EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment
C6 - Health measures

TISSUES AND CELLS REGULATORY COMMITTEE
24 FEBRUARY 2006
SUMMARY REPORT

The Regulatory Committee established by Directive 2004/23/EC of the European Parliament and of the Council setting high standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells was convened on 24 February 2006 under the Chairmanship of Mr Tapani PIHA, Head of Unit, Sanco C6. The topics for discussion were the draft Commission Directive as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells; the Report on the regulation of reproductive cell donation in the European Union and the Proposal for a working group on the specifications of the EU coding system.

All Member States except for Luxembourg were present at the meeting; were also present: Iceland, Norway and Bulgaria.

Item 1 Welcome and introductory remarks by the Chairman of the Committee

The Chairman welcomed the delegations (list of representatives appended in Annex I). The Chairman discussed the progress made on the first Commission Directive which was adopted by the Commission on 8 February 2006 and he introduced the draft second Commission Directive explaining that a formal vote could only be carried out once the draft Commission Directive had been translated into all Community languages. The aim of this meeting was to get an agreement in principle on the text. For the formal vote, this would be carried out through a written procedure. The Chairman discussed the planning for the meeting of the Competent Authorities on blood which is scheduled for 14 September 2006, and announced that a meeting of the Competent Authorities on tissues and cells will be organized in autumn 2006.

European Commission, B-1049 Brussels – Belgium. Telephone: (32.2) 299 11 11
Office: F101 – 07/74. Telephone: direct line (32-2) 298 54 87 – Fax: (32-2) 295 95 80

E-mail: tapani.piha@ec.europa.eu

Item 2 Adoption of the agenda

A brief presentation on the proposed Advanced Therapies regulation was added to the Agenda.

Item 3 Draft Commission Directive as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells.

The draft under discussion was a version that had been revised in two National experts meetings on 16 September 2005 and 17 October 2005.

A number of changes were agreed by the delegations during the meeting and the Commission was asked to finalise some language drafting before the written procedure.

Note 1

The French delegation suggested adding a specific Annex describing common standards for the authorisation of each tissue and cell preparation process. The Commission confirmed that the authorisation of the tissue and cell preparation processes is an underlying principle of Directive 2004/23/EC. However, it is also clear that not all competent authorities are ready for implementing such detailed authorisation mechanism; in addition the elaboration of common European standards for every specific preparation process is a major task. It has been stressed that this is a step by step process. Annex II of the draft second Commission Directive therefore at this stage contains the general requirements for such authorisation. The Commission committed to evaluate the need for adding a more detailed annex and invited other Member States to send in their position on the subject in writing

Note 2

The issue of the need for access to an archive of frozen serum was discussed The Commission suggested deleting the requirement concerning an archive of frozen serum based on legal scrutiny. Delegations raised diverging opinions.

Note 3

The Commission announced its intention to make guidelines concerning the specifications, the basic nomenclature and the implementation of the Single European Code in collaboration with the Member States.

Item 4 Advanced therapies regulation

Eduardo Fernandez-Zincke discussed briefly the progress on the proposed Advanced Therapies Regulation.

Item 5 Report on the regulation of reproductive cell donation in the European Union

Jessica Cox presented the report on the regulation of reproductive cell donation in the European Union, which is to be published on the Europa - Public Health website: http://europa.eu.int/comm/health/ph_threats/human_substance/tissues_en.htm.

Item 6 Proposal for a working group on the specifications of the EU coding system

The setting up of a working group on the specifications of the EU coding system was approved by the delegations. This working group will be presided by the Commission and will work conforming to the rules of procedure of the Regulatory Committee. Candidates should nominate their experts and send in their coordinates to the Commission as quickly as possible.

Tapani PIHA
Chairman of the Committee