

The supply of plasma-derived medicinal products in the future of Europe

Second edition

23-24
April 2024
Rome, Italy

CENTRO
NAZIONALE
SANGUE

 PLASMA
ITALIA
italiaplasma.it

The global Demand for PDMPs: current Scenario and future Trends

with the patronage of



Ministero della Salute

Patrick Robert

Marketing Research Bureau, USA

Disclosure

- Patrick Robert is a consultant for the Marketing Research Bureau, an independent company supplying market data and insights about the global plasma proteins industry.



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.

All the data and information originate from sources generally available to the public. Their accuracy is not guaranteed, and the Marketing Research Bureau assumes no liability for their use.

© 2024. Sharing, posting, or reproducing this material, in whole or in part, is prohibited, unless granted explicit authorization from the Marketing Research Bureau.



TABLE OF CONTENTS

The global Demand for PDMPs

1. Current Scenario: the Global PDMPs Market by

1.1 Product

1.2 Region

1.3 Company

1.4 Global Plasma Supply Trends

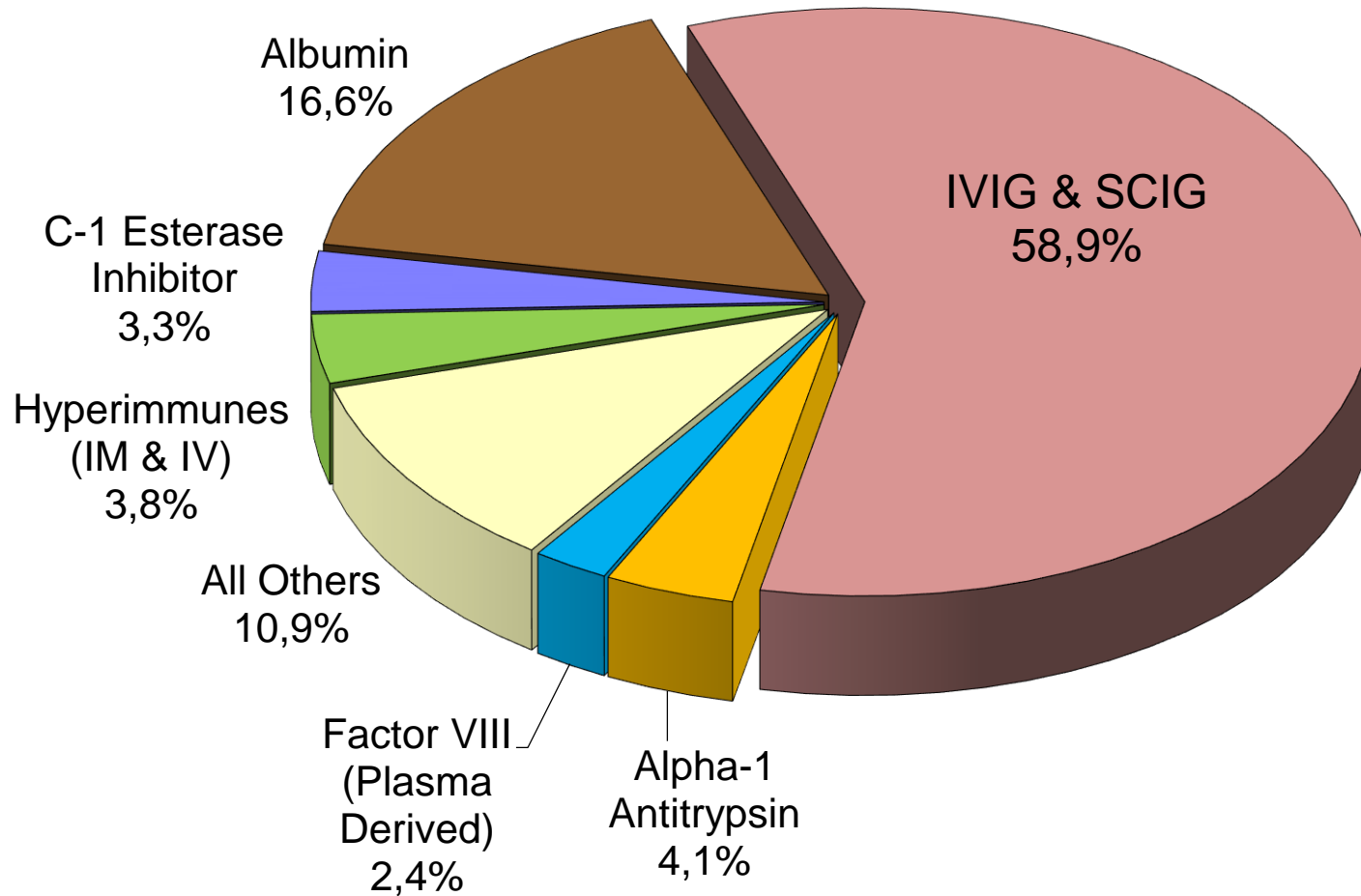
1.5 Patient Population by PDMP Category

2. Future Trends by Region and Product: Opportunities and Threats



The Global PDMPs Market by Product* in 2022

Total Market \$30.3 Billion



Other proteins include factor VII, factor XI, aPCC, PCC, antithrombin III, protein C, fibrinogen, factor XIII, fibrin sealant, haptoglobin and more.

Each protein requires dedicated technical, human and financial resources for clinical studies, regulatory affairs, manufacturing, packaging, storage, transportation and shipping, as well as marketing & sales, medical support, customer service, etc.

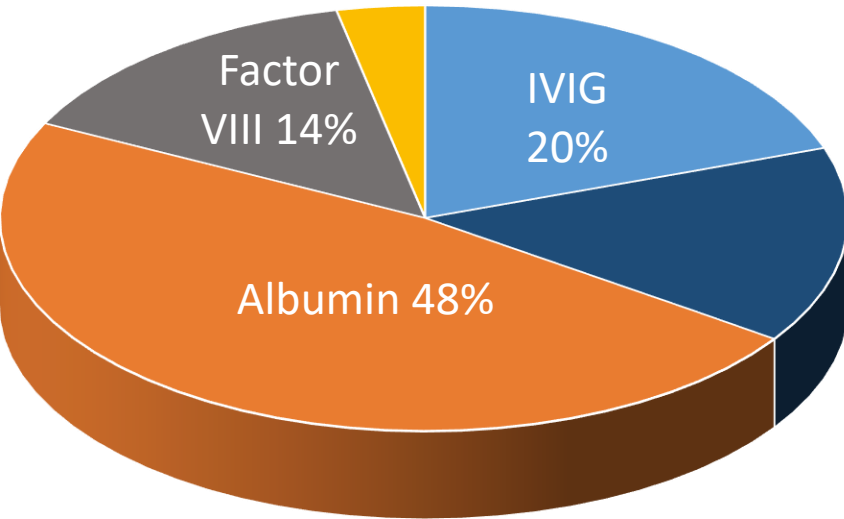
Therefore, concentrating efforts on IG production is more cost effective for some companies.

* Recombinant factors not-included



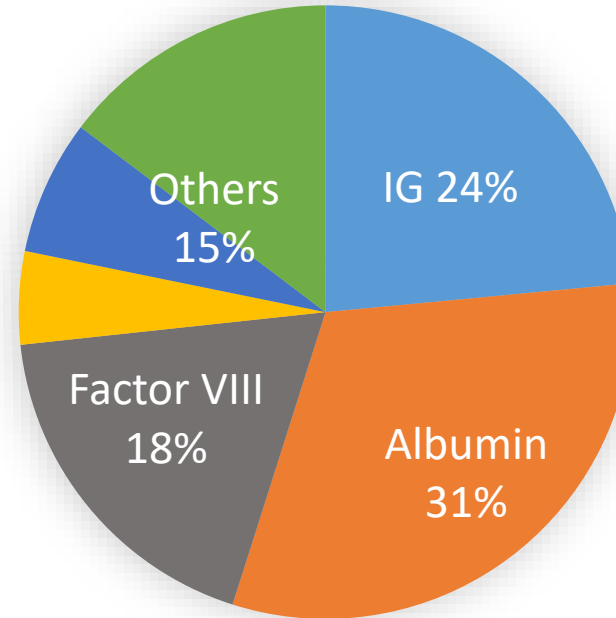
Over the past forty years, the market has experienced a steady expansion in units and dollars: 7.3% CAGR From 1996 to 2022. IG has gradually become the market driver, displacing coagulation factors whose sales have shrunk considerably, while albumin sales grew along with IG's, and those of hyperimmunes recorded moderate gains.

1984



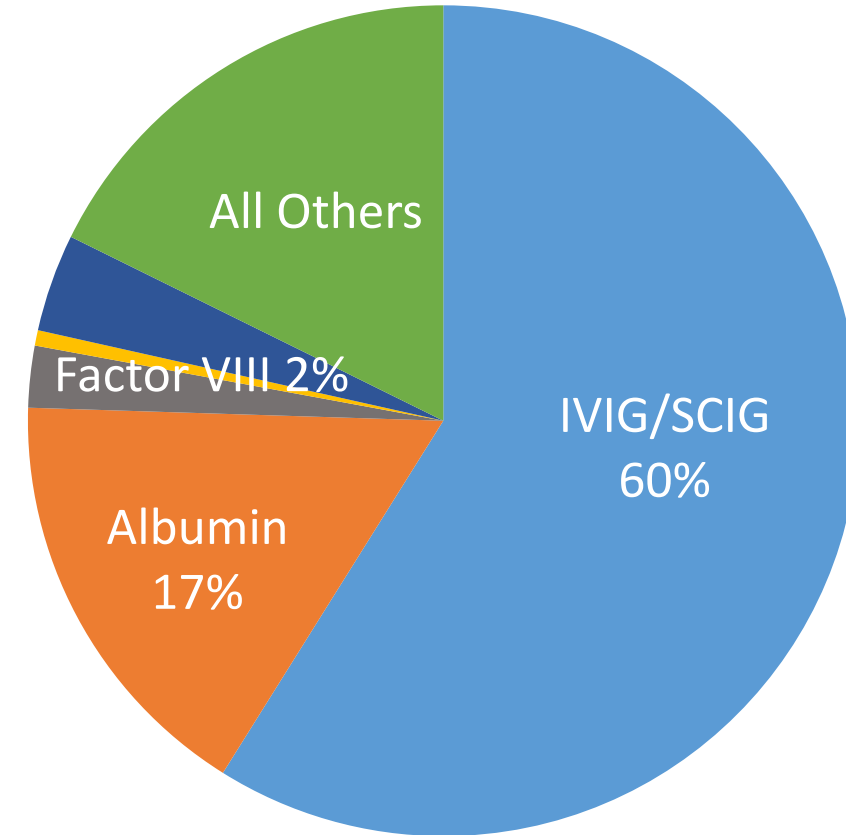
1984 Market: \$1.6 Billion

1996



1996 Market: \$4.8 billion

2022



2022 Market: \$30.3 billion

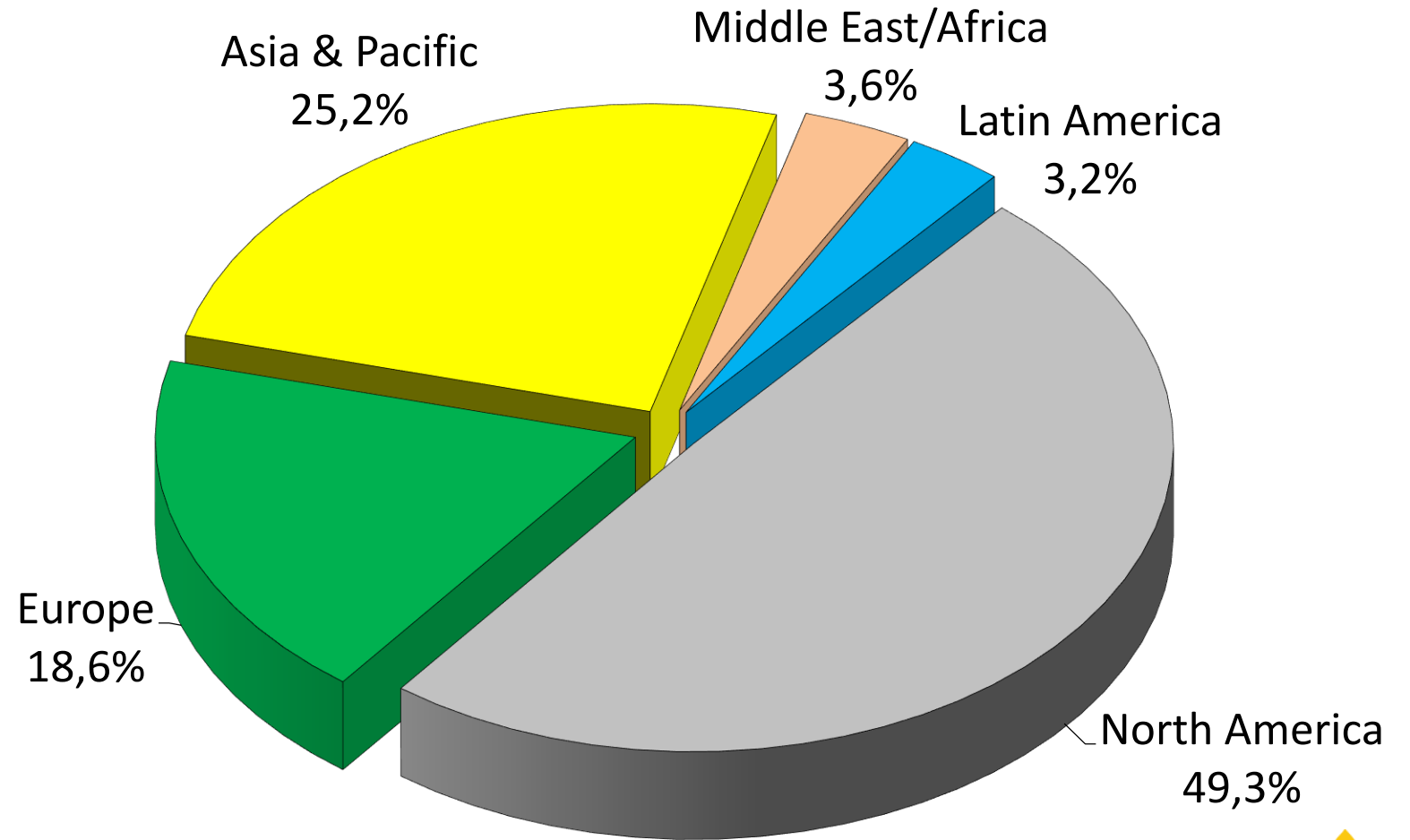
Note: the charts are not drawn to scale



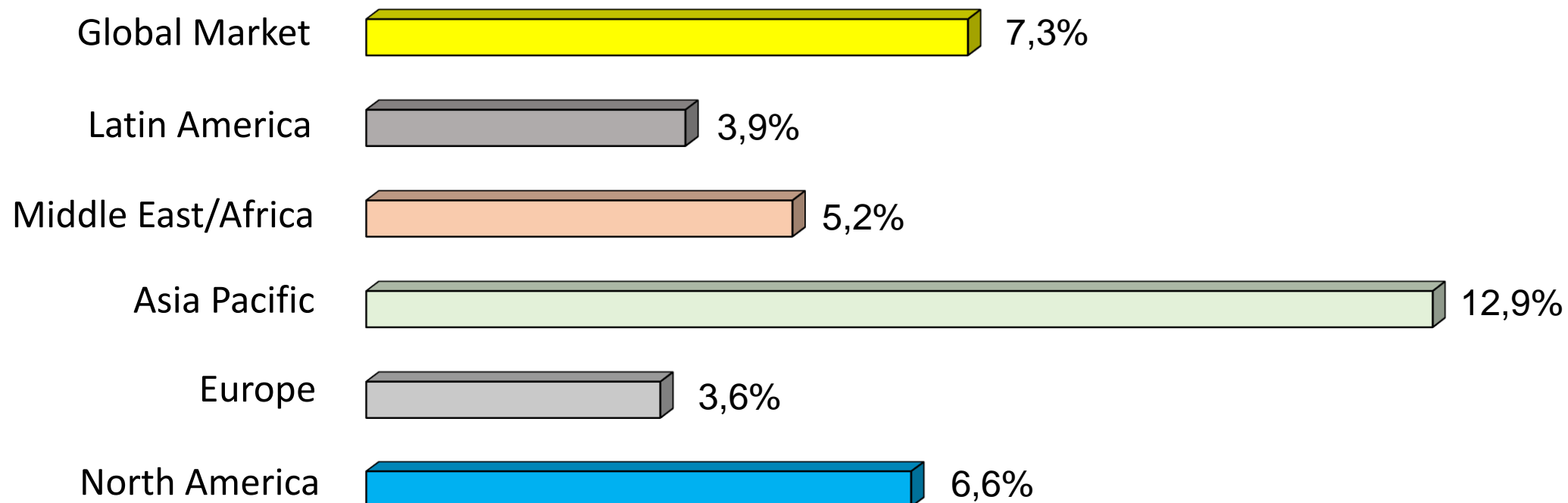
The Global PDMPs Market by Region in 2022 (Dollars)

North America is the largest PDMPs market in dollars, due to the use and funding of IG for non-approved indications, and a higher average IG price per gram in the U.S.

IG therapy is more conservative in Europe than the U.S. In other regions, IG consumption per capita is comparatively low for multiple reasons, including limited funding and product availability, fewer approved indications, lack of medical and public awareness, absence of patient advocacy groups, etc.



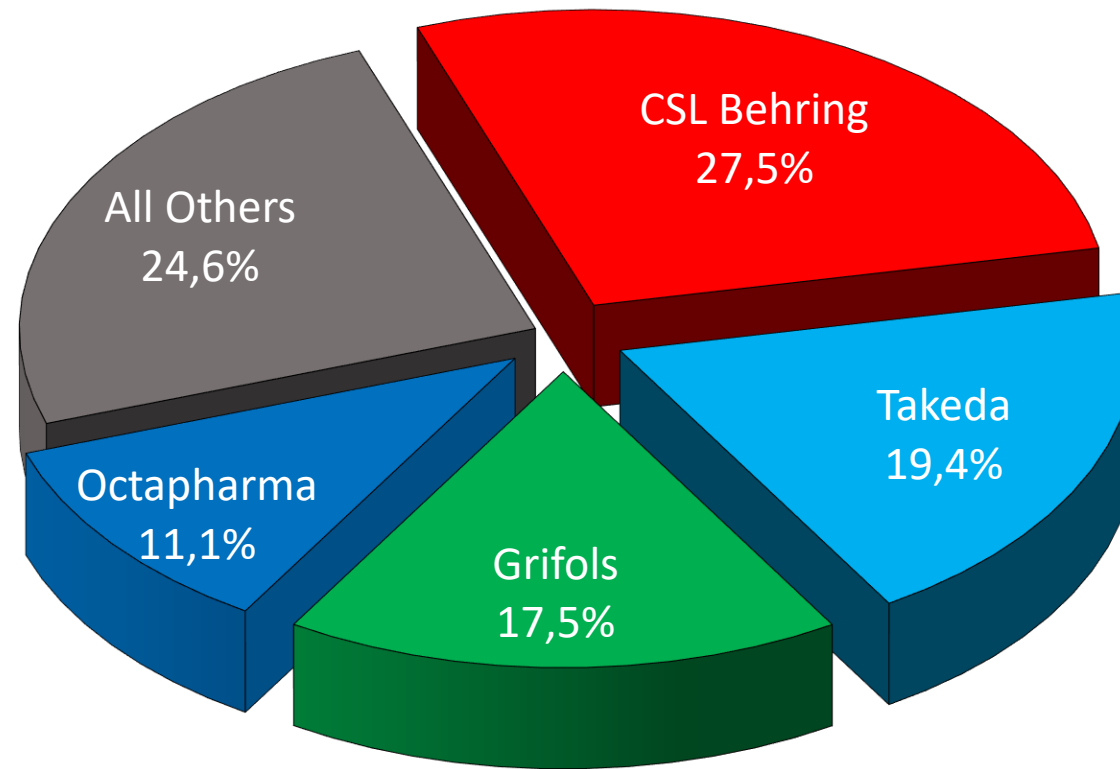
Annual Growth of the PDMPs Markets by Region from 2019 to 2022



The Global PDMPs Market by Company* in 2022 (Dollars)

The global plasma industry comprises about 60 firms located in some 30 countries. Four of them together capture over 75% of global PDMPs sales. Even though these four companies maintain a strong presence in the U.S. (collection of plasma) none of them is owned by a U.S. entity.

The fractionation industry is essentially a private sector activity even though non-profit fractionators operate in several countries (Argentina, Bulgaria, France, South Africa, Venezuela, etc.)

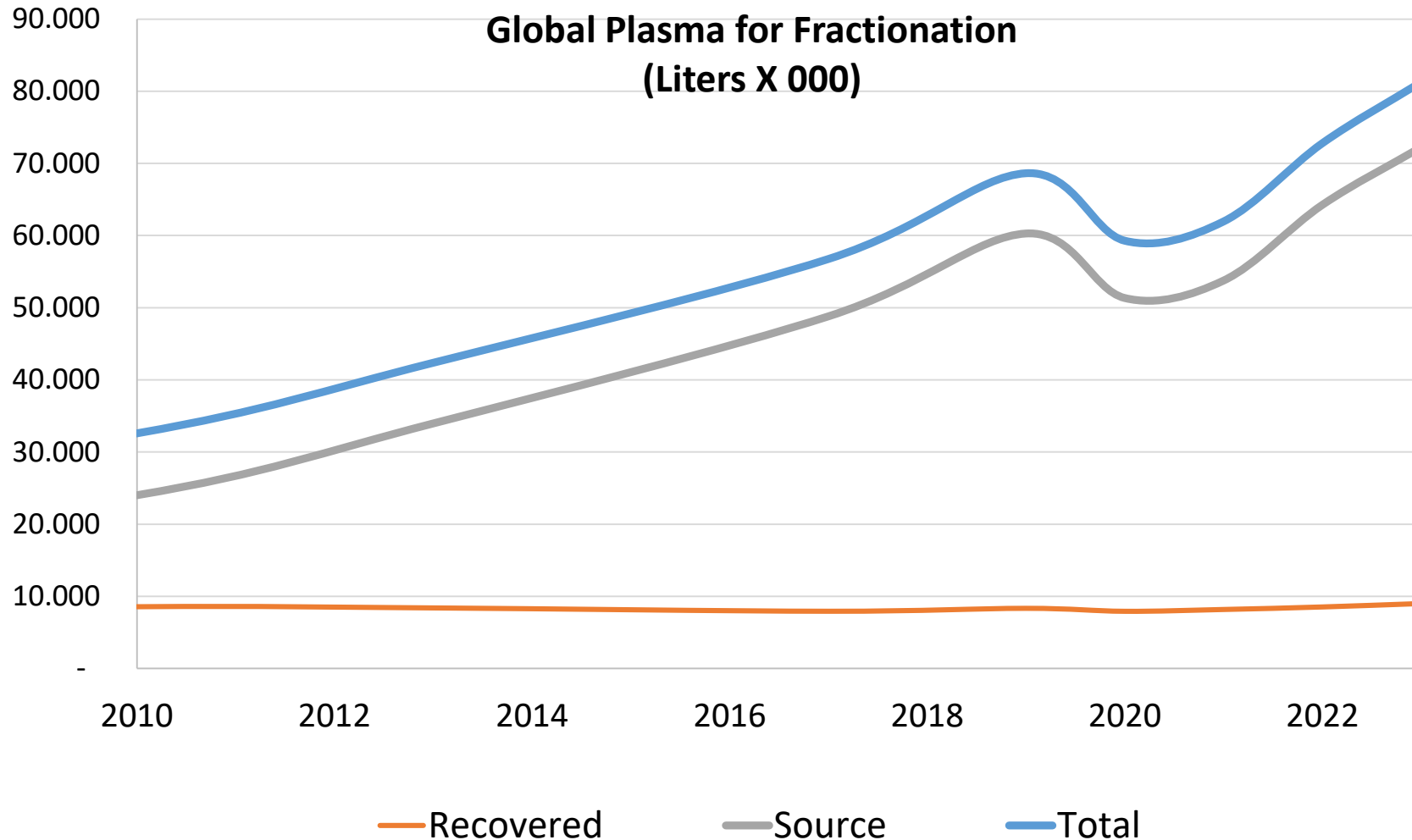


Until the year 2000, the fractionation industry faced various events that compromised the safety of the plasma. As a result, the industry went through mergers and acquisitions and vertical integration which led to the present market structure. Many non-profit fractionators have been closed.

* Recombinant factors not-included



Global Plasma Supply Trends from 2010 to 2023



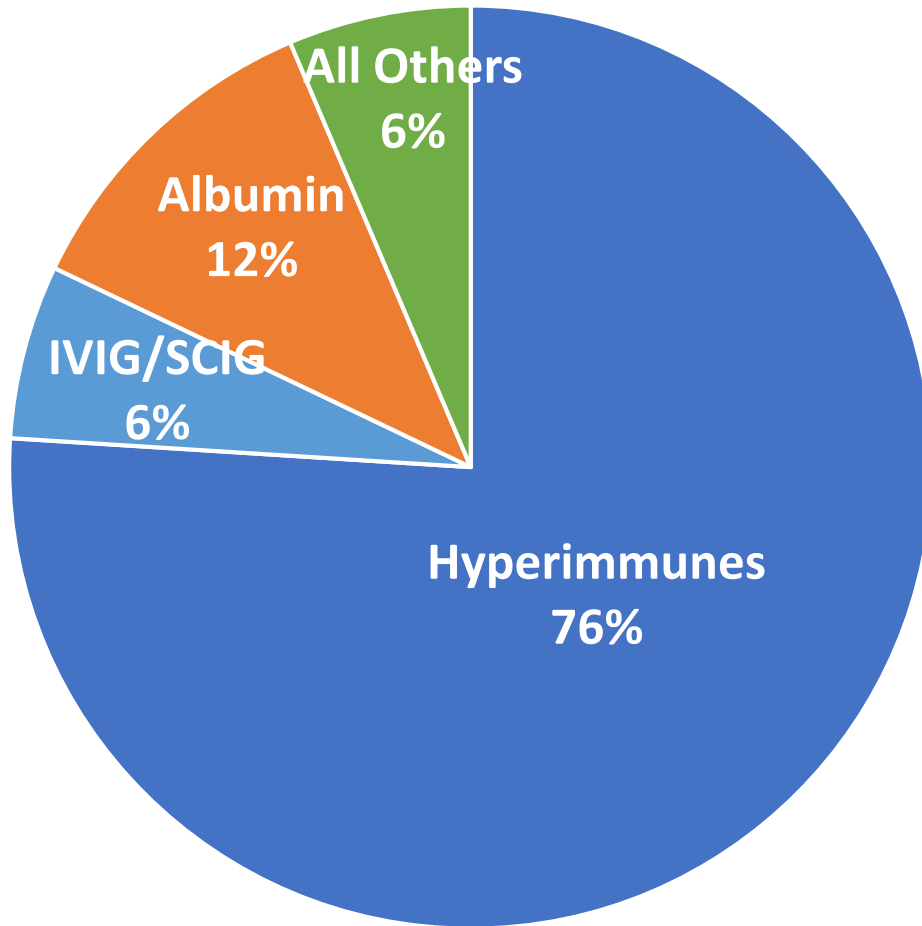
In 2022, the global volume of plasma for fractionation (source and recovered) represented about 72 million liters.

In 2023, source plasma volume grew 12-14% over 2022, driven by U.S. collections. In Europe, source plasma collections increased by about 3-6%.



Patient Population by PDMD Category in 2022

Percentage of People who were administered a PDMP in 2022 by Product



In 2022, approximately 16.5 million people received a plasma-derived product worldwide:

- 12.5 million were treated with a hyperimmune product, including 6.5 million in China alone.
- 1.0 million were prescribed polyvalent IG (300k in the U.S.) for chronic and acute conditions,
- 1.9 million were administered albumin (almost 50% in China), mostly for acute conditions,
- 1.0 million patients, or 6% of the total, received another plasma-derived product.
- Some 100,000 patients were treated with factor VIII, factor IX, von Willebrand factor complex or another plasma-derived factor.

Future Trends by Region and Product: Opportunities and Threats

The plasma industry is expected to continue to concentrate in the future, due to the pressure on profit margins caused by the ever-rising production costs (labor, logistics, regulatory requirements, climate change),

The cost of source plasma will continue to climb in the U.S. and Europe, because it is increasingly challenging to collect plasma in less favorable locations where the donor pool is limited.

The issue of compensation/non compensation of plasma donations will continue to divide the blood/plasma community where irreconcilable visions and attitudes slow progress and cooperation,

New biotech therapies developed will eventually curtail the sales of IG in some indications,



Future Trends by Region and Product: Opportunities and Threats

The difficulties to collect specialty plasma may lead to shortages of some hyperimmune globulin products,

Regarding recovered plasma, the decline of red cell usage in many countries, the aging of blood donors, and the difficulty to replace them by young ones will affect the ability to generate such plasma for fractionation,

On the other hand, new indications are expected to boost IG usage in the areas of autoimmune diseases, oncology and other conditions,

IG increasingly sets the tone of the companies industrial and commercial strategies because its sales are now critical to their economic viability.

* * *



Thank you!

