Haemovigilance in Europe: What do health authorities expect from haemovigilance?

Deirdre Fehily

Substances of Human Origin Team

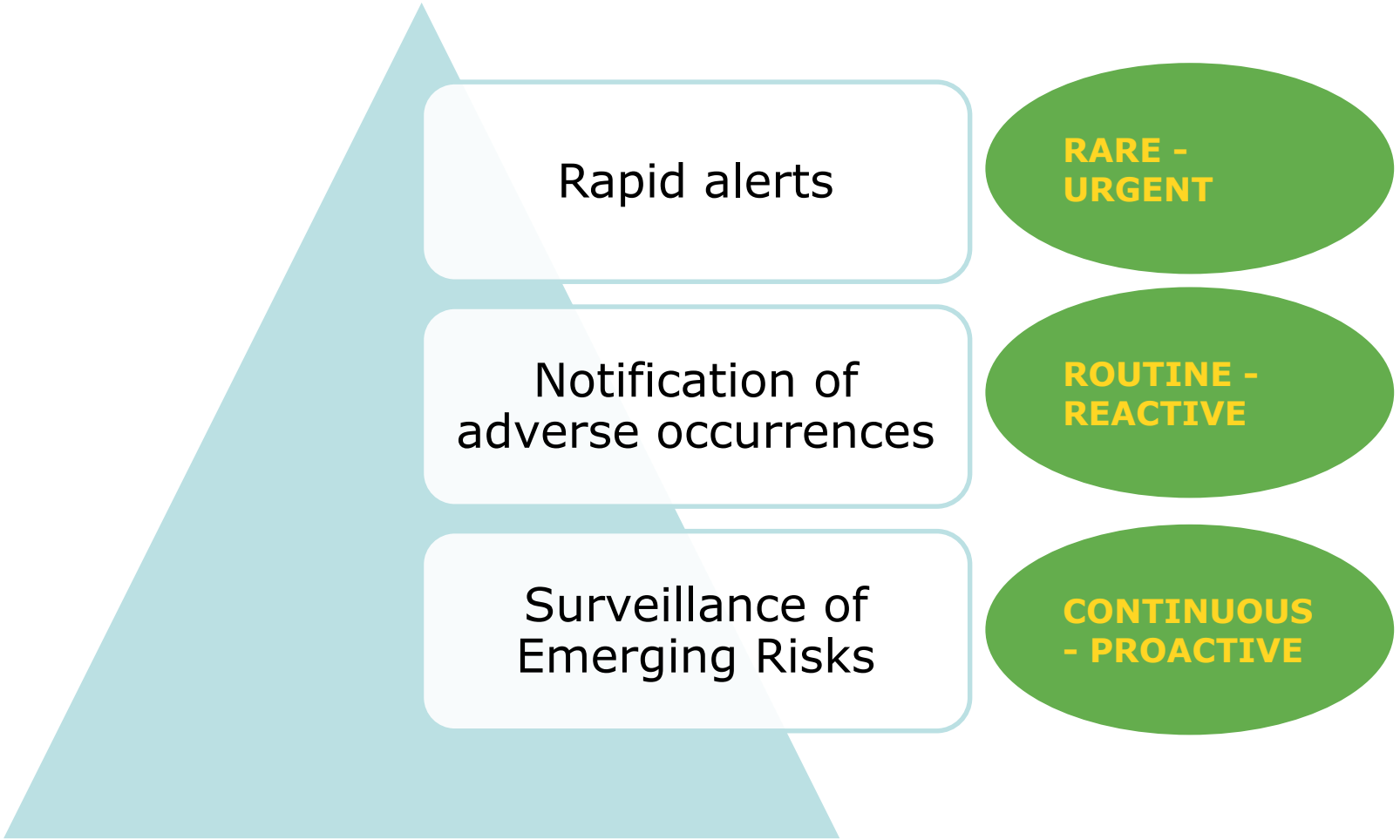
Directorate General for Health and Food Safety

Unit B4 – Health Products: quality, safety and innovation

European Commission

Health

Vigilance and Surveillance Pyramid



The Vigilance Reporting Chain

European Commission

Hospital/BE

- Detection of suspected SAR/SAE
- Reports to BB/BE
- Participates in investigation

BE

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

National Health Authority

- Receives notifications, evaluates and intervenes as necessary
- Reports annually to Regional system where relevant (e.g. EU Commission in EU)
- Issues national rapid alerts/guidance where appropriate

International Bodies

- Gathers and analyses cumulative SARE reports from individual countries
- Publishes cumulative report
- Highlights important trends
- Intervenes as appropriate
- Issues international rapid alerts when appropriate

EU Legal framework

SARE Reporting

- Directive **2002/98/EC**: definitions in Article 3 (Serious Adverse Reaction, Serious Adverse Event, Haemovigilance), notification requirements in Article 15.

- Directive **2005/61/EC**: more detailed requirements including that the Member States shall submit to the Commission an annual report, by 30 June of the following year, on the notification of serious adverse events and reactions received by the competent authority.

- Reporting to the Commission started in 2008, collecting data from the previous year.

- Templates in Part D of Annex II and Part C of Annex III of Directive 2005/61/EC have to be used.

SARE Reporting

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

Common Approach

Reporting Template

European Commission

Ref. Ares(2014)4023682 - 02/12/2014

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL
Directorate D - Health systems and products
D4 – Substances of Human Origin and Tobacco Control

Brussels, 2014
SANCO/D4/IH

COMMON APPROACH
FOR DEFINITION OF REPORTABLE SERIOUS ADVERSE EVENTS AND REACTIONS
AS LAID DOWN IN THE DIRECTIVE 2002/98/EC[1] *(THE BLOOD DIRECTIVE)*
AND COMMISSION DIRECTIVE 2005/61/EC[2]
VERSION 5 (2014)

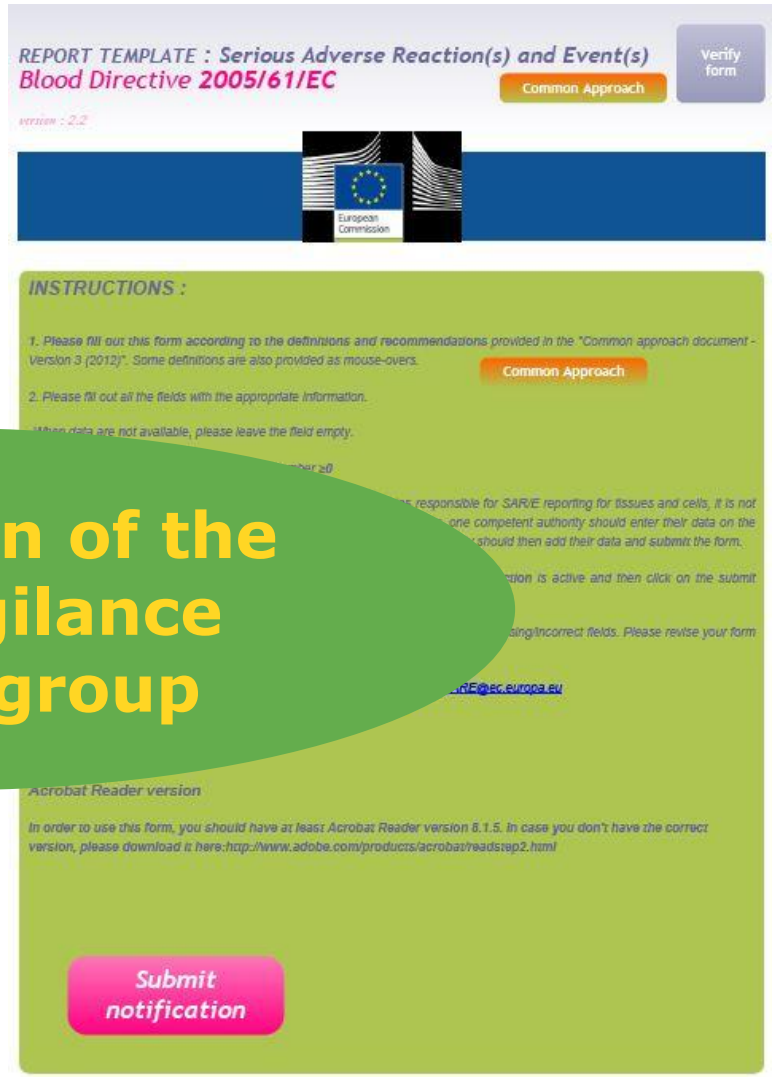
Article 8 of Directive 2005/61/EC provides that *"Member States shall ... Commission an annual report, by 30 June of the following ... serious adverse events and reactions received ... formats in Part D of Annex II and Part C of ...*

However, precisely which serious ... notified to the Commission ma... Commission and Member Sta... authorities for blood and blood ... scope and definitions of the se... intended to inform the first annual ...

End of 2007, the Commission convened ... initial common approach was laid down. Sinc... experts have taken place, and the current documen... meetings. These include:

- Meeting of national experts (19 December 2007),
- Working Group on "Common approach for definition of reportable serious adverse events and reactions Blood and blood components Directive 2002/98/EC and Commission directive 2005/61/EC" (29 April 2009),

[1] Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ L 33, 8.2.2003, p. 30).
[2] Commission Directive 2005/61/EC implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events (OJ L 256,1,10, 2005, p.32).
[3] DG Health and Consumers (DG SANCO). Summary report of the meeting of competent authorities for blood and blood components. Brussels: DG SANCO; 2007. http://ec.europa.eu/health/ph_threats/human_substance/documents/blood_mi_20071018_en.pdf (accessed 26 March 2013).



Contribution of the Haemovigilance working group

Health

http://ec.europa.eu/health/blood_tissues_organs/key_documents/

European Commission

European Commission > DG Health and Food Safety > Public health > Blood, tissues and organs > Key documents

BLOOD, TISSUES AND ORGANS

Search

All topics | Policy | Blood | Tissues and cells | Organs | Indicators | Projects

Go back to **Blood, tissues and organs** > Key documents

- **Blood - Legislation and guidelines**
- **Blood - Other key documents**
- **Blood - Reports on implementation**
  - 11 November 2015 — **2014 RAB annual summary of activity**
  - 11 June 2015 — **Summary of the 2014 annual reporting of serious adverse events and reactions for blood and blood components**
  - 15 July 2014 — **Summary of the 2013 annual reporting of serious adverse events and reactions for blood and blood components**

Click here to view the whole list

- **Organs - Legislation and guidelines**
- **Organs - Other key documents**
- **Tissues and cells - Legislation and guidelines**
- **Tissues and cells - Other key documents**
- **Tissues and cells - Reports on implementation**

e-newsletter 25 February 2016

'owards better prevention and management

Latest updates

Summary minutes - Meeting of the Competent Authorities for Tissues and Cells (3-4 December 2015)
Released 03 March 2016

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Highlights

Journalist Workshops on organ donation and transplantation - 5th edition

Related information

Press material | Key documents
Videos | Eurobarometers
Events | Consultations

2014 SARE Report (2013 data)

European Commission

EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY
DIRECTORATE-GENERAL

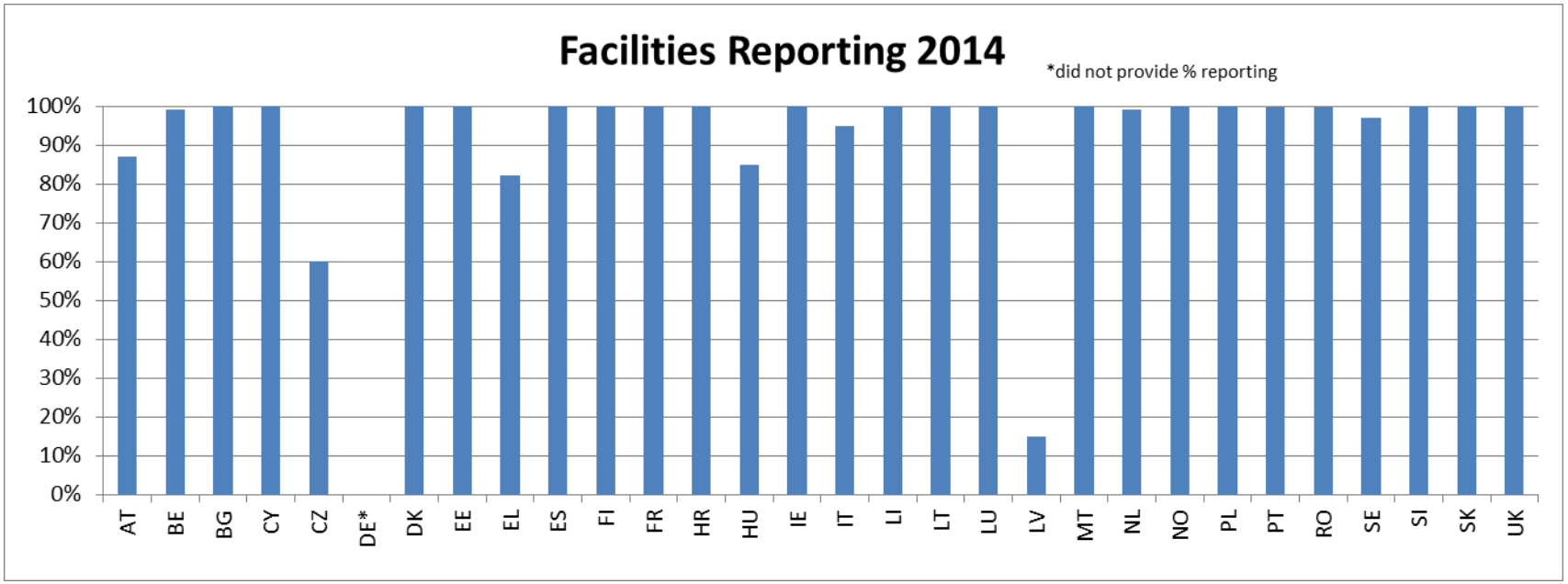
Directorate D - Health systems and products

D4 – Substances of Human Origin and Tobacco Control

Brussels,
SANTE. D4/ IH/ac ARES(2014)

SUMMARY OF THE 2014 ANNUAL REPORTING OF SERIOUS ADVERSE EVENTS AND REACTIONS (SARE) FOR BLOOD AND BLOOD COMPONENTS (DATA COLLECTED FROM 01/01/2013 TO 31/12/2013)

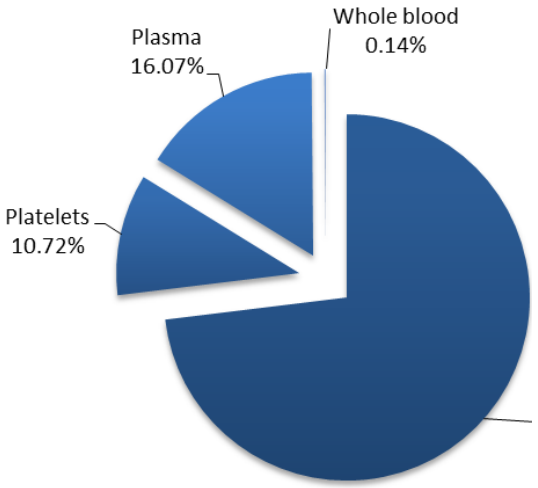
Data Completeness



Denominators

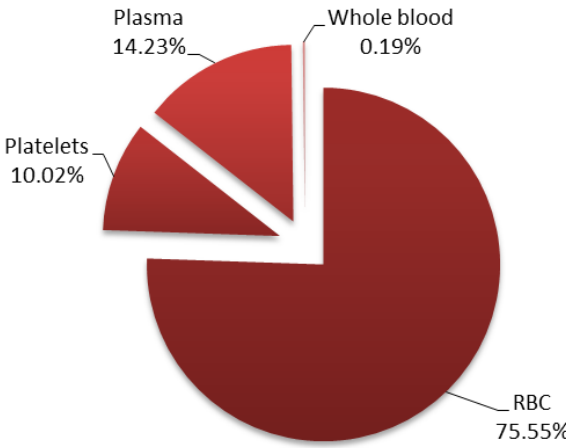
European Commission

Units Issued



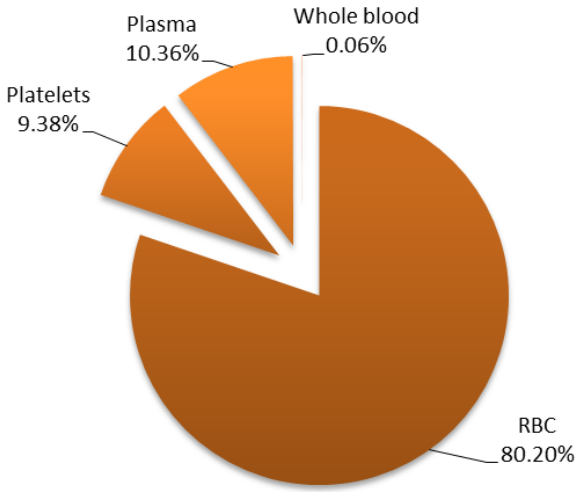
Total (100,000 units)	240.3
Countries reporting	27

Units Transfused



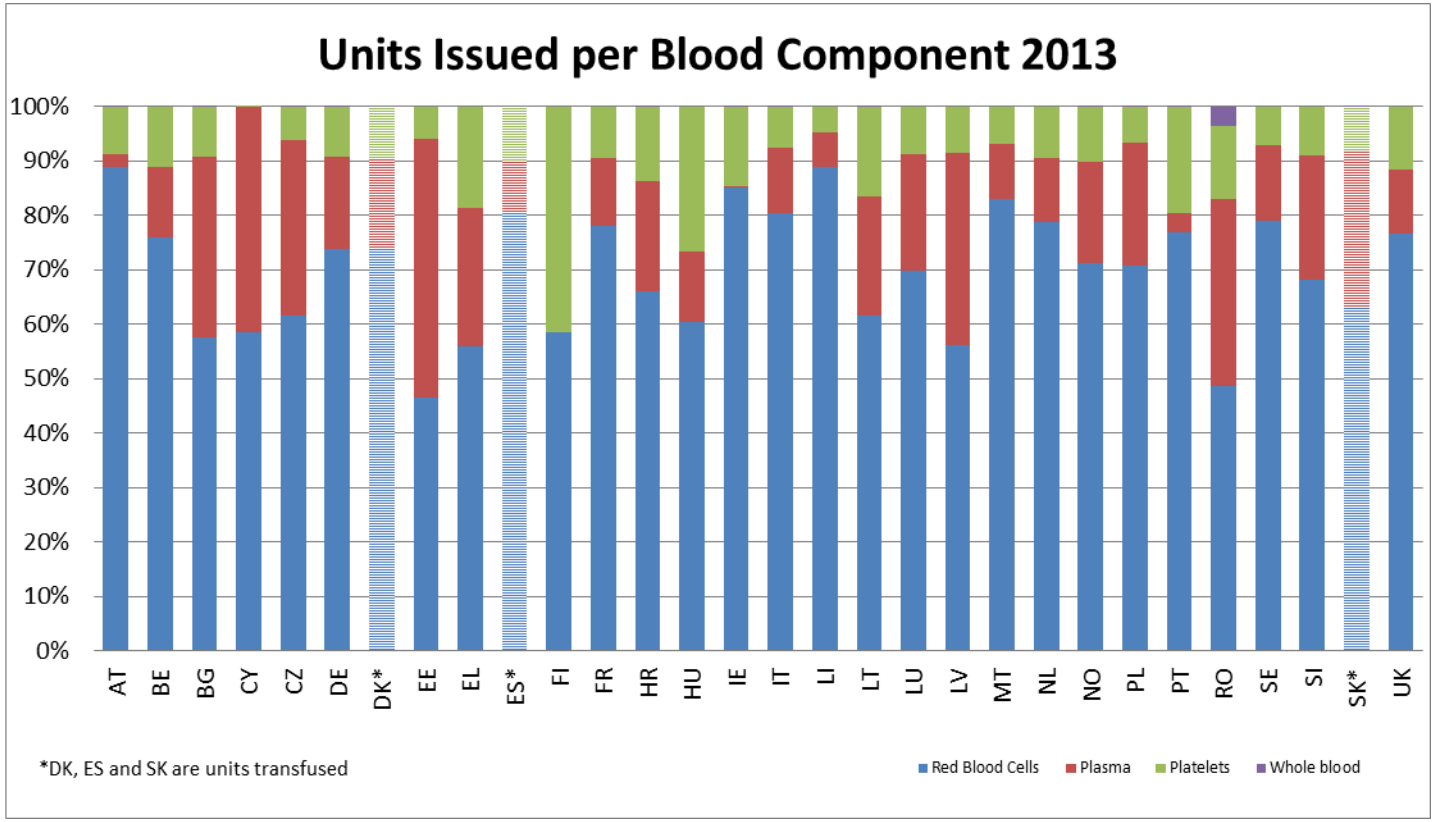
Total (100,000 units)	164.2
Countries reporting	22

Recipients



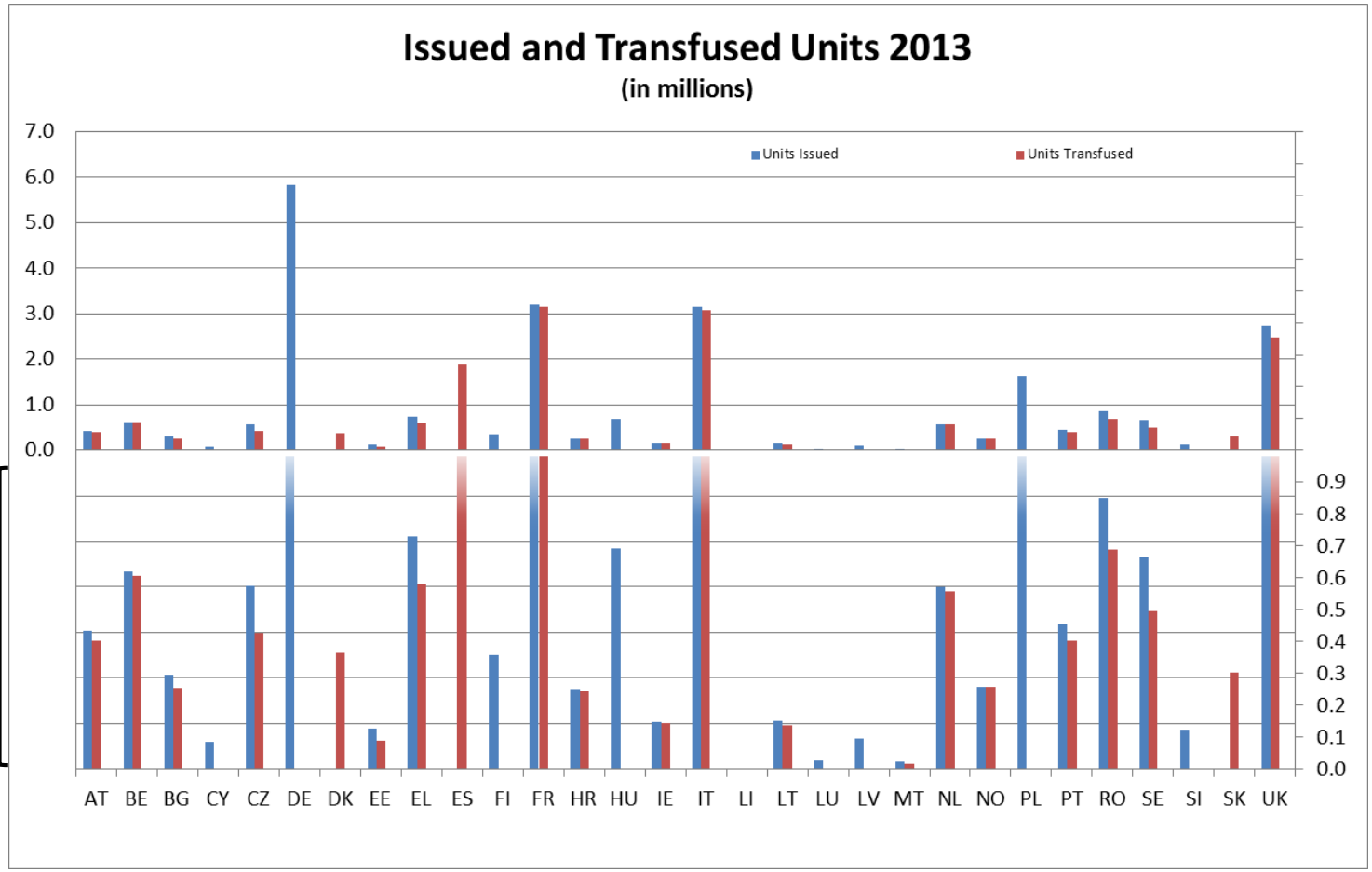
Total (100,000 individuals)	24.9
Countries Reporting (per component)	16

Units Issued per Component



Units Issued and Transfused

European Commission

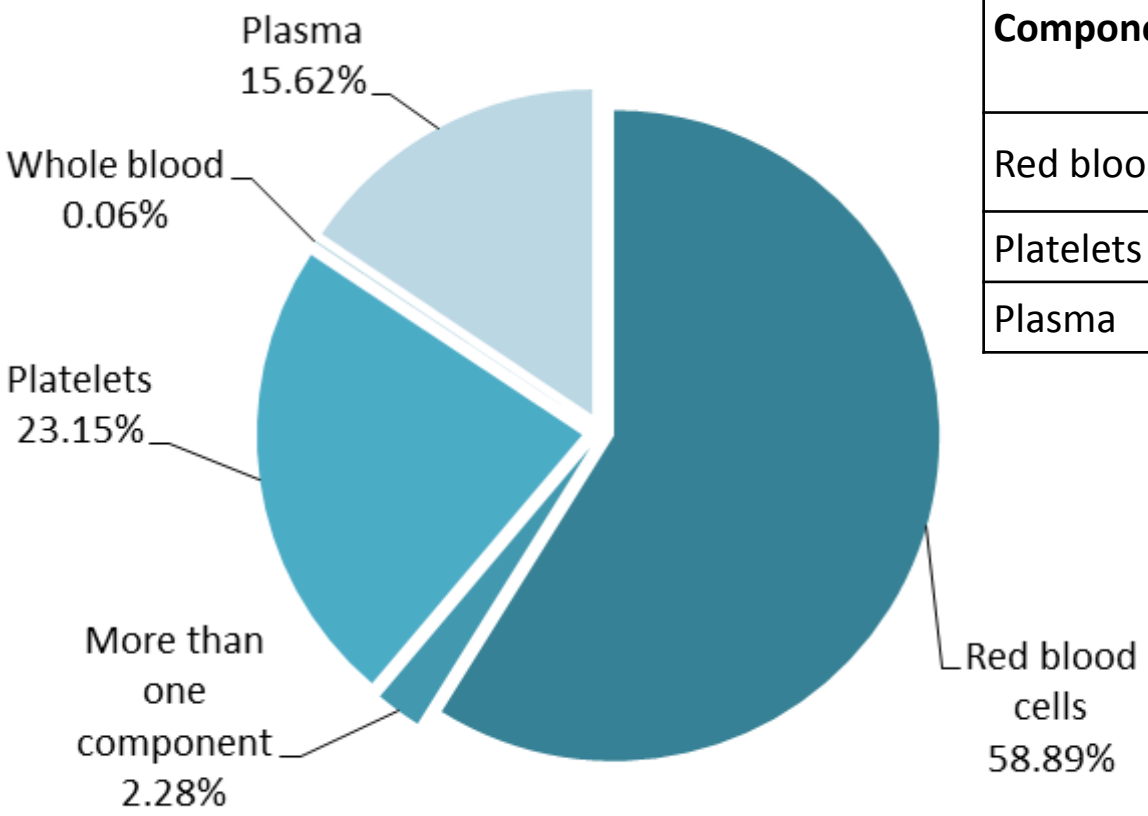


Serious Adverse Reactions - 2013

A total of **1,739 SAR** with a 'likely' or 'certain' attribution to the blood or blood component transfused (Imputability 2 and 3) were reported by the 28 Member States, Liechtenstein and Norway

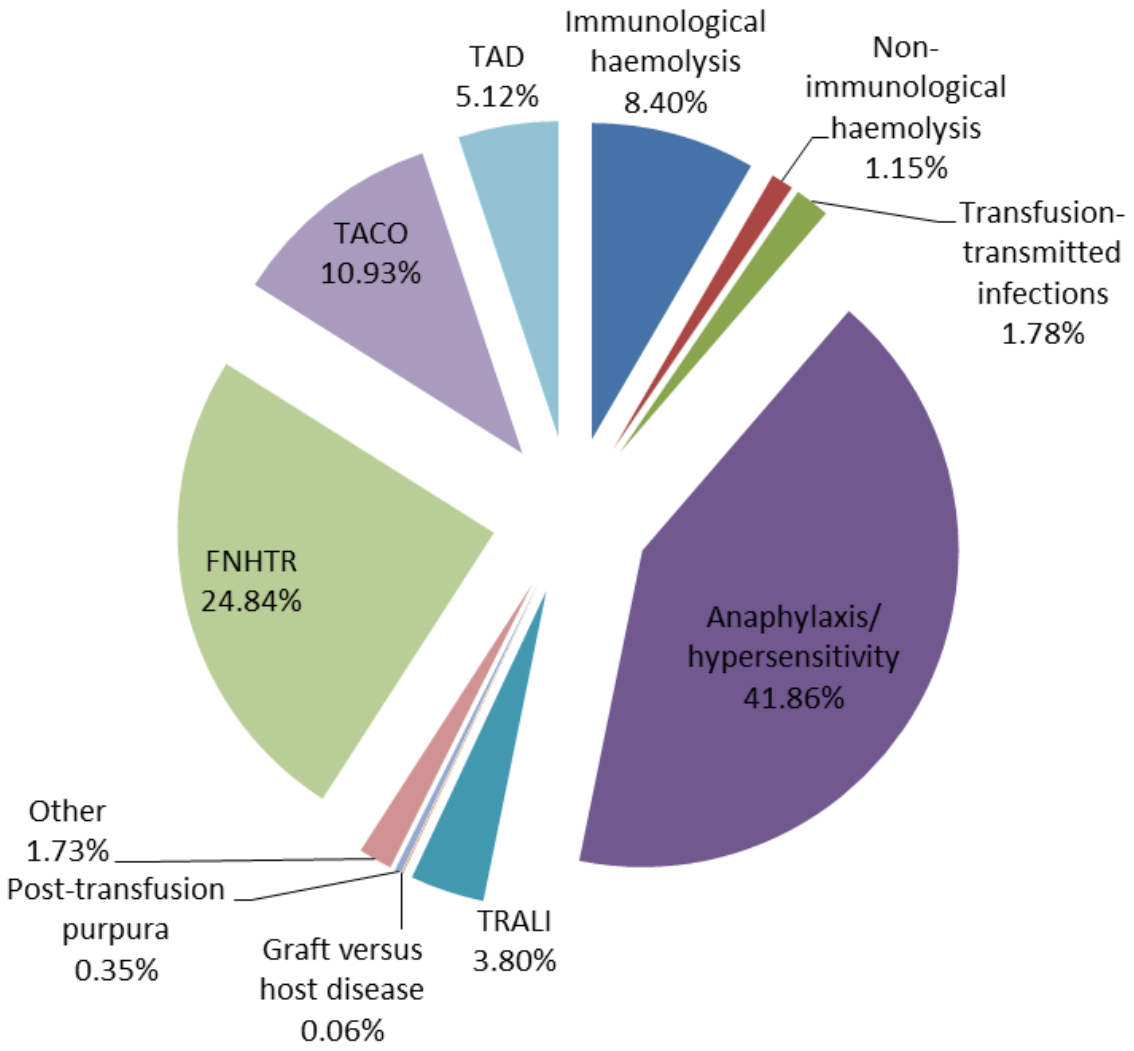
For the **22 countries** that provided data for both the number of SAR and units transfused per blood component, there were **9.8 SAR per 100,000 units transfused**

SAR per Component (imputability level 2-3)



Component	Units transfused SAR^{-1}
Red blood cells	13,118
Platelets	4,428
Plasma	9,319

SAR Types (imputability levels 2-3)



Deaths

(Imputability levels 2-3)

European Commission

22 deaths:

- immunological haemolysis (5)
- non-immunological haemolysis (1)
- bacterial infections (2)
- anaphylaxis (1)
- post-transfusion purpura (1)
- TRALI (5)
- TACO (6)
- Unclassifiable complication of transfusion (1)

SAR in Donors

Voluntary Reporting

26 EU Member States + Norway and Liechtenstein provided data regarding collections in 2013:

15,353,382 whole blood collections

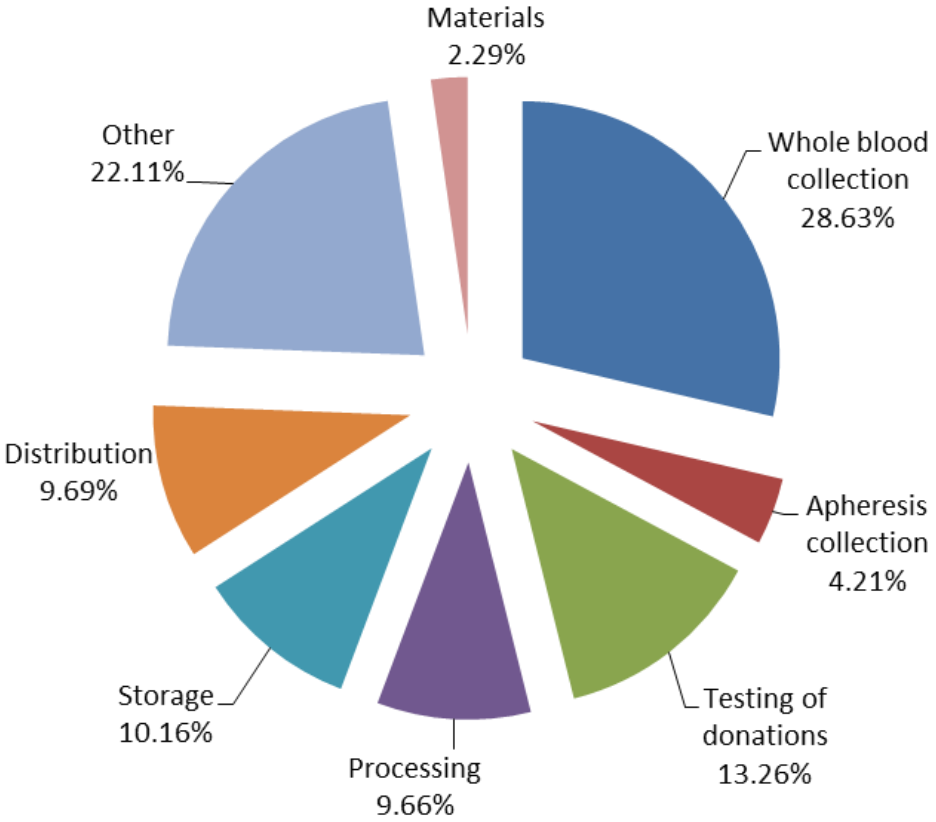
1,596,067 apheresis collections

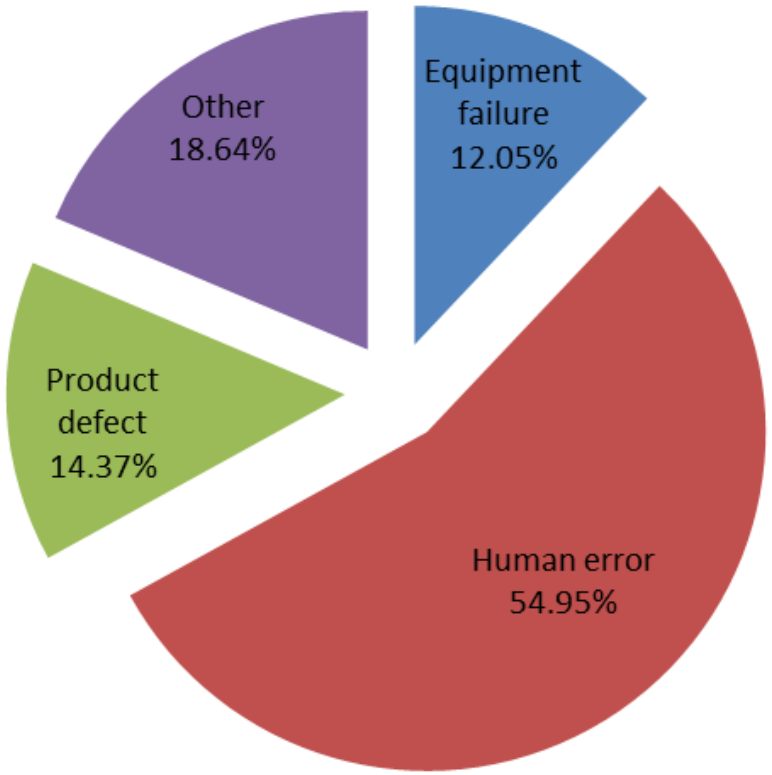
23 countries reported a total of **2,470 SAR** in donors (**14.6 SAR per 100,000 collections** for those countries which reported both SAR in donors and figures on collections)

Additional details: blood vessel injuries, nerve injuries, vasovagal episodes, or cardiovascular reactions.

Serious Adverse Events

2,972 SAE
(7 countries notified no reportable SAEs)





SARE Summary

European Commission

- **Denominators: 24.0 million units issued, reports for 16.6 million units transfused (roughly 75% RBCs, 15% plasma, 10% platelets and <1% WB).**
- **SAR: 1,739 SAR (imputability levels 2-3) and 22 deaths.**
- **SAE: 2,972 SAE reported. About 30% occur during WB collection but 20% still reported as 'other'. Around 55% are reported to be the result of human error.**

Annual Trending

European Commission

	2011		2012		2013		2014	
	Countries reporting	Number	Countries reporting	Number	Countries reporting	Number	Countries reporting	Number
Units issued	26	22817166	29	24821809	27	25129344	27	24043766
Units transfused	19	16718258	17	12311691	20	13351948	22	16564817
Recipients transfused	11	2298304	16	2964839	19	3595155	20	3216938
SAR (2-3)	30	1259	30	1574	30	1831	30	1739
SAR death (2-3)	30	20	30	14	30	22	28	22
SAE	28	16360	25	4113	28	2953	30	2972
SAR in donors					18	2494	23	2470

EU Rapid Alerts for Blood (RAB)

European Commission

Legal framework –

Article 9 of Directive 2005/61/EC

"ensure that their competent authorities communicate to each other such information as is appropriate with regard to serious adverse reactions and events"

RAB aims

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.

RAB should work alongside existing national alerting systems

CIRCA-BC platform - Blood Alerts
(until 02/2014)

European Commission

***Medical devices**:*

- *Automated Blood Collection System (May 2013)*
- *Blood Group System Cassettes (July 2013)*
- *Blood Bags (Sept 2013)*

***Infectious diseases**:*

- *Dengue (August 2013)*
- *West Nile Virus (August to October 2013)*
- *Chikungunya (July-August 2013) - official alert received Jan 2014*

Dedicated SoHO Rapid Alert Platform

European Commission

Rapid Alert for Tissues & Cells (RATC)

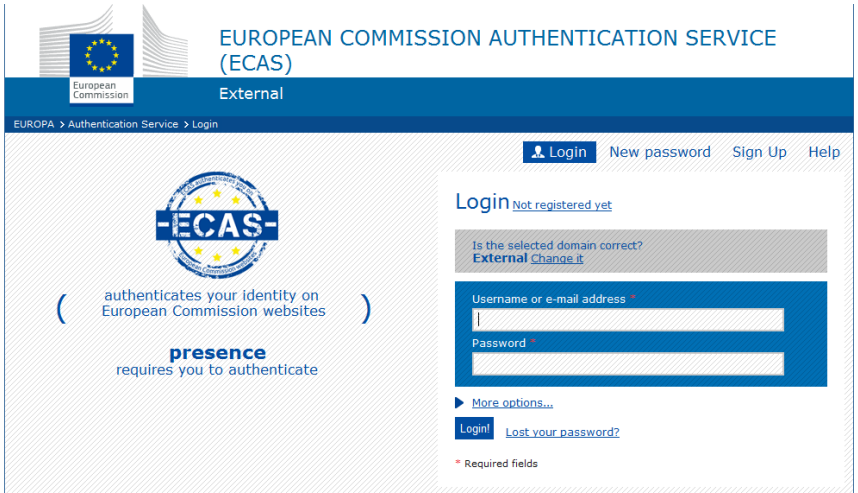
- **Operational since the 1st of February 2013**

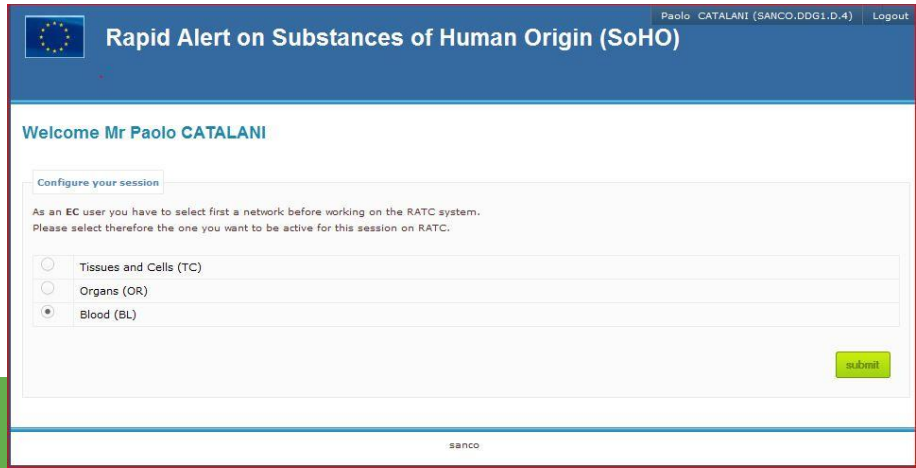
Rapid Alert for Blood and blood components (RAB)

- **Operational since the 6th of February 2014**
- **35 Competent Authorities**
- **SOP and user manual available**
- **First training course 15/01/2014**
- **Thanks to the RAB working group**

The Application

- An "administration" module available for restricted list of users within the official list of Competent Authorities (CA) and members of the European Commission (EC) in order to create, follow-up and consult alerts and final reports
- An alert form and notification process
- A set of notifications/reminders (based on deadlines and specific events)
- A search functionality
- An easy to use and user friendly interface





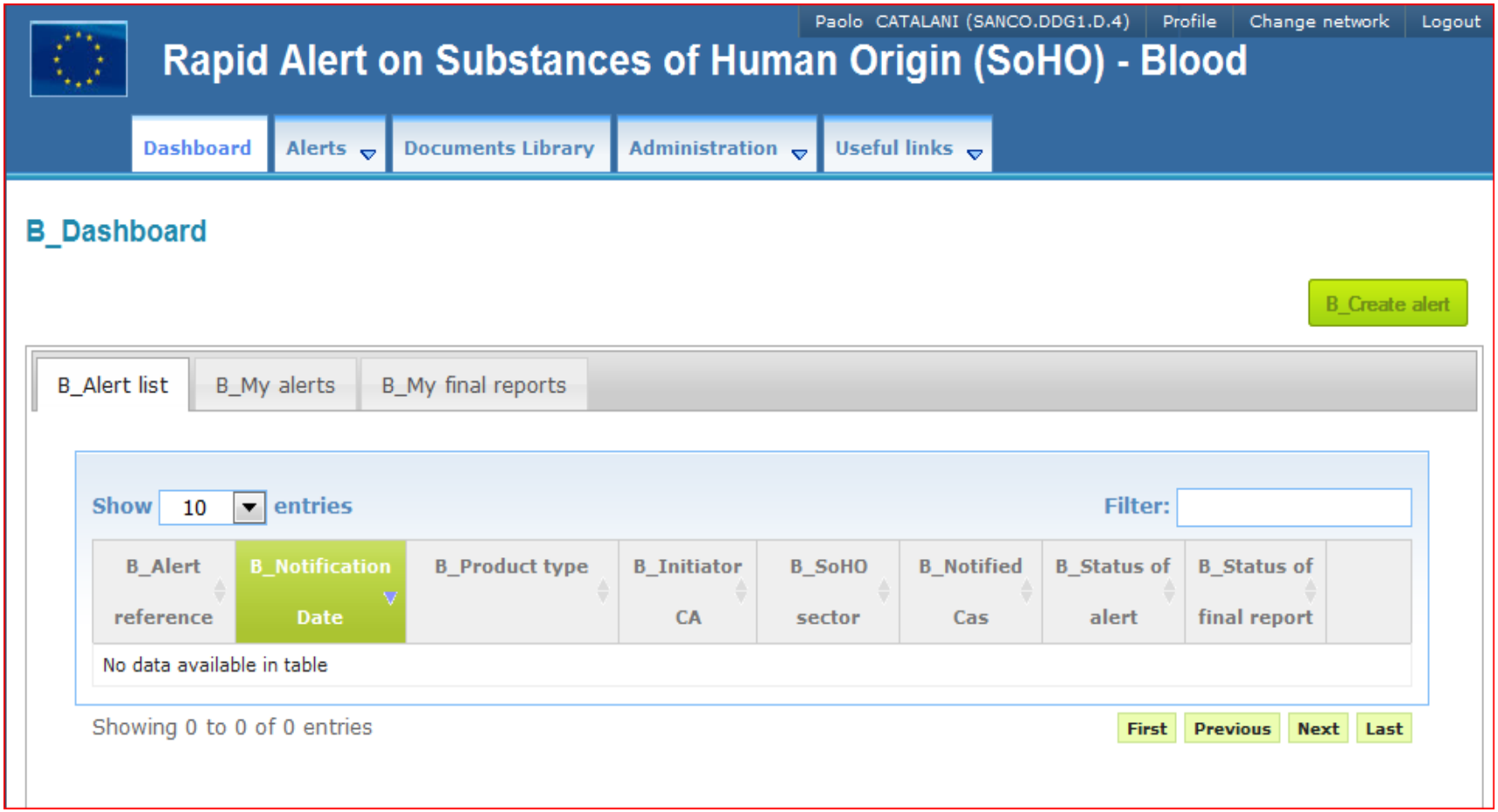
Health

RAB – Key Stakeholders

- **Main stakeholders**
  - **CA** (Competent authorities) *[27 Member States, +- 50* Competent Authorities*]*
  - **EC** (Unit D4 - Substances of human origin and Tobacco control)
- **Other potential stakeholders**
  - Pharmaceutical sector (EMA)
  - Epidemiological sector (ECDC/EWRS contact points)
  - EC (Other SANCO business units: Medical devices, Pharmaceutical, Health threats)
  - WHO
  - Other Network (T&C, Organs)

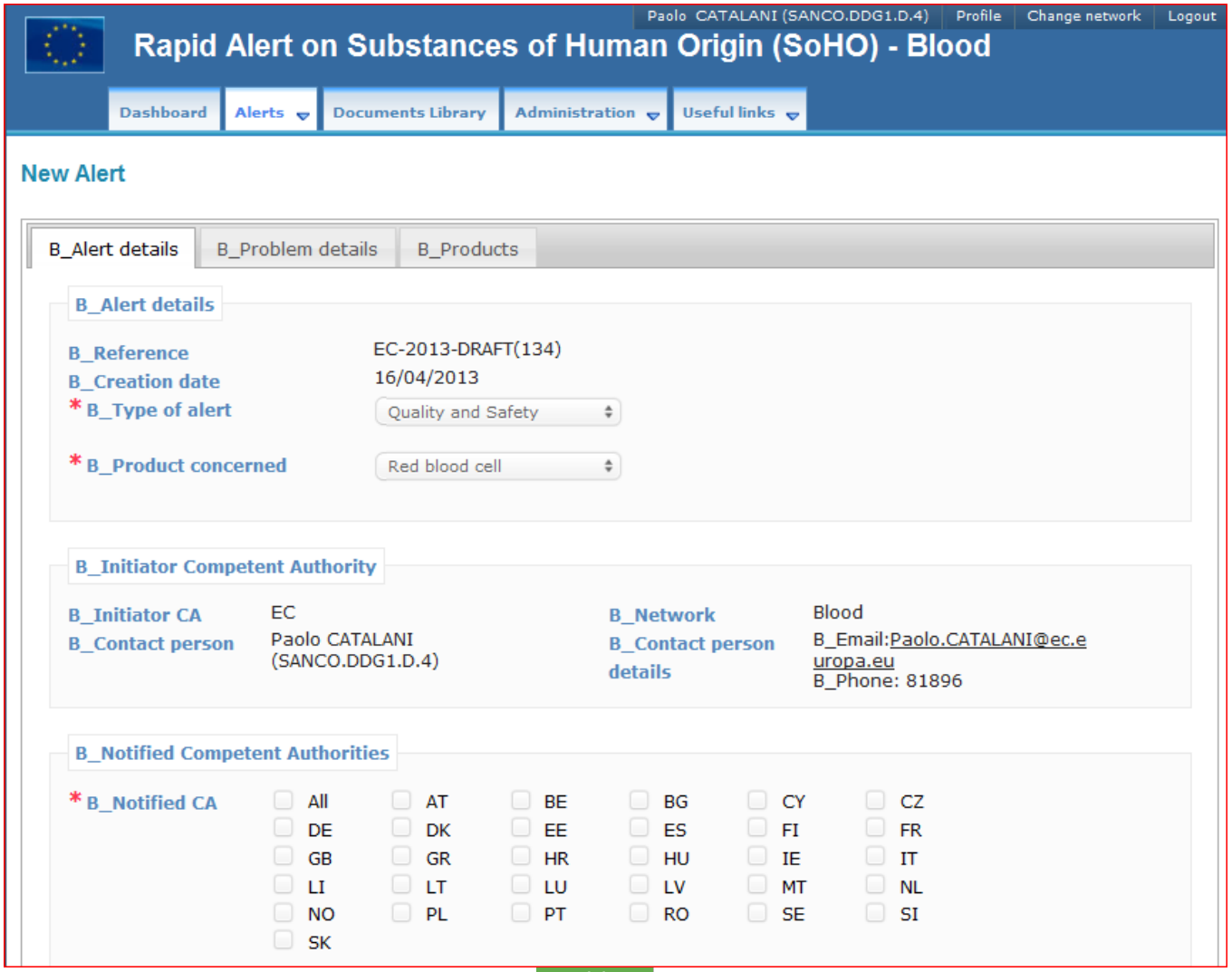
RAB - Dashboard

European Commission



RAB – Creating an Alert

European Commission



RAB Alerts in 2014

European Commission

Epidemiological Notices:

38 alerts launched by 6 Member States on West Nile Virus (Austria, Greece, Hungary, Italy, Romania).

1 alert on Legionnaires disease (Portugal)

Information Notice:

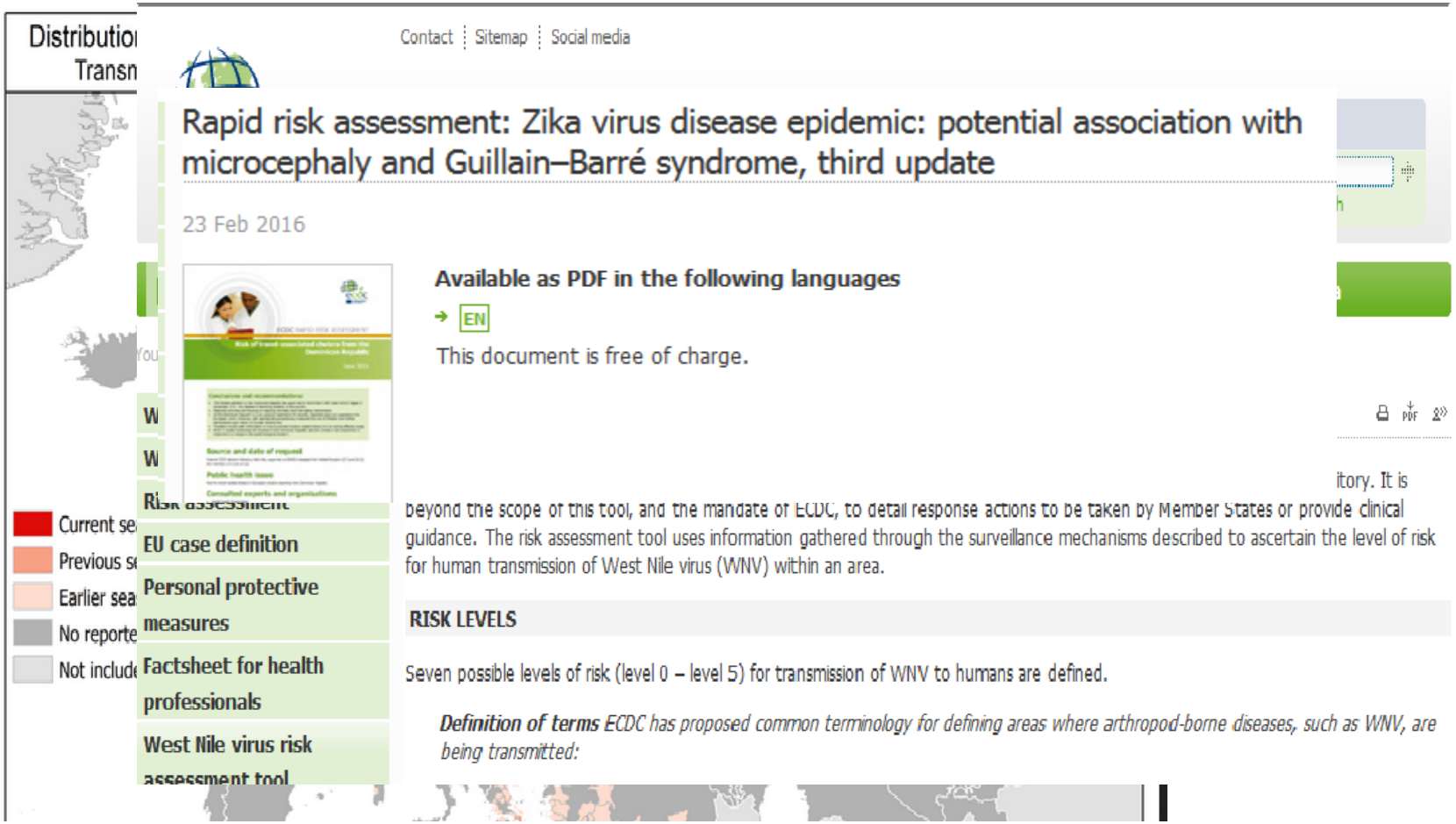
1 alert on contamination during platelet transfusion (Greece)

No **Quality and Safety Defect** alerts and no **Bilateral Communications**

Surveillance for Emerging Risk

European Commission

ECDC Role



EU-funded projects Blood

	Donation	Collection	Testing	Processing	Storage	Distribution	Optimal use	Hemovigilance	Clinicla follow-up	Auditing	Inspection	Economic study
EU-Q-Blood-SOP	■	■	■	■	■	■						
Optimal Blood Use Project							■					
EuBIS											■	
DOMAINE Donor Management in Europe	■											
CATIE Competent Authority, Training of Inspections in Europe, funded by the EC. CfT No. EAHC/2011/Health/13											■	
CREATIV-CEUTICAL STUDY												■
PBM PATIENT BLOOD MANAGEMENT							■		■			
VISTART								■		■	■	

A new Joint Action Started in 2015

Public Health Programme – Work Programme for 2014

2.2.4.2. Strengthening the Member States' capacity of monitoring and control in the field of blood transfusion and tissue and cell transplantation (Point 4.5. of Annex I to the Programme Regulation)

Priorities of the year, objectives pursued and expected results

This action aims to support Member States in their efforts to improve the implementation of the EU requirements for the safety and quality of blood and blood components and tissue and cell products.

Description of the activities to be funded by a grant awarded without a call for proposals on the basis of Article 190(1)(d) of the Rules of Application

This action will promote further cooperation between Member States competent authorities in the area of blood transfusion and tissue and cell transplantation. The action, to be taken forward by national bodies mandated in this field, should build on the outcome of previous EU-funded projects (e.g. EUBIS, CATIE, EUSTITE, SOHO V&S, etc.) and should provide support in various aspects like managing national vigilance systems, traceability and implementation of the Single European Code for tissues and cells, and training of inspectors. Common practical concerns and best practices should be identified, allowing for cross-fertilisation between the transfusion and transplantation sectors.

Implementation

Implementation by the Agency

VISTART

European Commission

European Commission

GENERAL OBJECTIVE OF THE ACTION

The key objectives of the action are to:

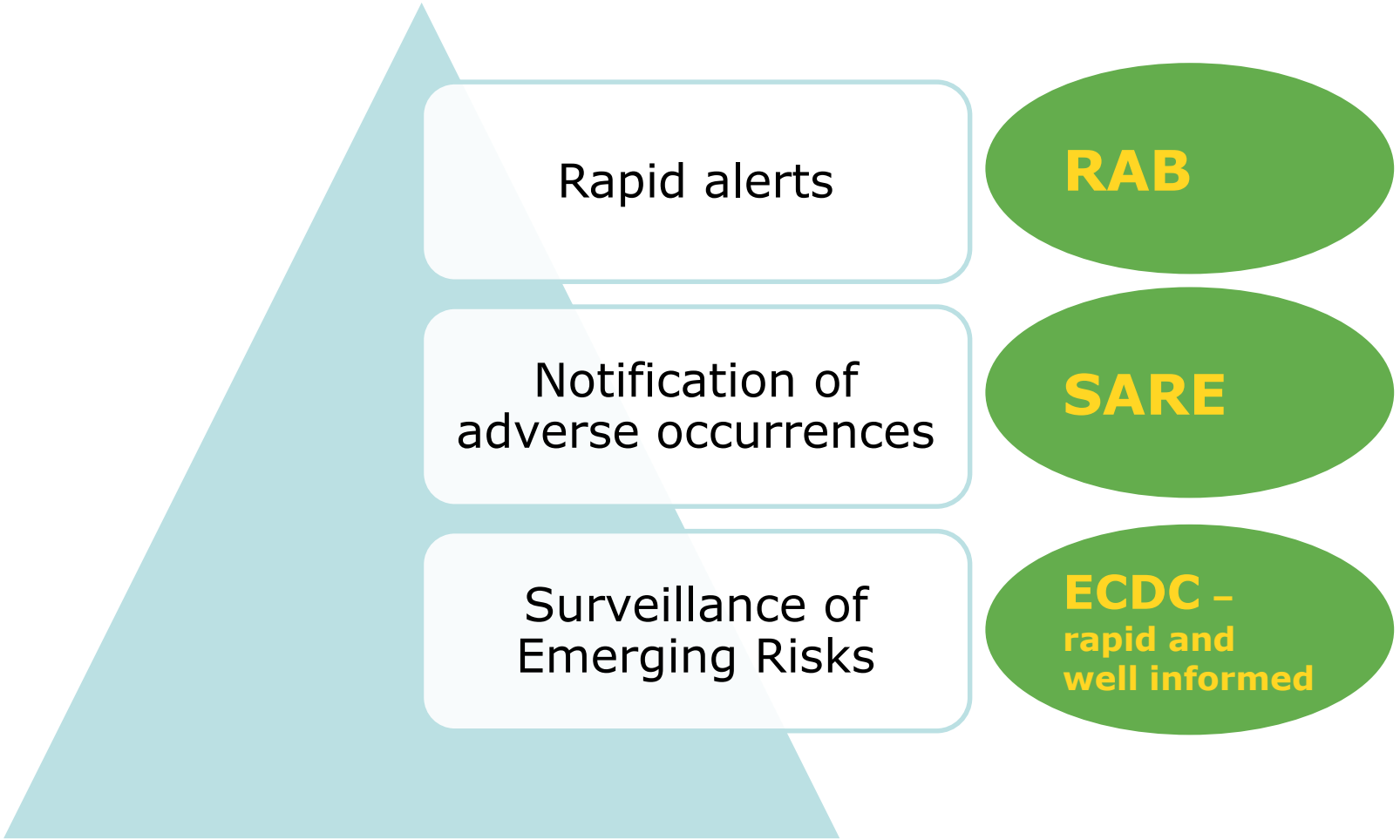
- promote and facilitate harmonisation of inspection, authorisation and vigilance systems for blood, tissues and cells and
- to increase inter-MS collaboration and confidence in each other's inspection and vigilance programmes.

Co-funded by the Health Programme of the European Union

What do Health Authorities expect from haemovigilance

- **Information** on serious adverse events and reactions
  - **Qualitative – what goes wrong?**
  - **Quantitative – how frequently?**
  - **Benchmarking – how does my Member State compare?**
- **Trending** of that information
  - **Are we improving?**
- Good **investigations** and appropriate corrective and preventive actions – feeding standards and legislative provisions
- Good **communication** – particularly when urgent action is needed – limiting the damage
- High quality and timely **information on emerging risks** – actions to mitigate.

EU Haemovigilance Pyramid



Thank you

Health