EUROPEAN HEMATOLOGY ASSOCIATION

SEPTEMBER 2016

Position Paper

Application of EU legislation on human blood and blood components

EU legislation on human blood and blood components[1] sets out important standards to guarantee the safety and quality of blood and its products. In a recent report[2], the European Commission highlighted the progress made possible by the implementation of such legal framework. But it also pointed out gaps and difficulties which should be addressed to ensure a high level of health protection.

Patient safety is of utmost importance for hematologists. Therefore, the European Hematology Association (EHA) would like to constructively support the European Commission and Competent Authorities on Blood and Blood Components in tackling still existing challenges related to the application of the current rules.

To make this possible, EHA calls upon EU authorities to involve hematologists in:

1. Structured interaction with the European Commission and Competent Authorities
2. Forthcoming Joint Action on "Authorisation of preparation processes in blood and tissues and cells"

[1] Directive 2002/98/EC and the relevant implementing Directives 2004/33/EC, 2005/61/EC and 2005/62/EC
[2] COM (2016) 224 final

1. Structured interaction with the European Commission and Competent Authorities

During the meeting of the Competent Authorities on Blood and Blood Components held on November 11-12, 2015, the European Commission mentioned the possibility to organize meetings with stakeholders to benefit from mutual exchange of information and good practices in this area.

EHA welcomes the Commission's suggestion and believes that hematologists – who prescribe almost half of blood products and all products for chronically transfused patients suffering adverse events – should be part of these discussions. There are indeed several issues addressed in the Commission's report on the implementation of the EU blood legislation, which have an impact on the daily work of hematologists and which would benefit from their perspective, such as:

Notification of serious adverse reactions and events (SARE)
Root cause analysis helps understand reasons behind SARE. Members States reported interest in further developing this approach and address the challenge of involving local professionals in these analyses. Hematologists' input can be of great value for the further definition and implementation of such a system but also in facilitating the involvement of professionals in this process.

Shortages and self-sufficiency
Good practices in patient blood management can contribute to significantly reduce blood demand for many treatments. Being at the forefront of hematology research into new therapies and treatments, hematologists can provide valuable input not only based on their clinical expertise but also on their role in implementing and disseminating such good practices.

Donor screening, donor testing and inactivation technologies
Member States expressed interest in an increased level of donor protection and highlighted the need to reflect on several issues related to deferral, testing and pathogen inactivation policies, which are relevant for the daily work of hematologists.

> EHA calls upon the European Commission and Competent Authorities to initiate a structured involvement of hematologists in current and future discussions regarding the application of EU legislation on human blood and blood components.

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2. Forthcoming Joint Action on "Authorisation of preparation processes in blood and tissues and cells"

EHA recognizes the efforts undertaken by the European Commission to support Member States in the implementation of the Blood Directives' requirements. In particular, EHA is pleased to see that a Joint Action on "*Authorisation of preparation processes in blood and tissues and cells*" will be financed under the Work Programme 2016 of the EU Health Programme.

Innovations in the preparation processes might lead to changes in the clinical outcomes for patients who benefit from transfusion. EHA strongly believes that important arguments can be contributed by hematologists, and is eager to provide input to the preparation and execution of the Joint Action. In addition, EHA can also provide a platform to disseminate its outcomes.

> EHA calls upon the European Commission and Competent Authorities to involve hematologists in the preparation and implementation of the Joint Action on "Authorisation of preparation processes in blood and tissues and cells".

About EHA

EHA is a not-for-profit membership organization that promotes excellence in patient care, research and education in hematology. EHA's Annual Congress is attended by some 10,000 delegates. The association also publishes Haematologica, Europe's primary hematology journal. Being the leading hematology organization in Europe, EHA represents the interests of the discipline, its clinicians and its scientists in Europe.

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