CPME/AD/EC/181109/196_Final/EN

On 18 November 2009, CPME Executive Committee adopted the following Statement : **Comments on the compromise proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare (Oct 23rd 2009)** (CPME 2009/165 Final EN)

Comments on the compromise proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare (Oct 23rd 2009)

Although CPME is very much in favour of having a Directive of patients' rights in cross border health care and has stated before its support for this initiative (even when the proposed text is not the ideal one) it has a feeling that the amendments proposed by the Swedish Presidency may reflect the desire of some Member States to limit the scope of cross-border care. They represent a significant retreat from an EU-based approach to the provision, standards and availability of cross-border care. This creates an unwelcome bias towards what CPME considers excessive Member State control. In particular, although there is a welcome restatement and an emphasis on the quality of care, the definition and regulation of factors that contribute to patient safety and quality of care are largely voluntary, and are defined and regulated at Member State level. It should be recognised that the EU has a clear added value that gives the opportunity to improve harmonisation of standards, outcome measurement and quality data. This chance will be missed if future proposals are framed in a tight legalistic way.

Our specific comments are:

Recital 3 and 4 remove all references to the right of access to treatment as defined by Charter of Fundamental Rights of the European Union, and to the principles of social cohesion, protection and justice. CPME regrets that the high-level context in which the right to travel for treatment is expressed has been diminished.

CPME welcomes, in respect of patient safety concerns, the exclusion provided in Recital 9 of a healthcare provider on the grounds of "legitimate concerns over the safety and quality of care provided". However, in order for this to be done in a fair and consistent way, a sound regulatory basis for such an exclusion would need to be developed, as well as clarity over how a provider "outside of the statutory social security system or national health system" in the Member State

Rue Guimard 15 - 1040 Brussels - Belgium
Tel. : +32 (0)2 732 72 02 - Fax : +32 (0)2 732 73 44 - E-mail : secretariat@cpme.eu - Web : http://www.cpme.eu

of treatment might be defined. CPME is of the opinion that care providers could only be excluded on the basis of the quality of care they deliver, and certainly not on the grounds of the "private or public" aspect of their service.

CPME welcomes the exclusion of internet-based purchases (Recital 10aa) on the grounds that their quality cannot be adequately regulated.

CPME insists that cross-border care can only be delivered safely when these aspects, as mentioned in recital 4a, are developed in a pan-European context, rather than left to Member States to provide and regulate, This concern goes to the heart of the problem with these proposals, in which measures that would enhance patient care have been discarded, leaving a document that mainly concentrates on protecting Member State interest rather than patients interests and limiting the opportunities and scope of cross-border care. This retreat from an EU-based approach is reflected in the statement that "it is the authorities of the Member State on whose territory the healthcare is provided, who are responsible for ensuring compliance with those operating principles." In addition, we regret that Recital 12 only requires Member States to provide information on safety, as well as quality standards "enforced" on its territory, without setting these within an EU-wide framework.

CPME has welcomed moves towards flexibility regarding prior authorisation, and is therefore disappointed to see the removal (Recital 26a) of a process which gave Member States the freedom to set up voluntary systems of prior notification, under which patients might obtain written confirmation in advance whether they will be reimbursed.

We welcome the addition (Recital 39 and elsewhere) of medical devices, and the suggestion that "recognition of prescriptions should also apply for medical devices that are legally placed on the market in the Member State where the device will be dispensed."

CPME welcomes the proposals for an increase in the "continued development" of European reference networks (Recital 40). The suggestion that support should be given to assist this development is also welcome, but this must be done within an EU-based context. Therefore, CPME strongly supports the suggestion that "the Commission should develop criteria and conditions that the networks should fulfil in order to receive support from the Commission." This move towards harmonisation of standards is strengthened in this paragraph, with its emphasis on ICT system "interoperability", in contrast to the "harmonisation" referred to in previous texts.
That said, the positive tone of Recital 40 is contradicted by the deletion of Recital 42, which rightly stressed the need for the use of "routine statistics" for "efficient monitoring, planning and management of healthcare in general and

cross-border healthcare in particular…", and called for integration of data collection systems. This deletion is very disappointing, as is the reference to the importance of ECDC.

CPME regrets that in Recital 36 the referral to the European Health Portal has been deleted. As this is an information system helpful to European patients and citizens we strongly suggest keeping this referral in the text.

CPME agrees with the view in Recital 43 that the evaluation of new health technologies requires enhanced co-operation but sees the proposals to achieve this as timid, and far too dependent on the creation and maintenance of "voluntary networks connecting national authorities or bodies responsible for health technology assessment…." This overly cautious approach goes against moves to create EU-wide regulation of technology and devices.

As to the deletion of Recital 45 CPME requests that discussions about a legal and regulatory basis for harmonisation of the hospital treatment definition will start so that consistency can be developed.

In summary, while there seems to be an increased emphasis on safety, the lack of measures to establish EU-wide criteria for quality and greater harmonisation of output measurements, and the emphasis on Member State autonomy in many areas that require a much wider approach, are all restrictive of patient opportunity and choice, and fail to meet the need for cross-border care to be delivered safely. The version as now proposed in the eyes of the CPME is weaker than the text that was adopted by the European Parliament in first reading. However the CPME appreciates the efforts of the Swedish Presidency to support the possibility of reaching agreement on the directive. These comments are made based on the text as presented by the Swedish Presidency on 11th November (2008/0142(COD)).