



46° Convegno Nazionale di Studi di Medicina Trasfusionale

Rimini, 13-15 maggio 2026

The future of transfusion medicine, a European perspective

Pierre Tiberghien

*Etablissement Français du Sang, Paris
Université Marie et Louis Pasteur, Besançon
European Blood Alliance, Bruxelles*

I declare that in carrying out the function stated above at this event, I do not have any personal or third-party commercial interests, and that any relationships that I have had in the last two years with subjects with commercial interests are not such as to influence my function in order to draw any advantage.

Transfusion medicine in Europe: looking back to inform the future

- **Early development of blood transfusion in Europe, early 1900s**
Major scientific discoveries making transfusion feasible, such as:
 - ✓ Discovery of the ABO blood groups by Karl Landsteiner in 1900.
 - ✓ Development of anticoagulation and blood storage techniques during World War I
- **Emergence of a European ethical model following World War II**
Voluntary unpaid blood donation, solidarity, public service values
- **Early harmonization, Council of Europe, 1950s–1960s onward**
Promotion of self-sufficiency in blood products, ethical guidance on donation, quality and safety recommendations, early technical harmonization
- **HIV and hepatitis crises: A turning point, 1980s–1990s**
Thousands of infections and deaths, loss of public trust, legal and political crises, major reforms of blood systems
Strong push that blood transfusion be regulated with standards comparable across Europe
- **The Emergence of European Union public health mandate**
Strengthened by the Treaty of Amsterdam, 1997
- **The EU Blood Directives, 2002 onward**

Transfusion medicine in Europe: looking back to inform the future

- **Early development of blood transfusion in Europe, early 1900s**

Major scientific discoveries making transfusion feasible, such as:

- ✓ Discovery of the ABO blood groups by Karl Landsteiner in 1900.
- ✓ Development of anticoagulation and blood storage techniques during World War I

- **Emergence of a European ethical model following World War II**

Voluntary unpaid blood donation, solidarity, public service values

- **Early harmonization, Council of Europe, 1950s–1960s onward**

Promotion of self-sufficiency in blood products, ethical guidance on donation, quality and safety recommendations, early technical harmonization

- **HIV and hepatitis crises: A turning point, 1980s–1990s**

Thousands of infections and deaths, loss of public trust, legal and political crises, major reforms of blood systems

Strong push that blood transfusion be regulated

- **The Emergence of European Union public health**

Strengthened by the Treaty of Amsterdam, 1997

- **The EU Blood Directives, 2002 onward**

Creation of the **European Blood Alliance** in 1998

- **To strengthen cooperation** between European **not-for-profit blood services** at a time when Europe was moving toward **greater regulatory harmonisation** and **increasing expectations** regarding **blood safety, quality, and self-sufficiency**



































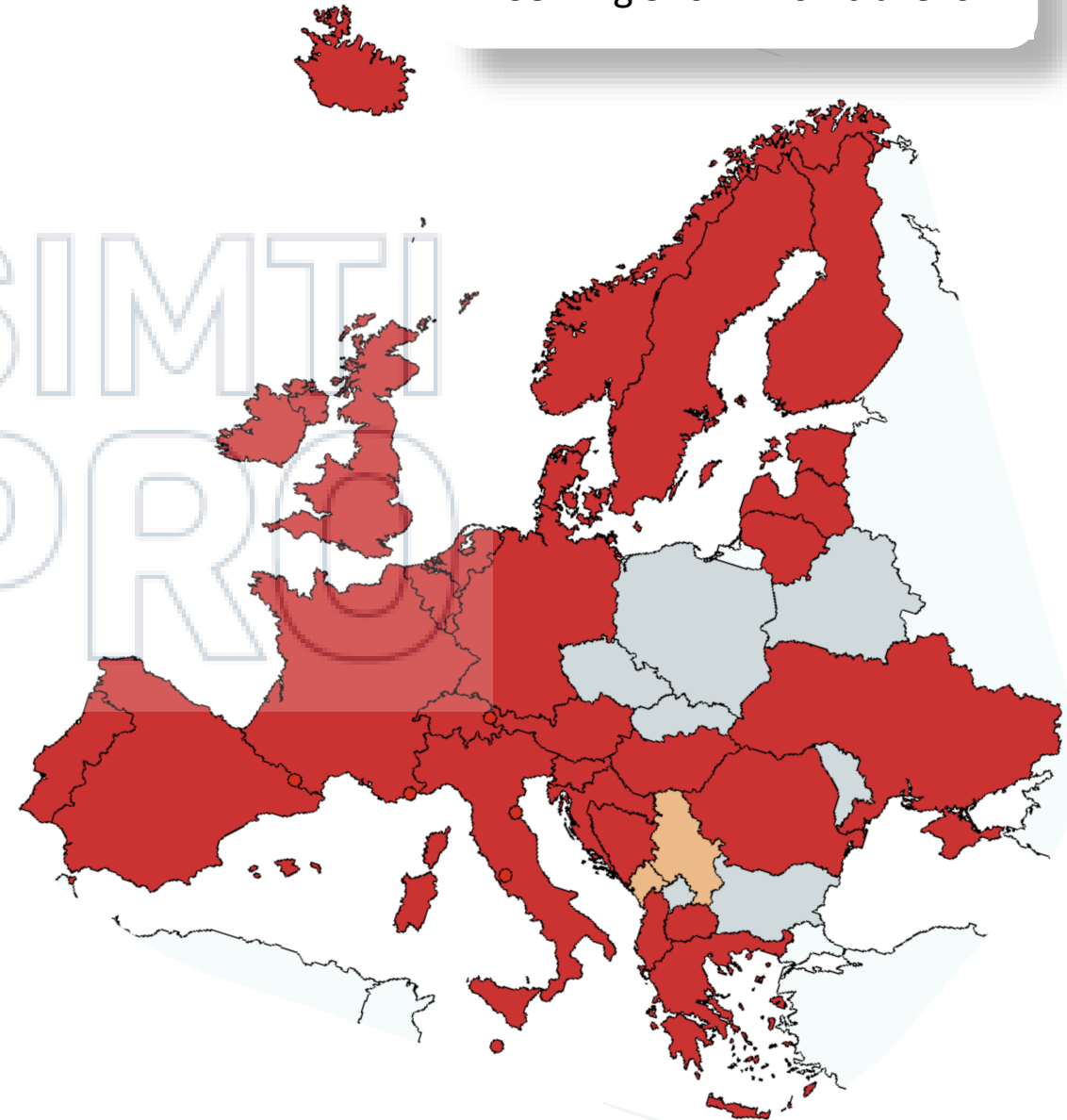
EUROPEAN
BLOOD
ALLIANCE

17 million donations
Serving 510 million citizens

Public and non-profit blood establishments across Europe

32 member countries, one observer

	Austria		Iceland		Portugal
	Belgium		Ireland		Spain
	Croatia		Italy		Sweden
	Denmark		Latvia		Switzerland
	Estonia		Lithuania		United Kingdom
	Finland		Luxembourg		Bosnia & Herzegovina
	France		Malta		North Macedonia
	Germany		Netherlands		Ukraine
	Greece		Norway		Albania
	Hungary		Slovenia		Romania





EUROPEAN
BLOOD
ALLIANCE

Our **Vision:**

A Safe and Sustainable Blood Supply for Europe

Our **Core Values:**

- Patient Care
- Donor Health
- Voluntary Unpaid Donation
- Openness through Information Sharing
- Excellence through Evidence





EUROPEAN
BLOOD
ALLIANCE

Innovation and New Products

- Non-DEHP blood bags
- Platelet Lysate
- Whole Blood
- Dried Plasma
- Blood Byte Circle (A.I.)

**Contingency
Planning**

**EU
Legislation**

**Emerging
Infectious
disease Monitor**

**Quality Control
proficiency
testing**

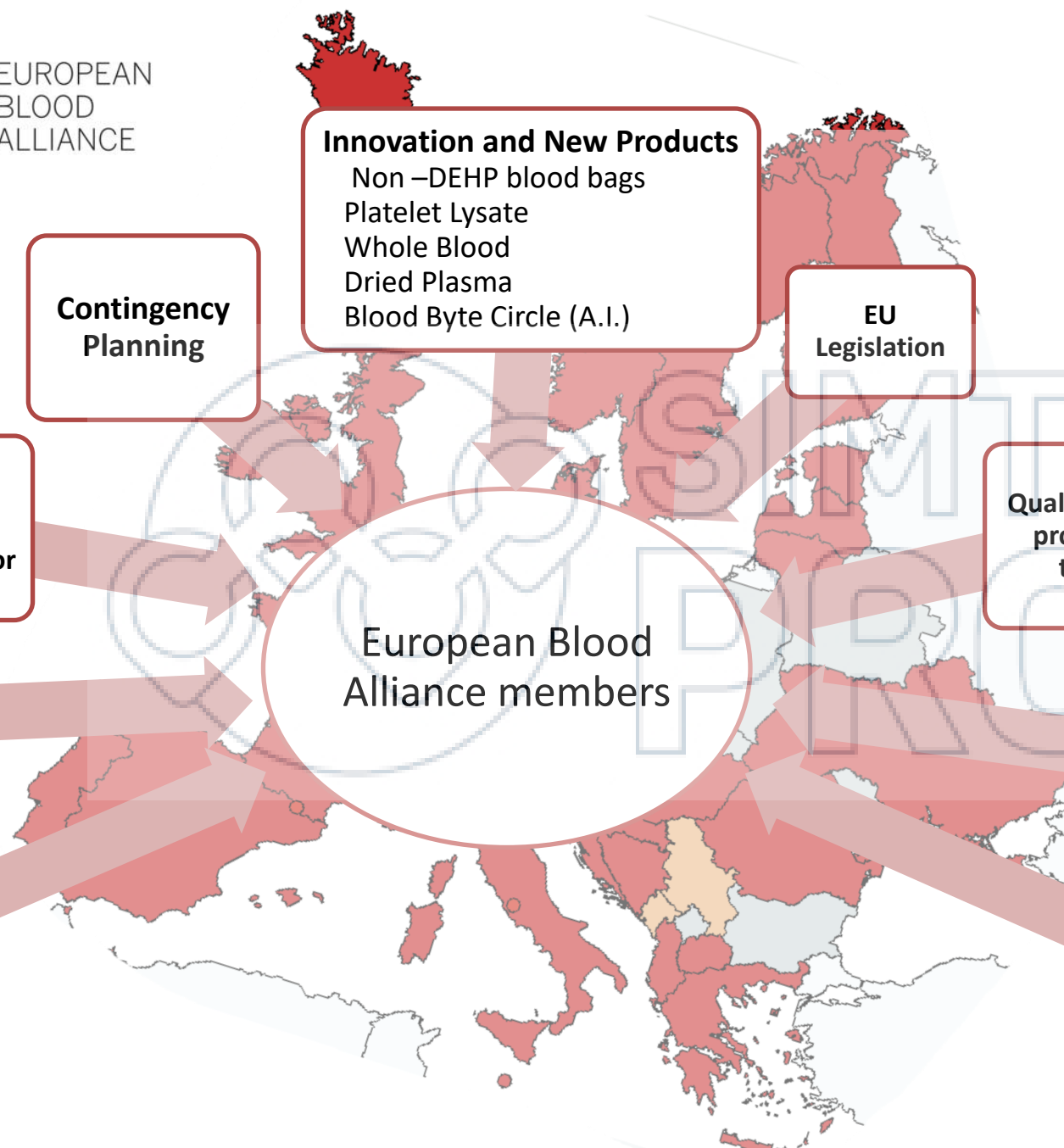
European Blood
Alliance members

**Donor
Health**

**Rare Blood
Provision**

Benchmarking

Data protection



EU Blood Directives



- Transfusion medicine in Europe has been profoundly shaped by the European Union (EU) Blood Directives adopted in 2002 (**Directive 2002/98/EC and its implementing technical directives**).
- Their primary objective was the **protection of citizens' safety**, a core EU competence, while the organisation of healthcare systems remained largely within national prerogatives.
- These texts established a **harmonised regulatory framework** governing the collection, testing, processing, storage and distribution of blood and blood components across Member States.

Directive 2002/98/EC – quality and safety standards for the collection, testing, processing, storage and distribution of human blood and blood components

Entered into force on 8 February 2003, incorporated in EU countries national law by 8 February 2005.

Among the key points:

EU countries must ensure that:

- blood is collected and tested only by authorized establishments with **suitably qualified personnel**.
- the establishments have **quality systems in place** and are inspected at least once every 2 years.
- **blood and blood components can be traced** from donor to recipient and vice versa
- any **serious adverse events** arising from accidents or errors are **notified to the competent authority**.
- the necessary measures are taken to **encourage voluntary and unpaid blood donations**.

Transfusion medicine in Europe



- Over the past two decades, the **EU Blood Directives** supported the development of **high-quality, trusted and resilient transfusion systems** throughout Europe.
- Shared safety requirements, common quality standards and strong ethical principles, particularly voluntary unpaid donation, have fostered **high-quality practices across EU Member States**.

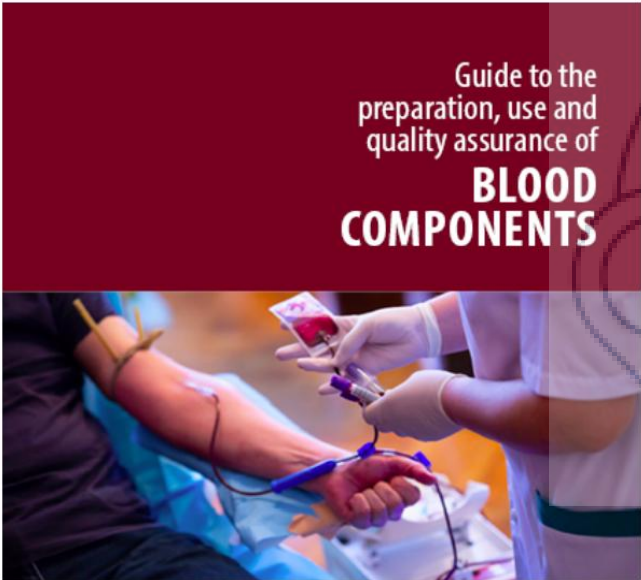


- In parallel, the European Directorate for the Quality of Medicines and HealthCare (**EDQM**) of the **Council of Europe** has played an important role as well, notably through its regularly updated **“Blood” Guide** to the preparation, use and quality assurance of blood components, which has become a key scientific and technical reference in Europe and beyond.

Transfusion medicine in Europe



- Over the past two decades, the **EU Blood Directives** supported the development of **high-quality, trusted and resilient transfusion systems** throughout Europe.
- Shared safety requirements, common quality standards and strong ethical principles, **enabled high-quality practices across EU**



European Committee
on Blood Transfusion
(Partial Agreement)
(CD-P-TS)

EDQM
22nd Edition
2025



- A comprehensive technical guide that sets out harmonised European **standards for the entire blood transfusion chain**, from donor selection and blood collection to processing, testing, storage, distribution and clinical use.
- Intended for healthcare professionals, blood establishments, regulators and policymakers, **supporting safe and effective transfusion practice.**

Directorate of Medicines and HealthCare (**EDQM**) of
as well, notably through its regularly
and quality assurance of blood components,
reference in Europe and beyond.

From the Blood Directives to the SOHO Regulation



- However, evolving challenges have highlighted **the need to update** the 2002 regulatory framework, including **limited flexibility, insufficient provisions for preparedness and resilience, and the need to better address donor protection, innovation and supply sustainability.**
- These considerations led to the adoption of the **EU Substances of Human Origin (SoHO) Regulation** in 2024, with implementation in 2027.
- The SoHO Regulation modernises the legal framework by **strengthening donor safety, reinforcing voluntary unpaid donation, enhancing oversight of transfusion practices, improving EU-level coordination—particularly in crisis situations—and extending a coherent regulatory approach across all SoHOs.**

2024/1938

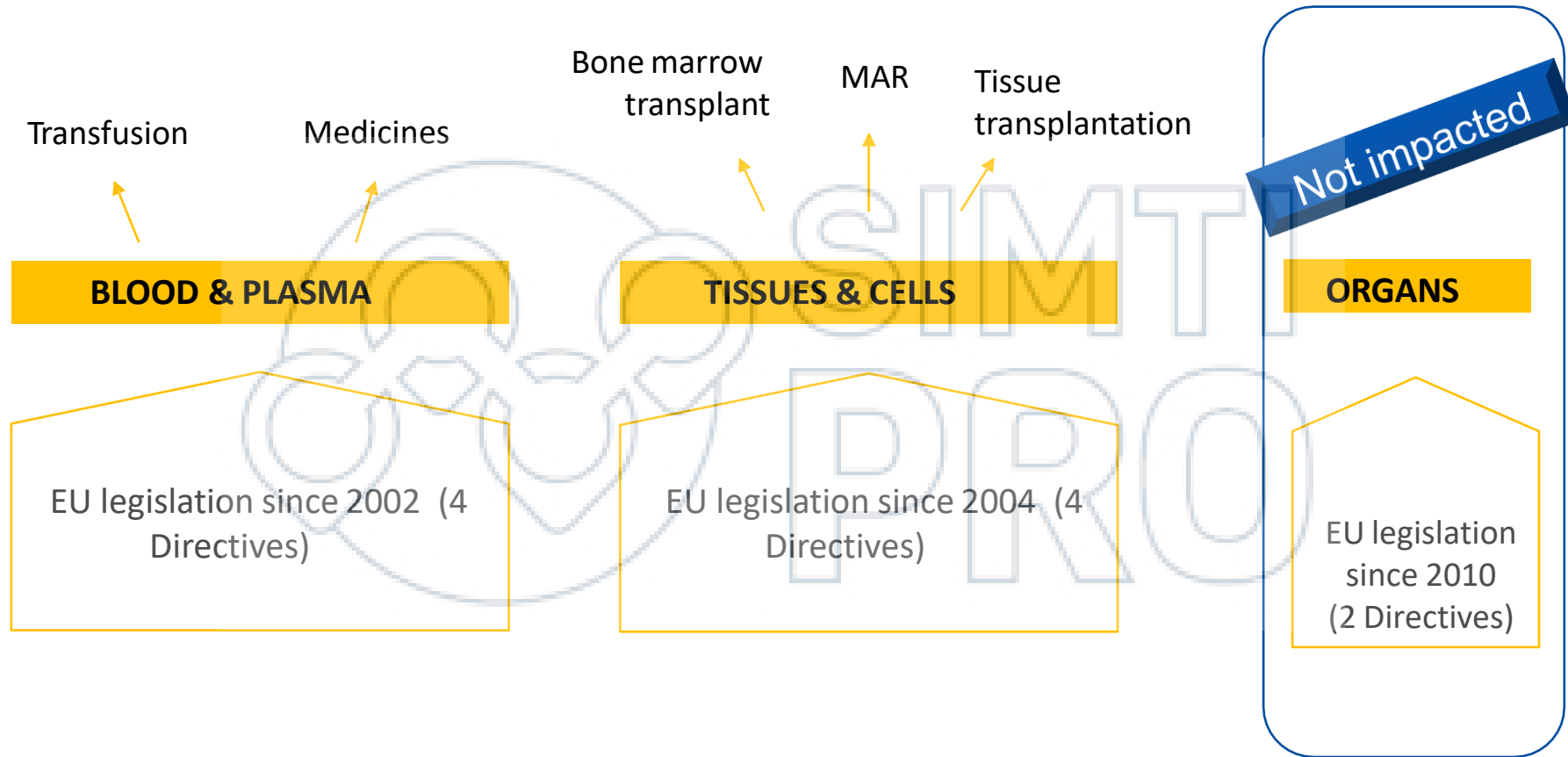
17.7.2024

REGULATION (EU) 2024/1938 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

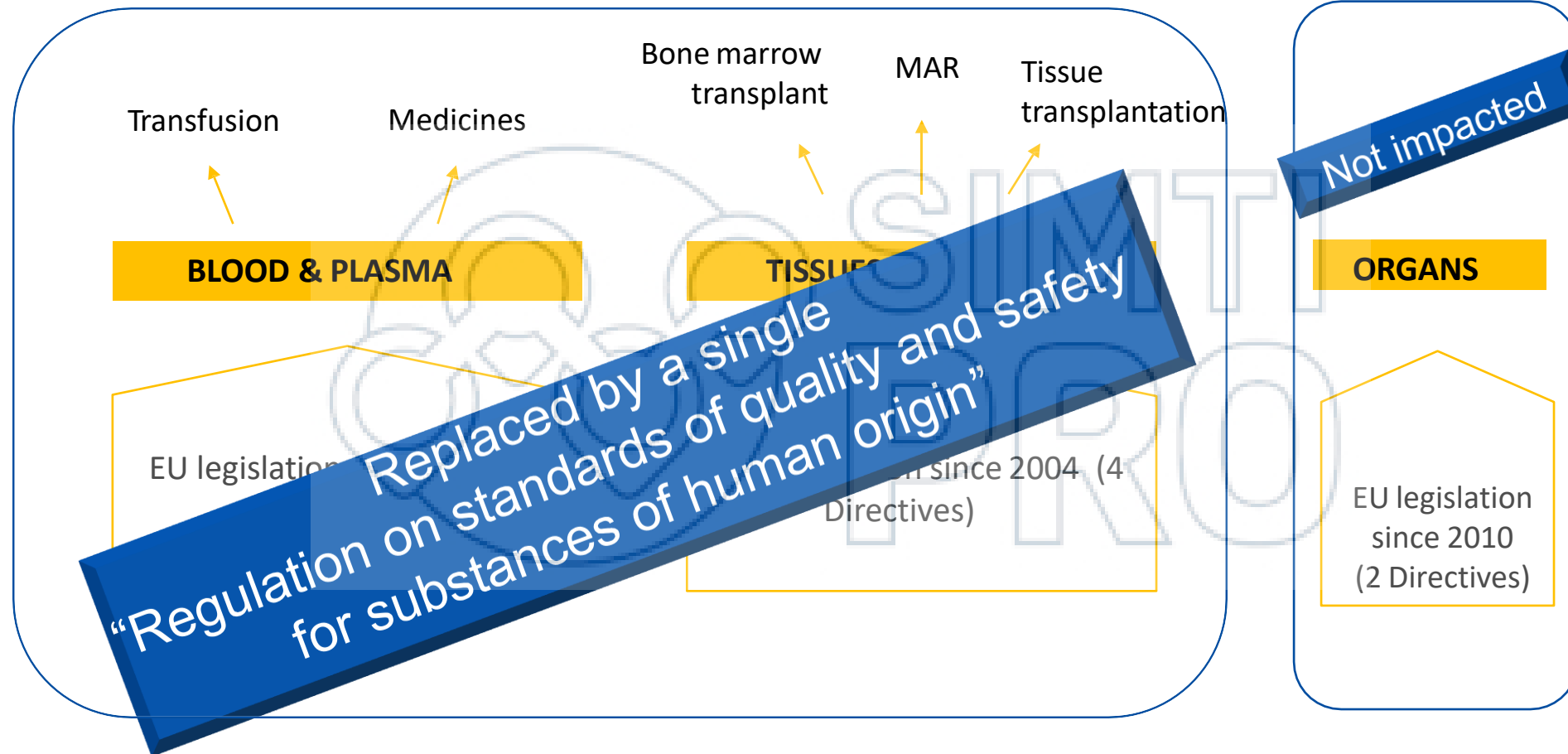
of 13 June 2024

on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC

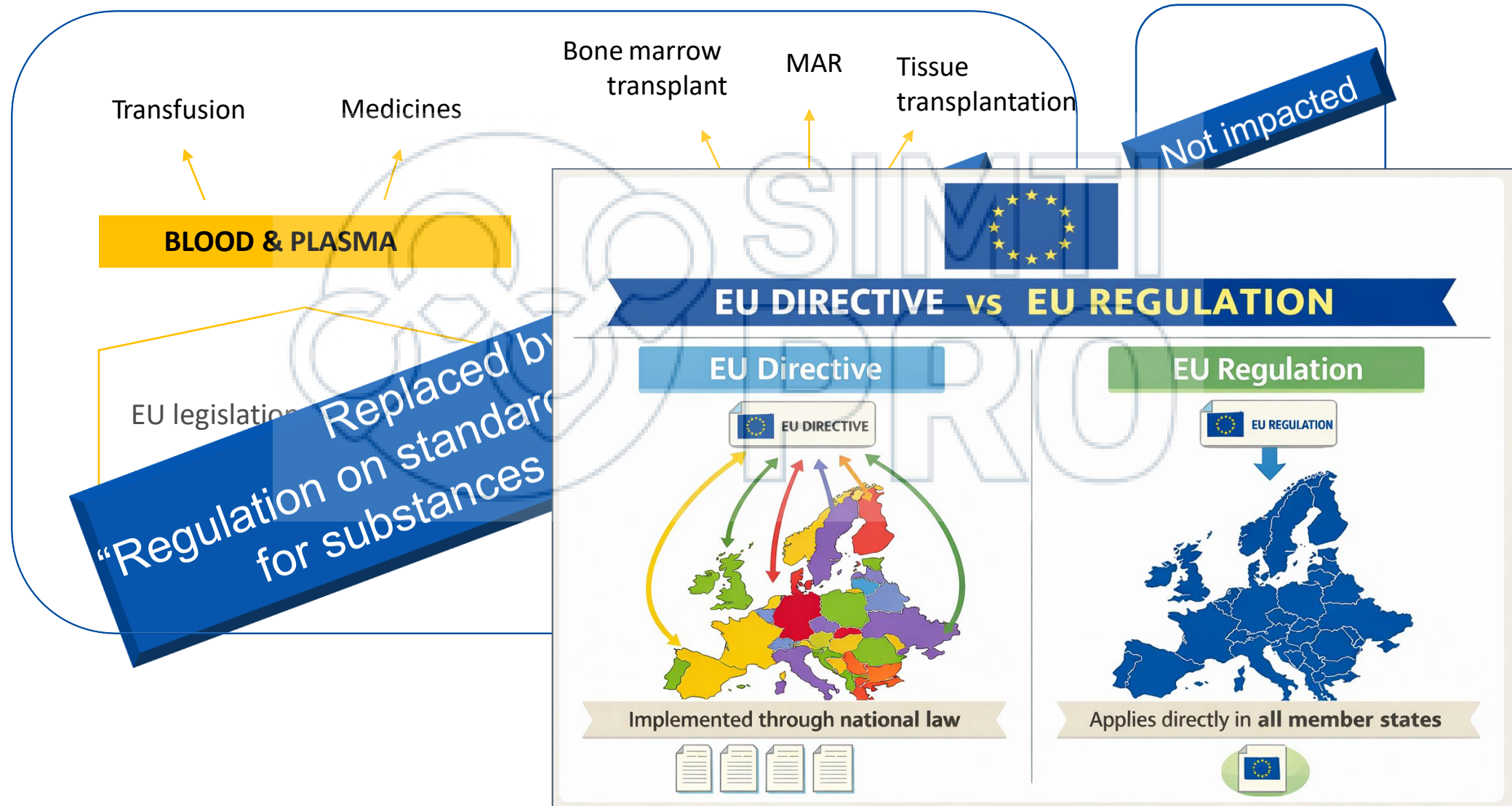
From the Blood Directives to the SOHO Regulation



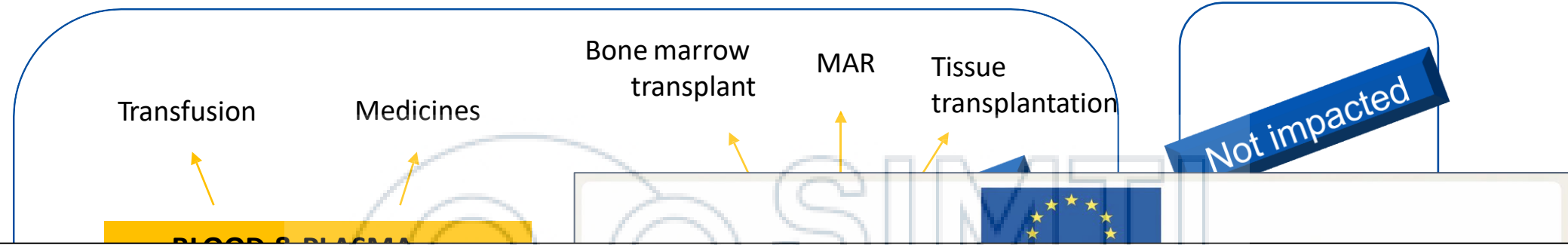
From the Blood Directives to the SOHO Regulation



From the Blood Directives to the SOHO Regulation



From the Blood Directives to the SOHO Regulation



The European Blood Alliance welcomed the adoption of the SOHO regulation:

“A historic step forward for patients, donors, the blood sector, and all European citizens”

The SoHO Regulation:

- **Strengthens the health protection of donors and patients**
- **Reaffirms the principle of voluntary unpaid donation and forbids financial gains**
- **Contributes to increase the resilience and continuity in supply of SoHO**
- **Sets an agile and robust quality and safety standards system**



Implemented through national law



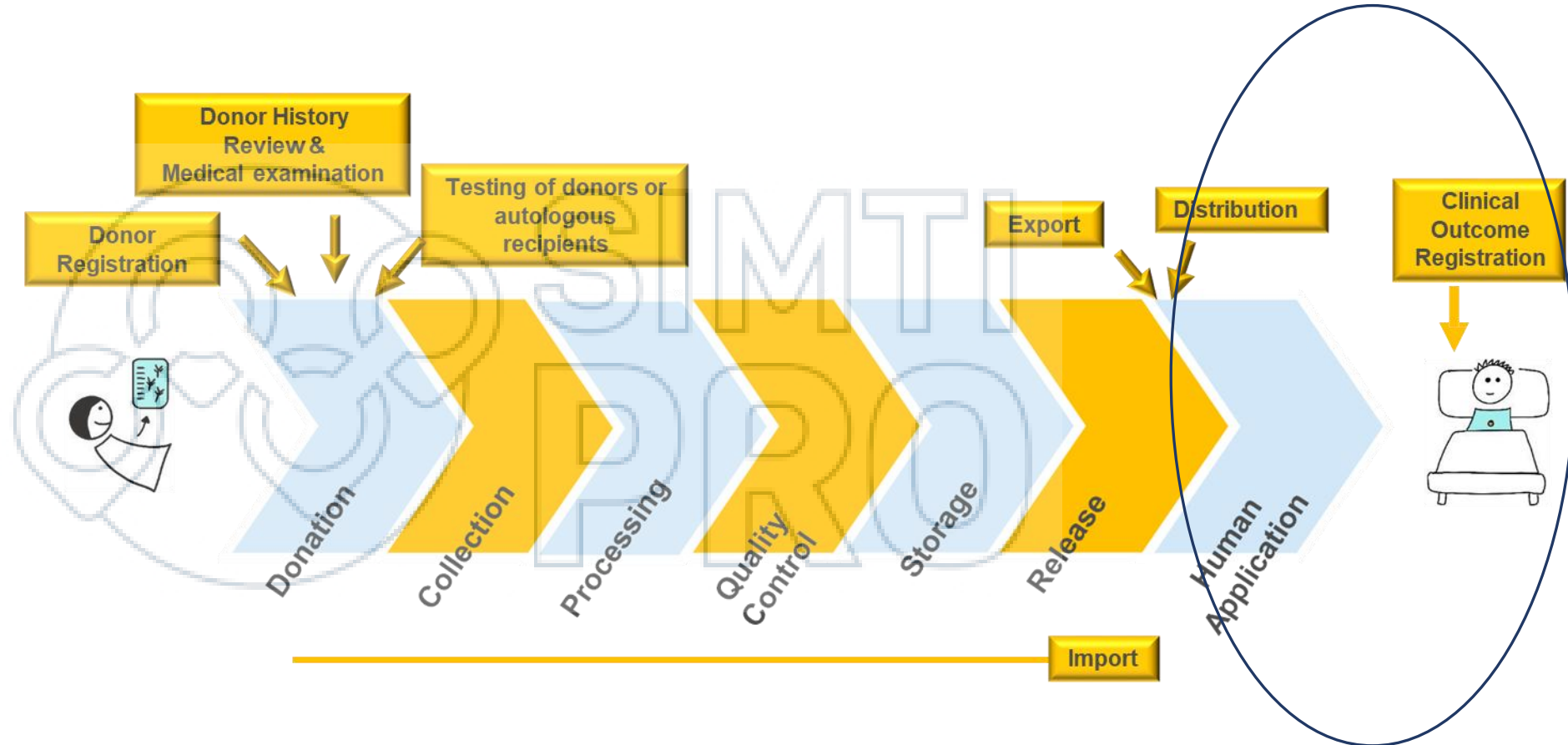
Applies directly in all member states



Supervision of all SoHO activities that directly impact safety, quality or effectiveness

SOHO regulation:

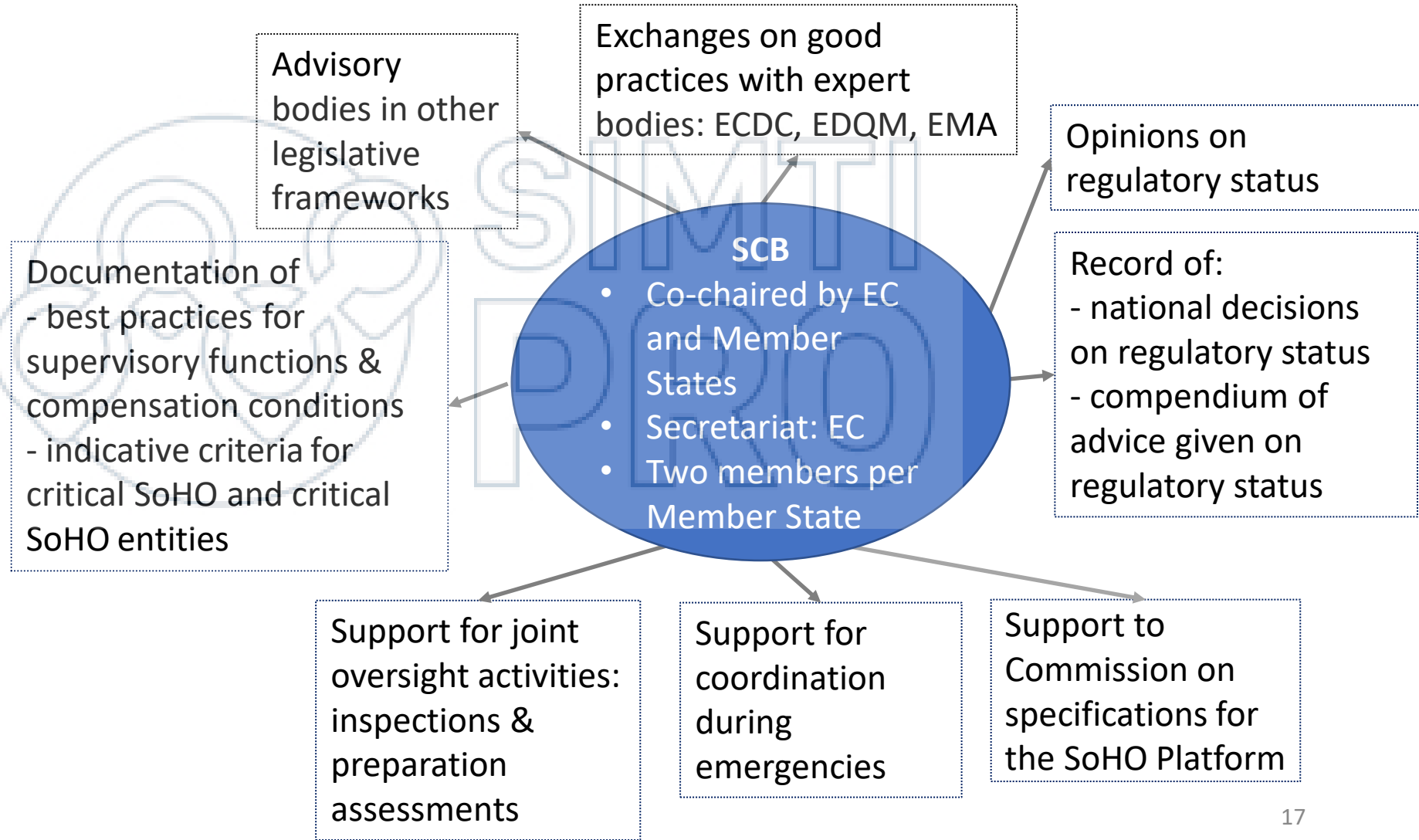
- Scope
- Coordination
- SoHO entities and establishments
- SoHO Preparations
- Standards and hierarchy of technical guidelines
- Clinical monitoring
- Donor Protection and Voluntary Unpaid Donation
- Recipient and offspring protection
- Vigilance
- Supply continuity
- Digitalisation – the SoHO platform



Strong EU-wide coordination SoHO Coordination Board (SCB)

SOHO regulation:

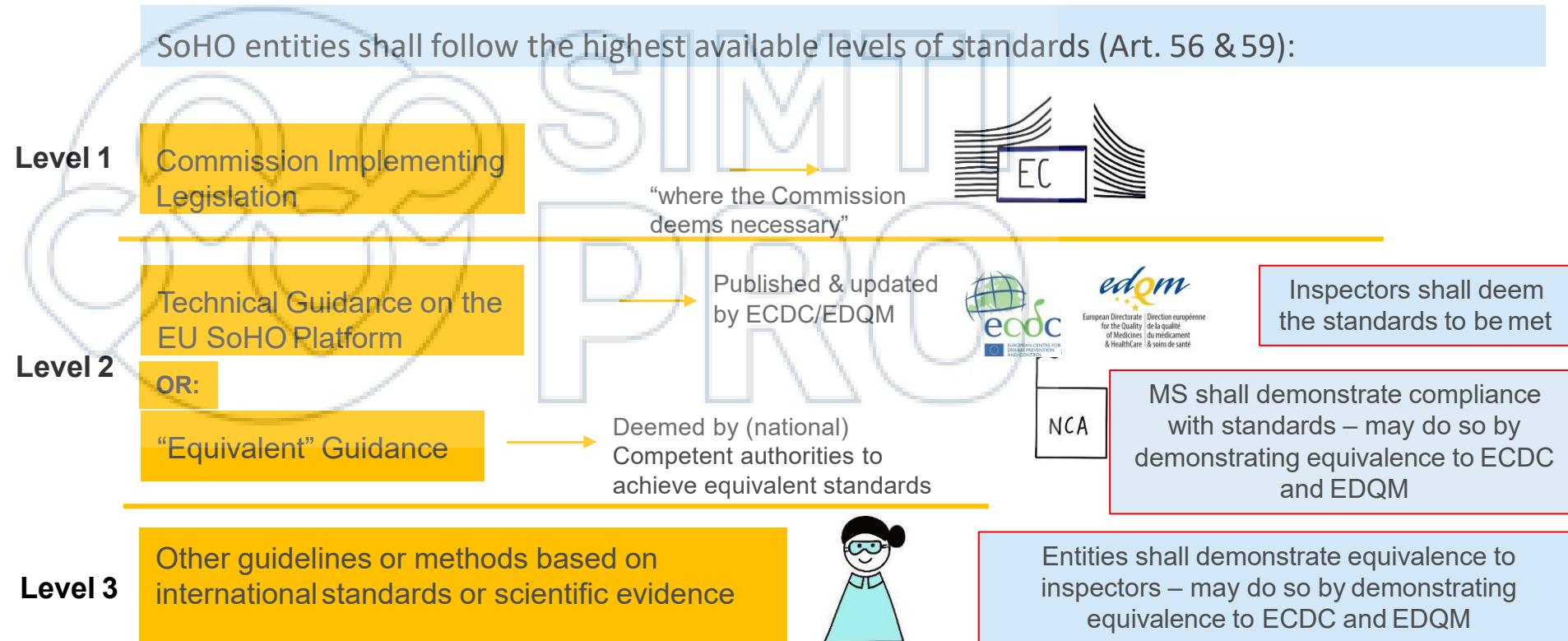
- Scope
- **Coordination**
- SoHO entities and establishments
- SoHO Preparations
- Standards and hierarchy of technical guidelines
- Clinical monitoring
- Donor Protection and Voluntary Unpaid Donation
- Recipient and offspring protection
- Vigilance
- Supply continuity
- Digitalisation – the SoHO platform



Implementation of standards through technical guidelines

SOHO regulation:

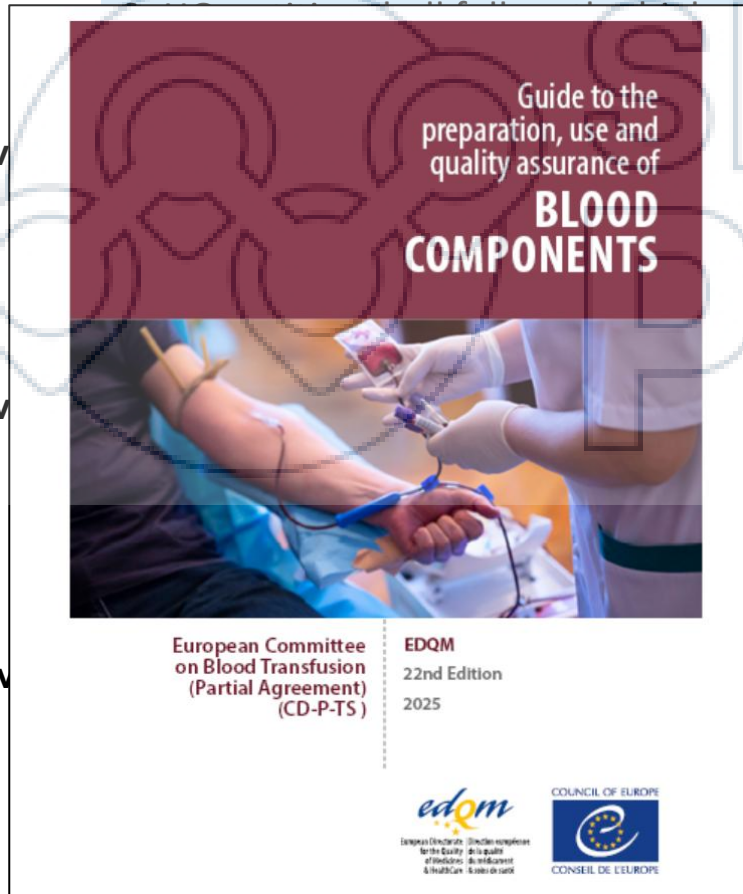
- Scope
- Coordination
- SoHO entities and establishments
- SoHO Preparations
- **Standards and hierarchy of technical guidelines**
- Clinical monitoring
- Donor Protection and Voluntary Unpaid Donation
- Recipient and offspring protection
- Vigilance
- Supply continuity
- Digitalisation – the SoHO platform



Implementation of standards through technical guidelines

SOHO regulation:

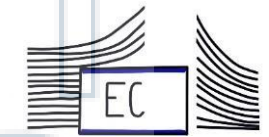
- Scope
- Coordination
- SoHO entities and establishments
- SoHO Preparations
- **Standards and hierarchy of technical guidelines**
- Clinical monitoring
- Donor Protection and Voluntary Unpaid Donation
- Recipient and offspring protection
- Vigilance
- Supply continuity
- Digitalisation – the SoHO platform



available levels of standards (Art. 56 & 59):

Level
Level
Level

where the Commission deems necessary”

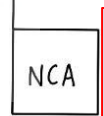


Published & updated by ECDC/EDQM



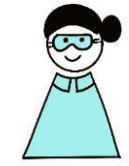
Inspectors shall deem the standards to be met

ed by (national) competent authorities to the equivalent standards



MS shall demonstrate compliance with standards – may do so by demonstrating equivalence to ECDC and EDQM

ence



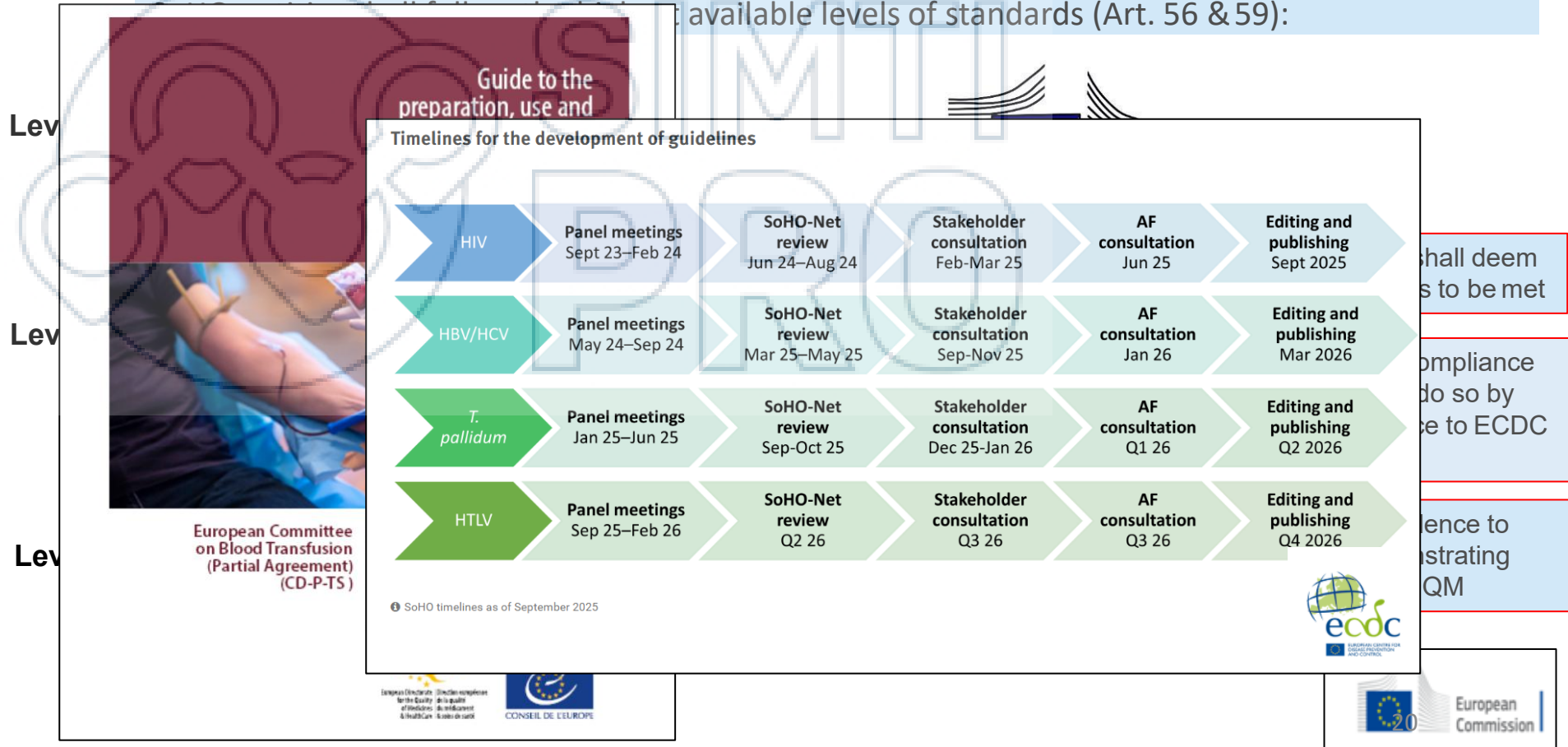
Entities shall demonstrate equivalence to inspectors – may do so by demonstrating equivalence to ECDC and EDQM

Implementation of standards through technical guidelines

SOHO regulation:

- Scope
- Coordination
- SoHO entities and establishments
- SoHO Preparations
- **Standards and hierarchy of technical guidelines**
- Clinical monitoring
- Donor Protection and Voluntary Unpaid Donation
- Recipient and offspring protection
- Vigilance
- Supply continuity
- Digitalisation – the SoHO platform

available levels of standards (Art. 56 & 59):

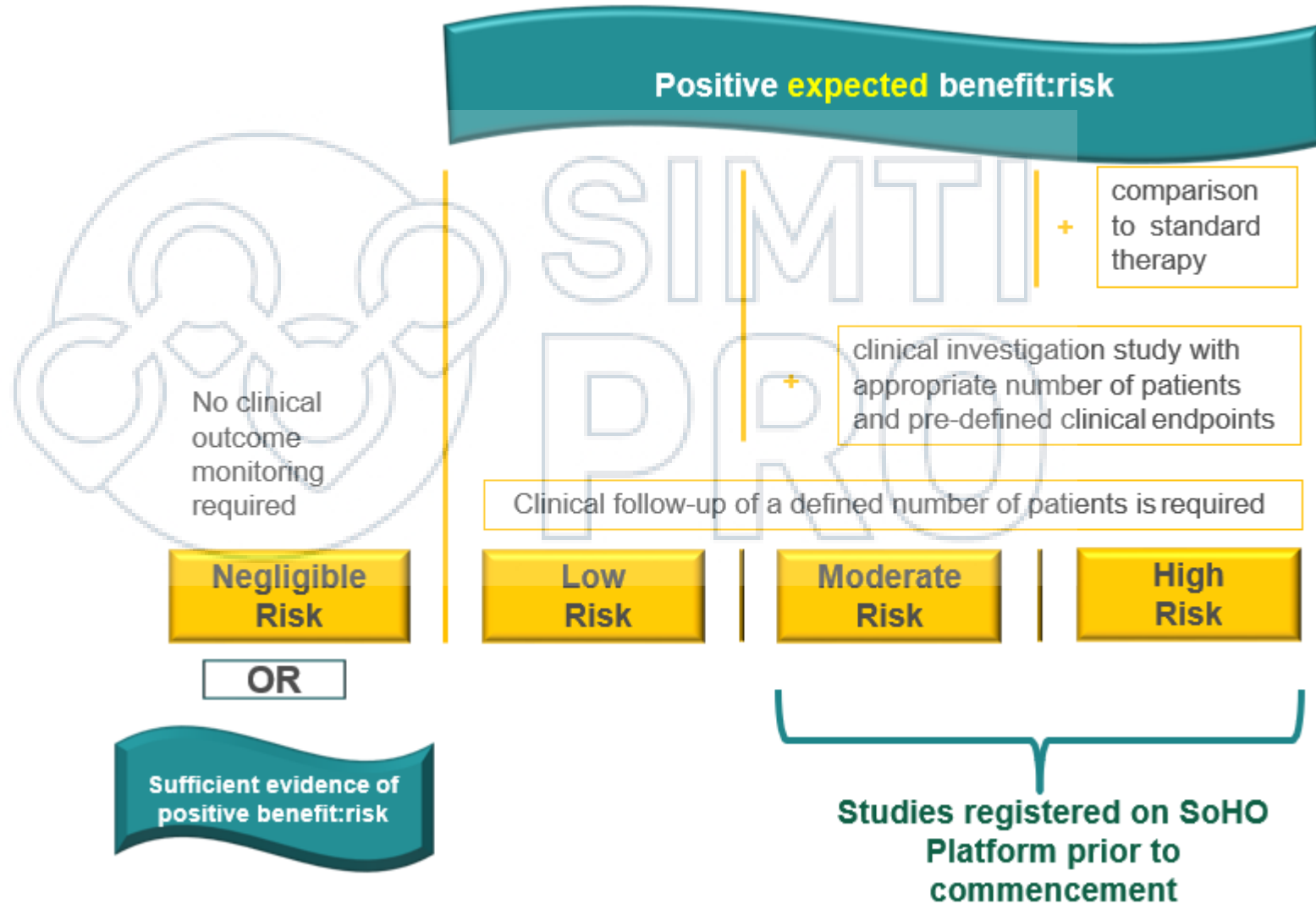


Clinical outcome monitoring plans

To gather (further) evidence of safety and effectiveness

SOHO regulation:

- **Scope**
- Coordination
- SoHO entities and establishments
- SoHO Preparations
- Standards and hierarchy of technical guidelines
- **Clinical monitoring**
- Donor protection and Voluntary unpaid donation
- Recipient and offspring protection
- Vigilance
- Supply continuity
- Digitalisation – the SoHO platform



Strengthened SoHO donor protection

SOHO regulation:

- Scope
- Coordination
- SoHO entities and establishments
- SoHO Preparations
- Standards and hierarchy of technical guidelines
- Clinical monitoring
- **Donor protection and Voluntary unpaid donation**
- Recipient and offspring protection
- Vigilance
- Supply continuity
- Digitalisation – the SoHO platform

Protection of SoHO living donors before, during, and after the donation.

- Including for donations by relatives
- Information & consent
- Physical and mental integrity, non-discrimination, data protection & safeguarding of anonymity
- Donor health evaluation
- **Risk-proportionate approach to donor monitoring:** registration of donors subjected to surgical procedures, medicinal product treatment, frequent or repeated donations implying risk to health.
- **Required reporting of serious adverse reactions in donors**

Protection of the dignity and integrity of SoHO deceased donors

- Information & consent by relatives, when applicable

Reaffirmed voluntary and unpaid donation (VUD)

SOHO regulation:

- **Scope**
- Coordination
- SoHO entities and establishments
- SoHO Preparations
- Standards and hierarchy of technical guidelines
- Clinical monitoring
- **Donor protection and Voluntary unpaid donation**
- Recipient and offspring protection
- Vigilance
- Supply continuity
- Digitalisation – the SoHO platform

- **NO financial incentives or inducements** to donate
- **Compensation** of living donors for losses can be allowed in accordance with the principle of VUD
- When a Member State allows compensation – **upper limit to be set in national legislation** – transparent criteria based on best practices established by the SOHO coordination board
- Compensation conditions set in MS to be **shared** with the other Member States via the SOHO coordination board
- Donation **promotion and publicity activities must not refer to compensation** (without prejudice to national laws on information provision)

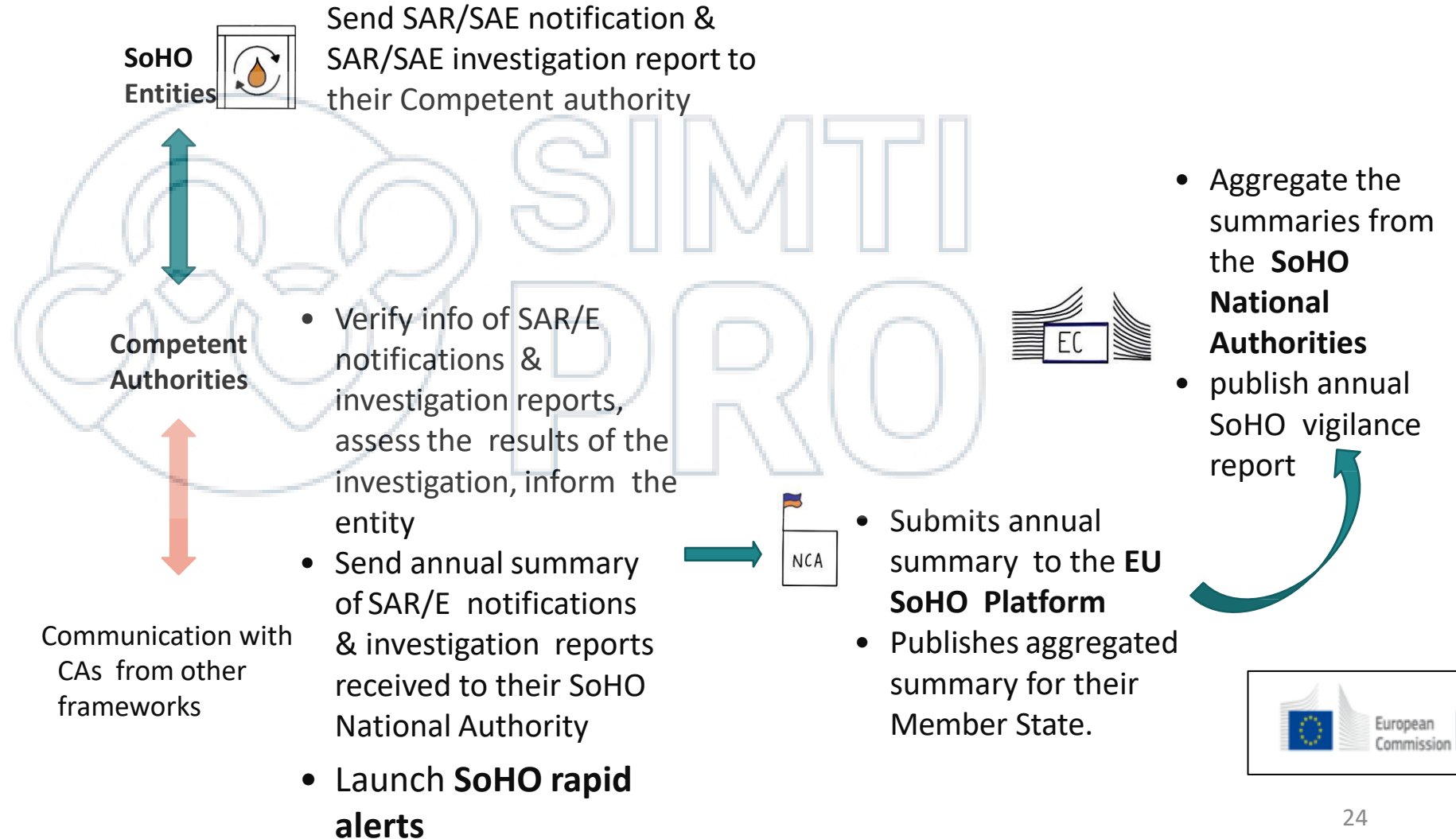
Principle maintained
Based on Recommendations
of the Council of Europe
Committee on Bioethics

Expanded vigilance

- Best practices agreed and documented by SCB
- SAR/E detected in **donors** and during **clinical outcome monitoring** must be reported

SOHO regulation:

- Scope
- Coordination
- SoHO entities and establishments
- SoHO Preparations
- Standards and hierarchy of technical guidelines
- Clinical monitoring
- Donor protection and Voluntary unpaid donation
- Recipient and offspring protection
- **Vigilance**
- Supply continuity
- Digitalisation – the SoHO platform



Resilience of Supply

SOHO regulation:

- Scope
- Coordination
- SoHO entities and establishments
- SoHO Preparations
- Standards and hierarchy of technical guidelines
- Clinical monitoring
- Donor protection and Voluntary unpaid donation
- Recipient and offspring protection
- Vigilance
- **Supply continuity**
- Digitalisation – the SoHO platform

A '**critical SoHO**' is a SoHO that for which an insufficient supply will result in **serious harm or risk of harm** to patients or a serious interruption in manufacture of critical products regulated by other legislation.

A '**critical SoHO entity**' is a SoHO entity that carries out **activities contributing to the supply of critical SoHOs** and the scale of those activities is such that a failure to carry them out cannot be compensated by activities of other entities or alternative substances or products for recipients.

Critical SoHO

Supply of **critical SoHO** is protected by:

- **Obligations on Member States to ensure a sufficient, adequate and resilient supply**
 - Facilitate donation
 - Communication and education
 - Optimal use
- Activity data collection and monitoring
- **Supply alerts**
- **National SoHO emergency plans**
- **SoHO Entity emergency plans**
- Derogations and additional measures in emergency situations

SOHO Platform

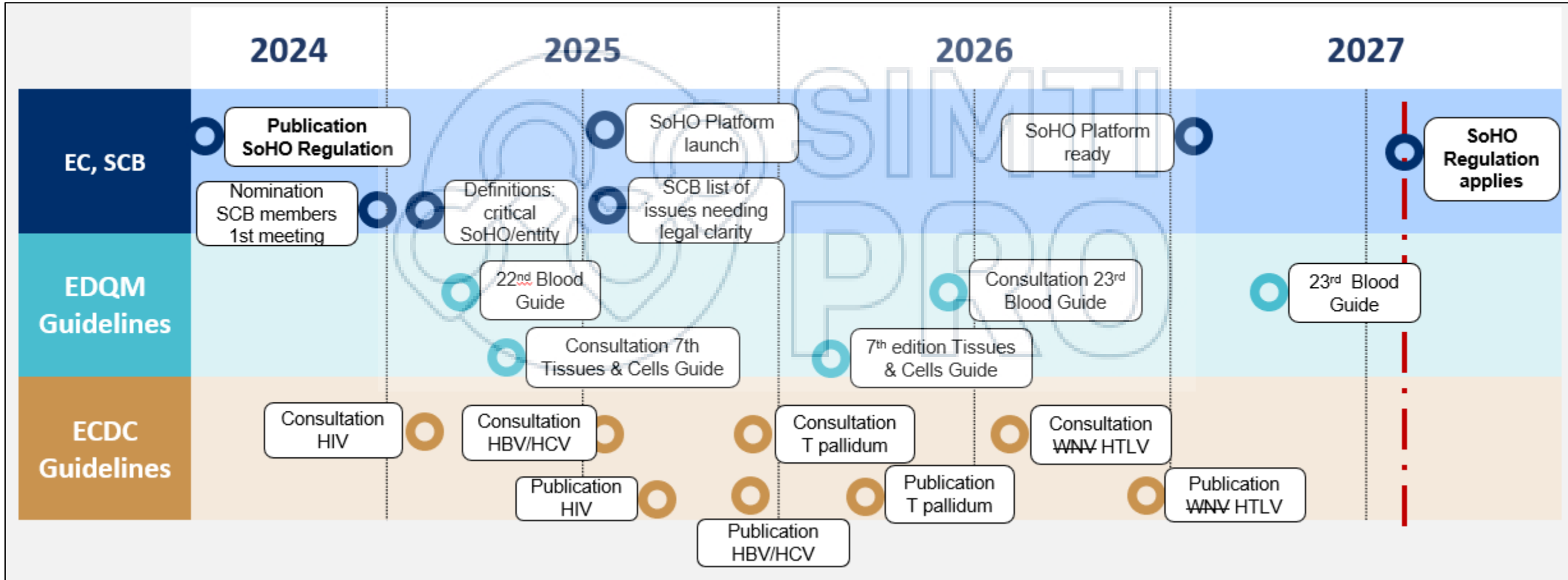
A EU-wide digital platform for information / data registration and sharing

SOHO regulation:

- Scope
- Coordination
- SoHO entities and establishments
- SoHO Preparations
- Standards and hierarchy of technical guidelines
- Clinical monitoring
- Donor protection and Voluntary unpaid donation
- Recipient and offspring protection
- Vigilance
- Supply continuity
- **Digitalisation – the SoHO platform**



SOHO Regulation - Timeline



- **Better, comparable and interoperable data: detailed and agile** enough to meet the full potential regarding donor and patient health, on a day-to-day basis as well as for research, requirement **high quality clinical outcome data**, ...
- **Increased donor health protection:** For instance, regarding donation frequencies and potential risk to health. **Clinical data (and funding) will be necessary.** Meeting the requirement for Member States to develop **national (and searchable) donor registries** may be challenging.
- **More robust SoHO supply system(s):** An opportunity for Member States to **improve resilience**, for the EU to develop **EU wide strategies** regarding supply /self-sufficiency of SoHO, such as plasma for fractionation. **Information exchanges / alerts** about shortages and supply disruption will be beneficial, but requires agility, transparency, day-to-day monitoring and analysis.
- **Harmonised standards**, including for VUD: An **opportunity for further harmonisation** across the EU, while recognizing national specificities.
- **Regulatory agility: Soho coordination board** activities, **interfaces between the SOHO regulation and “neighbouring” EU legislation** (Pharma regulation and directive, Critical care act, European Health Donor Space regulation,)

- **Better, comparable and interoperable data: detailed and agile** enough to meet the full potential regarding donor and patient health, on a day-to-day basis as well as for research, requirement **high quality clinical outcome data**, ...
- **Increased donor health protection:** For instance, regarding donation frequencies and potential risk to health. **Clinical data (and funding) will be necessary.** Meeting the requirement for Member States to develop **national (and searchable) donor registries** may be challenging.
- **More robust SoHO supply system(s):** An opportunity for Member States to **improve resilience**, for the EU to develop **EU wide strategies** regarding supply /self-sufficiency of SoHO, such as plasma for

and supply disruption will be beneficial, analysis.

further harmonisation across the EU,

gaps between the SOHO regulation and the, Critical care act, European Health

EBA and its members are committed engage with European institutions to support implementation and share expertise,

To ensure that the Regulation keeps its **modern, ambitious spirit – an agile and responsive tool** - , far from being an additional administrative burden

Support for the implementation of the SOHO regulation



The screenshot shows the European Commission website for the European Health and Digital Executive Agency (HaDEA). The page is titled "Supporting the implementation of the new SoHO regulation" and is categorized as a "CALL FOR TENDERS | Ongoing". The main heading is "Supporting the implementation of the new SoHO regulation". A large watermark "SIMPLY PRO" is visible in the background.

PAGE CONTENTS

- Details
- Description

Details

Status	ONGOING
Publication date	17 September 2025
Deadline date	11 November 2025, 16:00 (CET)
Programme Sector	Health
Programme	EU4Health
Tags	Prior Information Notice

Description

HaDEA has published the call for tenders [HADEA/2025/OP/0043](#) - Support the implementation of the new Substances of Human Origin (SoHO) Regulation 1938/2024, including dissemination and training of SoHO professionals to comply with the new technical and regulatory requirements.

The scope of the call for tenders is to prepare SoHO professionals across the EU for the 2027 implementation of the Regulation (EU) 2024/1938 on Substances of Human Origin. The objectives of this call are to develop training programmes, awareness and capacity building activities, technical assistance and supporting measures to facilitate the implementation of the new SoHO Regulation by the professional sector (Scientific societies and associations).

- The scope of this call for tenders is to **prepare SoHO professionals across the EU** for the 2027 implementation of the SOHO Regulation (EU) 2024/1938 on Substances of Human Origin.
- The objectives of this call is to develop training programs, awareness and capacity building activities, technical assistance and supporting measures to **facilitate the implementation** of the new SoHO Regulation by the professional sector (Scientific societies and associations).

Support for the implementation of the SOHO regulation

IMPLEMENT-SoHO, 3.5 million € , 2026-2028



Predi[t
*By



Task 1

- Map out the current status and needs of the SoHO Scientific Societies

Task 2

- Training and capacity building activities for SoHO Scientific Societies

Task 3

- Dissemination Activities

Task 4

- Scientific Opinions

Task 5

- Campaigns for Promotion of Altruistic Donation

IMPLEMENT-SoHO

IMPLEMENT-SoHO

From regulation to practice: enabling ethical and effective SoHo (Substances of Human Origin) across Europe.

A Europe Health Data Space to facilitate the access to secondary health data across the EU



Empower individuals to control their health data

Foster a single market for digital health services and products

Ensure interoperability and security of health data and a level playing field for manufacturers



Unleash the power of the health data economy

Ensure a consistent and efficient framework for the reuse of health data for research, innovation, policy-making and regulatory activities

- The European Health Data Space (EHDS) Regulation recognises the **strategic importance of health data access for individual care, public health and research.**
- Its **interaction with data generation and reporting obligations under the SoHO Regulation** will be critical for evaluating the **efficacy and safety of both established and innovative blood components, plasma-derived medicinal products and cellular therapies**, and for advancing knowledge on **donor safety**, including potential long-term effects of repeated plasma or platelet donation.

A Europe Health Data Space to facilitate the access to secondary health data across the EU



- The European Health Data Space (EHDS) Regulation recognises the **strategic importance of health data access for individual care, public health and research.**
- Its interaction with data generation and reporting obligations under the SoHO Regulation will be critical for evaluating the **efficacy and safety of both established and innovative blood components, plasma-derived medicinal products and cellular therapies**, and for advancing knowledge on **donor safety**, including potential long-term effects of repeated plasma or platelet donation.

EHDS Regulation

Empower individuals to control their health data

2022

Start of legislative process

Foster a single market for digital health services and products

2024

Core compromise reached

Ensure interoperability and security of health data and a level playing field for manufacturers

Early 2025

Legal finalisation

March 2025

Regulation exists legally

2025–2027

Rules + infrastructure built

2029

Core EHDS becomes operational

2031

Expanded datasets

2035+

International extension

A Europe Health Data Space to facilitate the access to secondary health data across the EU



EBA submission on the European Health Data Space proposal,

July 2022

- **EBA welcomes this proposal**
- Long-standing request for **more and better data to increase donor protection and reinforce patient care**
- Calling on the EU and Member States to **reinforce donor vigilance requirements through a pan-European donor vigilance program.**
- Reporting of data on Substances of Human Origin (SOHO) should be further developed to provide **public access to key anonymized data on European registries**
- **EHDS regulation and the SoHO Regulation need to be well aligned**
- Necessity to include methods to **unambiguously identify and trace individuals (donors or transfused patients) as they come in contact with the health care system**
- However, implementing must ensure that **EHDS does not become a burden to healthcare professionals**
- Lastly, concerns regarding **varying interpretation of the General Data Privacy Regulation (GDPR)** across EU countries that may hinder data sharing.

<https://europeanbloodalliance.eu/resources/eba-response-the-european-commissions-proposal-for-a-european-health-data-space-ehds-july-2022/>

The European health data space proposal; An opportunity for improved blood donor protection and transfusion recipient care. Tiberghien et al; Transf clin bio, 2023

Critical Medicines Act: Improving the availability and securing supply of critical medicines in the EU



- The **Critical Medicines Act** aims to **strengthen Europe's resilience and strategic autonomy** in the face of **supply vulnerabilities and geopolitical instability**.
- Although not directly related to transfusion medicine (blood components fall under the SOHO regulation and not under the pharmaceutical legislation) its objectives remain highly relevant to **blood, plasma and plasma-derived medicinal products**.

Key features

- **Strategic Projects for critical medicines** or their ingredients can be designated, so that they benefit from easier access to **funding and fast-tracked procedures**.
- **Public procurement** to incentivise the **resilience** of supply chains of critical medicines or to **improve access** to other medicines of common interest.
- **Collaborative procurement** among different member states will be supported by the EC to address **availability and access disparities** of critical medicines and other medicines of common interest.
- **International partnerships** with like-minded countries/regions will be explored, to **broaden the supply chain and reduce dependencies on single suppliers**.

Critical Medicines Act: Improving the availability of medicines



- The **Critical Medicines Act** aims to **strengthen Europe's resilience and strategic autonomy** in the face of **supply vulnerabilities and geopolitical instability**.
- Although not directly related to transfusion medicine (blood components fall under the SOHO regulation and not under the pharmaceutical legislation) its objectives remain highly relevant to **blood, plasma and plasma-derived medicinal products**.



supply of critical

critical medicines or their designated, so that they access to **funding and fast-**

to incentivise the **resilience** critical medicines or to other medicines of common

ement among different e supported by the EC to **and access disparities** of d other medicines of


rships with like-minded l be explored, to **broaden reduce dependencies on**

Biotech Act: strengthening the EU Biotechnology sector and Improving patient access to innovative therapies

Recent proposal by the European Commission

Aims:

- establish a framework at EU level that **strengthens the competitiveness** of the health biotechnology sector, from research to production
- create conditions **facilitating the development** and timely placing on the EU market of biotechnology innovations, products and services



EBA position on the European Commission's proposal for a European Biotech Act

The European Blood Alliance (EBA), representing public and non-profit blood establishments across Europe, welcomes the European Commission's proposal for a European Biotech Act.

EBA wishes to remind EU and national policymakers that public and non-profit blood establishments are the original precursors of personalised medicine and have played an historic and central role in the development of many groundbreaking biotechnological therapies, including advanced therapy medicinal products (ATMPs). Blood establishments continue to play a fundamental role in these and other advanced treatments, and any effort to boost Europe's biotech sector must ensure it leverages the expertise, knowledge, and capacity of public and non-profit blood establishments.

Public and non-profit blood establishments and other SoHO entities operate within highly regulated public health frameworks and possess long-standing expertise in the collection, processing, storage and clinical use of substances of human origin. Their involvement is therefore essential to ensure that biotechnology innovation remains aligned with public health objectives and ethical principles governing SoHO activities.

The European Commission's Biotech Act proposal includes interesting measures to support research, development, and innovation across several health biotechnology sectors, including blood and blood components and other Substances of Human Origin (SoHO).

The proposed measures to support strategic projects, as well as the new EU Health Biotechnology Support Network, will be valuable additions to the European biotech ecosystem. To be successful, these efforts must involve blood establishments and other scientific experts in their design and development.

EBA also welcomes, but advises caution over, the overall effort to simplify certain procedures in existing legislation and to introduce regulatory sandboxes to facilitate innovation, notably regarding SoHO donor protection.

Finally, EBA welcomes the proposal to establish a Union regulatory status repository. Given the increasing number of innovative therapies combining substances of human origin with medical devices, medicinal products or advanced therapy medicinal products, early regulatory clarification and transparent access to regulatory status decisions will be essential to avoid inconsistencies and ensure legal certainty for developers and competent authorities.

Proposals for amendments

1. **Innovation must never come at the expense of donor protection and wellbeing.**

In this respect, EBA urges the European Parliament and Member States in the Council to consider the

EBA proposals for amendments:

- Donor protection and wellbeing
- Participation of experts in strategic project assessment
- **Role of public and non-profit sectors in biotech innovation and improving patient access to innovative therapies**

Public blood establishments have historically played a central role in the development of innovative therapies such as hematopoietic transplantation and, more recently, advanced therapy medicinal products (ATMPs). Their continued involvement, alongside transfusion experts, will be essential.

The future of transfusion medicine: A European perspective

- **The SoHO Regulation: a modern and (hopefully) agile framework**
Strengthening donor and patient protection, voluntary unpaid donation, vigilance and clinical outcome monitoring, supply continuity and crisis preparedness
- **Health data and interoperability: transforming transfusion medicine in Europe**
Interaction between the SoHO Regulation and the EHDS should enable improved donor surveillance and protection, real-world evaluation of blood component efficacy and safety, better interoperability and traceability, large-scale public health and translational research
- **Blood and plasma supply: now a strategic European concern**
SOHO regulation and the Critical Medicines Act to improve supply security, reduce external dependencies, coordinate European preparedness, thrive towards strategic autonomy for critical SoHO, including plasma-derived therapies
- **Public blood establishments: more than ever innovation actors**
European Biotech Act: blood establishments and transfusion medicine expertise remain essential, notably for innovative ex-vivo cell therapies
- **Shared European values across transfusion medicine**
Trust, voluntary unpaid donation, donor protection and equitable patient access to high quality therapies



EUROPEAN
BLOOD
ALLIANCE



Europe moving (and staying) ahead !

