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HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

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1ST NATIONAL EXPERT MEETING ON ORGAN DONATION AND TRANSPLANTATION AT COMMUNITY LEVEL

BRUSSELS 13 JULY 2007
9:00 – 17:00

SUMMARY REPORT

The first national expert meeting on organ donation and transplantation at Community level was convened on 13 July 2007 under the Chairmanship of Mr Tapani Piha (TP), Head of Unit, SANCO C6.

26 Member States were present at the meeting and also representatives of the WHO, the Council of Europe, Eurotransplant and Scandiatransplant. The list of participants is appended in annex 1.

1. Welcome and introductory remarks

The Chairman TP welcomed the delegations. The aim of this first meeting of the national experts is twofold. First to **present the Communication** from the Commission to the European Parliament and the Council on Organ Donation and Transplantation: Policy Action at EU level, adopted on 30 May 2007. Second, to discuss the two main proposals in the Communication: the main priorities of an **action plan** for a strengthened cooperation between Member States on organ donation and transplantation and the basic quality and safety principles that should be in place at community level.

2. Adoption of the agenda

The agenda was adopted without objections or addenda

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3. Presentation of the Communication

On 31 May the Commission adopted a **Communication** on organ donation and transplantation. The Communication sets out future activities of the EU in the field of organ donation and transplantation.

4. Introduction to the action plan

Following the Communication the Commission presented a first discussion document on a future action plan for a strengthened cooperation between Member States. The Action Plan is designed to respond the main policy challenges in the field of organ donation and transplantation: Improve quality and safety of organ donation and transplantation, increase organ availability and make transplantation systems more efficient and accessible.

The document presented at the meeting, which served as a basis for discussion, contained an extensive list of possible actions and a basis for a mechanism of coordination. The objective set for the meeting was to decide how these actions should be prioritised at Community level within the next years.

The list of actions was divided in four packages:

4.1. First package: Quality and safety

Under the first package of actions the Commission presented four measures to improve quality and safety of organ donation and transplantation. The participants supported the idea of a strengthened cooperation between Member States, leading to the compilation of information that will assist in determining the acceptable levels of risk in the use of expanded donors, the promotion of good medical practices and the evaluation of post-transplant results. Concern was expressed regarding the complexity and feasibility of an EU wide register suggested under Action 1. Common definitions of terms and methodology to evaluate results were deemed necessary.

4.2. Second package: Increase organ availability Organisation/Activities

Representatives recognised that increasing organ availability should be the main objective of the action plan. The promotion of the role of organ donor coordinators and the introduction of quality improvement programmes were suggested. The vast majority of the participants agreed on the importance of such measures. Participants underlined that some of the technical preparation of the guidelines or programmes proposed in the working document has already been done. In their opinion the added value of the Community action in this field is to actually promote the implementation of such measures and monitor such implementation.

4.3. Third package: Increase organ availability Public Awareness

The EU Commission suggested several measures which would increase public awareness and as a consequence increase organ availability. The creation of a European organ donor card was discussed as one possible action. To facilitate the implementation of the EU organ donor card the EU Commission suggested as one possible option its integration into the existing EU health insurance card. The participants in the meeting generally agreed that raising public awareness is important to increase organ availability. Representatives from some Member States with presumed consent (opting-out) system

mainly contested the idea of a European organ donor card. Several countries expressed support for this idea, taking into consideration its promotional effects and the impact on organ availability.

4.4. Forth package: Making transplantation systems more efficient and accessible.

Most of the Members States supported the actions proposed in the document oriented to collect data on transplantation medicine that would be helpful for designing and monitoring efficient policies, support and guide transplant systems, support the training of professionals and explore initiatives that could facilitate the interchange of organs between national authorities in specific circumstances. Participants also agreed on the importance of having EU wide agreements on issues concerning transplant medicine.

5. Method of coordination

The chairman introduced how the method of coordination between MS could work in the future. It will be based on agreed objectives, common indicators and it will have a regular reporting from MS, evaluation and recommendations

The method will establish regular meetings of the experts group.

6. The quality and safety principles

Ms Carline Trouet (CT) took the Chairmanship of the meeting on behalf of Tapani Piha.

The Commission made an introduction to the quality and safety principles in organ donation and transplantation. The intention was to present the basic quality and safety principles that should be in place in every transplant system and to have a first exchange of views on each of the principles.

The Commission invited the experts to participate in a working group to follow up on the quality and safety principles.

6.1. National oversight authority

The majority of the experts agreed that the designation of a national Competent Authority is crucial for the oversight of the quality and safety of transplantation activities. The Competent Authority should ensure that basic standards are in place in every MS. It was stated that it is up to the Member States how to organize such a Competent Authority (CA). The role and the functions of the CA shall be further elaborated within the Working Group.

6.2. Authorisation of activities

Generally all representatives of the Member States agreed that all activities of donation, testing procurement, preservation and transportation of human organs have to be authorized by the competent authority in the respective country. Some experts expressed concern that too stringent authorisation requirements in the EU legal framework might create another layer of bureaucracy. It was stated that it is crucial not to create obstacles, which would decrease transplantation activity.

6.3. Quality system and quality standards

The need for quality system and quality standards in the field of organ donation and transplantation has been acknowledged by the participants in the meeting. Some experts expressed an opinion that the legal framework should not contain a very detailed but rather a general framework for quality standards. It was proposed that special attention is paid to the wording of the legal instrument, especially in respect to the evaluation systems. Several experts made a remark that the future legal framework has to take into consideration already existing Quality Standards.

6.4. Inspections and control measures

The majority of the participants expressed support for the organisation of inspections by the Competent Authorities. It was stated, however, that the EU legal instrument should not create bureaucracy and impose unnecessary burden on the Member States. Some experts commented that the experience from the Eustite project and the inspection of tissues and cells establishments should be taken into account. It was stated that it is important to look at already existing regulations with respect to inspections

6.5. Traceability and Notification of serious adverse events and reactions

The majority of respondents agreed that traceability from the donor to the recipient and vice versa as well as the existence of a system to report, investigate and transmit information about serious adverse events and reactions is necessary. It was agreed that such measures will have a positive influence on the EU citizens' trust in the quality and safety of organ donation and transplantation.

The linkage with the notification of serious adverse effects of human tissues and cells was highlighted, owing to the fact that an organ donor is often also a tissue donor. The usefulness of a rapid response system and a network for communication was widely agreed upon. The definition of an adverse reaction requires further elaboration.

6.6. Organ characterisation

The participants discussed the need for the Competent Authority to ensure that a basic set of information on organ characterisation is transmitted to the organisations responsible for transplantation. This basic set of information should enable the transplant team to undertake the appropriate risk assessment. The conclusions of the project Alliance-O which developed a European Guideline for organ safety and a pilot Action for the Realization of a European Donation Form were agreed upon as a initial step.

6.7. The Creation of a Working group on quality and safety

The Commission invited the experts to participate in a subsequent working group which should further elaborate on the presented quality and safety principles. The Working Group, coordinated by the Commission, will define the content of the future EU legal framework and present a draft proposal at the next experts' meeting. Representatives of the following countries volunteered to participate in the Working Group: Spain, France, UK, Sweden, Slovenia, Portugal, Poland, Germany, Hungary, Belgium, Ireland and Italy have volunteered to participate. A meeting of this working group is planned by October (exact date to be confirmed)

7. Conclusion of the meeting/next steps

It was concluded at the meeting that there is a huge potential and a need for the European Member States to learn from each other in the field of organ donation and transplantation.

A more elaborated working document, containing an action plan and the Quality and Safety Principles will be presented on the next experts meeting on 20 November 2007.

ANNEX: LIST OF PARTICIPANTS

KURZ	Johann	AUSTRIA	Bundesministerium für Gesundheit, Familie und Jugend
FÜSZL	Sylvia	AUSTRIA	Bundesministerium für Gesundheit, Familie und Jugend
COENE	Leen	BELGIUM	FPS Health, Food Chain Safety and Enviroment
MUYLLE	Ludo	BELGIUM	AFMPS/FAGG
DEYANOV	Georgi	BULGARIA	Bulgarian Executive Transplant Agency
KYRIAKIDES	George	CYPRUS	Surgical and Transplant Center of Cyprus
BREZOVSKY	Pavel	CZECH REPUBLIC	Ministry of Health of Czech Republic
POKORNA	Eva	CZECH REPUBLIC	Czech Transplant Society
KRISTENSEN	Marianne	DENMARK	National Board of Health
GRUNNET	Niels	DENMARK	Scandiatransplant
DMITRIEV	Peeter	ESTONIA	Tartu University Hospital
KATTELUS	Mervi	FINLAND	Ministry of Social Affairs and Health
LASTELLE	Jean-Laurent	FRANCE	Ministére de la Santé
LOTY	Bernard	FRANCE	Agence de la Biomédecine
NICKEL	Lars Christoph	GERMANY	Bundesministerium für Gesundheit
KIRSTE	Günther	GERMANY	Deutsche Stiftung Organtrasplantation
KÓBORI	László	HUNGARY	Semmelweiss Egyetem Transzplantációs és Sebészeti Klinika
ONEILL	Freda	IRELAND	HSE
NANNI COSTA	Alessandro	ITALY	Istituto Superiore di Sanità
ROZENTALS	Rafails	LATVIA	Latvian Transplantation Centre of Paul Stradins Clinical Hospital
DAUGAVVANAGA	Anita	LATVIA	Health and Medical Technologies State Agency
SIROKOVA	Julija	LITHUANIA	National Bureau on Transplantation
SCHARLL	Gerard	LUXEMBOURG	Ministére de la Santé - Direction de la Santé

DELICATA	Nadine	MALTA	Ministry of Health, Elderly and Community Care
CZERWIŃSKI	Jarosław	POLAND	Poltransplant
BARROSO	Eduardo	PORTUGAL	Autoridade para os Serviços de Sangue e para a Transplantação
AGUIAR	Maria João	PORTUGAL	Autoridade para os Serviços de Sangue e para a Transplantação
ZOTA	Victor	ROMANIA	National Transplant Agency
LACA	Ľudovít	SLOVAKIA	Slovak Transplant
AVSEC-LETONJA	DANICA	SLOVENIA	Slovenija-Transplant
SOJAR	Valentin	SLOVENIA	University Clinical Centre of Ljubljana
MATESANZ	Rafael	SPAIN	Organización Nacional de Trasplantes
GÄBEL	Håkan	SWEDEN	National Board of Health and Welfare
WELIN	Åsa	SWEDEN	Swedish Council for Organ and Tissues Donation
ELENBAAS	Marit	The Netherlands	Ministry of Health, Welfare and Sport
VAN LINGEN	Corine	The Netherlands	Dutch Ministry of Foreign Affairs
NORMAN	Triona	UK	Depatrment of Health - Human Tissues
FALVEY	Sue	UK	UK Transplant
SPIESER	Jean-Marc	EDQM - Health Care of Council of Europe	EDQM - Health Care of Council of Europe
BEHR-GROSS	Marie-Emmanuelle	EDQM - Health Care of Council of Europe	EDQM - Health Care of Council of Europe
OOSTERLEE	Arie	Eurotransplant	Eurotransplant
DI BUCCHIANICO	Marion	Eurotransplant	Eurotransplant
JAKOBSEN	Arnt	Scandiatransplant	Scandiatransplant
NOËL	Luc	WHO	WHO
PIHA	Tapani	DG SANCO	European Commission
FERNANDEZ ZINCKE	Eduardo	DG SANCO	European Commission
TROUET	Caroline	DG SANCO	European Commission

BREGEON	Thomas	DG SANCO	European Commission
BEHILLIL	Hesmahane	DG INFSO	European Commission