Similar Biologicals: An Emerging Market Opportunity for India

By

Nilesh Dhanotiya

Dissertation submitted for the partial fulfillment of the

MBA Pharmaceutical Management

Academic year, 2018-2020

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Nilesh Dhanotiya
MBA PM-10

CERTIFICATE BY SCHOLAR

This is to certify that the dissertation titled "**Similar Biologicals: An emerging Market Opportunity for India"** submitted by Nilesh Dhanotiya Enrolment No. 0143 under the supervision of **Mr. Rahul Sharma**for award of MBA in Pharmaceutical Management of the University carried out during the period from 18th February to 18th May, 2020 embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other institute or other similar institution of higher learning.

Table of Contents

Company Profile 1

Introduction 2

Similar Biologics are not generic? 3

Rationale: 6

Literature Review: 7

Methodology 9

Market Opportunity of Similar Biologicals for India 10

Government Initiatives: 13

Regulatory Environment: 13

Developed Markets 14

EMA (European Medical Agency) 15

USFDA 16

Growth Drivers 21

Restraints 22

SWOT Analysis 23

Competitive landscape of biotechnology companies in India 24

Implications: 27

Conclusion: 27

Bibliography 29

Acronyms:

CAGR: Compound Annual Growth Rate

WHO: World Health Organization

EMA: European Medical Agency

EPO: Erythropoietin

CDSCO: Central Drug Standard Control Organization

DBT: Department of biotechnology

ABLE: Association of Biotechnology Led Enterprise

DCGI: Drugs Controller General of India

RCGM: Review Committee on Genetic Manipulation

CTD: Common Technical Document

ICH:The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

Company Profile

Ikon Marketing Consultants is one of India's leading marketing consulting companies dedicated to the development and implementation of results-oriented marketing strategies. For eighteen years, we have been helping companies, SMEs, and start-ups build strong brands and drive business growth. The goal is to provide deep knowledge and expert advice to entrepreneurs who need to grow. For any strategic marketing issues related to the company's growth, marketing and sales strategies, brand or market needs, and consumer insights, we are all important solutions. We meet customers' strategic marketing needs in one stop.

we believe

- Customer success is our success
- Put the interests of customers in front of us
- to be frank
- Confidentiality of customer information
- Propose a cost-effective solution
- Bring exciting value to customers

We have a good network of partners in major cities in India and the United States, Europe, the Middle East and other countries in Asia, which allows Icon to identify customers from different regions and industries based on different consulting tasks.

What we do

We help customers solve their marketing problems and drive business growth through operational insight, innovative marketing strategies and implementation support.

We advise key decision makers on all issues related to marketing. From identifying market opportunities, formulating marketing strategies, brand strategies, digital marketing and international marketing strategies, we serve customers one-stop and meet their various strategic marketing needs. We not only provide advice to customers, but also provide advice and support to customers to implement recommended strategies to achieve the desired results.

We serve customers in various industries and regions from companies to start-ups, providing customer-driven, adaptable, and cost-effective practical marketing solutions. We work with customers to develop strategies for them in a collaborative manner and build the ability to implement them.

- Our customers can contact us at any time
- Accelerate business growth through marketing innovation and branding
- Solve complex marketing problems and improve performance
- Enter new markets and succeed with existing or new products
- Increase market share in existing markets
- Build a strong brand

- Attract and win online customers through digital marketing

Introduction

Biological is a therapeutic protein, which is produced or contained in the organism. In many therapeutic areas around the world, biological agents have been used to treat many diseases. Fundamentally speaking, it demonstrates the advantages brought about by the breakthrough progress made in the fields ofmolecular biology in the past few decades. Biologics are leading the way in various products, such as monoclonal antibodies, EPO, recombinant therapeutics, blood and blood, and vaccines.

Developments in the field of recombinant DNA application science have facilitated the large-scale production of organic products such as MABs, human augmentation factors, fusion proteins, and erythropoietin. In the United States and abroad, biological agents are becoming the basic stage of healthcare choice. At present, more than 900 vaccines and biological agents against more than 900 diseases are under scientific development.

In addition, the improvement of the applied science of analysis has also improved the characterization of large molecules. Just like nucleic acids and proteins, it can provide screening and identification of revolutionary organic products, which are composed of complex structures and various molecules.Therapeutic useful activity.

Now or in the coming years, there are many simple and complex biological agents on the market that are dealing with the loss of exclusivity, such as Humira,Herceptin and Enbrel etc. Nowadays, biologics account for more than Twenty percent of the entire pharmaceutical industry; it is valued at USD 98.70 billion.

In 2018, eight were the world's biological agents in top ten drugs. These eight biologics created a total of US$65.6 billion in sales, and have 6 monoclonal antibodies, 1 recombinant protein, and 1 vaccine.

India has approved more than one category of biosimilars, broadly speaking including vaccines, monoclonal antibodies, insulin and recombinant proteins. India has the second largest vaccine supplier in the world.

In India, there are more than 100 companies engaged in the production and advertising of biosimilars. According to India’s regulatory business, biosimilars are recognized as “similar biological agents”. The (CDSCO) has cooperated with the Ministry of Biotechnology to solve problems and challenges related to improving comparable biological agents.

In 2020, the global biosimilar market size is US$11.8 billion, and is expected to reach US$35.7 billion by 2025, with a compound annual growth rate of 24.7%.

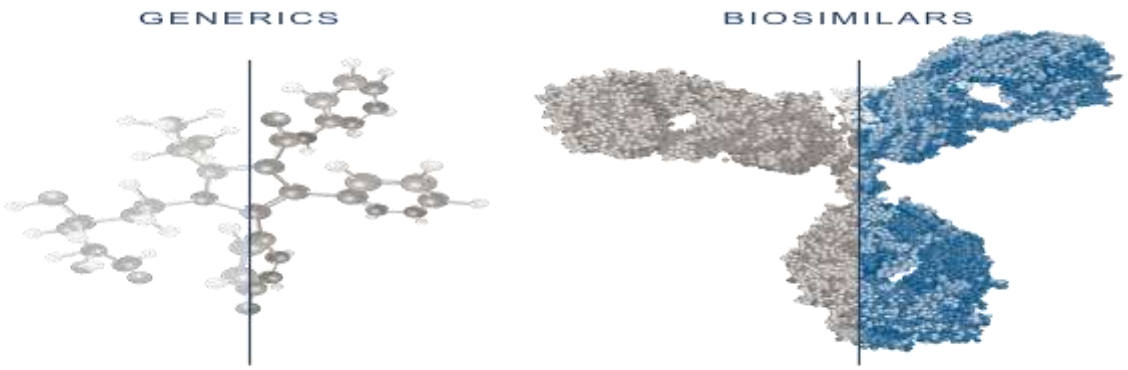
According to data from the Association of Leading Biotechnology Companies, India’s biosimilar market will expand with compound annual growth rate of 22%, reaching $12 billion by 2025.

Key words: Biologicals, Biosimilars, Antibodies, CDSCO and Biotechnology

Similar Biologics are not generic?

Despite the fact, generic drugs and biosimilar drugs only enter the market after losing patents for innovative products. Therefore, since generic drugs are generic drugs, they are not considered for use It has been determined that the active ingredients present in biosimilars are almost the same as the source of the designer, but due to the complex nature of biosimilars and their growth in biological systems, it is impossible to directly imitate approved biosimilars. Therefore, biosimilars are not only unique to their original biological products, but each step in the event phase must face computational research to ensure its physical and chemical and functional characteristics as well as safety, quality and efficiency are highly similar.

Figure: Structural difference between Generic and Biosimilar Products



Source: X Brane Biopharma

Table Difference between generics and Similar biologics

Generic	Follow on biologicals / Biologicals
Low Molecular Weight Generally	High Molecular weight
Homogeneous Drug Substance	Homogeneous Mixture
Made by organic and Chemically Synthesis	Made up with live cell/ organism
Non- Immunogenic	Often Immunogenic
Structure is known	Structure may /may not be completely known or define
Some process is critical	Many processes are critical
Well Characterized	Less Characterized
3-5 years development	8-10 years development

80-90% discount over refence product	20-30% discount

Similar Biologics definition by different Regulatory bodies

WHO

A biotherapeutic product which is similar in terms of quality, safety and efficacy to an already licensed reference biotherapeutic product

The EMA (European Medical Agency):

"A similar biological or 'biosimilar 'medicine is a biological medicine that is like another biological medicine that has already been authorised for use. Biological medicines are medicines that are made by or derived from a biological source, such as a bacterium or yeast. They can consist of relatively small molecules such as human insulin or erythropoietin, or complex molecules such as monoclonal antibodies.

Biosimilars can only be authorised for use once the period of data exclusivity on the original reference' biological medicine has expired. In general, this means that the biological reference medicine must have been authorised for at least 10 years before a similar biological medicine can be made available by another company."

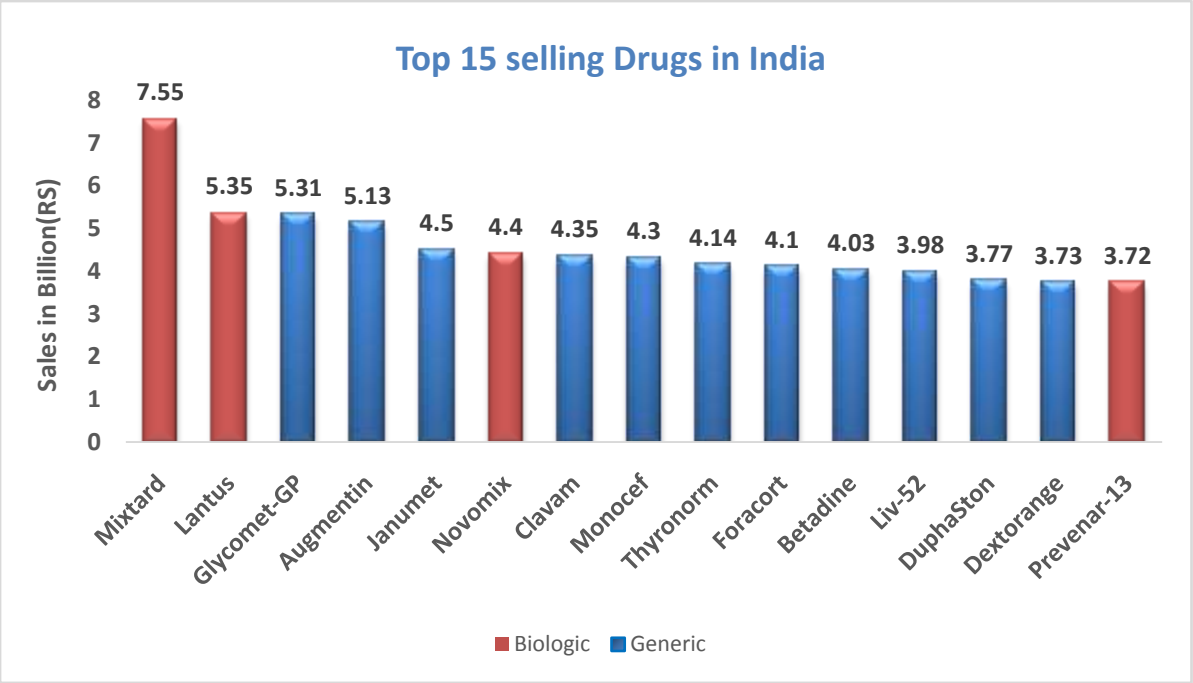
The USFDA's:

"Biosimilars are a type of biological product that is licensed (approved) by the FDA because they are highly similar to an already FDA-approved biological product, known as the biological reference product (reference product) and have been shown to have no clinically meaningful differences from the reference product. Minor differences in clinically inactive components are allowed. But there must be no clinically meaningful differences between the biosimilar and the reference product it was compared to in terms of the safety, purity, and potency of the product."

CDSCO

A Similar Biologic product is that which is similar in terms of quality, safety and efficacy to an approved Reference Biological product based on comparability.

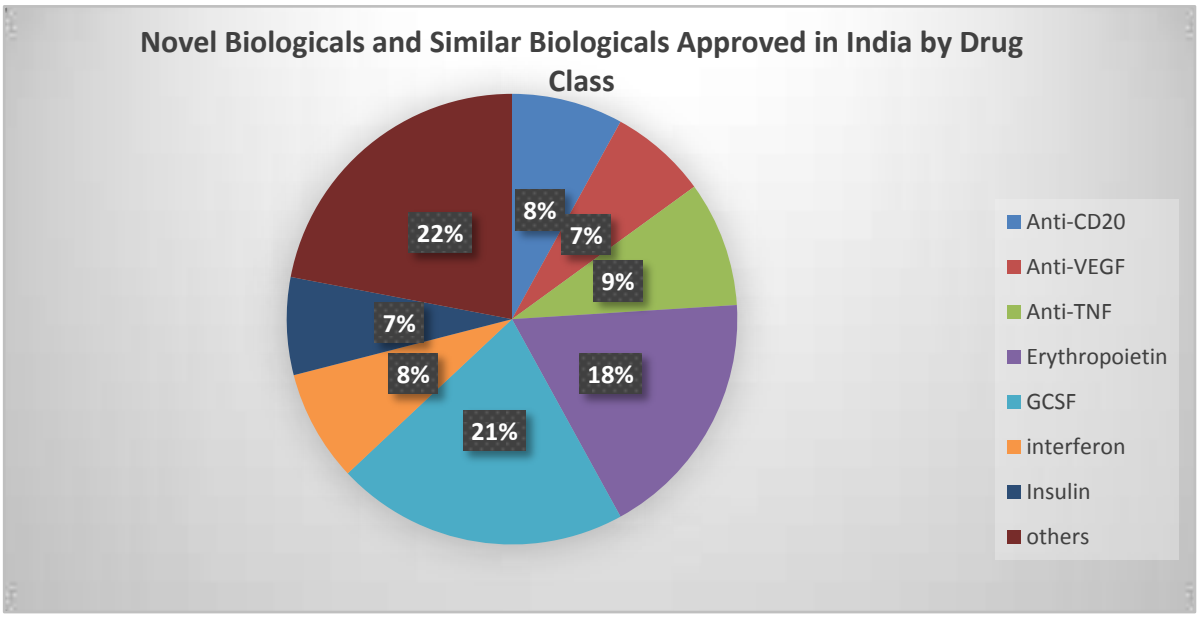
Graph: Top 15 selling drug in India



Source: Sales View IQVIA (2020)

In India there are four biosimilar among top 15 drugs. Highest sells have been given by two biosimilars which were insulins preparation like Mixtard and Lantas.

Graph:Similar Biologicals Approved in India by Drug Class



Source: IPSOS data, June 2017

In India the most popular biosimilars by number of current approvals are first generation Granulocyte Colony Stimulating factors (GCSF) which was 21% and Erythropoietin (EPO) products which was 18%. Molecules wise, Epoetin alpha for anemia, filgrastim for low blood neutrophil and rituximab for oncology and autoimmune indications are several the foremost crowded biosimilars in India.

Rationale:

The field of biosimilars is still developing and developing in the United States, and India may also play a vital role in the world in the manufacture and use of biosimilars. [26] According to the Enterprise Federation led by the Biotechnology Association, India's comparable biologics market will grow at a compound annual growth rate (CAGR) of 22%, reaching $12 billion by 2025. India's exports of biosimilars or similar biological products amounted to US$51 million. The health care record also envisages equal opportunities related to Indian biopharmaceutical institutions.

By 2025, the global market for biosimilars is expected to grow to 37 billion US dollars, and many companies are expected to enter this profitable field. As the demand for low-cost healthcare continues to rise, the governing body is taking many initiatives to reduce the cost of overpriced remedies. In countries like the US, the demand for Cost effective healthcare emerged in 2010, when the ACA became a regulation in 2010.Many groups will have their patent expire inside the imminent year, which can open the window of probability for different biopharmaceutical corporations to explore the probability of improvement of biosimilar products.

Although biologic therapy is indicated for the remedy of sever chronic inflammatory diseases, get entry to this therapeutic modality might also be limited. The addition of biosimilar to the market may also improve get admission to such remedies by using growing the range of biologic drugs available. Though the regulatory landscape concerning biosimilar improvement and approval in various throughout distinctive regions of the world, many nations are striving towards harmonization of established criteria, such as those set forth by way of the EMA, FDA, and WHO, which have established related ideas and pointers defining biosimilars and stringent method required to enhance and license a biosimilar.

Research Question: **What is the market opportunityfor Similar Biologics in India?**

Objectives:

- To find and determine the Pipeline Biosimilars for opportunity in India.
- To analyse the Patent Exclusivity of Biologics/Follow on Biologics in US and Europe.
- To find the key factors which can influence the market growth like strength, weakness, opportunity and threat (SWOT) Analysis.

- To analyse the regulatory framework in developed Countries like US and Europe and emerging market like India for the Biosimilars/Similar Biologicals.

Literature Review:

In forthcoming year, couple of epic biologicals are supposed to off patent which have been generated opportunities for Similar biologicals which has extensively relied on Safety, efficacy and quality of reference product by assuring comparability testing with reference product. Similar biologicals /follow on biologics/ Biosimilars are likely to be biosimilars.

Similar biologics may be requiring specific marketing approval along with documentation because they are not generic version of biologics. As they are neither biologics and nor generic version of biologics so they will be requiring different regulatory pathway for balancing cost benefit and risk management. Europe was the first who established guidelines for biosimilars followed by Japan and USA. The guidelines for Similar biologicals in India was made in 2012. India has firmly established itself as a global producer of comparable biological agents. Due to the rapid population growth, it is also a huge market for biologics The Indian pharmaceutical/biotech industry is in a favourable position to fully utilize this huge opportunity provided by biologics and biosimilars, and already has an extensive biosimilar product line development of. Measures taken by the Indian government to support the pharmaceutical industry necessary infrastructure, funding and global cooperation to bridge technology the knowledge gap and further development of regulatory guidelines will help to grasp this opportunity in view of technological innovation and economies of scale, India is expected to achieve $12 billion in revenue Market size of biologics and biosimilars by 2025.

According to Deloitte, report"(Deloitte, 2015)" ; In the past few years, biologics have gained tremendous appeal in the pharmaceutical industry. In 2013, global sales of biologics exceeded 150 billion US dollars. With increasing global attention to improving healthcare opportunities and cost of care, biosimilar manufacturers have provided attractive opportunities. Analysts predict that by 2020, the global biosimilar market will reach 2.5-35 billion US dollars. Since the first biosimilar approval in the European Union (EU) in 2006, more than 700 biosimilars have been approved (-450) or are being launched (-250) worldwide. In major markets such as the European Union, regulators and payers have realized the potential financial benefits of biosimilars and are promoting their popularity. For example, France has begun to automatically replace certain biosimilars with reference products.

(Bikash R. Meher, 2019). Biosimilarsin India; Current Status and Future Perspectives.PubMed,12-15. There are many key biologics are scheduled to lose their patent by the year 2020, which will provide the opportunity to other biopharmaceutical companies to develop the similar biologics. Biosimilar or similar biologic used has increased in the recent year following the approval of the first biosimilar in early 2000. India is one of the leading manufacturers of similar biologics. India has developed a new guideline in 2012 for the pre- and post-marketing approval of similar biologics.

(Rushvi P, 2016)Biosimilars: An Emerging Market Opportunities in India. In recent years, many epic biological products are going off patents, which has produced. The simplified approach to biosimilar products relies on extensive comparability testing with Reference. Biological products (RBP) ensure product quality, safety and effectiveness. Biosimilars are products like biosimilars. But don't point them out. Therefore, they require unique market approvals with many documents because they are not a universal version of biological products. This has led to the establishment of strict the balance between product cost-benefit and risk management. The first draft guidelines for biosimilars are established by Europe, Japan and the United States later developed draft guidelines. Although recently India has Guidelines for biosimilars were formulated in June 2012. India has a thriving pharmaceutical industry in generic drugs Although it can become an emerging market for biopharmaceutical drugs. Regulatory structure of biosimilars. This article describes the generic drugs in India by comparing the guidelines for biosimilars developed by India and the World Health Organization. The approval process will be based on the comparable quality certification between the biosimilar product and the original drug because the changes are small, the product may cause unbearable changes in safety and efficacy. In many cases, where biosimilars are highly species-specific, non-clinical research can become more difficult and potentially costly. Therefore, strict regulatory guidelines are required. The biosimilar market will soon exceed $80 billion drug prices in the next seven years.

(Misra, 2012).Biosimilars are biological products and replicas of their innovative biopharmaceuticals. They were developed after the patents of innovative biopharmaceuticals expired and submitted to a separate market for approval. In view of the structure and manufacturing complexity of biopharmaceuticals, biosimilars should not be regarded as "biosimilars". These are quite unique molecules with limited data at the time of approval, so there are concerns about the safety and effectiveness of biosimilars. This article will explore the differences between biosimilars and chemical generics, concerns related to biosimilars and the need for appropriate regulations to approve them.

Methodology

Type of study: Descriptive Study, Secondary Research

Data CollectionSource:

- Data is accumulated from severalorganizations' financial reports as well as publicly available and market research reports.
- Data collection is done by observing existing records.
- Data is collected from various publications, government sites, companies annual report and research Publications.

Data analysis Software: MS ExcelOffice 365

Type of Data: Qualitative and Quantitative

Study Duration: Feb 2020 to May 2020

Inclusion criteria: Article and Market research report of Indian biosimilar market

Exclusion Criteria: Biosimilar data or report before 2018

Key Words: - Biosimilar, Similar Biologics and Biopharmaceuticals

Study limitation:

1. The data was found may not enough to claim therapeutic market size of biosimilars.
2. Market research report and literature review were time constrains.
3. Limited reports were Published.

Operation definitions:

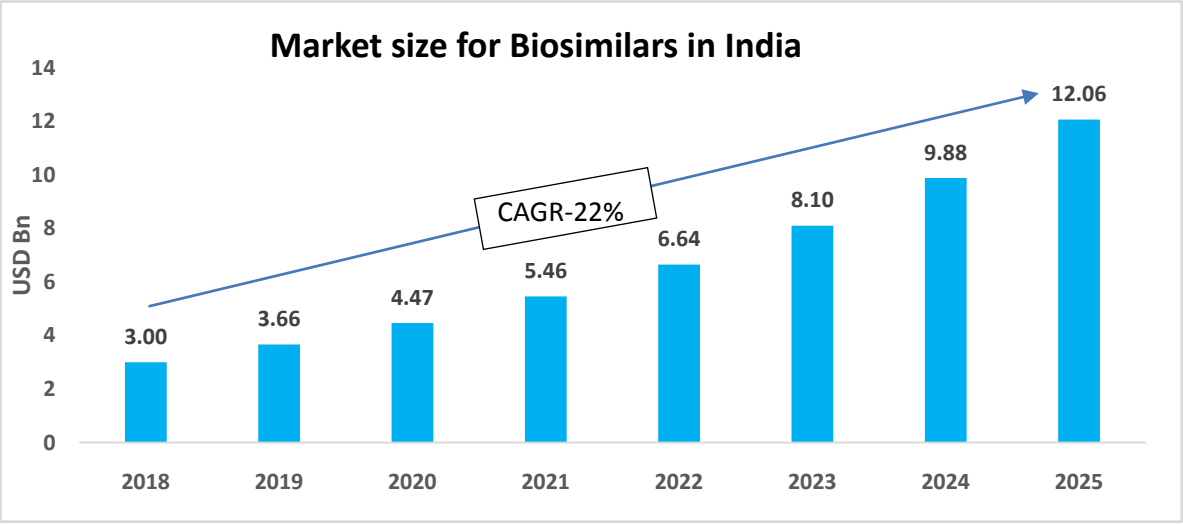
Biologics: - Biologics are very specific, highly effective medicines made in living cells. They improve health in many complex conditions, including Crohn's disease, ulcerative colitis, diabetes, rheumatoid arthritis, cancer, osteoporosis, psoriasis, HIV, multiple sclerosis, growth deficiencies, and more.

Biosimilar: - A biosimilar is a biologic product developed to be highly like a previously FDA-approved biologic, known as the reference product. A biosimilar must have no clinically meaningful differences from the reference.

Market Opportunity of Similar Biologicalsfor India

According to a report from the Associated Chamber of Commerce of India (Assocham), the global market for biosimilars will reach US$240 billion, so the Indian market will exceed US$35 billion by 2030. Indian pharmaceutical companies including Biocon, Glenmark Pharmaceuticals, and Zydus Wellness are actively working on the biosimilar market. For example, Biocon received revenue of Rs 15.17 crore or nearly 28% of revenue from biosimilars in FY19. However, the tonnage will depend on the factors for obtaining key technologies.India is presently a rising community for biosimilars and biosimilars and has consistently could consider the little atoms expected to frame generics. They despite everything come up short on the capacity and condition to create figured out variants of biotech drugs. In any case, notwithstanding the 201 dynamic nonexclusive medications of pharmaceutical organizations, 123 biosimilar drugs have additionally been presented, which is changing this procedure. India as of now has 95 affirmed local biosimilars, positioning first on the planet.

Graph: Revenue of Similar Biologicals 2018-2022



Source: Association of Biotechnology Led Enterprise (ABLE) 2019

At the worldwide Bio-India 2019 occasion held in New-Delhi, the worldwide investigation organization Clarivate Analytics discharged the report. Reliable with the Biotechnology Leaders Association (ABLE), India's biosimilar market will develop at a compound yearly development rate (CAGR) of 22%, arriving at 12 billion US dollars by 2025. The primary biosimilars got administrative endorsement in 2000. 9.8 billion biosimilars were endorsed in September 2019.

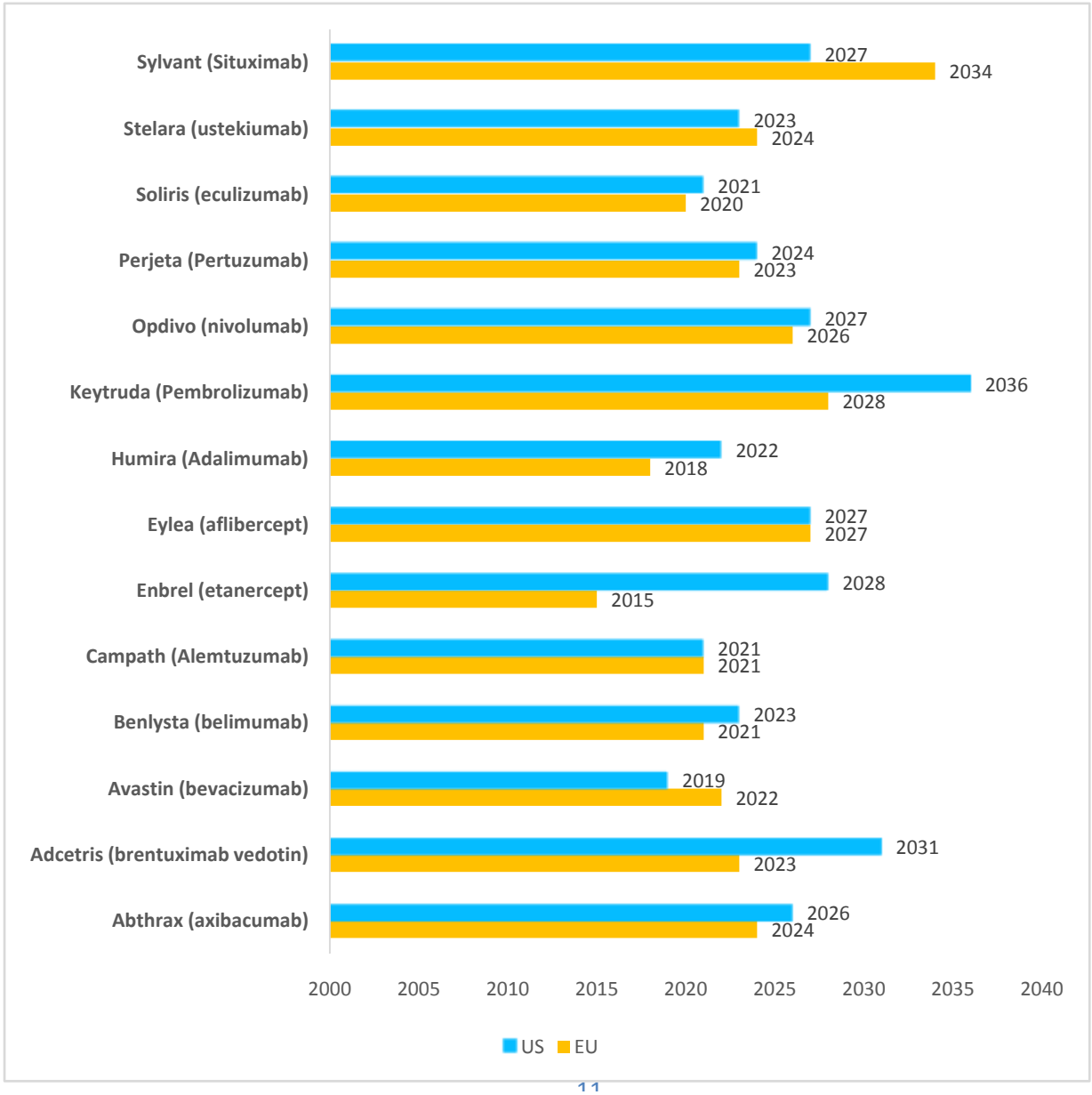
In order to simplify the regulatory approach to urge faster approval and ensure the quality, safety and effectiveness of the cGMP manufacturing process, the 2016 Central Pharmaceutical Standards Control Organization (CDSCO) and DBT issued revised “Comparative Biological Agent Guidelines ". There are 2,700 biotechnology start-ups, 100

biotechnology incubators and 600 biotechnology companies nationwide. In the next five years, this number will increase four to five times.

The report also pointed out that of the ten blockbuster molecules developed globally in 2018, only two were small molecule therapies. India is ready to capitalize on biotherapeutic technology as the two companies have begun to develop many biosimilars in India, so biotechnologies and biotechnology skills in the pharmaceutical industry are growing.

Clarivate Analytics' senior solutions consultant Mandarina Goel said that in terms of the overall market and revenue, biologics have achieved major market share in India. By the end of 2019, the sales of biological agents of US$200 billion had increased to US$386 billion, with a compound annual growth rate of 10%. By 2027, the global biosimilar market opportunity is expected to grow to US$70 billion. In the next two to three years, due to recent regulatory approvals, the market for biosimilars will grow, so 10 patents for best-selling biologics will expire.

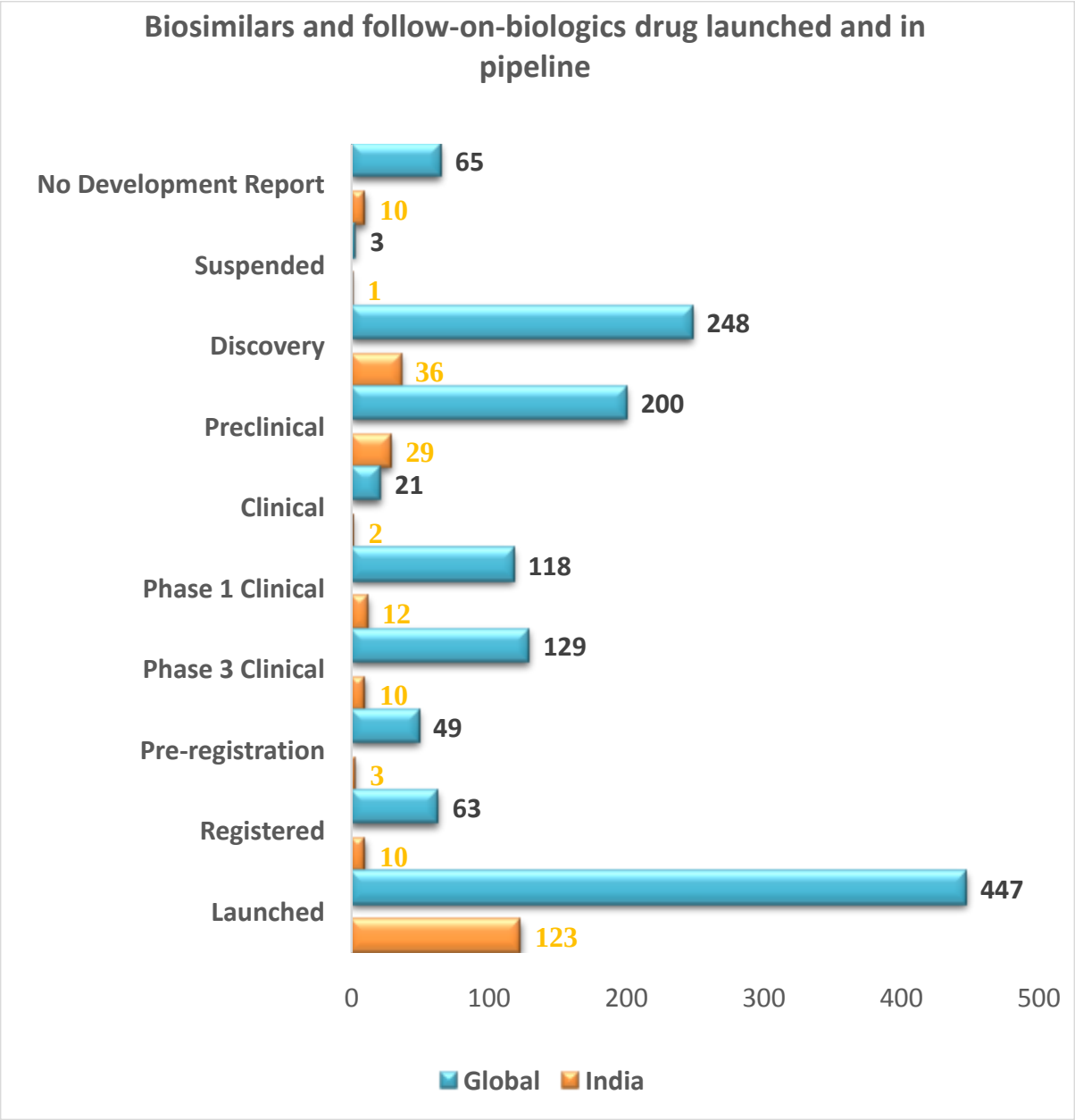
Graph: Patented biologicals going off Patent



Source: Generic and Biosimilar Initiative Journal (GaBi) 2019

The patent for biological agents expires. Estimated value $64B by 2020, global biologics sales are at risk due to patent expiration, the biosimilar industry is expected to grow at a double-digit compound annual growth rate 15%. In addition, there is a value of $ 36B (Source: L.E.K. analysis of data from Evaluate Pharma) (2016). Biologics will remove patent protection from 2020 to 2030, thereby promoting research and development.The third and fourth wave of biosimilar activities.

Graph: Biosimilars and follow-on-biologics drug launched and in pipeline India And Globally



Source: Cortellis Competitive Intelligence (2019

Government Initiatives:

- The Indian government is eager to promote biopharmaceutical within “Make in India” Programme. This initiative is launched by the department of biotechnology. Indian government and Biotechnology Industry Research Assistance Council is aimed to make India as a hub of biopharmaceutical and biotechnology centric innovation and research.
- PPP (Public private Partnership) model is also motivated to grasp the attention of industry, investors and philanthropic agencies. BIRAC has passed funding for start-up from 70000USD to 1M USD per single start up. A fund called the Biotechnology Innovation Fund-AcE has mobilized more than INR 3 billion for specific investments in the biotechnology innovation and entrepreneurship ecosystem to expand scale R&D and innovation.
- The DBT in cooperation with the World Bank, launched an industry academic cooperation program "National Bio-pharma Mission" with an amount of US$250 million Implemented by BIRAC. The purpose of the mission is to strengthen research and Development of Many biological therapies, such as insulin glane (Vitane Pharmaceuticals), Herceptin (SerumInstitute) and plasma separation (BIBCOL). The mission also supports development Some vaccines, such as universal influenza vaccine (MynVax), Pneutgar-15 (Tergene).
- There are more than 2,700 biotechnology start-ups in the country, and this number is likely to grow to ten thousand by 2025. BIRAC plans to cultivate 300-500 start-up companies every year.
- DBT and CDSCO issued revised guidelines for similar biological products in August 2016 provides a simplified and effective regulatory approach to the manufacturing process safety and effectiveness in compliance with cGMP standards. This regulatory impetus has led to India. Patients can get world-class biosimilars at the most affordable price in the world.
- DBT has now trained more than 7,000 personnel in biotech industries under the Biotechnology Industrial Training Programme (BITP). Additionally, there are capacity building training and mentorship workshop including business, IP, legal mentorship, Entrepreneurship Development (ED), Grant Writing & conducted routinely and already covered 10,000 candidates.

Regulatory Environment:

Regulatory considerations-The large and complex nature of biomolecules in the global landscape does not guarantee that biosimilars are like Innovator Biologics. Therefore, regulators are concerned that unique functions not found in biosimilars may reduce efficacy or produce Side reactions. The procedure utilized for items likewise presents provokes identified with quality affirmation. The approvals at present allowed for deals of biosimilars require the payer to demonstrate that it is good with the reference biologic regarding biosimilar investigation and quality chances.

Biosimilars or resulting biologics ought to likewise set up tantamount clinical reactions, which implies that designers must show that there is no clinically significant connection

among biosimilars and the first maker regarding security, virtue, adequacy, or viability the distinction.

After some time, the administrative structures of the US FDA, EMA, and WHO can help improve the coordination of biosimilar permitting pathways, yet in creating nations or developing markets, there are yet noteworthy contrasts in guideline. A few nations, particularly India, Singapore, Malaysia and South Korea, have given biosimilar rules for the EMA model. Different nations, for example, Russia, have no standards or rules. In countries like Russia, biosimilars are managed in the same way as new biological products, and similar requirements must be met to gain market recognition.

Table: Difference between Developed and Developing Regulatory Market

Factors	Developing Market	Developed Market	
	India	**US**	**Europe**
Regulatory Body	CDSCO (Central Drug Standard Control Organization)	US FDA (US Food and Drug Administration)	EMA (European Medical Agency)
Choice of Reference Product	Reference Should be the Novel Product and should be approved in India and licenced in ICH Countries.	FDA licensed or non-US licensed: if able to create an acceptable relationship the reference product.	EMA licensed in a country with same scientific & regulatory Standard.
Framework Approval	2012	2010	2005
Safety and Efficacy requirement	Structural and functional comparability between similar and reference product.	Biosimilar are inferred from analytical, animal studies and clinical trials.	Biosimilar is approved on the basis on PK comparative study and supportive PD data.

Developed Markets

Developed markets like the US, EUS, and Japan give more tight development chances to biosimilars, and they are emphatically bolstered by governments and payers with straightforward administrative channels to control costs. Prior, the development potential so far was a blend of the real world and promotion, as confirm by the horrible showing of European biosimilars in the course of the last seven to eight years.

Proceeded with administrative vulnerability, proceeded with worries among patients and specialists about the closeness, wellbeing and viability of biosimilars, just as proceeded (visit

warming) banters about programmed replacement and universal non-patent terminology (INN) are relied upon to Create long haul obstructions to long haul elective medication. In these business sectors, it is practical that development (i.e. inside the classification of organic preferred position) can overcome impersonation (i.e. inside the biosimilar), particularly in the US.

Geologically, the United States invests a great deal of energy in science and is the fundamental driver of the long haul biosimilar advertise potential. Because of the cutting-edge economy, this has influenced the drawn-out structure of biosimilars, however up until this point, the development rate has been moderate. Europe is the most dynamic. As far as biosimilars are concerned, there is still a relatively mature field in Europe, and due to the trend of adopting early antibody products, many European countries are also emerging in this market.

In the two years since its establishment, biosimilars still accounted for a large share of the original drugs despite falling prices in some European markets. Contrary to developed countries, the regulatory framework for biosimilars responded late, but currently the United States has recently approved 4 biosimilars (adalimumab, biosimilars), while Japan has accepted the biosimilars of insulin glargine. Accept, more and more obvious. The arrival has been confirmed, so it can only improve the current biosimilar pipeline.

EMA(European Medical Agency)

EMA was the first institution to establish guidelines for biosimilars, starting in 2005. Regulatory approval usually takes 6-8 years to go public. All EU member states have centralized policies. It has only been ten years since the European Medical Agency (EMA) obtained the first market approval of biosimilars in Europe. Since then, through the EMA (2017) in the EU obtained nearly 23 kinds of biosimilars sales rights. Europe is the most progressive market for biosimilars, representing around 80% of the particle's worldwide expense. Then again, regardless of having a solid administrative establishment, until this point in time, just a couple of makers have had the option to dispatch biosimilars in the locale.

These incorporate existing nonexclusive medication organizations, the conventional medication divisions of significant organizations and new organizations, particularly. Medis and Ratio Pharma. Biosimilars are predominantly settled in three treatment zones in Europe, erythropoietin (EPO), granulocyte province invigorating variable (G-CSF) and human development impediment (G-CSF) for the treatment of paleness brought about by renal dialysis. To decrease the white platelet tally after chemotherapy. After ten years, the development of the biosimilar showcase is disillusioning and is viewed as a European presentation. What's more, the opposition execution of European biosimilars in various nations and medication classes is extraordinary. Contrasted and the non-erythropoietin filgrastim, the piece of the overall industry of biosimilars in European nations is extremely low. In Europe, the lull is slower than anticipated because of the absence of programmed substitution of biosimilars and specialists, and patients' absence of comprehension of

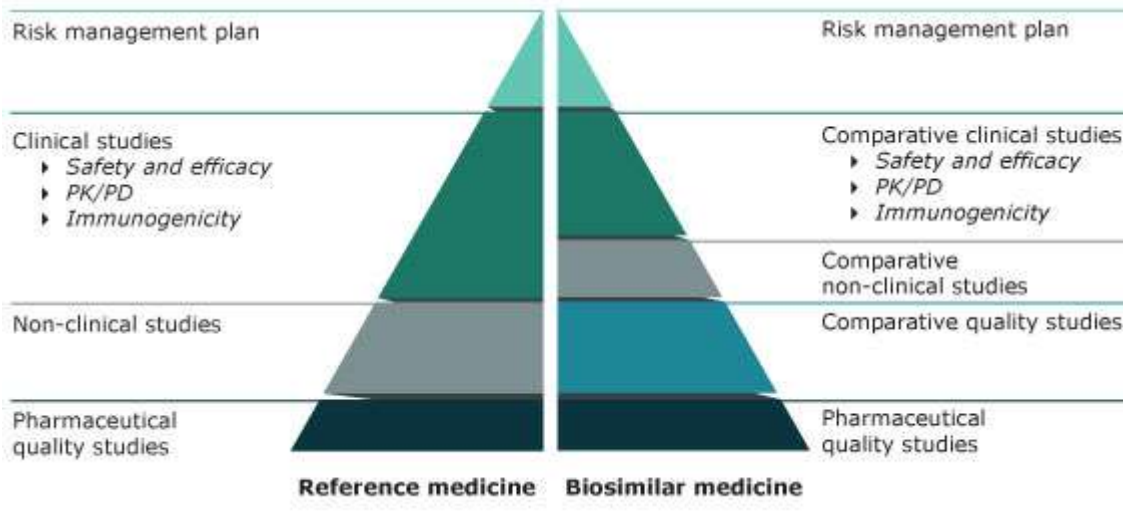
biosimilars. In Europe, different repayment frameworks are likewise observed as hindrances to showcase appropriation.

With respect to decreases, notwithstanding the five significant European nations, the costs of various medication classes additionally differ incredibly. The price of the activator is falling sharply and is in line with biosimilars. Prices, especially in reductions, compared with the original drug before the loss of specificity, the price reduction is as high as 48%.

Key learning:

- 8 years of exclusive data rights.
- 8 + 2 years of marketing authorization franchise.
- During the data monopoly period, there is an important new instruction every second + 1-year market monopoly.
- 1" Interchangeable products are not exclusive.
- European Regulatory Authority: EMEA and CHMP

Figure: Comparison of data requirements for approval of a biosimilar versus the reference medicine



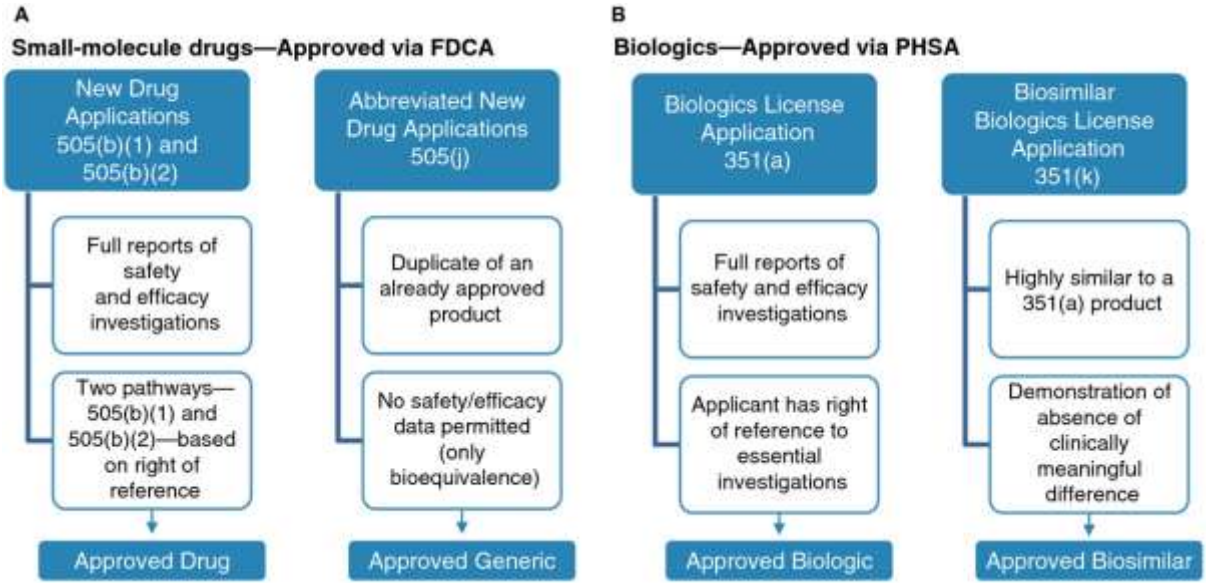
Source: European Medical Agency

USFDA

As per the "Affordable Care Act" marked by President Obama on March 23, 2010, a compacted endorsement pathway was made for natural items, which can be joined with organic items "biosimilars" Or "compatible" Such affirmed guidelines are otherwise called the 2009 Biologics Price Competition and Innovation Act (FDA, 2017). The "Biopharmaceutical Price Competition and Innovation Act" (BPCIA) was ordered in 2010 and built up an endorsement way for biosimilars in the United States.

As per BPCIA guidelines, the FDA has built up a structure that depicts a more bit by bit approach, wherein all information of biosimilars are investigated, non-clinical and clinical examinations, and a far-reaching assessment is led. Head examination with reference yield or unique yield. Simultaneously, biokinetics doesn't require clinical preliminaries to acquire FDA endorsement contrasted with reference items; this may require broad explanatory abilities, just as non-clinical and clinical pharmacology information. Presently, FDA doesn't require similar investigation and clinical research between biosimilars, which implies that biosimilars must be assessed based on assigned reference items or unique items. In this case, biosimilars can be approved for one or more disease indicators without clinical examination. This is called extrapolation. Based on analysis and clinical data that determine the biological similarity between reference drugs and biosimilars in clinical studies, if the biosimilar sponsor provides a scientific basis for this situation, FDA may provide additional instructions. The scientific basis for extrapolation must include the following mechanisms of action, pharmacokinetics, immunogenicity, and expected toxicity differences among different patient populations.

Figure: USFDA Regulatory Pathway for small molecule and Biologicals



Source:[*https://www.researchgate.net/figure/Approval-pathways-for-A-small-molecule-drugs-versus-generics-and-B-biologics-versus_fig2_262197373*](https://www.researchgate.net/figure/Approval-pathways-for-A-small-molecule-drugs-versus-generics-and-B-biologics-versus_fig2_262197373)

India(Developing Market)

In India, biosimilar guidelines were introduced in 2012. About 80% of India's pharmaceutical manufacturing costs are out-of-pocket expenses. Indian arket participants have extensive experience in generic drugs and have entered other countries through export. But the biggest problem faced by Indian market participants is the unsafe manufacturing image and cheap

medicine. A global pharmaceutical company and a domestic company provide benefits to improve the quality of biosimilars sold in India. There are about 19 biosimilars in the development pipeline, and non-primitive biosimilars have increased significantly.

Given the enormous measure of working class discretionary cashflow that expands spending on marked items, this is the reason it opens the best open doors for marked biosimilars. About 70% of the nation's populace is delegated country, that is, a low-level populace, which has driven the heads of spending organizations to concentrate on clinical costs. Comparative with the author's biologics, a rebate of 20-30% may not be adequate to understand this human field.

In India, biosimilars primarily incorporate immunizations, streptokinase (indigo kinase, mountain kinase, STPase), recombinant and demonstrative proteins, granulocyte province development factor (GCSFGrastim, Neukine), erythropoietin, (insulin, insulin) rituximab (MAD), epidermal development factor receptor (hostile to EGFR).

Key learning:

- The names of the administrative offices are CDSCO, DCGI and DBT
- Recently settled administrative rules for biosimilars
- Reference life forms or crude creatures must be authorized in India, else, they ought to be authorized or sold in nations or locales under the recommended administrative channels for at any rate 4 years.

Stage	Application	Approval	Agency involved
Manufacturing and Marketing permission	Form 44	Form 45/46 (finished products)	CDSCO
Manufacturing License for test, Analysis and examination	Form 30	Form 29	State FDA / CDSCO
Preclinical studies permission	Form C3	Form C4	RCGM
Submission of Preclinical study report	Form C5	FORM C6	RCGM
Clinical Trial	Form 44	Permission letter	CDSCO
Registration and Import License	Form 40/ Form 8	Form 28D	CDSCO
Manufacturing	Form 27 D	Form 28D	State FDA/ CDSCO

Table: Var

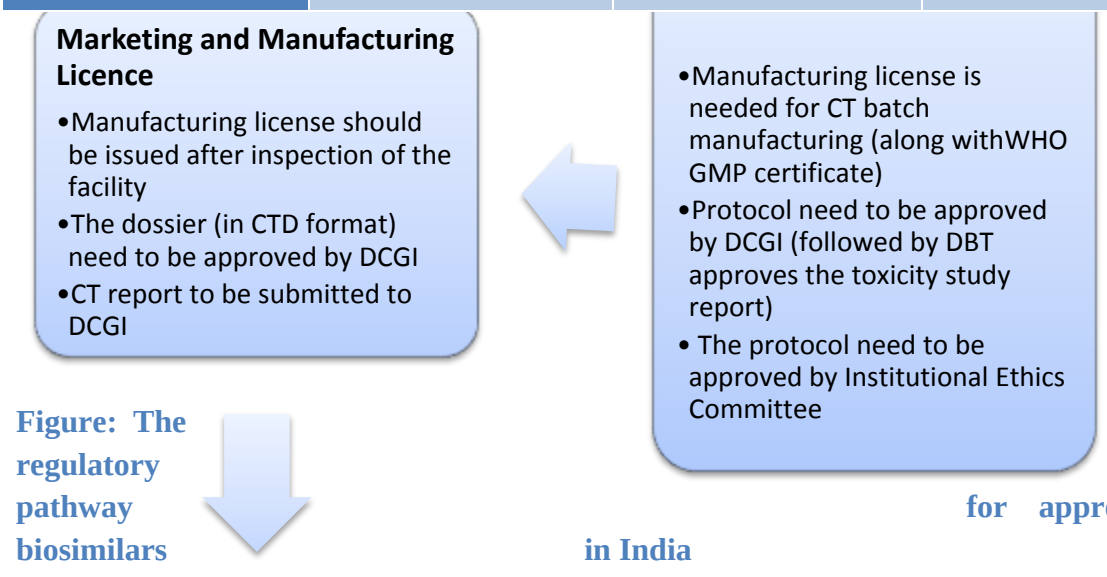


Figure: The regulatory pathway for approval of biosimilars in India

Source: Supplement to Journal of The Association of Physicians of India (2017)

Table: Biosimilars and follow-on biologics launched by Indian pharmaceutical companies in India since 2015

First launched	Drug name	Active indications	Company
February 28, 2015	**teriparatide**	Osteoporosis	Zydus-Cadila Group
June 19, 2015	**ranibizumab, Viropro**	Age related macular Degeneration	Axxiom Inc; Intas Pharmaceuticals Ltd
August 5, 2015	**rituximab**	Chroniclymphocytic leukemia; non-Hodgkinlymphoma; rheumatoidarthritis	Hetero Group
Dec. 17, 2015	**erythropoietin**	Anaemia	Serum Institute of India Ltd
January 9, 2016	**trastuzumab**	Breast tumour	Zydus-Cadila Group
January 12, 2016	**adalimumab**	Ankylosing spondylitis; Inflammatory bowel disease; psoriasis; psoriatic arthritis; rheumatoid arthritis; ulcerative colitis	Reliance Life Sciences Group
January 12, 2016	**rituximab**	Non-Hodgkin lymphoma; rheumatoid arthritis	Reliance Life Sciences Group
June 27, 2016	**bevacizumab**	Metastatic colorectal cancer	Hetero Group
Sept. 6, 2016	**bevacizumab**	Cancer	Reliance Life Sciences Group
Sept. 30, 2017	**bevacizumab**	Cancer; non-small-cell lung cancer	Zydus-Cadila Group
Nov. 23, 2017	**bevacizumab**	Brain tumour; cancer; metastatic colorectal cancer; non-small-cell lung cancer; ovary	Biocon Ltd
January 3, 2018	**adalimumab**	Rheumatoid arthritis	Hetero Group
June 30, 2018	**Peg filgrastim**	Neutropenia	Biocon Ltd
July 25, 2018	**peg filgrastim**	Neutropenia	Lupin Ltd
		Breast tumor;	Dr.

July 26, 2018	**trastuzumab**	metastatic breast cancer; metastatic stomach cancer	Reddy'sLaboratories Ltd
Aug. 19, 2019	**bevacizumab**	Fallopian tube cancer; glioblastoma; metastatic breast.	Dr.Reddy's Laboratories Ltd

Source: Cortellis Competitive Intelligence 2019

Table:Biologics and Biosimilars approved in India (2014 – 2019)

Year	Biologics (r-DNA derived drug product)	Biosimilars (r-DNA derived drug product)
2019	01	**03**
2018	42	**18**
2017	17	**05**
2016	24	**08**
2015	28	**15**
2014	23	**12**
98 biosimilars have been approved in India till date		

Source: Biologics Division, CDSCO

India approved its first biosimilar as early as 2000. Now, India has been leading until September 2019, and has approved more than 98 biosimilars (source: CDSCO). The approval of biosimilars in the regulated market further stimulated Indian pharmaceutical companies to invest in the huge and growing biosimilar market to increase their global market share. In addition, product patents for more than 10 heavyweight biologics with a total revenue of US$60 billion will expire in two to three years, which will further promote the development of the biosimilar market.

Growth Drivers:

1. **Strong skilled manpower pool:**

   The National Biopharmaceutical Mission (NBM) is a cooperative mission of academia and industry, which aims to promote discovery research to early development of biopharmaceuticals. The purpose of the mission is to establish and nurture ecosystems to prepare India's technology and product development capabilities in biopharmaceuticals (including vaccines, biologics, medical devices and diagnostics) to compete globally in the next decade force.

2. **Raising Demand for Alternatives Treatment**:

   There is a continuing need for cheaper alternatives to biological agents, thereby increasing the efficiency of subsequent markets. Since the 1980s, many biological agents have been developed and put on the market. Insulin, human growth hormone, erythropoietin, monoclonal antibodies and some major recombinant methionine synthesis.

3. **Drug Patent Expiration**:

   For 11 well-established biologics, patent losses expire between 2019 and 2030, accounting for nearly 48% of all biologics sales, and the number of major biologics brands that sell products such as Herceptin. Mob Thera, Enbrel, Humlag and Remicade are expected to face patent exclusivity within upcoming decade. It will eventually open a way for subsequent products to deepen its foundation in the biopharma market.

4. **Therapeutic field**:

   At present, the market is undergoing a major transformation towards diseases such as heart disease, cancer and diabetes. High molecules treatment can be selected. However, due to the high cost of treatment and the low tolerance of the middle-class population for this treatment option, the demand for biosimilars has increased.

5. **Prescriber's support**:

   Prescribers are vital who have the right to make decisions between the originator or similar biological products. Consideration should be given to fully providing or enhancing their knowledge of subsequent biological agents. Doctors will provide patients with cost-effective treatment options.

Restraints

1. **Administrative guidance**:

   The regulatory policies formulated by biosimilar regulatory agencies are constantly evolving. Many large markets are still facing mature challenges in developing biosimilar approvals. In emerging markets, the approval mechanism for biosimilars should be more systematic.

2. **Complexity of Manufacturing**:

   As similar generic drugs cost risk and time of synthesizing biological agents are very high, and these products are delivered to patient at expensive price. However, the development cost of generic drugs is between US$1 million and US$5 million, and the growth cost of biosimilars is between US$100 million and US$200 million. The development and execution of biological sequences is very complicated because the difference is from one cell to another. Therefore, biosimilars are not direct copies of their original products.

3. **Competition**:

This is closely followed by competing biologics from two sources, which are bioproducts produced by product companies and product knowledge provided to consumers. Biosimilars are expected to first have the "brand name" feature by deceiving their inventors or herbs. Moreover, because generic drugs offer large discounts to the public, the discounts given to biosimilar drugs are much smaller than those of generic drugs. The cost of developing biosimilars exceeds normal levels, making the biosimilar market less attractive to payers.

SWOT Analysis

Similar biologics, biosimilars or subsequent biologics are the fastest-growing businesses, and their assumption is that they will have strong value in forthcoming years.

1. **Strength**

- ❖ Can Produce low PriceSimilar biologicals with similar efficacy and potency as reference product.
- ❖ Low cost labour in India
- ❖ Government initiatives like “Make in India” and “National Bio- Pharma” have increased the research and development of biopharmaceutical in India.
- ❖ A collaboration with abroad universities to fill the gap between technology and Knowledge.
- ❖ Compared to the original product, the development time and cost are significantly less.
- ❖ Rapidly increasing healthcare costs and the growth of low- and middle-class income groups have increased the scope of biosimilars have been expanded.

2**. Weaknesses**

- ❖ In many countries, the regulatory pathway for biosimilars is still in uncertain situation.
- ❖ Physicians assume a significant job in endorsing biosimilars to patients. In any case, there are yet numerous specialists who don't utilize enormous particles, and they are more ready to endorse unique medications.
- ❖ When developing markets, discounts for biosimilars are lower than the heavy discounts offered by generics. Ordinary organisms offer consumers a discount of 80-90% for reference products, while subsequent biological preparations are only discounted by 20-30% over the original product. This makes it more difficult for low- and middle-income people to afford.
- ❖ Insufficient knowledge of the products of patients and prescribers.
- ❖ The government lacks funds in the developing market.
- ❖ Development process is much complex than small molecule development.

3**. Opportunities**

- ❖ Many Blockbuster Biologicals are going to off patent which will open gate for Similar biologicals in India.

- ❖ Biosimilars are a rapidly growing market in the field of biopharmaceuticals.Because of the biological agents that can be used to treat many long-term illnesses, the cost of treatment has also peaked. Biosimilars or subsequent biologics provide alternative options for purchaser. Due to the price of biosimilars is relatively cost effective than the price of the original drug.
- ❖ Biomedicine can be used to treat many chronic diseases, such as cancer, diabetes, blood diseases, and other diseases, and this treatment is very effective for curing. Therefore, cost-effective alternatives provide room to lead the market.

4.**Threats**

- ❖ The development of this industry requires a lot of investment.
- ❖ The weekly regulatory framework poses risks to the growth of the biosimilar industry.
- ❖ The guidelines for approving biosimilars vary from region to region. This creates a vague environment for market participants to develop products.
- ❖ Low cost of alternative in the Market like China

Competitive landscape of biotechnology companies in India

1.Biocon

- ➢ Established in 1978, the global biopharmaceutical company is a leading global biopharmaceutical company, actively participating in the manufacture and development of innovative technologies with large-scale chemical synthesis, microbial fermentation, mammalian cell culture, protein and antibody purification, and various aseptic formulations.
- ➢ Our vision: to strengthen global healthcare for patients, partners and healthcare systems through innovative and affordable biopharmaceuticals.
- ➢ Our mission: to become a world-renowned comprehensive biotechnology company
- ➢ Insugen® ranks among the top three human insulin brands in India
- ➢ CANMAb™ is not. 1 Brand of Trastuzumab in India
- ➢ Basalog®, not any two insulin glargine brands in India
- ➢ Major biosimilar brands: -
    - Insugen®
    - Basalog®
    - BIOMAbEGFR®
    - CANMAb™
    - ALZUMAb™
    - KRABEVA®
    - TACROGRAF™

2. **Indian Serum Institute**

- Established in 1966, India Serum Institute Co., Ltd. is the global leading manufacturer of measles and DTP vaccines.
- The company produces low-cost biological agents, including anti-snake, diphtheria, tetanus and whooping coughand MMR (measles, mumps and rubella) vaccines.
- **Pipeline products**: DTaP vaccine, pentavalent meningococcal conjugate vaccine (A, C, Y, W-135, X, ErepoXen (polysialylated erythropoietin) and HPV vaccine.

3. **Panacea Biotech Co. Ltd**.

- Panacea biotic was founded in 1976.
- It has strong R&D capabilities and extensive pipelines, including: Develop various complex pharmaceutical general compound technology, Develop the latest chemical entity (NCE) And Vaccines.
- Vision: Leading health management company
- Mission: support life innovation
- Panacea Biotech ranked fourth in vaccines and 15th in pharmaceuticals.

4. **Novo Nordisk**
    - Founded in 1923, Novo Nordisk is a global leader in diabetes care, producing the widest range of diabetes products and developing the most advanced products related to insulin delivery systems.
    - Novo Nordisk has 19 products in preparation.
    - Treatment area:-
        1. Diabetes
        2. Obesity
        3. Haemophilia
        4. Growth disorders
        5. NASH
        6. Red blood cell disease
        7. Cardiovascular disease

5. **GlaxoSmithKline Pharmaceuticals Ltd.**
    - GSK India is one of the earliest pharmaceutical organizations in India. It was set up in 1924. GSK India is an essential gathering, delivering an assortment of physician recommended medications and antibodies in the fields of dermatology, against infectives, diabetes, oncology, cardiovascular and respiratory illnesses and different medicines.
    - The organization additionally delivers antibodies to forestall hepatitis An and B, intrusive maladies brought about by Haemophilus influenzae, chickenpox, DPT, cervical malignant growth, rotavirus, streptococcus pneumonia, and so forth. Our

goal is to become one of the most innovative, best performing and trustworthy healthcare companies in the world.

- About 40% of children worldwide use the GSK vaccine for immunization of at least one serious disease
- Product Portfolio: -
    - Boostrix
    - Cervarix
    - Havre
    - Infanrix hexa
    - Priorix Measles, mumps, rubella vaccine
    - Rotarix Human Rotavirus Vaccine, Live Attenuated
    - Synflorix
    - Varilrix Varicella Vaccine, live attenuated

6. BioGenomics

- BioGenomics may be a science-driven enterprise. Led by a team of distinguished scientists, business professionals, and molecular biologists, microbiologists and protein engineers. BioGenomics has developed dozens of biopharmaceutical and biotechnology products in just ten years.
- Vision: BioGenomics has a strong scientific foundation. Our goal is to innovate and adapt to the changing social and economic needs of healthcare at all stages from laboratory benches to production workshops.
- Mission: Deliver the highest quality products through a safe, compliant environment and advanced infrastructure.

7. Zydus Cadila

- Established in 1952, Zydus Cadila might be a completely incorporated worldwide medicinal services organization that will give total social insurance arrangements from dynamic pharmaceutical fixings, creature wellbeing related readiness items to human services items.
- The organization is the main Indian pharmaceutical organization that propelled the world's first medication NCE-Lipaglyn used to treat diabetes and dyslipidaemia.
- Zydus has 8 biosimilars in the regulatory market and India's pipeline.
- Zydus therapeutic area for Biologics: -
    - Heptiza
    - Bionext
    - Ostivia
    - Oncology
    - Celexa
    - Gen
    - Occucare
    - Kidney dialysis
    - Kidney transplantation
    - Kidney Science

- Vaxxicare
- Biological protection

8. **Indian Immunological**
   - Indian Immunology Co., Ltd. (IIL) was established by the National Dairy Development Board (NDDB) in 1982. Its main goal is to produce FMD vaccines for the poor at reasonable prices. IIL also provides various adult vaccines as child vaccines.
   - There are 150 registered products in Indian Immunology. Prepared the first tissue culture rabies vaccine.
   - The world's first pig cysttail arc disease vaccine.
   - There are nine vaccines in preparation.

9. **Intas Biopharmaceuticals Ltd**
   - Intas Biopharmaceuticals Limited was founded in 1980 by Dr. Urmish Chudgar, the first haematologist. It is the independent biotechnology department of Intas Pharmaceuticals Ltd. It is a manufacturer of medium-sized generic drugs located in Ahmedabad, India. This unit merged with parent company Intas Pharmaceuticals Limited in 2013. Now, Intas Biopharmaceuticals is led by Mr. HasmukhChudgar
   - In 2015, the company launched Accofil, a drug used to treat systemic diseases. In 2016, Intas acquired Teva Pharmaceuticals' assets in the United Kingdom and Ireland for $764 million.
   - Intas Pharmaceuticals has launched its first biosimilar product Accofil in the European market for the treatment of systemic.

Implications:

1. It will provide an option of affordable alternatives of biologics.
2. Finding solutions in order to resolve the rising healthcare costs due to an ageing population is the task today’s global healthcare systems are facing, and biosimilars will be a solution.

Conclusion:

Biosimilars are the way forward for biopharmaceuticals because they can meet the unmet needs of society and provide medical services. Regulators should establish transparent and structured approval channels in developing markets and developing markets, and should promote awareness of biosimilars among physicians, patients and payers.

Indian Biopharmaceutical Market is growing because of raising demand for alternatives at global level and India has strong manpower pool. Blockbuster Biologicals are going to off patent which will open gate for Similar biologicals in India.

Government initiatives like “Make in India” and “National Bio- Pharma” have increased the research and development of biopharmaceutical in India. A collaboration with abroad

universities to fill the gap between technology and Knowledge. India can Produce low Price Similar biologicals with similar efficacy and potency as reference product are the key strengths of Indian biopharmaceutical industry. Insufficient knowledge of the products of patients and prescribers. The government lacks funds in the developing market are the weaknesses. Blockbuster Biologicals are going to off patent which will open gate for Similar biologicals in India. The guidelines for approving biosimilars vary from region to region. This creates a vague environment for market participants to develop products. Low cost of alternative in the Market like China are the threats for Indian biopharma market.

Indian companies are in race of producing biosimilars as we can see there are plenty of biosimilars in the pipeline. Indian biotech giants are Biocon, Serum institutes, Zydus Cadila and Intas.They are top biopharmaceutical companies in India and their good number of products are in pipelines.

The patent for biological agents expires. Estimated value $64B by 2020, global biologics sales are at risk due to patent expiration of key biologicals like Opdivo, Keytruda, Humira, Eylea, Enbrel, Avastin, Sylvant, Campath, Abthrax and Stelara, the biosimilar industry is expected to grow at a double-digit compound annual growth rate 15%. In addition, there is a value of $ 36B (Source: L.E.K. analysis of data from Evaluate Pharma) (2016). Biologics will remove patent protection from 2020 to 2030, thereby promoting research and development. The third and fourth wave of biosimilar activities.

The Indian pharmaceuticalbiotech industry is in a favourable position to fully utilize this huge opportunity provided by biologics and biosimilars, and already has an extensive biosimilar product line development of. Measures taken by the Indian government to support the pharmaceutical industry necessary infrastructure, funding and global cooperation to bridge technology the knowledge gap and further development of regulatory guidelines will help to grasp this opportunity in view of technological innovation and economies of scale, India is expected to achieve $12 billion in revenue Market size of biologics and biosimilars by 2025.

India has firmly established itself as a global producer of comparable biological agents. Due to the rapid population growth, it is also a huge market for biologics. Despite the great potential and high expectations in India, the challenges are great, and to maintain leadership in order to realize the potential of truth and continue to be a global leader, Indian biopharmaceutical companies must upgrade their technology and need to improve human skills. To this end, they have an enabling environment from government and regulatory agencies

Bibliography

1. *Overview-Biosimilar*. (2020, june 5). Retrieved from European Medical Agency: https://www.ema.europa.eu/en/human-regulatory/overview/biosimilar-medicines-overview

2. Bikash R. Meher, S. B. (2019). Biosimilars in India: Current Status and Future Perspectives. *Pharmaceut Reg Affairs 5*, 12-15.

3. BIOLOGICS, G. O. (2016). *Regulatory Requirements for Marketing Authorization in India.*

4. *Biosimilar*. (2020, June 10). Retrieved from XBrane: https://xbrane.com/en/biosimilars/

5. Deloitte. (2015). *Winning with Biosimilars Opportunities in the Global Market.*

6. Derbyshire, M. (2019). Patent expiry dates for biologicals: 2018 update. *Generics and Biosimilars Initiative Journal (GaBI Journal)*, 24-31.

7. GOEL, D. M. (2019, november 29). *India: The emerging hub for biologics and biosimilars*. Retrieved from Clarivate cortellis: https://clarivate.com/cortellis/article/india-the-emerging-hub-for-biologics-and-biosimilars/

8. *Industries Scenerio*. (2020, june 10). Retrieved from Invest India: https://www.investindia.gov.in/sector/biotechnology

9. lexorbis. (2020, june 9). *Emerging Trends For Biologics And Biosimilars In India*. Retrieved from lexorbis: https://www.lexorbis.com/emerging-trends-for-biologics-and-biosimilars-in-india/

10. Luis H. Camacho, C. P. (2016, April 30). Biosimilars 101: considerations for U.S. oncologists in. *Cancer Medicine*, p. 893.

11. MarketsandMarkets. (2019). *Biosimilars Market | Global Forecast to 2025 |.*

12. Misra, M. (2012). current perspectives and future implications. *Indian journal of Pharmacology*, 12-14.

13. Ranjit Shinde, D. R. (2019, May 19). *Understanding the biosimilars opportunity for Indian pharma*. Retrieved from ET Market News: https://economictimes.indiatimes.com/markets/stocks/news/understanding-the-biosimilars-opportunity-for-indian-pharma/articleshow/69335230.cms

14. Rushvi P, C. K. (2016). Biosimilars: An emerging Market opportunities in India.

15. Sharma, S. K. (2017). Use of Biologics and Biosimilars in Rheumatology. *Journal of the Association of Physician of India*.

16. Sullivan, F. a. (2015). *Biologicals Industry overview.* Retrieved from HKEX: https://www1.hkexnews.hk/listedco/listconews/sehk/2017/0613/a9924/ewuxibiologics-20170103-14.pdf

17. *Will Asia Go Big in Biosimilars Adoption and*. (2016). Retrieved from L.E.K Insight Work: https://www.lek.com/sites/default/files/insights/pdf-attachments/1926_Asia_Biosimilar_adoption_manufacturing_Executive_Insights_a.pdf