

REGIONAL VARIATIONS IN IMMUNE GLOBULIN USAGE

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The Future for Blood and Plasma Donations

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METHODOLOGY AND DISCLOSURES

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Regional Variations in Immune Globulin Usage

- **Quantitative Aspects (Kilograms)**
- **Qualitative Aspects (Clinical Use)**
- **Hyperimmune Globulins**



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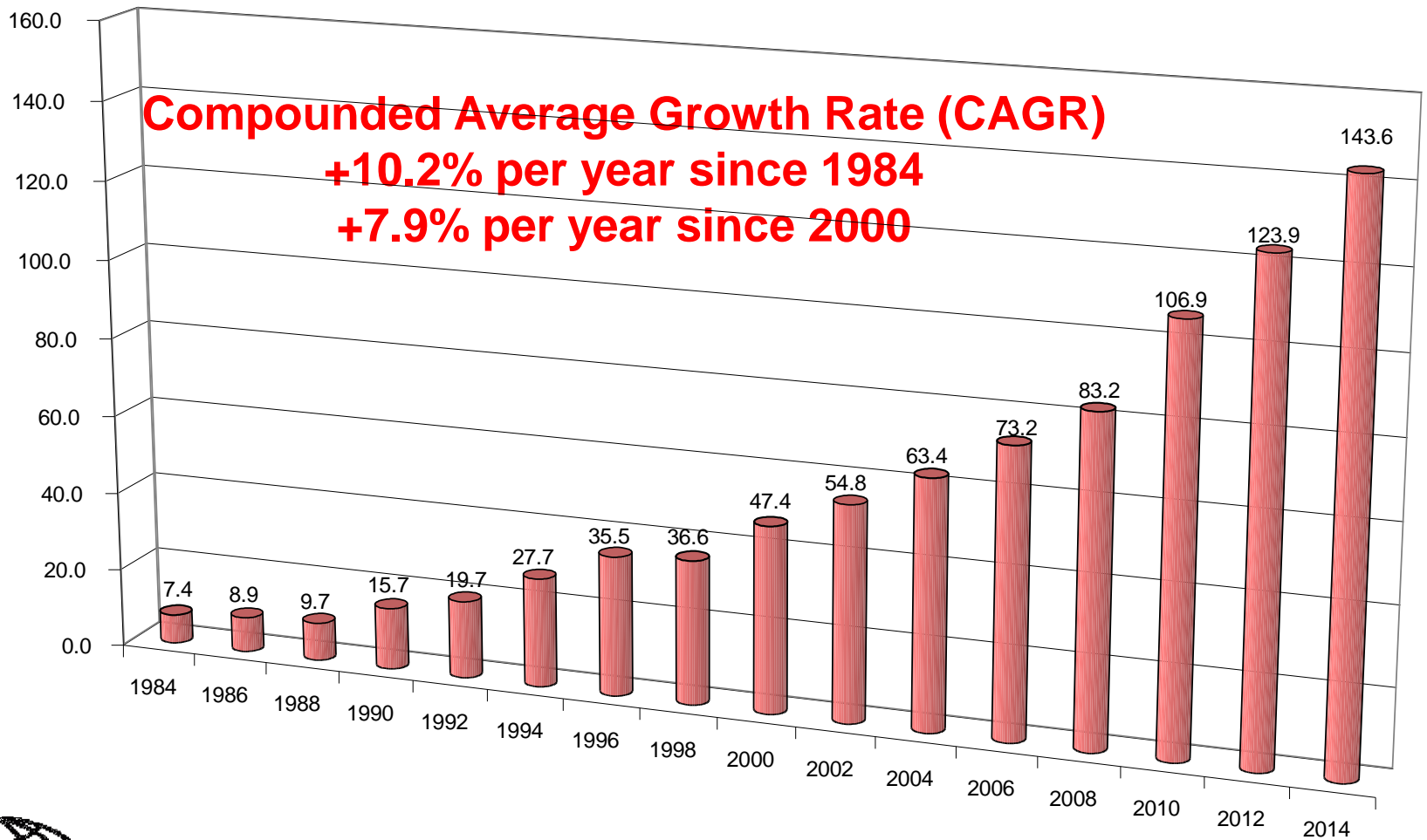
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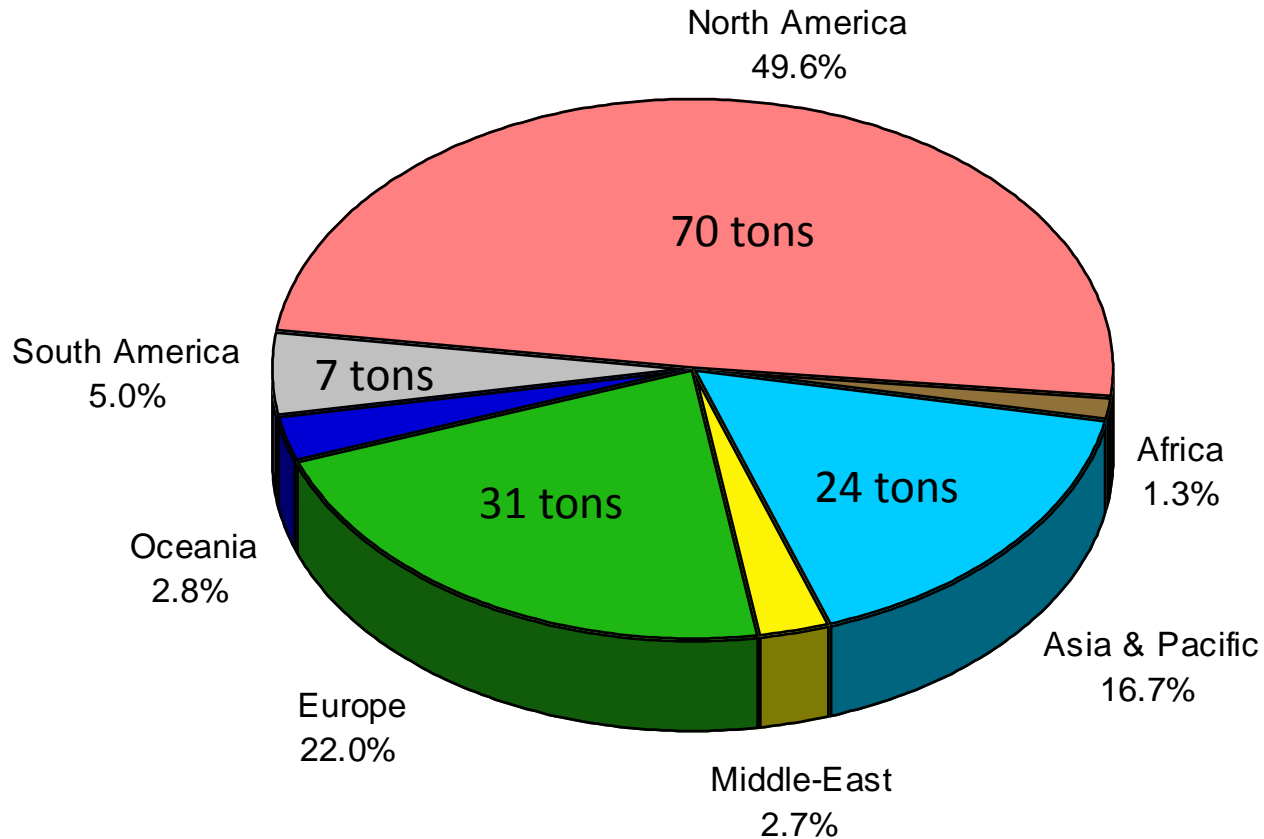
WORLDWIDE DEMAND FOR INTRAVENOUS & SUBCUTANEOUS IMMUNE GLOBULIN (IVIG/SCIG) 1984 - 2014

Metric Tons



THE WORLDWIDE IVIG/SCIG MARKET IN UNITS BY REGION - 2014

Total Market 140.6 Metric Tons



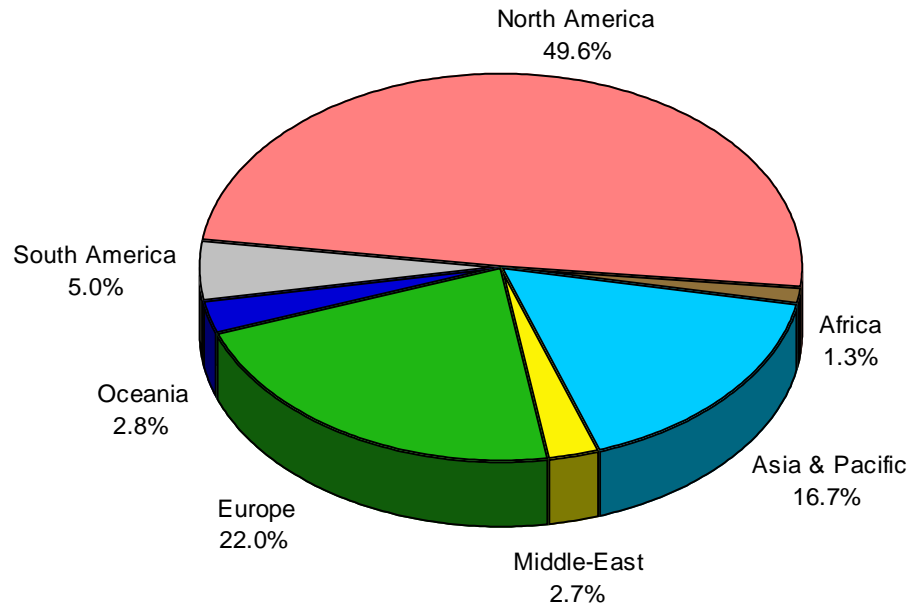
**Based on MRB Interim
Worldwide Report 2014
(European data are 2011)**



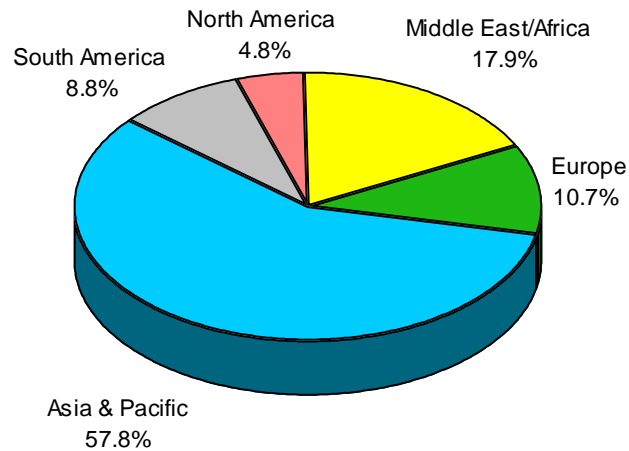
THE WORLDWIDE IVIG/SCIG MARKET IN UNITS BY REGION - 2014

Wide discrepancies exist between the regional breakdown of the world population and the IVIG consumption

Total Market 140.6 Metric Tons



World Population by Region - 2013



REGIONAL VARIATIONS IN IVIG USAGE

The comparatively high consumption level in North America stems from:

- **Longer experience with IVIG,**
- **Safety, efficacy, availability,**
- **Physicians' awareness, manufacturers' promotion,**
- **Open market, ample supply and product choice,**
- **Reimbursement of usage for off-label indications.**

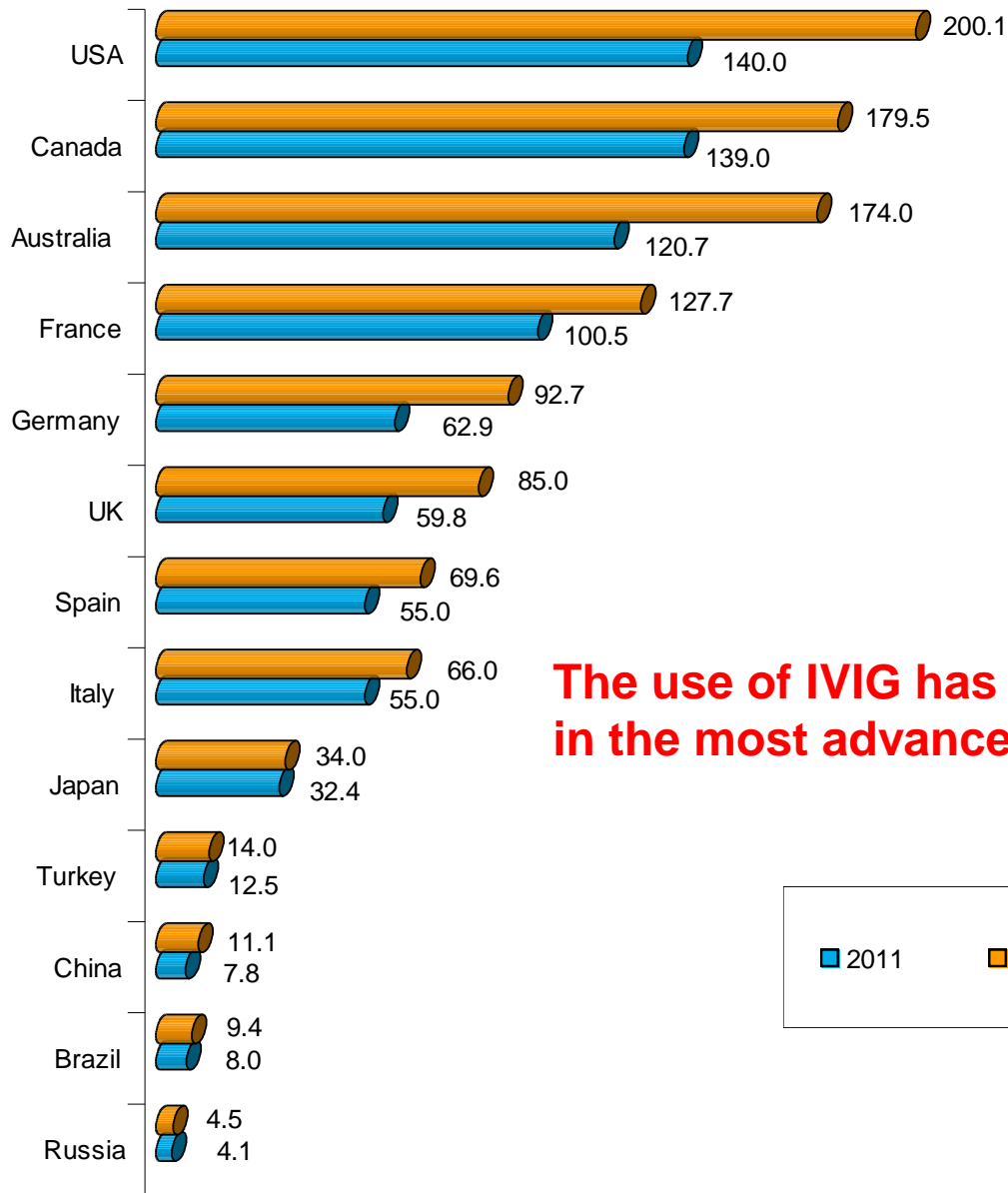


REGIONAL VARIATIONS IN IVIG USAGE

- **In low consumption regions:**
 - Little usage in chronic conditions (mainly GBS)
 - No or limited off-label usage,
 - Volatile Supply,
 - IVIG competition with antibiotics or plasmapheresis,
 - Limited product knowledge and awareness,
 - Under-diagnosis of PID, CIDP, MMN, and others,
 - Negative image of blood products,
 - Cost, limited funding and reimbursement,
 - No or limited training of physicians about IVIG.
- Each region has its own set of limitations



INTRAVENOUS/SUB-CUTANEOUS (IVIG/SCIG) CONSUMPTION BY COUNTRY (Kilograms per Million People)



**The use of IVIG has grown faster
in the most advanced countries**



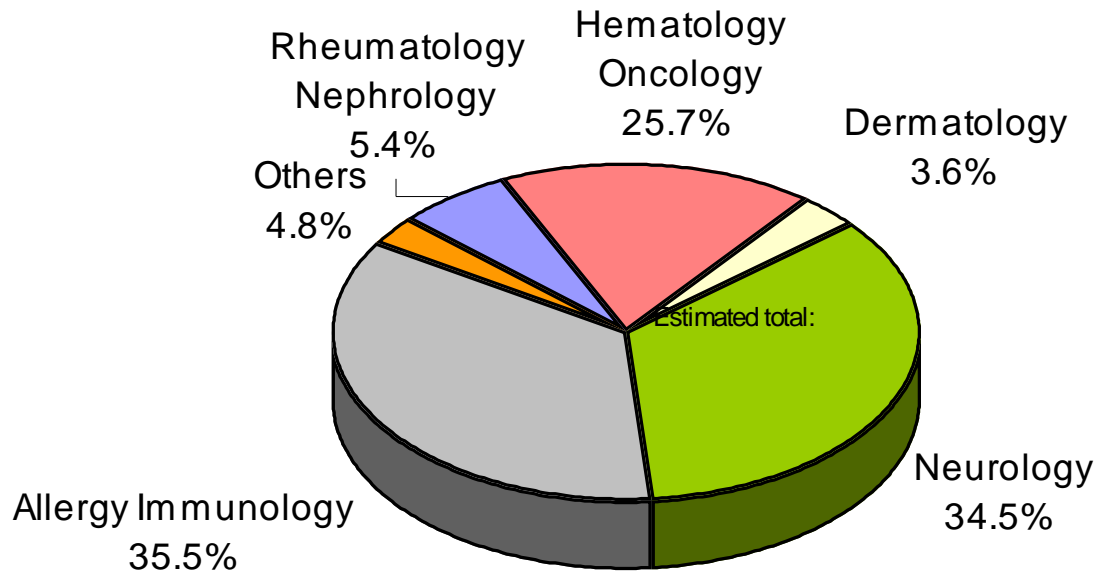
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Regional Variations in Immune Globulin Usage

- Quantitative Aspects (Kilograms)
- **Qualitative Aspects (Clinical Use)**
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IVIG/SCIG USE BY MEDICAL SPECIALTY IN THE US - 2015 (Percentage of total Grams)

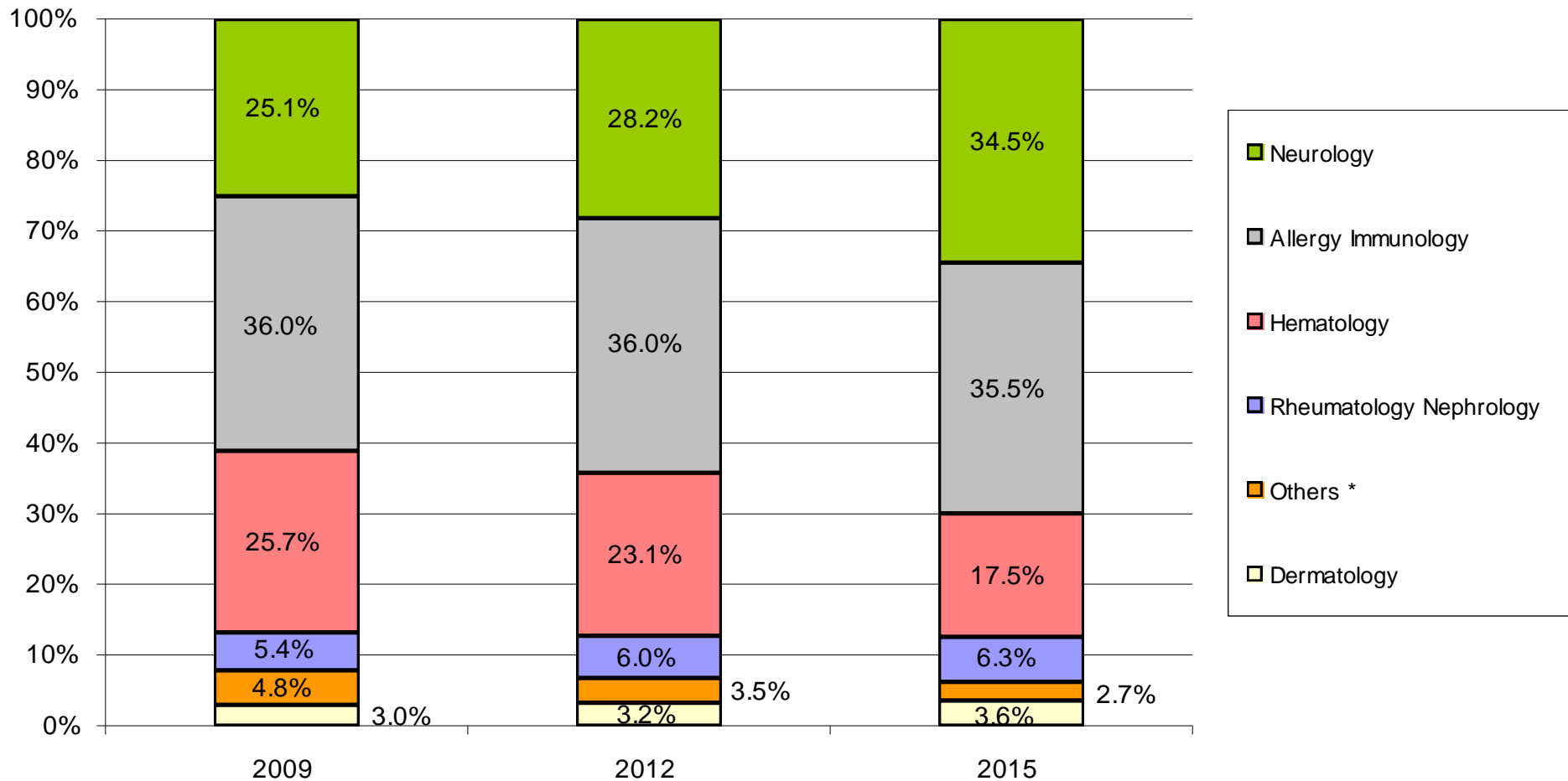


Estimated Total: 65 tons

In the US and most industrialized countries, neurological and immunological conditions represent over two thirds of IVIG usage



IVIg Usage by Medical Specialty 2009, 2012 and 2015 Likely Scenario (Percent Grams)



* Dermatology, Obstetrics/Gynecology, Cardiology, Infectious Diseases, Ophtalmology

IVIg usage does not change much over time

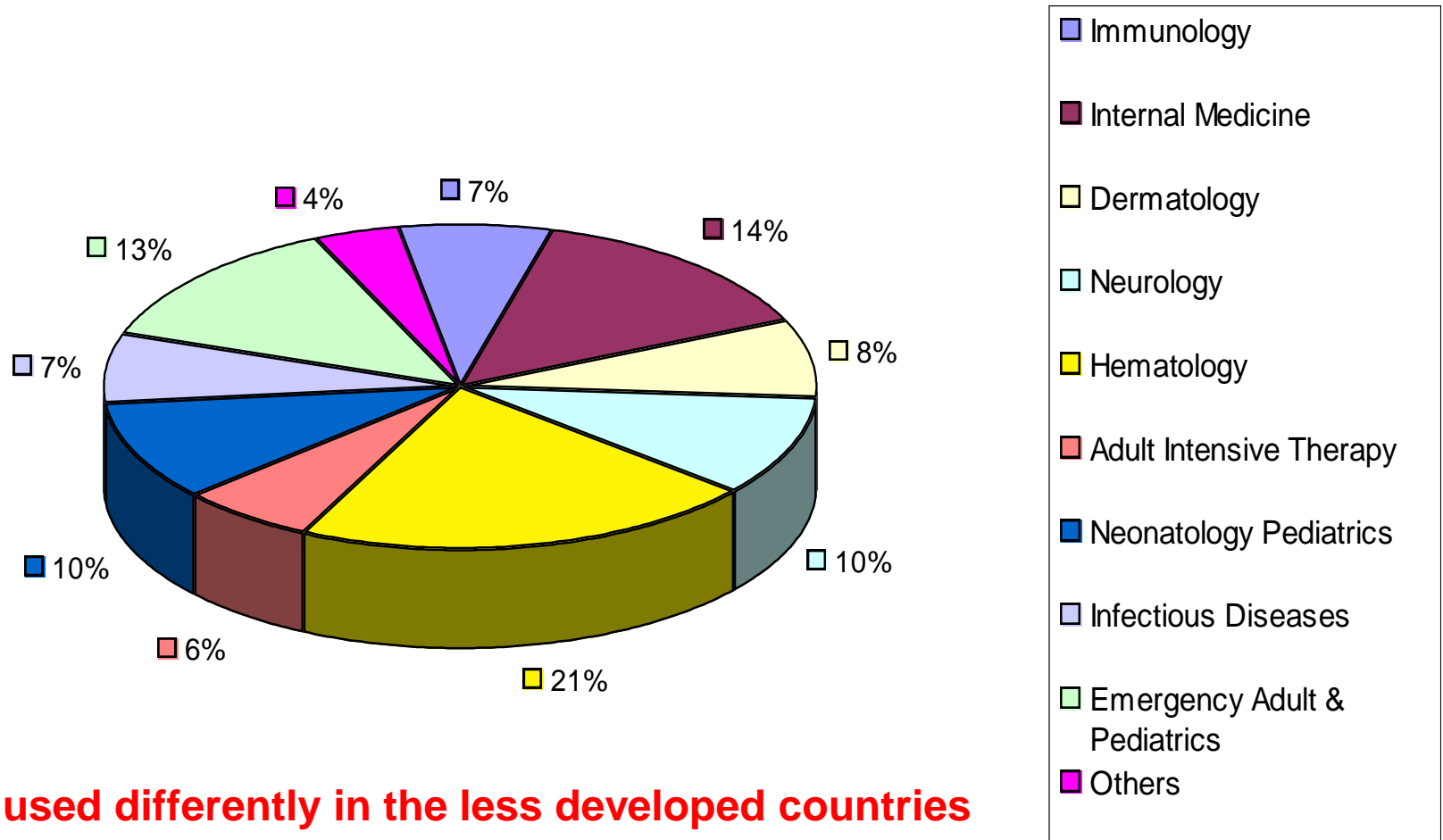


The top ten indications of IVIG use 88% of the total grams, and the top three, 56%.



IVIG USAGE BY MEDICAL SPECIALTY IN VENEZUELA - 2007

(Percentage of Grams used per Year)



IVIG is used differently in the less developed countries

Courtesy of Quimbiotec, Caracas, Venezuela 2009



REGIONAL VARIATIONS IN IVIG USAGE

- In the less developed countries, IVIG is used mostly for acute medical conditions, due to therapy cost and poor diagnosis of PID, CIDP and other chronic diseases,
- Improved diagnosis, product awareness, funding, patient organizations' influence, better health care services,
- Going forward, the consumption will grow faster in the emerging markets than in the most advanced countries which will reach maturity, as the number of new IVIG indications dwindles and alternative therapies surface.
- As a result, more plasma will be needed as raw material for making increased quantities of IVIG.



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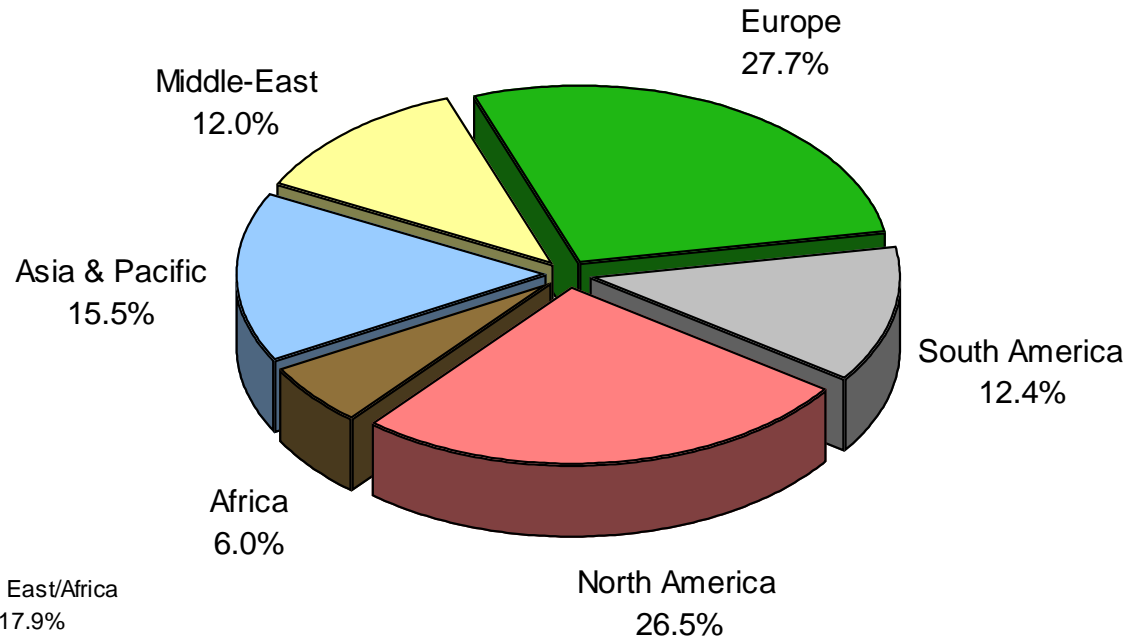
REGIONAL VARIATIONS IN HYPERIMMUNE GLOBULINS USAGE

- **As they target patient populations affected by specific diseases, hyperimmune globulin products usage depends on epidemiological and socio-economic factors,**
- **Each region has its own set of conditions relating to hyperimmune globulin products usage,**
- **Vaccination reduces the need for passive immunization with hyperimmune globulin products,**
- **Monoclonal antibodies may compete with hyperimmune globulin products in the future.**

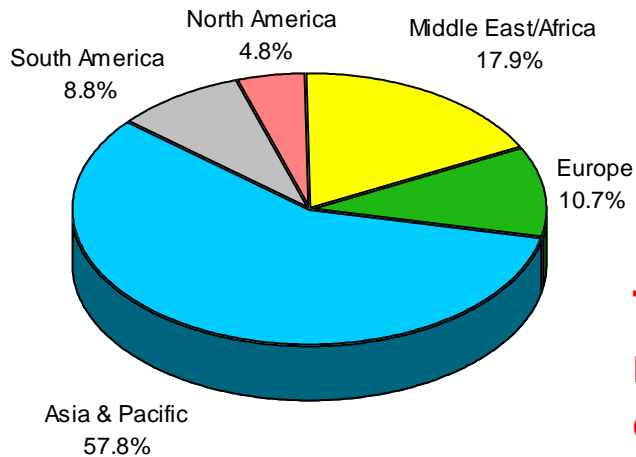


THE RHO(D) IMMUNE GLOBULIN MARKET BY REGION - 2014

Total Market: 4,386 million



World Population by Region - 2013

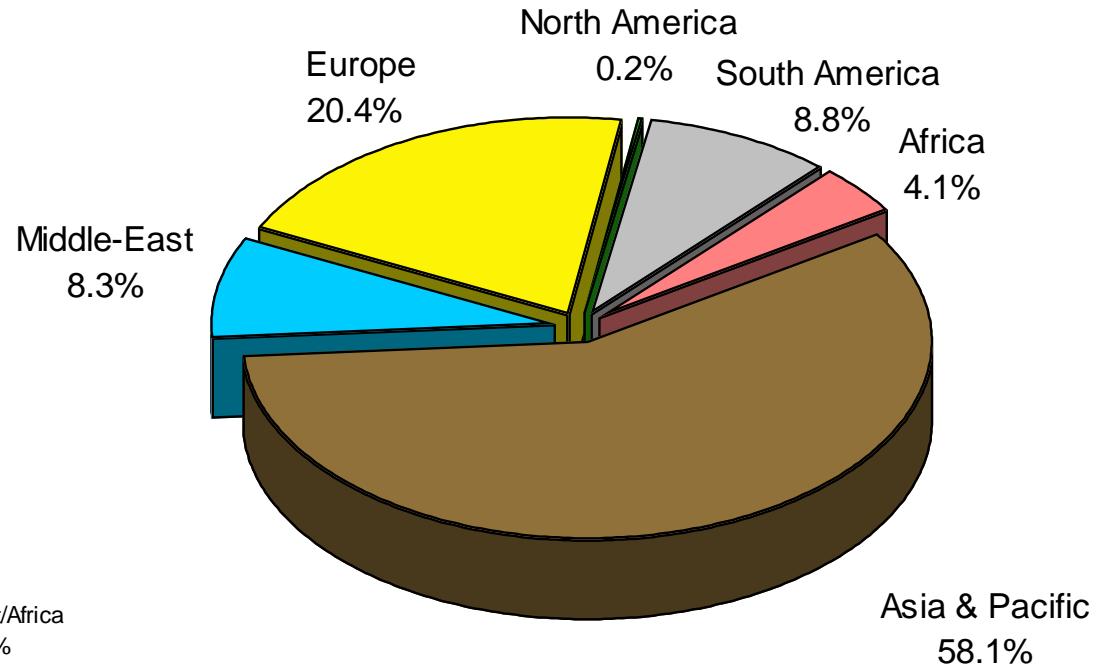


The use of Rho(D) immune globulin is relatively equally distributed outside of the Asian & Pacific region

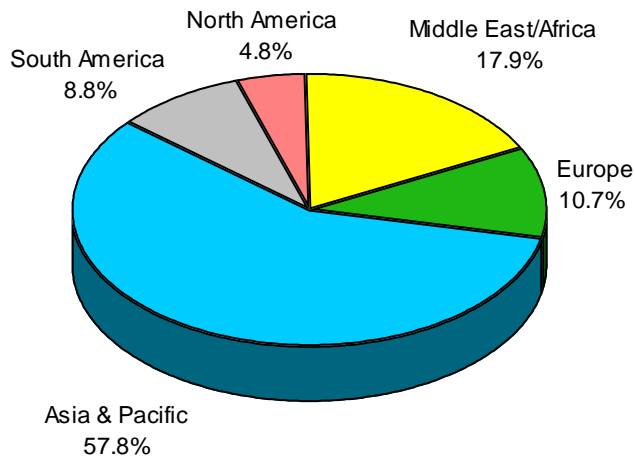


TETANUS IMMUNE GLOBULIN MARKET BY REGION - 2014

Total Market: 6,965.3 Million International Units



World Population by Region - 2013

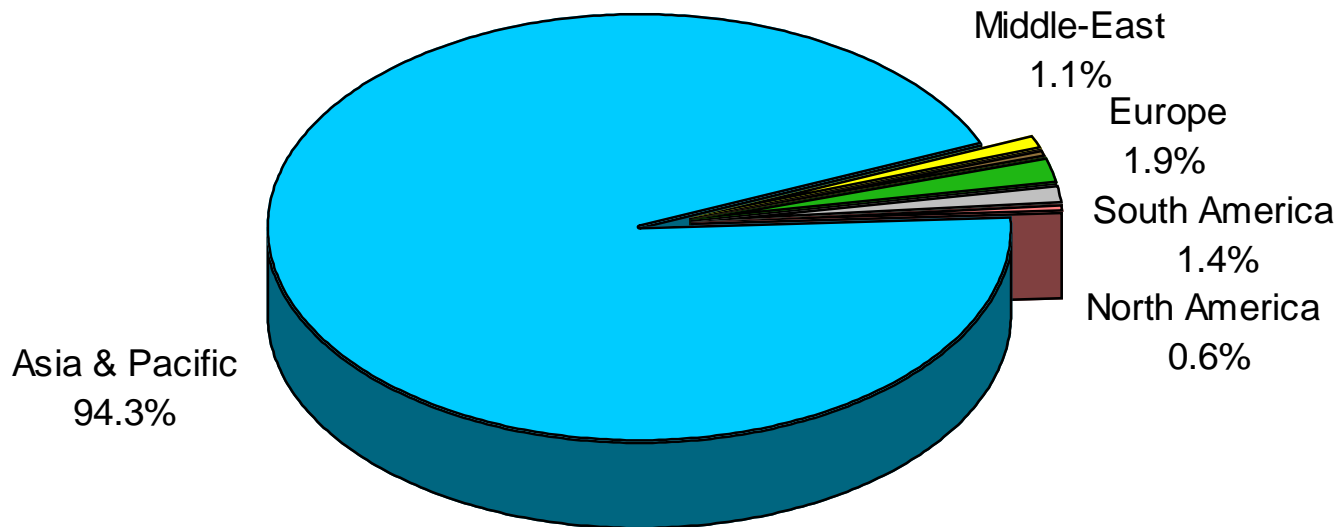


Over 50% of tetanus immune globulin usage is in Asia & Pacific where vaccination is not widespread



HEPATITIS B IMMUNE GLOBULIN MARKET BY REGION - 2014

Total Market: 9,290.6 Million International Units

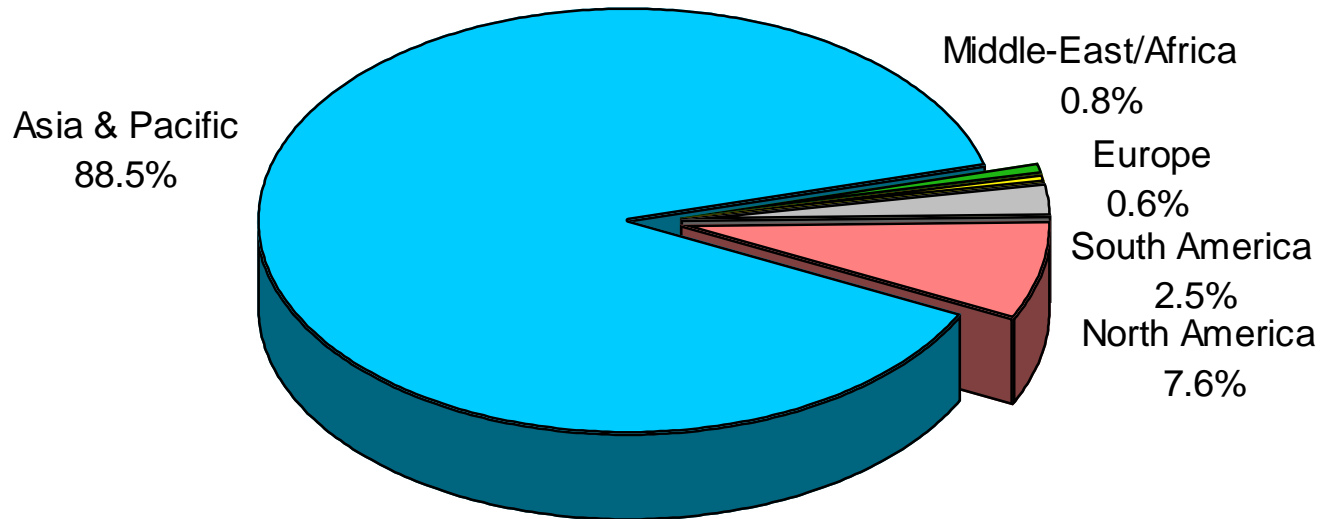


Hepatitis B immune globulin is primarily used in the Asian & Pacific region due to high incidence of the disease and lower vaccination rates



RABIES IMMUNE GLOBULIN MARKET BY REGION - 2014

Total Market: 4,032.8 Million International Units



Rabies immune globulin is primarily used in the Asian & Pacific region, due to high disease prevalence and low immunization level



REGIONAL VARIATIONS IN IMMUNE GLOBULINS USAGE

- **Whether polyvalent or specific, the immune globulin products are life-saving drugs used worldwide**
- **The consumption level of immune globulin products varies significantly from one region to another but they are now becoming mainstream, as testified by their inclusion in WHO's list of essential medicines.**
- **Due to their efficacy and safety, immune globulin preparations will be needed for a long time to come, requiring growing volumes of plasma, including plasma containing specific antibodies.**



Thank you

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