EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

Ad-Hoc Meeting between Stakeholders and representatives of members of the Competent Authorities on Substances of Human Origin Expert Group (CASoHO E01718)

2 December 2017

Summary Minutes

This first ad-hoc meeting between selected stakeholders and representatives of the competent authorities for Blood and Blood components took place on 2 December 2016. The purpose of the meeting was to provide an opportunity for an informal exchange of views between the stakeholders, representatives and the Commission services on topics of mutual interest.

PARTICIPATION:

Competent Authorities from all EU-28 Member States were invited, as were competent authorities from Norway, former Yugoslav Republic of Macedonia, Montenegro and Turkey. Representatives of the European Centre for Disease Prevention and Control (ECDC), the European Medicines Agency (EMA), the Council of Europe and the World Health Organisation were present as observers.

Stakeholders: representatives of the European Blood Alliance (EBA) and of the European Hematology Association (EHA).

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

1 WELCOME

The chair welcomed participants to this ad-hoc meeting. The agenda was adopted without any changes.

2 INTERACTION WITH STAKEHOLDERS

- Terms of Reference

The Commission services presented the terms of reference, reminding the participants in particular that the meeting would only address EU-level topics of relevance for multiple countries. Country-specific topics are to be addressed bilaterally between stakeholders and

concerned Member State authorities. It was agreed to draft minutes of this meeting for publication by DG-SANTE.

- Overview on the results of the open call

The Commission services presented the process of a call to stakeholders for expressions of interest that was launched in October 2016. The list of approved stakeholder organisations interested in participating in ad-hoc meetings with representative members of the competent authorities on SoHO expert group was published in November 2016[1]. Further updates were foreseen.

The Commission services reminded participants that in future stakeholders will be invited to the meetings depending on the agenda topics of EU-relevance.

3 INTRODUCTION OF STAKEHOLDERS PRESENT

EBA represents blood establishments in 27 countries, collecting 16 million whole blood donations per year. Some members also organise plasma collection, and/or are active in tissue and cell collection. The core mission of EBA is to ensure safety, security and cost-efficiency, as well as the assurance of self-sufficiency through voluntary non remunerated blood.

EHA represents more than 4300 haematologists in over 100 countries. Key activities focus on (a) education, through the development of a common curriculum, (b) research, (c) awareness building and (d) lobbying and developing position papers, including one on the EU legislation on safety and quality of blood and blood components.

4 REQUEST TO AMEND DIRECTIVE 2014/110/EU ON TEMPORARY DEFERRAL CRITERIA FOR DONORS OF ALLOGENEIC BLOOD DONATIONS REGARDING WEST NILE VIRUS

EBA introduced this topic by reminding participants that it advocates proportionate and well-targeted blood-safety measures, ensuring safe and sustainable blood supplied to patients. Based on a consultation of EBA Emerging Infectious Disease (EID) Monitor experts, EBA considered that there was a necessity to amend the Directive 2014/110/EU on two points.

Firstly, it was suggested to clarify" *a risk area of locally acquired West Nile Virus transmission"* as referring to an affected risk area as specified in "West Nile fever maps" at the European Centre for Disease Prevention and Control (ECDC) website and used in West Nile virus preparedness plan in Europe. Such clarification would reduce confusion and improve consistency in the EU-wide application of the legislation.

Secondly, EBA suggested to keep regulatory requirements of testing donations for West Nile Virus based on risks, and to allow for mini pool (MP) NAT testing when justified. MP NAT testing has been proven to be of an adequately high sensitivity compared to the individual NAT testing, in particular with the incidence and prevalence rates of WNV in the EU Member States.

[1] http://ec.europa.eu/health/sites/health/files/blood_tissues_organs/docs/2016_call_ls_en.pdf

EBA estimated that using individual NAT testing costs 2 million EUR more per year than using MP NAT testing in the EU. All participants agreed that these economic aspects are an important consideration, to be balanced with the added benefit, in particular as not all EU Member States have similar economic possibilities.

It was further clarified that the requirement of the EU Directive for individual NAT testing was translated in German in such a way that in Germany, when transposing, allow for MP NAT testing.

Participants expressed support for the two proposals put forward by EBA.

The Commission subsequently explained that this proposal will be presented at the next meeting of the Expert Group on Substances of Human Origin, of which the blood Competent Authorities will meet in June 2017. While the possible support of this Expert Group can at that occasion be recorded, the Commission will have to take account of other legislative needs and activities before planning the process of amending EU legislation.

5 REPORTING ON SERIOUS ADVERSE REACTIONS AND EVENTS (SARE) IN A CLINICAL SETTING

EHA introduced this agenda point, by recapitulating legal definitions and examples of serious adverse reactions and serious adverse events. Some data were presented from NL, provided by TRIP, indicating highest numbers of reported SARE with gametes and haematopoetic stem cells (HSC).

EHA emphasized the need to cover donor reactions, while this is not foreseen in current EU legislation. All participants shared and supported this view.

Overall key success factors for a good vigilance system mentioned by EHA included collaboration with different professional associations, support from authorities, and continuous learning. EHA brought some additional practical proposals, in particular to cover reporting on thrombo-embolic events and consider an immunovigilance registry for preventive matching.

Finally, it was suggested to extend and build on the experience from haemovigilance to organise biovigilance for other substances of human origin (SoHO).

The Commission services welcomed this proposal, and explained that the CASoHO Expert Group, during their meeting of blood competent authorities the previous day, had indeed agreed with the idea to setting up such an Expert Sub-Group covering vigilance of blood, tissues and cells. This proposal will be further discussed with the tissue and cell competent authorities, and SANTE will consequently organise the establishment of the Vigilance expert sub-group under the CASoHO Expert Group.

6 FINAL REMARKS

The chair closed the first meeting and thanked participants for their inputs.