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

Meeting of the Competent Authorities for Tissues and Cells

9 - 10 June 2016

Summary Minutes

This meeting of the tissues and cells competent authorities (CAs) took place on 9 and 10 June 2016. The previous meeting took place on 3 and 4 December 2015.

PARTICIPATION:

Competent authorities from all Member States (MS) were represented at the meeting with the exception of those from Luxembourg, and Slovakia. In addition, competent authorities from Norway, Serbia and Turkey, as well as representatives of the Consumer, Health and Food Executive Agency (CHAFEA), the European Centre for Disease Prevention and Control (ECDC), and the Council of Europe were present as observers.

European Commission (DG SANTE):

Chair: Mr D. SCHNICHELS

Commission Representatives: Mr S. VAN DER SPIEGEL, Ms. D. FEHILY, Ms I. SISKA, Ms I. PUCINSKAITE-KUBIK, Mr P. CATALANI, Mr R. Mc GEEHAN

Administrative Assistant: Ms A. CORNEA

1. WELCOME AND ADOPTION OF THE AGENDA

The agenda was adopted without major modifications. As had been announced prior to the meeting, agenda point 5.2 was moved to the first day and an additional point was added under Any Other Business at the request of the German authorities. No conflicts of interest were reported.

2. LEGAL MATTERS

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

The Commission briefly updated the participants about the status of the transposition check and the on-going infringement proceedings and pilot procedures. It was reported that as of the

beginning of June 2016 the transposition check had been satisfactorily closed for 25 Member States while there were two pilot procedures open. Since the December 2015 meeting two pilots had been successfully closed. The Commission informed the group that two Member States are still the subject of formal infringement proceedings with one case having now reached the Reasoned Opinion stage - the final stage before a decision is made on the need to refer the case to the Court or not.

2.2. Transposition of Directives (EU) 2015/565 (Coding) & 2015/566 (Import) – Progress and planned use of exemptions

The Directives on the import and coding of tissues and cells were adopted in April 2015 and the Commission informed the group that the period between their entry into force and the deadline for transposition (October 2016) is fast approaching. With this in mind the Commission initiated a second discussion on progress towards transposition and in particular planned use of the exemptions which, under the Directives, the Member States have the discretion whether to put in place or not.

According to the input from the group during the discussion and also from written submissions provided by competent authorities who were unable to attend the meeting, the following picture has emerged so far:

Transposition in general

- No Member State has completed transposition for either import or the coding Directive;
- All Member States have begun the process of drafting the national transposing legislation. A number of representatives stressed that the draft texts were still subject to Parliamentary approval and that planned use of exemptions may be altered due to such negotiations;

Import

- Currently, 14 MS plan to exempt one-off imports from the documentation requirements in Annex I part F and Annex III to the Directive while seven MS have decided not to use this exemption;
- Ten MS plan to exempt one-off imports from the requirements on written agreements while seven MS have decided not to use this exemption;

Coding

- Currently, 18 MS plan to exempt T&C (other than reproductive cells for partner donation) which remain within the same centre while five MS have decided not to use this exemption;
- 13 MS plan to exempt imported T&C when they remain in the same centre while six MS have decided not to use this exemption;
- Six MS plan to allocate unique donation identification numbers at national level while 15 MS are planning localised allocation;
- Eight MS plan to use only one of the three product coding systems (EUTC, Eurocode, ISBT128) while 13 MS plan to allow the use of more than one system.

A number of representatives clarified that for the allocation of unique identification numbers and the use of product coding systems, different approaches are taken within their Member States for replacement tissues and cells and for reproductive tissues and cells.

2.3. Direct distribution of sperm – follow-up actions (DK CA)

Following the discussions in previous meetings of the Expert Group on this subject, the Commission informed the group that it had formally contacted the Danish Ministry of Health in order to request further information and explanations as to how the requirements of the tissues and cells Directives and, in particular, those relating to traceability and reporting of serious adverse reactions are implemented and enforced in the case of direct distribution.

The Danish CA also informed the group that the Danish Ministry of Health was considering changes to national legislation relating to this practice. It was stated that a consultation on the proposed changes would take place over the summer in Denmark to seek the views of relevant stakeholders. While the consultation is not aimed at the Member State tissues and cells competent authorities, the Danish CA agreed to provide the group with a summary of the proposed changes, once the consultation had been launched. The members of the Expert Group were thus encouraged to send any comments they had on the proposed changes directly to the Danish CA and Ministry of Health.

2.4. Mapping by the Commission of the more stringent safety and quality requirements in the Member States – Publication of documents and next steps

The Commission presented an overview of the results of the mapping exercise on the more stringent requirements (MSR) for T&C in which authorities from all 28 MS and Norway participated. Poland did not submit a report for reproductive T&C, but will be able to contribute within the next weeks before publication. The main goals of this exercise were to map legally binding more stringent requirements, practices implemented in response to national professional recommendations and identify countries with MSR also at regional level. The partial results were presented at the December 2015 CA meeting. Since then, necessary clarifications have been requested and the current mapping exercise and the final results have been included in an overview table.

For non-reproductive T&C, NAT testing for HIV, HBV and HCV is a very common MSR, legally binding or recommended in more than 16 MS. The less common MSR for non-reproductive T&C (in 7-15 MS) are tests for HTLV-2, CMV, Epstein-Barr virus, malaria, toxoplasmosis, trypanosomiasis, *Treponema pallidum* (antibody testing), ABO and RhD blood group testing, HLA testing. For reproductive T&C the most common MSR (7-13 MS) are: NAT testing for HIV, HBV, HCV, antibody testing for HTLV-2, CMV (technique not specified), testing for malaria, trypanosomiasis, *Neisseria gonorrhoeae*, *Plasmodium sp.* (antibody testing), ABO and RhD blood group testing, and genetic testing.

The Commission made a proposal to update the results every two years which was agreed by the group. The Commission also announced that the final results will be published on the public health section of its Europa website in the coming weeks.

Nota Bene: The results have since been published and can be found here.

2.5. Organisation of oversight in the ART sector in EU Member States (EL ART CA)

Following previous presentations on the oversight of the ART sector in Spain, the Greek ART CA gave a presentation on how oversight of this sector is put in place in Greece. The Greek ART CA had submitted an information report to the Commission services and presented the main points of this report to the group. The first part of the report involves the legal framework, in which the civil code was amended to introduce medical assisted reproduction. In 2015, specific legislation was put in place for the establishment of clinics and human reproductive banks and there is a ministerial decision on cryopreservation banks. At the moment in Greece there are 46 clinics that have yet to be fully authorised by the relevant CA. There is now an independent Authority for Medically Assisted Reproduction that will address the problem of medical tourism.

In response to questions from the group, Greece clarified that payment for oocyte donations is forbidden by law while expenses for travel and nurses up to 1200 euros may be reimbursed. Given the on-going efforts to authorise all tissue establishments in the ART sector in Greece and the need to include these in the EU Tissue Establishment Compendium, the Commission asked the Greek ART CA to give a further update on progress in the next meeting of the T&C competent authorities. The Greek ART CA agreed to do so and also asked the Commission to make its information report available to the group via CIRCA-BC.

3. REPORTS

3.1. Update on the Report on implementation of the Tissues and Cells Directives and the principle of voluntary and unpaid donation (VUD) for tissues and cells – Published Report

The Commission informed the group that the Commission Report on the implementation of the tissues and cells Directives was published in April 2016. This is the second Report of its kind and also includes detailed technical annexes, in the form of Commission Staff Working Documents, on the findings on implementation and the implementation of the principle of voluntary and unpaid donation. The replies for each Member State to the original survey were also provided with the Report. The Report shows that, overall, there is a good level of implementation of the requirements across the EU. However, the Report also points to some gaps and difficulties in the implementation and enforcement of the requirements, as well as differences in interpretation across the EU Member States. The Report concludes that the findings show the need for a more formal and detailed evaluation of the legislation in line with the Commission's principles of Better Regulation.

3.2. Follow-up actions and next steps

In line with the conclusions of the Report on Implementation, the Commission informed the group that the next step in its policy cycle would be an ex-post evaluation of the tissues and cells legislation. While the Commission stressed that any such evaluation would first require internal approval, the key parts of such an evaluation were thus outlined as well as the aims and objectives of evaluating the legislation. The first major step would be to produce a roadmap which would outline the purpose, content, scope and planned evidence base on which the evaluation would be based. Secondly, an external

contractor would be requested to produce an independent report, answering a number of focused evaluation questions following an analysis of the evidence base. Input from all relevant stakeholders would also be an important part of the evaluation with a 4-week period for comments following publication of the roadmap and a 12-week open public consultation to gather stakeholder views. The Commission stated that it expected such an evaluation to run until the fourth quarter of 2018.

Martin Seychell, Deputy Director General of DG SANTE addressed the group on the findings of the implementation report and expected evaluation. He stated that the key question would be to assess whether the legislation is still fit for purpose for the tissues and cells of today but also of tomorrow and in the future. It was stressed that the timeframe foreseen for this evaluation would be long but that it is important to be thorough in this process and that once finished there would also be a period of reflection on necessary next steps based on the findings of the evaluation. It was also pointed out that the evaluation exercise would not prevent the Commission carrying out any necessary amendments of the technical Directives while the evaluation takes place. The Deputy Director General encouraged the T&C CAs to work closely with the Commission during this process.

The group welcomed the expected evaluation and a number of points were raised which members of the group stressed should be taken into consideration in an evaluation exercise. These included the different levels of implementation across the MS, in particular relating to authorisation and inspection procedures, the lack of clarity due to inconsistent and unclear definitions, the links with other neighbouring sectors and the borderlines between the different SoHO sectors, the lack of requirements on donor protection, clinical effectiveness, and preparation processes, and the need to ensure the legislation is kept up-to-date with scientific and technical progress as well as new and emerging disease threats. The group also asked the Commission to provide clarity on the role and responsibility of the external contractor in such an evaluation process.

4. PRESENTATION OF PROJECTS, JOINT ACTIONS AND STUDIES UNDER THE 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)

An update on the ARTHIQS Joint Action was given with a focus on its work package 5. The 36-month long JA is entering its final year and work is on-going on a number of WPs in order to ensure all deliverables are provided in a timely fashion. For WP5 on HSC donor follow-up, a survey has been circulated and responses provided by CAs. The results of this survey will be included in the final guidelines on HSC donor follow-up and the presentation showed that there are still a number of open questions on what to include in the guidelines which will need to be answered before they are finalised. The most relevant results include the variety of procedures applied across MS. However, it is not clear what are the best practices for collecting information during follow-up, and what are the maximum number of donations from a given donor. The guidelines are under finalisation and proposed contents include the state-of-the-art, the regulatory framework, and an overview of the current models for follow-up, responsibility, and data reporting.

For the Cord Blood Banking part of WP5, a second questionnaire was circulated with the objective to assess the management of CBB organisations and provide input for a guide on Member State approaches to CBB. A technical meeting was held in Zagreb in March where a draft version of the guide was finalised. Several CAs and the Commission pointed out that it was not clear whether the term "autologous" referred to the same person being both donor and recipient or whether this meant use of cord blood within the same family. The WP leader committed to making sure that the use of this term in the guide is unambiguous.

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 began in October 2015 and a representative of one of the joint coordinators (the Italian national transplant agency – CNT) gave a second presentation on this JA to the group. Whereas the first presentation in the previous T&C CA meeting focused on giving an overview of the JA, including its objectives and the contents of the work packages, this second presentation focused on the work carried out so far in the WPs. With the exception of WPs 8 and 9, all WPs are now up and running and working on their respective deliverables.

As part of WP2 on dissemination, the website for the JA is now public and provides the central info point for the public on the JA. There was also a focus on the work carried out in WP5b on preparation process authorisation and the results of a survey of MS CAs was presented to the group. It was clarified that CAs who also oversee pharmaceutical products are part of this work package although the objective is not to cover products considered as falling within the scope of EU medicinal products legislation.

The work under WP6 is also well under way with the aim being to produce guidelines for the inspection of blood and tissue establishments. To a significant degree, this work will also form the basis for the work under WP7 – inspector training, WP8 – collaborative inspections and WP9 – inter-inspection system auditing. The Commission called on the CAs to follow the work in these WPs, in particular, closely and provide input where appropriate, as the uptake of the work produced will largely depend on the willingness of the CAs to use it in their future operations.

4.3. Presentation of projects funded through the 2015 call of the Public Health Programme

Under the 2015 call of the third Public Health Programme the Commission sought calls for proposals on common assessment methodology on quality, safety and efficacy of transplantation therapies. Due to the quality of the proposals, not one but two proposals were selected and have begun work in the first half of 2016. The leaders of both projects gave a first presentation of their respective projects to the group.

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

EURO GTP II is led by the Tissue Bank of Barcelona and brings together 14 associated partners and 13 collaborating partners, amongst them tissue establishments, CAs, universities, scientific associations and the Council of Europe's EDQM. This project will

work primarily on establishing good practices with regard to preparation processes and procedures for patient follow-up. There will be a particular focus on novel preparation processes and clinical indications. The project aims to produce four main deliverables: 1. A good practice guide; 2. A database which will act as a compendium of recognised preparation processes and applications per tissue and cell type and information on how these are authorised by CAs; 3. An interactive assessment tool which will provide information on the good practice procedures to follow for a given preparation process or application, and; 4. A proposal for a management model for the long-term sustainability of the deliverables produced as well as for the development of accreditation and training programmes on the above.

The Commission, along with the group, welcomed this project and urged it to work closely with VISTART on the proposals for preparation processes and also to regularly update the CAs given that they are the bodies which will ultimately authorise each preparation process and decide on the information it requires for such authorisation. Moreover, the Commission called on the project coordinator to make any proposal for the long-term sustainability of the project deliverables at an early stage so that a suitable host could be found. The coordinator explained that plans are already in place to work closely with the other related EU-funded actions and agreed to keep the CAs up-to-date with progress in this project.

4.3.2. *European Cornea and Cell Transplantation Registry (ECCTR)*

ECCTR brings together eye banks, universities and professional associations from Italy, United Kingdom, Sweden, Netherlands and Ireland. The main objective is to build a common assessment methodology and establish an EU web-based registry and network for academics, health professionals and authorities 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, surgical procedure, etc… to allow for evidence-based decisions in the future. The intention is to maintain this registry even once the project has come to an end.

Along with the horizontal work packages on coordination, dissemination, and evaluation, there will be four operational WPs on software development, cooperation with other EU-funded actions, including VISTART and EURO GTP II, data collection from clinics and eye banks, and evaluation of the collection data. The final report is expected to include guidelines on the assessment of the quality, safety and efficacy of cornea transplants. In response to questions from the group, the project leader clarified that the information provided in the registry would also include information on the evaluation of the donor such as basic information on the donor and the storage time of the cornea. ECCTR will assess how the donor parameters will affect the safety and efficacy of the transplant. As with EURO GTP II, the Commission called on ECCTR to work with other relevant EU-funded actions as foreseen in its work plan and to continue to regularly update the group on progress in this project.

5. SURVEILLANCE AND VIGILANCE

5.1. Update on infectious disease risks

5.1.1. *Epidemiological update (ECDC)*

ECDC presented an epidemiological update on West Nile Virus, Yellow Fever and the Zika Virus. ECDC monitoring of the EU for WNV affected areas has shown that no cases have been reported so far for the 2016 season.

The Zika Virus is now active in Central and South America, Central Africa and S-E Asia and ECDC reported on the drafting of a guide for preparedness activities in Europe. The key parts of this draft guide are: designation of affected areas, risk assessment, initiation/cessation of SoHO safety measures, laboratory screening tests, and T&C safety measures for living and post-mortem donations of non-reproductive and reproductive T&C. Several members of the group raised questions about the draft guidance relating to reproductive cells and whether the proposed deferral periods were long enough and whether NAT testing was necessary and, if so, feasible given a lack of commercially available testing kits for reproductive cells and validated screening tests. The draft guide was circulated to all members before the meeting and they were invited to provide their comments in writing, directly to ECDC, by June 20th.

Nota Bene: The final version of the guide is available on the ECDC website.

5.1.2. *Other*

The competent authorities were asked whether they have additional information or updates to report. In relation to Zika, the French CA informed the group that a number of its citizens travel to affected areas and that it had reports of transmission of the virus through sperm 93 days after infection. The Greek CA also mentioned that there are regular imports of HSC from Brazil and asked whether NAT testing is recommended for these imports. ECDC stated that it would take this information into account for the on-going preparation of the guide.

5.2. Update on the development of the EU Coding Platform

5.2.1. *Debrief from the meeting of the Expert Sub-Group on Coding*

The Commission briefly reported back to the group on the meetings of the Expert Sub-Group on the Coding of Tissues and Cells since the December 2015 CA meeting. The primary task of this sub-group is to provide expert advice to the Commission in relation to the EU Coding Platform. The sub-group has worked on producing a final list of the EUTC as well as providing advice on mapping the ISBT128 and Eurocode product codes to the EUTC for inclusion in the EU Tissue and Cell Product Compendium. This initial work is now complete and this part of the Coding Platform is ready to be made public although it will require regular updates.

The Commission clarified the meaning and purpose of having authorisation categories in this Compendium. It was pointed out that there is no distinct authorisation category for donation and the Commission agreed to look into the possibility of changing the procurement category to a category covering both donation and procurement. The Commission reminded all CAs that, if they felt there was not a suitable product code in the EUTC for any given tissue or cell, before classing it under the 'other' product

category, they should first ask the Commission to consult with the sub-group on whether a new product category is necessary or whether an existing one should be used.

5.2.2. *Preparations for the roll-out of the Single European Code (SEC)*

The Commission also updated the group on progress made towards the completion of the EU Tissue Establishment Compendium. The Commission thanked the CAs for their efforts in providing the relevant information on the tissue establishments and informed the group that this Compendium now contains entries for over 2600 TEs and thus the vast majority of TEs in operation in the EU. The Commission reminded the CAs that even though the initial task of filling the Compendium with the relevant TE entries had now been almost completed, the on-going task of keeping the information on TEs up-to-date remains with the CAs.

A number of points relating to this Compendium were clarified: TE entries cannot be deleted once they have been uploaded; the "date of change" represents the last update of the TE information, while the "last update" is related to the authorisation; TE codes cannot be modified once assigned and these do not equate to authorisation numbers / codes. The Dutch CA queried whether it would be possible to see historical data relating to a TE. This is not currently the case but as the historical data is not deleted, the Commission agreed to see if it would be possible to make this visible. The Commission also clarified while the SEC look-up and the Compendia are accessible by the general public, the TE Management and Administration parts are restricted to the relevant CAs and the Commission respectively.

The Commission reminded the group that a number of information documents relating to the SEC are available on its website and that it aimed to make the EU Coding Platform, including both the EU Tissue and Cell Compendium and the EU Tissue Establishment Compendium, available to the public in the third quarter of 2016.

Nota Bene: The EU Coding Platform is now fully online here.

5.3. Rapid alerts for tissues and cells (RATC)

5.3.1. *Update on the RATC Platform*

The Commission gave a brief update on the Rapid Alert Platform. The Commission stated that it planned to make some changes aimed at improving the functioning of the platform by Q3 2016. Amongst these are plans to limit the number of notification emails to cases where an alert is launched or closed. Following a request from the group, it also agreed to look into whether it can be made possible to allow users to make a comment or ask a question related to an on-going alert without that user declaring that it is affected by the alert as is currently necessary. Following the closure of an alert, a deadline of 30 days will be introduced for the submission of the final report with a recommendation to provide this within 15 days. ECDC will also be given access to the platform with read/comment rights.

5.3.2. *Update on alerts*

The Commission presented an overview of the 2016 alerts so far and informed the group that the summary report on 2015 activities had been published in May 2016. So far in 2016, 16 alerts have been launched with the vast majority of these coming from the

Danish CA and related to the ART sector. One particular alert was mentioned following the death of a patient in Spain following the distribution of tissues from a tissue establishment in Luxembourg which had originated from a donor in France. This alert highlighted the RATC platform as a means to quickly circulate information relating to tissues and cells with (potential) quality and safety defects.

5.4. Serious adverse reactions and events (SARE)

5.4.1. *Final Results of the 2015 SARE annual reporting exercise (2014 data)*

The Commission presented the final results of the 2015 annual reporting exercise having presented the preliminary results in the December 2015 CA Meeting. All countries submitted reports except Cyprus. The denominators for this reporting exercise were not complete and therefore the results should be considered with caution. A total number of 190 SAR were reported, with 109 SAR for non-reproductive T&C and 81 SAR for reproductive T&C. For the severe adverse events (SAE), a number of 551 SAEs were reported by 19 countries. For the SAR in donors, 620 cases were reported by 19 countries.

In the discussion which followed the presentation, the Portuguese CA confirmed that it had reported a relatively high number of rejected grafts for cornea transplants compared with other reporting countries. It was pointed out that graft failure in cornea transplant is a relatively common occurrence and that there may be an issue of under-reporting these as SARs. The Commission suggested that the work package of the VISTART Joint Action looking at SARE could look into this possible under-reporting. The UK ART CA, supported by French and Portuguese counterparts called for reporting in the ART sector to be done per cycle and it was also suggested that VISTART look into this possibility. The group agreed that for the HSC, SAR in donors (53 reported in 2015) it is important to have precise categories of SAR. The Commission asked the CAs to submit their comments on the final draft report by July 30, 2016.

Nota Bene: The summary on 2015 SARE reporting has since been published here.

5.4.2. *Launch of the 2016 SARE annual reporting exercise (2015 data)*

The Commission informed the group that the 2016 annual reporting exercise, based on 2015 data, would be launched in the coming weeks with a 2-month deadline for submissions. The Commission also reported to the group on the discussions held in the May 2016 meeting of the blood CAs. There it was pointed out that the launch of the annual reporting exercises for blood and T&C often overlap, with a view to meeting the June 30th deadline for submissions. This creates a significant reporting burden for CAs responsible for both blood and T&C. The Commission agreed that for the 2017 reporting exercises onwards it would aim to stagger the deadlines for submissions and launch the exercises at the end of the first quarter of each year. The group welcomed this approach.

5.4.3. *Presentation of a national vigilance system (ABM, FR)*

In the previous meeting of the T&C CA in December 2015, the group agreed that it would be useful to have presentations of national vigilance systems and the French CA agreed to give the first such presentation while the Dutch CA agreed to ask the Dutch agency responsible for vigilance to present at the next meeting.

The T&C vigilance system in France is (soon to be) the responsibility of *Agence de la Biomedicine* (ABM). The vigilance principles are based on mutually confidential exchanges between the health professionals and ABM. ABM has as the main objectives of this system to prevent and/or reduce adverse events and reactions and is involved in risk management. There are two vigilance systems: the biovigilance system and the ART vigilance system, with similar notification circuits. ABM assesses the SAREs and notifies them, provides professionals with frequent feedback and organises training sessions. Plans for the future include a follow-up procedure for some reactions in patients and better definitions of SAR and SAE (expected and acceptable or not). There is a system of local vigilance coordinators, appointed by tissue establishments, in place and there is a plan to ensure that only doctors will fulfil this role in the future.

6. INTERNATIONAL DEVELOPMENTS

6.1. Update on TTIP

Negotiations on the proposed Transatlantic Trade and Investment Partnership (TTIP) are on-going and plan to also cover trade in pharmaceuticals but not those substances which the EU considers to fall under SoHO legislation. The negotiations may have more of an impact on the plasma derivatives sector than for tissues and cells.

6.2. Council of Europe

The representative of the Council of Europe's European Directorate for the Quality of Medicine announced that the draft of the latest edition of its Tissues and Cells Guide is due to be finalised in November 2016. A consultation period will take place in December or early next year by invitation only and the T&C CAs will be able to send their comments as part of this consultation. The Commission agreed to pass on information on this consultation to the group. In March/April next year the text will be finalised and the latest edition of the Guide is due for publication in summer 2017. For the first time, the guide will be available for free, in a downloadable, electronic format.

7. UPDATE ON THE REVISION OF THE EU MEDICAL DEVICES LEGISLATION

The Commission stated that for the revision of the medical devices legislation there was nothing new to report in terms of any changes relating to tissues and cells to the technical contents of the text.

8. AOB

8.1. Update on CA group interaction with stakeholders

Following discussions in the previous meeting of the T&C CAs, as well as discussions with the blood and organs CAs, the Commission presented draft Terms of Reference for ad-hoc meetings between the CASoHO Expert Group and SoHO-related stakeholders. On the basis of these Terms of Reference, the Commission plans to establish a list of interested stakeholders and from this list, invite relevant stakeholders to the ad-hoc meetings to be held back-to-back with meetings of the Expert Group. The draft ToR set out how these meetings will be organised and clarify that members of the Expert Group will be invited to the stakeholders meeting in their sector (blood, T&C, or organs) and will be free to decide whether to attend or not.

The group welcomed the draft ToR and also made a number of suggestions for improvements including making it clear what the purpose of the meetings will be and that this will not be about promoting products. The Commission agreed to accommodate these comments and stated that it would provide a final draft for written comments to all members of the Expert Group before finalising the ToR and launching the call for expressions of interest, with a view to organising the first such ad-hoc meeting following the blood CA meeting in December 2016.

Nota Bene: *The call for expressions of interest has been published and is available here.*

8.2. Other points

The German CA presented a point to the group concerning extracts from tissues and cells (HMP) and questioned whether such extracts fall within the scope of the Directive. The German representative pointed out that, even if not technically covered by the Directive, the same quality and safety concerns apply and that they therefore plan to apply the requirements of the Directive. If necessary this can be justified as a more stringent measure. This approach was supported by several members of the group.

9. CONCLUSIONS OF THE MEETING

The Chair thanked the group for their positive participation in the meeting and informed the group that the next meeting of the tissues and cells competent authorities has been provisionally scheduled for 15-16 February 2017. As usual, the date will be confirmed at the latest six weeks ahead of the meeting.