Malta, the European Union and the Medical Profession

I • EU accession – New frontiers for the Maltese Medical Profession

Louis Deguara

Political background

The Nationalist Party has, for the last thirty years, strongly believed that Malta's future is that of a full member of the European Union. This decision is rooted in political and economic considerations.

In this paper I will discuss why the medical profession should consider Malta's accession to the EU positively. I will also provide information that should dispel some of the common myths that doctors may have heard in circulation.

What EU Membership will mean for the Maltese medical profession

The Maltese medical profession will mainly be affected by the implications of the main EU Directives regulating free movement of doctors. At the outset it should be emphasised that a number of changes that are being carried out in the area of training and regulation of doctors had long been envisaged. Due to several pressing priorities most of the recommendations relating to specialist training or restructuring of working hours had never been taken up in earnest by successive governments. The EU accession process has acted as a catalyst for reform and provided an opportunity to set the ball rolling. The reforms that are being instituted have been discussed and decided upon with the medical profession. Indeed, irrespective of the outcome of the referendum, a new order has been set. We should recognise the opportunities that the accession process has provided in this regard.

Rights

Doctors who are fully registered with the Malta Medical Council will have the right to take up and pursue training or practice in any other Member State immediately upon accession without having to take any further exams such as the PLAB. The doctors' directive provides for automatic recognition to facilitate free movement. However it is not only doctors wishing to work/train overseas who will benefit from the provisions of the directive being transposed into the proposed Bill to regulate health care professions.

The provisions of the Bill that relate to granting of automatic recognition and enabling free movement of doctors between Malta and EEA countries will *only* come into force upon accession. However a number of provisions in the directive will be implemented as soon as the Health Care Professions Act is adopted later this year. This is being done because my Government firmly believes that EU legislation in this sector provides a model that we should adopt and follow in order to provide the necessary safeguards both for doctors and patients in Malta.

Therefore as a result of changes in the legislation, the Medical Council will be governed by a majority of elected doctors. The principal functions of the Medical Council remain mostly unchanged but the Council has been given more autonomy from the Ministry of Health.

The Medical Council will now be required to set up and maintain specialist registers. In order to be included in the specialist registers, a doctor would have to be in possession of a certificate testifying that he/she is a specialist. This certificate may be issued by the Malta Specialist Accreditation Committee that will be set up by the proposed legislation or by any equivalent competent authority in the EEA. Malta has been careful during the negotiations to ensure that existing doctors and specialists would benefit from Acquired Rights.

Louis Deguara MD, MP
Ministry of Health, Palazzo Castellania,
Merchants' Street, Valletta, Malta
Email: louis.deguara@gov.mt

Natasha Azzopardi Muscat MD, MSc, MSc(Lond.), DFPHM, DLSHTM
Office of Review, Ministry of Health
Palazzo Castellania, Merchants' Street, Valletta, Malta
Email: natasha.muscat@gov.mt

Malta is also obliged to provide structured specialist training in those areas where it is deemed that specialist training may be carried out fully or partly locally. This has been recognised by the team carrying out the evaluation of training for health care professionals earlier this year. These changes will revolutionise the way in which training is provided with benefits accruing to the trainees, trainers and the institutions in which training will be provided. The process has already started in partnership with the medical profession as represented by the specialist associations.

The new legislation will also provide for vocational training in general practice. Again this will change the face of training in general practice in Malta with benefits accruing to the health care system as primary care will undoubtedly be strengthened through the implementation of a programme of vocational training.

Doctors will also benefit from the introduction of the EU Working Time Directives. Malta has committed itself to introduce these measures for doctors as stipulated in the relevant Directive. Although this will signify the adoption of new practices for the employer and the professionals, I believe that this is truly the right way forward.

Obligations

Doctors will also have new obligations as a result of EU membership. Doctors will be obliged to show that they are carrying out continuing medical education. This obligation is written into the SLIM Directive published in 2001. The European Union has left it up to each Member State to decide how this policy will be implemented. Government has already taken steps to recognise the obligation of CME and is providing financial assistance for doctors it employs.

The medical professions will also be pivotal in ensuring that Malta carries out its role in ensuring pharmacovigilance successfully through the systematic reporting of adverse drug reactions and side-effects.

Dispelling the myths

Myths on the topic of Maltese doctors and EU accession have tended to centre round arguments of sudden influxes of doctors from the EU coming to take over work from Maltese doctors. Experience from other Member States has shown that in reality mobility amongst doctors is limited to less than 2% of doctors in the EU. Clear patterns of flows emerge with doctors migrating from poorer to richer countries, to countries where language is familiar and to countries with traditional links. Although recognition of qualifications is automatic, doctors still have to register with the competent authority and set about actually taking up activities. Even though language cannot be used as a barrier to free movement, employers can still require effective knowledge of language when advertising for certain positions where linguistic ability is clearly a must. Furthermore, the Maltese Government has successfully negotiated a special agreement whereby Malta may activate mechanisms should a sudden influx of workers threaten the labour market in any particular sector. This will be decided upon jointly between employing authorities and the medical profession in the case of doctors.

Another myth relates to the availability of medicines on the local market. For the first time ever, Malta will have a system for registration of medicines that will ensure that only those medicines that fit set criteria for quality, safety and efficacy will be available on the Maltese market. Government is taking all the necessary steps to ensure that this system is implemented as smoothly as possible and has achieved a four-year transition period for its implementation. The Ministry of Health has also obtained funds in the region of 0.9 million Euros to assist in capacity building for this project. A Twinning Arrangement with the UK and Ireland is about to be signed for the implementation of this project.

Achievements to date

The Ministry of Health has been very busy over the past three years with preparations for EU accession. It has successfully contributed to the Screening process, to the drawing up of the National Plan for the Adoption of the Acquis and it has embarked on an ambitious exercise re-writing almost all of the legislation regulating health and health care in Malta. It is generally accepted that existing health legislation no longer answers today's needs. The Acquis only served to make us focus on the urgency of bringing it up to date.

What remains to be done

What remains now is to actually start reaping the fruit of all the time and energy invested by the Ministry of Health and other stakeholders including the medical profession who were partners throughout the whole process.

It is expected that by the end of 2002 Parliament will adopt the new legislation regulating health care professions and medicines. This will pave the way to set up the necessary structures such as the Specialist Accreditation Committees. Implementing structured specialist training and continuing medical education will proceed earnestly thereafter.

Conclusion

Change always brings with it a fear of the unknown. The transition period will be a learning experience for all those involved. Participating in EU research and public health programmes will also be a novelty with some lessons to learn in the process.

However I have no doubt that the medical profession in Malta will meet the challenges it will face, will seek to maximise opportunities and sail through the transition with flying colours.

II • The EU accession process
How EU membership will influence the Maltese Medical Profession

Natasha Azzopardi Muscat

Introduction

The accession process has provided several valuable insights into the policies and workings of the European Union. Many policy changes that have a potential impact on doctors are already being implemented as part of the accession process whilst others have been devised and will be implemented in the coming months. These policies that are being implemented according to the National Plan for the Adoption of the Acquis, had mainly been mooted and discussed for several years. In this sense the EU accession process has served as a catalyst to bring about changes that had been long deemed desirable and necessary.

The objective of this paper is to describe EU policies in the spheres that concern doctors and analyse how the Maltese Medical Profession could expect to be affected by these policies.

EU policy in health and health care

It is a widely held belief that the European Union has never really involved itself with health and health care because Member States have always safeguarded their rights to keep health care policy making firmly within national jurisdiction. As a result the EU, until recently, never felt the need to give health a high profile. It was only with the latest reorganisation of the Commission that health now officially features in the newly created Directorate General for Health and Consumer Protection. This could be viewed as a reactive decision in response to public health issues that had received immense publicity, notably the BSE-CJD outbreak.

However a closer look at EU legislative instruments will show that health and health care in Community policies has existed from the start. In 1951 the European Coal and Steel Treaty established basic provisions for occupational health and safety. However the real breakthrough that laid the basis for actions that influence health and health care originated from the Treaty of Rome in 1957. This Treaty established the four "freedoms" namely:

- Free Movement of Persons
- Free Movement of Goods
- Free Movement of Services
- Free Movement of Capital

Although this Treaty does not make explicit reference to health or health care, a study that reviewed Community instruments illustrated that the main EU policies affecting health/health care today arise almost entirely from the Acquis on Free Movement of Persons and to some extent Free Movement of Goods.

It was only the Maastricht Treaty in 1992 that formally recognised health matters specifically as an EU competence. This competence is further reinforced in Article 152 of the Amsterdam Treaty. The article does show up incongruencies between the stated overall objective of working to ensure a high level of health protection across all the Union and the very specific areas mentioned as being foci for EU action e.g. blood safety, cells and tissue safety, drugs. A new Directive on blood quality and safety was adopted last year and the Commission is currently preparing to launch a Directive of quality and safety of cells and tissues. Malta has been asked to contribute to this exercise as a candidate country by means of a detailed questionnaire on current practices in this sphere.

Mutual recognition of professional qualifications

The expected impact of European Union legislation and policy on the Maltese medical practitioner arises almost entirely from the Acquis on Mutual Recognition of Professional Qualifications. This Acquis is in the form of Directives with the most relevant Directives being 93/16/EEC[1] and 2001/19/EC[2]. A Member State must introduce directives into the national legislation for them to become law. The above mentioned Directives are being transposed into Maltese legislation through the Bill to regulate Health Care Professions.

Legislation regulating health care professions in the EU can be split into two categories. Sectoral Directives exist for doctors, dentists, midwives, nurses, pharmacists and vets. All other regulated health care professions fall under the General Systems Directives.

The Sectoral Directives detail the training of the professionals. For doctors this includes both basic and specialist training. Although a migrating medical practitioner will still need to seek registration with the national competent authority equivalent to the Malta Medical Council, in practice this cannot be refused on academic grounds since training for doctors is harmonised across the EU.

This situation is different for the professions regulated by the General Systems Directives. Here the EU does not harmonise training. Qualifications and experience are assessed by the national competent authorities and only in those cases where a "significant" shortfall of knowledge or experience exists can the competent authority impose that the prospective migrant choose between carrying out an adaptation period under supervision or an aptitude test. This system is important for doctors because the EU is proposing to move away from the sectoral Directives towards the General Systems of recognition for all professions. This has met with resistance from the organised bodies

representing doctors at a European level.

Doctors can expect the following to arise directly as a consequence of the EU accession process. Upon accession Maltese doctors will have the right to seek registration and take up activities in any EU Member State in line with the provisions laid out in Directive 93/16/EC[1]. Likewise, EU nationals who are doctors may seek registration with the Medical Council to take up activities in Malta. The Medical Council cannot refuse registration on the basis of insufficient linguistic capability but the onus for ensuring effective communication with peers and patients shall be placed on the migrating doctor. However the employer may always require certain linguistic competence wherever this may be justified. [9]

The doctors' Directive covers both employed and self-employed doctors. It should be noted that as a result of negotiations, Malta has obtained safeguards that allow action to be taken should the numbers of employed EU nationals threaten to disrupt a particular sector.[10] This will also apply to employed doctors. Of course it should be emphasised that free movement will only be implemented upon accession even though the legislation will be adopted later in 2002.

Other changes are taking place now as a result of the EU accession process. Malta has to set up a system to accredit specialists. Once specialists are accredited they may be registered in specialist registers to be kept by the Medical Council. Malta also needs to develop structured specialist training. The Ministry of Health is working closely with the specialist associations in order to move towards implementation of structured specialist training.

The doctors' directive also lays out the requirement for a system of vocational training in general practice. This system will shortly be launched bringing new opportunities for the development of general practice in Malta.

Working Conditions for Doctors

Doctors are now included in the Working Time Directive. [6] The employer may not oblige doctors to work more than 48 hours a week averaged out over a period of time. The Directives also stipulates breaks and rest periods. This is important for clinicians and also for patient safety. Doctors may opt out of the Working Time Directive if they wish to do so as long as they do not endanger their health or that of others. Training and work practices may therefore need to be restructured.

Coordination of social security – Health Care

Coordination of social security including health care is carried out through regulations 1408/71/EEC. This provides for temporary visitors such as tourists in possession of an E111 form (or health card in the future) to obtain care that is considered to be immediately necessary. Malta can then request reimbursement for such care post event. The Health Division still needs to formulate an operational definition of "emergency" care.

Patients may opt to apply for elective treatment overseas by means of the E112 procedure. This would require authorisation as is done at present though the Treatment Abroad Advisory Committee.

Although Article 152 highlights that the organisation and delivery of health care systems is a national matter, recent rulings of the European Court of Justice have decreed that it is unacceptable practice to refuse to authorise treatment across borders, if the care is scientifically proven and unavailable in the Member State within an acceptable time period. However the ECJ also took into account that the financial sustainability of health care systems should be kept in mind. These rulings raised concern by Member States with Health Ministers seeking to influence the course of the debate., As a result, a high-level process of reflection was launched at the Seville Council in June 2002.

Medicines

The European Union policy in this sector centres round ensuring quality, safety and efficacy of medicines. This will necessitate change to the current system of licensing products for human use. [7]

Doctors will be directly involved in the implementation of a new system of pharmacovigilance. The directive on clinical trials has implications for doctors engaged in clinical research.

Public health

The EU health strategy for the coming years has the following three priorities:

- Improving health information
- Reacting rapidly to health threats
- Tackling determinants of health to reduce inequalities in health

It is expected that Malta will benefit from experience and expertise in other countries in the above three sectors through the recently adopted Public Health Programme.

Conclusion

The medical profession is already experiencing the effects of EU accession as a number of preparations and changes are taking place. EU accession brings with it new opportunities for networking and opportunities for those wishing to work overseas. EU accession also brings new opportunities and challenges for the medical profession locally. The medical profession should seek to welcome these changes and lend full support to their implementation, in partnership with the authorities.

References

1 Council Directive 93/16/EEC of 5 April 1993 to facilitate the free movement of doctors and the mutual recognition of their diplomas, certificates an other evidence of formal qualifications. Official Journal L 165: 1-24 Brussels, 7 July 1993.
2 Directive 2001/19/EC of the European Parliament and of the Council of 14 May 2001 concerning the professions of nurse responsible for general care, dental practitioner, veterinary surgeon, midwife, architect, pharmacist and doctor. Official Journal L 206 1-50
3 Malta's Negotiating Position Paper'– Chapter 2 Free Movement of Persons http://www.gov.mt/frame.asp?l=1&url=http://www.mic.org.mt/ Accessed on 06.09.02
4 Expert mobilisation in the field of sectoral directives on professional recognition – Doctors- Draft Report (Unpublished)
5 Council Directive 93/104/EC of 23 November 1993 concerning certain aspects of the organisation of working time. Official Journal L 307: 18-29
6 Directive 2000/34/EC of the European Parliament and of the Council of 22 June 2000 amending Council Directive 93/104/EC concerning certain aspects of the organisation of working time to cover sectors and activities excluded from that Directive. Official Journal L 195: 41-45
7 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, Official Journal L311, 28/11/2001:67-128
8 Jinks C, Ong BN, Paton C. Mobile Medics? The mobility of doctors in the European Economic Area; Health Policy 2000 Nov 1;54(1):45-64
9 Birt C. The European Union: Open to the practising physician? Clinical Medicines 2(3) May/June 2002 224-226
10 Results of the Negotiations – Chapter 2 Free Movement of Persons http://www.gov.mt/frame.asp?l=1&url=http://www.mic.org.mt/ Accessed on 09/09/02
11 Results of the Negotiations – Chapter 1 Free Movement of Goods http://www.gov.mt/frame.asp?l=1&url=http://www.mic.org.mt/ Accessed on 09/09/02
12 Jakubowski E, MacLehose L. EU accession – is it healthy? Euro Observer 3(3) 3-5
13 National Plan for the Adoption and Implementation of the Acquis Jan 2002: Section 3.1.2 Free Movement of Persons http://www.gov.mt/frame.asp?l=1&url=http://www.mic.org.mt/ Accessed on 09/09/02
14 The Treaty of Rome Commission of the European Communities Brussels 1957.
15 The Impact of the Single European Market on Member States Volume 50 Biomedical and Health Research. Edited by: R. Busse, M. Wismar and P.C. Berman 2002, ISBN: 1 58603 209 7
16 The Treaty of Rome as amended at Maastricht (the Treaty on European Union) Article 129, Commission of the European Communities Brussels 1991
17 The Treaty of Rome as amended at Amsterdam Article 152, Commission of the European Communities Brussels 1997
18 Mossialos E, McKee M. The Amsterdam Treaty and the future of European Health Services. J. Health Serv Res Policy 1998 Apr 3(2):65-7
19 Directives 89/48/EEC and 92/51/EEC on the general systems for the recognition of professional qualifications
20 European Commission staff working paper on the future regime for professional recognition. Document MARKT/D/8131/3/2001 Brussels 21 May 2001
21 Regulation EEC 1408/71 of the Council on the application of social security schemes to employed persons and their families moving within the Community, Official Journal 1971 (II) 416. See also Council Regulation EC 118/97nOfficial Journal 1997 L28,1 (for most recent codified version).
22 European Court of Justice, Judgement of the Court Case- Case C-157/99 Garaets-Smits and Peerbooms [2001] ECR I - 0000
23 Mossialos E, McKee M. Is a European healthcare policy emerging? BMJ 2001 Aug 4; 323(7307):248
24 Mossialos E, McKee M. Health Care and the European Union. BMJ 2002 Apr 27; 324(7344):991-2
25 Directive 2001/20/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of Member States relating to the implmentation of Good Clinical Practice in the conduct of Clinical Trials on medicinal products for human use, Official Journal L121,01/05/2001:34-44
26 Piha T. The new EU heatlth strategy – moving forward through communication and debate. Eurohealth Vol 6(4) Autumn 2000 6-9
27 Mossialos E, McKee M. A new European Health Strategy BMJ 2000 Jul 1; 321(7252):6
28 Programme of Community Action in the field of Public Health (2001-2006), Official Journal c 301 31/10/2001:27-40