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Report

drawn up on behalf of the Committee on the Environment
Public Health and Consumer Protection

on a European Charter on the Rights of Patients

Rapporteur: Mrs Marie-Jane PRUVOT

PE 83.244/fin.

At its sitting of 16 December 1980 and 16 January 1981, the European Parliament referred the motion for a resolution tabled by Mrs Krouwel-Vlam (Doc. 1-715/80) and the motion for a resolution tabled by Mrs Squarcialupi (Doc. 1-815/80) pursuant to Rule 47 of the Rules of Procedure to the Committee on the Environment, Public Health and Consumer Protection as the committee responsible and to the Legal Affairs Committee for an opinion.

At its meeting of 19 March 1981 the Committee on the Environment, Public Health and Consumer Protection decided to draw up a report and appointed Mrs Pruvot, rapporteur.

The Committee considered the draft report at its meetings of 3 November 1982, 15 June 1983 and 17 October 1983. At the last meeting it adopted the motion for a resolution as a whole by 8 votes to 1 with 4 abstentions.

The following took part in the vote: Mr. Collins, chairman; Mrs. Weber and Miss Hooper, vice-chairmen, Mrs Pruvot, rapporteur, Mr Del Duca, Mr Forth, Mrs van Hemeldonck, Mrs Maij-Weggen (deputizing for Mr Ghergo), Mr Muntingh, Mrs Pantazi, Mrs Schleicher, Dr Sherlock and Mrs. Squarcialupi.

The opinion of the Legal Affairs Committee is attached.

The report was submitted on 27 October 1983.

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The Committee on the Environment, Public Health and Consumer Protection hereby submits to the European Parliament the following motion for a resolution:

MOTION FOR A RESOLUTION

on a European Charter on the Rights of Patients

The European Parliament,

- having regard to the motion for a resolution tabled by Mrs Krouwel-Vlam (Doc. 1-715/80),
 - having regard to the motion for a resolution tabled by Mrs Squarcialupi (Doc. 1-815/80),
 - having regard to the report of the committee responsible and the opinion of the Legal Affairs Committee (Doc. 1-970/83);
- A. whereas the right to the best possible medical treatment is a fundamental right recognized throughout the Community,
- B. whereas the organizations which represent patients, doctors and the various health care establishments, both public and private, have redoubled their efforts to provide better information for patients, but this information is far from complete;
- C. whereas a considerable amount of work has already been done on the drafting of a Charter on the Rights of Patients,
1. Considers it necessary for patients' rights to be defined at European level;
 2. Calls on the Commission to submit as soon as possible a proposal for a European Charter on the Rights of Patients;
 3. Stresses that this charter must incorporate the following rights:
 - (a) the right to available treatment and care appropriate to the illness,
 - (b) the right to free choice of medical practitioner and health care establishment,

- (c) the right to information concerning diagnosis, therapy and prognosis, the patient's right of access to his own medical data, and the patient's right to give his consent to or to refuse the treatment proposed;
 - (d) the right to medical confidentiality, the only possible exceptions to which should be on a limited number of serious and well-defined grounds, having due regard for the integrity of the human person;
 - (e) the right to complaint based on "damage to the interests of the patient";
 - (f) the right to an appeal procedure before the courts;
 - (g) the rights and duties of medical practitioners,
 - (h) the definition of the legal status of the patient in a health care establishment;
 - (i) the right to respect for private life and for religious and philosophical convictions on a basis of pluralism;
 - (j) the right to a dignified death;
4. Considers that it may be necessary in certain well defined circumstances, to limit the rights of patients where such rights would be in conflict with the common good;
 5. Is of the opinion that the specific problems pertaining to the rights of the mentally ill and of children should not be dealt with in this context but in a special charter;
 6. Instructs its President to forward this resolution to the Commission and Council of the European Communities.

EXPLANATORY STATEMENT

INTRODUCTION

1. In December 1980, Mrs KROUWEL-VLAM tabled a motion for a resolution, pursuant to Rule 25 of the Rules of Procedure, requesting the Commission to submit a proposal on the introduction of a European Charter on the Rights of Patients and stating the provisions to be contained in the charter.
2. In January 1981, Mrs SQUARCIALUPI tabled a motion for a resolution on the same subject.
3. In the last ten years, various organizations representing patients have redoubled their efforts in calling for better information for patients and a great deal of work has been done in this field, both within the Member States and at international level.

DEVELOPMENT OF THE RECOGNITION OF PATIENTS' RIGHTS

4. A comprehensive study on this subject has already been carried out by the Council of Europe in the form of a report drawn up in 1976 by Mrs HUBINEK and Mr VOOGD. This report refers to the various moral codes drawn up since 1945:

- The International Code of Medical Ethics (London 1949)
- The Geneva Declaration (1948).

The report also quotes from the Patient's Bill of Rights in existence in the USA since 1972, which aroused considerable interest throughout the world at the time of its publication (see Annex I).

Reference should also be made to the statements by international and European professional organizations:

- Nuremberg Code on experiments on humans (1947)
- Twelve principles of social security and medical care (October 1963 - World Health Organization)
- Helsinki/Tokyo Declaration (World Health Organization - 1964 and 1975)

- Charter of Hospital Doctors of the EEC (Standing Committee of Doctors of the EEC - April 1967)
- Sydney Declaration - WHO (1968)
- Statement of the American Hospital Association on a Patient's Bill of Rights (1972)
- Respect for personal rights in hospital treatment - La Baule 1979 - European Committee on Private Hospitalization
- Resolution on the Patients' Charter - Standing Committee of Doctors of the EEC - Dublin 1980
- Declaration on patients' rights - WHO Lisbon (1980)
- Nuremberg Declaration on medical practice
- Copenhagen Declaration on the control of expenditure on health care.

5. In 1974, the French Ministry of Health and Social Security issued a decree entitled 'Charter of the Rights and Duties of the Sick'. More recently, the Hospital Committee of the EEC has adopted a Charter on the Rights of Patients.

6. In April 1980, the Committee of Ministers of the Council of Europe adopted a recommendation on the implementation of programmes to encourage the active participation of patients in their treatment.

7. Finally, the Commission has announced that it is able to endorse the general objectives of a charter on the rights of patients¹.

THE EUROPEAN CHARTER ON THE RIGHTS OF PATIENTS

8. The resolution tabled by Mrs KROUWEL-VLAM states that a European Charter on the Rights of Patients should form the basis for national legal provisions on the rights and duties of the individual. Although it is definitely possible to pass legislation in this field, it is by no means certain that rights such as the right to dignity can be governed by specific texts.

9. The rapporteur therefore feels that a charter of this kind, if adopted by the Member States, should be restricted to laying down guidelines and that the question of legislation as such should be left to the discretion of the Member States. Anyone seeking to introduce legislation in this field must tread warily in view of the moral and religious issues involved.

¹ Written Question No. 242/79

Private and public hospitals must guarantee the patient complete moral, philosophical, political and religious freedom - conditions which are essential for a relationship of trust between patient and doctor.

10. The rapporteur naturally agrees with the authors of the resolution on the following rights:

A. Right to treatment and care appropriate to the illness

- This right raises the problem of supplying the medical profession with the instruments needed to cure certain types of illness. It therefore presupposes that there will be no restrictions as regards care or organization to impede access to care facilities in keeping with the current state of scientific progress.
- For economic reasons the medical equipment available is limited and since it will therefore be used by a greater number of patients, is likely to prove inadequate.
Can legislation impose a programme for the provision of medical care and prevent the supply of equipment which might be available? The practical implementation of this right of access to medical care implies that society must provide minimum cover of costs (social security system).
- This right should also enable the patient to be treated in the country of his choice according to the equipment and facilities available in that country.
Some facilities are already available:
 - as a result of certain administrative arrangements, a person who is involved in an accident or who falls ill in a country other than his own may be treated in that country under the social cover provided by the Member State of which he is a national;
 - the corollary to this right is the 'technical and moral independence' which must be granted to the practitioner (Administrative regulations preventing or restricting these decisions).

B. Right to free choice of medical practitioner

This right implies the right to change doctors. Some countries (Denmark,

Netherlands, Great Britain) which operate a system of lists (all citizens must register with a doctor even if they are not ill), place restrictions on this right in so far as it takes time to change lists.

In order to receive treatment , a patient must prove that the facilities or therapy appropriate to his illness are not available in his own country.

Except in this one case, the cost of travel and medical care is not reimbursed by the social security authorities of his country of origin.

C. Right to information concerning diagnosis, therapy and prognosis

The doctor provides the patient with this information in order to obtain his consent - a form of joint decision. The information given should take account of the patient's understanding without affecting the treatment or the patient's state of mind. This right should enable the patient to give his consent to the course of treatment 'freely and with full knowledge of the facts'.

The patient, who is generally unfamiliar with the scientific and technical aspects of the care he requires, cannot decide on his own course of treatment.

Having heard details of the treatment prescribed by the practitioner, he must give or withhold his consent to the treatment he is to follow. The problem may present itself differently according to the urgency of the case.

D. Right to confidentiality

It is hard to define this prerogative.

Is it absolute or relative?

Should it be restricted to the interests of the patient or his family?

This restriction (applied generally or for each individual case) raises personal issues many of which are covered by private law (succession, divorce etc.).

E. Right to take legal proceedings

Legal proceedings should make it possible to establish to what extent the

patient has received 'conscientious', diligent care in keeping with the current state of scientific progress and the rules of medical practice. What attitude should we adopt towards a conciliation body to which patients could submit their complaints and before which the doctor would have no legal privileges?

It could be a permanent body or could be replaced by a mediator selected by both parties.

This procedure would not exclude the possibility of legal proceedings.

F. Legal position of the patient in health care establishments

In this connection it will also be necessary to define the rights concerning the management of the patient's property.

G. Right to die with dignity

Doctors' determination to continue therapy does not always allow the patient to die as he would have wished. This is a philosophical issue.

In any event, the patient must be allowed dignity.

12. In certain cases, it may prove necessary to restrict the rights outlined above. For example, access to medical records can be of great importance to researchers, and the right to privacy could in this case be in contradiction with the advancement of medical knowledge.

13. The legal situation of patients unable to make a clear and reasoned decision concerning the treatment needed to effect a cure raises such substantial problems that it would have to be dealt with in a special charter. The position of these people, i.e. children and mentally handicapped, is too specific to be covered in a general charter.

14. The rapporteur feels that in view of the worldwide movement for the protection of the rights of the sick, it would be appropriate for the Commission to submit proposals along the lines suggested above. Sufficient work has already been done in this field to enable it to draw conclusions and it would be superfluous for our committee to add to the considerable number of studies already carried out.

The Commission should base its proposal on the report by the Council of Europe and the texts referred to in paragraph 4. In the meantime, the committee will make no further detailed comments.

MOTION FOR A RESOLUTION (Doc. 1-715/80)

tabled by Mrs Krouwel-Vlam, Mrs Seibel-Emmerling, Mr Collins, Mrs Fullet, Mrs Roudy, Mrs Weber, Mr Muntingh, Mr O'Connell and Mr Adam
 on behalf of the Socialist Group
 pursuant to Rule 25 of the Rules of Procedure
 on a European Charter on the Rights of Patients

The European Parliament,

- whereas the right to the best possible medical treatment is a fundamental social right acknowledged by each of the Member States of the Community,
- whereas, as a result of the rapid development of medical technology in respect of both diagnosis and therapy in the last few decades, the services provided to the individual patient have become extremely impersonal because of the administrative gigantism and systematization of health care,
- whereas developments in the field of medicine which have led to widespread rationalization in the organization of health care and changing social attitudes towards democratization and the right of the individual to greater participation and to legal protection imply that the need for legal recognition and definition of the rights of the patient/consumer is greater than ever before,
- whereas under pressure from the increasing number of patients' organizations, action groups and the activity of consumer associations in certain Member States the first steps have been taken towards making the relationship between patient and practitioner subject to legal rules,
- having regard to the declaration of the European Council of 1976 on the rights of patients;

1. Notes that:

in pursuance of the declaration of the European Council a European Charter on the Rights of Patients must be established which, as the basis for the individual domestic legal provisions, must contain at least the following provisions in this sector:

- the right to treatment and care appropriate to the illness,
- the right to free choice of medical practitioner,
- the right to information concerning diagnosis, therapy and prognosis,
- the right of the individual to a say in decisions concerning type of treatment,
- the right to confidentiality,
- the right to a legal procedure whereby medical treatment can be measured against current medical standards,

- the rights and duties of physicians (or other medical practitioners),
- the legal position of the patient in health care establishments,
- the right to an independent complaints procedure;

2. Requests the Commission to submit a proposal on the introduction of a European Charter on the Rights of Patients based on the report of the European Council.

MOTION FOR A RESOLUTION (Doc. 1-815/80)

tabled by Mrs Squarcialupi

pursuant to Rule 25 of the Rules of Procedure

on the charter of rights of the sick

The European Parliament,

- believing that good health is one of the principal rights of the citizen and that its possession depends in large measure on proper medical care,
- having regard to the fact that in many Community countries, despite increases in health-service expenditure which in some cases can no longer be met, such care is still largely lacking,
- whereas all persons suffering from illness are entitled to appropriate forms of therapy and to dignified treatment as human beings,
- bearing in mind the evolution of disease, which in the course of the industrial society's development has progressed from illnesses due to natural causes to those provoked by factors present in the industrial environment,
- approving the citizens' health-consciousness and their desire to have a direct say in the management of their physical and mental wellbeing,

1. Urges the Commission to:

- undertake studies - such as those on the relationship between patients and medical and paramedical personnel, or between the public and the health services - that will best clarify the situation of sick people in Community countries;
- submit at the earliest date proposals for a charter of the sick person's rights, on the lines already laid down by the Community's Hospitals Committee, that will also comprise the rights of the mentally sick and of hospitalized children,

2. Asks, moreover, to draw up a report on the extensive and complex problem of relations between medical institutions and the sick.

OPINION
of The Legal Affairs Committee
on
a European Charter on the Rights of Patients
Draftsman : Mrs I Van den HEUVEL

On 16 December 1980 Mrs Krouwel-Vlam and others tabled a motion for a resolution on 'a European Charter on the Rights of Patients' (Doc. 1-715/80)¹.

The motion for a resolution was referred to the Committee on the Environment, Public Health and Consumer Protection as the committee responsible.

On 19 March 1981 the Committee on the Environment, Public Health and Consumer Protection appointed Mrs Pruvot rapporteur.

The Legal Affairs Committee was asked to deliver an opinion and on 18 March 1981 appointed Mrs van den Heuvel draftsman.

At its meeting of 18/19 May 1982 the Legal Affairs Committee considered the draft opinion and requested the draftsman to submit an amended text to it at a subsequent meeting.

At its meeting of 23/24 November 1982 the committee considered the revised draft opinion and adopted the conclusions contained in it by 11 votes with 3 abstentions.

The following took part in the vote: Mrs Veil, chairman; Mr Luster and Mr Chambeiron, vice-chairmen; Mrs van den Heuvel, draftsman; Mrs Baduel Gloor, Mr D'Angelosante, Mr Geurtsen, Mr Goppel, Mr Janssen van Raay, Mr Poniridis, Mr Sieglerschmidt, Mr Tyrrell, Mrs Vayssade and Mr Vié.

¹ see Annex I

Introduction

1. The action taken in various countries by pressure groups and more specifically by patients' organizations with the aim of improving the lot of patients cannot be seen in isolation. It forms part of the general striving for emancipation which is now apparent among various groups of the population.
2. This action has rapidly won the support of the medical profession and has led to a start being made with legislation at government level in a number of countries.
3. The developments that have taken place in medical science, and in particular discoveries in the biological and biochemical fields, have given rise to disquiet among both (potential) patients and the medical profession. Technological developments, which have estranged medical practitioners from their patients and threaten the human relationship between them, have been a major factor in creating this climate of unease.
4. If one considers the complex moral, legal and social problems created by such developments as organ transplants, biogenetics and experiments on patients, it becomes clear not only why patients have come to feel a greater need to have a say in their treatment but also why the medical practitioners responsible for such treatment have called for a clearer link to be established between the humanitarian and technical/medical aspects of their profession. The demands made by patients' organizations, supported by the medical profession, are aimed in the first place at establishing the patient's right to information and, in addition, his right to guarantees as to the confidentiality of medical data and safeguards against any form of coercion regarding the treatment he or she is to undergo.
5. Proper information is essential if a patient is to safeguard his rights in his relationship with medical staff: A patient is only in a position to consent to (or refuse) medical treatment if he is provided with information which he can understand.
6. The trust which has to exist between a patient and medical staff should not present an obstacle to establishing a set of legally-binding rules to govern mutual obligations. Mutual trust is implicit in the conclusion of any agreement.

The doctor-patient relationship is no more delicate a matter than any other relationship governed by law (cf law governing matrimonial and parental relationships).

7. A patient's freedom to choose his doctor and hospital implies that he is fully aware of the facilities and conditions of treatment available. This is particularly important in the choice of a general practitioner. (Patients generally consult their G.P. on the choice of a specialist.)

8. The right to information concerning diagnosis and prognosis cannot be an absolute right. Under certain circumstances a doctor must remain free to withhold information if he feels that such information might be detrimental to his patient's recovery. However, if the information process is continuous, this will be necessary only in exceptional circumstances.

9. The right to information should take effect from birth and end at death. The latter does not apply to rights with posthumous effect such as the right to donate organs after death. The right to information should therefore not be transferable although, in the case of very young children for example, the parents should be informed. In cases where patients are incapable of making their wishes known, consent can be assumed. Clearly people can make provision for such an eventuality by means of a prior written statement.

10. A special situation arises in the case of persons who refuse treatment on religious grounds. Adults and young people with full powers of discretion have a legal right to refuse treatment. Where people in this category are incapable of making their wishes known, the provisions of the foregoing paragraph should apply. We must assume that Article 9 of the European Convention on the Protection of Human Rights also applies to children. As long as children are unable to voice their own opinions, religious grounds cannot be invoked and necessary medical treatment withheld on the grounds of the religious convictions of parents or others. Temporarily it may be necessary to suspend parental powers in whole or in part.

A European Charter

11. The motion for a resolution tabled by Mrs Krouwel-Vlam and others on 16 December 1980 (Doc. 1-715/80) calls for a European Charter on the Rights of Patients.

12. The European Commission has already expressed a favourable opinion on this matter in answer to a written question by Mr van Aerssen¹.

13. Although the protection of the medical practitioner is also an essential aspect of his relations with his patients, it should not be taken into consideration here. Most Member States already have rules establishing the rights and duties of medical practitioners. If these rules need to be supplemented, it should be done in some other way and not by a Charter on the Rights of Patients.

Legal basis

14. The provisions of the Treaty are not directly relevant to legislation in the area of public health unless reference is made to the statement in the Preamble to the Treaty that the essential objective of the Community's efforts must be the constant improvement of the living conditions of the citizens of Europe.

15. If one examines whether existing statutory and administrative provisions on patients' rights in the Member States have an impact on the common market within the meaning of Article 100, the answer is that they do not. The only other possibility afforded by the Treaty is to invoke Article 235.

16. This article makes general provision for action to attain Community objectives, one of which is the improvement of living conditions, and thus provides sufficient room for manoeuvre.

¹ Question No 242/79. Commission's answer: 'the Commission is able to endorse the general objectives of a Charter designed to safeguard the rights of hospital patients in the Member States of the European Community'.

17. This approach is consistent with point 15 of the Final Communiqué of the 1972 Paris Summit.

18. The Legal Affairs Committee has endorsed this view, for instance in connection with the reports on:

- the safeguarding of the fundamental rights of citizens (Doc. 297/72),
- the granting of 'special rights' to citizens of the European Community (Doc. 346/77).

19. Thus, Article 235 of the EEC Treaty is being invoked more and more frequently as a basis for measures in subsidiary areas of policy.

20. In the draftman's view it would be logical for the Community policy on consumers and public health to be accompanied by the drawing up of rules establishing the rights of patients.

21. The high degree of Community commitment to the protection of human rights is a further argument in favour of implementing the proposal made in the motion for a resolution.

International development of patients' rights

Health care as a fundamental social right

22. 'The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being ...'

This principle, laid down in the preamble to the Charter of the World Health Organization, adopted in 1946, provides the basis for a fundamental human right to health (care), as enshrined in the Universal Declaration of Human Rights, Article 25:

'Everyone has the right to a standard of living adequate for the health and well being of himself and his family including food, clothing, housing and medical care and necessary social services and the right of social security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.'

At European level, this universal right to medical care and health is given legal expression in the European Social Charter, Article 11 of which reads:

'With a view to ensuring the effective exercise of the right to protection of health, the Contracting Parties undertake, either directly or in co-operation with public or private organizations, to take appropriate measures designed inter alia:

1. to remove as far as possible the causes of ill-health,
2. to provide advisory and educational facilities for the promotion of health and the encouragement of individual responsibility in matters of health ...'

23. Finally, reference should be made to the resolution adopted by the World Health Organization (WHA 23, 41) in 1971 which states that 'the right to health is a fundamental human right'.

Rights of patients as a fundamental human right

24. The rights of patients are also linked with fundamental human rights. The Universal Declaration of Human Rights (1948) states in Article 3 that:

- everyone has the right to life, liberty and security of person,

and Article 5 refers to the fact that no one shall be subjected to inhuman or degrading treatment.

25. Article 12 of the Universal Declaration calls for legal protection of the individual against arbitrary interference in his personal affairs. It is obvious that in the case of the sick, who find themselves in a highly dependent and vulnerable position, these fundamental human rights need to be developed further.

26. Support for this view can be found in the International Covenant on Economic, Social and Cultural Rights (1966) which was unanimously adopted by the General Assembly and can therefore be seen as the codification of the results achieved by the Universal Declaration of Human Rights.

CONCLUSIONS

1. The Legal Affairs Committee welcomes the idea of giving legal expression to the rights of patients within the European Community.
2. The Legal Affairs Committee recommends that the committee responsible should request the European Commission to draw up proposals to this effect. The Commission has already reacted favourably to this proposal in its answer to the Written Question by Mr Van Aerssen (No. 242/79).
3. The Committee recommends further that these proposals be drawn up in the light of the health legislation already adopted by the Council, including that on pharmaceutical products and the specific directives on freedom of establishment for doctors and persons in the paramedical professions.
4. The Committee suggests that the draft charter for hospital patients drawn up by the Hospital Committee of the EEC and the work already done by the Council of Europe in this area, in particular the report submitted by Mr Voogd, also be taken into consideration by the committee responsible.
5. Such a charter should contain at least the following provisions:

- the right to available health care, including financial arrangements to ensure that care is available to every patient;
- the right to free choice of medical practitioner or hospital,
- the right to receive, as a rule, information concerning diagnosis, therapy and prognosis;
- the right to decide whether or not treatment should be started or continued;
- the right, as a rule, to inspect one's own medical records;
- the right to the protection of privacy;
- the right to a complaints procedure before an independent body.

