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Why India must turn Biosimilar Powerhouse by 2030

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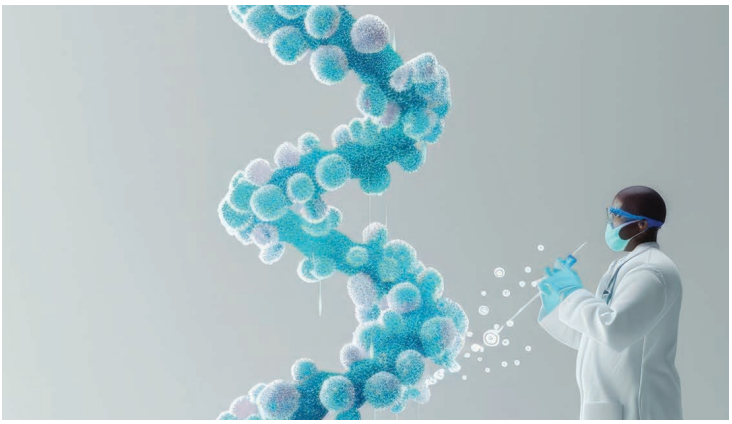
Biosimilars could potentially enhance patient access to treatment of various malignant and nonmalignantconditions by reducing costs. Since the introduction of the first biosimilar in 2000 in India, a vaccine for hepatitis B, the development and utilisation of "biosimilars or similar biologics" have experienced significant growth. Each year, regulatory bodies are approving numerous similar biologics for the management of both cancerous and noncancerous illnesses. India has firmly positioned itself as a key player in the global production of similar biologics, benefiting from its large population. Despite the considerable potential and high expectations for India, there are substantial challenges that must be overcome to maintain this leadership position. To realise their full potential and sustain their global leadership, Indian biopharmaceutical companies must enhance their technological capabilities and enhance the skills of their workforce. This will require a supportive environment from both the government and regulatory agencies.



As Indian biopharma sector already proved its mettle in the manufacture of biosimilars and captured vast global markets as one of the key supplier of low cost, high quality medicines for various therapeutics, industry leaders and lead scientists opined that country's biotech industry stands at a pivotal juncture of dynamic transformation from current capabilities of a mere replicator of existing original brands to becoming innovator in developing new and complex molecules by giving renewed push to its R&D sector.

With more than 55 blockbuster branded biologics going off patent from 2022 to 2032 globally, according to McKinsey report August 2022 the Indian biosimilars manufacturers can grab this opportunity to bring in not just affordable biosimilars products in place of costly branded biologics but can also grab the huge business potential offered by the global markets for biosimilars products. At present, the Indian biologics and biosimilars market is rapidly growing, from $6 billion in 2022 to a projected $12 billion by 2025.

To achieve these growth statistics, **Dr Ramesh Mathur, Senior Vice President R&D from Biological E Limited**, while highlighting how India had come a long way in exhibiting its success in the biosimilars segment during the past two decades, noted that it is high time that all stakeholders of the industry must give a new push towards research and development (R&D) and take measures towards bringing in innovations in biotech sector to develop innovator molecules rather than going after the low hanging fruits just to make easy profits with little efforts.

Dr Mathur further emphasised India's evolution from a manufacturing hub to an innovation-driven force in biosimilars and stressed the need to move beyond replication towards developing novel molecules and complex biomolecules. He posed

critical questions on fostering an ecosystem conducive to such innovations, underscoring the shift from reliance on existing products to pioneering new entities.

Growth in India

With fast changing dynamics in the life sciences industry globally, currently India stands as a pioneer in the global biosimilars market. In fact, India is the first country in the world to approve a biosimilars product way back in the year 2000 for Hepatitis B, over two decades ago.

According to a report from India Brand Equity Foundation (IBEF), the Indian biosimilars market is estimated to grow at a compounded annual growth rate (CAGR) of 22 per cent to become $12 billion by 2025. This would represent almost 20 per cent of the total pharmaceutical market in India.

Sharing his views **Ravi Uday Bhaskar, Former Director General of Pharmaceutical Export Promotion Council of India (Pharmexcil)** said that India has a huge potential to tap into the global biosimilars market. “India is the 3rd largest producer of Active Pharmaceutical Ingredients (API) accounting for an 8 per cent share of the global API industry touching exports worth $27.8 billion in 2023-24 and projected to touch $31 billion by 2025. The country has huge potential to tap the global biosimilars market, which is fast emerging. As India is regarded as the global pharmacy of the world with its supply of affordable high quality generic medicines to the world, India can equally gain the same reputation in the biosimilars space. Already India is meeting more than 60 per cent of global vaccine demand and given the huge off patent regime ahead for branded biologics, I feel India has the potential to grab this opportunity and can lead the world in biosimilars space as well,” said Uday Bhaskar.

India boasts an impressive portfolio of over 98 approved biosimilars domestically (as of September 2019), a feat unrivalled by any other nation, underscoring its formidable presence in the biosimilars arena. The biosimilar landscape in India is characterised by a multitude of pharmaceutical entities actively involved in the production and distribution of biosimilar products. The key players in the biosimilars segment in India include, Biocon Ltd, Intas Pharmaceuticals Ltd, Dr. Reddy's Laboratories Ltd, Reliance Life Sciences Pvt. Ltd, Zydus Cadila Healthcare Ltd, Lupin Limited, Wockhardt Limited, Panacea Biotec Ltd, Emcure Pharmaceuticals Ltd and Torrent Pharmaceuticals Ltd are among others.

Regulatory Advancements

To address the issues and challenges associated with the development of biosimilars and similar biologics, Central Drugs Standard Control Organisation (CDSCO) in collaboration with the Department of Biotechnology (DBT) had developed “Guidelines for the Regulatory Requirements for Marketing Authorisation in India” in 2012 and has revised it in 2016. These guidelines address the regulation of manufacturing processes as well as quality, safety, and efficacy of similar biologics in the country.

However, experts from the industry are of the view that despite amendments into the drug regulatory rules and regulations, the lack of proper understanding of the subject among the regulators has become a big challenge causing regulatory hurdles and blockade in the way of new approvals of biosimilars products. For instance biosimilars companies who approach for approval of clinical trials for orphan drugs are told to conduct trials on a large number of subjects, while the orphan disease population may not even cross 20-30 people among the vast population. **Dr Sreenivasu Karra, Director R&D at Clonz Biotech**, while pinpointing regulatory challenges and the need for stronger industry-academia collaborations, he emphasised the role of regulatory agencies in adapting to the evolving biopharma landscape, particularly in enabling the development of new biological entities through collaborative efforts with academia and with better understanding of existing situations.

Echoing a similar opinion expert, **Dr Satish Sadagopan, Head of Biologicals, Senior General Manager from Anthem Biosciences** said that more flexible regulations would further enable more companies to venture investing into new areas of research for finding innovative solutions and new drug molecules that could help treat even orphan diseases.

Apart from top 20 leading biopharma companies including Biocon Ltd, Intas Pharmaceuticals Ltd, Dr. Reddy's Laboratories Ltd, Reliance Life Sciences Pvt. Ltd, Zydus Cadila Healthcare Ltd, Lupin Limited, Wockhardt Limited, Panacea Biotec Ltd, Emcure Pharmaceuticals Ltd, Torrent Pharmaceuticals Ltd, Pfizer Inc., Novartis International, Roche Holding, Sanofi S.A., Merck & Co., Inc., GlaxoSmithKline plc, AstraZeneca plc, Johnson & Johnson, Boehringer Ingelheim GmbH and Fresenius SE & Co. KGaA, that are already producing and marketing their biosimilars across the globe, there are over 100 companies are standing in queue to grab the off patent opportunity in the coming 5-10 years.

“It is estimated that over 100 biopharma companies in the country are working on various platforms to produce biosimilars products to treat deadly diseases like cancer, diabetes, hepatitis, orphan and other autoimmune diseases. As per official records more than 98 biosimilars products have already been given approval by the CDSCO as on September 2019 in India,” informed Dr Uday Bhaskar.

Highlighting about the efforts of the Department of Biotechnology and the Ministry of Health in India, Kiran Mazumdar-Shaw, Chairperson & Managing Director, Biocon Limited, stated that the Indian government had established a strong foundation with a clear regulatory pathway ensuring safe and effective biosimilars, with an emphasis on affordability. Many of these biosimilars are supplied to highly regulated markets in North America, Europe, and Japan. With the advent of Ayushman Bharat, India’s universal healthcare programme, these life-transforming biosimilars are now accessible to the poorest patients in the country suffering from cancer, diabetes, and other immune-mediated diseases. Global Bio India serves as a platform to showcase India’s growing stature as an emerging hub for biologics and biosimilars.

Government Support

The Department of Biotechnology (DBT) and its public sector enterprise Biotechnology Industry Research Assistance Council (BIRAC), under the Ministry of Science and Technology have made sustained efforts through funding, policy advocacy, new initiatives, capacity building, human resource development, promoting innovation and infrastructure creation in research institutions, small and medium size industries, large industries as well as nurturing emerging enterprises.

The National BioPharma Mission (NBM), a joint initiative of the World Bank and DBT, is further solidifying the country’s foundation in this field. Collectively, these initiatives are positioning India's biotech sector for its next level growth phase. “I see that there is a great potential for Indian biotech sector to become a global hub for manufacturing of biologics; innovating globally competitive, novel, affordable - vaccines, biosimilars and advanced immunotherapeutic, that is accessible to all for India and the World,” stated **Dr Rajesh S Gokhale, Secretary, Department of Biotechnology, Government of India**

Off-patent of Original Biologics

According to McKinsey’s analysis, more than 55 blockbuster drugs that will lose exclusivity in the United States and Europe from 2022 to 2032 will collectively have more than $270 billion in expected peak sales. By 2025, 19 global blockbuster brands are set to lose exclusivity. From 2026 to 2032, the pace quickens, with 39 blockbusters set to lose it. This group includes at least five megabrands with annual sales exceeding $10 billion will lose their exclusivity.

Between 2020 and 2022, more than 91 drugs have gone off patent globally, says GreyB report. Similarly, it adds that from 2022 to 2027, 31 blockbuster biological drugs are expected to go off-patent providing a huge scope for the Indian biopharma firms to invest and venture into the biosimilars manufacturing markets. The imminent expiration of biological product patents accounts for combined revenue of $60 billion, in the next two to three years.

As per a report from World Health Organization (WHO), currently, high prices of biological drugs are restricting the healthcare systems from providing affordable, population-wide access to such medicines. This creates a huge space for generic companies to manufacture biosimilars of the originator biologics whose patents have expired.

In particular the Indian firms supported by the Department of Biotechnology are expected to take advantage of the off patent regime and further penetrate into the global biosimilars markets providing low cost high quality medicines to treat deadly diseases like, cancer, autoimmune diseases, and diabetes treatments account for over 60 per cent of the biologics market.

The pipeline for biosimilars in India is robust, fueled by the government's initiative to offer subsidies to the local biosimilars manufacturers. This growth is also driven by the expiration of existing biologics patents and the Central Drugs Standard Control Organisation (CDSCO)'s aligning guidelines closely with global regulators, including the United States Food and Drug Administration (USFDA) and the Medicines and Healthcare products Regulatory Agency (MHRA).

Challenges and Scope

The major challenge for biosimilar development in India is the high cost of clinical trials and regulatory hurdles. The development of biosimilars in India costs around $10-20 million due to stringent regulatory procedures required for their approval. Unlike generic drugs, biosimilar manufacturers face numerous problems in development, clinical improvement, manufacturing, registration, and product marketing.

"Though biosimilars benefit from the initial work done by innovators", observed **Dr Pratima Srivastava, Vice President, Discovery Biology Solutions, Aragen Life Sciences**, "there's still much to understand". "Reverse-engineering of biosimilars involves deducing DNA from the protein product and optimising it for production. Automation, machine learning, and robotics accelerate this process. However, advanced instrumentation and skilled professionals are often lacking in India", added Dr Pratima.

Delving into the intricacies of reverse engineering of biosimilars, Dr Tathagata Dutta, President and Chief Technology Officer, Jodas Expoim highlighted the rigorous analytical processes involved in ensuring equivalence to originator products. He stressed the importance of comprehensive understanding and characterisation of biosimilars, from genetic sequences to clinical efficacy, utilising advancements in technology such as next-generation sequencing and automation.

Talking about innovation and collaboration among biopharma firms, Dr Kripa Murzello, Head R&D Biologicals at Bharat Serum and Vaccines Ltd, highlighted the evolving mindset towards Indian biopharma capabilities and emphasised the importance of collaboration between industry and academia. She underscored the transformative impact of such partnerships in advancing research capabilities and overcoming commercial constraints.

Future Prospects

With emerging trends like cell and gene therapy, oligonucleotides, and the role of artificial intelligence (AI) in biotechnology, the future prospects and technological advancements are very bright for the biosimilars sector in India. Industry experts expressed optimism about India's potential to lead in these areas, provided there is continued investment in technological infrastructure and talent development.

India's biosimilars market holds immense potential, with opportunities to innovate and develop complex molecules. Overcoming regulatory challenges, fostering collaborations, and leveraging advanced technologies will be key to advancing R&D in biosimilars and achieving global leadership in this field.

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