CHAPTER: 15

MARKET OPPORTUNITY ANALYSIS FOR BIOSIMILARS FROM PERSPECTIVE OF REGULATORY ENVIRONMENT OFFERED IN EU5, U.S., JAPAN AND PHARMERGING MARKETS

Ankuri Setia
Student, IIHMR University

Dr. Anoop Khanna
Professor, IIHMR University

DOI: https://doi.org/10.52458/9788196897475.2023.eb.ch-15
Ch.Id:- IIHMR/NSP/EB/PHPMBT/2023/Ch-15

INTRODUCTION

The pharmaceutical sector is undergoing unprecedented transformations, driven by unique factors. On the demand side, there is a noticeable shift with an aging population, heightened prevalence of "Western" diseases, and a substantial increase in global access to pharmaceuticals. Simultaneously, the supply side is witnessing heightened competition from emerging market players, coupled with a change in the approaches to drug development, manufacturing, and delivery. Meanwhile, policymakers grapple with the inherent challenge of balancing the aspiration to enhance access to superior medicines and the imperative to restrain the growth of healthcare expenditures.

Central to these changes is the Biosimilars market, where these alternative products are poised to compete with some of the most expensive drugs in the market, albeit requiring significant investments. The potential of biosimilars lies in their ability to deliver cost savings, enhance patient access, and foster innovation [1].

Biosimilar drugs serving as more affordable alternatives to biologic drugs, which are among the most expensive pharmacotherapies available, constitute a rapidly emerging sector within the pharmaceutical industry [2]. The ongoing challenge for payers has been to rationalize the use of "Biologics," making the introduction of biosimilars likely to be embraced by physicians, payers, and patients. This acceptance is expected to occur following the expiration of patents for biologic drugs in significant pharmaceutical markets such as Europe and the U.S. Consequently, it will aid in managing the continually rising pressure on healthcare budgets, expanding healthcare coverage to larger populations. However, this expansion must be carefully balanced against limited budgets and the escalating demand for innovative drugs [3].

RATIONALE

This research aids in identifying the most promising markets worldwide by analyzing available forecasted secondary data. The opportunity assessment assists pharmaceutical multinational companies in determining the geographies where they should consider investing in

biosimilars. This decision was contingent upon the regulatory favorability of each market, given the substantial investments required for the development and introduction of biosimilars.

RESEARCH QUESTIONS

1. What were the shared regulatory viewpoints considered in the biosimilar regulatory approval process across the targeted regions?
2. From a regulatory standpoint, which region or regions present the most promising market for entities looking to enter the biosimilar landscape?

AIM

To determine and analyze Market Opportunity for biosimilars by means of secondary/desk research carried out on the regulatory environment that exists and that was predicted in the geographies under this study.

RESEARCH OBJECTIVES

1. To examine the comprehensive regulatory landscape for biosimilars in the seven primary markets (EU5, U.S., and Japan) and two emerging pharmaceutical markets (China and Russia).
2. To identify and select the biosimilar regulatory factors that exert the most significant influence on shaping the regulatory framework in these regions.
3. To evaluate the adherence of the considered regions to the established parameters and assign rankings accordingly.
4. To identify the most favorable region or regions as a biosimilar market based on regulatory considerations and rankings.

RESEARCH METHODOLOGY

The study adopted an exploratory secondary/desk research approach focusing on biosimilar molecules and their manufacturers in selected geographies: EU5 (United Kingdom, France, Germany, Spain,

Italy), the United States of America, Japan, and Pharmerging markets (China, Russia). The data collection involved recording the regulatory scenario in these geographies, considering relevant regulatory parameters. ZS-specific data sources and publicly available secondary research data sources were utilized for data extraction. The methodology included the initial selection of study geographies based on market trends, projected potential markets, and regulatory environments for existing biosimilars. The shortlisted geographies encompass the EU5, the U.S., Japan, and China, forming a comprehensive scope for the exploration of biosimilar landscapes.

RESULTS & DISCUSSION

All EU5 countries which wers already the biggest market for biosimilars till date showed the highest ranking that means it offers the least stringent regulation in terms of extrapolation of indication. So, this means that study results of clinical studies carried out for one indication could be extrapolated for other indications of the same drug provided scientific justification is adequately provided. All EU5 shows highest ranking than rest of the geographies thus indicating the presence of well-established and clear-cut regulatory approval guidelines. Unites States and China can be seen to achieve highest ranking because as per FDA the government in United States will offer high support to MNC'S entry into their biosimilar market to go global and develop them as biggest market for biosimilar in coming years by means of designing such supportive policies that are friendly to potential biosimilar entrants. Out of all EU5 government support is highly offered in Germany and Italy keeping prescription quotas, biosimilars under hospital prescribed drugs. Domestic trial requirements are same in EU5 and United States these two being ICH countries accept each other trial results so they have similar ranks however, the lowest ranking is for Japan and China due to data unavailability. In Russia the condition is strictly to conduct local trials, so rank is low.

CONCLUSION

According to the findings of the study, the United States emerged as the most favorable, or conversely, the least restrictive market for biosimilar manufacturers. This was attributed to specific parameters in the U.S. market that are comparatively less restrictive. For instance, the U.S. government, aimed to expand globally and position itself as a prominent biosimilar market, permits the use of reference products from other countries, provided that their standards closely align with those of the FDA, such as the International Conference on Harmonization (ICH Countries). This stands in contrast to Europe, where only drugs approved within the respective country can be outsourced in batches from other countries. Allowing extrapolation of clinical data of non-EEA registered reference product to Biosimilars being manufactured in domestic countries if reference product qualifies in the bridging studies.

REFERENCES

1. *http://thomsonreuters.com/products/ip-science/04_013/anoutlookonusbiosimilarcompetition-cwp-en.pdf*
2. *http://www.ema.europa.eu/ema/*
3. *http://www.fda.gov/*