EU Blood Directive: What Are the Latest Developments?

BY BRUNO SANTONI, PPTA EXECUTIVE DIRECTOR, EUROPE

Several activities are taking place within the context of the current Blood Directive 2002/98/EC and its potential revision. Indeed several stakeholders, including PPTA, are engaged in the reflection around the current functioning of the directive. This column provides an overview of the most recent developments.

It was on Jan. 21, 2016 that a delegation from the European Commission (EC) visited the Biotest AG manufacturing site in Dreieich, Germany and a CSL Plasma collection center in Frankfurt, Germany. The meeting was organized by PPTA in order to provide an opportunity for the EC to see the functioning and organization of our sector. Throughout the day, companies showcased their operations and sites and presented the challenges they face within the current regulation. A key point that was addressed was the need to develop an environment that fosters more plasmapheresis in the EU so that increasing clinical need can be met. All participants of the meeting expressed their great satisfaction with the information exchange that was made available. The reports of the meeting are published by the EC on their website. Indeed, as part of their transparency goal, the EC is now publishing reports of meetings they hold with stakeholders. This is a useful source of information that allows the industry to follow the positions expressed by the different stakeholders to the EC. It’s important, though, to note that at this stage there is no formal consultation process by the EC regarding the Blood Directive. A full process of evaluation of the existing legal framework is likely to start before the end of the year. This will include public and targeted consultations and PPTA will, of course, be part of the interactions and dialogue.

PPTA is also advocating to be invited as a stakeholder at one of the next National Competent Authorities meetings that the EC (DG SANTE B4) is organizing with blood sector representatives of EU countries. Being at this meeting would allow PPTA to present and discuss key aspects of the sector directly with national representatives who are best informed on the specific needs of their country.
From what we observe, there is an increased understanding by several key players that the EU needs to differently build its future related to blood and plasma if it wants to stay at the forefront of scientific and societal developments.

It is also important to note that on April 26, 2016 the EC published their report on the implementation of the Blood Directive in the EU countries and also the results of their survey on voluntary and unpaid donation practices vis-à-vis donors. Although not all practices were identified, this third report is of great value as it describes more completely than in previous reports the different practices and compensation systems that are in place by countries in order to collect blood and blood components, including plasma.

Another development is the July 25, 2016 publication in the Official Journal of the European Union of COMMISSION DIRECTIVE (EU) 2016/1214, which amends Directive 2005/62/EC regarding quality system standards and specifications for blood establishments. It establishes that Member States shall ensure there are good practice guidelines available to and used by all blood establishments, which include detailed principles and guidelines for good manufacturing practices. In doing so, Member States shall take into account the Good Practice Guidelines jointly developed by the Commission and the European Directorate for the Quality of Medicines (EDQM) and Healthcare of the Council of Europe and published by the Council of Europe. The Member States have until Feb. 15, 2018 to implement these requirements.

In parallel, PPTA and the European Plasma Alliance (EPA) have been invited by EDQM to participate in their meeting of the TS093 Extended Plasma Supply Management Working Group on Sept. 20, 2016. The meeting will address topics such as self-sufficiency, safe and sustainable plasmapheresis, frequency of donation, and plasma master file. PPTA and EPA are strongly engaged in preparing the meeting and interacting with the TS093 group so that a constructive dialogue is developed for the questions that will be raised.

The current situation with regard to the Blood Directive is very dynamic. From what we observe, there is an increased understanding by several key players that the EU needs to differently build its future related to blood and plasma if it wants to stay at the forefront of scientific and societal developments. We will keep on reporting major advances related to this topic in The Source magazine.

References:
1 http://ec.europa.eu/health/blood.tissues.organs/events/index_en.htm
4 Good Practice Guidelines, included in the Guide to the preparation, use and quality assurance of blood components, Appendix to Recommendation No. R (95) 15 of the Committee of Ministers on the preparation, use and quality assurance of blood components adopted on October 12, 1995.