

Market assessment of the Pharmaceutical API segment

May 2021 (updated addendum July and November 2021)

Table of contents

1	Global macro-economic overview	4
1.1	Global GDP review and outlook.....	4
2	Macro-economic assessment of India	11
2.1	A review of India's GDP growth	11
2.2	Review of private final consumption growth in India.....	16
2.3	Fundamental growth drivers of GDP	18
3	Overview of Global Pharmaceutical industry	25
3.1	Review of global pharmaceuticals industry.....	25
3.2	Regulations in key markets.....	35
4	Assessment of Indian bulk drug industry	44
4.1	Overview of Indian bulk drug industry.....	44
4.2	Review and Outlook of Indian bulk drug industry	47
4.3	Review of key demand drivers for Indian bulk drug industry	58
4.4	Review of key regulations in Indian bulk drug industry.....	66
4.5	Key success factors and risks in Indian bulk drug industry	68
4.6	Focus on Research & Development	71
4.7	Capital expenditure requirement or investment required for setting up a new plant	74
4.8	Five force analysis for Indian bulk drug industry	76
5	Assessment of Indian Pharmaceutical market.....	78
5.1	Review and outlook on Indian domestic formulations market	78
5.2	Review of key growth drivers for the industry	86
5.3	Review of key risk factors and challenges for the Indian pharmaceutical industry	89
5.4	Recent trends in Indian pharmaceutical industry.....	90
5.5	Formulation exports	92
5.5.1	Formulations exports to regulated markets	95
5.5.2	Formulations exports to semi-regulated markets	97
5.6	Indian Trade (unbranded) Generics market.....	100
6	Assessment of key API for therapeutic areas	103
6.1	Anti-histamine & Anti-allergy.....	103
6.2	Pain Management.....	109
6.3	Vitamins	113
6.4	Anti-hypertension	117
6.5	Anti-gout.....	122
6.6	Anti-Asthmatic / respiratory therapy medicines	126

7	Competitive landscape of Indian pharmaceutical industry	131
7.1	Operational overview	131
7.2	Financial Overview.....	137
8	Annexure	144
8.1	Overview of regulated pharmaceutical country list	144
8.2	Evolution of the Indian pharmaceutical industry	145
8.3	Regulatory environment in India	153
9	Addendum dated 28 June 2021	158
9.1	Export data for key product categories	158
9.2	Addendum to macro-economic section for updated GDP projections (June 2021)	160
9.3	Outlook for GDP growth in fiscal 2021.....	161
9.4	Review of private final consumption growth	164
10	Addendum dated 23 July 2021	167
10.1	Anti-histamine & Anti-allergy.....	167
10.2	Pain Management.....	167
10.3	Vitamins	168
11	Addendum dated 29 July 2021	169
11.1	Global GDP review and outlook.....	169
11.2	Overview of Global Pharmaceutical industry	172
12	Median attrition rates for select pharmaceutical players (Addendum dated 15th June 2021)	179
13	Addendum dated 3rd Nov 2021	180
13.1	Operational Overview	180
13.2	Financial Overview.....	181
13.3	Annexure.....	187

1 Global macro-economic overview

1.1 Global GDP review and outlook

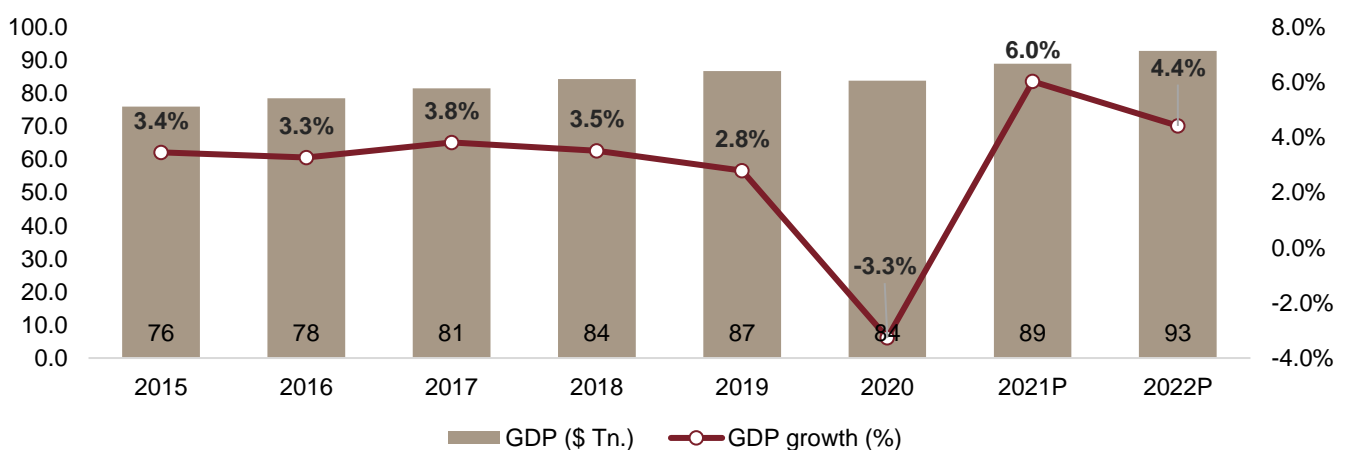
Global gross domestic product (GDP) declined sharply in 2020 owing to the Covid-19 pandemic, but expected to rebound strongly by the end of 2021 on account of policy support and vaccination drive

Global real GDP growth was in the 3-4% range during 2015-2018, according to the International Monetary Fund (IMF). It declined to 2.8% in 2019. In 2020, the IMF estimates global real GDP to de-grow 3.3% owing to the Covid-19 pandemic, which has disrupted businesses across the world. In response, almost all major countries announced stimulus packages, which has resulted in a recovery in the second half of 2020. By the end of 2021, global GDP is expected to rebound strongly and grow 6.0% on-year. The 2021 forecast is revived to 6.0% in April 2021 update from 5.5% (January 2021), which was revised up wards in January 2021 update by IMF by 0.3 %points relative to the previous forecast of 5.3% in October 2020, reflecting expectations of a vaccine supporting and strengthening economic activity during latter half of 2021 and additional policy support in a few large economies will provide further support in 2021–22 to the global economy. The fiscal support announced for 2021 in some countries, including most recently in the United States and Japan, together with the unlocking of Next Generation EU funds, will help lift economic activity among advanced economies with favourable spill overs to trading partners.

Although recent vaccine approvals have raised hopes of a turnaround in the pandemic later this year, renewed waves and new variants of the virus pose concerns for the outlook. Global prospects remain highly uncertain one year into the pandemic. Amid exceptional uncertainty, the global economy is projected to grow 6.0 percent in 2021 and 4.4 percent in 2022. The outlook depends not just on the virus spread and vaccination drive to contain it—but it also hinges on how effectively economic policies deployed under high uncertainty can limit lasting damage from this unprecedented crisis.

Trend and outlook for global GDP (CY2015-2021P)

(USD trillion)



P: Projection

Source: IMF economic database, World Bank national accounts data and OECD national accounts data, CRISIL Research

Advanced economies have been able to provide expansive fiscal support to individuals and companies (direct tax and spending measures as well as equity injections, loans, and guarantees), and central banks have reinforced the fiscal policy support with expanded asset purchase programs, funding-for-lending facilities, and, for some, interest rate cuts. Reflecting the strong policy support and the anticipated widespread availability of vaccines in summer 2021, the projected output loss compared with the pre-COVID forecast is relatively smaller for advanced economies than other countries.

Recovery paths vary within advanced economies, with the US and Japan projected to regain end-2019 activity levels in the second half of 2021, while in the euro area and the United Kingdom activity is expected to remain below end-2019 levels into 2022.

Emerging market and developing economies are also projected to trace diverging recovery paths. Considerable differentiation is expected between China—where effective containment measures, a forceful public investment response, and central bank liquidity support have facilitated a strong recovery—and other economies. Oil exporters and tourism-based economies within emerging markets group face particularly difficult prospects considering the expected slow normalization of cross-border travel and the subdued outlook for oil prices. The pandemic is expected to reverse the progress made in poverty reduction across the past two decades. Close to 90 million people are likely to fall below the extreme poverty threshold during 2020–21.

India is expected to regain the top spot as the world's fastest growing economy in 2021

India was one of the fastest growing economies in 2018 and 2019. In 2020, GDP of all countries – including that of developed ones such as the US and the UK but except China's – is expected to de-grow primarily due to the negative economic impact of the pandemic. India's GDP is expected to decline by 8.0% in 2020. Further, GDP growth of all major economies is expected to rebound in 2021 as economic activities resume and also due to the low base of 2020. Among the major economies, India, with a growth rate of ~12.5%, is expected to be the fastest growing in 2021 followed by China with 8.4%.

Asia-Pacific has been hit hard by the coronavirus pandemic and is recovering from a severe recession. The outlook varies by country depending on infection rates and containment measures, policy responses, reliance on contact-intensive activities, and external demand. Output is expected to remain below pre-pandemic trends over the medium term, with the most vulnerable in society likely to be hit the hardest. The projections remain highly uncertain, with significant downside risks. The Asia and Pacific region is also starting to recover tentatively, but at multiple speeds. Economic activity in Emerging and Developing Asia is expected to contract by -1.0% in 2020, due to a sharper-than-expected downturn in key emerging markets, and to grow by 8.6% in 2021 and 6.0% in 2022

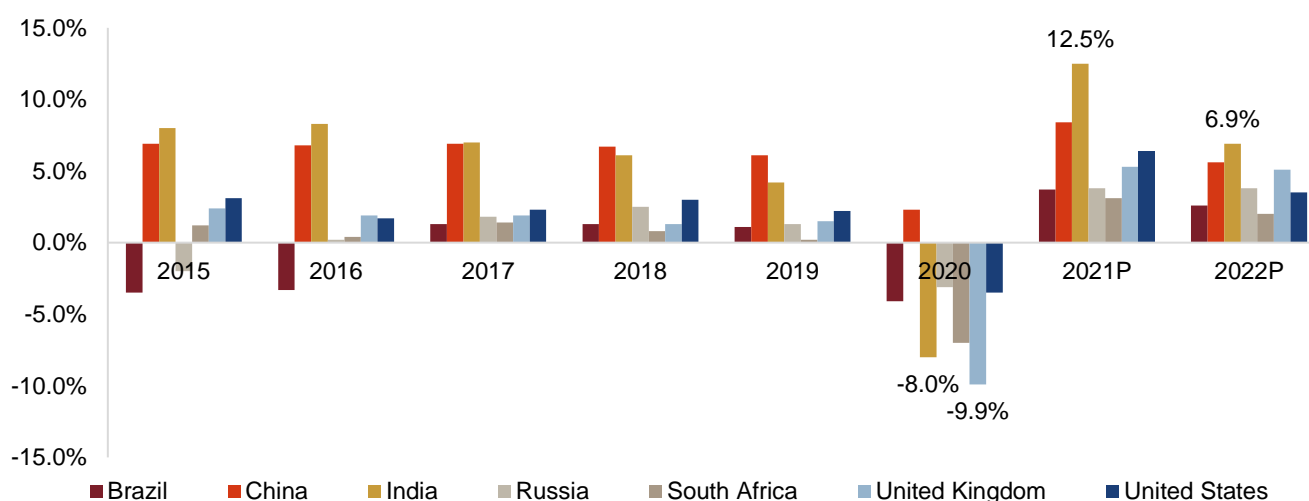
Real GDP growth by geographies

	2017	2018	2019	2020	2021	2022
Advanced Economies	2.5	2.2	1.6	-4.7	5.1	3.6
United States	2.3	3.0	2.2	-3.5	6.4	3.5
Euro Area	2.6	1.8	1.3	-6.6	4.4	3.8
Japan	2.2	0.3	0.3	-4.8	3.3	2.5
United Kingdom	1.2	1.3	1.4	-9.9	5.3	5.1
Emerging Market and Developing Economies	4.8	4.5	3.6	-2.2	6.7	5.0
China	6.9	6.7	5.8	2.3	8.4	5.6
India	6.8	6.5	4.0	-8.0	12.5	6.9
ASEAN	5.3	5.3	4.9	-3.4	4.9	6.1
Middle East and Central Asia	2.6	2.1	1.4	-2.9	3.7	3.8
World	3.8	3.5	2.8	-3.3	6.0	4.4

P: Projected

Emerging Asia comprises the ASEAN-5 (Indonesia, Malaysia, Philippines, Thailand, Vietnam) economies, China, and India.
Source: IMF economic database, World Bank national accounts data and OECD national accounts data, CRISIL Research

Trend of real GDP growth rate (%) for major economies (2015-2021P)



Note: Data for India represents financial year, forecasts for India are CRISIL Research forecasts

Source: IMF, CRISIL Research

Review of global per capita GDP

India's per capita GDP growing at ~3x global per capita GDP growth rate

Global GDP per capita clocked a compound annual growth rate (CAGR) of 1.9% between calendar year (CY) 2013 and 2019, as per the World Bank data. Meanwhile, India's corresponding figure clocked a CAGR of ~5.7%, ~3 times faster than the global number.

Global and Indian per capita GDP growth at constant 2015 USD (2013-2021P)

	2013	2014	2015	2016	2017	2018	2019	2020	CAGR CY13-20
Per capita GDP – Global (constant 2015 US\$)	9,836	10,025	10,223	10,389	10,619	10,843	11,004	10,520	1.9%
On-year growth (%)	1.7%	1.9%	2.0%	1.6%	2.2%	2.1%	1.5%	-4.4%	
Per capita GDP – India (constant 2015 US\$)	1,416	1,503	1,606	1,719	1,817	1,915	1,973	1,798	5.7%
On-year growth (%)	5.1%	6.2%	6.8%	7.1%	5.7%	5.4%	3.0%	-8.9%	

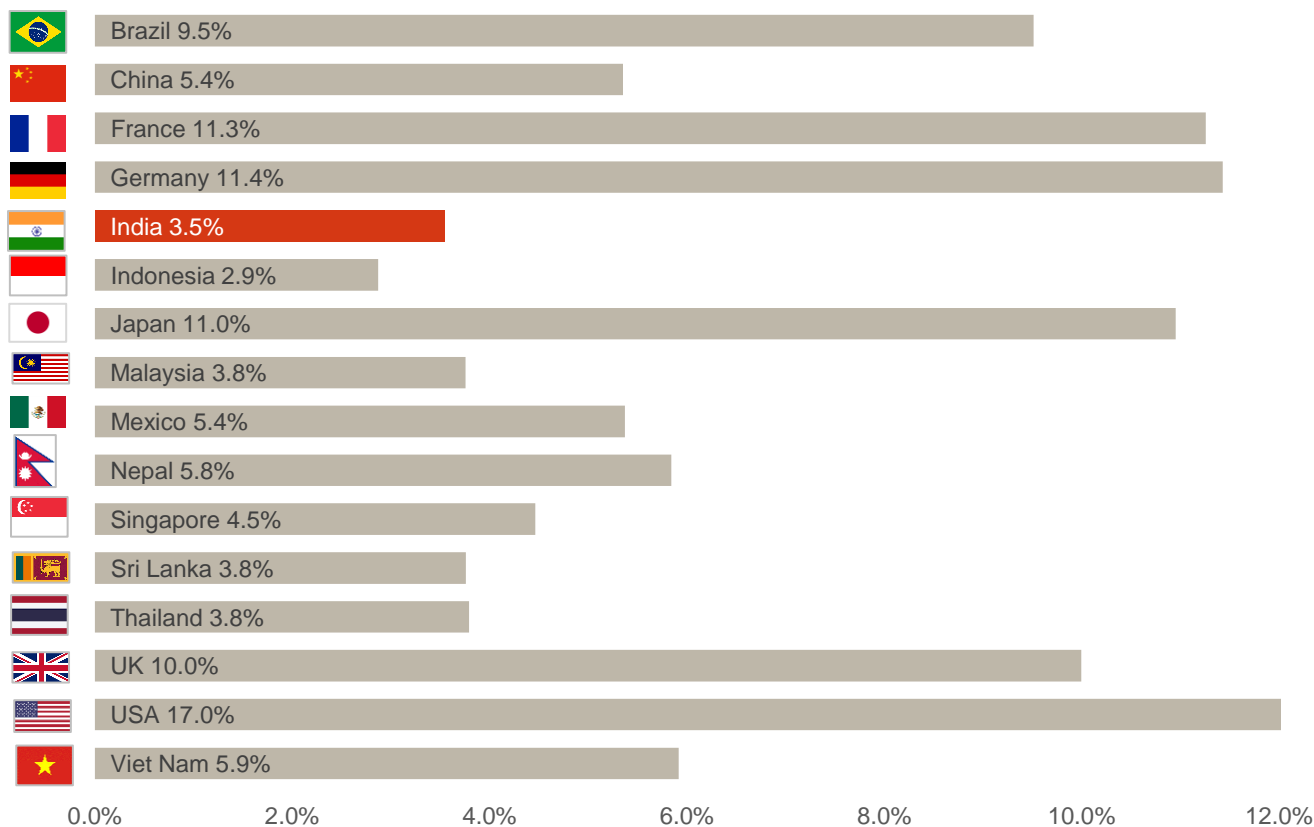
Source: World Bank, CRISIL Research

Healthcare expenditure

Global healthcare spending has been rising faster in keeping with the economic growth. As economy grows, public and private spending on health grows, too. Also, increase in sedentary work is giving rise to chronic diseases, which is also pushing up healthcare spending. Fast growing economies with low spending on health are seeing it increasing dramatically as they move up the income ladder.

India lags peers in healthcare expenditure

Total healthcare expenditure as % of GDP (2018)



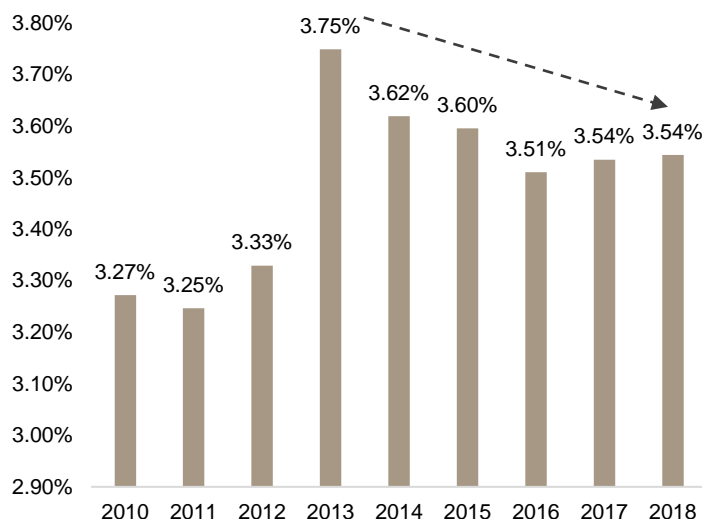
Source: Global Health Expenditure Database, World Health Organization; CRISIL Research

According to the Global Health Expenditure Database compiled by the World Health Organization (WHO), in 2018 India's expenditure on healthcare was 3.5% of GDP. In fiscal 2019, India's real GDP was Rs 139.8 trillion (constant fiscal 2012 prices) and healthcare expenditure is estimated at ~Rs 4.9 trillion. As of 2018, India's healthcare spending as a percentage of GDP trails behind not just developed countries, such as the US and UK, but also developing countries such as Brazil, Nepal, Vietnam, Singapore, Sri Lanka, Malaysia and Thailand.

India spends too little on its healthcare

Current healthcare expenditure (CHE) as % of GDP in India (2010-2018)

Per capita current expenditure on health in USD (2018)



Source: Global Health Expenditure Database- World Health Organisation, CRISIL Research

India's current healthcare expenditure has decreased over 2013-2018. Healthcare expenditure in India is more through private expenditure than public expenditure. The country's low healthcare expenditure is primarily due to under-penetration of healthcare services and lower consumer spending on healthcare.

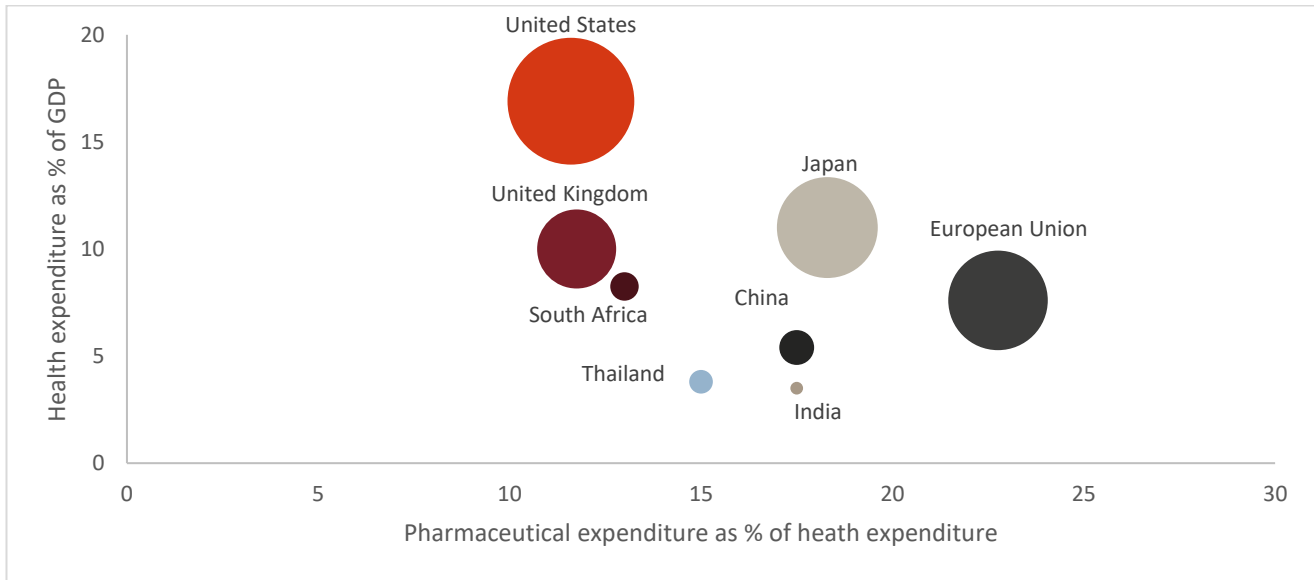
Further, India's public spending on healthcare services remains much lower than its global peers. For example, India's per-capita total expenditure on healthcare (at an international dollar rate, adjusted for purchasing power parity) was only \$73 in 2018 versus the US' \$10,624, the UK's \$4,315 and Singapore's \$2,824.

Global average pharmaceutical expenditure spend is around \$ 800 per capita, India spends USD 10-15 per capita

Pharmaceutical care is constantly evolving, with many novel drugs entering the market. These offer alternatives to existing treatments, and in some cases, the prospect of treating conditions previously considered incurable. However, the costs of new drugs can be very high, with significant implications for health care budgets. In 2017, retail pharmaceuticals accounted for almost one-fifth of all health care expenditure, and represented the third largest spending component in OECD countries after inpatient and outpatient care. Most spending on retail pharmaceuticals is for prescription medicines (75%), with the remainder spent on over-the-counter (OTC) medicines (19%) and medical non-durables (5%).

India spends very low on its healthcare expenditure and almost 65% is out-of-pocket expenditure by public. Government of India plans to increase its healthcare spending to 2.5-3.0% by 2025 (Covid pandemic has increased the healthcare spending and GOI estimated to spend 2.5-3.0% of GDP in 2022). Pharmaceutical spends forms 15-20% of the healthcare expenditure on pharmaceutical expenses, but the per capita actual spend on pharmaceutical expenses is drastically below global average. India pharmaceutical spend is even below countries such as Thailand and South Africa.

Pharmaceutical spending of key countries



Note: Size of the bubble indicates pharmaceutical spending per capita in USD for the year 2019

Source: Global Health Expenditure Database- World Health Organisation, World Bank database, CRISIL Research

2 Macro-economic assessment of India

2.1 A review of India's GDP growth

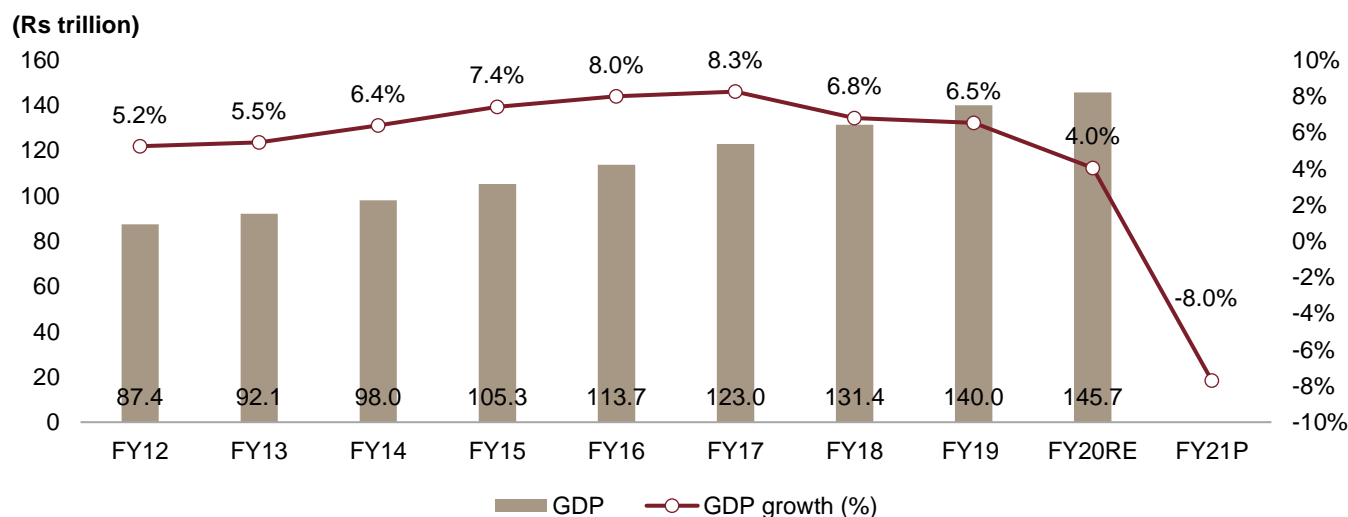
GDP clocked a 6.6% CAGR between fiscals 2012 and 2020

In 2015, the Ministry of Statistics and Programme Implementation (MoSPI) changed the base year for calculating India's gross domestic product (GDP) between fiscals 2005 and 2012. Based on this, the country's GDP increased at an eight-year compound annual growth rate (CAGR) of 6.6% to Rs 146 trillion in fiscal 2020 from Rs 87 trillion in fiscal 2012.

Fiscal 2020 estimates show that investment decline has added to the economy's woes

In fiscal 2020, India's GDP grew 4.0% as per first revised estimates for fiscal 2019. Private consumption dropped to a decadal low of 5.3% from 7.2% in fiscal 2019 – clearly a fallout of the slowdown in spending by the Central and state governments and muted private sector appetite for fresh investments. Over the past four years, a sharp increase in government spending, especially on infrastructure (roads, railways and highways), had kept investment spending growth at 8%, on average. In fiscal 2020, though, government investment spending took a backseat. Meanwhile, weak consumption demand and low capacity utilisation kept investments in the manufacturing sector in the lull.

Real GDP growth in India (new GDP series)



RE: Revised estimates

Source: First Revised Estimates of National Income, Consumption Expenditure, Saving and Capital Formation For 2019-20, Central Statistics Office (CSO), MoSPI, CRISIL Research

Gross Value Added at basic prices (constant 2011-12 prices)

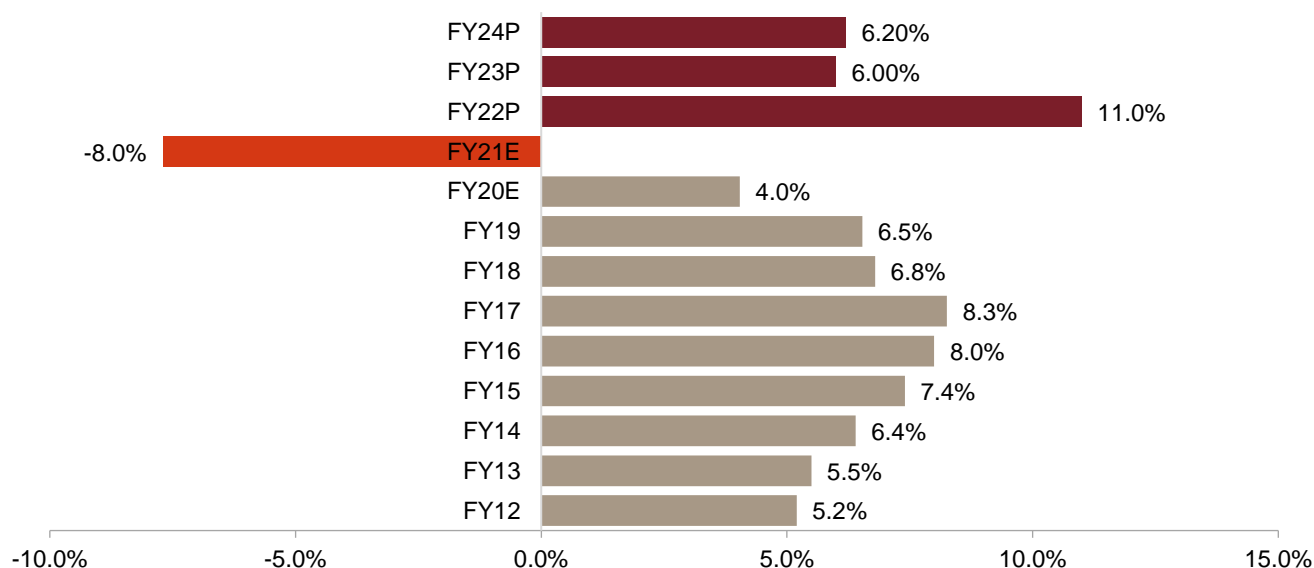
Rs. Trillion	FY12	FY13	FY14	FY15	FY16	FY17	FY18	FY19	FY20	CAGR
GVA at basic prices	81.1	85.5	90.6	97.1	104.9	113.3	120.7	128.0	133.0	6.4%
Y-o-Y Growth (%)		5.4%	6.1%	7.2%	8.0%	8.0%	6.6%	6.0%	3.9%	

Source: CRISIL Research

Economy contracted by 8.0% in fiscal 2021

India is getting back on its feet slowly, with divergent growth trends

Fiscal 2021 has been a challenging year for the Indian economy, which was already experiencing a slowdown before the Covid-19 pandemic created the 'perfect storm'. Though data suggests that there has been some pick-up in recent months, recovery is weak and uneven. The country's gross domestic product (GDP) is expected to contract 8% by end-fiscal. And indeed, the scars of the pandemic continue to run deep for small businesses, the urban poor, and most of the services sector. At the same time, monetary policy has begun normalising and some tightness in domestic financial conditions is inevitable. Against this backdrop, policy support remains critical, apart from action in the external environment. This fiscal, policy response to the pandemic has been more on damage control and providing support to the economy. In fiscal 2022, though, the government is expected to normalise some of the extraordinary or unconventional policy moves, while trying to ensure there is smooth revival in growth. Some of its biggest challenges ahead will be: broad-basing growth to services and labour-intensive manufacturing sectors and ensuring financial conditions stay supportive.

Real GDP growth (% on-year)


E: Estimated; P: Projected by CRISIL Research; GDP calls updated as of Mar 2021

Source: Provisional Estimates of Annual National Income, 2019-20, CSO, MoSPI, CRISIL Research

Key fiscal measures announced by the Centre to deal with the pandemic impact

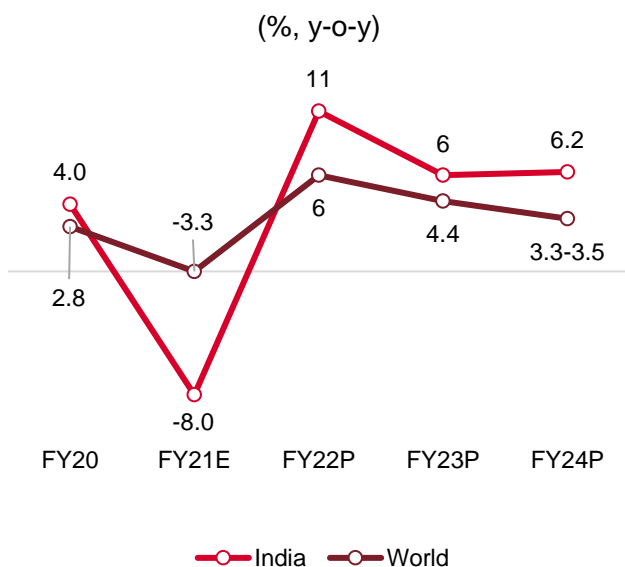
To mitigate the pandemic's negative impact on the economy, the Central government has announced a Rs 20.9 trillion package, amounting to 10% of the country's nominal GDP. The package is a mix of fiscal and monetary measures (to revive growth in the short term) and reforms (to boost long-term economic prospects). Liquidity support has been a major part of India's response so far. Globally, too, liquidity measures have played a lead role in policy response. The immediate fiscal cost to be borne by the government would be ~Rs 2.6 trillion, or 1.2% of nominal GDP. Further, execution of the government's measures to revive the economy and pace of implementation of the announced reforms are key monitorables.

Fiscal 2022 base case GDP growth to be at 11% on a weak base and rising-global-tide effect; but second wave of infections will impact the growth forecast in negative direction with cases continue to rise pan-India

CRISIL forecasts India's GDP growth to rebound to 11% in fiscal 2022 as four drivers converge:

1. **Weak base:** An 8% contraction in GDP in fiscal 2021 will provide a statistical push to growth next fiscal
2. **Global upturns:** Higher global growth in 2021 - world GDP by 5.0%, advanced economies 4.3%, emerging economies 6.3% - should lift exports
3. **Covid-19 curve:** India is seeing a fortuitous mix of flattening of the infection curve, second wave and learning to live with the virus, rollout of vaccines, and herd immunity. In the Second wave cases are rising faster than in the first wave. As result of localized lockdowns and rising cases in the second wave there is downside risk for the economy. However, second wave will have a more pronounced impact on contact-based services sectors which are already struggling. Thus GDP growth will be impacted considering risk tilted to downside.
4. **Fiscal push:** Stretch in the fiscal glide path and focus of Union Budget 2021-22 on capex are expected to have a multiplier effect on growth

In next three fiscals, India's growth to be greater than the global GDP



Fiscal 2022 GDP growth to rebound to 11% on the back of a very weak base and the rising-global-tide effect

CRISIL sees India's GDP growth rebounding to 11% in fiscal 2022, due to a very weak base, flattening of covid curve, rollout of vaccinations, investment focused government spending and benefit from the 'rising global tide lifts all boats' effect. Yet economy is expected to reach pre-pandemic levels only by Q2 of fiscal 2022. Services will take longer to recover than manufacturing.

Over fiscals 2023-2025, growth is seen averaging at ~6.2% annually. In this scenario, trend in GDP is unlikely to have strong growth in the next three fiscals. CRISIL Research estimates that the economy will see a permanent loss of ~12% real GDP due to this. Real GDP will only merely catch up to the fiscal 2020 level by fiscal 2022. Beyond fiscal 2022, India is seen growing faster than the world.

Note: Forecasts for World are for calendar year; FY20=2019; P: Projected; updated as of Mar 2021; India numbers from for FY20 and FY21 are based on MOSPI latest GDP estimates and FY22 onwards are CRISIL Research estimates while World GDP growth rates are from IMF world economic outlook update as of April 2021

Source: S&P Global Ratings, CRISIL

With capital and labour constrained by their own set of challenges, the push will have to come from efficiency improvements, for which economic reforms are critical. These need to be relentlessly pursued to create an upside to medium-term growth. The government needs to take more steps to address the current pain in the economy. It should stretch itself fiscally to support vulnerable households and small businesses that have been hit hard by the pandemic. CRISIL believes that this will also help preserve productive capacity in the economy and, together with reforms, can give a sustainable push to growth over the medium run.

For fiscal 2022, our earlier December GDP growth forecast of 10% was largely mediated on a low-base effect and support from the 'global-tide-lifts-all-boats' effect and flattening of Covid-19 curve. With the revised 11% growth forecast (due to the capex push and return to expenditure normalization, as communicated in Union Budget 2021-22), we expect the economy to get back to its pre-pandemic levels in the second quarter of fiscal 2022. But fiscal 2022 GDP growth will be under review as second wave of COVID-19 sets in. Even with 11% growth in fiscal 2022 scenario, full-year real GDP will only be 2.4% higher than that in fiscal 2020.

A second wave of Covid-19 in India suggest the pandemic remains an ongoing risk. India's second Covid-19 wave has wreaked havoc, with daily cases crossing a staggering 3 lakh in the week through April 25. India's daily infections recorded the highest number of cases in a single day among countries worldwide in the last week, and daily deaths have crossed the peak of the first wave. Worryingly, their steep trajectory seems to be following that of daily cases. The March 2020 nation-wide lockdown led to a massive migrant exodus. This time, even though there

have been no nationwide restrictions, the increasing number of cases have prompted states to announce localised restrictions and curfews in different forms. There has been no restriction on economic activity and the impact on GDP is expected to have limited downside risk. But with increase in cases in May 2021 and depending upon the restrictions which aim at decline in spread of covid-19, there is downside risk to GDP growth if spread of covid-19 is not brought under control.

Risks to the fiscal 2022 forecast

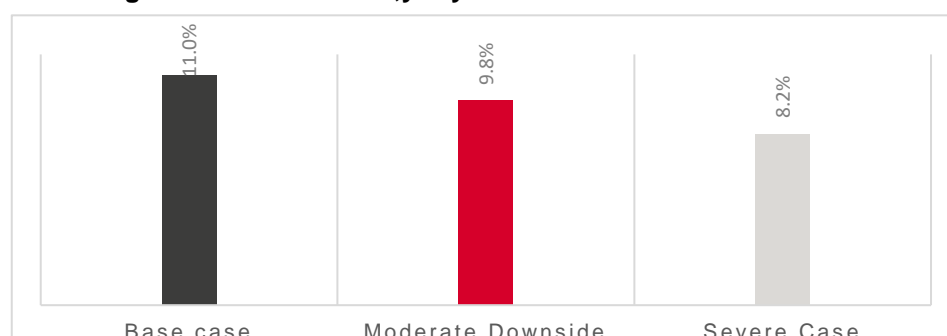
- **Premature withdrawal of policy support globally:** Most major economies have taken on debt to fund their Covid-19 fiscal stimulus packages. This has added to existing high debt levels, and will need to be reduced soon, entailing normalisation of the stimulus. Any premature withdrawal of monetary or fiscal stimulus could threaten to slow the pace of economic recovery
- **Worsening stress in the financial sector/deteriorating financial conditions:** Rise in non-performing assets, especially from smaller enterprises, is leading to stress and impairing the financial system's ability to support a sustained, rapid pick-up in growth. The Reserve Bank of India is expected to keep the policy repo rates stable, but firmer 10-year government security yields could put upside pressure on market interest rates benchmarked to it
- **Unfavourable monsoon:** After two consecutive years of normal monsoon, a third year of timely and well-distributed rains is not a given. In the past 20 years, only once has the Indian economy seen three good monsoon years in a row.
- **A second wave, currently localised:** A second or third wave of Covid-19 infections in several economies, and its recent resurgence in India suggest that the pandemic remains an ongoing risk. In the Second wave cases are rising faster than in the first wave. As result of localized lockdowns and rising cases in the second wave there is downside risk for the economy. However, second wave will have a more pronounced impact on contact-based services sectors which are already struggling. Thus GDP growth will be impacted considering risk tilted to downside.

Base case of 11% GDP assumes cases surge and lockdowns peak by mid-May. In this scenario, the economy returns to pre-pandemic level by September 2021 quarter

Scenario 1: Moderate downside of 9.8% GDP growth assumes case surge and consequent lockdowns peak by May-end. Scenario 2: Severe downside of 8.2% GDP growth assumes peak is pushed to June-end

In scenarios of Moderate and severe case catch-up to pre-Covid-19 GDP level is pushed beyond September quarter. Permanent loss to GDP over the medium term rises to ~12% from 11% in the base case

GDP growth Fiscal 2022 %,y-o-y



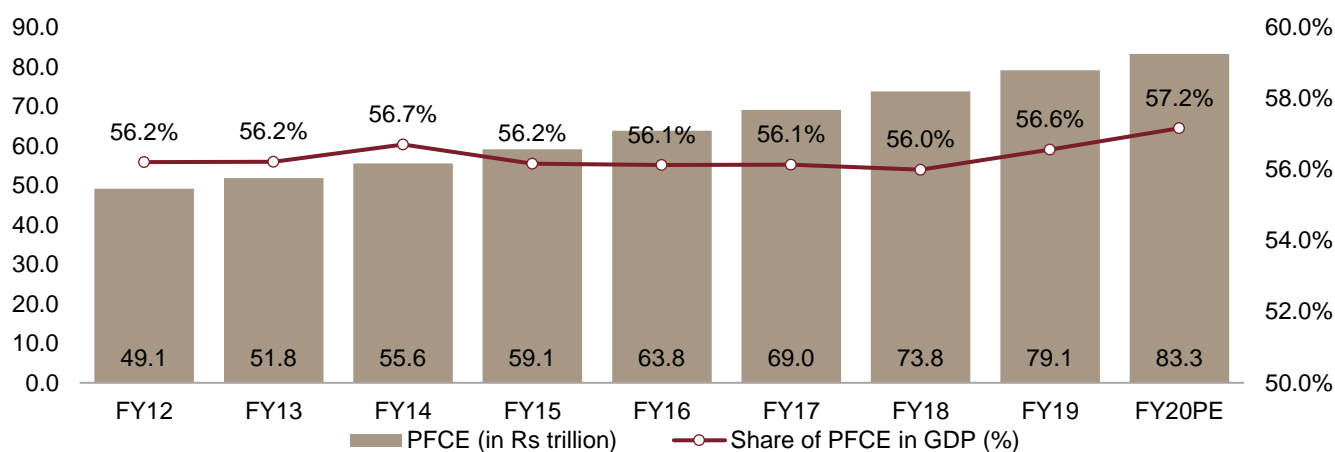
Source: S&P Global ratings, CRISIL Research, May 2021

2.2 Review of private final consumption growth in India

Private final consumption expenditure to maintain dominant share in GDP

Private final consumption expenditure (PFCE) at constant prices clocked 6.8% CAGR between fiscals 2012 and 2020, maintaining its dominant share in the GDP pie, at ~57% or Rs 83.3 trillion. Factors contributing to this growth included good monsoons, wage revisions due to the implementation of the Pay Commission’s recommendations, benign interest rates, and low inflation.

PFCE (at constant prices)



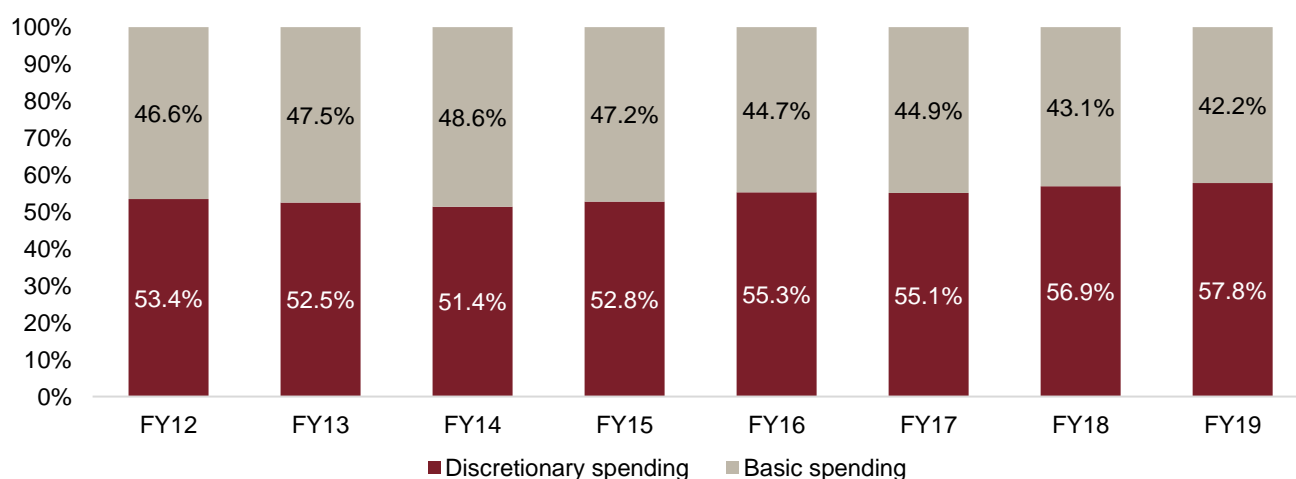
PE: Provisional estimates

Source: Provisional Estimates of Annual National Income, 2019-20, CSO, MoSPI, CRISIL Research

Consumption expenditure to be driven by discretionary items

CRISIL Research estimates basic items constituted 42.2% share of total consumption expenditure of Indian consumers in fiscal 2019, while discretionary items accounted for the remainder 57.8%, up from 53.4% in fiscal 2012, suggesting rising disposable income of households.

Broad split of PFCE consumption into basic and discretionary spending



Note: Basic items include food, clothing and housing. Discretionary items include education, healthcare, electricity, water supply, footwear, personal care products, processed foods, alcoholic and non-alcoholic beverages, tobacco, narcotics, fuel and gas, furnishing and household equipment, vehicle and personal transportation, spending on recreation and culture, communication, restaurants and hotels, financial insurance and other financial services, and other items not elsewhere classified (n.e.c.)

Source: MoSPI, CRISIL Research

Within the consumption basket, health expenses rose at 10% CAGR between fiscals 2012 and 2019, compared with overall PFCE, which increased annually by 13%. As income levels improve and, consequently, discretionary spending increases, CRISIL Research expects the healthcare industry to gain.

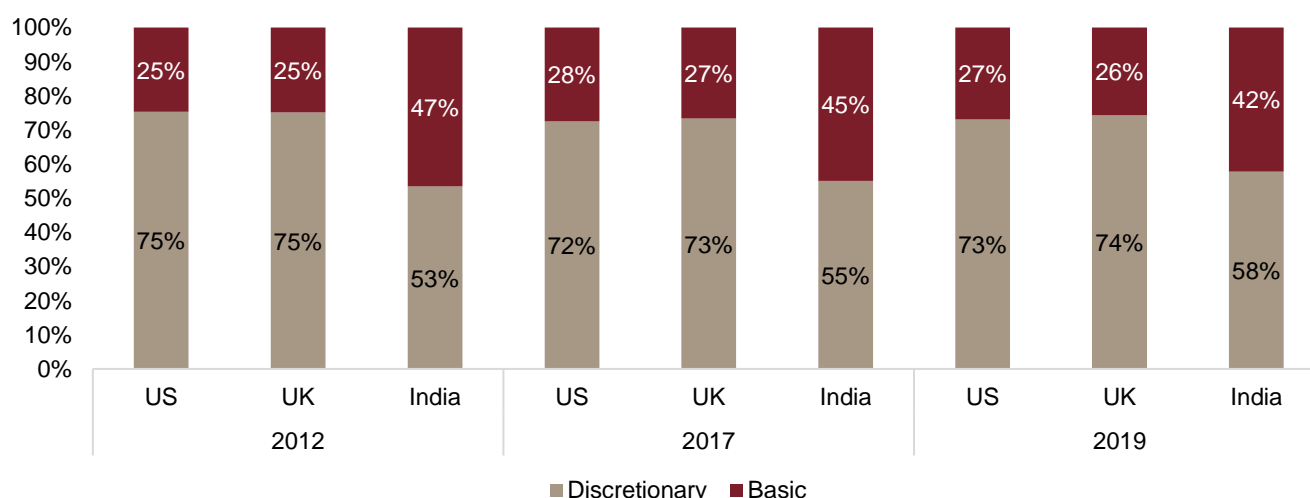
Trend of healthcare in PFCE

Particulars (at constant prices)	FY12	FY17	FY18	FY19	FY20	CAGR FY12-FY19
Total PFCE (Rs billion)	49,104	69,002	73,307	78,844	83,217	13%
Health PFCE	1,813	3,085	3,218	3,472	3,800	10%

Source: MoSPI, CRISIL Research

India's discretionary spending is lower than that of advanced economies such as the US and the UK, and is expected to grow with a rise in per capita income. In 2012, discretionary items formed ~75% share of spending for both the US and the UK, compared with ~53% for India. The share increased to ~76% for the US, 77% for the UK and 55% for India in 2017, and stood at 73%, 74% and 58%, respectively, in 2019. As the Indian economy advances and household disposable income rises, the share of discretionary spending is expected to increase and drive growth in overall consumption expenditure. This is expected to augur well for healthcare which rely primarily on discretionary and basic spending for their growth.

Comparison of consumption pattern of India, the US and the UK



Notes:

- 1) CRISIL Research has used consumer/ household spending data (the US and the UK) and private final consumption data (India) to arrive at the broad split into discretionary and basic items, as defined earlier.
- 2) Data for the US is for 2011, 2016 and 2018, and for the UK and India is for fiscals 2012, 2017 and 2019.

Source: MoSPI, Office of National Statistics – UK, Bureau of Economic Analysis – US Department of Commerce, CRISIL Research

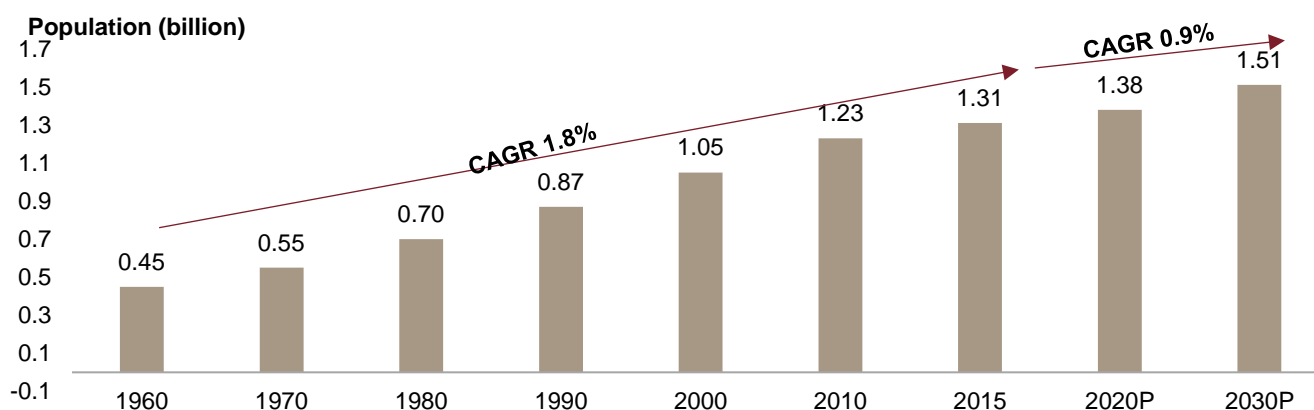
2.3 Fundamental growth drivers of GDP

India's population projected to touch 1.5 billion by 2030

India's population clocked 1.8% CAGR over 2001-2011 to reach ~1.2 billion, as per Census 2011. As of 2010 census, the country had about 246 million households.

According to the United Nations' report, *World Urbanization Prospects: The 2018 Revision*, India and China, two of the most populous countries, accounted for nearly 37% of the world's population in 2015. The report projects 1% CAGR for India's population, which is expected to reach 1.5 billion by 2030, making it the world's most populous country, surpassing China (for which the projected population is 1.4 billion).

India's population growth



P: Projected

Source: *World Urbanization Prospects: The 2018 Revision*, United Nations, CRISIL Research

Global population to increase at 0.8% CAGR between 2019 and 2050

According to the latest UN population estimates, world population grew by 1.1 % in 2019, or 82 million people, to reach a global total of 7.7 billion. In the coming decades, the slowdown in the rate of population growth is projected to continue. By 2050, it is forecast to fall below 0.5 per cent

Global population growth rate

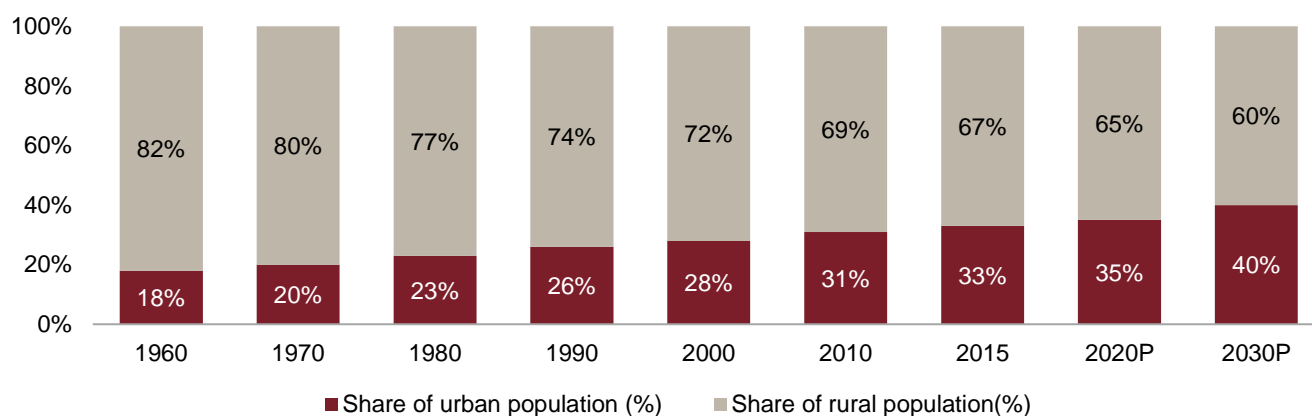
Group of economies	Population			Annual growth rate		
	(Millions)			(Percentage)		
	2014	2019	2050	2014–2019	2019	2019–2050
World	7 295	7 713	9 735	1.1	1.1	0.8
Developing economies	5 944	6 338	8 318	1.3	1.2	0.9
Developed economies	1 046	1 065	1 102	0.4	0.3	0.1

Source: United Nations (2019). *World Population Prospects 2019*, United Nations (2019). *World Urbanization Prospects 2018*, CRISIL Research

Urbanisation likely to reach 40% by 2030

The urban population in India has been rising over the years and stood at ~31% of total in 2010. The rising trend is expected to continue. The United Nations report has projected that nearly 40% of the country’s population will live in urban areas by 2030.

India’s urban versus rural population



P: Projected

Source: World Urbanization Prospects: The 2018 Revision, United Nations, CRISIL Research

People from rural areas move to cities for better job opportunities, education and quality of life. The entire family or only a few individuals (generally an earning member or students) may migrate, while the rest of the family continue in the rural house.

India’s population median age to reach 31.4 years by 2030

As per the United Nations, the median age of the global population rose to ~30 years in 2015 from ~22 years in 1970, with the more developed countries exhibiting median ages significantly above the global level. Hence, while the median ages in the US and the UK were 39.8 years and 42.4 years, respectively, that of India was significantly lower at 28.2 years, indicating a favourable demographic dividend. Even among the BRIC (Brazil, Russia, India and China) countries, India's median age was the lowest, with Brazil, China and Russian recording median ages of 31.3 years, 37.0 years and 38.7 years, respectively.

This trend is expected to continue up to 2030, implying strong potential for increase in income and basic and healthcare spending, as a higher proportion of the population engages in employment activities.

Trend in median ages across key countries

Country	1970	1990	2010	2015	2020P	2030P
Brazil	18.7	22.4	29.0	31.3	33.5	37.7
China	19.3	24.9	35.2	37	38.7	43.0
India	19.4	21.1	25.1	26.7	28.2	31.4
Russian Federation	30.8	33.4	38.0	38.7	39.6	42.6
UK	34.2	35.8	39.6	40.2	40.8	42.4

US	28.4	32.8	36.9	37.6	38.3	39.8
World	21.5	24.0	28.5	29.6	30.9	33.0

P: Projected

Source: UN population estimates, CRISIL Research

India's per capita income rose at a healthy pace between fiscals 2012 and 2020

India's per capita income, a broad indicator of living standards, clocked ~5% CAGR between fiscals 2012 and 2020, rising from Rs 63,642 to Rs 94,954. This growth was led by better job opportunities, propped up by overall GDP growth. Moreover, population growth remained fairly stable at ~1% CAGR.

Per capita net national income at constant prices

	FY12	FY13	FY14	FY15	FY16	FY17	FY18	FY19	FY20PE
Per capita net national income (Rs)	63,462	65,538	68,572	72,805	77,659	82,931	87,828	92,085	94,954
On-year growth (%)	2.1	3.3	4.6	6.2	6.7	6.8	5.9	4.8	3.1

PE: Provisional estimates

Source: Provisional Estimates of Annual National Income, 2019-20, CSO, MoSPI, CRISIL Research

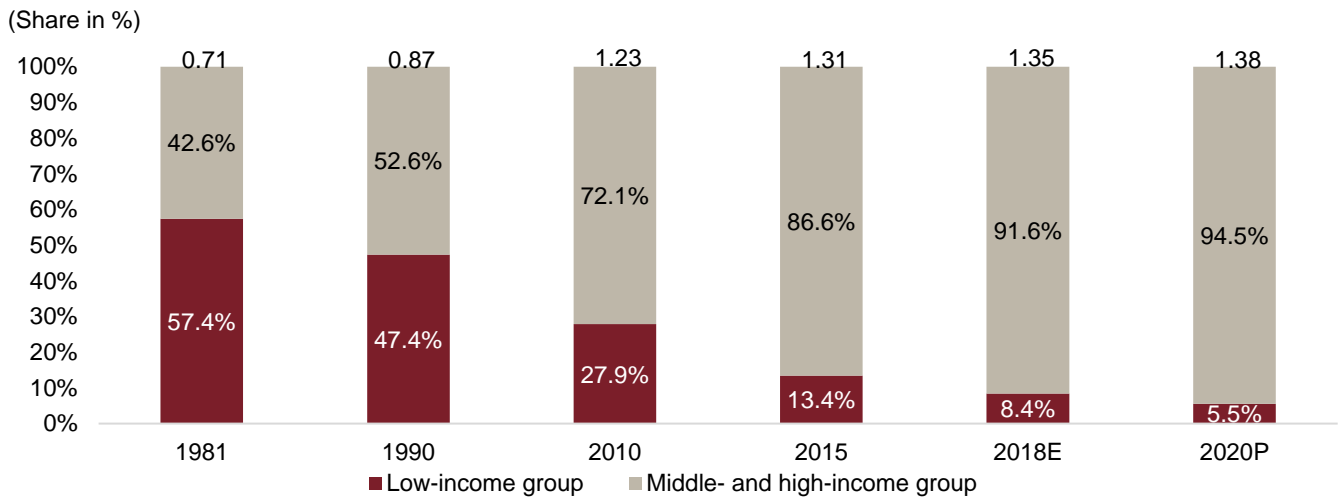
Decline in poverty levels indicates rise in middle- and high-income group in India

The World Bank, in its report 'Global Economic Prospects, January 2019', estimates the number of poor (defined as those living at or below the international poverty line of purchasing power parity of USD1.90 per day) in India declined sharply from 405 million people in 1981 to 175 million people in 2015. In percentage terms, the share of poor in India's total population declined from 57.4% to ~13.4% over the period, and was estimated at 8.4% in 2018. Decline in poverty has been attributed to improvement in macroeconomic parameters such as growth of the economy, employment rate and income equality, and adoption of employment and other public welfare schemes by the government.

In 2020, the World Bank projected the absolute number of poor in India reduced to ~77 million people, thus lowering the percentage share to ~5.5%.

Decline in the poor population indicates that the middle- and high-income group in India has grown at a fast clip, from 42.6% in 1981 to 86.6% in 2015, and was expected to reach 94.5% by 2020. A positive economic outlook along with growth across key employment-generating sectors, such as real estate, infrastructure and automobiles, is expected to have a cascading effect on overall per capita income levels of the population in the medium-to-long term. This, in turn, is expected to drive consumption expenditure and healthcare basic and discretionary spending.

Broad split of population into income groups



E: Estimated, P: Projected

Notes:

The values bar column indicates the total population in billion for respective years as per UN population estimates.

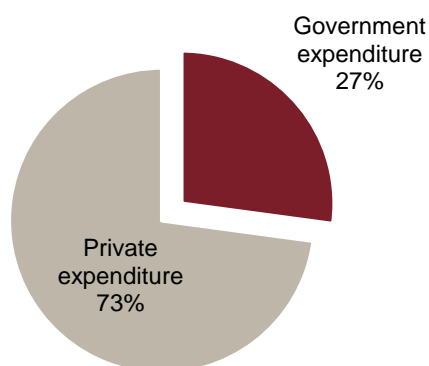
The World Bank defines poor as those living at or below the international poverty line of purchasing power parity of USD1.90 per day. Data for 2018 is estimate and data for 2020 is projection and calculated using data from the World Bank (2018).

The low-income group includes the proportion of the population earning less than or equal to USD1.90 per day; the middle- and high-income group includes the proportion of the population earning more than USD1.90 per day.

Source: World Bank, CRISIL Research

Public healthcare expenditure is low, private sector accounts for the bulk

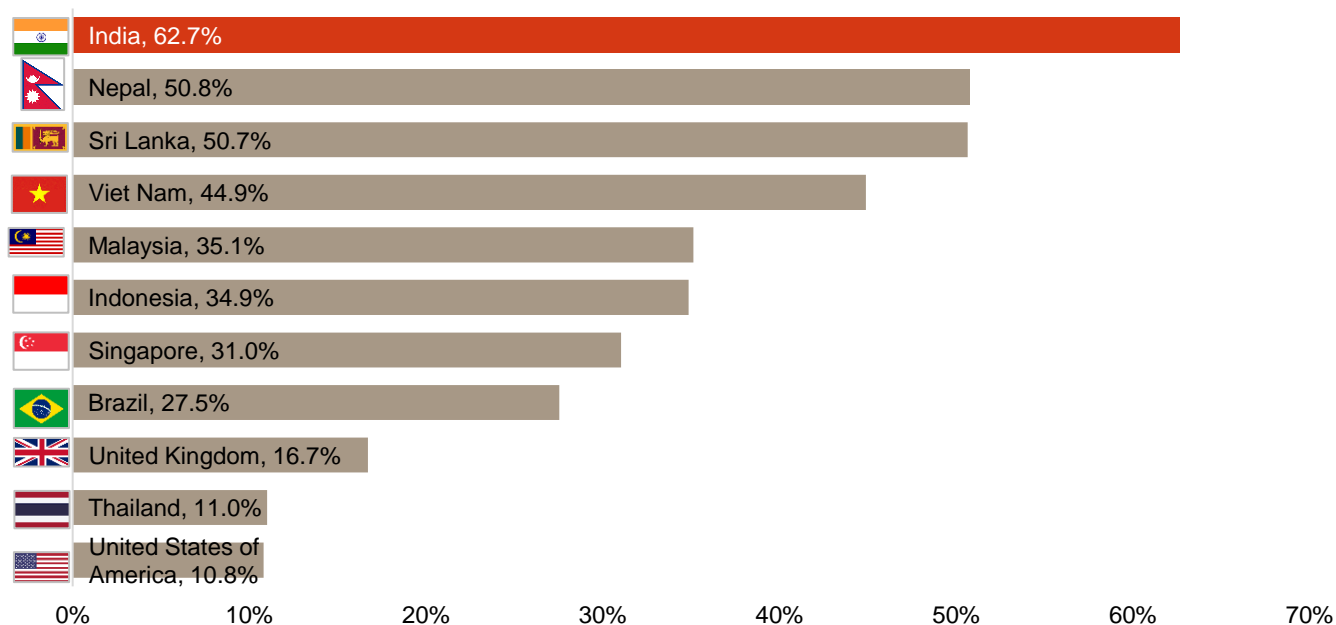
General expenditure on health as percentage of CHE (2018)



India's CHE is skewed towards private expenditure compared with public expenditure. Government expenditure on healthcare has been range-bound at 20-30% of CHE over calendar years 2010-2018. The rest of the expenditure is private in nature – expenditure from resources with no government control (voluntary health insurance), and direct payments for health by corporations (profit, non-for-profit and non-government organisations) and households. However, the government aims to increase public healthcare expenditure to 2.5% of GDP from the current 1.2%, according to the National Health Policy 2017.

Source: Global Health Expenditure Database – WHO, CRISIL Research

Out-of-pocket (OOP) as percentage of CHE (2018)



Source: Global Health Expenditure Database – WHO, CRISIL Research

In India, OOP expenditure on health was nearly 63% of total health expenditure in 2018 (highest among all the countries compared above). Insurance cover in India does not cover outpatient treatments (only recently an insurance company has started covering outpatient treatments under its health insurance), which makes OOP expenditure for outpatient treatments greater than for inpatient treatments.

Nearly 25% of the rural population and 18% of the urban population are dependent on borrowings for funding their healthcare expenditure. Almost 68% of the rural population and 75% of the urban population use their household savings on healthcare-related expenditure. Health expenditure contributes to nearly 3.6% and 2.9% of rural and urban poverty, respectively. Annually, an estimated 60 to 80 million people fall into poverty due to healthcare-

related expenditure. However, Pradhan Mantri Jan Arogya Yojana (PMJAY) is expected to take care of the affordability aspect of healthcare expenditure to some degree, especially for the deprived population.

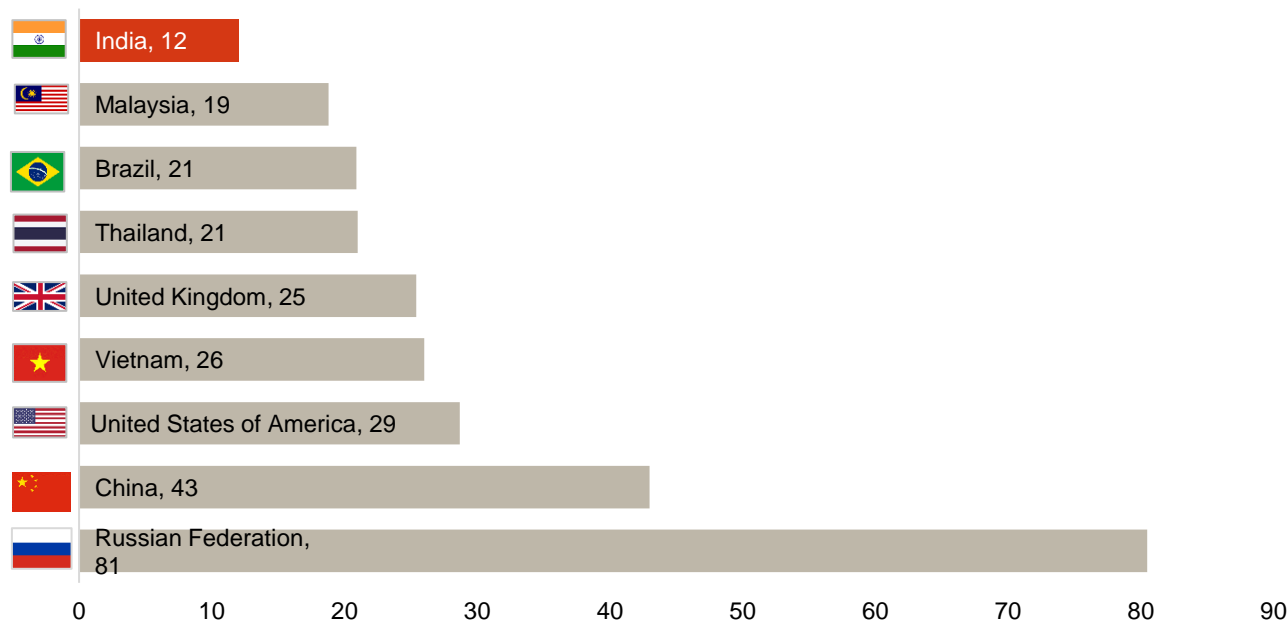
Though low healthcare spending represents a pain point in healthcare financing, it also means that there exists a substantial potential for those involved in provision of auxiliary healthcare services.

The quality of healthcare in a country can be gauged by the adequacy of healthcare infrastructure and personnel, which, in turn, can be assessed from bed density (bed count per 10,000 population) and the availability of physicians and nurses (per 10,000 population).

India’s health infrastructure in dire need of improvement

The adequacy of a country’s healthcare infrastructure and personnel is a barometer of its quality of healthcare. For India, this is where the concern begins. The country comprises nearly a fifth of the world’s population, but has an overall bed density of merely 12, with the situation being far worse in rural areas. India’s bed density not only falls far behind the global median of 29 beds but also lags behind that of other developing nations, such as Brazil (21 beds), Malaysia (19 beds) and Vietnam (26 beds).

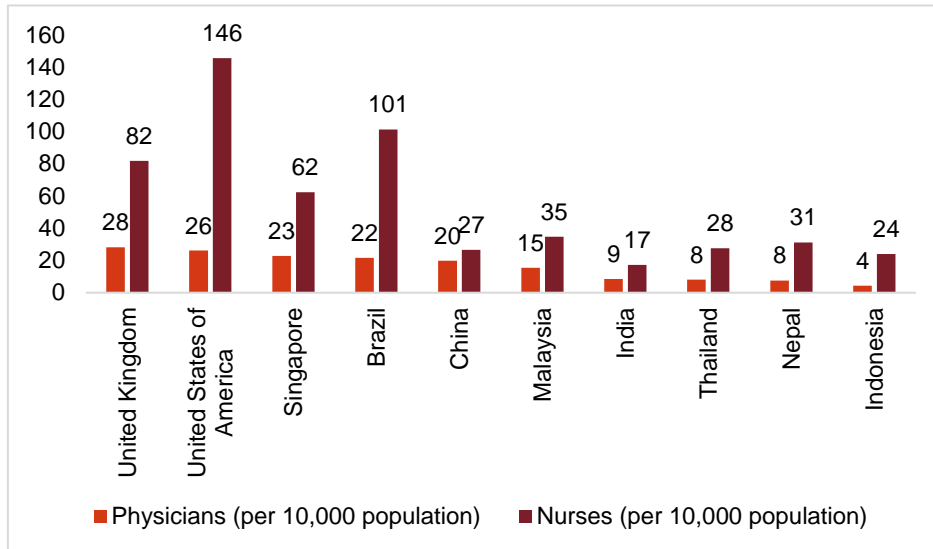
Bed density across countries – hospital beds (per 10,000 population)



Note: India’s bed density is estimated by CRISIL Research

Source: Tracking Universal Health Coverage: 2017 Global Monitoring Report, World Bank database, CRISIL Research

Healthcare personnel: India versus other countries



The paucity of healthcare personnel compounds the problem. At nine physicians and 17 nurses per 10,000 population, India trails the global median of 16 physicians and 38 nurses. On this parameter, India even lags behind Brazil (22 physicians, 101 nurses), Malaysia (15 physicians, 35 nurses), and other Southeast Asian countries.



Source: WHO World Health Statistics 2020

3 Overview of Global Pharmaceutical industry

3.1 Review of global pharmaceuticals industry

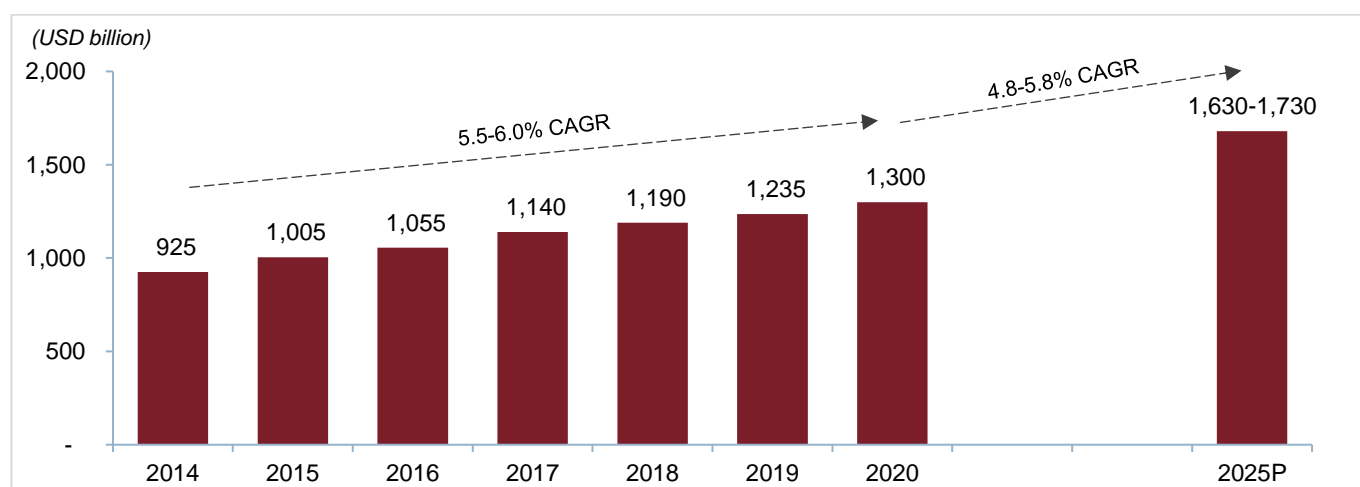
The global pharmaceutical industry is characterized by the concentration of consumption, production, and innovation in a relatively small number of high-income countries which continue to account for a major chunk of this market in value terms on account of higher priced drugs and newer products. However, over the recent few years, production as well as consumption has started to shift to middle-income countries, like India and China; these “pharmerging” markets also account for a higher share in volume terms and have outpaced growth in high-income markets. These double-digit-growth countries are now the strategic focus points for many multinational pharmaceutical companies. Though, for pharmaceutical research and development (R&D), high-income countries continue to dominate expenditure in both the public and private sectors.

The market saw a relatively slower growth in CY18-CY19 on account of pricing pressure, however, it stabilised coming in to CY20. Rising drug research and development activities for drug manufacturing, increasing prevalence of chronic diseases, rising importance of generics, and the increasing uptake of biopharmaceuticals will continue to be some of the key drivers for the global pharmaceuticals industry. In addition, strategic initiatives like new drug launches and biological products, acquisitions, collaborations, and regional expansion are also likely to fuel the market growth in the near future. However, the unfavourable drug price control policies across various markets and high manufacturing costs are expected to be some of the growth limiting factors.

Global pharmaceutical market to grow at steady ~5.3% CAGR over the next five years

Global pharmaceutical market has grown by around 5.5-6.0% CAGR from ~USD 925 billion in CY14 to ~USD 1,300 billion in CY20. It is expected to sustain this growth over the next five years to reach USD 1,630-1,730 billion in CY25.

Figure 1: Global pharmaceutical market by value



P: Projected

Source: Mordor Intelligence, Pharma company reports, CRISIL Research

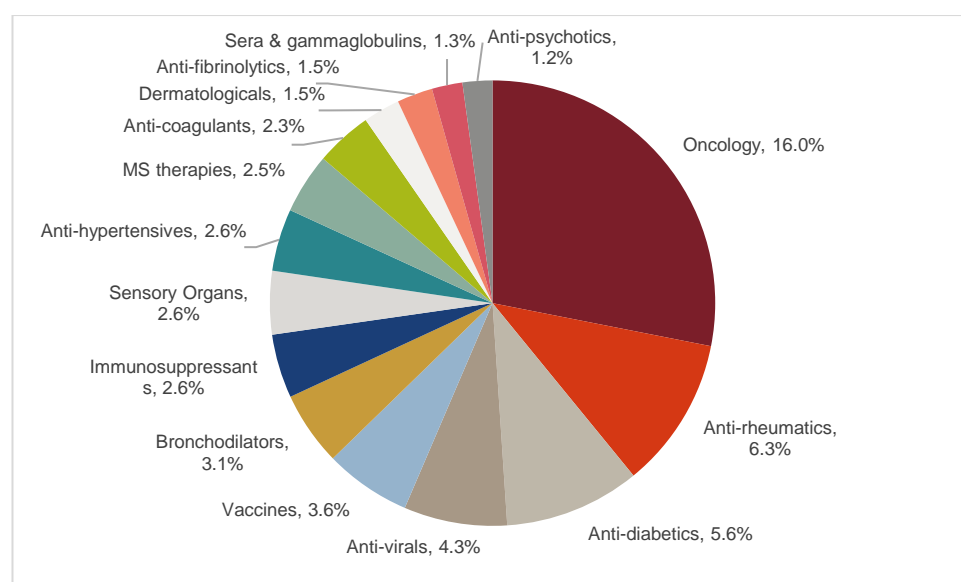
New product launches, widespread population aging and sedentary lifestyles leading to increased chronic disease prevalence, technological advances, new methods for drug discovery, and an increase in pharmaceutical drug usage have been some of the key growth drivers for the industry. Globally, the pharmaceutical companies are offering drugs

for customized individual treatment for better treatment against different diseases, and precision medicine which aims to provide medical care according to the patient's individual characteristics, needs, preferences, and genetic makeup.

Oncology drugs contributes to larger share of the pharma market

Oncology is the largest therapy area in pharmaceutical market by value with close to 16% share in pharmaceutical sales in 2019. It is one of the more expensive areas to develop new therapeutic drugs. Around 40% of R&D spend in pharma sector goes into oncology segment. The growth of oncology sales can be partly attributed to the growth of the immune-oncology sub-segment. Oncology, Anti-rheumatics and anti-diabetics have been the fastest growing therapeutic segments in the last five years. Rising incidence of diabetes aided growth in the anti-diabetics segment.

Therapy-wise share in global pharmaceutical market (value) (2019)



Note: Overall pharmaceutical market was sized at USD 1,235 billion in 2019

Source: Industry reports, CRISIL Research

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

As per Pharmaceutical Research and Manufacturers of America (PhRMA), the United States biopharmaceutical industry has been one of the world leaders in the development of new medicines. The entire biopharmaceutical and pharmaceutical industry invested an estimated ~USD 83 billion in research and development (R&D) in CY19 which was ~4.5% higher compared to CY18. Similarly, as per the European Federation of Pharmaceutical Industries and Association (EFPIA), in Europe, the pharmaceutical research & development investment was around ~Euro 36.5 billion in CY18 compared to ~Euro 35.3 billion in CY17.

Increasing R&D expenditure by global players is expected to lead to development of innovative medicines in the treatment of various diseases. Globally, the number of clinical trials has been increasing with the increasing prevalence of chronic diseases, and the growing demand for clinical trials in developing countries is also fuelling the market's growth. The global market is also driven by a rising number of biologics. The need for orphan drugs and the demand for advanced technologies, globalization of clinical trials, and technological evolution to conduct clinical trials are further projected to drive the pharmaceutical market growth.

North America to continue to dominate the global pharmaceutical market; however, Asia-Pacific region to remain the fastest in terms of growth

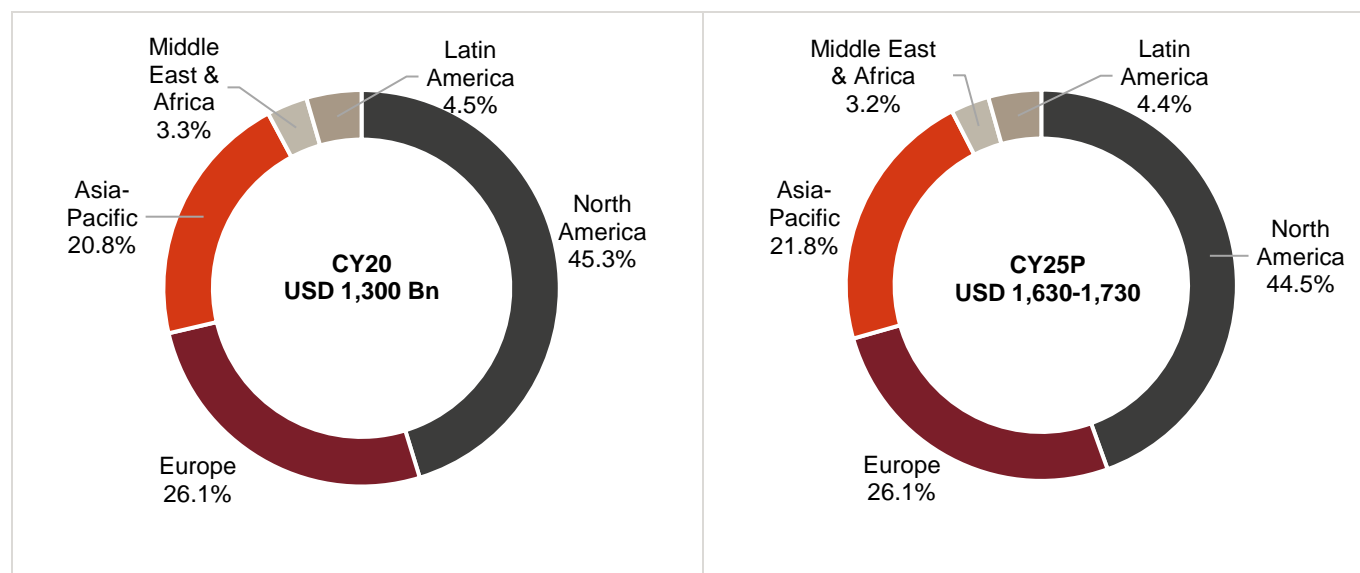
Global pharmaceutical market has grown over the years owing to manifold increase in the value terms mainly in the markets of North America, Europe and Asia Pacific. North America is the largest pharmaceutical market in the world with the value of ~USD 587 billion as of CY20 followed by Europe and Asia-Pacific which stood at ~USD 338 billion and ~USD 270 billion, respectively, during the corresponding year.

Growth in the North American market particularly in the US is fuelled by the rising healthcare expenditure and increased R& D activities in the pharmaceutical industry. As of CY19, the R&D expenditure in the pharmaceutical industry in the United States was amounted to USD 83 billion which has increased by ~4.5% over the previous year. Europe has also seen considerable investment in R&D with approximately 36.5 billion Euro invested in the year 2018. Emerging markets like Asia and Africa have also seen traction over the years and have grown steadily from CY16 to CY20. Major reasons for growth in the emerging markets like Asia and Africa have been the rise in per capita income and improvement in the healthcare infrastructure. Markets like South America and Middle East have grown at a slower pace compare to other regions.

Emerging markets represent an exceptional opportunity for the pharmaceutical industry on account on expected rise in healthcare spending from current low levels and increase in per capita income to support this rise in expenditure. Emerging markets comprise of Brazil, India, China, South Africa, Asean-5. Emerging Asia comprises the ASEAN-5 (Indonesia, Malaysia, Philippines, Thailand, Vietnam) economies, China, and India. Emerging markets are expected to grow faster the overall global pharmaceutical market.

As of CY20, North America leads the global pharmaceutical market (in value terms). North America has been the dominant market in the global pharmaceutical industry and constitutes ~45% of the overall consumption (in value terms) of the global pharmaceutical market. North America is followed by Europe which accounts for ~26% of the global pharmaceutical market. Asia pacific which is the fastest growing market constituted ~21% of the global pharmaceutical market during the year. Smaller markets of South America and Middle East & Africa Constituted around 4% and 3% of the global pharmaceutical market, respectively.

Region-wise segmentation of global pharmaceutical market

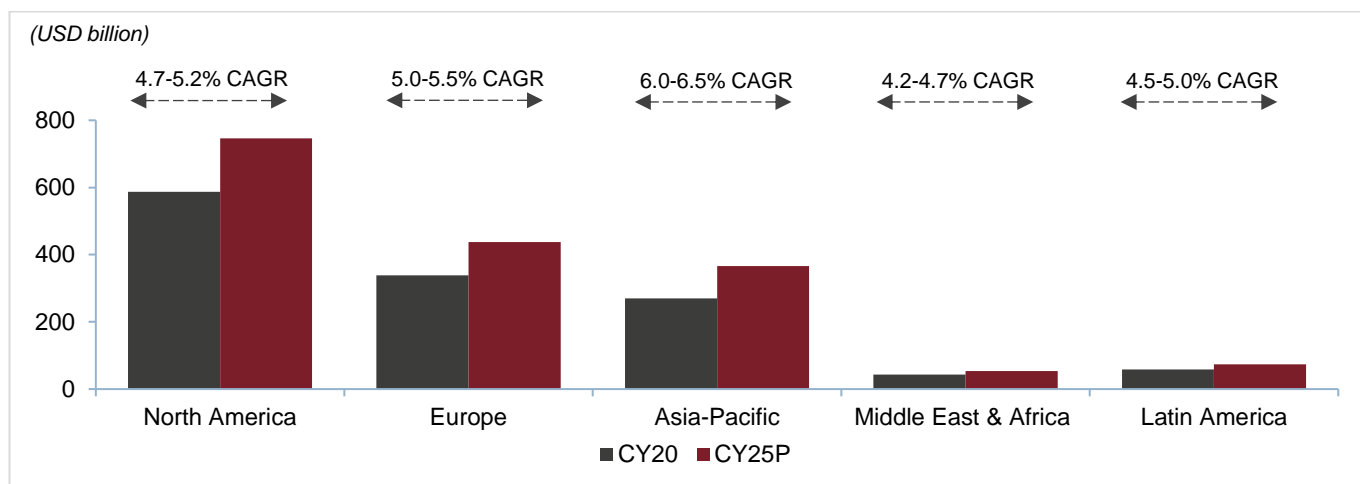


P: Projected

Source: Mordor Intelligence, CRISIL Research

Going ahead, North America will continue to maintain its pole position in terms of market share in value terms albeit at a slightly reduced share compared to CY20 levels; its share is expected to decline marginally from ~45.3% in CY20 to ~44.5% by CY25. North America is expected to lose this share largely to Asia-Pacific region which is expected to remain the fastest growing region.

Region-wise global pharmaceuticals market outlook (USD billion)



Note: Global pharmaceutical market - CY20: USD 1,300 Bn and CY25P: USD 1,630-1,730
 P: Projected

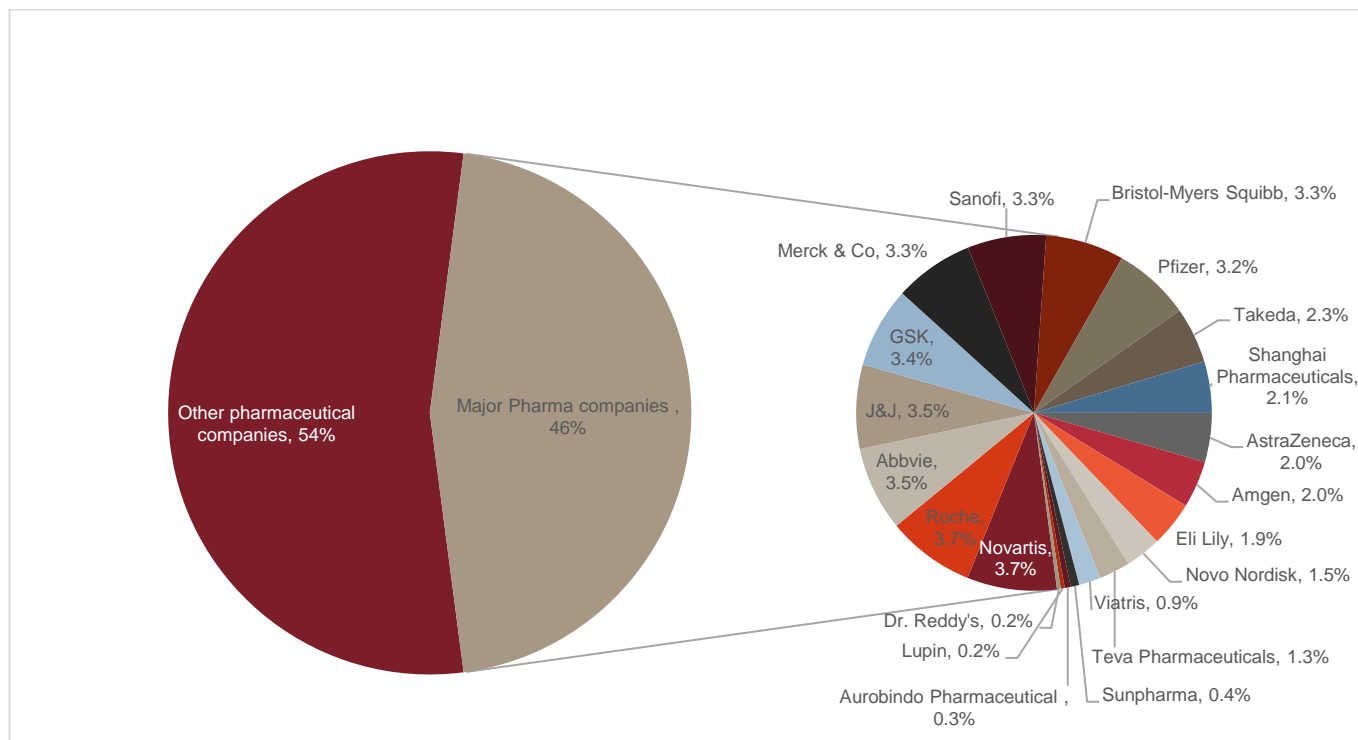
Source: Mordor Intelligence, CRISIL Research

The emerging economies such as Brazil, China and India are witnessing rapid growth in the market and research leading to a gradual shift of economic and research activities from Europe to these fast-growing markets. During the period 2014-2019 the Brazilian, Chinese and Indian markets grew by 11.2%, 6.9% and 11.1% respectively compared to an average market growth of 5.4% for the top 5 European Union markets and 6.1% for the US market.

Top MNC companies contribute to almost 45-50% share in global pharmaceutical market

Roche gained second position; Johnson & Johnson slips down

- The top 10 players maintained a global market share of about 33-35% in 2020.
- Novartis leads the global pharmaceutical companies with highest pharmaceutical revenue (USD 48Bn in 2020), its revenue grew by 3% in 2020
- Roche leads in terms of overall revenues(USD 47.5 Bn in 2020), as its revenue grew by 10.2% on year in 2019. Growth was primarily driven by increase in sales of drugs like Ocrevus, Perjeta and Tecentriq by 57%, 29% and 143% on year respectively in 2019. Oncology segment grew by 6% on year during the year.
- Johnson & Johnson witnessed fall in revenue from cardiovascular therapy by 10.7% on year in 2019. Total pharmaceutical sales grew only by 3.6% during the year

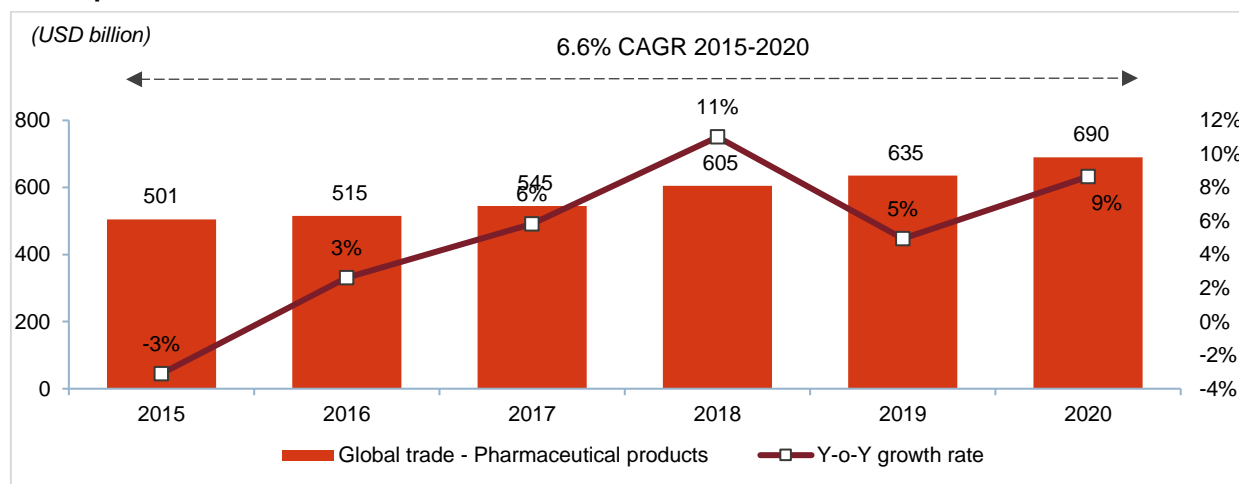


Note: Global pharmaceutical market - CY20 estimated at USD 1,300 Bn
Source: Company reports, CRISIL Research

Trade contributes to nearly 50-55% of Pharmaceutical global sales

Global pharmaceutical industry has around 50-55% of its sales derived from trade transactions. The overall global pharmaceutical industry is estimate at USD 1,300 Billion in 2020. Countries reported trade of roughly USD 690 billion in 2020 for pharmaceutical products. Global trade (import and export) saw an increase of 6.6% CAGR from USD 501 billion in 2016 to USD 690 billion in 2020. Calendar year 2020 witnessed change of geographic share in total trade, as China reported drop in exports during the COVID-19 pandemic.

Global pharmaceutical trade



Source: UN Comtrade, International Trade Centre – Trade map, CRISIL Research

USA, Germany, Belgium, China, Switzerland, United Kingdom, Japan are some of the key importing countries in pharmaceutical industry. India is not a major importing nation and contributes to less than 1% of total pharmaceutical imports. USA is one of the key importers of pharmaceutical products and contributed to 20.1% of global imports in 2020. USA saw increase in imports in 2020 on account of pandemic driven demand for pharmaceutical products. USA largely imports pharmaceutical products from Ireland, Germany, Switzerland, and India with EU nations contributing to 65% of its total imports and India (as an exporter) contributing to 6% of USA imports over the last five years from 2016 to 2020.

Most of complex finished pharmaceutical products consumed in the United States are manufactured locally or imported from western European countries such as Germany, Belgium, Switzerland. Imports contribute to only 25% of consumption in United States, but given the large size of the consumption market in US, US is the largest importer of pharmaceutical products in the world.

European region is among the major exporting regions. Within European pharmaceutical industry Switzerland, Germany, Italy, France, United Kingdom, Denmark and Belgium are key pharmaceutical production markets. These countries also contributes majorly to pharmaceutical exports from the region. Germany contributed 14.2%, Switzerland contributed to 12.8%, and Belgium contributed to 8.9% of overall pharmaceutical exports in 2020. USA is among the top 5 exports in the pharmaceutical trade. India contributed to 2.7% of the pharmaceutical exports in 2020.



Share of top countries in pharmaceutical product imports

	2016	2017	2018	2019	2020	CAGR 2016-2020
Global Import (USD bn)	531.0	564.9	622.4	655.7	693.4	6.9%
y-o-y growth in global imports (%)	3.7%	6.4%	10.2%	5.3%	5.8%	-
Share of countries	2016	2017	2018	2019	2020	CAGR 2016-2020
United States of America	17.4%	17.1%	18.6%	19.6%	20.1%	10.8%
Germany	9.1%	9.4%	9.2%	8.9%	9.5%	8.0%
Belgium	6.6%	6.2%	6.5%	6.9%	7.4%	10.2%
China	3.9%	4.5%	4.5%	5.1%	0.4%	-39.0%
Switzerland	4.6%	5.1%	4.8%	4.8%	5.6%	12.2%
United Kingdom	6.2%	5.9%	4.9%	4.3%	3.7%	-5.7%
Japan	4.6%	4.0%	4.1%	4.2%	4.1%	4.0%
Italy	4.0%	4.2%	4.3%	4.2%	4.1%	7.4%
France	4.2%	4.1%	4.1%	3.8%	4.1%	6.6%
Netherlands	2.9%	2.7%	2.7%	2.8%	5.1%	22.8%
Spain	2.6%	2.5%	2.5%	2.4%	2.5%	5.9%
Russian Federation	1.7%	1.9%	1.7%	2.1%	1.6%	5.0%
Canada	2.1%	2.1%	2.0%	2.1%	2.1%	5.9%
Australia	1.5%	1.4%	1.3%	1.3%	1.3%	2.9%
Austria	1.1%	1.1%	1.2%	1.2%	1.1%	8.6%
India	0.3%	0.3%	0.3%	0.4%	0.4%	9.8%

Share of top 15 countries in global imports (excludes India)	72.5%	72.1%	72.4%	73.7%	72.8%	

Source: UN Comtrade, International Trade Centre – Trade map, CRISIL Research

USA is key customer for India, but India contributes to only 6% of USA pharmaceutical imports

India exports 	18.3	USA imports 	139.5
USA share in India's exports	38%	India's share USA imports	6%

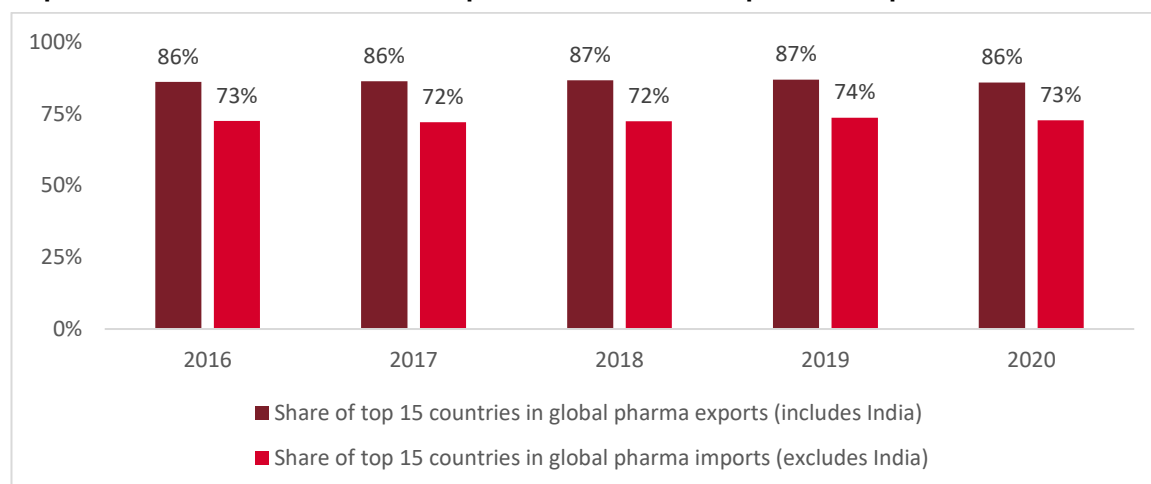
Source: UN Comtrade, International Trade Centre – Trade map, CRISIL Research

Share of top countries in pharmaceutical product exports

	2016	2017	2018	2019	2020	CAGR 2016-2020
Global Export (USD bn)	499.9	528.6	587.1	617.5	688.6	8.3%
y-o-y growth in global exports (%)		5.7%	11.1%	5.2%	11.5%	-
Share of countries	2016	2017	2018	2019	2020	CAGR 2016-2020
Germany	15.2%	15.8%	16.4%	14.6%	14.2%	6.5%
Switzerland	13.4%	13.3%	12.8%	13.4%	12.8%	7.1%
United States of America	9.4%	8.5%	8.2%	8.7%	7.8%	3.6%
Ireland	6.4%	7.3%	9.1%	8.6%	9.5%	19.9%
Belgium	8.4%	8.1%	8.1%	8.5%	8.9%	10.0%
France	6.1%	6.0%	5.8%	5.8%	5.5%	5.6%
Italy	4.3%	4.8%	4.7%	5.4%	5.2%	14.0%
Netherlands	4.7%	4.9%	4.9%	4.9%	7.2%	20.3%
United Kingdom	6.5%	6.2%	5.1%	4.4%	3.6%	-6.6%
Denmark	2.5%	2.4%	2.5%	2.8%	2.8%	11.4%
India	2.6%	2.4%	2.4%	2.6%	2.7%	8.9%
Spain	2.2%	2.1%	2.0%	2.1%	2.0%	6.5%
Austria	1.7%	1.7%	1.7%	1.8%	1.7%	8.2%
Sweden	1.4%	1.5%	1.5%	1.7%	1.7%	12.9%
China	1.4%	1.4%	1.5%	1.5%	0.2%	-33.0%
Share of top 15 countries in global exports (excludes India)	86.1%	86.4%	86.7%	86.9%	85.9%	

Source: UN Comtrade, International Trade Centre – Trade map, CRISIL Research

Export is more concentrated with top 15 countries as compared to imports



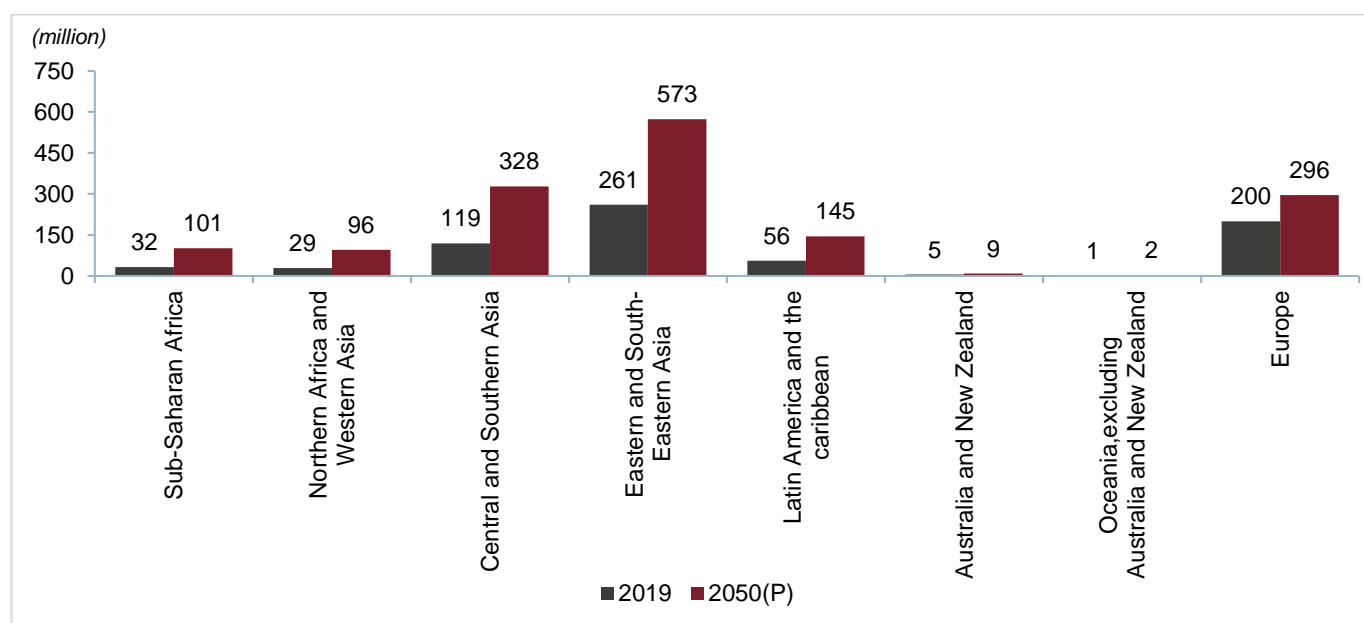
Source: UN Comtrade, International Trade Centre – Trade map, CRISIL Research

Key growth drivers for global pharmaceutical industry

Rise in ageing population

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

Figure 2: Number of persons aged 65 years or over by geographic region, 2019 and 2050



P: Projected

Source: UN population ageing 2019, CRISIL Research

Incidence of chronic diseases

Incidence and prevalence of chronic diseases are increasing rapidly all around the world. Rising incidences of diseases, such as cancer, cardiovascular diseases, obesity, and diabetes, are primarily observed and have a significant impact on the economy of the country, which is likely to drive the demand for pharmaceuticals. According to the Organization for Economic Co-operation and Development's (OECD's) Health at a Glance, the 2019 report, almost one third of people aged 15 years and over reported living with two or more chronic conditions. Cardiovascular diseases are found to be most prevalent across the world, and are the leading causes of death. As per the 2020 updates of the WHO, ischemic heart disease is responsible for 16% of the world's total deaths. Since 2000, the largest increase in deaths has been for ischemic heart disease, rising by more than 2 million to 8.9 million deaths in 2019. Growing cases of chronic diseases are expected to further increase the demand for drugs and accelerate the development of pharmaceuticals, globally.

Better access to medicine in emerging markets

As the world's population topped 7.7 billion in 2020, per capita usage of medicine per person per day is also estimated to have increased following similar trend. Much of the increased usage is driven by emerging pharmaceutical markets like China, India, Brazil and Indonesia where substantial increases have been made in average medicine volume usage. India's level of medicine usage is a reflection of both a very basic healthcare infrastructure and the ease of access for medicines where even the most complex medicines can be readily available. The gap in average medicine usage between developed markets and emerging markets is closing, owing to reasons like increased per capita income, improvement in healthcare infrastructure, and increase in insurance coverage. The use of medicines requires both the healthcare infrastructure to diagnose diseases and administer drugs appropriately, as well as the financial wherewithal to pay for them. While costs are often substantially lower for medicines in emerging markets, so is the ability to pay. The rise of government safety nets and private insurance is one key factor that will increase volume usage across emerging markets. The extent and pace of investments, both public and private, will be a key determinant of continued increases in usage.

Strong development of generics market

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

On the other hand, healthcare reforms in the US are driving higher insurance coverage and greater usage of generic medicines. The US is the largest pharmaceuticals market for both innovator brands and generic drugs. It has been at the forefront of medicine research and healthcare spending. Driven by the Hax-Watchman Act, the generic drugs industry has grown tremendously over the years to ~USD100 billion in CY19. The Act is a US federal law introduced in 1984 to regulate procedures for approval and marketing of generic drugs in the country. Driven by greater dependence on generic medicines and enactment of Patient Protection and Affordable Care Act, growth in the market is expected to continue.

The Act, first enacted on March 23, 2010, was aimed at bringing a large section of the population under public and private insurance coverage. The Affordable Care Act (2010) included provisions to ensure that insurance companies do not refuse to cover patients with pre-existing conditions, and expand Medicaid coverage to include more people from low-income groups. The decline in uninsured population in the US will continue to drive demand for generic drugs and aiding the growth of Indian manufacturers. However, continued pricing pressures on base business in the US market.

3.2 Regulations in key markets

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

New drug application (NDA)

New drug application (NDA) is an application submitted to the respective regulatory authority in specific markets for permission to market a new drug. To obtain this permission a sponsor / company submits preclinical and clinical test data for analyzing the drug information, description of manufacturing procedures.

Different Phases of clinical trials:

- Pre-clinical study – Testing in animals - Mice, Rat, Rabbit, Monkeys
- Phase I - Human pharmacology trial – estimation of safety and tolerability in humans
- Phase II - Exploratory trial includes estimation of effectiveness and short-term side effects
- Phase III - Confirmatory trial includes confirmation of therapeutic benefits from the drug
- Phase IV - Post marketing trial includes studies done after drug approval

After NDA received by the agency, it undergoes a technical screening that checks that sufficient data and information have been submitted in each application.

At the conclusion of the review of an NDA, there are 3 possible actions i. not approvable ii. Approvable (drug can be approved but minor deficiencies can be corrected like-labeling changes and possible request commitment. iii. Complete Approval

Several countries have their own pharmaceutical regulatory authorities

Regulatory bodies impose regulations to ensure that drugs meet safety and quality standards. It is extremely vital that players in the pharmaceutical industry maintain high standards, considering the number of lives at stake. Regulatory bodies also ensure that pharmaceutical companies do not charge unreasonable prices from consumers.

The stringency of regulatory procedures varies across countries. On the basis of established regulations and patent laws, the global pharmaceutical industry can be broadly classified into regulated and semi-regulated markets.

Regulated markets include the US, EU and Japan that have established systems of patent laws and sophisticated regulatory systems for controlling drug quality. On the other hand, semi-regulated markets include countries such as China, India and South Africa, which have less stringent systems of patent laws and less sophisticated regulatory systems for drug quality control.

However, there is no single harmonized protocol for drug approval across countries. Countries have their own regulatory authorities and drug approval mechanisms.

Drug Regulatory agency in the USA

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

Food and Drug Administration:

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

Major responsibilities of FDA:

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

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

Drug approval process in United States:

Investigational New Drug (IND) Application:

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

New Drug Application (NDA):

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

The NDA application requires detailed data regarding the manufacturing process, facilities, quality control & quality assurance, product description, packing and labeling. FDA personnel will assess clinical data, tests drug samples,

audit the manufacturing facilities, and check labelling. FDA review completes within 180 days of receipt of application. Post approval of the NDA, the applicant can manufacture and market the drug. On denial of approval of the NDA, FDA sends a response letter including specific deficiencies and recommendations for the applicant in order to make the application viable. Unsuccessful applicants can request a hearing.

Abbreviated New Drug Application (ANDA):

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

Drug Regulatory agency in Europe

European Medicines Agency (EMA)

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

Major responsibilities of EMA:

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

Drug approval process in EU:

There are two regulatory steps to go through prior to approval of a drug for marketing in the EU, akin to the US FDA requirements. These two steps are i. Clinical Trial Application (CTA), ii. Marketing Authorization Application (MAA).

CTA approval is done at the member state level, whereas MAA are approved at both the member state and centralized levels. There are a total of four procedures through which approval for manufacture and marketing of a drug can be obtained, depending on the drug class and the preference of the manufacturer:

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

Centralized process:

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

National process:

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

Mutual recognition:

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

Decentralized procedure:

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

Drug Regulatory agency in India**Central Drugs Standard Control Organization (CDSCO):**

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

Within the CDSCO, Drug Controller General of India (DCGI) is responsible for regulation of pharmaceutical products and medical devices. The Drug Technical Advisory Board (DTAB) and the Drug Consultative Committee (DCC)

advise the DCGI. Licensing and classification of Medical devices is the function of the Central Licensing Approval Authority (CLAA). It is also responsible for setting and enforcing safety standards, performing post-market surveillance, issue of warnings and recall of pharmaceutical products for adverse events.

Major responsibilities of CDSCO:

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

Drug approval process in India:

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

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

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

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

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

Drugs & Clinical Trials New Rules 2019:

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

Drug Regulatory agency in China

China pharmaceutical market is dominated by domestic pharmaceutical sales, as the country has strictly monitored pharmaceutical imports and approval to foreign players.

National Medical Products Administration

The National Medical Products Administration (NMPA) (formerly China Food and Drug Administration, CFDA) was founded on the basis of the former State Food and Drug Administration (SFDA). In March 2013, the regulatory body was rebranded and restructured as the China Food and Drug Administration, elevating it to a ministerial-level agency. In 2018, as part of China's 2018 government administration overhaul, the name was changed to 'National Medical Products Administration' and merged into the newly-created State Administration for Market Regulation. The CFDA replaced a large group of overlapping regulators with an entity similar to the Food and Drug Administration of the United States, streamlining regulation processes for food and drug safety. The NMPA is directly under the State Council of the People's Republic of China, which is in charge of comprehensive supervision on the safety management of food, health food and cosmetics, and is the competent authority of drug regulation in mainland China.

Major responsibilities of NMPA:

- To supervise the safety of drugs, medical devices and cosmetics
- To undertake standards management for drugs, medical devices and cosmetics
- To regulate the registration of drugs, medical devices and cosmetics
- To undertake quality management for drugs, medical devices and cosmetics
- To undertake post-market risk management for drugs, medical devices and cosmetics
- To undertake management of qualifications for licensed pharmacists
- To organize and guide the supervision and inspection of drugs, medical devices and cosmetics
- To engage in international exchange and cooperation in the regulation of drugs, medical devices and cosmetics
- To guide the work of drug regulatory departments of all provinces, autonomous regions, and municipalities directly under the Central Government.
- To complete other tasks assigned by the CPC Central Committee and the State Council.

Drug approval process in China:

The drug approval process in China is much different when compared with European Union and the US. The drug approval process can be divided in three phases:

- Phase 1: In the first phase the application is submitted to the NMPA. NMPA receives the application for preliminary review for acknowledging the dossier content. The centre for Drug evaluation (CDE) department or committee receives the application and reviews pharmacology, toxicology, and clinical related data and requests further information for review. National institute for the control of Pharmaceuticals and Biological products (NICPBP) conducts sample examination, it also sends recommendations to CDE. It takes 120 days period time for both NICPBP and CDE to review the application after CDE review. The further recommendations are sent to NMPA to make decision on approval for clinical trial, the decision period is mostly 20 days or 30 days, after the decision on approval the final result is delivered to the applicant
- Phase 2: This phase mainly involves processing of clinical studies for conducting clinical trials. It takes 12 to 18 months for clinical trials and 3 to 6 months for bioequivalence trials (bio efficacy test, BE tests). After these clinical and bioequivalence trials, the applicant starts preparing Drug approval application.
- Phase 3: The phase 3 process is final approval step, the application dossier is submitted to NMPA. After submission, the NMPA conducts basic review on the received application dossier for verification. Post that, CDE department conducts the scientific review for evaluation and further recommendations were send to NMPA. The decision on final approval is completed within 20 days. With the final approval the decision result is sent to the applicant.

Drug Regulatory agency in Japan

Pharmaceuticals and Medical Devices Agency

PMDA is an Independent Administrative Institution responsible for ensuring the safety, efficacy and quality of pharmaceuticals and medical devices in Japan. The PMDA was established in April 2004. PMDA has primary

responsibility for administering the approval of new pharmaceutical products and medical devices in Japan, although final authority to issue approvals still rests with the Ministry of Health, Labour and Welfare (MHLW). It is similar in function to the Food and Drug Administration in the United States.

Responsibilities of PMDA:

The service of the PMDA is divided into three main categories:

- Relief service for adverse health effects
 - Relief service for adverse drug reactions
 - Relief service for infections acquired through biological products
 - Health allowance etc., for SMON patients
 - Health allowance for HIV-positive and AIDS patients
 - Financial assistance under “Act on Special Measure” concerning the payment of benefits to assist individuals affected by Hepatitis C through specified Fibrinogen products and Specified Blood Coagulation Factor IX products contaminated by Hepatitis C virus
- Review
 - Consultations on clinical trials and other issues
 - Regulatory reviews of drugs, medical devices, and regenerative medical products
 - Re-emanation or re-evaluation
 - Inspection and conformity assessment of Good Clinical Practice (GCP), Good Laboratory Practice (GLP), and Good Practice Systems and Programs (GPSP)
 - Auditing of manufacturers to ensure they conform to Good Manufacturing Practice (GMP) and have a suitable Quality Management System (QMS)
 - Inspection of registered certificate bodies
 - Development of standards, e.g., Japanese Pharmacopoeia
- Post-marketing safety measures
 - The collection, analysis and distribution of data on the quality, efficacy, and safety data of medicines and medical devices
 - Advising consumers on approved products
 - Research on the development of industry standards
 - Acceptance of submitted labelling information (package inserts)

Drug approval process in Japan:

The Ministry of Health, Labour, and Welfare (MHLW) is to be notified of the study protocol beforehand and provide various requirements to be met by the sponsor when requesting medical institutions to perform clinical studies. The study protocol includes clinical studies to collect data to be submitted with approval applications for new drug manufacturing and marketing, the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics.

Process for new drug:

The entire process of approval review from review-related inspections and clinical trial consultation to review works is undertaken by the PMDA. Application forms for drug marketing authorization are submitted to the PMDA. A compliance review of the application data (certification from source data), GCP on-site inspection, and detailed review are undertaken by review teams of the PMDA once the application forms for new drugs marketing authorization are received by it. The team then prepares a review report. The approval review process consists of expert meetings of review team members and experts to discuss important problems. A general review conference attended by team members, experts and representatives of the applicant is held after the expert meeting.

Process for generic drug:

The application is to be submitted to PMDA. PMDA reviews submitted data such as 1) specification and test methods, 2) stability tests, 3) and bioequivalence study and determines the equivalence (quality, efficacy, and safety) of generic

drugs to the original drugs. The MHLW then approves manufacturing/marketing business of the applied drugs. Applications for generic drugs cannot be filed until completion of the re-examination. Branded products are protected from patent and re-examination period during this period.

	USA	Europe	India	Japan	China
Regulatory authority	Food and Drugs Authority (FDA)	European Medicines Agency (EMA)	DCGI	Pharmaceutical Medical Device Agency (PMDA)	National Medical products administration (NMPA)
TSE/BSE study data	Not required	Required	Required	Required	Required
Authorities involved in review/granting generic drug approval	1. Centre for drug evaluation and research 2. Office of generic drugs.	1. European medical agency. 2. Committee for Human Medicinal Products 3. European union	1. Central Drugs Standard Control Organization 2. Drugs Controller General India	1. Pharmaceutical Medical Device Agency 2. Office of generics 3. Ministry of Health Labour and Welfare	1. China Drug Administration 2. The National Institute for Control of Pharmaceutical and Biological Products 3. Provincial Institutes for the Control of Pharmaceutical Products
APPLICATION TYPE – generics	a. For new drug- NDA b. For generic drug – ANDA c. For biological application – BLA	Marketing authorisation Application.	Marketing authorisation Application.	New generic drug Application	New generic drug Application.
Registration process	One registration process	Multiple registration process 1. Centralised procedure 2. Decentralised procedure 3. Mutual recognition procedure 4. National procedure	One registration process	One registration process	One Registration Process 2 types: Standard review procedure Special review procedure
Approval timeline	18 months	12 months	2 - 18 months	12 months	12-18 Months
Fees	\$ 2.8 million – NDA application with clinical data \$ 1.4 million – NDA application without clinical data USD 0.2 million ANDA application	National fee (including hybrid applications): £103,059 Decentralised procedure where UK is CMS: £99,507	Rs. 50,000	For every review meeting separate fees.	Generic drugs made in China: 318,000 Renminbi(46,349.61USD) Generic drugs made outside China: 502,000 Renminbi(73,177.85 USD)

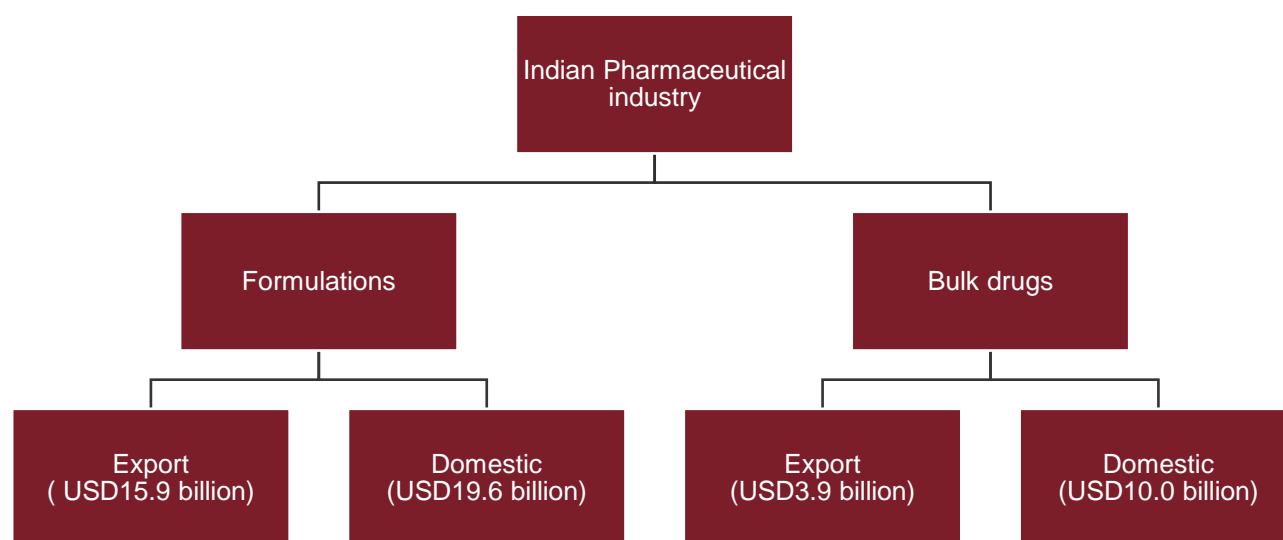
4 Assessment of Indian bulk drug industry

4.1 Overview of Indian bulk drug industry

Majority of bulk drugs produced in India are used for captive consumption

The Indian pharmaceutical industry can be broadly classified into formulations and bulk drugs. Formulations, can be further divided into domestic and export formulations. Bulk drugs can also be similarly categorised.

Bulk drugs serve as raw materials for manufacturing finished dosage forms or formulations. US Food & Drug Administration defines a bulk drug as any substance which is an active ingredient in a finished dosage. However, the term does not include intermediates used in the synthesis of the bulk drug itself.



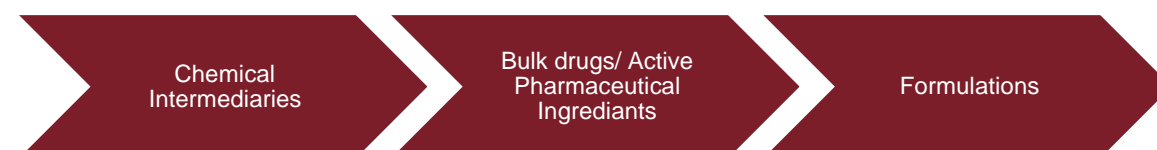
Note: Values for exports and domestic mentioned are as of fiscal 2020.

Source: CRISIL Research

Majority of bulk drugs produced in India are used for captive consumption

About USD3.9 billion worth of bulk drugs were exported in fiscal 2020. A major part are sold in the domestic market and also used for captive consumption with many large formulation players performing backward integration.

Pharmaceutical value chain



Source: CRISIL Research

Revenue model of bulk drug players

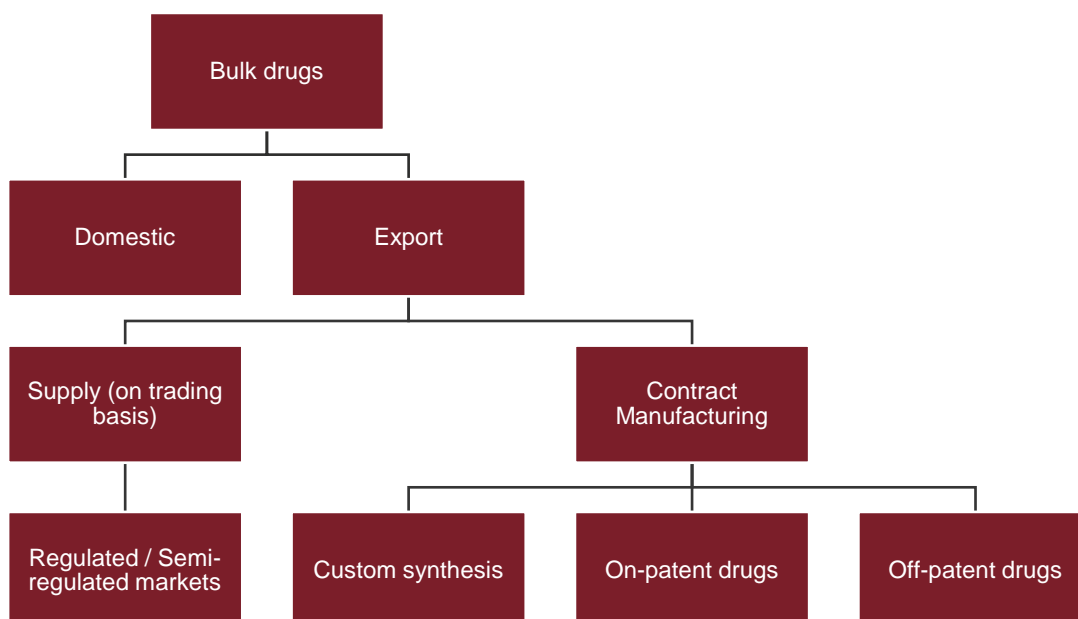
Bulk drugs are exported either under a contract manufacturing service between Indian manufacturers and global innovator companies or are merely supplied on a trading basis. The latter method is followed when exporting to semi-regulated markets or while supplying bulk drugs for manufacture of off-patent drugs in regulated markets. Typically, regulated markets offer higher profits than semi-regulated markets.

Exports to regulated markets also occur in the nature of contract manufacturing for on-patent and off-patent drugs. Besides, bulk drugs are also supplied (in smaller quantities) during drug development to innovator companies. Players operating in this segment earn higher margins as compared to other exporters. The margins vary according to the player's area of expertise; for example, custom synthesis carries very high margins compared to supply for manufacture of off-patent drugs.

API exports to regulated markets have been on a rise. India's active pharmaceutical ingredient (API) export to regulated markets constituted roughly 49% of its total API exports as of March 2020. The same was ~47% in 2013-14.

The nature of Indian bulk drug exports to regulated markets has also changed over a period of time. Initially, exports were routed through merchants. Increasingly, most medium and large-sized exporters are directly exporting to generic or innovator companies in regulated markets. Further, profitability is higher for players who supply bulk drugs for manufacturing on-patent drugs in regulated markets as compared to players who supply bulk drugs for generics' manufacture.

Revenue model adopted by bulk drug players



Source: CRISIL Research

Types of operations of API players

Custom synthesis

Custom synthesis is production of drug compounds as per client (global innovator) specifications for development of niche drugs and for research needs. It entails production and synthesis of intermediates and supply of bulk drugs on a customised basis to innovator companies for usage in drug discovery processes.

Global pharmaceutical firms, who primarily conduct research and development (R&D) on new drugs, are major clients of Indian bulk drugs firms specialising in custom synthesis. These contracts are generally spread over the period of the innovator's patent. In some instances, clients may also provide a custom manufacturer with R&D facilities and processes. Companies in this segment usually experience higher margins than other bulk drug companies.

Supply of off-patent drugs

A majority of Indian players supply bulk drugs to generics manufacturers in regulated markets. Original innovators also present export opportunities. For in many cases, global innovators do not devise the most cost-effective way of producing a drug when it is first patented, since on-patent drugs anyway fetch extremely high margins. Once the drug goes off-patent, the innovator looks to outsource manufacturing of these drugs to low-cost destinations such as India and China. This helps innovator companies to compete with generic firms; this opens up another avenue for exporters of bulk drugs. Indian bulk drug companies exporting to regulated markets also supply to other generic formulators who enter the market after the first generic manufacturer's entry. These formulators constitute a large clientele for bulk drug manufacturers

Exports to semi-regulated markets

Indian bulk drug players have traditionally maintained a strong foothold in semi-regulated markets such as Latin America, Commonwealth of Independent States (CIS), Asia and Africa. Although a current good manufacturing practice (cGMP)-compliant facility is a basic export requirement, other regulations are less stringent in these markets than they are in regulated markets. Semi-regulated markets, therefore, attract small bulk drug manufacturers who cannot tap regulated markets. However, low entry barriers have also intensified competition in these markets, pressurizing player margins, which are almost at par with what they earn in the domestic market (5-10%).

4.2 Review and Outlook of Indian bulk drug industry

The bulk drug industry in India is ranked third-largest globally in terms of volume, behind China and Italy – About 35 per cent of bulk drugs produced in India are exported and the remaining bulk drugs are sold in the domestic market, including captive consumption by several large formulation players. India is the largest provider of generics drugs globally contributing to 20% in global supply by volume of generics drugs. India ranks lower in terms of value of pharmaceutical at 14th position as compared to 3rd position in volume terms.

India enjoys cost advantage over regulated markets

Bulk drug manufacturing costs are significantly lower in India than in the regulated markets of the United States (US) and Europe, as illustrated in the chart below. China is a major exporter of bulk drug intermediates globally as it enjoys competitive advantage due to government support, coupled with low power and labour costs. On the other hand, India is a preferred destination for the procurement of active pharmaceutical ingredients (APIs), especially in regulated markets, compared with China. This is on account of its advanced process chemistry skills, which aid the manufacture of bulk drugs and complex intermediaries.

Overview of cost of manufacturing

Country	Units
US	100
Europe	85-90
India	
<i>India - In US FDA approved plants</i>	45-50
<i>India - In others</i>	35-40
China	35-40

Note: Cost indexed to US

Source: Industry, CRISIL Research

Bulk drugs industry highly fragmented

There are over 2700 API manufacturers in India. The bulk drugs industry in India is highly fragmented with major presence of small unorganised players. Unorganised players constitute almost half of the bulk drugs industry. While there are a large number of standalone bulk drug manufacturers, most formulators are backward integrated and also produce bulk drugs. The larger players operate in the domestic as well as export markets, focusing more on the latter. Some the key players in the API segment include Divis Laboratory, Wanbury, Hetero Drugs, Cadila Pharmaceuticals, Hikal, Supriya Lifescience, Solara Active Pharma, Neuland Labs, Aarti Drugs, Megafine Pharma, not in any specific order. The Indian bulk drugs exports was Rs 275 billion in fiscal 2020. The industry has remained highly fragmented, with 14-16 of the major bulk drug-manufacturing companies (including large formulation companies) comprising ~33-35% share.

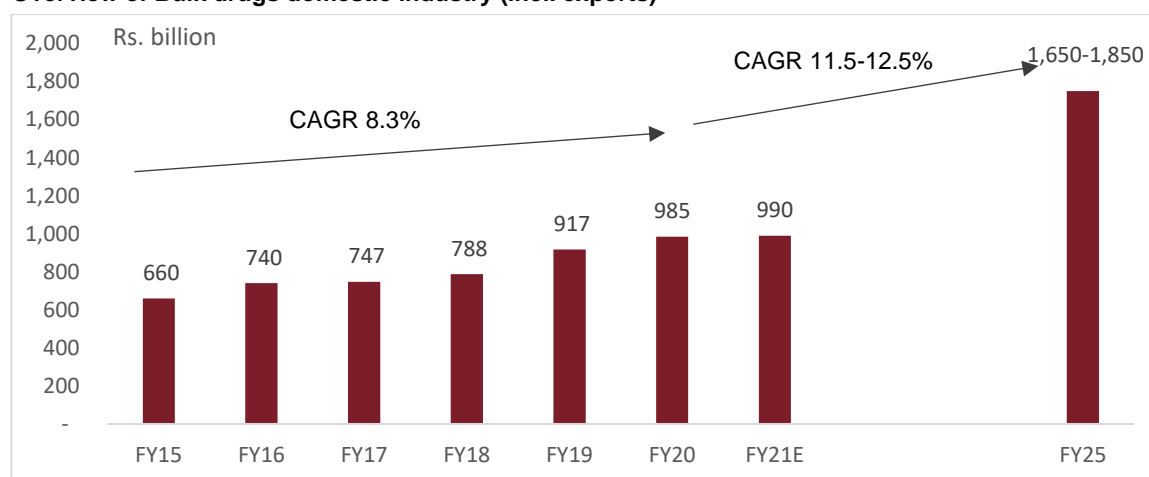
In fiscal 2020, bulk drug exports fell ~1% on-year (in USD terms) owing to disruptions caused by Covid-19. India restricted exports in the last two months of the year to ensure domestic supply.

Bulk drugs industry in India grew at 8.3% CAGR between fiscal 2015 and 2020

The overall bulk drugs industry grew from Rs. 660 billion in fiscal 2015 to Rs. 985 billion in fiscal 2020 registering a CAGR of 8.3% in rupee terms. Growth in the industry was supported by growth in formulation manufacturing in India. The formulation industry grew at CAGR of 8.5%-9.5% during the same period and API imports grew at a tepid pace of 1.8% during the period under consideration. Thus the domestic bulk drugs industry was supported by demand in formulation, manufacturing by local players and backward integration by large formulation players.

Going forward the bulk drugs industry is expected to clock a growth rate of 11.5%-12.5% between fiscal 2025 and fiscal 2020, largely driven by growth in bulk drugs exports, which is expected to deliver a CAGR of 9.5-10.5% in rupee terms (8.0-9.0% in dollar terms) during the period under consideration.

Overview of Bulk drugs domestic industry (incl. exports)



P: Projected

Source: DGCIS, CRISIL Research

Overview of growth in Indian Pharmaceutical industry (in rupee terms)

Industry segment	Past growth FY15-FY20	Forecasted growth FY20-FY25P	Growth factors
Domestic formulation industry	8.5%-9.5%	10.5%-11.5%	Increased healthcare expenditure and penetration of health infrastructure
Formulation and biologics exports	10.5%	14.0-15.0%	Increased penetration of generics in global pharmaceuticals
Domestic bulk drugs industry	8.3%	11.5%-12.5%	Growth in formulation drugs manufacturing, Bulk drug parks, PLI scheme - Govt impetus
Bulk drugs exports	5.6%	9.5-10.5%	Shift from China market – Alternative to supply from China

P: Projected

Source: CRISIL Research

COVID-19 impact on pharmaceutical sector has been minimal

The COVID-19 impact on the pharma sector has been less pronounced than observed in the other sectors, as pharmaceuticals were included under the essential services category and were exempt from the restrictions under

the nationwide lock-down. But COVID-19 pandemic put a brake on production and the supply chain of major pharmaceutical companies and on export of certain critical API and drugs. The pandemic highlighted the global reliance on China for APIs for various drugs. 44 Chinese companies were deemed non-operational during the pandemic due to lockdown restrictions placed by the government of China. This impacted exports of key material from China. This has led to various nations rolling out programs for indigenous API production and nations across the EU have reassessed their healthcare models for fighting against pandemic and ensuring a constant inflow of API production. Leading pharmaceutical companies are changing their business models and offering solutions based on key performance indicators as required by country.

The healthcare costs of the public and the current COVID-19 outbreak has led pharmaceutical manufacturers to realign their models to cater to a large patient pool. The API industry needs to restructure its production process in order to mobilize operations in the event of unprecedented circumstances. The COVID-19 virus was the perfect measure for pharma companies to assess their standing and address challenges of the future and realign their supply chain dependencies.

Growth in bulk drug industry in fiscal 2021 was 1%, drastically below average annual growth rate of 8-9%. Bulk drug industry grew by Rs 5 billion in fiscal 2021 on account of increased demand from pandemic related treatment and well-being.

Active pharmaceutical ingredients (APIs) forms the major cost for formulation players

Active pharmaceutical ingredients (APIs) form the major cost for formulation players. The raw material cost also includes the cost for inert materials i.e the materials used to stabilise the impact of APIs and preserve them for a longer period of time. However, the inert material cost does not form more than 10% of the overall raw materials cost.

Raw materials cost: The break-up of costs varies substantially, based on the revenue size of players and the geography served. As domestic SME and other small-sized players are present in low value drugs and have low bargaining power with bulk drug players, raw materials cost forms ~60-70% of the overall cost. Further, for players selling only in domestic markets, the employee cost and selling expenses are comparatively lower as compared to export-based players.

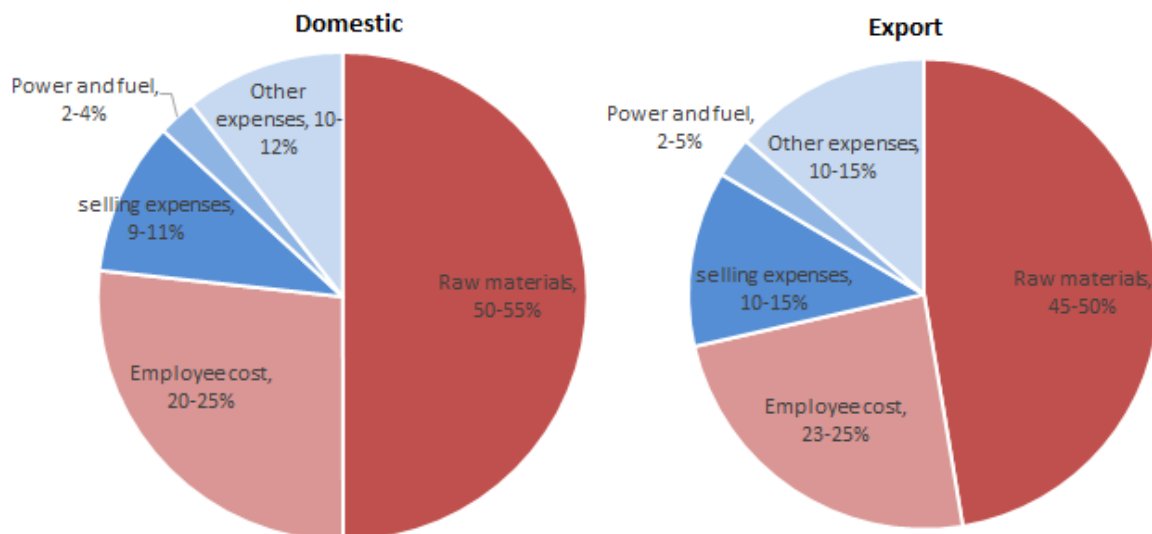
Employee costs: Large formulation players employ PhDs for research and development (R&D) activities, in order to explore new opportunities in the generic space. Further, a few major players are also looking at opportunities in the biopharma segment, thereby incurring employee costs in the segment. However, India-based players focused only on the domestic market do not have the scale to invest in R&D, and therefore have low employee costs

Selling expenses: Packaging and selling expenses also form a substantial cost for branded formulation players. The players have marketing teams that work with various stakeholders in the value chain to promote their branded products. The selling expenses, however, are lower for smaller players who sell primarily through traders, avoiding direct sales to wholesalers

Power costs: The power and fuel costs are less than 5% for the majority of players and therefore none of the companies have their own captive sources of power

Other costs: For players selling in regulated markets, packaging costs are higher when compared to the costs involved in the domestic market on account of USFDA norms

Direct cost break-up for pharmaceutical players



Source: Industry, CRISIL Research

Bulk drug exports

Bulk drug exports to gain momentum in medium term

Bulk drug exports, which rose ~7% CAGR during fiscals 2008 to 2013, decelerated sharply to 1.4% CAGR from fiscals 2014 to 2018 because of competition from China and other Asian countries. Traditionally, the Indian pharmaceuticals market has been a major export hub for bulk drugs owing to low manufacturing cost. However, with enhancing capability of Chinese players, especially in the intermediates space, along with significantly lower production cost, Indian bulk drug manufacturers have lost market share in recent years. Further, because of the patent cliff (when many patents expired on innovator drugs) during 2012 to 2014 many Indian players who manufactured key patent molecules recorded a substantial decline in revenue.

In fiscal 2019, bulk drug exports increased ~10% on-year on the back of a short-term opportunity in the export market because of supply disruption from China. Chinese players had been forced to shift their manufacturing facilities inland and outside the cities as the government continues to crack down on polluting industries. With this, overall supply of bulk drugs from China was impacted.

Covid-19 pandemic led disruptions slows down growth in FY20

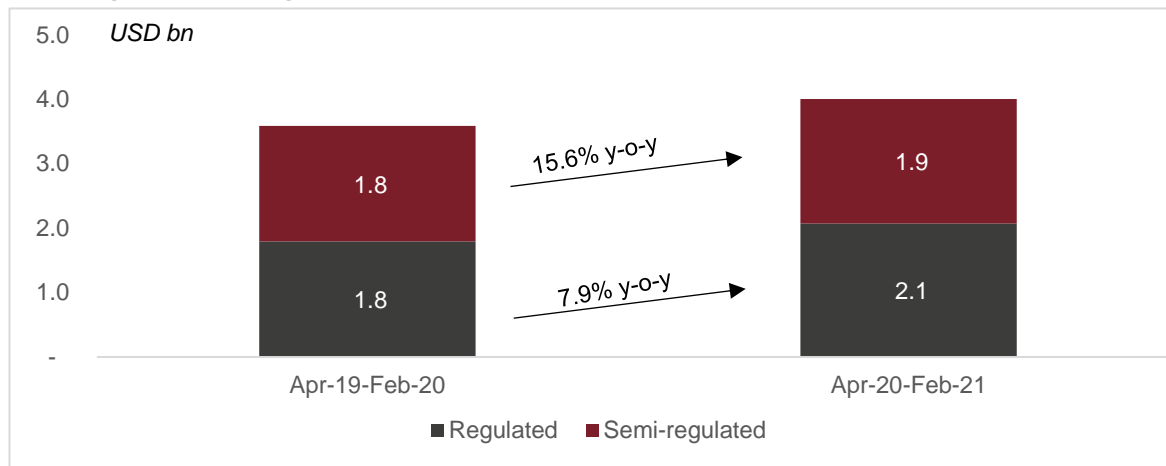
In fiscal 2020, bulk drug exports de-grew by ~0.6% y-o-y in wake of the coronavirus pandemic restricting export growth in the last two months (February-March) of the year.

The Indian government restricted the exports of 13 key API molecules during the month of March in an executive order. These molecules constituted ~30-40% of overall bulk drug exports. However, the restrictions were lifted in April, paving way for increased exports.

Exports grew by ~4% on-year from Apr-Jan FY20. Exports to Iran has increased in fiscal 2020 owing to a rupee payment mechanism agreed between Indian and Iran. Bulk drug exports to China increased as well because of shortages of some products owing to the supply disruption because of the relocation of industries.

Exports during fiscal 2021 are likely to record growth of around ~11% on-year, led by demand for drugs following pandemic. Stocking of APIs by customers, diversification of supply chain from China and improved demand has led to a rise in exports in FY21 so far. Further, export-focused players are likely to see benefit of currency depreciation for FY21.

Bulk drug exports during Apr- Feb of FY21



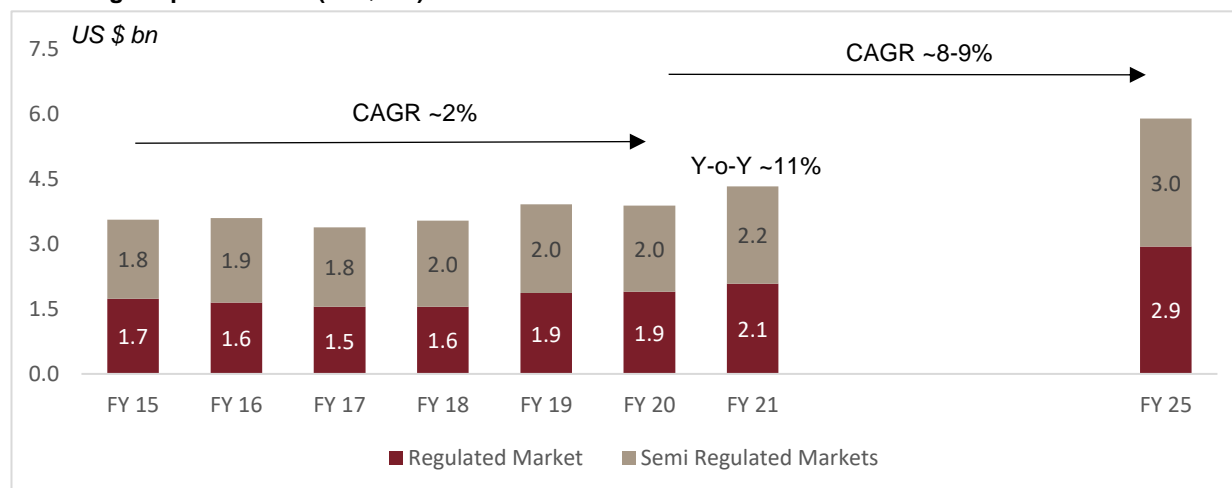
Source: CRISIL Research

Indian Bulk drug exports to grow at 8-9% CAGR from FY20-25 owing to government schemes and various other factors (growth in USD terms)

On the other hand, the government’s new scheme to promote Indian bulk drug industry, which includes providing incentives for manufacturing is also likely to aid growth in the long term.

Even though pricing pressure by formulation players will continue to impact the growth of Indian bulk drug players, transition towards the specialty segment and higher capabilities of Indian players versus Chinese players in high-value API will aid growth over the medium term. Further, demand is expected to pick up regulated markets, as customers source from India as part of de-risking value chain from China. Consequently, overall export is projected to recover to 8-9% CAGR over the next five years, from fiscal 2020 to fiscal 2025, as players focus on niche molecules and specialty segments. Growth will be supported by increasing focus of Indian players in the specialty products segment, where competition is comparatively low.

Bulk drugs export outlook (US \$ Bn)



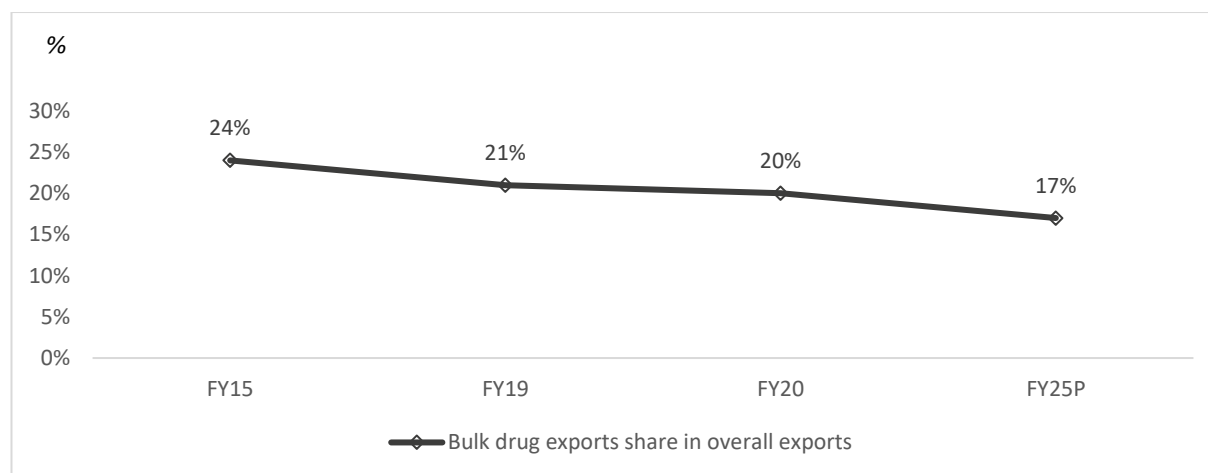
P: Projected

Source: DGCIS, CRISIL Research

In long term, share of bulk drugs in overall exports to see a dip owing to faster growth in formulations

Despite the pick-up in bulk drug exports, the share of bulk drugs in the export basket will continue to shrink over the next five years as formulation exports are expected to grow at a faster pace during next five years. The reason for the faster growth in formulation exports is because of players climbing up the value chain.

Trend in share of bulk drug exports in overall exports



P: Projected

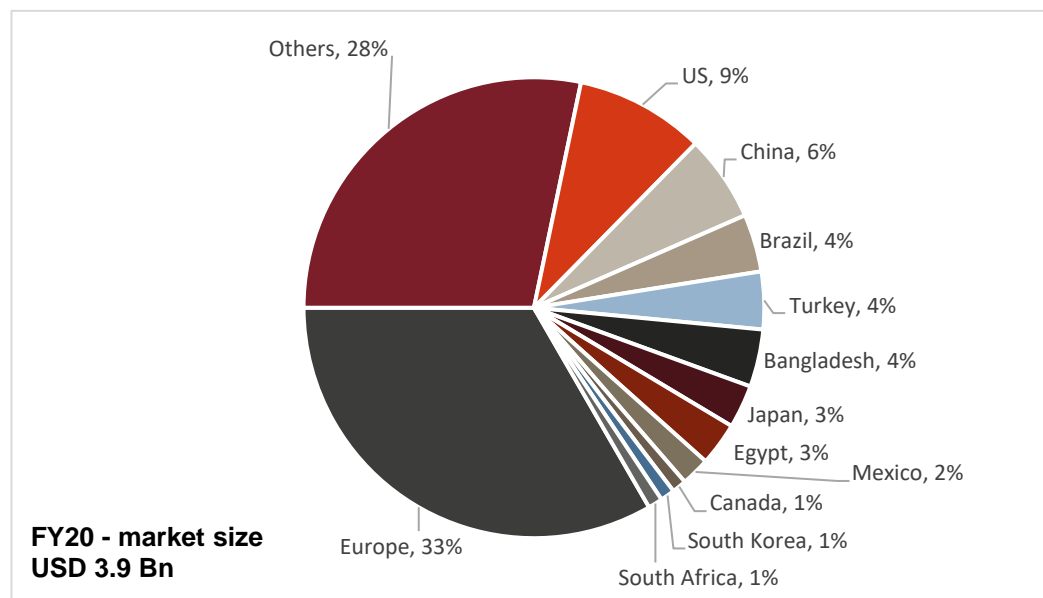
Source: DGCIS, CRISIL Research

Production linked incentive scheme to aid in medium term

On the domestic front, bulk drug production for captive consumption is likely to continue to record strong growth. In fact, domestic bulk drug manufacturers are expected to continue to register double-digit growth, supported by strong domestic sales. The government’s production-linked incentive scheme would also aid domestic manufacturing in the medium term.

The geographic mix for bulk drug exports varies substantially compared with formulations. The US accounted for ~9% of the bulk drug exports in fiscal 2020, compared with a ~39% share in formulation exports. This is mainly because of China's large share in global bulk drug and intermediates trade compared with India. Further, Japan, which constitutes negligible share in formulation exports, accounts for ~3% share in bulk drug exports.

Share of countries in bulk drug exports (FY20) (USD 3.9 Bn)



Source: DGCIS, CRISIL Research

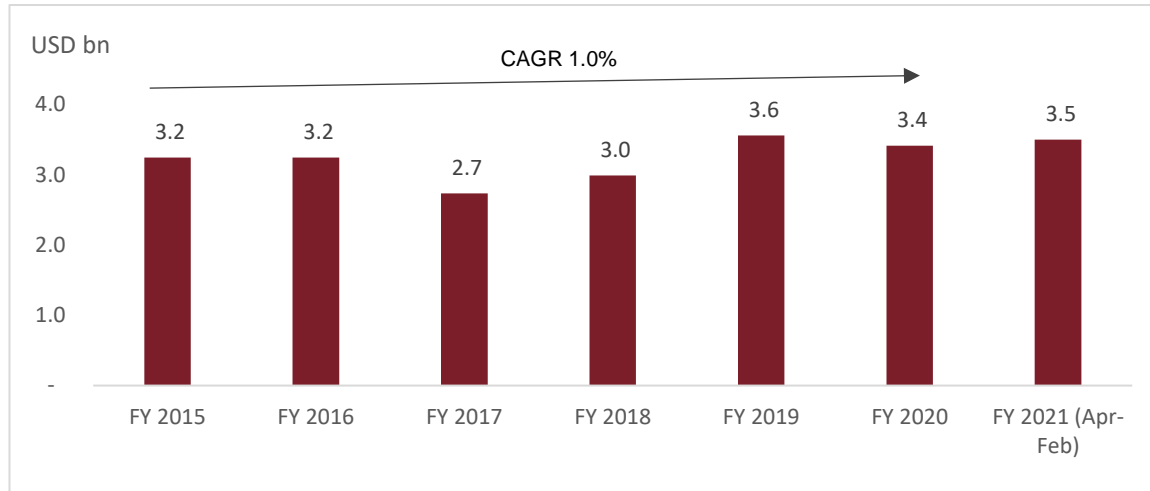
Bulk drug Imports

Though bulk drug imports are stagnant, reliance on China remains monitorable

Bulk drug imports to India have been stagnant over the past 2-3 years. In fiscal 2019, imports increased ~29% on-year (in Rs terms) mainly from China. Imports during Apr-Jan period of fiscal 2020 recorded de-growth of 1% on-year. Covid-19 led disruptions from China during February and March further disrupted supplies, thereby imports for the full year falling by ~3% on-year. However, China continued to account for ~68% share in India's overall bulk drug imports for FY20.

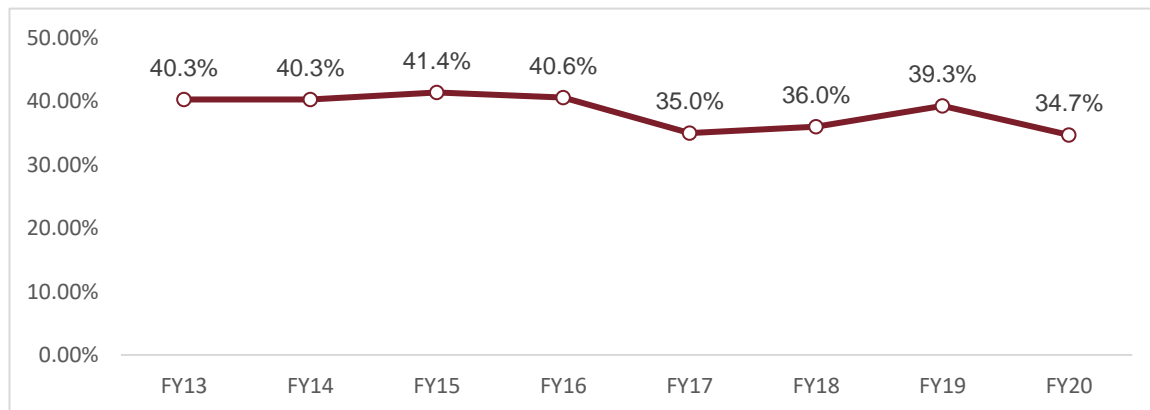
Bulk drugs imports (API and KSI) increased from USD 3.2 billion in fiscal 2015 to USD 3.4 billion in fiscal 2020 registering a CAGR of 1.0% over the last five fiscals. Fiscal 2019 was the highest imports of APIs and KSIs worth USD 3.6 billion.

Imports of bulk drugs and intermediates



Source: DGCIS, CRISIL Research

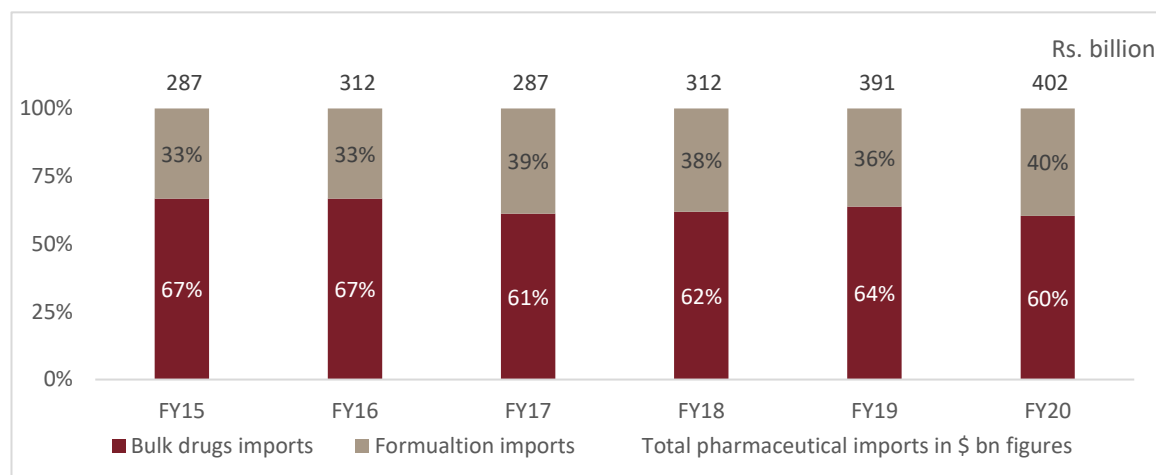
Imports as a percentage of overall bulk drugs consumption



Source: DGCIS, CRISIL Research,

Imports of drugs during fiscal 2020 was of Rs. 402 billion with bulk drugs and intermediates comprising 60% of the total pharmaceutical imports followed by drug formulations and biologicals with 40% share. India imports largely from China, USA, Italy and Germany. India largely imports API and intermediate from markets like China than importing formulation drugs.

Share of bulk drugs imports in overall pharmaceutical imports



Source: DGCIS, CRISIL Research

Increasing dependency on API imports from China

Imports from China have been increasing over the years due to low-cost advantage enjoyed by Chinese manufacturers. Government support in the form of infrastructure and low power cost has helped lower overall production cost for bulk drugs and intermediates for Chinese players. In fiscal 2020, Indian players imported ~68% of the raw material requirement from China.

High dependence on Chinese imports is a concern for the domestic pharmaceuticals industry. The recent coronavirus outbreak has been detrimental in revealing the consequences of a supply disruption from China and its potential impact.

Therefore, the central government has earmarked ~Rs 100 billion for the bulk drug industry, including Rs 30 billion for promotion of bulk drug parks (for next five years) and Rs 69.4 billion towards production-linked incentive scheme for promotion of domestic manufacturing of critical KSMs/Drug Intermediates and APIs in the country (for next eight years). The scheme has identified 53 critical APIs/intermediates where India's reliance on China is high and most of which are used to produce essential drugs

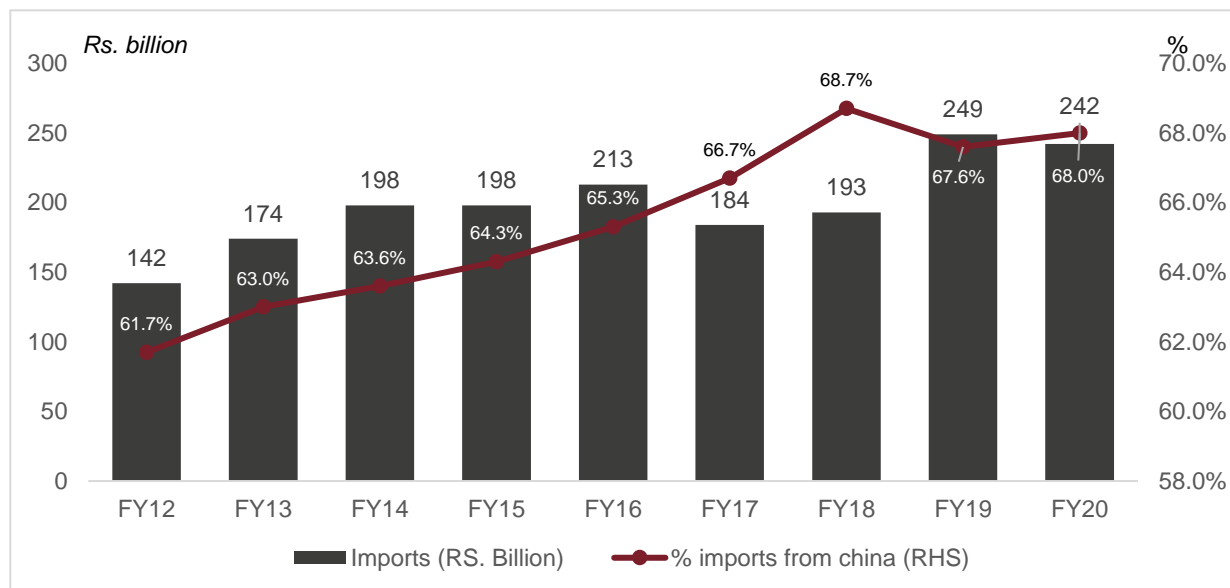
Top 5 categories with largest import share from China

Categories	Imports from China
Antibiotics	75-80%
Hormones, Prostaglandins, Thromboxane & Leukotrienes	50-55%
Provitamins & vitamins	55-60%
Other heterocyclic compounds	80-85%
Other organic compounds	70-75%

Note: Top 5 categories of imports occupy 80% of share of API imports

Source: DGCIS, CRISIL Research

Overview of imports from China

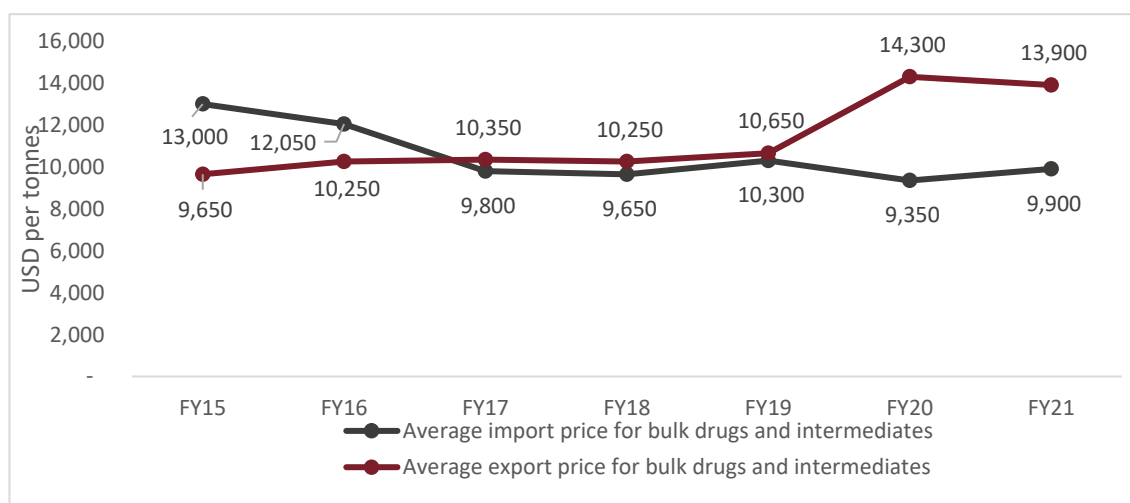


Source: DGCIS, CRISIL Research

Average export prices for bulk drugs have increased over last two fiscals

Export value of API and intermediates have increased in fiscal 2020 and 2021 driven by rise in prices due to pandemic situation and increased production and export of value added API from KSI. Average import price for API and intermediates was USD 9,900 per tonnes as compared to export prices of USD 13,900 per tonnes in fiscal 2021. Export price have increased from \$ 9,650 per tonnes in fiscal 2015 to USD 13,900 per tonnes in fiscal 2021.

Average imports and export prices for bulk drugs and intermediates

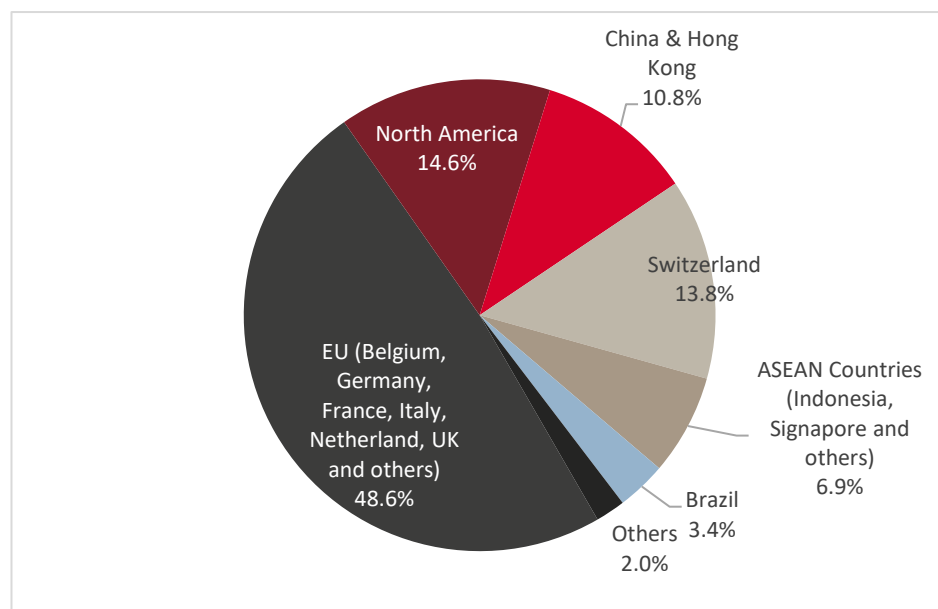


Source: DGCIS, CRISIL Research

In India and globally as well, API imports are concentrated to specific geographies than formulation imports

Countries are more dependent on select few countries for API imports such as China and India – that is API imports is more concentrated, whereas formulation imports are diversified across various countries as per exports database. In India API imports are more concentrated from single market such as China (with 65-70% share) than formulation imports with EU region contributing the highest, with countries share as Belgium – 12.9% , Germany – 8.2% , France – 6.1%, Italy – 4.7%, Netherland – 4.3%, UK – 3.7% in fiscal 2020 formulation imports by India.

Share of countries in formulation imports (FY20)



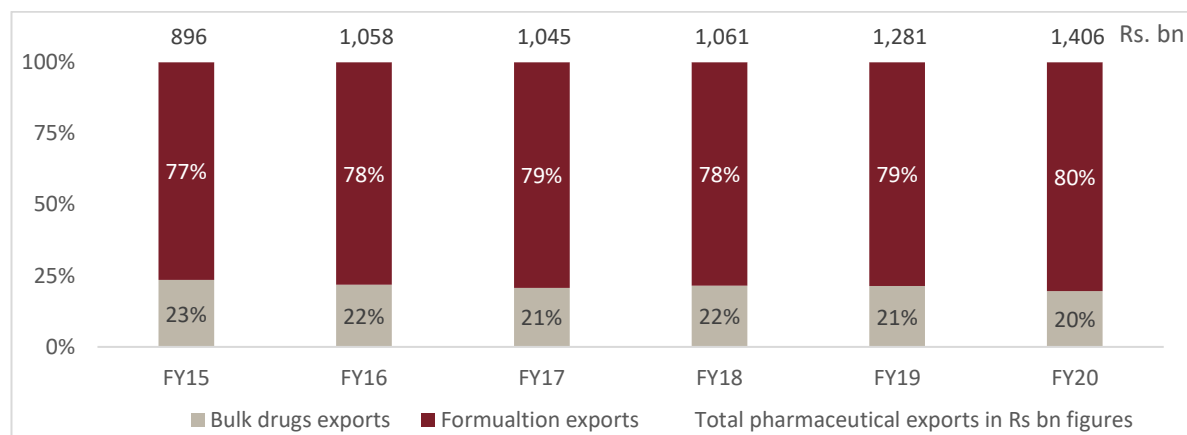
Source: DGCIS, CRISIL Research

India's share of formulation exports is higher than API exports

India has higher share in formulations exports than in bulk drugs exports in global trade. Exports of drugs during fiscal 2020 was of Rs. 1,406 billion with bulk drugs and intermediates comprising 20% of the total pharmaceutical exports followed by drug formulations and biologicals with 80% share. India exports largely to USA market. India exports generics formulation drugs which forms

With Pharma players diversifying from procuring API from China, India has high growth potential for API exports going forward. Bulk drugs exports are expected to clock 8.0-9.5 growth over the next five years – Fiscal 2020 to fiscal 2025

Share of bulk drugs exports in overall pharmaceutical exports



Source: DGCIS, CRISIL Research

4.3 Review of key demand drivers for Indian bulk drug industry

The recent supply disruption in the wake of the coronavirus pandemic has resulted in the government taking proactive steps to boost domestic manufacturing and bring down the costs. A regulatory boost, along with strong process chemistry skills will continue to help the Indian bulk drugs industry garner a big share of the global bulk drug exports pie. We expect growth to pick up in the coming years on account of product diversification and increased global demand.

Supply chain and quality disruptions in China to aid in medium term

On the demand front, India now has the opportunity to establish and grow its strong footing on the global market as customers now look at securing their supply chains and reduce dependence on China. Following the coronavirus pandemic breakout, China was unable to supply bulk drugs/API to its customers. Consequently, prices of these drugs have also increased now. Even though, supply from China has resumed, with quality issues in recent times and declining global image, India might gain a competitive edge in the sector. CRISIL Research expects, exports are likely to register good 8-9% CAGR growth in the medium term from fiscal 2020 to fiscal 2025.

Regulatory boost for domestic industry

The Union Cabinet, on March 21, 2020, approved the below schemes for the development of the Indian bulk drug sector. These schemes are aimed at providing regulatory boost to the sector by reducing manufacturing cost of bulk drugs. One of the major factors for China's dominance in bulk drugs is the regulatory support it gets from its government, with common facilities across plants and various subsidies being provided, which helps them bring down the cost considerably. With the newly announced schemes, the Indian government is also looking at creating common infrastructure facilities and reduce dependence on some critical drugs.

Name of the scheme	Details
Production-Linked Incentive	<ul style="list-style-type: none"> Tenure: FY21 to FY30 Financial outlay: Rs. 69.4 billion Scheme applicable for greenfield projects Financial incentive to be provided for 41 identified key products which cover all 53 identified API's The networth of applicant (including that of group companies) as on date of application \geq30% of total proposed investment Maximum number of selected applicants : 136 The incentive under scheme shall be applicable only on sales of eligible product to domestic manufacturers
Creation of bulk drug parks	<ul style="list-style-type: none"> Tenure: FY21 to FY25 Financial outlay: Rs. 30 billion Three bulk drug parks will be supported under the scheme Maximum grand-in-aid for one bulk drug park will be limited to Rs. 10 billion Minimum 50% of land area for bulk drug manufacturing units 3 states to be selected through challenge method

Source: PIB, CRISIL Research

The manufacturers of pharmaceutical goods registered in India will be grouped based on their Global Manufacturing Revenue (GMR) to ensure wider applicability of the scheme across the pharmaceutical industry and at the same time meet the objectives of the scheme.

The details for the same are as shown below:

Target Groups	Global Manufacturing Revenue (FY 2019-20) of pharmaceutical goods	Quantum of Incentive	Rate of Incentive	Minimum Cumulative Investment per participant (Rs. Crore)	Minimum Percentage Growth in Sales (YoY)
Group A	more than or equal to Rs 5,000 crore	Rs 11,000 crore	Incentive on incremental sales over FY 2019-20 will be 10% for FY 2022-23 to FY 2025-26, 8% for 2026-27 and 6% for 2027-28	Rs. 1,000 crore over 5 years. FY 2021-22: 200 FY 2022-23: 400 FY 2023-24: 600 FY 2024-25: 800 FY 2025-26: 1000	For first year of production, participants shall have to achieve Minimum threshold sales which will be specified by value for each Group in the scheme guidelines. For subsequent years, the participants have
Group B	between Rs 500 (inclusive) crore and Rs 5,000 crore	Rs 2,500 crore		Rs. 250 crore over 5 years. FY 2021-22: 50 FY 2022-23: 100 FY 2023-24: 150 FY 2024-25: 200 FY 2025-26: 250	

Group C	goods less than Rs 500 crore	Rs 1,750 crore		Rs. 50 crore over 5 years. FY 2021-22: 10 FY 2022-23: 20 FY 2023-24: 30 FY 2024-25: 40 FY 2025-26: 50	to achieve a minimum percentage growth of 7% Year on Year.
---------	------------------------------	----------------	--	--	--

The list of products eligible for the PLI scheme is as under

S. No.	List of identified products	S. No.	List of identified products
1	Amoxicillin	28	Ciprofloxacin
2	Azithromycin	29	Losartan
3	Erythromycin Stearate/	30	Telmisartan
4	Ceftriaxone	31	Artesunate
5	Cefoperazone	32	Norfloxacin
6	Cefixime	33	Ofloxacin
7	Cephalexin	34	Metronidazole
8	Piperacillin Tazobactam	35	Sulfadiazine
9	Sulbactam	36	Levofloxacin
10	Dexamethasone	37	Meropenem
11	Prednisolone	38	Paracetamol
12	Metformin	39	Tinidazole
13	Gabapentin	40	Ornidazole
14	Rifampicin	41	Ritonavir
15	Vitamin B1	42	Diclofenac Sodium
16	Vitamin B6	43	Aspirin
17	Clindamycin Phosphate	44	Levetiracetam
18	Clindamycin HCL	45	Carbidopa
19	Streptomycin	46	Levodopa
20	Neomycin	47	Carbamazepine
21	Gentamycin	48	Oxcarbazepine
22	Doxycycline	49	Valsartan
23	Potassium Clavulanate	50	Olmesartan
24	Oxytetracycline	51	Atorvastatin
25	Tetracycline	52	Acyclovir
26	Clarithromycin	53	Lopinavir
27	Betamethasone		

Below is the list of 41 eligible products for which the scheme is proposed covers the 53 APIs which have been approved by government. Table also provides the details of the eligibility criteria for Minimum annual production capacity, maximum No. of applicants to be selected, rate of incentives and the threshold of investments

S. No.	Name of KSM/DI/API	Minimum annual production capacity (Metric tonnes)	Maximum No. of applicants to be selected	Rate of incentives (in%)	Maximum incentive p.a. (Rs. Crore)	Maximum incentive for each selected applicant	Eligibility Threshold Investment (Rs. Crore)
--------	--------------------	--	--	--------------------------	------------------------------------	---	--

						pa (Rs. Crore)	
Fermentation based KSMs/Drug Intermediates							400
1	Penicillin G	5000	2	Y1-Y4:20 Y5:15 Y6:5	Y1- Y4:240 Y5:180 Y6:60	Y1- Y4:120 Y5:90 Y6:30	
2	7-ACA	1000	2	Y1-Y4:20 Y5:15 Y6:5	Y1- Y4:240 Y5:180 Y6:60	Y1- Y4:120 Y5:90 Y6:30	
3	Erythromycin Thiocynate (TIOC)	800	2	Y1-Y4:20 Y5:15 Y6:5	Y1- Y4:120 Y5:90 Y6:30	Y1-Y4:60 Y5:45 Y6:15	
4	Clavulanic Acid	1.5 lakh Kg	2	Y1-Y4:20 Y5:15 Y6:5	Y1- Y4:120 Y5:90 Y6:30	Y1-Y4:60 Y5:45 Y6:15	
Fermentation based niche KSMs/Drug Intermediates/APIs							50
5	Neomycin	80	2	Y1-Y4:20 Y5:15 Y6:5	Y1-Y4:20 Y5:15 Y6:5	Y1-Y4:10 Y5:7.5 Y6:2.5	
6	Gentamycin	40	2	Y1-Y4:20 Y5:15 Y6:5	Y1-Y4:20 Y5:15 Y6:5	Y1-Y4:10 Y5:7.5 Y6:2.5	
7	Betamethasone	2	2	Y1-Y4:20 Y5:15 Y6:5	Y1-Y4:20 Y5:15 Y6:5	Y1-Y4:10 Y5:7.5 Y6:2.5	
8	Dexamethasone	2	2	Y1-Y4:20 Y5:15 Y6:5	Y1-Y4:20 Y5:15 Y6:5	Y1-Y4:10 Y5:7.5 Y6:2.5	
9	Prednisolone	15	2	Y1-Y4:20 Y5:15 Y6:5	Y1-Y4:20 Y5:15 Y6:5	Y1-Y4:10 Y5:7.5 Y6:2.5	
10	Rifampicin	100	2	Y1-Y4:20 Y5:15 Y6:5	Y1-Y4:20 Y5:15 Y6:5	Y1-Y4:10 Y5:7.5 Y6:2.5	
11	Vitamin B1	200	2	Y1-Y4:20 Y5:15 Y6:5	Y1-Y4:20 Y5:15 Y6:5	Y1-Y4:10 Y5:7.5 Y6:2.5	
12	Clindamycin Base	60	2	Y1-Y4:20 Y5:15 Y6:5	Y1-Y4:20 Y5:15 Y6:5	Y1-Y4:10 Y5:7.5 Y6:2.5	
13	Streptomycin	50	2	Y1-Y4:20 Y5:15 Y6:5	Y1-Y4:20 Y5:15 Y6:5	Y1-Y4:10 Y5:7.5 Y6:2.5	
14	Tetracycline	200	2	Y1-Y4:20 Y5:15 Y6:5	Y1-Y4:20 Y5:15 Y6:5	Y1-Y4:10 Y5:7.5 Y6:2.5	
Key Chemical Synthesis based KSMs/Drug Intermediates							50
15	1,1 Cyclohexane Diacetic Acid (CDA)	1500	4	10	40	10	
16	2-Methyl-5Nitro-Imidazole (2-MNI)	800	4	10	40	10	
17	Dicyandiamide (DCDA)	8000	4	10	40	10	
18	Para amino phenol	4500	4	10	40	10	
Other Chemical Synthesis based KSMs/Drug Intermediates/APIs							20
19	Meropenem	4	4	10	10	2.5	
20	Atorvastatin	30	4	10	10	2.5	
21	Olmesartan	25	4	10	10	2.5	

22	Valsartan	25	4	10	10	2.5	
23	Losartan	40	4	10	10	2.5	
24	Levofloxacin	115	4	10	10	2.5	
25	Sulfadiazine	20	4	10	10	2.5	
26	Ciprofloxacin	150	4	10	10	2.5	
27	Ofloxacin	100	4	10	10	2.5	
28	Norfloxacin	15	4	10	10	2.5	
29	Artesunate	20	4	10	10	2.5	
30	Telmisartan	45	4	10	10	2.5	
31	Aspirin	750	4	10	10	2.5	
32	Diclofenac Sodium	175	4	10	10	2.5	
33	Levetiracetam	140	4	10	10	2.5	
34	Carbidopa	2	4	10	10	2.5	
35	Ritonavir	5	4	10	10	2.5	
36	Lopinavir	7	4	10	10	2.5	
37	Acyclovir	75	4	10	10	2.5	
38	Carbamazepine	65	4	10	10	2.5	
39	Oxcarbazepine	65	4	10	10	2.5	
40	Vitamin B6	35	4	10	10	2.5	
41	Levodopa	10	4	10	10	2.5	

Note: In table above, Y1-Y4 is FY 2023-24 to FY 2026-27, Y5 is FY 2027-28 and Y6 is FY 2028-29.

Recent updates on PLI scheme

Below is the list of companies with approved KSM/DI/APIs, product categories, its committed production capacity and committed investments.

S.No.	Name of approved Applicant	Name of Eligible Product	Committed Production Capacity (in MT)	Committed Investment (in Rs. crores)
1	M/s Aurobindo Pharma Limited (through LyfiusPharmaPvt. Ltd.)	Penicillin G	15000	1392
2	M/s Karnataka Antibiotics & Pharmaceuticals Ltd.	7 - ACA	1000	275
3	M/s Aurobindo Pharma Limited (through LyfiusPharmaPvt. Ltd.)		2000	813
4	M/s Aurobindo Pharma Limited (through Qule Pharma Pvt. Ltd.)	Erythromycin Thiocyanate (TIOC)	1600	834
5	M/s Kinvan Pvt. Ltd.	Clavulanic Acid	300	447.17
6	M/s Natural Biogenex Private Limited	Betamethasone	12	31.43
7	M/s Natural Biogenex Private Limited	Dexamethasone	10	26.19
8	M/s Natural Biogenex Private Limited	Prednisolone	15	39.29
9	M/s SymbiotecPharmalab Private Limited		15	5
10	M/s Macleods Pharmaceutical Limited	Rifampicin	200	198.36
11	M/s Optimus Drugs Private Limited	Vitamin B1	200	35
12	M/s SudarshanPharma Industries Limited		200	57
13	M/s Optimus Drugs Private Limited	Streptomycin	50	30
14	M/s Saraca Laboratories Limited	1,1 Cyclohexane Diacetic Acid (CDA)	3000	50
15	M/s EmmennarPharma Private Limited		1500	21.94
16	M/s Hindys Lab Private Limited		3000	37.6
17	M/s AartiSpeciality Chemicals Limited	2-Methyl-5Nitro-Imidazole (2-MNI)	4000	77.87
18	M/s Meghmani LLP		13500	55.06

19	M/s Sadhana Nitro Chem Limited*	Para amino phenol	36000	197.27
20	M/s Anasia Lab Private Limited	Meropenem	8	26.12
21	M/s Rajasthan Antibiotics Limited		48	28.25
22	M/s Centrient Pharmaceuticals India Private Limited	Atorvastatin	180	137.74
23	M/s Anasia Lab Private Limited	Olmesartan	75	27.09
24	M/s Andhra Organics Limited		75	30.5
25	M/s Solana Life Sciences Private Limited	Artesunate	40	20
26	M/s RMC Performance Chemicals Private Limited	Aspirin	1500	12
27	M/s Surya Remedies Private Limited	Ritonavir	20	20
28	M/s Honour Lab Limited	Lopinavir	49	31.01
29	M/s Hindys Lab Private Limited	Acyclovir	525	30.37
30	M/s Dasami Lab Private Limited	Carbamazepine	260	30.28
31	M/s Dasami Labs Private Limited	Oxcarbazepine	195	25.58
32	M/s Hetero Drugs Limited		195	19
33	M/s Hazelo Lab Private Limited	Vitamin B6	70	21.53

Total of 33 applications with committed investment of Rs.5082.65 crore have been approved by the government under the PLI Scheme for KSMs, Dis and APIs. This approval will help in employment generation of approx. 9300 people. The commercial production is expected to start from 1st April, 2023 onwards and the spending on PLI by the government over the six years period would be up to a maximum of Rs. 5,440 crores. Setting of these plants will make the country self-reliant to a large extent in respect of these bulk drugs. The remaining 95 applications under the Target Segment-IV will be undertaken for inspection and approval till 31 March, 2021.

India stands to benefit from China plus one strategy of global pharmaceutical players

Over the last two decades, many global pharmaceutical companies have increased their dependence on China to source intermediates and APIs. China is the largest global supplier of API and intermediates. The increased reliance on China was on the back of fast-growing Chinese manufacturing of intermediate and API at a lower cost. Many companies even chose to invest in China, drawn by its cheap labour, easier norms and huge market. However, China is slowly losing its cost advantage with rising labour and other costs. The first blow to the global pharma industry came in 2017 when the supply chain was disrupted due to China's environmental crackdown. As part of the Blue sky policy, thousands of industrial parks and chemical companies were closed either temporarily or permanently. This resulted in the steep price hike and shortage of raw materials and APIs for the global pharma industry.

This supply disruption has impacted the pharma industry, and global players recognized the need to de-risk their dependence on China. There was a slow shift from the global pharma companies to source from alternate sources like India. The outbreak of the Covid-19 pandemic in China in early 2020 again resulted in supply chain disruption for the pharma industry. The Covid-19 pandemic has resulted in anti-China sentiment and awakened renewed interest for diversification from procuring from China and looking at additional supplier apart from China with the China +1 strategy. This will help to enhance supply chain resilience by diversifying sourcing/manufacturing activities into other countries.

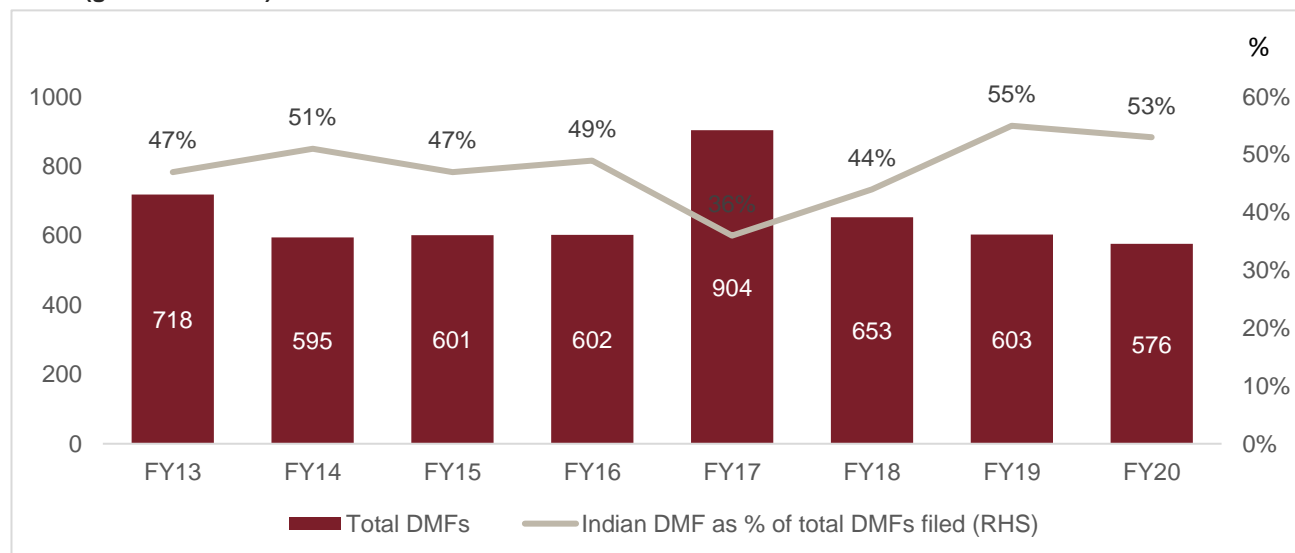
India stands a chance to be the biggest beneficiary of this China+1 strategy of global pharma giants. The domestic API manufacturers have already witnessed increased enquiries from the worldwide innovator. The global innovators are now looking to develop India as the second source and shift from China to India. The Government of India has also recognized the need to reduce the dependence of the pharma industry on China for APIs and key starting material (KSM). The announcement "Production-Linked Incentive Scheme" for APIs and KSM will provide the required impetus to the domestic industry to invest in new facilities and compete with Chinese players.

India has highest number of US FDA-approved facilities outside the US, leads US DMF submissions

India has the highest number of US Food and Drug Administration (FDA) approved facilities outside the US. The country also has skilled manpower and advanced process chemistry skills. Some bulk drug manufacturers have forward-integrated into pre-formulations (pelletisation / granularisation of bulk drugs before they are converted into finished dosages) as well.

Though China is a major destination for bulk drug manufacturing, it has a major share primarily in the manufacturing of bulk drug intermediates. India has consistently maintained its leadership in drug master file (DMF) submissions. This proves the capability of Indian players to meet required export quality standards for regulated markets. A DMF is an indicator of the bulk drug manufacturing capabilities of players (in terms of quality standards maintained at their facilities for processing, packaging, storage of drugs, etc.), which is used by global pharmaceutical companies that are outsourcing production activities (innovators).

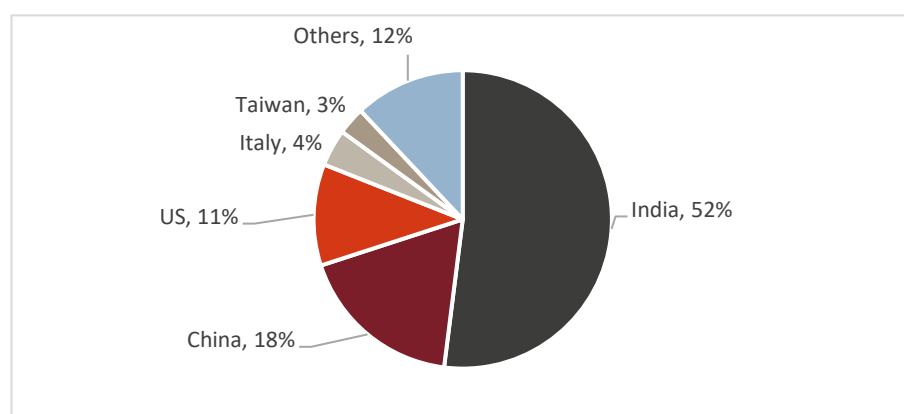
DMFs (global vs. India)



Source: USFDA, CRISIL Research

India is considerably ahead of its competitors in terms of the total number of DMFs.

Country-wise DMFs (2019)



Note: Active, Type II DMFs considered
 Source: USFDA, CRISIL Research

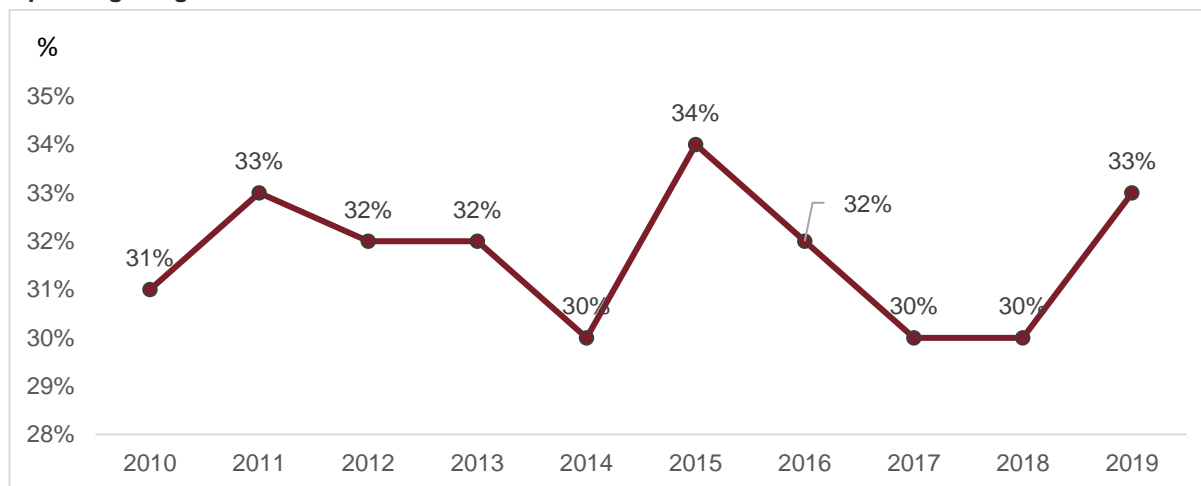
Focus on niche and specialty products to aid growth

A focus on specialty products and niche molecules would aid the growth of bulk drug players. Players have a healthy pipeline of complex generics and limited competition products, which are difficult to manufacture but command a higher premium. The pricing pressure is also expected to normalise in regulated markets in the coming years. Further, the supply disruption from China is expected to aid business opportunities for bulk drug players in the global market. Also, recent quality issues related to Chinese APIs have slightly dented the country's image globally, which would in turn boost business for India, the next largest and cost-effective API supplier after China. Some multinational corporations (MNCs) are looking at alternative sources for bulk drug procurement following Chinese issues.

Outsourcing of bulk drugs from MNCs to continue

In view of high operating expenses, CRISIL Research believes MNCs will look at bulk drug outsourcing to control cost and improve profitability. Margins of global innovator players dipped substantially from 2015 to 2018. Going ahead as well, MNCs are likely to continue outsourcing bulk drugs manufacturing to India.

Operating margin trend of MNCs



Note: Seventeen global MNCs considered
 Source: Company reports, CRISIL Research

India is emerging as the key player in CDMO segment

India is becoming a preferred destination for outsourcing the pharmaceutical activities across pharma value chain. As big pharma companies continue their focus on reducing the costs particularly fixed costs associated with the development and manufacturing of the drugs. Contract development and manufacturing organization (CDMO) are being viewed as the capable and value added service provider with the essential technical expertise.

India has proved track record of outsourcing in services like information technology, knowledge process outsourcing etc. apart from its strong foothold in the pharmaceutical exports. In the pharmaceutical industry, India is one of the largest exporters of over-the-counter and prescription drugs to the United States. India has the largest manufacturing base outside of the US for products sold in the US market. India accounted for 12% of all drug manufacturing sites for the US market for fiscal 2019 (US fiscal year Sep-October). Indian CDMO players have

significant experience in development and manufacturing of pharmaceutical products this has enabled them to build good business practices and quality manufacturing processes. This experience has aided the India's position as the leading manufacturer of Pharmaceutical products.

Global pharmaceutical players are continuously witnessing cost pressures and looking for ways to shorten time to market. Thus the industry is looking for established CDMO partners, particularly in Asian markets such as India and China. China will not be the most preferred partner for CDMO outsourcing on account of regulatory headwinds in China, incidences such as Covid-19 pandemic, closure of certain API and chemical industries on account of environment pollution, and political confrontations with the developed economies of the world. On the other hand, Indian CDMO companies over the last decade have demonstrated their capabilities on the global platform and are best positioned to benefit from increased R&D outsourcing in the pharmaceutical industry.

Major players look to improve capacities to reduce China dependence

Players such as Aurobindo, Divis Labs, and Aarti Industries are looking at expanding their API capacities with an aim to reduce dependence on China.

Recent supply and quality issues in China have resulted in disruptions in the industry. Indian players are now looking at capitalising the opportunity as even some global MNCs are moving away from China as they consider alternate sourcing of APIs.

- Divis Laboratories has invested Rs 25 billion in capex since FY18. the company has now announced new capex at Kakinada, with an investment of Rs 6 billion to be spread over 2–3 years. Apart from this, the company has several other investments in line
- Aurobindo made Rs 150 million in local intermediate maker in FY20 to ensure continuous supply of intermediates in event of Chinese disruption.
- Aarti Industries had announced a capex plan of Rs 23 billion over fiscal 2019 to fiscal 2021 in multiple chains to increase market share
- Aarti Drugs has guided for a capex in the range of Rs 10-12 billion annually for next couple of years

The new production-linked incentive scheme announced by government will also see new Greenfield projects coming up which will boost bulk drug production in the country.

However, dependence on Chinese imports (key starting materials / intermediates) would continue because unless the government provides continued support in the form of infrastructure and tax subsidies, it would not be possible for Indian players to match the manufacturing costs of its Chinese counterparts.

4.4 Review of key regulations in Indian bulk drug industry

As healthcare is of prime importance, the pharmaceutical industry is subject to various laws and regulations, both in the domestic and international markets. Over the past few years, these regulations have been made more stringent to ensure greater efficiency, safe consumption of drugs and prevent sales of spurious products.

Being the raw materials for various drug formulations, bulk drugs are evaluated with respect to their chemical and physical properties, process patent status and availability. In addition, bulk drug manufacturing facilities are audited for their compliance with current Good Manufacturing Practices (cGMP).

Current Good Manufacturing Practices

The cGMP are norms that describe the methods, equipment, facilities and controls etc required for the production of pharmaceutical products, mainly formulations. However, with the implementation of Schedule M in India w.e.f January 1, 2005, even bulk drug manufacturers have to comply with the cGMP norms. Further, since many manufacturers export to markets such as USA, they must comply with the importing country's CGMP norms as well.

Some of the common requirements of cGMP are:

- Properly designed and maintained equipment and facilities
- Approved standard operating procedures
- An independent quality assurance unit
- Well-trained personnel and management
- Adherence to and proper documentation of process and product controls
- Lab controls and other controls necessary to provide drug quality assurance

Drug master files

Since a significant share of the bulk drugs manufactured in India are exported to regulated markets such as the US and Europe, the exporting companies must comply with the regulations of those regions. A drug master file (DMF) is a document provided to the respective regulatory agency by a bulk drug manufacturer, containing detailed confidential information about the facilities, processes, or articles used for manufacturing such as for processing, packaging, storing the bulk drug and the cGMP status of the bulk drug. In Europe, this document is known as European Drug Master File (EDMF) or an Active Substance Master File (ASMF) and in the US it is termed a Drug Master File (DMF). Over the years, Indian players have been filling several DMFs with the US FDA. Consequently, from 2014-2019, India accounted for ~37% of the total DMF filings made in the US.

New pricing policy departs from fixing bulk drug prices

In the past, prices on bulk drugs and their formulations was regulated based on cost of manufacturing and a suitable return to the manufacturer. However under the National Pharmaceutical Pricing Policy 2012, there has been a departure from this practice and currently pricing control is being extended only to the final formulations, which are deemed essential medicines for healthcare delivery.

Drug price control order (DPCO)

In India, the Drug Price Control Order (DPCO) (a regulation enforced by the central government), fixes the ceiling prices of some APIs, also called scheduled bulk drugs. The National Pharmaceutical Pricing Authority (NPPA) collects data and reviews the pricing structure of different APIs and provides recommendations to the Union Ministry of Chemicals and Fertilisers. However as per the National Pharmaceutical Pricing Policy 2012 (NPPP), price controls have been extended only over the final formulation and not over the bulk drugs used for the manufacturing of the formulation. The pricing formula and list of medicines along with their dosage strengths to be included as part of the NPPP 2012 has been notified in the new drug price control order 2013 (DPCO 2013).

The DPCO 2013 empowers the NPPA to regulate prices of 348 essential drugs listed in the National List of Essential Medicines (NLEM). However, in 2015, there were amendments made to the NLEM as 106 medicines were added and 70 medicines were deleted. The new list (NLEM 2015) contains a total of 869 medicines to be regulated as of March 2019.

The new policy fixes the pricing mechanism for formulations as under:

- The NLEM fixes prices of drugs based on: Sum of prices of all the brands of medicines having more than or equal to 1% of the market share of the total market turnover of that medicine divided by total number of manufactures producing such brands of the medicine.
- Later, the prices will be increased annually based on the increase/decrease in the Wholesale Price Index. This is applicable to both domestic as well as imported drugs.

4.5 Key success factors and risks in Indian bulk drug industry

Key success factors

Critical success factors mainly applicable to bulk drug exporters are listed below

Greater focus on regulated markets

Over the past few years, bulk drug exports to regulated markets have assumed a significant proportion of total bulk drugs exports. This is because of the large amount of drugs going off-patent in regulated markets that triggers an influx of generic drugs in these markets and thus greater export opportunities for API players. Also, the share of bulk drug exports catering to on-patent drugs is steadily rising, reflecting the confidence of global innovators in Indian players.

Maintenance of quality standards

The importance of adhering to quality standards set by regulatory authorities across the globe can be gauged from the high number of US Food & Drug Administration (FDA)-approved facilities and drug master files (DMFs) obtaining currently. A company with more DMFs and US FDA-compliant facilities is likely to seize more of upcoming opportunities in export markets.

Protection of intellectual property

Indian players, especially those involved in contract manufacturing deals, should be capable of producing bulk drugs without infringing on patent processes and in a cost-effective manner. Protection of intellectual property (IP) rights has gained prominence in the last few years post India's commitment to the World Trade Organisation. Global pharmaceutical players are extremely concerned about this parameter while outsourcing pharmaceutical activities to low-cost destinations such as India. Since this subject has gained importance and is being carefully monitored, global pharmaceutical players will gradually develop a feeling of confidence and trust towards Indian players.

Long-term relationship with generic manufacturers

A bulk drugs player who ties up with a generic manufacturer is to some extent assured of steady sales volumes. Several big Indian formulation companies such as Cipla and Dr Reddy's, market generics in regulated

markets and compete directly with other foreign players. Alliances with any such company would cushion a domestic player from price and volume fluctuations. Apart from supplying to domestic generic companies, bulk drugs manufacturers who tie up directly with global generic manufacturers in regulated markets, enjoy stable and consistent revenue growth and better margins than those who operate primarily in the domestic market.

Lower manufacturing costs

A player's strength to penetrate further into the regulated market will largely depend on their ability to supply bulk drugs at a low cost while adhering to the highest standards of quality and safety.

Custom synthesis for innovators

Bulk drug players who conduct custom synthesis and supply bulk drugs for manufacturing on-patent drugs earn relatively higher margins than those who operate in the generics segment. This is a niche area where protection of intellectual property (IP) assumes the highest significance in addition to advanced chemistry skills. India scores higher than other countries like China and Eastern European counterparts in IP protection and quality consistency and also enjoys more confidence from global innovators; hence, it is well-placed to garner outsourcing opportunities for supplying APIs.

Updating product portfolio

A key difference between the bulk drugs industry and other commodity industries is the rapid pace of innovation in the former. Older molecules are substituted by newer, more effective molecules which enter the market. It thus becomes incumbent for manufacturers to constantly update their product portfolio to sustain profits. Players with newer molecules are more insulated against price and product competition than those whose portfolio consists of traditional, older drugs.

Key risk factors

Pricing pressure in global generic market

Bulk drug supplies to formulation players in regulated markets constitutes a major share of revenue for the Indian players. Except for few large players, most of the Indian players in the bulk drugs industry serve the global generic players. The wholesale consolidation in the US market and increasing competition among the generic players had led to price erosion among the generic players. This had impacted the Indian bulk drug players in the recent past. On the other hand, increase in tender-based procurement and focus on pricing controls in the European markets may impact players across the pharmaceutical value chain. Thus, these remain a key risk to the sector.

Change in Government regulations

The Government has been taking various steps in-order to control the prices of formulation drugs and make it more affordable to the consumers. The National Pharmaceutical Pricing Authority (NPPA) has fixed retail prices of 869 formulations under price control based on price revision as per annual wholesale price index (WPI) of 1.88% increase. The pricing pressure on formulation drugs also puts pressure on realisations for bulk drug players, as formulation players look to protect their margins.

Further, the Government is also working towards the use of generic generics and move away from branded generics. The increase in penetration of generic generics will also have an impact on margins for the bulk drug players. However, its implementation will remain a challenge, as the Government will primarily have to ensure that a standard quality is maintained across all the plants in the country.

Compliance with USFDA regulations

Adherence to cGMP (Good manufacturing Practices) prescribed by the USFDA and maintaining data integrity remain key challenges for the Indian players. As of FY20, India had ~53% share in overall DMF (Drug Master Files) filings with the USFDA. Post high number of warning letters and imports in 2013 and 2014 for the formulation players, the Indian players hired US-based consultants in-order to achieve complete compliance with the US FDA regulations. Therefore, the larger players have already taken substantial steps to implement corrective measures and make the facilities US FDA compliant. During 2014 to 2016, the compliance issue among the major bulk drug players were relatively low as compared to formulation players. However, the regulatory stringency from USFDA has increased in fiscal 2019, with major players receiving regulatory alerts. Therefore, compliance of other smaller bulk drug players will remain a key monitorable.

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 250 Crore) 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.

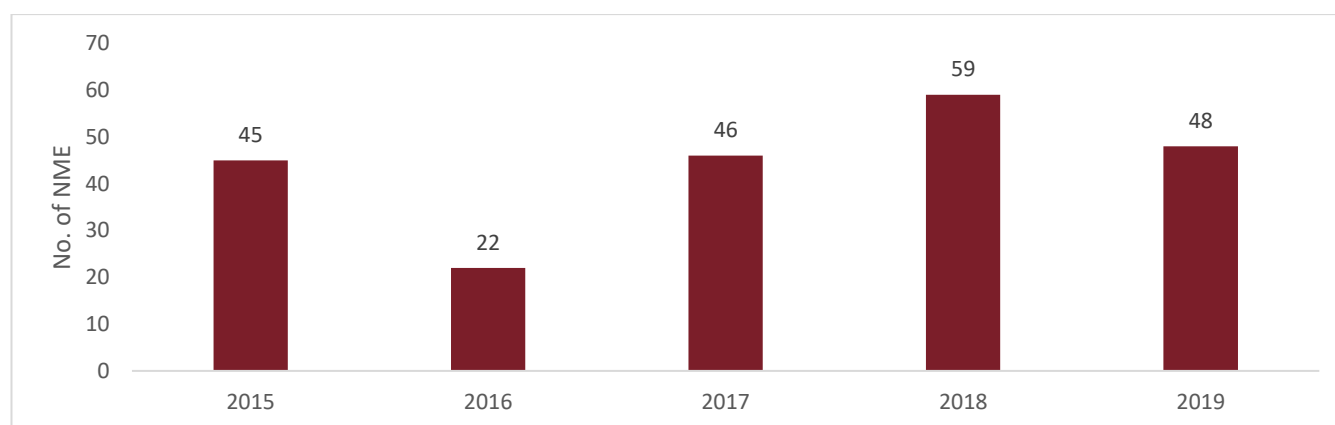
Dependence on China for imports

India imports ~70% of intermediaries required for APIs (Active Pharmaceutical Ingredients) from China. Over the last few years, many chemical based companies have been shut down in China due to failure to meet environment norms. Any such step 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. Also, the pandemic which started spreading in the previous year (2020) has resulted in supply disruptions and price rise for key APIs. Although, China has now gradually resumed operations and raw materials have started flowing in, the cost pressures are likely to remain for the year as Chinese traders exploit the situation.

4.6 Focus on Research & Development

Good quality research and development (R&D) is crucial to the long-term revenue generation and success of the pharmaceutical industry. The product development process in the pharmaceutical sector is characterized as complex, lengthy and costly. R&D costs influence decisions and policy options about how to best incentivize innovation to meet health needs and to make end products available at affordable prices. This research synthesis focuses on the cost aspect of the process. New molecules entity approved by FDA have increased considerably from 2017 onwards, highlighting the increased investments in R&D. Global R&D expenditure have increased from 18.8% in 2012 to 20.8% in 2020.

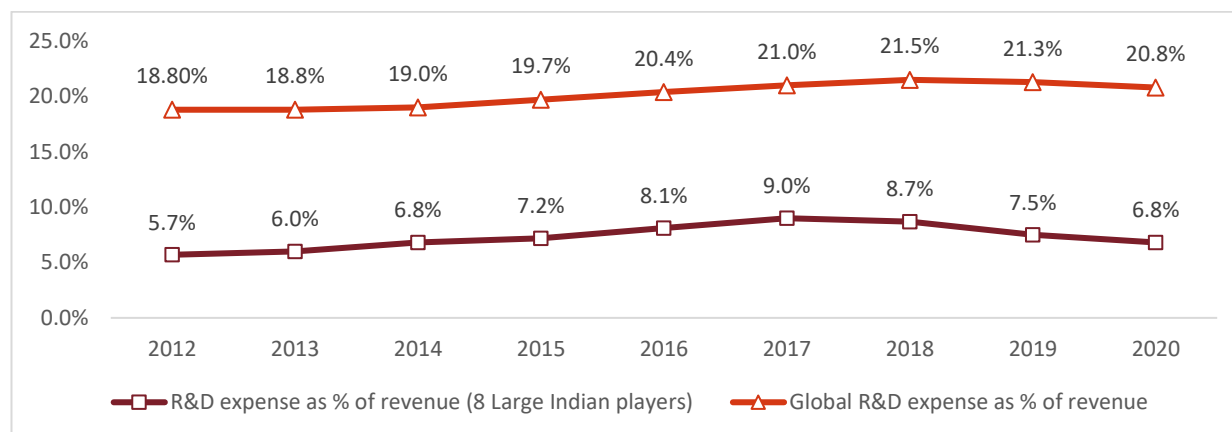
New molecule entity approved by FDA



Source: US FDA, CRISIL Research

Investment in R&D by pharma industry as a whole in India has been low, only around 0.6% of turnover. The Indian pharmaceutical industry average R&D expenditure is around 2% of turnover contributed by around 150 companies. The low investment in R&D is due to low profitability and comparatively small size of companies. In the last few years most of the top Indian pharma companies have increased their R&D investments, but investment as a percentage of revenue remains under half of the investment level recorded by the top ten global companies. A considerable proportion of this investment also goes into generic drug research, leaving insufficient funds for new chemical entity (NCE) and new biologic entity (NBE) research. In addition to the high risk associated with R&D investments in innovative research, market factors such as price controls and patent protections also act as deterrents. The research potential is further limited by inadequate grants and funds by the government bodies, especially for early research projects with start-ups/entrepreneurs and in academia. The procedure to apply for and receive the grants is also very complex. Private equity and venture financing, which is critical to push the projects to next stage of development, is also currently limited in the Indian market due to the long gestation period and high-risk nature of pharma R&D.

To build a strong R&D base, it is critical to increase both private and public expenditure on R&D. Public funding is required to strengthen capabilities in basic research, especially in high risk and high priority areas. Private funding commitment, especially from the larger organizations, is critical to convert innovative ideas to successfully commercialized products. India's R&D expenditure have increased on an average over the last 4-5 years to around 7-8% of total revenues as compared to 6-7% of revenues a decade ago. This has helped India pharmaceutical industry to increase its technical and technological expertise and cater to complex pharmaceutical drugs and API demand. This has helped to boost growth in domestic manufacturing and export capabilities. Exports from India for formulations and biologics have registered as growth of 10.5% between 2015 and 2020.

R&D as % of operating income for 8 large MNC players in India vs global large pharma players


Note: R&D numbers are set of eight large players

Source: Company filings, CRISIL Research

The leading Indian API players continue to focus on R&D programs in relation to new products development for lifestyle related diseases like cardiovascular, diabetics, anticoagulant, cholesterol etc. These products would be developed along with their DMFs in a time-horizon of two to four years. Several companies are focusing on R&D on API that are off patents and will be working on non-infringing route of synthesis. Investment in R&D for API and intermediates will help India to produce pharmaceutical products domestically and reduce import dependence and increase exports of pharmaceutical drugs.

Backward integration for key intermediates in API's

India is one of the world's leading suppliers of drugs - mostly generic formulations - but depends on imports for its requirement of APIs and KSMs, particularly from China, which accounted for more than 60% of requirements in some therapy areas. India's reliance on pharmaceutical ingredient imports has risen over the past few decades due to the higher cost of domestic production, with the gap in cost reaching to almost 20%-30%, particularly for energy-intensive fermentation-based ingredients used in anti-infectives. Import dependence is more than 90% for some life-saving drugs, including penicillin and ciprofloxacin.

In an attempt to gain greater control over bulk drug supplies, large domestic pharmaceutical companies are increasing backward integration in key API and intermediates segments. Considering the growth in formulations in international and domestic market, Indian companies are taking steps to strengthen their API and intermediates manufacturing. Backward integration remains the key to meet the increasing demand for cost-effective APIs. In addition to the apparent benefits of greater cost efficiencies and quality control, in-house intermediates manufacturing facilities offer greater manufacturing flexibility and minimize the reliance on third party suppliers. Indian companies are also marketing and exporting APIs both in the domestic and international markets, making it crucial to procure high quality KSM / intermediates at effective cost to compete with Chinese API suppliers. The micro, small and medium enterprises (MSMEs) in the pharmaceutical sector in India need to adopt backward integration to reduce the dependence for importing active pharmaceutical ingredients (APIs) and excipients from China. Government of India's scheme for production-linked incentives (PLI) are set to boost the manufacturing of drug intermediates and APIs

Many of the large domestic pharmaceutical companies have also increased backward integration into bulk drugs especially for some of their key product segments in order to maintain control over quality and costs. Furthermore, with many of the domestic pharmaceutical companies present in the highly competitive US generic formulation

market, the requirement for in-house API / intermediates /KSM supply is gaining prominence. In addition to the apparent benefits of greater cost efficiencies and quality control, in-house API / intermediates / KSM manufacturing facilities offer better manufacturing flexibility and minimizes the reliance on third party suppliers. API / Intermediates alone contribute to 25% of total pharmaceutical revenue, and hence are crucial for cost control and management.

While a majority of the bulk drug manufacturing capabilities of the large Indian pharmaceutical companies are meant for in-house consumption, the surplus production capacities are generally utilized for sales to third parties and has resulted in some companies gaining a sizeable market share.

The importance of backward integration into bulk drugs is highlighted by the substantial API manufacturing capabilities of some of the leading global generic players such as Teva and Mylan. In addition to sourcing a majority of their API requirements from in-house facilities, Teva is also amongst the leading global suppliers of APIs to third parties (though it accounts for only ~4% of its revenue) for both generic and formulation customers. In an attempt to vertically integrate its operations, Mylan acquired Matrix Laboratories - a leading supplier APIs in 2007. Even Aurobindo pharma, apart from manufacturing generic formulations also manufactures APIs as backward integration. Under the PLI scheme, Aurobindo pharma has got approval for three bulk drugs - Penicillin G, 7 - ACA, and Erythromycin Thiocyanate (TIOC) - all of which are currently 100 per cent dependent on imports.

4.7 Capital expenditure requirement or investment required for setting up a new plant

The capital expenditure or investment costs required for setting up a plant varies substantially based on the complexity of the API (active pharmaceutical ingredient) manufactured and the therapy served; further, the minimum economic capacity also differs based on the same variables. The cost of setting up a US FDA compliance plant is higher as compared to WHO (Indian GMP) compliant plant primarily on account of higher investments in impurity checks to be conducted at US FDA compliant plants.

The cost involved in setting up a bulk drug plant is largely similar to formulations players. However, bulk drug players have the benefit from wide customer base for a single line of product and therefore face lower demand risk. Further, the selling and marketing expenses are also lower in bulk drug segment. Therefore, SME players (<Rs 250 Crore) are either involved in contract manufacturing or bulk manufacturing and despite similar costs do not forward integrate to manufacture formulation drugs.

Type	Costs
WHO (Indian GMP)	Rs. 50 million per 1000 tonnes
US FDA	Rs. 75 million per 1000 tonnes

Source: CRISIL Research

Plant and machinery: Typically the plant and machinery are procured largely from domestic players irrespective of whether the plant has to adhere to Indian GMP or US FDA regulations. Therefore, the costs do not vary substantially across players. Further, the minimum investment in plant & machinery (single reactor) can vary from ~Rs 50 million to ~Rs 500 million based on the size of production. Many contract manufacturing players who operate in single line of products operate on a small scale with minimum investment of ~Rs 50-70 million on machinery. However, the export-based players generally refrain from operating on a small scale, as the other fixed costs involved is higher.

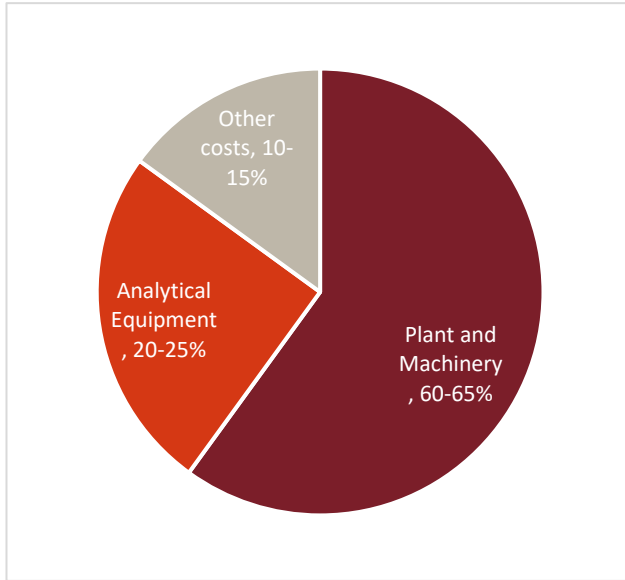
Analytical equipment: Analytical equipment are required in Pharmaceutical plants in-order to check the quality of the drug produced. The costs involved in setting up of analytical equipment vary based on the market for which the player intends to manufacture the drug. The player seeking a US FDA or a European WHO certification have to invest substantially higher in procurement of analytical equipment due to more stringent quality norm requirements. Therefore, the share of analytical equipment for regulated market based export players is 20-25%. On the other hand, for a player manufacturing drugs for domestic market, the investment in analytical equipment would not form more than ~15% of overall costs.

Land costs: These costs vary depending on the project being Greenfield or brownfield. For Greenfield projects, land acquisition cost will be a higher portion, while brownfield projects are usually done on land which is pre-owned.

For a minimum economic size plant with total capex of ~Rs 5 Crore, the land required is merely 0.5-0.7 acre.

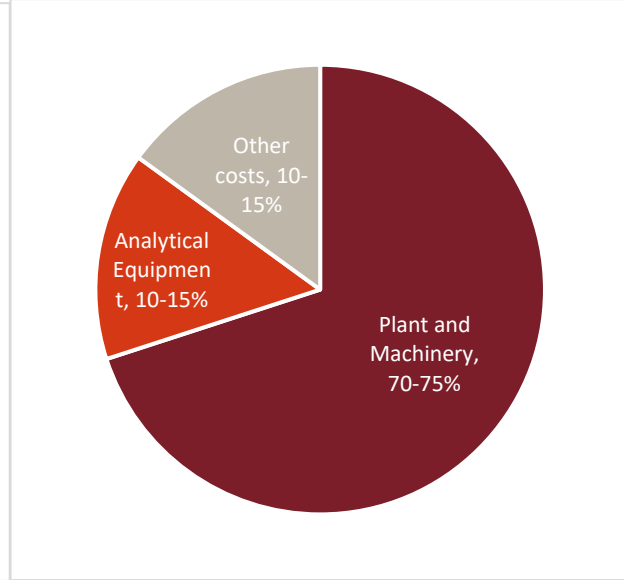
Break-up of costs under major regulations

US FDA / WHO Europe



Source: CRISIL Research

Indian GMP



Source: CRISIL Research

4.8 Five force analysis for Indian bulk drug industry

Product mix and technical capabilities determine the fortunes of Indian bulk drugs manufacturers who export to semi-regulated and regulated markets. Players carrying out customised synthesis for multinational corporations in regulated markets compete better than counterparts commoditised products such as older generation antibiotics largely in semi-regulated markets.

Overview of five force analysis



Source: CRISIL Research

Threat of new entrants: Medium

Low capital intensity to establish a domestic business attracts many small players to this industry. Yet setting up shop as an exporter requires more capital to meet various regulatory and compliance norms. This limits competition among exporters who have to fulfill stringent quality norms set by global innovator companies for contract manufacturing and custom synthesis deals.

Bargaining power of buyers: High

Bulk drugs are generally supplied to global innovator firms, which have a high bargaining power. Indian players who manufacture new and complex bulk drugs too have some bargaining power. However, players with old-generation products in their portfolio have little or no bargaining power.

Bargaining power of suppliers: Medium

Inputs such as chemicals and intermediates are abundantly available in India. Moreover, chemicals are generally easy to transport and are widely traded internationally. India imports certain raw materials at a low cost from China. However, the commoditised nature of some of these chemicals exposes bulk drug manufacturers to some input cost risk.

Threat from new substitutes: Low

Bulk drugs available in India cater to a majority of ailments, limiting any threat of substitutes. As the input for any particular formulation remains fixed as per the pharmacopeia (an official publication containing a list of medicinal drugs with their effects and directions for their use) and the regulatory approved formulation type, the bulk drug to be used for such a formulation is not substitutable. The only substitution available may be either in terms of price or grade of the same bulk drug. Further, if there is any substitute, it may only happen with a different generation or type of a bulk drug when the approved formulation type is changed.

Competitive rivalry: Medium

The growing presence of global players in the Indian bulk drugs market and the threat from cheaper Chinese imports has heightened the competitive rivalry. In export markets too, other low-cost destinations (mainly China) are gradually strengthening their presence.

5 Assessment of Indian Pharmaceutical market

5.1 Review and outlook on Indian domestic formulations market

Domestic growth estimated to have seen a sharp slowdown in FY21 led by demand disruptions due to Covid-19

The domestic formulations industry is facing regulatory changes and increased price controls, which will put some pressure on revenue growth in the medium term. However, double digit growth in the chronic segment and expansion of the Ayushman Bharat scheme in the coming years are expected to lend support to demand. Further, Covid-19 vaccine would provide a significant upside to the sector.

Growth in the domestic formulations industry was stable and strong in fiscal 2020, despite government interventions. Drugs under the National List of Essential Medicines (NLEM) comprised ~20% of the overall domestic market in fiscal 2020. Growth for NLEM drugs improved during the fiscal, with both volume and value growth. Further, prices were revised upwards by ~4% from April 2019 for medicines under the NLEM, in line with the wholesale price index (WPI). On the non-NLEM front, the industry expanded ~10% on-year, driven by increase in pricing.

The recent Covid-19 pandemic, which started spreading across the world since early 2020, had necessitated lockdown all over the country in the first quarter of fiscal 2021. With this, the domestic pharmaceutical sales were hit in the first quarter. As lockdown continued in April and May, the domestic pharma market registered a 6% decline in growth for the quarter. Closure of smaller clinics and hospital OPDs, postponement of surgeries resulted in slower sales of drugs in domestic market. Some support was provided by increase in sales of chronic therapies like Cardiac and anti-diabetes. The growth further deteriorated in the second quarter and the market registered a flat growth in first half of fiscal 2021. The demand have picked up in the second half, and domestic market growth moderated to 1.3% in fiscal 2021 (in value terms).

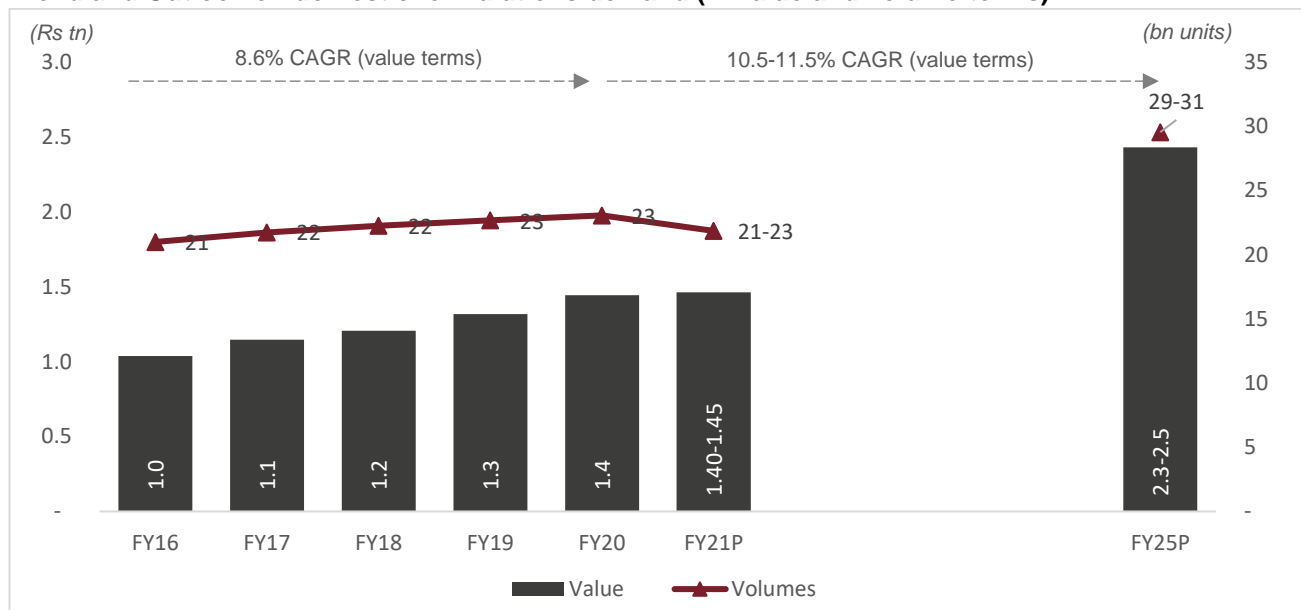
Growth is expected to pick up as things return to normalcy gradually. The National Pharmaceutical Pricing Authority (NPPA) has fixed retail prices of 869 formulations under price control based on price revision as per annual wholesale price index (WPI) of 1.88% increase.

Fiscal 2022 revenue growth will be led by Covid-19 vaccines. The government has started distribution of vaccines among target groups from mid-January 2021. This will boost revenues for the sector in fiscal 2022 as vaccination drive gathers pace. Currently, Serum institute and Bharat Biotech have received approvals for their vaccines. Several other players are in the pipeline as well. Covid-19 vaccine distribution will aid revenues for players in the near to medium term

Domestic formulations market to grow at ~11% CAGR over the next five years

Indian domestic formulations market (consumption) grew at a healthy rate at 8.6% CAGR over the last five years from fiscal 2016 to fiscal 2020. Domestic Formulations segment is expected to grow at ~11% CAGR over the next five years from fiscal 2021 to fiscal 2025 driven by strong demand in generic segment. The domestic formulations demand is expected to reach Rs 2.3-2.5 trillion by fiscal 2025.

Trend and Outlook on domestic formulations demand (in value and volume terms)



Source: AIOCD AWACS, CRISIL Research

Growth in chronic segment to continue to boost growth in medium term

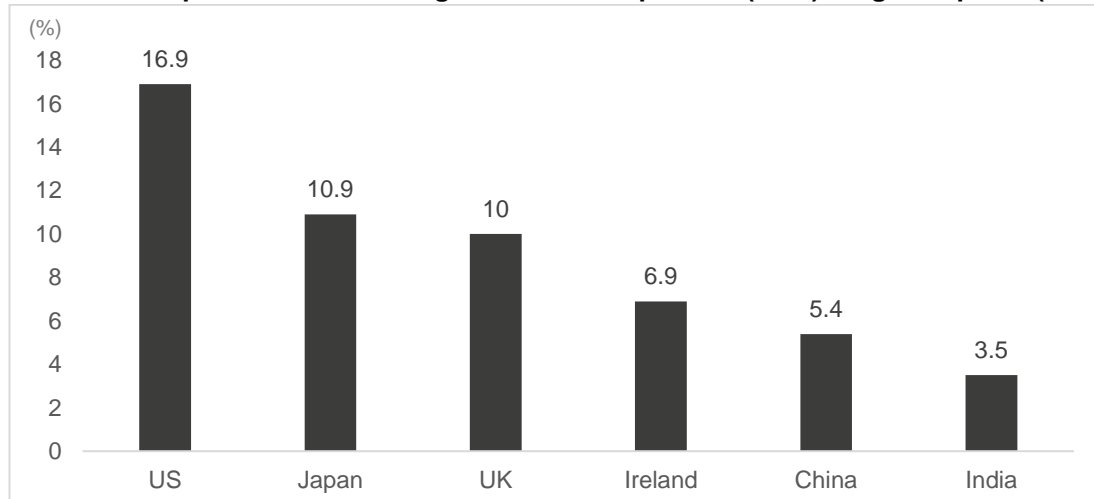
New product launches in the chronic segment is likely to aid growth in the sector in medium term. Further, the rise in the anti-diabetic, cardiac, and dermatology segments would support growth of the domestic industry.

Chronic portfolios of major companies have seen a double digit growth in the past five years, with anti-diabetes being the fastest growing segment. Further, prices have been revised upwards by ~2% from April 2020 for medicines under the NLEM, in line with the wholesale price index (WPI).

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

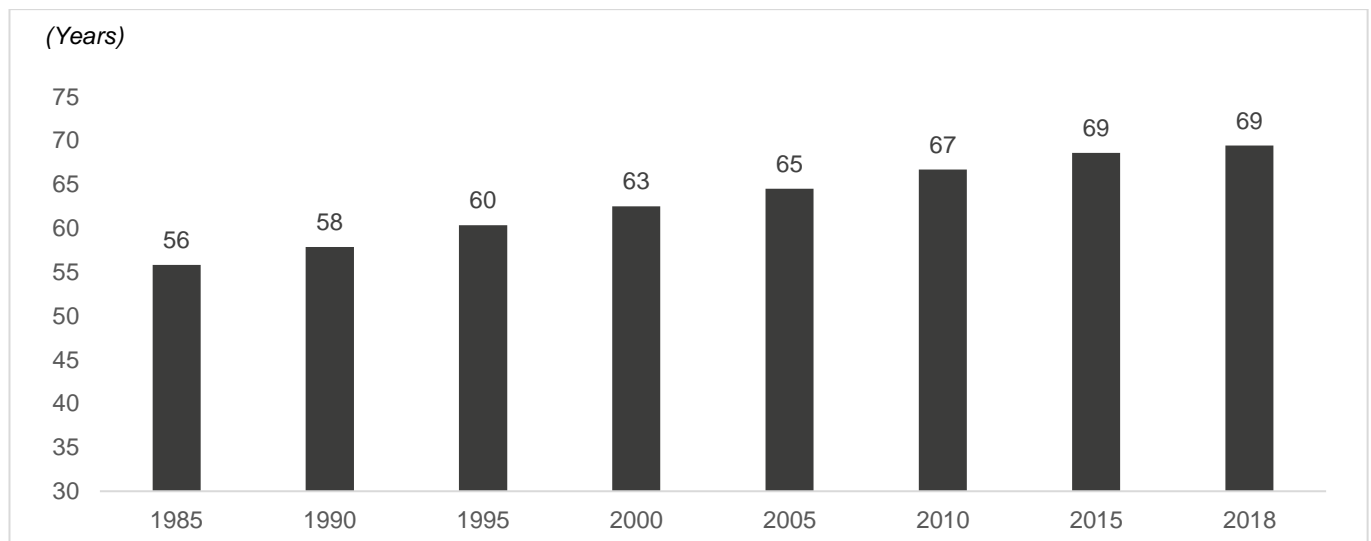
The sector is also expected to benefit from factors such as rising incidence of lifestyle-related diseases, and better healthcare, diagnostic and hospital infrastructure, which has helped improve the disease detection rate. CRISIL Research expects such factors to increase healthcare expenditure, thereby aiding growth in the domestic market.

Healthcare expenditure as a % of gross domestic product (GDP) for global peers (2018)



Source: World Bank, CRISIL Research

Life expectancy at birth (years)



Source: WHO world health statistics 2020, CRISIL Research

Chronic disease care drugs (meant to treat many non-communicable diseases) are seeing high growth rates, 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 prevalence of chronic diseases has been significantly increasing in the last few years. 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 diseases that pressurizes the healthcare system.

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. Changes in lifestyle

and food habits, aided by higher disposable income, have caused an unprecedented increase in chronic diseases, such as, cardiovascular, diabetes, oncology and central nervous system. Chronic therapy medications have to be consumed by a patient over an extended period of time as opposed to acute therapeutic category for which the drug is consumed for a shorter or a limited period. As a result, the chronic therapeutic category has been growing at a CAGR of ~10% between Fiscals 2016 and 2020, and has outperformed overall domestic formulations in terms of consumption, which grew at a CAGR of ~8.6% during the corresponding period.

Within the key therapeutic category, certain key therapeutic areas, such as, anti-diabetic, Gastro-Intestinal cardiovascular and nutraceuticals, have grown at a CAGR of approximately 14.3%, 7.6%, 10.3% and 7.8%, respectively, during fiscal 2016 and fiscal 2020. Majority of the therapies for the diseases in these high growth and key areas in the chronic therapeutic areas require 'multi-drug therapy', i.e. the specific use of two or more drugs for single or multiple chronic conditions in an individual. Multi-drug therapy has gain importance over the past few years in the healthcare sector. Multi drug therapy is use of combination of drugs to treat certain diseases. As it was seen in the study conducted by WHO for leprosy treatment, diseases become drug resistant when used over the prolonged period of time making it ineffective in treating that particular diseases. Multi drug therapy addresses this issue by use of multiple drugs in right combinations and proportions. This also means use of more pharmaceutical products for the treatment of single disease. Going ahead multi drug therapy is expected to aid the growth of pharmaceutical consumption.

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

	Disability adjusted life years (DALYs)	
	2009	2019
Communicable diseases		
Tuberculosis	3.8%	3.4%
Diarrhoeal diseases	6.7%	4.3%
Respiratory Infections	10.2%	7.7%
Non-Communicable diseases		
Cancers	4.3%	5.8%
Diabetes Mellitus	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 Research

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. Conversely, life years lost due to diarrhoea, tuberculosis, and respiratory infections have dropped. CRISIL Research expects this shift in the disease profile to continue, with non-communicable chronic ailments adding to disease woes.

Non-communicable diseases (NCD) in India

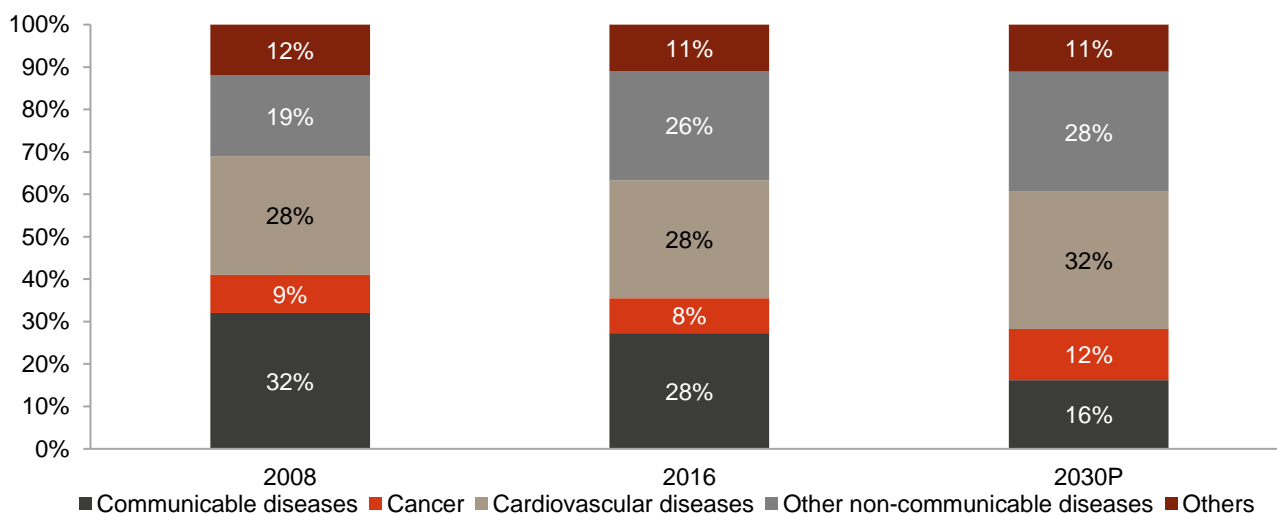
As opposed to the decreasing rate in communicable diseases, lifestyle-related illnesses or non-communicable diseases (NCDs) have been increasing rapidly in India over the past few years. Contribution of NCDs to the disease profile rose to 55% in 2016 from 30% in 1990. Statistics show these illnesses accounted for nearly 62% of all deaths in India in 2016.

As per the World Economic Forum, the world will lose nearly \$30 trillion by 2030 on treatment of NCDs, and India’s burden from this will be \$5.4 trillion.

NCDs: A silent killer

CRISIL Research believes NCDs exhibit a tendency to increase in tandem with rising income levels. WHO projects an increasing trend in NCDs by 2030, following which CRISIL forecasts demand for healthcare services associated with lifestyle-related diseases such as cardiac ailments, cancer and diabetes, to rise. Another emerging market in the country is orthopaedics, which currently comprises a very small proportion compared with NCDs, but has a potential market in the country. The orthopaedics market can be classified into four different segments, viz., knee, hip, trauma and spine, of which the knee replacement market holds the biggest share, followed by trauma and spine. Hip replacement in India is still a very small segment compared with knee replacement, whereas it is opposite around the world.

Causes of death in India



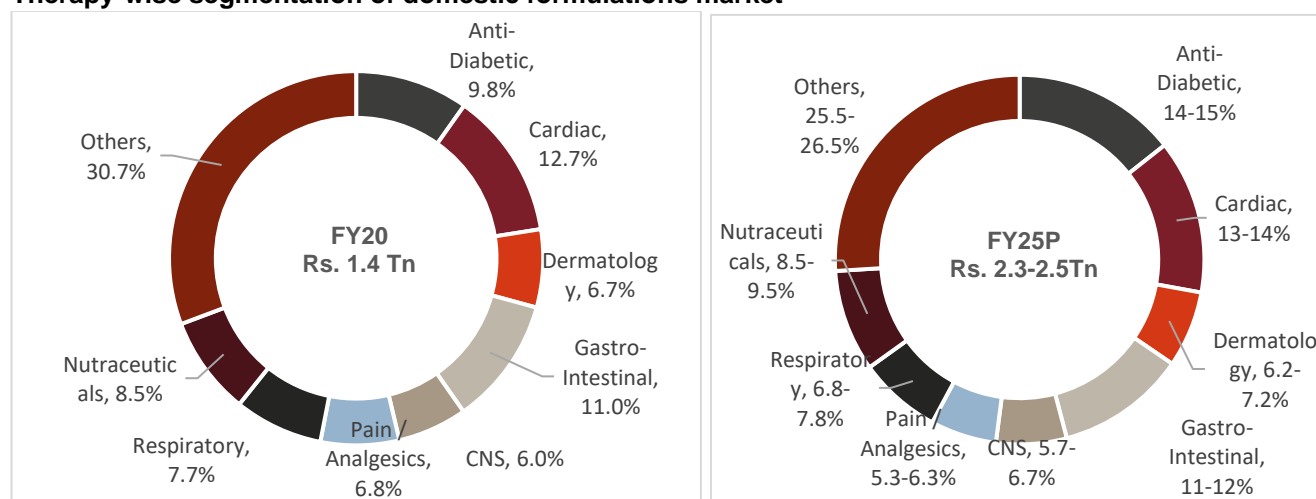
Source: WHO Global Burden of Disease, India: Health of the Nations’ States, CRISIL Research

Chronic segment’s share in the domestic formulations to grow over the next five years

As of fiscal 2020, Anti-diabetic and cardiac were the largest therapeutic segments catered by the Indian formulations industry, accounting for nearly 1/4th of the market share. By fiscal 2025, these two will continue to remain the largest segments accounting for almost 30% of the market share. As the prevalence of chronic diseases have grown in the country, chronic diseases such as diabetes and cardiac disorders are more prevalent in Indian population. Anti-diabetic constituted 9.8% of all therapies catered by Indian pharmaceutical market and which is expected to grow to 14-15% by fiscal 2025. Similarly cardiac constituted ~12% of all therapies catered by Indian pharmaceutical market

and which is expected to grow to 13-14% by fiscal 2025. The chronic therapeutic category typically provides for higher margins in comparison to the acute therapeutic category. Over the period under consideration, chronic therapeutic segments are expected to see a higher growth compared to acute therapeutic segment; while chronic segment is projected to grow at 16-18% CAGR, the acute segment is projected to grow at 11-13% CAGR during fiscal 2020 to fiscal 2025. Under chronic segment, Anti-diabetic, Cardiac, Neuro and Respiratory therapies are expected to grow at ~20%, ~12%, ~12% and ~10% CAGR, respectively, from fiscal 2020 to fiscal 2025. In the acute segment, Gastro-intestinal, Pain analgesics and Nutraceuticals are some of the key therapeutic areas which are expected to grow at ~12%, ~7%, ~12% CAGR, respectively, during the corresponding period.

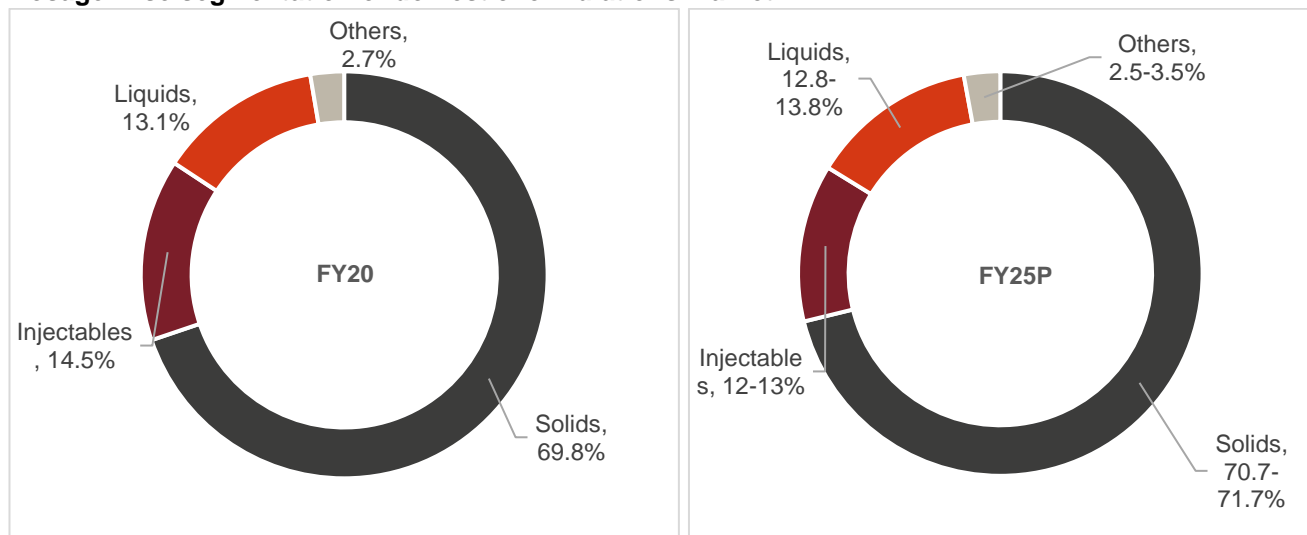
Therapy-wise segmentation of domestic formulations market



Source: AIOCD AWACS, CRISIL Research

Oral solids to continue to account for major share of the domestic formulations market

In dosage terms, oral solids dominate the domestic formulations industry with ~70% share as of fiscal 2020. Oral solids are expected to see their share improve marginally to ~71% by fiscal 2025. The injectables segment constituted 14-15% of the all dosage forms catered by domestic formulations industry in fiscal 2020. The segment has grown at a slightly lower pace (6.3% CAGR) compared to overall domestic formulations market in terms of consumption (8.6% CAGR) during the last five years from fiscal 2016 to fiscal 2020.

Dosage-wise segmentation of domestic formulations market


Source: AIOCD AWACS, CRISIL Research

However, its growth is expected to pick up over the coming five years from fiscal 2020 to fiscal 2025 largely due to strong growth in chronic therapeutic segments like Anti-Diabetic, Oncology as well as acute segments like Anti-infective, Hormones, etc. However, during fiscal 2021 to fiscal 2025, its share in the domestic formulations market is expected to decline slightly due to lower growth compared to overall industry on account of flat performance in fiscal 2021. However, injectables segment is expected to see a strong growth in fiscal 2022 and 2023 on the back of COVID vaccinations, but will return to normal growth trajectory thereafter. As Covid-19 vaccinations will provide the upside for injectable in the years 2022 and 2023 but thereafter as the vaccine demand fades growth trajectory will return to normal.

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

At 90-95%, 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 over 5,500 stores are currently operational in the country. Yet, of India's ~8.5 lakh pharmacies, Jan Aushadhi stores represent less than 1%. Therefore, the share of sales through Jan Aushadhi stores is very low.

The sales of medicines under the PMBJP scheme have grown at a rate of ~124% CAGR between fiscal 2015 and fiscal 2020 and are estimated to be Rs 6 billion in fiscal 2021.

However, Jan Aushadhi Yojana is not expected to have a significant impact on the industry in the coming five years. Lack of awareness among consumers, non-prescription by doctor for unbranded generics in comparison with branded counterparts are some of the challenges faced. CRISIL Research estimates the sale of drugs through Jan Aushadhi stores is thus likely to account for merely ~2% of total domestic pharmaceutical sales by fiscal 2024. On the other hand, a significant increase in scale might impact the volumes of chronic drugs in the market, thereby affecting the market share of branded players.

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. 5 lakhs per family per year for secondary and tertiary care hospitalization to over 10.74 crores poor and vulnerable families (approximately 50 crore 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

Ayushman Bharat, a Government of India scheme, is unlikely to have a major impact in the short term. This is because the initial years will be spent in getting majority of the population enrolled as well as private hospitals empaneled in the scheme, which is very low currently. Nevertheless, 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 34%. Ayushman Bharat also aims to upgrade 1.5 lakh primary healthcare centers (PHC) to provide diagnostic services and free medicines for preventive care. This could be a huge spin-offs for the industry as well. Strengthening of PHCs is necessary to take domestic industry growth to a higher trajectory.

Ayushman Bharat is expected to provide volume momentum to the healthcare sector, with the scheme on its full scale implementation providing healthcare assurance of Rs 5 lakh per family (on floater basis) to nearly 10.74 crore families (the actual coverage would be greater on account states extending the scheme to even some sections of the uncovered populace). As on November, 2020, nearly 14 million treatments had taken place under Ayushman Bharat since the inception of the scheme in September, 2018.

As of March 2020, ~23,300 hospitals have been enrolled in the Scheme. Package rates has been the area of concern for most corporate hospitals, reflecting in the low participation of the private sector. Out of 33,000 private hospitals (as per ROHINI database), only 29% have participated in the scheme. However, it should be noted that though the share of private sector is 45% in facilities enrolled for the scheme, but ~52% of spend has taken place here. This clearly indicates the preference of beneficiaries for private hospitals, given that the government infrastructure is already over- burdened. Amongst the treatments sought, 57% of the total spend has been on tertiary treatments, with orthopaedics, cardiology, cardio-thoracic, oncology and urology being the most preferred, indicating the unmet demand in this category.

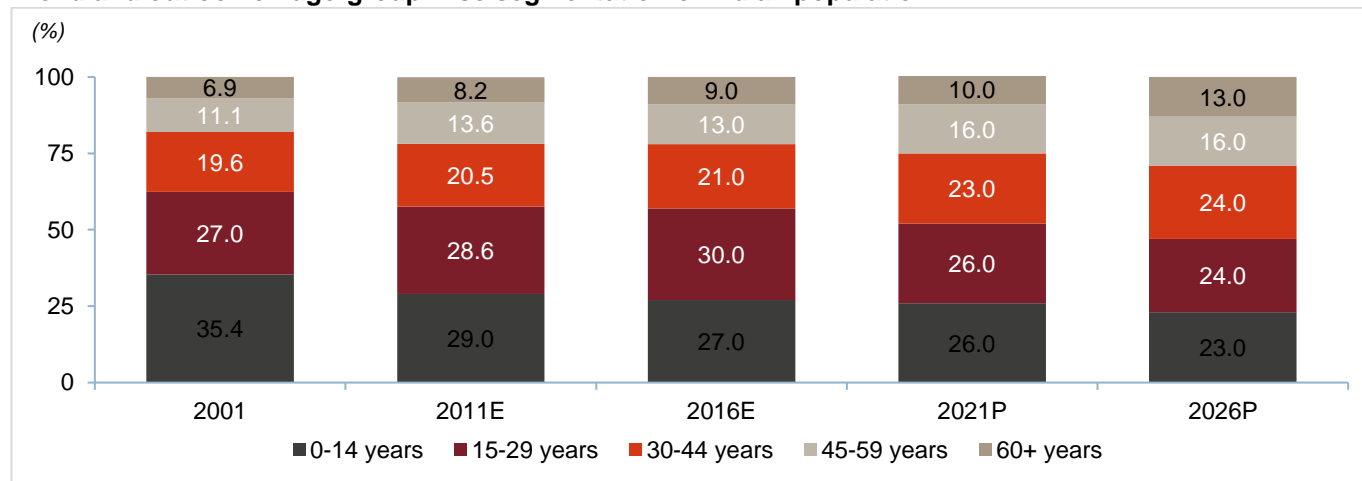
5.2 Review of key growth drivers for the industry

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 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.

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.

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



Source: Census, CRISIL Research

With the Indian population expected to grow to ~1.4 billion by 2026 and considering the above mentioned factors, the need to have ensure healthcare services to this vast populace is an imperative. But this also provides a huge opportunity to expand into a space that bears huge potential.

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

India's per capita income, a broad indicator of living standards, clocked ~5% CAGR between fiscals 2012 and 2020, rising from Rs 63,642 to Rs 94,954. The growth in per capita income was led by better job opportunities, propped up by overall GDP growth. Moreover, population growth has remained fairly stable at ~1% CAGR. 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.

Trend in per capita net national income at constant prices

	FY12	FY13	FY14	FY15	FY16	FY17	FY18	FY19	FY20PE
Per capita net national income (Rs)	63,462	65,538	68,572	72,805	77,659	82,931	87,828	92,085	94,954
On-year growth (%)	2.1	3.3	4.6	6.2	6.7	6.8	5.9	4.8	3.1

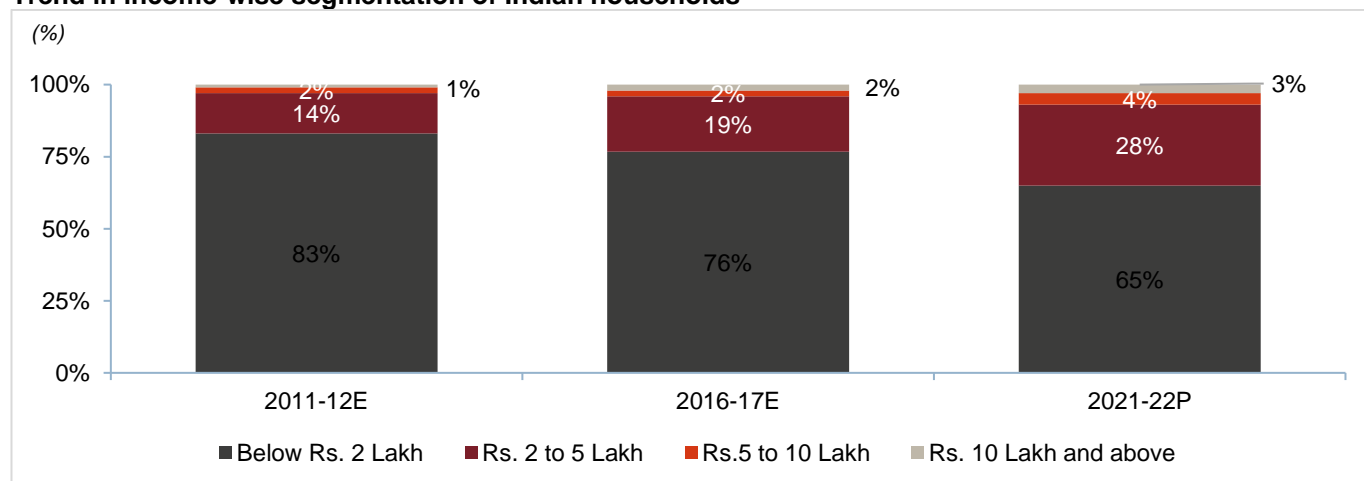
PE: Provisional estimates

Source: Provisional Estimates of Annual National Income, 2019-20, CSO, MoSPI, CRISIL Research

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 industry 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.

Trend in income-wise segmentation of Indian households

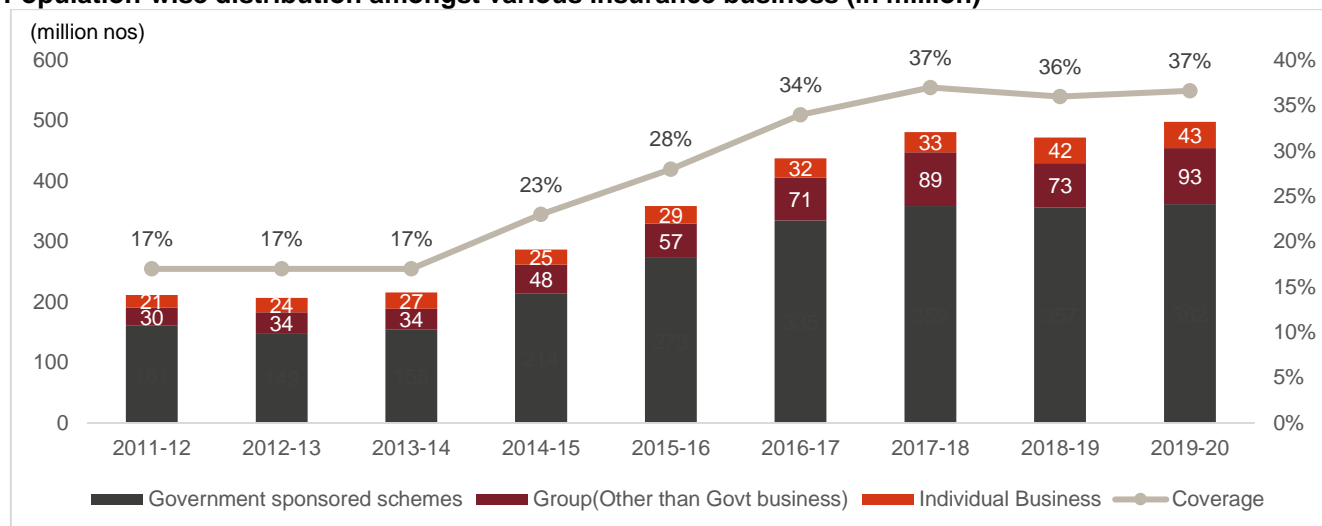


Source: CRISIL Research

Improvement in health insurance penetration in India

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 (IRDA), nearly 472 million people have health insurance coverage in India (as of 2018-19), as against 288 million (in 2014-15), but despite this robust growth the penetration in fiscal 2019 stood at only 36%.

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 Annual report 2019-20

As is evident from the above chart, the share of government provided insurance is greater than other insurance businesses due to insurance policies availed by individuals not covered under any schemes. Government or government-sponsored schemes such as the Central Government Health Scheme (CGHS), Employee State Insurance Scheme (ESIS), Rashtriya Swasthya Bima Yojana (RSBY), Rajiv Arogyasri (Andhra Pradesh government), Kalaingar (Tamil Nadu government), and etc. account for 75% 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.).

Incidence of chronic diseases

Incidence and prevalence of chronic diseases are increasing rapidly all around the world. Rising incidences of diseases, such as cancer, cardiovascular diseases, obesity, and diabetes, are primarily observed and have a significant impact on the economy of the country, which is likely to drive the demand for pharmaceuticals. According to the Organization for Economic Co-operation and Development’s (OECD’s) Health at a Glance, the 2019 report, almost one third of people aged 15 years and over reported living with two or more chronic conditions. Cardiovascular diseases are found to be most prevalent across the world, and are the leading causes of death. As per the 2020 updates of the WHO, ischemic heart disease is responsible for 16% of the world’s total deaths. Since 2000, the largest increase in deaths has been for ischemic heart disease, rising by more than 2 million to 8.9 million deaths in 2019. Growing cases of chronic diseases are expected to further increase the demand for drugs and accelerate the development of pharmaceuticals, globally.

Non-communicable diseases (NCD) in India

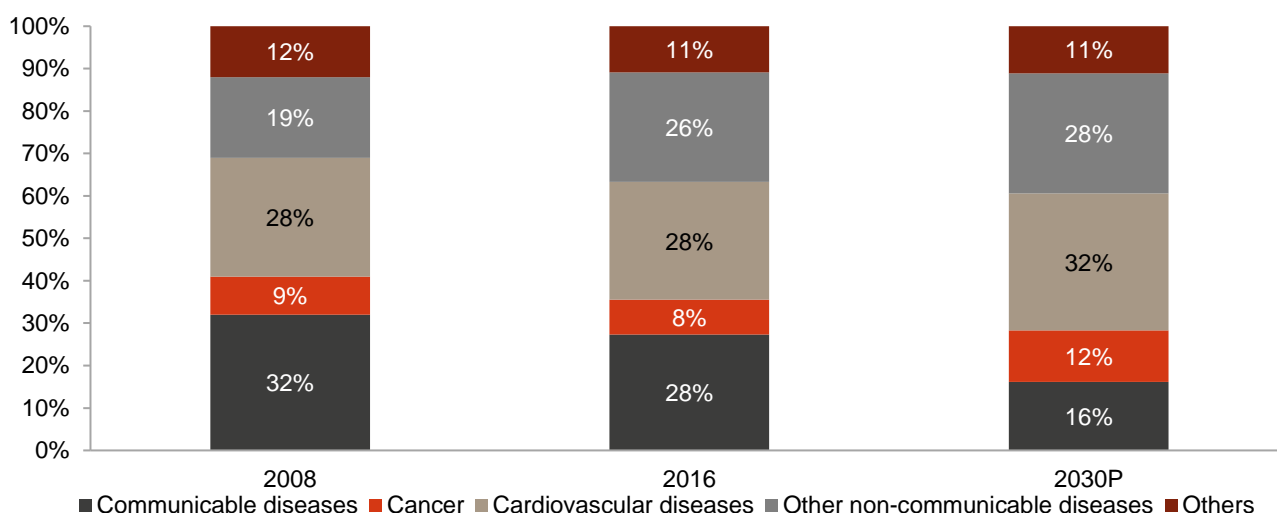
As opposed to the decreasing rate in communicable diseases, lifestyle-related illnesses or non-communicable diseases (NCDs) have been increasing rapidly in India over the past few years. Contribution of NCDs to the disease profile rose to 55% in 2016 from 30% in 1990. Statistics show these illnesses accounted for nearly 62% of all deaths in India in 2016.

As per the World Economic Forum, the world will lose nearly \$30 trillion by 2030 on treatment of NCDs, and India’s burden from this will be \$5.4 trillion.

NCDs: A silent killer

CRISIL Research believes NCDs exhibit a tendency to increase in tandem with rising income levels. WHO projects an increasing trend in NCDs by 2030, following which CRISIL forecasts demand for healthcare services associated with lifestyle-related diseases such as cardiac ailments, cancer and diabetes, to rise. Another emerging market in the country is orthopaedics, which currently comprises a very small proportion compared with NCDs, but has a potential market in the country. The orthopaedics market can be classified into four different segments, viz., knee, hip, trauma and spine, of which the knee replacement market holds the biggest share, followed by trauma and spine. Hip replacement in India is still a very small segment compared with knee replacement, whereas it is opposite around the world.

Causes of death in India



Source: WHO Global Burden of Disease, India: Health of the Nations' States, CRISIL Research

5.3 Review of key risk factors and challenges for the Indian pharmaceutical industry

Changes in government regulations

The government has been taking various steps in order to control the prices of drugs and make it more affordable to consumers. Between 2013-14 and 2014-15, the industry saw drug prices being regulated for more than 500 medicines under the Drug Price Control Order (DPCO), thereby negatively impacting the industry. Further, the revised National List of Essential Medicines (NLEM) 2015 added more than 100 new drugs under price control, with many high-value chronic from anti-diabetes and HIV being covered. As of November 2016, the National Pharmaceutical Pricing Authority (NPPA) notified ceiling prices for 540 drugs. The NLEM 2015 contains about 870 scheduled drug formulations. Therefore, the government's firm stance on pricing even in future might have a negative impact on the profitability for some players, which are selling branded generics at a high premium price. However, going forward, we believe that though the Government will continue to keep a close tab on the prices, it is unlikely to add a large number of drugs as it did between 2013 and 2015, as many major drugs have already been added. Further, even the ceiling prices prescribed by the NPPA are calculated based on the average prices of existing

drugs sold in the market, and therefore not all players in the segment are impacted. Currently, prices of about 900-1000 scheduled formulations have been fixed so far.

The government is also working towards the use of generic generics and moving away from branded generics. Branded generics accounted for ~90-95% share in the domestic market in fiscal 2020, and implementation of traded generics will have significant impact on the profitability of players. Greater use of trade generics is not expected to disrupt branded generics segment whose share (in value terms) in total generics is expected to remain range bound over the next five years leading up to fiscal 2025. However, its implementation will remain a challenge, as the government will have to ensure that a standard quality is maintained across all the plants in the country. On the other hand, the government will also have to propose a fixed margin (as was proposed in the Draft Pharma Policy - 2017, which was scrapped later) to be enjoyed by pharmacists' selling all drugs, without which the power to prescribe branded drugs will merely shift from doctors to pharmacists. Some of the reforms mentioned in the Draft Pharma Policy such as discontinuation of loan licensing (contract manufacturing), regulating marketing practices, banning of brand names, etc., if implemented, will negatively disrupt the domestic pharmaceuticals industry.

Fluctuation in foreign exchange rates

The volatility in currency has an impact on import of raw materials. ~68% of the intermediates are imported from China. Though, the large export-based players hedge against currency volatility and try to protect their realisations, the smaller players do not have any hedging policies. They rely solely on natural hedging (assuming increase in cost of material will be equal to increase in realisations and vice versa), which in many cases might impact their profitability.

Dependence on China for imports

India imports ~68% of intermediates 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 during February and March in China 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

Over 100,000 drugs across various therapeutic categories, are produced annually in India. The domestic formulations industry is highly fragmented in terms of both, number of manufacturers and products. There are 300-400 organised players and about 15,000 unorganised players. However, organized players dominate the market, in terms of sales. In fiscal 2020, the top 10 formulations companies accounted for ~43% of total sales. Indian pharma companies operate largely from Maharashtra, Gujarat and Andhra Pradesh. However, after the government imposed an MRP-based excise duty system in 2005, many players have shifted their manufacturing bases to excise-free zones such as Baddi (Himachal Pradesh), Haridwar (Uttaranchal) and Sikkim.

5.4 Recent trends in Indian pharmaceutical industry

Growth in outsourcing trend and its advantages to larger players

Pharmaceutical companies are always under pressure to commercialize their product as early as possible. One of the key strategies for accelerating new products in the healthcare industry is outsourcing. Outsourcing, or the use of

contract services, allows sponsor organizations to access technology, capacity, resources and expertise that may not be readily available in-house. Pharmaceutical manufacturers and developers of all extents, but chiefly the leading international pharmaceutical companies, now regularly outsource many functions and tasks earlier thought-to-be in-house principal proficiencies. The primary nature of the pharmaceutical industry has transformed as process efficiencies and cost management have become vital for persistence.

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. Access to a contract provider and implementation of a sound outsourcing strategy can result in a successful project that meets (or even exceeds) a sponsor's original expectations. Outsourcing helps big pharmaceutical company reduce costs as they don't have to invest in the capex for every product that they commercialize.

Asset light model and cost control

Maintaining an asset-light business model for larger pharmaceutical players means outsourcing capital intensive activities such as manufacturing, storage and logistics to specialist organizations in these fields which helps companies focus on their core activities like growing their portfolio of products and investment in various other products. Asset light business model for pharmaceutical companies enables company to outsource activities right from molecule research and development to commercial manufacturing of the particular drug.

In the process of research and development of the molecule which can take significant amount of time to conclude, companies by outsourcing these activities don't have to own the facilities for the longer period of times which can save company costs on maintain and running the costs of such facilities. Company also get to enter in to flexible contracts with the outsourcing players.

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 as research on the patents to be expired happen months before even it gets expired. 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. Working with agile and adoptive approach may help pharmaceutical companies in reducing time to market of the product.

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. Especially after covid-19 business have to be more flexible in their processes especially in areas like supply chain management which were impacted due to Covid-19 pandemic. Pharmaceutical industry especially has to be flexible in its supply chain management as there is long value chain that goes on to make the final product. Indian Pharmaceutical industry is heavily dependent on imports for the raw material required in the manufacturing process. After pandemic many players in the industry are diversifying their sources in order to bring more flexibility to their supply chains and hence 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. Businesses have to be very quick to respond these evolving scenarios. Pharmaceutical companies in India are subjected to various regulatory norms from countries like US, UK and PIC. With ever changing regulatory environment companies have to be agile enough to respond and comply with these changes.

5.5 Formulation exports

Exports remain resilient in fiscal 2021, Covid-19 vaccine sales to boost growth in FY22

India's formulations exports continued on growth path in fiscals 2020 and 2021 led by newer launches and opportunities in limited competition products, amid reducing pricing pressures in the US market. Exports increased by ~11% on-year during fiscal 2020. This is despite the increased scrutiny by USFDA on the regulatory front.

The exports had recovered to double-digit growth in fiscal 2019 following two years of weak growth on account of easing pricing pressure and a better product pipeline. Fewer product launches, regulatory hurdles and pricing pressure in regulated markets had resulted in sluggish growth during fiscals 2017 and 2018. Adverse currency fluctuation and subdued economic activity in Europe also affected growth.

Although, the recent Covid-19 caused logistic and demand disruption across the world, formulation exports have grown at a robust pace during Apr-Dec fiscal 2021 at about 18% y-o-y. A spike in demand for pharma products, induced by the Covid-19 pandemic, and hoarding of supplies by some nations in the wake of production disruptions, have boosted exports.

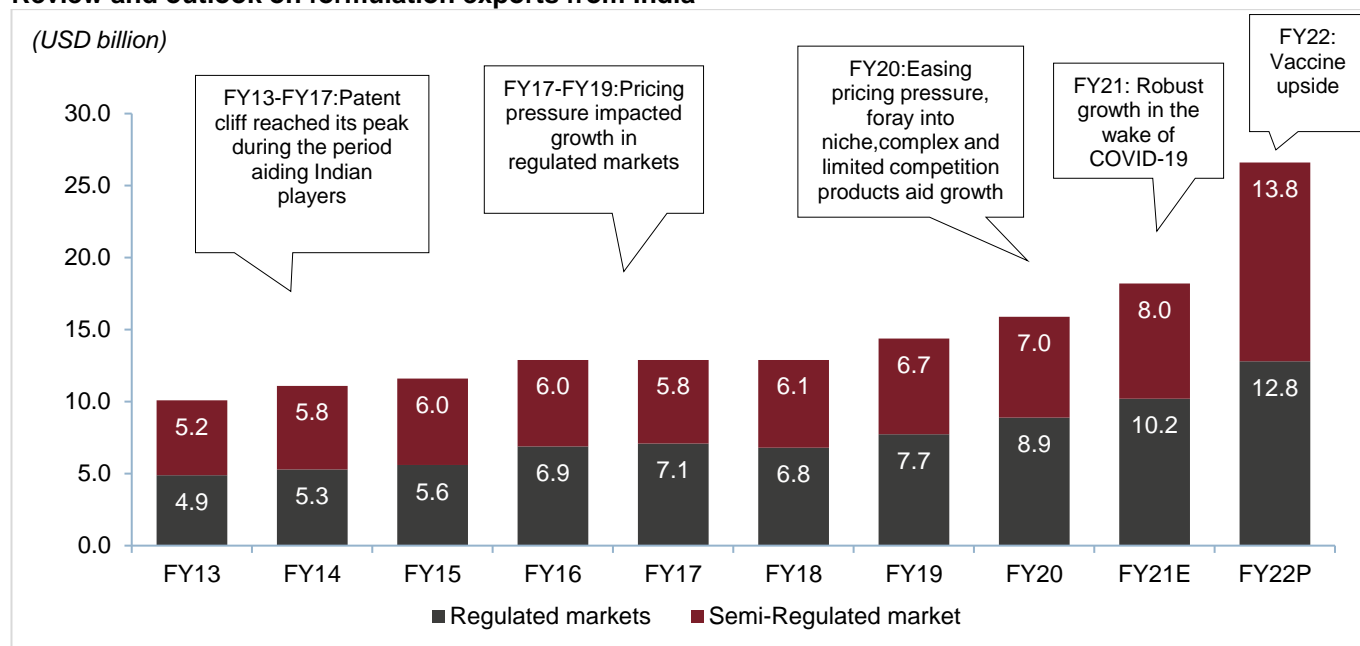
Covid-19 Vaccine supply opportunity in medium term

The new and emerging opportunities to supply vaccines globally augurs well for Indian formulation exporters. There has been an initiation in inoculation across several nations. India too, has started domestic inoculations and exported vaccines on goodwill to several mid and low income nations.

As the private market opens up, and more companies receive approvals, the rate of vaccination is likely to increase and Indian players are likely to see benefit. The vaccine cost per dose in export markets is likely to range around Rs 1,000 per dose. India has established itself in low-cost vaccine manufacturing and is capable of supplying vaccines to low income nations.

Exporters will find relatively better opportunities to supply in semi-regulated markets than regulated ones because of stringent approval guidelines in the latter.

Review and outlook on formulation exports from India



Note: E: Estimated, P: Projected

Source: CRISIL Research, Directorate General of Commercial Intelligence & Statistics (DGCIS)

Note: The US, Canada, West Europe, South Korea, Japan and Australia are regulated markets, which have robust regulatory frameworks. Semi-regulated export markets have less-developed regulatory frameworks. These include Africa, Latin America, Asia, the Middle East and the rest of Europe, comprising Russia and Ukraine.

Covid-19 vaccine sales to drive formulation exports growth over next five years

CRISIL Research expects India's formulation exports to increase at 13-14% compound annual growth rate (CAGR) from fiscals 2020-25, compared with ~6-7% CAGR over the previous five years. The growth will be largely driven by vaccine sales. Covid-19 vaccines are being developed by several players globally. India too has players like Serum Institute, and Bharat Biotech manufacturing vaccines. As the private market opens up, and more companies receive approvals, the rate of vaccination is likely to increase and Indian players like Bharat Biotech, Serum Institute, Cadila, Aurobindo and Dr. Reddy's, among others are likely to see benefit. India has established itself in low-cost vaccine manufacturing and is capable of supplying vaccines to low income nations.

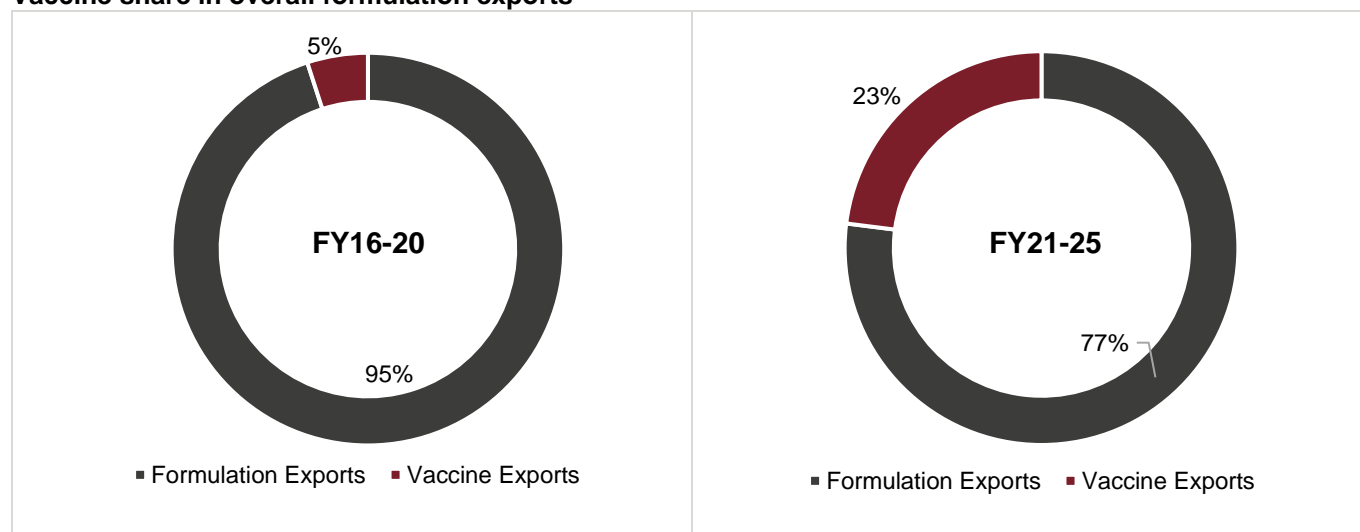
Exporters will find relatively better opportunities to supply in semi-regulated markets than regulated ones because of stringent approval guidelines in the latter.

Although, currently the government is prioritizing domestic inoculations, there is a likelihood that fiscal 2022 may see exports of Covid-19 vaccines. With this assumption, we believe that exports are likely to see a boost in fiscal 2022. Consequently, vaccine share in overall formulation exports is also likely to increase by over 4 times in next 4-5 years. Going forward, during fiscals 2020 to 2025, growth in vaccine exports is expected to be higher on account of an upside from potential Covid-19 vaccine launches. The share of vaccines in total formulation export is expected to increase from 5% in FY16-20 to 23% in FY21-25. Thus, while the vaccines exports are expected to especially see a strong growth of more than ~35% CAGR, the remaining for formulations exports are expected to grow at ~10% CAGR during the corresponding period.

Manufacturers launching complex and specialty drugs and those receiving limited competition drug approvals would also enjoy higher growth. Incremental revenue for formulation exporters would be supported by new launches in the

conventional generics segment. Even though pricing pressure persist, we forecast it to keep reducing. However, the United States Food and Drug Administration (USFDA) regulatory overhang from 2019 continues to be a monitorable.

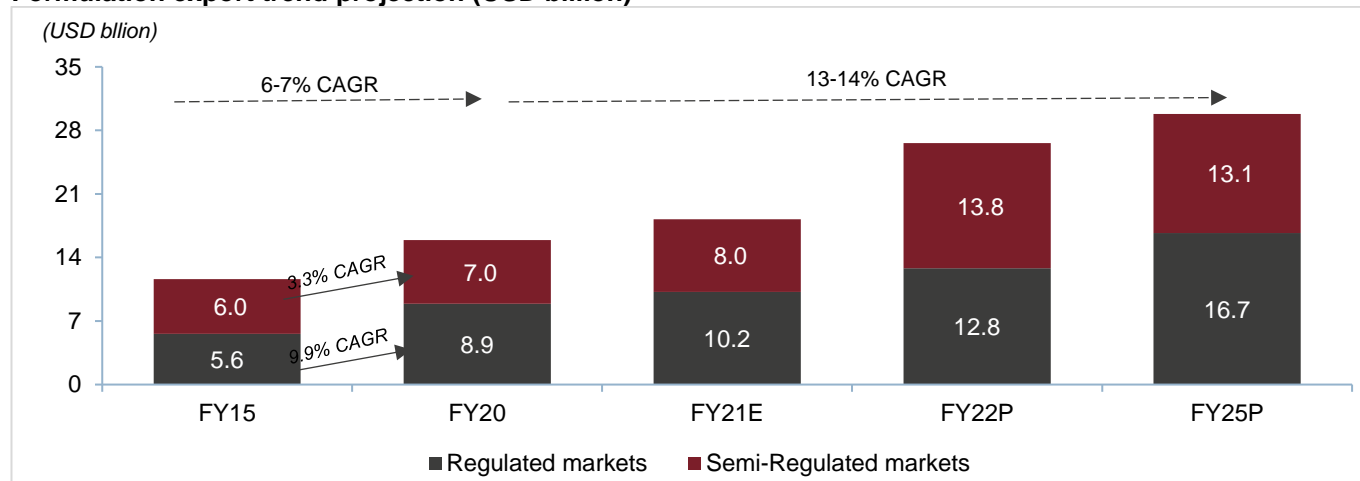
Vaccine share in overall formulation exports



Source: CRISIL Research, DGCIS

Further, the exports growth in fiscal 2021 is estimated to be at ~13-14% on-year, up from ~12% growth reported in fiscal 2020. Exports remained resilient in fiscal 2021 owing to continued demand for various products.

Formulation export trend projection (USD billion)



Note: P- Projected

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

Note: The forecast is based on Currency movement, Thrust by developed countries to reduce overall spend on medicines, Patent expiry generating significant opportunity for generic medicines, Regulatory environment, including regulatory approval time for dossiers, for instance, abbreviated new drug applications (ANDAs), Continent-specific factors: Consolidation among large buyers in the United States (US), impact of the Patient Protection and Affordable Care Act (Obamacare) in the US, and continued austerity measures in Europe, Continued dependence of semi-regulated markets on low-cost generic medicines.

5.5.1 Formulations exports to regulated markets

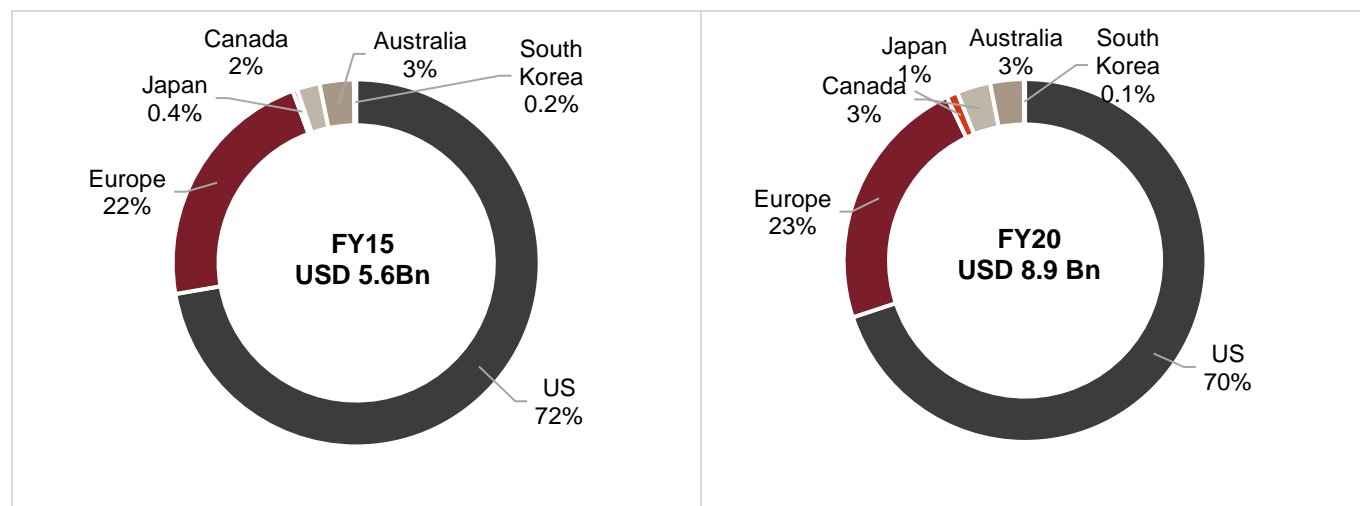
Specialty products and vaccine to drive growth in regulated market in FY22

As against a strong 12% CAGR from fiscals 2013 to 2016, exports to regulated markets registered a de-growth of 1% between fiscals 2016 and 2018 on account of pricing pressures and weak product launches. During fiscals 2014 to 2016, Indian companies were issued a number of warning letters and import alerts, which impacted new product approvals of Indian players. On the pricing front, wholesale consolidation and faster abbreviated new drug application (ANDA) approvals led to price erosion in the US market in fiscal 2018, further acting as a headwind to growth.

Following a dull performance in fiscal 2018, exports to the regulated markets improved in fiscal 2019, registering ~14% on-year growth. Rupee depreciation also aided growth in exports.

Fiscal 2020 registered good growth in exports (~11% on-year). In early fiscal 2020, the coronavirus pandemic gripped the world and lockdown were initiated in far too many nations including the US. However, pharma being an essential commodity stood resilient during the tough times. The formulation exports during April and November 2020 increased by ~18% on-year led by specific opportunities and new product launches. Drug shortages in the US also augurs well for Indian exporters. Further, opportunities in supplying products to treat coronavirus symptoms will also bode well for exporters. Indian players continued to have a strong pipeline of product launches for fiscal 2021 as well. Fiscal 2022 growth will be supported by continued product diversification, ramp-up in complex, specialty products and vaccine sales to some extent.

India's formulations exports to regulated markets (FY15-20)



Source: CRISIL Research, DGCIS

The US, Canada, West Europe, South Korea, Japan, and Australia are regulated markets, which have robust regulatory frameworks. Semi-regulated export markets have less-developed regulatory frameworks. These include Africa, Latin America, Asia, the Middle East and the rest of Europe, comprising Russia and Ukraine.

Exports to regulated European markets have grown ~12% on-year in fiscal 2020 as players look at tapping into the under-penetrated European markets which offer huge opportunities for uptake of generic drugs.

Focus on specialty and niche products to boost formulations exports to the US

The US market accounts for 37-39% of Indian formulation exports. More than 50% of India's incremental exports over the past five fiscals was to the US.

Over fiscals 2013-16, formulations exports growth was at a strong ~18% CAGR, driven by patent expiry of blockbuster drugs over 2012-14. However, growth fell to ~2% CAGR over fiscals 2016-19 on account of pricing pressures experienced during fiscals 2017 and 2018. Fiscal 2019 has been a year of recovery with abating pricing pressures and players moving away from conventional generics to limited competition molecules. Exports growth remained at double digits in fiscal 2020 as well on back of new launches, especially limited competition and complex drugs. Apr-Dec fiscal 2021 formulations exports registered a growth of ~14% on-year.

The formulation exports to the country are expected to increase at ~12-15% CAGR over the next five years as pricing pressure normalises and manufacturers look at niche molecules, specialty drugs, complex generics, and biosimilars.

Indian players gain volume opportunities in the US as global players exit non-profitable drugs

Due to Generic Drug User Fee Amendments (GDUFA) implementation from 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 declined in 2018 but continued to remain on higher levels in 2019. Although USFDA approvals have increased, pricing pressure is expected to be moderate as companies rationalize their portfolio as reflected in higher ANDA withdrawals.

Specialty and complex generics – moving from ‘nice-to-have’ to a ‘must-have’ business

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 fiscals 2019 and 2020 have been high in comparison to previous three years.

Sun Pharma has a major pipeline of specialty drugs in order to mitigate the impact of base erosion in the US. It had launched plaque psoriasis treatment drug Ilumya in October 2018. It also launched Xelpros in the US, used for treatment of open-angle glaucoma. The company launches two specialty products in fiscal 2018 and three in fiscal 2019. It recently launched Cequa for dry eye disease in the US. Other major players have also increased their portfolio of complex generics and specialty products. Complex generic products are hybrid drugs whose authorization depends partly on the results of the tests on the reference medicine and partly on new data from clinical trials and are expected to have same clinical effect and safety profile as the branded drugs. The manufacturing of complex generic products require higher specialized capabilities and are required to undergo stringent clinical trials compared to conventional generics, which may not be the strength of majority CDMOs in the Indian Pharmaceutical Industry. In addition the manufacturing of complex generics provides for higher profitability owing to limited competition with few players. The complex generic products market has a high barrier to entry as these products are generally difficult to develop and require special know-how from the development and manufacturing perspective compared to conventional generic products. Complex generic drugs and ‘value-added generics’ enable the manufacturers and marketers to provide a differentiated product to the market with improved safety, efficacy and cost.

Biologics present huge opportunity during the next five years

Strong growth between fiscals 2012 and 2015 was characterised by patent cliffs for blockbuster drugs and Para IV (180 days marketing exclusivity) opportunities for Indian players. Biologics share in total patent expiries by value is expected to be higher in next five years, signifying a tremendous opportunity for players. Seven of the top 10 drugs

sold globally in calendar year 2019 were biologics. The top 10 biologics had a combined global sales worth over \$65 billion. The top players have already started moving towards biosimilar. However, they still lag behind global peers. Also, companies are increasingly focusing on specialty and complex molecules/drugs, which command higher returns.

Developing a biosimilar molecule needs 30-fold more investment than a plain vanilla generic. The investment can go as high as \$150 million for a biosimilar. Only three players from India have received biosimilar approvals in regulated markets – Biocon (US), USV and Intas Pharma (Europe).

Formulations export momentum to European markets to continue

During the past five years, pharma exports to European markets clocked a slower 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.

Exports to Europe grew by a sharp 12% on-year in fiscal 2020. Sharp currency depreciation has also aided the exports. We expect healthy growth in formulation exports to Europe over the next five years on rising generic penetration in the UK, France and Germany, among others. Easing of pricing pressure would also aid growth in these markets. High incidence of chronic diseases, an ageing population, and adoption of specialty medicines are set to drive growth in the European markets. Exports increased by ~24% on-year during Apr-Dec fiscal 2021.

5.5.2 Formulations exports to semi-regulated markets

Players increasing focus on semi-regulated markets

Semi-regulated export markets have less-developed regulatory frameworks. These include Africa, Latin America, Asia, the Middle East and the rest of Europe, comprising Russia and Ukraine. India's formulations exports to semi-regulated markets are expected to post 13-14% CAGR over the next five years to touch ~\$13.1 billion in fiscal 2025, as players eye growth opportunities in newer markets with low generic penetration. 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 83% 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-virals and anti-malarial.

The demand for the treatment of chronic diseases will boost generics off-take due to limited budgets and high out-of-pocket expenditure in the semi-regulated markets. Also, governments in various countries are looking to strengthen their regulations to allow import of generic drugs in order to reduce their healthcare expenditure. In Addition to this several developing Asian countries which are semi-regulated doesn't have domestic capacities to manufacture pharmaceutical products. With increasing awareness for healthcare and similar disease profile to that of India, Indian pharmaceutical players have an opportunity to tap in to these semi-regulated market. Indian players exporting to these countries also have cost efficiencies and skills to cater to these semi-regulated markets.

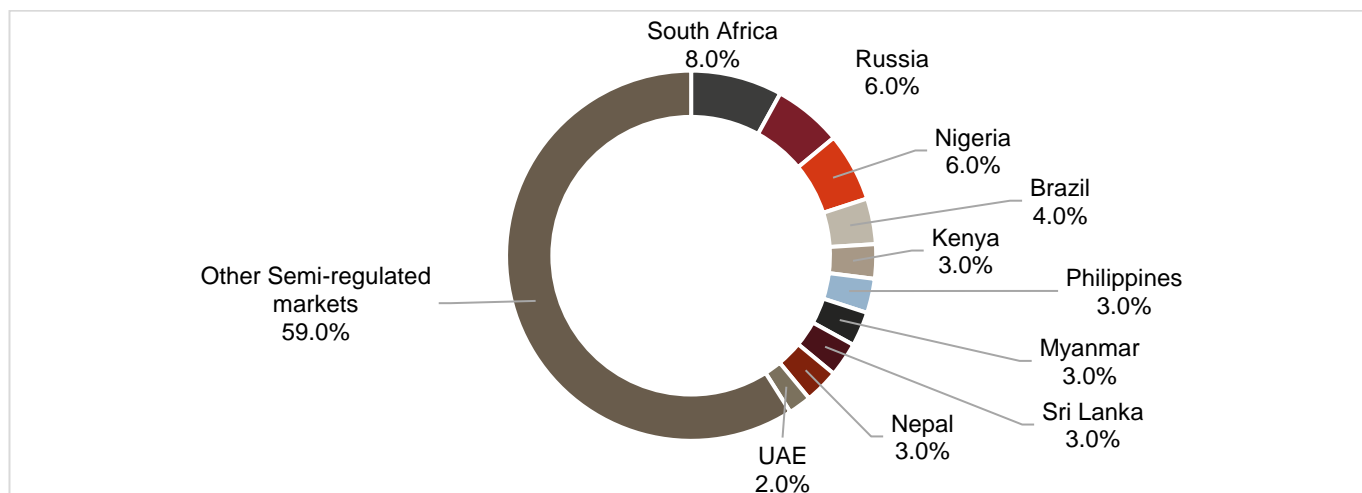
Growth in these markets are expected to remain healthy in fiscal 2022 led by demand for antivirals and antibiotics.

Players look to tap under-penetrated markets for growth

Overall growth in semi-regulated markets for fiscal 2020 improved by ~6% on-year, as players looked at penetrating smaller markets. Growth in markets like Kenya and Brazil improved by ~11% and 9% on-year during the period. 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. Also as some of the underdeveloped countries don't have access to quality healthcare and medicine, generics presents a real opportunity to expand in to these markets as traded generics products exported from India are comparable to branded generics products manufactured in some of these underdeveloped countries. Further, governments in the region are looking to streamline regulations to allow import of generics, which will help reduce government expenditure. Increase in healthcare spending and rising demand for medicines to treat chronic and lifestyle-related ailments would support growth in the semi-regulated markets. Covid-19 vaccine exports will provide further boost to revenues in fiscal 2022 as India is a key supplier of low cost vaccines to several nations in the region. All the major players are now looking to increase its presence in semi-regulated markets and act as its next engine of growth. In semi-regulated markets, Cipla has a head-start over other players due to significant presence in South Africa and other emerging markets. Dr. Reddy's, Lupin, Sun Pharma are some of the other major Indian players having exposure to exports in semi-regulated markets.

India's pharmaceutical exports to semi-regulated markets (FY20) (USD 7.0 Bn)



Source: CRISIL Research, DGCIS

Countries like Sri Lanka, Vietnam and Myanmar also present significant opportunities for Indian exports segment. Sri Lanka is a south East Asian Country with population of around 22 million. Sri Lanka's pharmaceutical market likely to expand over the coming years. The country's growing and ageing population will act as key drivers of market growth. Additionally, there is a latent and growing demand for the treatment of chronic diseases, which will be supported by government efforts to upgrade healthcare services. Government's pro-generic medicines policies, as well as low per-capita spending on medicines, will be an added advantage to generic producers like India. Some of the strength of Sri Lankan Pharmaceutical Markets are robust pharmaceutical market growth and Government's commitment to improving access to healthcare. This presents Indian exporters with an opportunity mainly because

Sri Lanka depends totally on imports for their requirement of Bulk Drugs and Local industry is yet to catch up with the needs of the country.

Myanmar is an ASEAN country with the population of around 55 million. Myanmar is a growing economy and is continuously supported by Government reforms. Indian generic firms are the main foreign companies operating in Myanmar. Majority of multinational pharmaceutical firms do not have operations in the country. It is expected that the situation will improve as the country undergoes economic reform that will lead to a growing appreciation of better healthcare provision. Given the poor quality of infrastructure in the country and fragmented nature of the industry, foreign pharmaceutical firms are likely to leverage pharmaceutical distribution.

Vietnam is an emerging economy with population of approximately 100 million. Vietnam has focused on strengthening the domestic pharmaceutical industry to cater to need of its domestic market. However the domestic pharmaceutical industry in Vietnam is not well equipped to sustain the growing demand. Players exporting to Vietnam can leverage on opportunities in the novel therapeutics and complex treatments. With the current global economic disruptions caused by COVID-19 and ongoing trade uncertainties with China, emerging markets such as Vietnam provide an opportunity for Indian players diversifying their export portfolio.

5.6 Indian Trade (unbranded) Generics market

Overview of Indian trade generics market

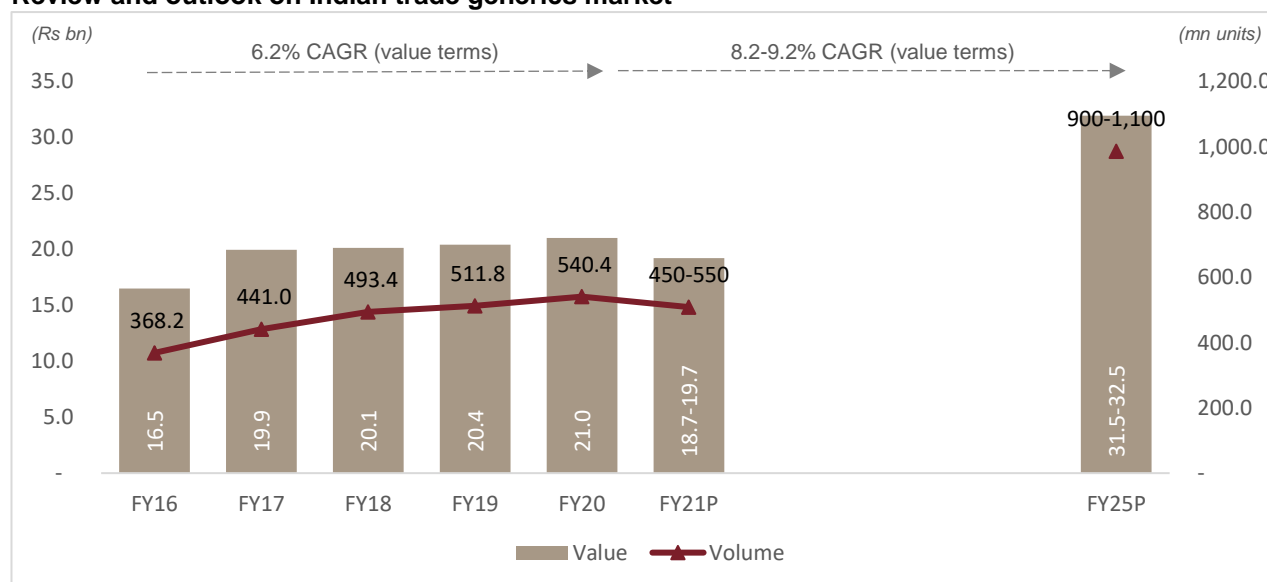
Trade generic products are generic medicines, i.e. drugs for which the patents have expired, which are sold directly to the distributor and not marketed through medical representatives, and are typically used as a substitute for more expensive branded generic medicines in order to offer affordable medicines to patients by the retailers and pharmacies. Trade generics in India has been overshadowed by the rise of branded generics. Branded generics forms a majority of the part in overall Indian generics pharmaceutical market. Many of the small and medium sized Indian pharmaceutical firms operate in the traded generics industry. With its lower costs and similar quality to branded generics, traded generics market is gaining traction in the Indian pharmaceutical market, albeit at the slower rate. Government of India has also taken keen interest in promoting traded generics with initiatives like Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana where it provides traded generics through Jan Aushadhi Kendras.

Traded generics provide good opportunity for Indian generics manufacturer to export to some of the semi regulated market as these market share similar disease profile as well as have lower healthcare expenditure. Many of the pharmaceutical players are adding trade generic to their portfolio; Abbott Healthcare Limited, Biogenetic Drug Private Limited, Medipol Pharmaceuticals India are some of the players operating in Indian trade generics market.

Indian trade generics segment to clock a higher growth over the next five years on account of govt initiatives and rising awareness levels

In particular, the generics has been significantly growing at CAGR of ~2.7% (in volume terms) during fiscal 2016 and fiscal 2020 in India. In particular, the trade generics segment has been growing at CAGR of 10.1% (in volume terms) during fiscal 2016 and fiscal 2020 in India, which is higher than the domestic formulations growth (in volume terms). Indian trade generics industry has grown at the healthy rate at 6.2% CAGR in the last five years from fiscal 2016 to fiscal 2020; it is estimated to have been around Rs 21 billion in fiscal 2020. Indian trade generics industry is expected to grow at 8.2-9.2% CAGR in the next five years owing government initiatives and awareness for low cost trade generics and is expected to reach Rs 31.5-32.5 billion by fiscal 2025.

Review and outlook on Indian trade generics market



Source: AIOCD AWACS, CRISIL Research

In volume terms, its growth is expected to continue to outpace the overall domestic formulations volume sales during the next five years period from fiscal 2020 to fiscal 2025; traded generics segment is expected to clock volumes sales at ~13% compared to overall domestic formulations volumes growth of ~5% during the corresponding period. However, in value terms, traded generics growth will continue to lag that of the overall market due to lower realisation levels.

5.6.1 Growth drivers for Indian trade generics market

Trade generics are characterised by their low costs compared to branded generics which are slightly priced higher than the trade generics. Trade generics are of similar quality to branded generics but are sold at relatively lower prices. With increasing population, trade generics presents an excellent opportunity to provide for the healthcare need of the population. Also trade generics is the great option for people in rural areas who are less privileged to access the healthcare facilities.

The rural markets are characterised by lower penetration of healthcare facilities, low per capita consumption of medicines, a wide base of patients with acute and chronic diseases, and low penetration of generics. In terms of medicine consumption, these markets are mainly driven by low-cost generics. The demand for the treatment of chronic diseases will boost generics off-take due to limited budgets and high out-of-pocket expenditure. Also, government is focusing on rising awareness and promote use of generic medicines in the country.

Government push for schemes such as Jan Aushadhi Yojana, encouraging traded generics use

At 90-95%, 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 7,000 stores are currently operational in the country. Yet, of India's ~8.5 lakh pharmacies, Jan Aushadhi stores represent less than 1%. Therefore, the share of sales through Jan Aushadhi stores is very low.

CRISIL Research estimates the sale of drugs through Jan Aushadhi stores is thus likely to ~2% of total domestic pharmaceutical sales by fiscal 2024. It is expected that a significant increase in scale might impact the volumes of chronic drugs in the market, thereby affecting the market share of branded players (in volume terms).

The generics pharmaceutical industry in India has seen significant growth of ~7% CAGR (in value terms) during the last five years from fiscal 2016 to fiscal 2020.

5.6.2 Trends in Indian trade generics market

India yet to accept trade generics completely

Although trade generics are considered to provide similar quality as that of branded generics or branded innovators, there still apprehension about use of trade generics extensively. There is apprehension among physicians in prescribing generics medicines to their patients. Most of these apprehensions are related to quality of the product.

Apart from this, poor patient acceptability due to various issues like poor packaging, lack of brand promotion initiatives, etc., are affecting the extent of penetration of traded generics drugs in the country, even though India is becoming a leader for all developing countries in the supply of generic medicines. The government and the policy makers in India and other similar developing countries have been focusing on building confidence among physicians and the patients regarding traded generic medications.

Covid-19 induced buying of generic drugs as people favour low cost drugs

Higher sales of generic drugs and India's Jan Aushadhi initiative, that makes available quality drugs at affordable prices through dedicated stores selling generic medicines, are impacting volumes of branded generics players. As the buying capacity of consumers has reduced in light of the COVID-19 lockdown, there is a growing preference for generics and lower-priced medications.

Investment in quality infrastructure inhibiting the growth of trade generics in India

Traded generics are often criticized for its quality as compared to branded generics. Traded generics players will need to invest in technology and equipment to meet the quality standards of branded generics drugs. This will facilitate faster approval as well as quality compliance. On the other hand if Generic companies, invests in technology and equipment upgrades they will try to recover these costs by increasing the selling price for the drug and hence will close in on the prices of branded generics. This presents a case for more awareness building among the physicians and patients to use generics medicines

6 Assessment of key API for therapeutic areas

6.1 Anti-histamine & Anti-allergy

Rising prevalence of allergic diseases aiding anti-histamine and anti-allergy category

Antihistamines are drugs which help to treat allergies. Normally, people take antihistamines as an inexpensive, generic, OTC drug that helps in itching, runny nose and sneezing, nasal congestion, hives teary eyes, dizziness, cough and nausea. Antihistamines are also used to treat motion sickness, insomnia and anxiety. The drug basically works by acting against a chemical called histamine which leads to many allergic symptoms.

Anti-allergic medicines help to treat allergies caused due allergens. An allergy is a condition caused by hypersensitivity condition in which immune system response abnormally to the allergens such as pollens, peanuts, dust mites, molds, animal fur, foods such as milk, egg, soy, wheat, etc., and certain medications. Normally, people take anti-allergic as an inexpensive, generic, OTC drug that helps in broad range of inflammatory disorders such as hay fever or allergic rhinitis, asthma, atopic dermatitis and allergic reactions like itchy, runny or blocked nose, wheezing, chest tightness and others. In addition, food allergies can cause symptoms such as vomiting, diarrhea, or respiratory symptoms, after ingestion of an allergen.

Major formulations players in Anti-histamine & Anti-allergy market

GSK	Johnson & Johnson
Merck & Co.	Novartis
Pfizer Inc.	Amgen Inc.
Cytokinetics, Inc.	AbbVie Inc.
Wockhardt	Lupin Ltd.

Source: CRISIL Research

Anti-histamine and anti-allergy therapeutic areas is expected to grow at 8.0-10.0% between 2020 and 2025

Anti-histamine and anti-allergy therapeutic areas is estimated at USD 3.5 billion in fiscal 2020 growing at 8% CAGR between 2015 and 2020. Geographically, the global antihistamines market can be segmented into US, Europe, Asia Pacific and Middle East & Africa. US is the largest market globally due to rising prevalence of allergy rhinitis and rising demand for diagnosis and treatment of allergic disease. According to the American College of Allergy Asthma and Immunology, allergic asthma, food allergy and eczema are the most common types of allergies found in the U.S. Also the growth is expected from high price of antihistamines in this region and also rise in the trend of self-medication.

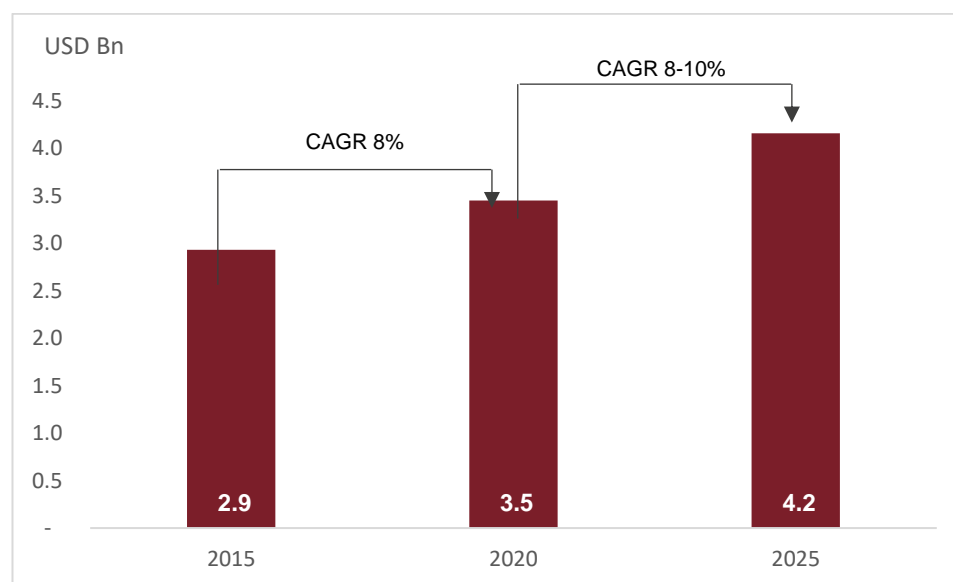
Europe is the second largest end market that holds a noticeable share of the global antihistamine drugs market. According to the European Academy of Allergy and Clinical Immunology (EAACI), more than 50% of all Europeans will suffer from allergy in coming years. For instance, according to the European Academy of Allergy and Clinical Immunology (EAACI), in 2017, around 400 million people suffered from rhinitis worldwide.

In Asia Pacific, increase in the demand for drugs for the treatment of allergies and skin diseases helps to drive the market growth. It has been observed that, there has been a rise in dermatology clinics across Asia Pacific from past

few years. High rates of allergic rhinitis and increasing awareness regarding treatments available for allergy is poised to drive the growth of this market in Asia Pacific.

Also the Middle East & Africa, market continues to shows steady positive growth due to the rising prevalence of nasal allergies. The anti-histamine and anti-allergy therapeutic API market is expected to clock 8.0-10.0% CAGR between 2020 and 2025 driven by rise in healthcare spending by public and government and penetration of pharmaceutical drugs with increased share of generics drugs.

Growth of anti-histamine and anti-allergy therapeutic segment (generics)



Source: Lifescience Intellipedia, CRISIL Research

Growth drivers

- Antihistamine is expected to grow at a healthy growth rate due to increase in allergies and other diseases from changing lifestyle and demand for new drugs for the treatment of these diseases. According to the WHO, allergies are the fourth largest global pathology condition after cancer, AIDS, and cardiovascular diseases. It is gaining traction from a number of factors such as the presence of vast unmet medical needs, growing prevalence of asthma and allergic rhinitis along with high consumption of tobacco, an upsurge in allergies as a result of environmental pollution.
- The major key factors that will help drive the growth in global allergy treatment market is due to significant increase in the prevalence of allergic diseases, rise in preferences toward OTC drugs for allergy treatment, growing elderly population, growing incidences of chronic diseases such as asthma and surge in self-medication in consumers. Furthermore, increasing number of people are suffering from dust allergies, pollen allergies are some other factors expected to trigger the growth of the global target market over the forecasted period.
- Increased usage of biosimilars will be key monitorable for growth of anti-allergy pharmaceutical market. Stringent drug regulatory approval is another key monitorable factor for global allergy treatment market.
-

Molecules in anti-histamine and anti-allergy segment (generics)

Molecule	Global market volume (MTS)	Global market value (USD Mn)	Share in total value	Past growth 2015-2020	Future growth 2020-2025
Fexofenadine Hydrochloride	1,423	339	10%	--	--
Loratadine	916	299	9%	10%	10-15%
Cetirizine Hydrochloride	796	127	4%	3%	0-5%
Montelukast	98	88	3%	3%	0-5%
Mometasone Furoate Monohydrate	89	60	2%	--	--
Doxylamine Succinate	547	60	2%	--	--
Desloratadine	75	59	2%	6%	5-10%
Diphenhydramine Hydrochloride	1,790	27	1%	10%	10-15%
Cinnarizine	682	26	1%	--	--
Levocetirizine Dihydrochloride	52	22	1%	--	--
Promethazine Hydrochloride	235	8	0%	--	--
Dimenhydrinate	159	4	0%	--	--
Diphenhydramine	350	6	0%	2%	0-5%
Montelukast Sodium	1,557	1,401	40%	9%	5-10%
Rupatadine	0	500	14%	6%	5-10%
Methyl Prednisolone	339	254	7%	6%	5-10%
Bilastine	187	137	4%	6%	5-10%
L-Epinephrine	494	40	1%	8%	5-10%
Chlorpheniramine Maleate	1,570	31	1%	4%	5-10%
Methyl Prednisolone Hemisuccinate	23	22	1%	6%	5-10%
Prednisone	53	20	1%	3%	5-10%
Dextromethophan (Base+HBR)	1406	430	<0.5%	6%	5-10%
Pheniramine Maleate	378	12	<0.5%	5%	5-10%
Mepyramine Maleate	107	6	<0.5%	7%	0-5%

Source: Lifescience Intellipedia, CRISIL Research

Major molecules in anti-histamine and anti-allergy segment (generics)

Molecule	Innovator	Approval year	Patent priority
Fexofenadine Hydrochloride	Richardson Merrell Subsidiary Of Sanofi Aventis	1996(US), 2000(JP)	2012
Loratadine	Schering Plough/Merck Pharmaceuticals	1993(US)	2018
Cetirizine Hydrochloride	Ucb	2010 (US)	2016
Montelukast	Merck & Co	1988(US)	--
Mometasone Furoate Monohydrate	Merck & Co	1997(US)	2014
Doxylamine Succinate	--	--	--
Desloratadine	Merck Sharp & Dohme (MSD) in GB	2001(US)	2014
Diphenhydramine Hydrochloride	Parke Davis Subsidiary Of Pfizer Inc	1972 (US)	2034
Cinnarizine	Ceridia	1955(US)	--
Levocetirizine Dihydrochloride	Glaxosmithkline Plc, Ucb	2017 (US)	2012
Promethazine Hydrochloride	Charleston Laboratories	1951(US)	2028
Dimenhydrinate	--	--	--
Diphenhydramine	Compass Point Research, Nda Partners	1943(US)	--
Montelukast Sodium	Merck And Co Inc	1998 (US), 2008 (US)	1992
Rupatadine	Uriach	2003 (EU)	--
Methyl Prednisolone	2-BBB Medicines	1995 (US)	1986
Bilastine	Faes Farma	2010 (US)	--
L-Epinephrine	Hoechst Roussel Subsidiary Of Sanofi Aventis	--	2005
Chlorpheniramine Maleate	Lipocine, Cypress Pharmaceutical	1979 (US)	1983
Dextromethorphan	F Hoffman La Roche AG	1958(US)	--
Methyl Prednisolone Hemisuccinate	Upjohn Co Subsidiary Of Pfizer Inc	1955(US)	2015
Prednisone	Schering Corp Subsidiary Of Merck And Co	1955(US)	2000
Dextromethorphan Hydrobromide	F- Hoffmann La Roche AG	1954	1958
Pheniramine Maleate	Schering Corp Subsidiary Of Merck And Co	1948(US)	--
Mepyramine Maleate	Carter Products Subsidiary Of Carter Wallace	2009 (US)	--

Source: Lifescience Intellipedia, CRISIL Research

Molecule	Raw material availability in India	Average exports from India (tonnes)	Growth in exports 2015-2020	Export potential	Suppliers in market
Fexofenadine Hydrochloride	High	178	17%	High	High
Loratadine	High	116	10%	High	High
Cetirizine Hydrochloride	High	110	7%	High	High
Montelukast	High	1	-47%	Low	Medium
Mometasone Furoate Monohydrate	High	0	26%	Low	Medium
Doxylamine Succinate	High	7	21%	High	Medium
Desloratadine	High	13	14%	High	High
Diphenhydramine Hydrochloride	High	100	<0%	Medium	High
Cinnarizine	High	89	-2%	Low	57
Levocetirizine Dihydrochloride	High	1	2%	Low	High
Promethazine Hydrochloride	High	24	10%	High	Medium
Dimenhydrinate	High	25	-2%	Low	Medium
Diphenhydramine	High	16	22%	High	Medium
Montelukast Sodium	High	81	6%	High	High
Rupatadine	High	0	-	Low	Medium
Methyl Prednisolone	High	1	-	Low	High
Bilastine	High	20	29%	High	Medium
L-Epinephrine	High	0	-	Low	Medium
Chlorpheniramine Maleate	High	250	5%	High	Medium
Dextromethophan (Base+HBR)	High	190	12%	High	Medium
Methyl Prednisolone Hemisuccinate	High	2	12%	Low	Medium
Prednisone	Low	0	-	Low	Medium
Pheniramine Maleate	High	54	1%	High	Medium-High
Mepyramine Maleate	Low	13	0%	Medium	Medium

N.A – not available Source: Lifescience Intellipedia, CRISIL Research

Major antihistamine suppliers in India

Molecule Name	Demand in India	Major Suppliers
Chlorpheniramine Maleate	High	Supriya Lifescience Ltd Keshava Organics
Diphenhydramine Hydrochloride	High	Supriya Lifescience Ltd Wanbury
Pheniramine Maleate	Medium	Supriya Lifescience Ltd Harika Drugs Pvt. Ltd Sanofi India Keshava Organics
Mepyramine Maleate	Low-medium	Supriya Lifescience Ltd Keshava Organics
Fexofenadine Hydrochloride	High	Dr Reddys Laboratories Ind Swift Granules India Virupaksha Organics Ltd
Azelastine Hydrochloride	High	Cadila Healthcare Ltd Msn Laboratories Pvt Ltd Cipla Industries Pvt Ltd
Naphazoline Hydrochloride	High	Precise Chemipharma Pvt Ltd Mehta Medicare Pvt Ltd Micro Labs Ltd Manus Aktteva Biopharma LLP

6.2 Pain Management

Pain management, pain killer, pain medicine, pain control, are therapeutics areas that are used to ease the suffering and reducing chronic pain.

Paracetamol (acetaminophen), or a nonsteroidal anti-inflammatory drug (NSAID) such as ibuprofen are used to relieve mild pain. Paracetamol, an NSAID or paracetamol in a combination product with a weak opioid such as tramadol, may provide greater relief than their separate use. A combination of opioid with acetaminophen are frequently used for mild to moderate pain.

Common types of pain and typical drug management

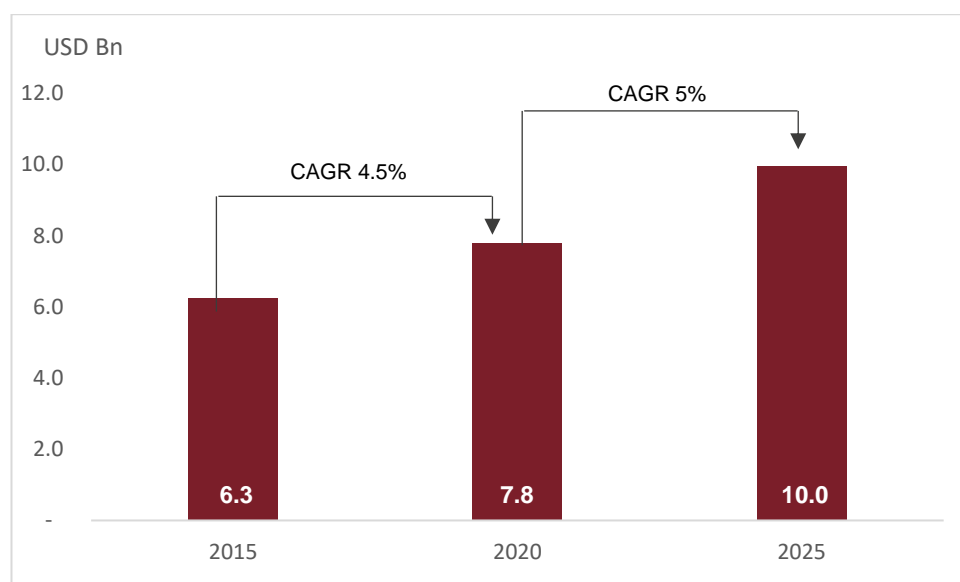
Pain type	typical initial drug treatment
Headache	Paracetamol /acetaminophen, NSAIDs
Migraine	Paracetamol, NSAIDs
Menstrual cramps	NSAIDs
Minor trauma, such as a bruise, abrasions, sprain	Paracetamol, NSAIDs
Severe trauma, such as wound, burn, bone fracture, or severe sprain	Opioids
Strain or pulled muscle	NSAIDs, muscle relaxants
Minor pain after surgery	Paracetamol, NSAIDs
Severe pain after surgery	Opioids
Muscle ache	Paracetamol, NSAIDs
Toothache or pain from dental procedures	Paracetamol, NSAIDs
Kidney stone pain	Paracetamol, NSAIDs, opioids
Pain due to heartburn or gastroesophageal reflux disease	Antacid, H2 antagonist, proton-pump inhibitor
Chronic back pain	Paracetamol, NSAIDs
Osteoarthritis pain	Paracetamol, NSAIDs
Fibromyalgia	Antidepressant, anticonvulsant

Source: CRISIL Research

Pain management market is expected to grow at 5.0% between 2020 and 2025

Global pain management market is estimated at USD 7.8 billion in 2020. The market grew at a CAGR of 4.5% between 2015 and 2020. Growth in the pain management market was driven by rise in surgeries and medical procedures, incidence of flu and fever. The segment is expected to see a growth of 5.0% over the next five years from 2020 to 2025 supported by increased surgeries, increased incidence of chronic diseases, and rise in flu related illness with rapidly changing climatic changes

Growth of pain-management therapeutic segment (generics)



Source: Lifescience Intellipedia, CRISIL Research

Molecules in pain management segment (generics)

Molecule	Global market volume (MTS)	Global market value (USD Mn)	Share in total value	Past growth 2015-2020	Future growth 2020-2025
Lidocaine Hydrochloride	1,457	1722	22%	5.2%	2 - 8%
Capsaicin	180	700	9%	3.6%	0 - 5%
Pregabalin	2,575	596	8%	3.6%	0 - 5%
Duloxetine Hydrochloride	3,381	471	6%	3.4%	0 - 5%
Paracetamol	89,938	461	6%	3.7%	0 - 5%
Midazolam	138	450	6%	6.3%	5 - 10%
Gabapentin	9,264	435	6%	4.7%	2 - 8%
Zoledronic Acid Trihydrate	4	351	4%	4.7%	2 - 8%
Naproxen	6,199	242	3%	4.8%	2 - 8%
Pentoxifylline	3,798	209	3%	7.5%	5-10%
Aspirin	23,434	151	2%	2.5%	0 - 5%
Diclofenac	3783	116	1%	3.3%	0 - 5%
Ketamine Hydrochloride	300	71	1%	5.6%	5 - 10%

Source: Lifescience Intellipedia, CRISIL Research

Major molecules in pain management segment (generics)

Molecule	Innovator	Approval year	Patent priority
Lidocaine Hydrochloride	Showa Yakuin Kako	1948 (US)	1994
Capsaicin	Johns Hopkins University	2009(US), 2009(EU)	2001
Pregabalin	Northwestern University	2004(US)	1993
Duloxetine Hydrochloride	Eli Lilly And Co	2004(US), 2004(EU), 2010(JP)	1993
Paracetamol	Mcneil Consumer Healthcare A Subsidiary Of J&J	1951 (US)	2001
Midazolam	F Hoffman La Roche Ag	1985(US)	2008
Gabapentin	Pfizer Inc	1998 (US)	1997
Zoledronic Acid Trihydrate	Ciba Geigy Subsidiary Of Novartis Ag	2007 (US)	--
Naproxen	Iceutica - Iroko Pharmaceuticals	2006 (US)	1972
Pentoxifylline	Sanofi Aventis	1984(US)	1977
Aspirin	Bayer	1899(US)	2001
Diclofenac	Novartis Ag	1988(US)	2010
Ketamine Hydrochloride	Pfizer	1970(US)	2013

Source: Lifescience Intellipedia, CRISIL Research

Molecule	Raw material availability in India	Average exports from India (tonnes)	Growth in exports 2015-2020	Export potential	Suppliers in market
Lidocaine Hydrochloride	High	234	21%	High	High
Capsaicin	High	0	-63%	Low	High
Pregabalin	Low	278	13%	High	High
Duloxetine Hydrochloride	High	186	21%	High	High
Paracetamol	Low	13,721	9%	High	High
Midazolam	High	1	30%	Low	High
Gabapentin	High	504	-28%	Low	High
Zoledronic Acid Trihydrate	High	-	-	Low	High
Naproxen	High	688	6%	High	High
Pentoxifylline	High	464	0%	High	High
Aspirin	High	663	-32%	Low	High
Diclofenac	High	110	17%	High	High
Ketamine Hydrochloride	High	60	0-5%	Medium	Low

N.A – not available Source: Lifescience Intellipedia, CRISIL Research

For the fourth time since 2006, the World Health Organization (WHO) again in 2015 recommended not to place ketamine under international control after review of the latest evidence by the WHO Expert Committee on Drug Dependence. The Committee concluded that ketamine abuse does not pose a global public health threat, while controlling it could limit access to the only anaesthetic and pain killer available in large areas of the developing world. The medical benefits of ketamine far outweigh potential harm from recreational use. Ketamine provides access to essential and emergency surgery as an affordable anaesthetic. WHO recommended it is important for the international community to work in harmony to strike a balance between legitimate use of ketamine for medical and veterinary purposes and prevention of trafficking in and abuse of ketamine.

6.3 Vitamins

Rising interest in personal health and well-being is driving demand for vitamins

The consumers are increasingly shifting towards including vitamins and supplements in their daily routine due to fast-developing interest as well as awareness over personal health and well-being. Vitamins are organic chemical compounds and an important nutrient for the working of metabolism in the human body that is demanded in small amounts. Vitamins cannot be produced in the body, but it can be absorbed by supplements or food. Insufficient intake of vitamins leads to deficiencies and illnesses like xerophthalmia, scurvy and night blindness.

Micronutrients are vitamins and minerals which our body needs in very small amounts but their impact on a body's health are critical. Deficiency in any one of them can cause severe and even life-threatening conditions. Vitamins and minerals perform a range of functions, including enabling the body to produce enzymes, hormones and other substances needed for normal growth and development. Deficiencies in iron, vitamin A and iodine are the most common around the world, particularly in children and pregnant women. Low- and middle-income countries bear the disproportionate burden of micronutrient deficiencies on account of improper diet, low availability of high nutrient and balance food.

Micronutrient deficiencies can cause life threatening health conditions, but they can also lead to less clinically notable reductions in energy level, mental clarity and overall capacity. This can lead to reduced educational outcomes, reduced work productivity and increased risk from other diseases and health conditions. Many of these deficiencies are preventable through nutrition education and consumption of a healthy diet containing diverse foods, as well as food fortification and supplementation, where needed. This is where demand for pharmaceutical vitamins products and APIs rise.

Vitamins is a capital intensive sector as the new product development is a highly capital-intensive process. Research and development are the key success factors for vitamins and dietary supplements, which require significant investments. Moreover, stringent regulations regarding the health benefits claim and labeling of the products are key factors for players to ensure going forward.

Major formulations players in vitamins market

Roche	GSK pharmaceuticals
Pfizer	Bayer AG
Abbott	Cadila Pharma
Sun Pharmaceuticals	Merck Ltd.
P&G Health	Johnson & Johnson
Apex Labs (India)	

Source: CRISIL Research

Vitamins market is expected to grow at 8.0-10.0% between 2020 and 2025

Global vitamins market is estimated at USD 1.5 billion in 2020. The market grew at a CAGR of 6.0% between 2015 and 2020. Growth in the vitamins market was marked by increased awareness about nutraceuticals benefits, increased prevalence of vitamin deficiencies due to dietary changes. Increased interest and concerns over personal

health and well-being have resulted in consumers to incorporating vitamins and supplements as part of their daily routine.

The global vitamins market has been segmented largely based on type of vitamins as vitamin B, vitamin C, vitamin E and others. According to WHO, in 2018, more than 2 billion people were suffering from micronutrient deficiencies, thus leading to consumption of some or other vitamins. Also the growing birth-rates and senior citizens in developing countries is leading to growth of pediatric and calcium vitamins.

Vitamins fortified consumer products are also seeing rise in demand

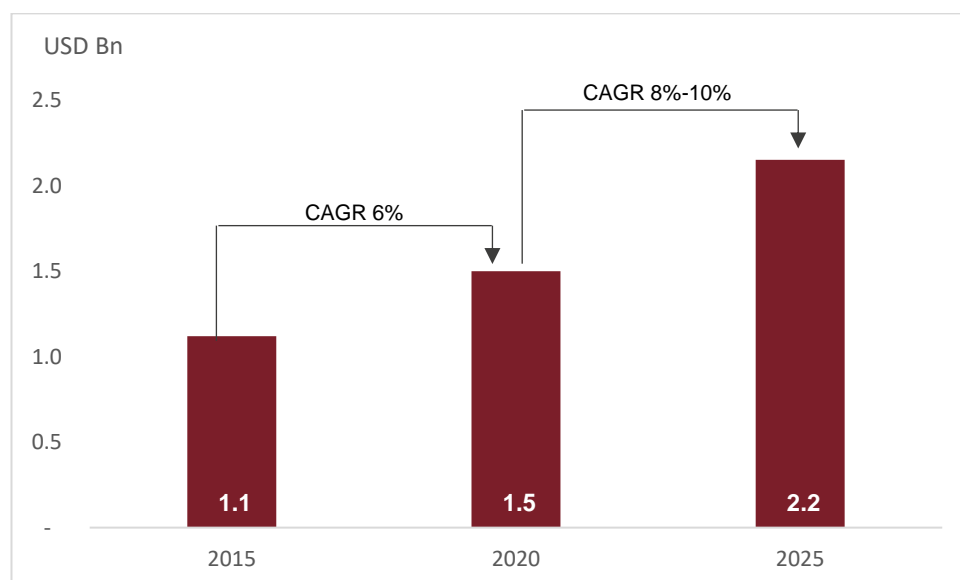
On the basis of application, the global vitamins market has been divided into healthcare products, food & beverages, animal feed and others. The food & beverage segment is further classified into Bakery & Confectionery Products, Dairy Products, Infant Food, Beverages and Others.

The global vitamins market has also been segregated, on the basis of source, into natural and synthetic.

Distribution channel, such as hypermarket, supermarket, mass merchandise, specialty stores and other medical stores are contributing to rapid penetration of vitamin rich products. OTC channel accounted for the largest revenue share of nearly 75% in 2020 and is expected to witness steady growth moving ahead on account of rising consumer awareness regarding the health benefits of dietary supplements. Supermarkets/hypermarkets contribute significantly to the sales of dietary supplements in Europe and North America owing to higher prevalence. The availability of a wide range of products and higher discounts are responsible for the growth of sales through supermarkets/hypermarkets.

The vitamins market is expected to clock 8.0% CAGR between 2020 and 2025 driven by rise in awareness about vitamins and health benefits, penetration of vitamins fortified foods and various programs in developing and emerging countries for balanced diet and food supplements.

Growth of vitamins



Source: Lifescience Intellipedia, CRISIL Research

Growth drivers

- The working population around the globe is struggling to fulfill the daily nutrient requirements owing to hectic work schedules and changing lifestyles. This is increasing their dependency on dietary supplements to fulfill the nutrient requirements owing to their high convenience, which, in turn, is expected to drive the market over the forecast period. More than 60% of consumers all over the globe are taking vitamins (in food products) on daily basis, while 55% are enticed to take supplements so as to maintain healthy life.
- The rising number of fitness centers, health clubs, gymnasium, along with the growing awareness about fitness among the younger population, will in turn lead to increase in the demand for energy and weight management. Also, acceptance of sports as a career is expected to boost the demand for dietary supplements, like proteins, vitamins, and amino acids, which will trigger the market growth.
- Technological advancements is the major key drivers in the global vitamins & supplements market which will boost the growth over the forecasted period.
- Covid-19 Pandemic is Increasing Demand for Immunity-Boosting Vitamins
 Due to the outbreak of Covid-19 pandemic, consumers are demanding products to increase their natural self-defense system. The unprecedented coronavirus (Covid-19) outbreak has largely affected the North American and European countries, such as the U.S., Italy, Spain, the U.K., France, and Germany. The dietary supplement industry is largely concentrated in these regions, which in turn, benefitted from the situation as the market witnessed a surge in demand for immunity-boosting supplements. According to U.S National Health and Nutrition Examination Survey, more than 50% of U.S population has been consuming immunity-boosting products during the pandemic.

Molecules in vitamins segment (generics)

Molecule	Global market volume (MTS)	Global market value (USD Mn)	Share in total value	Past growth 2015-2020	Future growth 2020-2025
Thiamine Mononitrate / Thiamine	6,196	250	17%	3.4%	0-5%
Cyanocobalamin	2,161	311	21%	2.8%	0-5%
Cholecalciferol	1,772	108	7%	6.4%	5-10%
Folic Acid	723	110	7%	3.4%	0-5%
Trimethoprim	3,067	100	6%	6.7%	5-10%
Alpha-Tocopherol	4,019	100	8%	4.9%	2-6%
Nicotinamide /Niacinamide	3,060	46	3%	4.3%	2-6%
Riboflavin 5 - Phosphate Sodium	635	60	4%	4%	2-6%

Source: Lifescience Intellipedia, CRISIL Research

Major molecules in vitamins segment (generics)

Molecule	Innovator	Approval year	Patent priority
Thiamine Mononitrate / Thiamine	--	1947(US)	--
Cyanocobalamin	Todd A.R.	1942(US)	2004
Cholecalciferol	Abiogen Pharma	1921(US)	--
Folic Acid	Williams, R.J	1946(US)	--
Trimethoprim	Ascent Pediatrics Inc	--	--
Alpha-Tocopherol	--	1922(US)	--
Nicotinamide /Niacinamide	GenDerm Corporation; National Institutes of Health (USA); University of Washington	1947	--
Riboflavin 5 - Phosphate Sodium	Glaukos Corp	1947	1953

Source: Lifescience Intellipedia, CRISIL Research

Molecule	Raw material availability in India	Average exports from India (tonnes)	Growth in exports 2015-2020	Export potential	Suppliers in market
Thiamine Mononitrate / Thiamine	Low	3	-10%	Low	High
Cyanocobalamin	Low	8	41%	High	High
Cholecalciferol	High	18	22%	High	High
Folic Acid	High	169	6%	High	High
Trimethoprim	Low	528	21%	High	High
Alpha-Tocopherol	Low	47	31%	High	High
Nicotinamide /Niacinamide	High	1,834	15%	High	Low-Medium
Riboflavin 5 - Phosphate Sodium	Low-medium	80	5%	Medium	High

N.A – not available Source: Lifescience Intellipedia, CRISIL Research

6.4 Anti-hypertension

Hypertension is most prevalent cardiovascular chronic diseases

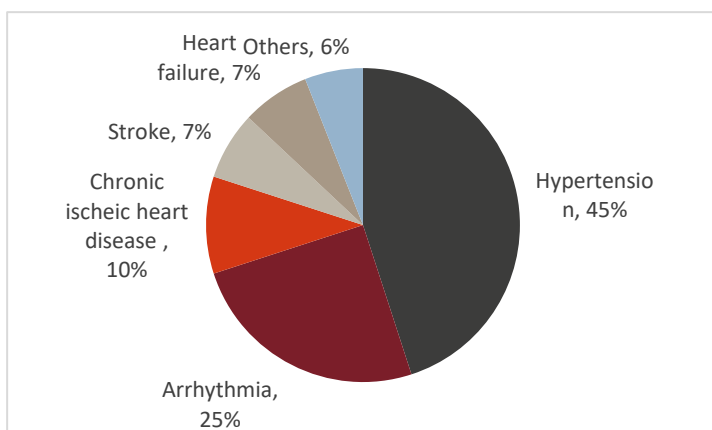
Cardiovascular Diseases (CVD) are a group of disorders affecting the heart and blood vessels and are the most common cause of death globally. Hypertension is a serious medical condition and can increase the risk of heart, brain, kidney and other diseases. It is a major cause of premature death worldwide with 1.13 billion people worldwide having hypertension. In 2015, 1 in 4 men and 1 in 5 women had hypertension. An estimated 17.9 million people died from CVDs in 2016, representing 31% of all global deaths. Of these deaths, 85% are due to heart attack and stroke. Following are the major diseases that drive pharmaceutical sales

- Hypertension - due to high blood pressure
- Atrial fibrillation - abnormal heart rhythm, also known as an arrhythmia
- Chronic ischemic heart disease - reduced blood supply to the heart
- Stroke - an interruption of the blood supply to part of the brain
- Heart failure - inability of the heart to pump blood around the body efficiently
- Angina - when a part of the heart does not receive enough oxygen
- Myocardial infarction - interrupted blood flow damaging or destroying part of the heart muscle

There is a wide range of pharmaceutical drugs available for heart disease, a number of which are taken for chronic use.

- Statins - cholesterol-lowering medications used for lowering LDL cholesterol levels
- Anticoagulants - for preventing blood clots.
- Diuretics - to maintain and lower blood pressure. Causes the body to rid itself of excess fluids and sodium through urination. Helps to reduce the heart's workload.
- Beta-Blockers – for lowering blood pressure, heart attack and heart failure
- Angiotensin - Converting Enzyme (ACE) inhibitors - for heart failure and high blood pressure
- Calcium channel blockers - for reducing the workload of the heart, used to treat high blood pressure
- Angiotensin II receptor blockers - for reducing blood pressure

Major heart disease contribution (2018)



Source: CRISIL Research

Anti-hypertensive drugs form 2.6% of total spending on pharmaceutical drugs across the globe in value term.

Major formulations players in anti-hypertension market

Atrahs Pharma (selling rights divested by AstraZeneca)	Johnson & Johnson
Merck & Co.	Novartis
Pfizer Inc.	Amgen Inc.
Cytokinetics, Inc.	AbbVie Inc.
Wockhardt	Lupin Ltd.

Source: CRISIL Research

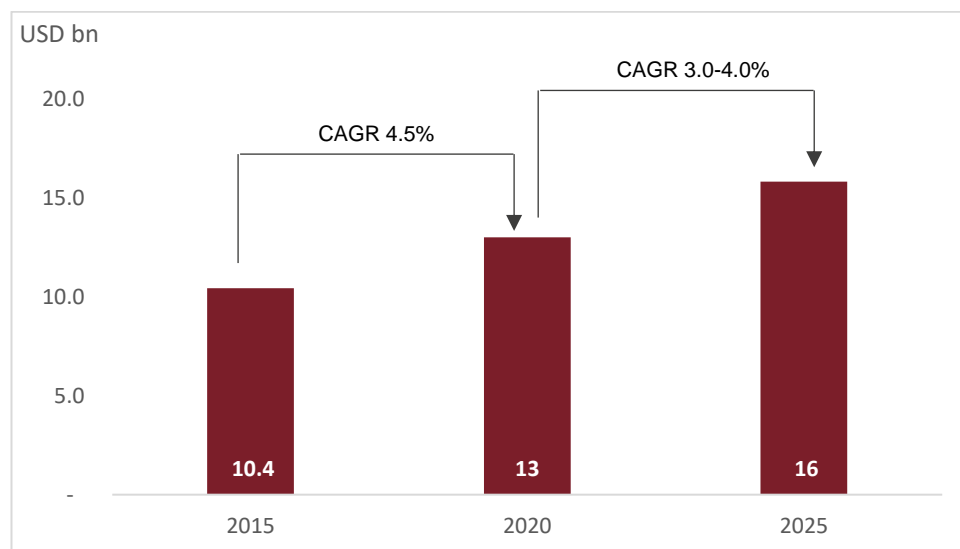
Anti-hypertension therapeutic areas is expected to grow at 3.0-4.0% between 2020 and 2025

Global anti-hypertension therapeutic area API market is estimated at USD 10.4 billion in 2015. The market grew at a CAGR of 4.5% from 2015 to USD 13 billion in 2020. Growth in the anti-hypertension market was marked by increased volumes from rise in generics products through expiry of patent drugs, increased hypertension prevalence across the globe

The African continent region has the highest prevalence of hypertension (27%) while the North and South America has the lowest prevalence of hypertension (18%). Trends analysis show the number of adults with hypertension increased from 594 million in 1975 to 1.13 billion in 2015. This increase is largely from low- and middle-income countries. This increase is due mainly to a rise in hypertension risk factors in those populations. But in terms of value North America accounts for the largest antihypertensive drugs market share. Increased prevalence of hypertension among working population and rising awareness about the risk factors, prevention, diagnosis, and treatment of high blood pressure in the US is one of the major reasons for the higher sales of the antihypertensive drugs.

The anti-hypertension therapeutic area API market is expected to clock 3.0-4.0% CAGR between 2020 and 2025 driven by rise in awareness program by government and non-government programs, sales of generics drugs.

Growth of anti-hypertension therapeutic segment (generics)



Source: Lifescience Intellipedia, CRISIL Research

Growth drivers

- Increased hypertension incidence in developing and under-developed nation.

Regions	Incidence rate of hyper-tension
Africa	27%
South east Asia	25%
Europe	23%
Eastern Mediterranean	26%
Western Pacific	19%
American continent	18%
Global	22%

Source: WHO, CRISIL Research

Hypertension contributes to an estimated 1.6 million deaths annually in India, due to ischemic heart disease and stroke. 55-60% percent of deaths related to stroke and 20-25% of deaths related to coronary heart disease are related to hypertension. Hypertension is one of the most common non-communicable diseases in India.

- Increased consumption of alcohol, obesity and overweight, physical inactivity, and high salt intake through processed foods and high salt diet contributes to the increased incidence of hypertension globally.
- Currently there is low awareness, treatment and control of hypertension in low- and middle-income countries. With government and non-public efforts to decrease prevalence of hypertension and increase awareness about treatment, the demand for hypertension drugs will rise

Molecules in anti-hypertension segment (generics)

Molecule	Global market volume (MTS)	Global market value (USD Mn)	Share in total value	Past growth 2015-2020	Future growth 2020-2025
Hydrochlorothiazide	148,473	3,652	28%	10-15%	5-10%
Amlodipine	54,184	2,648	20%	5-10%	0-5%
Nisoldipine	21,324	600	5%	0-5%	0-5%
L-Arginine	6,770	2,180	17%	5-10%	5-10%
Losartan Potassium	5,130	399	3%	5-10%	5-10%
Amlodipine Besylate	2,676	259	2%	5-10%	0-5%
Valsartan	2,484	333	3%	10-15%	5-10%
Atorvastatin Calcium	1,425	396	3%	5-10%	5-10%
Bisoprolol Fumarate	281	92	1%	5-10%	5-10%

Source: Lifescience Intellipedia, CRISIL Research

Major molecules in anti-hypertension segment (generics)

Molecule	Innovator	Approval year	Patent priority
Hydrochlorothiazide	Wyeth KK	1959 (US)	1987
Amlodipine	Pfizer Inc	1996 (US)	--
Nisoldipine	Bayer AG	1990(US)	1992
L-Arginine	--	--	--
Losartan Potassium	Bristol Myers Squibb	1995(US)	1989
Amlodipine Besylate	Pfizer Inc	1992(US), 1993(JP)	2002
Valsartan	Ciba Geigy Subsidiary Of Novartis AG	1996(US)	1992
Atorvastatin Calcium	--	--	1989
Bisoprolol Fumarate	Merck KgaA	1992(US)	1980

Source: Lifescience Intellipedia, CRISIL Research

Molecule	Raw material availability in India	Average exports from India (tonnes)	Growth in exports 2015-2020	Export potential	Suppliers in market
Hydrochlorothiazide	High	165	13%	High	High
Amlodipine	High	100	22%	High	Medium
Nisoldipine	High	-		Low	Medium

L-Arginine	Low	17	-4%	Low	High
Losartan Potassium	High	571	14%	High	High
Amlodipine Besylate	High	289	12%	High	High
Valsartan	High	267	5%	High	High
Atorvastatin Calcium	High	355	19%	High	Medium
Bisoprolol Fumarate	High	16	22%	High	Medium

N.A – not available Source: Lifescience Intellipedia, CRISIL Research

6.5 Anti-gout

Anti-gout medications is to treat abnormal production of uric acid

Anti-gout medication are also called anti-hyperuricemic agents. These agents work to either correct overproduction or under-excretion of uric acid. Gout is a common metabolic disorder caused by high body uric acid levels, and marked by episodic deposition of uric acid crystals in joints (acute gouty arthritis) and other tissues such as the kidney (urate nephropathy or nephrolithiasis).

Treatment of acute gout attacks uses nonsteroidal anti-inflammatory agents such as indomethacin, naproxen, sulindac or celecoxib. Colchicine (1961: Colbenemid and others) is used both during acute episodes and in chronic maintenance therapy. However, the major approach to long term prevention of gout and the complications of uric acid nephropathy is the use of uricosuric acids such as probenecid (1951: Benuryl) and benzbromarone (not available in the United States) and/or inhibitors of xanthine oxidase, such as the xanthine derivative allopurinol (1966: Aloprim) and the newer non-nucleoside xanthine oxidase inhibitors such as febuxostat (2009: Uloric, Adenuric).

Newer approaches to gout include use of lesinurad (Zurampic: 2015), a drug that inhibits the reabsorption of uric acid in the distal tubules of the kidney, and use of recombinant enzymes that metabolize uric acid such as pegloticase (Kystexxa), which is used in combination with xanthine oxidase inhibitors to treat severe gout, and rasburicase (Elitek: 2002) which is used to treat the hyperuricemia associated with tumor lysis syndrome induced by cancer chemotherapy.

Overview of classes of drugs used to treat gout:

- Nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, and colchicine all reduce the pain and inflammation associated with an acute gout attack.
- Xanthine oxidase inhibitors like allopurinol reduce the amount of uric acid produced by the body.
- Probenecid improves the kidneys' ability to remove uric acid from the blood.

Type of medication	intake	Application
Xanthine oxidase inhibitors – Allopurinol, febuxostat	intravenous powder for injection (500 mg); oral tablet (100 mg; 300 mg)	Allopurinol is used to treat gout or kidney stones. inhibits uric acid production
Probenecid, sulfinpyrazone, benzbromarone	oral tablet (>0.5 g)	Probenecid is used to treat gout and gouty arthritis. probenecid reduces the amount of uric acid in your body by causing it to be passed in your urine.
Colchicine	oral capsule (0.6 mg); oral tablet (0.6 mg)	Colchicine affects the way the body responds to uric acid crystals, which reduces swelling and pain
sulfinpyrazone	Oral	Sulfinpyrazone is used in the treatment of chronic gout (gouty arthritis), which is caused by too much uric acid in the blood.
Nonsteroidal anti-inflammatory drugs (NSAIDs) - Meloxicam, Ketoprofen	-	Reduce both pain and inflammation.
Corticosteroids	Can be taken orally or injected directly into the affected joint on intravenously.	very effective at reducing inflammation

Major formulations players in anti-gout market

Pfizer, Inc	Casper Pharma
AR Scientific, Inc	Teva Pharmaceutical Industries
Takeda Pharmaceutical	AstraZeneca Plc
Iroko Pharmaceuticals	Hikma Pharmaceuticals
Horizon Pharma	Mylan

Source: CRISIL Research

Anti-gout therapeutic areas is expected to grow at 8.0-10.0% between 2020 and 2025

Global anti-gout therapeutic area API market is estimated at USD 1.4 billion in 2020. The market grew at a CAGR of 8.0% from 2015 to 2020. Certain products Colcrys of Takeda Pharmaceutical saw decline in revenues in tune of 10% from 2015 onwards. Growth in the anti-gout market was marked by increased incidence of gout disease, penetration of bio-similar products in the anti-gout market,

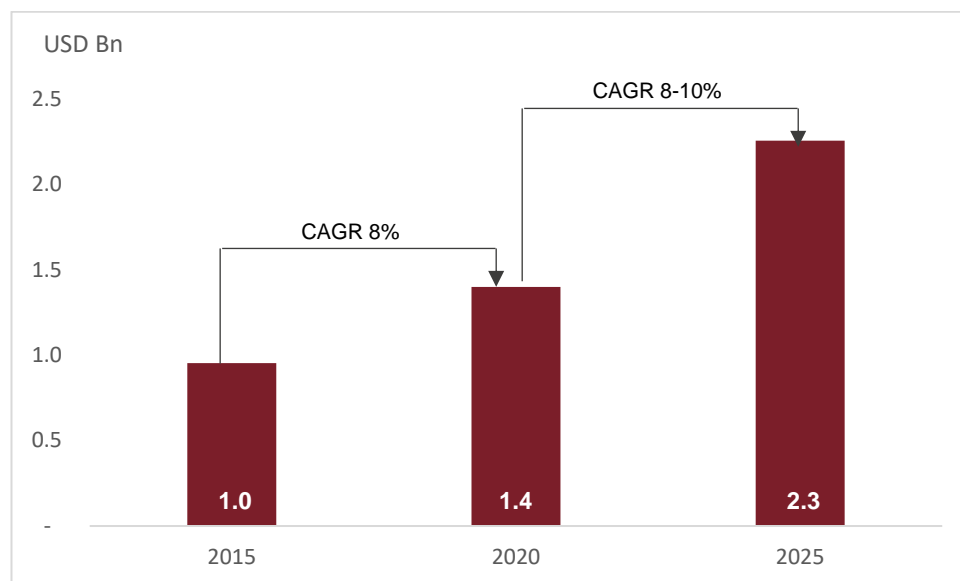
The incidence of gout has more than doubled over the recent 20 years that in from 1990's to 2020's. This increase together along with occurrence of comorbid conditions such cardiovascular risk, renal disease, diabetes mellitus represents a significant health challenge.

North America held the largest market share in consumption, followed by Europe, due to increase in research and development on anti-gout drugs in the regions. Asia Pacific market is expected to grow at a rapid pace over the next five years due to increase in government initiatives for the health care sector. The anti-gout drugs market in Latin America and Middle East & Africa is projected to grow at a moderate pace during the forecast period.

Large MNC players in the pharmaceutical domain such as Takeda Pharmaceutical and AstraZeneca adopted inorganic growth strategies for expansion in anti-gout segment. In June 2012, Takeda Pharmaceutical acquired URL Pharma, and become a leader in gout therapy by adding Colcrys to its portfolio.

The anti-gout therapeutic area API market is expected to clock 8-10% CAGR between 2020 and 2025 driven by rise in prevalence of gout, higher geriatrics populations in developed markets, and increase in sedentary lifestyle and chronic disease.

Growth of anti-gout therapeutic segment (generics)



Source: Lifescience Intellipedia, CRISIL Research

Growth drivers

- The general prevalence of gout is 1–4% of the general population. In western countries, it occurs in 3–6% in men and 1–2% in women. It occurs in men 2–6 folds more than women.
- In some countries, prevalence may increase up to 10%. Prevalence rises up to 10% in men and 6% in women more than 80 years old. Annual incidence of gout is 2.68 per 1000 persons.
- Worldwide incidence of gout increases gradually due to poor dietary habits such as fast foods, high purine diet, lack of exercises, Increasing alcohol consumption, increased incidence of obesity and metabolic syndrome,
- Rising geriatric population is also one of the factors for higher incidence of gout disease in developed markets
- First-line treatment for acute and chronic gout is dominated by generic drugs.
- Biologics drugs such as Krystexxa, Canakinumab, and Riloncept have been introduced in the anti-gout medication market. Increasing adoption of these biologics because of their ability to produce powerful anti-inflammatory action is likely to drive the share of biologics and biosimilar market during the forecast period. Furthermore, several other drugs that are in clinical trials currently are expected to be launched during the forecast period, and are likely to propel the industry.

Molecules in anti-gout segment (generics)

Molecule	Global market volume (MTS)	Global market value (USD Mn)	Share in total value	Past growth 2015-2020	Future growth 2020-2025
Allopurinol	1,871	260	18%	15%	10-15%
Betamethasone	48	191	13%	12%	10-15%
Diclofenac Sodium	7,190	166	12%	4%	<5%
Celecoxib	1,008	127	9%	8%	5-10%
Dexamethasone	64	121	9%	9%	10-15%
Etoricoxib	694	102	7%	11%	10-15%
Ketoprofen	74	52	4%	11%	10-15%

Molecule	Global market volume (MTS)	Global market value (USD Mn)	Share in total value	Past growth 2015-2020	Future growth 2020-2025
Prednisolone	345	51	4%	9%	10-15%
Meloxicam	157	36	3%	16%	10-15%

Source: Lifescience Intellipedia, CRISIL Research

Major molecules in anti-gout segment (generics)

Molecule	Innovator	Approval year	Patent priority
Allopurinol	Ardea Biosciences Subsidiary Of Astrazeneca Ab	1966(US)	1968
Betamethasone	Mitsubishi Chemical	1961(US)	1966
Diclofenac Sodium	Geigy Subsidiary Of Novartis	1988 (US)	1994
Celecoxib	Pfizer Inc	1998(US), 2003(EU), 2007(JP)	1993
Dexamethasone	Allergan Inc Subsidiary of AbbVie Inc	2018 (US)	2000
Etoricoxib	Merck	2002(US)	--
Ketoprofen	Rhone Poulenc Subsidiary Of Sanofi Aventis	2009 (US)	1971
Prednisolone	Levolta Pharmaceuticals	1995 (US)	1998
Meloxicam	Thomae Subsidiary Of Boehringer Ingelheim	2019 (US), 2004 (JP)	1999

Source: Lifescience Intellipedia, CRISIL Research

Molecule	Raw material availability in India	Average exports from India (tonnes)	Growth in exports 2015-2020	Export potential	Suppliers in market
Allopurinol	Low	1,500	10-15%	High	Low-Medium
Betamethasone	High	29	<5%	High	Medium
Diclofenac Sodium	High	1,093	10-15%	High	High
Celecoxib	Low	0	10-15%	Low	High
Dexamethasone	High	40	5-10%	High	Medium
Etoricoxib	High	3	-	High	Medium
Ketoprofen	Low	0	<5%	Low	Medium
Prednisolone	High	173	-	High	Medium
Meloxicam	Low	-	7%	Low	Medium

N.A – not available Source: Lifescience Intellipedia, CRISIL Research

6.6 Anti-Asthmatic / respiratory therapy medicines

There are two main types of treatments under anti-asthmatic therapy

Controller medications are the most important because they prevent asthma attacks. When you use these drugs, your airways are less inflamed and less likely to react to triggers and quick-relief medications, also called rescue medications that relax the muscles around your airway.

There are two key asthma treatments drugs present in the market

- Bronchodilators (most commonly $\beta 2$ -agonists) that reverse airway narrowing by relaxing airway smooth muscle, and
- Corticosteroids, which treat the underlying airway inflammation; inhaled corticosteroids (ICS) are known as preventers (called “controllers”).

The inhaled route, with the use of a spacer, is the best way to administer both of these classes of medicines. Inhalation is more effective and has fewer side effects than the oral route. Acute asthma symptoms require shortacting $\beta 2$ -agonists (SABA). ICS are the first line asthma preventer for those with frequent or persistent symptoms. Most people diagnosed with asthma respond well to these forms of treatment, thus they are “asthma essential medicines”

Major formulations players in asthma / respiratory market

GSK plc.	Merck & Co.
AstraZeneca plc.	Teva Pharmaceutical Industries
F. Hoffmann-La Roche Ltd	Novartis International AG,
Boehringer Ingelheim	Sunovion Pharmaceuticals
Cipla Ltd.	Vertex Pharmaceuticals Inc

Source: CRISIL Research

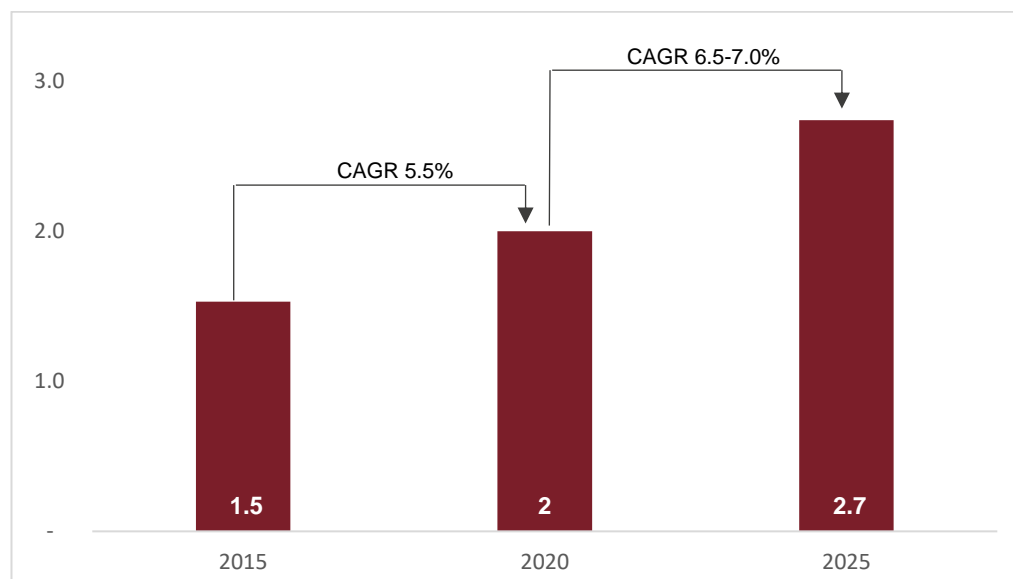
Anti-Asthmatic / respiratory therapeutic areas is expected to grow at 6.5-7.0% between 2020 and 2025

Global anti-asthmatic therapeutic area API market is estimated at USD 2.0 billion in 2020 with a CAGR of 5.5% from 2015 to 2020. Growth in the market was supported by rise in incidence of asthma among global population, entry of generic drugs for key patented drugs and healthcare spending rise in APAC region.

Globally North America is the largest market for anti-asthma drugs. Europe is the second-largest market for anti-asthma drugs. The developing region especially Asia Pacific is accounting for major newer cases due to greater screening and better health care facilities distribution. However the developing regions market particularly Asia Pacific will be the fastest growing and will be the key to the future. According to industry interactions anti-asthma drugs market is expected at USD 25-30 billion in 2021-2022.

The anti-asthmatic therapeutic area API market is expected to clock 6.5% CAGR between 2020 and 2025 driven by rise in prevalence of asthma, new products and treatment introduced in the market and growth of generics drugs in anti-asthmatic area.

Growth of anti-asthmatic therapeutic segment (generics)



Source: Lifescience Intellipedia, CRISIL Research

Growth drivers

- Asthma is one of the major non-communicable diseases. It is a chronic disease of the air passages of the lungs which inflames and narrows them.
- According to the Centers for Disease Control and Prevention (CDC), 1 in 12 people have asthma
- Increasing prevalence of asthma globally. It was estimated that more than ~340 million people suffered from asthma in 2016. Asthma is the most common non-communicable disease among children. Most deaths occur in older adults. According to WHO estimates, there were 417,918 deaths due to asthma at the global level and 24.8 million DALYS attributable to Asthma in 2016
- More than 25 million Americans have asthma. with 8.0 percent of adults and 7.0 percent of children suffering from asthma
- Number of asthmatic patients are increasing on account of increased environment pollution and particulate matter and unhealthy sedentary lifestyles.
- Anti-asthma drugs market is driven by large number of asthma patients, advantages of modern drug therapy, and potential of biologics. Also market is witnessing rise in demand for asthma drugs due to COVID-19.
- Increasing number of new product launches. New drugs are introduced in asthmatic therapy for improvement in treatment and reduce dependence on inhaler. In Sept 2020, FDA approved Trelegy Ellipta (GSK plc.) as the first once-daily single inhaler triple therapy for the treatment of both asthma and COPD in the US

Molecules in anti-asthmatic segment (generics)

Molecule	Global market volume (MTS)	Global market value (USD Mn)	Share in total value	Past growth 2015-2020	Future growth 2020-2025
Salbutamol Sulphate	460	48	24%	6.0%	5-10%
Salmeterol Xinafoate	1.5	46	23%	5.1%	5-10%
Methoxyphenamine Hydrochloride	507.0	28	14%	2.2%	<5.0%
Doxofylline	446.5	19	9%	5.5%	5-10%
Theophylline	818.7	10	5%	5.2%	5-10%
Formoterol Fumarate Dihydrate	0.6	8	4%	8.1%	8-12%
Levalbuterol Hydrochloride	0.9	3	1%	8.9%	8-12%

Source: Lifescience Intellipedia, CRISIL Research

Major molecules in anti-asthmatic segment (generics)

Molecule	Innovator	Approval year	Patent priority
Salbutamol Sulphate	Allen And Hanburys Subsidiary Of Glaxosmithkline Plc	2001 (US)	2004
Salmeterol Xinafoate	Glaxosmithkline Plc	1994(US)	1991
Methoxyphenamine Hydrochloride	Burt, W.E.	1949(US)	1953
Doxofylline	--	2014(US)	--
Theophylline	Albrecht Kossel	1979(US)	1981
Formoterol Fumarate Dihydrate	--	--	--
Levalbuterol Hydrochloride	Sepracor	1999(US)	1990

Source: Lifescience Intellipedia, CRISIL Research

Molecule	Raw material availability in India	Average exports from India (tonnes)	Growth in exports 2015-2020	Export potential	Suppliers in market
Salbutamol Sulphate	High	70	10-15%	High	Medium-High
Salmeterol Xinafoate	High	0.9	-2%	Low	High
Methoxyphenamine Hydrochloride	High	119.7	-5%	Low	High
Doxofylline	Low	0.0	-	Low	High
Theophylline	High	1.5	15-20%	Medium	High
Formoterol Fumarate Dihydrate	High	0.2	-	Low	High
Levalbuterol Hydrochloride	High	0.2	-	Low	High

Source: Lifescience Intellipedia, CRISIL Research

Supriya Lifescience products (existing and in pipeline)

Molecule	Future growth 2020-2025	Export potential	Suppliers in global market	Therapy segment
Ketamine Hydrochloride	5 - 10%	Medium	Low	pain management
Chlorpheniramine Maleate	5-10%	High	Medium	anti-histamine and anti-allergy
Pheniramine Maleate	5-10%	High	Medium-High	anti-histamine and anti-allergy
Riboflavin 5 - Phosphate Sodium	2-6%	Medium	High	Vitamin
Salbutamol Sulphate	5-10%	High	Medium-High	anti-asthmatic
Diphenhydramine Hydrochloride	10-15%	Medium	High	anti-histamine and anti-allergy
Cetirizine Hydrochloride	0-5%	High	High	anti-histamine and anti-allergy
Bisoprolol Fumarate	0-5%	High	Medium	anti-hypertension
New products in pipeline				
Allopurinol	10-15%	High	Low-Medium	anti-gout
Dextromethorphan Hydrobromide	5-10%	Medium	High	anti-histamine and anti-allergy
Pentoxifylline	5-10%	High	High	pain management
(s)-ketamine hydrochloride	0-5%	Medium	Low	pain management
Phenylephrine hydrochloride	0-5%	High	Low-Medium	decongestant
Benfotiamine	5-10%	Medium	High	diabetic neuropathy

Source: Company Website, Company annual reports, CRISIL Research

Key observations:

- Supriya Lifescience Ltd. is the largest exporter of Chlorpheniramine Maleate in India contributing to 45-50% of the API exports from India in FY 2020 in volume terms. Major export destination includes China, Hong Kong, Indonesia, Brazil. USA and Europe contributes around 2-3% of total exports from India in FY 2019 and 2020. (HS code data from DGFT –2933 39 14)

Supriya Lifescience Ltd. is the largest exporter of Ketamine Hydrochloride in India contributing to 60-65 % of the API exports from India (FY2017-FY2020). Major export destination includes Brazil, Europe and emerging nation in African continent. Ketamine hydrochloride is used as affordable anaesthetic drug largely in emerging and developing markets. (HS code data from DGFT – 30049096, 30039036)

- Derivatives of pyridine, such as pyrilamine maleate, dexchlorpheniramine maleate, brompheniramine maleate dextromethorphan maleate exports from India increased at 12% CAGR between fiscal 2016 to fiscal 2020. Supriya Life science ltd. contributes to around 3-4% of pyridine derivatives export from India. Supriya Life science ltd export of Diphenhydramine HCl, Pheniramine Maleate, Pyrilamine Maleate/Mepyramine Maleate, Dexchlorpheniramine Maleate, Brompheniramine Maleate and

Dexbrompheniramine Maleate grew at 47% in fiscal 2021 even as overall Derivatives of pyridine exports remained flat. . (HS code data from DGFT – 29333919)

The important pyridine derivatives include niacin, nicotinamide, isonicotinoylhydrazine, nicotine, strychnine, and vitamin B6. Major export destination includes USA, Europe and China.

- Supriya Lifescience Ltd. is among the largest exporter of salbutamol sulphate in India contributing to 37% of the API exports from India in FY 2020 in value terms. Supriya Lifescience share in salbutamol Sulphate exports have increased from 25-30% in fiscal 2017 to 35-40% in fiscal 2021. Singapore, USA, Thailand, Indonesia, Europe are key export destinations for India. Salbutamol Sulphate, an anti-asthmatic therapeutic product, saw rise in demand in FY 2021 on account of rise in demand for anti-asthmatic drugs during COVID-19 pandemic. Exports of salbutamol Sulphate from India saw a rise of 75-80% in fiscal 2021, with major export destination being Singapore, USA, Thailand, China, Bangladesh, Germany and Indonesia. (HS code data from DGFT –29051420)
- Supriya Lifescience Ltd. contributed to 25-30% of exports of Vitamin B2 (riboflavin, lactoplavin) and its salts from India in FY2019 and FY 2020 in volume terms. Europe and USA are major export destination for India. Supriya Lifescience Ltd. is among the largest exporter of Riboflavin-5-phosphate sodium in India. . (HS code data from DGFT – 29362310)
- India has potential in export markets as low-cost quality supplier for pharmaceutical products as other global suppliers face high competition on pricing front because of high production costs.

7 Competitive landscape of Indian pharmaceutical industry

For the peer comparison section, CRISIL Research has considered listed and unlisted pharmaceutical companies involved in same line of business and having certain similar products as Supriya Lifesciences Limited. CRISIL Research has included mix of API manufacturing and formulation players to illustrate the player diversity in pharmaceutical industry. The formulation players having production of API for in-house consumption are also captured in the analysis. We have largely included listed players for the competitive assessment for availability of latest financial data.

7.1 Operational overview

Company Name	Incorporated year	Registered Office	Segments Present
Aurobindo Pharma Limited	1986	Hyderabad, India	Bulk drugs, Formulations, Contract Manufacturing
Divi's Laboratories Ltd	1990	Hyderabad, India	Generic bulk drugs, Contract manufacturing and Nutraceuticals
FDC limited	1940	Aurangabad, India	Formulations, Functional foods, API
Granules India Limited	1991	Hyderabad, India	Formulations, Bulk Drugs, Intermediates, Contract Manufacturing
IPCA laboratories Limited	1949	Mumbai, India	Bulk drugs and Formulations
Mangalam drugs and organics Limited	1972	Mumbai, India	Bulk drugs, Intermediates and Speciality chemicals
Supriya Lifescience Limited	2008	Mumbai, India	Bulk drugs and intermediates
Teva API B.V	1935	Petah Tikva, Israel	Bulk drugs
Unichem Laboratories Limited	1962	Mumbai, India	Bulk drugs, Formulations and Contract manufacturing
Wanbury Limited	1988	Thane, India	Bulk drugs and Formulations

Source: Company Website, CRISIL Research

Key manufacturing facilities and their approvals

Company Name	No of facilities	Location	Accreditation
Aurobindo Pharma Limited	16 (Formulation)	India, USA, Portugal and Brazil	FDA - US, MHRA - UK , TGA - Australia, MCC - South Africa, ANVISA - Brazil, Health Canada, WHO, GCC DR
	13 (API)	India	
Divi's Laboratories Ltd	2	Hyderabad, India	FDA - US,EU GMP, PMDA - Japan, MFDA - south Korea, COFEPRIS - Mexico
		Vishakhapatnam, India	FDA - US, MHRA - UK, TGA - Australia, COFEPRIS- Mexico, PMDA - japan, MFDA - south Korea
FDC limited	6	Roha, India	WHO, FDA - US
		Waluj, India	PICS,MHRA - UK, FDA - US, WHO
		Goa (I &II)	MHRA - UK, WHO, IDA - Netherlands
		Goa (III)	MHRA - UK, PPB-Kenya, NDA-Uganda, WHO
		Sinnar, India	UNICEF, W.H.O, MSF, FDA - Tanzania, PMPB - Malawi, Ethiopia and IDA - Netherlands.
		Baddi, India	WHO
Granules India Limited	3 (API)	Bonthapally, India	FDA - US, INFRAMED, EDQM, WHO GMP, ISO 14001, OHSAS 18001
		Jeedimetla, India	FDA - US, EDQM, COFEPRIS- Mexico, WHO GMP, HALAL
		Vizag, India	FDA - US , KFDA - Korea, EU GMP, WHO GMP
	3 (intermediates)	Gagillapur, India	FDA - US, COFEPRIS - Mexico, INFRAMED, TGA -Australia
		Jeedimetla, India	INFRAMED, HALAL
		Bonthapally, India	NA
	2 (Formulations)	Gagillapur, India	FDA - US, COFEPRIS - Mexico, INFRAMED, TGA -Australia
		Virginia, USA	NA
IPCA laboratories Limited	9 (Formulations)	Athal, India	MHRA - UK , TGA - Australia, WHO - Geneva, EU Certification by German Authority, Health Canada, GCC, MOH -Columbia, FDA - Ghana, MOH - Oman, NDA - Uganda, NHRA – Bahrain
		Ratlam, India	MCC-South Africa, INVIMA - Colombia, WHO-Geneva, State Administration of Ukraine, MOH - Belarus, NAFDAC- Nigeria, DIGEMID - Peru, FDA - Ghana, MOH - Tanzania, MOH - Russia, MCA - Zimbabwe, NDA - Uganda
		Kandla, India	MHRA - UK, MCC - South Africa, TGA - Australia, National Drug Authority (NDA) - Uganda, EU - GMP, Agency for Medicinal Products and Medical Devices (HALMED) –Croatia , TFDA - Tanzania, MCAZ - Zimbabwe ,ICHA - Ivory Coast, NAFDAC CGMP -Nigeria, GCC
		Silvassa, India	WHO - GMP, TGA - Australia, Health - Canada, Local FDA
		Dehradun,India	WHO-GMP, FDA - Ghana, NAFDAC – Nigeria, TFDA (Tanzania Food & Drugs Administration) , FDA-Uttarakhand
		Indore, India	MHRA - UK, Health - Canada, MCC - South Africa, TGA – Australia, WHO - GMP
		Sikkim, India	WHO - GMP
		Pithampur, India	WHO - GMP
		Tarapur, India	WHO-GMP NDA (Uganda), Pharmacy &Poisons Board- MOH (Nairobi, Kenya)
	8 (API)	Ratlam, India	TGA - Australia, EDQM, PMDA - Japan, WHO - Geneva, Health - Canada, EU-GMP (LaGesso, Berlin), MOH - Russia, MFDS - Korea, CDSCO- India, COFEPRIS- Mexico, EUWC
		Indore, India	WHO-Geneva, CDSCO- India, EUWC

Company Name	No of facilities	Location	Accreditation
		Ankleshwar, India	PMDA –Japan, CDSCO- India, COFEPRIS- Mexico, EUWC
		Nandeswari, India	CDSCO- India, EUWC
		Aurangabad, India	FDA - US, MOH - Russia, MFDS, CDSCO- India, EUWC
		Mahad, India	State FDA
		Ranu, India	CDSCO- India, COFEPRIS- Mexico, EUWC
		Boisar, India	USFDA, CDSCO- India, EUWC
Mangalam drugs and organics Limited	2	Vapi, India	NA
Supriya Lifescience Limited	2*	Ratnagiri, Mumbai	FDA – US , EU-GMP – AIFA(Italy), EDQM- Europe, TGA-Australia, ANVISA-Brazil, BfArM-Germany, KFDA-Korea, PMDA-Japan, CFDA/NMPA- China, COFFEPRIS- Mexico
Teva API B.V	NA	NA	NA
Unichem Laboratories Limited	3 (Formulations)	Goa, India	FDA - US, TGA Australia, TFDA Tanzania, MCC South Africa, ANVISA Brazil, NDA Uganda, MHRA UK, MHRF Russia, MCA Zimbabwe
		Baddi, India (Plant 1)	JAZMP - Slovenia, ANVISA - Brazil, NAFDAC - Nigeria, Ministry of Health - UAE,TFDA - Tanzania, NDA - Uganda, PPB - Kenya, MOH - Yemen, WHO GMP - India, FDA - Philippines, Ministry of Health - Cambodia, MOH - Oman, MHRA - UK,MCC - South Africa ,MCA - Zimbabwe, FDB - Ghana, MOH - Ukraine
		Baddi, India (Plant 2)	TFDA - Tanzania, ANVISA - Brazil, Ministry of Health - Cambodia, DPM - Ivory Coast, WHO GMP - India, NDA - Uganda, PPB - Kenya, MOH - Yemen, MOH - Oman, FDA - Philippines, NAFDAC - Nigeria, FMHAC - Ethiopia, MCAZ - Zimbabwe, FDA - Ghana
		Baddi, India (Plant 3)	MHRA-UK
		Ghaziabad, India	MHRA – UK,TFDA – Tanzania, TGA – Australia, FDA - USA, FDB – Ghana, FDA – Uttar Pradesh, MCC – South Africa
	3 (API)	Roha, India	FDA - USA,IMB,KFDA – South Korea, EDQM,PMDA - Japan, TGA - Australia, WHO GMP
		Pithampur, India	FDA – USA,WHO – India, KFDA – South Korea
		Kohlapur, India	FDA – USA,WHO – GMP
Wanbury Limited	2	Patalganga, India	FDA - US , EUGMP
		Tanuku, India	

Note: NA: Not Available

* - Ambarnath plant for Supriya Lifescience is currently WIP and is expected to be operational in fiscal 2022

Source: Company website, CRISIL Research

Major therapeutic areas

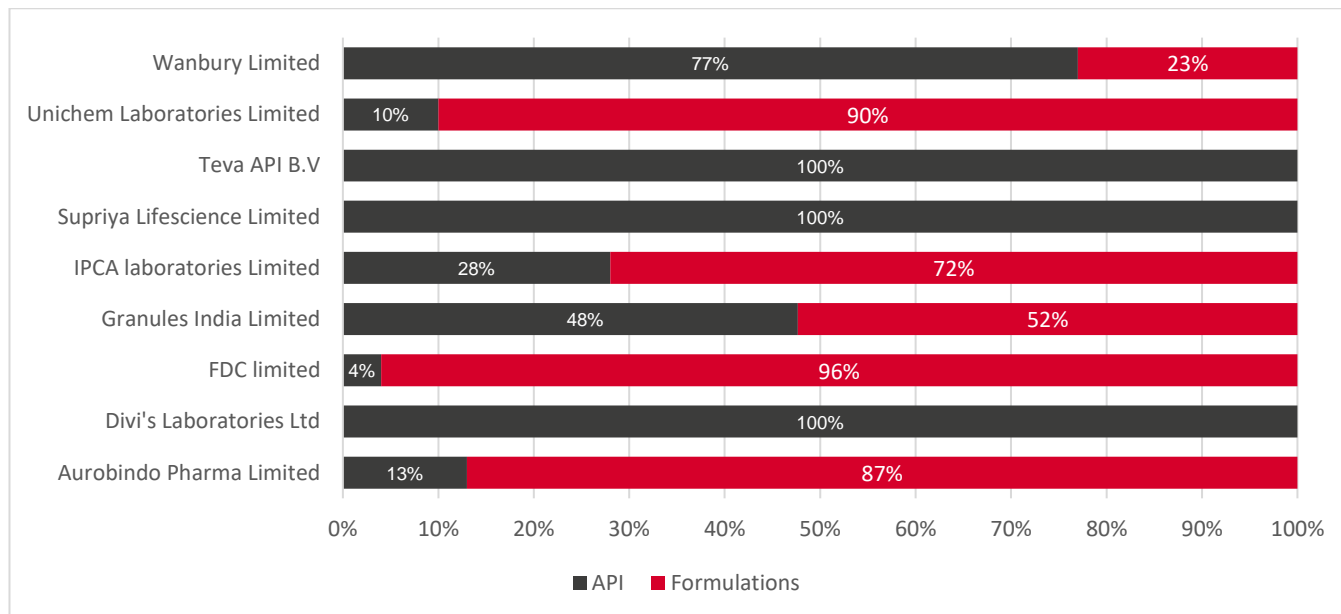
Company name	Description	Major therapeutic areas
Aurobindo Pharma Limited	<ul style="list-style-type: none"> Aurobindo Pharma Limited (APL) was founded in 1986. The company commenced operations in 1988-89 with a single unit manufacturing Semi-Synthetic Penicillin (SSP) at Pondicherry. Aurobindo Pharma became a public company in 1992 and listed its shares on the Indian stock exchanges in 1995. Aurobindo exports to over 150 countries across the globe with around 90% of revenues derived from international operations. 	Neurosciences (CNS), Cardiovascular (CVS), Anti-retroviral, Anti-diabetics, Gastroenterology and Anti-biotics
Divi's Laboratories Ltd	<ul style="list-style-type: none"> Divis Laboratories Limited was incorporated in the year 1990 and registered at Hyderabad. This company is publicly held. Promoters hold 52 percent of shares. Company is listed on Bombay Stock Exchange, National Stock Exchange. Group companies include 2 subsidiaries. Key business activities include chemical and chemical products, pharmaceuticals, medicinal chemical and botanical products contributing to 100 percent of turnover of company. 	Antineoplastic, Antiparkinson, Anti-Hypersensitive, Anti-Tussive, Analgesic, Neuropathic Pain, Contrast Medium, Anti-Inflammatory, Antiepileptic, and Anti-Viral
FDC limited	<ul style="list-style-type: none"> The company was incorporated as partnership firm in 1936 later got incorporated as private firm - Fairdeal Corporation (Private) Limited. In 1986, the name got changed to FDC limited. The company is listed on both National stock exchange and Bombay stock exchange. FDC markets more than 300 products in India and exports to more than 50 countries 	Anti-infective, Gastrointestinal, Vitamins/ Minerals/ Nutrients, Ophthalmology, Cardiac, Dermatology, Respiratory, Gynaecology
Granules India Limited	<ul style="list-style-type: none"> The company was initially incorporated as Triton Laboratories in the year 1984 and began operations by manufacturing paracetamol API. After getting incorporated as Granules India Pvt Ltd in 1991, the company went for IPO in 1995. To expand its operations into US markets, the company has formed a wholly-owned subsidiary - Granules USA Inc. In 2007, it also entered into a joint venture (JV) with Hubei Biocause Heilen Pharmaceutical Co Ltd in China. In July 2011, GIL started contract manufacturing operations by forming a 50:50 JV with Belgian firm Ajinomoto Omnicem. The company has presence in more than 75 countries 	Analgesic, Antipyretic, Anti-diabetic, Antifungal, Antihistamine, Antihypertensive, Anti-fibrotic, Anti-infective, Antiretroviral, Anti-ulcerative, Multiple sclerosis, Chelating agent, Mucolytic, Muscle Relaxant, Anticoagulant, Antibiotic, Anti-Thrombocytopenic, Contrast Agent, Antifungal, Antipsychotic, Antiplatelet, Nootropic, Phosphate binder, Anticonvulsant, Others
IPCA laboratories Limited	<ul style="list-style-type: none"> IPCA Laboratories Limited (Ipca) was set up in 1949, Ipca manufactures formulations, active pharmaceutical ingredients (APIs), and drug intermediates. The company is a leading supplier of APIs such as atenolol (antihypertensive), chloroquine and artemisinin derivatives (anti-malarial), furosemide (diuretic), and pyrantel salts (anthelmintic). 	Cardiovascular, Anti-diabetics, Pain Management, Anti-malarial, Anti-bacterial, Anthelmintics, Central Nervous System (CNS), Gastro Intestinal (G.I), Cough Preparations, Dermatology, Neuro Psychiatry, Others
Mangalam drugs and organics Limited		Anti-malaria, Anti-Retroviral, Anti-Hypertensive, Anti-Inflammatory, Anti-Convulsant, Anti-Viral, Anti-Rheumatic Arthritis Agent, Anti-Bacterial

Company name	Description	Major therapeutic areas
Supriya Lifescience Limited	<ul style="list-style-type: none"> Supriya Lifescience Limited (SLL) was set up in 1985 under the name 'Supriya Chemical' by Mr. Satish Waman Wagh. It was reconstituted as a closely held public limited company in 2008. The company manufactures bulk drugs and drug intermediates. Its manufacturing unit is located in Lote Parshuram and Chiplun, and is headquartered in Mumbai. 	Analgesic, Anti-Histamine, Anti-Hypertension Anti-Allergic, Vitamins Anti- Asthmatic, Pain Management
Teva API B.V	<ul style="list-style-type: none"> Established in 1935, Teva API BV is an international company with headquarters in Israel. The company is a standalone business unit of Teva Pharmaceutical Industries Limited. The company manufactures more than 350 active pharmaceutical Ingredients (API) with 15 production facilities and 6 R&D centers situated across the world. 	Allergology, Analgesic, Anesthetic, Angioedema, Bactericide, Cardiovascular, Coagulation Inhibitors, Dermatology, Diabetes, Endocrinology & Metabolism, Epileptic, Gastroenterology, Oncology, Genitourinary, Hematology, Immunology, Incontinence, Infectious Disease, Inflammation, Lipid Lowering, Liver Therapy, Migraine, Muscle Relaxant, Neurology - Psychiatry, Nocturia, Ophthalmology, Osteoporosis, Parkinson, Postpartum Haemorrhage, Preterm Labor Prevention, Prolactinoma Treatment, Psoriasis, Respiratory, Rheumatology, Urology
Unichem Laboratories Limited	<ul style="list-style-type: none"> Unichem Laboratories Limited was incorporated in the year 1962 and registered at Mumbai. This company is publicly held. Promoters hold 50 percent of shares. Key director shareholders of the company include Prakash Amrut Mody holding 46 percent of the shares. Company is listed on Bombay Stock Exchange, National Stock Exchange. Group companies include 5 subsidiaries, 1 associate. 	Cardiology, gastroenterology, diabetology, psychiatry, neurology, anti-bacterial, anti- infective and pain management.
Wanbury Limited	<ul style="list-style-type: none"> The company was incorporated in the year 1990 as pearl Distributors Pvt Ltd. Later, in the year 1991 the company went public with name changing to "pearl organics limited." After the merger of wander in 2004 the company changed its name to Wanbury Limited. The company caters over 50 countries with more than 13 API products and a portfolio close to 70 formulation brands. 	Anti-diabetic, Anti Analgesic, Anti-depressant, Anti Histaminic, Anti Inflammatory, Anti- Arthritis, Anti Thrombotic, Anti-epileptic, Anti- hypertensive

Note: NA: Not Available

Source: Company Website, Company annual reports, CRISIL Research

Segment wise revenue mix for fiscal 2020

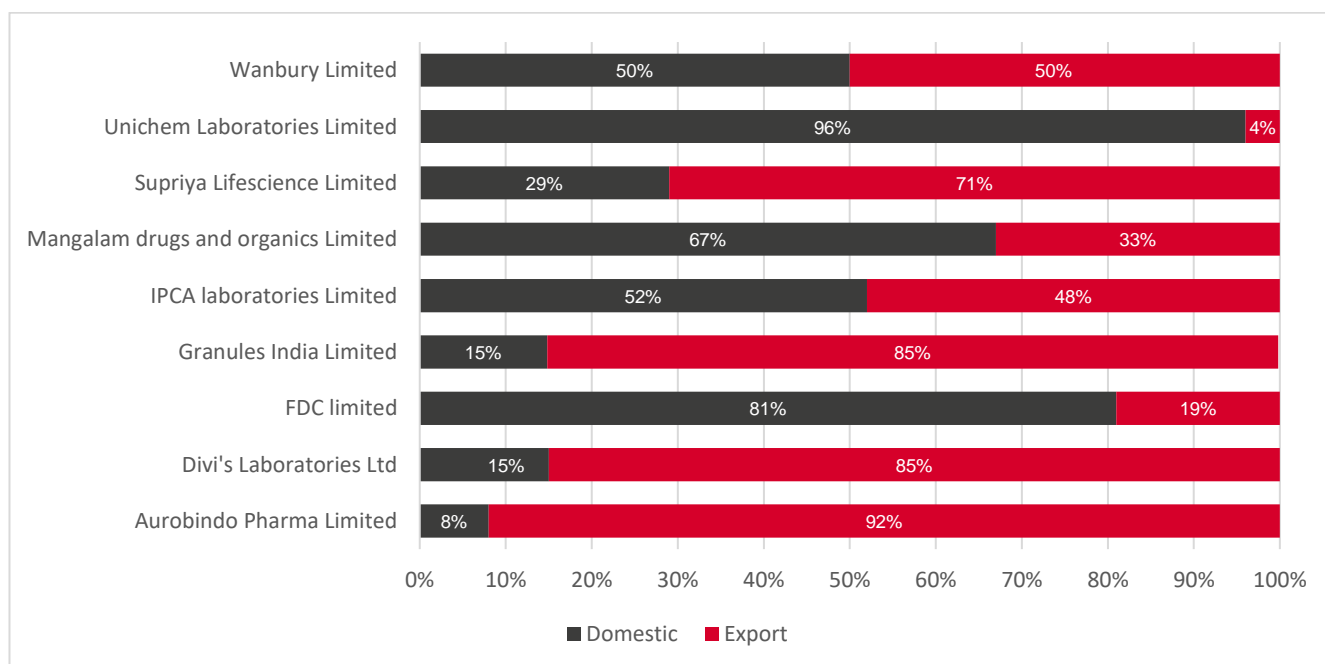


Note:

- Segmental breakup of revenue is not available for Mangalam Drugs and Organics Limited
- Divi's laboratories is involved in the production of API, Intermediates and Nutraceutical Ingredients

Source: Company annual reports, CRISIL Research

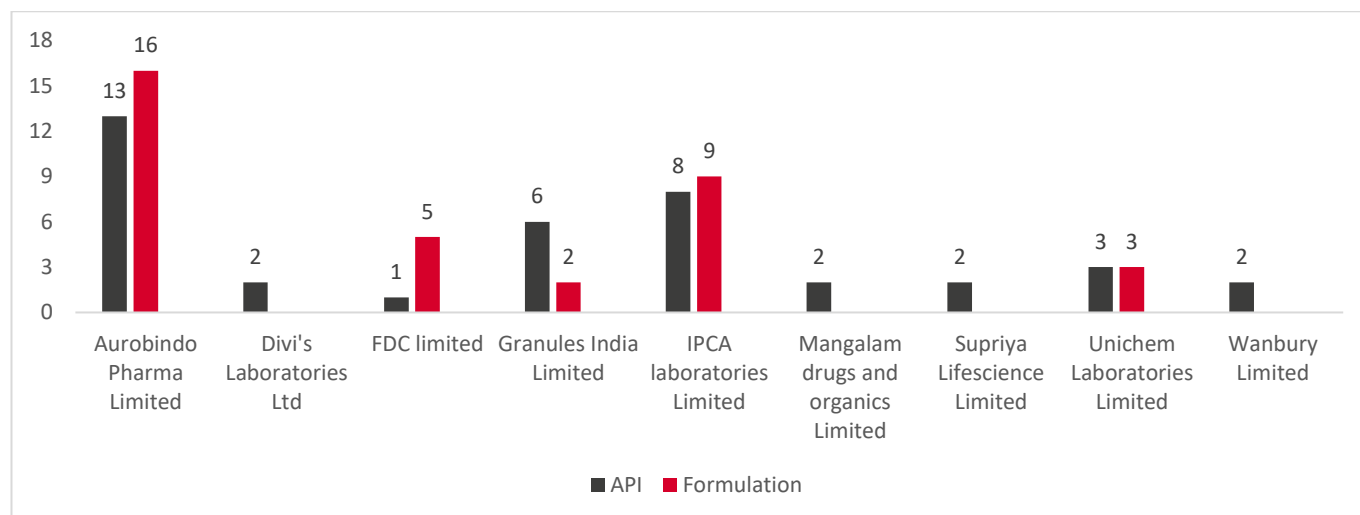
Geographical revenue mix for fiscal 2020



Note: Geographical mix is not available for Teva API BV

Source: Company annual reports, CRISIL Research

Key manufacturing facilities (number of manufacturing plants / locations)



Note: Data for Teva API BV is not available

Source: Company Website, Annual Reports, CRISIL Research

7.2 Financial Overview

Key financial ratios for listed players considered

Operating Income (In Million) for key players FY17-20

Operating Income (In Million)	Year Ending	Currency	FY17	FY18	FY19	FY20	3-Year CAGR
Aurobindo Pharma Limited	Mar	INR	149,396.2	165,465.4	196,432.0	231,374.8	16%
Divi's Laboratories Ltd	Mar	INR	40,681.5	38,938.2	49,479.8	53,985.2	10%
FDC limited	Mar	INR	10,114.2	10,735.4	10,889.2	13,414.4	10%
Granules India Limited	Mar	INR	14,153.2	16,846.2	22,792.0	25,986.5	22%
IPCA laboratories Limited	Mar	INR	31,518.0	33,148.4	37,814.0	46,561.2	14%
Mangalam drugs and organics Limited	Mar	INR	3,003.6	2,760.7	2,278.3	2,826.8	-2%
Supriya Lifescience Limited	Mar	INR	1,875.1	2,173.5	2,818.2	3,200.2	20%
Teva API B.V (USD)	Dec	USD	356.4	375.8	411.8	N.Av	N.Ap
Teva API B.V	Dec	INR	26,427.3	27,864.5	30,530.8	N.Av	N.Ap
Unichem Laboratories Limited	Mar	INR	15,195.0	8,180.0	11,800.5	12,106.2	-7%
Wanbury Limited	Mar	INR	4,332.8	3,706.6	3,913.7	3,674.5	-5%

Note:

- N.Av: Not Available
- N.Ap: Not Applicable
- 1 USD = 74.1429 INR

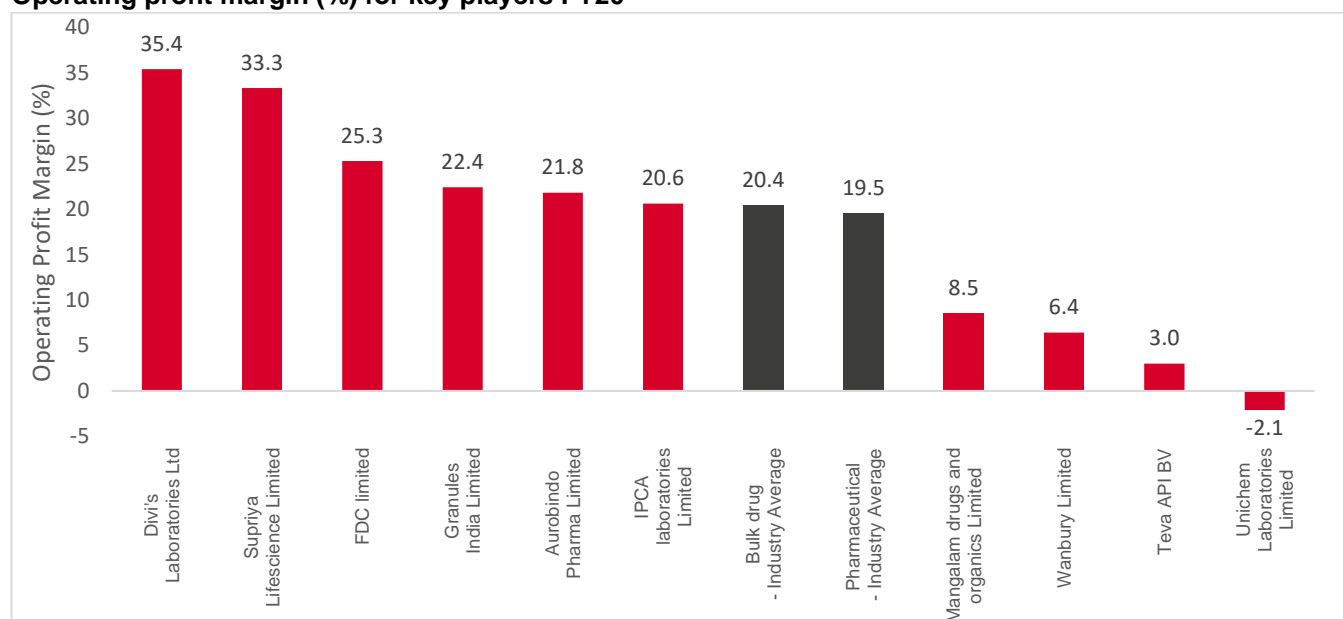
Net Profit (In Million) for key players FY17-20

Net profit (In Million)	Year Ending	Currency	FY17	FY18	FY19	FY20	3-Year CAGR
Aurobindo Pharma Limited	Mar	INR	23,011.9	24,229.1	23,645.0	28,295.2	7%
Divi's Laboratories Ltd	Mar	INR	10,604.2	8,770.1	13,527.4	13,765.4	9%
FDC limited	Mar	INR	1,885.3	1,735.1	1,697.9	2,398.8	8%
Granules India Limited	Mar	INR	1,645.2	1,325.9	2,364.1	3,354.0	27%
IPCA laboratories Limited	Mar	INR	1,945.4	2,394.2	4,422.2	6,035.6	46%
Mangalam drugs and organics Limited	Mar	INR	222.8	198.9	-80.3	82.5	-28%
Supriya Lifescience Limited	Mar	INR	54.7	113.0	398.1	711.1	135%
Teva API B.V (USD)	Dec	USD	4.6	8.4	12.5	N.Av	N.Ap
Teva API B.V	Dec	INR	341.2	622.3	930.0	N.Av	N.Ap
Unichem Laboratories Limited	Mar	INR	1,086.8	25,449.1	-238.0	-601.8	-182%
Wanbury Limited	Mar	INR	620.1	-320.1	-248.5	644.6	1%

Note:

- N.Av: Not Available
- N.Ap: Not Applicable
- 1 USD = 74.1429 INR

Operating profit margin (%) for key players FY20

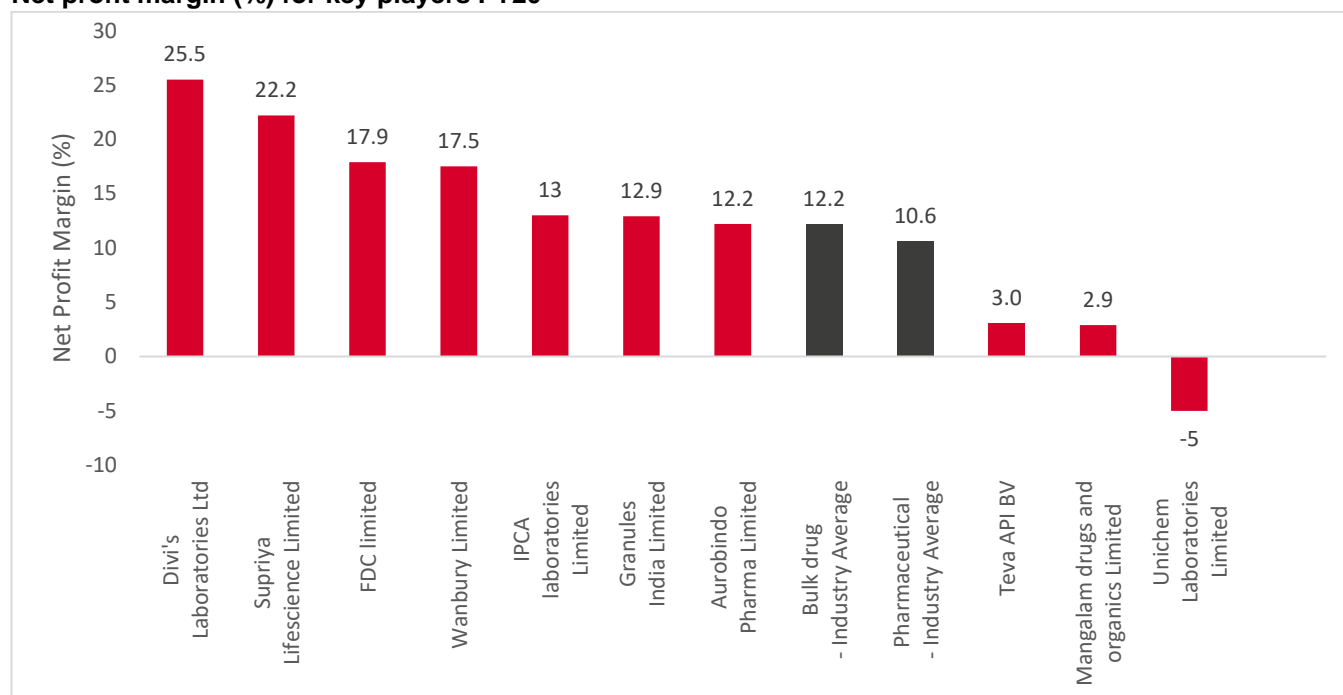


Note:

- Value for Teva API BV is as of December,2019
- Refer to annexure for list of companies included in Bulk drug – industry and Pharmaceutical – Industry averages

Source: Company annual reports, CRISIL Research

Net profit margin (%) for key players FY20

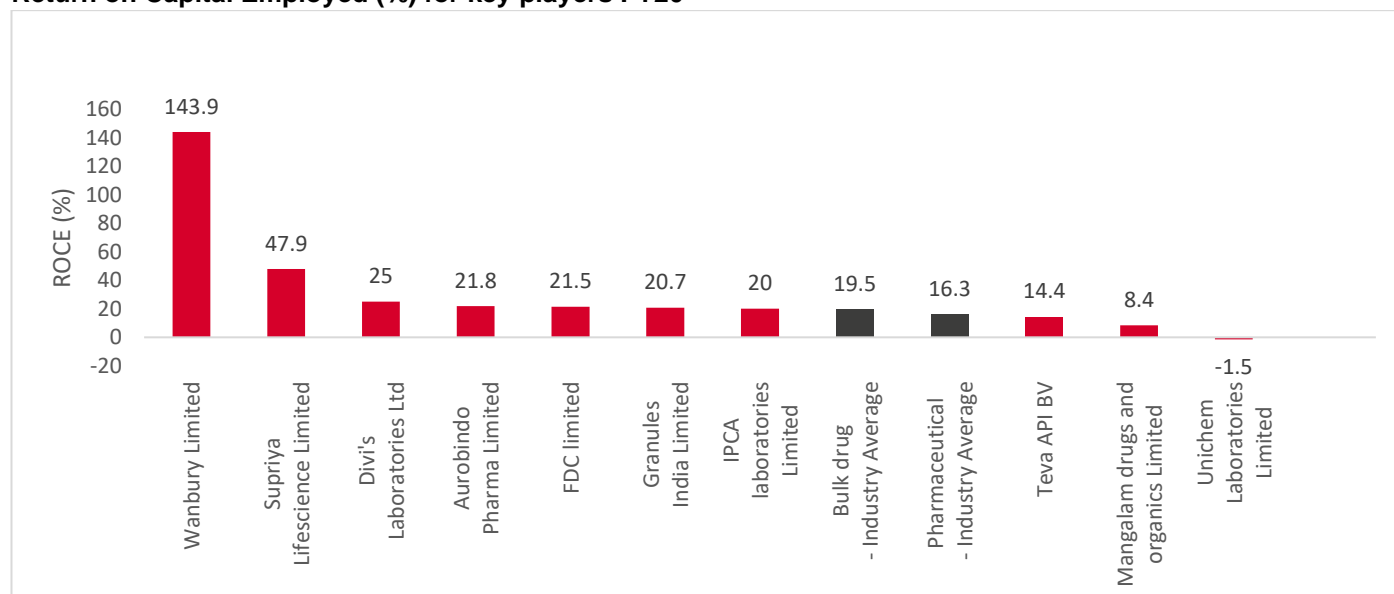


Note:

- Value for Teva API BV is as of December,2019
- Refer to annexure for list of companies included in Bulk drug – industry and Pharmaceutical – Industry averages

Source: Company annual reports, CRISIL Research

Return on Capital Employed (%) for key players FY20

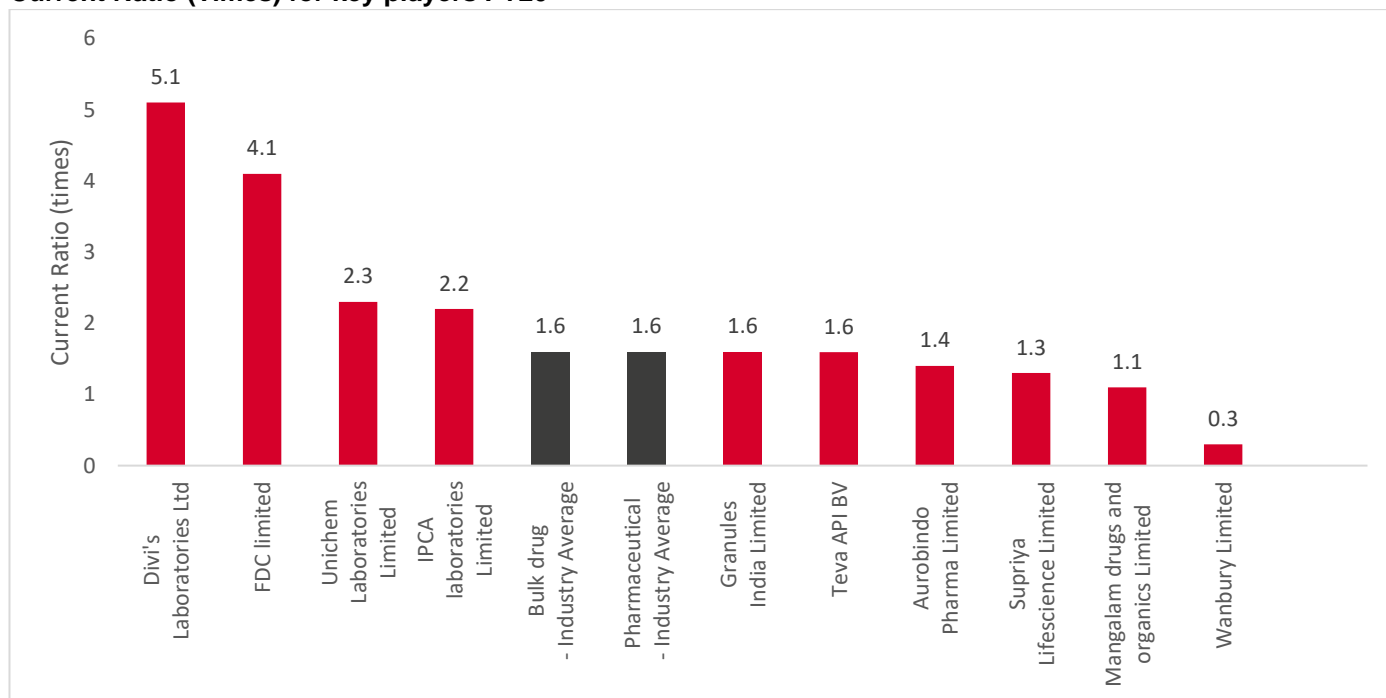


Note:

- Value for Teva API BV is as of December,2019
- Refer to annexure for list of companies included in Bulk drug – industry and Pharmaceutical – Industry averages

Source: Company annual reports, CRISIL Research

Current Ratio (Times) for key players FY20

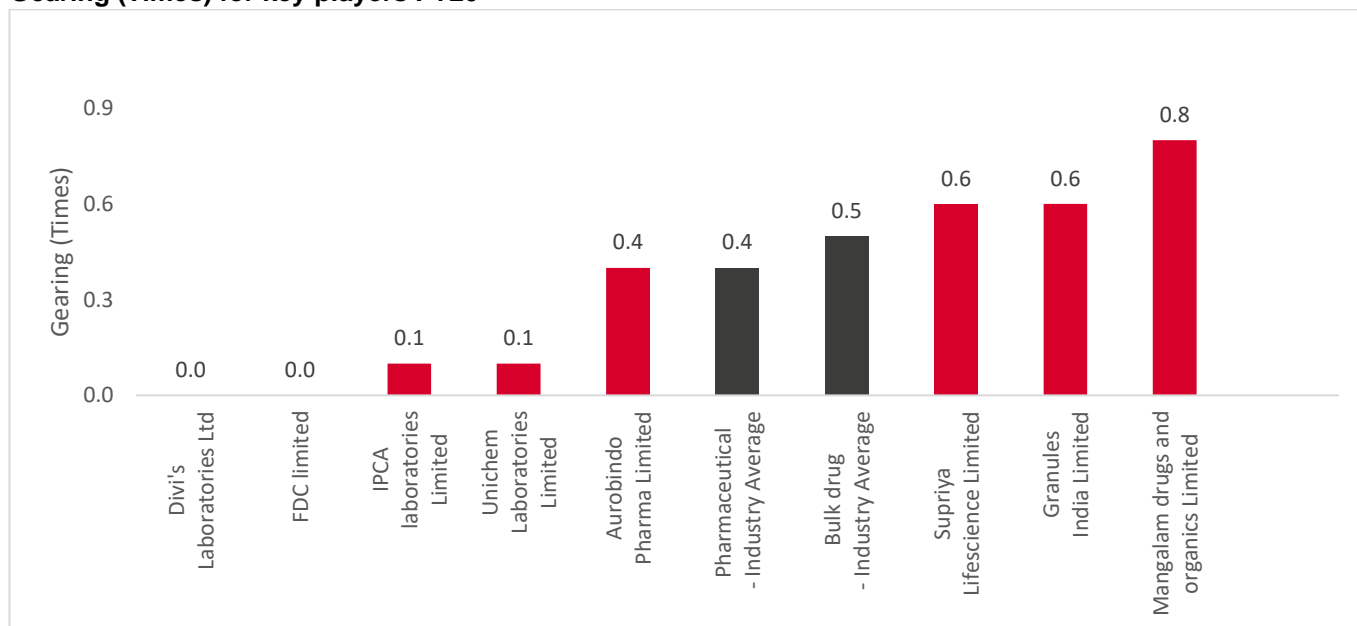


Note:

- Value for Teva API BV is as of December,2019
- Refer to annexure for list of companies included in Bulk drug – industry and Pharmaceutical – Industry averages

Source: Company annual reports, CRISIL Research

Gearing (Times) for key players FY20

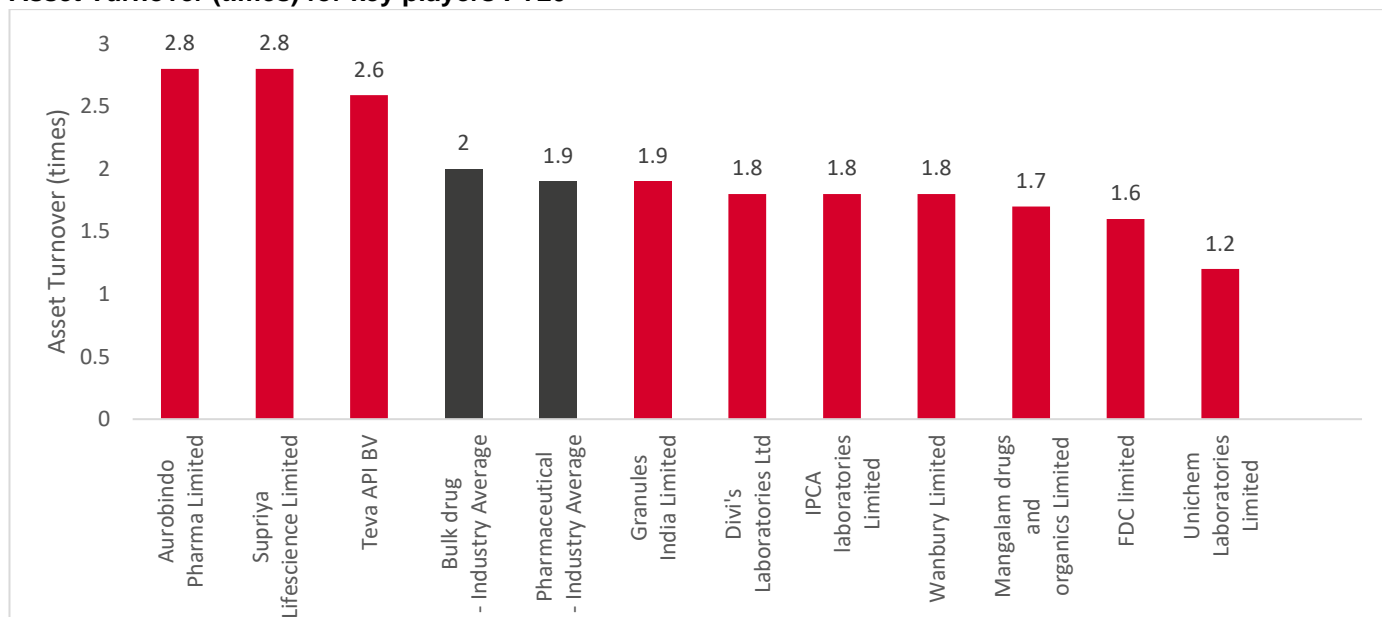


Note:

- Wanbury Limited are not considered due to negative gearing ratio
- Data for TEVA API BV is not available
- Refer to annexure for list of companies included in Bulk drug – industry and Pharmaceutical – Industry averages

Source: Company annual reports, CRISIL Research

Asset Turnover (times) for key players FY20

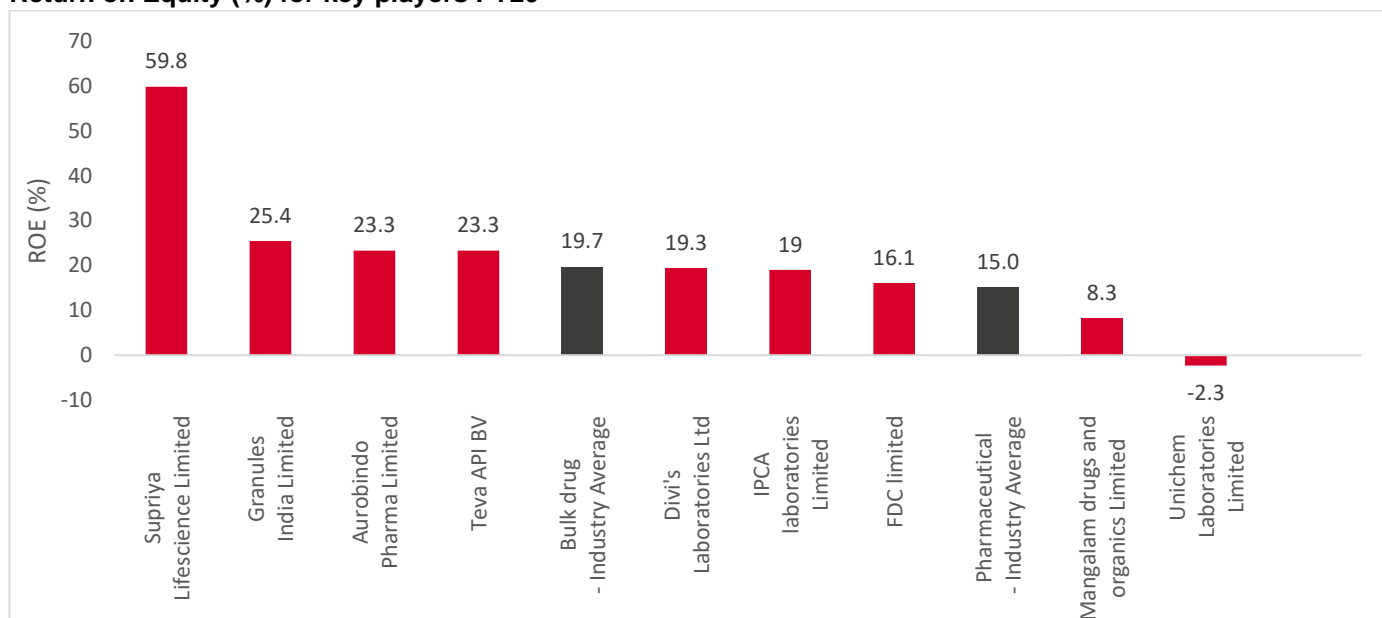


Note:

- Value for Teva API BV is as of December, 2019
- Refer to annexure for list of companies included in Bulk drug – industry and Pharmaceutical – Industry averages

Source: Company annual reports, CRISIL Research

Return on Equity (%) for key players FY20

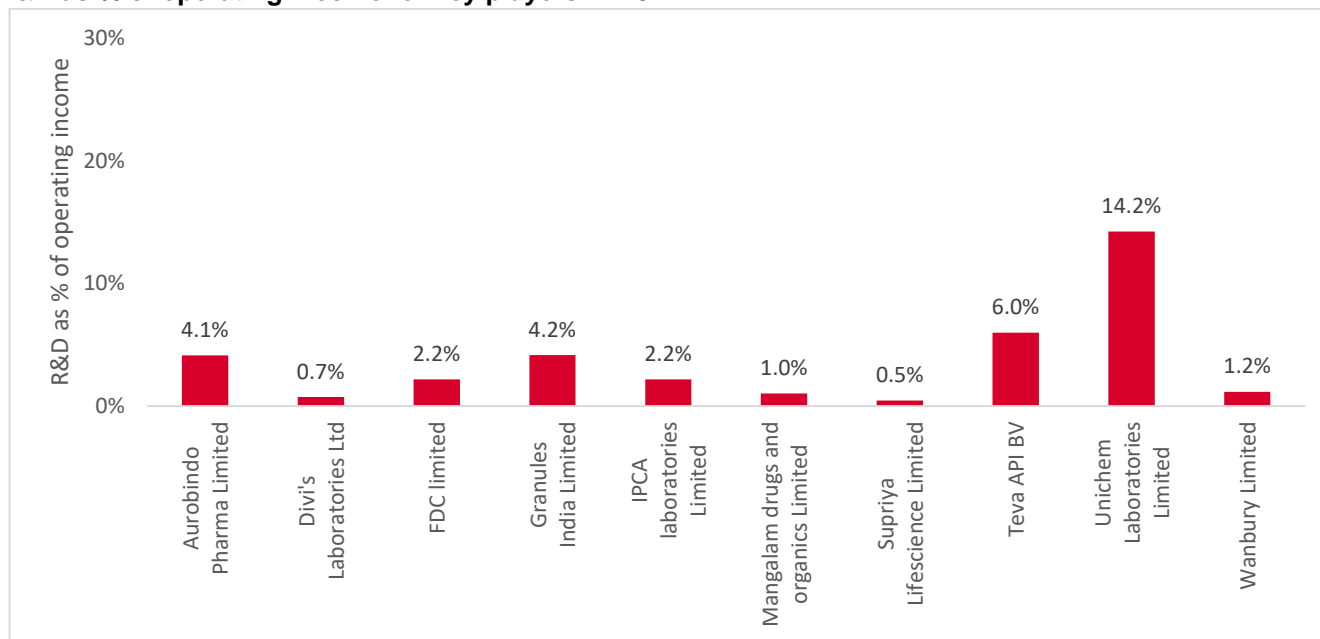


Note:

- Value for Teva API BV is as of December, 2019
- Wanbury limited is not considered due to negative tangible network
- Refer to annexure for list of companies included in Bulk drug – industry and Pharmaceutical – Industry averages

Source: Company annual reports, CRISIL Research

R&D as % of operating income for key players FY20

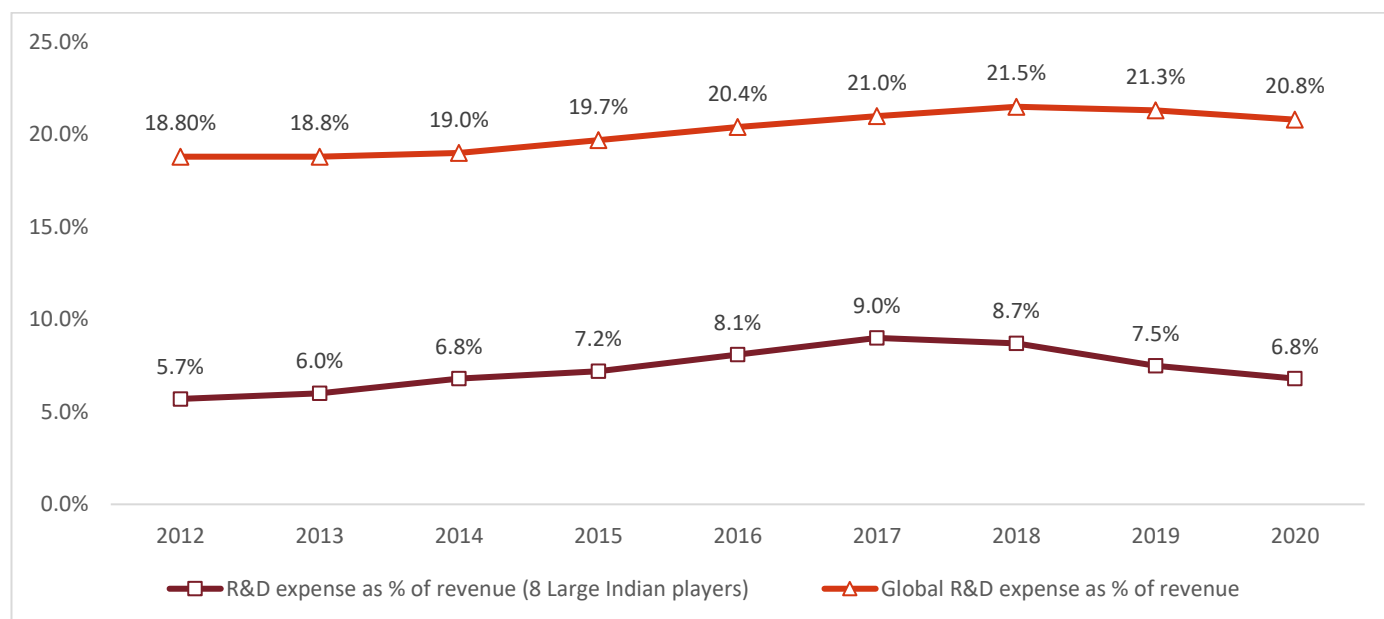


Note:

- Value for Teva API BV is as of December, 2019 and represents R&D of Teva Pharmaceuticals (Parent Company) as % of its operating income

Source: Company annual reports, CRISIL Research

R&D as % of operating income for 8 large MNC players in India vs global large pharma players



Note: R&D numbers are set of eight large players

Source: Company filings, CRISIL Research

Key Observations:

- For fiscal 2020, Supriya Lifescience Limited has recorded an operating income of Rs. 3,200 Million with a compounded annual growth rate (CAGR) of ~20% from FY17 to FY20
- For fiscal 2020, Supriya Lifescience Limited has recorded net profit of Rs. 711.1 Million with highest compounded annual growth rate (CAGR) of 135 % from FY17 to FY20 among the peers considered. Its net profit margins increased from 2.9% in FY17 to 22.2% in FY20 supported by decline in raw material and inventory cost. Supriya Lifescience operating margins improved from 11.8% in FY2017 to 33.3% in FY20
- Among the peers compared above, for fiscal 2020, Supriya Lifescience reported operating profit margin of 33.3% which is higher than bulk drug industry average of 20.4% and pharmaceutical industry average of 19.5% for the same period.
- Supriya Lifescience Ltd, in fiscal 2020 recorded net profit margin of 22.2% among the pharma players considered above. The company recorded higher net profit than the bulk drug industry average of 12.2% and pharmaceutical industry average of 10.6% for fiscal 2020
- For fiscal 2020, bulk drug players such as Wanbury Limited and Supriya Lifescience Limited record higher ROCE among peers compared above. However, Wanbury Limited has higher RoCE due to extraordinary income occurred during the fiscal 2020.
- Supriya Lifescience limited has recorded a RoCE of 47.9% greater than the bulk drug industry average of 19.5% and pharmaceutical industry average of 16.3% for fiscal 2020. In terms of current ratio, Supriya Lifescience Limited (1.3 times) is positioned below the bulk drug industry average and pharmaceutical industry average of 1.6 times respectively.
- In terms of asset turnover, Supriya Lifescience Limited (2.8 times) stands at a comparable level with pharma players such as Aurobindo Pharma Limited and Teva API BV.
- Supriya Lifescience Limited, for fiscal 2020, in terms of Return on Equity (RoE) positions itself higher than the bulk drug industry average of 19.7% and pharmaceutical industry average of 15%.
- Supriya Lifescience Limited with R&D spending 0.5% of operating income for fiscal 2020, has lower R&D spends among the peers considered above
- The average industry spending on R&D among the Indian players is estimated at 6.8% of operating income in FY20 as compared to 20.8% R&D spending by global pharmaceutical companies

8 Annexure

8.1 Overview of regulated pharmaceutical country list

Australia
Austria
Belgium
Bulgaria
Canada
China
Cyprus
Czech Republic
Democratic People's Republic Of Korea
Denmark
Finland
France
Germany
Greece
Hungary
Indonesia
Ireland
Italy
Japan
Netherland
New Zealand
Poland
Portugal
Romania
Singapore
Spain
Sweden
Switzerland
United Kingdom
United States Of America

Note: The above mentioned countries and European Union nations are considered as regulated pharmaceutical markets while the rest of the countries would be semi-regulated or non-regulated markets.

8.2 Evolution of the Indian pharmaceutical industry

The evolution of the Indian pharmaceutical industry can be broadly divided into two periods, the pre-patent regime and post-patent regime. In the pre-patent regime (before 2005), India recognised only process patents. In 2005, India entered the product patent regime which marked the end of a protected era and signaled a new phase in the integration of India players into the global market.

The evolution of the pharmaceutical industry majorly depends upon the regulations and policies that govern the industry. These regulations play a major role in influencing the performance & profitability of pharmaceutical companies and in turn, the industry as a whole. Before 2005, the Indian regulatory system recognised only process patents (patents given on the basis of the process of production of a pharmaceutical drug). This helped build a firm foundation for the strong and competitive domestic pharmaceutical industry. During this phase, the prevalent price control mechanisms helped companies deliver medicines at affordable prices, to patients across India. In January 2005, the Indian government passed an ordinance to introduce the product patent regime in line with its commitments to the WTO.

The evolution of the pharmaceutical industry can be broadly divided into:

Pre-patent phase (till 2005) and

Post-patent phase (post 2005)

This chapter lists the different phases that the Indian pharmaceutical industry has gone through, during the pre-patent (till 2005) and post-patent (post 2005) regimes.

Pre-patent regime (before 2005)

Process patents helped the Indian pharmaceutical sector flourish, amid a fast growing generics industry. During this regime, multinational companies (MNCs) were reluctant to directly introduce new products in India. Domestic companies leveraged this situation, by re-engineering these products and marketing them in India.

Up to 1970

In the 1950s, the government realised the need to set up indigenous drug production facilities in India, to minimise dependence on imports and enable access to essential drugs at lower prices. To fulfill this objective, the government set up the Hindustan Antibiotics Limited in 1954 and Indian Drugs and Pharmaceuticals Limited (IDPL) in 1961. Soon, these companies established themselves as major producers of critical drugs, such as penicillin and other antibiotics, which were being imported at that time.

Despite these initiatives, MNCs dominated the domestic market until 1970. In 1970-71, the size of the Indian pharmaceutical industry was at around Rs 4,000 million. Lower income levels restricted Indian consumers' per capita spending on healthcare. Further, the market was small in size and vital drugs needed to be sourced largely through imports. Even as there were over 2,000 players in the domestic industry, MNCs largely dominated the industry, by importing formulations from their parent companies and selling them in India.

1970 to 1979

To speed up the indigenisation process and boost self-reliance of the domestic pharmaceutical industry, the government introduced two landmark regulations in 1970, as follows:

Indian Patent Act, 1970

The Indian Patent Act aimed at encouraging domestic players to manufacture drugs and ensure self-sufficiency in medicines. The Act granted patents, based on the process of manufacturing, as against the global practice of granting patents, based on the new drug alone. As a result, several Indian players began manufacturing products, based on the same bulk drug, yet through different processes. This strengthened domestic players' process chemistry skills and increased their expertise in developing low-cost generic drugs.

Drug Price Control Order (DPCO), 1970

The DPCO governed prices of all bulk drugs and formulations, to ensure widespread availability of medicines, at reasonable prices. Together, the Indian Patent Act and the DPCO, significantly influenced the structure and growth pattern of the domestic pharmaceutical industry.

Decline in share of MNCs

Introduction of these regulations caused great dismay among MNCs, who were left with little incentive to introduce new products in India. They shifted their focus towards vitamins, cough preparations, NSAIDs (pain killers) and eventually built up a strong brand equity in these products. Hence, it is not surprising that the share of multinationals in total production of formulations began to decline after 1970. Further, the Foreign Exchange Regulation Act (FERA), 1974 was introduced, which required all multinationals to dilute their equity holdings. A combination of all these factors led to a dramatic reduction in MNCs' share in total industry production.

Growth of small-scale units

At the same time, the number of domestic small-scale units increased rapidly, due to following reasons:

Low-entry barriers (a formulations unit could be set up for Rs 120-150 million)

Abundant availability of bulk drugs

Numerous incentives, such as waiver of price control on drugs produced by them, offered to SSIs

A vast, geographically dispersed market.

Additionally, several large producers began outsourcing production to small units (under the loan licensing scheme) to contain costs, which further encouraged growth of SSIs.

1979 to 1987

Nine years after implementing the DPCO, the government lowered the number of products under price control to 163 from 347, in 1979. In addition, the government permitted a higher mark-up on the cost of production - from 40-60 per cent in 1970, to 75-100 per cent in 1979. During this period, bulk drug production also increased, due to a surge in export demand.

Spread of research know-how

Sales of Indian pharmaceutical companies, such as Cipla, Ranbaxy, Lupin and Torrent, rose significantly during this period. Drawing upon the process patent regime and availability of skilled research personnel, some players gradually began investing in research activities and introduced new products, through process re-engineering. For instance, Lupin Laboratories introduced Rifampicin in 1980; Torrent launched Ranitidine in 1985 and Dr Reddy's introduced Norfloxacin in 1987. Government research institutes, such as Central Drug Research Institute (CDRI) and Council of Scientific and Industrial Research (CSIR), also contributed to the gradual build-up of the indigenous research base.

Not to be left behind during this growth era, smaller players also capitalised on the manufacturing knowledge base, created by IDPL and Hindustan Antibiotics.

Bulk drug production increases

The DPCO further regulated the production pattern of pharmaceutical companies, by fixing a ratio between the amount of formulations and bulk drugs produced by companies. This led to a spurt in investments in production of key bulk drugs, such as antibiotics and cardiovascular drugs, thereby increasing their production.

Market share of multinationals continued to slide

As domestic players gained expertise, the share of MNCs in total production continued to slide. Most formulations that MNCs imported and distributed in India, had a limited market. This was because of the high tariff structure which made them costlier. MNCs were unable to match the low prices offered by Indian producers, who were more cost-competitive. MNCs, therefore, continued to focus on select therapeutic groups, such as cough preparations, analgesics and vitamins (Inadequate patent protection deterred them from new product launches).

Indian players leveraged the opportunity to widen their exports

After creating a niche for themselves in the domestic market, several Indian players such as Ranbaxy, Lupin, Torrent and Dr Reddy's, turned their sights towards exports. They initiated steps to capitalise on their technical skills of reverse engineering and their low-cost structure, to tap overseas markets. Consequently, the share of exports in total bulk drug production soared to 19 per cent in 1986-87, from 5 per cent in 1980-81.

1987 to 1994

Domestic players continued to build on their strengths, in the late eighties and the early nineties. During 1987 to 1994, production of formulations posted a CAGR of 18 per cent per annum, compared to 10 per cent CAGR during 1980-1987. Sharp rise in the number of new drugs introduced and low prices boosted growth. Further, rising per capita income levels encouraged people to spend more on modern allopathic drugs.

Growth in bulk drugs driven by exports

Bulk drug production also continued to increase during 1987-1994, led by higher exports. Total bulk drug production registered a CAGR of 16 per cent and bulk drug exports grew at a CAGR of 40 per cent. By 1994, bulk drug exports accounted for nearly 50 per cent within the total bulk drug production.

Increased investments

To meet the ever-growing demand for drugs, investments in new capacities (largely driven by Indian players), increased to nearly Rs 13,800 million in 1994-95 from Rs 7,000 million in 1986-87.

Renewed interest from multinationals

MNCs considered the liberalisation programme, initiated by the Narasimha Rao government in 1991, as a major turning point. Key reforms included reduction in tariff barriers and relaxation of FERA regulations. This restored MNCs' confidence to an extent and encouraged greater foreign investment in the domestic pharmaceutical industry. Most multinationals attempted to curb costs by relocating plants and retrenching the work force and also quickened the pace of new product launches.

Exceptions included Sara Lee (which held a stake in Nicholas Laboratories in India) and Switzerland-based Roche, who sold their Indian operations to the Piramal Group in 1987 and 1993, respectively.

Growth of Indian producers

Reforms also benefited Indian producers, who were able to introduce more bulk drugs (due to increased imports of bulk drug intermediates), because of lower tariff and non-tariff barriers. Domestic players also made efforts to widen their global presence, by setting up branch offices and subsidiaries abroad.

Increased competition

The surge in demand intensified competition in the industry. The number of manufacturing units rose to over 20,000 units in 1994, from an estimated 10,000 units in 1987. Most new producers introduced brands in large-sized and fast-growing categories, such as antibiotics, NSAIDs and cough preparations. Hence, the number of competing brands, within a single category, soared to over 100 in many cases.

1995 to 2001

In 1995, the government further amended the DPCO, by lowering the number of drugs under price control from 146 to 74. According to CRISIL Research's estimates, the market share of drugs covered by price control norms, declined from 70 per cent in 1987-88 to 52 per cent in 1997, and further, to 40 per cent in 2001. One of the key developments in 1995 was the government's decision to adhere to the product patent regime from 2005 onwards, as a member of the World Trade Organisation (WTO).

Increased interest of multinationals

The government's commitment to recognise product patents in drugs after 2005, rekindled MNCs' interest in the domestic market. Parent companies of several multinationals began increasing their equity stakes in their Indian operations. For instance, Sanofi-Torrent and Eli Lilly-Ranbaxy purchased the equity stake of their Indian partners, to increase their presence in the domestic market. Low production costs also drew MNCs' attention towards India. Thus, at a time when most MNCs were on a cost-cutting spree, India was increasingly seen as a cost-effective market and an alternative manufacturing base. (Globally, multinationals were shutting down facilities that were economically unviable and relocating plants to low-cost countries).

The heightened pace of consolidation in the international market also affected the structure of the domestic pharmaceutical industry. Despite low growth in sales, the ranking of multinationals in the Indian market improved, due to mergers taking place in international markets.

Indian producers leverage on their strengths

India's commitment to recognise product patents limited Indian producers' ability to reverse engineer international proprietary drugs. On the flipside, since several Indian producers had already achieved a critical mass in terms of size of operations, they turned their focus towards their global operations.

To strengthen their presence in both, domestic and international markets, Indian producers have followed a number of strategies, which comprise:

Setting up manufacturing and marketing joint ventures abroad

Building world-class production facilities for bulk drugs, to tap the fast growing market for generic drugs in developed countries

Entering into alliances with multinationals for new drug launches

Conducting clinical trials in India, to help multinationals reduce development costs of new drugs

Strengthening their brand (and market) franchises

Significantly expanding their geographical reach within India.

Growth, profitability and competition

Between 1995 and 1997, demand in the pharmaceutical industry continued to grow by over 15 per cent. However, due to intense competition in the domestic bulk drugs segment, many producers began to market generic formulations, especially in the alimentary and anti-infective segments. To better compete with smaller players on the basis of prices, large domestic formulation manufacturers increased their focus on generic-generic formulations. These formulations are sold under the bulk drug name, and have lower price realisations, compared to branded formulations. Rising share of low-priced, generic-generic drugs led to a decline in growth of the pharmaceutical industry, in value terms, to 10-12 per cent over the past 2-3 years, from around 15 per cent in 1996-97.

There was growing pressure to introduce new products at affordable prices, for ensuring reasonable volumes. However, newer products, which were generally priced higher than older drugs, helped boost profitability of Indian pharmaceutical companies despite stiff competition. Operating margins of domestic players increased to 21.6 per cent in 2001-02, from 20.9 per cent in 1996-97.

Increased competition in the domestic market, especially in large and old products, affected margins of bulk drug producers heavily. In order to maintain profitability, many of them have forward integrated into manufacturing formulations. Large bulk drug producers have also increased exports of new molecules to semi-regulated markets, which offer relatively higher margins.

2001-2004

During 2001-04, domestic formulation sales continued to decline, except for few segments. While Indian players continued to use new drugs to drive their domestic sales, their greater focus on generic markets became apparent. Several players invested in research and development (R&D) activities and upgraded their manufacturing facilities, to comply with current good manufacturing practices (cGMP) norms.

This was, in part, encouraged by huge success recorded by Dr Reddy's Laboratories and Ranbaxy, with respect to their drugs - fluoxetine and cefuroxime axetil, respectively. The government's move to further amend the Patents Act, to consider drugs under "inventions" as eligible for patent protection, further forced Indian players to seriously mull over the generic markets option.

On the other hand, the government's move on product patents and its decision to grant exclusive marketing rights (EMRs) heightened MNCs' interest in the domestic market.

Post-patent regime

In line with its commitments to the WTO, the Indian government passed an ordinance to introduce the product patent regime w.e.f. January 2005. This aided the integration of India into the global pharmaceutical market and rendered duplicating of post-1995 patented drugs illegal. While this discouraged process re-engineering of products patented post 1995, the amendment aimed at gradually enhancing confidence of large global players on Indian companies.

In 2005, the Indian pharmaceutical industry witnessed a series of regulatory developments, ranging from the implementation of value added tax (VAT), shift from excise duty levy to an MRP-based levy system and Schedule M implementation to recognise the product patent regime. While implementation of the VAT and shift in the excise duty regime had short-term implications, the implementation of Schedule M (compliance with tenets of cGMP) and adherence to the product patent regime will have medium and long-term implications, respectively.

Enactment of product patent regime

India entered the product patent regime on January 1, 2005. This marked the end of a protectionist era and better integrated India with the global pharmaceutical market.

While the earlier process patent regime helped the Indian pharmaceutical industry develop into a world-class generics industry, the product patent regime aimed at encouraging new drug discoveries over the long-term. Traditionally, pharmaceutical MNCs had maintained a low-key presence in the Indian market, due to the absence of product-based patents and rigid price controls. Hence, the recognition of product patents will gradually boost confidence levels, placed by large global players on India.

From January 2005 till date, India has seen a handful of patented product launches. Pfizer has launched three of them, while Roche and GSK launched two and one, respectively. The launch of patented products in India has been slow as innovators are taking their time, to seek clarity on data protection, patenting of derivatives and pre- and post-grant opposition. While not much has changed on this front, MNCs' approach towards the domestic market is slowly changing.

Rising focus on exports

India gained a foothold on the global arena, with innovatively-engineered generic drugs and active pharmaceutical ingredients (API). The country now seeks to become a major player in outsourced clinical research and the contract research and manufacturing services (CRAMS) segments. India has the highest number of manufacturing facilities (332 sites) approved by the US Food and Drug Administration (US FDA). Further, in 2011, one-third of all Abbreviated New Drug Applications (ANDA) approved by the US FDA, belonged to Indian companies.

Implementation of Schedule M

The mandate issued to small-scale pharmaceutical units, necessitated compliance with the Schedule M norms. Schedule M of the Drugs and Cosmetics Act outlines various requirements for manufacturing good quality drugs and pharmaceuticals, by applying cGMP.

Affixing of prices by NPPA

The government fixed prices of nine commonly used drugs, in cases where it was noticed that companies have increased prices for no legitimate reason. As a result, pharmaceutical companies will no longer be able to increase medicine prices, at their discretion.

Major companies were asked to revise drug prices to levels fixed by the National Pharmaceutical Pricing Authority (NPPA). The regulator directed companies to make relevant changes in their maximum retail prices (MRPs). Drugs, which have come under the scanner, cater to major therapeutic areas, such as diabetes, cardio-vascular, allergies and infections.

In 2019, the Department of Pharmaceuticals proposed to rationalize the trade margins on drugs in order to bring down the prices. The trade margin is the difference in price at which the importers/manufacturers sell to stockists and the price at which drug is sold to the consumers. According to the proposal 43% trade margins should be applied to non-scheduled drugs. This followed the government move of capping the trade margins of 42 cancer drugs at 30% in April 2019.

New Drugs (Prices Control) Order (DPCO),2013

Prior to the 2013 regime, the DPCO 1995 included 74 bulk medicines within its ambit and the pricing of the drugs were fixed on the basis of manufacturing costs declared by the drug manufacturers. The new DPCO 2013 empowers the National Pharmaceutical Pricing Authority (NPPA) to regulate prices of 348 essential drugs under the National List of Essential Medicines (NLEM) through market based pricing. The prices are fixed at the weighted average price of brands that have more than 1% share. The NPPA keeps adding drugs to the NLEM, with over 900 drugs under price control so far

Fixed Dose Combination (FDC) ban, 2018

The Union Health Ministry banned 325 fixed-dose combination (FDC) drugs, following the recommendations of DTAB, which found that the combinations lacked "therapeutic justification. The ban was followed by two years of

legal battle between pharmaceutical companies and the government, which challenged the Health Ministry's March 2016 decision to ban 344 FDCs as the combinations lacked "therapeutic justification. As per our analysis, at the company-level, the impact was limited as most major companies had already discontinued or reformulated their products in anticipation of the ban. However, some of the smaller companies have been hit by the ban. Companies like Macleods Pharmaceuticals, Medley pharmaceuticals, FDC limited are likely to have been majorly hit as they have about 5-9% revenue exposure to the FDC market.

Rising patent litigations in the Industry

Since the advent of the new product patent regime, two clauses of the intellectual property right laws in India remain a significant area of contention between foreign drug companies and generic Indian producers:

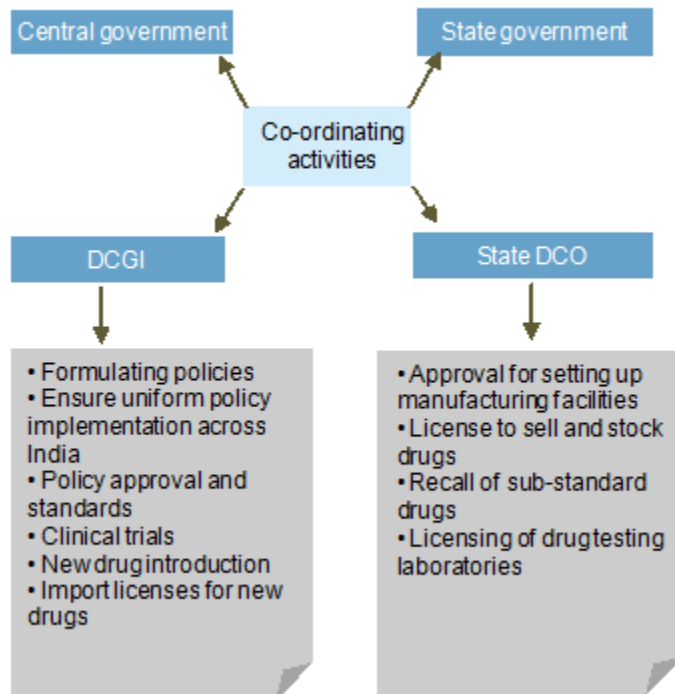
Ever greening of a drug product will not attract a new patent grant (ever greening is the method by which a drug company claims patent on a drug product by modifying characters of an already existing drug, and hence claiming inventiveness).

To make essential drugs affordable, the government can grant compulsory licenses for already patented drugs.

In view of the above, there have been many recent IPR-related cases in the country. For example Novartis has faced such litigations on its innovative drugs Gleevec, Galvus and Onbrez against Indian companies. These IPR related issues have bogged many patent granted innovative medicines from MNC companies in the past couple of years. However, outcomes in these litigations have largely been against MNC companies, with the potential to dissuade them from bringing their innovative medicines to India.

8.3 Regulatory environment in India

Regulatory bodies



Source: CRISIL Research

The Drugs and Cosmetics Act, 1940 (Drugs Act) and Drugs and Cosmetic Rules, 1945 (Drug rules) regulate the import, manufacture, distribution and sale of drugs in India. Under the provisions of these Acts, the Centre appoints the Drugs Technical Advisory Board (DTAB) to advise the central government and the state governments on technical matters.

The responsibility to enforce the Drugs Act is entrusted with both the central government and the respective state governments. Under the Drugs and Cosmetics Act, state authorities are responsible for regulating the manufacturing, sale and distribution of drugs, whereas the central authorities are responsible for approving new drugs and clinical trials, laying down the standards for drugs, controlling the quality of imported drugs and co-ordinating the activities of state drug control organisations.

The Drugs Controller General of India (DCGI) is the central body that co-ordinates the activities of state drug control organisations, formulates policies and ensures uniform implementation of the Drugs Act throughout India. It is also responsible for approval of licenses of specified categories of drugs, such as blood and blood products, IV Fluids, Vaccine and Sera.

Indian pharmaceuticals industry is mainly regulated on the basis of patents, price and quality

Patents

Before 2005, the regulatory system in India focused only on process patents. Indian pharmaceutical companies thrived during the process patent regime. They would re-engineer products of global innovator companies, which were unavailable in India, and launch them in the country as generics, as India did not recognise the product patents. In this manner, Indian companies gained process chemistry skills, but did not focus on R&D for new drug discovery.

In January 2005, India complied with the World Trade Organisation (WTO) to follow the product patent regime [sale of re-engineered products (for drugs patented after 1995) is restricted]. However, enterprises, which had made significant investments and were producing and marketing the concerned product prior to January 1, 2005 and which continue to manufacture the product covered by the patent on the date of grant of the patent, are protected, and the patentee cannot institute infringement suits against them, but would be entitled to reasonable royalty.

Drug prices

The Drug Price Control Order (DPCO) fixes the ceiling price of some APIs and formulations. APIs and formulations falling under the purview of the legislation are called scheduled drugs and scheduled formulations. The National Pharmaceutical Pricing Authority (NPPA) collects data and studies the pricing structure of APIs and formulations and accordingly makes recommendations to the Ministry of Chemicals and Fertilisers.

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

A revision to the NLEM was announced in December, 2015 which increased total number of essential medicines to 376. Drugs under the National List of Essential Medicines (NLEM) comprised ~20% of the overall domestic market in fiscal 2020. Growth for NLEM drugs improved during the fiscal, with both volume and value growth. Further, prices were revised upwards by ~4% from April 2019 for medicines under the NLEM, in line with the wholesale price index (WPI).

Under the policy, the ceiling price for each drug under control would be fixed as the simple average price of brands having more than 1 per cent market share (by value) in the sales (MAT - Moving Annual Turnover) of that particular molecule. Thus, prices of brands which are higher than this ceiling will need to be lowered. The ceiling prices will be allowed an annual increase as per the Wholesale Price Index (WPI). Prices will be recalculated using MAT only once in five years or when the NLEM is updated.

Price of drugs that were part of the earlier policy, but do not come under the current policy, would be frozen for a year and, thereafter, allowed a maximum annual increase of 10 per cent. A 10 per cent increase would also be the limit for prices of drugs outside the government's price control.

Quality

No drug can be imported, manufactured, stocked, sold or distributed in India unless it meets the quality standards laid down in the Drugs Act. All companies have to comply with Schedule M of the Act, which outlines various requirements for manufacturing drugs and pharmaceuticals by applying cGMP (current Good Manufacturing Practice). cGMP has to be followed for control and management of manufacturing and quality control testing of drugs.

Ban on fixed dose combination drugs (FDC)

In September 2018, the Union Health Ministry banned 325 fixed-dose combination (FDC) drugs, following the recommendations of an expert committee, which found that the combinations lacked "therapeutic justification". The recent ban follows over two years of legal battle between pharmaceutical companies and the government, which challenged the Health Ministry's March 2016 decision to ban 344 FDCs.

According to the CDSCO Policy guidelines on the approval of FDCs in India, all FDCs that have not yet been approved in any country - with regulations similar to those in India - will have to go through clinical trials along with the entire list of clearances for those FDCs to be marketed in India. As 325 FDC drugs were not available from the second half of the fiscal 2019, the domestic market growth was impacted to the tune of 30-50 bps in FY19.

List of companies considered for Pharmaceutical industry average

Name of the company
Aarti Drugs Limited
Aarti Industries Ltd (Consolidated)
Ajantha Pharma Ltd (Consolidated)
Alembic Pharmaceuticals Ltd
Alembic Pharmaceuticals Ltd -(Consolidated)
Alpa Laboratories Limited
AstraZeneca Pharma India Ltd
Aurobindo Pharma Limited-(Consolidated)
Bal Pharma Ltd
Bliss GVS Pharma Ltd
Cadila HealthCare Ltd-(Consolidated)
Cipla Limited -(Consolidated)
Divis Laboratories Ltd -(Consolidated)
Dr Reddys Laboratories Ltd -(Consolidated)
FDC Ltd -(Consolidated)
GlaxosmithKline Pharmaceutical Ltd (consolidated)
Granules India Ltd (consolidated)
Ind-Swift Laboratories Ltd (consolidated)
Indoco Remedies Limited
IPCA Laboratories Ltd (consolidated)
J B Chemicals Pharmaceuticals Ltd (consolidated)
Juliant Pharmova Ltd (consolidated)
Kopran Ltd (consolidated)
Lupin Ltd (consolidated)
Mangalam Drugs and Organics Ltd
Morepen Laboratories Ltd (consolidated)
Natco Pharma Ltd (consolidated)
Nectar Life Sciences Ltd (consolidated)
Neuland Laboratories Ltd (consolidated)
Parenteral Drugs (India) Ltd (consolidated)
Pfzer Ltd
Procter and Gamble Health Ltd
RPG Life sciences Ltd
Sanofi India Ltd
Shilpa Medicare Ltd
Strides Pharma Science Limited (consolidated)
Sun Pharmaceutical Industries Ltd (consolidated)
Suven Life Sciences Ltd
Themis Medicare Ltd (consolidated)

Torrent Pharmaceutical Limited (consolidated)
TTK Healthcare Ltd
Unichem Laboratories Ltd
Venus Remedies Ltd (consolidated)
Wanbury Ltd (consolidated)
Wockhardt Limited (consolidated)

List of companies considered for Bulk Drug industry average

Name of the company
Aarti Drugs Limited
Aarti Industries Ltd (Consolidated)
Aurobindo Pharma Limited-(Consolidated)
Bal Pharma Ltd
Divis Laboratories Ltd -(Consolidated)
Granules India Ltd (consolidated)
Ind-Swift Laboratories Ltd (consolidated)
Juliant Pharmova Ltd (consolidated)
Kopran Ltd (consolidated)
Mangalam Drugs and Organics Ltd
Morepen Laboratories Ltd (consolidated)
Nectar Life Sciences Ltd (consolidated)
Neuland Laboratories Ltd (consolidated)
Shilpa Medicare Ltd
Suven Life Sciences Ltd
Wanbury Ltd (consolidated)

9 Addendum dated 28 June 2021

9.1 Export data for key product categories

Units	HS code	Product	Particulars	FY2017	FY2018	FY2019	FY2020	FY2021
Rs. Lacs	29333914	Chlorpheniramine Maleate	India's total export	3,406	4,711	4,711	6,652	8,049
Rs. Lacs	29333914	Chlorpheniramine Maleate	Supriyalife science export	1,496	2,379	3,985	4,928	5,790
%	29333914	Chlorpheniramine Maleate	% share of SLS in total exports	44%	50%	85%	74%	72%
tonnes	29333914	Chlorpheniramine Maleate	India's total export	233	296	235	290	286
tonnes	29333914	Chlorpheniramine Maleate	Supriyalife science export	110	134	143	130	131
%	29333914	Chlorpheniramine Maleate	% share of SLS in total exports	47%	45%	61%	45%	46%
Rs. Lacs	30039036	Ketamine	India's total export	98	64	5	-	2,619
Rs. Lacs	30049096	Ketamine	India's total export	253	336	928	411	362
Rs. Lacs	other HS codes	Ketamine	India's total export	3,003	6,261	6,612	10,508	13,220
Rs. Lacs	Total	Ketamine	India's total export	3,354	6,662	7,545	10,919	16,200
Rs. Lacs		Ketamine	Supriyalife science export	1,969	3,613	4,920	7,034	9,511
%		Ketamine	% share of SLS in total exports	59%	54%	65%	64%	59%
Rs. Lacs	29051420	Salbutamol Sulphate	India's total export	3,123	3,031	4,560	4,002	8,074
Rs. Lacs	29051420	Salbutamol Sulphate	Supriyalife science export	676	637	1,483	1,485	3,043
%		Salbutamol Sulphate	% share of SLS in total exports	22%	21%	33%	37%	38%
tonnes	29051420	Salbutamol Sulphate	India's total export	60	52	63	60	114
tonnes	29051420	Salbutamol Sulphate	Supriyalife science export	16	15	30	29	36
%		Salbutamol Sulphate	% share of SLS in total exports	27%	29%	48%	48%	31%
Rs. Lacs	29362310	Vitamin B2 (Riboflavin, Lactoplavin) And Its Salts	India's total export	3,949	4,384	5,852	4,881	7,406
Rs. Lacs	29362310	Vitamin B2 (Riboflavin, Lactoplavin) And Its Salts	Supriyalife science export	1,249	1,490	1,614	1,298	2,061
%	29362310	Vitamin B2 (Riboflavin, Lactoplavin) And Its Salts	% share of SLS in total exports	32%	34%	28%	27%	28%
tonnes	29362310	Vitamin B2 (Riboflavin, Lactoplavin) And Its Salts	India's total export	75	84	85	81	113
tonnes	29362310	Vitamin B2 (Riboflavin, Lactoplavin) And Its Salts	Supriyalife science export	22	28	23	20	29
%	29362310	Vitamin B2 (Riboflavin, Lactoplavin) And Its Salts	% share of SLS in total exports	29%	33%	27%	25%	26%

Rs. Lacs	29333919	Other Derivatives Of Pyradine	India's total export	64,491	69,524	77,681	108,107	128,298
Rs. Lacs	29333919	Other Derivatives Of Pyradine	Supriyalife science export	2,076	2,161	2,709	2,567	3,780
%	29333919	Other Derivatives Of Pyradine	% share of SLS in total exports	3.2%	3.1%	3.5%	2.4%	2.9%
tonnes	29333919	Other Derivatives Of Pyradine	India's total export	5,901	7,425	7,346	10,674	10,273
tonnes	29333919	Other Derivatives Of Pyradine	Supriyalife science export	101	102	113	103	117
tonnes	29333919	Other Derivatives Of Pyradine	% share of SLS in total exports	1.7%	1.4%	1.5%	1.0%	1.1%

Source: DGFT, Lifescience Intellipedia, CRISIL Research

- Supriya Lifescience Ltd. is the largest exporter of Chlorpheniramine Maleate in India contributing to 45-50% of the API exports from India during FY 2017 to FY 2021 in volume terms. Major export destination includes China, Hong Kong, Indonesia, Brazil. USA and Europe contributes around 2-3% of total exports from India in FY 2019 and 2020. (HS code data from DGFT –2933 39 14)
- Supriya Lifescience Ltd. is the largest exporter of Ketamine Hydrochloride in India contributing to 60-65% of the API exports from India (FY2017-FY2021). Major export destination includes Brazil, Europe and emerging nation in African continent. Ketamine hydrochloride is used as affordable anaesthetic drug largely in emerging and developing markets. (HS code data from DGFT – 30049096, 30039036)
- Derivatives of pyridine, such as pyrilamine maleate, dexchlorpheniramine maleate, brompheniramine maleate dexbrompheniramine maleate exports from India increased at 19% CAGR (value) and 15% CAGR (volume) between fiscal 2017 to fiscal 2021. Surpiya Life science ltd. contributes to around 2.5-3.0% of pyradine derivatives export from India between fiscal 2017 to fiscal 2021 . Supriya Life science ltd export of Diphenhydramine HCl, Pheniramine Maleate, Pylamine Maleate/Mepyramine Maleate, Dexchlorpheniramine Maleate, Brompheniramine Maleate and Dexbrompheniramine Maleate grew at 47% in fiscal 2021 even as overall Derivatives of pyridine exports remained flat. . (HS code data from DGFT – 29333919)
The important pyridine derivatives include niacin, nicotinamide, isonicotinoylhydrazine, nicotine, strychnine, and vitamin B6. Major export destination includes USA, Europe and China.
- Supriya Lifescience Ltd. is among the largest exporter of salbutamol sulphate in India contributing to 31% of the API exports from India in FY 2021 in volume terms. Supriya Lifescience share in salbutamol Sulphate exports have increased from 25-30% in fiscal 2017 to 30-40% in fiscal 2018 to fiscal 2021. Singapore, USA, Thailand, Indonesia, Europe are key export destinations for India. Salbutamol Sulphate, an anti-asthmatic therapeutic product, saw rise in demand in FY 2021 on account of rise in demand for anti-asthmatic drugs during COVID-19 pandemic. Exports of salbutamol Sulphate from India saw a rise of 75-80% in fiscal 2021, with major export destination being Singapore, USA, Thailand, China, Bangladesh, Germany and Indonesia. (HS code data from DGFT –29051420)
- Supriya Lifescience Ltd. contributed to 25-30% of exports of Vitamin B2 (riboflavin, lactoplavin) and its salts from India in FY2017 to FY 2021 in volume terms. Europe and USA are major export destination for India. Supriya Lifescience Ltd. is among the largest exporter of Riboflavin-5-phosphate sodium in India. . (HS code data from DGFT – 29362310)
- India has potential in export markets as low-cost quality supplier for pharmaceutical products as other global suppliers face high competition on pricing front because of high production costs.

9.2 Addendum to macro-economic section for updated GDP projections (June 2021)

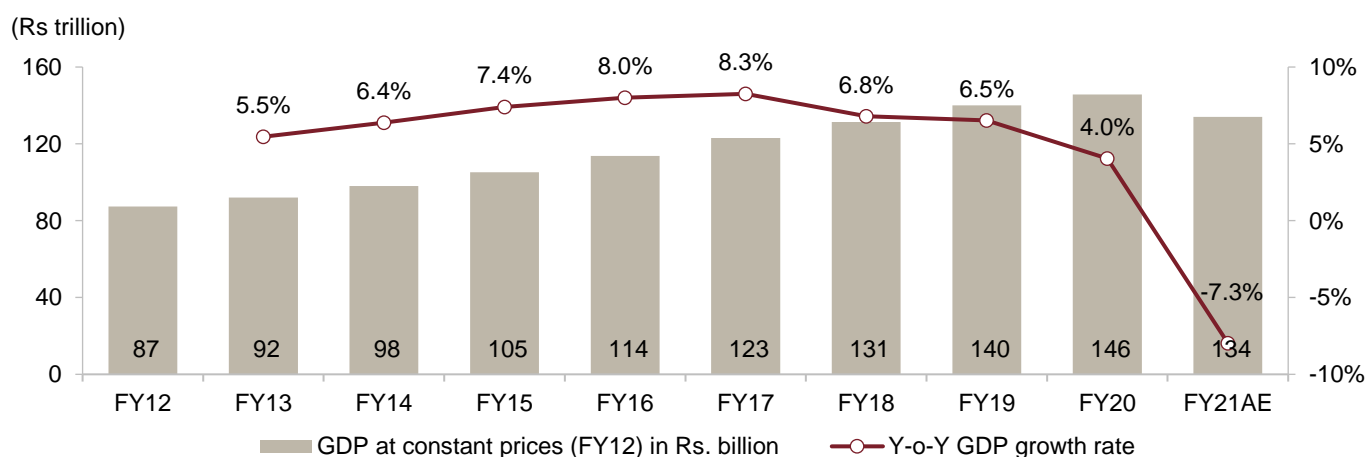
GDP grew at 6.6% CAGR from fiscals 2012-20

In 2015, the Ministry of Statistics and Programme Implementation (MoSPI) changed the base year for calculating India's GDP between fiscals 2005 and 2012. India's GDP increased at a CAGR of 6.6% to Rs 146 trillion in fiscal 2020 from Rs 87 trillion in fiscal 2012.

Fiscal 2020 estimates show investment decline has added to the economy's woes

In fiscal 2020, India's GDP grew 4.0% as per advanced estimates. Private consumption declined to a decadal low of 5.3% from 7.2% in fiscal 2019, hurt by the slowdown in spending by central and state governments and a muted private-sector appetite for fresh investments. Over the past four years, a sharp increase in government spending, especially on infrastructure (roads, railways, highways), has kept the overall investment spending growth at 8% on average. In fiscal 2020, though, government investment spending took a back seat. Meanwhile, weak consumption demand and low capacity utilisation kept investments in the manufacturing sector tepid.

Real GDP growth in India (new GDP series)



AE: Advance estimates

Source: Second advance estimates of national income 2020-21, Central Statistics Office (CSO), MoSPI, CRISIL Research

Gross Value Added at basic prices (constant 2011-12 prices)

Rs. Trillion	FY12	FY13	FY14	FY15	FY16	FY17	FY18	FY19	FY20	FY21	CAGR
GVA at basic prices	81.1	85.5	90.6	97.1	104.9	113.3	120.7	128	133	124.5	4.88%
Y-o-Y Growth (%)		5.4%	6.1%	7.2%	8.0%	8.0%	6.6%	6.0%	3.9%	-6.4%	

Source: CRISIL Research

As of fiscal 2021, total GVA saw CAGR of 4.88% from fiscal 2012 to fiscal 2021. Total GVA at constant prices has seen a de-growth of 6.4% in fiscal 2021.

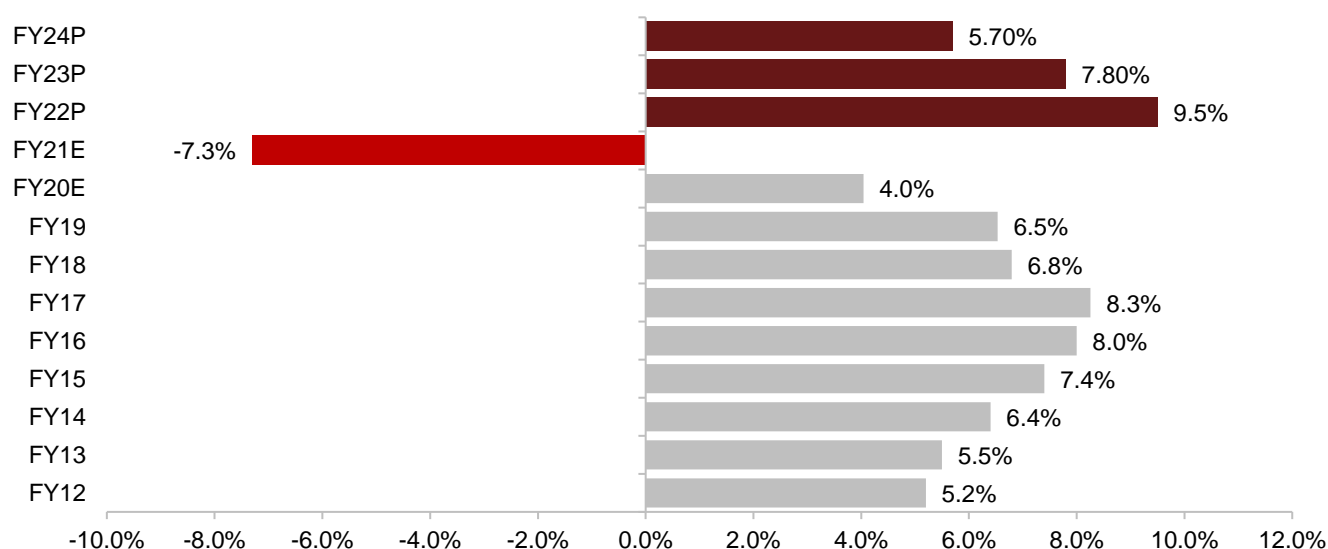
9.3 Outlook for GDP growth in fiscal 2021

Economy contracted 7.3% in fiscal 2021

Fiscal 2021 has been a challenging year for the Indian economy, which was already experiencing a slowdown before the pandemic created the 'perfect storm'. Though data suggests there has been some pick-up in recent months, recovery is weak and uneven. GDP contracted 7.3% (in real terms) last fiscal, after growing 4.0% in fiscal 2020. At Rs 135.1 lakh crore last fiscal, India's GDP (in absolute terms) went even below the fiscal 2019 level of Rs 140.0 lakh crore. Also, after contracting in the first half because of the Covid-19 pandemic, the economy rebounded in the second half, growing 0.5% and 1.6% on-year in the third and fourth quarters, respectively. While the economy shrank as a whole in fiscal 2021, agriculture and allied activities, and electricity, gas, water supply and other utility services were the outliers, logging positive growth. On the other hand, the contact-intensive trade, hotels, transport and communication sectors, and services related to broadcasting were hit the most and continued to shrink in all the quarters. Construction – a labour-intensive sector – was also severely hit in the first half but rebounded in the second half.

India is getting back on its feet slowly, with divergent growth trends. Though data suggests there has been some pick-up in recent months, recovery is weak and uneven. And indeed, the scars of the pandemic continue to run deep for small businesses, the urban poor and most of the services sector. The gains made by the economy in the fourth quarter of fiscal 2021 seem to have fizzled out in the first quarter of fiscal 2022 because of the fierce second wave of Covid-19, leading to localised lockdowns in most states. At the same time, monetary policy has begun normalising, and some tightness in domestic financial conditions is inevitable. Against this backdrop, policy support remains critical, apart from action in the external environment. In fiscal 2021, the policy response to the pandemic focussed more on damage control and measures to support the economy. This fiscal, though, the government is expected to normalise some of the extraordinary or unconventional policy moves, while trying to ensure there is smooth revival in growth. Some of its biggest challenges ahead will be broad-basing growth to the services and labour-intensive manufacturing sectors and ensuring financial conditions stay supportive.

Real GDP growth (% on-year)



E: Estimated; P: Projected by CRISIL Research; GDP calls updated as of Mar 2021;

Source: Second advance estimates of national income 2020-21, CSO, MoSPI, CRISIL Research

Key fiscal measures announced by the Centre to deal with the pandemic impact

To mitigate the pandemic's negative impact on the economy, the Central government has announced a Rs 20.9 trillion package, amounting to 10% of the country's nominal GDP. The package is a mix of fiscal and monetary measures (to revive growth in the short term) and reforms (to boost long-term economic prospects). Liquidity support has been a major part of India's response so far. Globally, too, liquidity measures have played a lead role in policy response. The immediate fiscal cost to be borne by the government would be ~Rs 2.6 trillion, or 1.2% of nominal GDP. Further, execution of the government's measures to revive the economy and pace of implementation of the announced reforms are key monitorables.

Fiscal 2022 base case GDP growth to be 9.5%

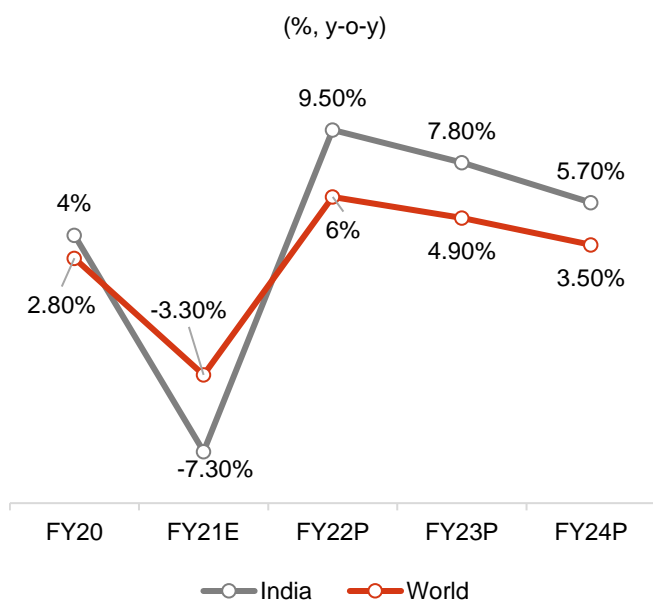
CRISIL forecasts India's GDP growth to rebound to 9.5% in fiscal 2022 as four drivers converge:

1. **Weak base:** A 7.3% contraction in GDP in fiscal 2021 will provide a statistical push to growth next fiscal.
2. **Global upturns:** Higher global growth in 2021, i.e., world GDP up by 5.0%, advanced economies 4.3%, emerging economies 6.3%, should lift exports.
3. **Covid-19 curve:** India is witnessing the second wave of Covid-19 infections and at the same time learning to live with the virus, with the rollout of vaccines. These should broaden growth this fiscal, especially in the services and unorganised sectors.
4. **Fiscal push:** Stretch in the fiscal glide path and focus of Union Budget 2021-22 on capex are expected to have a multiplier effect on growth.

Risks to GDP growth

1. **A third wave this fiscal:** This could bring further disruption to mobility and economic recovery.
2. **Slower pace of vaccination:** Insufficient pick-up in pace of vaccinations, accentuating risks of a third wave.
3. **Elevated inflation:** Significant cost-push pressures on account of surging international commodity prices and supply disruptions has raised cost of production for manufacturing firms. Pass-through to consumer prices could further pose as a headwind to recovery in demand.
4. **Premature tightening of global monetary policies:** Resurgence of inflation globally could lead major central banks to unwind their extraordinary easy monetary policies sooner than expected. This could hit sentiment, possibly leading to capital outflows from the Indian economy and some tightening in domestic financial conditions.

In next three fiscals, India's growth to be greater than the global GDP



GDP growth to rebound to 9.5% in this fiscal on the back of a very weak base and the rising-global-tide effect.

CRISIL sees India's GDP growth rebounding to 9.5% this fiscal, due to a very weak base, flattening of the Covid curve, rollout of vaccinations, investment-focused government spending, and benefit from the 'rising global tide lifts all boats' effect. Yet, the economy is expected to reach pre-pandemic levels only by the second quarter (Q2) of this fiscal. Services will take longer to recover than manufacturing.

Over fiscals 2023-25, growth is seen averaging at ~6.1% annually. In this scenario, strong growth in GDP is unlikely in the next three fiscals. CRISIL Research estimates the economy will see a permanent loss of ~12% real GDP due to this. Real GDP will catch up to the fiscal 2020 level only by fiscal 2022. Beyond fiscal 2022, India is seen growing faster than the world.

Note: Forecasts for World are for calendar year; FY20=2019; P: Projected; updated as of July 2021; India numbers from FY20 and FY21 are based on MOSPI latest GDP estimates and FY22 onwards are CRISIL Research estimates while World GDP growth rates are from IMF world economic outlook update as of April 2021

Source: S&P Global Ratings, CRISIL

Fiscal 2022 is also seen emerging as a story of two halves. The first half will be characterised by a base effect-driven recovery amid the challenge associated with resurgence in Covid-19 infections. But the second half should see a more broad-based growth, as vaccine rollout and herd immunity support sectors that are lagging. These include most of the services sectors, especially contact-based travel, tourism and entertainment. Also, stronger global growth should support India's exports to some extent. Revival will not be uniform across sectors, though. The rural economy has been more resilient than the urban, and manufacturing leads services in recovery. But trade has rebounded faster than the rest of the economy, with exports as well as imports scaling pre-pandemic levels.

The second wave suggests the pandemic remains an ongoing risk. India's second wave has wreaked havoc, with daily cases crossing a staggering 3 lakh in the week through April 25. India's daily infections recorded the highest number of cases in a single day among countries worldwide, and daily deaths crossed the peak of the first wave. Worryingly, their steep trajectory seems to be following that of daily cases. The March 2020 nation-wide lockdown led to a massive migrant exodus. This time, even though there have been no nationwide restrictions, the increasing number of cases have prompted states to announce localised restrictions and curfews in different forms. There has been no restriction on economic activity and the impact on GDP is expected to have limited downside risk. But with increase in cases in May 2021 and depending upon the restrictions, there is downside risk to GDP growth if the spread is not brought under control

Risks to the fiscal 2022 forecast

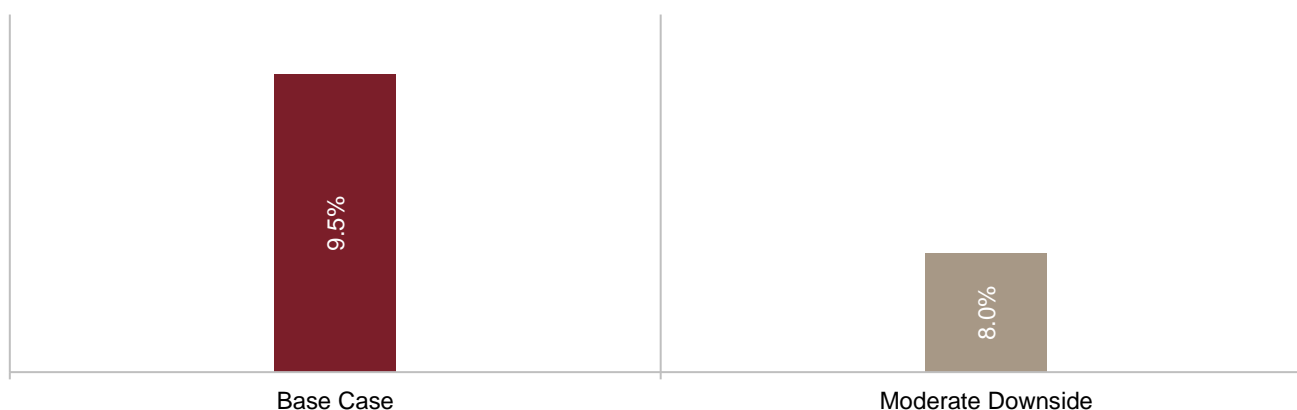
The base case of 9.5% GDP growth assumes that Covid-19 restrictions will continue and mobility will remain affected in some form or other, at least till August. The pace of economic recovery will also be a function of what the pace of vaccination is in the coming months. We find that countries with over 40% of their population vaccinated are seeing a faster and more broad-based economic recovery. The government plans to vaccinate

India's entire adult population (68% of total population) by this December – a tall order even if there are sufficient vaccines available. CRISIL's base case is 70% of the adult population vaccinated by December.

There is one other scenario affecting our GDP forecast.

- Scenario 1: Moderate downside of 8% GDP growth assumes a third and a slower-than-anticipated pace of vaccination.

GDP growth in fiscal 2022%, y-o-y



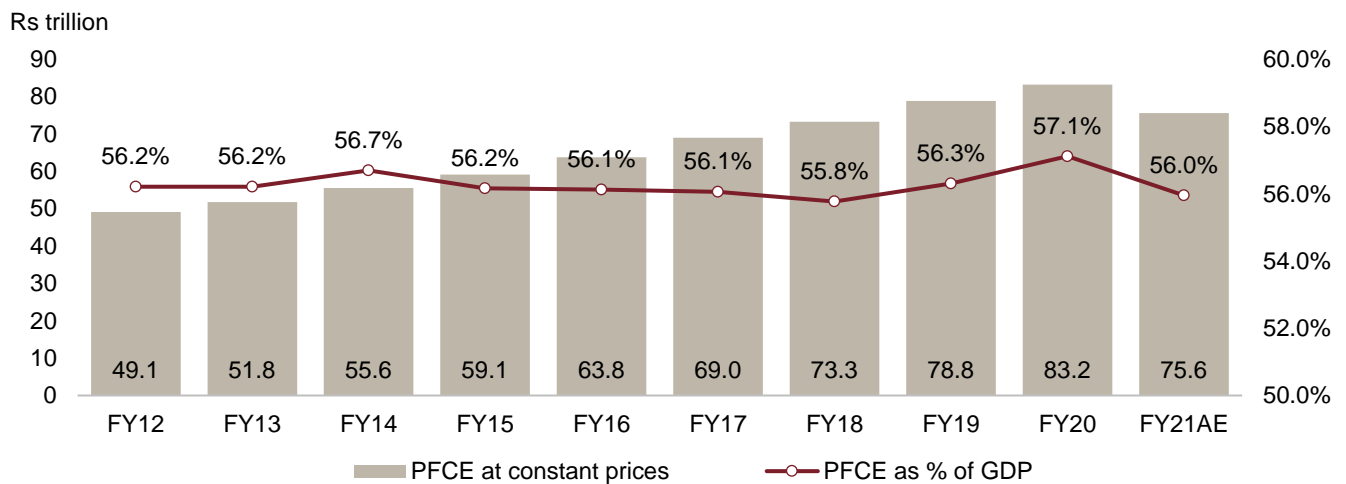
Source: S&P Global ratings, CRISIL Research, Jun 2021

9.4 Review of private final consumption growth

Private final consumption expenditure to maintain dominant share in GDP

Private final consumption expenditure (PFCE) at constant prices clocked 6.8% CAGR between fiscals 2012 and 2020, maintaining its dominant share in the GDP pie, at ~57% or Rs 83.3 trillion. Factors contributing to the growth included good monsoons, wage revisions due to the implementation of the Pay Commission's recommendations, benign interest rates, and low inflation. PFCE declined in fiscal 2021 to Rs 75.6 trillion on account of the pandemic, where consumption demand was impacted on account of strict lockdown, employment loss, limited disposable spending, and disruption in demand-supply dynamics.

PFCE (at constant prices)



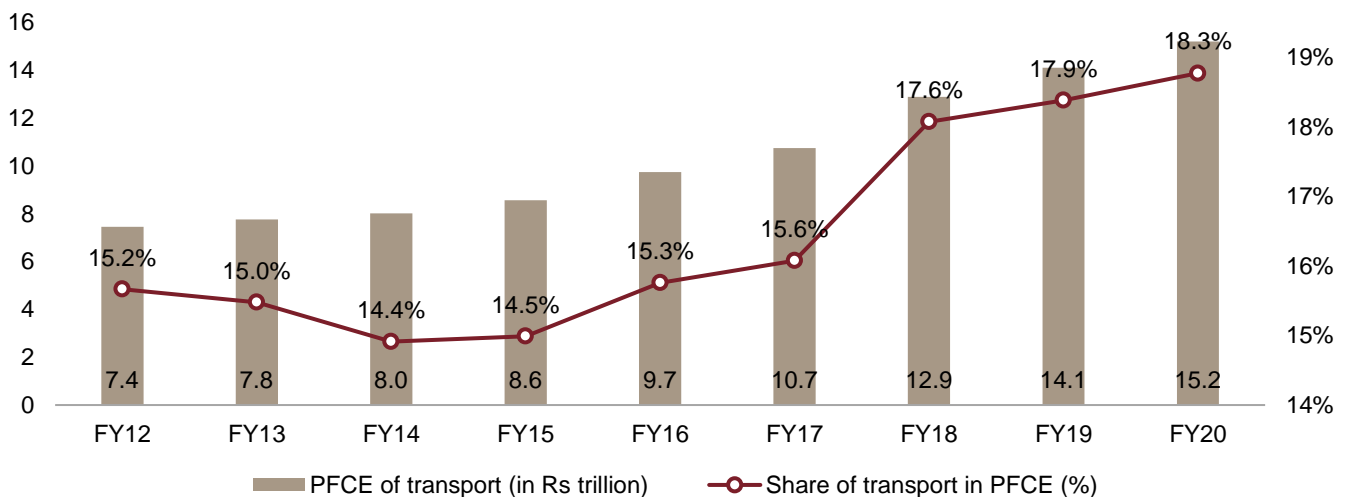
AE: Advanced estimates

Source: Second advance estimates of national income 2020-21, CSO, MoSPI, CRISIL Research

Share of transport in PFCE rose to 18.3% in fiscal 2020

The contribution of transport to PFCE at constant prices increased at a 10.1% CAGR between fiscals 2013 and 2020. Its share in PFCE, which had declined a tad in fiscals 2013 and 2014, picked up from fiscal 2015 to 15.6% in fiscal 2017. It further increased to ~17.9% in fiscal 2019 and 18.3% in fiscal 2020, outpacing total PFCE growth during the year.

Share of transport in PFCE (at constant prices) trending up

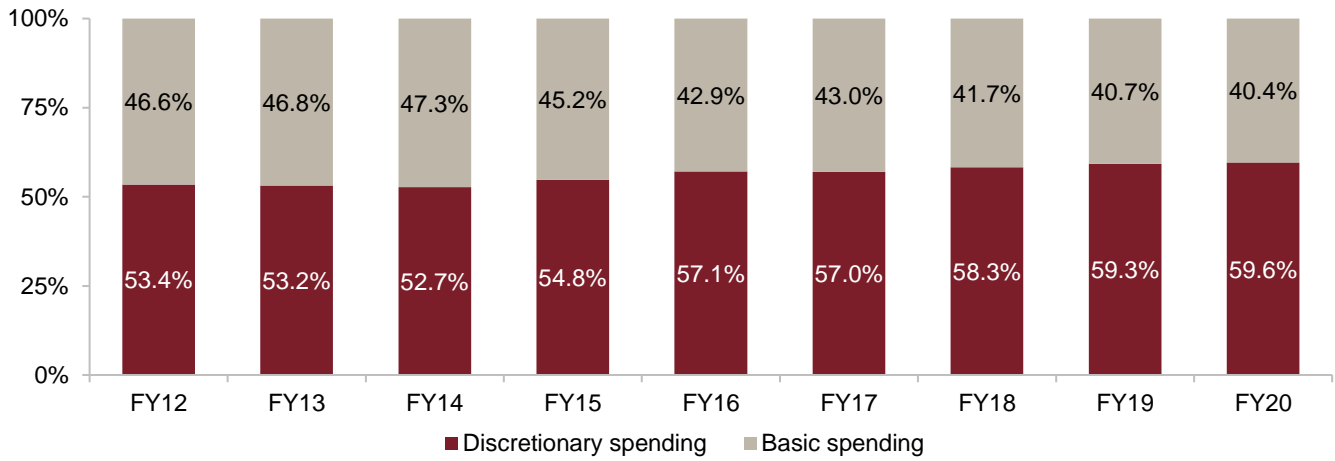


Source: Second advance estimates of national income 2020-21, CSO, MoSPI, CRISIL Research

Consumption expenditure to be driven by discretionary items

According to CRISIL Research, basic items accounted for 40.4% of the total consumption expenditure of Indian consumers in fiscal 2020, with discretionary items accounting for the remainder 59.6%. It is worth noting that the share of discretionary items in consumption increased to 59.6% in fiscal 2020 from 53.4% in fiscal 2012. The increased spending on discretionary items suggests rising disposable income of households.

Broad split of PFCE consumption into basic and discretionary spending



Note: Basic items include food, clothing and housing. Discretionary items include education, healthcare, electricity, water supply, footwear, personal care products, processed foods, alcoholic and non-alcoholic beverages, tobacco, narcotics, fuel and gas, furnishing and household equipment, vehicle and personal transportation, spending on recreation and culture, communication, restaurants and hotels, financial insurance and other financial services, and other items not elsewhere classified (n.e.c.)

Source: MoSPI, CRISIL Research

10 Addendum dated 23 July 2021

10.1 Anti-histamine & Anti-allergy

Molecule	Global market volume (MTS)	Global market value (USD Mn)	Share in total value	Past growth 2015-2020	Future growth 2020-2025
Phenylephrine Hydrochloride	430	68.3	2%	7%	5-10%

Note: Global market volume are based on internal analysis of Lifescience Intellipedia for specific molecule variant

Source: Lifescience Intellipedia, CRISIL Research

Molecule	Innovator	Approval year	Patent priority
Phenylephrine Hydrochloride	Schering plough – Bayer Healthcare Pharma	1938	--

Source: Lifescience Intellipedia, CRISIL Research

Molecule	Raw material availability in India	Average exports from India (tonnes)	Growth in exports 2015-2020	Export potential	Suppliers in market
Phenylephrine Hydrochloride	High	75	20%	High	Medium-High

Source: Lifescience Intellipedia, CRISIL Research

10.2 Pain Management

Molecule	Global market volume (MTS)	Global market value (USD Mn)	Share in total value	Past growth 2015-2020	Future growth 2020-2025
S-Ketamine Hydrochloride	5	30	<0.5%	5.5%	5-10%

Note: Global market volume are based on internal analysis of Lifescience Intellipedia for specific molecule variant

Source: Lifescience Intellipedia, CRISIL Research

Molecule	Innovator	Approval year	Patent priority
S-Ketamine Hydrochloride	Janssen Pharma	2005	2012

Source: Lifescience Intellipedia, CRISIL Research

Molecule	Raw material availability in India	Average exports from India 2016-2018 (tonnes)	Average exports from India 2019-2018 (tonnes)	Growth in exports 2016-2020	Export potential	Suppliers in market
S-Ketamine Hydrochloride	High	0.006	0.2	168%	Medium	Low

Note:

- Higher % growth in exports is due to low exports in the year in 2018 compared to previous fiscals coupled with rise in exports for 2019 and 2020

- Growth numbers for exports are from 2016 to 2020

Source: Lifescience Intellipedia, CRISIL Research

10.3 Vitamins

Molecule	Global market volume (MTS)	Global market value (USD Mn)	Share in total value	Past growth 2015-2020	Future growth 2020-2025
Benfotiamine (Vitamin B1)	170	18.4	1.2%	6.60%	5-10%

Note: Global market volume are based on internal analysis of Lifescience Intellipedia for specific molecule variant

Source: Lifescience Intellipedia, CRISIL Research

Molecule	Innovator	Approval year	Patent priority
Benfotiamine (Vitamin B1)	Sankyo	1962	--

Source: Lifescience Intellipedia, CRISIL Research

Molecule	Raw material availability in India	Average exports from India 2015-2020 (tonnes)	Average exports from India 2015-2017 (tonnes)	Average exports from India 2018-2020 (tonnes)	Growth in exports 2015-2020	Export potential	Suppliers in market
Benfotiamine (Vitamin B1)	High	32	11	54	59%	High	High

Note: Higher % growth in exports is due to rise in exports for the period 2018 over 2017(135% on-year growth) and 2020 over 2019 (81% on-year growth)

Source: Lifescience Intellipedia, CRISIL Research

11 Addendum dated 29 July 2021

11.1 Global GDP review and outlook

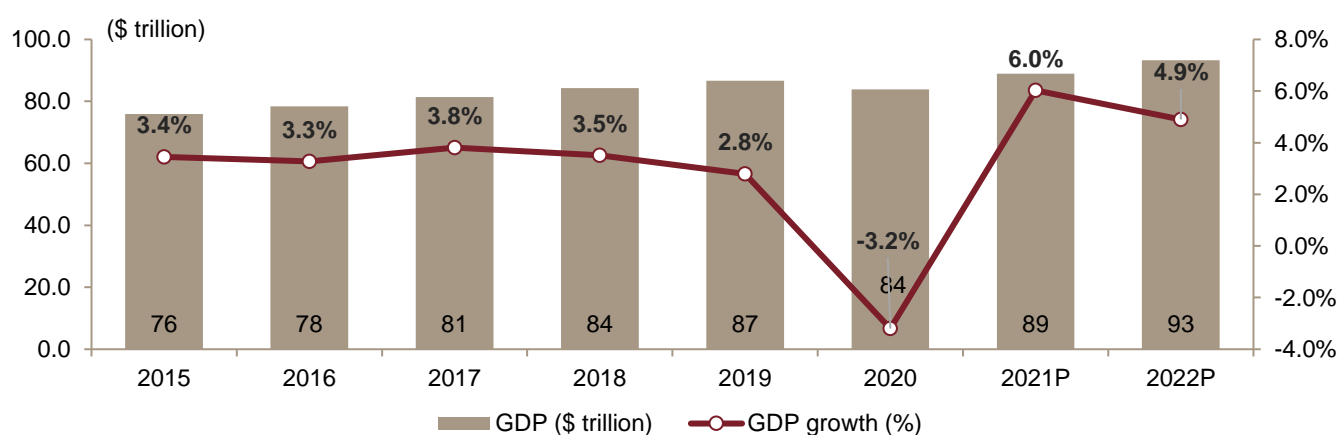
While global gross domestic product (GDP) declined sharply in 2020 owing to the Covid-19 pandemic, it is expected to rebound strongly by the end of calendar year 2021 on account of policy support and the vaccination drive

According to the International Monetary Fund (IMF), global real GDP grew at 3-4% compound annual growth rate (CAGR) from calendar year 2015-18. It declined to 2.8% in 2019. The IMF estimated global real GDP de-grew 3.2% in 2020 owing to the pandemic, which has disrupted businesses across the world. In response, almost all major countries had announced stimulus packages, which resulted in a recovery in the second half of 2020.

In July'21 update, IMF maintained its forecast for global GDP growth in 2021 at 6.0%. In April, the IMF revised upwards its global GDP growth forecast, estimating a 6.0% on-year uptick by 2021-end. The IMF had in January forecast growth at 5.5%, which was again a revision from the 5.3% increase forecast in October 2020. These changing estimates reflect the impact of vaccines supporting and strengthening economic activity during the latter half of 2021 and the additional policy support in a few large economies which will provide further support in CY 2021-22 to the global economy. The fiscal support announced for 2021 in some countries, including most recently in the United States (US) and Japan, together with the unlocking of Next Generation EU funds which are covid-19 relied package announced for European Union countries, will help lift economic activity among advanced economies with favourable spill overs to trading partners.

Although recent vaccine approvals have raised hopes of a turnaround in the pandemic later this year, renewed waves and new variants of the virus pose concerns for the outlook. Global prospects remain highly uncertain one year into the pandemic. Amid exceptional uncertainty, the global economy is projected to grow 4.9% in 2022. The outlook depends not just on the virus spread and vaccination drive to contain it, but it also hinges on how effectively economic policies can limit lasting damage from this unprecedented crisis.

Trend and outlook for global GDP (CY2015-22)



P: Projection

Source: IMF economic database, World Bank national accounts data and OECD national accounts data, CRISIL Research

Advanced economies have been able to provide expansive fiscal support to individuals and companies (direct tax and spending measures as well as equity injections, loans, and guarantees). Central banks have reinforced the fiscal policy support with expanded asset purchase programmes, funding-for-lending facilities, and, for some, interest rate cuts. Reflecting the strong policy support and the anticipated widespread availability of vaccines in summer 2021, the projected output loss compared with the pre-pandemic forecast is relatively smaller for advanced economies than other countries.

Recovery paths vary within advanced economies, with the US and Japan projected to regain 2019-end activity levels in the second half of 2021, while in the euro area and the United Kingdom (UK), activity is expected to remain below 2019-end levels into 2022.

Emerging market and developing economies are also projected to trace diverging recovery paths. Considerable differentiation is expected between China, where effective containment measures, a forceful public investment response, and central bank liquidity support have facilitated a strong recovery, and other economies. Oil exporters and tourism-based economies within the emerging markets group face particularly difficult prospects considering the expected slow normalisation of cross-border travel and the subdued outlook for oil prices. The pandemic is expected to reverse the progress made in poverty reduction across the past two decades. Close to 90 million people are likely to fall below the extreme poverty threshold during CY 2020-21.

In July 2021 update, IMF prospects for emerging market and developing economies have been marked down for 2021, especially for Emerging Asia. By contrast, the forecast for advanced economies is revised up. These revisions reflect pandemic developments and changes in policy support.

India is expected to regain the top spot as the world's fastest growing economy in 2021

India was one of the fastest growing economies in 2018 and 2019. In 2020, GDP of all countries – including that of developed ones such as the US and the UK but except China's – is expected to de-grow primarily due to the negative economic impact of the pandemic. India's GDP is expected to decline by 7.3% in 2020. Further, GDP growth of all major economies is expected to rebound in 2021 as economic activities resume and also due to the low base of 2020. Among the major economies, India, with a growth rate of ~9.5%, is expected to be the fastest growing in 2021 followed by China with 8.1%.

Asia-Pacific has been hit hard by the coronavirus pandemic and is recovering from a severe recession. The outlook varies by country depending on infection rates and containment measures, policy responses, reliance on contact-intensive activities, and external demand. Output is expected to remain below pre-pandemic trends over the medium term, with the most vulnerable in society likely to be hit the hardest. The projections remain highly uncertain, with significant downside risks. The Asia and Pacific region is also starting to recover tentatively, but at multiple speeds. Economic activity in Emerging and Developing Asia is expected to contract by -0.9% in 2020, due to a sharper-than-expected downturn in key emerging markets, and to grow by 7.5% in 2021 and 6.4% in 2022

Real GDP growth by geographies

	2017	2018	2019	2020	2021P	2022P
Advanced Economies	2.5	2.2	1.6	-4.6	5.6	4.4
United States	2.3	3.0	2.2	-3.5	7.0	4.9
Euro Area	2.6	1.8	1.3	-6.5	4.6	4.3
Japan	2.2	0.3	0.3	-4.7	2.8	3.0
United Kingdom	1.2	1.3	1.4	-9.8	7.0	4.8
Emerging Market and Developing Economies	4.8	4.5	3.6	-2.1	6.3	5.2
China	6.9	6.7	5.8	2.3	8.1	5.7
India	6.8	6.5	4.0	-7.3	9.5	7.8*
ASEAN	5.3	5.3	4.9	-3.4	4.3	6.3
Middle East and Central Asia	2.6	2.1	1.4	-2.6	4.0	3.7
World	3.8	3.5	2.8	-3.2	6.0	4.9

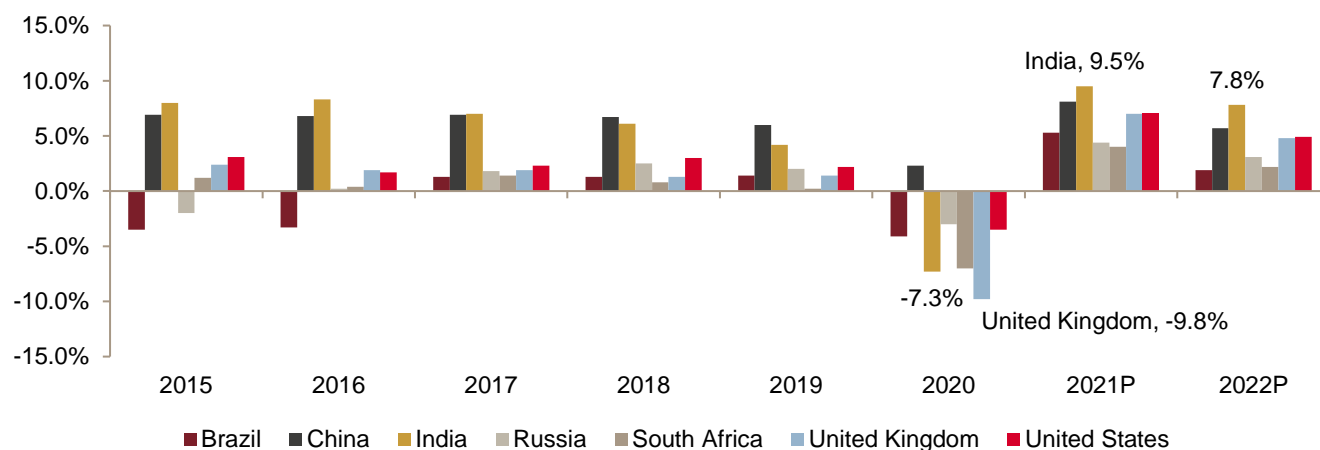
P: Projection as per IMF update – July’21

** Numbers for India for year 2021 and 2022 are as per CRISIL research forecast. IMF forecast for CY20:-7.3% and CY21:9.5%, CY22:8.5%.

Emerging Asia comprises the ASEAN-5 (Indonesia, Malaysia, Philippines, Thailand, Vietnam) economies, China, and India.

Source: IMF economic database, World Bank national accounts data and OECD national accounts data, CRISIL Research

Trend of real GDP growth rate (%) for major economies (2015-21P)



Note: Data for India represents financial year, forecasts for India are CRISIL Research forecasts

Numbers for India for year 2021 and 2022 are as per CRISIL research forecast. IMF forecast for CY20:-7.3% and CY21:9.5%,CY22:8.5%.

Source: IMF, CRISIL Research

11.2 Overview of Global Pharmaceutical industry

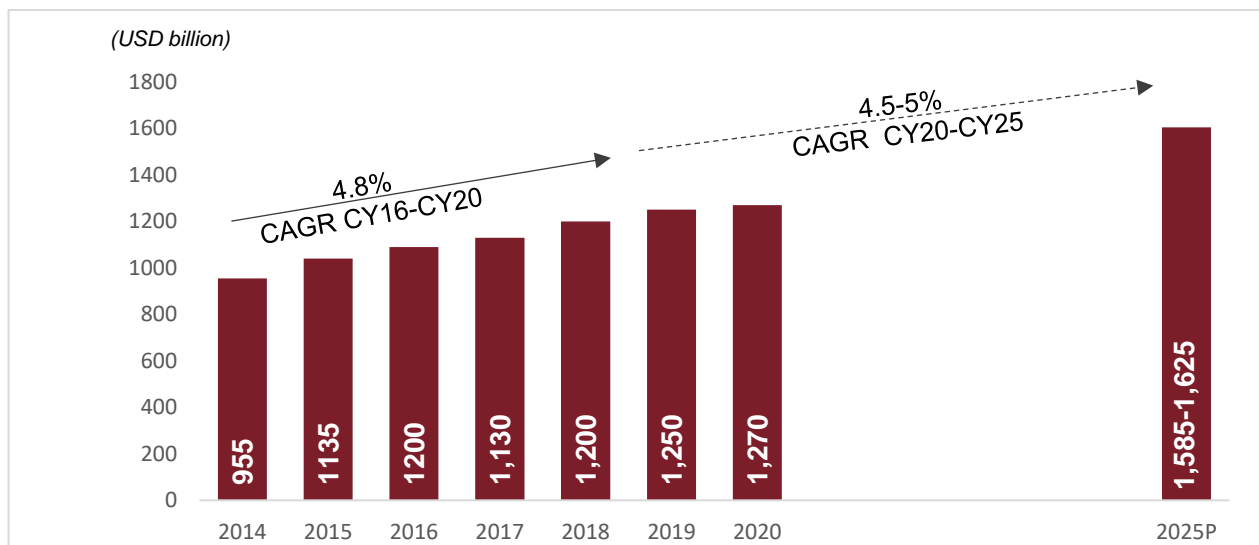
The global pharmaceutical industry is characterized by the concentration of consumption, production, and innovation in a relatively small number of high-income countries, which continue to account for a major chunk of this market in value terms on account of higher priced drugs and newer products. However, over the recent few years, production as well as consumption has started to shift to middle-income countries, like India and China; these “pharmerging” markets also account for a higher share in volume terms and have outpaced growth in high-income markets. These double-digit-growth countries are now the strategic focus points for many multinational pharmaceutical companies. Though, for pharmaceutical research and development (R&D), high-income countries continue to dominate expenditure in both the public and private sectors.

The market saw a relatively slower growth in CY18-CY19 on account of pricing pressure, however, it stabilised coming in to CY20. Rising drug research and development activities for drug manufacturing, increasing prevalence of chronic diseases, rising importance of generics, and the increasing uptake of biopharmaceuticals will continue to be some of the key drivers for the global pharmaceuticals industry. In addition, strategic initiatives like new drug launches and biological products, acquisitions, collaborations, and regional expansion are also likely to fuel the market growth in the near future. However, the unfavourable drug price control policies across various markets and high manufacturing costs are expected to be some of the growth limiting factors.

Global pharmaceutical market to grow at steady ~5% CAGR from 2020 to 2025

Global pharmaceutical market has grown by around 4.8% CAGR from ~USD 955 billion in CY14 to ~USD 1,270 billion in CY20. It is expected to sustain this growth over the next five years to reach USD 1,585-1,625 billion in CY25.

Global pharmaceutical market by value



P: Projected

Source: Mordor Intelligence, Pharma Company reports, CRISIL Research

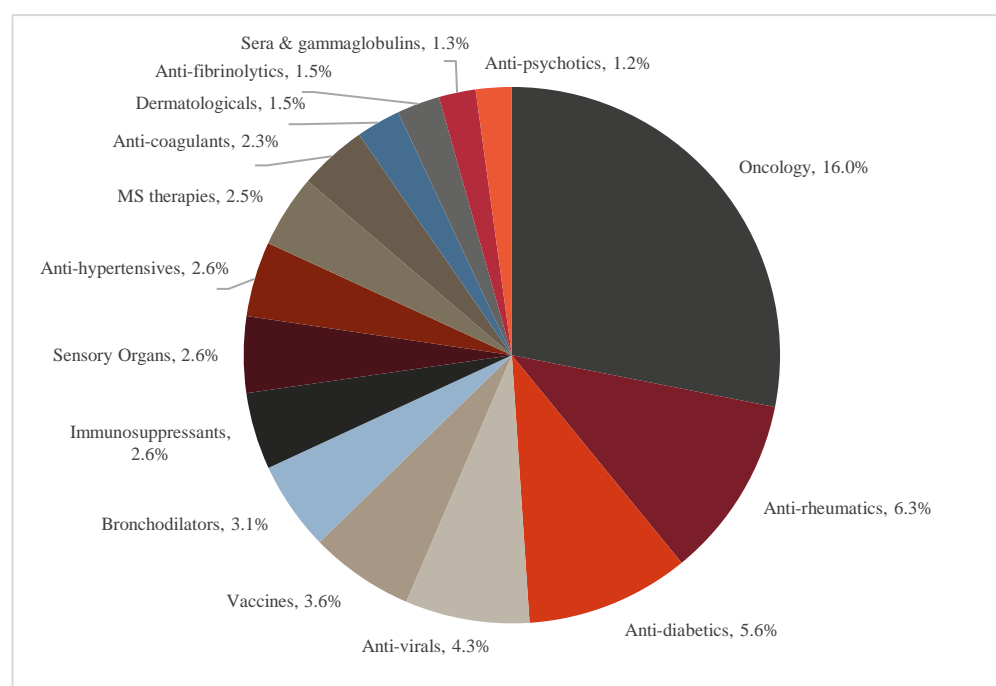
New product launches, widespread population aging and sedentary lifestyles leading to increased chronic disease prevalence, technological advances, new methods for drug discovery, and an increase in pharmaceutical drug usage have been some of the key growth drivers for the industry. Globally, the pharmaceutical companies are offering drugs

for customized individual treatment for better treatment against different diseases, and precision medicine which aims to provide medical care according to the patient's individual characteristics, needs, preferences, and genetic makeup.

Oncology drugs contributes to larger share of the pharma market

Oncology is the largest therapy area in pharmaceutical market by value with close to 16% share in pharmaceutical sales in 2019. It is one of the more expensive areas to develop new therapeutic drugs. Around 40% of R&D spend in pharma sector goes into oncology segment. The growth of oncology sales can be partly attributed to the growth of the immune-oncology sub-segment.

Therapy-wise share in global pharmaceutical market (value) (2019)



Note: Overall pharmaceutical market was sized at USD 1,250 billion in 2019
 Source: Industry reports, CRISIL Research

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

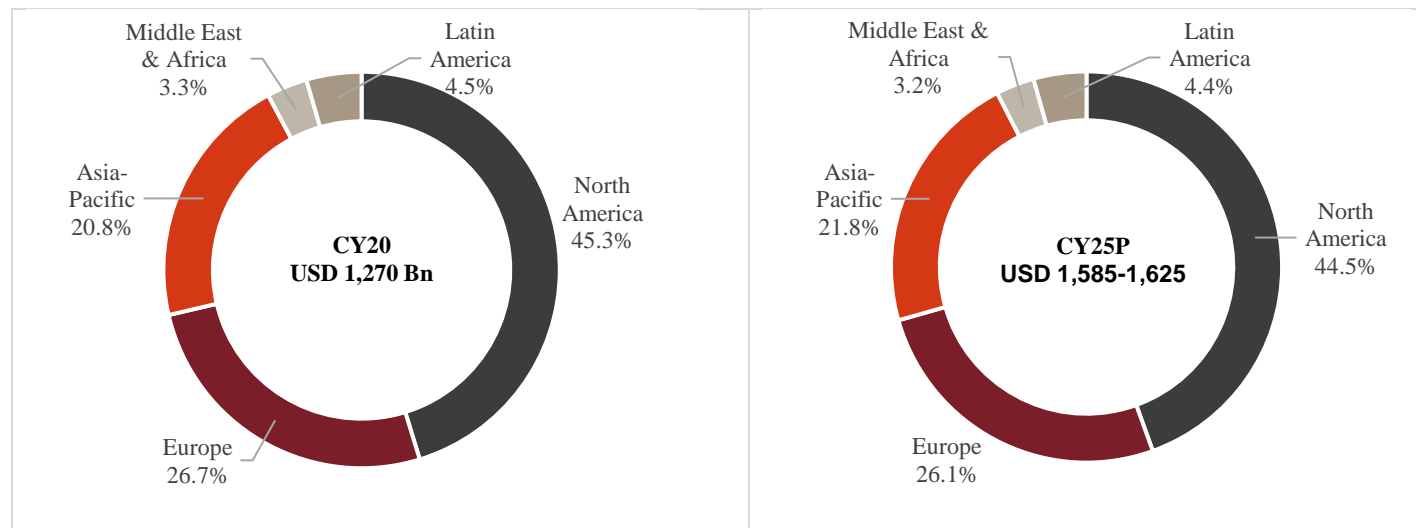
Increasing R&D expenditure by global players is expected to lead to development of innovative medicines in the treatment of various diseases. Globally, the number of clinical trials has been increasing with the increasing prevalence of chronic diseases, and the growing demand for clinical trials in developing countries is also fuelling the market's growth. The global market is also driven by a rising number of biologics. The need for orphan drugs and the demand for advanced technologies, globalization of clinical trials, and technological evolution to conduct clinical trials are further projected to drive the pharmaceutical market growth.

North America to continue to dominate the global pharmaceutical market; however, Asia-Pacific region to remain the fastest in terms of growth

Global pharmaceutical market has grown over the years owing to manifold increase in the value terms mainly in the markets of North America, Europe and Asia Pacific. North America is the largest pharmaceutical market in the world with the value of ~USD 575-585 billion as of CY20 followed by Europe and Asia-Pacific which stood at ~USD 335-340 billion and ~USD 265-270 billion, respectively, during the corresponding year.

Emerging markets represent an exceptional opportunity for the pharmaceutical industry on account on expected rise in healthcare spending from current low levels and increase in per capita income to support this rise in expenditure. Emerging markets comprise of Brazil, India, China, South Africa, ASEAN-5. Emerging Asia comprises the ASEAN-5 (Indonesia, Malaysia, Philippines, Thailand, Vietnam) economies, China, and India. Emerging markets are expected to grow faster than the overall global pharmaceutical market.

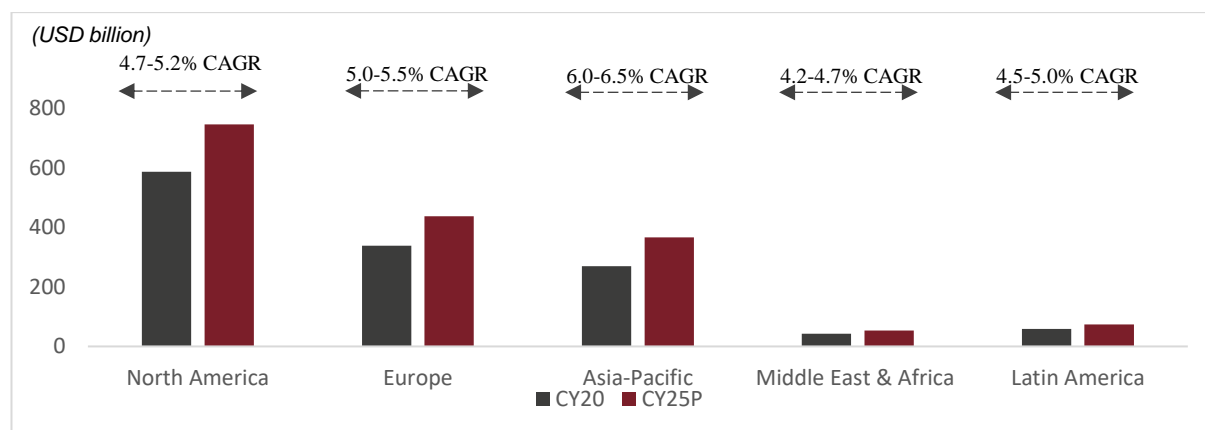
Region-wise segmentation of global pharmaceutical market



P: Projected

Source: Mordor Intelligence, CRISIL Research

Region-wise global pharmaceuticals market outlook (USD billion)



Note: Global pharmaceutical market - CY20: USD 1,270 Bn and CY25P: USD 1,580-1,625

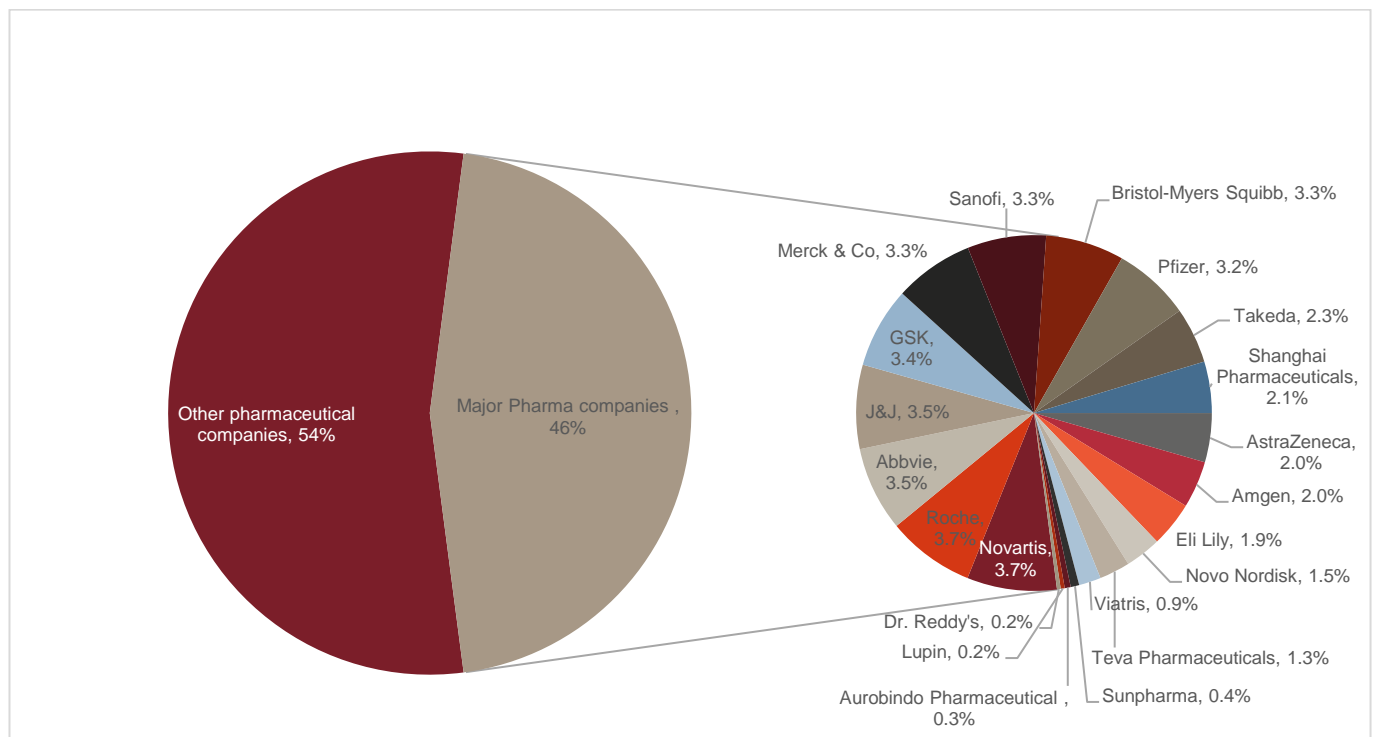
P: Projected

Source: Mordor Intelligence, CRISIL Research

Top MNC companies contribute to almost 45-50% share in global pharmaceutical market

Roche gained second position; Johnson & Johnson slips down

- The top 10 players maintained a global market share of about 33-35% in 2020.
- Novartis leads the global pharmaceutical companies with highest pharmaceutical revenue (USD 48Bn in 2020), its revenue grew by 3% in 2020
- Roche leads in terms of overall revenues(USD 47.5 Bn in 2020), as its revenue grew by 10.2% on year in 2019. Growth was primarily driven by increase in sales of drugs like Ocrevus, Perjeta and Tecentriq by 57%, 29% and 143% on year respectively in 2019. Oncology segment grew by 6% on year during the year.
- Johnson & Johnson witnessed fall in revenue from cardiovascular therapy by 10.7% on year in 2019. Total pharmaceutical sales grew only by 3.6% during the year

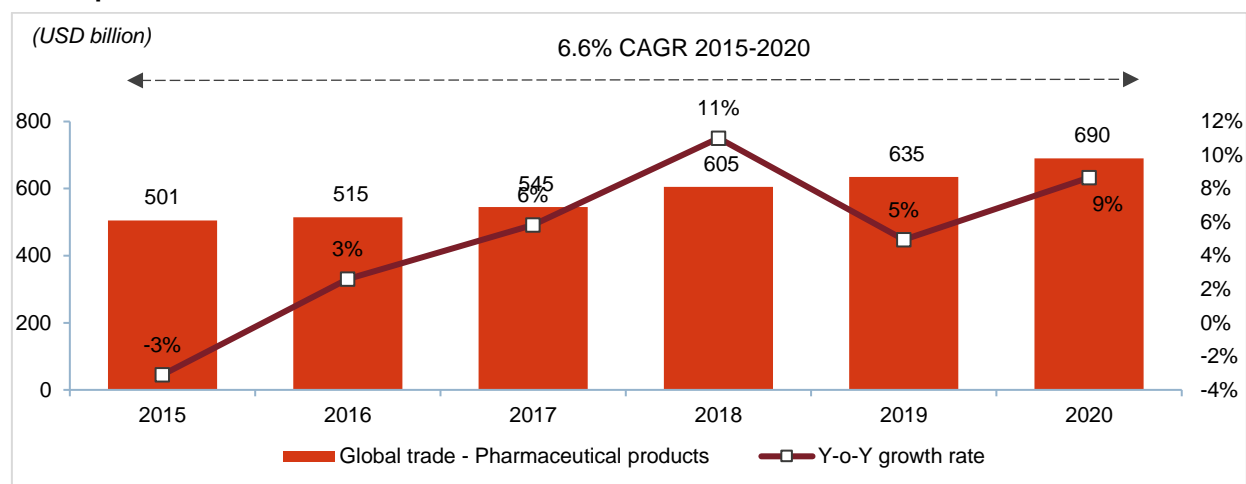


Note: Global pharmaceutical market - CY20 estimated at USD 1,270 Bn
Source: Company reports, CRISIL Research

Trade contributes to nearly 50-55% of Pharmaceutical global sales

Global pharmaceutical industry has around 50-55% of its sales derived from trade transactions. The overall global pharmaceutical industry is estimate at USD 1,300 Billion in 2020. Countries reported trade of roughly USD 690 billion in 2020 for pharmaceutical products. Global trade (import and export) saw an increase of 6.6% CAGR from USD 501 billion in 2016 to USD 690 billion in 2020. Calendar year 2020 witnessed change of geographic share in total trade, as China reported drop in exports during the COVID-19 pandemic.

Global pharmaceutical trade



Source: UN Comtrade, International Trade Centre – Trade map, CRISIL Research

USA, Germany, Belgium, China, Switzerland, United Kingdom, Japan are some of the key importing countries in pharmaceutical industry. India is not a major importing nation and contributes to less than 1% of total pharmaceutical imports. USA is one of the key importers of pharmaceutical products and contributed to 20.1% of global imports in 2020. USA saw increase in imports in 2020 on account of pandemic driven demand for pharmaceutical products. USA largely imports pharmaceutical products from Ireland, Germany, Switzerland, and India with EU nations contributing to 65% of its total imports and India (as an exporter) contributing to 6% of USA imports over the last five years from 2016 to 2020.

Most of complex finished pharmaceutical products consumed in the United States are manufactured locally or imported from western European countries such as Germany, Belgium, Switzerland. Imports contribute to only 25% of consumption in United States, but given the large size of the consumption market in US, US is the largest importer of pharmaceutical products in the world.



European region is among the major exporting regions. Within European pharmaceutical industry Switzerland, Germany, Italy, France, United Kingdom, Denmark and Belgium are key pharmaceutical production markets. These countries also contributes majorly to pharmaceutical exports from the region. Germany contributed 14.2%, Switzerland contributed to 12.8%, and Belgium contributed to 8.9% of overall pharmaceutical exports in 2020. USA is among the top 5 exports in the pharmaceutical trade. India contributed to 2.7% of the pharmaceutical exports in 2020.

Share of top countries in pharmaceutical product imports

	2016	2017	2018	2019	2020	CAGR 2016-2020
Global Import (USD bn)	531.0	564.9	622.4	655.7	693.4	6.9%
y-o-y growth in global imports (%)	3.7%	6.4%	10.2%	5.3%	5.8%	-
Share of countries	2016	2017	2018	2019	2020	CAGR 2016-2020
United States of America	17.4%	17.1%	18.6%	19.6%	20.1%	10.8%
Germany	9.1%	9.4%	9.2%	8.9%	9.5%	8.0%
Belgium	6.6%	6.2%	6.5%	6.9%	7.4%	10.2%
China	3.9%	4.5%	4.5%	5.1%	0.4%	-39.0%
Switzerland	4.6%	5.1%	4.8%	4.8%	5.6%	12.2%
United Kingdom	6.2%	5.9%	4.9%	4.3%	3.7%	-5.7%
Japan	4.6%	4.0%	4.1%	4.2%	4.1%	4.0%
Italy	4.0%	4.2%	4.3%	4.2%	4.1%	7.4%
France	4.2%	4.1%	4.1%	3.8%	4.1%	6.6%
Netherlands	2.9%	2.7%	2.7%	2.8%	5.1%	22.8%
Spain	2.6%	2.5%	2.5%	2.4%	2.5%	5.9%
Russian Federation	1.7%	1.9%	1.7%	2.1%	1.6%	5.0%
Canada	2.1%	2.1%	2.0%	2.1%	2.1%	5.9%
Australia	1.5%	1.4%	1.3%	1.3%	1.3%	2.9%
Austria	1.1%	1.1%	1.2%	1.2%	1.1%	8.6%
India	0.3%	0.3%	0.3%	0.4%	0.4%	9.8%
Share of top 15 countries in global imports (excludes India)	72.5%	72.1%	72.4%	73.7%	72.8%	

Source: UN Comtrade, International Trade Centre – Trade map, CRISIL Research

USA is key customer for India, but India contributes to only 6% of USA pharmaceutical imports

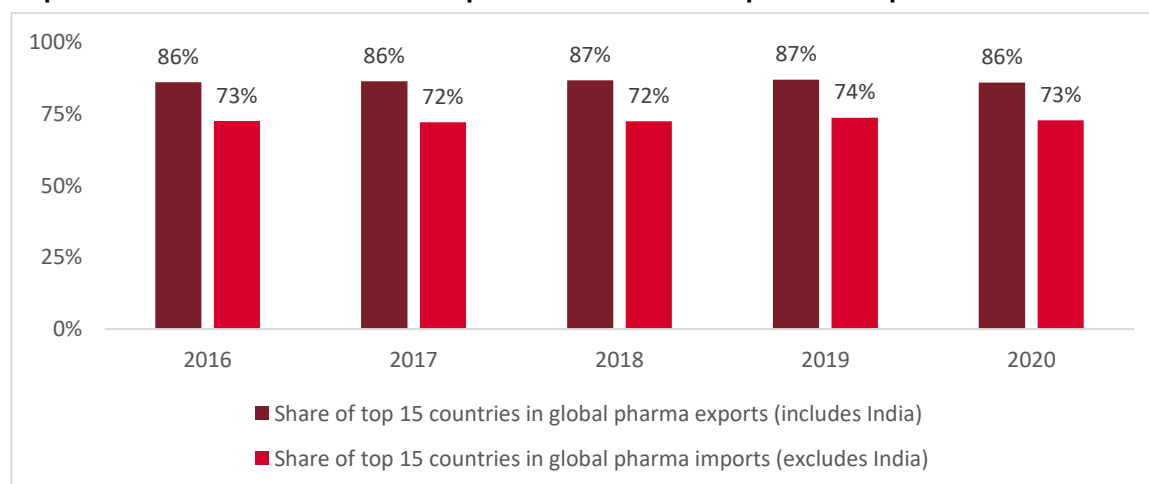
India exports 	18.3	USA imports 	139.5
USA share in India's exports	38%	India's share USA imports	6%

Source: UN Comtrade, International Trade Centre – Trade map, CRISIL Research

Share of top countries in pharmaceutical product exports

	2016	2017	2018	2019	2020	CAGR 2016-2020
Global Export (USD bn)	499.9	528.6	587.1	617.5	688.6	8.3%
y-o-y growth in global exports (%)		5.7%	11.1%	5.2%	11.5%	-
Share of countries	2016	2017	2018	2019	2020	CAGR 2016-2020
Germany	15.2%	15.8%	16.4%	14.6%	14.2%	6.5%
Switzerland	13.4%	13.3%	12.8%	13.4%	12.8%	7.1%
United States of America	9.4%	8.5%	8.2%	8.7%	7.8%	3.6%
Ireland	6.4%	7.3%	9.1%	8.6%	9.5%	19.9%
Belgium	8.4%	8.1%	8.1%	8.5%	8.9%	10.0%
France	6.1%	6.0%	5.8%	5.8%	5.5%	5.6%
Italy	4.3%	4.8%	4.7%	5.4%	5.2%	14.0%
Netherlands	4.7%	4.9%	4.9%	4.9%	7.2%	20.3%
United Kingdom	6.5%	6.2%	5.1%	4.4%	3.6%	-6.6%
Denmark	2.5%	2.4%	2.5%	2.8%	2.8%	11.4%
India	2.6%	2.4%	2.4%	2.6%	2.7%	8.9%
Spain	2.2%	2.1%	2.0%	2.1%	2.0%	6.5%
Austria	1.7%	1.7%	1.7%	1.8%	1.7%	8.2%
Sweden	1.4%	1.5%	1.5%	1.7%	1.7%	12.9%
China	1.4%	1.4%	1.5%	1.5%	0.2%	-33.0%
Share of top 15 countries in global exports (excludes India)	86.1%	86.4%	86.7%	86.9%	85.9%	

Source: UN Comtrade, International Trade Centre – Trade map, CRISIL Research

Export is more concentrated with top 15 countries as compared to imports


Source: UN Comtrade, International Trade Centre – Trade map, CRISIL Research

12 Median attrition rates for select pharmaceutical players (Addendum dated 15th June 2021)

Attrition rate

Fiscal year	2017-2018	2018-2019	2019-2020	2020-21
Attrition rate	14.25%	15%	15%	NA

NA – Not available

Source: Company annual reports, CRISIL Research

CRISIL Research has collated attrition rate provided by 7 listed pharmaceutical companies in their annual report for gratuity assumptions. CRISIL Research has calculated the average attrition rate based on the median concept. From a sample set of 7 listed pharmaceutical companies, the average attrition rate observed was 15% for 2019-2020.

The above attrition rate is for total employees and not just Key Management Personnel (KMP)

Companies considered in sample set
Alkem Laboratories Limited
AstraZeneca Pharma India Limited
Aurobindo Pharma Limited
Cipla Limited
Granules India Limited
Laurus Labs Limited
Syngene International Limited

13 Addendum dated 3rd Nov 2021

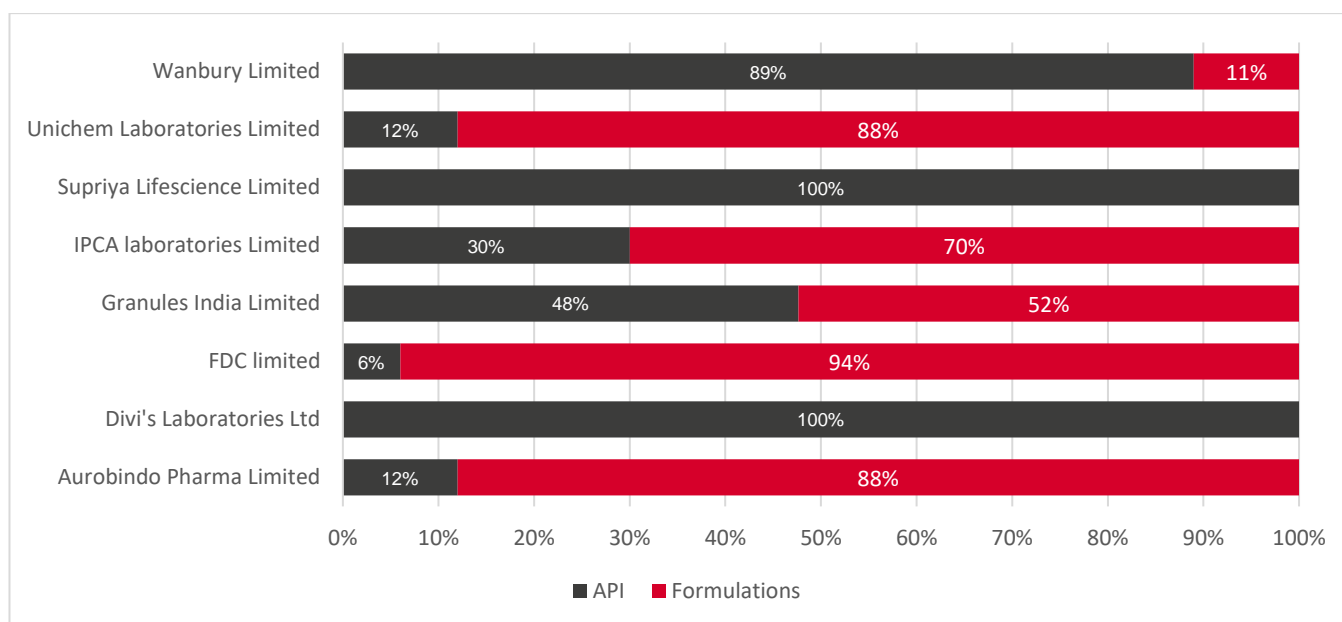
3rd November 2021

Competitive landscape of Indian pharmaceutical industry(Update for fiscal 2021)

For the peer comparison section, CRISIL Research has considered listed and unlisted pharmaceutical companies involved in same line of business and having certain similar products as Supriya Lifesciences Limited. CRISIL Research has included mix of API manufacturing and formulation players to illustrate the player diversity in pharmaceutical industry. The formulation players having production of API for in-house consumption are also captured in the analysis. We have largely included listed players for the competitive assessment for availability of latest financial data.

13.1 Operational Overview

Segment wise revenue mix for fiscal 2021

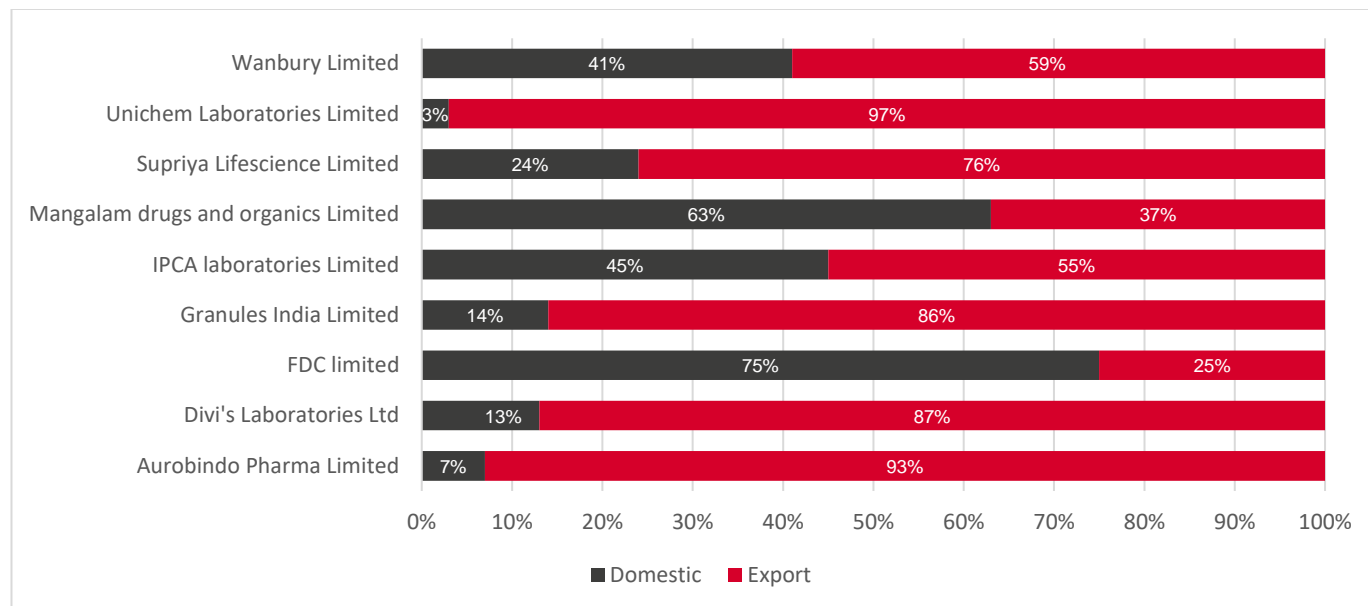


Note:

- Segmental breakup of revenue is not available for Mangalam Drugs and Organics Limited
- Divi's laboratories is involved in the production of API, Intermediates and Nutraceutical Ingredients

Source: Company annual reports, CRISIL Research

Geographical revenue mix for fiscal 2021



Source: Company annual reports, CRISIL Research

13.2 Financial Overview

Key financial ratios for listed players considered

Operating Income (In INR Million) for key players FY17-2021

Operating Income (In INR Million)	FY17	FY18	FY19	FY20	FY21	FY17-21 CAGR
Aurobindo Pharma Limited	149,396.2	165,465.4	196,432.0	231,374.8	2,49,470.0	14%
Divi's Laboratories Ltd	40,681.5	38,938.2	49,479.8	53,985.2	69,720.7	14%
FDC limited	10,114.2	10,735.4	10,889.2	13,414.4	13,377.2	7%
Granules India Limited	14,153.2	16,846.2	22,792.0	25,986.5	32,375.4	23%
IPCA laboratories Limited	31,518.0	33,148.4	37,814.0	46,561.2	54,329.9	15%
Mangalam drugs and organics Limited	3,003.6	2,760.7	2,278.3	2,826.8	3,842.1	6%
Supriya Lifescience Limited	1,875.1	2,173.5	2,818.2	3,200.2	3,893.6	20%
Unichem Laboratories Limited	15,195.0	8,180.0	11,800.5	12,106.2	12,351.4	-5%
Wanbury Limited	4,332.8	3,706.6	3,913.7	3,674.5	3,928.7	-2%

Source: Company annual reports, CRISIL Research

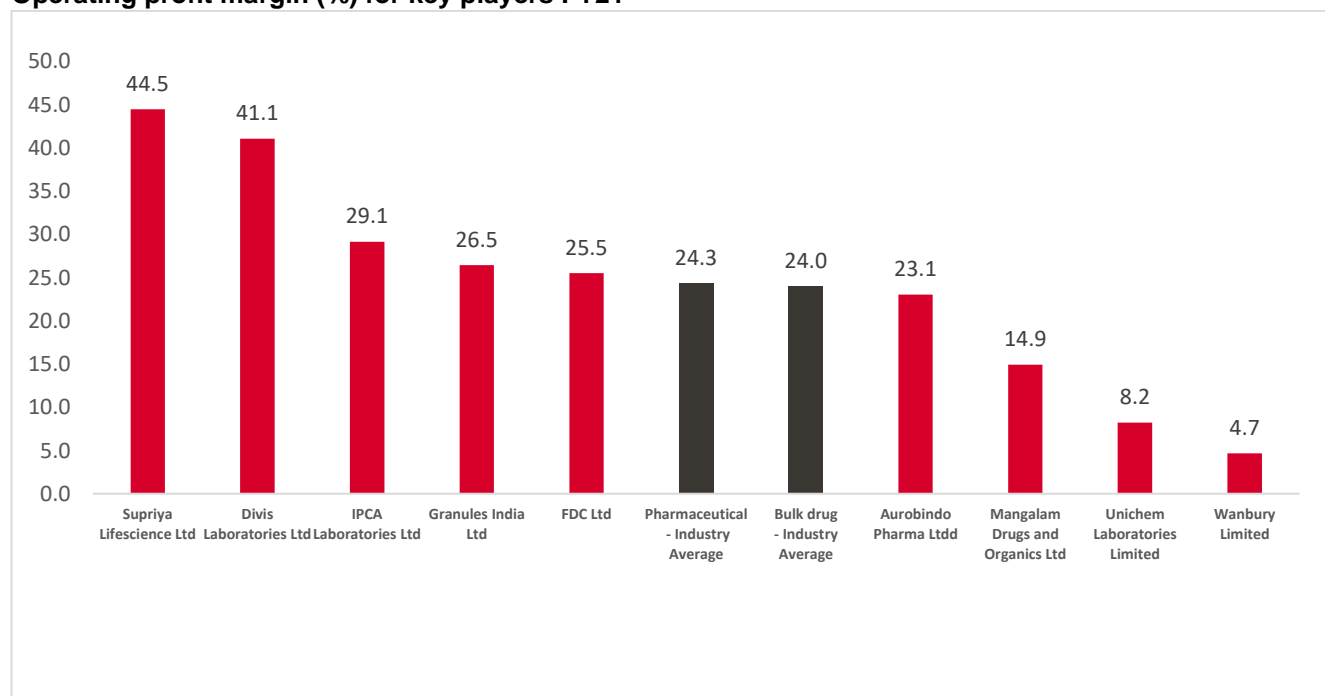
Net Profit (In INR Million) for key players FY17-21

Net profit (In INR Million)	FY17	FY18	FY19	FY20	FY21	FY17-21 CAGR
Aurobindo Pharma Limited	23,011.9	24,229.1	23,645.0	28,295.2	53,338.2	23%
Divi's Laboratories Ltd	10,604.2	8,770.1	13,527.4	13,765.4	19,842.9	17%
FDC limited	1,885.3	1,735.1	1,697.9	2,398.8	3,011.8	12%
Granules India Limited	1,645.2	1,325.9	2,364.1	3,354.0	5,494.6	35%
IPCA laboratories Limited	1,945.4	2,394.2	4,422.2	6,035.6	11,411.4	56%
Mangalam drugs and organics Limited	222.8	198.9	-80.3	82.5	279.7	6%
Supriya Lifescience Limited	54.7	113.0	398.1	734.03	1,238.3	118%
Unichem Laboratories Limited	1,086.8	25,449.1	-238.0	-601.8	343.3	-25%
Wanbury Limited	620.1	-320.1	-248.5	644.6	-126.1	23%

Note:

- N.Ap: Not Applicable

Source: Company annual reports, CRISIL Research

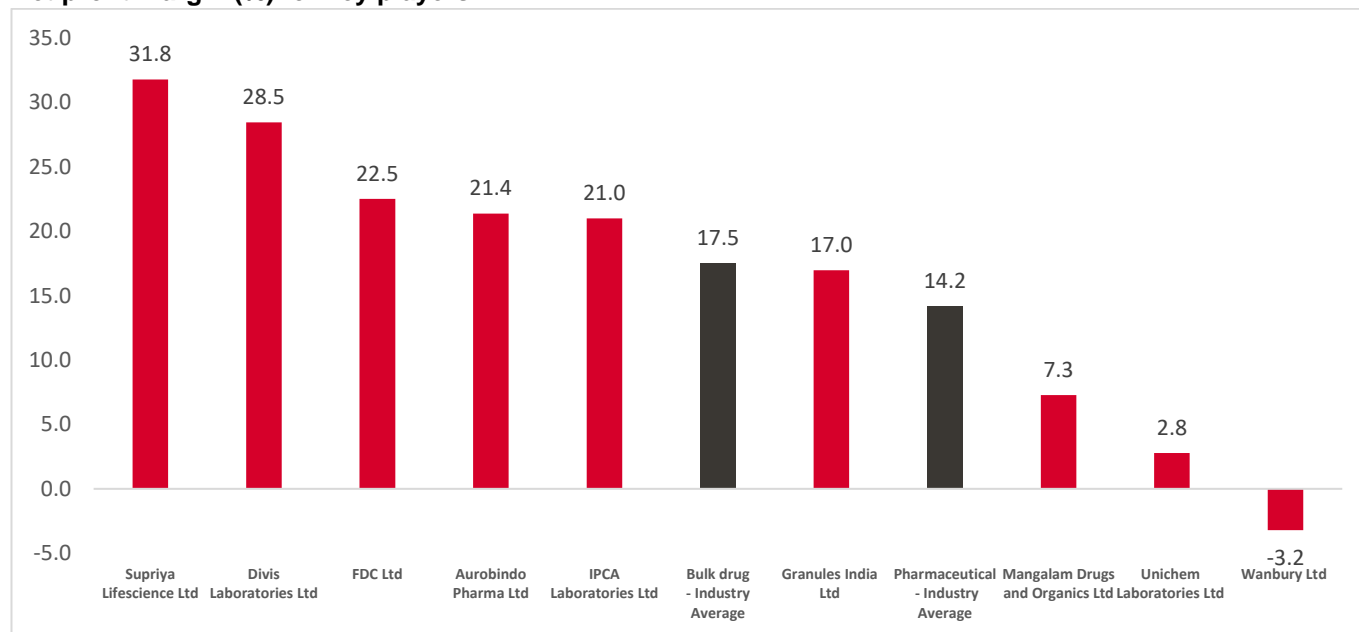
Operating profit margin (%) for key players FY21


Note:

- Refer to annexure for list of companies included in Bulk drug – industry and Pharmaceutical – Industry averages

Source: Company annual reports, CRISIL Research

Net profit margin (%) for key players FY21

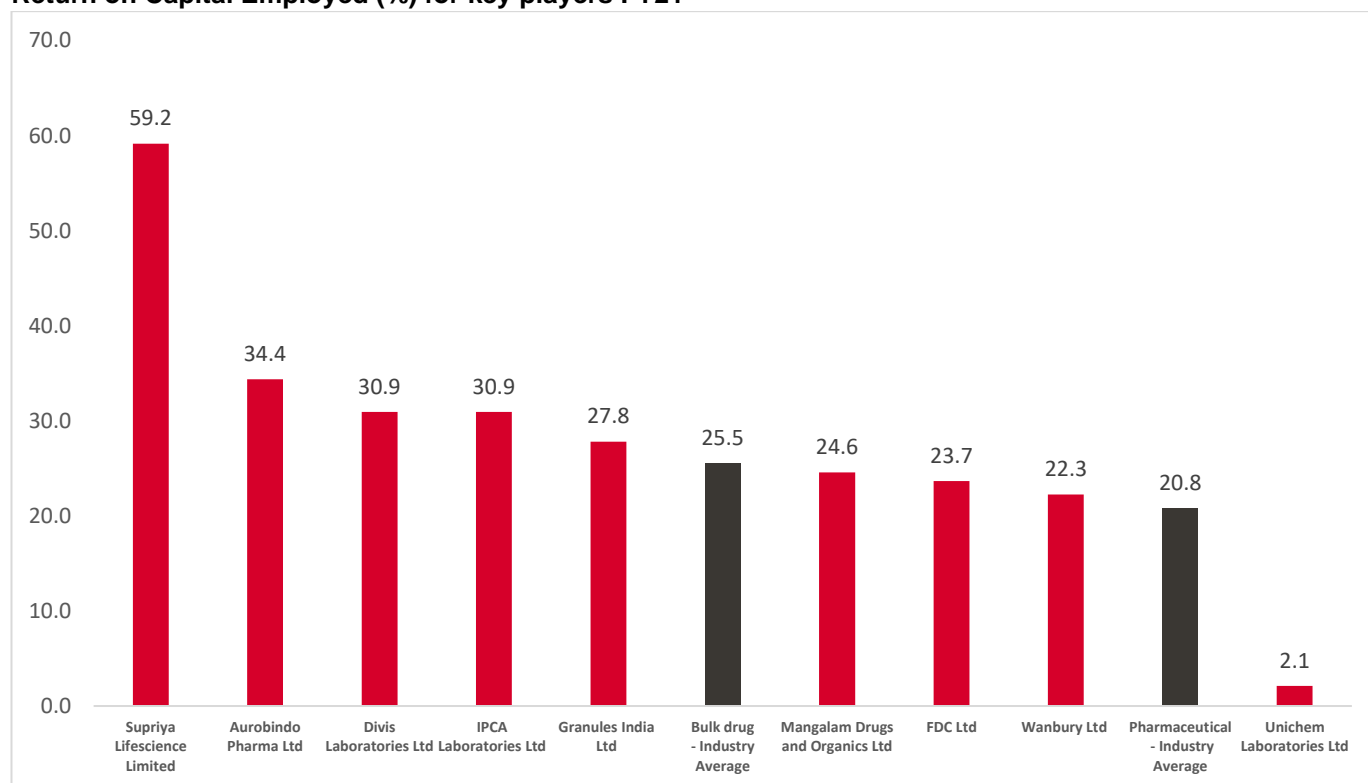


Note:

- Refer to annexure for list of companies included in Bulk drug – industry and Pharmaceutical – Industry averages

Source: Company annual reports, CRISIL Research

Return on Capital Employed (%) for key players FY21

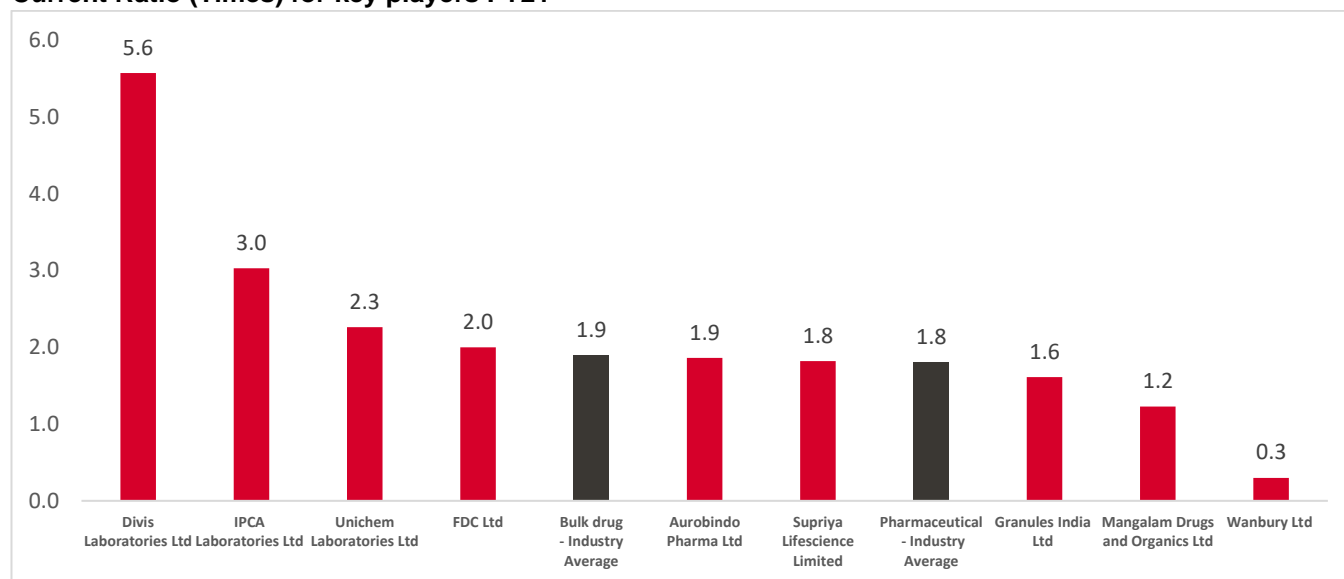


Note:

- Refer to annexure for list of companies included in Bulk drug – industry and Pharmaceutical – Industry averages

Source: Company annual reports, CRISIL Research

Current Ratio (Times) for key players FY21

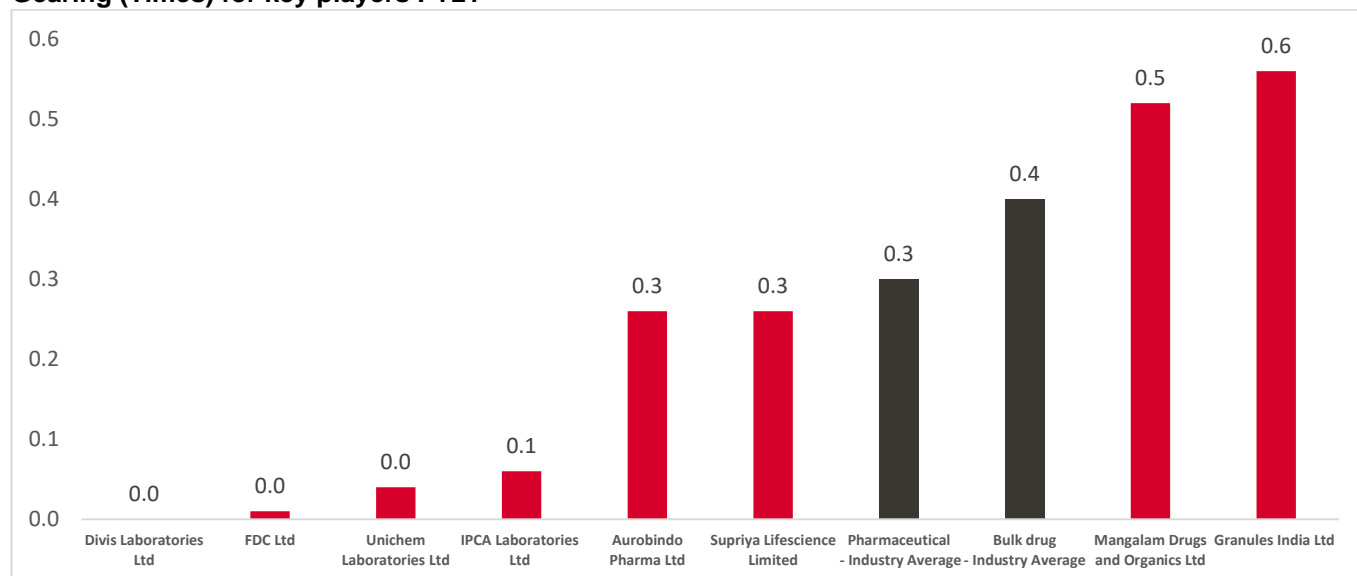


Note:

- Refer to annexure for list of companies included in Bulk drug – industry and Pharmaceutical – Industry averages

Source: Company annual reports, CRISIL Research

Gearing (Times) for key players FY21

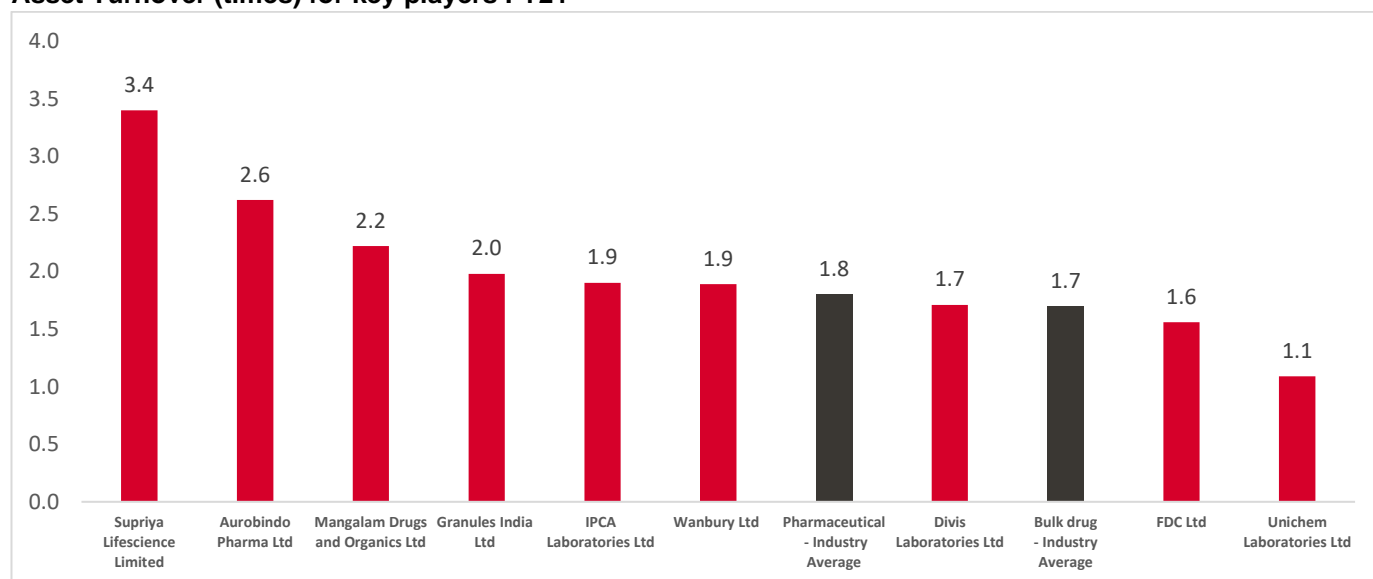


Note:

- Wanbury Limited are not considered due to negative gearing ratio
- Refer to annexure for list of companies included in Bulk drug – industry and Pharmaceutical – Industry averages

Source: Company annual reports, CRISIL Research

Asset Turnover (times) for key players FY21

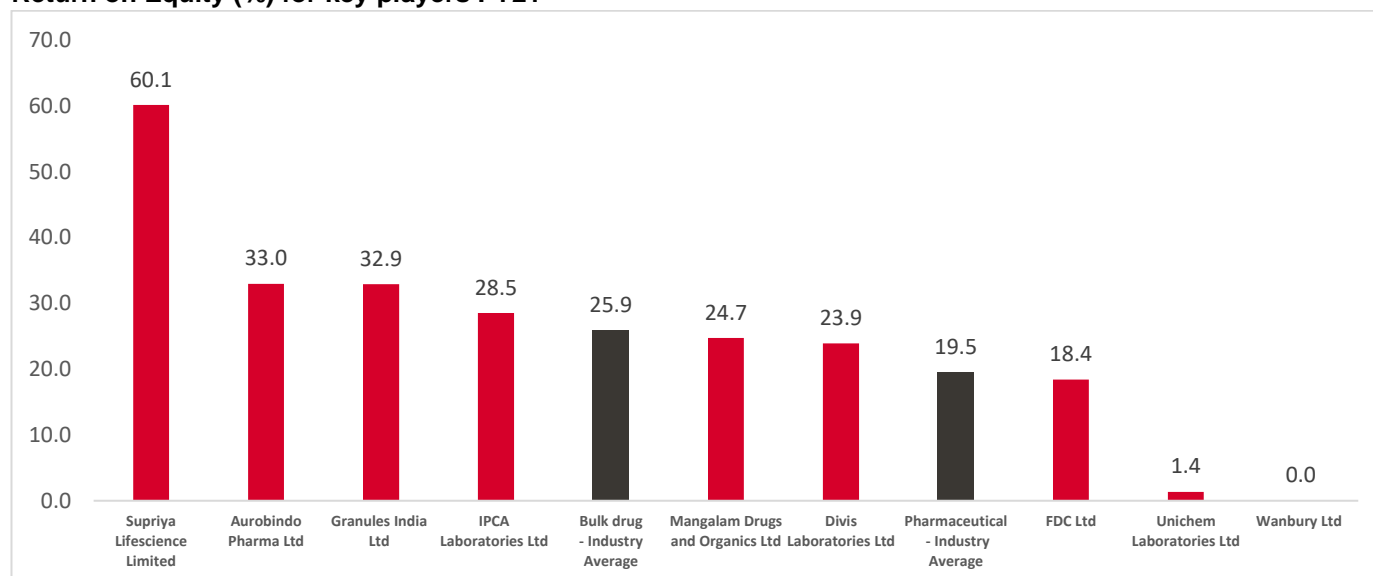


Note:

- Refer to annexure for list of companies included in Bulk drug – industry and Pharmaceutical – Industry averages

Source: Company annual reports, CRISIL Research

Return on Equity (%) for key players FY21



Note:

- Refer to annexure for list of companies included in Bulk drug – industry and Pharmaceutical – Industry averages

Source: Company annual reports, CRISIL Research

Key Observations:

- For fiscal 2021, Supriya Lifescience Limited has recorded an operating income of Rs. 3,894 Million with a compounded annual growth rate (CAGR) of ~20% from FY17 to FY21
- For fiscal 2021, Supriya Lifescience Limited has recorded net profit of Rs. 1238.3 Million with highest compounded annual growth rate (CAGR) of 118 % from FY17 to FY21 among the peers considered. Its net profit margins increased from 2.9% in FY17 to 31.8% in FY21. Supriya Lifescience operating margins improved from 11.8% in FY2017 to 44.7% in FY21
- Among the peers compared above, for fiscal 2021, Supriya Lifescience reported operating profit margin of 44.7% which is higher than bulk drug industry average of 24.0% and pharmaceutical industry average of 24.3% for the same period.
- Supriya Lifescience Ltd, in fiscal 2021 recorded net profit margin of 31.8% among the pharma players considered above. The company recorded higher net profit than the bulk drug industry average of 17.5% and pharmaceutical industry average of 14.2% for fiscal 2021
- For fiscal 2021, bulk drug players such as Aurobindo pharma Limited and Supriya Lifescience Limited record higher ROCE among peers compared above.
- Supriya Lifescience limited has recorded a RoCE of 59.2% greater than the bulk drug industry average of 25.5% and pharmaceutical industry average of 20.8% for fiscal 2021. In terms of current ratio, Supriya Lifescience Limited (1.8 times) is positioned below the bulk drug industry average (1.9 times) and above pharmaceutical industry average of 1.8 times respectively.
- In terms of asset turnover, Supriya Lifescience Limited (3.4 times) has highest value in the peers considered for fiscal 2021
- Supriya Lifescience Limited, for fiscal 2021, in terms of Return on Equity (RoE) positions itself higher than the bulk drug industry average of 25.9% and pharmaceutical industry average of 19.5%.

13.3 Annexure

List of companies considered for Pharmaceutical industry average

Name of the company
Aarti Drugs Limited
Aarti Industries Ltd -(Consolidated)
Ajanta Pharma Ltd -(Consolidated)
Alembic Pharmaceuticals Ltd
Alembic Pharmaceuticals Ltd -(Consolidated)
Alpa Laboratories Limited
AstraZeneca Pharma India Ltd
Aurobindo Pharma Limited-(Consolidated)
Bafna Pharmaceuticals Ltd.
Bal Pharma Ltd
Bliss GVS Pharma Ltd
Cadila Healthcare Ltd -(Consolidated)
Cipla Limited-(Consolidated)
Divis Laboratories Ltd -(Consolidated)
Dr. Reddys Laboratories Ltd -(Consolidated)
FDC Ltd -(Consolidated)
GlaxoSmithKline Pharmaceuticals Ltd -(Consolidated)
Granules India Ltd -(Consolidated)
Gufic Biosciences Limited
Ind-Swift Laboratories Ltd -(Consolidated)
Ind-Swift Ltd
Indoco Remedies Limited
IPCA Laboratories Ltd -(Consolidated)
J B Chemicals and Pharmaceuticals Limited-(Consolidated)
Jagsonpal Pharmaceuticals Ltd
Jubilant Pharmova Limited-(Consolidated)
Kilitch Drugs (India) Ltd
Kopran Ltd -(Consolidated)
Lyka Labs Ltd -(Consolidated)
Mangalam Drugs and Organics Ltd
Marksans Pharma Ltd -(Consolidated)
Morepen Laboratories Ltd -(Consolidated)
Natco Pharma Ltd -(Consolidated)
Nectar Life Sciences Ltd.-(Consolidated)
Neuland Laboratories Limited-(Consolidated)
Orchid Pharma Limited-(Consolidated)
Parenteral Drugs (India) Ltd -(Consolidated)

Pfizer Ltd
RPG Life Sciences Limited
Sanofi India Limited
Shilpa Medicare Ltd -(Consolidated)
SMS Pharmaceuticals Ltd
Strides Pharma Science Limited-(Consolidated)
Sun Pharmaceutical Industries Ltd -(Consolidated)
Suven Life Sciences Limited
Themis Medicare Ltd -(Consolidated)
Torrent Pharmaceuticals Limited-(Consolidated)
TTK Healthcare Ltd
Unichem Laboratories Ltd -(Consolidated)
Venus Remedies Ltd -(Consolidated)
Wanbury Ltd -(Consolidated)
Wockhardt Limited-(Consolidated)

List of companies considered for Bulk Drug industry average

Name of the company
Aarti Drugs Limited
Aarti Industries Ltd -(Consolidated)
Aurobindo Pharma Limited-(Consolidated)
Bal Pharma Ltd
Divis Laboratories Ltd -(Consolidated)
Granules India Ltd -(Consolidated)
Ind-Swift Laboratories Ltd -(Consolidated)
Jubilant Pharmova Limited-(Consolidated)
Kopran Ltd -(Consolidated)
Lyka Labs Ltd -(Consolidated)
Mangalam Drugs and Organics Ltd
Morepen Laboratories Ltd -(Consolidated)
Nectar Life Sciences Ltd.-(Consolidated)
Neuland Laboratories Limited-(Consolidated)
Orchid Pharma Limited-(Consolidated)
Shilpa Medicare Ltd -(Consolidated)
SMS Pharmaceuticals Ltd
Suven Life Sciences Limited
Wanbury Ltd -(Consolidated)

About CRISIL Limited

CRISIL is a leading, agile and innovative global analytics company driven by its mission of making markets function better.

It is India's foremost provider of ratings, data, research, analytics and solutions with a strong track record of growth, culture of innovation, and global footprint.

It has delivered independent opinions, actionable insights, and efficient solutions to over 100,000 customers through businesses that operate from India, the US, the UK, Argentina, Poland, China, Hong Kong and Singapore.

It is majority owned by S&P Global Inc, a leading provider of transparent and independent ratings, benchmarks, analytics and data to the capital and commodity markets worldwide.

About CRISIL Research

CRISIL Research is India's largest independent integrated research house. We provide insights, opinion and analysis on the Indian economy, industry, capital markets and companies. We also conduct training programs to financial sector professionals on a wide array of technical issues. We are India's most credible provider of economy and industry research. Our industry research covers 86 sectors and is known for its rich insights and perspectives. Our analysis is supported by inputs from our large network sources, including industry experts, industry associations and trade channels. We play a key role in India's fixed income markets. We are the largest provider of valuation of fixed income securities to the mutual fund, insurance and banking industries in the country. We are also the sole provider of debt and hybrid indices to India's mutual fund and life insurance industries. We pioneered independent equity research in India, and are today the country's largest independent equity research house. Our defining trait is the ability to convert information and data into expert judgments and forecasts with complete objectivity. We leverage our deep understanding of the macro-economy and our extensive sector coverage to provide unique insights on micro-macro and cross-sectoral linkages. Our talent pool comprises economists, sector experts, company analysts and information management specialists.

CRISIL Privacy

CRISIL respects your privacy. We may use your contact information, such as your name, address, and email id to fulfil your request and service your account and to provide you with additional information from CRISIL. For further information on CRISIL's privacy policy please visit www.crisil.com/privacy.

Disclaimer

CRISIL Research, a division of CRISIL Limited (CRISIL) has taken due care and caution in preparing this Report based on the information obtained by CRISIL from sources which it considers reliable (Data). However, CRISIL does not guarantee the accuracy, adequacy or completeness of the Data / Report and is not responsible for any errors or omissions or for the results obtained from the use of Data / Report. This Report is not a recommendation to invest / disinvest in any company / entity covered in the Report and no part of this report should be construed as an investment advice. CRISIL especially states that it has no financial liability whatsoever to the subscribers/ users/ transmitters/ distributors of this Report. CRISIL Research operates independently of, and does not have access to information obtained by CRISIL's Ratings Division / CRISIL Risk and Infrastructure Solutions Limited (CRIS), which may, in their regular operations, obtain information of a confidential nature. The views expressed in this Report are that of CRISIL Research and not of CRISIL's Ratings Division / CRIS. No part of this Report may be published / reproduced in any form without CRISIL's prior written approval.