



Brussels, 3 September 2014

8TH COMPETENT AUTHORITY

MEETING ON ORGAN DONATION AND TRANSPLANTATION

11 March 2014, 10:00-18:00

12 March 2014, 9:00-14:30

BRUSSELS

Place: CCAB (Centre de Conférence A. Borschette, AB) - Room AB-4B

MINUTES

DAY 1: TUESDAY 11 MARCH 2014 (10:00 – 18:00)

1. WELCOME AND INTRODUCTORY REMARKS

2. ADOPTION OF THE AGENDA

The agenda was adopted without changes or amendments.

3. INTRODUCTION OF NEW PARTICIPANTS

4. RULES OF PROCEDURES FOR SOHO GROUPS (COMM)

The final draft version of specific Rules of Procedure (RoP) for the Competent Authorities on Substances of Human Origin Expert Group (CA SoHO) was presented to the December meeting of the tissues and cells Competent Authorities (CAs) by DE who had led the drafting of these rules. There were no further comments on the RoP and it was thus considered that the Tissues and Cells CAs agree to the use of these rules.

The RoP were now presented to the two other configurations of the CASOHO group i.e. to the Competent Authorities for Blood and Organs for potential comments.

After a clarification question, the Organs' CAs agreed to the rules of procedure. The RoP are available on CIRCA-BC.

The group was also informed that the Commission intended to close the Expert Group on Donor and Organ Characterisation (E02608 in the Commission Register of Expert Groups). While this group had been set up to discuss the preparation of Delegated Acts, the Competent Authorities expert group is also available for such discussions and thus a second expert group on organs was no longer needed. The Commission confirmed that where the CA SoHO expert group is to be consulted on the preparation of a Delegated Act related to the organs' legislation, this would be explicitly stated in the agenda allowing Member States the flexibility to decide who should represent them in such discussions.

5. MID-TERM REVIEW OF THE ACTION PLAN ON ORGAN DONATION AND TRANSPLANTATION (2009-2015)

5.1. Commission Staff Working Document on the mid-term review of the Action Plan (COMM)

This Commission Staff Working Document (CSWD) is the Commission's contribution to the mid-term review of the Action Plan on Organ donation & transplantation (2009-2015). It builds upon Council Conclusions adopted in December 2012, and upon the ACTOR study published in June 2013.

This document focuses on EU level, for the period 2014-2015. Main conclusions proposed for each priority action were already presented at the last CA meeting in September 2013, and Member States (MS) were invited to provide comments to the final draft from 17 February to 7 March. The Commission received comments from 8 Member States, all were taken into account. Other services of the Commission were consulted as well. The document was to be finalised by the end of March and afterwards published on Commission's website [NOTE: in the meantime the document was adopted and published on 25 April 2014¹].

Two main areas were highlighted to focus on at EU level in 2014-15: living donation programmes (Priority Action 3) and cross-border exchanges of organs (PA 8), respectively supported by the two EU-funded Joint Actions ACCORD and FOEDUS. The need for all countries to actively participate in these two Joint Actions was confirmed. It was also asked if other applications for "normal projects" and grants are possible. The Commission confirmed that other applications would still be possible, for example after "call for proposals", under the new EU Health Programme 2014-2020 [NOTE: The 2014 work plan of the Health Programme was adopted on 26 May 2014²].

¹ http://ec.europa.eu/health/blood_tissues_organ/docs/midtermreview_actionplan_organ_en.pdf

² http://ec.europa.eu/health/programme/events/adoption_workplan_2014_en.htm

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

6.1. Technical WG on Living donation: finalisation of the “living donation toolbox”

6.1.1. Presentation of results by Working group members (in particular UK, ES, NL)

No further comments were received, but WG members have still improved the document in February and March 2014. The Commission wants to thank the UK, ES and NL representatives (Working group members) for their active contribution and review of the final document, that will be made available to other CAs on the CIRCA BC platform once finalised (by end of March 2014).

The Council of Europe already asked for copies to use in non-EU, European countries and proposed to present the toolbox during the next CD-P-TO meeting in Strasbourg on 3-4 April 2014.

6.2. Technical Working Group on Indicators: Overview of activities

6.2.1. Remaining presentation to close the 2013 exercise

(presentations on parts 1: donation, 2: waiting lists and 3: allocation took place in September 2013)

The Commission introduced the exercise, reminding that the aim is to set a common framework for indicators. It was announced that the 2014 exercise would be similar to the 2013 exercise in structure, as decided during the Working Group (WG) meeting on 13 February 2014. The Commission informed the CA group about changes in the Policy officer heading the Working group at Commission level from the 2014 exercise. During this CA meeting, results from Parts 4 to 6 of the 2013 exercise were presented by WG members.

Three remaining presentations by members of the Working group:

Part 4. Transplantation (WG member, ES)

For kidney transplantation data were presented from 28 Member States + Iceland and Norway. All countries do perform kidney transplantations and the numbers of kidney transplants occurring thanks to organ living donations is still rising. For liver transplantation, deceased donations are increasing slightly.

Part 5. Health outcomes (WG member, Eurotransplant)

The lack of data completeness was highlighted again, however the comparison with scientific data internationally published seem to reveal consistency between European and international data. This also indicates that long-term-evaluation and follow-up is challenging but nevertheless remains necessary. Follow-up data are essential to assess quality and safety of organ transplantation. Some MS mentioned that other indicators are needed to enhance quality, however feasibility within this Indicators' exercise needs to be assessed.

While some MS recalled that efforts to capture follow-up data are ongoing since long, the WHO reminded that Europe is leading globally in this field.

Part 6. Health resources (WG member PT)

A detailed presentation was brought on this issue, revealing differences and similarities in resources allocated to transplantation activities in Europe, reflecting differences and similarities in national health systems. The presenter also suggested to work on some other indicators, and will submit a document for discussion.

6.2.2. Discussion and next steps

There was an overall agreement that the next exercise needs to focus/select the analyses, where the main learnings are. The **2014 exercise** was shortly introduced and will be launched before Summer 2014. As usual data collected by ONT for the Council of Europe Newsletters will also be used for this exercise, to avoid duplication of efforts for Member States.

Sections of the 2014 exercise on donation, waiting list and allocation will be presented during the CA meeting in September 2014.

7. LEGISLATION

7.1. National set-up of Competent Authorities

7.1.1. Overview of answers given to short survey on "who are NCAs" after transposition of Art. 17 Directive 2010/53/EU (COMM)

While a number of reminders have been sent out since the last CA meeting, no further answers have been given. Therefore replies from a number of Member States are still missing. The Commission will no longer chase Member States for these replies although Member States' Competent Authorities will still have the opportunity to present their set-up in future CA meetings.

7.1.2. Presentation of national set-up by Sweden

SE presented its national set-up, which involves the use of a number of pieces of national legislation which transpose the EU organs legislation into national law and lay down the roles and responsibilities of the competent authorities. It also involves registration instead of authorisation for transplant centres.

7.1.3. Discussion and exchange of views on the different national set-ups

7.2. Transposition of Directive 2010/53/EU

7.2.1. State of Play of the transposition check (COMM)

The Commission presented a preliminary overview of the status of MS' replies to the questionnaire on their transposition of Directive 2010/53/EC. The Commission explained that the main focus of the work at the moment was identifying information gaps in the replies and contacting MS to clarify open points and fill the gaps in the replies to the questionnaires. The presentation provided first-hand information about the transposition

check ongoing, including an introduction to the transposition check as such with an example and a very first analysis of the outcomes. Letters requesting clarification or further information have been sent to a number of Member States and their cooperation in this matter was requested.

7.4. Plans for implementation survey 2014 (COMM)

The Commission presented the topics to be covered by the first “implementation survey” for Directive 2010/53/EU, survey implemented to fulfil the obligation laid down in its Article 22. The planning was also announced (survey to be launched by Summer 2014).

Compared to the on-going work of the “transposition check” that aims at checking that Member States have transposed all requirements laid down in the Directive, the “implementation survey” aims at mapping how transplant activities related to Directive 2010/53/EU work in practice.

7.5. Implementing Directive 2012/25/EU

As the transposition deadline was approaching (10 April 2014), Member States were asked to report how advanced their transposition was. Only few of them had already fully transposed, while most of them are in the process of transposing.

Related to Article 8 of Implementing Directive 2012/25/EU, a “contact detail website” is being prepared, with the support of Eurotransplant IT services, to facilitate communication between relevant Competent Authorities when organs are exchanged cross-border. The Commission had sent to Member States on 7 March 2014 letters asking them for their national contact details: MS were expected to send their 3 sets of details by 24 March 2014.

Before the launch of the website, MS will receive their password to duly keep their data updated, as from the launch of the website, Member States will be responsible to update their data directly online if needed (neither Eurotransplant nor the European Commission will be responsible to update national data). There will be a unique log-in and password per country, therefore MS with several CAs should coordinate internally among these CAs.

8. VIGILANCE AND SURVEILLANCE

8.1. Update on alerts and activities linked to the SoHO field (ECDC)

ECDC presented the current activities and alerts from communicable diseases usually relevant for transfusion and transplantation (see presentation).

8.2. Rapid alert systems in the field of Substances of Human Origin (SoHO) (COMM)

The Commission presented the results of the short survey done among Organs’ CAs to assess if a dedicated “rapid alert system” similar to those developed for Tissues&Cells and Blood would be relevant. The results of the survey shows that no specific tool is

needed for the moment, the specific group on the CIRCA BC platform can continue to be used.

The Commission also presented the new “Rapid Alert System for Blood” (RAB) launched on 6 February 2014.

8.3. Update on NOTIFY project (WHO, CNT, COMM)

A WHO representative made a presentation on the NOTIFY project:

The NOTIFY project was launched as a collaboration brought together by WHO with the co-sponsorship of CNT and the EU-funded SOHO V&S (2009-2013). The project was initiated in February 2011 in Bologna when it was decided to develop further the concept of building global vigilance and surveillance system for organs, tissues and cells (“Bologna Initiative for Global Vigilance and Surveillance of Human Cells, Tissues and Organs for Clinical Application” - BIG V&S). Besides professionals in the field, several regulatory authorities have been involved from the start (COMM, FDA, Health Canada, EU MS Competent Authorities).

The NOTIFY project provides a public, free of charge portal/library where experts from across the globe collaborate to share didactic information on documented adverse reactions associated with the application of human organs, tissues and cells. The value of the database relies on the fact that only documented cases have been included (published in peer reviewed journals or in the official reports of regulatory authorities) and the selection was performed by well-recognized experts in the field.

DAY 2: WEDNESDAY 12 MARCH 2014 (9:00 – 16:00)

9. COMMUNICATION ACTIVITIES

9.1. Journalists Workshop on Organ Donation and Transplantation (October 2013, Brussels) (COMM)

The Policy officer in charge of the Workshop at Commission level presented the objectives, agenda and results of the previous edition (2013) and gave an overview from all editions together (2010 to 2013). Speakers were thanked and as well as CAs who supported the preparation in proposing journalists interested in transplantation for their country.

The Communication Unit of DG SANCO presented the methodology used for the on-going evaluation of the outcomes of previous journalist-workshops.

9.2. Brochure on SoHO projects, published by the “Consumers, Health and Food Executive Agency” CHAFEA (previously EAHC)

EU-funded projects on organ transplantation activities are presented in this brochure, projects’ coordinators were consulted for the pages on their projects. They were thanked

for their contribution. Brochures can be ordered and feedback on the brochures is welcome.

On CHAFAEA website: http://ec.europa.eu/chafea/health/EAHC_conference_2013_-_Transplantation_Blood_Transfusion.html

To download the brochure:

http://ec.europa.eu/chafea/health/EAHC_conference_2013_-_Transplantation_Blood_Transfusion.html

9.3. UPDATE ON MEDIA ISSUES (TOUR DE TABLE)

10. PRESENTATION OF PROJECTS ON ORGANS (FUNDED UNDER THE EU HEALTH PROGRAMME) – PART 2

10.1. Conference

10.1.1. LIDOBS Conference, 29. and 30. May 2014 (project's coordinator, Hospital Clinic of Barcelona)

The project coordinator presented this Conference on organ living donation (building upon previous EU-funded project EULID and ELIPSY) and answered to questions. Distribution of LIDOBS flyer.

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

10.2. Joint Actions

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

Several presentations took place:

General overview by the coordinator (ES)

Work package on living donor registries (NL)

This WP is directly linked to Priority Action 3 of Action Plan (confirmed priority for 2014-2015 in the Commission Staff Working Document: protecting living donors and ensuring their follow-up by establishing registers). The pilot phase, implemented with the Hospital Clinic de Barcelona, is about to start and will test two technical possibilities: 1) direct entry for countries without register so far, 2) upload possibility for countries which have a national register already. 10 Member

States have volunteered to take part in the testing, which announces a good level of involvement.

WP coordinators and members are also invited to formulate, in their final recommendations, options taking into account the question of the global governance of a “register of registers”.

Work package on intensive care units (UK)

This WP, directly linked to Priority Action 1 of the Action Plan (transplant donor coordinators), makes good progress, involving more hospitals than originally foreseen, the “rapid improvement” phase is on-going should help them to find quick solutions adapted to their needs, to improve cooperation with ICUs and thus to possibly identify more donors.

Work package on twinning (FR) - Different twinning partnerships are ongoing:

- France-Bulgaria : twinning is to support the development and organisation of the organ procurement system at national and regional levels: the drafting of Standard Operating Procedures was considered as a priority and is on-going.

- Hungary-the Netherlands (+ESOT): Full training for surgeons entails: an e-learning platform, practical (hands-on) sessions and a set of retrieval from a deceased donor to perform either as a main surgeon. Hungary organised their first national practical session in January in Budapest. The Hungarian Organ Coordination Office (OCO) included this training option within the educational programme for medical doctors

- Italy with Cyprus, Czech Republic, Lithuania and Malta: this twinning is aiming at developing of an authorisation and audit system for transplant centre based on the Italian model, but adapted to national requirements and needs. Auditors were nominated (2 to 4 per country) and completed the e-learning by a face-to-face training: an audit exercise organised in an Italian Transplant Centre (February, Rome).

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

10.2.2. *Joint Action FOEDUS “Facilitating exchange of organs donated in EU Member States”(2013-2016) (IT)*

Several presentations foreseen:

General overview by the coordinator (IT)

Work package 4 on guidelines for cross-border cooperation and analysis of barriers/obstacles (Eurotransplant)

This WP will map barriers and obstacles among existing cooperation agreement. This WP started with some delay (survey still to be circulated among partners) and this delay should be caught up to be able to deliver on time and also not to delay other related work packages.

Work package 5 forms for cross-border organ exchanges: consensus on donor and organ medical information (FR)

This WP started in January 2014 National form used by partners for cross-border organ exchanges (English) were collected and the analysis of differences and similarities was performed in order to draft a proposal of donor medical form to be used for cross-border organ exchanges. Additionally, criteria systematically used by at least 75% of the 22 MS having answers to the COORENOR study regarding organ donor assessments and criteria were added and considered as a consensus. CORRENOR was a previous EU-funded project (with fewer countries and before transposition of the Directive). Such form complies with the annex of the Directive 2010/53/EU: minimum (part A) and optimal (part B) data set for the “organ and donor characterisation”.

On this Work package, the Commission highlighted that the work is very important to reach on a cooperative basis an agreement to characterise organs and donors. It is directly linked to the annex of the Directive 2010/53/EU: minimum (part A) and optimal (part B) data set for the “organ and donor characterisation” (for which an “expert group” met in September 2011 at EU level and advised the Commission not to fix this “organ and donor characterisation” in the form of a “delegated act” for the moment). As a consensus now needs to be achieved through this FOEDUS collaboration, it will be crucial to involve as many EU Member States as possible, this is the reason why a Joint Action (involving more countries, and in these countries the Competent authorities) was chosen to move ahead on this topic.

Work package 6 on upgrading the IT platform for international exchange of organs for transplantation (CZ)

The work on this WP is starting in March 2014 and will build upon the IT-tool delivered within the EU-funded COORENOR project. All MS are asked to check that they are well connected now and can technically use the tool. Creating trust and knowledge about the system, as well as improving the tool, will now be the main task of the WP leader and partners, to make sure that MS feel comfortable to use the system to offer organs otherwise not allocated in their country, and therefore “lost” for transplantation.

Work package 7 on communication and public awareness (DE and SI) Two technical WP meetings took place so far in July 2013 and January 2014. The main objectives for this WP is to support CAs willing to improve their communication strategies/policies, by creating a manual for them, based on a needs’ analysis from the transplant community (Workshop early July 2014) and on the advice of communication experts (Workshop in November 2014). The coordinators invited MS to nominate participants for the first workshop in July 2014 (ideally Communication staff from CAs and/or CA representatives usually answering to the press on transplant activities in the country).

Project’s website: <http://www.foedus-ja.eu/>

11. TRAFFICKING ISSUES AND COUNCIL OF EUROPE ACTIVITIES

11.1. HOTT Project (Combating trafficking in persons for the purpose of organ removal, project coordinators)

A long-awaited presentation from the coordinators of the project entitled, “combating trafficking in persons for the purpose of organ removal” introduced the work of this project which is otherwise known as the HOTT project. This project is being led by the Erasmus University Medical Center and aims to increase knowledge and raise awareness of organs-related trafficking as well as provide recommendations on the non-legislative response including pointers on how to improve cross-border enforcement and guidance for transplant professionals on the prevention of transplant tourism.

The work on transplant tourism was of particular interest to the CA group who raised a number of points related to this. It was suggested that the project team conduct further interviews with patients who seek transplantation outside their home country and that patients from a wider range of countries are interviewed. A healthy debate ensued about the nature of such activities and it was pointed out that undergoing a transplant, even one which is paid for, does not in itself mean any crime has been committed. The debate showed that a number of different approaches to citizens going abroad for organ transplantation exist across the EU MS.

The CA group confirmed its interest in cooperating with the project team and in hearing more about the results of the project as it progresses. It was mentioned that an international symposium is planned within the framework of the project and is scheduled to take place in Rotterdam in November 2014.

Project’s website: <http://hottproject.com/>

11.2. Council of Europe activities

Two new Resolutions which were adopted by the Council of Europe Committee of Ministers in December 2013 were presented. Both of these would be helpful tools to fight illicit practices and to protect patients and donors. In general the focus of these resolutions is to be complementary to and avoid overlaps with EU-led initiatives. In particular, Resolution 2013(56) on live kidney donation programmes will support the Commission’s focus on living donation for 2014-2015, while Resolution 2013(55) is in the scope of Priority Action 7 of the Action Plan, for which the Commission Staff Working Document acknowledges the important role of the Council of Europe.

Resolution CM/Res(2013)56 on the development and optimisation of live kidney donation programmes *(Adopted by the Committee of Ministers on 11 December 2013 at the 1187th meeting of the Ministers’ Deputies)*

<http://www.edqm.eu/en/New-Resolution-on-live-kidney-donation-programmes-adopted-by-the-Committee-of-Ministers-1587.html?mbID=167>

Resolution CM/Res(2013)55 on establishing procedures for the collection and dissemination of data on transplantation activities outside a domestic transplantation system¹ *(Adopted by the Committee of Ministers on 11 December 2013 at the 1187th meeting of the Ministers’ Deputies)*

<http://www.edqm.eu/en/New-Resolution-on-organ-transplantation-adopted-by-the-Committee-of-Ministers-1587.html?mbID=166>

12. ANY OTHER BUSINESS

The Spanish CA ONT announced the upcoming celebration of its anniversary on 24 March 2014.

13. CONCLUSION OF THE MEETING

The next meeting of the Competent Authorities on Organ Donation and Transplantation is foreseen to take place on the 10 – 11 September 2014 (dates to be confirmed once room made available).

Dominik Schnichels
Head of Unit