EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

Brussels,
SANCO C6

NATIONAL EXPERT MEETING ON
ORGAN DONATION AND TRANSPLANTATION AT COMMUNITY LEVEL:
WORKING GROUP ON QUALITY AND SAFETY

BRUSSELS 31 JANUARY 2008
9:00 – 17:00

SUMMARY REPORT

The second meeting of the **Working Group on Quality and Safety** in organ donation and transplantation was held in Brussels on 31 January 2008. It was chaired by Tapani Piha. Thirteen countries, Eurotransplant and Scandiatransplant were represented by 17 experts.[1]

1. WELCOME AND INTRODUCTORY REMARKS

Tapani Piha welcomed the participants to the meeting and thanked them for their continued valuable input and advice on the draft working paper on quality and safety framework on donation, procurement, testing, transport, preservation, transplantation and characterization of human organs. He underlined the fact that organ donation and transplantation continues to be an important issue for the European commission and has recently been the subject of high profile political attention in several Member States.

The aim of this meeting was to further refine the draft document and discuss any outstanding issues. It was suggested to work through the document section by section since significant changes had been made to the previous draft.

2. FOLLOW UP TO THE COMMISSION COMMUNICATION ON ORGAN DONATION AND TRANSPLANTATION

Health Council

[1] Member States represented: Belgium, Denmark, France, Germany, Italy, Poland, Portugal, Slovenia, Spain, Sweden, UK, the Netherlands, representatives of Eurotransplant and Scandiatransplant.
ANNEX 1: List of Participants

The Health Council of 16 November 2007 adopted Council Conclusions on Organ donation and Transplantation[2]. In these conclusions, the health Council recognised the importance of having high standards of safety and quality and invited the Commission to continue its work on the action plan and the proposed EU framework on quality and safety for human organs.

European Parliament

Dr. Adamos Adamou MEP (CY, GUE-NGL) presented his draft on report on Organ donation and transplantation to the European parliament's Environment, Public health and Food Safety Committee on 22 January 2008. Two other committees; the Legal Affairs committee and the Civil Liberties Justice and Home Affairs committee also presented opinions to Dr. Adamou's report on 22 January 2008. In general, they all support the communication's main areas of action; improving safety and quality, increasing organ availability, making transplantation systems more efficient and accessible. The report will be adopted in Plenary in April 2008.

3. UPDATE ON EC ACTION PLAN AND FRAMEWORK ON QUALITY AND SAFETY

The Commission briefed the experts on the proposed EC 'organ package' that is currently under preparation. This will consist of a non-binding Action Plan with several key priority actions and a binding legal framework on increasing safety and quality.

4. DISCUSSION ON THE WORKING PAPER

Tapani Piha opened the working session and provided the caveat that this working document does not represent an official position of the European Commission or its services. The suggestions contained in it do not prejudge the form and content of any future proposal by the European Commission. Before going through each section, several participants congratulated the Commission on producing a much improved document and appreciated the efforts to incorporate their comments from the last meeting in October 2007.

4.1. Introduction, Quality and Safety Principles- General provisions

There was general agreement on the scope and objectives but it was felt that the introduction needed to better reflect the content of the proposed legal framework.

4.2. Obligations of Member State authorities

4.2.1 Supervision of procurement of human organs

Participants agreed that this section reads much better than before but that more clarity is needed on the definition of the Competent Authorities (CA) and how they will be nominated. It was agreed that the principle of establishing basic requirements or conditions to authorise procurement was important.

4.2.2 Organ Characterisation

[2] 15332/07

The Commission explained that Organ characterisation refers to a basic set of information on each organ procured thus ensuring that there is continuity of information from the point of procurement to the point of transplantation. The aim is to further assist the transplant team in their risk-assessment.

Experts were worried that the data set would be too stringent and lead to a reduced rate of transplantation. It was suggested that a Technical Annex with a minimal set of organ characteristics should be elaborated. It was agreed that a small group of experts would develop a Draft Technical Annex on Organ Characterisation based on the previous work of the EC funded project Alliance O.

4.2.3 Accreditation, designation, authorisation or licensing of organ transplantation

Several participants expressed the view that it would be too burdensome for CA to list their criteria for accrediting establishments. However, this information should be made available to other CAs.

4.2.4 Import/Export of human organs (exchange of human organs)

It was suggested that the name of this section be changed to **exchange of human organs** instead of import/export of human organs.

The Eurotransplant and Scandiatransplant once again mentioned their special concern about the authorization needed when importing organs from third countries. Norway, Iceland and Croatia, while not EU members, maintain regular organ exchange with EU countries. They suggested using organ characterisation as a basis for importation.

4.2.5 Register of establishments and reporting obligations

There was general agreement about the need for an organ donation register, compiled by every establishment and sent to the CA for collation into a national register. There was discussion about the usefulness of an annual report from each establishment, given the relatively small numbers for each establishment. Participants agreed that comparable information on organ donation would be desirable. In terms of post-transplant data, this would be covered in the Action Plan.

4.2.6 Traceability

There was general agreement on the importance of traceability and this should be extended for organs going to third countries. There was concern about using comitology procedure to ensure traceability.

4.2.7 Notification of serious adverse events and reactions

There was concern about the definitions used. It was suggested to look at the definitions used in Pharmaco-vigilance and to clarify which serious adverse events and reactions are reportable.

4.3. <u>Donor protection</u>

4.4.1 Principles governing organ donation

It was agreed to enable MS to further define their own interpretation of compensatory costs. Participants agreed that the text should denounce any form of commercialization.

4.4.2 Consent

No comments on this section.

4.4.3 Data Protection and confidentiality

The issue of ensuring anonymity of data was raised and it was recognised that in some cases, families go to great lengths to find the names of the donors or recipients and can take comfort in knowing the recipients of the donor organ(s) and therefore we should aim for anonymity at all times but allow for exceptions.

4.4.4 Protection of Living Donor

Participants welcomed this new section. However, there was some concern about the general wording and practical implication on the provision of long term health care for living donors and the applicability to donors from third countries (donating to relative living in the EU). The principle of voluntary and unpaid donation should be added to this section as well. The relevant CAs should be informed of any cross border transplantations.

4.5 Provisions on Quality and Safety

4.5.1 Quality National Programmes

Each CA should establish quality national programmes. There was some concern about how detailed these programmes should be. The current and future role of regional organ exchange organisations/Networks (international organisations) in quality and safety provisions, needs to be acknowledged and further developed.

4.5.2 Auditing and control measures

Several participants disagreed with having auditing procedures as part of the framework.

4.5.3 Personnel

Some participants felt that the section on personnel was too detailed and should be simplified.

4.5.4 Conditions of Procurement

This section was the focus of much discussion on the training needs of personnel and the hospital conditions. It was argued that standard operating procedures should suffice for organ procurement. In terms of training, it was acknowledged that qualified personnel were the most important factor and that training courses could be phased in over time.

4.5.5 Transport of human organs

It was suggested to include the concept of cost /benefit analysis when looking at minimising the transport time. It was felt that the inclusion of temperature was not useful and could lead to confusion.

4.6 Cooperation between Member States, exchange of information and reports

4.6.1 Cooperation between Competent Authorities

There was a question raised about the feasibility of achieving interoperability with Member States. The Commission agreed to check on wording of text on interoperability with DG INFSO but emphasised the need to exchange and access information within the whole EU in a coherent and systematic manner.

4.6.2 Reports, Committees and Technical requirements

Experts questioned the need for reports but the Commission explained that this was a general rule that Member States report to the EC every 3 years on the implementation of a Directive.

The Commission explained that the advantage of having a Regulatory Committee was that this Committee could update a technical annex more rapidly.

5. CONCLUSIONS AND NEXT STEPS

The chair thanked the national experts for their hard work and support in this drafting procedure. A new version of the document will be distributed. He welcomed their written comments and continued collaboration.

ANNEX 1: LIST OF PARTICIPANTS

MUYLLE	Ludo	BELGIUM	AFMPS/FAGG
LIFFRAN	Genevieve	FRANCE	Ministére de la Santé
LOTY	Bernard	FRANCE	Agence de la Biomédecine
HEEMANN	Uwe	GERMANY	President of the German Transplant-society Nephrology Klinikum rechts der Isar Munich
PENA	Joao	PORTUGAL	
NANNI COSTA	Alessandro	ITALY	Istituto Superiore di Sanità
GRUNNET	Niels	DENMARK	Danish National health Authority
WALASZEWSKI	Janusz E.	POLAND	Poltransplant
AGUIAR	Maria João	PORTUGAL	Autoridade para os Serviços de Sangue e para a Transplantação
AVSEC-LETONJA	Danica	SLOVENIA	Slovenija-Transplant
DOMINGUEZ GIL	Beatriz	SPAIN	Organización Nacional de Trasplantes
ERICZON	Bo-Goran	SWEDEN	Karolinska Institutet
HAASE-KROMWIJK	Bernadette	The Netherlands	Nederlanse Transplantatie Stichting
NORMAN	Triona	UK	Department of Health - Human Tis-sues
FALVEY	Sue	UK	UK Transplant
RAHMEL	Axel	Eurotransplant	Eurotransplant
JAKOBSEN	Arnt	Scandiatransplant	Scandiatransplant