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Chair, Legal & Regulatory Affairs Committee
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Main activities in 2022

Much of the work of the Committee in 2022 focussed on the **EU proposal for a regulation on Substances of Human Origin (SoHO)**. This draft regulation is of fundamental importance for everyone working within the SoHO field and the EBMT has been engaging with stakeholders and regulators to ensure that the interests of the EBMT members are represented.

The EBMT published its response to the proposal in September 2022. EBMT welcomed the proposal, which was published on 14th July. The key points the EBMT identified as particularly important were the introduction of the joint regulation approach promoting harmonisation across the Member States as well as the principles of voluntary unpaid donations and donor protection measures. We highlighted the importance of ensuring the Serious Adverse Occurrences are registered, but only, if those are unexpected and may be attributed to the SoHO activity. These issues were also discussed in a meeting with DG Sante attended by Prof Chabannon, Sofie Terwel and Tuula Rintala. The full statement is available here.

EBMT also collaborated with the **CoRe SoHO consortium**, the World Marrow Donor Association, National Marrow Donor Program/Be The Match and ICCBBA on joint statements highlighting issues important to our community.

EBMT has continued to work in partnership in the Common Representation on Substances of Human Origins (CoRe SoHO) along with the European Eye Bank Association, the European Blood Alliance and the European Association of Tissue Banks through regular meetings and a joint EU event is planned for Q1 in 2023 to engage with the EU Parliamentarians on the proposed SoHO regulation. EBMT will continue the efforts to ensure that the professionals' perspective is included during the revision and consultation period.

Following the EU consultation concerning the **European Health Data Space** (EHDS) 2021, EBMT has continued to meet with colleagues from World Marrow Donor Association and European Cystic Fibrosis Society to further understand the challenges for the Registry holders such as the EBMT.

As part of developing an Advocacy policy for the EBMT there was also a **revision of the Terms of Reference (ToR) of the Legal and Regulatory Committee**, which

was presented to the EBMT Board in October 2022. As part of the process there were meetings with Advocacy leads from European Haematology Association (EHA), Anthony Nolan Trust, European Association for the Study of Liver and Lymphoma Coalition. The new ToR further commits the organisation to develop an active advocacy role at the European level. The Board also approved a new Legal and Regulatory Affairs Coordinator position to support the Committee and this strategic objective. The key objectives for the Committee are:

1. Define a policy and advocacy strategy for EBMT
2. Track EU legislative proposals and report to EBMT board and membership
3. Advocate EBMT and her members' interests
4. Build relationships with regulators, policy makers and partner organisations to achieve objective 2 and 3

Other:

Prof Dr Nina Worel continues to represent EBMT in drafting the next **EDQM Guide** to the Quality and safety of tissues and cells for human application currently in its 4th edition.

LRAC continues to actively participate in the Policy and Advocacy work package of the **GoCART coalition** to increase interaction with multiple different stakeholders.

EBMT is registered in the EU Transparency Registry under identification number 652992023103-09. Click here 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 here.

Visit the LRAC Committee Webpage