Increasing role of biosimilars in last few years

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BIOLOGICAL products are very complex in nature as they are produced in a living environment that could be yeast, bacteria or a cell. Along with the complexity, these products are quite expensive to cater to the patients. These biological products have transformed treatment methods for various serious diseases including cancer, dermatological conditions, rheumatoid arthritis, etc.

The therapy for chronic disease has seen a shift from conventional chemical drugs to biological drugs since last decade. Biologics are drugs that are regulated by the Food and Drug Administration (FDA) used to treat chronic diseases. These are large molecule drugs and made up of living cells which make them unique and more complex than a chemically synthesized drug that is made up of small molecules. Due to the complexity of large molecules, characterization of biologics becomes difficult. Slight differences in these products are normal and are accepted by the FDA within certain limits however, it becomes important to maintain and control within-product variations so as to maintain the right amount of active ingredients in the drug. . In developing a biological product, vast amount of research and innovation is essential for the end product. To solve this, biosimilar can play an important role.

In order to reach a larger base of patients that need biologics, their identical copies are manufactured with similar bioactivity and structure. These drugs are called biosimilars. Generic drugs are copies of small molecule drugs whereas biosimilars can be similar to or sometimes interchangeable with an FDA approved biological product. Biosimilars are drugs that are highly similar to biologics in function and structure in addition to being interchangeable with a FDA-approved biological product. High end technological support is needed to compare characteristics of a reference product and a biosimilar that includes chemical identity, bioactivity and structure.

The existence of an alternative pathway paves way for providing more treatment options, extended access to important lifesaving medicines and fundamentally lower costs as a result of increased possibilities in front of pharmaceutical companies. Biosimilars are at a nascent stage today with an estimated market size of $2.2 billion out of the total $32 billion Indian pharma market.

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India has robust pipeline for biosimilar drugs

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It is a fairly new area in pharma as the guidelines and procedures are not set by the FDA for biosimilars. Since, they are prepared with the help of living cells, just like biologics, it becomes important to understand the composition and if it is suited for the stated ailment. A biological product might be different than a biosimilar in terms of application as the suitability matters for the patients. Hence, biosimilars when developed are clinically tested to test the suitability for a particular patient in question.

They provide various advantages in the long run, such as availability of more treatment options, increased access to medication to save lives and majorly, economies of scale.

Biosimilars are safe and effective, approved by the FDA and cost competitive. Biosimilars could provide enormous savings to consumers through more product competition. Inherent variability in case of biosimilars can exist because of their biological nature. The molecules are bigger than that of a chemically synthesized product. Biological products did not have an abbreviated approval pathway that made it difficult for them to be manufactured at low costs as the requirement was of a full data package. This gets reflected in the cost of these products in the marketplace. Data packages between a biosimilar product and the originator product are different and that is where abbreviated approval pathway comes into picture.

Indian pharma market holds a prominent position in the global market scenario dominating branded generics and making up around 80 per cent of the retail market, according to a report by Mckinsey. Due to the intense competition present in this industry, the price levels tend to be low making it further favorable to the patients. The pharmaceutical industry in India ranks third in the world in terms of volume and 10th in terms of value. The industry has given rise to numerous innovations in products, infrastructure and processes. India's indigenous manufacturing methods have paved way for the development of another set of generics, this time biogenerics or biosimilars.

According to an Assocham report in 2017, the domestic biosimilars market is expected to reach $40 billion by 2030. With a CAGR of approximately 30 per cent, biosimilars are slated to become popular very soon, as the more affordable version of biologics. Development of a biosimilar might take approximately 5-9 years to be fully developed with a cost that is only 1/26th the cost of developing a biologic. Hence, it has the potential of providing treatment options at a significantly lower cost.

However, the safety profile of the drug also needs to be monitored to ensure it has the same profile between the

products. Hence, conclusively it is determined if the product is safe and effective and it will work the same way in the body whether it's a biosimilar or a reference product. It also needs to be ensured that the same clinical result is achieved in any given patient; the application needs to include data or information that supports this. Also, medication given more than once and the impact of switching back and forth between the interchangeable products is evaluated with the switching study.

A biosimilar has to be highly similar with no clinically meaningful differences as compared to a reference product in terms of structure and functions. A biosimilar goes through two major tests against reference or originator drug. The first one being 'analytical comparison for structural and functional usages' wherein the biosimilar should have the same primary sequence and quaternary and tertiary structure that assists the functions. It is then followed by an eye for no clinically meaningful differences i.e. Pharmacokinetics-Exposure in the body, release of drug in the body, its circulation in the body to see if the transit is similar to that of the reference drug.

With the rising acceptance of this biogeneric, it is fast gaining popularity among pharmaceutical companies in India and abroad. The guidelines and procedures are moving towards providing biosimilars with the status that the industry has been waiting to attain. Adding to the catalysts is the recent USFDA approvals to various pharmaceutical organizations like Pfizer, Biocon, etc. With these progressions, the industry is fast striding forward. Biosimilars are drugs aimed at the treatment of serious and life-threatening diseases. The medical fraternity, including doctors and care givers too are now becoming familiar with the biological drugs, which widens the platform to explore this arena on a larger scale.

India has a robust pipeline for biosimilar drugs that is in line with the Indian government's plans to offer grants to Indian biosimilar manufacturers. The pharma companies are focusing all their efforts in developing their portfolio in this segment with the country's large pharma players investing in huge numbers for the Research and Development of Biosimilars. As patents of many biologics are expiring in the next few years, this aspect presents a great opportunity for the companies in India to focus their resources on the development of biosimilars.

According to Decision Resources Group's analysis, more than 40 biosimilars are in the clinical development phase in India; a number higher than that in the US and almost similar to those in development in the European Economic Area (EEA). Another trick of the trade lies in strategic partnerships with companies outside of the Indian market to uplift their profiles in the world markets. Differential pricing strategies present another set of opportunity in market

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Need to look forward, step out of duplicating drugs

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expansion. This could work by targeting different economical sections of consumers with differentiated pricing strategies.

However, India needs to now shift its focus and look forward in stepping out of the process of duplicating drugs. With the availability of the necessary resources and the benchmarks set by us in the field of biosimilars, it provides us with the opportunity to give up the pleasure of taking merit in the development of duplicating drugs and reach for a step higher. Since the inception of the pharmaceutical industry in India, in 1950s, we have been emphasizing on generics and the creation of identical drugs. With the increase in the biologic drugs, we can widen our focus and explore the domain of creating biobetters. Biobetters are improved versions of originator biologics. They provide increased efficacy as compared to the biosimilars. Biobetters can be a comparatively easier way for the innovator companies to build on what they already have, extending a franchise, rather than letting it fade away to biosimilars and other competitors. ◆

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