The Blockbuster Biosimilar Drugs

A blockbuster and revolutionary molecule, biosimilar drugs is set to capture a significant market share in the pharma sector. This class of therapeutics boasts of having better clinical outcomes at a significantly low cost. The Indian pharmaceutical segment is unstoppable, especially with biosimilar drugs proving to be the magic molecule leading the legion. Touted as being safe and cost-effective, these bioequivalent counterparts of biologics will shift the dynamics of the conventional treatment paradigm

Sonali Patranabish

Cashing in on the peg of affordability and accessibility the biosimilar class of pharmaceutical drugs has displayed tremendous potential in recent times as a safe and effective alternative to pricey biologicals. These copycats of biological drugs have immense potential in their ability to address issues like competitive pricing and the long-drawn development process of their original counterparts. Healthcare professionals are being urged to prescribe biosimilar variants given that they are priced at 50 per cent lower in comparison to biologics. This class of drugs made from living cells can cure anything from cancer to even autoimmune conditions like arthritis and is proven to have superior therapeutic outcomes.

As per a CII report, biosimilar drugs will occupy a chunk of the biopharmaceutical industry, almost 40 per cent by 2030.Pakistan, through London and finally to an orthodox undervaccinated community in New York.

Karthik Kondepudi
Partner at Herbochem

Robust regulatory framework

The Indian biosimilar drug market has been growing exponentially in the recent past. Encouraging strategies by the government have further aided the expansion of this sector which is expected to reach a market size of $2018 by 2030. Given the increasing demand in this sector, the government has taken proactive steps towards strengthening the regulatory framework for biosimilar drugs in India.

The Ministry of Health and Family Welfare has set up the Central Drugs Standard Control Organization (CDSCO) to ensure that biosimilars are approved responsibly, following the guidelines established by notable international authorities.

Karthik Kondepudi, Partner, Herbochem shares a word of praise for the agile nature of the Indian regulatory space that is indeed commendable.

He further goes on to add that clinical trials in India are extensive and encomapsses thorough quality and efficacy checks through comparative studies. According to Mr Kondepudi these comprehensive studies help to validate similarity across various parameters like pharmacokinetics and immunogenicity.

Ensuring the efficacy and safety of biosimilars requires rigorous evaluation and transparent communication

Dr Vikas Gupta
CEO, Alkem Laboratories

Dr Vikas Gupta , CEO, Alkem Laboratories stated, "Ensuring the efficacy and safety of biosimilars requires rigorous evaluation and transparent communication. The complexities involved in manufacturing these drugs and the intricacies of marketing them add additional layers of difficulty that must be addressed to fully realise their potential."

Biosimilars vary slightly from their original biological variants. This is an irrefutable fact. Deviations can be avoided only if a manufacturer can have access to the original cell line of the innovator. This positions biosimilars in the spotlight and a burgeoning question arises if these classes of drugs can be swiftly swapped instead of their biological counterparts. Though the guidelines on similar biologics make it very clear that this class of drugs are equally effective and safe, naysayers claim that there is a lot of ambiguity in the law.

Sridevi Khambhampaty, VP – Biopharmaceutical Development, Syngene International, "The initial reservations about their efficacy and safety compared to original biologics have been weakened by the extensive body of clinical and phase 4 studies data which have proven their safety and efficacy."

Arduous and rigorous development process

While these blockbuster molecules have huge market potential, their development can take anything between five and nine years pegged at $100 million. Creating these molecules involves a rigorous process. It starts with understanding the reference molecule. It also requires significant investment, skilled expertise, and top technology.

Sridevi Khambhampaty
VP – Biopharmaceutical Development, Syngene International

Karthik mentioned, "Biosimilars demand difficult manufacturing processes, lifting production costs and technological obstacles. Ensuring quality is top. But, it's hard. This is especially true for small manufacturers with few resources."

"Biosimilars offer a cost-effective alternative with their potential to transform patient care. Khambhampaty said that the large phase 3 clinical studies needed for biosimilar development are the biggest cost. However, many organisations and NGOs work for patients' rights. The NGOs and organisations have criticised the current guidelines. They are for similar biologics. Stakeholders have asked the government to revise the guidelines. This w ill speed up biosimilar drug development.

The initial reservations about their efficacy and safety compared to original biologics

Biosimilar manufacturers must do toxicity and animal testing. They must also do efficacy testing on many markers and parameters. This testing shows whether a drug is safe and effective. It will make production faster and cheaper. All this could mean better accessibility to quality medicines at a low cost.

Meeting strict regulations in India requires lots of preclinical and clinical data. It demands a large investment in research and development. Comparing clinical trials shows that biosimilarity has its barriers. These include patient recruitment and regulatory navigation. This is especially true in India's diverse population. "Biosimilar developers often face patent disputes. These disputes block market entry and raise costs," says Karthik.

Patent experts claim "Patent thickets" make it harder. They make it harder for biosimilars to enter the market. Many patents by a single company hinder competitors. They are vying to create and replicate the same molecule. Companies want all the credit for inventing a new molecule. However, overlapping patents can harm the affordability of cheap drugs for needy patients. Moreover, innovative companies keep trade secrets. Tiny details, like a temperature change, can affect the product's makeup and how well it works.

Biosimilars - A beacon of hope

Today, the biosimilar market has put India on the global platform. India has become a competitive player in this area. It has penetrated international markets too. Relaxing rules and approvals will cut the time to enter markets. Removing these blockades and entry barriers. This will make more healthcare professionals adopt biosimilars soon. This new sector will become the next big thing in pharma. It will launch Indian pharma into the global market. It will also meet the increased demand from commercial buyers.

According to Dr Vikas, the biosimilar market in India holds great promise. The government continues to support us. And innovation and collaboration in the industry are relentless. With this support and effort, there have been big strides.

"The Indian biosimilar manufacturers and clinicians should publish their comparability data. They should also publish their clinical experience. This will enhance public knowledge on the safety and efficacy of these products. This will help boost transparency and aid the uptake of biosimilar products by doctors and patients," opines Khambhampaty.