

POSITION STATEMENT on EC PUBLIC CONSULTATION on blood, tissues and cells for medical treatments and therapies

Significant scientific and technological developments in the blood, tissue and cell (BTC) sector enable improved or novel processing and testing protocols, and novel and innovative applications of BTC. Such advancements, however, may pose a quality and safety risk and have a direct or indirect impact on the clinical outcome of the recipients, into which BTC are transfused, transferred, injected, grafted or implanted^{1, 2}.

Considering the widespread use of SOHO in new developed therapies and the need to call for a legislation able to cover borderline competences, the revised EU BTC Directives revision opens a possibility to fill a regulatory gap.

The latest discussion at the level of BTC Competent Authorities (CAs) meeting highlighted the following attitude:

- Member States (MS) welcome the creation of a EU list of national inspectors with specialized/senior expertise that could be invited to join or support national inspection systems,
- There is a large shared view on the need to have an upfront risk-assessment as starting point to assess and authorize novel BTC preparation and the need to collect clinical outcome data,
- Some MS welcome the proposal to have a EU-level exchange tools to optimize the use of BTC amongst MS.

The GAPP Joint Action aims at providing the EU Competent authorities in the field of blood, tissue, cells and reproductive tissues and cells with tools for the authorization of new procedures for preparation processes at Blood and Tissue Establishments (BTEs), and to support both harmonization and innovation in this field. Taking into account the relevance of the adoption of a new legislation for the BTC CAs and its impact on the preparation process authorization, the GAPP consortium would take the opportunity to promote its own view for further consideration.

1. GAPP consortium believes that the new BTC Directive should address the aspects of technological innovation and its regulatory framework;
2. BTC CAs should have the mandate to be informed about any innovation related to BTC products to perform the preparation process authorization (PPA);
3. CAs should have access to the information related to the evaluation of clinical assessment and follow-up of clinical outcome, to support CA evaluation and PPA to ensure BTC safety and efficacy;
4. Clarity and transparency across regulatory borderlines regarding e.g. testing laboratories, infectious disease test kits and sterilisation³ should be achieved;

¹ VISTART [676969]; Vigilance and Inspection for the Safety of Transfusion, A. R. and T.: Deliverable 5.2 - Principles for Competent Authorities for the evaluation and approval of Clinical Follow Up Protocols for Blood, Tissues and Cells prepared with newly developed and validated processing methods. 1– 32 (2018).
https://webgate.ec.europa.eu/chafea_pdb/health/projects/676969/outputs (last access 09/03/2021)

² Study supporting the evaluation of the EU legislation on blood and tissues and cells. Directorate General for Health and Food Safety. (2018). https://ec.europa.eu/health/blood_tissues_organs/policy/evaluation_en (last access 09/03/2021)

³ https://www.gapp-ja.eu/wp-content/uploads/2021/03/D7.1_Ref.-Ares2021_1371683_19022021.pdf (last access 09/03/2021)

5. Requirements to collect and evaluate the clinical outcome data should be also included⁴;
6. The dynamic adaptation of the BTC Directives to rapid technological innovation should be granted through the use of continuously updated Technical Guides for the quality and safety of blood and tissues and cells;
7. EC should consider the possibility to establish a new Advisory Board in charge of supporting the CAs in the evaluation of new BTC products that could work together with already established working groups falling under other EU directives (e.g. IVD, medical devices, ATMP/medicinal products).

The GAPP consortium

⁴ https://www.gapp-ja.eu/wp-content/uploads/2020/10/D8.3_Ref.-Ares_2020_4146352_06082020.pdf (last access 09/03/2021)