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Global Generic Drugs Market Assessment, By Application [Neurovascular, Cardiovascular, Dermatology, Oncology, Respiratory, Diabetology and Others], By Type [Biosimilar Generics, Small Molecule Generics], By Brand [Branded Generic, Pure Generic], By Route of Administration [Oral, Injectable, Topical and Others], By Distribution Channel [Hospital Pharmacy, Retail Pharmacy, Online Pharmacy], By Region, Opportunities, and Forecast, 2016-2030F

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Abstracts

The Global Generic Drugs market size was estimated at USD 335.65 billion in 2022 and is projected to reach USD 582.76 billion in 2030, growing at a CAGR of 7.06% for the forecast period between 2023 and 2030F. Multiple factors contributing to the growth of the global generic drugs market are the increasing number of patients with chronic diseases, the rising geriatric population, technological advancements, government initiatives, rising healthcare costs, and expiring patents of blockbuster drugs.

Generic drugs are becoming increasingly popular in developed and developing countries because they are less expensive and reduce dependency on multinational pharmaceutical companies for developing drugs. It requires less investment to make copies of these drugs after obtaining the patent holder's permission. As the patents of several branded drugs expire, the global market for generic drugs will expand rapidly. Favorable policies in various nations that aim to lower overall healthcare costs and minimize the spread of chronic diseases are facilitating growth. However, factors such as stringent regulations, quality issues, and decreasing profit margins can hinder the growth of the global generic drugs market.

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Increasing Prevalence of Chronic Diseases

The increasing prevalence of chronic diseases is having a substantial impact on the global generic drugs market. Chronic diseases such as cardiovascular, neurological, diabetes, and respiratory conditions are becoming increasingly common worldwide due to several factors, including changes in lifestyle, aging population, and environmental factors. According to National Institute of Health (NIH), the number of people 50 years of age and older who have at least one chronic condition is predicted to rise from 71.522 million (69.065–73.781) in 2020 to 142.66 million (134.74–153.39) in 2050, a 99.5% (95.1%?107.9%) increase. By 2060, a projected 48 million individuals (47% of all fatalities worldwide) are estimated to lose life due to serious health-related suffering, an 87% increase from 26 million in 2016. 83% of these casualties are expected to take place in low- and middle-income nations.

Growing Geriatric Population

The increase in the geriatric population is yet another factor that has significantly contributed to the rising demand for generic drugs. As people age, they often suffer from multiple health issues and chronic conditions, requiring long-term medication. Generic drugs, offer cost-effective alternatives to brand-name medications and become essential in managing these health concerns. Moreover, as patents for innovator or brand-name drugs expire, generic versions become available, providing affordable options without compromising on quality or efficacy. This accessibility to more affordable medications becomes crucial in addressing the healthcare needs of the aging population, thereby driving the demand for generic drugs.

One in six individuals on the planet will be 60 years of age or older by 2030. At this point, there will be 1.4 billion people over the age of 60, up from 1 billion in 2020. The number of individuals in the world who are 60 years of age or older is expected to double (to 2.1 billion) by 2050. It is anticipated that between 2020 and 2050, the number of people 80 years of age or older will treble, reaching 426 million.

North America to Dominate the Market while Asia-Pacific is the Fastest Growing Region

North America is poised to dominate the global generic drugs market, with a market share of over 40% in 2022. This is mainly attributed to the high consumption of generic drugs and increasing prevalence of chronic diseases like cancer and diabetes in the region. Also, the region has an established framework for the approval process of

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generic medications and has global leaders in research and development activities. Asia-Pacific is expected to be the fastest-growing region in the Global Generic Drugs market due to the increasing adoption of generic drugs in the healthcare system to reduce healthcare spending. Governments in countries like China, India, and Japan are heavily promoting the use of generic drugs through incentivization and substitute programs. Additionally, the region's focus on better quality generics and supportive policies and investments position Asia-Pacific as a key market player in the global generic drugs market.

United States is the leading region within the North America generic drugs market. This leading position is driven by factors such as patent expirations, a streamlined FDA approval process, and a regulatory environment that fosters competition. The availability of generic alternatives after patent expirations contributes to cost containment in healthcare in the region, as generic drugs offer more affordable options. The United States market continues to prioritize the adoption of generic drugs to address rising healthcare costs while maintaining therapeutic effectiveness. As per the United States Generic & Biosimilar Medicines Savings Report 2023, generic drugs takes 90% of all the prescription in the United States but represents only 17.5% of total prescription drug spending and less than 2% of all healthcare spending.

Cardiovascular Drugs Contribute to Major Market Share

Cardiovascular drugs dominated the global generic drugs market with around one-third of the total market share in 2022. The growth is mainly attributed to the increasing prevalence of cardiovascular diseases across the globe due to sedentary lifestyle and unhealthy food habits. As per World Health Organization (WHO), cardiovascular diseases are the major cause of the global mortality rate marking nearly 17.9 million deaths per year worldwide. Heart attacks and strokes account for over 80% of cardiovascular deaths, with about a third of these fatalities happening prematurely among individuals below the age of 70 years. An unhealthy diet, low physical inactivity, consumption of tobacco, and excessive alcohol consumption are the primary behavioral factors that significantly contribute to heart diseases and stroke. These behaviors can lead to high blood pressure, increased blood glucose levels, elevated blood lipids, as well as overweight and obesity in individuals. According to a recent World Health Organization (WHO) report, non-communicable diseases, or NCDs like cardiovascular diseases, account for over three-quarters of all fatalities worldwide.

Biosimilar Generics to Dominate the Market

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The biosimilar generics segment held the dominant market share in the global generics drug market in 2022 and is expected to maintain its dominance over the forecast period. Biosimilars are generic versions of biologics, but at much more affordable prices, making them a dominant segment across the market. Several other factors also contribute to the expected dominance of biosimilar generics, like the patent expiration of many blockbuster biologic drugs, opening opportunities for biosimilar manufacturers to enter the market with more affordable versions.

Moreover, biosimilars offer an alternative way to reduce the rising healthcare costs for patients and healthcare systems without compromising quality. Due to these factors and the ongoing need for cost-effective alternatives, the biosimilar generics segment is poised to maintain its dominance in the global generics drug market, especially in addressing the healthcare needs of aging populations and chronic disease management.

For instance, according to United States Generic & Biosimilar Medicines Savings Report 2023, the use of biosimilar generics is on the rise which compels the innovators to reduce the cost of biologics, thus saving USD 9.4 billion in the year 2022 alone.

Oral Drugs Being the Most Preferred Route of Administration

The oral generic drug segment dominated the global generic drugs market, holding nearly two-thirds of the market share in 2022 globally. Among the different methods of drug delivery, oral administration is preferred over injectables due to its numerous advantages. These benefits encompass safety, high patient adherence, easy ingestion, avoidance of pain, and the ability to accommodate a wide range of medications, making it a versatile option. Hetero, a pharmaceutical company based in Hyderabad, India, declared in 2022 that its generic form of the COVID-19 oral antiviral treatment candidate nirmatrelvir had obtained approval from the World Health Organization Prequalification of Medicines Program (WHO PQ).

Retail Pharmacy to Dominate the Market

Retail pharmacy will dominate the global generic drugs market over the forecast period. Retail pharmacies serve as pivotal nodes within the distribution network and act as accessible hubs for patients to acquire generic medications. Their ubiquitous presence fosters convenience and facilitates widespread access to affordable generic drugs. Leveraging this convenience, retail pharmacies establish a direct link between consumers and a diverse range of generic medications, catering to a spectrum of

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medical needs. Moreover, the increasing demand for cost-effective healthcare solutions propels the significance of generic drugs, and retail pharmacies stand as the primary gateway for consumers to procure these affordable alternatives to brand-name medications.

Technological Advancements

With the advent of RPA (Robotic Process Automation) and AI in the pharmaceutical industry, automation has helped in overcoming difficulties and improving efficiency. RPA and AI aid in increasing productivity, lowering costs, and improving performance. Through automation, these technologies also assure regulatory compliance within an organization's process. Artificial intelligence, machine learning and natural language processing are being used extensively in research and development of pharmaceutical drugs. Predictive analytics and natural language processing are used to scan databases of brand name medicine compounds for similar compounds that scientists can use to develop generic drugs. Machine learning is used to determine a compound's solubility in order to ensure that it retains its effectiveness over time.

Government Initiatives

Developed countries' governments are trying to reduce healthcare costs by promoting the manufacturing of generic drugs. On the other hand, healthcare industries in developing countries are affected by issues like affordability and accessibility. In the United States, the Food and Drug Administration (FDA) has taken various steps to expedite the approval process for generic drugs, including the Generic Drug User Fee Amendments (GDUFA) program, which aims to speed up the review of generic drug applications. In the European Union, the European Medicines Agency (EMA) has also implemented initiatives to streamline the approval process for generic drugs, such as the generic medicines work-sharing initiative, which allows regulators from different countries to work together to assess the safety and efficacy of generic medicines. Overall, these initiatives by governments around the world are helping to increase the availability and affordability of generic drugs, thereby improving access to healthcare for patients. To promote the use of generic drugs, the Indian government established more than 9,000 Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJK) till 2022. These centers sell generic drugs at much lower rates with the help of government subsidies.

Impact of COVID-19

The COVID-19 pandemic had a short-term and long-term impact on the pharmaceutical

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sector. Short term impacts such as demand change, panic buying, supply shortage of API (active pharmaceutical ingredient) and finished products. Long-term impacts include delayed approvals for non-COVID-related pharmaceutical products, ethical considerations, and consumption trend changes in health-related products. Supply chain was a major factor impacting the generic drugs market. Many countries rely on India and China to produce generic drugs, and the pandemic led to disruptions in the production and distribution of drugs due to factory closures and supply chain disruptions.

The pandemic also increased demand for certain generic drugs, particularly those used to treat COVID-19 symptoms such as fever and respiratory distress, which led to shortages of these drugs in some regions and price hikes. Furthermore, the pandemic has also highlighted the importance of investing in research and development for new generic drugs, particularly for COVID-19 treatments and vaccines.

Impact of Russia-Ukraine War

Russia’s invasion of Ukraine affected millions of people, not just in Eastern Europe nations but throughout the world. Drug developers experienced development delays, lost business continuity, and the threat of noncompliance for on-market drugs. Drugmakers such as Novartis, AbbVie, Eli Lilly and hundreds of companies announced a pause or withdrawal of business in Russia. The Director General of Pharmexcil (Pharmaceutical Export Promotion Council of India) expressed concerns about Indian pharmaceutical exports losing ground in the CIS (Commonwealth of Independent States). He also expressed that India might lose a few millions in terms of exports to CIS and Russia, since Russia is one of the top five exporting destinations of India and Ukraine is the third largest exporter of pharmaceuticals for India. Indian drug companies such as Dr Reddy’s Laboratories and Sun Pharma have strong presence in Ukraine and Russia.

Key Players Landscape and Outlook

The Global Generic Drugs market is dominated by Viatris, Fresenius SE & Co. KGaA., Novartis AG, Teva Pharmaceuticals, Sun Pharmaceutical Industries Ltd., Cipla, Dr. Reddy's Laboratories, Lupin and many others.

> In March 2023, MPP (Medicines Patent Pool), a United Nations-supported public health organisation, announced that it has entered into sublicensing agreements with three drug companies-Aurobindo Pharma, Cipla, and Viatris- for the

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manufacturing of generic variants of ViiV Healthcare's long-acting HIV prevention medicine. According to the agreement, the organizations would produce the generic version of the medication in India, with Cipla also planning to produce the drug in South Africa.

In May 2023, Teva Pharmaceutical Industries Ltd. revealed a fresh strategic framework encompassing four primary pillars intended to reposition the Company for a forthcoming phase of expansion. The strategy is designed to fortify the Company’s robust commercial portfolio, featuring AUSTEDO, AJOVY, UZEDYTM, and biosimilars, while simultaneously amplifying its innovative pipeline. Additionally, it aims to maintain the Company's dominance in the generics sector and concentrate on streamlining its business operations.

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