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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

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**Meeting between the European Hematology
Association (EHA)
and
DG SANTE B4
9 November 2016
Summary Minutes**

The European Hematology Association ("EHA") had requested a meeting with DG SANTE to discuss their position paper on the application of the EU legislation on blood and blood components and in this context inquire about possibilities to participate in current and future discussions regarding the application of the EU blood legislation and receive information on its envisaged evaluation.

Following an introduction of the participants, EHA gave a short presentation about the Association and its work. They explained that EHA is a non-governmental and not-for-profit membership organisation that promotes excellence in patient care, research and education in European haematology. The EHA represents the interest of the discipline, its clinicians and scientists in Europe and advocates for *inter alia* the harmonisation of the haematologist's education/qualification. The association is based in The Hague and their members are individual scientific researchers or physicians. Although their work primarily focuses on haematology and transfusion there is also a certain overlap with the field of tissues and cells, particularly in relation to the collection and transplantation of haematopoietic stem cells. EHA organises congresses annually (attended by around 10,000 delegates) and runs educational programmes among other initiatives. EHA is involved in several European projects such as the PROFILE project.

During the meeting, EHA elaborated on their Position Paper on the application of the EU legislation on blood and blood components, expressing interest in a sustainable cooperation with the EC and the National Competent Authorities (NCAs) in order to address legislative gaps and shortcomings of the EU legislation on blood and blood components.

Since several issues addressed in the European Commission's report on the implementation of the EU blood legislation have an impact on the daily work of haematologists (such as the notification of serious adverse events and reactions; shortages and self-sufficiency; donor screening, donor testing and inactivation technologies) the Association considers that it could provide valuable input based on its members expertise.

The manner of possible cooperation proposed included structured interactions with the European Commission and NCAs as well as participation in Public Health Programme Joint

Actions (they noted in particular their interest in the joint action on 'Authorisation of preparation processes in blood and tissues and cells').

DG SANTE B4 briefly presented its work in the field of blood and blood components, focusing on the legislation and its implementation. The latter is supported by the Public Health Program, meetings with NCAs every 8 months and the publication of summary reports on serious adverse reactions and events, on rapid alerts, on the implementation of the principle of voluntary and unpaid donation and other topics. It also described close collaboration with ECDC, Council of Europe and European Medicines Agency among others.

SANTE B4 pointed out that it is currently planning an evaluation of the Union legislation on blood, tissues and cells and that this exercise will address whether the legislation has achieved its original objectives and is still fit for purpose more than ten years since its adoption. This exercise will involve considerable consultation with stakeholders. EHA was encouraged to participate in this process.

Furthermore, DG SANTE, unit B4 informed the EHA about the first ad-hoc stakeholder meeting with NCAs and SANTE B4 taking place on 2 December 2016¹, immediately following the regular NCA meeting of 1-2 December 2016. The call for expression of interest was already launched as an open with no application deadline. EHA as any other interested stakeholder is invited to submit their application and propose specific topics for discussion at one of these meetings. When appropriate, accepted stakeholders will be invited to the meetings concerning the respective agenda topics. EHA expressed its interest in participating and proposing topics.

In addition, DG SANTE explained that EHA could possibly make a contribution to the work of VISTART WP5a and provide support (sending experts) in the context of EU cooperation with applicant, candidate and European Neighbourhood countries on request. EHA expressed their willingness to possibly support these activities.

In summary, the parties agreed that due to the EHA's expertise in the field of blood and blood components a cooperation at EU level would be of added value in many areas.

¹ http://ec.europa.eu/health/blood_tissues_organs/consultations/call_adhocstakeholdermeeting_en.htm