

Your Voice In Europe: ROADMAP feedback for Evaluation of Union legislation on blood, tissues and cells

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Feedback:

As a company engaged in unlocking the potential of blood and active in blood component, therapeutic apheresis and cellular technologies, we very much welcome the publication of this roadmap and the opportunity to participate in this evaluation exercise.

We agree with the Commission's approach to address in one single evaluation of the EU legislation on blood, tissues and cells for efficiency reasons. This, insomuch as these two texts are looked at separately and they remain two differentiated pieces of legislation.

Secondly, we share the Commission's opinion that an evaluation of the main Directives is necessary in view of the considerable degree of scientific, technological and epidemiological developments. In this regard, we would like to highlight recitals 2 and 29 of Directive 2002/98/EC (hereinafter, the Blood Directive), which refer to the need for appropriate use of scientific process in the detection and inactivation and elimination of transfusion transmissible pathogenic agents:

"In order to safeguard public health and to prevent the transmission of infectious diseases, all precautionary measures during their collection, processing, distribution and use need to be taken making appropriate use of scientific progress in the detection and inactivation and elimination of transfusion transmissible pathogenic agents"

"Tests should be carried out in conformity with the latest scientific and technical procedures that reflect current best practice as defined by, and regularly reviewed and updated through, an appropriate expert consultation process. This review process should also take due account of scientific advances in the detection, inactivation and elimination of pathogens which can be transmitted via transfusion"

Since the adoption of the Blood Directive, various pathogens have threatened the EU recent examples being the Zika Virus, Hepatitis E – against which a number of countries have started to take measures, creating a fragmented policy in Europe-, and Hepatitis C, demonstrating that new solutions in the area of pathogen reduction are required.

Furthermore, the ECDC (whose establishment is also subsequent to the adoption of the Blood Directive) itself has undertaken actions which demonstrate the concern about certain

pathogens as a cost to public-health (e.g., Chikungunya, West Nile fever...).

The need to mitigate such risks and ensure high levels of public health protection, quality and safety standards becomes all the more important in light of the new and upcoming challenges and risks of transmitting emerging diseases, such as those related to climate change. As recognised by the ECDC ('The climatic suitability for dengue transmission in Europe', 2009, amongst other publications), climate change is expected to promote more intense and prolonged outbreaks of vector-borne disease and alter the geographic boundaries of transmission.

The time is now right to implement the Commission's provision on the now available technology for the detection, inactivation and elimination of transfusion transmissible pathogenic agents as a standard for European citizen's safety.

The automation of blood processing provides another example where Europe has seen a significant development since 2002. Nowadays, this technology does not only provide a more consistent and more efficient collection of blood while ensuring a higher quality of the blood components, additionally it facilitates the handling of collections and minimises human errors, traceability and other risks mentioned in the roadmap (e.g., cross-contamination during processing, environmental contamination).

With regards to the implementation of the Blood Directive, we share the concerns expressed in the implementation report from April 2016 ("Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the implementation of the Directives 2002/98/EC, 2004/33/EC, 2005/61/EC and 2005/62/EC setting standards of quality and safety for human blood and blood components". COM (2016) 224 final) and in previous reports, that because the Blood Directive did not provide a basis for full harmonisation, there are many differences between Member States in the approaches they have taken to implementation. We also commend the commission in the Council of Europe Good Practice Guidelines, ("For Implementing Standards and Specifications for the Quality System in Blood Establishments") and the recent amendment for the implementation of the standards and specifications set out in the Annex to Directive 2005/62/EC, its Article 2, as amended by Directive (EU) 2016/1214.

It could be argued hence that the minimum requirements approach led to a disharmonised and inconsistent level of implementation. We do understand that, back in 2002, the fact various Member States came from diverse levels of technological sophistication and resources, demanded a minimum approach. However, in view of the threats mentioned above (pathogens, climate change) and other considerations, this approach is no longer appropriate. Therefore, we strongly defend that a potential revision of the legislation should be based on maximum standards.

Having a strong and binding EU legislation would also help to address what we believe is one of the main reasons behind the lack of harmonisation: the existence of various bodies (national, international, supranational) involved in the draft of provisions on blood safety (e.g., national legislation, EU legislation, publications from the Council of Europe and WHO etc.). Only by putting in place compelling European legislation the EU will achieve a degree of harmonisation of safety and quality at Union level and will be able to adapt to scientific developments.