COMITÉ PERMANENT DES MÉDECINS EUROPÉENS
STANDING COMMITTEE OF EUROPEAN DOCTORS

Answers to the health services consultation Sec (2006)1195/4

The CPME would like to present the position of the European medical profession to the current consultation on health services and would continue to cooperate actively to the next steps of this Community action which is urgently needed in the interest of the patients.

The Standing Committee of European Doctors (CPME) and associated independent organisations, which are the European Association of Senior Hospital Doctors (AEMH), the European Conference of Orders (CEOM), the Group of Practitioners and Specialist in Free Practice (EANA), the European Forum of Medical Students Association (EMSA), the European Federation of Salaried Doctors (FEMS), the Permanent Working Group of European Junior Doctors (PWG), the European Union of General Practitioners (UEMO) and the European Union of Medical Specialists (UEMS) represent over 2 million doctors.

Introduction

The Standing Committee of European Doctors supports the free movement of patients and health professionals within the EU. The CPME wishes to emphasise the importance of achieving the highest possible level of medical training, medical practice and healthcare within the European Union[1].

High quality of care and free movement of patients and professionals are intertwined topics that should all be addressed within a Community framework.

As the discussion on the proposal for a Directive concerning services has clearly shown, healthcare is a case apart from other services and cannot therefore be treated as a mere economic/commercial service. Health services have specific characteristics that should be recognised and protected. As they deal with citizens' lives and well-being, health services need stricter controls and regulation than most other services. It is essential that Member States take responsibility for guaranteeing the quality and equal availability of healthcare for their citizens in all circumstances.

[1] Article 3 of the CPME Statutes
The objectives of the Standing Committee, a non profit-making organisation, are:
- the study and promotion of the highest level of medical training, medical practice and healthcare within the European Union;
- the study and promotion of the free movement of doctors within the European Union;
- the representation within this framework of the medical profession in the Member States of the European Union, to European Union authorities and any other authority and/or organisation dealing with questions directly or indirectly concerning the medical profession;
- and any action which might further the achievement of the aforementioned objectives.

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When dealing with health services, two perspectives should be considered: the right of the patient to receive safe and high-quality care all over the Union and the right of physicians to move, to obtain recognition of their medical qualifications and to establish a practice in another member state.

Patients prefer to be treated as close as possible to their home and family, where they can easily communicate without language problems. However, when necessary or by choice, they must be able to receive care abroad and their rights and the quality of their treatment must not be compromised.

Highlighting the free internal market, patients have challenged their national systems in court with regard to trans-border healthcare services and the several European Court of Justice rulings on the subject amount to a considerable body of case law. These individual case rulings concern new rights enabling patients to be reimbursed for ambulatory care and, under certain conditions, for hospital care received abroad.

These possibilities should be enshrined in a legal text in order to ensure legal certainty. However Member States remain responsible for offering the best possible care for their citizens.

Physicians move either to provide temporary services or to settle more permanently in another country. This is already regulated by the Directive 2005/036/EC.

Medical confidentiality, integrity and protection of data are overarching issues to be taken into account in all the answers given to the questions below. E-Health developments have to be supportive in this context.

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CPME answers to the questions as formulated by the Commission

Question 1) What is the current impact (local, regional, national) of cross-border healthcare on accessibility, quality and financial sustainability of healthcare systems, and how might this evolve?

With regard to patient mobility, two situations must be recognised:

- Movement of patients that is “organised” and supported by national authorities, either by specific agreements between bordering countries (i.e.: France and Belgium or Luxembourg and Germany) or contracts between institutions in different Member States.
  The impact is directly managed by the national authorities, without any unforeseen financial consequences.

- Patients who decide themselves to be treated abroad.

Currently there is a form of cross-border care regulated by Regulation 1408/71. This is applicable to retired people obtaining care in their secondary country of residence, to cross-border workers working in one country and living with their family in another, and to tourists when they need essential care.

There are also geographical reasons that could justify cross-border care. For instance in the case of small countries that are faced with the need to acquire care for their citizens abroad. In Luxembourg in recent years, up to 7% of the healthcare budget has been spent on cross-border care. Bigger countries have less populated areas where the nearest hospital is located in another country (for example, Norway, Sweden, Finland).

In order to formulate policy on cross-border healthcare, reliable and comparable data is essential. More transparency on the flow of patients is needed and it should be regularly provided by the national authorities and the insurance organisations.

The situation might evolve in the future under pressure from patients because they will become more and more interested in both the quality and the accessibility aspects of the care provided. The question will then be: where can I best be treated? The CPME is of the opinion that Europe should stimulate cooperative solutions in the area of rare diseases, for treatments that require a high level of technique, as well as the development of centres of reference.

Question 2) What specific clarifications and what practical information is required by whom (e.g.: authorities, purchasers, providers, patients) to enable safe, high-quality and efficient cross-border healthcare?

Different stakeholders have a role to play in order to improve the information given to the patients and to facilitate patient empowerment under optimum conditions[2].

The member state authorities should uniformly implement the existing rules on patient mobility in order to avoid discrepancies of patients being dependent on their country of affiliation.

However there is a need for a clear definition of both hospital and ambulatory care. The ECJ has also referred to 'undue delay' in obtaining diagnosis or therapy, a concept that is very difficult to define precisely.

As the differentiation between hospital and non-hospital care can carry financial consequences, the CPME recommends that the definition of hospital care should be as narrow as possible in order to facilitate free movement of patients.

[2] CPME document 2004/080

The CPME has previously suggested a definition[3] which reads "medical care under the supervision and responsibility of medical doctor(s) and provided in specific facilities where medical surveillance is available 24 hours a day and which normally requires accommodation in the facility."

However, the CPME considers it necessary to review this definition in order to be able to distinguish more effectively between hospital and ambulatory care. Further on in the process, the CPME intends to propose a revised definition.

With regard to the difficult concept of 'undue delay', the CPME wishes to stress that medically acceptable waiting times can only be defined on a case-by-case basis. They must therefore be determined by means of independent medical expertise that takes the patients' need fully into account.

Patients must have access to up-to-date and easily understandable information about their rights provided by the national authorities. This should include the conditions for obtaining care abroad, the rules for reimbursement together with clear information regarding appeal procedures when treatment is denied.

Physicians and other health professionals have a key role to play in providing their patients with information on the availability of care close to home and abroad. This highlights the need to have access to comparable information. For this purpose, the European Commission should provide a framework/template and encourage Member States to provide relevant information on the quality and availability of care in their countries.

Member States should be responsible for the content of the data, which should be offered in a standardised format. The system should be managed technically at EU level and could be included or linked to the EU Health portal.

Moreover, it is important to stress the need to exchange reliable, safe and confidential data. Developments in e-health should help to ensure this necessary security.

Question 3) Which issues (e.g.: clinical oversight, financial responsibility) should be the responsibility of the authorities of which country? Are these different for the different kinds of cross-border healthcare described in section 2.2 above?

Clinical oversight should be the responsibility of the country where the care is given, as supervision from the home country is not realistic.

In most cases, continuity of care is better ensured in the country of residence.

[3] CPME document 2004/148, page 4

Exceptions to this principle exist in the case of part-time residence or cross-border workers. The individual options of the patients should always be taken into account. Safeguarding the confidentiality of medical information must be a high priority. Telemedicine services should be supervised in the country where the provider is registered.

Financial consequences: When properly authorised, the cost of the medical care should be borne by the Member State where the patient is affiliated. The specific conditions required for reimbursement should be easily available for all parties concerned.

With regard to hospital care, the CPME would like to emphasise that many systems do not determine the real costs of the different medical procedures as they do not factor in the infrastructure costs. It is therefore very difficult to get these costs reimbursed from the country of affiliation of the patient. (In Luxembourg for example, this "loss" is estimated at around 10%). The CPME would therefore like to stress that efforts should be made to calculate the real cost of care more precisely so that reimbursements by the country of affiliation will actually cover all the expenses.

Question 4) Who should be responsible for ensuring safety in the case of cross-border healthcare? If patients suffer harm, how should redress for patients be ensured?

In order to reduce the number of adverse events in the health sector, new approaches should be developed and implemented. To this end, different initiatives were suggested in the Luxembourg Declaration on Patient Safety[4] of 5 April 2005 that deserves closer attention and action.
As referred to under question 6, the CPME considers the issue of patient safety to be closely linked to the quality of care and to the training of health professionals.

The High Level Group or a similar organization should continue to ensure that the necessary attention is given to the patient safety issue along with its follow-up at EU level. It is crucial to create a permanent platform to promote exchange of information and best practices.
In order to encourage the reporting of adverse events, it is imperative that safety systems are based on a learning approach rather than a blame culture.
However, a 'no blame' system should not jeopardize the rights of patients to obtain compensation for medical errors. Therefore, the CPME favours a system where the liability issue and the development of non-fault compensation systems at national level go hand in hand[5].

Moreover, health professionals should subscribe to appropriate professional liability insurance when providing cross-border healthcare.

[4] CPME document 2005/061
[5] CPME document 1999/026

Question 5) What action is needed to ensure that treating patients from other Member States is compatible with the provision of a balanced medical and hospital services accessible to all (for example, by means of financial compensation for their treatment in 'receiving' countries)?

This is an issue that mostly concerns individual Member States.

However, the CPME would welcome reliable data on patient mobility. This should include the cost for patients treated abroad and the real costs for the receiving Member State. Furthermore, new methods of calculation should be developed so that all costs concerned could be reimbursed by the country of affiliation (see also question 3).

Question 6) Are there further issues to be addressed in the specific context of health services regarding movement of health professionals or establishment of healthcare providers not already addressed by Community legislation?

The mobility of professionals is tackled at EU level by Directive 2005/036/EC on the recognition of professional qualifications. This text covers both the temporary provision of services and establishment in a host member state. The Directive ensures the coordination of minimum training requirements based on the duration of training. However, the CPME wishes to stress that this time criterion alone is not sufficient when recognising the requirements of modern medicine. Therefore, Directive 2005/036/EC should be continuously updated.

The Edinburgh Declaration of 23 November 2005 on healthcare professionals crossing borders is an example of the need to add to the provisions of the existing legislation. This agreement concerns the communication between competent national authorities concerning serious matters likely to affect the professional's right to practice. This example of cooperation is important in order to enhance patient safety and this approach could be used again on other topics concerning professional mobility.

The CPME favours also the promotion of common professional rules/codes of conduct at Community level.

Question 7) Are there other issues where legal certainty should also be improved in the context of each specific health or social protection system? In particular, what improvements do stakeholders directly involved in receiving patients from other Member States – such as healthcare providers and social security institutions – suggest in order to facilitate cross-border healthcare?

The question of cross-border healthcare is complex because it has been developed on the basis of two pillars: Regulation 1408/71 and ECJ rulings. The conditions and

the rules of reimbursement are therefore different. The least that is required is an understandable clarification for citizens/patients of these two sets of rules.

Question 8) In what ways should European action help support the health systems of the Member States and the different actors within them? Are there areas not identified above?

The CPME supports initiatives that would provide economy of scale to healthcare systems and improve the exchange of information between national systems. However, these actions should duly respect the principle of subsidiarity and the competency of the Member States to organise their health systems and to take the necessary national political decisions on the future of their own systems, while at the same time recognising the freedom of movement for patients and professionals

Different issues are at stake and the most appropriate methods for decision-making have to be used.

The open method of coordination (OMC) has already proven its effectiveness in the social affairs sector and in the health sector (high-level reflection group on patient mobility and healthcare developments in the EU). This method, which brings together representatives of the Member States and the most relevant stakeholders, should certainly continue to be used in this context.

Collections of comparable data compiled by the European Commission and the networking of centres of reference are good suggestions. Initiatives in the e-health sector would also be important for supporting the development of the health systems.

Question 9) What tools would be appropriate to tackle the different issues related to health services at EU level? What issues should be addressed through Community legislation and through non-legislative means?

In order to offer patients legal certainty, rules on the free movement of patients and on the financial aspects should be tackled in a binding legislative act. The framework of the proposed system should be covered by a Directive.
This should be supported by a memorandum of understanding to ensure a common interpretation and implementation of the rules on patient mobility. This MoU should be prepared by the EC in close cooperation with the Member States and the stakeholders.

In addition, other tools such as recommendations could be used. Mixing different tools is not a problem, provided that all proposals are underpinned by a common clear vision on the mobility of patients as well as physicians and other health professionals in the context of the EU health systems.

CPME/AD/Brd/080400/026/EN

At its Board meeting in Brussels on 8 April 2000, the CPME adopted the following policy: Proposal for a directive on health-care liability (CPME 1999/026 Final EN/FR)

Proposal for a directive on health-care liability

I. Considerations

1. In the member states the liability of a doctor or hospital vis-à-vis patients in cases of treatment-induced injury is basically covered either by general legislation on liability for injury in the services sector or by special regulations. The basis of liability may differ depending on legal conditions and procedures under which a patient can claim for treatment-induced injury, as well as the extent of compensation.

2. Systematic comparison reveals two basic liability systems in Europe. On the one hand a liability and compensation system based on the fault and personal liability of the doctor, and alternatively, a liability and compensation system which takes the form of patient insurance and also provides for compensation in cases of no fault. Despite the different conditions and consequences for doctors and patients it can be said that the medical profession in the individual member states of the European Union has learnt to live with the various liability and compensation systems.

3. In 1990 the Commission proposed a directive on liability in the services sector. The aim of the proposal was to harmonise liability for injury inflicted by a provider on a person's health and physical integrity by the introduction of the concept of the reversal of the burden of proof. Treatment provided by doctors and hospitals was also considered as falling under the scope of the directive. The Commission's concept of liability for injury to health inflicted as a result of a service would have led to a considerable worsening of the liability situation for doctors, whereby, because of the broad definition of injury, it would, in essence, have led all doctors to become strictly liable for medical examinations and treatment, so that any adverse event would be considered their responsibility and their liability.

   Like many national governments, the European medical profession rejected this proposal because it felt it would have had a negative impact on the image of medicine and on the relationship of trust between doctor and patient as well as causing a considerable increase in insurance premia and a restriction of the conditions to practise the profession.

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As a result of a detailed discussion on the principle of subsidiarity the Commission withdrew the proposal for a directive and has not yet tabled a comparable new proposal to regulate this area.

4. The European medical profession is of the view that further development of the liability system for medical services in Europe is necessary.
This is because :

   1. Doctors bear increasing responsibility as medical innovation and treatments, plus patient expectations continue to advance.
   2. National case law has already aggravated the legal situation regarding liability of doctors.
   3. The increasing inbalance between patient demand and available resources increase the risk of inadequate health-care and adverse outcome.

   For these reasons it is necessary to elaborate on the further development of liability. Moreover in those legal systems which provide patient compensation for errors of treatment on the basis of the individual responsibility and personal liability of the doctor for any fault, the principle of fault is no longer consistently applied. In many liability systems the dividing line between liability for the consequences of fault and responsibility for accidents, for which no blame is attributed, has become blurred. For this reason it is advisable – from a European standpoint – to examine in an unbiased manner the pros and cons of both basic systems – patient insurance on the one hand and individual liability of the doctor and hospital in cases of errors of treatment.

5. The Standing Committee of the European medical profession has listed the pros and cons of the systems in Europe with respect to financing, procedure, advantages for patients, doctors and the health system (annex). The important result of this analysis was that for both patients and doctors an alternative source of compensation for injury to patients could be envisaged which would incorporate the cost factor both for contributors and for the health system. It would lie outside the court system with decision on compensation by independent arbitration panels. The important point here is that it is a non-court based system. This would make things simpler and faster for patients and would make it possible to predict the level of compensation. The advantage to doctors would be less of the professional pressure normally linked to lengthy legal cases. The unproven claim that such a change to the compensation system could lead to a deterioration of the quality of medical treatment can be countered with the fact that this system of out-of-court compensation is not absolute, because every patient has the right to seek compensation through the Courts. This means that, if the patient is dissatisfied with the compensation or feels that the doctor should be

subject to the judgement of a court, then a court settlement remains open, although the consequence of this would be that the fault of the doctor in cases of health-care injury would have to be proven.

A future system, supported by the European medical profession, should therefore be based upon the principle of guaranteed patient compensation, for injury to health incurred during health-care, as well as on a procedure open to both patients and doctors that would permit an appropriate out-of-court settlement.

II. Proposal for a directive on health-care liability

Article 1

This directive obliges the member states to introduce a compensation system for unexpected adverse outcomes in health-care according to the principles in the following articles. The existing legal provisions and procedures in the member states covering claims for compensation for the injured patient, in cases of negligent infringement of professional obligations arising from a treatment contract or agreement shall not be affected by this directive.

Article 2

(1) Patients suffering from an adverse outcome incurring during individual healthcare shall benefit from the protection of the system.
For the purposes of this directive,

1 « adverse outcome » shall mean a painful or lasting impairment of health, which has unexpectedly arisen as a result of health-care given by a doctor or hospital.

2 « Unexpectedly » shall mean injury to health which is not the natural consequence of the illness or of the inherent risk of the illness becoming more acute.

3 « Individual health-care » shall be that care provided to an individual patient under the responsibility of a doctor.

4 « Patient » shall mean an individual receiving health-care in a medical institution (e.g. hospital) or from a doctor.

5 There must be a relevant association between the adverse outcome and the health-care provided.

Article 3

If the conditions are met the patient shall receive compensation under the procedure laid down in article 4. The compensation shall be at an appropriate level to reflect the impairment of the patient's physical and mental condition as a result of the eligible injury to health. It shall include damages for pain and suffering. The member states shall fix the levels for compensation in such cases.

Article 4

(1) An interdisciplinary panel of independent experts composed of representatives of the medical professions in consultation with both jurists and patient's representatives shall decide on the level of compensation in the Member State.

(2) The member states shall ensure that the patients right of appeal to the courts shall be maintained.

Article 5

The member states shall determine the manner of funding the compensation. This may be provided by either a special form of insurance funded by collective contributions, service providers or patients, or may form part of an existing social security system.

Article 6

(Entry into force)

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COMITÉ PERMANENT DES MÉDECINS EUROPÉENS
STANDING COMMITTEE OF EUROPEAN DOCTORS

CPME/AD/Brd/030905/148/EN

At its Board meeting, Brussels, 3 September 2005, the CPME adopted the following policy: Commission proposal for a directive on services in the internal market: Reaction of CPME (CPME 2004/148 Final – revised date EN/FR)

Commission proposal for a directive on services in the internal market (COM (2004) 2 Final)

Position paper of the CPME

Executive summary

The CPME has examined carefully the Commission's proposal for a Directive on services in the internal market (COM (2004) 2 Final).

The CPME supports opportunities for opening up freedoms for patients, consumers and professionals and welcomes some of the provisions of the proposal, like the implementation in a legal text of the rules for the assumption of non hospital health care in article 23, the requirement of professional insurance in article 27 or the role of the codes of conducts in article 39.

Some basic elements of the current text of the proposal generate however many uncertainties on their effects on the health care sector and impact on its organisation and financing. More specifically, amendments to the proposal are necessary on the following issues:

- on the freedom of establishment, the list of prohibited requirements should not interfere with the right of the Member States to require authorisation and registration procedures for regulated health providers.

- on the free provision of services, the application of the country of origin would be detrimental for the patients. Therefore, the general derogation given in article 17 – 8) is not clear and large enough and should encompass the exercise of the medical profession.

In the light of the above, the CPME recommends exclusion of the health care sector from the current draft of the Directive.

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Motivation for CPME position:

As the differentiation between hospital and non-hospital care can carry financial consequences, the definition of hospital care should be as clear as possible. The definition given in article 4 should be improved.

CPME position:

Hospital care should be defined as medical care under the supervision and responsibility of medical doctor(s) and provided in specific facilities where medical surveillance is available 24h/day and which normally requires accommodation in the facility.

Prohibited requirements

Article 14

Article 14 of the draft directive lists prohibited requirements. According to it a member state can not inhibit access or service activity by requiring that a service provider has been entered, for a given period, in the registers held in the state or has exercised the activity for a given period in the state.

Article 9 describes authorisations. According to it a member state can require authorisation if the need for an authorisation scheme is objectively justified and the authorisation scheme is not discriminatory.

The conditions for granting authorisation for a new establishment (article 10) shall not duplicate requirements and controls which are equivalent or essentially comparable as regards their purpose, to which the provider is already subject in another Member State or in the same Member State.

Motivation for CPME position:

The wording (paragraph 8) in article 14, when related to the practise of medicine, can give rise to different interpretations. In some states registration of health care professionals lead to their authorisation. In other states other procedures are followed. Articles 9 and 10 clarify requirements for authorisation, where statements can be supported.

It is vital that the Member State where medical services are provided can effectively supervise the provider and services. For this purpose, the competent authorities in each MS must have the relevant information on service providers. Registration is the most effective way to collect this information with the purpose of granting authorisation. Registration must however not be used to inhibit or delay establishment or provision of services. Therefore registration procedures must be simple but information required should be comprehensive in the interests of patient safety.

COMITÉ PERMANENT DES MÉDECINS EUROPÉENS
STANDING COMMITTEE OF EUROPEAN DOCTORS

CPME/AD/Brd/110904/080/EN

At its Board meeting, Brussels, 11 September, 2004, the CPME adopted the following policy : On Information to Patients and Patient Empowerment (CPME 2004/080 Final EN/fr)

19/7/2004

On Information to Patients and Patient Empowerment

In order to achieve optimal results from treatment, a good patient-doctor relationship is essential. One of the prerogatives is patient empowerment and this requires an informed patient. But information as such is not enough to achieve an informed patient. Also communication must be established/secured. The patient is the key stakeholder. Accurate information must be based upon international medical science. It is the patient's right to decide among suggested and proven therapies including medication. Many stakeholders are involved in this process of provision.

The principal route to an informed patient is the patient-doctor meeting (the clinical consultation). This leads to a joint decision on the individual patient's health care. Doctors are obliged to follow professional ethical codes and to safeguard that all treatment is in accordance with international medical science. Medicine is not and should not be treated as a commercial market where one can shop for different therapies.

Basics

All information must be relevant and validated from the patient's viewpoint. The information must be medically correct and understandable for the patient.

Verbal and written information must be seen as two sides of the same coin. Both must be aviable. Communication means that it must be possible to ask questions. And to get a professional advice.

In those situations where an interpreter is needed during a patient-doctor consultation a qualified interpreter is preferred over a family member so as not to put patient confidentiality at risk.

Written patient information is important. The quality of translation must be addressed thru quality criteria.

Many patients have impaired abilities that also must be taken into consideration (blind, deaf, mental, social).

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Often time for reflection is needed after a patient doctor consultation. A patient might want to collect more information from different sources. It is important to secure this possibility before a decision on therapy is made.

Information on the Internet or printed information can never replace information and communication in a clinical consultation. It must be seen as complementary to direct communication between the patient and the doctor.

CPME position on information to patients:

- The patient is the key stakeholder and accurate evidence based information must be the basis for the patient's right to decide among suggested and proven therapies including medication.
- The patient-doctor meeting (the clinical consultation) must always be seen as the principal route to an informed patient.
- Qualified interpreters should be used when needed.
- Written patient information is important to achieve an informed patient.
- Communication skills for health care professionals should be promoted both as part of the pre-registration period and as part of continuous professional development (CPD).

Stakeholders and their role in information to patients

The patient is the key stakeholder. All information must safeguard the patient's right to self-determination as an empowered patient.

Patient organisations are important stakeholders representing different patient groups and their interests. They have an important role as partners in validating patient information.

Doctors are the key supplier of information to patients. It is also an ethical obligation to secure communication in order to achieve a joint patient-doctor decision on treatment.

Organisations of both health professionals and industry have a responsibility to set up quality criteria on patient information and as stakeholders to uphold professional standards on patient information.

Pharmacists are experts on medicines and have an important role to advice the patient on his/her medication. Furthermore, some patients seek health care information at the pharmacies and also advice about treatment. It is very important that the collaboration between the doctors and pharmacists is well established in order to secure accurate information about medicines in relation to diagnosis and treatment.

Pharmaceutical industry has its prime role in securing medicines to cure diseases. Also, industry has a responsibility in search for new knowledge and to find new medicines. On information to patient it is important to remember that the goal of the industry is to make a profit. It means that all information to patients must be validated as information and not marketing. More and more it is obvious that the pharmaceutical industry focus on health information to promote their drugs. Direct to patient information from the industry must

therefore be seen as primarily marketing, whether or not a specific treatment is mentioned.

National Health Agencies have a responsibility to evaluate information to patients. Also they play a key role in informing health care professionals in the member states in established treatment of diseases. It is very important that their work is of the highest standards.

EMEA´s role is still unclear. Primarily they should act as a centre of expertises in relation to the national agencies and have a responsibility to involve all stakeholders on a European level to set up standards for patient information. Health care as such, including information to patients still remains the responsibility of each member state

Politicians as representatives of the population elected through democratic procedures have a key role in setting out standards on information to patient and to set out responsibilities regulated by law.

All providers of health care (including physicians, hospitals and insurers) have a paramount responsibility to inform patient on a broad set of issues like results, quality assurance systems including patient safety, accessibility of care etc.

WHO is at present the key global organisation in public health and patient empowerment. It has taken the lead to secure health care on a global level through intergovernmental cooperation.

CPME position on stakeholders:

- Professional organisations have an obligation to set up quality criteria on patient information and to uphold professional standards on patient information.
- The pharmaceutical industry has a key role on information on medicines for health professionals. It is important that the industry take responsibility to secure accurate and up to date information on drugs, also on the Internet.
- National Health Agencies have a responsibility to evaluate information to patients.
- A network should be established supported by the EU involving all relevant stakeholders on information to patient.

Information and marketing/advertising

It is the responsibility of the pharmaceutical industry to inform doctors and other health care professionals about their products. The information must be accurate and cover all aspects of the drugs.

Information to patients about medicines is important to patient empowerment. However, it is not a primary responsibility of the industry to inform patients about health. Furthermore, any information about health from the industry must be seen in the light of its primary goal, to make a profit.

There is an obvious need to clearly define information in contrast to marketing. A European network involving all relevant stakeholders at the European level should be identified and invited to define and promote clear rules about information to patients from the pharmaceutical industry in relation to health and medicines. Only thru such a system approved information should be accepted as information and not marketing. Direct information to patients on medication must be under strict national/European supervision and not include prescription-only drugs.

CPME position on information:

- Information must be differentiated from marketing
- Informing patients about medicines is important to patient empowerment.
- Direct information to patients on medication must be under strict supervision and under no conditions include prescription-only drugs.
- A European network involving all relevant stakeholders at the European level should be identified and invited to define and promote clear rules about information to patients from the pharmaceutical industry in relation to health and medicines.

E-health

E-health must be seen as complimentary to an established patient-doctor relationship and improve patient information. Information to individual patients only thru e-communication is not in accordance with professional ethics. It is important to take into account personal- and patient data protection in connection with teleconsultation and e-prescription. Many member states have established secured Internet connection between health care deliverers, also involving pharmacies.

CPME position on E-health:

- E-health must be seen as complimentary to an established patient-doctor relationship.
- Secure and interoperable data networks dedicated to health services should be developed across the EU.
- A reliable method enabling doctors and patients to identify each other over the net should be developed.

Validation of Information

It is important to remember that the best way of information is a personal meeting. Still, there is a need for further fact finding to obtain patient empowerment. Today the Internet plays an important role thru public health information sites. There is an obvious need to establish an international quality approved system. Quality criteria for health information web sites were set up 2002 by the commission. National agencies have the responsibility to disseminate these criteria and to secure the quality on the national net sites.

The pharmaceutical industry provides information on non-prescription drugs and life style drugs. This information needs to be comprehensive and include all data required to make an informed decision. It should also take into account that the drug may be non-prescription in one member state and Rx in another.

CPME position on validation of information:

- CPME supports the creation of a EU health portal for validated health information web sites.
- National agencies have the responsibility to disseminate the quality criteria set up by the commission on health information web sites.

European Commission
DG Health and Consumer Protection

Présidence luxembourgeoise
du Conseil de l'Union européenne

Patient Safety – Making it Happen!

Luxembourg Declaration on Patient Safety

LUXEMBOURG DECLARATION

Access to high quality healthcare is a key human right recognised and valued by the European Union, its Institutions and the citizens of Europe. Accordingly, patients have a right to expect that every effort is made to ensure their safety as users of all health services.

Background:

The health sector is a high-risk area because adverse events, arising from treatment rather than disease, can lead to death, serious damage, complications and patient suffering. Although many hospitals and healthcare settings have procedures in place to ensure patient safety, the health care sector still lags behind other industries and services that have introduced systematic safety processes.

A number of investigations from all over the world have underlined the need for and the possibility of reducing the number of adverse events in the health sector. Current data show that almost half of all preventable adverse events are a consequence of medication errors.

Accordingly, tools must be introduced aimed at reducing the number and consequences of adverse events. The health sector should be designed in a way that errors and adverse events are prevented, detected or contained so that serious errors are avoided and compliance with safety procedures is enhanced.

As a result of the work done in this field by many players and institutions and the evidence gathered, it is now clear that the first step that needs to be taken should be to establish a culture of patient safety throughout the entire health system. Risk management must be introduced as a routine instrument within the running of the entire health sector. A precondition for risk management is an open and trusting working environment with a culture that focuses on learning from near misses and adverse events as opposed to concentrating on "blame and shame" and subsequent punishment.

Health sector induced harm to patients imposes a heavy burden on society. Investment in patient safety therefore has the potential to generate savings in expenditure coupled with an obvious benefit to patients.

Focus on patient safety leads to savings in treating patients exposed to adverse events and the consequential improved use of financial resources. In addition, savings are achieved in administration costs associated with complaints and applications for compensation. Most importantly, patient safety contributes to an increase in quality of life. In order to achieve this, the culture of safety can be improved significantly in various ways.

In light of the above, the conference recommends that "Patient Safety" has a significant place high on the political agenda of the EU, nationally in the EU Member States and locally in the health care sector.

The conference recommends the EU Institutions:

- To establish an EU forum with participation by relevant stakeholders to discuss European and national activities regarding patient safety.
- To work in alliance with WHO Alliance towards a common understanding on patient safety issues, and to establish an "EU solution bank" with "best practice" examples and standards.

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Patient Safety – Making it Happen!

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- To create the possibility of support mechanisms for national initiatives regarding patient safety projects, acknowledging that patient safety is in the programme of DG Health and Consumer Protection
- To ensure that EU regulations with regard to medical goods and related services are designed with patient safety in mind.
- To encourage the development of international standards for the safety and performance of medical technology.
- To ensure that the European regulatory framework protects the privacy and confidentiality of patient records in the best interests of the patient, while at the same time ensuring that relevant patient information is readily available to health care professionals.

The conference recommends to the National Authorities:

- To provide patients with full and free access to their personal health information whilst ensuring data accuracy and that patients fully understand their treatment. It is acknowledged that "informed patients" are well positioned to safeguard their own health.
- To consider the benefits of a national voluntary confidential reporting systems of adverse events and near misses.
- To work towards the introduction of risk management routines, for example, by developing guidelines and indicators as a part of a quality assessment system in the health care sector.
- To optimise the use of new technologies, for example, by introducing electronic patient records. Such records would include the personal medical profile and decision-making support programs for health professionals with a view to reducing medication errors and increasing compliance rates.
- To establish national fora, with participation by relevant stakeholders, to discuss patient safety and national activities.
- To safeguard working conditions for all health care professions and to ensure that policies on recruitment and retention are linked to patient safety.
- To recognize and support the user training provided by medical devices, tools and appliances manufacturers thereby ensuring the safe use of new medical technology and surgical techniques.
- To include patient safety in the standard training of health professionals combined with integrated methods and procedures that are embedded in a culture of continuous learning and improvement.
- To ensure that national regulatory framework protects the privacy and confidentiality of patient records in the best interests of the patient, while at the same time ensuring that relevant patient information is readily available to health care professionals.
- To create a culture that focuses on learning from near misses and adverse events as opposed to concentrating on "blame and shame" and subsequent punishment.

The conference recommends to health care providers:

- To facilitate a collaborative care approach between health professionals and health care providers, aimed at enhancing patient safety.
- To implement work place projects focusing on patient safety and to establish an open culture to deal with errors and omissions more effectively.
- To initiate a co-operation between patients/relatives and health care professionals in order that patients/relatives are aware of near misses and adverse events.

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