New traceability and vigilance tools at EU-level

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European Commission
• **Traceability**
  → New EU code for tissues and cells – EUROCET 128 consortium

• **Vigilance**
  → EU rapid alerts platforms
Traceability

Health and Consumers
Traceability for T/C(1)

→ The ability to locate and identify the T/C during any step from procurement – processing – testing – storage – distribution/disposal

→ The ability to identify:
  ➢ the donor and
  ➢ the tissue establishment or the manufacturing facility and
  ➢ the recipient(s) at the medical facility/facilities applying the tissue/cells to the recipient(s)

+ the ability to locate and identify all relevant data relating to products and materials coming into contact with those T/C (Directive 2006/86/EC)
Coding of tissues and cells

Directive 2004/23/EC

CHAPTER V

EXCHANGE OF INFORMATION, REPORTS AND PENALTIES

Article 25

Coding of information

1. Member States shall establish a system for the identification of human tissues and cells, in order to ensure the traceability of all human tissues and cells pursuant to Article 8.

2. 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.

Directive 2006/86/EC

Annex VII

(a) Donation identification:
   — Unique ID number
   — Identification of the tissue establishment

(b) Product identification:
   — Product code (basic nomenclature)
   — Split number (if applicable)
   — Expiry date
### Traceability for T/C(4)

**DIRECTIVE 2006/86/EC - ANNEX VII**

**a) Donation identification:**
- Identification of the tissue establishment
- Unique ID number

**b) Product identification:**
- Product code (basic nomenclature)
- Split number (if applicable)
- Expiry date

<table>
<thead>
<tr>
<th>ISO country code</th>
<th>TE Code</th>
<th>Unique Donation number</th>
<th>Product code</th>
<th>Split number</th>
<th>Expiry date</th>
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Traceability for T/C(5)

Code-translator application

Full description of DONATION / PRODUCT

ID: BE654321
Country: Belgium
Comp Authority: Federal Agency
Phone: ............
Email: ............
Tissue establishment: ............
Address: ............

Compendium of tissue establishments in EU + codes
Compendium of EU Tissues and Cells Products + codes

Femoral head 1
Expiry date: 2015/12/31
Call for tender
EAHC/2011/HEALTH/03
“Reference compendia for the application of a single European coding system for human tissues and cells”
• On the label of tissues and cells to be circulated between EU MS

• On the label of tissues and cells imported from third Countries

• Correlation with other international codes possible
Next steps

- Development of tools for implementation of the Single European Code for tissues and cells – March 2014
- Adopting legislation for the implementation of the Single European Code for tissues and cells – 2014
- Application of the new code – 2015
Vigilance = the surveillance of therapeutic use in humans of organs, tissues and cells, blood

EU legislation on blood, tissues and cells - basic elements of vigilance

- MS are responsible for monitoring of Serious Adverse Reactions and Events (SARE) at national level
- Rapid notification of SARE to the MS and European Commission
- Annual notification of SARE to the European Commission

European Commission – provides support for the development of SoHO vigilance at EU level
Secure alert platform launched by the European Commission on 1 February 2013

**Aim**: Improving the safety of patients undergoing transplantation and medical procedures involving human tissues and cells by insuring timely exchange of urgent information between Member States and the European Commission

**Expected output**: cross-border incidents are prevented/ contained and immediate measures taken to ensure patients' safety.

Used **only for alerts related to human tissues or cells circulated between Member States**.

Used in parallel with existing national vigilance systems which collect and manage alerts on tissues and cells donated and used within a Member State.
**Alerts:**

- Quality and safety defects of tissues/cells
- Alerts related to other sectors (e.g. medical devices)
- Illegal and fraudulent activities
- Outbreaks of communicable diseases which may have cross-border implications

<table>
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<th>Alert reference</th>
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<th>Creation date</th>
<th>SoHo sector</th>
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Development of alert platforms for blood and organs

- Take advantage of EU funded projects (SOHO V&S)
  E.g. Guidelines for Competent Authorities – Investigation and communication of SARE & Detection and investigation of IFA
Thank you!


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2006 – June 2010: alerts circulated via emails
11 rapid alerts
e.g. outbreaks of communicable diseases (Hepatitis A, Chikungunya, Q fever)

July 2010 – January 2013: CIRCA platform
19 rapid alerts
e.g.
• transmission of genetic diseases via sperm donations
• freezing bags for storage of stem cells
• counterfeit certificate for the processing and storage of cells
• false documentation for tissues imported from third countries
• outbreaks of communicable diseases West Nile virus, Malaria, Dengue.

Since February 2013: New RATC platform
5 alerts