

# Biovigilance at the EU level: now and looking to the future

Ingrida Pucinskaite-Kubik

European Commission  
Health and Food Safety Directorate-General  
Unit B4 – Medical products: quality, safety, innovation  
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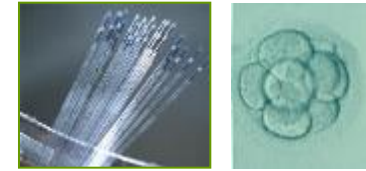
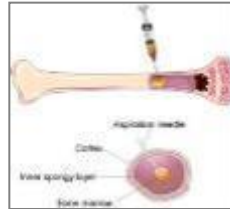
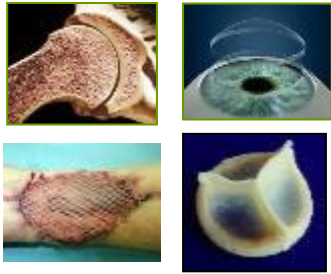
- 1. Background**
- 2. EU legal framework - Vigilance requirements**
- 3. Functioning of T&C Vigilance system**
- 4. Way forward**

# 1. Background

## EU Tissues and cells sector



## 3 sub-sectors



ART sector\*

### Replacement tissues

- Bone
- Ocular tissue
- Skin
- Cardiovascular tissues

Local + regional exchange

> 300,000 units distributed for transplantation/year\*\*

### Haematopoietic stem cells

- Bone marrow
- Peripheral blood stem cells
- Umbilical cord stem cells

Global exchange

> 30,000 units distributed for transplantation/year\*\*

### Reproductive cells and tissues

- Oocytes
- Sperm
- Embryos
- Ovarian tissue
- Testicular tissue

Local + regional exchange

> 500,000 units distributed for clinical application/year\*\*

Used for live-saving/enhancing therapies  
(e.g. leukemia, extensive burns, blindness)

\*ART = assisted reproductive technologies  
\*\* Partial data

# 1. Background

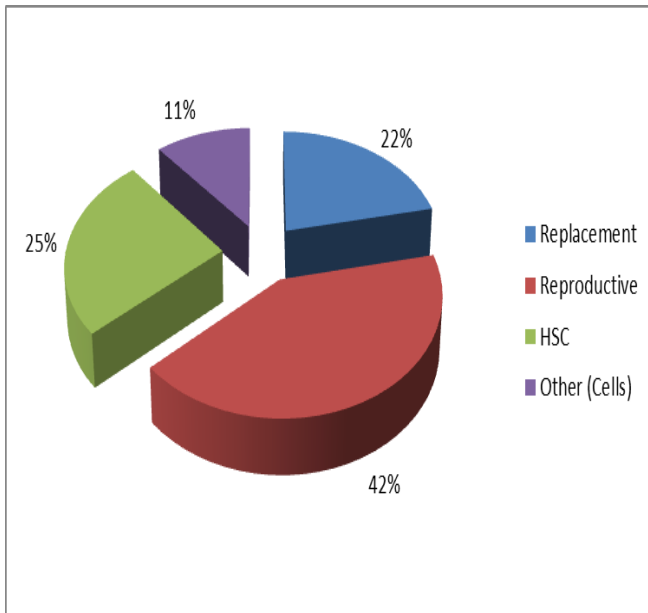
## EU Tissues and cells sector



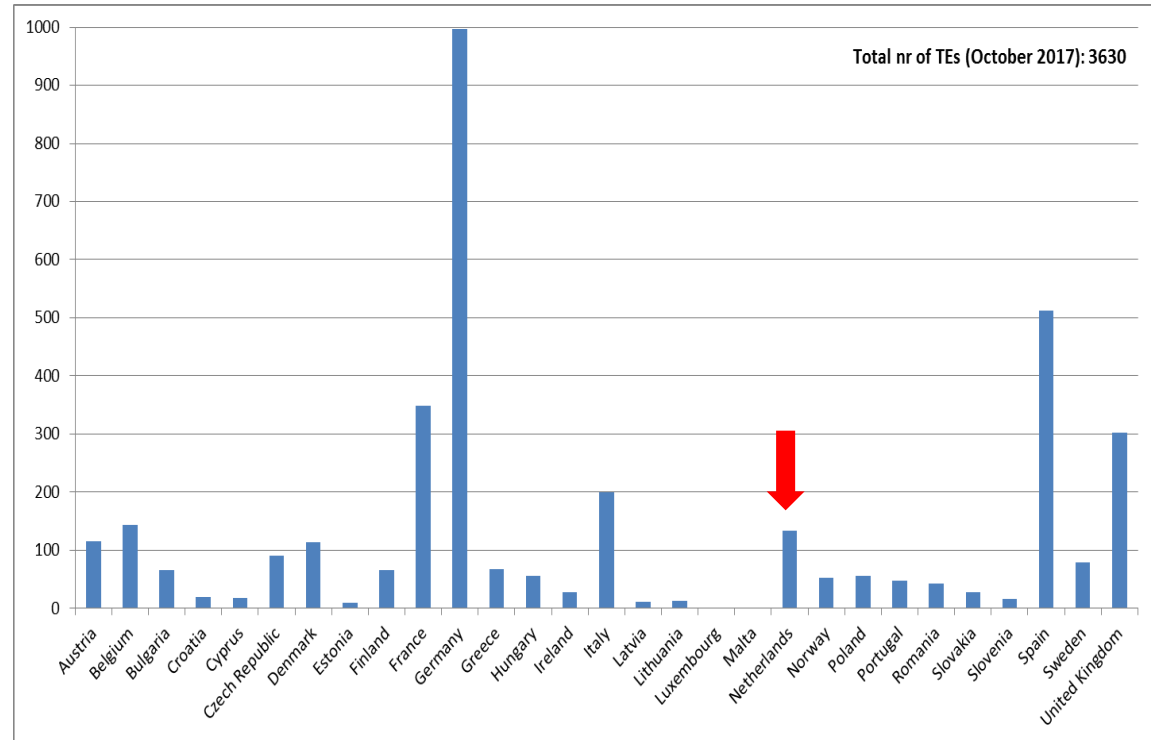
## Establishments and Authorities

**Tissue establishments: 3630**

**Per tissue type**



**Per country**




**T&C Competent Authorities: 58** national + 29 regional/local

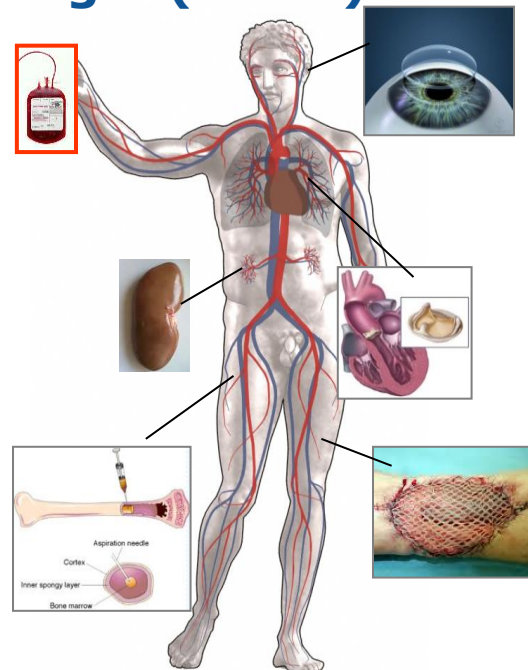
## 2. EU legal framework

## Substances of Human Origin (SoHO)



- **DG SANTE - Substances of Human Origin (SoHO)**
- **T&C as one of three sub-sectors**

- 
- A large red curved arrow pointing from the "T&C as one of three sub-sectors" bullet point to the list of sub-sectors.
- ❖ **Blood and blood components**
  - ❖ **Tissues and Cells**
  - ❖ **Organs**



- EU legal basis - TFEU - Article 168 4(a)
- Clear Mandate for EU-level action concerning quality & safety of SoHO
- Parallel approach across 3 SOHO sectors – Blood, **TC** and Organs



### EU Tissues and Cells Legislation

2004

#### **Main Act 2004/23/EC**

Sets standards for the quality and safety of the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells



2006

#### ***Implementing Directives:***

2006/17/EC – requirements for the donation, procurement, testing of human tissues and cells

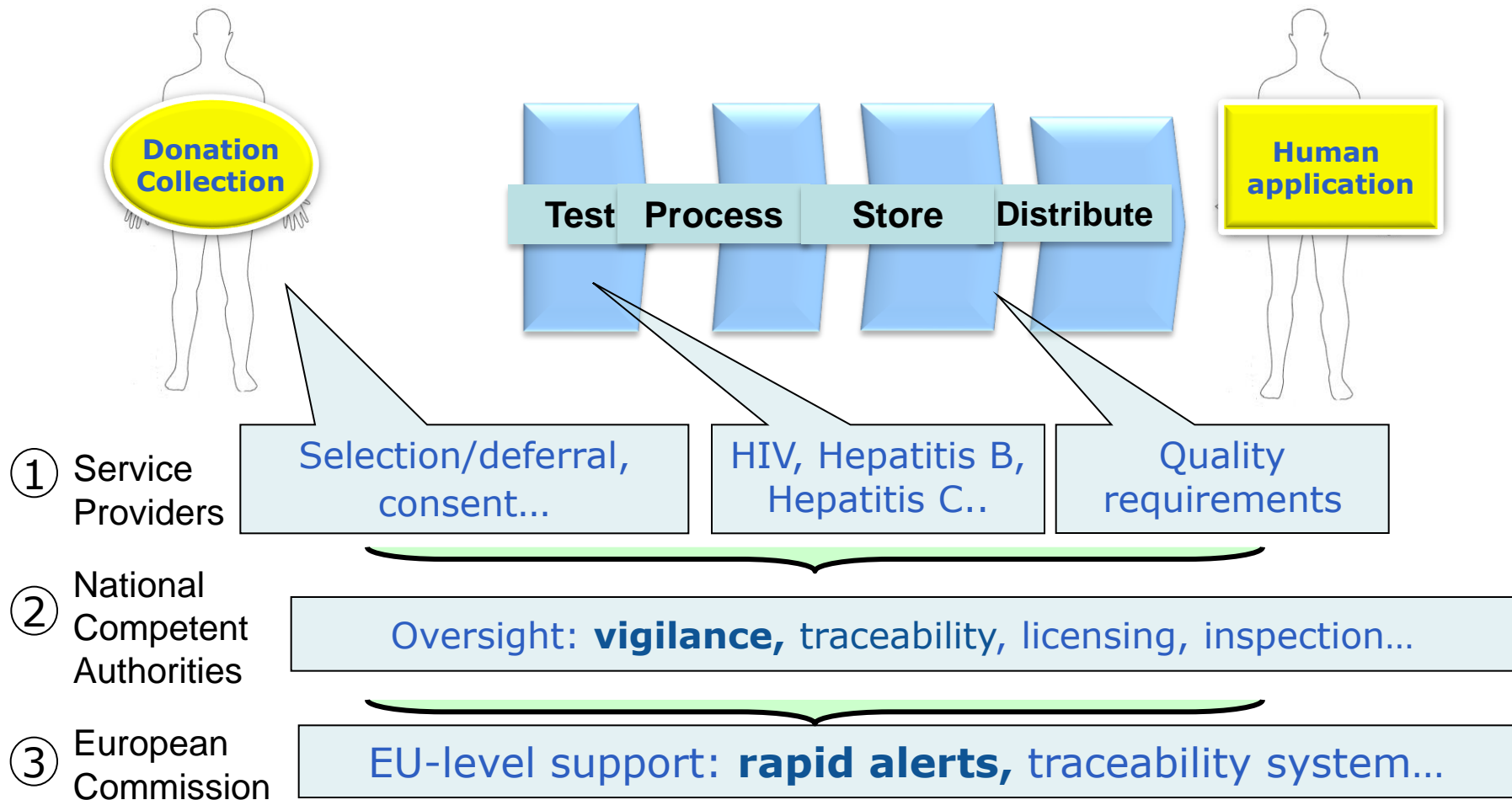
2006/86/EC → **vigilance requirements**, traceability requirements, requirements for coding, processing, preservation, storage and distribution of human tissues and cells, as amended by:

2015

2015/565 → technical requirements for coding

## 2. EU legal framework

## 3 levels of requirements





### ➤ **Vigilance**

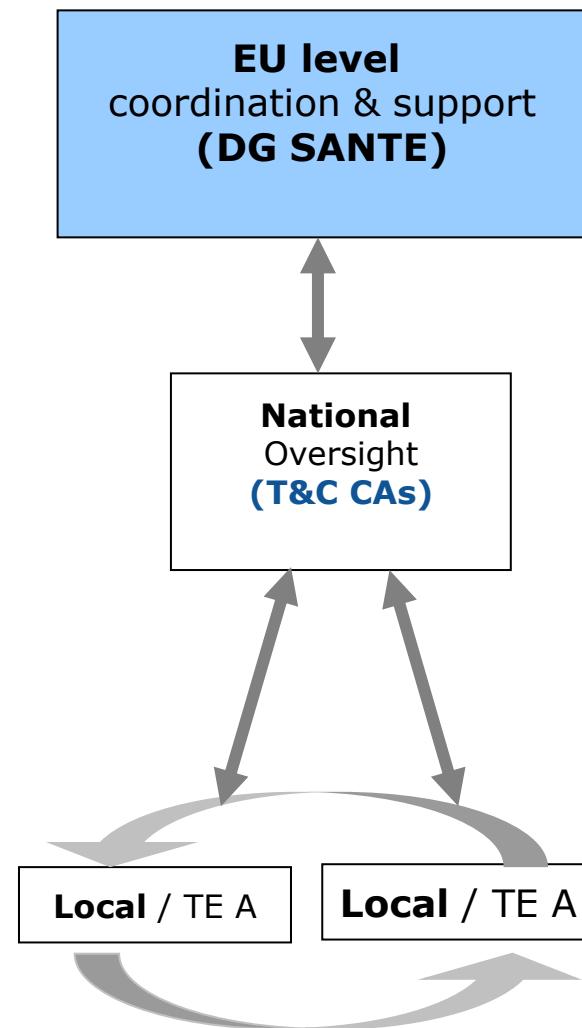
- One of the key elements of the regulatory framework for SoHO

### ➤ **EU legislation on 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

### ➤ **European Commission** – provides support for the development of SoHO vigilance at EU level

- EU vigilance mandate is limited and complementary to national systems
- Annual SARE report, CA meetings, rapid alert platform

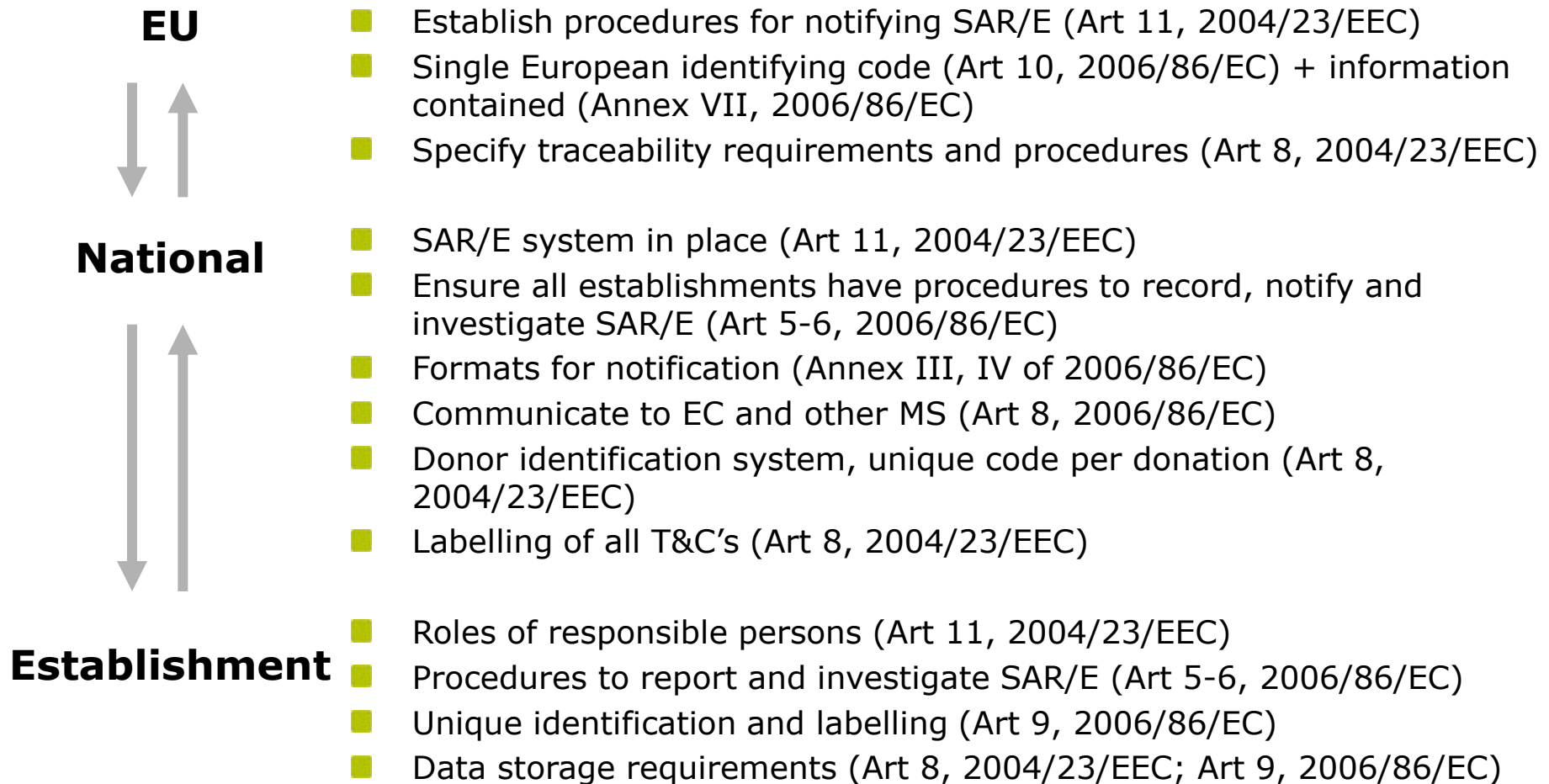




## 2. EU legal framework



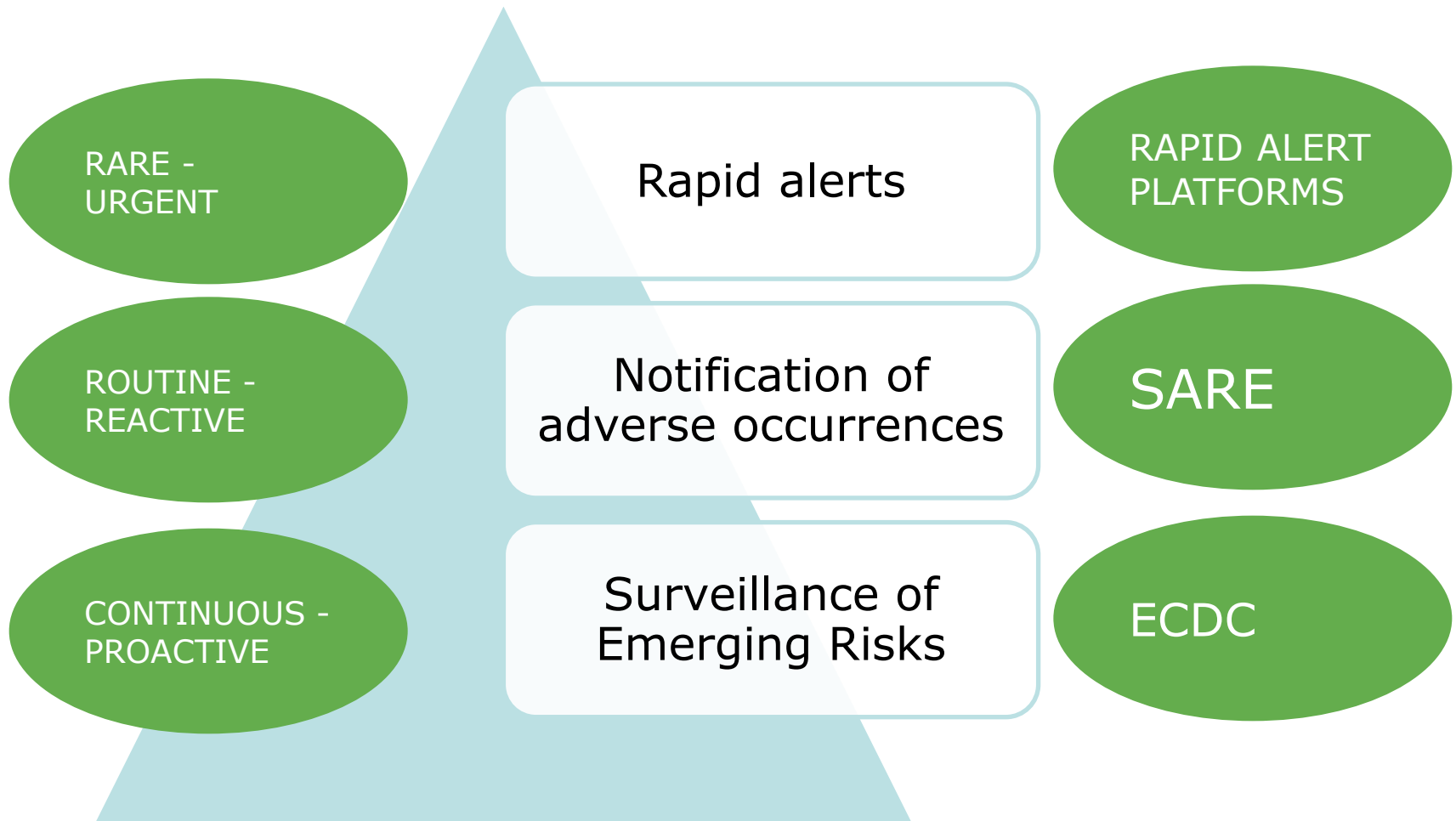
### Vigilance: EU requirements links three levels



### 3. Functioning of TC Vigilance system



## Supporting vigilance

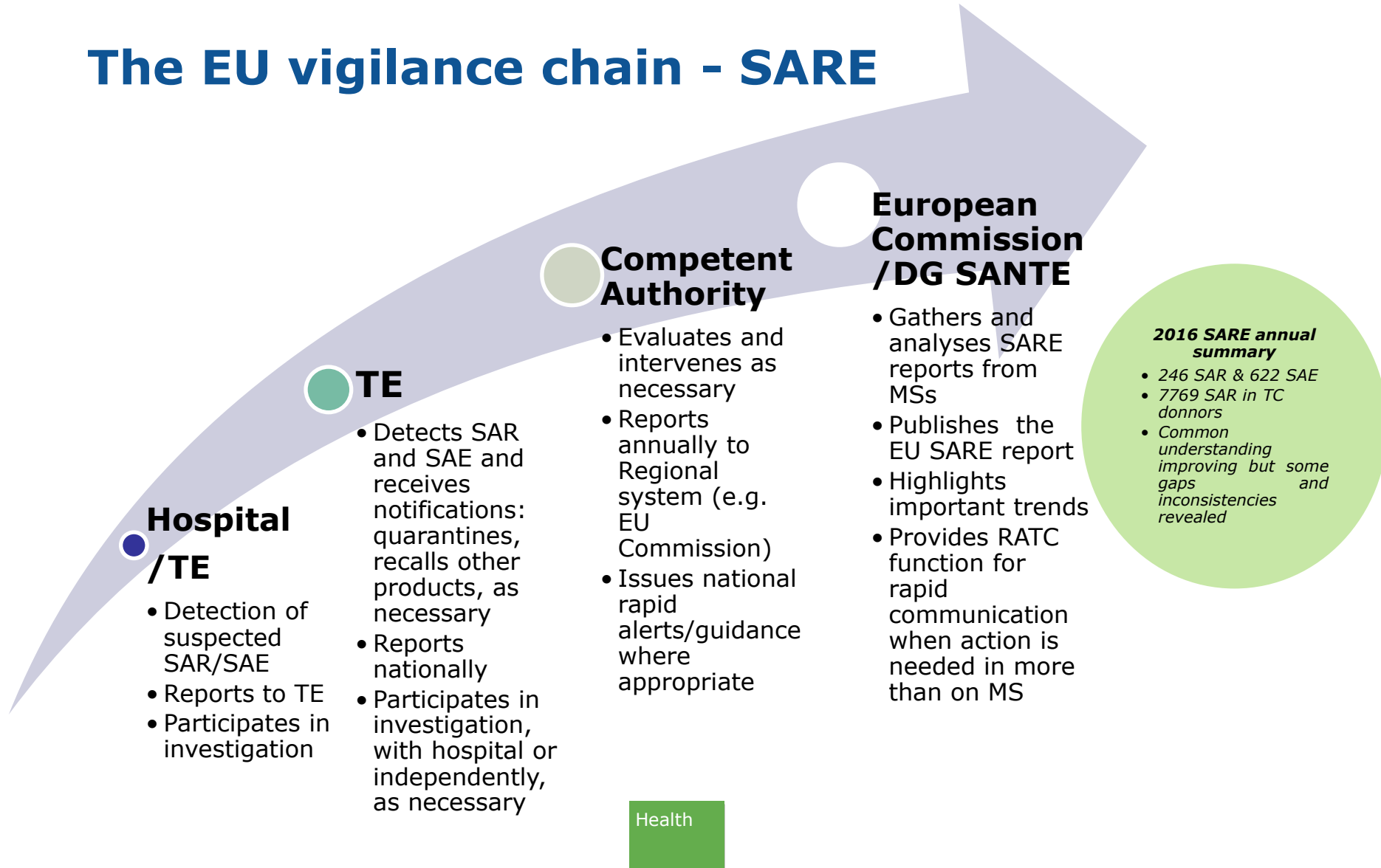


### 3. Functioning of TC Vigilance system



**SARE**

## The EU vigilance chain - SARE



# Aims and challenges

## ❖ Data Collection – feasible, accurate, complete



- Need to agree upon and work with agreed definitions and denominators
- Limited and easy input of data (user-friendly template)

## ❖ Analysis - comprehensive and simple

- Well structured
- Identify potential issues relevant at EU level

## ❖ Feedback to MS/Publication of results



- Aggregated data
- Suggest recommendations for future actions to improve safety and quality in SoHO fields

## WHO Notify library

- a global collection of analysed adverse occurrences
- Important information for investigation



*EU funded projects supported the development of vigilance of TC at EU level – EUSTITE and SoHO V&S*

### 3. Functioning of T&C Vigilance system



RATC



#### Rapid Alert for Tissues & Cells (RATC)

- Secure alert platform launched by the European Commission on 1 February 2013
- **Aim:** to connect Member States in the case of
  - SARE with potential cross border impact
  - Transmissible disease outbreaks
  - Information notices, in case of problems with devices, tests, etc.by insuring timely exchange of urgent information
- **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.
- RATC should work **in parallel with existing national vigilance systems** which collect and manage alerts on tissues and cells donated and used within a Member State.

## 4. Way forward



- **Existing Vigilance instruments** - BTC Evaluation highlights shortcomings
- **Strengthening Vigilance** in the field of SoHO across the EU. Ongoing activities:
  - **BTC evaluation** → possible revision of BTC legislative framework
  - **Vigilance expert sub-group** at the EU level
  - Other: Collaboration with EDQM and ECDC, Joint action (e.g. Vistart): recommendation and follow up

## 4. Way forward



### BTC Evaluation – legal requirements on Vigilance under evaluation

- The purpose of the evaluation - to provide a comprehensive assessment of the directives, examining their **functioning across the EU**
- The evaluation to assess the extent to which the Directives have met their **original objectives** and if they remain **fit for purpose**.
- The evaluation is expected to provide a sound **evidence base** which will be used to consider the need for any changes to the legislation.

#### Key elements

(Estimated timing)

Roadmap consultation

Q1 2017

Public consultation

Q2-3 2017

External contract

Q2 2017 – Q2 2018

Commission report (SWD)

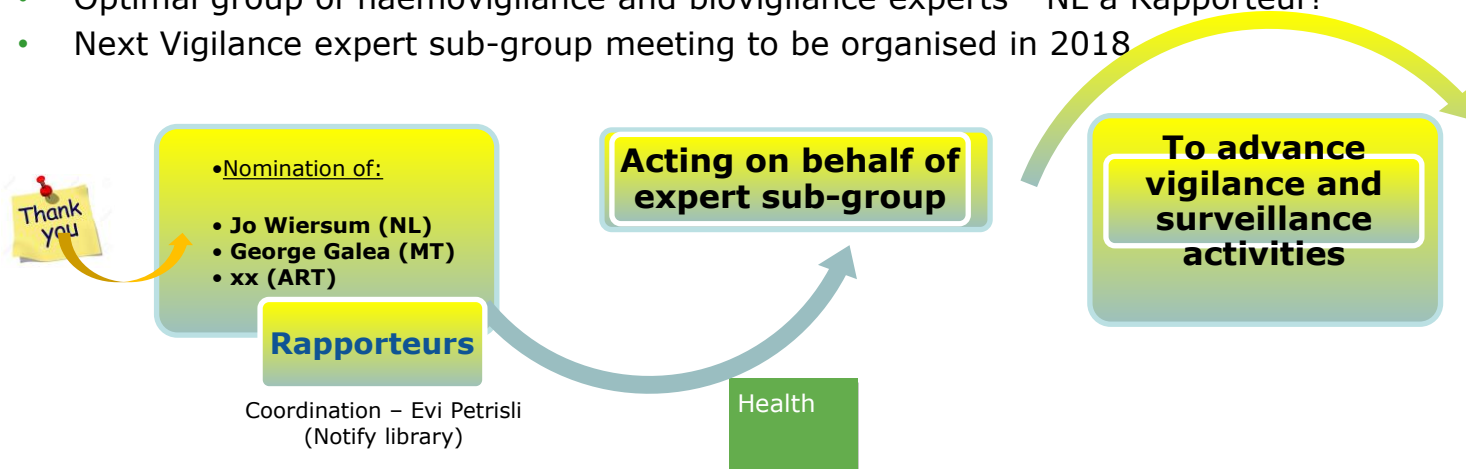
Q4 2018

## 4. Way forward



### Vigilance expert sub-group

- **Vigilance expert sub-group**
  - established in January 2017 under the CASoHO Expert Group
  - replaces the Haemovigilance Working Group
  - remit of the previous sub-group extended (covers Blood and TC)
- **Objective → to provide technical expertise to the Commission:**
  - To facilitate conduct of annual reporting by Member States on SARE associated with Blood and TC, the improvement of the Common Approach document and on the analysis and publication of annual summaries
  - To facilitate functioning of the RAB and RATC
  - To facilitate other vigilance and surveillance activities
- **20 countries** nominated 39 experts
  - Optimal group of haemovigilance and biovigilance experts - NL a Rapporteur!
  - Next Vigilance expert sub-group meeting to be organised in 2018







# Bedankt!

Ingrida Pucinskaite-Kubik  
European Commission  
DG Health and Food Safety  
Unit B4 - SoHO team  
[Ingrida.pucinskaite-kubik@ec.europa.eu](mailto:Ingrida.pucinskaite-kubik@ec.europa.eu)