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

14th Meeting of the Competent Authorities for Organs

27-28 June 2018, Brussels

SUMMARY MINUTES

This meeting of the Competent Authorities on Organ donation and transplantation took place on 27 and 28 June 2018. The previous formal meeting had taken place on 5 and 6 April 2017 and an informal meeting was held in Rome on 15 and 16 January 2018.

PARTICIPATION:

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

The European Organ Exchanges Organisations (EOEOs), Eurotransplant and Scandiatransplant also attended the meeting. External speakers from the Catholic University of Leuven (BE), the TPM-DTI Foundation and University of Barcelona (ES) and DSO (DE) came for their respective agenda points.

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

1-3. WELCOME AND ADOPTION OF THE AGENDA

The chair welcomed the participants, noting a full and interesting agenda. The representatives attending for the first time were asked to present themselves. The DG SANTE SoHO team members introduced themselves to the new representatives and informed the meeting of the usual house rules.

The agenda was adopted without modification. Participants were invited to declare any conflicts of interest. None were declared.

4. LEGISLATION

4.1 Transposition and implementation of EU legislation

The Commission informed the group that its verification of Directive 2010/53/EU is complete and that it does not intend any follow-up action at this stage unless any issues with transposition or implementation of the legislation are brought to its attention. The group were also reminded that under Directive 2012/25/EU there is an obligation to provide up-to date contact details in order to facilitate the exchange of information between competent authorities for the purposes of cross-border organ exchange. A request was made for the Commission to send an annual reminder e-mail.

The Commission also reminded the group that this point on the agenda is an opportunity for members of the group to raise any points relating to the transposition and implementation of the Directive. One such point was raised on Directive 2012/25/EU and the contact details website established on this basis. While the contact details of competent authorities are available, contact details of the donor consent national registries are not available where these are outside the competent authority set-up. It was pointed out that such information would be useful for ad hoc consultation where/when the consent status of a potential donor from another country is unclear / unknown. The Commission agreed to look into the feasibility of adding such information if there is sufficient interest from the group for doing so.

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

The Commission gave an update on the evaluation of the blood and the tissues and cells (BTC) legislation. The 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.

The Commission presented the key messages emerging from the BTC evaluation. The competent authorities welcomed the BTC evaluation and pointed to commonalities between the BTC and Organs sectors. In particular, the authorities recognized that the outcome of the BTC evaluation will be of importance for the Organs field as it addresses VUD (Voluntary Unpaid Donation), donor safety and other issues which are being debated by the broader SoHO community.

Concerning donor safety (donor counselling, donation frequency, donor vigilance, traceability and follow up) the Open Public Consultation organized by the Commission as part of the BTC evaluation revealed that these areas were more adequately addressed in the Organ legislation than in the BTC legislation. On VUD and compensation, it was mentioned that the requirements are considered clearer and stricter in the Organ legislation than in the BTC legislative framework. The participants added that communication between the BTC and Organs sector is not always optimal (e.g. for vigilance) and that this shortcoming could be noted in the BTC evaluation.

The Commission invited the competent authorities to follow the process and to share the outputs from the BTC Evaluation with the relevant national, regional and local administrations.[1]

A final Evaluation Report in the form of a Commission Staff Working Document is expected to be published in H1 2019. Any decision on a potential change in legislation can only be taken once the evaluation has been concluded.

[1] Summary of the Stakeholder consultation on the BTC Evaluation;
https://ec.europa.eu/health/blood_tissues_organs/consultations/implementation_legislation_en,
https://ec.europa.eu/health/sites/health/files/blood_tissues_organs/docs/2018_consultation_evaluationbtc_report_en.pdf

5. ACTION PLAN ORGANS

5.1 EU-level activities

5.1.1. FOEDUS Joint Action

The Czech representative summarised the latest developments of the FOEDUS Organ Exchange Portal.

The FOEDUS organ exchange platform allows for rapid exchange of surplus organs, in particular for pediatrics. This low cost platform is in place now for 2,5 years, allowing for several additional transplants per month. There are 13 countries who have access to the portal and three more are interested in joining.

Since 2013, the platform has been used to offer over 500 surplus organs, and led to 64 effective transplants. Hearts and livers form the majority of transplanted organs, and often the recipients are children. Every month there are (on average) 15 organs offered and 2 organs transplanted by the participating countries. The FOEDUS platform was considered an efficient and simple tool for international organ exchange.

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 would reinforce the platform's added value. Several NCAs from Eurotransplant Member States expressed the strong preference for Eurotransplant to work with the FOEDUS-EOEO IT platform. The MS representatives encouraged EOEOs to collaborate with FOEDUS in the future. Eurotransplant showed willingness to consider joining the Foedus platform and suggested to take the question back for further internal consideration.

5.1.2. Pilot project grant on chronic kidney diseases - EDITH (DSO-DE)

The EDITH Pilot project on chronic kidney diseases was presented by the German representative. This 3 year project started in January 2017 and is funded from the EU budget, on the initiative of the European Parliament[2]. It has an objective to assess the different treatment modalities for end-stage kidney disease, including transplantation. Importantly, the EDITH project focuses on creation of the registers to follow-up of living kidney donors, and of kidney transplant recipients. The project will finish by the end of 2019.

The findings of the project should support decision making regarding future investment in transplant programmes in MS. The Commission noted that when the EDITH project results become available, it will be important for the National Competent Authorities to ensure that the results are disseminated and inform the national political level of this work.

The Commission encouraged the authorities to actively participate in the project and expressed its high expectations for this project, including a clear overview on cost/benefit of treatment options for end-stage renal disease (ESRD), 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.

The participants mentioned that sustainability of the project might become an important aspect in the future, i.e. after the project is finished.

[2] The project is led by Deutsche Stifttung 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.

5.2. National Practices

5.2.1. Recent activities in the UK, with a focus on ex-vivo treatments (HTA)

The UK representative gave an update on changing views and behavior of minority communities on organ donation and transplantation, best practices in perfusion technology and ex-vivo organ perfusion devices. In the UK, one third of the kidney waiting list is made up of people who are from black or Asian communities. There is a challenge to address the religious and cultural barriers to deceased donation and encourage living donation amongst minority communities. Increasingly new technology is being used to assess and recover the functioning of donated organs. The representative mentioned that there might be a need for pan-European overview of the evidence, costs and use of perfusion technology.

Concerning the use of ex-vivo perfusion as a platform to deliver treatments to organs prior to implantation in the UK, during the past few years it has become quite commonplace. The authorities were informed that this not only allows organs to be sourced from much further afield it also means clinicians have much more time to assess an organ function, removing the risk of an organ failing post-transplant. Examples of the perfusion devices mentioned were OrganOx (livers), Organ Care System (heart lungs, liver) and LifePort (kidney and liver), Organ Assist (kidney, liver, lung). The authorities discussed technologies, and the control measures applied for organ perfusion circuits.

The presentation raised questions on how perfused organs are regulated, in particular as some ex-vivo therapies might be applied, including the ex-vivo application on organs of ATMP's. An active discussion on authorization for preparation processes is needed. The Commission echoed that in the Blood, Tissues and Cells evaluation a message comes out strongly that there is a need to strengthen the programmes for authorization of preparation processes in that field.

5.3. EU-funded Research Projects

5.3.1. Biomarkers of renal graft injuries in allograft recipients (BIOMARGIN)

This project aims at identifying biomarkers obtained by non-invasive methods which would help predict the potential failure of grafts. The presentation was given by a representative of KU Leuven (BE).

This EU funded program started in 2013 and is building a long lasting collaboration across Europe involving researchers and SMEs. The program has received in-kind support from 13 partners from 4 European countries in the form of self-contributions (clinicians' and researchers' working time).

The objectives of the BIOMARGIN project is to detect and validate blood and/or urine biomarkers, at different omics levels, of renal allograft lesions, with good diagnostic performance as compared to histological biopsy analysis. It also aims to detect and validate mechanism-based classifiers of graft lesions to help histological interpretation of the biopsy and early prognostic biomarkers of chronic graft deterioration and ultimately graft loss. The deliverables of the project are tools for clinicians (analytical techniques, interpretation algorithms available on a dedicated website) to facilitate access to information in a timely manner.

The financial support received from the Commission to advance this project was welcomed as it enabled innovations to be promoted towards scientific societies and patient associations.

5.3.2. Horizon 2020 and Horizon Europe (DG RTD)

The Commission briefly presented current and planned RTD funding opportunities in organ transplantation.

Approaches to transplantation in EC Framework Programmes include research to improve efficiency, organ preservation, biomarkers for organ transplantation, cell transplantation such as immunogenicity, matching and improving tolerance. Alternatives to organ transplantation are also addressed, for example regenerative medicine, xenotransplantation, artificial organs and health service and public health research.

Under Horizon 2020, in 2014-2017, 25 projects including areas of organ, tissue and cell transplantation, preservation, xeno-, bio-artificial, regenerative medicine, health service research were funded. Details about a number of projects in the field of innovative approaches to solid organ transplantation were provided including EUROSTAM, BIO-DrIM, BIOMARGIN, COPE, HepaMAb. Translational research on cell-based immuno-therapy was considered in THE ONE STUDY, Innovative Strategies for translation of stem cell based therapies in regenerative medicine in STELLAR and new concepts in patients' stratification in EU TRAIN.

The representative also presented the Commission proposal for Horizon Europe (the next EU Research and Innovation programme (2021-2027). Horizon Europe is the Commission proposal for this € 100 billion research and innovation funding programme. The objective is to strengthen the EU's scientific and technological bases, to boost Europe's innovation capacity, competitiveness and jobs, to deliver on citizens' priorities and sustain our socio-economic model and values. The Health Cluster under Horizon Europe builds links between discovery, clinical, epidemiological, environmental and socio-economic research, academia – industry – healthcare providers – patients, bringing together expertise within the EU and beyond. More information is available at http://ec.europa.eu/horizon-europe

5.4. Evaluation of the Action Plan

5.4.1. FACTOR study – final results

The Commission presented the final results of the review of the EU Action Plan on Organ Donation and Transplantation documented in the Factor study[3].

Overall, the EU Action Plan helped spur a 17% increase in organ transplants between 2008 and 2015. In the period, the total number of organ donors at the EU level has significantly increased, from 12.3 thousand in 2008 to 14.9 thousand in 2015, 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.

Spain, France, UK, Poland and the Netherlands were five main contributors. Bulgaria, Lithuania, Finland, Croatia, Hungary, Czech Republic, Slovenia, Latvia and Denmark were the Member States with sharpest overall increase. A small number of countries showed a decline, notably Germany where numbers fell with 20%. The Action Plan led to appointment of local coordinators for deceased donation and registries for living donors.

The Action Plan has helped countries in different ways, but most importantly by setting a shared agenda and by facilitating EU-wide cooperation.

There was a lively discussion with the authorities on the outcomes of the final evaluation of the Action Plan and possible follow up steps. A new Action Plan at this point is not considered

[3] https://ec.europa.eu/health/sites/health/files/blood_tissues_organs/docs/2017_euactionplan_2009-2015_impact_en.pdf

necessary by the authorities but an implementation of the Action Plan priorities at the national level should be a priority.

5.4.2. Results of a survey on national priorities

The Commission has conducted a survey with Organs Competent Authorities on national priorities following the EU Action Plan on Organ Donation and Transplantation. The aim of the survey was to gather information on national plans and interest in EU collaboration for the 10 original priority actions in the 2009 action plan and for 15 additional topics. 24 MS and one EEA country responded to the survey.

The priority actions, going beyond those identified in the EU Action Plan, were the following: increased use of non-standard risk donors (donors with malignancies, specific infectious diseases etc.), developing specific exchange programmes between countries, addressing ethical issues related to organ donation by, for example, refugees, handicapped persons or psychiatric patients, the implementation of new techniques and the development of concerted support actions to enhance transplant self-sufficiency in Eastern and Southern European countries, as well as Mediterranean countries.

In conclusion, further EU collaboration was perceived as necessary by the Member States for Living Donor Programs, Organisational models, Post Transplant Results, Accreditation Systems, Education of professionals through exchange of staff/training abroad, Minorities and New Groups, Bio-vigilance.

The Commission reminded the participants that a number of EU funded projects had produced tools and guidance and invited the authorities to further explore and use them.

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 threats relevant to the safety of organ transplants, an ECDC West Nile Virus expert meeting held in Vienna on 15-16 March 2018 and an ECDC-awarded framework contract on assessing the risk of bacterial infections transmission by SoHO.

The NCAs were also informed regarding Ebola virus disease in the Democratic Republic of Congo in 2018, Dengue in France, Reunion, in 2018 and WNV cases in humans over recent years in the EU.

6.2. Update on Commission activities related to vigilance and surveillance

The Commission presented the ongoing work on Rapid Alerts on Blood (RAB), and on Tissues and Cells (RATC), the Vigilance Expert Subgroup work and the NOTIFY (WHO) collaboration. For the NOTIFY project, a work package under the VISTART Joint Action has created a link/network amongst vigilance experts on blood, tissues and cells.

On the Rapid Alert Platform, the participants were informed that an IT link between RATC and the EU Coding Platform for Tissues and Cells is envisaged. On the 22 May 2018, the summary of activities 2017 had been published, for the first time in a single document for RATC and RAB[4].

The Commission also informed the meeting regarding a first meeting of the new Vigilance Expert Sub-group (VES), under the CASoHO expert group, which had taken place on 7 April

[4] https://ec.europa.eu/health/sites/health/files/blood_tissues_organs/2017_ra_soho_summary_en.pdf

2017. This expert group is focusing on T&C and blood, using outputs of the VISTART WP4 and the evaluation of the legislation to propose improvements to vigilance for T&C and blood.

The Competent authorities reiterated an interest in having an expert network within the existing SoHO Vigilance expert sub-group to focus on organ vigilance. In particular, they expressed interest in improving 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. The Commission suggested following up on this, in due course, by proposing to the other groups (blood and T&C) an extension of the Terms of Reference of the VES to include organs.

7. COMMUNICATION ACTIVITIES

7.1. Pilot Project EUDONORG (training and social awareness) (DTI-ES)

The EU-funded EUDONORGAN service contract[5] started in September 2016 and will finish in autumn 2019. The contract was awarded to a transnational Consortium involving leading countries in organ donation and transplantation management from Central and Southern Europe: Croatia, Italy, Slovenia and Spain co-ordinated by the University of Barcelona. The project aims to provide training and to increase social awareness regarding organ donation in the European Union (EU) and neighboring countries with the ultimate goal of increasing the number of organ donors. Following the completion of the training work package in 2017, the consortium is now working to achieve the second objective, six social awareness events on organ donation to be organised across the EU.

In 2018- 2019, Poland, Belgium, Greece, Hungary, Portugal and Sweden will host events in a co-ordinated effort with EUDONORGAN and the national competent authorities to highlight to EU citizens the need for increased levels of organ donation.

The authorities mentioned that the EUDONORGAN project was a unique opportunity to learn from others and take home knowledge and skills to help raise awareness of organ donation in their home countries.

The Commission encouraged the authorities to further support EUDONORGAN in organizing the events and to actively participate in them.

(Nota bene: the EUDONORGAN event in Poland/Warsaw was the first social awareness event attended by around 100 healthcare professionals, patient organizations and journalists from Poland and neighboring countries.)

7.2. Update on media issues and projects

The Commission informed the group of its recent participation in the European Parliament's session on Kidney Transplants. MEP's showed an interest in this field.

The Commission also informed the authorities of the meeting with US authorities, HRSA (Health Resources and Services Administration), with whom it discussed Global Kidney Exchange and also biovigilance and the role of a Disease Transmission Advisory Committee.

[5] http://eudonorgan.eu/

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

8.1. European Reference Networks – TRANSPLANTCHILD

The Commission presented the European Reference Networks, of which one is focusing on organ transplantation in children.[6]

ERNs are virtual networks involving healthcare providers across Europe for rare diseases or highly specialized procedures in order to promote sharing of knowledge/expertise and review a patient's diagnosis and treatment, by convening a "virtual" advisory board of specialists, using a dedicated IT platform (CPMS : Clinical Patient Management System) and telemedicine tools.

ERNs are not directly accessible to individual patients. However, with the patient's consent, and in accordance with the rules of their national health system, patient case can be referred to the relevant ERN member in their country by their healthcare provider.

ERN Transplantchild includes combined Hematopoietic Stem Cell Transplantation (HSCT) and Solid Organ Transplantation (SOT) as a highly specialised and complex procedure. However, it does not include primary diseases or conditions that lead to or indicate the need for transplantation and allocation of/and access to organs for the purpose of organ transplants. Within the network there are 18 centers from 11 EU states (covering 600 pediatric transplantations per year). It was emphasized that Competent Authorities are the cornerstone for the development of transplant programmes. The network and Competent Authorities share a global and cross-cutting approach to the transplantation process. The authorities were invited to take an active role and raise their involvement within the network. They were also asked to provide access to information and data regarding paediatric transplantation in Europe and support in the development and implementation of a common global registry.

The authorities agreed to provide data to help map out EU paediatric transplant activities.

8.2. Digital Data in SoHO (COM)

The Commission presented its Communication on Digital Health[7] and Care, a SoHO registry meeting of 29-30 January organized by the Commission and the initiatives of the Commission on Real World data. The objective was to raise awareness of these initiatives, and their possible future role.

Participants expressed an interest in Commission developments on Real World Data and possibilities to further support registries in the SoHO sector.

8.3. Structural Reform Support Service (SRSS)

The Commission presented the SRSS (Structural reform support service)[8]. SRSS is a recently launched Commission service with a mandate to support MS with the preparation, design, and implementation of growth-enhancing reforms, provide tailor-made support on the ground and coordinate technical support provided by the Commission. One of the policy areas of SRSS support includes reform of Healthcare systems.

Under the SRSS programme[8], the Competent Authorities/ national health administration might consider applying for technical support (e.g. for joint inspections, exchange visits or training). It

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

[7] Communication: https://ec.europa.eu/digital-single-market/news-redirect/624248
Staff working document: https://ec.europa.eu/digital-single-market/en/news/staff-working-document-enabling-digital-transformation-health-and-care-digital-single-market

[8] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2017.129.01.0001.01.ENG
https://ec.europa.eu/info/departments/structural-reform-support-service_en

was noted that applications must be made in response to a call in October of each year; that the application process can be supported by a dialogue with the relevant SRSS Commission service and that it was important that any application is highlighted by the MS concerned as a priority area. Applications must come via the national contact point for SRSS and might be filtered at a national level. The list of responsible national organisations had been provided to the meeting participants in CircaBC.

Participants expressed interest in possibilities for supporting national services in particular joint inspections, training and oversight frameworks through the SRSS.

9. INTERNATIONAL

9.1. Global Kidney Exchange (COM)

The Commission presented a formal statement developed by the Organs Competent Authorities on a proposed concept of global kidney exchange.

Previously, the NCAs had discussed the Global Kidney Exchange (GKE) concept presented by Dr Rees of Toledo/US and Professor Roth of Stanford/US during a meeting of NCAs in Rome on 15 January 2018. The GKE concept is presented as a way to increase live kidney transplant opportunities at both High Income Countries and Low and Middle Income Countries and was further described in the American Journal of Transplantation. In their review of the GKE concept, EU NCAs expressed concerns that the concept, as currently presented, may not be in line with the principles of organ donation and transplantation defined in EU legislation and practice. These views reflected concerns expressed by several other international bodies. In the light of the concerns listed above, the NCAs consider it inappropriate for any transplant center in the EU to participate in the proposed GKE scheme. The statement of the NCAs on GKE was published in May 2018.[9] The authorities expressed an overall satisfaction with the process and outcome of discussions on GKE, which led to the published common statement expressing strong concerns.

9.2. Council of Europe activities (ONT-ES)

The ONT representative gave an update on CoE activities.

A Guide for the implementation of the principle of prohibition of financial gain with respect to the human body and its parts from living or deceased donors[10], adopted by CD-P-TO and BH-BIO, was presented. The guide describes the following concepts:

- financial neutrality (donors should neither lose, nor gain, financially, as a result of donating);
- financial gain (financial gain with respect to the human body and its parts, as such, includes payments or inducements in kind either directly to living donors, to the families of deceased donors or to other third party);
- reimbursement and compensation (reimbursement and compensation must never be connected to the donation as such, must not vary according to their final objective not with the quality of what has been donated, or the outcome for the recipient) and
- inappropriate financially driven competition (the reimbursement and compensation should not lead to inappropriate competition between establishments working in donor recruitment, in particular in the context of fixed rate compensation schemes).

[9] https://ec.europa.eu/health/sites/health/files/blood_tissues_organs/docs/nca_statement_gke_adopted_en.pdf
[10] https://rm.coe.int/guide-financial-gain/16807bfc9a

On organ trafficking, it was stressed that the existing CoE instruments against organ trafficking and human trafficking (including for the purpose of organ removal) provide comprehensive legal frameworks to prevent and combat transplant activities that violate basic human rights.

Other activities such as CoE technical guidance, awareness raising activities in Organ Donation and international monitoring were presented.

It was noted that CD-P-TO had also adopted a statement on the global kidney exchange concept, on 10 April 2018[11]. It recommends that member states of the CoE, Health authorities, hospitals and professionals not to engage in GKE as currently proposed. The recommendations are in line with the statement issued by the Organs Competent authorities (cf. point 9.1).

9.3. WHO activities (WHO)

WHO gave an overview of WHO activity on Medical Products of Human Origin (MPHO, equivalent to SoHO in the EU). The representative presented the new WHO organisational model. One of the strategic priorities is to help countries strengthen health systems to achieve Universal Health Care (UHC) including organ transplantation that should be included under UHC policies. Furthermore, WHO assistance to Member States for developing MPHO systems was explained. In this context, WHO capacities include a number of instruments such as twinning partnerships for improvement of Services Organization, Economic Analysis and Evaluation, Costs, Effectiveness, Expenditure & Priority Setting, Health System Governance, Prevention & Management of Non-communicable Diseases and National Capacity Building. The representative also presented the establishment of a WHO Task Force on Donation and Transplantation of Human Organs and Tissues (DTTF). The objectives of DTTF are to identify and analyze barriers for implementation of the principles at global and national level, to advise and contribute to the development of a strategic plan and monitor completion of activities listed in the plan, to encourage improved surveillance and collection of data on practices relating to safety, quality, efficacy, epidemiology and ethics and to provide evidence based support and capacity building at regional and country levels.

The participants expressed an interest in having an update, in particular on DTTF activities, at the next CA meeting.

The WHO representative welcomed the collaboration with the Organ Competent Authorities and suggested working to strengthen it in the future.

9.4. WHA side-event on transplantation (ONT-ES)

A number of World Health Assembly Member States, led by Spain, organized a side event during the World Health Assembly in May 2018. The aim of the event was to raise knowledge about organ transplantation and to highlight the importance of kidney transplantation vs dialysis. The event was considered as successful and the case was well made.

10. ANY OTHER BUSINESS

SANTE asked if any MS has an interest in hosting an informal CA meeting. CAs were invited to express their interest after the meeting.

11. CLOSING OF THE MEETING

The Chair thanked the group for their positive participation in the meeting. The next meeting of Organs competent authorities is planned for early 2019. As usual, the date will be confirmed at the latest six weeks ahead of the meeting.

[11] https://www.edqm.eu/sites/default/files/statement_cd_p_to_global_kidney_exchange_concept_april_2018.pdf