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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

Brussels, 5 August 2015

**10TH COMPETENT AUTHORITY MEETING
ON ORGAN DONATION AND TRANSPLANTATION**

11 March 2015, 10:00-18:00

12 March 2015, 9:00-16:00

BRUSSELS

Place: CCAB (Centre de Conférence A. Borschette, AB) - Room AB – 1C

DRAFT MINUTES

- 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.

4. PRESENTATION OF EUROPEAN PROJECTS ON ORGAN TRANSPLANTATION (FUNDED UNDER THE EU HEALTH PROGRAMME)

4.1. Joint Actions funded under the EU Health Programme

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

4.1.1.1. Overview of ACCORD (ES, Organización Nacional de Trasplantes)

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

The main coordinator ONT provided an overview of progress made between the final meeting that took place on 14-15 January and the final dissemination meeting that will be organised in Madrid on 2 June 2015. Most work packages in their final drafting phases for the remaining deliverables. A “dissemination and implementation plan” was also drafted, with input from all partners, for ensuring follow-up of ACCORD results in the partner countries. The 2nd Newsletter was recently issued and widely shared. <http://www.accord-ja.eu/dissemination>

*4.1.1.2. Status of Work Package 4 - **Living donor Registries** (NL, Dutch National Transplant Foundation NTS)*

NTS presented the latest results, in particular the experience gained through the ‘pilot’ implemented in 2014 with the support of the partner Hospital Clinic of Barcelona, allowing two types of countries to test it (direct entry for countries without register, and file upload for countries with existing register). Totally 9 countries participated in the pilot, with more than 2900 kidney living donors for which the 1-year follow-up data could be captured.

Beyond general recommendations - already delivered - on the governance of a future registry, WP leaders were also asked, during and after the final meeting in Madrid mid January, to investigate needs, wishes and expectations of WP partners for the future, to use a common registry a) as their national registry, b) for supra-national data sharing, c) as a potential hosting institution, d) regarding financing models. The results of these investigations were presented (general consensus to have a follow-up activity for a common registry, possibly with some EU-funding) and other Competent Authorities or parties not yet involved in this WP were also invited to express their needs/wishes/expectations towards NTS (after the CA meeting), to achieve a more complete picture at EU level.

*4.1.1.3. Status of WP 5 - **Cooperation between Critical Care professionals and Donor Transplant Coordinators** (UK, Department of Health)*

The UK representative briefly presented recent results on behalf of her colleagues leading WP5. Most of the hospitals involved took part in all stages: after the training phases on “rapid improvement methodologies” (PDSA cycles), they could implement the proposed actions and see some results. Some lessons learnt, from several hospitals in the same countries, are to be forwarded to/ discussed with the CAs at national level, this is critical for follow-up and further improvement in the deceased donation processes. The possibility of a roll-out action (further trainings) is currently being explored by WP leaders and ONT. If such training courses are organised outside of the UK, interested CAs could then be asked to support by providing support such as rooms etc.

*4.1.1.4. Status of WP 6 - **Twinnings** (FR, Agence de la biomédecine, France)*

The French representative presented the results of this WP with three main components and the following countries involved: 1) Hungary-the Netherlands (+ ESOT): procurement surgery, including through an eLearning tool, 2) Italy-Malta, Czech Republic, Lithuania and Cyprus on auditing and authorisation schemes, 3) France-Bulgaria: “operating procedures” were developed, Bulgaria could experience visible qualitative and quantitative results in 2014.

Another deliverable within this WP will be the manual on guidelines for twinning activities. It will be made available beyond the WP consortium and will be useful also for collaborative twinning activities in the field of organ donation and transplantation that take place within other schemes (not only Joint Actions).

4.1.2 Joint action FOEDUS “Facilitating exchange of organs donated in EU Member States” (2013-2016) (IT)

4.1.2.1. Overview of FOEDUS (IT, Centro Nazionale Trapianti, CNT)

The coordinator CNT provided a general overview on the state of play for FOEDUS. . The interim meeting took place already in June 2014, the final meeting is expected for the last months of 2015, while final results should be delivered in 2016.

4.1.2.2. Overview of WP 4: Definition of guidelines for cooperation in cross-border organ exchanges and analysis of barriers/obstacles (Eurotransplant)

Eurotransplant Medical Director reported about the latest WP meeting that took place early March 2015 in the Netherlands. To address issues hindering cross-border organ exchange, the WP will come up with constructive and practical recommendations that will supplement the EU legislation in the field.

4.1.2.3. Overview of WP 5: Consensus on donor medical information recommended for international organ exchanges (FR, Agence de la Biomédecine, ABM)

Based upon the form already developed within the COORENOR project, this WP has further consolidated a consensus on the donor medical information recommended for international organ exchanges. This form can now be used on the IT platform (WP 6). The WP works also on an additional “voluntary” deliverable supporting an improved donor maintenance.

4.1.2.4. Overview of WP 6: Upgrading IT Platform for International Exchange of Organs for Transplantation (CZ, KST)

The Czech representative presented latest updates on the IT platform, in particular new users registered on the platform. All CAs - even for countries not involved in FOEDUS or in this WP - were made aware that they can get access to the platform (and post organs offers for organs that would otherwise not be allocated and for urgent requests for patients in specific cases). This is a tool that can be used by all Member States, also if they are engaged in bi- or multilateral agreements: the tool is flexible and offers can be adapted to the situation of each country.

4.1.2.5. Overview of WP7: Communication and public awareness (DE / SI)

The German representative presented, also on behalf of the Slovenian WP co-leaders, latest results, in particular results of the 2nd Workshop organised under WP 7 in November 2014 to test, fine-tuning and consolidate messages prepared by and for CAs to the general public in the field of organ donation & transplantation. The end product of WP 7 will be a manual at the attention of the CAs, to support their communication efforts and strategies.

4.2. Conferences

4.2.1. *Funded under a 2013 grant of the EU Health Programme: **LIDOBS Conference about organ living donation**, on 6-7 November 2014 (Hospital Clinic of Barcelona, HCB)*

Project's website: <http://www.eulivingdonor.eu/lidobs/> <http://wp2.eulivingdonor.eu/>

HCB reported about the preparation, organisation and results of the LIDOBS conference that took place in November 2014. Guidelines were agreed upon on different aspects of organ living donation, building inter alia upon EULID and ELIPSY results. The three steps implemented for the LIDOBS project are: 1) review the collection of materials available for them regarding: living organ donation, results of former European Union funded projects in the field prior to LIDOBS; publications and other international references and previous international consensus documents; 2) share and discuss their ideas with the group, offer their personal experience in the field with the aim of giving a novelty of the available data; 3) Moving forward to LIDOBS consensus and recommendations. Several CAs participated in the LIDOBS Conference.

4.2.2. *Information about a 2017 Congress and call for support by CAs: 14th Congress of the International Society for Organ Donation and Procurement (ISODP)*

The Commission was asked by ISODP president-elect to have the opportunity to explain and advertise this 2017 Congress towards CAs, and to ask for European support on the scientific programme.

4.3. Follow-up of EU-funded projects (COMM / CHAFEA)

Following a request on 'improvement project management' by Austrian and Dutch CAs after the previous CA meeting, the Commission presented an overview of the different schemes and funding mechanisms for EU activities, applied to the field of organ donation & transplantation. This overview covered CA meetings, Working groups under the Action Plan, EU-funded projects under the EU Health Programmes, Research Programmes or Enlargement/TAEIX support, as well as 'pilot projects' decided by the European Parliament (EP). The responsibilities of partners and ownership of results applying for the different sorts of projects were also reminded.

As presented in the slides, there was consensus among CAs that it is primarily the task of the contracting party(ies) and of partners involved in the consortium - together with the Commission - to reflect from the start of a project whether and if so how results of a project are maintained/kept up to date beyond the end of the project (except from tenders/procurement where the EU is owner of the results and the Commission has the responsibility to decide about dissemination and future of the results).

While CAs were familiar with projects funded under the EU Health Programme, the EP 'pilot projects' were new to them. The Commission explained that the initiative comes from Members of the European Parliament (MEPs) and that once funding is decided on EP side, the Commission launches the calls for projects' applications in form of "call for tenders" (procurement) or "call for proposals" (grant, co-funding). Once information will be publicly available for all stakeholders, CAs will also be informed about 'pilot projects' to be launched in 2015 in the field of organ donation and transplantation.

4.4. Update on EU-funded Research projects

4.4.1. Update on the different on-going Research projects (DG RTD)

A representative of DG Research and Innovation of the Commission provided an update on the various Research projects funded under the 2012 call on solid organ transplantation.

*4.4.2. Presentation of the **BIO-DriM project** (project's coordinator; Department of Nephrology and Internal Intensive Medicine, Charité - University Medicine Berlin & Berlin-Brandenburg Center for Regenerative Therapies (BCRT), DE)*

Project's website: <http://www.biodrim.eu/>

The coordinator of the BIO-DriM project (BIOmarker-Driven personalized IMMunosuppression) presented the main objectives of the project and first steps achieved in the implementation of biomarker-driven strategies for personalizing immunosuppression. Biomarker-driven personalized immunosuppression could offer improved treatment options to each single patient after transplantation. Validated biomarkers will enable the characterization of patient populations and their stratification, to optimize the personalized immunosuppressive therapy and to improve the quality of life of transplant patients, to decrease the adverse effects and costs of chronic immunosuppression, thus improving the long-term outcome of transplantations.

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 Commission gave an update of progress concerning its transposition check for Directive 2010/53/EU. The Commission informed the group that it plans to carry out the detailed legal analysis in the second and third quarters of 2015. In order to be able to carry out this task the Commission reminded the group that it will require further information from a number of Member States and will be contacting them bilaterally in the coming weeks and months. Currently four Member States have yet to provide a completed questionnaire while another three Member States have yet to reply to the Commission's requests for further information.

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

5.2.1. Presentation of the list of Competent Authorities implementing tasks under Article 17 (COMM, from national answers to the implementation survey, first draft before corrections)

The Commission presented, as a first result of the 2014 ‘implementation survey’ for Directive 2010/53/EU, the list of all CAs named by Member States to implement all tasks listed in Article 17 of the Directive. This first version of the list was prepared by compiling national answers. The Commission already identified some gaps (tasks not

covered) or inconsistencies, therefore Member States/CAs are invited to pro-actively provide corrections if deemed relevant and will receive ‘follow-up questions’ from the Commission as of April.

5.2.2. First results of the ‘implementation survey’ for Directive 2010/53/EU (COMM)

The first ‘implementation survey’ for Directive 2010/53/EU was launched in August 2014. The Commission received the last of 29 national answers on 23 December 2014 and could present the first aggregated results. The main topics covered are: A) identification of CAs and overall set-up (including European Organ Exchange Organisations and regional levels); B) Organ procurement, donor and recipient protection; C) Transport and preservation; D) Organ transplantation (in particular authorisation schemes); E) Framework for quality and safety; F) General comments. These will be also the main sections for the final report to be sent to other EU institutions.

As of April 2015, some follow-up questions will be sent to and answered by Member States/CAs). While the Commission could already start correcting data originally provided by Member States, these corrections by Member States will be necessary for the accuracy of the final report that will also be circulated to CAs before adoption.

5.2.3. Reminder on the “Contact detail website” established to support Commission Implementing Directive 2012/25/EU (COMM)

Website: <http://txcontactlist.eu>

Following the launch in August 2014 of the ‘contact detail website’ with the support of Eurotransplant, Member States were reminded that they now have the responsibility to update their contact data (login and passwords shared with nominated persons).

At the request of Germany, Eurotransplant kindly agreed to present at the next Organs’ CA meeting an overview of accesses to the website.

Nota Bene: At the difference of FOEDUS IT platform that is meant for quick ‘organ offer’ in a secure environment, the ‘contact detail website’ is openly accessible and meant to provide for each country contact details for three types of information (organ and donor characterisation, traceability, vigilance), as required under Implementing Directive 2012/25/EU. The two tools are therefore complementary.

6. VIGILANCE AND SURVEILLANCE

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

The ECDC representative presented - and was congratulated for the work - on HTLV-1.

The geographical distribution of areas with a high prevalence of HTLV-1 infection is available under:

<http://www.ecdc.europa.eu/en/publications/Publications/geographical-distribution-areas-high-prevalence-HTLV1.pdf>

The HTLV-1 prevalence maps and list of countries/areas across the world will support national authorities to implement and apply quality and safety requirements defined in the EU legislation.

7. ACTION PLAN ON ORGAN DONATION AND TRANSPLANTATION (2009-2015): NATIONAL ACTIONS

7.1. National action plans

7.1.1. Croatian Action Plan (HR, Ministry of Health)

The Croatian representative presented strategies put in place in the country in the last years, and impressive results achieved. Croatian coordinating role in the region, e.g. through the WHO South Eastern European Health Network (SEEHN), was also highlighted. Congratulations followed this comprehensive presentation.

7.1.2 Bulgarian Action Plan (BG, Bulgarian Executive Agency for Transplantation, BEAT)

The BEAT representative presented activities undertaken in Bulgaria, also with the support of EU-funded projects such as ACCORD and FOEDUS, and could report positive results for 2014.

7.2. On priority action 10 of the EU Action Plan (accreditation system for organ donation/procurement and transplantation programmes)

7.2.1. UEMS, EBS Qualification in Transplant Coordination (Director of the Hungarian Organ Coordination Office)

The Director of the Hungarian CA, also involved in accreditation and certification activities, presented the UEMS/EBS qualification in transplant coordination. Several CAs confirmed their interest for healthcare professionals from their country and/or wishes to have in the future also the oral examinations implemented in other languages.

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

8.1. Technical WG on Living donation

While the previous version on the 'living donation toolbox' developed under this WG is available for the whole CA group since April 2014, the UK and ES representatives updated the CA group on the latest discussion regarding the two recent publications about potential risks for living donors. At the last CD-P-TO meeting, the European Society for Organ Transplantation was asked to support and to provide 'European lines' on this topic. Once available, these 'lines' will be integrated in a new and final version of the toolbox meant for CAs developing/improving the living donation programmes.

8.2. Technical Working Group on Indicators: Presentation of second set of results from the 2014 exercise

8.2.1. Introduction (COMM);

8.2.2. Part 4: Transplantation (ES, Working group member ONT);

8.2.3. Part 5: Health outcomes (DE, WG member DSO);

8.2.4. Part 6: Health resources (PT, WG member ISPT)

The Commission gave a short introduction of the three remaining sections of the indicators exercise for 2014: transplantation, health outcomes and health resources [the three first presentations took place in September 2014].

Spain presented data on transplantation in the 28 EU Member States, Iceland, Norway, Turkey and fYROM. The data shows that overall from 2009-2013 there have been increases in both kidney and liver transplants due to living (kidney) and deceased (liver) donation. For heart, lung, pancreas and small bowel transplants, we observe more specialisation in transplant activities with some countries performing a high number of transplants for a specific organ. Rates of paediatric transplants are also much higher in some countries compared to others. Belgium explained that their high rate of paediatric transplants was due to an increase in living split donation.

Germany presented anonymised health outcomes data for the 28 EU Member States, Norway, Turkey and fYROM. The data shows the existence of registers does not necessarily correspond to the reporting of follow-up data. The data on recipient and graft survival is also patchy with some countries not achieving at least 80% data completeness. Follow-up of living donors shows that deaths at three months are rare, with only one death reported for the roughly 3,000 patients followed up.

More generally, the health outcomes data is difficult to interpret due to incomplete data and the need to consider risk adjustments for recipients and donors, as well as allocation policies that select the most urgent and therefore most sick patients. Member States stressed the importance of collecting follow-up data for recipients and living donors to ensure that centres are performing well, but that this data must be carefully interpreted considering the difficulties outlined above.

Portugal gave a general presentation outlining the difficulties in comparing health resources data between countries.

8.2.5. Indicators exercise next steps: options forward

The group agreed to the proposal by the working group for the continuation of the indicators exercise. In future, the Spanish CA will manage the exercise, which will include data from the Council of Europe Transplant Newsletter and some additional analyses. The collection of health outcomes data will be stopped, but professional organisations and national authorities will be asked to present findings from their registries at future meetings. The working group will also look into preparing a short report based on the data collected the past five years.

The Commission added that it had been approached by representatives of the “European Liver Transplant Registry” (ELTR) who proposed to present their register to CAs at the next Organs’ CA meeting (some CAs already have a cooperation in place with ELTR).

FR added that national CAs could also be in the position to present during CA meeting their national efforts/strategies/registers to follow-up transplanted patients. The Commission confirmed that such presentations are also welcome.

9. TRAFFICKING AND LIVING DONATION

9.1. Update on trafficking issues (COMM)

The Commission gave the group an update on recent developments in the field of organs-related trafficking. A debrief of the international symposium of trafficking in human beings for the purpose of organ removal (THBOR) was presented. This symposium was organised under the auspices of the EU-funded HOTT project and the event was used as an opportunity for the project coordinators to present their latest findings and in particular those linked to the second and third deliverables. The group was informed that the discussions during the symposium underlined the need for organs CAs to play an important role in the fight against THBOR not least as a facilitator for cooperation between law enforcement bodies and medical professionals. This point was also stressed by the Commission in its opening speech at the symposium.

The HOTT project is on-going with a focus moving forward on developing the final deliverables namely, indicators to help data collection and identification of THBOR and recommendations to improve the non-legislative response. The final deliverables are expected by August 2015 and the project coordinators have agreed to give a full debrief of the project in the September 2015 CA meeting. The Commission informed the group that it had suggested to the project coordinators that organs CAs should be involved in the development of the final deliverables and offered to facilitate such involvement should the coordinators wish to seek CA involvement.

The Commission also gave a brief update on discussions regarding the Council of Europe Convention against Trafficking in Human Organs since the September 2014 CA meeting. The adoption of this Convention had been brought to the attention of EU Member States during a December 2014 Council of Ministers meeting where it was introduced as an information point. Within the Commission an initial meeting between relevant Commission departments had also been held to discuss the Convention. The Commission's department for home affairs (DG HOME) is responsible for Commission policy in the domain of the fight against organised crime and confirmed that it does not currently plan to introduce any criminal sanctions at EU-level in the field of organ trafficking. The Commission informed the group that it plans to continue to monitor progress towards ratification of the Convention and any further discussions which take place at Council of Minister level on a potential EU signature of the Convention.

9.2. Council of Europe activities against trafficking in human organs

An update on the Council of Europe Convention against Trafficking in Human Organs was given by the Spanish representative on behalf of the representative of the Council of Europe (excused). The group was reminded of the main objectives and provisions of this Convention which was adopted in 2014 and will be open for signatures at the end of

March, 2015. The group was informed that a signing ceremony will take place on March 25, 2015 in Santiago de Compostela, Spain, along with an international conference on the fight against organ trafficking. All members of the group were invited to attend these events where at least 11 EU Member States and another three Council of Europe Member States are expected to sign the Convention. The Commission explained that a ratification by the EU is currently not envisaged.

9.3. Special request on living donor insurance to all CAs (PT, ISPT, summary of answers received from different national authorities)

The Portuguese CA is currently developing a Portuguese model for living donor insurance and to do so was interested to collect and analyse data from various EU Member States. A request for information was launched via the Commission (on CIRCA BC and via email automatic notification) and PT could present a summary of answers received. Some CAs (DE) missed the first request but would be interested in answering the question (they already did orally by saying that they are in favour of a life-long follow and a full coverage for living donors). PT then kindly agreed to present at the next Organs' CA meeting an updated overview if additional answers and updates reach them.

10. COMMUNICATION ACTIVITIES

10.1. Feedback after 2014 Journalist Workshops on Organ Donation and Transplantation: feedback to CA group (26/11/2014, Brussels) (COMM)

The Commission briefly updated the CA group on the 2014 Workshop and thanked all speakers and all CAs who supported by advertising the Workshop towards journalists from their country. The Commission also informed that the 2015 edition, originally foreseen for November, was post-poned to June/July 2016, because of new activities to be launched in 2015 (2 'pilot projects' decided by the European Parliament in the field of organ donation & transplantation).

Webpage of the Workshop (where presentations, documents prepared for the press pack and articles shared by participating journalists are available):

http://ec.europa.eu/health/blood_tissues_organs/events/journalist_workshops_organ_en.htm

10.2. Communicating organ donation to different communities: "Impact of globalisation and immigration in Europe for organ donation – lessons from the UK" (Professor of the University of Bedfordshire,)

These 'lessons learnt' and policies implemented in the UK to address the impact of immigration on transplant waiting lists and for broadening the donor pool, were of great interest, in terms of communication, organ donation and management of waiting lists, for many European countries.

10.3. Update on media issues (tour de table)

11. ANY OTHER BUSINESS

12. CONCLUSION OF THE MEETING

For information: the **dates *foreseen*** for the next Organs' CA meetings are **29-30 September 2015** (to be confirmed as usual via official invitations six weeks prior to the meeting).