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On 26 October 2010, the CPME Executive Committee adopted the "CPME position on Cross Border Health Care, EP draft recommendation for second reading presented by Rapporteur Françoise Grossetête" (CPME 2010/120 Final EN)

Patients' rights in cross border healthcare

26.10.2010

The **Standing Committee of European Doctors** (CPME) is the representative organisation of European doctors through its full members, the most representative National Medical Associations of 27 countries in Europe. CPME works closely together with its other members, four National Medical Associations from associated and observer countries as well as with specialised European medical associations.

CPME aims to promote the highest standards of medical training and medical practice in order to achieve the highest quality of health care for all patients in Europe. CPME is also concerned with the promotion of public health, the relationship between patients and doctors and the free movement of doctors within the European Union.

The Standing Committee of European Doctors (CPME) supports a rights based approach that would create legal clarity regarding patients' rights. CPME hopes that the Directive on patients' rights will enable cross border healthcare to be carried out in a clear framework of safe, high quality and efficient healthcare throughout the EU – which will be beneficial both to patients and to physicians. CPME recalls that all EU citizens should have full confidence that they will be treated by a medical specialist in any treatment received under the cross border health care directive.

In the ongoing institutional debate several areas have been revised while others have been removed. In order to uphold the principles of quality, safety and equity, CPME calls on EU Member States and EU Institutions to maintain provisions, as they are set out in the report by MEP Françoise Grossetête (EPP, FR) adopted by the ENVI Committee on 28 September 2010 that relate namely to eHealth, health technology assessment, prior authorisation and rare disease for the following reasons:

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eHealth

◆ Safety of cross-border care would be seriously undermined without the effective and efficient transfer of patient information. Information must be transferred via secure systems that safeguard confidentiality and treat relevant medical information only. In the absence of other effective cross-border patient safety measures, the electronic transfer of patient data represents a reliable method of ensuring that data is shared across borders. It is also essential that the patient's prior consent is given and that the transfer of data is carried out for medical purposes only. CPME also notes that consent for the transfer of patient information from one data system to another requires informed consent in addition to the normal consent processes for treatment.

CPME therefore supports amendments 44 and 45 which highlight the need to address the issues related to data protection. That having been said, amendment 44 sets out an obligation for the national contact points to provide information on "the level of accessibility to healthcare facilities for people with disabilities". CPME has strong reservations that national contact points will be able to carry out this task fully and would also like to highlight that there is no link with eHealth.

◆ eHealth also facilitates continuity of care (as highlighted in amendment 35), in a patient-centered and efficient way. Moreover, eHealth could also help address the alarming rise in health inequalities while creating an enabling environment for innovation and the improvement of health care delivery provided that access to eHealth for all is ensured.

However, this can only be possible if legal clarity and interoperable systems are put into place. CPME therefore supports amendment 29 which brings attention to the need for interoperability namely of systems and terminologies. This amendment, and also amendment 86, appear to alter the balance of responsibility for standards-setting and the design of IT systems away from Member States towards the Commission. CPME recognises that Member States should retain the right and responsibility to deliver healthcare through IT systems that best serve their needs. However, in relation to cross-border care, patient safety demands that semantic and technical interoperability, and the efficient identification and authorisation of patients is essential for safe care to take place. CPME has supported the high-level Council conclusions on these issues, and notes that changes to the Data Protection Directive are likely to improve harmonisation of the protection of patient-identifiable information through such measures as "Privacy by Design".

◆ Trust in eHealth technologies from both patients and healthcare professionals are essential to avoid misapprehension and misunderstanding, which can be reinforced in a cross-border setting. CPME therefore welcomes amendment 26 which puts particular emphasis on the need for legal clarity.

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CPME therefore calls for the creation of and support for effective measures by facilitating the electronic transfer of patient data in cross-border care to ensure patient safety. CPME underlines the need for secure systems that safeguard confidentiality and treat relevant medical information only. Furthermore, it is essential that the patient's prior consent is given and that the transfer of data is carried out for medical purposes only.

Health technology assessment (HTA)

◆ CPME acknowledges that HTA is increasingly seen as a priority at EU level to ensure the sustainability of current healthcare systems supporting evidence-based decision making.

CPME emphasises that HTA should be used in order to ensure patient centred and effective health policies, provide decision makers with more accurate, evidence-based tools for prioritising healthcare treatments in terms of their utility, efficiency and cost-effectiveness – and not merely to control healthcare costs. CPME insists on best available evidence, common methodological and process standards and common review processes. HTA has to be firmly rooted in research and scientific methods and should summarise information in a transparent, unbiased and robust manner.
However, HTA should not be restricted to academic exercise, but be accompanied by peer review, performed by health professionals working within the same relevant healthcare setting.

◆ CPME welcomes amendments 87 and 93 of the new report from MEP Mrs Grossetête that recognise the importance of *"full stakeholder participation of all relevant groups, including –but not limited to- health professionals, patients representatives, (...)",* in the functioning of the proposed HTA Network.

CPME is a member of the EUnetHTA stakeholder forum and is ready to play an active role in the discussions on this topic to ensure that fundamental ethical principles are upheld.

◆ CPME supports a further strengthening of a European HTA Network as defined in amendments 88 and 90, including clear objectives along the lines of the recommendations of the Pharmaceutical Forum Relative Effectiveness WG.
HTA is international in scope, therefore better co-ordination through a European HTA Network would reduce duplication of work to a large extent and help to spread best practice.

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◆ Finally, CPME strongly believes that HTA must overcome the serious conflicts between economics and ethics – not least when such decisions involve life-saving technologies, e.g. new treatments for cancer.

CPME recalls the principle of justice in medical ethics which give healthcare professionals the responsibility to look at the cost-effectiveness dimension of healthcare. However, pure economically driven HTA process would be contrary to fundamental EU principles and contrary to the patient centred care which has been proven to lead to better health outcomes. CPME thus calls for an ethical HTA framework, which allows physicians and patients to be meaningfully involved in related processes.

Rare diseases

◆ CPME welcomes the amendments that make a clear reference to rare disease, as defined by amendments 20, and that highlight the inherent needs and obstacles (e.g. as regards reimbursement or information and expertise via European reference networks in amendment 28 that are confronted by affected patients). CPME therefore also supports amendment 81 which sets out the objective of European reference networks, and welcomes the inclusion of prevention.

European reference networks are a significant part of the Cross Border Healthcare Directive, and this amendment provides the necessary objectives that these networks propose to achieve. Specifically, the addition of Amendment 81 *(b) to contribute to the pooling of knowledge regarding sickness prevention and the treatment of major commonly occurring disorders* and *(f) to provide quality and safety benchmarks and to help develop and spread best practice within and outside the network.* If achieved, these objectives may have significant positive health outcomes for Europeans.

However, CPME is opposed to amendments 16, 47 and 64. Seeking any care in another member state without prior authorisation could cause unpredictable costs to national health system. CPME holds that any treatment that is reimbursed should be scientifically proven and quality assured. An alternative could consist in requiring prior authorisation also in the case of rare diseases (if applied to other diseases nationally) but not to limit the reimbursement to the same or similar treatment as would be available in the home state.

Information

◆ Given the sensitivity of this issue, CPME has systematically called for information concerning the treatment sought in a transparent and timely way to ensure that the rights of patients are safeguarded. Therefore, CPME welcomes the amendments that aim to improve the quality and the accessibility of information for patients, namely as regards the type of information "is made publicly available *in advance*" (amendment 21) and that information be available in "*accessible formats and to potential sources of additional assistance for vulnerable patients, disabled people and people with*

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complex needs" (amendment 25) to allow them to make an "*informed choice*" (amendment 34).
However, CPME would like to express concerns about the feasibility for complete and accurate information to be made available concerning the treatment options, prices and liability insurance of individual doctors. Furthermore, registration numbers may be problematic as regards the possible misuse of that information.

Prior authorisation

CPME also supports amendment 19 which states that "*this Directive allows for a system of prior authorisation if there is sufficient reason to expect that the social security system will be seriously undermined. This should also cover cases of already existing systems of prior authorisation which are in conformity with conditions laid down in article 8"*.

- Moreover, CPME welcomes amendment 22 which strives to find a balance between the needs of patients and the overall balance national health services ("*prior authorisation may be refused only if the patient is not entitled to the treatment in question, or on the basis of a clinical evaluation, or on the basis of exposure of the general public to a substantial safety hazard" and that "in the event of refusal, an appeal procedure should be available*").

- CPME also welcomes the call for the decisions relating to cross border care be made expeditiously in order to give patients as much certainty and within as short time limits as possible. CPME therefore welcomes amendment 24 which states that "*it is appropriate that patients should normally have a decision regarding the cross-border healthcare within fifteen calendar days. However that period should be shorter where warranted by the urgency of the treatment in question*". In any event, CPME holds that a clarification is required regarding the gatekeeper function in seeking prior authorisation for treatment abroad.

However, it is not clear to CPME what is meant by "characteristics of healthcare provided by a specific healthcare provider" as set out in amendment 7. Does this refer to quality, safety, content of the care, or something else? CPME calls for this amendment to be clarified.

Furthermore, CPME is opposed to amendment 59, insofar as it aims at deleting paragraph (e) of Article 8 par.5. It is not clear why Member States should be obliged to bear the costs of treatment provided by health professionals who raise serious and specific concerns relating to the quality of care or patient safety.

Reimbursement

- Given the inherent personal and financial strain that are linked with cross-border healthcare, CPME welcomes the many amendments that seek to clarify

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reimbursement procedures and address the concerns of patients (e.g. amendments 62 and 63 relating to prior authorisation and reimbursement) and the exemption proposed for rare disease patients (amendment 64).

CPME therefore supports the proposal for a "voluntary system of prior notification" (amendment 53) which would allow patients to receive a written confirmation of the maximum amount that would be reimbursed for cross-border treatment. CPME also supports amendment 56, which clearly sets out the conditions under which prior authorisation for reimbursement can be used.

However, CPME has strong reservations as regards amendment 68, which calls for the establishment of a European clearing house to facilitate the reimbursement of costs, as this may constitute a complex bureaucratic layer that may not necessarily have much added value.

In CPME's view this directive should not create another, separate reimbursement system between countries alongside the one that already exists in the social security coordination regulation.

◆ CPME specifically welcomes the clarifications brought namely by amendments 12 ("*patients should enjoy a guaranteed assumption of the costs of health and goods connected with healthcare provided in a Member State other then their member State of affiliation at least at the level as would be provided for treatment which is the same or equally the same or equally effective had they been provided or purchased in the Member State of affiliation*"), 16 (rare disease), and 17 ("*if there are several methods available for treating a certain disease or injury, the patient should have the right to reimbursement for all methods of treatment that are sufficiently tried and tested by international medical science, even if they are not available in the patient's Member State of affiliation"*).

CPME also supports amendments that encourage Member States to cover other related costs, such as therapeutic treatment, accommodation and travel costs related to cross-border treatment (e.g. amendment 48).

Information sharing between authorities

◆ CPME supports amendments 72 and 73. Information on disciplinary and criminal measures that have an implication on a doctor's entitlement to practice have to be proactively shared between Member States. Amendment 73 is a valuable amendment to the text, as it provides another layer of protection for patients and the quality of care that they receive while abroad. The broader implications of this amendment could also assist in determining if health care professionals have any criminal convictions or have faced disciplinary action which would impact on their

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application to work as a health care professional in another Member State. This should also be cross-referenced in the Professional Qualifications Directive.

Involvement of professional representations

◆ Finally, CPME welcomes all amendments that aim at greater involvement and consultation of health professionals, i.e. amendments 27, 31, 42, 87 and 93.

CPME thus welcomes the amendments as set out above of the EP draft recommendation for second reading presented by Rapporteur Françoise Grossetête and calls on the institutions to continue their commitment to working towards patient safety, effective interoperability in eHealth across Europe, balanced prior authorisation and reimbursement requirements and responsible HTA.

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