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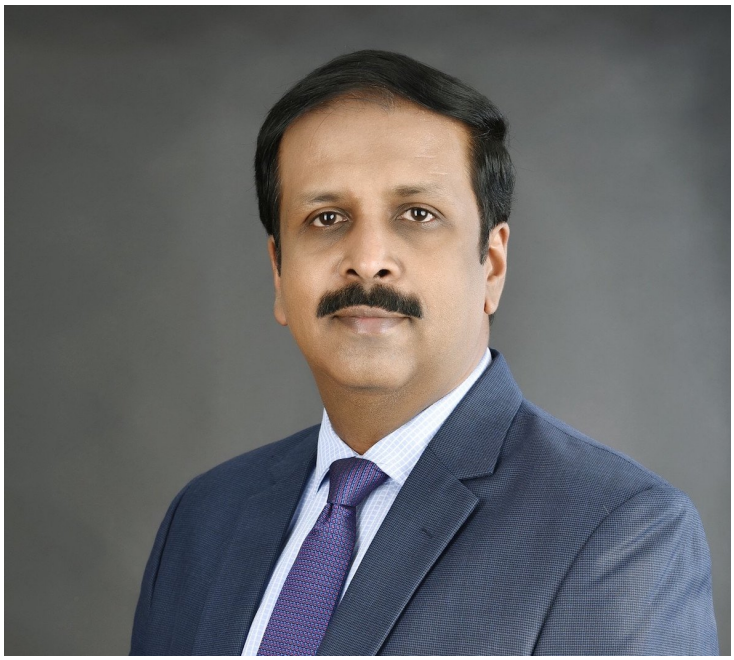
Capitalising on global biosimilar opportunity

28 January 2022 | Views | By Poornachandra Tejasvi, Senior Director, Emerging Markets, Informa Pharma Intelligence

The potential demand for biosimilars undoubtedly generates an enormous opportunity for biopharmaceutical companies. However, biosimilar development and commercialiszation is an inimitably complex endeavour requiring a precise, stepwise strategy to ensure timely regulatory approval and optimum market access. Even companies that are aiming to protect the market share of a branded biologic product are compelled to adapt to the increased competition from biosimilars. Given these dynamics, the uniqueness of biosimilars necessitates that an integrated, strategic development and commercial plan must be shaped in the very initial stages of any biosimilar development program to keep the momentum.



With the ongoing challenges and opportunities evolving at a global scale, the life science industry continues to push forward by identifying and executing possibilities and solutions for the healthcare needs of the world. Therefore, the primary prerequisite task at hand for the Indian life sciences companies is to establish a strong presence in biosimilars as the next frontier.

The biosimilars segment is expected to generate major traction in global markets over the next decade, rising from $12 billion in 2020 to at least $36 billion by 2025 at a CAGR of 24%; as per recent studies. India, whose pharmaceutical market is growing at 15% annually, twice the world market growth rate, has tremendous potential to replicate its generics dominance in this segment, suggest new studies. India’s expertise, infrastructure, and investments can help the country command a share of 20%-30% within the next decade for which the current share is 8% in the overall biopharma manufacturing space.

With India's strength in the global generics market, Indian pharma and biotech companies are now gearing up to transition

into research and development (R&D) and innovation to establish themselves as key players to develop Biosimilars, Novel Chemical Entities, Novel Biological Entities and Innovative Therapies for the global and Indian pharmaceutical markets.

The current momentum in the segment can perhaps be gauged by the fact that India has around 127 approved biosimilars, propelled by companies like Reliance Life Sciences, Zydus Cadila, Intas, Biocon, Dr.Reddys, Sun Pharma, Lupin, etc. making it the country with the largest number of approved biosimilars after Germany and the US as per Informa's Pharma Intelligence report 2021. The Indian biosimilar market was worth around $300 million in 2015 and is expected to reach $40 billion by 2030.

The export of similar biologics from India to highly regulated or emerging markets represents around $51 million. Trastuzumab, used in select breast and stomach cancer, was the first biosimilar manufactured by an Indian company to receive marketing authorisation by the USFDA. The regulatory framework of Biosimilars in India is governed by "Guidelines on Similar Biologics; Regulatory Requirements for Marketing Authorization in India" was updated in 2016. Patent protection for a biosimilar is not synonymous with marketing authorization in India. Patent protection is provided for a specified time for a biosimilar if it complies with the norms associated with novelty, inventive step and is industrially scalable.

Several biologics are coming off-patent over the next few years opening up huge opportunities for cost-efficient Indian manufacturers. Genentech/Roche's ranibizumab was set to go off-patent in 2021 in the US, followed by Regeneron Pharmaceuticals' Aflibercept which will lose its patent protection in the US in 2023 just to name a few, as per the Informa Pharma Intelligence report.

Similarly, with biologics like Avastin, Humira and Levemir coming off-patent, more Indian pharmaceutical manufacturing companies will work towards biosimilar production to increase their market share in these therapy areas globally. Clinical research activities in the country have also seen an upswing over the last two years of the pandemic, strengthening contract research and development capabilities across the country. This will improve speed to market with relevant data points that are necessary for getting marketing approvals in developed and emerging markets.

To keep up the momentum, the Indian industry will have to keep the following aspects in mind to drive an innovative commercial model:

- Portfolio management: Indian companies must continue to make well-informed decisions regarding which biologics to target for biosimilar development and remain a trusted source for research and development of biosimilars. Some of the areas that they could target could be aligned with next-generation treatments for autoimmune diseases and cancer.
- Regulatory support: Continued support from the Central Drug Standard Control Organization and Drugs Controller of India to support biosimilar companies by regular regulatory review of requirements for biosimilars followed by government mechanisms to incentivize investment and drive confidence, which will go a long way to gain faster traction in the global market.
- Clinical trials: With only 5% of globally active/planned trials taking place in India, and only 2% of these trials focused on biosimilars, the Indian government has a huge opportunity to position India as a leading country for clinical trials.
- Pricing, reimbursement and market access: The Indian market is price sensitive and has medication access limitations. However, the rise in affordability and biosimilars being a cheaper option would support its uptake across the country.
- Manufacturing: India must continue to manage and maintain its superiority as the 'pharmacy of the world' by increasing the globally recognised manufacturing units for generics and biosimilars, with relevant certifications from global bodies to meet the rising demand.

While most players are keen to bolster their presence in developed markets, a considerable opportunity exists in emerging markets for biosimilars, where India tops the list. Biosimilars players will need to adopt a long-term strategy to provide affordable products and improved access to the large pockets of non-consumption, which will entail growing sales – though at a lower margin than in developed markets – among an increasingly affluent and health-conscious population. It will also require identifying the therapeutic areas having the largest potential to impact the local population. Participating entities will be expected to provide access, partner for home-grown capabilities, and leverage the importance of branding and building customer engagement in fruitful ways.

In a country that accounts for the second-largest population in the world, access to the latest medicine at the most affordable price point is key to ensure that a maximum number of people are provided with the best available care. Similarly, biosimilars will be a game-changer for market access in the other developed and emerging markets that do not have the required manufacturing scale or capability to cater to their respective requirements. With multiple indicators pointing in the right direction for India, the time is ripe to rise to the occasion and be a world leader in biosimilars.

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