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A REVIEW ON BIOSIMILARS

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ABSTRACT
Over the last three decades, the tremendous claim for the financial success of biopharmaceutical products have seen the accessible switch for close copies of these biological product (biosimilars). Biologics is considered as one of the fastest growing sectors of the pharmaceutical industry, whereas a biosimilar is formally organized and approved replica of an originator biologic therapies. As the use of biological therapies expands, the number and diversity of induced autoimmune disorders should be expected to increase. The expiry of patent protection for many biological medicines has led to the development of biosimilars in UK or follow on biologics in USA. More specifically, the overarching aims of this article were to review the current issues revolving around biosimilar and take a critical glance related to definition; types of biosimilars, biosimilars differ from generic drugs, focusing/clinical standards on safety and efficacy, potential impact on financial burden in healthcare and future prospects of biosimilars in India, Europe and the rest of the world.

KEYWORDS: Biopharmaceutical products, biologics, biological products, generic drugs, auto-immune disorders, safety and efficacy.

INTRODUCTION

The ascent of biologic drugs has endorsed various challenges and opportunities, flourishing interest in their approvals and further development.[1] On expansion novel biotechnology products have led pharmaceutical companies to endeavor replicating existing products, to maintain a steady stream of such biologics. With ongoing landscape of these products promising continuous growth, biological therapy is expanding the reach of medicine without restricting the research and development of small molecule drugs.

Biopharmaceutical medicines are originator medicinal products derived from living organisms using biotechnology. Biotechnology refers to the use of biological systems (e.g., bacteria, yeast, and human cells) to identify, sequence, and manipulate DNA anticipated producing therapeutic and medical diagnostic products. The class of biopharmaceuticals has been available for more than 20 years and includes blood coagulation modulators, enzymes, erythropoietins, gonadotrophins, granulocyte colony-stimulating factors (G-CSFs), human growth hormones, human insulins, interferon's, interleukins, monoclonal antibodies (MoAb), tissue plasminogen activators and vaccines.

Isolation and purification

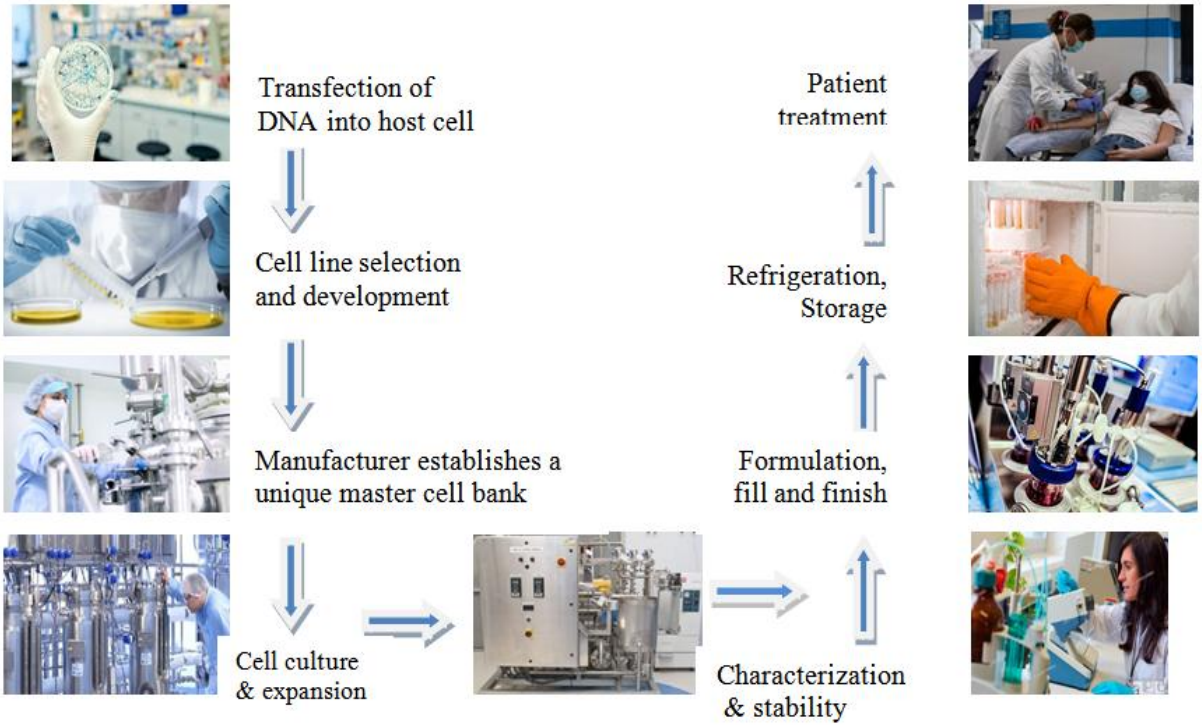


Fig. 1: A typical biotechnology manufacturing process includes multiple stages.

Biopharmaceuticals tend to have a large size, a complex structure and are manufactured (Fig-1) from a unique line of living cells making it impossible to ensure an identical copy. This contrasts with chemical medicines, which tend to have a small size, simple structure and are manufactured using a predictable chemical process that generates identical copies.

With fast and advanced development of modern biological technology (Fig-2) especially recombinant DNA technology[2], to greater extent biologic drug products has played important roles in treating many life threatening and chronic diseases. As a result, biologic drugs have comprised a growing segment in the pharmaceutical industry. The use of Biologics and spending on these products has been increasing; For instance, Spending on biologics in the United States comprise 120.1 billion dollar in 2017, a 12.5% increase over 2016.[3] The amount spent on "original" biologics subject to biosimilar competition in 2017 was 10.6 billion dollar (8.8% of 120.1 billion dollar), and the amount spent on biosimilars in 2017 was 0.9 billion dollar (0.7% of 120.1 billion). Since 2011, biologics spending has increased by 10% each year.

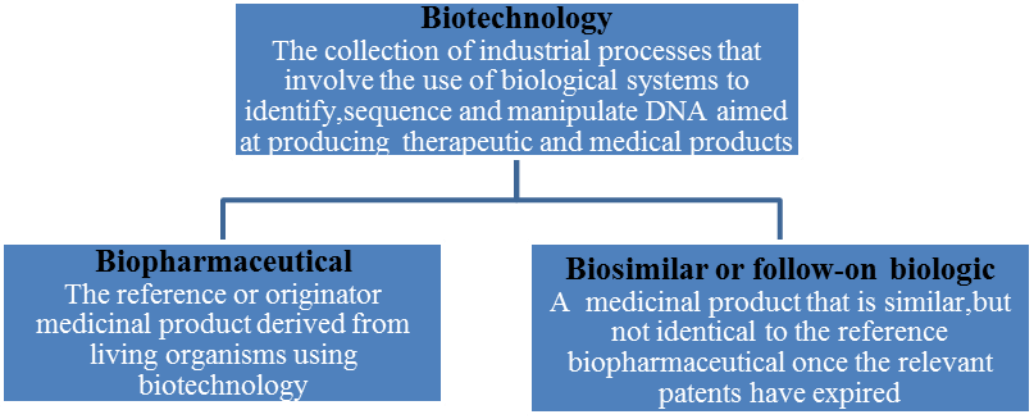


Fig. 2: Outline of biotechnology medicines.

Biologics

Biologics represent one of the rapid growing segments of the pharmaceutical industry and these drugs are essential part of modern pharmacophore. A Biologic drug or biologics is a product especially produced from living organism or contains components of living organisms either human being, animal, yeast or microorganisms using biotechnology (i.e., recombinant DNA technology,

controlled gene expression) that have introduced many unique treatments of life: rare illness and cautionary such as diabetes, rheumatoid arthritis, anaemia, crohn's disease, multiple sclerosis and cancer.[4] Biologics are made by living cells through well-controlled processes (Fig-3). Manufacturing changes can create variability in the biologic molecule.

Modify host cells (e.g., bacteria, yeast, Mammalian) to produce Recombinant proteins | **Grow cells** under controlled conditions | **Extract, refold, purify** to generate drug substance (downstream process) | **Formulate to stable finished drug product** vial, syringe, cartridge

Fig. 3: Manufacturing process of biologics.

Biological products are distinct and are usually large, complex molecules. As they change the demeanor of operation of natural biologic intracellular and cellular actions; biologic drugs are referred to as biologic response modifier. Most advanced therapies are available for biologic drugs like having revolutionized cancer treatment, changed lives of people with rare diseases, reversed the course of immune related conditions, and have afforded hope for many patients who previously had no effective treatment options for their conditions. Types of biologic drugs include allergic extracts, recombinant proteins, blood components, vaccines, proteins, Human tissues, and cellular and gene therapies. Biologics are most commonly used drugs over the counter drugs (OTC) and most prescription drugs synthesized by chemical process. These are less complicated and are more easily defined. From table-1 observe that the molecular structure of a commonly used chemical drug is much smaller than biologic drugs. For e.g., the chemical drug aspirin contains 9 carbon atoms, 8 hydrogen atoms, and 4 oxygen atoms while the large biologic drug Remicade contains over 6,000 carbon atoms, almost 10,000 hydrogen atoms, and about 2,000 oxygen atoms. Inflectra, an anti-inflammatory drug which is biosimilar to Remicade, was approved by the Food and Drug Administration (FDA) in April 2016.

Table 1: Relative size of Chemical and Biologic drugs.

TYPE OF DRUGS	DRUG	MOLECULAR FORMULA
CHEMICAL DRUGS	Aspirin	$C_9H_8O_4$
	Tylenol (acetaminophen)	$C_8H_9NO_2$
SMALL BIOLOGIC DRUGS	Lantus (insulin glargine)	$C_{267}H_{404}N_{72}O_{78}S_6$
	Zarxio (filgrastim)	$C_{845}H_{1339}N_{223}O_{243}S_9$
	Growth hormone (somatropin)	$C_{990}H_{1528}N_{262}O_{300}S_7$
LARGE BIOLOGIC DRUGS	Enbrel, Erelzi (etanercept)	$C_{2224}H_{3472}N_{618}O_{701}S_{36}$
	Remicade, Inflectra (infliximab)	$C_{6428}H_{9912}N_{1694}O_{1987}S4_6$

Biosimilars

In United States and Canada, biosimilars also known as follow-on biologic and subsequent entry biologics.[5] Whereas, Indian regulatory agencies called biosimilars as 'similar biologics'. Biosimilars are defined as a biologic medicinal product which are approved biologics that have been demonstrated to be highly similar (but not identical) in comparison to originator biologic therapy.[6] Biosimilars are agents that are similar in terms of safety, efficacy and immunogenicity to a reference biologic and can only be approved if a manufacturer manifests that there are no clinically meaningful differences when directly compared with the reference medicine.[7] It is a concept that is commonly summarized as "similar but not the same" and it's a fact that biosimilar need not be an exact copy of the reference biological. The use of biosimilars may reduce the cost of biologics and eventually lead to better patient's access to these lifesaving drugs assured by Health-care experts and physicians. Thus, a biosimilar is intended to work as a therapeutic comparable to the reference product and each biosimilars are unique because of difference in manufacturing (fig-4). It was evident that from a study carried out in United States biosimilars have huge potential to reduce the overall cost of treatment, where it was estimated over 10 years biosimilar can save 54 billion US dollar in the United States.

Fig. 4. Difference in manufacturing.

As per WHO biosimilar is a bio therapeutic product that is similar in terms of quality, safety and efficacy to an already licensed reference bio therapeutic product".[8] Whereas, according to the USFDA, a biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product.[9] Across worldwide Europe was the first to formulate the policy framework for the approval of the biological product.[10] In 2006, Omnitrope (a recombinant human growth) was the first biosimilar approved (Table-2) in Europe by European Medicines Agency (EMA).[11] After a period in 2015, United States approved filgrastim-sndz, a biosimilar to filgrastim (granulocyte CSF), whereas filgrastim was approved by the USFDA in 1991.[12,13] In june-2018, pegfilgrastim-jmdb was approved to reduce the risk of infection following myelosuppressive chemotherapy.[14] Presently biopharmaceutical companies have developed numerous biosimilars and also used immensely across the world for areas such as diabetes, ophthalmology, respiratory to cancer and connective tissue disease.[15-18]

Table 2: European Medicine Agency.

INN(molecule)	Product Name	Therapy area	Approved Date
Epoetin alfa(HX575)	Abseamed Epoetin alfa Hexal	Chemotherapy-induced anaemia Anaemia associated with CKD	August 2007
Epoetin zeta (SB309)	Silapo Retacrit	Chemotherapy-induced anaemia Anaemia associated with CKD	December 2007
Filgrastim (XM02, EP2006, PLD108)	Biogastrim Ratiogastrim Tevagrastim Filgrastim ratiopharm Zarzio Filgrastim Hexal Nivestim Grastofil Accofil	Cancer Hematopoietic stem-cell transplantation Neutropenia Neutropenia	September 2008 Withdrawn April 2011 February 2009 June 2010 October 2013 September 2014
Follitropin alfa	Bemfola	Anovulation (IVF)	March 2014
Infliximab (CT-P13)	Inflectra Remsima	Ankylosing spondilitis Crohn's disease, Psoriatic arthritis, Rheumatoid arthritis Ulcerative colitis	September 2013
Somatropin	Omnitrope Valtropin	Pituitary dwarfism Prader-Willi syndrome Turner syndrome Pituitary dwarfism Turner syndrome	April 2006 April 2006 Withdrawn May 2012
	Somatropin Biopartners	Growth hormone deficiency	August 2013

In January 2019, the US Food and Drug Administration (FDA) had approved 18 biosimilars(Table-3), additionally 7 products launched in 4 therapeutic areas,[19] these were the early days of the biosimilar marketplace in the US, and as of 2020 will likely see more biosimilar launches. A program was created by FDA to provide detailed, product-specific advice to manufacturers that plan to submit applications for biosimilar approval. While in July 2018, the number of manufacturer biosimilar programs enrolled in the FDA's biosimilar development program was 68, as of 2019 the number of programs enrolled exceeded 90.[20,21] As evidenced from the adoption of biosimilars in Europe over the last 12 years, manufacturers, payers, and providers in the US expect biosimilar competition will potentially lead to consistent price reduction.[22]

Currently as many biosimilars are advanced in stages of development, the rate of regulatory approvals in the US is slightly leading when compared of Europe and is expected to accelerate. There are many factors that are considered in selecting a biosimilar product that includes:

1. Manufacturer heritage and expertise in developing, manufacturing, and reliably supplying biological medicines, including logistics, inventory management, and environmental impacts of production
2. Education provider
3. Support programs for patients
4. Product attributes, such as packaging, storage, stability, excipients, dosage forms and strengths; routes of administration; and device designs
5. Available pre-clinical and clinical data, real-world evidence generation

Further, biosimilar adoption is not the only measure of success. Reference products may lower prices to compete and to attempt to retain market share.[23] This is also a positive consequence that results from biosimilar competition.

Table 3: Biosimilars in Development and Approved by the FDA in Haematology, Inflammation and Immunology, and Oncology Therapeutic Areas.

Manufacturer	Number of Biosimilars submitted to FDA	Number of Biosimilars Approved by the FDA	Relevant Therapeutic Areas
Adello Biologics	3		Haematology, Immunology & Inflammation
Amgen	5	2	Inflammation & Immunology, Oncology
Apobiologix (Apotex)	7		Haematology, Inflammation & Immunology, Oncology
Archigen (Samsung BioLogics/AstraZeneca)	1		Inflammation & Immunology, Oncology
Boehringer Ingelheim	1	1	Inflammation & Immunology, Oncology
Celltrion	5		Inflammation & Immunology, Oncology
Celltrion/Teva		2	Inflammation & Immunology, Oncology
Coherus BioSciences	2	1	Haematology, Inflammation & Immunology
Formycon/Aristo Pharma GmbH	1		Inflammation & Immunology
Fresenius Kabi	2		Haematology, Inflammation & Immunology
mAbxience	2		Inflammation & Immunology, Oncology
Mylan/Biocon	4	2	Haematology, Inflammation & Immunology, Oncology
Mylan/Mabion	4		Inflammation & Immunology, Oncology
NeuClone	5		Inflammation & Immunology, Oncology
PFEnex	2		Haematology
Pfizer	4	5	Haematology, Inflammation & Immunology, Oncology
Prestige BioPharma	5		Inflammation & Immunology, Oncology
Samsung Bioepis/Merck	3	2	Inflammation & Immunology, Oncology, Rare disease
Sandoz		3	Haematology, Immunology & Inflammation
Xbrane Biopharma	2		Haematology, Immunology & Inflammation

India has a successful biosimilar ecosystem when compared to other countries. Moreover, Indian pharmaceutical companies have ascended as the global market leaders in biosimilars. India approved its first biosimilar much before the United States and Europe. In 2000, India has approved and marketed its first biosimilar for hepatitis B, no specific guideline was available at that time for the development and marketing of biosimilar.[24] Since then several biosimilars were developed and marketed in India by various biopharmaceutical companies. Currently, for marketing novel biologic, an Indian biopharmaceutical company got the USFDA's acknowledgment. Herceptin (active drug is trastuzumab) was the first biologic to be approved by FDA, which is used in certain breast and stomach cancer. This was also the first similar biologics manufactured by an Indian company, which received approval to market in the United States. Presently, more than 100 Indian biopharmaceutical companies are engaged in manufacturing and marketing of biosimilar.

Central Drugs Standard Control Organization (CDSCO) in collaboration with the Department of Biotechnology (DBT) has developed "Guidelines on Similar Biologics", to address the issues and challenges associated with the development of similar biologics.[25,26] These guidelines addresses the regulation of manufacturing process as well as quality, safety, and efficacy of similar biologics and also the pre- and post-marketing regulatory requirements for similar biologics. In earlier guideline, CDSCO has brought some important changes previously it was essential for the reference biologic for which biosimilar is to be developed has to be approved and marketed in India but it has now changed to either India or any other international council for harmonisation countries (i.e., European Union, Japan, United States, Canada, and Switzerland). Another difference between the 2012 guidance and the document issued in 2016 is the emphasis on the post-marketing studies, which CDSCO says are planned "to further reduce the residual risk of the similar biologic," CDSCO has made it imperative for the biopharmaceutical company to conduct a Phase-IV study with a minimum of 200 patients within 2 years of getting approval for marketing.

Various steps have been taken by Indian companies to involve them in manufacturing and marketing, to tap its great potential. India has achieved the distinction of being the second largest supplier of vaccines in the world. Various biosimilars have been approved by India for use in different diseases. Some of the biosimilars approved in India are in (Tab-4).

Table 4: Examples of some of the biosimilars approved in India.

Product name	Active drug	Indications
Glaritus	Insulin glargine	Diabetes mellitus
Grafeel	Filgrastim	Neutropenia
Epofer	Epoetin alfa	Anaemia
Adfar	Adalimumab	Rheumatoid arthritis, Crohn's disease
Erbutex	Cetuximab	Colorectal carcinoma
Krabeva	Bevacizumab	Colorectal cancer
Herceptin	Trastuzumab	Breast cancer
Intacept	Etanercept	Rheumatoid arthritis
Abcixirel	Abciximab	Autoimmune disease
Relibeta	Interferon beta-1a	Multiple sclerosis
Relipoietin	Epoetin alfa	Anaemia, autologous blood transfusion, chronic kidney failure, HIV
Shankinase	Streptokinase	Arterial occlusions, deep vein thrombosis, pulmonary embolism
Razumab	Ranibizumab	Wet macular degeneration, macular edema, degenerative myopia
Terifrac	Teriparatide(parathyroid hormone)	Postmenopausal women with osteoporosis who are at high risk for fracture

Some of the major companies operating biosimilars market are Actavis, Inc., Sandoz International GMBH, Teva Pharmaceutical Industries Ltd., Celltrion, Inc., Hospira Inc., Biocon Ltd., Mylan, Inc., Cipla Ltd, Amgen, Inc., Dr. Reddy's Laboratories Ltd., Stada Arzneimittel Ag and Wockhardt Ltd.

Types of Biosimilar

In addition to biosimilars, the lapse of patents for original biologic products has led to the creation of multiple classes of biologics that includes:

1. Non-comparable biologics: These are those biosimilars that do not meet requirements of similarity to the original medicinal product since they have not been through the strict requirements including comparability studies among other requirements, as stipulated by the relevant bodies, such as the EMA, the World Health

Organization (WHO) or the US Food and Drug Administration (FDA).

2. Biobetters: Highly differentiated biosuperior drugs, known as "Me-Betters" are needed to serve patients who have increasingly become resistant to current therapies of care. These "Me-Betters" or "biobetters" are new biologics based on an existing approved biologics. These are superior products to the originator biologic with improved administration of the product, greater stability as well as other better performing indicators. Biobetters can deliver the mechanism of action of potency improvements, enhanced half-life, better safety and immunogenicity, and better and broader efficacy. Today, there are numerous biosimilars and biobetters in development.

E.g.: Humira(adalimumab) is one of the extremely successful biobetters, an immunosuppressive drug used to treat arthritis, plaque psoriasis, ankylosing spondylitis, Crohn's disease, and ulcerative colitis and other diseases. Humira works by binding to tumor necrosis factor-alpha (TNF), which normally binds to TNF receptors, leading to the inflammatory response of autoimmune diseases. After infliximab and etanercept, Humira was the third TNF inhibitor to be approved in the USA "biobetter" of the two agents, it was constructed from a fully human monoclonal antibody, which was an improvement over infliximab, a mouse-human chimeric antibody, and etanercept, a TNF receptor- IgG fusion protein. As of 2017, the drug has made more than 18billion in the U.S.

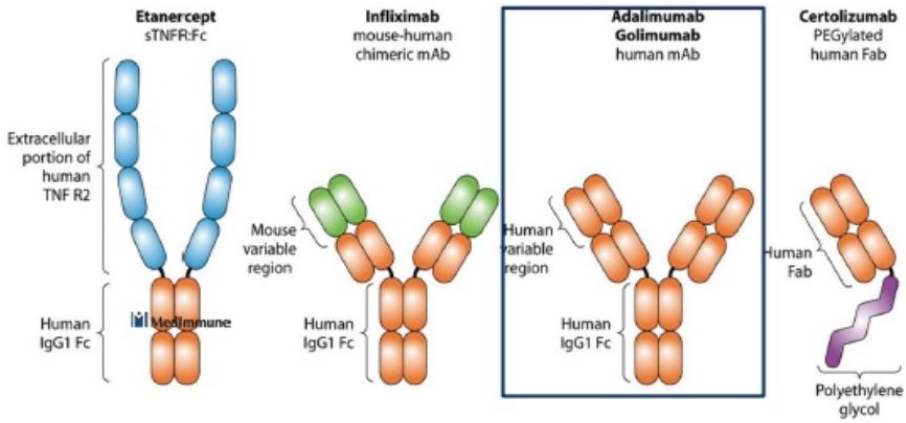
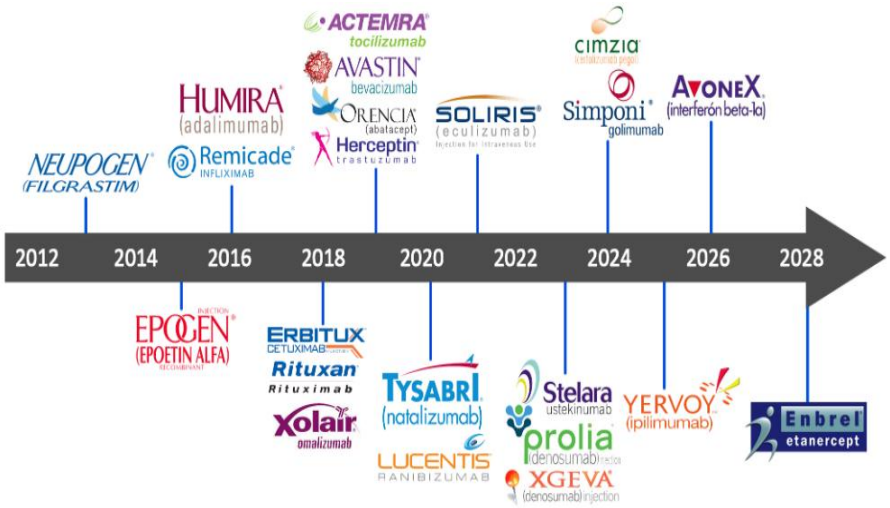


Fig. 5: Example of Biobetters/Biosuperiors (ANTI-TNFS).

Recent and Future Patent Expirations of Major Biologics

The global biologics market is expected to reach around $291 billion in 2020 and by 2022, 50 percent of the pharmaceutical market share is expected to be in biologics. It is expected that by 2030 the biosimilar market will be a greater than a $240 billion opportunity, as patents on major biologics continue to expire.



Biosimilars Are Different From Generic Drugs

Biosimilars or follow-on biologics are biopharmaceutical drugs that are related to approve biological drugs. Generic drugs are composed of small molecules and are identical copies of their reference products. However, biosimilars are composed of more complex molecules such as human insulin and monoclonal antibodies consisting of heterogeneous mixtures and many are derived from plants, animal, bacteria, viruses and yeast.[27]

Biologics, whether reference or biosimilar are produced from 2 methods: recombinant DNA technology and controlled gene expression.[28] In terms of raw material and their manufacturing process, biosimilars are different from other generic drugs. Biosimilars offer less costly treatment when compared to other biological and synthetic drugs. Manufacturing of biological is more challenging than generic drugs because, when manufacturers seek the approval for a generic, they must establish bioequivalence tests that allow the two identical. As Generic products are not derived from living organisms (Unlike biologics), they do not require the additional testing requirement of clinical studies. Even minor changes in manufacturing process can cause significant changes in efficacy or immunogenicity.[29,30] It is very important to understand the difference between biosimilars and generics because a comparison of these two drugs makes it clear as why there are so many challenges with the production of biosimilars of biological compared to the relatively easy task of making a generic of a small molecule drug.[31]

For e.g.: Aspirin, which is considered a small molecule drug, measures just 180 Daltons and has 21 atoms and has little ability to initiate an immune response and remains relatively stable over time. In contrast, a typical monoclonal antibody biological drug measures 150,000 Daltons contains 20,000 atoms, degrades over time and has the ability to generate a significant immune response. Thus, the production of a biological is an inherently unstable situation requiring special handling and storage.

Biosimilars and generic drugs are versions of brand name drugs and may offer more affordable treatment options to patients. These are approved through different abbreviated pathways that avoid duplicating costly clinical trials. But biosimilars are not generics. For e.g., the active ingredients of generic drugs are the same as those of brand name drugs. In addition, the manufacturer of a generic drug must demonstrate that the generic is bioequivalent to the brand name drug. Biosimilar drugs are used in prevention and treatment of various severe diseases such as cancer, diabetes, autoimmune diseases, heart attacks, rheumatoid arthritis, oncology, growth hormone deficiency, chronic kidney failure, haematological disease and infectious disease.

Table 5: Difference between Biologics and Generic Drugs.

	BIOSIMILARS (Monoclonal Antibody)	**GENERICS (Acetylsalicylic acid)**
Structure	Complex with many options for post-translational modification	Simple and well defined
Size	Large MW = ~150,000 Da	Small MW = 180 Da
Stability	Sensitive to storage and handling conditions	Relatively stable
Characterizations	Difficult to characterize fully owing to a mixture of related molecules	Easy to fully characterize
Manufacturing	Each manufactured in a unique living cell line Similar but not identical copy can be made	Predictable chemical process Identical copy can be made
Time To Market	7-8 years	2-3 years
Immunogenicity	Higher potential	Lower potential
Patients(n)	~500	20-50
Clinical Studies	Extensive clinical studies, including Phase I-III Pharmacovigilance and periodic safety updates needed	Often only Phase I studies Short timeline for approval
Regulation	Needs to demonstrate “similarity” Regulatory pathway defined by Europe (EMEA) No automatic substitution allowed	Needs to show bioequivalence Abbreviated registration procedures in Europe and US Automatic substitution allowed

With generics, the responsibility to prescribe lies with the physician, whereas accountability to dispense lies with the delivering pharmacist. Likely the extensive use of generics, physicians is being encouraged to prescribe medicines using their international non-proprietary names (INN), as opposed to their commercial ones. Biosimilars need to follow certain strict criteria’s like quality, safety and efficacy, due to the complexity of recreating a product which is made by living organisms. These criteria include the submission of data from preclinical and clinical studies, to test the degree of similarity to the originator and the consequent safety and efficacy of the final product. Importantly, due to the complexity of the process, different batches of a particular mob could even be considered biosimilar versions of the mob likely they do not follow a purely chemical pathway but are made from living cells. Thus, generics and biosimilars differ immensely since the latter’s requirements are similar to those of an originator biologic (including clinical trials and comparability studies).

List of FDA-Pending Biosimilars

Biosimilar	Manufacturer	Brand name & Designation	Innovator product	FDA Filing Date	Current Status
Abrilada	Pfizer	Adalimumab-afzb	Humira	Nov 15,2019	Q3 2023
Amjevita	Amgen	Adalimumab-atto	Humira	Nov 23,2016	Q1 2023
Admelog	Sanofi-aventis	Insulin lispro	Humalogs	-	Pending
Bevacizumab	Samsung Bioepis	SB-8	Avastin	Nov 19,2019	FDA decision expected Q4 2020
Bevacizumab	Mylan/Biocon	MYL-14020	Avastin	Dec 2019	FDA decision expected Dec 20, 2020
Bevacizumab	Mylan Fresenius Kabi	TBD	Humira Humira	-	Pending FDA approval
Bevacizumab	Pfizer	TBD	Herceptin	-	Pending FDA approval
Cyltezo	BI	Adalimumab-adbm	Humira	Aug 25,2017	Q3 2023
Eticovo	Samsung Bioepis	Etanercept-ykro	Enbrel	Apr 24,2019	Q2 2020 or 2029
Grastofil	Apotex	Filgrastim	Neupogen	-	Pending
Hadlima	Samsung Bioepis	Adalimumab-bwwd	Humira	July 23,2019	Q2 2023
Herzuma	Teva/Celltrion	Trastuzumab-pkrb	Herceptin	Dec 14,2018	Q1 2020
Hyrimoz	Sandoz	Adalimumab-adaz	Humira	Oct 15,2018	Q3 2023
Lapelga	Apotex	Pegfilgrastim	Neulasta	-	Pending
Ontruzant	Merck/Samsung Bioepsis	Trastuzumab-dttb	Herceptin	Jan 18,2019	Q1 2020
Ranibizumab	Coherus Biosciences/Bioeq	TBD	Lucentis	Dec 2019	FDA decision expected Q4 2020
Rixathon	Sandoz	TBD	Rituxan	-	Pending FDA approval
Rituximab	Amgen/Allergen	TBD	Rituxan	Dec 20,2019	FDA decision expected Q4 2020
SB5	Merck/Samsung Bioepsis	Adalimumab	Humira	Sep,2018	Pending FDA approval
Trazimera	Pfizer	Trastuzumab	Herceptin	-	Pending
Truxima	Celltrion	Rituximab	Rituxan	-	Pending

CONCLUSION

We live in an era of biologic medicine, there is need to use well-designed clinical trials to establish biosimilarity as they have an opportunity to provide competition in the market. With an aging population and growing demand for treating chronic conditions, biologic use is on the rise and in an environment where health decisions are increasingly made based on value and cost. Biosimilars have grown to become an indispensable tool in modern medicine from its first use i.e., since 1980s and will play a vital role in improving patient access to desired medicine, much like the advent of generic medications more than 35 years ago. The challenge with biosimilars is to know the differences which matter clinically. The launch of new biosimilars over the next decade could save consumers as much as $250 billion and boost access to biologic treatments for an additional 1.2 million patients by 2025. That expands treatment options for chronically ill patients and allows greater use of biologic medicines overall by providing more affordable access to individuals who in the past have either forgone treatment or settled for less effective medicine. Advancements in biologic research have pushed the frontiers of science, bringing lifesaving treatments to patients suffering from deadly diseases, such as cancer.

From the future prospectives, the global market for the biosimilar is expected to grow and many companies will have their patent expire in the forthcoming year, which will open the window of opportunity for other biopharmaceutical companies to explore the possibility of development of biosimilar products. India is a powerful compitetor in the world in manufacturing and using of biosimilars. Indian biosimilar market was approximately US$300 million in 2015. The domestic sales are close to US$250 million and growing at a compound annual growth rate of 14%. The export of biosimilar from India stands at an astonishing US$51 million. India has the potential to become a global player in similar biologics or biosimilars. Biosimilar presents a US$240-billion global opportunity to Indian biopharmaceutical industry and the domestic market is expected to grow US$40 billion by 2030. Institute of Medical Sciences' health-care report also envisages a similar opportunity for Indian biopharmaceutical companies associated with manufacturing and marketing of biosimilars.

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