PLASMA AND IMMUNOGLOBULIN (IgG) PERSPECTIVE IN LATIN AMERICA

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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 some fifty countries and published in its syndicated reports.

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• From Plasma to Immunoglobulin (IgG)

• The Global Plasma Products and IgG Markets

• IgG Consumption in Latin America

• Re-defining Self-Sufficiency
Plasmapheresis Station
Fraction V

- Albumin (25 grams)

Factor VIII
- 200 IUs

Factor IX
- 275 IUs

ONE LITER OF PLASMA

Fraction II

- Polyvalent IGIV (3-5 grams)

Fraction IV

- ATIII (250 IUs)

- Alpha-I Antitrypsin (0.25 grams)
Fractionation Process

1. Pooling
2. Cryo Eff.
3. Eff. I or Eff. II+III
4. Eff. IV-1 or Eff. IV-4
5. Cryo Paste
6. Fr I Paste Discard
7. Fr II + III Paste
8. Fr IV-1 Paste
9. Fr IV-4 Paste
10. Fr V Paste
11. Factor VIII
12. IGIV
13. Albumin
REGIONAL DISTRIBUTION OF FRACTIONATION PLANTS 2017

TOTAL NUMBER OF FRACTIONATION PLANTS: 80
NON-PROFIT: 19    COMMERCIAL: 61
NUMBER OF COMPANIES OPERATING FRACTIONATION PLANTS: ca. 45
REGIONAL DISTRIBUTION OF FRACTIONATION THROUGHPUT 2017

GLOBAL FRACTIONATION THROUGHPUT 2017: 54.5 MILLION LITERS
80 plasma fractionation plants are in operation worldwide. They belong to some 45 companies or non-profit organizations.

Asia has the highest number of fractionation plants (38) followed by Europe (26) and North America (8). The largest plants in terms of processing capacity are located in the United States.

Europe has the world’s highest fractionation throughput (47%). The multinational companies move intermediate paste and plasma from one manufacturing site to another across continents to maximize their production efficiency.
The Human Factor

- The plasma industry differs from the traditional pharmaceutical sector in the following ways:

  - **Technical aspect**: the fractionation of plasma is a complex process, due to the biological nature of its raw material: human plasma,

  - **Socio-economic & ethical aspect**: the use of plasma and blood as raw material to make IgG creates social, economic and ethical issues, that do not exist in other industries

  - **Patient/Industry Relationships**: The patients’ organizations exercise a strong influence on the industry policies and processes with regard to product safety, supply and access.
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• More Plasma from Latin America!
THE WORLDWIDE PLASMA PROTEINS MARKET BY COMPANY - 2016

WITHOUT RECOMBINANT FACTORS

Total Market 21,174 Million

- CSL Behring: 26.0%
- Shire: 21.7%
- Grifols: 19.2%
- All Others: 33.1%
THE WORLDWIDE PLASMA PROTEINS MARKET BY PRODUCT - 2016

WITHOUT RECOMBINANT FACTORS

Total Market $21,174 Million

- Albumin 15.7%
- Polyvalent IVIG/SCIG 47.3%
- Factor VIII (Plasma Derived) 7.6%
- Factor IX (Plasma Derived) 1.5%
- All Others 23.2%
- Hyperimmunes (IM & IV) 4.7%

Breakdown by Products: IgG is almost half of the total market
North America has 5% of the world population and consumes 46% of the global IgG supply; Latin America has almost 9% of the world population and only consumes 5% of the world’s IgG supply.

The regional discrepancies stem from history, public health priorities, poor diagnosis, and funding.

TOTAL: 152 METRIC TONS
THE GLOBAL IVIG & SCIG CONSUMPTION BY REGION 2008 - 2017
(Kilograms)

Compounded Annual Growth Rates
over nine years

North America 9.7%
Europe 8.5%
Asia Pacific 7.5%
Latin America 9.7%
Middle East 15.2%
Total World 8.8%

Total World 188.4 Metric Tons (2017)
In 2017, IgG consumption in the U.S. is 60% higher than Europe’s. Latin America and the Middle East have comparable consumption levels. The IgG consumption in either Germany’s or France’s is larger than the consumption in the whole of Latin America and the Middle East, illustrating the extent of unmet needs.
Between 2008 and 2017, the consumption per capita almost doubled in the US, Canada, and France. It also increased strongly in the Middle East, Asia & Pacific and Latin America, but from low starting points.
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AVERAGE EXPENDITURE ON PLASMA PRODUCTS BY COUNTRY
IN LATIN AMERICA - 2016
Plasma-derived Products
(Dollars per Capita)

- Puerto Rico: $3.80
- Argentina: $3.03
- Uruguay: $2.75
- Costa Rica: $2.13
- Colombia: $1.88
- Chile: $1.71
- Mexico: $1.56
- Panama: $1.44
- Average: $1.43
- Brazil: $1.31
- El Salvador: $1.15
- Ecuador: $1.06
- Guatemala: $0.92
- Dominican Republic: $0.62
- Peru: $0.56
- Honduras: $0.45
- Venezuela: $0.05
DISTRIBUTION OF THE IMMUNOGLOBULIN MARKET BY COMPANY IN VOLUME IN LATIN AMERICA - 2016
Total Quantity: 6,645 kilograms

- CSL Behring: 26%
- Green Cross: 18%
- Grifols: 17%
- Octapharma: 11%
- Hemoderivados: 9%
- Shire: 8%
- Kedrion: 5%
- All Others: 6%
- CSL Behring: 26%
- Total Quantity: 6,645 kilograms
Compounded Annual Growth Rates (CAGR)
Colombia: 14.9%
Argentina: 13.5%
Mexico: 11.3%
Brazil: 10.5%
Chile: 9.6%
All Others: 4.2%
In 2019, 9,150 Kilograms are forecasted for the whole Region.
In 2016 almost 7 metric tons of IgG were used in Latin America. Assuming the same growth rate, this quantity will jump to over 15 tons by 2025.
In 2016 almost 1.9 million liters of plasma were needed to make IgG for Latin American patients (3.8 grams/liter). Using the historical growth rate, this quantity will almost double by 2025. 3.7 million liters of plasma will be needed to meet the demand in 2025, preferably coming from Latin America.
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The United States generate 65% to the world’s plasma for fractionation (source and recovered) with only 5% of the world population.

Latin America has almost 9% of the world’s population but produces only 1% of the plasma for fractionation.
The United States generates 71% to the world’s source plasma for fractionation, and Latin America, less than 1%.
Conclusion

• The IgG demand in Latin America has grown faster than in several other regions.

• IgG is an expensive therapy, which limits its penetration but funding is becoming available for chronic diseases treatment in Latin America.

• The dependency on the United States for the global supply of source plasma is now challenged. A diversification of supply appears desirable for political, socio-economic and health policy reasons.

• To ensure an adequate supply of IgG in future years, more source and recovered plasma should come from Latin America.
THANK YOU FOR YOUR ATTENTION

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