

Sector Report

Indian Pharmaceutical Sector

Credence Capital

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Indian Pharma Sector Report

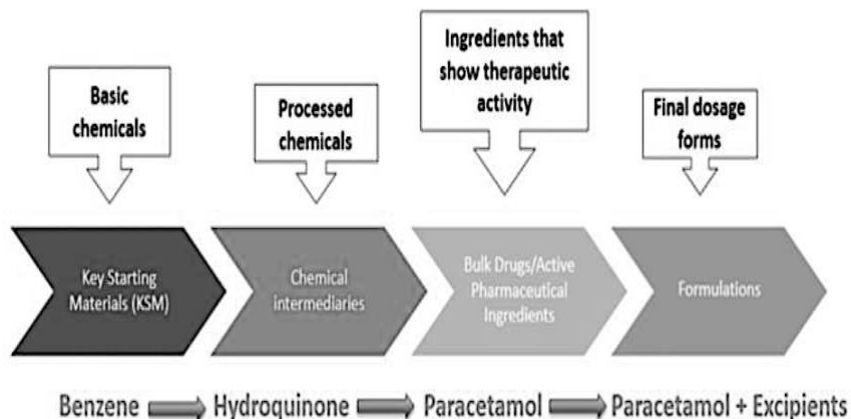
Introduction

- The global pharmaceutical market was valued at US\$1.4 Trillion in 2021 and is expected to reach ~US\$1.8 Trillion by 2026, growing at a CAGR of 3-6%. This includes the spending on COVID-19 vaccines, which is projected to reach a cumulative value of US\$251 Billion during this period. Excluding the spending on COVID-19 vaccines, the industry is expected to record ~5% CAGR between 2021 and 2026.
- Over the past two years, global spending on medicines underwent a significant re-prioritisation for the development of vaccines and novel therapeutics to contain the pandemic. While the impact from COVID-19 in 2020 and 2021 has been significant, the long-term impact on growth trends is expected to normalize.
- Within the global pharma market, India ranks tenth in value terms but is ranked third in volume terms. This is because the market is dominated by branded generics, making up 70-80% of the retail market with intense competition and low-price levels.
- Indian pharmaceutical sector supplies over 50% of the global demand for various vaccines, 40% of the generic demand for US and 25% of all medicines for UK. According to the Indian Economic Survey 2021, the domestic market is expected to grow 3x in the next decade. India's domestic pharmaceutical market stood at US\$ 42 billion in 2021 and is likely to reach US\$ 65 billion by 2024 and further expand to reach US\$ 120-130 billion by 2030. In terms of overall revenue, the Indian pharmaceutical market increased by 13.9% in January 2022. India is the largest producer of vaccines worldwide, accounting for ~60% of the total vaccines, as of 2021.
- The country has an established domestic pharmaceutical industry, with a strong network of 3000 drug companies and about 10,500 manufacturing units. Out of these, 1,400 units are World Health Organization (WHO) good manufacturing practice (GMP) approved; 1,105 have Europe's certificate of suitability (CEPs); more than 950 match therapeutic goods administration (TGA) guidelines; and 584 sites are approved by the US Food and Drug Administration (USFDA).
- India supplies 20% of global generic medicines, in terms of volume, making the country the largest provider of generic medicines globally. This is expected to expand even further in coming years.
- In addition to the increase in spending, Epidemiological factors like 20% increase in the patient pool, new diseases, and lifestyle and increasing prevalence of lifestyle diseases will boost the demand for pharmaceuticals in India. India exports its pharma products to more than 200 countries. The bulk of the exports are to countries situated in North America, Africa, and the European Union.

- Indian drug & pharmaceutical exports stood at US\$ 2,119.08 million in June 2022. • Indian drug & pharmaceutical exports stood at US\$ 24.60 billion in FY22 and US\$ 24.44 billion in FY21
- The major players in the Indian pharmaceuticals sector are Sun Pharmaceuticals, Dr. Reddy's Laboratories, Divi's Laboratories, Cipla, Biocon, Aurobindo Pharma, Torrent Pharmaceuticals, Lupin Ltd., Zydus Cadila Healthcare, and Abbott India among others. Major pharmaceuticals hubs are spread over Andhra Pradesh, Gujarat, Maharashtra, Telangana, and Goa.

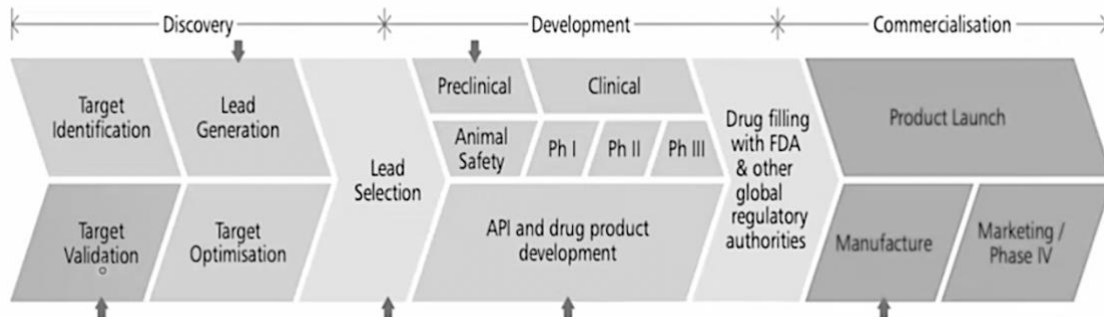
Value Chain of Pharma Sector

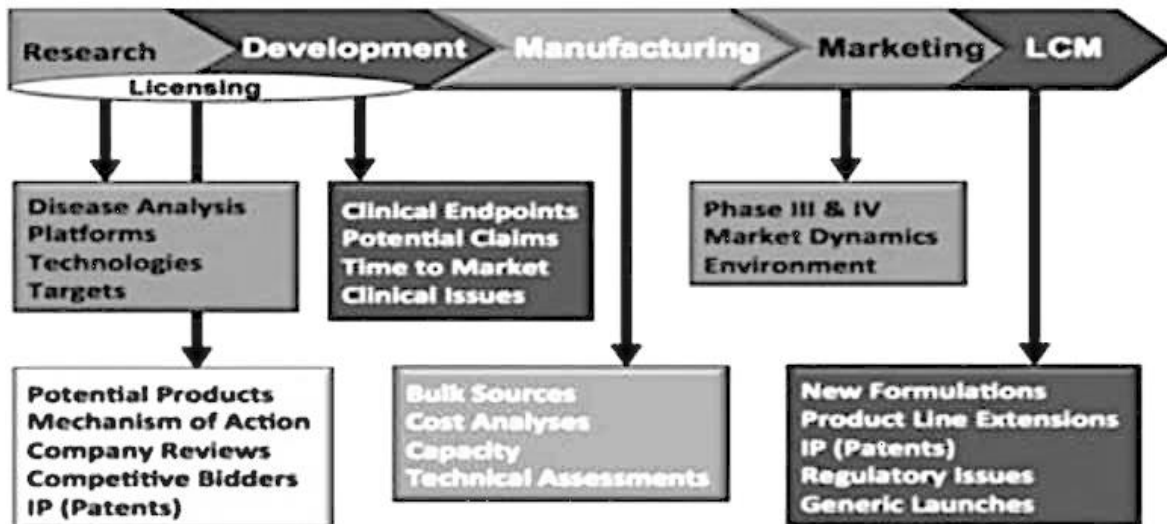
Pharmaceutical Value Chain



Source: CRISIL Research

- Manufacturing of a pharmaceutical drug is a 10-step process. Key starting materials (KSM), the basic chemicals which are largely crude oil derivatives, go through a series of chemical reactions before reaching the final stage at which point the drug shows therapeutic activity.
- The product developed in the first 4-5 steps is known as an intermediate that is processed further (next 3 steps) to obtain a bulk drug or active pharmaceutical ingredient (API).
- The API produced is unstable and/or highly reactive and hence needs to be stabilized with the help of excipients (chemically inactive substances). The API along with excipients make up the formulation drug.





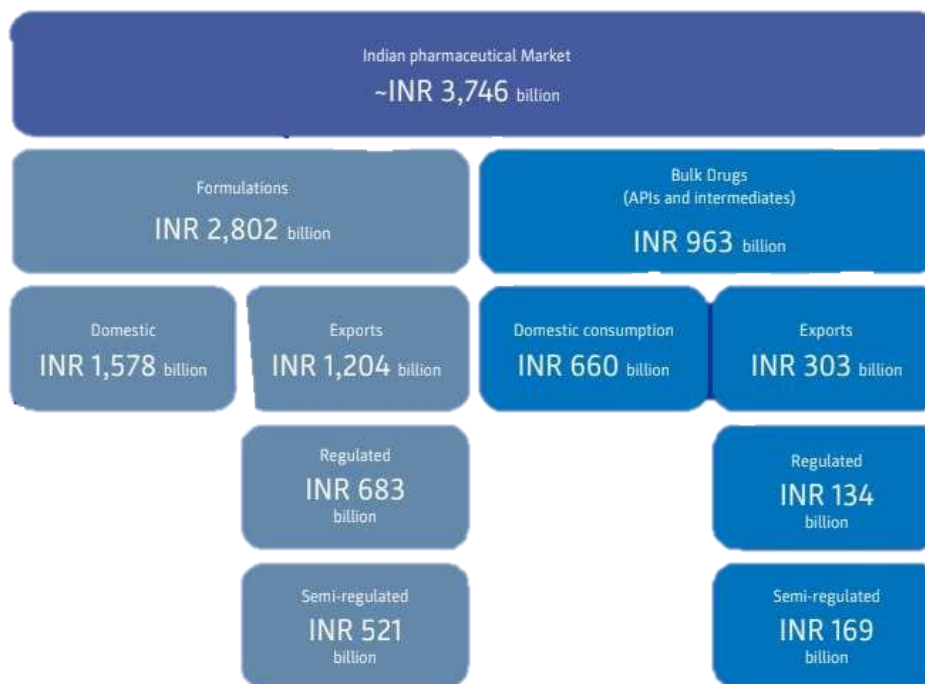
Source: Alpha Invesco

Another way to view the value chain can be through a functional approach. The same can be seen from the diagram above and has been explained in detail below:

- **Research & Development:** The R&D stage represents the discovery and development of the new innovator drug
- **Testing:** Tests are performed on animals and tissues in labs before three phases of human clinical trials
- **Approval:** A New Drug Application (NDA) is filed with the regulatory agencies like the US FDA with safety and efficacy data from the clinical trials
- **Distribution:** The distribution of medicines in most markets is carried out wholesalers, which act as a link between manufacturers and retailers to ensure the continuous supply of medicine.
- **Marketing:** Marketing is mostly concentrated around helping the physicians understand the accessibility, safety, effectiveness, and techniques of consuming the medicine
- A generic drug that is a medication created to be the same as an already marketed brand name drug in dosage form, safety strength, route of administration, quality, performance characteristics and intended use usually skips the value chain process till drug approval.

In case of generic drugs, the companies are required to submit an abbreviated new drug application (ANDA) to FDA for approval to market a generic drug that is the bioequivalent to the brand product

Structure of Pharma Sector in India



Source: KPMG, CII API Industry Report 2020

As mentioned earlier, the Indian Pharma industry can be broadly divided into API/Bulk Drugs and the Formulations category. Within the API/Bulk Drugs and Formulations sub-segments, the products can be sold within the branded and the generic categories.

Domestic API consumption is expected to reach \$ 18.8 billion by FY22. India is the largest exporter of formulations in terms of volume, with 14 % market share and 12th in terms of export value. Generic drugs, with 71% market share, form the largest segment of the Pharmaceutical industry in India. This is set to grow as exports of generics to the US rise, and as more branded drugs become off-patent. In the domestic market by revenue, Anti-Infectives (13.6%), Cardiac (12.4%) and Gastrointestinal (11.5%) had the biggest market share.

Upcoming Sub-Segments in Indian Pharma Sector

Two upcoming sub-segments in the Indian Pharmaceuticals sector are the Biosimilar and the Contract Research and Manufacturing Services (CRAMS) area.

Biosimilar

- The Biosimilar market is expected to reach a size of US\$ 40 billion by 2030 and CRAMS industry has posted 48 per cent CAGR between FY15-18 and expected to witness a strong growth over 25 per cent over 2018-21.

- Biosimilar are medicines made from living cells through highly complex manufacturing processes and must be handled and administered under carefully monitored conditions.
- Biosimilar are used to prevent, treat, diagnose, or cure a variety of diseases including cancer, chronic kidney disease, autoimmune disorders, and infectious diseases. A biosimilar is a biologic that is like another biologic drug already approved by the FDA.

CRAMS

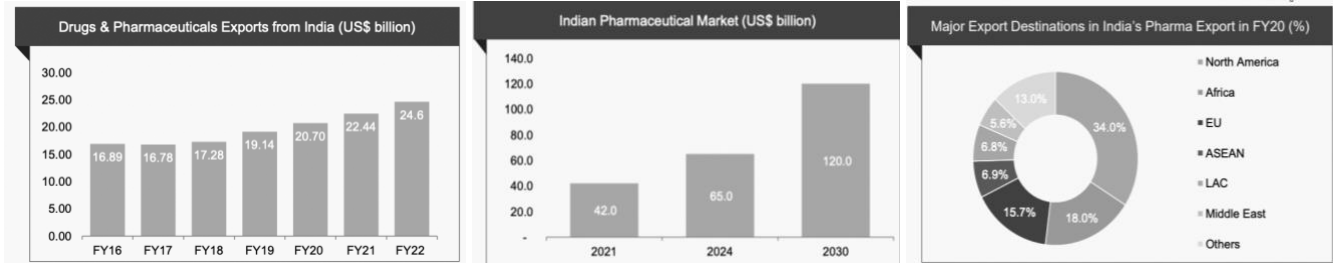
- Pharmaceutical companies are increasingly outsourcing research activities to academic and private contract research organizations (CROs) as a strategy to stay competitive and flexible in a world of exponentially growing knowledge, increasingly sophisticated technologies, and an unstable economic environment.
- India is amongst the preferred destinations for outsourcing of research as well as manufacturing activities. The growth in the CRAMS space in India has been witnessed since 2005 when India began compliance with the World Trade Organization's (WTO) intellectual property rules.
- Several key pharma players are now outsourcing their early drug development activities covering pre-clinical and early phase research to some of the leading CRO players in the market which were earlier handled by pharma companies themselves. New age CRAMS providers can cater to not just the pharmaceutical clients, but also biotech, agrochemicals, nutrition, animal health, consumer goods and others.

Major Listed Players in Pharma Sector in India*

S.No.	Name	CMP Rs.	P/E	Mar Cap Rs.Cr. †	Div Yld %	NP Qtr Rs.Cr.	Qtr Profit Var %	Sales Qtr Rs.Cr.	Qtr Sales Var %	ROCE %
1.	Sun Pharma Inds.	1028.00	31.08	246712.59	0.97	2255.90	10.20	10952.28	13.78	18.35
2.	Divi's Lab.	3411.45	30.25	90530.96	0.88	493.60	-18.61	1854.54	-6.69	35.07
3.	Cipla	1047.60	32.60	84544.14	0.48	797.41	11.25	5828.54	5.59	17.50
4.	Dr Reddy's Labs	4261.90	22.83	70974.93	0.70	1114.20	11.89	6331.80	9.42	13.96
5.	Torrent Pharma.	1554.65	43.87	52636.60	0.26	312.00	-1.27	2291.00	7.21	18.86
6.	Abbott India	22211.00	53.78	47425.44	0.65	265.52	38.05	1379.48	12.88	38.38
7.	Zyflus Lifesci.	452.35	23.32	45767.04	0.55	526.10	-19.08	4134.70	9.97	14.70
8.	Alkem Lab	3054.60	33.24	36505.13	1.12	347.72	-39.21	3079.37	9.98	18.65
9.	Lupin	754.05	447.08	34291.22	0.53	134.47	106.19	4145.52	1.32	-7.16
10.	Blocon	251.55	46.53	30201.09	0.20	81.80	-72.82	2319.70	26.04	8.96
11.	Gland Pharma	1597.10	25.58	26306.92	0.00	239.63	-20.88	1048.31	-2.98	24.79
12.	Aurobindo Pharma	447.55	11.69	26226.60	2.01	410.37	-41.23	5739.37	-3.41	12.87
13.	Syngene Intl.	620.80	58.63	24923.09	0.08	101.50	11.01	768.10	26.02	13.26
14.	Glaxosmi. Pharma	1300.55	53.02	21998.40	2.31	193.42	2.26	916.87	-1.85	36.66
15.	Ipsca Labs.	855.60	35.41	21723.13	0.47	145.89	-42.49	1600.95	3.66	20.39
S.No.	Name	CMP Rs.	P/E	Mar Cap Rs.Cr. †	Div Yld %	NP Qtr Rs.Cr.	Qtr Profit Var %	Sales Qtr Rs.Cr.	Qtr Sales Var %	ROCE %
16.	Laurus Labs	366.50	25.02	19749.38	0.55	227.44	15.08	1498.16	27.37	23.40
17.	Pfizer	4300.00	37.31	19663.53	0.82	311.07	19.62	637.47	0.19	29.18
18.	Ajanta Pharma	1168.60	22.17	14945.82	0.60	156.60	-20.08	938.10	6.02	29.15
19.	J B Chem & Pharm	1923.10	38.64	14871.99	0.86	111.08	13.64	809.44	36.50	23.37
20.	Piramal Pharma	116.70	36.29	13931.88	0.00	-37.34	-205.36	1720.01	9.03	7.16
21.	Sanofi India	5639.30	26.24	12951.52	3.21	130.90	-19.44	691.90	-8.30	34.77
22.	Suven Pharma	493.00	29.14	12571.72	0.41	72.06	-25.70	278.40	-7.51	40.83
23.	Glenmark Pharma.	424.75	12.49	11987.88	0.59	278.67	1.08	3375.25	7.24	15.99
24.	Alembic Pharma	556.25	41.05	10925.01	1.80	133.35	-18.68	1475.01	14.14	10.93
25.	Natco Pharma	547.15	24.49	9968.72	0.82	56.80	-12.75	432.10	14.55	3.91

*Non-Exhaustive List

Domestic Indian Pharma Market



(Source: IBEF)

- India is the world's largest provider of generic medicines; the country's generic drugs account for 20% of global generic drug exports (in terms of volumes). Indian drugs are exported to more than 200 countries in the world, with the US as the key market.
- India is the 12th largest exporter of medical goods in the world. The country's pharmaceutical sector contributes 6.6% to the total merchandise exports.
- Exports of Indian pharmaceuticals, including bulk drugs, intermediates, drug formulations, biologicals, AYUSH & herbal products and surgical products, reached US\$ 16.28 billion in FY20.
- Medical Device industry is expected to reach US\$ 50 billion by 2030, growing at a CAGR of 15%.
- India's drugs and pharmaceuticals exports stood at US\$ 24.60 billion in FY22 and US\$ 22.44 in FY21.
- In FY21, North America was the largest market for India's pharma exports with a 34% share and exports to the U.S., Canada and Mexico recorded a growth of 12.6%, 30% and 21.4%, respectively.
- India's formulation surged 18% and the bulk drug exports rose 9% y-o-y in the first half of FY21, according to a report by Crisil.
- According to a report released in September 2021 by the global consulting firm Kearney in collaboration with the Confederation of Indian Industry (CII), India's vaccines industry could grow from US\$ 2 billion to US\$ 5 billion in the next decade, as new Indian and global pharmaceutical companies have started including vaccines as a key part of their portfolios.
- India could restart deliveries of COVID-19 shots to global vaccine-sharing platform COVAX in November-December 2021 for the first time since April 2021. The World Health Organization (WHO), which co-leads COVAX, has been pushing India to resume supplies for the programme.

Growth Drivers

The growth drivers for the sector include:

- **Increase in population with chronic diseases:** A steady rise in the population of the country currently estimated at 1.38 billion with an annual growth rate of close to 1.13% per year with an increase in prevalence of chronic diseases. The population is expected to rise to 1.5 billion by 2030
- **Cost Leadership of Indian Manufacturers:** Cost competence of Indian manufacturers vis-à-vis companies in the USA and Europe. 4 out of the top 10 global generic companies are Indian companies. Labour and production are way cheaper in India than many other countries in the developed world
- **Strong R&D Infrastructure:** An Indian pharmaceutical company spends anywhere between 8-13% of its revenue on R&D. Strong research and development activities helps the industry to move forward in combating any unforeseen circumstances or any ongoing ones. India's R&D infrastructure is lauded by many because of the cost-effectiveness, upcoming biotech industry, government initiatives, upcoming biotech industry and more
- **Changes in lifestyle patterns:** Growing number of diseases due to change in urban lifestyles with 32% of the population living in the urban areas and expected to grow in the future years. The penetration of non-communicable diseases (NCDs) such as cardiovascular diseases and diabetes has expanded. Deaths due to NCDs in India have increased from 37 per cent in 1990 to 61 per cent today
- **Favourable Government Policies:** The Indian Government has recently approved a new Production Linked Incentive (PLI) scheme which offer a total incentives of INR 15,000 crore to selected applicants for identified pharma products. The incentive structure within the scheme groups applicants based on their Global Manufacturing Revenue (GMR) of pharmaceutical goods in FY 2019-20. The incentive will be provided on incremental sales over the sales in the base year (FY 2019-20)
- **Increase in Budgetary Allocation to HealthCare:** Under Budget 2020-21, total allocation to health and wellbeing expenditure has been increased from INR 1.02 lakh crore to INR 2.23 lakh crore. The total outlay includes allocations made for Ministry for Health and Family Welfare, AYUSH Ministry and amongst other things allocation for drinking water and sanitation
- **Better Accessibility of Drugs:** Increased accessibility of drugs due to expansion and growth in infrastructure in Tier-II and other urban/rural areas along with a change in attitude towards modern medicines and therapies has led to an increased accessibility of drugs. This increased accessibility is going to translate into additional demand

Risk factors

Notwithstanding the benefits certain risk factor for the sector include:

- **Overdependence on Imports:** Dependence on foreign countries, particularly China for Active Pharmaceutical Ingredients (APIs). India imports over 60% of its API requirements (expected to reach a size of \$ 18.8 billion by FY22). API and other key ingredients for popular painkiller paracetamol are also imported from China. China has also hiked the prices of key starting materials (KSMs) used for making medicines by 10-20% affecting API domestic production in India.
- **Price Controls:** Further price controls can inhibit the growth potential of the sector. The National Pharmaceutical Pricing Authority (NPPA) undertakes price control decisions for essential and life-saving medicines. It has, so far, fixed ceiling prices of 860 scheduled formulations and retail prices for 1,189 new drugs
- **Regulatory Risks:** Regulatory approvals like those of US FDA have become more difficult due to the pandemic and resultant travel restriction. In the year 2019, Indian companies received 19 warning letters from the United States Food and Drug Administration out of total 41 issued by the Office of Manufacturing Quality (manufacturing plants located outside of the USA) a 4-year high and representing close to 45% of the total such letters issued by the US FDA. While the inspections reduced significantly in 2020 due to travel restrictions on account of Covid-19, the same can now be expected as travel restrictions start easing out. Some of the companies that received such warnings in the past include Lupin, Zydus, Aurobindo, Glenmark etc
- **Input Cost Inflation:** Any increase in the prices of Key Starting Materials and other input cost inflation is a serious threat to the industry and can seriously impact the margins and the profitability of the industry
- **Increasing presence of Alternative Medicines:** A considerable growth has been seen in the space of the homeopathic product market expected to grow at a CAGR of 14%. Homeopathic remedies are generally safe, and the risk of a serious adverse side effects arising from taking these remedies is thought to be minimal in comparison to chemical-based pharma products

Post Covid Trends in the Indian Pharma Sector

The Post Covid Scenario looks extremely promising for the Indian Pharmaceutical Sector. Some of the key themes that one should watch out for have been stated below:

- **Domestic Formulations:** Domestic Industry rose from lows of FY21. The segment registered a growth of 3-5% y-o-y growth in FY21 led by chronic therapies and Covid related drugs.
- **Bulk Drug Exports:** Global players de-risking supply chain from China. PLI scheme offers potential to reduce dependence on China and scale up efforts in the medium term
- **Covid 19 Vaccine:** The vaccination opportunity offers huge upside in both domestic and export sectors. India is expected to fully vaccinate 60-65% of adult population by December 2021. Exports are expected to resume only in the second half of FY22 once the domestic needs are met
- **Formulation Exports:** Diversification into complex, specialty products and biosimilars will aid revenue growth. PLI scheme offers potential to scale up exports in the medium term
- **China Plus One Strategy:** Pharmaceutical players worldwide have been hugely dependent on China for their supply of intermediates and APIs. After the pandemic experience, global pharmaceutical majors will want to reduce their dependence on China; and there ought to be more backward integration as companies attempt to establish themselves as end-to-end manufacturers.
- **Greater Government Outlays:** Greater outlays are expected in preventive healthcare and for public health emergencies. While that is good for all nations, and especially India where such spends are woefully inadequate, it is not certain how it will directly benefit pharmaceutical companies, other than hospital equipment suppliers
- **Telemedicine:** The increased internet penetration and awareness about virtual modes of interaction are likely to fuel the Telemedicine trend further. Both the patients and the doctors will be more at ease now while interacting through a virtual medium compared to the earlier situation
- **Return of Medical Tourism:** The Covid 19 pandemic seriously affected medical tourism via travel restrictions. However, as travel restrictions ease across the world we can expect medical tourism to once again pick up and slowly edge towards the pre-pandemic levels

Key Metrics used in the Pharma Industry

1. R&D expense as a % of Revenue

Most pharma companies have very high research and development (R&D) budgets because they can only survive and grow by discovering and developing new drugs. Knowing the R&D budget as a percent of revenue helps understand if the company is creating a strong pipeline of future drugs to come on the market. Comparison of R&D spend as a percentage of revenue with the average industry R&D spend will give us an idea as to how much importance is being placed by the Company on R&D.

2. Operating Profit Margin

Profit margin is another vital metric. Operating profit margin lets the investor understand the impact from R&D to see if the program is bringing successful candidates to the market, whether the marketing and selling costs are having a positive impact on revenues (market share gains), and whether external factors are negatively impacting the company.

3. PE and PEG Ratios

To understand the market's expectation of the future portfolio and performance of the company, it is important to benchmark these valuation ratios to the industry ratio and the firm's ratio over the period of last 5-10 years.

Some other ratios that can be considered are:

- a) Revenue CAGR over the last 3-5 years
- b) Employee Cost as a % of Revenue
- c) Dividend to earnings
- d) Drug portfolio and pipeline

Some qualitative factors that need to be considered as well are:

- a) Management of the company along with relevant experience
- b) Quality of patents and product portfolio and pipeline
- c) Technology infrastructure developed by the company
- d) Risk mitigation practices with reference to legal, compliance and foreign exchange risks

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