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

Meeting of the Competent Authorities for Blood and Blood Components

27-28 February 2018

Summary Minutes

This meeting of the blood and blood components competent authorities took place on the 27th and 28th February 2018. The previous meeting took place on the 22nd and 23rd June 2017.

PARTICIPATION:

Competent Authorities from all Member States (MS) attended the meeting, except for Luxembourg and Spain. In addition, competent authorities from Norway and from candidate countries, the Former Yugoslav Republic of Macedonia, Serbia, Turkey and Montenegro were present. Representatives from the European Centre for Disease Control and Prevention (ECDC) and the Council of Europe (CoE), as well as a representative of the consultancy contracted by the European Commission, ICF Consulting Ltd, and the rapporteur of the Vigilance Expert Sub-Group also attended.

European Commission/DG SANTE, unit B4. The head of unit chaired the meeting.

1 WELCOME AND INTRODUCTORY REMARKS

The chair welcomed the participants and asked for representatives attending for the first time to present themselves. The Commission introduced the new secretary to the SoHO team and informed the meeting of the usual house rules.

2 ADOPTION OF THE AGENDA

The agenda had to be altered due to the non-attendance of some presenters. Point 5.3 (Transpose project) as well as Point 6.2. (Member State Surveillance Updates) and Point 10 (EMA update), were cancelled. Furthermore, Point 9 (Council of Europe Update) was presented after Point 5 (Presentations of EU funded Activities) on the first day of the meeting and Point 7 (New Data Protection Regulation) was postponed and presented after point 8 (Continuity of Supply/Emergency Planning).

Participants were invited to declare any conflicts of interest. None were reported.

3 REGULATORY MATTERS: POINTS FOR INFORMATION

3.1. Transposition, complaints, court cases and parliamentary questions

The Commission updated the group on the status of the transposition of the blood legislation, complaints, court cases and parliamentary questions. The verification exercise of the transposition of Directives 2002/98/EC, 2005/61/EC and 2005/62/EC has now been completed and all resulting infringement proceedings have been closed. All Member States (MS) have now officially notified the Commission of their transposition of Directive 2014/110/EU into national law. Further, the Commission informed the participants that the deadline for transposition of Directive (EU) 2016/1214 (amendment of Directive 2005/62/EC to reflect the development of the GPG) was on the 15 February 2018 and that, by this deadline, 13 MS had notified their transposing measures. Letters of Formal Notice will thus be sent to the 15 remaining MS and called on these MS to move forward with the transposition and notify the Commission once completed.

The Commission informed the participants that currently three complaints are being assessed in the areas of plasma procurement and contract manufacturing as well as labelling requirements for PDMPs – VUD label. As these complaints raise concerns about public procurement practices in the Member States concerned, the Commission explained that its business department, DG GROW, is now in the lead for these cases with DG SANTE closely associated. The Commission reported that one complaint was closed with no further action, another is currently being assessed by the Commission and a third is subject to preliminary ruling before the court. The latter relates to the C-296/15 *Medisanus* Court case regarding the Slovenian public procurement rules for plasma derived medicinal products. Issues were raised in the group as to possible national implications the court case may have, at which point the Commission encouraged the competent authorities, in particular those from countries with similar practices as those used in Slovenia, to consider how the ruling may relate to their national systems. However, due to the on-going assessment of the Slovenian response, the Commission pointed out that it could not make any other comments at this stage but invites competent authorities to contact them in case of serious unclarified concerns.

The Commission also confirmed that infringement proceedings, Court cases and complaints would be taken into account as part of the on-going Evaluation of the blood and tissue and cell legislation (BTC evaluation).

3.2. HU decree of 2016, which put national blood donor registry in place

The Hungarian authority presented their new decree adopted in 2016. It was adopted as a result of an increasing number of plasma donors incentivised by financial remuneration. This development was seen as having a detrimental impact on the whole blood donation rate and on the sustainability of the donor pool going forward, particularly because the paid plasma donors are mostly young students and the whole blood donor pool is ageing. The goals of the decree were to establish a national blood donor registry, to maintain blood donation rates by requiring plasma donors to give a whole blood donation at least once per year before continuing to donate plasma, to enhance and facilitate communication among plasma centres and blood establishments and to adapt other measures to safeguard the blood supply. It was considered too early to assess the success of the intervention but the Hungarian representative had anecdotal evidence that plasma donors accepted the change.

The authorities raised a number of questions in relation to the decree, especially concerning whether whole blood donations are still legally perceived as voluntary, on how to evaluate plasma donation frequency and regarding the proportional contribution of private and public collection centres. Additionally, the need to adapt the EU legislation to include these topics, in response to demographic changes such as an ageing population and decreasing number of donors, was raised by the participants.

4 EVALUATION OF THE BLOOD LEGISLATION

4.1. ICF presentation

An external contractor, ICF Consulting Ltd., currently conducting an independent study supporting the Commission in their BTC evaluation, presented their preliminary results. The representative presented the draft answers to the evaluation questions. Additionally, a number of further evidence-gathering steps involving competent authorities and others were outlined, for which the timely collaboration of the authorities was requested. These included questions concerning the cost-efficiency of the required 2-yearly inspections and information regarding the national legislation in place before the EU legislative framework was adopted. It was stressed that responses would be required in a relatively short time period.

Authorities asked whether national competent authorities could be informed of inputs received during focus groups and expert interviews from participants from their country, in order to gain a clearer picture of the national views. ICF's representative stressed that the organisations that have participated will be listed but not their replies or personal information as to do this might inhibit the openness of the exercise.

Lastly, the Commission highlighted that this study constitutes part of the inputs that the Commission is gathering, which will be taken into consideration in the final Commission Evaluation Report.

4.2. Preliminary feedback from consultation activities

The Commission presented their ongoing analysis of the open public consultation submissions and their work on documenting key messages on the relevance, effectiveness, efficiency, coherence and EU added value criteria that have come forward so far. In general terms, stakeholders have raised gaps, inadequacies or inconsistencies under each of the criteria but particularly under effectiveness and relevance. [The report of the consultation has since been published[1]]. Participants were invited to comment on the findings so far for each criterion, particularly in relation to any gaps or inaccuracies noted. It was underlined that opportunities to comment were now becoming limited before the full evaluation report would be published towards the end of 2018. Issues that were raised by CAs in the discussions included: support for a the shift of the "voluntary unpaid donation" terminology to the WHO and Council of Europe proposed concept of "financial neutrality"; the problems caused by the inflexible two-year inspection cycles and a perceived need for requirements for clinical follow up data for novel preparation processes. Participants were invited to make a closer analysis of the key messages presented send any further comments during a period of two weeks from the meeting.

The Commission highlighted the publishing of the Draft Meeting Minutes on CIRCA-BC from the ad-hoc meeting with stakeholders that took place in June 2017; participants were which every party was welcomed to review and suggest modifications. Along with other such stakeholder meetings, the minutes will be taken into account in the BTC evaluation.

5 PRESENTATION OF EU-FUNDED ACTIONS

In general, the Commission noted that there was an appreciation and interest in the group for more meetings and projects in the field of blood and blood components, as they are considered to be very beneficial in terms of collaboration and to provide excellent opportunities for professionals and authorities to exchange experience and expertise with each other.

5.1. VISTART Joint Action on blood, tissues and cells

The VISTART Joint Action, due to be completed by October 2018, was presented to the meeting.

The initial objectives of the Joint Action were to promote and facilitate harmonization of the inspection systems for blood, tissues and cells as well as increasing Inter-Member State collaboration and confidence in each other's inspection, authorisation and vigilance programmes. All inspection related Work Packages (6-9) were presented

[1] https://ec.europa.eu/health/blood_tissues_organs/consultations/implementation_legislation_en

together, addressing their main goals, milestones achieved and deliverables still to be developed. Their presentation focused particularly on sustainability and on how to offer further training/dissemination for inspectors. For Work Package 7, the first and second edition of training courses was described in greater detail as well as the plans for ensuring sustainability of the training. For Work package 8, on frameworks for joint inspections, the consortium reporting on a number already conducted and on further planned joint inspections. Work Package 9, on the establishment of a Common European SoHO inspection programme (CESIP), offers CAs/Inspectorates a first opportunity to participate in a dedicated audit programme of inspection systems in Europe, providing opportunities for improvements in developed systems and identifying the needs for capacity building in developing systems. The next training of auditors for this programme, which is seen as a key element to ensuring a harmonized approach to both performing and participating in the CESIP Audit Programme, was announced for September 2018 and calls for interest were requested.

Work Package 4 on Vigilance reporting for blood, tissues and cells and Work Package 5 on international collaboration for vigilance communication were also presented. For the former, the meeting was updated regarding work on horizon scanning for ensuring adequate responses to new risks. The involvement of ECDC and other relevant professional associations was valuable for the survey conducted and the guidance under development. The first draft of the guidance was due for sharing at the end of June 2018. For Work Package 5, the group was informed that the submission of cases from the CA annual SARE reports to the Notify Library, using the guidance and documentation developed in the work package, is now open. The next meeting of Work Package 5, Part A would be held on 1st-2nd of March in Brussels as a joint meeting with the WHO Notify Project.

5.2. New Joint Action on Preparation Process Authorisation (GAPP)

The new three-year EU funded Joint Action, facilitatinG the Authorization of Preparation Process for blood and tissues and cells (GAPP), which aims to support the development of a common and optimal approach to both assess and authorise preparation processes in blood, tissues and cells establishments, was introduced by the leader, Italy. The action has 28 associated partners from 24 Member States and 15 collaborating organisations. By providing tools and training to increase the harmonisation of those MS activities that regulate the areas of blood transfusion, transplantation of tissues and cells and ART. The Blood CAs were provided with a first overview of the activities that aim to develop common and optimal approaches to assessing and authorising preparation processes, devoting particular attention to new innovative processes under development in these sectors. This included a presentation of the work plan, the project deliverables, milestones, next steps and the announcement of the kick-off meeting in June 2018 in Rome.

6 SURVEILLANCE AND VIGILANCE: UPDATE ON INFECTIOUS DISEASES RISK

6.1. ECDC update on infectious diseases

The ECDC representative informed the group of recent infectious disease transmissions that pose potential threats for blood transfusion. These included the detection of mosquitoes that transmit yellow fever in Tenerife, the first human influenza A (H7N4) case reported in China, the transmission of Hep E through blood donation in Japan and the monitoring of the South Korean Winter Olympics due to 244 confirmed norovirus infections.

In particular, hepatitis A (HAV) was discussed with regard to its epidemiological shift as it affects increasing numbers of adults that could be blood or plasma donors. The disease is often asymptomatic or mild and transmitted through contaminated water, food, via the faecal-oral route and blood transfusion (TTHA). The HAV virus can survive and remain infective during storage in all conditions prescribed for all types of blood components. The risk of transmission through plasma-derived medicinal products is mitigated by testing of donated plasma pools by NAT and the use of pathogen inactivation technologies that effectively eliminate HAV in plasma-derived products. ECDC informed the group that in cases of outbreaks, donors in affected areas should be asked standard agent-non-specific questions to identify risk groups and agent-specific screening questions concerning a history of possible exposure to HAV, whereas in non-affected areas, donors should be asked about

recent travel history. In the case of exposure, donors should be tested using NAT and deferred for one year if positive. Furthermore, in male donors with an increased risk of HIV, HBV and HCV infection due to having sex with men (MSM), permanent or temporary deferral of blood donation is advised.

6.2. Member States surveillance updates

No Member State had specific national surveillance information to report.

6.3. Rapid alerts – General Overview

The Commission informed the participants that by the end of 2017, a number of epidemiological, Q&S, information notices, bilateral enquiries and illegal/fraud cases had been reported via the platform. Although the number of rapid alerts for blood (RAB) and for tissues and cells (RATC) reported each year has decreased each year, the reports are important with 21 uploaded for blood in 2017. The Commission noted that for the first time, the 2017 RAB and RATC activities will be summarised in one single report for publication.

6.4. SARE reporting – presentation of 2017 exercise (2016 data) by EDQM

The Council of Europe (EDQM) debriefed the participants on the preliminary analysis of the 2017 SARE reporting exercise in which a total of 2,599 serious adverse events (SAE) and 2,950 serious adverse reactions (SAR) (imputability level 1-3) and 1,737 SAR (imputability level 2-3) were reported. The data collection has gradually improved with 83% of countries having reported complete data. In total, 24.8 million units were issued for transfusion and 20.6 million units were reported as transfused in 2016. A number of CAs raised concerns regarding differing definitions between Member States for the terms 'issued' and "distributed units". One CA noted that all "issued" unit numbers are estimates by default, as the number of units issued to the blood banks does not necessarily correspond to the number of units transfused by clinicians.

EDQM noted that some countries still do not report any SAE or SAR and do not report all denominators. It was stressed that, in their submissions, MS must differentiate between "0" and "N/A" (not available) when reporting. In conclusion, SARE reporting is improving but continues to be subject to inconsistencies and heterogeneity.

The Council of Europe informed all participants that the launch of the new SARE reporting exercise would start in March 2018 with a deadline for submissions of June 2018. EDQM invited the group to carefully read the Common Approach document and pay special attention to the changes in the reporting template.

6.5. Feedback from Vigilance Expert Sub-Group

A sub-group to this expert group (CASoHO E01718) working on vigilance across blood, tissues and cells was established in 2017 with the aim of reviewing and improving the Commission's vigilance related activities, particularly the SARE and rapid alerts programmes. One of the vigilance Expert Sub-group's (VES) rapporteurs provided an update of the work of the VES. The group considers that good annual summary reports are being issued, including SARE and denominators, but that more can be gained from the data collection exercises with the implementation of various improvements to the reporting templates and their associated instructions for compilation (the Common Approach documents). The VES has compiled a long list of issues that might/should be addressed to improve the quality and usefulness of the exercise.

The rapporteur presented proposals for harmonization and improvements categorized into three levels: "quick fixes" involving changes that do not impact on how data is currently collected; changes which will involve advance notice because of changes in the way data will be collected at MS level and finally, possible future improvements that would imply a revision of EU legislation. Several proposals for implementation in the 2018 reporting exercise (2017 data) were described.

The VES considers that improving reporting of SAR in donors is a priority and, consequently, a list of donor reaction types will be included in the 2018 exercise, although those MS that cannot provide donor SAR broken down in this way will still be able to provide just a total number. CAs requested that the SARE reporting criteria and the "severity" definition also gain more attention and clarification in the future. The representative thanked

all competent authorities for their contribution to SARE reporting and emphasized that improvements in reporting are an on-going process that will require time.

6.6. SARE reporting – 2018 exercise

The Commission announced that the new SARE reporting exercise would be launched at the end of March or first week of April 2018 and that the deadline for submission will be the end of June 2018, with no extensions possible. Three changes have been introduced in the reporting template including a new "transfusion-transmitted fungal infections" field in the SAR list, "donor selection" in the serious advent events dropdown list and including a requirement to provide the number of SAE by blood component.

The Commission invited all CAs to carefully read the Common Approach document proposal of the Vigilance Expert Subgroup (VES) and highlighted that complying with the new approach is a work in progress that can be adapted gradually, thereby reassuring some CAs that are unable to comply with the changes in the coming year. The Commission asked that the slides introducing the changes be shared by the CAs with the people that are responsible for filling in the reporting template in the respective countries.

The CAs were informed that a Global Vigilance Networking Meeting would take place on the 1st and 2nd of March 2018 in Brussels. This would be a joint meeting between the VISTART Joint Action and the Notify library. The aim is to explore improved dissemination of vigilance experiences gathered all around the world for mutual learning.

7 NEW DATA PROTECTION REGULATION

The new General Data Protection Regulation (GDPR) was presented to the meeting by the Data Protection Coordinator of DG SANTE who gave an overview of the regulation and its relevant provisions in terms of health and emphasising aspects that might affect blood services and CAs.

Under the GDPR, the Commission remains the guardian of the Treaties and ensures dialogue with MS, national Data Protection Authorities (DPAs) and stakeholders. The central role of enforcers lies with the DPAs. The regulation provides a set of data protection rules in the EU, for which there is one interlocutor and one interpretation that will create a level playing field and simplify the process.

It was underlined that the new regulation is an evolution, rather than a revolution, with the basic architecture and core principles remaining unchanged. The concept of personal data has been clarified but is not new. Article 9 sets out standards about sensitive data that include health data, genetics and biometric data and requires explicit consent through clear affirmative action, also applicable to all future research intended to be conducted with the data. Furthermore, the concepts for pseudonymisation and anonymization were clarified and several principles of processing explained. It was highlighted by the Commission that all forms of possession/storage of data is considered as 'processing'. The requirements include fair and lawful processing, purpose limitation, data minimisation, rules for further processing and data retention, the latter meaning that data cannot be held for a longer period of time than necessary. In this regard, questions were raised by the German CA as to whether their data storing timeline of 30 years can be ensured through this regulation. The Commission argued that the only requirement of the regulation is that the timeline needs to be justifiable, however encourages CAs to address such concerns to the Commission's justice department (DG JUST). Further principles of processing are data accuracy and accountability.

In terms of international transfers of personal data, the regulation sets out clearer rules defining when EU law is applicable and provides a renewed and diversified toolkit for international transfers. On a question raised by EDQM whether a non-EU based company that is using data from EU citizens must comply with the regulation and what legal steps will be taken if they do not, the Commission clarified that all companies that are offering goods and services in the Union, or monitor behaviour within the Union, have to comply. The Commission

suggested that for more information, especially regarding specific cases, participants should address their enquiries to DG JUST.

8 CONTINUITY OF SUPPLY

The topic of emergency planning to ensure continuity of the blood supply had been raised previously in both the blood CA meeting in June 2017 and in the stakeholder consultation meeting for the BTC evaluation. It had also been discussed at meetings at EDQM where it had been indicated that a chapter on this topic would be included in the Quality Manual being developed in the B-QM programme. The CD-P-TS committee at EDQM showed interest in including a chapter on this topic in the Blood Guide. At the previous meeting of this group, a number of CAs had indicated their interest in collaborating with EBA and EDQM in a small working group to develop some guidance on this topic.

Before establishing a working group of the CAs on this topic, the Commission indicated that they considered that reflection is needed to establish clearly what the scope, level of application and format the output of any such group should take. It would need to be decided whether the group would address critical devices and reagents supply, emergencies of all kinds that might affect the blood and blood component supply for Transfusion and or the supply for manufacture of plasma derived medicinal products. It was considered that any guidance for the blood establishment level would focus on communication with donors and clinicians, with suppliers and with other establishments. This was not considered to be the appropriate level to be addressed by this group. However, actions at national or EU level addressing inter-MS communication and sharing, national stock monitoring, prediction of the impact and measures to take and regulatory decisions that might be needed to facilitate cross-border exchanges were considered the responsibility of authorities. It was noted that, such emergency plans would normally be established by civil protection and other such agencies and that blood supply should be integrated in those plans.

Thirteen MS indicated that they already have contingency plans in place, although it was noted that some address this at the authority level (e.g. Czech Republic), whilst others have organised it on the level of blood establishments (e.g. Germany). The Commission noted that there was significant interest in the room from those CAs that do not yet have an established contingency plan in place, to learn from the aforementioned countries that do. The CAs of France, Romania, the United Kingdom, Hungary and Croatia indicated their interest in further developing this work in a working group.

The Commission encouraged the work in this field and highlighted the need to ensure overall coherence and avoid duplication. The next step would be for discussions between the Commission and the Council of Europe on how to make further progress on this topic and to report back to the CAs before establishing the working group.

9 COUNCIL OF EUROPE UPDATE

9.1. Council of Europe update

Updates from EDQM presented to the group reported on the meetings of the European Committee (Partial agreement) on Blood Transfusion (CD-P-TS). The report described the 14th plenary session in November 2017 and the meeting of the Subordinate Working Party, GTS, that is tasked by the CD-P-TS with the periodic revision of the "Guide to the Preparation, Use an Quality Control of Blood Components". A briefing on the 20th edition of guide, due for publication in 2019, was provided. In addition, the objectives and tasks of the plasma supply management working group (TS093) and the risky sexual behaviour working groups (TS100) were presented. EDQM informed the group that the resulting recommendation on risky sexual behaviour would be made publicly available on their website and can be used for the Commission's BTC evaluation.

The EDQM working group on European Treaties (TS103), also overseen by CD-P-TS, has been reviewing old agreements and decided to update the Exchange of Therapeutic Substances of Human Origin Agreement of 1958. In emergency situations, EDQM specified that the treaty does not oblige the countries that sign it to exchange blood or blood components but will provide a legal framework for doing so. In relation to this, the French CA has agreed to share the output of an inter-Member State surplus blood exchange group that involved Greece, Cyprus, Italy, France, Poland and the United Kingdom with the rest of the group.

Another working group that is also led by CD-P-TS works on Malaria (TS116) reports a lack of harmonised approaches to the eligibility of donors that travel to areas where Malaria is endemic. Denmark, Finland and the UK have been nominated to constitute a working group and a survey is planned that will be followed by an update to the 20th edition of the blood guide.

The EDQM representative informed the group regarding Regulation (EC) 1907/2006 REACH that defines a list of chemicals of high safety concerns to human health or the environment and should be withdrawn from use. The list includes plasticisers in use in medical devices used in blood collection and transfusion that cannot be replaced rapidly as there are not yet CE marked alternatives available.

A second EDQM presentation followed presenting results from the Blood-Proficiency Testing Scheme (B-PTS) for blood establishment testing laboratories. It was noted that, though compliant with IVD legislation, some assays raised safety concerns for SoHO that will be further investigated as part of the 2018 B-PTS programme. EDQM informed participants that the Root Cause Analysis (RCA) guidance has been published in June 2017 and is available for free on the EDQM website.

The EDQM representative also updated the group on aspects of the Blood Quality Management Programme (B-QM) that provides support to blood establishments through an educational programme focused on developing and improving comprehensive and integrated quality management systems. Participants were informed that the proceedings of the 2017 conference on "Sharing best practices: quality risk management, change control, validation and qualification" including a detailed summary of the presentations and discussions will be publicly available in April 2018 and that the drafting of the "quality manual" is still on-going and will, as previously mentioned, include a chapter on contingency planning. A training course for blood establishments and inspectors that will take place on the 23rd and 24th of October 2018 with the key purpose of sharing experiences on Statistical Process Control (SPC) was announced and all here present were invited to nominate participants.

9.2. GPG – Follow up Q Finland, responses collected

Some requests for technical clarification of certain Good Practice Guidelines (GPG) provisions had been raised by the Finnish CA at the previous meeting. Since then, the Commission had gathered comments from this group and consulted with EDQM and the GPG drafting group in order to provide clear answers. These had been provided by the Commission to Finland, who were satisfied with the answers, and they were shared with this meeting. The Council of Europe (EDQM) assured the group that all comments would be addressed in the next edition of the GPG for greater clarity. They invited CAs to send additional questions or comments on the text that directly point out room for improvement up to mid-April to allow them to be discussed at the subsequent meeting of the GPG drafting group.

The Commission reminded all participants that the requirements of the Directive 2005/62/EC and the respective annexes have to be met. In addition to the Directive, the Council of Europe has issued the GPG in order to support blood establishments. These guidelines to some extent include standards and specifications from the legislation's annex and it was noted that those texts must not be changed, in order to maintain coherence with the legislation. The Commission invited EDQM to establish structured procedures for the provision of timely responses to requests for clarification on the GPG.

11 WHO UPDATE

As the WHO was not able to send a representative to this meeting, an update presentation had been provided that was presented by the Commission.

The update on the WHO Blood Transfusion Safety Programme included the publication of guidance on the protection of the blood supply during infectious disease outbreaks, a global point-prevalence survey to establish who benefits from transfusion, the announcement of a WHO collaborating centres and key implementing partners for blood and transfusion safety meeting taking place May 2018 in Shanghai, ongoing work on strengthening of blood transfusion services in countries as well as the announcement of World Blood Donor Day taking place 14 June 2018 in Greece with the slogan: "Be there for someone else. Give blood. Share life"

12 ANY OTHER BUSINESS

12.1 Meeting of SoHO Registries

The Commission debriefed participants on a meeting it had organised with 10 registries in the SoHO field, mainly covering organs and tissues and cells. Several of the registries are organised by professional associations that collect data from and for professionals in order to improve clinical practice.

The different registries presented their set-up and organisation to each other, allowing for a rich exchange of experiences. A key challenge these registries face in common, and the trigger to organise this meeting, was the application of the new EU Regulation on data protection (GDPR). Commission experts on this regulation were available for questions and answers. Other topics of common concern were data quality and standards, governance, sustainability and funding.

The meeting included an exchange of information and views with other Commission-related programmes on health data, including the Innovative Medicines Initiative, DG Research and DG CNECT. This highlighted the topic of possible interest from different authorities (e.g. pharmaceutical, SoHO, health technology assessment) to use registry data in a manner secondary to its original purpose. In this context, registry data might support decision-making processes related to authorisations, vigilance and cost/benefit assessments.

12.2 New meeting registration system

The Commission informed all participants that a new system to register participation and remuneration to Commission's meetings (AGM) was being implemented. For this, the Commission required a list of individual nominated representatives per country; this was being organised by the secretariat of the SoHO team in DG SANTE and the collaboration of all CAs was requested.

12.3 Changes to plastics in blood component processing sets

The Danish CA gave an update on some existing blood processing sets which have needed the replacement of a component material with an alternative. The relevant EU customers had already been appraised of the change in October 2016 and 2017, including the qualification/validation programmes underway. As the existing product is CE marked, a change in notification was submitted to the Notified Body and its finalisation was expected imminently. The manufacturer has informed the relevant EU customers, as these processing sets are to replace the existing product, after the inventory of the latter has been depleted. The manufacturer has followed the expected regulatory requirements for a modification to an existing medical device.

12.4 EC mission to United States

In the light of an imminent US mission by Commissions representatives, CAs were invited to communicate to them any particular issues that they would wish the Commission to bring forward in meetings with the regulators there.

12.5 Updates to the DG Santé SoHO web pages

The Commission informed the group that a note on the possible impact of BREXIT for the SoHO field had been published on the website[2] and encouraged all CAs to review it and communicate any particular concerns.

A short presentation of the recently updated DG Sante website (SoHO pages) followed, pointing out where to find the aforementioned note, all meeting minutes and updates on the BTC evaluation.

13 FINAL REMARKS

The Commission thanked all participants for the fruitful and constructive discussions and informed the group that they would send a follow up email summarising actions from the meeting. The next meeting of the blood CAs is scheduled for the 10-11 October 2018.

[2] https://ec.europa.eu/health/sites/health/files/blood_tissues_organs/docs/2017_btc_brexit_en.pdf