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

Meeting of the Competent Authorities for Blood and Blood Components

10-11 October 2018

Summary Minutes

This meeting of the blood and blood components competent authorities took place on the 10-11 October 2018. The previous meeting had taken place on 27th and 28th February of the same year.

PARTICIPATION:

Competent Authorities from all Member States (MS) attended the meeting, except for Luxembourg and Estonia. In addition, competent authorities from Norway and from the Former Yugoslav Republic of Macedonia were present. Representatives from the European Centre for Disease Control and Prevention (ECDC), the Council of Europe (EDQM) and Consumers, Health, Agriculture and Food Executive Agency (CHAFEA), 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. A representative of the European Medicines Agency joined the meeting by teleconference on the 11th October.

1 WELCOME AND INTRODUCTORY REMARKS

The chair welcomed the participants and asked 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

No additional topics were added to the agenda although the order was changed for some topics to accommodate the travel plans of particular speakers.

Participants were invited to state any conflicts of interest. None was declared.

3 REGULATORY MATTERS: POINTS FOR INFORMATION

3.1. Transposition, complaints, court cases and parliamentary questions

The deadline for transposition of Directive (EU) 2016/1214 (amendment of Directive 2005/62/EC to reflect the development of the GPG) was 15/02/2018 and, by this deadline, 13 Member States had notified their transposing measures. Letters of Formal Notice were sent to 15 Member States. As of 08/10/2018, 27 Member States had notified transposing measures.

In July 2018, DG SANTE began the conformity check. DG SANTE considers the transposition in 23 Member States as adequate and complete. Clarifications were being requested from four Member States and notification was awaited for the other Member State. Of the 23 Member States fully assessed at the time of this meeting, 17

had used a reference to the GPG in their transposition, one had fully translated and integrated the GPG in the national law, three had translated the GPG in an annex of the national law and two MS had used a reference to their official gazette/homepage where translated versions had been published.

DG SANTE informed the participants that of the three complaints against Member States in the areas of plasma procurement and contract manufacturing, one had been closed with no further action, the second was subject to a preliminary ruling before the court and the third is being assessed by the Commission. The complaint regarding VUD labelling of PDMPs was ongoing. As these complaints raise concerns about public procurement practices in the Member States concerned, the Commission explained that its Directorate General GROW is leading for these cases with DG SANTE closely associated.

The preliminary ruling on case C-296/15 addressed the key question of whether a tender specification that industrially manufactured medicinal products must be obtained from nationally donated plasma ('priority of supply' rule) is contrary to public procurement rules. The court found that Directives 2001/83 and 2002/98 are not relevant to this question and that the priority supply rule should be assessed against TFEU Article 34 on the free movement of goods. It noted that the priority supply rule is, *prima facie*, a restrictive measure prohibited under TFEU Article 34 and does not comply with public procurement rules in 2004/18. The priority supply rule would therefore need to be justified on TFEU Article 36 grounds, i.e. public health protection. The case has been referred back to the national tribunal for a final ruling. DG SANTE advised the national authorities to bring national legislation in line with the final ruling that was expected by end 2018. DG SANTE would follow up with the Member State concerned and take into account the ruling in the associated on-going complaint.

4 EVALUATION OF THE BLOOD LEGISLATION

DG SANTE summarised the state of play of the Blood, Tissues and Cells Evaluation (BTC Evaluation), explaining that the Commission's Evaluation Report was expected to be published in the first part of 2019.

4.1. Feedback from consultation activities

DG SANTE presented an overview and key issues coming forward from their stakeholder consultation activities, focusing on activities and messages emerging since the previous blood authorities meeting. A Summary Report of the Open Public Consultation (OPC) was published in April 2018[1], along with the individual stakeholder submissions, where the required permission for publication had been given. Submissions had been received from a broad spectrum of stakeholders with a wide geographical reach, as well as a good representation of the different sub-sectors involved (blood, tissues, cells) and the different types of stakeholder (authorities, establishments, industry, patients, donors etc.).

Apart from the OPC, targeted stakeholder consultation activities had continued with further multilateral meetings between invited stakeholders and Member State authorities and further bilateral meetings with key stakeholders at their request. Since the previous meeting of the competent authorities, bilateral meetings had taken place with a number of stakeholders in the blood field including the US FDA, the American Association of Blood Banks, the American Association of Tissue Banks, Medtech Europe, the Plasma Protein Therapeutics Association, the International Plasma Fractionators Association and the European Blood Alliance. The key messages emerging from those meeting were summarised and the meeting participants were referred to the webpage where summary minutes are published[2].

Austria noted that their authority conducts frequent inspections of plasma collection and fractionation in the US, considerably more than they do in Austria. They noted that the inspection frequency applied by US authorities is lower than that required in the EU. They asked whether plasma collection and plasma derived medicinal product (PDMP) manufacture would be included in the US Mutual Recognition Agreement with the EU. Such a step

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

[2] https://ec.europa.eu/health/blood_tissues_organs/events_en#anchor1

would be welcomed by Austria as a means of reducing inspection workload, although they noted that there are differences between the US and the EU for some issues related to donor eligibility that would need to be explored. DG SANTE explained the MRA would be fully applicable as from mid-2019, though not including PDMPs. A possible extension to additional products such as vaccines and PDMPs would be discussed by 2022 although it was noted that plasma itself remained outside the scope of the MRA.

The UK noted that the EMA inspectors working group has adopted the system of risk-based inspection scheduling for US inspections and suggested that it should be applied in the blood sector also. The EMA document has been published by EMA. UK also argued that the 2-yearly inspection requirement in the blood legislation can be complied with by desk-based inspection. Austria confirmed that they regularly perform desk-based inspections for the US.

There was some discussion on the topic of self-sufficiency, particularly for plasma for medicinal product manufacture, and questions regarding the availability of data to support the comments regarding the EU's dependence on the US for a sufficient supply of plasma. DG SANTE pointed to the presentations and minutes of a multi-lateral stakeholder meeting where this subject was one of the main topics and where robust data had been presented. The Commission also invited the competent authorities to send further data if available. A number of Member States noted that more work needs to be done to establish evidence-based standards for the treatment of patients with PDMPs. It was noted, in particular, that there is considerable off-label use and a need for plasma-use management and guidance at EU level.

DG SANTE noted that, in the context of their grant agreement with the Council of Europe (EDQM) a major symposium was being organised by EDQM on the subject of plasma supply in Europe and would take place at the end of January 2019. The symposium would explore supply needs, the challenges to achieving higher levels of plasma collection in Europe and strategies to overcome them.

4.2. ICF presentation

The external contractor, ICF Consulting Ltd., completing an independent study to support the BTC evaluation, presented their activities since the previous meeting and their key answers to the evaluation questions. In summary, the findings were shown to be in line with those emerging from DG SANTE's stakeholder consultation activities. The participants were informed that the independent study would be published at the same time as the Commission's Evaluation Report.

4.2. BTC Evaluation – next steps

The chair summarised the next steps and the planned timing for publication, noting that it would be up to the new Commission, in place after the 2019 elections, to consider how to address the shortcomings and gaps identified during the process. She thanked Member States for all their contributions to the process so far and urged them to inform DG SANTE if they had any concerns regarding the findings outlined to date. In addition, they were invited to submit any additional data/evidence they considered important and encouraged to disseminate the report once published.

5 PRESENTATION OF EU-FUNDED ACTIONS

5.1. VISTART Joint Action on blood, tissues and cells

DG SANTE congratulated the VISTART Joint Action leader and all the partners for the success of the Joint Action that was now coming to an end and had delivered a large number of highly valued guidance documents, recommendations and training courses. Although all technical work-packages had completed, or almost completed, their activities by the time of this meeting, an extension had been granted until February 2019 for the completion of the administrative aspects of the dissemination and evaluation work-packages. The full action was presented by its co-ordinator, Italy, with all the outcomes summarised. The presentation focused particularly on sustainability of the action's outputs, including how to offer further training/dissemination for inspectors as well as maintaining a programme of joint inspections and of inter-Member State inspection system audits. The

recommendations of the vigilance work-packages are being taken up by the Vigilance Expert Sub-group and the methods of sustaining the other outputs were also addressed.

[Item **6.0** on the agenda, below, was taken at this point as it was relevant to the sustainability of the outputs of VISTART work-packages 6, 7, 8 and 9.]

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 over 26 associated partners from 17 countries and 14 collaborating organisations; it kicked-off in May 2018. Its key objectives are to:

- Increase consistency and efficacy of competent authority regulatory activities through harmonisation of EU-level tools for authorisation procedures for preparation processes at blood and tissues establishments.

- Develop a concept model for a European Knowledge-sharing platform that can support authorities in the assessment and evaluation of novel preparation processes.

- Establish an international network of specifically trained assessor/inspectors that can support CAs in the assessment and evaluation of preparation processes of BTC products.

The Blood CAs were provided with an 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. The work plan, the project deliverables and the milestones, for the 10 work packages were described.

5.3. Transpose Project

This project, TRANSfusion and transplantation: PrOtection and Selection of donors, is led by Sanquin in the Netherlands. The aim of the project is to build risk-based guidelines and a standard Donor History Questionnaire for the procedures followed for collection of substances of human origin, including blood, plasma, gametes, haematopoietic stem cells and replacement tissues. The deliverables are partly generic, and partly substance-specific. The steps include:

- To collect and compare EU and national donor selection and protection criteria;
- To identify key risks to be considered for the donation and collection of 5 groups of substances (whole blood, plasma, haematopoetic stem cells, replacement tissues and gametes),
- To identify the information needed from donors or their families to allow the application of appropriate donor deferral or exclusion criteria for the protection of recipients; and
- To propose approaches to control and minimise these risks.

Five separate questionnaires were developed for Blood, Plasma, Tissues, ART, Stem cells and were shared with 130 experts in the various SoHO sub-sectors to collect feedback. Results were compiled in a database and were the topic of a focus group during a meeting in Copenhagen in September with WP5 and WP6 leaders. The results of these expert opinion reviews were being documented for submission to scientific journals.

In parallel, risks were listed and categorized. These will be scored according to severity and level of evidence according to expert estimates and compared with actual reported adverse incidents. Two articles on this exercise have been submitted to scientific journals for publication.

The outcome of these activities will form the basis for the development of the common Donor Health Questionnaire (DHQ) that will be completed by February 2019.

6 PROPOSAL TO ESTABLISH AN EXPERT SUB-GROUP ON INSPECTIONS

DG SANTE presented a proposal for the establishment of an Expert Sub-group on Inspection, noting that the Rules of Procedure for the CASoHO Expert Group allows for the establishment of such sub-groups in article 7. The tasks of the proposed sub-group would be to:

- review / update guidance / working documents such as:
  - Inspection guidelines
  - Code of practice for joint inspections
  - CESIP documents
- coordinate training courses
  - Inspector / auditor training
- oversee inspection-related collaboration
  - Joint inspections / audits of inspection systems

disseminate results and monitor uptake of outputs.

With these working objectives, the sub-group would ensure the sustainability of the tools, guidance and courses developed for inspections in the VISTART Joint Action.

The proposal was that the sub-group would work across blood and tissues & cells with similar working methods to those of the Vigilance Expert Sub-group. The sub-group should include active inspectors and should meet physical,y as well as virtually, reporting back to both competent authority groups. DG SANTE would circulate draft terms of reference for a written consultation with both groups of authorities and, once agreed, would organise a first meeting in Q1 of 2019.

The proposal received positive support, with a number of Member States welcoming the initiative and committing to participation in the sub-group as a way of developing a more uniform approach to inspection across the EU. The Commission agreed to initiate the written procedure.

7 DIGITAL DATA IN SOHO

DG SANTE presented and number of topics related to digital data and relevant to the work of the expert group.

7.1. SoHO Registries Meeting – Brussels, January 29-30

Triggered by requests for advice regarding the implications of the General Data Protection Regulation (GDPR) for SoHO Registries, the Commission had convened a meeting of registries to discuss data protection and other topics of shared interest. The meeting was held on January 29-30 2018 and was attended by representatives from nine organisations that host and maintain registries in the fields of bone marrow transplantation, organ transplantation, and IVF. The key topics addressed were compliance with the GDPR, ensuring quality of data in SoHO registries, registry governance, registry sustainability and funding and the potential for the secondary use of data from SoHO registries. The participants had appreciated the opportunity to share experiences with each other and to discuss the GDPR with Commission experts working on that legislation. [Note: a second meeting of SoHO Registries will be held on February 20, 2019].

7.2. Commission Communication on Digicare

DG SANTE summarised a Commission Communication on the digital transformation of health & care (DIGICARE) that had been published on April 25, 2018 together with a report[3,4]. The objective was to increase the availability of data in the EU to improve healthcare, and clinical research. Registries like those brought

[3] https://ec.europa.eu/digital-single-market/news-redirect/624248

[4] https://ec.europa.eu/digital-single-market/en/news/staff-working-document-enabling-digital-transformation-health-and-care-digital-single-market

together in the SoHO registry meeting (point 7.1) are considered to contain such Real World Data (RWD). Of relevance to the field of SoHO was that, Pillar 2 of the Communication includes a plan to support pilots to demonstrate the benefit of the use of RWD for health technology assessment, clinical & regulatory decision-making. This should address the needs of different target groups (healthcare professionals, regulators, HTA bodies, policy-makers) and result in guidance documents that will bring together the results of completed, on-going, planned and future EU-funded initiatives.

7.3. Real World Data

DG SANTE also informed the group that Real World Data is generally seen as an important contributor to research and policy and that SoHO is a field where the accurate collection and sharing of such data can be valuable for many purposes including vigilance, authorisation and demonstration of clinical effectiveness. Through the Public Health Programme, DG SANTE is already supporting two projects and a Joint Action where RWD will be gathered in a database, ECCTR, EuroGTP II and the GAPP JA. The authorities were encouraged to reflect how RWD can be of use for their tasks as SoHO authorities.

A number of authorities noted the existence of further SoHO registries in their Member States, including one in Germany on haemophilia and one in Scandinavia for blood donors and transfusion outcomes (SCANDAT). It was agreed that these registries would be invited to present their work at the next Blood Competent Authorities meeting.

The Council of Europe (EDQM) informed the meeting that they plan a 2020 conference on horizontal issues including GDPR and they asked whether the Communication on Digital Data in Health is an indication that new funding will be available to support this area of work. DG SANTE confirmed that both DG RTD and DG CNECT are reflecting on funding programmes with this focus.

8. THE COMMISSION'S STRUCTURAL REFORM SUPPORT SERVICE (SRSS)

The Commission (SRSS) informed the authorities about the SRSS, explaining that it is a relatively new service, launched in 2015, to support Member States with the preparation, design and implementation of growth-enhancing reforms[5]. The service can engage in any policy area identified by a Member State as a reform priority, including health. No co-financing by the beneficiary is required and the SRSS engages in dialogue with Member States to discuss technical support needs. The support given is in the form of technical expertise that is financed by the programme; there is no direct financial assistance to the beneficiary. A number of health related projects have already been supported, addressing topics such as cancer screening programmes, spending review on medicines and health system performance assessment. For the period 2019-2020, a total budget of 222.9 million Euros has been approved. All requests per Member State must be submitted in a centralised way via the national SRSS Co-ordinating Authority; some of these national authorities conduct a pre-selection at national level. A list of the national SRSS Co-ordinating authorities was provided to the meeting participants in CIRCABC. When a request is approved for support, the SRSS contracts the technical support provider.

9. SURVEILLANCE AND VIGILANCE: UPDATE ON INFECTIOUS DISEASES RISK

9.1. 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 Monkeypox cases in the UK imported by travellers returning from Nigeria, a summary of the 10th Ebola outbreak in the Democratic Republic of Congo and the current situation in the EU with regard to West Nile Virus (WNV) and Dengue. The risks of Monkeypox to SoHO safety are considered very low although theoretically possible for a number of reasons that were

[5] https://ec.europa.eu/info/departments/structural-reform-support-service_en

described, including the absence of any reported cases of SoHO transmission and the fact that chronic carriage of the virus has not been reported. For Ebola virus, individuals who have ever been infected are permanently excluded from donating of blood cells and tissues in the UK and FDA (excluding donors of convalescent plasma for treatment of EVD) and eight-week deferral is applied in a series of circumstances where there has been possible exposure. WNV was particularly widespread during the 2018 season, with 142 deaths in the EU and a number of Member States reporting their first human cases. Autochthonous transmission of Dengue was reported in mainland France in October and blood and tissue & cell safety measures were posted in the EU rapid alert platforms.

ECDC also reported on their most recent SoHO activities. A WNV meeting was held in March in Vienna from which conclusions would be published. An assessment of the risk of tick-borne encephalitis virus transmission through SoHO had been prepared and the work on bacterial transmission through SoHO was ongoing.

9.2. Member States surveillance updates

Short updates on the WNV situation in Member States were given by IT, HR, FR, RO, SL, and AT. The reports addressed the detection of increasing numbers of human cases and the measures taken to prevent transmission by blood transfusion. Measures included testing, deferral, pathogen inactivation and improving pre- and post-donation information for donors. In the worst affected Member States, measures to ensure the blood supply were also implemented, including strengthening promotion and increased collection, supply monitoring and distribution of components from unaffected to affected areas for urgent needs. Challenges included testing capacity in single centralised NAT testing laboratories. In Romania in particular, around 1,000 donors were deferred and there were some delays in releasing and distributing blood components, particularly platelets, and some planned surgery was delayed as a consequence. Member States had communicated these developments via the EU Rapid Alert platform for Blood (RAB) hosted by the Commission.

9.3. Rapid alerts – General Overview

DG SANTE provided the participants with a summary of alerts posted in the RAB and RATC platforms up to October 2018. Although the number of rapid alerts for blood (RAB) and for tissues and cells (RATC) reported each year were generally decreasing, 2018 showed an increase due to the WNV outbreaks in many Member States. The Commission noted that on the 22 May 2018, a summary of RAB/RATC activities for 2017 had been published, for the first time in a single document for the two sectors[6].

A meeting had been held with the Data Protection Officer at DG SANTE, to discuss the impact of the new GDPR on the rapid alert and the coding T&C platforms. A few changes in the RATC/RAB disclaimers and an update of the DPO notification on the application are needed and plans were in place for implementation by end of 2018.

Sweden informed the meeting regarding on ongoing investigation into a blood donor that had made 22 donations, in accordance with the normal health and screening requirements and had since been diagnosed with suspected Creutzfeldt Jakobs disease. These donations were used for blood and blood components for transfusion or for further processing in the manufacture of certain medicinal products by a European pharmaceutical firm. A rapid alert communication in the medicinal sector has been issued by the Swedish Medicinal Product Agency. The initial focus of the blood competent authority's work on this case was to determine if any of the blood or blood components from this donor had been distributed to any EU or EEA countries, or elsewhere. [Subsequent to the meeting SE launched an information notice in the RAB platform to inform the other authorities that only patients in Sweden had received blood and blood components from this donor].

9.4. SARE reporting –2017 exercise (2016 data) and 2018 exercise (2017 data)

[6] *https://ec.europa.eu/health/sites/health/files/blood_tissues_organs/2017_ra_soho_summary_en.pdf*

The Council of Europe (EDQM) presented the key data and messages in the summary report of the 2017 SARE reporting exercise (2016 data). The Council of Europe conducts the analysis of the data reported by the Member States as part of a Grant Agreement with the European Commission. The preliminary data had been reported in the previous meeting and the final data included in the draft report had changed only minimally. A total of 2,950 serious adverse reactions (SAR) (imputability level 1-3) and 1,737 SAR (imputability level 2-3) were reported. Seven countries did not report SAR of imputability 1. the most frequently reported SAR were the following: anaphylaxis/hypersensitivity, febrile non-haemolytic transfusion reactions (FNHTR), transfusion-associated circulatory overload (TACO) and immunological haemolysis.

A total of 1,737 serious adverse events (SAE) were reported by 30 countries with great variability in the numbers reported; two countries reported 62% of the total SAEs, indicating a need for standardising criteria for SAE reporting. Twenty-three Member States reported 7,658 SAR in donors on a voluntary basis. 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 20.9 million units were reported as transfused in 2016.

EDQM noted that some countries still do not report any SAE or SAR and do not report all denominators. EDQM proposed steps to improve the exercise, including improving definitions and guidance and mandatory reporting of donor SAR with criteria and definitions. The draft summary report had been shared with the authorities and comments were requested by the end of the month.

DG SANTE summarised progress with the 2018 exercise that was launched on April 12 with a deadline of the end of June. It had included some clarifications in the Common Approach document and some changes in the reporting template. All 28 Member States and Norway had already submitted their reports. It was noted that the analysis of the data would not begin until early 2019.

9.5. 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. During 2017, the VES had compiled a long list of issues that might/should be addressed to improve the quality and usefulness of the SARE exercise and categorised them as:

- ‘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
- possible future improvements that would imply a revision of EU legislation.

Several priority proposals for implementation in the 2018 reporting exercise (2017 data) had been proposed and implemented. A full VES meeting was scheduled for November 2018 and a new wave of proposals for improvement would be discussed and prioritised there for possible implementation in the 2019 exercise or beyond. It was reported that the VES would also start to address vigilance issues for organs.

DG SANTE thanked the VES for their work and noted that this expert sub-group is providing an excellent bridge to the vigilance officers in Member States that are completing the SARE submissions each year. The level of activity in the group was clearly high and the results were clearly likely to bring significant improvements.

10 CONTINUITY OF SUPPLY

The topic of emergency planning to ensure continuity of the blood supply had been raised in previous meetings 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 relevance of continuity of supply of critical medical devices had emerged as a key element in these discussions.

DG SANTE reported that it was taking this topic forward in two ways. Firstly, a stakeholder meeting (immediately prior to this meeting) with key device suppliers and the European Blood Alliance (EBA) had discussed the topic of critical device supply. Both EBA and Medtech had agreed to provide the Commission with lists of key devices that are essential to maintain the blood supply. Secondly, an activity on this topic had been included in the new Direct Grant to Council of Europe (EDQM) that will begin in 2019 and last for 3 years (see next agenda item). Those Member State authorities that indicated an interest in participating in a working group on blood and blood component supply continuity will be invited by EDQM to work with them and other stakeholders on this subject.

11 COUNCIL OF EUROPE UPDATE

DG SANTE provided an update to the participants on the new Direct Grant with the EDQM that is due to being in January 2019. The new agreement will include the activities that were already in previous agreements, B-PTS (blood donor proficiency testing scheme), B-QM (quality management in blood establishments) the EDQM Guides and the analysis of the blood, tissues & cells SARE data annually. This new 3-year agreement would be enlarged to include activities on the following additional topics: continuity of the blood supply; increasing plasma supply in Europe; support for assessment and other missions to neighbouring and applicant countries; post-mortem testing of blood samples for tissue donation; activity data reporting for tissues & cells; training for national vigilance officers on SARE reporting and training for tissue establishments on quality management.

EDQM then presented their recent activities, focusing on the results of the B-PTS programme and the B-QM programme during 2018 and the planned Symposium on Plasma Supply Management. Twelve B-PTS studies had been performed during the year with an average number of 67 participants. The studies addressed testing for HBV, HCV and HIV by NAT; anti-HCV; anti-HIV/P2; anti-Treponema; HBsAg/anti-HBc and ABO, Rh, Extended Phenotyping and Irregular red cell anti-bodies. In contrast to the previous year, results at the time of this meeting indicated 100% satisfactory performance. EDQM has also provided guidance on Root Cause Analysis of non-satisfactory external quality assessment reports that has been downloaded around 500 times. EDQM is considering a new study on bacterial testing with a feasibility study in 2019.

The B-QM programme was also proceeding with a high level of activity. The proceedings of a conference on quality risk management, change control, validation and qualification held in 2017 was published, a training course on statistical process control was scheduled for later in October 2018 and work on guidance for the implementation of quality management was ongoing. The Symposium on plasma supply was scheduled for January 29 and 30, 2019. The symposium would aim to review the scientific evidence supporting donor eligibility and protection, the obstacles to European strategic independence of plasma for fractionation and approaches to overcoming those obstacles.

During the discussion that followed the EDQM presentation, EDQM clarified that 1-2 laboratories from each EU Member State were participating in the B-QM scheme. This can cover a significant proportion of tested donations in countries with centralised services or a small proportion in countries that still have high numbers of local blood establishments conducting testing. Authorities reported that experiences of participation in the two schemes had been positive and had brought improvements.

12 EMA UPDATE

EMA participated in the meeting by teleconference, to provide an overview of the Plasma Master File (PMF) Certification System to the blood authorities. It was noted that the PMF is a stand-alone document, which is separate from the dossier for marketing authorisation for plasma derived medicinal products (PDMP). It provides all relevant detailed information on the characteristics of human plasma used as a starting material for the manufacture of PDMPs or medical devices incorporating stable derivatives of human blood or human plasma. The information extends from the collection and testing of single donations, up to the manufacture and testing of fractionation pools. The PMF is assessed at community level by EMA and the certificate provided can form part of the marking authorisation application at national level for multiple products manufactured from that plasma. The certificate is valid in all EU Member States but can only be used when products are authorised in more than

one Member State. EMA published guidance on requirements for PMF certification in February 2004 (CPMP/BWP/4663/03).

EMA described the two EMA working parties that have a role in the process of guidelines drafting. The Biologicals Working Party (BWP) addresses quality aspects while the Blood Products Working Party (BPWP) addresses clinical aspects. Both maintain updated guidance available on the EMA website.

Participants asked whether EMA would make a statement on the acceptable deferral time for men having sex with men (MSM) who wish to donate plasma, noting that deferral times for whole blood donation have been reduced in many Member States but that PDMP manufacturers do not wish reduce times unless EMA provides guidance. EMA noted that they consider deferral times a Member State responsibility but plan to make a statement regarding the topic, subject to resource allocation connected with the business continuity plan for relocation to Amsterdam.

13 ANY OTHER BUSINESS

13.1 Feedback on Stakeholder meeting October 10 2018

DG SANTE debriefed participants on a meeting it had organised with key stakeholders and many of the authorities present at this meeting on the previous day. Attendance of authorities had been high and the topics addressed were the importance of medical devices to the continuity of the blood supply and the state-of-the-art regarding pathogen reduction of blood components during processing. The summary minutes of that meeting will be published separately.

13.2 Changes to plastics in blood component collection and processing sets

DG SANTE noted that both the European Blood Alliance and Medtech Europe had highlighted in their responses to the Open Public Consultation for the BTC Evaluation their concerns regarding the inclusion of DEHP on the REACH list of materials that would not be allowed in medical devices. The Commission informed the participants that it planned to address this topic in a future stakeholder meeting.

14. FINAL REMARKS

All participants were thanked for their active and constructive interventions during the meeting and were reminded that all presentations and associated documents would remain accessible in the CircaBC platform. The next Blood Competent Authorities meeting is scheduled for June 18-19, 2019.