



worldwide network for blood and marrow transplantation

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Stefaan van der Spiegel, Team Leader SOHO
Substances of Human Origin - Unit C6 Health Law and International
DG SANCO
European Commission
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Re: Coding and Labelling of Cellular Therapy Products

Dear Mr van der Spiegel:

In 2004 an international initiative was established in order to bring about global standardization of the terminology, coding and labelling for cellular therapy products. This initiative is supported by AABB, APBMT, ASBMT, ASFA, EBMT, FACT, ICCBBA, JACIE, ISBT, ISCT, JACIE, NMDP and the WMDA.

Considerable progress has been made with the creation of an international committee to oversee the process (The Cellular Therapy Coding and Labelling Advisory Group), the publication of an approved terminology, the adoption of this terminology by the major cellular therapy accreditation bodies, and the registration of more than 280 banks worldwide to use the ISBT 128 Standard.

A recent consensus statement released by the above organizations calls for the full implementation of ISBT 128 coding and labelling in order to improve global traceability and enhance patient safety. The statement further calls on other relevant professional bodies, accreditation bodies, regulators and health authorities to support this drive for global standardisation. <http://www.iccbba.org/docs/tag/ctclag-joint-statement.pdf>. The accreditation bodies AABB, JACIE and FACT already require accredited facilities to use the published ISBT 128 terminology. The draft versions of their next standards require facilities to have implementation plans to move towards full implementation of ISBT 128 coding and labelling.

The global implementation of ISBT 128 for cellular therapy is an important patient safety initiative that should be urgently progressed, and we are keen to encourage cell therapy banks throughout the world to move forward.

A number of cellular therapy establishments in the EU have already implemented ISBT 128, but others are concerned that moving in this direction





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may not be compatible with the yet to be published European Coding System for Tissues and Cells and are thus reluctant to proceed without clear guidance from the Commission.

This is a critical time in the move towards global standardization and we would be grateful for the support of the Commission in this essential global initiative. In particular we think it is important that European cellular therapy establishment be given a clear indication that the implementation of ISBT 128 for cellular therapy products will be compatible with the European Coding System.

The Worldwide Network for Blood and Marrow Transplantation (WBMT) strongly supports this concept and urges the Commission to consider adopting these standards for the European Coding System for Tissues and Cells. It is in full alignment with the World Health Organization Guiding Principles on Cell, Tissue and Organ Transplantation as well as with Resolution WHA 63.22 of the sixty-third World Health Assembly in 2010, concepts the WBMT incorporates into its activities and wishes to promote. Our organization is agreeable to reviewing proposals you are considering, or could submit one for your consideration upon request.

We hope that the Commission is able to respond positively to this appeal and look forward to hearing from you.

Sincerely,

D. Niederwieser

President

Y. Kodera

Vice-President

D. Confer

Treasurer

H. Greinix

Position holder/ past-president

