

Specialty Generics Market Report by Route of Administration (Injectables, Oral, and Others), Indication (Oncology, Autoimmune Diseases, Infectious Diseases, and Others), Distribution channel (Retail Pharmacies, Specialty Pharmacies, Hospital Pharmacies), and Region 2024-2032

Market Report | 2024-04-08 | 134 pages | IMARC Group

AVAILABLE LICENSES:

- Electronic (PDF) Single User \$3899.00
- Five User Licence \$4899.00
- Enterprisewide License \$5899.00

Report description:

The global specialty generics market size reached US\$ 74.7 Billion in 2023. Looking forward, IMARC Group expects the market to reach US\$ 172.5 Billion by 2032, exhibiting a growth rate (CAGR) of 9.4% during 2024-2032. The rising number of strategic collaborations aiming to leverage the capabilities, resources, and market presence, the evolution of online pharmacies and telemedicine platforms and increasing government initiatives are some of the major factors propelling the market.

Specialty generics refer to generic versions of high-cost, brand-name specialty drugs. These medications are used to treat complex, chronic conditions such as cancer, rheumatoid arthritis, multiple sclerosis, and HIV. They differ from traditional generics in that they are typically biologic-based, require special handling and administration often injectables, and are often distributed through limited networks. The development of specialty generics presents unique challenges due to the intricate nature of the molecules involved and the complex processes used in their manufacturing. As a result, regulatory pathways for their approval can be more stringent compared to conventional generic drugs. In addition, specialty generics hold immense potential in healthcare. They offer patients access to vital treatments at a reduced cost, while also alleviating the financial burden on healthcare systems.

The evolution of advanced distribution channels, such as online pharmacies and telemedicine platforms, has also propelled the growth of the specialty generics market. These channels facilitate easy access to medications, ensuring patients in even remote locations can obtain the drugs they need. Along with this, government healthcare programs and private payers are continuously seeking strategies to contain escalating healthcare costs. Emphasizing the use of generic drugs, especially specialty generics, is a

Scotts International. EU Vat number: PL 6772247784

tel. 0048 603 394 346 e-mail: support@scotts-international.com

www.scotts-international.com

primary strategy. Therefore, several governments and insurance companies now incentivize or mandate the prescription of generics where available, thereby driving demand. In addition, specialty generics, being more affordably priced, have become the preferred choice for many in regions, ensuring essential treatments are within reach of larger segments of the population. Thus, this is significantly supporting the market. Apart from this, the production of generics for more niche, and specialized conditions is contributing to the market. Moreover, strategic collaborations aiming to leverage the capabilities, resources, and market presence of partnering entities are creating a positive market outlook.

Specialty Generics Market Trends/Drivers:

Increasing Demand for Affordable Healthcare Solutions

As the global population continues to rise and the burden of non-communicable diseases (NCDs) expands, there's a significant push to provide affordable healthcare solutions. The specialty generics industry is uniquely poised to address this demand. Specialty generics, which are bioequivalent versions of brand-name drugs, offer patients and healthcare systems the therapeutic efficacy of innovative medicines but at a reduced cost. Additionally, aging populations in various developed countries, such as Japan, the United States, and numerous European nations, are leading to an increased incidence of chronic diseases. These conditions often require prolonged and complex treatment regimens, which can be financially taxing for both individuals and national healthcare systems. Furthermore, in developing nations, the expansion of middle-class populations and their demand for advanced healthcare solutions is putting a strain on existing infrastructures.

Patent Expirations of Branded Drugs

One of the most significant drivers of the specialty generics industry is the expiration of patents for branded drugs. When patents expire, it opens the door for other manufacturers to produce and market generic versions of those medications. Given that research and development (R&D) costs for generics are typically lower than for novel drugs, these medications can be priced more affordably while maintaining therapeutic efficacy. Each year, drugs with billions of dollars in annual sales lose patent protection. This presents a golden opportunity for specialty generic manufacturers to tap into established markets with a ready consumer base. Thus, the accessibility of these medications then benefits the wider population, especially those in low-to-middle-income households, positively influencing the market.

Technological Advancements in Drug Development

The specialty generics industry is evolving with the broader pharmaceutical sector. Along with this, recent technological advancements in drug development and manufacturing are enabling the production of more complex generics, such as biosimilars, which were previously challenging to produce. In addition, tools, such as artificial intelligence and advanced analytical methodologies have streamlined the research and development (R&D) process for these drugs. This means that specialty generic manufacturers now address a broader range of diseases and conditions than ever before. Furthermore, innovations in manufacturing processes are ensuring that these drugs are produced with consistent quality, meeting the rigorous standards set by global regulatory bodies. As a result, it is also contributing to the market.

Specialty Generics Industry Segmentation:

IMARC Group provides an analysis of the key trends in each segment of the global specialty generics market report, along with forecasts at the global, regional and country levels from 2024-2032. Our report has categorized the market based on route of administration, indication and distribution channel.

Breakup by Route of Administration:

Injectables

Scotts International. EU Vat number: PL 6772247784

tel. 0048 603 394 346 e-mail: support@scotts-international.com

www.scotts-international.com

Oral
Others

Injectable dominates the market

The report has provided a detailed breakup and analysis of the market based on the route of administration. This includes injectables, oral, and others. According to the report, injectable represented the largest segment.

The injectables route of administration has emerged as a significant market driver within the specialty generics industry. This growth can be attributed to the increasing prevalence of chronic diseases and complex medical conditions. Injectables offer advantages, including precise dosing and rapid onset of action, making them suitable for managing critical health conditions. In addition, the expiration of patents for certain branded biologics and specialty drugs has opened doors for generic manufacturers to enter the market with cost-effective alternatives. Moreover, the rising focus on research and development in the pharmaceutical sector has led to innovative injectable products with improved therapeutic outcomes. These market drivers collectively contribute to the growth and prominence of the injectables route of administration in the specialty generics industry.

On the contrary, the oral route of administration plays a pivotal role as a market driver within the specialty generics industry, due to the changing consumer preferences. Numerous patients prefer oral formulations due to ease of administration, eliminating the need for injections and reducing potential discomfort. Along with this, the vast array of chronic diseases and conditions requiring long-term treatment has contributed to the popularity of oral drugs.

Breakup by Indication:

Oncology
Autoimmune Diseases
Infectious Diseases
Others

Oncology dominates the market

A detailed breakup and analysis of the market based on the indication have also been provided in the report. This includes oncology, autoimmune diseases, infectious diseases, and others. According to the report, oncology represented the largest segment.

The rising prevalence of cancer continues to rise globally, necessitating a constant demand for effective and affordable oncology treatments. With an increasing number of patients requiring long-term therapies, the accessibility and cost-effectiveness of specialty generics become essential in improving cancer care. In addition, the expiration of patents for several branded oncology drugs has opened opportunities for generic manufacturers to enter the market, offering more affordable alternatives without compromising on quality. Apart from this, advancements in research and technology have led to the development of innovative formulations and drug delivery systems, enhancing the efficacy and patient compliance of oncology generics. Moreover, government initiatives and policies aimed at reducing the burden of cancer by promoting generic drug usage have further propelled market growth.

On the other hand, the infectious diseases route of administration has emerged as a crucial market driver within the specialty generics industry, influenced by the ongoing global burden of infectious diseases, including outbreaks and pandemics, has underscored the urgent need for effective and accessible treatment options.

Breakup by Distribution channel:

Scotts International. EU Vat number: PL 6772247784

tel. 0048 603 394 346 e-mail: support@scotts-international.com

www.scotts-international.com

Retail Pharmacies
Specialty Pharmacies
Hospital Pharmacies

Retail pharmacies dominates the market

The report has provided a detailed breakup and analysis of the market based on the distribution channel. This includes retail pharmacies, specialty pharmacies, and hospital pharmacies. According to the report, retail pharmacies represented the largest segment.

The retail pharmacies distribution channel plays a pivotal role as a market driver within the specialty generics industry, primarily influenced by the widespread presence of retail pharmacies ensuring convenient and accessible distribution of specialty generic medications to a broader patient base. As these pharmacies are typically located in various communities and neighborhoods, patients can easily access their prescribed medications without the need for specialized healthcare facilities. In addition, the rising prevalence of chronic diseases and the growing demand for long-term treatment options have amplified the significance of retail pharmacies in delivering specialty generics. Furthermore, the retail pharmacies' established relationships with healthcare providers allow for streamlined communication and collaboration, facilitating efficient prescription processing and patient care. As the demand for specialty generics continues to grow, retail pharmacies' essential role in distribution and patient support is set to reinforce the industry's expansion and accessibility to critical medications.

Breakup by Region:

North America
United States
Canada
Europe
Italy
Germany
Spain
United Kingdom
France
Asia-Pacific
China
India
Japan
South Korea
Latin America
Brazil
Mexico
Middle East and Africa

North America exhibits a clear dominance, accounting for the largest specialty generics market share

The report has also provided a comprehensive analysis of all the major regional markets, which includes North America (the United States and Canada); Europe (Italy, Germany, France, United Kingdom, and Spain); Asia Pacific (Japan, China, India, and South Korea); Latin America (Brazil, Mexico); and the Middle East and Africa. According to the report, North America accounted for the largest market share.

Scotts International. EU Vat number: PL 6772247784

tel. 0048 603 394 346 e-mail: support@scotts-international.com

www.scotts-international.com

The North America region is driven by the increasing prevalence of chronic diseases and complex medical conditions. It is leading to a growing demand for specialized treatment options. Specialty generics, with their cost-effective alternatives to branded specialty drugs, have gained traction in managing these conditions effectively. Additionally, the expiration of patents for certain branded specialty medications has created opportunities for generic manufacturers to enter the market, providing patients with more affordable treatment options. In addition, favorable government policies and initiatives aimed at promoting the use of generic medications have supported the expansion of the specialty generics industry in North America. These policies encourage generic drug usage, leading to enhanced patient access and overall cost savings in the healthcare system. Moreover, advancements in research and development leading to the introduction of innovative specialty generics with improved therapeutic outcomes are positively influencing the market.

Competitive Landscape:

The global specialty generics market is experiencing significant growth due to the escalating investments in research and development to develop innovative formulations, drug delivery systems, and combination therapies to improve the efficacy and patient compliance of their products. Ensuring compliance with regulatory standards and obtaining necessary approvals from health authorities in various countries is a critical aspect for specialty generic companies to launch and market their products. Along with this, the expansion of product portfolios to cover a wider range of therapeutic areas, such as oncology, immunology, and rare diseases, to cater to diverse patient needs is positively influencing the market. Apart from this, companies are offering patient support programs that provide counseling, adherence assistance, and financial aid to patients, thereby improving patient outcomes and medication adherence. Furthermore, collaborating with pharmaceutical companies, research institutions, and healthcare organizations allows specialty generics companies to access new technologies is contributing to the market.

The report has provided a comprehensive analysis of the competitive landscape in the market. Detailed profiles of all major companies have also been provided. Some of the key players in the market include:

Teva Pharmaceuticals Industries

Akorn, Inc.

Mylan N.V.

Mallinckrodt

Sandoz International GmbH

Pfizer, Inc.

Sun Pharmaceutical Industries Ltd.

Valeant Pharmaceuticals

Apotex Corp.

Endo International plc

Recent Developments:

In July 2023, Sandoz International GmbH declared intentions to establish a new technical development facility in Slovenia. Sandoz's Biopharma Technical Development skills will be significantly enhanced by the opening of a new end-to-end drug substance and drug product development centre.

In August 2022, Akorn, Inc. declared that a generic version of Cetrorelix Acetate for Injection, 0.25 mg (Cetrorelix) has been given FDA clearance. This is the first AP-Rated bioequivalent formulation of Cetrorelix that has been authorized by Merck Serono.

In February 2022, Mallinckrodt issued a Complete Response Letter (CRL) in relation to the Company's New Drug Application (NDA) asking for approval of the investigational drug terlipressin to treat adults with hepatorenal syndrome (HRS), a severe and potentially fatal condition marked by a rapid decline in kidney function for which there is not yet an FDA-approved cure.

Key Questions Answered in This Report

Scotts International. EU Vat number: PL 6772247784

tel. 0048 603 394 346 e-mail: support@scotts-international.com

www.scotts-international.com

1. What is the size of the global specialty generics market?
2. What are the key factors driving the global specialty generics market?
3. What has been the impact of COVID-19 on the global specialty generics market?
4. What is the breakup of the global specialty generics market based on the route of administration?
5. What is the breakup of the global specialty generics market based on the indication?
6. What is the breakup of the global specialty generics market based on the distribution channel?
7. What are the key regions in the global specialty generics market?
8. Who are the key players/companies in the global specialty generics market?

Table of Contents:

1	Preface
2	Scope and Methodology
2.1	Objectives of the Study
2.2	Stakeholders
2.3	Data Sources
2.3.1	Primary Sources
2.3.2	Secondary Sources
2.4	Market Estimation
2.4.1	Bottom-Up Approach
2.4.2	Top-Down Approach
2.5	Forecasting Methodology
3	Executive Summary
4	Global Specialty Generics Market: Introduction
5	Why are Specialty Generics So Lucrative?
6	Global Specialty Generics Market
6.1	Market Overview
6.2	Market Performance
6.3	Impact of COVID-19
6.4	Market Breakup by Route of Administration
6.5	Market Breakup by Indication
6.6	Market Breakup by Distribution Channel
6.7	Market Breakup by Region
6.8	Market Forecast
6.9	SWOT Analysis
6.9.1	Overview
6.9.2	Strengths
6.9.3	Weaknesses
6.9.4	Opportunities
6.9.5	Threats
6.10	Value Chain Analysis
6.11	Porters Five Forces Analysis
6.11.1	Overview
6.11.2	Bargaining Power of Buyers
6.11.3	Bargaining Power of Suppliers
6.11.4	Degree of Competition
6.11.5	Threat of New Entrants

Scotts International. EU Vat number: PL 6772247784

tel. 0048 603 394 346 e-mail: support@scotts-international.com

www.scotts-international.com

- 6.11.6 Threat of Substitutes
- 6.12 Key Market Drivers and Success Factors
- 7 Market Breakup by Route of Administration
 - 7.1 Injectable
 - 7.1.1 Market Trends
 - 7.1.2 Market Forecast
 - 7.2 Oral
 - 7.2.1 Market Trends
 - 7.2.2 Market Forecast
 - 7.3 Others
 - 7.3.1 Market Trends
 - 7.3.2 Market Forecast
- 8 Market Breakup by Indication
 - 8.1 Oncology
 - 8.1.1 Market Trends
 - 8.1.2 Market Forecast
 - 8.2 Autoimmune Diseases
 - 8.2.1 Market Trends
 - 8.2.2 Market Forecast
 - 8.3 Infectious Diseases
 - 8.3.1 Market Trends
 - 8.3.2 Market Forecast
 - 8.4 Others
 - 8.4.1 Market Trends
 - 8.4.2 Market Forecast
- 9 Market Breakup by Distribution Channel
 - 9.1 Retail Pharmacies
 - 9.1.1 Market Trends
 - 9.1.2 Market Forecast
 - 9.2 Specialty Pharmacies
 - 9.2.1 Market Trends
 - 9.2.2 Market Forecast
 - 9.3 Hospital Pharmacies
 - 9.3.1 Market Trends
 - 9.3.2 Market Forecast
- 10 Market Breakup by Region
 - 10.1 North America
 - 10.1.1 Market Overview
 - 10.1.2 Market Performance
 - 10.1.3 Market Breakup by Country
 - 10.1.3.1 United States
 - 10.1.3.1.1 Market Trends
 - 10.1.3.1.2 Market Forecast
 - 10.1.3.2 Canada
 - 10.1.3.2.1 Market Trends
 - 10.1.3.2.2 Market Forecast
 - 10.1.4 Market Forecast

Scotts International. EU Vat number: PL 6772247784

tel. 0048 603 394 346 e-mail: support@scotts-international.com

www.scotts-international.com

- 10.2 Europe
 - 10.2.1 Market Overview
 - 10.2.2 Market Performance
 - 10.2.3 Market Breakup by Country
 - 10.2.3.1 Italy
 - 10.2.3.1.1 Market Trends
 - 10.2.3.1.2 Market Forecast
 - 10.2.3.2 Germany
 - 10.2.3.2.1 Market Trends
 - 10.2.3.2.2 Market Forecast
 - 10.2.3.3 France
 - 10.2.3.3.1 Market Trends
 - 10.2.3.3.2 Market Forecast
 - 10.2.3.4 United Kingdom
 - 10.2.3.4.1 Market Trends
 - 10.2.3.4.2 Market Forecast
 - 10.2.3.5 Spain
 - 10.2.3.5.1 Market Trends
 - 10.2.3.5.2 Market Forecast
 - 10.2.4 Market Forecast
- 10.3 Asia Pacific
 - 10.3.1 Market Overview
 - 10.3.2 Market Performance
 - 10.3.3 Market Breakup by Country
 - 10.3.3.1 Japan
 - 10.3.3.1.1 Market Trends
 - 10.3.3.1.2 Market Forecast
 - 10.3.3.2 China
 - 10.3.3.2.1 Market Trends
 - 10.3.3.2.2 Market Forecast
 - 10.3.3.3 India
 - 10.3.3.3.1 Market Trends
 - 10.3.3.3.2 Market Forecast
 - 10.3.3.4 South Korea
 - 10.3.3.4.1 Market Trends
 - 10.3.3.4.2 Market Forecast
 - 10.3.4 Market Forecast
- 10.4 Latin America
 - 10.4.1 Market Overview
 - 10.4.2 Market Performance
 - 10.4.3 Market Breakup by Country
 - 10.4.3.1 Brazil
 - 10.4.3.1.1 Market Trends
 - 10.4.3.1.2 Market Forecast
 - 10.4.3.2 Mexico
 - 10.4.3.2.1 Market Trends
 - 10.4.3.2.2 Market Forecast

Scotts International. EU Vat number: PL 6772247784

tel. 0048 603 394 346 e-mail: support@scotts-international.com

www.scotts-international.com

- 10.4.4 Market Forecast
- 10.5 Middle East and Africa
 - 10.5.1 Market Overview
 - 10.5.2 Market Performance
 - 10.5.3 Market Forecast
- 11 Competitive Landscape
 - 11.1 Market Structure
 - 11.2 Key Players
 - 11.3 Profiles of Key Players
 - 11.3.1 Teva Pharmaceuticals Industries
 - 11.3.2 Akorn, Inc.
 - 11.3.3 Mylan N.V.
 - 11.3.4 Mallinckrodt
 - 11.3.5 Sandoz International GmbH
 - 11.3.6 Pfizer, Inc.
 - 11.3.7 Sun Pharmaceutical Industries Ltd.
 - 11.3.8 Valeant Pharmaceuticals
 - 11.3.9 Apotex Corp.
 - 11.3.10 Endo International plc.

Scotts International. EU Vat number: PL 6772247784

tel. 0048 603 394 346 e-mail: support@scotts-international.com

www.scotts-international.com

Specialty Generics Market Report by Route of Administration (Injectables, Oral, and Others), Indication (Oncology, Autoimmune Diseases, Infectious Diseases, and Others), Distribution channel (Retail Pharmacies, Specialty Pharmacies, Hospital Pharmacies), and Region 2024-2032

Market Report | 2024-04-08 | 134 pages | IMARC Group

To place an Order with Scotts International:

- ☐ - Print this form
- ☐ - Complete the relevant blank fields and sign
- ☐ - Send as a scanned email to support@scotts-international.com

ORDER FORM:

Select license	License	Price
	Electronic (PDF) Single User	\$3899.00
	Five User Licence	\$4899.00
	Enterprisewide License	\$5899.00
		VAT
		Total

*Please circle the relevant license option. For any questions please contact support@scotts-international.com or 0048 603 394 346.

☐** VAT will be added at 23% for Polish based companies, individuals and EU based companies who are unable to provide a valid EU Vat Numbers.

Email*	<input type="text"/>	Phone*	<input type="text"/>
First Name*	<input type="text"/>	Last Name*	<input type="text"/>
Job title*	<input type="text"/>		
Company Name*	<input type="text"/>	EU Vat / Tax ID / NIP number*	<input type="text"/>
Address*	<input type="text"/>	City*	<input type="text"/>
Zip Code*	<input type="text"/>	Country*	<input type="text"/>

Scotts International. EU Vat number: PL 6772247784

tel. 0048 603 394 346 e-mail: support@scotts-international.com

www.scotts-international.com

Date

2025-06-06

Signature



Scotts International. EU Vat number: PL 6772247784

tel. 0048 603 394 346 e-mail: support@scotts-international.com

www.scotts-international.com