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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 a being the most significant registry holder in this area in the EU. It is expected that 2021 will be an important year when a legislative proposal for the revised EU Tissues and Cells Directives will emerge and other regulatory initiatives around cellular therapies and healthcare data will be launched.

Jürgen Küball
Chair, Legal & Regulatory Affairs Committee
Netherlands

Eoin McGrath
JACIE Operations Manager
Spain

Representing the views of the cellular therapy community in Europe

EBMT contributed to two EMA consultations during 2020. The first was on **secondary use of data for regulatory purposes** and EBMT representatives attended the virtual workshop on 29 September. The second consultation was on the **draft guideline on registry-based studies** with EBMT invited to give the registry-holder perspective at the virtual workshop on 19 October. Both are very relevant to EBMT as a registry-holder particularly with regard to collaborations with industry on Post Authorisation Safety Studies (PASS). Policy and practice are still under development and all initiatives that help clarify and harmonise practices are warmly welcomed.

The EU Commission launched the first part of the review of the Tissues and Cells Directives with an Inception Impact Assessment in November 2020. EBMT was among the 82 responses submitted by different stakeholders. A further public consultation is expected to open early in 2021 all leading to a **proposal for legislation** in late 2021. EBMT will monitor the progress of the review in 2021 and ensure that the professionals' perspective is taken into account.

EBMT Registry, data and interactions with new stakeholders

Following the successful outcome to the EMA qualification process in 2019, EBMT engaged with the EUnetHTA Joint Action to qualify the registry for Health Technology Assessment (HTA measures the added value of a new health technology compared to existing ones. Examples of health technologies include medicinal products, medical equipment, diagnostic and treatment methods, rehabilitation, and prevention methods - More information here). A meeting of the EBMT and the EUnetHTA consortium took place in Paris on 7 February. Unfortunately the process suffered significant delays in 2020 due to the pandemic and is expected to conclude in the first quarter of 2021. The EUnetHTA registry qualification process featured as a workshop at the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) virtual meeting on 20 May.

The registry was also highlighted during a symposium entitled *Is Europe ready to define quality standards for RWD sources?* at the DIA virtual meeting on 1 July.

The Innovative Partnership for Action Against Cancer (IPAAC) Joint Action invited EBMT to present on the use of the registry for novel cellular therapies in Ljubljana, Slovenia on 25 February. IPAAC also performed a survey during 2020 of real-life monitoring of innovative immunotherapies with a focus on patients treated with CAR-T cells which included references to the EBMT registry. Results are expected later in 2021.

Influencing guidance on best practice

EBMT continues as a contributor to the EU GAPP Joint Action which will facilitate the development of a common and optimal approach to assess and authorize preparation processes in blood and tissues establishments. 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. WP8 will produce guidance to assessing clinical data which again is relevant to registry holders. EBMT was represented at the GAPP meeting in Brussels on 5 February.

On 7 October 2020, the Council of Europe issued Recommendation CM/Rec(2020)61 of the Committee of Ministers to member States on establishing harmonised measures for the protection of haematopoietic progenitor **cell donors**. The document recommends that governments to establish harmonised haematopoietic progenitor cell donor protection measures, which should be identical irrespective of the type of donor (related or unrelated, adult or minor). The document can be accessed at https://rm.coe.int/09000016809fdd5b.

Prof. Nina Worel alongside other colleagues from the tissues sector was instrumental in achieving this decision.

On the same date, Recommendation CM/Rec(2020)5 on the quality and safety of tissues and cells for human application was also issued. It recommends that member States take all necessary measures and steps to ensure that quality and safety standards for the donation, preparation and clinical application of tissues and cells are carried out in accordance with the *Guide to the quality and safety of tissues and cells for human application*.

https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=09000016809fdcde

Other

Prof. Dr. Nina Worel is representing EBMT in drafting the EDQM *Guide to the quality and safety of tissues and cells for human application*, now 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) along with the European Eye Bank Association, the European Blood Alliance and the European Association of Tissues Banks. Full details from the Transparency Register can be found at http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=50165272 72.