

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

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Related document: Evaluation of Union legislation on blood, tissues and cells

Feedback:

PPTA comments

on EU Commission roadmap for the Evaluation of Union legislation on blood, tissues and cells

PPTA welcomes the publication of the Commission's Roadmap which gives a very useful orientation on the background, direction and structure of the foreseen evaluation of related Union legislations.

PPTA submits the following comments on the Roadmap:

I. General comments

PPTA understands that the Commission intends to evaluate jointly Directives 2002/98/EC (the "Blood Directive") and Directive 2004/23/EC (the "Tissues and Cells Directive") with their respective technical Directives given "the many commonalities between the two acts" and the need for ensuring more alignment and legal consistencies.

PPTA recognizes that there are similarities between the two Directives and that a joint evaluation should create an opportunity for the EU Commission to define "voluntary and

unpaid donations” in a new Blood Directive, as the concept is already defined in the Tissues and Cells Directive. The experience and maturity of the Tissues and Cells Directive in the area of donor compensation should be used, however PPTA highlights the importance to consider the specificities and differences related to the plasma donations and patient needs of life-saving Plasma Derived Medicinal Products (PDMPs).

PPTA welcomes the usage of the terminology “voluntary AND unpaid donation” in the text of the roadmap as it should indeed replace ‘voluntary unpaid donation’ in the future legislation due to the confusion that this term creates.

PPTA considers that the voluntary and unpaid concept is related to the supply of plasma for increasing patients in needs of PDMPs to treat life-threatening conditions and that the EU Commission should propose its own definition.

Similarly to the distinction made for “Tissues” and “Cells”, a differentiation should be made between whole blood and blood components (plasma); and between transfusion medicine and blood components used for manufacturing. Also here the lesson of greater clarity of the Tissues and Cells Directive should be learned and hence applied to the Blood (and Plasma) Directive.

PPTA would thus respectfully caution against lumping together an assessment of rules that must, for the most part, be designed to accommodate the complex specifics of extremely different realities.

Consequently, it is important to ensure that the joint evaluation of the Blood Directive and the Tissues and Cells Directive is extensive and sufficiently detailed to draw the reader’s attention to the specific differences between the nature of tissues and cells, blood and blood components. Doing an unspecified joint evaluation of both Directives could result in missing to assess relevant key topics, and thus unsatisfactorily address the specificities of each type of therapy and each sector covered by the review.

II. Regarding the methodology

PPTA is recommending to prepare questionnaires and surveys that will be used during the process of the evaluation (e.g: the open public consultation) with the consultation of stakeholders. There are numerous examples in our sector where the design of the consultation led to misinterpretations and misunderstandings. This made the interpretation of the results almost impossible. We are open to provide our resources and expertise to help in this process.

Public consultations should be accompanied with educative materials so that respondents are better informed before answering.

For the public consultation, the timeline needs to be more generous. Generally

speaking, the possibility to comment more extensively on these complex areas needs to be increased.

Given the complexity of the sectors and legislations that will be evaluated, PPTA recommends the Commission to request from the study provider to justify an extensive knowledge and relevant experience regarding the sectors subject to the evaluation.

We question the Eurobarometer as a valid source of evaluation of the population acceptance for practices related to compensation for blood and plasma donations. Indeed the Eurobarometer is, to our knowledge, not providing educative information to the respondents and this creates a bias of methodology. We encourage the services preparing the Eurobarometer to use another method of evaluation for these questions (e.g: focus groups).

PPTA is interested to understand which parallel work of the Council of Europe and of the WHO specifically is being referenced here and to what extent the Commission plans to incorporate such work into Union action. We understand that the parallel work developed by the Council of Europe and the World Health Organisation can be taken into account in the evaluation process, however we encourage the EU Commission to have a critical look at their methodologies and potential biases. There is a lack of consultation with stakeholders within the policy development processes of these organizations and this contains the non-negligible potential risk to develop policies that could bring in danger the supply and access to care of essential PDMPs for patients.

PPTA¹ specific comments on EU Commission roadmap² for the Evaluation of Union legislation on blood, tissues and cells

Specific comments in the text of the roadmap

Considering wording and specific information contained in the roadmap, PPTA is suggesting adaptations and corrections in future EU Commission documents pertaining to similar topics:

Regarding A2. Justification.

Roadmap wording:

“The sector is also undergoing organisational change including the market entry of private

¹ <http://www.pptaglobal.org/>

² http://ec.europa.eu/smart-regulation/roadmaps/docs/plan_2016_154_evaluation_eu_legislation_on_blood_en.pdf

operators (commercial/for profit companies) into a traditionally non-profit oriented sector with mainly public actors.”

PPTA comments:

We recommend that an appropriate distinction is done for the plasma sector in any future consultation documents and in general since the private sector of plasma collection has been active in Europe since the early 1950s.

Regarding B1. Content and subject area of evaluation

Roadmap wording:

“In the EU, every year 20 million blood donations are handled by 1300 blood establishments, enabling around 26 million transfusions to patients.”

PPTA comments:

Every year 7,35 million liters of plasma for manufacturing of medicinal products are collected and manufactured into medicinal products for patients in need. We think this information will be useful, and should therefore be included, in the forthcoming consultation documents.

Regarding B2. Original objectives of the intervention

Roadmap wording

5. *“To achieve Union sufficiency through the encouragement of voluntary and unpaid donation and a strong public sector.”*

PPTA comments:

For the Blood Directive, it is our recollection that the EU Commission took a neutral position regarding the public or private sector related to plasma collection and PDMPs. We encourage the EU Commission to stay neutral in future work and consultation documents.

Regarding C1. Topics covered by the scope of the Evaluation

Roadmap wording:

“Aspects which fall within the competence of Member States, such asethical decisions, are not covered by this evaluation.”

PPTA comments:

PPTA is unclear about the meaning of the wording “*ethical decisions*” in this context.

In particular, PPTA would like to ensure that the scope of the Evaluation will cover the concepts of VUD and donor compensation, as it is suggested by the Roadmap's language (D.1 Evidence from monitoring: *"Commission reports on the implementation of the principle of voluntary and unpaid donation will provide key inputs into the evaluation"*).

PPTA very much supports an assessment of these concepts as these are currently interpreted in an absolutely inconsistent manner in the Member States.

Regarding C2. Issues to be examined "Effectiveness"

Roadmap wording:

Nr 7 *"To what extent, if any, has the legislation impacted on patient access to blood, tissues and cells."*

PPTA comments:

PPTA would recommend including in the future consultation documents a more explicit recognition of different types of blood products (as defined by the Blood Directive as: *"any therapeutic product derived from human blood or plasma"*) in order to highlight the fundamental differences between patient access to, on the one hand, blood and blood components for transfusion and, on the other hand, plasma for manufacturing and plasma-derived medicinal products ("PDMPs").

Regarding D. Evidence base

Roadmap wording: D.1. Evidence from Monitoring

"The Commission Reports on the implementation of the principle of voluntary and unpaid donation will provide key inputs into the evaluation".

PPTA comments:

PPTA acknowledges that the third EU Commission VUD Report on human blood and blood components reflects a significant effort to gather an overview on the VUD practices. The Report nevertheless is still incomplete, since several practices in EU Member States were not reported.