ISBT 128 and the Single European Code

INTRODUCTION

There is wide recognition of the need to standardise the terminology, coding and labelling of medical products of human origin (MPHO) in order to improve traceability and transparency. The 2010 World Health Assembly Resolution WHA63.22 calls on member states to "encourage the implementation of globally consistent coding systems for human cells, tissues and organs as such in order to facilitate national and international traceability of materials of human origin for transplantation." ICCBBA is working closely with World Health Organization (WHO) in order to achieve this objective using the ISBT 128 Information Standard and has been accepted as a nongovernmental organization in official relations with WHO.

European Commission Directive 2015/565 of 8 April 2015 lays down the detailed requirements and timescales for the introduction of the Single European Code (SEC).

The purpose of this document is to demonstrate the compatibility between ISBT 128 and the SEC, and to encourage cell and tissue establishments to proceed with the implementation of ISBT 128 knowing that ISBT 128 codes can readily be accommodated into the SEC.

ISBT 128 is a voluntary standard in most countries although it is mandated in some EU Member States. However there is strong support from scientific and professional societies particularly in the fields of cellular therapy and eye banking. JACIE accredited cell therapy facilities are now required to have an ISBT 128 implementation plan in place.

TWO CODING SYSTEMS WITH DIFFERENT OBJECTIVES

The purpose of the SEC is to achieve harmonisation across disparate coding systems. In addition, the SEC, via the TE Compendium, will provide access to information on the identity and authorization status of the source tissue establishment.

The purpose of ISBT 128 is to achieve global standardisation of coding and labelling for MPHO in order to enhance safety, ensure accuracy, and improve efficiency. ISBT 128 not only provides a firm foundation to support global traceability and biovigilance, but also provides tissue establishments with standardised electronically readable information which can deliver improved process efficiency and cost savings including improved accuracy and speed of information capture, better stock management, and more rapid recall capability.

THE SINGLE EUROPEAN CODE

The SEC is an alphanumeric code that carries information on the TE, the donation number, the product code, divisions, and expiry date in a standard format.

It should be noted that the Unique Donation Number field is compatible with an ISBT 128 donation identification number, and the product identification element identifies both a coding system and product code from within that system, thus allowing

ISBT 128 and the Single European Code

The format of the Single European Code has been established as follows:

DONATION IDENTIFICATION

ISO Country Identifier	*TE Code (TEC)*	*Unique Donation Number*
2 characters (alphabetic)	6 characters (alpha/numeric)	13 characters (alpha/numeric)

PRODUCT IDENTIFICATION

Coding System Identifier	*Product Code*	*Split Number*	*Expiry Date*
1 character (alphabetic)	7 characters (alpha/numeric)	3 characters (alpha/numeric)	8 characters (numeric)

ISBT 128 to be identified as the coding system and the ISBT 128 product description code to be entered in the Product Code field.

In fact all of the information in the SEC can be derived from the information held in ISBT 128 barcodes with the exception of the ISO Country Identifier and the TE Code, both of which are constant for each TE. ISBT 128 uses a Facility Identification Number to uniquely identify tissue establishments.

THE NEED FOR CHANGE

The introduction of the SEC will require all tissue establishments in the EU to make changes to the way they label their tissue and cell products. As a minimum, the SEC will need to be added to the label of every finished tissue and cell product, and a control system will be required to ensure correct assignment of the unique identifier and the linking of the SEC to TE records. These changes will impact existing computer systems and operational procedures, and will require training and validation. They will require mapping activities to associate all tissue products with their appropriate product code, and introduction of serialisation (split numbers) if these are not already used.

For those tissue establishments not yet using ISBT 128, this would be the ideal time to introduce the standard. Many of the changes required for the SEC will involve similar process steps to those required to introduce ISBT 128 and both time and effort could be saved by combining the activities.

WHY INTRODUCE ISBT 128?

If you do not currently use a coding system to identify your tissue and cell products, the EC will be providing a generic product code list. This will allow you to map your products to a generic term and to use the associated code in the SEC.

The EU generic code will allow you to meet the requirements for the SEC so that tissues and cells in the EU can be traced to a specific TE

and any regulator, clinical user or other interested party can consult the published compendium to confirm the authorisation status of that TE. The product terminology in the SEC is very high level; as an example, an EU generic term may be "MUSCULOSKELETAL, BONE, SHAPED GRAFT". This term would be used for "bone cube, ring, dowel, strut, wedge, peg or any other bone products, whether demineralised or not, and from any anatomical source, that are shaped for a particular surgery". The SEC does not aim to bring direct benefits to routine operations within the TE.

Introducing ISBT 128 provides the opportunity not only to improve traceability but also to realise process improvements that enhance safety, improve efficiency, and reduce cost.

ISBT 128 supports terminology that can be as general or detailed as the user wishes, and provides a wealth of important information for the clinical user. For example, an ocular tissue code from ISBT 128 is "CORNEA|Anterior and posterior layers|Left|Hypothermic storage".

ISBT 128 is a comprehensive system for the identification and coding of MPHO and ICCBBA, as a nongovernmental organization in official relations, is working closely with the WHO to achieve globally consistent coding systems. ISBT 128 terminology is developed through an international consensus that involves scientific and professional societies, technical and clinical experts, and regulators. In the fields of cellular therapy and ocular tissue, there is now an international consensus for the use of ISBT 128.

In addition, ISBT 128 information is represented in machine readable codes meaning that information can be rapidly and accurately captured using scanners. The ISBT 128 Standard is widely supported by instrument manufacturers, software developers, and labelling systems. Many of their systems offer ISBT 128 as a standard feature.

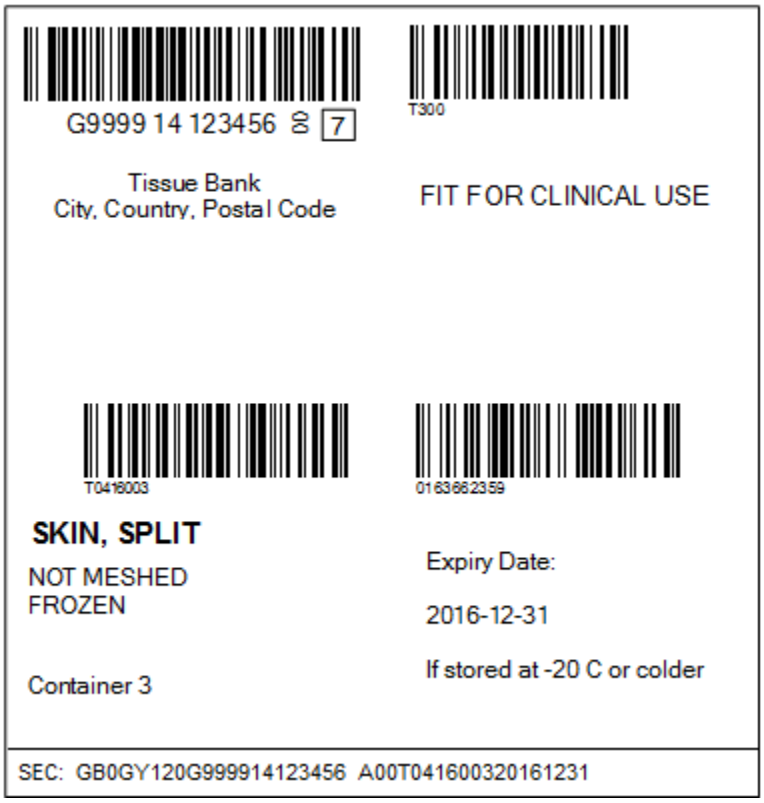
ISBT 128 can deliver real process improvements through its use of internationally standardised bar coded information. It can help to improve accuracy and efficiency at each point where information needs to be written to, or captured from, the label. Product descriptions can be tailored to the level of detail needed to meet the needs of clinical users. Stock management can be streamlined and product recall can be performed rapidly and accurately.

ISBT 128 AND SEC LABELLING

The final requirements for the SEC have been published in EC Directive 2015/565, and the regulation will be applied in Member States from 29 April 2017. SEC labelling will need to be in place on most tissue and cell products placed into storage from 29 October 2016.

An ISBT 128 label carrying an SEC is shown on the next page. The label is identical to a standard ISBT 128 label with the exception of the line of text at the bottom which carries the SEC.

ISBT 128 and the Single European Code



INFORMATION MAPPING IN THE LABEL IS AS FOLLOWS:

ISBT 128 Information		*SEC Information*	
Facility Number	G9999	ISO Country Identifier	GB
		TE Code	0GY120
Donation Identification Number	G999914123456	Unique Donation Number	G999914123456
		Coding System	A (ISBT 128)
Product Description Code	T0416	Product Code	00T0416
Divisions	003	Split Number	003
Expiration Date	2016-12-31	Expiry Date	20161231

ISBT 128 and the Single European Code

WHAT DOES ISBT 128 COST?

To use ISBT 128 you need to be registered and licensed with ICCBBA and this involves payment of registration and license fees. The income generated is used to maintain the standard and support global activities in standardisation of terminology and identification.

Fees shown in this document reflect 2016 rates.

All facilities are required to pay an initial registration fee of US$200. In addition facilities pay an annual license fee based on the following:

CELL THERAPY FACILITIES

The annual license fee is based on the total number of Donation Identification Numbers (DINs) assigned in the previous year. DINs are assigned to each collection or pooling event.

IF	*Then*
Your facility does not assign DINs or assigns <1,000 per year	Your annual license fee is US$230
Your facility assigns between 1,000 and 20,000 DINs per year	Your annual license fee is US$350
Your facility assigns ≥20,000 DINs per year	Your annual license fee will be US$350 plus US$0.01465 times the number of collections per year above 20,000. For example, you collect 30,000 units per year. Fee is US$350 + (10,000 * 0.01465) = US$496.50 per year.

TISSUE AND EYE BANKS

The annual license fee is based on the number of tissue products distributed that are labelled with ISBT 128.

IF	*Then*
Your facility does not label final tissue products but does use ISBT 128 bar codes on procurement or in-process tissue products	Your annual license fee is US$220
Your facility distributes ≤ 1,000 labelled products a year	Your annual license fee is US$220
Your facility distributes between 1,000 and 5,000 labelled products a year	Your annual license fee is US$336
Your facility distributes >5,000 labelled products a year	Your annual license fee will be US$336 plus US$0.1137 times the number of labelled products per year above 5,000. For example, you label 8,000 products per year. Fee is US$336 + (3,000 * 0.1137) = US$677.10 per year.

NEXT STEPS

If you decide that you wish to move forward with the implementation of ISBT 128 please contact the ISBT 128 help desk at iccbba@iccbba.org. Our staff will guide you through the licensing process and provide technical support on use of the standard.