

Assessment of the Indian pharmaceuticals industry

June 2024



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1. Global macroeconomic assessment

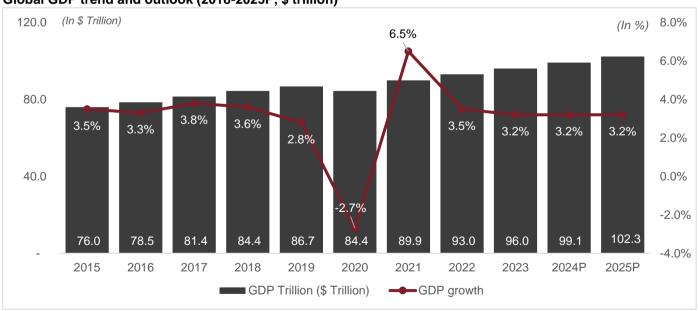
1.1 Global GDP outlook

Global GDP is estimated to grow at 3.2% in CY 2024 and CY 2025 amid moderating inflation and steady growth in key economies

As per the International Monetary Fund's (IMF) April 2024 update, global gross domestic product (GDP) growth is estimated at 3.2% for 2023 and projected to grow at the same rate in 2024, 2025 and 2026. The latest estimate for 2024 is 0.1 percentage points higher compared with IMF's previous forecast in January 2024, mainly due to greaterthan-expected resilience in the United States (US) and several large emerging markets and developing economies, as well as fiscal support in China. Emerging market and developing economies are also expected to experience stable growth through 2024 and 2025, with regional differences.

With disinflation and steady growth, the likelihood of a hard landing has receded, and risks to global growth are broadly balanced. Amid favourable global supply developments, inflation has been falling faster than expected. On the upside, faster disinflation could lead to further easing of financial conditions. On the downside, new commodity price spikes from geopolitical shocks and supply disruptions or more persistent underlying inflation could prolong tight monetary conditions. Property sector distress in China or, elsewhere, a disruptive turn to tax hikes and spending cuts could also lead to moderation in growth in the near term.





Note: E: Estimated, P: Projection

Source: IMF economic database, CRISIL Market Intelligence and Analytics (MI&A)

India among the world's fastest-growing key economies

Following the recovery from the COVID-19 pandemic, India exhibited a faster growth rate of 7.2% in FY23, surpassing both advanced economies at 2.6% and emerging and developing economies at 4.1%. This trend is expected to continue, with India leading the growth compared to its key counterparts.



United States: In the United States, growth is projected to shift from 2.5% in 2023 to 2.7% in 2024 and 1.9% in 2025, with the lagged effects of monetary policy tightening, gradual fiscal tightening, and a softening in labour markets slowing the aggregate demand.

United Kingdom: Growth in the United Kingdom is projected to rise modestly from an estimated 0.1% in 2023 to 0.5% in 2024, due to lagged negative effects of high energy prices wane. Then in 2025, as disinflation allows an easing in financial conditions and permits real incomes to recover, the economy is expected to see a growth of 1.5%.

Euro zone: Growth in the euro area is projected to recover from 0.4% in 2023, which reflected relatively high exposure to the war in Ukraine, to 0.8% in 2024 and 1.5% in 2025. As per IMF estimates, the growth in is driven by strong household consumption as the energy prices subside and inflation falls, supporting the real income growth. Further, in recent years, the EU technology industry has faced disruptions due to currency fluctuations on account of fall in Euro and Pound against US dollar impacting the imports coupled with Russia-Ukraine war disrupting the supply chains which further impacted the sector.

In terms of **emerging and developing economies**, growth is projected to be relatively stable at 4.2% in 2024 and 2025, respectively.

Real GDP growth comparison among India vs Advanced and emerging economies

Real GDP growth (Annual % change)	2018	2019	2020	2021	2022	2023	2024P	2025P
Canada	2.7	1.9	-5.0	5.3	3.8	1.1	1.2	2.3
China	6.8	6.0	2.2	8.4	3.0	5.2	4.6	4.1
Euro Zone	1.8	1.6	-6.1	5.9	3.4	0.4	0.8	1.5
India*	6.5	3.9	-5.8	9.8*	7.0*	8.2*	6.8*	6.5
Japan	0.6	-0.4	-4.1	2.6	1.0	1.9	0.9	0.6
UK	1.4	1.6	-10.4	8.7	4.3	0.1	0.5	1.5
USA	3.0	2.5	-2.2	5.8	1.9	2.5	2.7	1.9
Advanced economies	2.3	1.8	-3.9	5.7	2.6	1.6	1.7	1.8
Emerging market and developing economies	4.7	3.6	-1.8	7.0	4.1	4.3	4.2	4.2
World	3.6	2.8	-2.7	6.5	3.5	3.2	3.2	3.2

Note: P: Projected. * Numbers for India are for financial year (2020 is FY21 and so on) and as per the IMF's forecast. ^India GDP estimate for the FY24 is 7.6% according to provisional estimates from MoSPI. Note: Projection as per IMF update

Source: IMF economic database, World Bank national accounts data, OECD national accounts data, c

India's per capita GDP grows faster than global average

Between 2018 and 2023, global per capita GDP clocked a CAGR of 3.1% and that of emerging markets and developing economies a higher 4.4%, according to the IMF. Meanwhile, India witnessed a higher per capita GDP CAGR of 4.8% during the same period.



GDP per capita, current prices (\$)

Regions	2018	2019	2020	2021	2022	2023	2024P	2025P	CAGR (2018-23)
Canada	46,618	46,431	43,573	52,521	55,613	53,548	54,866	57,021	2.8%
China	9,849	10,170	10,525	12,572	12,643	12,514	13,136	14,037	4.9%
Euro area	39,866	39,014	37,938	42,587	41,062	44,463	45,826	47,322	2.2%
India	1,974	2,050	1,916	2,250	2,366	2,500	2,731	2,984	4.8%
Japan	39,850	40,548	40,172	40,114	34,005	33,806	33,138	34,922	-3.2%
United States	63,165	65,505	64,367	70,996	77,192	81,632	85,373	87,978	5.3%
World	11,472	11,518	11,111	12,527	12,894	13,359	13,836	14,368	3.1%
India	1,974	2,050	1,916	2,250	2,366	2,500	2,731	2,984	4.8%

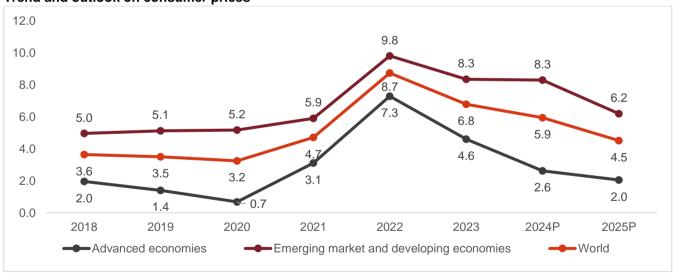
Notes: E - estimated; P - projected

Source: IMF, CRISIL MI&A

Global inflation to subside in the medium term

As per the IMF, global headline inflation is expected to decline from an estimated 6.8% in 2023 (annual average) to 5.9% in 2024 and 4.5% in 2025. In advanced economies, the decrease in 2024 is expected to be sharper at 2.0 percentage points to 2.6%. In emerging market and developing economies, though, it is projected to remain constant at around ~8.3%.

Trend and outlook on consumer prices



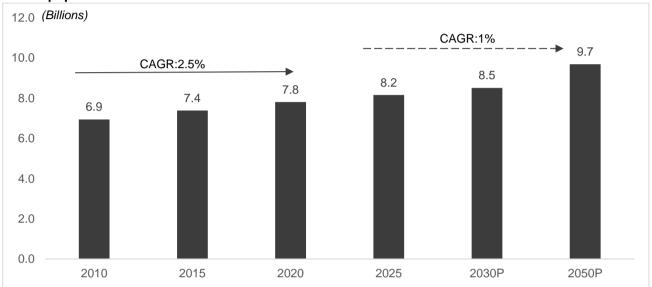
Notes: P – projected Source: IMF, CRISIL MI&A



Global population expected to reach 8.5 billion by 2030

Owning to 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.





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

2.1 Overview of healthcare spending

Global healthcare expenditure recorded a new high of US\$ 9.8 trillion, accounts for ~10% of global GDP

The pharmaceuticals industry is driven by a number of demographic and macroeconomic factors, such as lifestyle changes, which have led to more chronic diseases (diabetes, cancer and cardiovascular diseases); increased uptake of medicines owing to higher per capita income and awareness; wider spread and availability of health insurance; and population growth. These factors are expected to drive growth of the pharmaceuticals industry.

Global healthcare spending has been rising in sync with economic growth. As economy grows, public and private spending on health grows, too. Further, sedentary lifestyle has heightened the risk of chronic diseases, which is also raising healthcare spending. This is evident primarily in fast-growing economies. Furthermore, Covid-19 pandemic has also contributed to increased healthcare expenditure due to increasing focus on healthcare by the governments.

India's healthcare spending as a percentage of GDP increased

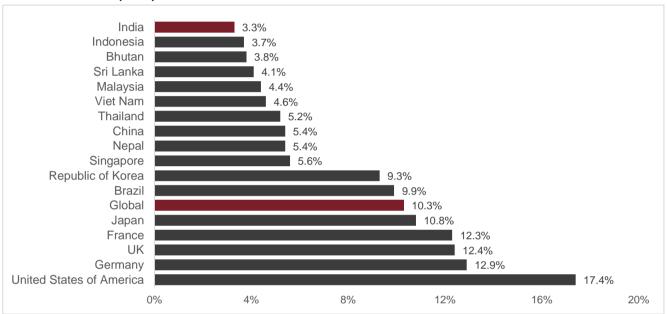
In 2021, healthcare expenditure as a percentage of GDP increased to 10.3% globally (~\$ 9.8 trillion), owing to prioritization of public health during the pandemic, availability of better medical facilities, advancements in medicine



and increase in disposable incomes. During the year, the US, Germany and UK recorded high current healthcare expenditure (CHE) as a percentage of GDP at 17.4%, 12.9% and 12.4% respectively.

India's CHE as a percent of GDP is much lower than that of its global peers. In 2021, India's expenditure on healthcare was 3.3% 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. However, India's CHE as a percentage of its GDP improved post onset of Covid to by ~3% percentage points, suggesting higher focus on healthcare.

CHE as % of GDP (2021)



Source: Global Health Expenditure Database of the World Health Organization (WHO), CRISIL MI&A

Additionally, it is to be noted that majority of countries have seen an uptick in their CHE as percentage GDP ratio post Covid, signifying increased focus on healthcare. Countries like USA, UK, and Canada saw a significant increase of 2.2, 2.1 and 2.0 percentage points respectively. Furthermore, even though share of CHE as percent of GDP had moderated in 2021, it still stands higher than the average ratio during pre-Covid (2017-2019) for most of the countries.

Current healthcare expenditure as a percentage of GDP (2021)

Country	Pre-Covid							
	2017	2018	2019	2020	2021			
USA	16.8	16.6	16.7	18.8	17.4			
Germany	11.3	11.5	11.7	12.7	12.9			
UK	9.6	9.7	10.0	12.2	12.4			
France	11.4	11.2	11.1	12.1	12.3			
Japan	10.7	10.7	11.0	11.0	10.8			
Brazil	9.5	9.5	9.6	10.2	9.9			
Republic of Korea	7.0	7.5	8.2	8.3	9.3			

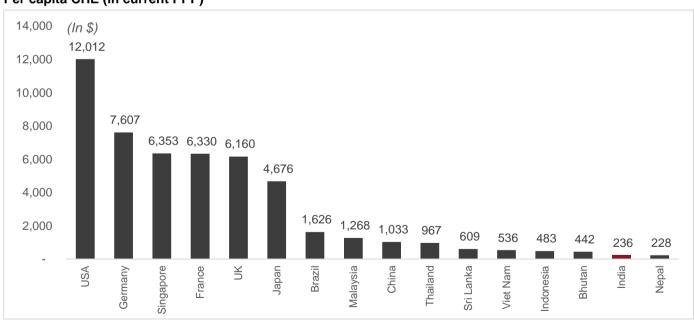


Country		Pre-Covid		Post- start of Covid		
	2017	2018	2019	2020	2021	
Singapore	4.4	4.1	4.4	5.7	5.6	
Nepal	4.7	4.5	4.4	5.2	5.4	
China	5.1	5.2	5.4	5.6	5.4	
Thailand	3.9	3.9	3.8	4.4	5.2	
Viet Nam	5.0	5.0	5.0	4.3	4.6	
Malaysia	3.7	3.8	3.8	4.1	4.4	
Sri Lanka	3.3	3.6	3.9	4.0	4.1	
Bhutan	3.3	3.2	3.6	4.4	3.8	
Indonesia	2.9	2.9	2.9	3.4	3.7	
India	2.9	2.9	3.0	3.3	3.3	

Source: Global Health Expenditure Database of the World Health Organization (WHO), CRISIL MI&A

In 2021, per capita CHE (at the international dollar rate, adjusted for purchasing power parity) for the US stood at ~\$12,012, for Germany at ~\$7,607 and for Canada at \$6,552 For India, it was considerably lower at \$236.

Per capita CHE (in current PPP)



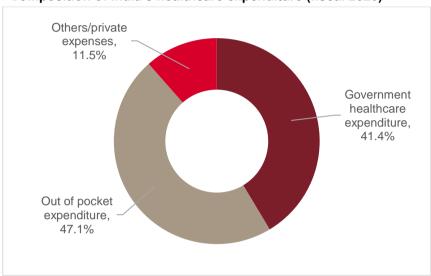
Source: Global Health Expenditure Database of the World Health Organization (WHO), CRISIL MI&A

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

Pharmaceutical expenditure constituted ~21% of healthcare spending in India in 2020

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.

Furthermore, it is observed that generally pharmaceutical spending as a percent of CHE is relatively higher in emerging economies compared to developed economies. In 2021, Egypt and Mexico had pharmaceutical spending as a percentage of CHE at 29.5%, and 22.1%, respectively. Similarly, India pharmaceutical spending as a percent of CHE stood at 21% in 2020, relatively higher compared to developed economies like USA, UK, Germany, etc.

Pharmaceuticals and Other medical durable goods, as % of Current Health Expenditure (CHE)

Countries	2017	2018	2019	2020	2021
Egypt	27.0	29.8	N.A.	31.9	29.5
Lebanon	9.3	9.3	25.5	24.6	24.4
Mexico	23.0	22.7	22.2	21.5	22.1
India	23.0	22.4	22.0	21.0	N.A.
Canada	16.4	15.9	15.8	14.2	13.8
Germany	14.2	14.2	13.7	13.6	13.9
Finland	12.2	12.4	12.4	12.3	11.3
USA	12.0	11.8	11.8	11.0	11.7
UK	11.8	11.3	11.0	10.6	9.5
UAE	3.5	3.8	3.8	8.6	9.7

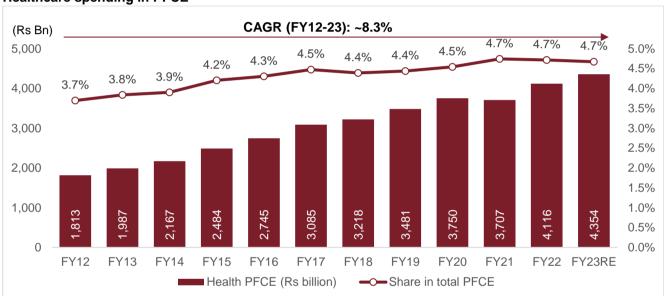
Source: Global Health Expenditure Database - WHO, World Bank database, OECD, CRISIL MI&A



Healthcare expenditure accounted for 4.7% of private consumption spending in FY23

Personal healthcare expenditure increased from Rs 1,813 billion in fiscal 2012 to Rs 4,354 billion in fiscal 2023, 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 ~6% CAGR between fiscals 2012 and 2023, considering the rise in prices of health products and services. Health expenditure as a percentage of total PFCE jumped to 4.7% in fiscal 2021, as healthcare spending rose because of the pandemic and has remained relatively constant till fiscal 2023.

Healthcare spending in PFCE



Source: MoSPI, CRISIL MI&A



2.2 Indian macroeconomic assessment

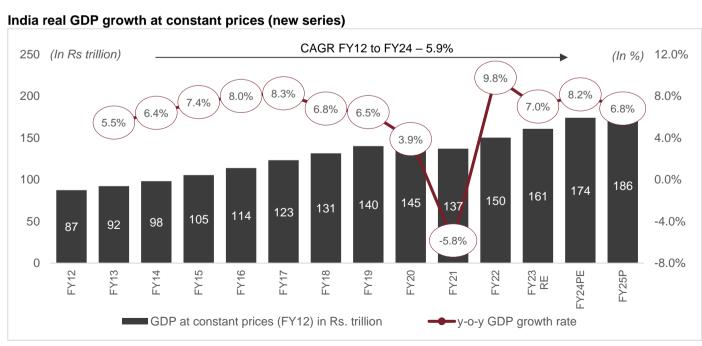
India's GDP grew at 5.9% CAGR between FY12 and FY24

India's GDP grew at 5.9% compounded annual growth rate (CAGR) between FY12 and FY24 to Rs 173.8 trillion in FY24. A large part of the lower growth rate was because of challenges heaped by the Covid-19 pandemic in FY20 and FY21. In FY22, the economy recovered with abating of the pandemic and subsequent easing of restrictions and resumption in economic activity.

In FY23, GDP rose 7% on continued strong growth momentum, propelled by investments and private consumption. The share of investments in GDP was at 33.3% and that of private consumption was at 58.0%.

The National Statistics Office (NSO) in its provisional estimates of Annua Gross Domestic Product (GDP) for FY24, estimated India's real GDP growth to be 8.2% which is higher than its Second Advanced Estimate of 7.6%. Even as the agricultural economy slowed sharply following a weak monsoon, the surge in non-agricultural economy has more than made up for it. The government's investment push, along with easing input cost pressures for industry, has also played a major role in shoring up growth. However, services have been slowing owing to waning pent-up demand (post the pandemic), with the exception of financial, real estate and professional services, which has powered ahead on the back of robust growth in banking and real estate sectors.

Analysis of the FY24 year's growth reveal notable dichotomies. Growth has primarily been fueled by fixed investments, exhibiting a robust 9% expansion, while private consumption growth lagged at 4%, trailing overall GDP growth. On the supply side, the manufacturing sector experienced the most substantial growth at ~9.9%, while the agriculture exhibited more modest growth rate of 1.4%. These trends underscore the varied performance across sectors, highlighting the nuanced dynamics shaping India's economic landscape in FY24. Overall, real GDP of India is estimated to have grown at 8.2% in FY24 compared with 7.0% in FY23.



RE - revised estimates, PE - Provision estimates, P - projection

Notes: The values are reported by the government under various stages of estimates



Actuals, estimates and projected data of GDP are provided in the bar graph

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

CRISIL forecasts India's GDP to grow 6.8% in FY25

After a strong GDP print in the past three fiscals, CRISIL expects GDP growth to moderate in FY25 as fiscal consolidation will reduce the fiscal impulse to growth, rising borrowing costs and increased regulatory measures could weigh on demand, net tax impact on GDP is expected to normalize, and exports could be impacted due to uneven growth in key trade partners and any escalation of the Red Sea crisis. On the other hand, another spell of normal monsoon and easing inflation could revive rural demand.

At an overall level, India's real GDP is expected to be 6.8% in FY25. This slower growth rate vs. FY24 will be because of slowing global growth, impact of rising interest rates, waning of pent-up demand for services and increasing geopolitical uncertainty. Still, the manufacturing sector, investments and domestic demand will remain resilient.

Robust growth in per capita income over FY12-24

India's per capita income, a broad indicator of living standards, rose from Rs 63,462 in FY12 to Rs 99,404 in FY23, logging 4.2% CAGR. Growth was led by better job opportunities, propped up by overall GDP growth. Moreover, population growth remained stable at ~1% CAGR. Furthermore, according to FY24PE, per capita net national income (constant prices) is estimated to have increased to Rs 106,774; thereby registering a year-on-year growth of ~7.4%.

Per capita net national income at constant prices

	FY12	FY13	FY14	FY15	FY16	FY17	FY18	FY19	FY20	FY21RE	FY22RE	FY23RE	FY24PE
Per-capita NNI (Rs)	63,462	65,538	68,572	72,805	77,659	83,003	87,586	92,133	94,270	86,054	94,054	99,404	106,744
Y-o-Y growth (%)		3.3	4.6	6.2	6.7	6.9	5.5	5.2	2.3	-8.7	9.3	5.7	7.4

Note: RE: revised estimates, PE - Provision estimates

Source: CSO, MoSPI, CRISIL MI&A

2.3 Demographic factors to support India's growth

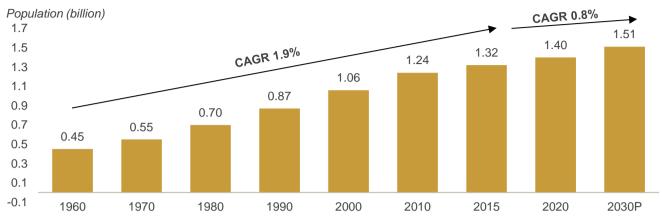
India's population projected to log 0.8% CAGR between 2020 and 2030

Census 2011 estimated India's population at ~1.2 billion, clocking a CAGR of 1.9% between 2001 and 2011. The number of households was estimated at ~246 million.

As per the United Nations Population Fund's (UNFPA) State of World Population Report of 2023, India's population by mid-2023 is estimated to have surpassed China by ~2.9 million.



India's population growth



Note: P: projected

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

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

iculari age trena 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

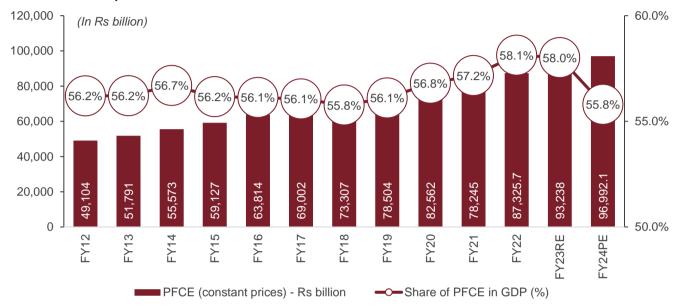
PFCE to maintain dominant share in India's GDP

Private final consumption expenditure (PFCE) at constant prices clocked 6% CAGR between FY12-23, maintaining its dominant share of ~58.0% in FY23 (~Rs 93,238 billion in absolute terms, up 6.8% year-on-year). Growth was led by healthy monsoon, wage revisions due to the implementation of the Seventh Central Pay Commission's (CPC) recommendations, benign interest rates, growing middle age population and low inflation. As of FY24PE, PFCE is



estimated to have further increased to Rs 96,992 billion, registering a y-o-y growth of ~4% and forming ~56% of India's GDP.

PFCE at constant prices



Note: RE: revised estimates; PE: Provisional estimates

Source: MoSPI, CRISIL MI&A

Healthy growth in GVA FY24 in line with GDP growth

As of FY24PE, GVA has reached to Rs 158.7 trillion, up from 148.0 trillion, registering a y-o-y growth of ~7.2%. Financial, Real Estate & Professional Services had the highest contribution to GVA at ~23.3%, whereas construction and manufacturing GVA had the registered the highest annual growth at ~9.9%.

GVA at constant prices

ova at constant prices									
Rs trillion	FY12	FY19	FY20	FY21	FY22	FY23 RE	FY24 PE	Share in GVA FY24	Annual growth in FY24
Agricultur e, forestry and fishing	15.0	18.8	19.9	20.7	21.7	22.7	23.0	14.5%	1.4%
Mining and quarrying	2.6	3.3	3.2	2.9	3.1	3.2	3.4	2.1%	7.1%
Manufact uring	14.1	23.3	22.6	23.3	25.6	25.0	27.5	17.3%	9.9%
Electricity , gas, water supply & other utility services	1.9	2.9	3.0	2.9	3.2	3.5	3.7	2.4%	7.5%
Construct ion	7.8	10.3	10.4	10.0	11.9	13.1	14.4	9.0%	9.9%



Trade, Hotels, Transport, Communi cation & Services related to Broadcas ting	14.1	25.4	26.9	21.5	24.8	27.8	29.6	18.6%	6.4%
Financial, Real Estate & Professio nal Services	15.3	27.1	29.0	29.5	31.2	34.1	36.9	23.3%	8.4%
Public Administr ation, Defence & Other Services	10.3	16.3	17.3	16.0	17.2	18.8	20.2	12.7%	7.8%
Total GVA at current prices	81.1	127.3	132.4	126.9	138.8	148.0	158.7	100.0%	7.2%

Note: RE: revised estimate, PE: Provision estimates

Source: MoSPI, CRISIL MI&A

2. Assessment of Indian pharmaceutical market

Introduction to India's pharmaceutical market

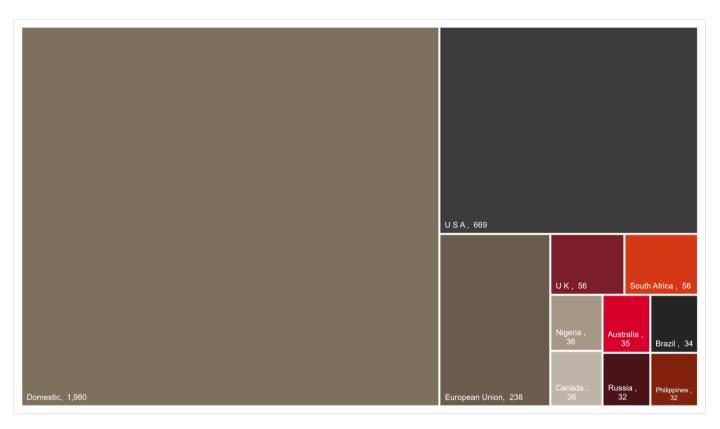
The Indian pharmaceutical industry is the world's third largest by volume and was valued at Rs 3.6-3.8 trillion (including bulk drugs and formulation exports) as of fiscal 2024. The industry can be broadly classified into formulations and bulk drugs. Formulations can further be divided into domestic 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 2024) (Rs billion)

Domestic (52%)

Export (48%)





Note: Total exports from India in FY24 stood at Rs 1,830 billion. The above chart only represents top 10 export destinations. Source: DGFT, CRISIL MI&A

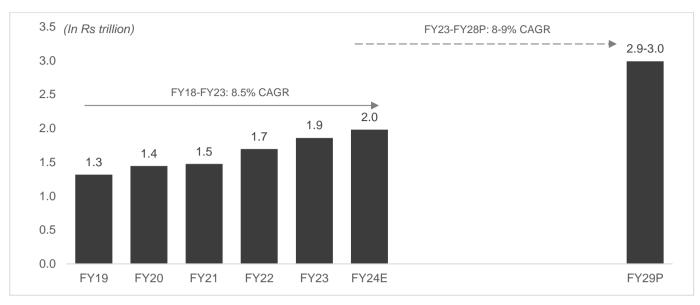
Overview and outlook of Indian domestic Formulation market

Domestic formulations market to grow at ~8-9% CAGR over fiscal 2024 to fiscal 2029

The Indian domestic formulation market has seen healthy growth in the recent times. As of fiscal 2024, the Indian domestic formulation market contributed to approximately ~2% of the total global pharmaceutical market. Indian domestic formulations market (consumption) grew at a healthy rate at a CAGR of 8.5% CAGR from fiscal 2019 to fiscal 2024. The Indian domestic formulations segment (consumption) is expected to grow at a CAGR of 8-9% CAGR over the next five years from fiscal 2024 to reach ~Rs. 2.9-3.0 trillion in fiscal 2029, 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: CRISIL MI&A

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 8.5-9.5% from fiscal 2024 to fiscal 2029. 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 2024, chronic therapies and acute therapies constituted 53% and 47% of the total domestic formulation market, respectively. As of fiscal 2024, 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% 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 8.5-9.5% from fiscal 2024 to fiscal 2029 than the acute therapies segment which is expected to register a CAGR of 7.0-8.0% from fiscal 2024 to fiscal 2029.

Key therapy areas in domestic formulation market

Therapy Name	Share in total market FY19	Share in total market FY24	Share in total market FY29P	CAGR (FY19 to FY24)	CAGR (FY24 to FY29P)
Cardiovascular	12.4%	13.2%	14.1%	9.7%	10.0-11.0%
Anti-Infectives	12.6%	12.3%	11.7%	8.0%	7.5-8.5%
Gastrointestinal	11.2%	11.7%	11.6%	9.3%	8.5-9.5%
Anti-Diabetic	9.6%	9.1%	9.7%	7.2%	10.0-11.0%
Vitamins / Minerals / Nutrients	8.6%	8.8%	8.9%	8.8%	9.0-10.0%
Respiratory	7.4%	8.1%	8.2%	10.3%	9.0-10.0%
Pain / Analgesics	6.8%	7.1%	6.9%	9.5%	7.5-8.5%
Derma	7.6%	6.6%	6.4%	5.4%	7.5-8.5%
Neuro / CNS	6.0%	6.1%	6.1%	8.8%	8.0-9.0%
Gynecological	5.1%	5.0%	5.0%	7.8%	8.5-9.5%

Notes: P-Projected Source: CRISIL MI&A

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 segments. 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 linger 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.



Key growth drivers for the Indian domestic formulation industry

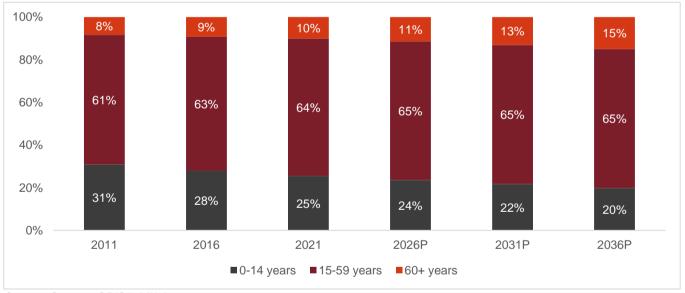
With life expectancy improving and changing demographic profile, healthcare services a must

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

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)	
Communicable diseases	2009	2019	
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

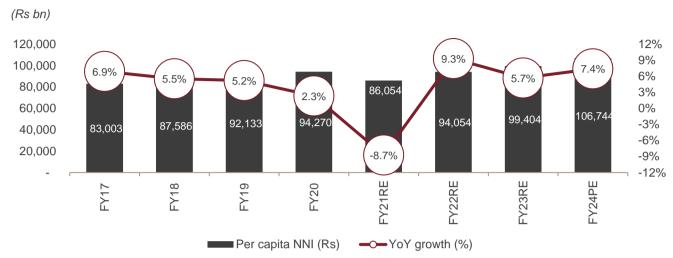
Rising income levels along with strong awareness for health has resulted in people seeking quality healthcare services

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 9.3% on-year to Rs 94,054. Furthermore, NNI per capita further increased to Rs 99,404 in FY23 and Rs 106,744 in FY24. 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.

With per capita income rising to upper middle-income category by FY31, the share of PFCE is expected to be dominant in India's GDP growth.







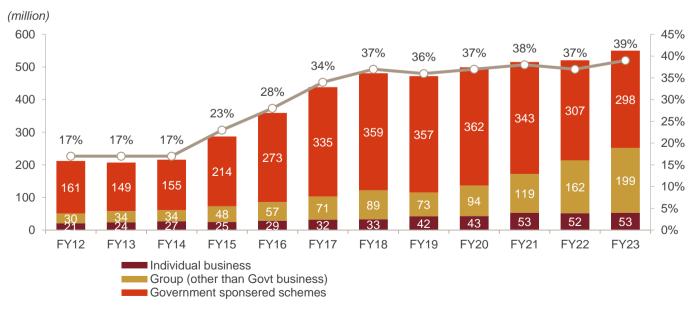
RE: Revised estimates, PE: Provision estimates

Source: PIB, MoSPI, CRISIL MI&A

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 550 million people have health insurance coverage in India (as of fiscal 2023), as compared to 288 million (as of fiscal 2015). Despite this robust growth, health insurance penetration in India stood at only 39% in fiscal 2023. 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



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), Kalaignar (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.).



Overview and outlook of Indian pharmaceutical formulation exports market

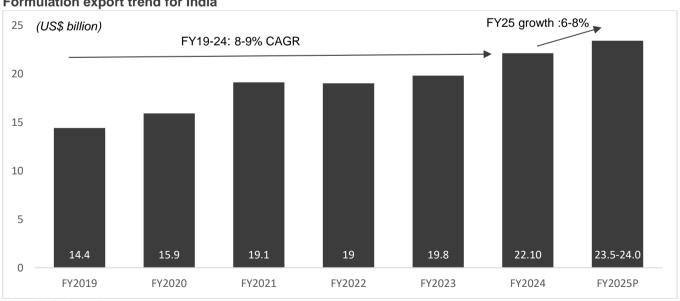
New product launches, complex generics, specialty drugs to drive formulation exports growth over medium term

Formulation exports grew by ~4.5% during fiscal 2023 after witnessing a high base-led flat growth during fiscal 2022. The pharma industry continued to witness pricing pressure in the US, the main export market, during fiscal 2022 and fiscal 2023. However, strong exports to the European market helped offset this to an extent.

For fiscal 2024, India exported formulations worth USD 12.3 bn to regulated markets, with US alone contributing ~66% of the total exports (to regulated markets). India's share of formulation exports is low in value terms as India is primarily into trade generic and branded generics exports. However, India's share in formulation exports to US markets has improved over the years as it capitalized on opportunities created by patent expiries. Europe is another major export destination for India with a share of ~24% (overall exports to regulated markets). India exported formulation worth USD 10.1 bn to semi-regulated markets in fiscal 2024. These exports are largely directed towards Africa, Asia, Russia, and Latin America, with Africa having the largest share. Demand from these markets is driven by an increase in volume led by increasing accessibility to healthcare and the launch of products in newer markets. India's share in total exports to semi-regulated markets has also increased over the years.

Manufacturers launching complex and specialty drugs and those receiving limited competition drug approvals are expected to register higher growth. Incremental revenue for formulation exporters would be supported by new launches. Even though pricing pressure for generics persists, it is expected it to reduce in the near to medium term. United States Food and Drug Administration (USFDA) regulatory overhang continues to be monitorable. Moving ahead, formulation exports are expected to witness healthy growth in fiscal 2025, on account of recovery in the US and select African and Latin American countries, while exports to other geographies are likely to support this growth. Consequently, formulation exports are expected to register growth of 6-8% in fiscal 2025.

Formulation export trend for India



Note: P: Projected

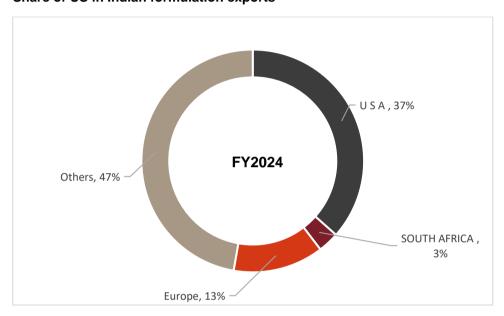
Source: The Directorate General of Commercial Intelligence & Statistics (DGCIS), CRISIL MI&A



US occupies a major share in Indian formulation exports

In terms of formulation exports, United States (US) stands as the major importer of formulations from India. Share of the US in the overall formulations stands around 37%. In value terms, exports to US have grown at a CAGR of approximately 8-9% from fiscal 2019 to fiscal 2024. European union (including United Kingdom) and South Africa stand as the next major importers of formulations from India.

Share of US in Indian formulation exports



Note: Europe includes UK

Source: The Directorate General of Commercial Intelligence & Statistics (DGCIS), CRISIL MI&A

Formulation exports to regulated markets

Exports growth to remain moderate in near term

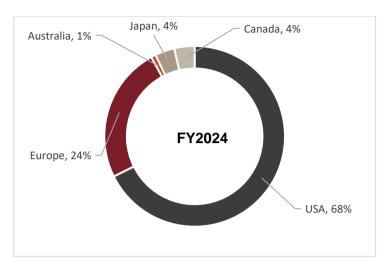
Exports to regulated markets are set to grow by around 13% (in \$ terms) during fiscal 2024. Growth was supported by the launch of new products in the US market and the easing of pricing pressure. Exports to European markets are also expected to support the growth as there was shortage observed for certain cancer drugs, which fuelled the growth. In the medium term, with companies focusing on complex generics and specialty products, pricing pressure is expected to abate. Continued launch of new products across regulated markets is expected to support the growth of formulation exports from India.

India's exports to regulated markets are set to grow by around 11-13% in fiscal 2025. Growth is likely to be supported by the launch of new products in the US market and the expected easing of pricing pressure. Exports to Canada and Japan are expected to boost the growth in overall exports due to increasing demand in these markets. In the medium term, with companies focusing on complex generics and specialty products, pricing pressure is expected to abate. Formulation exports to the regulated markets are expected to gain momentum, as the focus of manufacturers on

Formulation exports to the regulated markets are expected to gain momentum, as the focus of manufacturers on niche molecules, specialty drugs, complex generics, and bio-similars is expected to drive growth in the long term.



India's formulation exports: Share in regulated markets (FY2024)



Source: CRISIL MI&A, DGCIS

Focus on specialty and niche products to boost exports to the US in medium to long term; Easing pricing pressure to further support the growth

The share of US in formulation exports to regulated markets is ~68 . This shows the dependency of the pharma industry on the US market. In fiscal 2022, exports to the regulated market declined by 4% over a high base of 17% growth in fiscal 2021. The decline was primarily attributed to the degrowth in the US markets which declined by 10% due to pricing pressure in the US. In fiscal 2023, the US market witnessed a slow recovery by growing at ~6%, while in fiscal 2024, exports to the US market witnessed healthy growth on account of easing pricing pressure, further supported by new product launches.

Export momentum to European markets to continue

During the fiscal period between 2015 to 2020, pharma exports to European markets clocked a slow 6-7% CAGR owing to stricter pricing regulations and adverse currency movements. Even the United Kingdom (UK) and Germany, which traditionally had less stringent pricing mechanisms, introduced regulations to control the government's healthcare expenditure.

It is expected that there will be healthy growth in formulation exports to Europe over the next five years on rising generic penetration in the UK, France and Germany, among others. Also, players shifted their focus towards Europe due to the ongoing pricing pressure in the US. While the rising clawback tax rates in these markets will remain a key monitorable in the near term. High incidence of chronic diseases, an aging population, and adoption of specialty medicines are set to drive growth in the European markets.



Formulation exports to semi-regulated markets

Players look to tap under-penetrated markets for growth

Semi-regulated markets registered a growth of 4% (in \$ terms) during fiscal 2022 on a high base of fiscal 21 as players targeted new geographies and new product launches. Indian players are also targeting newer and smaller markets in Asia and Africa through both new launches and institutional sales. In fiscal 2023, exports witnessed a decline of ~6% due to ongoing economic and geopolitical crisis in select African countries. For e.g. countries like Zimbabwe, Ghana, Nigeria, Egypt and Uganda were running low of forex reserves and their local currencies depreciated significantly against USD, hence the countries decided to cut down their imports to retain the forex reserves.

Exports improved by 8% in fiscal 24 and the growth is expected to revive in fiscal 25 with an improvement of ~7-9%, on account of improvement in forex reserves and currency stability. As pricing pressure continues in the conventional generics segment in the regulated markets, albeit at a slower rate now, more players are looking to enter semi-regulated markets, thereby boosting volume growth and increasing market share.

This trend is projected to continue, with players expected to record healthy sales in these markets. Also, low competition from many global generic players in the region and low penetration of generics will aid growth for players. Further, governments in the region are looking to streamline regulations to allow the import of generics, which will help reduce government expenditure. An increase in healthcare spending and rising demand for medicines to treat chronic and lifestyle-related ailments would support growth in the semi-regulated markets.

Players increasing focus on semi-regulated markets

India's pharma exports to semi-regulated markets to demonstrate strong growth in near future, as players eye growth opportunities in newer markets with low generic penetration and newer launches in the existing markets. The semi-regulated markets are characterized by lower penetration of healthcare facilities, low per capita consumption of medicines, high population growth rates, a wide base of patients with acute and chronic diseases, and low penetration of generics. Many markets also exhibit disease profiles similar to those in India. In terms of medicine consumption, these markets are mainly driven by low-cost generics.

Region-wise, Africa and Asia (accounting for ~85% of the semi-regulated markets) will remain key drivers. The African market is expected to continue to dominate because several Indian companies have already established a large footprint in drug therapies such as anti-viral 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.



Key growth drivers for Indian formulation exports

India - a preferred manufacturing hub

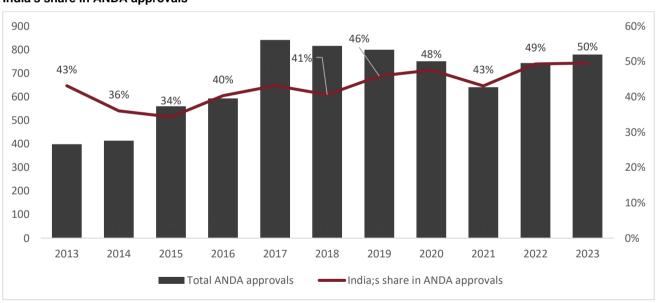
Indian pharmaceutical companies continue to enjoy a sizeable market share in the US generics market. The number of firms seeking abbreviated new drug application (ANDA) approvals and tentative approvals from the US Food and Drug Administration (FDA) is also on the rise. Mid- and small-sized formulation manufacturers, who are traditionally engaged in contract manufacturing, are also looking at tapping the generic drugs opportunity in regulated markets.

India maintains lead in total ANDA approvals and US-approved plants

Due to Generic Drug User Fee Amendments (GDUFA) implementation in October 2012, a large portion of the backlog was cleared by the USFDA by 2017 (calendar year). The number of applications with no communication from the USFDA fell from ~1,700 in 2013 to 218 in April 2018. Competitive intensity peaked in 2017 with higher ANDA approvals and consolidation in the customer base, leading to price erosions.

The number of approvals for Indian players declined in 2018 but continued to remain at higher levels in 2019 and 2020. In 2021, the share of India decreased to 43% primarily due to delayed inspection because of Covid-19. As the inspections resumed, the share of India increased back to ~49% in CY2022. Increasing ANDA approvals leading to new product launches will offset the impact of pricing pressure in US markets. For the year 2023, India's share in ANDA approvals stood at ~50%.

India's share in ANDA approvals



Source: US FDA, CRISIL MI&A

Increasing healthcare cost drives preference for generic drugs in regulated markets

Developed economies spend a major portion of their gross domestic product (GDP) on healthcare. Going forward, demand for pharmaceutical products in developed markets is expected to be driven by factors such as an ageing population and growing incidences of chronic diseases. CRISIL believes that austerity measures adopted in Europe will continue to drive demand for generic drugs, though pricing realisations by suppliers may not be as favourable as in the past. At the same time, healthcare reforms in the US are driving higher insurance coverage and greater usage of generic medicines.



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 20% of the overall domestic pharmaceutical market.

Fluctuation in foreign exchange rates

Bulk drug players meet ~70% of their intermediary requirements through imports and ~40% of the end-products are exported to regulated as well as semi-regulated markets. As the bulk drug industry is fragmented, many small bulk drug players (<Rs 2.5 billion) export to the semi-regulated markets without hedging against their currency risk. Therefore, bulk drug players will continue to face the risk of currency volatility. However, the large bulk drug players who have long-term contract with formulation players are unlikely to face major risk, as they hedge against currency appreciation.

Dependence on China for imports

India imports ~70% of intermediaries required for active pharmaceutical ingredients (API) from China. Over the past few years, many chemical-based companies have been shut down in China due to failure to meet environment norms. Further, Covid-19 led disruptions had further disrupted supplies. Any such disruptions in the bulk drug industry will adversely impact the Indian API industry and subsequently the formulations industry. Further, the Chinese bulk drug industry receives extensive support from the government in the form of subsidies. Any change in policy in this front, 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.

Indian pharmaceutical companies building specialty and complex generics capabilities

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 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.

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 10,607 stores (as of 31 Jan 2024) are operational in the country, with a product basket of ~1,965 drugs and 293 surgical items. 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 2024.

CRISIL MI&A 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 39%. 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-off 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 0.5 million per family (on floater basis) to nearly 107.4 million families (the actual coverage would be greater on account states extending the scheme to even some sections of the uncovered populace). As of June 2024, nearly ~68.6 million treatments had taken place under Ayushman Bharat since the inception of the scheme in September 2018. The claim amount for these treatments has been ~Rs. 902.0 billion, indicating average treatment cost of ~Rs 13,146 per hospital admission.

Package rates has been another area of concern for most corporate hospitals, reflecting in the low participation of the private sector. As of June 2024, a total of 29,945 hospitals including 12,932 private hospitals have been empanelled under the scheme, indicating a share of ~43%.

Another point to note is the increase in average treatment cost increases as healthcare coverage increases. In case of Rashtriya Swasthya Bima Yojana (RSBY) which had a coverage of Rs 30,000 witnessed an average treatment cost of Rs 4,825, while state schemes which had health cover ranging from Rs 0.1-0.2 million witnessed an average treatment cost of Rs 8,900. In case of PMJAY, the average amount per treatment till date is around ~Rs 13,146.



3. Assessment of Indian Injectables pharmaceutical market

Overview of injectables drugs

Injectable drugs are a form of dosage, in which the active pharmaceutical ingredients (compounds which are responsible for eliciting the therapeutic effects) are dissolved in a liquid medium, which ensures quick medical effect. The route of administration via injections is selected based on the required onset of the action and the pharmacokinetic profile desired for the medication. In situations, where rapid therapeutic effects are needed such as emergencies, the medication is typically administered intravenously i.e. directly into the bloodstream. This ensures immediate bioavailability and swift response.

However, in situations where slower absorption rate is preferred, or if the medication should avoid the direct entry into the bloodstream, the medication is typically employed through intramuscular (IM), or subcutaneous (SC), route. Certain medications necessitate administration through injections due to their instability in the gastrointestinal environment. Insulin is one example. Most vaccines also have to be injected for this reason.

Overview of injectables drugs market in India

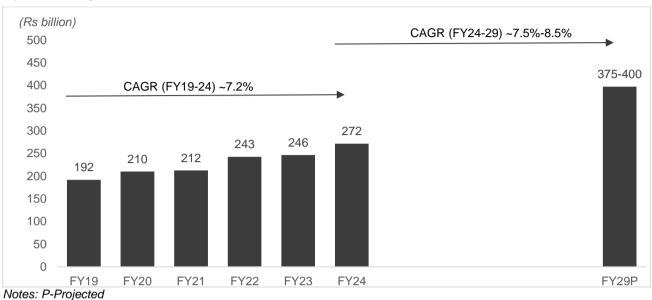
Injectables are the second largest dosage form in the Indian domestic formulation market with share of approximately ~13% as of fiscal 2024. Injectables have gained importance in the recent year in the Indian pharmaceutical market with invention of newer drug delivery systems and development of complex injectables. Indian pharmaceutical companies are also developing and investing in new complex molecules in the injectables formulation segment.

Indian injectable market expected to grow at 7.5-8.5% CAGR from fiscal 2024 to fiscal 2029

Indian injectables market in Indian domestic formulation industry has recorded steady growth in recent years. The market grew at a CAGR of 7.2% from Rs. 192 billion in fiscal 2019 to Rs. 272 billion in fiscal 2024. Going ahead, the Indian injectables market is expected to grow at a CAGR of 7.5-8.5% over the next five fiscal years from fiscal 2024 to fiscal 2029 to reach Rs. 375-400 billion by fiscal 2029. Novel delivery systems and increased incidence of chronic disease is expected to drive the growth in the Indian injectables industry. In addition, some of the key research areas like new forms of drug delivery systems as well as emergence of self-administered injectables is expected to drive demand in the Indian domestic injectables segment.



Injectables drugs market in India



Source: CRISIL MI&A

Growth drivers and trends for Indian injectable market

Rise in chronic diseases

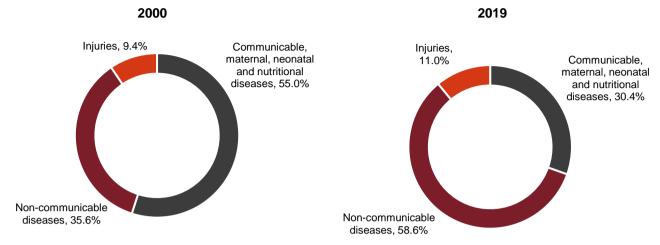
There is an increase in the prevalence of diabetes and other chronic diseases for which treatment is primarily administered using injectables. Diabetes and other chronic disease has seen major prevalence in the world population. According to the World Health Organization (WHO), communicable diseases were a major contributor to disability-adjusted life years (DALYs) in India in 2000, with approximately 55% share. The major reasons were lack of basic public healthcare facilities and vaccination, which led to communicable diseases.

DALY helps assess the overall burden of disease in a country as it is a time-based measure that combines years of life lost due to premature mortality and disability. One DALY represents the loss of the equivalent of one year of full health.

By 2019, there was a notable shift in the disease burden landscape in India. The share of communicable diseases in total DALYs in the country witnessed a significant decline to about 30.5%, indicating progress in controlling infectious illnesses through vaccination drives and availability of public healthcare services. Conversely, non-communicable diseases witnessed a substantial increase and accounted for 58.6% of the DALYs in India, considerably higher than the average share of non-communicable diseases in total DALYs for lower-middle-income countries, 52.5%. This shift can be attributed to the growing ageing population in India and lifestyle changes, leading to a more-sedentary living. Furthermore, injuries accounted for 11%, showcasing a slight increase compared with 2000.



Contribution of major disease groups to total DALYs in India



Source: WHO, CRISIL MI&A

Contribution of major disease groups to DALYs (2019)

Region	Share of communicable, maternal, neonatal, and nutritional diseases in total DALYs	Share of non- communicable diseases in total DALYs	Share of injuries in total DALYs
Global	27.2%	62.5%	10.3%
Low income	55.3%	33.8%	10.9%
Lower middle income	37.6%	52.5%	9.9%
Upper middle income	11.9%	77.2%	9.6%
High income	5.5%	84.9%	10.3%

Note: India comes in the lower middle-income group according to WHO classification

Source: WHO, CRISIL MI&A

Growth of biologics

Biologics are making robust progress in the Indian pharmaceutical industry. Most of the biologics and biosimilar drugs are administered through injectables. In biologic drugs, Injectables in the pharmaceutical industry are witnessing increased adoption as the preferred drug delivery systems due to their ease of handling, less overfills and more safety to patients. Biologics share in total products by value is expected to be increase in the near term, thus many biologic drugs are expected to witness uptake indicating a good opportunity for injectables players. Which in turn is expected to rise demand for the injectables drug delivery devices for such formulations.

Ease of administration

In an effort to deliver medication in an efficient and improved way with minimal side effects, there has been huge innovation in the field of Novel Drug Delivery Systems (NDDS). This thrust to provide safety, high efficacy reduction in side effect, patient compliance and other economical aspects have also created demand for self-administered medication. New type of injectable delivery devices such as auto injectors, pen injectors, pre-filled syringes (PFS) and needle-free injectors cater to this demand further propelling growth of injectables in market



Emergence of New drug delivery systems

The development of new injectables delivery devices has facilitated increased access to self-administered medications which are convenient and safe to use. NDDS helps the patients reduce frequency of their hospital visits. Apart from Diabetes, NDDS has also found applications in segments like Oncology and hormone therapy which entail delivery of multiple doses over the course of the treatment.

New therapeutic areas for Injectables

The market for injectables is growing for new ailments such as rheumatoid arthritis, multiple sclerosis, cancers and autoimmune disorders. Pharmaceutical players, especially in the injectable segment are investing in research and technology that will cater to formulations in this new segment of diseases.

Increased focus on complex molecules

In recent years, pharmaceutical manufacturers have shifted focus to building capacities for complex and niche products due to the fading of opportunities in traditional molecules and presence of higher realisations in the complex molecules segment. Furthermore, investments are being made in development of complex molecules for treatment of diseases such as rheumatoid arthritis, multiple sclerosis, cancers and auto-immune disorders. Due to ease of administration and improved safety, injectables such as prefilled syringes are being used to administer these treatments which is likely to increase the demand for the injectable products.

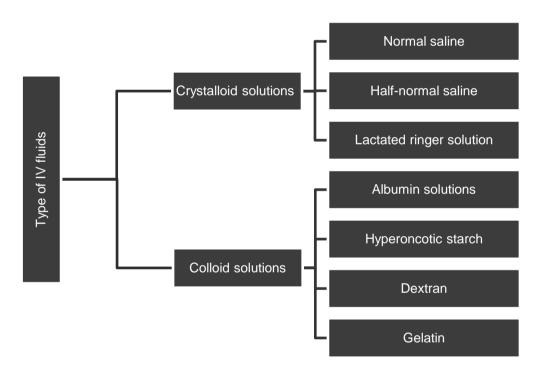


Qualitative overview of IV fluids products in the Indian Injectable pharmaceutical industry

The administration of intravenous fluids is one of the most common and universal interventions in medicine. Crystalloid solutions are the most frequently chosen, by far, with normal saline (NS) and lactated Ringer's (RL) both being frequent choices globally.

The 2 primary types of IV fluids include crystalloid and colloid solutions. Crystalloid solutions include normal saline, half-normal saline, lactated Ringer solution, combination of Dextrose and normal Saline, Electrolytes, etc. Colloid solutions are albumin solutions, hyperoncotic starch, dextran, and gelatin. Crystalloid solutions are typically preferred as the first-line treatment, whereas colloid solutions are not the recommended initial option for hypovolemia, unless it is not due to bleeding.

Overview of IV fluids



Source: National Library of Medicine, CRISIL MI&A

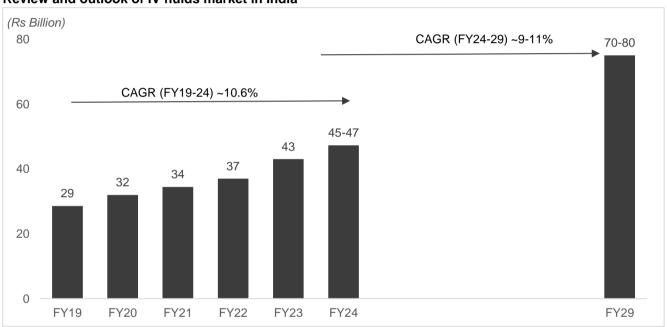
The application of IV Fluids spans from routine hydration and electrolyte balance to emergency medicines and more complex clinical treatments including fluid resuscitation, nutrient delivery and medication administration. Many adult hospital inpatients need IVF therapy to prevent or correct problems with their fluid and/or electrolyte status. With rising awareness and access to healthcare facilities, people are seeking more treatments from clinics and hospitals which is expected to support uptake of IV fluids products in the Indian market.



IV fluids industry in India to grow at a CAGR of 9-11% between fiscal 2024-2029

IV fluid market consisting of key products like normal saline, dextrose, lactate ringer and electrolytes have seen traction in recent years owing to growth of overall healthcare system in India. Indian IV fluids market is estimated to be valued at ~Rs 45-47 billion as of fiscal 2024, compared to ~Rs 29 billion in fiscal 2019. This growth was supported by multiple factors including rising population, increasing prevalence of chronic diseases, and growing demand for IV fluids in medical treatments due to fast acting way. Going ahead with growth of overall healthcare delivery market in India and the factors outlined above the industry is estimated to register a CAGR of ~9-11% between fiscals 2024-2029 and reach Rs ~70-80 billion by fiscal 2029 owning to sustained demand from end use segments like hospitals and clinics.

Review and outlook of IV fluids market in India



Source: CRISIL MI&A

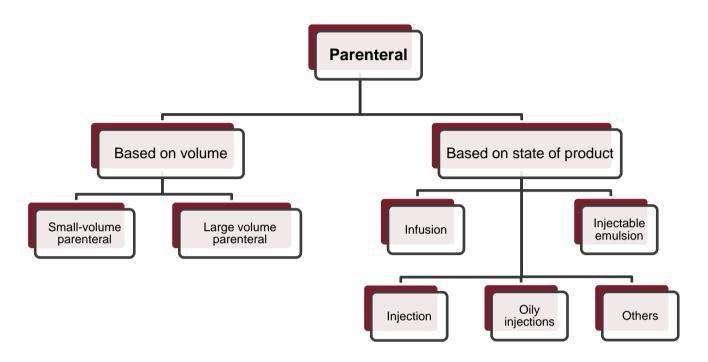
Qualitative overview of small volume parenteral products (SVP) in the Indian Injectable pharmaceutical industry

As per National Library of Medicine, Parenteral products are sterile products that are administered as an injection, infusion or implantation and must be manufactured and compounded using materials and methods (aseptic techniques) that ensure sterility of the product. They usually contain one or more active ingredients intended for administration and are packaged in either single-dose or multi dose containers.

Additionally, administration of a contaminated parenteral product can cause the patient significant harm, including bloodstream infections, sepsis, meningitis and death. Hence, due care and precaution should be exercised during its handling.



Overview of Parenteral



Source: CRISIL MI&A

Parenteral products can be further bifurcated based on their volume into Large- volume parenteral solutions (LVPs) and Small- volume parenteral solutions (SVPs).

- Large-volume parenteral solutions (LVPs)- LVP as products in a container labelled as containing more than 100ml of a single dose injection intended for administration by IV infusion. LVP can be administrated through multiple routes including direct injection into the blood, open body cavities, and surgical areas. Examples include electrolyte solutions, carbohydrates, nutrients solutions, etc.
- Small-volume parenteral solutions (SVPs) a solution volume of less than 100 mL (as defined by USP) or less that is intended for intermittent intravenous administration (usually defined as an infusion time not lasting longer than 6-8 hours). Large part of SVP product includes water for injection (diluent used for dissolving dry powder injection), Ophthalmic, Respiratory Care products, etc. In non-therapeutic (medical device) product range, there are products like eye and wound irrigation, OTC Ophthalmic products etc. Examples of SVPs include solutions, suspension, emulsion, etc.

Parenteral products can also be bifurcated based on state of products into injections, infusions, powders for injections, implants, Concentrated Solutions for Injection, Injectable Emulsion, and oily injections.

Parenteral products can be highly useful in cases where patients cannot intake drug through oral route or drugs are not suitable for oral intake. Additionally, these products allow rapid absorption of the drug, thereby providing fast action. Furthermore, parenteral routes are better suited for drugs which have poor absorption in the gastrointestinal tract or are destroyed by digestive secretions.

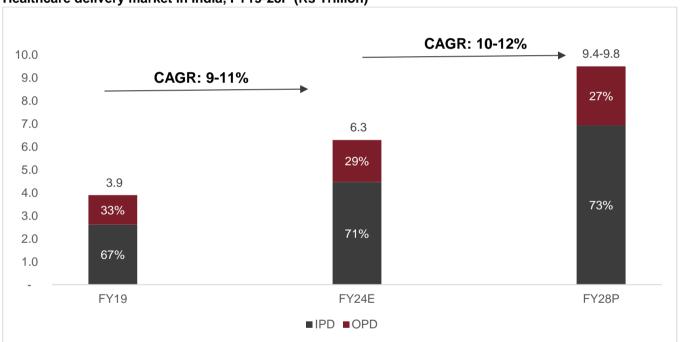


Review of overall healthcare delivery market in India

Healthcare delivery industry estimated to grow to ~Rs 9.4-9.8 trillion by FY28

Healthcare delivery market in India consists of inpatient department (IPD) treatments at government and private hospitals and outpatient department (OPD) treatments at government, private hospitals and clinics. CRISIL MI&A estimates the Indian healthcare delivery market to have reached ~ Rs 6.3 trillion in value terms by end of FY24, with growth being contributed by continuation of regular treatments, surgeries and in-patient department (IPD) including average revenue per occupied bed (ARPOB) expansion for the sector. Growing and high realization medical tourism will contribute more to the industry. Within the overall healthcare delivery market, the in-patient department (IPD) is expected to account for nearly ~71% (in value terms), while the balance is to be catered by the out-patient department (OPD). Though in terms of volumes, OPD volumes outweigh IPD volumes, with the latter contributing the bulk of the revenues to healthcare facilities.

Healthcare delivery market in India, FY19-28P (Rs Trillion)



Note: IPD indicates inpatient department at government and private hospitals; while OPD indicates outpatient department at private, government hospitals and private clinics

Source: CRISIL MI&A

With long term structural factors supporting growth, renewed impetus from PMJAY and government focus shifting onto the healthcare sector, healthcare delivery market is expected to grow at 10-12% compounded annual growth rate (CAGR) and reach Rs 9.4-9.8 trillion by FY28. The other contributors to the demand are more structural in nature, like, increase in lifestyle-related ailments, increasing medical tourism, rising incomes and changing demography.

In India, healthcare services are provided by the government and private players, and these entities provide both IPD and OPD services. However, the provision of healthcare services in India is skewed towards the private players (both for IPD and OPD) with private players accounting for approximately 67% share as of FY2024. This is mainly due to the lack of healthcare spending by the government and high burden on the existing state health infrastructure. The



skew is more towards the private players owing to the expansion plans of private players being cantered on it, further buttressed by increasing reliance on private facilities till government infrastructure is properly put in place

Key growth drivers of healthcare delivery industry

A combination of economic and demographic factors is expected to drive healthcare demand in India. CRISIL MI&A believes the PMJAY scheme launched by the government would also support these drivers.

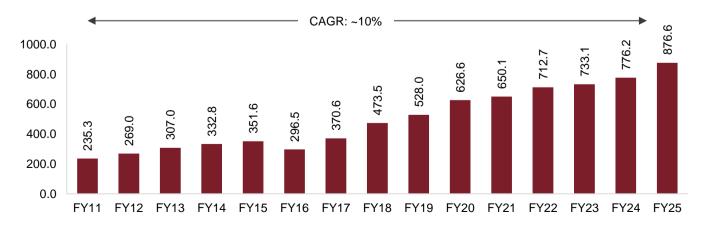


Source: CRISIL MI&A

Government policies to improve healthcare coverage

The healthcare budget has seen increases on-year. Between FY11 and FY25, the budget for the MoHFW clocked a CAGR of ~10%. In recent years, the utilisation rate has been 100% or above, as has been the case since FY16. This, too, is a strong growth driver for the industry and particularly the PPP initiative from government so as to achieve the government's goal of providing healthcare services to all.

Budget estimates for MoHFW



■Budget Estimates for MOHFW (Rs. billion)

Source: Union Budgets, CRISIL MI&A



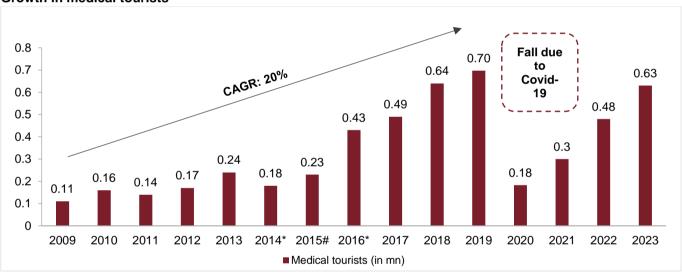
Medical tourism in India

Medical value travel, which is also referred to as 'medical tourism', has gained momentum over the years and India is fast emerging as a major tourist destination, owing to the relatively low cost of surgery and critical care, along with the presence of technologically advanced hospitals with specialized doctors and facilities, such as e-medical visa.

India benefits from medical value travel stemming from neighboring countries such as Bangladesh, Nepal and Bhutan. Eastern India is geographically well positioned for medical value travel from Bangladesh, Nepal and Bhutan, from patients who prefer to obtain quality healthcare services in India.

According to the latest data available with the Ministry of Tourism, of the total foreign tourist arrivals in India, the proportion of medical tourists has grown from 2.2% (0.11 million tourists) in 2009 to 6.4% (0.62 million tourists) in 2019. However, the number of medical tourists fell sharply in 2020(0.18 million tourists) because of international travel restrictions due to Covid-19. The number of medical tourists has recovered well to 0.63 million tourists in 2023 (January-December 2023).

Growth in medical tourists*



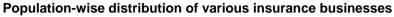
Note:* includes all types of medical attendant visa # includes medical visa and medical attendant visa Source: Ministry of Tourism, CRISIL MI&A

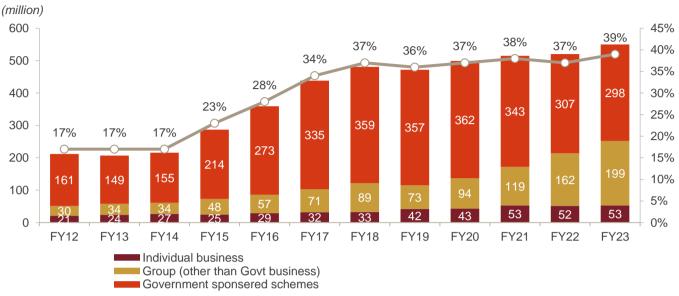
Growing health insurance penetration to propel demand

Low health-insurance penetration is one of the major impediments to growth of the healthcare delivery industry in India, as affordability of quality healthcare facilities by the lower income groups continues to remain an issue. As per the Insurance Regulatory and Development Authority of India (IRDAI), nearly 550 million people have health insurance coverage in India (as of 2022-23), as against 288 million (in 2014-15), but despite this robust growth the penetration in FY23 stood at only ~39%. CRISIL MI&A believes that while low penetration is a key concern, it also presents a huge opportunity for the growth of healthcare delivery industry in India. And with the PMJAY scheme, the insurance coverage in the country is expected to increase considerably.

Furthermore, with health insurance coverage in India set to increase, hospitalization rates are likely to go up. In addition, health check-ups, which form a mandatory part of health insurance coverage, are also expected to increase, boosting the demand for a robust healthcare delivery platform.







Source: Insurance Regulatory & Development Authority of India report 22-23, CRISIL MI&A

Increasing health awareness to boost hospitalisation rate

Majority of the healthcare enterprises in India are more concentrated in urban areas. With increasing urbanization (migration of population from rural to urban areas), awareness amongst the general populace regarding presence and availability of healthcare services for both preventive and curative care would increase.

CRISIL, therefore, believes that hospitalisation rate for in-patient treatment as well as walk-in out-patients will improve with increased urbanization and increasing literacy.

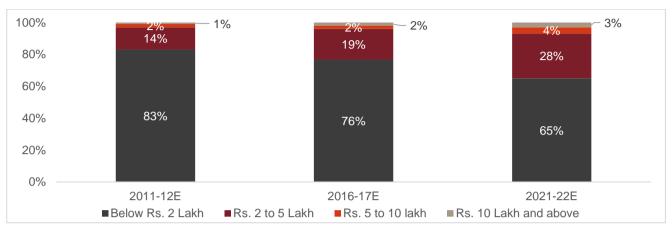
Rising income levels to make quality healthcare services more affordable

Even though healthcare is considered a non-discretionary expense, considering that an estimated 83% of households in India had an annual income of less than Rs 2 lakh in 2011-12, affordability of quality healthcare facilities remains a major constraint.

Growth in household incomes, and consequently, disposable incomes, is, therefore, critical to the overall growth in demand for healthcare delivery services in India. The share of households falling in the income bracket above Rs 2 lakhs is expected to go up to 35% in 2021-22 from 23% in 2016-17, providing potential target segment (with more paying capacity) for hospitals.



Income demographics

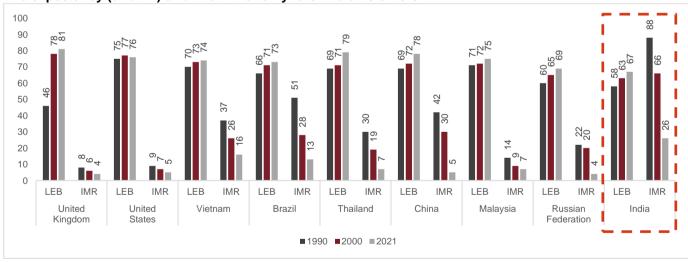


Source: CRISIL MI&A

With life expectancy improving and changing demographic profile, healthcare services are 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 12.5% by 2026. However, the availability of a documented knowledge base concerning the healthcare needs of the elderly (aged 60 years or more) continues to remain a challenge. Nevertheless, the higher vulnerability of this age group to health-related issues is an accepted fact.





Note: LEB – life expectancy at birth; IMR – infant mortality rate (probability of dying by age one year per 1000 live births)

Source: World Bank, CRISIL MI&A

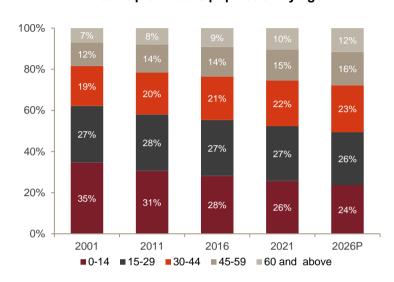
According to the Report on Status of Elderly in Select States of India, 2011, published by the United Nations Population Fund (UNFPA) in November 2012, chronic ailments such as arthritis, hypertension, diabetes, asthma, and heart diseases were commonplace among the elderly, with ~66% of the respective population reporting at least one of these. According to the Report on Status of Elderly in Select States of India, 2011, published by the United Nations Population Fund (UNFPA) in November 2012, chronic ailments such as arthritis, hypertension, diabetes, asthma, and heart diseases were commonplace among the elderly, with ~66% of the respective population reporting

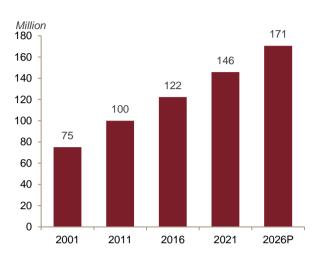


at least one of these. In terms of gender-based tendencies, while men are more likely to suffer from heart, renal and skin diseases, women showed higher tendencies of contracting arthritis, hypertension, and osteoporosis.

Break-up of India's population by age

India's population of 60 and above years





P: Projected

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

Key trends of healthcare delivery industry

Diversification into different format / areas to increase reach and efficiency

Despite the challenges present in the healthcare delivery system in India, innovations and newer business models are being explored. The main objective of these innovations are to increase efficiencies through optimum resource utilisation and widen the reach of healthcare services. Though different business models might being applied depending on the location and services to be provided, the PMJAY is expected to lead to the adoption of new business models focusing on volume-driven, affordable healthcare.

Single speciality healthcare units

Single-specialty healthcare units are those that treat patients with specific medical conditions, with the need of specific medical/surgical procedures. A single-specialty healthcare unit can be a hospital, clinic, or care centre. The advantage of these units is that, by focusing on providing care in a single segment, they can increase efficiencies as well as create a niche in the target segments. Nowadays, birthing centres are among the fastest growing single specialty centre. Specific regulatory headwinds, however, can affect the margins of these business units.

Day-care centres

The objective of day-care centres is to reduce the need for overnight hospitalisation. In this type of setup, a patient is allowed to go home on the same day after being treated. These centres have also given rise to the concept of outpatient surgeries.

While this model is very popular in the eye care segment, other segments such as arthroscopic, general, cosmetic, and dental surgery have also been using this as a popular care delivery model. The advantage of the day-care centre model is that patients can save on bed/room rentals associated with overnight hospitalisation. The healthcare units,



on the other hand, can have a streamlined setup with optimum equipment, staff and infrastructure, which helps bring down operational costs.

End-of-life/geriatric care centres

The objective of end-of-life care centres or hospices and palliative care centres is to provide care and support to patients, who are suffering from terminal illness with a life expectancy of six months or less. Hospice and palliative care focus more on pain management and symptom relief rather than continuing with curative treatment. These centres are designed to provide patients a comfortable life during their remaining days and cover physical, social, emotional, and spiritual aspects apart from the medical treatment. Such type of care can be delivered onsite, where special facilities are set up, in the hospital premises, or at the patient's home.

Palliative care is delivered with the help of an inter-disciplinary team which may consist of the patient's physician, hospice doctor, a case manager, registered nurses, counsellor, a dietician, therapist, pharmacologist, social workers, and various trained volunteers. Depending upon the patient's ailment and medical condition, the team prepares a customised care programme which comprises services such as nursing care, social services, physician services and trained volunteer support.

Home healthcare

The primary objective of home healthcare services is to provide quality health care at the patient's premises. In India, these services are still in the nascent stages. CRISIL MI&A believes that with increasing geriatric population, institution of families and increasing disease burden causing a strain on conventional health delivery systems, home healthcare will be a preferred alternative. A number of healthcare start-ups have started vying for growth in this space.

The revenue from ICU beds decreases as weeks pass by and, hence, reducing the strain (both on hospitals and patients) can be explored through home healthcare. Patients can avail of ICU care at home at nearly a fifth of the prices of hospital care. Hospitals can also benefit by this model not just through reduced overcrowding, but also prevention of associated hospital acquired infections.

Shortfall in bed capacity: Major opportunity for healthcare delivery players

With population of the country increasing there is need to augment hospital capacity in terms of beds. This presents key opportunity for hospital players to cater to the healthcare demand of the rising population. In terms of supply creation, major hospital chains are now looking at brownfield expansion at existing facilities & have also expanded into the next level of creamy tier II and III locations. This expansion in bed capacity is expected to cater to the rising demand for healthcare services.

Capex in terms of beds planned by key players

Company Name	Planned capex in terms of no. of beds
AHEL Apollo Hospitals Enterprise Limited	2,860
FHL Fortis Healthcare Ltd	2,200
GHL Global Health Ltd	1,250
JLHL Jupiter Lifeline Hospitals Ltd	1,300
KIMS Krishna Institute of Medical Sciences Limited	1,835
MHIL Max Healthcare Group	4,150
NHL Narayana Health Limited	1,000



Note: Capex plan is for next 4-6 fiscals and includes potential expansion of the existing facilities and setting up of new facilities. Source: Investor Presentation, Conference call transcripts, CRISIL MI&A



4. Review of competition in the Indian pharmaceutical market

In this section, CRISIL MI&A has analysed some key players operating in the pharmaceutical industry in India.

Data in this section has been obtained from publicly available sources, including annual reports and investor presentations of listed players, regulatory filings, rating rationales, and/or company websites. Financials in the competitive section have been re-classified by CRISIL MI&A, based on annual reports and financial filings by the relevant players. The financial ratios used in this report may not match the reported financial ratios by the players on account of standardisation and re-classification done by CRISIL MI&A.

Note: The list of competitive landscape peers considered in this section is not exhaustive but an indicative list.

Operational Overview

Company	Year of Incorporation	Overview
Aculife Healthcare Pvt Ltd	2014	Aculife Healthcare Pvt. Ltd. has its registered office in Gujarat, India and is engaged in manufacturing and selling of various pharmaceutical products. Its product portfolio includes manufacturing of large and small volume infusions and bags, ophthalmics, respules, liquid and gaseous anaesthesia, electrolytes Special Solution, parenteral nutrition and general injectables.
Amanta healthcare	1994	Amanta Healthcare Limited is a Sterile liquid pharmaceutical products manufacturing and formulation development and has headquarters at Ahmedabad, Gujarat, India. The Company manufactures Large Volume Parenterals (LVPs) and Small Volume Parenteral (SVPs). The product group comprises of fluid therapy, formulations, diluents, ophthalmic, respule and irrigation solutions, etc.
Axa Parenterals (India) Ltd	2005	AXA Parenterals Ltd. is into manufacturing & marketing of Sterile parenterals preparations, other medicines and hospital products
B. Braun Medical India Pvt Ltd	1984	B. Braun Medical (India) Pvt. Ltd. was incorporated in the year 1984 as a subsidiary of B. Braun Melsungen AG and has a registered office in India. The company has products catering to therapeutic segments such as anesthesia, surgery, interventional cardiology, orthopedics, dialysis treatment, hospital care, etc.
Denis Chem Lab Ltd	1980	Denis Chem Lab Ltd is engaged in the business of manufacturing pharmaceuticals transfusion solution in bottles and has its registered office in Gujarat. The company manufactures IVFs bottles under three packaging categories: glass bottles, euroheads, and plastic bottles.
Fresenius Kabi India Pvt Ltd	1995	Fresenius Kabi India Pvt.Ltd. is a 100% subsidiary of Fresenius Kabi AG Germany, which is a part of the Fresenius Health Care Group. The Company is engaged primarily in production of intravenous fluids and trading of intravenous fluids, medical devices and oncology drugs.
Otsuka Pharmaceutical India Pvt Ltd	2012	Otsuka Pharmaceutical India Private Limited (OPI) is a fully-owned subsidiary of Japanese company, Otsuka Pharmaceutical Factory, Inc. (OPF), Japan. The company has its headquarters in Ahmedabad, India. OPI's product portfolio includes anti- infectives, Basic Intravenous (IV) Infusions, and Enteral Nutrition (EN)



Shree Krishnakeshav Laboratories Ltd	1964	Shree Krishnakeshav Laboratories Ltd started was incorporated in the year 1964 as McGaw Ravindra Laboratories (India) Ltd and manufactures I.V. fluids in glass bottles and quality cognate products. In 1984, the company changed its name to Shree Krishnakeshav Laboratories Limited. Its product portfolio includes, Large Volume Parenteral (LVP), Small Volume Parenteral (SVP) and Pre-Filled Syringes (PFS)
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Source: Company websites, annual reports, CRISIL MI&A

Key operational parameters

Company	Exports	Exporting Countries	Manufacturing plants	Installed Capacity
Aculife Healthcare Pvt Ltd	Yes	70+ countries	5	N.A.
Amanta Healthcare Ltd ¹	Yes (29.51%)	47+ countries	1	66.6 million bottles per annum (p.a) of LVP 240 million bottles p.a. of SVP
Axa Parenterals (India) Ltd ²	Yes	11+ countries	1	 50 million bottles p.a. of 100 ml to 500 ml 50 million vials of 5ml, 10 ml, 20 ml & 30 ml sizes
B. Braun Medical India Pvt Ltd	Yes	64 countries	3	N.A.
Denis Chem Lab Ltd ³	Yes	N.A.	1	 23 million p.a. glass bottles 50 million p.a. plastic bottles 43 million p.a. Euroheads bottles
Fresenius Kabi India Pvt Ltd ⁴	N.A.	N.A.	1	N.A.
Otsuka Pharmaceutical India Pvt Ltd ⁵	Yes (21.76%)	60+ countries	1	N.A.
Shree Krishnakeshav Laboratories Ltd	N.A.	50+ countries	N.A.	N.A.

Note:

N.A.- Not available

- 1. As per credit rating rationale dated August 2023
- 2. AXA Parenterals Ltd. has I.V. Fluid plant in Roorkee, Uttarakhand, India as per its website
- 3. For Denis Chem Lab Ltd, as per rating rationale dated May 2023, the company has manufacturing facility in Gandhinagar.
- 4. For Fresenius Kabi India Pvt Ltd, the data is as per fiscal 2023 annual report

Source: Company websites, annual reports, rating rationales, CRISIL MI&A



Product offerings

Company	Product Portfolio
Aculife Healthcare Pvt Ltd	Infusions (Bottle and Bag), Injectables, Anaesthesia (Gaseous and Injectable), Critical Care Medicines (Including Parenteral Nutrition), Ophthalmics, Respiratory Products, Dermatology & Gel Segment, Oral Shots
Amanta healthcare Pvt Ltd	Formulations, Fluid Therapy, Diluents, Respules, Injections, Ophthalmics, Medical Devices
Axa Parenterals (India) Ltd	Fluid Therapy – LVP, Eye Drops, Ear Drops, Nasal Drops, Respules, Injectables
B. Braun Medical India Pvt Ltd	Abdominal Surgery, Cardio-Thoracic Surgery, Continence Care & Urology, Degenerative Spinal Disorders, Diabetes Care, Extracorporeal Blood Treatment, Infection Prevention, Infusion Therapy, Interventional Vascular Therapy, Neurosurgery, Nutrition Therapy, Orthopaedic Joint Replacement, Ostomy Care, Pain Therapy, Sterile Goods Management, Wound Management
Denis Chem Lab Ltd	Glass bottles, Euroheads, and plastic bottles
Fresenius Kabi India Pvt Ltd	Oncology drugs, Parenteral Nutrition, MedTech, Innovative I.V. Containers, Enteral Nutrition, Nephrology.
Otsuka Pharmaceutical India Pvt Ltd	Enteral Nutrition, Anti-infectives, Oncology, Intravenous Fluids, Intravenous Fat Emulsion, Parenteral Amino Acids Solution, Total Nutrient Admixture
Shree Krishnakeshav Laboratories Ltd	Anti-Infectives, Dextrose Solutions, Dextrose & Saline Solutions, Saline Solutions, Sodium Lactate Solutions, Irrigation Solutions, Potassium Chloride Injections, Multiple Electrolytes Solutions, Osmotic Diuretics, Invert Sugar Solutions, Peritoneal/Hemo Dialysis Solutions, Medical Disposables

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

Source: Company websites, annual reports, rating rationales, CRISIL MI&A



Financial overview

Financial snapshot key competitors considered (fiscal 2024)

Parameters	Amanta healthcare Ltd	Denis Chem Lab Ltd
Operating Income (OI)- Rs Million	2,803.76	1,678.22
OI CAGR (FY22-24)	11.51%	10.87%
Operating Profit Before Depn. Interest and Taxes (OPBDIT) - Rs Million	573.82	212.33
OPBDIT CAGR (FY22-24)	4.64%	21.64%
PAT - Rs Million	35.33	111.56
PAT CAGR (FY22-24)	-74.68%	33.46%
OPBDIT%	20.47	12.65
PAT%	1.26	6.65
ROE%	5.42	14.66
ROCE%	12.77	19.52
Gearing Ratio	3.06	0.01

Note:

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

FY2024 financials have been updated using quarterly results filed by Denis Chem Lab Ltd

ratios calculated as per CRISIL MI&A 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

Source: Company filings, CRISIL MI&A

Financial snapshot key competitors considered (fiscal 2023)

	Operating income		OPBDIT		PAT	
Company name	FY23	CAGR FY21-FY23	FY23	CAGR FY21-FY23	FY23	CAGR FY21- FY23
Aculife Healthcare Pvt Ltd*	5,114.00	6.40%	453.90	-31.91%	99.00	-60.47%
Amanta healthcare Ltd	2,615.06	23.53%	544.81	18.44%	-22.15	n.m.
Axa Parenterals (India) Ltd**	1,917.58	22.67%	312.20	10.52%	201.80	15.38%
B. Braun Medical India Pvt Ltd*	6,105.74	20.81%	562.03	n.m.	7.50	n.m.
Denis Chem Lab Ltd	1,608.22	21.42%	187.92	34.24%	78.60	86.31%
Fresenius Kabi India Pvt Ltd	8,325.23	19.45%	1,033.94	n.m.	963.46	n.m.



Otsuka Pharmaceutical India Pvt Ltd	5,393.07	26.38%	-180.96	n.m.	-760.76	n.m.
Shree Krishnakeshav Laboratories Ltd^	1,338.51	N.A.	218.95	N.A.	106.42	N.A.

Note:

- Financials above are as per CRISIL MI&A 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
- *-consolidated financial statements
- **- Axa Parenterals (India) numbers are based on consolidated financial statements. CAGR numbers of Axa Parenterals (India) Ltd represents CAGR for FY2022 to FY2023 as FY2021 consolidated financials are not available for the company
- ^-Numbers as of fiscal 2022

n.m.-Not meaningful, NA-Not available Source: Company filings, CRISIL MI&A



Financial ratios of key competitors considered (fiscal 2023)

Company name	OPBDIT%	PAT%	ROE	ROCE	Gearing ratio
Aculife Healthcare Pvt Ltd*	8.88	1.94	4.96	6.94	1.38
Amanta healthcare Pvt Ltd	20.83	-0.85	-3.26	13.26	3.39
Axa Parenterals (India) Ltd*	16.28	10.52	15.10	16.65	0.31
B. Braun Medical India Pvt Ltd	9.20	0.12	0.49	18.63	0.57
Denis Chem Lab Ltd	11.69	4.89	11.38	15.71	0.03
Fresenius Kabi India Pvt Ltd	12.42	11.57	22.27	22.80	0.00
Otsuka Pharmaceutical India Pvt Ltd	-3.36	-14.11	n.m.	-11.71	-4.86
Shree Krishnakeshav Laboratories Ltd^	16.36	7.95	132.77	64.45	1.30

Note:

n.m.- not meaningful

N.A.- Not available

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

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

^Numbers as of fiscal 2022

Source: Company filings, CRISIL MI&A

Key observations

- Amanta Healthcare Ltd had operating income of Rs 2,803.76 million in FY2024. Amanta's sale of IV Fluid for the FY2024 was Rs 1,777.90 million.
- IV fluid solutions are usually available in two variations, i.e. single port and two port. As per the prices notified by NPPA in March 2024, price of two-port IV fluid product (non-glass with special features) is generally higher than the single-port IV fluid product products (non-glass). For example, single port glucose injection 5% of 500ml has ceiling price of Rs 37.98, whereas two port glucose injection 5% of 500ml has ceiling price of Rs 82.27. The two-port packaging offers special features like self-collapsibility, self-sealability, and absence of air-vent.
- Amanta Healthcare Ltd sells two port IV fluid products under the brand SteriPort. B. Braun Medical
 India Pvt Ltd sells IV fluids under the brand Ecoflac plus. Simillarly Denis Chem Lab Ltd sells IV fluids
 under the brand Aqua Pulse, Otsuka Pharmaceutical India Pvt Ltd sells IV fluids under the brand
 Unibag and Shree Krishnakeshav Laboratories Ltd sells IV fluids under the brand Freeflex.

^{*-}consolidated financial statements



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