EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

# Meeting between the European Blood Alliance (EBA) with DG SANTE B4

# 11 January 2016

## Summary Minutes

Participants:

**EBA**: Kari Aranko, Executive Director, EBA;

**DG SANTE**: Stefaan Van der Spiegel, team leader; Deirdre Fehily, policy officer.

Mr Aranko met with DG SANTE to update them on EBA's efforts to promote Patient Blood Management (PBM) in the EU. The meeting was also used for a general exchange of information between EBA and DG SANTE.

**Patient Blood Management (PBM)**

1. Mr Aranko presented EBA's work to date on PBM (Patient Blood Managememt in Europe, PaBloE). PaBLoE project team has conducted two surveys in 7 hospitals. One addressed red blood cells (RBC) usage, including questions on current PBM activity, and the other addressed knowledge of clinicians on PBM. Initial results were reported at the ISBT Congress in July 2015 and will be submitted for publication. As a second phase an audit process (using an audit tool already in use in the UK) is soon to begin in the Haematology departments of 7 hospitals in different countries. In this prospective audit the goal is to record transfusions of RBC and platelets to patients treated for haemato-oncological indications. The aim is to gather more detailed information on usage of blood components in haemato-oncological indications. In addition an audit of pre-operative anaemia management practices in surgical patients has been planned with a possible intervention to start later this year. The aim of these activities is to identify the principles of good practice that could then be generally promoted by EBA as effective for the implementation of PBM. At this point, PBM guidance has not been drafted by EBA.

2. DG SANTE provided an update on progress in the EU contract on PBM led by the Austrian Institute of Technology. A survey has been completed and implementation guidance is in draft. Currently, a pilot at 5 teaching hospitals in 5 countries is underway. Following the pilot, the

guidance document will be revised. EBA enquired whether such guidance would be endorsed by the Commission or the national competent authorities (NCAs). DG SANTE explained this would not be the case - at least initially, however the guidance provided by the contract, would be the basis for discussions with the NCAs and possibly other stakeholders.

3. EBA and DG SANTE agreed that it could be useful to have EBA comments on the PBM implementation guidance document before it is finalised and published.

4. Changing patterns in blood component usage across the EU were discussed. General falling use of red cells is seen in most Member States, partly due to PBM initiatives and programmes promoting 'Optimal Use', and partly due to advancement of surgery techniques. In some European countries, however, initiatives are still underway to set-up/build more blood collection.

5. The changing patterns of blood usage have had a significant impact on the organisation and sustainability of blood services in many countries. In several cases, national blood services are looking to redeploy personnel/restructure or have already done so.

6. Several national blood services have redirected resources to increased collection of plasma for fractionation, although this is not always easy as it requires a significantly different collection infrastructure. An EBA working group has been assessing how the plasmapheresis is organized and managed in different countries and based on that has recommended best practices.

7. Mr Aranko outlined the interest of EBA in co-ordinating a clinical trial to establish how best to treat pre-operative anaemia (iron supplements or transfusion). A clinical protocol has not yet been drafted. EBA will keep DG SANTE informed of progress in this field.

8. EBA is collaborating with the International Society for Blood Transfusion (ISBT) to develop a training course on transfusion medicine (mainly e-learning) aimed at young doctors. They are aware that the level of awareness of junior doctors is low, notably regarding PBM, even though they are the ones often prescribing transfusion.

**DG SANTE Reorganisation**

DG SANTE informed Mr Aranko of the planned reorganisation in DG SANTE (effective February 1st 2016) whereby the SoHO team will be in the same unit as two other teams, one working on Health Technology Assessment and one on aspects of pharmaceuticals including clinical Trials and plasma derived medicinal products.

**West Nile Virus**

In the light of the new deferral rules set in the Directive 2014/110/EU for prospective donors leaving a risk area of locally acquired West Nile Virus unless an individual Nucleic Acid Test (NAT) is negative, EBA has elaborated a paper on the options for implementation or a proposal for a revision if appropriate and will share this with DG SANTE.

**Optimal use of plasma derived medicinal products**

EBA is interested in looking into the optimal use of plasma derivatives, noting that usage is substantially higher in the U.S. for some products (e.g. Intra-venous Immunoglobulin, IVIG).

**Medical Device legislation**

EBA supports that Blood Establishments should be considered as "health institutes" that can be included under the exemptions for in-house manufacture. They are also concerned that a ban on the use of a plasticide, di-2-ethylhexyl-phthalate (DEHP), in blood bags might be implemented too quickly, without allowing time for alternatives to be validated. Mr Aranko will send DG SANTE the relevant references.

**ATMP activities in EBA organisations**

EBA will send DG SANTE additional information on its annual survey regarding its members' involvement in tissue and cell and Advanced Therapy Medicinal Products (ATMP)-related activities.

**EBA stakeholder meeting**

EBA is planning for a stakeholder meeting later this year or early next year and would like to invite DG SANTE to participate and make a presentation.

**DG SANTE SoHO consultation with stakeholders**

DG SANTE informed EBA that discussions with NCAs regarding the possibility to organise – where appropriate - meetings between DG SANTE, NCAs and stakeholders (including EBA) are proceeding.