Market Analysis –World Biosimilars 2021

The World Biosimilar 2021 market in Europe reached a value of US$ 2,934.6 Million in 2018. The market is further projected to reach a value of US$ 11,663.1 Million by 2024, growing at a CAGR of 24.9% during 2019-2024.

The European biosimilar market represents the most mature in the world and continues to rally momentum. This market is expected to grow robustly in the next five years, as a number blockbuster biologics are scheduled to lose patent protection in Europe.

Biosimilars are bio therapeutic products which are similar to already licensed reference biologics, in terms of quality, safety and efficiency. Biosimilar manufacturers wait till the patent of the reference product expires and then seek approval from the regulatory authorities in order to produce their biosimilar versions. These manufacturers use the state-of-the-art technology for comparing the characteristics, such as purity, chemical identity and bioactivity, of the proposed biosimilar to its reference product.

In 2005, a science-based regulatory framework was established in the European Union (EU) for ensuring the production of high-quality biosimilars. Later in 2006, the European Medicines Agency (EMA) approved the first biosimilar medicine, Omnitrope. Since then, a number of biosimilars belonging to various therapeutic classes have been approved in Europe.

Biosimilars Market in Europe:

Biosimilars are less expensive than their branded counterparts as they do not require extensive research and testing which saves both money and time; thereby lowering the costs. Moreover, they also have short marketing times as launching a biosimilar does not require extensive marketing as the safety and efficacy profile of their branded counterparts have already been established. Several blockbuster biologics are expected to lose their patent protection over the next 5 to 10 years. This expiration of patents and other intellectual property rights is expected to create huge opportunities for biosimilar manufacturers. The European population is ageing with around one fifth of the total EU population above 65 years of age. There has resulted in a significant increase in the burden of lifestyle diseases in the region. The prevalence of diseases such as diabetes, autoimmune diseases, oncology, etc. has been increasing rapidly in Europe. This is also expected to propel the market growth during the next few years. As a result of rising healthcare costs, governments across a number of European countries have formulated policies incentivising physicians, pharmacists and patients in favour of biosimilars over branded biologics.

A study conducted by the consultancy company GFK on behalf of the European Biosimilars Group It analysed the main factors that support a sustainable European biosimilar drugs market. The study revealed that biosimilar medicines provide a major opportunity with considerable benefits, since they lead to cost savings throughout Europe, contribute to the sustainability of National Healthcare Systems and improve patient access to innovative treatments. However, in order to achieve these benefits in the long term, the biosimilar medicines market must continue to be sustainable.

The study concluded that the main factor influencing the sustainability of the biosimilar medicines market and enabling bio similar drug implementation is that this market must be attractive and deliver continuing benefits, in both the short and long term, to the four key stakeholder groups: physicians, payers, patients and industry. However, the study emphasizes that the “attractiveness” and “benefit” concepts are different in each of these groups. In this way, for physicians it involves having more opportunities to treat more patients with appropriate therapies. For payers, it entails cost savings and the financial sustainability of healthcare systems. For patients, it means having improved access to medicines. Finally, for the industry, it involves a reasonable return on investment with the continued attractiveness of R&D investment in new medicines development.

On the other hand, other factors that strongly influence the development and implementation of biosimilars include the prescribing physician’s trust, the complexity of clinical development and the uncertain regulatory framework. In order to increase the prescribing physicians’ trust, they must have a good understanding of biosimilars. In fact, as we already stated in a previous post, the consultancy company PwC (PricewaterhouseCoopers) revealed that only 17% of survey respondents chose the correct biosimilar definition from a list provided (PwC Health Research Institute, Top Issues Consumer Survey, 2015). Therefore, a series of training programs have been established providing clear information about them, including courses, discussion forums, conferences and newsletters. The complexity of clinical development is another important factor because it has a direct impact on obtaining marketing authorization approval from regulatory authorities, such as the Food and Drug Administration (FDA) in the Unites States, and the European Medicines Agency (EMA) in Europe. The more complex a drug’s clinical development is, the more time is required to obtain the marketing authorization and the longer it takes to implement it. Finally, the legal framework regulating the development, approval, marketing and implementation of biosimilars, depending on the country, is quite uncertain and vague. However, it is true that Europe has been pioneering in the establishment of a legal framework and guidelines for the approval of biosimilars.

Market Summary:

Country-wise, the market has been segmented into Italy, Germany, United Kingdom, France, Spain and Others. In 20120, Italy represented the largest market for biosimilars in Europe. The report has analysed the market on the basis of molecule. In 2020, Infliximab dominated the market, accounting for the highest sales. Other major molecules include Insulin Glargine, Epoetin Alfa, Etanercept, Filgrastim, Somatropin, Rituximab, Follitropin Alfa, etc. The report has also analysed the market on the basis of indication. Autoimmune diseases represented the biggest indication for biosimilars in 2020. Other major indications include oncology, autoimmune diseases, blood disorders, growth deficiency, diabetes, etc. On the basis of manufacturing type, the report has segmented the market into in-house manufacturing and contract manufacturing. In 2020, in-house manufacturing accounted for a higher share.