

Plasma-Derived Medicinal Products (PDMPs) and Plasma Supply into the Future

**European Blood Alliance and
International Plasma and Fractionation Association (EBA-
IPFA)
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METHODOLOGY

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 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. © 2020



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- **Present and Future Demand for Plasma-derived Medicinal Products (PDMPs) - polyvalent IgG, Albumin and Coagulation factors Demands - Global and Regional Markets**
- **Plasma Collectors and Fractionators**



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- **Present and Future Demand for Plasma-derived Medicinal Products (PDMPs): Polyvalent Immune globulin (IgG)**
- Plasma Collections and Fractionation in 2018





THE GLOBAL IgG DEMAND FROM 2010 TO 2026 (Metric Tons)

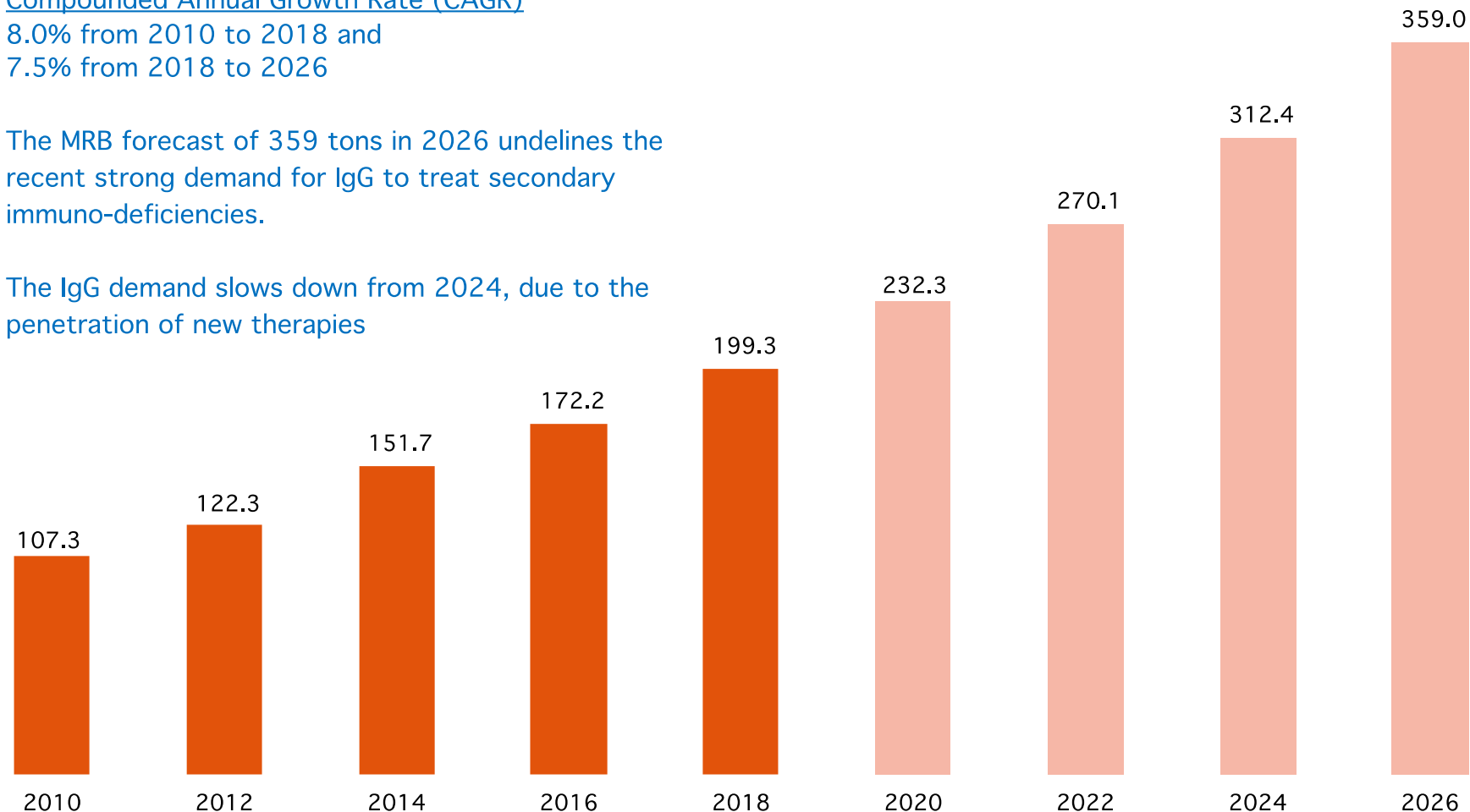
Compounded Annual Growth Rate (CAGR)

8.0% from 2010 to 2018 and

7.5% from 2018 to 2026

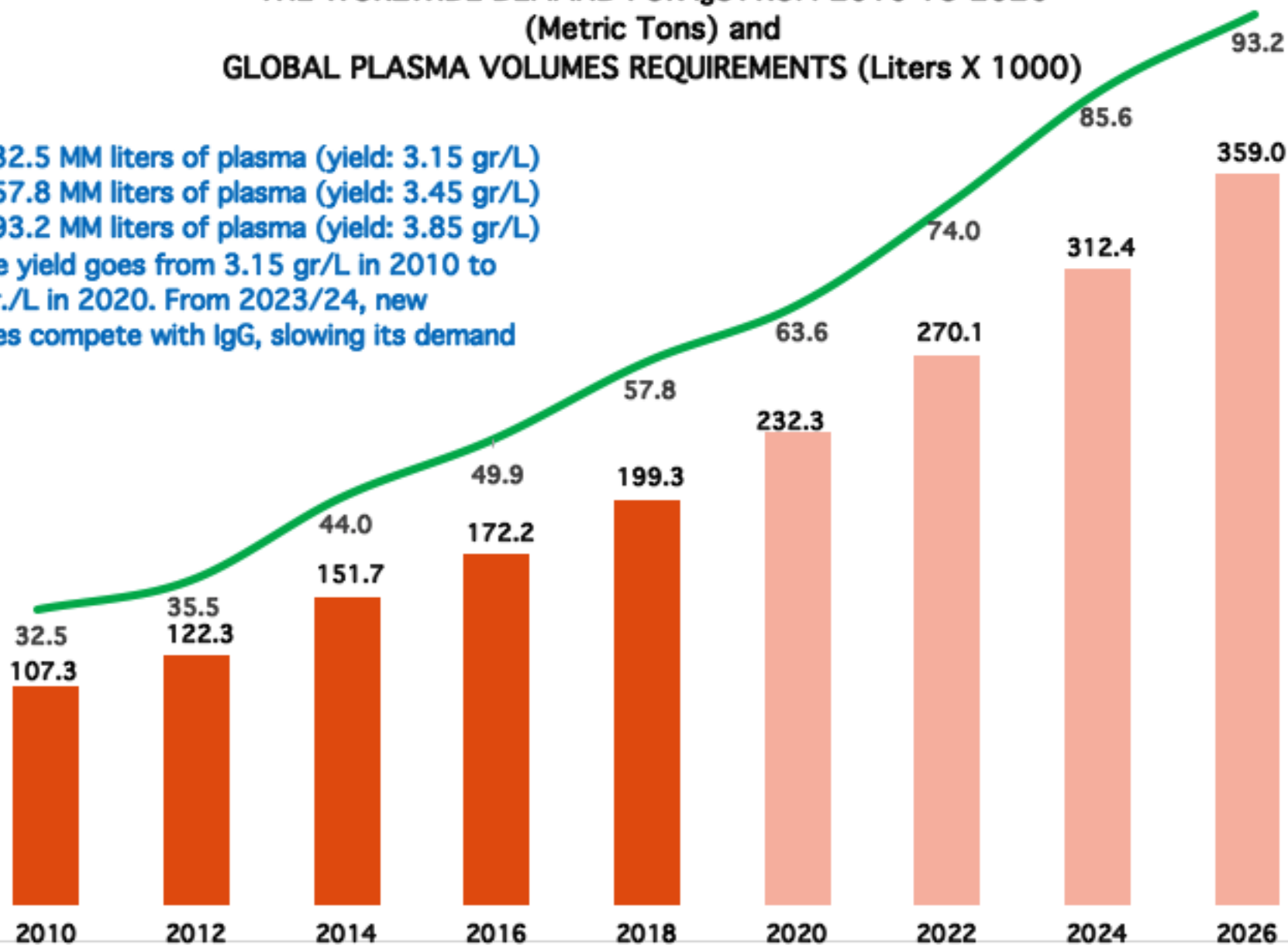
The MRB forecast of 359 tons in 2026 undelines the recent strong demand for IgG to treat secondary immuno-deficiencies.

The IgG demand slows down from 2024, due to the penetration of new therapies



THE WORLDWIDE DEMAND FOR IgG FROM 2010 TO 2026
(Metric Tons) and
GLOBAL PLASMA VOLUMES REQUIREMENTS (Liters X 1000)

2010: 32.5 MM liters of plasma (yield: 3.15 gr/L)
2018: 57.8 MM liters of plasma (yield: 3.45 gr/L)
2026: 93.2 MM liters of plasma (yield: 3.85 gr/L)
Average yield goes from 3.15 gr/L in 2010 to
3.85 Gr./L in 2020. From 2023/24, new
therapies compete with IgG, slowing its demand



- In 2026, the global IgG consumption is forecasted to reach 359 metric tons, with a slower growth from 2022 onward because:
 - New therapies (FcRn, gene therapy, new drugs) replacing IgG will be progressively adopted in some indications: ITP, MMN, CIDP, MG, Pemphigus Vulgaris, etc.,
 - Also, in some mature markets, the IgG demand may slow down as fewer new patients are diagnosed, and
 - The pressure to collect growing volumes of plasma for fractionation may represent a constraint, slowing IgG production and consumption.



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- **Present and Future Demand for Plasma-derived Medicinal Products (PDMPs): **Albumin****
- **Plasma Collections and Fractionation in 2018**

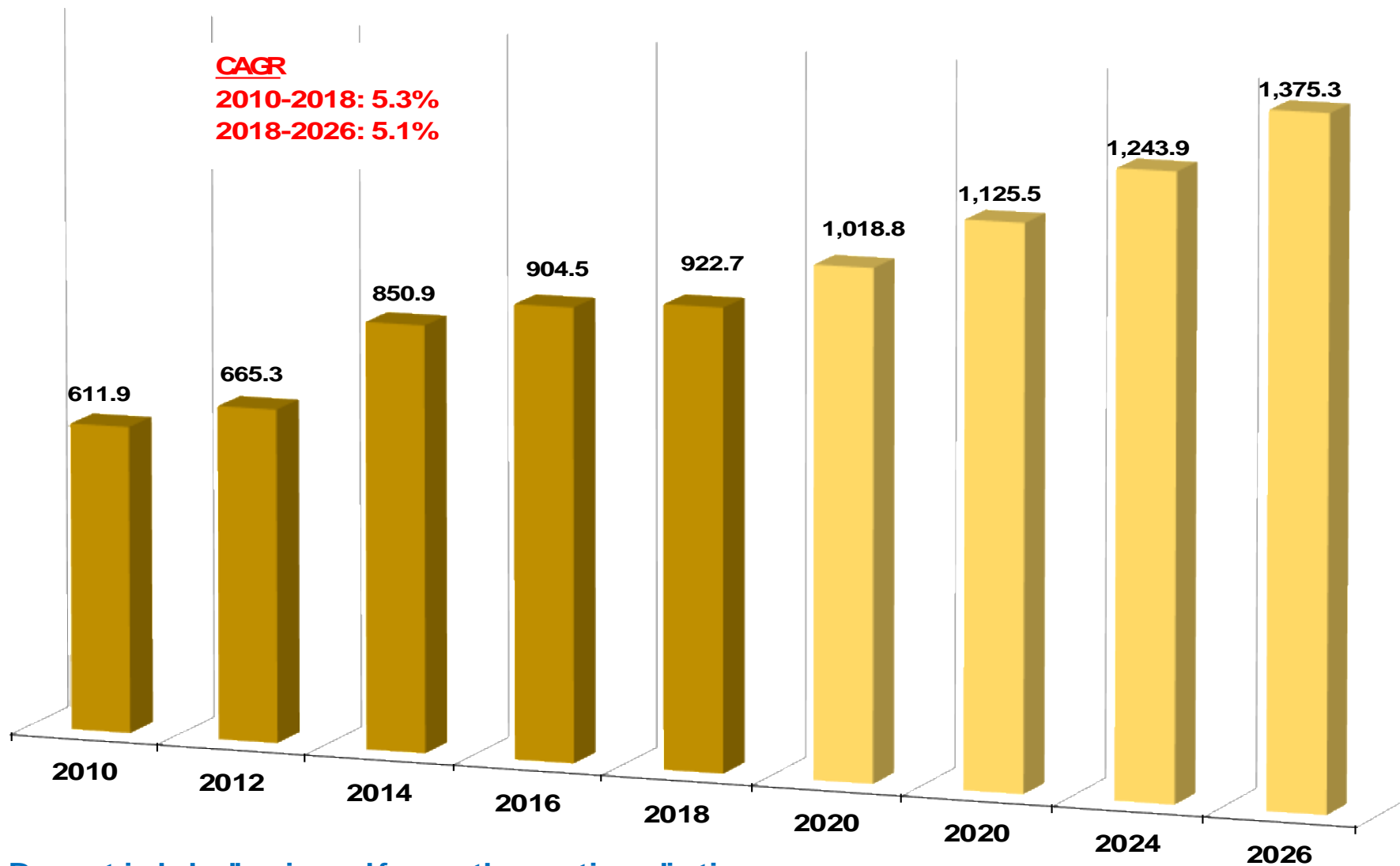


Theoretically, in 2026 approximately 93 million liters of plasma will generate several by-products, including:

- Some 2,400 metric tons of albumin (25.7 Gr./L) and 14 billion factor VIII units (150 IU/L),
- These quantities may exceed the demand for these products, resulting in a build up of inventories of cryoprecipitate, fraction V, and possibly other plasma fractions,
- This may create an unfavorable cost recovery structure, putting pressure on IgG pricing.



GLOBAL ALBUMIN CONSUMPTION FROM 2000 TO 2018 & FORECAST 2018 TO 2026 (Metric Tons)



Note: Does not include albumin used for non-therapeutic applications

- The albumin demand is forecast to reach approximately 1,400 tons by 2026 but it will be higher if:
 - New medical indications are approved for the use of albumin,
 - China's albumin demand continues to grow and the country continues to import albumin from other countries.



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- **Present and Future Demand for Plasma-derived Medicinal Products (PDMPs): Coagulation factor VIII**
- Plasma Collectors and Fractionators

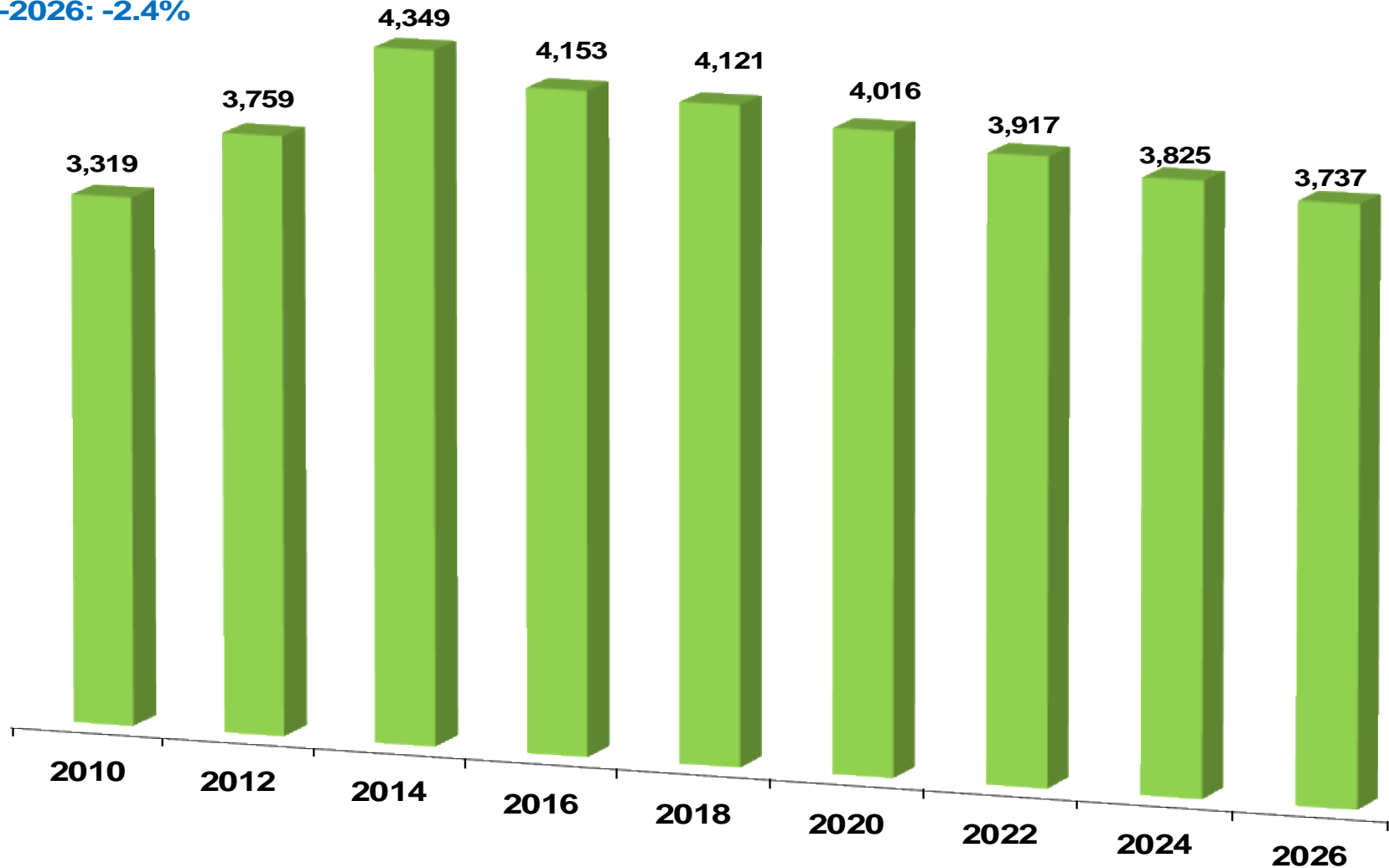


THE GLOBAL FACTOR VIII CONSUMPTION FROM 2010 TO 2018 AND FORECAST FROM 2018 TO 2026 (International Units x Million)

CAGR

2010-2018: +2.7%

2018-2026: -2.4%



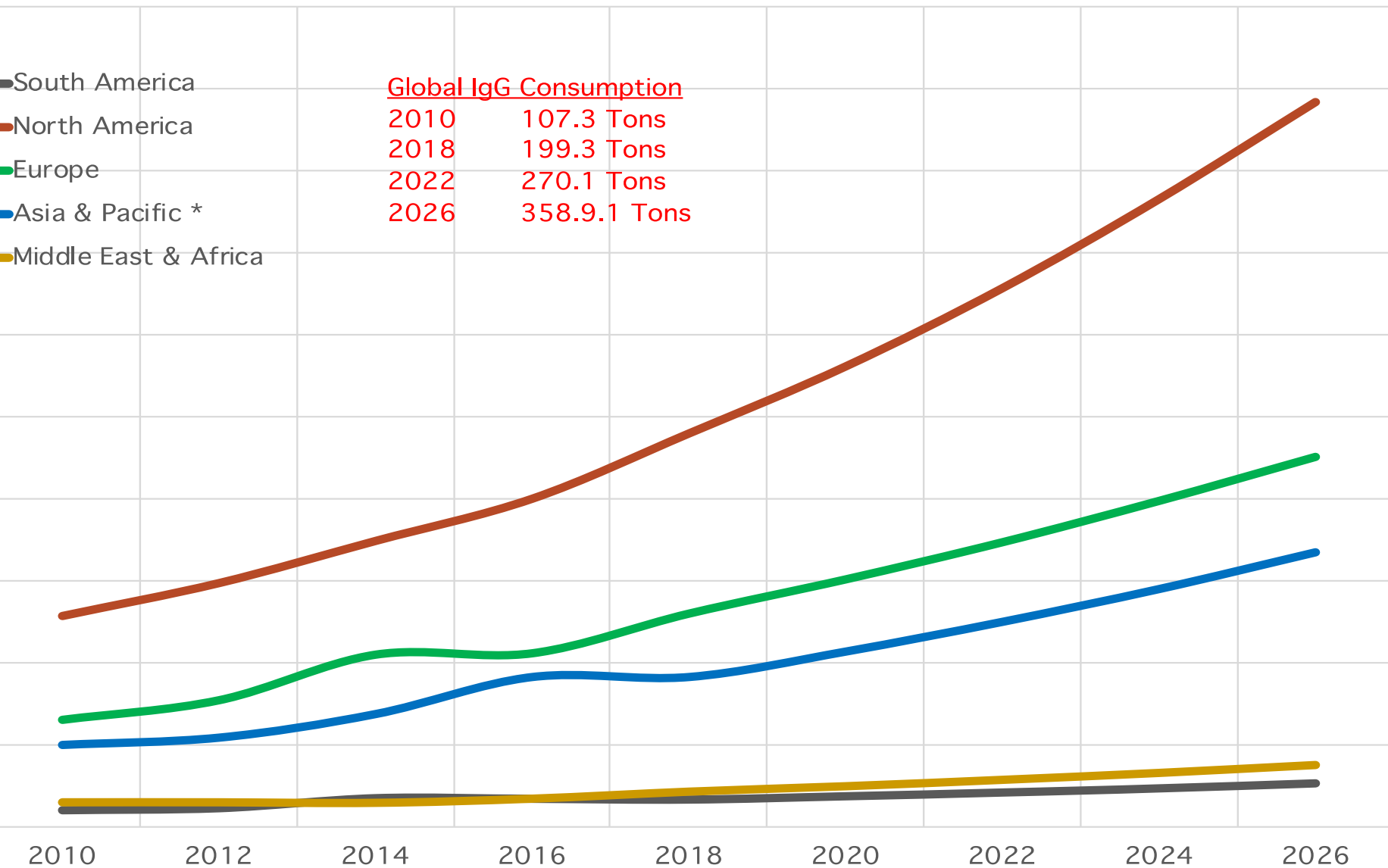
- The global consumption plasma-derived factor VIII will decline from 2019 onward as a result of the market penetration of new hemophilia A therapies, such as new recombinant factor VIII products (standard and EHL), monoclonal antibodies and eventually gene therapy,
- These new therapies will push the plasma-derived and recombinant factor VIII products from the high-income countries to emerging markets,
- In the high-income countries, plasma-derived factor VIII will maintain a niche in the immuno-tolerance induction treatment of hemophilia A patients with an inhibitor. It will also remain attractive to some other hemophilia patient groups, such as those with comfortable with their current products.

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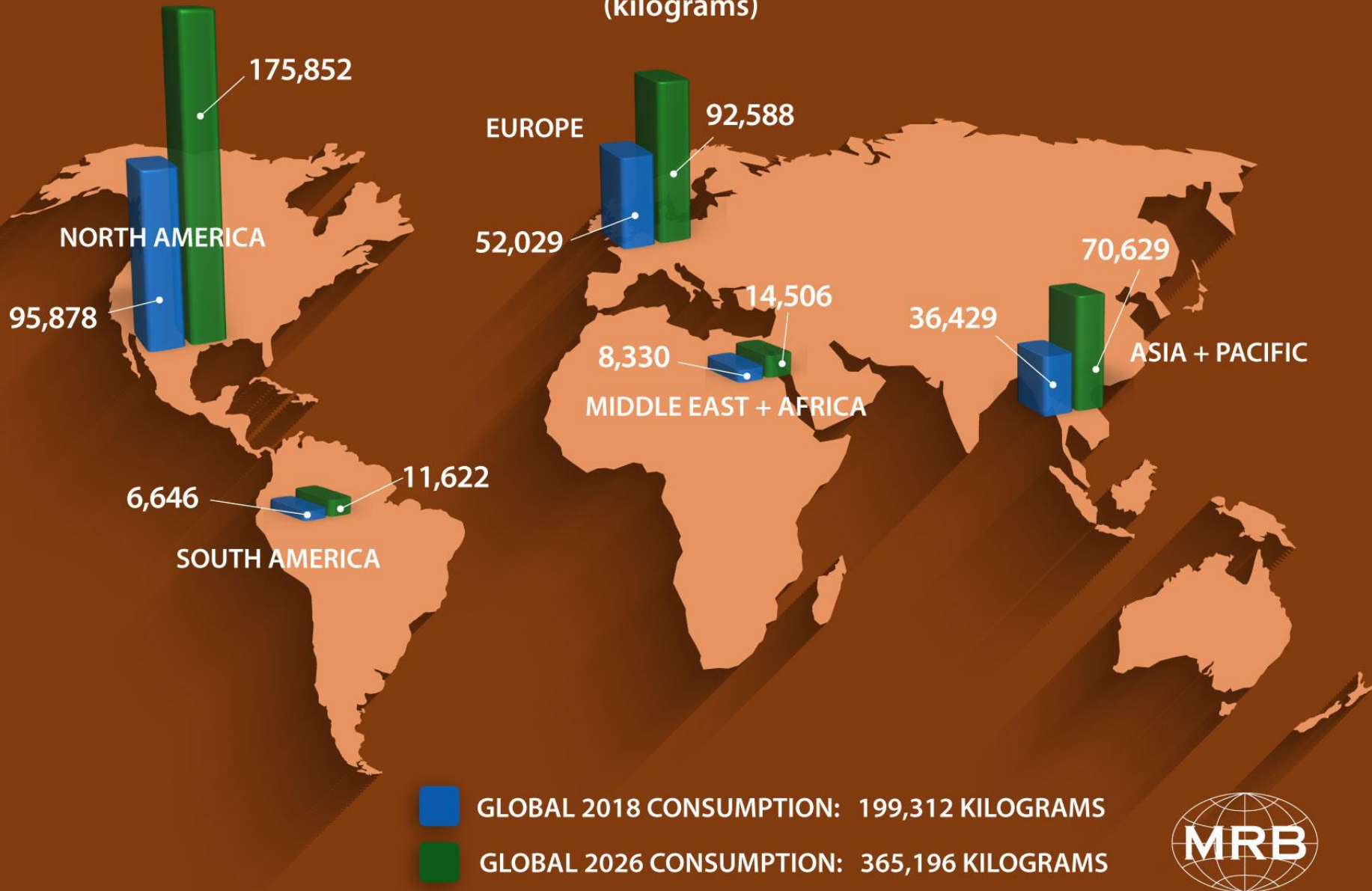
- **Present and Future Demand for Plasma-derived Medicinal Products (PDMPs) – The future IgG Market by Region**
- Plasma Collections and Fractionation in 2018



POLYVALENT IgG CONSUMPTION BY REGION FROM 2010 TO 2026 (Kilograms)

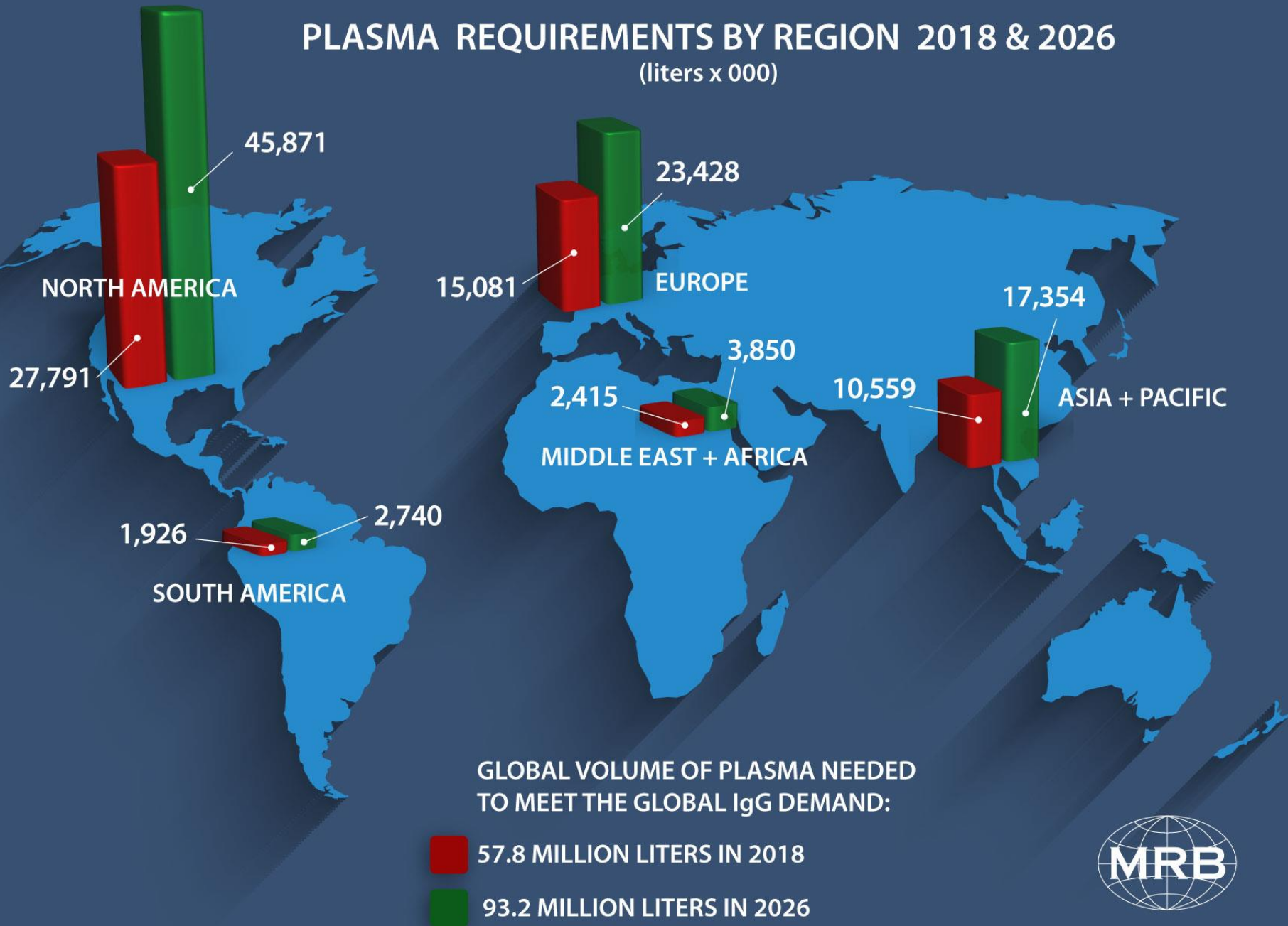


IgG CONSUMPTION CONSUMPTION BY REGION IN 2018 & 2026 (kilograms)



PLASMA REQUIREMENTS BY REGION 2018 & 2026

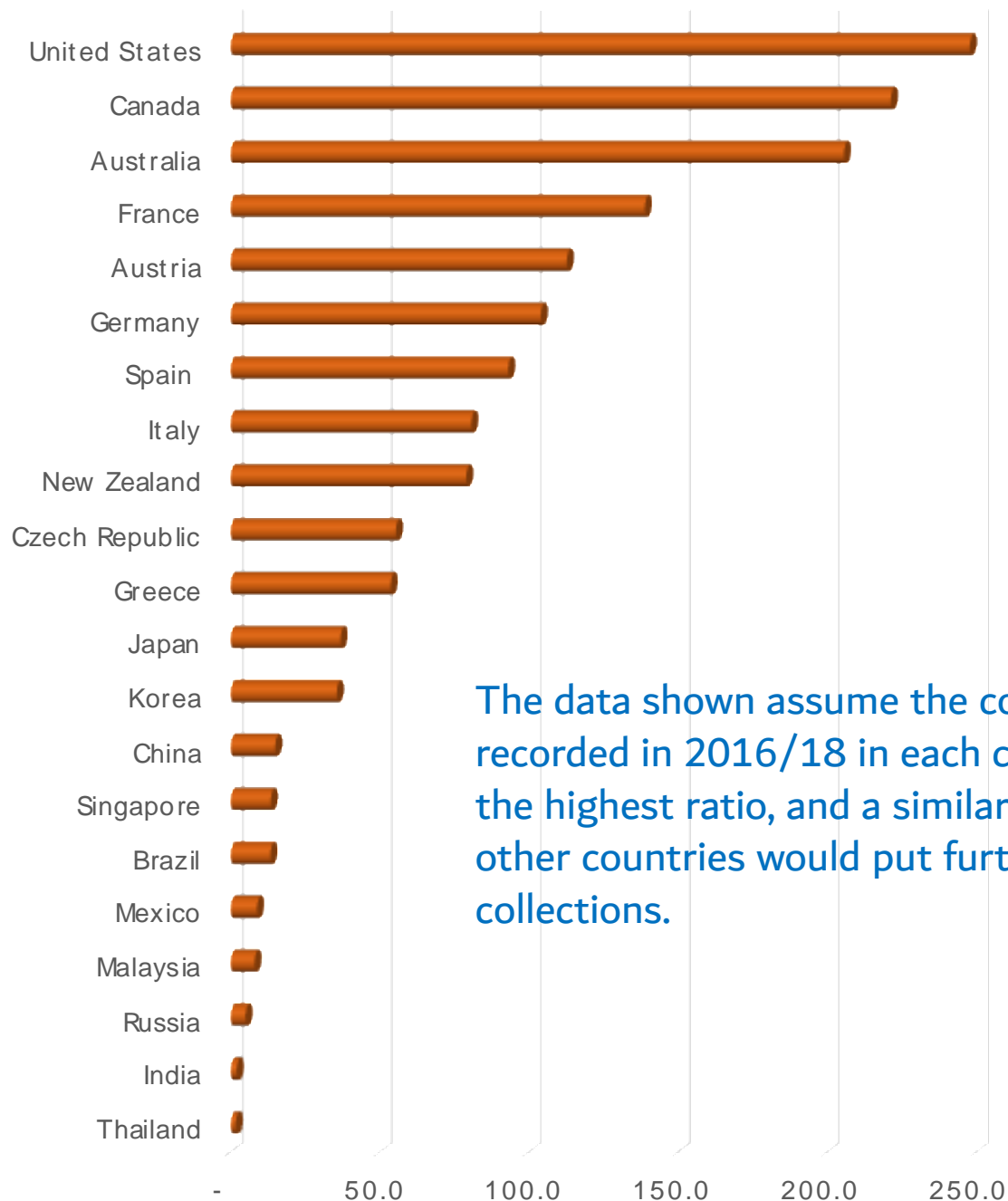
(liters x 000)



IMMUNOGLOBULIN USAGE TRENDS AND REGIONAL PLASMA NEEDS

- The higher per capita consumption of IgG in North America is attributed to:
 - Influence of patient groups, public awareness,
 - Price differences from country to country,
 - Manufacturers' promotional activity and education,
 - Market structure and purchasing process, etc.
 - Off-label usage,
- If these parameters still apply by 2026, the comparatively high volume of plasma for fractionation needed to treat patients in North America will reduce the availability of US plasma for patient treatments in other countries.
- Therefore, other countries will have to generate more plasma for treating their own patients.

IGG CONSUMPTION IN SELECTED COUNTRIES 2016-2018



The data shown assume the consumption per capita recorded in 2016/18 in each country. North America has the highest ratio, and a similar per capita consumption in other countries would put further pressure on plasma collections.



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- **Present and Future Demand for Plasma-derived Medicinal Products (PDMPs): Polyvalent Immune globulin (IgG)**
- **Plasma Collections and Fractionation in 2018**



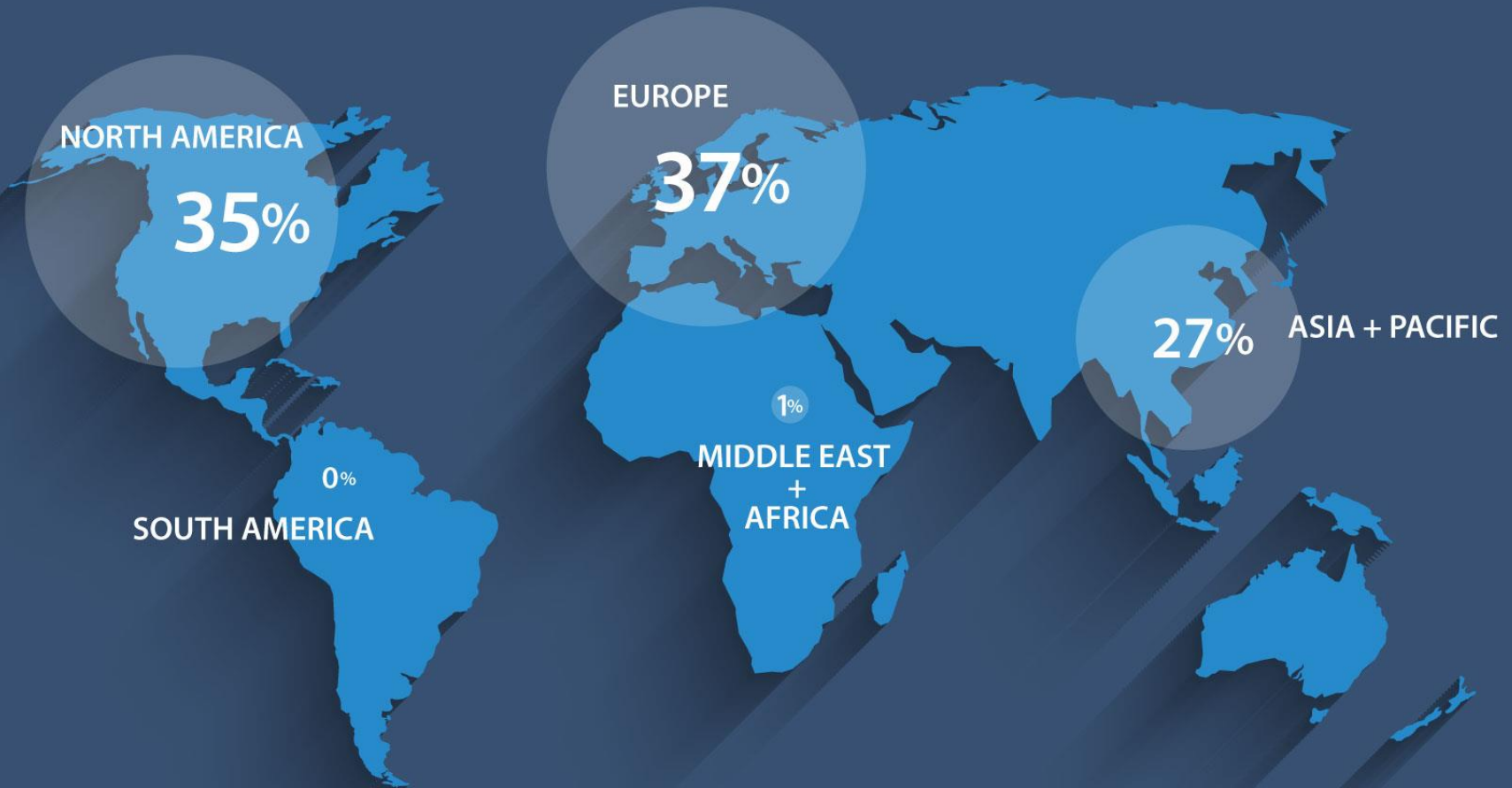
REGIONAL DISTRIBUTION OF FRACTIONATION PLANTS 2018



TOTAL NUMBER OF FRACTIONATION PLANTS: 76



REGIONAL DISTRIBUTION OF FRACTIONATION THROUGHPUT 2018



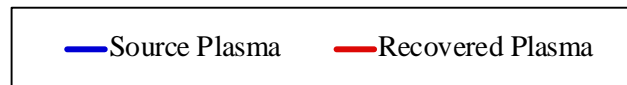
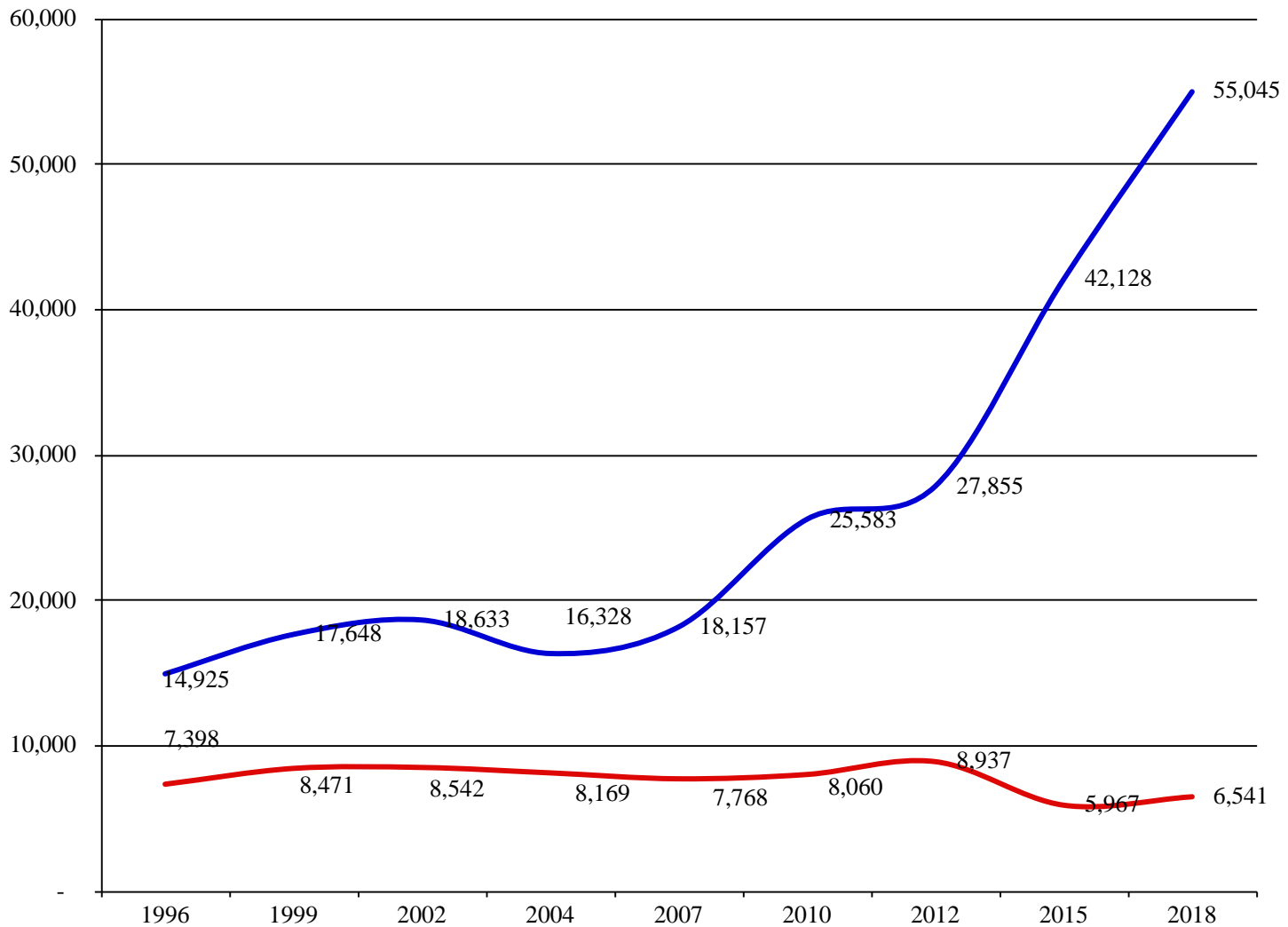
GLOBAL FRACTIONATION THROUGHPUT 2018:
80 MILLION LITERS



TYPE OF PLASMA FRACTIONATED WORLDWIDE FROM 1996 TO 2018
COMMERCIAL COMPANIES & NON-PROFIT ORGANIZATIONS

(Thousand Liters)

Total in 2018: 61,586,000 Liters



Thank you!



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