

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

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European Commission Health and Food Safety Directorate-General Unit B4 – Medical products: quality, safety, innovation **22 November 2017, TRIP Biovigilance Symposium - Rotterdam**

Health



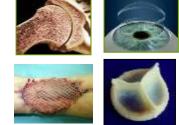


- 1. Background
- 2. EU legal framework Vigilance requirements
- 3. Functioning of T&C Vigilance system
- 4. Way forward

1. Background EU Tissues and cells sector

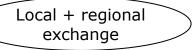


3 sub-sectors



Replacement tissues

- Bone
- Ocular tissue
- Skin
- Cardiovascular tissues



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

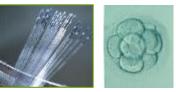


Haematopoietic stem cells

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



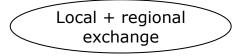
> 30,000 units distributed
for transplantation/year**



ART sector*

Reproductive cells and tissues

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



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

3

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

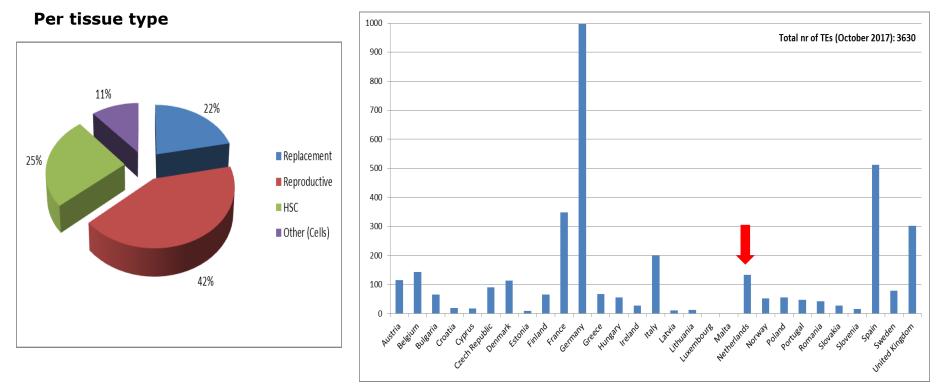
*ART = assisted reproductive technologies ** Partial data

1. Background EU Tissues and cells sector



Establishments and Authorities

Tissue establishments: 3630

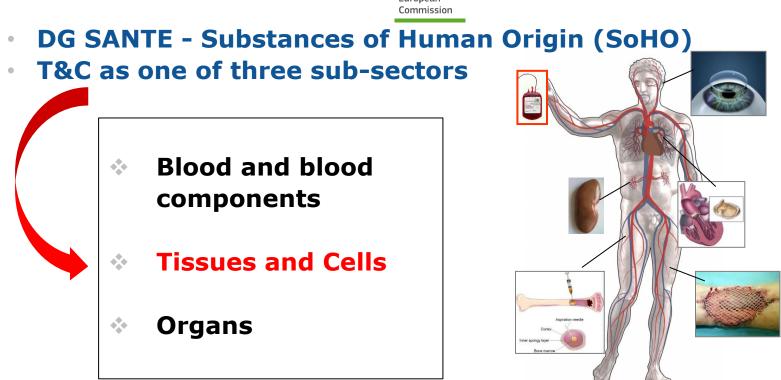


Per country

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



Substances of Human Origin (SoHO)



- 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



Commission

TC legislation

EU Tissues and Cells Legislation

2004

Main Act 2004/23/EC

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

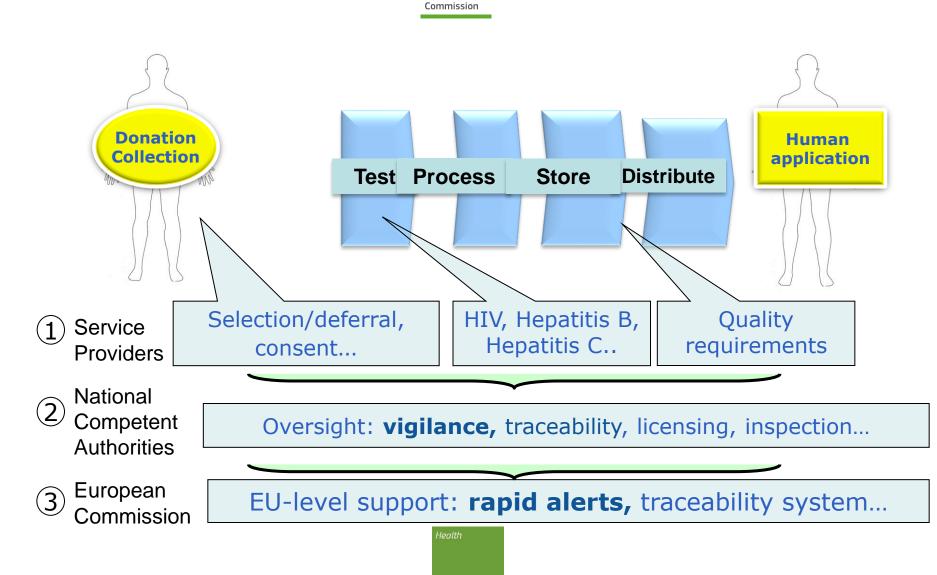


Implementing Directives:

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: 2015/565 → technical requirements for coding



3 levels of **requirements**

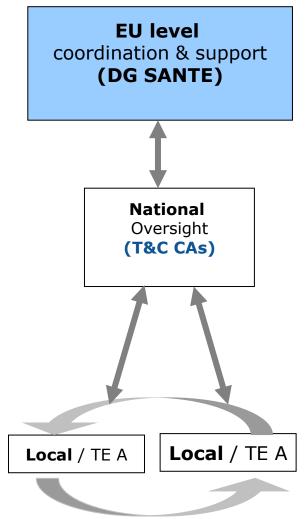




Vigilance

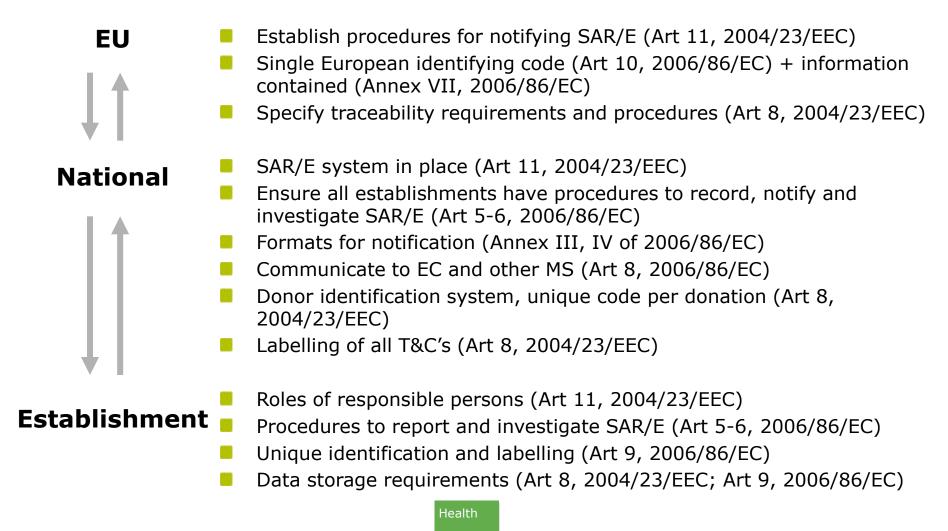
Vigilance

- 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





Vigilance: EU requirements links three levels





RAPID ALERT RARE -Rapid alerts **PLATFORMS** URGENT Notification of SARE **ROUTINE -**REACTIVE adverse occurrences Surveillance of **CONTINUOUS** -ECDC **Emerging Risks** PROACTIVE

Hospital

• Detection of

Reports to TE

Participates in

investigation

suspected

SAR/SAE

/TE



SARE

The EU vigilance chain - SARE

- TE
 - Detects SAR and SAE and receives notifications: quarantines, recalls other products, as necessary
 - Reports
 nationally
 - Participates in investigation, with hospital or independently, as necessary

Competent Authority

- Evaluates and intervenes as necessary
- Reports annually to Regional system (e.g. EU
- Commission)
- Issues national rapid alerts/guidance where appropriate

European Commission /DG SANTE

- Gathers and analyses SARE reports from MSs
- Publishes the EU SARE report
- Highlights important trends
- Provides RATC function for rapid communication when action is needed in more than on MS

2016 SARE annual summary

- 246 SAR & 622 SAE
- 7769 SAR in TC donnors
- Common understanding improving but some gaps and inconsistencies revealed



SARE Reporting

Aims and challenges

Data Collection – feasible, accurate, complete

- Need to agree upon and <u>work</u> 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

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

WHO Notify library

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

Earthorne		
_	DG Health and Food Safety > Public health > Blood, tissues and urgans > Nev documents	
	SUES AND ORGANS	Search Search
All topics	Policy Blood Tissues and cells Organs Indicators Projects	
Cobacil to Blood, Br	sees and organs > Kay documents	
8		
Blood - Legis	lation and guidelines	State of Health
Blood - Report	ts on implementation	• 📀 in the EU 💧 🕤
Blood - Other	key documents	
Crgans - Legi	slation and guidelines	AMR
Crgans - Rep	orts on implementation	Anterioretical Resistance >
Organs - Othe	r key documents	
Tissues and o	ells - Legislation and guidelines	e-newsletter 12 January 29
Tissues and o	ells - Other key documents	Special Edition - Scientific Committees
Tissues and o	ells - Reports on implementation	Latest updates
> 12 October 2016		COM(2016) 809 - Report from the Commission on the
in 2014) 🔊 🥧	e 2015 annual reporting of serious adverse reactions and events for tissues and cells	(data collected implementation of Directive 201053/EU on standards of quality and safety of human organs intended for transplantation (2) - Released 9 January 2017
> 31 May 2016	sual summary of activity	SWD(2010-451 - Commission Staff Working Document or

Health







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.





- Existing Vigilance instruments BTC Evaluation highlights shortcommings
- 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





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 \rightarrow 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!

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