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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 2014

Summary Report

The meeting of the Competent Authorities on Tissues and Cells was convened on 3 and 4 December 2014. The previous meeting of Tissues and Cells National Competent Authorities (CAs) took place on 2 and 3 June 2014.

PARTICIPATION:

All Member States (MS) were present at the meeting. In addition, Norway, the Former Yugoslav Republic of Macedonia and Turkey, as well as the European Directorate for the Quality of Medicines and Health Care (EDQM) of the Council of Europe (CoE), the World Health Organisation, the Consumer, Health and Food Executive Agency (CHAFEA), the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMEA) attended the meeting.

European Commission (DG SANCO):

Chairs: Mr D. SCHNICHELS, Mr S. VAN DER SPIEGEL

Commission Representatives: Ms I. SISKA, Mr R. Mc GEEHAN, Mr P. CATALANI

Administrative Assistants: Ms A. CORNEA

1. ADOPTION OF THE AGENDA

The proposed draft agenda was adopted without the addition of any new points and no conflicts of interest were brought to the attention of the chair.

2. LEGAL MATTERS

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

The Commission presented an overview on the current status of the transposition of the Tissues and Cells Directives. It was reported that as of December 2014 the transposition check had been satisfactorily closed for ten Member States, there were ten pilot procedures open, while a further six pilot procedures were pending. Two Member States were the subject of formal infringement proceedings with one of these having been referred to the Court. Regarding the pilot procedures, the Commission clarified that these

remained open due to a lack of reply from certain Member States, the replies were being translated or Member States had indicated that national legislation would be amended to take into account the points raised by the Commission. In such cases the Commission recalled the need to be informed when such amendments had been adopted.

The main issues to be clarified during the pilot procedures refer to the transposition of requirements related to the scope of the Directive, some definitions, supervision of human tissue and cell procurement, third party agreements, inspections and control measures, and publicly accessible report/register in the Directive 2004/23/EC.

2.2. Update on the draft Commission Directives on import and coding

The Commission explained that since the June 2014 meeting, draft texts on both Draft Commission Directives had been discussed in meetings of the Tissues and Cells Committee (C26100 in the Comitology Register) which took place in July and September 2014. Following these discussions and the completion of the WTO Technical Barriers to Trade notification period during which no comments were received, the Commission submitted finalised drafts texts to seek the opinion of the Committee via written procedure in October 2014. The Tissues and Cells Committee gave positive opinions (voted in favour of) on both texts on October 31st, 2014.

The Commission informed the group that the next steps towards final adoption would be translation into official EU languages following which the approved texts would be sent to the European Parliament and the Council for a 3-month scrutiny period. Provided there is no opposition to the texts from either Parliament or Council, the final adoption by the Commission and publication in the Official Journal of the European Union (OJ) is foreseen for the end of March or early April 2015. The Commission Directives will then enter into force 20 days following their publication in the OJ with transposition deadlines set 18 months following entry into force. The Directives will become applicable across the EU a further six months after the transposition deadline (likely April 2017).

The Commission also stated that it would provide the Competent Authorities with a period for comments on the translated versions of the draft texts during the scrutiny period. It was clarified that such comments should be limited to errors or omissions in the language used rather than suggestions for substantive or stylistic changes in the texts.

2.3. Debrief from the first Working Group meeting on the update of the Operational Manual on inspections and presentation of the updated version

Following the mandate granted by the expert group at the June 2014 T&C CA meeting, a working group (expert sub-group) on the update of the Operational Manual was duly established with members representing competent authorities from ES, FR, IE, IT, PL, PT. The first meeting was held in October 2014 during which the members discussed and agreed upon an updated version of the Operational Manual which takes into account the future requirements and procedures for the inspection of importing tissue establishments and their third country suppliers.

The proposed changes to the manual were largely and logically limited to Annex V which deals with the import of tissues and cells. Following the working group meeting, the revised version of the Manual was circulated to all T&C competent authorities with a deadline for comments of 28th November, 2014. Given that no comments were received before this deadline, the Commission put forward the updated Operational Manual for endorsement by the wider T&C competent authority group. However, Germany requested more time to assess the proposed changes and endorsement by the group was therefore not possible. A deadline of January 16th, 2015 was set for subsequent comments on the proposed updates.

2.4. Interpretation Questions

2.4.1. Feedback on the regulatory status of breast milk and faeces

In the June 2014 T&C CA meeting presentations were made on the developing fields of human breast milk donated to third parties (breast milk banking) and the donation of faeces for faecal microbiota transplants. The discussions which followed focused on the uncertain regulatory frameworks for the donation through to human 'application' of these substances of human origin and the Commission agreed to consult its Legal Service on their regulatory status and report back to the expert group in December 2014.

The Commission began its feedback by explaining that it had asked its Legal Service two specific questions:

1. Should either or both of these substances be considered as falling within the scope of Directive 2004/23/EC?
2. If not, could such substances be regulated under the mandate laid down in Article 168(4) of the Treaty on the Functioning of the European Union (TFEU)?

On the first question it was explained that two criteria would need to be satisfied in order for either substance to be considered as falling under the EU T&C legislation. Firstly, such substances would need to be considered as a 'tissue' or 'cell' and secondly, would need to be considered as intended for 'human application' as per the definitions of these terms in Article 3 of Directive 2004/23/EC. The Commission stated that it felt that it was clear that both breast milk and faeces contain cells and also contain a number of other components. Therefore such 'combined substances' *could* be considered as 'cells' in the sense of the Directive depending on their ability to satisfy the second criterion. It was pointed out that the definition of 'human application' revolves around the concept of 'use of the tissues and cells on or in a human recipient and extracorporal applications'. It would thus be necessary to interpret the meaning of the term 'use' which is not further defined in the Directive. Two possible interpretations of this term were put forward, either:

- 'Use' covers only therapeutic purposes; or
- 'Use' covers combined substances when it is the tissues or cells within the combined substance which is the focus of the use.

On the first of these possibilities, it was noted by the Commission that the legislator had not limited the scope of the Directive to therapeutic uses and that non-therapeutic uses of human tissues and cells also presented quality and safety risks. On the second possibility it was stated that the legislator had not included all types of human substances within the Directive and that the focus of the use of human breast milk and faeces is not the cells contained therein. For these reasons it was concluded that these substances do not fall within the scope of the EU T&C legislation.

On the second question the Commission pointed out that Article 168(4) TFEU is unequivocal in laying down a mandate for the adoption of measures setting high standards of quality and safety with respect to all substances of human origin. As both human breast milk and faeces are uncontestably substances of human origin it was concluded that this Treaty Article provides a legal basis for future regulation of these substances in terms of their quality and safety.

The clarity provided by the feedback from the Commission was welcomed by the group although a question was raised about what this meant for the classification of such substances at Member State level, particularly in countries that do (plan to) regulate such substances under their transposed tissues and cells legislation. The Commission clarified

that as these substances are not considered as falling within the scope of a particular quality and safety legislative framework at Union level, Member States are free to decide on the most suitable framework either by creating a specific regulatory framework at national level or by applying one of the existing legislative frameworks, including the tissues and cells quality and safety requirements, to these substances.

France also mentioned that for breast milk donated by third parties it plans to publish a decree of GMP-style quality and safety guidelines. The Council of Europe added that it did not plan to make any regulatory classification of such substances but that it did plan to include a chapter in its Tissues and Cells Guide on 'other' substances including breast milk and faeces. The objective of this chapter will be to provide basic quality and safety guidance.

2.4.2. Regulation of lymphocyte immunotherapy

The UK's Human Tissue Authority introduced the topic of lymphocyte immune therapy (LIT) to the group and raised the question of how the steps leading to its human application should be regulated across the Union. LIT is used as a treatment for recurrent miscarriage and involves the application of allogeneic human cells (lymphocytes) which are separated from the whole blood collected from a donor, often the husband or partner of the recipient. In such a situation both the EU tissues and cells legislation, the EU blood legislation or a combination of both could be relevant.

Prior to the CA meeting the UK had approached its counterpart CAs from other MS to survey them on how they were currently regulating the activities leading to LIT. While a considerable majority of respondents indicated that these activities were regulated under T&C legislation, a variety of responses were received with some MS also indicating a combination of both blood and T&C legislation. Other replies also stated that other regulatory frameworks were used or that the therapy was not used within their MS. The UK itself indicated that, in the absence of legal clarity on the issue, it was currently adopting a pragmatic approach allowing for the procurement to take place by establishments authorised to carry out procurement under the tissues and cells legislation or to carry out collection under the blood legislation. The UK also pointed out that a cross-sector decision-making process is needed at EU-level to deal with such classification issues.

In the discussion which followed Germany declared that it considered the initial steps of donation, procurement (collection) and testing to fall under the blood legislation and stated its interest in hearing why a number of MS indicated that they regulate it under the T&C legislation. The UK pointed out that both donor lymphocytes for infusion and haematopoetic stem cells fall entirely under T&C legislation. In particular a parallel could be drawn with donor lymphocytes infusion where identical processing techniques are applied although the actual procurement method is different. The UK also pointed out that a greater number of tissue establishments were equipped to carry out the procurement and then processing than blood establishments. From a practical point of view it thus made more sense to allow TEs to oversee the donation, procurement (collection) and testing rather than restrict this to BEs many of which are not further equipped to carry out the further stages leading to LIT.

While a majority in the group were in favour of allowing procurement under the tissues and cells legislation, Germany nevertheless called on the Commission to consult its Legal Service on the issue in order to provide some legal clarity. The Commission reminded the group of the case law of the Court which has ruled that, in certain circumstances, it is possible for Member States to have different interpretations of EU legislation when it comes to classification issues. Bearing this in mind the scope for the Commission to

provide legal certainty on this matter may be limited but it agreed to consult its Legal Service and report back to the group in the next meeting.

3. REPORTS

3.1. Update on the implementation of the tissues and cells Directives

Following previous presentations in the December 2013 and June 2014 meetings which provided preliminary results based on the implementation survey, the Commission gave a full overview of its findings so far. This overview included a summary of the replies concerning the last sections of the survey (quality management, responsible person and personnel, tissue and cell reception, processing, storage, labelling and packaging; relations between tissue establishments and third parties), together with information on the likely contents of the draft report on the implementation of the Tissues and Cells Directives which will be finalised in 2015. The Commission then presented its overall preliminary findings on all of the sections in the survey which stimulated considerable discussion within the group on a number of points.

Based on the findings the discussion initially focussed on inspection and control measures. While the results of the survey show that the vast majority of Member States respect the maximum 2-year interval between inspections, Denmark questioned whether fixed intervals were still appropriate or whether there should be a move towards a risk-based approach given that CAs now have considerable experience in authorising and inspecting and have a handle on which establishments require greater oversight. The UK pointed out that guidelines are also being developed in this direction. Italy suggested that 'joint' inspections with the participation of inspectors from CAs in more than one Member State could be introduced in a more formal way. To this end the 2015 Joint Action will look at ways to improve cooperation and collaboration between CAs from different MS with respect to inspections.

Another topic of debate was the potential for MS to introduce (or maintain) more stringent measures as provided for in Article 4 of Directive 2004/23/EC. While the right to take such measures was not questioned, several members of the group pointed out that this had an inevitable effect on the cross-border distribution of tissues and cells and that it was often difficult to obtain accurate information on which measures were in place in which MS. There were thus calls for a mapping exercise which would collate all such measures while it was also suggested that the CASoHO Expert Group could be used by CAs to alert their counterparts in other MS to planned measures and discuss these before they are put in place. The UK also mentioned that it was currently carrying out a mapping exercise with US counterparts designed to show US exporters where US standards are equivalent to those in the EU. This exercise may be useful to flag some of the more stringent measures in place and the UK agreed to share this with the group once finalised.

It was pointed out that more stringent measures in place in a number of MS, as well as prohibitions or restrictions on the use of specific tissues and cells from specific sources were a particular issue when it comes to the cross-border distribution of reproductive cells and, in particular, where such cells are distributed directly to individuals/recipients rather than to organisations responsible for human application. Questions arose as to whether from a legal point of view such direct distribution could be prohibited or restricted and, from a practical point of view, how such internet sales could be policed. The Commission agreed to consult its Legal Service on the question of cross-border direct distribution in light of national prohibitions or restrictions on distribution and / or use of reproductive cells. With regards to reproductive cells another potential issue was raised concerning the requirement to test donors at the time of each donation. In the case of non-partner donors

of sperm this would not be practical as donors may donate on numerous occasions within a short period of time.

Traceability and data storage were further areas of discussion. It was pointed out that for multi-tissue donors, different donor identification numbers should be used per type of tissue donated. Regarding data storage a question was raised about whether the requirement to store data for 30 years was the correct length of time for such storage. Denmark stated that such a lengthy storage period could be necessary in the ART sector given the possibility of the discovery of a genetic disease years after the initial donation. The question of what happens to the data records in the event that a tissue establishment ceases operations was also raised. Several MS commented that they have measures in place requiring the transfer to another TE, however, there may still be an issue where another TE is unwilling or unable to store the data. It was pointed out that in some other sectors regulatory authorities would store the data in such a scenario.

Registries and annual reporting were the final major discussion points. The Commission once again clarified that one publicly accessible summary report of the annual reports provided by TEs would suffice to satisfy the requirement in Article 10 of 2004/23/EC provided that it was clear that the individual annual reports were also publicly available on request. The group were asked whether the annual reports compiled were considered useful or seen as more of an administrative burden on CAs and TEs. Overall the responses suggested that the annual reporting exercise is seen in a positive light. Several MS observed that they review the reports provided by the TEs to compile their own annual report and need to use the reports to compile annual statistics. Others suggested that while they did not review the TE annual reports on a systematic basis, these are an important reference point if any (potential) issues of non-compliance are flagged. Some Member States advocated for a harmonised format of the TE annual report that should include clearly defined key information (e.g. distributed/processed during the year, SAR/SAE reported, training activities, etc…), providing for comparable data and allowing CAs to collect accurate information at regional/national level.

The Commission thanked the group for its informative comments on the findings and explained the next steps towards finalisation of the report. In the first half of 2015 the Commission plans to draft the final version of the report with an indicative timeline of July 2015 for publication. The Commission also explained that the CAs would be given a 2-week consultation period before final publication in which to verify the information provided relating to their MS. As with previous ones[1], this report, in addition to being sent to the European Parliament and to the Council, shall be also published on the Europa website, together with the individual Member States' replies.

3.2. Update on the third report on the implementation of the principle of voluntary and unpaid donation for tissues and cells

The survey to collect data on the implementation of the principle of VUD was launched in January 2014 and a presentation of the preliminary analysis of this data was given in the June 2014 T&C CA meeting. The Commission's presentation this time focused on its analysis of one of the main sections of the survey, namely section 3, concerning practices vis-à-vis donors (e.g. compensation, incentives, follow-up registries etc…). The presentation showed that across the Member States various approaches have been taken to implement the provisions of Article 12 of Directive 2004/23/EC. The analysis showed that a majority of those countries surveyed have guiding principles in place on the awarding of compensation to donors of tissues and cells, while a number of different types of

[1] http://ec.europa.eu/health/blood_tissues_organs/key_documents/index_en.htm#anchor7_more

compensation are granted to living donors. The organisation responsible for setting the form and value of compensation also varies significantly across the EU/EEA. In the ART sector around two thirds of EU/EEA countries have restrictions or prohibitions in place for non-partner donations.

A discussion followed the presentation and a major element of this was a debate on the forms and amount of compensation granted with some members of the group suggesting that some of these could or should be seen rather as incentives which should be restricted. There was also a suggestion that it would be interesting for the group to have data on the cases where the available compensation is actually awarded rather than just what is allowed. A further point was raised on the practice in some countries of issuing lump sum amounts of compensation. The UK's Human Fertilisation and Embryology Authority (HFEA) mentioned that it was currently carrying out an analysis on the benefits of such an approach and agreed to share its findings with the group.

The Commission thanked the CAs for their continued cooperation in this matter and explained that further communication may be necessary to clarify the data provided. As for the report on implementation, the Commission stated that CAs would be given an opportunity to provide comments on the draft VUD report before publication which will be aligned with the implementation report and foreseen for July 2015. As with previous ones[2], this third report, in addition to being sent to the European Parliament and to the Council, shall be also published on the Europa website, together with the individual Member States' replies.

4. SURVEILLANCE AND VIGILANCE

4.1. Update on infectious disease risks

4.1.1. Epidemiological update – ECDC

ECDC presented an epidemiological update focused on the Ebola Virus Disease (EVD) and Enterovirus D68 with an overview of the extent of the reported outbreaks in different regions both in Europe and further afield. The ECDC representative confirmed that the maps showing the extent of the EVD outbreak are available on its website and are updated on a weekly basis as part of its communicable diseases weekly report. In terms of recommendations on donor deferrals it was stated that the same recommendations are in place for tissues and cells and organs as those in place for blood – a two-month deferral period with a derogation for potential donors who have tested negative for EVD.

ECDC also informed the group that the risk assessments concerning the transmission of WNV, Malaria and Dengue through SoHO are now ready and are due for publication. The further risk assessments on the transmission of Trypanosoma Cruzi, Chikungunya and Leishmania through SoHO are due to follow in the course of 2015.

4.1.2. Update on HTLV mapping

ECDC also gave an update on the mapping of HTLV–I high prevalence areas. This map is required for the implementation of Directive 2012/39/EU (deadline for transposition 17 June 2014) and shows high prevalence areas for all global regions. On the basis of the draft report received from its contractor in September 2014, ECDC has developed the maps for each region (North and South America, Europe, Asia, Africa, and Oceania) which will be accompanied by a technical report. Following a question on how often the

[2] http://ec.europa.eu/health/blood_tissues_organs/key_documents/index_en.htm#anchor7_more

maps will be updated, ECDC confirmed that it will monitor the situation and amend the maps as and when necessary. In general ECDC does not expect prevalence to evolve very quickly and stated that once every ten years may be a reasonable timeframe for updates.

4.1.3. Other

Member States were asked whether they have additional information or updates to report, but there was no report of any additional information on infectious diseases.

4.2. Update on the development of the European Coding Platform

4.2.1. Hosting of the Eurocet128 database by the European Commission

To support the introduction of the Single European Code (SEC) an EU Coding Platform is under development and the Commission gave an update on progress on the technical elements of this development. The EU Coding Platform was initially developed by the Eurocet128 consortium as part of a contract which came to an end at the end of 2014. The Commission explained that it was thus in the process of verifying the work carried out as part of the contract deliverables in order to ensure a smooth transfer of the Platform database to the Commission's IT department whose servers will host the platform.

The Commission stated that the next stage of the Platform's development will be to prepare for it to become fully operational at which point it will be fully online. In preparation of this the Commission informed the group that agreements were being prepared with the administrators of product coding systems whose product codes will be permitted to be used as part of the SEC. These agreements are necessary to ensure that information on these product codes is provided in a timely manner with a view to its inclusion and publication on the Platform. The Commission also reminded the group that NCAs would need to verify and, where necessary, provided updated information before the Platform is fully online on the tissue establishments under their control.

The Commission also proposed to the group the establishment of a new Expert Sub-Group (Working Group) and explained that such a sub-group was necessary to support the Commission implement the technical requirements of the new coding legislation. In particular the sub-group would be consulted on the need for the inclusion of potential new product codes in the Platform. The group agreed to establish this new Expert Sub-Group on the Coding of Tissues and Cells and the following members confirmed their interest in becoming members of the sub-group: AT / DE / DK / HR / IT / NL / PL / PT / UK. The terms of reference of the new sub-group were set as follows:

1. The sub-group shall provide technical expertise to the Commission's services to facilitate the implementation of the requirements for the Single European Code (SEC) including expertise on the establishment and operation of its supporting architecture (the EU Coding Platform). In particular, the Commission's services may call upon the sub-group to provide advice and expertise on the following:

- Any (potential) changes to the product categories in the Tissue and Cells Product Compendium;
- Issues surrounding updates of the Tissues and Cells Product Compendium and / or the Tissue Establishment Compendium;
- Potential suspensions of the use of certain product codes as part of the SEC;
- Any other issues concerning the implementation of the SEC requirements.

2. The members of the CASoHO Expert Group shall put forward their chosen representatives to be members of the sub-group.

3. The sub-group shall report to the CASoHO Expert Group on its deliberations.
4. The Commission shall chair meetings of the sub-group, its services shall provide secretarial support and physical meetings shall take place at Commission offices.
5. It is foreseen that the sub-group shall meet physically 1-2 times a year with virtual meetings also possible.

The Commission stated that it expected the Platform to be ready for its live launch by the end of the first half of 2015 following the provision of updated data on TEs by NCAs and the conclusion of the agreements with product coding system administrators.

4.3. Rapid alerts for tissues and cells (RATC)

4.3.1. Follow-up and closure of alerts launched in 2013 and 2014

The second day of the meeting began with presentations by the German and Danish CAs concerning various rapid alerts which they had launched over the course of 2013 and 2014 and which a large proportion remain unclosed in the RATC system. Several members requested further data from their German counterparts and the Commission reminded those members that follow-up questions should be posed in the RATC system. DE stated that it planned to provide further information and would welcome comments following the provision of this information. The Commission explained that once a final report had been uploaded and no further comments had been received in relation to an alert, it should then be closed.

The Danish presentation related to a number of alerts launched concerning the ART sector. Denmark explained that the definition of 'serious adverse reaction' in Danish law had now been amended to take into account children born with genetic diseases following non-partner sperm donation while reporting requirements had also been changed accordingly. In the majority of cases the alerts related to donor sperm which had been distributed to individuals (natural persons as opposed to legal persons) which raised issues in terms of traceability from donor to recipient. Another potential issue is ensuring the protection of personal data of the presumed recipient while at the same time allowing for effective communication of information over the RATC platform. A MS qualified as "affected" by such an alert in the RATC platform has no information available about recipients and their resultant offspring concerned which could be used to determine action to be taken such as offering counselling where children are born with a genetic defect.

The members of the group were also reminded to ensure that their contact details for communication over the RATC platform were correct and up-to-date.

4.4. Serious adverse reactions and events (SARE)

4.4.1. Preliminary results of the 2014 SARE annual reporting exercise (2013 data)

Following the submission of 2013 data to the Commission in mid-2014, the Commission presented an initial overview of the preliminary findings of the 2014 SARE reporting exercise. This presentation provided an overview of the overall provisional figures for the total number of SAR and SAE as well as comparing this data with the figures from previous years. The overview also included the usual breakdown of data per tissue and cell sector and type of SARE reported. The Commission also questioned the lack of any reported SAR in 12 Member States and the lack of reporting for SAR linked to OHSS in the case of partner donation in the ART sector following the change of reporting on this in the Common Approach Document. Overall the Commission cautioned against any definitive conclusions being drawn based on these provisional findings.

The Commission stated that it expected to have the final results for the 2014 report ready for presentation at the June 2015 CA meeting while final publication would likely take place in the second half of 2015. Regarding the 2013 report, the Commission confirmed that the final draft report was ready and would be circulated to the members for comments prior to publication foreseen for March 2015.

5. PRESENTATION OF PROJECTS, JOINT ACTIONS AND STUDIES UNDER THE HEALTH PROGRAMME

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

An update on the Joint Action ARTHIQS (Assisted Reproductive Technologies and Haematopoietic stem cells Improvements for Quality and Safety throughout Europe) was given by a representative of the coordinator, the French Biomedicine Agency (ABM). ARTHIQS, which includes 17 partners and nine collaborators from 18 different Member States, kicked-off in May 2014 and will last for three years. The main objectives are to develop guidelines for key aspects of service provision and regulation in ART and HSCT sectors, notably by increasing donor and recipient / beneficiary safety, also tackling inspection of ART centres and cord blood banks.

Detailed presentations were given on the activities foreseen and already underway in Work Package 4 on ART and Work Package 5 on HSC for transplantation. It was reported that WP4 partners had been sent a questionnaire to fill in which will provide valuable information on how competent authorities in the ART function and carry out their various tasks. Under WP5 a questionnaire has also been developed and distributed to partners aiming to gather information on the development of follow-up registries of living HSC donors. It was clarified that while the WP4 questionnaire would be limited to collaborating partners, the questionnaire for WP5 would be sent to all Member States. Some CAs not participating in the JA also expressed their willingness to participate to the ART survey launched by WP4 and the Commission encouraged a wider participation in order to collect more information on the oversight of this sector in different Member States. Further updates on ARTHIQS will be reported in future meetings of the group and will include a report on the results of the questionnaires.

5.2. Update on the study on the economic landscape of the tissues and cells sector (Rathenau Institute)

A representative of the Rathenau Institute representing the consortium who was awarded the contract for the call for tender EAHC/2012/Health/19[3] provided an update on the development of this study. This presentation reiterated the main goals of the study and focused on the preliminary findings from a survey of Member States' competent authorities. The survey has proved a valuable source of data on the volume of tissue and cell flows both intra-EU and in terms of import / export from and to third countries. Some initial analysis of the different pricing structures for various tissues and cells throughout the EU was also presented along with some thoughts on likely trends and forecasts for future development.

It was also communicated that country factsheets would be developed which the CAs will have an opportunity to verify while still in draft form. The group was also reminded that any concerns over the accuracy of the data presented should be sent to the Commission who will pass these on to the contractor. As the study progresses further updates will be provided in the June 2015 CA meeting.

[3] http://ec.europa.eu/eahc/documents/health/tenders/2012/EN/EAHC_2012_19_contract_notice.pdf

6. INTRODUCTION TO THE ACTIVITIES OF THE COMMITTEE ON ADVANCED THERAPIES (CAT)

The Chair of the Committee on Advanced Therapies gave an introduction to the work of this Committee which was established under the 2007 ATMP legislation. The presentation outlined the types of products covered by the ATMP legislation as well as the some on-going research activities in the field. The tasks of the Committee were outlined along with some statistics. The main focus of the presentation was then to give an overview of the results of CAT's refection paper on the classification of advanced therapies. This overview was well received by the group which has a particular interest in the advice CAT gives on the classification of such therapies as this can have a bearing on how such products, as well as tissues and cells, are regulated across the EU. Several technical inputs were provided by the group based on the reflection paper. One example was highlighted (amnion used for cornea replacement), where the reflection paper seems to suggest that the product would be considered as an ATMP whereas it is widely considered to be/in use as a classical tissue preparation with established use since many years. The CAT Chair thanked the group for such inputs and stated that other such examples would be welcome as the impact of the findings of the reflection paper on the tissue and cell sector may not always be apparent within the Committee itself. The Commission agreed to collect and send these inputs from the T&C authorities for further follow-up to the CAT. Participant NCAs look forward to further follow-up on these inputs.

The Commission informed the group that the presentation by the CAT Chair was part of on-going efforts to foster closer cooperation between regulatory and advisory bodies in the tissues and cells and medicinal products sectors on issues of mutual interest. In the first half of 2015 a meeting of such bodies is scheduled to take place in Brussels hosted by the Commission.

7. AOB

7.1. Update of the revision of the Medical Devices Legislation

The Commission gave a brief update on progress towards a revision of the Medical Devices legislation. The 2012 proposal for a new Medical Devices Regulation is currently being discussed at Council Working Group level with a view to forming the Council's Common Position following the first reading in the European Parliament which was concluded in April 2014. The Commission explained that while the proposed text will make it clear that demineralised bone matrix falls under the tissues and cells legislation, discussions are on-going in the Council to find a suitable wording on the borderline between the medical devices and tissues and cells legislation.

Collagen fillers were identified as the main, and perhaps only, borderline products that need further clarification. The Commission admitted that the current wording does not adequately deal with substances such as collagen and that further work would be needed on this. A small group of tissues and cells competent authorities agreed to look at the wording and propose an amended version taking into account its current shortcomings. The amended wording will be brought to the attention of the Council Working Party as a technical input into their discussions on the issue. Some countries questioned whether a broader committee was now needed at EU level to rule on borderline cases. The Commission stated that the proposed Medical Devices Regulation would empower the Commission to rule if a substance / product should be classified as a medical device or not following a positive vote by Member State representatives at Committee level.

7.2. Clarification of 'same surgical procedure' by the FDA

Denmark briefly brought to the attention of the group a proposal by the US FDA which would clarify their interpretation of the concept of what would be considered to fall within the same surgical procedure. Contrary to the current interpretation in the EU, the FDA proposal would also allow tissues and cells to be taken away from an operating theatre, including for storage, within the same surgical procedure. Denmark encouraged any members interested in the proposal to address their comments directly to the FDA.

7.3. Prohibition of human placental tablets / capsules

Denmark briefly introduced an information point on a report in the Danish media claiming that the EU / European food Safety Agency wanted to ban human placental capsules. The Commission stated it was unaware of such a report but, following consultation with the relevant DG SANCO unit dealing with novel foods, informed the group that such a report may be linked to a recent UK court decision which upheld the view of the UK food safety authorities which consider that the processing of human placenta and returning it to mothers in tablet or capsule form could be considered as placing food on the market.

Where a significant degree of consumption by humans prior to May 1997 can't be demonstrated such a substance would likely fall under the novel food Regulation (EC) No 258/97 and require an authorisation under the requirements of this legislation. In such a situation an application would be made to the relevant MS' novel food authority which would make an initial assessment with a period for objections by other MS. If objections are made then the Commission would make a final decision on authorisation and may consult EFSA for additional technical assessment. The Commission stressed that as far as it was aware the UK view was not final while it was also aware of other MS that held the view that placenta in this form should not be considered as food. The Commission advised CAs to contact their counterpart authorities in the food sector to clarify the situation at national level.

8. CONCLUSIONS OF THE MEETING

The Chair thanked the members, observers and invited participants for their positive contributions to the meeting and reminded the members that a reminder would be sent out listing all points where follow-up is necessary. The next meeting is provisionally scheduled for June 3-4, 2015. However, the dates will only be finalised once meeting rooms have been confirmed.