Current Developments: EU Blood Directive

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The European Commission has been assessing the EU's Blood Directive of 2002 since 2013 with the objectives of understanding the complexities of the sector, evaluating how the Directive functions, and, depending on the outcome, possibly starting the legislative process for the revision of this key legal act. Where do we stand today? What is the outlook?

WHERE DO WE STAND?

Overview: The Blood Directive is currently undergoing an evaluation process, in which PPTA actively participates as one of the EU Commission's recognized and trusted stakeholders. The evaluation process is in line with the Commission's Better Regulation Package and aims to assess whether the legislation has achieved its original objectives and whether or not it is still fit for purpose. The evaluation started in 2017 with a road map and continued with a comprehensive EU public consultation as well as a stakeholder event organized by the EU Commission. ICF Consulting Services Ltd. (ICF) has been tasked with conducting an independent study, for which a report was due Summer 2018. The evaluation process is expected to conclude later this year with the publication of the Commission's final evaluation report, which will be based on information gathered from these various sources.Key findings from the EU public consultation published by the Commission include (among others):

- "Inadequate and/or unclear key definitions in the Blood Directive."
- "Legislation not up-to-date with scientific, technological, epidemiological, or societal developments and process of updating not flexible or quick enough to adapt to them."
- "Absence of any provisions for ensuring sufficiency of supply, highlighted particularly by patient groups that see lack of access as key risk to patients."

Such findings show the stakeholders' dissatisfaction with the functioning of the Blood Directive and indicates the need for revision.

THE ICF STUDY

At the time of publication, the results of this independent study had not yet been published, but preliminary findings were presented to a validation focus group where PPTA participated. The final ICF study will produce an evidence base that enables the Commission to complete its own final evaluation relating to directive 2002/98/EC and the associated implementing directives, referred to collectively as "blood legislation." The ICF study findings are addressed in five evaluation criteria: relevance, effectiveness, efficiency, coherence, and EU added value. Below are the summarized main study findings:

- Blood legislation does "not take sufficiently into account the differences between blood and blood components and plasma for fractionation."
- It also does not clearly define: **Compensation** in relation to the VUD (voluntary and unpaid donation) principle" and leaves unclear the scope of the term "**self-sufficiency**."
- Blood legislation is "not adequately adapted to changes and developments, and therefore is unable to meet current regulatory needs." The legislation is "inflexible, especially regarding the consideration of detailed technological requirements, and there is a lack of inclusion of scientific and technological advancements, which can help increase safety and quality."
- European Directorate for the Quality of Medicines guidelines are considered to be relevant because they are updated biannually, but "some stakeholder[s] feel that they should be created and implemented in a transparent way."
- EU blood legislation is "not sufficiently adaptable to keep pace with clinical demand and practice, commercialisation, and internationalisation developments in the sector."
- The directive's "lack of emergency preparedness plans" is highlighted.
- It is stressed that "more should be done to encourage plasma collection in the EU, in particular by the EU Member States (MSs)", which might be "achieved through an adaptation of the VUD principles or through other measures like a strategic plan for collection capacity."
- Finally, the summary findings conclude that the EU blood legislation has "added value to the regulation of blood across MSs by setting up common standards for safety and quality, and even helped to facilitate the development of comprehensive legislative framework for the first time for several MSs"; however, "a more uniform

interpretation is needed at a national level across the EU to help increase harmonisation and facilitate mutual recognition of procedures, tests, and products."

- These findings again stress that the current blood legislation has merit but also addresses important shortcomings that would justify the need to revise this outdated legislation.

It confirms PPTA's opinion that the Blood Directive is not adapted to scientific and technological regulatory advancements, and it neither addresses a crisis preparedness plan element nor does it keep pace with clinical demand. Thus, the directive needs to be revised.

OUTLOOK

PPTA eagerly awaits the publication of the EU Commission's official evaluation report, which will be available by the end of 2018. It is understood that this report will focus on the evaluation outcome and will not contain any explicit recommendations for further handling of the EU blood legislation. Therefore, any possible revision of the blood legislation will not be started before the European Parliament elections in May 2019. The identification of next steps and the possible start of a legislative process regarding the revision of the EU Blood Directive will be reserved for the new European Commission elected in Fall 2019.

Until then, PPTA will continue advocating for a directive revision. Conceptually, there seem to be three possibilities for a revision:

1. Full revision of the EU "Mother" Directive 2002/98/EC with a new structure and new content; or
2. Recasting of the "Mother" Directive 2002/98/EC, keeping the structure but changing the content; or,
3. Amending only the secondary EU Blood Directive legislation, the "Daughter Directives," with focus solely on regulatory and quality requirements.

There are several signals for openness regarding a potential revision of the directive. These signals come from leading members of the European Parliament and also from the current EU Health Commissioner, Mr. Vytenis Andriukaitis. On World Blood Donor Day, held June 14, 2018, Mr. Andriukaitis published a statement that alludes to potential directive revisions, by stating the following: "The European Commission is currently carrying out the first formal evaluation of the blood legislation since its adoption in 2002. As there have been many scientific, societal, and epidemiological changes since 2002, I believe that our citizens deserve to benefit from the latest developments in health and safety." •