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An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Single European Code for Tissues and Cells

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19th June 2015

Overview:

- The Single European Code (SEC): Legislative Basis;
- Eurocet 128 Consortium;
- EU Coding Platform;
- The structure of the SEC;
- How to construct the SEC?
- Label specifications;
- When will the SEC apply? - Exemptions
- Next steps
- Some Worked Examples.

Single European Code: Legislative Basis.

- Article 25 (2) of Directive 2004/23/EC.

  “The Commission, in cooperation with the Member States, shall design a single European coding system to provide information on the main characteristics and properties of tissues and cells”;

Single European Code: Legislative Basis

- Directive 2006/86/EC Article 10

  "A single European identifying code shall be allocated to all donated material at the tissue establishment:

- To ensure proper identification of the donor;
- To ensure traceability of all donated material;
- To provide information on the main characteristics and properties of tissues and cells"

Single European Code: Legislative Basis

- Directive 2006/86/EC Article 10

  The code shall incorporate at least the information set out in Annex VII.

Information contained in the European Coding System

(a) Donation identification:

— Unique ID number

— Identification of the tissue establishment

(b) Product identification:

— Product code (basic nomenclature)

— Split number (if applicable)

— Expiry date

Directive 2015/565

- Amending Directive 2006/86/EC as regards certain technical requirements for the coding of tissues and cells
- Published Official Journal of European Union 8th April 2015;
- Entered into force 28th April 2015;
- 18 month transposition deadline (29th October 2016);
- full implementation required 6 months post transposition (29th April 2017).

Implementation of SEC: Eurocet 128 Consortium

Eurocet 128 Consortium - Objective

- To build the “EU coding platform” –

- IT platform hosted by Commission which contains;

1. EU Tissue Establishment Compendium
2. EU Tissue and Cell Product Compendium;
3. A translator application to assist searches of both compendia .

1. EU Tissue Establishment Compendium

A register of all authorised EU Tissue Establishments detailing;

- Tissue establishment information; (name, address, contact details)
- Authorised activities;
- Tissue and cell type per activity;
- TE code;
  - ISO two country character prefix (IE – Ireland);
  - six character alpha-numeric TE number (assigned by the HPRA – linked with existing national TE number);

e.g. TE Code for a TE in Ireland: IE0TE123

All TE specific information will be associated with this TE code.

Publicly accessible / Search by name of TE or by Code

EU Tissue Establishment Compendium

- Currently being updated
- Data to be recorded in the EU TE Compendium – new Annex VIII of Directive 2006/86/EC
- Any substantial changes to authorisation will require updating on TE Compendium (HPRA responsibility)

2. EU Tissue and Cell Product Compendium

Register of all tissue and cells circulating in the Union and the respective product under the three permitted coding systems

includes;

- Existing national and international coding systems: **ISBT 128, Eurocode;**
- EU Tissue and Cell product codes (**EUTC Code**) that must be used where a national or international system is not in use.

ISBT 128, Eurocode and EUTC Code will be identified in the SEC by a coding system identifier (A, B and E, respectively)

EU T&C Product Compendium

- Currently mapping all ISBT 128 and Eurocode tissue and cell codes to their corresponding EUTC Codes;

- EUTC High level descriptions;
  - REPRODUCTIVE, OOCYTE

  (Embryo, Oocyte, Ovarian Tissue, Sperm, Testicular Tissue)

- ISBT 128 – more detailed
- donor - intended recipient relationship/ preservation / collection, recovery method is coded
  - OOCYTE, Allogeneic, Cryopreserved, Extracted

EU T&C Product Compendium - Example

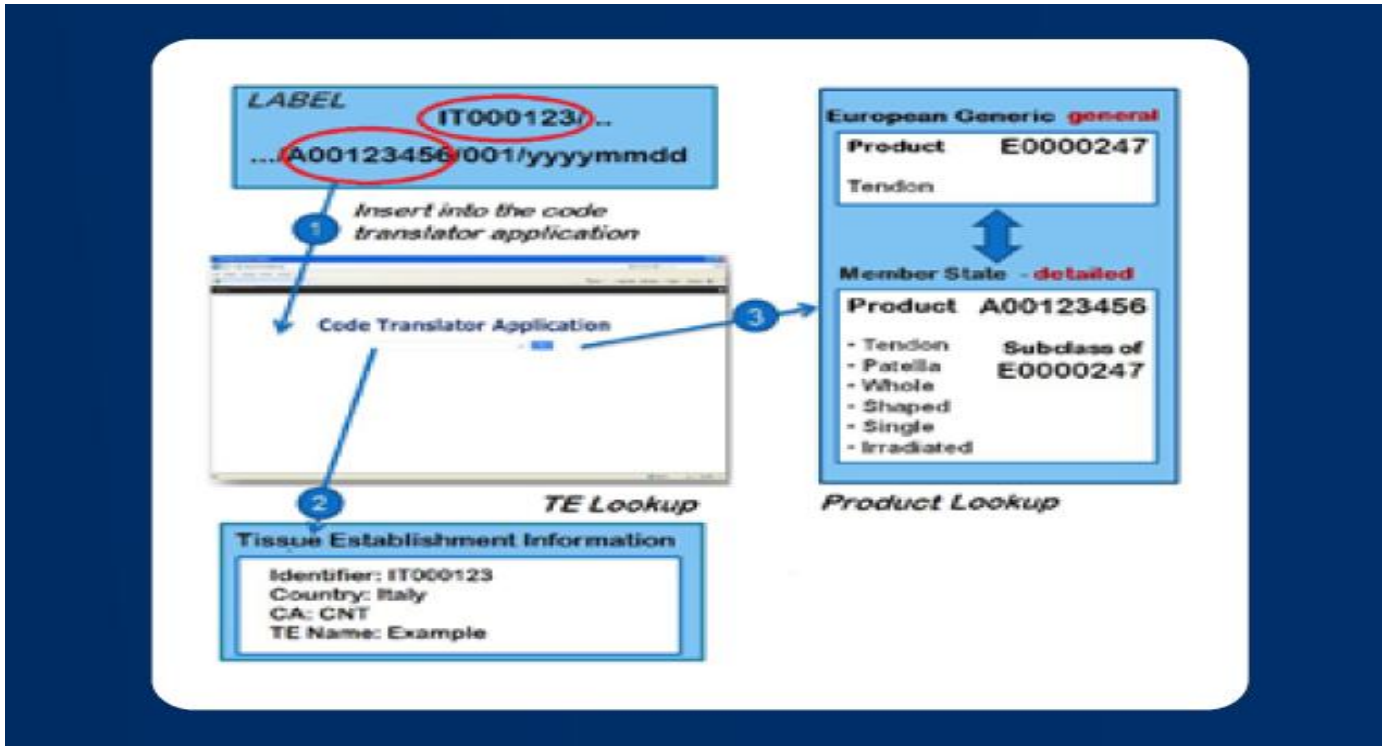
EUTC Code	EUTC Product description	ISBT 128 code	ISBT 128 product description	
57	Reproductive, Oocyte	V0003	Oocyte	Autologous, extracted
		V0004	Oocyte	Autologous, cryopreserved, extracted
		V0005	Oocyte	Allogeneic, extracted
		V0006	Oocyte	Allogeneic, cryopreserved, extracted
		ETC.....		

EU T&C Product Compendium

- ICCBBA regularly updates the ISBT 128 product code database, but does not have the authority to update this in the product compendium –
- responsibility of Commission - in consultation with expert sub group (MS CA / ICCBA / Eurocode);

3. Translator application tool

A translator application will be developed that will allow searches of both compendia – construct SEC



Structure of the SEC

- Alphanumeric code that carries information on the TE, the donation number, the product code, divisions and expiry date in a standard format (ISO format YYYYMMDD)
- It will consist of a donation identification sequence and a product identification sequence.
- New Annex VII of 2006/86/EC

Structure of Single European Code

Donation Identification Sequence			Product identification Sequence			
TE Code		Unique Donation Number	Product Code		Split Number	Expiry date
ISO Country Code	TE Number		Product Coding System identifier	Product Number		
2 Alphabetic Characters	6 Alpha – numeri Characters	13 alpha-numeric characters	1 alphabetic character **E = EUTC A=ISBT128 B=Eurocode**	7 alpha - numeric characters	3 alpha numeric characters	8 numeric characters

How to construct SEC

- Donation Identification Sequence:
  - E.g. IE-0TE00X-000000A1234567

DONATION IDENTIFICATION

ISO country	TE code	Unique donation number (local/national)
2 characters	6 characters (alpha-numeric)	13 characters (alpha-numeric)

How to construct SEC

- Product Identification Sequence
  - E.g. A000S123-001-20140802
  - E.g. E0000041-002-20140911

PRODUCT IDENTIFICATION

Product code	Split number	Expiry date
1 symbol + 7 characters (alpha-numeric)	3 characters (alpha-numeric)	8 characters (alpha-numeric)

- **A= ISBT128**
- **B= Eurocode**
- **E =EUTC**

Specifications for Product labels

- Eye readable format;
- Must be preceded by the text SEC;
- As a single line of characters – with DIS and PIS separated by a single space

  or two successive lines;
- Printed;
- Where possible the SEC must appear on the affixed label of the product;
- **Note: If label size precludes inclusion of SEC – accompanying documentation.**
- For imports – country of procurement (exporting country) must be on final label for distribution (amended Annex II – Part E of 2006/86/EC)

When does the Single European Code need to be applied?

- SEC shall be applied to all tissues and cells that are distributed for human application
- Tissues and cells “released for circulation” to another operator at least the donation identification sequence shall be applied.

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Exemptions:

- **Reproductive cells from partner donation;**
- Tissues and cells distributed directly for immediate transplantation to the recipient; as referred to in Article 6(5) of 2004/23/EC;
- Tissues and cells imported into the Union in case of emergency authorised directly by the competent authority as referred to in Article 9(3)b of 2004/23/EC

Exemptions

- Tissues and cells other than reproductive cells for partner donation, when these tissues and cells remain in the same centre;
- **Tissues and cells that are imported into the Union, when these tissues remain within the same centre from importation to application, provided that the centre comprises a tissue establishment authorised, designated, accredited, or licensed to carry out importing activities;**

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Transitional period

- Tissues and cells already in storage on 29 October 2016 – exempt – provided they are released for circulation in the Union within 5 years of that date.

What does this mean for ART Clinics?

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- Partner Reproductive Cells – Exempt
- Apply SEC - Non partner gametes or embryos – distributed outside of clinic;
- Distribution of partner gametes within EU for processing of non partner embryos?
- Imported non-partner gametes and embryos used at the importing TE will not be required to use the Single European Code – unless Distributed

Major implication for ART Clinics?

- Receipt of non partner gametes / embryos.
- SEC must be applied on products;
- SEC to be referenced in SAE/R reporting (Donor Blocks);
- SEC to be retained for 30 years;
- Essential to confirm the method by which suppliers intend to apply SEC / what coding system / how split numbers are applied;

Next steps for ART TE's

- Familiarise with legislation – **Note:** changes to Annexes of 2006/86/EC – labelling / SARE reporting / traceability data
- Identification of when and if you will need to apply the SEC;
- Plan for the modification of procedures and documentation relevant to labelling, storage, **distribution (NB: acceptance procedures),** and import;
- Review of IT systems, label designs and printing systems to accommodate the SEC;

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SEC Worked Examples

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17th June 2015

Scenario 1 – application of SEC

- An ART TE in Ireland receives distributed non partner sperm from a TE in Denmark (that uses the ISBT 128 coding system)

The SEC is printed on the accompanying documentation as follows;

SEC DK0TE001G000013765432 A00V003500300000000

- The Irish ART TE use the non partner sperm to process 8 non partner embryos for the couple. All of which were vitrified and stored in 4 Straws (2 embryos per straw);
- The couple notify the Irish ART TE that they are moving home and request that their embryos be transferred to another Irish ART TE closer to their new home.

= distribution of non partner embryos = therefore SEC needs to be applied

Scenario 1: application of SEC

- Irish TE has TE Code TE033, the unique donation number for the couple is 10479. The TE do not use ISBT 128 or Eurocode. They search the EU Tissue and Cell product compendium looking for EUTC. They find that embryo maps to the EU Generic term “Reproductive, Embryo” and this has a code of “56”. The TE have established that a split number will be designated to each individual straw that contains 2 embryos. There is no Expiry date.

SEC IE0TE033000000010479 E00005600010000000

SEC IE0TE033000000010479 E00005600020000000

SEC IE0TE033000000010479 E00005600030000000

SEC IE0TE033000000010479 E00005600040000000

Scenario 3 - Import

- **Tissues/cells imported from third countries (**for distribution) in the EU should be also labelled with the SEC by the importing TE
- For the donation identification:
  - the codes for country and TE will be the ones corresponding to the importing TE.
  - the donation identification number should be a new one, allocated by the importing TE unless the supplier is using ISBT 128.
  - If the supplier is using ISBT 128 the globally unique donation number should be retained.
- For the product identification:
  - The product identification number of the product should map to the EU generic codes or ISBT product codes in the EU Product compendium.

Scenario 3 - import

- Generis IVF in the USA supplies non partner sperm to an ART TE in Ireland (TE0041). The TE receives 4 straws for use in treatment of one of their patients. The straws were identified with unique donation number, Donor identification and date of freeze. There was no expiry date.
- The patient decides to move to another ART TE in Holland and requests that the donor sperm straws be distributed.

- Distribution of imported non partner sperm = SEC Applied

Scenario 2: Import

- The TE assigns the next available donation number from its own unique donation number allocation sequence which is 705721, and determines that the appropriate EU Generic product code for non partner sperm is " Reproductive, Sperm" and the corresponding code is "59. The TE have established that a split number will be designated to each individual straw There is no Expiry date.
- The SEC is assigned on the label as:

  SEC IE0TE0410000000705721 E0000059001000000000.

  SEC IE0TE0410000000705721 E0000059002000000000.

  SEC IE0TE0410000000705721 E0000059003000000000.

  SEC IE0TE0410000000705721 E0000059004000000000.

  Country of Procurement: USA

Thank you