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Global Biosimilars Market Regulations & Pipeline Insight

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Abstracts

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The evolution of biosimilars has currently reached different stages across the world. Owing to variable clarity in the guidelines and diverse regulatory pathways, various definitions of biosimilars (or the broader group of follow-on biologics) have emerged across countries. Till now the European region has the best-established framework for biosimilars. The US is currently almost aligned to the European standards. Biosimilars are also known as follow on biologics in the US and subsequent entry biologics in Canada, are biologic products which are approved in a country, which has an abbreviated approval process for biologic products which references an originator biologic in the regulatory submission.

The global biosimilars market is categorized into monoclonal antibody biosimilars (mAbs), insulins, interferons, erythropoetins, filgrastim, somatropin and follicle stimulating hormone (FSH). Among the segments of the biosimilars market, the monoclonal antibodies (mAbs) and insulin market would witness maximum growth, with these two segments accounting for a dominant share of more than 40% of the total global biosimilars market by 2018. Additionally, with the mAbs having one of the strongest R&D pipeline in the biologics market, it is expected that many new next-generation technologies which would push mAb therapeutics into newer areas such as solid tumours, cardiovascular and neurological disorders would be introduced into the market.

In terms of innovation in the biosimilars, it is most likely that the future market would witness the introduction of follitropins, interferons and low molecular weight heparins products, in addition to mAbs. Also, it is expected that some pharmaceutical companies

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could increasingly start focusing on specific therapeutic classes based on their capacity to manufacture and their strategic fit.

Almost all the countries across the globe are currently experiencing an increase in their ageing population with a parallel increase in the incidence of chronic diseases. However, an increase in the demand for high quality healthcare is generally associated with the issue of controlling spiraling healthcare expenditure. With the regulated and streamlined introduction of biosimilars into the market, it is most likely that there would be an increase in the accessibility and affordability of the much in demand biologic medicines. The next few years are likely to witness a new set of complex biosimilars products being developed owing to a significant number of leading brands of biologic drugs losing their patents by 2020.

“Global Biosimilars Market Regulations & Pipeline Insight” Report Highlights:

Market Overview

Detailed Regulatory Pathways For 12 Countries/Regions

Global Biosimilars Pipeline by Phase, Indication, Company & Country

Biosimilars Pipeline: 276 in Development Phase

Majority Biosimilars in Preclinical Phase: 76 Biosimilars

Marketed Biosimilars by Indication, Company & Country: 113 Biosimilars

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