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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate B - Health systems, medical products and innovation
B4 – Medical products, quality, safety, innovation

Brussels, 22 July 2016

**Competent Authorities on Substances of Human Origin Expert Group
(CASoHO E01718) – 12th Meeting on Organ Donation and
transplantation**

17 March 2016, 10:00-18:00

18 March 2016, 9:00-13:00

BRUSSELS

**Place: CCAB (Centre de Conférence A. Borschette (AB),
Rue Froissart 36, 1040 Bruxelles, Belgium) - Room AB-5B**

SUMMARY MINUTES

This meeting of the Competent Authorities (CAs) on Organ donation & transplantation was convened on 17 and 18 March 2016.

PARTICIPATION:

All EU Member States (MS) except Luxemburg (excused) were represented at the meeting. In addition, Norway, the Former Yugoslav Republic of Macedonia, Montenegro, Serbia and Turkey, as well as representatives of the Consumer, Health and Food Executive Agency (Chafea) and the European Centre for Disease Prevention and Control (ECDC) joined as observers, as well as the three European Organ Exchanges Organisations (EOEOs) Eurotransplant, Scandiatransplant and the South Alliance for Transplants (SAT).

External speakers (from the European Renal Association – European Dialysis and Transplant Association (ERA-EDTA), University of Oxford (UK), TPM-DTI Foundation (ES)) came for their agenda points, except the Dutch Research Institute NIVEL, contractor for the study on the final review of the Organs' Action Plan, who was allowed by the CA group to stay for the whole duration of the CA meeting given the nature of their tasks and the necessity to understand interactions in the CA group and to identify issues and stakeholders at stake in the field.

European Commission (DG SANTE):

Chairs: Mr D. SCHNICHELS, Mr S. VAN DER SPIEGEL

Commission Representatives: Ms H. LE BORGNE, Mr R. Mc GEEHAN,
Mr P. CATALANI, Ms D. FEHILY, Ms I. PUCINSKAITE-KUBIK

Administrative Assistants: Ms A. CORNEA

1. WELCOME AND INTRODUCTORY REMARKS

2. ADOPTION OF THE AGENDA

3. INTRODUCTION OF NEW PARTICIPANTS

4. LEGISLATION

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

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

The Commission presented the latest state of play in the transposition check of the organs legislation. The full analysis of the replies from those countries who have replied has now been completed (24 of 28 Member States). Further clarification is needed for all 24 MS and this will take the form of administrative letters.

4.2. Update on the first “implementation survey” for Directive 2010/53/EU

*4.2.1. State of play for the **report on the implementation of Directive 2010/53/EU, including updated list of Competent Authorities implementing tasks under Article 17** (COMM)*

After presenting in March 2015 first findings based on the 29 national answers (28 EU Member States and Norway) and in September 2015 consolidated results after bilateral clarification questions, the Commission provided a brief update on this report, which is currently being finalised. Before publication Organs Competent authorities will also be consulted.

The updated and comprehensive list of Organs Competent authorities implementing, for each Member State, tasks listed in Article 17 of Directive 201/53/EU is available on CIRCA BC and will be published on SANTE website.

5. PRESENTATION OF EU-FUNDED PROJECTS IN THE FIELD OF ORGAN TRANSPLANTATION

5.1. EU-funded Research Projects

*5.1.1. **Presentation of the COPE project** (Consortium on Organ Preservation in Europe, University of Oxford, UK)*

The coordinator of this Research project presented, in presence of the Scientific officer in charge in DG Research, the main objectives, work packages and latest results of this project including ongoing clinical trials.

This Consortium involves 14 partners (eight Educational Institutions, five SME's and the European Society of Organ Transplantation) from six EU Member States, within three

multi-centre international clinical trials, two multi-centre experimental programmes and one consolidated integrated biobank.

DE and ES respectively asked questions about the biobank and the related issue of data collection as well as about the inclusion of DCD donors in the COPE project. Results presented in March 2016 were still preliminary, more will be available in Spring 2017 on these and other issues, therefore the coordinator remains available for future updates.

Website: <http://www.cope-eu.org/>

COPE is also the official organ preservation task force of the European Society for Organ Transplantation (ESOT):

<http://www.esot.org/resources/consortium-organ-preservation-europe>

5.2. Tender under the EU Health Programme: Final review of the Commission Communication “Action Plan on organ donation and transplantation (2009-2015): Strengthened Cooperation between Member States”

During the previous CA meeting in September 2015, the European Commission presented a call for application, under the EU Health Programme, to deliver a study on the uptake and impact of the Action Plan on organ donation and transplantation (2009-2015). Since then, a contractor was selected to implement this tender: the Dutch Research Institute NIVEL (same contractor than the mid-term review in 2012: ACTOR study). The kick-off meeting for this final study (FACTOR study) took place in January 2016.

The Commission emphasized that the contractor had been asked - in the Terms of References as well as during the kick-off meeting - to re-use, as much as possible, data already available (Transplant Newsletters, websites etc.) or already collected (in particular for the ACTOR study), as well as to shorten questionnaires and to pre-fill these national questionnaires as much as possible for Competent authorities, so that they merely need to check/confirm/add if necessary.

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.

5.2.1. Presentation of the FACTOR study by external contractor (NIVEL)

The representative of the Dutch Research Institute NIVEL presented the objectives set for the FACTOR study: “study on the uptake and impact of the EU Action Plan on Organ Donation and Transplantation (2009-2015) in the EU Member State; Final Review”. Four specific objectives were defined, namely to provide: 1) a brief assessment of organ donation and transplantation activities in each of the Member States, including the set-up and organisation at central and local level; 2) a mapping overview and assessment of the state of implementation and activities carried out, ongoing and/or planned in each of the member States on each of the 10 priority actions of the Action Plan; 3) an assessment of the engagement of Member States and Commission in common EU initiatives and the outcome of these initiatives in relation with the 10 priority actions; 4) an assessment of strengths, weaknesses, opportunities and threats of and for the implementation of the

Action Plan and recommendations for the period after the original time-frame 2009-2015, both at EU and national levels.

The contract will run for 16 months, from January 2016 to April 2017, and the interaction between the contractor and Competent Authorities will take place mainly from March to December 2016, via national questionnaires, interviews and during a stakeholder conference to be held at the end of 2016. The contractor also asked the CA group if they were already volunteers to take part in this stakeholder conference and seven countries answered positively (AT, DE, ES, FR, IE, NL, UK). In the first months of 2017, the draft report with the findings will be peer reviewed by five experts.

After FACTOR presentation, ES asked if the stakeholder conference would involve stakeholders other than Competent Authorities, for example professional or patients' associations. NIVEL answered that positively (but also mentioned a limited number of places available, given budget constraints).

It was clarified that the support and inputs of the Competent Authorities to this study will be important not only for the final review of the Action Plan, but also for reflection and planning of possible future activities with support of the European Commission, and of course for Member States actions.

5.3. Call for proposals under the EU Health Programme

While there is currently no project funded under the EU Health Programme after a call for proposals running in the organ transplantation field, the Commission asked the coordinator of the ETPOD project (European Training Program on Organ Donation), concluded a few years ago, to come to present their remarkable dissemination activities.

These ETPOD activities are directly linked to the priority action 1 of the Organs' Action Plan (train transplant donor coordinators), are supporting national efforts and should be taken into account for the final review of the Action Plan. They can be inspiring for other EU-funded projects (in terms of dissemination and follow-up) and are relevant for the "pilot project" on organ donation (training and social awareness) to start in 2016 (see point 5.5.1.).

5.3.1. Feedback on the dissemination of the ETPOD project (European Training Program on Organ Donation, University of Barcelona, ES)

ETPOD is a project funded under the EU Health Programme already in 2005, and implemented from January 2007 to December 2009. It could therefore be considered as an "old" project however dissemination efforts were continued still over the last years, bearing their fruits not only in Europe but also elsewhere in the world (Algeria, Brazil, Egypt, Lebanon, Libya, Tunisia).

ETPOD involved a consortium of 20 partners from 17 countries (16 EU Member States and Turkey). It was meant to improve health professional competences in organ donation; it designed and implemented an educational programme "learn to teach" via blended learning and national seminars as well as it evaluated the impact in organ donation in all countries of the consortium and provided dissemination activities. Totally, ETPOD dissemination activities were rolled-out through 169 seminars, involving 8473 participants.

Website: <http://etpod.il3.ub.edu/>

5.4. Final updates on the last two Joint Actions on organ donation and transplantation funded under the EU Health Programme

5.4.1 Joint Action ACCORD (Achieving Comprehensive Coordination in Organ Donation) (2012-2015) (ES) (ACCORD coordinator ONT)

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

The coordinator of this successful Joint Action provided a short oral update on the latest developments and key messages to pass to Organs' Competent authorities. According to national dissemination plans developed by each partner at the end of the Joint Action, many Member States are updating their registries for living donors according to ACCORD WP4 recommendations also endorsed in a Council of Europe Recommendation. WP5 implemented additional training courses to improve the links between intensive care professionals and transplant coordinators, therewith improving donation rates; three scientific articles are currently under drafting to report about WP5 results. WP 6 on twinning also delivered tangible results for twinned partners involved and beyond.

5.4.2 Joint action FOEDUS "Facilitating exchange of organs donated in EU Member States" (2013-2016) (IT) (FOEDUS coordinator Centro Nazionale Trapianti - National Institute of Health (CNT-ISS), IT)

Discussions focused in particular on the following work packages and topics:

5.4.2.1. Work Package 4: template agreements and recommendations (Eurotransplant)

After a survey conducted in 2014-2015, this work package produced general recommendations for cross-border exchange of organs. These recommendations deal with medical preconditions, general considerations (agreement, transplant laws and role of Competent authorities), quality standards of donor characterisation, language, contact management, costs and follow-up of the transplanted patients and organs (including reporting of Serious Adverse Events and Reactions). This work package also delivered a proposed "Cooperation agreement for the cross-border exchange of organs" that can be used/adapted by Member States/Competent authorities engaging in new cross-border exchanges or willing to formalise their existing exchanges.

5.4.2.2. WP5 Donor Medical Information, Quality, Safety and management aspects to facilitate and increase cross-border organ exchanges (Agence de la Biomédecine, FR)

The French work package leader updated the group on the latest developments and documents delivered: the form for cross-border organ exchanges (based on national forms and on the experience on donor evaluation from the past EU-funded project COORENOR), the follow-up form for organs accepted for cross-border exchange, recommendations on donor maintenance.

5.4.2.3. WP6 FOEDUS-EOEO portal (Kordinacni Stredisko Transplantaci (KST), CZ)

The Czech WP leader presented the latest results and statistics regarding the IT-tool for quick organ offer (for the period 1 June 2015 to 29 February 2016, i.e. 9 last months). 24 countries are registered within the portal and of these 7 (CH, CZ, FR, IT, LT, PL, SK) post organ requests and 9 (BG, CH, CZ, ES, FR, IT, LT, PL, SK) actively offer organs, thus representing a population of 244 million inhabitants. 134 organ requests were made, and 131 organs offered, of which 38 were accepted (N.B. these are organs already not allocated in the country of origin, given their specificities they might be difficult to allocate, however they can still save lives of patients for which there is a match). Of these 38 organs accepted, 23 could finally be transplanted: 9 livers (14 offered), 5 hearts (9 offered), 4 kidneys (7 offered), 4 lungs (6 offered), 1 small bowel (1 offered). The 23 transplanted patients were 12 children (9 aged 0-3, 2 aged 4-9, 1 aged 10-19) and 11 adults (4 aged 20-39, 5 aged 40-59, 2 aged 60-86). These 9 months of use of the portal and the number of patients transplanted (with organs that would without the portal not have been offered) is a proof that this IT-tool can definitely be used for quick cross-border organ. The IT-tool is not meant solve to logistical, financial, legal aspects around cross-border organ exchange but has now proven to be very convenient and appropriate for cross-border organ offers and request between countries/competent authorities/allocation platforms.

Within the last weeks of the project, remaining FOEDUS budget will be used to explain and initiate other Member States who might be interested in using this portal for exchanging organs. Interested Member States can contact the Project Coordinator (CNT).

5.4.2.4. WP1 FOEDUS final balance, future prospects, including sustainability of the portal (CNT, IT)

The Joint Action coordinator CNT presented the main outputs already delivered (sustainability plan for WP1, layman's final report for WP2, report on current practices regarding cross-border organ exchanges and Recommendation for international organ exchange for WP4, donor form for cross-border organ exchanges and fast track form for WP5, Terms of use of IT portal for cross-border exchanges for WP 6 and Manual on how to communicate with media in the field for WP7) and the outputs still under preparation by the end of the project end of April 2016 (Final evaluation report for WP3, Results of pilot testing of IT portal for WP6).

While the technical discussion on the portal took place under the previous agenda point, CNT also coordinated the discussion on the future of the portal and on the number and profiles of users: all EU Member States and their Competent authorities / Organ Procurement Organisations / European Organ Exchange Organisations (EOEOs) are invited to join and to seriously consider the use of this portal which can help patients otherwise not served. CNT and KST are available to avoid duplication of efforts for partners joining, and in particular to overcome possible technical issues between different IT systems (for example for Scandiatransplant and Eurotransplant) that would hinder a proper connection and full use of the portal. Finally, the solution proposed by the consortium to maintain the portal in the long term was discussed in February 2016 and agreed upon: the technical option preferred was chosen and partners decided that the portal should be hosted by a Competent authority (not by the European Commission) supported by a board of CAs. Eight countries already committed to financially support the portal in the future (CZ, EE, FR, IT, PL, RO, SK, CH) and three other countries expressed first interest to support, but need to confirm (BG, LT, UK). CNT also highlighted the key principles set as one agreement between partners for the sustainability of the portal:

1. Sticking to the principle of offering “surplus organs”, on first-come, first-served basis. Basic rules of functioning are those fixed in the international agreement, developed under WP4.
2. No patient may appear simultaneously on more than one waiting list maintained by Parties.
3. The portal is open to any EOEO/national authority wishing to participate in international cross border exchanges.
4. The governing board will be made of representatives of the authorities/bodies that actively use and/or support financially the portal.
5. Costs of maintenance/further development would be shared and covered on a volunteer basis for the first year and then re-discussed by the board.

5.5. Information point on the two “pilot projects” decided by the European Parliament (COMM)

The Commission briefly presented the state of play for both pilot projects decided by the European Parliament in 2015 in the field of organ donation & transplantation: For both pilot projects, Financing decisions and Annex (explaining the scope of the projects) available on CIRCA BC, as well as under the website: http://ec.europa.eu/health/blood_tissues_organs/key_documents/index_en.htm#anchor3_more

5.5.1. State of play for the tender on organ donation (training and social awareness)

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" (this original name has been adapted since July 2015)

For this tender, the open call for tenders was launched before Christmas, the evaluation took place in February 2016 but still needed to be endorsed by the Public Procurement Committee within the Commission. It is expected that the contract would be signed before Summer 2016 for the project to start mid 2016, for three years.

Competent authorities are reminded that they will be involved at different stages of the project, e.g. to nominate coordinators to be trained in the first phase of the project or to host/propose speakers for the awareness-raising events in the second phase. Details of what is expected from the contractor, and where CAs can contribute, are available in the tender specifications available on the CIRCA BC platform since 11 February 2016 (and were published on Commission website¹ in December 2015).

5.5.2. State of play for the grant on chronic kidney diseases

¹ http://ec.europa.eu/dgs/health_food-safety/funding/contracts_en.htm

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".

The call to apply for this grant has not yet been launched but Competent authorities will be informed once it is the case, like all other stakeholders who asked to be informed. The applicants will have sufficient time to apply. [N.B. This call was launched² after the CA meeting, on 31 March 2016. Organs CAs were informed on 1 April 2016. Applicants have until 16 June 2016 to apply.]

6. PRESENTATION BY A PROFESSIONAL ASSOCIATION

6.1. Presentation of the ERA-EDTA Registry on renal diseases in Europe (*European Renal Association –European Dialysis and Transplant Association*)

Website: <http://www.era-edta.org/page-7-37-0-37-eraedtaregistry.html>

After a presentation of the European Liver Transplant Registry (ELTR) at the CA meeting in September 2015, the representative of the European Renal Association – European Dialysis and Transplant Association (ERA-EDTA) joined the CA group in March 2016 to present data from the ERA-EDTA registry, in particular 1) the prevalence of chronic kidney diseases (CKD) in Europe, 2) the current access to renal replacement therapy in EU countries and 3) challenges to address in the field.

7. VIGILANCE AND SURVEILLANCE

7.1. Update on alerts and activities linked to the field “Substances of human origin” (SoHO) (*European Centre for Disease Prevention and Control, ECDC*)

The ECDC representative presented updated information on the zika virus disease: its transmission, clinical presentation, potential complications, diagnostics, treatment and vaccine, prevention, timeline, the current outbreak and the situation in Europe as well as preparedness regarding zika in EU/EEA countries, the response and support by ECDC. Were also explained the risk of SoHO donation in zika viraemic phase, the detection of zika virus RNA in infected humans (detected in brain, liver, spleen, kidney, lung and heart from one fatal adult case, no information is available whether the virus could be infectious in those organs if transplanted), the donors of SoHO at risk of being infected and transmit zika virus, the reported transmissions of zika virus infection through SoHO, the options for prevention of transmission through organ transplantation, the upcoming mosquito season and related diseases, as well as a risk matrix of scenarios for zika viruses cases in EU/EEA.

² <http://ec.europa.eu/research/participants/portal/desktop/en/opportunities/3hp/calls/pp-1-2016.html#c.topics=callIdentifier/t/PP-1-2016/1/1/1/default-group&callStatus/t/Forthcoming/1/1/0/default-group&callStatus/t/Open/1/1/0/default-group&callStatus/t/Closed/1/1/0/default-group&+identifier/desc>

The updated Rapid Risk Assessment (RRA) on the zika virus disease epidemic developed by ECDC was also shared with CAs. See also:

http://ecdc.europa.eu/en/healthtopics/zika_virus_infection/Pages/index.aspx

Several countries (ES, DK, DE, BE, PT, IT) explained their current national policies regarding zika and highlighted the difficulty to develop a policy and national recommendations on zika for the Organs' sector, because of the lack of data regarding a possible transmission via SoHO and regarding the possible reaction in transplanted, immuno-suppressed patients. The CA group would welcome further guidance from ECDC, in particular with scientific data coming from infected areas such as Brazil.

ECDC and the Commission also announced the preparation of a "zika preparedness plan" for the whole SoHO sector, to be developed firstly with the Blood Competent authorities and then presented to and discussed with the Tissues&Cells and Organs Competent authorities.

N.B. This plan has been developed and published on 15 July 2016 under the name "guide for preparedness for Zika and safety of substances of human origin". It can be found the document on ECDC's site:

http://ecdc.europa.eu/en/publications/_layouts/forms/Publication_DispForm.aspx?List=4f55ad51-4aed-4d32-b960-af70113dbb90&ID=1527

7.2. Reporting and management of Serious Adverse Events and Reactions (SARE) - biovigilance

7.2.1. Some elements from the EU legislation and EU-funded projects (COMM)

This agenda point on biovigilance was proposed by UK representatives who are building up the UK vigilance system for the Organs' sector. The Commission presented 1) the state of play on vigilance in the Organs' legislation and tools available for Organs' Competent authorities and 2) the experience from the Tissues&Cells field at EU level.

In the Organs' field, the Council of Europe Recommendation Rec(2006)15 on the responsibilities of a National Transplant Organisation and WHO Guiding Principles on human cell, tissue and organ already state that vigilance systems are a national obligation. Directive 2010/53/EU, in its Article 4 and 11, provides for definitions of Serious Adverse Events and Reactions (SARE) and confirms that the management and reporting SARE are key elements of the quality and safety system to be in place at national level. But contrarily to the EU legislation in the field of Blood and Tissues&Cells, the Organs legislation does not foreseen a mandatory (annual) reporting at EU level.

In the case of cross-border organ exchange, Commission Implementing Directive 2012/25/EU foresees in its Article 7 a procedure for SARE reporting, and proposes templates for the Initial report of suspected SARE (Annex I) and for the Final report of SARE (Annex II). Competent authorities who have used these templates are invited to share (anonymised) versions with the rest of the CA group, and to share their experience in this matter via a presentation during an upcoming CA meeting or on CIRCA BC.

Beyond the EU legislation, some guidance on vigilance is also available thanks to cooperation: in the Council of Europe Guides for Organs and Tissues&Cells or EU-funded projects such as EUSTITE and SoHO V&S in the Tissues&Cells field, or EFRETOS in the Organs field: the whole chapter 10 of EFRETOS final deliverable is about organ vigilance and is still available online: <http://www.efretos.org/>

In a second presentation, the Commission also presented SARE reporting; the experience with Tissues&Cells, based on the legal obligation for the Member States (Directive 2006/86/EC) and the annual reporting exercise organised by the Commission, the outputs from the EU-funded EUSTITE project, the “Common approach document” with reporting criteria for seriousness and for imputability and SARE categories. The existence of the NOTIFY initiative was also mentioned.

7.2.2. Approach in and questions from the United Kingdom (Human Tissue Authority (HTA), UK)

The HTA representative presented the UK approach for the reporting and management of SARE (organised through a service-level agreement between NHSBT and HTA) as well as questions to ask to the rest of the Organs CA group regarding reporting and recording (report individually each SAR? Is incorrect data reporting always to be reported as an SAE? What is the approach in other Member States?) as well as regarding terminology, language and categories used to help identify trends in SARE. While other CAs could concretely answer and explain their national approaches on these specific questions, the CA group felt that further presentations and discussions would be needed on this topic.

7.2.3. Discussion on organs vigilance with the CA group

Following these three presentations, Competent authorities confirmed that they were still building up their national vigilance and would therefore benefit to learn from other countries how they had/were building up their own systems. Italian, Spanish, Belgian and Scandiatransplant vigilance systems could be (national) examples to be presented at an upcoming CA meeting, but all volunteers are welcome. Competent authorities also expressed interest in seeing vigilance in the Organs field being the subject of a future EU-funded project.

8. NATIONAL ACTIONS RELATING TO AND THE EU ACTION PLAN ON ORGAN DONATION AND TRANSPLANTATION (2009-2015)

8.1. Presentation of the Spanish non-standard risk donor project (*Organización Nacional de Trasplantes (ONT), ES*)

The ONT representative presented the methodology applied and results achieved within this Spanish project based on the proactive follow-up of recipients transplanted with organs from donors with specific conditions (extended donor criteria) that can affect the safety and quality of organs for transplantation. ONT representative was congratulated by Germany, Italy and the European Commission for this outstanding work. A short discussion followed on the categories used for standard/non-standard (risk) donors. The EU-funded projects DOPKI, Alliance-O and EFRETOS were mentioned as important contributions regarding these categories and the follow-up of transplanted patients.

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

9.1. Final update from the Technical WG on Living donation: final version of the living donation toolkit developed by the Working group (*Department of Health (DH), UK*)

After the previous CA meeting, Competent authorities were offered the opportunity to comment the toolkit. Early 2016, the UK and ES members of the Working group have finalised the toolbox, taking into account not only the recent publications on possible risks for living donors (widely discussed in the field of transplantation), but also the lines asked to the European Society for Organ Transplantation (ESOT) and to the Council of Europe on living donation. The updated and proposed final version was shared with Organs CA on 8 March 2016 and during this CA meeting that the CA group accepted this version as final and agreed on the publication of this toolkit on Commission's website, so that CAs could circulate the link to their national stakeholders.

The CA group thanked the different members of the Living donation Working Group over the time (and other contributors who kindly provided input for different chapters). The UK and ES representative in particular were unanimously applauded for their hard work and resilience on this toolkit. The toolkit was published on Commission website³ on 21 March 2016 (as well as on CIRCA BC): http://ec.europa.eu/health/blood_tissues_organ/docs/eutoolbox_living_kidney_donation_en.pdf

9.2. Presentation of the donation and transplantation activities in the EU (with data from the Transplant Newsletters and from the Indicators' Working group) (*Organización Nacional de Trasplantes (ONT), ES*)

ONT is the Competent authority collecting and processing the data for the annual Council of Europe Transplant Newsletters and was also a key institution involved in the Indicator's Working Group under the EU Action Plan on Organ donation and transplantation chaired by the European Commission. The ONT representative kindly agreed to present data and results of several years of EU Indicators exercises and Transplant Newsletters.

The data focused firstly on organ donation: deceased donation (from Donation after Brain Death, DBD, or after Circulatory Death, DCD), looking also at variations in rates 2009-2014, actual and utilised donors, "utilisation rates" per donor age and at the ratio of organs transplanted versus procured. On organ donation, the key messages are: variations exist across countries (also in the extent to which aged donors (> 60 years) are considered), DCD is considered only in a minority of countries and there is overall a progressive increase in actual donation rates in several countries and EU 28 (18.4 donors per million population to 19.7 in 2014). The second part focused on waiting lists per organ type (kidney, liver, heart, lung and pancreas) and revealed a large variability in prevalent and incident cases. It can also be noted that the highest indication is observed in countries with the highest transplantation activity (but far beyond self-sufficiency). The third part focused at transplantation activities, per organ type and over time 2009-2014. The main messages for all types of transplants are variations across countries, and

³ Toolbox also accessible from this page :

http://ec.europa.eu/health/blood_tissues_organ/key_documents/index_en.htm#anchor3

for kidney transplants: an important contribution of living donation as well as a progressive increase in activity in several countries and EU 28 (36.0 kidney transplants pmp in 2009 to 38.6 in 2014). For liver transplants there is slight increase in activity in several countries and EU 28 (13.5 transplants pmp in 2009 to 14.5 in 2014), while heart transplant activity is stable and lung transplant activity is progressively increasing. Finally, the last section looks at transplant resources in each country, in particular the population per kidney centre, per liver centre, per heart centre or per lung centre, showing again variations between countries where these centres are available (and showing countries where such centres do not exist).

These comprehensive results clearly show progress made in the last years in the field as well as areas where improvements and cooperation can still enable to improve donation and transplantation rates.

10. INTERNATIONAL

10.1. Council of Europe activities: update

The Council of Europe representative could not attend this CA meeting (excused) but the Commission reminded the CA group about two key Council of Europe deliverables of great value produced recently or to be published soon:

- 1) The Newsletter Transplant 2015, containing the most recent international figures on donation and transplantation for the year 2014, available for download at: https://www.edqm.eu/medias/fichiers/newsletter_transplant_vol_20_no_1_sept_2015.pdf
- 2) The Guide to the Quality and Safety of Organs for Transplantation: after the “open consultation” conducted in February/March 2016, this Guide is in a final stage of preparation, before publication later this year.

10.2. Presentation of the 2016 European Organ Donation Day (EODD) to be organised by Turkey on 8 October 2016 (*Turkish Ministry of Health, TR*)

The representative of the Turkish Ministry of Health presented the ambitious activities planned for the 2016 EODD in Istanbul [*N.B. since this CA meeting in March 2016, Members of the Council of Europe CD-P-TO group met in Strasbourg in April 2016 and decided to cancel their participation in the Turkish 2016 EODD, due to security reasons.*]

11. COMMUNICATION ACTIVITIES

11.1. Short information point on the 2016 Journalist Workshop on Organ Donation and Transplantation (COMM)

The Commission informed the CA group that due to the two “pilot projects” the 2015 edition of the Workshop would be post-poned to November 2016, but still to be confirmed [*N.B. since this CA meeting in March 2016, the Commission decided to cancel the 2016 edition.*]

12. ANY OTHER BUSINESS

12.1. Discussion with stakeholders (COMM)

The Commission introduced a proposal for interaction between the competent authority group and EU-level stakeholders, approach already presented to and discussed with the Blood and Tissue&Cell Competent authorities sub-groups. The idea would be to create an opportunity for discussions on topics of mutual interest on a European level. The main principles for this interaction were outlined as being a clear separation of the Expert Group meeting and the stakeholder interaction i.e. discussion with stakeholders could be held before or after the group meets but would not be part of the Expert Group meeting. Secondly, the topics and stakeholders would be selected based on their EU-level representativeness and such a selection would be done in consultation with the competent authorities.

Within the Organs’ sub-group, there was no objection to go ahead with the approach as accepted in the Blood and Tissues&Cells sub-groups.

12.2. Report on the Conference on “Transplantation and Physical activity” held on 24-25 July 2015 at Krems/Austria (AT)

The Austrian representative presented the activities and results of the first Conference on “Transplantation and Physical Activity” held in Austria in July 2015. Other CA representatives who participated in this Conference reported about their participation. The Bulgarian CA representative presented the second Conference to be organised on the same issue in Bulgaria in Summer 2016 and warmly invited CA representatives and Commission to attend.

12.3. Other points

The Spanish CA representative informed the group about the next European Organ Donation Congress to be held in Barcelona on 28 and 29 October 2016 (with Pre-congress educational workshops on 27 October).

See: <http://www.esot.org/events-education/events/4118/overview>.

13. CONCLUSION OF THE MEETING

The Chair thanked the group for their positive participation in the meeting.

*For information, the **next Organs' Competent Authority meeting**, originally scheduled for 28 and 29 September 2016, **has to be cancelled**. No other Organs' CA meeting will take place in 2016, but Organs' authorities will be informed in due time about CA meeting(s) to be scheduled in 2017 (probably first quarter).*