# INDEPENDENT MARKET ASSESSMENT OF GLOBAL PHARMA AND CDMO MARKET

**4th September 2025**

## 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 Methodology. Quantitative market information was sourced from interviews by way of primary research as well as from trusted portals. Therefore, the information fluctuates 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.

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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 Contract Development and Manufacturing Organization (CDMO) Market in selected geographies within the limitations of, among others, secondary statistics and primary research 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.

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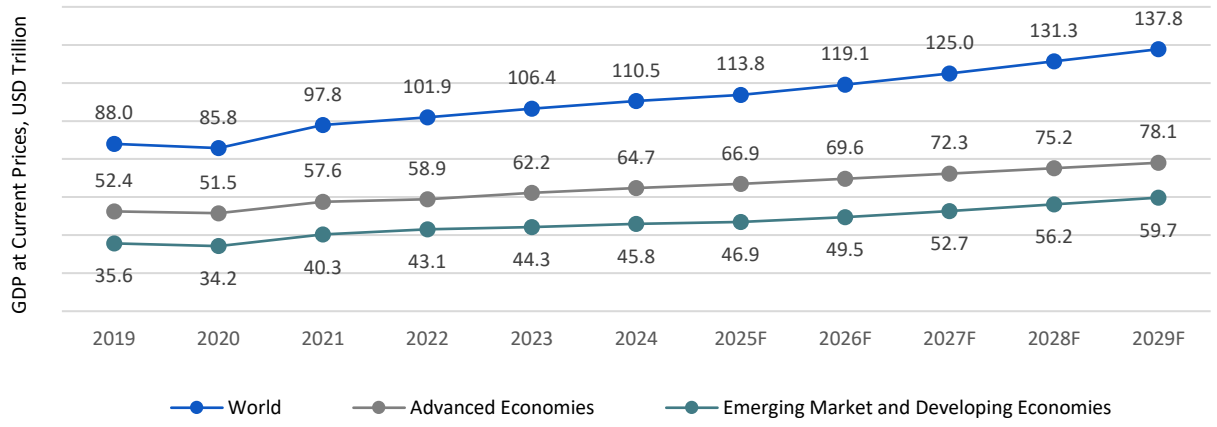
# 1 GLOBAL MACROECONOMIC OVERVIEW

## 1.1 OVERVIEW OF GLOBAL GDP TREND AND IMF OUTLOOK

***Owing to a considerable revival in H2 2024, there is compelling evidence of economic growth and potential for expansion, despite weaker consumer confidence and policy uncertainties in advanced economies.***

Characterized by steady growth and notable deceleration in global inflation, the global economy continues to exhibit noteworthy resilience against a backdrop of significant disruptions such as the latest wave of trade tariffs and retaliatory measures threatening global supply chains, ongoing geopolitical tensions, including the Russia-Ukraine conflict, the Israel-Gaza conflict, instability in the Middle East, and mounting energy and food crises.

**Exhibit 1.1: GDP at Current Prices, Global, 2019-2029F**




*Source: World Economic Outlook-April- 2025, 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." F - Forecast*

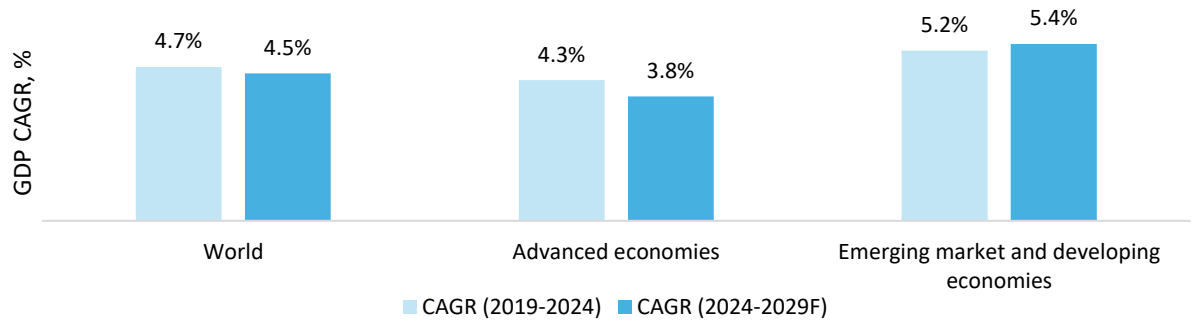
Despite multiple challenges, the global economy has been flexible. A marginal decline in global inflation from 4.8% to 4.7%[1] as of January 2025, reflects favorable supply-side dynamics, such as the easing of energy prices and a strong rebound in labor[2] market participation. Accelerated disinflation in certain regions/ countries such as the Euro area, the USA, the UK, and Canada, combined with supportive monetary policies, is expected to alleviate cost pressures and foster a conducive environment for growth. Looking ahead, global GDP is projected to grow at a healthy compounded annual growth rate (CAGR) of 4.5% between 2024 and 2029, laying the groundwork for long-term expansion.

### 1.1.1 OVERVIEW OF GDP OF KEY ECONOMIES

Advanced economies continue their positioning at the forefront of this growth trajectory. Although their growth is forecasted at a comparatively moderate 3.8% over the next five years, strong structural fundamentals ensure continued stability. In 2024, advanced economies accounted for approximately 58.8% of global output, a figure projected to remain above 56% through 2029, underscoring their sustained influence on global economic dynamics.

[1] International Monetary Fund (IMF): Global Annual Inflation and Industrial Production
[2] Economic Outlook: Global growth to remain resilient in 2025 and 2026 despite significant risks

**Exhibit 1.2: GDP CAGR at Current Prices, By Regions, 2019-2029F**




*Source: World Economic Outlook-April 2025, Frost & Sullivan*
*Note: F - Forecast*

Advanced economies are at present navigating a period of rapid policy realignment, which calls for a more streamlined approach to creating stable trade environments. Some of the key priorities include rebalancing growth-inflation trade-offs, re-examining medium-term growth prospects through structural reforms, streamlining regulatory policies and frameworks, and further reducing labor constraints to improve productivity and ensure overall economic stability and future growth.

The USA projects only 2.2% growth in 2025. Further escalation in trade tensions- such as raising bilateral tariffs on non-commodity imports between the USA and other nations could further decline global output by around 0.3% in the next 2-3 years. Nevertheless, the labor market conditions show considerable stability in these economies, supported by modest productivity gains. This helps stabilize the unit labor cost in line with the central bank inflation targets.

The Euro area[3] The real GDP growth rate is projected to be a low 1% in 2025, largely due to the heightened uncertainty within the region. However, despite ongoing macroeconomic conditions, employment in the region has risen to 3 million[4] between 2022 to 2024 with a simultaneous growth in real wages resulting in a fall in inflation rates. In fact, in some parts of Europe, there is a strong minimum wage increase supported by the ongoing wage momentum, resulting in a robust base pay growth, accompanied by high winter bonus payments in other advanced economies such as Japan, which ensures a steady market growth. Also, the economic rebound post the pandemic within the region stagnated during 2022-23, but achieved the goal of reducing inflation, with the region returning to growth in 2024, and is expected to expand by 0.8% in the coming years.[5] These dynamics reflect a complex but cautiously optimistic outlook, where targeted reforms and labor market resilience are key to sustaining growth in an increasingly uncertain global environment.

On the other hand, emerging markets and developing economies are fast becoming increasingly pivotal to global economic expansion. Driven by rapid industrialization, urbanization, and favorable demographics, these regions are projected to grow at a robust CAGR of 5.4% between 2024 and 2029, becoming key drivers for global economic growth. Asia remains the epicenter of this growth, particularly India. While China and India both achieved growth rates of 5–7% from 2019 to 2024, India is now projected to outpace China by nearly 1.7 times in the 2024–2029 period. Despite ranking higher on the inflation index at 4.5%[6] in 2025, India's continued resilience, particularly in the

[3] OECD Economic Outlook, Interim Report March 2025
[4] European Commission: Euro Area Report
[5] European Commission: Euro Area Report
[6] OECD Economic Outlook, Interim Report March 2025

pharmaceutical sector during and after the pandemic, and its strategic positioning in global supply chains under the "China Plus One" strategy, have elevated its global economic stature. This is resulting in a projected GDP growth of 6.4% in 2025 and 6.6% in 2026. In contrast, China faces headwinds from a weakening property sector, geopolitical tensions, and declining export momentum.

Across other emerging economies, including Africa and Central Asia (CCA), a surge in global uncertainty during the early months of 2025 is projected to drive an increase in headline inflation. This rise is further fueled by tighter financial conditions and subdued energy prices, according to the IMF's Regional Economic Outlook: Middle East and Central Asia. The region is currently experiencing strong economic output, largely due to prolonged and stronger-than-expected spillover effects on domestic demand from the Russia-Ukraine war. However, these effects are expected to normalize over the next 2–3 years, as hydrocarbon production levels off and fiscal stimulus measures remain relatively modest. As a result, inflation may stabilize during this period.

Driven by stronger private consumption and improved trade performance, economic growth in Africa is projected to reach 3.8% in 2025 and rise to 4.1%[7] in 2026. However, the continent continues to face significant challenges, including persistent trade tensions, transnational, regional, and domestic conflicts, widespread socio-economic hardship with approximately 468 million people currently living in poverty, and adverse climatic conditions. Accelerating the implementation of the African Continental Free Trade Area (AfCFTA) Agreement could play a pivotal role in supporting medium- to long-term growth by addressing critical issues such as food insecurity, job creation, and industrial development. Within the Middle East and GCC region, countries such as the United Arab Emirates are expected to showcase a modest growth in GDP to 5% between 2025 to 2026, driven by a lowering in consumer prices between 2%-2.1% in the next 4-5 years[8].

### 1.1.2 OVERVIEW OF GDP GROWTH OF KEY COUNTRIES

***Whilst the USA holds a strong influence on the global markets, the on-off trade policy situation is creating uncertainties. Central Asian economies, on the other hand, show a promising GDP growth in the range of 7%-12% owing to a growing focus on private sector development, education, and finance access.***

The USA, Western Europe, and the UK are particularly driving global expansion. Strong consumer demand, technological leadership, and dynamic capital markets are the primary drivers for the USA markets. Western Europe, on the other hand, benefits from resilient manufacturing bases, deep integration across regional markets, and green transition investments, while the UK is leveraging its global financial services sector, innovation ecosystem, and expanding trade partnerships. In May 2025, the UK government made a historic free trade deal with India covering multiple industries, including medical devices, electrical machinery, aerospace, and automotives, amongst others, which is expected to increase bilateral trade between the countries by USD33-USD34[9] billion by 2040.

Although the USA aims to hold a significant influence on global financial markets, recent on-and-off trade policy developments have introduced new uncertainties. The average tariff rate has increased to 24%, though this is expected to decrease to around 17% following potential changes in tariffs on Chinese goods between Q2 and Q3 2025. The recent announcement of tariff cuts from as high as 145% to as low as 30% by the USA and subsequently by China to just 10% for 90 days is expected to streamline the trade policies between the two nations, in turn supporting the USA economy.

[7] Economic Report on Africa – United Nations Economic Commission for Africa, 2025
[8] IMF - World Economic Outlook, April 2025
[9] World Economic Forum: 'Historic Free Trade Deal'

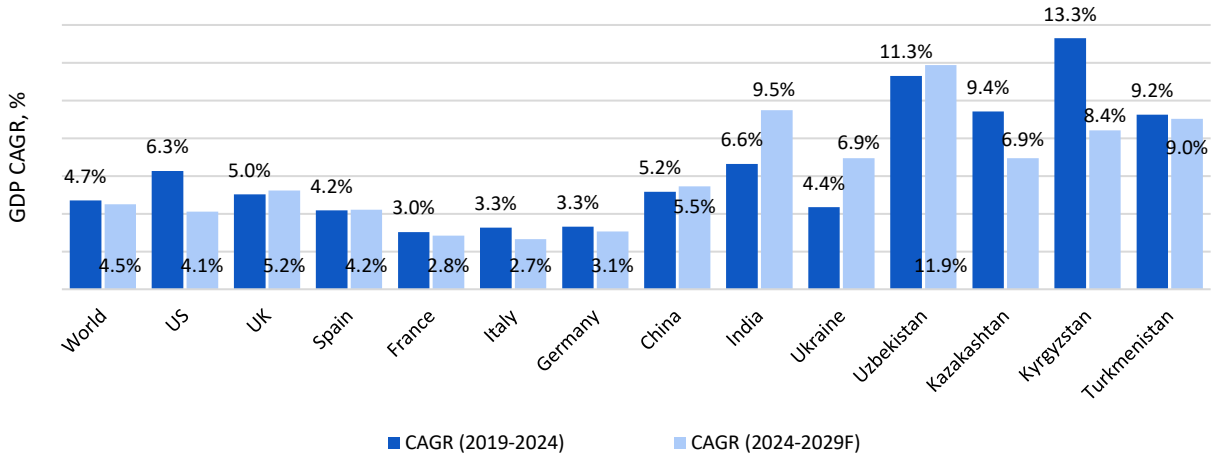
Nevertheless, the prevailing uncertainties have contributed to an expected rise in inflation to 3.5–4% in 2025, alongside a projected increase in unemployment from 4.2% to 5% due to declining immigration and resulting labor supply constraints. Consequently, the USA real GDP growth is forecasted at a subdued 1.1% for both 2025 and 2026.

Within the central Asia region, Kazakhstan, Uzbekistan, Kyrgyzstan, Turkmenistan, and many more, although they are smaller economies but show a promising GDP growth in the range of 7% -12%[10] between 2024-2029. Despite a higher inflation due to external price pressures, greater energy prices, and expansionary fiscal policies, in countries like Turkmenistan, Uzbekistan, and Kazakhstan, the IMF report in 2025 indicates a steady focus on private sector development, education, and financial access, which will be responsible for a strong regional growth.

Africa, considered the second-fastest-growing region after Asia, is backed by rich natural resources, an expanding consumer market, and a tremendous growth in youth. The region is expected to show a real GDP of 4.1% in 2025. Despite a steady growth in real GDP, elevated inflation, ongoing debt burdens, and fiscal deficits, as well as currency depreciation, remain key challenges, advocating for urgent reforms in the financing architecture[11] for debt stabilization, as well as long-term and sustainable growth. The eastern Africa region, although rich in renewable sources of energy, including geothermal, wind, etc., has a high reliance on inter- and intra-regional power pools such as oil imports. However, the Zambia-Tanzania-Kenya (ZTK) interconnector for the Eastern Africa and Southern Africa Power Pools can significantly reduce this dependence, propelling these economies.

Within the GCC region, major countries like Saudi Arabia are indicating a shift from being an oil-based economy to a non-oil-based economy by means of investments in economic diversification, such as real estate, manufacturing, and tourism. These newer focus areas are helping to offset the impact of OPEC+ oil production cuts, which had a strong impact on hydrocarbon output. In this regard, the non-oil GDP growth rate within the region has outpaced the overall economic growth of 1.8%, averaging at a modest 3.8%. Moving forward, the region is expected to remain economically resilient owing to its focus on opening up trades in multiple segments, technology advancements, and overall advancement in urban development.

**Exhibit 1.3: GDP CAGR at Current Prices, Select Countries, 2019-2029F**




*Source: World Economic Outlook- April 2025, Frost & Sullivan*
*Note: F - Forecast*

[10] Regional Economic Outlook: Middle East and Central Asia, 2025
[11] The Africa's Macroeconomic Performance and Outlook 2025

Across the emerging markets and developing economies, India is on track to become the world's third-largest economy by 2027[12], overtaking Japan and Germany. According to the IMF, India's GDP is projected to surpass USD 6.1 trillion by 2029 despite tariffs from the USA. The country has set its sights on achieving developed economy status by 2047, supported by strong growth projections of 10.2% between 2024 and 2029. This trajectory is underpinned by rising domestic consumption, substantial public and private investment, expanding international partnerships (such as the trade policy with the UK), policy reforms under the Atmanirbhar Bharat initiative, and a thriving micro, small, and medium enterprise (MSME) sector.

Among India's high-potential industries, the pharmaceutical sector stands out. With a strong foundation in both domestic and export markets, India's pharmaceutical sector is well-positioned to capitalize on the country's emergence as a global manufacturing hub.

The expansion of emerging markets and developing economies is set to drive demand across strategic sectors, particularly healthcare, and catalyze global investment. This confluence of favorable conditions across both developed and developing economies is expected to reinforce a more interconnected, resilient, and sustained global economic expansion.

### 1.1.3 OVERVIEW OF THE GLOBAL GDP PER CAPITA

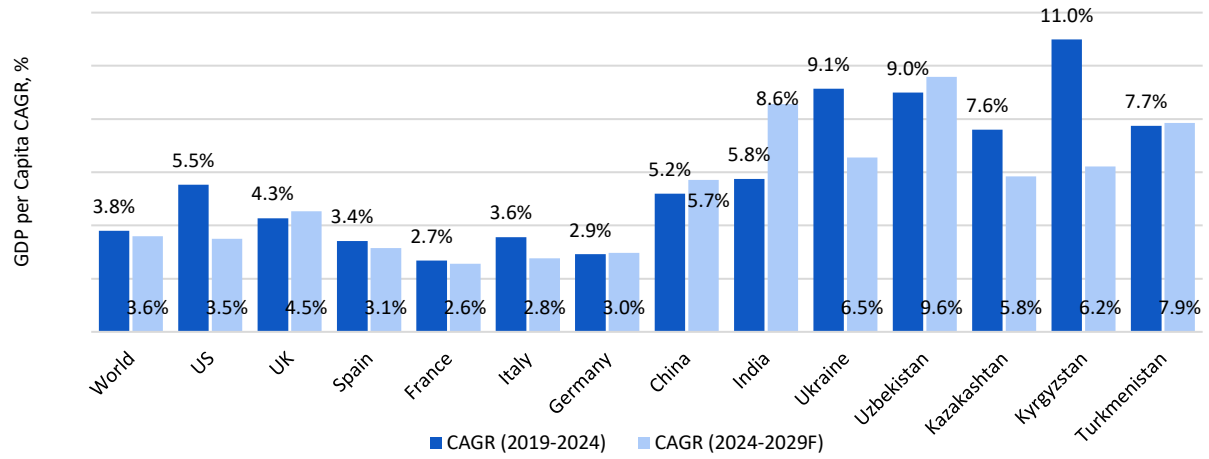
***The upward trend in GDP per capita is a key indicator of economic growth, serving as an indirect measure of enhanced affordability.***

GDP per capita is a strong indicator of economic prosperity, providing clear insights into the average income and subsequent spending capacity of individuals within a country. GDP not only reflects the economic growth and output, but also the associated well-being of the population in this context.

According to IMF data, despite the current geopolitical challenges, global GDP per capita has shown a sizable expansion, rising from USD 11,550 in 2019 to USD 13,930[13] in 2024, indicating a CAGR of 3.8%. In 2024, among the G7 nations (Canada, France, Germany, Italy, Japan, the UK, and the USA; additionally, the European Union as a non-enumerated member), the USA led with the highest GDP per capita at current prices, reaching USD 85,812 in 2024, closely followed by Germany, Canada, and the UK. Looking ahead, the GDP per capita growth in advanced economies is estimated to range between a projected 3-6% from 2024 to 2029, emerging economies are poised to experience nearly double that growth rate, with India standing out at 8.6% projected growth during the period.

[12] Ministry of External Affairs
[13] International Monetary Fund (IMF)

**Exhibit 1.4: GDP per Capita CAGR at Current Prices, Select Countries, 2019-2029F**




*Source: World Economic Outlook-April 2025, Frost & Sullivan*
*Note: F - Forecast*

Alongside the developed economies, countries such as the Philippines, Panama, the Dominican Republic, and South Africa are also poised to witness sizable growth. Their strengths lie in a robust agriculture sector, logistics, the Panama Canal's strategic importance in the global shipping industry, tourism rebound, hydroelectricity production, and political stability, among other areas. Nevertheless, their smaller size and population render them relatively less attractive for large-scale investments as compared to India and China.

The G7 nations, on the contrary, although they illustrate mature economies, are characterized by market saturation, aging populations, global banking uncertainties, ongoing conflicts (Israel-Palestine and Russia-Ukraine), and tighter monetary policies, and many more, underscoring the dynamic shift towards rapidly growing Emerging and Developing Asian economies.

Although there is a general decline in inflation across the CCA region, countries such as Turkmenistan show a rising inflation to 4.8% pushed by external pricing pressures. Similarly, Uzbekistan, Kazakhstan also contributed to near double inflation rates due to higher energy prices and expansionary fiscal policies, respectively[14]. Infact, Kazakhstan's central bank raised policy rates by 225 base points to manage the inflation rates. Overall, the GDP per capita in these countries is expected to be in the range of 5%-9% between 2024-2029.

Across countries in Africa like Kenya, with the operationalization of AfCFTA underway, in countries like Kenya and Rwanda, the National Implementation Committees (NIC) along with the East African Community (EAC) have been designing a schedule of tariff concessions for certain select products, especially those functioning under the Guided Trade Initiative (GTI), which will in turn support these economies in managing the ongoing economic challenges. Also, within the Africa region, initiatives such as the LAPSSET Corridor, designed to boost connectivity and trade across East Africa, aims to links Kenya, Ethiopia, and South Sudan through a comprehensive network of seaports and airports including the Lamu Port, three strategically positioned airports, a 1,800-kilometre highway system, and vital crude oil pipelines connecting Turkana and South Sudan to Ethiopia. Furthermore, the Lamu Special Economic Zone will be central to the corridor, focusing on manufacturing. By enabling the efficient movement of goods and people, the LAPSSET Corridor could unlock the economic potential of historically underserved regions and foster regional integration.

[14] Regional Economic Outlook: Middle East and Central Asia, 2025

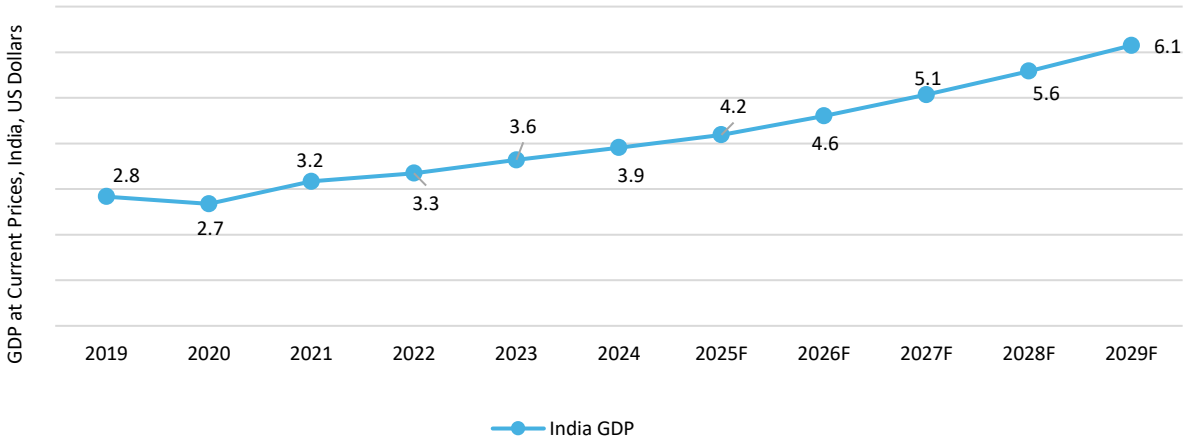
This rising per capita income, particularly in emerging markets like India and Indonesia, supports growth in healthcare access and pharmaceutical consumption. While advanced economies continue to lead in absolute terms, emerging and developing nations are rapidly closing the gap, driven by structural reforms, strategic infrastructure investments, and demographic advantages. This global shift underscores a dynamic rebalancing of economic power, with Asia and parts of Africa poised to play increasingly influential roles in shaping future growth trajectories.

# 2 INDIA MACRO ECONOMIC OUTLOOK

## 2.1 INDIA GDP OUTLOOK

***India is expected to outshine several developed and developing economies to emerge as the third-largest economy by 2027. As developed countries like the USA and other developing nations like China continue to grapple with the potential effects of the trade tariffs, accompanied by structural challenges alongside India's economy shows resilience and stability, supported by both private consumption and public sector initiatives***

**Exhibit 2.1: GDP at Current Prices, India, 2019-2029F**

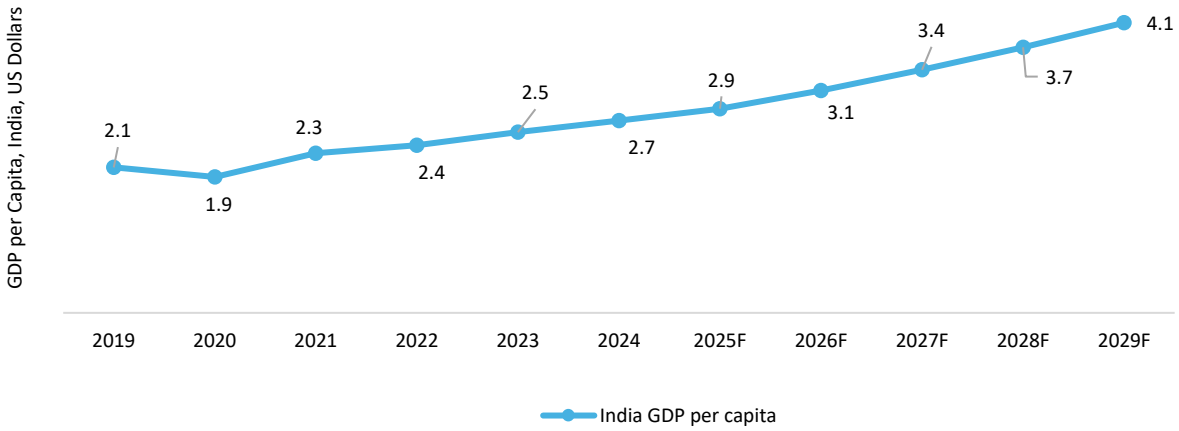



*Source: World Economic Outlook-April 2025, Frost & Sullivan*
*Note: F - Forecast*

India's GDP is projected to grow at 6.2%[15] in 2025 and 6.6% in 2026, outperforming its Asian and global peers, where growth is expected to average 2 to 3%. Although China continues to be the strongest market, having enjoyed growth rates of 5%-6%, India's forecasted GDP between 2024 to 2029 is expected to be 1.7 times that of China, considering the latest changes in the geopolitical situations and heightened global trade tensions with the USA. Despite global inflationary pressures and political unrest, India's economy has shown remarkable stability, supported by robust private consumption and public sector initiatives.

[15] India: World's Fastest-Growing Major Economy: Press Information Bureau – Government Of India

**Exhibit 2.2: GDP per Capita at Current Prices, India, 2019-2029F**




*Source: World Economic Outlook-April 2025, Frost & Sullivan*
*Note: F - Forecast*

India's resilience during the pandemic, along with the rise of the "China Plus One" strategy, has further elevated its global economic standing. Meanwhile, China faces headwinds from a weakening property sector, geopolitical uncertainty, U.S. trade tariffs, and slowing exports, with a projected growth rate of 5.9% from 2023 to 2027.

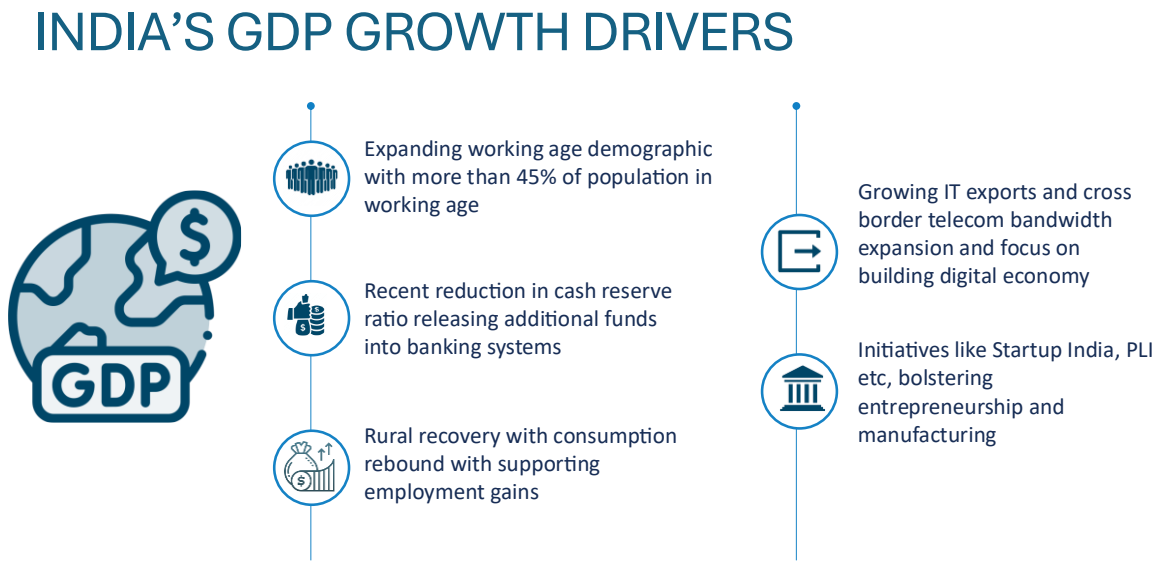
The country aims to achieve developed economy status by 2047, supported by a projected 9.5% growth rate between 2024 and 2029. India's relatively young population, with a median age of 28.8[16] (which represents half of India's population (~50.5%) falls within the 25 to 64 age group, representing the core working-age demographic[17]), is one of the major drivers providing a competitive advantage not only in terms of the workforce but also in the high demand and consumption power of a young population.

Other growth drivers include rising domestic demand, increased global and domestic investment, government support to improve logistics infrastructure, measures to streamline tax systems, strategic reforms under Atmanirbhar Bharat, and a thriving small and medium-sized enterprise (MSME) sector.

Being a domestic demand-driven economy, to continue the growth trajectory, India needs to take strong steps towards boosting employment to create at least 90-100 million.[18] Non-farm jobs in the next 5-7 years will boost the overall economic growth. With the aim of achieving a GDP growth rate of 8%-9% up to 2030, there needs to be a simultaneous uptick in the employment rate by at least 1.5% per year. India is strategically positioned to leverage its young population not only for workforce productivity but also for its domestic consumption, driven by rising income levels and aspirational demand.

[16] Economic and Social Commission for Asia and the Pacific
[17] World Bank
[18] Indian Economy Growth Rate & Statistics: Indian Brand Equity Foundation

### 2.1.1 INDIA'S GDP GROWTH DRIVERS




- **Demographic dividend:** India is the world's most populous country with a total population of 1.46 billion as of April 2025 and enjoys a significant demographic advantage, characterized by a rapidly expanding working-age population. In 2022, 49.8%[19] Of India's population fell within the working-age bracket of 25 to 64 years, up from 47.8% in 2017, and this share is projected to rise further to 51.7% by 2027. This youthful demographic provides India with a substantial competitive edge in terms of labor force availability. On the other hand, despite facing relatively high inflation, India's labor market has demonstrated considerable resilience.
    - The unemployment rate witnessed a minor decline to 4.9%[20], signaling a positive employment outlook in 2025. India's large pool of graduates, particularly in Science, Technology, Engineering, and Mathematics (STEM), many of whom are proficient in English, sets the country apart in the global talent landscape. This is especially advantageous for skill-intensive sectors such as pharmaceutical research and development (R&D) and advanced manufacturing.
    - across multiple sectors.
- **CRR cuts fueling growth with fresh funds:** Cash Reserve Ratio in December 2024, the Reserve Bank of India (RBI) cut the Cash Reserve Ratio by 50 basis points, bringing it down from 4.5%[21] To 4% injecting close to INR 1.16 lakh into the Indian Banking Systems. Lower the CRR, higher the liquidity and funding capacity, and better the economic growth, owing to more funds available across industries and a greater scope for economic growth. In addition, a neutral stance on the repo rate at 6.5% will balance inflation and thereby further stabilize economic growth.
- **Commendatory government reforms for the manufacturing sector:** Manufacturing contributed to 16–17% of India's GDP (pre-pandemic) and employs over 27 million[22] workers, and is poised for significant expansion as well. With prioritization of manufacturing across sectors, including automotive, engineering, chemicals, pharmaceuticals, and consumer durables through the implementation of policies like the Production-Linked Incentive (PLI) scheme, PM Gati Shakti- National Master Plan (NMP), and Industrial development schemes in states with industrial backwardness, the manufacturing sector is expected to account for 25% of GDP by

[19] World Bank – Population distribution by Age Group, India
[20] Government Of India, Ministry of Statistics and Programme Implementation
[21] Reserve Bank of India
[22] India Brand Equity Foundation

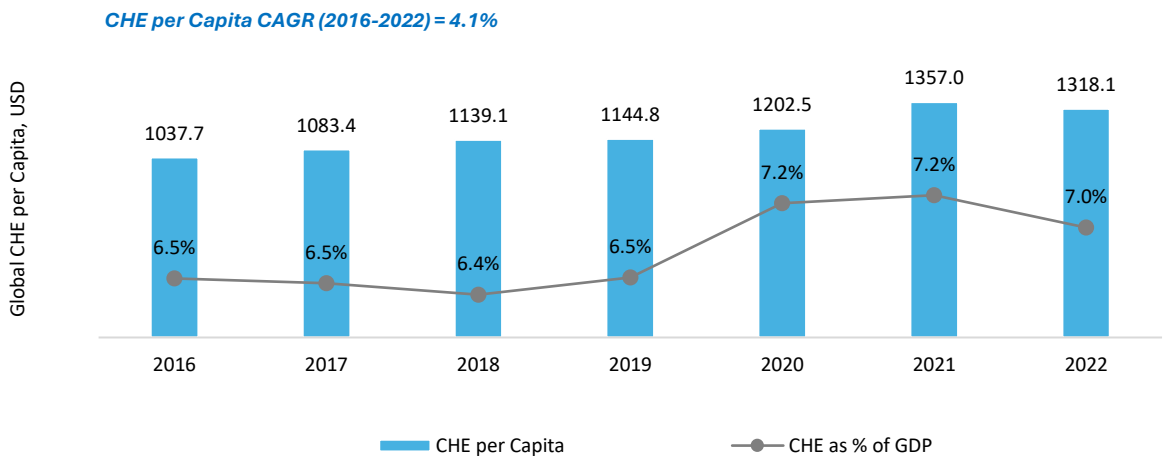
2025[23]. These reforms will simultaneously help improve India's Business Environment Rankings (BER) for infrastructure improvement from the 14th position in the 2018-2022 period to the 10th position in the 2023-2027 period, taking India ahead of the Philippines, Indonesia, and Vietnam.

- **Employment gains in Rural areas to fuel consumption comeback:** MSMEs contribute to about 30% of the country's GDP, which is further impacted by the employment rates. According to the Periodic Labour Force Survey (PLFS), there is an improvement in salaried employment, especially with respect to female labor force participation, with post-graduate women's employment reaching 39.6% as of 2024. Initiatives such as MUDRA loans, PLI schemes, and other credit guarantees are, in turn, supporting these MSMEs in regaining momentum.
- **IT exports and digitization boosting productivity:** Software development, business process outsourcing, and many more are amongst the high-skilled employments which are known to enhance productivity and growth across multiple sectors. Several local IT companies in India have established global footprints, attracting foreign investments and fostering unprecedented innovation. Also, a strong penetration of the internet and broadband services has catalyzed the fintech industry as well as e-commerce. For instance, India's digital infrastructure, led by UPI and the India Stack ecosystem, has transformed access to payments, insurance, and e-health services.

## 2.2 OVERVIEW OF THE GLOBAL AND REGIONAL HEALTHCARE AND PHARMACEUTICAL (PHARMA) EXPENDITURE

***Federal policies and healthcare reforms, improved economic conditions, and personal health wellness awareness are contributing to increased healthcare spending. Current health expenditure varies significantly across countries, with India lagging its Western counterparts.***

**Exhibit 2.3: Current Healthcare Expenditure (CHE), Global, 2016-2022**




*Source: World Health Organization - Global Health Observatory (2025), 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.*
*The growth surge in healthcare expenditure in 2021 may be attributable to pandemic-related spending.*
*The data is provided based on the latest available numbers*

***Global Trends in Current Healthcare Expenditure (CHE)***

[23] India: World's Fastest-Growing Major Economy: Press Information Bureau – Government Of India

Current Healthcare Expenditure (CHE) as a percentage of GDP has shown a steady global increase, driven by a confluence of economic, demographic, and behavioral factors. Rising economic growth has enhanced spending capacity, enabling greater investment in healthcare infrastructure and services, with a focus on improving accessibility and quality. Simultaneously, initiatives aimed at enhancing affordability have encouraged broader utilization of healthcare services.

In the post-pandemic era, there has been a notable shift in public behavior toward wellness and preventive care, further amplifying demand. While technological advancements in medicine have improved outcomes, they often come with higher associated costs. Additionally, the growing burden of chronic diseases and aging populations continues to exert upward pressure on healthcare spending. Both voluntary and government healthcare expenditures surged in response to the COVID-19 pandemic, contributing to a significant global rise in CHE from 6.5% of GDP in 2016 to 7.0% in 2022, reflecting a compound annual growth rate (CAGR) of 4.1% over the period. According to OECD 2023 data, automatic health schemes encompassing government budgets and insurance now fund mor e than 70% of all healthcare spending of OECD countries, with government schemes alone accounting for 50%–60% of current health expenditure (CHE) in many markets

***Governmental Role in Healthcare Expenditure***

Globally, there has been a consistent increase in government participation in healthcare financing, reflecting a broader commitment to achieving universal health coverage. Government schemes now account for approximately 50%–60% of CHE, with higher contributions observed in Western markets, particularly in Europe. In contrast, government spending remains comparatively lower in regions such as Central Asia and India, highlighting significant regional disparities.

Developed regions have also seen a marked decline in Out-of-Pocket (OOP) expenditures, which dropped to around 16%–17% as of 2022. However, in emerging economies particularly in the Central Asia and Caucasus (CCA) region OOP spending remains high, ranging from 30% to 70%. For instance, In the United Kingdom, government contributions account for approximately 80% of CHE. In the USA, governmental contributions stood at 55%, whereas in the CCA countries as well as Eastern Asian Countries, the contribution stood at 14%-15% in Turkmenistan and 39% in India indicating a wide disparity within the Central and other parts of Asia. While the specific drivers and magnitudes of healthcare spending vary across regions, the overarching global trend reflects a growing commitment to healthcare investment. This is evidenced by the consistent rise in CHE as a share of GDP across both advanced and emerging economies

***Regional Disparities in Healthcare Expenditure***

***Diverse healthcare landscape across regions integrated with social, economic and demographic factors, create definitive regional variations in healthcare expenditures.***

Healthcare spending varies significantly across regions, with high-income countries in Europe and North America consistently reporting higher expenditures. In contrast, Central Asian countries excluding smaller nations such as Burkina Faso and Benin spend nearly half the global average on healthcare. For example, in 2022, North America allocated approximately 16.7% of its GDP to healthcare, while the EU4 (France, Germany, Italy, and Spain) spent between 8% and 10%. Meanwhile, Central and East Asia reported healthcare expenditures ranging from just 4% to 8% of GDP.

Most regions experienced an increase in per capita current healthcare expenditure up to 2020–2021. However, this trend reversed in subsequent years. Between 2021 and 2022, East Asia and the Pacific saw a 4.7% decline, while the Euro Area experienced a sharper drop of 7.8%. Sub-Saharan Africa, Latin America, and the Caribbean were the only regions to record a decline in absolute healthcare spending.

India’s current healthcare expenditure stands at just 3.0% of GDP significantly lower than many of its Asian and developing peers highlighting substantial potential for the expansion of affordable healthcare solutions. These disparities in spending largely stem from differences in the maturity of healthcare delivery systems and reimbursement mechanisms.

**Exhibit 2.4: Current Healthcare Expenditure as % of GDP, Select Countries, 2016 and 2022**

| Country | CHE, 2022, USD Billion | CHE as % of GDP, 2016 | CHE as % of GDP, 2022 | GHE as a % of CHE 2022 | Out-of-Pocket Expenditures as a % of CHE |
|---|---|---|---|---|---|
| **US** | 4247.7 | 16.8% | 16.5% | 55.2% | 11.1% |
| **UK** | 342.9 | 9.8% | 11.1% | 83.1% | 13.3% |
| **Spain** | 137.5 | 8.9% | 9.7% | 74.0% | 19.2% |
| **France** | 330.7 | 11.5% | 11.9% | 75.4% | 8.9% |
| **Italy** | 184.5 | 8.2% | 9.0% | 74.4% | 22.7% |
| **Germany** | 514.3 | 11.2% | 12.6% | 80.3% | 10.7% |
| **China** | 963.8 | 5.0% | 5.4% | 54.9% | 33.6% |
| **India** | 113.1 | 3.5% | 3.3% | 39.1% | 46.0% |
| **Ukraine** | 13.1^ | 7.6% | 8.2%^ | 52.1%^ | 45.3%^ |
| **Turkmenistan** | 4.2 | 5.6% | 5.4% | 14.9% | 79.2% |
| **Kazakhstan** | 8.3 | 3.4% | 3.7% | 61.5% | 30.9% |
| **Kyrgyzstan** | 0.59 | 6.4% | 4.9% | 53.7% | 38.4% |
| **Tajikistan** | 0.8 | 7.0% | 7.6% | 23.4% | 65.2% |
| **Uzbekistan** | 5.9 | 4.7% | 7.4% | 34% | 65.3% |
| **Ghana** | 2.7 | 3.4% | 3.7% | 55.4% | 25.0% |
| **Nigeria** | 20.43 | 3.6% | 4.3% | 14.5% | 76.1% |
| **Liberia** | 0.54 | 9.9% | 13.5% | 9.6% | 62.2% |
| **Niger** | 0.68 | 4.5% | 4.4% | 35.3% | 40.3% |
| **Mauritiana** | 0.44 | 3.2% | 4.5% | 39.2% | 40.8% |
| **Sierra Leone** | 0.32 | 15.8% | 7.9% | 19.0% | 52.7% |
| **Senegal** | 1.14 | 4.3% | 4.1% | 22.0% | 48.8% |
| **Guinea** | 0.78 | 5.4% | 4.0% | 18.4% | 55.5% |
| **Guinea – Basso** | 0.14 | 8.3% | 8.1% | 13.6% | 64.9% |
| **Togo** | 0.49 | 6.6% | 6.0% | 11.0% | 63.2% |
| **Benin** | 0.47 | 2.8% | 2.7% | 19.2% | 42.5% |
| **Burkina Faso** | 1.3 | 6.0% | 6.8% | 40.2% | 34.6% |

*Source: World Health Organization - Global Health Observatory (2025), Frost & Sullivan*
*Data provided as per the last updated/ latest available numbers on the Global Health Observatory*
*Note: ^ Represents 2021 data, * represents 2019 data, ** represents 2020 data*

**Exhibit 2.4.1: Domestic General Government Health Expenditure as % of GDP, India, 2019 to 2022**

| Country | GHE as a % of GDP | | | |
|---|---|---|---|---|
| Year | 2022 | 2021 | 2020 | 2019 |
| India | 1.0% | 1.2% | 1.4% | 1.3% |

*Source: World Health Organization - Global Health Observatory (2025), Frost & Sullivan*
*Data provided as per the last updated/ latest available numbers on the Global Health Observatory*

***Pharmaceutical expenditures have risen in parallel with overall healthcare spending, largely driven by the increasing prevalence of chronic diseases, a growing elderly population, the rise of self-medication practices, and the relative affordability of pharmaceuticals compared to alternative treatment options.***

Global pharmaceutical spending has remained consistently within the 1%–2% of the GDP range across all regions. This steady growth is driven by several key factors, including rising healthcare demands, continuous advancements in medical treatments, and broader access to medications. The increasing prevalence of chronic diseases, heightened health awareness among patients and caregivers, and the expanding geriatric population, particularly in developed nations, are all contributing to a sustained rise in demand for pharmaceutical products.

Furthermore, the introduction of innovative drugs and therapies, encompassing both small and large molecules, has further fueled investment in the pharmaceutical sector. As countries work to strengthen healthcare infrastructure and promote equitable access to essential medicines, pharmaceutical spending is expected to continue its upward trajectory, playing a pivotal role in shaping the future of global healthcare expenditure. Regionally, pharmaceutical spending reflects similar patterns observed in overall current health expenditure (CHE), though significant disparities persist across different areas.

**Exhibit 2.5: Pharmaceutical and Other Durable Goods Spending, Select Countries, 2022**

| Country | Pharmaceutical and Other Durable Goods Spending, 2022, USD Billion | Pharmaceuticals and Other Durable Goods Spending as a % of GDP, 2022 | Pharmaceuticals and Other Durable Goods Spending as a % of CHE, 2022 |
|---|---|---|---|
| US | 521.2 | 2.0% | 12.3% |
| UK | 32.8 | 1.1% | 9.6% |
| Spain | 20.1 | 1.4% | 14.6% |
| France | 42.6 | 1.5% | 12.9% |
| Italy | 32.0 | 1.6% | 17.3% |
| Germany | 69.8 | 1.7% | 13.6% |
| India | 18.5* | 0.6%* | 22.0%* |
| Ukraine | 3.12** | 2.0%** | 26.4%** |

| | | | |
|---|---|---|---|
| **Turkmenistan** | 0.13 | - | - |
| **Kazakhstan** | 1.2^ | 0.6%^ | 15.6%^ |
| **Kyrgyzstan** | 0.11 | 1.3%* | 29.7%* |
| **Tajikistan** | 0.8 | 1.7%* | 23.9%* |
| **Uzbekistan** | 51.1* | 1.9%* | 34.9%* |
| **Ghana** | 0.15 | 0.2% | 5.5% |
| **Nigeria** | 0.44^ | 0.1%^ | 2.5%^ |
| **Liberia** | 0.23** | 7.7%** | 59.3%** |
| **Niger** | 0.14 | 0.9% | 21.1% |
| **Mauritiana** | 0.10^ | 1.1%^ | 28.4%^ |
| **Sierra Leone** | 0.01^ | 0.2%^ | 2.6%^ |
| **Senegal** | 0.44^ | 1.6%^ | 35.5%^ |
| **Guinea** | 0.24^ | 1.5%^ | 39.7%^ |
| **Guinea – Basso** | 0.00^ | 0.2%^ | 2.3%^ |
| **Togo** | 0.17^ | 2.1%^ | 37.4%^ |
| **Burkina Faso** | 184 | 1.0% | 14.4% |

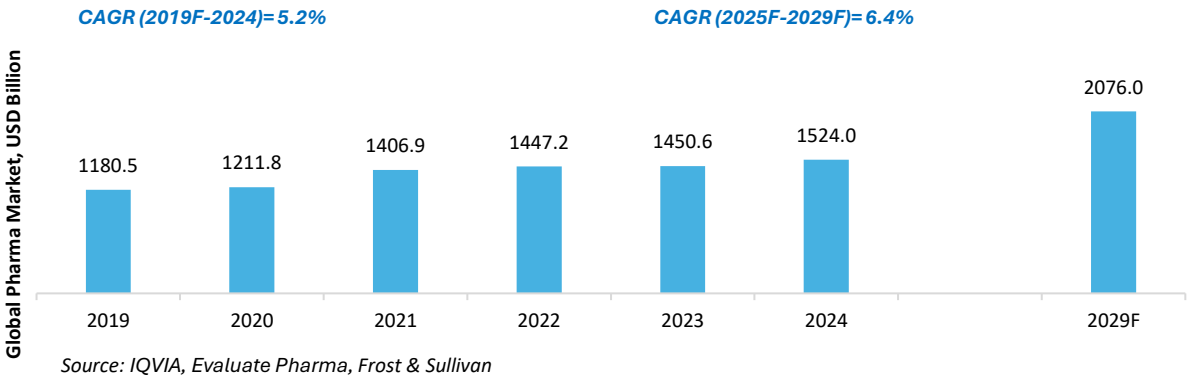
*Source: World Health Organization - Global Health Observatory (2025), Frost & Sullivan*
*Data provided as per the last updated/ latest available numbers on the Global Health Observatory*
*Note: ^ Represents 2021 data, * represents 2019 data, ** represents 2020 data*

# 3 GLOBAL PHARMACEUTICAL MARKET OVERVIEW

## 3.1 OVERVIEW OF THE GLOBAL PHARMA MARKET

***There is a general rise in awareness amongst patients and caregivers, alongside a growing geriatric population and a simultaneous increase in chronic illnesses; the Pharma industry is poised for robust growth in the next 5-7 years. In addition, the introduction of new therapies and the launch of more generics due to the patent cliffs will further propel growth.***

**Exhibit 3.1: Global Pharma Market, 2019-2029F**




*Source: IQVIA, Evaluate Pharma, Frost & Sullivan*
*Note: F - Forecast*

Supported by a growing novel therapy pipeline, the global pharma industry is set to showcase robust growth. The industry is at a critical juncture with a surge in innovative therapies as well as a potential influx of generics with multiple blockbuster therapies going off patent, indicating strong supply dynamics. For instance, in 2024, the USFDA approved 50 novel drugs with 64%[24] being small molecule therapies and 36% large molecules (including monoclonal and bispecific antibodies, cell and gene therapies, and peptide therapies).

On the other hand, there is a rising demand for healthcare owing to large demographic shifts in chronic diseases, heightened awareness amongst patients and caregivers alike, and an improvement in public health insurance, further propelling growth. In this regard, the OTC market has also gotten a thrust post-pandemic with consumer empowerment to self-manage small ailments, eCommerce growth, trends in preventive care, and innovations in formulations. In 2024, the top 15 companies captured more than 50% revenue share of the market. However, there is a surge of small to mid-segment players in the industry, which are significantly contributing to the therapeutic novel pipelines and are expected to slowly capture a greater market share of over 50% by 2029-2030. Most leading players, owing to a loss of patents of their blockbuster drugs, will likely lose market share through the forecast period, replaced by emerging as well as small to mid-segment biopharma companies.

The pandemic had a critical impact on global businesses, exposing the inherent vulnerabilities in global supply chains, rampant price volatility, and an overreliance on Chinese manufacturing hubs. However, it also catalyzed innovation, particularly in cutting-edge technologies such as mRNA-based therapies. Between 2024 and 2029, the global pharmaceutical market is projected to grow at a CAGR of 6.4%, outpacing the historical growth rate of 5.2% observed from 2019 to 2024.

Some of the key growth drivers solidifying this growth momentum include:

- **Ageing Population:** The global population is undergoing a critical demographic shift, with the percentage population over 60 expected to nearly double from 12% to 22% by 2050, reaching around 2.1 billion[25]. This demographic shift in the aging population is a critical driver for the pharma industry, considering it creates a greater demand for innovation as well as generics drugs, as the increase in age will result in greater prevalence of chronic diseases and age-related conditions, thereby driving demand for drugs targeting conditions like hypertension, diabetes, osteoporosis, and neurodegenerative diseases.

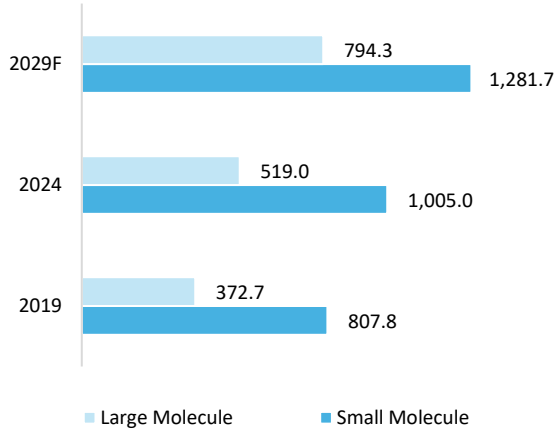
[24] Food and Drug Administration (FDA)
[25] World Health Organization (WHO)

- **Growing Prevalence of Chronic Diseases:** Chronic diseases are emerging as a global health challenge affecting patients across all demographics. In fact, one in three adults suffers from multiple chronic conditions (MCCs), and non-communicable diseases account for over 70%[26] of global deaths in 2019 according to the WHO, World Health Statistics Report, 2024. Developing nations are witnessing a sharp rise in chronic disease burden due to urbanization, lifestyle changes, and aging populations. For instance, India has seen a 25% increase in diabetes prevalence over the past decade, while sub-Saharan Africa is experiencing a surge in hypertension and cardiovascular diseases. With the global economic burden of chronic diseases projected to reach USD 47 trillion by 2030, the demand for pharmaceuticals is set to grow. Lifelong treatment regimens are often necessary for managing these conditions, further fueling market expansion. Cancer, another major contributor to chronic disease prevalence, continues to escalate, with the global incidence projected to increase by nearly 47% between 2020 and 2040, reaching approximately 28 million cases annually. As a result, pharmaceutical demand will continue to be bolstered by the need for sustained treatment regimens.
- **Expansion of Health Insurance:** The expansion of health insurance coverage has improved global access to pharmaceuticals. In India, the number of individuals covered by health insurance rose from approximately 482 million in FY2014 to over 572 million in FY2024, largely due to government initiatives like Ayushman Bharat. In Central Asia, across countries like Kazakhstan, health reforms aim at progressing towards Universal Health Coverage (UHC), where the country transitioned to social health insurance (SHI)[27] In 2020, which now covers about 84% of the population (2024), ensuring equity, access, and service quality. On a global scale, the Universal Health Coverage (UHC) service coverage index increased from 51% in 2000 to 68% in 2021, reflecting broader access to essential health services. This growing insurance penetration has played a pivotal role in reducing out-of-pocket healthcare expenses and enhancing the affordability of essential medications, particularly in low- and middle-income countries.
- **Consumer Behavioral Shifts**: Post the pandemic, there is a significant shift in consumer behavior in terms of taking proactive measures in managing health. There is a notable shift towards preventive care, which is spurring the demand for pharmaceuticals, particularly the over the counter (OTC), nutritional supplements, and other wellness solutions. Consumers are increasingly prioritizing early diagnosis, medication adherence, and proactive disease management, with the help of digital tools, leading to a general rise in telemedicine, e-pharmacies, further fueling pharmaceutical sales.
- **Patent-cliff Driven Value Growth**: Several blockbuster drugs such as Revlimid, Tecfidera, and Vyvanse faced patent expiry between 2019 to 2024, opening avenues for the launch of low-cost generics, significantly improving access to essential medications. Looking ahead, the period from 2025 to 2029 is expected to witness another wave of expirations, unlocking a significant opportunity for generic manufacturers such as Alembic Pharmaceuticals, Zydus Pharma, Aurobindo Pharma, and many more, in small molecule generics alone. This shift is poised to reshape market dynamics and broaden treatment accessibility globally.

[26] World Health Statistics, 2024- Monitoring health for the SDGs, Sustainable Development Goals
[27] WHO - Health systems in Action – Kazakhstan – 2024 Edition

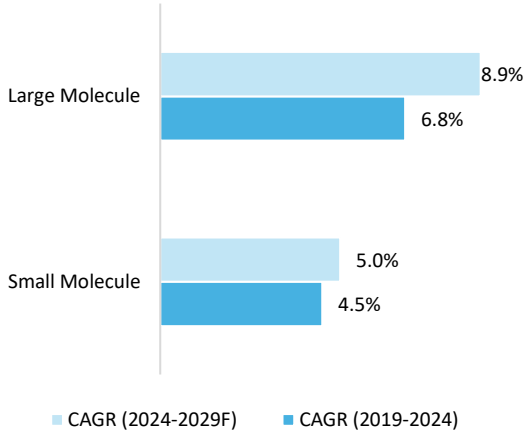
## 3.2 GLOBAL PHARMA MARKET BY MODALITIES

**Exhibit 3.2: Global Pharma Market by Modality, 2019, 2024, 2029F, USD Billion**




*Source: IQVIA, Evaluate Pharma, Frost & Sullivan*
*Note: F- Forecast*

**Exhibit 3.3: Growth Rate of Global Pharma Market by Modality, 2019-2029F**




*Source: IQVIA, Evaluate Pharma, Frost & Sullivan*
*Note: F- Forecast*

Small molecules have historically dominated the pharma markets owing to their affordability and ease of administration, including a very broad therapeutic coverage. In 2024, small molecule drugs accounted for USD 1,005.0 billion, capturing nearly 65.9% of the total global pharmaceutical market. The segment showcased a relatively modest CAGR of 4.5% (2019–2024) and is expected to grow at a CAGR of 5.0% (2024–2029F). Its dominance by value will remain intact due to widespread usage in both acute and chronic therapies, a strong generics base, and a high volume of global prescriptions.

Also, small molecules will remain pivotal in the expansion of access in underserved geographies, where pricing sensitivity, infrastructure limitations (in the form of logistic and regulatory pathways favor their adoption over complex biologics. Small molecules offer scalable solutions for high-burden disease areas and continue to lead in terms of volume-driven growth, global reach, and cost-effectiveness. With continued R&D pushing their therapeutic potential and ongoing patent cliffs generating new generics, small molecules are well aligned with the industry needs and will continue to dominate the global pharma markets.

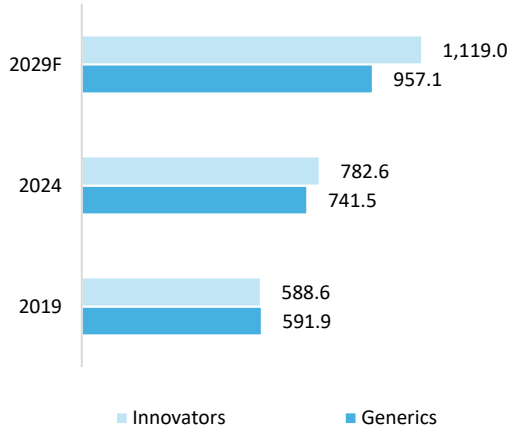
In contrast, large molecule drugs, or biologics, are gaining momentum, with a strong projected growth of 8.9% between 2024 to 2029. The segment was valued at USD 519.0 billion in 2024 and expected to reach USD 794.3 billion in 2029. M&As and industry partnerships are expected to continue to propel innovation within the segment. Apart from branded biologics, biosimilars, which are almost 60% cheaper, are gaining momentum, particularly in oncology, autoimmune diseases, and diabetes. Initiatives such as the FDA's June 2024 proposal that will allow interchangeable biosimilars without switching studies, expediting approvals, and the Centers for Medicare & Medicaid Services (CMS) now permitting biosimilar substitutions in formulary maintenance, supporting Medicare and Medicaid adoption, will lead to an improved biosimilar demand and subsequent adoption.

## 3.3 GLOBAL PHARMACEUTICAL SMALL MOLECULE MARKET BY DRUG TYPE

***Innovator drugs will keep gaining market share with breakthrough science and expanded utilization to new therapy areas such as obesity/ weight loss, diabetes, and oncology. On the other hand, generics companies have been transforming the pharma landscape through constant innovation (specialty and branded generics like injectables), product diversification, accompanied by cost-saving strategies through low-cost production technologies that easily navigate regulated and unregulated markets effectively.***

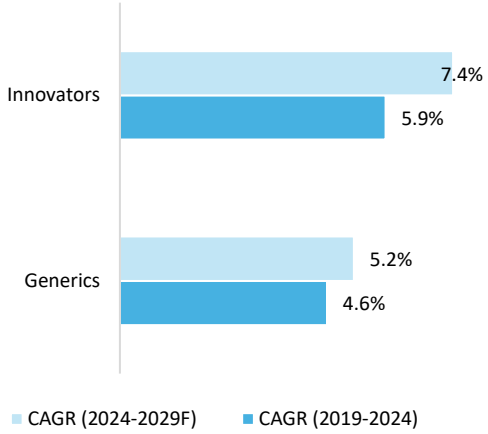
The pharmaceutical industry is undergoing a dynamic shift, driven by a wave of innovative, potentially curative therapies that are redefining growth trajectories. While these novel treatments—targeting critical unmet needs such as anti-obesity and NASH—are propelling the innovator segment, their high costs and limited accessibility to developed markets have intensified healthcare spending. The innovator segment currently accounts for 51.3% of the global pharma market, valued at USD 782.6 billion in 2024 and projected to reach USD 1,119.0 billion by 2029. As patents for many of these therapies expire, they pave the way for more affordable generic alternatives, promoting health equity and cost containment.

**Exhibit 3.4: Global Pharma Market by Drug Type, 2019, 2024, 2029F, USD Billion**




*Source: IQVIA, Evaluate Pharma, Frost & Sullivan*
*Note: F- Forecast*

**Exhibit 3.5: Growth Rate of Global Pharma Market by Drug Type, 2019- 2029F**




*Source: IQVIA, Evaluate Pharma, Frost & Sullivan*
*Note: F- Forecast*

Governments worldwide are responding to rising healthcare costs by encouraging generic drug adoption. In emerging markets, this includes mechanisms like compulsory licensing, while regulated markets offer incentives such as market exclusivity and favorable reimbursement policies. The generics segment, valued at USD 741.5 billion in 2024, represents 48.7% of the global market and is poised for accelerated growth due to the impending patent cliff, particularly for small-molecule drugs. This shift is expected to unlock a USD 145 billion opportunity over the next 5–7 years. Generics typically capture up to 66.1% of the market in their first-year post-launch, rising to 82.7%[28] by the second year, underscoring their growing dominance.

[28] Factors Associated with Generic Drug Uptake in the United States, 2012 to 2017, Pubmed, National Centre for Biotechnology Information

Pharma companies are increasingly diversifying their portfolios with reformulated generics such as extended-release, inhalable, and implantable formulations, enhancing both efficacy and patient convenience. There is also a strong push toward specialty and complex generics, supported by strategic sourcing partnerships across Eastern Europe and Latin America, and the adoption of advanced technologies like AI, and predictive analytics. These efforts are helping generic manufacturers streamline operations, mitigate supply chain risks, and maintain competitiveness alongside innovator companies.

Globally, while demand for innovative therapies continues to rise, generics remain essential due to their affordability and accessibility, especially in regions with high out-of-pocket healthcare spending. Even traditionally brand-focused markets like the Middle East are shifting toward generics, supported by incentives and streamlined regulatory pathways. In developed markets, Japan has set a target of 80% generic penetration, Canada has implemented pricing reforms to stabilize generic costs (with generics priced between 25%–55%[29] of branded drugs), and the USA sees generics accounting for over 90%[30] of prescriptions. Europe has reached nearly 60%[31] penetration, while APAC shows mixed dynamics—Australia and South Korea are driving growth, whereas Japan is experiencing a decline in market share.

### 3.3.1 GROWTH DRIVERS AND MARKET DYNAMICS OF THE GLOBAL GENERICS PHARMA MARKET

- **Impending Patent-cliff:** Several notable novel therapies catering to cardiovascular, oncology, and metabolic segments have gone off patent in the last year, which presents a potentially large and lucrative window for the introduction of new generics into the pharmaceutical market. Moreover, some drugs that have a higher demand for lack of alternative therapies, can even reach this level in as little as 30 to 90 days of launch. Looking ahead to 2024–2029, a surge in generic drug approvals combined with a rapid adoption is expected to reshape the pharmaceutical landscape, benefiting both consumers through lower costs and generics-focused companies through expanded market opportunities.
- **Persistent Drug Shortages in Key Markets:** Drug shortages have emerged as a critical global issue, particularly acute in major pharmaceutical markets like the USA. Unlike oral generics, which typically see multiple manufacturers enter the market after patent expiration, specialized drugs such as injectables often have only a few approved producers, making the supply chain more susceptible to disruptions. Also, manufacturing delays due to natural disasters, supply chain disruptions, and geopolitical instability, further add to the challenges. Moreover, with an already challenging supplier network, issues with the procurement of API, KSM, excipients, and specialized packaging materials can make the situation more strained.
- **Uneven Price Erosion:** Government initiatives and the private sector are together contributing to the explosive growth in the generics market, but at the same time, they have also increased competition, exerting a downward pressure on prices. A recent analysis by the U.S. Food and Drug Administration (FDA)[32] highlights this trend: when only one generic version of a drug is available, the median discount compared to the invoice-based wholesale price is approximately 30%-35%. This discount increases significantly with market competition, rising to 43.8% with two generics and reaching 55% when three are available and about 70% when four generics are launched. Indian pharmaceutical companies hold a competitive edge in this environment, benefiting from lower manufacturing costs and strong research and development capabilities. These advantages enable them to sustain profitability even in the highly competitive U.S.

[29] Canadian Generic Pharmaceutical Association
[30] Association for Accessible Medicines
[31] Medicines for Europe
[32] Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices

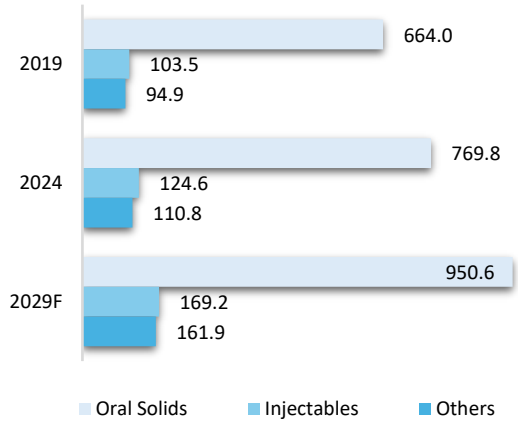
generics market. In response to pricing pressures and commoditization, a growing number of technologically advanced firms are shifting focus toward complex generics.

- Although generics are typically more affordable than branded drugs, the prolonged price erosion appears to have stabilized. In some cases, prices even increased in early 2025, signaling a potential shift in market dynamics. This trend may benefit generic pharmaceutical companies that can scale production, fortify supply chains, and maintain high-quality standards, positioning them to fill critical gaps and capture greater market share.

### 3.3.2 GLOBAL PHARMACEUTICAL SMALL MOLECULE MARKET BY FORMULATION TYPE

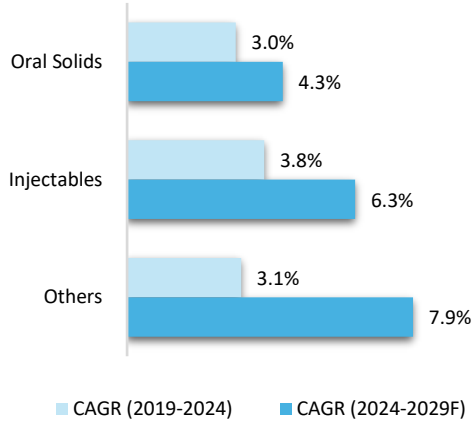
***Although oral solid dosage forms (OSDs) capture the majority of the market by value, injectables are emerging as the fastest-growing drug delivery segment, outpacing traditional oral solids growth, due to their superior bioavailability, rapid therapeutic action, and ability to address the limitations of oral drug absorption. With advancements in drug formulation and delivery systems, injectables are becoming the preferred choice for treating chronic diseases, complex conditions, and biologic therapies.***

**Exhibit 3.6: Global Small Molecule Pharma Market by Formulation Type, 2019, 2024 and 2029F, USD Billion**




*Source: Evaluate Pharma, Frost & Sullivan*
*Note: F - Forecast*

**Exhibit 3.7: Growth Rate of Global Small Molecule Pharma Market by Formulation Type, 2019-2029F**




*Source: Evaluate Pharma, Frost & Sullivan*
*Note: F - Forecast*

As the global pharma market continues to evolve, formulation types play a crucial role in shaping the trends. Historically, oral solid dosage forms have dominated the industry, capturing the largest share, accounting for over 70% of the small molecule market. In 2024, OSDs were valued at USD 769.8 billion and projected to grow with a modest CAGR of 4.3% through 2029. However, these drug forms are witnessing a declining profitability owing to constant pricing pressures, strong competition, distributor consolidation, and buyer concentration, especially in developed markets such as the USA.

Contrary to that, the injectables market is emerging as a significant driver of the pharma industry, which can be attributed to its improved bioavailability, especially being promising in biologic drug delivery and higher efficacy. The segment has especially benefited from the rise in biologic therapies such as monoclonal antibodies, vaccines, and peptide therapies, which require injectable forms of drug administration. Nevertheless, the small molecule

injectables segment is also gaining traction owing to their enhanced bioavailability, rapid absorption, and precise dosing, making them suitable for both acute and chronic conditions.

The small molecule injectable drugs market was therefore valued at approximately USD 124.6 billion in 2024, with a projected growth of 6.3% up to 2029, reaching USD 169.2 billion. Across the injectables market, antibiotics and antivirals, as well as injectable chemotherapy drugs, are some of the leading small-molecule therapies driving the market. As the prevalence of chronic diseases increases, there is a simultaneous rise in advanced therapies such as mRNA-based small molecule therapies, hormonal therapies, etc., paving way for the advancement of the injectables segment. Furthermore, a growing preference for long-acting formulations and novel drug delivery mechanisms has positioned injectables as a cornerstone of pharmaceutical innovation.

In addition, innovations across novel drug delivery mechanisms, such as nanoparticles, liposomes, and degradable implants, are further improving the stability, bioavailability, and therapeutic impact of injectable drugs. These advancements are especially considered beneficial for acute and chronic conditions by reducing the frequency of dosing and improving compliance. As the market expands, the shift towards patient-friendly, precise, and effective injectables continues to gain momentum, offering superior therapeutic outcomes across diverse patient demographics. The market is also witnessing the emergence of newer formulations such as long-acting injectables (LAIs) and drug delivery technologies like auto-injectors, which are driving the demand and enhancing patient compliance. Injectables are preferred over oral solid dosages (OSDs) for their profitability and pricing stability, facing fewer competitors (5–7 vs. 12–15[33] for OSDs). While OSDs may see up to 95% price erosion post-generic entry, injectables typically face only 60–70%.

Injectable drug manufacturing is far more complex and capital-intensive than oral solid dosages (OSDs), requiring sterile environments, aseptic processing, and advanced technologies like lyophilization. Building a sterile facility can cost over USD 200 million and take up to three years, with global supply chain issues adding delays. Regulatory agencies like the FDA and EMA impose strict standards due to sterility risks, often requiring extensive clinical data even for generics. Manufacturing changes post-approval can trigger reassessments, increasing costs and timelines. Additionally, the need for specialized skills in aseptic techniques and nanoparticle engineering has created a global talent shortage, making capacity expansion and sustained production a major challenge.

## 3.4 GLOBAL SMALL MOLECULE PHARMACEUTICAL MARKET BY THERAPY AREA

The global burden of chronic diseases is rising steadily, driven by lifestyle-related risk factors such as poor diet, physical inactivity, and urbanization. This has led to a surge in demand for long-term therapies to manage conditions like cardiovascular diseases, diabetes, and obesity. Between 2024 and 2029, the chronic therapies segment is expected to grow significantly, supported by an expanding patient base and advancements in personalized medicine and therapeutic technologies. In 2024, chronic diseases, including Oncology, Central Nervous System (CNS), and Cardiovascular (CVS), account for over 35% of the global pharmaceutical market. These segments are expected to maintain momentum due to repeat prescriptions and extended treatment durations.

Oncology remains the largest and fastest-growing chronic therapy area. The market is valued at USD 182.9 billion in 2024 and is projected to grow at a CAGR of 7.5%, reaching USD 262.7 billion by 2029. Growth is driven by innovation in targeted therapies, immunotherapy, and biologics, alongside a rising global cancer incidence. The CNS segment is gaining traction due to increasing cases of neurodegenerative and psychiatric disorders such as depression, schizophrenia, Parkinson's, Alzheimer's, and multiple sclerosis. The market grew from USD 82.8 billion in 2019 to

[33] The Evolution of Supply and Demand in Markets for Generic Drugs

USD 84.4 billion in 2024 and is forecasted to reach USD 116.6 billion by 2029. Pain management, particularly chronic pain, is a key growth driver within CNS, with both anesthetic and non-anesthetic drugs contributing to expansion.

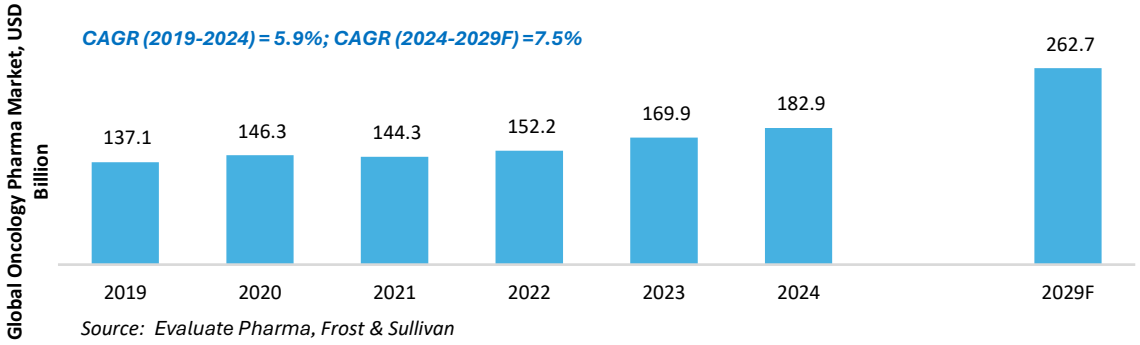
Hormone therapies are emerging as a high-growth area, supported by rising awareness and broader indications for hormone replacement and growth hormone treatments. The market is valued at USD 14.3 billion in 2024, with an expected CAGR of 10.6%, reaching USD 23.6 billion by 2029. Conditions related to aging, women's health (e.g., menopause, thyroid), and male hormonal deficiencies (e.g., hypogonadism) are fueling this growth. Additionally, the global hormone therapies market, specifically for HRT and growth hormone treatments, is projected to grow from CAGR of 6%-7%.

## 3.5 GLOBAL ONCOLOGY SMALL MOLECULE PHARMACEUTICAL MARKET

***Driven by cutting-edge innovations in the form of cell and gene therapies, immunotherapies, antibody drug conjugates, and bispecific antibodies, as well as strategic investments and a deeper understanding of cancer biology, the oncology sector is bound to showcase strong growth.***

The oncology segment accounts for ~18%-22% of the total pharmaceutical market and remains the fastest-growing therapy area, projected to grow at a 7.5% CAGR through 2029. With a general shift towards precision health, Oncology is undergoing a rapid transformation, marked by advancements in diagnosis, treatment, management, and monitoring. According to the International Agency for Research on Cancer (IARC), an estimated 20 million new cancer cases were diagnosed globally in 2022, resulting in 9.7 million deaths. By 2040, the number of new cancer cases per year is expected to rise to 29.9 million, and the number of cancer-related deaths to 15.3 million.[34], underscoring the persistent and significant unmet medical need. Economically, the impact is profound, with the global cost of cancer between 2020 and 2050 projected to reach USD 25.2 trillion.[35], reflecting the immense strain on healthcare systems worldwide.

**Exhibit 3.8: Global Small Molecule Oncology Market, 2019-20298F**




*Source: Evaluate Pharma, Frost & Sullivan*
*Note: F - Forecast; The numbers represent only Small Molecule Segment*

Whilst being categorized as a single therapeutic area, oncology encompasses over 20 distinct indications, with breast cancer, multiple myeloma, non-small cell lung cancer (NSCLC), prostate cancer, and kidney cancer collectively representing 50-60% of the oncology market[36]. Factors including demographic shift, advances in precision medicine and other targeted immunotherapies, and lifestyle changes predisposed to disease will drive the oncology market from USD 182.9 billion in 2024 to reach USD 262.7 billion with a CAGR of 7.5%.

Across the different therapies approved for oncology treatment, five of the top 20 drugs in 2024 generated over USD 5 billion.[37] in annual revenue, each, highlighting the sector's prominence. Across regions, emerging regions (including

[34] National Cancer Institute
[35] Estimates and Projections of the Global Economic Cost of 29 Cancers in 204 Countries and Territories From 2020 to 2050
[36] IQVIA, Global Oncology Trends, 2024, 2025
[37] Evaluate Pharma

some of the unregulated but developing economies) are expected to contribute the highest to the Oncology segment growth, which is attributable to the improved access to cancer therapies in these regions.

The global oncology landscape is undergoing a profound transformation, driven by rising cancer incidence, sustained R&D investment, and the evolution of cancer into a chronic condition. By 2050, annual cancer cases are projected to exceed 35 million, a 77% increase from 2022, with low (99%) and medium HDI (142%) countries expected to see the most dramatic proportional rise in both incidence and mortality. Countries of High Human Development Index (HDI) such as the USA, Canada, France, the UK, Japan, amongst others are also expected to experience the largest absolute increase, with an additional 4.8 million new cases projected in 2050 compared to 2022[38]. This surge underscores the urgent need for affordable and accessible treatments, particularly in resource-limited settings. Innovation in oncology is further accelerated by technological advancements and robust R&D efforts, with over 8,800 clinical compounds in development representing more than 40% of the global pipeline in 2025, up from 35.2% in 2019 and 26.8% in 2010[39].

In addition, novel modalities like radioligand therapies are expanding therapeutic potential, while expanded indications and early-line integration are broadening patient access. The market is also poised for significant volume growth due to upcoming patent expirations worth nearly USD 50 billion between 2025 and 2029, driving the adoption of generics and biosimilars. Whilst oncology-specific biosimilars are seeing significant uptake, there is also a strong push for small molecule generics, with some molecules reaching over 60%[40] of volume uptake within the first three years. Despite persistent drug shortages and supply chain challenges, generic manufacturers are playing a vital role in stabilizing access. Moreover, the specialized nature of oncology therapies ensures greater immunity to price erosion, reinforcing their long-term profitability and strategic importance in global healthcare.

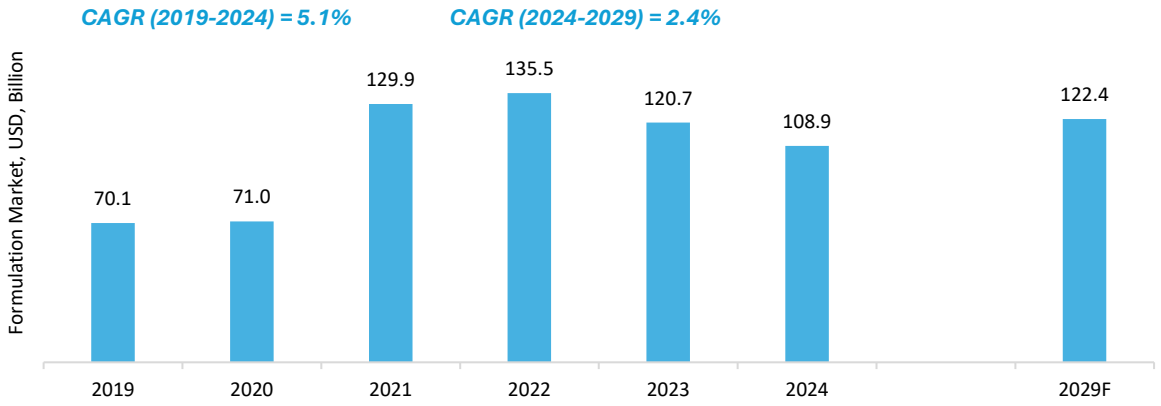
## 3.6 GLOBAL SMALL MOLECULE ANTI-INFECTIVES MARKET

***With the growing prevalence of AMR infections, both emerging and developed nations showcase a continued demand for antibiotics, resulting in the segment witnessing a growth of 2-5% in the next five years.***

Anti-infectives are an important class of drugs characterized by a wide range of infectious diseases, including viral, bacterial, parasitic, or fungal. Some of the key indications include respiratory infections, hospital-acquired infections, HIV, pneumonia and many more. Valued at USD 108.9 billion in 2024, the global systemic anti-infectives market is expected to show a modest CAGR of 2.3% to reach USD 122.4 billion in 2029. Due to a very small pipeline of development, the anti-infectives market is expected to witness slower growth compared to other segments. Whilst the COVID-19 pandemic provided a boost to the segment between 2021-2022, owing to a stronger push towards anti-microbial and anti-bacterial therapy pipelines, post-pandemic, the market showed a sudden decline due to the termination of these clinical trials and also a simultaneous decline in terms of demand, across all regions, resulting in a deviation from its growth trajectory. The rise in CAGR is attributable to the continued demand for antibiotics to pre-pandemic levels and growing demand from emerging markets with expanding healthcare access. Whilst a growing biologics pipeline within antibiotics could result in a stronger biologic segment growth, the small molecules segment will showcase a moderate growth through the forecast period.

[38] Global cancer burden growing, amidst mounting need for services, WHO
[39] Citeline: Pharma R&D Annual Review 2025
[40] IQVIA - Biosimilars in the United States 2023–2027

**Exhibit 3.9: Global Small Molecule Systemic Anti-infectives Market**




*Source: Evaluate Pharma, Frost & Sullivan*
*F: Forecast; The forecast numbers represent only the small molecule segment*

## 3.6.1 DIFFERENT CLASSES OF ANTIBIOTICS

***Antibiotics are primarily grouped into different classes based on their chemical structure, the spectrum of activity, mechanism of action, and effectiveness against different bacteria.***

Antibiotics are powerful, lifesaving drugs used to fight infections. Before the beginning of the 20th century, infectious diseases accounted for high global mortality, and the average life expectancy was 47 years, even in the industrialized world[41]. Since the discovery of penicillin in 1928, antibiotics have revolutionized medicine, saving millions of lives. These therapies are indispensable in treating infections, preventing complications during surgeries, and supporting immune-compromised patients. The discovery of antibiotics helped tackle many infections and paved the way for conducting advanced surgical procedures such as organ transplants and cancer treatment, thus reducing preventable deaths. Antibiotics largely helped increase average life expectancy by 23 years[42]. Overall, antibiotics capture the majority in the anti-infectives market in the range of 45%-50%.

Given the wide utility of antibiotics, several classes have been discovered over the decades to address the multitude of bacterial challenges. Some of the key classes of antibiotics are listed below[43]:

## 3.6.2 GLOBAL BETA-LACTAM AND CEPHALOSPORIN DRUG MARKET

***Beta-lactams are critical lifesaving drugs used to treat bacterial and protozoan infections, with dominant revenue contribution from cephalosporins, which are broad-spectrum antibiotics largely used in hospitals.***

Within the anti-infectives segment, antibiotic classes such as Beta-lactam and beta-lactamase inhibitors are the most widely used classes. These include penicillin and its derivatives, such as methicillin and amoxicillin, as well as other groups of antibiotics known as the cephalosporins, carbapenems, and monobactams. These therapies have the ability to fight against a broad spectrum of bacterial and protozoa infections and are prescribed for treatment of a multitude of infections, including Urinary Tract Infections (UTI), respiratory infections, skin infections, Complicated Intra-Abdominal Infections (cIAI), Nosocomial infections (hospital-acquired pneumonia, ventilator-associated

[41] NCBI: The treasure called antibiotics
[42] Science Direct: Antibiotics- past, present, future
[43] Science Direct, PMC

pneumonia), blood stream infections, to name a few. The global small molecule beta-lactam market captures about half of the antibiotics market (USD24-26 Billion).

Whilst LMIC countries are the key drivers of this market segment, developed markets such as the USA are also showing a surge in demand for beta-lactams, owing to the rising burden of common infections such as UTI as well as serious infections like sepsis (lifetime incidence of 50−60% in adult women in the USA), as well as high incidence of nosocomial infections (15% of all hospitalized patients suffer from these infections) is expected to propel growth in the market. Especially across the unregulated markets, schemes, and campaigns such as ReAct – Action on Antibiotic Resistance, India's National Action Plan on AMR, which includes awareness campaigns, infection prevention, and regulation of antibiotic sales, are some of the initiatives that are propelling antibiotic uptake. Also, African countries are taking multiple measures, including their individual National Action plans, the WHO's Global AMR Surveillance System (GLASS)[44]WHO's Antimicrobial Stewardship Training Package (enabling healthcare providers with the right skills in managing AMR cases) and many more, which is expected to propel the regional markets.

#### *3.6.2.1 Global Cephalosporin Drug Market*

Cephalosporins are a class of beta-lactam antibiotics widely used to treat a variety of infections caused by both Gram-positive and Gram-negative bacteria. Since their discovery in 1945, there have been constant advancements in terms of structural modifications to enhance their spectrum of activity and resistance to bacterial enzymes.

Their broad-spectrum efficacy makes them particularly valuable for empiric therapy, especially in serious infections either an unknown causative organism or multiple pathogens are involved, such as in febrile neutropenia or polymicrobial anaerobic infections which often require combination therapies for comprehensive coverage, achieving synergistic effects. Cephalosporins are well-suited for these scenarios due to their compatibility with other antibiotic classes and their ability to target a wide range of bacterial species.

Each structural change has given rise to a new generation. So far, there are five generations of cephalosporins, with select examples listed in the table below:

[44] WHO - Urgent action needed to tackle growing antimicrobial resistance threat in African region

| Key Cephalosporin Products Across Different Generations | | | | |
|---|---|---|---|---|
| **1st Gen** | **2nd Gen** | **3rd Gen** | **4th Gen** | **5th Gen** |
| • Cephalothin<br>• Cefazolin<br>• **Cefadroxil**<br>• **Cephalexin**<br>• Cephradine<br>• Cefroxadine<br>• Ceftezole<br>• Cefatrizine<br>• Cefazedone<br>• Cefalonium | • **Cefuroxime**<br>• **Cefuroxime Axetil**<br>• **Cefaclor**<br>• **Cefprozil**<br>• Cefoxitin<br>• Cefmetazole<br>• Cefminox<br>• Cefotetan<br>• Cefsulodin<br>• Flomoxef<br>• Ceforanide<br>• Cefamandole<br>• Cefonicid | • **Cefotaxime**<br>• **Ceftazidime**<br>• **Ceftriaxone**<br>• **Cefdinir**<br>• **Cefixime**<br>• **Cefpodoxime (Proxetil)**<br>• Ceftibuten<br>• Ceftizoxime<br>• Cefcapene Pivoxil<br>• Cefditoren Pivoxil<br>• **Cefoperazone**<br>• Cefotiam<br>• **Cefprozil**<br>• Cefteram Pivoxil<br>• Latamoxef<br>• Cefpiramide<br>• Cefodizime<br>• Cefetamet Pivoxil<br>• Cefmenoxime<br>• Ceftiofur<br>• Cefovecin | • **Cefepime**<br>• Cefozopran<br>• Cefpirome<br>• Cefedericol<br>• Cefoselis<br>• Cefquinome | • Ceftobiprole<br>• Ceftaroline<br>• Ceftaroline Fosamil<br>• Ceftolozane |
| Narrow spectrum; good Gram-positive activity and relatively modest Gram-negative activity; made inactive by Gram-negative beta-lactamases (derived from *Cephalosporium acremonium*) | Better Gram-negative coverage (more beta-lactamase stability) but less Staphylococcal activity | A wider spectrum of action compared to C1G and C2G. Less active than the narrow spectrum against Gram-positive cocci but much more active against *Enterobacteriaceae* and *P. aeruginosa* | Broadest spectrum of action; active against high-level cephalosporinases of *Enterobacteriaceae* and *P. aeruginosa* (better beta-lactamase stability) | Broad spectrum; active against the common Gram-negative bacteria; some Gram-positive activity (drug-resistant *S.pneumoniae*); notable for activity against Methicillin-resistant *S.aureus* (MRSA), unlike any other beta-lactam antibody |

*Source: WHO CC; Drug Bank; Frost & Sullivan*
*Note: Drugs highlighted in BOLD are available with Cotec Healthcare*

The five generations of cephalosporins are useful against skin infections, UTIs, lower respiratory tract infections, sexually transmitted diseases, surgical prophylaxis, and other infections like meningitis. These compounds are also useful in combination with other antibiotics, such as penicillin, aminoglycosides, or beta-lactamase inhibitors.

Across the smaller sub-segments of antibiotics, cephalosporins dominate the market, contributing to about half of the antibiotics market (USD 12-14 Billion), owing to the broad-spectrum activity of these drugs as well as their comparatively superior safety profile with mild adverse effects. Historically, growth in the cephalosporin segment has been driven by: (i) the launch of novel beta-lactam-related drugs (such as cefiderocol or ceftobiprole); (ii) the use of new antibiotic combinations, including beta-lactamase activity inhibitors (for instance, ceftazidime/avibactam, ceftolozane/tazobactam). It has allowed for the continued dominance of cephalosporins across its five generations.

While market growth was impacted during COVID-19, resulting from a decline in clinic visits and elective procedures, the market is expected to resume its growth trajectory given the continued high infectious disease prevalence, increase in R&D activity, efforts to improve access to antibiotics, and upcoming genericization of the latest generation of cephalosporins, thus making them more affordable. Resultantly, the market is forecasted to grow at a CAGR of 3-6% between 2022 and 2029.

Due to their broad-spectrum antibacterial activity, low toxicity, and relatively low incidence of allergic reactions, cephalosporins are highly effective in managing multi-pathogen infections and play a critical role in treating severe hospital-acquired infections. Their clinical advantages make them a preferred choice in inpatient settings, where injectable formulations are commonly used. However, this trend varies by region. In areas such as Central and South America and Southeast Asia, oral cephalosporin formulations are more prevalent, comprising around 60% and 80% of the market share, respectively, due to differences in healthcare infrastructure and prescribing practices. Cotec Healthcare is involved in the cephalosporin segment, with a portfolio particularly focused on third-generation cephalosporin antibiotics. The company offers a wide range of products, including Cefixime, Cefprozil, Cefoperazone, and Ceftriaxone. These formulations are designed to address various indications such as meningitis, typhoid fever, urinary tract infections (UTIs), bone and joint infections, respiratory tract infections, and ENT infections. In addition to its third-generation offerings, Cotec Healthcare also manufactures first, second, and fourth generations of cephalosporins. Its products are available in various dosage forms, including injectables (both liquid and dry), capsules, and tablets, catering to diverse clinical needs and patient preferences.

## 3.7 GLOBAL SMALL MOLECULE CNS MARKET – PAIN MANAGEMENT

***The pain management segment is evolving rapidly, supported by innovation in non-opioid alternatives, extended-release formulations, and targeted delivery systems. With analgesics/ pain management accounting for 6–8% of the CNS market, the demand for both acute and chronic pain therapies remains robust.***

The Central Nervous System is one of the top 5 segments of the pharmaceutical industry, which is expected to witness multiple new therapies as well as generic launches in the next 5 years. Among central nervous system (CNS) drug categories, analgesics/ pain management drugs represent a key segment, which accounts for 7%-8% of the total CNS market.

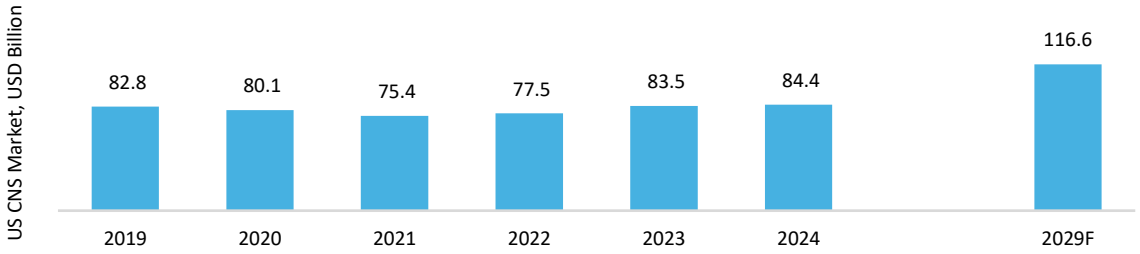
As the global ageing population rises alongside the rise in prevalence of chronic diseases, the demand for effective pain relief medications will continue to grow. Characterized by their ability to provide a targeted and fast-acting approach, the global pain management drug market encompasses a wide range of pharmacological therapies aimed at alleviating pain from various etiologies, including musculoskeletal disorders, neuropathic conditions, cancer, and post-operative recovery, among other areas. These drugs are aimed at both acute and chronic pain management. Pain management drugs are typically categorized into anesthetics and non-anesthetics

For Acute pain drugs such as anti-inflammatory drugs, including non-anesthetic drugs like NSAIDs (Ibuprofen, naproxen), Acetaminophen (paracetamol), opioids (morphine, oxycodone), as well as anesthetics such as lidocaine

and bupivacaine, have been in active usage, which provide rapid and effective relief to support healing and pain management and avoid the transition to chronic pain. Chronic pain management drugs include antidepressants and anticonvulsants as well as certain fast-acting topical agents and muscle relaxants, which cater to a long list of conditions, including neuropathic pain or cancer-related pain, muscle spasticity, post-herpetic neuralgia, osteoarthritis pain, and many more. Cotec Healthcare holds a portfolio of non-anesthetic drugs, including diclofenac sodium, Paracetamol and Ibuprofen. These are available in multiple forms, such as injectables, tablets, as well as topical ointments, allowing the company to serve various needs within the pain medication market.

The expansion in the analgesics segment within the broader CNS drug market is largely driven by the high prevalence of chronic pain. Other growth drivers include the increase in the number of surgical procedures and post-operative pain management, as well as an aging population more susceptible to pain-related conditions such as chronic back pain, osteoarthritis, and many more.

**Exhibit 3.10: Global Small Molecule CNS Market, 2019-2029F**



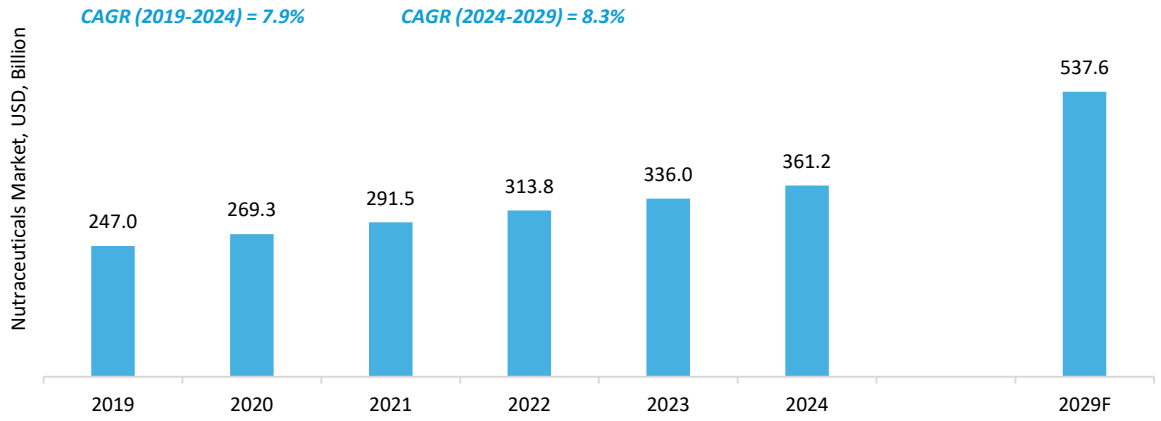

*Source: Evaluate Pharma, Frost & Sullivan*
*Note: F - Forecast; The forecast numbers represent only small molecule segment*

The continued development and regulatory approval of innovative analgesics, including extended-release formulations and non-opioid alternatives, are poised to further accelerate growth in this segment. Drug delivery methods play a critical role in determining therapeutic efficacy, patient adherence, and commercial viability. Moving forward, the pain management pipeline is robust, with a focus particularly on non-opioid therapies. Products such as Nav1.7 sodium channel blockers are currently in development, providing a significant push to the market through 2029. In addition, innovations in drug delivery systems (e.g., extended-release formulations, transdermal patches) and precision medicine approaches are enabling more targeted and effective pain relief with fewer side effects. Also, healthcare systems and insurance companies are increasingly adopting value-based care and multimodal pain management, combining pharmacological and non-pharmacological therapies (e.g., physical therapy, cognitive behavioral therapy) to improve outcomes.

## 3.8 GLOBAL NUTRACEUTICALS MARKET

Nutraceuticals play a pivotal role in preventive healthcare, chronic disease management, and overall wellness and are driven by aging populations and a shift toward natural and functional health solutions. These classes of supplements include dietary supplements, which include vitamin D, calcium, and omega-3 capsules, mainly targeting bone health, cardiovascular function, and immune resilience. These are amongst the most administered nutraceuticals and are available in various formulations such as tablets, capsules, powders, and liquids. Apart from these, the other commonly used supplements include Probiotics like Lactobacillus and Bifidobacterium. Across the fast-growing Nutraceuticals market, Cotec Healthcare contributes to the dietary supplements segment through its portfolio spanning key supplements such as calcium, iron, vitamin C, vitamin D, and B-complex vitamins (B1, B2, B12), as well as zinc and folic acid. These supplements are available in tablet and capsule formats to meet general consumer health requirements. With its growing popularity for health management, the nutraceuticals market is valued at USD 361.2 billion in 2024 with an expected CAGR of 8.3% to reach USD 537.6 billion in 2029.

**Exhibit 3.11: Global Nutraceuticals Market, 2019-2029F**




*Source: Frost & Sullivan*
*Note: F - Forecast; The market values include both pharmaceuticals and non-pharmaceutical products.*

The global nutraceuticals market is experiencing robust growth, driven by an aging population, rising health awareness, and the increasing prevalence of chronic diseases. By 2030, over 20% of the global population will be aged 60 and above, fueling demand for dietary supplements and functional foods aimed at managing lifestyle-related conditions such as obesity, diabetes, cardiovascular disease, and cognitive decline. Countries like France and Germany are piloting reimbursement models for prescribed nutraceuticals, while private insurers in the U.S. and Canada are integrating clinically validated supplements into chronic disease management plans. The COVID-19 pandemic further accelerated demand for immune-boosting supplements like Vitamin C, D, and zinc. Simultaneously, the expansion of e-commerce and direct-to-consumer channels, supported by subscription models and influencer-driven marketing, is reshaping consumer access and engagement. Innovative formulations—ranging from capsules and powders to functional beverages and gummies—are attracting diverse demographics, especially younger consumers drawn to products like collagen drinks and nootropic-infused supplements. This convergence of demographic shifts, technological innovation, and evolving healthcare strategies is positioning nutraceuticals as a cornerstone of preventive and personalized health management.

## 3.9 GLOBAL HORMONES MARKET

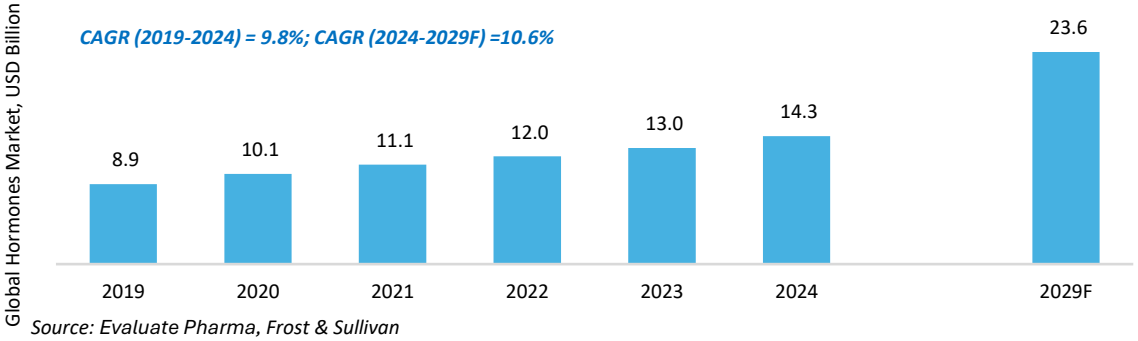
***Driven by expanding therapeutic applications, rising chronic disease burden, and increasing access through public health initiatives, the small molecule hormones market is poised for sustained growth with a strong demand across both developed and emerging markets, leading to a CAGR of 10.6% in the next 5 years.***

The global Hormones market is expected to witness steady growth, which is attributable to the rising awareness of reproductive health and associated advancements in the availability of Hormonal therapies, as well as a general increase in the prevalence of endocrine disorders across various age groups and genders. The market is valued at USD 14.3 billion in 2024 and is expected to reach USD 23.6 billion by 2029, registering a CAGR of nearly 10.6%.

The Hormones market essentially comprises a wide range of products, including progestins, estrogens, androgens, and corticosteroids. These products have a wide application across multiple therapy areas, including contraception, hormone replacement, oncology, and chronic inflammatory conditions. The market is primarily driven by a growing demand for hormone therapies, long-acting formulations, as well as a steady push by a growing aging population, as well as a growing application of these innovative therapies in chronic disease management. On the other hand,

there is an enhanced regulatory support for generics and greater adoption of hormonal therapies in emerging markets, which continue to broaden access and contribute to volume expansion of these therapies. Whilst developed/mature markets remain value-dense, emerging regions are contributing to incremental growth in this market through improved diagnosis rates and health system coverage for hormonal indications.

**Exhibit 3.12: Global Hormones Market, 2019-20298F**




*Source: Evaluate Pharma, Frost & Sullivan*
*Note: F - Forecast*

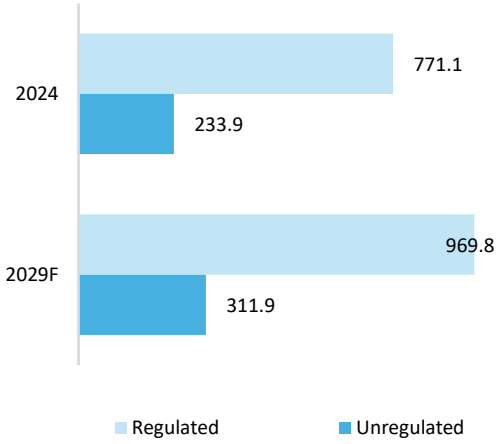
The global hormones market exhibits distinct regional patterns shaped by demographics, healthcare infrastructure, reimbursement models, and public health priorities. While demand is universal, the therapeutic focus, ranging from reproductive health to endocrine and inflammatory conditions, varies significantly by geography.

Hormonal therapies are becoming key drivers in chronic disease management, especially in women's health, metabolic and endocrine disorders, and supportive oncology care. Long-term use in conditions like menopause, hypothyroidism, and autoimmune diseases sustains demand, while corticosteroids and thyroid hormones remain staples. Public health programs in low- and middle-income countries, backed by the WHO and United Nations Population Fund (UNFPA) are expanding access to hormone-based contraceptives, especially injectables. Rising adoption of HRT, gender-affirming treatments, and puberty-suppressing agents is broadening their reach. A strong generics pipeline and local manufacturing efforts are improving affordability and access. With stable pricing, essential medicine status, and predictable demand, hormonal therapies offer resilient margins and strategic value for manufacturers.

## 3.10 SMALL MOLECULE PHARMA MARKET BY REGIONS

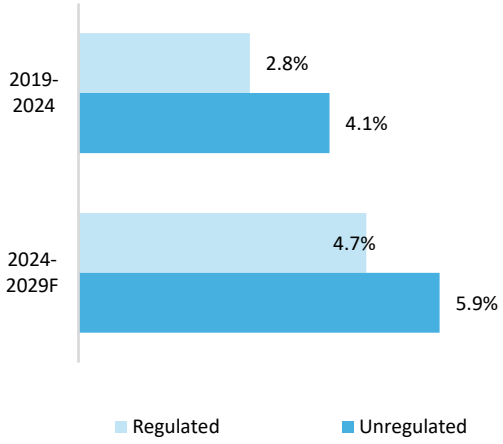
***Driven by a higher demand for innovative therapies, higher prices for comparable products and the infrastructure to support innovation, Regulated Markets continue to dominate the global pharma markets. Particularly North America, accounts for over 50% of the total share in 2024. Emerging markets are outpacing developed economies in healthcare growth, driven by population expansion, rising disease burden, increased government prioritization of health, growing private sector investment in infrastructure, and the scaling of local manufacturing capabilities***

**Exhibit 3.13: Global Small Molecule Pharma Market by Regulated vs. Unregulated, 2024 and 2029F**



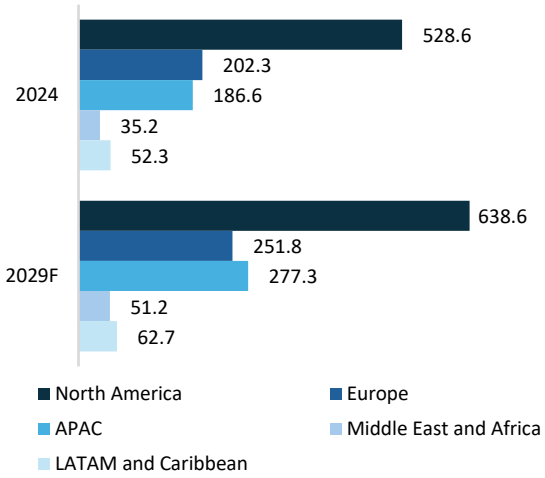

*Source: Frost & Sullivan*
*Note: F - Forecast*

**Exhibit 3.14: Global Small Molecule Pharma Market by Regulated vs. Unregulated, 2024 and 2029F**



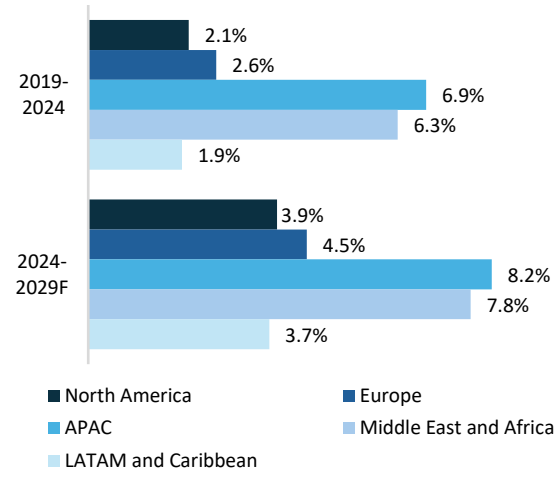

*Source: Frost & Sullivan*
*Note: F - Forecast*

**Exhibit 3.15: Global Small Molecule Pharma Market by Regions, 2024 and 2029F**




*Source: Evaluate Pharma, Frost & Sullivan*
*Note: F - Forecast*

**Exhibit 3.16: Global Small Molecule Pharma Market by Regions, 2024 and 2029F**




*Source: Evaluate Pharma, Frost & Sullivan*
*Note: F - Forecast*

Across the global pharmaceutical market, the regulated segment accounts for approximately 76–77% of the total market value. Countries such as the USA, Canada, Australia, Japan, South Korea, Saudi Arabia, the UK, France, and others are early adopters of innovative therapies, including high-cost treatments nearing a million dollars per dose. This drives growth in the innovator drug market, increasing healthcare expenditure and prompting governments and insurers to promote cost-effective generics where possible, a trend common across developed economies. Regulated markets are defined by stringent oversight from agencies like the US FDA, Australia's TGA, Japan's PMDA, the UK's MHRA, and the European Medicines Agency (EMA). These bodies ensure drug safety, efficacy, and quality across manufacturing, marketing, and distribution. Despite tight regulations, these markets remain hubs of pharmaceutical innovation. As inflation eases, regulated countries may adopt value-based or dynamic pricing models to better align with market conditions and consumer needs. Within APAC's regulated markets, Australia and South Korea show mixed growth dynamics, while Japan faces market share decline due to pricing pressures.

North America leads the regulated segment, projected to reach USD 638.6 billion by 2029, maintaining a 45–50% share of the global market. The United States alone contributes 40–45%, driven by high healthcare spending, strong R&D infrastructure, and a regulatory framework that supports innovation. Growth is further fueled by the rapid adoption of anti-obesity drugs and expanded indications for oncology therapies. Europe is expected to reach USD 251.8 billion by 2029, with a CAGR of 4.5%. Despite newer regulatory hurdles like the EU Health Technology Assessment (HTA) starting with oncology drugs in 2025 and expanding to orphan drugs by 2028, the region maintains a 23–25% global market share, supported by robust R&D, insurance coverage, and high diagnosis rates.

In the Asia Pacific, regulated markets such as Australia, Japan, and South Korea show CAGRs of 3–5%. Japan is countering pricing pressures through investments in biologics, biosimilars, and personalized medicine, with pharma companies forming joint ventures to boost R&D. Australia benefits from strong regulatory support via the Therapeutics Good Administration (TGA) and Pharmaceuticals Benefit Scheme (PBS), while South Korea's growth is led by companies like Samsung Bioepis, Celltrion, and Samsung Biologics, supported by bio-cluster investments and international collaborations.

In contrast, the unregulated segment comprising India, China, the Middle East, Africa, and Latin America accounts for 23–25% of the global market in 2024 and is expected to grow at double-digit rates, outpacing the global average. Over 40% of this growth is driven by the adoption of generics, especially in countries like India, China, Indonesia, Egypt, Turkey, Russia, and others. These markets are gaining ground as developed nations tighten healthcare budgets, while emerging economies invest in infrastructure, domestic manufacturing, and insurance expansion.

In APAC's unregulated markets, India and China lead the charge. India's growth is fueled by Ayushman Bharat, widespread generic adoption (nearly 90% of prescriptions), and a shift from acute to chronic disease burdens. These factors are driving sustained demand for pharmaceuticals. In Central Asia, countries like Kazakhstan and Uzbekistan dominate, with prescription drugs making up 60–70%[45] Of the market. Turkmenistan relies heavily on imports managed by government agencies, while Tajikistan faces challenges due to limited insurance coverage and high out-of-pocket expenses (around 70–72%), impacting market growth.

The Rest of the World (RoW)—including Latin America, the Middle East, and Africa—is also experiencing strong growth. The Middle East and Africa are projected to grow at a CAGR of 7.8% between 2024 and 2029, driven by improved infrastructure, rising health expenditures, and increased access to generics. Governments are expanding insurance, incentivizing local manufacturing, and partnering with global firms to improve access and affordability.

As urbanization and healthcare access improve, demand is shifting toward treatments for noncommunicable diseases like cancer, diabetes, and cardiovascular conditions. This opens new opportunities for global pharma companies to expand portfolios into emerging markets. For example, Kazakhstan recently completed Phase II trials

[45] IQVIA – Eurasian Pharma Markets, 2024

for a promising anti-cancer drug, and Novo Nordisk partnered with Aspen Pharmacare in South Africa to locally produce insulin and improve access across Africa.

### 3.10.1 KEY RISKS AND CHALLENGES IN THE GLOBAL PHARMA MARKET

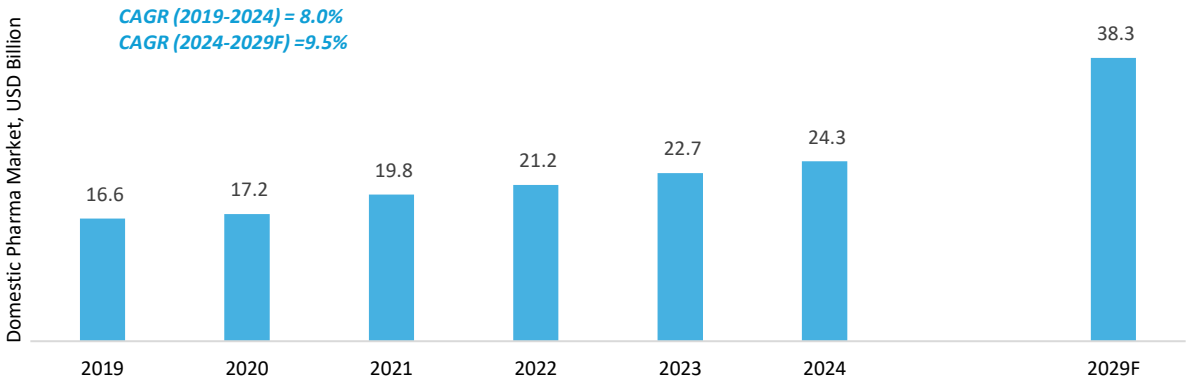
- **Regulatory Compliance:** Over the years, pharmaceutical companies have been navigating through increasingly complex and dynamic regulatory landscapes, with regulatory authorities such as the EMA, FDA, and other national agencies introducing newer mandates, digital platforms, and pricing regulations that demand significant operational agility. For instance, the European Medicines Agency (EMA) has rolled out the Product Lifecycle Management (PLM) and IRIS – for Regulatory Procedure Management (RPM) portals, which require companies to adapt their submission processes and internal workflows. 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 in the Age of Emerging Technologies**: Rise of newer technologies such as technology-enabled drug discovery, automations across manufacturing processes, and many more, result in large volumes and veracity of data which pertains to the drug intellectual property. Protecting intellectual property (IP) rights is therefore 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. To stay ahead, pharma companies are also investing in advanced IP analytics, conducting regular patent landscape assessments, and proactively monitoring for potential violations.
- **Pricing Pressures:** Driven by a combination of factors, including payer scrutiny, need for affordable drugs, reimbursement challenges, and many more, pharmaceutical pricing remains a contentious issue globally, with governments, insurers, and consumers exerting constant 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, Supply chains and Distribution:** Accessing diverse markets and establishing efficient distribution channels present formidable challenges for pharmaceutical companies, especially in emerging economies and low- and middle-income countries, with fragmented healthcare systems, limited infrastructure and supply chain capabilities (like sourcing raw materials, maintaining inventories, and many more) that hinder distribution. In addition to regulatory hurdles, logistical complexities (due to geopolitical tensions, natural disasters, pandemics, etc.), and cultural considerations can impede market entry and distribution efforts.
- **Product Development Risks:** Product development in the pharmaceutical industry is constantly facing critical challenges owing to the complexity, cost, and time involved in developing a drug, 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:** Both established pharma companies and emerging biotech companies have created a highly competitive environment within the pharmaceutical market, underscoring the importance of constant innovation. Alongside novel therapies, companies also need to face intense competition from generic manufacturers. Therefore, pharma players need to continuously invest in R&D to develop differentiated products and therapies, navigate patent cliffs, and sustain competitive advantage in an evolving landscape.

# 4 INDIA PHARMACEUTICAL INDUSTRY OVERVIEW

***The Indian Pharmaceutical Market (IPM) is witnessing robust growth, driven by a confluence of demographic, economic, and policy-related factors. These include a rising burden of chronic diseases, expanding insurance coverage, increasing demand from Tier II and III cities, and government initiatives aimed at improving drug accessibility.***

## 4.1 INDIA PHARMACEUTICAL INDUSTRY OUTLOOK

**Exhibit 4.1: India Pharma Market, India, 2019-2029F**




*Source: Frost & Sullivan*
*NOTE: Only includes domestic market. Almost 80-90% of the market is small molecule market*

The Indian pharmaceutical market is witnessing a value increase from USD 16.6 billion in 2019 to 38.3 billion in 2029, with an expected CAGR of 8.0% between 2019 to 2024 to reach USD 20.13 billion and a further CAGR of 9.5% between 2024 to 2029. The small molecule segment accounts for 80% - 90% of the total market, in 2024 by value as well as in terms of volume of drugs, with the biologics (including biosimilars) segment ranging between USD 4.5 to USD 5.5 billion in 2024. The IPM is ranked third[46] in the world in terms of pharmaceutical production volumes contributed by generics, OTC drugs, other bulk drugs as well as contract research and manufacturing industry, and is amongst the fastest growing pharma industries in the world. A growing chronic patient population, improved insurance penetration, growth in trade generics, demand from tier II and III cities, and a greater focus of local and union government bodies through schemes focused on drug access are propelling growth in the IPM. The government spending on healthcare in India is witnessing an upward trajectory, with 2023 values reaching USD 66.4 billion[47].Key segments of IPM include Generics, APIs, Vaccines, Biosimilars, OTC medicines, amongst others. Renowned for its cost-effective and high-quality pharmaceuticals, India has earned the global reputation of being the “Pharmacy of the World”.

[46] Press Information Bureau, Government of India
[47] India Brand Equity Foundation

## 4.2 INDIAN PHARMACEUTICAL INDUSTRY CHARACTERISTICS

### 4.2.1 OUTLOOK BY THERAPY AREAS

***Systemic Anti-infectives (SAI), Cardiovascular (CVS), Gastro-intestinal (GI), and Anti-diabetics are the top 4 therapy areas contributing to over 45% of the market in 2024. Furthermore, Pain Management (PM) is a key area expected to grow on par with the CVS segment at a CAGR of 10.2% and 10.0% respectively, between 2024 and 2029. The nutraceuticals segment is another strong growth area with a CAGR of 9.8% between 2024 to 2029.***

**Exhibit 4.2: Domestic Pharma Market by Therapy Area, FY19 to FY29F**

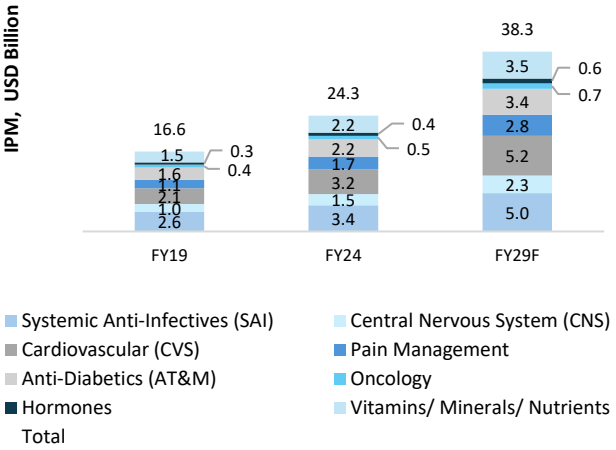
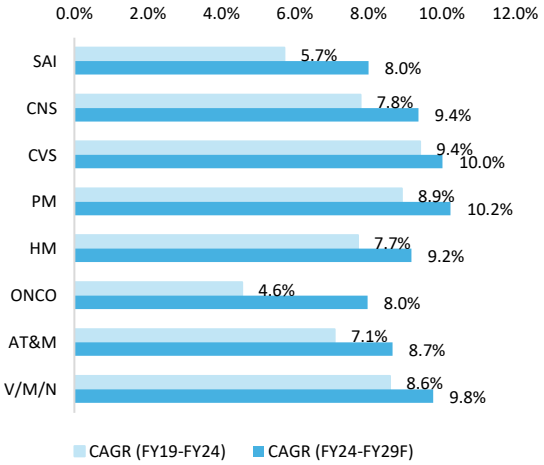



**Exhibit 4.3: Growth Rate of Domestic Pharma Market by Therapy Area, FY19-FY29F**




*Source: Frost & Sullivan*

*Note: Others (not displayed in the chart) include Respiratory, Blood, Sensory Organs, Immunology, Genitourinary, etc. AT&M is Alimentary Tract and Metabolism and represents only the anti-diabetics segment, HM is Hormones and is separated from the AT&M segment, which constitutes the anti-diabetics, ONCO is Oncology, PM is Pain Management and has been separated from the CNS segment; V/M/N represents the vitamins, Minerals, and Nutrients segment.*

Aligned with the disease epidemiology, the leading therapeutic areas in the Indian Pharmaceutical Market (IPM) in 2024 were systemic anti-infectives, central nervous system (CNS) (including pain management), and cardiovascular system (CVS). These segments contributed 14.0%, 13.0%, and 13.3%, respectively, to the overall market in FY24. They are projected to grow at compound annual growth rates (CAGRs) ranging from 8%-10% between FY24 to FY29. In addition to these, Hormonal therapies and oncology account for 1.7% and 1.9% respectively, in 2024 and are expected to grow at a CAGR ranging from 8%-9% between FY24 to FY29. Pain management, an important segment of CNS, is also expected to show a considerable CAGR of 10.2% between FY24 to FY29 owing to a surge in acute and chronic pain conditions.

### 4.2.2 OUTLOOK BY DOSAGE FORMS

***Across the IPM, 70.1% of the market is commanded by oral solids; the fastest growth is expected in inhalation and liquid formulations at a CAGR of 10.5% each between FY24-FY29*.**

**Exhibit 4.4: Domestic Pharma Market by Dosage Forms, FY19 to FY29F**

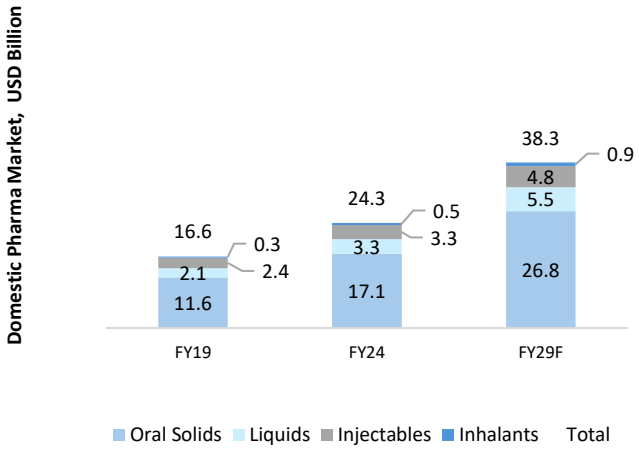
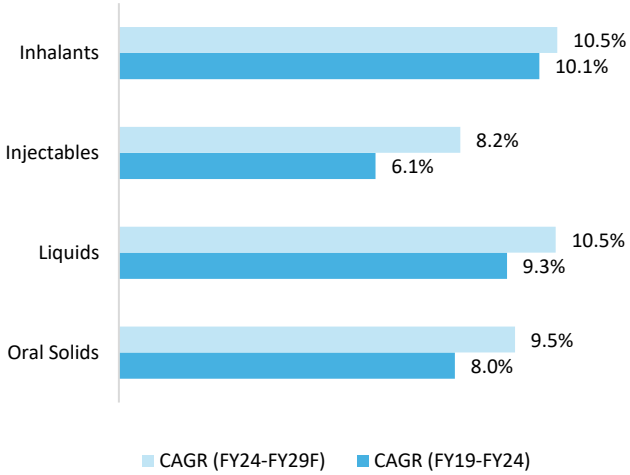



**Exhibit 4.5: Growth Rate of Domestic Pharma Market By Dosage Forms, FY19-FY29F**




*Source: Frost & Sullivan*
*Note: Others have not been displayed on the charts. "Others" segment includes implantable, inhalable, aerosol, etc.*

Oral solid dosage forms continue to dominate the Indian pharmaceutical market, primarily due to their ease of administration, patient convenience, and dosing flexibility. These advantages contribute to their widespread adoption and affordability. The segment is poised for sustained growth, supported by ongoing innovations such as modified-release formulations, orally disintegrating tablets, lipid-based systems, coated particles, and multi-particulate delivery technologies. As a result, the oral solids market is projected to grow at a CAGR of 9.5%, rising from USD 17.0 billion in FY24 to USD 26.8 billion by FY29.

Simultaneously, other formulation types, including injectables, inhalations, and oral liquids, are also experiencing steady growth. Injectables are favored for their rapid onset and precise dosing, while inhalation and topical formulations are preferred for their targeted, disease-specific action. Oral liquids are gaining traction, particularly in pediatric and geriatric care, and implants are beginning to establish a presence in the Indian market.

The "others" category, encompassing implants, sprays, inhalation products, and more, is expected to register the strongest growth, with a projected CAGR of 12.9% between FY24 and FY29. Meanwhile, the injectables segment, valued at INR USD 3.3 billion in FY24, is forecast to grow at a CAGR of 8.2%, reaching USD 4.8 billion by FY29.

## 4.3 KEY GROWTH DRIVERS FOR THE IPM

***Evolving chronic disease prevalence supported by growing awareness amongst patients, growing urbanization paving way for increased affordability, government schemes such as the Production Linked Incentive (PLI), Strengthening of Pharmaceutical Industry (SPI), and Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) are fueling demand for pharmaceutical products, thereby leading to strong growth. These initiatives will improve domestic production and reduce import dependency. While high out-of-pocket (OOP) expenditure continues to***

***steer demand toward cost-effective generics, this trend further strengthens the generics market, positioning it as a key engine of sectoral growth.***

In 2025, the union budget allocated INR 1,03,280 crore to health and family welfare, Ayush, and health research indicating an 8.3-fold increase from INR 12,482 crore in 2014–15. As disease prevalence continues to rise programs like Ayushman Bharat and the National Health Mission have expanded coverage and infrastructure, with the share of OOP expenses in total health expenditure dropping from 62.6% to 39.4% between 2015 and 2025, indicating improved financial protection for citizens.

The IPM is showcasing a promising growth in the next 3-5 years, which is attributable to multiple government initiatives such as Free Drug Service initiative (FDSI), Scheme for Strengthening of Pharmaceuticals Industry (SPI) for financial assistance for improving manufacturing infrastructure of MSMEs are some of the key initiatives which are propelling local pharma manufacturing. Under the National Health Mission (NHM), state and Union Territories receive financial and technical support there by ensuring steady supply of life saving medicines at public healthcare facilities.

Also, there are additional access- focused schemes creating lucrative opportunities for public sector operations for the pharma companies and CDMOs in India. For instance, PMBJP, implemented by the Department of Pharmaceuticals, is a flagship scheme that provides generic medicines at significantly lower prices through over 16,000 Janaushadhi Kendras across the country where in medicines are procured via open tenders from both public sector undertakings and private manufacturers. These ensure a stable supply chain for public procurement agencies like the Central Government Health Scheme (CGHS) and Jan Aushadhi Kendras, thereby supporting pharma companies in operating within the public sector, through a transparent and cost-effective model, improving access to essential medicines.

Some of the key drivers for the IPM include:

- **Rising prevalence of Chronic diseases:** India is experiencing a steady rise in the prevalence of both communicable and non-communicable diseases, creating a large market for pharmaceutical drugs. The country contributes to almost 15%-20% of the global burden for highly prevalent diseases (including respiratory infections (~20%), cardiovascular (~14%-15%), diabetes (17%-19%), cancer (8%-9%)[48]. This increase is largely driven by changing lifestyles, environmental factors, and rapid urbanization. By 2025, India is expected to witness a growth in the elderly population to reach 158.7 million (11.1% of the total population[49]), with chronic conditions becoming more prevalent among older adults. For instance, diabetes affects 10–11% of those aged 45–59[50] and rises to 14–15% in those above 59, while hypertension ranges from 18–40% depending on age. Furthermore, Urbanization, growing at 2–2.3%[51] annually, adds nearly 10–11 million people to cities each year, further contributing to the rise in chronic diseases. With these demographic and environmental shifts, the prevalence of chronic conditions is expected to continue increasing.
- **Enhanced Drug Accessibility:** The government has taken significant steps to improve drug affordability and accessibility. The (PMBJP, launched in 2008) aims to provide affordable generic medicines through dedicated Janaushadhi Kendras. From fewer than 100 stores in 2014, the network has expanded to 16,000 outlets as of June 2025, offering a product basket of 2047 drugs[52]. Off these total Janaushadhi kendras, more than 50% are based in Tier I cities, whilst about 43%-44% being in Tier II and remaining in Tier III cities

[48] US-India Chamber of Commerce: Clinical Trial Opportunities in India
[49] Health of the Elderly in India: Challenges of Access and Affordability
[50] Gender and Age Differentials in Prevalence and Pattern of Nine Chronic Diseases Among Older Adults in India: An Analysis Based on Longitudinal Ageing Study in India
[51] Worldbank
[52] Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)

and these ensure steady access of generic drugs across regions. Simultaneously, the government has developed 1,74,453[53] Ayushman Bharat Health and Wellness Centers as of 2024, further enhancing healthcare access across the country.

- **Rise in insurance penetration:** Health insurance coverage has expanded significantly, enabling broader access to healthcare services across all socio-economic segments. By 2025, about 55%-56% of individuals in India are expected to be insured, which translates to over 700 million people[54] reflecting growing awareness and affordability. Apart from that, the Pradhan Mantri Jan Arogya Yojana (PM- JAY), policy aims to offer medical coverage of INR 5 lakh per family per year for secondary and tertiary care hospitalization, there by covering more than 12 crores[55] poor and vulnerable families (constituting the bottom 40% of India's population).
- **Expanding Tier II and Tier III cities:** Whilst major metros like Delhi and Mumbai remain key markets, pharmaceutical companies are increasingly targeting Tier II and III cities across India such as Nashik, Indore, Visakhapatnam, Jaipur, Mohali, Surat, and Dehradun. These cities offer advantages like lower competition and real estate costs, along with growing healthcare infrastructure. In addition to that the shift is also supported by enhanced insurance penetration, increase in ecommerce platforms as well as e-pharmacy platforms such as Tata 1mg with an extensive distribution network and growing patient inclination towards localized care.

## 4.4 EVOLVING DYNAMICS OF PUBLIC PROCUREMENT - MARKET STRUCTURE AND VALUE CHAIN

India's public sector, guided by a robust legal and regulatory framework, plays a key role in ensuring access to essential medicines, particularly for underserved populations. Central and state agencies, including Central Government Health Scheme (CGHS), PSUs, Ministry of Health and Family Welfare (MHFW), the National Health Authority (NHA), the Central Drugs Standard Control Organization (CDSCO), and the Department of Pharmaceuticals (DoP), use structured, multi-stage pharmaceutical tendering processes to procure high-quality drugs through fair and competitive bidding. It ensures transparency, quality, and cost-efficiency while enabling Indian pharma companies to secure steady revenue streams via long-term contracts. Through policy, procurement mechanisms, and regulatory oversight, the government supports both public healthcare delivery and industry stability. Across the Indian Pharmaceutical Market, government agencies and public sector entities are amongst the largest buyers of pharmaceuticals, mandating a highly regulated process for procuring pharmaceutical drugs.

One of the primary mechanisms through which the government ensures drug availability is centralized tendering and procurement. The pharmaceutical tendering process in India's public sector is a comprehensive, multi-stage procedure designed to ensure transparency, cost-effectiveness, and quality in drug procurement. The bidding and tendering process is governed by the Drugs and Cosmetics Act, 1940, the Indian Contract Act, 1872, as well as the Sale of Goods Act, 1930, and the Competition Act, 2002. Also, under section 124 of the DC Act, the Indian Pharmacopoeia has laid the quality standards for the drugs being sold in India, which has also created the standard for cGMP in the country.

CGHS is responsible for supplying medicines to government employees, pensioners, and their families. On the other hand, individual State Health Departments manage the drug procurement at state-wide hospitals and healthcare centers. Separately, the Public Sector Undertakings (PSUs) in Pharmaceuticals are the government-run pharma companies engaged in bulk drug procurement, and the Defense & Railways Health Services supply medicines for military personnel and railway employees. In addition, stand-alone agencies like HLL Lifecare Limited and

[53] Ministry of Health and Family Welfare
[54] IRDAI
[55] National Health Authority - Pradhan Mantri Jan Arogya Yojana (PM-JAY)

Government Medical Store Depots (GMSDs) also play a role. These entities float tenders for bulk procurement of medicines, which are then distributed to public hospitals and health centers under schemes like the PMBJP and Ayushman Bharat schemes.

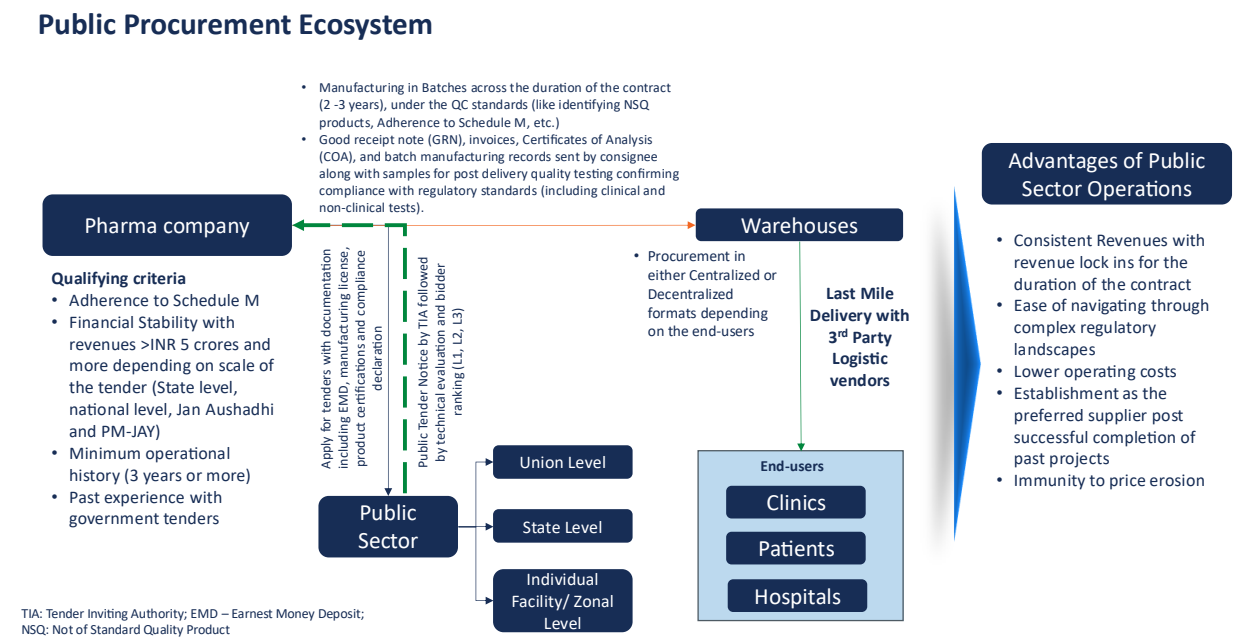
A typical drug tendering process usually follows a Two-Step Tendering which separates the technical and financial bids. The tendering process is a step-by-step approach as mentioned below.

- The procurement process begins with the Tender Inviting Authority (TIA) issuing a public tender notice via official e-procurement portals and print media. The tender document outlines eligibility criteria, pricing structures, GMP requirements, and quality control and assurance procedures. Prospective bidders review these details and attend a pre-bid meeting for clarifications. Based on feedback, the TIA may issue a corrigendum to revise the tender terms.
- Once finalized, bidders prepare submissions including technical documents (licenses, certifications, declarations), along with the Earnest Money Deposit (EMD) and tender fees. Documents are uploaded to the TIA's e-procurement portal and sometimes submitted physically. Bidders analyze market trends and the Last Purchase Rate (LPR) to determine competitive pricing, which is entered into the Bill of Quantity (BOQ), the financial bid component.
- The TIA conducts a technical evaluation to verify document authenticity, eligibility compliance, and the bidder's capacity to deliver quality products. If discrepancies arise, bidders are given time to clarify and provide additional information. Only those meeting all technical requirements are deemed qualified, and their names are published before moving to the financial evaluation.
- In the financial evaluation, bids of technically qualified participants are opened. A comparative rate chart ranks the bidders as L1 (lowest quote), L2, L3, etc. Non-L1 bidders may be invited to match the L1 rate to expand the supplier pool. Typically, L1 is awarded 60% of the contract volume, while L2 receives 40% at the L1 price. This ensures competitive pricing and supply continuity, reducing dependency on a single vendor.
- After final selection, the TIA issues a Letter of Intent (LOI) to successful bidders, requesting submission of the signed agreement, performance bank guarantee, and other required documents. This leads to the signing of a formal rate contract.
- With the contract in place, the TIA issues purchase orders (POs) for the awarded items. Suppliers begin raw material procurement and production planning. Manufacturing is conducted under strict quality control, with samples tested at various stages. Once approved by the Quality Control (QC) department, goods are packed and handed over to logistics for dispatch.
- The approved pharmaceutical products are dispatched on a door-delivery basis to the designated consignees. Each shipment is accompanied by essential documentation, including invoices, Certificates of Analysis (COA), batch manufacturing records, and other statutory papers. The supplier also uploads dispatch details to the purchaser's portal for tracking and verification. Upon receipt of the goods, the consignee generates a Goods Receipt Note (GRN) and sends samples for post-delivery quality testing to confirm compliance with the required standards.
- Finally, payments are processed based on the GRN and the results of the standard quality (SQ) tests. If the products meet all quality parameters, the purchaser releases the payment as per the agreed terms. The procurement cycle is considered complete once all purchase orders are fulfilled, payments are made, and both parties have met their contractual obligations. This marks the formal closure of the tendering process.

## 4.5 PUBLIC PROCUREMENT ECOSYSTEM IN THE IPM

***With the help of initiatives like the Jan Aushadhi Scheme, the public sector creates a self-reliant, globally competitive, and accessible pharmaceutical ecosystem that benefits both manufacturers and the public. As per an***

***economic survey of the Ministry of Finance in 2025, the government's share in total healthcare expenditure increased from 29% in FY19 to 48% in FY22[56]***




Drug procurement in India is a multifaceted process governed by a complex web of policies, regulations, and agencies operating at various levels. Overall, the government spent USD 66.4 billion on Healthcare in India in 2024, with the public health expenditure standing at 2.5% of the country's GDP in 2025 as per IBEF's Economic Survey 2024-25. Approximately 10%-12% of the government's health budget is allocated to hospitals and health centers, primarily for the procurement of generic medicines. The public procurement ecosystem functions through centralized and decentralized models, requiring collaboration with stakeholders across the supply and demand chain. On the supply side, pharmaceutical companies must coordinate with hospitals, clinics, and district-level health facilities, while managing diverse drug categories and adhering to rigorous manufacturing and quality control standards. According to the Ministry of Health and Family Welfare Audit report in 2020-2021, the CGHS was allocated a total budget of INR 3,435.6 crores for Procurement of Drugs and Medical Treatment. State agencies like TNMSC procured more than 300 essential drugs in 2023. Also, agencies such as the Armed Forces Medical Services (AFMS) holds 130 hospitals in different parts of the country with a drug list of over 1000 drugs. Similarly, the Indian Railways provide health services through 129[57] hospitals and 586 health units.

To participate in public sector procurement, pharma companies must meet stringent eligibility criteria. These typically include registration with the State Drug Control Authority, adherence to Indian Pharmacopeia (IP) standards, and compliance with the Essential Medicines List (EML) or government health program requirements. The revised Schedule M now aligns Indian manufacturing practices with global standards, incorporating Pharmaceutical Quality Systems (PQS), Quality Risk Management (QRM), and protocols for continuous monitoring and post-market quality verification. Financial stability is also crucial, with the latest Supreme court ruling out the clauses for minimum revenue requirement which override the Public Procurement Policy for MSEs, 2012. This change mandates at least 25% of procurement from MSMEs with the court ruling that the minimum turnover requirement need to be rational and proportional. Earlier, the turnover requirements varied from anything between

[56] Ministry of Finance
[57] Report of the Comptroller and Auditor General of India, March 2022

INR 5 crore to INR 20 crore to as high as INR 50 crore, depending on the type of contracts (state level, zonal level, national level etc.).

Public sector engagement offers significant strategic advantages. Government schemes such as Jan Aushadhi and procurement by state governments through dedicated medical corporations ensure consistent demand and high-volume sales, particularly benefiting generic drug manufacturers. Long-term contracts spanning 2–3 years provide revenue lock-ins and business continuity.

Moreover, supplying to government programs enhances brand visibility and public trust, positioning companies as preferred suppliers and fostering long-term partnerships. Successful participation not only strengthens domestic market presence but also opens avenues for international expansion.

### 4.5.1 ELIGIBILITY CRITERIA FOR PROCUREMENT

***To ensure working with qualified, complaint and capable pharma manufacturers, the government of India has created a comprehensive set of eligibility criteria for a company to participate in India's public pharmaceutical procurement ecosystem supplying medicines to government hospitals, public health programs, and schemes like Jan Aushadhi and many more.***

- **Mandatory registration with centralized drug control authorities:** Any pharma company applying for a government drug procurement tender must be legally registered entity under the Companies Act, 2013 with a valid Drug Manufacturing License under the Drugs and Cosmetics Act, 1940. It should also be registered with the Central Drugs Standard Control Organization (CDSCO) or the relevant State Drug Control Authorities in case willing to operate with state government procurement agencies. These registrations confirm that the company is authorized to manufacture and distribute pharmaceutical products in India.
- **Adherence to key protocols and policies:** Adherence to Schedule M[58], which outlines the key Good Manufacturing Practices is a crucial mandate for any pharma company operating in the country. The recently revised Schedule M essentially aligns Indian manufacturing standard to that if global standards including the Pharmaceutical Quality System (PQS) and Quality Risk Management (QRM), risk-based audits, self-inspection protocols, Product Quality Review (PQR) for continuous monitoring, computerized inventory and batch checking and sample batch retention for post market quality verification.
- **Steady Financial stability and past records:** Pharma companies applying for public procurement must demonstrate financial stability, with revenues of INR 5–20 crore for small-scale tenders and above INR 20 crore to even INR 50 crore for national-level contracts, supported by audited financials and a clean compliance record. Minimum investment thresholds may also apply based on the product type. These criteria ensure only companies with adequate infrastructure and capacity can meet public sector demands. Prior experience in supplying to government institutions and a strong track record—free from disqualifications or blacklisting—adds credibility and improves chances of selection, making compliance and operational readiness critical for success in public procurement.
- **Participation through e-tendering:** To apply for a government tender, the companies must register themselves on various websites depending on the type of participation they are looking for. For instance, GeM (Government e-Marketplace) for centralized procurement, CPPP (Central Public Procurement Portal) for e-tendering and PMBI (Pharmaceuticals & Medical Devices Bureau of India) for participating in Janaushadhi Scheme. Digitization ensures transparency in the entire tendering and project allocation process.
- **Adhering to Union/ State Level policies for public sector participation:** To apply to a state government agency, pharma companies must register with the relevant State Drug Control Authority, and ensure

[58] Implementation of Scheme for Schedule M compliance for SSI Pharma units

products conform to Indian Pharmacopeia (IP) or other specified standards. Products must align with the Essential Medicines List (EML) or government health schemes, meeting pricing, quality, and availability norms. While regulatory requirements pose challenges, schemes like Schedule M Compliance Support offer financial incentives—especially for MSMEs—for infrastructure upgrades. Once qualified, public-sector contracts provide volume stability, long-term visibility, and market credibility, making them a strategic opportunity despite the initial compliance burden.

### 4.5.2 BENEFITS OF WORKING WITH THE PUBLIC SECTOR FOR PHARMA COMPANIES

***As India aims to become a global pharmaceutical innovation hub in the coming years, companies aligned with public sector goals are better positioned to benefit from future reforms and global collaborations with easy navigation through regulatory channels.***

- **Enhanced Geographic Reach providing Access to both Urban and Rural markets:** The Indian government is one of the largest buyers of medicines, especially through schemes like Jan Aushadhi, and state-level health missions. Public procurement ensures steady demand and high volume-based sales, which can be particularly beneficial for generic drug manufacturers catering to bulk volume demands for rural, district and zonal level healthcare and medical facilities. Working with the public sector allows also pharma companies to play a direct role in improving healthcare access and outcomes, especially in underserved regions.
- **Enhanced Brand Visibility and Trust in Local Markets:** Supplying to government programs enhances a company's credibility and public trust, especially when drugs are distributed through national health schemes, whilst paving way for steady public private partnerships (PPP). It also helps build a reputation for quality and reliability, which can be leveraged in both domestic and international markets. For instance, Indian pharma companies such as Dr. Reddy's, Cipla, Sun Pharma and many more have been working with state governments, Ministry of Health and Family Welfare, by participating in programs such as PMBJP for providing easy medicine access at affordable prices
- **Business Longevity with Greater Certainty in Production Plans Ensuring Business Continuity:** With yearly production plans shaped through long-term contracts spanning 2-3 years, including supply to local health centers, hospitals, Janaushadhi kendras and many more, working in the public sector ensures steady revenue streams in addition to assured budgetary support, policy protection and subsidies in procurement of raw materials. Whilst private companies are constantly exposed to market competition, companies operating in the public sector prioritize accessibility which in turn ensures business longevity even in low margin segments, considering there is a constant demand for essential medicines.

Engaging with the public sector offers pharmaceutical companies in India a strategic pathway to expand their geographic reach within the country and enhance brand equity, whilst ensuring long-term business continuity. However, participation in public sector procurement is not without its challenges especially for small to mid-segment and new market entrants. Barriers such as the need for steady financial performance, consistent operational track records over the past 3–4 years, and robust compliance frameworks may often limit access for smaller or newer players.

### 4.5.3 BARRIERS TO PHARMA COMPANIES FOR PUBLIC DRUG PROCUREMENT

Pharma companies in India benefit highly from working with government agencies owing to steady revenue streams and comparatively easier regulatory navigation. However, for small to mid-segment players, there are certain barriers that may impede their participation with the public sector. Some of the challenges include:

- **Stringent Quality Compliance requirements with Lengthy and opaque processes:** Quality compliance is the most important aspect of Pharma manufacturing, which is also considered key to working with the

public sector. Small to mid-segment pharma companies with small facilities and inadequate infrastructure and resources, may face higher compliance burden (e.g., GMP certification, batch testing). Furthermore, alongside variations in compliance policies across different states, lack of transparency in the approval processes further adds to the challenges that create greater complexities.

- **Logistical and Distribution Challenges impacting drug accessibility:** With Indian states relying heavily on generic drug supply, especially across government hospitals and health centers, ensuring steady supply to across both rural and urban regions involves significant logistical costs, which may be a challenge for smaller players. For newer market entrants, navigating the supply chains through individual state governments in addition to managing clear records of their inventory (which will then be utilized by the local procurement agencies for demand forecasting) to avoid unnecessary overstocking or understocking can significantly increase the costs for running operations.
- **Inadequate infrastructure and higher entry costs:** Newer entrants often face a steep financial barrier when entering the public drug procurement market due to the substantial upfront investment required. Establishing GMP manufacturing infrastructure, implementing rigorous quality control systems, and navigating complex regulatory frameworks are capital-intensive activities that are particularly burdensome for small or emerging firms that have limited access to funding. As a result, new entrants struggle to compete effectively, often finding themselves excluded from large-scale procurement opportunities that favor well-capitalized and experienced manufacturers.
- **Competitive Pricing for Low-Cost Bids:** Government tenders often prioritize the lowest-cost bids with several MSMEs competing at the same time. Despite a competitive pricing landscape, the structured bidding process offers a reliable channel for consistent volumes. There is growing recognition that supporting innovation is essential to sustaining and scaling participation from emerging players. Therefore, enhancing procurement frameworks to better support innovation and timely payments could encourage broader participation and strengthen the sector's contribution to public health.

### 4.5.4 DRUG PROCUREMENT AT UNION AND STATE GOVERNMENT LEVELS

***The Ministry of Health and Family Welfare (MoHFW) is primarily responsible for nationwide drug procurement through public health programs. Under the purview of the MoHFW, the Medical Stores Organization, the attached office of the Department of Health, further procures drug for government hospitals, disease control programs, dispensaries.***

Drug Procurement in India across the public sector can happen either through a centralized or a decentralized/ pooled process. As opposed to a centralized process, the pooled procurement process is expected to provide a wider cost saving. For instance, a recently published paper on "A National Cancer Grid pooled procurement initiative, India", indicated that purchases made by hospitals that are associated with the National Cancer Grid using pooled procurement for about 40[59] key drugs saved close to INR 13 billion.

#### Union Level:

At the national or the union government level, the Ministry of Health and Family Welfare (MoHFW) is the primary authority responsible for drug procurement. Within the MoHFW, the Medical Stores Organization (MSO), an attached office under the Department of Health, manages the procurement and distribution of medicines for central government hospitals, dispensaries, disease control programs, and the Central Government Health Scheme (CGHS). The most used procurement model under the MoHFW is the Central Rate Contract (CRC) System, where the government directly finances, procures, and distributes medicines. This centralized model places the entire responsibility for drug selection, procurement, warehousing, and distribution under the MoHFW. However,

[59] A National Cancer Grid pooled procurement initiative, India

autonomous institutions like AIIMS and PGI, which operate under the MoHFW, follow a decentralized procurement approach.

The MoHFW maintains a National List of Essential Medicines (NLEM) to guide drug procurement. However, various agencies and autonomous bodies under the ministry often use their own Essential Drug Lists (EDLs), which can differ significantly. Additionally, the Medical Stores Organization (MSO) and other procurement bodies frequently purchase drugs outside these lists.

**Drug Procurement Models:**

- The Central Rate Contract (CRC) system, while intended to centralize procurement, lacks a standardized process for consolidating requirements and managing distribution. This inefficiency often results in unmet demands, pushing hospitals and dispensaries to rely heavily on local chemists. According to the Comptroller and Auditor General (CAG), nearly 80% of drug purchases between 2002 and 2008 were made locally, indicating a de facto decentralized system. This drug formulary was revised in the year 2022, post which newer drugs prescribed by doctors were also considered, which included about 641 drugs as of 2022. Also, due to shortage of drugs procured under the Central Government Health Scheme (CGHS), Authorized Local Chemists (ALCs) will continue to play a crucial role in drug procurement.
- Beyond the MoHFW, other central entities like the Ministry of Defense, Employees' State Insurance Corporation (ESIC), and the Bureau of Pharma PSUs of India (BPPI) also manage drug procurement through varied models individually. These organizations differ in their legal status, funding sources, and operational frameworks. For example, established in 2011, the Central Medical Services Society (CMSS), operates a centralized procurement system with 20 warehouses. BPPI on the other hand, under the Department of Pharmaceuticals, implements the PMBJP to provide affordable medicines.
- Similarly, while ESIC, formed in 1954, follows a statutory model funded by government and employee contributions. These agencies also vary in quality control practices and transparency, with some conducting random inspections and others requiring WHO-cGMP certification and batch-wise testing.

## State Level:

At the State Levels, drug procurement varies widely, with each state adopting its own model, which significantly influences the cost, quality, transparency, and efficiency of the procurement process. Key variations arise in several areas, including:

- The legal status of the procurement agency, whether it is a government department or an autonomous body. This affects its operational independence and funding sources to a large extent. However, in the present scenario, most large consuming states like Tamil Nadu, Uttar Pradesh, Rajasthan, and many more have now established dedicated medical supply corporations (e.g., TNMSC, UPMSC, RMSC), which are state-run procurement agencies. They are responsible for efficient centralized purchasing, drug warehousing, and distribution, whilst maintaining the highest quality standards.
- Secondly, the presence and management of an Essential Drug List (EDL) and the methodology for demand estimation are crucial. Agencies that regularly update their EDLs and use scientific methods for forecasting demand are better positioned to ensure timely and appropriate drug availability. With the establishment of dedicated medical supply corporations, these individual agencies regularly update their EDLs based on disease burden, utilization trends, and evolving treatment protocols there by aligning their drug procurement with that of the state and national health priorities.

Overall, the procurement process differs particularly in terms of tendering procedures and timelines, which directly impact the efficiency of the entire process. Quality control mechanisms also show significant variations, with some agencies enforcing strict pre-qualification criteria like minimum turnover, GMP certification, and production capacity, along with additional safeguards such as pre-dispatch and random batch testing. These state-level

autonomous bodies or state government-owned bodies procure and distribute anything between 80%-100%[60] of medicines and diagnostic products based on the requirements. Most of these bodies work through centralized distribution channels. Nevertheless, in many cases distribution of drugs utilizes regional/ district level warehouses and distribution channels as well as district medicine stores.

Supply chain management is another area of divergence; some agencies manage warehousing and distribution internally, while others outsource these functions. Finally, the presence of penalty clauses for non-compliance, including quality breaches or supply failures, and the use of blacklisting procedures, determines the robustness of the enforcement and accountability framework within each state's procurement system.

**Drug Procurement Models:**

The procurement models vary across states, with several states emulating Tamil Nadu's Pooled Procurement System. The Tamil Nadu Medical Services Corporation (TNMSC), established in 1994, is an autonomous agency led by IAS officers and contractual experts and operates under the Tamil Nadu Transparency in Tenders Act, 1988. This agency primarily manages the centralized procurement of drugs listed in a frequently updated Essential Drugs List (EDL). This model has been widely recognized for its transparency, efficiency, and cost-effectiveness, and is recommended by organizations like the WHO and World Bank. States such as Kerala, Odisha, Bihar, and Maharashtra have adopted variations of this model. Nevertheless, the outcome for each state varies depending on the local logistical, state, and zonal challenges and the accuracy of adoption of the model.

TNMSC[61] is responsible for conducting transparent tendering processes while ensuring timely drug delivery to different states and zonal warehouses. The agency uses a unique passbook system for drug distribution to various health facilities by allocating a fixed budget to each facility. TNMSC boasts of a robust quality control mechanism, including mandatory testing of initial batches as well as random sampling. Real-time inventory tracking through IT systems further enables efficient year-round procurement.

Apart from the TNMSC, some of the other state-level drug procurement agencies include Uttar Pradesh Medical Supplies Corporation Limited, Kerala Medical Supplies Corporation, Gujarat Medical Services Corporation Limited, Rajasthan Medical Services Corporation Limited, Bihar Medical Services and Infrastructure Corporation, and many more, which operate as autonomous bodies through either at centralized or decentralized levels, catering to the needs of local hospitals, dispensaries, or any other healthcare facilities.

## 4.6 KEY SUCCESS FACTORS FOR INDIAN COMPANIES

***India's pharmaceutical sector is strengthening its global competitiveness through regulatory excellence, backward integration, cost efficiency, and a shift toward complex, high-value products. Sustained growth will depend on strategic investments in geographic diversification, workforce development, and robust IP and quality systems to meet evolving global standards and market demands. Furthermore, to grow to even larger scales and compete with global CDMOs, Indian CDMOs will have to focus on quality, offer scalability-flexibility-competency, and be able to serve across larger parts of the pharma value chain.***

India is rapidly establishing itself as a global pharmaceutical manufacturing hub, as well as a demand center for pharmaceutical drugs, with competitive strengths extending beyond APIs to include FDF capabilities as well. The country's cost-effective but quality-driven production ecosystem, reinforced by a longstanding track record of supplying high-quality pharmaceutical drugs to highly regulated international markets, positions it uniquely to meet the evolving demands of the global pharmaceutical supply chain. As international pharma companies face mounting

[60] Journal of Global Health Reports - Access to medicines in the Indian Public Health System
[61] An Analysis of the Drug Distribution Model in the Public Health Services in Tamil Nadu - Scholars Academic Journal of Pharmacy

pricing pressures and increasing therapeutic complexity, India presents a compelling value proposition grounded in technical expertise, scalable manufacturing, and regulatory compliance.

Some of the critical success factors for Indian Pharma players include:

- **Regulatory Compliance and Quality Assurance:** Global regulatory authorities are increasingly tightening oversight to ensure the consistent delivery of high-quality pharmaceuticals within their jurisdictions. In line with this trend, India's Directorate General of Foreign Trade (DGFT) has mandated quality testing at central government-approved laboratories for all drug exports, effective June 1, 2023, an initiative aimed at reinforcing global confidence in Indian pharmaceutical products. Although India showcases a strong presence in global markets, the issuance of over 50 FDA warning letters to Indian firms between 2019 and 2024 highlighted the ongoing need for rigorous quality oversight. To preserve international confidence and market access, companies must therefore invest in proactive remediation strategies, strengthen quality infrastructure, and maintain robust audit readiness systems.
- India's longstanding credibility with highly regulated markets underscores its end-to-end manufacturing competence. In Q1 2025, Indian companies led the submission of 162 (47% of the total type II DMFs) US Drug Master File (DMF)[62], indicating a 51,4% growth over Q1 2024 submitted and operated 216 US FDA-approved API manufacturing facilities, significantly outpacing counterparts in the USA and China. Cotec Healthcare has manufacturing facilities accredited by multiple global regulatory authorities like WHO-GMP, FSSAI, ISO 9001-2015 and is present across different countries across the Central Asia and Western African region
- **Scale and Cost Efficiency with Comprehensive Service/ Product Offerings:** India offers significant scale and cost advantages in pharmaceutical manufacturing. Setting up a US FDA-compliant facility in India requires nearly 50% less capital and 40–70% lower operating costs than in developed markets. Sustaining this edge demands continuous scaling, process efficiency, and adoption of technologies like continuous flow chemistry. Strategic models such as risk-sharing partnerships also support smaller pharma and biotech firms. Labor costs are a major advantage, with India's average minimum wage at USD 55/month, far below China's USD 267/month, narrowing the cost gap amid rising wage inflation. A capable CDMO must also manage end-to-end supply chains—inventory, storage, and logistics—ensuring seamless delivery and global competitiveness in an increasingly cost-sensitive market.
- **Portfolio Complexity and Product Differentiation Across Drug Modalities and Delivery Platforms:** With the global pharma market becoming increasingly saturated, future success hinges on the ability to move up the value chain through portfolio complexity and innovation. Indian companies must demonstrate expertise across a wide range of drug types, delivery mechanisms, and dosage forms such as inhalers, transdermal patches, implantable, extended release injectables, liposomes and colloids and ophthalmic suspensions; and specialized delivery routes, including locally acting therapies, ophthalmic products, and innovative formats such as suspensions, emulsions, and gels. The ability to innovate and adapt to evolving pharmaceutical demands significantly enhances CDMO's strategic value to global clients.
- **Geographic Diversification and Enhanced Market Access:** India's formulation exports remain heavily concentrated, with over 40% directed to the USA markets. However, Indian companies are increasingly expanding into emerging regions such as Latin America, Southeast Asia, and Africa. Success in these markets will depend on developing region-specific product portfolios, forging strategic local partnerships, and building strong in-country regulatory capabilities to navigate diverse compliance landscapes effectively. For instance, Cotec Healthcare has a diversified presence across nonregulated markets across Central Asia (Kazakhstan, Turkmenistan, Tajikistan, etc.) and Western Africa region (Nigeria, Burkina Faso, Benin, and many more), deriving significant revenues across all these markets.

[62] Pharmacompass: USDMF Analysis

- **Investments in continuous improvement and building unique capabilities**: Upcoming patent expirations for novel small molecule drugs will drive demand for generics, boosting the need for CDMO services. To stay competitive, CDMOs must upgrade infrastructure and capabilities to meet evolving sponsor needs. Handling highly potent compounds requires investments in containment, automation, and skilled labor. Larger CDMOs are expanding capacity through acquisitions and technology upgrades like continuous manufacturing. Embedding digital solutions across workflows enhances efficiency and profitability. These advancements are essential for CDMOs to deliver value, maintain quality, and support pharma partners in a dynamic, innovation-driven market.
- **Technical proficiency in manufacturing complex products**: API and FDF manufacturing demand advanced capabilities—from multi-step synthesis and purification to biotech processes using fermenters and bioreactors. India's strong foundation, with over 3,500 engineering institutes and 1.5 million graduates annually[63], supports innovation, cost efficiency, and sustainable practices. As drug complexity and regulatory scrutiny increase, a highly skilled workforce is essential. CDMOs with expertise in complex chemistries—like beta-lactams, steroids, peptides, and stereochemistry—are well-positioned for growth. However, India still has a limited pool of API suppliers with such capabilities. To stay competitive, companies must invest in talent across regulatory affairs, advanced analytics, and quality systems to ensure compliance, scalability, and long-term innovation.
- **Proven Delivery Track Record and Operational Reliability**: To build lasting partnerships with pharmaceutical sponsors, CDMOs must demonstrate a consistent track record of timely project delivery supported by robust quality systems. Managing multiple clients across geographies requires mature operational frameworks that mitigate risks related to quality, logistics, regulatory compliance, and intellectual property. In cases where backward integration is absent, maintaining a dependable network of suppliers for key starting materials (KSMs) and intermediates is essential not only to meet timelines and milestones but also to prevent issues such as contamination or impurities. A CDMO with a history of successful execution is well-positioned to foster long-term, trust-based relationships with global clients.
- **Commitment to sustainability:** Sustainability initiatives, including waste reduction, energy consumption minimization, and a reduction in carbon footprint, have assumed pivotal significance within the pharmaceutical industry. Collaborating with CDMOs that align their manufacturing practices with sustainability objectives to reduce carbon emissions allows pharmaceutical companies to benefit from these environmentally responsible initiatives.

# 5 ROLE OF INDIAN COMPANIES IN THE GLOBAL PHARMA MARKET AND COMPETITIVE LANDSCAPE

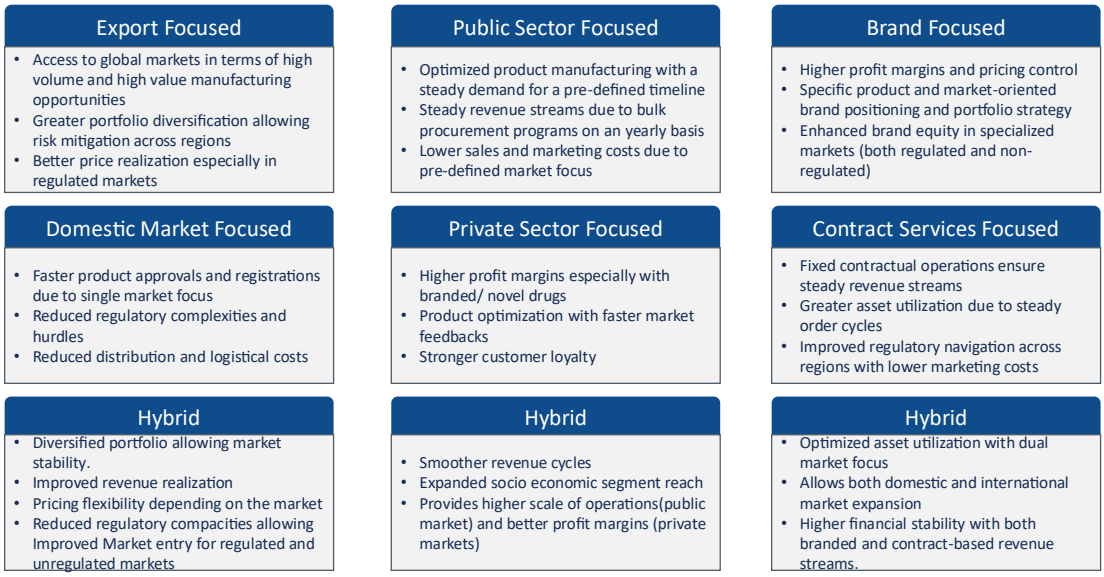
## 5.1 IPM COMPETITIVE LANDSCAPE

***IPM is dominated by Indian companies, accounting for more than 80% of the market share; moreover, the market is heavily concentrated, with more than 70% of the share residing with the leading 30 companies*.**

India's pharmaceutical market operates through diverse operating models. Based on their market focus, pharma companies can either be export oriented vs. domestic market focused. On the other hand, pharma companies could either operate as a pure play pharmaceutical player vs. operating in a hybrid models, with contract manufacturing services contributing significantly to their revenues. Based on their operating models, companies further focus on

[63] All India Council for Technical Education

either highly regulated markets such as the USA, and EU or emerging/ unregulated markets such as parts of Central Asia and Africa as well as South-east Asia.




Export-oriented companies focus on either a regulated market, such as the USA and EU, leveraging cost advantages and regulatory expertise, or unregulated markets in the underdeveloped and developing countries, catering to bulk demand for generic medications at lower costs. In contrast, domestic-focused firms prioritize branded and trade generics as well as OTC products, catering to the local demand. Pharma companies in India are known to work with the public sector through public schemes such as PMBJP, catering only to the demands of the domestic market, across Tier I, II, and III segments. On the other hand, some companies function only in the private sector, catering to both domestic and international markets, including both regulated and unregulated markets. For instance, companies such as Sun Pharma, Cipla, Biocon, and many more operate in both regulated and unregulated markets at a national and international level. Cotec Healthcare operates through a hybrid model across all three distinct business models, enabling a stable revenue stream. The company has business association with institutions like TNMSC, UPMSCL, KMSC, and many more. It also maintains a strategic focus on unregulated markets across Central Asia and Western Africa, positioning for itself as a pharma manufacturer as well as a contract manufacturer working in a B2B as well as B2G model.

Indian Pharmaceutical Market (IPM) companies have expanded not only due to rising volume demand but also through continuous innovation in drug formulations. Many firms with a strong domestic focus are now offering advanced dosage forms such as controlled or modified-release tablets, chewables, lozenges, and soft gel capsules to cater to evolving consumer preferences and therapeutic needs. This trend further aligns with the broader transformation of India's pharmaceutical sector, which is increasingly focusing on value-added formulations, complex generics, and innovation-driven growth to strengthen its global competitiveness. In line with the growing industry trend, Cotec Healthcare offers a range of drug formulations, including tablets, capsules, ointments, dry powders, syrups, and ampoules, which allows the company to participate across different segments of the pharmaceutical industry.

# 6 GLOBAL SMALL MOLECULE CONTRACT DEVELOPMENT AND MANUFACTURING ORGANIZATION (CDMO) MARKET OVERVIEW

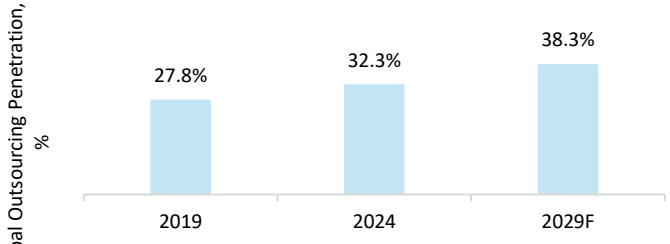
## 6.1 OVERVIEW OF THE GLOBAL SMALL MOLECULE CDMO MARKET

***CDMOs are expanding their service offerings by integrating upstream and downstream core capabilities, meeting the pharma client's demand for end-to-end services. With their one-stop-shop model, CDMOs serve as a single point of contact to reduce client interfaces, leading to brand differentiation in the market. As a result, Growth in the small molecule CDMO market is expected to outpace the growth of the global pharma market by nearly 100 basis points between 2024 and 2029.***

As small molecules continue to dominate the global pharma industry, the global small molecule CDMO market showcased a steady growth with an estimated value of USD 104.8 billion in 2024. With a greater number of innovator molecules and the subsequent novel drug approvals for small, mid-sized, and virtual pharma companies (lacking the requisite capacity and capability for drug development and manufacturing), small molecule CDMOs are continuing to support these companies with phase-appropriate services. Large pharmaceutical companies also continue to outsource small molecule manufacturing to CDMOs to focus on their core competency/strategic priorities, such as diversification in newer modalities such as large molecules, and therapeutic classes (e.g., nuclear medicine and novel indications for existing modalities), amongst other areas.

However, considering the dominance of small molecules, their well-established legacy will primarily propel CDMO service demand. CDMOs are increasingly focusing on high-potency and targeted small molecules by investing in specialized manufacturing capacities and capabilities to meet the heightened demand for complex molecules, such as cytotoxic payloads and linkers for analog-to-digital converters (ADCs), to target ADC market opportunities.

**Exhibit 6.1: Global CDMO Outsourcing Penetration, 2019-2029F**



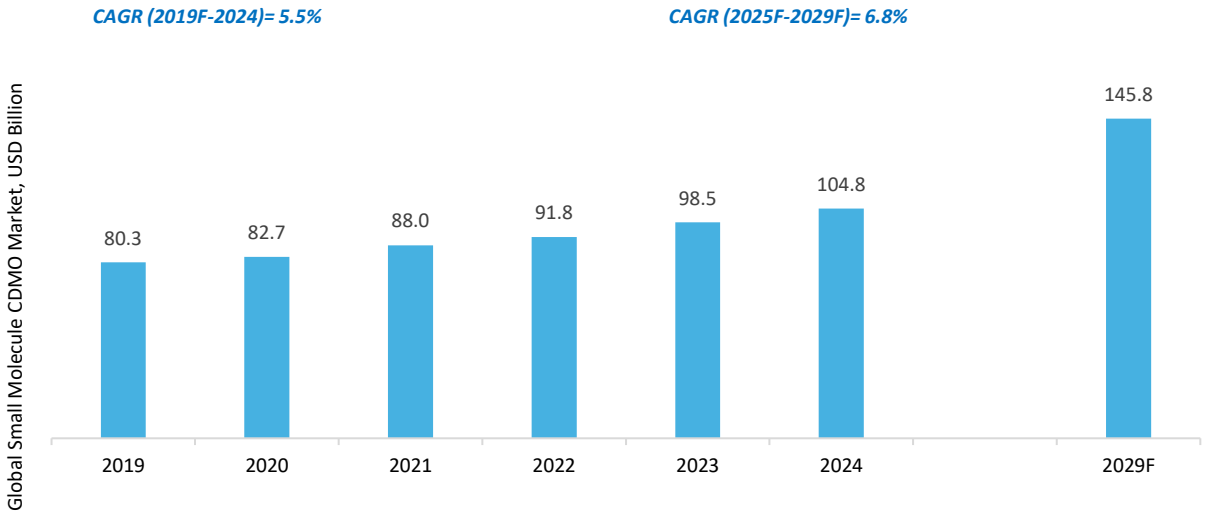

*Source: Industry KOL, Frost & Sullivan*
*Note: F- Forecast*

Driven by increasing drug complexities, technological advancements required to develop these novel therapies and the scale of service requirement, the CDMO outsourcing penetration rate is witnessing a steady increase. The outsourcing penetration stood at around 32%-33% in 2024. Furthermore, as pharma companies make a strategic shift from capital expenditure (Capex) to operational expenditure (Opex) models, CDMO outsourcing is set to grow to a range of 38%-42% by 2029.

Whilst outsourcing penetration is expected to witness an upward surge, the potential trade tariffs may result in temporary stagnancy, which could impact growth in the short term. As a result, the small molecule CDMO market is set to grow at a CAGR of 6.8% between 2024 and 2029. However, the overall growth trajectory will be supported by the expansion of asset-light pharmaceutical business models, the drive for cost efficiency and manufacturing optimization, the increasing demand for comprehensive end-to-end CDMO services, and the strategic advantage of economies of scale, which position CDMOs as indispensable partners in the evolving pharmaceutical ecosystem.

Also, to align better with the industry trends, larger global and regional CDMOs are building manufacturing facilities closer to the market with higher demand, thereby ensuring supply chain reliability and their ability to handle drug shortages. These organizations are transitioning to a dual-sourcing strategy in line with re-shoring or near-shoring initiatives. Furthermore, large CDMOs are also exploring acquisition opportunities across geographies to build an onshore presence in the European Union (EU) and the United States.

**Exhibit 6.2: Global Small Molecule CDMO Market, 2019-2029F**




*Source: Frost & Sullivan*
*Note: F - Forecast*

## 6.1.1 CDMO SERVICE MODEL

***Contract Development and Manufacturing Organizations (CDMOs) have evolved from managing intermediates and APIs to providing comprehensive pharmaceutical solutions, encompassing diverse dosage form manufacturing, regulatory support, and customized packaging services. As industry shifts toward an end-to-end service model, CDMOs are expanding their service portfolios into drug discovery and clinical development with services spanning from drug discovery to clinical development and manufacturing to commercialization across multiple geographies. In addition, they are also focusing on ESG-aligned practices, positioning themselves as strategic partners in the global drug manufacturing ecosystem.***

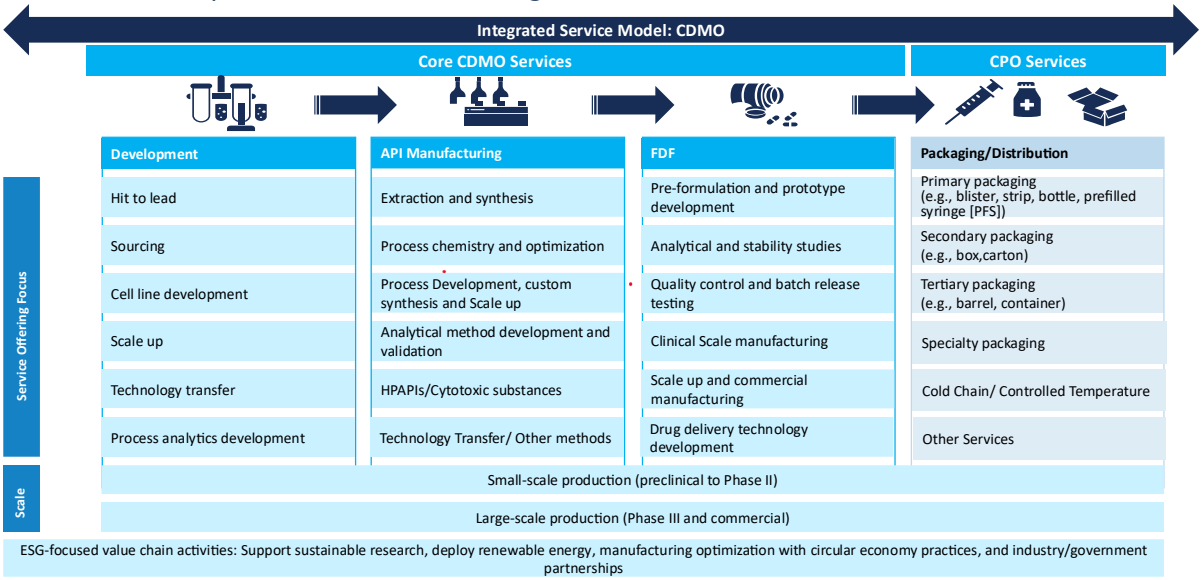
At the heart of the pharmaceutical value chain, CDMOs have historically been known to manage the production of intermediates and starting materials, which are subsequently synthesized into active pharmaceutical ingredients (APIs) and formulated into finished dosage forms. Be it the manufacturing of oral solid dosage forms, sterile injectables, hormonal therapies, nutraceuticals, ayurvedic medicines, or any other pharma products, CDMOs have maintained distinct capabilities to meet diverse product requirements. In addition to scalable manufacturing solutions, from small lab-scale batches and clinical trial supplies to full-scale commercial production, aligning with each stage of the drug development lifecycle, CDMOs have been tailoring their service portfolios to suit the development needs, by building specialized expertise in early to late-stage drug development (BA/BE testing, stability and quality testing, toxicity testing, etc.). Modern-day CDMOs extend their services well beyond the post-discovery phase, offering end-to-end solutions that encompass pre-formulation and formulation development,

bioavailability/ bioequivalence (BA/BE) studies for generics, and critical ancillary services such as clinical trial packaging, inventory management, and logistics coordination for both clinical and commercial distribution.

Beyond clinical and commercial scale manufacturing, CDMOs are slowly building capabilities towards offering a suite of support services that enhance product quality and regulatory compliance. These include analytical method development, stability testing, regulatory filing support, and technology transfer. Packaging services are also integral to CDMOs' service portfolios, spanning primary (e.g., blister packs, bottles), secondary (e.g., cartons), and tertiary (e.g., bulk containers) packaging, often tailored to meet global regulatory and distribution requirements.

In response to the growing demand for integrated, end-to-end services, CDMOs are enhancing their value proposition by streamlining operations, improving technology transfer processes, and cultivating long-term strategic partnerships with pharmaceutical sponsors. The industry is witnessing a shift toward single-CDMO engagements across the entire development continuum, driven by the desire to reduce complexity and improve continuity. Some of the recent trends include the adoption of continuous manufacturing, AI-driven process optimization, and ESG-focused practices like green chemistry and solvent recovery. There is a growing inclination towards building modular facilities for quicker manufacturing timelines, whilst also focusing on strategic partnerships, as well as process automation to address capacity constraints and improve scalability. The market is also witnessing a surge in M&A activity, as larger players acquire niche firms to expand their service portfolios. This evolution underscores the strategic importance of CDMOs, positioning them not merely as outsourced manufacturers but as indispensable partners in comprehensive drug development and production.

Contract Development and Manufacturing Value Chain

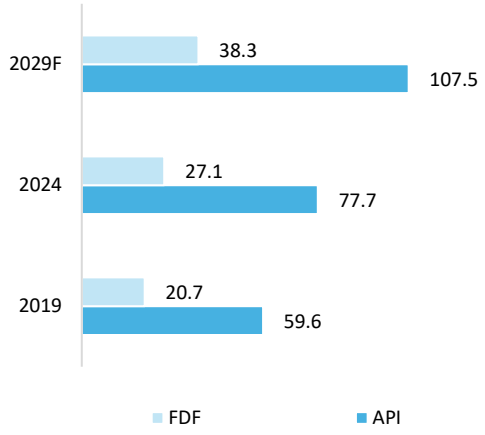



## 6.1.2 GLOBAL SMALL MOLECULE CDMO MARKET BY PRODUCT TYPE

***Together, the API and FDF CDMO segments represent distinct yet interconnected growth avenues, with integrated service providers gaining a strategic advantage in the evolving market landscape. The API segment dominated the small molecule CDMO market in 2024, accounting for approximately 74% of the total market, while the FDF segment contributed 25.9%, with comparable growth in both segments forecasted between 2024 and 2029.***

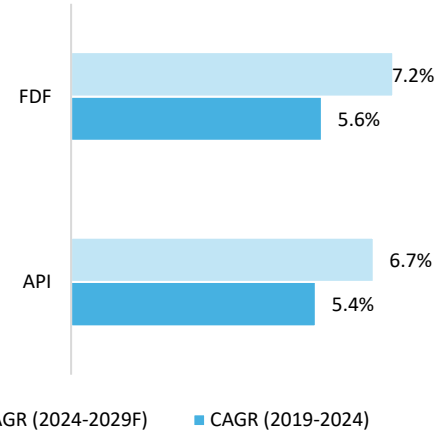
The growth of emerging pharma companies developing novel medicines and the increasing adoption of HPAPIs for complex drug development in oncology and rare diseases is boosting the demand for complex APIs. Simultaneously, the upcoming patent cliff is also expected to drive the demand for generics API. As a result, CDMOs are differentiating their services by developing specific expertise around different API categories (including HPAPI, biochemistry, and complex chemical synthesis of molecules), thereby driving revenue growth in niche, complex, and high-value segments within the API outsourcing market.

**Exhibit 6.3: Global Small Molecule CDMO Market by Product Type, 2019, 2024, 2029F, USD Billion**




*Source: Frost & Sullivan*
*Note: F- Forecast*

**Exhibit 6.4: Growth Rate of Global Small Molecule CDMO Market by Product Type, 2019- 2029F**



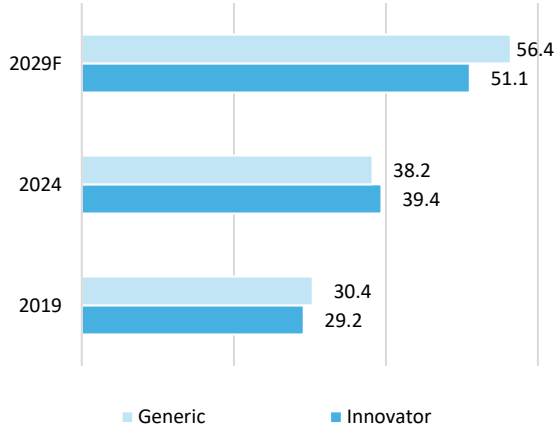

*Source: Frost & Sullivan*
*Note: F- Forecast*

While some CDMOs specialize in end-to-end services spanning the entire value chain, others have built specialized capabilities in either active pharmaceutical ingredient (API) manufacturing or finished dosage form (FDF) manufacturing. API manufacturing contributes to a larger share of the market, accounting for approximately 74% of total revenues, whilst FDF services contribute to the remaining 26%. Nevertheless, a growing preference for integrated services reflects the growing demand from pharmaceutical companies for simplified supply chains and single-partner models.

The API CDMO segment has expanded from USD 59.6 billion in 2019 to an estimated USD 77.7 billion in 2024, registering a CAGR of 5.5% during this period. Moving forward, the segment is expected to showcase a 6.7% CAGR to reach USD 107.5 billion by 2029.

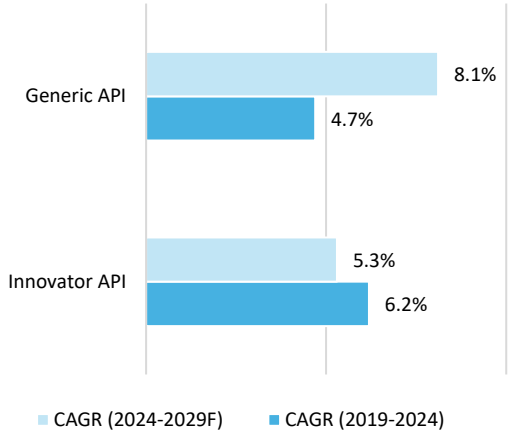
Many potent and highly potent small molecule drugs (across specific therapy areas like oncology) are being developed across the pharma industry, indicating a growing focus on targeted therapeutics. As more targeted therapeutics line up in the drug development pipelines, there is a simultaneous increase in the complexity of API synthesis and a greater demand for high-potency APIs (HPAPIs), as well as heightened focus on specialized containment, quality compliance, and advanced process capabilities. This growing demand for specialized API manufacturing will fuel the segment growth during 2024-2029.

**Exhibit 6.5: Global Small Molecule CDMO API Market by Product Type, 2019, 2024, 2029F, USD Billion**




*Source: Frost & Sullivan*
*Note: F- Forecast*

**Exhibit 6.6: Growth Rate of Global Small Molecule CDMO API Market by Product Type, 2019- 2029F**

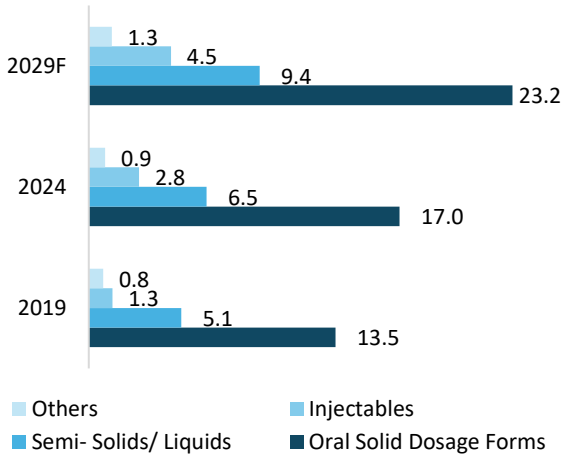



*Source: Frost & Sullivan*
*Note: F- Forecast*

The FDF CDMO market, on the other hand, has demonstrated steady growth, rising from USD 20.7 billion in 2019 to approximately USD 27.1 billion in 2024, translating into a CAGR of 5.6%. Forecasts suggest the segment will reach USD 38.4 billion by 2029, implying a continued CAGR of 7.2% over the next five years. Whilst oral solid dosage forms continue to dominate the FDF market, injectables are the primary drivers of growth owing to an increasing demand for specialty products, injectable cytotoxic drugs, and generic injectables.

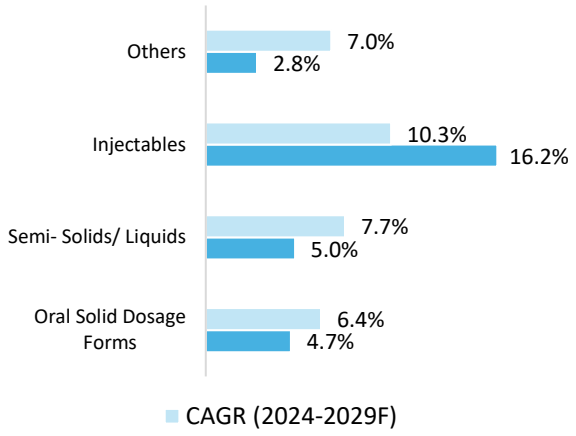
The increasing popularity of injectables is a result of their ability to provide rapid therapeutic effects through intravenous infusions. Furthermore, not only branded drugs, but the growing popularity of injectable generics, particularly oncology and specialty drugs, owing to their lower price than branded drugs, is bolstering segment growth. Also, growth in the FDF segment is driven by early integration of formulation development across the drug life cycle from preclinical stability testing to commercial scale-up, which helps de-risk development timelines and enhance drug performance.

**Exhibit 6.7: Global Small Molecule CDMO FDF Market by Dosage Forms, 2019, 2024, 2029F, USD Billion**




*Source: Frost & Sullivan*
*Note: F- Forecast*

**Exhibit 6.8: Growth Rate of Global Small Molecule CDMO FDF Market by Dosage Forms, 2019- 2029F**



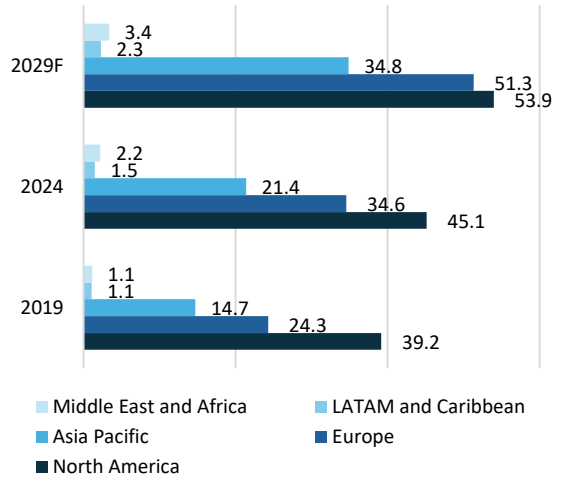

*Source: Frost & Sullivan*
*Note: F- Forecast*

Demand is particularly strong in complex formulations such as injectables, sustained-release, and nano-formulations. Also, the increasing popularity of 505(b)(2) regulatory pathways, which allow for reformulation of existing drugs (modified release/ controlled release formats), has further led to a greater reliance on formulation expertise. Development of innovative capsule material, targeted drug release formulations, taste-masking formulations, and better API stability are some of the other factors bolstering the segment growth.

Moreover, sterile manufacturing is also emerging as a key differentiator, especially with the rise of biologics-derived small molecules and peptide-based drugs. The proliferation of generic FDFs, particularly in price-sensitive markets, is also expanding opportunities for CDMOs offering cost-efficient, high-throughput solutions.

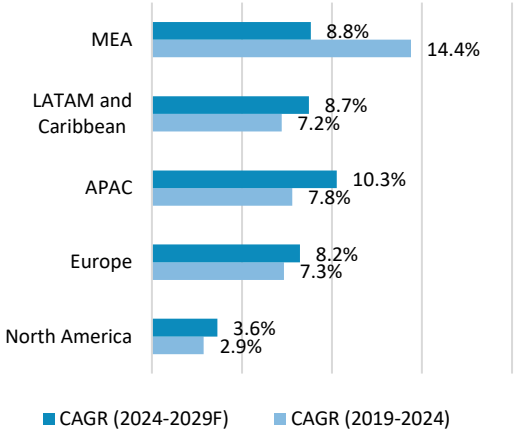
## 6.1.3 GLOBAL SMALL MOLECULE CDMO MARKET BY REGIONS

**Exhibit 6.9: Global Small Molecule CDMO Market by Regions, 2019, 2024, 2029F, USD Billion**




*Source: Frost & Sullivan*
*Note: F- Forecast*

**Exhibit 6.10 Growth Rate of Global Small Molecule CDMO Market by Regions, 2019- 2029F**




*Source: Frost & Sullivan*
*Note: F- Forecast*

*Note: Regional forecasts are provided based on the demand side*

The NA market, although dominating the global CDMO market, experienced a slower growth of 2.9% between 2019-2024. Across the region, the USA continues to lead pharmaceutical innovation, R&D, and is the largest drug market. Also, CDMO's increasing focus on environmental, social, and governance (ESG) commitments, supply-chain digitalization, lighthouse manufacturing techniques, and government-led supply-chain resilience strategies will lead to a favorable outsourcing environment in NA, driving revenue growth. Strengthening reshoring initiatives and government policies will give global CDMOs with sites in the United States an edge. The ongoing trend of complex and highly potent drugs and APIs favors US manufacturers who offer specialized facilities and containment capabilities. As a result, the region will witness an improvement in market growth between 2024 to 2029 to 3.6%.

The European CDMO market is anticipated to grow at a steady CAGR of 8.2% between 2024 to 2029, driven by a broad portfolio of generic APIs and formulations for both imports and domestic use. To bolster regional drug manufacturing, the EU has launched initiatives like the EU Pharmaceutical Strategy and the Critical Medicines Alliance, as well as funding mechanisms like EU4Health and the Recovery and Resilience Facility. Moreover, to ensure a consistent and flexible product supply, regional CDMOs are considering backward integration and right shoring by moving supply chain segments and processes to strategic locations. For example, the European Medicines Agency's Executive Steering Committee on Shortages and Safety of Medicinal Products has been working with industry stakeholders to manage the supply chains for certain antibiotics, such as amoxicillin, to address drug shortage-related challenges in the region. The group is further working towards bolstering supply and assisting Member States through regulatory support to regulate production capacity by seeking alternative sources of raw materials and production sites to meet immediate needs.

The APAC market will experience a strong growth of 10.3% from 2024 to 2029 because of various regulatory and infrastructure reforms in India, China, and Southeast Asian (SEA) countries. High costs and labor shortages in the United States/Europe, the ongoing European energy crisis, and increasing inflation driving raw material costs will

continue to increase outsourcing to APAC because of its significant cost advantage in terms of manufacturing and labor costs. India and China hold a significant market share of API and FDF outsourcing. In the mid-term, India will experience strong growth, with growing demand for APIs. Focusing on sustainable production, revamping labor regulations, skilled workforce, and business-friendly climate, and modernizing the manufacturing base (Industry 4.0 practices) will likely propel the outsourcing of pharmaceutical production to other emerging markets, including Vietnam, Malaysia, and Indonesia. To improve domestic manufacturing capacity, the Indian government introduced PLI with a scheme outlay of INR 15,000[64] Crores (USD 1.74 billion) for pharma manufacturing. PLI 1.0 (launched in July 2020) aims at improving India's bulk drug manufacturing capacity and covers key starting materials (KSMs)/drug intermediates (DIs) and APIs, and PLI 2.0 (launched in February 2021), promoted the manufacture of high value pharmaceutical products (biopharmaceuticals, complex generics, patented drugs or those nearing expiry, auto-immune, cancer drugs, and many more) and also covers APIs/ KSMs/ DIs that are not included in PLI 1.0.

With considerable investments driving the biopharmaceutical sector, the Middle East and Africa region will see a steady growth rate of 8.8% from 2024 and 2029. Most countries in Latin America and the Middle East manufacture generics for local consumption. Governments in the Middle East and Africa (MEA) encourage pharmaceutical manufacturing self-sufficiency, resulting in more partnerships and joint ventures, a better investment climate, simpler licensing, and relaxed manufacturing restrictions, making the outsourcing environment favorable. In addition, initiatives such as Saudi Arabia's Vision 2030, the UAE's Pharma Strategy 2030, Oman's Vision 2040, and many more are promoting local manufacturing to improve affordability and drug access in the region. As a result, the region is also witnessing multiple public-partnerships, with the local governments partnering with leading pharma companies with the aim of localizing manufacturing. Some of the other initiatives include the African Pharmaceutical Technology Foundation, a new African Development Bank Group project, which will work with the African Union to drive local drug production, bolstering Africa's pharmaceutical industry and revenue growth.

Across the LATAM[65] Region contract manufacturers, especially across the API segment in countries such as Brazil, Mexico, and Peru (which are also predominantly generics-driven markets), seamlessly supply to their local markets. The region is expected to show a growth of 8.7% between 2024-2029. Growth in the middle-class population will fuel demand for medicines and present opportunities to international CDMOs and pharma companies to acquire sites to supply the untapped Brazilian and South American markets, driving revenue growth. Also, the regional regulatory agencies are bringing in new policies and initiatives, such as ANVISA's Strategic plan for 2024-2027, fostering regulatory convergence and enhancing resilience.

## 6.2 GROWTH DRIVERS OF THE CDMO MARKET

***A sustained growth in outsourcing can be attributed to its multifaceted advantages, including cost efficiency, accelerated time-to-market, and access to specialized global expertise, to name a few, ultimately driving growth for CDMOs.***

Some of the key growth drivers for the CDMO market include:

[64] Ministry of Chemicals and Fertilizers
[65] Regulatory Systems, Trends, and Innovations in Latin America and the Caribbean

## Growth Drivers for CDMO Market


- Accelerating time to market through regulatory expertise and established manufacturing infrastructure.
- CMOs play a crucial role in optimizing production costs and streamline operations at scale enabled with multi-client operations.
- Eliminate capital expenditure for pharma companies through externalization of facilities and equipment.
- End-to-End service provision avoiding unnecessary complexities through processes.

- CMOs ensure business continuity through scalable capacity tailored to suit clinical and commercial needs of pharma manufacturers.
- Show adaptability to manufacture both high value medicines as well as off patent generics in varying volumes as per requirements.
- Operate across multiple global sites allowing easy navigation through logistical, regulatory and other geopolitical challenges.

- With growing complexity of drugs CMOs provide specialized capabilities through dedicated infrastructure for high potency and sterile products
- Ensure safety and compliance for clinical and commercial manufacturing.
- Provide deep scientific and technical expertise across modalities and platforms.
- Ensure steady Regulatory and technology transfer know how to minimize delays in global approvals.

- CMOs operate with custom operating models supporting both small and mid segment as well as large pharma companies.
- They provide enhanced commercialization planning through realignment of internal capabilities.
- Shifting from transactional sourcing/ project-based partnerships to long-term strategic partnerships.

## 6.3 TRENDS IN THE SMALL MOLECULE CDMO MARKET

**The pharmaceutical contract development and manufacturing landscape is evolving rapidly, driven by technology adoption, strategic partnerships, and shifting geographic preferences. CDMOs are increasingly integrating AI/ML-enabled platforms to enhance process efficiency and supply chain resilience. India is emerging as a preferred destination for pharma outsourcing, supported by regulatory strength, skilled labor, and government incentives. Meanwhile, market consolidation and the rise of smaller, innovation-focused pharma firms are reshaping demand dynamics, reinforcing the need for flexible and specialized CDMO partnerships.**

1. **Technology implementation through industry partnerships**: Alongside activities such as mergers and acquisitions for capability and capacity expansions, CDMOs are also equally focusing on technology adoption by incorporating AI/ML platform-enabled manufacturing solutions that improve process reliability and ensure supply chain resilience, as well as real-time tracking and monitoring, and enhance client flexibility. These new technologies are either developed in-house or acquired through partnerships with specialized tech vendors and manufacturing automation providers.
2. **India, the new preferred destination for pharma manufacturing services**: With the China+1 strategy taking stronger acceptance, India is increasingly being positioned as the next preferred destination for outsourcing pharma manufacturing. India offers a compelling value proposition in terms of providing cost-effective skilled labor, strong regulatory compliance (with more than 752[66] USFDA-approved and more than 2000 WHO GMP-certified Manufacturing plants and 286 EDQM-approved sites), and government incentives under initiatives like the PLI scheme, making it a strategically important location for pharma companies. Additionally, the country's proven track record in being the leading global supplier of generics and being

[66] India Brand Equity Foundation, Department of Pharmaceuticals

next only to China in terms of API production makes it a reliable partner for global pharma companies seeking to diversify their supply chains.

3. **Consolidation / M&A in the market and its impact on large players:** Large CDMOs focus on horizontal and vertical integration. They enhance their services along the value chain through M&A (to leverage economies of scale), capacity expansion, segment specialization, the extension of services to new modalities, and broadening the service range to cover a drug's life cycle. This ongoing consolidation trend will continue to bolster the focus on technology leadership capabilities and complex molecule production.
4. **Rise of smaller companies that rely almost entirely on CDMOs:** The rise of small to mid-sized pharmaceutical companies has significantly reshaped the drug development landscape, with these niche companies contributing to close to 70%[67] of the clinical stage drug development pipelines and more than 50%[68] of the FDA approvals in 2023. These agile firms focus on niche therapies or innovative formulations but lack the necessary capital-intensive in-house manufacturing infrastructure. Therefore, partnering with a reliable CDMO is imperative to handle activities across formulation development and clinical trial material production to commercial-scale manufacturing. Outsourcing partnerships with CDMO further allow these companies to reduce time-to-market and access specialized expertise and regulatory and technical know-how with cost-effective partnership models.

### 6.3.1 CHALLENGES FOR THE GLOBAL SMALL MOLECULE CDMO MARKET

***With the growing complexities of pharma pipelines and the subsequent need for innovative manufacturing capabilities, the CDMO industry constantly faces pressure to adapt and innovate. Also, a complex regulatory landscape, disruptive supply chains, shortage of skilled staff, and associated costs, are some of the key risks that can hamper the overall operations of these service providers.***

As the small-molecule CDMO industry continues to evolve in terms of operating business and service models, it brings forth its own challenges and risks. As the industry moves towards a more collaborative/ strategic partnership-based model, it brings along constant changes in the regulatory landscape, technological landscape and many more. Nevertheless, the industry continues its upward trajectory driven by a demand for more efficiency and expertise throughout the drug development and manufacturing process. As a result, it is imperative for market players to constantly adapt to the changing environment through investments in newer technologies, and better infrastructure, whilst also ensuring an alignment with the regulatory policies to remain compliant and competitive at the same time. Some of the key challenges include:

1. **Need for Experienced, Skilled, and Stable Workforce:** The demand for experienced professionals in areas such as aseptic filling, process engineering, and many more is intensifying. However, there is an inherent shortage of skilled talent pool, which directly impacts the quality of services as well as the timelines. Also, as the demand for specialized expertise in emerging areas increases, the challenge of hiring and retaining the right talent further exacerbates. Factors like competitive compensation and a lack of sufficient career development opportunities also add to the impending issue. As a result, there is a high turnover rate across the industry, which is also increasing year on year. For instance, as of February 2025, the healthcare industry turnover rate is in the range of 15%-20%[69] which can potentially be higher in the Contract manufacturing segment. Therefore, CDMOS needs to focus on attracting and retaining talent, by investing in training and development programs and creating a positive work culture that fosters innovation and collaboration.
2. **Operational challenges impacting timelines:** CDMOs often operate under tight timelines and budgets, making them vulnerable to disruptions such as equipment failures, supply chain bottlenecks, and workforce shortages. These risks stem from the complexity of manufacturing processes, stringent regulatory

[67] Citeline: Annual R&D Review, 2024-2025
[68] Making the Innovation Cut: New Drug Approvals Thus Far in 2024
[69] Turnover Rates by Industry 2025, Suchwork

requirements, and the need for high-quality standards across diverse product pipelines. For instance, Beta Lactam manufacturing is prone to contamination, therefore requiring separate manufacturing facilities including air handling systems, HVAC, equipment, high grade air filtration systems and many more there by requiring continuous monitoring, regulatory engagement and documentation.

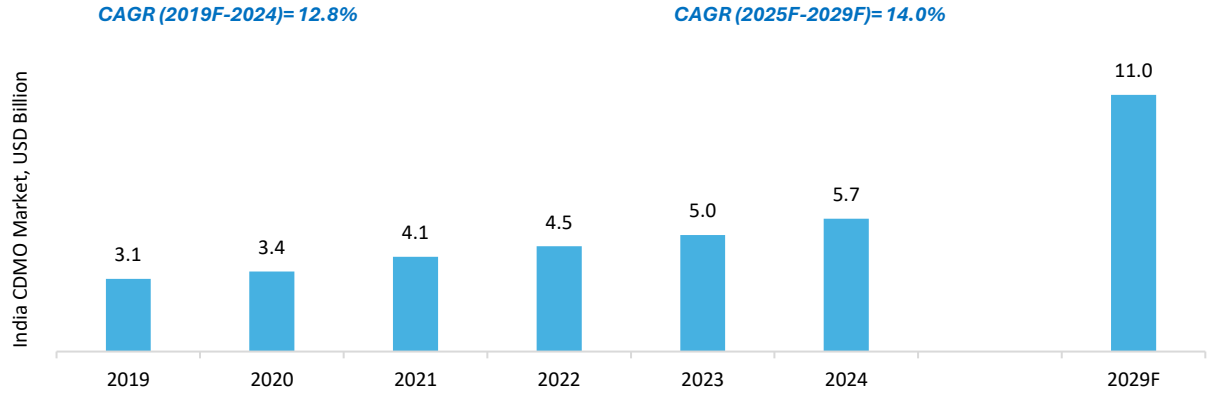
3. **Regulatory Compliance and Policy Change Risks:** As CDMOs operate in a very complex regulatory environment, companies need to adhere to stringent cGMP guidelines and keep an eye on the evolving regulatory landscape. The ever-changing regulatory frameworks under the International Committee for Harmonization (ICH) require outsourcing providers to constantly adapt. For instance, the recent policy changes across Europe including the European Union's Corporate Sustainability Reporting Directive (CSRD) and the Digital Operational Resilience Act (DORA), USA's draft regulatory guidance on "The Considerations for Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products" and many more may have a direct impact on the business and operating model for the CDMO.
    a. Adherence to the existing and newer regulations is critical for receiving approvals from the USFDA, PMDA Japan, China NMPA, and other such regulatory bodies. Furthermore, sustainable manufacturing is another key area evolving across the industry, which is now mandatory to follow for pharma manufacturers and CDMOs alike, with pharma companies increasingly factoring in compliance with EHS and ESG standards as one of the key criteria for selection of outsourcing partner.
    b. It is therefore essential for the CDMOs to stay updated on the compliance standards and ESG policies by either conducting in-house audits or receiving access to audits conducted by the Pharmaceutical Supply Chain initiative (PSCI) or Ecovadis (EcoVadis is one of the world's largest and most trusted providers of business sustainability ratings).

# 7 INDIA CDMO MARKET

## 7.1 INDIA CDMO MARKET OVERVIEW

***Large-scale, low-cost, and yet high-quality manufacturing capabilities with a high number of globally accredited plants, broad portfolio expertise, and technology innovation will propel the Indian CDMO industry; in 2024, it accounted for 5.4% of the global small molecule CDMO market.***

**Exhibit 7.1: India CDMO Market, 2019-2029F**




*Source: Frost & Sullivan*
*Note: F - Forecast.*

As the world's most populous nation and an expanding working-age population, India holds a strategic advantage over other countries in offering access to a substantially cheap labor force, reduced manufacturing cost (30%-35%[70] lower than western markets) whilst also standing out with a network of 3000 drug companies and over 10500 manufacturing units[71]. In 2024, the Union Minister for Chemicals and Fertilizers and Health and Family Welfare, inaugurated 27 green field bulk drug parks, while the union budget 2025-2026 proposed the allocation of INR 5,268.72 crore (USD 602.90 million) for the Department of Pharmaceuticals (DoP). Historically, India has displayed formidable proficiency in pharmaceutical manufacturing by producing vast quantities of affordable generic drugs while maintaining extensive manufacturing capabilities in alignment with international regulatory standards. The country is catering to about 200 nations spanning both regulated and unregulated markets. As a result, India's CDMO market is expected to witness double-digit growth.

The Indian CDMO market was therefore valued at USD 5.7 billion in 2024, having enjoyed a three-dimensional growth trajectory from global pharmaceutical companies outsourcing to Indian CDMOs, domestic pharma companies outsourcing to Indian CDMOs (to cater to the export market), and domestic pharma companies catering to the local pharmaceutical demand. This three-pronged growth will likely propel the market to reach USD 11.0 billion in 2029, driven by the growing reliance of local Indian and international firms on the local Indian CDMOs to scale operations efficiently and cost-effectively. Small Molecules segment accounts to more than 70% of the total Indian CDMO market.

Like global trends, both demand and supply-side factors are contributing to the growth of the pharmaceutical market. On one hand, the demand for CDMO services is steadily increasing as global pharma companies seek reliable partners. At the same time, Indian CDMOs have been expanding their manufacturing capacity and enhancing technical capabilities, positioning themselves as strategic collaborators in ensuring consistent and scalable supply. These players have positioned themselves as reliable partners with the ability to work on both innovator and generic drugs, as well as manufacture complex APIs and formulations at scale, enhancing their unique value proposition. India's strong contract manufacturing capabilities were particularly evident during the pandemic when global pharmaceutical supply chains were severely constrained.

Like that of India's pharma export markets, Indian export CDMO market takes a significant share across the CDMO market. Moreover, as Indian pharma companies expand their reach to regulated and semi-regulated global markets, the dependence on CDMOs is constantly increasing, which is attributable to CDMOs seamlessly managing the risk of supply chain disruptions and navigating through heterogeneous regulatory environments. Growth in the Indian CDMO export market can also provide opportunities for domestic market-focused CDMO players to expand services to cater to export markets.

On the other hand, the Indian domestic CDMO market is nascent in comparison, since IPM recently started outsourcing large-scale manufacturing to CDMOs. The growth across the segment comes in response to the growth in volume demand in the market for traditional and novel formulations, high penalties for poor quality-related performance, diversification of sales channels in the form of trade generics, and many more. This requires a specialized commercialization approach and the need to improve profitability by achieving cost-efficiencies, which are provided by the players operating in the domestic CDMO segment.

Since COVID, between FY23 to FY25, the overall India CDMO market grew at a CAGR of 14.7%. Notably, Cotec grew by almost 4X CAGR at 52.7% during the same period, bringing Cotec into the league of leading players (especially with respect to CAGR), like Innova Captab Limited, Akums Drugs & Pharmaceuticals Ltd., which showed a growth in the range of 6%- 20% during the same time period, underscoring Cotec's growing market relevance.

[70] India Brand Equity Foundation
[71] India Brand Equity Foundation

### 7.1.1 GROWTH DRIVERS FOR INDIAN CDMOs

***Capital inflow, US/EU/China+1 sentiment, heightened emphasis on quality, and increased drug demand will drive growth for Indian CDMOs***

- **State-level policies promoting clusters of Industrial growth:** Several Indian states are proactively encouraging the establishment of manufacturing plants by offering attractive incentives:

  **Uttarakhand[72]: Uttarakhand** has emerged as a pharma-friendly state, offering MSMEs subsidies on capital investment, power, transport, and stamp duty. The Investment Promotion & Facilitation Centre (IPFC) serves as a single-window system to streamline approvals. The Pharma City in Selaqui, Dehradun, provides ready infrastructure for pharmaceutical units. Also, the Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) facilitates MSMEs with a proven track record in meeting global and national regulatory standards with constant investments, earmarked with the recent INR 300 crore investment. According to the NCAER N-SIPI Index, over 90% of investors in Uttarakhand reported minimal land acquisition challenges underscoring its position as a key investment destination. Uttarakhand produces 22% of India's generic drugs. Leveraging Uttarakhand's highly supportive pharmaceutical manufacturing ecosystem, Cotec Healthcare has established their manufacturing facility in Roorkee. This unit is engaged in the production of a wide spectrum of pharmaceutical formulations, hormones, nutraceuticals, and herbal/ayurvedic products. Also, the company is certified by WHO state-of-GMP, FSSAI, ISO 9001, and ISO 14001.

  **Punjab[73]**As of 2025, Punjab continues to offer robust incentives to attract pharmaceutical and CDMO investments under its Industrial & Business Development Policy 2017, with several enhancements. The state provides a 100% exemption or reimbursement on land and building costs for purchase or lease, which is counted under fixed capital investment. Additionally, Punjab is developing state-of-the-art pharmaceutical parks in Bathinda and Fatehgarh Sahib, equipped with shared infrastructure to support manufacturing operations. Recurring incentives include a 100% GST reimbursement for up to 15 years, and companies can recover up to 200% of their fixed capital investment. There is also a 100% exemption on electricity duty for 15 years and a property tax exemption for up to 10 years. To support employment, Punjab offers subsidies of up to INR 48,000 per employee per year for women and SC/BC/OBC candidates, and INR36,000 for others, for a period of five years with no domicile restrictions

  **Jammu and Kashmir[74]:** The New Central Sector Scheme for Industrial Development of Jammu & Kashmir, launched by DPIIT, is a key driver of the region's economic transformation. Effective from April 1, 2021, to March 31, 2037, the scheme aims to position J&K as a competitive industrial hub by attracting fresh investments and supporting existing enterprises. With a financial outlay of INR 28,400 crore, it offers four incentives: Capital Investment Incentive, Capital Interest Subsidy, GST-linked Incentive, and Working Capital Interest Subsidy—reducing setup and operational costs for manufacturing units, including pharma and CDMO facilities. As of 2025, uptake has grown in sectors like pharmaceuticals, food processing, and light engineering. The government has prioritized ease of doing business, streamlined land acquisition, and single-window clearances. New units must begin operations within three years, and expansion projects must invest 25% more in plant and machinery to qualify. The scheme is catalyzing industrial growth, job creation, and positioning J&K as an emerging hub for small molecule CDMOs.

[72] Invest India, Uttarakhand
[73] Invest India, Punjab
[74] Invest India, Jammu and Kashmir

**Himachal Pradesh[75]:** Himachal Pradesh continues to solidify its position as another important pharmaceutical manufacturing hub in India, particularly through the Baddi-Barotiwala-Nalagarh (BBN) industrial belt, often referred to as the "Manchester of Pharma". As of FY 2024–25, pharmaceuticals accounted for 60% of the state's total exports, and 45% of all pharma exports from Northern India. To further boost domestic production of APIs and reduce import dependency, the state has received in principle approval under the Government of India's Bulk Drug Parks Scheme, which includes a grant of INR 1,000 crore for developing shared infrastructure such as solvent storage, testing labs, logistics, and effluent treatment facilities. Himachal Pradesh's power surplus status, favorable climate, and strong healthcare and educational infrastructure make it an attractive destination for pharmaceutical and CDMO investments.

- **Capital inflow from investors:** India's contract manufacturing sector is experiencing rapid growth, driven by rising global demand, regulatory reforms, and strong investor interest, with Private equity and pharma companies actively investing in this space. For instance, Sai Lifesciences and Anthem Biosciences raised capital in the range of USD 350 million to USD 370 million, indicating a growing investor confidence within the Indian CDMO segment. Also, the Indian government's support for 100% FDI in greenfield pharma and 74% in brownfield projects continues to attract global capital, fostering innovation, capacity expansion, and global competitiveness for Indian small molecule CDMOs as well as CDMOs.
- **Shifting Growth from China to India:** A Structural Trend- China's age-old dominance on the global CDMO market is diminishing with the changing geopolitical and trade landscape. As a result, leading global pharmaceutical companies need to diversify their manufacturing bases, with India emerging as a preferred alternative, driven by several key factors:
    - Trade Wars and Tariffs – The ongoing US-China trade tensions and tariffs on pharmaceutical raw materials have accelerated the shift towards India, as multinational companies increasingly seek reliable and cost-effective alternative suppliers.
    - Supply Chain Diversification – India became the key beneficiary of the COVID-19-related risks of over-reliance on China, which exposed several supply chain-related challenges. This prompted pharmaceutical companies to diversify their supply chains, making India a key beneficiary.
    - Regulatory and Compliance Issues in China – China's intensified crackdown on industrial pollution and heightened regulatory oversight have disrupted pharmaceutical manufacturing operations. In contrast, India's consistent regulatory framework and strong compliance record are positioning it as a more stable and reliable manufacturing hub.
    - Cost Considerations –With the rising workforce demands for better pay, manufacturing wages in China have been growing by 5%-6%[76] year on year. This differential has reinforced India's position as a more cost-effective destination for contract manufacturing.

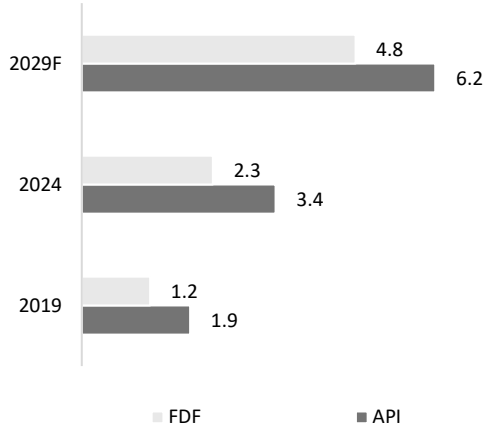
## 7.2 INDIA CDMO MARKET BY PRODUCT TYPE

***India's CDMO market benefits from India's advantageous position in manufacturing scale and compliance track records, catalyzing a strong double-digit growth across both the API and FDF segments. The India API CDMO segment mirrors the global market trend, dominating with a 59% share of the total Indian CDMO market.***

[75] Invest India, Himachal Pradesh

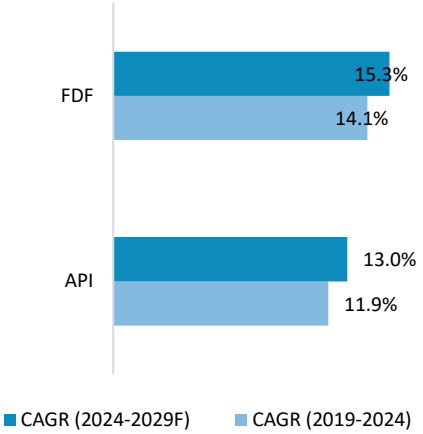
[76] Trading economics - China Average Yearly Wages in Manufacturing

**Exhibit 7.2: India CDMO Market by Product Type, 2019, 2024, 2029F, USD Billion**




*Source: Frost & Sullivan*
*Note: F- Forecast*

**Exhibit 7.3: Growth Rate of India CDMO Market by Product Type, 2019- 2029F**




*Source: Frost & Sullivan*
*Note: F- Forecast*

Driven by the shifting global supply chains and rising export demand, India's small molecule API CDMO market was valued at USD 3.4 billion in 2024. Similar to the global market trend, the API CDMO segment captured the majority share, standing at 59.0% in 2024. The segment is expected to witness expansion from USD 3.4 billion in 2024 to USD 6.2 billion in 2029, growing at a CAGR of 13.0%. India is fast emerging as the preferred choice for CDMO services due to its incredible capabilities to scale production whilst allowing a significant cost advantage and a resilient compliance record. Moreover, the acceleration in the market is also driven by global pharma companies' push to de-risk from Chinese companies, mounting investments in HPAPIs, and backward-integrated manufacturing capabilities aimed at serving global markets.

On the other hand, the FDF CDMO segment is also expected to show double digit growth, rising from USD 2.3 billion in 2024 to USD 4.8 billion in 2029, with a strong CAGR of 15.3% between 2024 to 2029. With the global patent cliffs, there is a rising demand for generic formulations, which can be supported by India's already strong generics manufacturing capabilities and competitive cost structure, driving export-led growth in this segment. Increasing complexity in formulations and greater outsourcing by mid-sized global pharma players are also enhancing India's position as a key partner for oral solids, injectables, and complex FDFs. Cotec Healthcare offers an expansive portfolio of 24 diverse formulations in the Finished Dosage Form (FDF) segment. This includes a wide range of dosage forms such as tablets, capsules, ampoules, injections, dry powders, and syrups, among others.

## 7.3 INDIA'S FAVORABLE POSITION IN THE GLOBAL SMALL MOLECULE CDMO MARKET

### 7.3.1 COMPETITIVE ADVANTAGES FOR INDIAN CDMOs

***Indian CDMOs are attracting global pharmaceutical companies with lower cost of manufacturing, advanced manufacturing capabilities, and supply chain resilience. They will therefore continue to benefit from a convergence of global outsourcing trends, India-specific policy reforms, and global market shifts.***

The Indian CDMO industry, which has been historically recognized for its significant cost advantage, has witnessed a transformation in recent years, with robust investments in advanced manufacturing technologies such as continuous processes, which are built on a broad suite of technical capabilities across multiple service lines. With capabilities in manufacturing both small and large molecules with complex chemistries, Indian CDMOs are now benchmarked against global competitors with a multitude of factors contributing to the same. Some of the key factors contributing to the growth of Indian CDMOs include:

- **Regulatory Reforms: GMP Compliance and Schedule M Updates-** The revised Schedule M guidelines and stricter Good Manufacturing Practices (GMP) compliance requirements are reshaping India's pharmaceutical sector by means of implementing a unified 'One Quality, One Standard Policy' nationwide. Originally, Schedule M, part of the Drugs and Cosmetics Act, outlines stringent guidelines for pharmaceutical manufacturing in India, covering various aspects such as facility maintenance, processes, quality control, safety testing, and more. Pharmaceutical companies in India were given 6 to 12 months to comply with the revised Schedule M guidelines, which became effective on August 2, 2023. As an immediate effect of the Schedule M, many smaller Contract Development and Manufacturing Organizations (CDMOs) faced shutdown notices, potentially benefiting larger players.
- In December 2023, the policy was revised to improve GMP requirements and stricter controls on facility designs and associated quality checks, ensuring enhanced production quality and safer drugs in compliance with domestic and international regulatory standards such as US FDA cGMP and WHO GMP. The latest revisions introduced a pharmaceutical quality system (PQS), quality risk management (QRM), product quality review (PQR), qualification and validation of equipment, and a computerized storage system for all drug products.
- While the government of India mandates the Schedule M for MSMEs and other pharma manufacturers, failure to abide could potentially lead to license cancellations, production shutdowns, as well as exclusion from both domestic and export markets. Especially in high-consumption states with dedicated medical supply corporations, drug manufacturers could potentially lose their government contracts and future access to government tenders. As of May 2025, out of the 10,500 manufacturing units in India (which includes MSMEs), many are yet to submit their upgrade plans under the revised Schedule M plans, with some of them claiming insufficient timelines, leaving them on the verge of potential closure. In this regard, for MSMEs who submitted their plans in Form A to the Central License Approving Authority were given an extension up to 31st December 2025[77].
- On a broader scale, non-compliance with the revised Schedule M could cause supply chain disruptions owing to the non-availability of essential drugs and overall drug pricing. Also, with respect to the export markets, the companies supplying medicines could face rejection of their shipments, with increased scrutiny from regulatory bodies in the destination countries. These additional inspections could also lead to greater costs (in the form of penalties) as well as a potential license suspension, losing access to these export markets.
- Companies struggling to meet these heightened standards (such as small and mid-segment pharma players) are increasingly resorting to CDMOs partnerships, leading to greater outsourcing volumes. On the other hand, CDMOs in India, with robust regulatory expertise and advanced infrastructure, are therefore emerging as preferred partners for both domestic and global pharmaceutical firms seeking to ensure

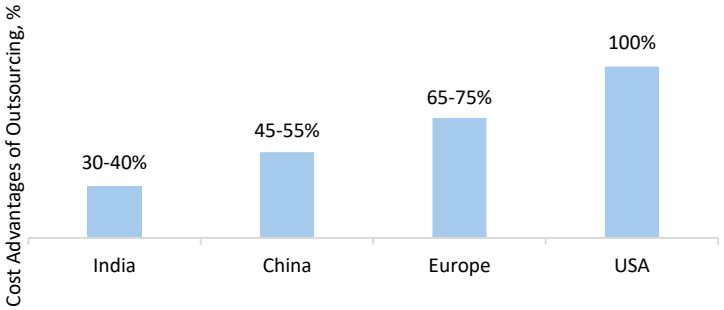
[77] Ministry of Health and Family Welfare

compliance with evolving quality benchmarks. In January 2025, Pharma companies (especially MSMEs) were provided with an extension for the implementation of these revised standards up to December 2025[78].

- **Foreign Direct Investment (FDI) Policy and Pharma-Sector Growth-** Under the liberalized FDI policy, the government of India allows 100% FDI in the Pharma sector. The FDI policy has played an instrumental role in attracting foreign investments in pharmaceutical manufacturing. From April 2000 to September 2024, FDI inflows reached USD 23.04[79] Billion with an additional INR 11,888 crore (USD 1.3 billion between April to December 2024). In FY25, the country witnessed a growth of 14% in the FDI inflows, reaching USD 81.04 billion[80]. As a result, Indian CDMOs could expand their manufacturing capacities, invest in cutting-edge technologies, and enhance regulatory compliance, which are key factors driving the sector's rapid expansion.
- **Ease of Doing Business: A More Predictable Industrial Environment-** With a multitude of stable policies and schemes, India's business environment has become more stable and predictable, enabling pharmaceutical companies to engage in long-term planning with reduced risk. According to the Economist Intelligence Unit (EIU) Business Environment Rankings (BER) for 2023-27, India showed an improvement in ranking from 14$^{th}$ in the 2018-22 period to 10th among 17 Asian economies[81]. This progress, driven by enhanced regulatory transparency and improved operational efficiency, positions India as a compelling hub for global pharmaceutical outsourcing.
- **Expert Talent Pool: A Growing Workforce Advantage-** India's demographic advantage plays a crucial role in the CDMO sector's expansion. As the most populous country in the world, 25%- 27%[82] the population in India falls between the age group of 20-60 years, allowing the country to enjoy a demographic dividend that strengthens its labor force. Additionally, India's regional labor market ranking improved from 16th in 2018–22 to 13th in 2023–27[83], surpassing China, Sri Lanka, and Bangladesh. This combination of a young, skilled, and cost-efficient workforce makes India an increasingly attractive destination for pharmaceutical outsourcing.
- **Competitive edge with a Regulatory-Compliant Infrastructure:** Having established themselves as strong contenders in the global CDMO industry, Indian CDMOs have made significant strides in enhancing quality control frameworks, obtaining certifications from global regulatory bodies such as the FDA, EMA, WHO-GMP, and ISO, as well as semi-regulated markets like Saudi Food and Drug Authority (SFDA) and South Africa's SAHPRA. With over 3,000[84] pharmaceutical companies operating across 10,500 manufacturing facilities, India ensures robust, high-quality, and regulatory-compliant pharmaceutical production on a large scale.
- **Advancements in Complex Formulation Development**: There is a growing demand for complex formulations that require enhanced solubility and bioavailability. As global drug pipelines take a turn toward more complex therapies, such as ophthalmic solutions, about 70% of these new drugs have low aqueous solubility profiles[85], making cost-effective solubilization technologies critical. In response, Indian CDMOs have invested in state-of-the-art solutions, including particle size manipulation, amorphous solid dispersions, salt and co-crystal engineering, and lipid-based drug delivery systems.

[78] Ministry of Health and Family Welfare
[79] India Brand Equity Foundation
[80] Ministry of Commerce and Industry
[81] Economist Intelligence Unit's (EIU) Business Environment Rankings (BER)
[82] Economic and Social Commission for Asia and the Pacific (ESCAP)
[83] Economist Intelligence Unit (EIU)
[84] India Brand Equity Foundation
[85] Pubmed – Bioavailability enhancement techniques for poorly aqueous soluble drugs and therapeutics

**Exhibit 7.4: Cost Advantages of Outsourcing to CDMO by Region, 2024**




*Source: Industry KOL, Frost & Sullivan*
*Note: Regional comparison is indexed to USA*

- **Cost Advantage: Solution to combating global pricing pressure-** India delivers substantial cost advantages in pharmaceutical manufacturing compared to both its Asian and Western counterparts. Notably, drug development and production costs in India are estimated to be 30–40% lower than in the United States or Europe. This cost efficiency strengthens India's competitive edge over other nations, offering significant value to global pharmaceutical companies facing mounting pressure from drug price erosion and narrowing profit margins.

## 7.3.2 RISK FACTORS/ BARRIERS TO ENTRY IN THE INDIAN CDMO MARKET

***The growth trajectory and strategic appeal of the Indian CDMOs are drawing interest from both established players and unconventional new market entrants. However, achieving meaningful scale and adopting advanced technologies are becoming increasingly critical for attracting and retaining pharmaceutical clients demanding significant capital investment, which in turn creates high barriers to entry. As a result, scalability and sustainability remain a critical challenge, especially for new entrants, reinforcing the competitive advantage of well-capitalized and technologically advanced CDMOs.***

The Indian small molecule CDMO segment's appeal is undeniable and has attracted unconventional companies to foray into the segment. However, high barriers to entry curtail the number of new entrants and the scalability of incumbents. Furthermore, the significant size and operations of existing CDMOs add to new entrants' challenges in establishing themselves in a highly competitive market. Some of the barriers to entry are discussed below.

- **High Capex**: High Capital Expenditure (Capex) remains a significant barrier to entry in the Indian CDMO market. A pharmaceutical manufacturing facility with all the necessary equipment, compliance, and regulatory measures can be highly capital-intensive. With the rising cost of capital (interest rates on loans), achieving viable returns on investments is increasingly difficult, considering multiple costs involved (starting from INR 5-10 crores and can go as high as INR 50 crores), as well as associated interest rates on bank loans. Hence, to enter the CDMO business, large funds for capital investments can be a hindrance and a barrier to entering the market.
- **Competing with large-scale CDMOs that provide end-to-end services:** Established CDMOs hold a clear edge over newer entrants by offering end-to-end services across the drug development value chain. Backed by stronger financial resources, they can deliver integrated solutions from early development to commercial-scale production, making them attractive partners for pharma companies. In contrast, smaller CDMOs, constrained by limited resources, often provide only select services. As sponsors increasingly prefer a single integrated partner, building such capabilities demands heavy investment in infrastructure, talent, compliance, and technology, creating high entry barriers.
- **Higher per-unit production cost:** Cost per unit remains a significant barrier to entry for new players in the CDMO industry. Established companies benefit from economies of scale, driven by larger production volumes, optimized operations, and a broader customer base. This allows them to achieve a lower cost per unit, making their services more competitive in pricing-sensitive markets. In contrast, newer entrants often

operate at limited capacity and with fewer clients face higher per-unit production costs, which can hinder their ability to compete on price and margin. This cost disadvantage further reinforces the dominance of mature CDMOs and raises the entry threshold for emerging players.

- **Challenges Maintaining Customer Relations and Market Entrenchment:** In the competitive CDMO market, companies with over 10–15 years of experience have built strong reputations and long-term partnerships with key pharma players. Their proven track records, regulatory reliability, and consistent delivery make them preferred partners. Many also engage with the public sector through government contracts and health tenders, enhancing credibility and ensuring steady demand. These relationships create high entry barriers for new players. As a result, newcomers must demonstrate operational excellence, regulatory compliance, and the ability to earn trust from both private sponsors and government stakeholders to compete effectively in this space.

### 7.3.3 CRITICAL SUCCESS FACTORS FOR INDIAN CDMOs

***To grow to even larger scales and compete with global CDMOs, Indian counterparts will have to focus on quality, offer scalability-flexibility-competency, and be able to serve across larger parts of the pharma value chain.***

Similar to other pharmaceutical sectors, certain risks and challenges are prevalent in the Indian CDMO industry. For instance, rapidly changing regulations, increased stringency for quality compliance, challenges in importing raw materials due to geopolitical tensions, and rising costs due to a global increase in inflation, to name a few. However, certain critical success factors can aid Indian CDMOs in navigating through these challenges, emerging as true and long-term partners for pharma sponsors and competing with global CDMOs, as discussed below.

- **Emphasis on quality and compliance**: With the growing global regulatory scrutiny, India has undertaken several measures, such as the Directorate General of Foreign Trade (DGFT) mandating the testing of all export drugs at designated central laboratories since June 2023. This move enhances international confidence in Indian pharmaceutical exports and sets a benchmark for CDMOs to achieve the utmost quality standards. A consistent record of regulatory audits and a wide range of accreditations are becoming essential for Indian CDMOs to access new markets and establish long-term global partnerships. For instance, WHO-GMP, FSSAI, and ISO 9001-2015 certifications for Cotec Healthcare's manufacturing facilities have allowed the company to cater to 14 countries.
- **Extensive operational capacities for diverse drug types, delivery models, and dosage forms**: Modern CDMOs showcase expertise not only in complex molecules (e.g., peptides, polymeric compounds) but also in advanced formulations such as dry powders, ointments, oral suspensions, gels, specialized delivery systems like ophthalmics, implantables, transdermals, and extended-release injectables, and many more. Their ability to innovate and adapt to evolving requirements strengthens their value proposition. For example, Cotec Healthcare manufactures a variety of dosage forms, including injectables, ointments, tablets, syrups, and dry powders. It has separate manufacturing units for each dosage form and product type, which allows it to compete across different segments of the Indian CDMO market.
- **Operational capabilities**: CDMOs must possess robust operational capabilities to accommodate a wide range of drug types, modalities, and formulations, as well as challenging project timelines. As pharmaceutical compounds become increasingly complex with higher molecular weights, multiple chiral centers, and stronger toxicity profiles, specialized processes are essential to ensure safe and effective handling. Additionally, the required production volumes can vary significantly, from less than half a ton to over 10 tons annually, depending on the drug's nature and its target market. This variability demands a high degree of agility from CDMOs in scaling operations up or down efficiently.
- **Maintaining strong delivery record**: A strong delivery record is essential for CDMOs to build long-term partnerships with pharma sponsors, supported by robust quality systems that allow them to manage multiple projects on time. Mature operational frameworks help mitigate risks in quality, logistics, regulatory compliance, and intellectual property, particularly in global operations. Equally important is a reliable network of KSM and intermediate suppliers, especially where backward integration is limited, ensuring supply chain continuity, adherence to milestones, and protection against contamination or impurities.

- **Robust Intellectual Property (IP) Protection**: Robust Intellectual Property (IP) protection is central to India's growing role in global pharmaceuticals and innovation. As per WIPO[86]India ranked 6th worldwide in total IP filings in 2023 and improved in the Global Innovation Index from 48th in 2020 to 39th in 2024[87] among 133 economies. This progress reflects India's commitment to a reliable IP environment. For CDMOs, this means prioritizing strict IP protection through confidentiality agreements and effective systems to manage patents, trademarks, and proprietary technologies.
- **Technical proficiency in manufacturing complex products**: Indian CDMOs hold significant expertise in complex chemical synthesis, such as analgesics and antipyretics, antidiabetics, anti-virals, and anti-microbials. They are uniquely positioned to lead in the evolving global pharmaceutical supply chain. Their long-standing capabilities in handling intricate small molecule processes, combined with cost-effective scalability, make them preferred partners for global pharma. For instance, Cotec Healthcare showcases capabilities across complex molecule manufacturing, such as Cephalosporins, supported by its broad beta-lactam portfolio of antibacterials and antimicrobials. Furthermore, Indian CDMOs are increasingly investing in the development and containment infrastructure required for Highly Potent Active Pharmaceutical Ingredients (HPAPIs), a segment gaining traction due to its precision targeting and therapeutic efficacy. This blend of technical depth and operational agility is enabling Indian CDMOs to move up the value chain and compete with global peers in high-barrier, high-value segments.
- **Capacity and scalability:** With the rising demand for generic drug manufacturing, there is an increased reliance on CDMOs, particularly those with larger manufacturing capacities/ facilities. To meet the growing demand, CDMOs are aggressively expanding capacity through greenfield investments and strategic acquisitions, aiming to offer large-scale, flexible manufacturing capabilities. For small molecule CDMOs, the ability to deliver high-volume, cost-efficient production while maintaining regulatory compliance and tech transfer agility has become a key differentiator. Indian CDMOs are also investing in both greenfield and brownfield expansions in line with the GMP standards. Additionally, specializing in specific categories like complex generics, and many more provides them with a competitive edge over other global CDMOs.
- **Commitment to sustainability:** Indian CDMOs are increasingly focusing on sustainability initiatives such as minimizing energy consumption, waste reduction, and a reduction in carbon footprint, as they are increasingly becoming pivotal to the pharmaceutical industry. As global pharmaceutical companies prioritize environmentally responsible supply chains, Indian CDMOs are aligning their operations with these expectations, investing in green chemistry, energy-efficient infrastructure, and zero-liquid discharge systems.

# 8 INDIAN CDMO COMPETITIVE LANDSCAPE

***The Indian CDMO landscape is fragmented but evolving, with players differentiating through either specialization in select dosage forms or broad market focus across regulated and semi-regulated geographies. This dual strategy, combined with cost advantages and regulatory strength, is positioning Indian CDMOs as vital partners in global pharma supply chains.***

The Indian CDMO industry is marked by a fragmented yet specialized and competitive landscape. This fragmentation creates intense competition but also provides flexibility and choice for pharmaceutical clients seeking outsourcing partners. Seeking differentiation based on formulation capabilities or end-market focus. Some of the Indian CDMOs have built deep specialization in select dosage forms such as oncology injectables, high-potency APIs (HPAPIs), ophthalmic, oral solids, dry powders, liquids/ gels/ semi-solids, and sterile formulations, while others have chosen to diversify their offerings basis specific end market focus across either regulated/ developed markets or emerging/ unregulated markets. This dual approach of super specialization versus broad market focus is shaping competitive strategies across the sector.

[86] World Intellectual Property Organization (WIPO)
[87] Department of Science and Technology Year End Review 2024

Coupled with cost advantages, regulatory credibility, and technical expertise, this evolving competitive landscape is positioning Indian CDMOs as critical partners in global pharma supply chains. Indian CDMOs have strategically positioned themselves for both regulated markets (like the USA, EU, Japan, Australia, and many more**)** by investing heavily in compliance, technology, and USFDA-approved facilities. On the other hand, some of the CDMOs target semi-regulated geographies such as Latin America, Africa, and Southeast Asia, where pricing pressures are less acute and entry barriers are comparatively lower. In terms of partnerships, they work through agile and flexible partnership models, providing scalable, multi-modal services with regulatory and technology transfer expertise to support both innovator pipelines and complex generics. Moving forward, Indian CDMOs are expanding their role from transactional outsourcing to long-term strategic partnerships, offering end-to-end services that span development, scale-up, commercial manufacturing, and packaging.

## 8.1 OPERATIONAL COMPARISON OF SELECT INDIAN CDMOs

Cotec Healthcare has emerged as a growing player in the Indian pharmaceutical contract development and manufacturing (CDMO) landscape with its manufacturing facility located on the Roorkee-Dehradun Highway in Kishanpur, Roorkee, Uttarakhand. The facility supports the production of a wide range of healthcare products, including pharmaceutical formulations such as antibiotics, anti-diabetics, anti-inflammatory agents, and pain medications, as well as ayurvedic and herbal preparations, hormonal therapies, and nutraceuticals. Cotec distinguishes itself in terms of dosage form diversity, with capabilities spanning approximately 24 distinct formulation types. These include injectables, tablets, capsules, ointments, eye drops, ampoules, vials, liquid and dry syrups, and infusions. This range allows them to serve diverse client needs with technical versatility.

The company also holds expertise in producing antibacterials, antimicrobials, calcium channel blockers, and angiotensin inhibitors, along with a portfolio in anti-inflammatory and pain management therapies. In FY24, Cotec's annual manufacturing capacity exceeded 4.05 billion dosage units, underscoring its operational scale and presence Indian CDMO sector. Cotec Healthcare is the second largest player in the CDMO industry in India in terms of number of dosage forms with capabilities across 24 distinct formulation types (among the peers assessed).

**Exhibit 8.1: Operational Analysis of Select Indian CDMOs, India, FY25**

| Name | HQ | No. of Mfg. Facilities | Facility Locations | Annual Production Capacity/ Capacity Utilization |
|---|---|---|---|---|
| **Tirupati Medicare** | Himachal Pradesh, India | 4 | HP, India | **Total Formulations: 5.11 billion** (only tabs, capsules, oral liq)<br>1. Tablets: 3470 million<br>2. Capsules: 1410 million<br>3. Oral Liquids: 270 million (bottles)<br>4. Oral Power: 25.9K Ton<br>5. Ointments, roll-ons, and Creams: 10 million (Bottles)<br>6. Oils: 40 million units (Bottles) |
| **Innova Captab Ltd. (Innova Captab)** | Maharashtra, India | 4 | HP, India | **Total Formulations: 26.42 billion**<br>1. Tablets and Capsules: 24,795 million<br>2. Ointments: 23 million<br>3. Dry Powder Injections: 607 million<br>4. Dry Syrup: 365 million<br>5. Oral Liquids: 71 million<br>6. BFS (Large and small volume parenterals and Respules): 562 million |
| **Synokem Pharma** | Delhi, India | 2 (CDMO) | UK, India | **Total Formulations: 10.96 billion**<br>1. Tablets: 4480 million<br>2. Capsules: 567 million<br>3. Oral Liquids : 4800 million<br>4. Ointment: 1080 million |

| | | | | |
|---|---|---|---|---|
| | | | | 5. Gel: 14.6 million<br>6. Sachets 14.6 million |
| **Akums** | Delhi, India | 14 | Pan India | **Total Formulations: 49.24 billion****<br>1. Oral Solids: 47,900 million<br>2. Sterile Preparations: 767 million<br>3. Liquids: 417.6 million<br>4. External: 158.4 million |
| **Windlas Biotech** | Dehradun, UK, India | 5 | UK, India | **Total Formulations: 8.63 billion**<br>**1.** Tablets and Capsules: 8522 Million<br>2. Pouch and Sachets: 54 million<br>3. Liquid bottles: 61 million |
| **Cotec Healthcare** | Uttarakhand, India | 1 | UK, India | **Total Formulations: 4.05 Billion**<br>1. General tablets – 3,214 million<br>2. Capsule – 454 million<br>3. Liquid (Syrups) – 48.4 million<br>4. Herbal Liquids – 10.1 million<br>5. Ointments – 48.5 million<br>6. Eye/ Ear drops – 18.2 million<br>7. Injections – 75.8 million<br>8. Infusions – 33.3 million<br>9. Medical soaps – 7.1 million<br>10. Beta Dry Syrup – 4.5 million<br>11. Beta Dry powder injection – 15.15 million<br>12. Hormones – 121.2 million |

*Source: Annual Reports, Company Websites as accessed in August 2025, DRHPs, Frost & Sullivan*
*Note: The CDMO selection is based on a focus on serving Domestic markets and the extent of availability of information.*

The Indian CDMO industry is focusing on building patient-centric dosage solutions with their portfolio spanning a multitude of therapy areas, multiple innovative formulations that enhance drug actions, and novel drug delivery systems (NDDS). With a global outreach and access, these companies are now well aligned with the global regulatory landscape and support in the manufacturing of different therapies such as hormone therapies like (corticosteroid hormones, thyroid hormones, somatostatin analogs, and reproductive hormones (Androgen, Estrogen, Progestin, Anti-androgens, Anti-estrogens, Aromatase inhibitors), antibacterial/ antimicrobial therapies and beta lactams (such as cephalosporins) as well as pain medications like NSAIDs.

Catering to both developed and emerging markets, companies focus mainly on unregulated markets, catering to the local needs. For example, Cotec Healthcare is concentrated on less developed by emerging geographies across Central Asia, and Western Africa, considering the region's much anticipated higher GDP growth in the coming years.

Across Central Asia, the company caters to countries like Ukraine, Uzbekistan, Turkmenistan, Tajikistan, Kazakhstan, and Burkina Faso alongside the Indian market. The company also plans to expand into the European region, while continuing to focus on Western Africa, owing to its active operations in the region. Across Western Africa, the company operates in Nigeria, Uganda, Senegal, Sierra Leone, and many more countries.

| Exhibit 8.2: Dosage Forms Analysis of Select Indian CDMOs, FY25 | | | | | | | |
|---|---|---|---|---|---|---|---|
| Dosage Forms | | Tirupati Medicare | Innova Captab | Synokem Pharma | Akums | Windlas Biotech | Cotec Healthcare |
| | Presence in the total number of dosage forms (30) | 13 | 6 | 8 | 28 | 15 | 24 |
| OL | Dry syrups | | | | | | |
| OL | Solutions, suspension | | | | | | |
| OL | Liquid Orals, Syrups | | | | | | |
| OS | Tablets | | | | | | |
| OS | Capsules | | | | | | |
| OS | Medicated Chewing Gums | | | | | | |
| OS | Chewable Tablets | | | | | | |
| OS | Orally Disintegrating tablets/powder | | | | | | |
| OS | Tablet-in-Tablet | | | | | | |
| OS | Bi-layered tablet | | | | | | |
| OS | Controlled/ Modified Release | | | | | | |
| OS | Powders | | | | | | |
| OS | Granules | | | | | | |
| OS | Effervescent Tablets | | | | | | |
| OS | Soft Gels | | | | | | |
| PR | Emulsions | | | | | | |
| PR | Dry Powder Injections | | | | | | |
| PR | Pre-Filled Syringe | | | | | | |
| PR | Injectables – Vials | | | | | | |
| PR | Injectables – Ampoules | | | | | | |
| PR | Injectables/Sterile Prep – Blow-filled Seal/Respules | | | | | | |
| TP | Ointments | | | | | | |
| TP | Sterile ophthalmic ointments | | | | | | |
| TP | Sterile intra-mammary ointments | | | | | | |
| TP | Creams | | | | | | |
| TP | Gels | | | | | | |
| TP | Sprays/Aerosols | | | | | | |
| TP | Eye Drops | | | | | | |
| IH | Dry powder inhaler | | | | | | |
| IH | Nasal aerosols, Spray and Powders | | | | | | |

*Source: Annual Reports, DRHP, Company Websites, as accessed in August 2025, Frost & Sullivan*
*Note: Ointments include, Hormonal ointments, Sterile Ophthalmic ointments, and sterile Intra-mammary ointments*
*Abbreviations: TP: Total parenteral; OS: Oral Solids; OL: Oral Liquids; IH: Inhalable; PR: Parenteral*

## 8.1.1 FINANCIAL BENCHMARKING OF 5 INDIAN CDMOs

Cotec Healthcare Private Limited is the fastest growing CDMO across the Indian CDMO industry in terms of revenue CAGR, when compared to its peers, with the FY25 revenue of INR 1,922.36 million, indicating almost 40% CAGR from INR 1,379.75 million in FY24. The Indian CDMO market includes multiple vendors, including Akums, Innova Captab Limited, and Windlas Biotech Limited, to name a few.

**Exhibit 8.3: Financial Analysis of Select Indian CDMOs, FY25, INR Million**

| Parameter/ Company | Innova Captab (FY25) | Akums (FY25) | Windlas Biotech (FY 25) | Sai Life Sciences Ltd. (FY25) | Cotec Healthcare FY 25) |
|---|---|---|---|---|---|
| Revenue from Operations | 12,436.76 | 41,181.58 | 7598.78 | 16.945.70 | 1,922.36 |
| Total Revenue CAGR FY23 – FY25 | 15.87% | 6.15% | 21.70% | 17.99% | 52.72% |
| EBITDA | 1,861.55 | 4644.80 | 941.07 | 4.056.61 | 314.42 |
| EBITDA CAGR (FY23-FY25) | 27.98% | 17.23% | 25.00% | 56.83% | 81.79% |
| EBITDA Margin | 14.97% | 11.28% | 12.38% | 23.94% | 16.36% |
| EBIT | 1,613.76 | 3,110.34 | 66.22 | 2.670.88 | 283.25 |
| PAT | 1,282.58 | 3,437.77 | 609.94 | 1702.00 | 200.00 |
| PAT Margin | 10.31% | 8.35% | 8.03% | 10.04% | 10.40% |
| PAT CAGR (FY22 – FY24) | 37.38% | 87.47% | 19.62% | 312.78% | 99.36% |
| ROCE | 13.15% | 12.52% | 12.79% | - | 36.43% |
| Return on Equity | 13.37% | 11.28% | 12.06% | - | 33.91% |
| Net Worth | 9.594.17 | 30,470.14 | 5,057.72 | - | 589.73 |
| Debt/Equity Ratio | 0.35 | 0.00 | 0.05 | - | 0.44 |
| Inventory Days | 93 | 102 | 63 | - | 75 |
| NAV/share (INR) | - | - | - | - | - |
| EPS diluted (INR) | 22.41 | 22.60 | 27.88 | 4.57 | 1.75 |
| EPS basic (INR) | 22.41 | 22.60 | 27.97 | 4.53 | 1.75 |
| Face Value (INR) | 10.00 | 2.00 | 5.00 | | 5.00 |

*Source: Annual Reports, DRHP, MCA, Frost & Sullivan*
*Note: "-" indicates Not Available; CDMO selection for analysis includes API and FDF CDMOs and is influenced by data availability and regional focus. For Synokem Pharma and Tirupati Medicare, FY25 data was unavailable, hence they are not included in the financial benchmarking.*