Simultaneous Implementation of the Single European Code and ISBT 128

Authors: Zbigniew Szczepiorkowski[1], Ineke Slaper-Cortenbach[2], Pat Distler[3], Paul Ashford[3]

Dartmouth-Hitchcock Medical Center, Lebanon, United States[1], University Medical Center Utrecht, Utrecht, Netherlands[2], ICCBBA, San Bernardino, United States[3]

Introduction

Two initiatives have spurred the movement towards globally standardized coding for cells and tissues:

- In 2013, WHO developed a strategy for the governance of medical products of human origin (MPHO) that included global use of ISBT 128 to ensure unique identification, optimal traceability, and interoperability between countries and across all MPHO.
- AABB, FACT, and JACIE required the use of ISBT 128 terminology and an implementation plan for full ISBT 128 coding and labelling.

In April 2015, the European Commission published Commission Directive (EU) 2015/565 that amends Directive 2006/86/EC specifying the implementation requirements for the Single European Code (SEC). Legislation requiring Tissue Establishments to apply the SEC to product labels takes effect 29 April 2017. Exceptions will exempt some cell therapy products from the SEC requirement but some may still be required to carry a SEC. The application of the SEC will also depend on national legislation.

ISBT 128, managed by the non-profit ICCBBA, is the global standard for terminology, coding, and labelling of MPHO. It is compatible with the SEC and provides additional benefits.

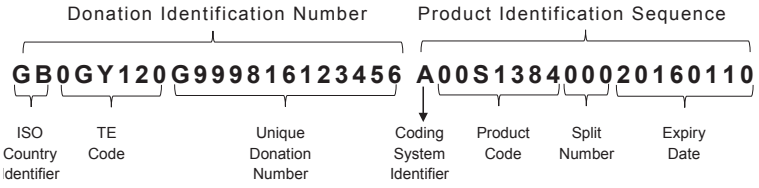
Methods

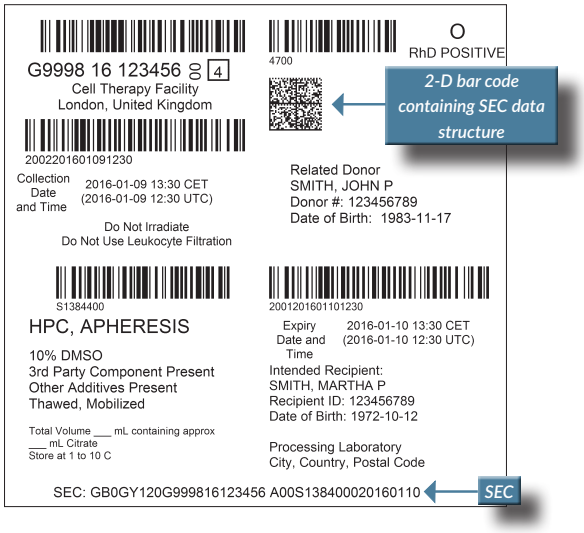
Experts in the fields of cells and tissues developed ISBT 128 international terminology using classes (high-level description, e.g., HPC, Apheresis) and attributes (additional details, e.g., Mobilized).

Eurocet 128 developed a high-level terminology for tissues and cells (EU Tissue Code - EUTC). ISBT 128 classes have been mapped to their corresponding EUTC (see table below).

ISBT 128 Class	EUTC
HPC, MARROW	PROGENITOR CELLS, HEMATOPOIETIC, BONE MARROW
HPC, APHERESIS	PROGENITOR CELLS, HEMATOPOIETIC, PERIPHERAL BLOOD
HPC, CORD BLOOD	PROGENITOR CELLS, HEMATOPOIETIC, CORD BLOOD

ICCBBA developed a data structure allowing the SEC to be encoded into a bar code.





Results

More than 240 cell and tissue classes within ISBT 128 are mapped to 90 EUTCs allowing 3228 ISBT 128 cell and tissue product description codes to be used within the SEC system to describe products.

The SEC can be encoded in either a linear or two-dimensional bar code.

Conclusions

Not all cellular therapy products will be carrying the SEC, but if SEC must appear on the product label or in accompanying documentation, this can be readily achieved using ISBT 128 codes in the SEC. Such an approach ensures that the consistency of ISBT 128 usage is maintained across all cellular therapy products whilst meeting the requirements of the Directive. This allows tissue establishments to:

- Provide descriptions of products useful in inventory management and biovigilance
- Label with internationally standardized bar codes for more accurate records and improved traceability
- Transfer products labelled with globally recognized bar codes beyond the EC countries
- Comply with accreditation standards
  - Align with the global commitment of scientific and professional societies to use of ISBT 128
  - Align with the WHO call for globally consistent coding systems

For those tissue establishments not already using ISBT 128, the SEC directive may require some changes to existing computer systems. Simultaneous implementation of ISBT 128 with these changes may provide:

- Greater efficiency in that:
  - Many implementation steps (e.g., transition planning and validation) are the same for both systems
  - Many processes (e.g., training and education of end users) can be done at the same time for both systems
  - ICCBBA provides mapping to EUTC so users do not need to do the mapping
- Potential cost savings:
  - One computer upgrade instead of two
  - Efficiencies in implementation of the two systems together

ISBT 128
More than Identification