



Brussels, 3 February 2014

7TH COMPETENT AUTHORITY
MEETING ON ORGAN DONATION AND TRANSPLANTATION
18 September 2013, 10:00-18:00
19 September 2013, 9:00-14:30
BRUSSELS
Place: CCAB (Centre de Conférence A. Borschette, AB) - Room AB-3C

MINUTES

DAY 1: WEDNESDAY 18 SEPTEMBER 2013 (10:00 – 18:00)

- 1. WELCOME AND INTRODUCTORY REMARKS**
- 2. ADOPTION OF THE AGENDA**
- 3. INTRODUCTION OF NEW PARTICIPANTS**

Absent: Austria, Liechtenstein.

Croatia welcomed as new EU Member State and Serbia as first time participant.

Changes announced in team “substances of human origin” (SoHO) of the Commission.

New colleagues present from: DE, FR, IE, EL, IS, RS¹, South Alliance for Transplants (SAT)

¹ Country codes are clarified in Annex 1

4. LEGISLATION

Preliminary remark: rules of procedures for SoHO Competent Authorities (COMM)

Within the group of competent authorities (CAs) for Tissues & Cells (T&C), the German CA has made a proposition to develop dedicated rules of procedure for the competent authorities on substances of human origin expert group (CASoHO 01718 in the Commission register of expert groups). This expert group regroups the meetings of the competent authorities meetings in the SoHO sector and thus such dedicated rules would apply for the meetings of all three sets of competent authorities (blood, organs, and tissues & cells). Once finalised and agreed within the T&C group, the proposed rule will be presented to the blood and organs CA groups for comments and potential changes. If and when all 3 groups agree to the draft rules they will be considered as adopted and replace the standard rules of procedure for expert groups which are currently being used.

4.1 National set-up of Competent Authorities (COMM)

4.1.1. Overview of answers given to short survey on "who are NCAs" after transposition of Article 17 Directive 2010/53/EU

This short survey (one slide per country) provides for an overview of the different national settings, available to all Member States even before results of the transposition check are available. The following countries have already contributed and provided their information: BE, BG, CY, CZ, DK, ES, FI, FR, HR, IE, IT, LT, LU, MT, NL, NO, PL, PT, SI, TR, UK (and DE sent a list of their CAs with clarification who does what).

All other countries are invited to send their answer by 17 February 2014 at the very latest to Richard.MCGEEHAN@ec.europa.eu

4.1.2. Presentation of national set-up by Portugal

PT presented their national set-up - including changes in the last 6 months.

4.1.3. Discussion and exchange of views on the different national set-up

Member States interested in presenting their national set-ups during the next meeting are invited to express their interest in doing so.

4.2 Transposition of Directive 2010/53/EU (COMM)

4.2.1. State of play of the transposition check

A presentation was made on the status of the transposition check. In March 2013, the Commission had sent Member States a questionnaire asking them to reply, by May 2013, to certain questions and provide the text of relevant provisions of national legislation in order to facilitate the task of assessing the degree of transposition of national laws with the Organs Directive. The presentation did not cover the substance/issues, but tackles the response rates, steps taken and timing of the next steps.

Most Member States notified the Commission about their transposition of Directive 2010/53/EU and have submitted their answers to the "transposition check" questionnaire. Results will be analysed and preliminary conclusions will be presented to CAs in future

CA meetings. Where information is missing, the relevant Member States will be contacted by the Commission. Member States who have not yet provided the full information (for example if national legislation was not yet fully adopted at the time of the CA meeting) are invited to complete the questionnaire and submit it to the Commission. *To facilitate this analysis and limit the need for additional requests seeking clarification, the Commission would be grateful if Member States could provide the relevant text of national legislation within the relevant boxes of the questionnaire rather than simply providing a copy of the national legislation.*

4.2.2. Discussion

During the next CA meeting in March 2014, it should be possible to have a first overview of some of the main issues relating to transposition and a discussion on these.

4.3 Cross-Border Healthcare Directive (CBHD): Directive 2011/24/EU on the application of patients' rights in cross-border healthcare (COMM)

Some MS have expressed concerns about the possible implications of the CBHD in the organs field. The CBHCD is currently being transposed by the MS (transposition deadline: 25 October 2013).

A colleague from Unit D2 (Healthcare systems) of COMM DG Health & Consumers (Unit in charge of the CBHD) presented the CBHD and possible implications for the organs field.

Unit D4 (Substances of human origin) then presented first issues/questions as they were brought forward in the transplantation sector:

- Do some key definitions in the CBHD cover organ recipients as well as living donors of organs. In particular (1) 'healthcare' (Art. 3 a: "health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices") and (2) 'patient' (Art. 3 h: "any natural person who seeks to receive or receives healthcare in a Member State;")
- Follow-up of living donors. It is mandatory under CBHD to ensure follow-up of patients by the same medical follow-up as for internal/national situations. The CBHD requires remote access to or at least a copy of patients' medical records. How does this relate to the requirements of the Organs Directive, in particular Art 15 and the set-up of living donor registries?
- CBHD requires information to help individual patients to make an informed choice. How does this relate to (national) consent requirements laid down in Article 14 of the Organs Directive.
- Would the national contact points foreseen in the CBHD also be competent for organs (and e.g. provide information regarding reimbursement)?
- Does the need for prior authorisation for treatments abroad, as foreseen in the CBHD apply to the reimbursement of medical interventions abroad for (living) donation or transplantation? Overall, the Commission mandate under the CBHD, to encourage Member States to cooperate in cross-border healthcare provision in

border regions, seems to be compatible with the work and focus on exchanging organs and patients for transplantation between Member States. However some practical aspects might still raise legal questions relating to both the CBHD and the Organs Directive.

Member States were invited to provide more questions/topics of concern for the CBHD.

- Some general concerns were raised related to the right to care, and to access to organs waiting lists for foreign citizens. It was clarified that the CBHD requires that foreign patients should have access to healthcare on the same terms and conditions as domestic patients, however access to organs does remain a national competence. This would imply that foreign patients may need to be put on national waiting lists for transplant surgery (e.g., for a living donor transplant from a relative) as domestic patients where they exist, however the right and conditions to be put on the waiting lists for an organs are to be defined by each Member State.
- Other concerns relate to the cost of treatment abroad, and who should reimburse a potential difference in cost. It was clarified that the patient should pay the difference (in cases where only the CBHD Directive applies, however if the Social Security Regulation (883/2004) applies the full cost is paid). So CBHD facilitates the access to cross-border healthcare but the level of reimbursement is maximally up to the level of treatment cost at home.

The objective of this discussion was not to solve these complex questions/issues, but rather to get a good overview of the potential issues. Member States are invited to send any potential further questions to the SoHO team/secretariat in SANCO.

It was suggested to prepare with the NCAs organs (if necessary in the form of a sub-group) the questions for clarification. The COMM will then assess how these questions and draft interpretations/clarifications can be taken forward, potentially with the involvement of the Implementing Committee on CBHD.

5. COMMUNICATION ACTIVITIES

5.1 2013 European Organ Donation Day (EODD) (BE and CoE)

As Belgium is hosting and organising the 2013 EODD with the Council of Europe, the floor was given to the Belgian and Council of Europe (CoE) representatives who presented the programme of the events for Saturday 12 October, but also during the days before (Concert on 11 October, bicycle tours from different Belgian cities...).

A website was created for this occasion: <http://eodd2013.be/en/eodd>

SI referred to the guidelines and booklet developed within the EU-funded EDD project to organise such events. BE and CoE confirmed that the organisation of this 2013 EODD is took account of these guidelines.

5.2 Council of Europe “Guide(s) to the quality and safety of organs for transplantation” (CoE)

The 5th edition of this CoE Guide was just published before this CA meeting and the CoE could send printed versions for CA representatives of EU countries and partners gathered in Brussels. CoE presented this 5th edition and its main updates, as well as plans for the 6th edition.

MS asked about “institutional subscriptions” and (online) access to them would be ready soon. CoE confirmed that there would be institutional subscriptions, with access to 200 users (per country) within the next week. CoE also confirmed that the Guide can be bought from the EDQM store (for 30 euros).

The CoE was thanked for this important work and underlined that the organs’ field needs good cooperation between institutions. The guide shows that CoE group CD-P-TO has an important role in providing scientific expertise that can be used by the CAs from the EU network established by Directive 2010/53/EU.

5.3 Fourth Journalists Workshop on Organ Donation & Transplantation, 7 October 2013, Brussels (COMM)

COMM presented the programme of the 4th edition of this 1-day event organised in Commission premises on 7 October 2013 in Brussels, in presence of Commissioner Borg.

[See also the dedicated webpage with presentations of and first articles published after the Workshop: http://ec.europa.eu/health/blood_tissues_organ/events/journalist_workshops_organ_en.htm]

COMM was asked whether it would consider funding in the future a “train the trainers” course for such journalists’ workshops, in order to reach more individuals – if experts are trained to reach out to local journalists. COMM answered that if a new “train the trainers’ course in transplant donor coordination” would be funded (like the one EU-funded organised by ONT/IAVANTE in 2011), it would certainly include again a module on communication, though no such specific courses are foreseen for journalists. A Work package of the EU-funded FOEDUS Joint Action (2013-2016) is dedicated to communication aspects and strategies. IT presented two considerations: 1) difficulty for the CA to “select/propose” journalists because they are many applicants; 2) Italian journalists see Europe as a reference point, often ask what happens in Europe. Therefore this workshop should be maintained at a European level. COMM also explained that the Council of Europe would also take part in the next COMM Journalists Workshop, presenting the Belgium/CoE 2013 EODD and synergies of COMM-CoE cooperation. In conclusion, efforts should be maintained in this area, also as highlighted in the ACTOR study published in July 2013.

5.4 Feedback on the 2013 Cluster meeting on substances of human origin- Executive Agency for Health & Consumers (EAHC)

This Cluster meeting on substances of human origin (SoHO), organised by EAHC with the support of the Spanish CA ONT, took place in Madrid in June 2013.

EAHC reported about the 2-days event, where many EU-funded projects were presented to journalists in the field of organ transplantation, but also blood transfusion and tissues&cells transplantation. Many coordinators of these European projects and CA representatives from the SoHO – and thus Organs’ – field were present.

COMM highlighted complementarities and synergies created between this unique EAHC 2-days event on SoHO topic and the 1-day annual Journalists workshops focused on organ donation & transplantation – directly relating to the EU Action Plan on Organ donation & transplantation (priority action 4).

[Note: a dedicated publication with SoHO related projects has been published in the meantime]

5.5 Update on media issues/scandal in Germany (DE)

DE representatives updated their CA colleagues about the situation in Germany, action taken by DE authorities and media situation.

Many MS thanked DE for updating them and sharing lessons learnt that could be useful for any MS in a similar situation. Some MS asked specific questions on the allocation of organs, on the control of transplant centres and on the number of transplant centres needed (or not), to which DE and Eurotransplant representatives answered: new (statistical and IT-) tools are currently being developed in order to prevent manipulation of data and as a “warning systems”, but control can only be insured by visiting the centres. Several MS also concluded that having too many small transplant centres with small number of transplants per year is not a good solution.

DE will update the CA group at the next CA meeting.

5.6 WHO Activities (WHO)

The new Medical Officer Transplantation for the Patient Safety Programme PSP/HIS of the WHO attended this CA meeting for the first time. He introduced himself and made a short presentation of WHO activities in the field.

6. VIGILANCE AND SURVEILLANCE

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

ECDC representative presented a short update on epidemiological issues relevant for the SoHO sector.

West-Nile-Virus (WNV) maps will be available may 2014. An EU preparedness Plan for blood competent authorities was created and ECDC asked to gather research results in these areas not only for the Blood sector, but also to extend this work to Tissues&Cells and Organs.

Regarding Malaria, ECDC reported about two missions to Greece, in close collaboration with the CA, to help solving problems related to how to implement blood safety measures for this area.

6.2 Rapid alert systems in the field of SoHO (COMM)

COMM presented an update on the two rapid alert systems developed, firstly for tissues&cells (RATC) and more recently for blood (RAB). The presentation included the good experience with these new IT systems as well as an overview of the alerts over the last months. The possible interconnectivity of alerts launched in the blood or T&C sector towards the organs field was addressed and the procedure (SOP) foreseen in RATC was explained: the T&C CA initiating the alert (Member State X) towards the colleagues of the other EU CA T&C, contacts the organs' CA in the same country (X), who can consequently decide to launch an alert towards the colleague EU-28 NCA organs.

MS were asked to express their possible needs/comments regarding a rapid alert system in the organ field. The only real "alert" shared at EU level so far in the Organs' field was the Viaspan alert in April 2012 (thus highlighting the need of a good interconnectivity also with other sectors such as pharmaceuticals and medical devices). IE highlighted that Viaspan has shown a need for a Rapid Alert system in the Organs' field (RAO).

MS asked for criteria which would be used to launch and manage alerts. At least 2 MS are possibly involved, for example infectious diseases going cross-border or a similar device used in different countries. COMM highlighted that if Organs CA express the wish to have a RAO, a Working group would be established, and different categories of alerts could be created within this group, specifically based on the needs of the Organs' sector.

COMM proposed to share with Organs' CAs the Standard Operating Procedures (SOP) developed for the RATC, to give an idea on how the system is designed, and also the first annual report. Within RATC, 4 types of alerts were created: 1) quality & safety issues, 2) information notices, 3) epidemiological alerts, 4) legal and fraudulent activities.

Pros and cons of such a rapid alert system for organs were discussed: advantages are a good interconnectivity and information, a challenge is the risk of uncontrolled information. The need for a good involvement of ECDC and integration with EWRS (EU/ECDC Early Warning and Response System for infectious diseases) were also mentioned. To conclude the discussion, MS will be invited to express their views on the need and value of a RAO before the next CA meeting.

7. TRAFFICKING

7.1 Report: Seminar on Illegal and Fraudulent Activities (IFA) in Organs, Tissues & Cells (OTC) (COMM)

COMM debriefed the CA group on the (partly) EU-funded Paris Seminar on Illegal and Fraudulent Activities which took place in April 2013. The seminar report is now available. This seminar, the 1st of its kind, took place at the headquarters of the French *Gendarmerie Nationale*. The aims of the seminar were to raise awareness amongst law enforcement officials of IFA in the OTC sectors and also to look at ways in which different authorities can cooperate to prevent, detect and investigate these types of IFA. COMM provided funding for the seminar by covering travel costs for EU and non-EU participants from CAs and law enforcement agencies.

The seminar achieved its main goals and was well received by participants and also received significant media coverage in light of last year's scandals, mainly on T&C. COMM continues to watch developments in IFA field closely with a view to guaranteeing quality and safety and the free flow of legitimate T&C exchanges. It is important for MS, in particular T&C CAs, to build working relationships with national law enforcement agencies and to share instances of IFA over the RATC platform.

7.2 Activities DG HOME and the HOTT Project (DG HOME, COMM)

A representative from COMM DG HOME's (Home affairs) unit dealing with the fight against organised crime presented DG HOME's role in combating human trafficking including trafficking of human beings for the purpose of organ removal. In response to a request for clarification, DG HOME confirmed that Directive 2011/36/EU combating trafficking in human beings including for the purposes of organ removal gives Member States the option of applying the provisions of the Directive with an extra-territorial scope and to develop criteria for the notion of 'exploitation' at a national level.

EU anti-trafficking policy also focuses on data collection and DG HOME highlighted the need for organs' CAs to be involved in the provision of data on human trafficking for the purposes of organ removal. Several CAs stated that they felt that this was not currently taking place and questioned where data was coming from within their MS. In order to improve the quality of the data provided there was consensus that greater coordination is needed between relevant national bodies and between MS and those compiling data at European level such as Eurostat and the Council of Europe.

DG HOME also briefly mentioned the HOTT project which they fund (the project coordinator had to cancel his participation).

Several Organs' CAs asked DG HOME to ask the project coordinator to inform and involve them more closely in the work of this project as they felt that the project would be of limited value without specific input from organs' CAs particularly when it comes to the provision of relevant and up-to-date data. DG HOME's representatives confirmed that it was indeed foreseen for the work of the project to involve such CAs and that this message would be passed on to the project coordinator along with the contact details of CAs interested in cooperating with those involved in the HOTT project. IT and FR in particular expressed such an interest.

DAY 2: THURSDAY 19 SEPTEMBER 2013 (9:00 – 14:30)

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

8.1. Technical WG on Living donation: update (COMM)

8.1.1. Presentation of results by COMM

COMM made a short presentation on the status of the Living Donation Toolbox. [The latest draft was uploaded on the CIRCA-BC platform in January 2014].

The objective is to bring together national expertise on different elements to organise effective living donation programmes. This expertise comes from MS with well-established programmes and aims to be of reference for other EU MS who have expressed interest in setting up and developing such transplant activities (basically all did during the CY Informal Health Council in July 2012).

8.1.2. Discussion and next steps

COMM asked for last comments and feedback within 3 weeks after CA meeting for UK and ES representatives will be able to finalise with COMM support.

CA participants were also asked to let COMM know (in written, to stefaan.van-der-spiegel@ec.europa.eu) whether there is need for translations of the toolbox once finalised. Like for the manual on transplant donor coordinators drafted within the Working group on deceased donation, COMM can verify possibility/capacity to translate (but no promise).

8.2. Technical Working Group on Indicators: 2013 exercise (COMM)

8.2.1. Short update on process for 2013 exercise and three first presentations by WG members(1. Donation, 2. Waiting lists, 3. Allocation)

COMM brought a short overview of the objectives and status of the 4th annual Indicators' exercise under the Action Plan on organ donation & transplantation.

Objective of the Working group is to build a common set of basic indicators on all steps of the donation to transplantation, including health outcomes and health resources. Target audience is the national competent authorities.

Key objective of this slot is to present a summary of results of first three parts of the 2013 exercise: 1. Donation (DE), 2. Waiting lists (UK), 3. Allocation (PL). Consequently Member States were asked for comments in order to finalise this 2013 exercise. The next 3 presentations (4. Transplantation, 5. Health outcomes and 6. Health resources) will take place in March 2014, based on further data still to be provided for October 2013.

Short introduction (COMM)

Activities that took place in 2013 were the following:

- quantitative data collection (with ONT, as same data used for the CoE Transplant Newsletters to avoid duplication of efforts),
- preparation of the qualitative questionnaire by COMM with the Working group (now done in form of excel sheets to allow check/correction from previous years + copy paste)
- within this qualitative part: consolidating qualitative data collected in the previous exercises, to allow for corrections (COMM prepared individual sheets for each country),
- MS were invited to correct/complete their individual sheets over Summer, in 2 steps: for August 2013 regarding the three first sections, for October 2013 regarding the three remaining sections.

An important step forward of this repeated exercise is that it is now possible to compare 4 years data (2009, 2010, 2011, 2012). On the other hand, the more data is available, the higher the need to select for presentation purposes (it is not possible to show everything). Presentations should be kept shorter, and formulate main conclusions, while a more detailed report could be developed apart. Given the limited resources at COMM level, WG members will be invited to take the lead on the different sections, not only for the CA presentations, also for this report. This will be discussed within the Working Group during the next physical meeting early 2014.

Part 1. Donation (DE)

Comments were made on the different types of donors (old donors, extended criteria donors) and on the possible need to stratify the questions to better visualise donation situations. Though this would have the disadvantage to lengthen the questionnaire and might not be feasible for all countries. It was also asked if living donation should be included or not. Points to be further discussed within the WG.

Part 2. Waiting lists (UK)

Since the management of waiting lists is a national competence and since the size of countries, the policies and the number of transplant programmes differ, it is statistically very difficult to compare waiting lists among countries, also as waiting lists are dynamic. However, the WG agreed that it is worth trying, and these slides only intend to provide general snapshots to give impressions on the different types of waiting lists (kidney/liver/heart...). Some MS highlighted the importance to see such data both in pmp (per million population) and in absolute numbers (both done for the first time her).

Part 3. Allocation (PL)

Several MS commented their own data, explaining their numbers for example through their integration in a “European Organ Exchange Organisation” or by the policy chosen (selection on the donor and not on the organ, development of a split liver programmes...).

8.2.2. Discussion and next steps

Due to the huge amount of data to be prepared by Commission's side in 2013 (pre-filling individually for each country), there was no physical Working group meeting in 2013. The WG decided about the format and content of the surveys via email consultations by Commission. There should be again a physical WG meeting in 2014, with new WG members (PT, SKT, FR).

The Commission will continue to support and coordinate the collection process and the preparation of the data, but if there is a wish to develop a more detailed report apart from the presentations, more involvement will be expected and asked from WG members, also on the preparation of presentations for CA meetings and the formulation of conclusions/messages relevant with the slides, to convey to the CA group.

While the quality of the exercise is gradually improving, it was considered that the current data quality still requires a lot of interpretation and further discussion. It was therefore agreed that the data should therefore not be shared outside the group of competent authorities/peers.

9. SET OF NATIONAL PRIORITY ACTIONS

9.1 Cyprus

CY presented its national actions relating to priority actions formulated under the Action Plan. Only DBD programmes exist in CY, there are no DCD programmes.

9.2 Portugal

PT presented its national actions relating to priority actions formulated under the Action Plan.

9.3 Scandiatransplant

Scandiatransplant (SKT) presented activities relating to priority actions of the Action Plan, in the 5 SKT countries.

9.4 Discussion

COMM called for interested Member State to present national set-up NCA during the next CA meeting. So far, no volunteer, but MS can still express their interest in written. Otherwise countries which did not yet present their activities under the Action Plan so far will be contacted individually.

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

10.1 ACTOR study (COMM)

COMM recalled that the contractor NIVEL in charge of this EU-funded study mapping the national uptake of the Action Plan (2009-2015) was present at the three last CA meetings: methodology, progress and draft results were expressed. As agreed, after the CA meeting in March 2013, Organs' CAs were offered to look at their respective

national sheets and comment it if needed their national data (most CAs provided comments). The ACTOR study was consequently finalised in June 2013 and published on Commission website (http://ec.europa.eu/health/blood_tissues_organs/docs/organs_actor_study_2013_en.pdf) as well as on the Organs' CIRCA BC group.

10.2. Staff Working Document on the Mid-term review of the Action Plan (COMM)

This document is the Commission's conclusion of the Mid-Term review, building on the ACTOR study (study by an external research team, focused on national level by also tackling common projects and initiatives at EU level), and responding to the December 2012 Council Conclusions on organ donation and transplantation (MS contribution, calling for MS action). As MS perspective was largely covered by the ACTOR study and the Council Conclusion, the Commission Staff Working Document (SWD) will concentrate on the EU level. It will take stock of progress made in the first half of the Action Plan (2009-2012), take into account ongoing projects such as the EU-funded ACCORD and FOEDUS Joint Actions and formulate priorities - for the EU level - for the two remaining years of the Action Plan (2014-2015).

COMM presented, for each of the 10 priority actions of the Action Plan, the main actions undertaken and conclusions formulated, as well as Commission's planned next proposals.

COMM recalled that it was important to differentiate the ACTOR study, which was an HP-funded project, while the SWD will be a Commission's document summarising common main results achieved so far at EU level, identifying gaps and proposing orientations for 2014-2015. The SWD also needs to be differentiated from the "implementation survey" which will be launched in 2014 regarding the implementation of Directive 2010/53/EU (where for example elements on authorisation schemes for transplant centres/procurement organisation will be clarified). The SWD will indicate where the "implementation survey" will also be useful for the implementation of the Action Plan, for example on priority actions 2 on quality improvement programmes and 10 on accreditation schemes.

COMM plans to finalise the document by the end of the year. MS (CAs) will be consulted and their comments taken into account before publication (but capacity for adaptations will be limited given that other Commission services will be consulted in parallel to the Member States).

11. PRESENTATION OF PROJECTS ON ORGAN DONATION & TRANSPLANTATION

11.1. Projects

11.1.1 ODEQUS

The coordinators of the project presented their results of the project, focusing on quality systems and indicators, for the hospital level, for the whole chain from donation to transplantation, for deceased but also for living donation. COMM highlighted that these results are directly relevant to priority action 2 of the Action Plan (quality improvement programmes) and can also help CAs to put in place at national level the "quality and

safety framework” expected since the adoption and transposition of Directive 2010/53/EU.

Two CAs of MS (ES, PT) involved in the project raised the attention of the group on the relevance of the project, whose results will be used as guidelines by the CA at national level to support hospitals in their efforts to improve quality in the donation and transplantation process

11.2. Joint Actions

11.2.1 Joint Action ACCORD (ES, ONT)

The coordinator of the project, ONT, gave a general progress report of the project. There are three main core work packages (as well as three "horizontal work packages" for coordination, evaluation and dissemination):

- Work package on links with Intensive Care Units (led by UK)
- Work package on living donation registers (led by NL)
- Work package on twinning activities (led by FR)

Regarding the WP on living donor registers, COMM insisted on the need to take into account and build upon results, methodologies and tools already developed in previous EU-funded projects which worked on the same topic.

The interim meeting of ACCORD, which started in May 2012, will take place in Madrid Mid October 2013.

11.2.2 Joint action FOEDUS (IT, CNT)

The Italian coordinator of the Joint Action gave an update on the ongoing activities of FOEDUS (which started in May 2013), to keep everybody updated on the work done and what is expected in the near future.

There are four main core work packages (as well as "horizontal work packages" for coordination, evaluation and dissemination):

- WP on "definition of guidelines for cooperation in cross-border organ exchanges and analysis of barriers/obstacles) (bi- and multilateral agreements) (led by Eurotransplant)
- Work package on medical cooperation to improve cross-border exchanges (led by FR)
- Work package on IT-tool to allocate organs "not used" at national level (led by CZ, follow-up of COORENOR)
- Work package on communication (co-led by DE and SI)

Member States not yet connected to the IT-tool developed in COORENOR and further improved within FOEDUS were strongly invited to connect their allocation bodies into this common IT platform.

For its work package, Eurotransplant asked the group whether it would be feasible to provide one single contact point per MS, to which the questionnaire developed in this

WP should be sent out. No objection from the group (PT explained how they would proceed between their two CAs). COMM concluded that indeed the questionnaire would be sent out to CAs and that COMM would support Eurotransplant in this process if needed.

11.3. Conferences and other EU funding

11.3.1 Report on the 2013 ELPAT Conference (COMM)

This conference funded under the EU Health Programme took place in April 2013, organised by ESOT platform on “Ethical, legal and psychological aspects of organ transplantation”. As the coordinators could not join for this CA meeting, COMM presented on their behalf (coordinators will be invited again for the next meeting).

11.3.2 Research projects (DG Research, COMM)

COMM representative of DG Research already attended the Organs’ CA meeting in September 2012 to present projects selected for funding by the Research Framework programme after the 2011 call for transplantation activities. Most of the projects have started early 2013. A short update was presented.

11.3.3 Possible use of structural funds (DG Health & Consumers, COMM)

Priority action 6 of the Action Plan encourage MS to possibly “use structural funds and other Community instruments for the development of transplantation systems”, and COMM to support by assessing this use. The mid-term review of the Action Plan shows that Organs’ CAs might have, in rare cases, used structural funds, for example to train healthcare professional (transplant coordinators, CZ), but that it was not often/easily done for most MS. As decision on the allocation of structural funds are made in the MS, Organs’ CA should be well informed regarding new plans and possibilities for using structural funds, to support a better access to them at national level.

A COMM representative following structural funds for health topics in DG Health & Consumers, presented the set-up of structural funds managed by DG REGIO and DG EMPL (e.g. from 2007-2013 around 5 bn EUR were programmed for health infrastructure, the figures for the new programming period 2014 – 2020 are still unknown as negotiations individual member states have not yet been concluded). He provided national contact details, which in particular can be of interest for countries with low organ donation rates.

The December 2012 Council Conclusions on organ donation & transplantation also called for use of structural funds for organ transplantation, and in the ACTOR study many CAs confirmed interest in using structural funds. In practice it is however quite complex and unclear for many CAs how to deal with this (political and financial) process. The objective of this presentation was to provide some guidance and contact points.

Some possible funding needs to support SoHO activities, as they came up in previous discussions in the sector, could e.g. relate to:

- Central capacity building to support transfusion and transplantation activities like:

- Department in the ministry or competent authority with experts who can ensure oversight of the activities in the field. This required nomination and training of inspectors, a system of authorization, accreditation and/or implementation of a traceability/vigilance communication system 24/7,
 - Central allocation offices in particular important for organs, to manage waiting lists and to decide 24/7 which donor organ goes to which recipient on the waiting list,
 - A central lab for testing of donor elements like immunological patterns, infectious diseases...
- Decentralised capacity building for transplant and transfusion teams
 - Trainings of professionals,
 - Support systems and infrastructure.
 - Dedicated databases for donor recruitment, donor follow-up and recipient/patient follow-up. Such registers have proven very important for specific population groups like Roma to find good donor/recipient matches, in particular for bone marrow donors (this is often related to specific genetic profiles).

National Authorities in eligible Member States, and with an interest to explore the use of structural funds to develop transplant capacity/activities, are encouraged to inform DG SANCO of this.

11.3.1. European Organ Donation Congress in Budapest, October 2014

The Hungarian CA announced that they will host the next European Organ Donation Congress in Budapest, 2-5 October, 2014. HU representative announced this event with few words and a leaflet.

12. ANY OTHER BUSINESS

Question on “rules of procedures”: see preliminary point under 4.

13. CONCLUSION OF THE MEETING

ANNEXES

ANNEX 1: COUNTRY CODES

Country code in alphabetical order	Short name, source language(s) (geographical name)	Short name in English (geographical name)	Official name in English (protocol name)
28 EU countries (From 1 July 2013)			
AT	Österreich	Austria	Republic of Austria
BE	Belgique/België	Belgium	Kingdom of Belgium
BG	България (*)	Bulgaria	Republic of Bulgaria
CY	Κύπρος (*)	Cyprus	Republic of Cyprus
CZ	Česká republika	Czech Republic	Czech Republic
DE	Deutschland	Germany	Federal Republic of Germany
DK	Danmark	Denmark	Kingdom of Denmark
EE	Eesti	Estonia	Republic of Estonia
EL	Ελλάδα (*)	Greece	Hellenic Republic
ES	España	Spain	Kingdom of Spain
FI	Suomi/Finland	Finland	Republic of Finland
FR	France	France	French Republic
HR	Republika Hrvatska	Croatia	Republic of Croatia
HU	Magyarország	Hungary	Hungary
IE	Éire/Ireland	Ireland	Ireland
IT	Italia	Italy	Italian Republic
LV	Latvija	Latvia	Republic of Latvia
LT	Lietuva	Lithuania	Republic of Lithuania
LU	Luxembourg	Luxembourg	Grand Duchy of Luxembourg
MT	Malta	Malta	Republic of Malta
NL	Nederland	Netherlands	Kingdom of the Netherlands
PL	Polska	Poland	Republic of Poland
PT	Portugal	Portugal	Portuguese Republic
RO	România	Romania	Romania
SE	Sverige	Sweden	Kingdom of Sweden
SI	Slovenija	Slovenia	Republic of Slovenia
SK	Slovensko	Slovakia	Slovak Republic

UK	United Kingdom	United Kingdom	United Kingdom of Great Britain and Northern Ireland
Other countries mentioned			
CH	Suisse/Schweiz	Switzerland	Swiss Confederation
fYRoM (MK for short mention)	поранешна југословенска Република Македонија (*)	the former Yugoslav Republic of Macedonia	
IS	Ísland	Iceland	Republic of Iceland
LI	Fürstentum Liechtenstein	Liechtenstein	Principality of Liechtenstein
ME	Crna Gora/Црна Гора	Montenegro	Montenegro
MD	Republica Moldova	Moldova	Republic of Moldova
NO	Kongeriket Norge/Noreg	Norway	Kingdom of Norway
RS	Србија (*)	Serbia	Republic of Serbia
TR	Türkiye	Turkey	Republic of Turkey

(*) Latin transliteration: България = Bulgaria; Ελλάδα = Elláda; Κύπρος = Kýpros; поранешна југословенска Република Македонија= poranešna jugoslovenska Republika Makedonija; Србија = Srbija

Sources: <http://publications.europa.eu/code/en/en-5000600.htm> and </en-370100.htm>