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Competent Authorities on Substances of Human Origin Expert Group (CASoHO E01718)

13th Meeting of the Competent Authorities for Organs

5 – 6 April 2017, Brussels

SUMMARY MINUTES

This meeting of the Competent Authorities on Organ donation and transplantation took place on 5 and 6 April 2017. The previous meeting took place on 9 – 10 June 2016.

PARTICIPATION:

Competent authorities from all EU Member States were represented at the meeting with the exception of Luxembourg. In addition, representatives of competent authorities from Norway, the Former Yugoslav Republic of Macedonia, Montenegro, Serbia, and Turkey were present. The representatives of the Consumer, Health and Food Executive Agency (Chafea), the Council of Europe (EDQM), the European Centre for Disease Prevention and Control (ECDC) and the World Health Organisation (WHO) were present as observers.

Three European Organ Exchanges Organisations (EOEOs), Eurotransplant, Scandiatransplant and the South Alliance for Transplants (SAT), also attended the meeting. External speakers from the Dutch Research Institute NIVEL, University Hospital Regensburg (DE), the TPM-DTI Foundation and University of Barcelona (ES) came for their respective agenda points.

European Commission (DG SANTE): Mr D. SCHNICHELS (chair), Mr S. VAN DER SPIEGEL, Ms D. FEHILY, Ms I. PUCINSKAITE-KUBIK, Mr P. CATALANI, Mr R. Mc GEEHAN.

Administrative Assistants: Ms A. CORNEA

1-3. WELCOME, INTRODUCTION OF NEW PARTICIPANTS, ADOPTION OF THE AGENDA

The agenda was adopted without major modifications. New participants were introduced.

No additional items were added under Any Other Business. No conflicts of interest were reported.

4. LEGISLATION

4.1. Transposition of Directive 2010/53/EU

The Commission updated the participants on the status of the transposition check of the organs legislation in the EU Member States (MS). It was reported that the legal assessment of 24 MS

has already been completed and two MS had been asked to send additional information in March 2016. Remaining MS were expected to provide further information in due course.

The Commission informed the group that administrative letters regarding the remaining open points identified in the transposition check had been prepared and were due to be sent out to the Member States concerned.

4.2. Update on the implementation survey for Directive 2010/53/EU

In January 2017, the Commission published the first implementation report and the associated detailed technical document (Staff Working Document) on the Member States' implementation of the Organs Directive (2010/53/EU). The report focuses on the set-up of National Competent Authorities and the oversight of procurement and transplantation activities.

All MS and Norway have established competent authorities for organs but there were significant differences in terms of their set-up and structures.

A need to improve effective communication between and within the countries was highlighted. MS are expected to concentrate their efforts to ensure an effective implementation of the Organs legislation. Future implementation surveys and reports should demonstrate MS progress in the field.

4.3. Evaluation of the EU legislation on blood, tissues and cells

The Commission summarised the background to the launch, at the beginning of 2017, of a full evaluation of the blood and the tissues and cells (BTC) legislation in line with the Commission's principles of Better Regulation.

The Implementation Reports for these two sectors had highlighted that overall there is a good level of implementation of the EU legal requirements across the EU. However, the reports also pointed to some gaps in the implementation and enforcement of the requirements and issues in interpretation across the MS. The reports suggested the need for a more formal and detailed evaluation of the legislation, which includes Directive 2004/23/EC, Directive 2002/98/EC and their implementing legislation.

The process was launched with the publication of a Roadmap summarising how the evaluation will be carried out. It also defined 5 key specific assessment criteria for the evaluation and the sources of information to be used as evidence to support it: relevance, effectiveness, efficiency, coherence and EU added value.[1] The plan for involving an external contractor to conduct a study and an overview of the stakeholder consultation strategy was presented.

The Commission informed the meeting that a final evaluation report in the form of a Commission Staff Working Document is expected to be published by the end of 2018. Any decision on a potential change in legislation can only be taken once the evaluation has been concluded.

The competent authorities welcomed the BTC evaluation and some pointed to commonalities between the BTC and Organs sectors.

The Commission invited the competent authorities to follow the process and in particular to provide inputs in the upcoming public consultation on the evaluation.

[1] The roadmap, along with all other key information relating tot he evaluation, is available on a dedicated DG SANTE webpage: https://ec.europa.eu/health/blood_tissues_organs/policy/evaluation_en

5. ACTION PLAN ORGANS

5.1. Indicators 2015 data (ONT-ES)

Spain presented the ONT/Council of Europe indicator data on organ transplantations and donations in Europe. Overall, the indicator data confirmed an encouraging trend of increasing transplant rates. There was an increase of 800 organ transplants compared with 2014, confirming a positive trend in transplant rates.

A discussion followed on how the competent authorities expect this trend to go in future and what could be done to sustain it. The representatives elaborated on new donor sources, in particular on the possibilities for donation after cardiac death (DCD), the value of cross-border exchange and collaboration in lung transplant programmes. It was highlighted that in particular DCD as a type of donation has a potential to significantly increase the numbers of patients transplanted.

5.2. EU-funded activities

5.2.1. FOEDUS Joint Action

The Czech representative gave an update on the state of play of the Organ Exchange Portal. The portal has allowed for 31additional transplantations of surplus organs in 2016, which is similar to 2015 numbers (23 in 9 months). It often concerns transplants for children with organs that are difficult to allocate and would otherwise not be used.

The setting of guidelines for cross-border organ exchange, along with a consensus on donors' medical data and its protection was welcomed by the representatives.

The portal has been used by 11 MS and recently, Bulgaria and Switzerland joined the portal. The Commission asked other MS and EOEOs if they consider collaborating and thus supporting the platform's activities. In particular, the Commission considered that participation of Eurotransplant and Scandiatransplant would reinforce the platform's added value. Belgium suggested that the national legislation in place does not allow it to work with the platform directly and with the two EOEO simultaneously. The only way to resolve this issue would be for Eurotransplant and Scandiatransplant to participate in FOEDUS, so that all transactions could be carried out through the platform. The representatives of Eurotransplant and Scandiatransplant explained that given the differences in procedures and the existing bilateral agreements between the countries, the collaboration with FOEDUS is not envisaged for the time being. Only few organs remain unallocated within these EOEOs, but the platform might offer them additional organs. The EOEOs will take the question back for further internal consideration.

Also the development of guidelines for cross-border organ exchange, along with a consensus on donors' medical data and data protection was welcomed by the representatives.

5.2.2. Pilot project grant on chronic kidney diseases - EDITH

Germany gave an overview of the EDITH Pilot Project. This 3 year project started in January 2017 and is funded from the EU budget, on the initiative of the European Parliament. It has an objective to assess the different treatment modalities for end-stage kidney disease, including transplantation, as well as support the establishment of follow-up registries.

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

An ongoing assessment of the different treatment options for end-stage renal failure, including from an economic point of view, was presented. The assessment includes factors that influence the choice of treatment, along with their impact on health expenditure and patient outcomes. The findings of the project might be useful in considering future investment in transplant programmes in MS.

The EDITH project also aims at supporting the establishment of a living donor follow-up register and a recipient follow-up register. The work packages of the project build upon work carried out under previous actions - ACCORD for living donation and EFRETOS for recipient follow-up.

The Commission expressed its high expectations for this project, including a clear overview on cost/benefit of treatment options, a functional and self-sustainable living donor follow-up register and a developed and proven recipient follow-up register, fed by real world data from clinicians in different MS and centers.

5.3. National Practices

5.3.1. Donation after Cardiac Death

Spain gave an overall update on the latest initiatives in the country to increase organ availability, one of these being the DCD programme. Other strategies were presented and discussed with participants. The good practices in the regions and medical centres with highest levels of transplantations and donations have been extended to other parts of the country.

A discussion followed on the profile of the average donor, which has changed significantly over the last decade. Greece and Finland commented that increasing the rate of donation for those above 70 years old was important to consider.

Participants consider DCD to be a practice that offers important potential to further increase donation and transplant numbers, and expressed interest in further knowledge sharing on this practice.

5.4. Final review of the Organ's Action Plan – FACTOR study

The Dutch Research Institute NIVEL, contractor for the study on the final review of the Organs Action Plan, presented the results of the FACTOR study. The study focused on the uptake and impact of the EU Action Plan on organ donation and transplantation (2009 – 2015).

Overall, the study revealed that since the adoption of the Action Plan, the total number of organ donors at the EU level has considerably increased, i.e. from 12.3 thousand in 2008 to 14.9 thousand in 2015. This amounts to a 21% increase over the period. An encouraging trend was also observed in the number of transplants over the period of the Action Plan. There was an increase of 4.641 transplants, from 28.066 transplants in 2008 to 32.707 in 2015; a 17% increase over the period.

Differences in growth of donation rates and organs transplanted between the countries can be observed. Whereas most countries have demonstrated a steady increase in donation rates and organs transplanted since the adoption of the Action Plan, some countries also have reported a fluctuation or fall-back.

NIVEL highlighted that the Action Plan has helped countries in different ways, but most importantly by setting a shared agenda and by facilitating EU-wide cooperation. Member States recognize in the FACTOR study that EU-funded projects have significantly contributed to the goals of the Action Plan.

The study indicates that MS appreciated the Action Plan, which served to build a common agenda and to engage political support. In the meeting, the NCA's expressed interest in a future Action Plan, possibly in a joint context of the planned activities for blood tissues and cells.

Italy highlighted the importance of having other fora (e.g. informal meetings) where the NCA could meet and continue the discussions on the state of play in organ donation and transplantation. [*Note: Since the meeting the first such informal meeting of NCAs for Organs has now been organised by CNT and will be held in Rome on January 15th and 16th 2018*].

NCA's have been consulted and asked for input on the draft final report. The representatives were reminded to submit any comments by 26 April 2017. The Commission mentioned that the final report will be published later in the year.

6. VIGILANCE AND SURVEILLANCE

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

ECDC gave a presentation on developments in the area of infectious diseases. Insights were shared on the Zika virus epidemic along with a first update on the EU guide to preparedness activities on preventing Zika virus transmission through substances of human origin.

The NCAs were also informed on the outbreak of yellow fever in Brazil and the case of a fatal tick-born encephalitis virus infection in an organ transplant setting.

6.2. Update on Commission activities related to vigilance and surveillance

The Commission presented the ongoing work on Serious Adverse Reactions and Events (SARE) reporting, along with the work on Rapid Alerts on Blood (RAB), and on Tissues and Cells (RATC).

A new version (version 1.2) of the RAB and RATC platform was released on 23 November 2016. The new version includes a number of modifications to improve the user interface and a possibility for alerts of epidemiological relevance to be automatically sent to ECDC who have the possibility to add comments.

The annual summary of RAB and RATC activities for 2016 will be published in due course on DG SANTE's web site.

[Note added subsequently: 2016 SARE reports and RAB and RATC annual summaries have since been published and are available here:

https://ec.europa.eu/health/sites/health/files/blood_tissues_organs/docs/2016_rab_summary_en.pdf

https://ec.europa.eu/health/sites/health/files/blood_tissues_organs/docs/2016_ratc_summary_en.pdf

xx link to SARE reports

6.3. National/regional experiences related to vigilance and surveillance

6.3.1. Belgium

Belgium presented their experience with SARE reporting. It was mentioned that the institutional changes have been introduced over the last few years to increase the effectiveness of SARE reporting, along with a traceability system of organ donors and recipients. It was highlighted that local, regional, national authorities should work together to ensure the effective functioning of the system.

6.3.2. Scandiatransplant

Scandiatransplant presented the implementation of a new SARE reporting approach amongst the Scandiatransplant members. The focus of the new approach is on governance. According to Scandiatransplant, the medical professionals asked for a novel IT tool in order to report SARE cases and this has been developed. Through the system, a unified reporting for five countries is ensured.

6.4. Possible needs in/for the organ sector

The Commission informed participants that a new SoHO Vigilance Expert Sub-group established under the Expert Group CASoHO E01718 in January 2017. The group replaces the previous Haemovigilance Expert Sub-group. It was clarified that this Sub-group shall provide technical expertise to the Commission in the following areas such as SARE, RAB/RATC and other vigilance and surveillance activities.

The Commission asked for the NCA's views on a possibility to include Organ vigilance experts in the newly created Vigilance expert sub-group.

NCA's expressed an interest in vigilance activities at EU-level for Blood, Tissues and Cells. The UK welcomed the EU efforts in creating the vigilance sub-group and proposed that combining organs with tissues and cells/blood vigilance might be of great interest to the practitioners in these fields. Spain commented on the importance of vigilance from a cross-border perspective and the useful exchange of information on both organ donors and recipients. Other representatives echoed that having a cross-sector Vigilance expert sub-group would also be beneficial to practitioners to exchange information and good practices.

The Commission will take this suggestion back to the Vigilance Expert Sub-group.

7. COMMUNICATION ACTIVITIES

7.1. Pilot Project EUDONORG (DTI-ES)

EUDONORGAN project[2] is a 3 year service contract awarded by the European Commission from the European Union budget, on the initiative of the European Parliament. It started in September 2016. The project is carried out by a transnational Consortium involving leading countries in organ donation and transplantation management from Central and Southern Europe: Croatia, Italy, Slovenia and Spain.

The objective of EUDONORG is two-fold: (1) to train professional trainers and patient associations on organization and communication of organ donation/transplantation, (2) to raise public awareness on organ donation, by organising a series of national events for the media.

As EUDONORGAN was open to welcome more participants for their planned training and awareness events, NCA's were invited to nominate participants.

The NCA's welcomed the progress achieved in this project and shared the view that journalists should be involved to maximize the impact of the project.

[2] http://eudonorgan.eu/

7.2. Update on media issues and projects (tour de table)

The Commission mentioned two initiatives at the European Parliament with interest in and support for organ donation: a session organised by the Pulmonary Hypertension Association – Europe (PHA EUROPE) and the declaration on idiopathic pulmonary fibrosis, calling a.o. for more organ transplantation.

The Commission asked the representatives if there were any media events they wanted to inform the meeting about. France mentioned a documentary movie called "Reparer les vivants" on organ transplantation which recently featured in movie theatres[3] with a high level of public interest and commercial success.

8. EU FUNDING FOR ORGAN DONATION AND TRANSPLANTATION

The Commission had invited a series of presentations on possible EU-funding programmes that can be of useful for professionals and/or authorities in the SoHO sector.

8.1. EU-funded Research Projects

8.1.1. ONE Project (Regensburg University – DE)

The ONE Study: Immune Cell Therapy in Renal Transplantation (the ONE Study) is a project funded under Horizon2020. The ONE Study consortium is made up of thirteen partners: eight are academic institutions and five are companies that support research. Five countries are represented: France, Germany, Italy, the United Kingdom and the United States of America.

The ONE Study's primary objective is preventing immunological rejection of transplanted organs without the need for long-term use of pharmacological immunosuppression. The ONE Study applies the novel concept of cell therapy to human clinical organ transplantation. This project aims at developing various immunoregulatory cell products in organ transplantation recipients, allowing a direct comparison of the safety, clinical practicality and therapeutic efficacy of each cell type.

8.1.2. Horizon 2020 plans (DG RTD)

The Commission gave a general introduction on Horizon2020 plans and potential applications for organ transplant related work.

8.2. Digital Single Market (DG CNECT)

The Commission briefly presented the Commission actions in the area of digital health and potential applications for transplant related work.

8.3. Continuous professional learning (DG EAC)

The Commission presented possible programmes under Erasmus+ to support training and education of professionals (e.g., transplant co-ordinators or surgeons) and authorities (e.g. inspectors).

Erasmus+ and structural funds seemed of particular interest, for example to support training programmes for professional inspectors, and might be explored further.

[3] https://www.france.tv/france-2/telematin/295239-spectacle-reparer-les-vivants-tartuffe.html

8.4. European Reference Networks (DG SANTE)

The Commission presented the newly launched European Reference Networks, of which one is focusing on organ transplantation in children.[4]

8.5. Structural funds (DG SANTE)

The Commission presented structural funds and other investment opportunities in health, which could be leveraged to support organ transplant programmes, in particular in EU regions with lower incomes.

9. INTERNATIONAL

9.1 Council of Europe activities (EDQM)

The Council of Europe presented recent activities of the European Committee on Organ Transplantation (CDPTO). Plans to update the Guide to the quality and safety of Organs for Transplantation and the Guide to the quality and safety of Tissues and Cells for human application were outlined. A number of other projects carried out by EDQM in the organ field were described.

9.2. Resolution on Medical Products of Human Origin (WHO)

WHO gave an overview of WHO activity on SoHO. The representative highlighted the Resolution on Medical Products of Human Origin (MPHO). The common principles on donation and use of MPHO included in the resolution were presented, in particular the principle 5 (financial neutrality). Importantly, the WHO Health Assembly has acknowledged altruistic voluntary and non-remunerated donation as the cornerstone of safety and quality in medical products of human origin and as a means to protect the donor against exploitation.

The Commission reminded the group that the Charter of Fundamental Rights of the European Union prohibits making the human body and its parts as such a source of financial gain. The EU Directives also include provisions for voluntary and unpaid donation.

[Note added subsequently: The principles outlined in the paper which were presented to the World Health Assembly in 2017 on achieving global consensus on governance of Medical Products of Human Origin were aligned with the EU legal framework.]

9.3. Trafficking related initiatives (ONT-ES)

Spain presented some of the latest activities addressing this topic.

The issue of organ trafficking has been a concern in recent decades. The presentation highlighted that transplant tourism entails illicit and criminal activities, is unethical to donors and recipients in need and represents a threat to public health.

The highlights of the Declaration of Istanbul Custodian Group (DICG) Workshop on the ethics of travelling for transplantation (April 2016, Madrid) and the 2017 Pontifical Academy Summit on Organ Trafficking and Transplant Tourism (February 2017, Vatican) were presented.

[4] ERN TRANSPLANT-CHILD: European Reference Network on Transplantation in Children. https://ec.europa.eu/health/sites/health/files/ern/docs/erntransplantchild_factsheet_en.pdf

10. ANY OTHER BUSINESS

10.1. Discussion with stakeholders (DG SANTE)

The Commission presented two stakeholder organisations, i.e. Pulmonary Hypertension Association – Europe (PHA EUROPE) and European Kidney Health Alliance (EKHA).

These organizations might be invited to present their key points of interest at the future NCA meetings.

11. CLOSING OF THE MEETING

The Chair thanked the group for their positive participation in the meeting.

The next meeting of Organs competent authorities has been scheduled for 27-28/6/2018. As usual, the date will be confirmed at the latest six weeks ahead of the meeting.

Note: CNT, the Italian Competent Authority has invited all NCA's for an informal interim meeting in Rome on 15-16 January 2018.