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Can India become a hotspot for CLINICAL TRIALS?

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DR CYRUS KARKARIA
President – Biotechnology, Lupin Limited

India's biosimilars industry staring at plethora of opportunities

Between now and 2030, biologic products worth US $170 billion will lose patent protection globally, writes Dr Cyrus Karkaria, President – Biotechnology, Lupin Limited

The Indian biopharmaceutical industry is one of the fastest growing globally and currently valued at US $60 billion. The country's biosimilars market size was valued at US $349 million in 2022 and is estimated to expand at a CAGR of 25.2% from 2022 to 2030 to reach US $2.1 billion in 2030.

Our biopharma companies are already major outsourcing partners to global pharma companies. Industry can boast about its cost competitiveness, fast-growing manufacturing base, intellectual capital, strong marketing, and distribution network in domestic and international markets. These trends, combined with India's huge population base, growing literacy and health awareness, increased purchasing power, growth in healthcare financing products and access to good quality medical care, will continue to propel the domestic Biopharmaceutical industry to new heights.

Trastuzumab biosimilar Ogivri, co-developed by Biocon and Mylan, became the first biosimilar from India to be approved in the US and the first Herceptin biosimilar globally. Neulasta, a pegfilgrastim biosimilar and India's 2nd biosimilar followed suit.

Challenges before the industry

Despite the quick success and competitive advantages, India carries a mere 3% share of the global biosimilar market space. High investment costs in the development of biosimilars, added to their complex clinical and developmental requirements, dampen the zest of companies, disregarding the market demand and their therapeutic advantages.

The world-class manufacturing facility, global quality standards and understanding of the global IP and regulatory landscape are key ingredients for the global development of

biosimilars. Indian biopharma companies have faced challenges in achieving market authorization in regulated/semi-regulated markets. The lack of defined guidelines for biosimilars in many emerging markets leads to tedious review processes, sometimes giving rise to unnecessary additional clinical studies, which is a cause of concern for the industry.

Indian Biopharmaceutical industry also needs a well-differentiated product portfolio and service offering to create a notable presence amongst US/EU regional players. Patient-friendly device development and digital platforms can help in this pursuit.

In terms of the supply chain, most of the biopharmaceutical products need cold chain infrastructure to increase access and expand the biopharma market. Cost-competitive logistics and distribution networks need to be developed to improve the reach of Biosimilars to smaller towns and cities.

As part of the biosimilar development exercise, procurement of Innovator products in multiple batches and from various geographies has been a cost-intensive exercise. Harmonization of regulatory guidelines, though long discussed, has yet to be fully substantiated.

High turnaround timelines for biosimilars from conception to launch and Product life cycle management to battle innovator moves are some of the other challenges to overcome.

Key trends in India and Asia-Pacific

APAC, a pack of enticing opportunities for manufacturing biosimilars, is on an exciting journey, with markets projected to grow at 30 % each year. In the last decade, there was a massive shift from developing and manufacturing biosimilars from the West to the East, most evidently, in South Korea, going from 0% in 2012 to ~ 43 % today in the global biosimilars market by value. Japan is the 2nd highest investor in the research and development of biosimilars after the United States. India has been a long player in the generics market and has a highly advanced biosimilar pipeline.

> **Despite the quick success and competitive advantages, India carries a mere 3% share of the global biosimilar market space.**

Governments are acknowledging this opportunity to boost the economy and are accelerating this shift to the East. The Indian Government has been actively promoting biological drug development under the 'Make in India' initiative, BIRAC driven 'National Bio-Pharma Mission, a collaborative initiative between DBT and the World Bank was initiated by the government.

Japan Biosimilar Association (JBSA) was

established in Japan to address challenges in the development of biosimilars. Recent policy changes have also supported uptake in Japan; the new guidelines published by the Japanese Ministry of Health, Labor, and Welfare in April 2020 incentivise medical institutes to prescribe self-injecting biosimilars.

In China, the inclusion in the National Reimbursement Drug List of advanced biologic treatments in 2017 & 2019 has increased the uptake of biologics and will allow the market to expand further. Estimates suggest that about 400 separate biosimilars are in active development in China. The Chinese government launched the Marketing Authorization Holder (MAH) plan to allow drug license holders to sell in China using a contract manufacturer.

Oncology offers significant opportunities

For the last few years, activities in biosimilar development have been focused on the "big six" top-selling monoclonal antibodies worldwide: adalimumab (Humira), infliximab (Remicade), etanercept (Enbrel), rituximab (Rituxan/Mabthera), trastuzumab (Herceptin) and bevacizumab (Avastin). The latter three play a significant role in treating oncology patients and top the list of the best-selling oncology treatments. However, biosimilars are now available for all these biologic agents and have decreased treatment costs by bringing about price competition between the reference product and its biosimilar competitors.

Future biosimilar opportunities will likely focus on the next wave of oncology products. Top cancer drugs predicted in the Oncology space include Opdivo, Keytruda, Tecentriq, Darzalex, Perjeta and Gazyva, with projected USD 5-10 B+ sales revenue. Second-tier molecules with predicted revenues of 800M to 2.5B USD include Yervoy (ipilimumab), Xgeva (denosumab), or Kadcyla (trastuzumab-emtansine).

Oncology is the major focus area for development for biosimilar companies globally, owing to the prevalence and expanding the scope of the disease and the rapid increase in cancer care costs, impacting healthcare providers, practices, payers, and patients. Despite the advances in cancer treatment, according to WHO estimates, worldwide cancer cases are expected to increase by approximately 60% over the next few decades, from 18.1 million in 2018 to 29.5 million by 2040.

For a country like India, innovator biologics, not being easily accessible to the masses, brings a solid opportunity for biosimilar companies for indigenous development to improve affordability and accessibility of such live saving drugs. The launch of the filgrastim biosimilar caused a 104% increase in filgrastim uptake in the UK, and a similar expansion of market access is expected with the next wave of oncology biosimilars globally.

Roadmap ahead

There are 98 approved biosimilars in India, with at least 50 on the market, the most of any

country in the world. Between now and 2030, biologic products worth some $170 billion will lose patent protection, opening the window of opportunity for Indian biopharma to explore more biosimilar products.

Indian companies are taking multiple steps to strengthen their core competencies in the field of R&D, manufacturing, quality system, etc., comply with stringent regulatory requirements and build the sales capabilities to tap into this huge market potential. Educating, attracting, and retaining the specialized workforce should continue to be an area of focus.

> **Companies seeking to be first to market with a biosimilar must also accelerate their drug development.**

Companies seeking to be first to market with a biosimilar must also accelerate their drug development. A McKinsey analysis of seven biosimilar launches in Europe shows that the three top-selling biosimilars for a range of molecules tend to be early entrants and capture more than 90% of the market between them. Balancing development costs & speed-to-market with high biosimilarity while ensuring broad clinical labels and commercial viability is the mantra for growth. It will determine long-term players in this segment.

To become the biotechnology hub at a global level, India must create a favourable climate for attracting and managing investments, which in turn fuel innovation. These can be facilitated by an environment of sizeable public funding, surpluses from traditional businesses of large corporations, protection for intellectual capital, vibrant venture capital participation, a competitive marketplace, and a demanding environment for academic researchers.

Flexible and innovative pricing and contracting practices must be adopted, such as performance-based and indication-based approaches. Introducing new manufacturing technologies, such as modular factories tailored to low-volume production, is another way for companies to differentiate themselves and cater to niche markets. ■

Dr Cyrus Karkaria leads Lupin's biotechnology division and is responsible for developing the company's global biosimilars portfolio. With over three decades of experience at Celldex Therapeutics, CuraGen and Biogen, Cyrus has a proven track record in managing biologic drug development and commercialization of products across multiple markets, including the U.S. Cyrus is a post-doctorate from Harvard Medical School and a Ph.D. from the University of Maryland. He also holds a Master's degree in biochemistry from Mumbai University.