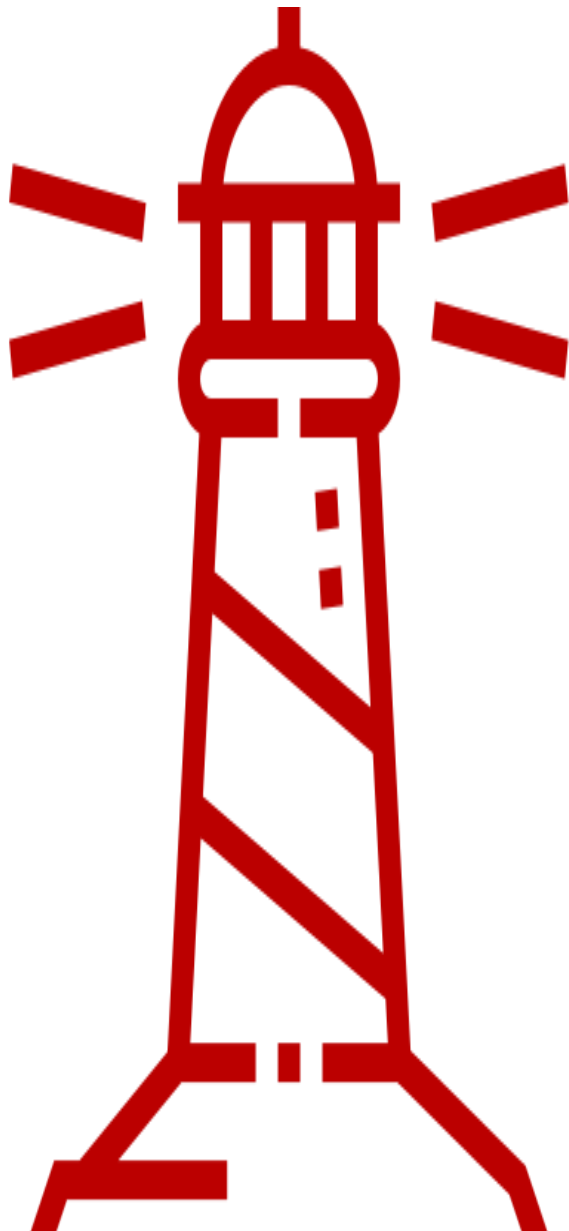




**Donnons
au sang**
le pouvoir
de soigner

SUSTAINABLE DONATION PRACTICES IN A DYNAMIC INTERNATIONAL LANDSCAPE: NAVIGATING LEGAL AND POLITICAL ENVIRONMENTS



What political decision or legal text do YOU think could impact your work nowadays?

**What political decision or legal text
do you think could impact your
work nowadays?**



The Slido app must be installed on every computer you're presenting from



Blood donation is political.

Everything is.



What is politics?

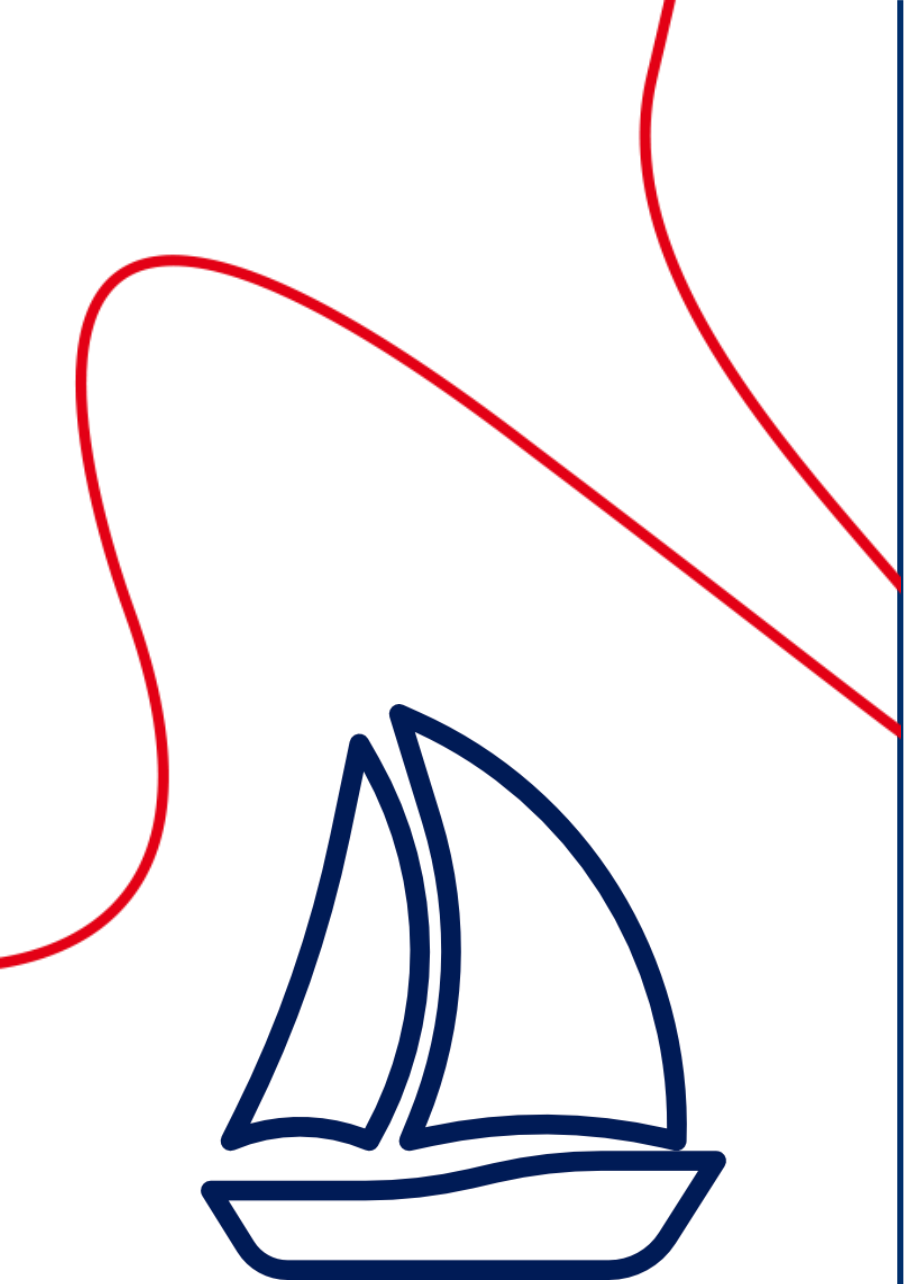
A wide understanding



- Power struggle
- Concertation, compromise, to take collective decisions
- Through a competition between interests, values, beliefs
- States politics, geopolitics, office/blood establishment politics



- **We depend on laws**
- **We depend on political decisions**
- **We can shape laws and political decisions**

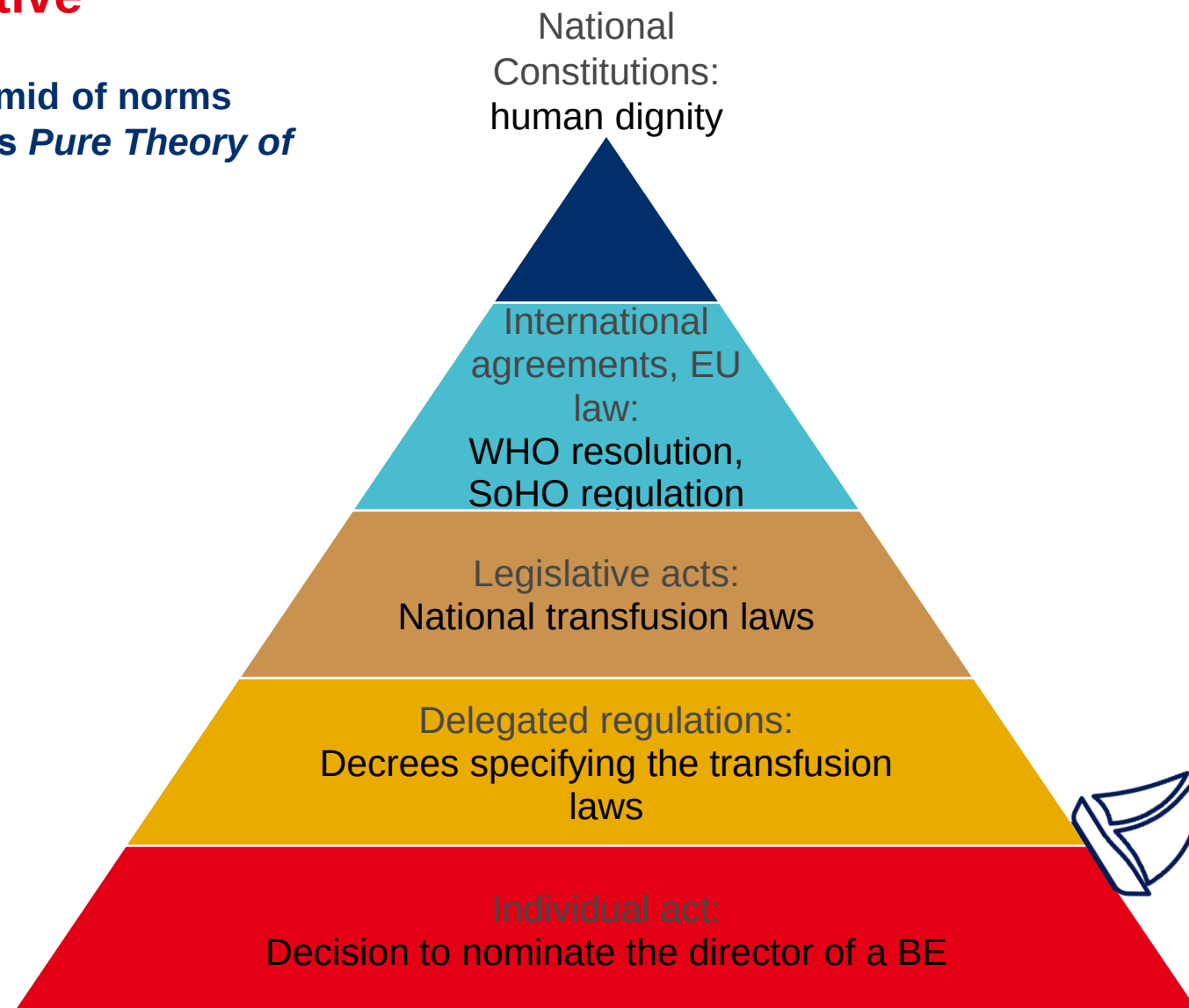


WE DEPEND ON LAWS

What is law? Blood donation's hierarchy of norms

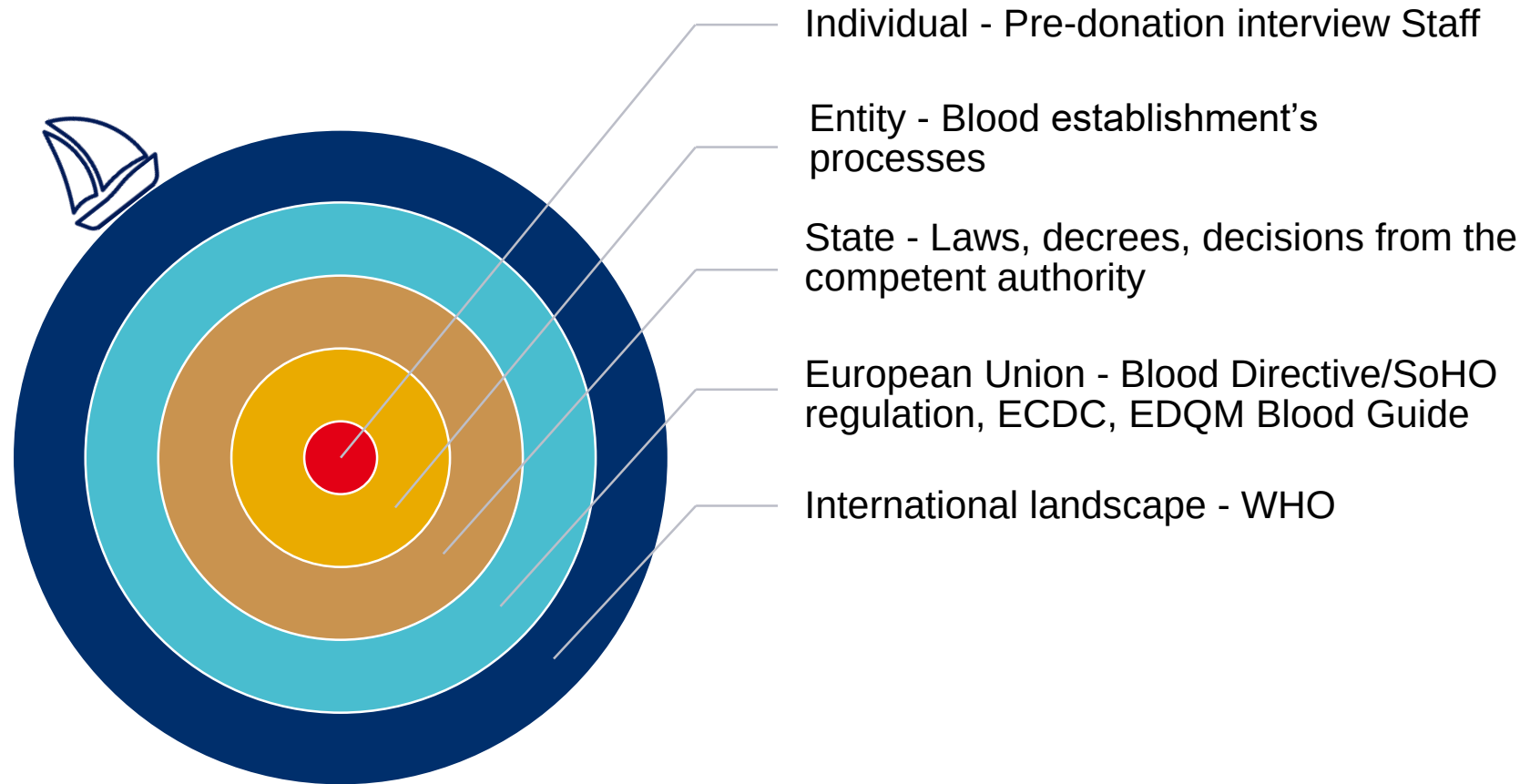
! Non exhaustive

Based on the pyramid of norms
from Hans Kelsen's *Pure Theory of Law* (1934)



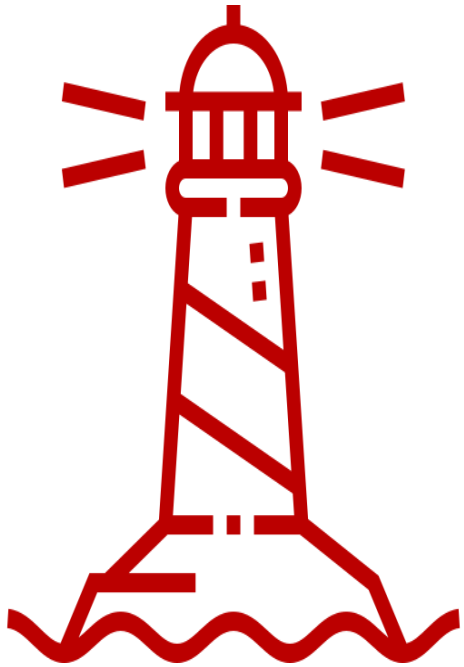
Example: Can I donate blood?

Various levels of norms



SoHO Regulation replacing the BTC Directives

A shift to anticipate

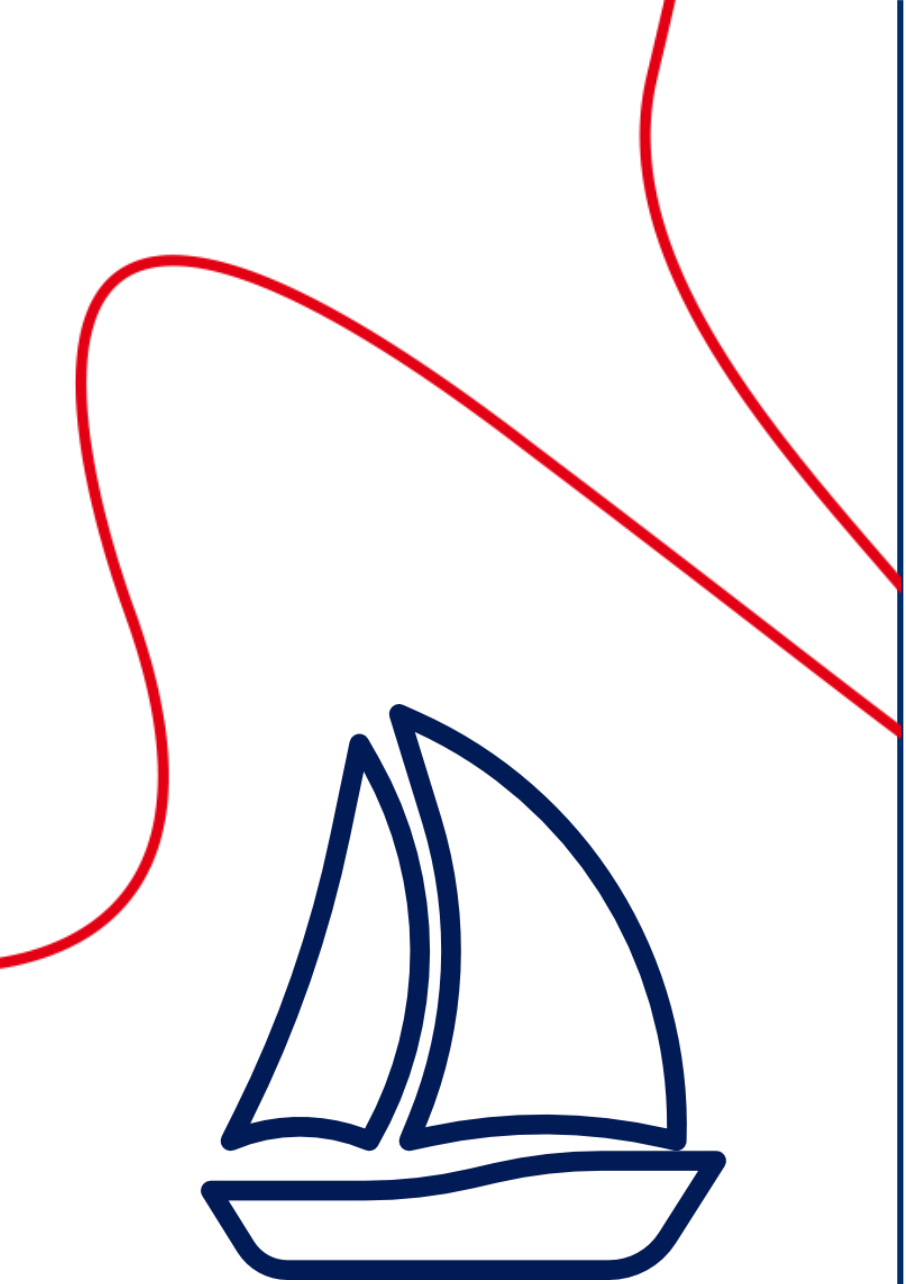


During the legislative process:

- Defending our practices
- Example: compensation

During the transition phase:

- Do an impact assessment of all your activities
- Example: Check that you align with the recommendations from EDQM's Blood Guide and ECDC, or anticipate alternatives "adequate to achieve compliance with the standards of the SoHO regulation".



WE DEPEND ON POLITICAL DECISIONS

What is a political decision?



The need for strategic autonomy, health sovereignty

Critical Medicines Act as a reaction to dependencies

« We must make our economy more resilient and less dependent. This is notably important in the health and pharmaceutical sector.»



Strasbourg, 11.3.2025
COM(2025) 102 final
2025/102 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795



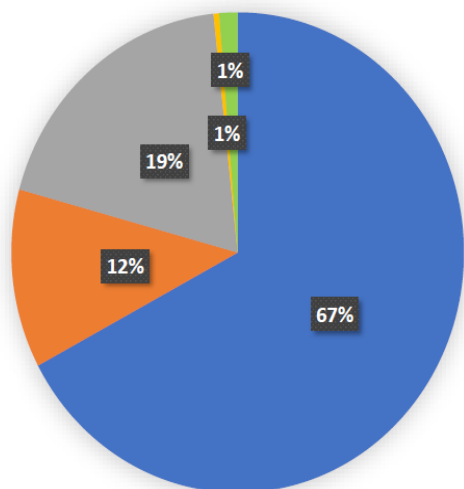
**Critical Medicines
Alliance**



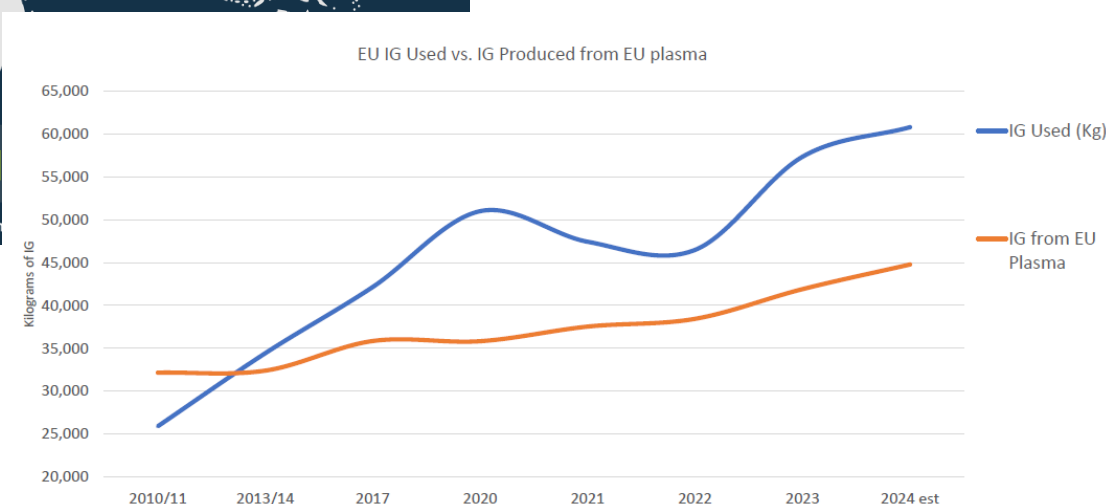
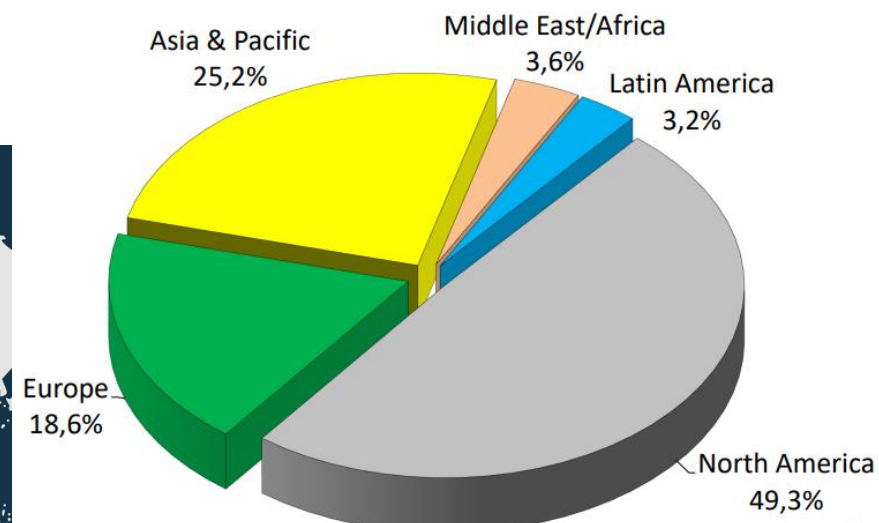
Plasma travels accross the globe

From plasma collection, manufacturing to consumption

Origin of Plasma for Fractionation - 2023



Total Plasma Collection volume 2023: ~85 M liters, up 19% over 2022.



Source: MRB, March 2025, EDQM stakeholder event –plasma supply continuity

[Interactive Map by Plasma Protein Therapeutics Association on Prezi Next](#)

efs.sante.fr

Établissement français du sang • ECDHM • 12/09/2025

14

The case of the Mexican plasma donors and the U.S. Customs and Border Protection

From June 15, 2021 to September 19, 2022, Mexican donors couldn't donate plasma



Plasma donation considered as "labour for hire" by the US CBP



HEALTH

Mexican residents donated a significant portion of plasma in the U.S. Now they can't

JULY 24, 2022 · 8:46 AM ET

HEARD ON WEEKEND EDITION SUNDAY



Ayesha Rascoe

Judge Lifts U.S. Ban on Mexicans Entering Country to Sell Blood Plasma

Pharmaceutical Companies Are Luring Mexicans Across the U.S. Border to Donate Blood Plasma

Companies offer high payments and bring-a-friend bonuses to Mexicans who cross the border on temporary visas to donate blood plasma. The U.S. offers weaker health protections for donors than most countries.

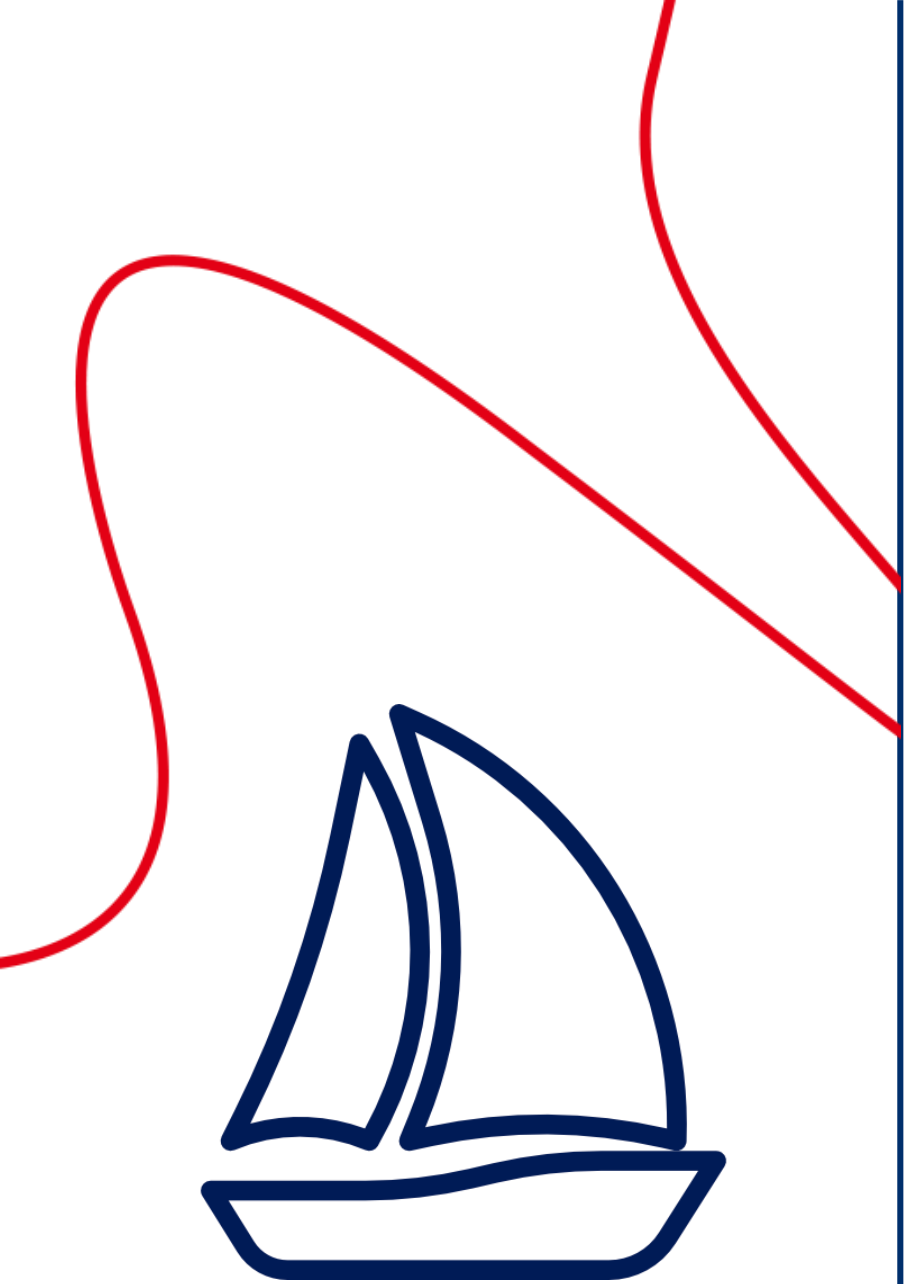
by Stefanie Dold and Jan Lukas Stroczyk, ARD German TV, and Dara Lind, ProPublica, Oct. 4, 2019, 12:01 p.m. EDT

Estimated loss of 10% of plasma collected in the US = 6% of the plasma collected globally

Short-term visas comprised as much as 10% of all visas issued in the U.S. when the practice was banned last year. Judge has granted a preliminary injunction.

Sources:

<https://www.npr.org/2022/07/24/1113257927/mexican-residents-donated-a-significant-portion-of-plasma-in-the-u-s-now-they-cant>



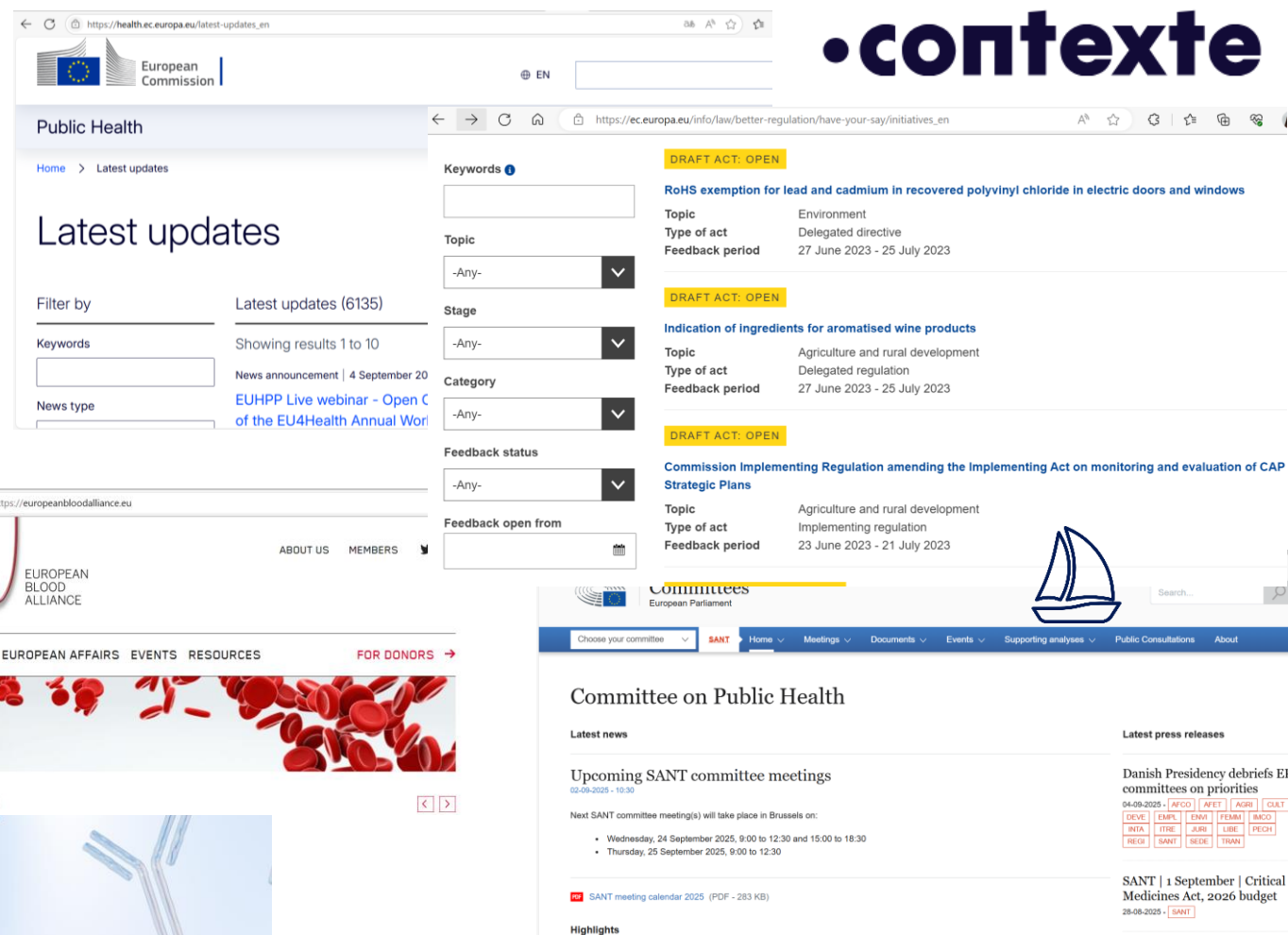
WE CAN SHAPE LAWS AND POLITICAL DECISIONS

Know your environment

Stay tuned, evaluate impact

EURACTIV
POLITICO
• contexte

- National, European media
- Social networks: X, LinkedIn
- Institutionnal websites
- Stakeholders' websites
- Specialized websites



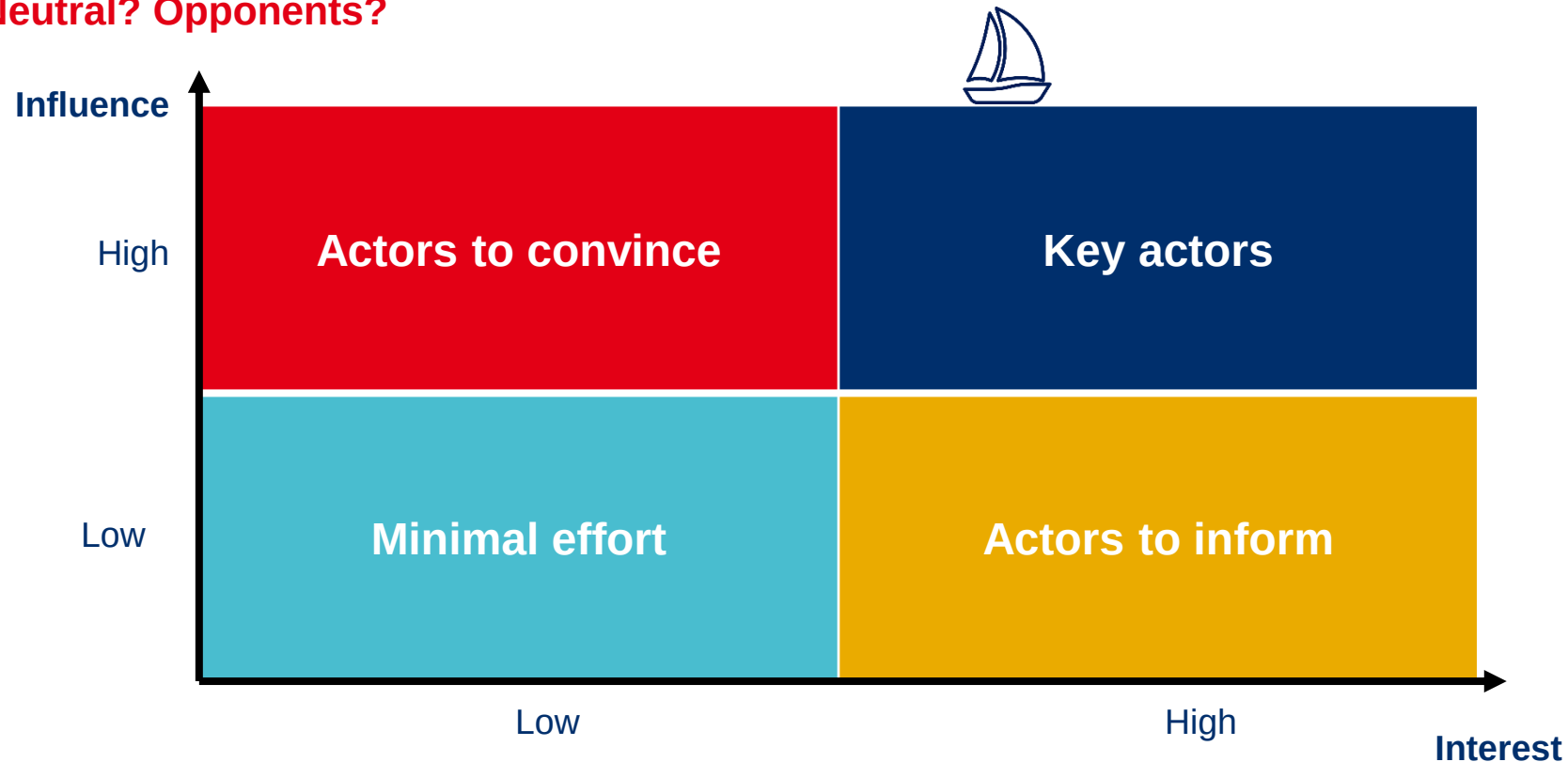
Know your environment

Mapping of the stakeholders

Institutions: minister, member of the (European) Parliament, European Commissioner, civil servants ...

Stakeholders: civil society, industry, ...

Allies? Neutral? Opponents?



Know your environment ... and yourself!

SWOT analysis



Blood donation is a reflect of your society

Listen to your society, anticipate the changes



Define your messages

Imagine your ideal world, set your red lines

Based on your news monitoring and impact analyses

- Impact can be economic, political, social, etc.
- In terms of image, activity, profitability, competition

Internally:

- Build awareness of advocacy, the EU, public affairs, etc.
- Consult all relevant experts

Discuss with allies, try to build common positions together

Your message:

- Clear, understandable, concrete
- One objective: CONVINCING

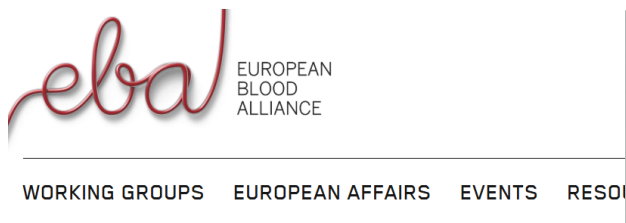
Build a narrative: positive, inspiring, etc.

- Add context: who are you? What is the topic? Define concepts.



Don't work alone ...

... It works!



OUR VOICE IN EUROPE

The voice of blood establishments in Europe

A core activity of EBA is representing blood establishments in our dialogue with legislators and policy-makers, contributing to Europe's progress towards an even safer and more sustainable supply of blood and blood components.

CORE SOHO

EBA is recognised as a not-for-profit body of information.



The Common representation of Substances of Human Origin (CoRe SoHO) is a consortium of professional scientific associations formed to provide representative technical expertise to the European decision-making organizations in the field of SoHO; above all, it seeks to be represented in official consultation forums responsible for the drafting of new regulations and revising existing legislation.



November 17, 2023

CORE SOHO WARNS AGAINST FRAGMENTATION OF PROTECTION STANDARDS

DOWNLOAD NEWS

CoRe SoHO statement on hierarchy of guidelines concerning protection of SoHO donors, recipients, and offspring

As the trilogue meetings on the SoHO Regulation begins, the *Common Representation of Substances of Human Origin* (CoRe SoHO), the consortium of professional scientific associations in the field of SoHO, calls on the co-legislators to adopt a hierarchical framework for those standards, or elements of standards, that affect donor, recipient, and offspring protection for which no implementing act has been adopted (articles 56/4 and 59/4).



Commit to Plasma

Home Signatories Download our Manifesto

Commit to Plasma

A Call to Action for national and European authorities

Endorse this Manifesto



Evidence-based policy-making

You have a key role to play!

The more you publish, the stronger your arguments will be.

- Data, evidence supporting your message

Not about quantity, quality:

- Peer-reviewed publications in recognized scientific journals
- Systematic reviews, meta-analysis, randomized controlled trials ...

Counter fake news, the ‘infodemic’

- Reports have shown an increase in the number but a decrease in quality of meta-analysis publications.



**Keep
going!**

Spread your message

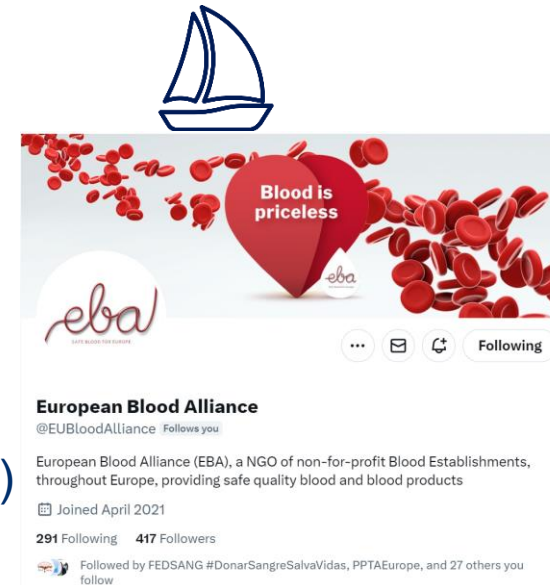
Anticipate, create trust, share knowledge

Written form

- Consultations (from the European Commission)
- Letters to M(E)Ps
- Press articles, op-eds, press conference, alert journalists
- Social media
- Studies
- Legal actions
- Sponsored content
- Write a book

Orally

- Meetings (if possible in person)
- Site visits
- Events (cocktails, conferences, seminars ...)
- Demonstrations, strikes



HOW WE PROVIDE EUROPEAN PATIENTS WITH SUSTAINABLE ACCESS TO PLASMA PRODUCTS

Pierre Tiberghien, EBA President

Peter O'Leary, EBA Executive Director

EBA CONCERNED WITH RULES ON MEDICAL DEVICES AND IN VITRO DIAGNOSTICS

[DOWNLOAD](#) [NEWS](#) [RESPONSES TO EU CONSULTATIONS](#)

The European Blood Alliance responded to the European Commission's target evaluation of Regulations 2017/745 and 2017/746 on medical devices and in vitro diagnostics. These Regulations aim to ensure the availability of safe and effective devices to protect patient safety and public health.

EBA welcomed the MDR and IVDR and their decisive contribution to a more harmonised framework across Europe. The implementation of the current MDR and IVDR, however, raised many challenges and had unintended consequences

SOHO REGULATION: VIBRANT DISCUSSION IN EUROPEAN PARLIAMENT

[NEWS](#)

There was a packed room in the European Parliament for "Blood establishments and the new SoHo Regulation: Protecting donors, delivering for patients", the event organised by EBA on 25 January. Co-hosted by MEPs Nathalie Collin-Oesterlé, Nicolás González Casares, and Tilly Metz, over 70 people on-site and over 150 on-line attendees also heard from representatives of EBA, the European Commission, donors, patients, and health professionals.

Ahead of submitting her report to the European Parliament's Committee

October 17, 2023

EBA POSITION ON EU PHARMA PROPOSAL

[DOWNLOAD](#) [NEWS](#) [POSITION PAPER](#)

17 October 2023

General Position on the European Commission's proposal for a reform of the EU pharmaceutical legislation

The European Blood Alliance, representing public/not-for-profit blood establishments, welcomes the European Commission's publication of its proposal for a reform of the EU pharmaceutical legislation.



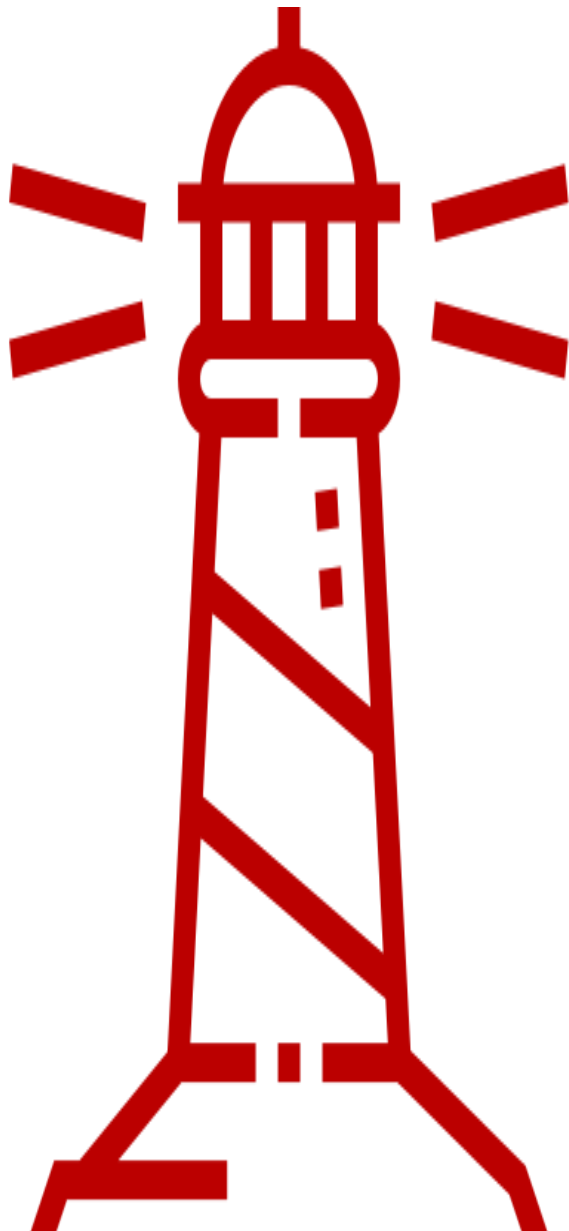
Anticipate !

VOTE !

Inform !

Engage !

Use your voice!



What political decision or legal text do YOU think could impact your work nowadays?

**What political decision or legal text
do you think could impact your
work nowadays?**



The Slido app must be installed on every computer you're presenting from



A thick red wavy line starts from the top center, curves down and to the left, then sweeps up and to the right, ending near the bottom right corner.

MERCI !

CONTACT

Marjolaine JACQUES

marjolaine.jacques@efs.sante.fr