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Can Biosimilars Repeat Success of Generics?

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The combination of many biologics coming off patent plus high biosimilar adoption rates paints a bright future for biosimilars, and their ability to have a dramatic impact on healthcare and the pharmaceutical industry in broadening access to a new class of impactful affordable medicines. Can biosimilars transform the industry like generics did? Let's find out.

As more biologics lose patent protection, over $200 billion worth of innovator biologics are set to go off-patent by 2030, the influx of biosimilars is poised to expand, offering cost-effective alternatives and significantly impacting healthcare.

Billions of people lack access to the medicines and healthcare services they need and biosimilars play a crucial role in creating a more sustainable healthcare ecosystem by increasing access and affordability to essential biologic medicines.

“Before the adoption of biosimilars, a much smaller number of patients were able to access high-quality biologic medicines. With biosimilars, we are able to treat many more patients and at an earlier stage in their disease. This included many individuals who may not have had access previously. This is especially important for patients with rheumatoid arthritis (RA) or inflammatory bowel disease (IBD), who can develop long-term complications if not treated at an early stage of disease development. Testament to this, is that patient access to biologic therapies has already increased by as much as 100 per cent in Europe after biosimilars were introduced,” said spokesperson from Samsung Bioepis, a leading biosimilar firm based in South Korea.

This is particularly true in Asia-Pacific, where non-communicable diseases (NCDs) cause nearly two thirds of all deaths and there is a significant disparity in access to medicines, as reported by The Lancet study. Biosimilars, priced typically 40-50 per cent lower than biologics, offer affordable alternatives for treating NCDs.

It is no wonder then that APAC is currently experiencing a boom in biosimilars, with many companies actively developing them. The region currently holds 30 per cent of the global biosimilars market. With 60 per cent of the global population residing in Asia, APAC leads in biosimilar development compared to other regions as reported by Generics and Biosimilars Initiative (GABI).

Governments in the region are actively supporting developments in biosimilars. South Korea, a leader in biosimilar manufacturing, provides capital, tax breaks, and regulatory guidance to local biosimilars companies. Samsung Bioepis and Celltrion, two major biosimilar companies, are based there. The country has approved 13 biosimilars, according to GABI.

In Japan, GABI observed that the government launched the Honebuto policy to develop biosimilars and promote National Health Insurance (NHI) schemes, high-cost medical care benefit programmes, and other reimbursements. To date, the Japanese regulator has approved 35 biosimilars.

China is a key market, having approved over 20 domestically developed biosimilars. In 2022, the oncology and immunology biosimilar market in China alone achieved sales of approximately $2 billion, as estimated by Clarivate. The Chinese government also offers various initiatives to support the development and adoption of biosimilars. Some of the leading names in the biosimilar market in China include Shanghai Henlius Biotech, Chia Tai Tianqing and Innovent Biologics.

India is the leading market with over 100 approved biosimilars and some of the top biosimilar companies include Biocon, Intas Pharmaceuticals, Dr. Reddy's Laboratories, Reliance Life Sciences, Gennova Biopharmaceuticals, Lupin, Gland Pharma, Zenotech Laboratories, Serum Institute of India, USV, Virchow Biotech and Wockhardt It is estimated that over 100 biopharma companies in India are working on various platforms to produce biosimilars products to treat deadly diseases like cancer, diabetes, hepatitis, orphan and other autoimmune diseases.

In Taiwan, the government announced an incentive programme to promote biosimilars starting July 2024 until 2026. The aim there is to increase biosimilar usage from 7.8 per cent to 30 per cent by 2026, as well as to create substantial savings over the three-year pilot programme.

Repeating Generics' Success Story

Generics have contributed for nearly four decades and now represent 80-90 per cent of prescriptions filled around the world. Can biosimilars repeat history? Experts believe so.

"Biosimilars are the next wave of affordable medicines. As large molecules lose patents, biosimilars are expanding access to key biologic therapies by making them affordable and increasing supply for providers and patients. These are competitive markets with the number of players often determined by the complexity of the product – the more complex, the less competitors and vice versa. Pharmaceutical manufacturers must successfully navigate the landscape across development, manufacturing, and commercialisation for each molecule to be successful. In the US today, for example, over 90 per cent of total prescriptions are filled by generics – from oral solids to complex injectables. Similarly, for the early biosimilars launched in the US over the last several years, adoption rates for biosimilars are over 80 per cent for many molecules. This projects well that biosimilars are and will be adopted in a similar fashion as generics over time," said **Anthony DiMeo, Vice President, Investor Relations & Media, Amneal Pharmaceuticals,** a global, diversified pharmaceutical company that offers access to high-quality, affordable, and essential medicines, primarily in the US.

There are several challenges in replicating this success though. Unlike generics, biosimilars are derived from living organisms, making their development and manufacturing processes inherently more complex and costly.

"Biosimilars have a larger molecular size and more complex structure compared to small-molecule generics, adding cost and complexity to their development and manufacturing. Biosimilars development may take six to nine years and cost $100-300 million per candidate. A simple small molecule generic, by contrast, can cost as little as $1-2 million and take approximately two years to develop," said **Simon Lee, Head, Asia Cluster, Sandoz, Switzerland.**

Sandoz is a pioneering company in the development of biosimilars, with ten marketed biosimilars and a robust pipeline comprising 24 molecules across various disease areas with high unmet needs. They lead the industry with biosimilar products reaching a wide patient base. Sandoz initiated the world's first biosimilar development programme in 1996 and was the first to receive approvals for biosimilars in Europe, Japan, Canada, and the US.

There are other numerous global challenges, from regulatory to commercial, that influence the adoption of biosimilars.

"Interventions such as pharmacy-level substitution and discount agreements for generics create cost pressures that are the root cause of supply shortages. To avoid the same fate for biosimilars and democratise access to biologic medicines, it's imperative to steer clear of implementing pharmacy-level substitution and discount agreements. These agreements can undercut the market for biosimilars by limiting their competitive edge and diminishing their availability. Similarly, automatic substitution and price-only tendering schemes should be avoided as they reduce competition between manufacturers and

pose risks to ensuring a reliable and secure supply of biologic medicines. By prioritising policies that promote fair competition and robust market participation, we can safeguard the sustainable growth and accessibility of biosimilars, thereby enhancing patient access to crucial biologic treatments globally," said Simon.

A sustainable market environment must be created and balanced incentives will matter to keeping all the necessary contributors available over the longer term.

"The catastrophic price erosion of generics to unsustainable levels is having a severe effect on the healthcare sector in multiple markets around the world, and we must avoid that happening for biologics too. It has led to supply shortages for drugs, especially in the oncology sector, which can have severe consequences for patient care. It is important to have policies that not only drive broader patient access to cost-effective medicines, but also policies that ensure long-term biosimilar sustainability through multiple products remaining commercially viable in the market place over time. A sustainable market for biosimilars will further foster future biosimilars from being developed, and may help mitigate the current void in the biosimilar pipeline," added spokesperson from Samsung Bioepis.

Biosimilars not only expand patient access to potentially life-changing medicines but also enhance treatment options for healthcare providers and deliver substantial cost savings to healthcare systems. The use of biosimilars is projected to save up to $290 billion by 2027, concludes IQVIA's Global Use of Medicines Report 2023.

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