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

## Meeting of the Competent Authorities for Tissues and Cells

## 15 – 16 November 2017

## Summary Minutes

This meeting of the tissues and cells competent authorities (CA) took place on 15 and 16 November 2017. The previous meeting took place on 21 and 22 February 2017.

PARTICIPATION:

Competent authorities from all Member States (MS) were represented at the meeting with the exception of Lithuania, Luxembourg, Cyprus and Croatia. No candidate countries attended the meeting.

In addition, competent authorities from Norway, as well as representatives of the Consumer, Health and Food Executive Agency (CHAFEA), the European Medicines Agency, the European Centre for Disease Prevention and Control (ECDC), the World Health Organisation and the Council of Europe (EDQM) were present as observers.

European Commission (DG SANTE):

Chair: Ms Anna Eva AMPELAS
Commission Representatives: Mr S. VAN DER SPIEGEL, Ms D. FEHILY, Ms I. PUCINSKAITE-KUBIK, Mr P. CATALANI, Mr R. Mc GEEHAN
Administrative Assistant: Ms A. CORNEA

### 1. WELCOME AND ADOPTION OF THE AGENDA

The newly appointed Head of the responsible unit at the European Commission (DG SANTE/unit B4) was introduced and took the chair. She welcomed the participants to a meeting with a full and interesting agenda.

The agenda was adopted without modification. No conflicts of interest were declared.

It was noted that the Summary Minutes of the previous meeting had been approved by email and published on the DG SANTE website.

## 2. LEGAL MATTERS

### 2.1. Update on the transposition of the Tissues and Cells Directives

The Commission updated the participants on the status of the transposition of the Tissues and Cells Directives, the on-going infringement proceedings and pilot procedures.

In June 2017, the remaining pilot was successfully closed. It was therefore reported that as of the beginning of November 2017 the transposition check had been closed for 27 MS. The Commission informed the group that one MS is still the subject of formal infringement proceedings that had reached the reasoned opinion stage[1]. In this case, an amended national law had been adopted on 20 September 2016 with implementing legislation adopted on the 31 December 2016. The amendments to national legislation have been notified to the Commission and were under assessment.

On transposition of Directives (EU) 2015/565 (Coding) & 2015/566 (Import), the Commission gave a short update reminding that the deadline for transposition had passed (October 2016). By this deadline, only 2 MS had notified the Commission of transposition and letters of formal notification were sent to 26 MS on November 24, 2016.

As of the beginning of 2017, 25 MS have notified complete transposition for Coding, with one notification of partial transposition and 2 MS yet to notify. For Import, 24 notifications, 1 partial and 3 non-notifications were received.

The Commission encouraged CAs in the remaining MS to communicate with their national counterparts, urging them to formally notify transposition as soon as possible, given that the provisions became applicable on 29 April 2017.

### 2.2. Same surgical procedure – case study (Malta)

The MT representative provided an overview on an ongoing discussion concerning Same Surgical Procedure to seek views from other MS. The case concerns the use of autologous tissue/cells that are removed from a patient, immediately processed in a device at the patient's side and returned to the same patient. Directive 2004/23 excludes from its scope tissues/cells that are used in 'the same surgical procedure'.

Earlier, it has been considered that as long as the processing was done in the same room then the exclusion from the requirements of the Directive should apply[2]. However, some stakeholders are now suggesting that such an exclusion is no longer appropriate as the 'close to the patient/bedside' technologies are becoming more and more important and there should be an authorisation of the process, not just a CE-marking of the device in which the substance is processed.

The CA acknowledged that the issue presented by MT concerns also the 'claim' that fat cells in these cases can help different conditions such as chronic cystitis, asthma, stroke, etc. They suggested that this needs a requirement for demonstrating 'efficacy'.

In the meeting, several CA suggested that bedside technologies should be in the scope of the legal framework, but subject to specific/minimal conditions which only refer to the

[1] The Reasoned Opinion stage - the final stage before a decision is made on the need to refer the case to the ECJ or not.

[2] Cf T&C CA meeting in 2011 where an issue concerning a specific device was discussed. The principle would appear to be similar.

preparation process authorisation and include the demonstration of safety, quality and efficacy.

The CA considered that a careful consideration should be given to this case in the context of the ongoing Blood, Tissues and Cells Evaluation (see details in point 3).

### 2.3. Danish non-partner donor testing protocol (ECDC)

Following the discussions in previous meetings on the requirements for testing of non-partner semen donors, ECDC assessed the risks associated with the donor testing protocol for non-partner donations currently being applied in Denmark. While the Directive calls for a donor test with every sperm donation, with a repetition after 180 days if NAT testing is not performed on the donation sample, Danish banks apply a test before the first donation and then again every 90 days, until 180 days after last donation.

The preliminary conclusions of the ECDC technical report suggest that the Danish protocol largely ensures an equivalent level of safety. However, under certain circumstances a minor increased risk of missing a window period infection remains, which could be mitigated by restricting release for a specified period. In other respects, particularly if the delayed release is implemented, the protocol could be considered as more stringent than the Directive requirement.

ECDC had shared the draft document describing their assessment of the testing protocol prior to the TC CA meeting. CA representatives were encouraged to submit their comments on the document after the meeting. Following the presentation of the ECDC assessment, DG SANTE agreed to consult the Commission's Legal Service on the question of whether the Danish protocol is in line with the Directive from a legal point of view. This consultation will take place once the CA have submitted their feedback on the ECDC document and the document has been finalised.

The DK representative used the opportunity to also give a short update on continuing progress with changes to the Danish legislation relating to the direct distribution of sperm to individuals, a topic discussed during previous meetings of the Expert Group. The Commission noted that it will continue following the developments in DK relating to this topic.

## 3. EVALUATION OF THE TISSUES AND CELLS LEGISLATION

### 3.1. State of play

The Commission is evaluating the blood and the tissues and cells (BTC) legislation in line with the Commission's principles of Better Regulation.

The BTC evaluation was formally initiated with the publication of the Roadmap in January 2017. An external contractor was engaged in April 2017 to work on a study to support evidence gathering. Since then, the main components of the stakeholder consultation, the OPC and the stakeholder event, have taken place. Whilst the stakeholder consultation has now been completed with a summary to be published early in 2018, the external study is ongoing. DG SANTE will begin the preparation of the final evaluation report (the SWD) with the aim to publish it by end of 2018.[3]

[3] The roadmap, along with all other key information relating to the evaluation, is available on a dedicated DG SANTE web-page https://ec.europa.eu/health/blood_tissues_organs/policy/evaluation_en

The external contractor, ICF Consulting Ltd presented the preliminary results of their study supporting the Commission in their BTC evaluation. ICF was close to completion of the preliminary phase of the study. The analysis phase will be undertaken in spring 2018 and a final study report is envisaged for mid-2018.

ICF presented their preliminary analysis elaborating on the specific fields to be explored in more depth and the need to collect further evidence during their assignment. The gaps in data identified by ICF are now being filled through targeted interviews and organising the focus group meetings, as well as gathering input from CA.

The Commission highlighted that this study together with the inputs received from the Open Public Consultation and the Stakeholder Event is important and will be a major input for the Commission when drafting the Final Evaluation Report.

### 3.2. Stakeholder Consultation - submissions by TC CA to the BTC evaluation

The Commission presented their ongoing work on the stakeholder consultation as an essential element of the evaluation.

In line with the requirements of the Better Regulation rules, it had conducted an online open public consultation giving an opportunity to citizens and professionals to provide their input. More than two hundred submissions had been received. The online consultation consisted of questions based on the key assessment criteria for the evaluation: relevance, effectiveness, efficiency, coherence and EU added value. Submissions to the online consultation would be published along with a summary report of the key issues raised.

Following the consultation, a stakeholder event organised by the Commission took place in September 20th 2017 in Brussels[4]. The event was attended by over 200 participants. The majority of participants were from EU Member States (21 Member States were represented) and 10 were from non-EU countries. The event brought together the key stakeholders including public authorities, patient and donor groups, professionals working with BTC, industry representatives and other relevant stakeholders. The stakeholders had an opportunity to express their views on key topics regarding the BTC legislation. The meeting was open to all interested stakeholders who registered to participate. The invitation to registration was published on the DG SANTE website.

The Commission summarised the key messages brought forward by the TC CA in the consultation. In general, participants considered that the impact of the legislation has been positive and provided added value. Issues that were brought forward frequently included the inflexible two-year inspection requirement, the absence of requirements for clinical follow up data as part of preparation process authorisation and the provisions for donor protection that were considered inadequate. The legislation was also considered insufficiently flexible to adapt to the many changes in the sectors.

In parallel, the Commission planned to continue to hold bilateral meetings with key stakeholders publishing summaries online and would invite key stakeholders to meet with this expert group at dedicated meetings, such as the one scheduled for 16 November, i.e. after this expert group meeting.

[4] The summary of the event has been published by DG SANTE and can be found at https://ec.europa.eu/health/sites/health/files/blood_tissues_organs/docs/ev_20170920_sr_en.pdf.

## 4. ACTIONS UNDER THE PUBLIC HEALTH PROGRAMME

### 4.1. Update of the 2013 Joint Action (JA) on good practices on donation, collection, testing, processing, storage and distribution of gametes for assisted reproductive technologies and of haematopoietic stem cells for transplantation (ARTHIQS)

Agence de la Biomedicine (FR) gave an update on the ARTHIQS Joint Action. The 3--year JA was coming towards completion. The overall objective of this JA was to build a common, increased level of expertise amongst CA to organise oversight of the ART/IVF and HSC transplants fields.

An overview of the achievements and outputs of the JA was given and final activities that were being completed were described.

In parallel with the finalisation of the main deliverables, 2 guides had been prepared, (i) Inspection guide and inspector competencies for ART and (ii) Cord Blood Banks Inspection checklist. As these documents aimed to become practical tools used by CA, some examples were presented.

It was mentioned that the deliverables from ARTHIQS will be shared for CA feedback.

In addition, Agence de la Biomedicine proposed the establishment of a continued expert group dedicated to ART issues. It was agreed that CA interested in having a representative in an ART network should contact the ARTHIQS leader.

In general, the Commission noted that there was an appreciation and interest in the group for such projects in the field of tissues and cells, as mechanisms to improve collaboration and providing good opportunities for sharing information and updates that improve regulatory practice.

### 4.2. Update on the 2014 Joint Action on vigilance and inspection for the safety of transfusion, assisted reproduction and transplantation (VISTART)

The VISTART Joint Action was launched in October 2015 and will close in autumn 2018. To date, a number of work-packages (WP) have produced deliverables.

VISTART brings together competent authorities from both the blood and tissues and cells sectors and is jointly coordinated by the Italian national CA for blood and tissues and cells, CNS and CNT, respectively. It has 16 associated partners and 21 collaborating partners many of whom are CA covering both blood and tissues and cells. The Action has work packages on coding, vigilance, inspector training, inspection guidelines, international 'joint' inspections, and inter-inspection system auditing.

A representative gave an overview of the inspection related work packages addressing their main goals, milestones achieved and upcoming deliverables. The partners were considering sustainability and how to offer further training/dissemination for inspectors in the future. The Commission invited CA representatives who had participated in the VISTART inspection training course in June 2017 to share their impressions and the feedback given was very positive.

An update on the state of play in in other VISTART work packages was given. One work package on SARE (WP4) has established working groups that have met on a number of occasions and have developed documents with recommendations for improving the vigilance system. WP4 would focus their subsequent work on the horizon scanning part of the project.

WP5(a) has worked on procedures to facilitate EU blood and tissue and cell CA in submitting specific SARE cases, of high didactic value, to the WHO Notify Library, for optimal learning at a global level. WP5(b) is developing principles for the evaluation of clinical follow-up data as part of BTC preparation process authorisation.

The work of the project can be followed at https://vistart-ja.eu/

### 4.3. Facilitating the Authorisation of Preparation Process for blood and tissues and cells (GAPP)

The new three-year EU funded Joint Action GAPP will start in May 2018. The project brings together 30 organisations from 21 Member States. This action aims to build a framework for CA for blood, tissues and cells for a common approach to Preparation Process Authorisation in the EU.

GAPP will focus particularly on the validation and authorisation of those preparation processes that are more complex and/or innovative. The work will incorporate the outputs of other EU-funded actions including VISTART, EuroGTP II and ECCTR.

By providing tools and training to increase the harmonisation of relevant activities, the Joint Action will contribute to a common implementation of Union legislation in tissues, cells and blood. The CA received a first insight into the anticipated development of a common and optimal approach to assess and authorise preparation processes in blood and tissues & cells. This included a presentation of the work plan, the project deliverables, milestones, next steps and the announcement of the kick-off meeting in June 2018.

### 4.4. Good practices for demonstrating safety and quality through recipient follow-up (EURO GTP II)

EURO GTP II is a three-year year project which started in June 2016. It is led by the Tissue Bank of Barcelona and brings together 14 associated partners and 13 collaborating partners, amongst them tissue establishments, CA, universities, scientific associations and the Council of Europe's EDQM. This project focuses on establishing good practices with regard to preparation processes and procedures for patient follow-up from the perspective of the professionals working in the fields concerned.

The project is expected to develop a good practice guide for tissue establishments; a database which will act as a compendium of recognised preparation processes and applications per tissue and cell type with information on how these have been authorised by CA; an interactive assessment tool which will provide information on the good practice procedures to follow for introducing new or changed preparation processes or applications and a proposal for a management model for the long-term sustainability of the deliverables produced as well as for the development of professional accreditation and training programmes on the above.

Further progress was reported including advanced stage development of on-line tools evaluation of novelty and assessment of risk of preparation processes. A practical example of the use of the Interactive Assessment Tool (IAT) was given.

The Commission noted that this project links to topics that are also covered by other EU-funded initiatives (Joint Action VISTART and the new Joint Action GAPP) and are relevant for CA who authorise preparation processes.

The work of the project can be followed at www.goodtissuepractices.eu.

### 4.5. European Cornea and Cell Transplantation Registry (ECCTR)

The three-year ECCTR project started in May 2016. Within the project eye banks, universities and professional associations from Italy, United Kingdom, Sweden, Netherlands and Ireland collaborate. The main objective is to build an EU web-based registry where ocular tissue transplant outcome data will be registered and shared. The objective is to assess and verify the safety, quality and efficacy of human tissue transplantations in ophthalmic surgery.

The online platform of the registry will provide information on donor cornea origin, recipient and surgical procedure to allow for evidence-based decisions in the future. This registry will be maintained by the European Society of Cataract and Refractive Surgeons (ESCRS) after the completion of the project.

Significant progress on the establishment of the registry and the linking to the three existing national registries (UK, the Netherlands and Sweden) has been achieved.

The registry was launched in 2017. It is expected that up to 3000 surgeries will be registered by mid-2018. The registry will provide a unique opportunity to monitor and compare results and to promote quality improvement in cornea transplantation.

### 4.6. TRANSfusion and transplantation: PrOtection and SElection of donors (TRANSPOSE)

TRANSPOSE representative outlined the objectives of the project and provided a short overview of the work packages and timeline.

TRANSPOSE aims to construct risk-based Guidelines and a standard Donor History Questionnaire for the procedures followed for collection of substances of human origin. The work addresses the selection and protection of donors. The objective of this project are: (i) to collect and compare EU and national donor selection and protection criteria; (ii) to identify the information needed from donors or their families to allow the application of appropriate donor deferral or exclusion criteria for the protection of recipients; and (iii) to propose approaches to control and minimise these risks.

The work of the project can be followed online: https://www.transposeproject.eu/

## 5. EUDONORGAN SERVICE CONTRACT

EUDONORGAN is a 36 month service contract awarded by the European Commission to a consortium involving organisations from four countries from Central and Southern Europe: Croatia, Italy, Slovenia and Spain including a very well established Foundation providing training in organ donation.

The project started in September 2016 and it focuses on training and awareness to increase organ donation in the European Union and the neighbouring countries. .

The objective of the first main activity, a Train the Trainers course, was to support capacity-building efforts, with the overall objective of monitoring and improving performance in the management of donated and transplanted organs.

EURODONORGAN have developed an interactive app for training that also addresses tissue donation. As agreed with EUDONORAN, DG SANTE briefly presented the project on their behalf. EUDONORGAN is to fine-tune the WebApp and facilitate access to it by CA interested in translating and adapting it for local use.

As its second main activity, EUDONORGAN will organise 6 awareness raising events in EU Member States, in each case with the participation of other MS from the region.

## 6. CODING – UPDATE ON THE STATUS OF THE COMPENDIA, GAPS AND QUERIES

The Coding Platform that supports the Single European Code for tissues and cells was launched in September 2016. The requirements of the legislation should have been implemented by MS by 29 April 2017.

The Tissue Establishment compendium on the Coding platform includes information from 28 Member States and Norway and Iceland.

There are around 3000 tissue establishments in the compendium, with the activities and authorisation status shown. CA have been active in updating their data.

To clarify specific implementation questions brought forward by the CA on the implementation of the Single European Code, a dedicated workshop was held in March 2017. The workshop was attended by CA representatives from 9 MS. The conclusions led to a revision of the Q&A document to address the issues that needed clarification. The document is available at: https://ec.europa.eu/health/sites/health/files/blood_tissues_organs/docs/sec_qa_en.pdf.]

The discussion that followed addressed two issues: (i) whether the TE Compendium is up to date, with procedures in place at CA to ensure prompt ongoing updating; and (ii) whether TEs at national level are prepared for the application of the SEC.

## 7. SURVEILLANCE AND VIGILANCE

### 7.1. Epidemiological – general update (ECDC)

ECDC gave an epidemiological update focusing on the most important recent developments.

These included the active threats such as plague in Madagascar but also SoHO relevant infections in the EU, including West Nile Virus (WNV), Malaria and Chikungunya. For WNV infections, since the beginning of the 2017 transmission season up to October 2017, EU member States reported 193 cases. Twenty deaths due to West Nile fever were reported in the same period. Five events of local malaria transmission were reported in the EU in that period.

ECDC informed the group of the Chikungunya outbreak in Italy and France in 2017. In Italy, 358 cases were reported and in August 2017 an outbreak of autochthonous Chikungunya was reported in southern France. The virus circulating belongs to the East Central South African (ECSA) sub-lineage.

### Other – Member State update

The competent authorities were asked whether they have additional information or updates to report. There were no specific updates.

### 7.2. RATC alerts

The Commission presented an overview of the 2017 alerts uploaded in the RATC and RAB platforms. The Commission informed the participants that in 2017 a number of epidemiological, Q&S, information notices, bilateral enquiries and illegal/fraud cases were reported. In terms of Rapid Alerts for SoHO, 13 alerts were launched in the RATC platform including cases on a HIV test kit, a washing solution contamination and a number of cases related to gametes in the year 2017. Overall, the number of reported cases in the RAB and RATC platforms has decreased over the period 2013-2017.

The Commission presented the priorities for 2018 and the recommendations from Vistart WP4 on rapid alerts. Another priority is to follow up the operational system, managing the related coding project and ensure interoperability. Concerning the VISTART recommendations, it was acknowledged that it will be necessary to keep different access privileges for RAB and for RATC. Users with RATC access will only receive relevant notifications.

The latest Annual RATC Report has been published and is available here: https://ec.europa.eu/health/sites/health/files/blood_tissues_organs/docs/2016_ratc_summary_en.pdf]

France gave an update on a recent RATC alert. The French authorities launched an alert released in the Rapid Alert system for Tissues and Cells concerning a HIV1 test. The details were shared with the participants.

### 7.3. Vigilance

The Commission reminded the participants that the Serious Adverse Reactions and Events (SARE) data collection exercise had been launched. The Council of Europe (EDQM) undertakes the analysis of the SARE country reports on behalf of the Commission through a grant agreement. The Commission highlighted a legal obligation that Member States submit their country reports on time, stressing that prolongation of the deadline would no longer be possible in the next reporting exercise due to the new contractual arrangement with EDQM.

The SARE report for the 2016 exercise (2015 data) had been shared with CA for comments.

Since the meeting, the report has been published here:

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

#### 7.3.1. SARE reporting – state of play and issues identified (EDQM)

EDQM presented their preliminary analysis of the country reports received in the 2016 exercise.

The numbers and types of SAR and SAE reported were presented, along with denominators and the EDQM team highlighted areas where improvements could be made. Twenty three MS had so far submitted the reports.

EDQM indicated that, in general, there has been a gradual improvement in the quality and completeness of data submitted. However, some MS still do not report any SAR or SAE and/or provide denominators. Inconsistency is observed between some country reports.

EDQM invited the group to carefully read the Common Approach document and pay special attention to the expected changes in the reporting template. They stressed that, in those MS where there are more than one CA responsible for the SARE country report, the submission to the Commission should be coordinated and jointly submitted.

Member State representatives were asked to review the data and to provide feedback if they considered that any elements were inaccurate or misinterpreted.

Plans for the launch of the SARE 2017 exercise were presented.

### 7.3.2. Vigilance expert subgroup

The Commission informed participants that a new SoHO Vigilance Expert Sub-group (VES) had been established under the Expert Group CASoHO E01718 in January 2017. This sub-group replaces the previous Haemovigilance Working Group and addresses issues related to vigilance across blood, tissues and cells; the scope may be extended to organs in the future. The terms of reference had been agreed with the Expert Group (both blood and tissue and cell authorities). The authorities were thanked for their active response to the call for nominations to the sub-group issued at the beginning of the year. Twenty countries had nominated 39 experts, with a good geographical and cross-sector representation.

A first well-attended meeting of the VES had been held on 7 April 2017 and was attended also by experts from EDQM (Council of Europe) and from the VISTART Joint Action. The group constructed a long list of issues that it considered should be addressed to improve BTC vigilance. The list included issues that would require changes to the SARE reporting template, to the Common Approach guidance for completing the template or to the legislation. A summary of the VES meeting is available on the DG SANTE website: https://ec.europa.eu/health/sites/health/files/blood_tissues_organs/docs/ev_20170407_mi_en.pdf

One of the VES rapporteurs presented the work carried out to date. The areas where practice improvement, guidance clarification or legal change might be required included the following: SAR definitions and categories, SAR denominators, Reporting of recipient deaths, SAR reporting criteria, Severity Assessment SAR, Imputability Assessment SAR, SAR in donors, SAE definitions and categories, SAE denominators, SAE reporting criteria.

Documents including an agreed VES work programme had been shared with the participants prior to the meeting.

The Commission expressed gratitude to the VES rapporteur for steering the group and taking forward this important work.

## 8. INTERNATIONAL DEVELOPMENTS

### 8.1. Council of Europe

The representative of the Council of Europe's European Directorate for the Quality of Medicine (EDQM) presented the third edition of the Tissues and Cells Guide. This guide was published in July 2017. For the first time, the guide was available for free, in a downloadable, electronic format (https://register.edqm.eu/freepub). A survey of users of the Guide indicated a high degree of usefulness for daily work, for training and education and for policy making.

EDQM reported that the drafting of the 4th edition started in September 2017. The finalisation of this edition and the publication are envisaged in September 2019.

The presentation also summarised other Council of Europe (CD-P-TO, EDQM) activities of relevance to this meeting, including the publication of data each year in the Newsletter Transplant. EDQM highlighted ongoing projects in the field of TC including a layman brochure on oocyte donation. Within DH-BIO, another committee of the Council of Europe (EDQM) separate from CD-P-TO, had worked on a study on trafficking of human tissues and cells and on the principle of 'financial gain' with respect to human tissues and cells.

Newly planned EDQM projects in the field of TC included (i) Harmonisation of activity data concerning the processing, distribution, use and import/export of TC in Europe, (ii) Donor protection and (iii) Borderline products with different regulatory classifications across MS.

In the context of the Commission Evaluation of the BTC legislation, EDQM noted that the EU directives on TC are effective in helping to unify standards across MS. However, technical standards as set out in the directives cannot keep pace with ongoing scientific and medical advances. They stressed that the directives cannot provide the level of detail required by TE or CA to respectively deliver safe and effective products and to underpin an effective inspection process; this requires technical guidance such as that regularly updated by EDQM. This was acknowledged by the CA.

### 8.2. World Health Organisation

The WHO representative gave a short update on WHO activities on Medical Products of Human Origin (MPHO).

A general programme of Work 2019-2023 was introduced highlighting its mission and strategic priorities. Furthermore, the MPHO Framework that had been discussed at the 70th WHO Assembly of May 2017 presented. Following that discussion, the priority actions on MPHO would be grouped under three challenges: increasing MPHO availability and accessibility, ensuring the efficiency of MPHO oversight systems, and improving quality and safety of MPHO. Three groups of key actors have been identified: authorities, professionals/associations and patients/public. A set of actions that can be developed by the WHO have been proposed:

- A briefing report to inform the public about the various types of MPHO, their modalities of use, their benefits and challenges;
- An Action Plan for interested Member;
- Global instruments for implementing the basic ethical, quality and safety principles.

The representative informed the meeting about a Global Task Force (GTF) of experts in the fields related to MPHO which was created following a proposal by MS at the WHO. The initiative will aim at identifying and analysing barriers for implementation of the principles, advising and contributing to the development of a strategic plan and monitoring completion of activities listed in the plan, encouraging surveillance and collection of data on safety, quality, efficacy, epidemiology and ethics etc. The GTF will be co-ordinated by the WHO. It will be a collaborative mechanism between interested parties as opposed to an independent legal entity.

## 9. INTERACTION WITH STAKEHOLDERS

### 9.1. Update on DG SANTE/B4 meetings with stakeholders

The Commission summarised the various bilateral meetings it had held with stakeholders since the last meeting of this group. The main issues raised were summarised and meeting reports have been published on the DG-Santé website.

### 9.2. Meeting with ART stakeholders (16/11/2017)

The Commission presented the list of stakeholder applications received and approved since the previous meeting. The agenda and stakeholder list for an ad-hoc meeting with stakeholders and competent authorities scheduled for the following day were also presented. The topics for discussion were genetic testing, focus on quality in ART (measuring and monitoring indicators), CE marking of consumables, media and equipment.

All CA had been invited to participate.

## 10. UPDATE ON THE REVISION OF THE EU MEDICAL DEVICES LEGISLATION

The Commission gave an update on the revision of the EU medical devices legislation.

Regulation (EU) 2017/745 on medical devices entered into force on 25/5/2017. The legislation includes in its scope devices manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable (in accordance with the definitions of the terms 'device' and 'derivative'). By contrast, non-viable tissues and cells themselves, e.g. demineralized bone matrix, or other matrices, would not fall within the scope of this Regulation, but remain subject to the Directives on tissues and cells. The Commission services in SANTE and GROW (responsible for medical devices) have prepared a joint statement on this position.

*Regulation (EU) 2017/745 on medical devices was published in the EU Official Journal on 5/5/2017. The text is at the following link: EUR-Lex - 32017R0745 - EN - EUR-Lex*]

## 11. AOB

The Netherlands gave a short presentation on a media-issue related to sperm donors in the country.

One CA raised a question on if and how to ensure preparedness for Brexit. The Commission referred to the notice to stakeholders published on the SANTE website. It was agreed that possible consequences and preparedness for the sector should be discussed with the CA's of the EU27, in the margins of the next CA meeting.

The Commission mentioned that ES had sent a presentation on the progress of their national authorisation database (Shira) for the IVF sector. The information was shared with the CA before the meeting. ES representatives suggested that once the platform is fully implemented, they will present it in one of the future CA meetings.

## 12. CONCLUSIONS OF THE MEETING

The Chair thanked the group for their active participation in the meeting and informed them that the next meeting of the tissues and cells competent authorities has been provisionally scheduled for 25-26 April 2018. [Note: this meeting was subsequently postponed to 20-21 June 2018].