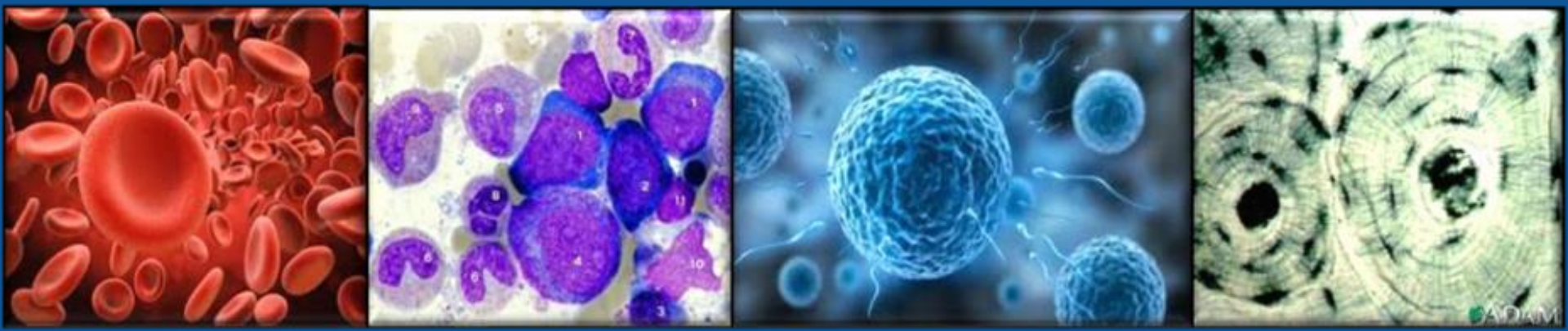
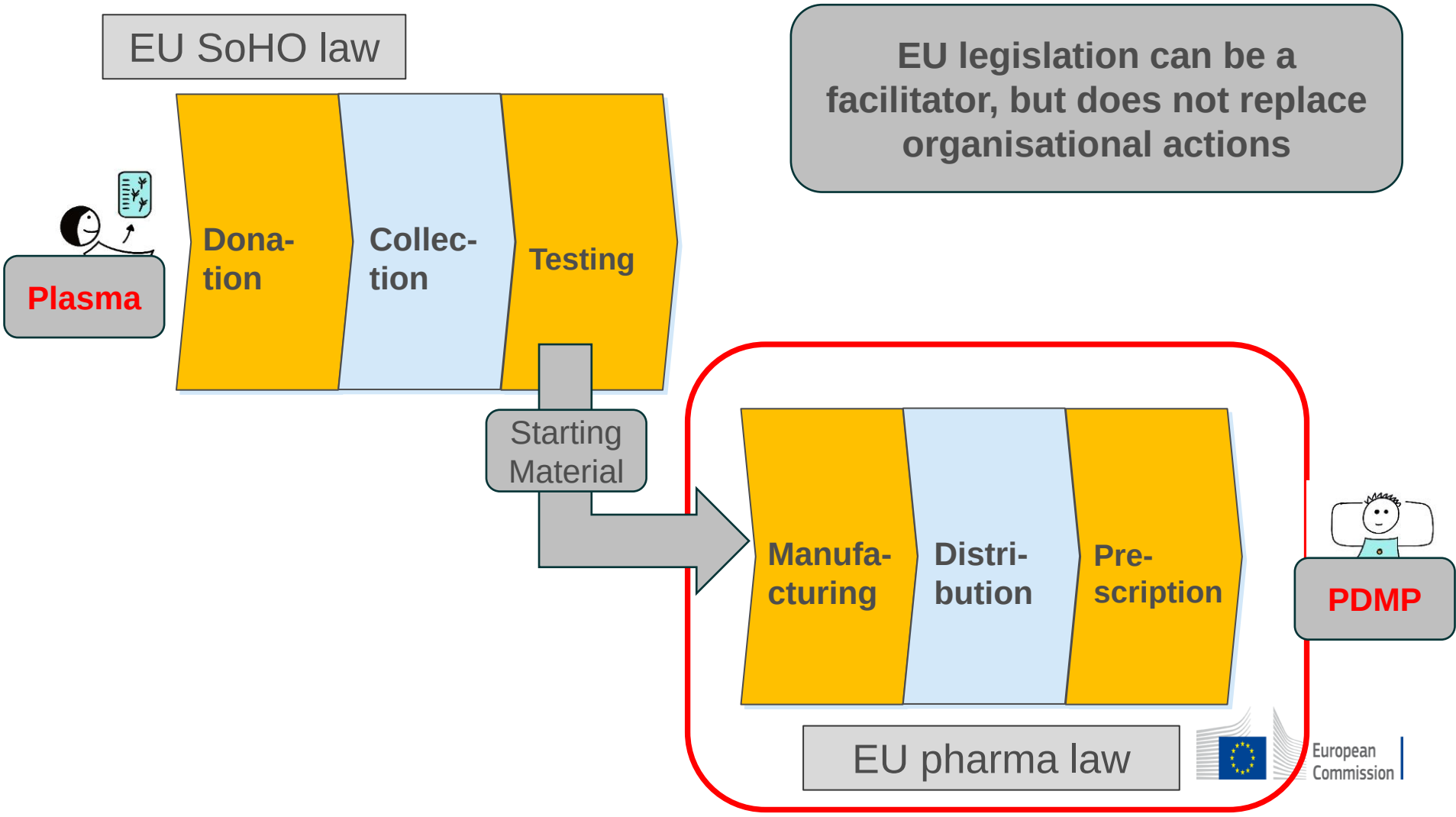
EU SoHO regulation and Plasma supply continuity

EDQM stakeholder event – plasma supply continuity
26-27th of March 2025

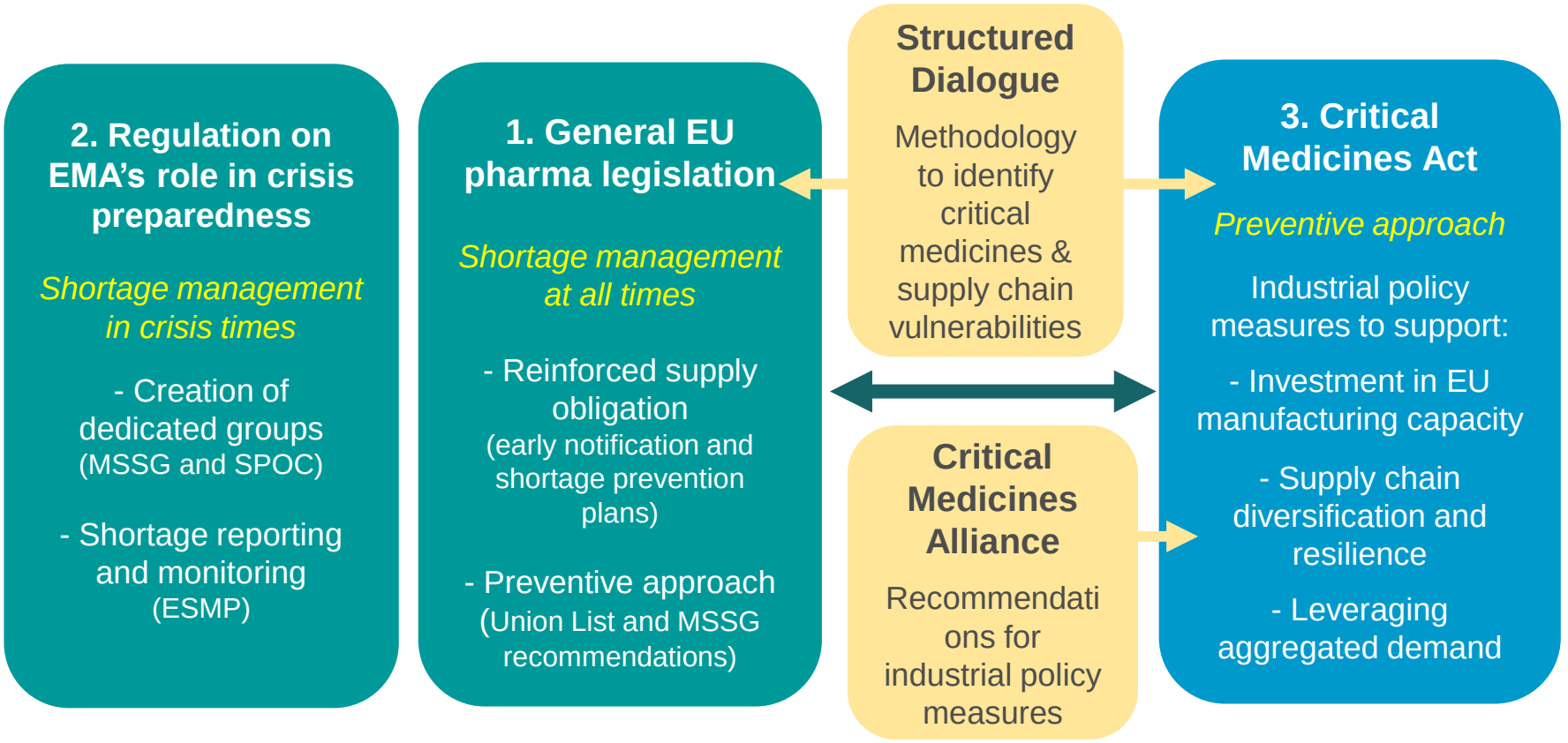
Dr Stefaan Van der Spiegel, European Commission



Take a step back first – dual framework



Comprehensive approach to ensure availability of critical medicines



European Commission

Getting the target right…

1. Union List of critical medicines

1. Ensuring medicines considered to be most **critical for health systems** are available at all times.

2. Critical medicines may be subject to coordinated Union level actions to **improve security of supply** following vulnerability analysis.

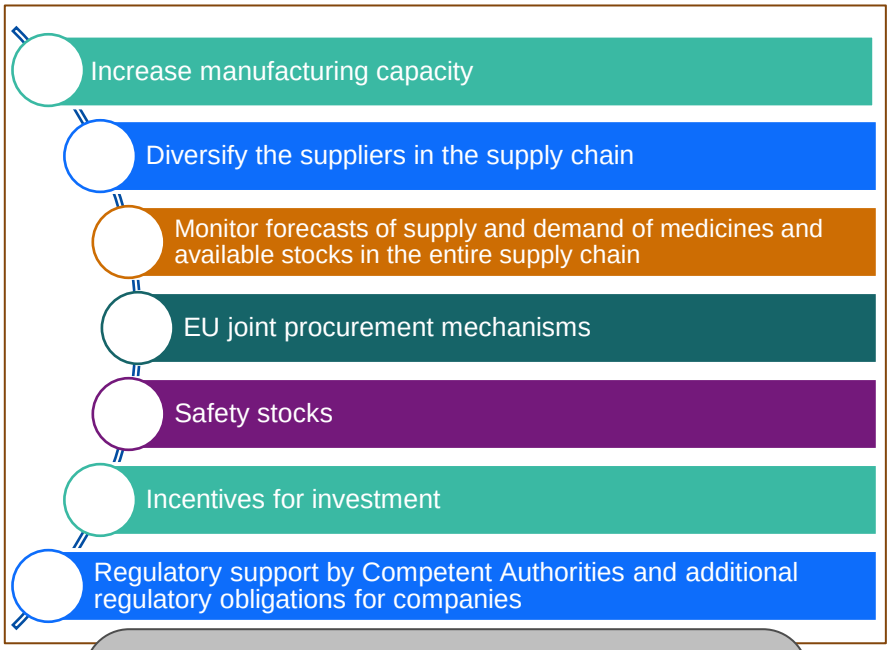
3. Provide **industrial capacity/ support** where medicines' supply chain vulnerabilities and dependencies are identified.

4. **Recommendations to Industry** on *"diversification of suppliers and inventory management"*

Current list includes, amongst others: normal Ig (IV and SC), Anti-D Ig, tetanus Ig and rabies Ig

[First version of the Union list of critical medicines agreed to help avoid potential shortages in the EU | European Medicines Agency (EMA)]

2. Strengthening supply chains of critical medicinal products



Under leadership of…
- EMA/HMA
- MSSG
- SPOC

[MSSG recommendations to strengthen supply chains of critical medicinal products]

European Commission EMA

2. EMA's roles in critical shortages of medicines

International cooperation

Global Regulatory Working Group on Drug Shortages

- Meets every quarter and share information about relevant drug supply issues (exchange of information and support each other)
- International cooperation on Drug Shortage Reporting, Signal Detection and Signal Assessment
- International cooperation and alignment on shortage mitigation and prevention strategies

Bilateral exchanges with e.g. FDA, HC, TGA, etc

- Shortages of concern to both regions
- Exchanges of best practices to mitigate and prevent shortages

MSSG Solidarity Mechanism

The VSM is used as a **last resort** to **temporarily alleviate critical shortages in a Member State**.

Allows a MS to **request assistance** from other Member States in obtaining stocks of a medicine **during critical shortages**

4 VSM procedures concluded, all successfully

Conditions:

1. EMA already notified of the shortage (SPOC WP)
2. No or insufficient therapeutic alternatives available
3. Insufficient quantifies to treat critical indications
4. No or insufficient relief from short-term measures
5. Urgency (e.g., < 1 month supply)

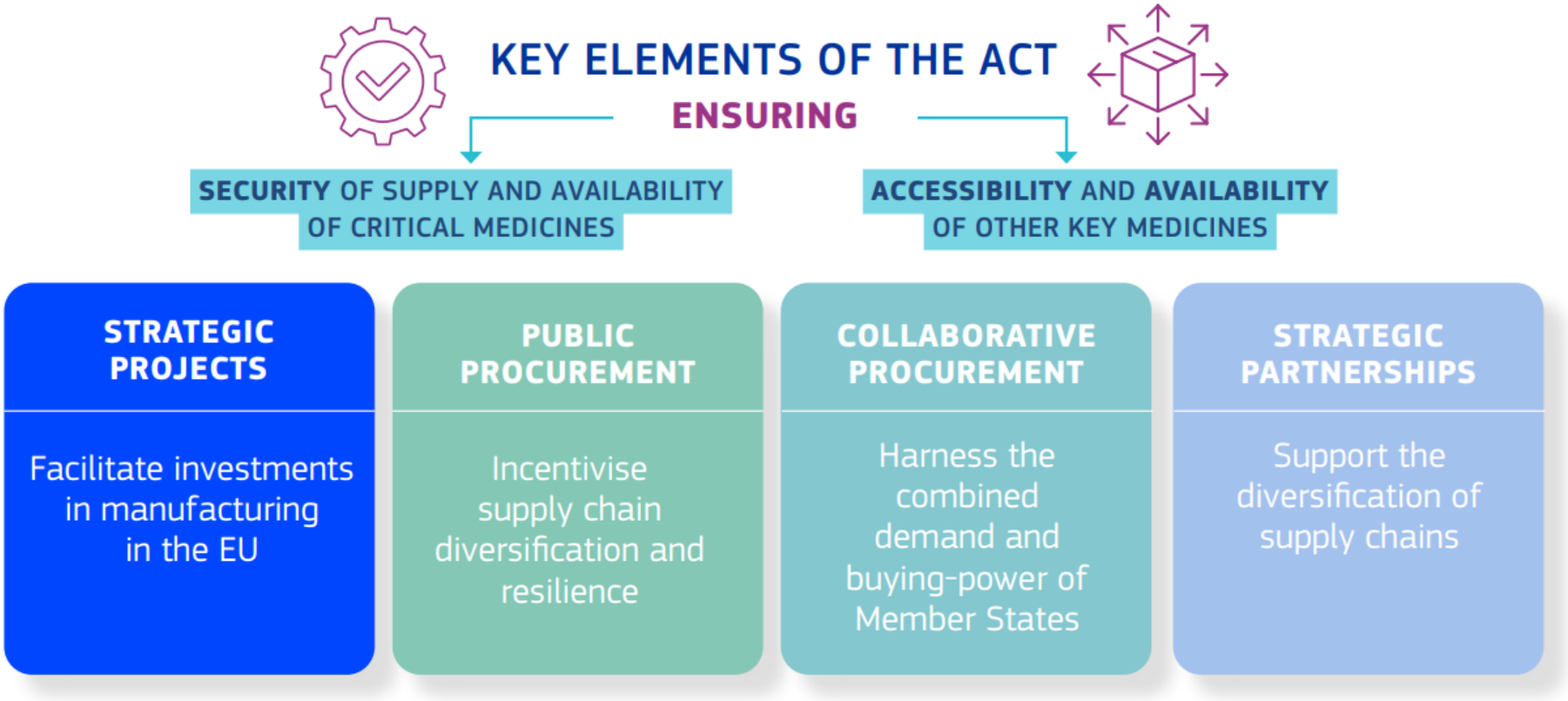
MSSG Solidarity mechanism process (europa.eu)

MSSG Toolkit

- Labelling exemptions
- Extension of shelf life
- Accelerating supply-critical variations
- Liaison with EDQM (CEP acceleration)

MSSG recommendations toolkit (europa.eu)

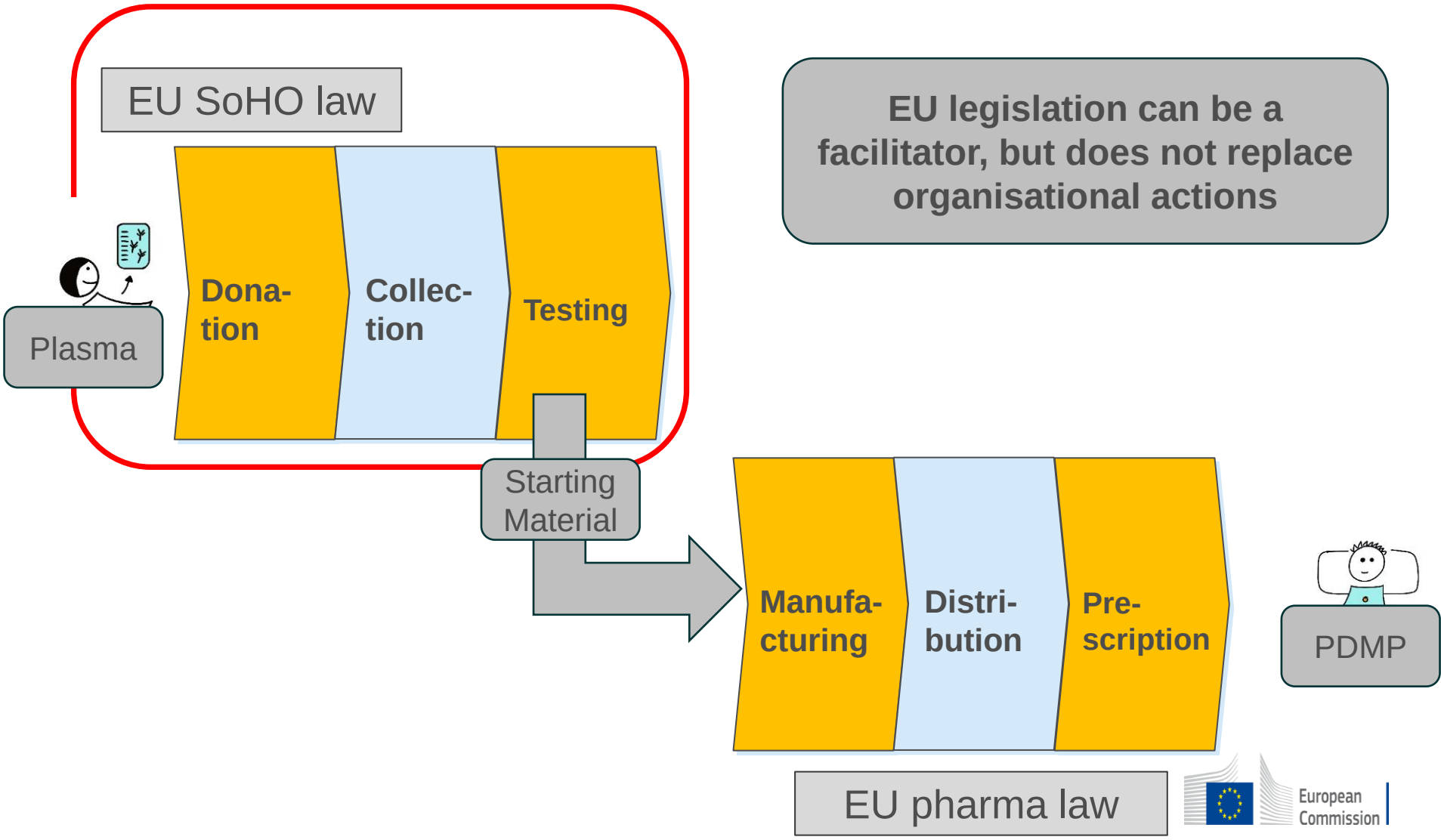
3. Critical Medicines Act



- Adopted on 11 March 2025
- Entails an industrial policy, and complements Pharma Reform
- EMA, MSSG's and SPOC roles

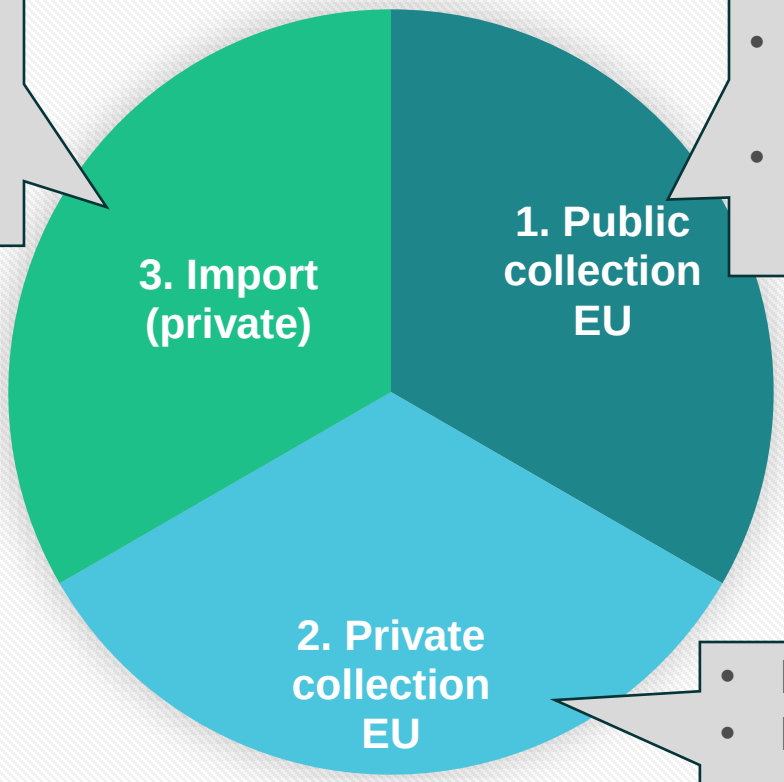
European Commission

Take a step back first – dual framework



Portfolio of plasma sources

- Increasing importance, as EU growth in collection (1. and 2.) < EU growth in demand
- Mainly US



- Recovered from whole-blood + (increasingly) plasma-only donation
- Low frequency donations
- Huge (potential) donor base (15million in EU)

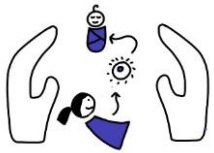
- Plasma-only donation
- High frequency donations
- Limited nr of donors (x00,000)

Supporting measures in new SoHO regulation

-> Addressing 5 gaps/shortcomings identified during the 2019 evaluation

- **1. Patients are not fully protected from avoidable risks**

EU safety and quality requirements are incomplete and have failed to remain up to date with frequently changing scientific and epidemiological developments. The outdated provisions are technical in nature



- **2. Avoidable risks for BTC donors and for children born from donated eggs, sperm or embryos**

Donor adverse reactions (including serious ones) are not systematically reported and the requirements for testing egg and sperm donors for genetic conditions are limited.

- **3. Divergent approaches to oversight cause unequal levels of safety and quality and barriers to the exchange of BTC across the EU**

Lack of general principles, provisions for verification of effective implementation of inspection, authorisation, vigilance.

- **4. BTC legislation lags behind innovation**

Limited clinical data on safety and efficacy of new ways of processing donations. Difficulties in defining the borderlines for novel BTC with other regulatory frameworks

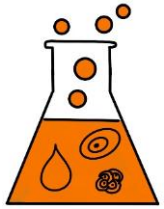
- **5. EU vulnerable to interruptions in supply of some BTC**

High dependence on plasma import. Lack of supply monitoring for crisis management.

Directive on Blood & blood components: 2002
Directive on Tissues & Cells: 2004

European Commission

Resilience of Supply



Critical SoHO

'Critical SoHO' are 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.

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

Part of EDQM agreement, building on previous work (B-SCEP)

European Commission

Need for comprehensive end-to-end actions, operational, not just legal (SUPPLY action EU4H)

- Improve organisational efficiency (public sector)

Dona-tion | **Collec-tion** | **Testing**

- Public awareness building
- Donor recruitment and retention
- …

- Coherence requirements
- Allocation (e.g., toll/contract manufacturing)
- …

Manu-facture | **Distri-bute** | **Pre-scribe**

- On/off-label use,
- Central approval system
- Prioritisation schemes
- …

European Commission

Efforts to come from all actors around and across the donor-recipient supply chain

EC/EDQM plasma symposium 2019

- **European Commission** (donor protection and vigilance, awareness building on need for collection, support strategic independence, optimize legal framework, …)
- **EDQM** (Council of Europe) (data reporting, awareness building evidence based guidance, networking and conference on optimal use)
- Member States/National Competent **Authorities** (national targets for collection, monitor/report, contingency plans, donor vigilance)
- **Blood Establishments** (increase collection, donor safety, good practice exchange)
- **Manufacturers** (Collaboration on optimal use, data and knowledge sharing (SARE, best practice, decision support)
- **Associations/Societies** of patients, donors and professionals (awareness building, optimal use, good practice)

European Commission

Thank you

European Commission

The 22nd Edition of the Blood Guide Plasmapheresis

Johanna Castrén, MD, PhD

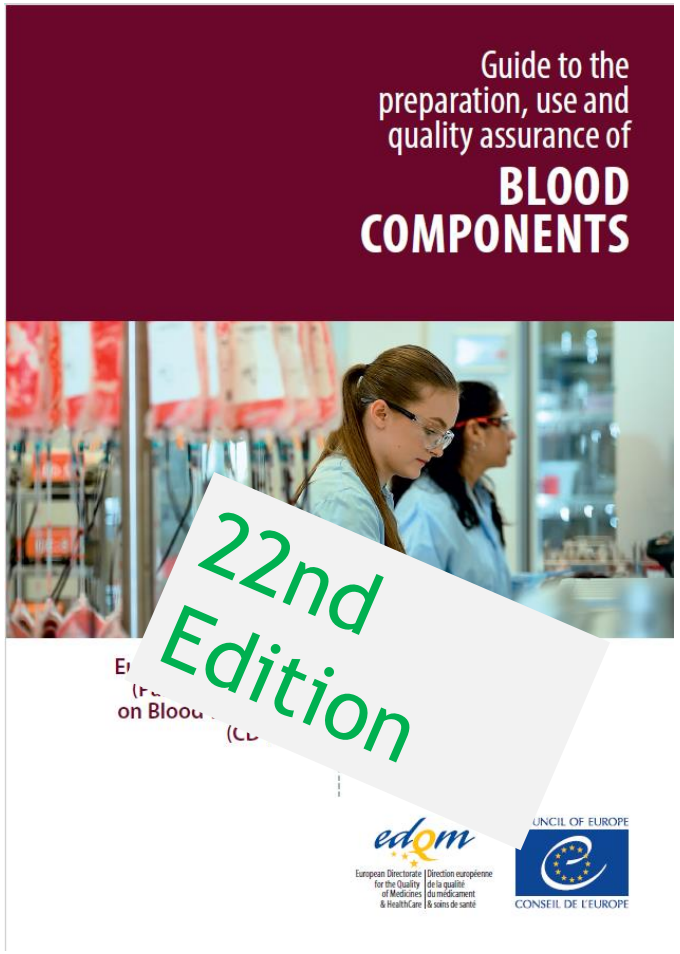
Chair - European Committee on Blood Transfusion (CD-P-TS)

Director, Blood Donation - Finnish Red Cross, Blood Service

Conflicts of Interest

- No

Timeline



Stakeholder consultation – May/June 2024

Adoption

- CD-P-TS November 2024

Final copy-editing, proofreading and layout

- November 2024/February 2025

Publication

- March/April 2025

History

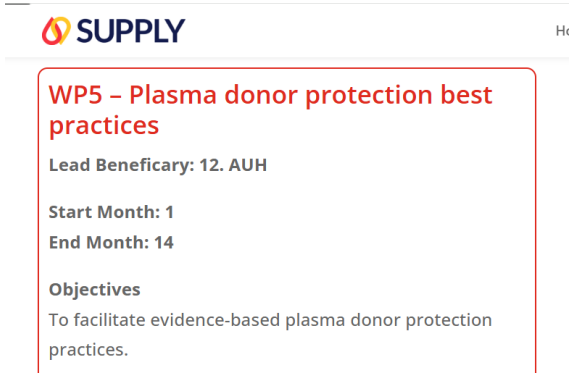
(Experience from Previous Editions)

What is safe?

Every change needs evidence – otherwise current standard remains

- Maximum annual number of plasma donations?
- Minimum interval between donations?
- How can we ensure donor health by using protein and IgG measurements?

Support / Collaboration



WP5 recommendations emphasize adhering to the Blood Guide (21st edition, 2023) until further evidence is available. The guide's suggestion of a maximum of 33 donations per year lacks supporting evidence for donor safety.

- **Maximum of 2 plasma donations /month** until safety of higher frequencies is confirmed. Personized donation practices in the future?
- **Monitoring IgG levels** (Optimal algorithms and test intervals?)
- **Urgent initiation of studies** to examine health consequences of varying donation frequencies.
- **Implementation of a standardized haemovigilance register.**

Call for further controlled studies to explore health effects, adverse events, and factors related to plasma donation

https://supply-project.eu/wp-content/uploads/2024/02/D5.3-Recommendations-on-protection-of-plasma-donors.pdf

”Two paths” strategy

A policy to seek collaboration, share data and understanding between stakeholders **without** making it dangerous for donors

We know that there are:

- Significant variation of practice
- Knowledge gaps
- Variation among donors
- A continuing demand for Ig

The text in the 22nd edition has two options:

Standard plasma collection approach

- Total proteins must be measured at least annually and must not be less than 60 g/L (Directive 2004/33/EC, Annex III)
- IgG levels should be measured at least annually and within local population reference ranges and should not fall below 6.0 g/L
- The minimum interval is recommended to be at least 2 weeks

Individualized plasma collection approach

- The donation interval is more frequent than at least 2 weeks but never more frequent than once a week
- Requires more frequent monitoring of adverse reactions, IgG level and iron stores
- Should be approved by the competent authority
- The monitoring should prove that this approach is as safe as the standard plasma collection approach

What is new?	What is not changed?	What is deleted?
The minimum interval at least 2 weeks	The donation interval can never be less than 1 week	The maximum number of plasma donations 33 per year
The competent authority should approve any plasma program where the donation interval is less than 2 weeks	Total proteins must be measured at least annually and must not be less than 60 g/L (Directive 2004/33/EC, Annex III)	Specific IgG algorithm
If interval between 1 and 2 weeks -> requirement of additional monitoring of the donor Donor adverse events, IgG levels, Red cell loss	IgG levels should be measured at least annually and within local population reference ranges and should not fall below 6.0 g/L	

Guide Ch2 (Donor selection) provided a background paper considering donor health and plasma donation

- We know that:
  - Hypo-IgG should be avoided in case of donor safety and the quality of plasma
  - Donating plasma reduces level of proteins in donor's plasma
  - Donating frequently can reduce iron stores
  - Adverse reactions and events do not increase with increasing frequency of donation
  - The effect on the donor is individual
  - Data are lacking

- Published studies show, that:
  - A 2 weeks interval is safe and can be recommended
  - Less than 1 week interval is not safe and should not be recommended
  - 1-2 weeks interval – is a grey zone, but with more frequent donation interval there is an increased risk of hypo-IgG and low ferritin. Therefore, increased monitoring on an individual basis is recommended

Two paths strategy - summary

Standard (group) plasma collection approach – this is safe

- Plasma donation frequency no more than 2 weeks
- Annual IgG level measurement

Individualised plasma collection approach – need to demonstrate this is as safe as the standard collection approach

- Encourage approval from competent authority – role for Competent Authority
- Plasma donation frequency never less than 1 week – less than 1 week is not safe
- More frequent monitoring of donor, not just IgG level
- Donation interval adjusted accordingly to results of monitoring

- We need data – encourage publication

Thank you ☺

CURRENT MARKET LANDSCAPE FOR PLASMA AND IMMUNOGLOBULINS IN EUROPE

Matthew Hotchko, PhD
Marketing Research Bureau
Strasbourg, France

EDQM Meeting
March 26-27, 2025

METHODOLOGY AND DISCLAIMER

THE DATA USED TO DEVELOP THE CHARTS AND TABLES SHOWN IN THIS PRESENTATION HAVE BEEN COMPILED FROM SURVEYS CONDUCTED BY THE MARKETING RESEARCH BUREAU IN OVER 90 COUNTRIES AND PUBLISHED IN VARIOUS SYNDICATED REPORTS.

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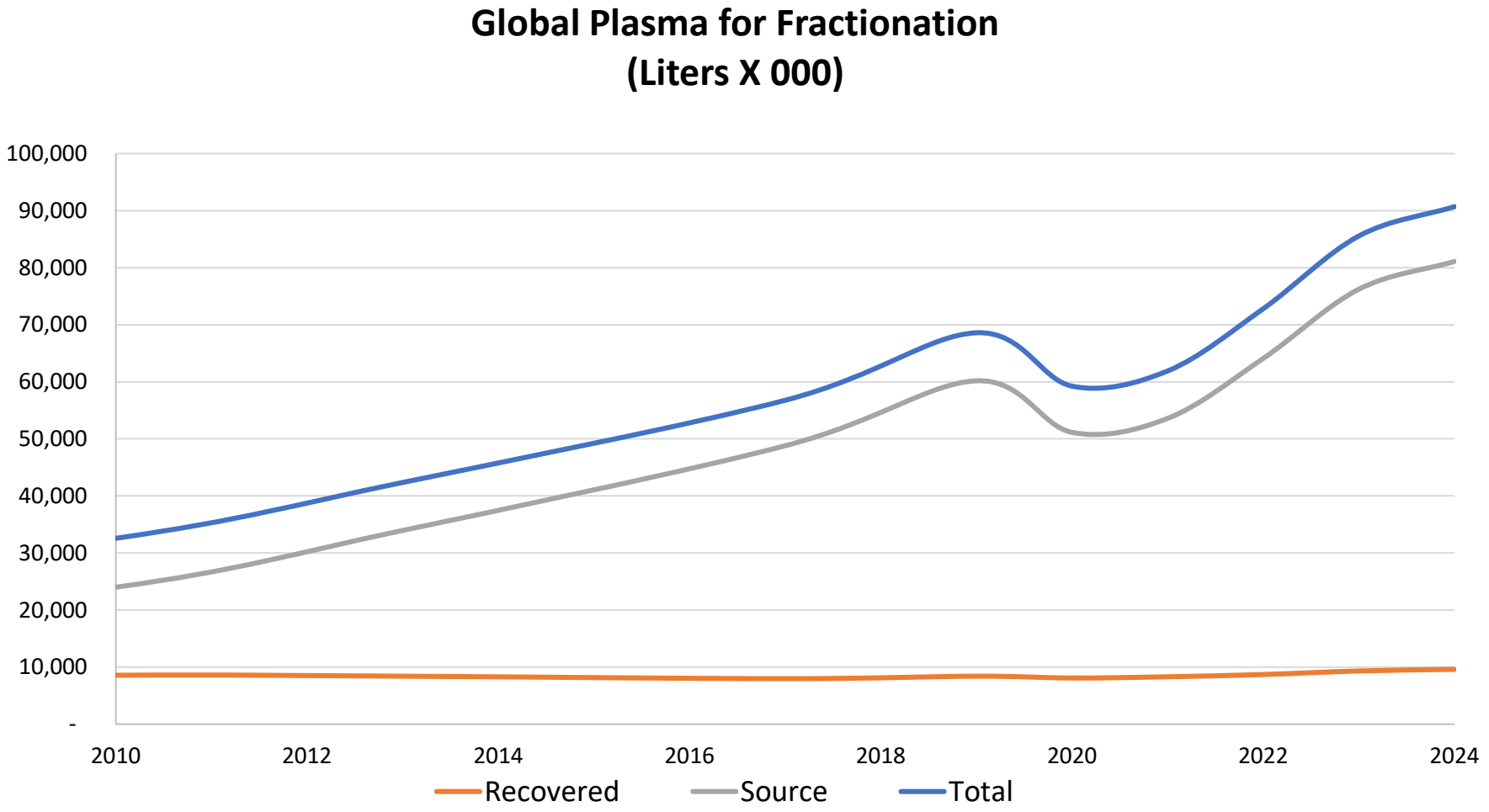
OVERVIEW

- Plasma Collection from 2010 to 2024 – Global and European Union
- Worldwide 2023 Plasma Collection and 2024 estimates
- Global and European IG Usage through 2024 and thoughts on the future
- EU Self-Sufficiency – Where does it stand today?
- EU Collections Volumes needed to reach 100% EU Self-Sufficiency

In 2023, global plasma collections continued to grow strongly and at a lower pace in 2024



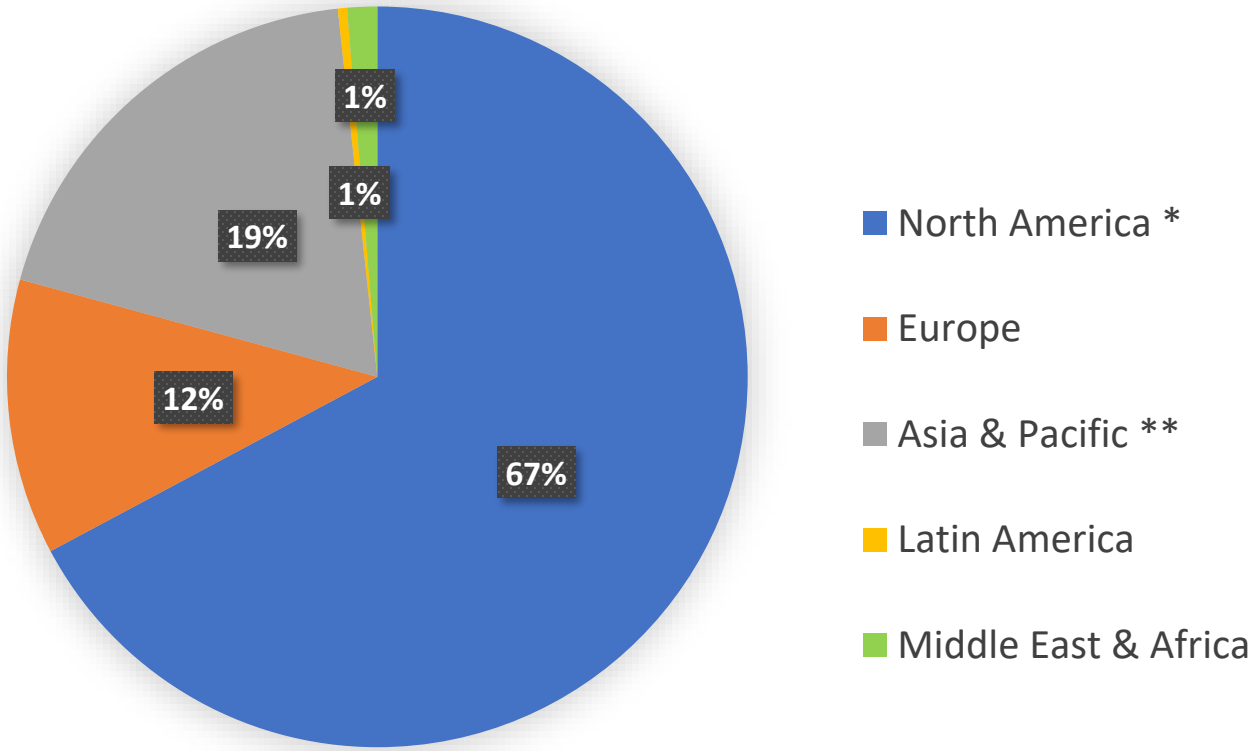
Global plasma collection recouped from the pandemic by 2022 and hit records in 2023 and 2024, to over 90 million liters

Since 2020, source plasma has grown 12% per year on average, providing 95% of the overall volume increase in the period

The volume of Recovered plasma (all public) grew 4.4% per year on average since 2020

Plasma Collections Growth in 2023 was strong while in 2024 it moderated

Origin of Plasma for Fractionation - 2023



2023 vs. 2024

- Up ~3-6%
- Up 6-8%
- Up >10%

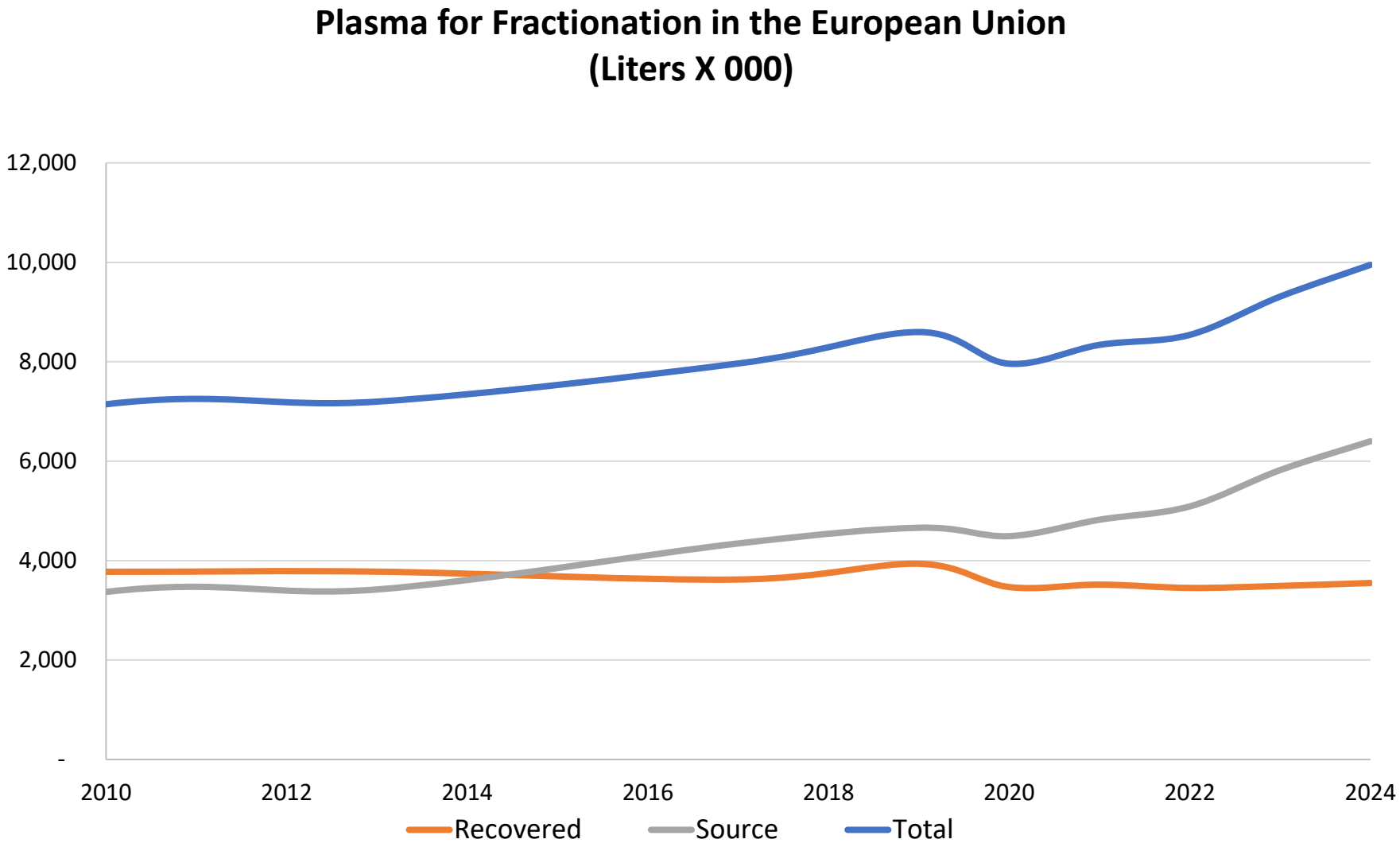
*United States represented ~99% of the North America total

** China represented >70% of Asia & Pacific total

2024 collections were estimated to be 5-6% higher than in 2023

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

In the European Union, plasma for fractionation has also been growing

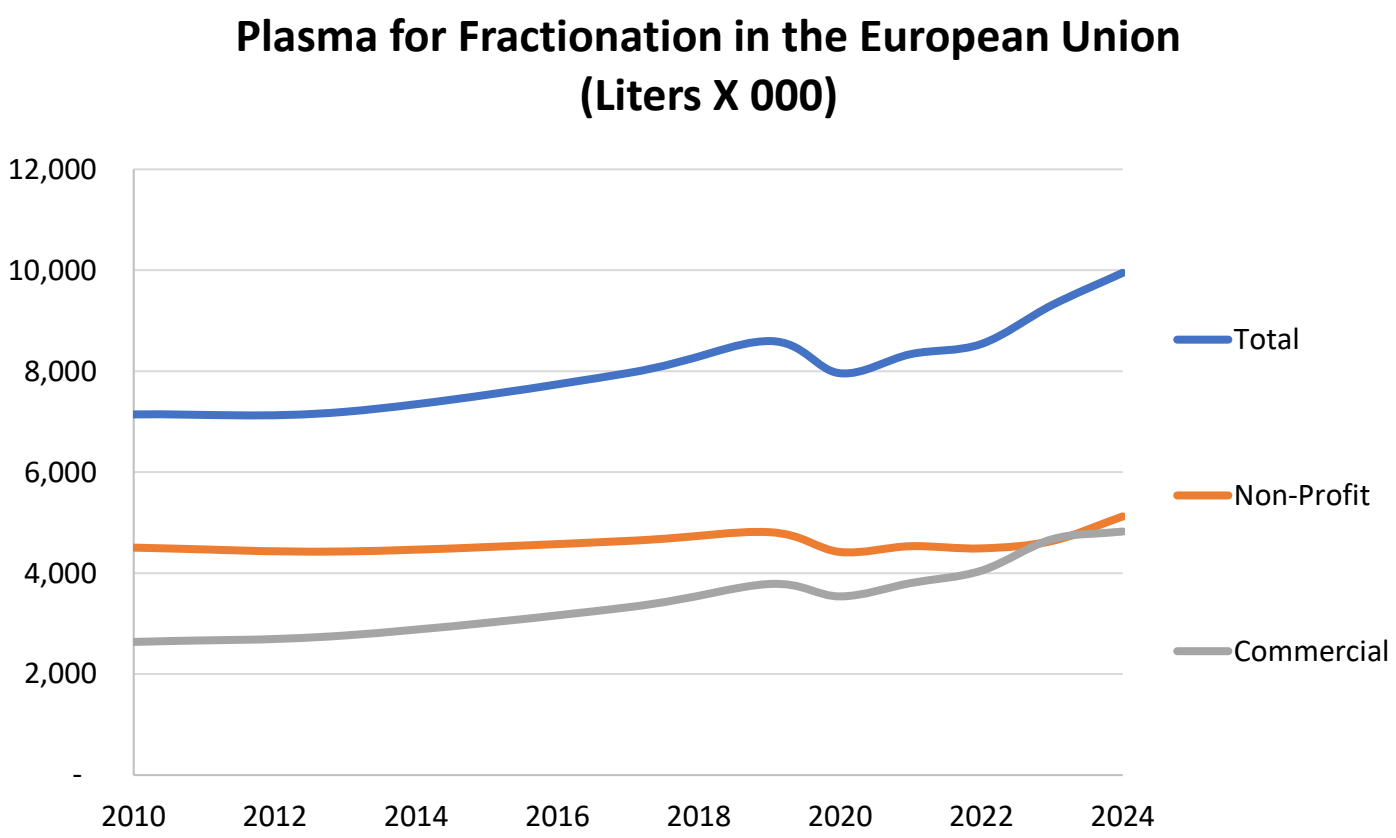


EU plasma collection at nearly 10 million liters in 2024, a 5.7% growth over 2020

Since 2020, source plasma has grown 9.3% per year, providing 96% of overall volume increase since then. 64% Share of 2024 total

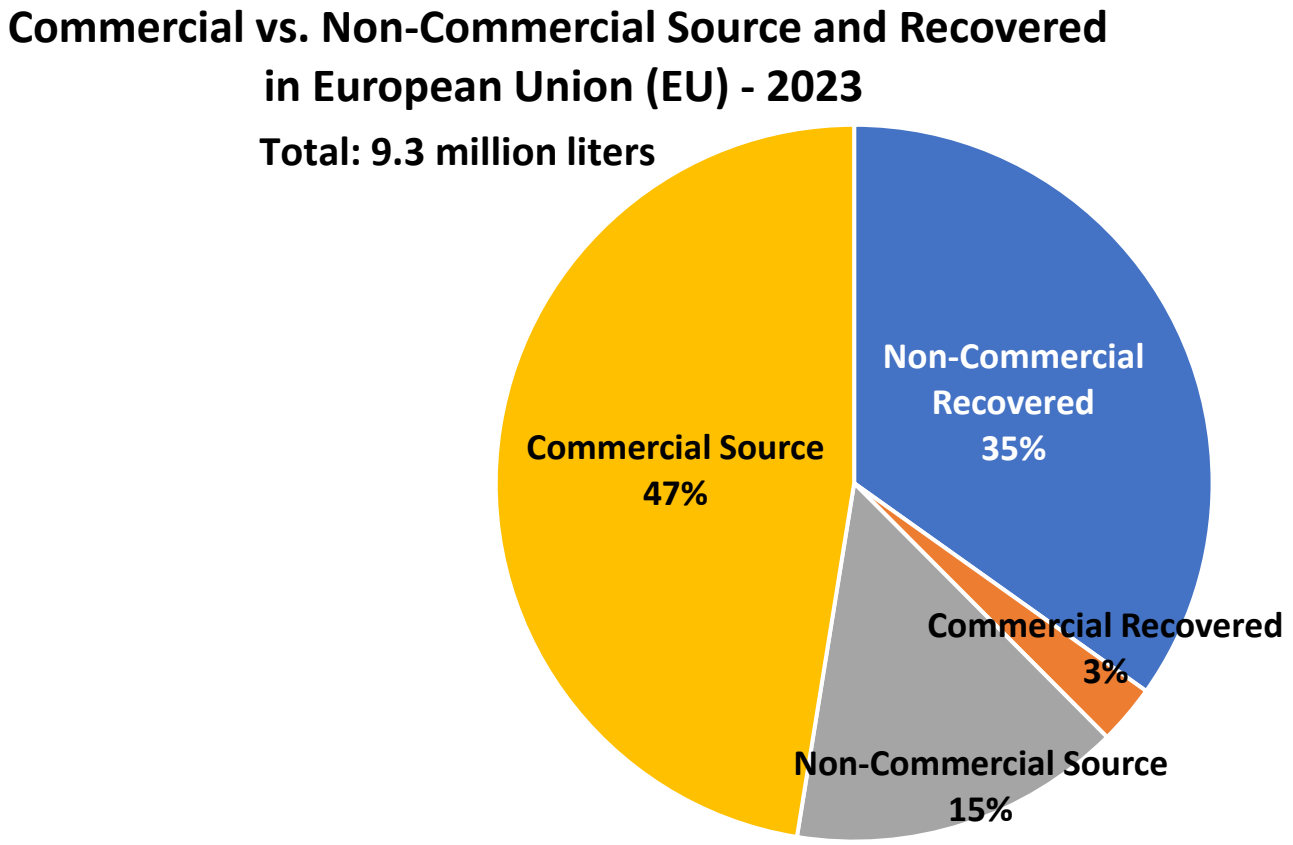
Recovered plasma volume (nearly all public) was flat at 0.6% growth per year since 2020. 36% Share of 2024 total

Europe Non-Profit and Commercial Collections have both recently grown

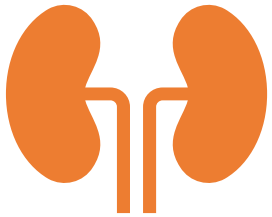


- Plasma collected by non-profit organizations has nearly always been larger than commercial organizations (50% share in 2023)
  - 2020-2024 CAGR: 3.8%
- Commercial organizations only collect in 4 countries, with 113 million people, or 25% of the total EU population but are not half of total collections (50% in 2023)
  - 2020-2024 CAGR: 8.0%

EU plasma source by type in 2023



What's driving Collections Growth in the EU?



Non-Profit

More investment in plasmapheresis collection, including stand along plasma centers

More outreach to donors, including advertising for plasma donations

Converting blood to plasma donors – who donate more frequently

Partnerships with donor organizations

Commercial

Expansion of plasma centers (>80 more centers between 2020 and 2024)

Higher donation fees (30-40 € per donation)

More advertising in media, including social media

Introduction of donor app on phones

Global IG Demand has been robust

IG and albumin are “last liter” products, meaning the demand for these drive all the investment and growth in plasma collections and fractionation

IG sales are now over 60% of total plasma derived sales globally

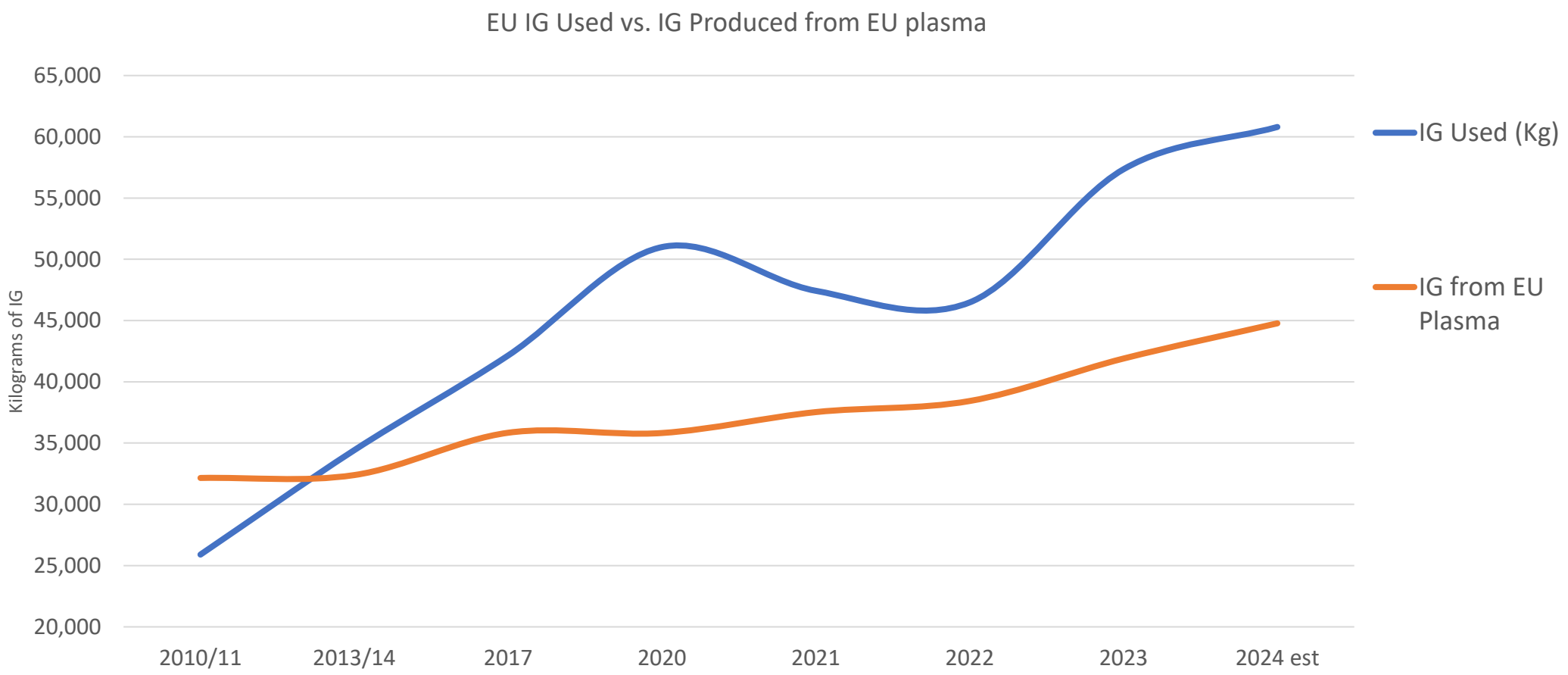
Global IG demand has grown over 20% in total from 2022 to 2024, to over 325 metric tons, as sales were constrained by supply in 2022, due to the pandemic.

IG demand has grown due to more usage in autoimmune conditions (including CIDP and MG) as well as immunodeficiencies (PID and especially SID)

EU Demand for Immunoglobulins

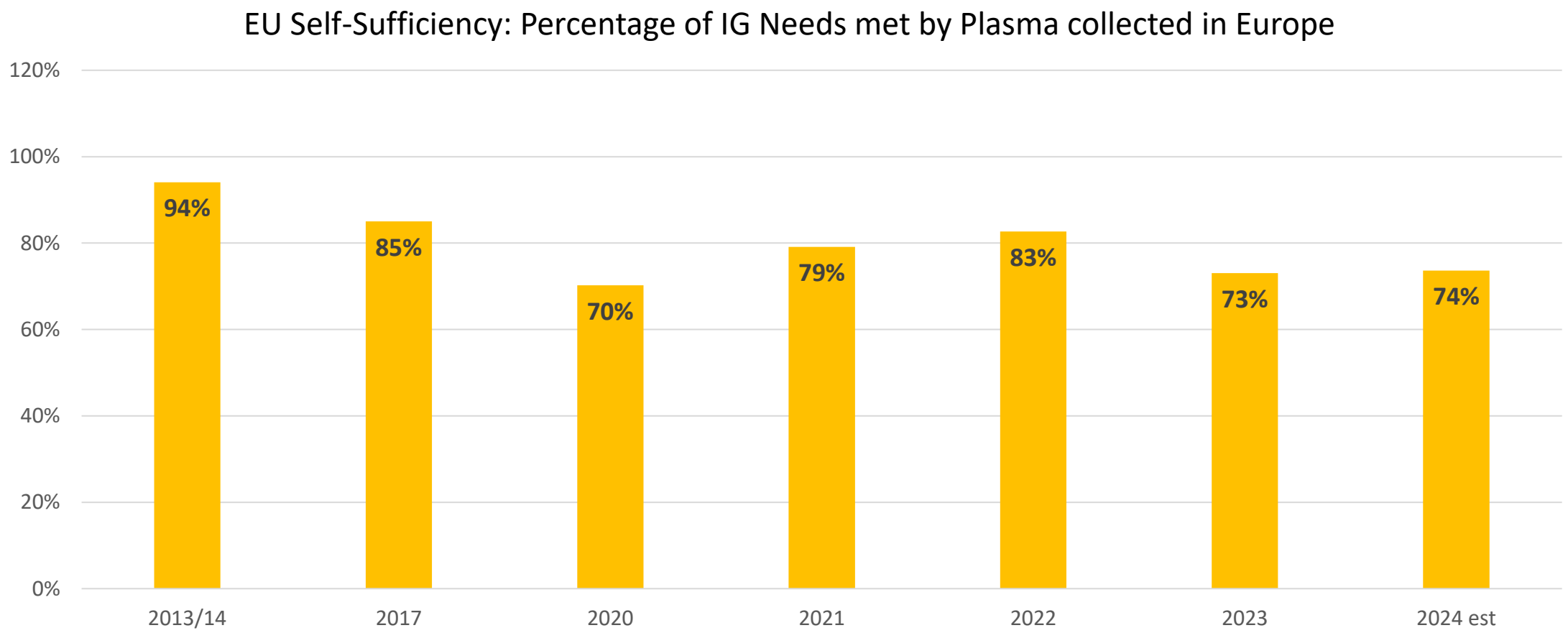
- Between 2020 and 2023, total European Union IG grew 4.0% per year to over 57 tons
- Growth has been driven by Immunodeficiencies (especially SID) and autoimmune conditions, including CIDP, MG and GBS
- 2023 – 2030 IG Growth rate forecasted to be 4.5% per year, leading to total market of over 77 tons in 2030.
- Future growth driven by SID, further penetration of autoimmune conditions, aging, better diagnosis
- This will require plasma growth of approximate the same rate (4.5%) to keep the same EU self-sufficiency rate as today

Over the past 10 years, the European Union has failed to collect enough plasma for fractionation to meet the current usage levels



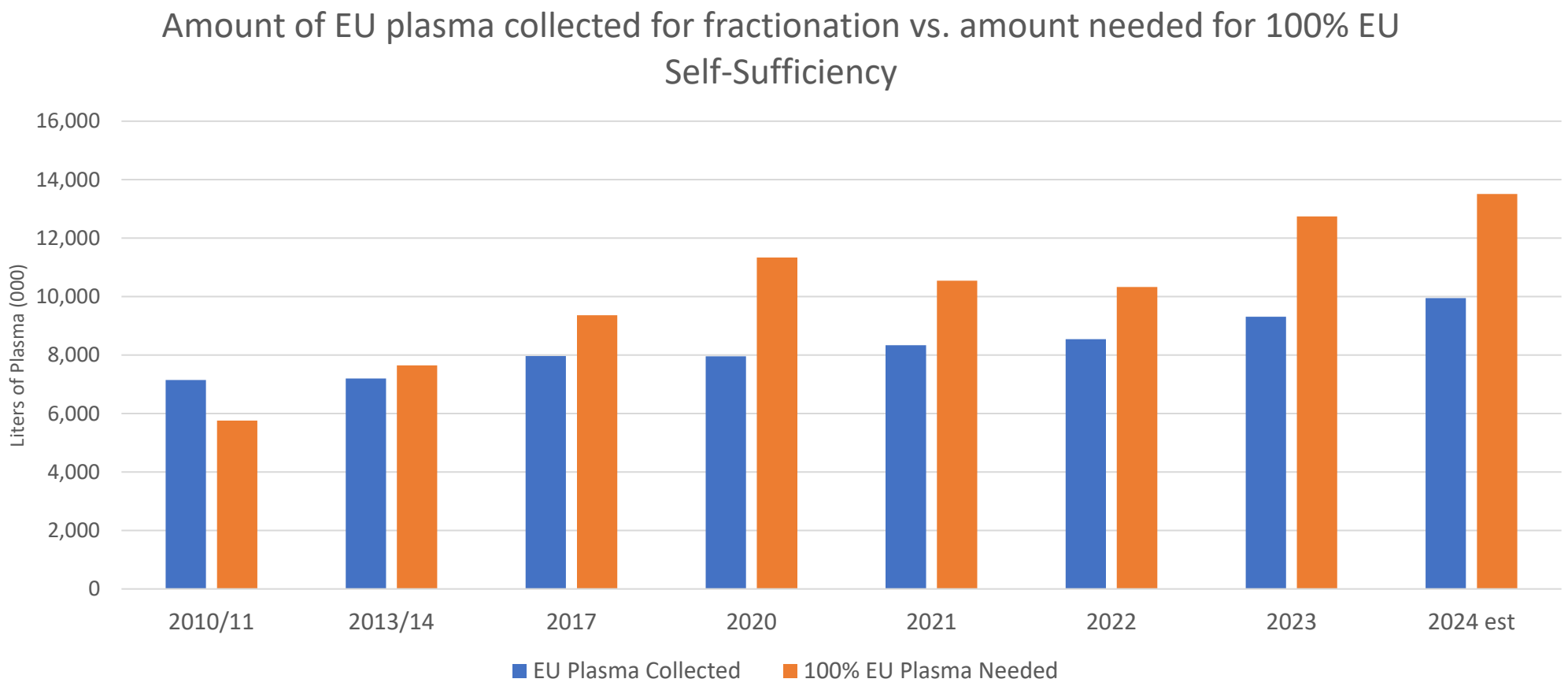
Note: IG yield from 1 L of plasma: 4.5 grams for both recovered and source plasma

Self-sufficiency levels have stabilized at around 70-80% since 2021, meaning around one fourth of IG is imported from the United States



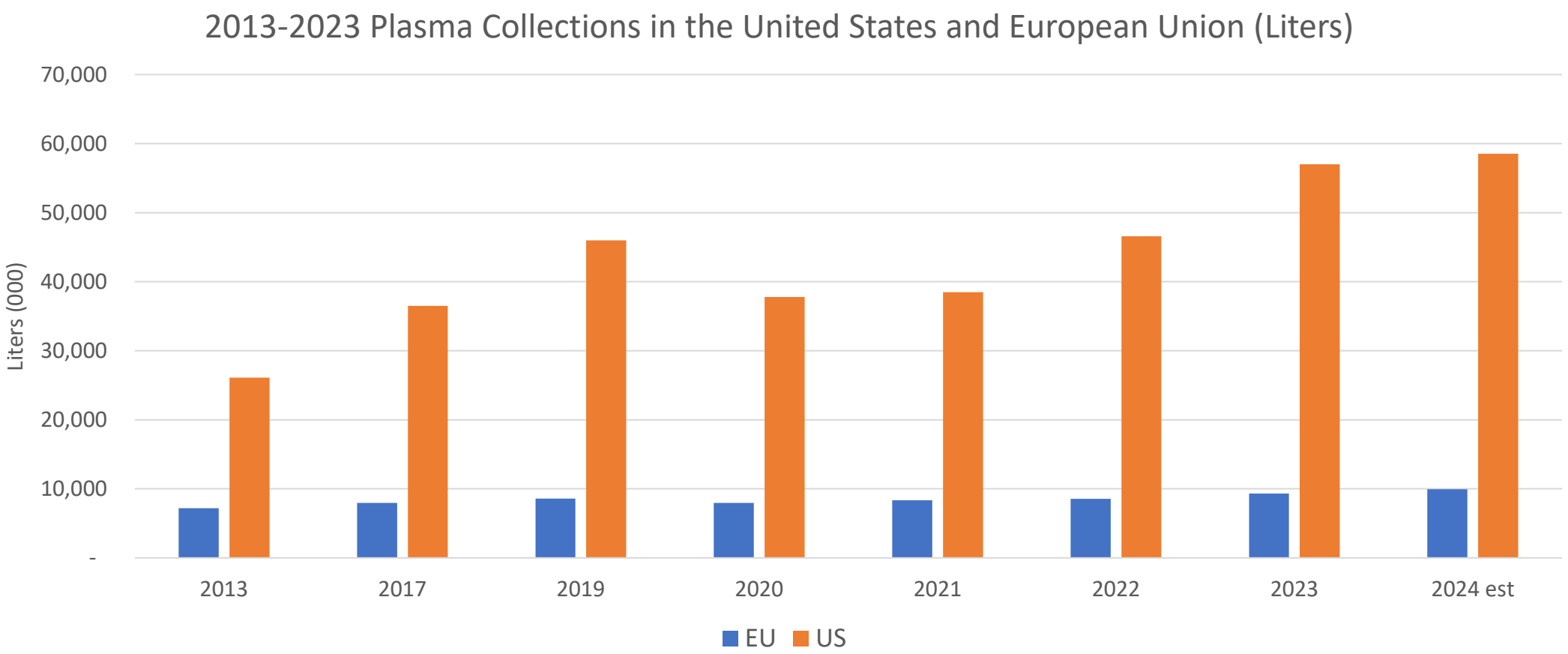
Note: IG Yield from 1 L of plasma: 4.5 grams for both recovered and source plasma

Estimation of EU Plasma Volume needed for 100% EU Self-Sufficiency: based on 2024 IG usage, 3.5 million liters, or 36% increase from present



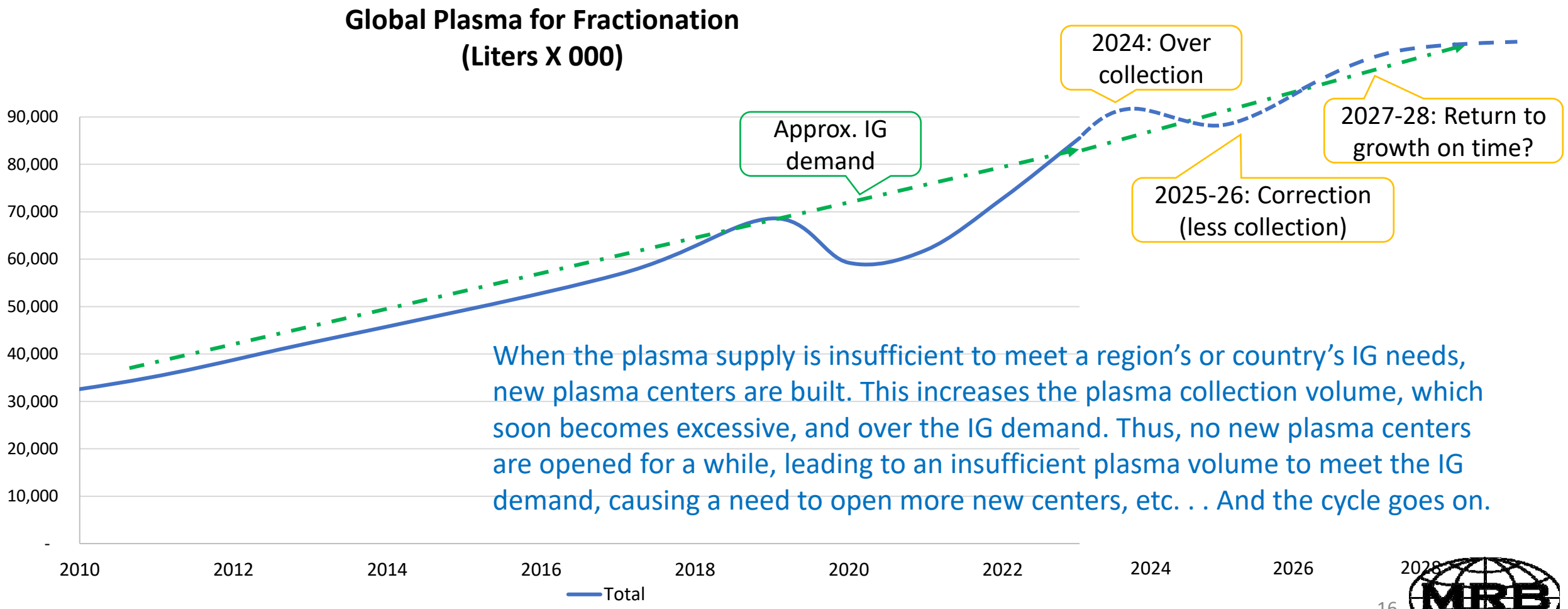
Deficit in Plasma (000 L)	(1,400)	450	1,400	3,375	2,200	1,800	3,400	3,500

Closer look at U.S. vs. EU Source Plasma Collections



2017-2024 CAGR
EU: 3.2%
US: 7.0%

Collection economics may lead to under-investment in plasma centers and under collection volumes in the future, repeating past cycles



When the plasma supply is insufficient to meet a region's or country's IG needs, new plasma centers are built. This increases the plasma collection volume, which soon becomes excessive, and over the IG demand. Thus, no new plasma centers are opened for a while, leading to an insufficient plasma volume to meet the IG demand, causing a need to open more new centers, etc. . . And the cycle goes on.

Conclusions

Record amounts of plasma have been collected since 2022, reaching over 90 million liters collected for fractionation in 2024 for the first time.	• In the European Union, 10 million liters are collected for fractionation
IG Demand has been robust	• Growth has been over 6% per year globally, and over 4% in Europe in recent years • Through 2030, EU IG growth is expected to be 4.5% per year
EU is not self-sufficient on plasma for IG production	• Most years, EU IG self-sufficiency has been 70-80% per year, with the balance coming from American plasma
EU would have needed to boost plasma collection by 3.5 million liters to reach self-sufficiency in 2024	• Collections would need to reach 14.2 million liters in 2025, or 42% more than 2024 • In 2030, to meet expected IG demand, collections needs to be >17 million liters, 70% higher than 2024 actual collections

Thank you!

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SUPPLY – Perspectives and What's Next

EDQM Stakeholder Event on Plasma Supply Continuity
March 26, 2025

Peter O'Leary, SUPPLY Project coordinator and Executive Director EBA

As the project outputs are those of the SUPPLY consortium, they cannot be considered to necessarily reflect the views of any individual organisation which forms part of the consortium.

Co-funded by the European Union

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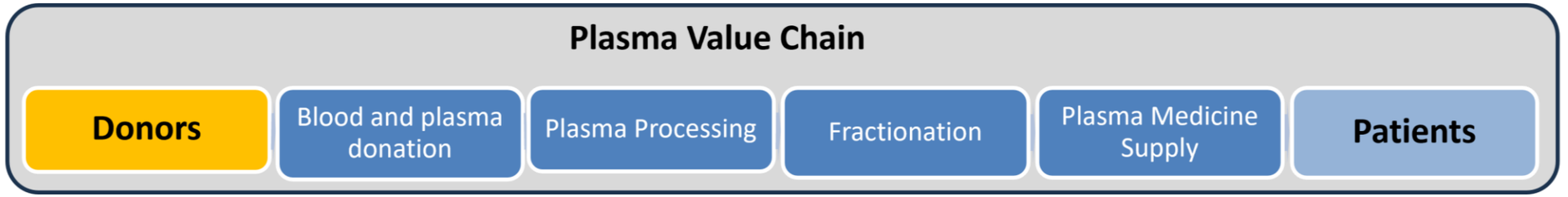

Goal – Provide Guidelines and Recommendations to..

Strengthening voluntary non-remunerated plasma collection capacity in Europe

- **Increase the volume and resilience of unpaid plasma collection in Europe by the public health sector**

And

- **Ensure safe and adequate access for EU patients to essential Plasma medicines**

SUPPLY | Co-funded by the European Union

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SUPPLY Resources

The SUPPLY Project consortium is an excellent example of solidarity: many stakeholders from different Member States working together to improve the lives of EU citizens. As the project outputs are those of the SUPPLY consortium, they cannot be considered to necessarily reflect the views of the European Blood Alliance or any individual organisation which forms part of the consortium. More details on the SUPPLY consortium can be found in the our partners section.

The SUPPLY project had many outputs including reports, tools, and position papers. Once the project has completed, all of these will be accessible and downloadable on this page.

Deliverable	Report
D1.1	Crisis Situations – The impact on the plasma-medicine-patient chain: Analysis and Recommendations (Scenario Evaluation Plan)
D2.1	Plasma Donor recruitment and retention – Current Practice (Analysis Report)
D2.2	Plasma Donor recruitment and retention strategies – Efficiency evaluation (Recommendations Report and Transfer Plan)
D3.1	Setting up a Plasma Centre: Practical tools (Plasma Collection Recommendations and Support Tool)
D3.2	The plasma journey from collection to transport to fractionator – Recommendations for Improvement
D3.3	Opportunities to increase Plasma volumes: Recovered and via plasmapheresis: Analysis and Recommendations
D3.4	Real-world experience: Implementation of the recommendations to increase Plasma volumes
D3.6	Focus on quality: An assessment of plasma donor characteristics, Immunoglobulin, and Total Protein in donated plasma

SUPPLY Home About News Our Partners Resources Work Packages

Deliverable	Report
D4.4	Member State steps on the European path to Strategic Independence for Plasma Medicines: A Position Paper
D4.6	Building Strategic Independence for Plasma Medicines: Policy Recommendations for the EU and EU Member States
D5.1	Protecting Plasma donor health: Current Practice (Analysis Report)
D5.2	Protecting Plasma donor health: a Support Tool for standardised Plasma Donor Vigilance data
D5.3	Protecting Plasma donor health: Recommendations
D6.1	Protecting Patients: 'A comparative analysis on the current use of immunoglobulins in individual countries: A clinical program'
D6.2	Protecting Patients: 'Final recommendations to achieve appropriate and prioritised use of immunoglobulins in Europe'

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Received: 25 July 2023 | Revised: 13 September 2023 | Accepted: 17 September 2023
DOI: 10.1111/vox.13544

REVIEW

Safety and protection o review and evidence ga

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Funding information
EU4Health Programme by the European Union, Grant/Award Number: 101056988; Foundation for Scientific Research of the Belgian Red Cross

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Contents lists available at ScienceDirect
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Original Articles

Balancing Donor Health anc of the Impact of Plasmaphe

Tine D'aes[a,b], Katja van den Hurk[c,d], Pieter Severijns[a], Emmy De Buck[a,b], Veerle Compernolle[i,j], Christian Eril

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ARTICLE INFO

Article history:
Available online xxx

Keywords:
Plasmapheresis
Plasma donation
Donor safety
Donor protection
Plasma donors

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Introduction

Plasma-derived medicinal products (PDMP immunoglobulin (Ig), and clotting factors ha

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E-mail address: hans.vanremoortel@rodekruis.be (H. V

https://doi.org/10.1016/j.tmrv.2024.150851
0887-7963/© 2024 The Authors. Published by Elsevier Inc

Please cite this article as: T. D'aes, K. van de Review of the Impact of Plasmapheresis Frequ

Received: 8 December 2023 | Revised: 15 March 2024 | Accepted: 9 April 2024
DOI: 10.1111/vox.13644

REVIEW

Incentives for plasma donation

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Marloes Spekman[2] | Eva-Maria Merz[2,3]
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Martin Oesterer[9] | Philipp Kluge[9] | Don

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Funding information
European Commission

Open Access funding enabled and organized by Projekt DEAL.

Abstract
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Received: 6 November 2023 | Accepted: 6 November 2023
DOI: 10.1111/trf.17601

COMMENTARY

Very-high frequency plasmap –absence of evidence is not e

Hans Van Remoortel[1,2] | Katja van den H
Peter O'Leary[7] | Pierre Tiberghien[7,8,9] |

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KEYWORDS: donors

1 | THE GROWING UTILIZATION OF PLASMA-DERIVED MEDICINAL PRODUCTS

The global utilization of Plasma-Derived Medicinal Products (PDMPs) has grown substantially, doubling in the past decade.[1] PDMP usage is expected to continue increasing in the years to come.[2] This expansion necessitates an increasing number of plasma donations, highlighting the critical importance of ensuring plasma donor safety. Although the majority of PDMP production worldwide originates from remunerated plasma donors in the United States, there is a significant movement toward increased plasma donations in Europe. Here, a large number of not-for-profit blood establishments are scaling up non-remunerated plasma donations for PDMP production.

TRANSFUSION

Received: 26 June 2024 | Revised: 5 September 2024 | Accepted: 4 October 2024
DOI: 10.1111/vox.13758

REVIEW

Securing commitment and contro derivatives for public health syst global landscape

Leni von Bonsdorff[1] | Albert Farrugia[1,2] |
Miguel A. Vesga[5] | Vincenzo De Angelis[3]

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Funding information
European Union's EU4Health Programme (2021–2027), Grant/Award Number: 101056988/SUPPLY

Abstract
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Keywords
fractionation, immunoglobu

Highlights
- In the Western world, i particularly immunoglob products sourced from c
- Part or all of this depen verted into PDMPs unde
- Achieving strategic inde the supply of these prod

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Received: 21 June 2024 | Revised: 13 September 2024 | Accepted: 4 October 2024
DOI: 10.1111/vox.13759

ORIGINAL ARTICLE

Vox Sanguinis ISBT

Securing commitment and control for the supply of plasma derivatives for public health systems. II: A survey of national pathways

Leni von Bonsdorff[1] | Albert Farrugia[1,2] | Fabio Candura[3] | Peter O'Leary[4] |
Miguel A. Vesga[5] | Vincenzo De Angelis[3]

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[2]Faculty of Medicine and Health Sciences, The University of Western Australia, Perth, Western Australia, Australia
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Funding information
European Union's EU4Health Programme

Abstract
Background and Objectives: Pressures on the supply of plasma-derived medicinal products (PDMPs) have led to the efforts to increase the level of plasma collected by public health authorities.
Materials and Methods: Public blood collectors were assessed regarding their routes towards domestically sourced plasma and PDMPs.
Results: The collectors' operations were specified and analysed. Models were classified according to the type of plasma collection system and contract fractionation arrangements.
Conclusion: *Commitment* and *control* to a public plasma collection system are the key features that need to underpin plasma collection.

Keywords
demand, fractionation, plasma, supply

Highlights
- Eight not for profit blood and plasma collectors were interviewed regarding their respective models for converting plasma from their organizations into plasma-derived medicinal products (PDMPs) for their public health systems.
- The models were assessed relative to the particular socio-economic features of the home countries of the collection agencies.
- We conclude that several viable pathways may generate PDMPs from publicly sourced plasma, as long as commitment exists to support the national blood system, and control is retained by the public health authorities in the management of any arrangements in place.

INTRODUCTION

Concerns around the security of the supply of plasma-derived medicinal products (PDMPs) have led to the recognition that plasma for fractionation (PFF) is a public health resource, essential as a strategic element in health policy [1]. This concept has given public plasma collectors a framework around which to formulate and advocate for a national plasma plan, aiming to achieve protection against the vagaries of the commercial market. This has led several countries to develop pathways for the generation of domestically sourced PDMPs. As one

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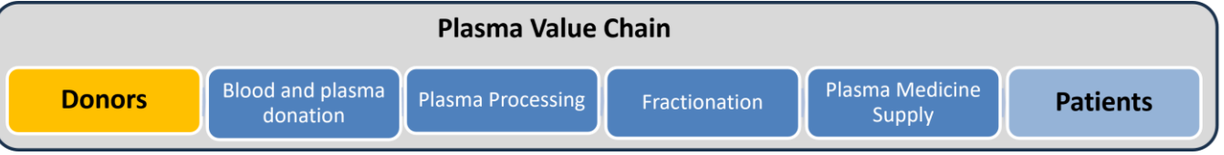
Listen to Patients

“The main safety concern for patients with Primary Immunodeficiency Diseases in the EU is SUPPLY. [We need] **continued and stable access to Immunoglobulins** as prescribed by the treating physician.”

International Patient Organisation for Primary Immunodeficiencies (IPOPI) 22nd EU PID Forum



Overview Findings

a large prospective study in plasma donors to examine the health consequences of plasma donation at varying frequencies is needed

Focus on retaining donors while building a sustainable donor base

- Invest to increase and improve plasma collection
- Comprehensive plasma-PDMP-patient strategies are required
- EU Member States create action plans!

Take consideration of the IgG level to determine the value of plasma

Introduce legal provisions at national level which *link* collected plasma to the usage of products manufactured from this plasma

Create national databases on Plasma Medicine (Ig) usage at patient level

Important to prioritise both donor *and* patient health

Continue to collaborate!

SUPPLY | Co-funded by the European Union

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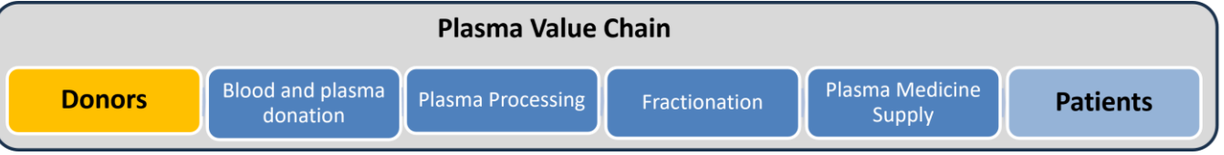

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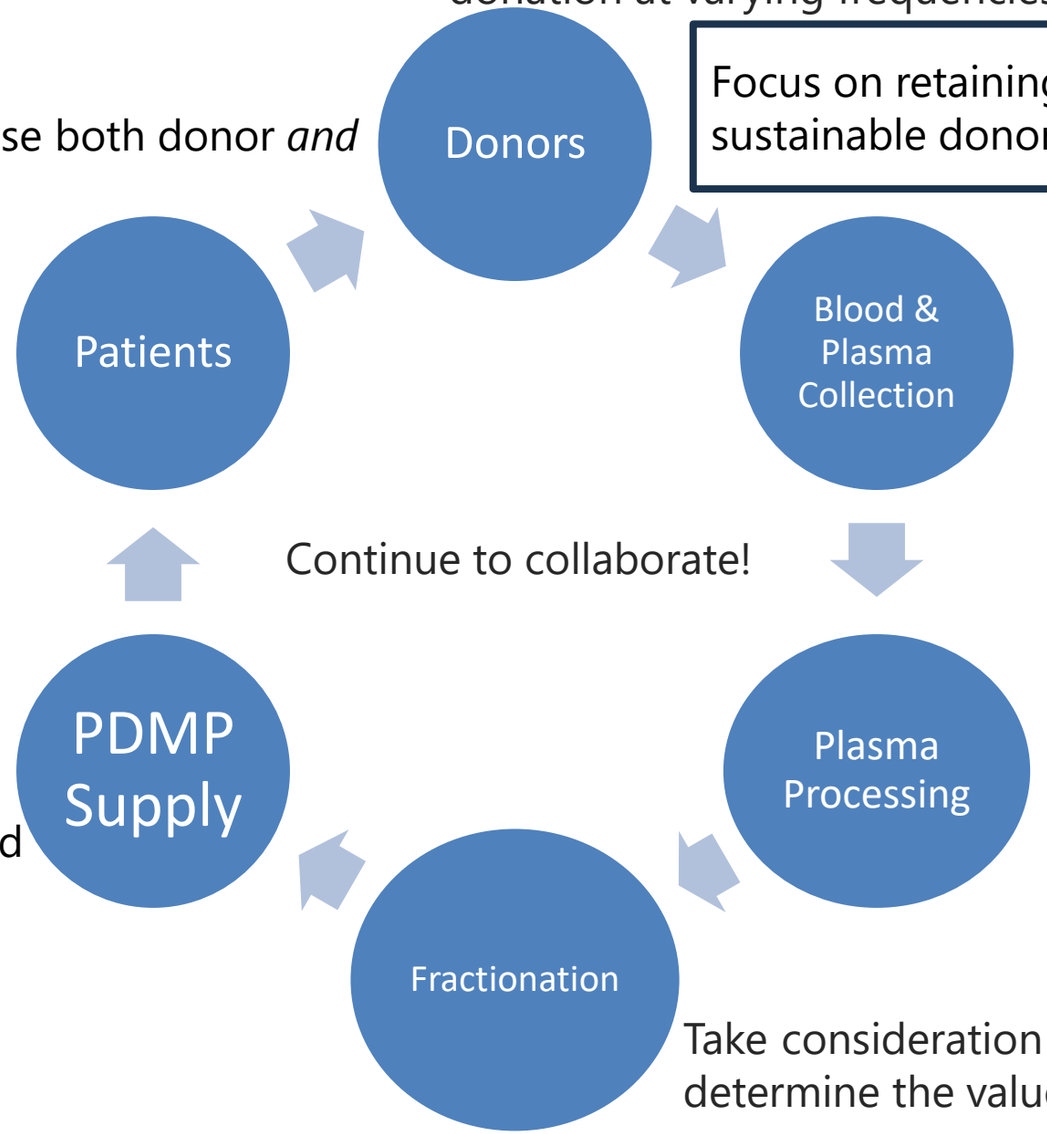

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EUROPEAN BLOOD ALLIANCE

SUPPLY Recommendation:

Focus on retaining donors while building a sustainable donor base

SoHO Regulation (2024/1938):

- Recital 65

‘Member States should be urged to increase their collection capacity and donor base for critical SoHO, in particular plasma, by developing non-profit and public plasmapheresis programmes.’

- Article 62(2) - Critical SoHO supply sufficiency

‘Member States shall make all reasonable efforts to ensure that SoHO donor recruitment and retention strategies are put in place for critical SoHO’

EUROPEAN
BLOOD
ALLIANCE

SUPPLY Recommendation:

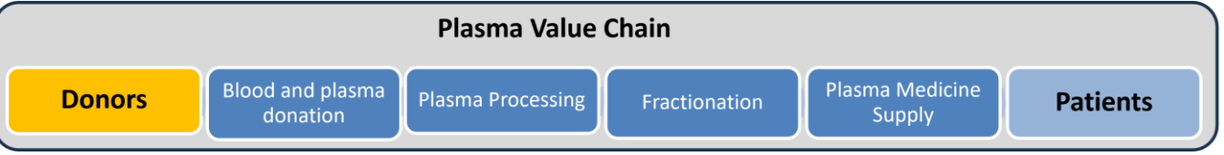
Focus on retaining donors while building a sustainable donor base

EBA Donor Marketing and Communication Working Group

To align with existing EBA Donor Studies Working Group (allow enhanced focus on Donor Health)

Targets for action include:

- Broadening the donor base, with a focus on recruitment and retention
- Increasing donation frequency (within EDQM guideline limits)
- Liaising with ADRP (Association for Blood Donor Professionals) – US based, but with global outreach.



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Blood & Plasma Collection

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Plasma Processing

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Fractionation

PDMP Supply

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Patients

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EUROPEAN BLOOD ALLIANCE

SUPPLY Recommendation:

- **Invest to increase and improve plasma collection**
- **Comprehensive plasma-PDMP-patient strategies are required**
- **EU Member States create action plans!**

SoHO Regulation 2024/1938:

- Member States and the Union should support the establishment of public donation facilities and promote the voluntary and unpaid donation of SoHO, including plasma, of high quality and safety, thereby also increasing self-sufficiency in the Union.

EUROPEAN BLOOD ALLIANCE

SUPPLY Recommendation:

- **Invest to increase and improve plasma collection**
- **Comprehensive plasma-PDMP-patient strategies are required**
- **EU Member States create action plans!**

‘Commit to Plasma’ Campaign

Calls on **national authorities** to:

- Publish National Plasma Plans by the end of 2026, with ambitious and clear commitments for national plasma collection goals and earmark the resources required to achieve these goals;

EUROPEAN BLOOD ALLIANCE

SUPPLY Recommendation:

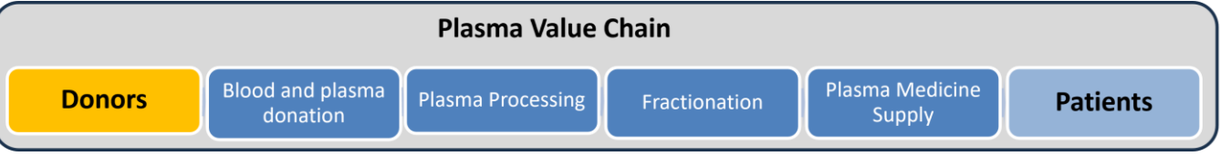
- **Invest to increase and improve plasma collection**
- **Comprehensive plasma-PDMP-patient strategies are required**
- **EU Member States create action plans!**

‘Commit to Plasma’ Campaign

Calls on the **European Commission**, the **European Parliament**, as well as other relevant institutions such as **EDQM**, to:

- Work towards equipping Europe with a European Plasma Coordination Plan by 2027, building on the National Plasma plans
- Collect and share national data and practices to accompany plasma-collection progress of Member States and Europe as a whole. Reliable, publicly accessible data is missing today

We ‘urge national and EU authorities to increase their political support and funding to public plasma collection programmes with a view to increase the public collection of plasma for fractionation in Europe by 40%, and at a minimum by 25%, by 2030. This would mean increasing the plasma contribution from Europe from 9 million litres in 2022 to at least 11 million litres in the next 5 years.’



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Continue to collaborate!

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Take consideration of the IgG level to determine the value of plasma

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EUROPEAN BLOOD ALLIANCE

SUPPLY Recommendation:

Take consideration of the IgG level to determine the value of plasma

Why?

IgG concentration has an impact on the yield during fractionation.

Source plasma donations of “low-frequency” donors have a higher concentration of IgG (Up to 10%)

Plasma *still* bought and sold on per-litre pricing.

Source Plasma from US ~20% higher price than Source Plasma from Europe

Why?

Licensing? PDMPs from European plasma can’t be used in other global jurisdictions – US, China?

But ‘Immunoglobulin (IG) is the dominant revenue-generating therapeutic protein from plasma fractionation’

- A higher price is paid for source plasma from Austria and Germany than from Czechia and Hungary
- Prices for plasma have fallen in Europe (and US) – due to the ‘oversupply of [US] source plasma’
- ‘oversupply of [US] source plasma’ but patients in Europe still suffering shortages of plasma medicines

➢ Vagaries of global commercial market

EUROPEAN BLOOD ALLIANCE

SUPPLY Recommendation:

Take consideration of the IgG level to determine the value of plasma

Valuing plasma based on Immunoglobulin content would contribute to a more abundant supply of Plasma medicines in Europe.

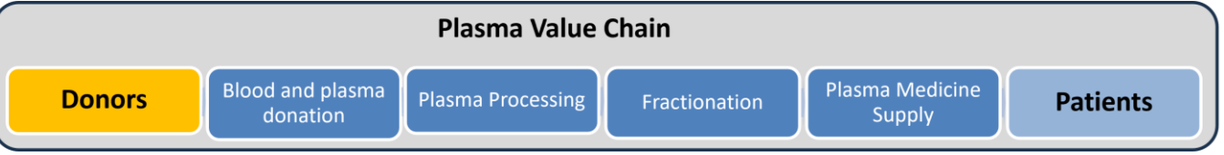
Recovered plasma has a higher protein content than Source Plasma (Up to 30%)

- Source plasma price higher than recovered plasma – why?
- Recovered Plasma in US ~26% higher price than recovered Plasma in Europe – If freezing and testing regimen is the same, why?

(Getting US Recovered plasma price: 3.5Million Litres EU Recovered Plasma = *additional* EUR134Million annually)

SUPPLY:
'Part or all of this dependence on the US can be offset by publicly collected plasma which may be converted into Plasma medicines under contracts that return the products to the public health system.

Achieving strategic independence in PDMPs can result in economic benefits and protects the supply of these products, and the patients who depend on them, from the vagaries of the commercial market.'



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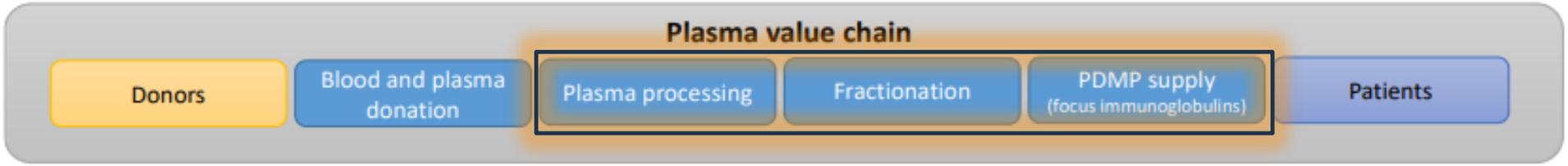

Commitment and Control

- It is of critical importance that national *commitments to collect sufficient volumes of plasma* to meet the optimum plasma-related requirements of populations are *accompanied by sufficient control/monitoring* over the collection-PDMP production-utilisation chain, ideally through legislative guarantees, to ensure that the patient population needs are met.

Why?

➢ Sufficient collection of plasma by a country ≠ sufficient supply of Plasma medicines for its patients

'Even in countries with a high supply of commercial source plasma (Germany, Czech Republic, Hungary, and USA) shortages of IV/SC-IgG has occurred.' (Strengers 2023)

SUPPLY | Co-funded by the European Union

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EUROPEAN BLOOD ALLIANCE

SUPPLY Recommendation:

Introduce legal provisions at national level which *link* collected plasma to the usage of products manufactured from this plasma

‘Medisanus case’ 2016

..the [‘clause requiring that a medicinal product be manufactured on the basis of plasma collected in the national territory’] is ‘not justified in the light of the objective of protection of the health and life of humans referred to in Article 36 TFEU.’

OPINION OF ADVOCATE GENERAL

SAUGMANDSGAARD ØE

delivered on 1 December 2016 (1)

Case C-296/15

Medisanus d.o.o.

v

Splošna Bolnišnica Murska Sobota

https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:62015CC0296&from=SV

Why are patients struggling to access life-saving immune globulin?

Immune deficient patients across the world are having issues getting access to the only drug that can keep them alive: immune globulin. Allie Nawrat investigates what is behind this ongoing shortage, whether medicine stockpiling is adding fuel to the fire, and what can be done to prevent a repeat of this situation in the future.

Allie Nawrat | February 24, 2020

EUROPEAN BLOOD ALLIANCE

WORKING GROUPS EUROPEAN AFFAIRS EVENTS RESOURCES

October 12, 2021

PLASMA SHORTAGE IN EUROPE: PROPER INVESTMENT IN PUBLIC BLOOD ESTABLISHMENTS IS THE ANSWER, NOT UNDERMINING ETHICAL PRINCIPLES

FDA extends immunodeficiency drug's shelf life as pandemic exacerbates shortages

By **Fraiser Kansteiner** · Jan 6, 2021 6:20pm

Safety warnings | Medicines | 28/06/2021

The supply of immunoglobulins[1)] in Austria is limited

The Brussels Times

BUSINESS ART & CULTURE EU AFFAIRS WORLD BELG

EU looks to reduce dependency on the US for human plasma needs

There is currently an estimated shortfall of over 5 million litres of plasma in the EU.

Tuesday, 7 March 2023

CSL war games manufacturing network in a world heading for trade war

FINANCIAL REVIEW

Updated Feb 11, 2025 – 9.40am, first published at 9.19am

EURACTIV Mar 7, 2025 19:56

US tariffs present dual threat for EU economy, health economists warn on pharma impact

Europe open: Shares down on Trump tariff impact; Grifols slumps

26 Feb, 2025 / Home / Market Report - Europe

EUROPEAN BLOOD ALLIANCE

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‘Medisanus case’ 2016

2025:

Would the ECJ maintain a position that national requirements for dedicated medicines are disproportionate to public health objectives?

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‘Medisanus case’ 2016

‘..there is scarcely any doubt that encouraging voluntary unpaid blood donations is a legitimate objective forming part of the more general objective of protecting the health and life of humans..

how can the fact that [a] hospital is required to obtain its supplies from medicinal products manufactured on the basis of national plasma encourage potential donors to make voluntary and unpaid donations of blood or blood components?’

OPINION OF ADVOCATE GENERAL

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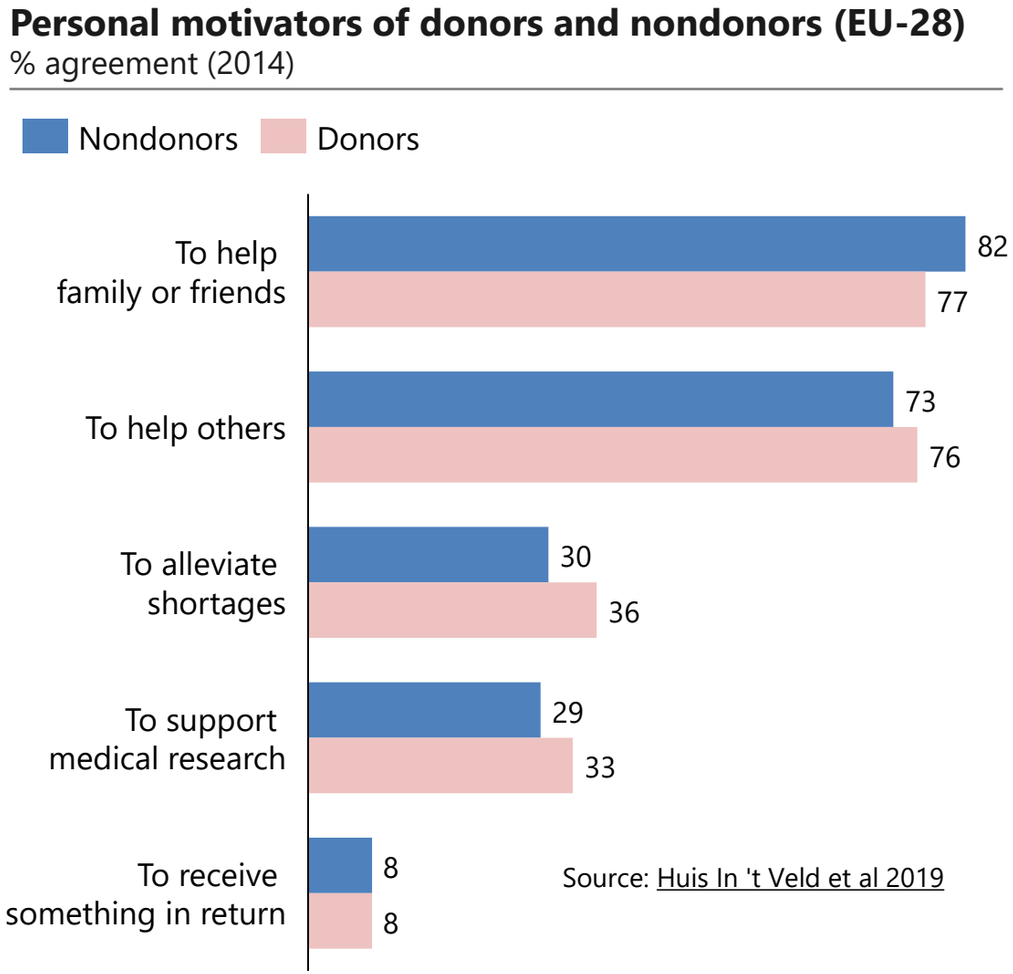
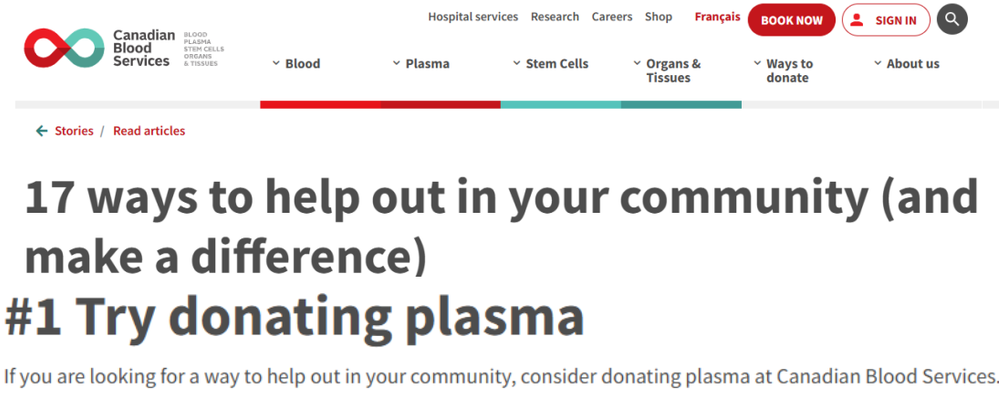
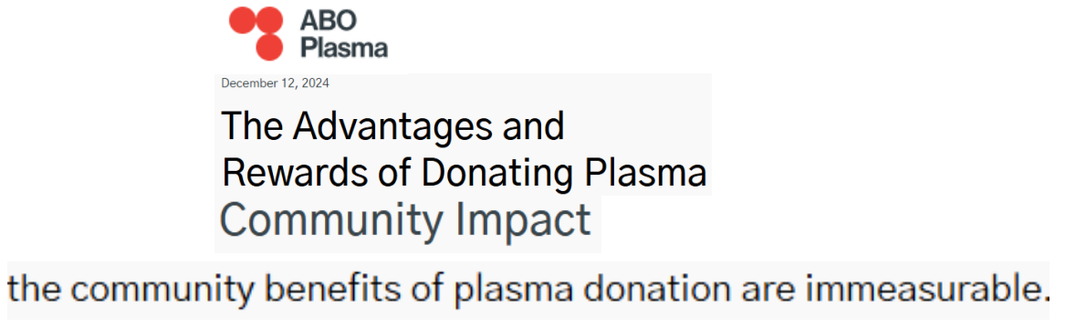
People donate to help family and friends







EUROPEAN BLOOD ALLIANCE

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‘Medisanus case’ 2016

..how can the fact that [a] hospital is required to obtain its supplies from medicinal products manufactured on the basis of national plasma encourage potential donors to make voluntary and unpaid donations of blood or blood components?’

BBC

Home News Sport Business Innovation Culture Arts Travel Earth Audio Video Live

First patients get UK-sourced plasma in generation

Dr Susan Walsh, CEO of Immunodeficiency UK, said they "urge" people in the county to try blood donation.

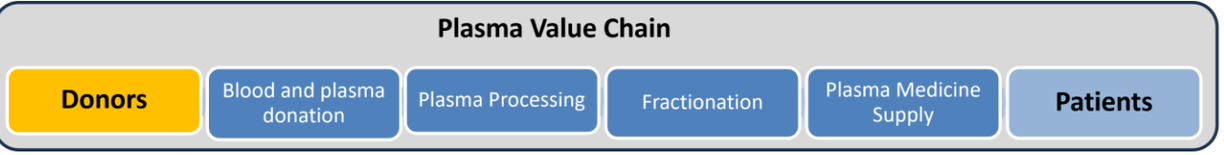
'Positive difference'

Abigail Hessey said it was "a relief" to know plasma was now collected from local blood donations as her daughter Bella (in the pink top) benefitted from immunoglobulin for a rare heart disease

NHS Blood and Transplant

‘For more than 25 years, the NHS has relied totally on the volatile international market for its plasma medicines, mostly from the US. It left the UK – and the patients who rely on them - exposed to shocks in supply and cost..

..**The best action you can take to help us in our mission to supply more plasma medicine is by becoming a donor’**



Overview Findings

a large prospective study in plasma donors to examine the health consequences of plasma donation at varying frequencies is needed

Focus on retaining donors while building a sustainable donor base

- Invest to increase and improve plasma collection
- Comprehensive plasma-PDMP-patient strategies are required
- EU Member States create action plans!

Take consideration of the IgG level to determine the value of plasma

Introduce legal provisions at national level which *link* collected plasma to the usage of products manufactured from this plasma

Create national databases on Plasma Medicine (Ig) usage at patient level

Important to prioritise both donor *and* patient health

Continue to collaborate!

SUPPLY | Co-funded by the European Union

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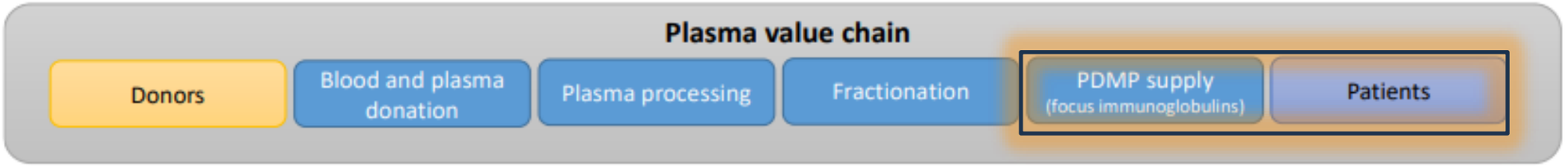

Key Points:

- Member States exhibit uneven data collection capacities for Ig usage.
- Diverse steps needed for systematic data collection.

Prerequisite:

Establish robust policies and regulations on data jurisdiction, control and management.

Step 1: Identify and map existing data sources on Ig use within each Member State.

Step 2: Establish a comprehensive centralized Ig-database and analytics hub.

- Interconnect aggregated data with the European Health Data Space for optimal analysis.

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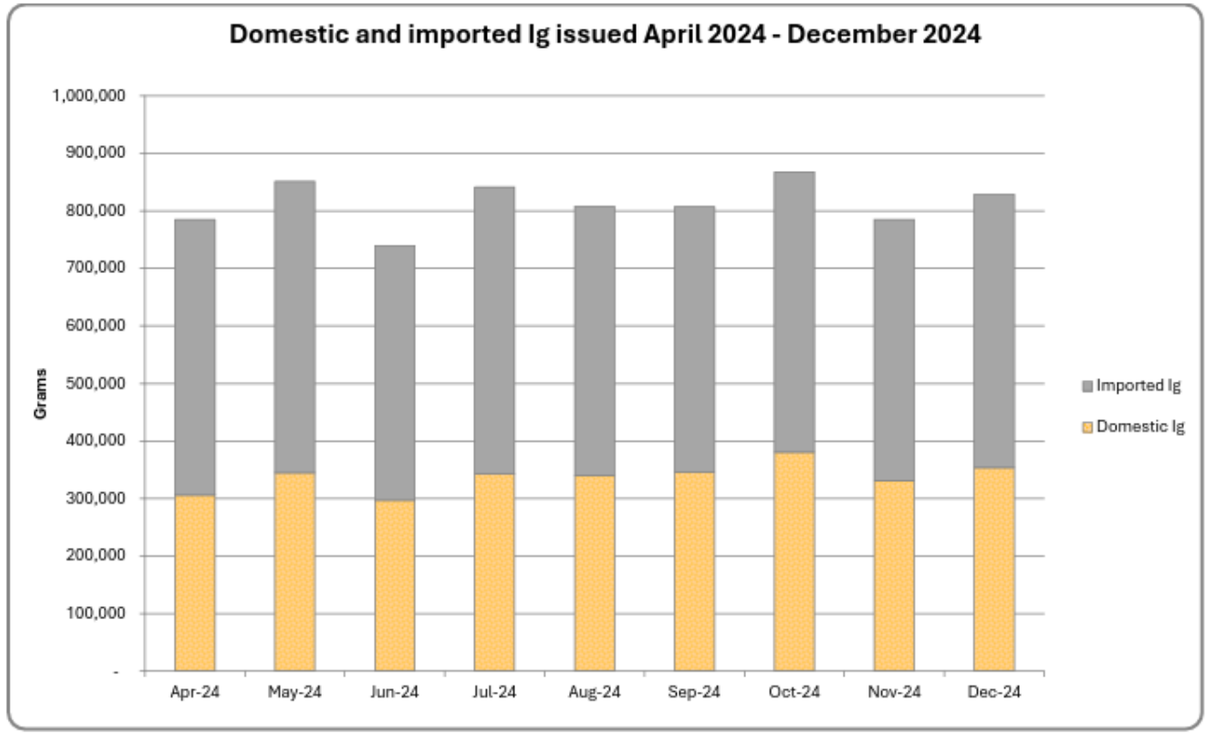
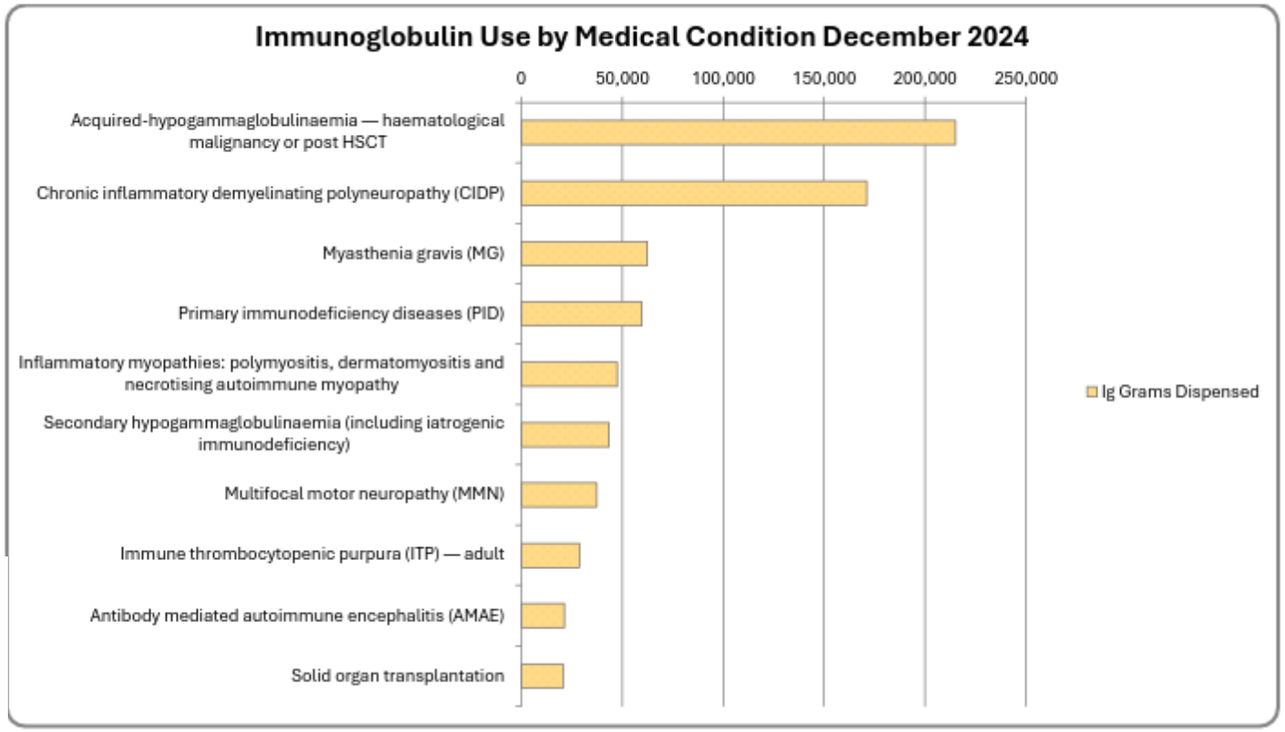
EUROPEAN
BLOOD
ALLIANCE

Monthly usage of Ig. This graph shows the amount of domestic and imported Ig products issued (grams) in the last 9 months.



Ig use by medical condition. This graph shows the medical conditions which account for the highest use (grams dispensed) of Ig products.



Search Donate Blood About NBA News and updates Resources BloodPortal login

NATIONAL BLOOD AUTHORITY AUSTRALIA

Blood Products Supply System Clinical Guidance Data and Research Patient Information

Immunoglobulin usage and data

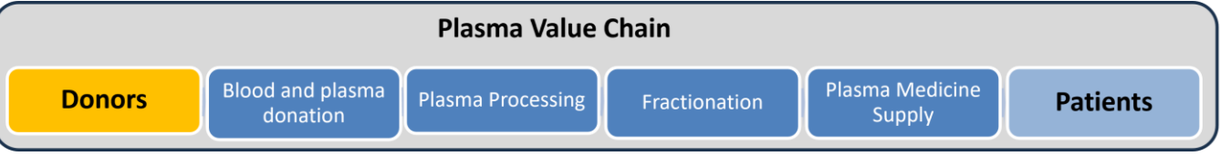
Home · Immunoglobulin products · Immunoglobulin usage and data

Immunoglobulin use in Australia

The National Blood Authority (NBA) manages the supply of Australia's government-funded immunoglobulin (Ig) products under the National Blood Agreement.

As part of our National Immunoglobulin Governance Program, we track and publish data on Ig usage and trends in Australia. Data is usually published approximately 3 months in arrears to accommodate data entry and reconciliation requirements.

On this page



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a large prospective study in plasma donors to examine the health consequences of plasma donation at varying frequencies is needed

Important to prioritise both donor *and* patient health

Donors

Focus on retaining donors while building a sustainable donor base

Blood & Plasma Collection

- Invest to increase and improve plasma collection
- Comprehensive plasma-PDMP-patient strategies are required
- EU Member States create action plans!

Plasma Processing

Take consideration of the IgG level to determine the value of plasma

Fractionation

PDMP Supply

Introduce legal provisions at national level which *link* collected plasma to the usage of products manufactured from this plasma

Patients

Create national databases on Plasma Medicine (Ig) usage at patient level

Continue to collaborate!

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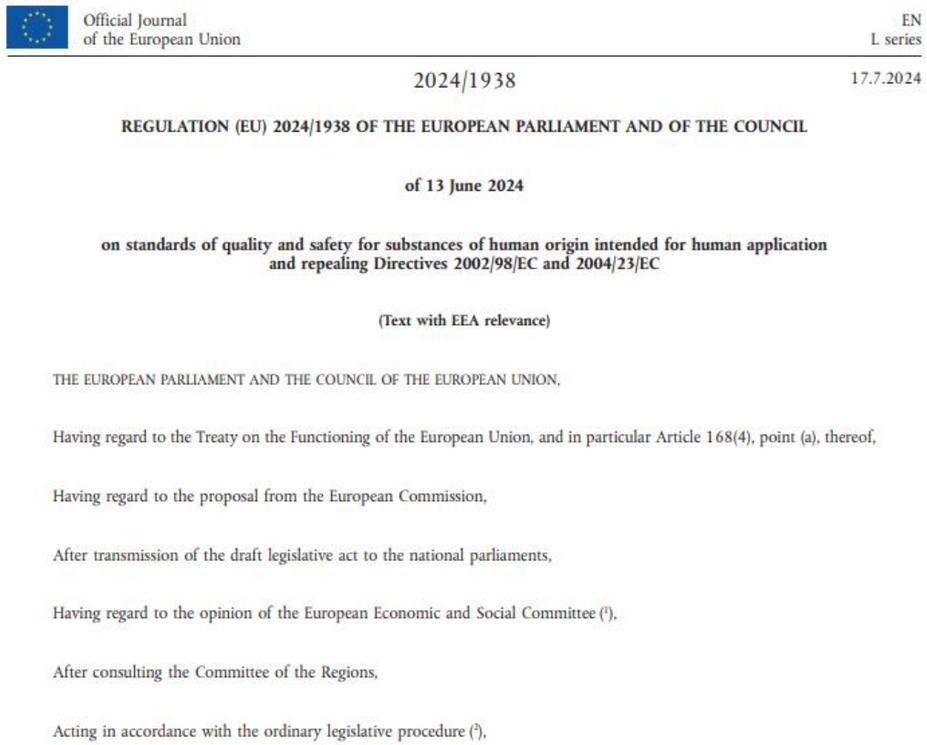
EUROPEAN BLOOD ALLIANCE



Official Journal of the European Union — EN L series

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 168(4), point (a), thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ([1]),

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure ([2]),

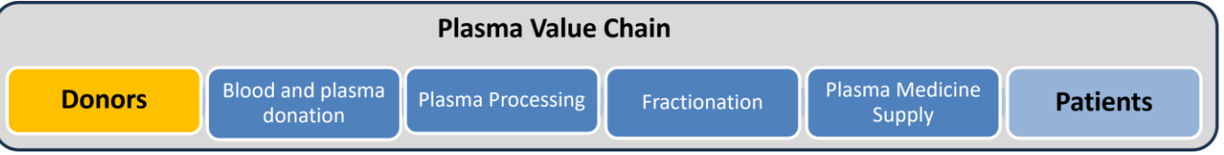
SUPPLY Recommendation:

Important to prioritise both donor *and* patient health

Chapter VI
SoHO Donor Protection

Chapter VII
Protection of SoHO Recipients and Offspring from Medically Assisted Reproduction

Chapter VIII
Supply Continuity



a large prospective study in plasma donors to examine the health consequences of plasma donation at varying frequencies is needed

Overview Findings

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Create national databases on Plasma Medicine (Ig) usage at patient level

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T5.2: Evaluate the available scientific evidence on plasma donor protection practices

The scoping and systematic reviews highlight the need for more controlled experimental studies that investigate both adverse events and health effects related to plasma donation.

****

SoHO Regulation – Article 53

‘in cases where SoHO can be donated repeatedly, and frequent donation might negatively influence the living SoHO donor’s health.. ..monitor relevant health indicators to evaluate whether [the plasma donor’s] health is not compromised’

Questions arise:

Which health indicators?
How might their health be compromised?
…

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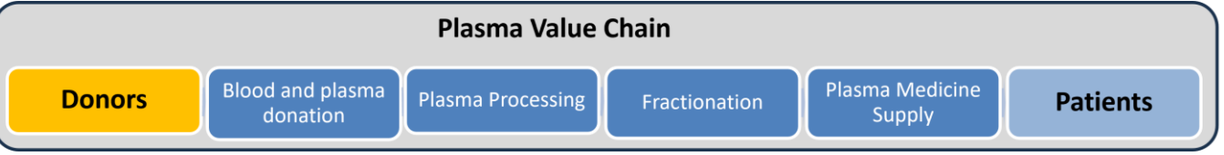

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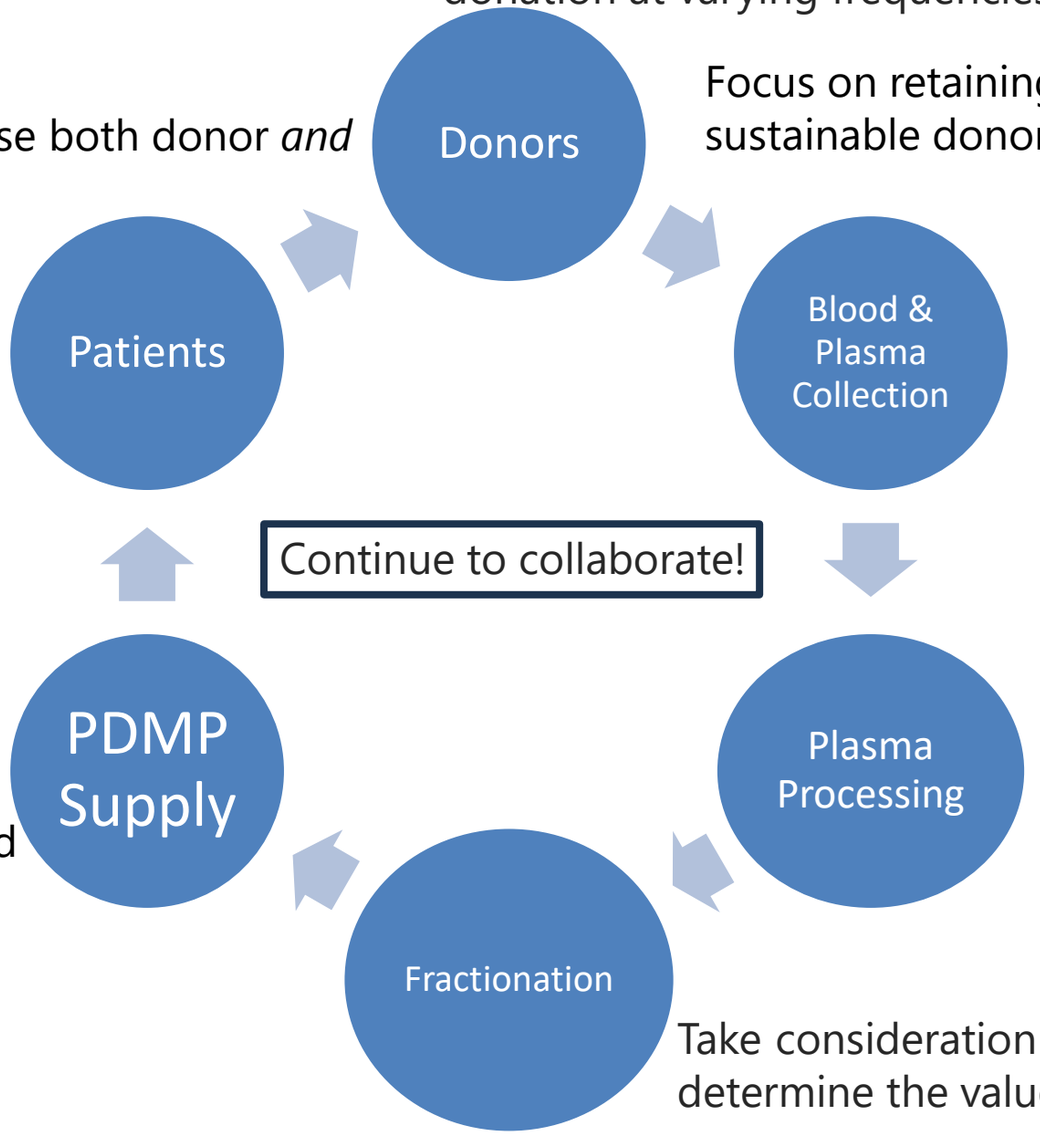

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EUROPEAN BLOOD ALLIANCE

‘Commit to Plasma’

Recent attendees at annual conference hosted by the Platform of Plasma Protein Users (PLUS)

Yours sincerely,

COUNCIL OF EUROPE / CONSEIL DE L'EUROPE

European Directorate for the Quality of Medicines & HealthCare

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You are here: European Directorate for the Quality of Medicines & HealthCare › Events & training › Upcoming events › EDQM Stakeholder Event on Plasma Supply Continuity

EDQM Stakeholder Event on Plasma Supply Continuity

DATES AND VENUE

Date: 26-27 March 2025

Location: Strasbourg, France

Language: English

INTRODUCTION

HOW TO REGISTER

This event is an IN-PERSON ONLY. Registration is free of charge.

Registration deadline: 21 March.

Register here

If you have any queries or experience any difficulties registering online, please email us via the EDQM HelpDesk

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SCIENCE MEDICINES HEALTH

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Home > Committees, working parties a
> Medicine Shortages Single Point of C

Medicine Shorta
Working Party

PPTA

WFH

A Safe and Sustainable Blood Supply for Europe

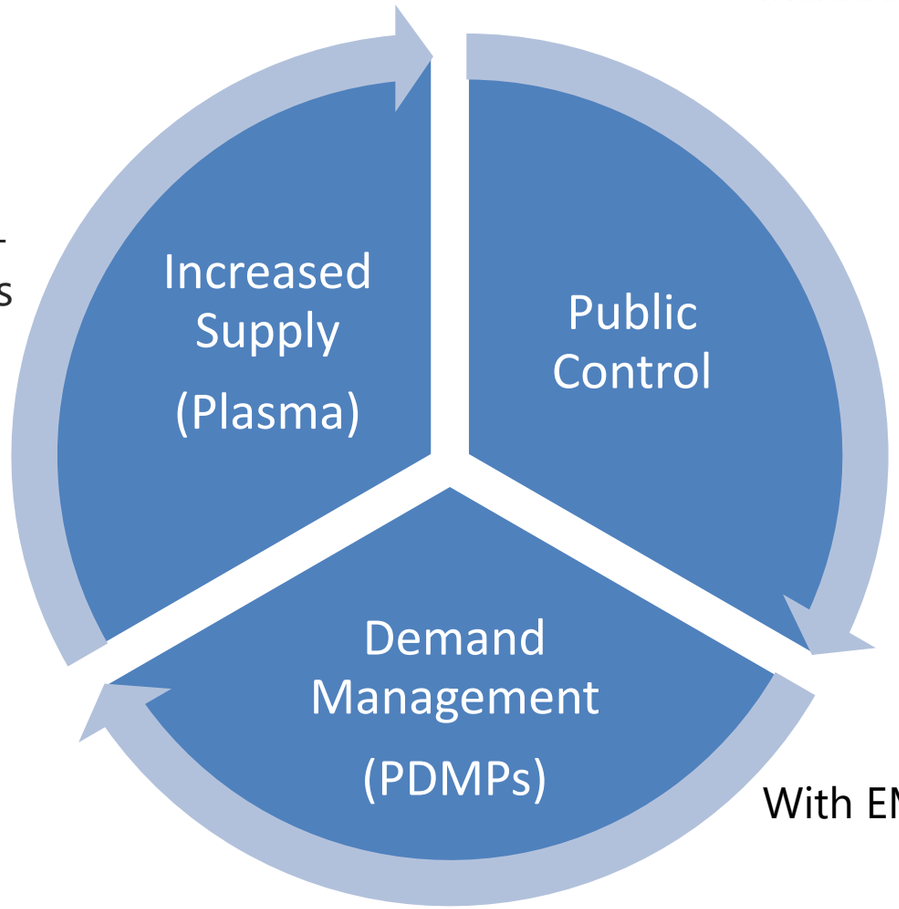
EUROPEAN BLOOD ALLIANCE

3-Pronged Approach in EU/Europe

Financial considerations, modelling, and planning should include entire plasma to medicines to patient cycle

'Commit to Plasma'

- Funding
- Comprehensive plasma-PDMP-patient strategies
- Recovered *and* Source Plasma



- National Actions/Decisions (Toll/Contract Fractionation)
- EU: Critical Medicines Act

With EMA, EHA, patients, etc

EUROPEAN BLOOD ALLIANCE

EU Member States and Europe *can* build strategic independence in plasma and plasma medicines to protect the interests of donors, patients, and citizens

Belgian Red Cross Flanders

"In 2024, Belgian Red Cross-Flanders launched a number of campaigns and they clearly worked. In 2024, we increased to 160,812 liters of plasma compared to 153,154 liters in 2023. The number of plasma donors also experienced a significant increase with +13.2% donors," said Prof. Philippe Vandekerckhove, CEO of Belgian Red Cross-Flanders.

CENTRO NAZIONALE SANGUE

2024 is a record year for plasma: collected over 900 tons

DANISH PATIENT SAFETY AUTHORITY

'Denmark increased their provision of plasma by 55% (80 to 124 tonnes) in 7 years (2017-2023)'

GOV.UK

- 'Treatments will help save 17,000 NHS patients' lives every year
- By sourcing our own medicine, we are building a more resilient and domestic medical supply chain and boosting economic growth.
- Move will deliver savings between £5 million to £10 million a year'

GOBIERNO DE ESPAÑA

Ministerio de Sanidad

sanidad.gob.es • 1 min read

Plasmapheresis: +53% (2017-2021) 👏

""the Ministry will not cease in its commitment to strengthen the national health system and improve people's lives."

EUROPEAN
BLOOD
ALLIANCE

EU Member States and Europe *must* build strategic independence in plasma and plasma medicines to protect the interests of donors, patients, and citizens

"The main safety concern for patients with Primary Immunodeficiency Diseases in the EU is SUPPLY. [We need] **continued and stable access to Immunoglobulins** as prescribed by the treating physician."

International Patient Organisation for Primary Immunodeficiencies (IPOPI) 22nd EU PID Forum

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Allie Nawrat | February 24, 2020

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Safety warnings | Medicines | 28/06/2021

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26 Feb, 2025 / Home / Market Report - Europe

EU Member States and Europe *must* build strategic independence in plasma and plasma medicines to protect the interests of donors, patients, and citizens

SoHO Regulation Recital 57

‘SoHO donation should be voluntary and unpaid.. ..[as it] contributes to the respect for human dignity and to protecting the most vulnerable persons in society.’

But. Europe *now* depends on US plasma

‘Sellers of plasma [in the US] tend to be low-income, underemployed and lacking a college degree, more likely to identify as Black or male.

More than two-thirds of plasma donors do so to pay for day-to-day essentials and emergencies’

Dooley, John and Gallagher, Emily, Blood Money: Selling Plasma to Avoid High-Interest Loans

European Commission

EN

Energy, Climate change, Environment

Climate Action

Home | About us | Climate change | EU Action | Citizens | News & Your Voice | Funding opportunities

Home > EU Action > Transport > Reducing emissions from the shipping sector

Reducing emissions from the shipping sector

maritime transport - a large and growing source of greenhouse gas emissions.

EU Member States and Europe *must* build strategic independence in plasma and plasma medicines to protect the interests of donors, patients, and citizens

"Climate change calls for action and also for cooperation and solidarity:

We have the choice: collective action or collective suicide"

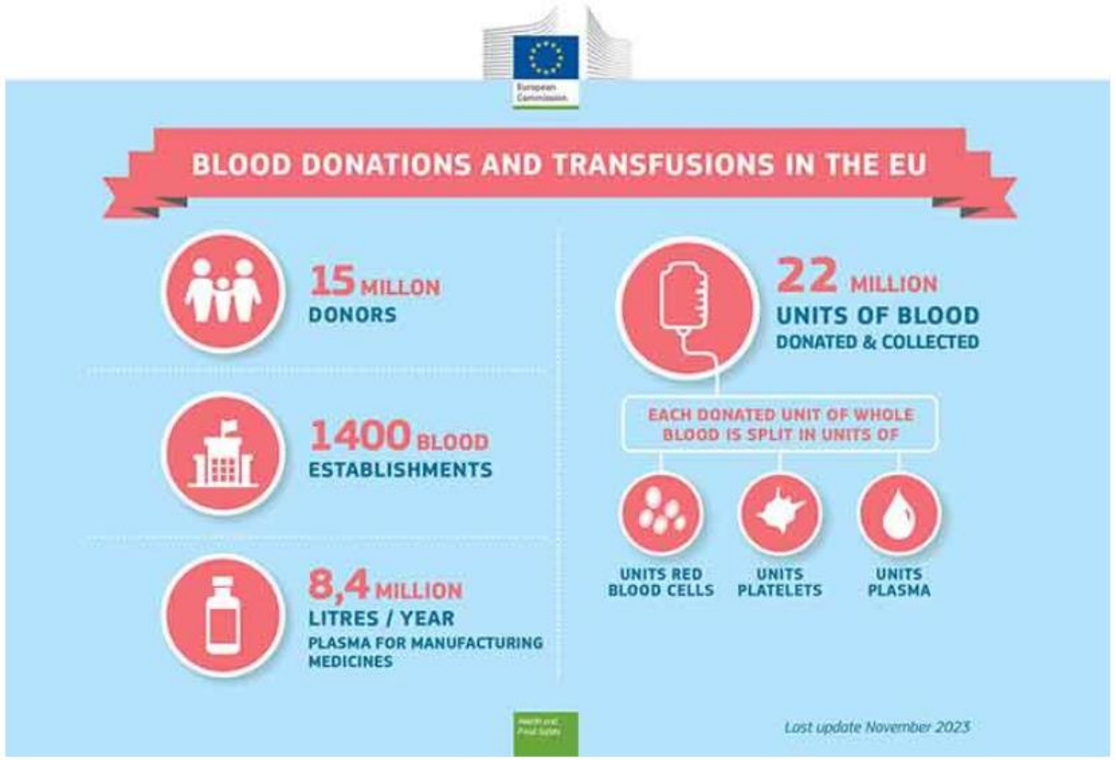
(António Guterres, 2023)

The convergence of:

- the likely environmental benefit of decreasing the need to transport US plasma donation
- the need for recruitment campaigns targeting younger donors
- younger people's motivation to make positive contributions to society

represents an opportunity for the inclusion of environmental messaging in plasma donation messages.

EUROPEAN
BLOOD
ALLIANCE



EU Population: 449 million
Eligible donor population 194 million
(aged 18-65, health, weight, etc)

How many plasmapheresis donors annually in the EU (estimate)?

<600,000

600,001-1.2Million

(estimate 800,000-900,000)

1.2Million - 1.8Million

>1.8Million

SoHO Regulation: Recital 57
‘the responsibility for donation [should be spread] evenly across the Union population to the extent possible’

EU/European Countries with no plasmapheresis program

		Population (Millions)
Finland*	EU	5.5
Ireland	EU	5.1
Malta	EU	0.5
Portugal	EU	10.2
Bulgaria	EU	6.7
Cyprus	EU	1.3
Slovenia*	EU	2.1
Croatia	EU	4
Greece	EU	10.3
Romania	EU	19.9
Total		**65.6**

		Population (Millions
Iceland		0.4
Scotland		5.5
Wales		3.1
Northern Ireland		1.9
Serbia		7.1
North Macedonia		2.1
Montenegro		0.6
Albania		2.8
Bosnia and Herzegovina		3.2
Moldova		3.4
Total		**30.1**

~65.6 Million EU Citizens have no access currently to a Plasmapheresis program
~95.7 Million European Citizens have no access to a Plasmapheresis program
(+ many more systems are in their infancy e.g. England)

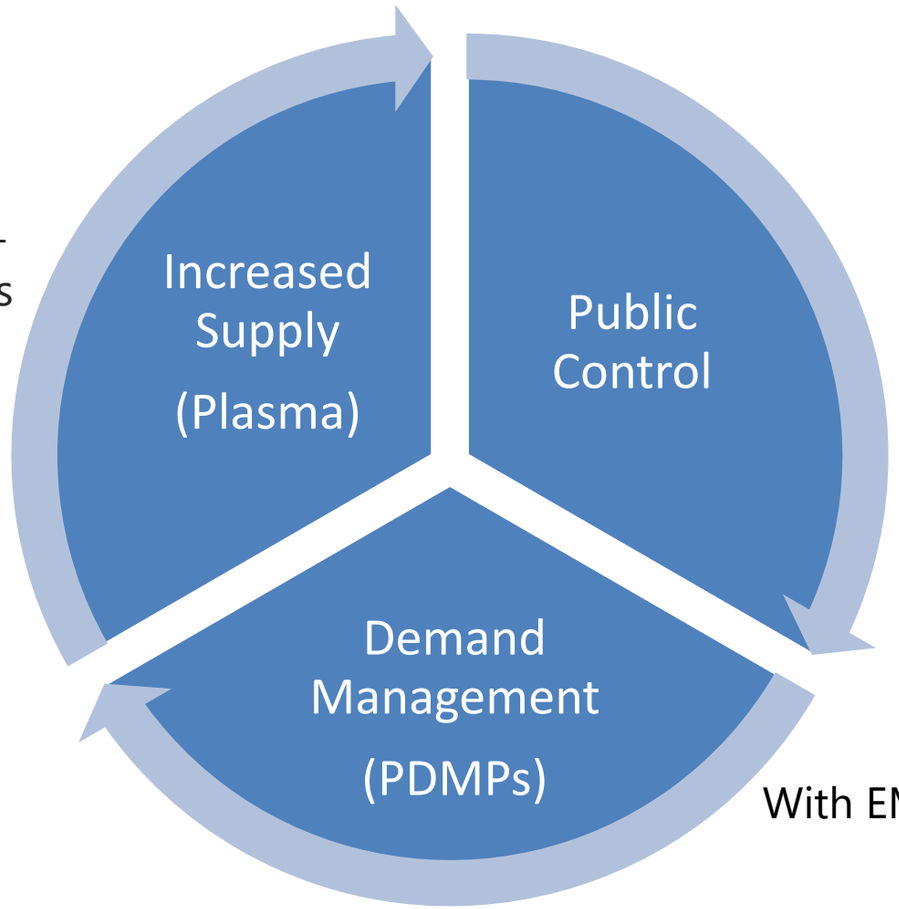
Other on-going efforts include:
- lowering the proportion of recovered plasma discarded
- increasing the frequency of plasma donations while maintaining donor health

EUROPEAN BLOOD ALLIANCE

EU Member States and Europe *can* and *must* build strategic independence in plasma and plasma medicines to protect the interests of donors, patients, and citizens

'Commit to Plasma'

- Funding
- Comprehensive plasma-PDMP-patient strategies
- Recovered *and* Source Plasma



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- EU: Critical Medicines Act

With EMA, EHA, patients, etc

EUROPEAN
BLOOD
ALLIANCE

Thank you

SUPPLY

Strengthening voluntary non-remunerated plasma collection capacity in Europe