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EAHM reaction to the Commission consultation process on cross-border health services
- EAHM policy adopted by the Board on 15 December 2006 -

Introductory comments

The European Association of Hospital Managers EAHM recognises the need for a European framework for cross-border health services, including hospital services, and supports the European Commission consultation and initiative.

The Commission communication shows that the prevalence of patient mobility is and will be on the increase, but that problems exist and constitute a growing challenge for the European Union.
EAHM welcomes and fully supports the objective of this initiative, which also is to provide a legal framework that will eliminate obstacles to the freedom of establishment for service providers and the free movement of services and healthcare professionals between Member States.

While EAHM accepts that health services fall into the scope of Arts 43 and 49 of the EC Treaty and therefore are services that perform an economic activity, we believe that a legal framework should take into account the complex nature of the delivery of healthcare involving the state and/or social insurance schemes.
Health care services differ from other services sectors, as the latter are commercially oriented and market bound. European countries carefully plan and manage healthcare systems, with extensive national regulation involved for reasons of universal availability of healthcare services.
Speaking about hospitals, it should be noted, that public and private non-for profit hospitals do not have the liberty of price-fixing for their services. Their relationship to the “client”, the patient, is also influenced by the third party, which is the payer. Furthermore, patients require

more protection than do consumers. Consumers can freely choose whether they receive a service – patients have a restricted choice.

Finally, hospitals have a duty to provide their services. Generally speaking, they do not have the possibility to refuse services, if conditions are not acceptable for them.

The principle of freedom to provide services therefore has its limits in the necessity to provide social and health services. The organisation of national health care systems should therefore solely remain in the responsibility of member states.

Answers to the questions:

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?

1.
EAHM believes that the extent to which European standardisation could facilitate compatibility and quality of services needs to be examined.
In its original „Proposal for a Directive of the European Parliament and of the Council on services in the internal market, COM/2004/0002 final", the Commission was trying to increase the use of voluntary European standards with the aim of facilitating compatibility between services supplied by providers in different Member States, information to the recipient and the quality of service provision. The draft however should have opted for stronger quality standards.

Further solutions (legislative or non-legislative acts) have to be sought in order to achieve a high level of convergence in quality standards.

The impact of the particular relationship between service provider and user upon the nature of the service implies proper assessment of the needs of users and then quality of the service on offer, including the manner in which it is provided and the extent to which it achieves its objectives. The needs of the user include the provision of information of the services offered.

According mechanisms need to be set up, ensuring the protection of recipients by providing for requirements regarding the quality of services provided.
To this end, first, the terminology of „Quality" of healthcare services needs to be defined commonly for all Member States.

Information i.e. on the good repute of providers at the request of a competent authority in another Member State and in relation to the provider's ability to conduct his business or his professional reliability are not sufficient.

If quality standards and patient protection shall be maintained, the cross-border provision of health services implies the need for a common approach to the definition, assessment and improvement of standards in health care.

EAHM therefore proposes the development of a European definition of „Quality" and the development of a European accreditation model for healthcare services.

Background
Governments of various European countries have stimulated the use of Quality Management systems, quality management being broadly defined as 'a procedure explicitly designed to monitor, assess and improve the quality of care', for example peer review, patient satisfaction surveys, complaints handling, audits, compiling a quality manual, etc.
Four principal models and national variants of external evaluation can be identified: medical speciality-driven visitation, European Quality Awards based on the model of the European Foundation of Quality Management (EFQM), certification using International Organisation for Standardisation (ISO) standards (ISO 9000 series) and traditional accreditation against explicit standards.

In an accreditation process, the standards used are the pre-conditions to achieve Quality in healthcare. Successful accreditation programs are therefore a significant factor in improving health care systems and care provision. They support the rationalisation of reimbursement mechanisms, enhance public trust in the quality of care and in the institutions providing it.

Definition
Accreditation of health care organisations is defined as an external peer assessment of the entire organisation's performance against a pre-determined set of standards, which are objective and measurable to the extent possible.
In comparison, the ISO system provides standards against which organisations or functions may be certificated by accredited certification bodies or organisations. ISO standards were originally designed for the manufacturing industry, and are now applied to health care, more generally speaking, to quality systems in hospitals and clinical departments.
Notable is that an ISO certification cannot be withdrawn once it is provided, and only when new standards are being certified a new evaluation of the services takes place. During an accreditation process the organisation is periodically re-evaluated. Because the Certification process today is on its way to apply to a healthcare institution as a whole, it can be seen as developing into an accreditation system.

Next to this, you find "registration" and "licensing", which are statutory programs, ensuring that professional staff or provider organisations achieve minimum standards of competence.
Unlike licensing, which tends to focus on the capability the organisation may have to deliver health care services, accreditation standards focus attention on the quality and safety of the services. Licensing generally is not time limited.
Accreditation is time limited, and the organisation must ensure that it continues to meet the standards in order to maintain its accreditation status.

Therefore, accreditation not only fosters, but requires a process of continuous improvement and should today be judged as the most efficient external evaluation process.

A European accreditation model is not about a fully-fledged harmonisation of healthcare practices, but a gradual alignment, having the aim of defining and sharing best practice and defining relevant guidelines. It would have to be established step by step, first addressing existing problems, next addressing further adaptation between countries. A European accreditation model can encompass differences but not contradictions in systems. Differences must remain possible, but must not restrict patient rights when it comes to cross-border provision of services.
It is important to opt for a quality management system, which focuses on the continuous improvement of quality standards.

Justification

The recent European Court decision in the case of Yvonne Watts (C-372/04) is a sign for future development. The ruling indicates that a state might refuse authorisation for treatment abroad, if it is not assured that the patient in question receives "high-quality treatment".

In particular, in this decision, the ECJ found that "a situation in which a person whose state of health necessitates hospital treatment goes to another Member State and there receives the treatment in question for consideration falls within the scope of the provisions on freedom to provide services regardless of the way in which the national system with which that person is registered and from which reimbursement of those services is subsequently sought operates."

It pointed out, next, "that the system of prior authorisation which governs the reimbursement in that state of the cost of hospital treatment provided in another Member State deters or even prevents the patients concerned from applying to providers of hospital services established in another Member State and constitutes, both for those patients and for service providers, an obstacle to the freedom to provide services."

However, it considered that "such a restriction can be justified in the light of overriding reasons", as has been defined already in previous rulings, i.e. in the *Smits and Peerbooms case (*Case C-157/99). The court referred again to this ruling and confirmed its view that, "from the perspective of ensuring that there is sufficient and permanent **access to high-quality hospital treatment**, controlling costs and preventing, as far as possible, any wastage of financial, technical and human resources, the requirement that the assumption of costs by the national system of hospital treatment provided in another Member State be subject to prior authorisation appears to be a measure which is both necessary and reasonable. Nevertheless, the conditions attached to the grant of such authorisation must be justified in the light of the overriding considerations mentioned above and must satisfy the requirement of proportionality."

The court even went further and gave reasons for which an institution might not refuse the authorization for treatment abroad. These are:

- "the existence of waiting lists,
- an alleged distortion of the normal order of priorities linked to the relative urgency of the cases to be treated,
- the fact that the hospital treatment provided under the national system in question is free of charge,
- the duty to make available specific funds to reimburse the cost of treatment provided in another Member State
- and/or a comparison between the cost of that treatment and that of equivalent treatment in the Member State of residence."

The court did not state "on grounds of treatment, which is of less high quality than in the home state" – this reason hence can still be put forward.

(For further reference EAHM also points to the presentation held by its Secretary General Willy Heuschen at the European Health Forum Gastein 2006, "Quality management of healthcare through accreditation and the scope for European cooperation").

A justification for the creation of an EU Agency for accreditation of healthcare organisations

is not only the transferral of power from member states to an EU level in terms of application of internal market rules to healthcare services but also the fact that the subsidiarity principle has its limits: it applies only “as long as member states fulfil their obligations”- which today is not the case.
EAHM believes that for the reasons named above, there is sufficient reason to justify action on a EU level.

However it needs also to be considered, that a European accreditation model functioning on a voluntary basis and not under an EU agency would per se not infringe the subsidiarity principle, (should it be judged to apply).

Regarding the standards to be applied, it should be noted that in a number of countries, i.e. Austria and Sweden, the same people have contributed to the development both of ISO 9000 and EFQM´s Excellence Model for the health care sector. The influence particularly of EFQM on ISO is evident in the way that the ISO standards have been revised, bringing the models closer together.
The ExPeRT project research team, ExPeRT standing for “external peer review techniques”, identified four main external peer review models aimed at measuring the quality of service management and delivery: health care accreditation, the ISO 9000 standards, the EFQM, and visitatie, which is Dutch for 'visitation'.
ExPeRT has demonstrated that in principle, convergence of the four main models in order to gain from each model's key strengths is feasible.

Practical example
Through accreditation, existing variations in quality between different health care organisations can, should and need to be reduced.

If one of the EU member states experiences a basic problem in terms of Quality of healthcare services, this problem might also affect other hospitals in other countries. One example is the problem of MRSA infection in hospitals, which is a well known phenomena: it is an infection due to a bacterium, which is resistant to many types of treatment.
After an outbreak period just before the new millenium in the Netherlands, the country vigorously implemented a search-and-destroy strategy and hereby controlled and heavily improved the infection occurance. In Germany and Belgium however, in the last few years, a dramatic increase of MRSA detection in hospitals can be recognised.
Dutch hospitals now fear an increase in infection figures through the mobility of patients and therefore isolate patients coming from abroad for a certain period of time.
But this is not a sustainable option: MRSA infection rates need to be reduced in **all** European countries. The Dutch policy is an excellent example for all others countries and their standards should be applied elsewhere in Europe.
Standards which can be defined in an accreditation process.

EAHM would like to point out that European accreditation of for example national accreditation agencies is not sufficient, as these do not exist in all member states.
Accreditation of all existing agencies is impossible due to large differences in structures.

Other thinkable measures promoting the quality of services could aim at quality charters.
Moreover, Member States, in cooperation with the Commission, are to encourage interested parties to draw up codes of conduct at Community level, representing an alternative method of regulation, aimed in particular at promoting the quality of services and taking into account the specific nature of each profession and service.

2.
In terms of accessibility to hospital care, there is a need for better planning of care for cross-border patients. In cases where healthcare planning involves the allocation of a certain number of cases in a specific medical domain and a hospital treats cross-border patients, the situation arises where the maximum capacity has been achieved, and local patients have to be refused treatment. Member states should set up planning mechanisms to allow for extra capacities when treating patients from abroad.
By providing concrete data on patient movements and supporting member states in their task, this planning can be effected on an improved basis.

3.
General aftercare in cross-border treatment, or more specifically, recovery information, needs to be improved. Aftercare in some cases is difficult to receive because national systems only function, if the patient received hospital care in his/her home country. The availability at home of the drugs and especially the aids devices that were prescribed in the hospital are often not optimal. Regarding drugs for instance, pricing mechanisms, the factual composition of drugs, their names and production etc. are regulated and therefore protected nationally, meaning the interest and protection of the patient surely is not the first goal pursued.
Hence only few patients receive professional aftercare after leaving the hospital.
These factual barriers need to be removed by member states and a European initiative in cooperation with patient organisations should enhance this by information gathering, the creation of incentives and creation of responsible authorities to abolish these barriers.

The EAHM also recommends the creation of networking-centres, better coordination of Health Technology Assesment as well as to further develop e-health systems and telemedicine.

Question 2: what specific legal clarification and what practical information is required by whom (eg; authorities, purchasers, providers, patients) to enable safe, high-quality and efficient cross-border healthcare?

1.
A possible framework directive needs to lay down a clear and concise definition of establishment and of temporary provision of services. It should be clear that the continuous provision of services in a host country is to be seen as “establishment” of a provider.

2.
It needs to be clarified that a hospital, when treating patients from abroad, is not bound to the restrictions that may occur through a membership to the national social security system, as for example the licensing status.

3.
It is necessary to define the terminology of “hospital services”. EAHM would propose to take into consideration the law in the respective member state of the patient concerned. The initially foreseen definition in the draft services directive (Article 4) therefore could be taken on board.
In cases where differences between the home and the host state occur, a clear regulation needs to be found, which national law is applicable. EAHM believes that in the light of the

jurisprudence of the European Court of Justice regarding the competence of member states in the organisation of intramural care, the regulation of the host state should be applicable. Moreover there should be a clarification that service providers in their state do not need to be included in the public social security system, in order to provide intra- or extramural care of patients from abroad.

4.
Further issues, that need to be addressed are the obligation to take out professional insurance, commercial communications by the regulated professions, the provisions on multidisciplinary activities or the settlement of disputes.

5.
In terms of "Practical information" it would be positive and helpful for hospitals to find data on cooperation possibilities between healthcare service providers beyond their state borders.

Question 3: which issues (eg: 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?

1.
EAHM strongly urges the Commission to consider the application of the principle that the host country´s law and regulation apply to all providers operating within its territory. There is no room for the application of the „Country of Origin Principle", as was foreseen in the original directive on services referred to already above. In what concerns health and social services and their complex nature, the ability of host authorities to licence, regulate and ensure competence must be beyond doubt. A case-by-case derogation for health professions and providers would not be sufficient. The Country of Origin Principle would lead to "flag of convenience" establishment.

2.
EAHM believes it is necessary to specify that service providers are prohibited from providing for refusal of access, or subjecting access to less favourable conditions, on grounds of the nationality or place of residence of the recipient, or different tariffs, where unjustified.
On the other hand it should be seen as necessary for service providers to apply different tariffs and conditions if they can prove that this is directly justified by objective reasons, such as actual additional costs resulting from the distances involved or the technical aspects of the service.
A clarification in the framework directive in the light of the statements named above would be welcomed.

3.
It is imperative for the host state that a posted worker should be required to register with the competent authority in that state.

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?

1.
It is vital that the host member state can effectively supervise the provider and services. The competent authorities in each member state must have the relevant information on service providers and registration is the best way to collect this information.

2.
Accidents happen in healthcare and it is important that patients have access to redress if they suffer because of bad practice. However, insurance systems vary greatly in Europe. In some countries legal provisions require that patients are insured, in other countries compensations are based on the indemnity insurance of doctors.

EAHM therefore believes there is a need for a universal compensation system for unexpected adverse outcomes in Europe.
To be considered in this system is that when establishing i.e. registries for adverse events, it must be borne in mind that this may not affect insurance possibilities and conditions for healthcare providers.

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)?

1.
A system of prior authorisation for the reimbursement of hospital care provided in another Member State appears justified by the need to plan the number of hospital infrastructures, their geographical distribution, the mode of their organisation, the equipment with which they are provided and even the nature of the medical services they are able to offer. The prior authorisation system must be proportionate to the general interest objective pursued.

2.
The timely reimbursement of hospitals for their services is an absolute necessity. Regarding reimbursement of services delivered to patients coming from abroad, EAHM believes that reimbursement three months after filing the reimbursement claim is a maximum waiting time. Relevant international reimbursement mechanisms need to be adapted accordingly.

3.
While EAHM supports the principle of cross-border patient rights, we nevertheless think there is a need to provide answers for some other very fundamental questions; namely; (1) could a possible requirement for a patient arriving in another Member State to pay up-front (before claiming reimbursements) discriminate against poorer patients?;
(2) how will travel costs be reimbursed?; and
(3) would patients be able to make a profit from other healthcare systems given that countries of affiliation.

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?

EAHM strongly urges for a recognition of practical experience and service performance of the medical doctors during their education/training period.
Whilst diploma of medical doctors are being recognised, the free movement of doctors still in training is being hindered by non-recognition of their professional activity in another state. In situations of cross-border cooperation between hospitals, this effectively hinders the cross-border provision of services, as there is no incentive for the doctors concerned to perform across borders.

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?

No answer.

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?

No answer.

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 what through non-legislative means?

1.
In accordance with case law, a medical service is a service despite the fact that the recipient might not be paying for it directly. Framework legislation on services of general interest should be drawn up in accordance with progress made on a framework directive for cross-border healthcare.

2.
EAHM believes it is necessary to adopt clarifications on the characteristic of remuneration. One possibility is a recital explaining that the proposal neither requires Member States to open up to competition services of general economic interest nor interfere with the way they are financed or organised.

3.
It would be appreciable to support a Model Project in a region where cross-border care for patients is being experienced already. Many of the cited problem areas above (planning capacities, quality issues, training of the medical profession, medication, regress possibilities etc.) could be practically solved between the cooperating authorities of the member states.

The Euregio Rhine-Meuse with its project IZOM could be a possible partner because of its long lasting cooperation experience. The region could act as example region for Europe.

Concluding remarks:

It is clear that that the protection and improvement of human health is an area of supporting, coordinating or complementary action where the main responsibilities reside with the Member States and Community action shall only complement national policies.
In this respect, the Commission *in principle* has to be cautious about insertion of Articles regarding health services and prove that these provisions do not introduce harmonisation process in the area. If the Commission does not deliver indications in this sense, even though it tends to codify the recent-case-law of the Court of Justice, could be seen as constituting a breach of the subsidiarity principle.
Public health concerns are however being protected if the quality of healthcare service are being improved. The EAHM believes that the subsidiarity principle does not apply to this regard, as the action is necessary because actions of member-state governments alone do not achieve the major objective of assuring high-quality and secure health care.

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