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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

Competent Authorities on Substances of Human Origin Expert Group

(CASoHO E01718)

15th Meeting of the Competent Authorities for Organs

18-19 February 2019, Brussels

SUMMARY MINUTES

This meeting of Competent Authorities on Organ donation and transplantation took place on 18-19 February 2019. The previous meeting had taken place on 27 and 28 June 2018 in Brussels.

PARTICIPATION:

Competent authorities from all Member States attended the meeting except Luxembourg, Albania, Montenegro, Serbia and Turkey. In addition, representatives of the competent authorities from Norway and Republic of North Macedonia were present. Representatives from the European Centre for Disease Control and Prevention (ECDC), the Council of Europe (EDQM) and few private experts also attended the meeting.

The meeting was organised and chaired by the representatives of the European Commission/DG SANTE unit B4 (Medical products: quality, safety, innovation).

1-2. WELCOME AND ADOPTION OF THE AGENDA

The chair welcomed the participants and asked representatives attending for the first time to present themselves.

The Substances of Human Origin (SoHO) team introduced themselves and informed the participants of the usual house rules.

No additional topics were added to the agenda although the order was changed for some topics to accommodate the travel plans of particular speakers.

Participants were invited to state any conflicts of interest. None were declared.

Before the participants continued with the formal agenda points, a Lithuanian artist shortly presented her artwork related to organ donation and transplantation.

3. LEGISLATION

3.1. Transposition and implementation

The Commission informed the group that its verification of Directive 2010/53/EU is complete and that there are no follow-up actions at this stage unless any issues with transposition or implementation of the legislation are brought to its attention.

3.2. Evaluation of the EU legislation on blood, tissues and cells (COMM)

The Commission summarised the state of play of the Blood, Tissues and Cells Evaluation (BTC Evaluation). The BTC Evaluation is to provide a comprehensive assessment of the BTC directives, examining their functioning across the EU, assessing if their original objectives have been met and whether they remain fit for purpose.

Key messages emerging from the BTC evaluation were presented pointing to commonalities between the BTC and Organs sectors. The Commission invited the competent authorities to follow the process. In particular, the authorities will be invited to share the Commission report on the BTC Evaluation with the relevant national, regional and local administrations. The final report will be published in 2019.

The organ authorities recognised that the outcome of the BTC evaluation will be of utmost importance for the organs field because the report might initiate discussions on topics like Voluntary Unpaid Donation and other aspects which are also of high importance to the organs community.

The information about the ongoing BTC Evaluation can be found here: https://ec.europa.eu/health/blood_tissues_organs/policy/evaluation_en

4. COMMUNICATION RELATED AREAS

4.1 EUDONORGAN Pilot Project- training and social awareness (DTI- ES)

EUDONORGAN representative gave an update about the EUDONORGAN project.¹ This three-year EU funded project will finish in autumn 2019. The project aims to provide training and to increase social awareness regarding organ donation in the European Union (EU) and neighbouring countries with the ultimate goal of increasing the number of organ donors.

Within the framework of the project, the EUDONORGAN representatives have been organising the social awareness events on organ donation across the EU. In 2018-2019 Poland, Belgium, Greece, Hungary, Portugal and Sweden host events in a co-ordinated effort with EUDONORGAN and the national competent authorities to highlight the need for increased levels of organ donation to EU citizens.

A successful EUDONORGAN conference took place on 18 February 2019 in the European Parliament in Brussels. The conference brought together over 120 healthcare professionals and other relevant stakeholders coming from 33 countries. At the end of the event, the participants joined the esplanade of the European Parliament for a commemorative act consisting in a launch of biodegradable balloons dedicated to organ donors. More information about the event is available at the dedicated website.²

The Commission encouraged the authorities to support EUDONORGAN in organizing and participating in the remaining social awareness raising events across the EU. Remaining events – Stockholm 14 March - MS participating: Sweden, Denmark, Estonia, Finland; Athens 15 April - MS involved: Greece, Bulgaria, Cyprus and Lisbon 9 April - MSs involved: Portugal, Spain, France, Italy and Malta.

The information about the EUDONORGAN project can be found here: <http://eudonorgan.eu/>

¹ <http://eudonorgan.eu/>

² <http://eudonorgan.eu/european-parliament-open-its-doors-to-awareness-event-why-organ-donation-matters-to-us-all/>

4.2 Update on media issues and campaigns

DG SANTE presented an overview of the media stories that highlighted organ donation and transplantation.

5. ACTION PLAN

5.1 National Practices

5.1.1 A National approach to improving organ donation and transplantation

The Lithuanian NCA representative gave an overview about the national approach to improving organ donation and transplantation. National Transplant Bureau (NTB) functions were presented as well as the development of organ transplantations over the last years and the prevalence rates of organ transplantation procedures in the country.

In 2016-2017, two Lithuanian Transplantation Centres were audited together with international auditors. The activities of both centres were in line with the European quality, human resources and technical requirements for such institutions. In 2010, Lithuania signed an agreement with Eurotransplant for organ exchange. Lithuania is part of the FOEDUS platform since 2016.

The representative also mentioned that following the upcoming reorganisation of NTB, supervision of the activities such as audit will be taken from the NTB and transferred to another institution. The representative asked other NCA to share their best practices when combining blood and organ donation management systems.

5.1.2 Improving organ utilisation in the EU (ODTI, Ireland)

An ODTI representative gave a presentation on utilisation of Organs in the EU. Donation rates per million population (PMP) donations per death rate, variance in utilisation rates and outcomes following transplants were outlined. The representative suggested that international donor conversion rates for lung transplantation need to be standardised.

Some representatives noted the need to have European wide data. The discussion between competent authorities touched upon the national competence when managing the authorisation of the centres and mentioned that there is a positive impact on the donation system having authorised centres in place.

5.2. EU LEVEL ACTIVITIES

5.2.1 FOEDUS organ exchange portal

The Czech representative summarized the latest developments of the FOEDUS Organ exchange portal.

The FOEDUS organ exchange platform allows for rapid exchange of organs that cannot be allocated in the donor allocation country (so-called “surplus organs”), in particular for pediatric donors. This low cost platform is in place now for 3 years, allowing for several additional transplants per month. There are 13 countries that have access to the portal and 2 new countries applied. Most active organ offering countries in the EU through the portal are France, Spain and Italy while most organ transplanting countries are Italy, Czech Republic and France. On average per months, there are 15 organs offered and 2 transplanted. It was acknowledged that the FOEDUS platform allows for rapid exchange of “surplus organs”,

which are usually difficult to match or find (e.g. for children). Moreover, it is low cost platform established. Competent authorities congratulated on a successful work.

The project raised discussion on sustainability, vigilance reporting, communication and logistics on the international level. Eurotransplant has been invited to access and use the platform. A representative of Eurotransplant expressed openness for this.

More information about the FOEDUS platform can be found here: <https://www.foedus-eoeo.eu/#/public>

5.2.2 Thematic Network: Improving organ donation and transplantation (EKHA)

A representative of EKHA, the European Kidney Health Alliance, gave a presentation on the Thematic Network on the European Commission Health Policy platform³ called Improving organ donation and transplantation. EKHA's proposal to bring together stakeholders to advance the work of improving Organ Donation and Transplantation in the EU was selected by the European Commission as one of four Thematic Networks for 2019.

The thematic network will bring together a broad group of stakeholders in the field of organ donation and transplantation to promote sharing best practices and supporting solutions to increase organ availability, enhancing the efficiency and accessibility of transplant systems and improving the quality and safety.

EKHA presented the first ideas on a joint statement due in autumn 2019, calling for a new EU Action Plan. EKHA stressed the need to maximise the role of donor transplant coordinators, to improve knowledge and communication skills of healthcare professionals, to share good practices, to promote public awareness and trust, and to identify good practices for evaluation and registration. EKHA added the need to consider clustering countries with similar challenges, an EU-wide opt-out, and to assess and eliminate financial barriers for (living) donors as well as for hospitals.

DG SANTE suggested that it would be important to align EKHA's efforts with the NCA views and the plans of the upcoming Council Presidency (HR) on the EU collaboration in the organ field.

5.2.3 Plans of the HR Council presidency in relation to organ donation and transplantation.

HR presented its preliminary Presidency plans in the SoHO field in the upcoming Council Presidency in the 1st half 2020.

The HR representative announced that organ donation and transplantation will be one of three health priorities under the Presidency. Possible focus might be a call for a new Organs Action Plan, and for a follow up of the Commission Evaluation on Blood, Tissues and Cells legislation. HR might aim for a resolution, and host a high-level conference on organ donation and transplantation in February 2020.

The participants shared their initial ideas on the topics to be considered by the HR Presidency, an approach to be followed, a communication strategy with relevant stakeholders and a call for a new EU-level action plan.

³ The EU Health Policy Platform is a platform for collaboration and communication between the Commission and health stakeholders

All competent authorities agreed on the importance to prioritise the topic of organ donation and transplantation. However, some NCA questioned the need to call for the new action plan as the implementation of the priority actions at the national level should rather be a priority. SANTE representatives confirmed that, with or without a new EU Action Plan, the first priority should be on national implementation. SANTE representatives also suggested to explore possibilities in other EU financial instruments like on research or on education. SANTE also reiterated the link to the ongoing evaluation of blood, tissues and cells legislation.

Spain suggested to the HR presidency to consider bringing forward a high-level declaration of commitment between the Member States in this areas. The authorities will be updated on HR plans at the next NCA meeting.

6. INTERNATIONAL

6.1. Council of Europe Activities

A representative gave an update on Council of Europe (CoE) activities within the European Committee on Organ Transplantation (CDPTO). The committee focuses on developing quality, safety and ethical standards, promoting non-commercialisation of organ donation and fighting against organ trafficking. CDPTO presented the 8th edition of its technical guide⁴ on Organs (2018). The guide is to provide professionals with a useful overview of the recent developments in the field and contribute to the harmonisation of these activities, facilitating uniform standards and practices.

The representative called on the NCA to help disseminate the guide in particular through conferences, trainings and their national websites.

CoE also presented work on vascularised composite allotransplants (face, hand, ...), on DCD and on trafficking-related activities, including traveling for organ transplantation and its position on the Global Kidney Exchange concept.

Other activities such as CoE instruments against organ trafficking and human trafficking, technical guidance, awareness raising activities in Organ Donation and international monitoring were presented.

6.2. United Nations Resolution 73/189

ONT gave a short presentation about the United Nations Resolution 73/189 “Strengthening and promoting effective measures and international cooperation on organ donation and transplantation to prevent and combat trafficking in persons for the purpose of organ removal and trafficking in human organs”. This resolution, adopted on 17 December 2018, was promoted by Guatemala and Spain, and co-sponsored by 69 countries. Through this resolution, the World Health Assembly urges member states to adopt measures to combat and prevent organ trafficking and trafficking in persons for the purpose of the removal of organs, and to protect victims of such crimes.

6.3. WHO activities

⁴ General info about the Guides: <https://go.edqm.eu/OTg>
Free download of the Guides: <https://www.edqm.eu/freepub/>
Purchase paper copies of the Guides: <https://store.edqm.eu>

The WHO representative introduced its current activities in organ transplantation: legislation, policy development, training of professionals, assisting authorities in development of organ allocation systems, follow up of the living donor, transplant patient follow up and management. The new country focus action framework and worldwide report on the activities of replacement was also introduced.

The WHO representative welcomed the collaboration with the Organ Competent Authorities and suggested strengthening it further in future.

7. VIGILANCE AND SURVEILLANCE

7.1. Update by the European Centre for Disease Prevention and Control (ECDC)

ECDC gave an update on the work carried on in the SoHO field. The presentation included an overview of Ebola virus disease outbreak in Democratic Republic of Congo (DRC) and transmission of tularaemia by solid organ transplantation as well as ECDC SoHO activities in 2019.

Concerning the Ebola virus, since the beginning of the outbreak in May 2018 there were hundreds of Ebola virus disease cases, including deaths. The overall risk of spread of Ebola virus within the EU/EEA is very low. However, the risk can only be eliminated by stopping transmission at the local level. ECDC is updating the recommendation for safety of SoHO. On human-to-human transmission of infection of tularaemia ECDC representative mentioned a case registered in July 2017 when fever and sepsis developed in 3 recipients of solid organs from a donor, a recipient died. ECDC suggested that clinicians should be aware of the possibility of tularaemia infection in patients receiving organ transplants. When evaluating potential organ donors with febrile illnesses, clinicians should consider risk factors for tularaemia such as recent contact with animal carcasses, arthropod bites and landscaping activities.

ECDC currently also assesses the risk of bacterial infections transmission through SoHO. It also envisages assessing the risk and prevention of fungal and parasitic infections transmission through SoHO. It also updates relevant recommendations and it will hold an expert meeting on pathogen inactivation of blood and blood components.

The Commission highlighted the importance of the work conducted by ECDC for the SoHO sector. NCA called for a more structured role for ECDC in SoHO, amongst others to allow for streamlined alert messages.

7.2. Update Commission activities related to vigilance and surveillance (COMM)

The Commission presented the ongoing work on Rapid Alerts on Blood (RAB) and Tissues and Cells (RATC), and the Vigilance Expert Subgroup work.

Concerning Rapid Alerts, it was noted that by February 2019 eight alerts were made on reproductive tissues and cells.

The summary of RAB/RATC activities of 2018 will be soon published. Update of the RAB/RATC disclaimers and of the Data Protection Officer notification are ongoing and to be implemented in due course

Note: the summary has been published in the meantime under https://ec.europa.eu/health/sites/health/files/blood_tissues_organ/docs/2018_ra_soho_summary_en.pdf

A dedicated BTC meeting of the VES (Vigilance Expert Sub-group) focusing on SARE is planned for May 2019. Importantly, the SARE annual reporting will move from a PDF to a web-form for the data collection by DG SANTE. Next VES meeting will be organised in November 2019.

The Commission also informed the meeting regarding the Vigilance Expert Sub-group (VES), under the CASoHO expert group. Overall, this expert sub-group focus on the vigilance aspect was included in the evaluation of the BTC legislation and might propose improvements to vigilance. Following the request of the NCA brought forward in the last NCA meeting, the Commission services extended the scope of VES to include the organ field. The aim is to improve vigilance in the organs sector to promote optimal and standardized approaches to SARE reporting for organs, building on experience from the blood and T&C sectors. Priority areas in the VES organ field suggested by NCA are engagement of clinicians, pilots on sentinel event report sharing across member states and annual meetings to share experiences.

The authorities reiterated their interest in elaborating vigilance in the organs sector, building on experience from the blood, tissues and cells sectors.

The ONT representative raised an issue concerning biovigilance of organs and tissues and cells. It was noted that there is a need to develop a systematic approach so that the information disseminated by the ECDC in relation to risks for donation would effectively reach the Organ and TC Competent Authorities. Competent authorities emphasized a necessity to strengthen cooperation between ECDC and the NCA to address issues related to biovigilance in the sectors.

8. OTHER EU AREAS OF POSSIBLE INTEREST FOR ORGAN DONATION AND TRANSPLANTATION

8.1. European Reference Network working on kidney diseases (EKRNet)

The authorities were interested in a presentation of European Reference Network on rare kidney diseases (EKRNet). It is a consortium of 38 expert nephrology centres in 12 Member States providing healthcare to 40 thousand patients with rare kidney disorders. ERKNet is dedicated to improve the knowledge about rare kidney diseases among patients and healthcare professionals. The network offers virtual consultation services to physicians throughout Europe who need advice for dealing with challenging cases with a rare kidney disease.

The EKRNet representative elaborated on ERKNet activities, provided information about their members and explained the network added value. Collaboration with corresponding expert workgroups was encouraged.

8.2. Activities of European Society of Organ Transplantation (ESOT)

The European Society of Organ Transplantation (ESOT) representative gave an interesting presentation outlining the objectives as well as current and future projects of the society. ESOT welcomed the collaboration with DG SANTE and presented its main topics of activity such as education, research, promotion of organ donation and transplantation, quality assurance to be further elaborated in the future.

It was also announced that the ESOT transplant Congress will take place in Copenhagen on 15-18 September, including a joint session with NCA's and SANTE on 17 September. The

session will focus on how to ensure quality, including perspectives from professionals, authorities, COM and expert bodies like CoE. NCA representatives are invited to join the Congress.

In parallel, the Danish Organ Competent Authority will organise an informal Competent Authority meeting on 18 September 2019 so that the representatives of the Competent Authorities could attend both events.

WHO representative suggested that the WHO regional office in Copenhagen might join ESOT Congress and the informal NCA meeting.

9. DATA MANAGEMENT

9.1 SoHO registries meeting (COMM)

The Commission outlined the objectives of the upcoming ad-hoc meeting on data registries planned on 20 of February 2019 and invited the competent authorities to participate. In the meeting, the experiences in registry building, data management and technologies, data protection were to be addressed.

The importance of mutual cooperation and sharing of good practices was highlighted. The outcomes of the previous meeting on data registries organised in January 2018 were summarised. The topics of common interest and challenges for registry holders include set-up, structure, data collection, data quality, outcomes and governance.

Authorities also expressed interest in possible use of the data from these registries to support their oversight tasks like vigilance and authorisations.

9.2. EDITH- Pilot project grant on chronic kidney diseases

The EDITH Pilot project on chronic kidney diseases was presented by the collaborating partners in charge of the different work packages.⁵ They provided an overview, state of play and outputs already achieved in the project that is moving towards the end.

One objective of the project is to assess the different treatment modalities for end-stage kidney disease, including transplantation. An important part of the project is a roll-out of a registry to follow up living kidney donors and recipients of kidneys.

The findings of the project including a clear overview on cost/benefit of treatment options for end-stage renal disease should support decision making at political level regarding future investment in transplant programmes in Member States.

The Commission emphasised the importance of a self-sustainable living donor follow-up register and a recipient follow-up register, fed by real world data from clinicians in different MS and centres.

The NCA and EDITH representatives agreed that it is necessary to ensure sustainability of the project after it finishes. This will require a neutral host/guardian as well as clear governance rules, a.o. on the collection, ownership and use of data. It was suggested to combine “scientific” and “political” oversight in the governance structure ESOT might be willing to play a guardian role regarding the scientific part. It was suggested that the CA of

⁵ The project is led by Deutsche Stiftung Organtransplantation (DE); 9 partners including NCA, European Organ Exchange Organisation, professional association, research institute and 20 collaborating partners from more than 15 countries participate in the project.

the participating (data delivering countries) could play a role in the political part. Based on these discussions DSO/DE, leading the EDITH project, will suggest a governance structure and propose a strategy for the project to become self-sustainable after the end of the project. The proposed sustainability plan is to be presented and discussed in the next competent authorities meeting.

10. EU-FUNDED RESEARCH PROJECTS

10.1. Research priorities for organ donation and transplantation in the EU (DG SANTE)

The Commission (DG SANTE) gave an overview of the recent exchanges with relevant stakeholders about the possible research priorities for organ donation and transplantation. From the previous ad-hoc exchanges with ESOT and Eurotransplant the following topics came forward: organ quality/preservation, alternative sources of organs (hybrids, xeno, marginal/extended criteria donors), follow-up data collection and use, benchmarking, improved matching, surrogate end-points for post-transplant outcomes, immunology, new technologies (testing, preservation, ...), studies of economics and set-up of changes in organisation, skills of professionals and regulation, communication and public literacy. Participants were invited to send in further thoughts.

10.2 Horizon Europe (DG RTD)

The Commission (DG RTD) presented proposal for Horizon Europe. Horizon Europe is the Commission proposal for a € 100 billion research and innovation funding programme for seven years (2021-2027). The objective is to strengthen the EU's scientific and technological bases, to boost Europe's innovation capacity, competitiveness and jobs and to deliver on citizens' priorities and sustain our socioeconomic model and values.

The programme consists of three pillars: open science, global challenges and industrial competitiveness and open innovation. Organ transplantation mission is included across all the pillars. DG RTD representative suggested that the stakeholders looking for funding for research look into different pillars to consider the specific information.

Horizon Europe dedicated website <http://ec.europa.eu/horizon-europe>

11. ANY OTHER BUSINESS

NA

12. CLOSING OF THE MEETING

The chair thanked the group for their active participation in the meeting. The next meeting of Organs competent authorities (informal CA meeting) will be organised by the Danish Organ Competent authority on 18-19 September 2019. Further information will be sent by the authority.