CURRENT MARKET LANDSCAPE FOR PLASMA AND IMMUNOGLOBULINS

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IPFA-EBA Symposium
March 14, 2022

Marketing Research Bureau
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Overview

1. 2020 Plasma protein usage and growth trends
2. Immunoglobulin demand versus COVID19 reduced plasma collections
3. Comparison of the trends in IG usage and the supply of plasma for fractionation in 2019 and 2020
24 Years of worldwide plasma proteins market growth (without recombinant products)

1996
- IVIG/SCIG: 24%
- Albumin: 31%
- Factor VIII: 18%
- Factor IX: 5%
- Hyperimmunes: 7%
- All Others: 15%

1996 Market: $4.8 billion

2020
- IVIG/SCIG: 24%
- Albumin: 31%
- Factor VIII: 18%
- Factor IX: 5%
- Hyperimmunes: 7%
- All Others: 20%

2020 Market: $26.6 billion

Note: Pie charts are drawn to scale
Market trends in past 5+ years

• Immunoglobulin sales have grown among the fastest for all plasma proteins
  • Strong volume and price growth – supply capped by plasma collections

• Albumin has also grown, but more slowly
  • Volume growth has been steady, driven by China, but pricing has declined

• Plasma derived factor VIII and IX demand has been declining due to recombinant and non-factor competition
  • Pricing has been negatively affected by increased competition
  • Decline in usage in high income countries, but growing in emerging markets

• Other Protein Trends:
  • Those with recombinant or non-plasma competition have declined (C1-INH)
  • Those without competition have grown (AAT)
  • Those prescribed for acute blood loss situations have grown (PCC and fibrinogen)
North America consumes the most IG, but Europe is over 25% total

2020 IG Usage by Region

- North America
- Europe
- Asia-Pacific
- Latin America
- Middle East-Africa
Immunoglobulin has become ever more dominant in terms of plasma economics for the entire industry

1. IG is the global plasma market driver since the 1990s. The IG manufacturers base their plasma collections on their immunoglobulin sales forecasts.

2. Albumin is also a last liter product today.

3. Since both products are made from practically every liter of plasma fractionated, the only way to increase (or decrease) the supply is to collect and fractionate more (or less) plasma.

4. Albumin demand growth has been slower than plasma collections (and thus supply), resulting in flat to declining prices

5. IG demand growth has been among the fastest compared to all plasma proteins

6. As a result, companies have collected plasma to meet the expected IG demand in the 2010s, with growth at rates averaging 8-9% per year.

7. But then…..

**COVID19 Pandemic happened, severely affecting plasma collections**
Globally, Source (Apheresis) plasma is providing all the volume growth for fractionation.

- The growth has come from Source (Apheresis) plasma (mainly commercial) despite the COVID-19 pandemic.

- The volume of Recovered plasma (all public) has declined in recent years, including during the COVID-19 pandemic.

- Global plasma volume for fractionation fell 14% in 2020 from 2019 due to COVID19 pandemic.
Pre-pandemic plasma collection for fractionation was dominated by United States

**Origin of Plasma for Fractionation - 2019**

- **North America**: 67%
- **Europe**: 14%
- **Asia & Pacific**: 18%
- **Latin America**: 1%
- **Middle East & Africa**: 1%

Total Plasma Collection volume 2019: 69 M liters

*United States represented over 99% of the North America total

**China represented almost 75% of Asia & Pacific total
How did the pandemic change plasma collection?

Total Plasma Collection volume 2019: 69 M liters
2020: 59 M liters (-14.5% vs. 2019)

Origin of Plasma for Fractionation - 2020

- North America *
- Europe
- Asia & Pacific **
- Latin America
- Middle East & Africa

2020 vs. 2019
- Down 18%
- Down 9%
- Down 7%

2021 est. vs. 2019
- Down 5-8%
- Down 0-3%
- Down 0-2%
Plasma is still dominated by United States after the pandemic, so countries still rely on US plasma for some immunoglobulin products.

**Origin of Plasma for Fractionation - 2020**

- **North America**: 65%
- **Europe**: 19%
- **Asia & Pacific**: 15%
- **Latin America**: 1%
- **Middle East & Africa**: 0%

*United States represents over 99% of the North America total*

**China represents 72% of Asia & Pacific total**

Total Plasma Collection volume 2020: 59 million liters
North America and Asia-Pacific produce enough plasma for their internal use, but other regions must import IG made from US plasma.

Since Europe consumes 25% of the worldwide IG supply but collects only 15% of the global plasma for fractionation, there is an imbalance that requires Europe to import IG produced from US plasma.
How has the industry responded to the pandemic challenge?

- Due to the challenge created by COVID-19 to the plasma supply, companies in the United States have responded aggressively to increase collections:
  - Over 100 new plasma collection centers gained FDA licenses in 2020, and almost 110 more in 2021
  - By end of 2021, nearly 1050 FDA licensed centers in US, up 24% from 2 years earlier
  - Donor fees were raised significantly, offering up to $1100-$1200 for 8 donations in first month.
  - Average donor fees went from under $60 a donation pre-pandemic to around $80 a donation in 2021

- At the same time, Europe has also made some moves to increase the regional plasma supply:
  - The United Kingdom has begun to use plasma (including source) for fractionation
  - Poland has acquired thousands of plasmapheresis machines, hoping to double or triple its volume of plasma for fractionation
  - Several countries have launched new programs to collect more source plasma
  - Private companies in Germany, Austria, Czech Republic and Hungary continue to add more plasma collection centers
Overall European collections declined by 9.4% in 2020 vs. 2019 due to the pandemic. In 2020, a total of 8.3 million liters of plasma were collected (source and recovered) in Europe.
European IG Usage vs. Plasma Collection in 2019 vs. 2020

As a result of the drop in collections, due to the pandemic and the continued rise in IG demand, the imbalance of collections and IG product need grew in 2020.
2019 and 2020 Imbalance of Plasma Collections and Need for IG in Europe

*Assume average blended yield of 4.5 grams IG per liter of plasma

The self-sufficiency of Europe, dropped 8 percentage points from 2019 to 2020.
Increase in Collections needed in 2019 and 2020 to meet needs of Patients in Europe

Increase in plasma collections required to meet the IG needs of all patients:
- 2019: 4.3 million liters
- 2020: 5.6 million liters

*Assume average blended yield of 4.5 grams IG per liter of plasma
Conclusions

• The COVID-19 pandemic has caused plasma collections to decrease in the United States, Europe and worldwide.

• At the same time, the IG demand has continued to increase in Europe between 2019 and 2020.

• As a result of these opposite trends, the self-sufficiency rate for Europe dropped in 2020 vs 2019, covering only 60% of the plasma needed by patients for the production of immunoglobulins.

• Europe would need to increase plasma collections by 5.6 million liters, or 67%, which is two thirds, to provide enough plasma for fractionation to meet the IG needs of all its patients in 2020.
Thank you!

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