

Goals and Value of “ Strategic Independence ”

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Two pillars of IPFA

1. Plasma and quality of plasma

- o supply of plasma from whole blood donors and plasmapheresis donors
- o focus on the suppliers of plasma (blood transfusion organizations)
- o focus on high quality of plasma for fractionation

2. Plasma fractionation and supply for patients

- o patients and hospitals: high need and demand for plasma products
- o expected developments in markets, worldwide

Different types of plasma

- Priority on recovered plasma from VNRBD
- Source plasma from VNRBD

Functions of plasma products in clinical therapy

- **Replacement therapy:**
pro- and anti coagulant factor concentrates,
polyvalent immunoglobulins, specific immunoglobulins,
albumin,
alpha 1-antitrysin,
C1-esterase inhibitor concentrate.
- **Immune modulating therapy:**
intravenous immunoglobulin,
alpha 1 antitrypsin.
- **Antagonist function:**
prothrombin complex concentrate, activated prothrombin complex concentrate.
- **Anti-inflammation:**
intravenous immunoglobulin,
anti-thrombin,
activated protein C.
- **Drug delivery:**
fibrin glue / tissue sealant,
transferrin

% diagnosed and treated patients worldwide:

- hemophilia A/B: 30 % and 25% (WFH)
- PID: <10 % “ 6 % (IPOPI)
- AAT deficiency: 10 % “ 3 % (AlphaOne)

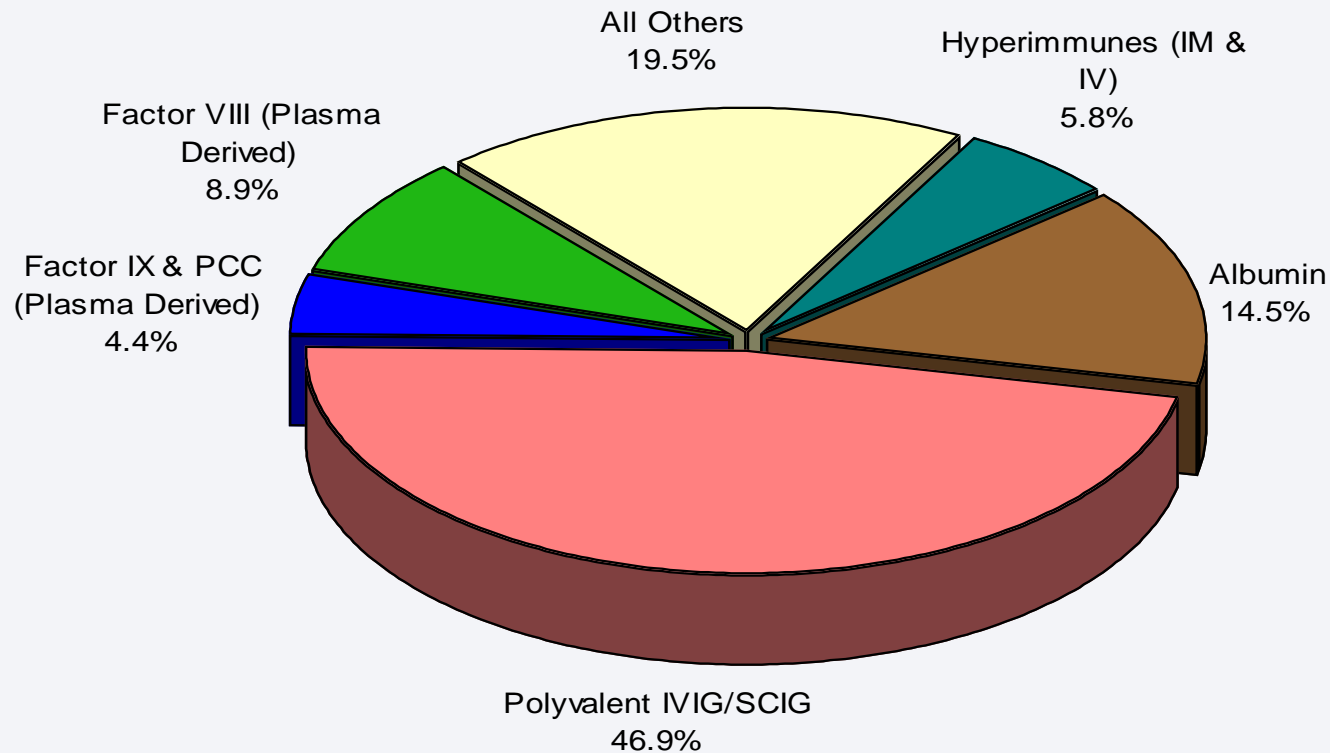




THE WORLDWIDE PLASMA PROTEINS MARKET BY PRODUCT - 2014

Without Recombinant Factors

Total Market \$18,514.0 Million



IVIG + SCIG = 47% of total market, albumin 15%, factor VIII 9%

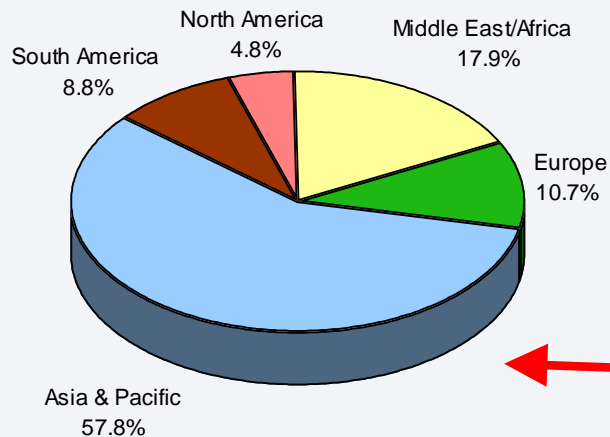


THE WORLDWIDE PLASMA PROTEINS MARKET BY REGION - 2014

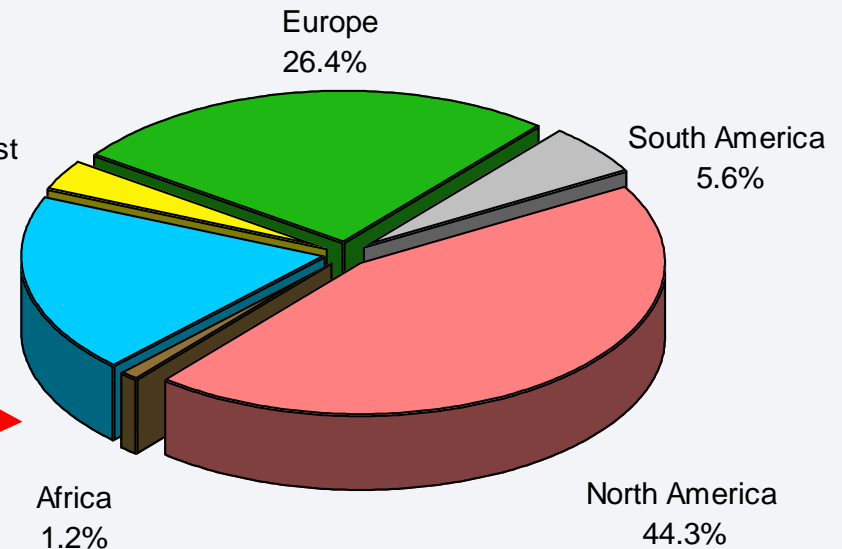
WITHOUT RECOMBINANT FACTORS

Total Market \$18,514.0 Million

World Population by Region - 2013



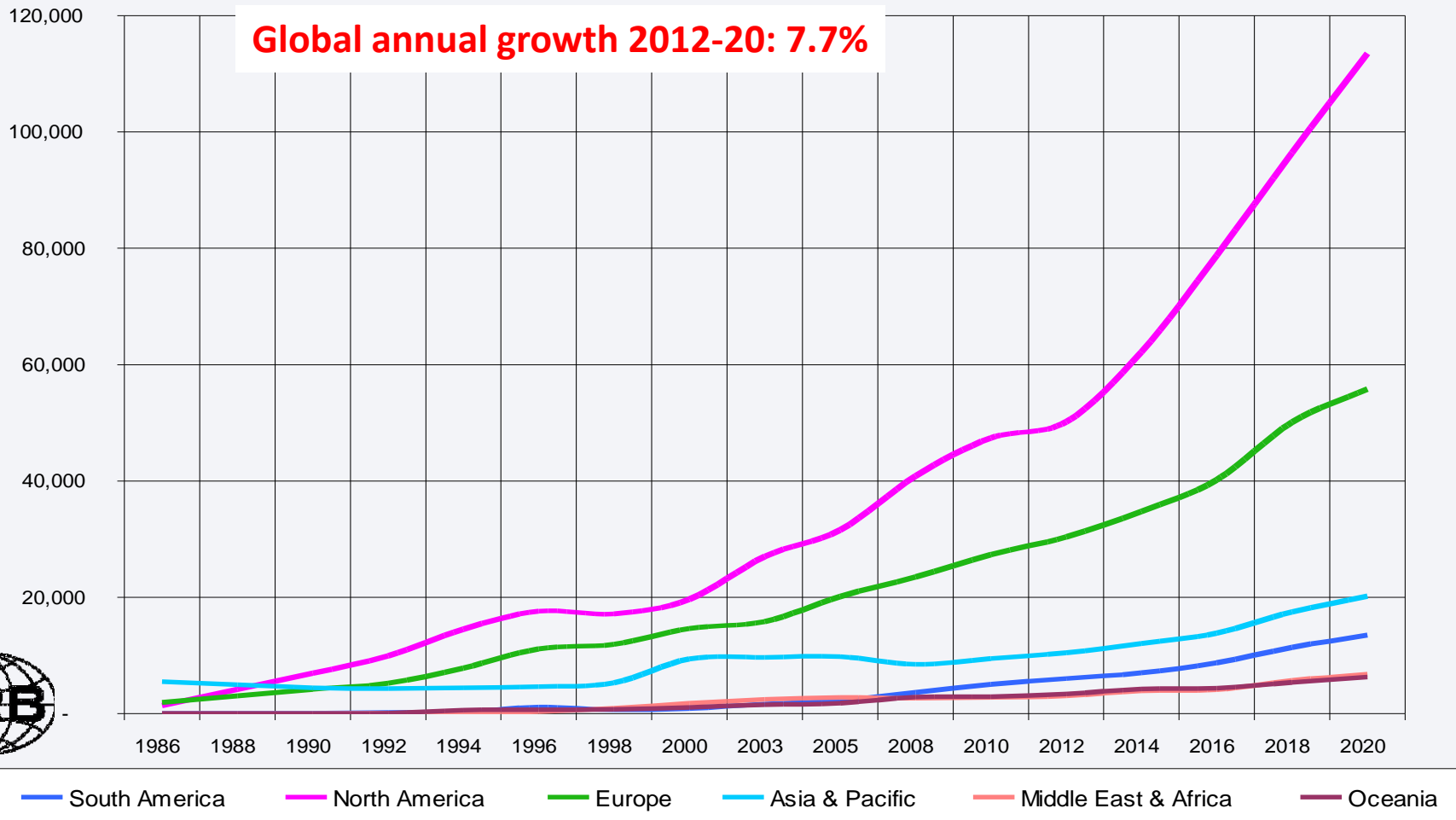
Asia & Pacific/Oceania
19.1%



North America holds 44% of the global market but has only 5% of the world population, while Asia & Pacific/Oceania hold 19% of the market with 58% of the world population.

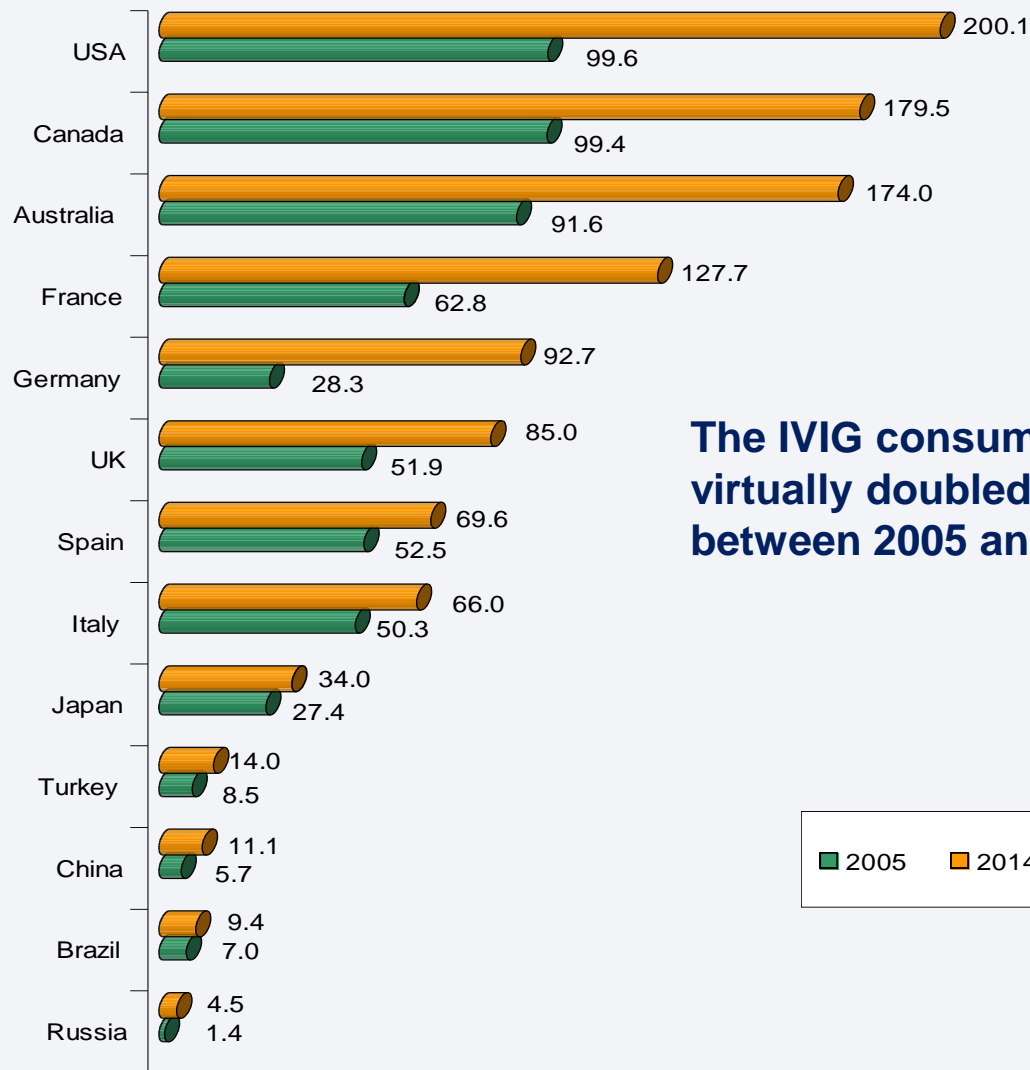
Intravenous Immunoglobulin

THE POLYVALENT IVIG MARKET BY REGION FROM 1986 TO 2020 (Est.) (Kilograms)





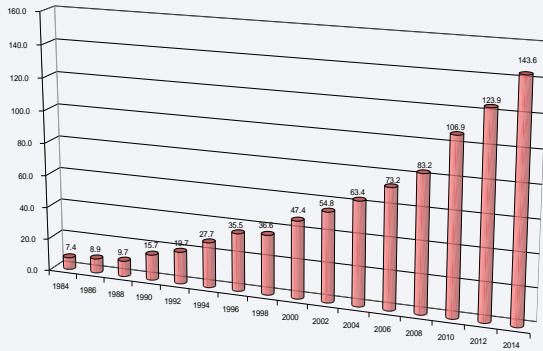
INTRAVENOUS/SUB-CUTANEOUS (IVIG/SCIG) CONSUMPTION BY COUNTRY (Kilograms per Million People)



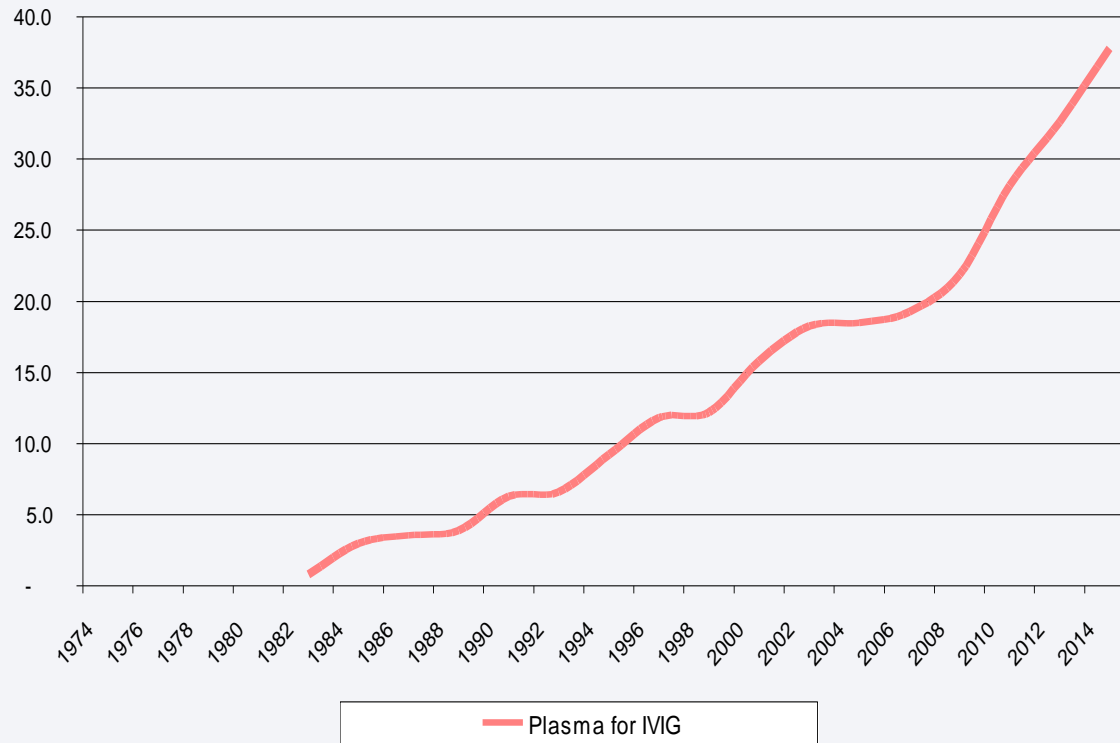
The IVIG consumption per capita has virtually doubled in many countries between 2005 and 2014



WORLDWIDE DEMAND FOR INTRAVENOUS & SUBCUTANEOUS IMMUNE GLOBULIN (IVIG/SCIG)
1984 - 2014
Metric Tons



PLASMA REQUIREMENTS FOR ALBU IVIG
1974 - 2014 - Million Liters

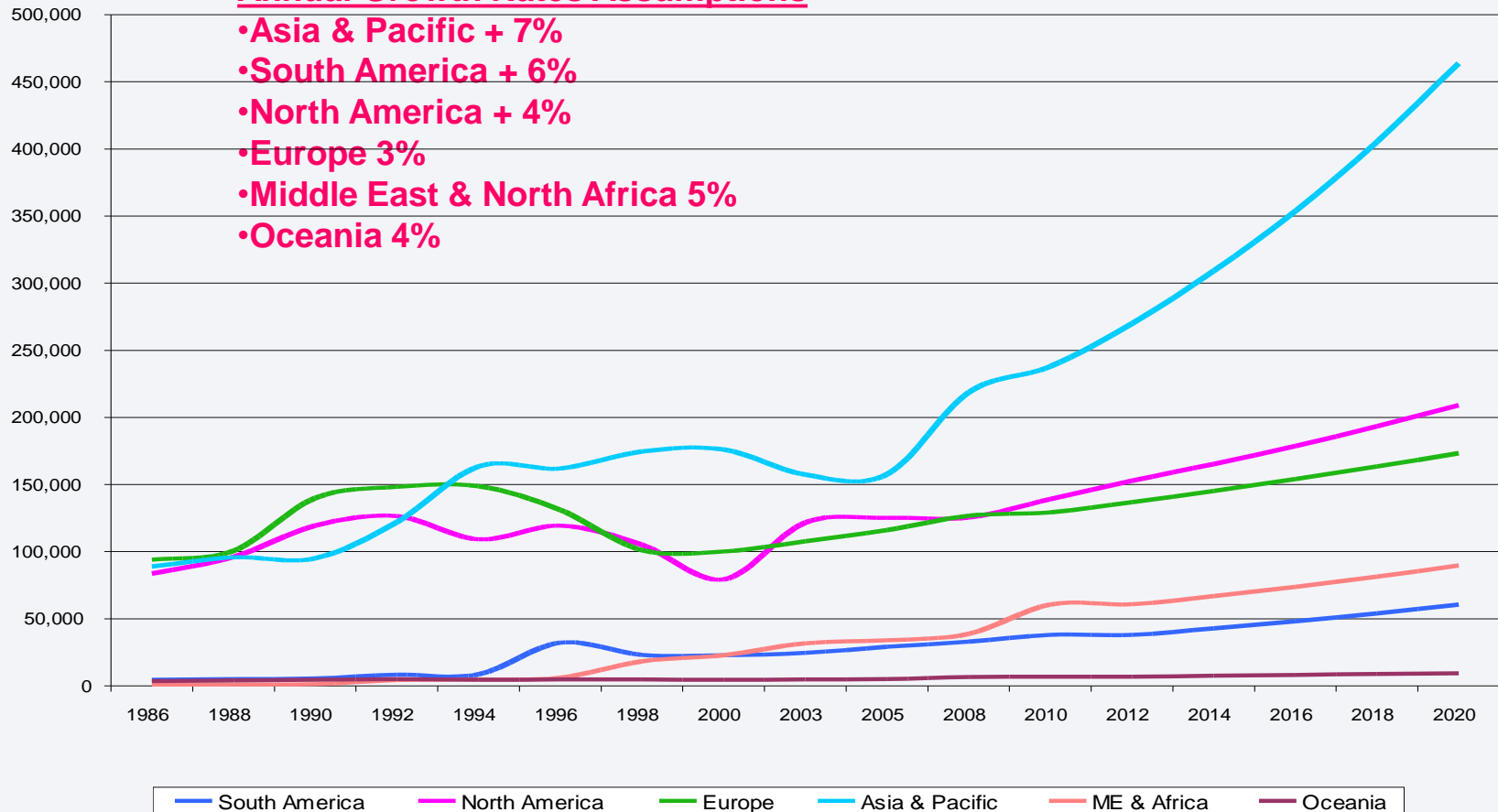


Albumin

THE ALBUMIN MARKET BY REGION FROM 1986 TO 2020 (Kilograms)

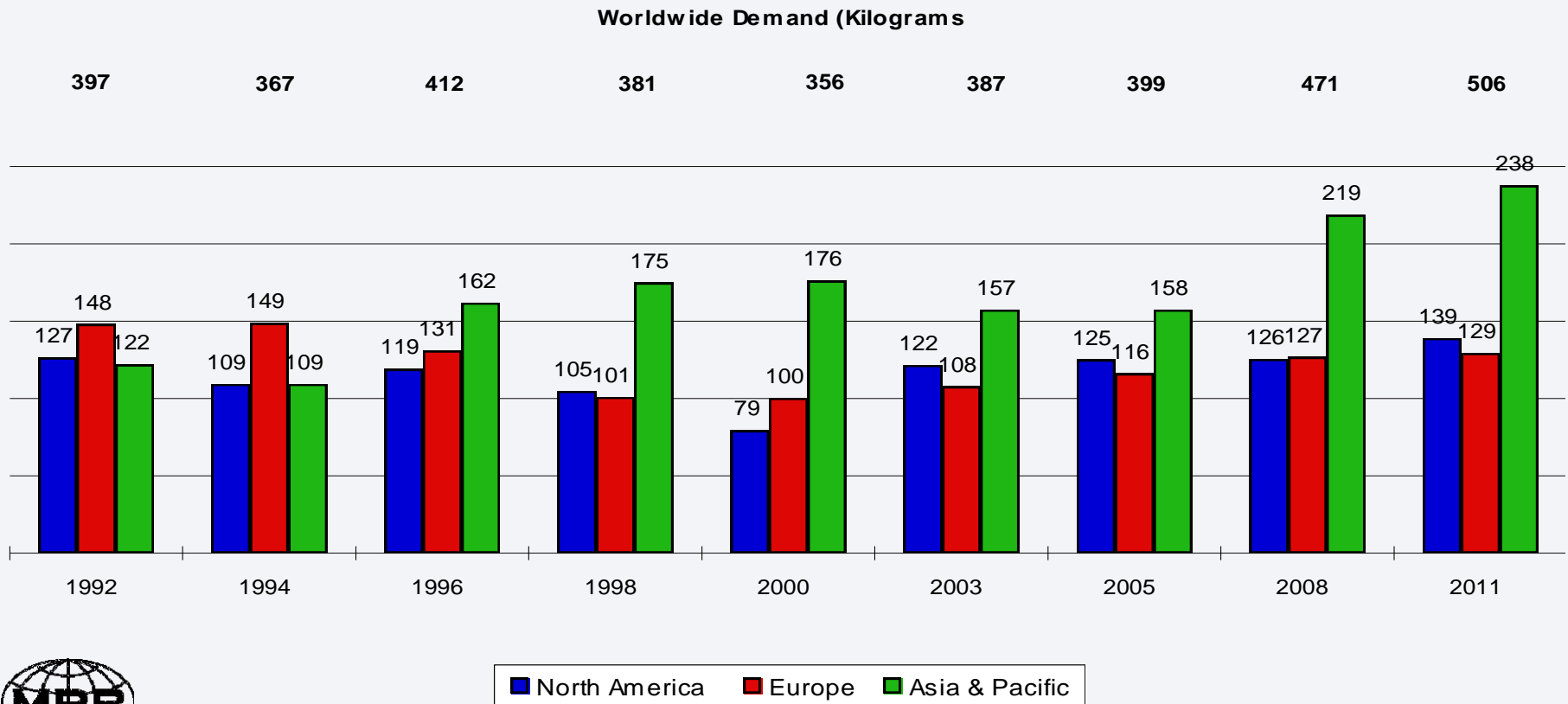
Annual Growth Rates Assumptions

- Asia & Pacific + 7%
- South America + 6%
- North America + 4%
- Europe 3%
- Middle East & North Africa 5%
- Oceania 4%

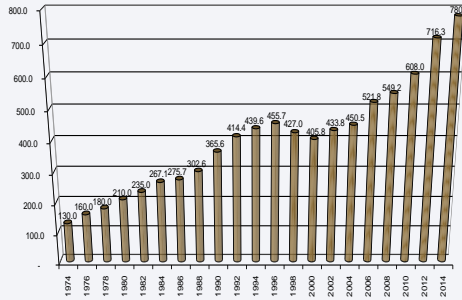


Over the years, the importance of albumin in Asia has increased

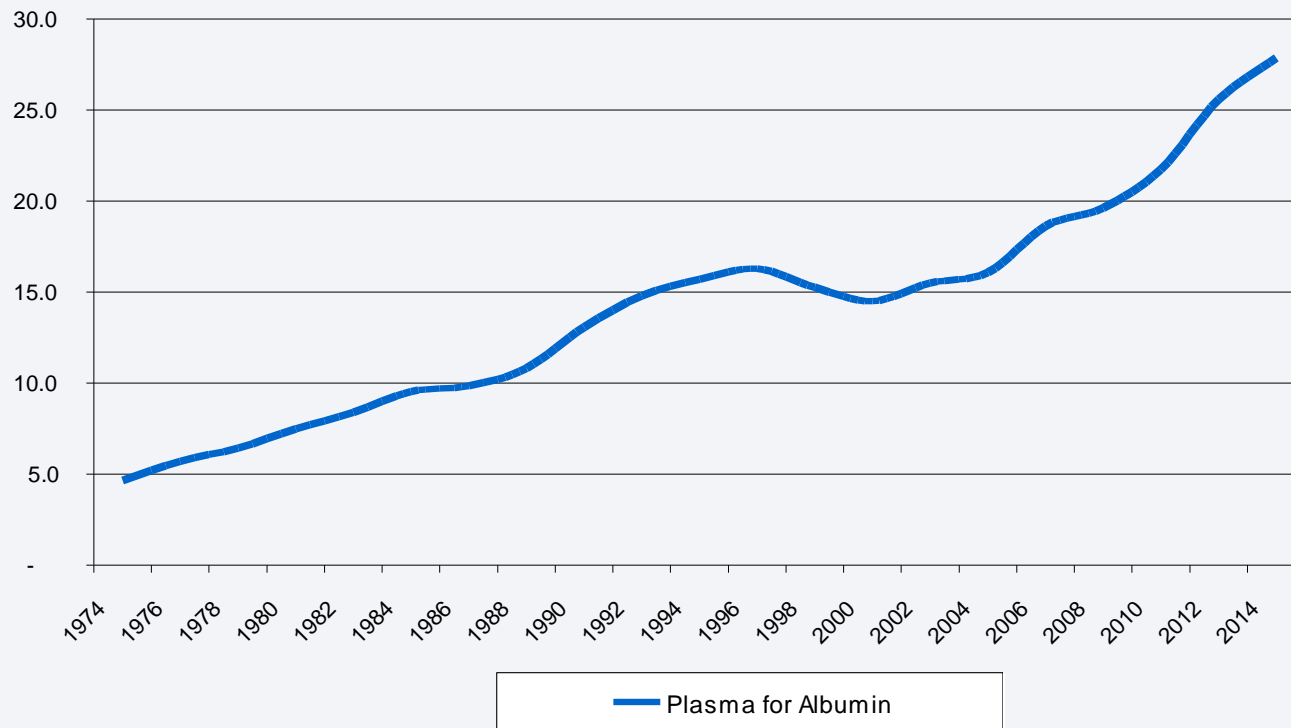
WORLDWIDE ALBUMIN DEMAND 1992 - 2011 (METRIC TONS)



WORLDWIDE ALBUMIN DEMAND 1974 - 2014
Metric Tons

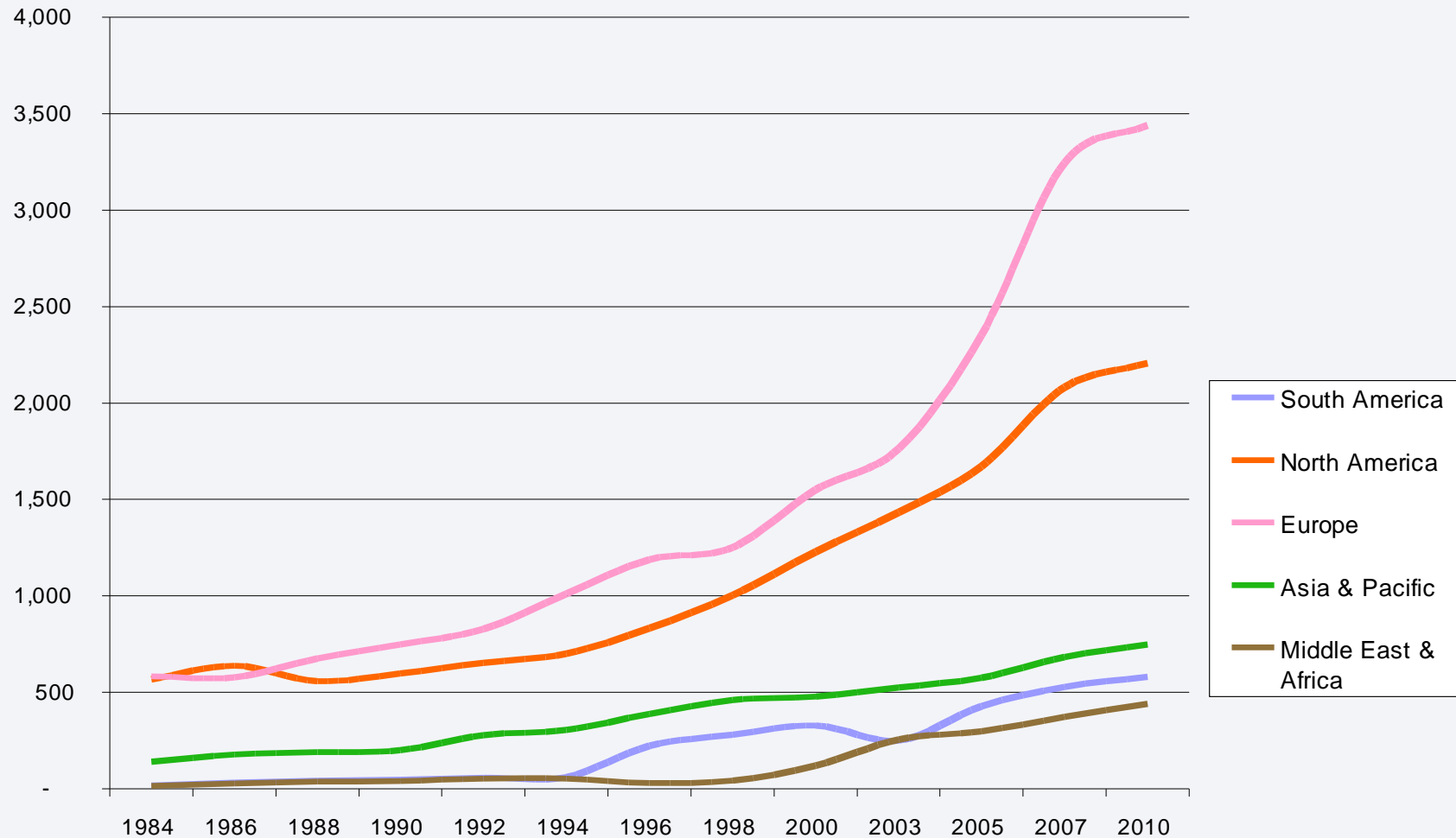


PLASMA REQUIREMENTS FOR ALBUMIN,
1974 - 2014 - Million Liters



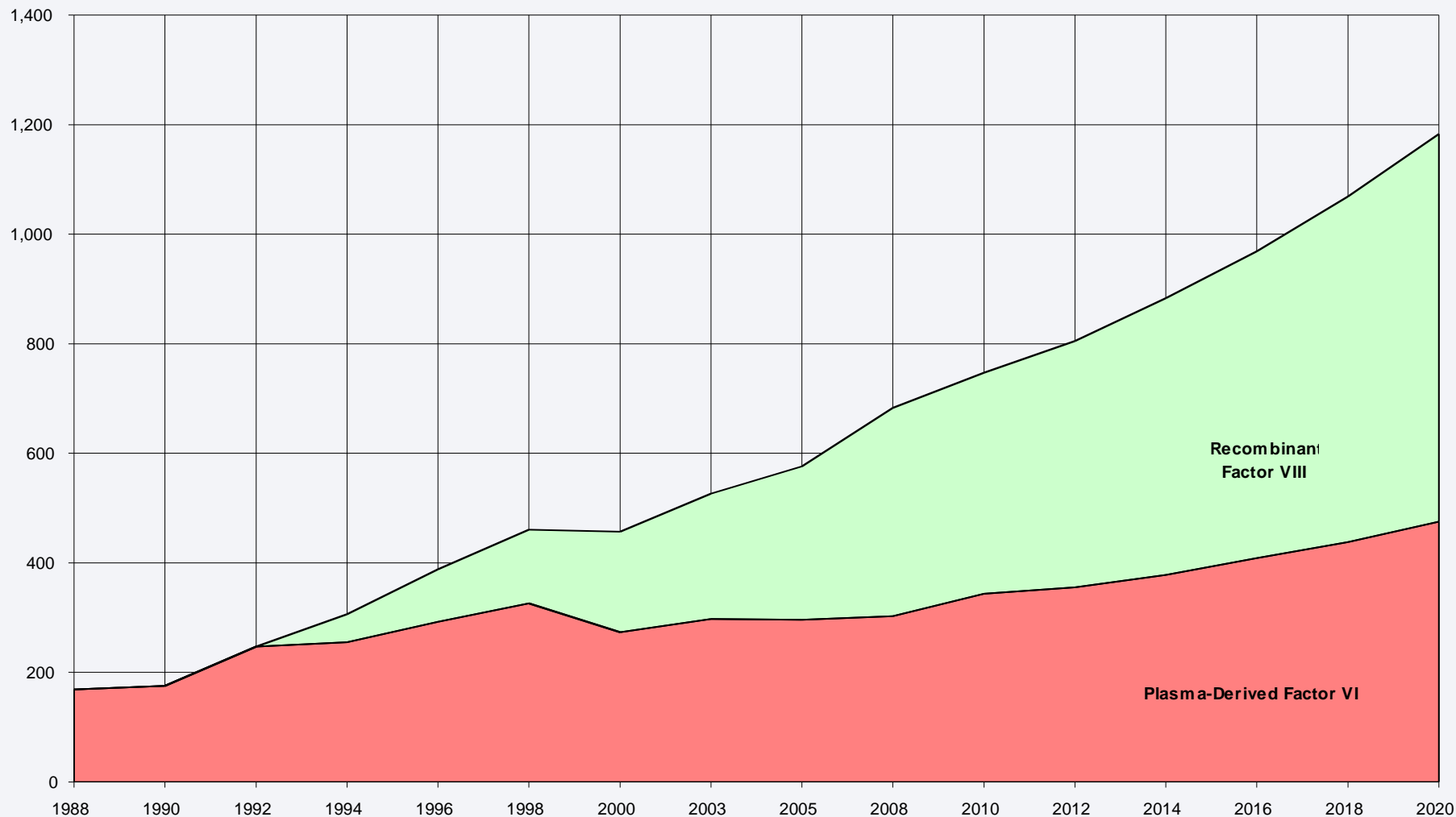
Factor VIII

GLOBAL FACTOR VIII CONSUMPTION BY REGION FROM 1984 TO 2010 PLASMA-DERIVED AND RECOMBINANT (International Units x 1,000)

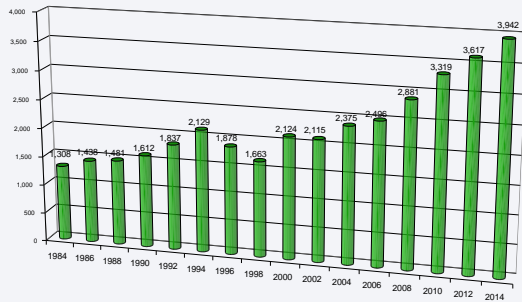




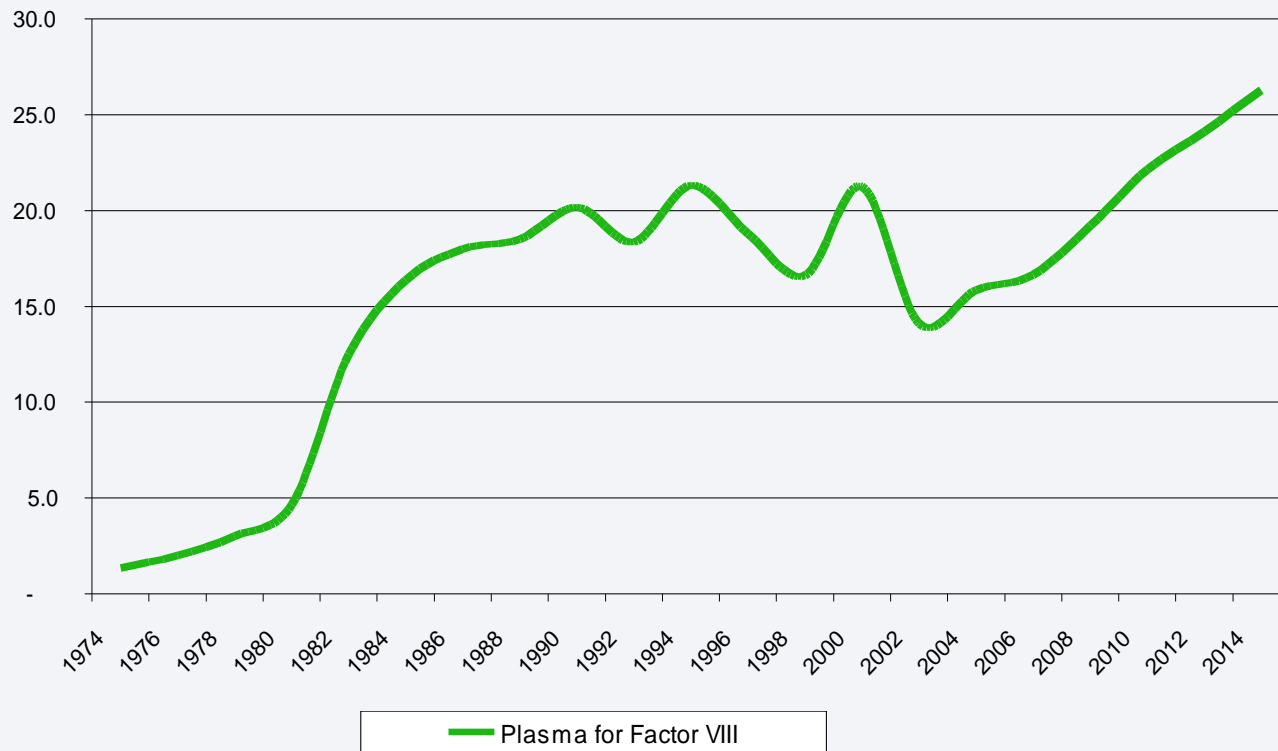
**THE FACTOR VIII MARKET IN ASIA & PACIFIC (including Australia & New Zealand)
FROM 1988 TO 2020 (Est.)
(International Units x Million)**



WORLDWIDE DEMAND FOR FACTOR VIII 1984 - 2014
Plasma-derived, Million International Units



PLASMA REQUIREMENTS FOR ALBI Factor VIII
1974 - 2014 - Million Liters



IPFA, embedded in community

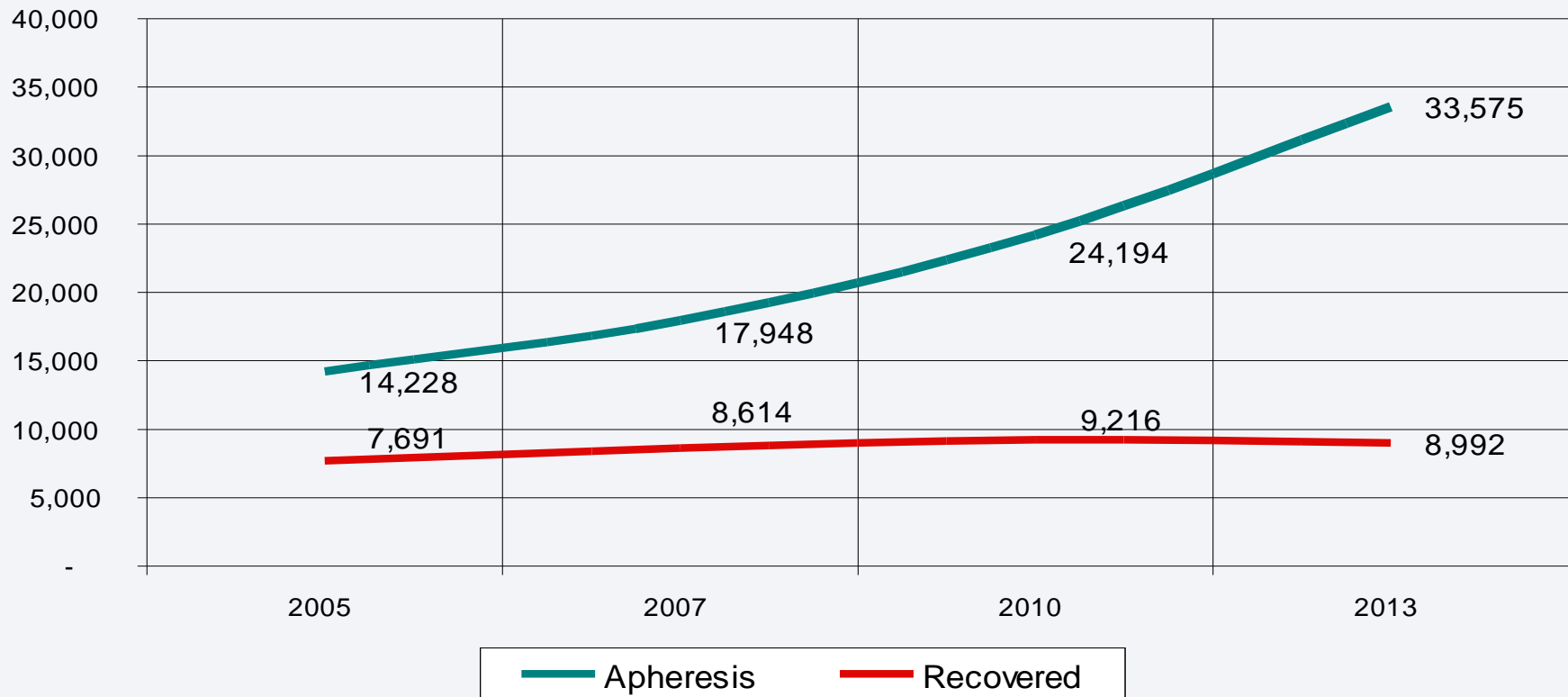


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Plasma for Fractionation



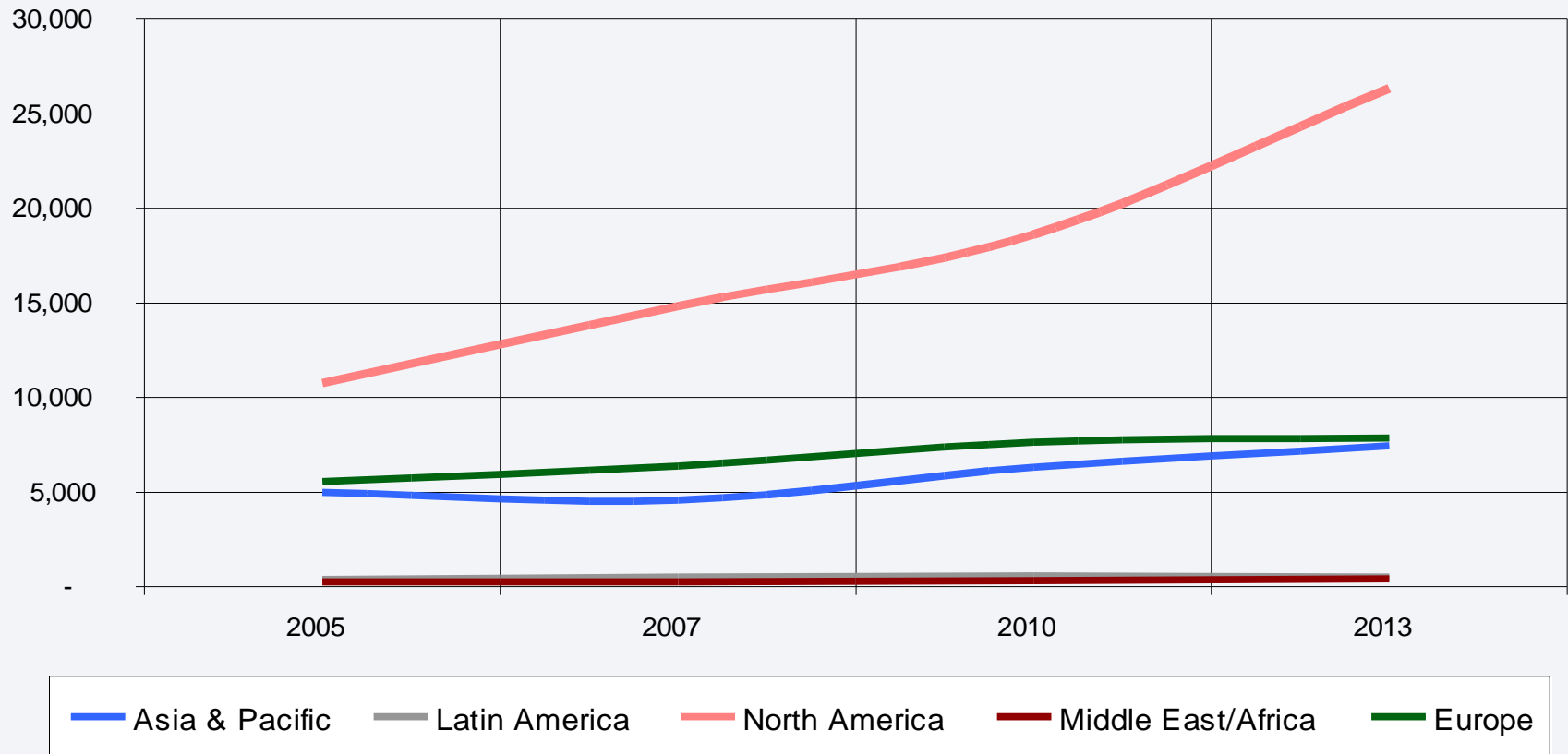
Plasma for Fractionation - World 2005 - 2013 (Thousand Liters)



The volume of source (apheresis) plasma has more than doubled since 2005, while the supply of recovered plasma has remained essentially stable. Several million liters of recovered plasma remains unused



Plasma for Fractionation by Region 2005 to 2013 (1000 x liters, recovered & apheresis)



Source (apheresis) plasma collections grow the fastest, particularly in the United States

Should we not consider ?

Plasma is a Strategic Resource

Countries/regions should aim at Strategic Independence.

Strategic Resources are critical materials, defined as :

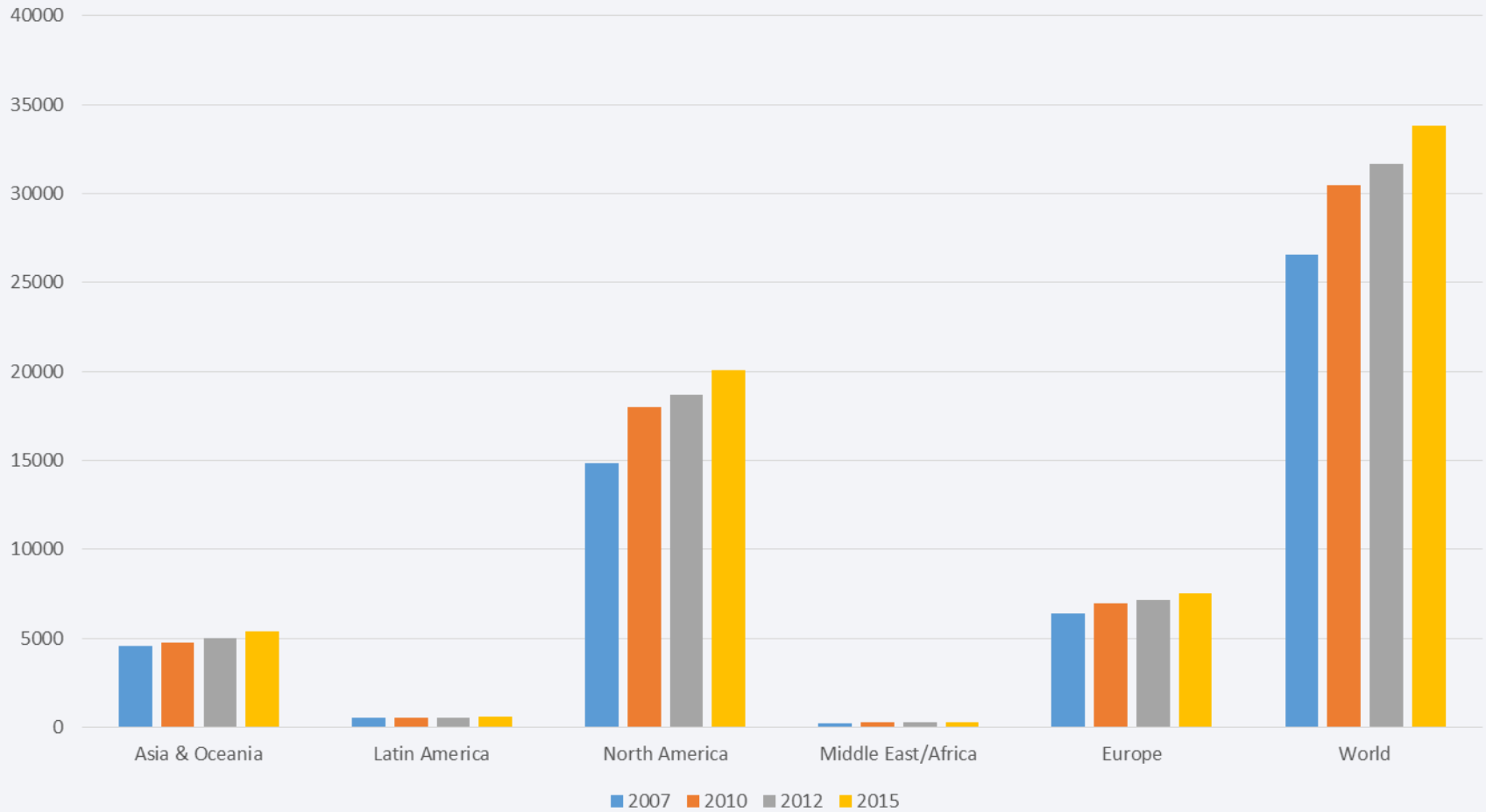
Economically important raw materials which are subject to a higher risk of supply interruption.

These materials are critical for a region or a country because their lack of domestic production and/or inability to guarantee national supply through importation.

Examples: energy, drinking water, rare metals, etc.

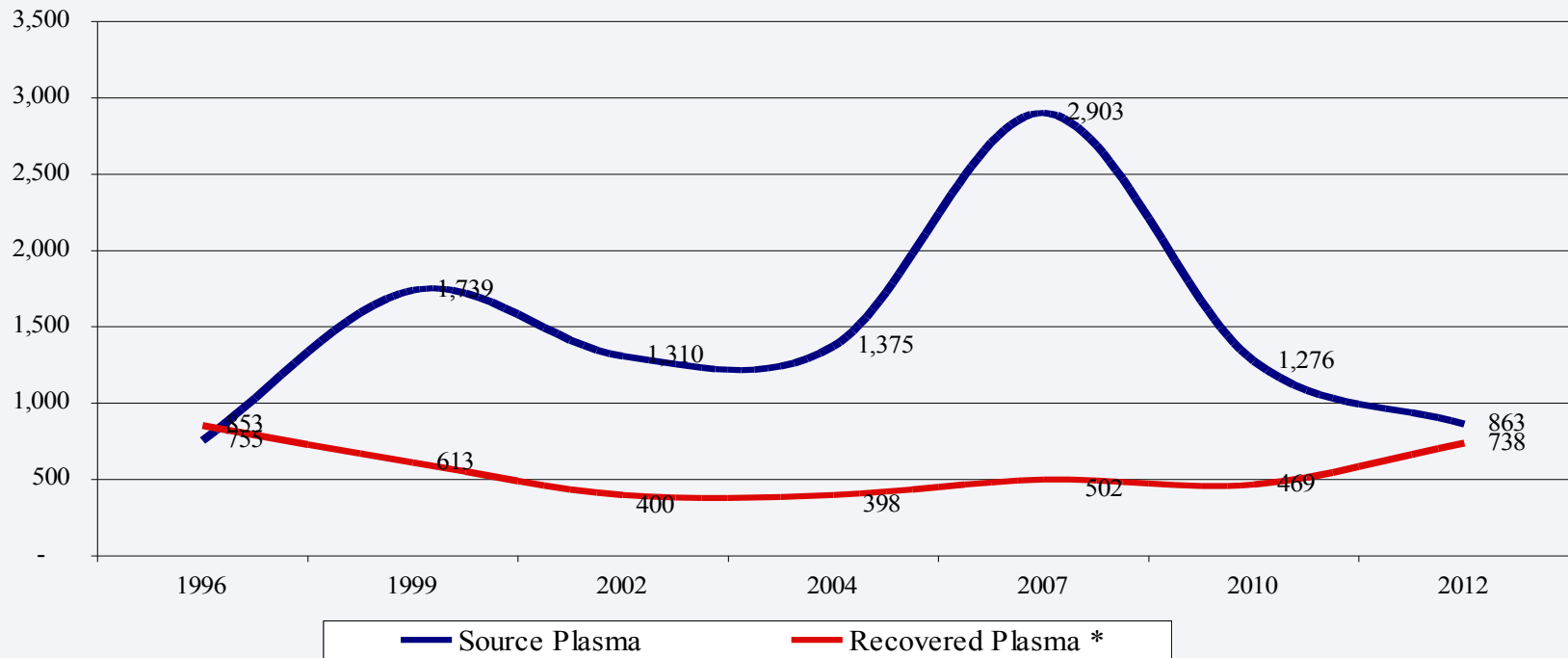


Global Plasma Collection Volume





TYPE OF PLASMA PROCESSED IN ASIA FROM 1996 TO 2012 NON-PROFIT ORGANIZATIONS (Thousand Liters)



Plasma should be a strategic resource, because:

what ifthis situation continues, and we face:

- Natural disasters
- Wars / regional conflicts
- No supply guarantee
- Transfusion Transmitted Infections in the US, that end the plasma collection in the US
- Price dependency (market movements...)
-

Goals and Value of Strategic Independence

- **Plasma is a strategic resource**, *comparable with water and with energy*
- **Countries/regions should aim at strategic independence**
 - Source material for production of plasma derived essential medicinal products
 - Blood products are life saving medicines for many patients in many different diseases
 - Important tool for public health improvements (patients and donors)
 - High value in public perception
 - Great economical value (equipment, tests, capacity, products, etc....)

How to proceed?

- Safeguarding the supply in a country or a region
- Involvement and commitment of authorities (MoH, policy makers, inspectorates)
- Cooperation of all stakeholders

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Thank you for your attention