COMITÉ PERMANENT DES MÉDECINS EUROPÉENS
STANDING COMMITTEE OF EUROPEAN DOCTORS

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At the CPME Board Meeting in Brussels on 13 June 2009, CPME adopted the following document "**CPME position on the Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on standards of quality and safety of human organs intended for transplantation**" (CPME 2009/118 final EN/Fr)" (referring to CPME 2009/118 EN/Fr)

CPME position on the Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on standards of quality and safety of human organs intended for transplantation

In 2006, the European Commission held an open consultation on the subject of organ donation and transplantation[1]. The results[2] were published in December 2006. In December 2008 these were followed by the above mentioned proposal.

CPME has reacted previously to the Commission's consultation and a statement of the Board was passed in June 2008 and transmitted to the Commission (CPME 2008/016).

CPME reaffirms its positions laid down in this document regarding the subsidiarity principle and the legal framework applicable to organ donations. We therefore attach the Document CPME 2008/016 to this statement

General appreciation of the initiative of the EU Commission

CPME basically welcomes the intention of the European Commission to continue its work on promoting transplantation medicine in the framework of various Community programmes and to promote cooperation between Member States in this sector with the aim of creating uniform access to healthcare throughout the EU.

[1] Organ donation and transplantation policy options at EU level. Consultation document. 27 June 2006.
[2] Report on the open consultation: policy options for organ donation and transplantation at EU level. Health & Consumer Protection Directorate-General, December 2006.

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In the opinion of the European Commission, the main problem in transplantation medicine is the shortage of organs. With the drafted directive it addresses the following aspects, among others:

- Establishment of national supervisory authorities for implementing the Directive;
- Quality and safety standards for the authorisation of establishments;
- Traceability and reporting of adverse events and reactions;
- Establishment of inspection structures and control measures;
- Obligatory characterisation of organs for risk assessment purposes.

However, the question arises as to the legal basis on which the EU Commission could implement the intended measures. (See also CPME 2008/016)

The measures planned by the EU Commission would, however, extensively intervene in national regulations concerning the donation or use of organs for transplantation. In Germany, for example, the powers assigned to state authorities would jeopardise the established structures of self-administration and thus an efficiently functioning system for transplantation medicine, as well as the institutions involved.

Demands on the quality of organs for transplantation

Regardless of the question as to the competence of the European Commission, it remains unclear whether and how EU-wide regulations concerning the quality and safety of organ donation and transplantation would be suitable for eliminating the organ shortage. In all EU Member States with advanced transplantation medicine quality and safety are subject to high standards that are constantly being further developed and adapted to the latest state of science and technology. It is thus hard to see what stands to be gained by a separate system of regulations on transplantation medicine under EU law. Rather it is to be feared that, based on the unsubstantiated argument that quality and safety of transplantation medicine are currently inadequate, the proposed EU Directive is intended to intervene extensively in the structure of transplantation medicine in the individual Member States. The predominant result of which would be excessive bureaucratisation.

The fundamental problem of deficits in the provision of transplantation medicine in a number of Member States of the EU however is not sufficiently tackled.

The goal set by the European Commission, i.e. elimination of the organ shortage, cannot be achieved by such a bureaucratic approach. For structural reasons alone, an organ shortage exists to a greater or lesser degree in all EU Member States, regardless of how transplantation medicine is established, regulated by law and accepted by the public in the individual countries. However, the exchange of an item that is in short supply in all Member States does not eliminate the shortage, but merely redistributes it. The organ shortage ultimately cannot be significantly reduced by international organ exchange.

Alternative approaches based on the EC Treaty

Every measure of the European Commission must give consideration to the priority of national regulations over EU-wide harmonisation pursuant to Art. 152 Para. 5 of the EC Treaty. There were, and still are, good reasons why a special regulation was stipulated in the EC Treaty regarding the donation and medical use of organs. Against this background, the aim should initially be to guarantee comparable transplantation medicine services for all patients in the EU. The EU Commission could, for example, contribute to achieving this development target by means of accompanying measures for aligning the conditions for providing transplantation medicine services in the Member States. This should be done by promoting the development of efficient transplantation medicine, especially in the Member States without established organ transplantation.

Regardless of this, the organ shortage should, as a key problem in the provision of transplantation medicine services, be counteracted by, for example, EU-wide public relations work and promotion programmes on organ donation, giving consideration to specific national and cultural features in the individual countries. An EU initiative on organ transplantation should encourage increasing willingness to donate, and not jeopardise past achievements through excessive bureaucratisation.

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