



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL
Directorate C - Public Health and Risk Assessment
C6 – Health measures

Tissues and cells Regulatory Committee

29 June 2005

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 29 June under the Chairmanship of Mr Tapani PIHA, Head of Unit, Sanco C6. The topics for discussion were the adoption of the Rules of procedure of the Committee and the draft Commission Directive as regards certain technical requirements for the donation, procurement and testing of human tissues and cells.

All Member States plus Norway, Bulgaria and Romania were represent at the meeting.

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 introduced the role of the Regulatory Committee. He also introduced the draft 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 Chairman thanked the delegation for their willingness to make progress with the dossier despite that language versions were not yet available. 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.

Item 2 Adoption of the agenda

The agenda was adopted without changes.

Item 3 Adoption of the rules of procedure of the Committee.

The Rules of procedure sent in advance were adopted without changes.

Item 4 Draft Commission Directive Implementing Directive 2004/23/EC of the European Parliament and the Council as regard technical requirements on donation, procurement and testing of human tissues and cells.

The Draft under discussion was a version that had been revised in two National experts meetings on 29 October 2004 and 15 November.

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

German delegation underlined that Anti-HVC-Ab testing could not be sufficient for detecting HVC and strongly recommended to encourage the use of NAT testing for HVC. The Commission explained its open position to introduce this type of test. However during the previous discussion it was clearly shown that some MS will have problems to introduce the NAT tests as binding criteria given the associated costs. It was decided to reconsider this issue in the future update of the annexes in view of the scientist evidence.

Note 2

The Netherlands supported by the UK proposed to limit the requirements for testing reproductive cells (partner donation-direct use). The Commission could support the proposal, however, several delegations expressed doubts about a total exclusion of partner donation-direct use.

Note 3

The German delegation suggested the need to take into account the particularities of hair and other materials taken from human deceased donors used for products such as tumour vaccines and homeopathic medicines (amino acids). It was decided that all tissues and cells that are applied to the human body should comply with the same standards, decision on specific requirements for these products could be taken in the future in views of scientific evidence.

Item 5 Short report on the New Proposal on Advanced Therapies

Nicolas Rossignol from DG ENTR introduced to the delegations the new proposal on advanced therapies. The draft proposal is designed to address all advanced therapies (gene therapy, somatic cell therapy and tissue engineering) within a single, integrated regulatory framework. This “Regulation on advanced Therapies” builds upon existing legislation on medicinal products. The representative of DG ENTR promised to involve this Committee in the further steps of this future regulation.

Item 6 Short report on the European Coding system

Christine Gilissen (SANCO C6) presented an overview of the future work on the European Coding system under Directive 2004/23/EC. A questionnaire was distributed to the delegations to collect information on the existing coding systems at national level and on the implementation of coding systems, such as ISBT 128.

Item 7 Short report on Reproductive Medicine

Eduardo Fernandez-Zincke informed the delegations about the European Parliament Resolution on Trade of human egg cells and about the state of play of the consequent survey carried out by the Commission.

Chairman of the Committee

Tapani PIHA