Similar Biologicals: An emerging Marker Opportunity for India

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Agenda

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- Methodology
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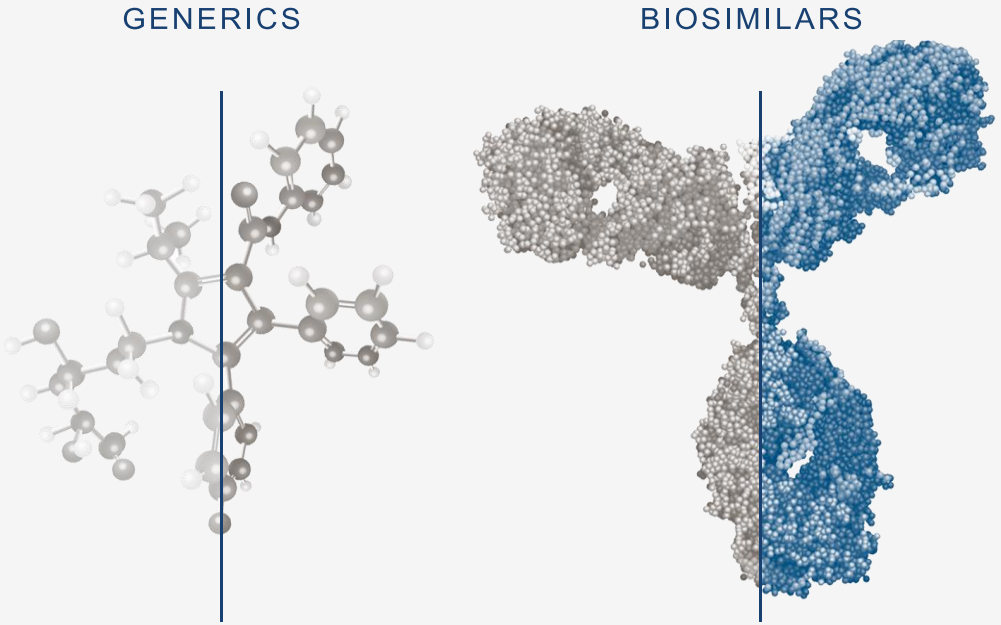
Introduction

Biological is a therapeutic protein, which is produced or contained in the living organism. 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 in terms of safety ,purity and potency.

Out of the top 15 selling drugs in India 4 were biologicals.

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

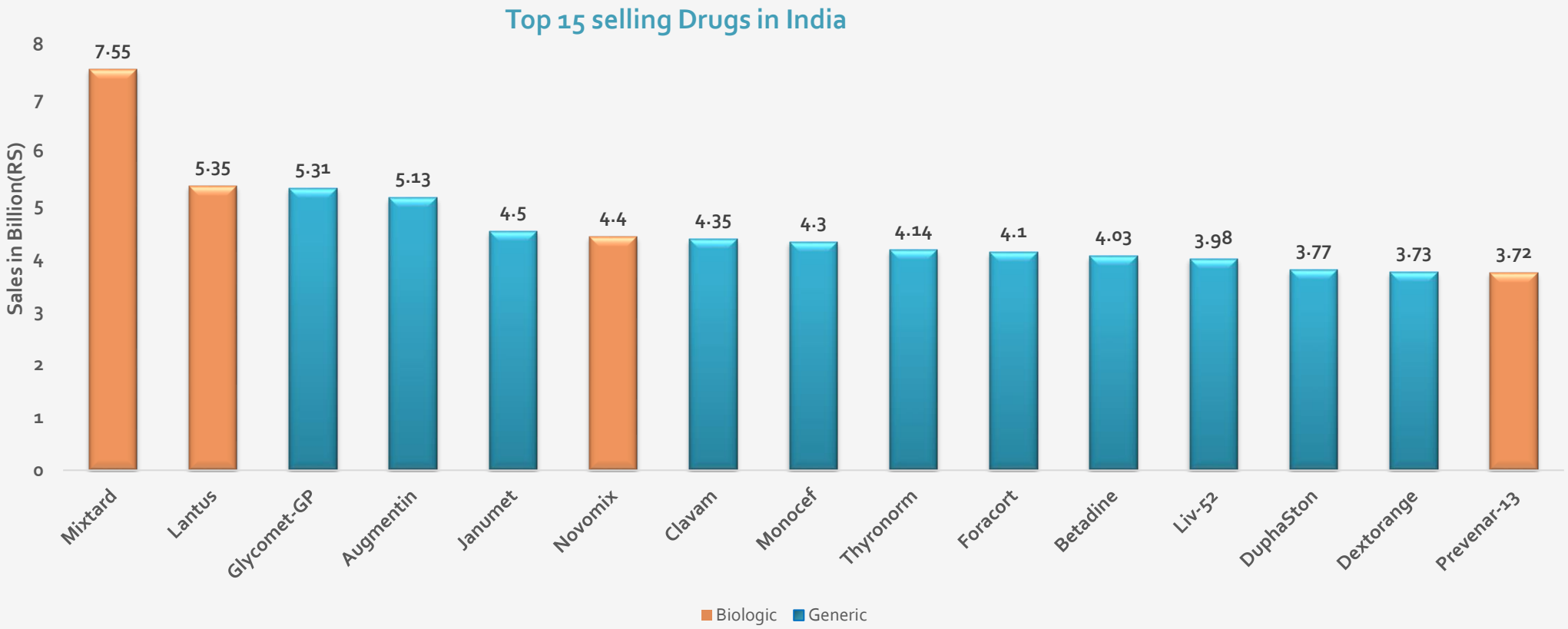
Similar Biologics definition by different Regulatory bodies

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."

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

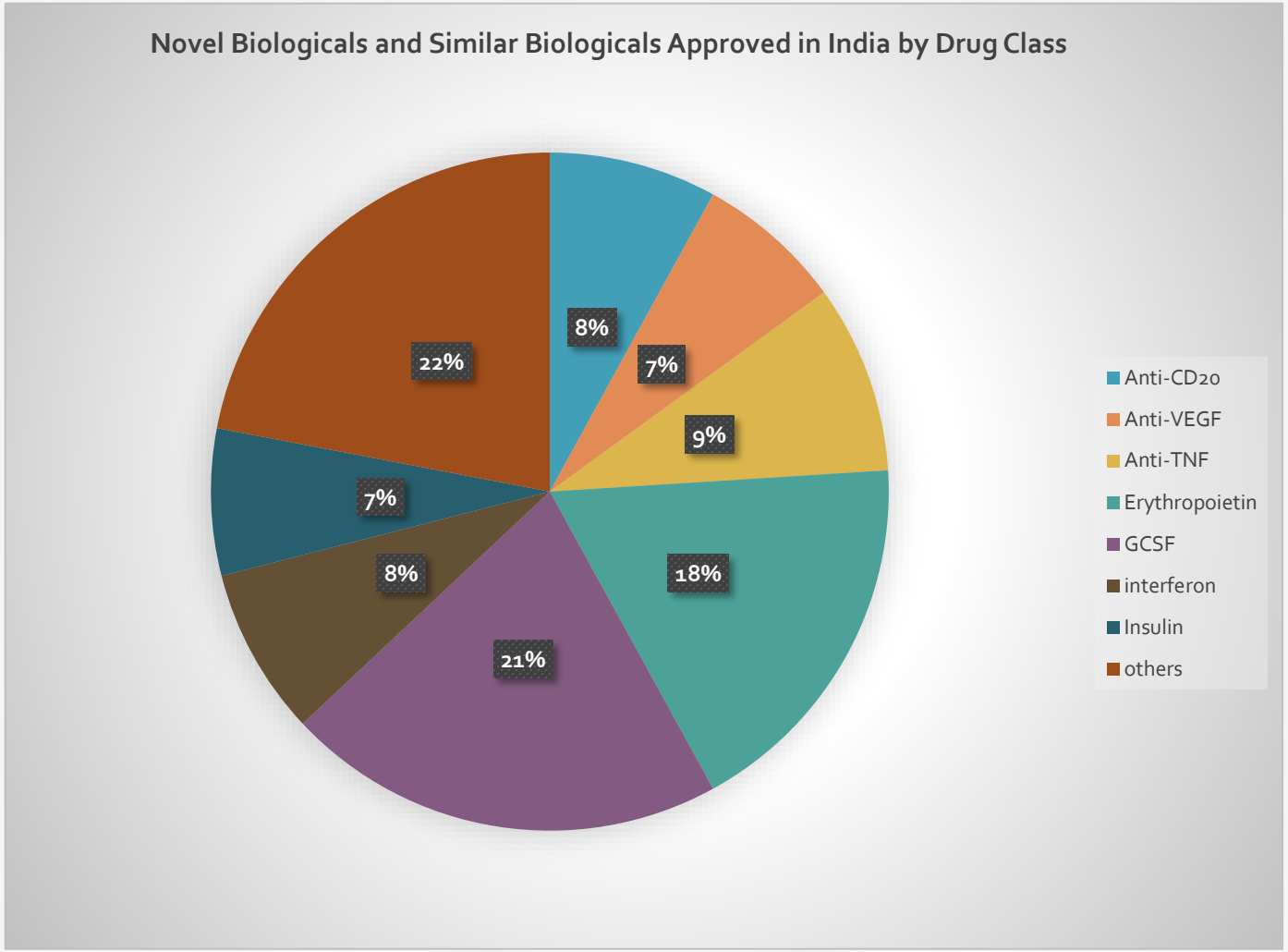
CDSCO
A Similar Biologic product is that which is similar in terms of quality, safety and efficacy to an approved Reference Biological product based on comparability.v

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 authorized 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 authorized 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 authorized for at least 10 years before a similar biological medicine can be made available by another company."



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.



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 .

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Research Question

What is the market opportunity for Similar Biologics in India?

OBJECTIVES

•To find and determine the pipeline biosimilars for opportunity in India.

•To analyze 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 analyze the regulatory framework in developed countries like us and Europe and emerging market like India for the biosimilars/similar biologicals.

Methodology

Type of study: Descriptive Study, Secondary Research

Data Collection Source:

- Data is accumulated from several organizations 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 Excel (365)

Type of Data: Qualitative and Quantitative

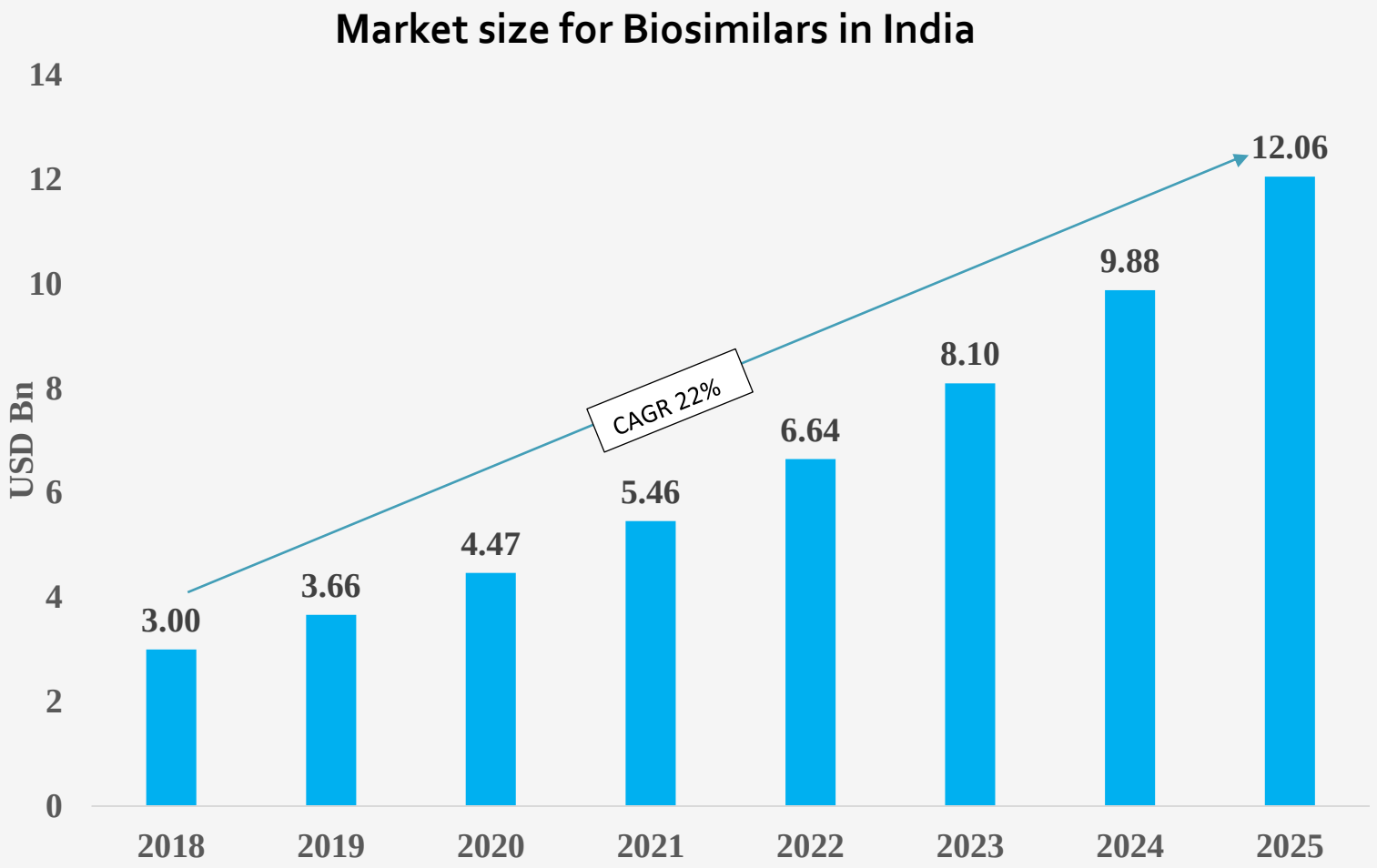
Study Duration: Feb 2020 to May 2020

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

Market overview



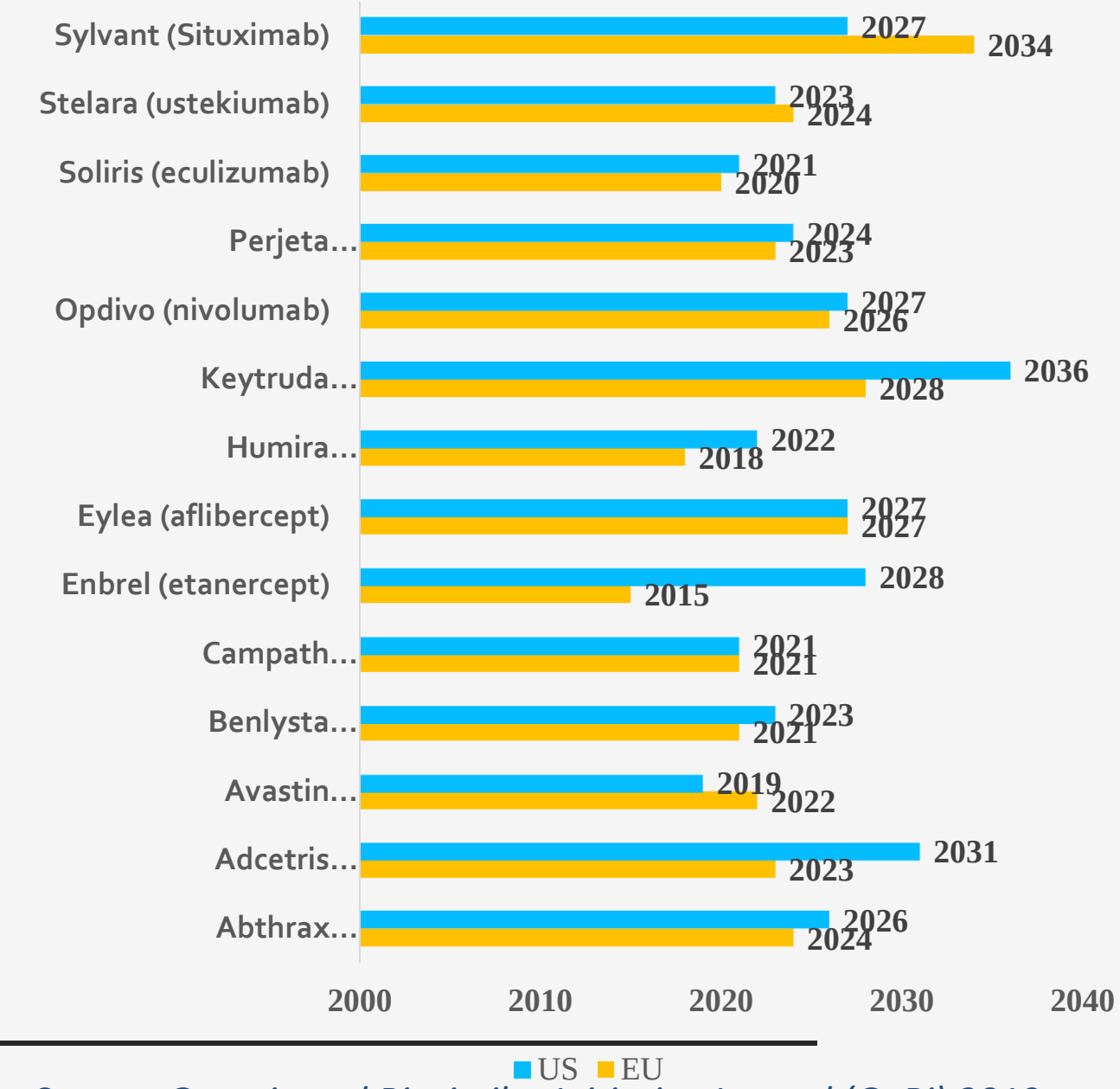
Source: Association of Biotechnology Led Enterprise (ABLE) 2019

Indian biosimilar Market was valued around 3billion US$ in 2018 and expected to grow with compound annual growth rate of 22 % to reach 12 billions US$ in 2025.

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%.

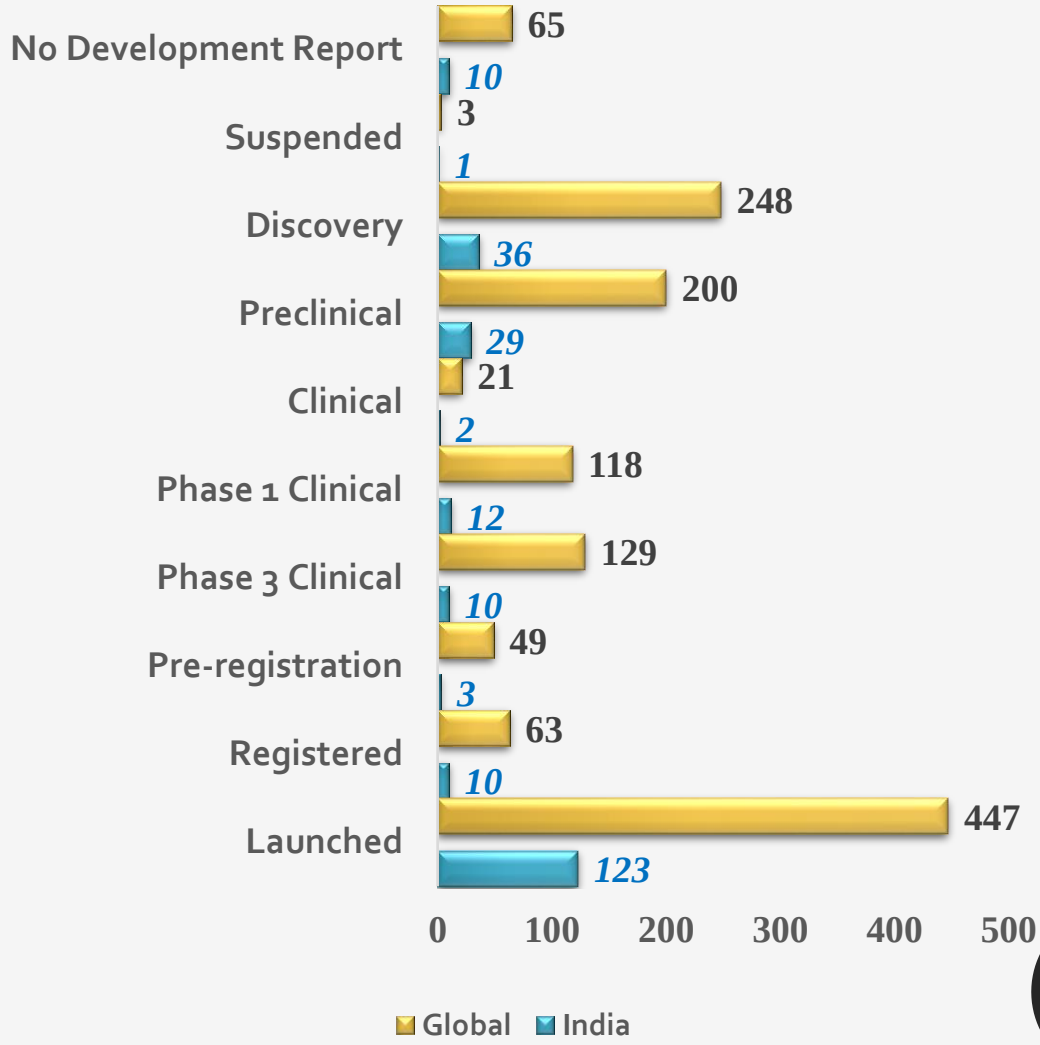
Source: MarketsandMarkets

Graph: Patented biologicals going off Patent



Source: Generic and Biosimilar Initiative Journal (GaBi) 2019

Biosimilars and follow-on-biologics drug launched and in pipeline



Source: Cortellis Competitive Intelligence (2019

Government Initiatives for Biopharmaceuticals

- 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.

- 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.

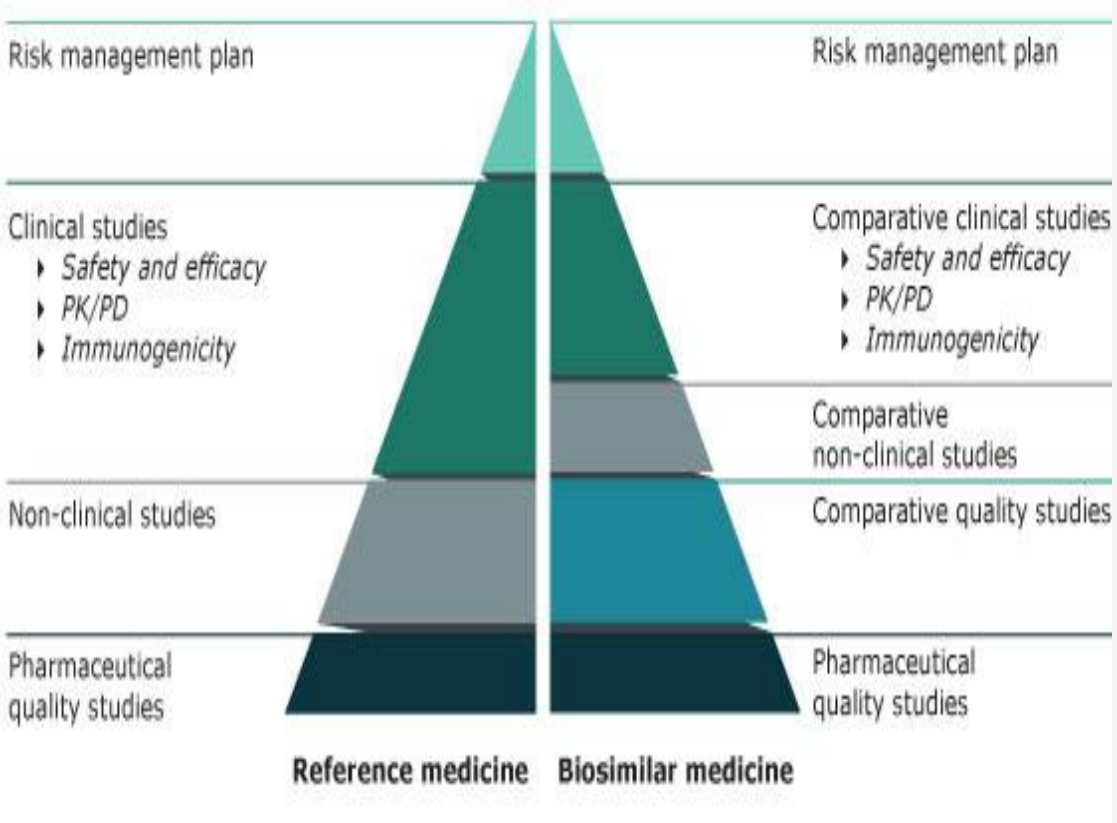
- PPP (Public private Partnership) model is also motivated to grasp the attention of industry, investors and philanthropic agencies. BIRAC has passed funding for start-up from 70000USD to 1M USD per single start up.

- 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

Regulatory Environment

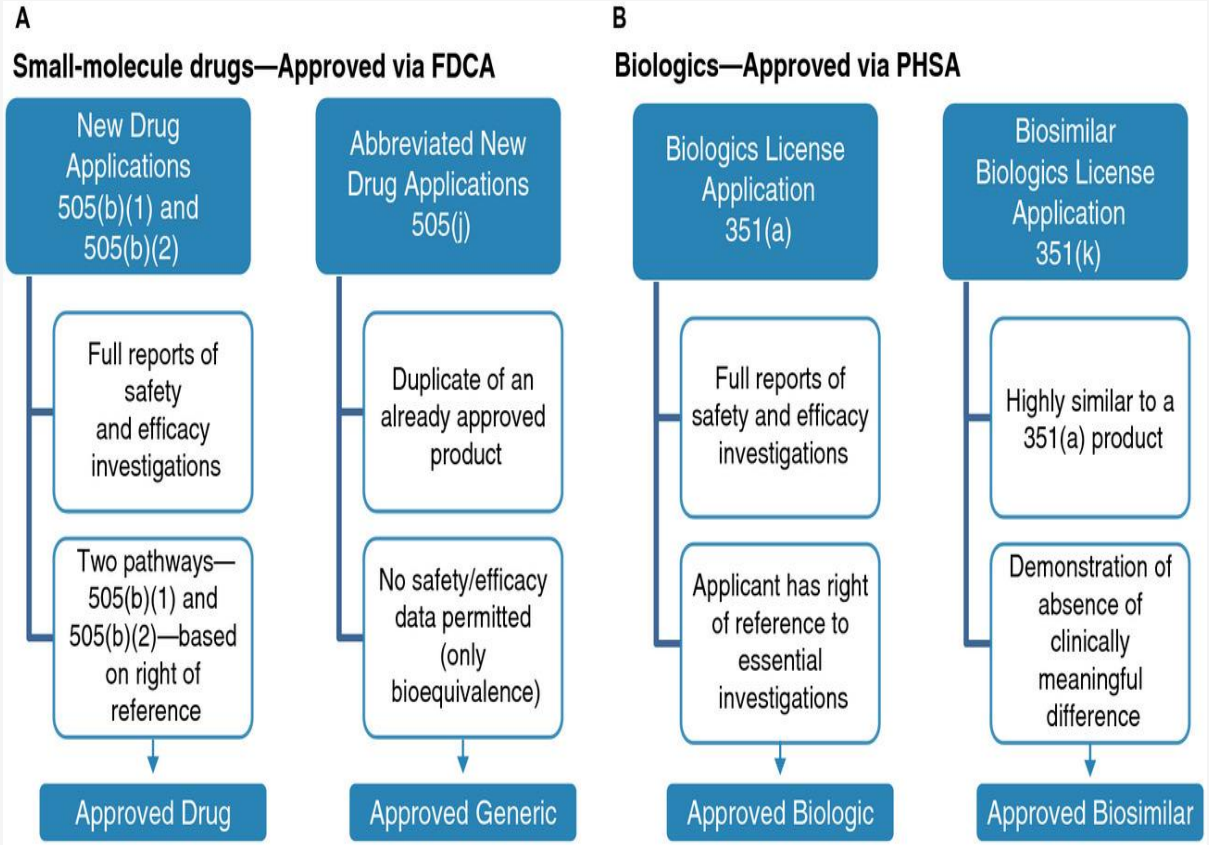
Factors	Developing Market	Developed Market	
	India	US	Europe
Regulatory Body	CDSCO (Central Drug Standard Control Organization)	US FDA (US Food and Drug Administration)	EMA (European Medical Agency)
Choice of Reference Product	Reference Should be the Novel Product and should be approved in India and 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.

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



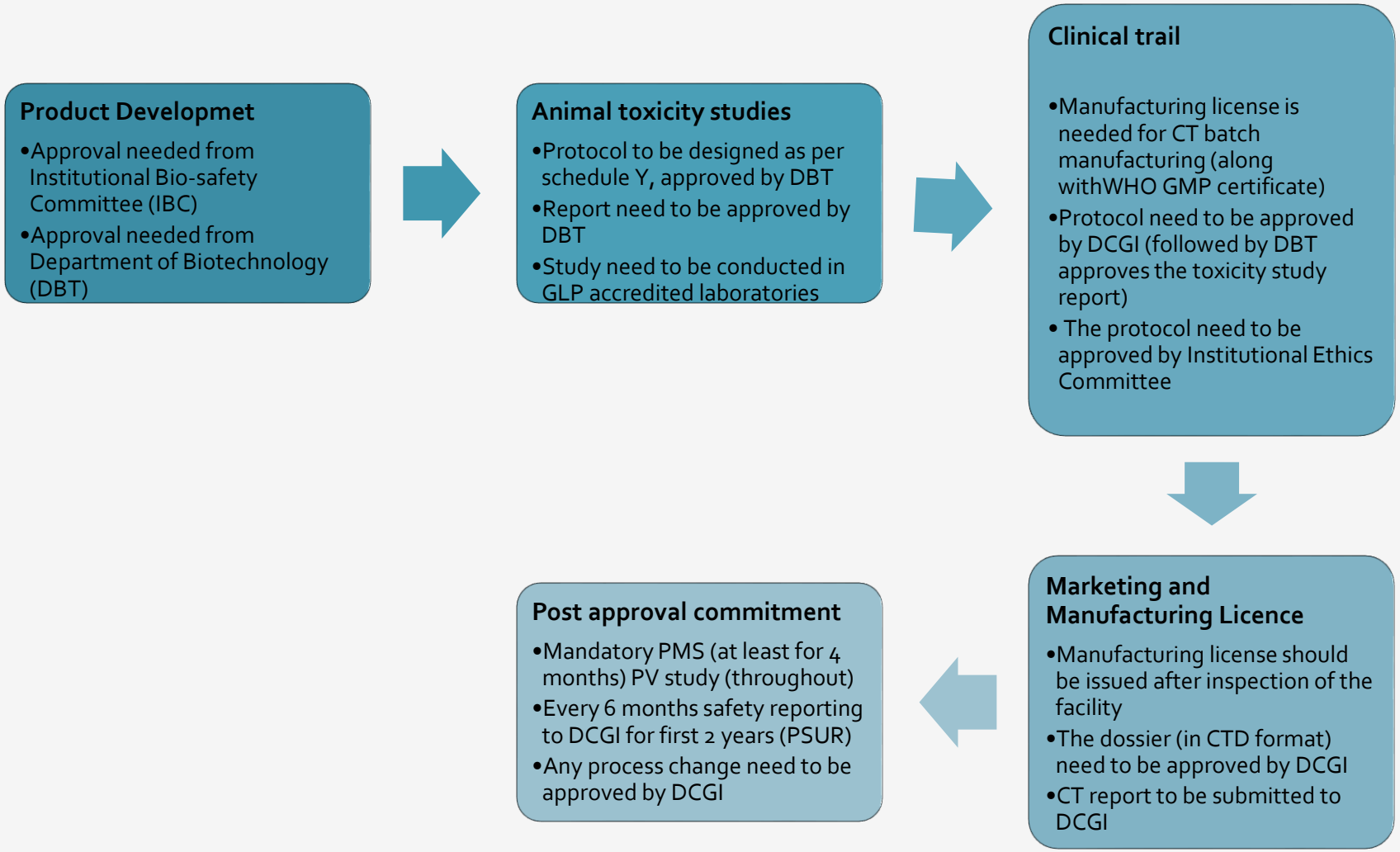
Source: European Medical Agency

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

The regulatory pathway for approval of biosimilars in India



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

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	Chronic lymphocytic leukemia; non-Hodgkin lymphoma; rheumatoid arthritis	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 2 5, 2018	peg filgrastim	Neutropenia	Lupin Ltd
July 26, 2018	trastuzumab	Breast tumor; metastatic breast cancer; metastatic stomach cancer	Dr. Reddy's Laboratories Ltd

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

Market Drivers

- Strong skilled manpower pool
- Raising Demand for Alternatives Treatment
- Drug Patent Expiration
- Therapeutic field
- Prescriber's support

Restraints

- Regulatory ambiguity
- Complexity of Manufacturing
- Competition

- Cost effective
- Low development cost and Time
- Easy approval
- Low labor Cost
- Rapidly increasing geriatric population

- Ambiguity in Regulatory framework
- Lack of Awareness among Physician
- Less affordable by low and middle class
- Developing cost is greater than small molecule drug

- High investment
- Low cost of alternatives

- Alternative option used as life saving
- Many Blockbuster Biologicals are going to off patent

Conclusion

- Biosimilars are the way forward for biopharmaceuticals because they can meet the unmet needs of society and provide medical services.
- 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.
- 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.

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.

Study limitation

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