Regional Update on Naming Developments for Biotherapeutics, incl. Biosimilars

IGBA Position

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Introduction

- **IGBA presents its Position on Regional Naming Developments for Biotherapeutics, incl. Biosimilars**
  - Latest developments in EU, US, Australia and Canada
  - Tracking and tracing can be ensured with a proper identification through product name and batch number
  - WHO Biological Qualifyer (BQ) or any introduction of suffixes are not a viable option to improve pharmacovigilance activities

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EU has implemented a thoughtful and successful system for track and trace of all medicines

- **EMA adopted a guideline to enhance pharmacovigilance for biological medicines:**
  - the **product name and the batch number** have to be included in adverse event reporting and in all product packaging throughout the supply chain
- **Europe has the largest experience with biologicals, incl biosimilar medicines**
- **Data from EudraVigilance database suggests continuous robust levels of product identification of biologicals from European clinical practice**
  - an ongoing EMA study of ADR reporting from 2011-2016 revealed **overall 95,5% identifiability of classes of biologicals for which biosimilars are approved** [1]
  - EU has demonstrated that identification of biologics, incl. biosimilars, for adverse event reporting is possible for medicines sharing the same INN
- **Education of all stakeholders encouraging them on the proper reporting of adverse events is essential**

1. Dr. Elena Wolff-Holz, Understanding the Science of Extrapolation and Interchangeability, ESMO Industry Satellite Symposium 2017, Madrid, 8 Sept, 2017

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Australia: consultation on naming sought

- **TGA launched a Consultation on the Nomenclature of Biological Medicines and proposed 4 options:**
  - Status quo unchanged
  - Status quo plus improvements in public reporting of adverse events, e.g. mandatory inclusion of name and batch number in reporting systems and educational measures
  - Bar code system (as in EU after February 2019)
  - Introduction of suffixes
- **IGBA submitted comments supporting proper identification (name plus batch number) of all biological medicines, incl. biosimilar medicines**
  - increased education on reporting product name and batch number is key for successful tracking and tracing of any medicinal product
  - full submission available on IGBA website
- **TGAs alignment with the EU would be consistent with TGAs practice of adopting EMA guidelines and the Australian Government policy to increase the use of affordable biosimilar medicines.**

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U.S.: inconsistent naming decisions

- **“Nonproprietary Naming of Biological Products” issued January 2017 (final)**
  - “FDA’s naming convention for biological products licensed under the PHS Act will be a proper name consisting of a core name and an **FDA-designated random four letter suffix**, e.g. replicamab-cznm
  - “...is warranted for both **newly licensed and previously licensed originator biological products, related biological products, and biosimilar products**.”
- **7 Biosimilar products approved, all with a 4-letter random suffix**
- **11 originator biologics approved since January 2017 – all without a suffix!**
- **This can only be interpreted as discriminative towards biosimilar medicines – all approved according to very stringent FDA requirements**
- **IGBA points out, this imbalance between originator biological products and biosimilar products CANNOT effectively „improve“ the U.S. pharmacoviligance system**

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Canada: consultations on naming anticipated

- **Health Canada continues to use same INN for biosimilar and reference products**
- **Health Canada is following global naming developments closely, including developments in the United States**
- **As a priority for 2017/18 Health Canada plans to consult with stakeholders on the development of a domestic naming policy**
  - Status quo (i.e. use of same INN) is an option that will be under consideration

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IGBA strongly supports same INN

- **A biosimilar medicine contains a version of an already approved active substance with no clinically meaningful differences – just like any version of the originator product after a significant manufacturing change**
  - Additional suffixes cause confusion among stakeholders (healthcare professionals, patients and insurers/payors) and undermine the biosimilarity concept
- **EU has demonstrated that proper identification can be ensured for products sharing the same INN**
- **There is no data available that demonstrates that added suffixes in the U.S. will improve the U.S. pharmacovigilance system**
  - We request consistent naming for biologic medicines, including biosimilar medicines
- **Increased educational measures towards all stakeholders and proper ADR reporting are key**

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