

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

User's data:

- Domain : Organisations other than business/companies/NGOs
- Domain - other : Public, Non Profit Organisation
- Name : ██████████
- Email : ██████████
- Country : Spain
- Organisation : Banc Sang i Teixits
- Headquarter : select
- Register : Bancs7115535373
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Related document: Evaluation of Union legislation on blood, tissues and cells

Feedback:

We hereby support the roadmap proposed by CE for the evaluation of the EU blood and tissues and cells legislation, and congratulate the high level of detail and depth of the evaluation foreseen in this initiative.

In addition, we would like to reinforce the idea of safety and quality requirements from donor to recipient (B1), that translates into efficacy/effectiveness as substantial criteria inherent to Quality and Safety of SoHO, as defined in the mandate of article 152 of the Treaty. We consider that to ensure Quality and Safety, mechanisms of follow up and efficacy evaluation need to be established, and this implies the involvement not only on the donation or tissue blood or ART establishments activities, but also end users and clinicians, whit the aim of protect our recipients and the general population.

Furthermore, we consider that three additional issues could be addressed within the scope of the proposed evaluation:

- *Screening requirements, namely, serological tests validation (time frame from death to test, validation of the quality of the sample, generation of the specific test, validation for cadaveric blood, etc), need to repeat the screening in a authorized –certified laboratory when a tissue is recovered from an organ donor with a serology test validated for in-house diagnosis instead of for a bank screening.*
- *Despite knowing that the EC has no competencies related with ethical issues, we suggest to consider a strong recommendation with the aim to prevent paid donation and financial gain associated with SoHO activities, based on the argument that economical motivation may have potential impact in the quality and safety of the tissues and cells. In this point it is important to prevent any fraudulent and illegal activities (this is in the mandate of the EC), and consider including this activities as biovigilance notifications/alerts, for the reason of the potential loss of traceability and impossibility of monitoring these activities by the NCAs.*

- Harmonization of authorizations in the different Member States, as way to achieve of mutual recognition: - acceptance of a global and joint authorization/certification, performed by inspectors/NCAs officers and technical experts; - clear definition of the roles and responsibilities of “tissue brokers”, that are currently authorized as Tissue Establishments by some Member States (just for import and distribution activities), but freely circulate products within EU.