International Federation
of Pharmaceutical
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IFPMA

Foro Sobre Medicamentos Biológicos

Retos regulatorios, científicos y económicos

Madrid, 13 de Marzo de 2015

Biological Medicines Forum

Regulatory, Scientific and Economic Challenges

Madrid, 13 March 2015

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Establishment of Similar Biotherapeutic Product (SBP) Guidelines has increased driven by WHO efforts*

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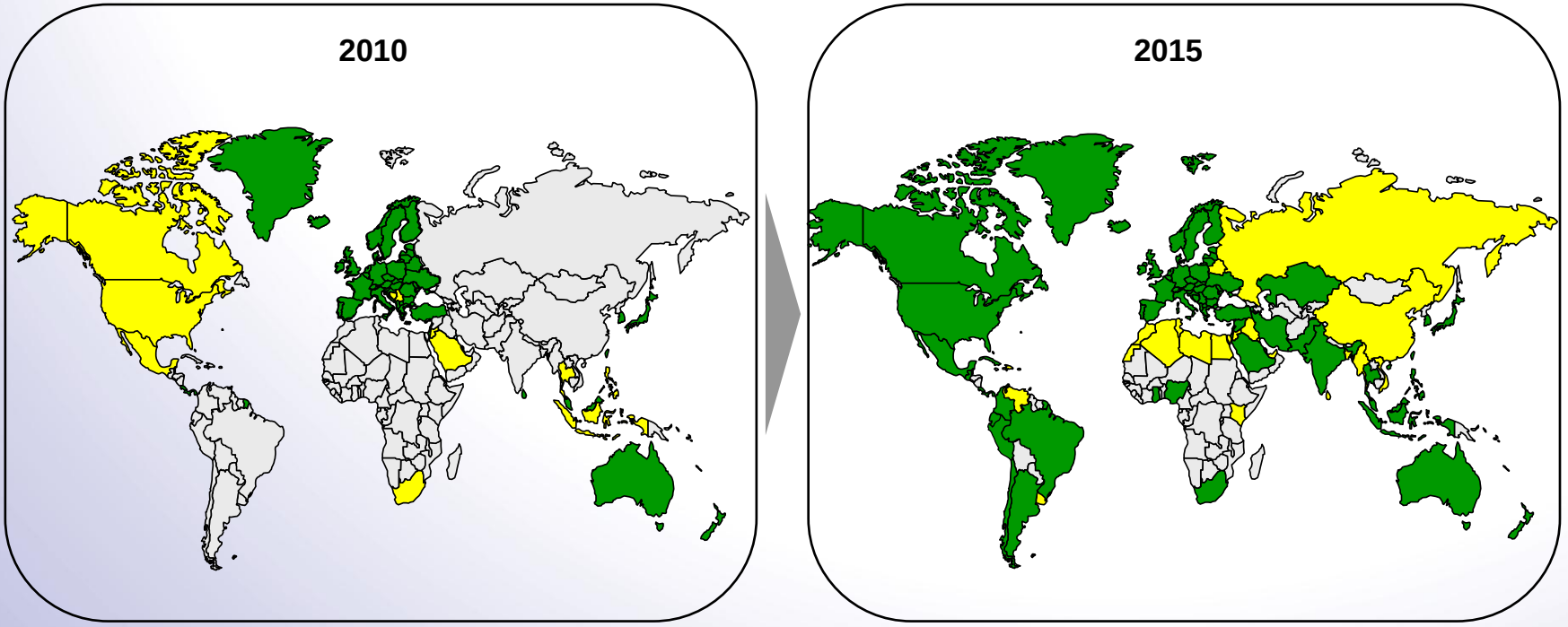
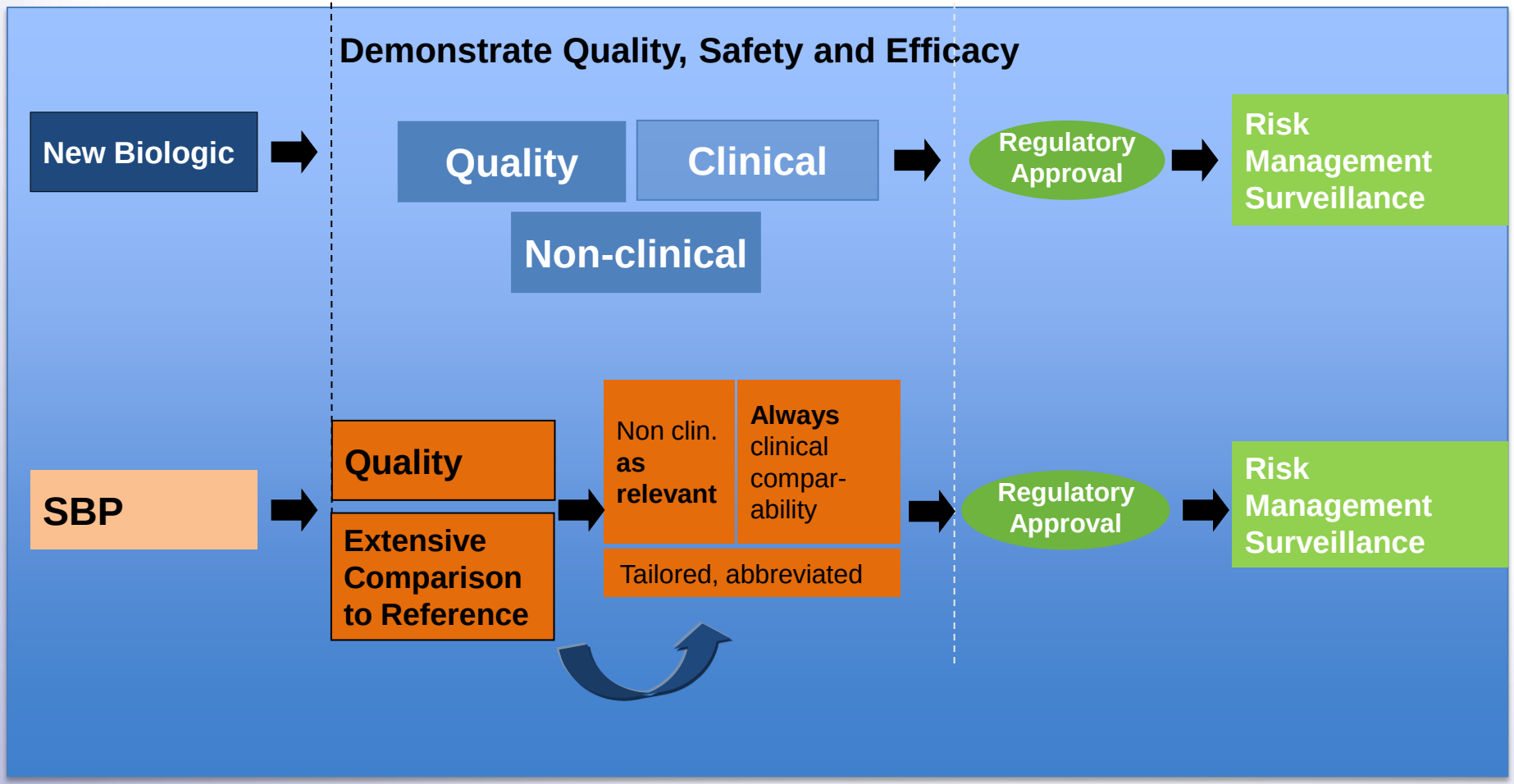
Large variability in adoption by National Regulatory Authorities



*Also known as “biosimilars”

Scientific basis for abbreviated biosimilarity pathway



Building knowledge and capacity at National Regulatory Agencies in emerging markets will increase adoption and convergence

67th World Health Assembly Resolution to promote access to biotherapeutic products (BTPs), including SBPs, and ensuring their quality, safety and efficacy*

*http://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R21-en.pdf

Call to Action for Member States

- **Develop and strengthen national regulatory** assessment and authorization frameworks to meet public health needs
- **Access** to BTPs, including SBPs, is important for patients **and new national regulations should not constitute a barrier**
- **WHO Guidelines may be adapted to the national context** and capacity

Implications

- Acknowledgment of **regulatory capacity gaps** in emerging markets
- **Regulatory robustness might be compromised** for access and local economic interest
- **"3rd pathways"** for approval of SBPs might be developed

Biotherapeutics – a more complex mix (derived from living material)

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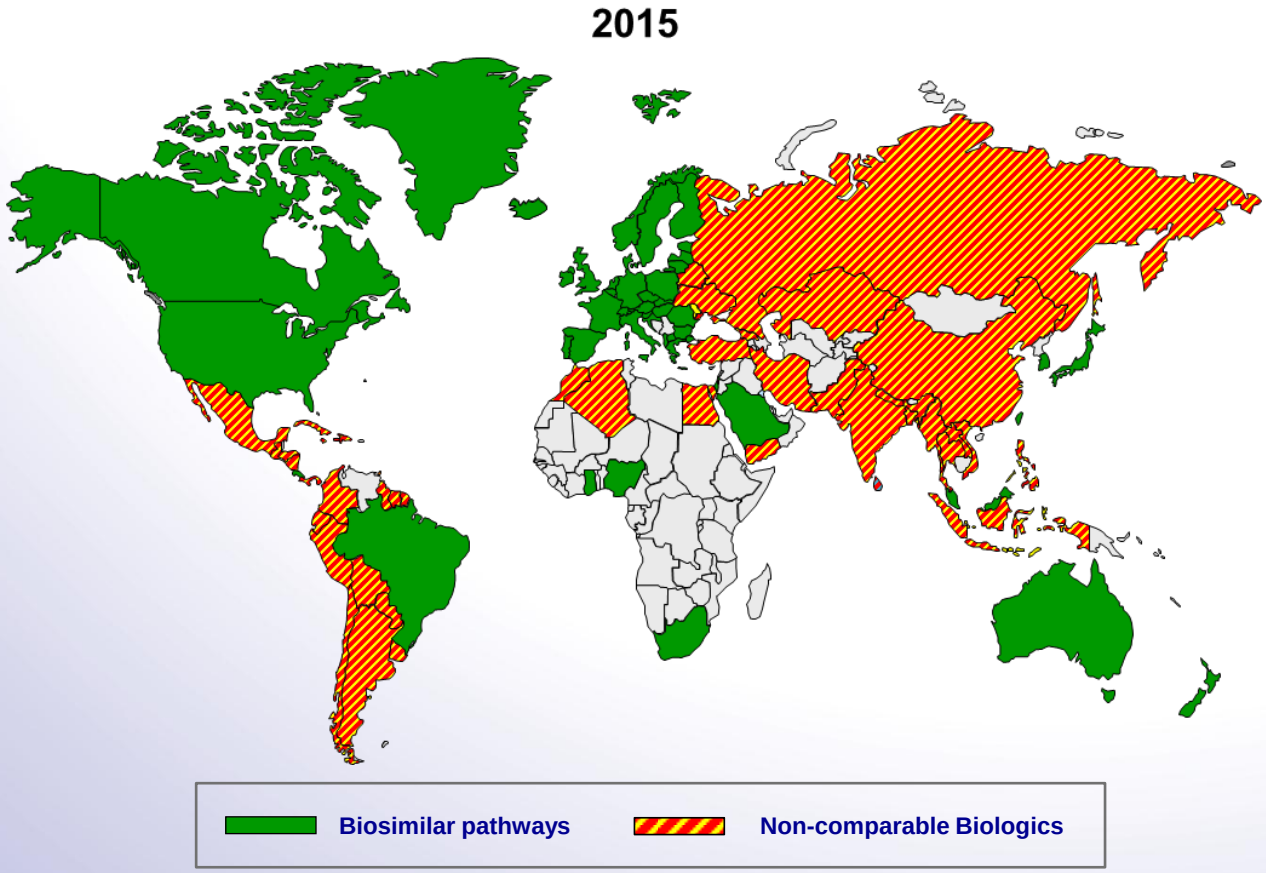
Innovator Biotherapeutic	SBP	Non-comparable Biotherapeutic
• Novel product, generally with patent protection • Marketing authorisation through full regulatory dossier	• Product highly similar to an innovator biotherapeutic that has already been authorized (reference medicinal product) • Subject to a tailored regulatory data package establishing biosimilarity through comprehensive comparability exercise	• Product that is not approved in accordance with the WHO SBP Guidelines, e.g. – Product developed on its own and not directly compared and analyzed against a licensed reference product – May or may not have been compared clinically – Can be subject to regulatory approval, but in some settings of a more abbreviated nature – Products with unclear approval standards

Emerging trends

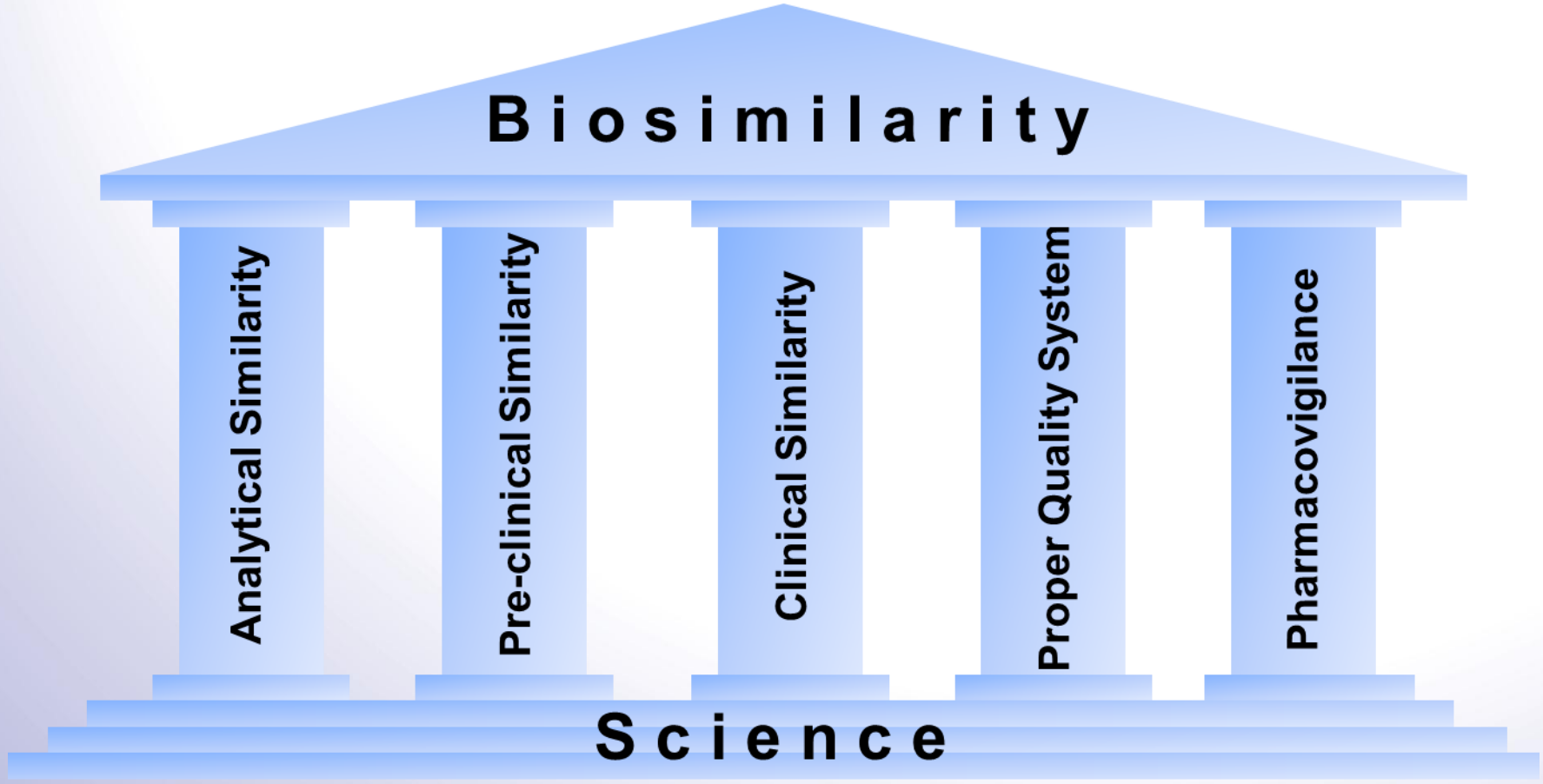
Access and local economic development will drive increase in Non-comparable Biotherapeutics



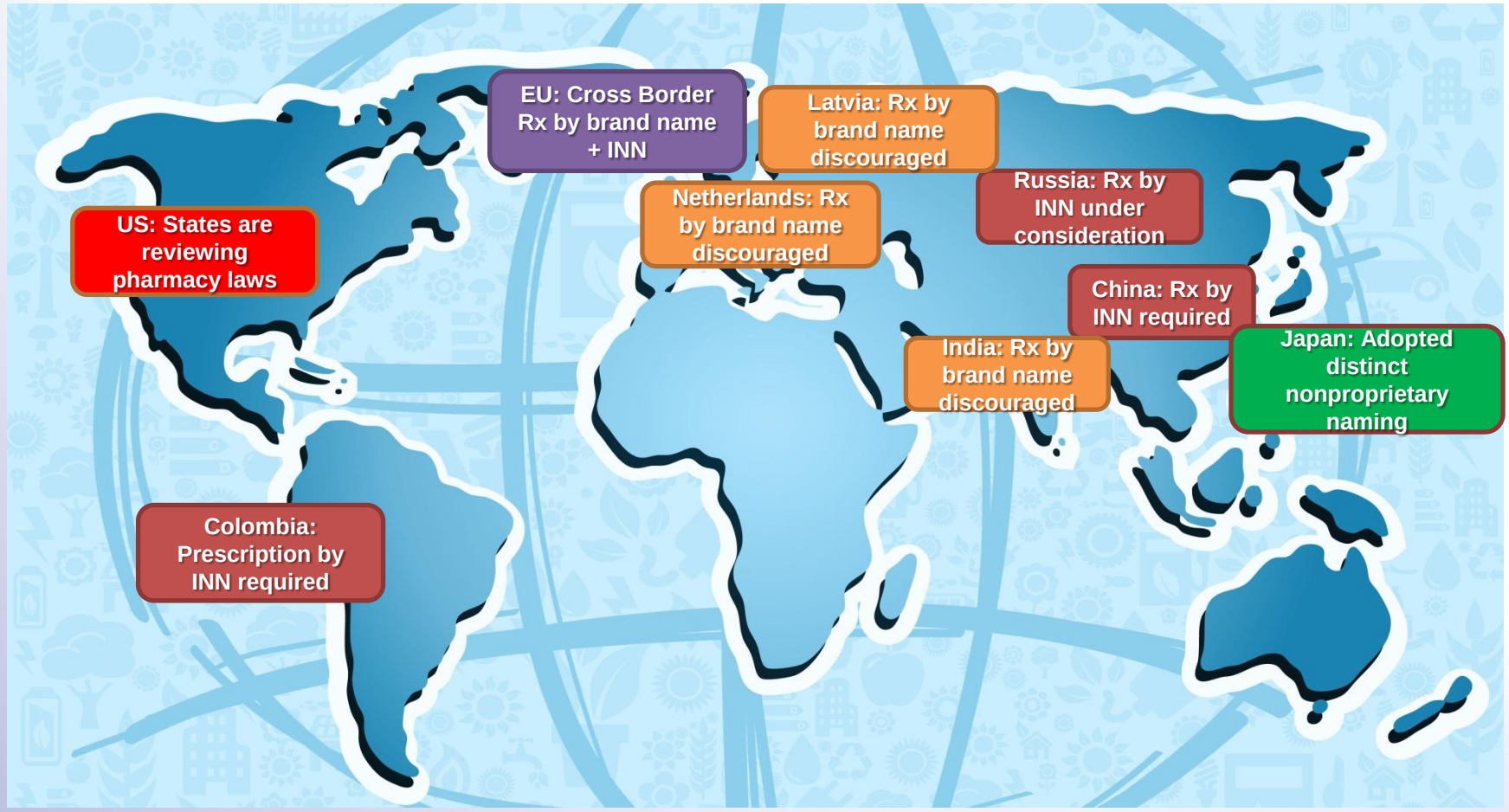
Pharmacovigilance today

- Systems developing at different rates, with different requirements
  - Many countries still without strong pharmacovigilance systems
  - International Nonproprietary Name (INN) system weakening, different approaches to naming at national levels
- Focus on the development of comprehensive pharmacovigilance systems including**:**
  - Need to establish basic pharmacovigilance guidance to ensure patient safety
  - Improving identification, naming of products, record keeping
  - Increased emphasis on robust adverse event collection/reporting, surveillance, signal detection and evaluation
  - Focus on risk in context of benefit
    - Important to take the entire prescription/dispensing/using/ADR reporting chain into consideration for traceability

Pharmacovigilance is a key pillar in concept of biosimilarity



Varying prescribing practices of biotherapeutics have implications for traceability (not comprehensive overview)

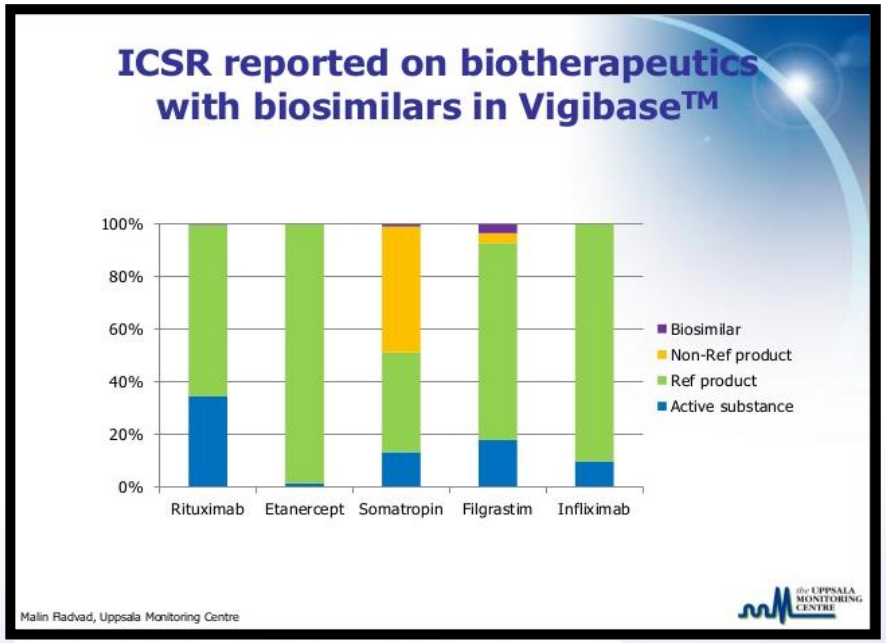


Issues addressed by the Biological Qualifier (BQ)

- Many countries world-wide use INN for **prescribing and dispensing** for biotherapeutics
  - In the US, trade names are not required for SBPs, so some biotherapeutic**s** prescription and dispensing may rely on the nonproprietary name

- In Europe, where brand/trade name is recommended for prescribing and dispensing biotherapeutics, recent evidence demonstrates that non-proprietary names are still extensively used*
- Global variations in policy and practice are reflected in reporting outcomes

*** 2014 UK study of 120 oncologists, rheumatologists and pharmacists. Conducted by Medix Ltd, on behalf of the Association of the British Pharmaceutical Industry, http://www.abpi.org.uk/Pages/default.aspx**



Latin America Conference on Biotherapeutic Medicines Experience: Sharing Experiences and Best Practices Nov 19-20, 2013, Lima, Peru

Summary

- **WHO continuous to drive global efforts for the global implementation of SBP Guidelines**
- **Building knowledge and capacity at national regulatory agencies in emerging markets is critical for proper adoption and global regulatory convergence and harmonization**
- **Pharmacovigilance** is an essential part of understanding and managing the risk and benefit of any medicinal product – particular importance for biologics
- Pharmacovigilance is also a key pillar in the concept of **biosimilarity**
- **Product-level traceability** is a prerequisite for effective pharmacovigilance
  - Globally accepted BQ could provide an effective means to deliver for all biologic medicines