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Meeting of the Competent Authorities for Tissues and Cells

2 and 3 December 2013

Summary Report

The meeting of the Competent Authorities on Tissues and Cells was convened on 2 and 3 December 2013. The previous meeting of National Competent Authorities (CAs) took place on 5 and 6 June 2013.

PARTICIPATION:

All Member States (MS), including Croatia participating as a MS for the first time, were present at the meeting. In addition, Liechtenstein, 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) and the European Centre for Disease Prevention and Control (ECDC) attended the meeting.

European Commission (DG SANCO):

Chairs: Mr D. SCHNICHELS, Mr S. VAN DER SPIEGEL, Ms I. SISKA

Commission Representatives: Mr R. Mc GEEHAN, Mr P. CATALANI

Administrative Assistant: Ms A. CORNEA

1. ADOPTION OF THE AGENDA

One new agenda point on the use of sibling depots in the EU was proposed by DK and it was agreed to add this point to the agenda in the AOB section. Croatia was formally welcomed as a Member State along with the Former Yugoslav Republic of Macedonia who attended for the first time along with several other representatives of group members attending for the first time or replacing regular representatives on this occasion.

2. RULES OF PROCEDURE FOR THE MEETINGS OF THE TISSUES AND CELLS COMPETENT AUTHORITIES

The final draft version of specific Rules of Procedure (RoP) for the Competent Authorities on Substances of Human Origin Expert Group (CASOHO) was presented by DE who had led the drafting of these rules. DE pointed out that following the June 2013 meeting the draft RoP had undergone some minor modifications and it was now clear that the provision on voting would

allow for, in the exceptional case of a vote, a dissenting opinion to be included in the meeting minutes should a dissenting member so request. DE also pointed out that work is still needed in order to implement the provision on conflicts of interest while the difference between the CASOHO expert group and the second SoHO expert group listed in the register of expert groups was not clear.

The Commission clarified that it plans to seek a declaration of any conflicts of interest from members' representatives once the RoP have been adopted and that the second SOHO expert group listed in the register regroups the various SOHO Working Group meetings for administrative purposes.

There were no further comments on the RoP and it was thus considered that the Tissues and Cells CAs agree to the use of these rules. The RoP will now be presented to the other configurations of the CASOHO group i.e. the Blood and Organs CAs for potential comments and, should they also agree to the rules in their current form, they will be considered as adopted for CA Meetings of all three configurations of the expert group.

3. LEGAL MATTERS

3.1. 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. Six MS have sufficiently transposed all Directives. In addition to the one pilot procedure on-going, 15 MS have been recommended for follow-up in the pilot system including two that did not respond to follow-up letters in the course of 2013. Six MS responses are under final analysis. One MS is the subject of infringement proceedings and has now been referred to the Court of Justice for failure to fulfil its obligation to transpose the EU legislation in relation to certain reproductive cells. The Commission notified the group that any further follow-up needed would be done in the form of EU Pilot procedures which is the standard cross-sector system used to communicate with MS via their Permanent Representations within set timelines when further clarifications are needed.

In response to questions from the group, the Commission clarified that the transposition check is a one-off check which, unlike the implementation reports, is not designed to be repeated at regular intervals.

3.2. Implementation of the Tissues and Cells Directive – 2013 Survey

As announced in the previous meeting, the Commission gave a presentation of provisional findings on the sections of the survey that have been analysed so far. At the time of the meeting the vast majority of MS along with NO and LI had answered the questionnaire and the Commission thanked the group not only for having sent their replies in a timely manner but also for having dedicated significant amounts of time in order to provide the detailed data sets asked for in the survey.

The Commission presentation focused on the first four sections (out of 16 overall) which have been analysed so far, these are: CA public information, procurement, testing, and authorisation. In terms of CAs, the survey shows that there are a number of approaches across the EU to the set-up of CAs concerning the number of CAs per MS, the scope of their responsibilities, and their roles and tasks relating to the tissues and cells sector. The presentation also highlighted the overall number of procurement organisations (POs) and tissue establishments (TEs), the testing requirements across the EU including those MS

requiring additional testing, and also a concern about the lack of oversight of the ART sector in a small number of MS.

During the discussion following the presentation a number of points were raised regarding the preliminary findings. Several members of the group made points relating to the data on POs – how these were counted and was there a risk of some duplication in the numbers? Overall the increased amount of information on POs was welcomed, in particular the data on POs supplying to ATMP manufacturers, but it was concluded that there was indeed a possibility that there could be some duplication in the data, in particular where TEs carrying out procurement may have been included in this data and that such data should therefore be clarified.

Another comment was made on the overall figure given for the number of TEs which is now significantly lower than previously thought. A possible explanation put forward was that the number had been over-estimated in the past due to a tendency to equate the number of TEs with the number of authorisations granted whereas, in fact, a single TE may have multiple authorisations. With the work of Eurocet128, criteria for data reporting have been specified and the current figure reflects the number in the Eurocet128 data. The greater amount of data on testing centres and testing requirements was heralded as a step forward although a comment was also made that while some MS may not have formal requirements for additional testing, such testing was in practice the norm in some MS. DK also clarified that they do require testing for hepatitis C.

The Commission expects to be in a position to present a draft report of the full findings from the implementation survey in the June 2014 CA meeting with the final report scheduled to be published in the second half of 2014. *In the meantime clarifications may be sought from the members on certain points and further follow-up will be needed where implementation gaps are identified such as in the ART sector in certain MS.*

3.3. Update on the third survey on the implementation of the principle of VUD for tissues and cells

The Commission provided further details on its plans to launch a survey with a view to gathering information on the implementation of the principle of VUD which will be compiled in the planned third VUD report which is due to be published in the course of 2014. This third survey will analyse in more depth MS' practices vis-à-vis donors and, for the purposes of the survey, definitions of key terms such as 'compensation', 'incentive', and 'shortage' have been developed. The planned launch of the survey is foreseen for late early 2014 with a deadline for replies in March 2014. Following analysis of the replies between March and May a presentation of initial findings is planned for the June CA meeting with publication of the final report likely towards the end of 2014. As usual a letter will be sent to the relevant parties in the MS to accompany the launch of the survey specifying the exact deadline for replies.

3.4. Debrief from the third meeting of the Import Working Group.

The Commission gave the group an update of progress in the Import Working Group and in particular the discussions which took place during the third meeting of this working group (WG) which was held in July 2013. The group currently includes 13 MS (AT, BE, DE, DK, ES, FR, HR, IE, IT, NL, PL, PT, UK). During this third meeting, the WG focused, for the first time, its discussions on a draft text which seeks to encapsulate the preferred approach of the WG for a legal text with binding requirements. It was explained to the CA group that this approach would see procedures for the verification of the

quality and safety standards of imported tissues and cells centred on the authorisation and inspection of importing tissue establishments. Requirements would also be placed on the establishments themselves in terms of steps they should take to ensure equivalency and the documentation they would need to provide to CAs in order to show the equivalency of imported tissues and cells with EU standards and ultimately be granted authorisations to import on this basis.

It was reiterated that, as a common starting point there is a need for a simple, though robust, set of requirements in order to prevent tissues and cells of lower quality or safety entering the EU – wherever their initial entry point.

This debrief sparked an exchange of views with many in the CA group interested to find out more about the work of this working group and the Commission's intentions now that this work is advancing. Some argued that the MS would need a period to informally consult stakeholders at national level before the Regulatory Committee would adopt the measure. The Commission reminded the members of several formal and informal contacts and presentations with associations on this subject. The Commission also confirmed that it would look into the possibility of holding meetings with stakeholders at EU level in the coming months, if it was felt that this was needed.

The Commission confirmed that in terms of the timeline, a 2014 adoption would require laying down a final text to the Parliament in July, due to the European Parliament elections and the installation of a new Commission towards the end of the year. Concretely, meetings of the Regulatory Committee to finalise and adopt the text will be planned in May and June.

Questions were also raised as to the need to put in place seemingly detailed binding requirements The Commission recalled that this issue had been discussed at length in the working group and that a set of binding requirements was required while it was explored whether the more detailed procedures should be included within the planned annexes to the text or whether these could be developed as guidelines to accompany the legal text. The Commission also acknowledged that the procedures put in place should be proportionate to what is necessary to verify such imports but that such a measure was indeed necessary to ensure high quality and safety standards.

It was further clarified that Directive 2004/23/EC provides that both importing TEs and CAs are responsible for this verification and that in order to ensure a clear division of tasks, the draft text seeks to ensure that the TEs should carry out this function in the first instances with oversight from the CAs. It was also confirmed that where organisations other than those already authorised to carry out one or more activities in the tissue and cells chain seek to import tissue and cells from third countries they would also be required to meet the requirements laid down in the proposed measure. It was also pointed out that the current approach doesn't distinguish between imports based on their country of origin and that authorisations from third countries and accreditation from international bodies such as JACIE could be taken into account.

The points raised will be taken back to the WG for further consideration.

3.5. Debrief from the first and second meetings of the Working Group for the implementation of the Single European Code for T&C

Following the call for volunteers made in the last CA meeting, seven MS (BE, FR, IE, IT, PL, SK, UK) expressed their interest in taking part in this newly formed Working Group. The Commission explained that the WG held its first meeting in September 2013 and a second one

in November. Over the course of these two meetings the WG agreed on a proposed course of action to amend Commission Directive 2006/86/EC by revising the current provisions relating to the SEC. This would require additions to the Article on definitions, revised text for Article 10, and the replacement of the current Annex VII with an Annex containing the detailed requirements for CAs and TEs. A transition period for the implementation of these requirements and alignment of the adoption procedure with the abovementioned import measure are also foreseen. The SEC WG is due to meet again on February 4, 2014 to continue this drafting exercise.

During the discussion which followed this debrief several points were raised about the practicalities surrounding the application of this code. The discussion covered the status/stage at which products are to be labelled with the SEC, application of the SEC on imported tissues and cells (by the importing tissue establishment) and the need for a transition period. The Commission confirmed that tissues and cells distributed without the code prior to the end of this transition period would not need to be retroactively labelled with the code.

The Commission presented a request submitted by CTCLAG for an exemption of tissues and cells facilities using ISBT128, including arguments in favour and against this exemption. There were no comments or suggestions from the Member States representatives, and it was agreed to continue with the current approach.

The Commission took note of the points raised and made the group aware that these would be taken back to the WG for further consideration there.

3.6. Interpretation questions

3.6.1. Import and distribution of starting materials for ATMPs

The UK introduced the issue of the import and subsequent EU distribution of starting materials for ATMPs with a view to clarifying whether such activities fall within the scope of the tissues and cells legislation. Article 9 of Directive 2004/23/EC lays down that imports of tissues and cells from third countries are undertaken by tissue establishments authorised to import while Article 3 of Regulation 1394/2007 on ATMPs states that the donation, procurement and testing of tissues and cells contained in ATMPs shall be in accordance with the tissues and cells legislation but makes no mention of their import. The question was thus raised as to what happens when such donation, procurement and testing takes place in a third country and whether the subsequent import of starting materials for ATMPs must be authorised under the tissues and cells legislation.

As shown by the UK presentation, different approaches have been adopted across the MS often depending on the level of processing the tissues and cells have undergone in the third country. Some MS take the approach that if the substances are classified as tissues and cells i.e. there has been no substantial manipulation, at the point of import then they should be imported by an authorised tissue establishment irrespective of their intended use while others felt that ATMP manufacturers should be able to import directly although this raises the question of how they ensure that the donation, procurement and testing taking place in a third country complies with the requirements of the tissues and cells legislation.

The UK mentioned that they were working with their counterparts who regulate ATMPs to develop a history file for such products and would report back on progress and in particular the approach developed for dealing with the import of such starting materials for ATMPs.

The Commission will take the question back for internal consultation with relevant colleagues in other units.

3.6.2. Documentation for cross-border exchanges of T&C (DE)

The requirements in terms of documentation for cross-border exchanges of tissues and cells from EU MS into Germany had arisen during the course of the Import WG discussions and Germany offered to clarify the requirements with an overview of the relevant German legislation and conditions specific to such cross-border exchanges for the benefit of the T&C CA group. DE explained to the group that tissues and cells are regulated under their Medicinal Products Act and that a distinction is made between those tissues and cells deemed to be industrially prepared or prepared using unknown procedures and those which are said to be prepared using known tissue and cell procedures. Depending on which category any given product falls under determines which authorisations are required as they are different for the two distinct types. In the first of these categories a manufacturing (based on GMP standards) and then a marketing authorisation are necessary while for the second category separate authorisations for the procurement, processing (based on GTP standards) and placing on the market (distribution) are required. Germany also outlined the division of responsibilities between the national and regional authorities and who was responsible for granting the abovementioned authorisations.

During the discussion which followed this presentation, DE confirmed that the German legislation makes reference to best practice guidelines such as those published by professional associations. Furthermore, Germany confirmed that the authorisation for placing on the market did not apply to establishments which apply, 'in-house', T&C that they procure themselves. Where a tissue establishment from another MS seeks to distribute a T&C product in Germany such as heart valves, the correct procedure to follow would be to apply to the German national CA (PEI) for an authorisation according to the German legislation, however, so far there has not been any instances where a product authorised for distribution in another MS had been refused an authorisation to be placed on the German market. In practice, according to DE, tissue establishments seeking to distribute into Germany had found it easier to apply for this German authorisation rather than seeking to obtain certification showing they comply with more stringent testing requirements in Germany to add to their authorisations to distribute granted by the CA or CAs in the MS where they are based.

DE also clarified that no authorisations had been granted or applied for by manufacturers of human bone substitutes and that any claims by companies to have such authorisations were false and were being investigated by the German authorities. Given the different authorisations, a question was asked about which authorisations should be requested by CAs where German tissue establishments wish to distribute in another MS. The answer to this depends on the type of T&C as per the earlier explanation of the classification in Germany, however, in the first instance the CA of the MS in question should ask PEI for the authorisation to market the product in Germany as this is not granted unless the manufacturing / processing authorisation has been granted by the regional authority. When considering applications for authorisation to market tissue and cells, PEI take into account both clinical and non-clinical data including verification of the authorisation granted by the regional authority for the procurement and processing. As part of this verification PEI also examine the donor documentation before granting any authorisation.

3.6.3. CE marked medical devices – 'when applicable / wherever possible / when appropriate'

DK introduction this subject in order to seek some clarifications of the meaning of certain phrases found in the tissues and cells legislation that appear ambiguous. Under point C6 of Annex I to Directive 2006/86/EC it is stated that: 'Critical reagents and materials must meet documented requirements and specifications and *when applicable* the requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices'. Directive 2006/17/EC, Annex IV, point 1.3.10 states that '*wherever possible*, only CE marked medical devices must be used…' while Annex II, point 2.1 to the same Directive lays down that 'tests must be carried out by a qualified laboratory, authorised as a testing centre by the competent authority in the Member State, using EC-marked (sic) testing kits *where appropriate*.' (Emphasis added).

The consensus opinion during the discussion which followed this presentation was that while such phrasing creates ambiguity it also leaves some room for some much-needed flexibility in interpreting the meaning. This is needed as a case-by-case approach is essential given that CE-marked equipment is much more prevalent in some tissues and cells sub-sectors than others. An example was given of the ART sector where availability is relatively high and therefore certain CAs take the approach that TEs must justify their use of non-CE marked equipment. On the other hand there are situations such as validation where the use of CE-marked testing kits isn't always possible or sectors where the only companies producing the necessary equipment find the cost of CE-marking too prohibitive.

The group did not therefore call on the Commission to clarify such wording at this stage but agreed that this would need to be looked at again during any future process to propose a revision of the Directive.

3.6.4. Breast milk banking

The question of how to regulate the allogeneic 'application' of breast milk has arisen following the proliferation of breast milk banks across the EU. As the Council of Europe have produced a questionnaire for its CD-P-TO members on the issue, it was decided that DE, rapporteur within the CoE group, would present the questionnaire as a way of initiating a preliminary discussion on this issue within the CA group. Some tissues and cells mentioned that they had not received the CoE questionnaire and it was agreed with the CoE representative that the Commission would send out the questionnaire to the CA group members for them to return to the CoE. During the discussion it was suggested that a majority of MS regulate such activity through food safety authorities although the emergence of applications of breast milk for therapeutic purposes may require a reassessment of such regulatory structures and closer cooperation between food safety and T&C CAs in order to ensure that disease transmission risks and ethical issues linked to donation are suitably dealt with. *The Commission was also called upon and agreed to verify the information available with the European Food Safety Agency (EFSA) on such practices and establish cooperation on the issue*.

4. SURVEILLANCE AND VIGILANCE

4.1. Update on infectious disease risks

4.1.1. Epidemiological update – ECDC

In the absence of any outbreaks of communicable diseases relevant to the SoHO sector in the final six months of 2013, ECDC presented its surveillance of HIV/AIDs in Europe in 2012 (the full report is available on the ECDC website). This presentation provoked some discussion on the deferral criteria used on potential donors in the light of criticism of deferrals of men who have sex with men from gay and lesbian support groups. The Commission confirmed that such deferrals should be based on an analysis of the risk of certain behaviour rather than be based on sexual orientation. It was also mentioned that this has been discussed within the CoE which has adopted a resolution calling on countries to collect up-to-date statistical data on perceived high risk in order to inform any future decisions on deferral. The Commission also informed the group that a national court had referred a question on the deferral of MSM from blood donation to the European Court of Justice for a preliminary ruling on this issue.

In the previous CA meeting ECDC had informed the group that risk assessments for SOHO-related communicable diseases will be provided starting in 2014. In this regard, ECDC has launched a call for tender on "Risk Assessment and Prevention of Infectious Disease Transmission through Substances of Human Origin", the first three diseases to be analysed being West Nile virus (WNV), malaria and dengue fever. ECDC gave an update on this process and stated that a contractor had now been selected. It is expected that the preparation of a risk assessment for a specific disease would take approximately one year. Once the work on WNV, malaria and dengue fever has been completed then other communicable diseases may be prioritised for assessment.

The Commission also informed the group that it was working on a reference library within the CIRCA-BC platform which is designed to be a one-stop shop on communicable diseases by storing ECDC risk assessments, preparedness plans and presentations from CA meetings as well as the deliverables of relevant EU-funded projects. *Once stocked, a notification will be sent to the members informing them that the library is up and running*. The group was then asked how they would prefer to be notified on updates to the library as receiving a notification for each update may not be unnecessary given that not all updates will be relevant for everyone. It was suggested that a weekly or monthly update via e-mail of new additions to the library may be a suitable middle way. The Commission clarified that this library would be hosted on the CIRCA-BC platform rather than the RATC platform as it is designed to be for the whole SoHO group and rapid alert platforms are not (yet) established in the other SoHO sectors.

4.1.2. Other – Member States will be asked whether they have additional info/updates to report

There were no new updates to report from the members.

4.2. Update on the development of the new European code for tissues and cells – EUROCET128 tender

An update was given on the progress made by the EUROCET128 consortium – the last such update which will be given to the CA group before the end of the consortium's contract at the end of May 2014. The work of the consortium has moved forward on schedule with the EU tissue establishment compendium now populated with the details of

TEs already provided by the CAs. TEs not included in the compendium (e.g. those not yet authorised such as TEs from countries that have not yet transpose the EU legislation for reproductive cells) will need to be manually introduced at a later stage. The Commission reminded the CA group that the consortium was reliant on the national CAs to provide them with the requisite information and that it would fall upon the CAs to regularly update the TE compendium should there be any changes to the information concerning the TEs such as contact details or changes to the authorisation status.

The Commission also explained that work on the T&C product compendium had also been finalised and that products and their codes were now embedded in this compendium while the overall Single European Code is fully compatible with ISBT128 and Eurocode. The next step in the process will be pilot testing of the code translator application which is foreseen to begin in early 2014 with the cooperation of the six MS who have kindly volunteered to be involved with this. The compendia should thus be fully available before the adoption and entry into force of the accompanying legal text which will revise the relevant provisions of Commission Directive 2006/86/EC.

The UK queried why its national codes could not be used. In theory it is for each MS to decide whether to use a national code or the EU generic code. An issue had been identified in the UK that there are two national coding systems implemented by different CAs and this may lead to a risk of duplication. The UK agreed that they would check to see if a way could be found to ensure that the two coding systems do not produce the same codes. If this can be guaranteed on an on-going basis, it may be possible to use both national codes for the purposes of the TE compendium. The same issue is also relevant for Portugal. A further query was made concerning the number of TE codes issued as this may not match the number of TEs identified. It was clarified that the TE codes were issued per donor allocation system and thus do not necessarily match the exact number of TEs.

4.3. Rapid alerts for tissues and cells (RATC)

4.3.1. Overview of RATC activities in 2013

The Commission informed the group that the report on the rapid alert system for human Tissues and Cells (RATC) for the period 2010-2012 has now been published on its website and another report giving an overview of 2013 activities is foreseen for publication in February 2014 following consultation with the CAs. So far in 2013 15 alerts have been launched with a majority relating to reproductive cells while this figure also includes two bilateral enquiries seeking to establish the authorisation granted to specific TEs.

The most recent alert had been launched on the same day as the CA meeting and the group therefore agreed it would be opportune that FR, the initiator of this alert, was to give a brief explanation of the context of this alert. FR explained that it had visited the site of a German TE which distributes T&C in France via a subsidiary TE authorised by the FR authorities. The same TE had already been the subject of an alert initiated by DE in 2012. Following this visit FR decided to launch a Rapid Alert based on quality and safety concerns raised by their findings during the visit. In addition to the RA, FR also planned to cooperate with the DE authorities who, while pointing out that they did not consider this visit to be an official inspection, *agreed to look into the FR findings in order to ensure that suitable follow-up actions are put in place and subsequently reported to the relevant CAs via the RATC platform in a timely manner.*

With regard to the planned update of the platform's standard operating procedures, the Commission notified the group that it had received comments on the SOP in writing from DK and IT however additional comments are welcome based on CAs' experiences of using the platform so far. NL raised a concern that it had made some bilateral enquires seeking information from other RATC users i.e. other CAs, but had not received a reply for over two months and thus questioned whether time limits for replies should be formalised within the SOP. The Commission reminded the group that the efficacy of the platform largely depending on the input from its users and urged them to respond to such enquiries in a timely manner. DK also recalled that the contents of alerts are confidential and as such should not be passed to unrelated third parties.

4.3.2. Mandate of the European Commission in relation to alerts from third countries

Agreement still needs to be reached on a harmonised approach to be followed for initiating an alert relating to information coming from third country sources or international organisations such as WHO. The approach proposed by the Commission would see it become responsible for initiating alerts from international organisations while MS CAs would be responsible for initiating alerts when informed of quality and safety concerns affecting tissues and cells imported to that MS (and for onward distribution in other MS) from third countries. This approach had received favourable opinions in the written feedback received by the Commission but this feedback has been limited and further views were sought from the group.

Questions were raised that memorandums of understanding to share information between health authorities of MS and third countries often include confidentiality clauses which would preclude further dissemination of the information. This is also true of MoUs between SANCO and the likes of the US FDA. Such MoUs may need to be tweaked to take into account the need to share such information across the RATC platform which itself is designed to keep information confidential between its users. A suggestion was also made to develop a list of contact points for third countries which would also potentially include contact points for professional associations. Such a list would also facilitate communication in the other direction. *WHO may be able to assist in the development of such a list and it was suggested that the Commission report back to the group on this possibility in the next CA meeting following the WHO Notify gathering in Brazil in December 2013.* It was also pointed out that in the framework of the Import WG plans are being put in place to require third country suppliers to inform importing TEs of any non-compliance which could affect T&Cs to be imported into the EU. The ITE would then inform its national CA of such non-compliance. *Further opinions in writing on the approach to take are welcomed with a view to updating the SOP to include a harmonised approach on this issue.*

4.4. Serious adverse reactions and events (SARE)

4.4.1. 2012 SARE final annual report (2011 data)

The Commission presented the findings of the SARE data collection exercise which will form the basis of the 2012 annual report. The analysis of this data shows an improvement of the levels of accurate data collected by CAs and reported to the Commission as provided for in the T&C legislation. Nevertheless there are still shortcomings in the data collection / provision which need to be overcome in order to perfect this reporting

exercise. The main outstanding issues relate to a lack of reporting of any SARE in a number of MS and a lack of data on the ART sector in certain MS linked to the lack of transposition and / or implementation of the legislation vis-à-vis this sector as already mentioned during the meeting.

The UK commented on data reporting regarding composite tissues. The working understanding of both T&C and organs CA groups is that allografts of such composite tissues should be considered as falling under the organs legislation and thus not reported by T&C CAs as part of the T&C SARE reporting exercise. The Commission agreed with this approach but reminded the group that SARE reporting was not a formal requirement of the organs legislation. T&Cs CAs should thus continue to coordinate with their organs counterparts to ensure SARE data on composite tissues is suitably collected.

Clarifications relating to the ART sector were also called for. FR pointed out that the donor is also *de facto* often the recipient and therefore it is not clear if a SAR should be reported as having occurred in the donor or recipient. Concerning OHSS, which should be reported via pharmacovigilance systems, the Commission encourages CAs to also report this for T&C especially related to ARTs. IT pointed out that the SoHO V&S project also came up with a recommendation on reportable OHSS which could be used.

A further issue relates to the reporting of SAR following sperm donations from non-partner donors where a genetic disease is transmitted to the new-born child from the donor. Technically speaking this SAR does not occur in the recipient but in the new-born child and therefore does not need to be reported if the wording of the legislation is followed. *Both the UK and IE felt that such cases should be reported as SAR and the Commission agreed that this should be clarified and a unified approach adopted.*

The Commission asked the group if they would like to also receive the raw data files to which the reply from the CAs was negative. The 2012 final report will be circulated to the CAs with a deadline for comments in February 2014 with final publication expected in the second quarter of 2014.

4.4.2. First analysis of the 2013 SARE annual reporting exercise (2012 data)

The Commission also gave an overview of its initial analysis of the 2012 data collected for the 2013 annual report. The CAs were once again thanked for their cooperation in providing such data although as with previous reports some data reporting was incomplete with no input at all from one MS. Many of the issues reported above remain valid for the 2012 data although it was also stated that more detailed data had been provided on the denominators of both SAR and SAE. *The Commission now plans to verify certain data via e-mail following which a draft version of the report will be made available for CA comments with a May 2014 deadline*. A final version of the report should be presented in the June 2014 CA meeting. Moreover the Commission also informed the group that the 2014 reporting exercise (on 2013 data) would be launched in April 2014 with the usual June 30th deadline for submissions.

To provide further clarity the Commission also presented a short overview (below) of the differences between the requirements placed on CAs in terms of providing information for the purposes of SARE reporting, EUROCET, and EUROCET128 and urged the CAs to continue their proactive support towards meeting the needs of all three.

5. PROJECTS PRESENTATIONS: PUBLIC HEALTH PROGRAMME

5.1. 2013 Joint Action on good practices on donation, collection, testing, processing, storage and distribution of gametes for assisted reproductive technologies and of haematopoietic stem cells for transplantation - update

An acronym has been agreed upon for this Joint Action which will be known as ARTHIQUS with its full title being: 'ARTHIQUS: Joint Action on assisted reproductive technologies and on haematopoietic stem cells for transplantation'. This JA will be led by FR who gave the group a brief introduction on its plans. FR explained that this JA is due to start in May 2014 for a duration of 36 months and includes the involvement of 17 MS. The overall objective of the action is to produce guidelines for the regulation of these two T&C sub-sectors that ensure increased levels of safety for donors and recipients of such T&C. Along with the work packages on coordination (led by FR – WP1), dissemination (CZ - WP2), and evaluation (SE - WP3), there are dedicated and separate work packages on ART (FR – WP4) and HSC (HR & IT – WP5).

PT mentioned that they were a member of the group which will work on WP5 but asked if it would also be possible to still become a member of the group which will work on WP4. FR explained that this was no longer possible but a list of observers has been developed for each WP who would receive all relevant information on progress and it is still possible to become an observer. MS also still have the possibility to nominate experts to participate as trainees for the training sessions planned for these WPs. A question was also raised about potential duplication with the work done under the auspices of the Council of Europe on their T&C guide which has detailed sections related to these two sub-sectors. This concern had already been foreseen and FR as JA leader intends to avoid this as the work of the action will provide guidance for regulatory authorities rather than for professional practitioners who are the target group for the CoE guide. The JA also intends to regularly communicate with the CoE to ensure such duplication is avoided and pointed out that key members of the JA leadership are also closely involved with the CoE work.

Those MS still interested in nominating experts to be added to the list of observers for the operational WPs are invited to contact the JA leader.

5.2. Introduction of the study into the economic landscape of the T&C sector

The Commission gave a brief update on the process of contracting this study. Following the launch of the call for tender, two proposals were received and the contract has been awarded to one of these two applicants. At the time of the CA meeting the contract had not yet been signed and thus a full introduction of the successful contractor and their plans for the study was not possible. Such an introduction will take place in the next T&C CA meeting in June 2014, the contractor however will be introduced to the CAs by email in early 2014 as they plan to start contacting CAs in order to start collecting information to supplement the data they collect from other actors in the sector such as professional associations. The information collected in the latest implementation survey will also be made available to the contractor with the aim of limiting duplication in their requests for information from the CAs. This study will become an important tool for the Commission as it looks to shape its policy on T&C in the coming years and CAs are therefore requested to cooperate with requests for information from the contractor.

6. AOB

6.1.1. Identifiable genetic diseases in non-partner donors

The issue of reporting genetic disease transmission from non-partner donations of sperm has already been mentioned in terms of SARE reporting. Here IE called for a discussion on what should or could be done in terms of guidance or conditions on the use of such reproductive cells once a genetic disease in a donor has been identified. Other than the requirement laid down in Annex III to Commission Directive 2006/17/EC that complete information on the associated risk of genetic disease transmission must be communicated and explained to the recipient where there is an identified history of genetic disease in the donor's family, there are no rules in the EU legislation on the use or non-use of such reproductive cells. This issue is further clouded by confusion created by the different type of blocks put on such donated cells once a genetic disease has been identified.

DK explained that the terms they use are 'temporary block' and 'conditional block' however the conditional block is permanent in its nature except that the donated cells may continue to be used for siblings only. The UK pointed out that, other than on public health grounds, a complete ban on the use of such cells may be difficult in light of fundamental / human rights provisions on the right to start a family and stated that in the case of a potential use for siblings it would expect a risk assessment to be carried out and the recipient couple to receive counselling on the risks of genetic disease transmission. In such a situation the intended recipient could also be offered pre-implantation genetic diagnosis with a view to discarding unhealthy embryos although the question would be raised as to who should pay for such diagnosis.

6.1.2. Direct distribution of reproductive cells to end users

Following discussions on this subject in previous CA meetings, DK gave an update of the latest situation in Denmark and informed the group that they had come to the conclusion that, under Danish law, sperm banks could not be prevented from distributing directly to end users as they felt that this would infringe free movement of goods rules. Nevertheless several MS pointed out that they have more stringent rules in place on who can purchase / use such reproductive cells or the permission needed from the CA prior to cross-border distribution into their MS. This provoked the question of how potential end-users and / or the distributing sperm bank should be made aware of such additional national rules. A further question was raised querying the extent of such situation and whether it would be possible to get data from the distributing TEs in order to establish the true extent of this issue. *CAs were therefore called on to try to obtain and provide generic data on this situation to be presented at the next CA meeting.*

On the same subject IE presented a guidance document it had compiled for end-users considering buying sperm via online sales sites and then inseminating this privately. IE still has to finalise the guidance and draw up a dissemination plan but will be happy to make the final version available to other CAs to use and *agreed to circulate the final version once ready.*

6.1.3. Use of sibling depot in the EU

DK presented the results of a survey it had carried out on the issue of 'sibling depot' i.e. allowing donated sperm to be used for siblings where a block has otherwise been put on

use of the donated sperm due to the discovery of a transmittable genetic disease in the donor. This issue had already been discussed earlier in the meeting and again the discussion reverted back to the question of how the blocks are defined. One suggestion was made for the new Joint Action to take up this issue and look at the possibility to develop guidelines to be used by CAs on a common terminology for block and on the information to be provided to recipients / couples during risk counselling. *This would mean additional work for the JA however they agreed to look at the possibility of taking up this suggestion.*

7. CONCLUSIONS OF THE MEETING

The Chair concluded the meeting by thanking the members for their positive participation and for their cooperation throughout 2013. The group was informed that the next T&C CA meeting would take place on June 3-4, 2014 and that the usual follow-up emails with action points and the Summary Report for this meeting would follow in due course.

DOMINIK SCHNICHELS