



Brussels, 6 February 2013

**FIFTH MEETING OF THE NATIONAL COMPETENT AUTHORITIES
ON ORGAN DONATION AND TRANSPLANTATION
13 AND 14 SEPTEMBER 2012**

SUMMARY REPORT

This Fifth Meeting of National Competent Authorities (NCAs) on Organ Donation and Transplantation was convened on 13 September and 14 September 2012. The previous meeting of NCAs¹ took place on 1 and 2 March 2012.

PARTICIPATION:

- All EU Member States present, except Poland (PL), Sweden (SE) and Slovakia (SK) excused.
- EEA countries: Norway (NO) present, Iceland (IS) and Lichtenstein (IS) absent.
- Candidate countries: Turkey (TR) and former Yugoslav Republic of Macedonia (FYRoM) were present.
- Observers: European Centre for Disease Prevention and Control (ECDC) and Council of Europe, European Directorate for Quality of Medicines (CoE, EDQM) represented. WHO absent.
- Private experts: Eurotransplant (ET) and Scandiatransplant (SKT), NIVEL (contractor for ACTOR study, from NL), Coordinators of the ELIPSY and ODEQUS (from ES), Norwegian Foundation for Organ Donation (NO).
- European Commission, Directorate General for Health and Consumers, Unit Substances of human origin and Tobacco control (SANCO D4).

¹ All country codes are explained in Annex 1

1. ADOPTION OF THE AGENDA

The agenda was adopted with the following changes: no presentation of Set of National Priority Actions is foreseen and DE asked to add a point concerning "Any other business" to explain current discussions in Germany.

The minutes of the previous meeting were approved and uploaded on the CIRCA platform. All presentations prepared for this NCA meeting and made available by speakers were also uploaded on CIRCA.

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

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

Objective: The objective is to build a common "toolbox" collecting Member States' expertise and experiences on how to set up Living Donation Programmes.

Work done: In the two previous meetings of the working group (WG) on 10 February and 6 July the structure and set up of the toolbox were discussed. The first draft of chapters was prepared by the individual members of the WG over summer and include knowledge gained via national programmes and European projects funded under the Health Programme. They cover legal aspects, ethical issues, donor selection, donor registries, psychological, financial, economic and organisational aspects.

Next steps: The aim is to finalize and complete the drafts of the chapters before the next CA meeting in March 2013, in order for them to be validated by the CA group during this CA meeting.

2.2. Technical Working Group on Indicators: 2012 Exercise and overview of Activities (COMM and WG members)

Objective: The objective of the WG is to build a common set of basic indicators on all steps from the donation to the transplantation, including health outcomes and health resources, to get a better picture and a common understanding of organ donation and transplantation at EU level.

Work done: The 2012 annual exercise is now the 3rd exercise after the 2010 and 2011 exercises.

Status: There have been meetings of the WG on 9 February and 5 July, discussing the structure of the online survey, questions to be (re-)asked or not and the way to present the results and key findings.

The number of participating countries was increased up to 30 for the ONT data collection and up to 26 for the Commission web-survey. There are still countries willing to contribute.

It has to be kept in mind that the work is still in progress. Data quality is still a main point of discussion. Furthermore this is an indicators' exercise, the results aim not to be exact science, but to offer common learning opportunities to Member States on their daily

activities. While some MS are very advanced and could offer much more data, the aim is to ensure to engage all MS in first place.

Next steps: The aim is to finalize and complete the exercise by the end 2012. As some countries might still contribute to the web-survey, the aggregated results could be updated by the end of the year. The results of the discussion with NCAs would be taken up by the Working Group for the 2013 exercise.

3. INTRODUCTION OF NEW PARTICIPANTS

Tour de table, with introduction of new participants.

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

As foreseen in the Communication from the Commission "Action Plan on Organ donation and transplantation (2009-2015)", a "mid-term review 2012" is to be carried out to figure out if and where progress was made/is still to be made under the Action Plan. As explained in the previous NCAs meetings, this review was now taking place via a study financed through a tender under the Health Programme. The NCAs were invited to support the contractor NIVEL by providing feedback and content on their own country and activities.

4.1. Update on the state of play of ACTOR study and presentation of preliminary results (contractor NIVEL)

NIVEL presented an update on the status quo of the ACTOR study and its preliminary results. Comments by NCAs were taken into account for the draft report.

4.2. Key messages on each priority action: discussion and exchange of views with participants (COMM and MS)

The COMM prepared a presentation on the key messages on each priority action for discussion and exchange of views with the participants. There are 10 priority actions around three common objectives: (1) increasing organ availability, (2) enhance efficiency and accessibility of transplantation systems and (3) improve quality and safety. The Action Plan is a basis for an overall assessment of the success Member States have in achieving the these common objectives. The mid-term review (2012) of these actions is carried out to evaluate the efficacy of this action plan and highlight the progress and identify the gaps at national and EU level and re-prioritize the work-focus for the 2013-2015 activities.

Next steps: In parallel to the study, Council conclusions will be adopted on organ donation and transplantation by the Council meeting of Health Ministers in December 2012, under Cypriot Presidency. Following discussions on points 4.1 and 4.2, some key messages were retained to propose a first wording to CY presidency, for the first Council Working Party meeting in October 2012.

[7.1.1.] PRESENTATION OF PROJECTS ON ORGANS: *ODEQUS*

(point initially for Day 2)

An update was made on the developments within the ODEQUS project. ODEQUS is developing indicators to overall quality in organ donation (deceased and living donation) at hospital level. The project will be finalised in 2013.

5. LEGISLATION

5.1. Presentation of some national set-up of Competent Authorities (Hungary)

Hungary gave an insight to the Hungarian legislation and presented the set-up, work and activities of the three Hungarian NCAs, for example the management of the waiting lists.

The question was raised about the validity of bilateral agreements which Hungary has with neighbouring countries such as Austria once Hungary will have fully joined Eurotransplant (probably in 2013). These agreements will be accordingly adapted.

5.2. Transposition of the Mother Directive 2010/53/EU

5.2.1. Update on the notification procedure and next steps (COMM)

The Commission presented the state of play of the notification procedure on 11 September 2012 and informed about the next steps:

- 10 Member States had communicated a full transposition (BG, CY, DK, EE, EL, HU, IE, NL, RO, SE),
- 5 Member States had communicated a partial transposition (BE, DE, FR, LT, PL).
- The remaining Member States did not formally notify the Commission yet.

The Commission informed the Member States that an automatic infringement procedure will be launched if no notification is reported. The Commission urged the Member States to complete and notify transposition in the coming months. The detailed transposition check will start in 2013 and will be further explained in the next NCA meeting in March 2013.

5.2.2. Tour de table and state of play in each Member State

The introduction by the Commission was followed by a tour de table, where each MS presented its NCA(s) and the state of play, the scope of the new legislation and the further implementation.

5.3. Update on the Implementing Directive (COMM)

Over Summer 2012, the Committee on organ transplantation (foreseen under art. 30 of Directive 2010/53/EU) provided a positive opinion in written procedure on the implementing directive. In September, the Directive was then subject to a Commission internal preparatory process leading to its adoption by the College of Commissioners. Consequently the Implementing Directive would be published in the Official Journal.

[The Directive was adopted by the Commission on 9 October 2012 and published the following day in the Official Journal: Commission Implementing Directive 2012/25/EU laying down information procedures for the exchange, between Member States, of human organs intended for transplantation. This Directive shall be transposed by 10 April 2014.]

As suggested by some representatives in the Committee, in order to facilitate a smooth implementation 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 relating to procedures for: a) the information on organ and donor characterisation, b) the transmission of the necessary information to ensure the traceability of organs, c) ensuring the reporting of serious adverse events and reactions. This set-up was further clarified with NCAs and after several suggestions were made, a name/link was proposed: "organ-tx-contact-points.eu". The Commission will further follow the development of such a website, with the logistical support of ET who proposed to host it.

5.4. Interpretation questions

5.4.1. Procurement teams from other countries (UK/COMM/ET)

The UK introduced a question on how to regulate procurement teams from other countries: who authorizes and supervises the procurement of a donor in a hospital in country A undertaken by a procurement/retrieval team of country B (NCA country A or NCA country B?). An authorization of every procurement team (also given the broad definition of "procurement organisation") by NCA country A could be very cumbersome and would be an administrative barrier.

The objective of the discussion was to clearly lay out the issue and to find option(s) for a legal solution.

5.4.2. "Vascularised composite allotransplantation"(FR/COMM)

FR proposed to make a presentation on face, leg, arm... transplantations and to use the wording of "vascularized composite allotransplantation" now used in the scientific community.

Subsequently COMM presented a summary of the discussions within the group of NCAs for Tissues and Cells regarding this topic, as well as the opinion of the legal unit in the Directorate General for Health and Consumers of the Commission. The draft conclusion was - now that an Organs' Directive was adopted - that such "vascularised composite allotransplantations" fall under the organs Directive, and not under the tissues and cells Directive - from both practical and legal points of view.

The discussion confirmed this position by the NCAs in charge of organ donation and transplantation. NCAs in charge of Tissues and Cells legislation will be informed in their next meeting in December 2012. This interpretation will be taken into account in a future revision of Tissues and Cells legislation.

5.4.3. Donor selection: interpretation of Chapter 3 of Directive (question from Liechtenstein)

The Commission presented Liechtenstein's request for a complete derogation of transposing Directive 2010/53/EU, given that no transplant or procurement activities take place within its borders.

Different opinions came up. Some countries argued that the country of origin of the donor needs to take responsibility. There should be provisions to regulate this question but the patient cannot be forced to go back to his country. Other countries argued that the country of transplant needs to take care of follow-up of the living donors.

Following this discussion, it was agreed that further discussions are needed to agree on an interpretation, via a commonly agreed wording based on Directive 2010/53/EU.

6. VIGILANCE AND SURVEILLANCE

6.1. Viaspan: lessons learnt

COMM prepared a presentation on the events concerning the "Viaspan alert" in Spring 2012. On 19 March, the company Fresenius Kabi reported to BMS a non-compliant media fill (aseptic process stimulation performed every 6-8 months) performed in February at a plant producing Viaspan in AT. The potential root cause was the failure combination of valve leakage and defective pressure gauge which caused the ingress of *Bacillus Cereus* (environmental germ). The previous media fill that took place in July 2011 was satisfactory. The available batches produced since July 2011 were tested for sterility with negative (i.e. no problems) result. Nevertheless as not all units could be tested, Fresenius Kabi and BMS recalled all batches produced since July 2011. These recall being a potential cause of shortage for the product used to store and transport organs for the purpose of transplantation in the whole EU, Commission services in charge of medical devices informed the unit in charge of organ transplantation, who informed the relevant NCAs (both groups for organs and tissues&cells). During this September NCA meeting, the issues discussed were mainly the communication channels for users and professionals and the speed of communication in the cases of such events.

The action of the Commission in these cases mainly consists in ensuring communication channels, to make sure that all EU NCAs are duly informed, can take action at national level if needed and can communicate among each other (for example through a mailing list). COMM asked how many NCAs were informed via COMM email and how many had already been informed by other channels (company and/or CAs for medical devices or pharmaceutical products). Several NCAs for organ donation & transplantation were first informed by COMM email. In the future, the "rapid alert system" currently developed tissues&cells could be used also for such alerts relating to organs.

Feedback: positive, as it showed that many people felt responsible for the issue.

6.2. Update on Alerts and activities linked to SoHO field (ECDC)

ECDC presented a report on the alerts and activities linked to the SoHO field. The recent technical documents published are the guidelines for the surveillance of invasive mosquitoes in Europe, the climatic suitability for dengue transmission in continental Europe and the legionnaires' disease in Europe. The communicable disease threats related

to organ transplantation in 2012 are mainly West Nile Virus, Malaria, Measles, Rubella, Chikungunya, Dengue and the Usutu virus.

6.3. Other related activities in the field of "substances of human origin" (COMM)

The Commission introduced the Rapid Alert System for Tissues&Cells (RATC), currently developed with and for the NCAs for Tissues&Cells and to be launched early 2013.

The participants showed a strong interest in the system and suggested to develop a similar platform in the field of organs. The Commission will assess this and come back with a proposal, as well as an update on the RATC, during the next NCA meeting.

Another IT-related issue was announced: the transfer from CIRCA to "CIRCA BC" in October/November 2012, with the creation of "ECAS profiles" (ECAS means "European Commission Authentication Service", through this system, only one password will be needed to access the different Commission platforms where users will be authorised).

On CIRCA(BC) a new section called "Publications" was created. If the NCAs want to share publications there, it is possible, they just need to inform COMM and to send the documents. There is also a section "From CAs to CAs" where NCAs can share other types of documents.

7. PRESENTATION OF PROJECTS ON ORGANS (FROM THE HEALTH PROGRAMME AND FROM THE RESEARCH PROGRAMME)

7.1. Projects under the Health Programme

7.1.1. ODEQUS [took place Day 1]

7.1.2. ELIPSY (Euro Living Donor Psychosocial Follow-Up)

The Spanish coordinators presented the project on living donation. The final meeting of ELIPSY will take place in October 2012. As the methodology and results of ELIPSY are relevant also for the Work Package on Living donation of the Joint Action ACCORD, appropriate contacts and links are being organised with the coordinators.

7.1.3. COORENOR (IT)

An update was made on the developments within the COORENOR project. The final meeting of COORENOR will take place in December 2012.

7.2. Joint Actions under the Health Programme

7.2.1. 2010 Joint action MODE (IT)

An update was made on the developments within the MODE Joint Action. The Joint Action is now finalised.

7.2.2. 2011 Joint Action ACCORD (ONT and WP leaders)

ONT presented the objectives and work packages under the 2011 JA ACCORD. The coordinators of the 3 core work packages were invited to present their WP: for the UK WP on links with Intensive Care Units, for NL WP on living donation registers and for FR WP on twinning activities.

The website on the Joint Action ACCORD is: <http://www.accord-ja.eu/>

7.2.3. 2012 Joint action FOEDUS (IT)

IT presented the FOEDUS Joint Action and provided an overview of the timeframe of the negotiation phase. Depending on the provision of necessary documents by all partners and therefore of the final signature of the contract with the Executive Agency (EAHC), this 3rd Joint Action for Organ donation and transplantation will start early/mid 2013.

7.3. Tender (COMM) under the Health Programme

The Commission presented the survey results for the tender "Train the Trainers in transplant donor coordination", done among NCAs (to know if the trainers trained via this project funded under the Health programme are "used" in their country) – this survey was requested by CAs during the previous CA meeting. As only a few NCAS (8) have answered to the survey, the survey will be re-circulated.

The Commission reminded the CAs to use the trainers trained at European level in order to (further) develop training programmes at national and regional level.

7.4. European Research Projects: results of 2011 call (COMM, DG RTD)

DG Research (RTD) gave an overview of the results concerning the results of 2011 call on European Research Projects. ET will be involved in one of the four proposals under negotiation.

8. COMMUNICATION ACTIVITIES

8.1. (TRANS)NATIONAL COMMUNICATION ISSUES

8.1.1. German/Eurotransplant case (DE/ET)

[discussed during day 1: the German authorities presented the state-of-play, measures taken/to be taken as well as the media impact.]

8.1.2. Facebook requests to national Competent Authorities: tour de table

Facebook is launching in several Member States - in partnership with the national authorities in charge - the possibility to indicate if you are in favour of organ donation within ones profile. Facebook users who do so are then referred to the national registers. The few countries who have this option in place expressed a positive experience, with a significant increase of persons registered in the official register and increased overall awareness. It is however important, as Competent Authority, to avoid that Facebook launches such this option without being associated and/or to proactively approach Facebook, to ensure the initiative is aligned with national practices and consent systems. Several participants indicated that the initiative is upcoming in their country.

8.1.3. Norwegian application

A representative of the Norwegian Foundation for Organ Donation (proposed by NO NCA) made an online presentation about their policy to improve organ donation and its perception in Norway. The presentation is available on internet under following link:

<http://prezi.com/sc8oxyj4zlfid/organ-donation-communication/>

8.2. COMMISSION COMMUNICATION ACTIVITIES: UPDATE

8.2.1. Public Health Conference (3 May 2012, Brussels)

8.2.2. SoHO booklet & 2013 Workshop prepared by Executive Agency for Health & Consumers (EAHC)

8.2.3. Next Journalists Workshop on Organ Donation and Transplantation (9 October 2012, Brussels)

The Commission presented the draft programme for the journalist workshop taking place on 9 October in Brussels. On 12 September, the selection of the participating journalists was on-going. About 60 journalists from 21 countries had expressed their interest to participate. The objective was to possibly invite journalists from large newspaper (large audience), and also from EU countries/media possibly not/less represented so far in the previous editions. The workshop would be on the one hand dedicated to organ donation and transplantation, including testimonies of a recipient, a living donor and a relative of a deceased donor as well as ethical aspects. On the other hand, the workshop would be dedicated to the role of the media, for example covering the communication activities of the Commission Directorate for Health, how to manage adverse publicity (example of Spain) and how to deal with new media (example of Belgian and its cooperation with Facebook).

Links to Workshops' webpages (with articles published and translated when authorised by authors and editors):

2012 Workshop: http://ec.europa.eu/health/blood_tissues_organ/events/journalist_workshops_organ_en.htm

2011 Workshop: http://ec.europa.eu/health/blood_tissues_organ/events/journalist_workshops_organ_en.htm#fragment1

2010 Workshop: http://ec.europa.eu/health/blood_tissues_organ/events/journalist_workshops_organ_en.htm#fragment2

9. ANY OTHER BUSINESS

a) NCAs representatives from FR, ES and NL advertised the 6th International Conference on Transplantation on Organ Donation after Circulatory Death (DCD) which will take place in February 2013 in Paris.

b) Dates foreseen for CA meetings Organs in 2013 (always still to be confirmed 6 weeks prior to the meeting):

- CA meetings: 13-14 March 2013 and 18-19 September 2013

(for Tissues and Cells CAs: 5-6 June and 3-4 December,

for Blood CAs: 17-18 April and 6-7 December)

- Working groups: no meeting in February, only one Working group meeting for Indicators in July (early July, probably 4 July).

- Journalists Workshop: early October, possibly before European Organ Donation Day (so that journalists can report about it).

Dominik Schnichèls

Annex 1: Country codes

Short name, source language(s) (geographical name) ⁽¹⁾	Short name in English (geographical name)	Official name in English (protocol name)	Country code ⁽²⁾
EU countries			
Belgique/België	Belgium	Kingdom of Belgium	BE
България (*)	Bulgaria	Republic of Bulgaria	BG
Česká republika	Czech Republic	Czech Republic	CZ
Danmark	Denmark	Kingdom of Denmark	DK
Deutschland	Germany	Federal Republic of Germany	DE
Eesti	Estonia	Republic of Estonia	EE
Éire/Ireland	Ireland	Ireland	IE
Ελλάδα (*)	Greece	Hellenic Republic	EL
España	Spain	Kingdom of Spain	ES
France	France	French Republic	FR
Italia	Italy	Italian Republic	IT
Κύπρος (*)	Cyprus	Republic of Cyprus	CY
Latvija	Latvia	Republic of Latvia	LV
Lietuva	Lithuania	Republic of Lithuania	LT
Luxembourg	Luxembourg	Grand Duchy of Luxembourg	LU
Magyarország	Hungary	Hungary	HU
Malta	Malta	Republic of Malta	MT
Nederland	Netherlands	Kingdom of the Netherlands	NL
Österreich	Austria	Republic of Austria	AT
Polska	Poland	Republic of Poland	PL
Portugal	Portugal	Portuguese Republic	PT
România	Romania	Romania	RO
Slovenija	Slovenia	Republic of Slovenia	SI
Slovensko	Slovakia	Slovak Republic	SK
Suomi/Finland	Finland	Republic of Finland	FI
Sverige	Sweden	Kingdom of Sweden	SE
United Kingdom	United Kingdom	United Kingdom of Great Britain and Northern Ireland	UK

Other countries	
Short name in English	Country code used
Croatia	HR
Iceland	IS
Liechtenstein	LI
Moldova	MD
Norway	NO
Turkey	TR
former Yugoslav Republic of Macedonia, the	FYRoM

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