EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment
C6 – Health Measures

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Blood Regulatory Committee

19 January 2005

SUMMARY REPORT

The Regulatory Committee, established by Directive (2002/98/EC) of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage, and distribution of human blood and blood components and amending Council Directive 2001/83/EC, was convened on 19 January under the Chairmanship of Mr Tapani Piha, Head of Unit, Sanco C6. The topics for discussion were two draft Commission directives dealing with quality systems for blood establishments, and traceability and notification of serious adverse reactions and events.

All Member States were represented in the meeting.

Item 1. Welcome by the Chairman.

The Chairman welcomed the delegations from the 25 Member States of the European Union. The List of Representatives that would be involved in the vote is appended in Annex 1.

Item 2. Adoption of the Agenda.

The Agenda was adopted following deletion of the remark that a vote was required for points 4 and 5.

Item 3. Introductory remarks by the Chairman of the Committee.

The Chairman reviewed the role of the Regulatory Committee and briefly commented on the participation of the observers.

He explained that a formal vote could only be carried out once the two Draft Commission Directives had been translated into all Community languages. The aim of this meeting was to get agreement in principle on the texts which had been discussed in previous meetings and revised taking into account consensus reached. For the formal vote, this would either be carried out through a meeting only of the delegated representatives of the Member States or through written procedure.

Item 4. Draft Commission Directive implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments.

The draft under discussion was a version that had been revised following a meeting on 15 December and consultation with DG Enterprise and the Commission's Legal Service. Several changes and modifications were introduced. They included a change in the definition of quality assurance; a change in Annex 4.2 of the words 'Equipment shall not present any hazard…' to '… shall be selected to minimise…'; in Annex 6.3 'repeatedly reactive' to 'confirmed positive'; in 6.6 from 'test results have been verified…' to 'test results show that all acceptance criteria have been met'.

The addition of 'hospital blood banks' to the definition of quality management, which only refers to blood establishments, was proposed but not accepted. It was pointed out that although hospital blood banks have a general obligation to establish and maintain a quality system under Article 11(1) of Directive 2002/98/EC, the Commission Directive cannot specifically address their quality systems as the established requirements are only directed to blood establishments in accordance with Article 11(2).

The suggestion that a sub-section of Annex II related to donors be introduced did not receive general endorsement and was not included.

The Commission explained that the transposition deadline in Article 3(1) would be about one year from the adoption, or 15 months from the launch of the written procedure.

Delegations gave their approval in principle on the draft Commission text as amended.

The Commission took note of the proposal from the Greek delegation on the need for standards and specifications relating to inspection and control measures for blood establishment that was circulated in the meeting.

Item 5. Draft Commission Directive implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events.

There was extensive discussion on the Draft Commission Directive that resulted in the introduction of several amendments. The major points of discussion related to the use of the term recipient rather than patient; the use of the word 'disposition' to indicate what happened to the blood unit if it was not transfused; the Community procedure for the notification of serious adverse reactions and events; the timing of the reporting to the competent authority subsequent to the event; and the notification formats.

Discussion about the reporting to the competent authority centred around whether there should be a specific time period set – such as within 48 hours or at the latest seven days. Several points of view were expressed with the result that no time frame was set.

Discussion about the notification format reflected the concern of Member States that it should be clear that this was only the minimum requirements that had to be reported. Some wanted the terms 'minimum requirements' specifically included on the notification format itself. Concern about using the proposed format was also expressed. However, it was pointed out that Directive 2002/98/EC required the Commission to establish Community procedures and a notification format.

The Commission assured the Committee that the reporting format in the draft Directive defines the minimum data needed for the notification and will not prevent Member States from collecting more extensive data and using their electronic systems to that end as long as the minimum defined in the Directive is respected.

The Commission agreed to take the matter of the minimum requirements up with its Legal Service. (The advice of the Legal Service on 8 February 2005 indicated that a reference to 'a minimum' would not have been justified in the operative part of the Directive as the Member States can adopt more stringent protective measures more generally with regard to any other traceability requirement. The Recital with the following wording would cover the issue '*This Directive therefore establishes the notification format defining the minimum data needed, without prejudice to the faculty of Member States to maintain or introduce in their territory more stringent protective measures which comply with the provisions of the Treaty as provided under Article 4.2 of Directive 2002/98/EC.')*

The Commission explained that the transposition deadline in Article 10 would be about one year from the adoption, or 15 months from the launch of the written procedure.

The Commission committed itself to follow closely the implementation of this Directive and suggest adaptation to technical and scientific progress, in particular as regards notification requirements and annual reporting.

Chairman of the Committee

Tapani PIHA [signed]

Annex 1

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Regulatory Committee Representatives

BELGIQUE / BELGIË	Red Cross – Blood Service
ČESKÁ REPUBLIKA	Institute of Haematology and Blood Transfusion
DANMARK	Lægemiddelstyrelsen (Danish Medicines Agency)
DEUTSCHLAND	Bundesministerium für Gesundheit und Soziale Sicherung
EESTI	Ministry of Social Affairs
ELLÁDA	University of Athens
ESPAÑA	Ministerio de Sanidad y Consumo
FRANCE	Ministère de la Santé, de la famille et des personnes handicapées, Direction générale de la santé
IRELAND	Irish Blood Transfusion Service
ITALIA	Centro Trasfusionale e di Immunologia dei Trapianti dell'Ospedale Maggiore di Milano
KYPROS	Ministry of Health
LATVIJA	State Blood Centre
LIETUVA	National Blood Centre
LUXEMBOURG	Ministère de la Santé
MAGYARORSZÁG	National Blood Supply Service
MALTA	National Blood Transfusion Service
NEDERLAND	Ministry of Public Health, Welfare and Sport
ÖSTERREICH	Bundesministerium für Gesundheit und Frauen
POLSKA	Institute of Haematology and Blood Transfusion
PORTUGAL	Instituto Português do Sangue
SLOVENIJA	Zavod za transfuzijo krvi RS (Blood Transfusion Centre of the Republic of Slovenia)
SLOVENSKO	Ministry of Health
SUOMI/FINLAND	National Agency for Medicines
SVERIGE	National Board of Health and Welfare
UNITED KINGDOM	Department of Health