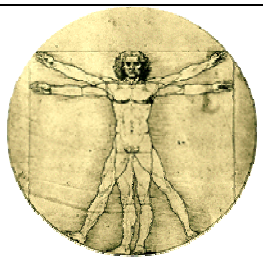

HEALTHCARE FORUM

COMMENTS
of
UEAPME[1] and the UEAPME NORMAPME Healthcare Forum[2]
regarding the
Communication from the Commission
Consultation regarding Community action on health services
(SEC(2006)1195/4)

General comments

- UEAPME and the UEAPME NORMAPME Healthcare Forum welcome this Communication, which allows a broad discussion on the future of the European and national health systems.
- They also support the Commission's intention to provide for more legal clarity and transparency in cross-border healthcare services.
- Patient safety and well-being must be the overriding principle for any initiative launched in the framework of the European health policy.

Specific comments:

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?

As regards custom-made medical devices (CMD), such as dental implants, orthopaedic prostheses, hearing aid devices, spectacles, orthopaedic footwear etc.), there are four possibilities of cross-border healthcare:

[1] UEAPME is the employer's organisation representing the interests of European crafts, trades and SMEs at EU level. UEAPME is a recognised European Social Partner. It is a non-profit seeking and non-partisan organisation. As the European SME umbrella organisation, UEAPME incorporates 81 member organisations consisting of national cross-sectorial SME federations, European branch federations and other associate members, which support the SME family.
UEAPME represents more than 11 million enterprises, which employ around 50 million people across Europe.
[2] The UEAPME NORMAPME Healthcare Forum brings together European representatives from almost 100,000 manufacturers of custom-made medical devices (CMMD) and related activities from all EU Member States and beyond. The overwhelming majority of these manufacturers are small enterprises.

a) The patient crosses the border with the aim to buy a CMD in another Member State. The major driver for this behaviour is the cost. But also waiting lists and the quality of health services should be considered as drivers. This phenomenon is usually limited to border regions. Even there, only a very small part of patients would actually make use of this possibility.
   As a matter of exception, one should mention dental care services. It has become very popular in Austria to go to Hungary to purchase these services.
b) The patient is on holidays in another Member States when a problem with his / her CMD (dental or orthopaedic prosthesis etc.) occurs. With the rise in tourism, the number of such cases is likely to increase without jeopardising national healthcare systems.
   This applies also to other health services. In typical tourist destinations (in particular winter sport), foreign patients account for a significant share of total patient numbers. Detailed statistics are, however, not available.
c) The CMD manufacturer wants to sell his products in another Member State, or a prescriber charges a CMD in another Member State to produce a CMD. This is increasingly done between high wage and low wage countries. However, the focus is clearly shifting outside of Europe to Asia (China). Again, money is the main driver. In this case, however, it is not clear who is the financial beneficiary, unless the prescriber passes the benefits on completely to the health insurance / patient.
d) The CMD manufacturer wants to establish in another Member State. Theoretically, this is possible provided the requirements of the directive on the recognition of professional qualifications are met. However, in practice, there may be other obstacles. The Czech health insurer refused to reimburse the CMD of a German manufacturer established in the Czech Republic on the grounds of "an already sufficient offer". On the request of the UEAPME NORMAPME Healthcare Forum, the European Commission is currently investigating this case. In total, there are only a few cases of cross-border establishment.

UEAPME and the UEAPME NORMAPME Healthcare Forum encourage the European Commission to establish more reliable figures on cross-border healthcare in the various regions.

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?

Transparency and access to information are certainly keys to the provision of quality cross-border health services. For CMD manufacturers, this includes three main considerations.

a) Allowing patients to take informed decisions

The EU-institutions and national governments must respect the patient's right to receive accurate information so that he/she can make informed choices regarding their treatment. This must also apply to cross-border treatments.

Agents (for ex. doctors) who put custom made devices (CMD) on the market do not know whether the CMD supplier is really the manufacturer or what parts / components where provided by other subcontractors. Unless all manufacturing sites are indicated on the Statement of conformity, traceability is not possible. However, traceability and transparency should be major goals of national and EU rules.

The agent who puts the CMD on the market does not know how exactly the CMD was manufactured and what components / materials where used. Only the manufacturer disposes of this information. In the case of an emergency, it is therefore indispensable to have direct access to the manufacturer.

UEAPME and the UEAPME NORMAPME Healthcare Forum therefore press the European and national decision makers to maintain the phrasing of the draft revised medical device directive (93/42/EEC) requiring the Statement of conformity to be passed on to the patient and to include the name and address of the manufacturer and all subsequent production sites.

Furthermore, the patient, who wants treatment in another Member State, should have the **right to know whether the CMD manufacturer is registered** and therefore likely to comply with the EU legislation. Again, the draft revised directive 93/42/EEC could provide the right tool by establishing a European database (EUDAMED) of registered manufacturers and their products. A part of this database will be available to the public. Unfortunately, the Commission and the Member States are already years behind the target date for EUDAMED's establishment and nobody knows when this will finally be achieved.
We insist on the fact that databases based on harmonised nomenclatures for CMD (custom-made medical devices) already exist and could be easily used for the European system (EUDAMED). As a matter of example, Italy is using such a database including all CMD manufacturers and types of CMD manufactured. This document is published and can also be consulted on the Internet by all interested parties. Sweden has introduced a similar system.

UEAPME and the UEAPME NORMAPME Healthcare Forum press the European and national decision makers to establish EUDAMED as soon as possible, to include CMD in this database and to allow the public access to essential parts of it (registered manufacturers etc.).

b) Allowing CMD manufacturers to access the information required to respond to the patient's needs

A rapid, efficient and effective treatment is only possible of the healthcare professional disposes of certain information regarding the patient (allergies, type of CMD used etc.). UEAPME and the UEAPME NORMAPME Healthcare Forum therefore support efforts to establish a European e-Health system, which would enable healthcare professionals across Europe to access certain information registered on the patient's health insurance card. Each healthcare professional should have access to the information he / she needs for the treatment.
Such a system should also allow access to information regarding the reimbursement schemes and procedures applicable in the case of cross-border health service provisions.

Parallel efforts of many Member States to establish their own national system will only increase the costs for the tax payer and hamper cross-border activities.

UEAPME and the UEAPME NORMAPME Healthcare Forum encourage Member States and the EU to agree on one pan-European e-Health system.
This system must allow ALL health professionals, including CMD manufacturers to access the information they need to offer quality treatments and minimise health risks.

c) Recognition of professions and qualifications

Patients, public authorities and health insurance companies should know whether the competence of health service providers coming from other Member States corresponds to the one in their home country. Directives 1999/42/EC and, from October 2007 onwards, 2005/36/EC, on the recognition of professional qualifications provide a detailed framework for this.

However, article 5 (Principle of the free – occasional and temporary - provision of services) of directive 2005/36/EC stipulates that "Member States shall not restrict, for any reason relating to professional qualifications, the free provision of services in another Member State:

(a) if the service provider is legally established in a Member State for the purpose of pursuing the same profession there, and
(b) where the service provider moves, if he has pursued that profession in the Member State of establishment for at least two years during the 10 years preceding the provision of services when the profession is not regulated in that Member State. The condition requiring two years' pursuit shall not apply when either the profession or the education and training leading to the profession is regulated."

Article 7 authorises the competent authority of the host Member State to "check the professional qualifications of the service provider prior to the first provision of services. Such a prior check shall be possible only where the purpose of the check is to avoid serious damage to the health or safety of the service recipient due to a lack of professional qualification of the service provider and where this does not go beyond what is necessary for that purpose."

Also regarding the establishment of certain healthcare professionals in other Member States, directive 2005/36/EC is likely to cause problems. Article 13 stipulates that the host Member State must permit access to and pursuit of that profession if the attestation of competence and evidence of formal qualifications attest a level of professional qualification at least equivalent to the level immediately prior to that required in the host Member State.

The consequences of these provisions are dangerous. Rapid technological progress (hearing aid devices, prostheses etc.), stricter standards and material requirements and higher safety levels require permanent qualification measure by CMD manufacturers. However, under the terms of the directive, a foreign CMD manufacturer would only need a two-year experience to be able to work in other Member States. Or, in the case of establishment, his / her qualifications can be one level below the requirements of the host country. The directive is therefore likely to undermine the patients' trust in qualifications and diplomas.

In this context, one most refer to the different classifications of CMD manufacturers at national level. In most of the EU countries, CMD manufacturers are already recognized as a healthcare profession, but in some Member States, they are still considered as craftsmen (trade profession). Clarification regarding the recognition of the profession as well as defining the skills and knowledge needed to become a CMD manufacturer would facilitate a cross border healthcare system and help to spread best practice.

UEAPME and the UEAPME NORMAPME Healthcare Forum invites decision makers to reconsider the above-mentioned provisions of directive 2005/36/EC. Furthermore, the status of CMD manufacturers should be clarified and the development of European qualification requirements promoted.

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?

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?

The responsibility for supervising health services and medical devices and ensuring safety should always lie with the Member State authority where the healthcare service is provided / the device put on the market.
The transposition of European healthcare-related legislation (for ex. the Medical Devices Directive – 93/42/EEC) should be harmonised in all Member States. Leaving too much room for interpretation, when putting European legislation into national law, does not form a solid base for cross–border healthcare activities. This applies particularly to the surveillance of healthcare service providers.
Unlike other manufacturers of medical devices, CMD manufacturers are not CE marking their products and are therefore not inspected by notified bodies. Instead, the national competent authorities are in charge of these checks. However, a German dental laboratory is only likely to be inspected every 125 years, whereas an Irish lab is controlled every year!

UEAPME and the UEAPME NORMAPME Healthcare Forum urges the Commission to issue guidance papers on market surveillance and monitor closely the practical national implementation of EU rules.

Patients abroad (as tourists or for a limited temporary presence) who need immediate or urgent healthcare do not have time to compare or search for healthcare services and devices. They need to rely on the system offered in the state in which they are staying. In this case, we consider it natural that patients are reimbursed according to their own national system and by their own country's compensation system (i.e. the country where they are insured). This should also apply to cases where harm is caused in the state where the health services/devices were provided.

A different approach may be considered when patients shop for low-price healthcare services abroad. In such cases, it seems unfair to put the burden of compensation in the event of harm entirely on the patients' country of origin (i.e. the country where they are insured). A different solution appears necessary.

To allow an efficient and effective dataflow (on paper or electronically), one should consider the establishment of harmonised document standards.

Issues relating to the applicable law should be resolved according to the international private law and the European conflict rules, respectively.

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 service accessible to all (for example, by means of financial compensation for their treatment in 'receiving' countries)?

UEAPME and the UEAPME NORMAPME Healthcare Forum believe that the overwhelming majority of patients will seek treatment as closely as possible to their homes. Even in border regions, they will mostly opt for a service provider from their own country. The Forum does therefore not anticipate major problems.

On the other hand, health insurance companies from all countries should be encouraged to achieve a certain performance level so as to reduce certain "push-factors". It must also be ensured that service providers are reimbursed quickly even in the case of cross-border treatments.

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?

This matter is dealt with in detail under question 2 (section c)).

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?

It should be clarified to what extent out-patient health cures are covered by the definition of health services.
We refer to the current discussions on the implementation measures relating to Regulation 883/2004 (Co-ordination of social security systems), which should clarify this issue.

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 following areas are particularly important:

- Maintaining a maximum of transparency regarding qualification requirements, lists of authorized healthcare services providers etc.;
- Assure the equal application of EU rules in all Member States, in particular with regard to market surveillance;
- Develop an EU-wide (instead of many national) e-health system and guaranteeing access to relevant information to all health service providers;
- Support the development of harmonized competence criteria for health service providers.

All these are have already been identified further above.

Furthermore, Europe should organise an effective exchange of experience and best practice. This dialogue should not only include governments and health insurance companies, but also representatives of the relevant professional organisations.

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?

Maintaining a maximum of transparency regarding qualification requirements, lists of authorized healthcare services providers etc.
Partially legislative: the draft revised directive 93/42/EC allows Member States to make the lists of authorised medical devices manufacturers publicly available.

Partially non-legislative.

Assure the equal application of EU rules in all Member States, in particular with regard to market surveillance

Non-legislative measure. The Commission should publish guidance papers and monitor closely national implementation measures.

Develop an EU-wide (instead of many national) e-health system and guaranteeing access to relevant information to all health service providers;
Legislative measure, although resistance from Member States is to be expected.

Support the development of harmonized competence criteria for health service providers.
Non-legislative measure.

Brussels, 9 January 2007

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