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

Meeting of the Competent Authorities for Tissues and Cells

3 - 4 December 2015

Summary Minutes

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

PARTICIPATION:

Competent authorities from all Member States (MS) were represented at the meeting with the exception of those from Croatia, the Czech Republic, Estonia, Luxembourg, Slovakia, and Slovenia. In addition, Norway, the Former Yugoslav Republic of Macedonia, Montenegro 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 I. SISKA, Mr P. CATALANI, Mr R. Mc GEEHAN, Ms. D. FEHILY

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 2.5 was moved to the second day. 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 December 2015 the transposition check had been satisfactorily closed for 22 Member States, there were two pilot procedures open, while a further three pilot procedures were expected. Since the June 2015 meeting four pilots had been successfully closed while the European Court of Justice had ruled on one infringement proceeding against Poland. The Court declared that by excluding reproductive cells and foetal and embryonic tissue from the scope of the provisions of national law transposing the Directives at issue, the Republic of Poland had failed to fulfil its obligations under Article 31 of Directive 2004/23/EC, under Articles 3(b), 4(2) and 7 of, and Annex III to, Directive 2006/17/EC, and under Article 11 of Directive 2006/86/EC. Poland must now act to rectify this situation. One additional Member State is still the subject of formal infringement proceedings with the 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) had almost reached its halfway point. With this in mind the Commission initiated a first 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;
- A majority of 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, five MS plan to exempt one-off imports from the documentation requirements in Annex I part F and Annex III to the Directive;
- Four MS plan to exempt one-off imports from the requirements on written agreements;

Coding

- Currently, 11 MS plan to exempt T&C (other than reproductive cells for partner donation) which remain within the same centre;
- Seven MS plan to exempt imported T&C when they remain in the same centre;
- Seven MS plan to allocate unique donation identification numbers at national level while 12 MS are planning localised allocation;
- Six MS plan to use only one of the three product coding systems (EUTC, Eurocode, ISBT128) while six MS plan to allow the use of more than one system.

The group also discussed ways to ensure traceability across procurements where tissues and cells are retrieved from a deceased donor by procurement teams operating for two or

more tissue establishments. Several representatives mentioned the important role played by transplant coordinators in ensuring this traceability in their countries.

2.3. Interpretation questions

2.3.1. Regulation of lymphocyte immunotherapy (LIT)

The topic of lymphocyte immunotherapy (LIT) was first introduced by the UK HTA during the CA meeting in December 2014 and initial feedback was given during the June 2015 CA meeting while the full feedback outlined below was also provided to blood competent authorities in the November 2015 meeting of the group.

Following the agreement to seek advice from its Legal Service, the Commission informed the group that its Legal Service was consulted on three issues: whether withdrawal of whole blood leading to extraction of lymphocytes falls within the scope of blood or tissues and cells legislation, whether Member States may choose to regulate this activity under either their national blood or tissues and cells legislation and finally whether within a Member State, its authorities have the discretion to regulate the activity under both their national blood and tissues and cells legislation.

The Commission reminded the group that only the European Court of Justice can give legally binding interpretations of Union legislation. After careful analysis of the situation put forward and the relevant legislation, the Commission put forward its working interpretation for the group's consideration. It was felt that justifiable arguments could be made for this activity falling under either the blood or tissues and cells legislation. This being the case, based on the specific nature of their national circumstances (assessment of risks to human health / desired level of human health protection / the existence of more stringent protective measures etc…), and given the fact that LIT is typically a local activity not involving cross-border steps, Member States benefit from a certain degree of discretion when deciding whether to classify this activity under either blood or tissues and cells legislation.

On the final point the Commission reminded the group of the importance of maintaining legal certainty within any given national legislative framework but did not exclude the possibility that in this specific case, authorities within one Member State could allow the same activity to be governed under both sets of legislation. This would depend on the establishment which performs it and provided that this is justified by an assessment of the risks to human health and the desired level of protection specific to that Member State focusing in particular on largely equivalent levels of quality and safety for these activities assured under both sets of national legislation.

2.3.2. Compatibility of national laws with Union law in relation to the cross-border distribution of sperm to natural persons

The topic of cross-border (direct) distribution of sperm to individuals was first raised in the June 2013 meeting and in the December 2014 meeting of the group a request was made to the Commission to clarify the legality of this practice with its Legal Service. Initial feedback on this question was provided in the June 2015 CA meeting.

The Commission informed the group that the Commission's Legal Service was asked whether a requirement to distribute sperm to an authorised tissue establishment or

authorised organisation responsible for human application (i.e. a restriction on direct distribution to natural persons) is in line with Union law and if such a restriction is in line with Union law, can Member States with such restrictions in place require the cooperation of the MS of origin in enforcing them.

The Commission reminded the group that only the European Court of Justice can give legally-binding interpretations of Union legislation. After careful analysis of the situation put forward and the relevant legislation, the Commission put forward its working interpretation for the group's consideration. The Commission stated that not only would such a restriction be admissible in order to implement EU quality and safety standards, the lack of such a restriction may be regarded as not being in line with Union legislation and in particular the provisions on traceability and the obligation to report (serious) adverse reactions.

The Commission informed the group that it had held discussions with the competent authority of the country from which such tissues and cells are distributed and that it planned to write to the Member State in question to ask for further information on the exact circumstances surrounding this practice and, in particular how the relevant provisions of the Union legislation on traceability and serious adverse reaction reporting are fulfilled.

The Danish CA informed the group that it had brought this issue to the attention its Ministry of Health and that discussions were ongoing on how best to deal with the situation. Several members of the group highlighted the need for further discussions between MS' competent authorities on how best to cooperate on this issue.

2.4. Mapping by the Commission of the more stringent safety and quality requirements in the Member States

As agreed in the June 2015 CA meeting, the Commission had begun a mapping exercise of more stringent quality and safety requirements in place across the EU Member States. The first survey on this focused on more stringent testing requirements with a distinction made between non-reproductive and reproductive tissues and cells. As of the beginning of December, replies to the survey had been received from all but one MS and also from Norway.

The first survey was performed by sending each Member State individualised questionnaires, pre-filled with the information on donor testing requirements provided for the 2013 implementation survey. On the basis on the replies received, the Commission has prepared a summary report of the results as well as country factsheets for each Member State. The Commission informed the group that it plans to publish the summary report along with the country factsheets and contact detail information for the relevant competent authorities in each MS. The competent authorities will first be given an opportunity to comment on these documents and verify the accuracy of the data represented in them. This approach and the planned publication were accepted by the group.

The participants welcomed this exercise and the group also agreed that the next survey should focus on mapping of the more stringent requirements in place relating to donor selection and evaluation while it was also pointed out that the results of the first survey can be used to look at the correlation between more stringent requirements and vigilance

data. The group also discussed the frequency with which the (first) survey should be repeated and the results updated. It was decided that, as a first step the competent authorities will be asked in writing how many changes to these testing requirements have been made in the last year in order to gauge a suitable frequency for updates.

2.5. Organisation of the oversight in the ART sector in Spain

As a follow-up to its initial presentation in the June 2015 meeting, the Spanish competent authority responsible for reproductive cells updated the group on developments since the last meeting. This presentation focused on an overview of the assisted reproduction sector in Spain and in particular the steps being taken by the CA to ensure full oversight of the sector.

The presentation outlined the national legislation transposing the EU tissues and cells legislation and includes a recent amendment which established a national registry of tissue establishments in the ART sector and their activities. It was clarified that this registry will include information on egg donors and the number of donations. As part of an ART action plan, efforts are continuing to ensure that all ART TEs are fully authorised, inspected and included in the EU Tissue Establishment Compendium. It was confirmed that, in terms of inspection, each establishment needs to undergo at least a desk-based inspection every two years and an on-site inspection at least once every four years.

The Spanish CA representative informed the group that the Spanish ART CA is located within the Ministry of Health and provided the necessary contact details. A number of detailed questions were also put forward by the group and a commitment was made to answer these questions in writing. The Spanish CA representative also highlighted the issue of direct distribution of sperm and the Commission was asked to continue looking into this. It was also underlined that some Spanish ART clinics are advertising their services, in the same way as they do in Spain in accordance with Spanish law, in other EU Member States including in some where such advertising is prohibited.

3. REPORTS

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

The contents of the Report on the implementation of the tissues and cells Directives had been extensively presented in previous meetings of the group. This agenda point was thus limited to providing the group with an explanation of the procedural steps required for publication and the final format of the report and its accompanying documents.

The Commission confirmed that the final draft version of the report had been finalised and would take the form of a Commission Report giving an overview of the overall state of implementation across the EU-28 (and the EEA countries). This report will be accompanied by a technical annex (including two Commission Staff Working Documents) which will provide more detail in line with the replies received to the general implementation and VUD surveys. The original replies to the implementation survey will also be published with the report. The Commission explained that a disclaimer will also

be used to explain that some of the data provided in the original replies has since been updated and been included in its updated form in the report and technical annex.

Following the meeting the next step will be to submit the report and its annex for internal consultation within the Commission. Parallel to this, the competent authorities will also be given an opportunity to verify the data relating to their Member State contained in these documents. Once this consultation period has ended and the necessary translation has been completed, the report will be officially adopted by the Commission and transmitted to the other EU institutions at which point it will be made publically available. Adoption and publication are expected in the first quarter of 2016. The Commission informed the group that the next logical step following publication would be to carry out an in-depth evaluation of the EU legislation and policy framework in the tissues and cells sector.

4. PRESENTATION OF PROJECTS, JOINT ACTIONS AND STUDIES UNDER THE HEALTH PROGRAMME (AND HORIZON 2020)

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 by a representative of the coordinator, the French biomedicine agency (ABM), with input from the leading authorities in charge of the main work packages. The 36-month long JA is now at its halfway point and a newsletter has been developed to be disseminated in January 2016 to mark this milestone. The newsletter will also complement the website and brochure which have been developed under work package (WP) 2 on dissemination. WP3 focuses on evaluation of the operational work packages of the JA and continues to assess progress made on the deliverables against the output indicators established before the start of the JA. According to the information given, the JA remains largely on track to achieve its stated goals in the 3-year timeframe provided.

In WP4 on assisted reproductive technologies a mapping exercise has been undertaken on the organisational set-up of ART oversight and the legislative frameworks in place throughout the EU. A report on this is being finalised and will be disseminated in due course. As the first comprehensive assessment of the organisational set-ups in the ART sector, the Commission commented on the importance of this exercise as a key deliverable of the JA. In terms of next steps, institutional guidelines and a *vademecum* for the inspection of tissue establishments in the ART sector will also be developed in the second half of the JA.

In WP5 on haematopoietic stem cells, the presentation focused on the work which has taken place on donor follow-up and it was stressed that an update on the work related to cord blood banking would be given in the next meeting of the group. The results of the survey on HSC donor follow-up (registries, practices and data collected in each MS) was thus presented along with the main conclusions to be drawn from the data received from those Member States whose authorities provided replies to the survey. The next planned step is to develop a guidance document based on the results of the survey which will include sections on the main safety issues, as well as criteria and a standard data set, IT specifications, and governance for the development of national registries. Following a

question from the group it was clarified that ethical and legal aspects would also be considered as part of the development of this document but guidance on this will only be included in the final version if consensus can be reached amongst the partners on such aspects. CAs will be given an opportunity to comment on the draft version of this document before its finalisation. As regards, the development of guidelines for authorising cord blood banks, the group will be updated about the progress of this document during the next CA meeting.

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

A first presentation was given by a representative of one of the joint coordinators (the Italian national transplant agency – CNT) of the VISTART Joint Action. Funded via the 2014 envelope of the third Health Programme, the JA officially started in October 2015 and brings together competent authorities from both the blood and tissues and cells sectors. It will be jointly coordinated by the Italian national CAs for blood and tissues and cells, CNS and CNT respectively, and has 16 associated partners and 21 collaborating partners many of whom are CAs covering both blood and tissues and cells.

In addition to the standard work packages on coordination, dissemination and evaluation, the JA has operational WPs on coding, vigilance, vigilance reporting, inspector training, inspection guidelines, international 'joint' inspections, and inter-inspection system auditing. These WPs will focus on the four main pillars of the JA: vigilance, inspections, new processes, and coding. The main objectives for each WP were presented to the group along with an overview of the main activities which had taken place to date since the official start of the JA.

One of the first activities is to survey the CAs on their Member States' plans for transposition and implementation of the SEC and it was clarified that the aim of this survey would be to assess training needs which Member States may have for the implementation of the SEC as the JA is designed to support the MS competent authorities in their implementation of the SEC. The survey was due to be sent out in December 2015 and the CAs were encouraged to respond to this and outline their training needs.

The group also made reference to several previous and on-going JAs and projects such as ARTHIQS and EUSTITE which have also worked on, or continue to work on, similar themes such as inspection guidelines and joint inspections and pointed out a risk of duplication with this work. The group was reassured that the results of previous work have been taken into account and the aim is to build on this rather than duplicate it while the coordinators for ARTHIQS and VISTART committed to aligning their efforts where needed. It was also clarified that in WP4 an analysis of the Common Approach Document would be undertaken and potentially changes proposed with a view to further harmonisation of annual vigilance and rapid alert reporting. It was pointed out that many CAs have well-established IT systems in place for such reporting and these may need to be altered at a significant cost if changes are proposed.

The coordinator will continue to keep the group updated on progress under this Joint Action in subsequent meetings of the group.

4.3. Update from the study on the economic landscape of the tissues and cells sector

The Commission gave a brief update on progress towards publication of the study on the economic landscape and responded to a number of questions related to this and the contents of the final study report. The Commission thanked those CAs who had provided comments on the first five chapters of the report and explained that chapter six would also be made available for comments once ready.

There were a number of comments from within the group on the recommendations contained in the report and the Commission reassured the group that these had either been removed completely or it had been made clear that these were based on the author's opinion. It has also been made clear in this document that competent authorities are not in a position to control the economic elements of the sector and there will be a general disclaimer added to the final version that the report is the work of the contractor and any views put forward are those of the contractor. Once finalised, the report will be made public.

4.4. Presentation of current tissue and cell-related Horizon 2020 calls for proposals

A representative of the Commission's department for research (DG RTD) provided an overview of developments in the field of EU-funded research with links to the tissues and cells sector. A brief introduction to Horizon 2020 – the EU programme for research and innovation for the period 2014-2020 was given. As part of this programme, funding is available for research on health and specifically calls for proposals will be made under the headings of clinical research on regenerative medicine and support for innovative SMEs in the biotechnology sector. Deadlines for these calls will fall in the first half of 2016 and CAs were invited to pass on the information to interested parties in their Member States.

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, Ebola, MERS CoV and the Zika virus. There was a particular focus on the Zika virus and competent authorities were invited to consult the rapid risk assessments available on the ECDC website and consider donor deferral in line with the deferral recommendations in place for West Nile virus. The ECDC representative also mentioned plans to update the ECDC Ebola risk assessment to take into account the risk of transmission through sexual contact with survivors and also to update it to include guidance on plasma donation.

An update was also given on the preliminary results of the priority setting exercise. This exercise aims to set a priority list of bacteria which are transmissible through substances of human origin. This will allow ECDC to prioritise which bacteria should be assessed (first) concerning the infection transmission risk they pose through SoHO. A group of experts has worked on this, reviewing relevant literature and developing criteria for the priority setting. A list of 15 bacteria was selected and a risk model was then used to rank these. For SoHO as a whole, the preliminary results show that Staphylococcus aureus is the highest ranked bacterium while Klebsiella spp, Streptococcus beta-haemolyticus, Escherichia coli, and Pseudomonas spp. all follow in group two of the ranking. There are

also individual rankings for blood, tissues and cells and organs and a final decision on prioritisation still needs to be made. It was also confirmed that the preliminary results appear to correlate accurately with reporting of serious adverse reactions while competent authority representatives were encouraged to also correlate the results with their national data and flag any discrepancies.

5.1.2. *Other – Member States will be asked whether they have additional information or updates to report*

The competent authorities were asked whether they have additional information or updates to report, but there were no reports of any additional information on infectious diseases.

5.2. Update on the development of the EU Coding Platform

5.2.1. *Update on the agreements with the organisations managing ISBT128 and Eurocode*

The Commission informed the group that the Decision establishing a model for agreements between the Commission and relevant organisations on the provision of product codes for use in the Single European Code was adopted and published in July 2015. Based on the model agreements, the agreements with Eurocode and ICCBBA were signed and entered into force in September 2015. These agreements are designed to ensure that updated ISBT128 and Eurocode product codes are regularly made available for inclusion in the EU Tissue and Cell Product Compendium and ensure that liability for the information provided remains with the organisations providing the information.

5.2.2. *Debrief from the meetings 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 June 2015 competent authority meeting. Since then the sub-group has met three times and its primary task is to provide expert advice to the Commission in relation to the EU Coding Platform. The first meetings have focused on establishing a procedural framework for the work of the sub-group while it has also begun the task of providing technical expertise on the mapping of product codes from ICCBBA and Eurocode which need to be mapped for inclusion in the EU Tissue and Cell Product Compendium which forms part of the EU Coding Platform. The Commission plans to hold the next meeting of the sub-group via telephone conference in February 2016.

5.2.3. *Preparations for the roll-out of the Single European Code*

An update was given by the Commission on the progress made towards the roll-out of the Single European Code and, in particular, the development of the EU Coding Platform. The Commission reminded the group that this would likely be the last meeting of the group before the platform is made public. The competent authorities were also reminded that they have two main tasks related to the platform. Firstly, CAs are required to populate and update the EU Tissue Establishment Compendium with the necessary details of all authorised TEs under their responsibility. *A deadline of 31 May, 2016 was agreed for this task with updates where necessary thereafter*. So far five Member States have yet to nominate their TE Compendium users and those MS were urged to do so, so that the necessary information can be provided. Secondly, CAs need to inform the

Commission whenever they feel a new product code may be needed in the EU Tissue and Cell Product Compendium.

The Commission also announced a number of measures to support Member States in their implementation of the new requirements. An information document for users and an FAQ document are under preparation and are due for publication in February 2016 and will be available on the Commission's public health website and circulated via CIRCA-BC. The Commission stated that it would also consider visiting Member States if the competent authorities felt this would be useful and they plan, for example, to hold workshops for stakeholders on SEC implementation. The group were also reminded that support will be available as part of the VISTART Joint Action which has a work package dedicated to SEC implementation *(see 4.2 for further details)*.

The Commission was asked whether the Coding Platform, once fully established, could be considered as a fulfilment of the competent authorities' requirement under Article 10 of Directive 2004/23/EC to establish and maintain publicly accessible registers of authorised tissue establishments. The Commission reminded the group that it could not give a legally-binding interpretation of Union legislation but as an initial reaction observed that this may be possible depending on exactly how each Member State had transposed this requirement into their national legislation and national rules on public accessibility given the platform will only be available in English.

5.3. Rapid alerts for tissues and cells (RATC)

The Commission gave a preliminary overview of activity on the tissues and cells rapid alert platform (RATC) for 2015. So far in 2015 there had been eight alerts, seven of which were related to reproductive tissues and cells and one epidemiological alert. This figure is considerably lower than the 25 alerts launched in 2014. The Commission informed the group that the final RATC summary report for 2014 has been published and updated the group on the work of the RATC Working Group (Expert Sub-Group) which met in June 2015. A number of changes were put forward following discussions in the Working Group aiming to improve procedures for the notification and closure of alerts and RATC users were invited to take note of these while the SOPs will be updated accordingly.

The Danish competent authority informed the group that it planned to launch a number of alerts related to reproductive cells in the weeks following the meeting. The Danish representative also informed the meeting of a modification to previous practices by a tissue establishment concerning the availability of sperm straws from donors with a condition, where a risk assessment gives a risk of 1 % or more for a repetition. In these cases sperm straws are no longer available to Danish recipients except for the use for siblings [as defined by national guidance], but remains available to recipients in other countries after completed informed consent. A number of competent authorities expressed concern at this situation, in particular given the practice of direct cross-border distribution of sperm to individuals .

5.4. Serious adverse reactions and events (SARE)

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

The Commission presented the preliminary findings of the 2015 SARE annual reporting exercise based on 2014 data with the final results to be presented in the June 2016 meeting. The preliminary results show almost 200 serious adverse reactions (SAR) and around 550 serious adverse events (SAE) reported while a significant number of Member States did not report any SARE. The Commission was still waiting for data submission from Cyprus and Luxembourg. For those countries that do report, the Commission observed a gradual improvement in data collection. The Commission also mentioned that the VISTART Joint Action will work on SARE reporting and carry out a quality control exercise on the current procedures for how and what to report and how the results are analysed and presented.

On the 2014 reporting exercise based on 2013 data, the Commission stated that the final summary report had been drafted and invited competent authorities to comment on this during the course of January 2016. The report will then be published on the Commission's public health website.

5.4.2. *Presentation of a national vigilance system*

In order to promote mutual understanding and share best practices, the Commission introduced a proposal for the presentation of national vigilance systems in future meetings of the group. The proposal was well received by the group and there was a consensus that this would be a useful addition to the meeting agenda. The French biomedicine agency (ABM) kindly offered to present their system in the June 2016 meeting.

6. INTERNATIONAL DEVELOPMENTS

6.1. Update from the Council of Europe

The Council of Europe's European Directorate for the Quality of Medicines and Healthcare (EDQM) gave an update of their recent activities related to the tissues and cells sector. An overview of the second edition of their quality and safety guide was given. The second edition of this guide was published in July 2015 and contains a number of additions compared with the first edition. The results of a survey on feedback from users were also presented and showed that the guide has been well received by users who, in addition to tissue establishments, include manufacturers, educational establishments, clinical users, and regulatory bodies.

Work has already begun on the third edition of the guide and publication is foreseen in the second or third quarter of 2017. Starting with the third edition, the electronic version of the guide will be open access and free of charge. EDQM also mentioned that their brochure “Umbilical Cord Blood Banking – A Guide for Parents” was under revision and would soon be available for comments with a view to publication in early 2016.

6.2. Other Developments

The Commission briefly informed the group about other international developments including three draft guidance documents being prepared by the US Federal Drug

Agency (FDA). These documents give guidance on how certain terms should be interpreted and may not always be in line with the terms and interpretations used across the EU. The Danish and Italian CAs offered some initial comments on these document s and other interested parties were made aware that they are subject to a public consultation period running until 29 April, 2016.

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

The Commission updated the group on the latest developments in the negotiations on the proposed revision of the EU medical devices legislation. The negotiations are now at an advanced stage between representatives of the European Parliament, the Council of Ministers and the Commission in order to seek an agreement on a final version of the proposed Regulation. So far these negotiations have not resulted in any further changes to provisions with a potential impact for tissues and cells. A further update will be given in the June 2016 meeting of the group.

8. AOB

8.1. Traceability and anonymity – transplantation cards

The Danish CA representative introduced to the group a potential conflict between current practice in certain tissue establishments and rules on data protection. Some supplier tissue establishments based in third countries or other EU Member States have been requesting information on recipients in the form of transplant cards to ensure traceability. On occasions these transplant cards have also contained personal information on the recipient such as their full name rather than, or in addition to, a recipient identification number. Such practice would seem contrary to Article 14 of Directive 2004/23/EC as well as national personal data protection rules. Several other competent authorities also stated that this was an issue they had come across. Given the limited time available, the Commission suggested a further discussion on this point in the June 2016 meeting of the group.

8.2. HTA guidance on cord blood banking

The UK (HTA) CA representative introduced to the group a planned information document on cord blood banking. This document will give an overview of what cord blood banking is and the established uses for cord blood, explain the services provided by public-sector and private-sector banks, contain a list of frequently asked questions, and give some examples of questions that parents and other interested parties could ask banks. The document is due for publication on the HTA website in the weeks following the meeting and will be made available to the group once published.

8.3. Mitochondrial donation in the UK

The UK (HFEA) CA representative presented to the group the new rules in the UK on mitochondrial donation. The new regulation entered into force on October 29, 2015 and will allow for the use of two techniques – pro-nuclear transfer (PNT) and maternal spindle transfer (MST) to avoid mitochondrial disease under strict licensing conditions. Any tissue establishment or organisation responsible for human application wishing to use one or both of these techniques will need to apply to the competent authority for an authorisation or an addition to their current authorisation to carry out fertility treatment.

In addition, any such organisation will need to apply, on a case-by-case basis, for an approval to use the technique for any given recipient. So far no authorisations have been applied for and the HFEA stated that it only expected the techniques to be used in a limited number of cases.

8.4. Discussion on CA group interaction with stakeholders

The Commission introduced a proposal for interaction between the competent authority group and EU-level stakeholders. The idea would be to create an opportunity for discussions on topics of mutual interest on a European level. The main principles for this interaction were outlined as being a clear separation of the Expert Group meeting and the stakeholder interaction i.e. discussion with stakeholders could be held before or after the group meets but would not be part of the Expert Group meeting. Secondly, the topics and stakeholders would be selected based on their EU-level representativeness and such a selection would be done in consultation with the competent authorities.

The general consensus within the group was in favour of such an initiative and several representatives pointed out that similar discussions take place in other sectors at EU-level as well as at national level. It was also observed that expectations for such discussions and the type of topics that could be discussed will need to be clearly outlined and that some form of document such as a Terms of Reference document should be used to provide a framework for these. The Commission committed to work on such a document and bring it back to the group in the next meeting and also put it to the blood and organs competent authorities for their comments.

8.5. Other points

The Dutch CA representative informed the group about a potential impact of Regulation 765/2008 on the work of accreditation bodies in the Netherlands. This Regulation is designed to standardise accreditation bodies and the work they carry out. In the Netherlands the application of this Regulation has led to the JACIE work being put on hold (it has been taken over by JACIE UK and ES). The Dutch CA representative invited other CAs to consider whether this may also be the case in their Member States. None of the other CAs indicated that they were aware of such situations in their Member State.

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 June 9-10, 2016.