



# BIOSIMILAR DEVELOPMENT INDUSTRY

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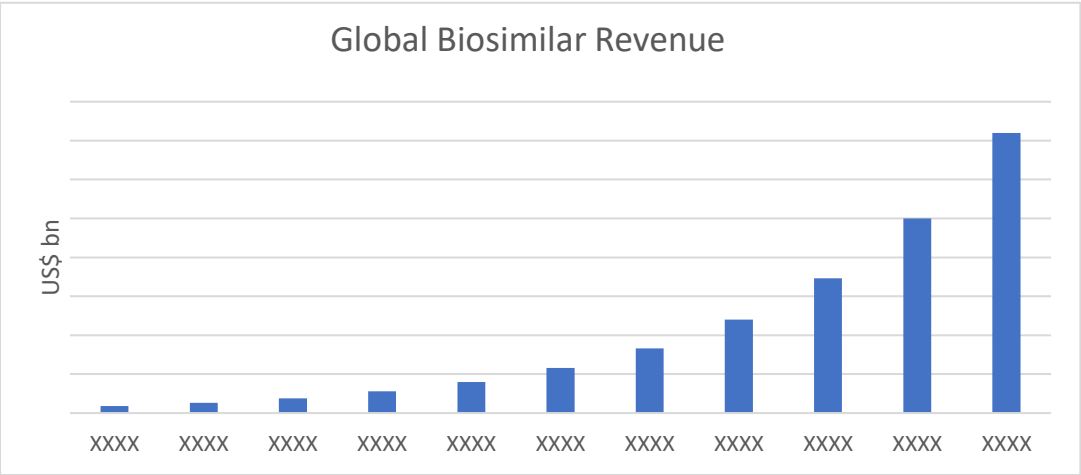
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Global Biosimilars Market Overview

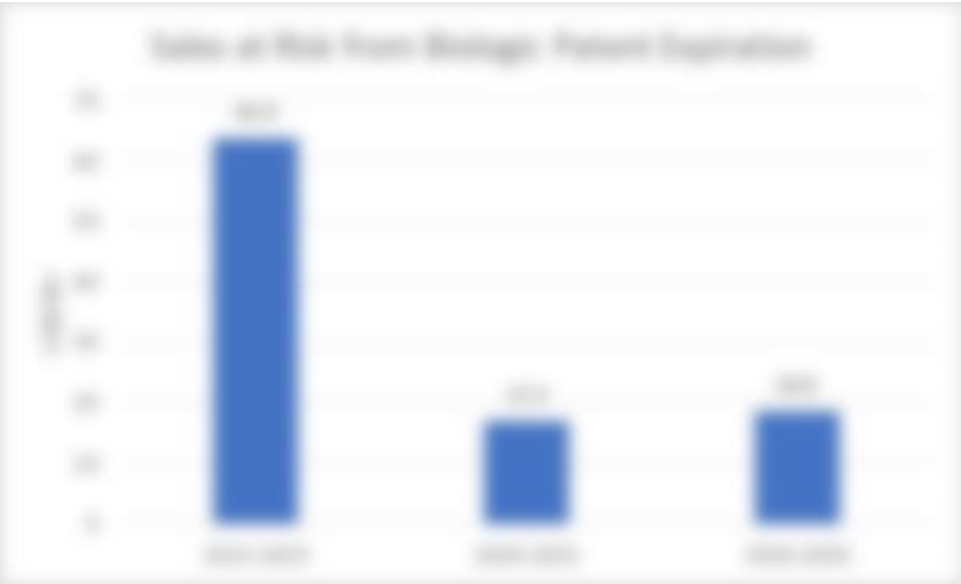
The global biologics market was dominated by original biologics in 2015, with biosimilars accounting for a small share of only XX% or US\$ XX Bn. However, it is expected to grow to US\$XX Bn in 2018 and US\$ XX Bn by 2023, a CAGR of XX% from 2015. North America, Europe and Japan account for approximately XX% of the global biosimilar sales, whereas Asia and Africa account for only XX% and XX%, respectively.

Chart 1: Global Biosimilar Revenue



The main factor driving the growth of biosimilars market in the near future is the expiry of major biologics patents by 2030. As we can see from the chart, about XX biologics patents of the major players are going to expire by 2030 putting about \$XX Bn sales at risk, providing opportunities for biosimilar manufacturers to produce biosimilars in those segments.

Chart 2: Sales At Risk From Biologic Patent Expiration



Source: XXXX

Chart 3: No. of Biologics Patent Expiring By 2030



Source: XXXX

The other factor contributing to the growth of the global biosimilars market is increasing awareness about biosimilars among patients and doctors. In some regions, there is a strong preference for branded drugs as they believe branded drugs have high quality and effectiveness despite the lower cost and proven efficacy of unbranded drugs. Biosimilar players are spreading awareness among patients and physicians about the quality and effectiveness of their products.

There is an increase in the rate of patients suffering from chronic illness such as cancer, heart diseases, diabetes, driving the demand for effective biologics medicines. As biosimilars have a lower cost compared to biologics, their demand is expected to increase more and thus drive the growth of the global biosimilar market.

South Korean Biosimilar Market

The South Korean pharmaceutical industry stood at US\$XX Bn, contributing XX% to the global drug market in 2016. This is due to a small domestic market that South Korean companies have failed to achieve economies of scale. But with expanding R&D investments, the domestic drug market has been successful in developing new drugs one after the other, which has resulted in higher exports. Exports had grown XX% from US\$XX Bn (2012) to US\$XX Bn (2016), respectively.

South Korea has emerged as one of the most aggressive countries in the South-Asian market for developing biosimilars. In 2009, South Korea released its biosimilar guidelines to create a competitive domestic market. Since then several domestic companies have invested heavily in becoming global leaders. This has resulted in several key collaborations between Korean companies and multi-national biopharma firms. Most of the biosimilars developed in the country are exported to European and the US markets. During January-June 2017, biosimilars accounted for XX% of the total pharmaceuticals.

Current Market Scenario

Korean Biosimilars Hitting Hard on Brand-Name Biologics

XXXXX and XXXXX are currently leading the race in the Korean biosimilar market. XXXX's XXXX/XXXX, a biosimilar to XXXX's (\$XXX) XXXX which is used to treat autoimmune disease and XXXX' XXXX, a biosimilar of XXXX's (\$XXX) rheumatoid arthritis drug XXXX, are major selling biosimilars. These biosimilars are giving tough times to their brand-name biologics. Sales for XXXX fell by XX% in 4Q 2017 compared to 2016, whereas sales for XXXX declined in 2017 by XX% to \$XX Bn.

Chart 4: XXXX & XXXX Quarterly Sales



Source: XXXXX

## First Mover Advantage

The first mover advantage for biosimilars has proved to be an important factor in establishing market share. The successful launch of a biosimilar is heavily dependent on seizing the window of opportunity after the originator biologic loses exclusivity and before competitor biosimilars reach the market.

After the launch of a biosimilar in a market, it has been noticed that the market size tends to shrink in the early stage, due to price cuts of the reference biologic. Later when patients start adapting to the biosimilar, overall market size starts recovering and rebounds. These trends can be seen in XXXX's biosimilar XXXXX's XXXX which was approved almost a year before XXXX's XXXX in the US:

**Chart 5: XXXX vs XXXX (US)**



Source: XXXXXXXX

## Approved Biosimilars in Korea

Korea has proved to be one of the most advanced biosimilar markets and has witnessed the approval of the world's first biosimilar monoclonal antibody. Till now, the Ministry of Food and Drug Safety (MFDS), the regulatory body for approval of medicines, has approved XX biosimilars. These biosimilars belong to different product classes including insulin, monoclonal antibody, HER2-inhibitor and tumour necrosis factor (TNF)-inhibitor.

The first biosimilar to be approved in Korea was XXXX's arthritis treatment XXXXX (XXXX) in July XXXX. XXXX stands on top of the biopharmaceutical export list with \$XX million exports in 2016, a XX% growth over the previous year and is available in XX countries.