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Letter to Editor

Expected Impact of Biosimilars on the Pharmaceutical Companies

Dear Editor

In the last three decades, biological products have gradually developed to be an essential basis in the pharmaceutical industry. Advancements in this field have encouraged the frontiers of science to bring life-saving treatments to patients suffering from incurable diseases, such as cancers and has also assisted clinicians in managing chronic diseases e.g., rheumatoid arthritis.[1] A biosimilar is defined as a biological product similar to a reference drug that has already been authorized for the treatment of a certain illness. Hence, it exerts the same therapeutic effects as the original medicine.[2] Biosimilars are also known as follow-on biologics, similar biological products, subsequent entry biologicals, and off-patent biotech products as synonyms.[3] The main challenge facing biosimilar manufacturers is to prove the similarity of their biological substances to the parent drug, since even a small variation can lead to undesirable changes in their safety and efficacy. Thus, there is a need for specific guidelines for all biological products. The guidelines of the European Medicines Agency (EMA), World Health Organization (WHO), and the United States Food and Drug Administration (US-FDA) are the reference standards for many countries. Sixteen countries have already adopted the mentioned guidelines, and three out of them have filled a draft as the basis of their own regulations up to now.[4] Since 2006, biosimilars have been marketed in Europe under the regulation of the EMA. In the United States of America (USA), the first biosimilar, known as Zarxio, was authorized by the US-FDA in March 2015. The launch of biosimilars in the European Union (EU) has led to 44% increase in patients' access to these products in the markets of France, Germany, Italy, Spain, and the UK. Currently, EMA and FDA have approved more than 62 and 29 biosimilar products, respectively.[5, 6] Biosimilars provide competition in markets and make the availability of critical drugs easier for patients. In fact, it seems that this is the era of biosimilar products. Therefore, in dealing with an aging population and growing demand for treating chronic conditions, the use of biological products is of great concern. Furthermore, in the present world, when health decisions are increasingly made on the basis of value and cost, biosimilar products will play a vital role in improving patient's access to essential drugs. The main aim of biosimilar manufacturers is to reduce treatment costs. It is predicted that the production of new biosimilars over the next decade can save consumers as much as $250 billion and eases the application of biological treatments for an additional 1.2 million patients by 2025. This expands the access of patients with chronic diseases to such products and offers an affordable opportunity for patients who had to leave the treatment or confine to less effective medicines before.[1]

Biosimilar products have caused a more positive impact on pharmaceutical companies and could lead to expansion of this industry due to the profits gained from their sale. Its medical significance is known throughout the world, and they have become great medications for diseases such as cancer and neutropenia.[7] There are several biosimilars, such as Riabni, Hulio, Abrilada, and Nyvepria, which have been licensed by the US-FDA from 2015 to 2020 (table 1); however, they are not produced in many countries. Furthermore, by 2025, several patents of reference products will be expired, and this can provide an opportunity to produce new biosimilar products.[8] Thus, encouraging manufacturers to produce biosimilar drugs is essential.

The global biosimilars market sale is predicted to reach $35.7 billion by 2025 from $11.8 billion in 2020 (figure 1).[9]

Biosimilar sponsors need to have deep pricing analyses, formulate educational campaigns and marketing initiatives for provider/ patient, and also take positions on basic regulatory issues, both current and future. Companies with high-margin branded biologics, best-in-class manufacturing, and large development structures have to use their resources to defend against the competition of biosimilars. Those taking a mixed approach should apply it in aligned commercial and product development strategies for biosimilar drugs.[10]

Biosimilar products are undoubtedly growing fast. However, their acceptance by physicians regulatory issues, technological reliability, and reduction of total costs are factors to be considered.[11] Some holders of established biological brands may wish to maintain their prices at the expense of losing their share of the market, while others may insist on discounting to keep their share.[10] An important fact is that companies need to understand what "value" means in each market, and manufacturers should balance the short- and

Table 1: Biosimilars approved by 2020

Biosimilar Drug	FDA Approval Date	Reference Product
Riabni™ (Amgen)	December 17, 2020	Rituxan® (Roche/Genentech)
Hulio® (Mylan)	July 6, 2020	Humira® (AbbVie)
Nyvepria™ (Pfizer)	June 10, 2020	Neulasta® (Amgen)
Avsola™ (Amgen)	December 6, 2019	Remicade® (Johnson & Johnson)
Abrilada™ (Pfizer)	November 15, 2019	Humira® (AbbVie)
Hadlima™ (Samsung Bioepis)	July 23, 2019	Humira® (AbbVie)
Ruxience™ (Pfizer)	July 23, 2019	Rituxan® (Roche/Genentech)
Kanjinti™ (Amgen/Allergan)	June 13, 2019	Herceptin® (Roche/Genentech)
Zirabev™ (Pfizer)	June 27, 2019	Avastin® (Roche)
Eticovo™(Samsung Bioepis)	April 25, 2019	Enbrel®(Amgen)
Trazimera™ (Pfizer)	March 11, 2019	Herceptin® (Roche/Genentech)
Ontruzant® (Samsung Bioepis/Merck)	January 18, 2019	Herceptin® (Roche/Genentech)
Herzuma® (Celltrion/Teva)	December 14, 2018	Herceptin® (Roche/Genentech)
Truxima® (Celltrion/Teva)	November 28, 2018	Rituxan® (Roche/Genentech)
Udenyca® (Coherus)	November 2, 2018	Neulasta® (Amgen)
Nivestym™ (Pfizer/Hospira)	July 20, 2018	Neupogen® (Amgen)
Fulphila™ (Mylan/Biocon)	June 4, 2018	Neulasta® (Amgen)
Retacrit® (Pfizer/Hospira)	May 15, 2018	Epogen®/Procrit® (Amgen/Johnson & Johnson)
Ixifi® (Pfizer)	December 13, 2017	Remicade® (Johnson & Johnson)
Ogivri® (Mylan)	December 1, 2017	Herceptin® (Roche/Genentech)
Mvasi™ (Amgen/Allergan)	September 14, 2017	Avastin (Roche/Genentech)
Amjevita™ (Amgen)	September 23, 2016	Humira® (AbbVie)
Erelzi® (Sandoz)	August 30, 2016	Enbrel® (Amgen)
Zarxio® (Sandoz)	March 6, 2015	Neupogen® (Amgen)

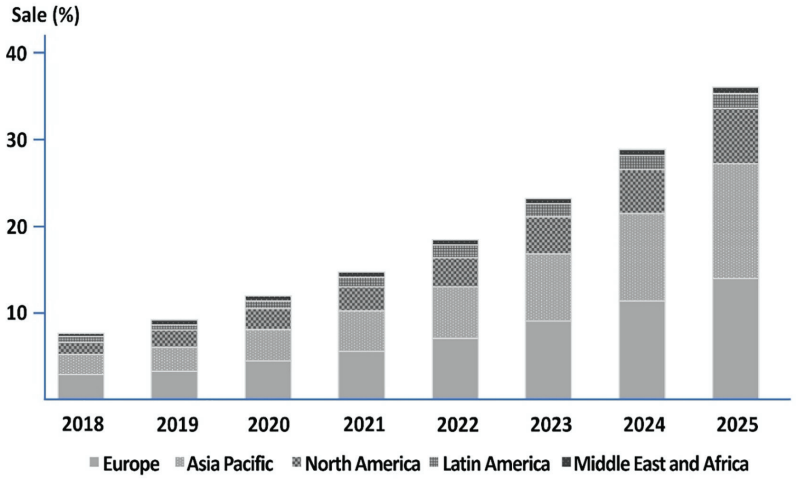

Figure 1: Biosimilars market is illustrated based on the region.

long-term benefits of the product.[12] The biosimilar market is currently controlled by a number of issues such as patent expiration of biological drugs, lower prices, the rise of chronic diseases, and cost-saving policies by governments. Considering the above-mentioned topics, the market is expected to have a fast growth during 2021–2026. With the uncertainties in the state of COVID-19, the direct, as well as the indirect influences of the pandemic on different industries, should be also continuously evaluated.[13]

Conflict of Interest: None declared.

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