



Informal Meeting related to Blood, Tissues and Cells, and Organs

29 July 2005

Report*

1. BACKGROUND

An informal meeting of experts, in their independent and professional capacities (Annex 1), was convened by the Health Measures Unit of the European Commission on 29 July in Brussels. The aim of the meeting was to have an open exchange of views as to areas that should be given attention by the European Commission over the forthcoming years in the fields of blood, tissues and cells, and organs.

The basis for discussion was the Public Health Programme and the references to blood, tissues and cells, and organs in the Calls for Proposals for 2003, 2004, and 2005 (Annex 2) as well as Article 152 on Public Health of the Treaty. Participants were invited to consider whether: the areas mentioned in the Work Plans 2003-2005 had been adequately covered; there should be continued focus on any of these areas over the forthcoming years; a focus should be given to new areas and if so to what?

2. DISCUSSION

2.1. General

Following a brief overview of the structure of the Health and Consumer Protection Directorate and activities related to public health (i.e. European Centre for the Prevention and Control of Disease – ECDC) and the Executive Agency), the activities of the Health Measures Unit (Substances of human origin, tobacco control legislation, International Health Regulations etc.) participants were introduced. This was followed by a brief presentation on the four Directorates General that are involved in projects related to public health and in particular substances of human origin – Health and Consumer Protection (SANCO), Research (RTD), Information Society and Media (INFOS), and Justice, Freedom and Security (JLS) - as well as the projects that had been approved for funding under the Public Health Programme's 2003, 2004, and 2005 Calls for Proposals and those funded by other DGs (Annex 3).

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Clarification was provided as to the difference between the Call for Proposals under the Public Health Programme and those under the Framework Programmes of DG Research. It was pointed out, however, that there is collaboration between the respective DGs in the areas being supported. The importance of assessing different clinical outcomes based on evidence was underlined.

2.2. Blood

Discussions on the subject of blood demonstrated that with the adoption of the blood Directives, much had already been accomplished in this area. However, of particular concern was the reliability of inspection systems from one Member State to another. The use of new technology using electronic coding (radio-frequency identification - RFID) in a chip for information exchange and the traceability of blood donations is an area for future examination. There is a need for evidence-based measures for optimal use of blood and blood components.

2.3. Cord blood

The use of cord blood and the need to examine clinical outcome as a quality measure was discussed. The NETCORD project supported under DG Research ended in 2005 (see section on stem cells). There is a need to set up a European cord blood banking organisation with facilitation of a common accreditation body like the Netcord Foundation for the accreditation of haematopoietic cell therapy (FAHCT) – an American organization based in Omaha Nebraska. Training of inspectors and uniform documentation for training personal of the cord blood banks is high priority. Relationships between public and private cord blood banks must be discussed with a clear definition of indications and quality control of the products.

2.4. Tissues and cells

The area of tissues and cells was identified as requiring a considerable amount of further work. There is a need to establish a clinical basis for quality in the area of tissues and cells. There is a need for an analysis of current practices and products for tissues and cells. There is the need to follow-up living donors of tissues and cells, including stem cells. These needs arise from a basic need for evidence-based practice and the selection of best practice. Training of people working in tissue banking is required as well as harmonisation of the required expertise and skills. A multilingual list of definitions related to tissues and cells as well as a catalogue of cellular and tissue related therapeutic activities that would ensure equivalence of meaning would be useful. The subjects related to new human derivatives such as breast milk and urine (used in medicinal products and homeopathic products) need to be considered. The need to support projects that help in the implementation of Articles 9 (Import and export) and 10 (Registers and reporting obligations) of Directive 2004/23/EC was also mentioned.

2.4.1. Stem cells

It was felt that the issue of stem cells had not been given sufficient attention. Besides peripheral blood progenitor cells, this is a relatively new area and their full potential in clinical use is still not clear. But the use of stem cells in gene therapy and immunotherapy needs to be pursued. In this area there is a fine line between research and public health policy that needs to be discussed and pursued.

2.4.2. Reproductive cells

The implementation of EU Directive 2004/23/EC in the entire area of reproductive cells requires careful study. The issue of compliance with the non-remuneration requirement of the Directive is particularly sensitive.

2.5. Organs

The fact that the area of organs has its own unique problems was highlighted. It was recognised that there is the need to balance the insufficiency of organs to meet the demand for their clinical use in transplantation with the quality and safety aspects. The extension of the categories of living donors (e.g. genetic, non-related, friends) needs to be considered. Also other means to expand the donor pool has to be analysed. The need to promote registers of living donors, as well as the monitoring and follow-up of those who had donated, was identified. The issue of reimbursement of costs as well as disincentives needs to be addressed as this could prove to be a core issue in Europe.

Reference was made to xenotransplantation of organs and tissues and cells and the problems associated with it.

Dissemination of knowledge in this area, to the general public and professionals, is an element for action.

3. CONCLUSION

The experts concluded that areas already identified in the previous work programmes should continue to be pursued and consideration should be given to the new areas identified during the meeting. Greater visibility with respect to the Call for Proposals and clarity of the areas that are open for financial support should be given.

Annex 1

Participants

Dr Jukka KOISTINEN	HELSINKI, Finland	Blood
Dr Maria de Fátima Do NASCIMENTO	LISBOA, Portugal	Blood
Dr P. ROŽMAN	LJUBLJANA, Slovenia	Blood / Tissues & cells
Dr. Claes WASSENAAR	BILTHOVEN, The Netherlands	Tissues & cells
Dr Anna VEIGA	BARCELONA, Spain	Tissues & cells
Dr Eliane GLUCKMAN	PARIS, France	Tissue & cells / Blood
Dr Georges GALEA	EDINBURGH, Scotland, UK	Tissues & cells / Blood
Dr Wojciech ROWINSKI	WARSAW, Poland	Organs
Dr George KYRIAKYDES	NICOSIA, Cyprus	Organs
Frances M. DELANEY	European Commission	
Eduardo FERNANDEZ-ZINCKE		
Tapani PIHA		

Annex 2

Extracts from the Work Plans of the Public Health Programme for 2003, 2004, 2005

1. WORK PLAN 2003

2.3.4. Safety of blood, tissues and organs

Article 152 of the Treaty calls for measures setting high standards of quality and safety of organs, substances of human origin, blood and blood derivatives. This action aims to support the implementation or preparation of legislative initiatives in these areas, taking fully into account the efforts of the Council of Europe and avoiding any duplication.

The action related to **blood** aims to address the requirements of the blood Directive (15) and the Commission's commitments during its adoption process. Priority will be given to:

1. Supporting exchange programmes/networking for professionals and/or establishments, with a special focus on applicant countries;
2. Actions related to Community self-sufficiency;
3. Identifying best practice in the donation and use of blood/blood products;
4. Training programmes in the blood sector.

The action on **human tissues and cells**, which will be pursued during consideration of the proposal for a Directive (16), will aim to identify factors that impact on quality and safety, as well as traceability and quality management requirements that will assist in establishing a coding system for tissues and cells. Priority will be given to:

1. Identifying factors influencing quality and safety;
2. Training programmes in the area of tissues and cells;
3. Identifying best practice, and procedures for information exchange in monitoring the donation-transplantation processes.

The action on **organs** will aim to assist the Commission in the development of a future legislative instrument in this complex area. Priority will be given to:

1. Identifying factors influencing the quality and safety of organs for transplantation;
2. Monitoring the organ donation-transplantation processes;
3. Developing networking for effective exchange of information between countries.

2. WORK PLAN 2004

2.2.4. Safety of blood, tissues and organs

The priority action related to blood under the 2004 work plan aims to support the development and implementation of quality management programmes to improve the safety of blood donations to be carried out in the Community.

The priority on organs aims to develop a strategy for the EU in order to raise awareness and increase availability of organs used for transplantation.

3. WORK PLAN 2005

2.2.4. Safety of blood, tissues and cells, organs.

This action aims to promote the quality, safety and availability of substances of human origin used for therapeutic purposes and to minimize the risks and ensuing threats to patients' health, particularly disease transmission, associated with their collection, processing, distribution and use. The activities should support the implementation of the existing EU legislation.

Priority will be given to the development of tools: that will provide practical guidance on how to install and maintain quality systems in blood establishments in the Member States; that will assist in the training of inspectors, using modern training techniques; and that will promote the optimal use of blood and blood components. These tools should be multilingual, provided in both paper and electronic form, and tested in a few environments to gauge their effective implementation. Tools that address optimal use of blood and blood components for different surgical procedures or illnesses should be based on best practice.

The implementation of quality systems in tissue and cells establishments needs in particular to take into account the needs of the new Member States. In addition, work should be extended during 2005 to inspection practices, through the preparation of guidelines concerning the conditions of the inspections and control measures and on the training and qualifications of the officials involved, and to serious adverse event reporting. In order to increase organ donation, implementation and evaluation of educational programmes are needed.

Annex 3

Projects approved under the 2003, 2004, 2005 Work Plans of the Public Health Programme

1. 2003

➤ JACIE

The project's aims are to provide vital impetus to the JACIE programme & ensure its integral role in standard setting, inspection and accreditation for health institutions & facilities involved in haematopoietic stem-cell collection, processing & transplantation in Europe.

➤ EUROPEAN QUALITY SYSTEM FOR TISSUE BANKING.

The main objective of this project is to analyse throughout different working areas the factors that may influence the final tissue quality and security for its transplantation providing finally a greater benefit to recipients. The project aims to develop the method to ensure standards of quality and safety in relation to tissue banking activities.

2. 2004

➤ EU-QMS

The overall objective of this project is to contribute to good quality management (QM) in blood services, based on the requirements set out in Directive 2002/98/EC and its technical annexes. It will deliver this through the development of a manual that will assist blood services to implement or expand their standard operating procedures (SOPs).

3. 2005

➤ EUROPEAN UNION STANDARDS AND TRAINING FOR THE INSPECTION OF TISSUES ESTABLISHMENTS (recently approved – negotiations to commence)

Development of a set of practical Guidelines for the Inspection of Tissue Establishments, based on best practice as described in a State-of-the-Art' document clearly outlining the proposed EU approach to national inspection of tissue establishments. Development of an Inspector Training course and course material optimised through a process of feedback and improvement after each course. The final version will be provided to the Community as a model for the future training of inspectors.

➤ EUROPEAN TRAINING PROGRAM ON ORGAN DONATION (recently approved – negotiations to commence)

The general objective is to design and validate a professional European Training Program on Organ Donation at different involvement levels, so as to contribute to increasing organ donation knowledge, maximizing the impact in the growth of organ donation rates and disseminating reliable information to the community in order to raise donation consciousness and to encourage a positive attitude towards it.

4. OTHER EU PROGRAMMES

➤ **EURODONOR-EUROCET**

Creation of a European Donation and Transplantation registry based on common protocols for data acquisition and processing (DG INFSO)

➤ **IMPROVING THE KNOWLEDGE AND PRACTICES IN ORGAN DONATION - DOPKI**

The main aim of DOPKI project is to improve knowledge and develop applicable methodology that could be used to increase the potential of organ donation (DG RTD)

➤ **ALLIANCE – 0**

Ensure better coordination between national research programmes on organ transplantation (DG RTD)