

Breadcrumb

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Entity Print

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Jürgen Küball
Chair, Legal & Regulatory Affairs Committee
Netherlands



Eoin McGrath
JACIE Operations Manager
Spain



Sofie Terwel
GoCART project lead
Netherlands

Representing the views of the cellular therapy community in Europe

Following several years of engaging with regulators and other stakeholders, EBMT is recognised as the reference organisation for expert input on HSCT and cellular therapy at EU level as well as being the most significant registry holder in this area in the EU. It is expected that 2022 will be an important year when a legislative proposal for the revised EU Tissues and Cells Directives will emerge.

EBMT contributed to two consultations from the European Commission in 2021. The first one was on the **Revision of the EU legislation on blood, tissues and cells** (BTC). EBMT experts Nina Worel, Boris Calmels and Per Ljungman contributed to the targeted consultation that was open to organisations (not individuals) that are directly involved in or impacted by the fields concerned and are familiar with the current legislation and its implementation. As part of the GoCART Coalition, EBMT contributed to the public consultation.

In follow up to the public consultations, DG Santé organised 8 online workshops during May and June in which EBMT representatives participated. These workshops focused among others on the authorization of novel BTC, technical rules for BTC protection of donors, ethical principles of voluntary unpaid donation, and borderlines with other regulated frameworks, such as advanced therapy medicinal products.

EBMT is also a partner in the Common Representation on Substances of Human Origins (SoHO) (CoRe SoHO) along with the European Eye Bank Association, the European Blood Alliance and the European Association of Tissues Banks. CoRe SoHO was invited to meet with the Deputy Director General of DG Santé to discuss the interests and needs of our work field. Dr. Julio Delgado presented the Barcelona CAR-T story as an example of a successful public or academic initiative facilitating patient access to advanced therapies. This meeting was followed up by a workshop on 27 October, to discuss the proposed SoHO-X platform, an EU project in its inception phase to develop the digital infrastructure to support the regulatory framework for BTC.

The public and targeted consultations and workshops will lead to a proposal for legislation that is expected early in 2022. EBMT will monitor the progress of the revision of the Blood, Tissue and Cell Directives next year and make every effort to ensure that the professionals' perspective is taken into account.

The second consultation from the European Commission that EBMT participated in concerned the **European Health Data Space** (EHDS). The survey focused on the use of health data for healthcare provision, research and innovation as well as policy-making and regulatory decision making; the development and use of digital health services and products; and the development and use of Artificial Intelligence systems in healthcare. This consultation was also followed up by an interactive workshop in which EBMT representatives participated to understand more about the infrastructure and ecosystem of the EHDS.

EBMT has also been invited to two meetings with the **Network of Competent Authorities on Pricing and Reimbursement**. The first meeting on 16 April focused evidence generation and exchange along the lifecycle of medicinal products. The second workshop focuses on the implementation of the drafted minimal data set requirements for pricing and reimbursement purposes. EBMT representatives joined this meeting to highlight what data is already captured by EBMT and how this could be made accessible for payers. Provided that patients'

consent to data sharing and applicable data protection measures are in place, EBMT supports these interactions with payers and reimbursement agencies to avoid duplication of data collection by centres.

Another initiative in the field of Health Technology Assessment (HTA) bodies and payers is **RWE4Decisions**. In 2021 EBMT participated in various workshops focussing on real-world evidence for decision making: meeting regulatory and HTA/Payer needs.

Influencing guidance on best practice

EBMT contributed to the EU GAPP Joint Action which will facilitate the development of a common and optimal approach to assess and authorize novel preparation processes in blood and tissues establishments excluding ATMP. WP6 is developing a Technical Annex offering overall guidance for regulators on authorisation of changes in donation, procurement and collection, processing, preservation, storage and distribution processes of different substances including HSC. WP8 will produce guidance to assessing clinical data which again is relevant to registry holders.

Other

Prof. Dr. Nina Worel is representing EBMT in drafting the next EDQM *Guide to the quality and safety of tissues and cells for human application*, currently in its 4th edition.

EBMT is registered in the EU Transparency Registry under identification number 652992023103-09. See http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=65299202 09 for full details.

EBMT is also a partner in the Common representation of Substances of Human Origin's (SoHO) (CoRe SoHO). Full details from the Transparency Register can be found at http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=50165272 72.