

Innovative Medicines for Malaysia

1ST NATIONAL BIO-THERAPEUTICS CONGRESS - PUTTING PATIENT FIRST

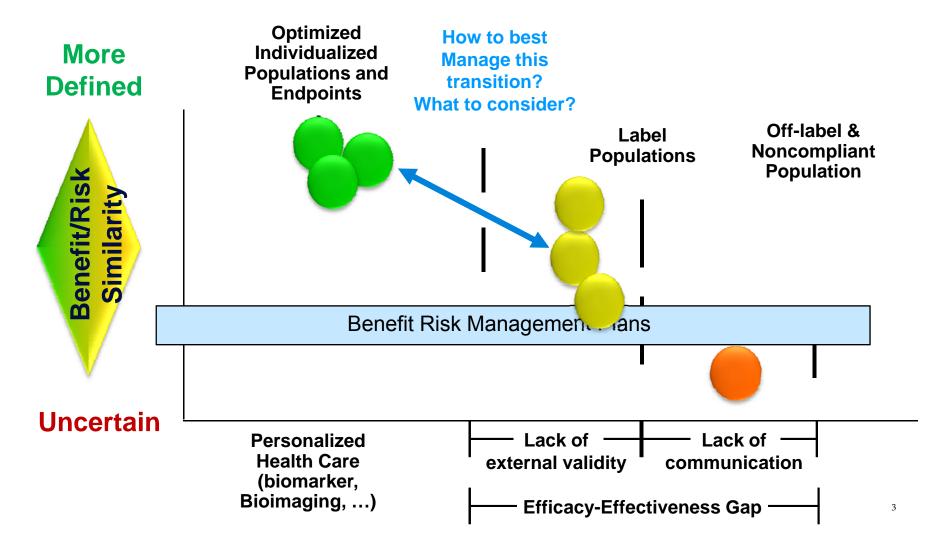
22 NOVEMBER 2014

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

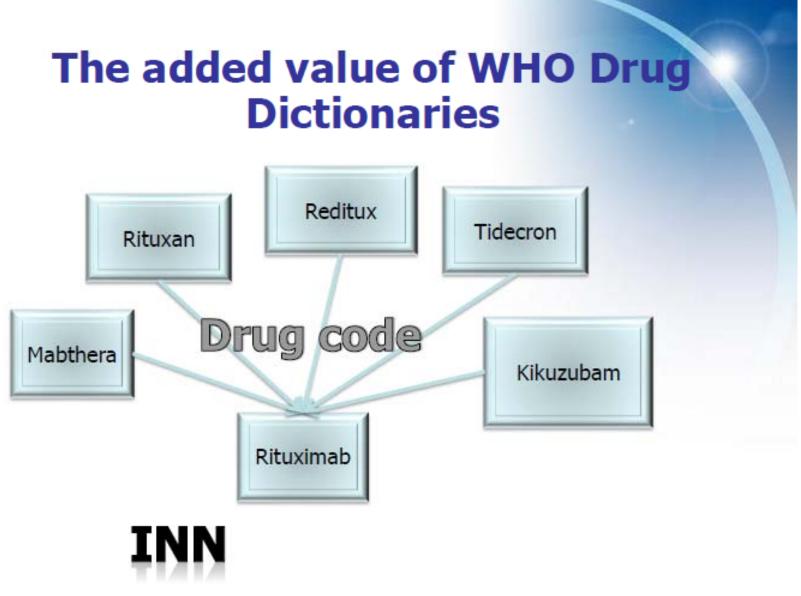
- Novel product, generally with patent protection
- Active substance derived from living material
- Usually based on protein/nucleic acid
- Marketing authorisation through full regulatory dossier

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

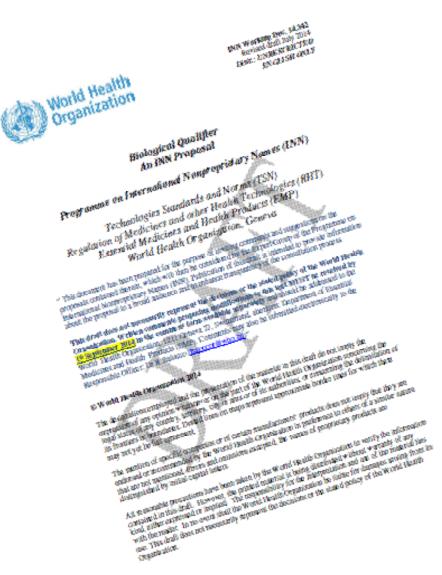
Non-comparable Biotherapeutic

- 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





WHO Draft Proposal on Biologic Qualifyer (BQ)



(1) http://www.who.int/medicines/services/inn/bg_innproposal201407.pdf, accessed July 30 2014

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

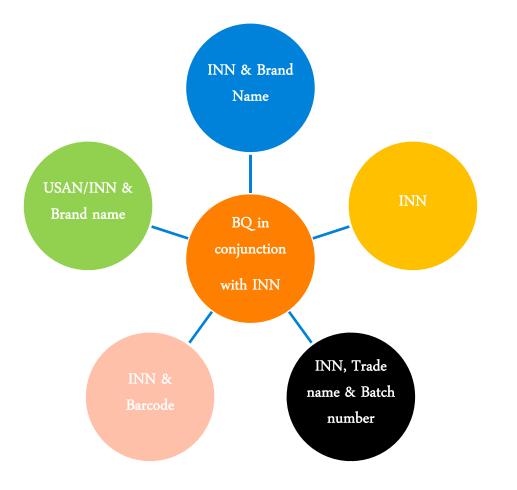
- Following discussions going back to 2010, the WHO INN Expert Group has now published a proposal for a Biological Qualifier
 - At the request of several regulatory authorities
 - Unique Identifier (= random 4 letter code) not part of the INN but used in conjunction with the INN for all biological substances 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 <u>all</u> biotherapeutics' active substances
 - Globally consistent and durable
 - Linked to the <u>parent company/entity</u> 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



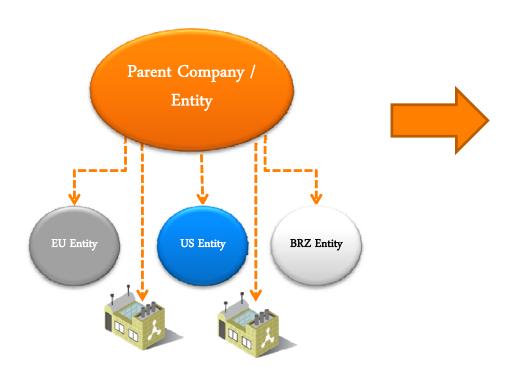
- PV requires accurate and shared monitoring of signals
- Variety of reporting requirements for ADR globally
 - Only one region specifically addresses biotherapeutics
- Within countries and regions, excellence in PV
- Critical goal is to link these systems globally
- BQ provides this unique global link, 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
- $\checkmark\,$ 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
 ³ basis in conjunction with the INN, wherever the INN is used





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