



# EU Blood Directive: What's Coming Next?

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The EU Commission has officially launched a full evaluation of the functioning of the EU Blood Directive by publishing its roadmap on the different steps that will take place until end of 2018.<sup>1</sup>

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**A**lso, the recent work of the Council of Europe's Committee on Bioethics (DH-BIO) regarding blood and plasma donor compensation gives rise to strong concerns and has the potential to negatively impact patient access to plasma protein therapeutics.

## EU BLOOD DIRECTIVE REVIEW PROCESS

In January, the EU Commission published the roadmap for evaluating the functioning of the Blood Directive and the Tissue and Cells Directive. On May 29, 2017, the EU Commission started a Consultation on the Blood Directive to targeted stakeholders, which ran until Aug. 31, 2017.<sup>2</sup> The targeted consultation, which is addressed to administrations, associations, and other organizations, is operated via an online questionnaire and is structured in 12 sections, of which seven sections (on blood and blood components) are relevant to the plasma-derived medicines industry. The questions address a variety of complex problems that the Commission identified in connection with the Blood Directive. This includes questions on coherence between the "Mother" Blood Directive 2002/98/EC and its "Daughter" Directives, as well as between these Directives and other EU legislation, such as the "Pharma Code" 2001/83/EC, or the EU legislation on communicable diseases. The Commission even asks for a consistency check with third (non-EU) country regulations.

PPTA will actively participate in this consultation process and is fully prepared; a set of recommendations has been prepared with extensive members' consultation throughout the past two years.

The EU Commission plans to organize a stakeholder event on Sept. 20 in Brussels with the objective to present and discuss the findings of the Consultation; 250 participants maximum will be allowed. PPTA is an invited stakeholder.

Furthermore, the EU Commission has appointed an external contractor, ICF Consulting, to prepare a study that supports the evaluation. This study will be based on the documents and reports provided, the relevant published literature, documents developed by other bodies (e.g., the EU Parliament, the Council of Europe, and the World Health Organization), and the results of the Consultation. Where information gaps remain, the contractor will explore additional sources of information. The evaluation work of the EU Commission will last until Q4 2018.

### EU COMMISSION STAKEHOLDER MEETING WITH NATIONAL COMPETENT AUTHORITIES

In parallel to this evaluation, the EU Commission has reviewed its process to select and approve stakeholders who can provide input at sessions held in conjunction with the National Competent Authorities meetings.<sup>3</sup> PPTA submitted its application in this process and was accepted by the Commission to be part of the stakeholder list.

Hence, on June 22, PPTA had the opportunity to present to all stakeholders data on donor health and perspectives on the availability of plasma-derived medicinal products in the EU as per request of the EU Commission. The increasing clinical need was highlighted with particular attention on the difficulty in the EU to collect sufficient plasma due to the current legislative framework. PPTA also highlighted the need to improve EU regulation consistency with regards to compensation for the time and efforts of donors.

Of note, the new head of Commission's DG Health B4 Unit "Substances of Human Origin" is Anna Eva Ampelas. Ampelas was previously head of the B2 Unit "Tobacco Control" and replaced Dominik Schnichels, who left for other important functions within the Commission.

### COUNCIL OF EUROPE/DH-BIO AND DONOR COMPENSATION ETHICS

In parallel to this, the Council of Europe (CoE) is currently working on providing further guidance on ethical aspects related to the donation of organs, blood and tissue, and cells.

The CoE mandated DH-BIO start working on "Guiding elements for the interpretation of Article 21 (Principle of

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the Prohibition of Financial Gain with respect to the human body and its parts from living or deceased donors) of the CoE Oviedo 1999 Convention on Human Rights and Biomedicine."

The CoE/DH-BIO structure does not foresee a public consultation of stakeholders in this respect. Requests by a variety of stakeholders, including patient organizations and PPTA, to consult were declined.

PPTA has been made aware of the current DH-BIO debates regarding the content of the "Guiding Elements" document and is deeply concerned about ongoing developments, as the current concept paper does not differentiate between substances of human origin and would cause major access issues that could have unintended consequences to patient access. We hope that the DH-BIO will recognize the impact of plasma donations for saving and improving patients' lives when considering the ethical matters of compensation. So far this has not always been considered in the discussions.

PPTA makes every effort possible to inform the 47 country representatives involved in this DH-BIO group of the specifics of our sector. Indeed most of these participants are not familiar with our sector and need to be educated before potentially damaging recommendations are published.

PPTA thus calls upon the policymakers in the CoE/DH-BIO Member States to adopt a well-balanced paper that duly takes into account the needs of the patients who rely on plasma-derived medicinal products; allows both the private and public sector to operate; and acknowledges a modern, ethical approach with regards to donor compensation for time, travel, and inconveniences. ●

#### References:

1. [https://ec.europa.eu/health/blood\\_tissues\\_organs/policy/evaluation\\_en](https://ec.europa.eu/health/blood_tissues_organs/policy/evaluation_en).
2. [https://ec.europa.eu/health/blood\\_tissues\\_organs/consultations/implementation\\_legislation\\_en](https://ec.europa.eu/health/blood_tissues_organs/consultations/implementation_legislation_en).
3. [https://ec.europa.eu/health/sites/health/files/blood\\_tissues\\_organs/docs/2016\\_call\\_ls\\_en.pdf](https://ec.europa.eu/health/sites/health/files/blood_tissues_organs/docs/2016_call_ls_en.pdf).