COMITÉ PERMANENT DES MÉDECINS EUROPÉENS
STANDING COMMITTEE OF EUROPEAN DOCTORS

Brussels, 29th April 2004

Future European regulatory framework for human tissue engineered products

It is of the utmost importance to get the best and safest treatments for citizens across Europe.

As such, CPME supports the Commission's consultation on a proposal for a European Parliament and Council Regulation on tissue engineering and tissue engineered.

Indeed, the production and distribution of therapeutic products prepared from human tissues raises important ethical, scientific and regulatory issues that have to be answered to ensure the trust of patients and healthcare professionals.

CPME notes with satisfaction that its initial concerns were integrated in the proposal. CPME would like anyway to voice other concerns regarding two points of the proposal namely the obligation for healthcare professionals to report adverse effects and the long term traceability of patients.

Regarding the obligation of reporting, CPME would like to ask for a very simple and anonymous way of doing it.

As far as the traceability is concerned, this could conflict with the healthcare professionals' principle of confidentiality and data protection /respect of privacy rules

CPME is a membership driven association with members from the enlarged EU, EFTA, incoming countries and the wider Europe. The CPME represents over 2 million doctors within the enlarged EU/EEC. CPME's aim is to promote the highest standards for public health and medical practice at the EU level.

We are at your disposal regarding any questions you may have.

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President

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