



Belgian
Red Cross

How Europe can ensure sustainable supply of blood components on a voluntary non-remunerated basis

Blood establishments and the new SoHO Regulation:
Protecting donors, delivering for patients

European Parliament, 25/1/2023

Key findings

1 Data are inconsistent, making it difficult to draw conclusions

- > Large variation in data on plasma collection for fractionation: further research and standardization is needed
- > Organizations can 'cherry pick' datasets to support their conclusions
- > No indications that countries with private collection systematically outperform VNRD countries in plasma supply

2 Payment is not a motivator

- > Perceptions have not changed in 20 years: people donate to help family and friends
- > Only 15% of potential plasma donors have already donated
- > Introducing compensation is a one-way street: US case study

3 Voluntary plasma donations are preferable on many fronts

- > Cost: PDMP prices have increased less in countries where only non-profit organizations collect plasma
- > Resilience: Plasma supply from non-profit organizations was more resilient during COVID-19
- > Safety: for patients and for donors

4 Sustainable supply of blood components is realistic with only voluntary non-remunerated donations

- > Illustrated by case studies in Belgium and Denmark
- > EU policy choices in 1993 had devastating consequences for plasma collection capacity & self-reliance
- > Public investment in collection centers can sufficiently increase plasma supply, and allows MoH to keep control over both supply and price-setting

1 Different data sources focus on different 'plasma types'

Data availability, measured as units or liters

	Plasma for fractionation	Plasma for transfusion
From whole blood (recovery)	<p>EDQM (2016) WHO (2016 & 2021)</p>	<p>Roberts et al. (2019) EDQM (2016) WHO (2016)</p>
From apheresis	<p>EDQM (2016) WHO (2016 & 2021)</p>	<p>EDQM (2016) Roberts et al. (2019) WHO (2016)</p>

Roberts et al. (2019) is only **peer-reviewed multi-country dataset** on supply and demand of blood products – *Lancet Haematology*

THE LANCET
Haematology

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The global need and availability of blood products: a modelling study

Nicholas Roberts, BS • Spencer James, MD • Meghan Delaney, DO • Christina Fitzmaurice, MD

Published: October 17, 2019 • DOI: [https://doi.org/10.1016/S2352-3026\(19\)30200-5](https://doi.org/10.1016/S2352-3026(19)30200-5) Check for updates

PlumX Metrics

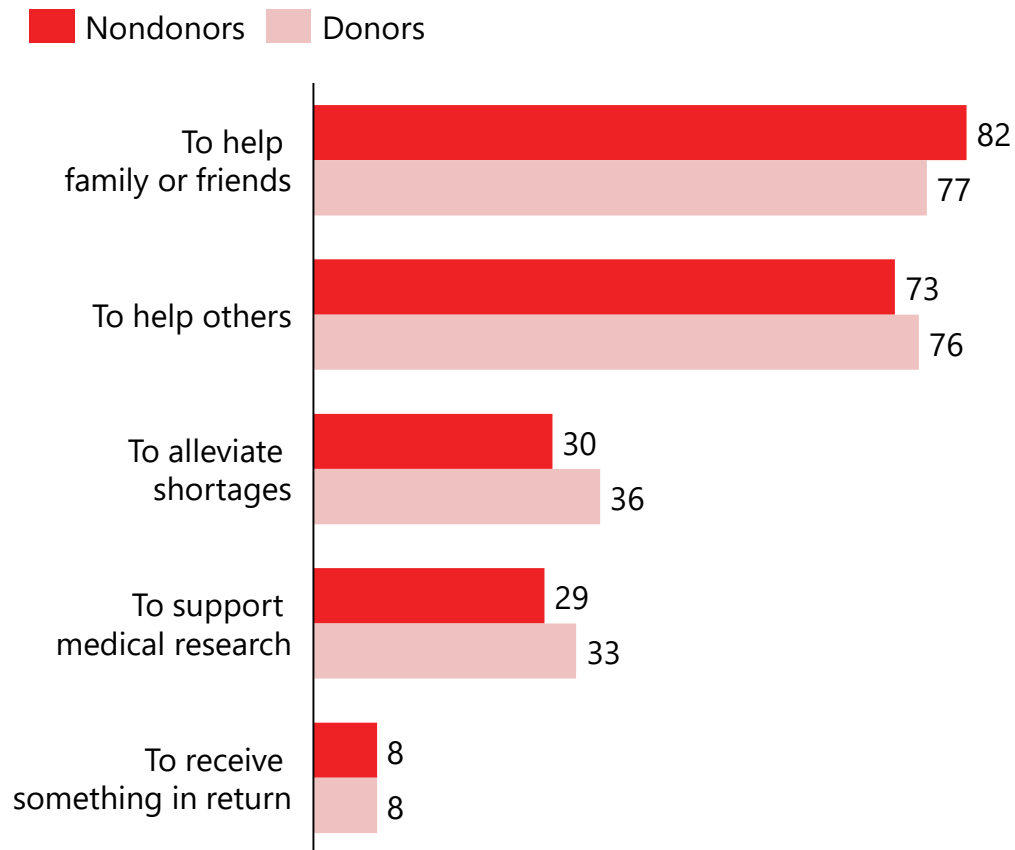
Summary

Background

Blood transfusions are an important resource of every health-care system, with often limited supply in low-income and middle-income countries; however, the degree of unmet need for blood transfusion is often unknown. We therefore aimed to estimate the blood transfusion need and supply at national level to determine gaps in transfusion services globally.

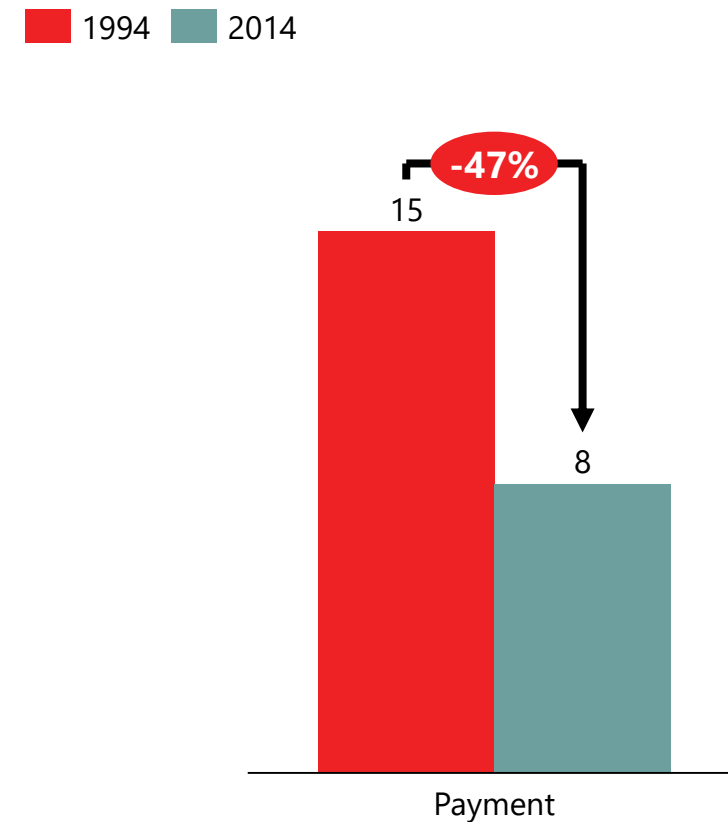
② Payment is not a motivator: people donate to help family and friends

Personal motivators of donors and nondonors (EU-28)
% agreement (2014)



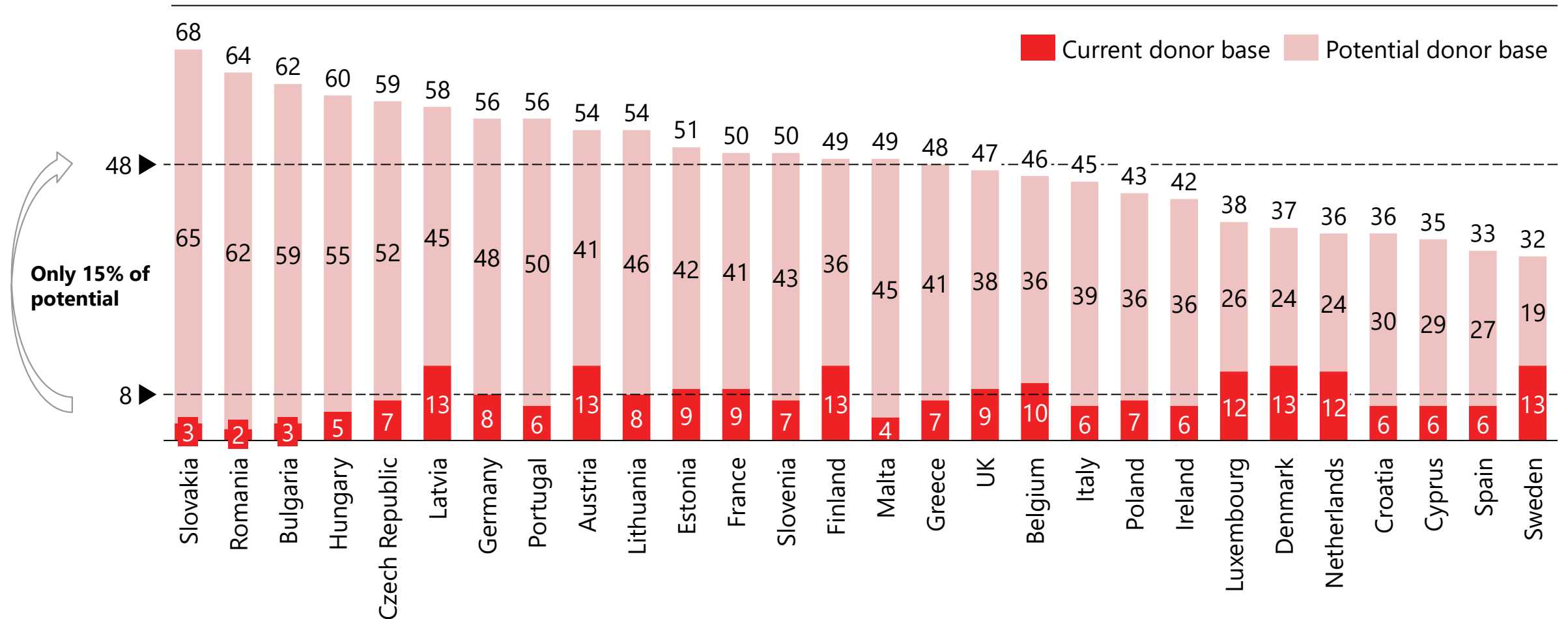
Attitudes over time towards motivators (EU-12)

% answering 'yes' to the question 'For donating blood or plasma during someone's lifetime, do you consider it acceptable to receive...?'



2 Only 15% of potential plasma donors in EU have already donated

Willingness to donate plasma, %



3 PDMP prices have increased less in countries where only non-profit organizations collect plasma

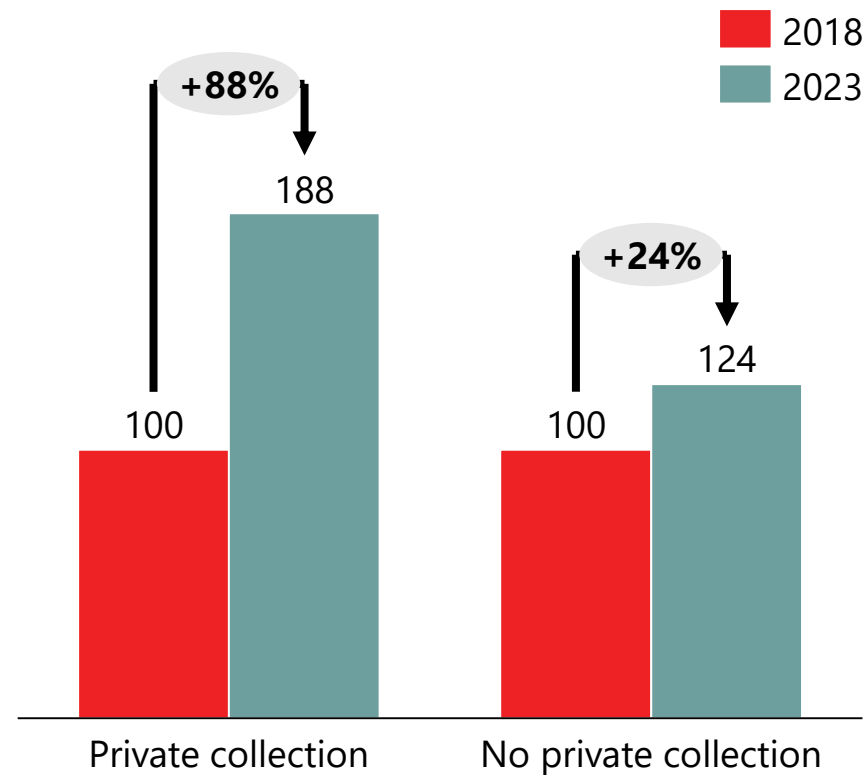
Public and private plasma collection of in EU



■ Private collection
■ No private collection

IG price by type of plasma collection

Price per g for Privigen, 2018=100¹



Price increase more than 3x higher in countries with private collection

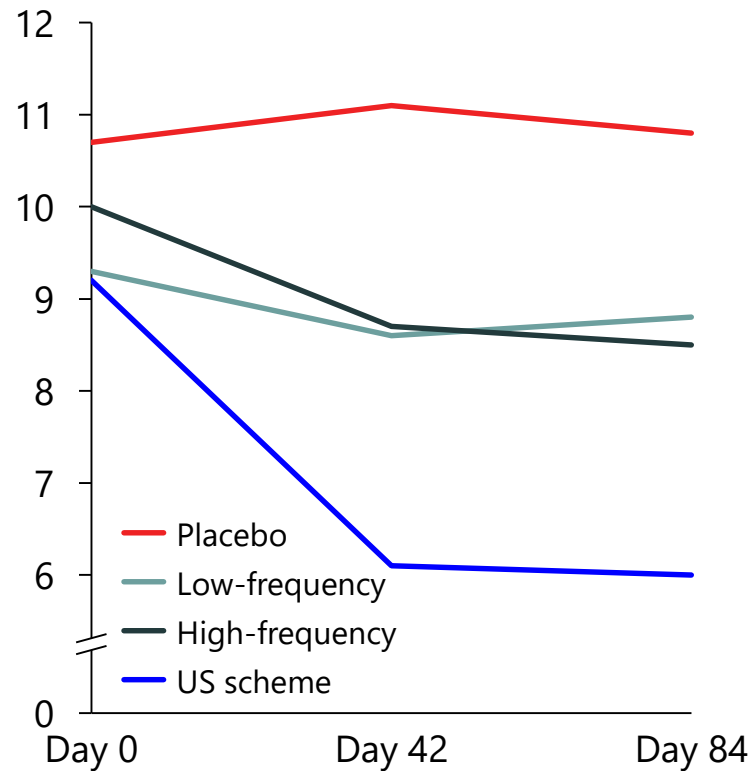
1: Based on 2018 data or earliest available year and 2023 data or latest available year; private collection: Germany, Austria; no private collection: Belgium, Switzerland, Finland, Luxembourg, France, Croatia

Source: Copenhagen Economics (2021); Belgian Red Cross-Flanders (2023)

3 Supply from voluntary donations is safer, and more resilient

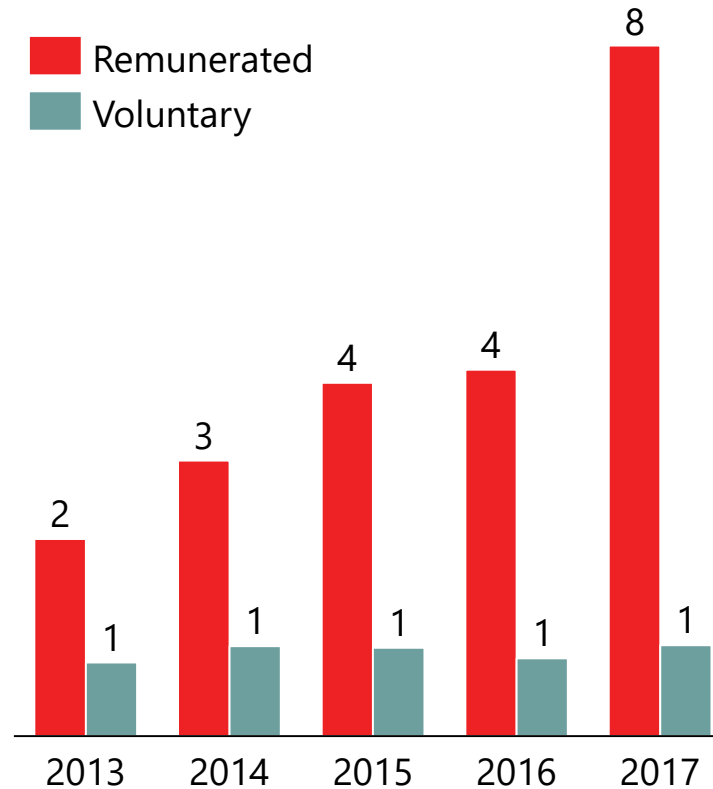
SAFETY OF DONORS: Immunoglobulin levels by donation frequency

IgG (g/L) levels over time



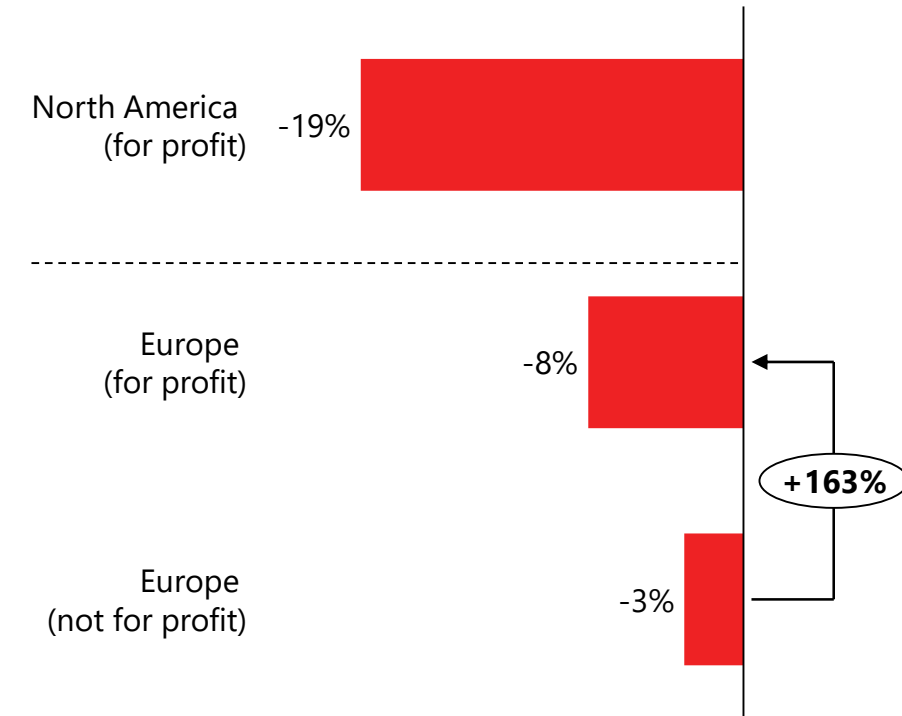
SAFETY OF PATIENTS: Prevalence of infectious disease markers, by year and donation type

Prevalence per 100 donations, first-time donors



RESILIENCE: change in total volume of plasma for fractionation, by region and sector

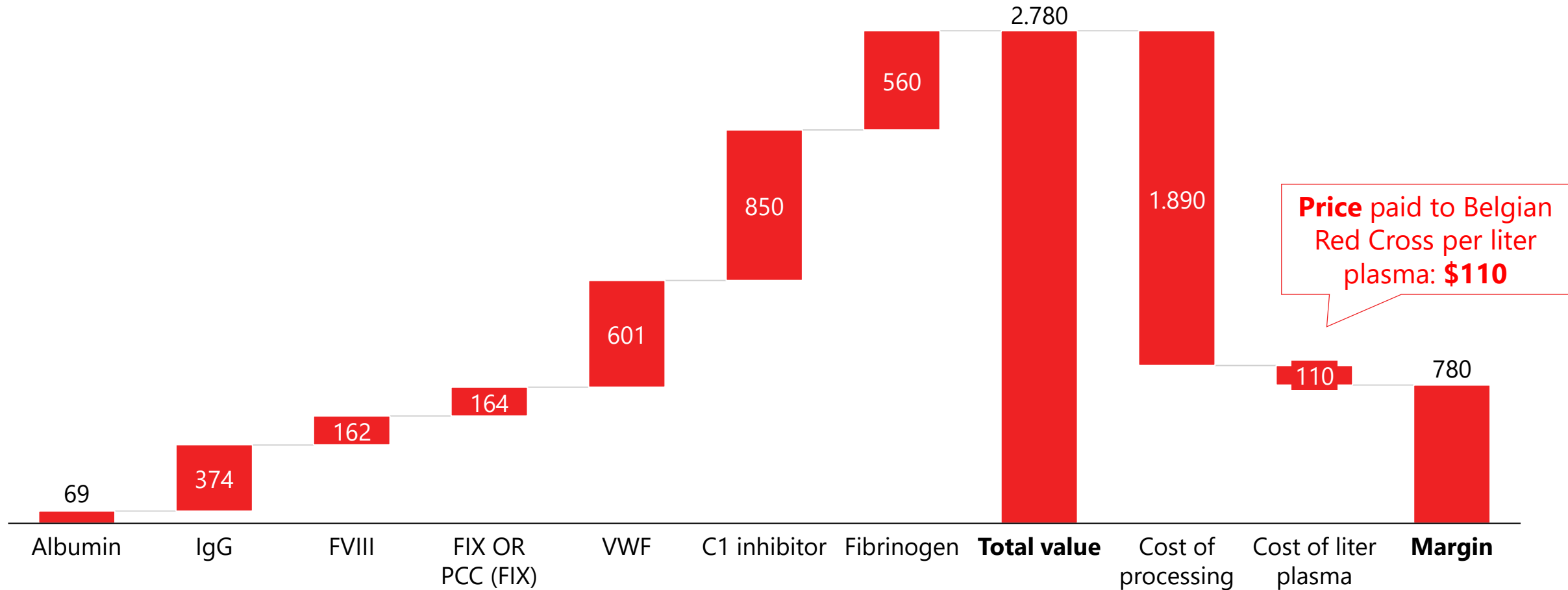
% change between 2019 and 2020



Note: 'for profit' = volume reported by Plasma Protein Therapeutics Association (PPTA): represents manufacturers of plasma-derived therapies, and collectors of source plasma used for fractionation; 'not for profit' = volume reported by EBA: the European Blood Alliance (EBA): association of not for profit Blood Establishments within EU, EFTA and the UK
 Source: Kalibatas & Kalibatiené (2022); Deldicque et al. (2023) – Preliminary results

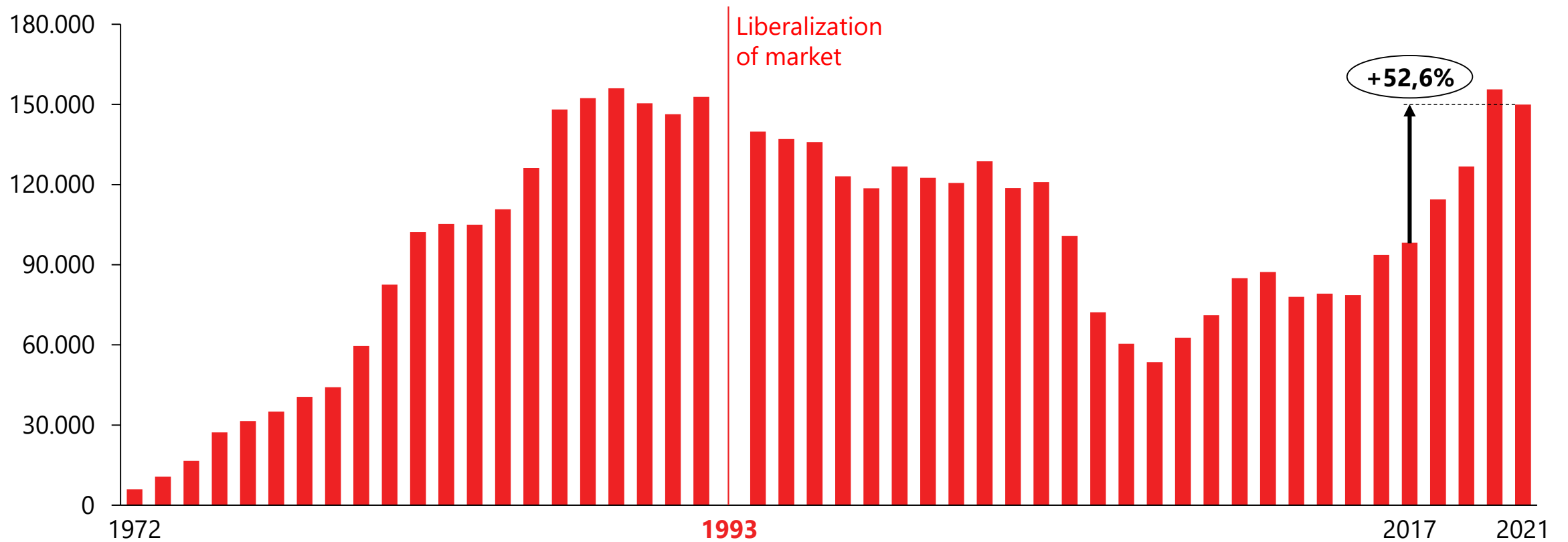
3 High margin per liter plasma

Breakdown of 1 liter plasma in value of end products and costs



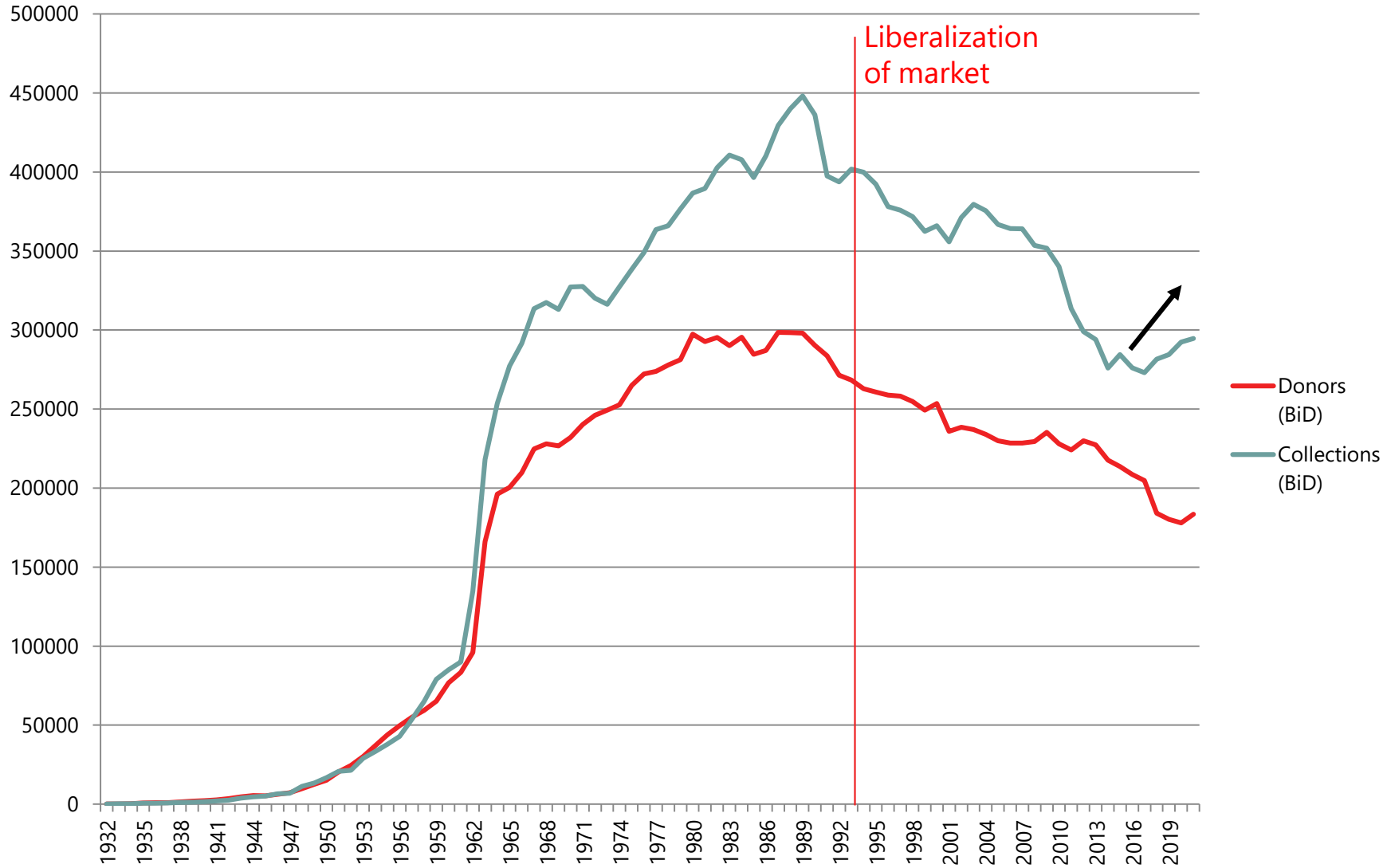
4 Historical overview plasma donations Belgian Red Cross

Donations for plasma apheresis, #donations



Note: Only donations for Belgian Red Cross-Flanders are shown here (~60% of total in Belgium)

4 Historical overview plasma donors/donations Denmark



Conclusion

- **Belgian & Danish self-sufficiency: was 100%**
 - Labile blood products that national governments legislate
 - Stable blood products until introduction of EU common market for pharmaceuticals (1993)
- Introduction of **EU common market** without measures to ensure minimal levels of plasma sourcing from **within EU**, led to:
 - Dumping of excess plasma from US
 - Shutdown of collection capacity in EU
- **Long term predictability of donor base is key**, and dependent on government policy
 - **National level:** Regulatory conditions created by governments (*define % of self-sufficiency; invest in additional collection centers*)
 - **EU level:** Higher EU independence for PDMP requires derogation of EU common market legislation to mandate minimal levels of **sourcing from within EU** (*f.i. annual increase over 10 yrs*)
- Increasing **PDMP self-sufficiency from VNRD plasma** is possible
 - By expanding **collection capacity** & leveraging existing **solidarity**
 - If governments/non-profits do not invest in collection capacity, **private collectors by default** will introduce payment
 - **End products (PDMP)**
 - **become more expensive** where private collectors manage the donor base
 - are **exported to highest bidder** potentially creating shortages in donor region

Implications for SoHO proposal

Current proposal for SoHO regulation (July 2022)
confuses two separate issues:

- **Paying donors is not a logical answer to lack of collection capacity**
- Compensation should **not** be **hidden payment** (semantics)

Introduction of payment is a one-way street: plasma payment eroded altruism also for other donations: **crowding-out** as seen in USA



Questions?