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

User's data:

- Domain : Non governmental organisation
- Name : Johan Prévot
- Email : johan@ipopi.org
- Country : United Kingdom
- Headquarter : select
- Size : select
- Publication : can be published with your personal information

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

Feedback:

The International Organisation for Primary Immunodeficiencies (IPOPI) welcomes the transparency with which the European Commission is acting with regards to the evaluation of the EU legislation on blood, tissues and cells and is willing to contribute to the evaluation by bringing in the voice of people with treatable rare plasma related disorders.

Scope of the legislation: the scope of the legislation shoudl clearly cover blood, blood components, including plasma for transfusion, and plama for manufaturing/fractionnation of the plasma-derived medicinal products (PDMPs). The used of the current terminology "bllod and blood components" should be enlarged to "blood, blood components, plasma for transfusion and plasma for manufacturing of PDMPs" to provide further clarity and consistency.

Effectiveness: The availability and contibuity of supply of blood components and PDMPs in the EU should be emphasised and the EU legislation should promote the availability of effectial and life-saving blood, blood components and PDMPs.
The EU Commission should explore options for more flexible adaptations of the technical requirements surrounding blood and plasma to mirror scientific and technical advances.

Efficiency: The revised Blood Directive should encourage Member States to implement good manufacturing practices and testing requirements in line with the European Medicines Agency Plasma Master File guidelines as a prerequisite to use such plasma for manufacturing of PDMPs.
Agreement was reached that Member States, where feasible, should be urged to develop plasmapheresis programmes. The revised Directive should ensure that efforts are made to avoid the wastage of recovered plasma.

EU Added Value: IPOPI recognises and supports the work of the EU in the field of blood and

blood components. The European Union should promote increased plasma collection to assist in meeting patients' growing medical needs for PDMPs. EU legislation has also guided national activities in this field that would have posed an obstacle to the availability and access to the widest range possible of PDMPs for patients with rare plasma related disorders.