IPOPI XVth Biennial Meeting 2018

Workshop on Immunoglobulins

“Plasma Collection”

Stephan Walsemann MD, PhD
Lisbon 26 October 2018

EPA

- Alliance of 12 European private sector plasma collectors
- 110 member centers (2018):
  - Germany: 71
  - Austria: 16
  - Czech Republic: 6
  - Hungary: 17
- 2,5 million liter collected (2017)

EPA Mission

Promote safe plasma collection practices in Europe with focus on donor health and safety in order to ensure patients access to safe products

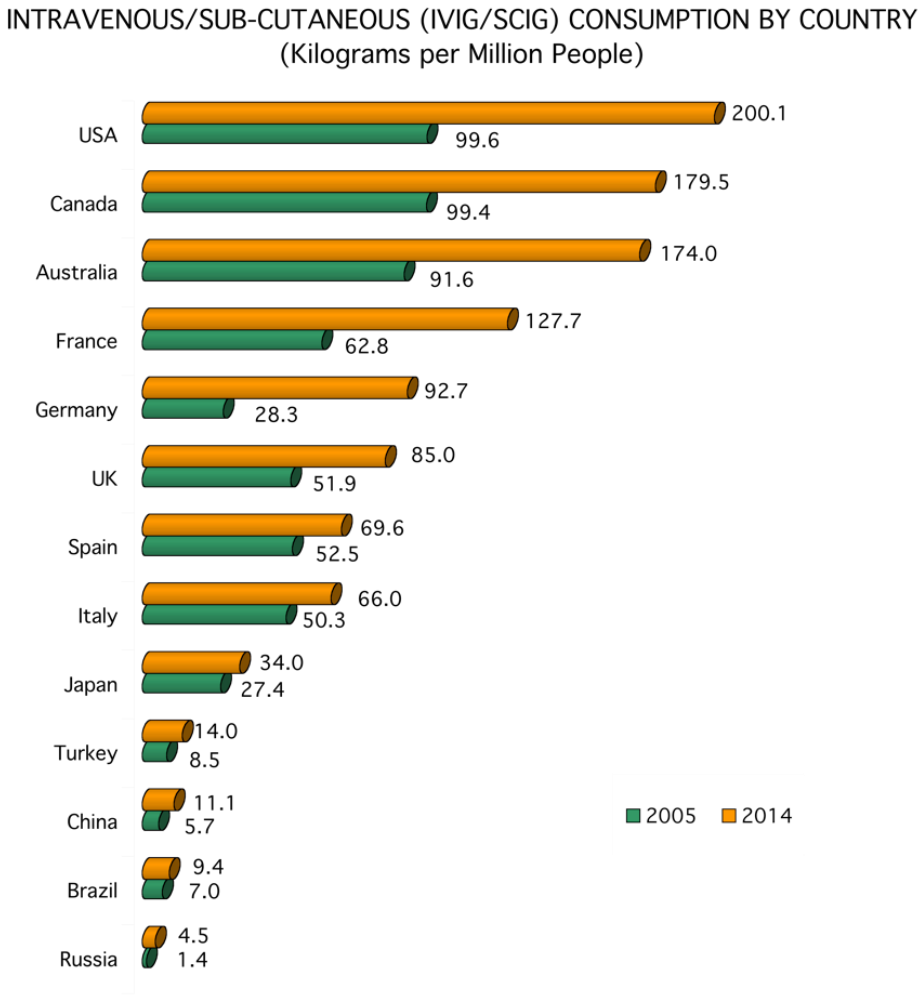
Plasma Collection in Europe

- In 24 of 28 countries only non for profit state or semi-state organizations like national blood banks and the Red Cross are allowed to collect blood and blood components

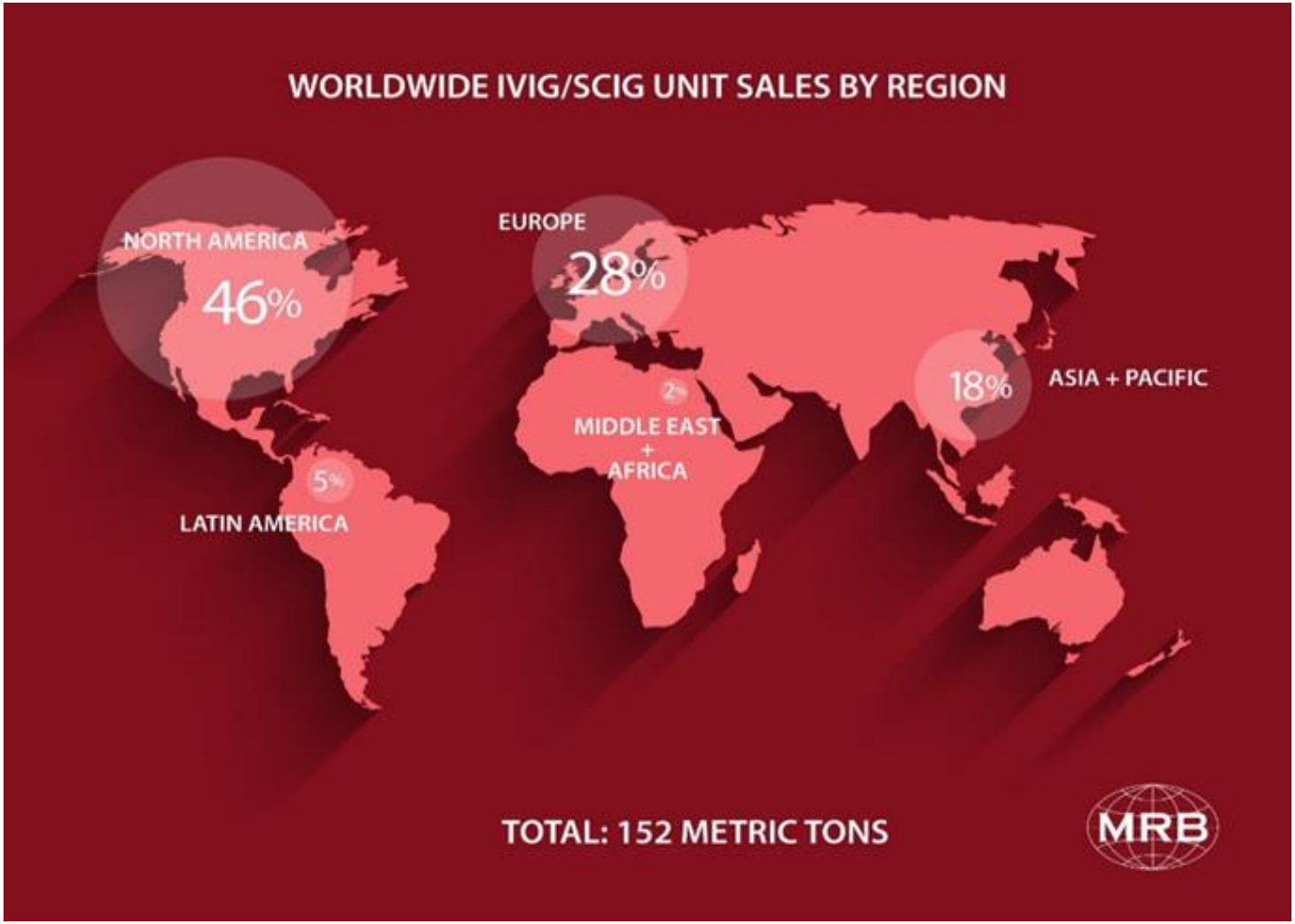
- Only in 4 countries private companies are allowed to collect compensated blood and plasma
  Germany – Austria - Czech Republic - Hungary

Most of European countries do not have sufficient **or no plasmapheresis** programs in place

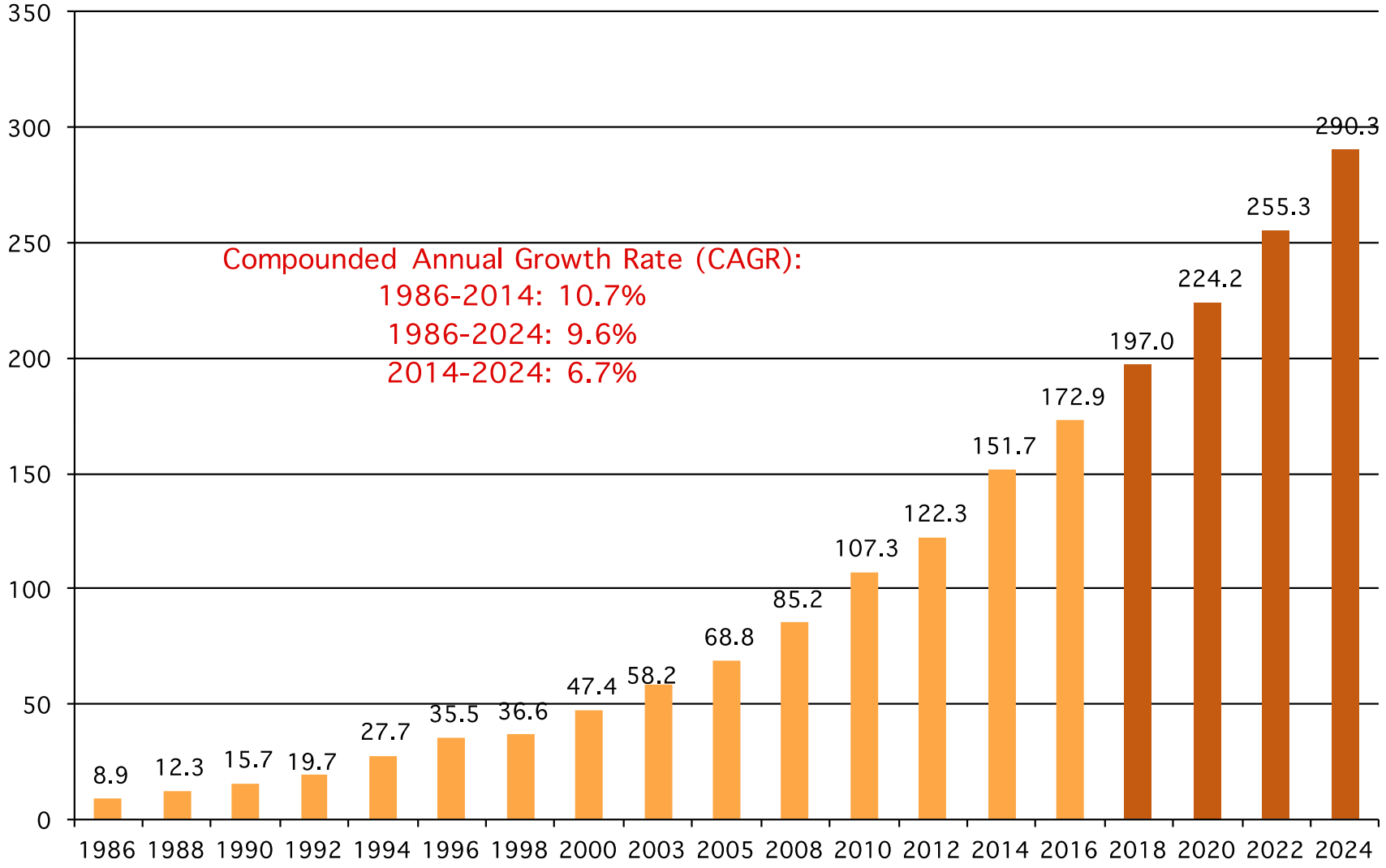
IG use in selected countries



IVIG/SCIG Sales by Region



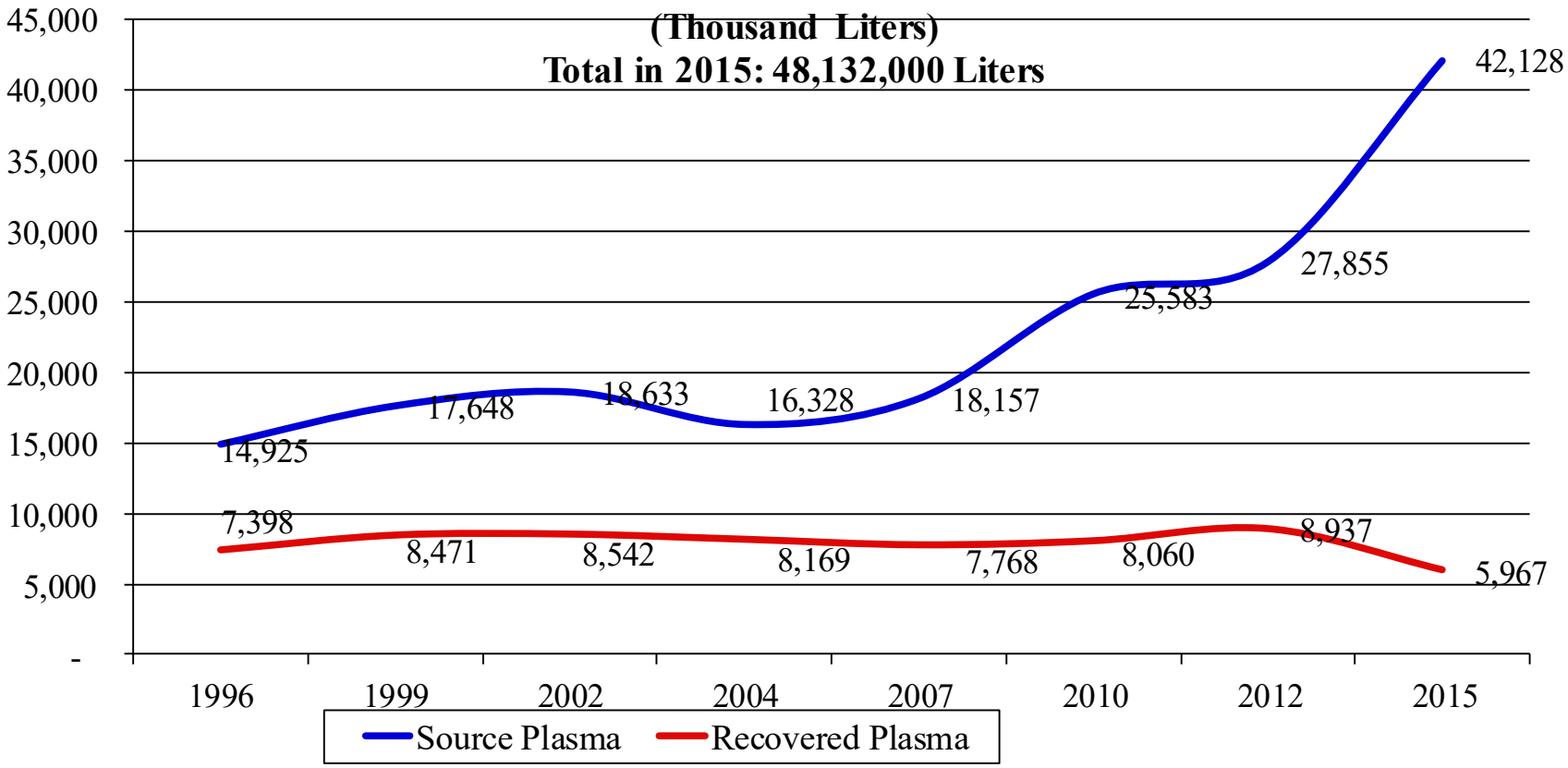
THE WORLDWIDE POLYVALENT IgG MARKET FROM 1992 TO 2024 (Metric Tons)



In 2024, based on a 3.9 grams of IgG per liter average yield, 290 tons of immune globulin will be produced from approx 75 million liters of plasma

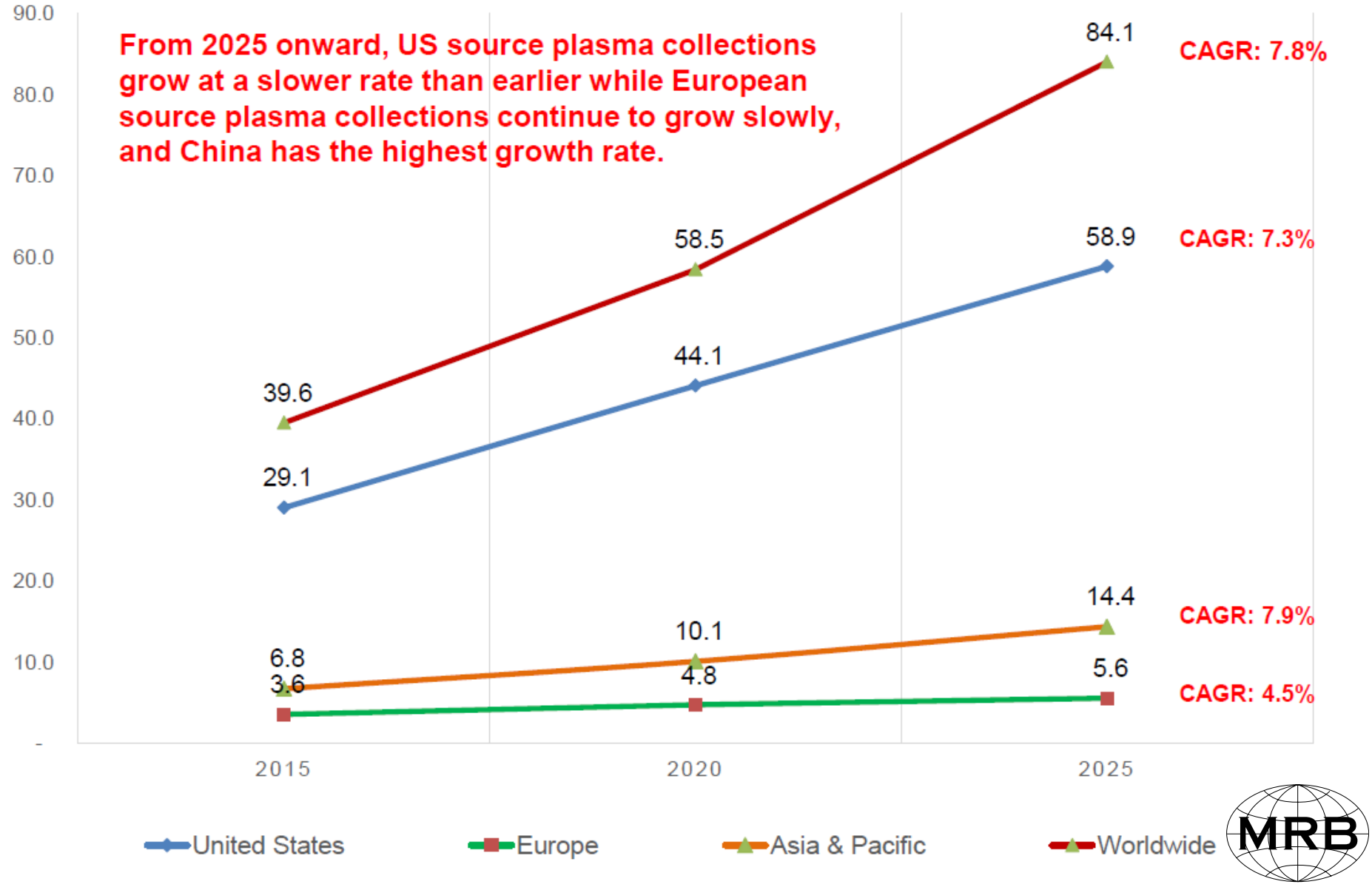
EPA
European Plasma Alliance

TYPE OF PLASMA FRACTIONATED WORLDWIDE FROM 1996 TO 2015
COMMERCIAL COMPANIES & NON-PROFIT ORGANIZATIONS
(Thousand Liters)
Total in 2015: 48,132,000 Liters

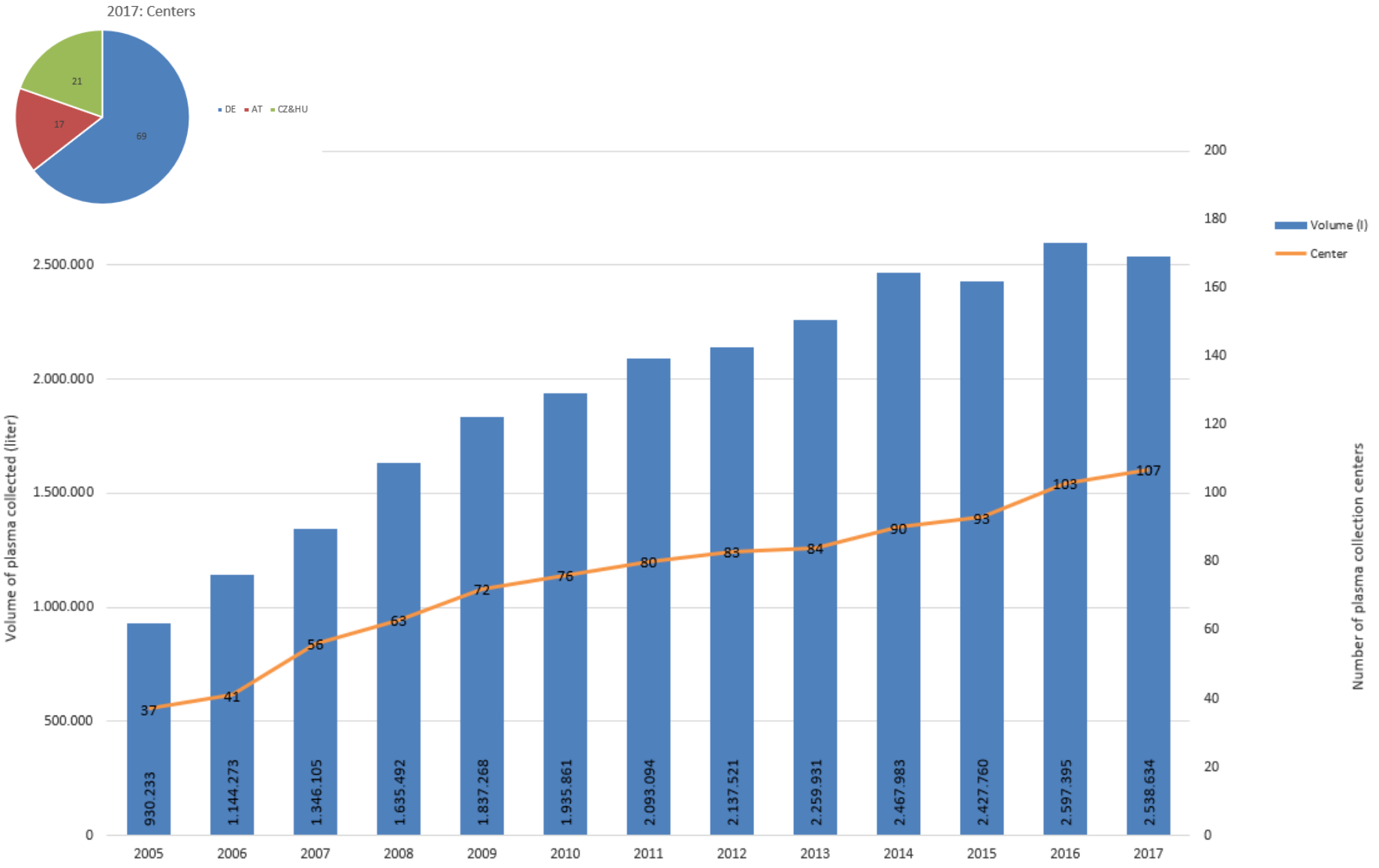


MRB

Source Plasma Collection by Region 2016 -2025

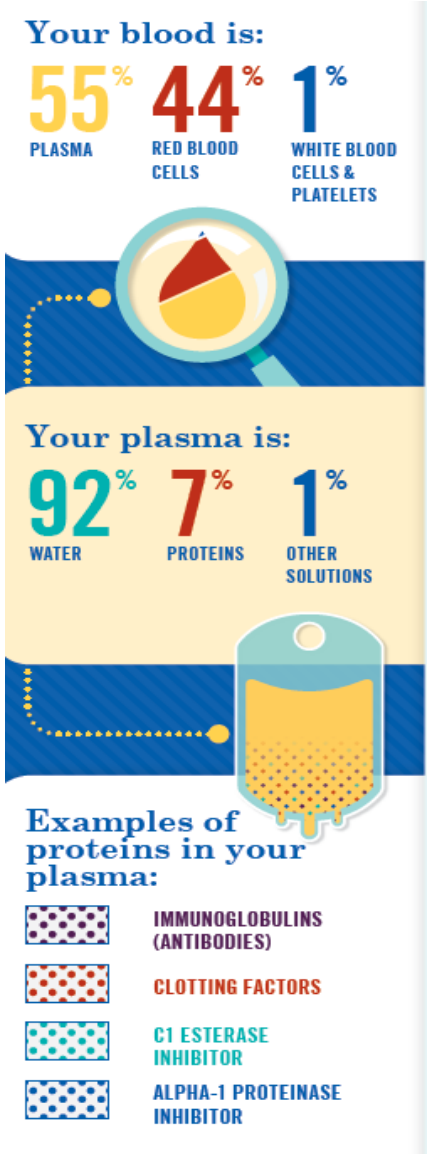


Yearly Overview 2005-2017



What is Plasma

- Plasma is the clear, straw-colored liquid portion of blood that remains after red blood cells, white blood cells and platelets are removed
- It contains hundreds of proteins
- Insufficient levels of any one plasma protein can cause a variety of chronic and life-threatening medical conditions
- Plasma protein disorder occur in a very small patient population and can be considered as rare diseases
- Plasma protein therapies are unique biological medicines manufactured from human plasma



Whole blood vs plasma donation

- Whole blood donation
  - Blood is taken from a vein in the arm
  - The blood flows through a tube into a sterile bag on a scale
  - The whole process takes approx. 30 minutes (medical exam and donation)
  - Can be done between 4-6 times/year

- Plasma donation
  - Collected through plasmapheresis
  - Plasmapheresis removes a donors plasma and returns the remaining blood components
  - The whole process can take between 1 – 1,5 hrs
  - Can be done more frequently

The process of plasma collection

Registration

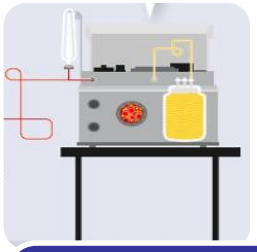
- Identification
- Donor questionnaire
- Vital signs:
  - Blood Pressure
  - Body Weight
  - Temperature
- Hemoglobin (non-) invasive

Medical Check

Physical examination

Last laboratory & Questionnaire to be controlled

- Decision on ability to donate or deferral



Donation

Disinfection & Venipuncture

Lab-tubes to be filled

Plasmapheresis machine with single-use sterile set:

Needle

Tubing

Separation unit

Plasma container

Citrate solution

Sodium Solution

Disconnection of plasma bag from tubing set using welding device

Laboratory

- On-site lab:
  - Hb (leucocytes)
- Central lab:
  Each donation
  - Serology
  - NAT
  Periodically
  - IgG
  - Total protein

Processing & Freezing

Weighing

Labelling

Freezing

Storage

Plasma in quarantine until released by qualified person

Shipping to fractionator

Safety

- Many engaged and healthy donors donate safely every day
- Plasma donation is performed by trained medical staff in an highly controlled clinical environment
- The plasma collection set is sterile and only used once
- Plasma Protein Therapies are highly complex to manufacture
  - Between 7-12 months to manufacture
- Companies must adhere to rigorous regulatory requirements to ensure manufacturing consistency and pathogen safety.

Authorization

- Based on manufacturing licenses of national competent medical authorities, EMA certifies plasma collection centers that collect plasma for manufacturing therapies through the Plasma Master File (PMF)
- This secures that the collection process in line with European regulations
- Each collection center is also under separate supervision of local and national regulatory authorities
- Fractionators also audit their suppliers

Safety & Quality – A top priority

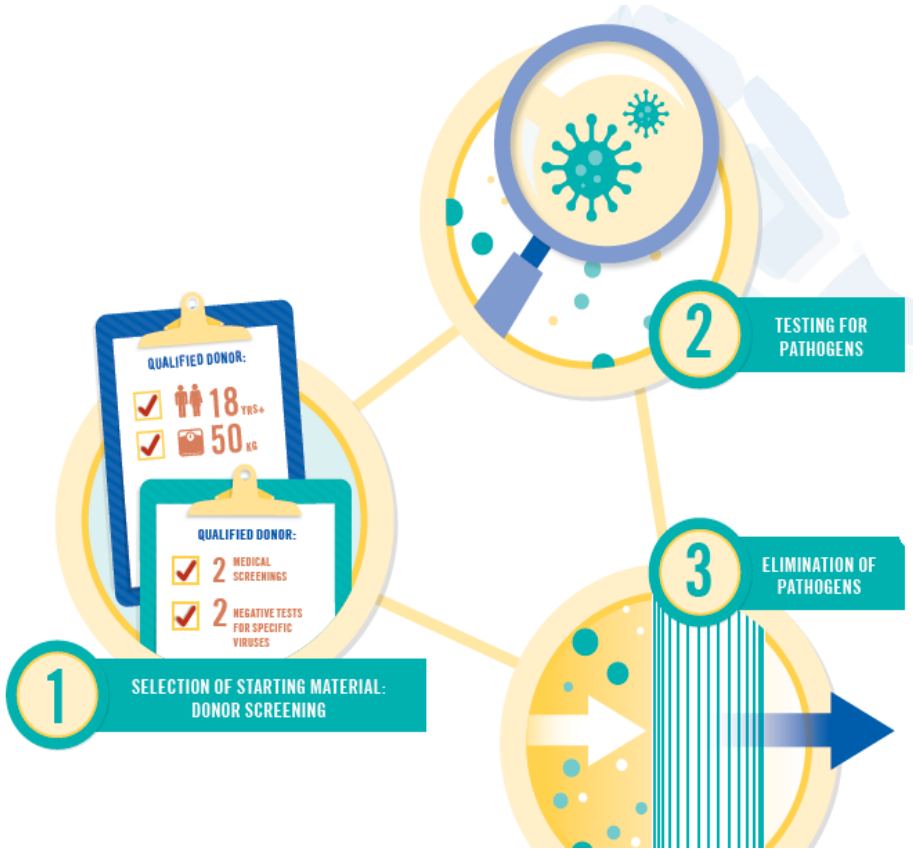
- PPTA developed the **International Quality Plasma Program** (IQPP) to further ensure quality and safety of source plasma.
- IQPP provides independent , third-party evaluation and recognition of a center's adherence to global voluntary standards for source plasma.
- Source plasma is collected from healthy donors that may receive compensation. Source plasma is only used for making plasma protein therapies.
- IQPP certification is available to plasma collectors worldwide that have been licensed by a competent national regulatory authority

INTERNATIONAL QUALITY PLASMA PROGRAM

Constant Vigilance for Safe Products

- Plasma Protein Therapies require constant vigilance for safe products
- The industry has a record of safety from pathogens for more than 20 years – Current manufacturing protocols are extremely effective against pathogens
- Plasma Protein Therapies' safety protocols are constantly evolving due to new and emerging pathogens e.g. zika

There are 3 types of safeguard measures used in plasma donation and manufacturing to ensure safe therapies



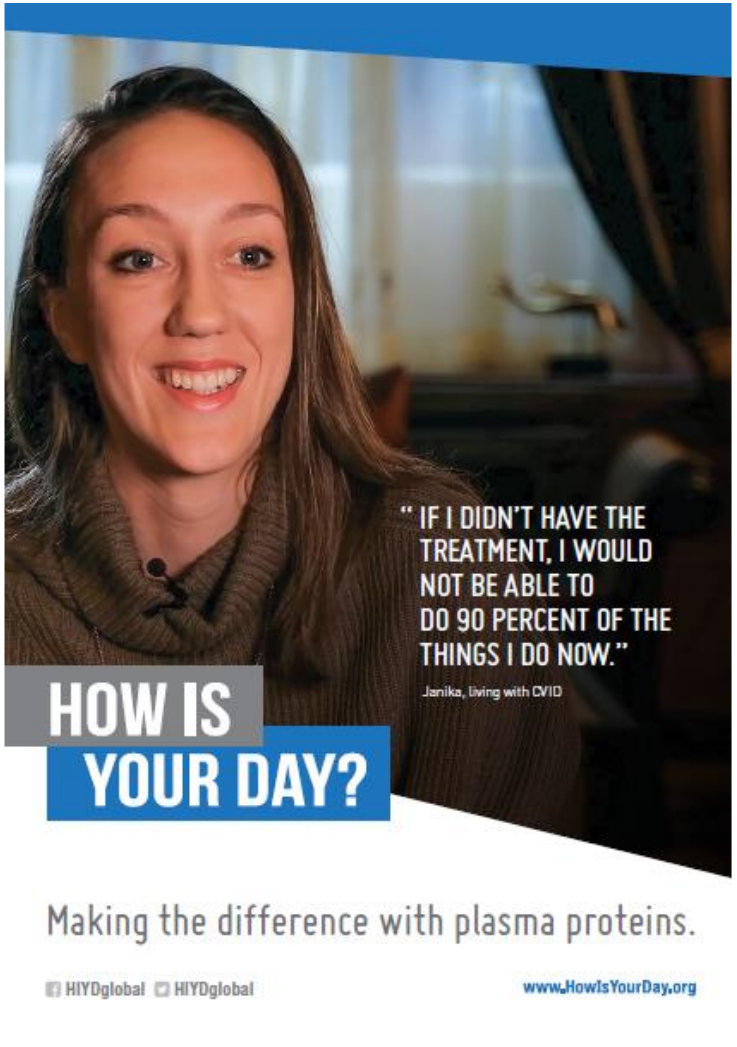
European Challenges

- A number of EU member states continue to support national self-sufficiency policies for plasma collection – Supporters of national self-sufficiency policies for plasma strive to serve 100% of domestic need without outside support
  - These policies are almost always linked to national use of plasma protein therapies
  - These policies are used to shield state-owned companies
- Policies are characterized as a “political” decision, but for the patient it could become a limitation to access to therapy

Plasma is a global resource

- Changes in clinical practice in developed countries have reduced the need for red cells and significantly reduced volume of recovered plasma in the past years
- The need for PDMP's worldwide continues to increase
- Majority of plasma supplies for the manufacture of PDMP's is met by commercial US industry
- Geographic imbalance in plasma collection concerns that local disruptions of plasma supplies could result in regional and global shortages of PDMP's
- Plasma collections should be increased outside the United States, including low and middle income countries

Making the difference - HIYD



Summary

- EPA member companies are committed to provide plasma for safe and effective therapies to patients worldwide
- Standards programs (IQPP) contribute to the safety and quality of plasma therapies by augmenting regulatory requirements
- In the future, plasmapheresis will be the main source to meet growing demand for plasma in the EU
- The plasma sector needs a specific recognition and framework in the EU legislation
- It's needed to develop plasmapheresis programs in EU MS to meet the clinical demand for plasma protein therapies
- The private sector of collectors can work in parallel with the public sector (as shown in AT, DE, CZ HU)
- The private sector of collectors should be supported and not hindered by EU regulation and MS

Thank you to all Plasma Donors