EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate B - Health systems, medical products and innovation
B4 – Medical products: quality, safety and innovation

Meeting between the Board of the European Association of Tissue Banks and DG SANTE B4

18 September 2018

Summary Minutes

Participants:

EATB: Jacinto Sanchez Ibanez, Simone Hennerbichler, Martin Boergel, Branka Golubic, Jill Davies.

DG SANTE (Unit B4 Medical products: quality, safety, innovation): S. Van der Spiegel, D. Fehily, I. Pucinskaite, R. McGeehan, A.E. Ampelas.

1. The meeting participants were welcomed and introduced. The meeting had been organised in the context of the formal evaluation of the blood, tissues and cells (BTC) legislation that is currently being undertaken by the European Commission[1]. The attendees represented the European Association of Tissue Banks (EATB). **EATB**[2] is a not-for-profit scientific association, aiming at supporting and promoting science, research and teaching in the field of tissue and cell banking and in related sciences internationally and especially in Europe. EATB has 231 members from 30 countries worldwide and is administrated with the support of a professional association management office (Vienna Medical Academy, www.medacad.org) based in Vienna. Its main tasks include:

    - organising of conferences, symposia and meetings
    - organising and promoting courses and workshops
    - establishing and presenting awards
    - supporting editorship of an international specialised journal
    - promoting scientific and technical knowledge concerning procurement, processing, storage, transplantation of tissues and cells for clinical and research purposes
    - assisting competent authorities and other regulatory bodies by the implementation of new or revised laws, guidelines and directives on a national, European and/or global level
    - establishing, updating and issuing acknowledged medical guidelines and standards in the field.

[1] https://ec.europa.eu/health/blood_tissues_organs/policy/evaluation_en
[2] www.eatb.org

2. Following the introduction of the stakeholder organisation, DG SANTE explained to the EATB representatives that the Commission is not currently working on a revision to any of the blood or tissue and cell Directives. The current initiative is limited to evaluating the existing legislation, with a view to establishing whether it achieved its original objectives and whether it is still fit for purpose. DG SANTE updated the stakeholders on progress with the evaluation. In general, the process is on schedule and the final report should be published in the first quarter of 2019. It was noted that EATB had participated in the public stakeholder event, making one of the key speaker statements, in the Open Public Consultation and in interviews and focus groups with a company contracted by the Commission to carry out a complementary study for the Evaluation. DG Santé presented the key findings of the Evaluation, to date, asking the participants to confirm whether they generally agreed or saw any gaps in the evidence gathered.

3. In general, the EATB agrees with the results published, to date, in the context of the Evaluation and they do not see major gaps in the findings so far. They wished, however, to underline a series of issues that have, for their members, the highest priority, as described in the following points.

4. They would wish to see a higher degree of harmonisation between the standards and requirements applied in Member States, in particular in relation to authorisation by Competent Authorities. Regarding authorisation, they consider that a framework for mutual recognition of authorisations between Member States would improve the distribution between them, enhancing patient access and efficiency of banks. They expressed the view that an EU agency for the sector, providing tools to support tissue exchange and mutual recognition, would enhance services to patients.

5. As an Association, they are fully committed to the principle of voluntary unpaid donation and to tissue banking services being organised as part of health services generally and, in that context, ensuring sufficiency of supply to meet demand.

6. They confirmed that for many tissues, particularly corneas, bone and heart valves, there are inadequate supplies and a consequent dependence on import, mostly from the US. The US has a surplus of bone and corneas, exporting 20,000 to 25,000 corneas a year. They noted that if clinical users purchase tissues from commercial suppliers that are importing, there is a risk that the extensive work done over many years to establish European donation programmes could be put at risk and strategies to ensure sufficiency could not be put in place. In this context, they see the partnership of clinicians and hospitals to build local and national programmes of donation and use as critical to having a sustainable supply of tissues for EU patients. They also expressed some concerns regarding the quality of some imported tissues. Some studies are ongoing that are exploring the costs of EU cornea banks to compare these with the costs of importing from outside the EU.

7. In the view of the EATB, many of the technical requirements to ensure safe tissues of high quality are outdated or too limited in the Directives. The new Good Practice Guidance and the new monographs to be published in 2019 by EDQM, as part of the Guide to the Safety and Quality of Tissues and Cells, are seen as more effective and up to date. They consider that those EDQM guidance documents should be the point of reference that is used in inspections, rather than directives that are difficult to keep updated. The EDQM documents are viewed as based on good and current scientific knowledge and as being developed in a transparent manner.

8. On the issue of oversight, they expressed concern that there is very significant discrepancy between the Member States in the way that inspections are performed and authorisations granted to tissue establishments. The EATB sees this as having a negative impact in the sector. They consider the issue to be related to very different backgrounds, levels of knowledge or experience among inspectors from different Member States. Where inspectorates have very broad sectors of responsibility, their technical knowledge is often not considered adequate for this field, where technical understanding is important. This is also relevant, in their view, for national situations where inspectorates are regional

and approaches vary between regions. In general, they see Competent Authorities as often not having enough resources, or clearly defined powers, to oversee the activities appropriately.

9. The representatives pointed to an absence of legal provisions for the authorisation of clinical users or their hospitals/clinics to receive and use human tissues for transplant. Some Member States have implemented national requirements for authorisation of centres that use human tissues or cells clinically, considering that this approach ensures quality, safety and traceability all the way to the recipient. EATB also expressed the view that obligations on clinical users in the legislation are too limited, not including requirements for providing clinical data to supplying tissue establishments on the outcomes of transplanted tissues.
10. In line with the comments expressed at a similar meeting with the Board of the European Eye Banking Association, they raised concerns regarding the EU requirement for taking blood for testing within 24 hours of donor death. They see this provision as not being evidence based and as causing a loss of tissue donations.
11. The representatives noted that many new types of substances of human origin are now used clinically but do not fall within with the scope of the existing SoHO legislation because of the way the scope is defined in the BTC directives. These substances remain un-regulated, or regulated differently in Member States, although the stakeholders consider that the BTC legislative framework would provide appropriate safety and quality assurance for patients receiving those treatments.
12. EATB also raised the issue of tissue use for research and bio-banking, noting that many donations begin as 'intended for transplantation' but in the end are unsuitable and are then used for bio-banking. In those circumstances, they consider that consent should be given specifically for any commercial use of the donated material. The exclusion from scope of 2004/23/EC of tissue that is 'not intended for human application' appears to be used as a loophole in some Member States, where the ovarian and testicular tissue stored for individuals is intended for IVF later and is therefore not regulated. The stakeholders also raised the issue of tissues used for autologous cosmetic treatment falling outside the scope and possibly not being regulated appropriately.
13. DG SANTE thanked the stakeholders for their valuable contributions to the meeting and to the BTC evaluation in general.