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A Review of Biosimilar as Medicine

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***Abstract*:** Biosimilars are a growing drug class designed to be used interchangeably with biologics. Biologics are created in living cells and are typically large, complex proteins that may have a variety of uses. Within the field of gastroenterology alone, biologics are used to treat inflammatory bowel diseases, cancers, and endocrine disorders. A biosimilar is a drug that is highly similar, but not necessarily identical, to a biologic drug (i.e., the reference drug) and shows no clinically significant differences in safety, purity, or potency. Biosimilar development does not establish safety and efficacy, but rather shows bio similarity to the reference drug. Unlike generic drugs, biosimilars are not an exact copy of their reference drug because of differences in the manufacturing.

Keywords: Biosimilar, Process, Development, Impact.

I. INTRODUCTION

Biologics are derived from the natural resources such as human, animal, or microorganism and manufactured by various biotechnology methods such as recombinant deoxyribonucleic acid technology, controlled gene expression, and antibody technology. Biologics have benefitted the patients with rheumatologic diseases, inflammatory bowel disease, malignant conditions, dermatological conditions, and other connective tissue disorders by halting the disease progression, alleviating the symptoms, and improving the quality of life.[1, 2] Biologics are one of the top selling drugs worldwide as well as in the United States but the major drawback of this drug has been its exorbitant cost, which makes it unaffordable and inaccessible to many patients, especially in developing countries where a large number of people are poor and the concept of health insurance is at its nascent stage.[3,4] biologic product, which is very similar to Food and Drug Administration (FDA)-approved biological product known as reference product and has no clinically meaningful differences in term of safety and effectiveness from the reference product.[5] Health-care experts and physicians are optimistic that use of biosimilars may reduce the cost of biologics and eventually lead to better patients' access to these lifesaving drugs[6].

II. NAMING OF BIOSIMILAR

To assign a proper name to a drug, a core name or generic is designated by the United States Adopted Names Council for originator biologic drugs. This core name carries over if the biologic drug is a related biologic drug, a biosimilar, or an interchangeable drug. Four meaningless lowercase letters are then added after a hyphen to the end of the core name [8].

III. IMPACT OF BIOSIMILAR

Even with the inherent constraints of biosimilar substitution, introduction of biosimilars in the Hong Kong market is expected to bring the impact on various aspects, including patient, public health system, private healthcare.

Pharmacodynomic Value of Biosimilars:

A fundamental aim in developing biosimilars is to improve patient outcomes by offering access to biologics with improved affordability. Bearing in mind that the primary purpose of biosimilar clinical study programs is to confirm comparable efficacy and safety in a sensitive patient population, the availability of such data has nevertheless enabled the development of cost models to ascertain the feasibility of potential cost savings with biosimilars compared with their reference products.

IV. BIOSIMILAR IS BIOLOGICAL MEDICINE

Biological medicines offer treatment options for patients with chronic and often disabling conditions such as diabetes, autoimmune disease and cancers. Biological medicines contain active substances from a biological source, such as living cells or organisms (human, animals and microorganisms such as bacteria or yeast) and are often produced by cutting-edge technology. Most biological medicines in current clinical use contain active substances made of proteins. These can differ in size and structural complexity, from simple proteins like insulin or growth hormone to more complex ones such as coagulation factors or monoclonal antibodies.

The EU approved the first biosimilar in 2006.

A biosimilar is not regarded as a generic of a biological medicine. This is mostly because the natural variability and more complex manufacturing of biological medicines do not allow an exact replication of the molecular micro-heterogeneity. The EU has pioneered the regulation of biosimilar medicines by establishing a solid framework for their approval and by shaping biosimilar development globally. The evidence acquired over ten years of clinical experience shows that biosimilars approved through EMA can be used as safely and effectively in all their approved indications as other biological medicines[10].

REFRENCES

[1] USFDA and health care provides www.fda.gov/BiologicsBloodVaccines/ResourcesforYou/HealthcareProviders/defaulhtm.

[2] Morrow T, Felcone LH. ‘‘Defining the difference: what makes biologics unique’’. Biotechnol Healthc 2004.

[3] Blackstone EA, Joseph PF. ‘‘The economics of biosimilars. Am Health Drug Benefits’’. 2013.

[4] Hofmarcher T, Jönsson B, Wilking N. ‘‘Access to high-quality oncology care across Europe’’. IHE Report 2014.

[5] Owens DR, Landgraf W, Schmidt A, Bretzel RG, Kuhlmann MK. 'The emergence of biosimilar insulin preparations—a cause for concern? Diabetes Technol Ther 2012.

[6] Sullivan T, ‘‘Biosimilar Update, Policy and Medicine’’, 2017.

[7] Harston A. ‘‘How the U.S. Compares to Europe on Biosimilar Approvals and Products in the Pipeline’’. Rothwell Figg IP Professionals: Biologics & Biosimilars. 2019.

[8] Zelenetz AD, Ahmed I, Braud EL, et al. ‘‘NCCN biosimilars white paper: regulatory, scientific, and patient safety perspectives’’. J Natl Compr Canc Netw. 2011.

[9] US Food and Drug Administration. ‘‘Non-proprietary naming of biological products: guidance for industry’’. January 2017.

[10] Vivian WY Lee & Franco WT Cheng; ‘‘A review of biosimilar in regulations and potential’’.

[11] impact: Hong Kong perspectives; Journal of Medical Economics;2019.

[12] https://www.ema.europa.eu.