



EUROPEAN COMMISSION  
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate B - Health systems, medical products and innovation  
B4 – Medical Products: quality, safety, innovation

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

### **Meeting of the Competent Authorities for Blood and Blood Components**

**22-23 June 2017**

### **Summary Minutes**

#### **PARTICIPATION:**

Competent Authorities from all Member States (MS) were represented at the meeting, apart from Luxembourg. In addition, competent authorities from Serbia and Turkey attended, as well as representatives of the Consumer, Health and Food Executive Agency (CHAFAEA), the European Centre for Disease Prevention and Control (ECDC), the European Medicines Agency (EMA), the Council of Europe (EDQM) and the World Health Organisation (WHO) were present as observers. A representative of a consultancy contracted by the European Commission, ICF Consulting Ltd, also attended along with some private experts that joined to present specific topics.

European Commission/DG SANTE/B4: Ms A-E AMPELAS (chair), Mr S. VAN DER SPIEGEL, Ms D. FEHILY, Mr R. MCGEEHAN, Ms I. PUCINSKAITE-KUBIK, Mr P. CATALANI and Ms A. CORNEA.

#### **1 WELCOME AND INTRODUCTORY REMARKS**

The newly appointed Head of the responsible unit at the European Commission (B4) was introduced and took the chair. She welcomed the participants to a meeting with a full and interesting agenda.

#### **2 ADOPTION OF THE AGENDA**

The agenda was adopted without any modifications. No conflicts of interest were reported.

### 3 REGULATORY MATTERS

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 MS have now officially notified the Commission of their transposition of Directive 2014/110/EU into national law. There are two on-going pilots based on complaints received relating to plasma collection and plasma-derived medicinal products. One of these is on the same topic as the Court case described below. Since the last meeting of the group in December 2016, no Parliamentary questions related to blood have been received.

The Commission informed the group that the European Court of Justice published its preliminary ruling in case C-296/15 on 8 June 2017. The case relates to Slovenian public procurement rules for plasma derived medicinal products. In its judgment the Court analysed the national legislation against the general Treaty provisions on the free movement of goods and Directive 2004/18. The Court found that, while, in principle, national measures encouraging voluntary and unpaid blood donation and aiming for national self-sufficiency in human blood and plasma are legitimate objectives of public health protection capable of justifying a restriction on the free movement of goods, the national measures at issue were not proportionate in achieving these objectives. Therefore, the Court ruled that the relevant provisions of Directive 2004/18 and Articles 34 and 36 TFEU preclude a clause in the Slovenian tender specifications that medicinal products manufactured on the basis of plasma had to be manufactured on the basis of Slovenian plasma. The Commission informed the group that the case would now go back to the referring national tribunal for a final ruling and that the Commission would take the ruling into account when dealing with the on-going complaint on the same topic. The Commission encouraged the competent authorities to consider any implications the ruling may have on their own systems of plasma collection and supply of plasma derived medicinal products.

3.1 The deadline for transposition of Directive (EU) 2016/1214 is 15 February 2018 and no MS have yet notified the Commission of transposition although the Estonian CA pointed out that that transposition is complete even if a formal notification has not yet been made. The Commission asked the CA representatives to explain the approach their MS is planning to take to transposition into national law and whether there were any particular challenges they were facing with the transposition of this Directive. From the information provided by the members of the group, a total of 14 MS intend to include a reference to the Good Practice Guidelines (GPG) in the transposing national legislation while six MS intend to include the GPG in the transposing national legislation. A number of the members taking this approach pointed out that they are obliged under national law to provide guidelines in the national language(s) and, as the GPG are only available in English, they need to be translated. Moreover, where included in the transposing legislation, this would need to be amended each time the GPG are updated. The Commission clarified that Directive (EU) 2016/1214 does not make the GPG legally binding but introduces a legally-binding obligation on the MS to make good practice guidelines available. The approach to be taken in the other 8 MS is not yet clear.

Finland raised some concerns in relation to the interpretation of technical requirements in the GPG for blood grouping and phenotyping. It was agreed the Commission would circulate the written questions to all the authorities for comment and provide them to EDQM. EDQM

agreed to consider the questions and competent authority comments together with the drafting group and respond in writing.

3.2 The Commission debriefed the group on the discussion in the December 2016 ad-hoc stakeholder meeting on the deferral criterion for West Nile Virus in Directive 2004/33/EC. During this stakeholder meeting the European Blood Alliance (EBA) pointed out some difficulties for blood establishments in the implementation of the criterion as amended in Directive 2014/110/EU. Following this amendment the deferral criterion now reads as: *'28 days after leaving a risk area of locally acquired West Nile Virus unless an individual Nucleic Acid Test (NAT) is negative.'* EBA questioned firstly, whether this wording precluded the use of mini-pool NAT testing and, secondly, whether 'a risk area of locally acquired West Nile Virus' equates to ECDC risk assessment terminology for WNV. The Commission invited the group to share their views on these points.

On the first point the group agreed that the cost implications put forward by EBA suggested a broad interpretation of the text should be favoured. The ECDC representative confirmed that the sensitivity level of mini-pool NAT is sufficiently high so as to not warrant a credible safety risk if used. The German CA pointed out that the type of NAT used is not the decisive factor for them but rather the sensitivity level of the individual donor sample, whether this is tested as part of a mini-pool or not. The group agreed on a working interpretation which leaves the discretion to MS to decide whether to use the deferral period or use NAT. Where NAT testing is permitted, MS will have the discretion to decide which type of NAT testing is permitted and any conditions which should be placed on its use i.e. whether a risk assessment is necessary to justify the use of a particular type of NAT or to set an acceptable sensitivity level.

On the second point the Commission presented the four types of risk area defined in the ECDC terminology for WNV risk assessments. The group agreed that the definition of an 'affected area' in the ECDC risk assessment terminology is consistent with the term 'risk area of locally acquired West Nile Virus' in Directive 2004/33/EC. The Commission informed the group that the points raised by EBA would also be taken into account as part of the on-going evaluation of the blood legislation.

#### **4 EVALUATION OF THE BLOOD LEGISLATION**

The Commission gave an overview of an evaluation of the EU blood and tissues and cells legislation that was launched at the beginning of the year.<sup>1</sup> This will be the first formal evaluation under Commission Better Regulation rules<sup>2</sup> since the adoption of the basic Acts in 2002 (blood) and 2004 (tissues and cells). The objective is to assess whether the legislation has achieved its original objectives and is still fit to purpose.

The Commission published a roadmap that was open to comment for a 4 week period. The roadmap outlined the various elements of the evaluation, including an ongoing study by an external contractor, ICF Consulting Ltd, and extensive consultation of stakeholders. A final evaluation report in the form of a Commission Staff Working Document is expected to be

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<sup>1</sup> All relevant information relating to the evaluation, is available on a dedicated DG SANTE webpage: [https://ec.europa.eu/health/blood\\_tissues\\_organ/policy/evaluation\\_en](https://ec.europa.eu/health/blood_tissues_organ/policy/evaluation_en)

<sup>2</sup> [http://ec.europa.eu/smart-regulation/guidelines/docs/swd\\_br\\_guidelines\\_en.pdf](http://ec.europa.eu/smart-regulation/guidelines/docs/swd_br_guidelines_en.pdf)

published by the end of 2018. Any decision on a potential change in legislation can only be taken once the evaluation has been concluded.

#### 4.1 External Study

The Commission introduced the contractors, ICF Consulting Ltd., that are conducting a study to support the evaluation. Their representative presented the main elements of the work that will aim to provide an input to the evaluation questions regarding the relevance, effectiveness, efficiency, coherence and EU-added value of the legislation. Their tasks include collecting and consolidating evidence through extensive review of existing reports, documents and publications and filling evidence gaps using focus groups and interviews. They will draft a summary report of the Open Public Consultation that will be published by the Commission. Their study report will also be published and will form a major input to the Commission's final Evaluation Report. ICF presented its project team which includes 3 thematic experts from the fields of blood, tissue and cell regulation and practice.

#### 4.2 Open Public Consultation

The Commission presented its work on the Open Public Consultation that had been launched on May 30<sup>th</sup> and would remain open until August 31<sup>st</sup> [*Note: the deadline was subsequently extended by two weeks due to the holiday period*]. The consultation was described as having 2 separate questionnaires, one for individuals and one for organisations. The questionnaire for individual citizens and asked more detailed questions if the respondent identified themselves as being involved professionally in an affected field; it was available in all EU languages. The questionnaire for organisations was divided into separate sections for blood and for tissues and cells and was available in English – although respondents could use their own language in their responses. The latter questionnaire contained many open fields for free text comments and gave the possibility to upload attachments to support the points made. It was noted that all those responses where permission was given would be published on the DG-Santé website.

The Commission services encouraged the competent authorities to actively participate in the stakeholder public consultation and, if approached by the external contractor, to give their full co-operation. It was also announced that, immediately following the Open Public Consultation, there would be a stakeholder conference on 20 September 2017. The conference would be open to any stakeholder interested in the evaluation and authorities were encouraged to inform their stakeholders about the event and to participate themselves. [*Note: the stakeholder conference took place on 20 September 2017 in Brussels. The event attracted a high level of interest with over 200 stakeholders attending.*<sup>3</sup>]

#### 4.3 Bilateral Meetings with Stakeholders

In parallel with this work, the Commission reported its continuing ad-hoc meetings with stakeholders. Since the previous meeting of this group, DG-Santé had met with the newly formed Common Representation for SoHO organisations (CoRe SoHO) – a consortium including the European Blood Alliance (EBA), the European Society for Blood and Marrow Transplantation (EBMT), the European Association of Tissue Banks (EATB) and the

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<sup>3</sup> A summary of the stakeholder conferences is available on the DG SANTE website: [https://ec.europa.eu/health/sites/health/files/blood\\_tissues\\_organ/docs/ev\\_20170920\\_sr\\_en.pdf](https://ec.europa.eu/health/sites/health/files/blood_tissues_organ/docs/ev_20170920_sr_en.pdf)

European Eye Banking Association (EEBA). The key points raised are described in the summary minutes published online<sup>4</sup>.

#### 4.4 An ad-hoc Meeting of Stakeholders and Competent Authorities

An ad-hoc meeting had been held on the morning, before the start of this meeting, with a group of stakeholders selected from the published, approved list. The topics chosen were blood donor protection and plasma supply. The summary minutes of that meeting will be published separately. The authorities shared the concerns of stakeholders regarding the need for greater donor protection in the legislation. They also expressed concern regarding the dependence of the EU on the United States for an adequate supply of plasma for the manufacture of plasma-derived medicinal products. The potential competitive impact of the collection of plasma by commercial companies, with donor compensation, on the rates of whole blood donation to the blood services was also raised and Hungary reported the adoption in 2016 of a new decree that would put a national blood donor registry in place and implement other measures to protect the blood supply. It was agreed that Hungary should present this initiative at the next meeting of this group.

## 5 PRESENTATIONS OF EU-FUNDED ACTIONS

### 5.1 VISTART Joint action on vigilance and inspection in blood and tissues and cells

A presentation of the ongoing VISTART Joint Action<sup>5</sup> was given by two of the action's partners. The first presentation focused on a set of work packages that are all focusing on inspection: inspection guidelines, inspector training, a framework for joint MS inspections and inter-MS inspection system auditing. The inspection guidelines were finalised at the beginning of the year and submitted to the Commission. The first of 2 advanced courses for inspectors, with e-learning and face-to-face modules, was held in April and May 2017 with 35 participants from 20 MS. Participant evaluation to date was very positive. A code of practice for joint MS inspection had been drafted and the first pilot joint inspection carried out in Croatia. The voluntary inspection system auditing programme was launched with 2 meetings of the working group already held. A series of supporting documents had been drafting, using inspection auditing programmes in related sectors as models. A joint work-package meeting is planned to discuss the sustainability of the important outputs of the VISTART inspection activities.

A second VISTART presentation addressed work on vigilance and on the development of regulatory principles for clinical outcome review as part of preparation process authorisation. Through a series of meetings and drafting iterations, recommendations for improving the Serious Adverse Reactions and Events (SARE) and Rapid Alert programmes at EU level were developed and were soon to be finalised. An initiative to build collaboration between MS SARE programmes and the WHO didactic library of adverse outcomes, the Notify Library, was well advanced, with many MS agreeing to select individual SAR or SAE with particular learning points to be shared in the global library. Finally, the development of regulatory principles for the evaluation and follow-up of clinical outcome protocols for newly developed

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<sup>4</sup> [https://ec.europa.eu/health/sites/health/files/blood\\_tissues\\_organ/docs/ev\\_20161202\\_mi\\_en.pdf](https://ec.europa.eu/health/sites/health/files/blood_tissues_organ/docs/ev_20161202_mi_en.pdf)

<sup>5</sup> The Joint Action VISTART aims to promote and facilitate the harmonisation of inspection, authorisation and vigilance systems for blood, tissues and cells. The Joint Action consortium includes 20 collaborating and 16 associated partners.

blood, tissue or cell processes was presented. The group is working towards a novelty grading proposal that would support authorities in deciding when to require a clinical follow-up programme that would be proportionate to the risks associated with the degree of novelty.

## 5.2 Publication of PBM Guides

DG-Santé funded a service contract to develop a pilot and guidance to help MS implement Patient Blood Management (PBM). The contract was completed in the Summer of 2016. The Commission had continued to discuss the main outputs, a guidance document for authorities and another for hospitals, with MS authorities up to their publication early in 2017. It was confirmed that the guides were published on the DG Santé website<sup>6</sup>.

## 5.3 New Joint Action on Preparation Process Authorisation

The Commission presented the thinking behind a new Joint Action that is due to start in 2018. The evaluation of the proposal had taken place over the previous two days and was positive. The Action will be led by Italy (jointly the National Blood and Transplant centres). The objective would be to build on the work on preparation process authorisation underway in VISTART to develop a common EU approach to preparation process authorisation systems, including the evaluation and approval of new donor selection protocols, laboratory validation studies including the approval of reagents, sterilisation/microbial inactivation methods, environmental monitoring and quality controls as well as the outcome of clinical studies where deemed necessary. The Action will also explore sharing of preparation process authorisation information between MS. It was noted that the exact details of the proposed work packages could change during the contract negotiation.

# 6 SURVEILLANCE AND VIGILANCE: UPDATE ON INFECTIOUS DISEASES RISKS

## 6.1 ECDC update

ECDC provided the group with an update of the current epidemiologic situation worldwide with an emphasis on the Zika and hepatitis A outbreaks.

The most important news on Zika was that the epidemic is slowing down in the Americas and the Caribbean with significantly fewer cases so far in 2017, compared with 2016, although new information on Zika virus circulation in South East Asia has emerged and in November 2016 the Texas Department of State Health Services reported the state's first case of local mosquito-borne Zika virus infection in Brownsville. The total number of autochthonous cases recorded in the US mainland include vector-borne, sexual, laboratory and congenital. Some cases have been published in the scientific literature and in the media of Zika transmission by blood transfusion. The EU recorded only travel related cases in 2016 (2024) with no autochthonous transmissions to date.

Since 2013, ECDC has published many documents related to the Zika epidemic including 10 Rapid Risk Assessments, 42 Epidemiological updates, Preparedness guides, Interim Guidance for healthcare providers & Zika Virus laboratory diagnosis as well as Scientific Advice, Policy Briefing & infographics.

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<sup>6</sup> [https://ec.europa.eu/health/blood\\_tissues\\_organ/publications\\_en](https://ec.europa.eu/health/blood_tissues_organ/publications_en)

For Zika risk in the field of SoHO, ECDC had published (August 2016) a Guide for Preparedness Planning in Europe in collaboration with DG Santé, SoHO authorities and experts. A simple email survey of blood authorities was conducted by DG Santé to establish whether the blood safety measures recommended in the document had been implemented. The results indicated that 48% had implemented the measures while 35% had not implemented them, or had implemented them partly. Just over half of those that had not implemented had based this decision on a national risk assessment. A similar survey of blood establishments by the European Blood Alliance indicated that donor deferral of those who had sexual contact with a man diagnosed with Zika virus infection or with a man who travelled or lived in a Zika-affected area had not been applied in most blood services. Similarly, donor deferral for those who had sexual contact with a woman diagnosed with Zika virus infection or with a woman who travelled or lived in a Zika-affected area had not been widely applied.

With the objective of doing a first update of the guide, ECDC had held a meeting in May of 2017 with an expert group to review the developing situation and discuss the most appropriate risk mitigation measures.

*[Note: the updated guide was published in August 2017<sup>7</sup>]*

On the subject of hepatitis A (HAV) it was reported that since June 2016, 1,466 confirmed HAV cases infected with three distinct strains of sub-genotype I A virus have been reported by 16 EU countries. Overall, most cases are reported among adult men who have sex with men (MSM); 100 women were also affected. Measures taken to prevent transmission of other forms of hepatitis and of HIV are considered sufficient to prevent HAV transmission through blood donation by potentially infected MSMs. It was noted that there is no risk of transmission of HAV through plasma derived medicinal products because all donated plasma is tested by NAT for HAV and pathogen inactivation technologies effectively reduces the HAV in plasma products. An ECDC Rapid Risk Assessment was due for publication *[Note: the document was published on 29 June 2017<sup>8</sup>]*

## 6.2 Member State updates

The Netherlands informed the group that they are now testing all blood donors for HEV.

# 7 SERIOUS ADVERSE REACTIONS AND EVENTS AND RAPID ALERTS FOR BLOOD

## 7.1 RAB alerts

The Commission services gave an overview on the rapid alerts for blood launched in 2017.

On the 23 November 2016 version 1.2 of the Rapid Alert Platform (RAB-RATC) was deployed and a new user manual for the RAB/RATC should be available by the end of 2017. On 11 April 2017 the annual summaries of RAB and RATC for 2016 were published on the DG SANTE web site<sup>9</sup>. Following discussion on the relevance of information notices

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<sup>7</sup> <https://ecdc.europa.eu/en/publications-data/zika-virus-and-safety-substances-human-origin-guide-preparedness-activities-0>

<sup>8</sup> <https://ecdc.europa.eu/en/publications-data/rapid-risk-assessment-hepatitis-outbreak-eueea-mostly-affecting-men-who-have-sex>

<sup>9</sup> [http://ec.europa.eu/health/sites/health/files/blood\\_tissues\\_organs/docs/2016\\_rab\\_summary\\_en.pdf](http://ec.europa.eu/health/sites/health/files/blood_tissues_organs/docs/2016_rab_summary_en.pdf)

(normally regarding infectious disease outbreaks) to all MS, it was proposed that alerts in this category should automatically be sent to all MS, without an option for selection. The Commission agreed to investigate making this automatic in the system.

## 7.2 Feedback from European Blood Alliance on rapid alert related to syphilis testing

The European Blood Alliance (EBA) had written to the Commission raising some concerns regarding the communication of this alert to all blood centres. Their letter and DG Santé response had been shared with the participants of this meeting. The Commission presented slides summarising the EBA concerns. The concerns related to 2 key topics: communication of the problem to the blood establishment level and supply continuity following the withdrawal of the testing kit by the manufacturer.

Regarding communication, EBA had consulted with their members and reported that proposed that blood establishments should be linked to the RAB platform for more efficient communication of alerts as the information reaching their members varied considerably between MS. The authorities did not consider it appropriate to give access to RAB to the establishments as the purpose of the platform is to allow secure sharing of confidential information between authorities. It was noted that it is the responsibility of individual authorities to ensure effective communication to affected stakeholders in their own MS. It was noted that the VISTART Joint Action is due to begin developing guidance on the communication of SoHO rapid alerts at national level.

On the question of continuity of supply, EBA had highlighted that the incident had caused difficulties for many blood establishments that used the particular test kit and did not have alternatives to ensure continued donor screening for syphilis. They proposed collaborative work on preparedness for continuity of supply of critical devices/diagnostics in the event of defects causing shortages. The authorities also indicated their interest in working on supply continuity and contingency planning and EDQM indicated that they were also looking into this topic as part of their work on Quality Management and had already distributed a survey to SoHO authorities relating specifically to this incident. It was agreed that a small working group of authorities should take the topic forward in collaboration with EBA and EDQM and FR, MT, RO and UK indicated their interest in developing a document to support continued supply of essential medical devices and diagnostics in the event of interruptions for whatever reason.

On the topic of critical device supply continuity, Romania and Bulgaria informed the meeting of a serious supply crisis they had experienced in the early part of 2017 following a recall by Biorad of Monolisa HCV-Ag/Ab ULTRA V2 test kits. This case further underlined the importance of having robust systems in place to ensure that interruptions to the supply of critical devices do not compromise the continuity of the blood supply.

## 7.3 Update on Medical Device vigilance by DG Grow

In the light of the syphilis test kit defect and its impact on the blood sector, DG Grow attended the meeting and described the system for medical device defect reporting in the EU. A Commission Guidance document on Medical Device Vigilance (MEDDEV 2.12-1 rev 8) had been provided to the participants prior to the meeting as background. It was stressed that, in



cases such as this, involving medical devices defects, the primary route of communication is the Field Safety Notice (FSN) that is issued by the device supplier to all its users. In this specific case, all blood establishments using the kit should have received the FSN promptly. There is no medical device alert system between authorities although reports are shared between them when incidents have been investigated and closed. The RAB platform communication is a secondary tool for the blood authorities share the information when they consider it necessary.

#### 7.4 Serious Adverse Reactions and Events (SARE)

The Commission informed the meeting that the 2016 Annual SARE exercise (2015 data) had been analysed by the Council of Europe (EDQM) under a contract with the European Commission. EDQM presented the results and provided a draft summary report, inviting the authorities to send any comments and corrections. The report would be finalised and published by the Commission. EDQM were thanked for their work on SARE analysis. [*Note: the report has since been finalised and published on the DG Santé website<sup>10</sup>*].

It was noted that the exercise showed a continued gradual improvement of data collection although some denominators are still incomplete for some MS. While Serious Adverse Reaction (SAR) reporting appears to be relatively consistent, the reporting of Serious Adverse Events (SAE) remains heterogeneous and some MS do not report any SAE.

The 2017 exercise (2016 data) had been launched in March and authorities were asked to comply with the submission deadline of the end of June 2017.

#### 7.5 Feedback from the Vigilance Expert Sub-group

The Commission informed participants that a new SoHO Vigilance Expert Sub-group had been established under the Expert Group CASoHO E01718 in January 2017. This sub-group replaces the previous Haemovigilance Working Group and addresses issues related to vigilance across blood, tissues and cells. Organ vigilance will be added to the scope in the future. The terms of reference had been agreed with the Expert Group (both blood and tissue and cell authorities). The authorities were thanked for their active response to the call for nominations to the sub-group issued at the beginning of the year. Twenty countries had nominated 39 experts, with a good geographical and cross-sector representation.

A first well-attended meeting of the newly formed sub-group had been held on 7 April 2017 and was attended also by experts from EDQM (Council of Europe) and from the VISTART Joint Action. The group constructed a long list of issues that it considered should be addressed to improve blood tissue and cells vigilance. The list included issues that would require changes to the SARE reporting template, to the Common Approach guidance for completing the template or to the legislation. The recommendations of VISTART work package 4 were discussed for each topic. The areas where practice improvement, guidance clarification or legal change might be required included the following:

- SAR definitions and categories
- SAR denominators

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<sup>10</sup> [https://ec.europa.eu/health/sites/health/files/blood\\_tissues\\_organ/docs/2017\\_sare\\_blood\\_summary\\_en.pdf](https://ec.europa.eu/health/sites/health/files/blood_tissues_organ/docs/2017_sare_blood_summary_en.pdf)

- Reporting of recipient deaths
- SAR reporting criteria
- Severity Assessment SAR
- Imputability Assessment SAR
- SAR in donors
- SAE definitions and categories
- SAE denominators
- SAE reporting criteria

It was agreed that the sub-group would nominate rapporteurs to steer the work and to feedback to the competent authority meetings. The first step would be to agree minutes of this meeting, prioritise the issues to be developed and build a work plan.

[*Note: A summary of the expert sub-group meeting has been published and is available on the DG SANTE website.<sup>11</sup>*]

## 8 UPDATE OF EDQM (COUNCIL OF EUROPE)

EDQM reported on its most recent activities in the blood field. The 19<sup>th</sup> Edition of the Guide to the Preparation, Use and Quality Assurance of Blood Components has recently been published, including the updated Good Practice Guidelines (GPG) as an Annex. The document can be freely downloaded from the EDQM website. A number of working parties to the EDQM Blood Committee (CD-P-TS) are working on topics including Plasma Supply. It is considered that compliance with the GPG, given the close alignment with GMP, will facilitate the supply of plasma by blood establishments to manufacturers of plasma derived medicinal products.

EDQM also gave a presentation on the blood proficiency testing scheme programme (B-PTS) and blood quality management programme (B-QM) that are run with support from the European Commission. B-PTS provides blood establishments with an external quality assessment of their blood donor testing. The number of laboratories participating in the PTS scheme continues to increase with 71 in 2017 compared to 58 in 2016 and the number of studies per year also increases with the addition of a study on hepatitis E in 2017. In a survey of participants, 98% express that they are satisfied or very satisfied with the programme. EDQM planned to publish guidance on the management and root cause analysis of non-satisfactory PTS results soon after this meeting.

B-QM is an educational programme to support blood establishments in developing and maintaining comprehensive quality management. During 2017, 4 mutual joint visits were planned, together with a major conference in October on *Sharing Best Practices: Quality Risk Management, Change Control, Validation and Qualification*. The conference would include a workshop on implementation of the GPG and, at the time of this meeting, was already fully subscribed, with 150 participants.

As the syphilis test kit defect discussed earlier in the meeting had been detected by the EDQM PTS programme, EDQM plan to analyse the case further, conducting a survey of blood

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<sup>11</sup> A summary of the expert sub-group meeting is available on the DG SANTE website: [https://ec.europa.eu/health/sites/health/files/blood\\_tissues\\_organ/docs/ev\\_20170407\\_mi\\_en.pdf](https://ec.europa.eu/health/sites/health/files/blood_tissues_organ/docs/ev_20170407_mi_en.pdf)

establishments on syphilis testing and developing guidance on contingency planning for blood establishments in the event of critical device supply interruption. As part of the B-QM programme, EDQM is developing a Quality Manual that will also address contingency planning.

## **9 EMA UPDATE**

EMA provided an update on a survey conducted by the Commission on their behalf. The survey explored strategies within the EEA for inspection and control measures of blood establishments involved in plasma (third country / EEA) and blood collection and aimed to i) identify current typical control measures adopted across the EEA, ii) identify best practices for inspection and control measure across the EEA and iii) identify opportunities for harmonisation. The results indicated that very few EEA countries carry out inspections or other control measures for plasma collection centres in third countries. For centres in EEA countries a number reporting using off-site control measures including the review of Annual Reports, with onsite inspection significantly more frequently carried out for blood establishments that carry out all of the prescribed activities (BE1, according to the proposed risk based approach).

On the subject of plasma master file data on infectious disease marker positivity, EMA reported that they assess the data annually as part of the PMF certification procedure. Assessment and presented data should be in line with 'Guideline on epidemiological data on blood transmissible infections' (EMA/CHMP/BWP/548524/2008 rev 1). No "universal" upper limit for incidence or prevalence rate has been established by EMA or other European authorities for acceptance of plasma for manufacture. Whether the epidemiological data is 'acceptable' or not is assessed during the EMA certification procedure based on the data and the evaluation by the PMF holder (e.g. monitoring of changes, comparison with alert limits), also taking into account if plasma from first time tested donors is used or not. PMF Holders should have alert limits in place which should be used as a quality control system to identify collection centres that perform worse than expected when compared to similar collection centres (e.g. same geographical area, collection centre within the same Blood Establishment) or that have rates falling outside the normal range of the donor population in the PMF. If a centre is identified that performs worse than expected, corrective actions should be taken and reported in the PMF. If considered necessary, a PMF holder can be asked to stop using plasma from the concerned centre/s until improvement is demonstrated.

Finally EMA provided an overview of the functioning of the pharmacovigilance reporting system that also covers medicinal products derived from plasma, including a summary of a recent case of a reaction to such a product.

## **10 WHO UPDATE**

WHO provided an overview of their work on blood donation and the safety of blood transfusion around the world. One WHO programme works on Blood Products and Related Biologicals (BLD) while a second works on Blood Transfusion Safety (BTS). The former focuses on standardization of blood products and in vitro diagnostics for testing blood donors, on the quality of blood products and on blood regulation while latter focuses on the establishment of robust blood transfusion systems based on voluntary and non-remuneration donation and with comprehensive haemovigilance. A number of guidance documents support

this work.<sup>12</sup> The important part played by external donors, including the EU, in the funding and regulation of blood services in developing countries was highlighted.

## **11 ANY OTHER BUSINESS**

### 11.1 New Data Protection Regulation

It was noted that the Regulation must be implemented in 2018. DG Sante agreed to include a presentation on its implications for the field of blood and blood components at the next meeting of this group.

## **12 FINAL REMARKS**

The Commission thanks the authorities for their active participation in the discussions and all the speakers for the valuable information that had been shared. The next meeting of the blood national competent authorities is scheduled for 27-28 February 2018.

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<sup>12</sup> <http://www.who.int/bloodsafety/haemovigilance/haemovigilance-guide/en/>  
<http://apps.who.int/iris/bitstream/10665/246169/1/9789241510431-eng.pdf?ua=1>  
<http://apps.who.int/iris/bitstream/10665/254987/1/9789241565431-eng.pdf>