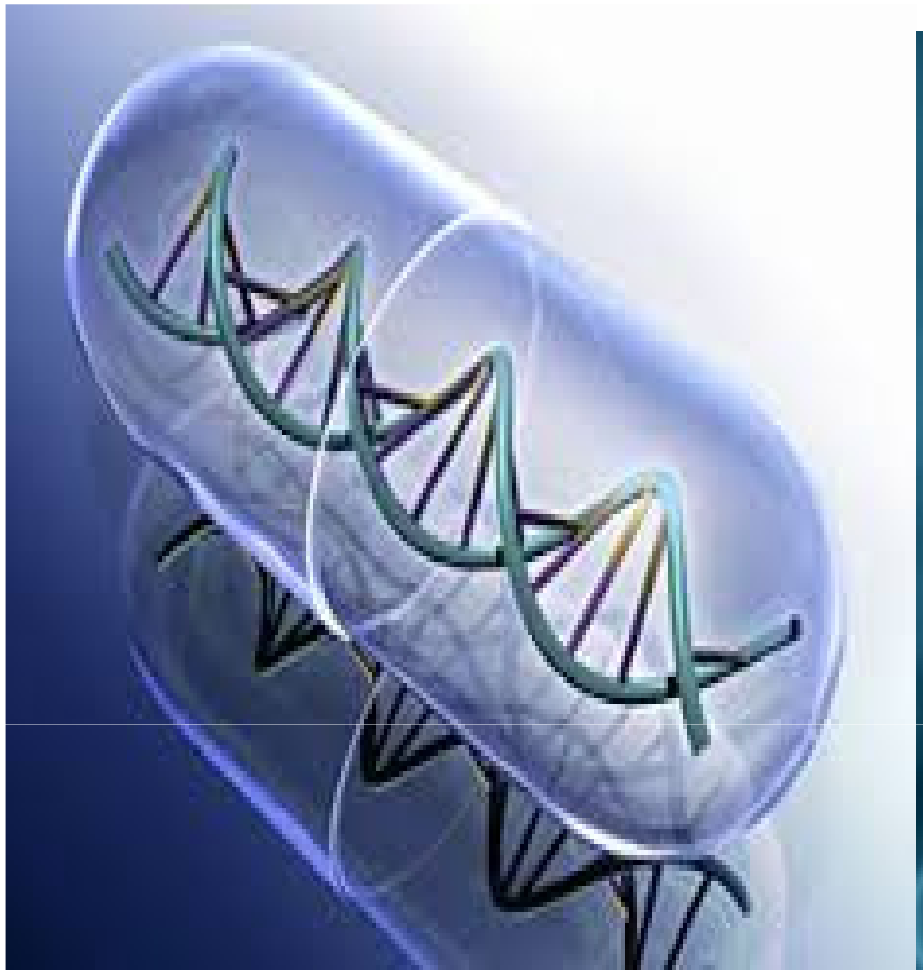
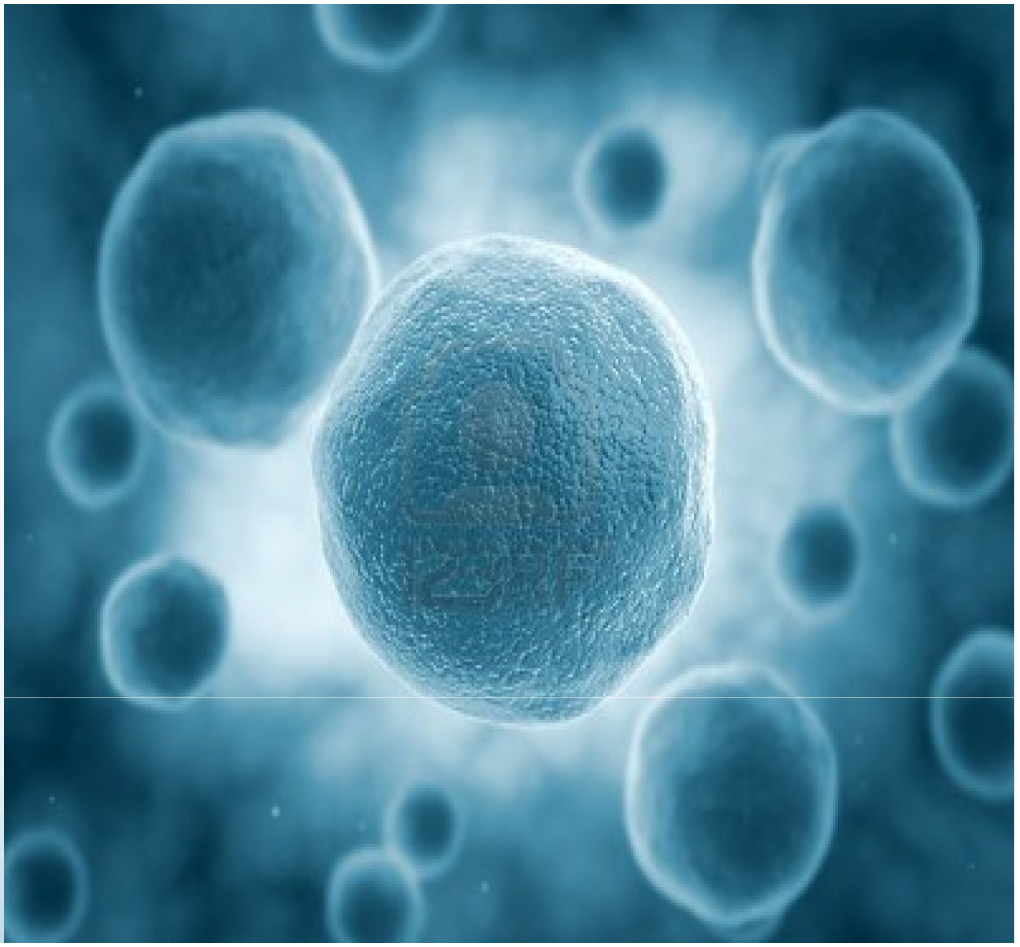


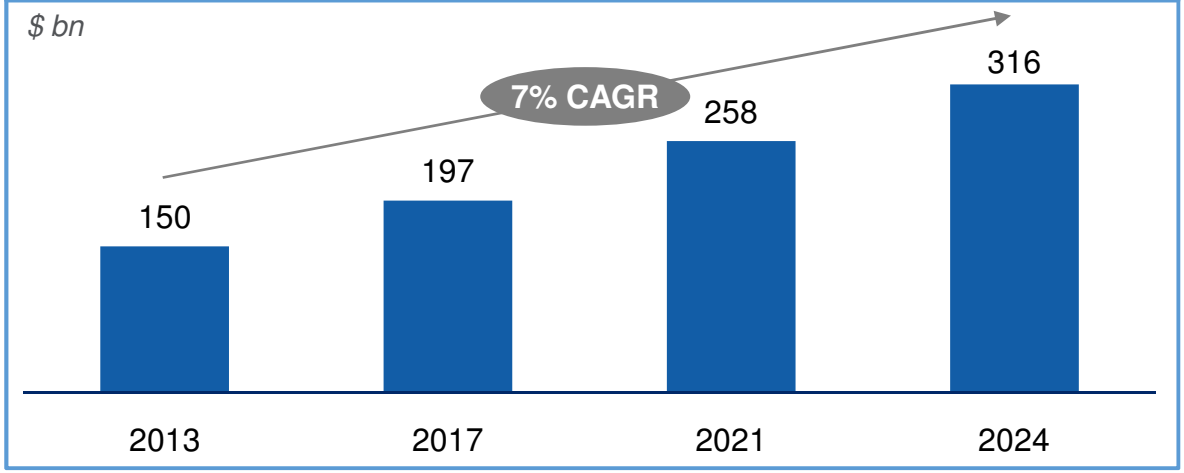


BIOSIMILARS: Commercialising biosimilars successfully

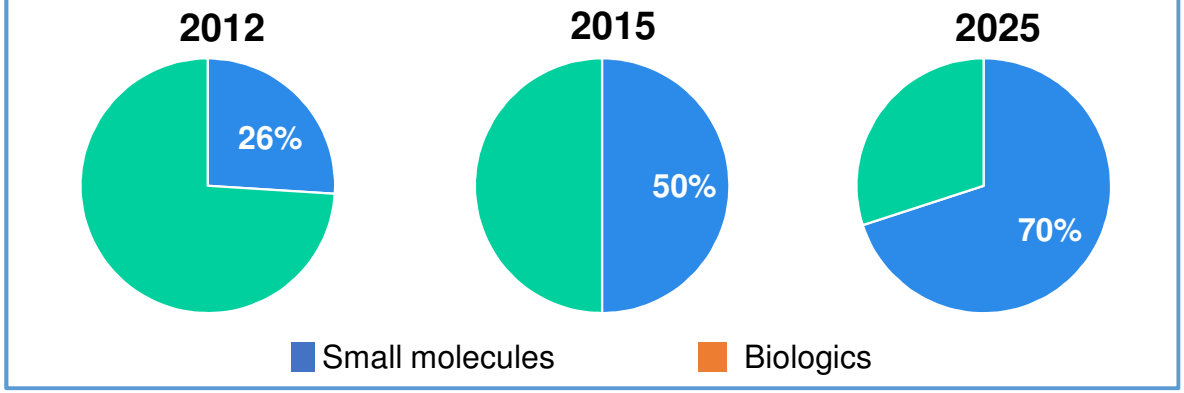
Cipla Biologicals Ltd.

The biologics market is growing faster than the overall pharma market and will do so over the next 10 years

Bio market expected to grow at ~7%, faster than the overall pharma growing at 4-5%



Biotech new products approval share is expected to grow from 26% in 2012 to 70% in 2025



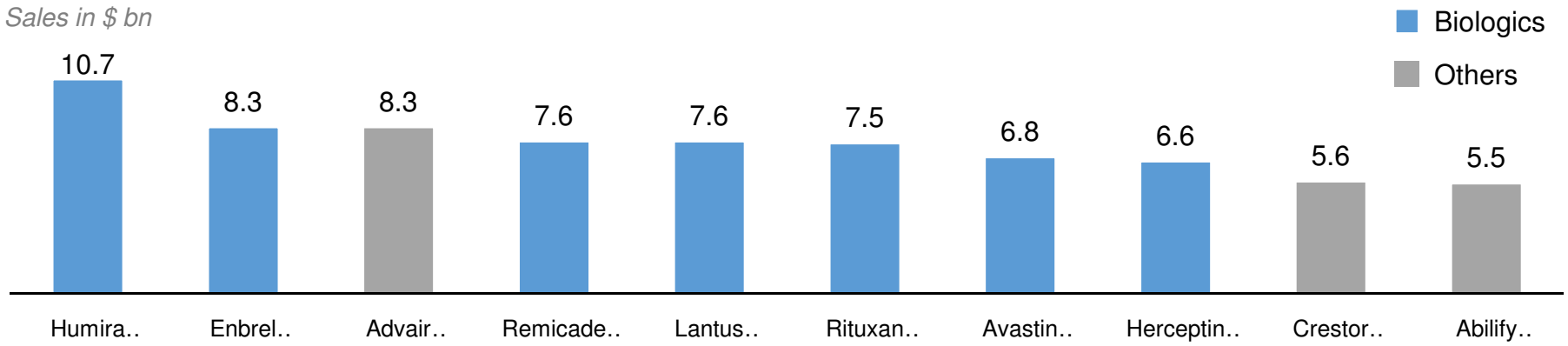
Key drivers of growth

- Enhanced efficacy
- Reduced side effects
- More patients achieve clinical remission with biologics compared to small molecules
- Personalized treatment
- Therapy for disease stages that are not treatable by existing small molecules

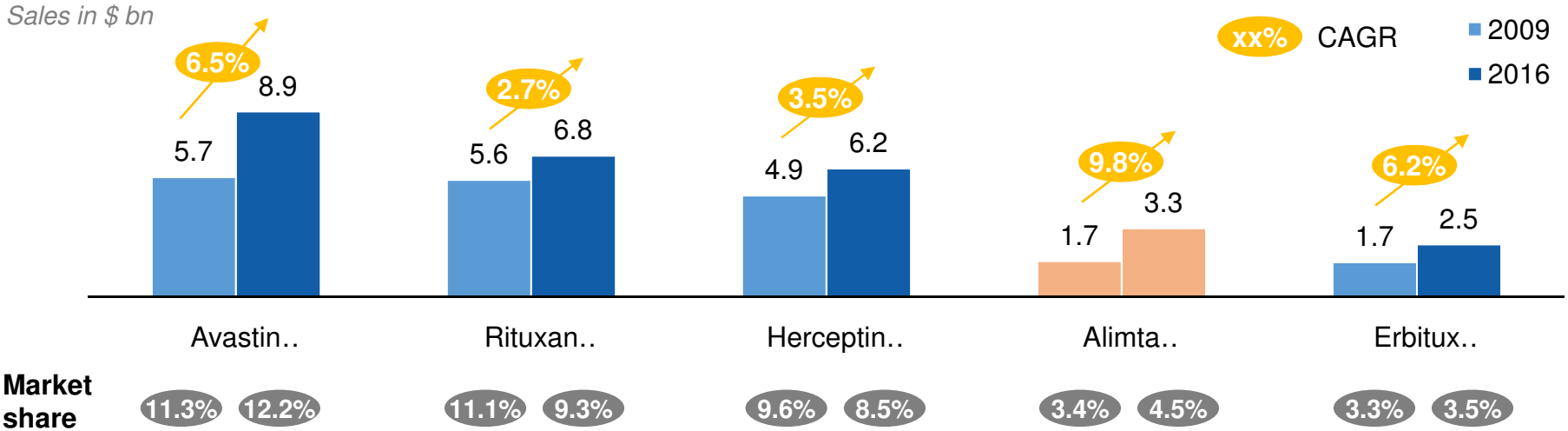
Source: McKinsey reports

The Pharma market is dominated by high priced innovator biologicals

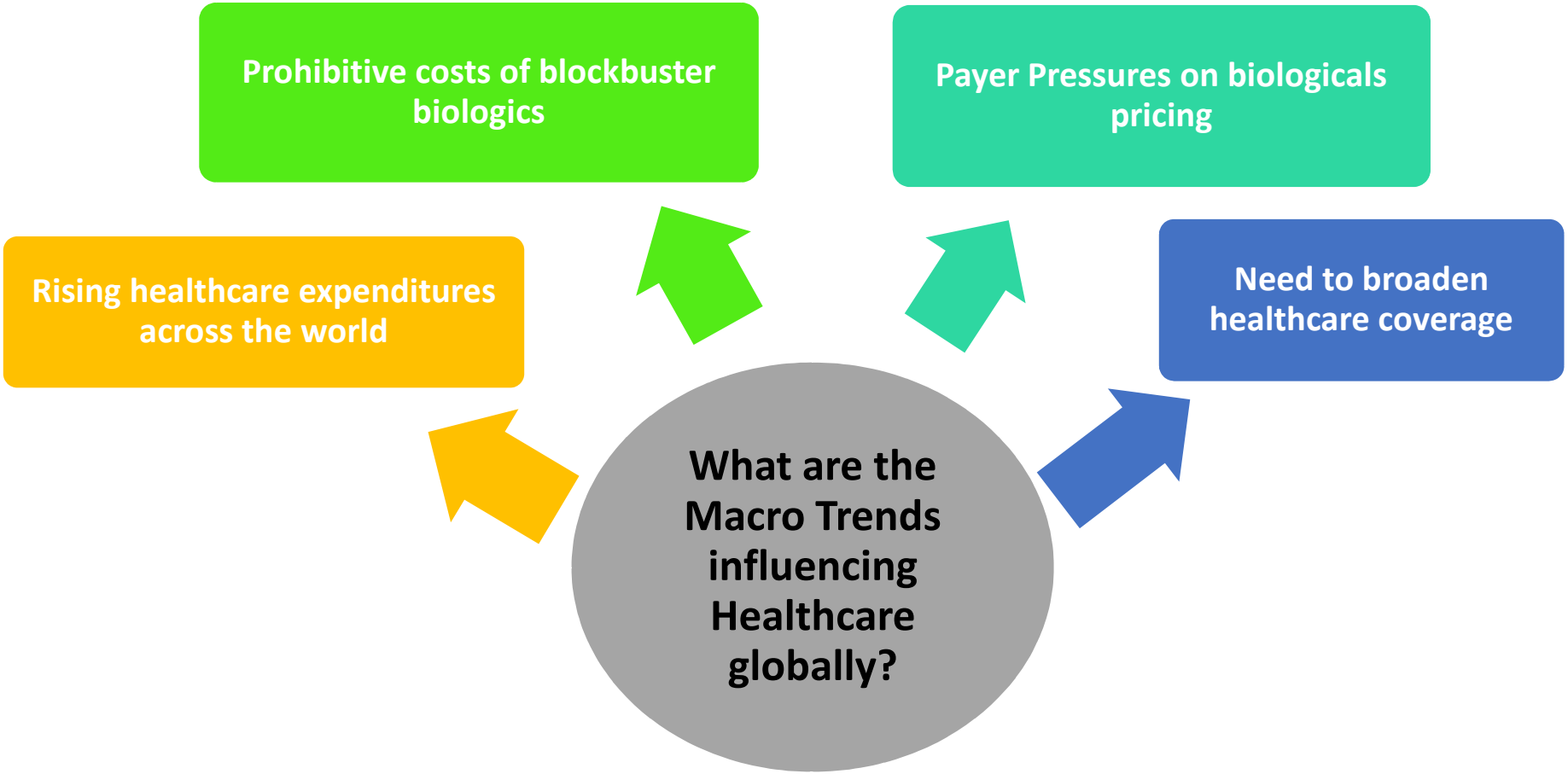
7 of the 10 pharma products (by $ sales) are biologics in 2013



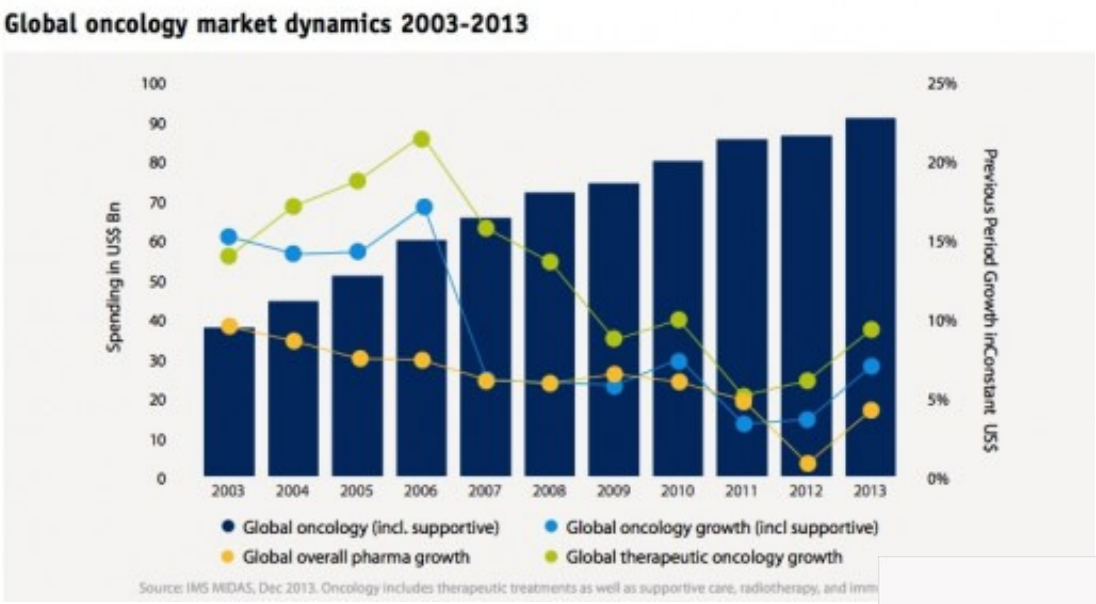
4 of the top 5 projected oncology products in 2016 are biologics Mabs



Source: McKinsey reports

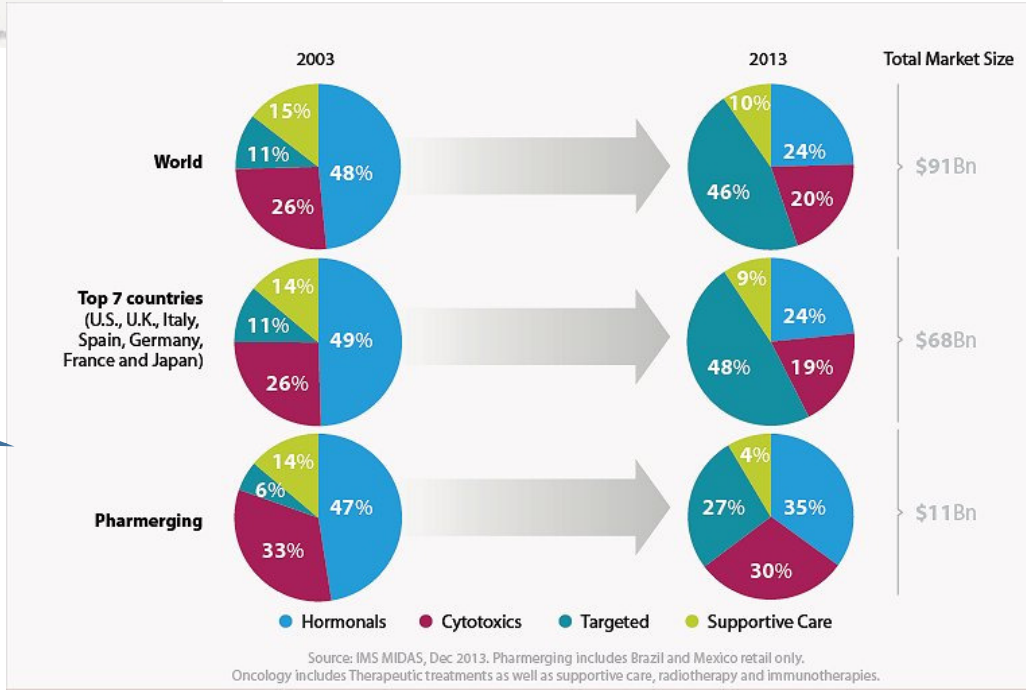

Prohibitive costs of blockbuster biologics
Payer Pressures on biologicals pricing
Rising healthcare expenditures across the world
Need to broaden healthcare coverage
What are the Macro Trends influencing Healthcare globally?

Drug treatments are getting costlier ….

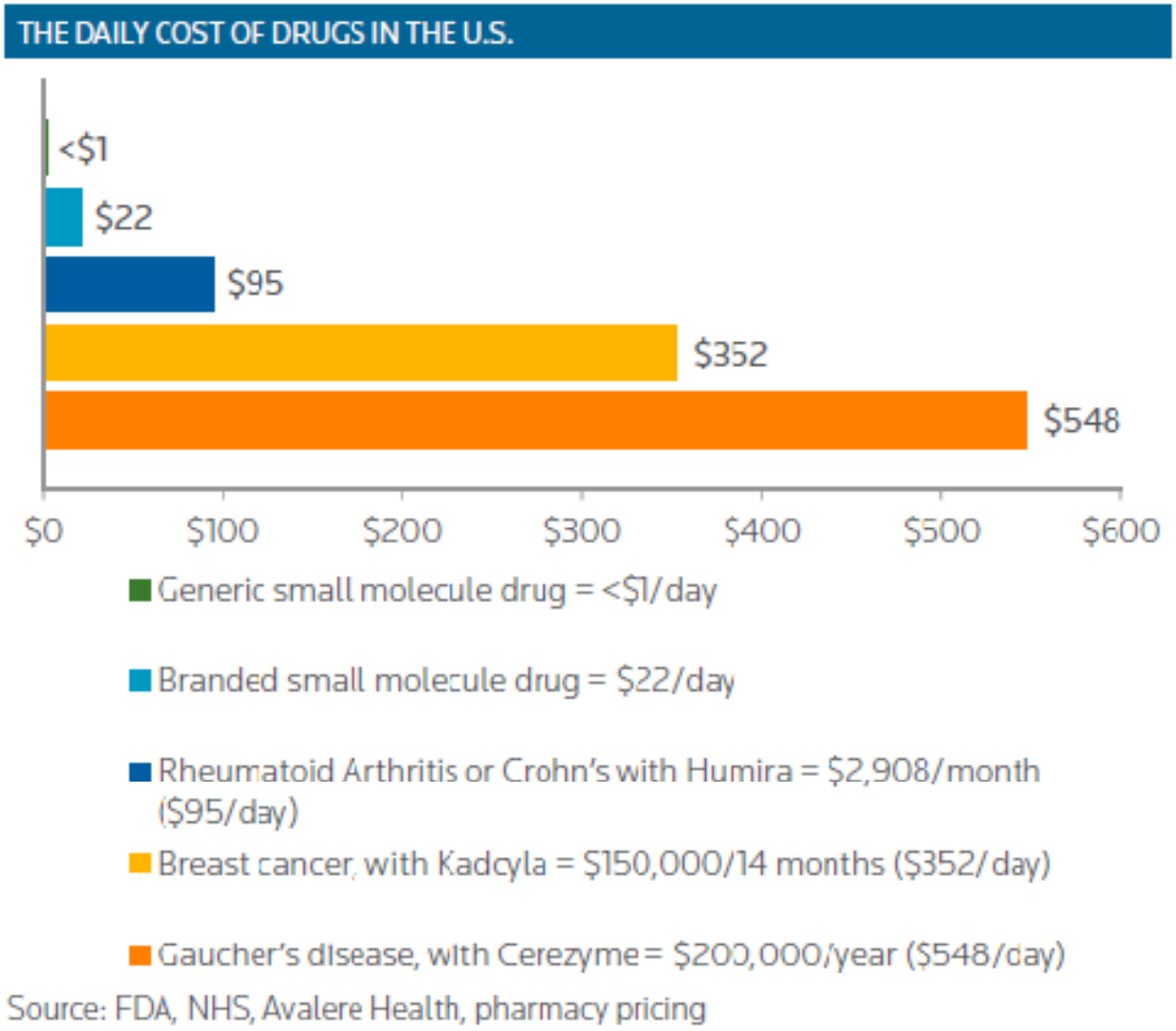


While global spending on oncology drugs has grown to $91 Bn in 2013, including supportive care….

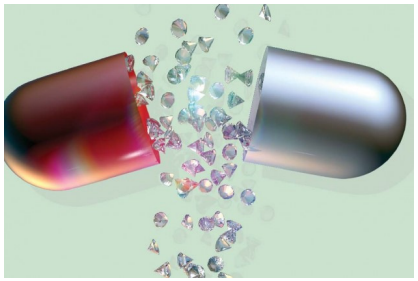
…….there is also a shift in conventional treatment to targeted therapies like Biologics



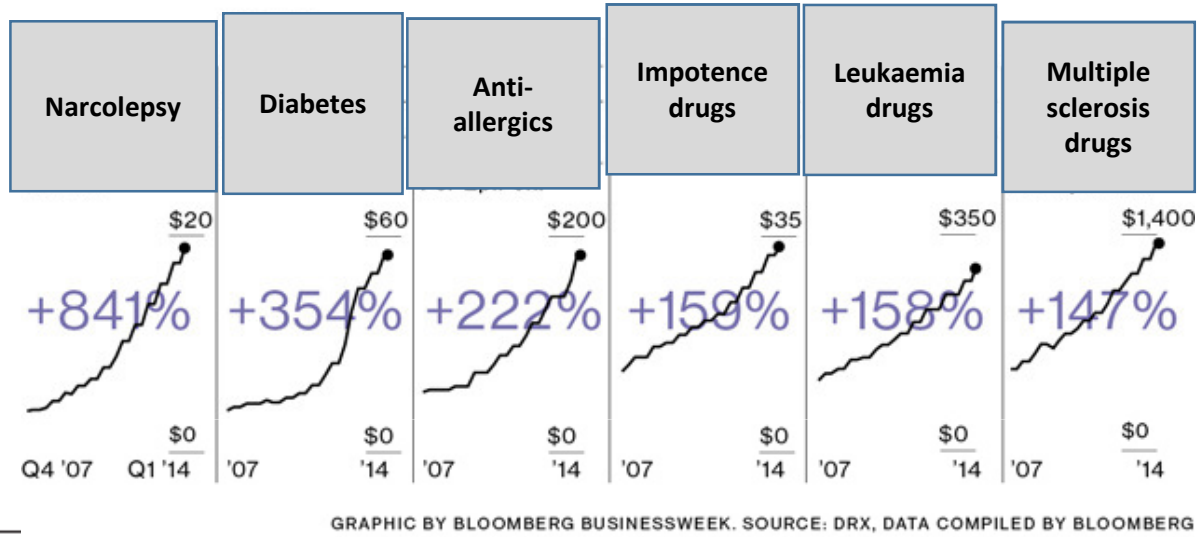
Biologic drug prices going up and up….



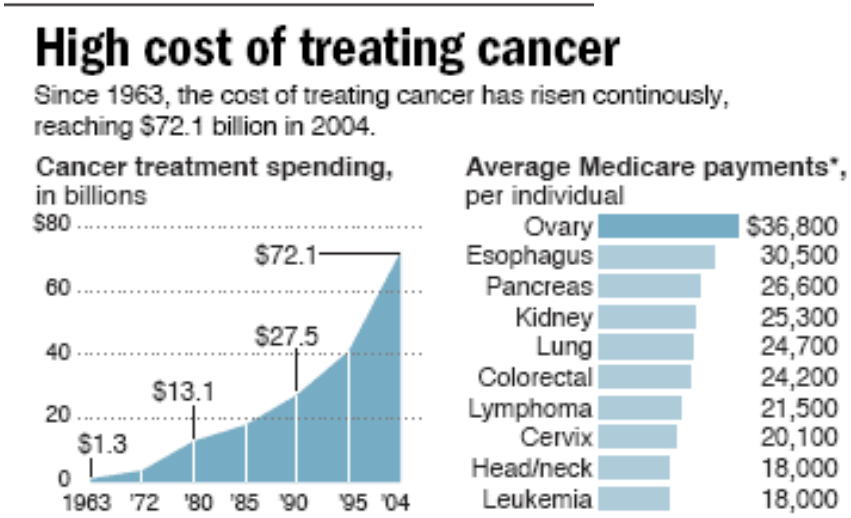
Overall Healthcare burden in the world is on the rise







GRAPHIC BY BLOOMBERG BUSINESSWEEK. SOURCE: DRX, DATA COMPILED BY BLOOMBERG



Healthcare costs all over the world have seen a spiralling increase due to inflated drug prices

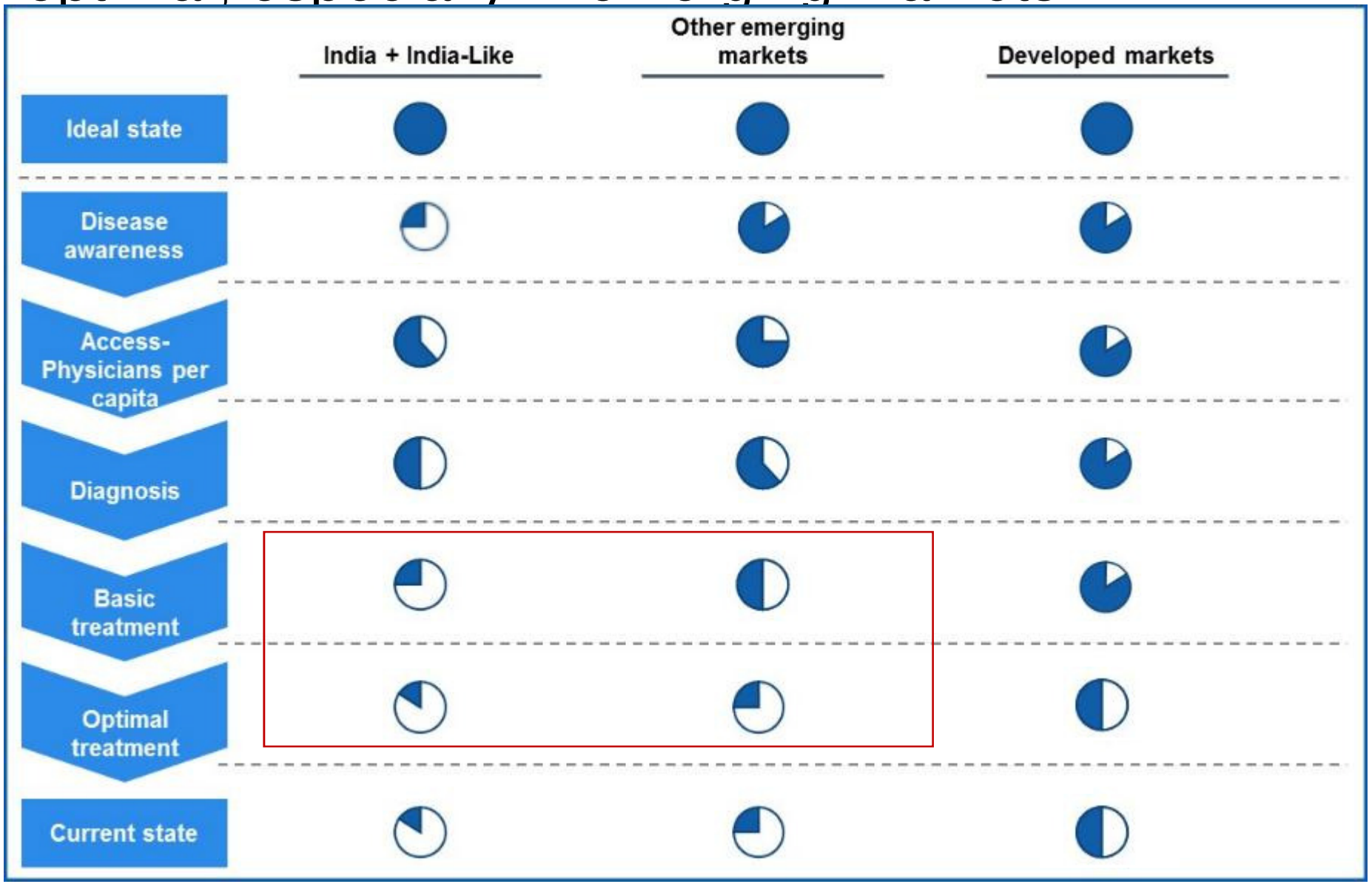
The impact of Healthcare expenses ….



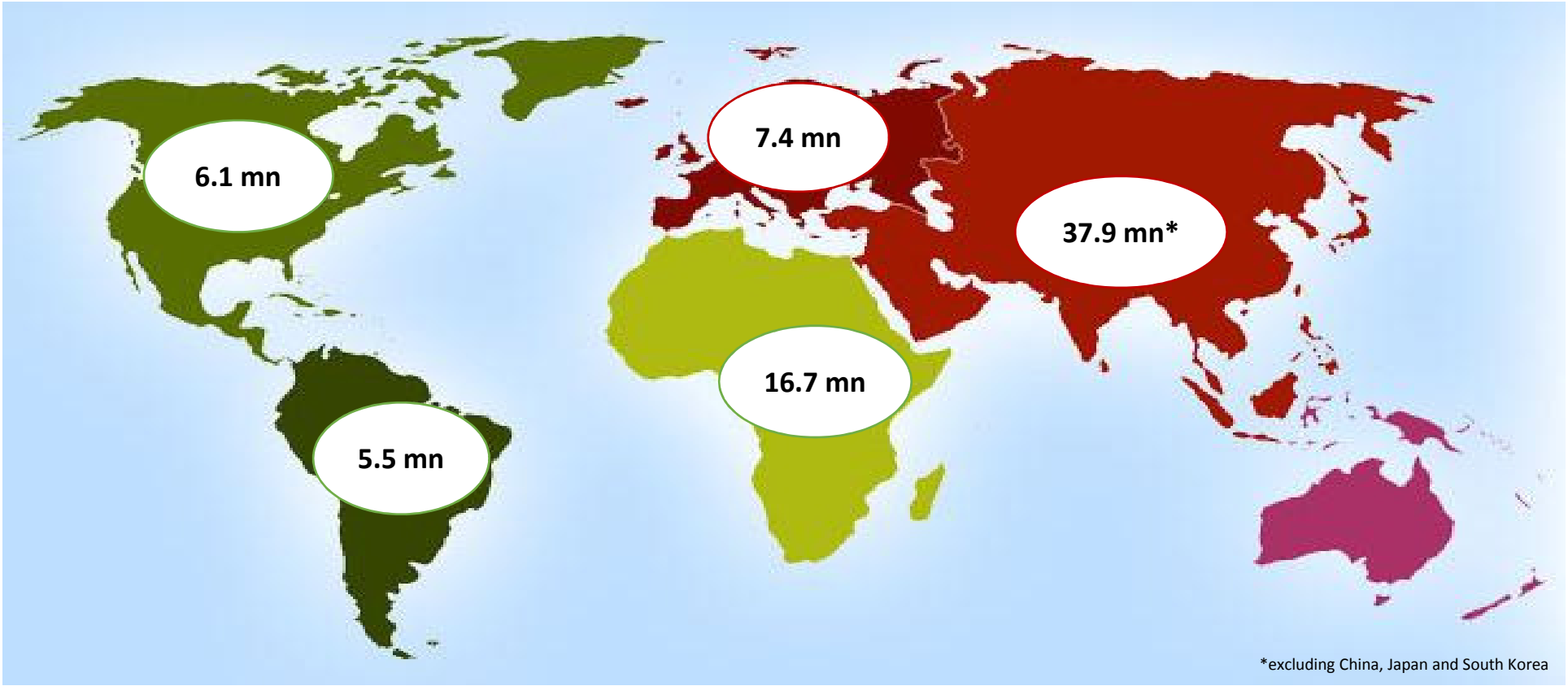
Why we need biosimilars



Global access to biologicals currently is far from optimal, especially in emerging markets

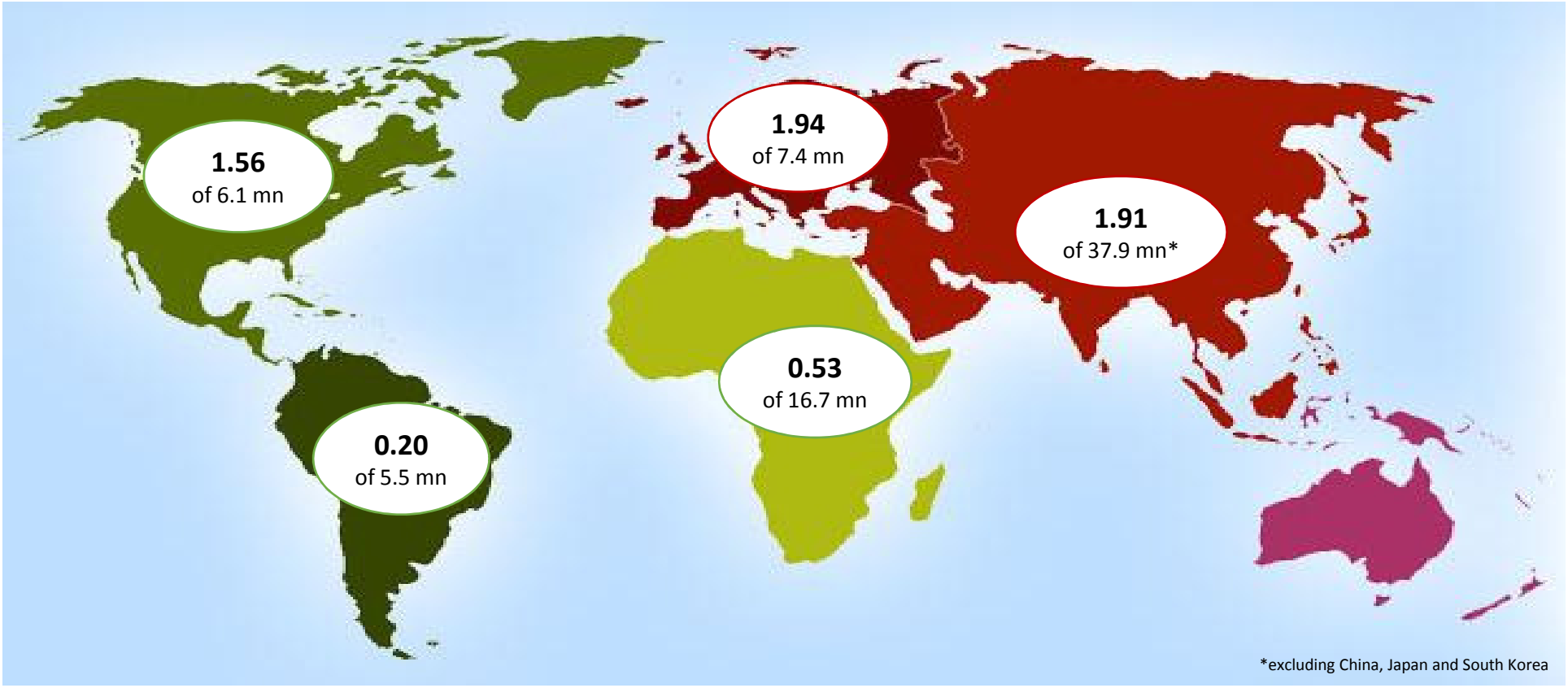


Worldwide more than 74 Mn patients should be on biological therapy



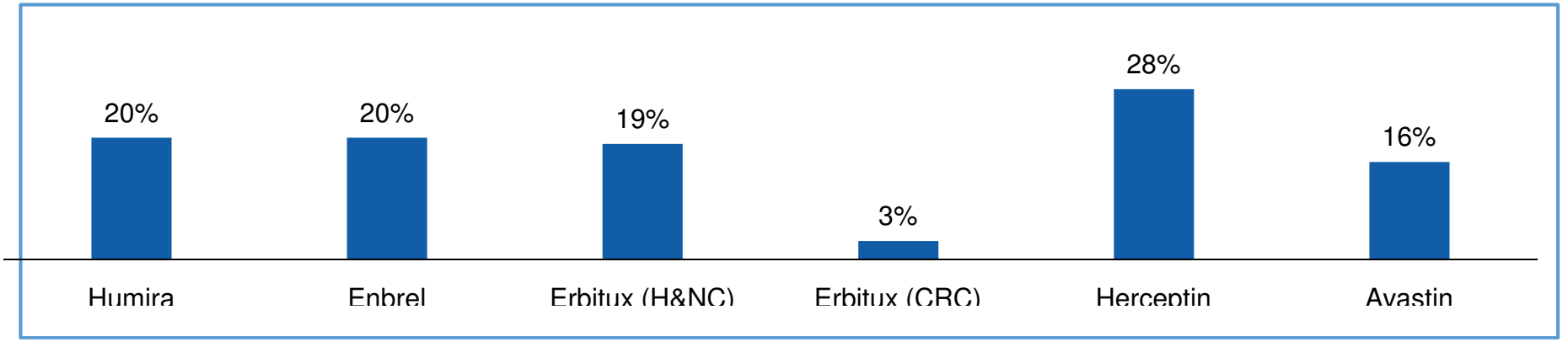
For diseases such as Breast cancer, Colorectal cancer, Head and Neck cancer, Rheumatoid arthritis, psoriasis etc….

However only ~8% being treated, with still lower levels in Emerging markets



Biologic drugs…still have a low penetration

% of addressable US patients treated by blockbuster biologics is low to due high cost and limited access (2008)



To address this gap

BIOSIMILARS

Comparable in quality, safety and efficacy
Affordable versions of innovator biologic drugs

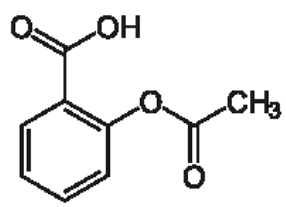
Biosimilars can potentially address the cost and access barriers created by innovator biologic drugs

Source: Industry reports, primary interviews

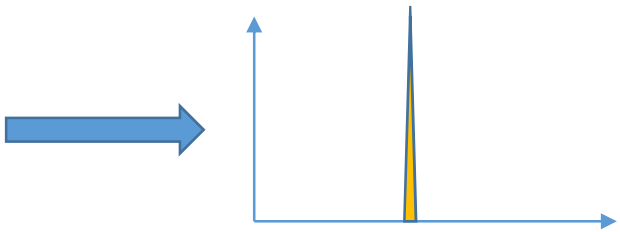
Key challenges



To be truly “biosimilar”, high technical expertise required - especially where structures are complex



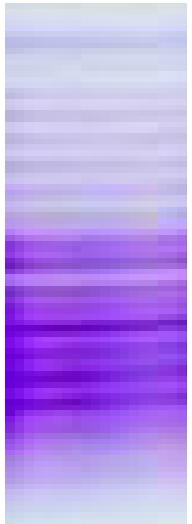
One drug



One peak

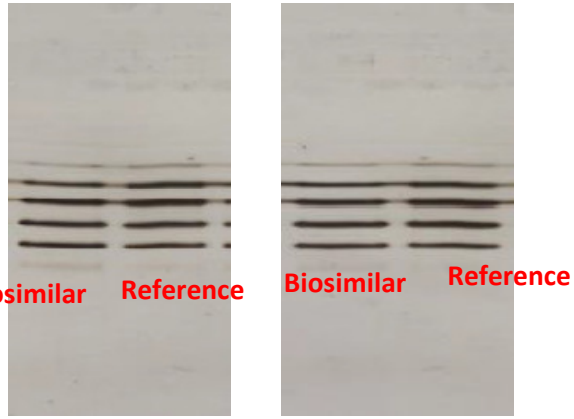


One protein

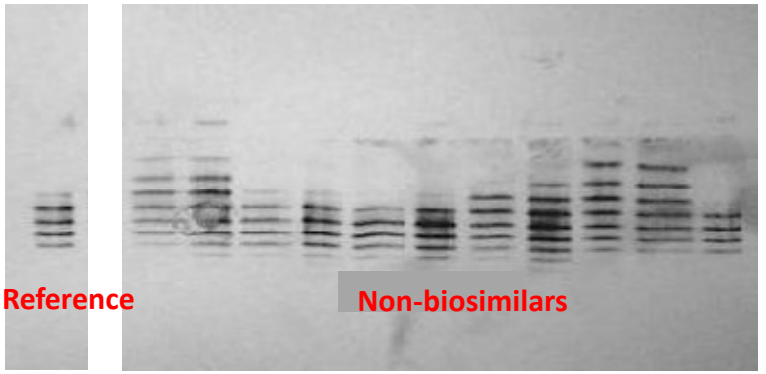


A mixture of isoforms

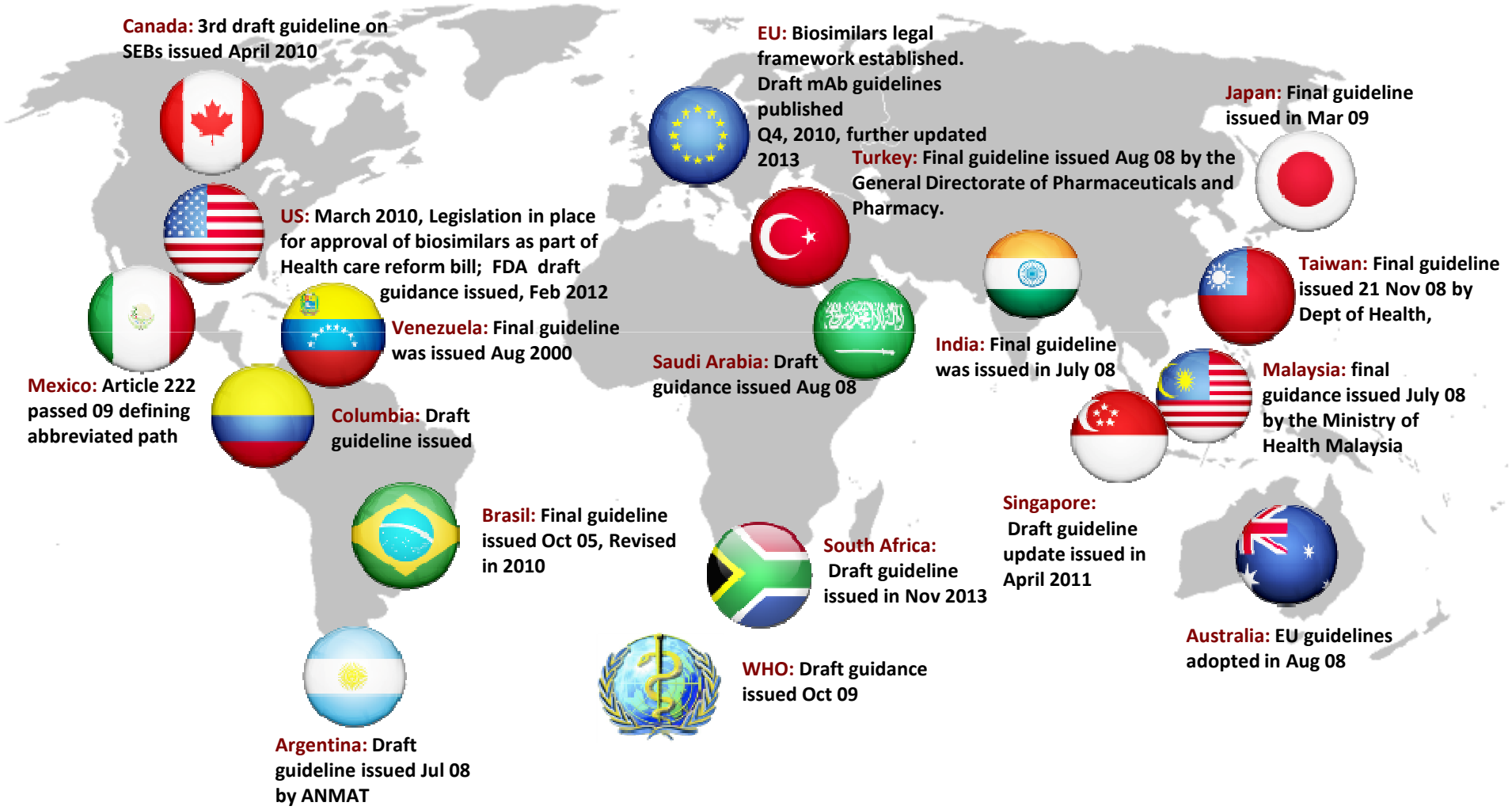
Biosimilars



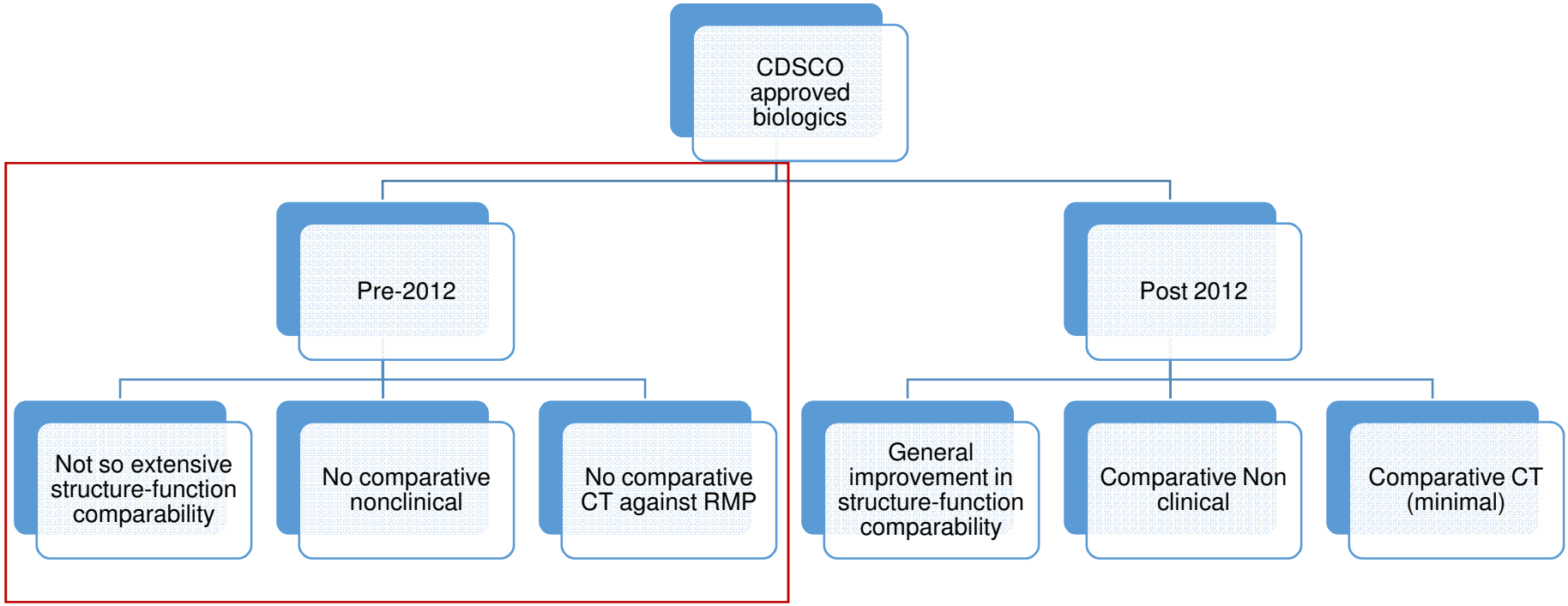
Non-biosimilars



Regulatory and clinical requirements rigorous, but ill-defined guidelines exist which vary across countries

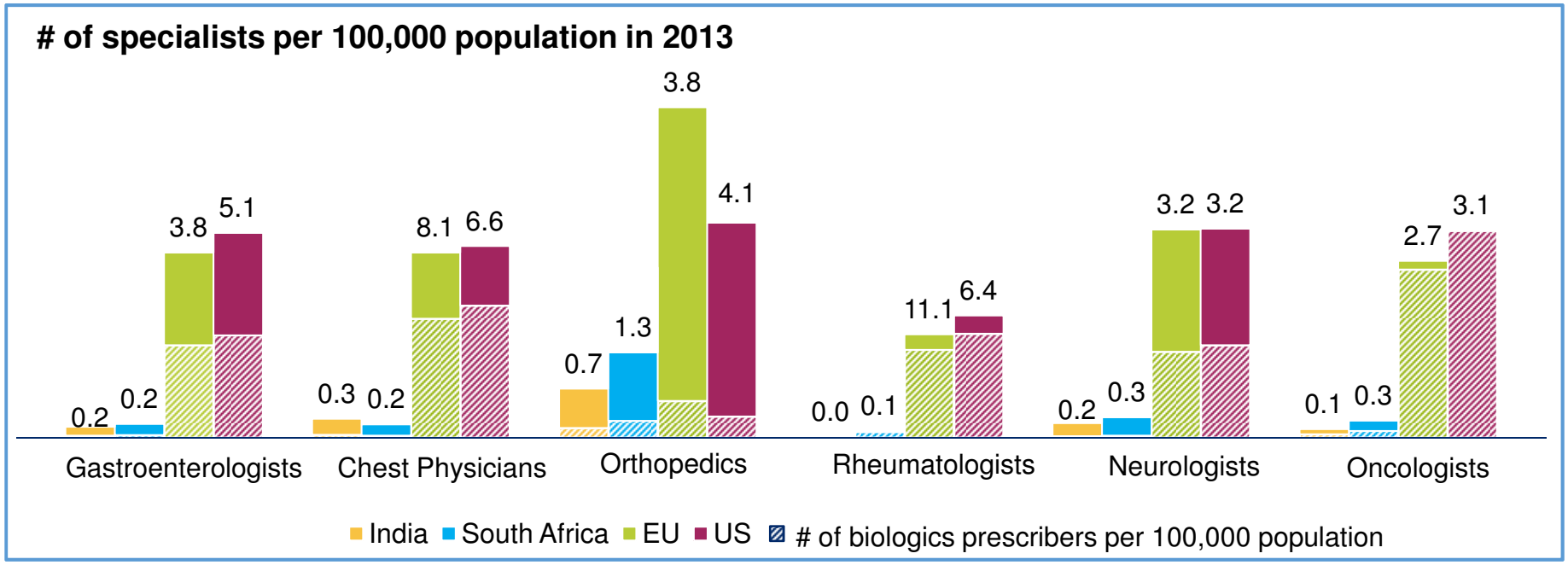


Regulatory environment in India for Biosimilars has changed since 2012

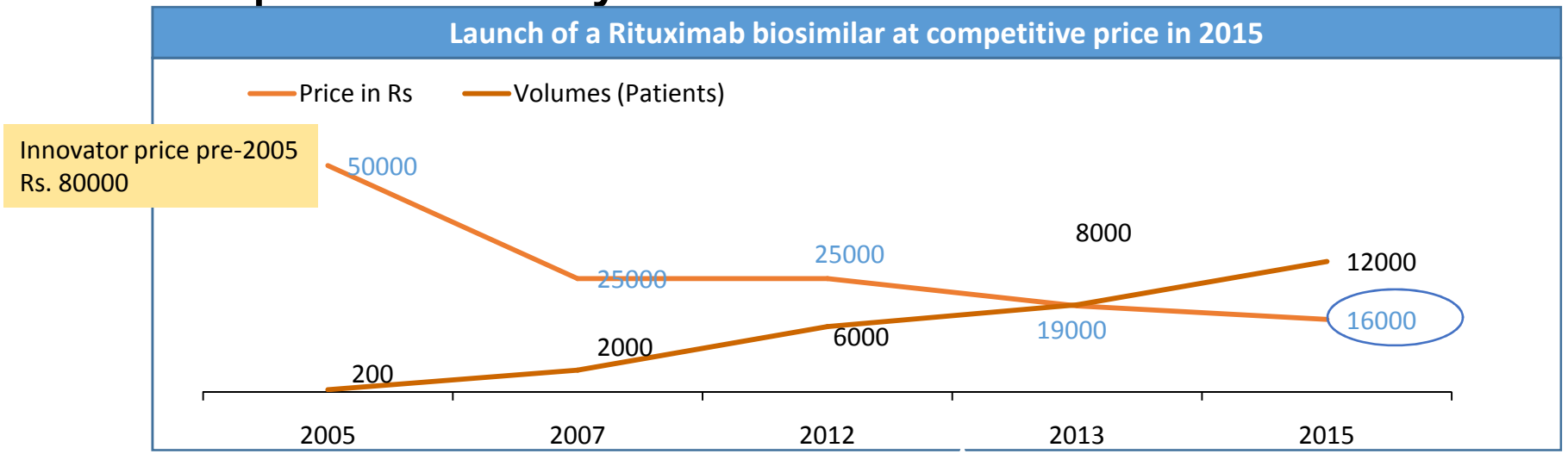


- Most of the cases the basic comparability package in terms of structure-function analysis and non clinical is absent
- Clinical trial is non-comparative
- Example: GCSF, EPO, DPO, Rituximab, Peg GCSF, Interferon etc.

Its important to have an overall functional healthcare system in place



Current levels of price drop with biosimilars still inadequate to truly create access



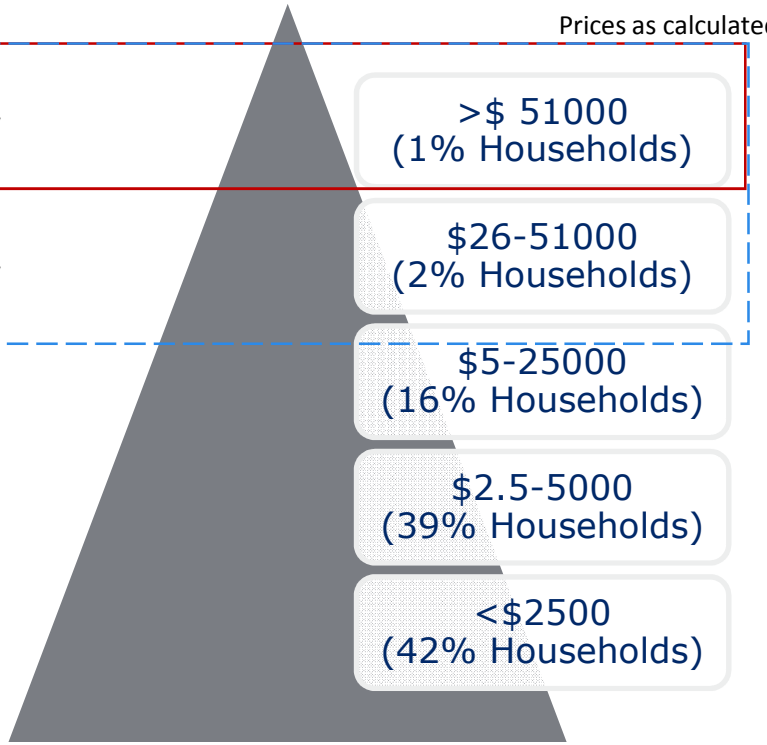
Prices as calculated for **500** mg / vial

2005

Rituximab – Annual avg. cost of therapy **$ 15,000**

2014

Rituximab – Annual avg. cost of therapy **$ 4,000**



1%

12%

Huge number of patients still not getting the full benefit of biosimilars….

In a nutshell…

Even if drugs were to be easily available and affordable, when we speak of patients getting access to biologicals, we need to ask ourselves:

- ✓How do we make sure there are enough physicians and paramedical staff to diagnose and treat patients with biologicals?
- ✓How do we make sure that patients are getting the right treatments at the right time in the correct doses?
- ✓How do we make sure that biologicals reach patients/hospitals where administered?
- ✓How do we ensure that they are stored correctly through out the supply chain?
- ✓Are we truly bring them within the reach of many and not just beyond the privileged few?
- ✓What are the measures in place to make sure that the drugs are safe for patients to use?

Only if we are addressing these questions will the true value of biosimilars be fully realised

- **End of Presentation**

Thank you for your kind attention

Your questions are welcome