CHAPTER: 14

MAJOR BIOSIMILARS IN THE MARKET CONTRIBUTING TO THE ECONOMY OF PHARMA INDUSTRY IN US AND THE IMPACT OF COVID-19 ON BIOSIMILARS MARKET GLOBALLY

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INTRODUCTION

Biologics, including certain vaccines, have been recognized since the nineteenth century. The Food and Drug Administration (FDA) of the United States approved the first bacteria-generated biologic, human insulin, in 1982. Examples of biologics encompass vaccines like those for human papillomavirus, gene therapies, transplant tissues such as tendons and ligaments, blood and blood products like platelets, recombinant proteins like insulin, stem cell therapies for cancers or genetic disorders, and monoclonal antibodies used to combat cancer and treat autoimmune diseases [3]. Despite being a longstanding concept, biologics have evolved, especially since the 1980s when modern recombinant DNA technology was employed in their production for treating various ailments. As our understanding of biology has advanced, it has become increasingly crucial in managing autoimmune diseases, cancer, and genetic disorders. The range of available biologics has significantly expanded, covering conditions such as ankylosing spondylitis, rheumatoid arthritis, psoriasis, diabetes, multiple sclerosis, SLE, Crohn's disease, and ulcerative colitis, all of which are immune-mediated disorders. Specific cancers like leukemia, lymphoma, gastric, breast, and colon cancers fall under this category. Rare genetic illnesses, including Gaucher disease, sickle cell disease, hemophilia, and cystic fibrosis, are also addressed by biologics. With patents and exclusivity dates for numerous biologics expiring or already expired, there is an emerging opportunity for the development and approval of comparable treatments, known as "biosimilars" [1,2].

RESEARCH QUESTIONS

1. Which prominent biosimilars currently play a significant role in the economic landscape of the pharmaceutical industry in the United States?
2. How has the global biosimilars market been impacted by the COVID-19 pandemic?

RESEARCH OBJECTIVES

1. To examine the present market situation of biosimilars in the United States.
2. To investigate the regulatory pathway governing the approval of biosimilars in the United States.
3. To identify the significant distinctions between the biosimilars markets in the United States and the European Union.
4. To recognize the obstacles and prospects associated with the acceptance of biosimilars in the United States.
5. To analyze the impact of the COVID-19 pandemic on the global uptake and adoption of biosimilars.

RESEARCH METHODOLOGY

The study was exploratory in nature, incorporating both qualitative and quantitative data collected from various secondary sources. The data was sourced from journals, articles, websites, and reports released by various research groups during the period from 2015 to 2021. This timeframe was selected because the first biosimilar was approved in the United States in 2015. Descriptive analysis was conducted to identify the major biosimilars influencing the US biosimilar market. To gain a better understanding of the current biosimilar market value, a search focused on countries of interest, particularly the USA, was also conducted. Comparative analysis was performed to highlight the significant differences between the US and Europe biosimilars markets. Europe was chosen for comparison due to holding the maximum share of sales in the global biosimilars market.

Descriptive analysis was employed to examine the challenges and opportunities influencing the adoption of biosimilars in the US, considering the impact of COVID-19 on global biosimilar uptake. Recommendations and suggestions were provided for post-COVID marketing of biosimilars and strategies to enhance overall biosimilar adoption in the United States.

RESULTS & DISCUSSION

Biosimilars reduced prices by providing significant wholesale acquisition cost (WAC) and average sales price (ASP) savings at launch, along with cost competition, leading to additional savings over time. Manufacturers introduced biosimilars at a WAC price generally 15% to 37% cheaper than the WAC of the reference drug, as illustrated in Figure 5. Almost all biosimilar manufacturers launched at a WAC price 3% to 24% lower than the reference drug ASP. The ASP of reference products began to decline due to competition from biosimilars, and biosimilar ASPs also experienced a decrease. For instance, the ASP for the infliximab reference product (Remicade) decreased by over 30%, while the ASPs for the biosimilars, Inflectra and Renflexis, decreased by approximately 40%. Over time, the adoption rate of biosimilars increased, with Neupogen (filgrastim) biosimilars accounting for over 75% of the market after 5 years.

CONCLUSION

The advent of COVID-19 undeniably disrupted the entire healthcare industry, prompting concerns among respondents about how regulatory authorities, pharmaceutical companies, treatment facilities, and patients will adapt to the ongoing pandemic. Beyond the anticipation that biosimilars will receive the attention they deserve, there is a focus on the policies governments, regulators, and payers need to implement to optimize the use of these crucial medications. Some experts foresee 2021 as the "year of the biosimilar," expecting stakeholders to address access constraints hindering biosimilar adoption and enact legislative measures not only to eliminate these barriers but also to yield long-term cost savings.

Although biosimilars are projected to eventually constitute a significant portion of the US pharmaceutical market, the path to successful biosimilar adoption remains challenging in these early stages. Substantial investments are required to demonstrate similarity and interchangeability, unlocking their full potential.

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