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 and DG SANTE B4
3 April 2018

Summary Minutes

Participants

European Blood Alliance (EBA): The President of EBA, Chair of EBA working group on Blood Directives and Executive Director of EBA

European Commission: DG SANTE (Unit B4)

In the context of the ongoing Evaluation of the EU legislation on blood, tissues and cells (BTC) DG SANTE met with EBA at the premises of DG SANTE. The purpose of the meeting was to discuss a list of topics submitted by EBA to DG SANTE prior to the meeting and also for DG SANTE to update the association on the state of play of the ongoing BTC evaluation exercise and the main messages transpiring from it to date[1].

Following the introduction of the participants, DG SANTE underlined to the EBA representatives that the Commission is currently evaluating the existing BTC legislation, with a view to establishing whether it has achieved its original objectives and whether it is still fit for purpose. Any decisions regarding possible revision of the legislation can only be taken after the completion of the evaluation[2]. DG SANTE thanked EBA for the list of topics submitted for the agenda and for their position papers (see Annex), noting that some of the points raised include proposals for future changes to the legislation, a topic not currently under discussion. Nonetheless, the documents and discussions provide evidence relevant to the assessment criteria addressed in the current evaluation and, as such, are useful inputs to the process.

EBA noted that the existing BTC legislative framework is based on the Public Health Article 168 of the EU treaty. In that context, they consider that the EU Blood directive should have been more explicit on endorsing the original intentions and emphasizing the no-financial-gain-principle and the concept of blood and blood component supply as a health service in contrast what EBA sees as a focus on quality and safety of blood and blood components as 'products'. EBA expressed concern that

[1] https://ec.europa.eu/health/blood_tissues_organs/policy/evaluation_en
[2] DG SANTE plan to conclude the evaluation by the end of 2018

European Court of Justice has in the recent decisions made reference to consumer market regulations in spite of the foundations of BTC legislation in the Public Health Article of the treaty.

The association then elaborated on the basis of blood safety and the importance of ensuring a sustainable supply of blood and blood components. In particular, they consider that voluntary unpaid donation (VUD) should be a cornerstone of the legislation. In addition, they see a need to update donor selection criteria and reinforce donor vigilance requirements. According to EBA, the regulatory landscape has triggered competition between VUD donors and plaid plasma donors. They are concerned that the payment of donors creates reliance on a narrow donor base, while a broad one is needed to ensure a robust supply of all blood components for transfusion.

In terms of sufficient supply of plasma in the EU, EBA indicated that all blood components should be regulated according to the same principles regardless of the final use of the components, i.e. transfusion or medicinal product manufacture. Plasma should be collected to meet the medical needs of patients and should be seen and managed as a strategic resource with EU sufficiency as an important objective and moving away from reliance on the US. A recent situation in Romania was discussed as an illustrative example: a severe shortage of plasma-derived medicinal products in the country resulted in a request for help from fellow EU and NATO countries to acquire an urgent supply of the medicines that are used to treat immunodeficiency and other serious diseases.

The Association suggested that while plasma was a limited resource, Belgium has proven that it is possible to collect sufficient plasma for its needs without paying plasma donors. Belgium as a country has a good donation tradition but they noted that it takes years to develop a strong donor base. That resource is easily threatened as it is very difficult to bring donors back to donation once they leave the programme. According to EBA, an adequate regulatory framework is a precondition for ensuring sufficiency of blood and blood components, including plasma at the EU level.

DG SANTE confirmed that a reliable supply and high levels of safety and quality in the BTC field are indispensable. The participants agreed that ensuring a stable and safe supply of blood components requires continuous focused attention and co-operation, both at the level of professionals in blood services and at the level of authorities.

With regard to the technical provisions of the EU Blood Directives, EBA made a reference to the CoE/EDQM Blood Guide. EBA considers that while the Commission should maintain its role of harmonizing and updating high level technical requirements in this field, experts should be involved in ensuring full adaptation of detailed technical guidance to scientific progress. EBA stressed that donor selection provisions should be regularly updated to reflect changing risks and should be evidence and risk based. They see legislative references to the EDQM Blood Guide as the best way to achieve this. In addition, they consider that blood components for topical/non-transfusion uses (serum eye drops, platelet rich plasma used in orthopaedics etc.) should be regulated in a common way across the EU under the BTC legislation.

EBA expressed the view that data sharing for increased transparency on Substances of Human Origin at EU level was needed. In particular, the collection and sharing of biovigilance data on blood, tissues and cells, as well as surveillance data, in particular data on the detection of infectious diseases in prospective blood and plasma donors was seen as an area in need of significant improvement for

greater characterisation of the donor pool and transparency. The role of European registries documenting clinical follow up was also discussed and considered by EBA to be of importance for monitoring and improving blood transfusion services.

EBA noted that their official positions on four of the key topics raised: VUD, sufficiency of blood and plasma, the need for flexible, evidence and risk based donor selection criteria and a call for reference by the EU to the EDQM guidance were explained in 4 published Fact Sheets (Annex). DG SANTE confirmed that these statements form part of the documentation for the BTC Evaluation.

DG SANTE thanked EBA for their inputs at this meeting, and also for their submission to the recent Open Public Consultation for the evaluation of the BTC legislation[3]. DG SANTE specifically expressed their gratitude to the EBA for their expert collaboration in the development of a preparedness plan to address the potential impact of ZIKA. DG SANTE also used an occasion to congratulate EBA on their upcoming 20th anniversary event.

The EBA representatives expressed their appreciation for the open and accessible process of evaluation being conducted by DG SANTE and for the opportunity to have this focused discussion.

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

Annex – EBA position papers on the key topics regarding the evaluation of EU Blood Directives

- **EBA Fact sheet on Voluntary Non-Remunerated Donors**
  https://europeanbloodalliance.eu/wp-content/uploads/2016/12/EBA_Pos_Paper-VNRD-1.pdf

- **EBA fact sheet on European self-sufficiency for blood components and plasma for fractionation**
  https://europeanbloodalliance.eu/wp-content/uploads/2016/11/EBA_Pos_Paper-EU_self_sufficiency-1.pdf

- **EBA fact sheet on Blood Donor Selection**
  https://europeanbloodalliance.eu/wp-content/uploads/2016/11/EBA_Pos_Paper-Donor_selection-1.pdf

- **EBA Fact Sheet on establishing a formal relationship between the European Directives on blood and blood components and the Council of Europe Guide**
  https://europeanbloodalliance.eu/wp-content/uploads/2016/11/EBA_Pos_Paper-CoE_guide.pdf