognised by the Minister to be appropriate and reliable, with inter-laboratory calibration exercises forming part of this accreditation;
(b) the laboratory's policy on instrument function checks and preventive maintenance of instruments;
(c) the laboratory's safety policies to the workers, the patients and the public in general.'

11.25

In relation to inspection of reports and premises, any authorised person may enter at any time of day and night to inspect the premises.[85] On the other hand, with regard to information requesting details regarding patients, 'such information may only be requested by and made available to an authorised person who is a medical practitioner.'[86] This proviso helps to ensure patient confidentiality.

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[82] *Lincensning of Private Medical Diagnostic Laboratories Regulations*, SL 458.25, regulation 10.
[83] *Licensing of Private Medical Diagnostic Laboratories Regulations*, SL 458.25, regulation 10.
[84] *Licensing of Private Medical Diagnostic Laboratories Regulations*, SL 458.25, regulation 11.
[85] *Licensing of Private Medical Diagnostic Laboratories Regulation*, SL 458.25, regulation 12.
[86] *Licensing of Private Medical Diagnostic Laboratories Regulation*, SL 458.25, regulation 12.

11.26

The final regulation[87] deals with the widespread use of medical diagnostic kits meant for home use. This article states that 'irrespective of where these tests are carried out' the above regulations do not apply. In other words, the same precautions need not be taken by any person, whether an individual patient at home, or in the laboratory! In particular, the article makes reference to the use of these tests by 'a medical practitioner in his consulting room or at the patient's home, or bedside, using doctor's office equipment in the exercise of his profession.' While one may understand the need for relaxation of these rules for patients performing their own tests on themselves, and for which they alone are responsible, it is difficult to understand why the same standards of reliability, safety and care normally to be expected of a laboratory should not apply to any professional person performing these tests on behalf of a patient.

6. The Forensic Laboratory

11.27

Maltese law makes few references relating to the role of the laboratory in investigating potential criminal offences.

Provision of specimens for analysis in case of infringement of traffic regulations: A police officer has the right to require a person to provide a specimen of breath for a road breath test[88] on suspicion that the driver has committed an offence in terms of driving or attempting to drive under the influence of alcohol or drugs or when involved in an accident.

Moreover a police officer has the right to require a person to provide specimens of breath, blood or urine for laboratory analysis 'in order to determine whether a person has committed an offence.'[89] The ***Traffic Regulation Ordinance***, article 15F, provides for analysis of two breath specimens. The one with the lower proportion of alcohol in the breath is to be used and the other discarded, provided that of the former 'contains no more than 50 microgrammes of

[87] *Licensing of Private Medical Diagnostic Laboratories Regulation*, SL 458.25, regulation 14.
[88] *Traffic Regulation Ordinance*, article 15C.
[89] *Traffic Regulation Ordinance*, article 15E(1).

alcohol in 100 millilitres of breath, the person who provided it may claim that it should be replaced' by any other specimen.

In the case of urine, two specimens are required with an interval of one hour between them, the second one being used for analysis.[90]

To note that: 'A person who refuses or fails to provide a specimen as provided under this article shall be guilty of an offence,' unless failure to provide the specimen was due to physical or mental incapacity to provide it.[91]

Analysis of these specimens must take place at a laboratory approved by the Minister, and the opinion of the analyst in that laboratory and the results of the analysis shall be admissible in evidence in any proceedings for an offence.[92]

Legislation specifies the laboratory[93] where the tests are to be carried out and as for the breath tests, it also specifies the devices[94] to be used.

7. DNA Laboratories and their Control

11.28

Perhaps one of the most controversial areas of laboratory work is that relating to DNA testing, particularly in relation to diagnosis of genetic disease. The technology of DNA testing is now simple and efficient and several hundred different tests can be performed on each individual sample within a relatively short period of time.

The main differences between DNA testing and other laboratory tests may be summarised as follows:

(a) *permanence:* unlike most other tests which depend on the current status of an individual, DNA tests reveal a permanent and unique characteristic of the individual. Unlike most other tests, they, therefore, remain relevant for the life-time of the individual;

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[90] *Traffic Regulation Ordinance*, article 15E(2).

[91] *Traffic Regulation Ordinance*, article 15E(4).

[92] *Traffic Regulation Ordinance*, article 15E(5).

[93] Malta National Laboratory, Evans Buildings, Merchant Street, Valletta, as laid out in Legal Notice 418 of 2004, *Breath Tests (Devices and Laboratories) Regulations, 2004.*

[94] The Lion Alcometer SD-400 is to be used for road tests and the Lion Intoxilyzer 6000 – 220/240 volts is to be used for the two breath tests carried out in the laboratory.

(b) *involve more than just the individual patient:* because we share our genes with other family members, a diagnosis on one individual is likely to have a bearing on other members of the family, including their risks of developing disease later on in life; and
(c) *need for counselling:* because of the above, tests involving DNA require more than the usual degree of counselling, to be undertaken by professional personnel, prior to provision of a sample. The results of the test should likewise be discussed in such an environment. They should not therefore be done where these facilities are not available.

Maltese legislation lacks specific directions relating to DNA testing laboratories. The subsidiary legislation to the ***Business Promotion Act,*** the ***Qualifying Companies (Export Services) Regulations*** states that one of the export services is 'the provision of specialised medical check-ups, diagnosis and services ancillary thereto from specialised high technology clinics established in Malta for persons not resident in Malta.'[95] In effect this has allowed the setting up of private laboratories to provide genetic services to anybody interested in performing such tests, including individual members of the public, both in Malta and overseas.

However the ***Patents and Designs Act*** prohibits the granting of a patent for 'processes for cloning the human body, processes for modifying the germ line genetic identity of the human body and uses of the human embryo for industrial or commercial purposes'[96] and for 'DNA sequence not containing any technical information and in particular any indication of its function.'[97]

With regards to the ***Veterinary Services Act,*** the Minister may, prescribe rules regarding veterinary medicinal products (medicinal products intended for animals) listed in the Sixth Schedule,[98] which include GMOs, genetically modified organisms. These rules may include testing of such products in accordance with article 29(b) of the Act, which allows for 'the establishment of the analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products.'

[95] *Qualifying Companies (Export Services) Regulations,* SL 325.01, regulation 3(1)(g).
[96] *Patents and Designs Act,* article 4(5)(c).
[97] *Patents and Designs Act,* article 4(5)(g).
[98] *Veterinary Services Act,* article 32.

Chapter 12

Research

1. Introduction

12.01
The scientist involved in any aspect of research must be aware of both local as well as international legislation, codes of ethics and other guidelines that are relevant to the pursuit of research. The research scientist in Malta should be guided by the following:

(a) laws of Malta that impinge on research;
(b) regulations which the Minister(s) may promulgate from time to time;
(c) other directives, including those issued by individual institutions, (Department of Health, hospitals, University departments, etc.);
(d) international Conventions which Malta has adhered to, or is in the process of adhering to, and EU legislation;
(e) international guidelines which, while not necessarily binding, indicate a level of practice that should be emulated (e.g. Helsinki Declaration, UNESCO, CIOMS, Council of Europe Conventions and related Protocols); and finally and importantly
(f) requirements set by international publishers for scientific papers.

One might get the impression that in Malta we have a dearth of legislation that specifically controls and determines research aspects. However, on closer scrutiny, one finds that several aspects of legislation may be found scattered in various laws and other regulatory directives, which the researcher should be aware of. In

addition, there is a continuous influx of new international legislation and codes of conduct which the researcher should be familiar with. It has to be borne in mind that, in case of a court action, it is normally a defence to argue that one has been practising at a level which is acceptable to a peer group, and this could be confirmed by comparison with ethical practice world-wide.

2. Ethics Committees in Malta

12.02

There are the following ethics committees which are functional in Malta:

The Bioethics Consultative Committee: This committee is in the first instance an advisory body to the Minister of Health who selects the members, currently on an annual basis. Its role in research is limited to formulating guidelines to be followed by various institutes, research establishments and individuals, as well as to pronounce its views on questions relating to research ethics as the need arises. It is not involved in the assessment of the ethical aspects of individual research projects. Over the years, it has organised conferences related to the basis of bioethics and has published various guidelines relating to research (see below).

University Research Ethics Committee (UREC): A Research Ethhics Committee was set up by the Senate of the University of Malta some years ago and in July 2004, Senate approved a new set of guidelines to 'regulate all research involving human subjects carried out at the University, both by students and by members of staff.'[1] Senate also appointed a new University Research Ethics Committee.

The guidelines were drawn up in close consultation with the Data Protection Commissioner's Office and this is the only university ethics committee which the Data Protection Commissioner will recognize in terms of the ***Data Protection Act.***

[1] University Research Ethics Committee (UREC), University of Malta (UoM), Guidelines, http://www.edu.mt/noticeboard/ethicsguidelines.pdf. See Appendix E.

The guidelines provide for each faculty to 'appoint its own Faculty Research Ethics Committee, whose membership will be proposed by the Faculty Board and approved by Senate, in a way similar to examination boards.'[2] The UREC must give the final approval to the decisions of these Faculty Ethics Committees.

Research Ethics Committee, Faculty of Medicine and Surgery, University of Malta: This body had been set up for over a decade by the Faculty of Medicine and Surgery, at the Medical School, to examine research projects of a biomedical nature submitted to it. Initially there was no obligation on the part of researchers to submit their project to this body. However since July 2004, in accordance with Senate's directions, the committee has to follow the procedures and guidelines prepared by the UREC.

'Each university member, student or member of staff, undertaking research involving human subjects will fill the proposal form and present it for approval to the faculty research ethics committee.' 'The faculty committee will discuss the research proposals according to the criteria present in the guidelines, and will give its advice whether the research is to be approved or not, and for what reasons. This advice is passed on to the University committee, which will give the final approval.'[3]

The Faculty Research Ethics Committees are expected to report to the UREC 'any serious or continuing non-compliance by investigators with requirements of the UREC' and 'any unanticipated problems or injuries' and 'any changes in the research activity.'[4] However there is no formal mechanism for supervising the activities of the research workers, so as to ensure that they follow the plan of research as approved.

Health Ethics Committee: The Ministry of Health, through the Director General of Health, who at present, is also the Superintendent of Public Health and hence, the Licensing Authority in terms of the ***Medicines Act***, set up a Health Ethics Committee in March 2005 with the following terms of reference:

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[2] UREC, UoM , Guidelines, A Summary, 3.2. See Appendix E.
[3] UREC, UoM, Guidelines, A Summary, 3.3–3.5. See Appendix E.
[4] UREC, UoM, Guidelines, III C(1). See Appendix E.

(a) 'to advise entities within the Ministry of Health on data protection issues';
(b) 'to assess and evaluate the justification for the collection of personal data in the health sector';
(c) 'to assess and evaluate the justification for the use of personal data in the health sector';
(d) 'to evaluate proposals for research being undertaken in the health sector'; this is to be undertaken 'in close collaboration with and in full recognition of the Research Ethics Committee in the Faculty of Medicine and Surgery in the University of Malta';
(e) 'to liaise with and advise the Data Protection Commission on data protection in use'; and
(f) 'to advise on any issues referred to it by the Minister or Director General.'[5]

The Committee is responsible for approving Clinical Trials in terms of the ***Medicines Act*** and its related subsidiary legislation, ***Clinical Trials Regulations*** (see below) as well as all other clinical trials, including those involving medical devices and intervnetions, in both the public and private sector.[6]

12.03

The legal basis of the presence of an ethics committee may be gleaned from the following legislation.

In relation to processing of data related to research or statistical information, the ***Data Protection Act*** states that sensitive personal data may be processed for research and statistics purposes, provided that this processing has been approved 'by the Commissioner on the advice of a research ethics committee of an institution recognised by the Commissioner.'[7] The Commissioner is currently recognising one committee per institution.

The ***Medicines Act*** establishes a Licensing Authority, one of whose functions is 'to establish standards for the carrying out of clinical trials.'[8] Moreover, it empowers the Minister to make

[5] http://www.sahha.gov.mt/pages.aspx?page=134
[6] Guidance Notes for Clinical Trials in Malta, http://www.sahha.gov.mt/pages.aspx?page=134
[7] *Data Protection Act*, article 16(2)(b).
[8] *Medicines Act*, article 3(2)(f).

regulations relating to 'the conduct of clinical trials'.[9] Subsequent subsidiary legislation, the ***Clinical Trials Regulations***, states that 'the Licensing Authority shall set up an Ethics Committee, which shall give its opinion, before a clinical trial commences, on any issue requested.'[10]

These regulations define 'the Ethics Committee' as 'an independent body, consisting of healthcare professionals and non-medical members, whose responsibility is to protect the rights, safety and wellbeing of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, expressing an opinion on the trial protocol, the suitability of the investigators and the adequacy of facilities, and on the methods and documents to be used to recruit and inform trial subjects and obtain their informed consent.'[11]

The ***Animal Welfare Act***[12] refers to 'ethical rules and standards which may be drawn up by the Council' set up under this Act, implying that an ethics committee is required for this purpose. Moreover, the Act requires that research approval is sought and obtained for certain types of animal experiments.[13] (See further below.)

3. Informed Consent in Research

12.04

There is unanimity of opinion relating to the overarching need for ensuring that in all research involving human beings, the research subject is well-aware of the procedures involved and that informed consent is freely given. There are however, in Malta, uncertainties about the obligations that research workers have in relation to submission of research protocols for vetting by research ethics committees.

The University Research Ethics Committee, UREC, states:[14] 'Research Investigators are responsible for ensuring that legally effective informed consent shall:

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[9] *Medicines Act*, article 106(h).
[10] *Clinical Trials Regulations*, SL 458.43, regulation 7(1).
[11] *Clinical Trials Regulations*, SL 458.43, regulation 3.
[12] *Animal Welfare Act*, article 33.
[13] *Animal Welfare Act*, article 36(2) and (3).
[14] UREC, UoM, Guidelines, V A(2). See Appendix E.

(a) be obtained from the subject or the subject's legally authorized representative;
(b) be in language understandable to the subject or the representative;
(c) be obtained under circumstances that offer the subject or the representative sufficient opportunity to consider whether the subject should or should not participate; and
(d) not include exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or release the Research Investigator, the Sponsor, the University or its agents from liability for negligence.'

The UREC guidelines go on to outline the basic information, which must be communicated to research subjects, to ensure informed consent.

The *Patients' Charter of Rights and Responsibilities* by the Hospital Management Committee of St. Luke's Hospital states that: 'A patient has the right to be well informed and completely free whether to accept, decline or withdraw at any stage to take part in clinical research or student training.'[15]

The concept of 'informed consent' implies the following:

(a) that the research subject is capable of receiving and understanding information;
(b) that s/he is capable of acting on such information;
(c) that the consent is freely given, i.e. that there is no pressure brought to take part in a research procedure.

As regards legislation, 'informed consent' is defined for the purpose of a clinical trial, in the subsidiary legislation, ***Clinical Trials Regulations***, as 'a decision, which must be written in one of the official languages of Malta or in a language understandable to the clinical trial subject and, or his legal representative, dated and signed, to take part in a clinical trial, taken freely after being duly informed of its nature, significance, implications and risks and

[15] *Patients' Charter of Rights and Responsibilities*, Hospital Management Committee, St. Luke's Hospital, article 02.07, http://www.slh.gov.mt/pdf/EnglishCharter.pdf.

appropriately documented, by any person capable of giving consent or, where the person is not capable of giving consent, by his or her legal representative; if such person is unable to write, oral consent may be given in the presence of at least one witness.'[16]

The ***Data Protection Act*** defines 'consent' as 'any freely given specific and informed indication of the wishes of the data subject by which he signifies his agreement to personal data relating to him being processed.' This does not refer specifically to research, but to any collection of data from a data subject being processed, including, in this context, for the purpose of research.

Personal data may be processed only if 'the data subject has unambiguously given his consent.'[17] However there are other conditions where processing is allowed, namely, when processing is necessary for compliance with a legal obligation, to protect the vital interest of the data subject, or in the public interest, etc. None of these provisos would be relevant to research activities involved with data collection, however.

Once the data subject has given his permission, he 'may at any time revoke his consent for compelling legitimate grounds relating to his particular situation.'[18]

Moreover, a data subject is 'entitled to object at any time to the controller on compelling legitimate grounds to the processing of data'[19] for which his consent was not originally required.

In the case of 'sensitive personal data', the Act states that 'no person shall process sensitive personal data' unless the data subject 'has given his explicit consent to processing' or 'has made the data public'. However, in the case of 'an important public interest' the Minister may require such processing to be done.[20]

12.05

A data subject is entitled to receive adequate information. The Controller is responsible for providing such information, namely:

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[16] *Clinical Trials Regulations*, SL 458.43, regulation 3.

[17] *Data Protection Act*, article 9(a).

[18] *Data Protection Act*, article 11(2).

[19] *Data Protection Act*, article 11(1). This relates to subarticles 9(e) and 9(f), which deal with data processed in accordance with the public interest, during the exercise of official authority or for a legitimate interest of the controller.

[20] *Data Protection Act*, article 12(1).

'(a) the identity and habitual residence or principal place of business of the controller and of any other person authorised by him in that behalf, if any;
(b) the purposes of the processing for which the data are intended; and
(c) any further information relating to matters such as:
    (i) the recipients or categories of the recipients of data;
    (ii) whether the reply to any questions made to the data subject is obligatory or voluntary, as well as the possible consequence of failure to reply; and
    (iii) the existence of the right to access, the right to rectify, and, where applicable, the right to erase the data concerning him.

and, insofar as such further information is necessary, having regard to the specific circumstances in which the data is collected, to guarantee fair processing in respect of the data subject.'[21]

The ***Malta Statistics Authority Act*** states that: 'No information obtained in any way under this Act which can be related to an identifiable person or undertaking shall, except with the written consent of that person or undertaking or the personal representative or next-of-kin of that person, if he be deceased, be disseminated, shown or communicated to any person or body except:

(a) for the purposes of a prosecution for an offence under this Act, or
(b) to officers of statistics in the course of their duties under this Act.'[22]

a. International legislation

12.06

The Council of Europe's ***Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*** (which Malta has not yet signed) makes it clear that research must be performed under certain standard conditions

[21] *Data Protection Act*, article 19.
[22] *Malta Statistics Authority Act*, article 41(1).

relating to consent. Moreover, these are emphasised in the Council of Europe's ***Additional Protocol to the Convention on Human Rights and Biomedicine Concerning Biomedical Research.***[23]

The Convention and the Protocol make a clear distinction between those subjects capable of giving consent and those who for some reason (age, mental infirmity, emergency situations) cannot give consent.

While encouraging the concept of scientific research, and emphasising its importance, they nevertheless point out the need for protection of the human being.

Those who are capable of giving consent: Research on these subjects can be carried out provided that:

(a) there is no better alternative. Research on human beings should not be undertaken if the same results could be obtained from research that does not use human beings;
(b) in view of the fact that these subjects are unlikely to reap the benefit of the research, one must ensure that the risks involved are not disproportionate with the expected benefit of the research;
(c) a competent body has examined the proposed project and is convinced of its scientific merit and that it is ethically acceptable;
(d) informed consent is given expressly and specifically, and it is documented. It is also emphasised that a research subject can withdraw his/her consent at any time without incurring the wrath of the researcher or suffering any untoward consequences.

12.07

Those who are incapable of giving consent: More difficult is the situation where the research subject is incapable of giving consent. This is particularly the case in research involving children under the specified legal age (18 years in Malta) and persons with mental disability. In such cases, extra precautions and regulations apply.

In the case of minors and those who suffer from a mental disorder rendering them incapable of giving informed consent, research may be carried out:

[23] The Committee of Ministers adopted the Protocol on 30th June 2004 and it was opened for signature on 25th January 2005.

(a) with the authorisation of his or her representative. In the case of a minor, his or her opinion should be taken into consideration proportionately to increasing maturity. This authorisation has to be given specifically for the particular procedure and has to be in writing. It is also pointed out that research should not be carried out if the person concerned objects to the procedure.
(b) the research is likely to produce direct benefit to the research subject. When this is not the case, research on minors could be carried out if it is envisaged that this might improve the scientific understanding of the particular disease or condition of persons of the same age category or afflicted with the same disease. In this case, the risk associated with the research should only entail 'minimal risk and minimal burden' to the research subject.[24]
(c) the research cannot be carried out on persons capable of giving consent.

Research on persons with a mental disability involves further considerations, which have been dealt with in the **Chapter 9: Mental Health**. (See also further specific guidelines in **Appendices G** and **H**.)

b. Guidelines by local ethics committees

12.08

The Bioethics Consultative Committee has issued guidelines relating to informed consent in a research context and these are to be found in the document, *Guidelines Relating to Consent of Patients to Medical Intervention,* which in the recommendation on participation in scientific research, states the following:

'1. The consent of the patient is a prerequisite for participation in scientific research.
2. All protocols must be approved by a recognised ethics review committee.

[24] Council of Europe's *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine,* article 17(2).

3. Such research should not be carried out on those who are unable to express their will unless it has the potential to produce a significant benefit to his or her health and with the consent of a legal representative. However research with no direct immediate benefit to the individual may be carried out where there is negligible risk and minimal burden for the individual concerned, provided that equally effective research cannot be carried out on subjects with full capacity, and there is no equally effective alternative method to research.'[25]

The document also emphasises that written consent forms are to be duly signed after adequate information is given to the participating patient.

The *University Research Ethics Committee (UREC)* prepared a set of guidelines to 'regulate all research involving human subjects carried out at the University, both by students and by members of staff.'[26]

The guidelines outline the UREC's policy, stating that its review of research proposals is 'to assure that (1) risks to subjects are minimized and reasonable in relation to the anticipated benefits; (2) there is informed consent; (3) rights and welfare of subjects are maintained; and (4) the requirements of data protection legislation are observed.' There is a detailed explanation of its procedures and an explanation of the type of research it will consider for approval. It explains informed consent and provides a proposal form,[27] which identifies the person taking responsibility for the research and for compliance with the regulations and with the ***Data Protection Act.*** It also outlines the responsibilities of faculty ethics committees.

The guidelines also state that UREC has 'the authority to suspend or terminate approval of research that is not being conducted in accordance with UREC requirements or that has been associated with unexpected serious harm to subjects.'

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[25] *Informed Consent: Proceedings of a Symposium for Medical and Paramedical Practitioners*, Ed. Maurice N. Cauchi, Bioethics Consultative Committee, Malta, 1998, ISBN 99909-68-68-3, Appendix: *Guidelines Relating to Consent of Patients to Medical Intervention*, recommendation 10.

[26] University Research Ethics Committee (UREC), University of Malta (UoM), Guidelines, http://www.um.edu.mt/noticeboard/ethicsguidelines.pdf. See Appendix E.

[27] http://www.um.edu.mt/noticeboard/proposalform.doc.

c. Other local guidelines

12.09

(a) The *Patients' Charter of Rights and Responsibilities*, issued by the Hospital Management Committee (St Luke's Hospital), refers to informed consent required to be given by a patient in hospital. It does not specifically deal with research involving such patients.

(b) The *Patient Charter* issued by the Malta College of Family Doctors refers to the right of a patient to 'give or withhold (your) consent to medical or other care and treatment.' It also advises that a patient can 'choose whether or not you wish to take part in research or student training.'

d. International guidelines

12.10

There are several guidelines which have been prepared with the aim of ensuring that the research subject provides informed consent. The first of these, the Nüremberg Code, was subsequently followed by the declaration of the World Medical Association (WMA) at Helsinki and the guidelines of the Council for International Organizations of Medical Sciences (CIOMS) and of UNESCO. The following is a summary of the relevant aspects of these guidelines.

The *Nüremberg Code* has formed the basis of modern day bioethical guidelines in medical research. It was formulated by the International Court in 1947, following the war crimes tribunal at Nüremberg, to provide a set of guiding principles for the conduct of medical research. It laid down ten standards, the first being the requirement of informed consent, obtained voluntarily from the research subject. The research should be 'such as to yield fruitful results for the good of society' and 'to avoid all unnecessary physical and mental suffering and injury.' The subject 'should be at liberty to bring the experiment to an end' and the researcher 'must be prepared to terminate the experiment at any stage' if there is the danger that 'a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject'.[28] Eventually the concepts were also applied to therapeutic procedures.

[28] The full text of the Nüremberg Code, 1947, is reproduced in Appendix F from *Trials of War Criminals before the Nüremberg Military Tribunals under*

12.11

The *Declaration of Helsinki*, entitled *Ethical Principles for Medical Research Involving Human Subjects*,[29] is an official policy document of the World Medical Association, the global representative body for physicians. It was first adopted by the General Assembly in Helsinki, Finland in 1964 and has been updated at regular intervals.[30]

In relation to informed consent it emphasises the need that participants in research projects 'must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail.'[31] It is only then that the physician may ask the subject for his or her consent, preferably in writing. If the consent cannot be obtained in writing, 'the non-written consent must be formally documented and witnessed.' The patients may also withdraw consent at any time without reprisal.

Emphasis is also made on the need for caution to be followed where 'the subject is in a dependent relationship with the physician'[32] for instance where the latter is both the researcher and the caring physician, since this may put undue pressure or duress on the patient. In such cases, 'the informed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of this relationship.' In the case where the subject is not competent to give consent, consent must be obtained from the legally authorised representative. These subjects should be included in a research programme only if 'the research is necessary to promote the health of the population represented and this research cannot instead be

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Control Council Law No. 10, Nüremburg, October 1946 - April 1949, Washington, D.C. U.S. G.P.O., 1949-1953, accessed at http://www.ushmm.org/research/doctors/Nuremberg.Code.htm, the United States Holocaust Memorial Museum website.

[29] The full text is reproduced in Appendix H. The text may be accessed at the website of the World Medical Association at http://www.wma.net/e/policy/b.3htm.

[30] The last update was in October 2000 (52nd WMA General Assembly, Edinburgh, Scotland) while clarifications were added at the General Assembly, Washington in 2002 and at the General Assembly, Tokyo in 2004.

[31] WMA *Declaration of Helsinki*, 2000, article 22.

[32] WMA *Declaration of Helsinki*, 2000, article 23.

performed on legally competent persons.'[33] Moreover, in the case of a minor, who 'is able to give assent to decisions about participation in research, the investigator must obtain that assent in addition to the consent of the legally authorized representative.'[34]

Research on other subjects who cannot give consent (e.g. mentally incapacitated) should be carried out only 'if the physical/mental condition that prevents obtaining informed consent is a necessary characteristic of the research population.'[35] The reasons for incapacitation should be stated on the research protocol, and that consent should be obtained as soon as possible from the individual or legally authorised surrogate.

12.12

The Council for International Organizations of Medical Sciences (CIOMS) issued *International Ethical Guidelines for Biomedical Research Involving Human Subjects* in 2002.[36] These were prepared in collaboration with the World Health Organization (WHO). Guideline 5 refers in detail to informed consent from research subjects.

Firstly, they emphasise the need to provide information in a way that can be understood by the layperson, particularly the fact that it is voluntary, that the person is free to refuse to participate and free to withdraw at any time. The researchers have to explain the purpose of the research, the procedures to be carried out, the duration of the study and how research differs from ordinary medical care. In the case of a controlled trial, the subject must be told about randomisation and the concept of double-blind trials, emphasising that the subject will not be told which group s/he will belong to until the end of the trial; that the subject will eventually be informed of the results; that subjects have the right to inspect information held about them at any time; and what steps have been taken to ensure confidentiality. They have to be told about risks, pain or discomfort or inconvenience, and about any benefits (including financial help to cover expenses, etc.). They should also be told about alternative treatments and about the sponsors of the research.

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[33] WMA *Declaration of Helsinki*, 2000, article 24.
[34] WMA *Declaration of Helsinki*, 2000, article 25.
[35] WMA *Declaration of Helsinki*, 2000, article 26.
[36] The full text is reproduced in Appendix G, as accessed at http://www.cioms.ch/frame_guidelines_nov_2002. htm.

In relation to specimens taken, the subject should be told what will happen to them at the end of the experiment or trial, and whether they will be stored indefinitely, or whether it is envisaged that commercial products will be developed and, if so, whether the participant will receive any benefits from development of such products.

In the case where the investigator is also the subject's physician, this should be clearly stated. There should also be information regarding arrangements relating to compensation in case of injury or complications, and that the research project has been approved by the Research Ethics Committee of the institute where the research is being carried out.

Unesco has incorporated similar guidelines on consent in the ***Universal Declaration on the Human Genome and Human Rights***, 1997, in the ***International Declaration on Human Genetic Data***, 2003 and in the ***Universal Declaration on Bioethics and Human Rights***, 2005.

e. EU legislation

12.13

(a) The ***Charter of Fundamental Rights of the European Union***[37] contains the following articles relevant to research:

(i) Article 1 on 'Human dignity';

(ii) Article 3 on the 'Right to the integrity of the person', which refers to the principle of 'free and informed consent' and prohibits 'eugenic practices' and 'the reproductive cloning of human beings';

(iii) Article 13 asserting freedom of research; and

(iv) Article 17 which states that 'intellectual property is protected.'

Currently the Charter is not legally binding. It was proclaimed at the European Council in December 2000, by the presidents of the Council, the European Parliament and the Commission. However, it was not then incorporated into the Treaties establishing the European Union but has now been incorporated

[37] *Charter of Fundamental Rights of the European Union*, 2000/C/364/01, Official Journal of the European Communities, 18.12.2000.

in the ***Constitution for Europe,*** which though signed in October 2004 is still in the process of ratification by the 25 Member States of the European Union.

(b) ***Directive 2001/20/EC*** of the European Parliament and of the Council, of 4 April 2001, on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, is now binding in Malta, through the Subsidiary Legislation 458.43, ***Clinical Trials Regulations.***

4. Personal Data

12.14

Research involving human beings often deals with data of a personal nature. Such data needs to be protected and indeed there are various aspects of Maltese legislation that refer to manipulation of data, even though data specifically taken for research purposes is only referred to in a rather superficial way. In addition, however, there are several international legal instruments and guidelines that the research worker needs to be aware of before embarking on research collaboration with overseas colleagues.

a. Definitions

The ***Data Protection Act*** defines 'personal data' as 'any information relating to an identified or identifiable natural person; an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity.'

Moreover, 'sensitive personal data' is defined as ' personal data that reveals race or ethnic origin, political opinions, religious or philosophical beliefs, membership of a trade union, health, or sex life.'

The ***Malta Statistics Authority Act*** defines 'confidential data' as 'data obtained by the National Statistics Office for the production of official statistics when such data allows statistical units to be identified directly or indirectly, thereby disclosing individual information.'

b. Regulatory approach to data anonymisation

12.15

The ***Data Protection Act*** refers to 'processing of personal data' which means 'any operation or set of operations which is taken in regard to personal data, whether or not it occurs by automatic means, and includes the collection, recording, organisation, storage, adaptation, alteration, retrieval, gathering, use, disclosure by transmission, dissemination or otherwise making information available, alignment or combination, blocking, erasure or destruction of such data.'

This Act refers to security measures relating to processing. It states that 'the controller shall implement appropriate technical and organisational measures to protect the personal data that is processed against accidental destruction or loss or unlawful forms of processing thereby providing an adequate level of security that gives regard to the:

(a) technical possibilities available;
(b) cost of implementing the security measures;
(c) special risks that exist in the processing of personal data;
(d) sensitivity of the personal data being processed.'[38]

These measures do not specifically mention anonymisation and the Act does not refer to anonymisation of data as such.

c. Fundamental rights and privacy

12.16

Informed consent has already been referred to above. Processing of personal data that involves 'particular risks of improper interference with the rights and freedoms of data subjects' must be submitted to the Commissioner for prior checking.[39]

Further protection to confidentiality is provided by the ***Professional Secrecy Act.*** This refers to persons who, by reason of their calling, profession or office, fall within the scope of article 257 of the ***Criminal Code,*** namely, 'members of a profession regulated by the ***Medical and Kindred Professions Ordinance,*** advocates,

[38] *Data Protection Act*, article 26.
[39] *Data Protection Act*, article 34(1)(a).

notaries, legal procurators, social workers, psychologists, accountants, auditors, employees and officers of financial and credit institutions, trustees, officers of nominee companies or licensed nominees, persons licensed to provide investment services under the ***Investment Services Act***, stockbrokers licensed under the ***Financial Markets Act***, insurers, insurance agents, insurance managers, insurance brokers and insurance sub-agents, officials and employees of the State.'[40]

To note that scientists as such are not mentioned, although medical scientists, pharmacists, medical doctors, dentists and dental surgeons are included in the ***Health Care Professions Act***.

The authority to disclose such secret information when so ordered by a Court has been discussed in the chapter dealing with medical issues.

12.17

Further regulation of data transmission is available in the ***Malta Communications Authority Act*** which defines 'communications' to include: 'electronic communications, postal services, data protection in electronic communications, electronic commerce and such other matters as the Minister may by Order from time to time prescribe.' There is also provision for a Directorate for Data Protection 'with responsibility for the regulation of all matters relating to data protection as may from time to time be assigned to the Authority by or under an Act of Parliament.'[41] However no such Data Protection Directorate has been established presumably in view of the subsequent creation by Parliament of the office of Data Protection Commissioner.

The ***Telecommunications (Regulation) Act***, prescribes 'measures to be taken by authorised providers for the purpose of ensuring the inviolability of the telecommunications transmitted and their confidentiality and the protection of privacy in relation to any telecommunications service including data protection

[40] *Professional Secrecy Act*, article 3. The professions previously covered by the *Medical and Kindred Professionals Ordinance* are now regulated by the *Health Care Professions Act*, except for veterinary surgeons who are covered under the *Veterinary Services Act*; however this Act was not amended accordingly.

[41] *Malta Communications Authority Act*, Schedule.

measures and matters related to the use of information obtainable in the telecommunications sector for the purpose of direct marketing.'[42]

d. Conditions for data processing

12.18

The ***Data Protection Act*** sets out the conditions that must be met in order to process data. These are:

(a) personal data is processed fairly and lawfully and in accordance with good practice;
(b) personal data is only collected for specific, explicitly stated and legitimate purposes; and should not be processed for any other purpose that is incompatible with this;
(c) personal data that is processed is adequate and relevant in relation to the purposes of the processing; no more personal data is processed than is necessary having regard to the purposes of the processing;
(d) personal data that is processed is correct and, if necessary, up to date; all reasonable measures should be made to ensure that data is correct;
(e) personal data is not kept for a period longer than is necessary, having regard to the purposes for which they are processed.[43]

Processing of personal data for scientific purposes should not be used 'for any decision concerning the data subject.'[44] In other words, there should be a clear distinction between data collected for research purposes and data collected during a routine clinical procedure.

e. Data processing for research and statistics

12.19

The ***Data Protection Act*** states that 'sensitive personal data may be processed for research and statistics purposes, provided that' this has been approved:

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[42] *Telecommunications (Regulation) Act*, article 38(2)(b).
[43] *Data Protection Act*, article 7.
[44] *Data Protection Act*, article 8.

(a) 'in the case of statistics, by the Commissioner himself;
(b) in the case of research, by the Commissioner on the advice of a research ethics committee of an institution recognised by the Commissioner for this purpose.'[45]

Any data subject has the right to check whether information is held about him or her. The Act states that: 'The controller of personal data at the request of the data subject shall provide to the data subject, without excessive delay and without expense, written information as to whether personal data concerning the data subject is processed: Provided that a request by the data subject under this subarticle shall only be made by the data subject at reasonable intervals.'[46]

However, certain data are excluded from this provision. Such is the case, for instance 'when data is processed solely for purposes of scientific research or is kept in personal form for a period which does not exceed the period necessary for the sole purpose of compiling statistics: provided that the provisions of this subarticle shall not apply where the data is used for taking measures or decisions regarding any particular individual or where there is a risk of breaching the privacy of the data subject.'[47]

5. Genetic Research

12.20

Research involving genetic conditions presents special issues that need further discussion and regulation. Subjects involved in genetic research present two distinct aspects not usually relevant to the same extent in non-genetic research. Firstly, there is the fact that any genetic information obtained about a research subject is also likely to be pertinent to other members of the family, and therefore one might argue that such research could be of interest not just to the individual but also to other members who may not have given their consent to research. Secondly, genetic information might reveal the probability of developing some disease later on in life (e.g. Alzheimer's disease, Huntington's disease), and this

[45] *Data Protection Act*, article 16(2).
[46] *Data Protection Act*, article 21(1).
[47] *Data Protection Act*, article 23(2).

information might be traumatic to the person taking part in such research.

Genetic manipulations that modify the germ line or the genetic identity of the human body are not prohibited as such in Maltese legislation. However, the ***Patents and Designs Act*** states that patents shall not be granted for 'processes for cloning the human body, processes for modifying the germ line genetic identity of the human body and uses of the human embryo for industrial or commercial purposes'[48] and neither for 'DNA sequence not containing any technical information and in particular any indication of its function.'[49]

Likewise, this Act states that a patent shall not be granted for 'processes and products for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefits to man or animal.'[50] It appears that it is not so much the genetic manipulation as such which is forbidden, as the possibility of causing them suffering. Even this consideration is relaxed if this suffering would lead to 'substantial medical benefits to man or animal.'

A special licence is required from the Minister for procedures meant to bring about 'the alteration of the genetic material of animals in a manner which ignores the natural barriers of sexual reproduction and of recombination.'[51]

12.21

In the human situation, modification of the genome could be of value particularly in the prevention and treatment of inherited diseases. Distinction has to be made between manipulations aimed at changing the somatic genome and manipulations of the reproductive genome. This crucial distinction is based on the fact that while somatic genome manipulation is restricted to the subject concerned, genomic manipulation of the reproductive genome will introduce changes into the general pool of human genes, with possible unknown consequences. Hence the need for legislation in this area.

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[48] *Patents and Designs Act,* article 4(5)(c).
[49] *Patents and Designs Act,* article 4(5)(g).
[50] *Patents and Designs Act,* article 4(5)(d).
[51] *Patents and Designs Act,* article 32.

This distinction is found in the Council of Europe's ***Convention on Human Rights and Biomedicine,***[52] which prohibits intervention on the human reproductive genome but not on the somatic[53] genome. Article 13 states that: 'An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.' Somatic genomic alterations are allowed only if carried out for preventive, diagnostic or therapeutic purposes.[54] In other words, genetic modification of sperm or ova, for fertilisation, or embryos is prohibited.[55] The Convention does not prohibit research involving genetic modification of germ cells, as long as these are not intended for procreation, and as long as the national law does not prohibit the procedures and the appropriate regulatory body has given approval.[56]

6. Genetically Modified Organisms (GMOs)

12.22

Modifying the genome of an organism is becoming a very important tool in molecular biology, enabling the analysis of physiological functions. The transfer of viral particles into bacteria has been going on for a long time and was perhaps the first example of artificial modification of the genome of these organisms. More recently, the detailed knowledge of the genome of the bacterial chromosome has enabled researchers to actually build new organisms through the artificial joining together of genes to produce a new organism. In recent years, splitting, splicing and joining pieces of DNA to produce a novel organism has become a relatively simple technique available to most students with a basic knowledge of biochemistry.

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[52] Council of Europe's *Convention for the Protection of Human Rights and Deignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine.*

[53] Somatic refers to the 'soma' or body cells (e.g. bone marrow, skin, etc.) as opposed to reproductive (ova, sperm) cells.

[54] Council of Europe's *Convention on Human Rights and Biomedicine:* Explanatory Memorandum, paragraph 90.

[55] Council of Europe's *Convention on Human Rights and Biomedicine:* Explanatory Memorandum, paragraph 91.

[56] Council of Europe's *Convention on Human Rights and Biomedicine:* Explanatory Memorandum, paragraph 91.

The ***Environment Protection Act*** defines a 'genetically modified organism' as 'any of the following:

(a) an organism derived from the formation of a combination of genetic material by any means other than natural means;
(b) an organism inheriting such combination of genetic material;
(c) an organism that results from the replication of an organism as derived in paragraph (a); or
(d) such other organism as may be prescribed by the Minister under this Act.'[57]

In the ***Veterinary Services Act***, a genetically modified organism is defined in more detail, in the context of veterinary medicinal products, as 'an organism in which the genetic material has been altered in a way that does not occur naturally by mating and, or natural recombination.

Within the terms of this definition genetic modification occurs at least through the use of the techniques of genetics, which are *inter alia*:

(a) recombinant DNA techniques using vector systems;
(b) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation;
(c) cell fusion (including protoplast fusion) or hybridization techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

The techniques which are not considered to result in genetic modification, on condition that they do not involve the use of recombinant DNA molecules or GMOs, are:

(a) polyploidy induction,
(b) *in vitro* fertilization,
(c) conjugation, transduction, transformation or any other natural process.'[58]

[57] *Environmental Protection Act*, article 2.
[58] *Veterinary Services Act*, Sixth Schedule, Part C.

The Minister may introduce regulations to 'control, manage and regulate the transport, introduction of, use (including contained use), release or placing on the market or in the environment of genetically modified organisms.'[59]

A special licence is required to trade in genetically modified organisms or to manage or otherwise have in one's possession genetically modified organisms.[60]

Specifically in relation to research, the ***Environment Protection Act*** requires that there has to be liaison 'with public entities, non-governmental organizations and international organizations on matters relating to environmental protection and the sustainable management of the environment and natural resources, and to undertake and promote research on such matters.'[61]

12.23

Further regulation relating to GMOs is contained in several legal notices related to the ***Environment Protection Act.*** They lay down measures relating to the contained use of GMOs, with a view to protecting human health and the environment. They refer to 'contained use', which emphasises the need to ensure that these organisms will not be released in the environment or come in contact with the general population.[62] This is in conformity with the European Council ***Directive 90/219/EEC*** and the amendment, ***Directive* 98/81/EC** on the contained use of genetically modified micro-organisms. There are also regulations dealing with the placing on the market of products consisting of GMOs or products produced from GMOs.[63] These incorporate the provisions of ***Directive 2001/18/EC.***

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[59] *Environment Protection Act,* article 9(2)(l).

[60] *Environment Protection Act,* article 11(1)(d).

[61] *Environment Protection Act,* article 7(1)(c)(ii).

[62] LN 169 of 2002, *Contained Use of Genetically Modified Micro-Organisms Regulations, 2002.* See particularly Annex IV to this Legal Notice. Also LN 194 of 2002, *Contained Use of Genetically Modified Micro-Organisms (Amendment) Regulations, 2002,* and LN 168 of 2004, *Contained Use of Genetically Modified Micro-Organisms (Amendment) Regulations, 2004.*

[63] LN 170 of 2002, *Delibrate Release into the Environment of Genetically Modified Organisms Regulations, 2002.*

The legal notices define classes of risk of the various organisms into four distinct classes, requiring a correspondingly higher level of containment. Importantly, the role of public consultation, on aspects of the proposed measures relating to 'contained used', is highlighted. They deal also with procedures to be followed in case of accidents.

Furthermore, it is stipulated that notification to the competent Authority is required when 'premises are to be used for the first time for contained uses' of genetically modified organisms.[64]

Among the techniques which are allowed in the production of GMOs there is 'self-cloning', which refers to the removal of nucleic acid sequences from a cell of an organism, which nucleic acid (or a synthetic equivalent) is then inserted, after *in vitro* modification or not, 'into cells of the same species or into cells of phylogenetically closely related species which can exchange genetic material by natural physiological processes where the resulting micro-organism is unlikely to cause disease to humans, animals or plants.'[65] It is to be noted that this wording is sufficiently clear to exclude human cell manipulation in this way.

Issues of confidentiality of personal data are also discussed.[66] Annexes are also attached dealing with the various techniques involved in genetic modification.[67]

In terms of Clinical Trials, written authorisation is required from the Licensing Authority 'before commencing clinical trials involving medicinal products for gene therapy, somatic cell therapy including xenogenic cell therapy and all medicinal products containing genetically modified organisms. No gene therapy trials may be carried out which result in modifications to the subject's germ line genetic identity.'[68]

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[64] LN 169 of 2002, *Contained Use of Genetically Modified Micro-Organisms Regulations, 2002*, regulation 6.

[65] LN 169 of 2002 as amended by LN 194 of 2002 and LN 168 of 2004, *Contained Use of Genetically Modified Micro-Organisms Regulations, 2002*, Annex II, Part A.

[66] LN 169 of 2002, *Contained Use of Genetically Modified Micro-Organisms Regulations, 2002*, regulation 17.

[67] The Annexes are contained in LN 194 of 2002 and LN 168 of 2004, both of which amended LN 169 of 2002, *Contained Use of Genetically Modified Micro-Organisms Regulations, 2002*.

[68] *Clinical Trials of Regulations*, SL 458.43, regulation 9(6).

As regards foods, the Minister may make regulations to 'prohibit or regulate' commercial operations with respect to genetically modified or irradiated foods, or foods derived from such sources.[69]

12.24

Directive 2001/18/EC of the European Parliament and of the Council[70] deals with the deliberate release of GMOs into the environment, which may be necessary in the development of new products derived from, or containing GMOs, and with placing such products on the market, including importation.[71]

In this Directive,[72] a genetically modified organism (GMO) means 'an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.'

Techniques used for this purpose include:

(a) recombinant nucleic acid techniques, which involve the formation of new combinations of genetic material by introduction of nucleic acids into a virus, or other organism, and their incorporation into a host organism in which they do not naturally occur but where they continue to propagate;
(b) direct introduction into an organism of heritable material prepared outside the organism;
(c) cell fusion or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells.[73]

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[69] *Food Safety Act*, article 10(1)(g).

[70] *Directive 2001/18/EC* of the European Parliament and of the Council, Official Journal of the European Communities, L 106/1, 17.4.2001.

[71] This Directive has been transposed into Maltese Law by LN 170 of 2002, *Deliberate Release into the Environment of Genetically Modified Organisms Regulations, 2002*.

[72] *Directive 2001/18/EC* of the European Parliament and of the Council, on the delibrate release into the environment of genetically modified organisms, Official Journal of the European Communities, L 106/1, 17.4.2001.

[73] *Directive 2001/18E*, Annex IA and IB of the Directive. They do not include *in vitro* fertilisation, polyploidy induction (i.e. having more than twice the normal number of chromosomes in a cell), or naturally occurring phenomena such as conjugation, transduction, transformation (i.e. processes involving transfer of DNA or parts of the chromosome from one bacterial cell to another). Mutagenesis and cell fusion are also exempt.

This extensive Directive should be read by anyone involved in production or distribution of GMOs.

Council Directive 90/219/EEC, on the contained use of genetically modified micro-organisms, 'lays down common measures for the contained use of genetically modified micro-organisms with a view to protecting human health and the environment.'[74] It deals with 'principles of good microbiological practice', 'good occupational safety and hygiene' and prevention and management of accidents. The state authorities must be notified of any activities to be carried out.[75]

The amendment to this Directive, ***Council Directive* 98/81/EC,** defines 'contained use' as 'any activity in which micro-organisms are genetically modified or in which such genetically modified micro-organisms are cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit their contact with the general population and the environment.'[76]

7. Research Involving Human Embryos

12.25

Embryo research has become a very active area world-wide because of the considerable benefits that are theoretically achievable through manipulation of the stem cells. Stem cells have the capacity to differentiate into cell lines that can produce a variety of products of potential therapeutic value. They may also be used as such to replace cells lost through disease (e.g. cardiac muscle in myocardial infarction or nerve cells in stroke).

While it is true that stem cells can be obtained from sources other than embryos, e.g. umbilical cord blood, it is the majority opinion among scientists that embryos are by far the most efficient source of stem cells.

Unfortunately, to obtain embryo stem cells, embryos must be destroyed in the process. Obtaining cells from embryos, prior to

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[74] *Directive 90/219/EEC,* Official Journal of the European Communities, L. 117, 8.05.1990.

[75] This Directive has been transposed into Maltese Law by LN 169 of 2002 as amended by LN 194 of 2002 and LN 168 of 2004, *Contained Use of Genetically Modified Micro-Organisms Regulations, 2002.*

[76] *Directive 98/81/EC,* Official Journal of the European Communities, L 330/13, 5.12.1998, article 1.

implantation, is regulated by international legislation (see below). Embryos for research purposes can be obtained either from embryos left over (not implanted) in the process of artificial fertilisation (IVF) or, as happens in certain countries (e.g. UK, Finland), embryos are specifically created for use in research. To note that the latter is also prohibited by the Council of Europe's Convention.[77]

Another alternative for scientists is to use cell-lines prepared from embryos. The legitimacy of this procedure in those countries where embryo research is forbidden (e.g. Germany) has been questioned.[78]

a. Maltese legislation

12.26
In Malta, the law tends to be spare with regard to the regulation of research on embryos and fetuses.

Definition of 'embryo': This term is not defined anywhere in the legislation.

Use of human embryos in research: There is no specific prohibition relating to the use of embryos in research in Maltese legislation, as long as these are not obtained through an abortion. The ***Criminal Code***[79] provides for penalties for procuring miscarriage for any reason. Moreover, the ***Patents and Designs Act***[80] states that patents shall not be granted for 'uses of the human embryo for industrial or commercial purposes.'

Approval of research on embryos and fetuses: There are no specific requirements relating to research that involves embryonic or fetal tissue. There is no legal prohibition on the use of naturally miscarried fetuses, subject to the usual requirements relating to informed consent.

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[77] Council of Europe's *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, article 18(2).

[78] In Germany cell lines established from embryos prior to January 2002 can be imported and used for research purposes.

[79] *Criminal Code*, articles 241 and 242.

[80] *Patents and Designs Act*, article 4(5)(c).

12.27

Research involving stem cells: There is no legislation controlling the use of stem cells.[81]

Law regarding human reproductive cloning: Cloning as such is not prohibited by law. However, the ***Patents and Designs Act*** states that no patents can be 'granted in respect of processes for cloning the human body.'[82] Note that this article does not distinguish therapeutic from reproductive cloning, although one would assume that it refers to the latter.

b. Maltese guidelines and regulations

12.28

The *Bioethics Consultative Committee (Malta)* has issued a document, *Ethical Considerations Relating to Human Reproductive Technology,* which gives guidelines relating to procedures on embryos, including the use of embryonic tissues for research and therapy.[83] The

[81] It is envisaged to transpose *Directive 2004/23/EC,* Official Journal of the European Union, L 102/48, 7.4.2004, done at Strasbourg on 31st March 2004, into Maltese legislation on the *Human Blood and Transplants Act 2006,* which was published as Bill No. 62 in the Government Gazette, No. 17,886, on 28th February, 2006. This bill incorporates licensing and controls to ensure adherence to the directive, which sets standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, including 'haematopoietic peripheral blood, umbilical-cord (blood) and bone-marrow stem cells, reproductive cells (eggs, sperm), foetal tissues and cells and adult and embryonic stem cells.' This directive only applies to research on human tissues and cells when applied to the human body. (*In vitro* research is excluded). Moreover the directive does not interfere with any decision taken by Malta concerning the use or non-use of any specific type of human cells, including germ cells and embryonic stem cells.

[82] *Patents and Designs Act*, article (4)(5)(c).

[83] *Ethical Considerations Relating to Human Reproductive Technology* reproduced in the book, *Patients' Rights, Reproductive Technology, Transplantation,* Ed. Maurce N. Cauchi, Bioethics Consultative Committee, Malta, 2000, ISBN 99909-993-1-7. In this document, particular emphasis is laid on guidelines relating to the use of embryonic tissues for research and therapy. In particular, the creation of embryos for research purposes is prohibited.

following are some of the issues relating to the use of embryonic tissue for research (and therapy):

(a) the creation of embryos for research purposes is prohibited.[84] Research on embryos and fetuses delivered naturally is acceptable subject to the normal conditions for performing research, including informed consent of the couple as well as the clearance by the appropriate research ethics committee;[85]
(b) any intervention seeking to modify the human germ cell line is not acceptable;[86]
(c) the fusion of a human gamete or embryo with that of another species is prohibited;[87] and
(d) in general, a procedure (including a diagnostic test) performed on the embryo is allowed so long as this is intended solely for the benefit of the embryo or has the aim of correcting a specific abnormality, as long as this cannot be achieved by any other method, and the necessary consent of the mother has been given, and there is no due risk to the embryo or mother, and moreover, that the expected benefits justify the risks associated with the procedure.[88]

c. European legislation

12.29

The Council of Europe's ***Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*** prohibits 'the creation of human embryos for research purposes.'[89] It also states that: 'Where the law allows research on embryos *in vitro*, it shall ensure adequate protection of the embryo.'[90]

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[84] *Ethical Considerations Relating to Human Reproductive Technology*, article 25.
[85] *Ethical Considerations Relating to Human Reproductive Technology*, article 26.
[86] *Ethical Considerations Relating to Human Reproductive Technology*, article 22.
[87] *Ethical Considerations Relating to Human Reproductive Technology*, article 24.
[88] *Ethical Considerations Relating to Human Reproductive Technology*, article 21.
[89] Council of Europe's *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, article 18(2).
[90] Council of Europe's *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, article 18(1).

This is ambiguous since it is difficult to envisage how the embryo is actually protected in situations where research on embryos is allowed by national law. In those countries where national legislation allows research on embryos left over from IVF procedures for instance, the embryo is destroyed in the process.

The Convention also prohibits the sale of embryos. It states that: 'The human body and its parts shall not, as such, give rise to financial gain.'[91] One can understand this to include also embryos and parts thereof. On the other hand it is unlikely that it covers the sale of stem cells derived from embryos.

8. Research Involving Animals

12.30

Animals are often used in biological research, for several reasons. In the first instance, laboratory animals and particularly mammals, share with the human being the vast majority of physiological and biochemical features, and even, as has been shown recently, marked genomic similarities. For instance, it has been shown that the genome of higher apes differs from the human genome by only about 1–2%. The genome of the mouse, recently discovered, is very similar to that of humans; both have around 30,000 genes with only 300 genes being unique to either species.

Secondly, many would feel considerable unease if new procedures and medicinals were tried on the human before their efficiency is tested in laboratory animals.

Thirdly, a number of procedures can only be performed on animals that may never recover from the procedure. For instance, in toxicity experiments, the dose of a drug or agent, such as radiation, that will kill 50% of the population (LD50 where LD stands for lethal dose) is by definition determined by the proportion of animals that never recover from the procedure.

There is, moreover, the questionable use of animals to determine whether products like cosmetics are likely to produce allergic reactions.

For these and other reasons, there is a need to ensure that the use of animals is restricted to the minimum necessary to obtain

[91] Council of Europe's *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, article 21.

scientifically valid answers, that animals are used only where other research methodologies are inadequate and that no undue pain is inflicted. This principle has been referred to as 'the 3 R's': namely:

(a) *reduction* refers to the need to reduce the number of animals used to the very minimum consistent with obtaining statistically significant results;
(b) *refinement* relates to planning of the experiment so as to reduce the need of animals;
(c) *replacement* involves using other methodologies that do not involve animals, e.g. cell (including bacterial) cultures for toxicity or biochemical experiments.

Finally, in relation to choice of animals, there is the widespread feeling that the closer the animal is to the human, from an evolutionary point of view, the greater the reluctance to use them as laboratory animals. For instance, use of higher apes has been banned by the Council of Europe. Related to this, there is also antagonism by the general public towards research on animals normally kept as pets (e.g. dogs and cats). There have also been objections to the use of animals considered as more intelligent, and therefore more likely to be distressed by laboratory conditions and experimental manipulations.

a. Ethics committees

12.31

The role of Animal Research Ethics Committees is to ensure that these and other related aspects are taken into consideration when research workers plan their experimental procedures.

The constitution of these committees varies but involves the participation of scientists, laypersons, ethicists and representatives of the institutions where the research is taking place.

The ***Animal Welfare Act*** refers to issuing licences for the conduct of biotechnological and other animal experiments.[92] Licences for biotechnology practices, are subject to ensuring that such practices do not 'affect the health or welfare of animals, and

[92] *Animal Welfare Act*, articles 32 and 35.

such practices shall not be in breach of ethical rules and standards which may be drawn up by the Council (for Animal Welfare).'[93] On this Council sit two persons who represent the interest of Animal Welfare groups.

Animal experiments are licensed if they 'are intended to benefit, either directly or indirectly, the health or nutrition of human beings or animals' and 'for any other purpose deemed by the Minister to be of sufficient value.'[94] Experiments must not be carried if the result 'may also be achieved by means other than an animal experiment, or by means of an experiment using fewer animals or entailing less distress than the experiment in question' or if the importance of the experiment 'does not justify the distress caused to the animal.'[95]

There is no mention of an Ethics Committee but experiments must be performed by competent authorised persons, or under their supervision,[96] so authorised by the Veterinary Services[97] and only if the experiment is first approved by a designated qualified person.[98]

Experiments are subject to regulations laid out in the legal notice, ***Animal Experimentation Regulations, 2003***, including that any procedure, where an animal 'will or may experience severe pain which is likely to endure, that procedure must be declared and justified to the Veterinary Services.'[99]

b. Legislation in Malta

12.32

The main legislation in Malta with respect to this topic is contained in the ***Animal Welfare Act*** and its related legal notices (see below).

The ***Veterinary Services Act*** deals with requirements in the veterinary field, veterinary medicinal products, feeding stuffs and zootechnical requirements, as well as regulating the veterinary profession.

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[93] *Animal Welfare Act*, articles 33(1).
[94] *Animal Welfare Act*, articles 35(2).
[95] *Animal Welfare Act*, articles 38.
[96] *Animal Welfare Act*, articles 36(3).
[97] LN 263 of 2003, *Animal Experimentation Regulations, 2003*, regulation 10.
[98] *Animal Welfare Act*, articles 36(3) and 38(1).
[99] LN 263 of 2003, *Animal Experimentation Regulations, 2003*, regulation 8.

It is concerned with maintaining animal health and public health, with regard to live animals and products of animal origin, and so addresses the control of contagious diseases, movement of animals, production, monitoring and marketing of animal products and importation conditions of live animals and animal products.[100] It covers the production, distribution and use of veterinary medicinal products[101] and the quality and use of feeding stuffs[102] as well as the zootechnical requirements in animal breeding.[103]

The National Veterinary Laboratory assesses veterinary pharmaceuticals and carries out 'post mortem examinations, microbiological analysis, laboratory diagnosis and analysis,' and 'identification of residues in accordance with internationally recognised procedures and standards,' with participation in 'comparative tests at international levels'.[104]

Specifically in relation to animal research, the Laboratory is to carry out 'research on additives, and on undesirable products and substances, which may be incorporated in feeding stuffs and products used in animal nutrition' and to sample and analyse feeding stuffs and assess the use of additives.[105]

Other relevant aspects may be found in the following legislation:

Fisheries Conservation and Management Act: covers the protection of turtles, dolphins and other aquatic animals;[106]

Environment Protection Act: is aimed at safeguarding flora and fauna, in particular by granting the status of 'protected species' and regulating the import and export of flora and fauna;[107]

Plant Quarantine Act: is aimed at preventing entry into Malta of plant pests and diseases and checking their spread; the Plant Health Service is to conduct research and surveys in the field of plant

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[100] *Veterinary Services Act*, article 4.
[101] *Veterinary Services Act*, articles 29-33.
[102] *Veterinary Services Act*, articles 22-28.
[103] *Veterinary Services Act*, article 34. See the various related Legal Notices of 2003.
[104] *Veterinary Services Act*, articles 50 and 51.
[105] *Veterinary Services Act*, articles 52.
[106] *Fisheries Conservation and Management Act*, article 38(2)(h).
[107] *Environment Protection Act*, articles 9(2)(k) and 11(1)(a)(i).

protection and the Minister may make regulations for importing and transporting plant material or pests for scientific research and other regulations for carrying out, co-ordinating and encouraging research in the field of plant protection;[108]

Patents and Designs Act: patents shall not be granted in respect of processes and products for modifying the genetic identity of animals, plant and animal varieties and essentially biological processes of the production of plants or animals;[109]

Public Health Act: regulations may be made to prohibit the keeping of animals, in any premises, and to determine where and when animals can be taken into the sea;[110]

Medical and Kindred Professions Ordinance: regulates administration of drugs to domestic animals;[111] and

Social Security Act: identifies certain zoonoses as industrial diseases[112] including glanders, leptospira, tuberculosis and brucellosis, which may be contracted by contact with animals or in the laboratory.

(a) The *Animal Welfare Act*

12.33

The ***Animal Welfare Act*** defines 'animal experiment' as meaning 'any use of any animal for experimental or other scientific purposes which may cause it pain, suffering, distress or lasting harm, including any course of action intended, or liable, to result in the birth of an animal in any such condition. An animal experiment starts when an animal is first prepared for use and ends when no further observations are to be made for that experiment. The elimination of pain, suffering, distress or lasting harm by the successful use of anaesthesia or analgesia or other methods does not place the use of an animal outside the scope of this definition.'

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[108] *Plant Quarantine Act* articles 3(2)(i), 14 and 32(1)(n).
[109] *Patents and Designs Act*, article 4(5)(d), (e) and (f).
[110] *Public Health Act*, article 26(h)(ii) and (d)(v).
[111] *Medical and Kindred Professions Ordinance*, article 104.
[112] *Social Security Act*, Fourth Schedule.

This Act establishes a Council for Animal Welfare responsible for overseeing the workings of the Act.[113]

This Act makes detailed regulations relating to experimentation dealing with biotechnology and animal experiments.[114] In summary, they deal with:

(a) the granting and revoking of licences to carry out an experiment;
(b) the conditions under which a licence is issued;
(c) the scope of licence for animal experimentation;
(d) the purpose of experiments;
(e) the obligations of licence holders; and
(f) the keeping of records on experiments.

12.34

To perform certain biotechnology experiments one requires a special licence from the Minister. These include:[115]

(a) 'the alteration of the genetic material of animals in a manner which ignores the natural barriers of sexual reproduction and of recombination;
(b) the application of biotechnological technology to animals or embryos' (presumably meaning animal embryos); and
(c) administration of substances 'which alter the functioning of an animal'.

Licences for biotechnology practices, 'shall be issued only when the practices in question will not affect the health or welfare of animals, and such practices shall not be in breach of ethical rules and standards which may be drawn up by the Council.'[116] This article emphasises the need to have such work conform to standards drawn up by the Council for Animal Welfare set up under this Act.

Licences are also required for other animal experiments. No animal experiments can be carried out unless a licence has been issued for the purpose. Licences will be issued only by the Minister

[113] *Animal Welfare Act*, article 4.
[114] *Animal Welfare Act*, articles 32–42.
[115] *Animal Welfare Act*, article 32(1).
[116] *Animal Welfare Act*, article 33(1).

on the advice of the Council for Animal Welfare. Such licences are issued only when the research envisaged is 'intended to benefit, either directly or indirectly, the health or nutrition of human beings or animals' and 'for any other purpose deemed by the Minister to be of sufficient value.'[117]

An experiment may be performed only by 'competent authorised persons, or under the direct responsibility of such a person,' and only after the proper authorisation of the scientific project is obtained.[118] The methodology of the experiment is to be determined 'by a person whose qualifications satisfy the requirements laid down in regulations.'[119]

Moreover the experiments must be conducted in establishments registered or approved by the Veterinary Services.[120]

It is interesting to note that a licence is not valid if not used within 'a continuous period of one year'.[121]

12.35

Purpose of experiments: Experiments may be performed on animals only if one cannot reach the same results by means other than an animal experiment or by an experiment using fewer animals.[122] This article also prohibits causing unnecessary distress.

Source of animals: It is unlawful to conduct experiments on animals that were not bred specifically for the purpose of conducting research, in an establishment licensed for the purpose,[123] unless a general or special exemption has been obtained under arrangements to be determined by the Minister.[124]

Obligations of licence holder: The obligations of a licence holder include ensuring that:

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[117] *Animal Welfare Act*, article 35(2)
[118] *Animal Welfare Act*, article 36(3).
[119] *Animal Welfare Act*, article 38(1).
[120] LN 263 of 2003, *Animal Experimentation Regulations, 2003*, regulations 14 and 18.
[121] *Animal Welfare Act*, article 37(3)(b).
[122] *Animal Welfare Act*, article 38(2)(a).
[123] *Animal Welfare Act*, article 39.
[124] LN 263 of 2003, *Animal Experimentation Regulations, 2003*, regulation 17.

(a) animals suffer as little distress as possible;
(b) there is administration of a local or general anaesthetic during experimentation, when feasible; and
(c) animals used in experiments should, if suffering pain or distress, be put to death as soon as the experiment permits.[125]

It is not clear from this Act what amount of pain or distress animals are allowed to suffer before the experiment is terminated or the animal killed. The Minister has the right to make regulations on any of these aspects, including which experiments must be carried out under anaesthesia.

The licence holder is also required to keep 'detailed records concerning the procurement of animals for experiments as well as the experiments conducted.'[126] It is also stated that a licence holder should 'ensure the services of a veterinary surgeon to supervise the welfare of the animals undergoing experiments.'[127]

Further details regarding the conduct of research procedures, the establishments and the staff, are found in the legal notice, ***Animal Experimentation Regulations, 2003***, which implements the provisions found under the European Union ***Council Directive 86/609/EEC***.

12.36

Research projects involving animals must be submitted to the Council for Animal Welfare. The Act states that 'experiments to which such regulations refer must be specifically declared to the Council and may not be held unless authorised by the Council.'[128] It is to be pointed out that the structure of this Council does not conform to the one recommended above, for the structure of a research ethics committee, largely because the functions of this Council include several other aspects of animal husbandry not specific to research activities.

Certain types of animal experiments are banned. As mentioned already, experiments which involve a certain amount of distress

[125] *Animal Welfare Act*, article 40.
[126] *Animal Welfare Act*, article 41(1).
[127] *Animal Welfare Act*, article 41(2).
[128] *Animal Welfare Act*, article 36(2).

and pain to animals, may be performed only under adequate anaesthesia.

While not specifically forbidden, certain experiments may not lead to patentable products. The ***Patents and Designs Act*** specifies that a patent shall not be granted in respect of:

(a) 'processes and products for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefits to man or animal';[129] and
(b) animal varieties and an 'essentially biological process of the production of plants or animals' other than 'a microbiological or other technical process or a product obtained by means of such a process.'[130]

c. International legislation

12.37

The ***Protocol to the Amsterdam Treaty on Protection and Welfare of Animals***[131] creates clear obligations regarding the welfare of animals as 'sentient beings' and leaves it to the individual Member States to introduce national legislation on the several issues relating to animal welfare. It states: 'Member States shall pay full regard to the welfare requirements of animals while respecting the legislative or administrative provisions and customs of the Member States relating in particular to religious rites, cultural traditions and regional heritage.'

Directive 86/609/EEC deals with the protection of animals used for experimental and other scientific purposes and its provisions have been incorporated into the ***Animal Experimentation Regulations, 2003.***

The Directive applies to the use of animals in experiments undertaken to develop and test as well as to manufacture 'drugs, foodstuffs and other substances', which may be of value to health and prevention, diagnosis or treatment of disease in human beings,

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[129] *Patents and Designs Act*, article 4(5)(d).

[130] *Patents and Designs Act*, article 4(5)(e) and (f).

[131] *Treaty of Amsterdam Amending the Treaty on European Union, the Treaties Establishing the European Communities and Related Acts*, Official Journal of the European Communities C340, 10th November 1997; it entered into force on 1st May 1999 and has been annexed to the Treaty establishing a Constitution for Europe as article III-121.

animals or plants, or for better understanding of physiological conditions, or for the protection of the natural environment.[132]

It insists on Member States ensuring adequate accommodation for experimental animals.[133]

With regard to choice of species of animals to work with, article 7 enjoins the use of 'the minimum number of animals' and the choice of experiments, which 'involve animals with the lowest degree of neurophysiological sensitivity, cause the least pain, suffering, distress or lasting harm and which are most likely to provide satisfactory results.'

Article 8 states: 'All experiments shall be carried out under general or local anaesthesia.' Where this is not feasible, analgesia may be used, provided that it is compatible with the object of the experiment.

Articles 9 and 10 deal with animals after the experiment is terminated. No animal should be kept alive if in pain. Animals should not be used more than once in an experiment entailing severe pain. Animals may be set free if the relevant authority allows this and there is no danger to public health or the environment.[134]

Reports have to be made to the relevant authority with respect to the number and kind of animals used.[135]

Several articles deal with the breeding and supply of animals for experimentation (essentially as in the ***Animal Welfare Act***). Records must be kept for 3 years.

The Directive also contains special provisions for identification of dogs, cats or non-human primates used as experimental animals.[136]

9. Research Involving Human Biological Material

12.38

There are no specific references in Maltese legislation to the use of human biological material (blood, organs, tissues, cells, DNA), for research.[137] However the following have relevance:

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[132] *Directive 86/609/EEC*, article 3.

[133] *Directive 86/609/EEC*, article 5.

[134] *Directive 86/609/EEC*, article 11.

[135] *Directive 86/609/EEC*, article 13.

[136] *Directive 86/609/EEC*, article 18.

[137] See footnote 81. Only human cells and tissues that in clinical trials are applied to the human body should comply with the quality and safety standards laid down in *Directive 2004/23/EC*, soon to be transposed into Maltese legislation.

The ***Patents and Designs Act*** deals with patentability of tissues (human or animal). It states that a 'method for the treatment of the human or animal body by surgery or therapy and a diagnostic method practised on the human or animal body shall not be regarded as an invention capable of industrial application for the purposes of' being patentable.[138]

A patent shall not be granted in respect of:

(a) 'the human body, at the various stages of its formation and development and the simple discovery of one of its elements, including the sequence or partial sequence of a gene,' provided that an element isolated from the human body or otherwise produced technically, including a sequence or partial sequence of a gene may be patentable, even if structurally it is identical to that of a natural element;[139]
(b) 'processes for cloning the human body, processes for modifying the germ line genetic identity of the human body and uses of the human embryo for industrial or commercial purposes';[140]
(c) 'processes and products for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefits to man or animal.'[141]

In other words, these procedures are not prohibited as such, under current legislation; however, financial gain resulting from application of these procedures is prohibited.

The Act does not directly refer to genetic modification of plant or other biological species but does mention that 'plant and animal varieties' are not patentable.[142] However 'inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.'[143]

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[138] *Patents and Designs Act*, article 4(4).
[139] *Patents and Designs Act*, article 4(5)(b), implementing article 5 of *Directive 98/44EC*.
[140] *Patents and Designs Act*, article 4(5)(c), implementing article 6(2)(a), (b) and (c) of *Directive 98/44/EC*.
[141] *Patents and Designs Act*, article 4(5)(d), implementing article 6(2)(d) of *Directive 98/44/EC*.
[142] *Patents and Designs Act*, article 4(5)(e).
[143] *Patents and Designs Act*, article 4(6).

'An invention, the exploitation of which would be contrary to public order or morality' is not patentable.[144] 'A right in a registered design shall not subsist in a design which is contrary to public policy or to accepted principles of morality.'[145]

The ***Patents and Designs Act*** incorporates the provisions of ***Directive 98/44/EC*** of the European Parliament and of the Council,[146] which deals with the legal protection of biotechnological inventions including patentability of human material.

The subsidiary legislation, ***Clinical Trials Regulations***, which applies ***Directive 2001/20/EC***, refers to ethical approval for trials involving medicinal products for gene therapy or somatic cell therapy or xenogenic cell therapy. Clinical trials are discussed in detail in section 11 of this chapter.

10. UNESCO Declaration on the Human Genome[147]

12.39

The UNESCO Declaration on the Human Genome includes several articles that relate to research on the human genome as follows:

Article 10: No research or research applications concerning the human genome, in particular in the fields of biology, genetics and medicine, should prevail over respect for the human rights, fundamental freedoms and human dignity of individuals or, where applicable, of groups of people.

Article 11: Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. States and competent international organizations are invited to co-operate in identifying such practices and in taking, at national or international level, the measures necessary to ensure that the principles set out in this Declaration are respected.

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[144] *Patents and Designs Act*, article 4(5)(a).

[145] *Patents and Designs Act*, article70.

[146] *Directive 98/44/EC* of the European Parliament and of the Council, on the legal protection of biotechnological inventions, Official Journal of the European Communities, L 213/13, 30.07.1998.

[147] http://unesdoc.unesco.org/images/0011/001102/110220e pdf/page=47

Article 12:

(a) Benefits from advances in biology, genetics and medicine, concerning the human genome, shall be made available to all, with due regard to the dignity and human rights of each individual.
(b) Freedom of research, which is necessary for the progress of knowledge, is part of freedom of thought. The applications of research, including applications in biology, genetics and medicine, concerning the human genome, shall seek to offer relief from suffering and improve the health of individuals and humankind as a whole.

The UNESCO Declaration makes several conditions for the exercise of scientific activity, as follow:

Article 13: The responsibilities inherent in the activities of researchers, including meticulousness, caution, intellectual honesty and integrity in carrying out their research as well as in the presentation and utilization of their findings, should be the subject of particular attention in the framework of research on the human genome, because of its ethical and social implications. Public and private science policy-makers also have particular responsibilities in this respect.

Article 14: States should take appropriate measures to foster the intellectual and material conditions favourable to freedom in the conduct of research on the human genome and to consider the ethical, legal, social and economic implications of such research, on the basis of the principles set out in this Declaration.

Article 15: States should take appropriate steps to provide the framework for the free exercise of research on the human genome with due regard for the principles set out in this Declaration, in order to safeguard respect for human rights, fundamental freedoms and human dignity and to protect public health. They should seek to ensure that research results are not used for non-peaceful purposes.

Article 16: States should recognize the value of promoting, at various levels as appropriate, the establishment of independent, multi-disciplinary and pluralist ethics committees to assess the ethical, legal and social issues raised by research on the human genome and its applications.

11. Clinical Trials

12.40

The ***Medicines Act*** provides directives in relation to clinical trials. It sets up a Licensing Authority, in effect the Superintendent of Public Health,[148] some of whose functions are:

(a) 'to establish standards for the testing or analysis of medicinal products or any substance which is used or is intended to be used therein;'[149]
(b) 'to establish standards for the carrying out of clinical trials';[150] and
(c) 'to establish standards for the reporting of adverse reactions, serious adverse reactions or suspected unexpected adverse reactions and make provision for the collection or submission of related information from any person or activity regulated by or under this Act.'[151]

The ***Clinical Trials Regulations,*** apply ***Directive 2001/20/EC*** and 'regulate the conduct of clinical trials, including multi-centre trials, in Malta on human subjects involving medicinal products as defined under the ***Medicines Act*** and in particular relating to the implementation of good clinical practice.'[152] These regulations apply only to interventional trials.

The regulations define 'clinical trial' as 'any investigation in human subjects intended to discover or verify the clinical, pharmacological and, or other pharmacodynamic effects of any investigational medicinal product and, or to identify any adverse reactions to any investigational medicinal product and, or to study absorption, distribution, metabolism and excretion of any investigational

[148] *Medicines Act*, article 3(1).
[149] *Medicines Act*, article 3(2)(e).
[150] *Medicines Act*, article 3(2)(f).
[151] *Medicines Act*, article 3(2)(g).
[152] *Clinical Trials Regulations*, SL 458.43, regulation 2(1).

medicinal product with the object of ascertaining its safety and, or efficacy. This includes clinical trials carried out in either one site or multiple sites, whether in one or more than one Member State.'[153]

An 'investigational medicinal product' is 'a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial.'[154] These 'investigational medicinal products and, or the devices used for their administration' are to be made available free of charge by the sponsor to the trial subjects, unless, in exceptional circumstances, the Licensing Authority establishes otherwise.[155]

a. Protection of trial subjects

12.41

The regulations are aimed at protection of the trial subjects. In fact a clinical trial may only be undertaken if:

(a) the Ethics Committee and, or the Licensing Authority, agree that 'the anticipated therapeutic and public health benefits', for the trial subject and other patients, 'justify the risks and may be continued only if compliance with this requirement is permanently and continuously monitored';
(b) the trial subject or the legal representative is given the opportunity 'to understand the objectives, risks and inconveniences of the trial' and is also 'informed of his right to withdraw from the trial at any time by revoking his informed consent without suffering any detriment';
(c) 'the rights of the subject to physical and mental integrity, to privacy' and to the protection of personal data in accordance with the ***Data Protection Act***, are safeguarded;
(d) the trial subject or the legal representative gives 'written consent after being informed of the nature, significance, implications and risks of the clinical trial. However if the individual is unable to write, oral consent may be given in the presence of at least one witness;
(e) provision has been made for insurance or indemnity to cover the liability of the investigator and sponsor.'[156]

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[153] *Clinical Trials Regulations*, SL 458.43, regulation 3.
[154] *Clinical Trials Regulations*, SL 458.43, regulation 3.
[155] *Clinical Trials Regulations*, SL 458.43, regulation 19(2).
[156] *Clinical Trials Regulations*, SL 458.43, regulation 4.

The subject must be provided with a contact point for further information. A named qualified person must be available 'to provide at all times the necessary medical care and make medical decisions on behalf of the subjects.'

Special provisions address clinical trials on minors and on incapacitated adults not able to give consent, where consent from parents or legal representatives must represent the potential trial subject's 'presumed will and may be revoked at any time, without detriment' to the subject who must receive 'information according to his capacity of understanding.' The subject's wishes must be 'given due consideration by the investigator'. There must not be any incentives or financial inducements. The research must benefit the particular group of people represented by the subject and relate directly to a clinical condition from which they suffer or 'be of such a nature that it can only be carried out on minors.' The Ethics Committee, must have specific expertise in paediatrics or the relevant disease in incapacitated patients or otherwise must take 'advice in clinical, ethical and psychosocial' issues in the particular field and in the patient population concerned.[157]

b. Ethical approval, authorisation and registration

12.42

It is 'an offence for the sponsor to start a clinical trial in Malta unless the Ethics Committee has issued a favourable opinion and the Licensing Authority has not informed the sponsor of any grounds for non-acceptance.' In fact both applications may run concurrently.[158]

Ethical approval: As already discussed, the Licensing Authority, that is the Superintendent of Public Health, has set up a Health Ethics Committee, whose remit includes assessing clinical trials before they commence. The committee has to consider relevance of the trial, its design and protocol, 'the anticipated benefits and risks', 'the suitability of the investigator and supporting staff' and 'the quality of the facilities'. Subjects are further protected by evaluating subject recruitment and the written information provided and by confirming that informed consent is obtained correctly.

[157] *Clinical Trials Regulations*, SL 458.43, regulations 5 and 6.
[158] *Clinical Trials Regulations*, SL 458.43, regulation 9(1).

The committee is also to look at 'arrangements for justly rewarding investigators and compensating trial subjects and the relevant aspects of any agreement between the sponsor and the site' of the trial, and at the 'provision for indemnity or compensation in the event of injury or death attributable to a clinical trial' and also at 'insurance or indemnity to cover the liability of the investigator and sponsor.'[159]

The committee has specified timescales in which to give its opinion to the applicant and to the Licensing Authority, with an option to obtain clarification from the applicant.[160] More time is set for 'trials involving medicinal products for gene therapy or somatic cell therapy or medicinal products containing genetically modified organisms' since consultation with other committees may be necessary. 'In the case of xenogenic cell therapy, there shall be no time limit.'[161]

For multi-centre clinical trials limited to Malta there need be only a single opinion by the Ethics Committee but for 'multi-centre clinical trials carried out in more than one Member State simultaneously, a single opinion shall be given by the Ethics Committee for each Member State concerned.'[162]

12.43

Authorisation: Regulation 9 deals with authorisation by the Licensing Authority, which receives the sponsor's valid request to conduct the trial. The Authority may request further information but has to reply within similar time frames as for the Ethics Committee, including those specific for medicinal products related to gene therapy. The Licensing Authority may consult the Ethics Committee. If the request is rejected, the sponsor may 'amend the content of the request' once.

A written authorisation from the Licensing Authority may be required for trials on medicinal products which do not have a marketing authorisation in Malta (Part A of the Annex to ***Regulation (EEC) No 2309/3***) and medicinal products, whose active ingredients are biological products of human or animal origin, or which contain such biological components, or which use such components during manufacture.[163]

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[159] *Clinical Trials Regulations*, SL 458.43, regulation 7(2).
[160] *Clinical Trials Regulations*, SL 458.43, regulation 7(3).
[161] *Clinical Trials Regulations*, SL 458.43, regulation 7(4).
[162] *Clinical Trials Regulations*, SL 458.43, regulation 8.
[163] *Clinical Trials Regulations*, SL 458.43, regulation 9(5).

A written authorisation from the Licensing Authority is always required for trials on 'medicinal products for gene therapy, somatic cell therapy including xenogenic cell therapy and all medicinal products containing genetically modified organisms. No gene therapy trials may be carried out which result in modifications to the subject's germ line genetic identity.'[164]

12.44

Registration: Clinical trials taking place in Malta, have to be registered, by the Licensing Authority, in a European database, accessible only to the competent authorities of the Member States, the Commission and the European Medicines Agency. Information registered includes:

(a) extracts from the request for authorization and any amendments to the request;
(b) any amendments to the protocol;
(c) 'the favourable opinion of the Ethics Committee;
(d) the declaration of the end of the clinical trial; and
(e) a reference to the inspections carried out in conformity with good clinical practice.'[165]

Further information requested by any Member State, the Agency or the Commission must be supplied.

c. Conduct of trials

12.45

Regulation 10 covers amendments to a clinical trial, once it has already started. Significant amendments require the sponsor to obtain approval from the Ethics Committee, who may request new informed consent. If the committee's opinion, within 35 days, is unfavourable, the amendments cannot be made. The amendments must also be approved by the Licensing Authority, who should preferably be informed by the sponsor. The latter should also preferably inform

[164] *Clinical Trials Regulations*, SL 458.43, regulation 9(6). *Council Directives 90/219 EEC*, of 23rd April 1990, on the contained use of GMOs and *2001/18/EEC*, of 12th March, 2001, on the deliberate release of GMOs into the environment, must also be satisfied.

[165] *Clinical Trials Regulations*, SL 458.43, regulation 11(1).

the competent authorities of the Member States concerned, about the reasons for, and content of, the proposed amendments.

These bodies must also be informed, by the sponsor, within 90 days of the end of a clinical trial. 'If the trial has to be terminated early, this period shall be reduced to 15 days and the reasons clearly explained.'[166]

The Licensing Authority is empowered to suspend or prohibit a trial if the conditions in the request for authorisation are violated, or if there are problems with the safety or scientific validity of the clinical trial; before such a decision is taken, the sponsor is asked to clarify the issues. The Authority must communicate the decision, and the reasons for it, to the competent authorities, the Ethics Committee, the Agency and the Commission. The Licensing Authority also regulates the sponsor or the investigator in terms of their obligations in the trial and any recommended action taken in this respect must be made known to the Ethics Committee, the other competent authorities and the Commission.[167]

The Licensing Authority must appoint inspectors, who on behalf of the Community, have to inspect the sites concerned by a clinical trial, including the manufacturing site of any investigational medicinal product, any laboratory used for analyses or the sponsor's premises, to 'verify compliance with the provisions on good clinical and manufacturing practice.' These inspections shall be coordinated by the Agency, and the results shall be recognised by all the other Member States. The inspection report is to be made available to the sponsor while safeguarding confidential aspects. It may be made available to the other Member States, to the Ethics Committee and to the European Medicines Agency, at their reasoned request.[168]

d. Adverse events

12.46

When a 'new event' relating to the conduct of the trial 'is likely to affect the safety of the subjects, the sponsor and the investigator shall take appropriate urgent safety measures which include information to the subjects, in order to protect the subjects against any immediate hazard.' The sponsor must immediately inform the

[166] *Clinical Trials Regulations*, SL 458.43 regulation 10(d).
[167] *Clinical Trials Regulations*, SL 458.43 regulation 12.
[168] *Clinical Trials Regulations*, SL 458.43 regulation 16.

Licensing Authority, the competent authorities of the Member States concerned and the Ethics Committee.[169]

The investigator must 'report all serious adverse events immediately to the sponsor,' followed by detailed, written reports. Subjects are to be identified only by unique code numbers. If a death occurs, the investigator shall supply the sponsor and the Ethics Committee with any additional information requested. All other adverse events or laboratory abnormalities 'critical to safety evaluations' must be reported as agreed in the protocol.[170]

It is the responsibility of the sponsor to ensure that all relevant information about serious unexpected adverse reactions that are fatal or life-threatening are reported as soon as possible to the competent authorities in all the Member States concerned, and to the Ethics Committee, no later than seven days after the case, and that relevant follow-up information is provided within an additional eight days. All other serious adverse reactions must also be reported to the same authorities and to the Ethics Committee within a maximum of fifteen days. An additional report of serious adverse reactions has to be made to these bodies once a year. The sponsor must also inform all the investigators.[171] However records of any other adverse event 'shall be submitted to the Member States in whose territory the clinical trial is being conducted, if they so request.'[172]

The Licensing Authority must also record all suspected unexpected serious adverse reactions to an investigational medicinal product[173] and immediately enter them in a European database to which, only the competent authorities of the Member States, the Agency and the Commission shall have access.[174]

e. Pharmacovigilance

12.47

The Medicines Authority, a corporate body set up under the ***Medicines Act***, is responsible for setting up procedures to ensure

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[169] *Clinical Trials Regulations*, SL 458.43 regulation 10(c).
[170] *Clinical Trials Regulations*, SL 458.43 regulation 17(1), (2) and (3).
[171] *Clinical Trials Regulations*, SL 458.43 regulation 18.
[172] *Clinical Trials Regulations*, SL 458.43 regulation 17(4).
[173] *Clinical Trials Regulations*, SL 458.43 regulation 18(1)(c).
[174] *Clinical Trials Regulations*, SL 458.43 regulation 18(3).

the safety, quality and efficacy of medicinal products to be placed on the market in Malta. Such procedures relate to collecting and assessing information, testing of such products and monitoring and obtaining relevant reports. It can then make recommendations to the Licensing Authority in relation to standards and licensing.[175]

As regards surveillance of medicinal products, in particular monitoring for adverse reactions in human beings, detailed regulations are found in the Subsidiary Legislation 458.35, ***Pharmacovigilance Regulations***, meant to ensure safety of such products. There may even be the need for 'a pharmacoepidemiological study or a clinical trial' on an authorised medicinal product.[176]

f. EU legislation

12.48

Directive 2001/20/EC of the European Parliament and of the Council[177] of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, makes the following important points:

(a) It refers to Council ***Directive 65/65/EEC*** of 26 January 1965 requiring that applications for authorisation to place a medicinal product on the market should be accompanied by a dossier containing particulars and documents relating to the results of tests and clinical trials carried out on the product;
(b) It refers to Council ***Directive 75/318/EEC*** of 20 May 1975 on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of medicinal products;
(c) Clinical trials should respect the protection of human rights and the dignity of the human being with regard to the application of biology and medicine, as for instance reflected in the 1996 version of the Helsinki Declaration;

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[175] *Medicines Act*, article 6(1).
[176] *Pharmacovigilance Regulations*, SL 458.35, regulation 5(2)(d).
[177] *Directive 2001/20/EC*, Official Journal of the European Communities, L. 121/34, 1.5.2001.

(d) The clinical trial subject's protection is safeguarded through risk assessment based on the results of toxicological experiments prior to any clinical trial, screening by ethics committees and Member States' competent authorities and rules on the protection of personal data;

(e) Protection should be provided for those incapable of giving legal consent to clinical trials. Such persons may not be included in clinical trials if the same results can be obtained using persons capable of giving consent. Normally these persons should be included in clinical trials only when there are grounds for expecting that the administering of the medicinal product would be of direct benefit to the patient, thereby outweighing the risks;

(f) Children represent a vulnerable population with developmental, physiological and psychological differences from adults, which make age and development related research important for their benefit. Medicinal products, including vaccines, for children, need to be tested scientifically before wide-spread use. The clinical trials required for this purpose should be carried out under conditions affording the best possible protection for the subjects. Criteria for the protection of children in clinical trials therefore need to be laid down;

(g) In the case of other persons incapable of giving their consent, such as persons with dementia, psychiatric patients, etc., inclusion in clinical trials in such cases should be on an even more restrictive basis. Medicinal products for trial may be administered to all such individuals only when there are grounds for assuming that the direct benefit to the patient outweighs the risks. Moreover, in such cases the written consent of the patient's legal representative, given in cooperation with the treating doctor, is necessary before participation in any such clinical trial; and

(h) In order to achieve optimum protection of health, obsolete or repetitive tests will not be carried out, whether within the Community or in third countries.

Chapter 13

Public Health Issues

1. Introduction

13.01

There is the potential of a clash between the interests of the individual and those of the public at large. This occurs, for instance, in situations involving risks of transmitting an infectious disease, or relating to confidentiality in situations where the courts demand otherwise. It is also accepted that the rights of the public at large supervene over those of the individual. Public health issues are considered (rightly) to be more important than individual rights. As has been said, the rights of the individual stop where the rights of another person or persons begin.

The ***Constitution of Malta*** makes several references to public health, mainly taking the form of prohibition of interference with basic human rights, unless these rights are in conflict with public order and safety, morality or decency or public health. These are referred to as follows:

(a) Protection for privacy of home or other property;[1]
(b) Freedom of conscience in the exercise of mode of religious worship;[2]
(c) Freedom of expression;[3]
(d) Freedom of assembly and association;[4] and
(e) Freedom of movement.[5]

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[1] *Constitution of Malta*, article 38(2)(a).
[2] *Constitution of Malta*, article 40(3).
[3] *Constitution of Malta*, article 41(2)(a)(i).
[4] *Constitution of Malta*, article 42(2)(a).
[5] *Constitution of Malta*, article 44(3)(a).

The ***European Convention Act*** incorporates the provisions of the ***European Convention for the Protection of Human Rights and Fundamental Freedoms***, in particular legislation relating to health and the need not to restrict rights and freedoms of the individual unless necessary to do so under certain conditions, including public health issues. These articles refer specifically to:

(a) the right to respect for private and family life, home and correspondence;[6]
(b) the right to manifest one's religion or beliefs;[7]
(c) the right to freedom of expression;[8]
(d) the right to freedom of peaceful assembly and to association with others, including forming trade unions;[9] and
(e) the right to freedom of movement.[10]

In the following pages, it will become manifest that on occasion, a number of these rights have to be infringed upon. This happens whenever there is a risk that individual action or inaction may jeopardise the health of the community, in which case the health authorities are obliged to take steps to protect the rights of the community, which supervene over the right of the individual.

2. Public Health Emergency

13.02
The ***Public Health Act*** provides for a declaration of a public health emergency by the Superintendent of Public Health. The declaration 'shall specify:

(a) the nature of the public health emergency; and
(b) the area to which the declaration applies.'[11]

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[6] *European Convention Act*, First Schedule, Article 8 of the Convention.
[7] *European Convention Act*, First Schedule, Article 9 of the Convention.
[8] *European Convention Act*, First Schedule, Article 10 of the Convention.
[9] *European Convention Act*, First Schedule, Article 11 of the Convention.
[10] *European Convention Act*, First Schedule, Article 2, paragraph 3, of the Fourth Protocol to the Convention.
[11] *Public Health Act*, article 14.

The Superintendent may take any of the following measures, 'necessary in order to reduce, remove or eliminate the threat to public health:

(a) 'segregate or isolate any person in any area; or
(b) evacuate any persons from any area; or
(c) prevent access to any area; or
(d) control the movement of any vehicle; or
(e) order that any person undergo a medical examination; or
(f) order that any substance or object be seized, destroyed or disposed of as he may direct; or
(g) order such other action be taken as he may consider appropriate.'[12]

Failure to comply with any of these directions is an offence.[13]

Other special powers in such an emergency, empower the Superintendent to 'authorise any person to:

(a) enter any place if necessary by using such reasonable force to:
  (i) save human life; or
  (ii) prevent injury to any person; or
  (iii) rescue any injured or endangered person; and
(b) close any area, premises, body of water or vehicles; and
(c) remove by reasonable force any person who fails to comply with a direction.'[14]

3. Prevention of Spread of Disease

Whose responsibility is it to ensure that disease does not spread within the community? Obviously it devolves on every person to ensure that all basic precautions are taken to ensure that infectious disease is not transmitted to others. Where immunisation against disease is available, as for instance for tuberculosis and for the common diseases of childhood (e.g. measles, whooping cough), it is usually considered obligatory to ensure not only personal protection, but also, perhaps more importantly, to boost herd

[12] *Public Health Act*, article 15(1).
[13] *Public Health Act*, article 15(2).
[14] *Public Health Act*, article 16.

protection, which reduces the overall susceptibility and the incidence of disease in a population.

Where immunisation procedures are not available, best illustrated with the recent epidemic disaster caused by the Human Immunodeficiency Virus, (HIV), personal precautions are essential, and knowingly indulging in sexual practices without adequate precautions is tantamount to assault.

Legislation in Malta in relation to containment of infectious disease is contained in the ***Prevention of Disease Ordinance***, which consists of 'laws for preventing the introduction and spread of infectious, contagious and epidemic diseases affecting either mankind or animals.' These provisions are to be repealed and replaced by part of the ***Public Health Act***,[15] mainly Part IV, dealing with Prevention and Control of Disease.[16]

In summary, these are the main features relevant to the current discussion:

(a) notification of infectious disease;
(b) inspection of premises;
(c) isolation and restriction of movement of persons;
(d) removal of persons from infected premises;
(e) disinfection of house and articles; and
(f) cleansing of a person.

a. Notification of disease

13.04

A disease for the purpose of Part I of the ***Prevention of Disease Ordinance*** refers to a 'disease of an infectious or contagious nature dangerous to mankind' but does not include venereal disease, which is specifically dealt with in the ***Venereal Diseases (Treatment) Act.***[17]

[15] The *Public Health Act* came partly into force in November 2003 but article 45, which deals with repeal of the Ordinance and other articles in various laws, and Part IV, were still not in force by 31st December 2005.

[16] There is also the *Plant Quarantine Act* which aims to 'prevent the introduction into Malta of plant pests and diseases, to control and check the spread thereof and to provide for other matters incidental and ancillary thereto.' However there is no mention of human infection in this Act.

[17] For the purposes of the *Venereal Diseases (Treatment) Act*, 'venereal disease' means gonorrhoea, syphilis or chancroid.

The duty of notifiying disease is placed on the public, medical practitioners and laboratories.

(a) General public

According to the Ordinance, the head of the family in a normal household (or, when he is not available, the nearest relative) should report to the local district medical office[18] any disease listed in the Ordinance in article 10(1).[19] When the patient is on board a ship the master is responsible for notification of such diseases. Similarly, when the patient is in a hotel, or school, the hotel-keeper or head of the school, has the responsibility of informing the Superintendent of Public Health or the district medical officer. It is an offence to fail to give such notice.[20]

However now in terms of the ***Public Health Act***, 'any person who becomes aware of any fact or situation which he reasonably ought to believe to be a public health risk or a potential public health risk shall, as soon as he becomes aware of such risk, inform the Superintendent.' Failure to do so, is an offence.[21] This would include reporting an infectious disease.

'The Superintendent may require any person to notify him of the presence or occurrence of any of the following:

(a) any notifiable disease or suspicion thereof;
(b) any human pathogenic organisms or suspicion thereof;
(c) any contaminant or suspicion thereof.'[22]

(b) Medical practitioners

13.05

The ***Prevention of Disease Ordinance*** lays down the duty of medical practitioners to notify the Superintendent of Public Health, of any

[18] *Prevention of Disease Ordinance*, article 5.

[19] These are 'plague, small-pox, cholera, diphteria, membranous croup, typhus, yellow fever, leprosy and epidemic cerebro-spinal meningitis', *Prevention of Disease Ordinance*, article 10(1).

[20] *Prevention of Disease Ordinance*, article 8.

[21] *Public Health Act*, article 18. In this Act, Superintendent means 'the Superintendent of Public Health and to the extent of any delegation or authority given includes an authorised officer.'

[22] *Public Health Act*, article 31(4). This is not yet in force on 1st March 2005.

patient suffering from an infectious disease. The medical officer must send a certificate stating 'the name, age and address of the patient, and the disease from which, in the opinion of such medical practitioner, the patient is suffering.'[23] In the ***Public Health Act,*** a 'medical practitioner who treats or examines any person for a notifiable disease shall report such notifiable disease to the Superintendent on the prescribed certificate.'[24] Consent is not required from the patient.[25]

The notifiable diseases were listed in the Ordinance in articles 10(1) and 10(2)[26] and in the Subsidiary Legislation 36.35, ***Infectious or Contagious Diseases (Extension) Order.***[27] Subsidiary Legislation 36.15, ***Notification of Tuberculosis by Medical Practitioners Order*** covered tuberculosis. However now in terms of article 27(a)(i) of the ***Public Health Act,*** the Superintendent of Public Health has established a new list of notifiable diseases.[28] This list includes new infectious diseases as well as cases of anitimicrobial resistance. It is noted that HIV infection has now become a notifiable disease, when previously, the diagnosis had been established by the laboratory anonymously. This is justified in relation to the need for adequate protection of contacts in relation to public health measures.

Article 3 of the ***Venereal Diseases (Treatment) Act*** refers to the medical practitioner's duty to notify the Chief Government Medical Officer of particulars relating to a patient suffering from venereal disease as well as the patient's contacts.

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[23] *Prevention of Disease Ordinance,* article 7.

[24] *Public Health Act,* article 31(1), which is not yet in force by 1st March 2005.

[25] *Public Health Act,* article 31(3), which is not yet in force by 1st March 2005.

[26] These are 'scarlatina or scarlet fever, typhoid or enteric fever, malarial fever, undulant fever, puerperal fever and the diseases known as measles, erysipelas, varicella, influenza, whooping cough, hydrophobia and tubercular phthisis,' *Prevention of Disease Ordinance,* article 10(2).

[27] The latter are 'acute encephalitis, acute flaccid paralysis, congenital rubella syndrome, Creutzfeldt-Jakob disease, leptospirosis and meningococcal septicaemia (without meningitis).

[28] Government Notice No. 75 of 2004, published in the Government Gazette of 27th January, 2004. See Appendix J.

(c) Laboratories

13.06

The licensee of a laboratory must inform the Superintendent of Public Health of 'any infectious disease diagnosed at the laboratory, notifiable under the ***Prevention of Disease Ordinance,***' with 'the details of name, address and identity card number of the patient, as well as the name, address and medical registration number of the referring medical practitioner.'[29] This duty will be covered by the ***Public Health Act*** when the relevant article comes into force; the responsibility for notification is on the 'person in charge of a laboratory'[30] and the report will not require the consent of the person, whose sample is submitted for analysis.[31]

(d) Disclosure of information by/to Superintendent of Public Health

13.07

Moreover 'the Superintendent or any authorised officer may for the purposes of the ***Public Health Act*** request any person to:

(a) give his personal details;
(b) give details of any licence, permit or exemption under this Act;
(c) provide any information relating to public health; and
(d) give information about his or any other person's activities in respect of any matter under this Act.'[32]

On the other hand, the Superintendent may, 'in the interest of public health, give information to any person or persons who may be affected by any notifiable disease or any human pathogenic organism or contaminant.'[33]

However some protection is envisaged in that 'no person may record, collect, transmit or store any records, information or forms for the purpose of this Act other than in accordance with the provisions of this Act or any regulations made thereunder.'[34]

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[29] *Licensing of Private Medical Diagnostic Laboratories*, SL 458.25, regulation 10.
[30] *Public Health Act*, article 31(2), not yet in force by 31st December 2005.
[31] *Public Health Act*, article 31(3), not yet in force by 31st December 2005.
[32] *Public Health Act*, article 8.
[33] *Public Health Act*, article 32, not yet in force by 31st December 2005.
[34] *Public Health Act*, article 19.

b. Inspection of premises

13.08

Where there is reason to believe that an infectious disease, or a person in contact with such disease, is present in a household, the Superintendent or any authorised officer has the power to enter such a house at any reasonable time.[35] S/he has the right to examine and inspect any person found on the premises,[36] or subject them to 'such medical investigations as may be deemed by him to be necessary in the interest of public health.'[37]

Where entry is refused, any magistrate may 'grant a warrant authorizing such entry, examination, inspection or medical investigation.'[38]

c. Isolation and restriction of movement of persons

13.09

Legislation also provides power to the Superintendent to restrict movement of a person suspected of spreading disease, including suspension from work for a period not exceeding four weeks (which may be extended up to ten weeks).[39] The Superintendent also has

[35] *Public Health Act*, article 6 (1)(a). The *Prevention of Disease Ordinance*, article 12(1) had interpreted this as 'at any hour by day or by night, after giving one hour's notice.'

[36] *Prevention of Disease Ordinance*, article 12(1) and *Public Health Act*, article 6 (1)(e) .

[37] *Prevention of Disease Ordinance*, article 12(1). Similar provisions exist in the *Public Health Act*, articles 28 and 29, not yet in force by 31st December 2005; article 29(1)(c) also allows the Superintendent to order treatment, immunisation and counselling and article 29(1)(d) orders the disclosure of contacts of the infected person. Article 28(3) makes it an offence to refuse to undergo a medical examination.

[38] *Prevention of Disease Ordinance*, article 12(2). The *Public Health Act*, article 29(3), not yet in force by 31st December 2005, not only authorizes entry but also empowers the Superintendent to apply for 'a warrant to apprehend and detain or quarantine any person' who fails to comply with examination, treatment, isolation, prevention of spread of disease and disclosure of contacts.

[39] *Prevention of Disease Ordinance*, article 13(1). The *Public Health* Act, article 29(1)(e), not yet in force by 31st December 2005, empowers the Superintendent to order an infected person from refraining 'from doing anything which may cause the spread of disease.'

the power to order that the diseased person be isolated and/or given medical treatment.[40] There are separate provisions in the ***Public Health Act***, already in force, in cases of a public health emergency. After declaring such an emergency, in a threat from an infectious disease, the Superintendent may 'segregate or isolate' or evacuate any persons from any area, prevent access to any area and control the movement of any vehicle.[41]

d. Removal of persons from infected premises

In the case of an infected person, forcible removal to hospital by order of a magistrate[42] may be necessary under certain conditions, e.g. where a person does not have proper accommodation, or where one cannot take proper precautions to prevent spread of disease. This detention may be extended by the magistrate for as long as may appear to him to be necessary for preventing the spread of the disease.

e. Disinfection of house and articles

13.10

The Superintendent has a duty to cause the occupier of any premises to ensure they are cleansed and disinfected[43] or otherwise to order the Department of Health to carry out the disinfection of the house and articles,[44] including destruction or disinfection of infected articles.[45] An officer has the right to enter premises for the purpose of such disinfection[46] and of removing persons from infected premises, by force (with the assistance of the police) if necessary.[47]

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[40] *Prevention of Disease Ordinance*, article 14 and *Public Health Act*, article 29(1)(a), not yet in force by 31st December 2005.

[41] *Public Health Act*, article 15.

[42] *Prevention of Disease Ordinance*, article 25. See *Public Health Act*, article 29(3), not yet in force by 31st December 2005.

[43] *Prevention of Disease Ordinance*, article 16. See also *Public Health Act*, articles 21(2) and 21(3).

[44] *Prevention of Disease Ordinance*, article 17(1) and *Public Health Act*, article 22.

[45] *Prevention of Disease Ordinance*, article 22(1) and *Public Health Act*, article 21.

[46] *Prevention of Disease Ordinance*, article 18. See also *Public Health Act*, articles 21(2) and 21(3).

[47] *Prevention of Disease Ordinance*, article 19.

An authorised officer, while exercising any power under the ***Public Health Act***, 'may request the assistance of a police officer or of any other person as he may require.'[48] It is an offence to assault, abuse or threaten an authorised officer or a police officer exercising a function under this Act, to hinder or delay the performance of any such function or to fail to comply with a requirement of such officers.[49]

f. Cleansing of a person

13.11

A person reported by a government medical officer to be 'verminous', may be cleansed. If the person consents to the procedure, he will be removed to a cleansing station. If that person does not so consent, a Magistrate may make 'an order for his removal to such a (cleansing) station and for his detention therein for such period and subject to such conditions as may be specified in the order.'[50]

In the case of a person incapable of giving consent, that is 'a person under the age of eighteen years or irresponsible through mental deficiency,' his parents or guardians will be expected to give such consent.[51]

g. Invasion of privacy

13.12

Several of the measures described by the ***Public Health Act*** and by the ***Prevention of Disease Ordinance*** (see below) are clearly invasive of one's personal privacy and conflict with the right of the person to behave in an autonomous manner. However this is demanded because of the danger such behaviour might pose to the public at large, and hence it is ethically justified.

According to the ***Public Health Act***,[52] in relation to activities relevant to public health, the Superintendent or an authorised officer may, at any reasonable time:

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[48] *Public Health Act*, article 6(3).
[49] *Public Health Act*, article 23(1).
[50] *Prevention of Disease Ordinance*, article 20(1). See *Public Health Act*, article 30, not yet in force by 31st December 2005.
[51] *Prevention of Disease Ordinance*, article 20(4).
[52] *Public Health Act*, article 6.

(a) enter, and inspect any area, premises, body of water or vehicle;
(b) require any person to answer any question and, or, produce any records;
(c) inspect, extract or seize any record including computer records;
(e) examine and, or, inspect any person or object or container;
(f) mark, seal, weigh and measure any object;
(i) remove a sample or seize any object or record; a receipt must be provided to the owner of any seized object;
(j) seal any area;
(k) take any photographs or make any sketches or other records of any person or premises;
(l) test and, or, examine any drainage system;
(m) carry out any test, examination, or measurement by instruments, monitor any situation, and make observations that may be required under this Act;
(n) give any order under this Act that he may deem necessary; and
(o) refer any matter to any relevant board under this Act.

Article 6 also stresses that the authorised officer must 'provide an identification document issued by the Superintendent' when requested by the owner being investigated and must 'give reasonable notice unless such notice would defeat the objective of the intended exercise.' The officer 'may request the assistance of a police officer or of any other person' as may be required.

The Superintendent may, 'in the national interest exempt:

(a) any person;
(b) any matter or activity;
(c) any area, premises, body of water;
(d) and any vehicle;

from any provision of this Act.'[53]

The Superintendent may order that 'any article, item or substance that causes a threat to public health is not imported, manufactured, sold, used, stored or transported or handled in any manner.'[54]

[53] *Public Health Act*, article 7.
[54] *Public Health Act*, article 20(1).

The Superintendent may require any person 'to treat, remove, recall, dispose of or destroy any articles, items, goods or substances that, in his opinion, may cause a threat to public health' and 'may require any person who is in possession or, at the time, is in control of any premises, area, vehicle or object, which, in his opinion, may cause a threat to public health, to clean, disinfect or disinfest such premises, area, vehicle or object.'[55] Moreover these requirements shall be carried out at the expense of the person required to comply with the said requirements. Otherwise the Superintendent may carry out the necessary procedures and the expenses are recovered as civil debts.[56]

There may however be grounds for reasonable compensation for any loss or damage suffered as a result of actions under the Act, which are the result of a direction by the Superintendent,[57] but not in a public health emergency.

h. Personal responsibility relating to infectious diseases

13.13

It is an offence if a person who, 'while suffering from a disease, wilfully exposes himself without proper precautions against the spread of the disease.'[58] An individual is therefore held responsible to ensure that he is not a risk to the public, and does not pass his infectious disease to other persons. This injunction would hold in the case of unprotected sexual intercourse by persons with sexually transmitted notifiable disease, e.g. AIDS.

The most recent update relating to transmission of a communicable disease is to be found in the ***Criminal Code***.[59] This states that:

(a) 'Any person who, knowing that he suffers from, or is afflicted by, any disease or condition as may be specified' by the Minister,

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[55] *Public Health Act*, article 21.

[56] *Public Health Act*, article 22.

[57] *Public Health Act*, article 17.

[58] *Prevention of Disease Ordinance*, article 27 and *Public Health Act*, article 33, not yet in force by 31st December 2005. The latter also makes parents or guardians responsible for preventing transmission of their children's disease.

[59] *Criminal Code*, article 244A.

'in any manner knowingly transmits, communicates or passes on such disease or condition to any other person not otherwise suffering from it or afflicted by it, shall, on conviction, be liable to imprisonment for a term from four years to nine years.' If the other person dies as a result of such disease or condition, the offender is liable to imprisonment for life.

(b) Where any such disease or condition 'is transmitted, communicated or passed on through imprudence, carelessness or through non-observance of any regulation by the person who knew or should have known that he suffers therefrom or is afflicted thereby that person shall on conviction be liable to imprisonment for a term not exceeding six months or to a fine *(multa)* not exceeding one thousand liri: Provided that where the other person dies as a result of such disease or condition, the offender shall be liable to' imprisonment for a term not exceeding four years or to a fine *(multa)* not exceeding five thousand liri.

(c) 'The Minister responsible for justice shall, by notice in the Gazette, specify' such diseases or conditions. The diseases or conditions to which this article applies are tuberculosis, hepatitis B infection, hepatitis C infection, HIV infection and AIDS.[60]

Other prohibitions include:

(a) children's attendance at school in cases of infectious disease;[61]
(b) engaging in occupations connected with food for sale;[62] and
(c) travel in a public vehicle, unless proper precautions are taken.[63]

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[60] Legal Notice 137 of 2005, *Communicable Diseases and Conditions Regulations, 2005*, published in the Government Gazette, No. 17,768 on 17th May 2005.

[61] *Prevention of Disease Ordinance*, article 28 and *Public Health Act*, article 29(2), not yet in force by 31st December 2005.

[62] *Prevention of Disease Ordinance*, article 29 and the *Food Safety Act*, article 22.

[63] *Prevention of Disease Ordinance*, article 30. Subarticle 4 states that 'for the purpose of this (article), "disease" means plague, small-pox, cholera, diphtheria, membraneous croup, typhus, yellow-fever, epidemic cerebro-spinal meningitis, scarlatina or scarlet fever, measles, varicella and any other disease to which the Minister responsible for public health shall, by regulation, direct that the provisions of this (article) shall apply.'

The ***Food Safety Act*** prevents employment in a job related to 'the preparation or the handling of any food intended for sale for human consumption' of a person suffering from, or being a carrier of, 'typhoid fever, paratyphoid fever or any other salmonella infection or dysentery, staphylococcal infection, and any other infection likely to cause food poisoning,' or any other disease identified by the Minister.[64] This responsibility lies both with the employer and the individual person.

Periodic medical examinations and investigations may be requested, by the Superintendent of Public Health, of any person working in an occupation considered capable of spreading disease, to ensure that he is disease-free and not a risk to the public.[65] Regulation 6 of the Subsidiary Legislation 231.46, ***Registration of Food Handlers Regulations***, states that: 'Food handlers are to submit to any medical examination or treatment as shall be required by the Superintendent.'

4. Prevention of Epidemic Diseases

13.14

Besides the general procedures laid out in the ***Public Health Act*** and already discussed above, in section 2 in relation to a public health emergency, special precautions and regulations are envisaged in the eventuality of epidemic disease.

The Superintendent, by public notice, may declare that there is an outbreak of a notifiable disease; such declaration shall be revoked when the outbreak is over. The Superintendent may give any directions considered necessary or appropriate for the control of an outbreak and any person who does not comply with the directions shall be guilty of an offence.[66]

The Minister responsible for public health may regulate the 'measures to be taken for the prevention of danger arising to public health from ships, aircraft or passengers arriving in Malta, as well

[64] *Food Safety Act*, article 22.

[65] *Prevention of Disease Ordinance*, article 15(1). Similar provisions exist in the *Public Health Act*, article 28(1), not yet in force by 31st December 2005.

[66] *Public Health Act*, articles 34(1) and (2), not yet in force by 31st December 2005.

as measures for the prevention of the conveyance of infection by means of any ship or aircraft or passengers leaving Malta.'[67] The Superintendent may also give information about such outbreaks outside Malta and in particular indicate any port or airport that may be infected.[68]

'The Superintendent may require any person to keep, use or dispose of any contaminant, human pathogenic organism and any other material or substance capable of causing disease in humans in accordance with any orders or regulations that may be issued under this Act.'[69]

Regulations may be made:[70]

(a) for the speedy interment of the dead;[71]
(b) for house-to-house visitation;
(c) for the provision of medical aid, distribution of medicine, the establishment of hospitals, the promotion of cleansing, ventilation and disinfection and otherwise for guarding against the spread of disease;
(d) for preventing any house or part of a house from being so overcrowded as to be dangerous to health; and
(e) for any other matter or thing which the Minister responsible for public health may deem expedient for the prevention or mitigation of such disease.

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[67] *Prevention of Disease Ordinance*, article 50.

[68] *Public Health Act*, article 34(3), not yet in force by 31st December 2005.

[69] *Public Health Act*, article 36, not yet in force by 31st December 2005.

[70] *Prevention of Disease Ordinance*, article 44.

[71] The *Code of Police Laws* deals specifically with burials and related issues (articles 135–147). In particular, in relation to prevention of spread of disease, article 144(1) states that it is unlawful to bury in a cemetery in which the sanitary authority has prohibited burial, or without precautions as 'prescribed by the sanitary authority' and article 144 (2) states that: 'It shall not be lawful to convey to any church or chapel the body of any person who has died of plague, cholera, smallpox or typhus fever or such other disease communicable by contagion or infection as the Superintendent of Public Health may determine.' The *Public Health Act*, article 37, not yet in force, will allow transport of persons dying of notifiable diseases only for burial purposes or to a designated mortuary; the latter move may be ordered by the Superintendent in the case of a notifiable disease being the cause of death or if, 'whatever the cause of death, the body is in such a state as to pose a risk to health.'

In such an eventuality, the medical practitioners exercising their profession within the area affected by the disease and any other medical practitioner engaged by the Government 'shall place themselves at the service of the persons suffering from such disease within the district.'[72] The ***Public Health Act***, actually states that such practitioners 'shall not refuse to treat persons suffering from such disease within the area.'[73]

a. Immunisation against communicable disease

13.15

Immunisation centres are established in Malta and Gozo to provide free immunisation against the common childhood infectious disorders (diphtheria, tetanus, poliomyelitis and such others as may be determined).[74]

Parents or custodians of a child who has attained the age of three months have the duty to ensure that the child is immunised,[75] except where the child is not fit to be immunised, in which case a certificate of postponement is issued by the medical officer in charge.[76] A certificate of immunisation is given to the parents or custodians of the child.[77] Records of immunisation have to be kept by the officer in charge of an immunisation centre.[78]

Where there is reason to believe that a child has not been properly immunised, even after due reminders to the parent or guardian, the Superintendent may deem it necessary, to safeguard the health of the child or of the community, to obtain a court order for 'directing the proper immunisation of such child in accordance

[72] *Prevention of Disease Ordinance*, article 45.

[73] *Public Health Act*, article 35, not yet in force by 1st March 2005.

[74] *Prevention of Disease Ordinance*, article 56. At present, in Malta, children are immunised against diphtheria, tetanus, pertussis, polio, haemophilus influenzae B meningitis, measles, mumps, rubella, hepatitis B and tuberculosis.

[75] *Prevention of Disease Ordinance*, article 57. They are informed of their duty by the Police, within seven days after the registration of the birth.

[76] *Prevention of Disease Ordinance*, article 58. The certificate of postponement is drawn up in accordance with Form No. 2 of the Schedule to SL 36.29, *Forms for Immunisation Regulations*.

[77] *Prevention of Disease Ordinance*, article 60. The certificate is drawn up in accordance with Form No. 1 of the Schedule to SL 36.29, *Forms for Immunisation Regulations*.

[78] *Prevention of Disease Ordinance*, article 61.

with the provisions of this Ordinance within such time as the said court may prescribe.'[79] Non compliance may lead to prosecution of parents or guardians for neglect to procure the immunisation of the child. The Superintendent may order a person to be vaccinated against tetanus if s/he is of the opinion that there is an increased risk of contracting the disease by reason of his/her occupation.[80] The Superintendent may order that a person suffering from a notifiable disease submits to immunisation.[81]

The Superintendent may make, vary or revoke orders 'ensuring the protection of the public by immunization against particular diseases' and may:

'(i) regulate and control the practice of any particular type of immunisation in humans;
(ii) prescribe forms, certificates, notices, immunisation certificates and postponement certificates;
(iii) prescribe those diseases against which immunisation of humans shall be compulsory;
(iv) regulate and control the importation, exportation, manufacture, storage and transport of any type of vaccine;
(v) publish schedules regarding compulsory or recommended immunisations.'[82]

These actions may be seen as big brother taking steps which interfere with the rights of the individual, particularly since, it may be argued, it is the health of the individual which is at risk and not that of the public. It is, however, a fact that if the proportion of persons allowed to remain unvaccinated rises considerably, with resultant reduction in 'herd immunity', then the risk of epidemics becomes much more significant. We see also that parental wishes may be overridden and immunisation performed irrespective of those wishes.

[79] *Prevention of Disease Ordinance*, article 64.
[80] *Prevention of Disease Ordinance*, article 64(1).
[81] *Public Health Act*, article 29(1)(c), not yet in force by 31st December 2005.
[82] *Public Health Act*, article 27(d), not yet in force by 31st December 2005.

5. Environmental Issues

13.16

The recent ***Environment Protection Act*** introduces several new concepts relating to our moral obligations and responsibilities vis-à-vis the environment and the 'duty of everyone together with the government to protect the environment and to assist in the taking of preventive and remedial measures to protect the environment and manage natural resources in a sustainable manner.'[83] The 'environment' includes 'the whole of the elements and conditions, natural or man made, existing on earth, whether together or in isolation, and in particular:

(a) the air, water and land;
(b) all the layers of the atmosphere;
(c) all organic and inorganic matter and all living organisms;
(d) all ecosystems; and
(e) the landscape.'[84]

The Act also encompasses protection of fauna and flora as well as control of genetically modified organisms.

The Act establishes an Authority to ensure that these aims are reached.[85] It also establishes a National Commission for Sustainable Development, whose functions include the formulation of a National Strategy for Sustainable Development, increasing public awareness and serving as a watchdog to identify trends which may significantly give rise to unsustainable development.[86] The Act provides for the appointment of environment inspectors[87] and any person who causes damage to the environment is required to make good any such damage.[88]

A number of legal notices and government notices referring to this Act have been issued and may be easily accessed from the Malta Environment Protection Authority (MEPA) website.[89]

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[83] *Environment Protection Act*, article 3
[84] *Environment Protection Act*, article 2.
[85] *Environment Protection Act*, article 6
[86] *Environment Protection Act*, article 8.
[87] *Environment Protection Act*, article 25.
[88] *Environment Protection Act*, article 24.
[89] MEPA website: http://www.mepa.org.mt/environment/index.htm?Legis.htm&1

13.17

Development and Planning: The ***Development Planning Act*** gives power to the Minister 'to regulate buildings and the construction, demolition or alteration thereof, as well as any other matter relating thereto, taking account of all relevant considerations, including safety, aesthetics, health and sanitation.'[90]

Clean Air: With respect to air pollution, the ***Clean Air Act*** refers to emission of smoke, grit, dust or gases and their 'becoming prejudicial to health'.[91] The Minister may make regulations 'controlling the emission from any chimney of such smoke or other matter as may pollute the air or be prejudicial to health or may constitute a nuisance.'[92]

13.18

Food and Drink: The right to health assumes that we are supplied with the basic commodities relating to food and drink.[93] Wholesome food and drink form the basis of our diet, and it is right for public health authorities to put great emphasis on ensuring the supply of these items without danger to health, which the consumer[94] has a right to expect. As has been mentioned already, one of the most important cause of mortality in past times, and still extant in third world countries, relates to the lack of commodities such as wholesome water and adequate and nourishing food. These we take for granted these days but it requires constant vigilance to maintain adequate standards within the community.

The ***Food Safety Act*** establishes a Food and Safety Commission and introduces provisions for enforcement of regulations in relation

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[90] *Development Planning Act*, article 60(1)(a).

[91] *Clean Air Act*, article 6(2). This is to be repealed by the *Public Health Act* when article 45 comes into force; article 26(e) and 26(k)(vi), already in force, give power to the Minister to control smoke.

[92] *Clean Air Act*, article 13(1)(c).

[93] United Nations General Assembly *Universal Declaration of Human Rights*, 1948, paragraph 25(1), states that: 'Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services.'

[94] The *Food and Safety Act*, article 2, defines consumer as 'any natural or legal person who, not in the course of a business, trade or profession, buys or otherwise receives food or food sources within the meaning of the provisions of this Act.'

to food.[95] The Commission has the duty 'to monitor, coordinate and keep under review all practices, operations and activities relating to food.'[96] It may make or issue public statements 'identifying and giving warnings or information about any of the following:

(a) food or food sources that are injurious to health or unfit for human consumption';
(b) 'the persons engaged in the supply of such food or food sources';
(c) practices, 'which are detrimental to the interests of consumers, and, or the persons who engage in such practices'; and
(d) 'any other matter that adversely affects or may adversely affect the health of consumers in connection with the acquisition or use of food or food sources.'[97]

The functions of the Commission are periodically supervised and audited by the Director of the Market Surveillance Directorate, in terms of article 27(2)(d) of the ***Product Safety Act***.[98] 'Where under any other law, a person or authority is empowered to take any measure or action which relates to food safety,' they are to immediately inform the Commission.[99]

13.19
This law:

(a) prohibits a person from knowingly rendering injurious to health any food intended to be sold for human consumption;[100]
(b) emphasises the responsibility of any person engaged in any food business to monitor the safety of all food within his control, and to inform the health authority of any food source suspected of causing injury;[101] and prohibits not only the selling of such food but also the supply of such food as a compensation or prize;[102]

[95] It repealed the *Food, Drugs and Drinking Water Act*. There are a number of legal notices in relation to the new Act, dealing with the food business and in particular with food hygiene, food content and food processing.
[96] *Food and Safety Act*, article 7(1).
[97] *Food and Safety Act*, article 8(1).
[98] *Food and Safety Act*, article 9(1).
[99] *Food and Safety Act*, article 9(2).
[100] *Food and Safety Act*, article 12(1).
[101] *Food and Safety Act*, article 13(1).
[102] *Food and Safety Act*, article 14(1).

(c) sets standards of hygiene by food-handlers[103] through regular inspection to check that 'the health standards concerning personal cleanliness and clothing are respected';[104]
(d) empowers the Minister to make regulations regarding 'requirements as to the clothing which is to be worn by persons in any premises';[105]
(e) prohibits the employment of persons suffering from or being carriers of certain infectious diseases, e.g. typhoid, paratyphoid and any other salmonella infection, staphylococcal infection, any other infection likely to cause food poisoning or any other prescribed disease;[106] and
(f) prohibits the importation of food, which is injurious to health or unwholesome or unfit for human consumption.[107]

Moreover it is an offence to use a food label or advert which 'falsely describes the food' or 'is likely to mislead as to the nature, substance or quality of the food,' or if the presentation of the food is misleading.[108]

This legislation emphases the obligation on the part of every citizen to be aware that his or her actions may impinge on the health and safety of others and that therefore there is an obligation on everyone to take precautions to ensure acceptable standards and reduce the risk to the health of others. This raises particular obligations in the case of those whose duty it is to supply the public with food and drink which may, under less than adequate circumstances, be a source of poisoning.

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[103] *Food and Safety Act*, article 15(1). The provisions of *Registration of Food Handlers Regulations*, SL 231.46, passed under the repealed *Food, Drugs and Drinking Water Act*, and still in force, require food handlers to be registered with the Superintendent; this is possible through possession of a valid certificate in good food hygiene practice issued by a body approved by the Superintendent.
[104] *Food and Safety Act*, article 15(2).
[105] *Food and Safety Act*, article 10(1)(b)(v).
[106] *Food and Safety Act*, article 22(1). See also LN 264 of 2002, *Hygiene of Food Regulations, 2002*, Part VIII.
[107] *Food and Safety Act*, article 23.
[108] *Food and Safety Act*, articles 18 and 19.

a. Plant protection from diseases

13.20

Malta has adhered on 13th May 1975 to the ***International Plant Protection Convention*** of November 1951.

The aim of the ***Plant Quarantine Act*** is to prevent the spread of plant pests (including genetically modified pests) and diseases, to and from Malta.[109]

It prohibits the importation of plant material, including plant pests, beneficial organisms and soil or packaging material, except in accordance with this Act.[110] A phytosanitary certificate may be required for the importation of certain types of plants.[111]

The Act allows for the appointment of inspectors and 'the Minister shall ensure that they receive adequate technical training to enable them to properly perform their duties.'[112]

Imported material may 'be examined and samples' taken by an inspector at any reasonable time.[113] The Police may seize any plant 'or other thing reasonably suspected of harbouring any plant pest' and it 'may be destroyed, disposed of, treated or otherwise dealt with as an inspector or authorised person thinks fit.'[114]

Customs officers and Post Office staff must assist 'in preventing the importation into Malta of anything contrary to this Act and in so doing may exercise all the powers conferred upon them by or under the ***Customs Ordinance*** and the ***Post Office Act*** or any law replacing the same' and they are to 'immediately notify an inspector or other designated officer of the Plant Health Service.'[115]

This Act also deals with export controls. 'Any person intending to export a consignment of plants or plant products to another

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[109] See also LN 97 of 2004, *Plant Quarantine (Harmful Organisms) Regulations, 2004.*

[110] *Plant Quarantine Act*, article 6. This does not include trade with member states of the European Union or, to such extent as may be prescribed, a state forming part of the European Economic Area or a state having similar arrangements with the European Union. See also LN 97 of 2004, *Plant Quarantine (Harmful Organisms) Regulations, 2004*, Schedules I -V.

[111] *Plant Quarantine Act*, article 12.

[112] *Plant Quarantine Act*, article 26(1).

[113] *Plant Quarantine Act*, article 18.

[114] *Plant Quarantine Act*, article 10.

[115] *Plant Quarantine Act*, article 15.

country shall submit the consignment to the Plant Health Service for pre-export examination.'[116]

Persons 'involved in propagating, storing, importing, exporting, producing or otherwise trading in plant material' may be required to register with the Plant Health Service.[117]

13.21

For the purpose of containment and eradication of plant pests, the Director of the Plant Health Service may, 'declare any plant pest to be a notifiable plant pest if it presents, or is likely to present, a threat to the production of, or trade in, plant materials or to the natural environment.'[118]

The occupier or owner of any land or premises on which such a notifiable plant pest is found, must immediately notify the Plant Health Service.[119]

The Director may:

(a) declare any area in Malta, which is infested or is suspected of being infested, to be an infested area;
(b) declare any such land or premises to be under quarantine;
(c) prescribe any measures for the treatment or disposal of plant material, plant pests, soil or packaging, and for the treatment of conveyances; and
(d) 'prescribe the period within which it shall be unlawful to plant or replant the whole or part of any infested place or area under quarantine.'[120]

The Director may order, the owner or occupier of affected land or premises, and if appropriate, also the owner or occupier of any land or premises in the vicinity, to take measures on their land 'to eradicate, contain or restrict the spreading of the notifiable plant pest.'[121] There

[116] *Plant Quarantine Act*, article 19(1). This does not include trade with member states of the European Union or, to such extent as may be prescribed, a state forming part of the European Economic Area or a state having similar arrangements with the European Union.
[117] *Plant Quarantine Act*, article 17.
[118] *Plant Quarantine Act*, article 20(1).
[119] *Plant Quarantine Act*, article 20(2).
[120] *Plant Quarantine Act*, article 21.
[121] *Plant Quarantine Act*, article 22.

is provision for compensating 'the owner of the plant material or item destroyed or harmed, from monies voted for that purpose by the House of Representatives.'[122]

6. Genetically Modified Food

13.22

There has been a public outcry against the production and distribution of genetically modified food. There is an innate fear that such food is not wholesome, or that it may somehow be a threat to health. The advantages of genetically modified goods are apparent, and include the possibility of growing crops where currently none can grow and ensuring longer survival and better presentation of food. On the other hand, as with all genetic manipulations, there is the danger of the unknown, including the possibility that modified DNA may in some way find its way into the human genome with unpredictable results.

The ***Environment Protection Act*** refers to a 'genetically modified organism' as 'any of the following:

(a) an organism derived from the formation of a combination of genetic material by any means other than natural means;
(b) an organism inheriting such combination of genetic material;
(c) an organism that results from the replication of an organism as derived in paragraph (a); or
(d) such other organism as may be prescribed by the Minister under this Act.'[123]

The ***Food Safety Act*** states that 'a food source shall be considered to be genetically modified if any of the genes or other genetic material in the food source:

[122] *Plant Quarantine Act*, article 25(1).

[123] *Environment Protection Act*, article 2. Refer also to Legal Notices relating to this Act: (a) LN 169 of 2002, *Contained Use of Genetically Modified Micro-Organisms Regulations, 2002;* LN 194 of 2002, *Contained Use of Genetically Modified Micro-Organisms (Amendment) Regulations, 2002;* LN 168 of 2004, *Contained Use of Genetically Modified Micro-Organisms (Amendment) Regulations, 2004* and (b) LN 170 of 2002, *Deliberate Release into the Environment of Genetically Modified Organisms Regulations, 2002.*

(a) has been modified by means of an artificial technique; or
(b) is inherited or otherwise derived, through any number or replications, from genetic material which was so modified; or
(c) has been modified by any other means as the Minister may prescribe.'[124]

The Minister may make regulations which:

(a) 'prohibit or regulate the carrying out of commercial operations with respect to novel foods and novel food ingredients, or food sources from which such foods are intended to be derived, of any class as may be specified in the regulations';[125] and
(b) 'prohibit or regulate the carrying out of such operations with respect to genetically modified or irradiated foods, or foods derived from such food sources, of any class as may be specified.'[126]

7. Consumer Rights

13.23

The average citizen has certain rights relating to ensuring health and safety. Some of these are summarised below.

Consumers are entitled 'to have adequate access to basic essential goods and services at reasonable prices and to be able to choose from a diverse range of goods and services' and 'to be protected against goods, production processes and services which are harmful to health.'[127]

It is to be pointed out however that this article is meant to be a declaration of principles and is not meant to 'be directly enforceable in any court or tribunal, but shall be adhered to in the interpretation and implementation of' the ***Consumer Affairs Act***.[128]

The ***Product Safety Act*** aims at ensuring safety of products available to the consumer. A consumer has the right:[129]

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[124] *Food Safety Act*, article 10(4).
[125] *Food Safety Act*, article 10(1)(f).
[126] *Food Safety Act*, article 10(1)(g).
[127] *Consumer Affairs Act*, article 43(2)(a) and (b).
[128] *Consumer Affairs Act*, article 43(1).
[129] *Product Safety Act*, article 3(1).

(a) to have, on the market, consumer products which are safe;
(b) 'to receive adequate information regarding the safety aspects and the proper use of such products; and
(c) to be adequately informed with regard to products which give rise to risks to the health and safety of consumers and which are sold or offered for sale to him.'

Again these rights are not directly enforceable in court but are to be the principles underlying the interpretation of the Act.[130]

Moreover, producers are obliged to place only safe products on the market.[131] Producers and importers shall:

(a) 'provide consumers with the relevant information to enable them to assess the risks inherent in a product throughout the normal or reasonably foreseeable period of its use, where such risks are not immediately obvious without adequate warnings;
(b) take those precautions necessary to prevent or minimise such risks'; and
(c) adopt measures 'to enable consumers to be informed of risks which these products might present and to take appropriate action including, if necessary, withdrawing the product in question from the market to avoid these risks.'

Distributors (including wholesalers and retailers) 'are under a duty to assist in monitoring the safety of products placed on the market, by passing on information on product risks to their suppliers and to consumers, and to co-operate in action taken to avoid these risks.'[132]

In the assessment of requirements for general safety, and in the absence of specific rules, one is to be guided by relevant voluntary National Standards, which give effect to a European Standard, or other relevant European technical specifications. In their absence, any other relevant National Standards or codes of good practice, in respect of health and safety, are to be followed, including standards of safety, which consumers are reasonably entitled to expect.[133]

[130] *Product Safety Act*, article 3(2).
[131] *Product Safety Act*, article 4(1).
[132] *Product Safety Act*, article 8.
[133] *Product Safety Act*, article 9(1).

Consumer rights are also protected in the ***Food Safety Act*** through prohibition of sale, 'to the prejudice of the purchaser', of food, which is not of 'the nature, substance or quality of the food demanded by the purchaser.'[134]

8. Safety at Work

13.24

The most significant cause of morbidity and mortality among young persons is related to accidents at work. These are however common at all ages where the occupation is particularly hazardous or involves the use of heavy machinery.

It is therefore very commendable to find the ***Occupational Health and Safety Authority Act*** stating that 'the protection of occupational health and safety is to be considered of public interest.'[135]

It is considered the moral duty of both employer and employee to ensure that the risks that one is exposed to are kept to the very minimum. The ***Occupational Health and Safety Authority Act*** enunciates a number of principles and duties in this respect.

a. Duties of employers

13.25

The duties of employers are specified in the ***Occupational Health and Safety Authority Act***. An employer has the duty 'to ensure the health and safety at all times of all persons who may be affected by the work being carried out for such employer.'[136] To note that this may be taken to include not only the worker himself but any third person who may be affected. 'The measures that need to be taken by an employer to prevent physical and psychological occupational ill-health, injury or death,' shall be based on:

(a) 'the avoidance of risk;
(b) the identification of hazards associated with work;
(c) the evaluation of those risks which cannot be avoided;
(d) the control at source of those risks which cannot be avoided;

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[134] *Food and Safety Act*, article 17(1).
[135] *Occupational Health and Safety Authority Act*, article 4(1).
[136] *Occupational Health and Safety Authority Act*, article 6(1).

(e) the taking of all the necessary measures to reduce risk as much as reasonably practicable, including the replacement of the hazardous by the non-hazardous or by the less hazardous;
(f) giving collective protective measures priority over individual protective measures;
(g) adapting the work to the worker, particularly in so far as the design of work places, the choice of work equipment and the choice of working and production methods are concerned, in particular with a view to alleviating monotonous work and work at a predetermined work-rate, and to reducing their effect on health;
(h) by adapting to technical progress in the interest of occupational health and safety; and
(i) by the development of a coherent overall prevention policy which covers technology, the organisation of work, working conditions, social relationships and the influence of factors related to the working environment.'[137]

In addition, an employer must provide 'such information, instruction, training and supervision as is required to ensure occupational health and safety.'[138] The employer is also obliged to ensure that a person is designated as the Workers' Health and Safety Representative, who is to be consulted on matters which relate to occupational health and safety.[139]

The protection of the health and safety of pregnant employees is ensured through the ***Protection of Maternity (Employment) Regulations***, Subsidiary Legislation 452.91, enacted in terms of the ***Employment and Industrial Relations Act***, which has been discussed in **Chapter 6: Pregnancy and the Family**.

b. Duties of employees

13.26

The duties of the worker are also emphasised. 'It shall be the duty of every worker to safeguard one's own health and safety and that of other persons who can be affected by reason of the work which

[137] *Occupational Health and Safety Authority Act*, article 6(2).
[138] *Occupational Health and Safety Authority Act*, article 6(3).
[139] *Occupational Health and Safety Authority Act*, article 6(4).

is carried out.'[140] 'It shall be the duty of every worker to co-operate with the employer and with the Health and Safety Representative or Representatives at the work place on all matters relating to health and safety.'[141]

'The workers' obligations in the field of occupational health and safety shall not affect the principle of the responsibility of the employer.'[142]

c. Duties of the Occupational Health and Safety Authority

13.27

Finally, it is the Occupational Health and Safety Authority, set up by the ***Occupational Health and Safety Authority Act,***[143] that has the responsibility for:

(a) ' ensuring that the physical, psychological and social well being of all workers in all work places are promoted and to ensure that they are safeguarded by whoever is so obliged to do'[144] and
(b) ensuring that the 'levels of occupational health and safety protection established by this Act and by regulations made under this Act are maintained.'[145]

It shall be the function of the Authority to:

(a) 'apply the provisions of this Act' and any of its ensuing regulations or orders;
(b) establish strategies for implementing the general national policy relating to occupational health and safety;
(c) 'advise the Minister regarding the making of regulations to promote, maintain and protect a high level of occupational health and safety;
(d) monitor compliance with relevant occupational health and safety legislation and to take enforcement action;

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[140] *Occupational Health and Safety Authority Act*, article 7(1).
[141] *Occupational Health and Safety Authority Act*, article 7(2).
[142] *Occupational Health and Safety Authority Act*, article 6(1).
[143] *Occupational Health and Safety Authority Act*, article 8(1).
[144] *Occupational Health and Safety Authority Act*, article 4(2).
[145] *Occupational Health and Safety Authority Act*, article 5.

(e) prepare regulations or Codes of Practice required to promote, maintain and protect a high level of occupational health and safety';
(f) promote dissemination of information on occupational health and safety and on prevention of injury, ill health or death;
(g) 'promote education and training on occupational health and safety, and emergency and first aid response at work';
(h) 'collate and analyse data and statistics'; the Authority may obtain 'information on any matter related to occupational health and safety' and this 'shall be deemed to have been given and received under the obligation of confidentiality';
(i) keep registers of hazardous work places, equipment or substances intended for use at work;
(j) investigate any matter concerning occupational health and safety, including any accident, injury, disease or death occurring due to any association with work, and investigate to ascertain the level of health and safety provided at any work place; assistance may be obtained from competent persons;
(k) 'promote and carry out scientific research aimed at better methods of preventing occupational ill health, injury, or death'; and
(l) 'keep registers of persons competent to give advice on matters related to occupational health and safety.'[146]

9. Safety at Sea

13.28
It is expected of an island-state like Malta to have extensive regulation relating to safety at sea and health on board a ship. Conditions of service of persons employed on Maltese ships and of Maltese citizens serving in foreign ships are governed by the ***Merchant Shipping Act.***[147] The Act states that 'no person shall be employed in any capacity in any Maltese ship unless there has been delivered to the master of the ship a certificate granted by a duly qualified medical practitioner certifying that the person is fit to be employed in that capacity.'[148]

[146] *Occupational Health and Safety Authority Act,* article 9(2)(h).
[147] *Merchant Shipping Act,* article 122C.
[148] *Merchant Shipping Act,* article 108. See also *Merchant Shipping (Medical Examinations) Regulations,* SL 234.24.

Among the regulations that can be made under this Act, are included 'the rights related thereto of persons employed in Maltese ships, securing safe working conditions, health and welfare for seafarers and apprentices employed in ships.'[149]

Moreover, the Minister may make regulations 'protecting the health of persons on board Maltese ships and requiring Maltese ships to carry such medicines, medical stores, equipment, facilities, appliances and books containing instructions and advice, as may be specified in these regulations, and the regulations may make different provisions for different descriptions of ships or different circumstances.'[150] The owner and master of every Maltese ship has the responsibility of ensuring that there are these facilities available on Maltese ships, otherwise 'the ship's certificate of registry, whether provisional or otherwise, may be suspended until the default has been remedied.'[151]

'It shall be the duty of the master to ensure that a ship with a total number of crew and passengers of one hundred persons or more engaged on an international voyage of more than three days, carries onboard as part of its safe manning a duly qualified medical practitioner responsible for the medical care of the persons on board.'[152]

13.29

Other safety features mentioned in this Act, which may be regulated by subsidiary legislation, include:

(a) 'the structural features of the ship;
(b) any machinery or equipment used on board;
(c) special safety measures on and below deck;
(d) any loading equipment;
(e) fire-fighting and fire prevention;
(f) any anchors, chains and lines;
(g) dangerous cargo and ballast';
(h) maintenance, inspection and testing of any equipment and conditions on its use;

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[149] *Merchant Shipping Act*, article 122C(2)(e).
[150] *Merchant Shipping Act*, article 152(1).
[151] *Merchant Shipping Act*, article 152(3).
[152] *Merchant Shipping (Safe Manning and Watchkeeping) Regulations*, SL 234.31, regulation 9.

(i) use of any material or process;
(j) provision and use of any protective clothing or equipment; and
(k) limitation on the hours of employment of masters, seamen and apprentices in any specified operation or in any specified circumstances.[153]

In fact there are regulations relating to appropriate training of seamen,[154] adequate crew accommodation, including hospital accommodation,[155] provision of medical supplies,[156] hours of work[157] and safe manning of ships.[158]

10. Responsibility for Maintaining Public Health

13.30
The Superintendent of Public Health is responsible for public health in Malta, with particular responsibility to:

(a) ensure that the provisions of the ***Public Health Act*** and of its related regulations are complied with;
(b) 'develop and implement strategies to promote and improve public health;
(c) issue standards for public health;
(d) advise the Minister on matters regarding public health in general and on matters relating to this Act in particular;
(e) carry out any other function assigned to him by this Act or any other law; and
(f) perform any other act which may be necessary or conducive to the better performance of the functions and responsibilities assigned to him by this Act.'[159]

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[153] *Merchant Shipping Act*, article 153.
[154] *Merchant Shipping (Training and Certification) Regulations*, SL 234.17.
[155] *Merchant Shipping (Crew Accomodation) Regulations*, SL 234.39, regulation 8 specifies that a ship 'carrying a crew of fifteen or more and engaged in a voyage of more than three days' duration, shall be provided with separate hospital accommodation.' Ships engaged in coastal trade may be exempted.
[156] *Medical Stores Regulations*, SL 234.05.
[157] *Merchant Shipping (Hours of Work) Regulations*, SL 234.27.
[158] *Merchant Shipping (Safe Manning and Watchkeeping) Regulations*, SL 234.31.
[159] *Public Health Act*, article 4.

The Superintendent may 'delegate any of his powers under this Act to any person' or entity or to a combination and these are to 'be subject to any direction by the Superintendent who may, at any time, revoke it.'[160]

13.31

The Department of Health has the specific obligation to ensure that all the structures relevant to the provision of medical services to guarantee public health, are in place. The ***Department of Health (Constitution) Ordinance*** has several provisions relating to administrative matters. It establishes the various officers within the Health Department. These include:[161]

(a) the Principal Medical Officers, all other Medical Officers and other staff of the hospitals and establishments forming part of the Department of Health;
(b) the School Medical Officers, the School Dental Surgeons, the Child Health Officers and the Port Medical Officers;
(c) the Senior Public Health Laboratory Officer, the pathologists, the bacteriologists and the analysts and other laboratory staff;
(d) the Sanitary Engineering Officer, the Health Inspectors, the Dental Hygienists, the Midwives, the Health Visitors and the Nurses; and
(e) such other officers as the Prime Minister may appoint from time to time.'

This Ordinance also establishes a Council of Health[162] consisting of Medical representation but also, importantly, lay representatives, including:

(a) a representative of a trade union representing industrial workers;
(b) two members with experience in human ecology, one of whom shall be a member of the teaching staff of the University of Malta; and
(c) an industrialist.

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[160] *Public Health Act*, article 5.

[161] *Department of Health (Constitution) Ordinance*, article 5. At present, there are several other categories of health care workers, including hospital based dental surgeons, pharmacists, members of the professions complimentary to medicine, e.g. radiographers and physiotherapists, and technical and administrative staff, who are covered by subarticles (b) and (e).

[162] *Department of Health (Constitution) Ordinance*, article 7.

13.32

The duties of the Council of Health are primarily to advice the Minister on any matter affecting public health in Malta.[163] It also may recommend 'any such measures, enquiries or scientific investigations as, in their opinion, are useful in the interests of the public health.'[164]

The ***Department of Health (Constitution) Ordinance*** also set up a General Services' Board among whose members are included, apart from medical officers, the Director of Public Works, the Senior Public Health Laboratory Officer, a representative of the Chamber of Architects and Civil Engineers and a lay person not in the service of the Government.[165] The duties of this Board[166] are in effect to supervise and ensure that the relevant Maltese legislation is being observed.

13.33

Other legislation, which relates to the protection of public health, apart from that which deals with health related issues, including food safety, animal welfare and plants, includes:

(a) The ***Constitution of Malta*** deals with the right to privacy of home and property as well as the right to freedom of worship, of expression, of assembly and of movement, but these are superceded by the interest of public health;[167]
(b) The ***Malta Communications Authority Act*** sets up an Authority, one of whose functions is the limitation of communication when necessary for 'the protection of public health';[168]
(c) The ***Malta Statistics Authority Act*** deals with matters in respect of which statistics may be collected, prepared and published. These include statistics relating to 'vital occurrences, morbidity, health and nutrition'.[169]

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[163] *Department of Health (Constitution) Ordinance,* article 10.
[164] *Department of Health (Constitution) Ordinance,* article 11(1).
[165] *Department of Health (Constitution) Ordinance,* article 44(1).
[166] *Department of Health (Constitution) Ordinance,* article 45.
[167] *Constitution of Malta,* articles 38, 40, 41, 42 and 44. See also Chapter 1: Human Dignity, Rights and Freedoms.
[168] *Malta Communications Authority Act,* article 4(1)(iv).
[169] *Malta Statistics Authority Act,* First Schedule.

Chapter 14

Societal Issues

For the greatest part of this book, the rights of the patients on the one hand, and the obligations of health professionals on the other, have been emphasised. However, it is worth pointing out that frequently, it is not the health professional that fails to live up to her or his obligations, but other members of the public themselves. An enormous amount of pain and harm results from the fact that some individuals are too happy to ignore the fact that their rights end where those of others begin. Taken to their extreme, these acts lead eventually to criminal activities.

There are a number of issues that relate to society as a whole, reflecting on decency and morals of society, which have not been covered in the previous pages. In this chapter, a number of such issues are brought together.

1. Civil Society in Malta

14.01

The concept of a 'civil society' that needs to be fostered and whose needs and ideas need to be known and met, is highlighted by the ***Malta Council for Economic and Social Development Act.*** Civil society is here interpreted to include 'all those organisations of persons established to seek the common good and whose main aims are neither to generate profits nor to seek executive power.'[1]

[1] *Malta Council for Economic and Social Development Act*, article 2.

This Act establishes the Malta Council for Economic and Social Development (MCESD) as a body corporate having a distinct legal personality. It is appointed by the Prime Minister and is 'composed of the following members:

(a) a chairperson who shall be appointed after consultation with the organisations referred to in paragraph (c);
(b) a deputy chairperson who shall be appointed by the Prime Minister from amongst members of the public service;
(c) nine persons nominated by representative national employers' and workers' organisations constituted bodies';
(d) 'four representatives of the Government, representing the Ministries responsible for Finance, Economic Services, Social Policy and European Union Affairs; and
(e) the Governor of the Central Bank of Malta, *ex officio*.'[2]

The Council appoints a Civil Society Committee, to be consulted on issues, which the Council may refer to it.[3] This committee is to be representative of Maltese civil society, and for this purpose, the membership is to contain the chairpersons of a number of organisations, namely:[4]

(a) the Local Councils Association;
(b) the National Youth Council;
(c) the National Council for the Elderly;
(d) the Consumers' Association;
(e) the National Commission Persons with Disability; and
(f) the National Commission for the Promotion of Equality (previously the Commission for the Advancement of Women).

In effect, the present Council is also represented by the chairpersons of the following associations:

Alliance of Pensioners Organisations;
Malta Federation of Professional Bodies;
National Council of Women; and
National Family Commission.[5]

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[2] *Malta Council for Economic and Social Development Act*, article 4(1).
[3] *Malta Council for Economic and Social Development Act*, article 6(1).
[4] *Malta Council for Economic and Social Development Act*, article 6(2).
[5] http://www.mcesd.org.mt

The function of the Council is as a consultative and advisory body to Government 'on issues relating to sustainable economic and social development,' providing 'a forum for consultation and social dialogue between social partners and, where necessary, with organisations of civil society.'[6]

The Council has to 'reconcile individual sectoral interests in order to achieve overriding national interests' and include consideration of 'the social implications of economic growth, including the need to achieve social inclusion in all its perspectives particularly equality between women and men in the mainstream of development, and the protection of the environment.'[7]

2. Equality Between Men and Women

14.02

The ***Constitution of Malta*** protects the equal rights of men and women. It states that: 'The State shall promote the equal right of men and women to enjoy all economic, social, cultural, civil and political rights and for this purpose shall take appropriate measures to eliminate all forms of discrimination between the sexes by any person, organisation or enterprise; the State shall in particular aim at ensuring that women workers enjoy equal rights and the same wages for the same work as men.'[8]

The ***Equality for Men and Women Act*** provides for the appointment of a National Commission for the Promotion of Equality for Men and Women,[9] whose functions include:[10]

(a) responsibility for relevant policies, and co-ordination between responsible agencies;
(b) identifying needs of persons who are disadvantaged by reason of their sex;
(c) monitoring the implementation of national policies with respect to the promotion of equality for men and women;
(d) working towards the elimination of discrimination between men and women;

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[6] *Malta Council for Economic and Social Development Act*, article 3.
[7] *Malta Council for Economic and Social Development Act*, article 5(2).
[8] *Constitution of Malta*, article 14.
[9] *Equality for Men and Women Act*, article 11.
[10] *Equality for Men and Women Act*, article 12.

(e) investigating complaints relating to contraventions of this Act; and
(f) providing assistance, where and as appropriate, to persons suffering from discrimination in enforcing their rights under this Act.

a. Sexual discrimination

Sexual discrimination is defined in the ***Equality for Men and Women Act*** as discrimination that is 'based on sex or because of family responsibilities and includes the treatment of a person in a less favourable manner than another person has been or would be treated on the grounds of sex or because of family responsibilities.'[11] It includes males and females irrespective of their age.[12]

Discrimination is presumed to be based on sex or because of family responsibilities where it involves:

(a) 'the giving of less favourable treatment, directly or indirectly, to men and women on the basis of their sex or because of family responsibilities;
(b) treating a woman less favourably for reasons of actual or potential pregnancy or childbirth;
(c) treating men and women less favourably on the basis of parenthood, family responsibility or for some other reason related to sex;
(d) any treatment based on a provision, criterion or practice which disadvantages a substantially higher proportion of members of one sex unless that provision, criterion or practice is appropriate and necessary and can be justified by objective factors unrelated to sex.'[13]

14.03
However, 'positive discrimination' is not prohibited by this Act. It is not considered discriminatory to:

[11] *Equality for Men and Women Act*, article 2(1).
[12] *Equality for Men and Women Act*, article 2(2).
[13] *Equality for Men and Women Act*, article 2(3).

(a) grant special protection to women during childbirth or pregnancy; or
(b) take measures of positive action for the purpose of achieving substantive equality for men and women.[14]

It is interesting to note that the Act is careful not to interpret restricted access to the priesthood or membership of a religious order, or community, as being contrary to equality of the sexes under this Act.[15]

(a) Employment

With regards to employment, discriminatory treatment is dealt with in the ***Employment and Industrial Relations Act,*** which emphasises that when advertising employment opportunities, selecting applicants or offering employment, it is unlawful to subject applicants to discriminatory treatment; it is also an offence to subject any employee to discriminatory treatment, in regard to conditions of employment.[16] 'Offering employment' includes 'recruitment or training of any person with a view to engagement in employment' and for employees, includes also 'promotion to a higher grade or engagement in a different class of employment.'[17] The Act specifically indicates that discriminatory treatment includes 'the engaging or selection of a person who is less qualified than a person of the opposite sex, unless the employer can prove that the action was based on acceptable grounds related to the nature of the work or on grounds related to previous work performance and experience.'[18]

The ***Equality for Men and Women Act,*** restates that it is discriminatory to 'publish or display or cause to be published or displayed any advertisement, or, otherwise to advertise a vacancy for employment which discriminates between job seekers' and further specifies that it is unlawful 'to request from job seekers information concerning their private life or family plans,' except when the particular work can be done only by a person of a specific sex.[19]

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[14] *Equality for Men and Women Act,* article 2(4).
[15] *Equality for Men and Women Act,* article 3.
[16] *Employment and Industrial Relations Act,* article 26(1).
[17] *Employment and Industrial Relations Act,* article 26(4).
[18] *Employment and Industrial Relations Act,* article 26(2).
[19] *Equality for Men and Women Act,* article 10(1).

Moreover 'employees in the same class of employment are entitled to the same rate of remuneration for work of equal value.'[20] This is again reiterated in the ***Equality for Men and Women Act,*** which states that it is 'unlawful for employers to discriminate, directly or indirectly, against a person in the arrangements made to determine or in determining who should be offered employment or in the terms and conditions on which the employment is offered or in the determination of who should be dismissed from employment.'[21]

14.04

It furthermore includes as discrimination the following:

(a) when employers 'arrange the working conditions in a manner that employees are assigned a less favourable status than others on the basis of sex or because of family responsibilities'; or
(b) 'alter the working conditions, or the terms of employment of employees to the detriment of such employees' after they have invoked any right accorded to them under this Act; and
(c) 'neglect their obligation to suppress sexual harassment.'[22]

It is interesting to note that this Act also mentions the situation of spouses working with a self-employed partner, when they are not employees or partners. It states that when performing the same work as their spouses or ancillary tasks related thereto, such spouse should 'be entitled to receive from their spouse a fair compensation for their activity, commensurate to the value of their contribution.'[23]

(b) Sexual harassment

14.05

Sexual harassment, as mentioned already, is an ever present preoccupation. As stated in the ***Equality for Men and Women Act,*** it is unlawful to sexually harass another person.[24] In the ***Employment***

[20] *Employment and Industrial Relations Act,* article 27.
[21] *Equality for Men and Women Act,* article 4(1).
[22] *Equality for Men and Women Act,* article 4(2).
[23] *Equality for Men and Women Act,* article 7(1).
[24] *Equality for Men and Women Act,* article 9(1).

and Industrial Relations Act, this statement already existed in terms of the duty of the employer and employee towards one another.[25] Sexual harassment is defined to mean:

(a) 'to subject other persons to an act of physical intimacy; or
(b) to request sexual favours from other persons; or
(c) to subject other persons to any act or conduct with sexual connotations, including spoken words, gestures or the production, display or circulation of any written words, pictures or other material, where the act, words or conduct is unwelcome to the persons to whom they are directed and could reasonably be regarded as offensive, humiliating or intimidating to the persons to whom they are directed; or
(d) the persons so subjected or requested are treated less favourably (when) by reason of such persons' rejection of or submission to such subjection or request, it could reasonably be anticipated that such persons would be so treated.'[26]

Penalties for persons who sexually harass other persons are a fine *(multa)* of not more than one thousand liri or imprisonment of not more than six months or both such fine and imprisonment.[27] This emphasises the seriousness with which legislation looks on this aspect of human conduct, which has often in the past been taken as a past-time.

Moreover 'persons responsible for any work place, educational establishment or entity providing vocational training or guidance or for any establishment at which goods, services or accommodation facilities are offered to the public,' are obliged to take 'such steps as are reasonably practicable to prevent' sexual harassment to any employee, trainee, student or client.[28]

An employee who alleges sexual discrimination or harassment by an employer, may lodge a complaint with the Industrial Tribunal[29] which is bound to ensure any discriminatory practices

[25] *Employment and Industrial Relations Act*, article 29(1).
[26] *Equality for Men and Women Act*, article 9(1). The same definition is to be found in almost the same wording in the *Employment and Industrial Relations Act*, article 29(2).
[27] *Equality for Men and Women Act*, article 9(3).
[28] *Equality for Men and Women Act*, article 9(2).
[29] *Employment and Industrial Relations Act*, article 30.

related to work are eliminated. The complainant also has 'a right of action before the competent court of civil jurisdiction requesting the court to order the defendant to desist from such unlawful acts and, where applicable, to order the payment of compensation for such damage suffered through such unlawful act.'[30] Complaints may also be investigated by the National Commission for the Promotion of Equality for Men and Women, and the Commission may refer a case to the Industrial Tribunal or to the competent civil court.

(c) Education and training

14.06

In relation to education and training, the ***Equality for Men and Women Act*** specifies that there should be no discrimination in following any course or vocational training, or awarding of educational support, implementation of curricula or assessment of students' skills and knowledge.[31] It is also incumbent on those responsible for educational establishments to ensure that 'curricula and textbooks do not propagate discrimination'[32] and to suppress sexual harassment.[33]

(d) *De facto* relationships

14.07

The law speaks of *de facto* separations but not of de facto stable relationships. The ***Social Security Act*** speaks of situations where 'the husband and wife are separated *de jure* or *de facto*.'[34]

However, it accepts *de facto* relationships (without explicitly stating so) in relation to children's allowance. It states that for the purpose of this Act, 'wife' shall include 'such woman who, in the opinion of the Director, is living with the head of the household as if she were his lawful wedded wife.'[35] The reverse also holds.

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[30] *Equality for Men and Women Act*, article 19(1).
[31] *Equality for Men and Women Act*, article 8.
[32] *Equality for Men and Women Act*, article 8(3).
[33] *Equality for Men and Women Act*, article 8(2) and 9(2).
[34] *Social Security Act*, article 82(3).
[35] *Social Security Act*, article 82(2).

De facto relationships are also considered in terms of calculating the means of a couple in terms of receiving an Age Pension[36] or a Disability Pension[37] and of calculating the means of a man, paying maintenance to his wife, even though the separation is *de facto*.[38]

3. Discriminatory Legislation

14.08

There are still remnants of older legislation in Maltese law that discriminates between sexes. For instance in the following examples, (a) to (d) discriminate against women while (f) to (g) discriminate against men:

(a) *Pensionable Age*: 'a child shall be deemed to cease to be of a pensionable age within the meaning of this Act, if a male, on attaining the age of eighteen years or dying under that age, and if a female, on attaining the age of twenty-one years or marrying or dying under that age';[39]

(b) *Widows' Pensions*: notification necessary, in writing, by the widow of a married contributor, relating to the marriage of any female child under the age of twenty-one;[40]

(c) *Curator ad Ventrem*: If the husband of a pregnant woman dies, 'the court may, upon the demand of any person interested, appoint a *curator ad ventrem* with a view to preventing any supposition of birth, or substitution of child, and administering the property up to the day of the birth, under such directions as the court may deem it proper to give.'[41] Moreover the court may appoint a female as *curatrix*, but may entrust the administration of the property to another person;[42]

(d) *Married Woman's Name*: an application by a married woman often needs to bear the husband's name and details, for instance, the ***Public Registry Act*** states that applications for certificates of the registrations of causes of preference respecting debtors

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[36] *Social Security Act*, Second Schedule, Part IV, article 4.
[37] *Social Security Act*, Second Schedule, Part V, article 4.
[38] *Social Security Act*, Second Schedule, Part IV, article 5 and Part V, article 5.
[39] *Widows' and Orphans' Pensions Act*, article 2.
[40] *Widows' and Orphans' Pensions Act*, article 13(4).
[41] *Civil Code*, article 170(1).
[42] *Civil Code*, article 170(2).

must 'in the case of a married woman, [provide] the name and surname of her husband and the date of her marriage';[43]

(e) *Pension Schemes*: the age for women is set below that of men, e.g. the ***Malta Dockyard Act*** stated that the early retirement scheme was open to 'every employee of the Malta Drydocks who will have attained the age of 56 years in the case of a man and the age of 55 in the case of a woman.'[44] For the purpose of pensions the respective dates are 61 for males and 60 for women.[45] Whether earlier retirement is a benefit or a discrimination depends on the individual circumstances;

(f) *Fees paid to witnesses before a superior court*: 'male witnesses under 18 years of age and female witnesses, whatever their age, unless engaged in a profession or business' are entitled to the same fee category; this is discriminatory to unemployed males over 18 years, who are thus not entitled to any fee;[46]

(g) *Adoption*: an adoption decree shall not be made in respect of a female in favour of a sole applicant who is a male, unless the court is satisfied that there are special circumstances which justify as an exceptional measure the making of an adoption decree.[47]

4. Violence

14.09

The capacity to inflict pain is innate in most of us, but mercifully normally kept under control. In some instances this bursts to the surface.

It is also understandable that those situations which present a weaker person in close proximity to, or in a dependent relationship to, a stronger one, are precisely those situations where the opportunity to inflict pain and harm are most common; hence the epidemic of domestic violence.

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[41] *Civil Code*, article 170(1).
[42] *Civil Code*, article 170(2).
[43] *Public Registry Act*, article 26(2).
[44] *Malta Dockyard Act*, Schedule, rule 5(a). This Act is now repealed.
[45] *Social Security Act*, article 2.
[46] *Witnesses (Fees) Ordinance*, Schedule A.
[47] *Civil Code*, article 115 (2)(b).

a. Domestic violence

There is currently a new Act, not yet in force, entitled the ***Domestic Violence Act,*** to make special provisions for domestic violence, with relevant amendments to the ***Criminal Code*** and the ***Civil Code.***[48]

The Act defines 'domestic violence' as 'any act of violence, even if only verbal, perpetrated by a household member upon another household member and includes any omission which causes physical or moral harm to the other; 'household member' includes:

(i) persons married or formerly married to each other;
(ii) persons living in the same household as the offender or who had lived with the offender within a period of one year preceding the offence;
(iii) persons whose marriage has been dissolved or declared null;
(iv) parents and their children;
(v) other adults sharing the same household;
(vi) persons who are, or have been, formally or informally engaged with a view to get married;
(vii) persons who are related to each other either by consanguinity or affinity up to the third degree inclusively;
(viii) persons having or having had a child in common.
(ix) the child conceived but yet unborn of any one of the persons mentioned in paragraphs (i) to (viii), both inclusive.[49]

The Act provides for the establishment of a Commission on Domestic Violence, appointed by the Minister responsible for Social Policy, after consulting 'public and private agencies or entities involved in the research, prevention and treatment of domestic violence.'[50] The functions of the Commission are to advise 'the Minister on all aspects of domestic violence' and in particular on:

(a) 'increasing the awareness and understanding of domestic violence and harassment and their consequences and on ways and means to reduce their incidence';

[48] *Domestic Violence Act,* published as a bill in the Government Gazette of Malta No. 17,766 on 13th May, 2005 and enacted as Act XX of 2005 on 16th December 2005.
[49] *Domestic Violence Act,* article 2.
[50] *Domestic Violence Act,* article 3.

(b) developing a comprehensive plan for a multi disciplinary approach, with respect to victims and perpetrators, of prevention, exposure of violence and early intervention;
(c) procedures for effective co-ordination on a national level of the activities of public and private agencies and entities engaged in relevant services;
(d) communication, consulting and networking with relevant national and international entities;
(e) collection of data in a manner that protects the identity of victims;
(f) areas on which research is necessary or desirable;
(g) standards for care facilities for victims and perpetrators;
(h) specialized training for professional groups;
(i) standards and protocols for practitioners; and
(j) educating the public.[51]

The Minister shall designate one or more bodies 'as the agency responsible for the provision of preventive, therapeutic and, or treatment programmes for victims and perpetrators of domestic violence'[52] and shall also make funds available.[53] Services are to include 'public help-line facilities for emergency access to specialised support services,' sheltered accommodation for victims, 'compilation and dissemination' of documentation on the rights of victims and on services available and collation of data 'for use by the Courts, prosecutors, law enforcement officers, health care practitioners, social workers and other agencies and entities, in a manner that protects the identity of victims.'[54]

The Act amends the ***Criminal Code*** to make it lawful for the Police to institute proceedings without the complaint of the private party in 'the case of any offence involving domestic violence.' An alleged victim may 'request the court to stay proceedings against the alleged perpetrator' but the court may decide to continue proceedings, 'giving particular consideration to the best interests of any minors involved.'[55]

[51] *Domestic Violence Act*, article 4.
[52] *Domestic Violence Act*, article 9(1).
[53] *Domestic Violence Act*, article 9(4).
[54] *Domestic Violence Act*, article 9(3).
[55] *Domestic Violence Act*, article 20, to introduce subarticle 543(e) in the *Criminal Code*.

Moreover where a crime, which usually requires a complaint for criminal proceedings, is accompanied 'with public violence, domestic violence as defined in article 2 of the ***Domestic Violence Act***, or with any other offence affecting public order, criminal action shall be taken independently of the complaint of the private party.'[56]

Violence committed on household members, as already defined, will be an aggravating circumstance in terms of punishment for illegal detention and crimes against morals, and in the latter case, another aggravating circumstance is 'when the crime is committed in the presence of, or within hearing distance of a minor.'[57] Similarly it becomes an aggravating circumstance for offences of grievous bodily harm.[58]

It will also be an offence to knowingly pursue a course of conduct which 'amounts to harassment of another person'[59] or which 'causes another to fear that violence will be used against him or his property' or against that of any of his household,[60] unless such conduct is allowed in law or is necessary for the protection of a person or property. Harassing a person includes 'alarming the person or causing the person distress.'

The Court of Magistrates will be empowered to 'issue a protection order against the accused' to provide for the safety or protection from harassment of the injured person or other individuals. This order 'may impose any restrictions or prohibitions on the accused' including access to persons and premises, taking into consideration the welfare of any children or any dependants and the accused's willingness to submit to treatment.[61] The court may also make a treatment order, requiring consent from an accused but not from a convicted person.[62]

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[56] *Domestic Violence Act*, article 21, to amend article 544 of the *Criminal Code*.

[57] *Domestic Violence Act*, articles 10 and 11, to amend articles 87 and 202 respectively of the *Criminal Code*.

[58] *Domestic Violence Act*, article 13, to amend article 222 of the *Criminal Code*.

[59] *Domestic Violence Act*, article 15, to introduce article 251A of the *Criminal Code*.

[60] *Domestic Violence Act*, article 15, to introduce article 251B of the *Criminal Code*.

[61] *Domestic Violence Act*, article 19, to introduce article 412C of the *Criminal Code*.

[62] *Domestic Violence Act*, article 19, to introduce article 412D of the *Criminal Code*.

As regards amendments to the ***Civil Code***, in the case of personal separation, when domestic violence is involved, the court will also be able to, on its own motion, issue a protection order and, or, a treatment order, either before proceedings commence and a demand for consideration of maintenance is made[63] or during actual proceedings.[64]

b. Elderly abuse

Another situation where violence is likely to be inflicted is in situations of long-term hospitalisation, particularly involving the weaker members of society, namely the elderly and the mentally impaired. There are many reports that human rights have been ignored in such situations. However carnal knowledge and indecent assault are presumed to be accompanied by violence when the person abused was unable to offer resistance owing to physical or mental infirmity.[65] These aspects have been discussed in the corresponding chapters.

c. Abuse by persons in authority

14.10

Finally, and perhaps the most widespread, is the overzealous application of control by those in authority. Taken to its extreme this is associated with torture and other forms of violence.[66] The ***Criminal Code*** states that it is an offence for a public officer or any person acting in an official capacity to unlawfully inflict severe pain or suffering, physical or mental, for any of the following reasons:[67]

(a) to obtain information or confession from the individual or a third person;
(b) as punishment for an act committed, or on suspicion of an act having been committed either by the individual or a third person;

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[63] *Domestic Violence Act*, article 22, to substitute article 37(2) of the *Civil Code*.
[64] *Domestic Violence Act*, article 23, to introduce article 39 of the *Criminal Code*.
[65] *Criminal Code*, article 201.
[66] For a useful discussion of these issues see: British Medical Association: *The Medical Profession & Human Rights: Handbook for a changing agenda*. Zed. Books, 2001.
[67] *Criminal Code*, article 139A.

(c) for the purpose of intimidation or coercion of the individual or a third person; and
(d) for any reason based on discrimination of any kind.

(a) Interrogation of arrested persons

The ***Police Act*** empowers the Minister to issue a Code of Practice for the Interrogation of Arrested Persons[68] and this refers to the prohibition of all kinds of oppression during interrogation, stating that 'any form of behaviour which may amount to inhuman or degrading treatment, or any form of physical or mental torture is not only prohibited but amounts to an offence under article 139A of the ***Criminal Code***.'[69] Moreover the police are also to ensure that 'no action be committed which may even give rise to allegations of ill-treatment.' Specific guidelines are given:

(a) the person interrogated should be seated;
(b) foul language, threats, deprecatory laughter and menacing gestures are forbidden;
(c) weapons must not be exhibited to the detained person, unless connected with the investigation; and
(d) the person being questioned is not to be bound by any rope, chain or other shackle, but may be handcuffed if necessary for his/her own safety or that of others or to prevent escape.[70]

In the case of persons under the influence of drugs, alcohol, medicine, or who are in a state of shock, 'precautions should be taken to ensure that the statement is made by them when they are able to appreciate the significance of the questions and their answers, and that the statement is not the result of undue influence by the interviewing officer.'[71]

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[68] *Police Act*, article 66.
[69] *Police Act*, Fourth Schedule, Code of Practice for Interrogation for Arrested Persons, rule 16.
[70] *Police Act*, Fourth Schedule, Code of Practice for Interrogation for Arrested Persons, rule 16.
[71] *Police Act*, Fourth Schedule, Code of Practuce for Interrogation for Arrested Persons, rule 17(c).

(b) Solitary and cellular confinement

14.11

Solitary confinement is defined in the ***Criminal Code***, which states that 'the punishment of solitary confinement is carried into effect by keeping the person sentenced to imprisonment, during one or more terms in the course of any such punishment, continuously shut up in the appointed place within the prison, without permitting any other person, not employed on duty nor specially authorized by the Minister responsible for the prisons, to have access to him.'[72]

Such punishment is applied in the cases prescribed by law.[73] The term of solitary confinement should not exceed ten continuous days[74] and another term may only be applied after an interval of two months.[75] When the law does not specify terms, it is unlawful to inflict more than twelve terms of solitary confinement.[76] A medical examination may be necessary to ensure that the convicted person is fit to undergo solitary confinement and where 'the medical officer of the prison certifies in writing that the prisoner is no longer fit to undergo such punishment, the execution of that punishment shall be suspended until such time as the prisoner is again certified to be medically fit to undergo such punishment.'[78]

Subsidiary legislation, the ***Prisons Regulations***, regulates 'cellular' confinement, and in particular this must be 'undergone in a cell which meets the standards of these regulations.'[79] Cellular confinement is a disciplinary measure meted out by the Director of Prisons and as such includes terms of solitary confinement, in total not exceeding fifteen days, applied, 'in case of any infringement of the prison regulations' in the two month interval between the terms of solitary confinement, prescribed by law under the ***Criminal Code***.[80]

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[72] *Criminal Code*, article 9(1).
[73] *Criminal Code*, article 9(6).
[74] *Criminal Code*, article 9(2).
[75] *Criminal Code*, article 9(3). For exceptions in case of disciplinary measures, see below.
[76] *Criminal Code*, article 9(5).
[77] *Criminal Code*, article 9(7).
[78] *Criminal Code*, article 9(8).
[79] *Prisons Regulations*, SL 260.03, regulation 82(1).
[80] *Prisons Regulations*, SL 260.03, regulation 2(2) which refers to the *Criminal Code*, article 9(4).

The prisoner has the right to 'petition a review of the disciplinary case to the Appeals Tribunal' when the punishment exceeds six days.[81] The Medical officer is responsible for monitoring the condition of prisoners undergoing this punishment and 'shall advise the Director if the termination or alteration of the relative punishment is considered necessary on grounds of physical or mental health.'[82] 'It shall also be the duty of the Medical Officer to monitor the condition of any prisoner sentenced to solitary confinement by any court.'[83] This means that the doctor has the responsibility of ensuring that the prisoner's well being is safe guarded.

d. Intoxication and crime

14.12

Intoxication is a state of diminished mental capacity usually resulting from excessive alcohol consumption. The ***Criminal Code*** also includes in the definition 'a state produced by narcotics or drugs.'[84]

Intoxication is normally not a defence to a criminal charge.[85] However, it could be a defence if:

(a) the state of intoxication was caused without one's own consent 'by the malicious or negligent act of another person'; or
(b) the person charged was insane (temporarily or otherwise) by reason of the intoxication.[86] However to absolve the person from pleading to the indictment or standing trial, insanity needs to be determined by a jury.[87]

Intoxication is also considered when 'determining whether the person charged had formed any intention specific or otherwise, in the absence of which he would not be guilty of the offence.'[88]

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[81] *Prisons Regulations*, SL 260.03, regulation 80(1).
[82] *Prisons Regulations*, SL 260.03, regulation 82(2).
[83] *Prisons Regulations*, SL 260.03, regulation 82(3).
[84] *Criminal Code*, article 34(5).
[85] *Criminal Code*, article 34(1).
[86] *Criminal Code*, article 34(2).
[87] *Criminal Code*, article 620(1).
[88] *Criminal Code*, article 34(4).

e. Sexual offences

(a) Rape (Carnal knowledge with violence)

14.13

Rape is defined as a crime against the individual concerned, as well as against the peace and honour of families and against morals. The ***Criminal Code*** states that 'whosoever shall, by violence, have carnal knowledge of a person of either sex, shall, on conviction, be liable to imprisonment for a term from three to nine years, with or without solitary confinement.'[89]

There is presumption of violence in the case of carnal knowledge and any other indecent assault in the following situations:

(a) when committed on a person under the age of twelve years;
(b) when the abused person was unable to offer resistance due to physical or mental infirmity, or in consequence of any fraudulent device used by the offender.[90]

Aggravating circumstances include the situation where the offender:

(a) was a public officer, or an employee of the injured party;
(b) was a tutor of the victim, such person being under the age of eighteen years;
(c) was aided by one or more persons;
(d) made use of arms;
(e) caused any bodily harm to the victim or any other person providing assistance to the victim; and
(f) when 'the person carnally known has not completed the age of nine years';
(g) when the crime amounts to domestic violence; and
(h) 'when the crime is committed in the presence of, or within hearing distance of a minor.'[91]

[89] *Criminal Code*, article 198.
[90] *Criminal Code*, article 201.
[91] *Criminal Code*, article 202. Subarticles (g) and (h) were introduced through the *Domestic Violence Act*, not yet in force by 31st December 2005.

(b) Defilement of minors

14.14

Defilement of a minor of either sex by lewd acts is punishable with imprisonment for a term not exceeding three years, with or without solitary confinement.[92] Aggravating circumstances include:

(a) offence committed on a person below age of twelve years, or with violence;
(b) offence committed by means of threats or deceit;
(c) offence committed by a relative or adoptive parent, or tutor or educator or carer.

To note that proceedings are instituted only on the complaint of the injured party, normally within a year from the day on which the act was committed or from when the person entitled to lodge the complaint gets to know about it. However proceedings can be instituted *ex officio* if the offence is 'committed with abuse of parental authority or of tutorship' or, as provided in article 544, it is accompanied with public violence, domestic violence 'or with any other offence affecting public order.'[93]

Other articles extend the scope of these articles to anyone who 'instigates, encourages or facilitates the defilement of a minor of either sex,'[94] and specifically to anyone who 'in order to gratify the lust of any other person induces a person under age to practise prostitution, or instigates the defilement of such person, or encourages or facilitates the prostitution or defilement of such person.'[95] Aggravating circumstances include the victim being below the age of twelve years, or when the offence is committed by deceit, or by a person who is related by consanguinity or affinity, or by an adopting parent, or tutor of the minor, or if the offence is committed habitually or for gain.

Any 'violent indecent assault, which does not, in itself, constitute any of the crimes, either completed or attempted,' referred to in this sub title on sexual offences, is also an offence.[96]

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[92] *Criminal Code*, article 203.
[93] *Criminal Code*, article 203(3) and article 544.
[94] *Criminal Code*, article 203A.
[95] *Criminal Code*, article 204 (1).
[96] *Criminal Code*, article 207.

(c) Abduction

Abduction by violence is considered a crime, whether it is done with intent to abuse or to marry such a person. It is also a crime to abduct a person under the age of eighteen years, 'by fraud or seduction.'[97] Punishment is less severe in the case where the offender releases the person abducted within twenty-four hours. In such a case, if the offender marries the abducted person, and there is no complaint from the party concerned, then there is no liability to prosecution.[98]

f. Homicide and bodily harm

14.15

Wilful homicide: A definition of homicide is given in the ***Criminal Code***, where it states that 'a person shall be guilty of wilful homicide if, maliciously, with intent to kill another person or to put the life of such other person in manifest jeopardy, he causes the death of such other person.'[99] The penalty for this is imprisonment for life.[100]

These penalties also hold where the offender did not intend to cause the death of any particular person, or where the offender kills a person other than the intended victim.[101]

However wilful homicide is excusable, with corresponding lower punishments, when it is committed by a person:

(a) 'provoked by a grievous bodily harm, or by any crime whatsoever against the person, punishable with more than one year's imprisonment';
(b) 'repelling, during the daytime, the scaling or breaking of enclosures, walls, or the entrance of any house or inhabited apartment';
(c) 'acting under the first transport of a sudden passion or mental excitement in consequence of which he is, in the act of committing the crime, incapable of reflecting'; it is assumed that there is no 'deliberate intention to kill or to cause a serious injury to the person,' when 'the cause be such as would, in persons of ordinary temperament, commonly produce the effect of rendering them incapable of reflecting on the consequences of the crime';

[97] *Criminal Code*, article 199.
[98] *Criminal Code*, article 200.
[99] *Criminal Code*, article 211(2).
[100] *Criminal Code*, article 211(1).
[101] *Criminal Code*, article 212.

(d) who exceeds the limits imposed by law, by the authority, or by necessity, in cases of justifiable homicide or bodily harm; 'any such excess shall not be liable to punishment if it is due to the person being taken unawares, or to fear or fright.'[102]

Involuntary Homicide: This refers to the situation where death occurs unintentionally and carelessly as for instance where a person dies on the operating table, or following a traffic accident. The ***Criminal Code*** states that 'whosoever, through imprudence, carelessness, unskilfulness in his art or profession, or non-observance of regulations, causes the death of any person, shall, on conviction, be liable to imprisonment for a term not exceeding four years or to a fine (*multa*) not exceeding five thousand liri.'[103]

When the harm that can ensue from any of the above conditions is short of death, this is considered as *involuntary bodily harm* and punishments are less than those of corresponding severity of bodily harm caused voluntarily.

Justifiable Homicide: This term covers homicide ordered or permitted by law or in 'self-defence or in the lawful defence of another person.'[104] This includes defending oneself against a break in, at night, of an apartment, or a theft with violence, or in 'the defence of one's own chastity or of the chastity of another person.'[105]

Bodily harm: The ***Criminal Code*** defines bodily harm as occurring when, though there is no 'intent to kill or to put the life of any person in manifest jeopardy,' harm ensues 'to the body or health of another person' or there is causation of 'mental derangement'.[106] A bodily harm may be either grievous or slight.[107] Moreover *grievous bodily harm* also has degrees, the gravest being when:

[102] *Criminal Code*, article 227.
[103] *Criminal Code*, article 225.
[104] *Criminal Code*, article 223.
[105] *Criminal Code*, article 224.
[106] *Criminal Code*, article 214.
[107] *Criminal Code*, article 215.

(a) it produces permanent debility of health or permanent functional debility of any organ of the body, or any permanent defect in the body or any permanent mental infirmity;
(b) 'it causes any serious and permanent disfigurement of the face, neck, or either of the hands of the person injured;
(c) if, being committed on a woman with child, it causes miscarriage.'[108]

However *grievous bodily harm* is less serious:

(a) if it can give rise to the danger of dying or to the danger of permanent debility of health, permanent functional organ debility, permanent mental infirmity or permanent physical defect;
(b) if it causes deformity or disfigurement in the face, neck, or either of the hands;
(c) 'if it is caused by any wound which penetrates into one of the cavities of the body, without producing any of the effects mentioned in article 218;
(d) if it causes any mental or physical infirmity lasting for a period of thirty days or more; or if the party injured is incapacitated, for a like period, from attending to his occupation;
(e) if, being committed on a woman with child, it hastens delivery.'[109]

Slight bodily harm is harm that does not have the effects already mentioned.

Suicide: Suicide or attempting to commit suicide is not a crime in Malta. On the other hand, inciting or helping others to commit suicide is a crime, as mentioned earlier. The ***Criminal Code*** states that 'whosoever shall prevail on any person to commit suicide or shall give him any assistance, shall, if the suicide takes place, be liable, on conviction, to imprisonment for a term not exceeding twelve years.'[110]

[108] *Criminal Code*, article 218.
[109] *Criminal Code*, article 216.
[110] *Criminal Code*, article 213.

14.16

Euthanasia: There is no specific mention of this in local legislation. Even though it appears to be covered by the article on suicide, the concept of euthanasia is wider and encompasses the idea of a painless and easy death. Helping a person to commit suicide is a criminal offence.

g. Trafficking of persons

14.17

The ***Charter of Fundamental Rights of the European Union*** prohibits trafficking in human beings as part of the prohibition of slavery.[111] Recent additions to the ***Criminal Code*** reflect this and make it illegal to indulge in traffic involving persons. This is defined as 'the recruitment, transportation or transfer of a person' including 'harbouring and subsequent reception and exchange of control over that person' and includes 'any behaviour which facilitates the entry into, transit through, residence in or exit from the territory of any country for any of the purposes mentioned.'[112]

Trafficking can be for the purpose of:

(a) 'exploiting that person in the production of goods or provision of services' including work 'under conditions and in circumstances which infringe labour standards governing working conditions, salaries and health and safety';[113] or
(b) for the purpose of prostitution or pornography;[114] and
(c) for the purpose of exploitation in the removal of organs, for instance, for transplantation.[115]

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[111] *Charter of Fundamental Rights of the EU*, Article 5(3), Official Journal of the European Communities, 2000/C, 364/01, Article 5. This Article is incorporated in the Constitution for Europe as Article II-5 and moreover the Constitution envisages legal cooperation, including a common immigration policy to prevent and combat trafficking (Article III-68) and introduction of minimum rules for cross border crimes (Article III-172). There is also a proposal to formulate administrative regulations to control movement of capital in this regard (Article III-49).

[112] *Criminal Code*, article 248E(1).

[113] *Criminal Code*, article 248A(1).

[114] *Criminal Code*, article 248B.

[115] *Criminal Code*, article 248C.

The means used may include;

(a) 'violence or threats, including abduction;
(b) deceit or fraud;
(c) misuse of authority, influence or pressure;
(d) the giving or receiving of payments or benefits to achieve the consent of the person having control over another person.'[116]

Where a minor is involved, the punishments meted out are correspondingly more severe.[117] These offences are further aggravated, whatever the age of the victim, when accompanied by grievous bodily harm or when they generate proceeds in excess of five thousand liri, or are committed with the involvement of a criminal organisation.[118]

It is also an offence for 'any person who with the intent to make any gain whatsoever aids, assists, counsels or procures any other person' to enter or to leave Malta illegally.[119]

14.18

The ***Criminal Code*** considers enslavement as 'a crime against humanity' when it is 'part of a widespread or systematic attack directed against any civilian population.'[120] 'Enslavement' is defined as 'the exercise of any or all of the powers attaching to the right of ownership over a person and includes the exercise of such power in the course of trafficking in persons, in particular women and children.'[121] This is a crime within the jurisdiction of the International Criminal Court.[122]

h. Racism and racial violence

14.19

Racial hatred is defined as 'hatred against a group of persons in Malta defined by reference to colour, race, nationality (including

[116] *Criminal Code*, article 248A(2).
[117] *Criminal Code*, article 248D.
[118] *Criminal Code*, article 248E.
[119] *Criminal Code*, article 337A.
[120] *Criminal Code*, article 54C(1).
[121] *Criminal Code*, article 54C(2)(c).
[122] *International Criminal Court Act*, First Schedule, Article 7, paragraphs 1(c) and 2(c).

citizenship) or ethnic or national origins.'[123] Incitement to racial hatred is forbidden by the ***Criminal Code***, which states that 'whosoever uses any threatening, abusive or insulting words or behaviour, or displays any written or printed material which is threatening, abusive or insulting, or otherwise conducts himself in such a manner, with intent thereby to stir up racial hatred or whereby racial hatred is likely, having regard to all the circumstances, to be stirred up shall, on conviction, be liable to imprisonment for a term from six to eighteen months.'[124]

The ***Press Act*** also deals with this matter, stating that whosoever, 'shall threaten, insult, or expose to hatred, persecution or contempt, a person or group of persons because of their race, creed, colour, nationality, sex, disability as defined in article 2 of the ***Equal Opportunities (Persons with Disability) Act***, or national or ethnic origin shall be liable on conviction to imprisonment for a term not exceeding three months and to a fine *(multa)*.'[125]

5. Public Morals

14.20

Committing 'an offence against decency or morals, by any act committed in a public place or in a place exposed to the public' constitutes an offence liable to imprisonment up to three months plus a fine.[126] The concept of an offence against decency and morals in private has no meaning in Maltese law, unless it involves minors.

a. Pornography

The ***Criminal Code*** deals with offences relating to pornographic or obscene articles.[127] It provides that: 'Whosoever, for gain, or for distribution, or for display in a public place or in a place accessible to the public, manufactures, prints or otherwise makes, or introduces into Malta, or acquires, keeps, puts in circulation or exports, any pornographic or obscene print, painting, photograph, film, book,

[123] *Criminal Code*, article 82A(2).
[124] *Criminal Code*, article 82A(1).
[125] *Press Act*, article 6.
[126] *Criminal Code*, article 209.
[127] *Criminal Code*, article 208.

card or writing, or any other pornographic or obscene article whatsoever, whether similar to the above or not, shall, on conviction, be liable to imprisonment for a term not exceeding six months or to a fine.'[128] Trading in pornographic or obscene articles is specifically prohibited, even if this is clandestine.[129]

14.21

It is prohibited to possess pornographic material, in certain situations, namely:

(a) when this is 'for gain, or for distribution, or for display in a public place or in a place accessible to the public';[130] and
(b) when possessing the 'indecent photograph, film, video recording or electronic image of a minor,' irrespective of whether this is for gain or distribution.[131]

Relating to indecent photographs, films, etc. involving persons under age, the ***Criminal Code*** states that: 'Any citizen or permanent resident of Malta, whether in Malta or outside Malta, as well as any person in Malta, who takes or permits to be taken any indecent photograph, film, video recording or electronic image of a minor, or distributes or shows such indecent photograph, film, video recording or electronic image, or is in possession of such indecent photograph, film, or video recording or electronic image, shall, on conviction, be liable to imprisonment for a term not exceeding six months or to a fine (*multa*) not exceeding two hundred liri, or to both such imprisonment and fine.'[132] References to a photograph include the negative as well as the positive version.[133] The minor represented in the photograph, or other material, is deemed to be the person against whom the offence has been committed.[134]

In other words, the law does not purport to protect the individual him/herself from the ill-effects of pornography, unless the subject is a minor, but the general public. In fact, where offences involving minors are committed by relatives, or adoptive parents

[128] *Criminal Code*, article 208(1).
[129] *Criminal Code*, article 208(2).
[130] *Criminal Code*, article 208(1).
[131] *Criminal Code*, article 208A(1).
[132] *Criminal Code*, article 208A.
[133] *Criminal Code*, article 208A(6).
[134] *Criminal Code*, article 208A(5).

or tutors, or carers, or where the child is not yet nine years old, the punishment is more severe[135] and includes 'the forfeiture of every authority and right granted to the offender over the victim' and a tutor would be perpetually barred from tutorship.[136]

Material may be considered to be pornographic, when so defined by regulations.[137] The subsidiary legislation, ***Pornography and Obscenity Regulations***, enlarges further on this aspect. It states that an object or article is 'deemed to be pornographic or obscene if:

(a) its dominant characteristic is the exploitation of, or undue emphasis on, sex, or any one of the following subjects, namely, crime, horror, cruelty and violence; or
(b) it directly or indirectly advertises or gives information on any article considered to be pornographic or obscene under these Regulations.

Provided that an article shall not be considered to be pornographic or obscene to the extent that it serves the public good on the ground that it is in the interests of science, literature, art or learning or other objects of general concern.'[138]

The subsidiary legislation, ***Broadcasting Code for the Protection of Minors*** prohibits the broadcasting of material which 'might seriously impair the physical, mental or moral development of minors, and in particular they shall not include programmes that involve pornography or gratuitous violence.'[139]

14.22

All cinematographic work, including films for television and any creative audiovisual work, is to be granted a classification certificate in writing.[140] Every broadcaster has to appoint a person(s) to be responsible for the issue of the certificates.[141] The certificate is to

[135] *Criminal Code*, article 208A(3).
[136] *Criminal Code*, article 197(4).
[137] *Criminal Code*, article 208(3).
[138] *Pornography and Obscenity Regulations*, SL 9.05, regulation 3.
[139] *Broadcasting Code for the Protection of Minors*, SL 350.05, paragraph 3. See further below, under 'Advertising'.
[140] *Television Programmes (Classification Certificates) Regulations*, SL 350.01, regulation 3.
[141] *Television Programmes (Classification Certificates) Regulations*, SL 350.01, regulation 4.

indicate whether the work concerned is suitable for general viewing, including suitability for viewing by young children, with or without parental guidance, or suitable for viewing only after a stated time.[142]

The transmission by post of 'any postal article of any kind or form whatsoever which is pornographic or obscene' is prohibited.[143] The Malta Communications Authority may order that any postal article, apart from a closed letter, which is suspect, 'be detained and opened' and if it is proven that the provisions of the law were contravened, such 'article may be destroyed.' However audiovisual material for the purpose of its being broadcast on television, according to the provisions of the ***Broadcasting Act***, is delivered without further examination or censorship.[144]

The postal operator 'shall withhold delivery of any suspect postal article to the addressee' and shall inform the Authority by the next day.[145]

Regarding detained printed matter, the addressee may lodge an appeal to the Printed Matter Appeals Board,[146] showing cause why the printed matter does not represent pornographic material[147] and so should be delivered.

Similarly when the Comptroller of Customs suspects that 'any printed matter, including any newspaper, of a pornographic or obscene character has been imported into Malta,' the Comptroller 'may detain and open' and 'with the written authority of the Minister responsible for customs, destroy such printed matter,' subject to the provisions of the Second Schedule of the ***Postal Services Act***.[148]

b. Prostitution

14.23

Prostitution can be a health as well as a moral hazard. Historically, some of the worst epidemics of venereal disease (e.g. syphilis) were

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[142] *Television Programmes (Classification Certificates) Regulations*, SL 350.01, regulation 5(1).

[143] *Postal Services Act*, article 47(1) and (2)(e).

[144] *Postal Services Act*, article 48(1).

[145] *Postal Services Act*, article 48(4).

[146] *Postal Services Act*, article 49(1) and Second Schedule 4(1).

[147] *Postal Services Act*, Second Schedule 4(4).

[148] *Customs Ordinance*, article 82(3) and (4).

transmitted largely through prostitution. More recently, AIDS has become the major health problem where prostitution has played a very important part.

From an ethical point of view, prostitution represents a very serious threat to the autonomy and freedom of an individual who is often induced to such a way of life either through extreme poverty or often enough through enforcement which is akin to slavery.

Inducing a person of age to prostitution is illegal in Malta. The ***Criminal Code*** states that: 'Whosoever in order to gratify the lust of any other person, by the use of violence, compels or, by deceit, induces a person of age, to practise prostitution, shall, where the act committed does not constitute a more serious offence, be liable, on conviction, to imprisonment for a term not exceeding two years, with or without solitary confinement. Provided that the offence shall be punishable with imprisonment for a term from one to four years, if it is committed:

(a) with abuse of authority, of trust or of domestic relations; or
(b) habitually or for gain.'[149]

When a relative or spouse, 'by the use of violence or by threats, compels, or, by deceit, induces the descendant or his or her spouse, of age, to prostitution, he or she shall, on conviction, be liable to imprisonment of a term from one to four years, with or without solitary confinement.' This offender also forfeits 'every authority and right' over the victim's person or property.[150]

Similar offences against minors are covered in **Chapter 7: Children.**

The ***White Slave Traffic (Suppression) Ordinance*** refers to compelling or inducing a person who has attained the age of twenty-one years to leave Malta for purposes of prostitution. The penalty for this is imprisonment, with or without solitary confinement, for a period of up to two years. This punishment is increased if the offence is committed by a relative, by consanguinity or affinity, by means of abuse of authority or trust, or committed habitually or for gain.[151]

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[149] *Criminal Code*, article 205.
[150] *Criminal Code*, article 197(3) and (4).
[151] *White Slave Traffic (Suppression) Ordinance*, article 2.

Penalties for inducing someone under twenty-one years of age for the same purpose, are correspondingly more severe, with imprisonment for a term between eighteen months to four years. More severe punishment is liable when children are involved.[152]

A conviction includes 'the forfeiture of every authority and right granted to the offender over the person or property' of the victim, irrespective of age, and a tutor would be removed from tutorship and barred from ever holding such office.[153]

In the case of a person charged or accused with an offence against the provisions of the ***White Slave Traffic (Suppression) Ordinance***, the spouse may give evidence if such spouse 'is a person on whom or in respect of whom the offence is committed or is a person on the earnings of whose prostitution the party charged or accused has lived.'[154]

Trafficking for the purpose of exploiting that person in prostitution has already been discussed in the relevant section above.

6. Health and Lifestyle

14.24

It is a moot point as to where a line is to be drawn relating to the rights of an autonomous being to indulge in practices which are clearly a health hazard, including habits of eating, drinking and consuming drugs of addiction, or even indulging in dangerous sports and risky occupations, and on the other hand, the responsibilities of Governments to ensure that public health is not threatened by such actions. It may even be argued that services that are costly and in short supply should not be provided to those who so readily stretch such resources unnecessarily by pursuing unhealthy lifestyles.

Several aspects of the law are meant to provide norms for a healthier lifestyle, prevent disease and uphold morals in society. On the one hand this could be seen as a paternalistic approach, interfering with the autonomous right of an individual to do what one pleases as long as it does not interfere with the rights of others.

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[152] *White Slave Traffic (Suppression) Ordinance*, article 3. See also Chapter 7: Children.

[153] *White Slave Traffic (Suppression) Ordinance*, articles 2(2) and 3(2).

[154] *Criminal Code*, article 635(1).

On the other hand, many of these laws and regulations are seen as common-sense directives, which would appear to be necessary to regulate the normal workings of society, and which would appear to represent the minimum acceptable interference of legislation with regard to the individual's lifestyle.

14.25

It is relevant to distinguish three different situations where the legislator needs to interfere with the activities of citizens:

(a) firstly, laws which have obvious public health significance but which infringe, to a greater or lesser extent, on one's own personal activity, with a view to protect the general good. These include regulations relating to waste disposal, sewage, pollution, etc.;
(b) secondly there are those regulations which prohibit activities which may be a threat to the moral structure of society. For instance, distribution of pornographic material, inducement to prostitution, sale of drugs of addiction, etc. The purpose of these laws is to protect the potential recipients of these goods and services;
(c) thirdly, laws and regulations which tend to regulate an individual's behaviour. These include rules relating to use of drugs of addiction, alcohol regulation, smoking, etc. This is particularly the case when dealing with young people.

a. Drugs of addiction

14.26

Drug addiction is considered to be a social disease, promoted by criminals who provide the drugs to unsuspecting victims. Society believes that such criminals should be severely punished and the law reflects this attitude.

With regard to the use of drugs for pleasure and other social purposes, these drugs are more likely to be of danger to the person who takes them rather than to bystanders and the general public. The emphasis in legislation in this case is the control of illegal sale and provision of these drugs, as well as the protection of younger people and new recruits.

It is not clear to what extent society means to prevent an individual from indulging in some form of drug use. Moved by the

desire to help such individuals, a number of regulations affect the drug user. These include laws against having these drugs available, and punishing those caught in possession of them, even when it is for personal use. This would appear to smack of paternalism, however well intended it happens to be.

14.27

Maltese legislation requires that every drug addict is registered, and no medical practitioner is allowed to administer drugs to such a person prior to reporting the case to the Superintendent of Public Health.[155] To note also that a person who would otherwise be bound by professional secrecy may divulge information to 'a competent public authority,' in Malta or outside Malta, carrying out an investigation relating to drug offences but medical practitioners and the legal profession are still bound by secrecy, when the offences involve drugs regulated by the ***Dangerous Drugs Ordinance***, unless compelled by law to reveal such information.[156]

It is prohibited to manufacture, sell or distribute drugs of addiction without a licence[157] or in conformity with specific regulations.[158] It is also an offence to manufacture, transport or distribute any equipment or materials knowing that they are to be used in or for the cultivation, production or manufacture of any drug contrary to the provisions of the ***Dangerous Drugs Ordinance*** and any such conduct is considered as 'an offence of selling or dealing in a drug against this Ordinance.'[159] One who conspires for the 'purpose of selling or dealing in a drug' against the provisions of this Ordinance or 'who promotes, constitutes, organises or finances the conspiracy,' is guilty of an offence.[160]

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[155] *Registration of Drug Addicts Regulations*, SL 31.21, regulation 3(3).

[156] *Criminal Code*, article 257.

[157] *Dangerous Drugs Ordinance*, articles 9–11, with respect to dangerous drugs listed in the First Schedule. See also the *Medicines Act*, article 20(1), which prohibits the sale of medicinal products unless the seller is in possession of a marketing authorisation from the Licensing Authority, and article 65(a).

[158] *Medical and Kindred Professions Ordinance*, articles 40 and 40A, with respect to psychotropic drugs listed in the Third Schedule.

[159] *Dangerous Drugs Ordinance*, article 22(IE).

[160] *Dangerous Drugs Ordinance*, article 22(1)(f).

On conviction by the Criminal Court, the maximum penalty for dealing in drugs or for transfer of monies or property in connection with drug dealing, is imprisonment for life. When the case is heard by a Magistrate, the maximum penalty for dealing is ten years imprisonment and a fine of not more than five thousand liri. Reduction of sentences is envisaged for attenuating circumstances. Possession for one's own use, convicted in a Magistrate's Court is liable to three months to a year's imprisonment or/and a fine between two hundred and one thousand liri. The treatment of a drug addict may also be required by the court as part of a probation order or even whilst in prison.[161]

Any non resident person arriving in Malta, 'in possession of a drug against the provisions of this Ordinance shall be exempt from any criminal liability if' the person 'surrenders the said drug to a Police officer or to a customs officer and declares that the same drug was for his exclusive personal use' and if 'the said drug is in such a quantity and is in possession of that person under such circumstances as to reasonably lead to the inference that the same drug was destined for the exclusive personal use of that person.'[162] So personal use is not tolerated but given a lighter sentence than in the case used for trafficking.

Essentially the same legislation is to be found in relation to psychotropic drugs regulated by the ***Medical and Kindred Professions Ordinance***.[163] Legislation is in accordance with the European ***Agreement on Illicit Traffic by Sea***.[164]

b. Alcohol

14.28

Alcohol is well known to be a major contributor to health problems, as well as being a prime culprit in producing social problems, including malaise within the family with subsequent break-ups.

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[161] *Dangerous Drugs Ordinance*, article 22(8) and (10) and *Probation Act*, article 7(5).

[162] *Dangerous Drugs Ordinance*, article 22(IF) and (1G) and *Medical and Kindred Professions Ordinance*, article 120A(1F) and (1G).

[163] *Medical and Kindred Professions Ordinance*, articles 40A and 120A.

[164] *Dangerous Drugs Ordinance*, article 30E on *Agreement on Illicit Traffic by Sea implementing Article 17 of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Pyschotropic Substances*, done at Strasbourg on the 31st January, 1995.

Legislation cannot control the personal habits of an individual, but may regulate the use of alcohol and try to discourage excesses by ensuring that offenders who are a danger to the public are apprehended and punished.

The relevant legislation refers to the sale of alcoholic beverages, its advertising on the broadcasting media, and the traffic regulations relating to drink-driving.

14.29

The bulk of Maltese legislation appears to be concerned largely with duties involved in distilling, importing and distribution of alcohol rather than with its societal impact. The ***Broadcasting Act*** shows a greater degree of social responsibility, in that it prohibits misleading advertising or targeting of minors. (See further below, under 'Advertising'.) Infringement of personal rights may be perceived when one is deprived of liberty on being found drunk and disorderly, or in being requested to provide bodily samples for analysis on being suspected of drink-driving.

The following legislation is relevant:

(a) *Manufacture*:
   (i) distilling of spirits is prohibited without the possession of a licence[165] with liability to a fine and imprisonment up to eighteen months;[166]
   (ii) preparation or making of wine also requires a licence, under penalty of a fine between two hundred and two thousand liri;[167]
   (iii) manufacture of alcoholic beverages requires a licence under penalty of a fine not exceeding five hundred liri or to imprisonment for not more than three months or both.[168]

(b) *Unlawful Possession*: when exceeding ten litres of alcohol, the offence is liable to a fine not exceeding one hundred liri plus a fine of ten cents for every litre or part thereof and seizure of such spirits.[169]

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[165] *Spirits Ordinance*, article 4.
[166] *Spirits Ordinance*, article 8.
[167] *Wine Act*, articles 3 and 26.
[168] *Alcoholic Beverages Regulations*, SL 41.02, regulations 3 and 5.
[169] *Spirits Ordinance*, article 67(1).

(c) *Control of Sales*:

(i) a licence is required for 'the sale by retail of wine, beer or spirituous liquor';[170]

(ii) a licence is required for the sale of wine, beer or spirituous liquor 'to be consumed on the premises' or 'sold in quantities less than one whole bottle';[171]

(iii) knowingly selling or delivering spirits, for unlawful retail or consumption,[172] or buying or receiving any spirit from a person, not having the authority to sell or deliver, are liable to a fine not exceeding two hundred liri and in addition to imprisonment for up to six months, with seizure of the spirits;[173] and

(iv) alcoholic beverages may not be sold from the manufacturing premises for consumption on the same premises.[174]

(d) *Certain Obligations of a retailer*: a shopkeeper selling by retail must not:

(i) 'permit drunkenness, or any violent or quarrelsome conduct' at the premises; or

(ii) sell to a drunken person, or to a person of unsound mind, or to persons under the age of sixteen years.[175]

(e) *Alcohol addiction*: the ***Constitution of Malta*** states that: 'No person shall be deprived of his personal liberty save as may be authorised by law' as 'in the case of a person who is, or is reasonably suspected to be, of unsound mind, addicted to drugs or alcohol, or a vagrant, for the purpose of his care or treatment or the protection of the community.'[176]

(f) *Advertising*: see below.

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[170] *Code of Police Laws*, article 185. Commercial premises require a licence issued by the regulatory authority, as established in the *Trading Licences Act*, article 13.

[171] *Shops for the Sale of Wine, Beer or Spirituous Liquors (Licences, Good Order and Public Decorum) Regulations*, SL 10.09, regulations 2 and 4.

[172] *Spirits Ordinance*, article 71.

[173] *Spirits Ordinance*, article 72.

[174] *Alcoholic Beverages Regulations*, SL 41.02, regulation 10.

[175] *Code of Police Laws*, article 185.

[176] *Constitution of Malta*, article 34(1)(i).

14.30

A definition of being 'drunk' is to be found in the ***Malta Armed Forces Act***, which states that 'a person shall be treated as being drunk if owing to the influence of alcohol or any drug, whether alone or in combination with any other circumstances, he is unfit to be entrusted with his duty'[177] 'or behaves in a disorderly manner likely to bring discredit to the service.'[178] Moreover, it states: 'Any person subject to military law who is guilty of drunkenness, whether on duty or not, shall, on conviction by court-martial, be liable to imprisonment for a term not exceeding two years or any less punishment provided by this Act,' this being detention only up to six months if the person is not on active service or duty at the time of the offence.[179]

(a) Sale of alcohol to children

14.31

The sale of alcohol to children is prohibited. Legislation exists that prohibits shopkeepers from selling, by retail, to persons under the age of sixteen years.[180] Subsidiary legislation prohibits children from frequenting places where alcohol is sold for consumption on the premises, or in quantities less than one whole bottle; this also binds the licencee to enforce the law, which states: 'It shall not be lawful for any person holding a licence under these Regulations to allow any child under sixteen years of age to enter or loiter at the entrance of any bar or other premises where barmaids or artistes are employed; nor shall it be lawful for any such child to enter or loiter at the entrance of any such bar or premises or to infringe any order given by any member of the Police Force to quit the neighbourhood thereof.'[181]

The EU Council Recommendation on the drinking of alcohol by young people, in particular children and adolescents, is more specific on this issue.[182]

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[177] *Malta Armed Forces Act*, article 42(2).

[178] *Malta Armed Forces Act*, article 56(2).

[179] *Malta Armed Forces Act*, article 56(1).

[180] *Code of Police Laws*, article 185.

[181] *Shops for the Sale of Wine, Beer or Spirituous Liquors (Licences, Good Order and Public Decorum) Regulations*, SL 10.09, regulation 18.

[182] European Council Recommendation of 5 June 2001 on the drinking of alcohol by young people, in particular children and adolescents, 2001/

c. Smoking

14.32

Smoking has had a long history of being considered a harmless pastime. However, there is no doubt any more that the smoker not only jeopardises his/her own health, but also poses danger to other members of the public.

The purpose of legislation in relation to smoking is to:

(a) educate the individual smoker and alert him/her to the long-term problems associated with the habit;
(b) protect the passive smoker who has a right to a clean atmosphere;
(c) enforce directives on those involved in any way in the production, sales and advertising of the product, to ensure that these do not have undue influence on people, particularly young persons, with the aim of preventing the initiation of the habit.

The ***Tobacco (Smoking Control) Act*** deals with the following issues:

(a) Advertising

14.33

This is defined as 'any form of commercial communication with the aim of directly or indirectly promoting tobacco products.'[183]

The Act details the type of advertising that is prohibited, stating: '(1) No person shall on television, radio or other broadcasting medium, or in cinemas, advertise cigarettes, cigars or other forms of tobacco, tobacco product or smoking requisites. (2) Radio, television and other programmes broadcast by other mediums shall not be sponsored by undertakings whose principal activity is the manufacture or sale of tobacco products.' Moreover a tobacco product must not 'bear the brand name, trade mark, emblem or other distinctive feature of any other product or service.'[184] These provisions do not apply to foreign newspapers

458/EC, Official Journal L 161, 16.06.2001 p. 0038-0041 accessed at http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/1_161/1_16120010616en00380041.pdf. (See Appendix K).

[183] *Tobacco (Smoking Control) Act*, article 2.

[184] *Tobacco (Smoking Control) Act*, article 4(1) and (2).

or magazines imported into Malta and whose main purpose is not that of tobacco advertising.[185] Advertising in the local press and other printed publications is prohibited unless intended exclusively for professionals in the tobacco trade.[186]

The 'sponsorship of events or activities involving or taking place in more than one Member State of the European Union or otherwise having cross-border effect' and the free distribution of tobacco products in such events, is prohibited. This presumably includes sports events.[187]

Further regulations relating to advertising of tobacco and smoking are contained in the ***Broadcasting Act*** which states that: 'All forms of advertising and teleshopping for cigarettes and other tobacco products shall be prohibited.'[188]

(b) Health warnings

These are to be shown in cinemas prior to the beginning of every film show, and after the interval, together with 'a notice that smoking is prohibited by law in the cinema.'[189] The person running a broadcasting station must broadcast a health warning immediately before the showing of any film or other broadcast in which smoking, smoking requisites or tobacco products, are shown or mentioned.[190]

Every package of cigarettes 'and any other tobacco product imported, sold, distributed or supplied' has to contain a health warning and information as to the ingredients and quantities contained.[191] Such warnings have to be prominently displayed in shops from which cigarettes or tobacco products or smoking requisites are sold.[192]

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[185] *Tobacco (Smoking Control) Act*, article 5.
[186] *Tobacco (Smoking Control) Act*, article 6.
[187] *Tobacco (Smoking Control) Act*, article 6A.
[188] *Broadcasting Act*, Third Schedule, Code for Advertisements, Teleshopping and Sponsorships, paragraph 15.
[189] *Tobacco (Smoking Control) Act*, article 7(1).
[190] *Tobacco (Smoking Control) Act*, article 7(2).
[191] *Tobacco (Smoking Control) Act*, articles 8 and 11.
[192] *Tobacco (Smoking Control) Act*, article 10.

(c) Prohibition of smoking in public places

14.34

'No person shall smoke any cigarette, cigar, tobacco or tobacco product on any public transport, in any cinema, theatre, hospital, clinic or other health institution, or in any television studio in any debate, discussion or other programme broadcast locally for public viewing whether live or pre-recorded' and 'nor shall any person smoke any such item in any classroom, corridor, yard or appurtenance of a school, day home or similar premises used by children under sixteen years of age.' It is the duty of the person in charge to ensure that adequate notices are made available at prominent positions in relation to this and that no smoking does take place where prohibited.[193] The exception to this wide-ranging prohibition is when there is an area in a hospital or school, etc. which has been specifically reserved as an area where smoking is allowed.[194]

Tobacco products cannot be sold in or from:

(a) 'hospital grounds, clinics, pharmacies or any other health care establishments;
(b) school grounds, colleges, or any other educational institution;
(c) sports or athletic facilities.'[195]

Subsidiary legislation exists which relates to:

(a) control of tobacco growing;[196]
(b) yield of cigarettes marketed in Malta;[197]
(c) prohibition of smoking within the precincts of the registries of the courts;[198]
(d) labelling of tobacco products and exhibition of health warnings;[199] and
(e) prohibition on smokeless tobacco.[200]

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[193] *Tobacco (Smoking Control) Act*, article 14(1).
[194] *Smoking in Premises Open to the Public Regulations*, SL 315.04, regulations 3–6.
[195] *Tobacco (Smoking Control) Act*, article 12(2).
[196] *Tobacco Growing (Control of) Ordinance* and *Prohibition of Tobacco Cultivation Order*, SL 106.01.
[197] *Tobacco Products (Cigarette Composition) Regulations*, SL 315.05.
[198] *Tobacco Smoking (Court Registries) Regulations*, SL 315.03.
[199] *Labelling of Tobacco Products Regulations*, SL 315.01.
[200] *Ban on Smokeless Tobacco Regulations*, SL 315.02.

d. Dangerous driving and infringements of traffic regulations

14.35

One of the major epidemics of recent years relates to the slaughter on the roads, the result of car accidents, which are often directly related to overindulgence in alcohol and possibly other drugs. As often as not, such accidents involve not only the driver (and passengers therein) of the car that loses control, but also innocent drivers and passengers of on-coming cars as well as pedestrians. It is therefore legitimate to restrict the rights of individuals in so far as these are meant to reduce the number of such traffic accidents.

'No person shall drive, attempt to drive or be in charge of a motor-car or other vehicle on a road or other place after consuming so much alcohol that the proportion of it in his breath, blood or urine exceeds the prescribed limit.'[201] The police have the power to stop persons driving or attempting to drive a vehicle in a public place, when suspected of being under the influence of alcohol, or on having committed a traffic offence or having been involved in an accident and to obtain samples for analysis of the level of alcohol in breath, urine or blood. For further discussion, see **Chapter 11**: **Laboratories**.

Amendments to the ***Traffic Regulation Ordinance***, enacted in 2000, regulate problems relating to drinking and driving. In brief these include the following:

(a) prohibition of driving a car when unfit to drive through drink or drugs;[202]

(b) prohibition of driving a car with alcohol concentration in the breath, blood or urine, above the prescribed limit.[203] 'The prescribed limit' is presently established in article 15I, as the case may require, as:

'(i) 35 microgrammes of alcohol in 100 millilitres of breath; or

(ii) 80 milligrammes of alcohol in 100 millilitres of blood; or

(iii) 107 milligrammes of alcohol in 100 millilitres of urine.'

(c) empowering police to subject a driver, suspected of having a high alcohol concentration in his body, to a breath test;[204]

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[201] *Traffic Regulation Ordinance*, article 15B.
[202] *Traffic Regulation Ordinance*, article 15A.
[203] *Traffic Regulation Ordinance*, article 15B.
[204] *Traffic Regulation Ordinance*, article 15C.

(d) empowering police to arrest an individual if the breath test suggests that the blood alcohol is above the prescribed limit, or if that person fails to provide a specimen of breath analyses for testing, provided that the 'person had been warned that the failure or refusal to comply with such a request was an offence';[205]
(e) provision of specimens of breath, blood or urine for laboratory analysis, with specified equipment in the case of breath analyses; a person who refuses or fails to provide a specimen is guilty of an offence unless such 'failure was due to physical or mental incapacity to provide it or because its provision would entail a substantial risk to his health';[206]
(f) detention of a person by the police until such person is fit to drive;[207] and
(g) penalties imposed on a person who contravenes the provision of these articles.[208]

Subsidiary legislation, the ***Wearing of Seat Belts in Motor Vehicles Regulations***, regulates the wearing of seat belts by all adults (over twelve years) travelling in passenger cars, mini buses and light goods vehicles, irrespective of their seating position.[209]

Children,[210] whether in the front or the rear passenger seats, must 'be restrained using a child restraint system that is suitable for the child's weight as set out in the First Schedule.'[211] 'A child restraint system facing the rear seat shall not be fitted to a front seat protected by an airbag unless such airbag has been deactivated.'[212]

If the vehicle is not fitted with a child restraint system, a young child (under three years) cannot travel in the front seat[213] but must

[205] *Traffic Regulation Ordinance*, article 15D.
[206] *Traffic Regulation Ordinance*, article 15E(1) and E(4).
[207] *Traffic Regulation Ordinance*, article 15G.
[208] *Traffic Regulation Ordinance*, article 15H.
[209] *Wearing of Seat Belts in Motor Vehicles Regulations*, SL 65.12, regulations 3–6.
[210] *Wearing of Seat Belts in Motor Vehicles Regulations*, SL 65.12, defines a 'child' under regulation 2, as 'a person under the age of twelve years and is less than 150 centimetres in height' while a 'young child' is a person under three years old.
[211] *Wearing of Seat Belts in Motor Vehicles Regulations*, SL 65.12, regulation 8.
[212] *Wearing of Seat Belts in Motor Vehicles Regulations*, SL 65.12, regulation 7(3).
[213] *Wearing of Seat Belts in Motor Vehicles Regulations*, SL 65.12, regulation 7(1).

be in the rear, either seated next to an adult person, or alone only if the rear doors of the vehicle are fitted and locked with a child-safety lock.[214] Also, in the absence of a child restraint system, older children must wear a seat belt, if available, provided that no seat belt shall be worn by a young child.[215]

All adults, above sixteen are responsible for ensuring they are wearing seat belts while the driver is responsible for ensuring s/he and any child are properly restrained.

There are exemptions from wearing seat belts for taxi drivers and for all drivers while reversing or manoeuvring in a limited space. One may be exempted if in possession of a medical certificate. Police Officers and Prison Wardens and firemen on duty, medical officers and attendants in an ambulance and those using a vehicle for 'local rounds of deliveries or collections' are exempted. Those supervising a learner performing any manoeuvre or when conducting a driving test, are also exempted.[216]

7. Advertising

14.36

The role of advertising is to bring to the attention of the public products which would not otherwise be known. While its main aim is to provide information about products which meet the needs of the public, it very often creates that very need by the way the product is portrayed.

There are several ethical issues involved in advertising. Drawing attention to oneself or one's product unfairly would jeopardise the rights of others for equal treatment. Giving misinformation to the public is likewise undesirable and may lead to unrealistic expectations and unnecessary expenditure.

The following are some areas relating to advertising where there is a strong bioethical component:

(a) advertising by health professionals in relation to services given;
(b) advertising health products;

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[214] *Wearing of Seat Belts in Motor Vehicles Regulations*, SL 65.12, regulation 12.
[215] *Wearing of Seat Belts in Motor Vehicles Regulations*, SL 65.12, regulations 10 and 7(2).
[216] *Wearing of Seat Belts in Motor Vehicles Regulations*, SL 65.12, regulation 14.

(c) advertising which discriminates between sexes;
(d) advertising relating to disabled persons;
(e) advertising which puts lifestyle products (smoking, drinking, etc.) in an unnecessary glamorous light;
(f) advertising which targets children and young adults.

14.37
A number of the issues mentioned above have been dealt with under the various headings in previous chapters. The following is a summary of relevant legislation.

a. Definition of advertising

Advertising is defined in various Acts, in relation to goods or services.

In the ***Consumer Affairs Act***, 'advertisement' means 'any form of representation, including a catalogue, a circular and a price list, about a trade, business, craft or profession in order to promote the supply or transfer of goods or services, immovable property, rights or obligations' and 'advertising' shall be 'construed accordingly'.

In the ***Malta Travel and Tourism Services Act***, an 'advertisement' means 'the making of a representation in any form in connection with a trade or business in order to promote the supply of goods or services, including the making of any such representation, any word, letter, model, sign, placard, board, notice, brochure or device, whether illuminated or not, in the nature of and employed wholly or in part for the purposes of advertisement, announcement or direction, and any boarding or similar structure used or adapted for use for the display of advertisements' and 'advertise' shall be 'construed accordingly'.

For the purpose of the ***Product Safety Act*** an advertisement 'includes any notice, device, circular, label, packaging, invoice, document, representation, broadcast or public announcement, visual or acoustic presentation or both' and 'to advertise' shall be 'construed accordingly.'

The ***Medicines Act*** defines advertising, in relation to medicinal products, to include 'any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products'.

In the ***Food Safety Act***, 'advertisement' includes 'any notice, circular, label, wrapping, invoice or other document or presentation, and any broadcast or public announcement by visual or acoustic presentation or both,' and 'to advertise' shall be 'construed accordingly'.

In the ***Trade Descriptions Act***, 'advertisement' includes 'a catalogue, a circular and a price list.'

In the ***Insurance Business Act***, 'advertisement' means any form of advertising, whether done verbally or in writing' and 'includes advertising in a publication, the display of notices, signs, labels or show cards, by means of letters, circulars, prospectuses, catalogues, price lists or other documents, by an exhibition of pictures or photographic or cinematographic films, by way of sound broadcasting or television, by the distribution of recordings or in any other manner.'[217]

The ***Investment Services Act*** states that an 'investment advertisement' means 'any form or medium of advertising or promotional activity, other than a prospectus, the contents of which, either invites persons, or contains material calculated to induce persons:

(i) to become or offer to become participants in a collective investment scheme; or
(ii) to subscribe for or otherwise acquire or underwrite an instrument; or
(iii) to purchase or otherwise procure an investment service.'

For the purpose of the ***Development Planning Act***, an 'advertisement' means 'any word, letter, model, sign, placard, board, notice, device or representation, whether illuminated or not, in the nature of and employed wholly or in part for the purposes of advertisement, announcement or direction, including any boarding or similar structure used or adapted for use for the display of advertisements.'[218]

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[217] The same definition is used in the *Insurance Brokers and Other Intermediaries Act* in relation to the activities of insurance intermediaries.

[218] The same definition is used in the *Local Councils Act*.

14.38

The following highlights some relevant aspects of these Acts with respect to ethical advertising.

The ***Development Planning Act,*** sets up the Malta Environment and Planning Authority, which may make orders for restricting or regulating advertisements, including:[219]

(a) for regulating the dimensions, appearance and position of advertisements, the sites on which advertisements may be displayed and the manner in which they are to be affixed to land;
(b) for requiring the consent of the Authority to be obtained for the display of advertisements or of advertisements;
(c) for enabling the Authority to require the removal of any advertisement that is being displayed in contravention of any order.

The ***Product Safety Act*** emphasises the consumer's rights with respect to advertising. A consumer has the right 'to receive adequate information regarding the safety aspects and the proper use of such products' and 'to be adequately informed with regard to products which give rise to risks to the health and safety of consumers and which are sold or offered for sale to him.'[220] Producers and importers are required to 'provide consumers with the relevant information to enable them to assess the risks inherent in a product throughout the normal or reasonably foreseeable period of its use, where such risks are not immediately obvious without adequate warnings.'[221] This would imply that hiding or glossing over important health issues in an advertisement would be against the requirements of this Act. It may be necessary to withdraw a product from the market to avoid risks to the consumer.[222]

It is an offence for distributors to supply products 'which they know or should reasonably know, on the basis of the information in their possession as practitioners in the relevant trade, business or occupation, do not comply with safety requirements.' They must

[219] *Development Planning Act*, article 49.
[220] *Product Safety Act*, article 3(1).
[221] *Product Safety Act*, article 6(1)(a).
[222] *Product Safety Act*, article 6(1)(c).

'pass on information on product risks to their suppliers and to consumers' and must 'cooperate in action taken to avoid these risks.'[223]

In relation to assessing if goods belong to a particular trade description, used in an advertisement, 'regard should be paid not only to the form and content of the advertisement but also to the time, place, manner and frequency of its publication and all other matters making it likely or unlikely that a person to whom the goods are supplied would think of the goods as belonging to the class in relation to which the trade description is used in the advertisement.'[224]

b. Advertising health services

14.39

Advertising of medicinal drugs, by health professionals, has been dealt with in detail in **Chapter 3: The Health Care Professions: Medical Issues** and **Chapter 4: Other Health Care Professions.** One may highlight the following issues:

(a) Medicinal products may only be advertised in accordance with such conditions as may be established by or under the ***Medicines Act.***[225]

(b) A doctor or dentist 'shall neither instigate nor condone any advertisement relative to his professional status or work.'[226]

(c) As regards advertising of treatment: 'No person shall advertise or permit or suffer to be advertised in any manner whatsoever, any medical or health service or treatment, not being a service provided by Government, or any other service or treatment which is or is described as being of a medical, therapeutic or curative value or effect, or in any other way beneficial to health, without the approval of the Council of Health.'[227] 'Treatment' includes 'any form of advice relating to the treatment or cure of maladies or ailments, or any advice relating to health.'[228]

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[223] *Product Safety Act*, articles 7 and 8.

[224] *Trade Descriptions Act*, article 7(3).

[225] *Medicines Act*, article 31 and *Medicinal Products (Advertising) Regulations*, SL 458.32.

[226] *Ethics of the Medical Profession*, SL 94.15, regulation 8 and *Ethics of the Dental Profession*, SL 94.14, regulation 8.

[227] *Medical and Kindred Professions Ordinance*, article 90(1). See also *Control of Advertising of Medicinals Regulations*, SL 458.14.

[228] *Medical and Kindred Professions Ordinance*, article 90A.

(d) The Superintendent of public health is empowered to make, vary or revoke orders 'controlling advertisements that may affect public health.'[229]

(e) The ***Broadcasting Act***, also makes it illegal to advertise particular products. It states that: 'Advertising for medicinal products and medical treatments available only on prescription, shall be prohibited.'[230] Teleshopping for medicinal products and medical treatment is forbidden[231] and in general any advertisements for other medicines must 'comply with the requirements of protection of the individual from harm.'[232]

c. Advertisements relating to work and lifestyle

Job discrimination: It is unlawful to discriminate between applicants when advertising or offering employment for a job, including on the grounds of gender.[233]

Advertising food: The advertising of food, such that it, 'falsely describes the food or is likely to mislead as to the nature, substance or quality of the food' is an offence.[234]

Advertising and smoking: This is dealt with earlier in this chapter in the section on smoking; however all forms of advertising and teleshopping for cigarettes and other tobacco products are prohibited.[235]

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[229] *Public Health Act*, article 27(b).

[230] *Broadcasting Act*, Third Schedule, paragraph 16.

[231] *Broadcasting Act*, Third Schedule, paragraph 17.

[232] *Broadcasting Act*, Third Schedule, paragraph 18. See also *Guidelines on Advertising Concerning Medicines, Treatments, Health Claims, Nutrition and Dietary Supplements*, Broadcasting Authority, at http://www.ba-malta.org/guidelines/m_code_med.htm.

[233] *Employment and Industrial Relations Act*, article 26 and *Equality for Men and Women Act*, article 10. See also *Code of Practice on Disability and Its Portrayal in the Broadcasting Media*, issued by the Broadcasting Authority, December 2002, at http://www.ba-malta.org/guidelines/guidelines-disability.pdf.

[234] *Food Safety Act*, article 18.

[235] *Tobacco (Smoking Control) Act*, articles 4–6 and *Broadcasting Act*, Third Schedule, Code for Advertisements, Teleshopping and Sponsorships, paragraph 15.

Alcoholic drinks and lifestyle: 'Advertising and teleshopping for alcoholic beverages shall comply with the following criteria' in the Code for Advertisements, Teleshopping and Sponsorships, laid down in the ***Broadcasting Act***:

'(a) it may not be aimed specifically at minors or, in particular, depict minors acquiring or consuming such beverage;
(b) it shall not link the consumption of alcohol to enhanced physical performance or to driving;
(c) it shall not create the impression that the consumption of alcohol contributes towards social or sexual success;
(d) it shall not claim that alcohol has therapeutic qualities or that it is a stimulant, or sedative, or a means of resolving personal conflicts;
(e) it shall not encourage immoderate consumption of alcohol or present abstinence therefrom or moderation therein in a negative light;
(f) it shall not place emphasis on high alcoholic content as being a positive quality of the beverages.'[236]

14.40
The Broadcasting Authority has issued guidelines relating to advertising of alcoholic drinks.[237] Briefly, they recommend that advertisements for alcoholic drinks:

(a) should not be broadcast before 9.00 p.m.;
(b) should not be directed at people under 18 years of age;
(c) children should not be seen or heard in such advertisements;
(d) should not imply that drinking is essential to social success, masculinity or femininity, etc.;
(e) should not encourage intoxicating effects; and
(f) should not encourage drinking and driving.

14.41
Advertising and minors: Special precautions are necessary when advertising is likely to affect younger persons. It is prohibited to

[236] *Broadcasting Act*, Third Schedule, Code for Advertisements, Teleshopping and Sponsorships, paragraph 19.
[237] Broadcasting Authority: *Guidelines on Alcoholic Drink Advertising Sponsorship and Teleshopping*, 2005, at http://www.ba-malta.org/guidelines/Alcohol_Teleshopping.pdf.

broadcast material which 'might seriously impair the physical, mental or moral development of minors, and in particular they shall not include programmes that involve pornography or gratuitous violence.'[238] More specifically, advertising should not 'directly exhort minors to buy a product or a service by exploiting their inexperience or credulity,' nor encourage them 'to persuade their parents to purchase the goods or services advertised' and it should not exploit the special trust minors place in parents, teachers and other persons.[239] In particular advertising should not lead minors to believe that they would be inferior to other minors or liable to be held in contempt or ridicule unless they have or use the product advertised.[240] It should not 'invite minors to purchase products or services by means of a communication at a distance, including mail, telephone, computer, e-mail or internet.'[241] Relevant also are injunctions against encouraging minors to eat frequently throughout the day[242] or indulge in confectionary and snack foods instead of normal meals.[243] This Code also prohibits advertising which shows children in dangerous situations, which small children might want to imitate, including leaning out of windows, playing in the road, using matches, gas, petrol, etc. and using toy weapons which can be confused with real weapons.[244]

It also states that 'no advertisement shall encourage minors to enter strange places or to converse with strangers.'[245] Minors should not be portrayed in a sexually provocative manner.[246]

Moreover, minors should 'not be used to present products or services which they could not be expected to buy themselves'[247] or make comments on products and services about which they could not be expected to have direct knowledge.[248]

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[238] *Broadcasting Code for the Protection of Minors*, SL 350.05, article 3.
[239] *Broadcasting Code for the Protection of Minors*, SL 350.05, article 6.
[240] *Broadcasting Code for the Protection of Minors*, SL 350.05, article 13.
[241] *Broadcasting Code for the Protection of Minors*, SL 350.05, article 15.
[242] *Broadcasting Code for the Protection of Minors*, SL 350.05, article 18.
[243] *Broadcasting Code for the Protection of Minors*, SL 350.05, article 19.
[244] *Broadcasting Code for the Protection of Minors*, SL 350.05, article 20.
[245] *Broadcasting Code for the Protection of Minors*, SL 350.05, article 21.
[246] *Broadcasting Code for the Protection of Minors*, SL 350.05, article 24.
[247] *Broadcasting Code for the Protection of Minors*, SL 350.05, article 21.
[248] *Broadcasting Code for the Protection of Minors*, SL 350.05, article 26.

There should be no advertisements, during minors' programmes, for the following products: alcoholic drinks; matches; medicines, vitamins or dietary supplements; slimming products, treatments and establishments; adult-only rated film trailers; and lotteries or similar games of chance.[249]

14.42

Gaming: It is forbidden to advertise premises in Malta where gaming takes place, or inviting the public to take part in any such gaming. However, these restrictions do not apply when directed towards tourists, and such advertising is allowed in locations frequented mainly by tourists, airports, seaports, hotels and holiday complexes, or overseas![250]

Tourism industry: Advertising hotels and other holiday premises as belonging to a higher classification than they actually are, or that they offer particular amenities or services which they do not offer, is forbidden.[251]

Investments schemes: There should be no advertisement of investment schemes, instruments and services, other than by a licence holder; a prospectus cannot be issued without the consent of the competent authority.[252]

Insurance schemes: No company 'shall issue or cause to be issued in Malta any advertisement or carry out or cause to be carried in Malta any promotional activity related to the business of insurance which misleads, or directly or by implication is likely to mislead, or deceive any prospective policyholder, or the insurance sector in general, or the general public with respect to its assets or corporate structure or financial standing or authorisation or any other material respect.' The competent authority may 'determine the form and content of insurance advertisements' and the manner in which any promotional activity shall be carried out.[253]

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[249] *Broadcasting Code for the Protection of Minors*, SL 350.05, article 29.
[250] *Gaming Act*, article 49.
[251] *Malta Travel and Tourism Services Act*, article 22.
[252] *Investment Services Act*, article 11(2) and (1).
[253] *Insurance Business Act*, article 48(1) and (2).

14.43

Misleading advertising is prohibited. An advertisement is misleading if 'it deceives or is likely to deceive the persons to whom it is addressed or whom it reaches, and if by reason of its deceptive nature, it is likely to affect their economic behaviour or is one which for those reasons, injures or is likely to injure a competitor of the person whose interests the advertisement seeks to promote.'[254] To determine whether an advertisement is misleading, account shall be taken of all its features, and in particular of any information it may have about:

(a) 'the characteristics of goods or services, including their availability, nature, execution, composition, method and date of manufacture or provision, fitness for purpose, uses, quantity, specification, geographical or commercial origin or the results to be expected from their use, or the results and material features of tests or checks carried out on the goods or services;
(b) the price or the manner in which the price is calculated, and the conditions on which the goods are supplied or the services provided;
(c) the nature, attributes and rights of the advertiser, including his identity and assets, his qualifications and ownership of industrial, commercial or intellectual property rights or any awards and distinctions made to him.'[255]

'Comparative advertising', means 'any advertising which explicitly or by implication identifies a competitor or goods or services offered by a competitor.'[256] This is permitted only under certain conditions including when advertising is not misleading, it is objective in nature, does not discredit other brands and does not take unfair advantage of the reputation of a trade mark of a competitor.[257]

[254] *Consumer Affairs Act*, article 48(2).
[255] *Consumer Affairs Act*, article 48(3).
[256] *Consumer Affairs Act*, article 49.
[257] *Consumer Affairs Act*, article 50.

8. Benefits

a. Social Assistance and sickness benefits

14.44

Positive assistance from the Government is expected in abnormal situations which interfere with the ability of the breadwinner(s) to provide adequately for the family. Several schemes for assistance and help are outlined in various legislation. The ***Constitution of Malta*** maintains that social assistance should be available for everyone. Article 17 states that:

(1) 'Every citizen incapable of work and unprovided with the resources necessary for subsistence is entitled to maintenance and social assistance'; and
(2) 'Workers are entitled to reasonable insurance on a contributory basis for their requirements in case of accident, illness, disability, old-age and involuntary unemployment.'[258]

Persons are entitled to Unemployment Benefit or Special Unemployment Benefit, if they also qualify for Social Assistance, provided that they have been paying relevant contributions and are registered as unemployed.[259]

Families where the head of the household is unemployed and is searching employment, or unable to work due to illness, qualify to receive Social Assistance if the family's income is below a set minimum for that household. Single or widowed unemployed females who care for elderly, disabled or ill relatives, on a full time basis, and do not have financial resources, also qualify for Social Assistance.[260]

A person following a drug or alcohol rehabilitation therapeutic programme may also be entitled to Social Assistance. The ***Social Security Act*** states that 'an insured person who has not yet reached his retirement age and who satisfies the relevant contribution conditions, shall be entitled to Sickness Benefit' for 'any day of incapacity for work, excluding any day in which, whether incapacitated or not, such person would not have been required to attend to work in the normal course of his duties.'[261]

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[258] *Constitution of Malta*, article 17(1) and (2).
[259] *Social Security Act*, articles 17 and 30.
[260] *Social Security Act*, article 30.
[261] *Social Security Act*, article 18(1).

Moreover, medical assistance is available for:[262]

(a) Sickness Assistance;[263]
(b) Leprosy Assistance;[264]
(c) Tuberculosis Assistance;[265]
(d) Free Medical Aid (including drugs, spectacles, dentures etc.);[266] and
(e) Milk Grant (for children under forty weeks of age).[267]

Sickness Assistance is discussed in detail in **Chapter 10: Old Age and Retirement**. The head of the household is entitled to this assistance if he or a member of his household is suffering from one of the diseases listed in Part I of the Fifth Schedule of the Act and the weekly means of the household are below a set minimum.

Free Medical Aid is available to everyone, irrespective of means, for the diseases set out in Part II of the Fifth Schedule and for those suffering from diabetes mellitus, tuberculosis, leprosy and polio-myelitis; for other diseases, a means test is available to qualify for Sickness Assistance.

Injury Benefit is available to 'an insured person who has not yet reached his retirement age' who 'suffers personal injury caused by accident arising out of or in the course of his employment or self-occupation' or for specific occupational diseases, mainly listed in the Fourth Schedule of the ***Social Security Act***, provided that 'within a period of twelve months from the date of the accident or the onset of the disease, he is, as a result of the injury or disease, incapable of work.'[268] Where there is resulting 'permanent loss of physical or mental faculty, the person concerned shall be entitled to Injury Grant or Injury Pension.'[269]

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[262] *Social Security Act*, article 19.
[263] *Social Security Act*, article 20 and Fifth Schedule, Part I.
[264] *Social Security Act*, article 21.
[265] *Social Security Act*, article 22.
[266] *Social Security Act*, article 23.
[267] *Social Security Act*, article 24. This is available for persons receiving Social Assistance or Tuberculosis Assistance.
[268] *Social Security Act*, article 28.
[269] *Social Security Act*, article 29. Further discussion is found in Chapter 8: Disability. Termination of employment in the case of injury has been discussed in Chapter 1: Human Dignity, Rights and Freedoms.

Maternity Leave and Benefit and Parental Leave were discussed in **Chapter 6: Pregnancy and the Family**.

b. Malingering

14.45

Obtaining benefits by claiming inability to perform one's duties is both illegal and immoral. The ***Malta Armed Forces Act*** specifies penalties for 'any person, subject to military law, who falsely pretends to be suffering from sickness or disability' or who injures him/herself (or helps another person to do so) with intent of rendering him/herself (or another person) unfit for service, or causes him/herself to be injured by any person with that intent.[270] Such person 'shall be guilty of malingering and shall, on conviction by court-martial, be liable to imprisonment for a term not exceeding two years or any less punishment provided by this Act.' Fines and/or imprisonment also are specified for persons who aid malingering by for instance supplying to or for an officer of the Armed Forces 'any drug or preparation calculated or likely to render him, or lead to the belief that he is, permanently or temporarily unfit for service.'[271]

In the ***Police Act***, 'malingering, that is to say, if a member of the Force feigns or exaggerates any sickness or injury with a view to evading duty' is listed as an offence against discipline.[272]

In the Public Service, malingering is considered as a minor offence[273] but: 'Officers who are undisciplined or lack concern for standards in their work, or who are prone to late coming, malingering, leaving the office without authorisation or resorting to unjustified sick leave, should not be allowed to progress to a higher scale as a matter of principle.'[274]

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[270] *Malta Armed Forces Act*, article 55.

[271] *Malta Armed Forces Act*, article 169.

[272] *Police Act*, Third Schedule, paragraph 9, in relation to article 33.

[273] Public Service Management Code, 6th Edition, December 2005, Appendix 10.VII, Minor Offences, with reference to paragraph 10.3.7.1.

[274] Public Service Management Code, 6th Edition, December 2005, Promotions, paragraph 1.3.11.1.

c. Exemptions from taxes

14.46

Another aspect of assistance is derived from tax exemptions. Certain items of expenditure are considered to be basic to the needs of society and Governments have endeavoured to reduce the tax burden on members of society on items considered essential to health.

The ***Social Security Act*** refers to exemption of a self-employed person 'from the payment of Class Two contributions' if the yearly income is below a set minimum, and to the award of benefits in relation to health and welfare.[275]

The ***Value Added Tax Act***[276] provides for exemptions for 'the importation of goods which are specifically designed for the education, employment or social advancement of a person suffering from some permanent physical or mental disability.'[276] A list of such goods has been prepared on the recommendation of the National Commission Persons with Disability, in agreement with the VAT department.[277]

[275] *Social Security Act*, article 12.

[276] *Value Added Tax Act*, Fifth Schedule, article 3(2).

[277] The list may be accessed at http://www.knpd.org

Appendix A

Declaration of Barcelona on the Rights of Mother and Newborn, 2001

PREAMBLE

The WORLD ASSOCIATION OF PERINATAL MEDICINE (WAPM), together with other national and international associations of Perinatal Medicine, Obstetrics, Paediatrics and Neonatology and the collaboration of Academies, Associations, Foundations, Institutes, Centres and Humanitarian Organisations all over the world whose aims are the defence and promotion of the rights of women and newborns, has decided, on the occasion of the 5th WORLD CONGRESS OF PERINATAL MEDICINE to be held in Barcelona (23–27 Sept. 2001), to make an INSTITUTIONAL DECLARATION, which has been named 'Declaration of Barcelona on the Rights of Mother and Newborn.'

The purpose of this declaration is to make sure that, in the 21st century, the human reproductive process may take place, anywhere in the world, in good physical, mental and social conditions, both for mother and child, overcoming the current imbalance.

In recognition of this, the members of the WORLD ASSOCIATION OF PERINATAL MEDICINE, together with the mentioned institutions, exhort all supranational political and health organisations, the governments of all the countries in the world, the legislators of the democratic Parliaments and non-governmental organisations (ONGs), and any public and private institutions whose purpose is the assistance to the reproductive health of Humanity, to take into account and respect, promote and put into practice this Declaration.

DECLARATION OF MOTHER'S RIGHTS

1. Maternity must be of free choice. Each individual woman has the right to decide the best time to have children, the time interval between siblings and how many she wishes to have. The use of efficient contraceptive methods must be accessible to every woman.
2. All women have the right to receive adequate education and information on reproductive health, pregnancy, delivery and newborn care. The Health Services and professionals have the obligation to provide such education to both the woman and her partner and should promote the attendance of both parents to preparatory courses as an integral part of prenatal care.
3. All women have the right to be guaranteed by the government of any country in the world a correct assistance and a pregnancy without unnecessary risks. All women have the right to an adequate Health System and protective measures during pregnancy. Health services during pregnancy must be quality ones and must have sufficient resources. Obstetric care has no frontiers. Obstetric care must bear in mind the respect for the diversity of cultures and beliefs.
4. All women have the right to receive adequate information on technological procedures and advances available for diagnosis and therapeutics, applicable to pregnancy and delivery and must have access to the safest procedures available. All pregnant women have the right to receive information on the available procedures of prenatal diagnosis. Their decision as to the performance of such tests must be a free, informed decision.
5. All women have the right to adequate nutrition during pregnancy. The woman's nutrition must allow her to receive all the necessary nutrients both for the correct growth of the child and for the good of her own health.
6. All working women have the right not to be rejected during or because of a pregnancy. Access to and continuity in the working world must be guaranteed to all women without this being a matter of discrimination due to her pregnancy. The right to maternity must be protected by the governments' labour laws in such a way that it guarantees maternity leave and adaptation of the working schedule, without this affecting her salary or involving a risk of losing the job. Mothers have the right to breastfeed their children during work hours.

7. All women have the right not to suffer discrimination, penalisation or social exclusion due to having voluntarily interrupted pregnancy.
8. The right to maternity cannot be limited on the grounds of social structure. Both single parent families and families where two parents exist have the same rights regarding maternity.
9. Every mother has the right to share responsibility with the father, as much concerning decisions and regarding the reproductive process. The father has responsibility for respecting the woman's decision. All women have the right not to be forced or coerced by their partner concerning maternity. The decisions concerning reproduction within a couple is a right that must be exercised with equity and co-responsibility between the man and the woman.
10. All women have the right to be informed of the benefits of breastfeeding and encouraged to start it right after delivery. However, all women have the right to freely choose which form lactation should take without being socially or culturally prejudiced.
11. All women have the right to participate in the decision-making process (diagnosis and therapeutics) which may affect both her and her fetus. All decisions must be free, informed decisions.
12. Those women who give birth at an institution have the right to decide on the clothing (of her own and the newborn), food, destiny of the placenta and other practices which are culturally important for the individual. All women have the right to be with their babies at all times, while in hospital, provided their health state allows it.
13. Those pregnant women with drug addiction, AIDS or other medical or social problems that might provoke their exclusion from society have the right to specific help programmes. Immigrant pregnant women have the right to be assisted in the same conditions as the women from the host country.
14. All women have the right to their intimacy and health professionals have the duty to respect the right to confidentiality. We health professionals should not accept the lack of resources as an excuse not to advance in the accomplishment of the rights of reproductive health of women and, in general, of societies.

DECLARATION OF THE NEWBORN'S RIGHTS

1. The universal declaration of human rights refers to all stages of life. All human beings are born free and with the same dignity and rights.
2. The dignity of the newborn, as the human being he/she is, is a transcendent value. Newborns must be protected in accordance with the Convention of the Rights of the Child.
3. Every newborn has the right to life. This right must be respected by all people and governments without discriminating on the grounds of race, sex, economy, geographical place of birth, religion or any other. States should take the necessary measures to protect children from discrimination.
4. Every newborn has the right for its life not to be put at risk due to cultural, political or religious reasons. Nobody has the right to carry out any action whereby the newborn's health is put at risk or his/her physical integrity is affected, be it in the short or in the long term. Under no circumstances may any mutilation be justified.
5. Every newborn has the right to a correct identification, filiation and a nationality. The state must guarantee this right to the same extent as for any other person at any age in life.
6. Every newborn has the right to receive sanitary, affective and social care which will allow him/her to undergo optimal physical, mental, spiritual, moral and social development later in life. The Society is responsible for the compliance of all requisites so that this right is respected. No medical act should be carried out without the informed consent of the parents, given the lack of autonomy of the newborn, and only emergency situations are excluded from this at which the physician is forced to act in defence of the child's best interests and there is no possibility of any intervention by the parents or guardian. There must be equity of attention and absolute rejection of all forms of discrimination, irrespective of economic or social class.
7. Every newborn has the right to correct nutrition, which guarantees his/her growth. Maternal lactation must be encouraged and facilitated. When it is not possible for the mother to breast feed, be it for personal, physical or psychological reasons pertaining to the mother, correct artificial lactation must be facilitated.

8. All newborn have the right to correct medical care. Children have the right to enjoy the highest degree of health and to have access to medical, rehabilitation and preventive services. The states must take all necessary measures aimed at abolishing traditional practices, which are detrimental to the health of the child. Governments must take care of both pre and post natal health care.
9. A pregnant woman carrying a foetus with anomalies, which are incompatible with life has the right to continue with the pregnancy or to choose to terminate pregnancy within the legal limits of each individual country if they so wish. If the foetus should actually be born, futile therapeutic measures should not be applied to the newly born.
10. It should not be attempted to keep alive any newborn whose immaturity is greater than the lowest limit of viability. In these cases, the geographical, social and economic situation of the place of birth will be taken into account when applying the right to justice. In extreme cases, the parents will have to be informed and participate in the decisions before the birth whenever possible.
11. Every newborn has the right to take advantage of the measures of each country regarding social protection and safety. This right refers as much to measures of protection and care in health as to the legal field.
12. The newborn may not be separated from its parents against their will. In cases in which there is evidence of abuse, and these circumstances indicate that the life of the newborn is at risk, the appropriate legislative and administrative measures shall be taken in order to guarantee the child's protection, even if this means separating the child from its parents. This norm will be applicable during the newborn's stay in hospital.
13. In case of adoption, every newborn has the right to be adopted with maximum guarantees. In states where adoption is recognised, the interest of the child must always prevail and all necessary guarantees that adoption is admissible and that all authorisations from the empowered authorities have been obtained must be guaranteed. Under no circumstances shall the sale of organs be justified.

14. All newborns and pregnant women have the right to protection in countries where armed conflict is present. In these situations, maternal lactation must be promoted and protected. The newborn is a person with specific rights which it cannot demand itself due to its physical and mental immaturity. These rights impose a series of obligations and responsibilities on society, which the legislative and executive institutions of all countries must enforce

Appendix B

Admission to a Mental Hospital

Conditions for admission to a mental hospital as provided for in the Subsidiary Legislation 262.01, ***Hospital Admission Forms Regulations***, to the ***Mental Health Act*** are summarised below:

First Schedule: *Application for Admission for Observation* (Articles 14 and 16 of the ***Mental Health Act***):

(a) the application is valid only for 14 days from the last examination date noted on the medical recommendation;
(b) the relationship to the patient must be stated (e.g. the patient's nearest relative or appointed by the Court);
(c) the application could be made by a mental welfare officer;
(d) two medical recommendations are to be appended to the application, from practitioners, one of whom must have had previous acquaintance with the patient, or the reason stated why this was not practicable.

Second Schedule: *Emergency Application for Admission for Observation* (Articles 15 and 16):

(a) the application is valid for 2 days from the last examination date noted on the medical recommendation;
(b) it is to be made by a relative of the patient or a mental welfare officer;
(c) having seen the patient no later than 3 days prior to the date of the application;
(d) one medical recommendation is to be attached, from a practitioner who had previous acquaintance with the patient, or the reason stated why this was not practicable. (A second medical recommendation must be made within 72 hours of admission to hospital).

Third Schedule: *Medical Recommendation for Admission for Observation* (Articles 14, 15, 17):

(a) one doctor must have previous acquaintance with the patient and one must have been approved by the Minister (Article 17 of the Act); only one needs to be a specialist – a psychiatrist;

(b) the doctor must state that the patient is suffering from a mental disorder that warrants detention in hospital for observation *and* that the patient should be so detained:
   i) in the interest of the patient himself or herself *or*
   ii) with a view to the protection of other persons;
(c) the doctor states that in his or her opinion it is of urgent necessity to admit the patient for observation;
(d) the medical recommendation cannot be made by a doctor if s / he is:
   i) the applicant;
   ii) a partner of the applicant or of a practitioner by whom another medical recommendation is given for the purpose of the same application;
   iii) employed by the applicant or by any such practitioner as aforesaid;
   iv) a person who receives or has an interest in the receipt of any payments made on account of the maintenance of the patient; or
   v) the husband or wife or a relative, by consanguinity or affinity up to the second degree, of the patient or of any such person as aforesaid, or of a practitioner by whom another medical recommendation is given for the purpose of the same application.

Fourth Schedule: *Joint Medical Recommendation for Admission for Observation* (Article 14):

(a) two medical practitioners are to make the recommendation jointly;
(b) one doctor must have previous acquaintance with the patient and one must be approved by the Minister;
(c) they must have examined the patient together or at an interval of not more than 3 days;
(d) they must state that the patient is suffering from mental disorder which warrants detention for observation:
   i) in the interests of the patient's own health or safety; or
   ii) with a view to the protection of other persons;
(e) a medical recommendation is not to be given by doctors in the categories already specified.

Fifth Schedule: *Application by Nearest Relative for Admission for Treatment* (Articles 14 and 16):

(a) the application is made by the nearest relative (or person appointed by the Court or by the nearest relative) who must have seen the patient within 14 days of the application;

(b) it is valid for 14 days from the date of the last medical examination noted on the medical recommendation;
(c) it must give the details of the disorder (mental illness, severe subnormality, subnormality and/or psychopathic disorder);
(d) a copy of the Court order or form of authority signed by the nearest relative is to be included, when relevant;
(e) medical recommendations are to be attached with the application, from two medical practitioners, one of whom must have previous acquaintance with the patient or otherwise to state why this was not practicable.

Sixth Schedule: *Application by a Mental Welfare Officer for Admission for Treatment* (Articles 14 and 16):

(a) the application is made by a Mental Welfare Officer, having seen the patient not more than 14 days prior to the application;
(b) it is valid for 14 days from the last examination date noted on the medical recommendation;
(c) it must give the details of the disorder (mental illness, severe subnormality, subnormality and/or psychopathic disorder);
(d) it includes a statement regarding consultation with the nearest relative or a person authorised by a relative or by the Court, to confirm that there is no objection to the application, unless this is impracticable or involves unreasonable delay;
(e) medical recommendations are to be attached with the application, from two medical practitioners, one of whom must have previous acquaintance with the patient or otherwise to state why this was not practicable.

Seventh Schedule: *Medical Recommendation for Admission for Treatment* (Article14):

(a) a medical recommendation is not to be given by doctors in the categories already specified;
(b) one must have prior acquaintance with the patient and one must have been approved by the Minister responsible for Public Health under article 17 of the Act;
(c) it must give the diagnosis (mental illness, severe subnormality, subnormality and/or psychopathic disorder);
(d) it must state that the disorder warrants detention in a hospital for medical treatment;
(e) it must give a clinical description of the patient's mental condition;
(f) it must state whether it is in the interest of the patient's own health and safety *or* for the protection of other persons;

(g) it must state why in-hospital treatment is necessary and why informal admission is not suitable.

Eight Schedule: *Joint Medical Recommendation for Admission for Treatment* (Article14):

(a) two medical practitioners are to make the recommendation jointly;
(b) one must have previous acquaintance with the patient and one must be appointed by the Minister as having special experience;
(c) they must examine the patient together or at an interval of not more than 3 days;
(d) they must give the diagnosis and the reasons for recommendation (as in the seventh schedule);
(e) none of the practitioners must belong to the categories mentioned above;
(f) it must state why in-hospital treatment is necessary and why informal admission is not suitable.

Ninth Schedule: *Report on a Hospital In-Patient* (Article 18):

(a) this is an application for compulsory admission to hospital for observation or for treatment;
(b) it is made by the medical practitioner in charge of the treatment;
(c) on behalf of an in-patient who is not liable to be detained under the ***Mental Health Act.***

Tenth Schedule: *Renewal of Authority for Detention in Hospital* (Article 21(4)):

(a) this application is made by the medical practitioner;
(b) to renew authority to detain a patient in hospital;
(c) in the interest of the patient's own health and safety, or for the protection of other persons;
(d) it is to include the diagnosis and the reasons why the patient cannot be treated informally or be discharged from hospital.

Eleventh Schedule: *Report Barring Discharge by a Nearest Relative* (Article 29):

(a) this is the response to a request by the nearest relative to order a patient's discharge;
(b) it is made by the responsible medical officer, stating that the patient should not be discharged from hospital because of possible danger to other persons or to himself / herself.

Appendix C

Protocol for Admissions to Mount Carmel Hospital

TO ALL MEDICAL PRACTITIONERS

This Department of Health Circular Alerts All Medical Practitioners to the Following Procedures, and of Their Personal Responsibility for the Consequences of Non-adherence.

With a view to optimizing service delivery, patient selection and resource utilization at Mount Carmel Hospital (MCH), and to offering a better and more organised service to patients and their referring medical practitioners, the following admission procedures shall operate henceforth.

INFORMAL ADMISSION

1. Patients will only be accepted for admission to MCH:
   (a) by medical referral;
   (b) using ticket of referral (DH 22) and ONLY;
   (c) after prior arrangement with the admitting firm/duty doctor at MCH.

   The admitting doctor will tell the referring agent which ward the patient should be transported to for admission.
2. If a patient turns up at MCH without the above arrangements, he will be referred back to his family/health centre doctor/referring agent. Such cases will be dealt with by the senior of the two duty doctors at MCH, and the patient's consultant/consultant on call will be involved.
3. In the case of referrals from St Luke's Hospital (SLH), Sir Paul Boffa Hospital (PBH), St Vincent de Paule Residence (SVPR), Corradino Corrective Facility (CCF) and the police, without prior arrangement, the patient will also be referred back to source. It is the referring agent's responsibility to make arrangements for an appropriate level of safe supervision pending proper arrangements.

COMPULSORY ADMISSION

4. In the case of patients referred for compulsory admission under the Mental Health Act (MHA) 1976, MHA compulsory admission papers only become effective if and when they are accepted by the 'manager' of the hospital.

Patients will only be accepted for compulsory admission to MCH:

(a) The application must be signed in accordance with the provisions of the MHA (1976) Article16. In the case of mental welfare officers, there should be consultation with the person (if any) appearing to be the nearest relative unless such practice would not be reasonably practicable or would involve unreasonable delay.
(b) The medical recommendation must be signed in accordance with the conditions of the MHA (1976) Article 17.
(c) The patient can only be admitted if the medical referral (DH22), MHA section papers and prior arrangement are in order.
(d) If the MHA section papers are not in order, the patient can only be admitted on condition that the MHA papers are rectified by the person who made the error as provided for under the MHA (1976) Article 20.
(e) If there is no prior arrangement and medical referral (DH22), the patient will not be admitted until the medical referral (DH22) is provided, even if the MHA section papers are in order.
(f) If the patient is sent without prior arrangement, from another establishment (e.g. SLH, PBH, SVPR, CCF or police source), the patient will be referred back to the referring agent. In such cases, the admitting/on-call consultant will be involved.

OTHER PROVISIONS

5. Patients with non-urgent chronic disabling disorder such as elderly infirm patients, those with dementia and other chronic organic brain syndromes:
   (a) Will not be admitted out-of-hours (0800–1400, Monday to Saturday excluding public holidays) and will be sent back to their referring agent;
   (b) They should be referred to psychiatric outpatients at SLH;
   (c) Elderly patients with chronic organic brain syndrome will only be accepted from other hospitals by prior arrangement with one of the consultants responsible for old age psychiatry.

6. Police cases will not be admitted to MCH without prior involvement of the admitting/on-call consultant. It should normally be quite possible for the person to be held in safe police custody, with adequate levels of police supervision, until the appropriate specialist assessment can be arranged.
7. Purely social admissions will not be admitted to MCH. They will be sent back to their referring agent.

Kindly ensure that henceforth, you comply with these provisions and inform the Director of Psychiatry of any problems arising in their implementation.

Dr Joseph R. Saliba
Director of Psychiatry

Appendix D

UN Principles for Older Persons[1]

Independence

1. Older persons should have access to adequate food, water, shelter, clothing and health care through the provision of income, family and community support and self-help.
2. Older persons should have the opportunity to work or to have access to other income-generating opportunities.
3. Older persons should be able to participate in determining when and at what pace withdrawal from the labour force takes place.
4. Older persons should have access to appropriate educational and training programmes.
5. Older persons should be able to live in environments that are safe and adaptable to personal preferences and changing capacities.
6. Older persons should be able to reside at home for as long as possible.

Participation

7. Older persons should remain integrated in society, participate actively in the formulation and implementation of policies that directly affect their well-being and share their knowledge and skills with younger generations.
8. Older persons should be able to seek and develop opportunities for service to the community and to serve as volunteers in positions appropriate to their interests and capabilities.
9. Older persons should be able to form movements or associations of older persons.

[1] *UN: Resolution 46/91*. Accessed at http://www.unac.org/iyop/unquest.html.

Care

10. Older persons should benefit from family and community care and protection in accordance with each society's system of cultural values.
11. Older persons should have access to health care to help them to maintain or regain the optimum level of physical, mental and emotional well-being and to prevent or delay the onset of illness.
12. Older persons should have access to social and legal services to enhance their autonomy, protection and care.
13. Older persons should be able to utilize appropriate levels of institutional care providing protection, rehabilitation and social and mental stimulation in a humane and secure environment.
14. Older persons should be able to enjoy human rights and fundamental freedoms when residing in any shelter, care or treatment facility, including full respect for their dignity, beliefs, needs and privacy and for the right to make decisions about their care and the quality of their lives.

Self-fulfilment

15. Older persons should be able to pursue opportunities for the full development of their potential.
16. Older persons should have access to the educational, cultural, spiritual and recreational resources of society.

Dignity

17. Older persons should be able to live in dignity and security and be free of exploitation and physical or mental abuse.
18. Older persons should be treated fairly regardless of age, gender, racial or ethnic background, disability or other status, and be valued independently of their economic contribution.

Appendix E

Guidelines for University of Malta Research Ethics Committee[1]

A Summary

1. The University Senate set up a Research Ethics Committee some years ago, and the committee appointed in June 2002 set itself the task of drawing up a set of guidelines which we are presenting together with this summary. These guidelines were approved at the July Senate meeting.
2. The guidelines envisage a simple structure that can safeguard both ethical standards and efficiency while ensuring proper accountability. These guidelines were drawn up in close consultation with the Data Protection Commissioner's Office, who have ensured that they are in accordance with the Data Protection Act.
3. The new set up involves the following steps:
   3.1 Senate has now approved the guidelines that will regulate all research involving human subjects carried out at the University, both by students and by members of staff. It has also appointed a new University Research Ethics Committee.
   3.2 Each faculty will appoint its own Faculty Research Ethics Committee, whose membership will be proposed by the Faculty Board and approved by Senate, in a way similar to examination boards.
   3.3 Each university member, student or member of staff, undertaking research involving human subjects will fill the proposal form and present it for approval to the faculty research ethics committee. The form clearly identifies the person taking responsibility for the research and for compliance with the regulations and with Data Protection legislation.

[1] University Research Ethics Committee (UREC), University of Malta, Guidelines, http://www.um.edu.mt/noticeboard/ethicsguidelines.pdf.

3.4 The faculty committee will discuss the research proposals according to the criteria present in the guidelines, and will give its advice whether the research is to be approved or not, and for what reasons.

3.5 This advice is passed on to the University committee, which will give the final approval. The dates of the University committee meetings will be advertised in good time, so that faculty committees can plan their work without causing any unwarranted delays.

4. There is no need to stress that for this system to function properly, the University needs to provide training for the members of the different committees, and give the University committee sufficient administrative support.

30 July 2004

Guidelines for University of Malta
Research Ethics Committee

I. General Policy

1. One of the principal and essential functions of a university is the carrying out of research in all areas of human knowledge and experience. The University is committed to carry out all research involving human subjects in strict adherence to ethical principles as set out in this policy.
2. This policy will apply to all research, as defined in this policy, that is conducted by University personnel or students and which involves human subjects.
3. Research on human subjects is a common feature of university life, both inside and outside the lecture room. In all such instances, the faculty member and the respective Faculty Research Ethics Committee has the responsibility to protect human subjects and to decide whether a project is exempt or needs to seek the University Research Ethics Committee approval.
4. The University acknowledges and accepts its responsibility for protecting the rights and welfare of human research subjects, and acknowledges that it bears full responsibility for the

performance of all research involving human subjects and for complying with laws and regulations that relate to such research.

5. The University ensures that before human subjects are involved in research, proper consideration will be given to:

   - the risks to the subjects;
   - the anticipated benefits to the subjects and others;
   - the importance of knowledge that may reasonably be expected to result;
   - the informed consent process to be employed;
   - the data protection provisions; and
   - the additional safeguards for vulnerable subjects.

6. It is the policy of the University that all research involving human subjects will be reviewed and approved by the respective Faculty Research Ethics Committee and by the University Research Ethics Committee. The collection of data and involvement of human subjects in research will not be permitted until the respective Faculty Research Ethics Committee and the University Research Ethics Committee have reviewed and approved the research protocol and informed consent has been obtained in accordance with these regulations. Special provisions must be made for soliciting the assent of children to be involved in research.
7. The University Research Ethics Committee has the responsibility and authority to review, approve, disapprove or require changes to appropriate research activities involving human subjects. The University Research Ethics Committee has the authority to suspend or terminate approval of research that is not being conducted in accordance with the University Research Ethics Committee's decisions, conditions and requirements or that has been associated with unexpected serious harm to subjects.
8. The University recognizes the need for appropriate additional safeguards in research involving subjects who are likely to be vulnerable to coercion or undue influence, such as children (under the age of 18), prisoners, mentally disabled persons or economically or educationally disadvantaged persons.
9. The University will provide adequate facilities and administrative support for the University Research Ethics Committee reviews

and record keeping duties and will maintain documentation of University Research Ethics Committee activities.

10. The University will exercise appropriate administrative overview carried out at least annually to assure that its practices and procedures designed for the protection of the rights and welfare of human subjects are being effectively applied.

II. Definitions

A. Research:

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

B. Human Subject:

A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.

C. Minimal Risk:

The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

D. Data Protection:

The Data Protection Act provides for the protection of individuals against the violation of their privacy, by regulating the processing of personal data. The University shall give proper consideration to the principles of good information handling.

Researchers shall obtain the consent, which has to be specific, from the data subjects prior to processing their personal data. In obtaining the consent, the researcher shall inform the data subjects about the purpose of processing, and about their rights under the Data Protection Act, namely the right to access, rectify, and where applicable erase the data concerning them. The data subject may also request written information about his personal data being processed by the researcher. In order to enable the data subject

to exercise his right of access, the researcher shall provide his identity and habitual residence, when obtaining consent. Therefore the data subject has the right to request the researcher to correct, and where applicable erase such personal data that has not been processed in accordance with the Act. The consent of the data subject may also be withdrawn at any time.

The principles of good information handling imply that, personal data, which should be collected for a specific purpose, shall be processed fairly and lawfully. Having regard to the processing purpose, the personal data being processed has to be adequate, relevant and not excessive. All reasonable measures shall be taken to ensure that personal data is correct and if necessary, up to date. Personal data shall not be retained for a period longer than necessary. In relation to this, all measures shall be taken to anonymise data if possible and ensure confidentiality.

E. Exemption Categories:

Research activities and certain course-related, classroom research projects are exempt from this policy for the protection of human subjects when the **ONLY** involvement of human subjects falls within one or more of the categories below:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests, survey procedures, interview procedures or observation of public behaviour, **unless:** (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation.
3. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the

information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

III. University Research Ethics Committee (UREC)

A. Membership:

1. The UREC is established to review all research at the University which involves the use of human subjects.

   The UREC must have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the University. If research subject to UREC regularly involves a category of vulnerable subjects, such as children, handicapped or mentally disabled persons or prisoners, the UREC shall include one or more individuals knowledgeable about and experienced in working with these subjects.

   The members will serve for a three-year term which can be renewed. The Chairperson and the members will be appointed by Senate.
2. The UREC shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in non-scientific areas. One of the members of the Committee will have expertise in ethics.
3. The UREC shall include at least one member who is presently not otherwise affiliated with the University. A member of the UREC may not participate in a review of any project in which the member has a conflicting interest.
4. A list of the names and qualifications of the UREC members is included in the University Calendar.

B. UREC Approval:

1. The main function of the UREC review is to assure that (1) risks to subjects are minimized and reasonable in relation to the anticipated benefits; (2) there is informed consent; (3) rights and welfare of subjects are maintained; and (4) the requirements of data protection legislation are observed.
2. The UREC shall review and have authority to approve, require modification in, or disapprove all research activities covered by this policy.

3. The UREC shall approve research based on a determination that all of the following requirements are satisfied:
   a. Risks to subjects are minimized:
      i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk; and,
      ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
   b. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and to the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the UREC shall consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research). The UREC shall not consider possible long-range effects of applying knowledge gained in the research as among those research risks that fall within the purview of its responsibility.
   c. Selection of subjects is equitable. In making this assessment, the UREC shall take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
   d. Informed consent will be sought from each prospective subject or the subject's legally authorized representative. When appropriate, the assent of children participating in the research should be obtained.
   e. Informed consent will be appropriately documented.
   f. Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
   g. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
   h. When some or all of the subjects are likely to be vulnerable to

coercion or undue influence, such as those mentioned in (3.c.) above, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

4. The UREC shall have authority to suspend or terminate approval of research that is not being conducted in accordance with UREC requirements or that has been associated with unexpected serious harm to subjects.
5. The UREC shall meet at least once every two months to review protocols. The calendar of its meetings will be established every year and communicated to faculty ethics committees at the beginning of the academic year.

C. UREC Reporting:

1. The Faculty Research Ethics Committees shall report to the UREC, and the UREC shall report promptly to the Rector and copy to the respective Dean the following:
   a. any serious or continuing non-compliance by investigators with requirements of the UREC:
   b. any suspension or termination of UREC approval;
   c. any unanticipated problems or injuries involving risks to subjects or others; and,
   d. any changes in the research activity which has been reviewed and approved by the UREC.
2. The UREC shall prepare and maintain, for a period of at least three years, adequate documentation of UREC activities including the following:
   a. Copies of all research proposals reviewed, approved sample consent documents, progress reports submitted by the Faculty Research Ethics Committees and reports of injuries to subjects.
   b. Minutes of UREC meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the UREC; the vote on these actions including the number of members; the basis for requiring changes in or disapproving research; and a written summary of the issues discussed and their resolution.
   c. Records of continuing review activities.
   d. Copies of all correspondence between the UREC and the investigators.
   e. A detailed list of UREC members and of faculty research ethics committees.

f. Detailed written procedures for the UREC.
g. Statements to subjects of significant new findings developed during the course of the research.

D. UREC Review Procedures:

1. All research protocols involving human subjects will be presented to the respective faculty research ethics committee, which will forward their advice to the UREC. The final decision rests with UREC.
2. The Faculty Research Ethics Committee can approve minor changes in previously approved research during the period for which approval is authorized.
3. Research which involves no more than minimal risk to the subjects **and** in which the only involvement of human subjects will be in one or more of the following categories shall normally be approved:

   a. Collection of hair and nail clippings, in a non-disfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.
   b. Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membranes prior to or during labour.
   c. Recording of data from subjects 18 years of age or older using non invasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).
   d. Collection of blood samples by venipucture, in amounts not exceeding 450 millilitres in an eightweek period and no more often than two times per week, for subjects 18 years of age or older and who are in good health and not pregnant.

e. Collection of both supra- and subgingival dental plaque and calculus provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.
f. Voice recordings made for research purposes such as investigations of speech defects.
g. Moderate exercise by healthy volunteers.
h. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.
i. Research on individual or group behaviour or characteristics of group behaviour or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behaviour and the research will not involve stress to subjects.
j. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

E. Full Committee Review:

1. If research does not satisfy the guidelines of exemption and/or external funding is being sought, UREC full-board review shall be conducted. A majority of the members of the UREC must participate in the review.
2. At least one member whose primary concerns are in non-scientific areas must participate in the review. UREC members who have a conflicting interest in a research project cannot participate in the review except to provide information.
3. Research protocols scheduled for review, as well as the advice from the Faculty Research Ethics Committees, shall be distributed to all members of the UREC in advance. When the UREC determines that consultants or experts will be required to advise the UREC in its review of a protocol, the research protocol shall also be distributed to the consultants or experts prior to the review.

F. Notification of UREC Decisions:

1. The UREC shall notify the research investigators and their respective Dean in writing of the UREC's decisions, conditions and requirements within two weeks of UREC review.
2. The UREC shall also provide to the research investigator reasons for the UREC's decisions to disapprove a research protocol and an opportunity for the researcher to respond. The UREC shall also inform the respective Dean of the reasons for disapproval.

IV. Implementation

A. Responsibilities of Deans and Heads of Department:

1. Deans and Directors of Institutes and Centres shall ensure that applicable University regulations and policies regarding the use of human subjects in research are followed.
2. Deans and Directors of Institutes and Centres shall ensure that the research activities covered by this policy are related to the academic programmes of the faculty and department.

B. Responsibilities of the Research Investigator:

1. Research Investigators shall prepare a protocol giving a complete description of the proposed research. In the protocol, research investigators shall make provisions for the adequate protection of the rights and welfare of prospective research subjects and ensure that pertinent laws and regulations are observed.
2. Research Investigators are responsible for preparing and submitting a protocol to the Faculty Research Ethics Committee and for including a sample of proposed informed consent forms with the protocol when appropriate.
3. Research Investigators shall submit a supplement to an original protocol to the Faculty Research Ethics Committee when:

    a. it is proposed to involve human subjects, and the activity previously had only indefinite plans for the involvement of human subjects; or

    b. it is proposed to involve human subjects, and the activity pre-viously had no plans for the involvement of human subjects; or

c. it is proposed to change the involvement of human subjects and that involvement is significantly different from that which was initially approved by the UREC.

4. Research Investigators shall be responsible for complying with all Faculty Research Ethics Committee and UREC decisions, conditions and requirements.
5. Research Investigators are responsible for reporting promptly to UREC any injuries to human subjects, any anticipated problems which involve risks to the human subjects or others and any serious or continuing non-compliance with the requirements of this policy or the determinations of the UREC. Prior to initiation, Research Investigators shall obtain the review and approval of the Faculty Ethics Committee and UREC for any proposed changes in the research activity.
6. To facilitate the review of research and the protection of the rights and welfare of human subjects, Research Investigators are encouraged to attend Faculty Committee and/or UREC reviews when invited to answer questions.

C. Responsibilities of Faculty Research Ethics Committees:

1. Each Faculty, Department, Institute and Centre in which staff and students conduct research projects involving the use of human subjects shall have an Ethics Committee and established guidelines for review and approval of such projects.
2. The Faculty Research Ethics Committee shall have at least three members who are appointed by the Faculty Board for a period of three years. The members shall have knowledge about the various types of research conducted within the faculty. At least one member should have expertise in ethics.
3. Faculty Ethics Committees shall be responsible for performing reviews of research projects as well as course-related research projects conducted by staff and students which involve human subjects.
4. Faculty Ethics Committees shall consider the research proposals and forward their advice to the UREC on whether the proposal should be accepted or rejected. The research proposals and the faculty committee's advice must arrive at the UREC office at least two weeks before the UREC meeting. **All projects which are to be submitted to external sponsors must be submitted to the UREC, regardless of whether they qualify for exemption or not .**

5. Faculties or departments which do not have a Research Ethics Committee shall each appoint a faculty member to coordinate human subject reviews and other related issues with the UREC.
6. In all cases, the rights and welfare of human subjects in research shall be protected in accordance with this policy.

V. Informed Consent

A. Research Investigator Responsibility:

1. Research Investigators shall be responsible for obtaining informed consent in accordance with these regulations and for ensuring that no human subject will be involved in the research prior to obtaining such consent. Informed consent is not required for projects determined by the department/school human subjects committee and the UREC to be exempt.
2. Unless otherwise authorized by the UREC, Research Investigators are responsible for ensuring that legally effective informed consent shall:

   a. be obtained from the subject or the subject's legally authorized representative;
   b. be in language understandable to the subject or the representative;
   c. be obtained under circumstances that offer the subject or the representative sufficient opportunity to consider whether the subject should or should not participate; and
   d. not include exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or release the Research Investigator, the Sponsor, the University or its agents from liability for negligence.

B. Basic Elements of Informed Consent:

1. Unless otherwise authorized by the UREC, Research Investigators at a minimum shall provide the following information to each subject:
   a. A statement that the study involves research, an explanation of the purpose of the research and the expected duration of the subject's participation, a description of the procedures to be followed and identification of any procedures which are experimental.

b. A description of any reasonably foreseeable risks or discomforts to the subject.
c. A description of any benefits to the subject or to others which may reasonably be expected from the research.
d. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
e. A statement describing the extent to which confidentiality of records identifying the subject will be maintained.
f. For research involving more than minimal risk, an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
g. An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research-related injury to the subject.
h. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

2. The UREC may approve a consent procedure which does not include or which alters some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the UREC finds and documents that:

a. the research involves no more than minimal risk to the subjects;
b. the waiver or alteration will not adversely affect the rights and welfare of the subjects;
c. the research could not practicably be carried out without the waiver or alteration; and
d. whenever appropriate, the subjects will be provided with additional pertinent information after participation.

3. In the case of research on genetic material, the consent form must indicate under what conditions the participant is giving consent, if at all, to the use of this material in further studies.

C. Documentation of Informed Consent:

1. Research Investigators shall be responsible for ensuring that informed consent is documented by the use of a written consent form approved by the UREC and signed by the subject or the subject's legally authorized representative, unless this requirement is specifically waived by the UREC. The informed consent form must be printed on University of Malta letterhead.
2. Research Investigators shall ensure that each person signing the written consent form is given a copy of that form.
3. In addition to the subject's signature, the consent form shall be signed by the Research Investigator and a witness, if appropriate.
4. The Research Investigator shall give either the subject or the subject's legally authorized representative adequate opportunity to read the form before signing it.
5. The UREC shall require documentation of informed consent by use of the written consent form or may waive the requirement for the Research Investigator to obtain a signed consent form for some or all subjects if the UREC determines that:

a. The only record linking the subject and the research would be the consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research and the subject's wishes will govern; or

b. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

6. When the documentation requirement is waived, the UREC may require the Research Investigator to provide subjects with a written statement regarding the research.

VI. Sanctions for Non-compliance

1. External funds may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

2. In instance of non-compliance, the individual(s) involved will be given notice by the UREC that research involving the use of subjects should be terminated.
3. The UREC shall inform the Rector and the respective Dean of instances of non-compliance.
4. At a minimum, the individual(s) involved will be reprimanded and reminded of their responsibilities.
5. In those cases determined to be serious violations, the Rector in consultation with the Dean and Head of Department, will recommend sanctions. Senate will make the final decision with regard to appropriate action against the individual(s) involved.

8 July 2004

Appendix F

The Nüremberg Code (1947)[1]

The Nüremberg Code is part of the judgment delivered by the Nüremberg Military Tribunal in the Doctors' Trial, that is, the case of the United States v. Karl Brandt et al. It consists of the opinion of the judges on medical experiments, set out as ten principles. The relevant part of the judgement is reproduced below.

Permissible Medical Experiments

The great weight of the evidence before us is to the effect, that certain types of medical experiments on human beings, when kept within reasonably well-defined bounds, conform to the ethics of the medical profession generally. The protagonists of the practice of human experimentation justify their views on the basis that such experiments yield results for the good of society that are unprocurable by other methods or means of study. All agree, however, that certain basic principles must be observed in order to satisfy moral, ethical and legal concepts:

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted;

[1] The Nüremberg Code from *Trials of War Criminals before the Nüremberg Military Tribunals under Control Council Law No. 10*, Nüremberg, October 1946–April 1949, Washington, D.C.: U.S. G.P.O, 1949–1953, accessed from the United States Holocaust Memorial Museum website at http://www.ushmm.org/research/doctors/Nuremberg_Code.htm

all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

Appendix G

Research Regulations

International Ethical Guidelines for Biomedical Research Involving Human Subjects[1]

Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO), Geneva 2002.

The Guidelines

Guideline 1: Ethical justification and scientific validity of biomedical research involving human beings

The ethical justification of biomedical research involving human subjects is the prospect of discovering new ways of benefiting people's health. Such research can be ethically justifiable only if it is carried out in ways that respect and protect, and are fair to, the subjects of that research and are morally acceptable within the communities in which the research is carried out. Moreover, because scientifically invalid research is unethical in that it exposes research subjects to risks without possible benefit, investigators and sponsors must ensure that proposed studies involving human subjects conform to generally accepted scientific principles and are based on adequate knowledge of the pertinent scientific literature.

Guideline 2: Ethical review committees

All proposals to conduct research involving human subjects must be submitted for review of their scientific merit and ethical acceptability to one or more scientific review and ethical review

[1] http://www.cioms.ch/frame_guidelines_nov_2002.htm

committees. The review committees must be independent of the research team, and any direct financial or other material benefit they may derive from the research should not be contingent on the outcome of their review. The investigator must obtain their approval or clearance before undertaking the research. The ethical review committee should conduct further reviews as necessary in the course of the research, including monitoring of the progress of the study.

Guideline 3: Ethical review of externally sponsored research
An external sponsoring organization and individual investigators should submit the research protocol for ethical and scientific review in the country of the sponsoring organization, and the ethical standards applied should be no less stringent than they would be for research carried out in that country. The health authorities of the host country, as well as a national or local ethical review committee, should ensure that the proposed research is responsive to the health needs and priorities of the host country and meets the requisite ethical standards.

Guideline 4: Individual informed consent
For all biomedical research involving humans the investigator must obtain the voluntary informed consent of the prospective subject or, in the case of an individual who is not capable of giving informed consent, the permission of a legally authorized representative in accordance with applicable law. Waiver of informed consent is to be regarded as uncommon and exceptional, and must in all cases be approved by an ethical review committee.

Guideline 5: Obtaining informed consent: Essential information for prospective research subjects
Before requesting an individual's consent to participate in research, the investigator must provide the following information, in language or another form of communication that the individual can understand:

1. that the individual is invited to participate in research, the reasons for considering the individual suitable for the research, and that participation is voluntary;

2. that the individual is free to refuse to participate and will be free to withdraw from the research at any time without penalty or loss of benefits to which he or she would otherwise be entitled;
3. the purpose of the research, the procedures to be carried out by the investigator and the subject, and an explanation of how the research differs from routine medical care;
4. for controlled trials, an explanation of features of the research design (e.g. randomization, double-blinding), and that the subject will not be told of the assigned treatment until the study has been completed and the blind has been broken;
5. the expected duration of the individual's participation (including number and duration of visits to the research centre and the total time involved) and the possibility of early termination of the trial or of the individual's participation in it;
6. whether money or other forms of material goods will be provided in return for the individual's participation and, if so, the kind and amount;
7. that, after the completion of the study, subjects will be informed of the findings of the research in general, and individual subjects will be informed of any finding that relates to their particular health status;
8. that subjects have the right of access to their data on demand, even if these data lack immediate clinical utility (unless the ethical review committee has approved temporary or permanent non-disclosure of data, in which case the subject should be informed of, and given, the reasons for such non-disclosure);
9. any foreseeable risks, pain or discomfort, or inconvenience to the individual (or others) associated with participation in the research, including risks to the health or well-being of a subject's spouse or partner;
10. the direct benefits, if any, expected to result to subjects from participating in the research;
11. the expected benefits of the research to the community or to society at large, or contributions to scientific knowledge;
12. whether, when and how any products or interventions proven by the research to be safe and effective will be made available to subjects after they have completed their participation in the research, and whether they will be expected to pay for them;

13. any currently available alternative interventions or courses of treatment;
14. the provisions that will be made to ensure respect for the privacy of subjects and for the confidentiality of records in which subjects are identified;
15. the limits, legal or other, to the investigators' ability to safeguard confidentiality, and the possible consequences of breaches of confidentiality;
16. policy with regard to the use of results of genetic tests and familial genetic information, and the precautions in place to prevent disclosure of the results of a subject's genetic tests to immediate family relatives or to others (e.g. insurance companies or employers) without the consent of the subject;
17. the sponsors of the research, the institutional affiliation of the investigators, and the nature and sources of funding for the research;
18. the possible research uses, direct or secondary, of the subject's medical records and of biological specimens taken in the course of clinical care;
19. whether it is planned that biological specimens collected in the research will be destroyed at its conclusion, and, if not, details about their storage (where, how, for how long, and final disposition) and possible future use, and that subjects have the right to decide about such future use, to refuse storage, and to have the material destroyed;
20. whether commercial products may be developed from biological specimens, and whether the participant will receive monetary or other benefits from the development of such products;
21. whether the investigator is serving only as an investigator or as both investigator and the subject's physician;
22. the extent of the investigator's responsibility to provide medical services to the participant;
23. that treatment will be provided free of charge for specified types of research-related injury or for complications associated with the research, the nature and duration of such care, the name of the organization or individual that will provide the treatment, and whether there is any uncertainty regarding funding of such treatment;

24. in what way, and by what organization, the subject or the subject's family or dependants will be compensated for disability or death resulting from such injury (or, when indicated, that there are no plans to provide such compensation);
25. whether or not, in the country in which the prospective subject is invited to participate in research, the right to compensation is legally guaranteed;
26. that an ethical review committee has approved or cleared the research protocol.

Guideline 6: Obtaining informed consent: Obligations of sponsors and investigators

Sponsors and investigators have a duty to:

- refrain from unjustified deception, undue influence, or intimidation;
- seek consent only after ascertaining that the prospective subject has adequate understanding of the relevant facts and of the consequences of participation and has had sufficient opportunity to consider whether to participate;
- as a general rule, obtain from each prospective subject a signed form as evidence of informed consent – investigators should justify any exceptions to this general rule and obtain the approval of the ethical review committee (See Guideline 4 Commentary, *Documentation of consent*);
- renew the informed consent of each subject if there are significant changes in the conditions or procedures of the research or if new information becomes available that could affect the willingness of subjects to continue to participate; and
- renew the informed consent of each subject in long-term studies at pre-determined intervals, even if there are no changes in the design or objectives of the research.

Guideline 7: Inducement to participate

Subjects may be reimbursed for lost earnings, travel costs and other expenses incurred in taking part in a study; they may also receive free medical services. Subjects, particularly those who receive no direct benefit from research, may also be paid or otherwise compensated for inconvenience and time spent. The payments

should not be so large, however, or the medical services so extensive as to induce prospective subjects to consent to participate in the research against their better judgment ('undue inducement'). All payments, reimbursements and medical services provided to research subjects must have been approved by an ethical review committee.

Guideline 8: Benefits and risks of study participation

For all biomedical research involving human subjects, the investigator must ensure that potential benefits and risks are reasonably balanced and risks are minimized.

- Interventions or procedures that hold out the prospect of direct diagnostic, therapeutic or preventive benefit for the individual subject must be justified by the expectation that they will be at least as advantageous to the individual subject, in the light of foreseeable risks and benefits, as any available alternative. Risks of such 'beneficial' interventions or procedures must be justified in relation to expected benefits to the individual subject.
- Risks of interventions that do not hold out the prospect of direct diagnostic, therapeutic or preventive benefit for the individual must be justified in relation to the expected benefits to society (generalizable knowledge). The risks presented by such interventions must be reasonable in relation to the importance of the knowledge to be gained.

Guideline 9: Special limitations on risk when research involves individuals who are not capable of giving informed consent

When there is ethical and scientific justification to conduct research with individuals incapable of giving informed consent, the risk from research interventions that do not hold out the prospect of direct benefit for the individual subject should be no more likely and not greater than the risk attached to routine medical or psychological examination of such persons. Slight or minor increases above such risk may be permitted when there is an overriding scientific or medical rationale for such increases and when an ethical review committee has approved them.

Guideline 10: Research in populations and communities with limited resources

Before undertaking research in a population or community with limited resources, the sponsor and the investigator must make every effort to ensure that:

- the research is responsive to the health needs and the priorities of the population or community in which it is to be carried out; and
- any intervention or product developed, or knowledge generated, will be made reasonably available for the benefit of that population or community.

Guideline 11: Choice of control in clinical trials

As a general rule, research subjects in the control group of a trial of a diagnostic, therapeutic, or preventive intervention should receive an established effective intervention. In some circumstances it may be ethically acceptable to use an alternative comparator, such as placebo or 'no treatment'.

Placebo may be used:

- when there is no established effective intervention;
- when withholding an established effective intervention would expose subjects to, at most, temporary discomfort or delay in relief of symptoms;
- when use of an established effective intervention as comparator would not yield scientifically reliable results and use of placebo would not add any risk of serious or irreversible harm to the subjects.

Guideline 12: Equitable distribution of burdens and benefits in the selection of groups of subjects in research

Groups or communities to be invited to be subjects of research should be selected in such a way that the burdens and benefits of the research will be equitably distributed. The exclusion of groups or communities that might benefit from study participation must be justified.

Guideline 13: Research involving vulnerable persons

Special justification is required for inviting vulnerable individuals to serve as research subjects and, if they are selected, the means of protecting their rights and welfare must be strictly applied.

Guideline 14: Research involving children

Before undertaking research involving children, the investigator must ensure that:

- the research might not equally well be carried out with adults;
- the purpose of the research is to obtain knowledge relevant to the health needs of children;
- a parent or legal representative of each child has given permission;
- the agreement (assent) of each child has been obtained to the extent of the child's capabilities; and
- a child's refusal to participate or continue in the research will be respected.

Guideline 15: Research involving individuals who by reason of mental or behavioural disorders are not capable of giving adequately informed consent

Before undertaking research involving individuals who by reason of mental or behavioural disorders are not capable of giving adequately informed consent, the investigator must ensure that:

- such persons will not be subjects of research that might equally well be carried out on persons whose capacity to give adequately informed consent is not impaired;
- the purpose of the research is to obtain knowledge relevant to the particular health needs of persons with mental or behavioural disorders;
- the consent of each subject has been obtained to the extent of that person's capabilities, and a prospective subject's refusal to participate in research is always respected, unless, in exceptional circumstances, there is no reasonable medical alternative and local law permits overriding the objection; and
- in cases where prospective subjects lack capacity to consent, permission is obtained from a responsible family member or a legally authorized representative in accordance with applicable law.

Guideline 16: Women as research subjects

Investigators, sponsors or ethical review committees should not exclude women of reproductive age from biomedical research. The potential for becoming pregnant during a study should not, in itself, be used as a reason for precluding or limiting participation. However, a thorough discussion of risks to the pregnant woman and to her

fetus is a prerequisite for the woman's ability to make a rational decision to enrol in a clinical study. In this discussion, if participation in the research might be hazardous to a fetus or a woman if she becomes pregnant, the sponsors/ investigators should guarantee the prospective subject a pregnancy test and access to effective contraceptive methods before the research commences. Where such access is not possible, for legal or religious reasons, investigators should not recruit for such possibly hazardous research women who might become pregnant.

Guideline 17: Pregnant women as research participants
Pregnant women should be presumed to be eligible for participation in biomedical research. Investigators and ethical review committees should ensure that prospective subjects who are pregnant are adequately informed about the risks and benefits to themselves, their pregnancies, the fetus and their subsequent offspring, and to their fertility.

Research in this population should be performed only if it is relevant to the particular health needs of a pregnant woman or her fetus, or to the health needs of pregnant women in general, and, when appropriate, if it is supported by reliable evidence from animal experiments, particularly as to risks of teratogenicity and mutagenicity.

Guideline 18: Safeguarding confidentiality
The investigator must establish secure safeguards of the confidentiality of subjects' research data. Subjects should be told the limits, legal or other, to the investigators' ability to safeguard confidentiality and the possible consequences of breaches of confidentiality.

Guideline 19: Right of injured subjects to treatment and compensation
Investigators should ensure that research subjects who suffer injury as a result of their participation are entitled to free medical treatment for such injury and to such financial or other assistance as would compensate them equitably for any resultant impairment, disability or handicap. In the case of death as a result of their participation, their dependants are entitled to compensation. Subjects must not be asked to waive the right to compensation.

Guideline 20: Strengthening capacity for ethical and scientific review and biomedical research

Many countries lack the capacity to assess or ensure the scientific quality or ethical acceptability of biomedical research proposed or carried out in their jurisdictions. In externally sponsored collaborative research, sponsors and investigators have an ethical obligation to ensure that biomedical research projects for which they are responsible in such countries contribute effectively to national or local capacity to design and conduct biomedical research, and to provide scientific and ethical review and monitoring of such research.

Capacity-building may include, but is not limited to, the following activities:

- establishing and strengthening independent and competent ethical review processes/committees
- strengthening research capacity
- developing technologies appropriate to health-care and biomedical research
- training of research and health-care staff
- educating the community from which research subjects will be drawn.

Guideline 21: Ethical obligation of external sponsors to provide health-care services

External sponsors are ethically obliged to ensure the availability of:

- health-care services that are essential to the safe conduct of the research;
- treatment for subjects who suffer injury as a consequence of research interventions; and
- services that are a necessary part of the commitment of a sponsor to make a beneficial intervention or product developed as a result of the research reasonably available to the population or community concerned.

Annex 1:

Items to be Included in a Protocol (or Associated Documents) for Biomedical Research Involving Human Subjects

(Include the items relevant to the study/project in question).

1. Title of the study;
2. A summary of the proposed research in lay/non-technical language.
3. A clear statement of the justification for the study, its significance in development and in meeting the needs of the country/population in which the research is carried out;
4. The investigators' views of the ethical issues and considerations raised by the study and, if appropriate, how it is proposed to deal with them;
5. Summary of all previous studies on the topic, including unpublished studies known to the investigators and sponsors, and information on previously published research on the topic, including the nature, extent and relevance of animal studies and other preclinical and clinical studies;
6. A statement that the principles set out in these Guidelines will be implemented;
7. An account of previous submissions of the protocol for ethical review and their outcome;
8. A brief description of the site(s) where the research is to be conducted, including information about the adequacy of facilities for the safe and appropriate conduct of the research, and *relevant* demographic and epidemiological information about the country or region concerned;
9. Name and address of the sponsor;
10. Names, addresses, institutional affiliations, qualifications and experience of the principal investigator and other investigators;
11. The objectives of the trial or study, its hypotheses or research questions, its assumptions, and its variables;
12. A detailed description of the design of the trial or study. In the case of controlled clinical trials the description should include, but not be limited to, whether assignment to treatment groups will be randomized (including the method of randomization), and whether the study will be blinded (single blind, double blind), or open;

13. The number of research subjects needed to achieve the study objective, and how this was statistically determined;
14. The criteria for inclusion or exclusion of potential subjects, and justification for the exclusion of any groups on the basis of age, sex, social or economic factors, or for other reasons;
15. The justification for involving as research subjects any persons with limited capacity to consent or members of vulnerable social groups, and a description of special measures to minimize risks and discomfort to such subjects;
16. The process of recruitment, e.g., advertisements, and the steps to be taken to protect privacy and confidentiality during recruitment;
17. Description and explanation of all interventions (the method of treatment administration, including route of administration, dose, dose interval and treatment period for investigational and comparator products used);
18. Plans and justification for withdrawing or withholding standard therapies in the course of the research, including any resulting risks to subjects;
19. Any other treatment that may be given or permitted, or contraindicated, during the study;
20. Clinical and laboratory tests and other tests that are to be carried out;
21. Samples of the standardized case-report forms to be used, the methods of recording therapeutic response (description and evaluation of methods and frequency of measurement), the follow-up procedures, and, if applicable, the measures proposed to determine the extent of compliance of subjects with the treatment;
22. Rules or criteria according to which subjects may be removed from the study or clinical trial, or (in a multi-centre study) a centre may be discontinued, or the study may be terminated;
23. Methods of recording and reporting adverse events or reactions, and provisions for dealing with complications;
24. The known or foreseen risks of adverse reactions, including the risks attached to each proposed intervention and to any drug, vaccine or procedure to be tested;
25. For research carrying more than minimal risk of physical injury, details of plans, including insurance coverage, to provide

treatment for such injury, including the funding of treatment, and to provide compensation for research-related disability or death;

26. Provision for continuing access of subjects to the investigational treatment after the study, indicating its modalities, the individual or organization responsible for paying for it, and for how long it will continue;
27. For research on pregnant women, a plan, if appropriate, for monitoring the outcome of the pregnancy with regard to both the health of the woman and the short-term and long-term health of the child;
28. The potential benefits of the research to subjects and to others;
29. The expected benefits of the research to the population, including new knowledge that the study might generate;
30. The means proposed to obtain individual informed consent and the procedure planned to communicate information to prospective subjects, including the name and position of the person responsible for obtaining consent;
31. When a prospective subject is not capable of informed consent, satisfactory assurance that permission will be obtained from a duly authorized person, or, in the case of a child who is sufficiently mature to understand the implications of informed consent but has not reached the legal age of consent, that knowing agreement, or assent, will be obtained, as well as the permission of a parent, or a legal guardian or other duly authorized representative;
32. An account of any economic or other inducements or incentives to prospective subjects to participate, such as offers of cash payments, gifts, or free services or facilities, and of any financial obligations assumed by the subjects, such as payment for medical services;
33. Plans and procedures, and the persons responsible, for communicating to subjects information arising from the study (on harm or benefit, for example), or from other research on the same topic, that could affect subjects' willingness to continue in the study;
34. Plans to inform subjects about the results of the study;
35. The provisions for protecting the confidentiality of personal

data, and respecting the privacy of subjects, including the precautions that are in place to prevent disclosure of the results of a subject's genetic tests to immediate family relatives without the consent of the subject;

36. Information about how the code, if any, for the subjects' identity is established, where it will be kept and when, how and by whom it can be broken in the event of an emergency;
37. Any foreseen further uses of personal data or biological materials;
38. A description of the plans for statistical analysis of the study, including plans for interim analyses, if any, and criteria for prematurely terminating the study as a whole if necessary;
39. Plans for monitoring the continuing safety of drugs or other interventions administered for purposes of the study or trial and, if appropriate, the appointment for this purpose of an independent data-monitoring (data and safety monitoring) committee;
40. A list of the references cited in the protocol;
41. The source and amount of funding of the research, the organization that is sponsoring the research and a detailed account of the sponsor's financial commitments to the research institution, the investigators, the research subjects, and, when relevant, the community;
42. The arrangements for dealing with financial or other conflicts of interest that might affect the judgement of investigators or other research personnel; informing the institutional conflict-of-interest committee of such conflicts of interest; the communication by that committee of the pertinent details of the information to the ethical review committee; and the transmission by that committee to the research subjects of the parts of the information that it decides should be passed on to them;
43. The time schedule for completion of the study;
44. For research that is to be carried out in a developing country or community, the contribution that the sponsor will make to capacity-building for scientific and ethical review and for biomedical research in the host country, and an assurance that the capacity-building objectives are in keeping with the values and expectations of the subjects and their communities;
45. Particularly in the case of an industrial sponsor, a contract stipulating who possesses the right to publish the results of the

study, and a mandatory obligation to prepare with, and submit to, the principal investigators the draft of the text reporting the results;

46. In the case of a negative outcome, an assurance that the results will be made available, as appropriate, through publication or by reporting to the drug registration authority;
47. Circumstances in which it might be considered inappropriate to publish findings, such as when the findings of an epidemiological, sociological or genetics study may present risks to the interests of a community or population or of a racially or ethnically defined group of people;
48. A statement that any proven evidence of falsification of data will be dealt with in accordance with the policy of the sponsor to take appropriate action against such unacceptable procedures.

Appendix H

World Medical Association Declaration of Helsinki[1]

Ethical Principles for Medical Research Involving Human Subjects

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996 and the
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
Note of Clarification on Paragraph 29 added by the WMA General Assembly, Washington 2002
Note of Clarification on Paragraph 30 added by the WMA General Assembly, Tokyo 2004

A. INTRODUCTION

1. The World Medical Association has developed the Declaration of Helsinki as a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects. Medical research involving human subjects includes research on identifiable human material or identifiable data.
2. It is the duty of the physician to promote and safeguard the health of the people. The physician's knowledge and conscience are dedicated to the fulfillment of this duty.

[1] World Medical Association Declaration of Helsinki, http://www.wma.net/e/policy/b3.htm. The Declaration of Helsinki (Document 17.C) is an official policy document of the World Medical Association, the global representative body for physicians.

3. The Declaration of Geneva of the World Medical Association binds the physician with the words, 'The health of my patient will be my first consideration', and the International Code of Medical Ethics declares that, 'A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient.'
4. Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.
5. In medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society.
6. The primary purpose of medical research involving human subjects is to improve prophylactic, diagnostic and therapeutic procedures and the understanding of the aetiology and pathogenesis of disease. Even the best proven prophylactic, diagnostic, and therapeutic methods must continuously be challenged through research for their effectiveness, efficiency, accessibility and quality.
7. In current medical practice and in medical research, most prophylactic, diagnostic and therapeutic procedures involve risks and burdens.
8. Medical research is subject to ethical standards that promote respect for all human beings and protect their health and rights. Some research populations are vulnerable and need special protection. The particular needs of the economically and medically disadvantaged must be recognized. Special attention is also required for those who cannot give or refuse consent for themselves, for those who may be subject to giving consent under duress, for those who will not benefit personally from the research and for those for whom the research is combined with care.
9. Research Investigators should be aware of the ethical, legal and regulatory requirements for research on human subjects in their own countries as well as applicable international requirements. No national ethical, legal or regulatory requirement should be allowed to reduce or eliminate any of the protections for human subjects set forth in this Declaration.

B. BASIC PRINCIPLES FOR ALL MEDICAL RESEARCH

10. It is the duty of the physician in medical research to protect the life, health, privacy, and dignity of the human subject.
11. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and on adequate laboratory and, where appropriate, animal experimentation.
12. Appropriate caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.
13. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol. This protocol should be submitted for consideration, comment, guidance, and where appropriate, approval to a specially appointed ethical review committee, which must be independent of the investigator, the sponsor or any other kind of undue influence. This independent committee should be in conformity with the laws and regulations of the country in which the research experiment is performed. The committee has the right to monitor ongoing trials. The researcher has the obligation to provide monitoring information to the committee, especially any serious adverse events. The researcher should also submit to the committee, for review, information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest and incentives for subjects.
14. The research protocol should always contain a statement of the ethical considerations involved and should indicate that there is compliance with the principles enunciated in this Declaration.
15. Medical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given consent.
16. Every medical research project involving human subjects should be preceded by careful assessment of predictable risks and

burdens in comparison with foreseeable benefits to the subject or to others. This does not preclude the participation of healthy volunteers in medical research. The design of all studies should be publicly available.

17. Physicians should abstain from engaging in research projects involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians should cease any investigation if the risks are found to outweigh the potential benefits or if there is conclusive proof of positive and beneficial results.
18. Medical research involving human subjects should only be conducted if the importance of the objective outweighs the inherent risks and burdens to the subject. This is especially important when the human subjects are healthy volunteers.
19. Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research.
20. The subjects must be volunteers and informed participants in the research project.
21. The right of research subjects to safeguard their integrity must always be respected. Every precaution should be taken to respect the privacy of the subject, the confidentiality of the patient's information and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.
22. In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely-given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed.

23. When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship with the physician or may consent under duress. In that case the informed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of this relationship.
24. For a research subject who is legally incompetent, physically or mentally incapable of giving consent or is a legally incompetent minor, the investigator must obtain informed consent from the legally authorized representative in accordance with applicable law. These groups should not be included in research unless the research is necessary to promote the health of the population represented and this research cannot instead be performed on legally competent persons.
25. When a subject deemed legally incompetent, such as a minor child, is able to give assent to decisions about participation in research, the investigator must obtain that assent in addition to the consent of the legally authorized representative.
26. Research on individuals from whom it is not possible to obtain consent, including proxy or advance consent, should be done only if the physical/mental condition that prevents obtaining informed consent is a necessary characteristic of the research population. The specific reasons for involving research subjects with a condition that renders them unable to give informed consent should be stated in the experimental protocol for consideration and approval of the review committee. The protocol should state that consent to remain in the research should be obtained as soon as possible from the individual or a legally authorized surrogate.
27. Both authors and publishers have ethical obligations. In publication of the results of research, the investigators are obliged to preserve the accuracy of the results. Negative as well as positive results should be published or otherwise publicly available. Sources of funding, institutional affiliations and any possible conflicts of interest should be declared in the publication. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

C. ADDITIONAL PRINCIPLES FOR MEDICAL RESEARCH COMBINED WITH MEDICAL CARE

28. The physician may combine medical research with medical care, only to the extent that the research is justified by its potential prophylactic, diagnostic or therapeutic value. When medical research is combined with medical care, additional standards apply to protect the patients who are research subjects.
29. The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic or therapeutic method exists.[3]
30. At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.[4]
31. The physician should fully inform the patient which aspects of the care are related to the research. The refusal of a patient to participate in a study must never interfere with the patient-physician relationship.
32. In the treatment of a patient, where proven prophylactic, diagnostic and therapeutic methods do not exist or have been ineffective, the physician, with informed consent from the patient, must be free to use unproven or new prophylactic, diagnostic and therapeutic measures, if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. Where possible, these measures should be made the object of research, designed to evaluate their safety and efficacy. In all cases, new information should be recorded and, where appropriate, published. The other relevant guidelines of this Declaration should be followed.

Appendix I

UNESCO's Universal Declaration on the Human Genome and Human Rights[1]

The General Conference,

Recalling that the Preamble of UNESCO's Constitution refers to 'the democratic principles of the dignity, equality and mutual respect of men', rejects any 'doctrine of the inequality of men and races', stipulates 'that the wide diffusion of culture, and the education of humanity for justice and liberty and peace are indispensable to the dignity of men and constitute a sacred duty which all the nations must fulfil in a spirit of mutual assistance and concern', proclaims that 'peace must be founded upon the intellectual and moral solidarity of mankind', and states that the Organization seeks to advance, 'through the educational and scientific and cultural relations of the peoples of the world, the objectives of international peace and of the common welfare of mankind for which the United Nations Organization was established and which its Charter proclaims',

Solemnly recalling its attachment to the universal principles of human rights, affirmed in particular in the Universal Declaration of Human Rights of 10 December 1948 and in the two International United Nations Covenants on Economic, Social and Cultural Rights and on Civil and Political Rights of 16 December 1966, in the United Nations Convention on the Prevention and Punishment of the Crime of Genocide of 9 December 1948, the International United Nations Convention on the Elimination of All Forms of Racial Discrimination of 21 December 1965, the United Nations Declaration on the Rights of Mentally Retarded Persons of 20 December 1971, the United Nations Declaration on the Rights of Disabled Persons of 9 December 1975, the United Nations Convention on the Elimination of All Forms of Discrimination Against Women of 18 December

[1] Adopted on the report of Commission III at the 26th plenary meeting, on 11 November 1997. http://portal.unesco.org/en/ev.php-URL_ID=13177&URL_DO=DO_TOPIC&URL_SECTION=201.html.

1979, the United Nations Declaration of Basic Principles of Justice for Victims of Crime and Abuse of Power of 29 November 1985, the United Nations Convention on the Rights of the Child of 20 November 1989, the United Nations Standard Rules on the Equalization of Opportunities for Persons with Disabilities of 20 December 1993, the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction of 16 December 1971, the UNESCO Convention against Discrimination in Education of 14 December 1960, the UNESCO Declaration of the Principles of International Cultural Co-operation of 4 November 1966, the UNESCO Recommendation on the Status of Scientific Researchers of 20 November 1974, the UNESCO Declaration on Race and Racial Prejudice of 27 November 1978, the ILO Convention (No. 111) concerning Discrimination in Respect of Employment and Occupation of 25 June 1958 and the ILO Convention (No. 169) concerning Indigenous and Tribal Peoples in Independent Countries of 27 June 1989,

Bearing in mind, and without prejudice to, the international instruments which could have a bearing on the applications of genetics in the field of intellectual property, inter alia the Berne Convention for the Protection of Literary and Artistic Works of 9 September 1886 and the UNESCO Universal Copyright Convention of 6 September 1952, as last revised at Paris on 24 July 1971, the Paris Convention for the Protection of Industrial Property of 20 March 1883, as last revised at Stockholm on 14 July 1967, the Budapest Treaty of the WIPO on International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedures of 28 April 1977, and the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPs) annexed to the Agreement establishing the World Trade Organization, which entered into force on 1 January 1995,

Bearing in mind also the United Nations Convention on Biological Diversity of 5 June 1992 and emphasizing in that connection that the recognition of the genetic diversity of humanity must not give rise to any interpretation of a social or political nature which could call into question 'the inherent dignity and (. . .) the equal and inalienable rights of all members of the human family', in accordance with the Preamble to the Universal Declaration of Human Rights,

Recalling 22 C/Resolution 13.1, 23 C/Resolution 13.1, 24 C/Resolution 13.1, 25 C/Resolutions 5.2 and 7.3, 27 C/Resolution 5.15 and 28 C/Resolutions 0.12, 2.1 and 2.2, urging UNESCO to promote and develop ethical studies, and the actions arising out of them, on the consequences of scientific and technological progress in the fields of biology and genetics, within the framework of respect for human rights and fundamental freedoms,

Recognizing that research on the human genome and the resulting applications open up vast prospects for progress in improving the health of individuals and of humankind as a whole, but **emphasizing** that such research should fully respect human dignity, freedom and human rights, as well as the prohibition of all forms of discrimination based on genetic characteristics,

Proclaims the principles that follow and **adopts** the present Declaration.

A. Human dignity and the human genome

Article 1

The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity.

Article 2

(a) Everyone has a right to respect for their dignity and for their rights regardless of their genetic characteristics.
(b) That dignity makes it imperative not to reduce individuals to their genetic characteristics and to respect their uniqueness and diversity.

Article 3

The human genome, which by its nature evolves, is subject to mutations. It contains potentialities that are expressed differently according to each individual's natural and social environment, including the individual's state of health, living conditions, nutrition and education.

Article 4

The human genome in its natural state shall not give rise to financial gains.

B. Rights of the persons concerned

Article 5

(a) Research, treatment or diagnosis affecting an individual's genome shall be undertaken only after rigorous and prior assessment of the potential risks and benefits pertaining thereto and in accordance with any other requirement of national law.

(b) In all cases, the prior, free and informed consent of the person concerned shall be obtained. If the latter is not in a position to consent, consent or authorization shall be obtained in the manner prescribed by law, guided by the person's best interest.

(c) The right of each individual to decide whether or not to be informed of the results of genetic examination and the resulting consequences should be respected.

(d) In the case of research, protocols shall, in addition, be submitted for prior review in accordance with relevant national and international research standards or guidelines.

(e) If according to the law a person does not have the capacity to consent, research affecting his or her genome may only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law. Research which does not have an expected direct health benefit may only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and if the research is intended to contribute to the health benefit of other persons in the same age category or with the same genetic condition, subject to the conditions prescribed by law, and provided such research is compatible with the protection of the individual's human rights.

Article 6

No one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity.

Article 7

Genetic data associated with an identifiable person and stored or processed for the purposes of research or any other purpose must be held confidential in the conditions set by law.

Article 8

Every individual shall have the right, according to international and national law, to just reparation for any damage sustained as a direct and determining result of an intervention affecting his or her genome.

Article 9

In order to protect human rights and fundamental freedoms, limitations to the principles of consent and confidentiality may only be prescribed by law, for compelling reasons within the bounds of public international law and the international law of human rights.

C. Research on the human genome

Article 10

No research or research applications concerning the human genome, in particular in the fields of biology, genetics and medicine, should prevail over respect for the human rights, fundamental freedoms and human dignity of individuals or, where applicable, of groups of people.

Article 11

Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. States and competent international organizations are invited to co-operate in identifying such practices and in taking, at national or international level, the measures necessary to ensure that the principles set out in this Declaration are respected.

Article 12

(a) Benefits from advances in biology, genetics and medicine, concerning the human genome, shall be made available to all, with due regard for the dignity and human rights of each individual.

(b) Freedom of research, which is necessary for the progress of knowledge, is part of freedom of thought. The applications of research, including applications in biology, genetics and medicine, concerning the human genome, shall seek to offer relief from suffering and improve the health of individuals and humankind as a whole.

D. Conditions for the exercise of scientific activity

Article 13

The responsibilities inherent in the activities of researchers, including meticulousness, caution, intellectual honesty and integrity in carrying out their research as well as in the presentation and utilization of their findings, should be the subject of particular attention in the framework of research on the human genome, because of its ethical and social implications. Public and private science policy-makers also have particular responsibilities in this respect.

Article 14

States should take appropriate measures to foster the intellectual and material conditions favourable to freedom in the conduct of research on the human genome and to consider the ethical, legal, social and economic implications of such research, on the basis of the principles set out in this Declaration.

Article 15

States should take appropriate steps to provide the framework for the free exercise of Research on the human genome with due regard for the principles set out in this Declaration, in order to safeguard respect for human rights, fundamental freedoms and human dignity and to protect public health. They should seek to ensure that research results are not used for non-peaceful purposes.

Article 16

States should recognize the value of promoting, at various levels, as appropriate, the establishment of independent, multidisciplinary and pluralist ethics committees to assess the ethical, legal and social issues raised by research on the human genome and its applications.

E. Solidarity and international co-operation

Article 17

States should respect and promote the practice of solidarity towards individuals, families and population groups who are particularly vulnerable to or affected by disease or disability of a genetic character. They should foster, inter alia, research on the identification, prevention and treatment of genetically based and

genetically influenced diseases, in particular rare as well as endemic diseases which affect large numbers of the world's population.

Article 18

States should make every effort, with due and appropriate regard for the principles set out in this Declaration, to continue fostering the international dissemination of scientific knowledge concerning the human genome, human diversity and genetic research and, in that regard, to foster scientific and cultural co-operation, particularly between industrialized and developing countries.

Article 19

(a) In the framework of international co-operation with developing countries, states should seek to encourage measures enabling:
   (i) assessment of the risks and benefits pertaining to research on the human genome to be carried out and abuse to be prevented;
   (ii) the capacity of developing countries to carry out research on human biology and genetics, taking into consideration their specific problems, to be developed and strengthened;
   (iii) developing countries to benefit from the achievements of scientific and technological research so that their use in favour of economic and social progress can be to the benefit of all;
   (iv) the free exchange of scientific knowledge and information in the areas of biology, genetics and medicine to be promoted.

(b) Relevant international organizations should support and promote the initiatives taken by states for the above-mentioned purposes.

F. Promotion of the principles set out in the Declaration

Article 20

States should take appropriate measures to promote the principles set out in the Declaration, through education and relevant means, inter alia through the conduct of research and training in interdisciplinary fields and through the promotion of education in bioethics, at all levels, in particular for those responsible for science policies.

Article 21

States should take appropriate measures to encourage other forms of research, training and information dissemination conducive to raising the awareness of society and all of its members of their

responsibilities regarding the fundamental issues relating to the defence of human dignity which may be raised by research in biology, in genetics and in medicine, and its applications. They should also undertake to facilitate on this subject an open international discussion, ensuring the free expression of various sociocultural, religious and philosophical opinions.

G. Implementation of the Declaration

Article 22

States should make every effort to promote the principles set out in this Declaration and should, by means of all appropriate measures, promote their implementation.

Article 23

States should take appropriate measures to promote, through education, training and information dissemination, respect for the above-mentioned principles and to foster their recognition and effective application. States should also encourage exchanges and networks among independent ethics committees, as they are established, to foster full collaboration.

Article 24

The International Bioethics Committee of UNESCO should contribute to the dissemination of the principles set out in this Declaration and to the further examination of issues raised by their applications and by the evolution of the technologies in question. It should organize appropriate consultations with parties concerned, such as vulnerable groups. It should make recommendations, in accordance with UNESCO's statutory procedures, addressed to the General Conference and give advice concerning the follow-up of this Declaration, in particular regarding the identification of practices that could be contrary to human dignity, such as germ-line interventions.

Article 25

Nothing in this Declaration may be interpreted as implying for any state, group or person any claim to engage in any activity or to perform any act contrary to human rights and fundamental freedoms, including the principles set out in this Declaration.

Date of Adoption 1997

Appendix J

Notifiable Diseases

Government Notice No. 75 of 2004, published in the Government Gazette of 27th January, 2004 in terms of the ***Public Health Act***, article 27(a)(i).

Acquired Immune Deficiency Syndrome
Acute encephalitis
Acute flaccid paralysis
Anthrax
Antimicrobial Resistance
Bacterial meningitis, other than meningococcal
Botulism
Brucellosis
Campylobacteriosis
Chlamydia infections
Cholera
Congenital rubella syndrome
Cryptosporidiosis
Dengue
Diphtheria
Dysentery (amoebic and bacillary)
Echinococcosis
Erysipelas
Foodborne illness-Unspecified
Giardiasis
Gonococcal infections
Granular conjunctivitis or trachoma
Hepatitis A
Hepatitis B
Hepatitis C
HIV-Infection
Infection with Enterohaemorrhagic E.Coli
Infections with Haemophilus Influenzae group B
Influenza

Legionellosis
Leishmaniasis
Leprosy
Leptospirosis
Listeriosis
Louse borne relapsing fever
Malaria
Measles
Meningococcal disease
Mumps
Nosocomial infections
Pertussis
Plague
Pneumococcal infections
Pneumonia
Poliomyelitis
Puerperal fever
Q-fever
Rabies
Rubella
Salmonellosis
Scarlet fever
Shigellosis
Smallpox
Sudden acute respiratory syndrome
Syphilis
Tetanus
Toxoplasmosis
Transmissible spongiform encephalopathies, variant
Creutzfeldt-Jakob's disease
Trichinosis
Tuberculosis
Tularaemia
Typhoid fever
Typhus fever
Varicella
Viral haemorrhagic fevers
Yellow fever
Yersinosis

Appendix K

European Council Recommendation on the Drinking of Alcohol by Young People

European Council Recommendation of 5 June 2001 on the drinking of alcohol by young people, in particular children and adolescents, 2001/458/EC, *Official Journal L 161, 16/06/2001 p. 0038–0041*

THE COUNCIL OF THE EUROPEAN UNION,
RECOMMENDS THAT:

I. In formulating their strategies and taking regulatory or other action appropriate to their individual circumstances, in the framework of a common approach across the Community, with respect to young people and alcohol, and with particular regard to children and adolescents, Member States, with the support as appropriate of the Commission, should:

1. promote research into all the different aspects of problems associated with alochol consumption by young people and, in particular, children and adolescents, in order to better identify and evaluate measures to deal with these problems;
2. ensure that the development, implementation and evaluation of comprehensive health promotion policies and programmes targeted at children, adolescents, their parents, teachers and carers, at local, regional, national and European level, should appropriately include the alochol issue, with a particular emphasis on settings such as youth organisations, sporting organisations and schools, and taking into account existing experiences for instance the 'health-promoting school';
3. produce and disseminate to interested parties evidence-based information on the factors which motivate young people, in particular children and adolescents, to start drinking;
4. foster a multisectoral approach to educating young people about alcohol, in order to help prevent the negative consequences of

its consumption, involving as appropriate, the education, health and youth services, law enforcement agencies, relevant non-governmental organisations and the media;

5. support measures to raise awareness of the effects of alcohol drinking, in particular on children and adolescents, and of the consequences for the individual and the society;
6. increase young people's involvement in youth health-related policies and actions, making full use of the contributions which they can make, especially in the field of information, and encourage specific activities which are initiated, planned, implemented and evaluated by young people;
7. encourage the production of advisory materials for parents to help them discuss alcohol issues with their children, and promote their dissemination via local networks such as schools, health care services, libraries, community centres as well as via the Internet;
8. further develop specific initiatives addressed to young people on the dangers of drink-driving, with a specific reference to settings such as leisure and entertainment venues, schools and driving schools;
9. take action as a matter of priority against the illegal sale of alcohol to under-age consumers and, where appropriate, require a proof of age;
10. suppport notably the development of specific approaches on early detection and consequent interventions aimed at preventing young people becoming alcohol-dependent.

II. Member States should, having regard to their different legal, regulatory, or self-regulatory environments, as appropriate:

1. encourage, in cooperation with the producers and the retailers of alcoholic beverages and relevant non-governmental organisations, the establishment of effective mechanisms in the fields of promotion, marketing and retailing;

   (a) to ensure that producers do not produce alcoholic beverages specifically targeted at children and adolescents;
   (b) to ensure that alcoholic beverages are not designed or promoted to appeal to children and adolescents, and paying particular attention *inter alia*, to the following elements:

- the use of styles (such as characters, motifs or colours) associated with youth culture,
- featuring children, adolescents, or other young-looking models, in promotion campaigns,
- allusions to, or images associated with, the consumption of drugs and of other harmful substances, such as tobacco,
- links with violence or anti-social behaviour,
- implications of social, sexual or sporting success,
- encouragement of children and adolescents to drink, including low-price selling to adolescents of alcoholic drinks,
- advertising during, or sponsorship of, sporting, musical or other special events which a significant number of children and adolescents attend as actors or spectators,
- advertising in media targeted at children and adolescents or reaching a significant number of children and adolescents,
- free distribution of alcoholic drinks to children and adolescents, as well as sale or free distribution of products which are used to promote alcoholic drinks and which may appeal in particular to children and adolescents;

(c) to develop, as appropriate, specific training for servers and sales persons with regard to the protection of children and adolescents and with regard to existing licensing restrictions on the sale of alcohol to young people;

(d) to allow manufacturers to get pre-launch advice, in advance of marketing a product or investing in a product, as well as on marketing campaigns before their actual launch;

(e) to ensure that complaints against products which are not being promoted, marketed or retailed in accordance with the principles set out in points (a) and (b) can be effectively handled, and that, if appropriate, such products can be removed from sale and the relevant inappropriate marketing or promotional practices can be brought to an end;

2. urge the representative producer and trade organisations of alocholic beverages to commit themselves to observe the principles above.

III. The Member States, with a view to contributing to the follow-up of this recommendation at Community level, and acting as

appropriate in the context of the programme of action in the field of public health, should report, on request to the Commission on the implementation of the recommended measures,

INVITES THE COMMISSION IN COOPERATION WITH MEMBER STATES:

1. to support the Member States in their efforts to implement these recommendations, especially by collecting and providing relevant comparable data, and by facilitating the exchange of information and best practices;
2. to promote further research at Community level into the attitudes and motivations of young people, in particular children and adolescents, in regard of alcohol consumption and monitoring of ongoing developments;
3. to follow-up, assess and monitor the developments and measures undertaken in the Member States and at Community level, and to ensure in this context a continuous, constructive and structured dialogue with all interested parties;
4. to report on the implementation of the proposed measures, on the basis of the information provided by Member States, no later than the end of the fourth year after the date of adoption of this recommendation and then regularly thereafter, to consider the extent to which the proposed measures are working effectively, and to consider the need for revision or further action;
5. to make full use of all Community policies, particularly of the programme of action in the field of public health, in order to address the matters covered in this recommendation.

Done at Luxembourg, 5 June 2001.