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HEALTH AND CONSUMERS DIRECTORATE-GENERAL
Directorate D – Health systems and products
D4 – Substances of human origin and Tobacco control

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THIRD COMPETENT AUTHORITY
MEETING ON ORGAN DONATION AND TRANSPLANTATION

26 SEPTEMBER 2011, 13.30-18:00

27 SEPTEMBER 2011, 9:00-18.00

BRUSSELS
Albert Borschette (CCAB), Rue Froissart 36,
ROOM: 3A

MINUTES

26 SEPTEMBER (13:30 – 18:00)

1. WELCOME AND INTRODUCTORY REMARKS

This Third Meeting of Competent Authorities on Organ Donation and Transplantation was convened for 26 September (afternoon) and 27 September 2011.

All Member States except Bulgaria, Liechtenstein and Luxembourg were present at the meeting. Took also part: experts from Croatia, Norway, FYROM, Turkey, the Council of Europe (CoE), Eurotransplant (ET) and Scandiatransplant (SKT).

Given the many new nominations, participants are asked if they wish to change or add CIRCA members for their country, where the meeting documents will be published.

2. ADOPTION OF THE AGENDA AND MINUTES OF PREVIOUS CA MEETING

The agenda was adopted without changes.

Few comments were given concerning the minutes of the 2nd CA meeting (28/2-1/3/2011), which were already commented and updated before Summer.

3. INTRODUCTION OF NEW PARTICIPANTS

Introduction of new Commission staff and new participants from the Member States.

4. TECHNICAL WORKING GROUP ON DECEASED DONATION

4.1. Manual on Transplant Coordinators – update on the evolution of the document

The manual has been finalised in June and the final English version is available on CIRCA. Members of the Working group are thanked for their work, in particular UK representatives for the coordination and final reading.

Following a discussion in the last CA meeting, translations of the Manual were requested in BG, DE, FR, LV, NL, RO. As the final users of the Manual are at national level, the national representatives working in these languages were/will be asked - once the translation were/will be available - to verify and correct their version by 15 November.

The corrected documents will be made available on the CIRCA website. Publicity should be made at national level now.

An analysis on needs and use of the Manual could be done within the Mid-term Review of the Action Plan in 2012.

The group agreed on circulating the Manual to CoE countries.

5. TECHNICAL WORKING GROUP ON INDICATORS

5.1. Overview of Technical Working Group Activities

5.1.1. *Indicators' Exercise 2011: Presentations of results by members of the Working Group*

COMM introduced and presented the activities of the Working group which took place since March 2011:

- audio-meetings took place in March, April and May for drafting the online web-survey (focus on allocation, waiting lists and health outcomes),
- collection of qualitative (COMM survey) and quantitative (with ONT, ES) data was organised from April to July,
- a physical meeting of the Working Group was organised on 13 July for the consolidation and discussion of the first results (BE, FR, HU, IT, NL, SI, ES, SE, PL, UK, Eurotransplant).
- additional answers were received during Summer: update of the data collected before CA meeting.

Last year, 20 countries participated in the first exercise, providing 2009 data. On 26 September, 22 countries had participated in the 2nd exercise (although the survey was longer), and that some countries were still willing to do so. This increased number of participants, the addition of new questions as well as the possibility to compare 2009 data with 2010 data should be key success factors of this voluntary exercise under the Action Plan.

COMM recalled the main objectives of this exercise. This is work in progress and data quality is still a main point of discussion. This is an indicators' exercise, the results may not be exact science, but should offer learning data to Member States on their daily activities. While some MS are very advanced and could offer much more data, the WG in first place needs to ensure to engage all MS.

Each of the 6 sections was presented by different Members of the Working Group (Donation, Waiting lists, Allocation, Transplantation, Health outcomes, Health resources). Main conclusions of the discussions.

1) On the data quality:

Following the first CA meeting in September 2010, a long term ambition was developed, allowing to collect and analyse more in-depth, for example by including the work on critical pathway and by redrafting the qualitative questionnaires.

The data is still subject to much improvements and discussion, it was agreed that the results of the exercise can not be published or handed out. However, as in 2012 a mid term review of the Action plan will take place and review among others the work of the Working groups, it will be important to demonstrate the progress of the WG on Indicators.

2) On technical improvements:

The COMM tool IPM is not easy to use, the WG should reflect on a more user-friendly way of data collection. As some questions won't need to be repeated in the next exercise, the online web-survey will probably will lighter in the next exercise.

3) On lessons learnt:

Practical ideas brought forward relate mainly to cross-border collaboration (cross-border programmes for transplants and a list of EU-wide centres of excellence for complicated transplants...). Each Member States is invited to have a look at the overall answers from its national perspective to draw national conclusions on where are strengths and opportunities for further improvement.

Some practical learning will be taken up at EU level:

- Several indicators show potential of increased cross-border exchange of organs and patients. The COORENOR project and planned 2012 Joint Action will focus on facilitating such cross-border collaboration.
- Some indicators show the potential of increased living donation. A working group in the Action plan and several projects are taking this forward.

Concerning the Indicators WG, the practical follow-up and political impact will be discussed in the next WG meeting.

Finally, the increasing number of participants (and for the web-survey, on more questions than last year) reflects a willingness to share and learn from each other, and is certainly a sign that the exercise can help to identify gaps and possible cross-border collaborations.

Next steps

Some countries are still willing to contribute to the web-survey (HR, GR, HU, IE, NO, TR), therefore the aggregated results will also be updated by the end of the year, before the next WG meeting.

The results of the discussion will be taken up by the Working Group for the 2012 exercise. Next WG meeting will take place early 2012.

The CA group agreed that data are not yet of sufficient quality to disseminate. Given the many ongoing discussions on data quality and interpretation amongst experts, it would be very difficult to ensure a correct public perception of these materials.

6. INTERNATIONAL ACTIVITIES

6.1. Cooperation between countries of the **Black Sea Area Project: Development of donation and transplantation of organs, tissues and cells activities (Council of Europe)**

This project aims to strengthen transplant activities in and enhance collaboration between the countries bordering the Black Sea (Romania, Bulgaria, Ukraine, Moldova, Turkey, Georgia and Russia). The cooperation is supported and presented by the Council of Europe. Much also depends on local political support and availability of funding to set up the local transplant system. Several EU experts are also involved in the Black Sea Area project.

6.2. South-Eastern European Health Network (HR)

This project aims to strengthen transplant activities and enhance collaboration between the countries in the South-Eastern Europe (Croatia, Serbia, Kosovo, Montenegro...Romania and Bulgaria). The cooperation is supported by the WHO, TTS, ISODP and ESOT. Croatia is one of the leading countries.

6.3. Bologna Initiative / Notify project (IT)

This global (WHO) initiative aims to build a global vigilance system, connecting ongoing EU efforts and projects to transplant activities in other continents.

6.4. Mediterranean Transplant Network (IT)

The IT CA presented this strengthened collaboration with North African countries like Egypt, where living donation is very developed.

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

Before introducing the discussion on implementing measures, COMM reminded about the current legal set-up of groups on organ donation and transplantation at EU level:

- a) the network of Competent Authorities established by Art. 19 of the Directive,
- b) the Expert group on donor and organ characterisation created by the Commission in order to carry out prior consultations on draft delegated acts (it met on 26 September morning for the first time), and finally
- c) the Committee on organ transplantation which will be set-up to adopt implementing measures (art. 29 and 30).

This does not include working groups under the Action plan as this is a voluntary tool.

7.1. Introduction

The Commission already presented first ideas for 3 implementing measures (vigilance, traceability and transmission of donor and organ characterisation information) in the CA meeting on 28 February and 1 March 2011, but they were not discussed as the new legislation (Regulation (EU) 182/2011) which, following the entry into force of the Lisbon Treaty, organises the discussion and adoption of implementing acts had been adopted very shortly beforehand (16 February).

This session is a follow-up aiming for inputs for the draft proposals. The next step then will be internal Commission consultations, formalisation of the Commission proposal and presentation in a Regulatory Committee in the beginning of 2012.

COMM introduced the objectives of the discussion and a legal overview of the adoption process for these implementing measures.

7.2. Implementing Measures

COMM provided a short introduction on the overall procedures for the implementing measures. COMM clarified that the scope of the implementing measure only relates to organs exchanged between Member States (i.e. not covering tissues and cells). COMM also reported about the discussion during the first meeting of the Expert group on Organ and donor characterisation gathered for the first time on 26 September to express opinions concerning a possible Delegated Act on part B of the Annex to the Directive. This group advised not to adopt a Delegated Act.

7.2.1. *Transmission of donor and organ characterisation information*

Exchange of views and discussion

Directive 2010/53/EU provides that the Commission shall adopt, assisted by the Committee on Organ Transplantation, where organs are exchanged between Member States, an implementing measure regarding procedures for the transmission of information on organ and donor characterisation.

Member States stated in the CA meeting in February 2011 that they felt that an implementing act for the transmission of donor and organ characterisation information is not needed.

But as the Expert group advised on 26 September 2011 not to pursue a Delegated Act on Organ and donor characterisation for the moment, COMM and the group of CAs proposed to reflect about an implementing measure on "procedures for the transmission of information on organ and donor characterisation as specified in the Annex in accordance with Article 7(6)" (this implementing measure may not be necessary if a Delegated act be proposed).

In a short brainstorming some elements of concern were identified which should be subject of such Implementing Measure:

- Use of a language that ensures mutual understanding, or English
- Keep track of who sent what to whom at which moment,
- Respect of data protection.
- Need to use written information
- Requirement of receipt
- Possibility to use a fixed data transmission format

These elements might also be of concern for the other Implementing Measures. DE explained that, depending on the level of detail, a standard operating procedure (SOP) might be a more appropriate format than a directive.

Some participants (UK, ET, SKT) volunteered to develop a short draft proposal for the Commission. The Commission will take this work into account in the Implementing Measures to be endorsed by the Committee on organ donation and transplantation to meet in the first half of 2012.

7.2.2. Traceability

Exchange of views and discussion

Directive 2010/53/EU provides that the Commission shall adopt, assisted by the Committee on Organ Transplantation, where organs are exchanged between Member States, an implementing measure regarding procedures for transmission of necessary information to ensure traceability.

In February, COMM 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. COMM also highlighted the need to keep some minimal records, allowing to re-trace and retrieve donor and recipient of every organ exchanged, at every

time, if necessary. (Different) national donor and recipient identification numbers should be recorded. No new ideas were brought up during the meeting.

The current proposal includes some further small changes, in particular some clarifications and rephrasing like 'description of organs' and 'to keep available'.

7.2.3. *Vigilance*

Exchange of views and discussion

Directive 2010/53/EU provides that the Commission shall adopt, assisted by the Committee on Organ Transplantation, 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 an interpretation tool, but this issue was not further discussed at this meeting.

The discussion focused on the basic outline of procedures for the reporting of serious adverse events and reactions in case of exchange of organs. 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.

COMM therefore prepared 2 documents:

- A short document with the potential text as it would be part of a legal proposal, covering vigilance/notification of alerts for organs exchanged cross-border;
- A recommendation or guidelines covering also possible national/local vigilance/notification of alerts on organs used locally and including EFRETOS project outcomes.

During the February meeting, 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 potential reported cases.

The current version adds the form of information to be exchanged in annex, based on the T&C legislation and on the EFRETOS project.

The current version also adds a procedure and form for exchange of **follow-up reporting**.

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.

The current version proposes a procedure and lets the form(at) open, subject to further collaboration (potential EU project).

The text would need further clarification and refining of some terminologies ("suspected SARE", "centre", "competent authority"). Also it was considered confusing to bring in elements relating to tissues and cells, which fall outside the scope of this implementing legislation.

Besides the drafting of legislation, it was suggested to discuss recent cases of transmission of viral infections through organ transplants, in order to define a common approach on how to act upon such cases.

8. SET OF NATIONAL PRIORITY ACTIONS

The Action Plan on Organ donation and transplantation is meant to cover the period 2009-2015. A mid term review is foreseen for 2012 and Competent Authorities will be asked by the future contractor to provide input for the review. The frame of the mid term review will be presented in the next CA meeting.

8.1. Presentation of Set of National Priority Actions

8.1.1. France

France presented its transplantation activity, the set-up of the "Agence de la Biomédecine" and the actions implemented under the national transplantation plan. Some key elements presented:

- France mentioned an ambition of 5000 transplants per year,
- a reduction of the refusal rate from 30% to 25%.
- Since 1999, there is a registry (Cristal) with centre-specific patient follow-up data. It was difficult at first to set this up, and have the data public. But now they are, following a discussion with each centre.
- FR also showed some cost/benefit estimates indicating a reduction in spending from 90,000€/year for a patient on haemodialysis to 20,000€/year for a patient post transplant.

8.1.2. Poland

Poland presented its transplantation activity, the set-up of "Poltransplant" and the actions implemented under the national transplantation plan. The upcoming joint meeting for CA Organs & Tissues and cells authorities in Katowice was also presented. Some key elements presented:

- PL has a 10-year plan with as key objectives: to double nr of transplants, to increase 5-fold the number of candidate bone marrow donors, to increase 10-fold the nr of living donors.
- Poltransplant has 26 staff members and an annual budget of 3,8million€.
- The number of transplant coordinators will be increased from 120 to 250 between 2010 and 2012.

8.2. Discussion and exchange of views on Set of National Priority Actions

The above MS presented their National Priority Actions; these National Action Plans (NAPs) are a reflection of the 10 priority actions of the EC Action Plan.

EL, IE, TK and ScandiaTransplant expressed interest to bring a presentation at one of the next CA meetings.

9. PRESENTATION OF NATIONAL COMPETENT AUTHORITIES

9.1. Presentation of some national set-up of Competent Authorities

Austria, Estonia and UK presented their national set-ups. AT included some data of patients with end-stage renal disease (8500), of refusal rates (10-15%).

9.2. Discussion and exchange of views on national set-up

The above MS presented the organisation, activities and set-up of their National Competent Authorities. All MS are currently in the process of setting up or reshaping their national competent authority, in order to comply with art 17 of Directive 2010/53/EC by August 2012. COMM therefore asked some countries with different organisations to present their national set-up, as example for the other MS.

The presentations are made available on CIRCA.

SL, SK and EL expressed interest to present their national set-up of Competent Authority during one of the next meetings of the Competent Authorities.

10. PRESENTATION OF PROJECTS ON ORGANS

10.1. Calls for Tender

10.1.1. TX coordinators: "Training the Trainers" (ONT)

ES presented the tender as implemented by ONT with the foundation IAVANTE. The 80 participants nominated by their national CAs were split in two groups for the face-to-face sessions: 1 in September 2011, 1 in November 2011. ONT gave feedback from the first face-to-face session. The overall results including elements on "post-assignment reports" will be presented during the next CA meeting.

10.2. Joint Actions

10.2.1. 2011 Joint Action ACCORD (ONT)

ONT (ES) leads the Joint Action and presented the process. ACCORD stands for Achieving Comprehensive Coordination in ORgan Donation throughout the European Union and can be divided into three main work packages: Living Donation (led by NL), Collaboration with ICU (led by UK) and Twinning (led by FR). The presentation is made available on CIRCA. 22 MS had expressed interest in participating as Associated Partners, 8 bodies (EOEO and MS) expressed interest in participating as Collaborating Partners.

10.2.2. 2010 Joint action MODE (IT)

This project focuses on Twinning and was presented by CNT.

10.2.3. 2012 Joint Action proposals (COMM)

COMM presented the proposal made at Commission level for a possible Joint Action funded under the European Public Health Programme in 2012: it will focus on cross-border exchanges and should address potential barriers and provide tools to MS. It will be presented to National Focal Points for the Health Programme and Member States will be invited to express their interest in participating.

10.3. Calls for Proposals

10.3.1. EFRETOS (ET)

This project develops registers for follow-up of patients after transplantation. The deliverables served a.o. to develop the implementing legislation. Before moving towards a European registry, MS are invited to look at proposals made to develop national registries. If this project is followed-up significant funding and Member States involvement and investment will be required. A Joint Action is therefore considered the right format. First collection and analysis of follow-up data will demonstrate feasibility and usefulness. Potential further developments will require an in-depth discussion between Member States on governance.

10.3.2. COORENOR (CZ/IT)

This group focuses a.o. on bilateral agreements on organ/patient exchange between Member States. The results will serve as a starting point for the 2012 Joint Action on organ exchange.

11. UPDATE ON NEXT JOURNALISTS WORKSHOP ON ORGAN DONATION AND TRANSPLANTATION, 18 OCTOBER, BRUSSELS

COMM presented the programme. About 35 journalists expressed their interest to meet 8 experts/actors/patients in the field of organ donation. This is the 2nd edition, following very positive feedback after the first edition in 2010.

Member States wishing to organise similar events will be able to upload on CIRCA the material prepared for this 2011 Workshop.

12. ANY OTHER BUSINESS

Greece mentioned its newly adopted law on organ transplantation which transposed the organs directive. The legislation aims to increase public thrust in the official transplant system, amongst others by strengthening living donation.

13. CONCLUSION OF THE MEETING

Antti Maunu

