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WHO Biological Qualifier Proposal: a key opportunity to advance global identification and pharmacovigilance

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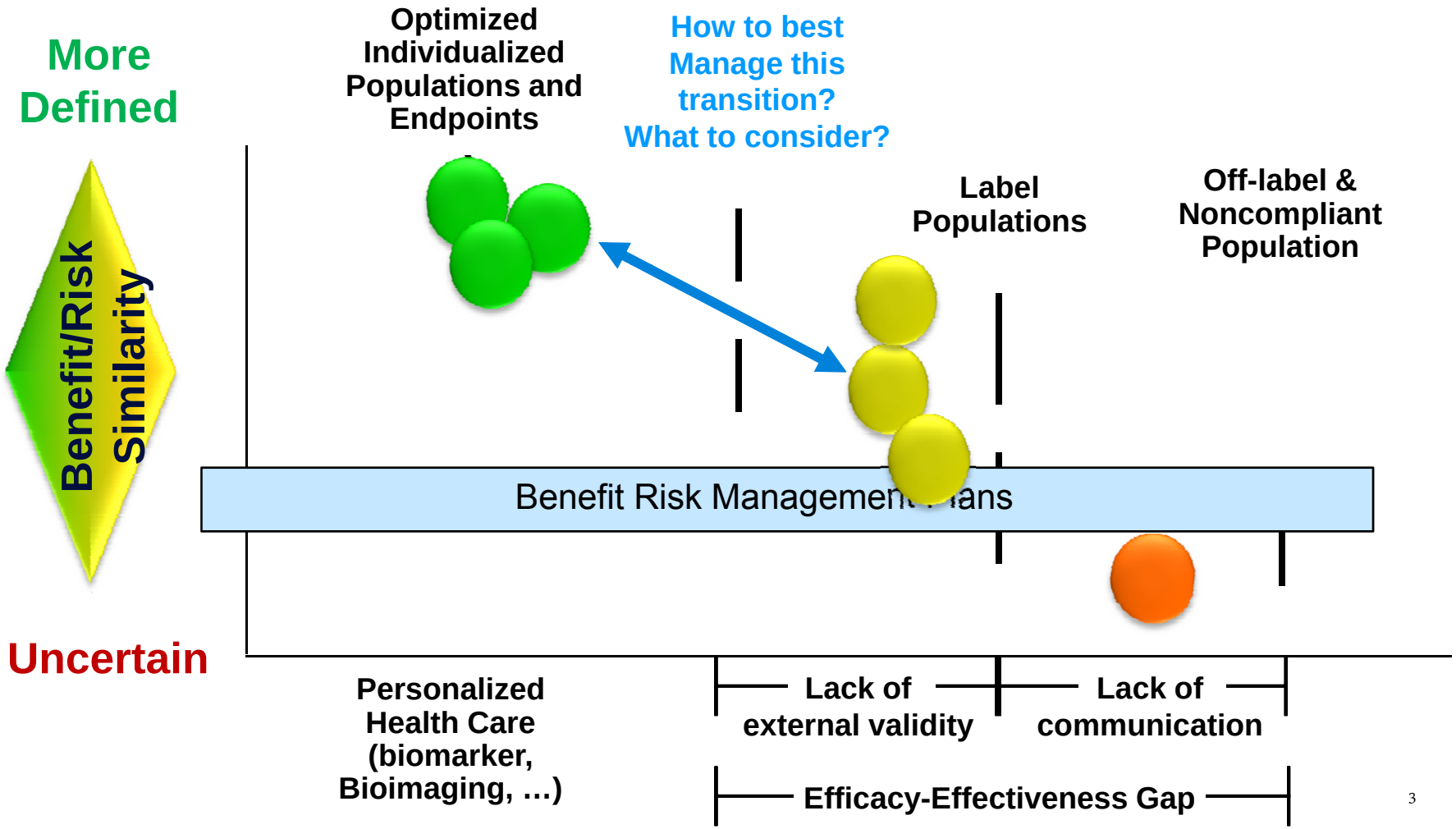
Risk mitigation strategies – Crucial for all Biologics but even more for/in case of Biosimilars?



Adapted from Thomas Lundgrenn (DIA QPPV Forum, 17-18 April 2013)

Biotherapeutics – an even more complex mix

Innovator Biotherapeutic

- Novel product, generally with patent protection
- Active substance derived from living material
- Usually based on protein/nucleic acid
- Marketing authorisation through full regulatory dossier

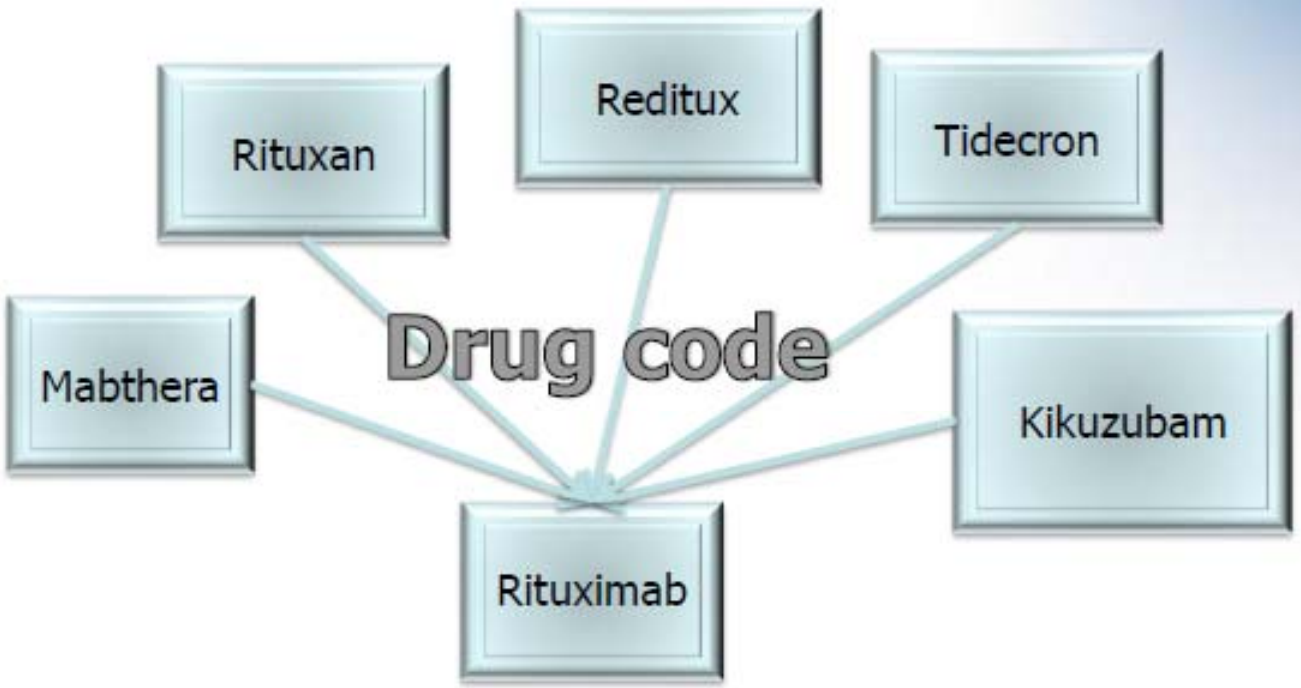
Similar Biotherapeutic Product (SBP)

- 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

Non-comparable Biotherapeutic

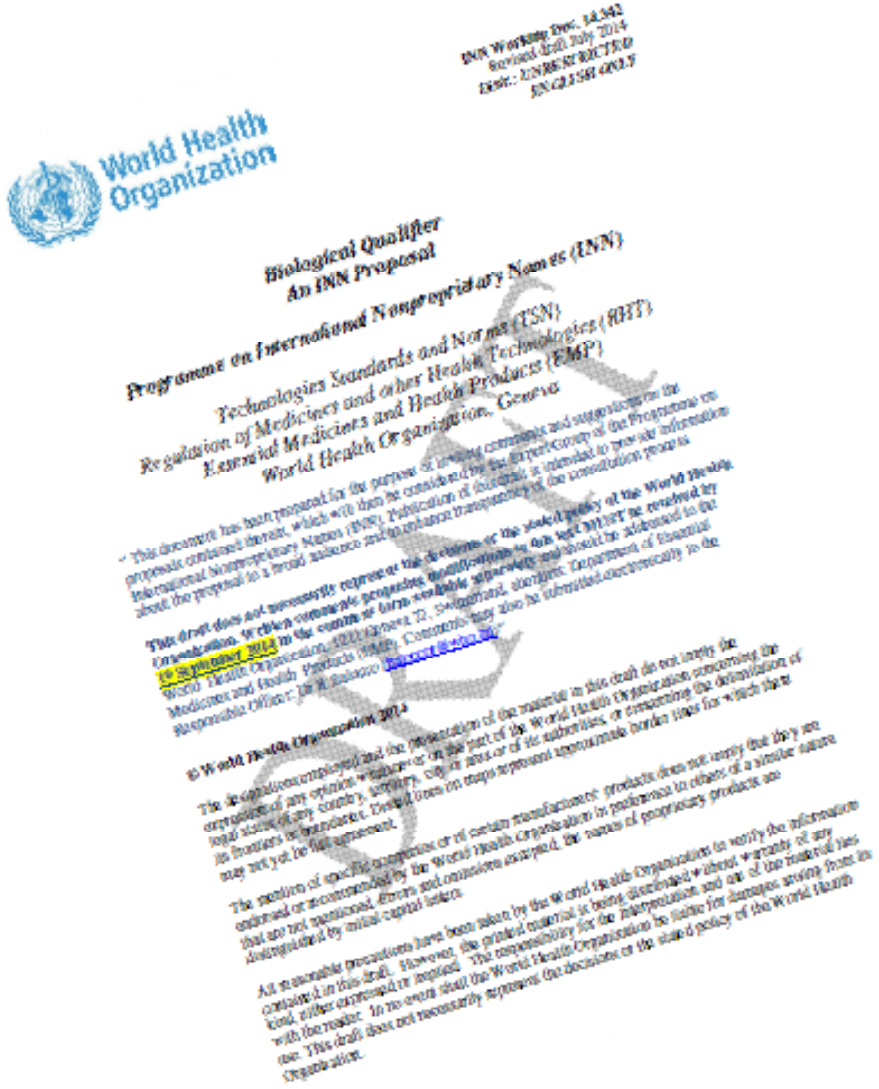
- Product that is not approved in accordance with the WHO SBP guidelines, e.g.
  - Product developed on its own and not directly compared and analyzed against a licensed reference product
  - May or may not have been compared clinically.
  - Can be subject to regulatory approval, but in some settings of a more abbreviated nature

The added value of WHO Drug Dictionaries



INN

WHO Draft Proposal on Biologic Qualifyer (BQ)



Biological Qualifier
An INN Proposal

Programme on International Nonproprietary Names (INN)

Technologies Standards and Norms (TSN)
Regulation of Medicines and other Health Technologies (RHT)
Essential Medicines and Health Products (EMP)
World Health Organization, Geneva

(1) http://www.who.int/medicines/services/inn/bq_innproposal201407.pdf, accessed July 30 2014

WHO Proposal for a Biological Qualifier (BQ)
Key opportunity to advance global identification and PV

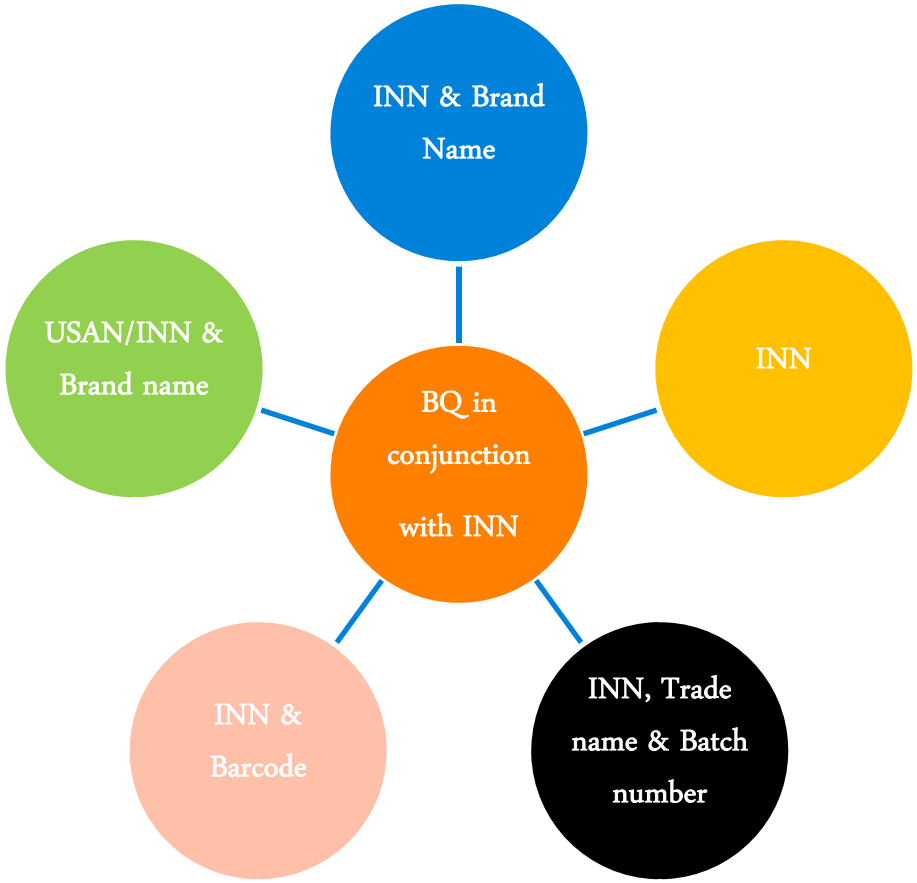
- Following discussions going back to 2010, the WHO INN Expert Group has now published a proposal for a Biological Qualifier
  - At the request of several regulatory authorities
  - **Unique Identifier (= random 4 letter code)** – not part of the INN but used in conjunction with the INN for all biological substances that are assigned INNs
  - **Voluntary scheme, prospectively and retrospectively globally applied to all biotherapeutics**

Industry welcomes Biological Qualifier proposal

- **Industry is supportive of WHO's efforts** with respect to development of a coding system that includes a BQ
  - Unifies and facilitates unique product identification and pharmacovigilance (PV)
- **Industry recommends** that the BQ should be:
  - Given to all biotherapeutics' active substances
  - Globally consistent and durable
  - Linked to the parent company/entity responsible for the licensure globally
  - Non-discriminatory in its application
  - Independent of a regulatory pathway

The BQ proposal has elements to meet the above needs.

Biological Qualifier – a unique and valuable link for (global) PV



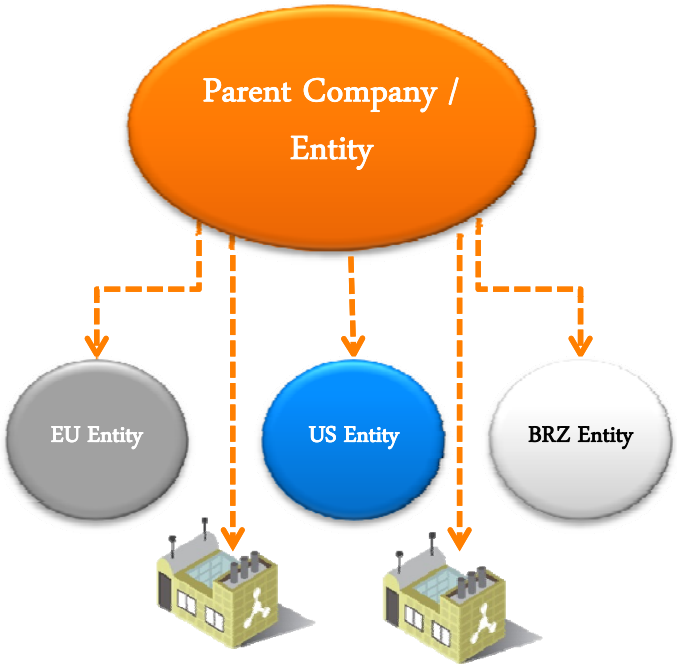
- PV requires accurate and shared monitoring of signals
- Variety of reporting requirements for ADR globally
  - Only one region specifically addresses biotherapeutics
- Within countries and regions, excellence in PV
- Critical goal is to link these systems globally
- **BQ provides this unique global link, enhancing oversight of patient safety**

BQ and the basis for identification

- Aim is to uniquely identify and link given licensed biotherapeutic active substance using a common global standard
- **Current WHO Proposal:** BQ assigned to a biotherapeutic active substance manufactured at a specific site
  - If manufactured at more than one site, same BQ code applied to alternative sites authorized within the same regulatory jurisdiction
- **Industry concerns**: linking to manufacturing site **will cause unnecessary and confusing proliferation of BQs** related to the same active substance
  - Would increase complexity of global supply chain

Linking to manufacturing site adds complexity and confusion; alternative basis for identification needed.

Industy Proposes to link BQ to Parent Company/Entity



Parent Company / Entity as the global consolidator:

- **Entity responsible for pharmacovigilance** and the global safety database
- Ultimately and **legally accountable** for drug substance as well as finished product
- **Supported by country/regional affiliates** and manufacturing sites for safety measures and pharmacovigilance in their region.

Linking the BQ to the parent company rather than the manufacturing site would:

- ✓ **reduce confusion and proliferation of BQs**
- ✓ **decrease complexity within the global supply chain**
- ✓ **assign clear responsibilities regarding product tracking and pharmacovigilance**

If BQ is implemented it should be done globally

- Industry recognises this is a **voluntary system** that DRAs elect to adopt in order to prevent further complexity in identification
  - To realize the full potential of this INN Proposal, **we strongly support global harmonization efforts** around nonproprietary naming of biotherapeutics
- WHO should consider developing educational workshops for DRAs to support the implementation of the BQ in healthcare systems
  - **Consistency in the use of BQ across countries**
  - **BQ used in conjunction with the INN**
  - **Capture feedback from DRAs and areas for additional support**
  - **DRAs adopting the BQ scheme should require applicants to apply for BQ prior to marketing authorization**
  - **BQ adoption should not delay regulatory approval**

Summary

- **Industry continues to support the implementation of the BQ**
  - We welcome further discussion and revising of the scheme and its application
- Focus should be on **refining the proposal** to ensure the intended outcomes are achieved:
  - **Unique global identifier to be used in conjunction with the INN**
  - **As a tool for PV**
  - **Link to case reports**
  - **Identification & signal detection**
- **Linking the BQ to the parent company/entity** instead of the manufacturing site is the means to avoid unwanted complexities / multiples of BQs / confusion; consideration of shorter code welcomed
- Once adopted, WHO, DRAs, applicants and other stakeholders need to work together to ensure **BQ is used consistently and on a global basis in conjunction with the INN, wherever the INN is used**


Thank You !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