IGBA Position on Identification of Biological, including Biosimilar Medicines

2019 Update of Facts & Figures

16.06.2019
IGBA Position
Successful traceability and identification are possible without an additional identifier

• No additional identifier is needed for successful traceability and identification in case of adverse event reporting and both are possible in a framework where biosimilar products and their respective reference products share the same International Non-Proprietary Name (INN)

• **Unique identification** of a medicinal product is ensured either with
  - Invented/"brand" names
    • or
  - INN + MAH (especially in countries with INN prescribing or where an invented/"brand" name is not available or not legally enforceable)
    • Marketing Authorisation Holder (MAH) is responsible for Pharmacovigilance

• It is the worldwide implementation of the WHO standards and the strengthening of national pharmacovigilance systems, and not an additional identifier, which will support patient safety and public health.
2019 Update
Supporting Facts & Figures
EU EudraVigilance demonstrates that identification is possible without a BQ

• 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
• EU approved biosimilar medicines have generated more than 700 million patient days of safe clinical experience
• The Vermeer study (Vermeer et al. Drug Safety (2013) 36: 617—625) reviewed over 2 million unique ADR reports in the European Union Eudravigilance system from 2004-2010, with product attribution rates ranging from 90-96%

[2] Biosimilar Medicines Clinical Use: An Experience Based-EU Perspective
2011-2016 study revealed that adequate identifiers were reported for 96.7% of the suspected Biologicals.

Product identifiability remained consistently high over time for classes of biologicals for which biosimilars were introduced.

European system for identification of ADRs to the level of the manufacturer is robust.

A Dec. 2017 publication systematically reviewed the periodic safety update reports (PSURs) of 3 biosimilars marketed worldwide for the assessment of the post-approval safety monitoring.

These 3 biosimilars collectively represent nearly 350 million patient days of treatment worldwide.

The data show that spontaneous adverse drug reactions are reported by brand name in the majority of cases and are attributable to a specific medicine.

Brand names remain the most frequently and reliable data element.

In countries where brand names are not available, INN and MAH serve as unique identifiers of a medicine.

Sagi et al., Pharmacovigilance of Biologics in a Multisource Environment, JMCP, Vol. 23, No. 12, December 2017
DanBio confirms successful identification of products sharing same INN

Danish national recommendation to use biosimilars – highest uptake of all EU countries:
• nearly 100% use of biosimilar Infliximab
• nearly 80% use of biosimilar Etanercept

Danish Executive Orders (Dec 2015) ensure traceability through:
• Physicians shall make records of brand name and batch number in patient records and provide brand name and batch number when reporting ADRs
• Increased focus on product information in reporting forms, e.g.
  • Pop up-message for biological medicinal products in HCP e-form
  • specific field for batch number in consumer e-form)

➢ Very high reporting of batch numbers for biosimilar medicines (75.4 % for Infliximab; 72.7% for Etanercept)
➢ Danish Agency’s report published on a biannual basis

---

1 Benedictine Lunddahl, Head of Pharmacovigilance, Danish Medicines Agency, March 2017
IGBA welcomes the Australian Government’s decision taken in January 2018:

- to maintain the existing naming convention for biological, including biosimilar medicines, i.e. using the Australian biological name (without a specific identifier suffix);
- to strengthen the adverse event reporting. This includes making the product's trade name, as well as the non-proprietary name, a mandatory field when reporting an adverse event to the Therapeutic Goods Administration (TGA);
- to avoid the complexity and potential confusion that would be associated with introduction of a suffix-based system with retrospective coverage;
- to align with the EU which has the largest experience with biosimilars sharing the same INN than their respective reference products and excellent product identification results in case of ADR reporting.
U.S. pharmacovigilance data not supportive of INN suffix

“Many currently licensed originator biologics in the United States have shared non-proprietary names for decades with no pharmacovigilance concerns.”¹ only since the advent of biosimilars some groups assert that there is a problem. But no physician or pharmacist survey was ever conducted to evaluate if these groups are concerned with differentiating the 75+ biologics that already share INNs

- FDA has approved 20 biosimilar products, all with a 4-letter suffix, but only 7 are marketed (status June 2019)
- First public presentation of US Zarxio pharmacovigilance data provided at the DIA Biosimilars Conference in October 2017²:
  - 994,443 patient days of exposure collected until then
  - 65 case reports since US launch of which 62 (95%) contain the brand name
- Data from FDA’s Adverse Drug Report System Public Dashboard shows that biosimilar medicines could be identified by their proprietary (brand) name in 99.1% of reported cases³
- No data exists to demonstrate that added non-memorable suffixes in the U.S. will improve the U.S pharmacovigilance system
- **IGBA strongly urges the FDA to re-evaluate the use of a product-specific suffix for biologics naming**

¹ McCamish M, Gallaher A., Orloff J., Biosimilar by name and biosimilar by nature. Table 1. The RPM Report. July/August 2013
² Carlos Sattler, MD, Head of Medical Affairs, Sandoz Inc, DIA Biosimilars Conference, Bethesda, MD, October 24/25, 2017
Resolution WHA 46.19 calls for identification via corporate name and INN

• The 1993 Resolution WHA 46.19 on nonproprietary names for pharmaceutical substances requests WHO member states to encourage manufacturers to rely on their corporate name and the international nonproprietary name, rather than on trademarks, to promote and market multisource products introduced after patent expiration.

• In order to ensure consistent traceability, and given the need for identification in case of Adverse Drug Reports (ADRs) and the role of the MAH being responsible for pharmacovigilance, National Regulatory Authorities (NRAs) are therefore strongly encouraged to implement
  – the use of INN + MAH (i.e. linked to corporate) to identify biological products, especially in countries where INN prescribing may also apply to biologicals or an invented/"brand" name is not available or not legally enforceable, and
  – to promote consistent inclusion of the batch/lot numbers into the reports
The report of the May 2017 WHO Expert Consultation on Improving Access to and Use of Similar Biotherapeutic Products, published in October 2017, revealed on page 4, that following the outcome arising from the meeting

- “No consensus was reached on whether WHO should continue with the BQ – it should be noted that WHO will not be proceeding with this at present.”

WHO further communicated to industry that **WHO has decided to put on hold** the implementation of the International Nonproprietary Names Biological Qualifiers (INN BQ) Recommendation pending further data collection and experience with uptake and safety of Similar Biotherapeutic Products

IGBA is consequently no longer participating at the bi-annual Open Sessions to Stakeholders-Consultation on INNs for pharmaceutical substances, to allow the INN Expert Committee to allocate its precious time to many other important items.

1 https://bit.ly/2gJ4L3o
Canada supports unique identification with product’s brand name and non-proprietary name

- On 14 Feb 2019, Health Canada announced the decision that both the brand name and non-proprietary name should be used throughout the medication use process
- Biologics that share the same non-proprietary name can be distinguished by their unique brand names

- Policy Statement on Naming of Biologic Drugs
  - Health Canada’s Canada Vigilance database shows that reporting by brand name is largely successful in achieving accurate product-level attribution of spontaneously reported adverse events for suspected biologics
  - This option avoids any potential perception that different suffixes indicate clinically meaningful differences between a biosimilar and its reference biologic drug

- “What We Heard Report”
  - 75% of respondents supported the use of the brand name with the non-proprietary name to distinguish among biologics
For more information, please contact

info@igbamedicines.com
www.igbamedicines.com