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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate D - Health systems and products
D4 – Substances of Human Origin and Tobacco Control

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11TH COMPETENT AUTHORITY MEETING

ON ORGAN DONATION AND TRANSPLANTATION

29 September 2015, 10:00-18:00

30 September 2015, 9:00-16:00

BRUSSELS
Place: CCAB (Centre de Conférence A. Borschette, AB) - Room AB – 2C

SUMMARY REPORT

The meeting of the Competent Authorities on Organ donation and transplantation was convened on 29 and 30 September 2015. The previous meeting of Organs Competent Authorities (CAs) took place on 11 and 12 March 201.

PARTICIPATION:
All Member States (MS) except Luxembourg and Slovenia (excused) were represented at the meeting. In addition, Iceland, Norway, the Former Yugoslav Republic of Macedonia and Montenegro, Serbia and Turkey, as well as the European Directorate for the Quality of Medicines and Health Care (EDQM) of the Council of Europe (CoE), the European Centre for Disease Prevention and Control (ECDC) attended the meeting, as well as representatives of the three European Organ Exchange Organisations (EOEOs) Eurotransplant, Scandiatransplant and the South Alliance for Transplants (SAT).

European Commission (DG SANTE):
Chairs: Mr D. SCHNICHELS, Mr S. VAN DER SPIEGEL
Commission Representatives: Ms H. LE BORGNE, Mr R. Mc GEEHAN, Ms I. SISKA, Mr P. CATALANI, Trainee: Ms B. FAURE
Administrative Assistant: Ms A. CORNEA

1. WELCOME AND INTRODUCTORY REMARKS

2. ADOPTION OF THE AGENDA

3. INTRODUCTION OF NEW PARTICIPANTS

Representatives of National Competent Authorities (CAs) who attended a CA meeting for the first time introduced themselves. Representatives from candidate countries

(Serbia, Montenegro, Former Yugoslav Republic of Macedonia and Turkey) were warmly welcomed.

4. PRESENTATION OF THE EUROPEAN LIVER TRANSPLANT REGISTRY (ELTR)

Representatives from ELTR presented their register, its history, its features and its usefulness, also for CAs cooperating with ELTR. The ELTR register captures over 95% of all liver transplanted patients in the EU. Their follow-up data are introduced by different liver transplant teams, audits are also performed to support transplant centres and to ensure consistency in such data. The consolidated data allow for valuable professional analyses on treatments. The register is currently supported by a few pharma companies, but ELTR stressed the need for a strengthened cooperation and links with public authorities. After the presentation, discussions with competent authorities related to the method implemented for the auditing process, which is based on a random selection of the centres to be audited and on the extent of the registry, which only focuses on liver transplantations. Participants stressed the need for increased collaboration with CAs to provide data to the register, which is a tool widely used at international level. Website: http://www.eltr.org/

5. LEGISLATION

5.1. Transposition of Directive 2010/53/EU (COMM)

5.2.1. State of play of the transposition check and next steps foreseen (COMM)

The European Commission gave an overview of the process of the transposition check and focused on the current situation concerning all Member States. At present, two Member States have not yet replied to the Commission's questionnaire while two still need to provide additional information. Additional information from six Member States is being translated and one country is to be assessed on the completeness of their reply. For eight Member States legal assessment of transposition is pending while for nine countries such legal assessment has been conducted.
The lack of direct transposition of the Directive's definitions and the unclear framework for quality and safety in national law were issues particularly highlighted.

The CA group was reminded of the need for Member States who have yet to submit their answer to the questionnaire or further information to do so by 30 October 2015.

5.2. Update on the 2014 "implementation survey" for Directive 2010/53/EU

*5.2.1. State of play and presentation of the **updated list of Competent Authorities** implementing tasks under Article 17 (COMM)*

After a first presentation at the previous meeting, the Commission presented an updated and comprehensive list of competent authorities implementing tasks under Article 17 in each of the Member States (including national levels, but also regional authorities and European Organ Exchange Organisations). A few Member States indicated that small corrections might still be needed. The deadline for sending final updates is 30 October 2015. A final list will be released by the European Commission by the end of the year 2015.

*5.2.2. Presentation of **updated results of the implementation survey**, after sending "clarifications questions" and receiving (most) answers to them (COMM)*

The Commission continued by providing the last and updated results of the first implementation survey, after sending "clarification questions" since April 2015 and receiving from Member States the corresponding clarifying answers. For urgent comments on the slides presented, competent authorities are invited to send remarks by 30 October 2015. Afterwards, while the report will be submitted to the usual "Inter-Service Consultation" within the Commission, a draft version of the final implementation report will also be sent to Member States and competent authorities will have the possibility to comment on it. (Reminder: the time period considered in this survey goes until December 2014).

*5.2.3. Example of **measures taken in Germany**: presentation of the work undertaken by the two commissions responsible for controlling the organ transplantation process in Germany, the "Prüfungskommission" (assessment commission) and the "Überwachungskommission" (monitoring commission).*

The Chairs of the two Commissions provided an overall outlook on the work implemented in Germany in the field, the challenges that need to be addressed and special insight on the lessons learnt after the scandals. They stressed the difficulty to regain public confidence and to secure upward trends in organs donation after the dramatic decline following the scandal. Discussions put the emphasis on the audit process, on the important role played by the media in earning public trust back, in showing the transparency of the newly reviewed system.

6. PRESENTATION OF EUROPEAN PROJECTS ON ORGAN TRANSPLANTATION

(Nota Bene: regarding EU-funded projects for which DG SANTE is in the lead, not only projects under the EU Health Programme managed with the support of Commission's Executive Agency CHAFEA)

6.1. Information point on the two "pilot projects" decided by the European Parliament *(COMM)*

General information on the two scheduled pilot projects (one on training and social awareness for organ donation in general; one for chronic kidney diseases) was given by the European Commission (SANTE Financial Unit A3 and Unit D4). The European Commission reminded Member States that the European Parliament has the prerogative

to decide on the focus topics of pilot projects and makes the final decision on such projects; the European Commission is in charge of their implementation, of the calls and of the tendering or application process.

The two financing decisions and annexes were adopted in July 2015 and published on Commission's website (and subsequently made accessible on CIRCA BC, Organs' group).

Commission Decision C(2015) 4582 final: Commission Decision on the adoption of a financing decision for 2015 on the pilot project "The Effect of Differing Kidney Disease Treatment Modalities and Organ Donation and Transplantation Practices on Health Expenditure and Patient Outcomes".

Commission Decision C(2015) 4583 final: Commission Decision on the adoption of a financing decision for 2015 for the pilot project "Platform for increasing organ donation in the European Union and neighbouring countries: EUDONORG 2015-2016".
For one pilot project (tender on organ donation), it is foreseen to launch the procurement procedure by the end of 2015. For the grant on chronic kidney diseases, the call for application will come at a later stage. Both projects will run for three years.

Participants outlined that the wording "pilot" for pilot projects was confusing since activities have already been achieved and experiences undertaken in the field. The Commission explained that this terminology is a generic wording for this type of funding proposed by the European Parliament.

The Commission expects from these two pilot projects successful results for all EU Member States.

6.2. Final evaluation of the Commission Communication "Action Plan on organ donation and transplantation (2009-2015): Strengthened Cooperation between Member States" *(COMM)*

The European Commission gave a brief presentation of the Action Plan on organ donation and transplantation (2009-2015) and of the call for application foreseen to deliver a study on its uptake and impact (topic published under the Annual Work Plan[1] of the EU Health Programme before 2015 Summer). On the basis of this external review, whose results should be submitted at the beginning of 2017, the European Commission will issue a document for the final evaluation of the Action Plan, after discussions with Member States on the main findings.

6.3. Joint Actions funded under the EU Health Programme

Projects and studies - funded under the EU Health Programme and managed with CHAFEA support - were then presented by the respective project coordinators.

*6.3.1 **Joint Action ACCORD** (Achieving Comprehensive Coordination in Organ Donation) (2012-2015) (ES)*

Project's website: http://www.accord-ja.eu/

Representatives from Spanish ONT presented the Joint Action Accord, outlining each Work Packages' outcomes and results.

- WP 4 on Living Donor Registries was piloted and successful, preparing the ground for further action (and for a Council of Europe Resolution). However, the lack of values in some patients' medical files is a major barrier to enhanced efficiency of the registry. A final report of this WP compiling all the results and conclusions is available on ACCORD website.

As discussed during ACCORD final meetings and during the last Organs' CA meeting in March 2015, competent authorities asked the Commission for further support on the "living donor registers". The Commission has therefore arranged for this topic to be covered in of one the two 'pilot projects' proposed by the European Parliament (the pilot project on chronic kidney diseases). This new project starting in 2016 for a three-year period should definitely build upon ACCORD WP4 results; and should address the issue of sustainability and hosting of this supranational Living Donor registry in the future.

http://www.accord-ja.eu/living-donor-registries

- WP 5 on intensive care and donor transplant coordination collaboration aimed at facilitating the cooperation between critical care professionals and donor transplant coordinators and optimise the donation rates from deceased donors (donation after brain death and donation after circulatory death). Assessing end-of-life practices, it allowed formulating a set of recommendations included in a report available online.

[1] http://ec.europa.eu/health/programme/events/adoption_workplan_2015_en.htm

http://www.accord-ja.eu/content/work-package-number-5-intensive-care-donor-transplant-coordination-collaboration

Further training sessions are currently performed, using remaining dissemination funding from WP2. In addition, several countries such as Spain or Italy have developed their own "national ACCORD" to roll out and build upon WP5 results and continue improving deceased donation rates. In the hospitals and countries involved, this WP showed impressive results.

- WP 6 on twinning on organ donation and transplantation also showed successful results. The French – Bulgarian twinning helped to produce and improve the quality of operating procedures and their compliance with the Directive's requirements. The twinning between Italy and Cyprus, Czech Republic, Malta, Lithuania permitted to improve authorisation schemes and auditing of transplant centres (report, guidelines…) and to set up e-learning modules and training programmes for national auditors, along the conduction of joint inspections in transplant centres. The Dutch-Hungarian twinning allowed developing an e-learning training for procurement surgeons and upgrade the Dutch IT platform into a larger platform in English, with the support of the European Society for Organ Transplantation.

http://www.accord-ja.eu/twinning

A few actions are still taking place, especially additional training courses organised by WP5 on ICUs. However, for the other work packages, all results are now available and ready for use at national level. The tools produced can be extensively used by competent authorities, which will have to organise related dissemination to pass the information on to transplant centres.

*6.3.2 **Joint Action FOEDUS** ("Facilitating exchange of organs donated in EU Member States" (2013-2016) (IT)*

The main results of the FOEDUS project's work packages (3 horizontal work packages: WP 1 to WP 3 and 3 core work packages: WP 4 to WP 7) were presented by their respective leaders. At present, some deliverables for the six first work packages are still under preparation, while two main practical outcomes have been achieved: the set-up of the international organ exchange portal and of the organ form, the production of a manual providing guidance on communicating with the media. FOEDUS final meeting took place on 21-22 September 2015; the joint action will finish at the end of April 2016.

WP 1 on Coordination and WP 6 on upgrading the IT platform for International Exchange of Organs for Transplantation were presented together by Italy and the Czech Republic. WP 6 has consolidated and tested the IT platform developed under the COORENOR project (2010-2012) and will constitute a pivotal tool for managing cross-border exchanges of organs otherwise lost/not offered to other countries. The platform will be hosted by Member States which will financially support it, several of them having already committed to co-finance the IT tool and others confirmed their interest. However, the number of active users still needs to be improved before reaching a final decision among FOEDUS consortium.

WP 2 on Dissemination, aimed at ensuring that all the results and deliverables are made available to the different stakeholders, was presented by Hungary. A final newsletter, a

final dissemination report as well as the final Layman's report are expected for 2016 and will be available online.

WP 3 on Evaluation was presented by Greece, outlining the successful outcomes of the Joint Action. General relations and communication between partners have shown to be positive. However, progresses were delayed by some factors such as late delivering of information or lack of commitment and weak feedback. A final evaluation report including suggestions for improving further action will be available in November 2015.

Results of WP 4 on the definition of guidelines for cooperation in cross-border organ exchanges and analyses of obstacles were not exposed and should therefore be fully presented during the next CA meeting. The main output of this WP will be the definition of guidelines on basic principles for such exchanges and recommendations to overcome hurdles and come up with examples of agreements.

WP 5 on consensus on donor medical information recommended for international organ exchanges was presented by France. The original objectives of providing medical advices for specific support (recommendations on donor maintenance) and fostering exchanges through harmonisation practices were met.

Outcomes of WP 7 on Communication and public awareness were jointly exposed by Germany and Slovenia. The final output of the WP is the production of guidelines on "how to communicate about organ donation and cross border exchanges", which were tested in five countries. The final results of the WP are summarised in a comprehensive Manual intended for competent authorities.

Presentations contributed to fruitful discussions with competent authorities during the meeting. The FOEDUS portal, operational since June 2015, was reported by participants to the project to be a helpful tool, which highlighted the importance of its use by competent authorities as well as the need for increased cooperation between Member States to support its further development.

DAY 2: 30 SEPTEMBER 2015 (9:00 – 16:00)

7. VIGILANCE AND SURVEILLANCE

7.1. Update on alerts and activities linked to the field “Substances of human origin” (SoHO) (ECDC)

ECDC representative presented ECDC's activities and the priorities set for the risk assessment of bacterial infection transmissions through substances of human origin (SoHO), giving insight on the developments made during ECDC's expert consultation meeting on 24-25 September 2015. The purpose of the meeting was to define a priority ranking in the spending allocated to address the various bacterial diseases transmissible through SoHO. The selection was made on the basis of a specific methodology and criteria such as the urgency of the threat, its likelihood of occurrence. The list will be the basis for conducting risk assessments on the negative impacts of the identified infections on SoHO supply. Bacteria selected for ranking include Acinetobacter spp, Bacillus spp, Brucella spp, Clostridium spp or Enterococcus spp.

Member States are invited to provide feedback on ECDC proposals for this ranking assessment regarding bacterial infections (and to propose further names of experts).

Additionally, a brief overview of the potential impact of the migration crisis on SoHO was given, pointing at the fact that immigrants are possibly both SoHO donors and recipients (the case of migrants in need for an organ transplant already happened in Germany for example) and have access to national health centres, which increases the need for a common framework to be defined in the EU (list of potential diseases, common list of the screening needed for each case of disease). ECDC is finalising and will make available in the coming days some guidelines. Germany also proposed to share a document developed by the Paul-Ehrlich-Institute (PEI) that could be useful for other countries as well.

8. National Actions relating to EU Legislation and Action Plan on Organ donation and transplantation (2009-2015)

8.1. Turkish activities and progress in the Organs' field (TR)

An overview of Turkish national actions relating to the 10 priority actions of the Action Plan was presented, as well as of activities (training courses, conferences, work with religious leaders etc.) organised by the Turkish Ministry of Health under EU funding. These actions were reported to be successful, however family approval rates for deceased donations are not as high as expected and the issue will now be further tackled. Reasons for non-donation often include religious considerations. However, the opposition of the family after death while the patient had expressed his consent when alive remains a common situation and a challenge.

8.2. Presentation of the new Finnish action plan on organ donation and transplantation (FI)

A representative from the Finnish Transplantation Office presented the new national action plan on organ donation and transplantation. Discussions following the presentation outlined the important role of patients' organisations, which is particularly high in Finland.

8.3. Presentation of the Spanish programmes for Donation after Circulatory Death (DCD) (ES, ONT)

ONT presented the results of Spanish programmes for Donation after Circulatory Death (DCD). The presentation showed the significant impact that had these programmes in the country especially in increasing the numbers of deceased donations, despite already high rates for Donations after Brain Death (DBD) (and without substitution from DBD to DCD). Consent rates are high in DCD, reaching levels of 95% in the uncontrolled DCD programme. Other countries with DCD programmes broadly agreed that family consent in DCD cases is less difficult.

9. TECHNICAL WORKING GROUPS (WG) UNDER THE ACTION PLAN: UPDATES

9.1. Update from the Technical WG on Living donation: final version of the living donation toolbox developed by the Working group

The updated version of the living donation toolbox developed by the Working group was shortly introduced. The recent conclusions of the CD-P-TO (Council of Europe), building upon the lines developed by the European Society for Organ Transplantation (ESOT), are reflected in the toolkit. The exercise has now come to an end and will be closed; CAs are given one month (by 30 October) to provide further comments, before the toolkit is finalised and published on Commission's website and CIRCA BC.
Some countries highlighted the importance of using this toolkit to develop and improve national living donation programmes.

9.2. Short update on the way forward with the Indicators' Working group *(COMM)*

The Commission briefly presented the developments and achievements of the Indicators' Working group. During the next CA meeting in 2016 March, ONT will present their exercise, together with other figures collected for the Council of Europe Newsletter. The European Commission will discontinue the exercise in the past form and the main element discontinued will be the section on health outcomes.

10. TRAFFICKING, INTERNATIONAL AND LIVING DONATION

10.1. Presentation of results by the HOTT project (Erasmus MC University Hospital, Rotterdam, the Netherlands)

The coordinators of the HOTT project consortium reported on the results of the HOTT project, which is nearing its end and has completed seven reports in total (literature review; organ recipients who paid for kidney transplants abroad; a case study report; recommendations on 1) 'Ethical/legal obligations of healthcare providers', 2) 'Protection of targeted or trafficked persons', 3) 'Improving cross-border cooperation', 4) 'Partnerships between transplant professionals'; Indicators.

Several members of the CA group pointed out that the project findings show that organs-related trafficking is also an issue within Europe as well as in third countries while the relationship between healthcare professionals and EU citizens travelling to third countries for transplantation was also highlighted as being a key point for further analysis. Several members explained that they already have successful systems for reporting of suspicions by healthcare professionals who treat patients who have been to third countries or are planning to go to third countries for treatment while others pointed out that the competent authorities have an important role to play in such reporting systems.

The HOTT Project representatives highlighted that these recommendations are directed to healthcare professionals (doctors, transplant centres etc.) or government entities, but that competent authorities could play an important role in disseminating the reports in their networks. The HOTT Project's Recommendations are available on the project's website (http://hottproject.com/reports/reports.html). In addition, competent authorities

can comment on the results of the reports directly sending their comments to the leaders of the related chapters.

The project's website: www.hottproject.com

10.2. Council of Europe activities: update

Council of Europe's representatives presented an update of the Council' activities in the field. The revision of the organs' guide has come to the final stage; the related document is expected to be open to consultation soon. The 2015 Newsletter Transplant, containing the most recent international figures on donation and transplantation for the year 2014, is now available on the Council of Europe webpage.

10.3. Presentation of the 2015 European Organ Donation Day (EODD) organised by Portugal on 10 October 2015 (PT)

Portugal gave a short presentation of the 2015 EODD which will take place on the 10th of October 2015, highlighting the measures taken to increase public awareness and ensure a broad participation to the event.

10.4. Special request on living donor insurance to all CAs (PT)

A brief overview of the different living donor insurance schemes in seven EU Member States (UK, France, The Netherlands, Lithuania, Estonia, Poland, and Portugal) was given by a representative from the Portuguese competent authority. The presentation outlined a few recommendations issued to ensure an equal selection of living donors in transplantation activities, especially the necessity of a neutrality criterion as regards to the living donor's insurance protection.

11. COMMUNICATION ACTIVITIES

11.1. Update on media issues

The next Journalists' Workshop organised by the European Commission will take place in November 2016.

12. ANY OTHER BUSINESS

12.1. Report on the Conference on "Transplantation and Physical activity" held on 24-25 July at Krems/Austria (AT)

This presentation will be made during the next Organs CA meeting in March 2016.

13. CONCLUSION OF THE MEETING

For information: the dates foreseen for the next Organs' CA meetings are:

- 17-18 March 2016,

- 28-29 September 2016.

Both time slots are as usual to be confirmed 6 weeks prior to the meeting.