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INDUSTRY OUTLOOK

PHARMACEUTICALS INDUSTRY: TRENDS AND PROSPECTS

26 August 2021

Introduction

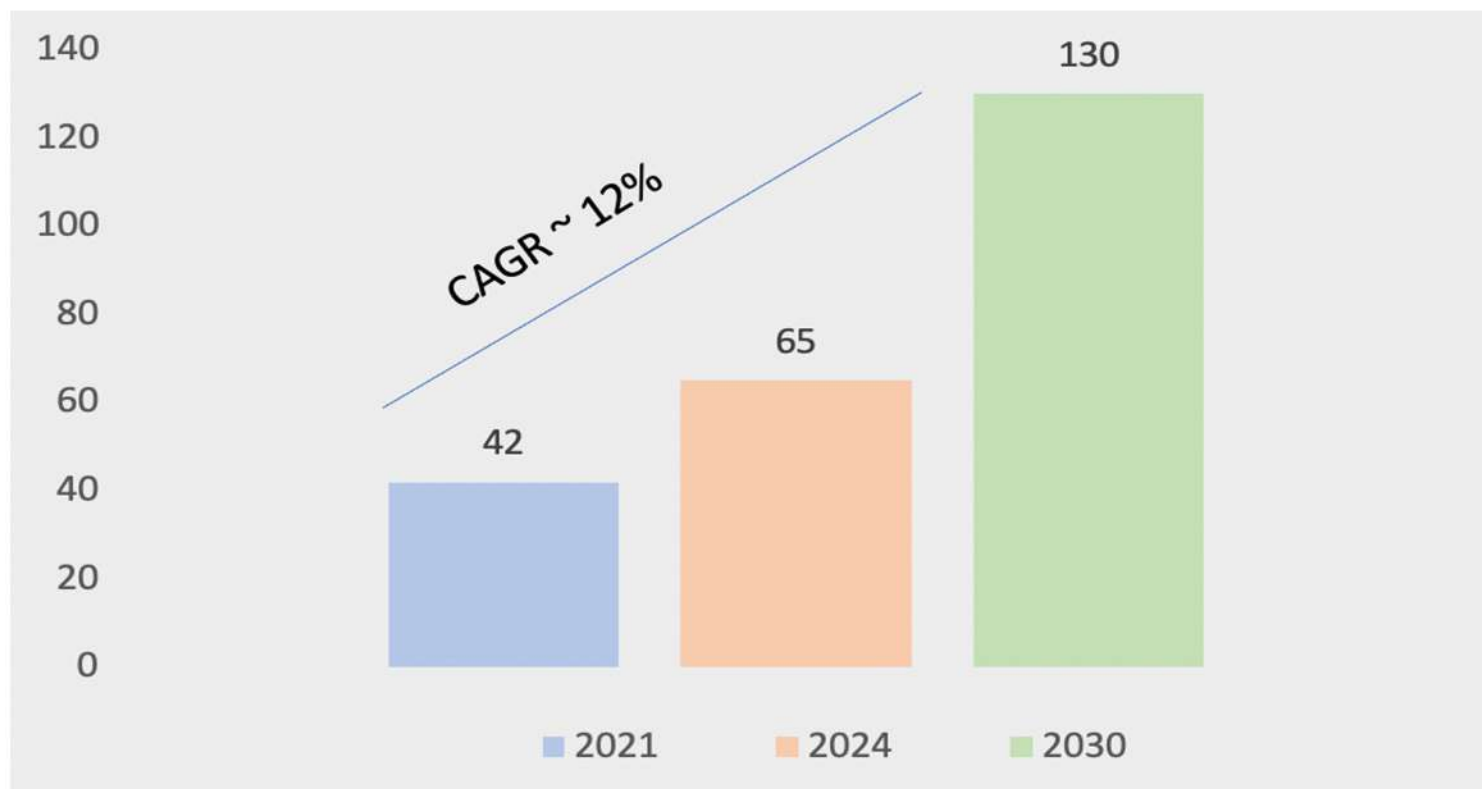
The pharmaceuticals industry is one of the pivotal pillars of the Indian economy, whereas the country ranks third worldwide for pharmaceutical production by volume and fourteenth by value (about USD 40 billion).[1] The country also contributes 3.5 per cent of total drugs and medicines exported globally by trading with more than 200 countries.[2] Moreover, the Indian pharma industry supplies over 40 per cent of the generics in the biggest pharma market – the US and about 25 per cent of the prescription drugs in the UK, along with catering to over 60 per cent of the global vaccine demand.[3] The figure (Figure 1) below gives the size of the Indian pharmaceutical industry with projections.

The market is expected to grow at approximately 12 per cent compound annual growth rate (CAGR). Clearly, then, with India being the largest provider of generic drugs globally and its significant contribution to the global market, the pharmaceutical sector is here to stay.



This thesis can also be substantiated by the remarkable country-wide network of 3,000 drug companies and about 10,500 manufacturing units and the four-fifth share in the production of the antiretroviral drugs to address the dreaded AIDS (Acquired Immune Deficiency Syndrome) disease.[4]

Figure 1: Indian Pharmaceuticals Market (US \$ billion)



Source: Indian Pharmaceuticals Industry Report, IBEF (May 2021).

Available at <https://www.ibef.org/industry/indian-pharmaceuticals-industry-analysis-presentation>

Some of the major domestic players in the industry include Sun Pharmaceutical Industries, Cipla, Lupin, Dr. Reddy's Laboratories, Aurobindo Pharma, Zydus Cadila, Piramal Enterprises, Glenmark Pharmaceuticals, and Torrent Pharmaceuticals among others.

E-Pharma

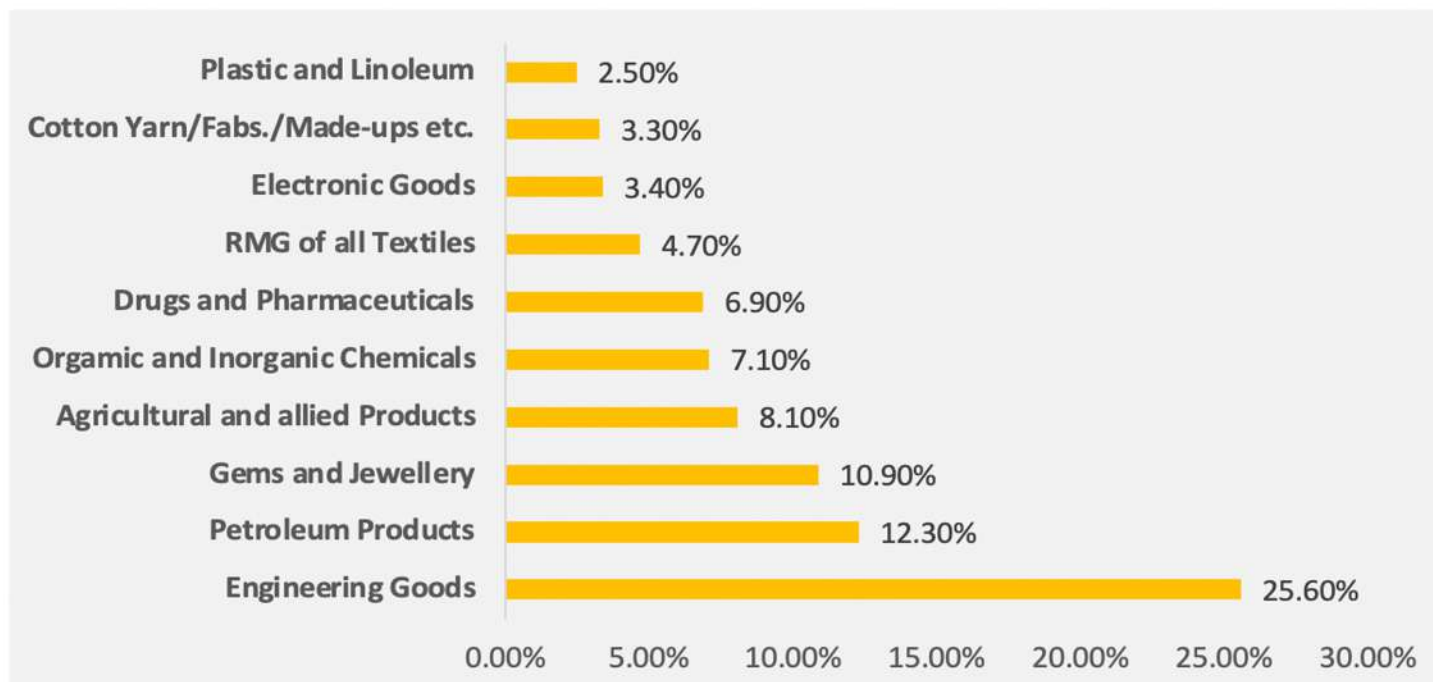
The recent surge in e-pharmacy has radically changed the pharmaceutical landscape with a range of flexible options available with households, including ordering online medicines, taking online consultation from practitioners, booking online tests among others. This segment is growing rapidly, and the market size at \$0.5 billion in 2019 is expected to grow at a compounded rate of 44 per cent to reach \$4.5 billion by 2025.[5] Furthermore, the overall global digital tech spend (which includes e-pharma and allied services) in healthcare is expected to exceed \$534 billion by 2025, from a \$180 billion in 2017,[6] with a majority chunk led by Artificial Intelligence (AI), Internet of Medical Things (IoMT), and Automation. The effects of these would also be seen in India as currently around 31 per cent of the patients use digital tools in India to search and schedule appointments and 27 per cent use online booking for diagnostic services. Also, more than 80 per cent of the doctors in India claim that patients value convenience more and expect the doctors to answer queries through mobile.[7]

Some of the well-known e-pharmacy players are Netmeds, EasyMedico and MedLife, and start-ups like 1 mg, Practo, Myra, etc. the size and share of all of them being varied. The long road ahead is expected to be traversed quickly by increasing penetration of pharma products, swifter adoption of e-commerce and up-scaling of internet penetration on a country-wide level.

Export Outlook

As the pharmaceutical industry is one of the most crucial sectors for the Indian economy, in the list of top ten export commodities, it stands at sixth place contributing roughly 7% to total exports (see Figure 2 below).

Figure 2: Average Share of Top 10 Goods* in Total Exports (for last 3 years)



Source: RBI's State of the Economy, (July 2021). Available at https://www.rbi.org.in/Scripts/BS_ViewBulletin.aspx?Id=20377. Note – *Top 10 export commodity groups account for around 85 of total exports.

The exports remain robust and have been increasing steadily (except 2017-18 where it dipped moderately), whereas the imports have been on a rise since 2017-18 (see Figure 3 below). The exports witnessed a year-on-year (YOY) growth rate of roughly 20 per cent in 2018-19 but so did the imports of roughly 26 per cent. The trend continued in 2020-21 for exports while that for imports dipped to roughly 13 per cent, which can be attributed to the combination of COVID and reduced dependency on international allies like China.



The tables below (Table 1 & 2) lay out the top ten export and import partners for India for the year 2020-21. As can be seen, US accounts for roughly 32 per cent of the total exports for the year 2020-21 whereas China accounts for roughly 40 per cent of the total imports. Interestingly, US is also the second largest importer after China.

Figure 3: Export-Import Trend for Recent Years



Source: <https://dashboard.commerce.gov.in/>

Note – Products include Ayush and Herbal Products; Bulk Drugs, Drug Intermediates; Drug Formulations, Biological and; Surgicals whereby Drug Formulations, Biological accounts for roughly 77 per cent, Bulk Drugs, Drug Intermediates accounts for roughly 18 per cent and the remaining two are almost distributed equally with 2-3% each.

Table 1: Top 10 Exporting Partners

Country Name	Export (₹ crore)
U S A	57,296.58
SOUTH AFRICA	6,173.19
U K	5,310.05
RUSSIA	4,377.54
GERMANY	4,268.05
NIGERIA	4,232.35
BRAZIL	3,893.98
CANADA	3,275.79
FRANCE	3,057.01
NETHERLAND	2,782.51

Source: <https://dashboard.commerce.gov.in/>

Table 2: Top 10 Importing Partners

Country Name	Import (₹ crore)
CHINA P RP	21,541.57
U S A	4,181.49
SWITZERLAND	2,925.63
BELGIUM	2,820.82
KOREA RP	2,512.57
GERMANY	2,045.03
FRANCE	1,712.19
SINGAPORE	1,419.46
ITALY	1,388.15
NETHERLAND	1,285.89

Source: <https://dashboard.commerce.gov.in/>

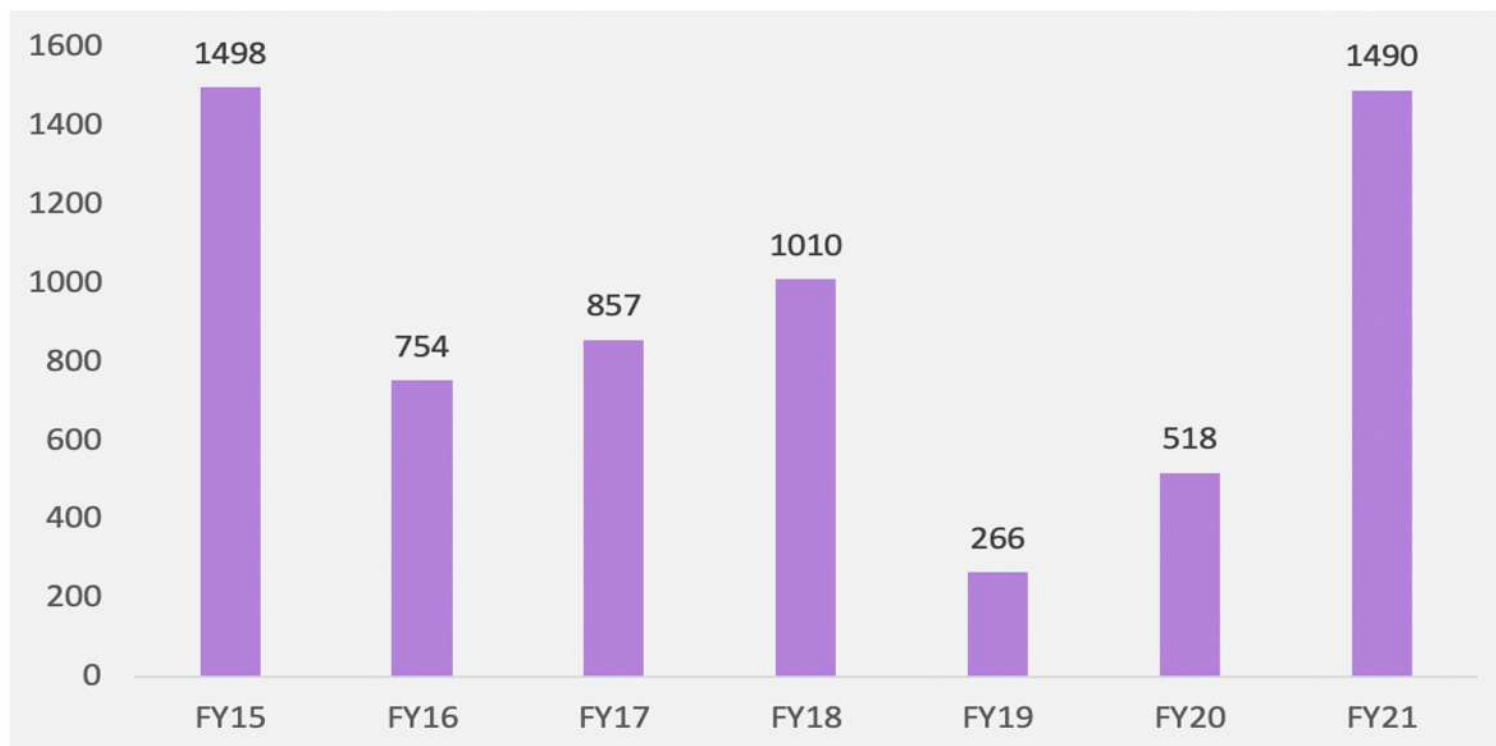
Foreign Direct Investment (FDI)

Of the list containing sixty three (63) sectors attracting FDI inflows from April 2000 to March 2021, Drugs & Pharmaceuticals ranked 9th attracting US \$17,991.11 million.[8] A glimpse of FDI equity inflows for recent years in the Pharma sector is given below (see Figure 4).

With the objective of making the sector more attractive to foreign investors, 74 per cent FDI under automatic route [9] has been permitted in brownfield pharmaceuticals. FDI beyond this is allowed through government approval route.[10] Additionally, the government has therefore permitted FDI up to 100 per cent under the automatic route for manufacturing of medical devices, without any distinction of greenfield or brownfield and such FDI will not be subjected to other conditions of the FDI policy on the pharmaceutical sector. [11]

Of late, there have been a slew of important events and developments in the drugs and pharmaceuticals space-far too numerous to list here. Some important signposts in this increasingly important sector include Sun Pharmaceuticals acquisition of the patent license for Dapagliflozin from AstraZeneca (June 2021); originating a real-time COVID-19 detection kit 'ViraGen' (May 2021) based on multiplex polymerase chain reaction (PCR) technology by Cipla; indigenous development of the technology of Oxygen Enrichment Unit (OEU) (April 2021) by the CSIR-CMERI, Durgapur; and the Central government's decision (January 2021) to set up three bulk drug parks at ₹ 14,300 crore (US\$ 1,957 million) to manufacture chemical compounds or APIs for medicines and reduce imports from China.[12] These and other developments have important implications not just for the sustenance of this sector but also its growth over the long haul.

Figure 4: FDI Equity Inflows in Pharma



Source: Compiled from Department for Promotion of Industry and Internal Trade (DPIIT) FDI Statistics

However, it is also important to provide a cushion to the domestic manufacturers. Thus, in efforts to boost domestic manufacturing, production linked incentive (PLI) scheme for promotion of domestic manufacturing of critical key starting materials (KSMs)/Drug Intermediates and Active Pharmaceutical Ingredients (APIs) in the country with financial implications of ₹6,940 crore have been introduced for the next eight years. [13]

Government Initiatives

This crucial sector with government support, enabling eco-system and a conducive policy frame can grow at a fast and sustained pace. Despite some changes in the government policy over the years, there has been a sense of continuity and it could perhaps reasonably be maintained that this has been the vision of all governments. Some catalytic initiatives are highlighted below. For example, total budget (2021-22) allocated to the department of pharmaceuticals was ₹470.41 crore.[14] Of late, there has been news about the formation of a new and separate ministry for the pharmaceutical and medical device industry, which has been long overdue. These demands have been brought to government's notice since 2015. Reportedly, the PMO is convinced of this need in the context of huge potential for growth in these two industry segments in the coming years and thus such a move can be expected soon.[15]

Production Linked Incentive (PLI)

With the aim of enhancing India's manufacturing capabilities by increasing investment and production in the sector and to contribute to product diversification to high value goods in the pharmaceutical sector, Department of Pharmaceuticals (DoP) notified the 'Production Linked Incentive (PLI) Scheme for Pharmaceuticals'. The approved outlay of the scheme is ₹15,000 crore.[16] In an earlier move, the government had approved the first PLI scheme worth ₹6,940 crore for 53 bulk drugs and ₹3,000 crore for the development of bulk drugs park towards making the industry self-reliant and discouraging sub-standard API imports. [17]

Affordable Drugs

Despite the country being one of the leading exporters of generic medicines to the world, the majority of Indians lack sufficient access to affordable medicines. To combat the problem, the government formulated Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) in 2008 to make available quality medicines consumables and surgical items at affordable prices for all and reduce out of pocket expenditure of consumers/patients. The Scheme has been approved for continuation with the financial outlay of ₹490 crore for the period from 2020-2021 to 2024-2025. The target is to open 10,500 PMBJP Kendras in all over the country by March 2025. It has also been decided to enhance the product basket of PMBJP up to 2,000 medicines and 300 surgical by March 2025. [18]

Import Exemptions

In an answer of a recent unstarred question[19], the Minister of State (MoS) in the Ministry of Finance gave details of COVID-19 relief goods on which GST/Customs duty has been reduced on imports. To mention a few, GST and IGST have been reduced from 12 per cent to 5 per cent on important medicines such as Remdesivir. An identical decrease has been made in medical oxygen, oxygen concentrators, and ventilators. Identical has been the case with Corona testing kits. Lastly, the reduction has been from 18 per cent to 5 per cent on hand sanitizers, and from 12 per cent to 5 per cent on pulse oximeters. The listed exemptions are to remain in force till 30th September 2021.

In sum, developments of wide-ranging ramifications, such as, Liberalized Foreign Direct Investment (FDI) with 74 per cent (74%) FDI under automatic route in brownfield pharmaceuticals, production linked incentive (PLI) scheme for promotion of domestic manufacturing of critical key starting materials (KSMs)/and Drug Intermediates and APIs augur well for the steady growth of the industry. This crucial sector with requisite government support, enabling eco-system and a conducive policy frame, viz., Production Linked Incentive (PLI), Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP), import exemptions could grow at a fast and sustained pace.

Industry Risk

One of the challenges faced by the Indian vaccine manufacturers is the crucial shortage of equipment, for example, small- and large-scale bioreactors and fermenters, with long waiting times for equipment ordered abroad.[20] Further, a steep rise in the cost of raw materials for essential drugs, called Active Pharmaceutical Ingredients (API) in pharma circles, is pinching the industry hard. The overall increase, averaging nearly 50 per cent in the wake of high-priced imports and supply disruptions from China, have raised doubts on the availability of drugs and could lead to shortages, particularly of those that are key in COVID therapy.[21] The industry faces concentration risk with nearly 70 per cent of the country's Active Pharmaceutical Ingredients (API) imported from China necessitating sufficient diffusion of sources and markets.



While nearly 70 per cent of the country's APIs are imported from China, the dependence rises to 90 per cent for certain life-saving antibiotics like cephalosporins, azithromycin and penicillin. Since these medicines are under price control, companies are forced to absorb the higher cost, raising questions about their viability. In this scenario, over time, certain medicines could disappear from retail shelves with companies switching to high-value products where margins are protected. The table below (Table 3) lists the per cent increase in various raw materials.

Table 3: Price Hike of Raw Materials for COVID Drugs (in ₹/kg)

	Mar'21	Apr'21	% Increase (approx.)
Ivermectin	18,000	54,000	200.00
Methylprednisolone	85,000	1,90,000	123.50
Meropenem	81,000	1,50,000	85.20
Doxycycline	7,500	12,000	60.00
Pipratazo	6,700	9,500	41.80
Enoxaparin	17,00,000	25,00,000	47.10
Paracetamol	550	800	45.50
Azithromycin	9,500	12,300	29.50

Source: "Pharma industry warns of Covid drug shortages as raw materials prices surge 200%" The Print (3rd May 2021). Available at <https://theprint.in/health/pharma-industry-warns-of-covid-drug-shortages-as-raw-materials-prices-surge-200/650792/>

The main reason behind the surge in prices is a huge demand for drugs, followed by anticipated shortages of raw material (owing to the suspension of cargo services by China), resulting in the hoarding of stocks here.

Of late, the gap in diagnostic services in India, particularly rural India, has acquired centre-stage because of the devastation caused to lives and livelihoods by the ubiquitous COVID 19 pandemic. Apart from the abominable lack of qualified pathologists, technicians, biochemists and other medical personnel, there is also a conspicuous absence of pathology laboratories and testing facilities. This has naturally led to a scramble to the urban areas for healthcare with attendant implications for loss of wages and the high cost of travel, testing and treatment necessitating development of adaptable and portable systems to leverage digital technologies. It is evident that in this overall setting and the emerging macro-economic landscape, digital technology can be a catalytic element of the transformation of the healthcare scenario in India.

The success stories in diverse parts of India, viz., Rajasthan, Arunachal Pradesh, Telangana, Kerala, Haryana, Andhra Pradesh, Bihar, Jharkhand, Uttarakhand, Maharashtra need to be replicated at the wider national level to bring about perceptible improvement in the rural healthcare system and enhance the quality of life for the poor and the vulnerable sections of society-what Mahatma Gandhi called the “teeming millions” of India.

The case for development of innovative business models and the need for technologies to go to scale is, therefore, well-founded and needs to be implemented in all seriousness. However, given the pathetic state of rural healthcare system in the country and the meagre expenditure on health earmarked in the Union Budget (the overall spending on health varied from 1.3 per cent of the GDP in 2010-11 to 1.5 per cent and 1.8 per cent of the GDP RE for 2019-20 and BE for 2020-21, respectively), there are strong and compelling reasons for enhancing the expenditure on the healthcare system in India and also altering the expenditure on the various sub-heads. In other words, both the size of the national healthcare pie has to increase and the pieces have to be worked out in a more judicious manner to meet emerging national requirements.

The Way Forward

Despite being wrecked by COVID, the industry can explore new and innovative options to generate and sustain new revenue streams. The increased demand for healthcare and insurance, for example, opens new avenues for investment, particularly in areas like chronic therapies for diseases such as such as cardiovascular, anti-diabetes, anti-depressants and anti-cancer treatment. In some cases, this shifting paradigm may require some course-correction, re-alignment of priorities and a change in focus in conformity with the evolving needs and requirements for sustained growth and structural transformation.

The Indian pharma market grew 37 per cent year-on-year and 15 per cent sequentially in Q1FY22.[22] The growth was driven by sales of COVID treatment drugs and other drugs. The recovery in acute therapies like gastro, anti-infectives, antibiotics and chronic therapies are expected to help pharma firms post strong growth. Moreover, the country has a low-cost of production, low R&D costs, innovative scientific manpower, and a large number of national laboratories that have the potential to steer the industry ahead to a higher level. As per industry analysts, the cost of manufacturing in India is approximately 33 percent lower than that of the US. [23]

Therefore, the industry can benefit from these attributes and accordingly scale up production, productivity and efficiency. But the realization of this potential necessitates harnessing economies of scale to move to a newer and higher orbit. The accent on productivity and efficiency has to be a pre-requisite of the overall structural transformation strategy.

ENDNOTES

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10. Under the Government Route, prior to investment, approval from the Government of India is required. Proposals for foreign direct investment under Government route, are considered by respective Administrative Ministry/ Department.
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18. A medicine under PMBJP is priced on the principle of a maximum of 50 per cent of the average price of the top three branded medicines. Therefore, the price of Jan Aushadhi Medicines is cheaper at least by 50 per cent and in some cases, by 80 per cent to 90 per cent of the market price of branded medicines. For more details see "Annual Report 2020-21", Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals and <http://janaushadhi.gov.in/>
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