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Cementing India's place as global leader in biosimilars

31 July 2024 | Views | By Dr Sudhira H S, Director, Gubbi Labs

Over the past decade, biologics and biosimilars have taken centre stage in medical advancements. Their potential in treating diseases previously considered untreatable, such as certain types of cancer, autoimmune disorders, and rare genetic conditions, has changed the face of healthcare. India, with its robust biotechnology and information technology sectors, has embraced this shift and is making significant strides in the development and manufacturing of biological drugs.

Biosimilars, also known as follow-on biologics, are the subsequent versions of innovative biological medicine that are introduced after the expiry of the original medicine's patent. The development of biosimilars is a complex and expensive process, but it has potential to improve the accessibility of life-saving treatments. Emerging technological trends in the biosimilar sector are redefining the way these medicines are developed, evaluated, and marketed. Given that India is a global hub for generic medicine, it is critical to examine the country's role in the rapidly evolving biosimilars landscape.

In recent years, the market for biosimilars or similar biologics, has seen significant expansion, particularly in India. India's biosimilars market size was valued at $349 million in 2022 and is estimated to expand at a compound annual growth rate (CAGR) of 25.2 per cent from 2022 to 2030 and will reach $2108 million by 2030.

India is one of the leading manufacturers of biosimilars, and has observed an increase in their use, improving the health of many patients suffering from a wide variety of diseases. The most significant advantage of biosimilars is that they cost less than the original drugs that they replicate.

An article noted that the expiration of patents on many key biologics by 2020 would provide a sizable opportunity for the development and use of biosimilars. With over one hundred biopharmaceutical companies engaged in the manufacturing and marketing of biosimilars, India has emerged as a global market leader in this segment. It was the first to approve a biosimilar back in 2000 for the treatment of hepatitis B- much before Europe and the United States.

Since then, several biosimilars have been developed and marketed in India by various biopharmaceutical companies. Given the country's high potential, Indian biopharma industries are striving to maintain leadership in this rapidly expanding sector. Companies in India are upgrading their technology and improving their human resource skills to stay competitive.

Globally, a remarkable reduction in the overall cost of treatment using biosimilars has already been seen. A US study predicted that over a decade, biosimilars could save $54 billion. India has a thriving biosimilar ecosystem compared to other countries. Enabling this, has been the notification of specific guidelines for the approval process.

The Central Drugs Standard Control Organisation (CDSCO), in collaboration with the Department of Biotechnology (DBT), developed “Guidelines on Similar Biologics; Regulatory Requirements for Marketing Authorisation in India” in 2012, which were revised in 2016.

Till date, there are more than one hundred biosimilars approved in India. The biosimilars approved for use in India include vaccines, monoclonal antibodies, insulin, and recombinant proteins.

Technological Trends in Biosimilars

One of the most significant technological trends in the biosimilar sector is the use of big data analytics. Big data in biosimilars entail collecting, analysing, and interpreting vast quantities of structured and unstructured data. As more biosimilars are introduced to the test market, big data can provide valuable insights into their effectiveness, potential side effects, and other salient characteristics. This granular data can aid in improving the efficiency of clinical trials and ensuring the safety of the biosimilar product.

Adoption of advanced analytical techniques is playing a key role in developing highly similar biosimilars. These include protein characterisation using mass spectrometry, chromatography, and high-resolution imaging techniques. In addition, cell line development is enhancing the processes to be effective. The establishment of optimal cell lines is critical for efficient biosimilar production. Improvements in cell line engineering, media optimisation, and bioreactor design have led to enhanced yield and productivity.

Furthermore, process optimisation measures through advanced techniques like perfusion culture, continuous manufacturing, and bioprocessing models have contributed to the reduction in production costs and improved scalability of biosimilars. Another critical technology trend in the sector is the rising adoption of personalised medicine and precision health, made possible by advancements in genomics, bioinformatics, and artificial intelligence. Personalised medicine addresses both efficacy and safety as it enables treatments to be tailored to the genetic makeup of the individual.

Future of Biosimilars in India

Clearly, the future of biosimilars in India appears promising. Despite a compelling need for a stronger intellectual property rights regime, the biopharma industry involved in biosimilars are getting to benefit with streamlined regulatory procedures, heightened research and development capacity, and greater public awareness about biosimilars.

India, with its vast pharmaceutical sector and expertise in generic medicine, has exhibited great leadership in the biosimilar market. Several domestic firms are making substantial strides in the global biosimilar market. Companies like Alembic, Biocon, Dr. Reddy's Laboratories, Enzene Biosciences, Indoco Remedies, Lupin are some have made their presence felt internationally, with many of their biosimilar products gaining approval from exigent health agencies like the US FDA, and the European Medicines Agency (EMA). For instance, Biocon's Insulin Glargine, a biosimilar for diabetes, has been widely accepted across several countries.

Besides, biopharmaceutical companies the Contract Development and Manufacturing Organisations (CDMOs) play an indispensable role in biologics and biosimilars production and their supply chain in India. Indeed, the country is transitioning from being primarily a generics powerhouse towards becoming a hub for high-value drugs.

Moreover, using cutting-edge technological trends is proving beneficial for India in unlocking the potential of the biosimilar sector. Technologies such as big data analytics, artificial intelligence, and personalised medicine can fast-track the development, testing, and delivery of safe and effective biosimilars.

The confluence of rapidly progressing technology and India's unique positioning as a global pharmaceutical hub provides remarkable opportunities. This has allowed for accessibility and affordability of biosimilar drugs, both domestically and globally. A strategic focus on technological adaptation, regulatory support, and capacity building is heralding an era of affordable and accessible healthcare solutions, cementing India's place as a global leader in the biosimilar market.

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This article is an excerpt of a larger report created by Gubbi Labs in collaboration with Cactus Communications

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