

Specialty Generics Market – Global Industry Size, Share, Trends, Opportunity, and Forecast, 2018-2028 Segmented by Route of Administration (Injectable, Oral, others), By Indication (Oncology, Autoimmune Diseases, Infectious Diseases, others), By Distribution Channel (Retail Pharmacies, Specialty Pharmacies, Hospital Pharmacies), by region, and Competition

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Abstracts

Global Specialty Generics Market has valued at USD 55.60 billion in 2022 and is anticipated to witness an impressive growth in the forecast period with a CAGR of 9.70% through 2028. Specialty generics, also known as complex generics, are a category of generic drugs that differ from traditional generic drugs in several ways. These differences relate to the complexity of the drugs themselves, the regulatory pathway for approval, and the therapeutic areas they target. For complex small-molecule specialty generics, regulatory agencies may require additional data and studies to establish therapeutic equivalence and bioequivalence when compared to the reference drug. This can involve more extensive clinical testing and analytical characterization. Specialty generics are often developed for the treatment of chronic and complex diseases, including cancer, autoimmune disorders, rheumatologic conditions, and neurological disorders. These drugs target specific disease pathways and mechanisms. Specialty generics, particularly biosimilars, typically undergo extensive clinical trials to demonstrate safety and efficacy. These trials involve pharmacokinetic and pharmacodynamic assessments, as well as clinical endpoints.

Escalating healthcare costs have put pressure on healthcare systems and payers to find cost-effective solutions. Specialty generics, including biosimilars and complex generics, offer the potential for substantial cost savings compared to their branded counterparts.

The prevalence of chronic diseases, such as diabetes, cardiovascular diseases, and cancer, continues to rise globally. Specialty generics are often used to treat these conditions, driving demand for these drugs. Advances in personalized medicine have led to the development of targeted therapies, many of which fall into the specialty generics category. These therapies are designed to be more effective and less toxic, creating opportunities for specialty generics in precision medicine. Advances in biotechnology and pharmaceutical manufacturing have made it more feasible to develop and produce complex generics and biosimilars, reducing barriers to entry into the specialty generics market.

Key Market Drivers

Technological Advancements

Biotechnology has revolutionized the production of biologic drugs, including biosimilars. Improved cell culture techniques and bioreactors allow for the efficient growth of cells that produce therapeutic proteins, monoclonal antibodies, and other complex molecules. This has made it possible to create biosimilars that closely mimic the originator biologics. High-resolution analytical tools, such as mass spectrometry, nuclear magnetic resonance (NMR) spectroscopy, and high-performance liquid chromatography (HPLC), have advanced the characterization of complex generics and biosimilars. These tools help manufacturers ensure the quality, purity, and consistency of their products. Innovative process intensification technologies improve the yield and efficiency of pharmaceutical manufacturing. This is particularly important for specialty generics that involve complex and costly production processes. Single-use bioreactors are increasingly used in the production of biologics, including biosimilars. They offer flexibility, reduce the risk of contamination, and accelerate manufacturing timelines. Continuous manufacturing processes, as opposed to batch processes, are being adopted in the production of certain specialty generics. Continuous manufacturing can increase productivity and reduce the time and resources required for production. Advances in gene editing techniques, such as CRISPR-Cas9, have improved the development of high-yield cell lines for biologic production. This results in higher efficiency and reduced production costs. Specialty generics may include novel drug delivery systems to enhance drug stability and patient compliance. Technologies like microneedles, nanoparticles, and liposomal formulations have been employed to improve drug delivery. 3D printing technology is being explored for the development of personalized dosage forms, including patient-specific formulations of specialty generics. This could lead to more precise dosing and improved patient outcomes.

AI and machine learning algorithms are used to analyze large datasets in drug discovery, development, and manufacturing. These technologies can accelerate research, predict manufacturing issues, and optimize production processes. Quality-by-Design (QbD) principles involve designing quality into pharmaceutical products from the start of the development process. This approach uses scientific understanding and risk assessment to ensure product quality and consistency. Automation and robotics are increasingly utilized in pharmaceutical manufacturing to reduce human error, improve efficiency, and enhance product quality. This is particularly important for sterile injectables and complex generics. Packaging technologies for specialty generics are evolving to improve drug stability and patient convenience. For example, prefilled syringes, auto-injectors, and smart packaging with integrated sensors are being used. Improved cold chain management and temperature monitoring systems are critical for the storage and distribution of specialty generics, particularly biologics and biosimilars that require strict temperature control. This factor will help in the development of the Global Specialty Generics Market.

Increasing Demand of Precision Medicine and Targeted Therapies

Precision medicine aims to customize medical care based on an individual's genetic makeup, biomarkers, and specific disease characteristics. Targeted therapies are designed to act on specific molecular targets associated with a disease. This approach allows for highly tailored treatment regimens. Precision medicine and targeted therapies are most associated with cancer treatment. With the increasing incidence of cancer and other diseases with well-defined molecular targets, there is a growing need for specialized drugs that can target these specific disease mechanisms. Many targeted therapies and precision medicine drugs are biologics or complex small molecules. As patents for these drugs expire, specialty generics, such as biosimilars and complex generics, are developed to provide more affordable alternatives to patients. Targeted therapies and precision medicine drugs are often high-cost treatments. Specialty generics offer the potential for significant cost savings while maintaining similar efficacy and safety profiles. This makes them attractive to healthcare systems and patients. The introduction of biosimilars in the oncology field has had a substantial impact. Biosimilar versions of monoclonal antibodies and other biologics used in cancer treatment have become available, providing cost-effective alternatives to originator drugs. Specialty generics enhance access to precision medicine and targeted therapies. They allow more patients to benefit from these advanced treatments, as they can be more affordable and accessible than branded counterparts.

Over time, healthcare providers and patients have become more accepting of

biosimilars and other specialty generics. Positive clinical data and real-world evidence have reinforced their safety and efficacy, leading to increased adoption. The entry of multiple manufacturers into the specialty generics market has increased competition, resulting in potential price reductions and ongoing innovation. This benefits both patients and healthcare systems. Pharmaceutical companies have been expanding their global reach by launching specialty generics in various regions, including emerging markets, where the demand for precision medicine and targeted therapies is rising. Precision medicine aligns with patient-centric care models, which prioritize individualized treatment and patient satisfaction. Specialty generics that offer effective, affordable, and accessible treatments support this approach. Pharmaceutical companies continue to invest in the research and development of specialty generics, focusing on molecular targets and pathways to develop more targeted and effective treatments. Regulatory agencies have established clear pathways for the approval of biosimilars and complex generics, including those for precision medicine and targeted therapies. This has accelerated market entry for these products. This factor will pace up the demand of the Global Specialty Generics Market.

Rise in Chronic Diseases

Chronic diseases, including cardiovascular diseases, diabetes, cancer, and respiratory disorders, are on the rise globally. Population aging, lifestyle factors, and changes in healthcare practices contribute to the increasing burden of these conditions. Chronic diseases typically require long-term or lifelong medication management. This sustained need for medication drives consistent demand for affordable and accessible treatment options, making specialty generics a preferred choice. Specialty generics, including biosimilars and complex generics, often offer cost savings compared to branded specialty drugs. Patients with chronic diseases may require multiple medications, and cost-effective alternatives are essential to manage healthcare expenses. Chronic diseases can disproportionately affect individuals with limited access to healthcare resources. Specialty generics improve access to essential treatments, making it possible for a broader population to manage their chronic conditions effectively. Patents on many specialty drugs used to treat chronic diseases have expired or are nearing expiration. This has created opportunities for the development and marketing of specialty generics, including biosimilars and complex generics. Regulatory agencies, such as the U.S. FDA and the EMA, have established pathways for the approval of biosimilars and complex generics, which include treatments for chronic diseases. This regulatory support has accelerated market entry for these products.

Over time, healthcare providers and patients have become more accepting of

biosimilars and specialty generics for chronic disease management. Real-world evidence and clinical data have demonstrated their safety and effectiveness. The entry of multiple manufacturers into the specialty generics market has increased competition, potentially leading to price reductions for chronic disease medications. Patient-centric care models emphasize individualized treatment plans and improved patient outcomes. Specialty generics align with these models by offering cost-effective, accessible, and personalized treatment options for chronic diseases. Pharmaceutical companies are expanding their global reach by launching specialty generics in emerging markets, where chronic disease prevalence is rising, and access to affordable treatments is limited. Various healthcare policy initiatives aim to improve access to affordable treatments for chronic diseases. These policies may encourage the use of specialty generics to reduce healthcare costs. Patient advocacy groups often support initiatives that increase access to affordable medications for chronic diseases, including biosimilars and other specialty generics. This factor will accelerate the demand of the Global Specialty Generics Market.

Key Market Challenges

Intellectual Property and Patent Litigation

Innovator pharmaceutical companies secure patents for their new drugs, which grant them exclusive rights to manufacture, market, and sell these drugs for a specified period, typically 20 years from the date of filing. During this exclusivity period, other companies are prohibited from manufacturing and selling generic versions of the drug. When the patents on brand-name drugs expire, it creates opportunities for specialty generics, including biosimilars and complex generics, to enter the market. These products aim to offer more affordable alternatives to the originator drugs. Innovator companies often file patent infringement lawsuits against generic manufacturers that attempt to market specialty generics. These lawsuits can delay the entry of specialty generics into the market, as they can take years to resolve in court. In the United States, the Hatch-Waxman Act provides a framework for the approval of generic drugs while respecting innovator patents. It includes provisions for patent litigation, known as Paragraph IV challenges, which can trigger patent disputes between innovators and generic manufacturers. Biosimilars, which are similar but not identical to biologic drugs, often face complex patent disputes. The biosimilar approval process may require exchanges of patent-related information between the biosimilar manufacturer and the innovator, potentially leading to litigation. Innovator pharmaceutical companies and generic manufacturers may reach settlement agreements that allow for the entry of generic or biosimilar drugs before the patent expires. Such agreements can have

implications for market competition and pricing. Some innovator companies employ strategies to extend their drug exclusivity, such as obtaining additional patents for variations of the original drug or for specific formulations. This can delay generic market entry.

Complex Manufacturing Processes

The manufacturing of specialty generics is subject to stringent regulatory requirements to ensure product quality, safety, and efficacy. Compliance with these regulations demands specialized knowledge, resources, and documentation. Biosimilars, which are highly similar but not identical to biologic drugs, require extensive analytical testing and comparability studies to demonstrate similarity to the reference biologic. This entails complex manufacturing and analytical processes. Manufacturing biologic drugs, including biosimilars, often involves bioprocessing and fermentation techniques. These processes can be technically challenging and require specialized facilities and equipment. The selection of appropriate cell culture systems and expression systems for biologics can significantly impact the quality and yield of the final product. Optimizing these processes can be time-consuming. The purification of biologics is a complex step involving multiple chromatography and filtration steps. Ensuring the removal of impurities and aggregates is critical to product safety and efficacy. Many specialty generics, including injectables and biologics, must be manufactured under sterile conditions to prevent contamination. Maintaining sterility throughout the manufacturing process is a complex undertaking. Rigorous analytical testing is required to assess the quality and consistency of specialty generics, particularly biosimilars. This includes testing for structural comparability, impurities, and stability.

Key Market Trends

Focus on Specialty Therapies

The growing prevalence of chronic diseases, including cancer, autoimmune disorders, and rare diseases, has created a substantial need for specialty therapies. Specialty generics, including biosimilars and complex generics, are developed to provide more affordable options for patients with these conditions. Many specialty therapies are biologics or other complex drugs. As patents for these drugs expire, pharmaceutical companies are focusing on the development of specialty generics to capture a share of this lucrative market. Specialty generics typically offer significant cost savings compared to their branded counterparts. This is particularly appealing for patients, healthcare systems, and payers, who seek effective treatments while managing healthcare costs.

Regulatory agencies, such as the U.S. FDA and the European Medicines Agency (EMA), have established clear pathways for the approval of biosimilars. This has accelerated the development and marketing of biosimilar specialty generics, especially for biologics used in oncology, rheumatology, and gastroenterology. Over time, healthcare providers, payers, and patients have become more accepting of biosimilars and other specialty generics. Real-world evidence and clinical data have demonstrated their safety and efficacy, leading to increased adoption. Pharmaceutical companies are expanding their presence in the specialty generics market by launching these therapies in various regions, including emerging markets, where the demand for specialty treatments is rising.

Segmental Insights

Route of Administration Insights

In 2022, the Global Specialty Generics Market largest share was held by injectables segment and is predicted to continue expanding over the coming years. Many specialty medications, particularly those used in critical or acute care settings, are administered through injections. These drugs include treatments for cancer, autoimmune diseases, infectious diseases, and certain rare conditions. Injectable medications are preferred when rapid onset of action or precise dosing is required. Some specialty generics require complex formulations or precise delivery mechanisms that are best achieved through injectables. These formulations may involve biologics, complex proteins, or highly potent drugs. Patents on several blockbuster injectable drugs, including biologics, have expired, or were set to expire. This created opportunities for the development and marketing of injectable specialty generics, such as biosimilars and complex generics. Over time, healthcare providers and patients have become more accepting of biosimilars and other injectable specialty generics due to the demonstrated safety and efficacy of these products. This has contributed to their market growth.

Indication Insights

In 2022, the Global Specialty Generics Market Oncology segment to witness fastest growth and is predicted to continue expanding over the coming years. Cancer is a leading cause of death worldwide, and the incidence of cancer continues to rise globally. As the population ages and lifestyle factors contribute to cancer development, there is a growing need for effective oncology treatments. Many cancer drugs, particularly biologics and targeted therapies, have faced or will face patent expirations. When the patents on these drugs expire, it opens the door for the development and

marketing of oncology specialty generics, including biosimilars and complex generics. Cancer treatments, especially novel biologics and targeted therapies can be prohibitively expensive. Specialty generics offer a more cost-effective alternative, making cancer treatment more accessible and affordable for patients and healthcare systems. Developers of oncology specialty generics are required to conduct extensive clinical trials to demonstrate safety and efficacy. Positive clinical trial data can boost confidence in these products and drive their adoption among healthcare providers and patients.

Distribution channel Insights

In 2022, the Global Specialty Generics Market was dominated by specialty pharmacy segment in the forecast period and is predicted to continue expanding over the coming years. Specialty pharmacies specialize in the distribution and management of complex and specialty medications, including specialty generics. They have trained pharmacists and staff who understand the unique requirements of these medications, such as proper storage, handling, and administration. Specialty pharmacies often provide patient-centric care and support services. They offer counselling and education to patients taking specialty medications, helping to ensure adherence to treatment plans and managing potential side effects. Many specialty pharmacies offer additional support services, such as financial assistance programs, copay assistance, and coordination of care among healthcare providers. These services help make specialty medications more accessible to patients. Specialty pharmacies are experienced in navigating the complex insurance and prior authorization processes associated with specialty medications. This can help patients gain access to needed medications more efficiently.

Regional Insights

The North America region dominates the Global Specialty Generics Market in 2022. North America, particularly the United States, has one of the largest pharmaceutical markets in the world. The size of the market, with a significant demand for various specialty and generic drugs, provides opportunities for specialty generics to thrive. The United States has a well-established regulatory pathway for approving generic and specialty generic drugs through the U.S. Food and Drug Administration (FDA). The regulatory framework allows for the development and approval of complex generics and biosimilars, making it an attractive market for manufacturers. The reimbursement systems in North America, particularly in the United States, are structured to accommodate generic and specialty generic drugs. This encourages the adoption of cost-effective alternatives, including biosimilars and complex generics.

Key Market Players

Teva Pharmaceuticals Industries Ltd

Viartis Inc.

Novartis AG

Hikma Pharmaceuticals PLC

Bausch Health Companies Inc.

Dr. Reddy's Laboratories Ltd.

Endo Pharmaceuticals Inc.

Apotex Corp.

Sun Pharmaceutical Industries Ltd

STADA Arzneimittel AG

Report Scope:

In this report, the Global Specialty Generics Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:

Specialty Generics Market, By Route of Administration:

Injectable

Oral

Others

Specialty Generics Market, By Indication:

Oncology

Autoimmune Diseases

Infectious Diseases

Others

Specialty Generics Market, By Distribution channel:

Retail Pharmacies

Specialty Pharmacies

Hospital Pharmacies

Global Specialty Generics Market, By region:

North America

United States

Canada

Mexico

Asia-Pacific

China

India

South Korea

Australia

Japan

Europe

Germany

France

United Kingdom

Spain

Italy

South America

Brazil

Argentina

Colombia

Middle East & Africa

South Africa

Saudi Arabia

UAE

Competitive Landscape

Company Profiles: Detailed analysis of the major companies present in the Global Specialty Generics Market.

Available Customizations:

Global Specialty Generics Market report with the given market data, Tech Sci Research offers customizations according to a company's specific needs. The following customization options are available for the report:

Company Information

Detailed analysis and profiling of additional market players (up to five).

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