2024

# OVERVIEW OF THE GLOBAL PHARMA MARKET

INDEPENDENT MARKET RESEARCH CONDUCTED FOR SENORES PHARMA

FROST & SULLIVAN
24/07/2024

## DISCLAIMER



The market research process for this study has been undertaken through secondary/desktop research and primary research, which involves discussing the market status with leading participants and experts.

The research methodology used is the Expert Opinion Method. Quantitative market information was sourced from interviews, primary research, and trusted portals. Therefore, the information is subject to fluctuations due to possible business and market climate changes. Frost & Sullivan's estimates and assumptions are based on varying levels of quantitative and qualitative analyses, including industry journals, company reports, and information in the public domain.

The data has been collated from publicly available sources such as the Ministry of Corporate Affairs (MCA) database.

Forecasts, estimates, predictions, and other forward-looking statements contained in this report are inherently uncertain because of changes in factors underlying their assumptions, events, or combinations of circumstances that cannot be reasonably foreseen. Actual results and future events could differ materially from forecasts, estimates, predictions, or such statements. All financial and operational details for Senores Pharmaceuticals Ltd. are for continuing operations and are provided by the company.

Frost & Sullivan has prepared this study independently and objectively and has taken adequate care to ensure its accuracy and completeness. We believe that this study presents an accurate and fair view of the Pharmaceutical Market in selected geographies within the limitations of, among others, secondary statistics and primary research, varying scenarios created due to the COVID-19 pandemic, and it does not purport to be exhaustive. Our research has been conducted with an "overall industry" perspective, and it may not necessarily reflect the performance of individual companies in the industry. Frost & Sullivan shall not be liable for any loss suffered because of reliance on the information contained in this study. This study should also not be considered a recommendation to buy or not to buy the shares of any company or companies as mentioned in it or otherwise.

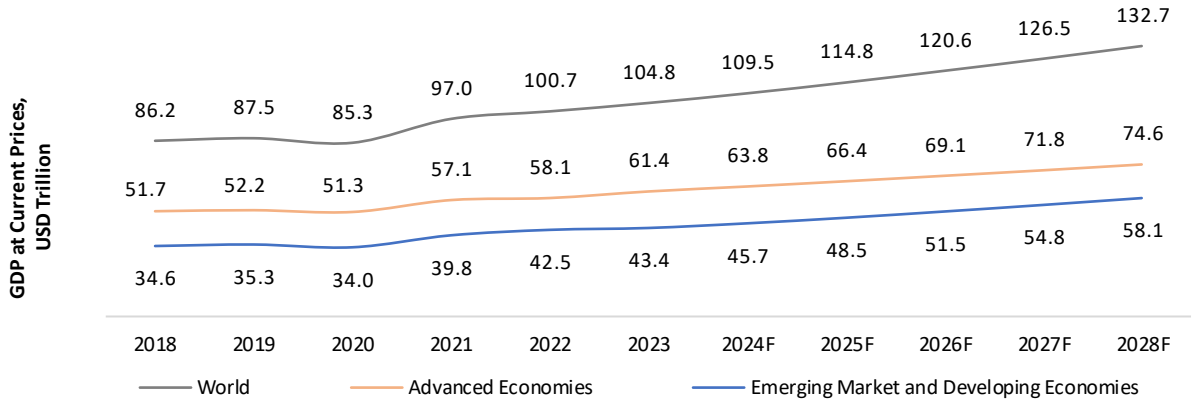
## CONTENTS

# 1 MACROECONOMIC OVERVIEW[1]

## 1.1 GLOBAL AND REGIONAL GDP OUTLOOK

**Strong evidence of resilient economic growth despite short-term aberrations from geopolitical and financial issues**

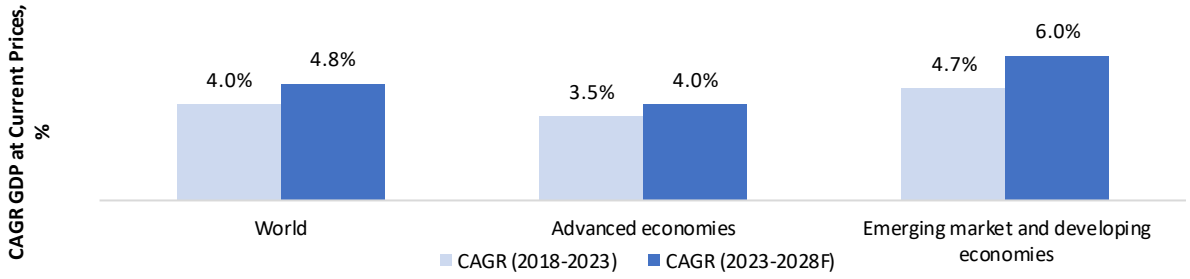
**Exhibit 1.1: GDP at Current Prices, Global, 2018-2028F**




*Source: World Economic Outlook-April 2024, Frost & Sullivan*

*Note: The above GDP values at current prices are the country's GDP based on the same period during the year as their fiscal data. For countries whose fiscal data are based on a fiscal calendar (e.g., July to June), this series would be the country's GDP over that same period. For countries whose fiscal data are based on a calendar year (i.e., January to December), this series will be the same as "Gross domestic product, current prices."*

**Exhibit 1.2: GDP CAGR at Current Prices, Global, 2018-2028F**



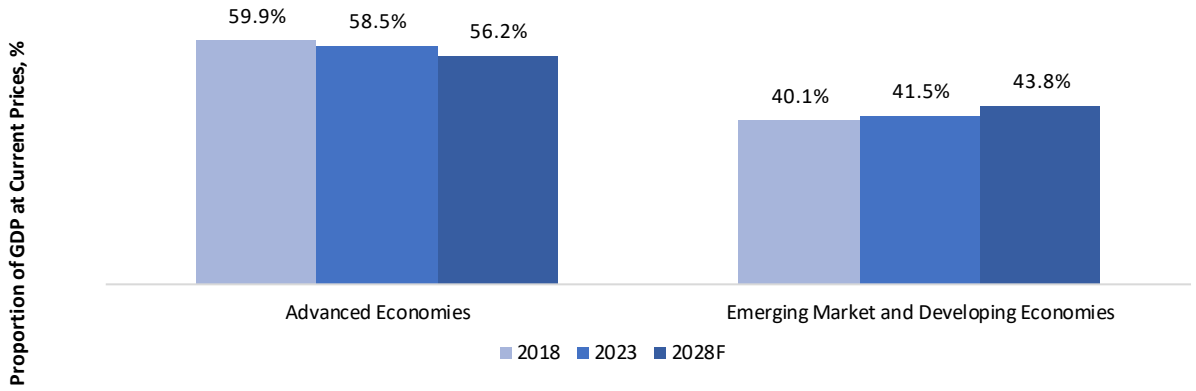

*Source: World Economic Outlook-April 2024, Frost & Sullivan*

The global Gross Domestic Product (GDP) is forecasted to grow by 4.8% from 2023 to 2028, exceeding the five-year average growth rate of 4.0% observed between 2018 and 2023. Despite facing challenges in energy and food markets due to geopolitical conflicts and notable monetary tightening aimed at addressing high inflation, economic activity has experienced deceleration but not stagnation. This trend is notable across both advanced and emerging economies. Advanced economies are anticipated to witness a growth rate nearly 50 basis points higher than their historical average, while emerging

[1] Unless otherwise mentioned, all the years are calendar years

economies are expected to outpace global growth, witnessing an increment of 130 basis points in their growth rate.

**Exhibit 1.3: GDP Contribution at Current Prices, Global, 2018-2028F**




*Source: World Economic Outlook-April 2024, Frost & Sullivan*

By 2023, advanced economies constituted nearly 58.5% of the global economy, a share projected to persist above 55% until 2028. Advanced economies remain pivotal in propelling global economic expansion, benefiting from robust infrastructures, advanced technologies, and substantial spending power, collectively fostering innovation and driving demand across various sectors. This innovation and sustained demand contribute to the creation of high-value goods and services, bolstering competitiveness and facilitating growth in both domestic and international markets. Furthermore, these economies wield significant influence in shaping global trade dynamics and investment patterns, attracting substantial foreign investment, facilitating technology transfers, and stimulating international trade flows.

Several advanced economies, notably the United States, have surpassed growth expectations owing to resilient consumption and investment. Fueled by low unemployment rates, wage growth, and consumer confidence, consumer spending has remained robust. Additionally, businesses have been investing across various sectors, driven by factors such as low interest rates, technological advancements, and favorable economic conditions, resulting in the US economy outperforming growth expectations.

Nonetheless, the rising importance of emerging markets and developing economies cannot be overlooked. Marked by rapid industrialization, urbanization, and demographic shifts, these regions are emerging as substantial contributors to global GDP growth, consumption patterns, and investment inflows. Forecasts indicate a compound annual growth rate (CAGR) of 6.0% between 2023 and 2028, with notable prominence in emerging economies across Asia, particularly India, the Philippines, and Vietnam. Alongside Sub-Saharan Africa and the ASEAN 5 (Indonesia, Malaysia, the Philippines, Singapore, and Thailand), India and China stand out as some of the largest and fastest-growing economies.

While China and India historically boasted growth rates of around 5.5% between 2018 and 2023, India's projected GDP growth is anticipated to surpass China's by nearly 1.7 times. India's economic resilience amidst the pandemic, notably in the pharmaceutical sector, combined with emerging geopolitical dynamics such as the "China plus one" strategy, have propelled India into the global spotlight. Conversely, China faces challenges stemming from a weakening property sector, geopolitical uncertainties, unfavorable policies like the Biosecurity Act, and declining export momentum. Consequently, India is

projected to ascend as the world's third-largest economy by 2027, surpassing Japan and Germany, with a GDP exceeding USD 5.0 trillion. India aims to achieve developed economy status by 2047[2], driven by robust growth projections of 10.3% between 2023 and 2028. This surge in growth is underpinned by escalating domestic consumer demand across sectors, substantial government and private global investments, bolstered global partnerships, reforms centered on the Atmanirbhar Bharat initiative, and a flourishing micro, small, and medium-sized enterprise (MSME) sector.

Some additional GDP growth drivers for India include:

- **Demographic dividend:** India stands out not only as the world's most populous nation but also as a distinctive example of expanding working-age demographics, a feature in stark contrast to many regions grappling with aging and diminishing working populations. As of 2023, a significant portion, accounting for 50.2% of India's population, fell within the working age bracket of 25 to 64 years. This marked an increase from 47.8% in 2017, with projections indicating a further rise to 51.7% by 2027[3]. India's youthful population presents a substantial competitive advantage in terms of labor force availability. Moreover, the nation benefits from a sizable pool of graduates, particularly in Science, Technology, Engineering, and Mathematics (STEM), who possess proficiency in English, setting India apart on the global stage. This advantage proves particularly advantageous in skill-intensive industries, such as pharmaceutical research and development (R&D) and manufacturing. Additionally, India's rapid urbanization and burgeoning working population, coupled with increasing incomes, are poised to stimulate demand for goods and services, thereby driving further economic growth.
- **Commendatory government reforms for the manufacturing sector:** Manufacturing has historically contributed 16-17% of the country's GDP[4]. With prioritization of manufacturing across sectors including automotive, engineering, chemicals, pharmaceuticals, and consumer durables through the implementation of policies like Production-Linked Incentive (PLI) scheme, PM Gati Shakti- National Master Plan (NMP), Industrial development schemes in states with industrial backwardness, the manufacturing sector is expected to account for 25% of GDP by 2025[5]. These reforms will simultaneously help improve India's Business Environment Rankings (BER) for infrastructure improvement from the 14th position in the 2018-2022 period to the 10th position in the 2023-2027 period, taking India ahead of the Philippines, Indonesia, and Vietnam[6]. As India solidifies its position in the global manufacturing landscape, the pharmaceutical industry holds particular promise. By servicing both domestic and export markets, pharmaceutical companies can harness the momentum of India's ascendance as a prominent manufacturing destination.

**Exhibit 1.4: CAGR GDP at Current Prices, Select Countries, 2018-2028F**

| Country | CAGR (2018-2023) | CAGR (2023-2028F) |
|---|---|---|
| World | *4.0%* | *4.8%* |
| Australia | *4.2%* | *3.9%* |
| Azerbaijan | *10.2%* | *3.8%* |
| Canada | *4.4%* | *4.7%* |
| Ecuador | *2.3%* | *2.9%* |
| France | *1.7%* | *3.2%* |

[2] IBEF Report on Government's Ambition
[3] Population Estimates and Projections: World Bank
[4] IBEF; Confederation of Indian Industries
[5] FDI in Make in India: Transforming the Manufacturing Landscape
[6] Economist Intelligence Unit: India's Manufacturing Moment

| | | |
|---|---|---|
| Germany | 2.3% | 3.2% |
| Ghana | 2.5% | 3.9% |
| India | 5.7% | 10.3% |
| Iraq | 2.3% | 5.0% |
| Italy | 1.5% | 2.6% |
| Philippines | 4.7% | 8.3% |
| Saudi Arabia | 4.7% | 4.8% |
| South Africa | -1.4% | 2.5% |
| United Kingdom | 3.1% | 5.6% |
| United States | 5.8% | 4.2% |
| Vietnam | 7.3% | 7.9% |

*Source: World Economic Outlook-April 2024, Frost & Sullivan*

The anticipated growth in emerging markets and developing economies, combined with steady expansion in advanced economies, is anticipated to spur demand across critical sectors, such as healthcare, and drive global investment. This convergence of favorable economic conditions across advanced and emerging economies is poised to fuel sustained global economic growth, leveraging the complementary strengths of each market and fostering a resilient and prosperous global economic landscape.

**Economic growth is also evident in the rising GDP per capita, an indirect indicator of improved affordability**

| Exhibit 1.5: CAGR GDP per Capita at Current Prices, Select Countries, 2018-2028F | | |
|---|---|---|
| Country | CAGR (2018-2023) | CAGR (2023-2028F) |
| Australia | 3.0% | 2.9% |
| Azerbaijan | 9.6% | 2.6% |
| Canada | 2.8% | 3.2% |
| Ecuador | 0.8% | 1.5% |
| France | 1.3% | 2.9% |
| Germany | 1.9% | 3.3% |
| Ghana | 0.4% | 1.3% |
| India | 4.8% | 9.4% |
| Iraq | -0.3% | 2.4% |
| Italy | 1.9% | 2.7% |
| Philippines | 3.4% | 7.2% |
| Saudi Arabia | 3.0% | 2.7% |
| South Africa | -2.6% | 1.0% |
| United Kingdom | 2.6% | 5.2% |
| United States | 5.3% | 3.6% |
| Vietnam | 6.1% | 7.2% |

*Source: World Economic Outlook-April 2024, Frost & Sullivan*

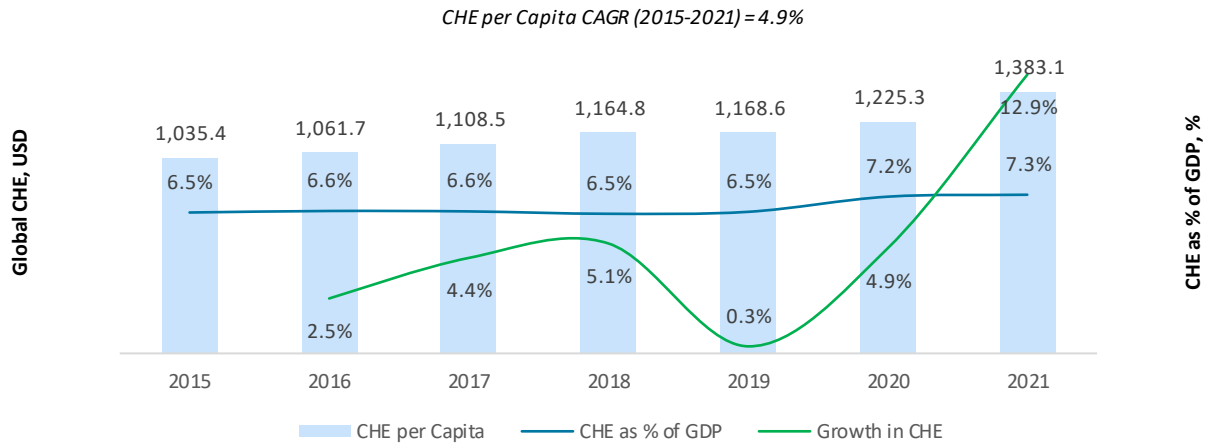
This growth is also evident in the growing GDP per capita, a crucial measure of economic prosperity, offering insights into the average income and subsequent spending capacity per individual. According to IMF data, global GDP per capita has significantly expanded, climbing from USD 11,500 in 2018 to USD 13,400 in 2023, indicating a CAGR of 3.1%. In 2023, within the G7 nations (Canada, France, Germany, Italy, Japan, the United Kingdom, and the United States; additionally, the European Union as a non-enumerated member), the United States led with the highest GDP per capita at current prices, reaching USD 81,632, closely trailed by Canada, Germany, and the United Kingdom. While advanced economies anticipate GDP

per capita growth rates ranging between 3-6% from 2023 to 2028, emerging economies are poised to experience nearly double that growth rate.

## 1.2 GLOBAL AND REGIONAL HEALTHCARE EXPENDITURE

**As disposable income levels rise and health and wellness awareness increase in the aftermath of the pandemic, the spotlight on healthcare has intensified, leading to a notable surge in discretionary spending within this sector.**

**Exhibit 1.6: Current Healthcare Expenditure (CHE), Global, 2015 - 2021**




*Source: WHO, Frost & Sullivan*

*Note: CHE data is based on the same period during the year as a country's fiscal data. In the case of countries whose fiscal data are based on a fiscal calendar (e.g., July to June), this series would be the country's CHE over that same period.*

Current healthcare expenditures (CHE) as a percentage of GDP are on an upward trajectory driven by various intersecting factors. Increased spending power, fueled by economic growth, allows for greater investment in healthcare, aiming to improve accessibility and quality. Efforts to enhance affordability further boost healthcare utilization. Meanwhile, advancements in medical technology, though beneficial, often come with increased costs. The prevalence of chronic diseases and aging populations also contribute to rising healthcare spending. Post-pandemic behavioral changes and a growing focus on wellness add to this trend. Both voluntary and government expenditures have surged since the pandemic, leading to a significant increase in global healthcare spending, from 6.5% of GDP in 2015 to 7.3% in 2021, representing a CAGR of 4.9% over the period. While global healthcare spending is on the rise, there are notable regional variations that underscore the diverse healthcare landscapes across different parts of the world, which are also influenced by a complex interplay of economic, demographic, and societal factors.

### 1.2.1 REGIONAL HEALTHCARE EXPENDITURE

**Current health expenditure varies significantly across countries, with the US leading the charts among key economies.**

While high-income countries like the UK, France, Germany, Canada, Sweden, Switzerland, and the US allocate higher healthcare expenditures than the global average, spending in Asian countries (excluding

exceptions like Japan) is nearly half the global average. For example, in the US, healthcare expenditure as a percent of GDP stood at 17.4% in 2021, Germany at 12.9%, Canada at 12.3%, and Australia at 10.5%. In contrast, Vietnam and India were only 4.6% and 3.3%, respectively[7]. The large difference in spending arises from the maturity of healthcare delivery and reimbursement systems.

| Exhibit 1.7: Current Healthcare Expenditure as % GDP by Country, 2021 | | | | |
|---|---|---|---|---|
| **Country** | **CHE as % of GDP, 2015** | **CHE as % of GDP, 2021** | **Pharmaceutical and Other Durable Goods Spending as % of GDP** | **Pharmaceutical and Other Durable Goods Spending as % of CHE** |
| **Australia** | 10.1% | 10.5% | 1.3%* | 12.0%* |
| **Azerbaijan** | 4.3% | 4.7% | Not Available | Not Available |
| **Canada** | 10.7% | 12.3% | 1.7% | 13.8% |
| **Ecuador** | 7.6% | 8.3% | Not Available | Not Available |
| **France** | 11.4% | 12.3% | 1.5% | 12.5% |
| **Germany** | 11.2% | 12.9% | 1.8% | 13.9% |
| **Ghana** | 4.5% | 4.2% | 0.2%*** | 6.4%*** |
| **India** | 3.6% | 3.3% | 0.7%* | 21.0%* |
| **Iraq** | 3.2% | 5.2% | 1.2% | 22.7% |
| **Italy** | 8.9% | 9.4% | 1.6% | 17.1% |
| **Philippines** | 3.9% | 5.9% | Not Available | Not Available |
| **Saudi Arabia** | 5.9% | 6.0% | 0.8%*** | 14.2%*** |
| **South Africa** | 8.1% | 8.3% | 0.7%** | 8.9%** |
| **United Kingdom** | 9.8% | 12.4% | 1.2% | 9.5% |
| **United States (US)** | 16.5% | 17.4% | 2.0% | 11.7% |
| **Vietnam** | 4.7% | 4.6% | Not Available | Not Available |

*Source: World Bank, Frost & Sullivan*

*Note: * Represents 2020 data, ** represents 2019 data, *** represents 2018 data*

On a global scale, governmental involvement in Current Healthcare Expenditure (CHE) has demonstrated a steady increase, reflecting a broader adoption of policies geared towards achieving universal health coverage. Government schemes now contribute to over 60% of CHE, with a concurrent decline observed in Out-of-Pocket (OOP) spending, which has decreased to nearly 16% as of 2021. However, significant regional disparities persist, particularly evident in the government's share of CHE. Governmental contributions constitute approximately 55% of CHE in the US, whereas in France, Germany, and Canada, governmental involvement exceeds 70%. In contrast, governmental expenditures constitute only about 35% of CHE in India.

While the specific drivers and magnitudes may vary between regions, the overarching commitment to investing in healthcare is reflected in an increase in CHE as a percentage of GDP across both emerging and advanced economies.

**Pharmaceutical expenditures have risen alongside overall healthcare spending, predominantly fueled by an uptick in chronic disease cases, expansion of the elderly population base, patterns of self-medication, and the relative affordability of drugs compared to alternative options.**

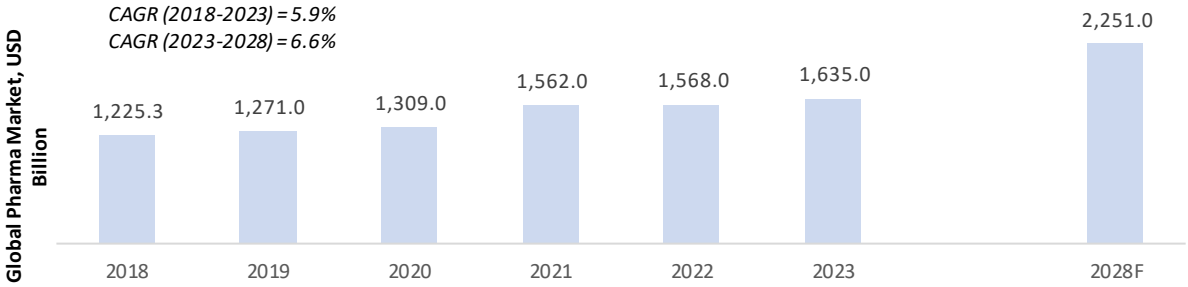
[7] World Bank- Global Health Expenditure Database

Global pharmaceutical spending has seen steady growth, propelled by various factors such as increasing healthcare needs, advancements in medical treatments, and expanding access to medications worldwide. With rising incidences of chronic diseases, the aging population, and a growing awareness of health issues, demand for pharmaceutical products continues to surge. Additionally, the launch of innovative drugs and therapies has further stimulated spending in the pharmaceutical sector. As countries strive to enhance healthcare infrastructure and ensure equitable access to medicines, pharmaceutical spending is anticipated to maintain its upward trajectory, shaping the future of healthcare spending on a global scale. Regionally, pharmaceutical expenditure mirrors similar trends as overall CHE, with high regional disparity. To illustrate, while the US spent nearly 11.7% of CHE on pharma in 2021, India spent 21.0% in 2020.

# 2 GLOBAL PHARMACEUTICAL MARKET OVERVIEW

**Pharmaceutical spending has grown in tandem with overall healthcare spending, particularly driven by an increase in chronic disease cases, the growth of the senior population, trends in self-medication, the availability of cost-effective generics, and the overall affordability of drugs compared to other available clinical alternatives.**

**Exhibit 2.1: Global Pharma Market, 2018 - 2028F**




*Source: IQVIA Global Use of Medicines- 2024, Evaluate Pharma, Frost & Sullivan*

The global pharmaceutical sector is undergoing a profound transformation across its entire value chain, driven by a strong emphasis on product innovation, healthcare equity (healthcare for all), operational efficiency, and enhanced engagement with healthcare providers and patients. Despite facing inherent challenges within this transformative landscape, the pharmaceutical industry has demonstrated remarkable agility and delivered groundbreaking innovations, particularly highlighted during the COVID-19 pandemic, enjoying resilient growth.

The global pharmaceutical market was valued at USD 1,635.0 billion in 2023 and is projected to reach USD 2,251.0 billion by 2028, growing at a CAGR of 6.6% from 2023 to 2028. This growth is primarily attributable to factors like:

- **Aging Population and Disease Burden**: The global demographic shift towards an aging population is a significant driver of pharmaceutical market growth. With the percentage of the global population over 60 years old expected to nearly double from 12% to 22% and reach ~2.1 billion by 2050[8] increase in the prevalence of chronic diseases and age-related conditions will drive demand for drugs targeting conditions like hypertension, diabetes, osteoporosis, and neurodegenerative disease, to name a few.

[8] World Health Organization

- **Increasing incidence of chronic diseases**: While the aging population is susceptible to chronic diseases, there is a growing incidence among the younger population as well, largely due to lifestyle changes. For instance, in a study done in the US in 2019, approximately one-half of young adults reported at least one chronic condition, with the most common being obesity (25.5%), depression (21.3%), and high blood pressure (10.7%)[9]. Globally, approximately one in three of all adults suffer from multiple chronic conditions (MCCs)[10]. The cost of chronic disease worldwide is estimated to reach USD 47 trillion by 2030[11]. Since the management of chronic diseases requires life-long use of pharmaceutical drugs, it is further driving the market growth.
- **Increasing demand from developing nations:** Developing nations face a dual demand for pharmaceutical drugs, driven by both the rising incidence of chronic conditions and the persistent burden of infectious diseases. For instance, India has earned the moniker of "diabetes capital of the world" with its 77 million diabetic and 25 million prediabetic population[12], reflecting a trend observed in many developing countries mirroring developed markets' demand for similar drugs. Simultaneously, the continued epidemic of tropical and infectious diseases, such as malaria and dengue, maintains a high demand for drugs combating these conditions. To quantify, there were an estimated 249 million cases of malaria worldwide in 2022, with the majority occurring in Africa (94%)[13]. Similarly, Tuberculosis (TB) also imposes a substantial burden, with approximately 10.6 million new cases globally in 2022, with 46 % occurring in the Southeast Asia Region and 23% in the African Region[14].
- **Consumer awareness and trends in self-medication:** The COVID-19 pandemic has had an immense impact on heightened consumer awareness of health, wellness, and preventive care, leading to massive growth in the over-the-counter (OTC) pharmaceutical market segment.
- **Growing Investments in R&D:** R&D investments contribute to the discovery of breakthrough treatments for prevalent and emerging diseases, driving market growth by expanding the range of therapeutic options available to patients. According to Evaluate Pharma, the global R&D expenditure on pharmaceuticals has increased from USD 184 billion in 2018 to USD 262 billion in 2023. This has resulted in the launch of several novel cell and gene therapies, monoclonal antibodies, and mRNA therapies, to name a few.

***Global Pharmaceutical Industry Characteristics***

**Operational model shifts in the pharmaceutical sector were necessitated by a combination of internal and external challenges that were exposed by the pandemic:**

In recent decades, the globalization of the pharmaceutical market has surged, with a growing reliance on key markets such as China. However, the COVID-19 pandemic has exposed numerous vulnerabilities within the supply chain, disrupting the reliable connection between production and distribution and leading to price fluctuations. Before the pandemic, China supplied nearly 40% of the world's Active Pharmaceutical Ingredients (APIs), according to estimates from The UK's Medicines and Healthcare Products Regulatory Agency.

[9] CDC: Morbidity and Mortality Weekly Report: Chronic Conditions Among Adults Aged 18–34 Years — United States, 2019

[10] NIH: The global burden of multiple chronic conditions

[11] Mayo Clinic: The Burden of Chronic Disease

[12] WHO: Diabetes in India

[13] Medicines for Malaria Venture

[14] WHO: Tuberculosis 2023

However, efforts to address pollution concerns led to the closure of several factories in China, exacerbating supply chain disruptions and causing shortages of APIs and intermediates. The uncertainty surrounding COVID-19 prompted anticipatory purchasing of medications globally, driving demand to unprecedented levels and high price volatility, and driving drug shortages. In the United States, annual medication shortages steadily rose from 5 in 2015 to 31 in 2019. However, within just six months in 2020, 27 new shortages were announced. The number of medication shortages in 2020 reached 87% of the total reported in 2019, highlighting the severity of the issue within a significantly shorter timeframe [15]. In Canada, too, average daily shortage prevalence rates rose from 901 in April 2017 to a peak of 2345 by April 2020[16].

**The shift in market dynamics due to the COVID-19 pandemic has led to strategic changes across the pharmaceutical supply chain, such as new outsourcing models, backward integration, and digital transformation.**

Many pharmaceutical firms are considering near-shoring- relocating production facilities closer to their primary consumer bases to mitigate risks and reduce reliance on distant suppliers, derisk supply chain concerns, decrease lead times, and enhance overall resilience.

Several companies are also embracing backward integration to decrease dependence on external suppliers of Active Pharmaceutical Ingredients (APIs) and intermediates. By vertically integrating production processes, firms can have greater control over quality and lead times, strengthening their competitive position and supply chain stability.

The COVID-19 pandemic exposed the vulnerabilities in the pharmaceutical supply chain, primarily due to a lack of agility, transparency, and digitization. Pharmaceutical companies are increasingly adopting digital solutions such as blockchain, real-time data analytics, and AI-enabled platforms. These technologies provide enhanced visibility into product flows, enabling proactive decision-making and risk management across the supply chain.

### Increasing push to switch to low-cost generics [17] to control spiraling healthcare costs and make healthcare more equitable:

**As operational shifts persist in the industry, commercial factors like the rising demand for pharmaceutical products—which is putting financial strain on healthcare systems—and the increasing availability of affordable generics will continue to drive the generics pharma segment forward.**

The pharmaceutical industry's evolution has led to a wave of groundbreaking medicines that promise potentially curative therapies. At the same time, the expiration of patents is set to bring a greater array of medications to diverse markets worldwide. The introduction of more cost-effective generic alternatives will mean greater accessibility and health equity.

While groundbreaking medicines with typically high prices will lead to increased market growth, they are likely to be restricted to developed economies and will increase healthcare expenditure for public and private healthcare systems. The increasing healthcare expenditures due to the rising demand for pharmaceutical drugs have put significant financial pressure on global healthcare systems. This has played

[15] National Library of Medicine: Medication shortages during the COVID-19 pandemic
[16] National Library of Medicine: COVID-19 and the prevalence of drug shortages in Canada
[17] Generics include branded and unbranded generics, innovators include Patented products and OTC

a role in shaping pro-generic drug strategies for many governments. In emerging markets, governments support widespread launches and adoption of generic drugs through policies such as compulsory licensing to make drugs more accessible to the larger population. In regulated markets, governments use multiple levers, such as market exclusivity and preferred reimbursement, to name a few, to encourage the switch to generics where available.

Resultantly, the generic drugs segment has grown as a solution to address growing global healthcare costs. The segment has also benefitted from advancements in complex generics and patent losses of innovator drugs. As a result, generic drugs accounted for 25.1% of the total pharmaceutical market by sales value in 2023 and are expected to grow at a CAGR of 5.1% between 2023 and 2028 to reach a value of USD 527.0 billion in 2028.

**Exhibit 2.2A: Global Pharma Market by Product Type, 2018 - 2028F**

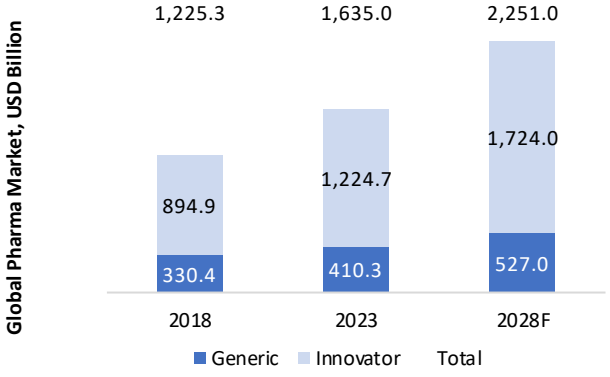
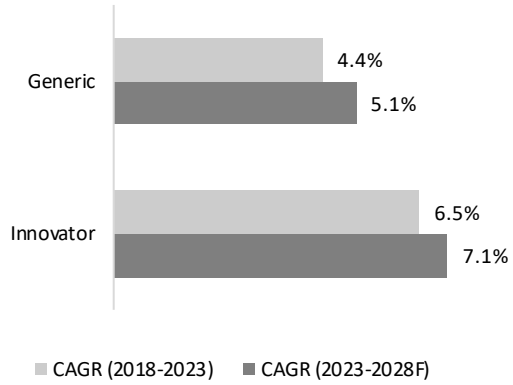



**Exhibit 2.2B: Growth Rate of Global Pharma Market by Product Type, 2018 - 2028F**



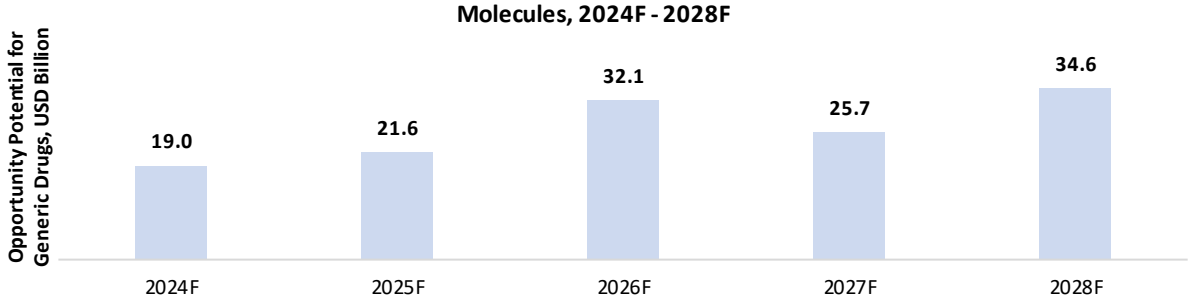

*Source: IQVIA Global Use of Medicines- 2024, Evaluate Pharma, Frost & Sullivan*

In addition to increased volume consumption of generic drugs, this growth impetus will also be accelerated by the upcoming patent cliff, particularly of key small molecules, which presents an opportunity worth USD 133.0 billion (in developed markets alone) in the next five years. Some of the blockbuster products that will open to generic competition include Xarelto (2023 Sales of ~USD 6 billion), Eliquis (2023 Sales of ~USD 12 billion), Vyndaqel (2023 Sales of ~USD 3 billion), and Jakafi (2023 Sales of ~USD 4 billion) to name a few[18]. According to research, generic uptake in the first year of launch can be 66.1% while in the second year can reach 82.7%, indicating a larger share of the market being captured by generic drugs[19].

[18] Evaluate Pharma

[19] Factors Associated with Generic Drug Uptake in the United States, 2012 to 2017

**Exhibit 2.3: Opportunities for Generic Drugs from Upcoming Patent Expiries of Small Molecules, 2024F - 2028F**




*Source: IQVIA, Global Use of Medicines 2022 and 2024, Frost & Sullivan*

*Note: Data shows the impact of patent expiry in developed markets only*

**In addition to offering cost savings, generics pharma companies have transformed the pharma landscape by constantly innovating to improve drug efficiency, effectiveness, and ease of use and employed strategic operational tactics to drive continuous value addition:**

**Generic pharmaceutical companies are driving significant industry transformation, focusing on innovation, diversification, and cost-saving strategies to navigate competitive and regulated markets effectively.**

Generic pharmaceutical firms have constantly strived to diversify their portfolios by introducing reformulated generics to include extended-release, inhalable, and implantable formulations, to name a few, to improve drug efficacy and, at the same time, patient convenience. Companies have also focused on increasing Research & Development (R&D) to foray into complex and specialty generics. Additionally, companies diversify sourcing and manufacturing networks to mitigate supply chain risks while embracing digital tools and technologies to enhance operational quality and productivity. Generic pharmaceutical companies are leveraging operational excellence, technology adoption, and streamlined supply chain management to achieve substantial cost savings while maintaining competitiveness and meeting regulatory requirements.

***Global Pharmaceutical Market by Regions***

**Regulated markets, particularly the US, continue to exert dominance and influence over the global pharma market, driven by high demand, appetite for innovation, and comparatively higher prices for comparable products.**

**Exhibit 2.4A: Global Pharma Market by Region, 2018 - 2028F**

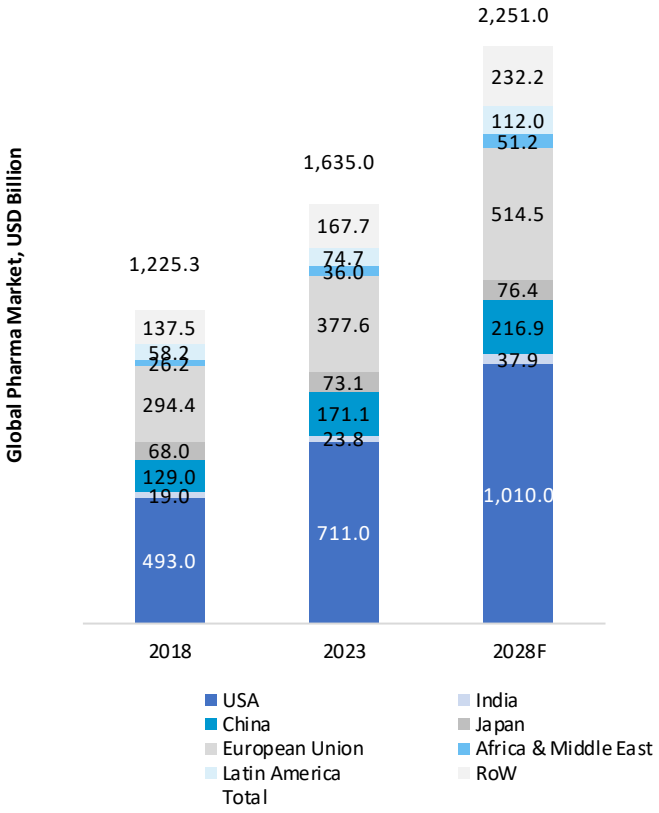
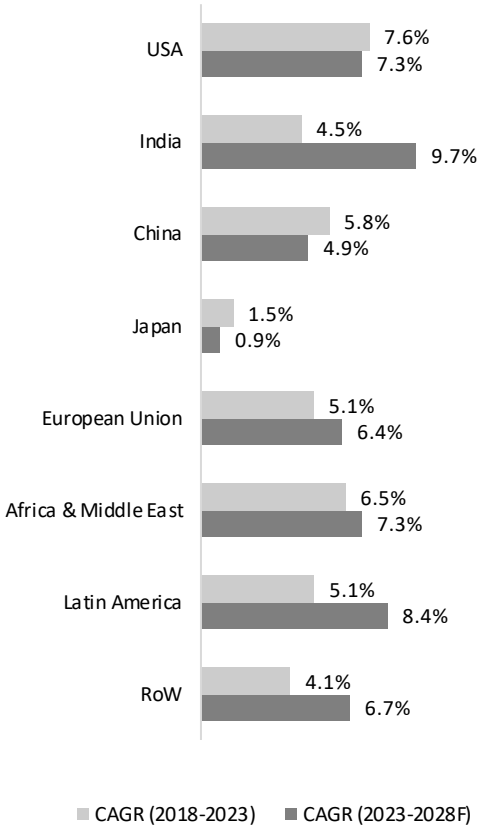



**Exhibit 2.4B: Growth Rate of Global Pharma Market by Region, 2018 - 2028F**




*Source: IQVIA, Global Use of Medicines 2022 and 2024, Frost & Sullivan*

*Note: Growth rate in local currencies, APAC* excludes India, China, and Japan, which are provided separately; RoW includes all other markets not covered above, such as the Rest of Europe, Rest of North America, etc.*

In 2023, the United States dominated the global prescription pharmaceutical market with a 43.5% share, followed by the EU region at 23.1%. This stronghold reflects the US's robust healthcare expenditure and significant investments in R&D. Similarly, Europe's leadership in R&D and innovative pharmaceutical introductions is reinforced by extensive reimbursement coverage and high treatment rates. Despite the historical precedence of these established markets, the burgeoning growth trajectory is distinctly observable in emerging markets across the Asia Pacific (APAC), Latin America, and the Rest of the World (ROW). These regions, characterized by dynamic economies such as the BRICS nations (Brazil, Russia, India, China, and South Africa) and the MIST countries (Mexico, Indonesia, South Korea, and Turkey), present new opportunities because of substantial population size, increasing affluence, and augmented financial capabilities of both governments (public health expenditure) and citizens (private health expenditure), enhanced life expectancy, improved access to pharmaceuticals, increasing coverage in medical insurance policies, better healthcare infrastructure along with awareness, changing disease patterns (from acute to chronic), and availability of low-cost generics. During the forecast period, while the US will retain its dominant position with almost 44% market share, the fastest growth is expected in

India, Russia, and Brazil, each breaching a CAGR of 8-10%, followed by China and South Korea, with an anticipated CAGR of 4.5-7.5% between 2022 and 2027.

Overall, the regulatory pharma market, comprising 38 countries accounted for 77.0% share by value in 2023. The emerging pharma market, which includes high-growth regions of the Middle East and Africa, Latin America, and APAC countries like India, accounted for the remaining 23.0% in 2023 but is expected to reach a share of 24.0% by 2028, outpacing the growth of the global pharma market.

**Exhibit 2.5A: Global Pharma Market by Regions, 2018 - 2028F**

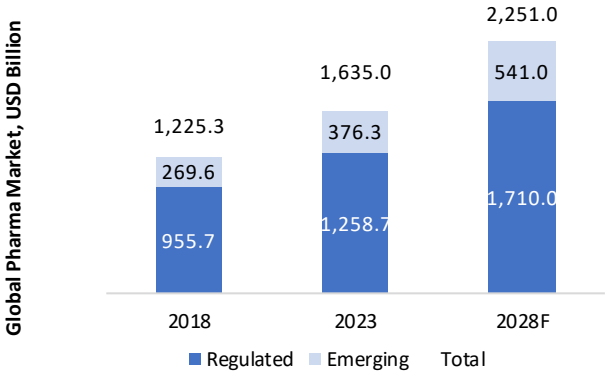
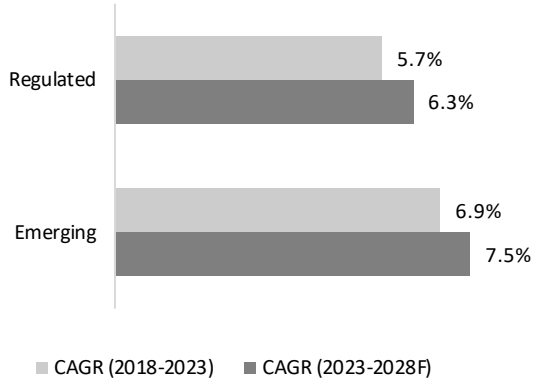



**Exhibit 2.5B: Growth Rate of Global Pharma Market by Regions, 2018 - 2028F**




*Source: IQVIA, Global Use of Medicines 2022 and 2024, Frost & Sullivan*

### *Key Risks and Challenges in the Global Pharma Market*

- **Regulatory Compliance:** Stringent regulations imposed by regulatory authorities across different jurisdictions pose a significant challenge for pharmaceutical companies. Adhering to diverse and evolving regulatory requirements demands substantial resources and expertise, and non-compliance can lead to severe penalties and reputational damage.
- **Intellectual Property Protection**: Protecting intellectual property (IP) rights is crucial for pharmaceutical companies, particularly given the significant investment in research and development (R&D) required to bring new drugs to market. The risk of patent infringement and the complexities of navigating patent laws globally present ongoing challenges for companies seeking to safeguard their innovations.
- **Pricing Pressures:** Pharmaceutical pricing remains a contentious issue globally, with governments, insurers, and consumers exerting pressure to control healthcare costs. Reimbursement challenges, pricing negotiations, and the rise of generic competition can erode profit margins and impact the commercial viability of pharmaceutical products.
- **Market Access and Distribution:** Accessing diverse markets and establishing efficient distribution channels present formidable challenges for pharmaceutical companies, especially in emerging economies with fragmented healthcare systems. Regulatory hurdles, logistical complexities, and cultural considerations can impede market entry and distribution efforts.
- **Supply Chain Disruptions:** As evidenced during the pandemic, the global pharmaceutical supply chain is susceptible to disruptions stemming from various factors, including natural disasters, geopolitical tensions, and pandemics. Ensuring the resilience and continuity of the supply chain, including sourcing raw materials and managing manufacturing capacities, is critical to mitigate risks and maintain product availability.

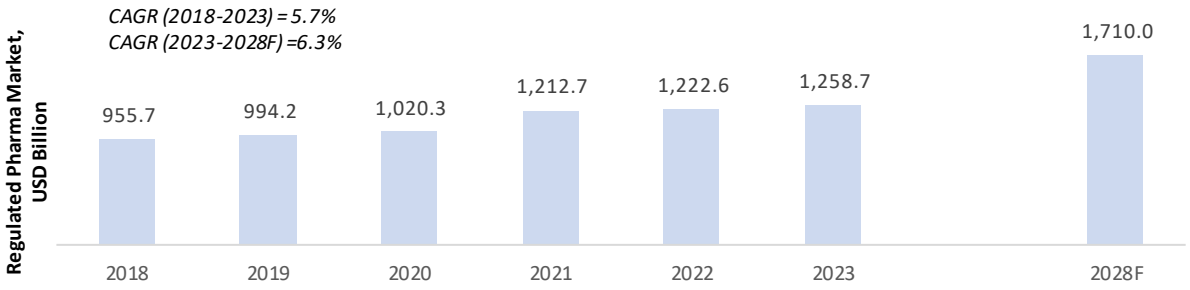
- **Product Development Risks:** The pharmaceutical industry is inherently risky due to the lengthy and costly process of drug development, coupled with uncertainties surrounding clinical trials and regulatory approvals. Failure to meet efficacy and safety standards, as well as unforeseen adverse events, can lead to substantial financial losses and setbacks in product pipelines.
- **Competition and Innovation:** Intense competition within the pharmaceutical market, both from established players and emerging biotechnology companies, underscores the importance of innovation. Companies need to continuously invest in R&D to develop differentiated products and therapies, navigate patent cliffs, and sustain competitive advantage in an evolving landscape.

## 2.1 REGULATED[20] PHARMACEUTICAL MARKET OVERVIEW

**Regulated markets will continue to dominate the global pharmaceutical sector, driven by their access to a growing innovative drug market and a thriving generics market.**

Regulated markets, comprising 77.0% of the global pharmaceutical sector, are projected to maintain a 76.0% share until 2028. The overall regulated pharma market is expected to reach USD 1,710.0 billion by 2028, up from USD 1,258.7 billion in 2023 growing at a CAGR of 6.3%.

**Exhibit 2.6: Regulated Pharma Market, 2018 - 2028F**




*Source: IQVIA Global Use of Medicines- 2024, Evaluate Pharma, Frost & Sullivan*

[20] Regulated markets as defined by WHO as 'Stringent Regulatory Authority' and includes 38 countries as of 2024. More countries are expected to be added to the list during the forecast years. All other countries are classified as emerging markets and include semi-regulated ones such as South Africa, Israel, India, Turkey, Philippines, and KSA and unregulated ones such as Somalia, Haiti, etc.

**Exhibit 2.7A: Regulated Pharma Market by Product Type, 2018 - 2028F**

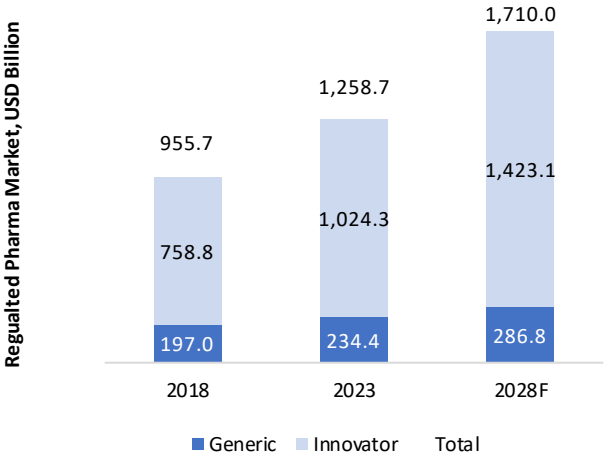
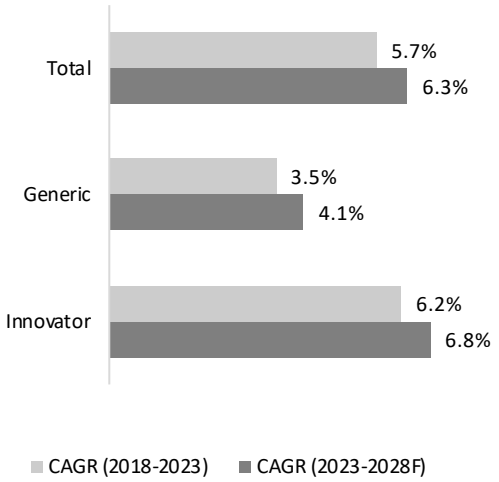



**Exhibit 2.7B: Growth Rate of Regulated Pharma Market by Product Type, 2018 - 2028F**




*Source: IQVIA Global Use of Medicines- 2024, Evaluate Pharma, Frost & Sullivan*

The pharmaceutical industry is known worldwide for its strict regulations, with governments implementing rigorous rules to protect public health. While regulatory frameworks may differ across countries, developed nations are characterized by meticulous government oversight (enforced by agencies such as the US Food & Drug Administration (FDA), Australia's Therapeutic Goods Administration (TGA), Japan's Pharmaceuticals and Medical Devices Agency (PMDA), UK's Medicines and Healthcare products Regulatory Agency (MHRA), and European Medicines Agency (EMA) of drug origin, manufacturing processes, marketing avenues, and sales channels to ensure the highest quality, safety, and efficacy of drugs consumed. Despite the stringent regulations, regulated markets serve as centers of innovation for products and services. These countries are often early adopters of new therapies, even those with costs reaching nearly a million dollars per dose, thereby driving growth in the innovator drug market.

However, growth in the innovative drug sector leads to increased healthcare spending and expenditure owing to their high cost per dose, forcing insurers and governments to pursue strategies that encourage the adoption of more cost-effective generics where available. This is observed to be a common trend across the developed economies. For instance, Japan has set a target of achieving an 80% market share for generic drugs, indicating a proactive approach toward cost containment by the adoption of generic drugs.

In Canada, recent negotiations between the government and the pharmaceutical industry have resulted in pricing stability and predictability for generic drugs, preventing price discounts and negotiations with generic drug manufacturers. Per new negotiations, generics will now be priced between 25% and 50% of patented counterparts when manufactured by multiple companies and 55% when produced by a single manufacturer. As a result, generic drugs are significantly more affordable than innovator drugs and consequently have significant market penetration in Canada at 75%,[21] while in the US, generic drugs

[21] Canadian Generic Pharmaceutical Association

account for more than 90%[22] of all prescriptions. In Europe, the penetration has reached nearly 60%[23]. This high market penetration has allowed the generics market to reach USD 234.4 billion in 2023. Continuing cost containment programs across the region and the increasing availability of new generics in the wake of upcoming patent expirations will further drive the generic drug market growth by 4.1% between 2023 and 2028.

**Exhibit 2.8A: Regulated Pharma Market by Regions, 2018 - 2028F**

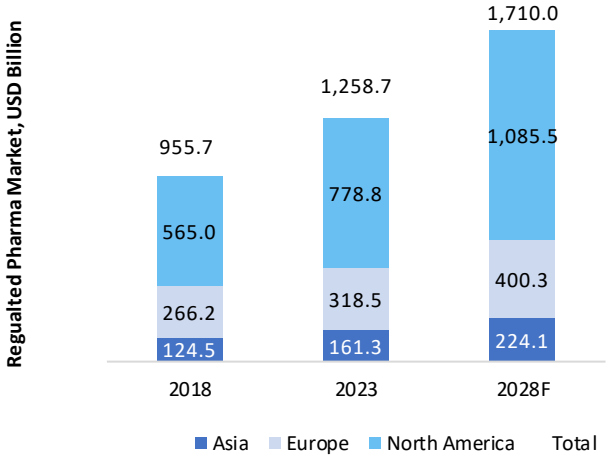
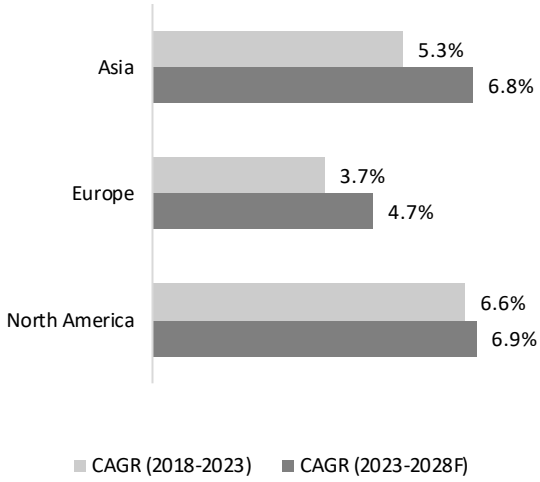



**Exhibit 2.8B: Growth Rate of Regulated Pharma Market by Regions, 2018 - 2028F**




*Source: IQVIA Global Use of Medicines- 2024, Evaluate Pharma, Frost & Sullivan*

The North American market, which includes the US and Canada, is expected to account for the majority share of 61.9% in 2023. This share is expected to increase further as the US has been introducing policies to encourage the adoption of new expensive innovative therapies as well as new generic introductions in the market. The European pharma market, mostly driven by the UK and EU4 countries (Germany, France, Italy, and Spain) is expected to lose its share in the total regulated pharma market. This is largely owing to overall macro factors like declining population, economic pressure, and pricing pressure exacerbated by the use of international reference pricing systems. On the other hand, the APAC market will experience mixed dynamics with some countries like Australia and South Korea driving growth, whereas Japan experiencing a decline in its market share.

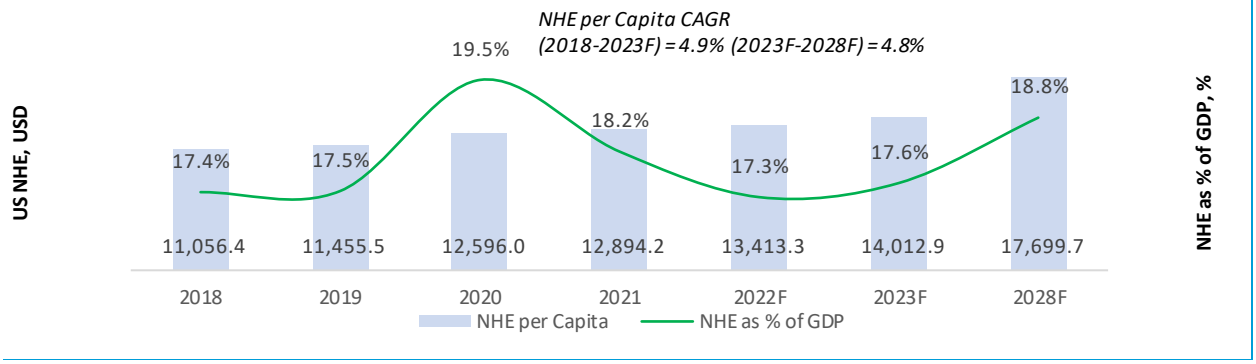
### 2.1.1 The US Pharmaceutical Market Overview

**In 2023, the US accounted for nearly 43% of the global market, 56% of the regulated market, and 91% of the North American market, and it is expected to maintain its dominance during the forecast period.**

The United States dominates the global healthcare market, boasting the largest and most advanced pharmaceutical industry. The government allocating approximately 17% or more of the GDP towards healthcare signifies a substantial and growing investment in the healthcare segment.

[22] Association for Accessible Medicines
[23] Medicines for Europe

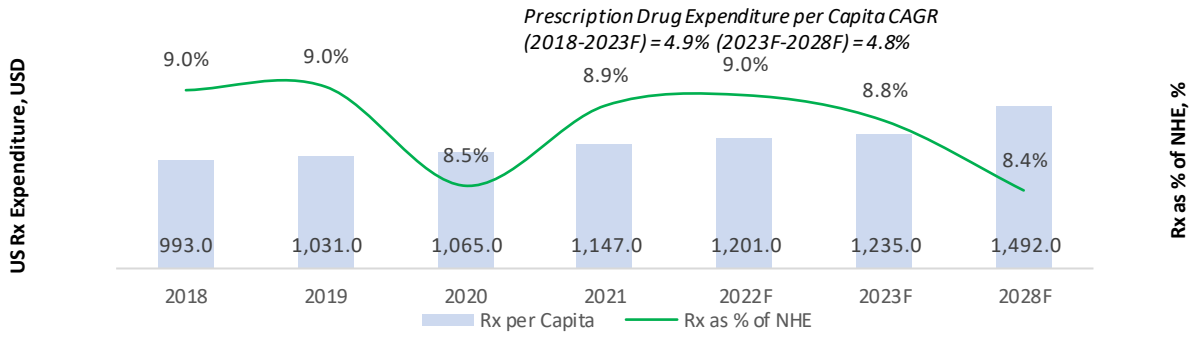
**Exhibit 2.9: National Healthcare Expenditure (NHE), US, 2018 - 2028F**




*Source: Centers for Medicare and Medicaid Services (CMS), Frost & Sullivan*

Within the overall NHE, retail prescription drugs alone account for 8-9% of the expenditure, translating into a per capita expenditure of USD 1,235.0 in 2023. The Centers for Medicare and Medicaid Services (CMS) forecasts this per capita expenditure to climb to USD 1,492.0 by 2028.

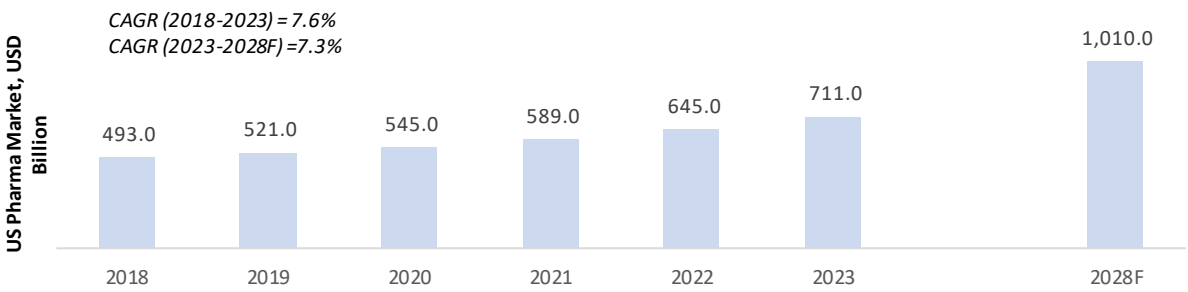
**Exhibit 2.10: Retail Prescription Drug Expenditure, US, 2018 - 2028F**




*Source: Centers for Medicare and Medicaid Services (CMS), Frost & Sullivan*

Cumulatively, across prescription and non-prescription, retail and non-retail, in 2023, the pharmaceutical sector amassed a staggering USD 711.0 billion, capturing a 43.5% share of the global market. The market is expected to reach USD 1,010.0 billion in 2028, growing at a CAGR of 7.3% between 2023 and 2028.

**Exhibit 2.11: US Pharma Market, 2018 - 2028F**




*Source: IQVIA Global Use of Medicines- 2023 & 2024, Evaluate Pharma, Frost & Sullivan*

**One of the biggest drivers of the US pharmaceutical market is favorable policies and the contribution of the government to innovation and reimbursement for healthcare services and products.**

Key market drivers include a robust healthcare infrastructure, including state-of-the-art healthcare facilities and advanced technology integration, significant investments in research and development (R&D), and a culture of innovation and breakthrough discoveries.

Furthermore, the US government is pivotal in driving pharmaceutical innovation through National Institutes of Health (NIH) funding initiatives supporting groundbreaking drug development and therapy research. In fiscal year 2022, NIH invested most of its USD 45 billion in research to enhance life and reduce illness and disability[24]. This commitment to R&D is further bolstered by streamlined FDA regulatory policies, which expedite the approval and introduction of new drugs, ensuring a continuous flow of innovative treatments to market. For instance, FDA approved 303 New Molecular Entities (NME) between 2018 and 2023[25]. Along similar lines, according to the PhRMA report on Global Access to New Medicines, the US leads in the share of first launches globally. In 2021, the US accounted for 65% of the first launches of the 67 new medicines launched globally, and of all the 460 medicines launched between 2012 and 2021, the US had access to 78% of the medicines within the first year of launch.

Another pivotal aspect of the US healthcare landscape is its widespread and evolving reimbursement mechanisms, spurred by the adoption of innovative approaches by payors, such as value-based care. Moreover, expanding health insurance coverage through government programs like Medicare and Medicaid and increased private insurance options has led to a surge in healthcare utilization and pharmaceutical consumption. These programs ensure that millions of Americans have access to essential medical services, including prescriptions, thereby driving demand within the healthcare market. In 2022, the insured rate rose to 92.1%, encompassing 304.0 million people, marking an increase from 2021's figures of 91.7% or 300.9 million insured individuals[26]. These programs ensure that millions of Americans have access to essential medical services, including prescriptions, thereby driving demand within the healthcare market. Additionally, the widespread adoption of breakthrough technologies, such as telemedicine and digital health solutions, enhances accessibility and quality of care for patients nationwide.

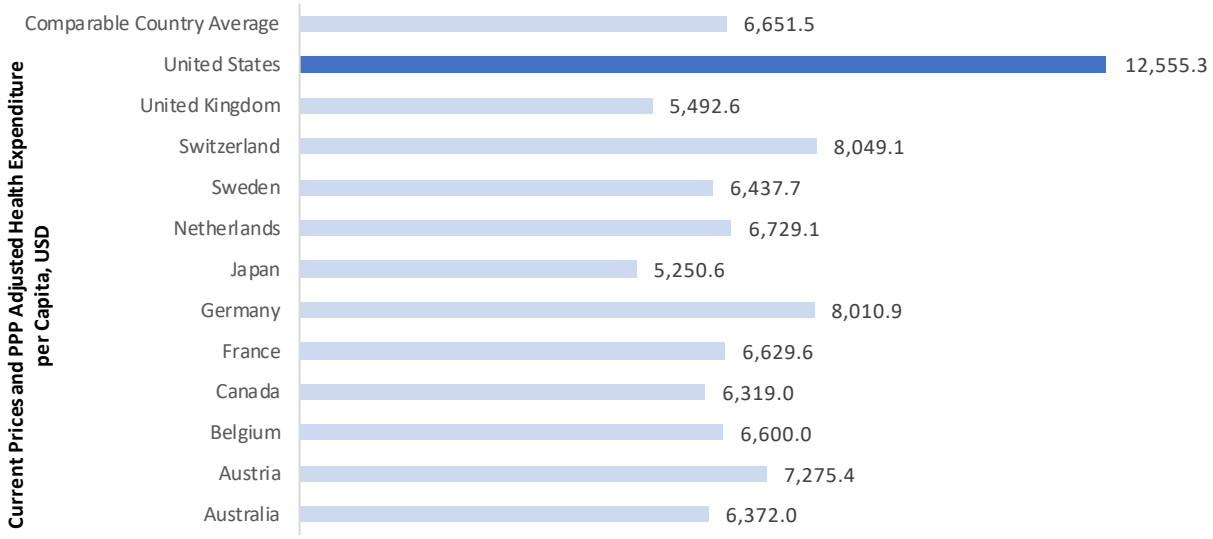
***Characteristics of the US Healthcare Market***

**Very high healthcare and pharmaceutical expenditure[27]**

[24] NIH Grants and Fundings
[25] US FDA: Novel Drug Approvals
[26] United States Census Bureau
[27] Peterson-KFF Health System Tracker

In 2022, health expenditures per person in the US crossed USD 12,000, surpassing other high-income nations by nearly USD 6,000. This stark contrast highlights the significant disparity in healthcare spending between the US and comparable countries, where the average expenditure per person is approximately USD 6,651—roughly half of what the US spends.

**Exhibit 2.12: Health Expenditures per Capita, 2022**




*Source: Peterson- KFF Health System Tracker, Frost & Sullivan*

Over the past five decades, this gap has only widened. While the US and comparable Organization for Economic Co-operation and Development (OECD) countries spent a similar percentage of GDP on healthcare in 1970 (around 6.2%), the US began to outpace its peers in the 1980s. Since then, healthcare spending as a share of the economy has grown faster in the US compared to other nations.

The COVID-19 pandemic further exacerbated this trend. Between 2019 and 2020, health spending as a share of GDP increased in the US and comparable countries due to increased healthcare needs and economic downturn. Although the economy has since recovered, health spending as a percentage of GDP in the US remains substantially higher.

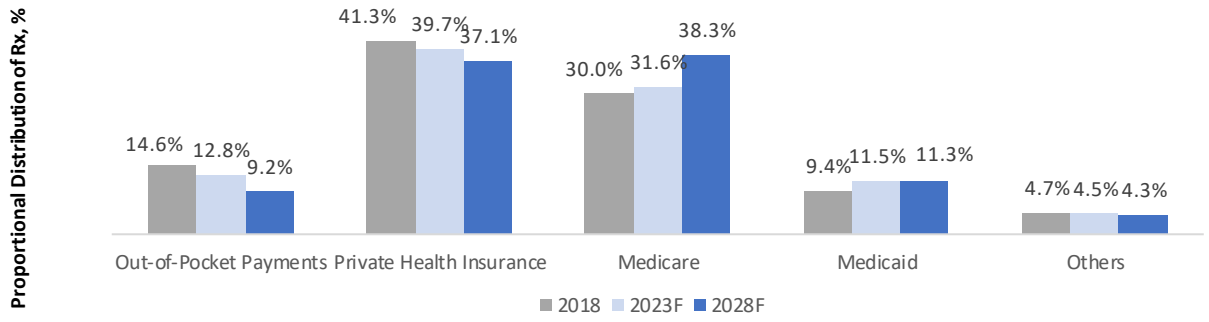
## Rising advocacy from public and private providers for adopting low-cost alternatives- generics to navigate the high healthcare costs.

With the increasing cost of healthcare and pharmaceutical expenditure, there has been a growing push from public and private insurers to switch to bioequivalent generics [28] to brand-name innovator counterparts but typically priced at a fraction of the cost. Existing research has overwhelmingly found that when generic drugs enter the market, prices fall substantially, with prices falling to as low as 30% of the branded drug price just three years after entry, with more generic entrants further lowering the price. These price reductions can result in savings for the healthcare system and reductions in patient out-of-pocket (OOP) costs. Generic drug dispensing across all prescription drugs (including those without generic alternatives) is 92% of the United States dispensed.

[28] According to FDA, Bioequivalence is the biochemical similarity of two (or more) drugs that share the same active ingredient(s) and desired outcome(s) for patients.

Even Medicare (Part D Drug Coverage[29]) and Medicaid (and Children's Health Insurance Program (CHIP)), which contributed to 43% of total retail prescription pharmaceutical drug expenditure, are promoting the use of generic drugs by implementing preferred drug lists and reimbursement structures. For example, Part D beneficiaries are advised to opt for generic medications instead of brand-name ones. In 2022, 43.3 million Medicare Part D enrollees filled 1.1 billion prescriptions for generic prescription drugs.

**Exhibit 2.13: Retail Prescription Drug Expenditure by Source of Funding, US, 2018 - 2028F**

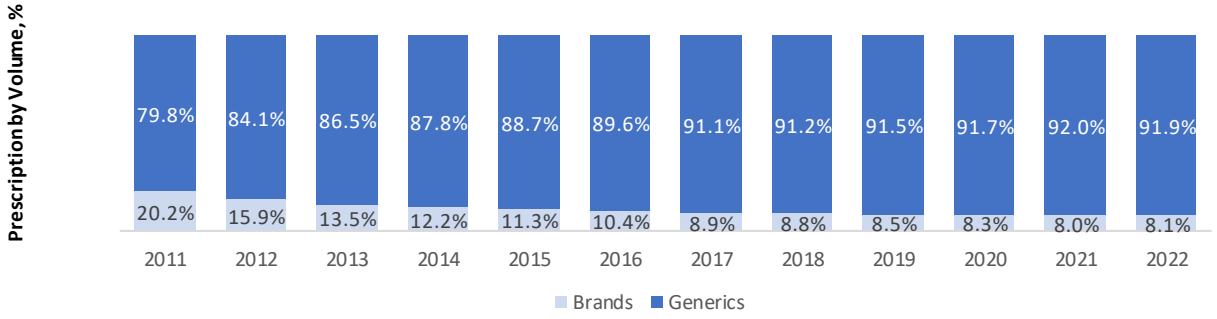



*Source: Centers for Medicare and Medicaid Services (CMS), Frost & Sullivan*

*Note: Others include third-party payors and other insurance companies*

Private payers, including health insurance firms and Pharmacy Benefit Managers (PBMs), also contribute to moving patients to generic drugs. They favor generic pharmaceuticals and encourage physicians to recommend generics over brand-name medications wherever clinically acceptable. They tend to favor pharmacy networks that offer generic medicine discounts or incentives. Many insurance providers offer financial incentives to patients to pick generics over brand-name drugs. For example, financial benefits may include reduced rates or larger coverage limits for generic medicine plans.

**Exhibit 2.14: Share of Prescriptions, US, 2011 - 2022**




[29] Medicare Part D, also called the Medicare prescription drug benefit, is an optional US federal-government program to help Medicare beneficiaries pay for self-administered prescription drugs.

*Source: IQVIA The Use of Medicines in the US, 2023, Frost & Sullivan*

*Note: Generics include branded and unbranded generics*

Resultantly, generic drugs made up around 92% of the prescriptions in the United States in 2022, up from 91.2% in 2018 and 79.8% in 2011.

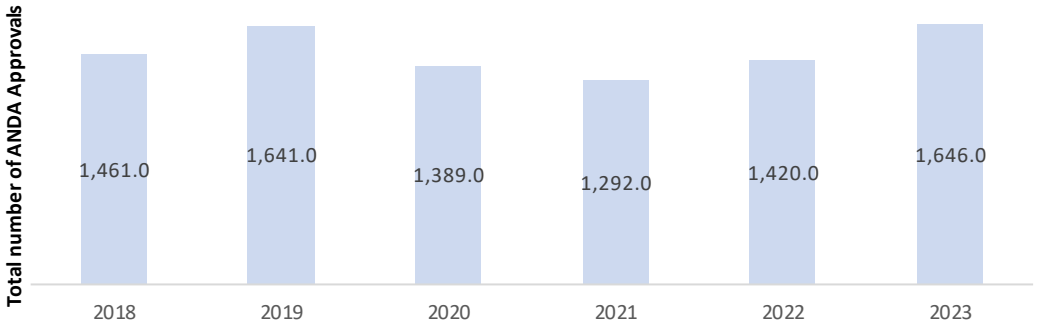
### Regulatory agency- FDA, supporting the momentum for generic drug adoption

**Regulation plays a pivotal role in shaping the industry landscape, with the Food and Drug Administration (FDA) overseeing drug approval processes and playing a critical role in easing the entry of generic drugs into the market.**

With the introduction of the Hatch-Waxman Act over thirty years ago and the latest regulations for complex generics, the FDA has enabled the availability and affordability of generic drugs in the US. Some of the mechanisms undertaken by the FDA are listed below.

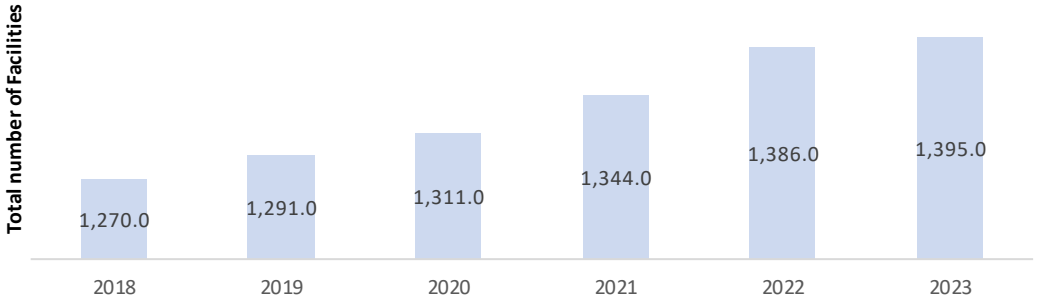
- **The Hatch-Waxman Act,** passed in 1984 in the United States, introduced the Abbreviated New Drug Application (ANDA) pathway for generic drugs. This streamlined approval process emphasizes demonstrating bioequivalence rather than the need for independent safety and effectiveness trials, reducing costs and time. Consequently, there has been a notable increase in approved ANDAs, reflecting a rise in available generics. Moreover, the Act permits generic manufacturers to challenge brand-name drug patents through Paragraph IV certifications, allowing earlier market entry. It also establishes market exclusivity periods for brand names and the first generic entrants. These exclusivity periods can range from five years for new NCEs to 180 days for ANDAs files with Paragraph IV certification. Full new drug applications under NDA and can receive 5 years of exclusivity for a new chemical entity drug product. A 505(b)(2) application or a supplement to a new drug application can receive 3 years of exclusivity. Whereas a successful Paragraph IV certified generic can receive 180 days of exclusivity.
- The Drug Price Competition and Patent Term Restoration Act led to a surge in generic drug applications, causing a backlog issue. To address this, Congress enacted the **Generic Drug User Fee Amendments (GDUFA)** in 2012. GDUFA introduced user fees paid by the industry annually to enhance the efficiency of the approval process. As a result, approval timelines dropped from one year in 2017 to 8-10 months by 2022, bringing transparency to the process. GDUFA applies to all firms manufacturing generic drugs for the US market, ensuring FDA user fees are paid. Additionally, Drug Master File (DMF) fees initiate FDA review for completeness assessment, aiding in Abbreviated New Drug Application (ANDA) submission. These fees expedite the delivery of safe generic drugs and improve review process predictability. Participation in GDUFA is evidenced by the increasing number of facilities making fee payments annually.

**Exhibit 2.15: ANDA Approvals by FDA, 2018-2023**




*Source: FDA: Orange Book, Frost & Sullivan*
*Note: Includes all ANDAs with unique product numbers and approval dates*

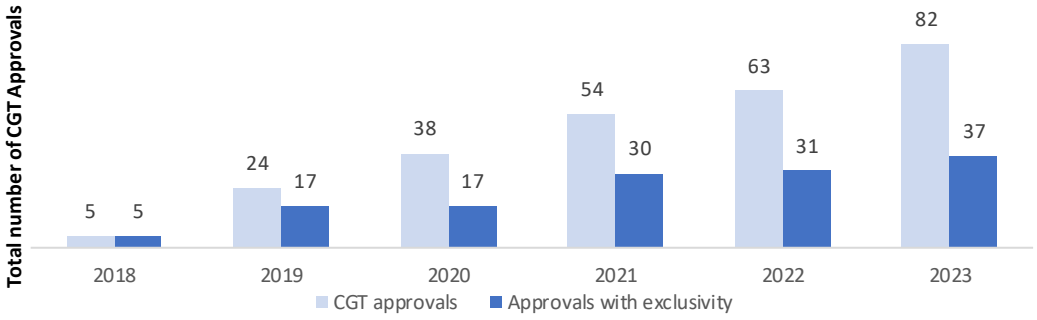
**Exhibit 2.16: Number of GDUFA Paid Facilities, 2018-2023**




*Source: FDA: GDUFA Paid Facilities List, Frost & Sullivan*

- The Food and Drug Administration Reauthorization Act of 2017 introduced a new pathway for generic drug approval known as the **Competitive Generic Therapy (CGT) designation**. This designation is granted when the FDA determines there is inadequate generic competition. Under this pathway, applicants receive additional resources and guidance from the FDA throughout the approval process. CGT-designated drugs are eligible for a period of exclusivity, typically 180 days (if the applicant begins marketing within 75 days of approval), during which competing generic versions of the drug cannot be marketed. This exclusivity period allows companies to establish a foothold in the market and generate revenue without immediate competition, providing a valuable opportunity for market penetration and revenue growth. At the applicant's request, the FDA may also expedite developing and reviewing an abbreviated new drug application (ANDA) for a drug designated as a CGT. The introduction of this pathway has prompted companies to take advantage of available exclusivity.

**Exhibit 2.17: Number of CGT Approvals, 2018-2023**




*Source: FDA: Competitive Generic Therapy Approvals, Frost & Sullivan*

The CGT (Competitive Generic Therapy) designation pathway is gaining traction, and some companies are particularly efficient in securing exclusivity for their approvals. For example, a Germany-based pharma achieved exclusivity for 80% of its CGT approvals, while Senores Pharmaceuticals Limited (Senores Pharma) followed closely with 75%, ranking second in terms of proportion of CGT approvals with exclusivity, among companies with a higher-than-average (greater than 3 ingredients with CGT approvals) number of CGT approvals. Senores Pharma's strategic focus on low-competition markets is evident, with 40% of its total approvals[30] between January 2018 and May 2024 obtaining CGT designation in a short span of time, significantly surpassing the industry average of 29.2% during the same period.

**Exhibit 2.18: CGT Analysis, 2018-2024***

| Company | Number of Ingredients with CGT Approval | Number of Ingredients with CGT Exclusivity | Proportion of Ingredients with CGT Exclusivity |
|---|---|---|---|
| Company 1 | 5 | 4 | 80.0% |
| Company 2 | 16 | 12 | 75.0% |
| Senores Pharma | 4 | 3 | 75.0% |
| Company 3 | 4 | 3 | 75.0% |
| Company 4 | 28 | 17 | 60.7% |
| **Industry Average** | **3** | **2** | **52.6%** |

*Source: FDA: Competitive Generic Therapy Approvals, Frost & Sullivan*
*Note: Data as of May 2024*

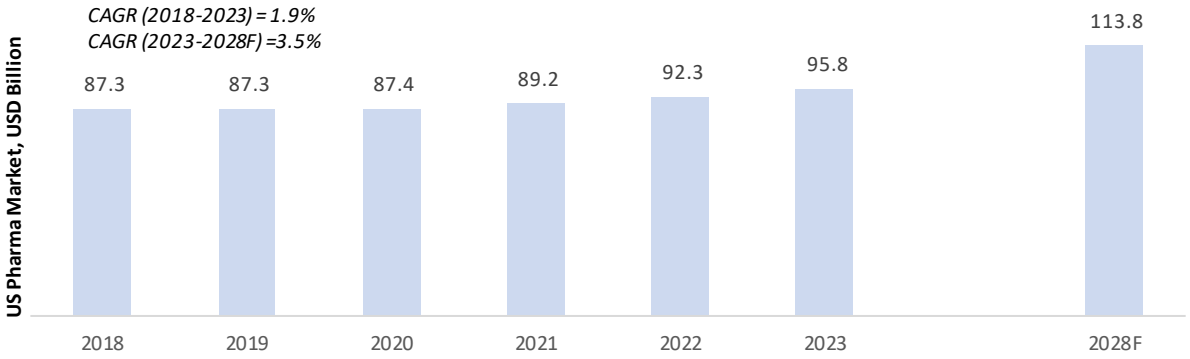
Since this pathway is characterized with fewer competitors in the market, it leads to lower and slower price erosion of the drugs, and also allows companies to secure a higher market share.

- The FDA has been taking steps to encourage the growth of the **complex generics** market, including drugs that are more challenging to develop and manufacture due to their complexity in formulations, delivery systems, APIs, or manufacturing processes. From issuing product-specific guidelines to streamlining regulatory pathways and harmonizing regulations with EMA (launch of parallel scientific advice program in 2021), the FDA is encouraging the growth of the complex generics market.

[30] Total approvals equates to unique application numbers

The above regulatory initiatives and the push from public and private payers have led to the generics market's growth. The market was valued at USD 92.3 billion in the US in 2023 and will reach USD 113.8 billion by 2028, at a CAGR of 3.5%.

**Exhibit 2.19: US Generic Pharma Market, 2018 - 2028F**

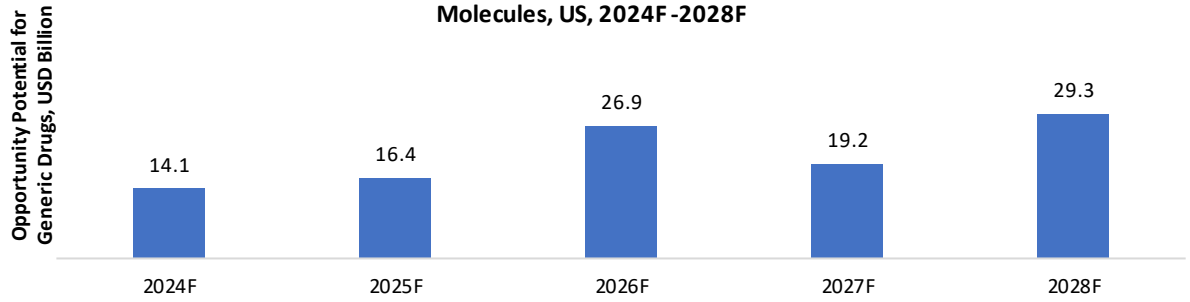



*Source: IQVIA The Use of Medicines in the US, 2023, IQVIA Global Use of Medicine 2023 & 2024, Evaluate Pharma, Frost & Sullivan*

## The generic drug market is expected to get a boost from the impending patent cliff.

The upcoming patent cliff is poised to boost the generic drug market's growth. As patents on numerous brand-name drugs are set to expire, generic manufacturers will have the opportunity to enter the market with their versions of these medications. As a result, the total opportunity available to the generics segment between 2024 and 2028 is nearly USD 105.9 billion.

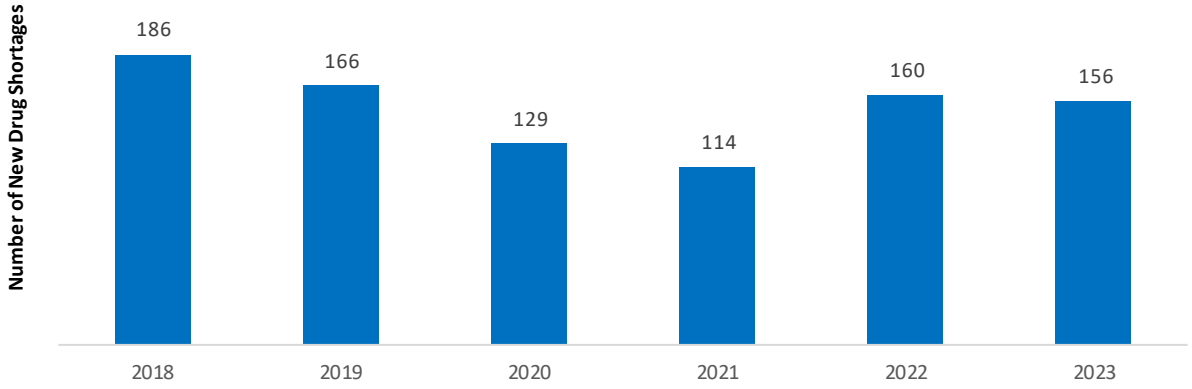
**Exhibit 2.20: Opportunities for Generic Drugs from Upcoming Patent Expiries of Small Molecules, US, 2024F -2028F**




*Source: IQVIA, Global Use of Medicines 2023 and 2024, Frost & Sullivan*

**Persistent drug shortages in the market reflect the need for an increased supply of generic drugs.**

**Exhibit 2.21: Number of New Drug Shortages in the US, 2018-2023**




*Source: ASHP, Frost & Sullivan*

The escalating prevalence of drug shortages within the United States healthcare system has emerged as a pressing issue characterized by a persistent imbalance between reported shortages and resolved instances.

This disparity arises when the demand for pharmaceuticals exceeds the available supply, whether due to a shortage of raw materials, manufacturing-related concerns, or a business decision to discontinue the product.

Drug shortage impacts an array of therapeutic sectors, but more notably pain/anesthesia, oncology, central nervous system, and infectious disease management. According to the American Society of Health-System Pharmacists (ASHP), there were 156 new shortages in 2023. According to IQVIA's drug shortage analysis, as of June 2023, a staggering 132 molecules faced active shortages in the US market. The shortages predominantly affect generic and injectable drugs, with 84% and 67% of shortages, respectively. Of the 132 drugs in shortage, 12 were branded, while the remaining 120 were generic. The limited ability of manufacturers to increase or add new capacity is a significant reason for the prolonged shortages, especially for medicines with complex manufacturing processes.

Furthermore, there's a growing concern that some generic drug prices may be too low to sustain profitable markets. While generic drugs are generally more affordable than their brand-name counterparts, excessively low prices may hinder the long-term viability of the generic drug market. Given the continued concerns related to drug shortages, the price erosion of generics has steadied, and in some cases, the prices of generics will increase in 2024.

**The need for the highest quality standards imposes entry barriers and shifts the market in favor of quality-driven generic drugs.**

The FDA conducts inspections and assessments of regulated facilities to determine a firm's compliance with applicable laws and regulations. It gives observations based on the level of objection. While Voluntary Action Indicated (VAI) is given when objectionable conditions or practices are found, the agency is not prepared to take or recommend any administrative or regulatory action. Official Action Indicated (OAI) is given when regulatory and/or administrative actions are recommended. An FDA Form 483 is issued to firm management after an inspection when an investigator(s) has observed any conditions that, in their judgment, may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts. Companies are encouraged to respond to the FDA Form 483 in writing with their corrective action plan and implement it expeditiously. Over the years, OAIs have decreased as companies become more quality-conscious, but concerns remain, particularly for Indian sites.

**Exhibit 2.22A: Official Action Indicated (OAI) by FDA by Site, 2018 - 2023**

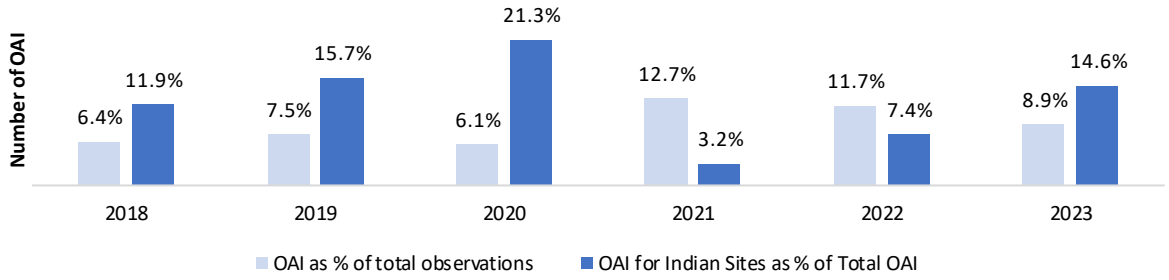



**Exhibit 2.22B: Official Action Indicated (OAI) and 483s by FDA, 2018 - 2023**

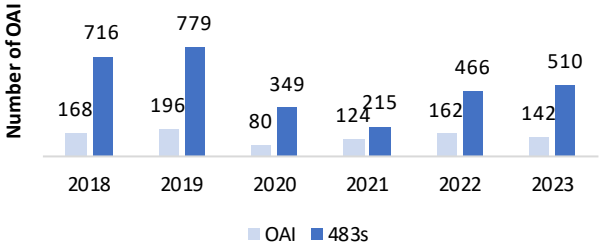
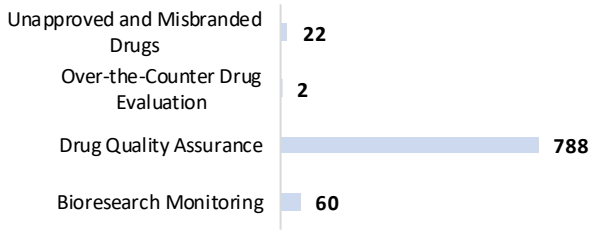



**Exhibit 2.22C: Official Action Indicated (OAI) by FDA, 2018 - 2023**




*Source: FDA Inspections and Observations Data, Frost & Sullivan*

*Note: The FDA's data includes only Form 483s issued through its electronic system; it only includes Form 483s issued to API manufacturers or Form 483s issued outside of the electronic system. Data is for the US financial year- October to September.*

In the last five years, between 2018 and 2023, the FDA has made nearly 872 drug-related OAIs, of which 90% were related to drug quality assurance. The number of Form 483s issued to drug establishments in FY23 was 510 compared to 215 in FY2021, an increase of about 137%. The temporary dip in 2020 and 2021 can be attributed to the COVID-19 pandemic when the FDA temporarily postponed all routine surveillance facility inspections, both domestic and foreign.

## Growing drug demand with a simultaneous need to control costs has increased import dependence, particularly from India.

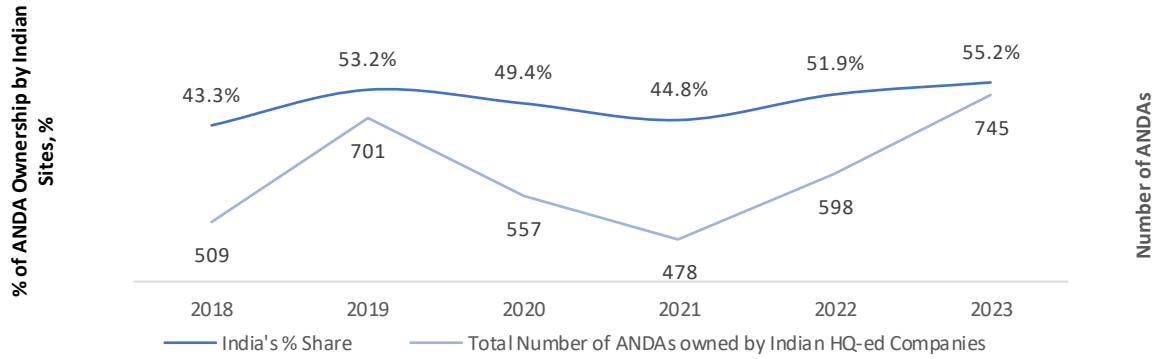
A measurable part of the US's demand for pharmaceutical and other medicinal products is met through imports worldwide. For instance, in 2023, the United States Imported Pharmaceutical formulations worth

USD 177.8 billion and API worth USD 66.6 billion[31]. Moreover, the dependence on India has increased significantly in the last decade, with total imports of formulations and APIs from India increasing from USD 9.0 billion in 2018 to USD 14.8 billion in 2023, growing at a CAGR of 10.5%.

In addition to serving as trade partners, Indian companies have also proven their mettle in the US generics segment by gaining an increasing number of ANDA approvals.

Seven of the top 10 companies with the highest ANDA approvals between 2018 and 2023 are Indian headquartered. Companies such as Aurobindo Pharma Limited (along with its subsidiaries Eugia Pharma Specialties Limited and Aurolife Pharma LLC), Zydus Lifesciences Limited, Alembic Pharmaceuticals Limited, and Sun Pharmaceutical Industries Limited (including subsidiary Taro Pharmaceutical Industries Limited) have consistently been gaining the highest ANDA approvals. Even relatively newer firms like Senores Pharma have gained 17 ANDA (3 in 2020, 6 in 2021, 4 in 2022, 4 in 2023) approvals during the same period.

**Exhibit 2.23A: % of ANDA Ownership by Indian HQ-ed Companies, 2018-2023**




*Source: FDA Orange Book Data, Frost & Sullivan*

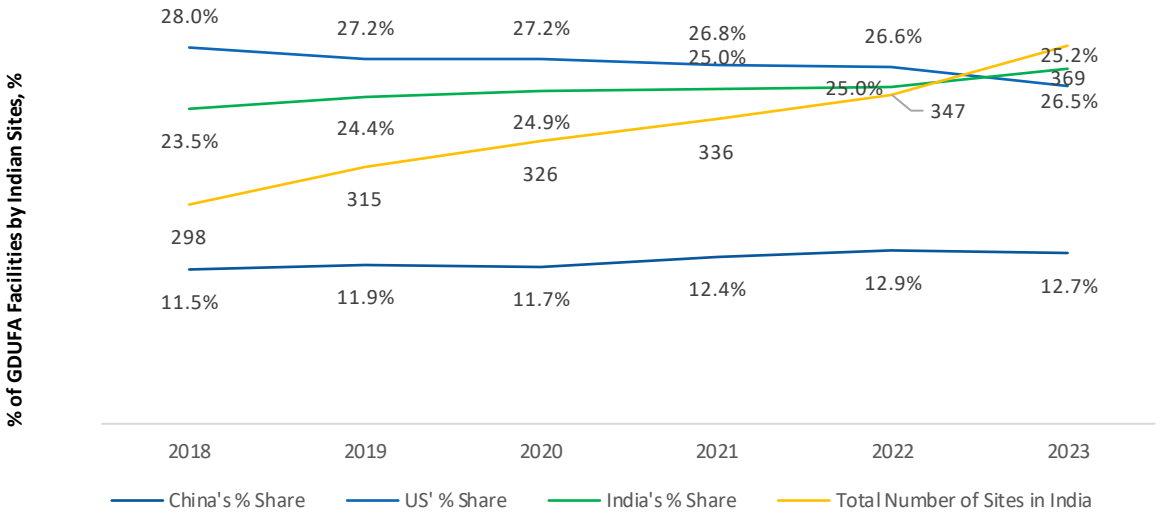
*Note: ANDA approvals by Indian companies include approvals held by subsidiaries of India-HQed companies and include all the unique product numbers and approval dates. The data is indicative and as of May 2024 and excludes discontinued products.*

Similarly, India is the global leader with the highest number of FDA-approved plants, accounting for 26.5% of the share in 2023 (369 facilities), almost twice that of China and a little higher than the US. Moreover,

[31] Trade Map: HS codes 30 and 29

this share has increased since 2018, when Indian manufacturers accounted for 298 approved facilities equating to 23.5% of the total share.

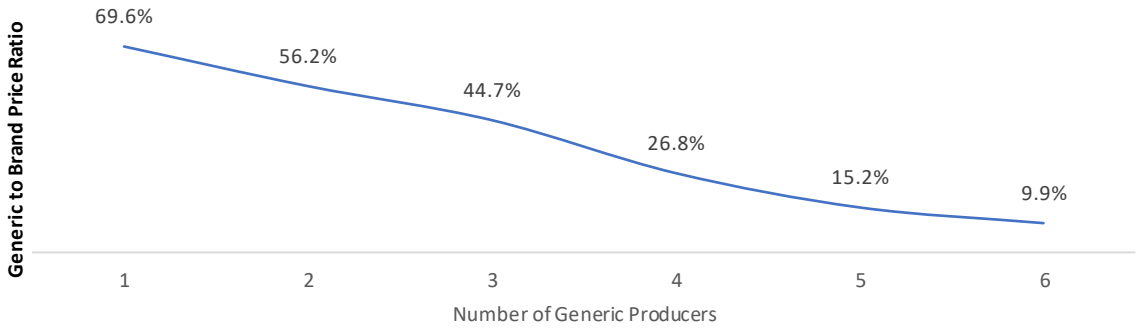
**Exhibit 2.23B: % of GDUFA Facilities by Sites in India, 2018-2023**




*Source: FDA GDUFA List, Frost & Sullivan*

## Price erosion in a highly competitive generics market

**Exhibit 2.24: Median Generic Prices Relative to Brand Price before Generic Entry**




*Source: FDA, Frost & Sullivan*

While initiatives by the government and private sector alike have brought explosive growth in the generics market, they have also increased competition, directly impacting the price commanded by generics.

A recent FDA analysis[32] it is revealed that the median discount on generic drug prices, measured against the invoice-based wholesale price, stands at 30% when only one generic version is available. This discount tends to increase as the number of generic manufacturers offering the drug rises. For instance, when two generics are available, the discount rises to 43.8%, and with three generics, it further increases to 55%.

[32] Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices

Indian pharmaceutical companies possess several advantages over their US counterparts, notably lower manufacturing costs, and robust research and development capabilities. These factors enable them to maintain profitability within the fiercely competitive US generics market. However, an emerging trend among technologically competent companies is the strategic pursuit of a portfolio specializing in complex generics.

Complex generics present multiple advantages for pharmaceutical companies. Their intricate formulations often yield higher margins, while the lower competition within this segment enhances the potential for capturing a larger market share. Given the inherent complexities in manufacturing these products, the anticipated number of generic competitors is typically limited to one, two, or at most three. As a result, while generic prices plummet by 85% (on an average of 5 competitors per product), it is not the same for complex products. Additionally, they tend to be less affected by price erosion, ensuring more stable pricing and profitability over time. Similar to complex generics, complex products that are difficult to manufacture also face lower competition and therefore enjoy lower price erosion and higher market share.

Similarly, the controlled substances[33] market (typically prescribed to treat severe pain, anxiety, insomnia, and Attention-deficit/hyperactivity disorder) is characterized by limited competition due to stringent regulatory requirements and oversight (scheduling by the Drug Enforcement Administration (DEA) and compliance with the Controlled Substances Act), higher profit margins, and stable demand, given their use as an essential medicine for indications such as pain management.

IQVIA data indicates that in 2021, the US controlled substance market accounted for USD 44.5 billion USD, and it is expected to grow at a CAGR of 5.2% and reach USD 74.3 billion by 2031. Controlled substances are a rapidly evolving market within complex generics in the United States, presenting pharmaceutical companies with regulatory and manufacturing challenges and opportunities.

DEA reports indicate a substantial growth of controlled substance manufacturing in the US pharmaceutical industry in the last decade. The demand for controlled substances is boosted by an increase in medical conditions such as mental health disorders, chronic pain, anxiety disorders, Attention-Deficit Hyperactivity Disorder (ADHD), and cancer, which has led to a surge in controlled substance prescriptions. For example, in 2019, an estimated 153.0 million analgesic prescriptions were dispensed, equivalent to producing 46.7 billion morphine milligram equivalents (MME). Benzodiazepines, a class of sedatives, were dispensed via 92.5 million prescriptions[34].

Consequently, manufacturers of complex generics enjoy market differentiation, as entry barriers for new competitors tend to be substantial. It affords manufacturers a stable revenue stream over prolonged periods and grants them the authority to establish drug prices akin to those of innovator drugs. Lower price erosion and competition translate not only into higher market share for companies with complex generics portfolios but also higher profit margins.

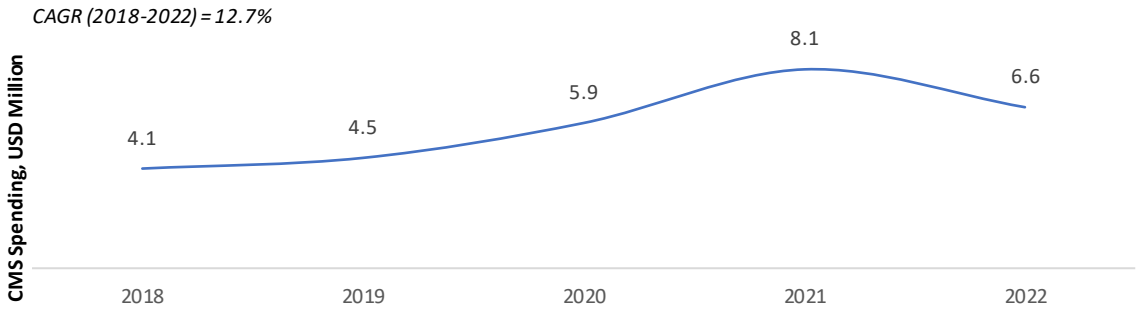
[33] Controlled substances are a drug or other substance that is tightly controlled by the government because it may be abused or cause addiction. Controlled substances include opioids, stimulants, depressants, hallucinogens, and anabolic steroids.

[34] HHS: Pain Management Best Practices

While more than 1,500 different drugs are available in the US market, some select products have been analyzed for this report below[35].

**Butalbital, Acetaminophen, and combinations:** The expenditure by the CMS on Butalbital, a barbiturate medication often combined with acetaminophen for managing tension headaches and migraines, has risen from USD 4.1 million in 2018 to USD 6.6 million in 2022. This increase reflects the sustained demand for the drug, driven by the ongoing prevalence of headaches and migraines and the established effectiveness of combination therapy.

**Exhibit 2.25: CMS Spending on Butalbital and Combinations: 2018 - 2022**




*Source: Centers for Medicare & Medicaid*

The FDA first approved a generic version of Butalbital in 1984, paving the way for subsequent generic versions and combination products. Currently, there are 34 Abbreviated New Drug Applications (ANDAs) for Butalbital and combination products, with 24 specifically approved for the combination of Butalbital, acetaminophen, and caffeine, the level of competition varies by different strengths and formulations.

**Exhibit 2.26A: ANDA Approvals for Butalbital, Acetaminophen, and Combination**

| Dosage Form and Route | Strength | Acetaminophen; Butalbital | Acetaminophen; Butalbital; Caffeine | Total |
|---|---|---|---|---|
| **CAPSULE;ORAL** | 300MG;50MG | 2 | | **2** |
| **CAPSULE;ORAL** | 300MG;50MG;40MG | | 10 | **10** |
| **CAPSULE;ORAL** | 325MG;50MG;40MG | | 5 | **5** |
| **SOLUTION;ORAL** | 325MG/15ML; 50MG/15ML; 40MG/15ML | | 1 | **1** |
| **TABLET;ORAL** | 300MG;50MG | 5 | | **5** |
| **TABLET;ORAL** | 325MG;25MG | 2 | | **2** |
| **TABLET;ORAL** | 325MG;50MG | 4 | | **4** |
| **TABLET;ORAL** | 325MG;50MG;40MG | | 9 | **9** |
| **Total** | | **10** | **24** | **34** |

[35] Volume data has been provided only for relevant products where Senores Pharma has an approved ANDA and where data is available

*Source: FDA Orange Book; Frost & Sullivan*

*Note: Only includes active ANDAs, Data as of May 2024*

**Exhibit 2.26B: Volume Share of Senores Pharma, Acetaminophen, Butalbital, and Combination, 11MCY23**

| Dosage Form and Route | Strength | Acetaminophen; Butalbital (Total Volume) | Senores Pharma's Market Share | Acetaminophen; Butalbital; Caffeine (Total Volume) | Senores Pharma's Market Share | Senores Pharma's Product Launch Date |
|---|---|---|---|---|---|---|
| CAPSULE;ORAL | 300MG;50MG;40MG | | | 2,56,41,320.0 | | Jul-23 |
| CAPSULE;ORAL | 325MG;50MG;40MG | | | 49,88,154.0 | 11.2% | Mar-22 |
| TABLET;ORAL | 300MG;50MG | 6,04,582.0 | 4.8% | | | Feb-23 |
| TABLET;ORAL | 325MG;50MG | 46,34,823.0 | 2.8% | | | Feb-23 |

*Source: Bloomberg Symphony Health Data, Frost & Sullivan*

Some of the companies with active ANDAs include Senores Pharma, Dr Reddy's Lab, Quagen Pharmaceuticals, and Strides Pharma Science, to name a few. However, not all companies commercialize the approved ANDAs. As shown in the table above, the total US sales volume in the first eleven months of CY23 was 35.81 million for the selected strengths and formulations. The highest sales were for Acetaminophen, butalbital, caffeine, and capsules in 300/50/40mg strength, while the second highest sales were for 325/50/40mg strength. Senores Pharma gained an 11.2% volume market share in the 325/50/40mg product segment during the first eleven months of CY23.

**Chlorzoxazone:** Chlorzoxazone, a centrally acting muscle relaxant, is primarily prescribed to alleviate muscle spasms and associated discomfort. It is exclusively available in the form of oral tablets, offered in strengths ranging from 250 mg to 750 mg. Since the FDA approved the first generic version before 1982, the market for chlorzoxazone has expanded significantly. Presently, there are 17 Abbreviated New Drug Applications (ANDAs) approved for the drug, with notable companies such as Senores Pharma, Teva Pharmaceutical Industries Ltd., Belcher Pharmaceuticals LLC, and Corepharma LLC among the key players in this segment. Notably, Senores Pharma was the first company globally to identify CGT for Chlorzoxazone 250mg and launched the product in 2021 with six months exclusivity. Between 2016 and 2021, there was only one other company with approval for the product. This has allowed the company to enjoy a 60.9% volume market share in the first eleven months of CY23.

**Exhibit 2.27A: ANDA Approvals for Chlorzoxazone**

| Dosage Form and Route | Strength | Chlorzoxazone | Total |
|---|---|---|---|
| TABLET;ORAL | 250MG | 5 | 5 |
| TABLET;ORAL | 375MG | 9 | 9 |
| TABLET;ORAL | 500MG | 7 | 7 |
| TABLET;ORAL | 750MG | 9 | 9 |
| **Total** | | **10** | **10** |

*Source: FDA Orange Book; Frost & Sullivan*

*Note: Only includes active ANDAs, Data as of May 2024*

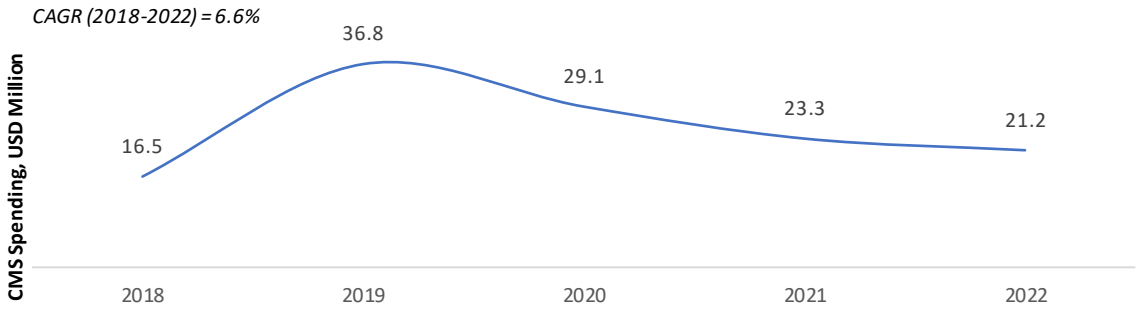
**Exhibit 2.27B: Volume Share of Senores Pharma, Chlorzoxazone, 11MCY23**

| Dosage Form and Route | Strength | Chlorzoxazone (Total Volume) | Senores Pharma's Market Share | Senores Pharma's Product Launch Date |
|---|---|---|---|---|
| TABLET;ORAL | 250MG | 7,04,490.0 | 60.9% | Oct-21 |
| TABLET;ORAL | 500MG | 3,56,33,078.0 | - | Mar-24 |

*Source: Bloomberg Symphony Health Data, Frost & Sullivan*

CMS spending on chlorzoxazone has exhibited an upward trend, reaching USD 21.2 million in 2022, compared to USD 16.5 million in 2018. As the population ages and the prevalence of musculoskeletal conditions rises, the demand for chlorzoxazone is anticipated to further escalate, prompting continued growth in both utilization and expenditure on the drug. In the table above, the total volume sales in the US for selected products during the first eleven months of CY23 amounted to 36.3 million units, with the highest sales attributed to the 500mg strength Chlorzoxazone tablets.

**Exhibit 2.28: CMS Spending on Chlorzoxazone: 2018- 2022**




*Source: Centers for Medicare & Medicaid Services*

**Diclofenac Potassium:** Diclofenac Potassium, a nonsteroidal anti-inflammatory drug (NSAID), is widely recognized for its potent anti-inflammatory, analgesic, and antipyretic properties. Its effectiveness extends to various conditions including gout, arthritis, migraines, and acute pain like sports injuries and post-surgical discomfort. Typically, available in 25mg and 50 mg oral tablets, the recommended dosage for adults ranges from two to three doses daily, adjusted based on the severity of the condition and individual response to treatment. The first generic version of Diclofenac Potassium received FDA approval in August 1998, marking the beginning of a broader market accessibility. Since then, there have been 13 Abbreviated New Drug Applications (ANDAs) approved for the drug, with companies like Aurobindo Pharma Ltd., Bionpharma Inc., Alkem Laboratories Ltd., and Senores Pharma among the key players in this segment.

**Exhibit 2.29A: ANDA Approvals for Diclofenac Potassium**

| Dosage Form and Route | Strength | Diclofenac Potassium | Total |
|---|---|---|---|

| | | | |
|---|---|---|---|
| CAPSULE;ORAL | 25MG | 3 | 3 |
| FOR SOLUTION; ORAL | 50MG | 3 | 3 |
| TABLET;ORAL | 25MG | 3 | 3 |
| TABLET;ORAL | 50MG | 7 | 7 |
| **Total** | | **13** | **13** |

*Source: FDA Orange Book; Frost & Sullivan*

*Note: Only includes active ANDAs, Data as of May 2024*

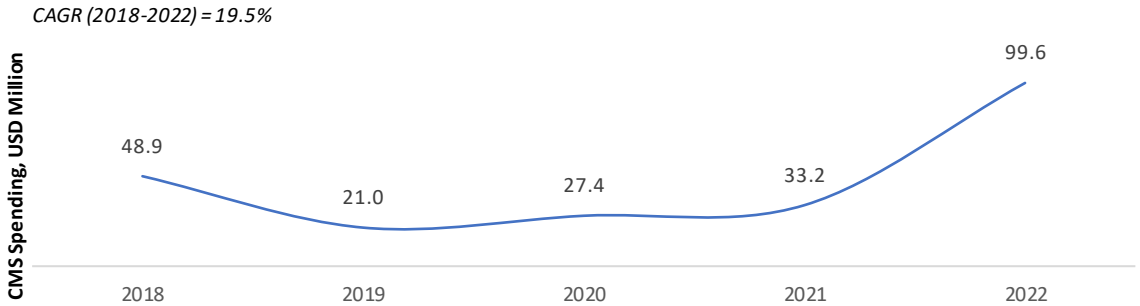
**Exhibit 2.29B: Volume Share of Senores Pharma, Diclofenac Potassium, 11MCY23**

| Dosage Form and Route | Strength | Diclofenac Potassium (Total Volume) | Senores Pharma's Market Share | Senores Pharma's Product Launch Date |
|---|---|---|---|---|
| TABLET;ORAL | 25MG | 38,10,452.0 | Not Available | Dec-23 |
| TABLET;ORAL | 50MG | 5,02,78,128.0 | Not Available | Mar-24 |

*Source: Bloomberg Symphony Health Data, Frost & Sullivan*

The expenditure by the CMS on Diclofenac Potassium reflects its substantial clinical utility and market demand. In 2018, CMS spending on the drug amounted to USD 48.9 million, experiencing a fluctuating but overall remarkable CAGR of 19.5% to reach USD 99.6 million in 2022.

**Exhibit 2.30: CMS Spending on Diclofenac Potassium: 2018- 2022**




*Source: Centers for Medicare & Medicaid Services*

**Ketorolac:** Nonsteroidal anti-inflammatory drug (NSAID) ketorolac tromethamine, also referred to as ketorolac, is prescribed to temporarily relieve moderate to severe pain. It is frequently prescribed for the management of postoperative pain, or the treatment of pain associated with conditions such as kidney stones or arthritis. The drug is available across several strengths in injectable, nasal, ophthalmic, and tablet formulations. As of April 2024, there are 30 ANDAs approved for the drug for companies like Sun Pharmaceutical Industries Limited, Apotex Inc., Senores Pharma, and Caplin Steriles Limited, to name a few.

**Exhibit 2.31A: ANDA Approvals for Ketorolac**

| Dosage Form and Route | Strength | Ketorolac | Total |
|---|---|---|---|
| INJECTABLE;INJECTION | 15MG/ML | 12 | 12 |
| INJECTABLE;INJECTION | 30MG/ML | 15 | 15 |
| SOLUTION/DROPS; OPHTHALMIC | 0.40% | 1 | 1 |
| SOLUTION/DROPS; OPHTHALMIC | 0.50% | 5 | 5 |
| TABLET;ORAL | 10MG | 9 | 9 |

*Source: FDA Orange Book; Frost & Sullivan*

*Note: Only includes active ANDAs, Data as of May 2024*

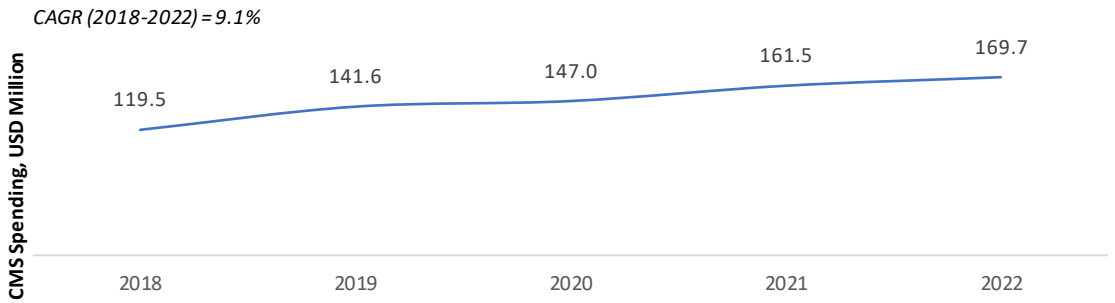
**Exhibit 2.31B: Volume Share of Senores Pharma, Ketorolac, 11MCY23**

| Dosage Form and Route | Strength | Ketorolac Total Volume | Senores Pharma's Market Share | Senores Pharma's Product Launch Date |
|---|---|---|---|---|
| TABLET;ORAL | 10MG | 4,95,33,286.0 | 14.6% | May-22 |

*Source: Bloomberg Symphony Health Data, Frost & Sullivan*

With its extensive utilization in outpatient clinics and hospital settings, CMS spending on ketorolac has grown by 9.1% CAGR between 2018 and 2022.
In the first eleven months of CY23, 49.5 million units of Ketorolac 10mg tablets were sold. Senores Pharma, which launched this product in May 2022, secured a volume market share of 14.6% in the first eleven months of CY23.

**Exhibit 2.32: CMS Spending on Ketorolac: 2018 - 2022**




*Source: Centers for Medicare & Medicaid Services*

**Mexiletine Hydrochloride:** Mexiletine Hydrochloride, also known as Mexiletine is primarily used as an antiarrhythmic agent for the treatment of irregular heartbeats and as a treatment for certain types of neuropathic pain. The drug is available as an oral capsule in the strengths of 150mg, 200mg, and 250mg. There are currently 8 ANDAs approved for the product across all its available strengths for companies including but not limited to Senores Pharma, ANI Pharmaceuticals, Hetero Drugs, and Teva Pharma.

**Exhibit 2.33A: ANDA Approvals for Mexiletine Hydrochloride**

| Dosage Form and Route | Strength | Mexiletine Hydrochloride | Total |
|---|---|---|---|

| | | | |
|---|---|---|---|
| CAPSULE;ORAL | 150MG | 8 | 8 |
| CAPSULE;ORAL | 200MG | 8 | 8 |
| CAPSULE;ORAL | 250MG | 8 | 8 |
| **Total** | | 8 | **8** |

*Source: FDA Orange Book; Frost & Sullivan*

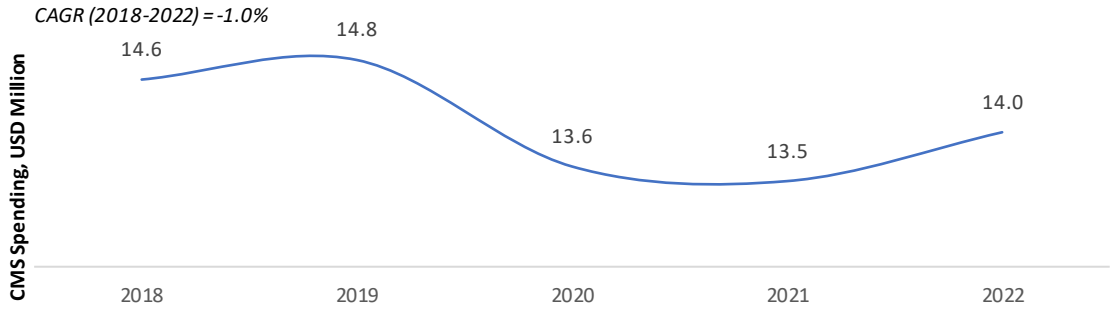
*Note: Only includes active ANDAs, Data as of May 2024*

**Exhibit 2.33B: Volume Share of Senores Pharma, Mexiletine Hydrochloride, 11MCY23**

| Dosage Form and Route | Strength | Mexiletine Hydrochloride, Volume | Senores Pharma's Market Share | Senores Pharma's Product Launch Date |
|---|---|---|---|---|
| CAPSULE;ORAL | 150MG | 1,92,87,002.0 | 13.8% | Jan-22 |
| CAPSULE;ORAL | 200MG | 65,97,330.0 | 16.2% | Jan-22 |
| CAPSULE;ORAL | 250MG | 10,69,409.0 | 10.0% | Jan-22 |

*Source: Bloomberg Symphony Health Data, Frost & Sullivan*

**Exhibit 2.34: CMS Spending on Mexiletine: 2018- 2022**




*Source: Centers for Medicare & Medicaid Services*

CMS spending on the drug was USD 14.0 million in 2022. The demand for mexiletine is significantly driven by the prevalence of cardiac arrhythmias. Conditions such as ventricular tachycardia and other serious irregular heartbeats that require effective management contribute to the need for this medication. As the global population ages, the incidence of cardiac conditions and chronic pain increases, the demand for the drug is expected to remain steady.

There were a total of 27.0 million units of Mexiletine sold across all three strengths of 150mg, 200mg, and 250mg, with the highest sales for the 150mg strength in the first eleven months of CY23. Senores Pharma started commercializing these products in January 2022 and has since secured a 14.2% overall volume market share, with 13.8%, 16.2%, and 10.0% volume market shares across the 150mg, 200mg, and 250mg strengths, respectively in the first eleven months of CY23.

***Key Risks and Challenges in the US Pharma Market***

- **Regulatory Compliance:** The FDA's rigorous approval process ensures drug safety and efficacy but can create significant challenges, particularly for companies not compliant with quality and regulatory requirements. This is evidenced by the continuing issuance of OAIs and 483s. Companies, that maintain proactive compliance strategies and stay ahead of regulatory requirements and changes can establish a competitive edge in the market.
- **Reimbursement Pressures:** Increasing pressure from the government, healthcare providers, and the public to reduce drug prices is driving legislative measures, such as the Inflation Reduction Act of 2022, which aims to control drug costs by allowing Medicare to negotiate prices for certain high-cost drugs. Reimbursement policies, formulary decisions, and pricing negotiations can impact the profitability of generic drugs.
- **Price Erosion:** In addition to downward pricing pressure, owing to market dynamics such as increasing competition, changes in reimbursement policies, customer consolidation, supply-demand gaps, etc. there is a constant risk of price erosion. Companies that can design an optimal product portfolio, incorporating a selection of complex and low-competition density drugs, can find insulation from pricing pressures, as lower competition results in reduced price erosion.
- **Market Access and Distribution:** The pharmaceutical value chain in the US has some unique characteristics. The involvement of stakeholders like Pharmacy Benefit Managers (PBMs) adds a layer to the traditional supply chain. PBMs manage prescription drug benefits for insurers and large organizations. They negotiate prices, handle formularies, process claims, and sometimes run specialty pharmacies. Additionally, the market is uniquely consolidated with a few key players spanning the entire value chain from PBMs to pharmacies, and insurance services. It influences the dynamics of negotiations and needs strong relationships and access to these key players for successful market access.
- **Supply Chain Disruptions:** As evidenced through drug shortages, the pharmaceutical supply chain is vulnerable. Ensuring the resilience and continuity of the supply chain, including sourcing raw materials and managing manufacturing capacities, is critical to mitigate risks and maintain product availability.
- **Generic Saturation:** In mature markets, such as the US, many blockbuster drugs have already lost patent protection, leading to intense competition among generic manufacturers. Finding niche opportunities or developing complex generics can help companies differentiate themselves in a crowded market.

#### 2.1.1.1 THE US CDMO AND CMO MARKET OVERVIEW

**The dependence on Contract Development and Manufacturing Organizations (CDMOs) and Contract Manufacturing Organizations (CMOs) has increased as they offer appended manufacturing capacities, access to new markets, mitigate investment, production, & supply risk, and bring the necessary technology overhaul.**

The pharmaceutical industry faces formidable challenges, including but not limited to

- substantial capital expenditure necessary for establishing and sustaining extensive manufacturing facilities,
- developing capabilities and investing in advanced R&D to develop a diverse product portfolio,
- building technical proficiency
- recruiting and retaining skilled personnel for drug manufacturing and quality control,
- managing pricing pressure from payors,
- navigating supply chain disruptions, and

- managing protracted regulatory approval processes.

To overcome these obstacles, pharmaceutical firms have turned to external partners. They are increasingly looking to CDMOs and CMOs as strategic collaborators to circumnavigate these challenges. Historically, pharmaceutical companies focused on high-volume product sales and forged partnerships with contract service providers to augment their manufacturing capabilities. Concurrently, contract manufacturers thrived by consolidating demand and reaping the benefits of economies of scale. The relationship between pharmaceutical sponsors and CDMOs and CMOs has since evolved, and pharmaceutical sponsors are increasingly forming partnerships with CDMOs and CMOs to ensure the quality of their products, expand their market presence, and receive regulatory support. More specifically, partnerships with CDMOs and CMOs help pharma companies with:

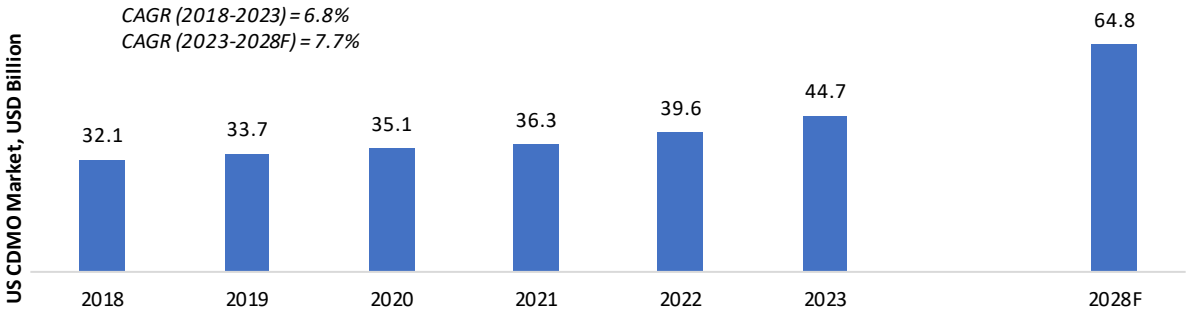
- **Focus on core competencies and move from Capex to Opex model:** Outsourcing non-core functions allows pharmaceutical and biotech companies to avoid high capital expenditure, allocate resources more efficiently, and concentrate on their core competencies, such as brand building, marketing, and strategic planning. Hence, pharma companies are drifting from Capex to Opex business models to focus on functions that drive the most value and, in the process, find co-owners for their assets through co-development and co-commercialization deals with contract service providers.
- **Cost advantages:** CDMOs and CMOs can typically help gain 35%-70%[36] savings by bringing their experience, expertise, and economies of scale in managing drug development and manufacturing.
- **Early to Market advantage:** By outsourcing manufacturing, pharmaceutical companies can avoid the time-consuming process of building and validating their manufacturing facilities, significantly reducing the time required to bring a drug to market.
- **Access to specialized and global talent:** CDMOs and CMOs employ highly skilled professionals with diverse backgrounds and extensive industry experience, offering valuable insights and knowledge across various therapeutic areas and disciplines. Additionally, these organizations maintain global networks and collaborations, enabling access to cutting-edge technologies, regulatory intelligence, and market insights from around the world. This global expertise allows pharmaceutical companies to leverage external resources, optimize internal processes (e.g., Human Resource Management), and utilize new-age technology.
- **Flexibility and scalability:** CDMOs and CMOs can scale production up or down as needed, allowing companies to efficiently manage variations in demand owing to unforeseeable changes (e.g., pandemics, wars, inflation) in the commercial market.
- **Access to advanced technologies:** With the rapid turnaround of technologies and processes, it is becoming increasingly difficult for pharmaceutical companies to keep up with the pace. CDMOs and CMOs on the other hand, invest significantly in cutting-edge technologies such as continuous and additive manufacturing, modular manufacturing, and HPAPI manufacturing, to name a few, to offer these benefits to their pharmaceutical customers.

These partnerships allow for the development of more complex products and formulations, better lifecycle management of drugs, as well as the establishment of local distribution channels. Additionally, sharing the risk with CDMOs and CMOs helps to reduce exposure and speed up project timelines, giving pharmaceutical companies a competitive edge in new markets.

[36] Industry KOLs

The US will continue to dominate the demand for outsourcing services, mostly as smaller pharma and biotech companies that prefer asset-light models enter the market, and external pricing pressure mandates working with partners that can help control the cost of manufacturing through economies of scale.

**Exhibit 2.35: US CDMO/CMO Market, 2018 - 2028F**




*Source: Frost & Sullivan*

Increasing trends in outsourcing (with average outsourcing penetration expected to jump from ~27% in 2018 to ~37% in 2028[37]) stemming from growing drug complexity and rapid technological turnaround, upcoming loss of exclusivity for drugs driving high-volume demand for generics, and increased business model shift from Capital Expenditures (Capex) to Operational Expenditures (Opex) will help propel the CDMO market to grow faster than the pharma market. As a result, the US CDMO market was valued at USD 44.7 billion in 2023 and is forecasted to reach USD 64.8 billion by 2028, growing at a CAGR of 7.7%. Moreover, the US CDMO market is the largest globally, accounting for 40-45% of the global share across the forecast period.

In the rapidly expanding landscape of CDMOs and CMOs, a multitude of service providers have emerged to meet the escalating demand. However, pharmaceutical sponsors increasingly favor partnering with one-stop-shop solution providers that seamlessly integrate both development and manufacturing services within a unified framework. This inclination stems from smoother project management, tangible cost & time efficiency, integrated expertise, and convenient tech transfer. Moreover, US-based CDMOs and CMOs offer some unique advantages to their partners, as listed below:

- US-based CDMOs and CMOs enjoy a strategic advantage due to their proximity to the largest pharmaceutical market (US pharma market) globally. This facilitates communication, collaboration, and logistical coordination, leading to faster response times and more efficient project management.
- This geographical advantage, coupled with preferential treatment in bidding for government contracts, contributes significantly to their competitive edge. The US government employs various procurement channels to acquire medicines, including direct purchases, contracts, and agreements with pharmaceutical firms. These government contracts typically span long-term durations, often extending nearly five years. Such extended contracts offer stability and reliability to businesses, ensuring a predictable revenue stream throughout the contract's lifespan. Furthermore, certain government contracts feature fixed-price arrangements, wherein the pricing is established upfront and remains consistent throughout the contract term. This pricing model adds certainty for both the government and the contractor, fostering transparent and

[37] Industry KOLs

predictable financial arrangements. Securing government contracts not only provides a stable revenue source but also serves as a powerful endorsement of a company's capabilities and offerings. It validates the quality and reliability of a CDMO's products or services, enhancing its reputation and credibility in the industry.

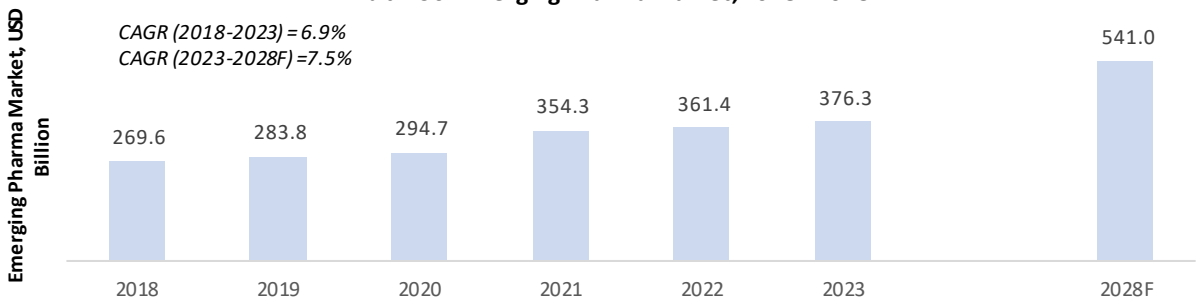
- US-based CDMOs and CMOs operate in accordance with stringent regulatory standards set by the U.S. FDA. Pharmaceutical companies often prioritize working with CDMOs and CMOs that adhere to FDA regulations, ensuring compliance and mitigating regulatory risks.
- Additionally, The United States is a hub for pharmaceutical innovation, with a robust ecosystem of research institutions, biotech startups, and industry-leading companies. US-based CDMOs and CMOs often have access to cutting-edge technologies, expertise, and resources, enabling them to offer innovative solutions and support to pharmaceutical clients.

Moreover, The United States offers strong intellectual property (IP) protection laws, safeguarding proprietary technologies, formulations, and processes developed by pharmaceutical companies. Working with US-based CDMOs and CMOs provides assurance that sensitive IP will be protected throughout the development and manufacturing process.

## 2.2 EMERGING PHARMACEUTICAL MARKET OVERVIEW

**Population growth, expanding disease burden, local government prioritization of healthcare, private sector investment in improving infrastructure, and local manufacturing are helping emerging markets outpace the growth of developed markets.**

**Exhibit 2.36: Emerging Pharma Market, 2018 - 2028F**




*Source: IQVIA Global Use of Medicines- 2024, Evaluate Pharma, Frost & Sullivan*

**Exhibit 2.37A: Emerging Pharma Market by Product Type, 2018 - 2028F**

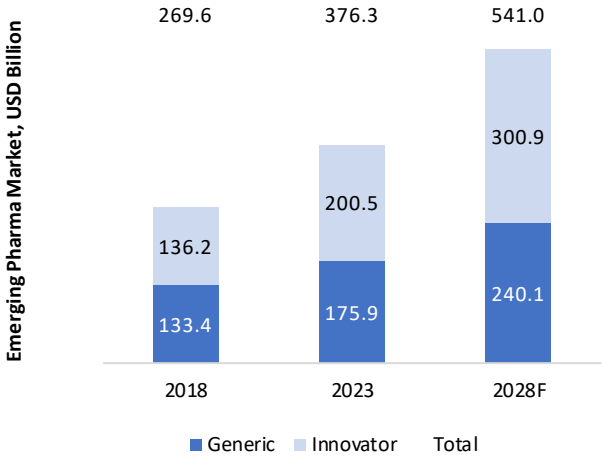
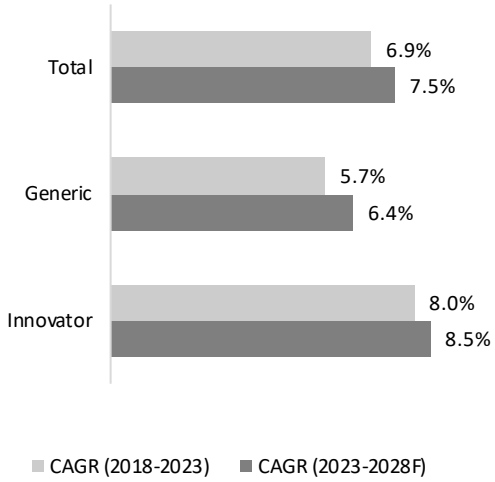



**Exhibit 2.37B: Growth Rate of Emerging Pharma Market by Product Type, 2018 - 2028F**




*Source: IQVIA Global Use of Medicines- 2024, Evaluate Pharma, Frost & Sullivan*

**Exhibit 2.38A: Emerging Pharma Market by Regions, 2018 - 2028F**

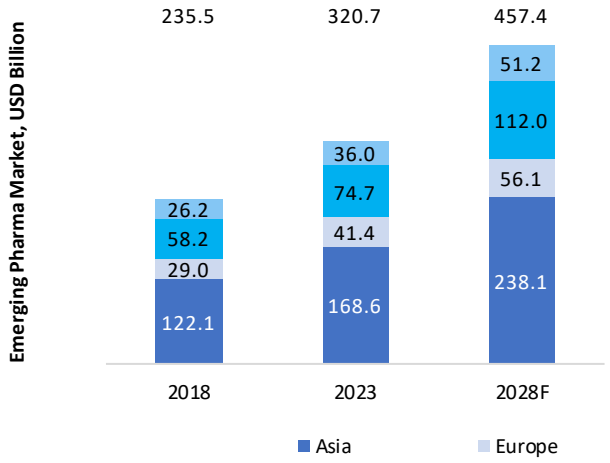
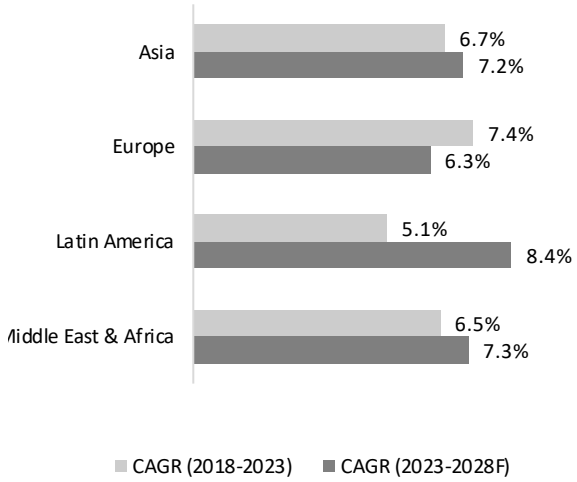



**Exhibit 2.38B: Growth Rate of Emerging Pharma Market by Regions, 2018 - 2028F**




*Source: IQVIA Global Use of Medicines- 2024, Evaluate Pharma, Frost & Sullivan*

Emerging markets have surpassed several developed economies, particularly in Europe, in pharmaceutical spending, reaching a total market size of USD 376.3 billion in 2023. A dual dynamic drives this shift: while developed economies are tightening healthcare budgets, many emerging markets are prioritizing healthcare, investing in infrastructure, services, domestic industry development, and broader health insurance coverage. Secondly, the paying power, affordability, and accessibility have ramped up significantly in emerging economies.

This strategic shift positions emerging markets as pivotal contributors to pharmaceutical sales growth in the coming years, projecting a CAGR of 7.5% between 2023 and 2028. Approximately 45% of this growth

will stem from generic drugs, indicating a pronounced preference for cost-effective options, especially in Asia, Europe, and the Middle East, encompassing key nations like Russia, India, China, Indonesia, Egypt, KSA, and Turkey.

Despite the increasing popularity of innovative drugs, generics are expected to maintain their importance in these price-sensitive markets. Generic drugs are typically more affordable than their brand-name counterparts, making them accessible to a larger portion of the population, especially in emerging markets where healthcare expenses may be a significant burden for patients, who rely heavily on out-of-pocket expenditures.

Even traditionally brand-sensitive regions like the Middle East are gravitating towards generics, implementing strategies such as special incentives for off-patent drugs and streamlined approval processes to reduce pharmaceutical expenditure.

Moreover, even healthcare systems and government health programs in emerging markets prefer the use of cost-effective alternatives that allow for greater coverage and provision of essential medications to a larger population. Consequently, governments often introduce policies such as generic substitution policies, reference pricing systems, tendering and procurement programs, price controls, and incentives for local production to nudge greater use of generics.

While the overall demand for pharmaceutical products is increasing in the region with the growth of population and affluence to opt for healthcare services, the evolving demand is characterized by a shift towards noncommunicable diseases like cancer, diabetes, and cardiovascular diseases as healthcare access expands and urbanization accelerates. This is creating lucrative opportunities for global pharmaceutical portfolios originally focused on regulated markets.

**The traditional price sensitivity of the markets, coupled with the government's localization incentives and price capping mechanisms, particularly favor the generics segment, which has outpaced the growth of the total pharma segment in the region.**

### 2.2.1 Indian Pharmaceutical Market Overview

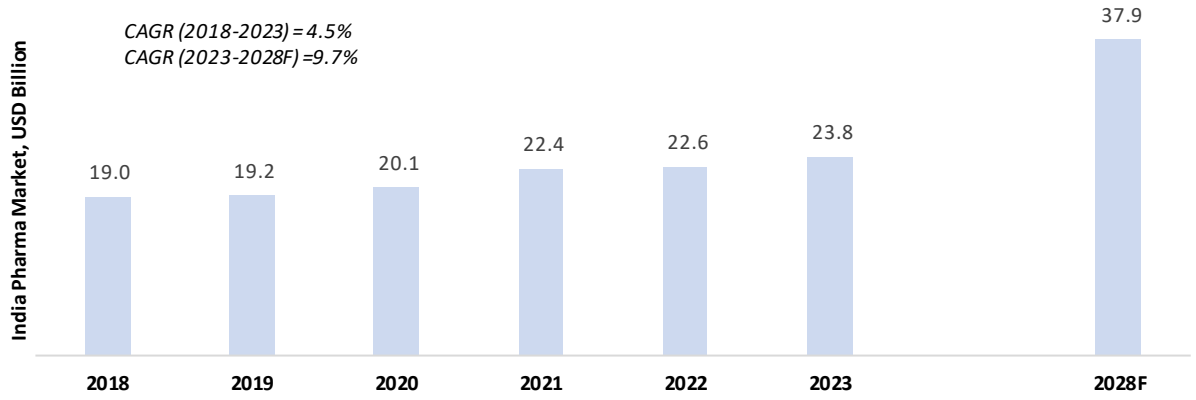
**The enviable growth of the Indian pharmaceutical market (IPM) is attributable to the government's prioritization of the segment, increasing chronic disease incidence, availability of affordable but innovative generics, and improved nationwide access to healthcare.**

**With a contribution of nearly 1.3%[38] to India's GDP, IPM registered a 4.5% CAGR in the last five years and a forecast of 9.7% for the next five years[39].**

[38] Make in India Initiative

[39] The high variance in growth rates stems from the currency conversion factor. While actual INR to USD conversion has been assumed till 2023, a constant rate has been assumed for the future years.

**Exhibit 2.39: India Pharma Market, 2018-2028F**

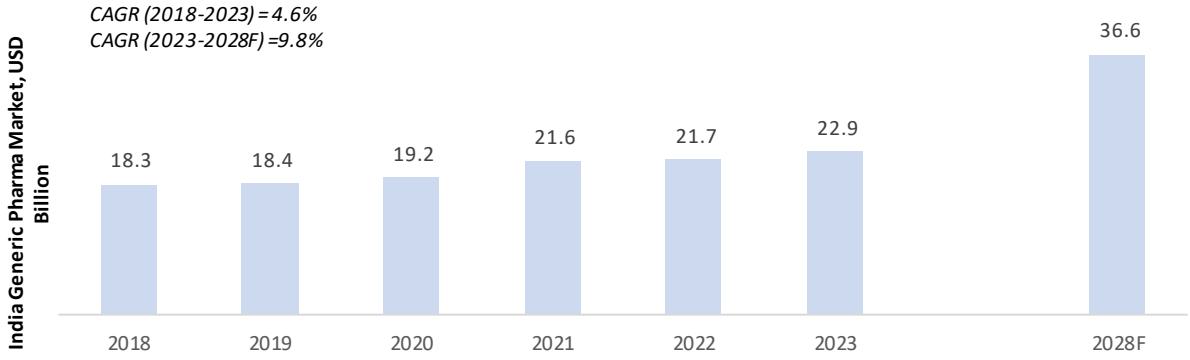



*Source: IQVIA -Indian Pharmaceutical Market Insight, Pharmarack, Frost & Sullivan*

The Indian pharmaceutical market is among the fastest-growing in the world, witnessing a value increase from USD 19.0 billion in 2018 to USD 23.8 billion in 2023. The pharmaceutical market in India is dominated by generics, which account for around 96.2% of drug consumption in the country in terms of value. However, only about 10% of the drugs in the domestic market are unbranded/generic generics, marketed with just their chemical names as commodity generics.

**Changing disease patterns, increased affordability, access, awareness, and government and private insurance expansion are fostering increased demand and consumption of pharma drugs; however, high OOP keeps the demand in favor of affordable generics.**

**Exhibit 2.40: India Generic Pharma Market, 2018-2028F**




*Source: IQVIA -Indian Pharmaceutical Market Insight, Pharmarack, Frost & Sullivan*

Some of the growth drivers for rapid growth in the IPM include an increase in chronic patient population, insurance penetration, trade generics, demand from tier II and III cities, and government schemes focused on drug access.

**Growth in Hospital Business Segment:** In recent years, India has witnessed significant growth in hospitals and hospital beds. From a current bed density of 1.6 per 1000 people[40], the country aims to achieve 2.0

[40] World Bank Data, One Health Trust

per 1000 by 2030, translating into 3.0 million beds by 2030[41]. While affordability and accessibility of the local population to healthcare services have resulted in an increased number of opted surgeries, medical tourism has also boosted the segment. For instance, medical tourists grew from 182,000 in 2020 to more than 500,000 in 2023[42]. India is increasingly becoming a favored destination as medical travelers visiting India often save between 30% and 70% on treatments compared to those sought in developed nations. This has resulted in a rapidly growing critical care drug segment. According to IQVIA, the hospital channel market was estimated to be between USD 3.0-3.6 billion in 2018 and is projected to continue growing at a similar pace as the overall Indian Pharmaceutical Market (IPM). In 2023, the market is estimated to be USD 4.7-5.7 billion and is expected to reach USD 7.4-9.0 billion by 2028. Some of the key products sold through hospital channels as critical care drugs include anesthesia, antibiotics, pain management, and intrathecal therapies. The competition in the market is comparatively limited with some of the suppliers in India including Piramal Pharma, Senores Pharma, Aurobindo Pharmaceuticals, and Mankind Pharmaceuticals, to name a few.

With a growing number of surgical and medical procedures in hospitals, demand for critical drugs such as injectables has also increased. Additionally, globally, almost 64%[43] of the new drug pipeline consists of injectables, indicating the growing significance of the segment and the next wave of opportunity for generic drug companies.

**Exhibit 2.41A: Indian Pharma Market by Dosage Form, 2018-2028F**

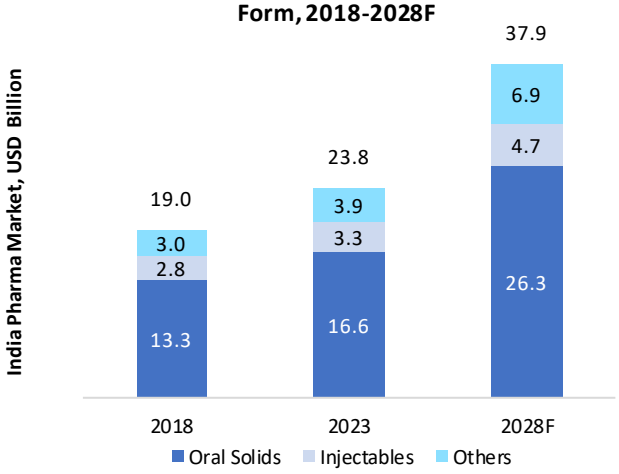
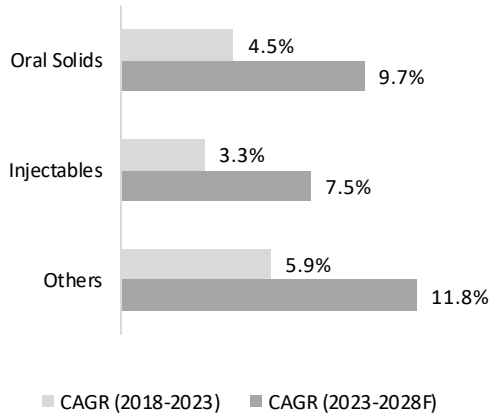



**Exhibit 2.41B: Growth Rate of Indian Pharma Market by Dosage Form, 2018-2028F**




*Source: Pharmarack, Frost & Sullivan*

*Note: Others include implantable, inhalable, aerosol, etc.*

Oral solids have dominated the Indian pharma market, owing to ease of administration, patient comfort, flexibility in dosing, and ease of manufacturing- lower manufacturing costs translating to overall lower costs. Moreover, the market will continue to grow in the country, given the innovations in oral solid formulations ranging from modified release formats to orally disintegrating tablets, lipid-based

[41] PIB: Committed to advancing the agenda of Universal Health Coverage through affordable and accessible healthcare for all

[42] Ministry of Tourism: Development of Medical Tourism Hubs

[43] Citeline - Pharmaprojects

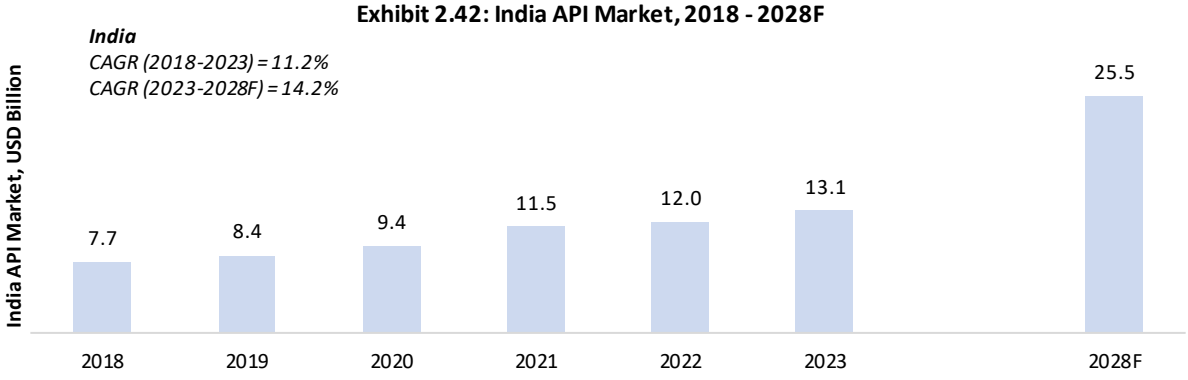
formulations, coated particles, and multi-particulate systems, to name a few. Consequently, the oral solids segment is expected to grow at a CAGR of 9.7%, from USD 16.6 billion in 2023 to USD 26.3 billion by 2028.

At the same time, other formulations like injectables, inhalations, and liquids are also witnessing rapid growth. Injectables pegged at USD 3.3 billion in 2023 are expected to grow at a CAGR of 7.5% from 2023 to 2028 to reach USD 4.7 billion in 2028. The growth of the injectables market is fueled by technical and scientific advantages over other dosage forms. Injectable medications offer precise dosing, rapid onset of action, and enhanced bioavailability compared to oral formulations. They can also be formulated as long-acting or sustained-release formulations, improving patient compliance and convenience. Injectable drugs are more stable and compatible with complex molecules, making them ideal for targeted drug delivery and the administration of biologics. While injectables are preferred for fast-acting and precise dosing characteristics, topical formulations and inhalation products are preferred for their localized and disease-specific action. Oral liquids have also gained popularity in pediatric and geriatric formulations, while implants are also beginning to gain traction in the country. As a result, the "others" segment, including liquids, implants, sprays, inhalation products, etc., is expected to contribute the highest growth of 11.8% between 2023 and 2028.

#### 2.2.1.1 INDIAN API MARKET OVERVIEW

**The growth in the formulations market also translates into corresponding growth in the API market. The Indian API market is expected to grow at 14.2% outpacing the growth of the overall Indian pharma market as it increases API production to support its domestic formulations industry for high-volume generic as well as high-value innovator drugs.**

**Exhibit 2.42: India API Market, 2018 - 2028F**




*Source: Frost & Sullivan*

The demand for pharmaceutical products corresponds directly to API sales, and as this demand grows, so does the need for APIs. As disease patterns shift from acute to chronic and translate into high drug volume consumption, the access to healthcare facilities and affordable medicine increases, along with an increase in the purchasing power of the middle class in the country; the growth of the API industry will follow suit. Moreover, with the increasing adoption of novel drugs, including biologics, coupled with the volume growth of the generics industry, the segment is expected to grow steadily. Notably, there is a rising preference for complex APIs like Highly Potent Active Pharmaceutical Ingredients (HPAPIs) or those derived from fermentation, contributing to improved drug efficacy and increasing production costs.

India is the third-largest producer of APIs, commanding an impressive 8% share of the Global API Industry. With over 500 distinct APIs manufactured within its borders, India emerges as a pivotal contributor, supplying 57% of APIs listed on the prequalified World Health Organization (WHO) roster.[44].

The escalating tensions between Western nations and China have catalyzed a significant shift in the sourcing strategies of global pharmaceutical majors. Moreover, as China started following stringent environmental norms leading to production cuts during winters (approximately 40% of the factories in China were shut down to curb air pollution), followed by geopolitical changes, trade wars, and the COVID-19 pandemic, large companies and multi-national companies recognized the need to de-risk their supply chain. Increasingly, these companies are seeking alternative API providers outside China. India has swiftly risen to prominence as a compelling alternative source for bulk drugs, showcasing a remarkable trajectory of growth in this sector. Moreover, India has a distinctive advantage over its other Asian peers such as Bangladesh, Vietnam, and Indonesia, because of its infrastructure, large and skilled English-speaking population, large pool of scientists, competitive labor prices, and sophistication in information and communications technology. The early signs of adoption of this strategy in favor of India are already reflected in the Indian Ministry of Statistics and Programme Implementation's Index of Industrial Production for the Manufacture of Pharmaceuticals, Medicinal Chemicals, and Botanical Products, which increased to 233.4 in FY24, up from 216.2 in FY23.

Additionally, the Indian API market particularly benefits from government policies promoting local production of APIs. From Production Linked Incentive (PLI) schemes, offering incentives ranging from INR 20 crore to INR 400 crore to bulk drug park development, the government's push for local formulation and API manufacturing is supporting the development of capabilities in complex areas such as fermentation, allowing the manufacturing of even broader portfolio of products and thus propelling the market on an accelerated growth path. This is also reflected in the growing number of FDA-approved API manufacturing sites in India, which has increased from 173 in 2018 to 209 in 2023.

Consequently, the India API market, valued at USD 13.1 billion in 2023, is forecasted to grow at a CAGR of 14.2% to reach USD 25.5 billion by 2028.

Overall, the Indian API market thrives on several overarching growth drivers:

- Burgeoning global demand for affordable medications, especially generics, leveraging India's cost competitiveness, skilled labor, and economies of scale.
- Coupled with a favorable regulatory environment that prioritizes adherence to international quality standards, this fosters enhanced market access and export opportunities.
- Furthermore, significant investments in research and development (R&D) drive technological advancements, enabling the production of complex APIs and specialty chemicals.
- Strategic collaborations and government initiatives, such as "Make in India," further bolster domestic manufacturing and export-oriented growth.
- Finally, the escalating burden of chronic diseases amplifies the need for pharmaceuticals, underpinning sustained growth in the Indian API market.

**Indian formulation companies are developing capabilities in APIs to enjoy backward integration synergies.**

[44] Invest India: Harnessing India's API Potential

Indian formulation companies such as Senores Pharma have started investing in backward integration, which involves formulation companies acquiring or establishing their own API manufacturing capabilities to benefit from:

- **Supply Chain Control:** Formulation companies gain greater control over their supply chain by producing their APIs. By ensuring a stable and reliable source of raw materials, they can mitigate risks associated with API shortages, quality issues, or price fluctuations.
- **Cost Savings:** Vertical integration allows formulation companies to capture cost efficiencies by eliminating markups associated with purchasing APIs from third-party suppliers. By internalizing API production, companies can potentially reduce production costs, improve margins, transfer cost benefits to their customers, and enhance overall profitability.
- **Quality Assurance:** Formulation companies can maintain stringent quality standards by overseeing API production in-house. They have greater oversight of manufacturing processes, quality control measures, and compliance with regulatory requirements, thereby ensuring the integrity and purity of the APIs used in their products.
- **Flexibility and Innovation:** With in-house API manufacturing capabilities, formulation companies have the flexibility to customize API specifications to meet specific formulation requirements. This enables them to innovate more freely, develop proprietary formulations, and differentiate their products in the market.
- **Reduced Time to Market:** Vertical integration streamlines the product development process, minimizing dependencies on external suppliers and accelerating time to market for new formulations. Additionally, it offers opportunities for optimizing manufacturing workflows and responding more swiftly to market demands.
- **Competitive Advantage:** Vertical integration can strengthen a company's competitive position by enhancing product offerings and solidifying relationships with customers and stakeholders.
- **Diversified revenue stream and business resilience**: Developing API capabilities, particularly for high-value Oncology APIs, also allows companies to sell APIs in the merchant market, contributing to enhanced financial stability, mitigation of revenue risk, and positioning the company for long-term sustainability.

#### 2.2.1.2 ROLE OF INDIA IN GLOBAL SUPPLY OF API AND FORMULATIONS

**While the growth in the domestic market is undeterred, India has gained new strides in the export market, particularly since emerging as a reliable supplier during the pandemic.**

India has been aptly crowned Pharmacy of the World, particularly for its manufacturing prowess and contributions to the global pharma sector. India is the largest provider of generic medicines worldwide, holding a 20% share in global supply by volume, encompassing a diverse range of 60,000 generic brands across 60 therapeutic categories. The industry's global reach is underscored by the fact that India exports pharmaceuticals to over 200 countries, supplying over 50% of Africa's generic medicine needs, almost 40% of the generic demand in the US, and about 25% of all medicines in the UK.[45].

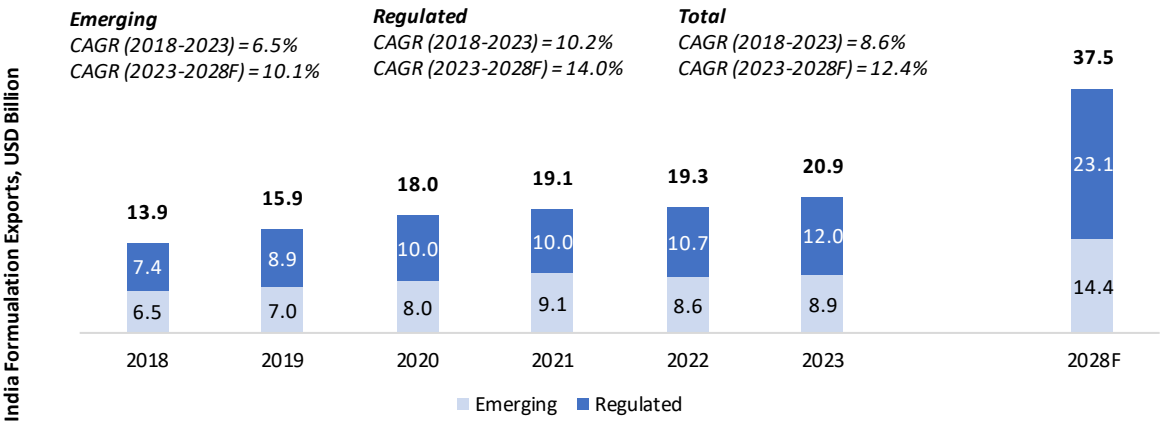
With a robust infrastructure, India boasts the highest number of US-FDA-compliant pharmaceutical plants outside the US. It houses over 3,000 pharmaceutical companies and has an extensive network of over 10,500 manufacturing facilities. The sector is further supported by a highly skilled resource pool, including

[45] Invest India: Formulating success: The Indian pharmaceutical industry.

500 API manufacturers contributing approximately 5.2% to the global API Industry by value[46]. The total pharmaceutical exports (API + FDF) for 2023 reached USD 24.0 billion, highlighting the sector's global competitiveness.

**While FDF exports have grown by 8.6% in the last five years, with strong growth in regulated markets, APIs have grown at 4.7% on the back of semi-regulated/ unregulated markets.**

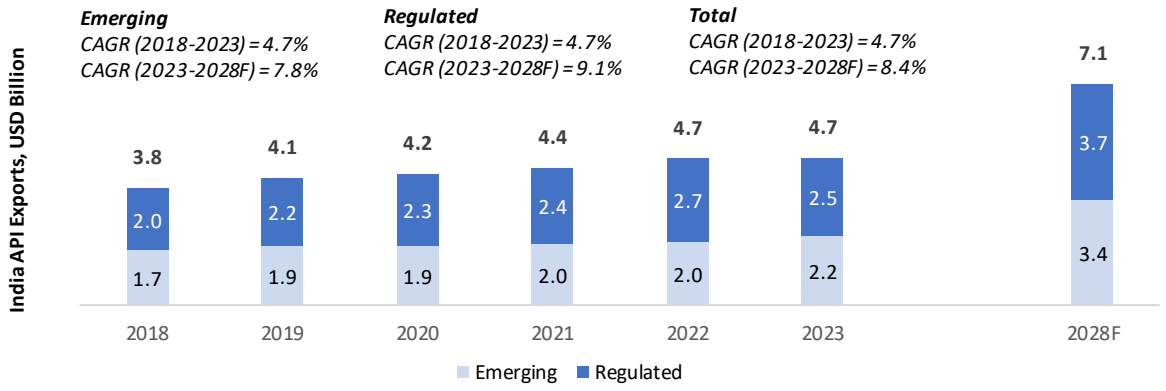
**Exhibit 2.43: India's Formulation Exports by Value, 2018 - 2028F**




*Source: Ministry of Commerce and Industry, Frost & Sullivan*

Globally, India is the 12th largest exporter of pharmaceutical formulations by value.[47]. Formulation exports from India have grown from USD 13.9 billion in 2018 to USD 20.9 billion in 2023 and are expected to grow to USD 37.5 billion by 2028 at a CAGR of 12.4% from 2023 to 2028. Regulated markets account for more than 50% of the share by value, partly because of the comparatively high value per unit. In 2018, regulated markets contributed USD 7.4 billion to total exports and grew at a CAGR of 10.2% from 2018 to 2023. Formulation exports to emerging markets (unregulated and semi-regulated markets) were valued at USD 12.0 billion in 2023, up from USD 6.5 billion in 2018.

**Exhibit 2.44: India's API Exports by Value, 2018 - 2028F**




*Source: Ministry of Commerce and Industry, Frost & Sullivan*

[46] Invest India Report

[47] IBEF: Pharmaceuticals- 2023; Trademap

*Note: API Exports comprise bulk drugs and intermediates.*

While India imports some bulk drugs, it is also one of the largest API exporters in global markets. High process efficiencies, the experience of working with regulatory bodies across the globe, and cost competitiveness have allowed India to emerge as one of the world's largest API suppliers. In 2018, India exported USD 3.8 billion worth of API, which jumped to USD 4.7 billion in 2023 and is expected to reach USD 7.1 billion by 2028, growing at a CAGR of 8.4% from 2023 to 2028. The export to regulated markets in 2018 was USD 2.0 billion and grew at a CAGR of 4.7% from 2018 to 2023. The API exports to semi-regulated markets were at USD 1.7 billion in 2018 and grew at a similar CAGR of 4.7% from 2018 to 2023 and will reach USD 2.2 billion in 2023.

The supply from India has particularly grown in the fast-growing pharmaceutical markets of Africa, the Middle East, and APAC. The attractiveness of Indian pharmaceutical products lies in their ability to reconcile affordability with uncompromising quality standards, a characteristic that resonates particularly well with semi-regulated markets seeking optimal healthcare solutions at competitive prices. Some of the markets have increasingly imported from India and are listed below.

**Exhibit 2.45: Exports of Formulations and API from India to Select Countries, 2018-2023**

| Country | API Exports (2018-2023) | API Export CAGR (2018-2023) | Formulation Exports (2018-2023) | Formulation Export CAGR (2018-2023) |
|---|---|---|---|---|
| **Azerbaijan** | 0.4 | 23.4% | 43.9 | 18.6% |
| **Democratic Republic of Congo** | 55.1 | 9.3% | 813.4 | 17.9% |
| **Georgia** | 4.2 | 12.4% | 141.0 | 26.4% |
| **Ghana** | 131.0 | 3.2% | 740.8 | 11.3% |
| **Guatemala** | 45.4 | 3.3% | 322.4 | 15.1% |
| **Kenya** | 253.9 | 6.2% | 1,603.5 | 9.1% |
| **Kuwait** | 7.1 | 5.7% | 22.3 | 28.1% |
| **Libya** | 0.2 | 56.8% | 79.6 | 8.4% |
| **Peru** | 67.6 | -1.2% | 539.4 | 12.5% |
| **Philippines** | 126.5 | -0.7% | 1,630.5 | 12.7% |
| **Tanzania** | 85.8 | 23.2% | 1,321.6 | 15.4% |
| **Uganda** | 78.5 | -11.3% | 1,001.3 | 0.6% |
| **Uzbekistan** | 11.8 | 16.4% | 677.6 | 12.4% |

| | | | | |
|---|---|---|---|---|
| **Vietnam** | 554.9 | 6.5% | 847.3 | 1.7% |

*Source: Ministry of Commerce and Industry, Frost & Sullivan*

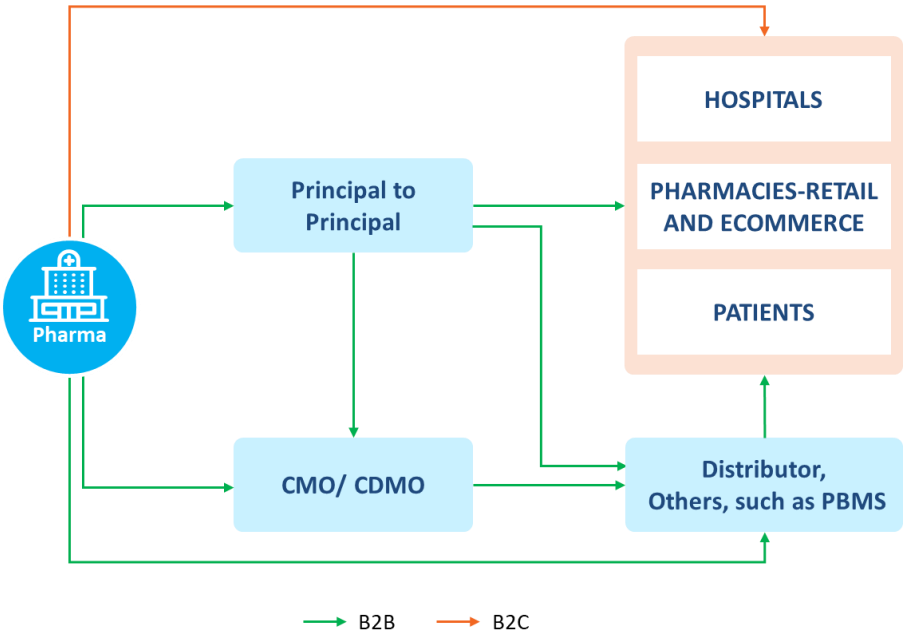
# 3 COMPETITIVE LANDSCAPE OF THE GLOBAL PHARMACEUTICAL MARKET

The pharmaceutical market is experiencing a notable surge in competition, fueled by its inherent attractiveness driven by its size, growth prospects, and the sector's critical role in healthcare. As a result, an influx of companies, ranging from multinational powerhouses to agile startups, are entering the fray, intensifying competition as each strives to capture a slice of this lucrative market. In this fiercely competitive landscape, pharmaceutical entities employ diverse tactics to distinguish themselves. Beyond the fundamental criterion of targeting markets and launching products aligned with companies' inherent strengths, differentiation strategies encompass strategic collaborations, mergers and acquisitions, and business models, to name a few.

For instance, in regulated markets, a diverse mix of local and international pharmaceutical companies compete for market share since the maturity and legacy of regulatory systems allow a diverse array of companies to navigate these markets with more advanced planning.

However, in recent years, with the accelerated growth in emerging markets, several companies have gravitated towards accessing these markets. Yet, competing in emerging markets for pharmaceutical companies is not straightforward. For large parts, pharmaceutical companies employ a high volume, low-profit strategy in many emerging markets to remain competitive and profitable. According to research by different agencies, pharmaceutical companies operating in emerging regions earn gross margins of 30–40%, while those in mature markets earn margins of 50–60%. This puts sales volume ahead of profit margins as a priority. Additionally, given the heterogeneity and relative nascency of regulations, which are changing more frequently in price-sensitive emerging markets, local companies often enjoy cost advantages, cultural familiarity, and agility in responding to market changes. Given the inherent differences in both markets, their market dynamics, regulatory environment, pharmaceutical companies' portfolios, and strategic objectives, pharmaceutical companies often employ different business models. Some of the commonly used business models include licensing agreements, joint ventures, and direct investment in local manufacturing facilities. These strategies allow companies to adapt to the unique challenges and opportunities presented by each market, ultimately enhancing their competitiveness and market presence.

**Exhibit 3.1: Select Business Models Adopted by Pharmaceutical Companies**




*Source: Frost & Sullivan*


*Source: Frost & Sullivan*

In addition to employing different business models, pharmaceutical companies also differentiate themselves by focusing on quality, regulatory compliance, product portfolio selection, brand recognition and trust, and investment in technology and innovation. In the fiercely competitive global pharmaceutical market, Indian companies have left a considerable imprint, evident in their remarkable export market growth. Their contribution to the US market is particularly noteworthy, reflected in the number of FDA-

approved sites, and a number of ANDA approvals as discussed in the sections above. Some of the Indian companies catering to the US market are analyzed below.

**Exhibit 3.2: Financial Analysis of Select Indian Pharmaceutical Companies, FY2024**

| Parameter/ Company | Ajanta | Alembic | Alkem | Aurobindo | Caplin Point | Gland | Jubilant | Glenmark | Piramal | Strides | Senores |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Operating Revenue (INR Million) | 42,087.1 | 62,286.3 | 1,26,675.8 | 2,87,045.0 | 16,941.0 | 56,647.2 | 66,448.0 | 1,16,354.6 | 81,711.6 | 40,511.2 | 2,145.2 |
| EBITDA (INR Million) | 12,565.4 | 9,606.9 | 24,348.4 | 61,913.6 | 6,186.5 | 15,033.1 | 8,247.0 | 11,343.7 | 13,683.5 | 4,181.8 | 444.1 |
| EBITDA Margin | 29.9% | 15.4% | 19.2% | 21.6% | 36.5% | 26.5% | 12.4% | 9.7% | 16.7% | 10.3% | 20.7% |
| PAT (INR Million) | 8,161.7 | 6,158.2 | 18,114.6 | 31,689.7 | 4,614.2 | 7,724.6 | 727.0 | (18,308.5) | 178.2 | (943.1) | 327.1 |
| PAT Margin | 19.4% | 9.9% | 14.3% | 11.0% | 27.2% | 13.6% | 1.1% | (15.7)% | 0.2% | (2.3)% | 15.2% |
| ROACE | 32.2% | 13.4% | 18.8% | 13.8% | 26.5% | 13.6% | 5.0% | 4.8% | 5.1% | 4.2% | 11.7% |
| ROAE | 23.5% | 13.4% | 18.0% | 11.2% | 21.7% | 9.3% | 1.3% | (20.7)% | 0.2% | (4.4)% | 23.6% |
| Debt to Equity | 0.00 | 0.09 | 0.11 | 0.21 | 0.00 | 0.04 | 0.63 | 0.13 | 0.58 | 1.17 | 1.07 |

*Source: Annual Reports, FY24 Earnings Call, Investor Presentations, Frost & Sullivan*

*Note: Ajanta Pharma Ltd. (Ajanta), Alembic Pharmaceuticals Ltd. (Alembic), Alkem Laboratories Ltd. (Alkem), Aurobindo Pharma Ltd. (Aurobindo), Caplin Point Laboratories Ltd. (Caplin Point), Gland Pharma Ltd. (Gland), Jubilant Pharmova Ltd. (Jubilant), Senores Pharmaceuticals Ltd. (Senores), Piramal Pharma Ltd. (Piramal), Glenmark Pharmaceuticals Ltd. (Glenmark), and Strides Pharma Science Ltd. (Strides).*

*Formulas used: EBITDA= Profit Before Tax (PBT) + Depreciation expense + Finance costs; EBITDA Margin= EBITDA/Revenue from Operations; Profit After Tax (PAT) Margin= PAT/ Revenue from Operations; Return on average capital employed (ROACE)= EBIT/Avg Capital Employed; EBIT= PBT + Finance Costs; Avg Capital Employed= Avg shareholders' equity (including minority visit) + Avg Long Term Debt+ Avg Short Term Debt; Return On Average Equity (ROAE)= PAT/ Avg Shareholders' Equity (including minority visit); Debt/Equity= (Non-current borrowings + Current Borrowings)/Shareholder's equity (including minority visit)*

**Exhibit 3.3: Operational Analysis of Select Indian Pharmaceutical Companies, FY2024**

| Parameter/ Company | Ajanta | Alembic | Alkem | Aurobindo | Caplin Point | Gland | Jubilant | Glenmark | Piramal | Strides | Senores |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Region Wise- US % | 22.9% | 27.8% | 21.9% | 47.8% | 18.0% | 54.0% | 81.1% | 24.0% | 41.0% | 50.0%* | 66.6% |
| Number of US ANDAs | 115 | 362 | 313 | 1143 | 29 | 182 | 84 | 329 | 19 | 266 | 19 |

*Source: Annual Reports, FY24 Earnings Call, Investor Presentations, FDA, Frost & Sullivan*

*Note: For Alembic and Aurobindo, the US revenue split is for its formulations Business; Jubilant data is for FY22 and the US and Canada; Glenmark and Piramal data is for North America; * Region-wise share for FY23. The number of ANDAs includes active ANDAs with unique product numbers and approval dates and also takes into account ANDAs held by disclosed subsidiaries, the numbers are indicative, Data as of May 2024.*

Senores Pharma is a global research-driven pharmaceutical company focused on developing and manufacturing a wide range of pharmaceutical products predominantly for the Regulated Markets across multiple therapeutic areas and a variety of oral and injectable dosage forms. The company also has a presence in the Emerging Markets across 43 countries. It markets products by entering into marketing and distribution agreements with foreign and Indian pharmaceutical companies. branded products. As of FY24, the company holds 19 ANDAs and has commercialized 21 products in regulated markets and 182 products in emerging markets.

Senores Pharma has built a portfolio of specialty and niche products that include advanced formulations such as extended-release versions, difficult-to-manufacture complex products, low-competition intensity products, and novel combinations. Examples of these advanced formulations include the extended-release versions that improve patient compliance and drug efficacy. These innovations have allowed the company to leverage new pathways like 505(q) and secure CGT designation.

Senores Pharma's success is driven by its prioritization of R&D, as evidenced by its R&D investment.[48], which stood at 33.3% of its operating revenue in FY24 and has grown by a CAGR of 277.6% between FY22 and FY24 (from INR 50.0 million to INR 713.4 million). This focus on R&D has allowed the company to maintain high profit margins compared to its industry peers. In FY24, Senores Pharma achieved a PAT margin of 15.3% and an EBITDA margin of 20.7%, whereas the average of its evaluated peers was 8.3% and 18.9%, respectively.

Senores Pharma also competes to provide manufacturing and development services to pharmaceutical companies in the CMO/CDMO industry. The company's competitors include full-service pharmaceutical outsourcing, CDMO companies; contract manufacturers focusing on a limited number of dosage forms; contract manufacturers providing multiple dosage forms; and marquee pharmaceutical companies offering third-party manufacturing services to utilize their excess capacity.

[48] Intangible assets developed and under development related to product development