

Assessment of Biosimilar Market and it's growth in India.

By

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Under the Supervision and Guidance of

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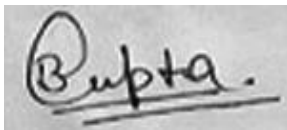
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DECLARATION BY STUDENT

I, Bhaskar Gupta Enrolment No. IIHMR-U/02/2020-22/0233 hereby declare that this dissertation titled **Assessment of Biosimilar Market and it's growth in India** is the bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

A handwritten signature in black ink, appearing to read 'B Gupta.', is shown on a light gray background. The signature is written in a cursive style with a horizontal line underneath.

Name of Student: Bhaskar Gupta

Date: 01-07-2022

CERTIFICATE

This is to certify that dissertation titled **Assessment of Biosimilar Market and its growth in India** is a record of the research work undertaken by **Bhaskar Gupta** in partial fulfilment of the requirements for the award of the degree MBA (Pharmaceutical Management) from the IIHMR University, Jaipur under my guidance and supervision and his/her approach to the research study has been sincere, scientific, and analytical.

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18th June 2022

INTERNSHIP CERTIFICATE

This is to certify that **Bhaskar Gupta**, S/o Mr. Jitendar Kumar Gupta from **IIHMR University, Jaipur, MBA (Pharmaceutical Management)** has successfully completed his Dissertation in **"Assessment in Biosimilar Market in India."** From 21ST March 2022 to 18th June 2022 at **FARE Labs Pvt. Ltd.** and has been awarded excellent grade on the basis of his performance.

He has accomplished the internship successfully. We have found him sincere and devoted during the internship.



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I hope that, in the future, I will be able to draw on my expertise and skills to make a useful contribution to the industry.

Abstract:

The study covers the field of biosimilars with the research done on secondary data sources and covers the overview of the global market of biosimilars drugs which tells us about how the development and growth this field is happening. The general molecules and the Indian company's biosimilar market is having, and their uses is a major part of the research. The market segmentation of biosimilars shows us that how much scope we have in this area and this directly correlates us and takes us to the thing that how much we can explore and where we stand in this field. The impact of the COVID 19 covers how the market has taken a up and down and how the market has shown his capability to affect the business provides us the opportunity of growth which will help us to access the healthcare system. The general trends of the Biosimilar market with future impact and trends for prediction of the growth of the biosimilars in India is a general indicator that how fast this market is growing as the cost of biologics is as compared to biosimilars is much higher and this also takes us to a fact that as the population is more and the cost of treatment is higher so this biosimilar market has a huge potential to grow.

Introduction:

Biosimilars (also known as subsequent bio-logicals or subsequent bio-logics) are biological medical product that are approximately identical copies of the biological product made by another company or the same company in the generic version of drug. Biosimilars are officially approved versions of the original "Innovator" product and can be mass produced when the exclusive rights for the patent of the original product expires. In contrast to generics of the small molecule type, which are more common than the biologics generally have macromolecular complexity and are highly sensitive to changes in the manufacturing process. Despite this non-uniformity, all bio-logicals products, including Biosimilars must maintain quality standard and clinical performance throughout their life cycle. Bio-logicals and Biosimilars are one of the fastest and consistently growing areas of the biotechnology industry, the biosimilar segment is becoming larger in market size & capitalization and there are recently over 250 approved biosimilars worldwide. One of the important steps to get moneyed biosimilar approval is the development of clinical and analytical biosimilars.

Biologics are essential medicines in the mitigation and treatment of many serious illnesses, including cancers and chronic conditions. Preserving access to these treatments is important as the need for them grows—since 2013, there has been a dramatic increase in patients diagnosed with autoimmune conditions such as Crohn's disease, psoriasis, ulcerative colitis, and RA. Biologics are the need of the present time but on the other hand these are too costly. So, Biosimilars are the only way forward to reduce cost of treatment and to decrease the overall expenditure cost for a patient and reduce the OOP. It will not only reduce the quality of healthcare will also give access across the healthcare system.

According to a report in Biospectrum, the biosimilars segment is expected to generate major traction and grow in global markets over the next decade, growing from US\$12 billion in 2020 to at least US\$36 billion by 2025 at a CAGR of 24%. The Indian biosimilar market was worth around \$300 million in 2015 and is projected to grow to \$40 billion by 2030.

There is a potential opportunity for the biopharmaceutical industry in India to become more productive due to the increase in patent expiry for a good number of biologic drugs. The recent success of a few launches of patented products has shown just how much potential the Indian biotech industry has. In FY16, growth in the sector was 57.14%. The

industry size has grown by \$1.6 billion since the end of FY16, has reach \$11.6 billion by the end of FY17.

According to the report of Research and market the India Bio-Similar Industry is expected to generate a revenue of INR 2891.70 bn in the period of 2018-23. Currently, Biologicals and biosimilars are one of the fast and consistently growing biotechnology sectors of India. The major biopharmaceutical manufacturers of India are in Sidcul, Sikkim, Hyderabad, Vishakhapatnam, Chennai, Mumbai, Pondicherry, Mysore, Ahmedabad, and Delhi NCR.

Some common Biosimilars prevailing in Indian market are: Glaritus, Relibeta, Grafeel, Epofer, Krabeya, Herceptin, Abcixirel, Shankinase.

Literature Review

1. Biosimilars aim to be an affordable, available and accessible alternative to highly expensive innovator biological product. However, reaching the goal of affordability without compromising quality is challenging and requires a collaborative effort from manufacturers and regulators, with the guidance of subject matter experts. For emerging biosimilar manufacturers and drug manufacturers expanding their biosimilar offerings, there is a steep learning curve regarding successful biosimilar manufacturing as translational learning from the pharmaceutical sector is limited.
2. Biosimilars are a type of biologic product that are made by a different company after the patent and exclusivity period for the original product has ended. The purpose of this article is that an uncertainty about the terminology of “biosimilars” due to misleading published reports about their apparent diseases has led to patient safety concerns. Therefore, a comparison is made between the various regulatory approvals worldwide in order to achieve harmony of regulations and escalating access to safe medicines worldwide. Every country should have a guideline for evaluating biosimilars, which should take a very similar approach to the WHO guidelines.
3. Biosimilars offer potential improvements to patient accessibility for many malicious and non-malignant diseases, reducing the cost of treatments. Since the first use of biosimilars, the development and use of "biosimilars or similar biologics" has grown significantly. Regulatory authorities grant approval of various similar biologics each year for the treatment of many cancerous and non-cancerous diseases. India has become a global player in the biologics industry by producing similar drugs. The Indian biologics market is growing rapidly, with high expectations from consumers and businesses. However, challenges abound, including maintaining leadership in this field. To stay at the top of their game and continue to be a global leader, Indian biopharmaceutical companies need to upgrade their technology and improve the manpower skills. For this to happen, the government and regulatory agencies need to provide an enabling environment.
4. The potential market for biosimilars is huge, and it's an opportunity for biological product manufacturer companies to make a good amount of money. However, developing and marketing a biosimilar is a complex and time-

consuming process, and companies must follow a specific, step-by-step strategy to receive regulatory approval and have their product reach the market as quickly as possible. Given the unique dynamics of biosimilars, it's important to have a well-planned development and commercial strategy in place from the very beginning of any biosimilar program.

5. Biosimilars are biological products that are clinically similar to a reference standard in terms of their strength, purity, and safety. A large number of biosimilars have been developed to treat cancer. This review looks at biosimilars and how they are used in cancer treatment. It also mentions some recent clinical trials involving biosimilars. Furthermore, it can also interfere with safety profiles, regulatory approval requirements, and other challenges posed by it. The work will be of great interest to researchers working in the field of biology and biosimilars.
6. Many of the important biological products are on the verge to expire by the end of 2020, which will provide other biopharmaceutical companies with the opportunity to develop similar biologics. The use of biosimilars has increased in recent years following the approval of the first biosimilar in 2000. India is one of the world's leading manufacturers of biologics similar to those marketed in other countries. In 2012, India established guidelines for the pre- and post-marketing approval of similar biologics.
7. Biosimilars are subsequent adaptations of an original biological drug that are manufactured to provide a therapeutic effect like the original drug. Over the next decade, the number of patent applications for existing biologics will increase, which will provide opportunities for several innovative companies to design services specifically for biosimilars. The market share of the biopharmaceutical sector is expected to grow in the humongous Indian pharmaceutical market and Global pharmaceutical markets like USA, UK, China, Germany, but biosimilar companies face many challenges in their product development, clinical trial improvement, manufacturing process and quality management, registration, and Marketing & Sales. The vicious competition in the market keeps new players from entering and limits the market's growth. Since these medications are not generic versions of biologics, they require separate approval from the marketing approval agency. Therefore, they need full documentation on quality, safety, and efficacy. The regulatory environment for pharmaceuticals around the world is becoming increasingly strict and is affecting exports. Various important factors

such as Divergent regulations, the funds allocated for direct investments and the lack of clarity regarding the achieved market maturity level have deterred Indian biosimilar suppliers from actively participating in global markets. This paper aims to provide a snapshot of the biosimilars market in India and around the world, as well as discuss some of the major challenges that need to be overcome in order to make this market a success. The report also discusses some trends that point to a bright future for the biosimilars pharmaceutical market.

Problem Statement

To access the present current market and trends and innovative drugs in biosimilars

Research Question

1. To access the market size of the biosimilars drugs in India.
2. To analyze the different trends in the biosimilar drug market.
3. To show the regulatory approval process of the different biosimilar project in India

Research Methods

Table 1: Research Methods

Study design	Descriptive
Data collection method	The data will be from secondary sources like different research papers.
Data analysis plan	Using different research papers inferences
Data used	Secondary data
Study duration	12 weeks

Discussions and trends:

Overview of Market of Biosimilars

The global biosimilar market reached \$ 13 bn in 2021. This market is currently driven by several factors, such as the expiration of successful biopharmaceutical patents, lower prices, a higher prevalence of chronic diseases, and cost-saving initiatives by governments and third-party taxpayers.

Considering all the above factors, the market is flashed to reach \$ 60.8 bn by 2027, with a CAGR of 26.1% in 2022-2027.

According to a report of Fortune Business Insights, (7) the size of the US biosimilars market has been estimated at \$ 6.73 billion in 2021. The size of the market. It is forecasted to increase from \$ 9.48 bn in 2022 to \$ 100.75 bn in 2029, growing at a CAGR of 40.2% over the forecasting period. The global COVID-19 pandemic is unprecedented and breath-taking, with higher-than-expected demand in all regions compared to pre-pandemic levels. Based on the analysis, the market of biosimilars showed a 105.4% higher growth rate in 2020 than in 2019.

According to a Journal published in Biosimilar Development, (8) The biological market in India will grow at a compound annual growth rate of 22% to reach \$ 12 bn by 2025. The market is currently dominated by simple biologics, such as diabetes treatments, oncology, ai diseases and CV diseases. Insulin-like and EPO-like biological products have between 80 and 85% market share in India. However, complicated molecular biological products such as mAbs in Asia-Pacific are estimated at \$ 5.94 billion in 2020 and are projected to reach \$ 10.9 billion by 2025 with a CAGR of 4.52% in India is ar boom.

Manufacturers of biosimilars in India:

Although in the recent times more and more companies are coming and developing this field, some companies have come up with new ideas, new beliefs and new innovation which are paving the ways to reduce the cost of treatment, some of the companies that have come up with the biosimilars are:

Intas: Filgrastim - Neukine, Pegfilgrastim - Pegasta, Rituximab - Mabtas, Ranibizumab - Razumab, Bevacizumab - Bevastas.

Biocon: Insulin Glargine - BASALOG, Insulin Disposable Glargine pen - BASALOG ONE, Rh-Insulin - INSUGEN-30/70.

Relaince Lifesciences: Abciximab - AbcixiRel, Adalimumab - AdaliRel, Bevacizumab - BevaciRel, r-hCG - ChorioRel, Darbepoetin - DarbeRel, FSH - FostiRel

Zydus Cadila: Adalimumab- Exemptia, Trastuzumab emtansine- Ujvira

Lupin: Filgrastim - Lupifil, Peg-Filgrastim - Lupifil-P, Etanercept

Dr. Reddy's Laboratories: Darbepoetin Alfa - Cresp, Filgrastim - Grafeel, Pegfilgrastim - Peg-Grafeel, Rituximab - Reditux.

Market Segmentation of Biosimilars

The biosimilars market for human growth hormone, EPO, mABs, insulin, interferon, and colony stimulating factors is broad. The market for the use of biosimilars is segmented into blood diseases, cancer, chronic and autoimmune diseases, and growth hormone deficiency. The use of biosimilars for the treatment of blood diseases is the segment with the highest sales due to expensive biological reference substances. and frequent use.

- **By Product:**

- Human Growth hormone
- Insulin
- Interferon
- Monoclonal Antibodies
- Peptides
- Granulocyte colony stimulating factors
- Erythropoietin

- Other
- **By Services:**
 - Clinical Trials
 - Contract research and Manufacturing Services
- **By Technology:**
 - MAb Technology
 - rDNA Technology
 - Chromatography
 - NMR Technology
 - Electrophoresis
 - Mass Spectrometry
 - Bioassay
 - Western Blotting
- **By Application:**
 - **Blood Disorders**
 - Chemotherapy Induced Anemia
 - Hemophilia
 - Pulmonary embolism
 - Oncology Diseases
 - **Chronic and Autoimmune disorders**
 - Diabetes
 - Neutropenia
 - Multiple Sclerosis
 - Cystic Fibrosis
 - RA
 - Leprosy
 - Growth Hormone Deficiency, others

Uses of different biosimilars in India and their market

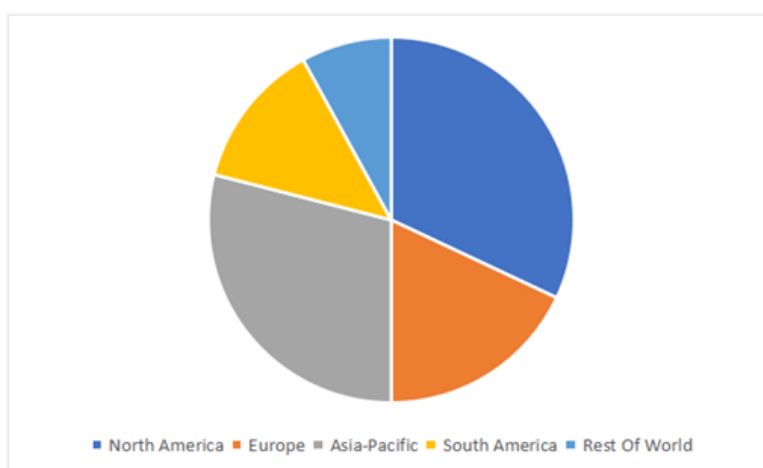
Adalimumab:

Adalimumab is used to relieve pain and swelling caused by certain types of arthritis. The drug is used to treat certain skin conditions (psoriasis vulgaris, hidradenitis suppurativa, etc.), as well as other conditions. The drug works by blocking proteins that are found in the body's immune system and can cause swelling and damage to the joints in arthritis and psoriasis. Adalimumab is a type of medicine known as a TNF blocker. This medicine helps to reduce joint swelling and may help to maintain joint function.

It is also used to treat certain enteropathy (colitis) and eye diseases like uveitis.

The market size of adalimumab is projected to be US \$ 5.1 bn by 2027. In addition, it is flashed to grow at a CAGR of 5.1% over the forecast period of 2022-27.

Adalimumab Market: Market Share (%) by region, 2021



As seen in the above pictorial description the Asia-Pacific market holds at least one-third of the market of Adalimumab, India being one of the major countries of this region have a huge potential of growth. The global arthritis market is being growing at a CAG Rate of 8.8% which will increase the use of Adalimumab for the treatment.

Filgrastim:

Filgrastim is a recombinant version of the naturally occurring G-CSF that stimulates the production of neutrophils. It is also commonly used when Leukemia is associated with an increase in white blood cells. Filgrastim has many side effects, including joint discomfort, chest pain, hair loss, and vomiting.

The global Filgrastim market is valued at US \$ 562.5 mn in 2020 and is estimated to reach US \$ 745.9 million by 2030 to treat low blood levels of neutrophils 2021 - Grow from 2030 with a CAGR of 2.80%.

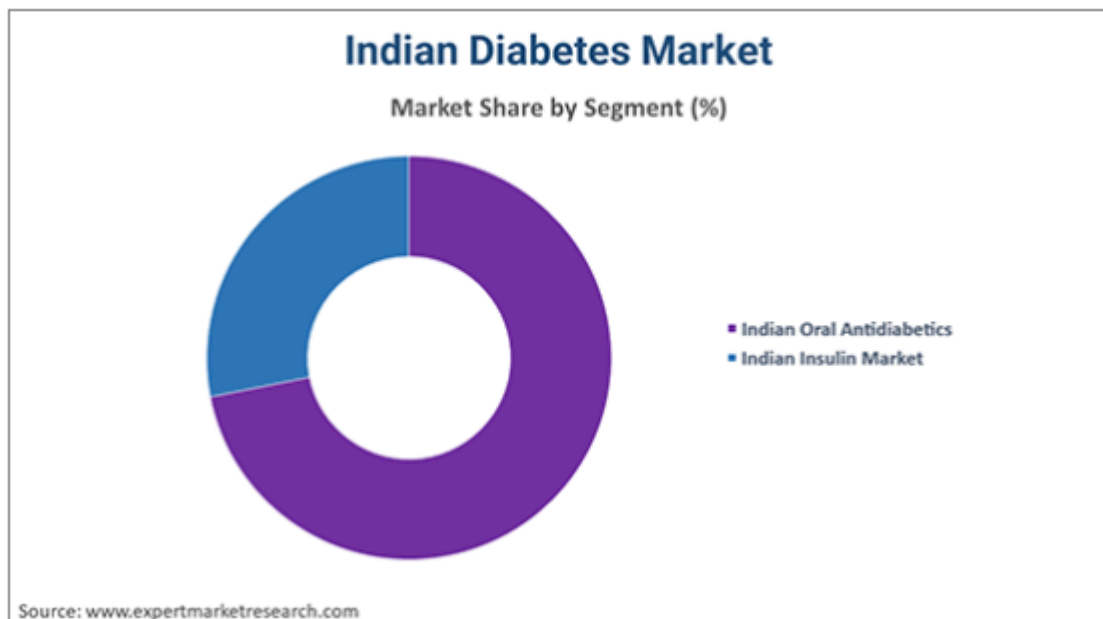


As seen from above pictorial representation the 2020 market share of filgrastim is almost the same as the biosimilar one but due to inflation rate and different economic factor of OOPe, the biosimilar version of Filgrastim will take the lead over the time in the forecast period from 2020-2030

Insulin Glargine:

Insulin is used in combination with a diet and exercise program to control blood sugar levels in people with diabetes. Controlling hyperglycemia helps prevent kidney damage, blindness, nerve problems, loss of limbs, and problems with sexual function. Proper diabetes management can also reduce the risk of heart attack and stroke.

India's diabetes market reached US \$ 1.957 bn in 2020. The market is estimated to grow at a CAGR of approximately 16.5% between the forecast period 2022 and 2027. The market size is projected to be worth about \$ 4,892.7 mn by 2026.

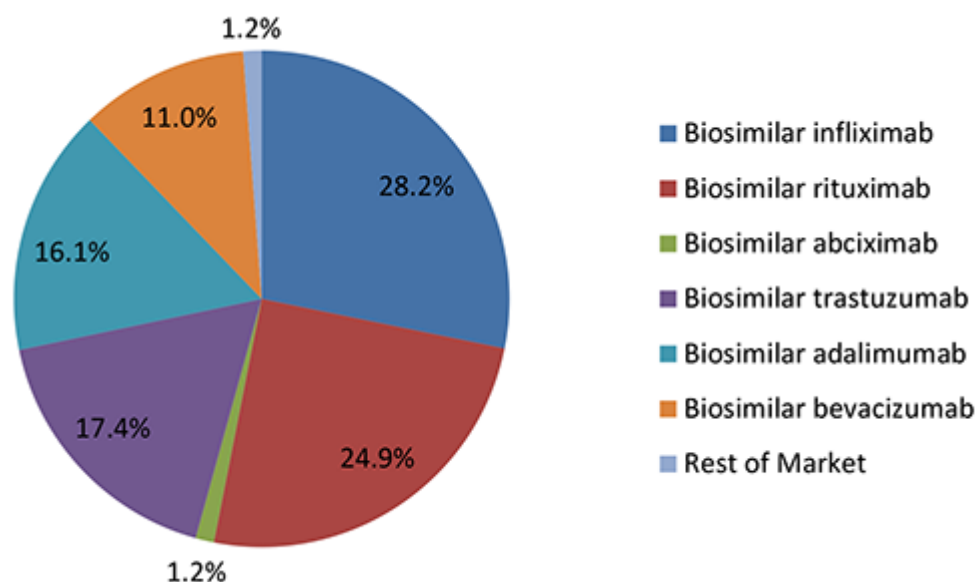


India is country with more and more cases of Diabetes Mellitus and the market reaching to a market size of \$4893 million by 2026, the use of Insulin will increase and will result in the growth of biosimilar market of the Insulin Glargine.

Monoclonal antibodies:

Biosimilar monoclonal antibodies (mAbs) are a type of biosimilar. They are large, complex proteins used by the immune system to identify and neutralize foreign substances such as bacteria and viruses and are usually given to treat diseases such as cancer and RA.

The global biosimilar monoclonal antibody market is expected to reach US \$ 5.9 bn in 2023 and will grow at a CAGR of 19% from period of 2016-2028.



Trastuzumab:

Trastuzumab is used to treat certain types of cancer like breast, stomach cancer. This drug is used to treat tumors that produce too much of the HER2 protein.

Trastuzumab is a type of drug known as a mABs. It helps to fight certain types of cancer. The treatment works by slowing or stopping the growth of particular cancer cells.

The global biosimilar market of trastuzumab is expected to grow from \$1.22 bn in 2020 to \$1.4 bn in 2021, with a compound annual growth rate (CAGR) of 14.8%. The market is projected to reach \$4.25 bn by 2025 with a growth rate of 32%.

Abciximab:

Abciximab is used to reduce the risk of CV disease like heart attack in patients who require percutaneous coronary intervention (PCI). A heart attack can happen when a blood vessel in the heart is blocked by a blood clot. Blood clots may form during PCI if certain cells in the blood stick together. Abciximab may help to prevent these clots by preventing certain cells from sticking together. Abciximab is used with other drugs to prevent blood clotting, such as aspirin and heparin.

Rituximab:

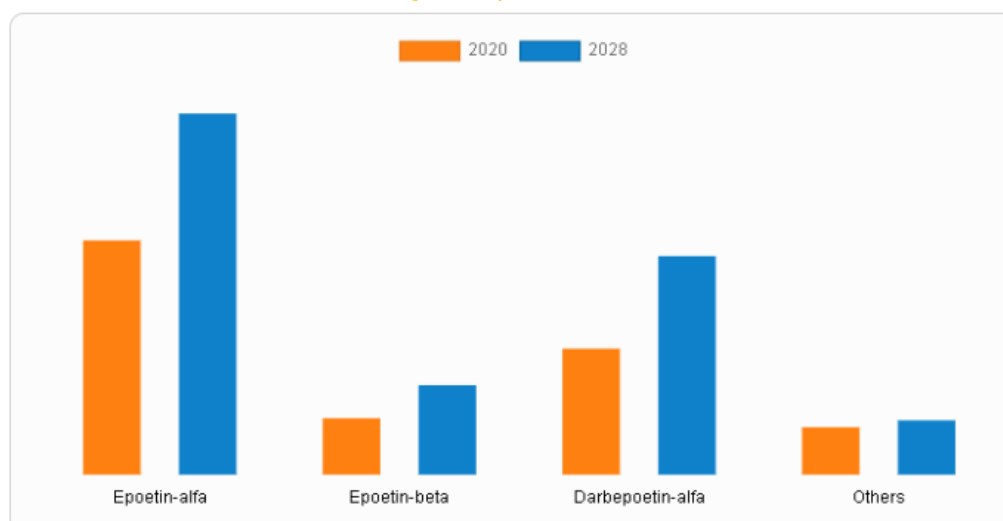
Rituximab is used to treat certain types of cancer like chronic lymphocytic leukemia, etc. The drug slows or stops the growth of certain cancer cells. Some brands of rituximab are also used to treat rheumatoid arthritis and may reduce joint pain and swelling. The drug is also used to treat certain types of vascular diseases and can reduce swelling of blood vessels. Rituximab is also used to treat conditions such as pemphigus vulgaris.

Erythropoietin:

EPO is a glycoprotein hormone that helps to produce red blood cells in the bone marrow. Erythropoiesis is the process of creating new red blood cells. The drug erythropoietin was developed to help treat end-stage renal disease (ESRD) and anemia caused by dialysis procedures.

Erythropoietin Drugs Market

By Therapeutic Class



Etanercept:

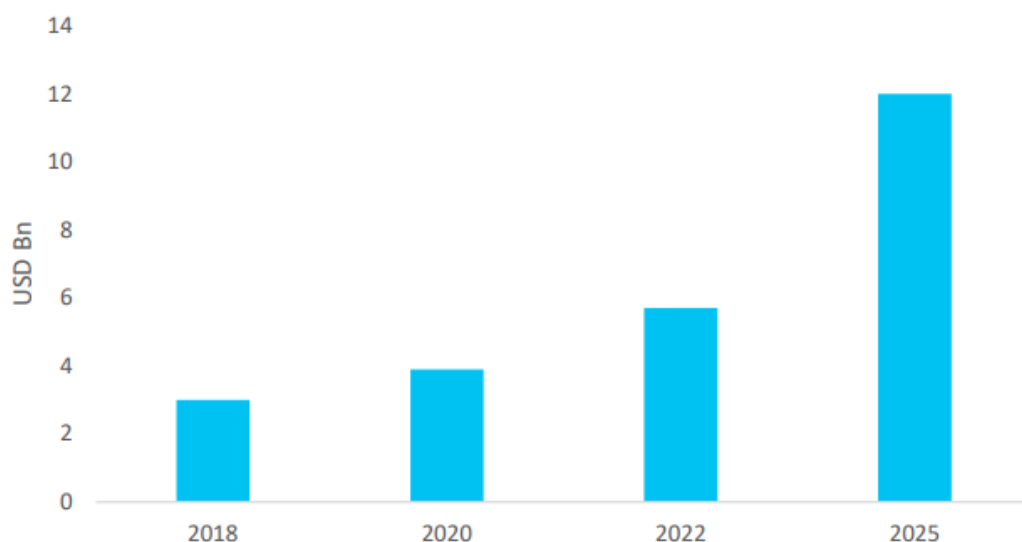
Etanercept is a recombinant molecule composed of two soluble TNF receptors (p75) subunits fused to the Fc portion of human IgG1. This fusion protein is a novel paradigm for TNF receptor therapy. TNF α is produced when the body is exposed to inflammation, such as from an illness or injury. The following drugs interfere with TNF α by inhibiting its activity. This results in increased inflammation and apoptosis. TNF receptors are a major factor involved in both of these processes. This drug is most often recommended for treating severe or moderate rheumatoid arthritis, ankylosing spondylitis, and other immune disorders.

The market size for Etanercept is estimated to be \$21.2 billion by 2027 at a CAGR of 3.9%

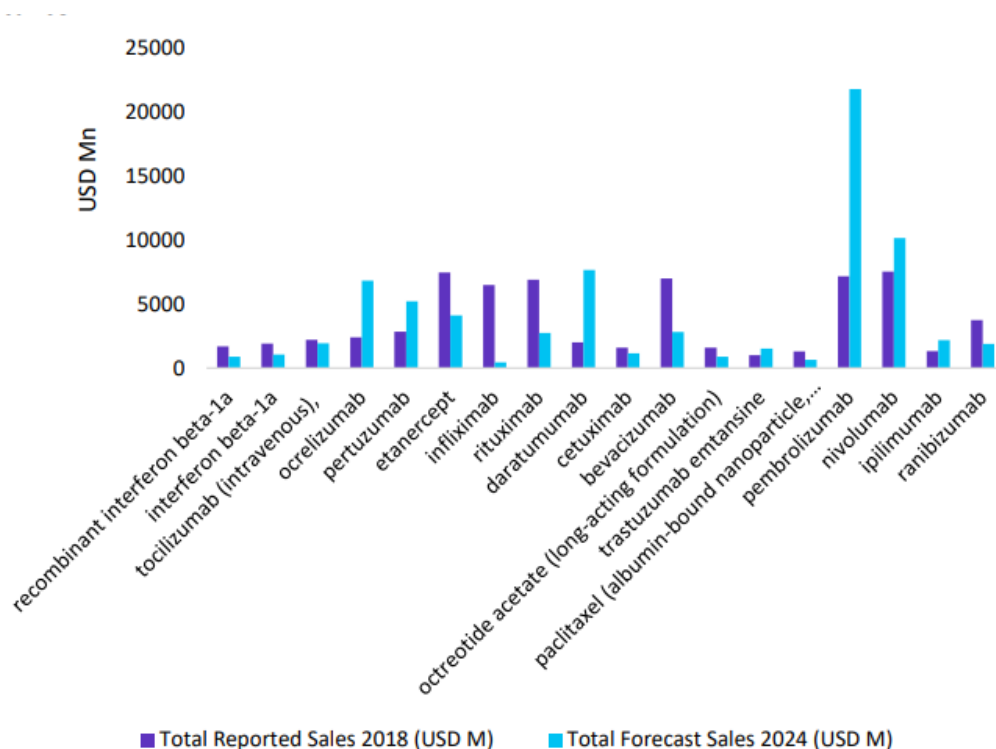
Trends in biosimilar market in India comparison to Different Pharma Products

Expected growth of the Biosimilar market.

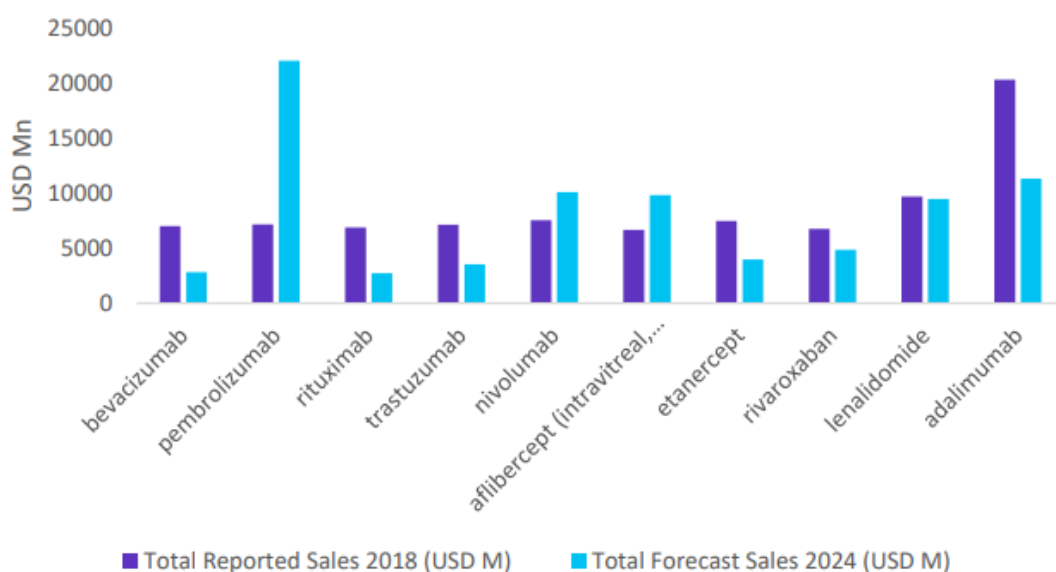
The Indian Biosimilar market is expected to grow at a very fast pace and reaching its value at USD 12 Billion in the year 2025. This is possible because of number of approvals and various robust opportunities for biologics and biosimilars. Contract research and clinical trial development and advancement has given a push in this area.



Sales of blockbuster biologics used in the treatment of cancer

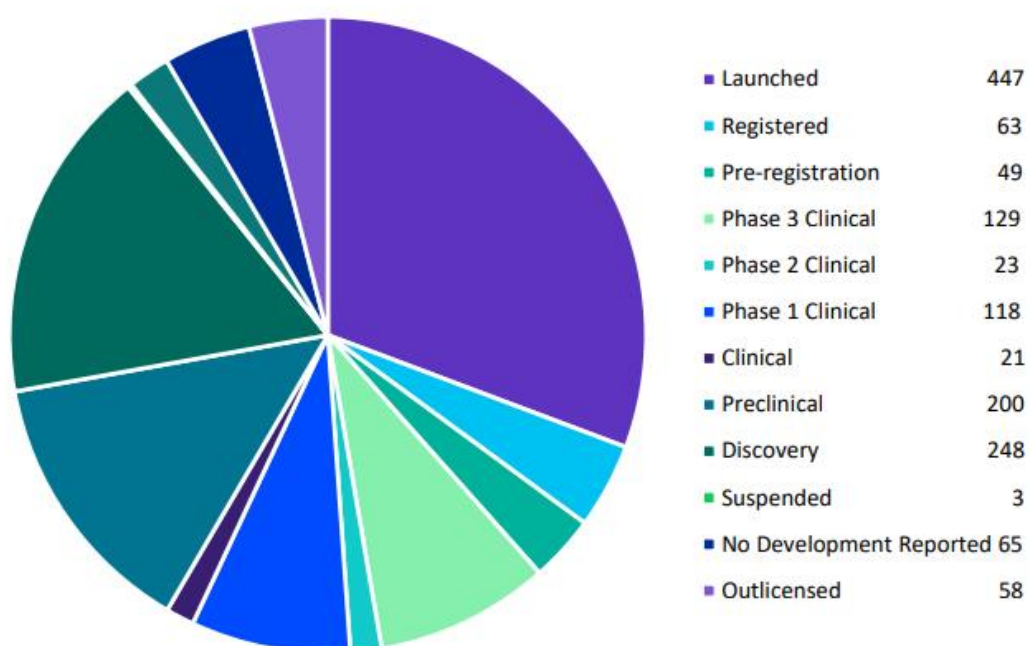


Top 10 Blockbuster Biosimilar drugs sales



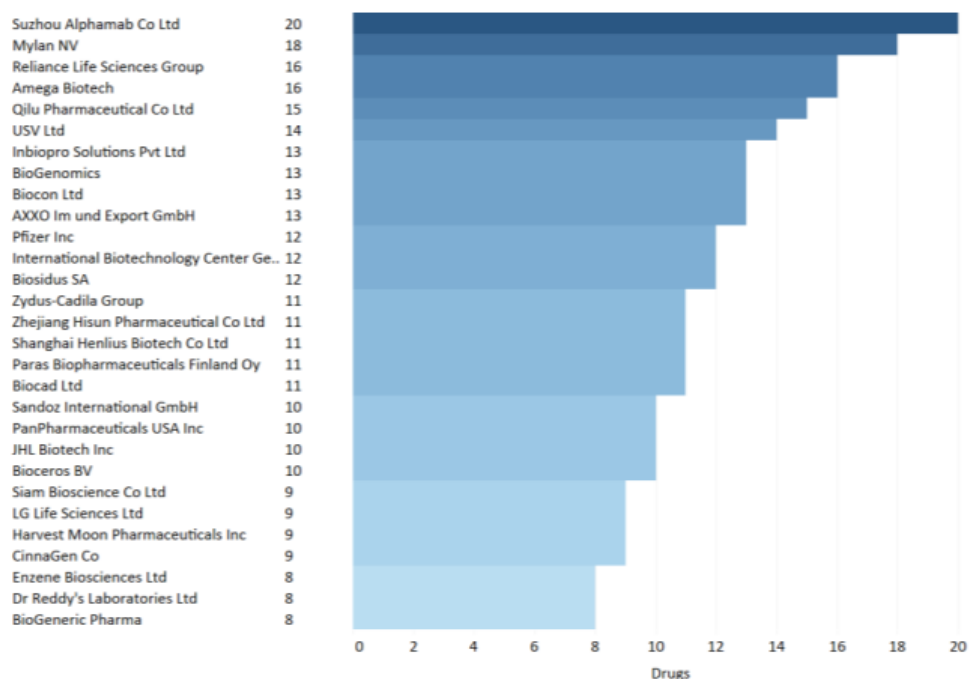
Source: Cortellis Competitive Intelligence

Different Biosimilars Launched and in-pipeline Drugs



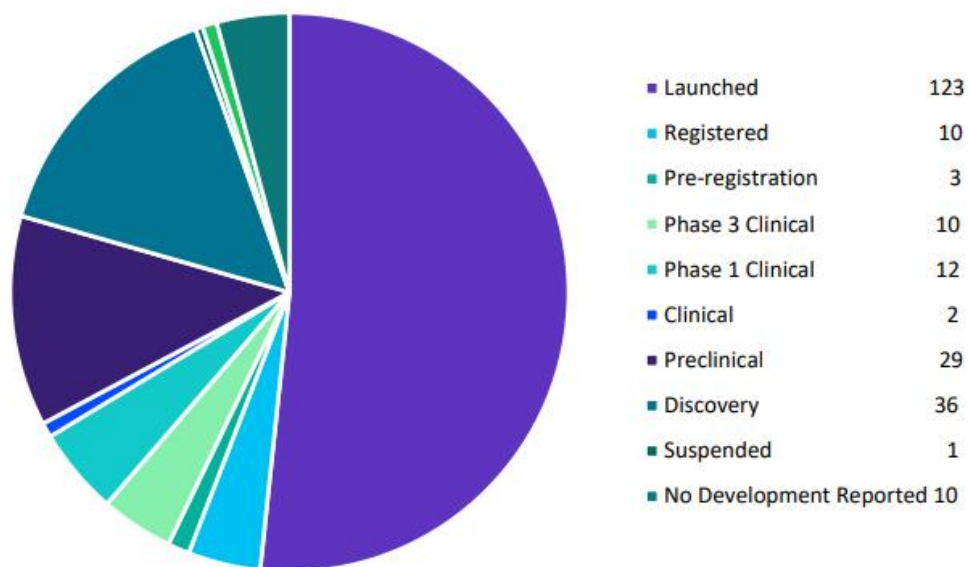
Source: Cortellis Competitive Intelligence

Global companies by biosimilars and follow-on-biologics drugs launched and in pipeline



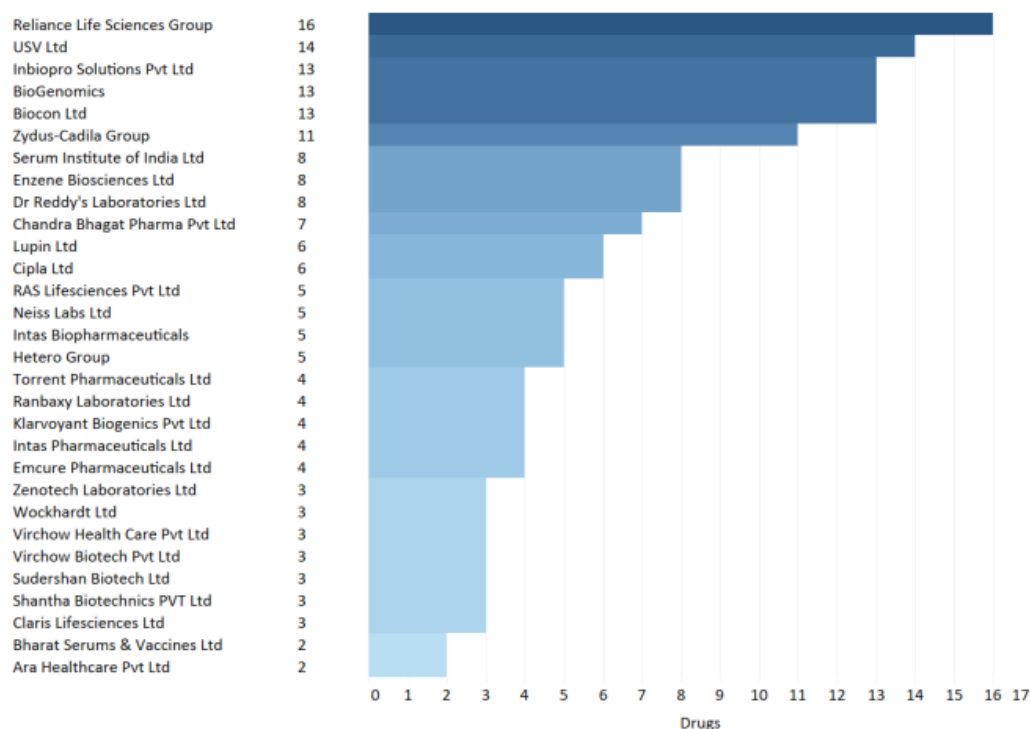
Source: Cortellis Competitive Intelligence

Biosimilars in pipeline of Indian Pharmaceutical Companies



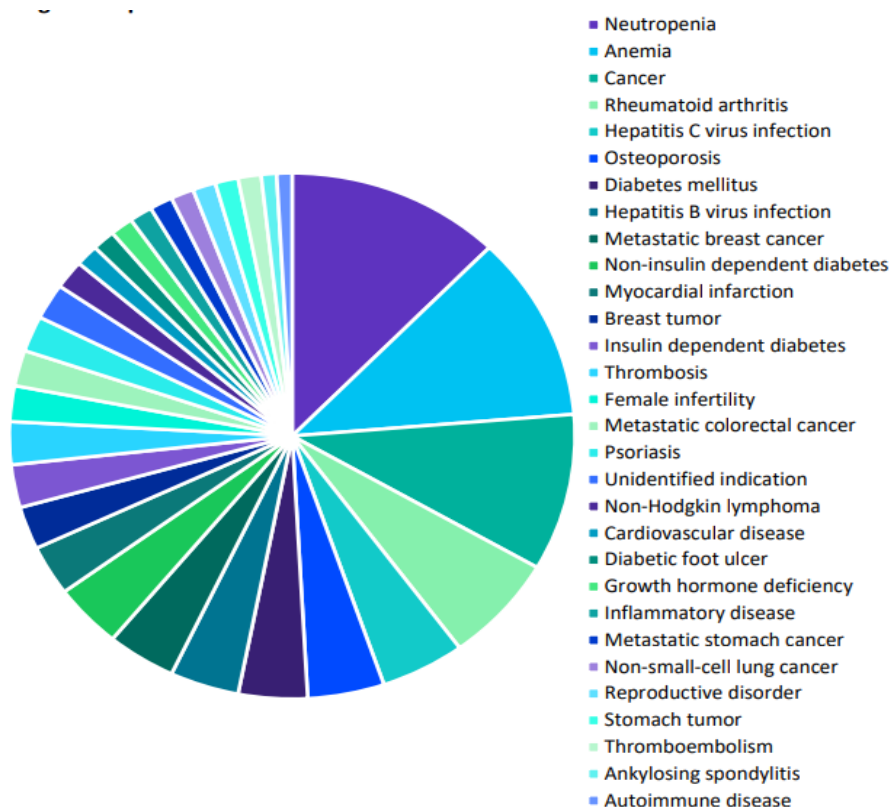
Source: Cortellis Competitive Intelligence

Top Indian companies by biosimilars and follow-on-biologics launched and under active development

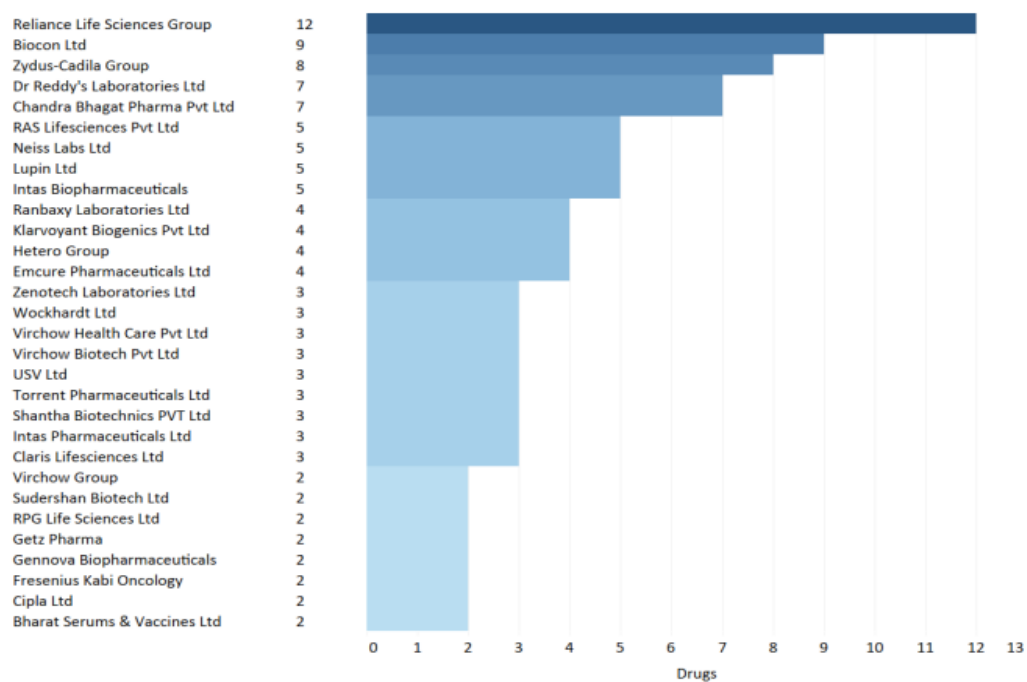


Source: Cortellis Competitive Intelligence

Targeted Indications for biosimilars and follow-on biologics being developed



Top Indian companies by biosimilars and follow-on biologics launched



Source: Cortellis Competitive Intelligence

Conclusion for market growth in Indian Biosimilar Market.

The pharmaceutical industry is facing many changes both in India and internationally. Biotherapeutics/biologics are more promising than small molecule therapeutics in many areas, such as oncology. Small molecule therapeutics have certain advantages, but biologics are more targeted and have fewer side effects. Therefore, biosimilar has become the treatment of choice for physicians and patients, generating significant revenue and enjoying greater market share. Rituximab and trastuzumab are on the WHO list of recommended medications. The blockbuster drugs that have generated the most revenue in recent years are novel biologics. The research and development community and the pharmaceutical industry are increasingly interested in follow-on biologics/biosimilars. As a cheaper alternative to novel biologics, they have the potential for large cost savings depending on the size of the patient population.

The Indian drug/biotech industry is very much positioned to take advantage of the tremendous open door presented by biologics and biosimilars and right now has a broad pipeline of biosimilars being worked on. Steps taken by legislature of India to help the drug business with the vital foundation, financing, and worldwide cooperation to connect the specialized information hole, and further advancement of administrative rules will assist with catching this open door.

Given advancement in innovation and economies of scale, India is probably going to accomplish USD 12 bn market size for Biologics and Biosimilars by 2025.

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