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D4 – Substances of Human Origin and Tobacco Control

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MINUTES OF THE SECOND COMPETENT AUTHORITY MEETING ON ORGAN DONATION AND TRANSPLANTATION 28 FEBRUARY 2011 - 1 MARCH 2011 BRUSSELS

28 FEBRUARY: MORNING SESSION

1. WELCOME AND INTRODUCTORY REMARKS

The Second Meeting of the Competent Authorities on Organ Donation and Transplantation was convened on 28 February and 1 March 2011. All Member States except Luxembourg, Estonia, and Liechtenstein were present at the meeting; were also present: experts from Norway, Croatia, FYROM, Turkey, WHO and the Council of Europe, Eurotransplant and Scandiatransplant.

2. ADOPTION OF THE AGENDA

The Agenda was adopted.

3. INTRODUCTION OF NEW PARTICIPANTS

Following up on the adoption of the Directive on quality and safety of human organs and in particular the set up of the network of the competent authorities, each participant presented its organisation, underlying its main tasks.

The Council of Europe announced the publication of the new guide on Quality and Safety of Organs and Tissues and Cells.

4. SET OF NATIONAL PRIORITY ACTIONS

The following Member States presented their National Action Plans (NAPs):

Slovenia

United Kingdom

Hungary

Netherlands

(All presentations are available on the Circa platform, under the specific section for Competent Authorities on Organ Donation and Transplantation).

Austria, Poland and France declared interest in presenting their National Action Plan during the next Competent Authority meeting in September. Norway asked to present its Plan in a years' time.

28 FEBRUARY: AFTERNOON SESSION

5. TECHNICAL WORKING GROUP ON LIVING DONATION

5.1. Living Donation Related Projects

5.1.1. EULID - Marti Manyalich

5.1.2. EULOD - Frederike Ambagtsheer, Emma Massey

5.1.3. ELIPSY - Marti Manyalich

3 projects were presented that tackle the issue of living donation. EULID and ELIPSY are projects funded from the Health Programme and EULOD from the 7th Research Framework.

EULID - its main objective is to analyze the current European situation regarding legal, ethical, protection and registration practices related to living organ donation, in order to set standards and recommendations that guarantee the living donor health and safety.

EULOD - aims to increase the collaboration between EU Member States in order to improve exchange of best practices on living organ donation programmes and to enhance the organizational models of organ donation and transplantation in the

EU member states. The scope of this RTD-funded project is complementary to other projects as it focuses more on new Member States and on unrelated living. It also includes trafficking.

It is important to make clear that this RTD-funded project is run by experts and does not necessary represent the views of the Competent Authorities. The project leader was asked to present the final outcome to this meeting in 2012.

ELIPSY - its main objective is to contribute to guarantee the good quality of organ living donation for transplant through a living donor long-term psychosocial and quality of life follow-up; it also aims to correlate those aspects with the recipient's outcome with the creation of a follow-up methodology.

There was a general request by the Competent Authorities to be regularly informed on the state of play of Commission funded projects, even if they do not necessarily include Competent Authorities. The Commission will follow-up on this during the coming meetings.

5.2. Overview of Technical Working Group Activities

The Commission presented the activities undertaken by the technical working group on living donation:

Meeting:

- 14 December 2011

Participants: NL, UK, FR, DE, SE, CY, ES, Scandiatransplant, NO and the Council of Europe

Topics: (1) MS presented living donation in their MS, (2) future steps for the technical working group.

5.2.1. Presentations by Member States

Following the presentations made during the first technical working group on deceased donation the following MS presented their experiences regarding living donation: UK, Norway, the Netherlands, and Spain.

5.2.2. Next steps

The following options were suggested by the participants of the technical working group on living donation:

- Creation of a manual on living donation providing guidance to MS;

- Twining/Coupling Member States together – countries with developed living donation programmes assisting those with less developed ones;

- Creation of a "living donation" encyclopaedia or "tool box" in which a great variety of information will be available; in this way Member States can cherry pick the information they need;

- Launch a Joint Study on living donation with the Council of Europe.

It was decided to opt for the third option which would be the creation of a living donation encyclopaedia/tool box gathering information regarding living donation.

An additional point made was to collect all information from existing and past projects in the field of organs and make this available to all Competent Authorities. The Commission committed to upload the available results of Projects on circa. Such overview will make clear where future knowledge needs to be developed.

It was also suggested to organise a quick survey on death rates amongst living donors. This information is of great value when discussing the possibility of living donation with patients and potential donors. The Commission will try to take this up within the next Indicators' exercise (Working group on Indicators under the Action Plan).

6. TECHNICAL WORKING GROUP ON DECEASED DONATION

6.1. Manual on Transplant Coordinators – evolution of document

The UK presented the new revised manual. The revised manual was very well received and endorsed in general by the Member States without any comments. However Member States may still send comments if necessary to the Commission by end of April. Member States must also inform the Commission if they feel there is any need to translating this document into their official EU language.

6.2. ETCO (European Transplant Coordinators Association)

ETCO (European Association of Transplant Coordinators) presented its activities and the new certification process (Certification European Transplant Coordinator, CETC) organized in close collaboration with the U.E.M.S. Board of Transplant Coordination, Division of Transplantation, Section of Surgery. (U.E.M.S.: European Union of Medical Specialists).

1 MARCH: MORNING SESSION

7. FUTURE STEPS IN THE IMPLEMENTATION OF DIRECTIVE 2010/53/EU

7.1. Introduction

Directive 2010/53/EU empowers the Commission to adopt implementing measures on the following:

7.2. Implementing Acts

7.2.1. Vigilance

7.2.2. Traceability

7.2.3. Transmission of donor and organ characterisation information

7.3. Exchange of views and discussion

The Commission presented first ideas for vigilance, traceability and transmission of donor and organ characterisation information.

Vigilance

Directive 2010/53/EU provides that the Commission shall adopt, where organs are exchanged between Member States, an implementing measure regarding procedures for ensuring the reporting of serious adverse events and reactions (SAE/R).

The Directive sets down the obligation of reporting SAE and SAR as these are defined in the Directive. Elements for deciding whether an adverse event or adverse reaction is serious within the meaning of the Directive and hence to be reported, could be developed within or in parallel with the implementing measure. Recommendations made within the EFRETOS project (funded under the Health Programme) could be considered as a basis for developing such a decision tool, but this issue was not discussed at this meeting.

On the other hand, the basic outline of procedures for the reporting of serious adverse events and reactions in case of exchange of organs was discussed. It was also noted that the EFRETOS recommendations on the vigilance of human organs for transplantation, as delivered by the consortium on 23 February, could be further taken into account in developing the implementing measure.

The basic structure for the **immediate reporting** was generally welcomed, however it was suggested that a support function at EU level for the exchange of information is not required, the focus could rather be on the procedures. On the other hand, it was suggested that a vigilance coordination level could be required at national level in order to assess and manage the cases.

The possibility of an **annual reporting** of SAR/E related to the quality and safety of organs was also discussed. Three options were considered: (1) annual reporting for SAR/E reported only in case of exchange of organs between MS, (2) annual reporting for all SAR/E reported at national level (possibly on a voluntarily basis), (3) no annual reporting at all at EU level. While many MS suggested to cover (1), a few MS deemed that the report was not necessary for national SAR/E. Several MS considered the annual reporting on a voluntarily basis as a useful tool whilst some MS expressed the view that it should be obligatory. This issue needs to be further discussed.

Traceability

Directive 2010/53/EU provides that the Commission shall adopt, where organs are exchanged between Member States, an implementing measure regarding procedures for ensuring traceability.

COM suggested that the exchange of information between the Competent Authorities of the Sending Member State and of the Receiving Member State should be as simple as possible. COM also highlighted the need to keep some minimal records, allowing to retrieve donor and recipient of every organ at every time.

No new ideas were brought up during the meeting.

It was also clarified that the scope of this work is on traceability of organs exchanged between Member States. It is up to the Member States to establish internal traceability systems as well as a connection between traceability of organs and traceability of tissues&cells. Another workstream, overseen by the Competent Authorities on tissues and cells is developing traceability of tissues and cells.

Transmission of donor and organ characterisation information

Member States stated that they feel that an implementing act for the transmission of donor and organ characterisation information is not needed. Once the delegated act on donor and organ characterisation information is finalised (Part B of the Annex), there will be no necessity for the creation of these procedures. The Commission clarified that such a decision should be endorsed by the Committee on organ donation and transplantation.

7.4. Next steps in setting the complementary data on donor and organ characterisation in Part B of the Annex

Explanation was given about the changes brought by the Treaty of Lisbon.

The creation of an expert group dealing with the delegated act on donor and organ characterisation was also announced. Member States will be asked for specific nominations. For reasons of efficiency, the Commission will try to organise meetings of this group back-to-back with future meetings of the Competent Authorities. Council and European Parliament will also be informed.

1 MARCH: AFTERNOON SESSION (14:00- 18:00)

8. PRESENTATION OF PROJECTS ON ORGANS

The following projects were presented by their project leaders.

8.1. Calls for Proposals

8.1.1. ETPOD - Xavier Guasch

European Training Program on Organ Donation – the objectives of ETPOD were:

(1) to build a solid European collaborative partnership in the organ donation/transplantation process;

(2) to design and validate a professional European Training Program on Organ Donation (ETPOD) mainly for transplant coordinators.

8.1.2. ODEQUS - Xavier Guasch

European Quality System Indicators and Methodology on Organ Donation

The aim of the project is to determine the standards of best practices and to develop quality indicators for Donation after Brain Death (DBD), Donation after Cardiac Death (DCD) and Living Donation (LD) in order to improve the overall quality and safety in organ donation.

8.1.3. EDD - Danica Avsec

Guidelines for improving the organisation of future European Donation Days - The aim of this Project was to:

- increase public awareness on organ donation and transplantation among general public; particularly young people should be addressed;

- express acknowledgement to all the people involved in the transplant process (transplant patients and their families, organ donor families, health care professionals);

- attract the attention of the political public.

8.2. Calls for Tender

8.2.1. TX coordinators: "Training the Trainers" – ONT

Train transplant donor coordinator trainers. The purpose with this tender is to assist Member States to put in place these key health professionals and give an incentive to provide continuous training within their Member State.

8.3. Joint Actions

8.3.1. MODE (2010) – Alesandro Nani Costa

Mutual Organ Donation and transplantation Exchanges (Jan. 2011 to June 2012)

Twinning amongst Member States - The main objective of this joint action is the transfer of best-practices in the field of organ donation and transplantation and the creation of positive synergies among participating Member States apt to support authorities in decision-making and policy contexts.

8.3.2. 2011 Joint Action – introduction

The Commission shortly presented the Organs Joint Action for 2011. The objective of the Joint Action is to assist Member States in reaching the full potential of deceased and living organ donation; the three areas of interest are the following:

(1) Register of Living Donation

(2) Strengthening the relationship between intensive care units and transplant donor coordinators

(3) Twinning of transplantation systems and peer reviews

Around 20 Member States have declared interest in participating in this Joint Action. The overall coordinator will be Spain.

The final proposal for the Joint Action needs to be submitted on: **27 May 2011**.

9. FEEDBACK FROM JOURNALISTS WORKSHOP ON ORGAN DONATION AND TRANSPLANTATION, 10TH NOVEMBER, BRUSSELS

The objective of this workshop was to present to Journalists from Member States the issue of organ donation and transplantation and provide them with all available tools so as to access the correct information on this issue and raise awareness about organ donation and transplantation. The workshop was successful and several articles have already been written by the participants.

10. CONCLUSION OF THE MEETING 18:00

The Competent Authorities thanked Olga Solomon and in particular Anna Pavlou for the great work done over the past years, developing the EU policy and legislation in the field of organ donation and transplantation.