

Statement of the European Blood Alliance position on the labelling, coding and identification of blood, blood components, tissues and cells

Recognizing

- the importance of a globally unique and generally accepted standard for labelling, coding and identification of blood and blood components as a prerequisite for ensuring safety and effectiveness of international and regional relief operations in major disaster and emergencies¹;
- that the World Health Organization in *Guiding Principles on Human Cell, Tissue and Organ Transplantation* has identified the need for international standardization of labeling, coding and identification²;
- the European Union requirement for a unique identification code for each donation of tissues and cells as specified in the European Directive 2004/23/EC³;
- the importance of a consistent approach to coding and labeling of substances of human origin to ensure effective traceability and vigilance of all donated human material;
- the need for a standard that is stable, flexible, and effectively managed to meet the rapidly changing needs of the transfusion and transplantation communities;
- the widespread successful adoption of the ISBT 128 information standard in many countries in Europe and throughout the world⁵;
- the international support for the use of ISBT 128 coding and labeling for cellular therapy products⁶;
- the ongoing effectiveness of ICCBBA in maintaining and developing the ISBT 128 Standard to the satisfaction of the professional user community;

the European Blood Alliance supports the universal use of the *ISBT 128* for labelling, coding and identification of blood, blood components, tissues and cells.

References

1. Proceedings of the Blood Safety and Availability Committee, Center for Biologics and Evaluation 1997. <http://www.fda.gov/ohrms/dockets/ac/97/transcpt/3304t2.rtf>. Accessed 20 Apr 2010.
2. World Health Organization Guiding Principles on Human Cell, Tissue and organ Transplantation. March 2009 http://apps.who.int/gb/ebwha/pdf_files/A62/A62_15-en.pdf. Accessed 20 April 2010
3. Directive 2004/23/EC of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. OJEU L102/48 (2004)
4. Ashford P, Fearon M, Bedford R. Report on the joint IBEPAG/ICCBBA survey on import/export and blood component labeling. *Vox Sang* 2010,98:85-6
5. Ashford P et al. Standards for Terminology and Labeling of Cellular Therapy Products. *Transfusion* 2007;47:1319-27