



Brussels, 15 July 2013

**SIXTH COMPETENT AUTHORITY**  
**MEETING ON ORGAN DONATION AND TRANSPLANTATION**  
**13 MARCH 2013, 10:00-18:00**  
**14 MARCH 2013, 9:00-16:30**  
**BRUSSELS**  
**Place: CCAB (Centre de Conférence A. Borschette) - Room AB-2B**

**MINUTES**

**DAY 1: WEDNESDAY 13 MARCH 2013 (10:00 – 18:00)**

**1. WELCOME AND INTRODUCTORY REMARKS**

The chair welcomed the participants. All Member States (MS) were represented except LU, SK and fYRoM.

**2. ADOPTION OF THE AGENDA**

The agenda was adopted. No new points were added.

**3. INTRODUCTION OF NEW PARTICIPANTS**

New participants were introduced from DE (DSO and MoH), NL (MoH), ScandiaTX, BG, EE, Montenegro, PT, CoE, LV and NO.

**4. LEGISLATION**

**4.1. National set-up of Competent Authorities**

COMM presented the first replies of MS who indicated the names of bodies taking up the different roles of NCA, following Art 17. MS were requested to complete information since otherwise information is only available after the implementation check. COMM suggested to create and make available one document containing all relevant

information. MS were invited to present their national set-up during the next CA meeting. CY and PT expressed interest.

## **4.2. Transposition of the Mother Directive 2010/53/EU**

COMM informed MS that the reply to the transposition questionnaire was due in Mid May (second extended deadline for last remaining answers: 26/8/2013), and that COMM has now launched a transposition check. COMM noted that four MS have not communicated transposition measures, that two MS have notified only partial transposition, and that these MS have received a reasoned opinion (first step in an infringement procedure) in March.

COMM explained that the three surveys foreseen for the Organs' CAs in 2013 (transposition check for Directive, Organs' indicators under Action Plan, implementation survey regarding Directive) have been planned in order **not** to take place at the same moment, meaning that the transposition check has a deadline of 15 May, the indicators over Summer (for 3 presentations in September) and for October (3 presentations in March 2014), and the implementation survey is planned for the end of the year.

## **4.3. Update on the Implementing Directive (SVDS)**

### *4.3.1. Adoption of Implementing Directive 2012/25/EU on 9 October 2012*

COMM summarised the main provisions in a short presentation. In a tour de table, FI, SI and NL indicated to have already completed transposition.

### *4.3.2. Contact detail website*

As suggested in the Regulatory Committee, in order to facilitate a smooth implementation of article 8 of Directive 2012/25/EU, the "interconnection between Member States" will be organised via a protected "contact detail website", where Member States will need to update their contact details for: a) the information on organ and donor characterisation, b) the transmission of the necessary information to ensure the traceability of organs, and c) ensuring the reporting of serious adverse events and reactions. MS discussed an appropriate name for the website. The majority favoured "organ-tx-contact-points.eu".

COMM expressed thanks to Eurotransplant (ET) for offering to design a website that hosts the contact details, allowing every MS to adapt own contact details. Initial hosting will be at/by Eurotransplant, as this allows a short-term implementation. But long-term options were kept open, also in function of hosting of other platforms (e.g. rapid alert system and/or platform for organ offering developed in COORENOR and now FOEDUS projects).

COMM presented dummy screenshots of the website. It was clarified that one administrator, able to adapt national contact details, should be assigned per MS. COMM invited those Member States who have these contact details fixed, to pass these on. MS who would like to provide different contact details for nighttime vs daytime, are requested to inform COMM by 1/4/2013. No MS indicated this need during the meeting.

#### **4.4. Interpretation questions**

##### *4.4.1. Procurement teams from other countries*

A question was raised by UK during the meeting of September 2012: who authorizes and supervises the procurement of an organ in MS A undertaken by a procurement/retrieval team of MS B (NCA MS A or NCA MS B)? COMM reminded that NCA's, following art 5.2 of Directive 2010.53/EC need to authorize all procurement activities within their territory, regardless whether these are undertaken by local procurement teams or procurement teams sent in from abroad. In order to avoid obstacles to cross-border procurement activities, CA concerned should conclude agreements or act on the basis of Memoranda of Understanding.

While some participants expressed trust in the current set up, others expressed the need for a minimal legal basis. It was agreed that a simple, pragmatic legal arrangement should be in place in order for MS to be compliant with article 5 of Directive 2010/53/EU. 2 concrete approaches were mentioned:

1. Eurotransplant mentioned the inclusion into a bilateral agreement of a requirement to send only procurement teams abroad that are fully authorised and supervised by the sending MS's NCA.
2. Countries like ES mentioned a form in which every visiting procurement team is authorised ad-hoc by the NCA of the MS of procurement.

It was argued that it is up to every MS to set-up its system. COMM expressed that this falls outside the remit of EU legislation and that it has no plans to address this topic.

##### *4.4.2. Living Donor follow-up: interpretation of Chapter 3 of Mother Directive*

This point was raised during the meeting of September 2012: which country is responsible for the life-long follow-up of living donors who make their donations abroad.

COMM presented the interpretation of Article 15 of the Directive, according to which the CA of the state of residence of a living donor is primarily responsible for ensuring the follow-up of this donor, even if the donation took place in another MS (unclear). In order to avoid a gap in the follow-up of living donors and thus to ensure the useful effect of this obligation, Article 15 of the Directive must be understood to require CAs and hospitals cooperate and exchange relevant information. COMM also informed that on this basis it has requested LI to transpose Articles 15 and 16 of Directive 2010/53/EU, as well as the corresponding definitions and general provisions. AT explained that it would be willing to cooperate with LI on this matter, but that more time would be needed to organise the follow-up on national level. COMM expressed its support for postponing the transposition of the mentioned provisions of the Directive by LI, as long as the general willingness to transpose was not put into question. DE stressed the need to have registers to be able to ensure effective follow-up.

DE representatives **presented their "National Priority Actions"** (originally foreseen under point 9.2). The presentation is available on CIRCA BC.

## **5. COMMUNICATION ACTIVITIES**

### **5.1. (TRANS)NATIONAL COMMUNICATION ISSUES**

#### **5.1.1. German/Eurotransplant case (DE/ET)**

This topic was a follow up to discussions in previous meetings. DE Health Ministry and DSO – supported by ET - presented an overview of the legal and media developments. DE authorities presented concrete action points that will help address future risks of manipulating waiting lists, including

- increase of number of local hospital donor coordinators/contact points.
- collection of more pre- and post-transplant data to allow better control of local management of the waiting list. ET will collaborate in an initial phase in providing these data.
- Auditing plans for every transplant programme.

#### **5.1.2. Facebook requests to national Competent Authorities: tour de table**

This topic was discussed in the previous meeting. Member States were asked for informing on further evolutions and experiences.

NL, BE, HR mentioned collaborations with Facebook. BE mentioned a 37% increase of registration in the national donor-register (mainly for the "yes" to donation) for the last year (Facebook action + presence in voting bureaus during local elections in October 2012), compared to 10% in the previous year.

#### **5.1.3. European Organ Donation Day 2013 (Council of Europe and BE)**

Belgium will host the next EODD 2013 edition in Brussels and presented the draft programme. The presentation is available on CIRCA-BC.

The meeting is back to back with the CD-P-TO meeting of the Council of Europe, which will also take place in Brussels. The Eurotransplant annual meeting will also take place in the same week in (closeby) Leiden. It was therefore hoped that many international participants can join the events in Brussels.

#### **5.1.4. Case of a Danish girl reported at the TV (DK)**

A Danish TV programme, reporting on the donation process, filmed a girl who woke up after the family had been approached to talk about the possibility of donation. This has created a lot of media attention and discussion on the place, timing and appropriateness of donor consent discussions with the family (<http://www.dailymail.co.uk/news/article-2219085/Carina-Melchior-The-girl-wouldnt-die-Miracle-Danish-girl-woke-doctors-prepared-organs-donated.html>, link to the article provided for in CIRCA BC and article printed in COMM binders).

It was clarified that the girl was never declared brain dead, however the topic of donation was brought forward too early to the family. Several MS confirmed the importance of sticking to the procedures, in particular when media are around.

## **5.2. COMMISSION COMMUNICATION ACTIVITIES: UPDATE**

### *5.2.1. Journalists Workshops on Organ Donation and Transplantation (9 October 2012, Brussels + 2013 edition)*

COMM presented results from 2010, 2011 and 2012 editions and made proposals for 2013 edition (presentation on CIRCA BC). NCAs are invited to suggest names of journalists to which the "invitation to apply" could be sent.

### *5.2.2. SoHO booklet & 2013 Cluster meeting prepared by Executive Agency for Health & Consumers (EAHC)*

COMM presented on behalf of EAHC the revamped project database, the brochure, the journalist meeting in Madrid and the EPH conference.

Member States were reminded of 3 key points:

- To give feedback on the new project database.
- For project coordinators, please encourage them to apply to EPH 2013 in the open programme, which will in Brussels (13-16 November 2013), the call for abstract is open now (EAHC will not do a specialised session on SOHO in 2013, but no need for mentioning this – only if asked).
- To provide contact details of general and specialised press in the Member States to be invited to the EACH cluster meeting in Madrid (June).

## **6. VIGILANCE AND SURVEILLANCE**

### **6.1. Update on Alerts and activities linked to SoHO field (ECDC)**

ECDC presented a short update on epidemiology.

### **6.2. Other related activities in the field of "substances of human origin" (COMM)**

COMM presented an update on the RATC system, which is launched in February and received good initial feedback. COMM also presented proposals for Rapid Alert systems for Blood and for Organs.

As during the introduction in the Sept. 2012 meeting, participants showed interest in the new system and the idea to develop a similar platform for organs. The Commission undertook to come back with an outline during the next NCA meeting.

## 7. FIGHT AGAINST TRAFFICKING

### 7.1. Update on on-going activities

COMM presented an overview of the activities to combat trafficking. This presentation included an introduction to the legal framework, the distinction between different types of trafficking such as trafficking of human beings, trafficking of organs and transplant tourism. The presentation included policy actions in the field including the funding of anti-trafficking projects. CoE presented its draft Convention.

The following points were raised:

- There are different approaches to transplant tourism across the EU Member States – in one country this has been criminalised while others expressed some understanding for the efforts of patients. It was concluded that more research is needed to discover the true extent of this activity.
- The European Union and CoE are both active in the field of anti-trafficking initiatives. COMM and CoE should avoid duplication of efforts in this area.
- With the Cross-Border Healthcare Directive soon to become applicable allowing for greater cross-border patient movements, it is important to distinguish between legal and illegal cross-border activities in the organ transplantation domain.
- Several authorities have been confronted with situations where people have advertised the sale of organs via websites and are unsure if these situations would fall within the definition of one or more of the different types of trafficking. Some MS suggested the need for a common communication.

COMM will continue to coordinate this with CoE and invite CoE to future discussions on this topic.

**DAY 2: THURSDAY 14 MARCH 2013 (9:00 – 16:00)**

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

**8.1. Technical WG on Living donation: update** (UK, COMM and WG members)

COMM presented the status of the manual on behalf of the UK. COMM explained that the objective is to bring together national expertise on different elements to organise an effective living donation programme. This expertise comes from MS that have well established programmes and aims to be of reference for other MS that have expressed an interest in setting up such transplant activities. COMM asked the MS to provide reference materials or examples they think relevant for other MS.

MS are invited to send comments and provide reference documents and/or illustrative examples by end March. A next conference call with the working group is planned by summer in order to finalise the document.

**8.2. Technical Working Group on Indicators: overview of Activities**  
(COMM and WG members)

*8.2.1. General presentation of process for 2013 exercise*

COMM presented the 2013 exercise, with as objective to present 3 sections in September 2013, the 3 other sections in March 2014.

COMM reminded to avoid overlap in timing between different surveys:

- transposition check: March/April (15 May),
- Indicators: Summer (for 3 presentations to be done in September on donation, waiting lists and allocation) and October (for 3 presentations to be done in March 2014 on transplantation, health outcomes, health resources).
- Implementation survey for the end of the year.

The new Indicators' survey, in a form of an excel document with several sheets, will be pre-filled by COMM for each country including data of the previous editions, and allow Member States to make corrections/updates/completions. As such it can be re-used in future years and it will enable to work with the same template.

*8.2.1. Discussion and Next steps*

The COMM proposal on timing and approach was supported. PT will join the WG and ScandiaTX proposed a change in membership to the new director.

## **9. SET OF NATIONAL PRIORITY ACTIONS**

### **9.1. Denmark**

DK presented its national priority actions. Presentation is available on CIRCA-BC.

### **9.2. Germany**

DE presented its national priority actions. Presentation is available on CIRCA-BC.

### **9.3. Discussion**

PT and CY agreed to bring presentations during the next CA meeting.

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

### **10.1. Council Conclusions on Organ donation and transplantation**

COMM, on behalf of CY Presidency (2<sup>nd</sup> half 2012) presented the Council Conclusions adopted by Health Ministers on 7 December 2012 (uploaded on CIRCA BC).

These Conclusions include several "invitations" made by the Council to Member States and Commission. The presentation also indicates where current/planned activities contribute to these "invitations". Several on-going EU projects are already contributing to these issues.

### **10.2. Update on the ACTOR study and presentation of final results (NIVEL)**

NIVEL presented the main findings of their study. These cover country-specific activities as well as EU level efforts.

It was announced that MS will receive a 3-5 pages individual draft country fiche for their comments. These documents are expected to be send by mid April, with a request to comment by end April.

### **10.3. Discussion and next steps**

Following feedback of the Member States on their country-specific fiches, the ACTOR Study will be finalised in May/June and published. [it was in the meanwhile finalised in June and published on COMM website and CIRCABC].

Subsequently COMM will prepare a Commission (Staff Working) document containing Commission contribution to the mid-term review of the EU Action Plan for organs. This will facilitate the discussion on future priorities. COMM will present the draft document during the next NCA meeting.



## **11. INTRODUCTION OF THE "SOUTH-EUROPE ALLIANCE FOR TRANSPLANTATION", SAT (IT/ES/FR)**

This Alliance was signed in Rome on 1 October 2012 between FR, IT and ES. IT holds the secretariat and made a short presentation of the planned collaboration which mainly covers exchange of know-how but also foresees exchanges of organs in future.

SAT requested the possibility of sending an observer to these NCA meetings. No MS expressed objections and COMM therefore confirmed that they will invite such observer from now on.

## **12. PRESENTATION OF PROJECTS ON ORGANS**

### **12.1. Projects**

#### *12.1.1. COORENOR, in particular web portal to exchange organs cross-border*

A brochure was distributed. IT presented the outcomes of the COORENOR project and CZ presented the work-packages focusing on an IT tool to offer organs non allocated, and therefore not "used" in the country of procurement.

This IT-tool will be further developed within FOEDUS, and other MS are strongly invited to join. It was reiterated that the IT-platform only serves to offer "non allocated organs" and/or request urgent organs, without further interfering in internal national allocation rules.

#### *12.1.2. ELIPSY*

The results of the project were presented as it was finalised end of 2012. Abstracts were also submitted to the ELPAT conference.

MS were called upon to increase the use and inputs on the questionnaires within their national transplant centres, and therewith strengthen the common knowledge basis.

#### *12.1.3. 2013 ELPAT conference*

COMM announced the ELPAT conference on 20-23 April 2013, where COMM will be represented.

### **12.2. Joint Actions**

#### *12.2.1. 2011 Joint Action ACCORD (ONT + WP leaders)*

Following an update by the coordinator (ONT/ES), the different work packages were presented:

- Work package on links with Intensive Care Units (UK) – presentation on CIRCA-BC
- Work package on living donation registers (NL) – presentation on CIRCA-BC
- Work package on Twinning activities (FR)

MS expressed great interest for the tools presented, in particular the e-learning tool to train doctors on thoracic organ procurement, which will be made available through NL/ESOT.

#### *12.2.2. 2012 Joint action FOEDUS (IT)*

A short introduction was presented. The kick-off was scheduled for 7/5.

### **12.3. Tender**

#### *12.3.1. Survey results for the tender "Train the Trainers in transplant donor coordination" (COMM)*

This survey was requested by NCAs one year ago. It was implemented in May/June 2012, reminders were sent in August/Sept 2012, Dec/February 2013. COMM made a short presentation (uploaded on CIRCA BC) with replies of 16 MS. The answers to the survey show a high satisfaction from participants and CAs in the European Training Course co-organised by the Spanish consortium ONT/IAVANTE.

### **13. ANY OTHER BUSINESS**

1) 4 CAs (FR, ES, NL and UK) reported on the ESOT DCD conference in Paris 7-8 February 2013.

2) fYRoM (Macedonia) reported that their transplant program has been substantially improved. In the last 11 months 32 patients were transplanted and 4 more transplants were scheduled this month. In addition, an agreement from the MoH allowed to start with transplantation for ESRD (end-stage renal disease) patients from Kosovo and Albania, two countries looking for this service since a year. One of the key factors of success was the cooperation within the SEEHN and political support at Ministerial level in fYRoM. Some results will be presented during the next meeting.

### **14. CONCLUSION OF THE MEETING**

The next meeting is foreseen for 18-19 September 2013 (to be confirmed over summer once room available).