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BIOSIMILAR MEDICINES: NAMING OF BIOSIMILARS

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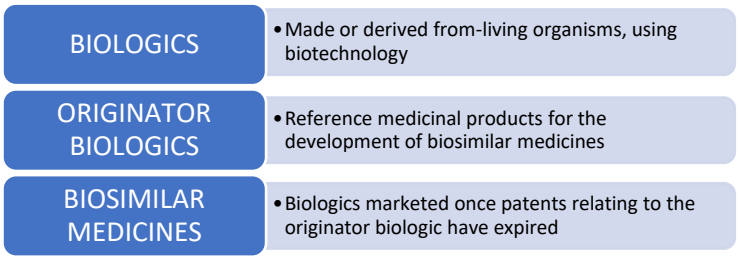
ABSTRACT

A biosimilar is a biological medicine highly similar to another already approved biological medicine (the reference medicine). Biosimilars are approved according to same standards of pharmaceutical quality, safety and efficacy that apply to all biological medicines. The European Medicines Agency (EMA) is responsible for evaluating the majority of applications to market biosimilars in the European Union (EU). The naming of biosimilars represents another potential challenge for the manufactures of the product, regulatory agencies, pharmacist, physicians and payers creating somewhat of a tug-of-war between the interest of each. Without unique identifiers for all biologics and biosimilars, accurate dispensing and correct identification of the brand, in case of adverse events, cannot be ensured.

KEYWORDS : Biosimilars, biosimilar medicine, biological medicine, international non-proprietary names

INTRODUCTION



Biological medicines have provided effective treatment options in a number of clinical specialities including gastroenterology, rheumatology, dermatology and oncology. Biologicals are expensive and their increasing use has contributed to escalating healthcare costs globally [1,2]. The market exclusivity periods for some originator biological medicines have expired, meaning competing manufactures can sell 'copies' of these medicines. These copies are known as biosimilars. Modern biologic medicines have demonstrated improved health outcomes for patients, however barriers to access still exist, one of the greatest being cost. In the coming years, the patents and exclusivity protection of many well known biologics are set to expire, and biosimilar medicines are emerging as an alternative treatment choice. Also, a somewhat attractive alternative treatment choice, because biosimilars are typically made available at a lower cost, improving accessibility and providing greater opportunity to patients, their doctors and the healthcare system overall.

Some examples of biopharmaceutical products and medicines that are made from biological agents include:

- Insulin for diabetes
- Vaccines to prevent many diseases, like shingles or the flu.
- Monoclonal antibodies for the treatment of cancers and autoimmune diseases
- Blood products and transfusions, such as in the treatment of haemophilia
- Enzymes used to remove blood clots
- Botox has both dermatologic and neurologic uses
- Hormones for hormone replacement and deficiencies, such as growth hormone disorders

Official Definitions of Biosimilars

The European Medicine Agency- A biosimilar is a biological medicine that is developed to be similar to an existing biological medicine (the 'reference medicine'). When approved, a biosimilars variability and any differences between it and its reference medicine will have been shown not to affect safety and effectiveness.

The United States Food and Drug Administration- A biosimilar is a biological product that is highly similar to a US licensed reference biological product notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency of the product.

The World Health Organization- A biosimilar is a biotherapeutic product which is similar in terms of quality ,safety and efficacy to an already licenced reference biotherapeutic product.

The abbreviated regulatory approval pathway which currently applies for chemically synthesised generic medicines, is not suitable for 'copies' of biological medicines. Approval as a generic is possible once an identical molecular structure to the originator (reference) medicine has been confirmed and bioequivalence has been demonstrated [6]. However due to the nature of their larger molecules, it is generally not possible to make an identical copy of a biological substance using a different manufacturing process. Therefore, a more tailored regulatory evaluation is required for 'copies' of biological medicines. Regulatory guidelines published by the EMA and FDA laydown robust science-based criteria for the approval of biosimilars [3,4].

Biological medications are generally large,complex molecules. These characteristics create potential safety concerns, especially with the possibility of an immune response. These concerns led the FDA to create a guidance document for the non-proprietary naming of biological products[5]. The document discusses the need of biological products to possess a non-proprietary name that contain a unique suffix. The intention of the FDA for adding the unique suffix to the proper name of each new biological product is to

1. Prevent a patient from receiving a medication that was not the intended biological product prescribed and avoid alternation or switching of biological products not deemed interchangeable
2. Allow for manufacturer-specific pharmacovigilance tracking
3. Implement these unique suffixes in ordering, prescribing, dispensing and recordkeeping[1].

This guidance was then open for public comment, and an updated version was subsequently released in March 2019[6].

The World Health Organization (WHO) has developed multiple guidance documents for the naming of biological products. The first was released in 2011; the most recent editions from 2016 and 2017 will be referenced in this article. These documents focused on the naming of biological products, specifically regarding the biologic's generic or proper name. The WHO documents describe how the proper name should be constructed to allow for uniformity between biological products[7,8].

INTERNATIONAL NONPROPRIETARY NAMES

The concept of one single non-proprietary name to be used worldwide for active pharmaceutical substances was established by the worldwide for active pharmaceutical substances was established by the World Health Organization (WHO) in 1950, by world health assembly resolution WHA3.11 and became operational in 1953. Since then, there have been more than 10,000 applications for an international non-proprietary name, or INN commonly called. INNs are intended for use in drug regulation, prescribing, dispensing, pharmacopoeias, labelling, pharmacovigilance and in scientific literature. They are also used by the World Health Intellectual Property Organization (WIPO), Trademark offices, and customs and excise agencies, including the World Customs Organization (WCO).

NAMING GUIDELINES FOR BIOLOGICS

As the number of biological products has increased, naming has become increasingly complex. The WHO has long been responsible foe international non-proprietary name (INN) assignment. These non-proprietary (generic or proper) names refer to the unique active-ingredient component of the drug which can relate information about the chemical name or, in the case of the larger biological molecules, relate information about the nature of the complex molecules[7]. This is not the proprietary (brand) name that is trademarked or registered for private use. The proper name aids healthcare professionals and patients in identifying the product and allowing product to be distinguished from each other[1].

In 2017, the WHO updated guidance for using INNs, which included summary information on nomenclature for biologics. Specifically, naming of biologics is related to structure and/or function, and each is assigned a specific letter group or stem, although not all groups of biological agents have been assigned a stem e.g. insulins[1]. Table 1 includes examples of biological groups with their associated stem[4]. There are also groups of biologics that have been assigned a scheme. Schemes include cell therapies, and monoclonal antibodies[4]. The nomenclature schemes for these therapies with example are included in table 1[4].

BIOLOGIC NOMENCLATURE: Selected stem Examples

Name of Group	Stem
Antisense oligonucleotides	-rsen
Cell therapies	-cell
Colony-stimulating factors	-stim
Enzymes	-ase
Growth hormone derivatives	-som
Vasoconstrictors, vasopressin derivatives	-pressin

Schemes

Cell therapies (example: spanlecortemlocel)	Prefix + infix1 + infix2 + suffix (random)+(manipulation)+(cell type)+("-cel")
Gene theripies World1: gene component	Prefix + infix + suffix (random) + (gene) + ("-[a vowel]gene")

World2: vector component (example: aglatimagene besadenovec)	(random) + (viral vector) + (-"vec"or"-repvec")
Monoclonal antibodies (example:pagibaximab)	Prefix + substem A + substem B + suffix (random) + (target class) + (species) + ("-mab")

SCOPE OF BIOLOGIC NAMING

In the FDAs 2017 guidance on biologic naming, the agency proposed retrospectively modifying the proper names of already licenced biological products by adding FDA-designated suffix, but this is no longer the intension of the FDA [1,2]. The agency is now proposing the addition of a unique suffix to biological products to new originator/reference, related, biosimilar interchangeable products. The FDA goal is to improve patient safety and allow for competition, lower prices, and greater access to biological products[2].

Vaccines are discussed and fall under the scope of the FDA guidance on naming; however, the FDA is determining if the currently used system for vaccine administration is capable of ensuring safe dispensing and pharmacovigilance without creating distinguishable proper names for vaccines[2].

Role of the pharmacist

Pharmacist will play a vital role in the educations of patients and healthcare providers regarding the new addition of unique suffixes to biological products. These unique suffixes will also allow pharmacist to assume a leadership role in the implementation and reporting of adverse-event information in reference to biological products. Pharmacist should also be familiar with the nomenclature of biological product origins and relative indication by breaking down the proper name. pharmacist also need to serve as experts on the purple book, a reference for all licenced biologics and approved biosimilar and interchangeable biological products.

Conclusion

There remains a knowledge gap with regard to biosimilars, and lack of consensus on how the naming convection is and should be utilized in clinical practice. The data also suggest that effective biosimilar education could aid in promoting familiarity with the naming convention among health care providers.

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