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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

Brussels,
SANTÉ

Meeting between representatives of ICCBBA and Eurocode and DG SANTE B4

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Summary Minutes

Participants:

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Background

The meeting was organised in the context of the ongoing Evaluation of the EU legislation on blood, tissues and cells (BTC)[1] and as part of targeted stakeholder consultation. As key stakeholders involved in supporting traceability of blood, tissues and cells, ICCBBA and Eurocode-IBLS were invited by DG Santé to discuss their views on the EU legislation in these sectors. The aim was to explore whether the current legislation adequately ensures traceability of these substances and whether there are gaps or shortcomings.

Introduction of Participants

ICCBBA[2] is an international non-governmental organization (NGO) in official relations with the World Health Organization (WHO) that manages, develops, and licenses ISBT 128; the international information standard for the terminology, coding and labelling of medical products of human origin. ICCBBA manages the allocation of globally unique identifiers to licensed facilities and maintains the ISBT 128 Standard, international databases for Facility Identification Numbers and Product Description Codes, supporting documentation, and educational materials. ISBT 128 is used by blood and tissue establishments in 87 countries. ICCBBA participated, with other partners, in a European Commission service contract to develop compendia and a

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

translator tool to support the Single European Code (SEC) for tissues and cells. It has published guidance for the application of the EU SEC for ISBT 128 users[3].

EUROCODE-IBLS[4] provides an international non-profit standard for labelling blood products and tissue to enhance security in blood transfusion and tissue transplantation. The standard provides a product bag number that is unique worldwide, unique coding of product properties, country codes following ISO 3166, centre codes according to national agreements, matching enhanced space saving barcode systems and charge-free access to all information via Internet. Eurocode is used primarily in Germany although some centres in Austria, Croatia and Spain also apply the standard.

Discussion points:

1. Effectiveness of current traceability systems for BTC

The key concern identified by the stakeholders is the lack of any requirement for monitoring the effectiveness of traceability by challenging/testing the systems. They do not consider that reviewing traceability during inspection is adequate. They point out that it is generally when there is a serious safety risk that the weaknesses in traceability become evident. They consider that a requirement for routine testing of systems – all the way from donor to recipient and back – in worst-case scenarios - is needed. This would identify the weak points, particularly at the hospital/clinical user stages where systems tend to be less robust. Such system testing would allow the 'traceability window' to be measured. The traceability window is the time from when a problem in a donor, patient or substance is detected to when the last unit/package of donated material, or the last recipient, has been located. Some standards (e.g. the standards of the Human Milk Banking Association of North American) define a minimum traceability window.

2. Traceability across different Substances of Human Origin

The view was expressed that current requirements do not ensure that there is traceability from one donor across the different substances they may have donated at different times in their lives, or after their death. The stakeholders considered that competent authorities should have the responsibility of ensuring that this cross-substance traceability is in place to minimise risk to recipients.

3. Traceability across different regulatory frameworks

In relation to coherence with other EU legislation, traceability across regulatory frameworks was discussed. It was noted that many demineralised bone products are medical devices in the US and need to be coded according to that standard (UDI) although other bone products and other tissues donated by the same donor are coded by a different system. Some of these products are exported from the US as medical devices but imported into the EU as tissues, needing the SEC. They stressed that traceability from tissues or cells to the manufacture of advanced therapy medicinal products is also an area where traceability needs to be secure.

4. Data retention requirements

[3] https://www.iccbba.org/uploads/14/db/14dbe4eb3638ba7e3839fbbed4437dcd/ST-012-ISBT-128-and-the-Single-European-Code-SEC-v1.3.1.pdf
[4] https://www.eurocode.org/

A further topic raised was the need to maintain traceability data over the 30 year period required by the directives. They stressed that robustness of traceability during this retention period should be ensured.

5. The expanding scope of SoHO

ICCBBA, in particular, noted that it is providing codes for a broader range of SoHO than that covered by the directives. There is steady increasing activity with new substances such as human milk, faecal microbiota transplants and serum eye drops for ophthalmic use. They are also increasing their supply of codes for medically assisted reproduction and fertility preservation (ovarian and testicular tissue).

6. Cost of traceability

In general, the experts noted that the significant costs are associated with the implementation of IT systems rather than with the use of codes themselves. The users of international coding systems generally already used IT systems before any EU traceability requirements were adopted and therefore the costs were not significant for those stakeholders.

7. General comments

Both organisations have noted a general trend towards automation in blood services and, associated with that, a move towards consolidation of activities in smaller numbers of centres. For example, the number of blood centres in Germany has decreased from hundreds to around 90; consolidation in the UK has been even more radical with very few large blood processing and testing centres now operating. In general, the coding organisations consider that standards for quality, safety and traceability should be global and that the EU legislation has contributed to the effort of achieving this aim.

8. Close

DG Sante thanked the participants for the open and informative meeting.