

Assessment of the global and Indian pharmaceuticals industry

December 2023

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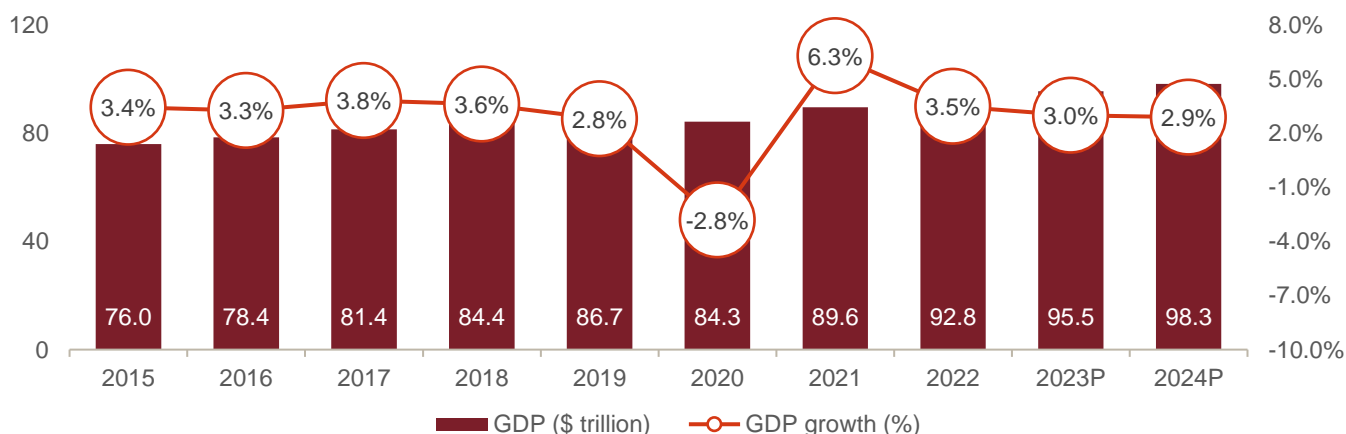
1 Global macroeconomic assessment

Global GDP is estimated to grow 3.0% in 2023 and 2.9% in 2024 amid tighter monetary policy and recovery from Covid-19 and Russia-Ukraine war effects

As per the International Monetary Fund’s (IMF) October 2023 update, global gross domestic product (GDP) growth is expected to moderate from 3.5% in 2022 to 3.0% in 2023 and in 2.9% 2024. The latest estimate is 0.1 percentage point lower for 2024 compared with IMF’s previous forecast in July, mainly due to the long-term consequences of the pandemic, the war in Ukraine, and increasing geoeconomic fragmentation. Economic slowdown compared with 2022 is expected to be mainly driven by distress in financial systems, broadening inflationary pressures, the Russia-Ukraine conflict and a slowdown in China. According to the IMF, the growth forecast for 2023 reflects the rise in central bank rates to fight inflation, especially in advanced economies as well as the impact of the war in Ukraine. The decline in growth in 2023 is driven by advanced economies; with stronger services activity offset by weaker manufacturing, as well as idiosyncratic factors. On average, these economies are expected to have broadly stable growth in 2024 with a pickup in 2025. By contrast, emerging market and developing economies, on average, are projected to see stable growth over 2022–24, with a slight pickup in 2025, although with sizable shifts across regions..

As per the IMF update, achieving sustained disinflation has been the top priority for most economies amid the cost-of-living crisis. With tighter monetary conditions and lower growth potentially affecting the stability of financial and debt markets, reopening of the Chinese economy would safeguard the recovery and ease supply chain bottlenecks.

Global GDP trend and outlook (2015-2024P, \$ trillion)



Note: P: Projection

Source: IMF economic database, World Bank national accounts data, the Organization for Economic Co-operation and Development (OECD) national accounts data, CRISIL Market Intelligence and Analytics (MI&A) Research

India among the world’s fastest-growing large economies

India was one of the fastest-growing economies in 2018 and 2019. In 2020, all countries, including developed ones such as the United States (US) and the United Kingdom (UK), except China, saw their GDP contracting due to the pandemic impact. India’s GDP shrank 5.8% in fiscal 2021 (financial year: April-March). In 2021, GDP growth of all

major economies rebounded as economic activities resumed and also due to the low base of 2020. Among the major economies, India, with a growth rate of ~9.1%, was the fastest growing economy in 2021, followed by China at 8.4%. The country also overtook the UK as the fifth-largest economy in the world in the April-June quarter of 2022 and registered GDP growth of 6.8% in 2022. India is expected to grow faster than China in 2023 and 2024 and its GDP is expected to grow 6.1% in 2023 and 6.3% in 2024 as per the IMF forecast.

Real GDP growth by geographies

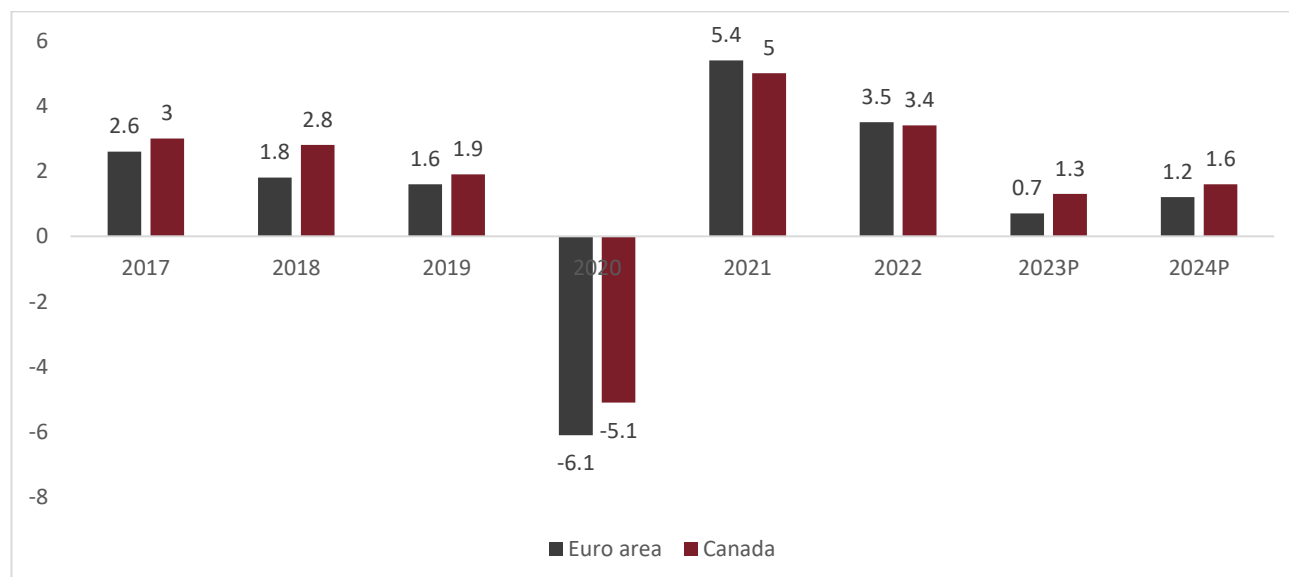
Regions	2017	2018	2019	2020	2021	2022	2023P	2024P
US	2.3	2.9	2.3	-2.8	5.9	2.1	2.1	1.5
Euro area	2.6	1.8	1.6	-6.1	5.4	3.5	0.7	1.2
Canada	3	2.8	1.9	-5.1	5.0	3.4	1.3	1.6
UK	2.4	1.7	1.6	-11.0	7.6	4.1	0.5	0.6
China	6.9	6.8	6.0	2.2	8.4	3.0	5.0	4.2
Japan	1.7	0.6	-0.4	-4.3	2.1	1.0	2.0	1.0
India*	6.8	6.5	3.9	-5.8	9.1	7.2	6.3	6.3
World	3.8	3.6	2.8	-2.8	6.3	3.5	3.0	2.9

Note: P: Projection as per IMF update

*Numbers for India are for financial year (2020 is fiscal 2021 and so on) and as per IMF forecast. CRISIL GDP forecast for India: 9.1% in fiscal 2022, 7.2% in fiscal 2023 and 6.0% in fiscal 2024

Source: IMF economic database, World Bank national accounts data, OECD national accounts data, CRISIL MI&A Research

Trend of real GDP growth rate (%) for Canada and Europe (2017-24P)



P: Projection as per IMF

Source: IMF, CRISIL MI&A Research

India's per capita GDP grows faster than global average

Global GDP per capita clocked a CAGR of 3.4% between 2017 and 2022, as per the International Monetary Fund (IMF) data. Meanwhile, India's corresponding figure registered a CAGR of 4.1%.

Per capita GDP at current prices

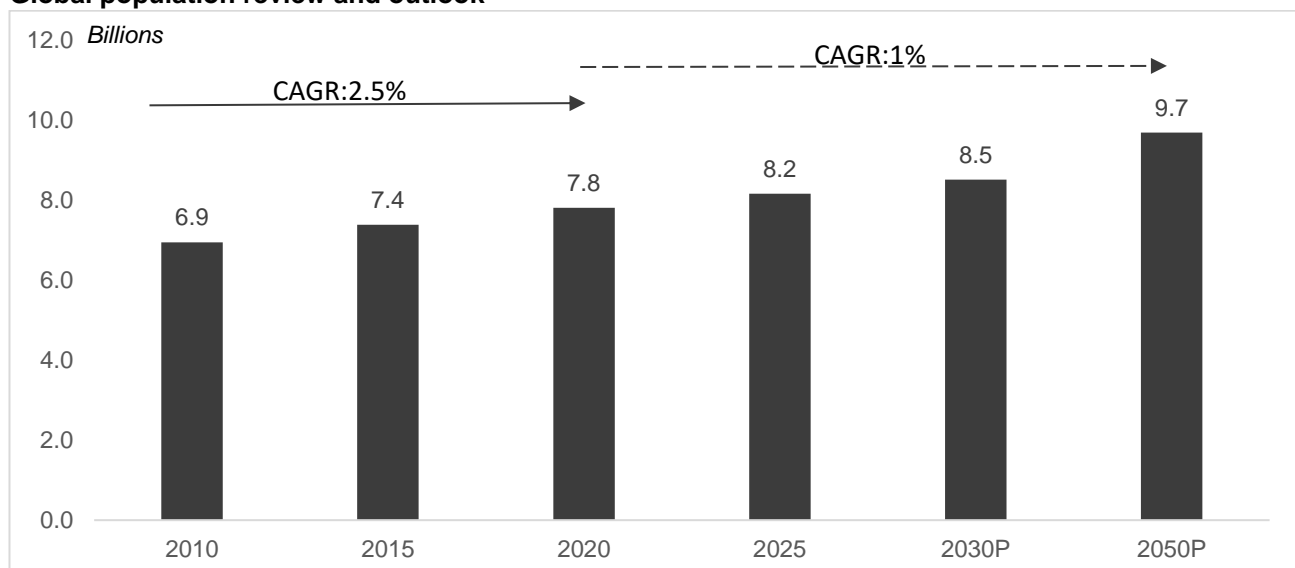
Regions	2017	2018	2019	2020	2021	2022	2023P	2024P
US	59,879	62,788	65,077	63,577	70,160	76,343	80,412	83,063
Euro area	36,939	39,865	39,001	37,915	42,404	40,819	44,566	46,926
Canada	45,192	46,626	46,450	43,384	52,388	55,037	53,247	55,528
UK	40,667	43,378	42,797	40,347	46,422	45,461	48,913	40,667
China	8,760	9,849	10,170	10,525	12,572	12,670	12,541	13,156
Japan	38,903	39,850	40,548	40,133	39,933	33,854	33,950	34,555
India	1,958	1,974	2,050	1,913	2,238	2,392	2,612	2,848
World	10,906	11,457	11,500	11,077	12,468	12,895	13,333	13,872

Source: IMF, CRISIL MI&A Research

Global population expected to reach 8.5 billion by 2030

Globally with improved life expectancy and increased penetration, world population have increased at steady 2.5% CAGR from 2010 to 2020 to reach 7.8 billion in the year 2020. In 2020, the growth rate of the global population fell under 1 per cent per year for the first time since 1950. The latest projections by the United Nations suggest that the world's population could grow to around 8.5 billion in 2030 and 9.7 billion in 2050.

Global population review and outlook



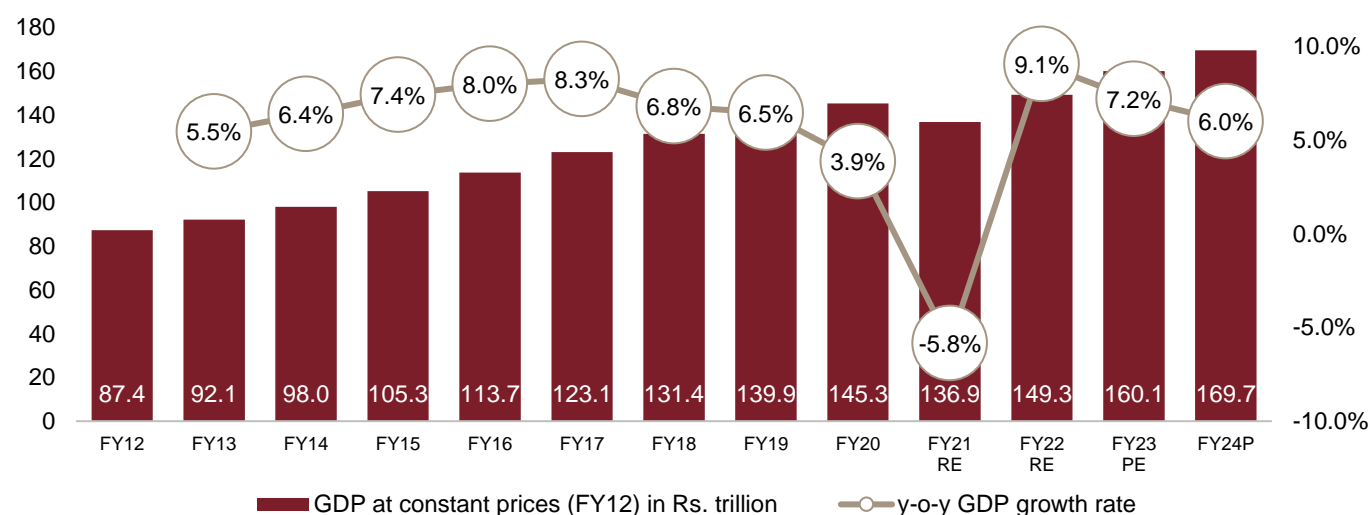
Source: United nations world population prospects 2022, CRISIL MI&A Research

2 Macroeconomic assessment of India

India GDP logged 6.2% CAGR during FY12-FY23

India clocked a compound annual growth rate (CAGR) of 6.2% in gross domestic product (GDP) to reach Rs 160 trillion in FY23 from Rs 87 trillion in FY12. In FY22, the economy recovered from the pandemic-related stress as restrictions were eased and economic activity resumed, though the last quarter did see inflation spiral due to geopolitical pressures. Resumption of economic activity and healthy trade flow led to a robust GDP growth of 9.1% for the year as against a decline of 5.8% in FY21. In FY23, the GDP rose 7.2% on strong growth momentum propelled by domestic demand from investment and private consumption through the year.

Real GDP growth in India (new series) – Constant prices



Note:

PE: Provisional estimates; RE: Revised estimates; P: Projected

Source: Central Statistics Office (CSO), Ministry of Statistics and Programme Implementation (MoSPI), CRISIL MI&A Research

CRISIL forecasts India's GDP to grow 6.0% in FY24

After the robust growth in FY2023, a slowdown seems inevitable in FY2024, driven by rising borrowing costs and global slowdown. Rate hikes are getting transmitted to broader lending rates with a lag and expected to peak in FY2024, hitting both global and domestic demand. S&P Global expects GDP growth for the United States and euro zone to slow in 2023. As these economies account for 33% of India's goods exports, the country is likely to see slower growth. Overall, real GDP of India is expected to grow 6.0% in FY2024 compared with 7.2% in FY2023.

While outlook for the external environment seems grim, India is positioned better with lower inflation rates and higher government capex. Government capex is expected to offer key support to the investment cycle this year. Private sector capex is also showing signs of a pick-up, because of the rising capacity utilisation. However, it will take time for the pick-up to be broad-based and for the segment to take the baton from the government. Overall, we expect India's real GDP to grow 6% this fiscal, compared with 7.2% in fiscal 2023.

India's GVA continues to record healthy growth

On the supply side, gross value added (GVA) grew 7.0% last fiscal, as per provisional estimates (compared with 8.8% in fiscal 2022). In absolute terms, real GVA rose to Rs 147.6 trillion in fiscal 2023 from Rs 138.0 trillion in fiscal 2022.

GVA at constant fiscal 2012 prices

Segment	FY21RE Rs trillion	FY22RE Rs trillion	FY23PE Rs trillion	Share in GVA FY23	Annual growth in FY23
Agriculture, forestry and fishing	20.8	21.5	22.3	15%	4.0%
Mining and quarrying	2.9	3.1	3.2	2%	4.6%
Manufacturing	23.3	25.8	26.2	18%	1.3%
Utility services	2.9	3.2	3.4	2%	9.0%
Construction	9.8	11.3	12.4	8.4%	10.0%
Trade, hotels, transport, communication and services related to broadcasting	21.6	24.6	28.0	19.0%	14.0%
Financial, real estate and professional services	29.6	31.0	33.2	22.5%	7.1%
Public administration, defence and other services	16.0	17.6	18.8	12.7%	7.2%
GVA at basic prices	126.8	138.0	147.6	-	7.0%

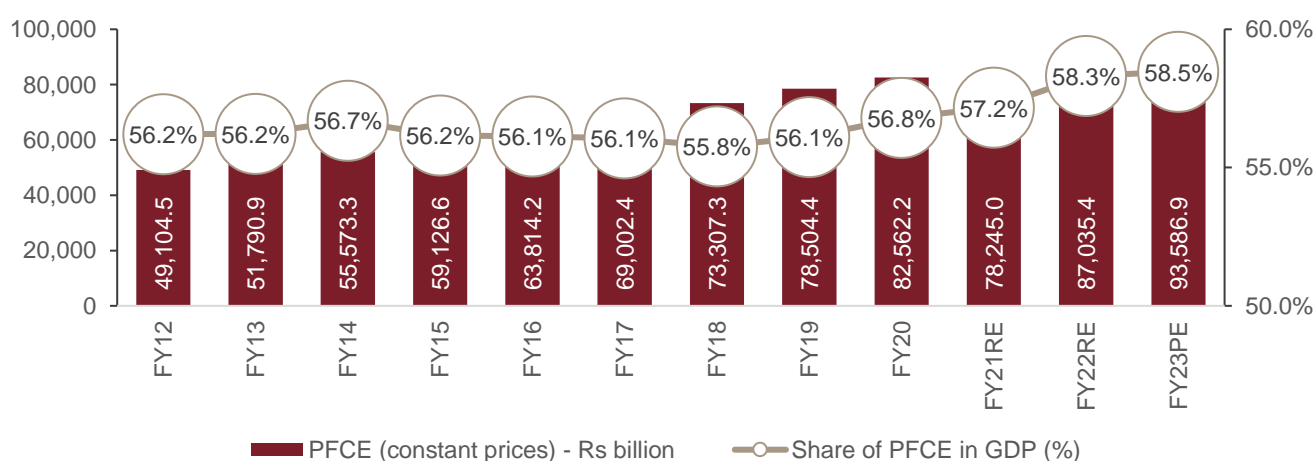
RE: revised estimate, PE: provisional estimate

Source: CRISIL MI&A Research

PFCE to maintain dominant share in India's GDP

Private final consumption expenditure (PFCE) at constant prices clocked a 6% CAGR between fiscals 2012 and 2023, maintaining its dominant share ever in the GDP pie at 58.5%, or ~Rs 93,587 billion in fiscal 2023, registering 7.5% y-o-y growth. Factors contributing to growth included good monsoons, wage revisions due to the implementation of the Seventh Central Pay Commission's recommendations, benign interest rates, and low inflation.

PFCE (at constant prices)



Note: PE: provisional estimates; RE: revised estimates

Source: MoSPI, CRISIL MI&A Research

India has seen robust growth in per capita income in recent times

India's per capita income, a broad indicator of living standards, rose from Rs 63,462 in fiscal 2012 to Rs 98,374 in fiscal 2023, at a 4.1% CAGR. Per capita income recovered 7.6% and 6.3% in fiscal 2023 and 2022, respectively, after declining 8.7% in fiscal 2021. Growth was led by better job opportunities, propped up by overall GDP growth. Moreover, population growth remained stable at ~1% CAGR.

Per capita net national income at constant prices

	FY12	FY13	FY14	FY15	FY16	FY17	FY18	FY19	FY20	FY21 RE	FY22 RE	FY23 PE	CAGR FY12-23
Per capita net national income (Rs)	63,462	65,538	68,572	72,805	77,659	83,003	87,586	92,133	94,270	86,054	92,583	98,374	4.1%
On-year growth (%)		3.3	4.6	6.2	6.7	6.9	5.5	5.2	2.3	-8.7	7.6	6.3	-

Note: RE: revised estimates, PE: provisional estimates

Source: Provisional Estimates of Annual National Income, 2022-23, CSO, MoSPI, CRISIL MI&A Research

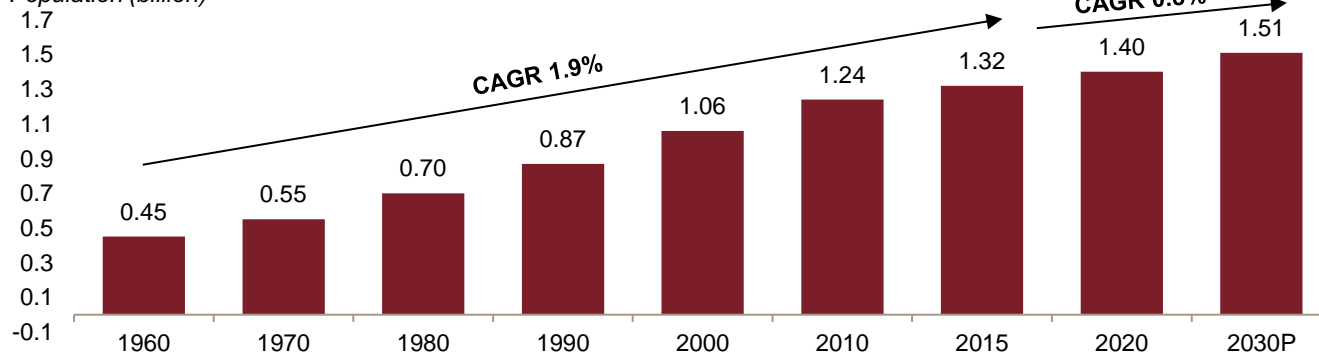
India's population projected to grow at 0.8% CAGR between 2020 and 2030

India's population grew to ~1.2 billion according to Census 2011, at a CAGR of 1.9% over 2001-11. As per the 2010 census, the country had ~246 million households.

According to the United Nation's (UN) World Population Prospects, 2022 revision, India and China, two of the most populous countries, accounted for nearly 36% of the world's population in 2021. The report projects India's population to increase to 1.5 billion by 2030, at a CAGR of 0.8% over 2020-30. According to UN estimates, India surpassed China to become the most populous country in April 2023 with 1.425 billion people, matching and then surpassing the population of Mainland China.

India's population growth

Population (billion)



Note: P: projected

Source: UN Department of Economic and Social Affairs, World Population Prospects 2022, CRISIL MI&A Research

Indian population's median age to rise to 30.9 years by 2030

According to the UN, the global median age rose to ~30 years in 2020 from ~20 years in 1970. This is lower than the median age in developed countries such as the US (37.5 years) and the UK (39.5 years).

Interestingly, India's median age is 27.3 years, indicating a favourable demographic dividend. Furthermore, it is the lowest among its BRIC peers: Brazil (32.4 years), Russia (38.6 years), and China 37.4 years. This trend is expected to continue up to 2030, indicating the strong potential for an increase in income, and basic and healthcare spending, with a large proportion of the population being employed. The median age is expected to reach 30.9 years in 2030, indicating a higher mid-age working population.

Median age trend across key countries

Country	1970	1990	2010	2015	2020	2030P
Brazil	17.3	21.5	28.2	30.3	32.4	36.5
China	18.0	23.7	34.1	35.6	37.4	42.7
India	18.3	20.0	24.0	25.5	27.3	30.9
Russian Federation	29.7	32.2	36.9	37.6	38.6	42.1
UK	33.2	34.8	38.5	39.0	39.5	41.6
US	27.2	31.8	36.1	36.6	37.5	39.7
World	20.3	23.0	27.3	28.5	29.7	32.1

Source: United Nations, Department of Economic and Social Affairs, Population Division (2022); World Population Prospects 2022, CRISIL MI&A Research

India spends relatively very little on healthcare

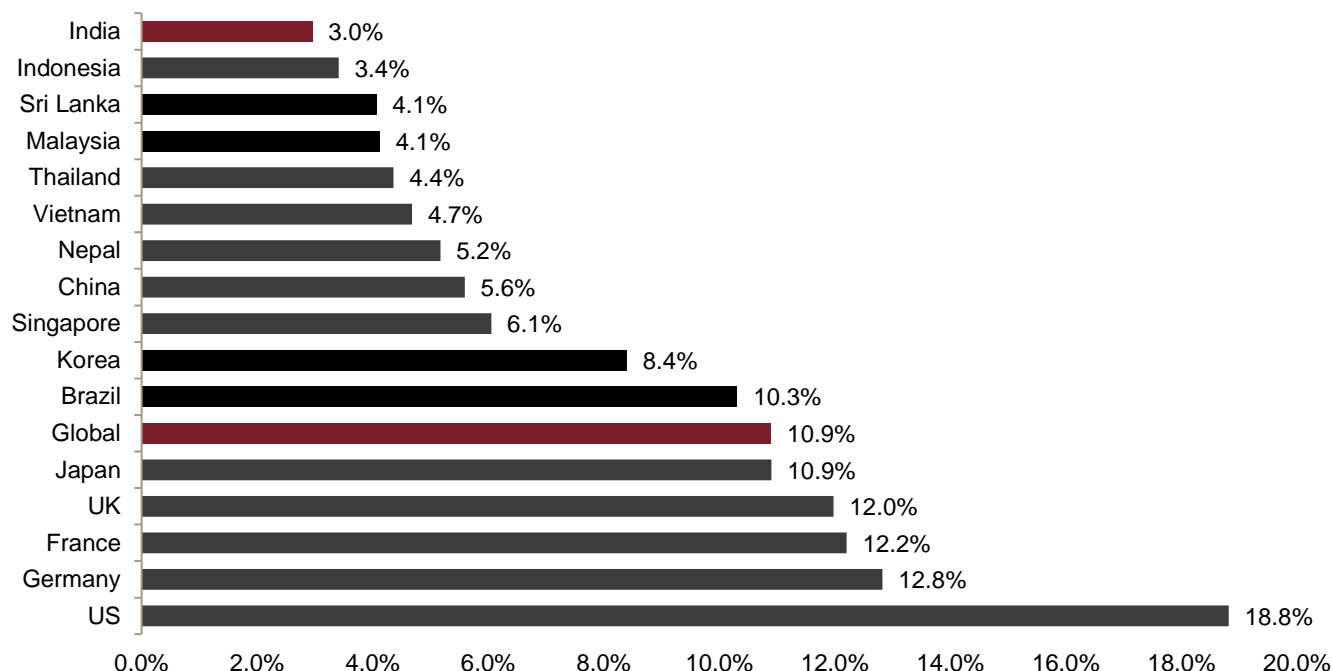
Global healthcare spending has been rising in sync with economic growth. As the economy grows, public and private spending on health grows, too. Further, an increase in sedentary work has heightened the risk of chronic diseases, which is also raising healthcare spending. This is evident specifically in fast-growing economies. The US, the UK, France and Germany are the top four nations with the highest healthcare expenditure as a percentage of GDP.

As per Global Health Expenditure Database compiled by the World Health Organization (WHO), global expenditure on healthcare increased slightly over 2011-2020. Globally, healthcare expenditure as a percentage of GDP increased from 9.4% in 2011 to 10.9% in 2020 due to availability of better medical facilities, advancements in medicine, and an increase in disposable income.

India's public spending on healthcare services is much lower than that of its global peers. In 2020, India's expenditure on healthcare was 3% of GDP; it trails not just developed countries such as the US and the UK, but also developing countries such as Brazil, Nepal, Singapore, Sri Lanka, Malaysia and Thailand. India's per capita healthcare expenditure (at an international dollar rate, adjusted for purchasing power parity) was only US\$57 in 2020, versus US\$11,702 for the US, US\$5,619 for Canada, US\$3031 for Korea, US\$4,927 for the UK and US\$3,537 for Singapore.

India lags peers in healthcare expenditure

Healthcare expenditure as % of GDP (2020)



Source: Global Health Expenditure Database – WHO, CRISIL MI&A Research

Per capita current expenditure on healthcare in US\$ (2020)

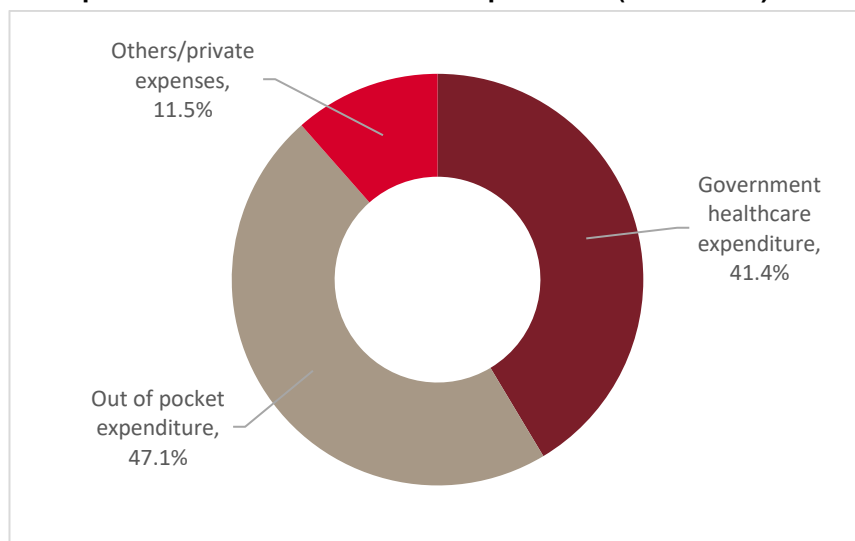
Country	Per capita current expenditure on healthcare in US\$ (2020)
India	57
China	583
Brazil	701
Global	1,535
Korea	3,031
Singapore	3,537
UK	4,927
Japan	4,388
France	4,769
Australia	5,901
Germany	5,930
Canada	5,619
US	11,702

Source: Global Health Expenditure Database – WHO, CRISIL MI&A Research

In terms of government expenditure as a percentage of GDP, India spends approximately 2.2% on healthcare. This includes expenditure on healthcare by central and state governments. In the national health policy document, 2017, it was recommended that the government's healthcare expenditure be increased to 2.5% of GDP by 2025. Also, the Fifteenth Finance Commission, in its report, had recommended that public health expenditure of union and states together be increased in a progressive manner to reach 2.5% of GDP by 2025. In keeping with this objective, the

central and state governments' budgeted expenditure on the healthcare sector reached 2.1% of GDP last fiscal and 2.2% in fiscal 2022, against 1.6% in fiscal 2021.

Composition of India's healthcare expenditure (fiscal 2020)



Source: Global Health Expenditure Database – WHO, National Health Accounts (NHA) 2019-20, CRISIL MI&A Research

Pharmaceutical expenditure constitutes ~35% of healthcare spending in India

Pharmaceutical care is constantly evolving, with many novel drugs entering the market. These offer alternative treatments and, in some cases, the prospect of treating conditions previously considered incurable. However, the cost of new drugs can be very high, with significant implications for healthcare budgets. In 2019, retail pharmaceuticals accounted for almost one-fifth of all healthcare expenditure and represented the third-largest spending component in Organisation for Economic Co-operation and Development (OECD) countries, behind inpatient and outpatient care. Most spending on retail pharmaceuticals is for prescription medicines (79%), with the remainder spent on over-the-counter (OTC) medicines (21%).

Pharmaceutical spending in key countries

Country	CHE as % of GDP (2020)	Pharmaceutical spending as % of CHE (2020)
US	18.8%	11.0%
Canada	11.0%	14.2%
UK	12.0%	10.6%
Germany	12.8%	13.6%
Spain	10.7%	15.1%
Italy	9.6%	17.6%
France	12.2%	13.6%
Brazil	10.3%	18.2%^
Australia	10.6%	11.9%
Mexico	6.2%	21.5%

Korea	8.4%	20.1%
India*	3.0%	35.1%

Note: 1) CHE: Current healthcare expenditure; 2) *pharmaceutical spending as % of CHE is as per NHA estimates 2023; 3) pharmaceutical spending as % of health spending is as per OECD data; 4) ^data as of 2019

Source: Global Health Expenditure Database – WHO, World Bank database, OECD, CRISIL MI&A Research

Healthcare expenditure accounts for 4.8% of private consumption spending

Personal healthcare expenditure increased from Rs 1,813 billion in fiscal 2012 to Rs 4,135 billion in fiscal 2022, supported by an increase in government schemes, health spending by states, an increase in income levels, and a rise in disease incidence. Healthcare expenditure in terms of constant prices logged an 8.6% CAGR between fiscals 2012 and 2022, considering the rise in prices of health products and services. Health expenditure as a percentage of total PFCE jumped to 4.8% in fiscal 2022, as healthcare spending rose because of the pandemic.

Healthcare spending in PFCE

	FY12	FY13	FY14	FY15	FY16	FY17	FY18	FY19	FY20	FY21	FY22	CAGR FY12-22
Health PFCE (Rs billion, at constant 2021 prices)	1,813	1,987	2,167	2,484	2,735	3,085	3,218	3,481	3,750	3,708	4,135	8.6%
Share in total PFCE (%)	3.7%	3.8%	3.9%	4.2%	4.3%	4.4%	4.4%	4.4%	4.5%	4.7%	4.8%	-

Source: National Accounts Statistics 2022, CRISIL MI&A Research

3 Assessment of global pharmaceutical market

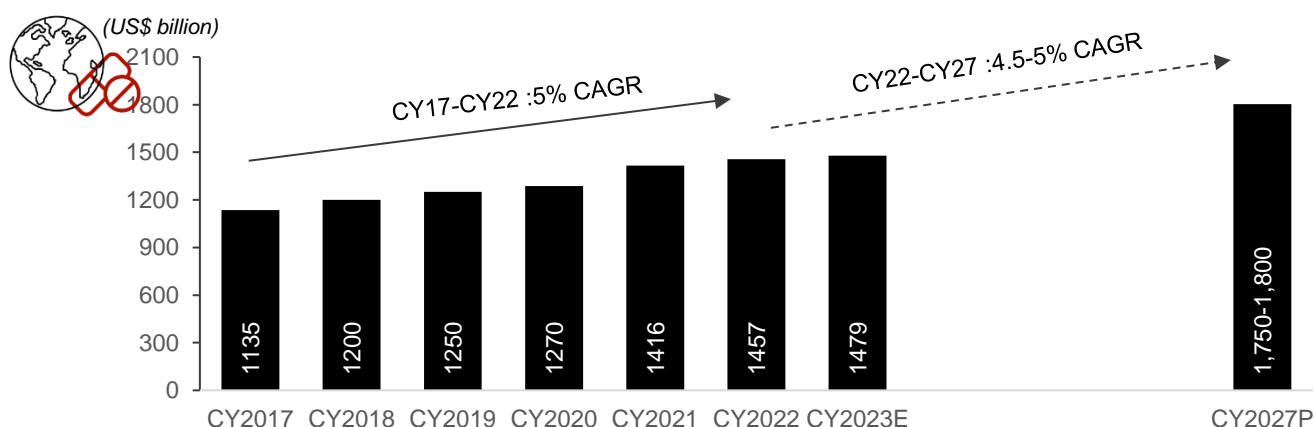
Overview of Global Pharmaceutical market

The global pharmaceutical industry is traditionally characterized by the concentration of consumption, production, and innovation in a relatively small number of high-income and developed regions like North America and Europe which continues to account for a major chunk of this market in value terms on account of higher priced drugs and newer products. However, over the past few years, production as well as consumption have picked up in middle-income countries, like India and China and Brazil; these “Pharmerging” markets also account for a significant share in volume consumption and have outpaced growth in high-income and developed markets. These emerging markets are now the strategic focus points for many multinational pharmaceutical companies, which is evident from pharmaceutical products exports from these countries. India and China had registered a 14% and 9% CAGR growth in pharmaceutical exports from calendar years 2017 to 2022, respectively. However, for pharmaceutical research and development (R&D), high-income regions continue to dominate expenditure in both the public and private sectors.

Global pharmaceutical market to grow at steady 4.5-5% CAGR from 2022 to 2027

Global pharmaceutical market has grown at a CAGR of 5% from approximately US\$ 1,135 billion in calendar year 2017 to approximately US\$ 1,457 billion in calendar year 2022. After showing strong growth in calendar year 2021 and 2022 on account of pent-up demand, the market is expected to moderate in the calendar year 2023. However, it is expected to sustain 4.5-5% CAGR growth over the next five years from 2022 to 2027 to reach approximately US\$1,750 to 1,800 billion in calendar year 2027. Globally, pharmaceutical companies are offering drugs for customized treatment and precision medicine for different diseases, which aims to provide medical care according to the patient's individual characteristics, needs, preferences, and genetic makeup. Also, generic medicines are seeing increased uptake with cost advantages and effective treatment options.

Global pharmaceutical market by value



Note :E-Estimated, P- Projected

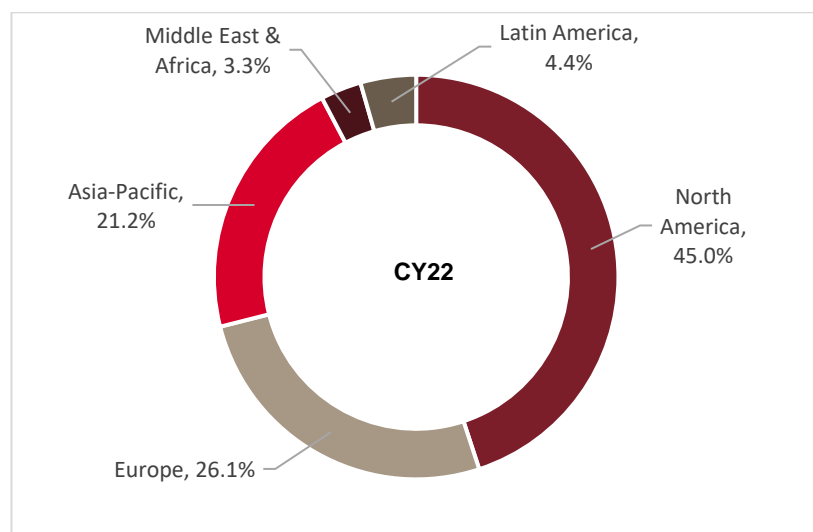
Source: Pharma Company reports, CRISIL MI&A Research

Significant R&D spends to continue to boost pharmaceutical growth across major markets like US and Europe

Global pharmaceutical market is dominated by developed markets like North America and Europe supported by higher uptake of innovative medicines and increase spend on healthcare. These developed markets are characterised by research and development spend in the pharmaceutical industry. As per Pharmaceutical Research and Manufacturers of America (PhRMA), the United States biopharmaceutical industry has been one of the world leaders in the development of new medicines. The entire US biopharmaceutical and pharmaceutical industry invested an estimated ~US\$ 122 billion in research and development (R&D) in CY20. Similarly, as per the European Federation of Pharmaceutical Industries and Association (EFPIA), in Europe, the pharmaceutical research & development investment was around approximately Euro 39.6 billion in CY20.

The emerging economies in Latin America and Asia-Pacific such as Brazil, China and India, are also witnessing rapid growth in the pharmaceutical market as a result of gradual shift of manufacturing and research activities from developed markets to these fast-growing markets. In India, along with developing capabilities via the inorganic route, companies are also looking at strengthening their in-house product pipelines through increased research and development (R&D) investment.

Segmentation of global pharmaceutical market based on region



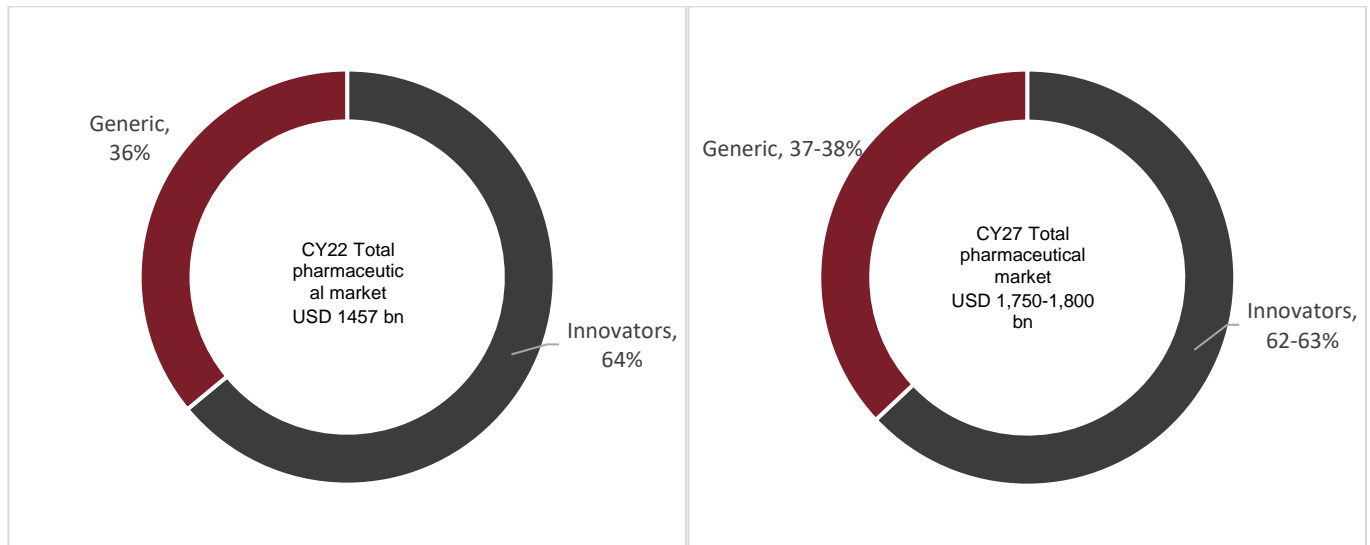
Note: Overall pharmaceutical market was sized at US\$ 1,457 billion in 2022

Source: CRISIL MI&A Research

Generic molecules consist of ~36% of total global pharmaceutical market as of CY2022

Generic formulation market is estimated to be around ~36% of the total pharmaceutical market as of 2022. There has been healthy growth of generics market in the recent years owing to strong development of generics market in countries like China and India. On the other hand, healthcare reforms in the regulated market such US are driving higher insurance coverage and greater usage of generic medicines although there have been some pricing pressure in the recent years in these regulated market. Innovator medicines still forms a major part of the global pharmaceutical market in value terms. As of 2022, innovator medicines constituted ~64% of the total global pharmaceutical market. Price differentiation and patent protection have helped the value growth of innovator segment across the globe. Going ahead generic molecules are expected to constitute ~37-38% of the total global market by 2027, the rise can be attributed to rising penetration of generics in biologics and complex molecules.

Segmentation of Global pharmaceutical market based on Innovators vs Generics



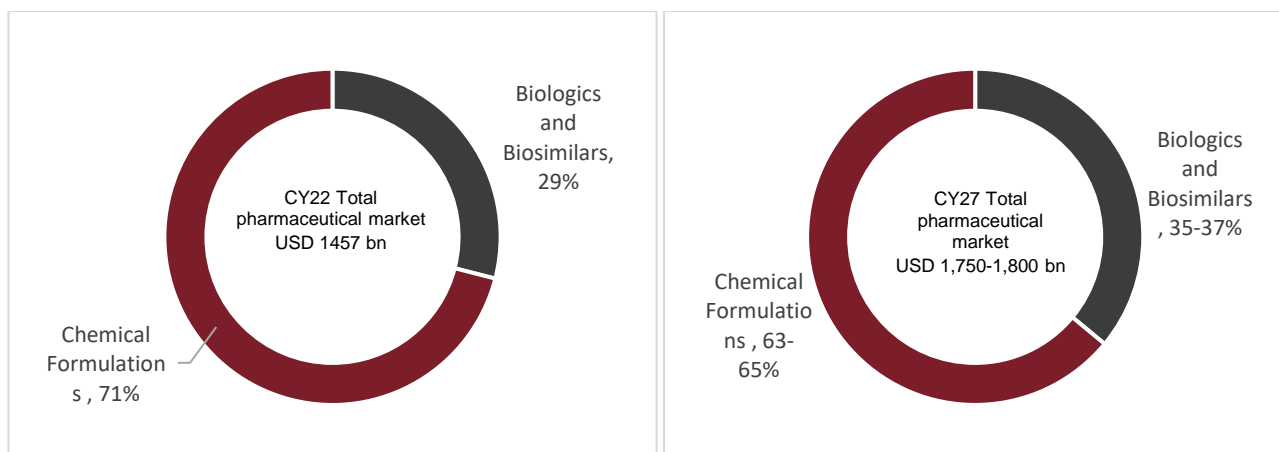
Source: CRISIL MI&A Research

Biopharmaceutical industry share to touch ~35-37% globally by 2027

The global biopharma industry has significantly outperformed the conventional pharmaceuticals segment over the past few years. As per CRISIL, the growth in global pharmaceuticals market supported by the biopharma segment's ~12-14% CAGR growth from 2017 to 2022. On the other hand, patent cliffs, and the lower number of high value new molecular entity (NME) launches during the period led to slower growth in the conventional pharmaceuticals segment. CRISIL expects the performance of the biopharma segment to continue, primarily driven by the biologics segment although there is expected to be some moderation in growth owing to the biosimilar launches in the regulated markets.

As per CRISIL estimates, of the top 50 global drugs as of 2020, 25-30 belonged to the biopharma segment. Therefore, the share of biopharma is expected to continue to increase, supported by new drug approvals coupled with the increasing sales of the current portfolio of biologics drugs.

Segmentation of Global pharmaceutical market based on Chemical formulation Vs Biologics & biosimilars



Source: CRISIL MI&A Research

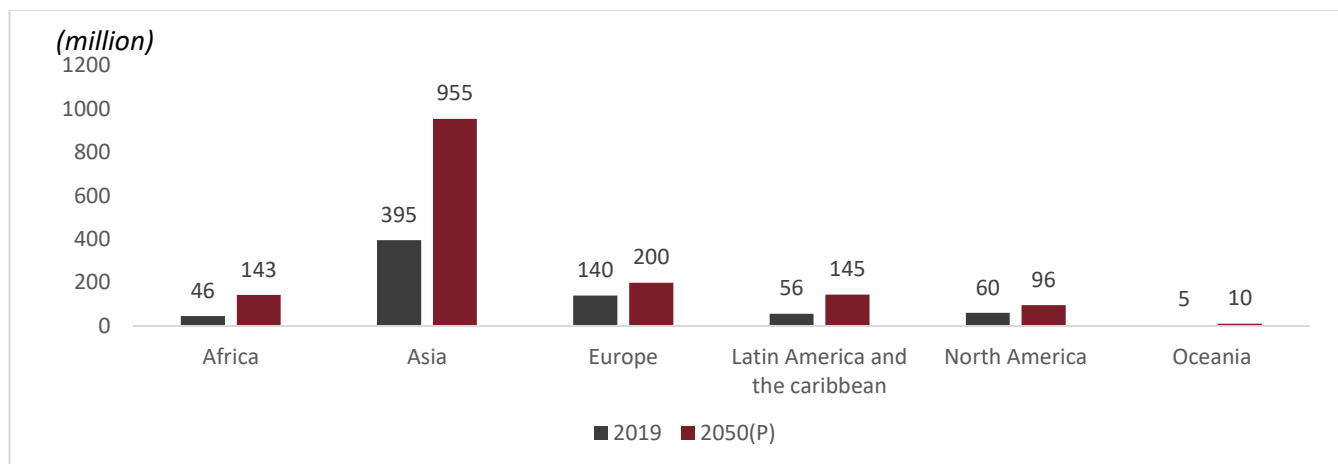
Key growth drivers for global pharmaceutical industry

The global pharmaceutical market is expected to be driven by the following factors: -

Rise in ageing population

According to the data from 'World Population Prospects: The 2019 Revision' published by the United Nations, the number of older people (aged 65 years or above) globally, is expected to more than double from 703 million in 2019 to 1.5 billion in 2050. Globally, the population group aged 65 years or over is registering faster growth rates than all younger age groups. Healthcare needs of the aging group which mainly consists of chronic diseases is expected to drive the growth of the global pharmaceutical industry.

Number of persons aged 65 years or over by geographic region, 2019 and 2050



P: Projected

Source: UN population ageing 2019, CRISIL MI&A Research

Incidence and prevalence of chronic diseases

Incidence and prevalence of chronic diseases are increasing rapidly all around the world. Rising incidences of diseases, such as cancer, cardiovascular diseases, obesity, and diabetes, are primarily observed and have a significant impact on the economy of the country, which is likely to drive the demand for pharmaceuticals.

According to the Organization for Economic Co-operation and Development's (OECD's) Health at a Glance 2021 report, almost one third of people aged 16 years and over reported living with serious illness. Cardiovascular diseases are found to be most prevalent across the world and are the leading causes of death causing an estimated 17.9 million deaths each year. Growing cases of chronic diseases are expected to further increase the demand for drugs and accelerate the development of pharmaceuticals, globally.

Better access to medicine in emerging markets

As the world's population reaches closer to approximately 8 billion in the year 2023, per capita usage of medicine per person per day is also estimated to have increased. Much of the increased usage is driven by emerging pharmaceutical markets, such as China, India, Brazil and Indonesia, where substantial increase have been made in average medicine volume usage. India's level of medicine usage is a reflection of both a very basic healthcare

infrastructure and the ease of access for medicines where even the most complex medicines can be readily available. The gap in average medicine usage between developed markets and emerging markets is closing, owing to reasons such as increased per capita income, improvement in healthcare infrastructure, and increase in insurance coverage. The rise of government safety nets and private insurance are also key factors that will increase medicine volume usage across emerging markets. The extent and pace of investments, both public and private, will be a key determinant of continued increase in medicine usage.

Strong development of generics market

Developed economies spend significant portion of their gross domestic product (GDP) on healthcare expenditure. Going forward, demand for pharma products in developed markets is expected to be driven by factors such as an ageing population and growing incidences of chronic diseases.

Healthcare reforms in the United States have resulted in higher insurance coverage and greater usage of generic medicines. The United States is the largest pharmaceuticals market for both innovator brands and generic drugs. It has been at the forefront of medicine research and healthcare spending. Driven by the Hax-Watchman Act, the generic drugs industry in the United States has grown tremendously over the years and was valued at approximately 125-150 billion in calendar year 2022. The Hax-Watchman Act is a United States federal law introduced in 1984 to regulate procedures for approval and marketing of generic drugs in the country. Driven by greater dependence on generic medicines and enactment of the Patient Protection and Affordable Care Act, growth in the generic drugs market in the United States is expected to continue.

Increased preference for affordable healthcare along with favourable regulatory environment for generic medicines such as the Hax-Watchman Act and Generic Drug User Fee Amendments (GDUFA) is expected to drive growth in the generic drugs market in the United States

In Europe, it is expected that austerity measures adopted by the government will continue to drive demand for generic drugs. The key growth driver for European market will be underpenetrated generic markets, such as Belgium (16.6%), the UK (28.0%), France (19.5%) and Germany (23.0%), which indicate tremendous untapped potential for growth of generic medicines.

Number of products going off patent in the United States to peak in 2024

The patent protection expiration of effective drugs aids the growth of generics formulation market. Pharmaceuticals players across globe track the patent exclusivity of the key drugs as research and development activities for these drugs start well in advance. The time-to-market of new products is an important source of pharmaceutical player's competitive advantage. Generic pharmaceutical companies tend to improve their market position by being first in the market when a patent on an original product expires. The expiry of patents for original products presents opportunity for generic companies and partner CDMO firms to launch generic versions of the products. The number of products going off patents in the United States from calendar years 2023 to 2028 are set out below:

Details on new drugs going off patent

Sr.No.	Year	Number of products going off patent
1	2023	433
2	2024	461
3	2025	427
4	2026	373

5	2027	165
6	2028	145

Note: Number of products going off-patent indicated the products which loose market exclusivity

Source: USFDA orange book files, CRISIL MI&A Research

Key trends in the global pharmaceutical industry

Pharmaceutical players building complex generics and specialty molecules portfolio

A complex generic is a generic that could have a complex active ingredient, complex formulation, complex route of delivery, or complex drug device combinations. Specialty drugs are high-cost prescription medications used to treat complex, chronic conditions such as cancer, rheumatoid arthritis, and multiple sclerosis. They can be used in rare or orphan disease indications. It may have unique storage or shipment requirements and might require additional patient education, adherence, and support beyond traditional dispensing activities.

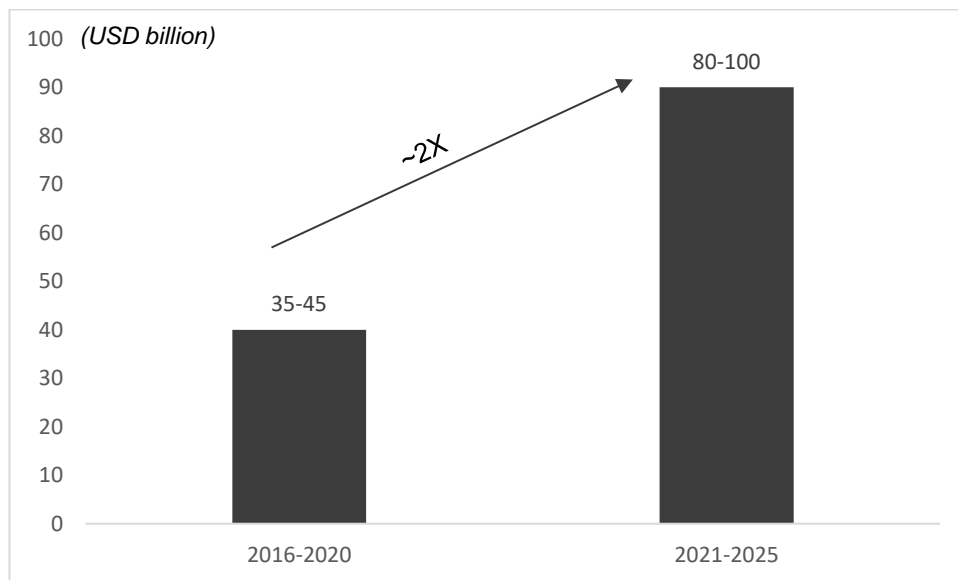
With declining opportunity in the conventional generics segment and pricing pressures on the existing portfolios, it has become important for generic players to look for high-value and high-margin drugs. Players have been developing niche products in order to weather the impact of pricing pressure. Some of the leading global generic companies has a major pipeline of specialty drugs in order to mitigate the impact of base erosion in the US.

Growth of biopharmaceuticals in the global market

Biopharmaceuticals are complex medicines made from living cells or organisms, often produced using sophisticated biotechnological methods. The global biopharma industry has shown significant growth in the recent years. The efficacy and safety of biopharmaceutical products, combined with their ability to address previously untreatable conditions, allows biopharma companies to command high prices for these biopharmaceutical innovative drugs.

Patented biopharmaceuticals, which recorded sales of about USD60-70 billion in 2019, are set to expire over the next 5-10 years in the US and Europe. Further, even among the drugs where patents have already expired, the penetration of biosimilars is very low due to regulatory challenges and difficult procedural requirements of all-phase clinical trials. In core pharmaceuticals, all-phase clinical trials are not required for generic launches. These expiries will present a lucrative opportunity for Indian players to launch biosimilar versions in regulated markets. Compared with a generic chemical molecule, such biopharmaceutical drugs can contribute higher revenue and margin realisation since most products catering to critical chronic ailments.

Global value of biopharmaceutical drugs going off-patent



Source: CRISIL MI&A Research

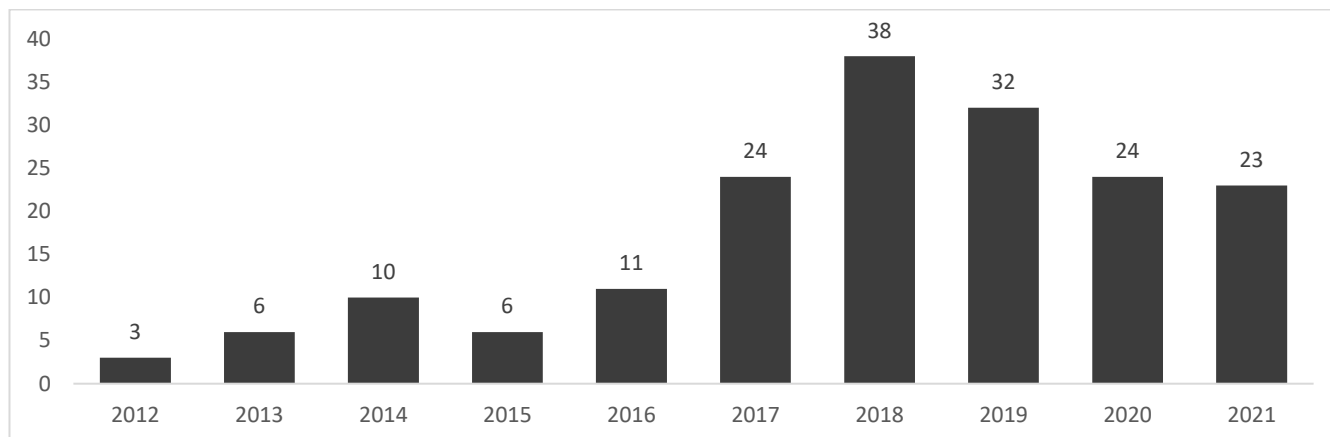
Regulated markets speed up biosimilars approvals, opportunity looms for Indian players

The regulated markets have been more cautious in allowing biosimilars, primarily due to quality concerns. Therefore, Indian players have largely concentrated on the semi-regulated markets for biosimilars launches. However, the demand and the margins enjoyed in the semi-regulated markets are substantially lower.

However, the regulated markets have now shown increased interest in promoting biosimilars in order to cut high healthcare expenditures. The first biosimilar (in regulated markets) was launched in Europe in 2007 and, till 2012, only a total of 21 biosimilars were launched. However, post 2012, over 40 biosimilars have been launched in various markets, thereby providing an opportunity to global generic players

The pace of approvals in the regulated markets has increased substantially over the last few years. Therefore, due to the opportunity visible in regulated markets, generics players have started to increase their focus on the biosimilars segment.

Number of biosimilars approvals in regulated market



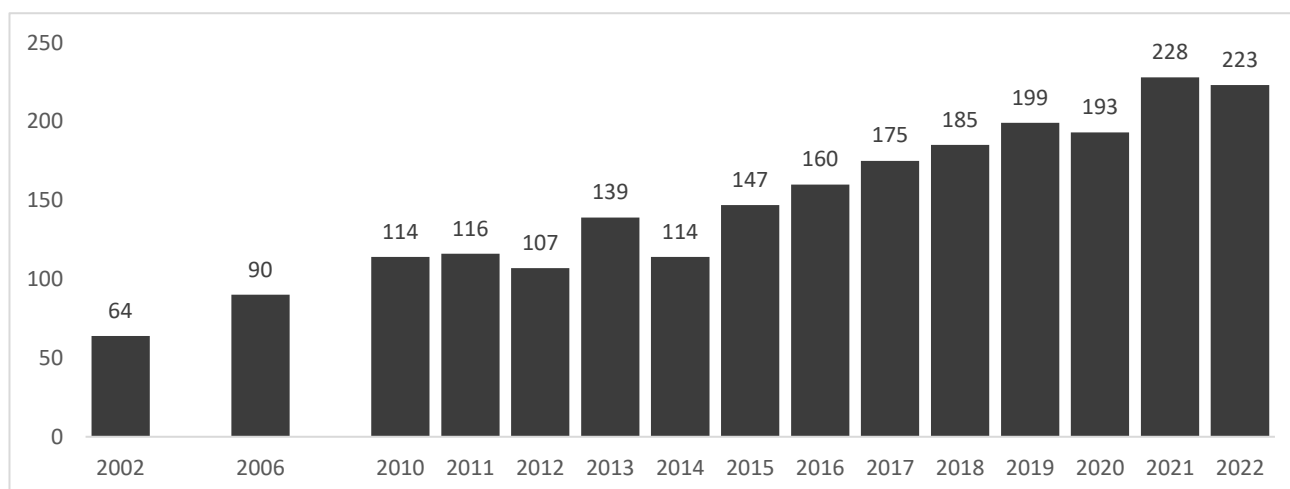
Source: CRISIL MI&A Research

Pricing pressure in regulated markets

The lucrative generic drugs opportunity in the regulated markets, especially in the US and Europe, had attracted players from various countries. Over the last few years, many companies -- mostly small and mid-sized players have set up operations in the US and invested in the US FDA-approved facilities to capitalize on the generic drugs opportunity. Indian companies, which traditionally used the contract manufacturing route to access regulated markets, have simultaneously obtained ANDA approvals for direct entry into the retail segment. The streamlining of regulations by the US FDA also facilitated the entry of mid and small-sized players after 2012.

Consequently, the number of companies seeking ANDA approvals has increased substantially over the last decade, intensifying competition and resulting in a sharp erosion in the price of generic drugs, especially in the case of large molecules and blockbuster drugs.

Number of companies (global) receiving final ANDA approvals



Source: CRISIL MI&A Research

Globally pharmaceutical players are diversifying the supply chains to adopt agile business environment

Chinese players had been forced to shift their manufacturing facilities inland and outside the cities as the government cracked down on polluting industries. With this, overall supply of bulk drugs and pharmaceuticals from China was impacted. Due to recurring quality and supply disruptions from China, following the Covid-19 pandemic, global customers adopted China+1 sourcing policy to secure their supply chains and reduce dependence on China. Globally players are looking for alternate supply destinations for their raw materials, which has given an opportunity for markets like India to establish itself as a reliable sourcing option. Players are also looking at sourcing options which are close to the manufacturing facilities so that supply chain disruptions will have least impact on the manufacturing capabilities of the business.

Regulations in key markets

It is very important for players to maintain high standards in the pharmaceutical industry, as it concerns the lives of people. Regulatory bodies impose regulations to ensure that drugs meet the safety and quality standards. Regulatory bodies not only ensure that pharmaceutical companies meet the set quality standards, but also ensure that the pharmaceutical companies do not charge unreasonable prices from consumers. Regulations are becoming more stringent in the pharmaceutical industry in order to ensure greater efficiency and safety in the consumption of drugs and prevention of sale of spurious products, making it tough for companies to get approvals to enter the market. Periodic checks by regulatory authorities of facilities also ensures that regulations and protocols are abided by even after approval is granted. Thus, maintaining approvals granted over the long run is important to continue marketing and supplying drugs in the regulated markets.

Drug Regulatory agency in the USA

The United States has the world's most stringent standards for approving new drugs. Drug approval standards in the United States are considered by the industry to be the most demanding.

Food and Drug Administration:

USA is the major market in the pharmaceutical industry. The USA has evolved from no regulations in the 1800's to one of the highly regulated market in the world. The food and drug administration (FDA) within the U.S. Department of Health and Human Services regulates the drug approval system and regulates the safety and effectiveness of drugs sold in the United States. The Department of Health and Human Services regulates the US pharmaceutical market through the US FDA, which ensures that human and veterinary drugs, biological products and medical devices are safe and effective. It lays down the procedures for product approvals (generic and new drugs) and is primarily responsible for enforcing the Federal Food, Drug and Cosmetic Act - the basic drug and food law in the US.

Major responsibilities of FDA:

Food and Drug Modernization Act states that the FDA has 4 major roles:

- To improve health by reviewing research and new products approval
- To assure that foods and drugs are safe and properly labelled
- To work with other countries to decrease the burden of regulation
- To cooperate with scientific experts and consumers to properly implement these obligations

Drug approval process in United States:

Investigational New Drug (IND) Application:

If the drug is found to be safe after drug discovery, preclinical trials are performed and results are reported, the drug developer sponsor files IND application to the FDA in order to initiate clinical trials on human volunteers. IND applications require information regarding animals used for pre-clinical studies, toxicological studies, and data including the composition, manufacturer, stability and clinical protocols of the trial. After approval of IND application, the investigators of the clinical trial can distribute a drug to multiple study locations across the US. A pre-IND meeting can be arranged with the FDA to discuss on issues like design of animal studies, intended study protocol for conducting the trials and chemistry, production & control of the IND.

New Drug Application (NDA):

If the clinical studies prove that a new drug is safe (without any unwanted or toxic effects) and effective the manufacturer files an NDA, It is the actual request made to the FDA to produce and sell the drug in the US.

The NDA application requires detailed data regarding the manufacturing process, facilities, quality control & quality assurance, product description, packing and labeling. FDA personnel will assess clinical data, tests drug samples, audit the manufacturing facilities, and check labelling. FDA review completes within 180 days of receipt of application. Post approval of the NDA, the applicant can manufacture and market the drug. On denial of approval of the NDA, FDA sends a response letter including specific deficiencies and recommendations for the applicant in order to make the application viable. Unsuccessful applicants can request a hearing.

Abbreviated New Drug Application (ANDA):

ANDA is an application filed for approval of generic drug product. Repetition of the clinical studies that were done for the original/brand name drug product are not required while filing ANDA. Rather, generic drug product manufacturers must prove that their product is bioequivalent (BE) to, an already approved brand name product. And hence, the generic drug applications are termed abbreviated. ANDAs are submitted for generic drugs to which NDA must be approved previously and listed (known as the Reference Listed Drug, RLD). ANDA may not be submitted up to five years after the date of the approval of the NME. After approval, an applicant may produce and market the generic drug product to provide a safe, effective and lower cost alternative medicine to the public. All approved drug products (innovator and generic) are listed in Orange Book (FDAs Approved Drug Products with Therapeutic Equivalence Evaluations).

Drug Regulatory agency in Europe

European Medicines Agency (EMA)

EMA is a European Union (EU) agency which evaluates and supervises medicinal products. Before 2004, it was known as the European Agency for the Evaluation of Medicinal Products or European Medicines Evaluation Agency (EMEA). The Agency is responsible for the scientific evaluation of medicines developed by pharmaceutical companies for use in the European Union and applications for European marketing authorizations. EMA is a decentralized agency of the European Union, located in London, before UK's withdrawal from the EU. It was relocated to Amsterdam in March 2019. The EMA was established in 1995 with funding from the EU and the pharmaceutical

industry, as well as indirect subsidy from member states, in order to harmonize the work of existing national regulatory bodies for medicines.

Major responsibilities of EMA:

- Continuous monitoring and supervision of the safety of medicines
- Scientific suggestions and protocol assistance
- Provides timely patient access to new medicines
- Support research and innovation in the pharmaceutical sector
- Orphan designation of medicines for rare diseases
- Developing scientific guidelines on needs for the safety, efficacy and quality testing of medicines and setting standards
- Promotes innovation and development of new medicines through European small and medium sized enterprises
- Provides information on the safety of medicines to the public
- Publishes impartial and clear information about medicines and their approved uses

Drug approval process in EU:

There are two regulatory steps to go through prior to approval of a drug for marketing in the EU, akin to the US FDA requirements. These two steps are i. Clinical Trial Application (CTA), ii. Marketing Authorization Application (MAA). CTA approval is done at the member state level, whereas MAA are approved at both the member state and centralized levels. There are a total of four procedures through which approval for manufacture and marketing of a drug can be obtained, depending on the drug class and the preference of the manufacturer:

- Centralized process
- National process
- Mutual recognition
- Decentralized procedure

Centralized process:

Centralized procedure allows the marketing of a medicine on the basis of a single EU-wide assessment and marketing authorization which is valid throughout the EU. Pharmaceutical companies submit a single authorization application to EMA. EMA opinion issued within 210 days after filing application, and submitted to European Commission for final approval. Centralized process is controlled through the EMA. Every EU member state is represented on the EMA Committee for Medicinal Products, which provides a single license valid in all EU member states.

National process:

National procedure allows applicants to attain a marketing authorization in only one member state. To obtain a marketing authorization in a country, an application must be submitted to the competent authority of the Member State. New active substances, which are not mandatory under centralized procedure, can obtain marketing approval under this procedure. Timeline for issue of EMA opinion is 210 Days. Each EU state can have its own procedures for approving drugs that fall outside of those needed to undergo the centralized process.

Mutual recognition:

Mutual recognition process permits applicants to get a marketing authorization in the Concerned Member States (CMS) other than the Reference member state (RMS), where the drug is already approved. Applicant must submit identical dossier to all the EU member states in which they want to obtain marketing approval, along with required information. As soon as one of the member states decides to evaluate the medicinal product (at which point it will become the RMS), it will inform this decision to other member states (which then will become the CMS), to which applications have also been submitted. RMS issues a report to other states on its own findings after completion of evaluation. Generic drug industry is the major user of this type of drug approval process. Time line for issuing the EMA opinion under this process is 390 days.

Decentralized procedure:

The procedure where companies can apply for the simultaneous authorisation of a medicine in more than one EU Member State if it has not yet been authorised in any EU country and does not fall within the scope of the centralised procedure. In decentralized procedure, according to the decision taken by the RMS & CMS the marketing authorization should be granted. Generally used for those medicinal products that did not receive any authorization in an EU country. Time taken for issue of EMA opinion is 210 days.

Drug Regulatory agency in India

Central Drugs Standard Control Organization (CDSCO):

The Central Drugs Standard Control Organization (CDSCO) under Directorate General of Health Services, Ministry of Health & Family Welfare Government of India is the National Regulatory Authority (NRA) of India. The CDSCO is the central drug regulatory authority for execution of functions assigned to the central government under the Drugs and Cosmetics Act. CDSCO and state regulatory bodies are jointly responsible for grant of licenses of blood and blood products, intravenous fluids, vaccines and sera.

Within the CDSCO, Drug Controller General of India (DCGI) is responsible for regulation of pharmaceutical products and medical devices. The Drug Technical Advisory Board (DTAB) and the Drug Consultative Committee (DCC) advise the DCGI. Licensing and classification of Medical devices is the function of the Central Licensing Approval Authority (CLAA). It is also responsible for setting and enforcing safety standards, performing post-market surveillance, issue of warnings and recall of pharmaceutical products for adverse events.

Major responsibilities of CDSCO:

- Central licensing authorities are responsible for
 - New drugs approval
 - Performing clinical trials
 - Establishing standards for drugs
 - Quality Control of imported drugs, import registration and licensing
 - Coordination of the activities of state drug control authorities by giving expert opinion to uniformly enforce the D&C Act
- State licensing authorities are responsible for:
 - Regulation of production, sale and marketing of drugs
- Other functions
 - Grant of license for blood banks, Large Volume Parenteral (LVP), vaccines, recombinant DNA products and some medical devices
 - Amendment of D&C Act rules
 - Ban of old drugs and cosmetics
 - Grant of test license, personal license, No Objection Certificate (NOC) for export
 - Testing of new drugs and cosmetics

Drug approval process in India:

The sponsor should obtain permission from the licensing authority (DCGI) and submitting the necessary data for manufacturing or importing of a new drug. Permission is obtained by filling form 44 and data is submitted according to Schedule Y of D&C Act 1940. To prove the efficacy and safety of imported drug in Indian population, clinical trials are conducted as per the Schedule Y guidelines and the report is submitted in specified format. DCGI is the authority which reviews the application and approves if acceptable.

Schedule Y of D&C Act 1940 and Rules 1945:

Schedule Y defines the clinical as the requirements and guidelines for import and manufacture of new drugs for sale or for clinical trials. It describes the details of application process for conducting clinical trials; responsibilities of the sponsor, investigators and the Independent Ethics Committee.

- Section 2.4 (a), Schedule Y: All phases of clinical trials must be performed for the drug substances which are discovered in India
- Section 2.4 (b), Schedule Y: For drug substances which are discovered in foreign countries; the applicant should submit the data available from those countries and the licensing authority may ask him to repeat all the studies or may permit him to proceed to next phase
- Section 2.8, Schedule Y: The licensing authority may require Pharmacokinetic studies (Bioequivalence studies) first to confirm that the data generated in Indian population is equal to data generated abroad and then require him to proceed to next phase.

Depending on the extent to which licensing authority is satisfied about its safety and efficacy, the exact requirements of clinical trials may vary from case to case. New drug approval in India is a complex process. The requirements should also meet necessary requirements along with New Drug Application to Food and Drug Administration (FDA). There is provision in Rule 122A of D&C Act 1940, that certain trails may be waived off if: i. The licensing authority considers that in the interest of public ii. May grant permission for import of drugs based on the data of the clinical trials conducted in other countries iii. In the case of drugs which are approved and being used for many years in other countries

Drugs & Clinical Trials New Rules 2019:

For the drugs manufactured in India, the new rules reduce the time to one month for approving and to 90 days for those developed in foreign countries. The rules also waive off the need for conducting a local Clinical Trial (CT) if the drug is approved for marketing in countries mentioned by the DCGI. The countries approved by DCGI are United Kingdom, European Union members, Australia, Canada, Japan and the United States. The new rules aim to encourage clinical research in India by providing transparent and effective regulations for CT and by assuring faster accessibility of new drugs to the Indian population.

Drug Regulatory agency in Canada

Health Canada is engaged in various activities and has numerous responsibilities related to health. Health Canada's HPFB (Health Products and Food Branch) is the national authority that regulates, evaluates and monitors the safety, efficacy, and quality of:

- Health products (including drugs, medical devices, biologic and genetic therapies, and natural health products)
- Foods
- Veterinary drugs (in order to protect the safety of Canada's food supply)

The Therapeutic Products Directorate (TPD) of HPFB is Canada's regulator of prescription drugs and medical devices for human use. Before giving permission to sell a product, the directorate must see scientific evidence of the product's safety, effectiveness, and quality, as required by the Food and Drugs Act and Regulations. Human Drugs fall under a number of different Schedules of the Food and Drugs Act and the Food and Drug Regulations. Following are the Schedules for some of the categories of the drugs:

- Schedule C (Radiopharmaceuticals excluding radionuclides)
- Schedule D drugs (Drugs derived from Human, Animal or microbial sources, such as insulin and blood based products)
- Schedule F (Prescription Drugs)

Process for authorization of new drug for sale in Canada

New drugs are regulated under Part C, Division 8 of the Food and Drug Regulations. Companies are granted market authorization by Health Canada in several ways. Regardless of the method of authorization, a manufacturer receives a Notice of Compliance (NOC) when it has met Health Canada's regulatory requirements for the safety, efficacy and quality of a product. The following provides a brief overview of three of the most common routes by which new drugs are authorized for sale in Canada.

Innovator drugs ("brand name drugs"): Manufacturers receive authorization to sell these products in Canada by submitting a New Drug Submission (NDS) pursuant to section C.08.002 of the Food and Drugs Regulations.

Subsequent entry drugs ("generic drugs"): Health Canada often authorizes manufacturers to market these drugs by requiring them to submit an Abbreviated New Drug Submission (ANDS) pursuant to section C.08.002.1 of the Food and Drug Regulations. These products will receive a declaration of bioequivalence to a Canadian Reference Product (pursuant to Section C.08.004 (4)), which will be stated on the NOC.

The Health Canada Changes in Manufacturer's Name and/or Product Name Policy outlines another option for manufacturers wishing to receive authorization through an NOC to market brand name and generic drug products. This policy applies to eligible drug submissions submitted to Health Canada for a change in the manufacturer's name and/or product name subsequent to a merger, buy-out or other corporate restructuring or the establishment of a licensing agreement.

Products that receive an NOC according to one of these mechanisms have met Health Canada's regulatory requirements for safety, efficacy and quality.

The type of submission being presented to Health Canada

1. CTA (Clinical Trial Application)
2. CTA-A (Clinical Trial Application Amendment)

3. NDS (New Drug Submission)
4. SNDS (Supplemental New Drug Submission)
5. ANDS (Abbreviated New Drug Submission)
6. SANDS (Supplemental Abbreviated New Drug Submission)
7. NC (Notifiable Change)
8. DIN (Drug Identification Number submission)
9. PDC (Post-Authorization Division 1 Change)

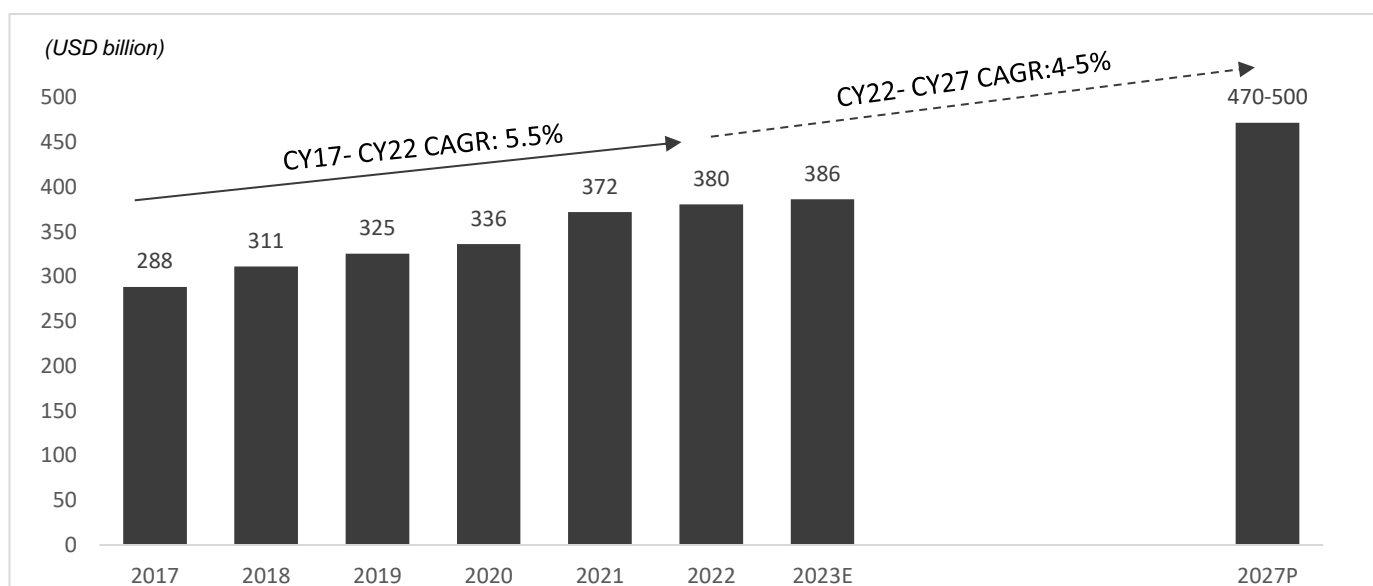
Europe and Canada Market

Review and Outlook on market size

Europe market to grow at steady ~4-5% CAGR from 2022 to 2027

Europe is one of the developed pharmaceutical markets in the world. The pharmaceutical markets in Europe have well established regulatory environment and there are established guidelines for manufacturing and marketing of the pharmaceutical products. In recent past there has been a shifted focus to use of generic medicines in markets like Europe. There has been as major opportunity in the regulated markets like Europe for generic players. More and more generic players are expected to tap in this opportunity and expand their presence in markets like Europe.

Review and outlook on Europe market



Note: E- Estimated, P- Projected

Source: CRISIL MI&A Research

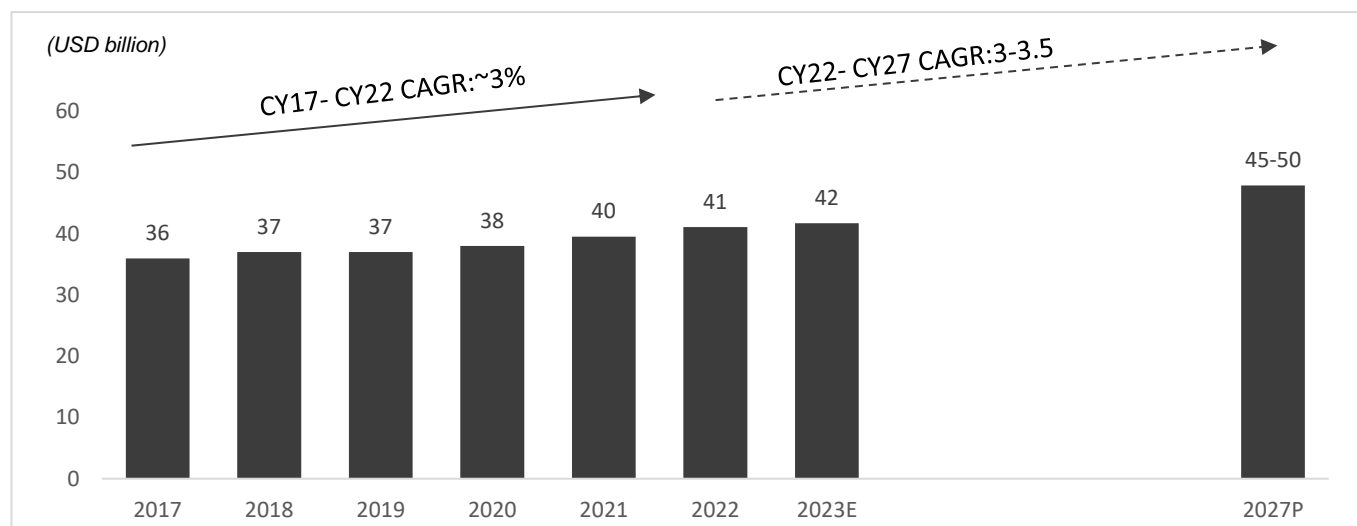
Europe pharmaceutical market have shown healthy growth in the past and forms ~26% of the global formulation market as of 2022. Europe market have grown at 5.5% CAGR from the year 2017 to 2022 growing from USD 288 billion in the year 2017 to USD 380 billion in the year 2022. The Europe market is expected to grow at ~4-5% CAGR from the year 2022 to year 2027 reaching approximately USD 470-500 billion by the year 2027. The major factors contributing to growth of this market is the growing demand for generics as well as faster approvals for biologics and biosimilars which presents a great potential in the global pharmaceutical market.

Canada market to grow at moderate ~3-3.5% CAGR from 2022 to 2027

Canada has been one of the developed pharmaceutical market in the North America region. The well-developed regulatory environment in Canada has seen major pharmaceutical players operating in this market in recent years.

The pharmaceutical market in Canada has seen moderate amount of growth in the last few years. Canada pharmaceutical market grew at ~3% CAGR from year 2017 to year 2022 and forms ~3% global formulation market as of 2022. The Canada pharmaceutical market was valued at USD 41 billion as of 2022. The market is expected to reach approximately USD 45-50 USD billion by the year 2027 growing at 3-3.5% CAGR from 2022 to 2027.

Review and outlook on Canada market



Note: E-Estimated, P- Projected

Source: CRISIL MI&A Research

Complex generic injectables market in Europe and Canada to see traction in coming years

As per the definition by USFDA, complex generics are products that have complex active ingredients, formulations, dosage forms, or routes of administration, or are complex drug-device combination products. Generics of complex brand name drugs (i.e., reference listed drugs) are usually more difficult to develop and requires deep understanding and development process which has often acted as a key entry barrier for players entering the complex generic space. However, with advent growing research and development activities as well as key value proposition presented by complex generics, players are gradually including complex generics product to their portfolio.

Complex generics drugs overview

Parameter	Details
Complex active ingredients	Complex mixtures of APIs, polymeric compounds, peptides, naturally sourced ingredients
Complex formulations	Liposomes, suspensions, emulsions, gels, parenteral microspheres, colloids

Complex routes of delivery	Locally acting such as ophthalmic, dermatological, locally acting GI drugs and inhalational drugs
Complex dosage forms	Long acting injectables and implants
Complex drug-device combinations	Metered Dose Inhalers, nasal sprays, dry powder inhalers and transdermal

Source: USFDA, CRISIL MI&A Research

Majority of the complex generics drugs have injectables and intradermal as their dosage forms. In recent years, several big pharmaceutical companies have entered the complex generic injectables market as they have seen the opportunity arising in the market owing to more new complex drug launches. In regulated markets like Europe and Canada there have been traction in the complex generics injectables space, thus many players have started to include complex generics in their product portfolio. The Europe complex generic injectables markets opportunity is valued at USD 20-22 billion in the year 2022 whereas complex generic injectables markets opportunity in Canada market is valued at USD 1.5-2 billion in the year 2022.

Key growth drivers for the market

Higher Spend of healthcare one of the key driving factor for regulated markets like Europe and Canada

Spend on healthcare in the regulated markets like Europe and Canada is among the highest globally. The share of GDP on total healthcare spend in European countries like Germany and France is one of the highest in the world. As of 2020, Germany spent 12.8% of the GDP on healthcare expenditure while France spent 12.2% of the GDP on the healthcare expenditure while Canada spends approximately 12.9% of the GDP on the healthcare. The well-developed pharmaceutical market in Europe and Canada is one of the major driving factor for the growth of pharmaceutical sector in these markets which are characterized by well-established healthcare infrastructure, high level of healthcare awareness and well established regulatory framework.

Development of generics market one of the key growth driver for the Europe and Canada market

The European generic drugs market (primarily Germany, the UK, France, Italy and Spain) is the second-largest regulated market for generic drugs. Healthcare expenditure, as a percentage of GDP, in Germany and France, respectively, is among the top ten globally. Increasing penetration of generic drugs will continue to drive volume growth in the Europe and Canada pharmaceutical market. Further, lower generic penetration in nations such as Belgium (16.6%), the UK (28.0%), France (19.5%) and Germany (23.0%) indicates tremendous untapped potential for growth of generics. Thus, while the pro-generic stance of governments in Europe will boost demand for generic drugs in the European pharmaceutical market. Factors such as increased healthcare costs and government measures to promote generic medicines in the developed market is expected to provide faster growth in these

segments in the Europe and Canada market. Also regulatory environment may help for higher number of generic prescriptions which in turn help generic segment as no additional marketing effort is required.

Speeding up of Biosimilars approval to give boost to the biologics and biosimilar market

The regulated markets have been more cautious in allowing biosimilars, primarily due to quality concerns. Therefore, Indian players have largely concentrated on the semi-regulated markets for biosimilars launches. However, the demand and the margins enjoyed in the semi-regulated markets are substantially lower.

However, the regulated markets have now shown increased interest in promoting biosimilars in order to cut high healthcare expenditures. The first biosimilar (in regulated markets) was launched in Europe in 2007 and, till 2012, only a total of 21 biosimilars were launched. However, post 2012, over 40 biosimilars have been launched in various markets, thereby providing an opportunity to global generic players. The global generic players have successfully launched biosimilars in the market.

Therefore, the European market provides a good opportunity for players due to relatively faster regulatory approvals. The high healthcare expenditure in the European market will further encourage the government's push for biosimilars.

Key recent trends in the market

Pricing regulation in the European market

There have been stricter pricing regulations in the recent years in the well-developed European markets. Even the United Kingdom (UK) and Germany, which traditionally had less stringent pricing mechanisms, introduced regulations to control the government's healthcare expenditure. Although austerity measures adopted in Europe will continue to drive demand for generic drugs, though pricing realizations may not be as favorable as in the past.

The lucrative generic drugs opportunity in the regulated markets in Europe, had attracted players from various countries. Over the last few years, many pharmaceutical companies mostly small and mid-sized players have set up operations in the regulated markets to capitalize on the generic drugs opportunity. Intensifying competition have resulted in a sharp erosion in the price of generic drugs, especially in the case of large molecules and blockbuster drugs.

There has been a price erosion in the European markets owing to players entering in to generics. However complex and specialty molecules have proved to be immune to the pricing pressure in some of the regulated markets. Player with differentiated offerings in such markets are expected to perform better than their peers. Players with differentiated product portfolio including complex and specialty molecules are better placed than the others.

Increasing healthcare cost drives preference for generic drugs in regulated markets like Europe

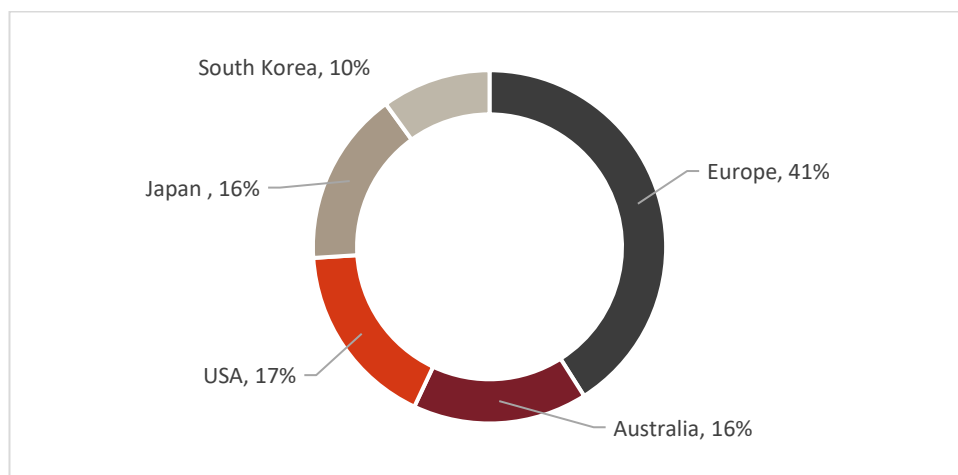
Developed economies spend a major portion of their gross domestic product (GDP) on healthcare. Going forward, demand for pharma products in developed markets like Europe is expected to be driven by factors such as an ageing population and growing incidences of chronic diseases. As per CRISIL, austerity measures adopted in Europe will continue to drive demand for generic drugs, though pricing realizations may not be as favorable as in the past.

Rising uptake of biosimilars

The European market has been at the forefront of approving biosimilars at a quick pace, thereby reducing healthcare costs for the consumer as well as the government. The first biosimilar was launched in the European market in 2007, as compared with 2015 in the US market. About 40 biosimilar drugs have been launched in the European market, including launches by Indian players - Intas Pharmaceuticals, Jata Pharma (USV's German subsidiary) and Biocon

The global generic competitors of Indian players have successfully launched biosimilars in the market. Therefore, the European market provides a good opportunity for Indian players due to relatively faster regulatory approvals. Biocon, in association with its commercialisation partner Mylan, received approval from the EMA for their co-developed biosimilars insulin glargine and pegfilgrastim in March and November 2018, respectively. Mylan and Biocon also received approval for their adalimumab biosimilar in Europe in September 2018. This product was introduced through Mylan's in-licensing arrangement with Fujifilm Kyowa Kirin Biologics. Over 70 biosimilars have been approved so far by the EMA. The high healthcare expenditure in the European market will further encourage the government's push for biosimilars.

Biosimilars approvals in regulated markets as of 2021



Source: EMA, USFDA, PDMA, CRISIL MI&A Research

Key players in Europe and Canada market

Company Name	Key product areas	Total revenue 2020 USD million	Total Revenue 2021 USD million	Total Revenue 2022 USD million	Revenue growth 2020-2022 CAGR
Generic players					
Teva Pharmaceuticals	Generic medicines, Biopharmaceuticals, API	16,659	15,878	14,925	-5.35%
Accord healthcare Ltd	Generic medicines	253	359	283	5.73%
Alkaloid AD Skopje	Generic and OTC pharmaceutical products	232	254	262	6.29%
Cipla	Generic medicines and OTC consumer products	2,466	2,643	2,939	9.17%
Dr. Reddy's	Generic medicines and API	2,560	2,631	2,937	7.12%
Branded/Innovator players					
Roche	Innovative medicines, Biopharmaceuticals	64,273	72,027	69,511	4.00%
GSK	Speciality medicines, Generic medicines, Vaccines	43,707	46,958	36,268	-8.91%
Sanofi	Vaccines, Consumer healthcare products	41,099	44,710	45,268	4.95%
Astrazenca	Biopharmaceuticals, Vaccines	26,617	37,417	44,351	29.08%
Bayer	Biopharmaceuticals, Consumer health	47,210	52,193	53,419	6.37%

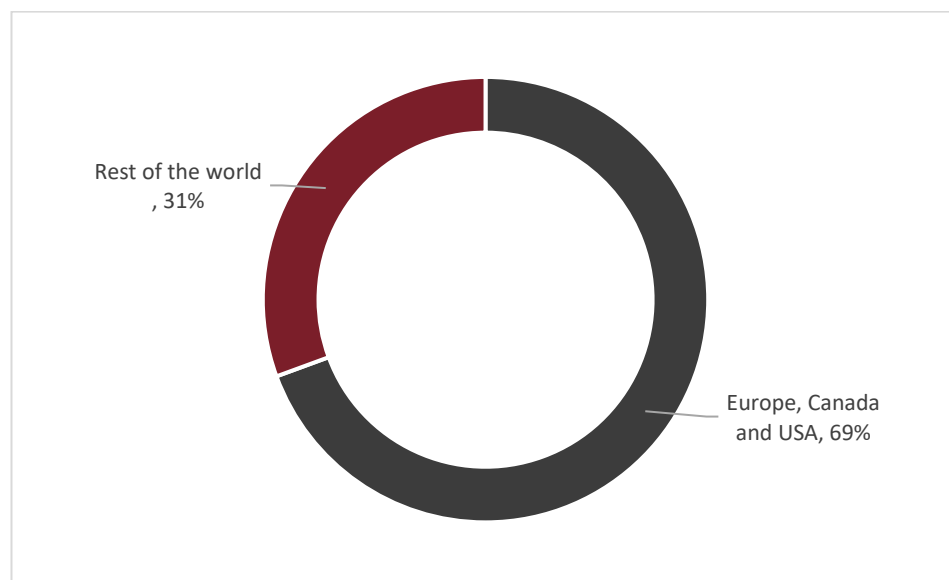
Note: The list above is an indicative list not an exhaustive list

Source: Company Annual reports, CRISIL MI&A Research

Rest of the World Market

For analysis of the rest of the world market CRISIL research has considered the pharmaceutical market which is global pharmaceutical market excluding Europe, Canada and USA. By this definition Rest of the world market consist of some of the key markets like Japan and emerging markets like Brazil, Mexico and China. The growth in this market is majorly driven by emerging markets mentioned above.

Segmentation of Global pharmaceutical market (2022)



Source: CRISIL MI&A Research

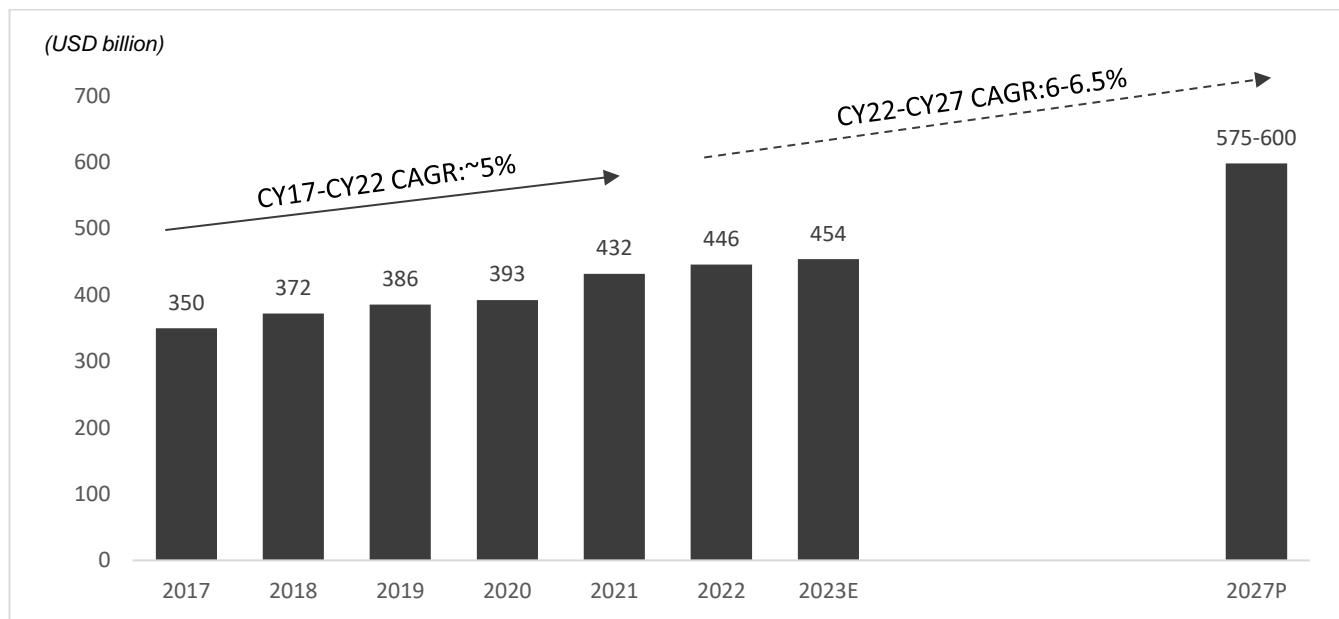
Review and Outlook on market size

Rest of the world market to grow at steady ~6.5% from 2022 to 2027

The rest of the world market which is global pharmaceutical market excluding Europe, Canada and USA has registered steady growth from the year 2017-2022 growing at ~5% CAGR in the same period. The growth is expected to continue in these markets which consists of fast growing emerging markets. The rest of the world market is expected to grow at ~6-6.5% CAGR from period 2022 to 2027 reaching ~USD 575-600 billion by the year 2027. Emerging countries like Brazil, Mexico, and India are at the forefront of this robust growth, fuelled by higher out-of-pocket expenditure, favourable demographic trends and a growing and increasingly prosperous middle class.

Review and outlook on rest of the world market

Consulting



Note: 1) Rest of the world market: Global pharmaceutical market excluding Europe, Canada and USA

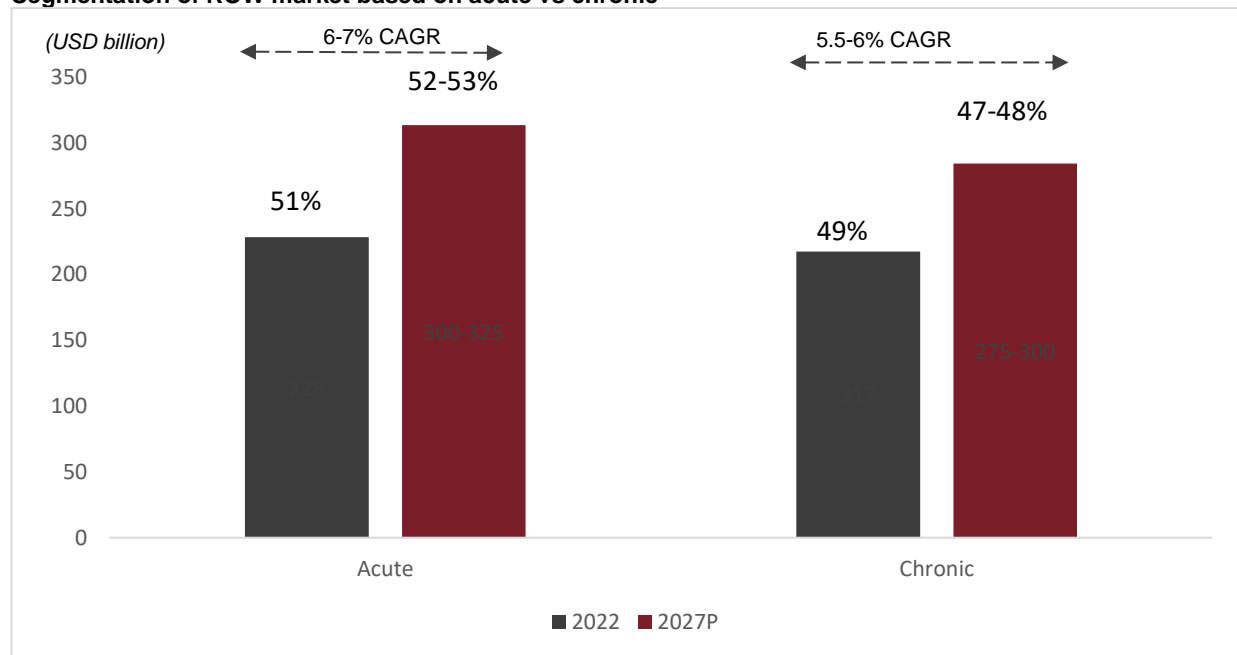
E-Estimated, P- Projected

Source: CRISIL MI&A Research

In emerging countries, dramatic increases in healthcare access is the largest driver of changes in the use of medicines historically. Pharmaceutical growth in the emerging countries will be led by China, which is expected to accelerate, driven by greater uptake and use of new original medicines.

While looking at the therapy areas, acute segment has been the dominant segment in the rest of the world market. Although share of chronic therapy segment is rising steadily on account of rise in prevalence of chronic diseases. In acute segment mainly rising prevalence of the infectious diseases is one of the key drivers of the growth for the segment. As of year 2022, acute segment was valued at USD 228 billion and is expected to reach around USD 300-325 billion by the year 2027. The acute segment is expected to grow at ~6-7% in the period 2022-2027. In case of chronic segment, as of year 2022 chronic segment was valued at USD 217 billion and is expected to reach around USD 275-300 billion by the year 2027. The chronic segment is expected to grow at ~5.5-6% in the period 2022-2027.

Segmentation of ROW market based on acute vs chronic



Note: P: Projected, Figure at the top Indicates percentage share of therapy class in total market

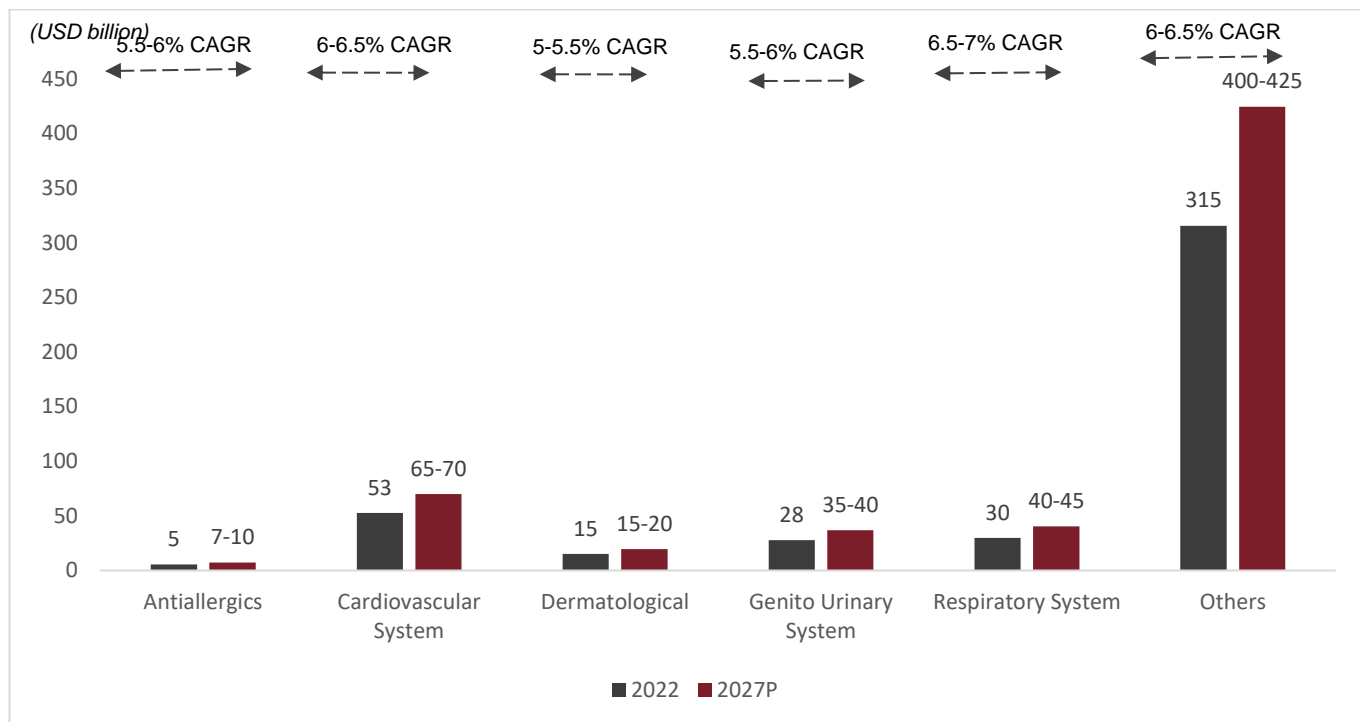
Source: CRISIL MI&A Research

Cardiovascular and Respiratory are the highest growing therapies in ROW market

Cardiovascular and respiratory therapy areas are two of the largest and highest growing therapy areas in the ROW market. Growing incidence of cardiovascular diseases in the ROW market are one of the key reasons for growth of these therapy areas in the ROW market. As per World Health Organization cardiovascular diseases (CVDs) are the leading cause of death globally. An estimated 20.5 million people died from CVDs in 2021 with four in five CVD deaths occurring in low- and middle-income countries. Cardiovascular therapy area was valued at USD ~53 billion as of year 2022 in the rest of the world market and is expected to grow at ~6-6.5% CAGR from 2022 to 2027 to reach USD ~65-70 billion by the year 2027.

The increasing contribution of respiratory diseases like asthma, chronic obstructive pulmonary disease (COPD), allergic rhinitis, sleep apnea, and tuberculosis to the overall disease burden across the globe has led to an increase in the demand for respiratory therapy area in this particular market. Respiratory therapy area was valued at USD ~30 billion as of year 2022 in the rest of the world market and is expected to grow at ~6.5-7% CAGR from 2022 to 2027 to reach USD ~40-45 billion by the year 2027. Apart from these two therapies Dermatological, anti-allergic and genitourinary therapy areas are some of the key therapies in the rest of the world market.

Segmentation of ROW market based key therapies



Note: P: Projected, others include oncology, Pain and analgesic, Neutraceuticals etc.

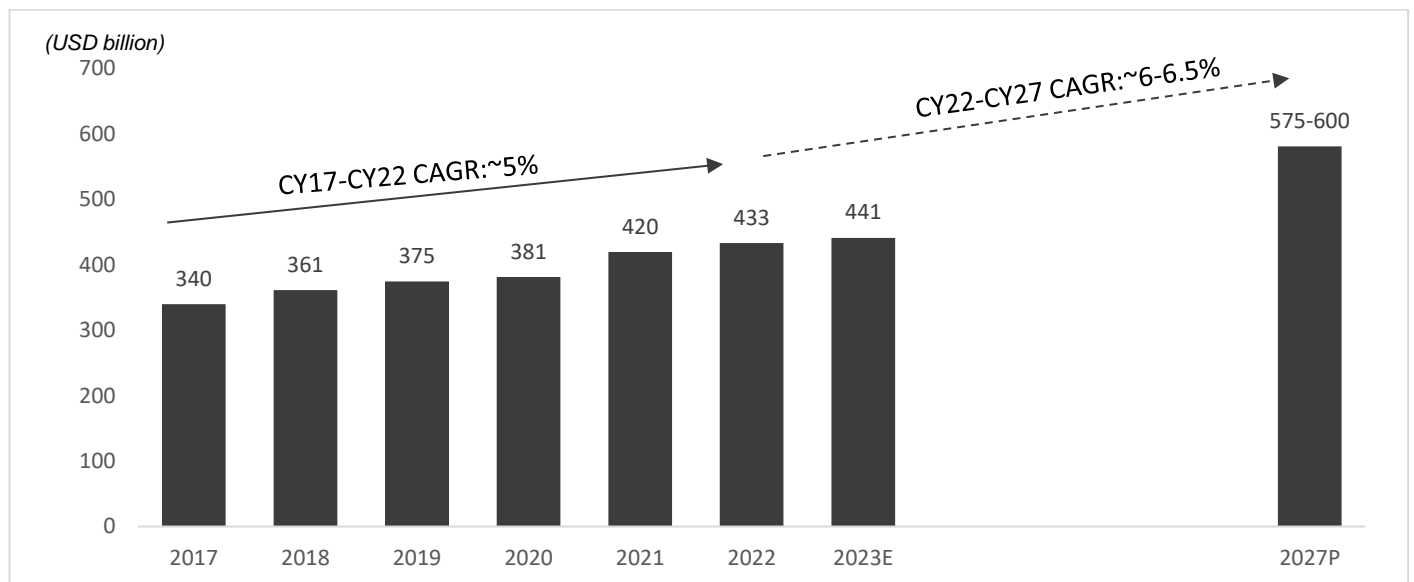
Source: CRISIL MI&A Research

Non-ARV Segment- rest of the world market

Review and outlook on market size

Non-ARV segment in the rest of the world market has shown similar growth to the ARV segment in the rest of the world market. The major therapies in the non-ARV market are the cardiovascular and oncology therapies which have seen substantial growth in the recent years in the overall pharmaceutical markets mainly because of rising prevalence of chronic diseases. Rest of the world market which consist of several emerging countries like China, Brazil, Mexico has seen rise in pharmaceutical spending on account of increased disposable income as well as rising awareness about healthcare.

Non-ARV segment: Rest of the world market



Note: E- Estimated, P- Projected

Source: CRISIL MI&A Research

Non-ARV market in the rest of the world market has grown at healthy pace from 2017-2022 growing at ~5% CAGR. In the year 2022 Non-ARV market was valued at USD 433 billion. This segment is expected to grow at ~6-6.5% CAGR from 2022 to 2027. By the year 2027, Non-ARV segment in rest of the world market is expected to reach USD 575-600 billion.

As the world's population reaches closer to 8 billion, per capita usage of medicine per person per day is also estimated to have increased following similar trend. Much of the increased usage is driven by emerging pharmaceutical markets like China, India, Brazil and Indonesia where substantial increases have been made in average medicine volume usage. India's level of medicine usage is a reflection of both a very basic healthcare infrastructure and the ease of access for medicines where even the most complex medicines can be readily available. The gap in average medicine usage between developed markets and emerging markets is closing, owing to reasons like increased per capita income and improvement in healthcare infrastructure. The use of medicines requires healthcare infrastructure to diagnose diseases and administer drugs appropriately, as well as the financial wherewithal to pay for them. While costs are often substantially lower for medicines in emerging markets, so is the ability to pay. The rise of government safety nets and private insurance is one key factor that will increase volume usage across emerging markets. The extent and pace of investments, both public and private, will be a key determinant of continued increases in usage.

Key players in Non-ARV segment

Sr.No.	Company Name	Key brand Name	Total revenue 2020 (USD million)	Total revenue 2021 (USD million)	Total revenue 2022 (USD million)
1	Amgen Inc.	Enbrel	25,424	25,979	26,323
		Prolia			
		Neulasta			
		Otezla			
2	Eli Lilly And Company	Trulicity	24,540	28,318	28,541
		Humalog			
		Alimta			
		Taltz			
3	Pfizer Inc.	Braftovi	41,651	81,288	100,330
		Sulperazon			
		Infelctra			
4	AbbVie Inc.	Humira7	45,804	56,197	58,054
		Skyrizi			
5	Roche	Tecentriq	64,273	72,027	69,511
		Hemlibra			
		Ocrevus			

Note: The list above is an indicative list not an exhaustive list

Source: Company Annual reports, CRISIL MI&A Research

Overview of Revenue earned by key Indian players in RoW market

Rest of the world market definitions for Indian players operating in international markets defer from company to company and each company has a different definition of the rest of the world market. Following are the revenue earned by some to the key Indian pharmaceutical companies from rest of the world market with definition of rest of the world market for each of the company.

Name of the company	Rest of the world market definition	FY22 Revenue share of RoW market	FY23 Revenue share of RoW market
Sun pharmaceutical industries Ltd.	Western Europe, Canada, Japan, Australia and New Zealand and Other markets	14%	14%

Cipla Ltd.	Geographical regions except India United States of America South Africa Rest of the world	22%	20%
Alkem Laboratories Limited	Except United States and India	7%	8%
Dr. Reddy's Laboratories Limited	Russia, other CIS countries, Romania and Rest of the World markets.	25%	21%
Aurobindo pharma Ltd	Except India, USA and Europe	10%	15%

Note: The list above is an indicative list not an exhaustive list

Source: Company Annual reports, CRISIL MI&A Research

Growth drivers for in rest of the world market

Rising Awareness of the healthcare along with rise in income one of the key growth driver for the market

As the awareness for better healthcare have increased in the developing and emerging countries, per capita usage of medicine per person per day is also estimated to have increased following similar trend. Much of the increased usage is driven by emerging pharmaceutical markets like China, India, Brazil and Indonesia where substantial increases have been made in average medicine volume usage. India's level of medicine usage is a reflection of both a very basic healthcare infrastructure and the ease of access for medicines where even the most complex medicines can be readily available. The gap in average medicine usage between developed markets and emerging markets is closing, owing to reasons like increased per capita income and improvement in healthcare infrastructure. The use of medicines requires both the healthcare infrastructure to diagnose diseases and administer drugs appropriately, as well as the financial wherewithal to pay for them. While costs are often substantially lower for medicines in emerging markets, so is the ability to pay. The rise of government safety nets and private insurance is one key factor that will increase volume usage across emerging markets. The extent and pace of investments, both public and private, will be a key determinant of continued increases in usage.

Development of generics market driving the pharmaceutical markets in RoW market

Emerging markets in rest of the world are characterised by lower penetration of healthcare facilities, high population growth rates, a wide base of patients with acute and chronic diseases, and low penetration of generics. In terms of medicine consumption, these markets are mainly driven by low-cost generics. Region-wise, markets in Africa and Asia will remain key drivers. The African market is expected to continue to dominate because of players establishing footprint in drug therapies such as anti-virals and anti-malarial.

The demand for the treatment of chronic diseases will boost generics off-take due to limited budgets and high out-of-pocket expenditure in the semi-regulated markets. Also, governments in various countries are looking to strengthen their regulations to allow import of generic drugs in order to reduce their healthcare expenditure.

Recent trends in rest of the world market

Preference for indigenous products

In the emerging and developing countries local manufacturing of the pharmaceutical products is one of the key factors impacting the access of healthcare to mass population. Indigenous manufacturing can provide affordable pharmaceutical products to people in need. As these countries are characterized by high degree of infectious diseases as well as burden of chronic illnesses, making medicines easily available and affordable is key success factors for these countries healthcare systems. As manufacturing of products indigenously will help reduced costs significantly as compared to importing them from the developed pharmaceutical market. However manufacturing pharmaceutical products indigenously will only be effective if it is made available at lower costs than the imported medicines from the developed market. Also the products manufactured indigenously should have some degree of differentiation as imported pharmaceutical products may come at comparable prices. So investment in the local manufacturing is subject to differentiated product portfolio of the manufacturers as well as the cost proposition.

Vertically integrated player with differentiated portfolio can have advantage in developing and emerging markets

The costs associated with the manufacturing pharmaceutical products need to be monitored in order to make indigenous products successful in local markets. Raw materials which is Active pharmaceutical Ingredients (APIs) or bulk drugs are one of the major cost component in the pharmaceutical drugs manufacturing. If a developing country with manufacturing facilities mainly use bulk active ingredients sourced from developed or other countries at high costs, such manufacture may have no impact on patient access to needed medicines. Player with vertical integration may benefit in such environment as they have required raw materials available internally for manufacturing finished dosage forms. Vertically integrated players may also benefit from supply chain simplicity and is better placed for supply chain management. Also the players with differentiated portfolio may gain advantage as the ability to provide differentiated portfolio with in-house sourcing of raw materials will a key proposition in these developing and emerging markets.

ARV drug market

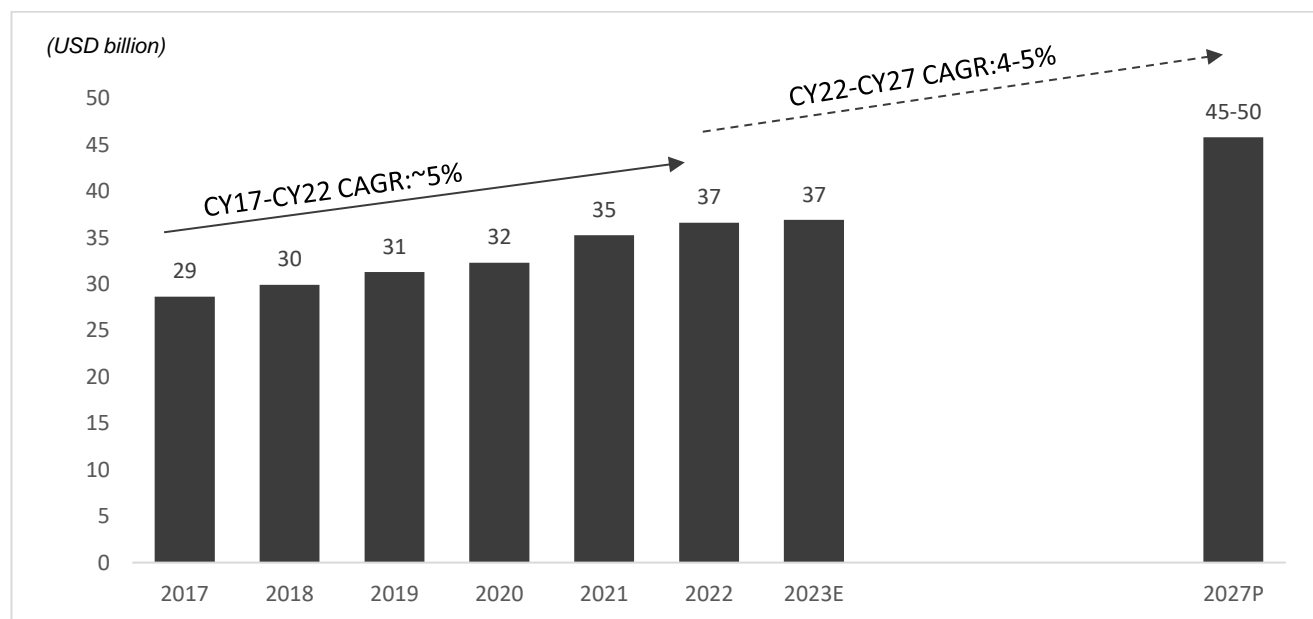
Review and Outlook on market size

Anti-retroviral drugs which are drugs used to treat HIV-infection. These medicines are also called as antiretroviral therapy (ART). HIV is treated with antiretroviral medicines, which work by stopping the virus replicating in the body. This allows the immune system to repair itself and prevent further damage. A combination of HIV drugs is used because HIV can quickly adapt and become resistant. Some HIV treatments have been combined into a single pill, known as a fixed dose combination, although these medicines often cost more to prescribe.

ARV(Anti-retroviral) drugs segment to grow at steady 4-5% CAGR

The global ARV drugs market has seen stable growth from year 2017 to 2022 and is expected to grow from USD 37 billion in the year 2022 to USD 45-50 billion in the year 2027 registering growth of 4-5% CAGR. As of 2022, global ARV drugs market is approximately ~3% of the global pharmaceutical market. Research on developing treatment regimens with improved efficacy and less severe side effects with the aim to decrease viral load, decrease transmission rates and increase accessibility worldwide will support the growth in the ARV segment across the globe. Also improvement in access to ARV medicines in the developing countries is expected to provide growth momentum for the ARV drugs market.

Global ARV market



Note: E-Estimated, P- Projected

Source: Pharma Company reports, CRISIL MI&A Research

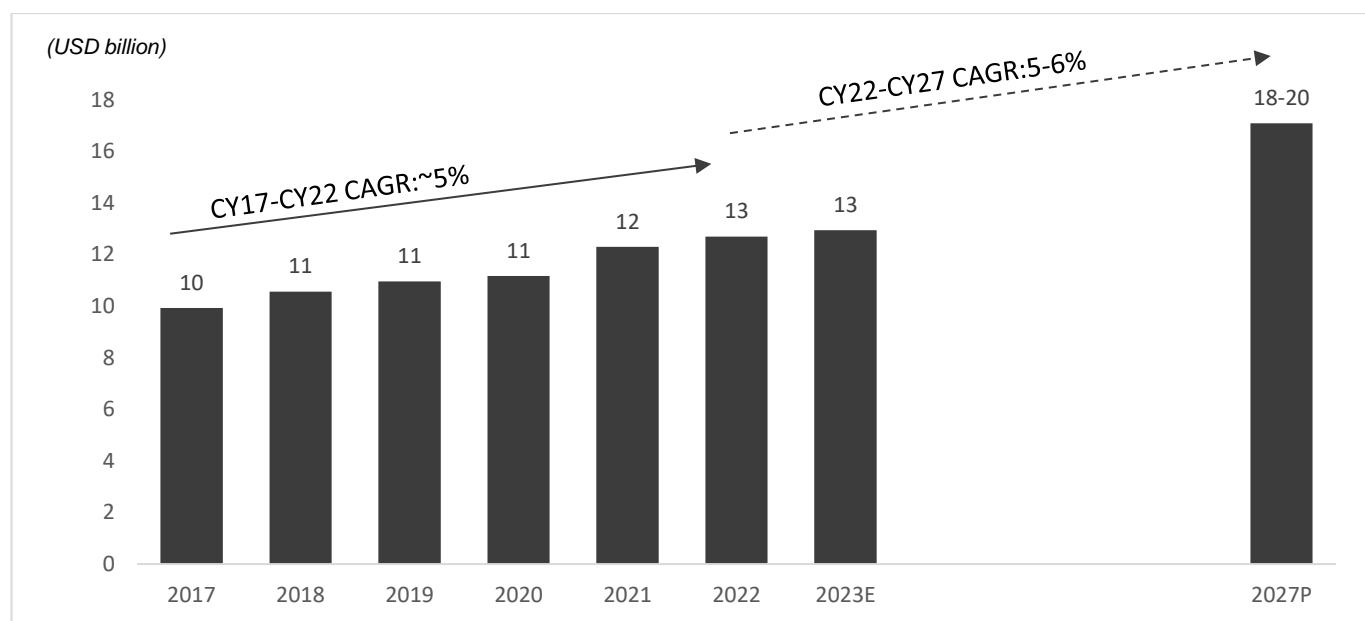
ARV Segment- rest of the world market

Review and outlook on market size

The ARV market which is medicines used to treat HIV infection has grown slightly faster than the Non-ARV segment in the rest of the world market mainly due to high prevalence of infection in the African region which is one of the key market in the rest of the world market.

ARV market in the rest of the world market has grown at healthy pace from 2017-2022 growing at ~5% CAGR. In the year 2022 ARV market in rest of the world was valued at USD 13 billion. This segment is expected to grow at ~5-6% CAGR from 2022 to 2027 growing slightly higher than overall ARV market. By the year 2027, ARV segment in rest of the world market is expected to reach USD 18-20 billion.

ARV segment- rest of the world market



Note: 1) Rest of the world market: Global pharmaceutical market excluding Europe, Canada and USA

Note: E- Estimated, P- Projected

Source: CRISIL MI&A Research

Majority of the ARV drugs sales are governed by government policy and type of therapy regime used

ARV market is characterized by procurement of ART drugs by the government as well as global agencies such as WHO and UNICEF. These procurement process are done on the tender bases system where in national government invites tender from the ARV drug manufacturers. The sales in this kind of system depends upon the type of therapy regime adopted by that country in the first line as well as second line of treatment. ARV drug manufacturers often position their offerings in line with the therapy regime adopted by these countries and might enjoy the advantage of being the first mover in that particular country. Having a competitive and first on the market portfolio in these markets may benefit ARV drug players.

USFDA Approved HIV drugs

Drug Class	Molecule Name/Generic Name	Brand Name	Company Name
Nucleoside Reverse Transcriptase Inhibitors	Abacavir	Ziagen	Viiv Healthcare
	Emtricitabine	Emtriva	Gilead Sciences, Inc.
	Lamivudine	Epivir	Viiv Healthcare
	Tenofovir Disoproxil Fumarate	Viread	Gilead Sciences, Inc.
	Zidovudine	Retrovir	Viiv Healthcare
Non-Nucleoside Reverse Transcriptase Inhibitors	Doravirine	Pifeltro	Merck & Co., Inc.
	Efavirenz	Sustiva	Bristol-Myers Squibb
	Etravirine	Intelence	Janssen
	Nevirapine	Viramune	Boehringer Ingelheim
	Rilpivirine	Edurant	Janssen
Protease Inhibitors	Atazanavir	Reyataz	Bristol-Myers Squibb
	Darunavir	Prezista	Janssen
	Fosamprenavir	Lexiva	Viiv Healthcare
	Ritonavir	Norvir	Abbvie Inc.
	Saquinavir	Invirase	Hoffman-La Roche; Genentech
	Tipranavir	Aptivus	Boehringer Ingelheim
Fusion Inhibitors	Enfuvirtide	Fuzeon	Hoffman-La Roche; Genentech
Ccr5 Antagonists	Maraviroc	Selzentry	Viiv Healthcare
Integrase Strand Transfer Inhibitor	Cabotegravir	Vocabria	Viiv Healthcare
	Dolutegravir	Tivicay	Viiv Healthcare
	Raltegravir	Isentress	Merck & Co., Inc.
Attachment Inhibitors	Fostemsavir	Rukobia	Viiv Healthcare
Post-Attachment Inhibitors	Ibalizumab-Uiyk	Trogarzo	Theratechnologies Inc.
Pharmacokinetic Enhancers	Cobicistat	Tyboost	Gilead Sciences, Inc.

Drug Class	Molecule Name/Generic Name	Brand Name	Company Name
Combination HIV Medicines	Abacavir And Lamivudine	Epzicom	Viiv Healthcare
	Abacavir, Dolutegravir, And Lamivudine	Triumeq	Viiv Healthcare
	Abacavir, Lamivudine, And Zidovudine	Trizivir	Viiv Healthcare
	Atazanavir And Cobicistat	Evotaz	Bristol-Myers Squibb
	Bictegravir, Emtricitabine, And Tenofovir Alafenamide	Biktarvy	Gilead Sciences, Inc.
	Cabotegravir And Rilpivirine	Cabenuva	Viiv Healthcare
	Darunavir And Cobicistat	Prezcobix	Janssen
	Darunavir, Cobicistat, Emtricitabine, And Tenofovir Alafenamide	Symtuza	Janssen
	Dolutegravir And Lamivudine	Dovato	Viiv Healthcare
	Dolutegravir And Rilpivirine	Juluca	Viiv Healthcare
	Doravirine, Lamivudine, And Tenofovir Disoproxil Fumarate	Delstrigo	Merck & Co., Inc.
	Efavirenz, Emtricitabine, And Tenofovir Disoproxil Fumarate	Atripla	Gilead Sciences, Inc.
	Efavirenz, Lamivudine, And Tenofovir Disoproxil Fumarate	Symfi	Mylan
	Efavirenz, Lamivudine, And Tenofovir Disoproxil Fumarate	Symfi Lo	Mylan
	Elvitegravir, Cobicistat, Emtricitabine, And Tenofovir Alafenamide	Genvoya	Gilead Sciences, Inc.
	Elvitegravir, Cobicistat, Emtricitabine, And Tenofovir Disoproxil Fumarate	Stribild	Gilead Sciences, Inc.
	Emtricitabine, Rilpivirine, And Tenofovir Alafenamide	Odefsey	Gilead Sciences, Inc.
	Emtricitabine, Rilpivirine, And Tenofovir Disoproxil Fumarate	Complera	Gilead Sciences, Inc.
	Emtricitabine And Tenofovir Alafenamide	Descovy	Gilead Sciences, Inc.
	Emtricitabine And Tenofovir Disoproxil Fumarate	Truvada	Gilead Sciences, Inc.
Lamivudine And Tenofovir Disoproxil Fumarate	Cimduo	Mylan	
Lamivudine And Zidovudine	Combivir	Viiv Healthcare	
Lopinavir And Ritonavir	Kaletra	Abbvie Inc.	

Source: National Institute of health (US government), CRISIL MI&A Research

Companies in ARV segment are focused on research and development to build competitive product portfolio

Anti-retroviral (ARVs) are the foundation of HIV/AIDS management, as currently there is no cure or vaccine available for HIV. In individuals with a non-resistant strain of HIV, the antiretroviral treatment can suppress the replication of HIV in majority of the cases. This huge patient pool shows that the market for anti-retroviral drugs is expected to grow in the coming future.

Based on drug class, ARV drugs are majorly classified into Integrase Inhibitors, Protease Inhibitors, Multi-class Combination Products, Nucleoside Reverse Transcriptase Inhibitors (NRTIs), Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs) and others. According to WHO, around 6300,000 people died from HIV in 2022. Many companies are focusing on developing breakthrough products for the treatment of antiretroviral drugs in order to maintain their competitive advantage and penetrate new regional markets. Additionally, the increase in funding for companies involved in the research related to anti-retroviral drugs is expected to boost ARV market.

Importance of vertical integration and key success factors in ARV segment

Vertical integration has been one of the key characteristics of pharmaceutical industry specially the generics pharmaceutical industry. Reason for vertical integration can be the better control over supply chain and drug development process especially for development of generics drugs. Early development and procurement of APIs has become more important to the profitability of downstream manufacturers in recent years. Having vertically integrated business model can help in better control over manufacturing and development of drugs and avoid sourcing complexities for APIs.

In ARV segment especially the supply of ARV drugs is done through global tenders issued by global agencies like Global Fund, US President's Emergency Plan for AIDS Relief (PEPFAR) and governments of respective countries. In key markets like USA and Africa to compete in these tenders manufacturers need to be very price competitive as well as should have reliable sourcing channels and manufacturing expertise.

Being vertically intergraded for ARV players can provide significant cost advantage especially in the ARV drug segment. ARV manufactures can move both downstream into formulations to improve margins, and upstream into intermediates to cut dependence on single source API providers like China, and ensure reliability of supplies.

Also one of the key success factors for the ARV segment is the early mover advantage. ARV drugs are usually administered through combination of multiple single dose drugs due to mutation occurring in the virus. Once a particular combination is approved for the treatment of HIV, companies usually try to take that product to the market as early as possible with required regulatory approvals. These multiple drug combinations are converted in to single pill product which is also known as single pill therapy regimen. If the company already has sourcing supply chains for manufacturing of those drug products it can take early movers advantage and can reap benefits by reducing time to market.

Growing shift towards Dolutegravir

For treatment of HIV, Antiretroviral therapy involves taking a combination of drugs each day. The major categories of antiretroviral drugs are Nucleoside reverse transcriptase inhibitors (NRTIs), Non-nucleoside reverse transcriptase inhibitors (NNRTIs), Protease inhibitors (PIs), Entry inhibitors and Integrase inhibitors.

Identification of novel drug targets has played a key role in discovery and development of new antiretroviral drug classes. HIV uses a protein called integrase to send its genetic material into the cells that it targets. Integrase inhibitors block this action. Integrase inhibitors emerged as a major antiretroviral drug class in 2007, with FDA approval of the integrase inhibitor raltegravir. Raltegravir quickly became a valued component for combination antiretroviral therapy, but HIV can follow several pathways to develop resistance to the drug. HIV variants resistant to raltegravir may also be resistant to elvitegravir, another first-generation integrase inhibitor.

Dolutegravir, which received FDA approval in 2013, is a second-generation integrase inhibitor that appears to have a high barrier to the development of HIV drug resistance. In clinical trials, dolutegravir was effective both for people living with HIV who had not previously taken HIV therapy and for people who were treatment-experienced, including those for whom first-generation integrase inhibitors were ineffective. Additional advantages of dolutegravir include convenient once-daily dosing, a good safety profile, and a relatively low production cost. Dolutegravir now is included in two of the first-line regimens that the U.S. Department of Health and Human Services medical practice guidelines recommend for adults with HIV, and it was recently added to World Health Organization guidelines as an alternative first-line agent for adults.

Key players manufacturing Dolutegravir

Sr. No.	Name of the company	Markets Catered	Major therapy areas
1	Aurobindo Pharma Ltd.	USA, Europe, Emerging markets	Anti-retrovirals, cardiovascular and CNS
2	Emcure	Europe, Canada, Emerging markets	Anti-retroviral, Gynaceology, Cardiovascular
3	Laurus Labs*	North America, Europe and emerging markets	Anti-retroviral, Anti-diabetic, Cardiovascular, Oncology
4	Mylan	USA, Europe, Emerging markets	Antibacterials, Antidiabetics, Antiretrovirals, Cardiovascular
5	Shanghai Desano Pharmaceuticals*	Asia, Africa and Latin America	Anti-virals, Anti-malarial
7	ViiV healthcare	Asia, Europe, North America, South America	Anti-retroviral

Note: *- Specialized in Dolutegravir API, Emerging markets majorly includes countries in Asia, the Middle East, South and Central America, Africa, The list above is an indicative list not an exhaustive list

Source: Company annual reports, company websites, CRISIL MI&A Research

Second Line of treatment in ARV segment

In 2016, WHO published the consolidated guidelines on the use of antiretroviral (ARV) drugs for treating and preventing HIV infection and recommended tenofovir disoproxil fumarate (TDF) + lamivudine (3TC) (or emtricitabine, FTC) + efavirenz (EFV) 600 mg as the preferred first-line antiretroviral therapy (ART) regimen for adults and adolescents. In 2019, based on new evidence assessing benefits and risks, the WHO recommends the use of the HIV drug dolutegravir (DTG) as the preferred first-line and second-line treatment for all populations, including pregnant women and those of childbearing potential.

For patients who failed first-line therapy, it may be necessary to transfer to second-line therapy in order to suppress HIV viral loads. The cost of second-line drugs is generally higher than that of first-line drugs and it is expected that the absolute number of patients on second-line antiretroviral therapy will increase over time. As per WHO, Cost of second-line combination treatments with protease inhibitors (PIs) is significantly higher than the average amount of first-line combination generic antiretroviral.

Players operating in second line treatment may be able to achieve higher margins with specialized single pill treatment with research and development in the second line of treatment and making a suitable pricing strategy according to markets they are distributing to, Also the international guidelines on Anti retro viral therapy such as WHO guidelines on first and second line of treatment shapes the demand and uptake in the ARV market. Traditionally newer ARV particularly in the second line of treatment evolve slowly and are less competitive than the first line of treatment.

The pricing in second line of treatment becomes critical component for players to achieve optimum profitability. The cost of second line treatment varies according to the region. The African region and developing nations have lower costs for second line treatment as compared to developed regions. Developing regions have generic versions of medicines while in developed nations the price is function of patents and licenses. Therefore players operating in this segment can achieve good margins with expertise in research and development and optimal pricing strategy.

4 Assessment of Indian pharmaceutical market

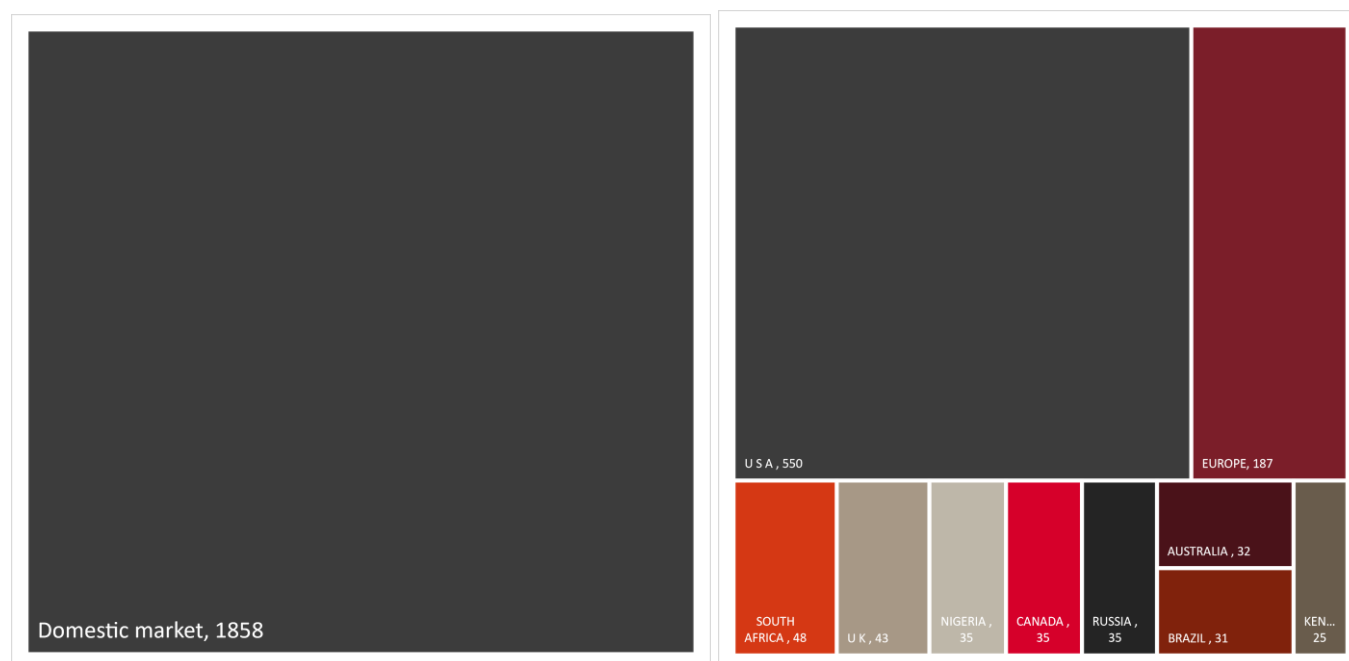
Introduction to India’s pharmaceutical market

The Indian pharmaceutical industry is the world’s third largest by volume and was valued at Rs 3.6-3.8 trillion (including bulk drugs and formulation exports) as of last fiscal. The industry can be broadly classified into formulations and bulk drugs. Formulations can further be divided into domestic formulations and export formulations, both having almost an equal share in the market. At present, low-value generic drugs constitute a large part of Indian exports. India accounts for ~3.5% of total drugs and medicines exported globally, and exports pharmaceuticals to more than 200 countries and territories, including highly regulated markets such as the US, the UK, the European Union and Canada. India has a complete ecosystem for the development and manufacturing of pharmaceuticals, with companies having state-of-the-art facilities and skilled/ technical manpower. Moreover, the country has several renowned pharmaceutical educational and research institutes and a robust ecosystem of allied industries.

Indian pharmaceutical industry (fiscal 2023) (Rs billion)

Domestic (54%)

Export (46%)



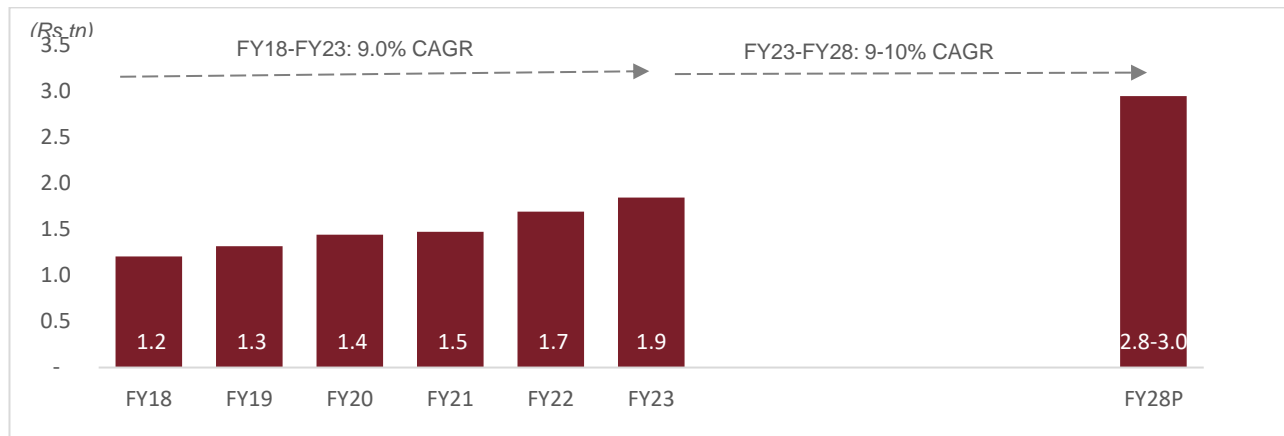
Source: DGFT, CRISIL MI&A Research

Overview and outlook of Indian domestic Formulation market

Domestic formulations market to grow at ~9-10% CAGR over fiscal 2023 to fiscal 2028

The Indian domestic formulation market has seen healthy growth in the recent times. As of fiscal 2023, the Indian domestic formulation market contributed to approximately 2-3% of the total global pharmaceutical market. Indian domestic formulations market (consumption) grew at a healthy rate at a CAGR of 9% CAGR from fiscal 2018 to fiscal 2023. The Indian domestic formulations segment (consumption) is expected to grow at a CAGR of 9-10% CAGR over the next five years from fiscal 2023 to reach ~Rs. 2.8-3.0 trillion in fiscal 2028, aided by strong demand because of rising incidence of chronic diseases, increased awareness and access to quality healthcare.

Review and outlook of Indian domestic formulation market



Notes: P-Projected

Source: AIOCD AWACS, CRISIL MI&A Research

Review of growth in Indian domestic formulation market

Particulars	FY12 (Rs trillion)	FY18 (Rs trillion)	FY23 (Rs trillion)	CAGR (FY18 to FY23)	CAGR (FY12 to FY23)
Indian domestic formulation market	0.6	1.2	1.9	9.0%	10.3%

Source: AIOCD AWACS, CRISIL MI&A Research

One of the key growth drivers for the Indian pharmaceutical industry is the increasing prevalence of non-communicable diseases such as cardiovascular disease, stroke, cancer, diabetes and chronic lung diseases. The chronic segment in general is expected to grow at a CAGR of 10-11% from fiscal 2023 to fiscal 2028. In addition, a growing population and, in turn, growing demand for medicine generally, is expected to fuel the growth of the Indian pharmaceutical industry. India is expected to become one of the leading countries in the world in terms of spending on medicine over the next few years. Along with the abovementioned factors, favourable initiatives and schemes from the Government of India to encourage companies to manufacture ingredients domestically (PLI scheme) will also support the growth of the domestic pharmaceutical industry.

Indian domestic formulation market by key therapies

Chronic segment is dominated by Anti-diabetic & Cardiovascular while anti-infectives & gastro-intestinal are the top therapeutic segments in acute segment

The Indian domestic formulation industry can be categorized into the chronic therapies segment and acute therapies segment. The chronic segment mainly comprises of anti-diabetic, cardiovascular, oncology etc. The acute segment mainly comprises of anti-infectives, gastro-intestinal, pain and analgesics etc.

As of fiscal 2023, chronic therapies and acute therapies constituted 53% and 47% of the total domestic formulation market, respectively. As of fiscal 2023, anti-diabetic and cardiovascular were some of the largest therapeutic segments catered by the Indian formulations industry in chronic therapies segment, together accounting for nearly one-fourth share of the Indian domestic formulation market. As the prevalence of chronic diseases have grown in the

country, chronic diseases such as diabetes and cardiovascular disorders are more prevalent in the Indian population. Anti-diabetic constituted approximately 9.1% of all therapies catered by Indian domestic formulation market. Similarly, cardiovascular constituted to approximately 13% of all therapies catered by Indian domestic formulation market. Sedentary lifestyles along with poor dietary habits have resulted in growing incidence of chronic diseases in Indian population, which is expected to drive the growth of therapies such as anti-diabetic and cardiovascular in the next few years.

In the acute segment, anti-infectives, gastro-intestinal and pain and analgesics are some of largest therapeutic areas catered in the Indian domestic formulation market. The chronic therapies segment in the Indian domestic formulation market is expected to register higher growth at a CAGR of 10-11% from fiscal 2023 to fiscal 2028 than the acute therapies segment which is expected to register a CAGR of 9-10% from fiscal 2023 to fiscal 2028.

Key therapy areas in domestic formulation market

Therapy Name	Share in total market FY18	Share in total market FY23	Share in total market FY28P	CAGR (FY18 to FY23)	CAGR (FY23 to FY28P)
Cardiovascular	12.1%	13.0%	13.9%	10.6%	10-11%
Anti-Infectives	13.1%	12.3%	11.8%	7.6%	8-9%
Gastrointestinal	11.4%	11.7%	12.3%	9.6%	10-11%
Anti-Diabetic	9.2%	9.1%	11.1%	9.0%	13-14%
Vitamins / Minerals / Nutrients	8.7%	8.9%	9.9%	9.5%	12-13%
Respiratory	7.5%	8.3%	9.0%	11.2%	12-13%
Pain / Analgesics	6.9%	7.0%	7.0%	9.5%	9-10%
Derma	7.3%	6.7%	6.1%	7.0%	8-9%
Neuro / CNS	6.1%	6.1%	6.7%	9.0%	11-12%
Gynecological	5.1%	5.1%	5.1%	8.9%	10-11%

Notes: P-Projected

Source: AIOCD AWACS, CRISIL MI&A Research

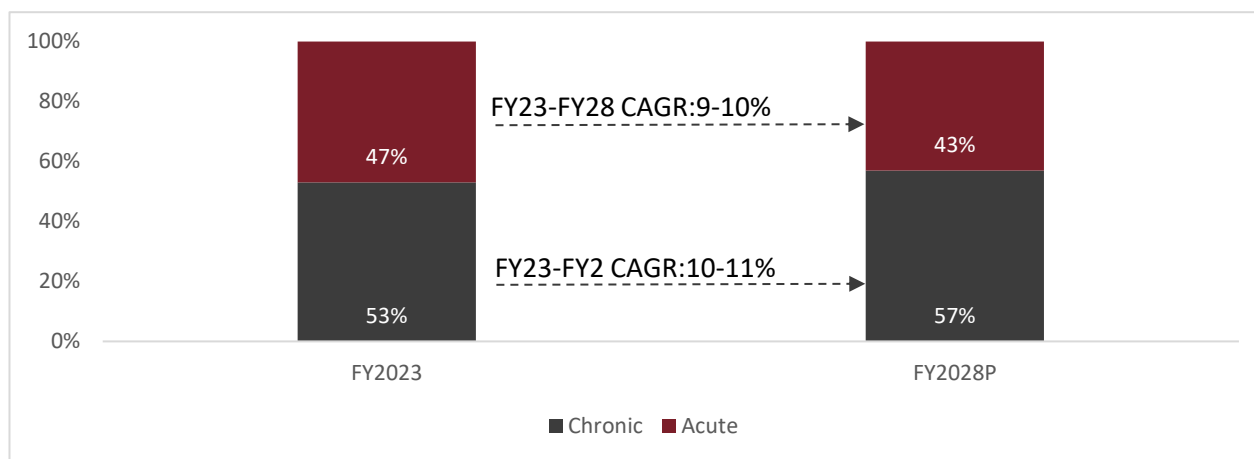
Rising prevalence of chronic diseases is likely to aid growth in the chronic segment in medium to long term. Further, the rise in the anti-diabetic and cardiovascular segments would support growth of the domestic industry.

Chronic portfolios of major companies have seen a significant growth in the past few years, with anti-diabetes being one of the fastest growing segment. Also chronic therapies usually have better margins for players as these it provides them with assured demand for chronic medications which are used for treatment for longer duration of time. Also multi-drug therapy in chronic diseases also helps players have strong demand for these medicines.

As per World Bank data, India's per capita expenditure on health is among the lowest among developing countries, representing significant potential.

The chronic segment is also expected to benefit from factors such as rising incidence of lifestyle-related diseases, and better healthcare, diagnostic and hospital infrastructure, which has helped improve the disease detection rate. In the Acute segment the growth is expected to be lower than the chronic segment, the key therapies such as gastro-intestinal and nutraceuticals are expected to aid the growth in the segment.

Chronic Vs Acute split in Indian domestic formulation market



Source: CRISIL MI&A Research

Key growth drivers for the Indian domestic formulation industry

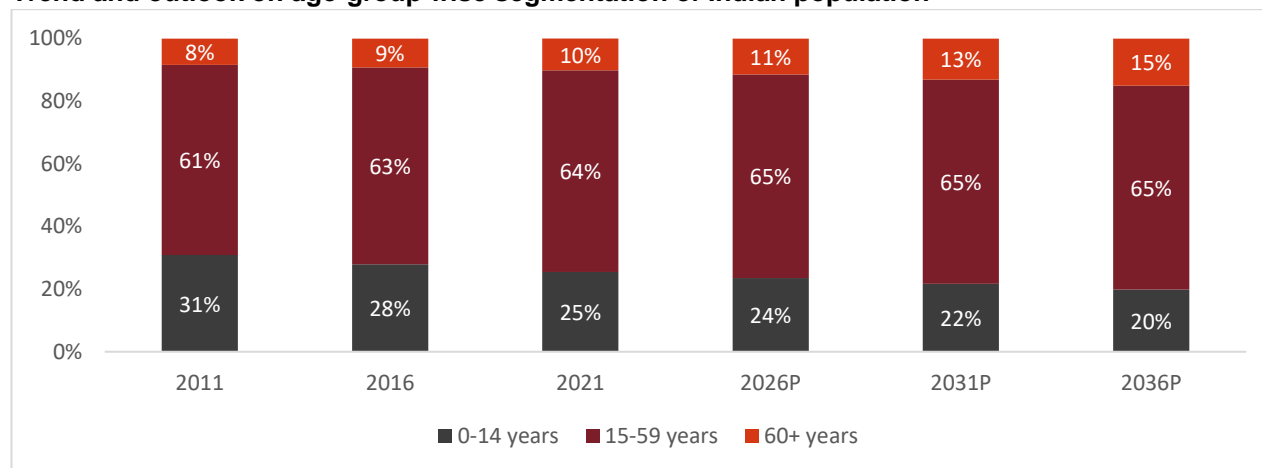
With life expectancy improving and changing demographic profile, healthcare services a must

With improving life expectancy, the demographic of the country is also witnessing a change. As of 2011, nearly 8% of the Indian population was of 60 years or more, and this is expected to surge to 11% by 2026 and 13% by 2031.

According to the Report on Status of Elderly in Select States of India, published by the United Nations Population Fund (UNFPA) in September 2023, chronic ailments such as arthritis, hypertension, diabetes, asthma, and heart diseases were commonplace among the elderly, over 30 percent of the elderly women and 28 percent of the men suffered from one chronic morbid condition and nearly one fourth (across both sexes) suffered from more than two morbid conditions.

With the Indian population expected to grow to approximately 1.4 billion by 2026, it is imperative to ensure availability of healthcare services to this vast populace. This is expected to present substantial growth potential for the Indian domestic formulation industry.

Trend and outlook on age-group wise segmentation of Indian population



Source: Census, CRISIL MI&A Research

Growth in chronic segment to continue to boost growth in medium term with long term treatments and prescriptions

Chronic disease care drugs (meant to treat many non-communicable diseases) are seeing high growth rates. The treatment for chronic diseases requires medium to long term treatment where medical practitioners prescribe chain of prescriptions to treat these diseases. Also, with chronic diseases these prescriptions are used more frequently as pharmacies dispense these medications with network effect across the pharmaceutical supply chain.

The rise in chronic diseases is primarily due to growth in the urban population, better awareness on healthcare, and greater penetration of services. Disability-adjusted life years lost for the Indian population reflect the shift in disease profile. The metric, published by the World Health Organization, is the number of life years lost due to premature mortality plus the number of years lived with disability. The data indicates a rise in the number of life years lost due to non-communicable diseases such as cancer, cardiovascular ailments, diabetes, and mental disorders between 2009 and 2019 in India. Conversely, life years lost due to diarrhoea, tuberculosis, and respiratory infections in India across the same period have dropped. CRISIL expects this shift in the disease profile to continue in the future.

Disability adjusted life years lost in India led by non-communicable diseases

Particulars	Disability adjusted life years (DALYs)	
	2009	2019
Communicable diseases		
Tuberculosis	3.8%	3.4%
Diarrheal diseases	6.7%	4.3%

Respiratory infections	10.2	7.7%
Non-communicable diseases		
Cancer	4.3%	5.8%
Diabetes	1.6%	2.7%
Mental disorders	3.7%	4.7%
Cardiovascular	10.5%	13.9%
Respiratory	4.8%	6.3%
Other non-communicable diseases	20.0%	24.5%
Total non-communicable diseases	44.9%	57.9%

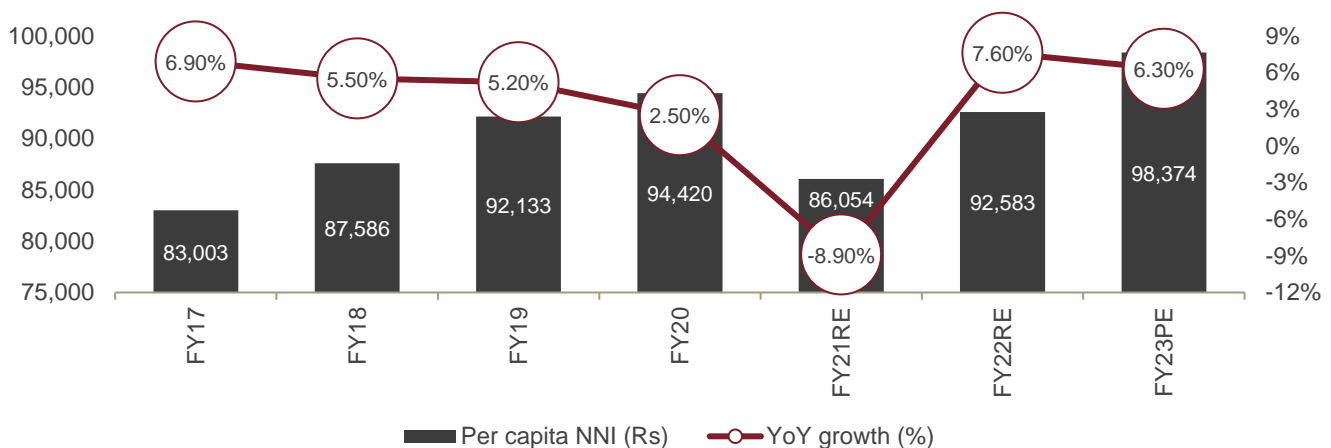
Source: The Institute for Health Metrics and Evaluation (IHME) / Global Burden of Disease Tool, CRISIL MI&A Research

Rising income levels along with strong awareness for health has resulted in people seeking quality healthcare services

The Covid-19 pandemic had caused a temporary setback to the Indian economy in FY21, leading to a decline in NNI per capita. However, the economy rebounded in FY22, with NNI per capita rising 7.6% on-year to Rs 92,583. Furthermore, NNI per capita further increased to Rs 98,374. With rising income levels and health awareness people are seeking better and quality healthcare services. This includes availing of better hospital services, better medicine and pharmacy services.

Per capita NNI

(Rs bn)



RE: Revised estimates, AE: Advance estimates; PE: provisional estimates

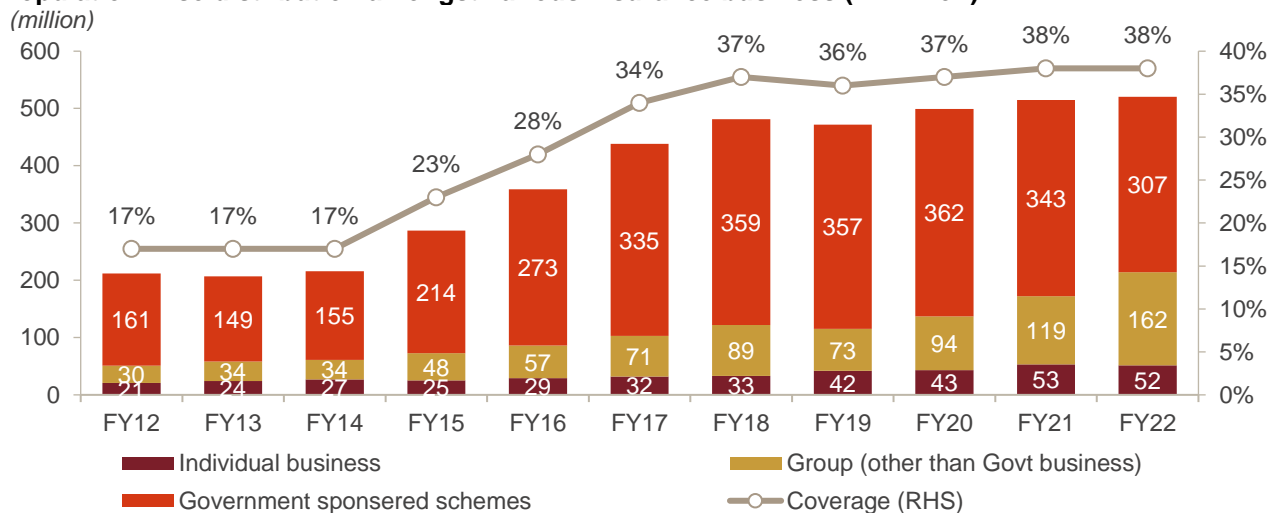
Source: Provisional Estimates of Annual National Income, 2022-23, CSO, MoSPI, CRISIL MI&A Research

Improvement in health insurance penetration in India

The health insurance penetration in India has seen improvement in recent years. As per the Insurance Regulatory and Development Authority (IRDA), nearly 521 million people have health insurance coverage in India (as of fiscal 2022), as compared to 288 million (as of fiscal 2015). Despite this robust growth, health insurance penetration in India stood at only 38% in fiscal 2022. With growing awareness for healthcare and government sponsored schemes

health insurance penetration in India is expected to reach approximately 46% in fiscal 2025. This is expected to aid growth in the overall healthcare industry in India.

Population-wise distribution amongst various insurance business (in million)



Note: Coverage represents insurance penetration levels in India i.e., no. of individuals covered.

Source: IRDA, CRISIL MI&A Research

Government or government-sponsored schemes such as the Central Government Health Scheme (CGHS), Employee State Insurance Scheme (ESIS), Rashtriya Swasthya Bima Yojana (RSBY), Rajiv Arogyasri (Andhra Pradesh government), Kalaingar (Tamil Nadu government), and etc. account for 60% of health insurance coverage provided. The remaining is through commercial insurance providers, both government (Oriental Insurance, New India Assurance, etc.) and private (ICICI Lombard, Bajaj Allianz, etc.).

Key risk factors and challenges for the Indian pharmaceutical industry

Changes in government regulations

Pharmaceutical industry is highly regulated as it deals with health of human life. The pharmaceutical industry entails higher requirement of certification and approvals, such as drug regulatory approvals, product (drug) effectiveness testing, biological and chemistry testing, manufacturing plant certifications, quality standards, entry to market qualification, etc.

The Indian Government has been taking various steps to control the prices of drugs and make it more affordable to consumers. Between fiscal 2014 and fiscal 2015, the industry saw drug prices being regulated for more than 500 medicines under the Drug Price Control Order (DPCO), thereby negatively impacting the industry. Drugs under the National List of Essential Medicines (NLEM) comprised approximately 15-20% of the overall domestic pharmaceutical market.

Fluctuation in foreign exchange rates

The volatility in currency has an impact on formulation exports realisations as well as on import of raw materials. As at fiscal 2023, India's formulation exports constitute approximately 46% of the overall pharmaceuticals industry and approximately 71% of the intermediates are imported from China. Although the large export-based players typically

hedge against currency volatility, smaller players generally do not have any hedging policies. Small players rely solely on natural hedging (assuming increase in cost of material will be equal to increase in realisations and vice versa), which in many cases currency volatility might impact their profitability.

Dependence on China for imports

As of fiscal 2023, India imported approximately 71% of intermediaries required for active pharmaceutical ingredients (API) from China.

Over the past few years, many chemical-based companies in China have shut down due to failure to meet environment norms. Further, Covid-19 led disruptions during February and March 2021 in China further disrupted supplies. Any such further disruptions in the bulk drug industry will adversely impact the Indian API industry and consequently the formulations industry.

Further, the Chinese bulk drug industry receives extensive support from the Chinese government in the form of subsidies. Any change in the relevant policy in China will also lead to pressure on margins for the Indian players.

Domestic formulation industry is highly fragmented; manufacturing bases concentrated in few states

The domestic formulations industry is highly fragmented in terms of both number of manufacturers and products. Over 100,000 drugs across various therapeutic categories are produced annually in India. In terms of number of manufacturers, there are 300-400 organised players and about 15,000 unorganised players in the industry, with organized players dominate the market in term of sales. Traditionally, Indian pharma companies operate largely in a few states, including Maharashtra, Gujarat and Andhra Pradesh. After the imposition of an MRP-based excise duty system in 2015, many players have shifted their manufacturing bases to excise-free zones such as Baddi (Himachal Pradesh), Haridwar (Uttaranchal) and Sikkim.

Pricing pressure in the US market

Wholesale consolidation in the United States pharmaceutical market has led to lower bargaining power for Indian players thereby exerting pricing pressures. Only three players in the United States pharmaceutical market held approximately 90% of the market share in 2022.

Further, faster Abbreviated New Drug Application (ANDA) approvals due to implementation of Generic Drug User Fee Amendments (GDUFA) has led to more players entering the US generic pharmaceutical market, thereby putting pressure on realisations.

Compliance with US FDA regulations

Adherence to good manufacturing practices (cGMP) prescribed by the US FDA and maintenance of data integrity remain key challenges for the Indian players. High number of warning letters were imposed on Indian players by US FDA in 2013 and 2014, resulting in Indian players hiring US-based consultants to advise on compliance with the US FDA regulations. Thereafter, the larger players have already taken substantial steps to implement corrective measures and make their facilities US FDA compliant. US FDA audit will still be challenging for mid and small-sized players, as their adherence to regulations is likely to be lower when compared with large players. On the other front, maintaining data integrity will remain a key concern, as it is a human resource issue and achieving organisational change within a short span of time is likely to be difficult.

Recent trends in Indian pharmaceutical industry

Time to market

The time-to-market of new products is an important source of pharmaceutical player's comparative advantages. Generic pharmaceutical companies in particular tend to improve their market position by being first in the market when a patent on an original product expires. Research and development for the pharmaceutical companies has been the area that takes significant amount of time.

For pharmaceutical companies it is important that they reduce the time between developments of molecule to its commercialization. This essentially means companies are using technologies and resources to reduce the time it takes for a developed molecule to reach the end user.

Agility and Flexibility

Flexibility and agility in business relate with the dimensions of choice and speed at various levels in the conduct of the business. These are required in view of changing business situation, customer needs, market dynamics, and competition. As a result of the Covid-19 pandemic, businesses are required to be more flexible in their processes especially in areas such as supply chain. This is particularly the case for pharmaceutical industry since the value chain from research and development to final product is long. Indian Pharmaceutical industry is heavily dependent on imports for the raw material required in the manufacturing process. Due to the Covid-19 pandemic, many players in the industry are diversifying their sources in order to bring more flexibility to their supply chains and the other business processes.

With evolving business scenario in Indian pharmaceutical industry, companies have to bring in the new technologies and processes in order to stay relevant in the industry. In addition, pharmaceutical companies in India are subjected to various regulatory norms from countries including the United States, the United Kingdom and PIC (Pharmaceutical Inspection Convention). With ever changing regulatory environment pharmaceutical companies must be agile enough to respond and comply with these changes.

Vertical Integration among pharma players

Vertical integration has been one of the key characteristics of pharmaceutical industry specially the generics pharmaceutical industry. Reason for vertical integration can be the better control over supply chain and drug development process especially for development of generics drugs. Early development and procurement of APIs has become more important to the profitability of downstream manufacturers in recent years. Having vertically integrated business model can help in better control over manufacturing and development of drugs and avoid sourcing complexities for APIs.

New Drug Delivery systems in Injectables

Injectables industry has seen new forms of drug delivery systems as well as emergence of self-administered injectables. Also, few technologies categorized as complex injectables have been proven to be better drug delivery systems like liposomes, nanoparticles, microemulsion, microparticles, micelles, PEGylation, etc. These are termed as New Drug Delivery Systems (NDDS). The new developments require a wider range of development capabilities

and manufacturing expertise to ensure reduced time to market. As a result pharmaceutical companies look for strategic, integrated value added partners, who can help deliver on the various front helping big pharma companies reduce complexities in supply chain.

Growth in outsourcing trend

Outsourcing has developed as an industry trend, and now comprises the full range of corporate activities –from screening and lead identification to toxicology and several other processes like preclinical studies, clinical trials, manufacturing, and marketing at all scales. Outsourcing also allows a sponsor to pursue multiple projects concurrently due to the additional resources available from the contract provider. Outsourcing helps big pharmaceutical company reduce capex costs as they do not have to invest in the capex for every product that they commercialize, and it also saves time in setting up their own manufacturing facilities.

Specialty and complex generics – must to have business for the Indian pharmaceutical players

A complex generic is a generic that could have a complex active ingredient, complex formulation, complex route of delivery, or complex drug device combinations. Specialty drugs are high-cost prescription medications used to treat complex, chronic conditions such as cancer, rheumatoid arthritis, and multiple sclerosis. They can be used in rare or orphan disease indications. It may have unique storage or shipment requirements and might require additional patient education, adherence, and support beyond traditional dispensing activities.

With declining opportunity in the conventional generics segment and pricing pressures on the existing portfolios, it has become important for Indian players to look at high-value and high-margin drugs. Players have been developing niche products in order to weather the impact of pricing pressure. Number of niche product launches during last few years have been high. Companies are increasingly focusing on building capabilities in complex and niche molecules. These products are relatively untapped in comparison with conventional generics and offer huge realization as they are difficult to crack. Major players have increased their portfolio of complex generics and specialty products.

Biosimilars presents opportunity for Indian players

Biologics share in total patent expires by value is expected to be higher in next few years, signifying a tremendous opportunity for players. The top 10 biologics had a combined global sales worth over \$65 billion. The top players have already started moving towards bio-similar.

Further, even among the drugs where patents have already expired, the penetration of biosimilars is very low due to regulatory challenges and difficult procedural requirements of all-phase clinical trials. These expiries will present a lucrative opportunity for Indian players to launch biosimilar versions in regulated markets. Compared with a generic chemical molecule, such biopharmaceutical drugs can contribute higher revenue and margin realization since most products catering to critical chronic ailments. Moreover, there are relatively fewer players per product on account of the higher cost of development and the drugs can be more effective.

Also in recent times there has been regulatory push for the guidelines in approving biosimilars in the regulated markets like USA and Europe. The US FDA announced the Biosimilars Action Plan in July 2018, to ease market access of biosimilars in the country. These factors are also expected to aid the growth in the biosimilars across globe.

Details on new drugs going off patent

Consulting

Sr.No.	Year	Number of products going off patent
1	2023	433
2	2024	461
3	2025	427
4	2026	373
5	2027	165
6	2028	145

Note: Number of products going off-patent indicated the products which loose market exclusivity

Source: USFDA orange book files, CRISIL MI&A Research

New technology adoption a key factor for companies to grow in the industry

Indian pharmaceutical industry still lags behind when it comes to employing newer technologies in the research and manufacturing processes. Automation and artificial intelligence are some of the key technological trends in the industry. World health organization also recommends application of automated systems right from documentation to the manufacturing of formulations. Newer technology helps in process efficiencies which can aid Indian pharmaceutical players but implementing those changes will be a key challenge for the industry players.

Overview of some of the key government schemes

Government push for schemes such as Jan Aushadhi Pariyojana, a step towards increasing generic generics penetration

Branded generics (drugs that are off-patent and sold on brand names) comprise a lion's share of the domestic pharmaceutical industry. Retailers as well as manufacturers earn margins of over 20% on branded generics. As branded drugs account for much of the market share, the government has undertaken steps to increase the uptake of unbranded generics. It introduced the Jan Aushadhi Yojana in November 2008 to sell low-cost, unbranded, but quality medicines to all citizens via stores called Jan Aushadhi Kendras.

The Jan Aushadhi scheme saw only about 100 stores till March 2014 since its inception. However, it received a push post 2014 and about 9,340 stores (as of April 2023) are operational in the country, with a product basket of ~2000 drugs and 300 surgical items. This number is expected to go up by fiscal 2025 to reach 10,500 stores. Yet, of India's ~0.9 million pharmacies, Jan Aushadhi stores represent only 1%. Therefore, the share of sales through Jan Aushadhi stores is very low. The sales of medicines under the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) scheme have grown from Rs. 0,3 billion in fiscal 2017 to an estimated Rs.10 billion in fiscal 2023.

CRISIL MI&A Research does not foresee any significant impact of Jan Aushadhi Yojana on the industry in short term. With lack of awareness among consumers, non-prescription by doctors, and low-quality assurance for unbranded generics in comparison with branded counterparts as some of the challenges faced.

Ayushman Bharat to support long term growth

Rising lifestyle diseases and growth in insurance penetration (mainly because of Ayushman Bharat) would aid demand for the pharmaceutical sector in the long term.

Ayushman Bharat PM-JAY is the largest health assurance scheme in the world which aims at providing a health cover of Rs. 0.5 million per family per year for secondary and tertiary care hospitalization to over 107.4 million poor and vulnerable families (approximately 500 million beneficiaries) that form the bottom 40% of the Indian population. The cover under the scheme includes all expenses incurred on the following components of the treatment.

- Medical examination, treatment and consultation
- Pre-hospitalization
- Medicine and medical consumables
- Non-intensive and intensive care services
- Diagnostic and laboratory investigations
- Medical implantation services (where necessary)
- Accommodation benefits
- Food services
- Complications arising during treatment
- Post-hospitalization follow-up care up to 15 days

The scheme can be a huge positive for the pharmaceutical industry in the long run, as it will accelerate healthcare coverage in the country, which is currently very low at 38%. Ayushman Bharat also aims to upgrade 1.5 lakh primary healthcare centers (PHC) to provide diagnostic services and free medicines for preventive care. This could be a huge spin-offs for the industry as well. Strengthening of PHCs is necessary to take domestic industry growth to a higher trajectory.

Ayushman Bharat is expected to provide volume momentum to the healthcare sector, with the scheme on its full scale implementation providing healthcare assurance of Rs 5 lakh per family (on floater basis) to nearly 10.74 crore families (the actual coverage would be greater on account states extending the scheme to even some sections of the uncovered populace). As on Aug 2023, nearly ~42 million treatments had taken place under Ayushman Bharat since the inception of the scheme in September, 2018. The claim amount for the ~54 million treatments has been ~Rs. 674.56 billion, indicating average treatment cost of ~Rs 12,200-12,700 per treatment.

Around ~27,000 hospitals have been enrolled in the Scheme. Package rates has been the area of concern for most corporate hospitals, reflecting in the low participation of the private sector. Out of 33,000 private hospitals (as per ROHINI database), only 33% have participated in the scheme. However, it should be noted that though the share of private sector is 40% in facilities enrolled for the scheme, but ~54% of spend has taken place here. This clearly indicates the preference of beneficiaries for private hospitals, given that the government infrastructure is already over- burdened. Amongst the treatments sought, 57% of the total spend has been on tertiary treatments, with orthopaedics, cardiology, cardio-thoracic, oncology and urology being the most preferred, indicating the unmet demand in this category.

Impact of some of the key regulatory changes on the Indian domestic formulation industry

UCPMP Guidelines

Unified code of pharmaceutical marketing practices (UCPMP) is a voluntary code issued by the Department Of Pharmaceuticals, Government of India in regards to marketing practices for Indian Pharmaceutical Companies and medical devices industry. At present, the UCPMP Code is applicable to Pharmaceutical Companies, Medical Representatives, Agents of Pharmaceutical Companies such as Distributors, Wholesalers, Retailers, and Pharmaceutical Manufacturer's Associations.

Some of the key points covered under the UCPMP guidelines is as follows

- All promotional materials issued by an authorised holder or with his authority must be consistent with the requirements of the code
- Medical representatives must at all points maintain high standards of ethical conduct in the discharge of their duties .They all must comply with the all requirements of the code.
- No gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised, to persons qualified to prescribe or supply drugs, by a pharmaceutical company or any of its agents i.e Distributors, Wholesalers, Retailers
- As regards travel facilities, the UCPMP Code prohibits extending travel facility inside the country or outside, including rail, air, ship, cruise tickets, paid vacations, etc., to HealthCare Professionals and their family members for vacation or for attending conference, seminars, workshops, CME programme etc. as a delegate. The Code also provides that free samples of drugs shall not be supplied to any person who is not qualified to prescribe such product. Meaning thereby that free samples can only be supplied to persons qualified to prescribe such product.

The code has been adopted by the all the major associations of pharmaceutical companies and the Department on various instances has reviewed implementation of the code by the pharmaceuticals associations. Besides UCPMP, there exists sufficient and enforceable legal regime to counter, control and dis-incentivize the unethical marketing practices such as “Indian Medical Council Professional Conduct, Etiquette and Ethics) Regulations, 2002” under the Indian Medical Council Act, 1956, provisions available under Income Tax Act, Drugs and Cosmetics Act, Prevention of Corruption Act, etc

Ban on fixed-dose combination (FDC) drugs

On Sep 12, 2018, the government prohibited the manufacture, sale or distribution of ~325 fixed dose combination (FDC) drugs for human use with immediate effect. The ban follows the recommendations by DTAB (Drug Technical Advisory Board), which suggested these drugs may pose health risks. Following the recommendations of DTAB, which found that the combinations lacked "therapeutic justification". This was preceded by a legal battle for two years between pharmaceutical players and government of India.

At the company-level, the impact of ban was limited as most major companies had already discontinued or reformulated their products in anticipation of the ban. Following the ban on FDC drugs major pharma companies have looked at reformulating, or reducing their FDC exposure in anticipation of further regulatory developments. According to the CDSCO Policy guidelines on the approval of FDCs in India, all FDCs that have not yet been approved in any country - with regulations similar to those in India - will have to go through clinical trials along with the entire list of clearances for those FDCs to be marketed in India. As 325 FDC drugs were not available from the second half of the fiscal 2019, the domestic market growth was impacted to the tune of 30-50 bps in fiscal 2019.

E-pharmacy

With e-commerce blooming in India, the popularity of e-pharmacy too is on the rise, despite poorly defined regulations and unfavorable conditions for its growth. The sale of medicines in India is governed by the Drug & Cosmetics Act (1940) and Pharmacy Act (1948) – both of which were passed decades before the advent of the internet. Indian e-pharmacies, however, have been constantly on the radar of Drugs Controller General of India (DCGI) since 2016.

Indian e-pharmacies have seen growth in popularity and customer base over the last few years with launch of many e-pharmacy platforms. In an attempt to formalize the online sale of drugs, the Union Health Ministry has recently laid down certain guidelines that require e-pharmacies to be registered with Central Drugs Standard Control Organization (CDSCO), the chief licensing and regulatory authority for pharmaceutical sales in India.

In order to regulate the online sale of medicines comprehensively, the Government had published draft rules dated 28th August 2018 for amendment to the Drugs and Cosmetics Rules, 1945 for incorporating provisions relating to regulation of sale and distribution of drugs through e-pharmacy. The draft Rules contain provisions for registration of e-pharmacy, periodic inspection of e-pharmacy, procedure for distribution or sale of drugs through e-pharmacy, prohibition of advertisement of drugs through e-pharmacy, complaint redressal mechanism, monitoring of e-pharmacy, etc.

The rising chronic disease burden in urban India is also likely to expand the online pharmacy market, outdoing the retail counterparts. The heavy price concessions and a wide variety of brands offered by e-pharmacies makes them an attractive proposition.

Price control in the Indian pharmaceutical industry

The Drug Price Control Order (DPCO) fixes the ceiling price of some APIs and formulations in the Indian pharmaceutical market. APIs and formulations falling under the purview of the legislation are called scheduled drugs and scheduled formulations. The National Pharmaceutical Pricing Authority (NPPA) collects data and studies the

pricing structure of APIs and formulations and accordingly makes recommendations to the Ministry of Chemicals and Fertilisers.

The new Pharmaceutical Policy, notified in 2012, was put out as the final price notification in May 2013, bringing 348 essential drugs in the National List of Essential Medicines (NLEM), under price control. A big change was made compared to earlier pricing policy with the introduction of cost controls on final market prices of formulations compared instead of cost-based controls on Bulk drugs in the previous pricing policies.

Under the policy, the ceiling price for each drug under control would be fixed as the simple average price of brands having more than 1 per cent market share (by value) in the sales (MAT - Moving Annual Turnover) of that particular molecule. Thus, prices of brands which are higher than this ceiling will need to be lowered. The ceiling prices will be allowed an annual increase as per the Wholesale Price Index (WPI). Prices will be recalculated using MAT only once in five years or when the NLEM is updated. In September 2022, revision to the NLEM was announced which increased total number of essential medicines to 384 from 376 included in NLEM 2015. Drugs under the National List of Essential Medicines (NLEM) comprised estimated ~15-20% of the overall domestic formulation market in fiscal 2023.

Overview of opportunities w.r.t. collaboration between global MNCs and Indian players for established/ new molecules

In-licensing

In domestic formulations industry In Licensing is the process by which intellectual property rights are transferred to the manufacturer of the drug by the licensor or the innovator under the agreed terms. The transfer of intellectual property rights can be related to a product or process. In domestic formulations industry, usually licensor transfers the technology for development and manufacturing of the product. In this type of arrangement development costs are borne by the drug marketer. Manufacturers uses the technology and manufactures the drug as per the requirement of the drug marketer. Drug manufacturer charge drug marketer Cost of goods sold plus the profit. Profitability in this arrangement depends on the operational and cost efficiencies of the drug manufacturers. Manufacturers also save on the drug development costs and can focus on manufacturing operations and efficiencies to increase the profitability.

Overview of key associations/ partnerships between Indian companies and global MNCs

Indian Company	MNC Partner	Therapy area	Year
Sun Pharma	AstraZeneca	Diabetes	2016
	MSD	Diabetes	2018
	Pharmazz Inc.	ischemic stroke	2023
Cipla	Novartis	Diabetes, Cardiovascular and Respiratory	2018-2019
	Johnson and Johnson	Diabetes	2018-2019
	Roche	Oncology	2018 and 2020
	Merck	Anti-Viral	2021
Lupin	Novartis	Cardiovascular and Respiratory	2016
	Lilly	Diabetes	2016-2017 and 2021
	Boehringer Ingelheim	Diabetes	2016 and 2018
	LG	Oncology	2014
	Alvion Pharmaceuticals P.C.	Cardiovascular	2022
Aurobindo	Gilead	Anti-Viral	2011-2012*
	MPP	Oncology	2023
Emcure	Gilead	Anti-Viral	2011-2012*
	Merck	Anti-Viral	2021
	Roche	Oncology	2012
	Sanofi	Oncology	2014
	Viiv Healthcare	Anti-Viral	2015*
Laurus Labs	Gilead	Anti-Viral	2011-2012*

Hetero	Gilead	Anti-Viral	2011-2012*
Zydus Cadila	Gilead	Anti-Viral	2011-2012* and 2021
Dr.Reddy's	Amgen	Oncology and Osteoporosis	2016

Note: *:Partnerships via Medicines patent Pool

Source: CRISIL M&A Research, Company Reports

MNCs are increasingly focusing on partnerships and collaborations to drive access and scale without major investments. MNCs in patented play have used co-marketing as a way to drive growth in the Indian domestic formulation market. MNCs typically look for Indian partners who have efficient and broader marketing and distribution network as well as the proven track record in the therapy area in which the licencing agreement is taking place. Manufacturing and operational expertise are as well as the vintage of player are key factors that MNCs usually look for while entering in to an in-licencing agreement with the Indian player. As India is one of the foremost manufacturer of the pharmaceutical products in the world, going ahead global MNCs are expected to leverage this advantage and will try to collaborate with the Indian players for manufacturing or co-marketing of their drug and establish a strong presence in the growing Indian pharmaceutical market.

Key PE and M&A transactions executed in the Indian Pharmaceutical market

India is one of the largest manufacturer of drugs by volume and one of the largest exporter of formulations. Pharmaceutical industry in particular has attracted investments from across the world in the recent years. Countries across the world are planning to minimize dependencies of raw material supplies and production from single source and diversifying the supply chains. India's pharma industry has become one of the preferred manufacturing and development hub which is expected to attract more investment and deal activities in the medium term.

Indian pharmaceutical industry is heading for consolidation as many pharmaceutical companies are seeking advanced supply chain opportunities in order to optimize the development of their molecule. Pharmaceutical companies are acquiring strategic firms to backward/forward integrate their businesses. Pharmaceutical companies are usually relying on the inorganic growth as it brings in expertise as well as potential client contracts. Indian Pharma companies with ability to finance such transaction with internal accruals are expected to perform well in the coming future owing to scaling up of the acquired asset fairly quickly.

The PE industry continues to invest in the Indian pharmaceutical and healthcare space and India continues to be a preferred investment hotspot. In recent years, most of the PE funds have been investing majorly into the API and the CRAMS space. One of the important reasons for this surge interest in these pharma segments is that the pharma sector has produced successful exits, on a consistent basis, for PE investors in India.

Key recent M&A and PE transactions in Indian pharmaceutical industry

Acquirer/Investor	Target/Investee	Transaction Value	Details
M&A Transactions			
Nirma Ltd.	Glenmark lifesciences Ltd	USD 680 million	75% stake
Viartis Inc.	Famy lifesciences Ltds	USD 300 million	100% stake
Mankind pharma	Panacea biotech domestic formulation bands	USD 253 million	-
Torrent pharma	Curatio health	USD 250 million	100% Stake
Eris Lifesciences	Oaknet Healthcare	USD 83 million	100% Stake
PE transactions			
Advent	Suven Pharmaceuticals Ltd	USD 770 million	50% Stake
TA Associates	Synokem Pharmaceuticals Ltd	USD 125 million	-
KKR & Co. Inc	JB Chemicals & Pharmaceuticals Ltd	USD 409 million	54% Stake
Alkem Laboratories Ltd, Eight Roads Ventures and FPrime Capital.	Enzene Biosciences Limited	USD 50 million	-

Source: CRISIL MI&A

Preference for CDMO v/s in-house manufacturing

The extent of outsourcing in India is estimated to be 35-40% in the pharmaceutical industry in fiscal 2023. Outsourcing has developed as an industry trend, and now comprises the full range of corporate activities –from screening and lead identification to toxicology and several other processes like preclinical studies, clinical trials, manufacturing, and marketing at all scales.

Players can enter into different partnership arrangements with CDMO players

Manufacturing contracts - In this segment, formulations are marketed directly to the end consumer by the drug marketing companies or big pharma companies. These companies bear the cost of formulation development and IP rights and only manufacturing of the formulations can be outsourced to contract manufacturing player. Contract manufacturers provide manufacturing services only. Outsourcing decisions for these companies will depend on the cost-benefit analysis between outsourcing to contract manufacturers and in-house manufacturing. Another important aspect that affects the profitability of the B2C players is the selling, general and administrative costs (SG&A). SG&A expenses can form significant part of the player's cost structure and hence can have a bearing on the player's operating profitability.

Manufacturing and development contracts – This segment involves contract manufacturers or value added service providers entering into an arrangement with the pharmaceutical marketing player. Pharmaceutical marketing player enters into an arrangement with the contract research and manufacturer (CRAM) or value added service provider, who can provide development support as well as manufacturing support as per the arrangement.

In such arrangements value added service provider can either have the IP rights and bear the cost of development or it can work in technology transfer arrangement where IP rights are owned by the drug marketer and so the costs of development need not be borne. In the former arrangement, value added service provider can charge licensing fee and transfer fee for the approved drug while in the latter arrangement, value added service provider charges for goods sold.

Overview of business margins for CDMO manufacturing vs Inhouse manufacturing

With advent of contract manufacturing formulation players often outsource their manufacturing needs to contract manufacturers. The decision to outsource depends on combination of factors such as capital outlay for manufacturing of a particular molecule, period of manufacturing of particular molecule and available capacity for manufacturing.

Formulation player may outsource manufacturing of their molecules for which they don't have additional capacity or molecules which are required in moderate quantity and for smaller periods, as this would mitigate risk associated with capital investments as well as facility maintenance and regulatory authorities. On the other hand, formulation players prefer inhouse manufacturing when it comes to their flagship products as it gives them better control over margins and manufacturing process.

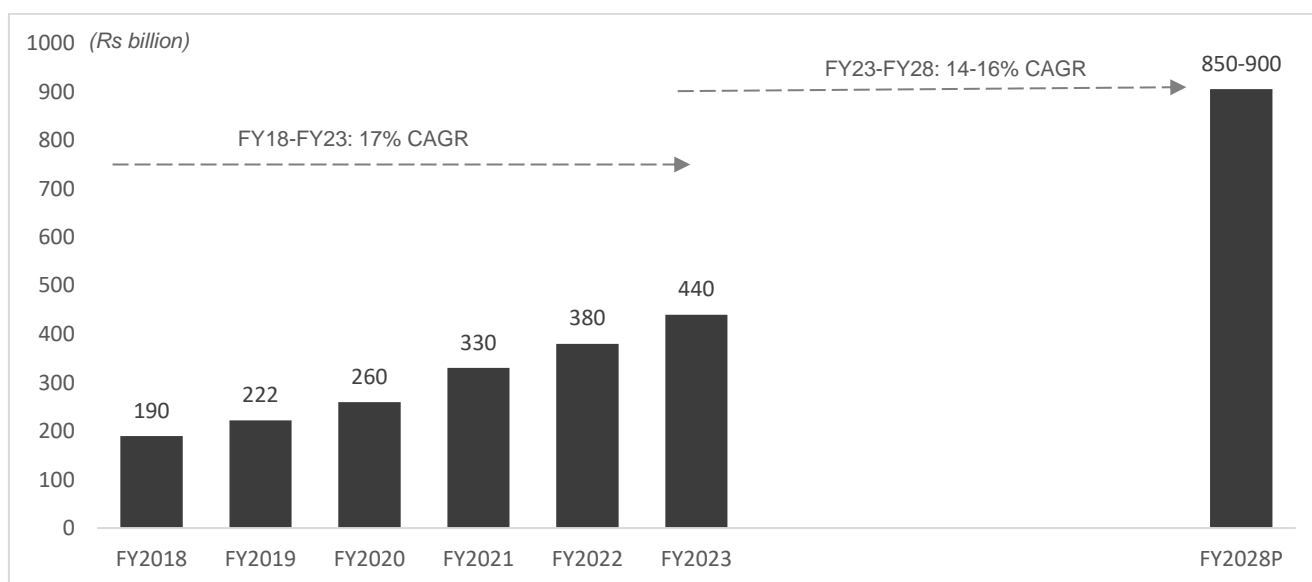
The cost of outsourcing to contract manufacturing may cost up to 5-10% higher for formulation players compared to inhouse manufacturing depending on type of molecule manufactured. The outsourcing helps formulation players in maintaining agile operations by having less capital-intensive operations. On the other hand, inhouse manufacturing provides formulation players with better control over cost margins and overall control of manufacturing process. The

decision to manufacture inhouse or outsourcing thus depends on cost benefit analysis and other aforementioned factors.

Overview of biologics market in India

Biopharmaceuticals or biologics are substances produced by manipulating living organisms via techniques such as genomics (mapping of genes), proteomics (study of structure of proteins), mutation analysis (change in the DNA sequence of a cell) and systems biology (study of complex interactions in a biological system) intended for human/animal treatment. Globally, these techniques are referred to as biotechnology, which in other words is a process technology or a drug discovery research tool. Biopharmaceuticals are drugs developed by applying biotechnology on living organisms / biologics for treatment of diseases.

Review and outlook of Indian biopharmaceutical industry



Note: Market included domestic and export sales of biopharmaceuticals
 Source: CRISIL MI&A

The Indian biologics industry can be roughly categorised under traditional vaccine makers and manufacturers focused more on therapeutic biologics. Further, there are players primarily focusing on recombinant therapeutics and monoclonal antibodies. Erythropoietin (used in severe anemia/cancer), Streptokinase and recombinant human Insulin, Filgrastim etc. are the most common recombinant drugs currently marketed in India. In the therapeutic category, Indian companies are present in areas such as immunological, oncology, osteoarthritis, anti-diabetic etc. During fiscal 2018 to fiscal 2023, the Indian biopharmaceuticals industry clocked a CAGR of ~17%, primarily on account of increase in sale of vaccines in the domestic as well as global markets. On the other hand, in the therapeutic segment, growth has been lower than that in the vaccines segment due to limited product launch by Indian players to enter the regulated markets of the US and Europe.

Going forward, growth is expected to be driven by new product launches in the domestic market and regulated exports market. Growth in exports is set to witness strong growth, driven by vaccines and biosimilars in the regulated and semi-regulated markets.

Higher effectiveness of biologics over conventional drugs has prompted global players to undertake more research and development in the segment. Therefore, the share of biopharmaceuticals segment is expected to increase to. Hence, more Indian players are likely to align their capabilities with the global trend and invest in biosimilars.

5 Review of competition in the IPM

Top 20 companies in IPM(Indian Pharmaceutical Market) by MAT (Moving Annual Total) sales

Sr. No.	Company Name	MAT sales – domestic formulation in Rs. million					CAGR MAT Sep 19-23	CAGR FY21-MAT Sep 23
		Sep 19	Sep 20	Sep 21	Sep 22	Sep 23		
1	Sun pharma Industries Ltd.	111,819.61	117,150.73	133,821.81	150,154.17	158,887.81	9.18%	11.57%
2	Abbott India Ltd.	86,430.18	90,074.33	103,153.45	109,212.37	120,845.84	8.74%	10.80%
3	Mankind Pharma Ltd.	59,138.69	64,038.76	73,408.07	87,196.55	98,406.09	13.58%	17.79%
4	Cipla Ltd.	72,578.42	74,237.95	86,602.47	87,218.32	95,886.54	7.21%	8.54%
5	(Zydus cadila)	55,688.21	57,826.47	66,441.55	69,586.25	73,330.42	7.12%	7.87%
6	Torrent Pharmaceuticals Ltd.	43,236.76	46,610.38	53,608.53	62,374.06	68,804.68	12.32%	14.96%
7	Alkem Laboratories Ltd.	48,345.42	48,949.40	58,573.21	60,589.98	66,181.67	8.17%	10.75%
8	Lupin Ltd.	51,648.30	53,573.37	60,857.06	61,572.21	64,560.13	5.74%	6.61%
9	Intas pharmaceuticals Ltd.	40,768.75	42,705.98	50,017.52	58,101.78	63,658.30	11.78%	15.15%
10	Macleods Pharmaceuticals Ltd.	38,493.60	41,118.96	49,681.77	55,150.36	61,998.94	12.65%	16.82%
11	Aristo pharmaceuticals Pvt.Ltd.	34,041.40	38,461.75	48,570.21	50,092.42	55,885.26	13.19%	14.13%
12	Dr. Reddy's Laboratories Ltd.	40,260.20	41,666.37	48,887.88	51,383.47	54,885.95	8.06%	10.57%
13	Emcure Pharmaceuticals Ltd.	35,050.80	37,641.26	47,815.91	49,892.58	52,834.15	10.80%	10.98%
14	GlaxoSmithKline Pharmaceuticals Ltd.	39,954.89	38,155.61	42,388.02	46,224.58	48,919.01	5.19%	10.24%
15	USV Pvt.Ltd.	26,890.44	29,354.44	33,061.18	35,796.00	39,270.50	9.93%	10.84%
16	Glenmark Pharmaceuticals Ltd.	28,327.98	33,058.57	41,193.88	35,275.95	38,657.35	8.08%	3.56%
17	Ipca Laboratories Ltd.	19,873.23	23,184.97	29,661.74	34,649.87	35,519.34	15.62%	15.24%
18	Pfizer Ltd.	30,701.62	34,254.49	38,500.90	36,956.16	34,112.89	2.67%	-0.82%
19	Micro Labs Ltd.	23,752.03	23,943.26	28,465.64	30,464.69	32,139.99	7.85%	11.27%
20	Sanofi India Ltd.	28,822.34	29,543.41	33,099.51	32,567.73	31,168.98	1.98%	0.93%
	Total IPM sales	1,380,959.18	1,432,262.37	1,653,544.02	1,762,870.89	1,895,010.42	8.23%	10.52%

Note- "MAT" refers to moving annual total, i.e. the value sales of the preceding 12 months. "MAT September" data denotes the moving annual total data starting from October 1 of the previous year to September 30 of the year stated. As an example, MAT September 2023 denotes the 12 month moving annual total of sales for the period between October 1, 2022 to September 30, 2023

IPM: Indian pharmaceutical market indicating total domestic formulation sales in India market

Domestic Sales refers to domestic formulation sales within India market

Note: Covered Markets considers molecule groups where Emcure has domestic sales in a given period; covered market is then defined as total sales for the above defined specific molecule groups for all entities present in IPM.

Source: AIOCD AWACS, CRISIL MI&A

Key Observations

- Emcure Pharmaceuticals Ltd., referred to as Emcure Pharmaceuticals or Emcure hereafter, is one of the leading Indian pharmaceutical company having expertise in pharmaceutical formulations like antiretrovirals & oncology products and complex APIs. Emcure also has expertise in biopharmaceuticals catering to therapy areas such as Cardiovascular, oncology, Neurology etc.
- Emcure is ranked 13th in the IPM with MAT sales of Rs. 52,834.15 million for September 2023.
- Between MAT September 2019 and MAT September 2023, Emcure was one of the fastest growing company in terms of domestic formulation sales, Emcure's total domestic product sales grew at a compound annual growth rate (CAGR) of 10.80% from Rs. 35,050.80 million to Rs. 52,834.15 million, outperforming the IPM, which grew at a CAGR of 8.23% during the same period.
- Emcure had a exports of Rs. 28,041.52 million in fiscal 2023 and the export have grown at CAGR of 18.32% from fiscal 2019 to fiscal 2023 outgrowing the overall Indian pharmaceutical exports which grew at CAGR of 11.51% CAGR during the same period.

MAT pharmaceutical formulation sales share for top 20 players in the IPM

Company Name	Sep 19	Sep 20	Sep 21	Sep 22	Sep 23
Sun pharma Industries Ltd.	8.10%	8.18%	8.09%	8.52%	8.38%
Abbott India Ltd.	6.26%	6.29%	6.24%	6.20%	6.38%
Mankind Pharma Ltd.	4.28%	4.47%	4.44%	4.95%	5.19%
Cipla Ltd.	5.26%	5.18%	5.24%	4.95%	5.06%
(Zydus cadila)	4.03%	4.04%	4.02%	3.95%	3.87%
Torrent Pharmaceuticals Ltd.	3.13%	3.25%	3.24%	3.54%	3.63%
Alkem Laboratories Ltd.	3.50%	3.42%	3.54%	3.44%	3.49%
Lupin Ltd.	3.74%	3.74%	3.68%	3.49%	3.41%
Intas pharmaceuticals Ltd.	2.95%	2.98%	3.02%	3.30%	3.36%
Macleods Pharmaceuticals Ltd.	2.79%	2.87%	3.00%	3.13%	3.27%
Aristo pharmaceuticals Pvt.Ltd.	2.47%	2.69%	2.94%	2.84%	2.95%
Dr. Reddy's Laboratories Ltd.	2.92%	2.91%	2.96%	2.91%	2.90%
Emcure Pharmaceuticals Ltd.	2.54%	2.63%	2.89%	2.83%	2.79%
GlaxoSmithKline Pharmaceuticals Ltd.	2.89%	2.66%	2.56%	2.62%	2.58%
USV Pvt.Ltd.	1.95%	2.05%	2.00%	2.03%	2.07%
Glenmark Pharmaceuticals Ltd.	2.05%	2.31%	2.49%	2.00%	2.04%
Ipca Laboratories Ltd.	1.44%	1.62%	1.79%	1.97%	1.87%
Pfizer Ltd.	2.22%	2.39%	2.33%	2.10%	1.80%
Micro Labs Ltd.	1.72%	1.67%	1.72%	1.73%	1.70%
Sanofi India Ltd.	2.09%	2.06%	2.00%	1.85%	1.64%
Total market share of top-20 players	66.32%	67.41%	68.21%	68.32%	68.39%

Note: Market share is calculated based on MAT sales data for domestic formulation sales
Source: AIOCD AWACS, CRISIL MI&A

Key Observations

- Market share of top-20 players in the IPM have increased from 66.32% in MAT September 2019 to 68.39% in MAT September 2023.

Market share movement for top 20 players in the IPM

Company Name	Market share MAT Sep 19	Market share movement from MAT Sep 19 to MAT Sep 23 (BPS)	Market share MAT Sep 23	Rank
Sun pharma Industries Ltd.	8.10%	29	8.38%	7
Abbott India Ltd.	6.26%	12	6.38%	10
Mankind Pharma Ltd.	4.28%	91	5.19%	1
Cipla Ltd.	5.26%	-20	5.06%	16
(Zydus cadila)	4.03%	-16	3.87%	15
Torrent Pharmaceuticals Ltd.	3.13%	50	3.63%	2
Alkem Laboratories Ltd.	3.50%		3.49%	11
Lupin Ltd.	3.74%	-33	3.41%	18
Intas pharmaceuticals Ltd.	2.95%	41	3.36%	6
Macleods Pharmaceuticals Ltd.	2.79%	48	3.27%	3
Aristo pharmaceuticals Pvt.Ltd.	2.47%	48	2.95%	4
Dr. Reddy's Laboratories Ltd.	2.92%	-2	2.90%	13
Emcure Pharmaceuticals Ltd.	2.54%	25	2.79%	8
GlaxoSmithKline Pharmaceuticals Ltd.	2.89%	-31	2.58%	17
USV Pvt.Ltd.	1.95%	13	2.07%	9
Glenmark Pharmaceuticals Ltd.	2.05%	-1	2.04%	12
Ipca Laboratories Ltd.	1.44%	44	1.87%	5
Pfizer Ltd.	2.22%	-42	1.80%	19
Micro Labs Ltd.	1.72%	-2	1.70%	14
Sanofi India Ltd.	2.09%	-44	1.64%	20

Note: Market share is calculated based on MAT sales data for domestic formulation sales
Source: AIOCD AWACS, CRISIL MI&A

Key Observations

- Emcure Pharmaceuticals Ltd. has market share of 2.79% as per MAT September 2023 sales which has increased from 2.54 % in MAT September 2019
- Emcure ranked 8th among top 20 players in IPM in terms of increase in market share from MAT September 2019 to MAT September 2023. Emcure gained 25 bps during this period in its market share, increasing from 2.54% in fiscal 2019 to 2.79%.

Acute VS Chronic MAT sales split for top 15 players as of MAT Sep 2023

Company Name	Acute therapy and Chronic therapy MAT Sales (Rs. million) for Sep 2023									
	Acute therapy	Market share in Acute Therapy	Chronic Therapy	Market share chronic therapy	Acute therapy Share in company sales (%)	Chronic Therapy share in company sales (%)	Acute CAGR MAT Sep1 9-MAT Sep 23	Chronic CAGR MAT Sep1 9-MAT Sep 23	Acute CAGR FY21-MAT Sep 23	Chronic CAGR FY21-MAT Sep 23
Sun pharma Industries Ltd.	68,708.33	7.65%	90,171.79	9.05%	43.25%	56.75%	10.33%	8.34%	14.45%	9.54%
Abbott India Ltd.	50,926.21	5.67%	69,898.58	7.01%	42.15%	57.85%	10.67%	7.43%	13.95%	8.67%
Mankind Pharma Ltd.	48,124.44	5.36%	50,260.57	5.04%	48.91%	51.09%	11.79%	15.42%	18.60%	17.02%
Cipla Ltd.	38,171.85	4.25%	57,707.61	5.79%	39.81%	60.19%	7.90%	6.76%	7.37%	9.33%
(Zydus cadila)	38,452.35	4.28%	34,877.77	3.50%	52.44%	47.56%	6.87%	7.40%	6.18%	9.84%
Torrent Pharmaceuticals Ltd.	17,023.86	1.90%	51,780.82	5.20%	24.74%	75.26%	11.54%	12.58%	17.03%	14.31%
Alkem Laboratories Ltd.	39,344.07	4.38%	26,825.40	2.69%	59.46%	40.54%	6.70%	10.50%	10.56%	11.02%
Lupin Ltd.	19,999.55	2.23%	44,560.58	4.47%	30.98%	69.02%	7.48%	5.00%	13.27%	4.04%
Intas pharmaceuticals Ltd.	15,151.77	1.69%	48,505.53	4.87%	23.80%	76.20%	10.20%	12.30%	18.81%	14.09%
Macleods Pharmaceuticals Ltd.	31,657.18	3.53%	30,340.04	3.04%	51.06%	48.94%	14.03%	11.30%	24.14%	10.59%
Aristo pharmaceuticals Pvt.Ltd.	37,975.27	4.23%	17,906.55	1.80%	67.96%	32.04%	12.30%	15.22%	14.50%	13.33%
Dr. Reddy's Laboratories Ltd.	28,917.57	3.22%	25,965.39	2.61%	52.69%	47.31%	6.92%	9.39%	11.44%	9.62%
Emcure Pharmaceuticals Ltd.	28,385.33	3.16%	24,448.05	2.45%	53.73%	46.27%	9.12%	12.93%	13.60%	8.19%
GlaxoSmithKline Pharmaceuticals Ltd.	30,887.62	3.44%	18,023.57	1.81%	63.15%	36.85%	5.03%	5.46%	10.11%	10.45%
USV Pvt.Ltd.	2,043.63	0.23%	37,226.86	3.73%	5.20%	94.80%	4.33%	10.28%	3.53%	11.29%
IPM	897,866.06	-	996,706.84	-	47.39%	52.61%	7.85%	8.58%	11.65%	9.53%

Note: Chronic therapy class also consists MAT sales from sub-chronic therapy class, There are some molecules which are not categorised in to acute or Chronic therapy areas by AIOCDs, hence the total of Acute and Chronic therapy is not equal to total IPM domestic formulation market sales, The total sales for such uncategorised molecules were Rs 437.51 million for MAT September 2023

Source: AIOCD AWACS, CRISIL MI&A

Key Observations

- For the MAT September 2023 period, in IPM, Emcure had chronic (chronic+subchronic) therapy MAT sales contributing to 46.27% of the total MAT sales compared to the 52.61% industry average for IPM

- For the period MAT September 2019 to MAT September 2023, Emcure's growth in Acute segment (9.12%) and chronic segment (12.93%) has outpaced the growth in total Indian domestic formulation Acute segment(7.85%) and Chronic segment (8.58%) by 1.2 times and 1.5 times respectively.

Acute Vs Chronic Spilt for total IPM

Therapy area	FY2021	FY2022	FY2023	FY21-FY23 CAGR
Acute	46.20%	48.15%	47.42%	13.69%
Chronic	53.80%	51.85%	52.58%	10.94%

Note: Chronic therapy class also consists MAT sales from sub-chronic therapy class

Source: AIOCD AWACS, CRISIL MI&A

Key Observations

- Both Acute and Chronic segments have demonstrated healthy growth and have grown at 13.69% and 10.94% CAGR respectively from FY2021 to FY2023.

Share of Injectables drugs revenue for top-20 players in IPM

Company Name	MAT Sep 2019	MAT Sep 2020	MAT Sep 2021	MAT Sep 2022	MAT Sep 2023
Sun pharma Industries Ltd.	3.49%	2.90%	3.35%	2.95%	3.11%
Abbott India Ltd.	24.37%	25.28%	25.53%	25.29%	24.38%
Mankind Pharma Ltd.	3.57%	3.03%	3.20%	2.99%	3.15%
Cipla Ltd.	13.24%	14.15%	19.14%	11.99%	10.55%
(Zydus cadila)	26.83%	26.50%	29.15%	27.05%	27.95%
Torrent Pharmaceuticals Ltd.	2.11%	1.80%	2.09%	2.23%	2.44%
Alkem Laboratories Ltd.	22.07%	21.77%	23.61%	21.32%	21.47%
Lupin Ltd.	15.64%	14.68%	15.69%	13.38%	14.30%
Intas pharmaceuticals Ltd.	13.28%	12.61%	13.57%	12.84%	14.53%
Macleods Pharmaceuticals Ltd.	11.39%	10.47%	14.24%	14.80%	15.55%
Aristo pharmaceuticals Pvt.Ltd.	35.41%	34.20%	37.57%	34.03%	33.67%
Dr. Reddy's Laboratories Ltd.	8.09%	7.39%	8.41%	7.61%	7.57%

Emcure Pharmaceuticals Ltd.	27.35%	26.78%	31.02%	27.53%	26.10%
GlaxoSmithKline Pharmaceuticals Ltd.	20.51%	19.42%	15.23%	11.86%	9.61%
USV Pvt.Ltd.	1.04%	1.06%	1.35%	1.21%	1.26%
Glenmark Pharmaceuticals Ltd.	5.41%	4.56%	6.13%	6.45%	7.33%
Ipca Laboratories Ltd.	8.30%	6.85%	5.98%	4.46%	5.16%
Pfizer Ltd.	26.29%	23.81%	23.34%	22.14%	19.28%
Micro Labs Ltd.	4.43%	3.79%	4.43%	4.15%	4.92%
Sanofi India Ltd.	45.77%	47.76%	48.11%	42.29%	40.03%

Note: Market share is calculated based on MAT sales data for domestic formulation sales
Source: AIOCD AWACS, CRISIL MI&A

Key Observations

- For Emcure, Sale of injectables and chiral products contributed to 26.10% and 5.40%, respectively, of its total domestic formulation Sales for MAT September 2023
- Emcure is ranked 4th among the top -20 players in the IPM in terms of share of injectables (26.10%) in total revenue indicating presence in injectables and chiral products for the company.
- Emcure's sales of Injectables contributed to 26.10% of to its domestic sales for MAT September 2023, which was one of the highest (Ranked 4th) shares among the top-20 players in IPM.

Largest therapy area in terms of sales and its contribution to MAT sales for key players

Company Name	Largest Therapy	MAT Sep 23 Therapy Sales (Rs. million)	Contribution to Sales (%)	CAGR Growth in Therapy (MAT Sep19- 23)	CAGR Growth in Therapy (FY21-MAT Sep23)
Sun pharma Industries Ltd.	Cardiovascular	27,494.15	17.30%	8.62%	10.38%
Abbott India Ltd.	Gastro Intestinal	24,354.49	20.15%	13.72%	14.33%
Mankind Pharma Ltd.	Anti-Infectives	16,883.53	17.16%	7.84%	14.24%
Cipla Ltd.	Respiratory	36,135.53	37.69%	12.90%	17.70%
(Zydus cadila)	Cardiovascular	11,279.18	15.38%	9.59%	8.51%
Torrent Pharmaceuticals Ltd.	Cardiovascular	18,172.93	26.41%	9.27%	9.51%
Alkem Laboratories Ltd.	Anti-Infectives	22,695.00	34.29%	4.53%	9.68%
Lupin Ltd.	Cardiovascular	14,805.72	22.93%	6.50%	5.45%
Intas pharmaceuticals Ltd.	Neuro / Cns	19,895.23	31.25%	12.61%	13.37%
Macleods Pharmaceuticals Ltd.	Anti-Infectives	18,789.80	30.31%	13.36%	23.33%
Aristo pharmaceuticals Pvt.Ltd.	Anti-Infectives	23,555.31	42.15%	11.18%	14.56%
Dr. Reddy's Laboratories Ltd.	Gastro Intestinal	10,110.06	18.42%	7.25%	9.27%
Emcure Pharmaceuticals Ltd.	Gynaecological	12,615.97	23.88%	10.74%	18.02%
GlaxoSmithKline Pharmaceuticals Ltd.	Derma	14,996.94	30.66%	13.18%	14.90%
USV Pvt.Ltd.	Anti Diabetic	19,052.01	48.51%	8.84%	11.11%

Source: AIOCD AWACS, CRISIL MI&A

Key Observations

- Anti-infective and anti-diabetic and cardiovascular are some of the major therapy areas catered by the players in the IPM as of MAT September 2023.
- Gynaecological is the largest therapy area catered by Emcure pharmaceuticals Ltd. which contributed 23.88% of the sales in the IPM for the company. MAT Sales in Gynaecological therapy areas have grown at 10.74% CAGR from September 2019 to September 2023 for the company.

Contribution of top-20 brands to players sales (Indian domestic pharma sales)

Company Name	Contribution to MAT Sales Sep 21 (%)	Growth in BPS Sep 21 vs Sep 22	Contribution to MAT Sales Sep 22 (%)	Growth in BPS Sep 22 vs Sep 23	Contribution to MAT Sales Sep 23 (%)
Sun pharma Industries Ltd.	36.52%	72	37.23%	-7	37.16%
Abbott India Ltd.	43.20%	38	43.59%	107	44.66%
Mankind Pharma Ltd.	51.20%	324	54.44%	88	55.32%
Cipla Ltd.	45.94%	344	49.38%	63	50.01%
(Zydus cadila)	35.26%	203	37.29%	48	37.77%
Torrent Pharmaceuticals Ltd.	55.45%	-24	55.20%	-54	54.66%
Alkem Laboratories Ltd.	65.08%	-40	64.68%	-99	63.69%
Lupin Ltd.	44.74%	7	44.81%	-167	43.14%
Intas pharmaceuticals Ltd.	39.97%	104	41.01%	-12	40.89%
Macleods Pharmaceuticals Ltd.	46.04%	-35	45.69%	-9	45.59%
Aristo pharmaceuticals Pvt.Ltd.	77.83%	-40	77.43%	-83	76.60%
Dr. Reddy's Laboratories Ltd.	52.06%	-8	51.98%	107	53.05%
Emcure Pharmaceuticals Ltd.	49.57%	388	53.45%	-81	52.64%
GlaxoSmithKline Pharmaceuticals Ltd.	82.28%	184	84.11%	135	85.47%
USV Pvt.Ltd.	91.96%	50	92.46%	90	93.36%

Note: The above analysis is done at the mother brand level

Source: AIOCD AWACS, CRISIL MI&A

Key Observations

- For Emcure Pharmaceuticals Ltd. the contribution of top-20 brands to its total domestic formulation MAT sales stood at 52.64% in September 2023. The share of top 20 brands for the company have grown from 49.57% in September 2019 to 52.64% in September 2023.

NLEM-2022 Exposure of top-20 players in the IPM

Company Name	MAT Sep 2023 Sales (Rs. million)	MAT Sep 2023 NLEM Sales (Rs. million)	NLEM Exposure as % of total sales (%)
Sun pharma Industries Ltd.	158,887.81	1,732.23	10.90%
Abbott India Ltd.	120,845.84	2,313.62	19.15%
Mankind Pharma Ltd.	98,406.09	1,484.45	15.08%
Cipla Ltd.	95,886.54	2,168.47	22.61%
(Zydus cadila)	73,330.42	1,620.71	22.10%
Torrent Pharmaceuticals Ltd.	68,804.68	477.72	6.94%
Alkem Laboratories Ltd.	66,181.67	1,311.69	19.82%
Lupin Ltd.	64,560.13	862.43	13.36%
Intas pharmaceuticals Ltd.	63,658.30	1,058.54	16.63%
Macleods Pharmaceuticals Ltd.	61,998.94	1,405.06	22.66%
Aristo pharmaceuticals Pvt.Ltd.	55,885.26	1,423.25	25.47%
Dr. Reddy's Laboratories Ltd.	54,885.95	751.09	13.68%
Emcure Pharmaceuticals Ltd.	52,834.15	623.19	11.80%
GlaxoSmithKline Pharmaceuticals Ltd.	48,919.01	1,061.54	21.70%
USV Pvt.Ltd.	39,270.50	388.84	9.90%
Glenmark Pharmaceuticals Ltd.	38,657.35	526.84	13.63%
Ipca Laboratories Ltd.	35,519.34	510.68	14.38%
Pfizer Ltd.	34,112.89	604.81	17.73%
Micro Labs Ltd.	32,139.99	762.64	23.73%
Sanofi India Ltd.	31,168.98	1,142.73	36.66%

Source: AIOCD AWACS, CRISIL MI&A

- Emcure Pharmaceuticals had 11.80% of its domestic formulations sales attributed to products listed in NLEM 2022 which was fourth lowest amongst the top 20 pharmaceutical companies in terms of Indian domestic formulation sales.

New products launched by top-20 players in IPM

Company Name/Year	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Sun pharma Industries Ltd.	68	76	90	61	77	105	101	132	129	125	105
Abbott India Ltd.	45	50	86	71	122	154	152	92	99	134	133
Mankind Pharma Ltd.	29	57	52	57	70	63	58	78	73	104	103
Cipla Ltd.	70	75	111	94	89	141	113	113	105	151	144
(Zydus cadila)	76	70	73	105	108	109	137	124	95	87	93
Torrent Pharmaceuticals Ltd.	42	48	50	65	71	60	68	70	96	123	89
Alkem Laboratories Ltd.	93	97	78	134	105	110	122	87	86	155	162
Lupin Ltd.	58	66	76	94	63	115	115	108	100	111	95
Intas pharmaceuticals Ltd.	66	66	82	130	145	110	124	106	90	103	84
Macleods Pharmaceuticals Ltd.	50	59	67	68	77	31	51	71	92	97	80
Aristo pharmaceuticals Pvt.Ltd.	35	15	25	16	29	29	32	32	27	30	46
Dr. Reddy's Laboratories Ltd.	30	51	70	71	75	49	47	60	61	62	51
Emcure Pharmaceuticals Ltd.	80	63	85	104	95	91	92	58	29	68	94
GlaxoSmithKline Pharmaceuticals Ltd.	8	15	20	7	9	30	15	9	26	7	9
USV Pvt.Ltd.	15	18	11	14	20	6	16	5	27	15	10
Glenmark Pharmaceuticals Ltd.	29	25	42	111	67	75	49	85	90	60	59
Ipca Laboratories Ltd.	37	33	28	19	23	34	31	31	43	65	27
Pfizer Ltd.	9	16	12	4	6	13	11	13	6	1	16
Micro Labs Ltd.	37	43	61	58	62	41	66	43	52	102	80
Sanofi India Ltd.	6	14	10	13	12	15	4	5	14	6	2

Source: AIOCD AWACS, CRISIL MI&A

Note: Green highlighted cells indicate the top three values for the period

- Emcure Pharmaceuticals have launched 94 products in the year 2023, the company have launched 859 new products from 2013 to 2023.

Share of therapies for Emcure Pharmaceuticals in company's domestic sales

Emcure						
Therapy name	MAT Sep 19	MAT Sep 20	MAT Sep 21	MAT Sep 22	MAT Sep 23	Cumulative April-Sept 23
Gynaecological	23.93%	21.27%	20.19%	25.00%	23.88%	24.19%
Cardiovascular	18.73%	20.06%	21.68%	17.25%	16.15%	15.93%
Anti-Infectives	12.68%	12.01%	12.21%	10.33%	10.63%	10.38%
Vitamins / Minerals / Nutrients	9.56%	10.77%	11.18%	9.40%	9.29%	9.35%
HIV Antivirals	4.15%	5.41%	5.53%	6.75%	7.01%	7.26%
Respiratory	5.82%	5.55%	5.08%	6.33%	6.73%	5.69%
Gastro Intestinal	6.60%	6.55%	6.64%	6.34%	6.23%	6.36%
Pain / Analgesics	5.52%	5.09%	4.79%	5.44%	5.63%	5.78%
Blood Related	3.99%	4.25%	3.84%	3.91%	3.91%	3.93%
Oncology/anti-neoplastics	2.63%	2.51%	2.96%	3.01%	3.66%	4.26%
Anti Diabetic	0.98%	1.52%	1.77%	2.31%	2.59%	2.64%
Hormones	1.13%	1.20%	1.24%	1.38%	1.62%	1.60%
Neuro / CNS	1.88%	1.62%	1.38%	1.30%	1.30%	1.31%
Others^	2.40%	2.16%	1.52%	1.25%	1.37%	1.33%
Total	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Note: ^-Others include anti-malaria, dermatology, ophthalmology, Urology, sex stimulants, vaccines, stomatology and other therapeutic areas

Source: AIOCD AWACS, CRISIL MI&A

Emcure Domestic formulation Sales-Therapy wise

Therapy name	Emcure							IPM		
	MAT Sep 19 Rs million	FY21 Rs million	MAT Sep 23 Rs million	Market Share Sep 19	Market Share FY21	Market Share Sep 23	CAGR Sept MAT 19-23	CAGR FY21-Sept MAT23	CAGR Sept MAT 19-23	CAGR FY21-Sept MAT23
Gynaecological	8,388.71	8,336.57	12,615.97	11.99%	11.77%	13.08%	10.74%	18.02%	8.36%	13.14%
Cardiovascular	6,563.76	8,762.86	8,533.29	3.82%	4.34%	3.47%	6.78%	-1.06%	9.38%	8.24%
Anti-Infectives	4,444.07	4,471.43	5,615.69	2.41%	2.42%	2.43%	6.02%	9.54%	5.76%	9.38%
Vitamins / Minerals / Nutrients	3,349.99	4,714.99	4,906.41	2.76%	3.48%	2.94%	10.01%	1.60%	8.25%	8.64%
HIV Antivirals	1,456.31	2,385.54	3,706.19	41.58%	52.75%	65.61%	26.30%	19.27%	12.69%	9.30%
Respiratory	2,039.85	1,866.13	3,558.38	1.98%	1.83%	2.25%	14.92%	29.46%	11.41%	19.28%
Gastrointestinal	2,313.14	2,711.03	3,290.33	1.51%	1.63%	1.50%	9.21%	8.05%	9.47%	11.86%
Pain / Analgesics	1,934.24	2,019.61	2,976.01	2.09%	2.14%	2.21%	11.37%	16.77%	9.82%	15.30%
Blood Related	1,397.52	1,709.61	2,067.46	9.00%	10.14%	9.34%	10.29%	7.90%	9.28%	11.51%
Oncology/anti-neoplastics	922.94	1,163.36	1,931.57	3.07%	3.92%	4.73%	20.28%	22.48%	7.93%	13.65%
Anti Diabetic	343.28	692.38	1,366.27	0.26%	0.46%	0.80%	41.24%	31.24%	6.31%	5.78%

Therapy name	Emcure							IPM		
	MAT Sep 19 Rs million	FY21 Rs million	MAT Sep 23 Rs million	Market Share Sep 19	Market Share FY21	Market Share Sep 23	CAGR Sept MAT 19-23	CAGR FY21-Sept MAT23	CAGR Sept MAT 19-23	CAGR FY21-Sept MAT23
Hormones	396.82	504.90	855.03	1.62%	1.94%	2.62%	21.16%	23.46%	7.49%	9.37%
Neuro / CNS	659.45	609.05	686.16	0.79%	0.66%	0.60%	1.00%	4.88%	8.20%	9.34%
Others^	840.73	772.57	725.40	0.44%	0.38%	0.29%	-3.62%	-2.49%	7.14%	9.56%
Total	35,050.80	40,720.04	52,834.15	2.54%	2.76%	2.79%	10.80%	10.98%	-	-

Note: Highlighted in green are therapeutic areas where Emcure has gained market share from Sept 2019, FY2021 to Sept 2023, ^Others include anti-malaria, dermatology, ophthalmology, Urology, sex stimulants, vaccines, stomatology and other therapeutic areas

Source: AIOCD AWACS, CRISIL MI&A

Key Observations

- Emcure Pharmaceuticals Ltd. is the largest player in the HIV-antivirals therapy area in the IPM with market share of 65.61% as of MAT September 2023. Emcure also has presence in molecules used in second line of treatment in HIV as of MAT September 2023 as per sales in the Indian domestic formulation market.
- Emcure Pharmaceuticals also has significance presence in the Gynaecological and blood related therapy areas with the market share of 13.08% and 9.34% respectively as of September 2023
- Emcure Pharmaceuticals is ranked one among peers in overall gynaecological and HIV Antivirals therapeutic areas and ranked two in blood related therapies from 2019 onwards till Sept 2023
- Emcure is market leader in gynaecology therapy in IPM with market share of 13.08% and is ranked 1 in gynaecology therapy in IPM as per MAT September 2023 sales.
- Emcure is ranked 8th in the hormones therapeutic area in terms of Domestic Sales for MAT September 2023
- Emcure have outgrown the Indian pharmaceutical industry in terms of domestic formulation sales between MAT September 2019 and MAT September 2023 in therapeutic areas such as gynecology, blood related, HIV, vitamins, minerals and nutrients, anti-infectives, pain and analgesics, respiratory, Oncology/anti-neoplastics and anti-diabetics.
- Emcure have portfolio of 11 chiral molecules out of which 6 products in chiral molecules were first to be launched in IPM namely S-amlodipine, S-atenolol, Dexketoprofen Trometamol, Dexrabeprazole, S-Metoprolol Succinate and S-Pantoprazole Sodium Salt.

Year wise Ranking of key therapies for Emcure in IPM based on domestic formulation sales

Therapy name	Emcure Rank					Cumulative April-Sept 23
	MAT Sep 19	MAT Sep 20	MAT Sep 21	MAT Sep 22	MAT Sep 23	
Gynaecological	1	1	1	1	1	1
Cardiovascular	8	8	5	10	10	10
Anti-Infectives	14	14	13	14	12	13
Vitamins / Minerals / Nutrients	8	9	9	9	8	8
HIV Antivirals	1	1	1	1	1	1
Respiratory	14	15	13	12	12	12
Gastro Intestinal	17	16	17	19	20	20
Pain / Analgesics	16	15	15	15	14	15
Blood Related	2	2	2	2	2	2
Oncology/anti-neoplastics	13	11	9	8	6	6
Anti Diabetic	35	32	30	27	26	26
Hormones	9	10	10	9	8	8
Neuro / CNS	20	23	22	24	25	25

Source: AIOCD AWACS, CRISIL MI&A

Volume/Price/New product growth split for Top 50 brands, >25Cr brands, 10-25Cr brands, 5-10Cr brands and <5Cr brands

Parameter	MAT SEP 23 (Rs million)	SEPT MAT 19-23			FY21- SEPT MAT 23		
		Unit Price growth	Volume growth	New product growth	Unit Price growth	Volume growth	New product growth
IPM Top 50 Brands	26,711.05	5.94%	3.18%	1.73%	6.61%	3.75%	1.81%
Emcure Brand in Top 50: Orofer	652.75	6.82%	-0.40%	0.19%	7.95%	3.60%	0.07%
IPM brands with sales >250 Mn	140,842.08	6.14%	0.38%	3.17%	6.28%	2.27%	2.59%
Emcure brand with sales >25 Cr	3,976.73	8.16%	2.51%	2.73%	8.78%	3.30%	1.10%
IPM brands with sales between 100-250 Mn	23,789.29	6.15%	-2.08%	4.42%	7.34%	1.29%	3.10%
Emcure brand with sales between 100-250 Mn	718.62	12.67%	-5.54%	3.66%	5.57%	-0.65%	3.05%
IPM brands with sales between 50-100Mn	10,917.47	6.45%	-0.09%	0.03%	7.52%	2.45%	0.03%
Emcure brand with sales between 50-100Mn	23.14	-6.98%	-1.25%	1.32%	-1.92%	6.31%	0.38%
IPM brands with sales <50 Mn	13,952.20	3.39%	-12.61%	6.99%	2.34%	-9.20%	7.90%
Emcure brand with sales <50 Mn	274.45	-0.96%	-15.92%	8.15%	9.61%	-19.39%	8.55%

Note: The above analysis is done at the mother brand level

Source: AIOCD AWACS, CRISIL MI&A

Key Observations

- Emcure Pharmaceuticals has higher growth under new product introduction as compared to overall IPM for brands with sales under Rs. 100 Mn for both Sept MAT 19-23 and FY21- Sept MAT 23 period

Top 20 brands Emcure (At mother brand level) – Subgroup market share, rank and growth analysis

Brands	MAT SEP 23 sales Rs million	Market share in covered market MAT SEP 23	Rank in Subgroup MAT SEP 23
OROFER	6,527.55	39.83%	1
BEVON	2,423.05	11.28%	3
MAXTRA	2,281.91	14.72%	2
ZOSTUM	1,654.10	30.01%	3
METPURE	1,416.16	78.18%	6
ESLO	1,316.22	39.26%	6
FERIUM	1,202.81	3.53%	9
PAUSE	1,174.83	30.12%	1
FERONIA	1,049.31	7.26%	5
AUGPEN	1,019.18	3.11%	8
ASOMEX	992.76	21.66%	13
SPEGRA	902.54	100.00%	1
MATERNA	787.73	10.51%	4
TEMSAN	783.68	2.94%	18
DYDROFEM	775.64	9.03%	3
VYLDA	731.65	4.98%	12
ELAXIM	709.92	51.40%	1
EXHEP	709.27	10.70%	4
VIROPIL	701.23	95.88%	2
PROXYM	652.32	30.06%	15

Note: The above analysis is done at the mother brand level

Source: AIOCD AWACS, CRISIL MI&A

Top 20 brands Emcure (at individual product brand level)– Subgroup market share, rank and growth analysis

Brands	Therapy area	MAT SEP 23 sales Rs million	Market share in covered market MAT SEP 23 (at subgroup level)	Rank in subgroup MAT SEP 23	Rank in overall IPM MAT SEP 23
OROFER-XT	Gynaecological	4,202.58	47.58%	1	16
BEVON	Vitamins / Minerals / Nutrients	2,269.44	10.64%	2	71
ZOSTUM	Anti-Infectives	1,654.10	30.01%	1	135
MAXTRA	Respiratory	1,524.40	35.18%	1	151
OROFER FCM	Gynaecological	1,378.81	34.29%	1	183
METPURE XL	Cardiovascular	990.79	84.10%	1	293
FERONIA XT	Gynaecological	919.29	14.63%	2	331
SPEGRA	HIV Antivirals	902.54	100.00%	1	342
OROFER-S	Gynaecological	876.42	34.60%	1	352
ESLO	Cardiovascular	799.39	44.87%	1	400
DYDROFEM	Gynaecological	775.64	9.03%	3	412
ELAXIM	Cardiovascular	709.92	51.40%	1	459
EXHEP	Cardiovascular	709.27	10.70%	4	460
VIROPIL	HIV Antivirals	701.23	95.88%	1	466
AUGPEN	Anti-Infectives	681.92	2.12%	10	481
MAXTRA P	Respiratory	637.51	8.22%	4	528
PAUSE	Blood Related	597.06	26.17%	2	594
MAXILIV	Gastro Intestinal	576.04	46.81%	1	626
ASOMEX	Cardiovascular	550.18	30.88%	2	665
FERIUM XT	Gynaecological	536.53	8.54%	3	686

Note: The above analysis is done at the individual brand level

Source: AIOCD AWACS, CRISIL MI&A

Key Observations

- 17 of Emcure's top 20 brands, that are used in treatments in the blood-related, gynaecology, anti-infectives, vitamins, minerals and nutrients, gastrointestinal, HIV, cardiovascular and respiratory therapeutic areas, were each ranked among the three highest selling brands in their respective therapeutic areas in the IPM, in terms of domestic Sales for MAT September 2023
- Emcure's Orofer brand is used as a nutritional supplement used to treat iron deficiency anemia and is ranked 1st in its molecule group for this indication as per domestic sales for MAT September 2023. In addition, Emcure Ferium-XT brand is ranked 3rd in its molecule group in terms of domestic Sales for MAT September 2023.

- Emcure's brand Maxtra is used for treating the common cold, and is ranked 2nd in its molecule group for this indication as per domestic sales for MAT September 2023.

Top-5 brands(Individual brands) sales and contribution for key therapies for Emcure

Therapy name	Emcure total therapy sales (Rs. million)	Top-5 brands sales MAT Sep 23 (Rs. million)	Market share of top-5 Emcure brands in total IPM therapy sales	Share in total Emcure therapy sales	Top-5 brands Emcure CAGR Sept MAT 19-23	Top-5 brands Emcure CAGR FY21-Sept MAT23
Gynaecological	12,615.97	8,152.76	8.45%	64.62%	9.90%	14.98%
Cardiovascular	8,533.29	3,759.54	1.53%	44.06%	7.20%	-0.82%
Anti-Infectives	5,615.69	3,427.42	1.48%	61.03%	9.17%	16.18%
Vitamins/Minerals/Nutrients	4,906.41	3,579.73	2.15%	72.96%	15.45%	3.85%
HIV Antivirals	3,706.19	2,443.98	43.27%	65.94%	44.19%	18.41%
Respiratory	3,558.38	2,803.44	1.77%	78.78%	14.52%	31.07%
Gastro Intestinal	3,290.33	1,694.70	0.77%	51.51%	18.10%	8.80%
Pain / Analgesics	2,976.01	1,524.63	1.13%	51.23%	10.49%	16.95%
Blood Related	2,067.46	1,774.00	8.01%	85.81%	9.82%	8.37%
Oncology/Anti-Neoplastics	1,931.57	1,294.09	3.17%	67.00%	44.22%	30.52%

N.A.-Player not present or does not have significant sales in the therapy area, Top-5 brands sales are in Rs. million

Note: The above analysis is done at the individual brand level

Source: AIOCD AWACS, CRISIL MI&A

Key biosimilar brands for Emcure

Brand Name	Therapy area	Molecule name	MAT Sep 2023 sales Rs. million	Market share in molecule group (%)	Rank in molecule group
Elaxim	Cardiovascular	Tenecteplase	709.92	51.40%	1
Tenectase	Cardiovascular	Tenecteplase	503.43	36.45%	2
Hamsyl	Oncology/Anti-Neoplastic	Asparaginase	2.03	2.04%	5

Note: The above analysis is done at the mother brand level

Source: AIOCD AWACS, CRISIL MI&A

- Emcure has six commercialized biologics products in IPM .Emcure's biosimilar brands, Elaxim, Tenectase and Hamsyl, were each ranked 1st,2nd, and 5th respectively in the IPM for their respective molecule, in terms of Domestic Sales for MAT September 2023.
- Emcure brand Elaxim is ranked top-1 in the tenecteplase molecule in high dosage category (30 mg to 50 mg) as per the sales in IPM as of MAT September 2023. Emcure brand Tenectase is ranked top-1 in

tenecteplase molecule in low dosage category (20 mg) as per the sales in IPM as of MAT September 2023. High dosage of tenecteplase molecule is used in the treatment of Acute myocardial infarction (AMI) while low dosage of tenecteplase molecule is used in the treatment of Acute Ischemic Stroke(AIS).

- Emcure was the first company to domestically launch the biosimilar for Tenecteplase, commonly used for acute myocardial infarction, and the biosimilar for Pegaspargase, commonly used for treating patients with leukemia.
- Emcure was the first pharmaceutical company in IPM to launch Encicarb brand in Ferric Carboxymaltose Complex molecule, an iron replacement medicine used to treat iron deficiency anemia.
- Emcure was the first pharmaceutical company in IPM to launch Treosulfan molecule under the brand name emtreo , a chemotherapy drug used to treat ovarian cancer.
- Emcure was the first pharmaceutical company in IPM to launch Instgra and Spegra brand in Dolutegravir molecule, for the treatment of HIV. Emcure have also launched anti-retroviral molecules such as Atazanavir, Ritonavir, Dolutegravir and Tenofovir
- Emcure have launched products for the first time in IPM in Troxipide and Ferric Carboxymaltose Complex, S-amlopidine, S-Metoprolol, S-Atenolol molecules.

Overview of growth of key brands for Emcure

Brand Name	Particulars	MAT Sep 19	MAT Sep 20	MAT Sep 21	MAT Sep 22	MAT Sep 23	MAT Sep 23 rank in Molecule/subgroup
Orofer XT	Sales (Rs. million)	2,844.96	2,888.76	3,364.44	3,743.62	4,202.58	1
	Market share in molecule (%)	43.31%	44.65%	45.21%	45.81%	47.58%	
Orofer FCM	Sales (Rs. million)	1,249.45	1,203.92	1,252.65	1,541.76	1,378.81	1
	Market share in molecule (%)	48.22%	50.31%	43.19%	40.56%	34.29%	
Tenectase	Sales (Rs. million)	130.24	153.73	190.45	359.78	503.43	2
	Market share in molecule (%)	16.90%	18.06%	18.71%	23.95%	36.45%	
Maxtra	Sales (Rs. million)	1,331.16	1,286.22	1,555.39	2,146.29	2,281.91	2
	Market share in molecule (%)	13.04%	12.44%	12.82%	14.66%	14.72%	
Bevon	Sales (Rs. million)	1,370.38	1,709.18	2,366.31	2,185.27	2,423.05	3
	Market share in molecule (%)	9.21%	10.57%	10.68%	10.23%	11.28%	

Note: The above analysis is done at the mother brand level except for brand Orofer XT and Orofer FCM which are individual brands

Source: AIOCD AWACS, CRISIL MI&A

Brand level analysis for Emcure Vs IPM

Particulars	MAT Sep 19	MAT Sep 20	MAT Sep 21	MAT Sep 22	MAT Sep 23	Cumulative April-Sep 23
Emcure						
No of brands with sales of Rs. 200 million to Rs. 500 million	23	28	35	33	34	27
No of brands with sales of Rs. 250 million to Rs. 500 million	15	22	25	25	22	19
No of brands with sales of Rs.500 million to Rs.1 billion	6	7	10	14	18	7
No of brands with sales of greater than 1 billion	7	7	10	9	10	2
Total IPM						
No of brands with sales of Rs. 200 million to Rs. 500 million	887	889	976	1036	1089	696
No of brands with sales of Rs. 250 million to Rs. 500 million	619	623	693	765	783	494
No of brands with sales of Rs.500 million to Rs.1 billion	337	347	388	433	462	246
No of brands with sales of greater than 1 billion	241	263	316	335	369	140

Note: The above analysis is done at the mother brand level

Source: AIOCD AWACS, CRISIL MI&A

No of brands in top-300 brands for Emcure

Particulars	MAT Sep 19	MAT Sep 20	MAT Sep 21	MAT Sep 22	MAT Sep 23	Cumulative April-Sep 23
No of brands of Emcure in top-300 brands in IPM	9	9	9	8	8	7

Note: The above analysis is done at the mother brand level

Source: AIOCD AWACS, CRISIL MI&A

Top brands sales of Emcure in top-300 IPM brands as of MAT September 2023

Brand Name	Therapy area	MAT Sep 19 Rs. million	MAT Sep 20 Rs. million	MAT Sep 21 Rs. million	MAT Sep 22 Rs. million	MAT Sep 23 Rs. million	FY21 Rs. million	CAGR Sept MAT 19-23	CAGR FY21-Sept MAT23
Orofer	Gynaecological	5,056.22	4,913.92	5,473.96	6,223.58	6,527.55	4,927.19	6.59%	11.91%
Bevon	Vitamins / Minerals / Nutrients	1,370.38	1,709.18	2,366.31	2,185.27	2,423.05	2,090.33	15.31%	6.09%
Maxtra	Respiratory	1,331.16	1,286.22	1,555.39	2,146.29	2,281.91	1,178.86	14.42%	30.24%
Zostum	Anti-Infectives	986.31	1,067.82	1,557.22	1,390.51	1,654.10	1,132.38	13.80%	16.37%
Metpure	Cardiovascular	1,106.00	1,217.65	1,281.73	1,347.43	1,416.16	1,216.23	6.37%	6.28%
Eslo	Cardiovascular	1,002.61	1,236.37	1,337.38	1,350.25	1,316.22	1,349.33	7.04%	-0.99%
Ferium	Gynaecological	1,034.61	971.08	1,042.54	1,161.87	1,202.81	986.42	3.84%	8.26%
Pause	Blood Related	851.44	930.42	1,011.59	1,133.25	1,174.83	954.99	8.38%	8.64%

Note: The above analysis is done at the mother brand level

Source: AIOCD AWACS, CRISIL MI&A

- As per MAT September 2023 sales, Emcure Pharmaceuticals Ltd. had total of 8 brands in the top-300 brands in IPM. It also had 11 brands clocking sales of more than Rs. 1 billion in sales.
- Eight of Emcure's brands, namely Orofer and Ferium generally used in gynaecological treatments, Bevon, generally used as a nutritional supplement, Maxtra, which is generally used in the treatment of respiratory diseases, Zostum, generally used as an anti-infective, Metpure and ESLO. generally used in the treatment of cardiovascular disease, and Pause generally used in the blood related treatments, were ranked among the 300 highest selling brands in the IPM, in terms of Domestic Sales for MAT September 2023

Top-5 molecule brands and molecule groups for Emcure in gynaecology therapy area

Particulars	MAT Sep 2023 sales Rs. million	Market share in therapy area MAT Sep 2023	Emcure Rank in therapy area/Group MAT Sep 2023	MAT Sep19-MAT Sep23 CAGR(%)	FY21-MAT Sep23 CAGR (%)
Molecule brands					
Orofer	6,527.55	6.77%	1	6.59%	11.91%
Ferium	1,202.81	1.25%	13	3.84%	8.26%
Feronia	1,043.96	1.08%	16	10.29%	5.66%
Dydrofem	775.64	0.80%	21	n.m.	128.45%
Materna	730.27	0.76%	24	44.30%	44.73%
Total of top-5 molecule brands	10,280.23	10.66%	-	10.22%	15.24%
Molecule groups					
Iron Combination Products	5,871.24	6.09%	1	9.60%	11.99%
Plain Iron	3,550.87	3.68%	1	4.71%	13.71%
Progestin Only Pills (Pops)	1,077.18	1.12%	4	190.45%	157.87%
Gonadotropins Including Other Ovulation Stimulants, Injectables	760.87	0.79%	3	45.79%	47.13%
Lactation Inducers	536.33	0.56%	1	14.99%	14.38%
Total of top-5 molecule groups	11,796.50	12.23%	-	11.94%	18.16%

Note: For molecule groups ranking company's rank in each of the group is considered, n.m. -Not meaningful

Note: The above analysis is done at the mother brand level

Source: AIOCD AWACS, CRISIL MI&A

Emcure's brand offerings for women's health

Brand name	MAT Sep 2023 sales Rs. million	Indication/Use	Adolescent	Pregnancy	Post-Pregnancy	Pre and post menopause
Orofer XT, Ferium XT, Feronia XT	5,658.41	Iron Deficiency, Anemia Management	✓	✓	✓	✓
Metpure, Numlo, Asomex,	4,854.14	Hypertension management	✓	✓	✓	✓

Temsan, Eslo						
Vylda, Emsita, Xilia	956.05	Diabetes management	✓	✓	✓	✓
Pause, Sylate, Evanev	1,456.92	Menstrual disorder management	✓			✓
Galact	536.33	Breastfeeding			✓	
Materna HCG, Materna HMG, Emprogest, Exhep, Tosiban	1,873.20	Infertility management		✓		
Dydrofen, Emydro, Zuviston	1,077.18	Pregnancy support		✓	✓	
Celol, Denmab, Osteri, Coralium	812.44	Post menopausal osteoporosis				✓
Pegex, Emtree, Eligard, Trazumab, Oxa, Citafine, Embremma, Bevarest	602.40	Cancer treatment	✓	✓	✓	✓

Note: MAT September 2023 sales indicates combined brand sales for brands mentioned in each row in the table above
Source: AIOCD AWACS, CRISIL MI&A

- Emcure has gynaecology therapy brands across the lifecycle of women's life in (Adolescence, pregnancy, post pregnancy, pre and post menopause). The key brands include Orofer & Ferium for Iron deficiency & anemia management, Pause & Sylate for menstrual disorder management, Dydrofem for pregnancy support and Materna for infertility management.

Top-5 molecule brands and molecule groups for Emcure in cardiovascular therapy area

Particulars	MAT Sep 2023 sales Rs. million	Market share in therapy area MAT Sep 2023	Emcure Rank in therapy area/Group MAT Sep 2023	MAT Sep19-MAT Sep23 CAGR(%)	FY21-MAT Sep23 CAGR (%)
Molecule brands					
Metpure	1,416.16	0.58%	36	6.37%	6.28%
Eslo	1,316.22	0.53%	42	7.04%	-0.99%
Asomex	992.76	0.40%	57	-0.29%	0.38%
Temsan	783.68	0.32%	74	6.48%	4.73%
Elaxim	709.92	0.29%	85	4.86%	1.30%
Total of top-5 molecule brands	5,218.74	2.12%	-	4.90%	2.27%
Molecule groups					
Calcium Antagonists, Plain	1,757.86	0.71%	2	3.59%	-2.48%
Fractionated Heparin	1,246.94	0.51%	2	16.24%	-18.95%
Tissue Plasminogen Activator	1,213.35	0.49%	1	14.04%	15.70%
Beta-Blocking Agents, Plain	1,083.67	0.44%	7	6.35%	5.08%
ARB+ Calcium Antagonist	655.27	0.27%	11	7.11%	7.41%
Total of top-5 molecule groups	5,957.10	2.42%	-	8.67%	-2.39%

Note: For molecule groups ranking company's rank in each of the group is considered

Note: The above analysis is done at the mother brand level

Source: AIOCD AWACS, CRISIL MI&A

Top-5 molecule brands and molecule groups for Emcure in Anti-infective therapy area

Particulars	MAT Sep 2023 sales Rs. million	Market share in therapy area MAT Sep 2023	Emcure Rank in therapy area/Group MAT Sep 2023	MAT Sep19-MAT Sep23 CAGR(%)	FY21-MAT Sep23 CAGR (%)
Molecule brands					
Zostum	1,654.10	0.72%	26	13.80%	16.37%
Augpen	1,019.18	0.44%	41	4.85%	23.79%
Merotec	397.13	0.17%	132	1.73%	-1.77%
Zostum-O	375.62	0.16%	144	13.35%	25.31%
Tazotum	295.38	0.13%	178	7.16%	-1.20%
Total of top-5 molecule brands	3,741.41	1.62%	-	8.99%	14.56%
Molecule groups					
Cephalosporins Third Generation + Lactamse Inhibitors	1,880.19	0.81%	5	12.54%	16.71%

Broad Spectrum Penicillin + Lactamase Inhibitor	896.73	0.39%	9	2.21%	23.23%
Cephalosporins Third Generation-Plain	855.06	0.37%	11	11.20%	13.23%
Carbapenems Plain	403.78	0.17%	11	2.85%	-0.98%
Medium And Narrow Spectrum Penicillins	350.02	0.15%	7	8.87%	4.51%
Total of top-5 molecule groups	4,385.77	1.90%	-	8.52%	13.96%

Note: For molecule groups ranking company's rank in each of the group is considered

Note: The above analysis is done at the mother brand level

Source: AIOCD AWACS, CRISIL MI&A

Top-5 molecule brands and molecule groups for Emcure in Vitamins/Minerals/Nutrients therapy area

Particulars	MAT Sep 2023 sales Rs. million	Market share in therapy area MAT Sep 2023	Emcure Rank in therapy area/Group MAT Sep 2023	MAT Sep19-MAT Sep23 CAGR(%)	FY21-MAT Sep23 CAGR (%)
Molecule brands					
Bevon	2,423.05	1.45%	8	15.31%	6.09%
Vitanova	490.80	0.29%	66	23.37%	19.88%
Zinconia	383.95	0.23%	86	32.75%	-11.43%
Coralium	302.19	0.18%	113	-0.57%	-3.96%
Hosit	191.43	0.11%	182	1.21%	1.63%
Total of top-5 molecule brands	3,791.43	2.28%	-	14.61%	3.96%
Molecule groups					
Multivitamin With Minerals	2,351.06	1.41%	3	14.80%	5.71%
Vitamin D	490.80	0.29%	8	23.37%	19.88%
Vitamin B12 Combinations	443.05	0.27%	13	0.98%	0.89%
Zinc Supplements	383.95	0.23%	1	32.75%	-11.43%
Calcium + Vit D	369.63	0.22%	5	-2.86%	-4.40%
Total of top-5 molecule groups	4,038.50	2.42%	-	12.40%	3.28%

Note: For molecule groups ranking company's rank in each of the group is considered

Note: The above analysis is done at the mother brand level

Source: AIOCD AWACS, CRISIL MI&A

Top-5 molecule brands and molecule groups for Emcure in respiratory therapy area

Particulars	MAT Sep 2023 sales Rs. million	Market share in therapy area MAT Sep 2023	Emcure Rank in therapy area/Group MAT Sep 2023	MAT Sep19-MAT Sep23 CAGR(%)	FY21-MAT Sep23 CAGR (%)
Molecule brands					
Maxtra	2,217.12	4.20%	15	13.60%	29.53%

Soventus	401.20	0.76%	84	12.36%	45.52%
Nukast	352.46	0.67%	98	18.99%	38.17%
Brophyle	183.15	0.35%	159	28.34%	9.02%
Floresp	135.62	0.26%	191	13.13%	5.38%
Total of top-5 molecule brands	3,289.54	6.23%	-	14.57%	28.96%
Molecule groups					
Antihistamine + Nasal Decongestant	1,461.91	2.77%	1	14.32%	32.64%
Antihistamine + Antipyretic + Nasal Decongestant	637.51	1.21%	4	12.87%	28.21%
Antihistamine + Antileukotriene Anti-Asthmatic	349.60	0.66%	14	17.03%	33.34%
B2-Agnoist + Expectorant + Mucolytic	306.23	0.58%	8	11.91%	45.48%
Bronchodilators Plain	137.38	0.26%	5	19.81%	4.15%
Total of top-5 molecule groups	2,892.64	5.47%	-	14.26%	30.80%

Note: For molecule groups ranking company's rank in each of the group is considered

Note: The above analysis is done at the mother brand level

Source: AIOCD AWACS, CRISIL MI&A

Top-5 molecule brands and molecule groups for Emcure in blood related therapy area

Particulars	MAT Sep 2023 sales Rs. million	Market share in therapy area MAT Sep 2023	Emcure Rank in therapy area/Group MAT Sep 2023	MAT Sep19-MAT Sep23 CAGR(%)	FY21-MAT Sep23 CAGR (%)
Molecule brands					
Pause	1,174.83	5.31%	2	8.38%	8.64%
Vintor	394.50	1.78%	14	19.43%	9.38%
Sylate	226.36	1.02%	28	6.02%	8.51%
Eporise	152.69	0.69%	34	7.33%	12.40%
Epofer	84.28	0.38%	57	32.27%	-3.11%
Total of top-5 molecule brands	2,032.66	9.18%	-	10.43%	8.44%
Molecule groups					
Synthetic Antifibrinolytics	1,251.77	5.65%	1	8.37%	8.86%
Erythropoietin Products	657.26	2.97%	4	16.63%	7.18%
Systemic Heamostatics	149.42	0.67%	2	4.97%	6.65%
Herbal Remedies To Increase Platelets	9.01	0.04%	17	-6.10%	-22.79%
Protein Solutions	-	0.00%	11	-100.00%	-100.00%
Total of top-5 molecule groups	2,067.46	9.34%	--	10.29%	7.90%

Note: For molecule groups ranking company's rank in each of the group is considered

Note: The above analysis is done at the mother brand level

Source: AIOCD AWACS, CRISIL MI&A

Covered market analysis for Emcure in IPM

Sales, growth and market share in Emcure's covered market for key therapies based on domestic formulation sales

Therapy name	Emcure								IPM	
	MAT Sep 19	FY21	MAT Sep 23	Market Share Sep 19	Market Share FY21	Market Share Sep 23	CAGR Sept MAT 19-23	CAGR FY21-Sept MAT23	CAGR Sept MAT 19-23	CAGR FY21-Sept MAT23
Gynaecological	8,388.71	8,336.57	12,615.97	25.72%	24.47%	29.49%	10.74%	18.02%	7.02%	9.53%
Cardiovascular	6,563.76	8,762.86	8,533.29	6.35%	7.71%	6.41%	6.78%	-1.06%	6.50%	6.49%
Anti-Infectives	4,444.07	4,471.43	5,615.69	3.21%	3.47%	3.26%	6.02%	9.54%	5.64%	12.35%
Vitamins / Minerals / Nutrients	3,349.99	4,714.99	4,906.41	5.76%	7.31%	5.44%	10.01%	1.60%	11.63%	14.39%
HIV Antivirals	1,456.31	2,385.54	3,706.19	42.01%	53.27%	66.07%	26.30%	19.27%	12.79%	9.43%
Respiratory	2,039.85	1,866.13	3,558.38	4.67%	4.40%	5.08%	14.92%	29.46%	12.53%	22.22%
Gastrointestinal	2,313.14	2,711.03	3,290.33	2.52%	2.87%	2.66%	9.21%	8.05%	7.75%	11.35%
Pain Analgesics /	1,934.24	2,019.61	2,976.01	3.40%	3.47%	3.47%	11.37%	16.77%	10.76%	16.75%
Blood Related	1,397.52	1,709.61	2,067.46	13.55%	14.95%	15.76%	10.29%	7.90%	6.21%	5.66%
Oncology/anti-neoplastics	922.94	1,163.36	1,931.57	5.25%	7.24%	10.23%	20.28%	22.48%	1.81%	6.67%
Anti-diabetic	343.28	692.38	1,366.27	0.61%	0.96%	1.29%	41.24%	31.24%	17.18%	16.52%
Hormones	396.82	504.90	855.03	5.56%	6.62%	10.73%	21.16%	23.46%	2.78%	1.76%
Neuro / CNS	659.45	609.05	686.16	1.44%	1.25%	1.23%	1.00%	4.88%	5.11%	5.36%
Others^	840.73	772.57	725.40	1.76%	1.75%	1.15%	-3.62%	-2.49%	7.12%	15.22%
Emcure total CVM sales	35,050.80	40,720.04	52,834.15	4.92%	5.49%	5.35%	10.80%	10.98%	-	-
IPM CVM sales	713,054.27	741,181.90	988,050.99	100.00%	100.00%	100.00%	-	-	8.50%	12.19%

Note: Highlighted in green are therapeutic areas where Emcure has gained market share from Sept 2019, FY2021 to Sept 2023, MAT sales are in Rs. million

Note: Covered Markets considers molecule groups where Emcure has domestic sales in a given period; covered market is then defined as total sales for the above defined specific molecule groups for all entities present in IPM.

^Others include anti-malaria, dermatology, ophthalmology, Urology, sex stimulants, vaccines, stomatology and other therapeutic areas

Source: AIOCD AWACS, CRISIL MI&A

Key Observations

- Emcure Pharmaceuticals Ltd. is the largest player in the covered HIV-antivirals therapy area in the IPM with market share of 66.07% as of MAT September 2023

- Emcure Pharmaceuticals also has significance presence in the Gynaecological and blood related therapy areas with the market share of 29.49% and 15.76% respectively in Emcure's covered market as of MAT September 2023
- In the Emcure's covered market for the period MAT September 2019 to MAT September 2023, Emcure has shown faster growth than the overall IPM market in 11 of its 13 therapy areas namely Gynaecological, Cardiovascular, Anti-Infectives, HIV antivirals, respiratory, gastrointestinal, pain analgesics, blood related, oncology/Anti-Neoplastics, Anti-diabetic and Harmones.
- In the Emcure's covered market the market share for Emcure in all the respective key therapies mentioned above is lesser than 66.07%

Year wise market share in Emcure's covered market for top-10 players

Company name	MAT Sep 19	MAT Sep 20	MAT Sep 21	MAT Sep 22	MAT Sep 23	Cumulative April-Sept 23
Sun pharma Industries Ltd.	9.37%	9.47%	9.07%	9.56%	9.40%	9.60%
Mankind Pharma Ltd.	5.10%	5.25%	5.29%	5.69%	6.07%	6.09%
Alkem Laboratories Ltd.	5.64%	5.46%	5.67%	5.41%	5.43%	5.54%
Emcure Pharmaceuticals Ltd.	4.92%	5.11%	5.71%	5.36%	5.35%	5.36%
Aristo pharmaceuticals Pvt.Ltd.	3.52%	3.83%	4.31%	4.05%	4.26%	4.37%
Macleods Pharmaceuticals Ltd.	3.66%	3.68%	3.89%	3.94%	4.07%	4.09%
Intas pharmaceuticals Ltd.	3.85%	3.92%	3.85%	3.95%	3.84%	3.87%
Torrent Pharmaceuticals Ltd.	3.94%	3.83%	3.58%	3.50%	3.56%	3.56%
(Zydus cadila)	9.37%	9.47%	9.07%	9.56%	9.40%	9.60%
Abbott India Ltd.	5.10%	5.25%	5.29%	5.69%	6.07%	6.09%

Source: AIOCD AWACS, CRISIL MI&A

Year wise Ranking in key therapies for Emcure in Emcure's covered market

Therapy name	MAT Sep 19	MAT Sep 20	MAT Sep 21	MAT Sep 22	MAT Sep 23	Cumulative April-Sept 23
Gynaecological	1	1	1	1	1	1
Cardiovascular	4	4	2	3	4	4
Anti-Infectives	9	9	9	9	9	9
Vitamins / Minerals / Nutrients	4	2	4	5	5	5
HIV Antivirals	1	1	1	1	1	1
Respiratory	7	8	8	7	7	7
Gastrointestinal	13	13	11	12	12	14
Pain / Analgesics	11	12	12	11	11	11
Blood Related	1	1	1	1	1	1
Oncology/anti-neoplastics	8	7	5	6	3	2

Anti-diabetic	23	23	22	24	22	21
Hormones	5	6	5	5	3	3
Neurology/CNS	17	18	17	18	17	15
Overall IPM Covered market rank	4	4	2	4	4	4

Source: AIOCD AWACS, CRISIL MI&A

Share of Emcure's covered market for key therapies in total IPM

Therapy name	MAT Sep 19	FY21	MAT Sep 23
Anti Diabetic	41.76%	48.41%	61.66%
Anti-Infectives	74.90%	69.73%	74.56%
Oncology/anti-neoplastics	58.38%	54.15%	46.22%
Blood Related	66.39%	67.80%	59.25%
Cardiovascular	60.13%	56.29%	54.04%
Gastro Intestinal	59.89%	56.86%	56.21%
Gynaecological	46.63%	48.11%	44.37%
Hiv Antivirals	98.97%	99.03%	99.31%
Hormones	29.25%	29.28%	24.45%
Neuro / Cns	54.38%	53.12%	48.42%
Pain / Analgesics	61.51%	61.69%	63.65%
Respiratory	42.51%	41.64%	44.25%
Vitamins / Minerals / Nutrients	47.91%	47.61%	54.17%
Total covered market	51.63%	50.23%	52.14%

Source: AIOCD AWACS, CRISIL MI&A

Covered market for respective key players in the IPM*

Company name	MAT Sep 23 Covered market as % of total IPM
Intas pharmaceuticals Ltd.	67.26%
Cipla Ltd	66.20%
Lupin Ltd	64.56%
(Zydus cadila)	63.39%
Sun pharma Industries Ltd.	62.14%
Mankind Pharma Ltd.	61.69%
Alkem Laboratories Ltd.	61.44%
Abbott India Ltd.	59.54%
Torrent Pharmaceuticals Ltd.	54.11%
Macleods Pharmaceuticals Ltd.	52.79%
Emcure Pharmaceuticals Ltd.	52.14%

Source: AIOCD AWACS, CRISIL MI&A

Note: *- Covered Markets considers molecule groups where respective companies above have domestic sales in a given period; covered market for respective players is then defined as total sales for the above defined specific molecule groups for all entities present in IPM.

- Emcure has the lowest covered market presence among the key top-20 players in IPM. Emcure Pharmaceuticals Ltd. has covered market share of 52.14% as of MAT September 2023.

Analysis of cardiovascular therapy area in IPM

Overview of cardiovascular market

Particulars	MAT Sep 2019	MAT Sep 2020	MAT Sep 2021	MAT Sep 2022	MAT Sep 2023	FY21	MAT Sep19- MAT Sep23 CAGR(%)	FY21- MAT Sep23 CAGR (%)
Total IPM cardiovascular market (Rs. million)	172,015.71	192,097.08	215,664.10	229,998.41	246,224.20	202013.10	9.38%	8.24%
Emcure cardiovascular therapy sales (Rs. Million)	6,563.76	7,550.85	10,364.77	8,606.02	8,533.29	8762.86	6.78%	-1.06%
Emcure market share in cardiovascular therapy area (%)	3.82%	3.93%	4.81%	3.74%	3.47%	4.34%		

Source: AIOCD AWACS, CRISIL MI&A

Analysis of Gynaecology therapy area in IPM

Overview of Gynaecology market

Particulars	MAT Sep 2019	MAT Sep 2020	MAT Sep 2021	MAT Sep 2022	MAT Sep 2023	FY21	MAT Sep19- MAT Sep23 CAGR(%)	FY21- MAT Sep23 CAGR (%)
Total IPM gynaecology market (Rs. million)	69,944.34	68,332.36	78,149.68	89,547.45	96,435.61	70,822.97	8.36%	13.14%
Emcure gynaecology therapy sales (Rs. Million)	8,388.71	8,008.06	9,656.31	12,472.67	12,615.97	8,336.57	10.74%	18.02%
Emcure market share in gynaecology therapy area (%)	11.99%	11.72%	12.36%	13.93%	13.08%	11.77%	-	-

Source: AIOCD AWACS, CRISIL MI&A

Split of Indian gynecology market in to Iron related compound and non-iron related compounds

Particulars	MAT Sep 2019	MAT Sep 2020	MAT Sep 2021	MAT Sep 2022	MAT Sep 2023	FY21	MAT Sep19- MAT Sep23 CAGR(%)	FY21- MAT Sep23 CAGR (%)
Iron Combination Products (Rs. million)	23,769.34	23,933.25	27,152.80	29,315.04	31,277.34	24,788.55	7.10%	9.75%
Non-Iron compounds (Rs. Million)	46,174.99	44,399.11	50,996.88	60,232.41	65,158.27	46,034.41	8.99%	14.91%
Share of Iron compounds (%)	33.98%	35.02%	34.74%	32.74%	32.43%	35.00%		
Share of non-Iron compounds (%)	66.02%	64.98%	65.26%	67.26%	67.57%	65.00%		
Rank of Emcure in Iron combination products	1	1	1	1	1	1	-	-
Market share of Emcure in Iron combination products	29.77%	28.85%	29.20%	31.00%	30.39%	28.53%		

Note: Iron combination products includes Iron Combination Products, Plain Iron and Haematinics Iron & All Combinations molecule groups

Source: AIOCD AWACS, CRISIL MI&A

Key Observations

- Iron combination products is one of the key category in Indian gynaecology therapy area with Iron combination products forming 32.43% of the total gynaecology therapy area as of MAT September 2023
- Emcure is leading player in iron combination products in IPM and is ranked 1st in the iron combination products in IPM from MAT September 2019 to MAT September 2023. Emcure had a market share of 30.39% in iron combination products as of MAT September 2023.
- Emcure is also present in other key categories in gynaecology therapy area such as Progestin, Gonadotropin and Menstrual disorders.

Top-10 players market share and sales in Indian gynaecology market

Company Name	MAT Sep 2019 Sales (Rs million)	MAT Sep 2019 Market share	MAT Sep 2020 Sales (Rs million)	MAT Sep 2020 Market share	MAT Sep 2021 Sales (Rs million)	MAT Sep 2021 Market share	MAT Sep 2022 Sales (Rs million)	MAT Sep 2022 Market share	MAT Sep 2023 Sales (Rs million)	MAT Sep 2023 Market share
Emcure Pharmaceuticals Ltd.	8,388.71	11.99%	8,008.06	11.72%	9,656.31	12.36%	12,472.67	13.93%	12,615.97	13.08%
Mankind Pharma Ltd.	3,015.75	4.31%	3,734.03	5.46%	4,813.41	6.16%	6,901.14	7.71%	7,802.05	8.09%
Sun pharma Industries Ltd.	3,997.33	5.72%	3,963.13	5.80%	4,658.61	5.96%	5,503.67	6.15%	5,716.71	5.93%
Bharat Serums	4,354.94	6.23%	3,717.68	5.44%	4,278.43	5.47%	4,857.45	5.42%	5,256.18	5.45%
(Zydus cadila)	3,059.12	4.37%	2,928.71	4.29%	3,387.69	4.33%	4,543.38	5.07%	4,665.13	4.84%
Pfizer Ltd.	3,375.58	4.83%	3,850.01	5.63%	4,122.40	5.28%	4,351.88	4.86%	4,473.41	4.64%
Abbott India Ltd.	4,758.07	6.80%	4,129.75	6.04%	4,275.73	5.47%	4,289.41	4.79%	3,972.08	4.12%
Lupin Ltd.	2,162.01	3.09%	2,098.99	3.07%	2,417.90	3.09%	2,931.02	3.27%	3,264.28	3.38%
Franco Indian pharmaceuticals Pvt Ltd	2,719.25	3.89%	3,029.01	4.43%	3,239.69	4.15%	3,041.74	3.40%	3,221.86	3.34%
Intas pharmaceuticals Ltd.	1,414.01	2.02%	1,357.34	1.99%	1,707.88	2.19%	2,120.57	2.37%	3,057.30	3.17%

Source: AIOCD AWACS, CRISIL MI&A

Key Observations

- As of MAT September 2023 sales, Emcure is the largest player in the gynaecology therapy area in the IPM with market share of (13.08%). Emcure's market share (13.08%) in Gynaecology therapy area is 1.6 times the next largest player (Market share of 8.09%) as of MAT September 2023.

Emcure domestic formulation Sales – specific molecule

Therapy Area	Molecule	Indication	SEPT MAT23 Emcure sales (Rs. Mn)	SEPT MAT 23 total IPM sales (Rs. Mn)	# of peers in India (MAT Sep 23)^	Market Share of Emcure				Market Rank of Emcure			# of brands of Emcure in molecule MAT sep 23
						MAT SEP 19	MAT SEP 23	FY23	CUMM APR-SEP 23	MAT SEP 19	MAT SEP 23	FY23	
Cardio-vascular	Tenecteplase	Tissue plasminogen activator	1,213.35	1,381.08	1	93.08%	87.86%	90.81%	86.43%	1	1	1	2
Nephrology	Epoetin alfa	Erythropoietin products	631.47	4,715.64	8	9.00%	13.39%	13.34%	13.85%	3	3	3	3
Oncology	Filgrastim	Colony-stimulating factors	87.24	1,047.46	2	5.51%	8.33%	7.97%	7.68%	5	3	3	3
Oncology	Pegfilgrastim	Colony-stimulating factors	67.38	913.16	3	6.59%	7.38%	9.15%	6.00%	5	4	4	1
Critical care	Tacrolimus	Immuno-suppressant, calcineurin inhibitor and antibacterial + antifungal +	249.56	2,522.67	5	3.46%	9.89%	6.43%	12.28%	7	3	4	1

Therapy Area	Molecule	Indication	SEPT MAT23 Emcure sales (Rs. Mn)	SEPT MAT 23 total IPM sales (Rs. Mn)	# of peers in India (MAT Sep 23)^	Market Share of Emcure				Market Rank of Emcure			# of brands of Emcure in molecule MAT sep 23
						MAT SEP 19	MAT SEP 23	FY23	CUMM APR-SEP 23	MAT SEP 19	MAT SEP 23	FY23	
		antiflammatory											
Gynaecological	Dydrogesterone	Progestin only pills (pops), oestrogen with progestogen and progestogens local applications	1,077.18	8,590.64	15	NA	12.54%	14.15%	11.24%	-	3	3	3
Anti-neoplastics	Eribulin	Microtubule inhibitor	11.85	13.14	1*	100.00%	90.19%	65.69%	99.28%	1	1	1	1
Cardiovascular	S-metoprolol	Beta-blocking agents, beta-blocker + calcium antagonist and arb + beta-blocker	1,083.66	1,178.12	1	88.15%	91.98%	91.15%	92.13%	1	1	1	2
Cardiovascular	S-amlodipine	Calcium antagonist	1,579.39	1,781.67	2	88.41%	88.65%	88.65%	88.49%	1	1	1	3
Gynaecological	Ferric carboxymaltose	Plain iron	2,600.14	4,022.30	4	76.99%	64.64%	69.25%	63.71%	1	1	1	6
Anti-neoplastic	Treosulfan	Alkylating agents -	1.21	1.21	1**	100.00%	100.00%	100.00%	100.00%	1	1	1	1
Cardiovascular	Ibutilide	Class iii anti-arrhythmics	1.99	1.99	1**	100.00%	100.00%	100.00%	100.00%	1	1	1	1
Gynaecological	Ferrous ascorbate	Plain Iron	0.87	0.87	1**	NA	100.00%	NA	100.00%	1	1	1	1
Pain / Analgesics	Etodolac	NSAID	544.64	1,098.51	11	45.95%	49.58%	48.08%	50.38%	1	1	1	2

Note: ^- Number of peers are filtered by indicating peers with sales of greater than Rs. 50 million in a molecule group for MAT Sep 2023 and excludes Emcure to arrive at the count.

Emcure's number of brands in molecule are on individual brand level

*- Only 2 peers are present with sales of greater than zero hence threshold of Rs.50 million not applied

** - Only 1 peer is present with sales of greater than zero hence threshold of Rs.50 million not applied

Source: AIOCD AWACS, CRISIL MI&A

Key Observations

- Emcure has a portfolio of molecules across complex injectables including lipid, liposomal and lyophilised injectables along with presence in biotherapeutic areas. In terms of sales in IPM each of the molecule listed in the table above is ranked in top-4 as of MAT September 2023.
- In several chiral molecules (S-metoprolol, S-amlodipine, Etodolac) and Iron combination products Emcure had the highest market share in the IPM for MAT September 2023.

Prescription data for some of the key players in the Indian domestic formulation industry MAT October 2023

Company Name	Share	
	Specialist Share	GP Share
Total IPM	58.95%	41.05%
Mankind Pharma Ltd.	52.30%	47.70%
Sun pharma Industries Ltd.	66.77%	33.23%
Alkem Laboratories Ltd.	58.42%	41.58%
Cipla Ltd.	61.79%	38.21%
Dr. Reddy's Laboratories Ltd.	58.72%	41.28%
Abbott India Ltd.	60.81%	39.19%
Macleods Pharmaceuticals Ltd.	58.71%	41.29%
Aristo pharmaceuticals Pvt.Ltd.	55.67%	44.33%
Torrent Pharmaceuticals Ltd.	69.74%	30.26%
(Zydus cadila)	59.70%	40.30%
Intas pharmaceuticals Ltd.	65.63%	34.37%
Emcure Pharmaceuticals Ltd.	70.29%	29.71%

Rx-Prescription, GPs- General practitioners

Source: CMARC, CRISIL MI&A

Key Observations

- Emcure has specialist prescription share of 70.29% as of MAT October 2023 which was highest among the key top-20 players in IPM.

Prescriber penetration for Emcure vs Some of the key players in IPM for July-October 2023 period

Company Name	Number of products used per prescriber	Penetration in prescribers(%)
Sun pharma Industries Ltd.	10	34.40%
Mankind Pharma Ltd.	9	30.20%
Alkem Laboratories Ltd.	6	38.10%
Cipla Ltd.	8	27.80%
Abbott India Ltd.	7	30.30%
Dr. Reddy's Laboratories Ltd.	6	29.10%
Torrent Pharmaceuticals Ltd.	7	27.10%
Macleods Pharmaceuticals Ltd.	6	28.00%
Aristo pharmaceuticals Pvt.Ltd.	6	25.50%
(Zydus cadila)	5	30.20%
Intas pharmaceuticals Ltd.	6	23.20%
Emcure Pharmaceuticals Ltd.	5	17.30%

Source: CMARC, CRISIL MI&A

Key Observations

- For the period July to October 2023, Emcure has 17.30% of prescribers prescribe more than 5 products compared to majority (9 out of 11) of the peers above where more than 25% of the prescribers prescribe for more than 6 products.

Sales split across regional zones for Emcure Vs total IPM

Regional zone	Emcure						Total IPM					
	MAT Sept 2019 Sales Share (%)	MAT Sept 2020 Sales Share (%)	MAT Sept 2021 Sales Share (%)	MAT Sept 2022 Sales Share (%)	MAT Sept 2023 Sales Share (%)	CAGR MAT Sep19-MAT Sep23	MAT Sept 2019 Sales Share (%)	MAT Sept 2020 Sales Share (%)	MAT Sept 2021 Sales Share (%)	MAT Sept 2022 Sales Share (%)	MAT Sept 2023 Sales Share (%)	CAGR MAT Sep19-MAT Sep23
All India only	13.15%	15.78%	17.27%	19.34%	19.02%	21.51%	6.60%	6.30%	6.07%	5.50%	5.65%	4.13%
East Zone	21.14%	21.36%	22.04%	21.06%	23.28%	13.51%	19.39%	20.18%	21.01%	21.08%	21.75%	11.40%
North Zone	16.45%	15.69%	15.36%	15.45%	15.15%	8.55%	25.78%	25.33%	25.17%	25.29%	25.65%	8.10%
South Zone	21.34%	21.61%	21.41%	22.23%	20.46%	9.65%	26.02%	26.41%	25.80%	27.08%	26.55%	8.78%
West Zone	27.92%	25.55%	23.92%	21.93%	22.09%	4.50%	22.22%	21.77%	21.95%	21.04%	20.39%	5.93%

Note: "All India only" is used in relation to the sale of products in certain niche businesses such as oncology or nephro science, whereby due to the relatively small number of distributors that distribute such products, it would be misleading to instead categorize the sale of such products across geographic regional zones.

Source: AIOCD, CRISIL MI&A

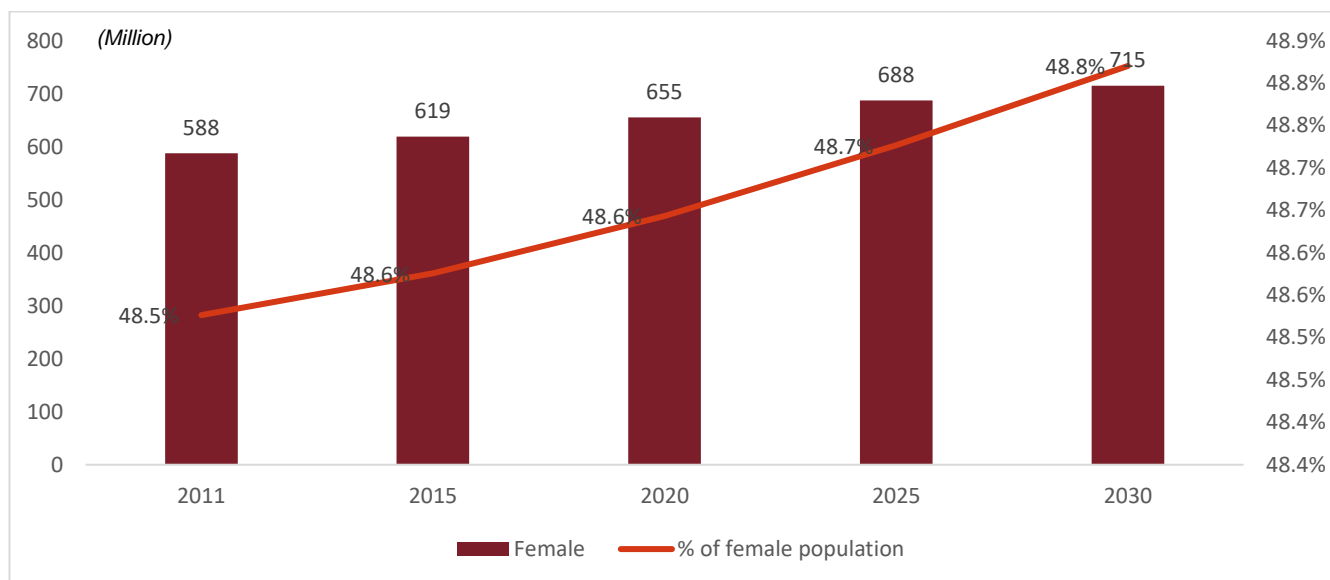
Overview of Women's health parameters in India

Women's population in India have increased steadily in the past few years, life expectancy also seen improvement

With changing socio-economic factors, the share of women in total population of India have risen steadily over the years. Women in India constitutes almost 49% of the overall population and share of women in the total population have been on the rise and expected to gradually rise in the future. Also, life expectancy for females in India is higher than males with average female living 3 years longer than males as per United Nations report.

From financial inclusion to social security, quality healthcare to education, women in India are now being put forward in nation's overall growth story.

Overview of female population trend in India



Source: Ministry of family welfare, CRISIL MI&A

Overview of life expectancy in India (2021)

Particulars	Life expectancy years
Male	66
Female	69
Total	67

Source: United Nations Population Division. World Population Prospects: 2022, CRISIL MI&A

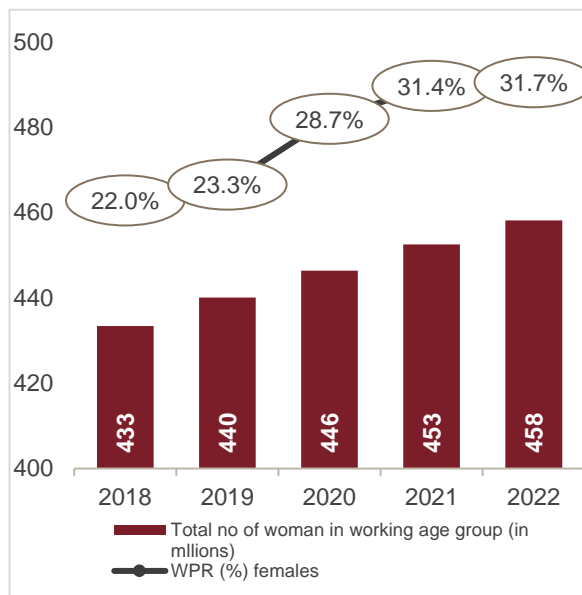
Working population and employment for women show constant increase

Female worker population ratio (WPR) in India has been steadily increasing since 2018. In 2018, the WPR was 22.0% which has increased to 31.7% in 2022. The total number of women in the working age group (15-64 years old) has also been increasing over the same period from 433.4 million women in 2018 to 458.2 million in 2022. This increase in female WPR can be positively contributed to number of factors like, changing social attitude towards working women, increased educational attainment among women and higher disposable income of households. Overall, the data reflects a positive trend in female workforce participation, with incremental improvements in the WPR over the years.

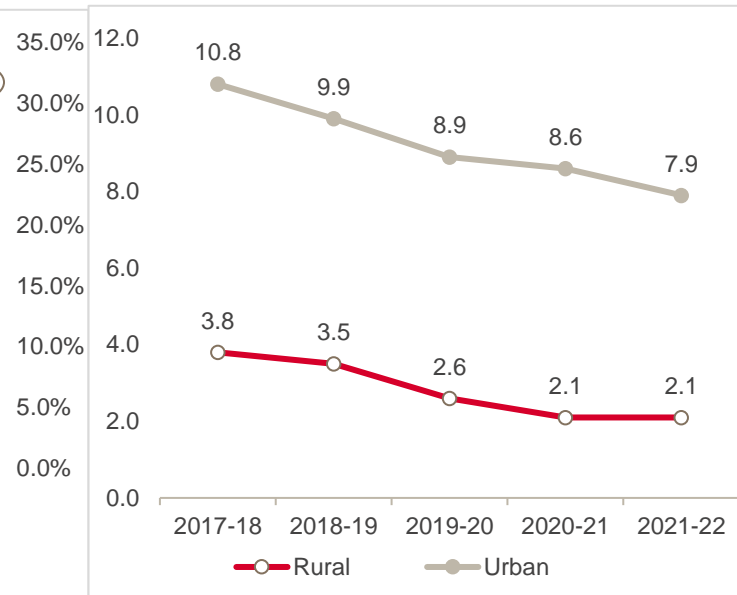
Unemployment rate for women in India has been declining in recent years, both in rural and urban areas. In rural areas, the unemployment rate has fallen from 3.8% in 2017-18 to 2.1% in 2021-22, while in urban areas, the

unemployment rate has fallen from 10.8% in 2017-18 to 7.9% in 2021-22. This decline in unemployment rate can be attributed to number of factors including increased education and employment opportunities for woman, changing social norms and increasing disposable income.

Worker population ratio for women



Unemployment rate of females (Rural and Urban)



Source: Periodic Labour Force Survey, National Statistical Office, Ministry of Statistics and Programme Implementation, CRISIL MI&A

More women are seeking healthcare services like hospital treatments, quality medicines etc. for maternal health

Increased education and healthcare awareness among female population of India have resulted in more women accessing healthcare services for maternal health. Rising disposable income as well as changing social norms have brought about this change where it has become a norm for women to visit and access different healthcare services like hospitals, medicines etc for maternal health.

Maternal health related parameters

Particulars	2015-16	2020-21
Mothers who had an antenatal check-up in the first trimester (%)	58.6	70.0
Women who have comprehensive knowledge of HIV/AIDS (%)	20.9	21.6
Institutional births (%)	78.9	88.6
Mothers who consumed iron folic acid for 100 days or more when they were pregnant (%)	30.3	44.1
Children age 12-23 months fully vaccinated (%)	62.0	76.4

Source: National Family Health Survey, CRISIL MI&A

Gynaecology therapy area in Indian pharmaceutical market have shown healthy growth over the years

There is still a lot of potential for women’s healthcare in India with awareness among female population for treatments of various diseases. Gynaecology medications as well as some of the nutraceuticals used in women’s health thus have seen increased demand in recent years. Gynaecology therapy area have seen the traction in recent years and have marginally outperformed the overall Indian domestic formulation market in terms of growth from September 2019 to September 2023. This can be attributed to rise in alertness regarding well-being and health in the Indian female population which in turn has resulted in a rise in the demand for gynaecological therapies. More women are seeking medical help for gynaecological diseases leading to greater penetration of the gynaecological drugs in the Indian domestic formulation market. This shows that Women’s healthcare industry especially gynecology in India is a growing market with tailwinds such as improved access and awareness in Women’s healthcare.

Overview of Gynaecology therapy area in Indian domestic market

Particulars	MAT Sep 2019	MAT Sep 2020	MAT Sep 2021	MAT Sep 2022	MAT Sep 2023	MAT Sep19- MAT Sep23 CAGR
Total IPM gynaecology market (Rs. million)	69,944.34	68,332.36	78,149.68	89,547.45	96,435.61	8.36%
Total IPM market (Rs. million)	1,380,959.18	1,432,262.37	1,653,544.02	1,762,870.89	1,895,010.42	8.23%
Share of Gynaecology market in total IPM market (Rs. million)	5.06%	4.77%	4.73%	5.08%	5.09%	-

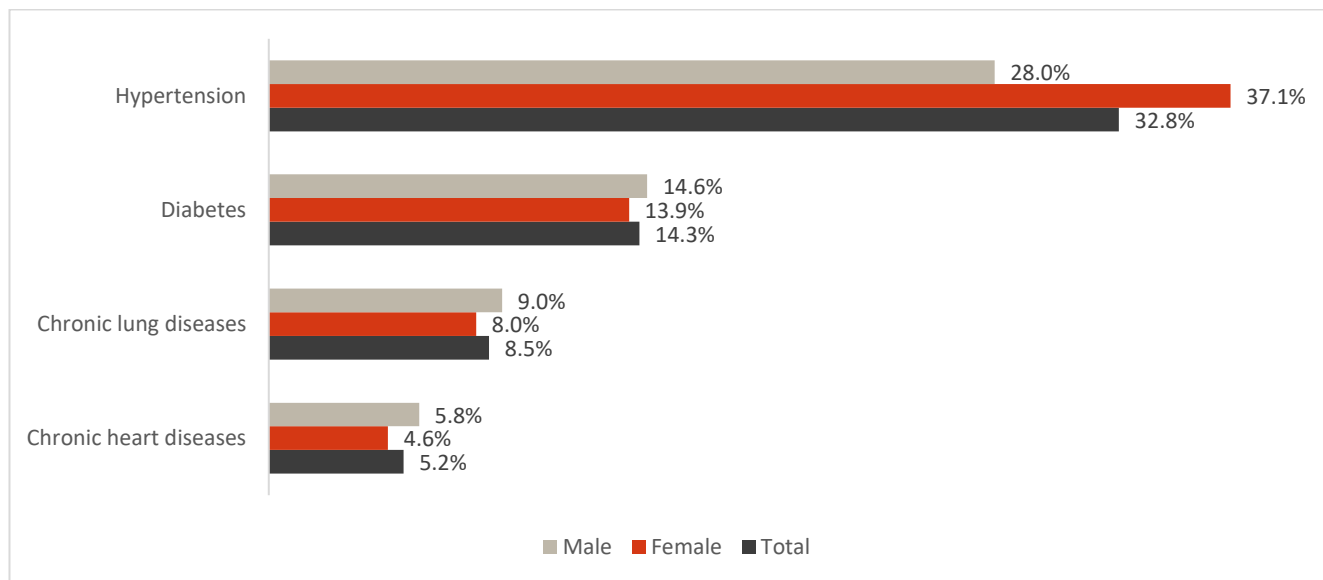
Note: IPM: Indian Pharmaceutical market, MAT-Moving annual total

Source: AIOCD AWACS, CRISIL MI&A

Prevalence of chronic disease like diabetes, blood pressure and cancer show need of quality healthcare for women

Women should be given equal prominence in terms of access to healthcare services like hospitals and medicines. Prevalence of chronic diseases in male and female population is similar and in fact some of the chronic diseases like hypertension, the prevalence is higher in females. Also, breast cancer and cervical cancer remain the most common cancer among women in India. According to the Indian Council of Medical Research, an estimated 87,000 women died from breast cancer in India in 2020. This highlights the urgent need to improve access to quality healthcare services for women in the country.

Comparison of key health indicators for women’s health(Prevalence of major diseases)



Source: International Institute for Population Sciences, CRISIL MI&A

Women still spend lesser on healthcare services compared to men, indicating potential for growth in healthcare spend among women

Women in India spend lesser on healthcare services as indicated by the average spend on healthcare services per hospitalization case. Women in India spend ~70% of the total spend incurred by men. This indicates a gap and further potential for growth in healthcare spend for women.

Average spend on healthcare services per hospitalization case

Particulars	Average spend on healthcare services (Rs.)
Male	18,643
Female	13,069
Total	15,937

Source: National Health profile 2022, CRISIL MI&A

Financial overview

Financial snapshot key competitors considered

Company name	Operating income				OPBDIT			
	FY21	FY22	FY23	CAGR FY21- FY23	FY21	FY22	FY23	CAGR FY21- FY23
Abbott India Limited	43,100.20	49,145.90	53,493.70	11.41%	9,191.40	10,828.50	12,062.70	14.56%
Alkem Laboratories Limited	88,686.90	106,433.00	116,115.90	14.42%	19,955.20	20,645.80	16,363.10	-9.45%
Cipla Limited	192,471.60	218,333.20	228,128.70	8.87%	43,692.20	46,035.60	51,151.10	8.20%
Dr. Reddy's Laboratories Limited	190,763.00	215,452.00	252,986.00	15.16%	47,040.00	39,506.00	73,200.00	24.74%
Emcure Pharmaceuticals Limited*	50,334.74	58,553.87	59,858.11	9.05%	12,193.14	13,666.86	12,001.97	-0.79%
J. B. Chemicals & Pharmaceuticals Limited	20,769.57	24,165.66	31,452.44	23.06%	5,994.82	5,432.37	6,961.18	7.76%
Mankind Pharma Limited	62,655.53	78,213.39	88,115.78	18.59%	17,037.82	20,429.18	19,731.88	7.62%
Torrent Pharmaceuticals Limited	80,217.20	85,058.50	96,188.00	9.50%	25,154.60	25,986.20	28,226.20	5.93%

Note:

- Financials above are as per CRISIL MI&A research standards
- OPBDIT: operating profit before depreciation, interest and taxes, PAT: profit after tax
- The list of competitors above is an indicative list and not an exhaustive list
- *-Data as per restated consolidated financials provided by the company

Source: Company filings, CRISIL MI&A

Financial snapshot key competitors considered

Company name	PAT				Tangible Network			
	FY21	FY22	FY23	CAGR FY21- FY23	FY21	FY22	FY23	CAGR FY21- FY23
Abbott India Limited	6,906.90	7,987.00	9,494.10	17.24%	26,009.90	28,111.60	31,810.20	10.59%
Alkem Laboratories Limited	16,159.10	16,803.20	10,068.10	-21.07%	70,781.80	83,720.50	89,424.10	12.40%
Cipla Limited	23,871.40	25,452.90	28,318.80	8.92%	137,500.40	162,765.90	191,995.40	18.17%
Dr. Reddy's Laboratories Limited	19,516.00	21,825.00	45,073.00	51.97%	135,570.00	159,686.00	196,663.00	20.44%
Emcure Pharmaceuticals Limited*	6,072.52	7,025.56	5,618.45	-3.81%	15,873.18	17,353.89	23,061.12	20.53%
J. B. Chemicals & Pharmaceuticals Limited	4,485.23	3,860.39	4,100.05	-4.39%	17,238.66	14,097.59	11,006.12	-20.10%

Mankind Pharma Limited	12,930.35	14,529.57	13,096.76	0.64%	48,388.04	44,398.80	58,448.53	9.91%
Torrent Pharmaceuticals Limited	12,496.90	7,749.90	12,438.80	-0.23%	15,119.10	21,474.10	7,710.60	-28.59%

Note:

- Financials above are as per CRISIL MI&A research standards
- OPBDIT: operating profit before depreciation, interest and taxes, PAT: profit after tax
- The list of competitors above is an indicative list and not an exhaustive list
- *-Data as per restated consolidated financials provided by the company

Source: Company filings, CRISIL MI&A

Financial ratios of key competitors (fiscal 2023)

Company name	Operating profit margin (%)	Net profit margin (%)	RoCE (%)	ROE (%)	Gearing ratio	Current ratio	Asset turnover ratio	Working capital days
Abbott India Limited	22.55	17.75	43.29	31.69	0.00	2.51	13.28	-31
Alkem Laboratories Limited	14.09	8.67	15.19	11.63	0.15	2.28	3.32	78
Cipla Limited	22.42	12.41	22.82	15.97	0.03	3.39	2.39	65
Dr. Reddy's Laboratories Limited	28.93	17.82	32.36	25.30	0.07	2.37	1.88	111
Emcure Pharmaceuticals Limited*	20.05	9.39	23.47	27.80	0.95	1.24	2.15	31
J. B. Chemicals & Pharmaceuticals Limited	22.13	13.04	36.70	32.66	0.50	2.77	2.72	57
Mankind Pharma Limited	22.39	14.86	30.14	25.47	0.03	1.75	3.16	-22
Torrent Pharmaceuticals Limited	29.34	12.93	36.37	85.24	6.93	0.98	2.09	-22

Note:

The list of competitors above is an indicative list and not an exhaustive list

ratios calculated as per CRISIL MI&A research standards are described below:

OPBDIT margin = OPBDIT/Operating income

Net profit margin = Profit after tax/Operating income

RoCE = Profit before interest and tax (PBIT)/ (Average total debt + average tangible networth + average deferred tax liability)

ROE = PAT/ Average tangible net worth

Gearing ratio = Total debt/Tangible net worth

Current ratio = Current assets/Current liabilities

Asset turnover ratio = Operating income/Average gross block

Working capital days = Inventory days + Debtors days - Creditors days

*-Data as per restated consolidated financials provided by the company

Source: Company filings, CRISIL MI&A

Key Observations

- Emcure has operating income of Rs. 59,858.11 million in fiscal 2023 and Net profit of Rs 5,618.45 million in fiscal 2023.
- For fiscal 2023, Return on Equity ratio for Emcure (27.80%) is in line with the peer set considered in IPM.

Financial ratios of key competitors (fiscal 2022)

Company name	Operating profit margin (%)	Net profit margin (%)	RoCE (%)	ROE (%)	Gearing ratio	Current ratio	Asset turnover ratio	Working capital days
Abbott India Limited	22.03	16.25	40.71	29.52	0.00	3.21	12.54	-35
Alkem Laboratories Limited	19.40	15.79	21.90	21.75	0.31	1.73	3.15	93
Cipla Limited	21.09	11.66	22.14	16.95	0.05	3.01	2.42	65
Dr. Reddy's Laboratories Limited	18.34	10.13	18.89	14.78	0.20	1.79	1.76	116
Emcure Pharmaceuticals Limited*	23.34	12.00	30.44	42.29	1.20	1.12	2.21	16
J. B. Chemicals & Pharmaceuticals Limited	22.48	15.97	31.07	24.64	0.02	3.36	2.18	68
Mankind Pharma Limited	26.12	18.58	38.88	31.32	0.20	1.68	3.58	-29
Torrent Pharmaceuticals Limited	30.55	9.11	24.97	42.36	1.89	1.21	1.90	-18

Note:

The list of competitors above is an indicative list and not an exhaustive list

ratios calculated as per CRISIL MI&A research standards are described below:

OPBDIT margin = OPBDIT/Operating income

Net profit margin = Profit after tax/Operating income

RoCE = Profit before interest and tax (PBIT)/ (Average total debt + average tangible net worth + average deferred tax liability)

ROE = PAT/ Average tangible net worth

Gearing ratio = Total debt/Tangible net worth

Current ratio = Current assets/Current liabilities

Asset turnover ratio = Operating income/Average gross block

Working capital days = Inventory days + Debtors days - Creditors days

*-Data as per restated consolidated financials provided by the company

Source: Company filings, CRISIL MI&A

Financial ratios of key competitors (fiscal 2021)

Company name	Operating profit margin (%)	Net profit margin (%)	RoCE (%)	ROE (%)	Gearing ratio	Current ratio	Asset turnover ratio	Working capital days
Abbott India Limited	21.33	16.03	37.92	27.45	0.00	3.44	11.42	-18
Alkem Laboratories Limited	22.50	18.22	26.80	25.07	0.24	1.88	2.86	81
Cipla Limited	22.70	12.40	23.18	19.12	0.13	2.88	2.28	80
Dr. Reddy's Laboratories Limited	24.66	10.23	20.58	15.02	0.22	1.80	1.67	113
Emcure Pharmaceuticals Limited*	24.22	12.06	28.84	45.34	1.46	1.07	2.10	64
J. B. Chemicals & Pharmaceuticals Limited	28.86	21.60	37.31	29.14	0.02	4.58	1.92	60

Mankind Pharma Limited	27.19	20.64	39.01	30.49	0.05	2.87	3.16	-18
Torrent Pharmaceuticals Limited	31.36	15.58	33.02	154.28	3.23	1.14	1.88	-89

Note:

The list of competitors above is an indicative list and not an exhaustive list

ratios calculated as per CRISIL MI&A research standards are described below:

$OPBDIT\ margin = OPBDIT / Operating\ income$

$Net\ profit\ margin = Profit\ after\ tax / Operating\ income$

$RoCE = Profit\ before\ interest\ and\ tax\ (PBIT) / (Average\ total\ debt + average\ tangible\ networth + average\ deferred\ tax\ liability)$

$ROE = PAT / Average\ tangible\ net\ worth$

$Gearing\ ratio = Total\ debt / Tangible\ net\ worth$

$Current\ ratio = Current\ assets / Current\ liabilities$

$Asset\ turnover\ ratio = Operating\ income / Average\ gross\ block$

$Working\ capital\ days = Inventory\ days + Debtors\ days - Creditors\ days$

*-Data as per restated consolidated financials provided by the company

Source: Company filings, CRISIL MI&A

Financial snapshot key competitors considered (H1FY2024, 6 months Ended September 2023)

Company Name	Operating income		PAT	
	Rs million	y-o-y growth	Rs million	y-o-y growth
Abbott India Limited	29,731.40	10.78%	6,031.80	28.02%
Alkem Laboratories Limited	64,078.90	13.30%	9,027.00	88.39%
Cipla Limited	130,070.40	16.10%	21,534.40	43.22%
Dr. Reddy's Laboratories Limited	136,605.00	18.12%	28,872.00	25.36%
Emcure Pharmaceuticals Limited*	32,192.51	15.34%	2,868.01	31.26%
J. B. Chemicals & Pharmaceuticals Limited	17,779.40	11.52%	2,929.00	35.43%
Mankind Pharma Limited	52,867.16	14.78%	10,053.65	39.58%
Torrent Pharmaceuticals Limited	52,510.00	0.00%	7,640.00	14.71%

Note:

- Financials above are as per CRISIL MI&A research standards.
- The list of competitors above is an indicative list and not an exhaustive list
- *-Data as per restated consolidated financials provided by the company

Source: Company filings, CRISIL MI&A

Financial parameters for listed players

CRISIL has compared the financial parameters for some of the listed players from the pharmaceutical industry in India for peer comparison and financial parameters are presented in below tables

FY2023	Adjusted EBITDA (Rs million)	Adjusted EBITDA Margin (%)	Return on Equity and net debt (%)	Domestic Revenue (Rs million)	International Revenue (Rs million)	Share of domestic revenue (%)	Share of international revenue (%)
Abbott Limited India	13,597.80	24.71%	1013.84%	52,145.70	702.90	98.67%	1.33%
Alkem Laboratories Limited	18,255.30	15.45%	19.26%	81,599.70	34,392.90	70.35%	29.65%
Cipla Limited	54,998.20	23.68%	20.55%	98,686.70	128,844.50	43.37%	56.63%
Dr. Reddy's Laboratories Limited	74,415.00	28.93%	27.32%	50,499.00	195,380.00	20.54%	79.46%
Emcure Pharmaceuticals Limited*	12,270.87	20.34%	22.12%	31,818.18	28,039.93	53.16%	46.84%
J. B. Chemicals & Pharmaceuticals Limited	7,056.93	22.34%	20.12%	16,396.46	15,096.37	52.06%	47.94%
Mankind Pharma Limited	20,416.28	23.00%	23.66%	84,470.20	2,958.30	96.62%	3.38%
Torrent Pharmaceuticals Limited	28,871.90	29.87%	20.12%	52,948.40	41,688.50	55.95%	44.05%

Note: The financial parameters above are not reclassified by CRISIL and taken as reported by players hence comparison should not be made with the tables in the rest of the competitive section.

Financials for all the players are on consolidated level

The financial parameters are calculated as described below:

Adjusted EBITDA = Earnings Before Interest, Taxes, Depreciation, and Amortization (Inclusive of exceptional items)

Adjusted EBITDA margin = Adjusted EBITDA / Revenue from operations

Return on equity and net debt = Earnings before interest and tax (EBIT) inclusive of exceptional items / [Total equity + Net debt (Net of cash & cash equivalents, long term and short term deposits)]

*-Data as per restated consolidated financials provided by the company

Source: Company filings, CRISIL MI&A

FY2022	Adjusted EBITDA (Rs million)	Adjusted EBITDA Margin (%)	Return on Equity and net debt (%)	Domestic Revenue (Rs million)	International Revenue (Rs million)	Share of domestic revenue (%)	Share of international revenue (%)
Abbott Limited India	11,649.30	23.32%	1335.96%	48,184.00	919.00	98.13%	1.87%
Alkem Laboratories Limited	22,155.70	20.52%	23.40%	75,266.40	31,075.50	70.78%	29.22%

Cipla Limited	48,208.70	21.87%	19.65%	98,275.40	119,358.00	45.16%	54.84%
Dr. Reddy's Laboratories Limited	43,224.00	19.62%	16.05%	43,986.00	170,405.00	20.52%	79.48%
Emcure Pharmaceuticals Limited*	13,933.81	23.54%	29.55%	32,046.66	26,507.21	54.73%	45.27%
J. B. Chemicals & Pharmaceuticals Limited	5,826.82	23.65%	24.19%	11,881.78	12,360.66	49.01%	50.99%
Mankind Pharma Limited	21,998.30	27.58%	30.01%	75,947.40	1,868.10	97.60%	2.40%
Torrent Pharmaceuticals Limited	26,278.30	30.19%	20.67%	46,614.40	37,573.60	55.37%	44.63%

Note: The financial parameters above are not reclassified by CRISIL and taken as reported by players hence comparison should not be made with the tables in the rest of the competitive section.

Financials for all the players are on consolidated level

The financial parameters are calculated as described below:

Adjusted EBITDA = Earnings Before Interest, Taxes, Depreciation, and Amortization (Inclusive of exceptional items)

Adjusted EBITDA margin = Adjusted EBITDA/Revenue from operations

Return on equity and net debt = Earnings before interest and tax (EBIT) inclusive of exceptional items / [Total equity + Net debt (Net of cash & cash equivalents, long term and short term deposits)]

*-Data as per restated consolidated financials provided by the company

Source: Company filings, CRISIL MI&A

FY2021	Adjusted EBITDA (Rs million)	Adjusted EBITDA Margin (%)	Return on Equity and net debt (%)	Domestic Revenue (Rs million)	International Revenue (Rs million)	Share of domestic revenue (%)	Share of international revenue (%)
Abbott Limited India	10,022.60	22.83%	468.02%	42,232.20	843.70	98.04%	1.96%
Alkem Laboratories Limited	21,756.00	23.91%	26.30%	58,208.60	30,441.50	65.66%	34.34%
Cipla Limited	45,056.30	23.19%	18.21%	77,357.30	114,238.60	40.38%	59.62%
Dr. Reddy's Laboratories Limited	42,093.00	21.77%	16.33%	36,252.00	153,470.00	19.11%	80.89%
Emcure Pharmaceuticals Limited*(Consolidated continued operations)	12,501.57	24.67%	23.99%	25,101.29	25,233.45	49.87%	50.13%
Emcure Pharmaceuticals Limited*(Consolidated including discontinued operations)	12,673.63	20.80%	22.64%	24,648.92	35,915.23	40.70%	59.30%
J. B. Chemicals & Pharmaceuticals Limited	6,727.92	31.22%	33.25%	9,104.51	11,320.69	44.57%	55.43%
Mankind Pharma Limited	18,307.29	28.67%	38.95%	60,285.34	1,858.97	97.01%	2.99%
Torrent Pharmaceuticals Limited	25,369.90	31.69%	18.73%	39,982.20	38,880.10	50.70%	49.30%

Note: The financial parameters above are not reclassified by CRISIL and taken as reported by players hence comparison should not be made with the tables in the rest of the competitive section.

Financials for all the players are on consolidated level

The financial parameters are calculated as described below:

Adjusted EBITDA = Earnings Before Interest, Taxes, Depreciation, and Amortization (Inclusive of exceptional items)

Adjusted EBITDA margin = Adjusted EBITDA/Revenue from operations

Return on equity and net debt = Earnings before interest and tax (EBIT) inclusive of exceptional items/ [Total equity+ Net debt (Net of cash & cash equivalents, long term and short term deposits)]

**-Data as per restated consolidated financials provided by the company*

^-Data as per financials for consolidated operations. The financials represent consolidated view of the company's operations including its United States of America('US') market business was demerged during fiscal 2021 and was approved by NCLT (National Company Law Tribunal) on June 4,2021.

Source: Company filings, CRISIL MI&A

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