Global Use of Plasma-Derived Medicinal Products

Patrick Robert
The Marketing Research Bureau, Inc.
SOURCE OF THE DATA

The data used to develop the charts and tables shown in this presentation have been compiled from the Marketing Research Bureau’s database, scientific articles, congress proceedings, companies’ annual reports, publications and statistics published by national and international organizations, as well as by various plasma industry stakeholders.

GENERAL INFORMATION

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

• Global Plasma Products Demand by Region
• Global Plasma Products Demand by Product.
  The Market Drivers
• Plasma Supply
Table of Contents

• Global Plasma Products Demand by Region
• Global Plasma Products Demand by Product.
• The Market Drivers
• Plasma Supply
North America holds 44% of the global market but has only 5% of the world population while Africa and the Middle East together hold 5% of the market with 18% of the world population.
Global Plasma Products Demand by Region

Per capita consumption of IVIG, factor VIII, albumin and alpha-1 antitrypsin

Global Plasma Products Demand by Product.

The Market Drivers

Plasma Supply
Table of Contents

- Global Plasma Products Demand by Region
  - Per capita consumption of IVIG, factor VIII, albumin and alpha-1 antitrypsin
- Global Plasma Products Demand by Product.
- The Market Drivers
- Plasma Supply
IVIG/SCIG CONSUMPTION PER CAPITA IN SELECTED COUNTRIES
2010 AND 2005 (Grams per thousand Inhabitants)

Canada: 140.1 (2010), 137.5 (2005)
USA: 120.7 (2010), 99.4 (2005)
Australia: 97.4 (2010), 91.6 (2005)
France: 62.8 (2010), 69.6 (2005)
Spain: 52.5 (2010), 58.3 (2005)
UK: 50.3 (2010), 56.5 (2005)
Italy: 41.5 (2010), 50.3 (2005)
Turkey: 7.0 (2010), 9.4 (2005)
Brazil: 7.8 (2010), 5.7 (2005)
China: 4.0 (2010), 1.4 (2005)
International differences in per capita consumption of IVIG/SCIG can be explained by:

- Market penetration of IVIG therapy, physicians’ awareness and training, diagnosis
- Use for chronic diseases treatment vs. acute conditions
- Competitive therapies and pharmaceutical drugs
- Absence of restrictions for and reimbursement of off-label IVIG use
- Product promotion, brand competition
- Influence of patients advocacy groups
- And, above all, funding!
Table of Contents

• Global Plasma Products Demand by Region

  Per capita consumption of IVIG, factor VIII, albumin and alpha-1 antitrypsin

• Global Plasma Products Demand by Product.

  The Market Drivers

• Plasma Supply
The Factor VIII consumption per capita reflects the public policy toward hemophilia, financial resources, and mode of treatment.
There is a huge gap between the industrialized and emerging countries.
GLOBAL FACTOR VIII CONSUMPTION BY REGION FROM 1984 TO 2010
PLASMA-DERIVED AND RECOMBINANT
(International Units x 1,000)
The recombinant products pushed the plasma-derived from the high income to the low-income countries.

Market penetration of recombinant factor VIII in 30 years in units.
The units growth rate will decline as the extended half-life recombinant products gain market share, due to the lower consumption per patient.
In Europe, recombinant products faced some initial resistance in some countries (France, Germany, Italy, etc)
THE FACTOR VIII MARKET IN ASIA & PACIFIC (including Australia & New Zealand)
FROM 1988 TO 2020 (Est.)
(International Units x Million)
Hemophilia care policy and funding have resulted in a low penetration of recombinant factor products in low income countries.
Table of Contents

• Global Plasma Products Demand by Region

  Per capita consumption of IVIG, factor VIII, albumin and alpha-1 antitrypsin

• Global Plasma Products Demand by Product.

  The Market Drivers

• Plasma Supply
Over the years, the importance of albumin in Asia has increased.

WORLDWIDE ALBUMIN DEMAND 1992 - 2011 (METRIC TONS)

Worldwide Demand (Kilograms)

North America  Europe  Asia & Pacific

1992 397 127 148 122
1994 367 109 149 109
1996 412 119 131 162
1998 381 105 101 175
1999 356 79 100 176
2000 387 122 108 157
2001 399 125 116 158
2002 471 126 127 219
2003 506 139 129 238

Over the years, the importance of albumin in Asia has increased.
Consumption of Plasma Products by Country

ALBUMIN CONSUMPTION PER CAPITA IN SELECTED COUNTRIES
2008-2010
(Kilograms per Inhabitant)

Medical practice, hospital budgets and tradition explain the differences in the consumption of albumin per capita.
Table of Contents

• Global Plasma Products Demand by Region
  * Per capita consumption of IVIG, factor VIII, albumin and alpha-1 antitrypsin
• Global Plasma Products Demand by Product.
  * The Market Drivers
• Plasma Supply
Restrictive health policies, cost of therapy and medical practice limit the use of alpha-1 antitrypsin usage to a few countries.
Table of Contents

- Global Plasma Products Demand by Region
- Global Plasma Products Demand by Product.
- The Market Drivers
- Plasma Supply
THE WORLDWIDE PLASMA PROTEINS MARKET BY PRODUCT - 2012

WITHOUT RECOMBINANT FACTORS

Total Market $15,222 Million

- Polyvalent IVIG/SCIG: 47.6%
- Albumin: 13.3%
- Factor VIII (Plasma Derived): 10.6%
- Factor IX (Plasma Derived): 2.5%
- All Others: 22.2%
- Hyperimmunes (IM & IV): 3.8%
IVIG = 28% of total market, albumin 29%, factor VIII 15%
THE WORLDWIDE PLASMA FRACTIONS MARKET
BY PRODUCT - 1986
(Without recombinant Factors)
Total Market $1,853.7 (MM)

IVIG = 21% of total market, albumin 45%, factor VIII 17%
Market Drivers

• From 1974 to 1980, albumin drove the plasma market because neither factor VIII nor IVIG were available in large quantities. One liter of plasma generated approximately 28 grams of albumin.

• In 1980, plasma-derived factor VIII became the market driver: its global needs determined the quantity of plasma to fractionate. Its production yield was 150-180 international units per liter of plasma.

• IVIG took over as the market driver in 2000, and will keep this role in the foreseeable future. Its production yield ranges from 3 to 5 grams per liter of plasma.
PLASMA REQUIREMENTS FOR ALBUMIN, FACTOR & IVIG
1974 - 2014 - Million Liters

WORLDWIDE ALBUMIN DEMAND 1974 - 2014
Metric Tons
WORLDWIDE DEMAND FOR INTRAVENOUS & SUBCUTANEOUS IMMUNE GLOBULIN (IVIG/SCIG)
1984 - 2014
Metric Tons

PLASMA REQUIREMENTS FOR ALBUMIN, FACTOR & IVIG
1974 - 2014 - Million Liters

Plasma for IVIG
PLASMA REQUIREMENTS FOR ALBUMIN, FACTOR & IVIG
1974 - 2014 - Million Liters

- Plasma for Albumin
- Plasma for Factor VIII
- Plasma for IVIG
Market Drivers

- **IVIG** drives the North American market because of history, funding of non-approved indications, ample supply, role of patient organizations, company promotion, etc.

- Albumin drives the Asian market because IVIG is not yet widely accepted and albumin is prescribed more liberally than in the west.

- Increased sales of recombinant factor VIII have reduced the demand for plasma-derived of factor VIII, resulting in donations of the latter product to low-income countries by Canada, Denmark, Italy, etc.
Table of Contents

• Historical Development
• Plasma Fractionation
• Worldwide Plasma Products Demand
• Plasma Supply
Source (apheresis) plasma collections grow the fastest, particularly in the United States.
The use of most plasma products continues to grow because of their safety and efficacy, and in spite of financial barriers,

The growing demand will require that large quantities of plasma be collected and fractionated,

The commercial and non-profit fractionators have the technical and logistical ability to meet future demand.
THANK YOU FOR YOUR ATTENTION

www.marketingresearchbureau.com

Orange, Connecticut, USA

+1 203 799 0298