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INDUSTRY OUTLOOK

PHARMA SECTOR IN INDIA: REDEFINING BUSINESS AND INNOVATION

21 June 2022

Introduction

The Indian pharmaceutical industry, widely known for generic medicines and low-cost vaccines, has evolved as a vibrant industry sector. In terms of volume of production, the Indian pharmaceutical industry is ranked third in the world behind China, and Italy and 14th largest in terms of value.

Supplying 20 per cent of the global supply of generic medicines, the Indian pharmaceutical industry of India is significant in the global pharmaceutical sphere. India has 8 out of 20 global generic companies in the world providing generic medicines to more than 200 countries. Also, the Indian pharmaceutical industry sources 65-70 per cent of World Health Organisation's (WHO's) vaccine requirements.

The Indian medicines are preferred worldwide, and India is justifiably called the "pharmacy of the world" because of competitive pricing and high quality. The Pharma sector currently contributes to around 1.72 per cent of the country's GDP.

The global pharmaceutical market is set to exceed US$1.5 trillion by 2023. Against this backdrop, the Indian pharmaceutical industry is currently valued at US$41 billion and is expected to grow to US$65 billion by 2024 and about US$120-130 billion by 2030. A significant raw material base and the availability of a skilled workforce have enabled India to emerge as an international manufacturing hub for generic medicines. Further, India is the only country with the largest number of US-FDA compliant pharma plants (more than 262 including APIs) outside of USA.

With a compound annual growth rate (CAGR) of 9.77 per cent in the last nine years, the Indian Pharma sector's output growth rose from ₹3,03,352 crore in 2015-16 to ₹4,27,109 crore in 2020-21 (see Table 1).

Table 1: Pharma Sector's Output Growth at Current Prices

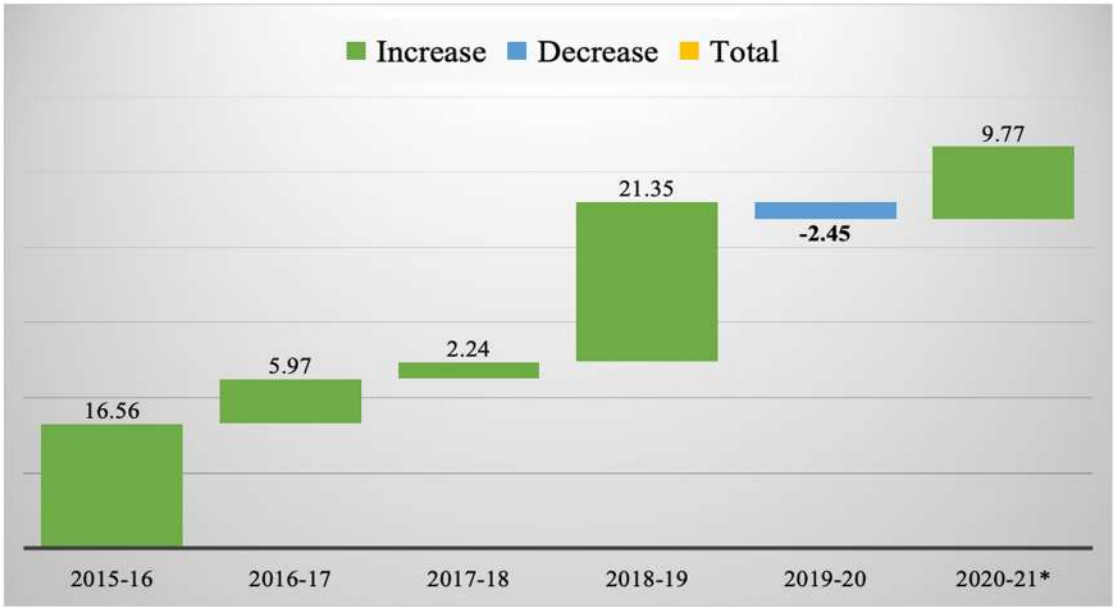
Year	Output (₹ in crore)
2015-16	3,03,352
2016-17	3,21,472
2017-18	3,28,677
2018-19	3,89,094
2020-21*	4,27,109

*Estimated based on trend growth rate (CAGR) of output at 9.77 per cent achieved during 2013-14 to 2019-20

Sources: National Accounts Statistics-2021, Ministry of Statistics and Programme Implementation, Annual Report 2021-22, Ministry of Ministry of Chemicals & Fertilizers Department of Pharmaceuticals, Government of India, https://pharmaceuticals.gov.in/sites/default/files/English%20Annual%20Report%202021-22%20%281%29.pdf

The pharma sector has maintained a significant growth over the years except during the COVID-19 pandemic when the mandatory lockdowns severely restricted economic activities (see Chart 1).

Chart 1: Pharma Sector's Output Growth Rate (in %) at Current Prices



*Estimated based on trend growth rate (CAGR) of output at 9.77 per cent achieved during 2013-14 to 2019-20
Sources: National Accounts Statistics-2021, Ministry of Statistics and Programme Implementation, Annual Report 2021-22, Ministry of Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals, Government of India, https://pharmaceuticals.gov.in/sites/default/files/English%20Annual%20Report%202021-22%20%281%29.pdf

The issues of disruptive innovations, regulations, compliances, and domain knowledge together with big-picture issues facing industries and organizations have become commonplace. Given the nature of the pharma products, the pharma products are marked by a bewildering diversity of regulation and compliance issues across countries. Outsourcing has also increasingly emerged as a salient feature of this steadily burgeoning industry.

Some of the major growth drivers of the industry are growth in healthcare financing products, demand in the generics market, rise in outsourcing activities, and demand for emerging segments. Andhra Pradesh, Gujarat, Maharashtra, and Goa account for the major pharmaceutical manufacturing clusters in India. The bulk drug clusters are located primarily in Ahmedabad, Vadodara, Mumbai, Aurangabad, Pune, Hyderabad, Chennai, Mysore, Bangalore, and Visakhapatnam (Vizag).

The pharmaceutical hubs offer investment opportunities in the production of API or bulk drugs, biosimilars, vaccines, nutraceuticals and food and drug testing and contract research. Major segments of Indian pharmaceutical industry include generic drugs, over the counter (OTC) medicines, bulk drugs, vaccines, contract research & manufacturing, biosimilars and biologics.

India is the largest supplier of generic medicines in the world and constitutes 20 per cent of the global supply and manufacturing 60000 different generic brands across 60 therapeutic categories. Some of the key 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.

Trade

The pharma sector in India has consistently maintained a position of trade surplus in the industry with Pharma exports in 2021-22 sustaining a positive growth despite global trade disruptions. Pharmaceutical exports include bulk drugs, intermediates, drug formulations, biologicals, Ayush & herbal products and surgical. About 55 per cent of Indian pharma exports cater to highly regulated markets.

During 2020-21, total pharma export stood at ₹180555 crore (US$24.35 billion) as against the total pharma import of ₹49436 crore (US$6.66 billion), thereby generating a trade surplus of $17.68 billion. Till end September 2021, total pharma export was ₹87864 crore (US$11.88 billion) as against total import of ₹33636 crore (US$4.66 billion), thereby generating a trade surplus of ₹54228 crore (US$7.22 billion).[1] During April-October 2020, India's pharmaceutical exports aggregated US$11.1 billion witnessing an impressive growth of 18.0 per cent, as against US$9.4 billion during the corresponding period a year ago.

This has led to an increase in the share of pharmaceuticals exports in India's total exports from 5.1 per cent in April-October 2019 to 7.3 per cent in April-October 2020, making it the third largest exported commodity. However, the total pharmaceutical exports and import were to the tune of ₹1,46,260 crore and ₹42,943 crore, respectively in the year 2019-20.

In the medical devices segment, India still has a trade deficit. However, the export value rose significantly over the years (see Table 2). Of the various segments in the healthcare system, this segment with high capital intensive, has the latent potential of growing at the fastest trajectory. Most of the high technology and innovative products originate from a well-developed ecosystem and innovation cycle, which is yet to be fully developed in India. India depends on imports to the extent of 85 per cent of its domestic requirements of medical devices.

Table 2: Export and Import of Medical Devices

(In US$ million)

Imports		Exports	
2019-20	2020-21	2019-20	2020-21
5845.41	6240.55	2292.87	2531.62

Sources: EEPC India, https://www.eepcindia.org/market-info/22/Export-Statistics, Annual Report 2021-22, Ministry of Ministry of Chemicals & Fertilizers Department of Pharmaceuticals, Government of India, https://pharmaceuticals.gov.in/sites/default/files/English%20Annual%20Report%202021-22%20%281%29.pdf

Confronted with the spectre of a once in a century pandemic with the nearest comparison being that of the Spanish flu of 1919, the Indian vaccine industry quickly developed Covid vaccine with indigenous technology in collaboration with India's research institutions, such as, the Indian Council of Medical Research, New Delhi. (ICMR) and the National Institute of Virology, Pune (NIV). The efficacy of these vaccines is entirely on par with those in the developed countries like America and the EU.

India provided 115 million doses of vaccines to over 97 countries. In a concerted attempt to enhance bilateral trade, India signed cooperation agreement with UAE and Australia which provided enhanced access to Indian pharma products to these markets.

India almost doubled its share in world pharma exports in a span of ten years from 1.4 per cent in 2010 to 2.6 per cent in 2019. India was at the 11th position in terms of its share in world pharma exports in 2019 with Germany, Switzerland and USA occupying the top three positions.

Table 3: Category wise Export Data

(In US$ million)

Segments	Exports 2019-20	Exports 2020-21	% Share (2019-20)	% Share (2020-21)
Consumables & Disposables	1082.53	1290.26	47.21	50.97
Surgical Instruments	49.77	53.64	2.17	2.12
Electronics Equipment	998.87	984.73	43.56	38.9
Implants	94.12	98.81	4.1	3.9
IVD Reagent	67.58	104.18	2.95	4.12
TOTAL	2292.87	2531.62		

Sources: EEPC, https://www.eepcindia.org/market-info/22/Export-Statistics, and Annual Report 2021-22, Ministry of Ministry of Chemicals & Fertilizers Department of Pharmaceuticals, Government of India, https://pharmaceuticals.gov.in/sites/default/files/English%20Annual%20Report%202021-22%20%281%29.pdf

In FY 2021, India's exports to the USA amounted to US$2531.6 million and constituted 23.7 per cent of the total exports followed by Germany, China, France, and Singapore constitute 5.3 per cent, 5.3 per cent, 3.0 per cent and 3.0 per cent respectively (see Table 4).

Table 4: Top Export Destinations

(In US$ million)

Country	Exports 2020-21	% Share
World	2531.6	100.0
USA	600.01	23.7
Germany	133.7	5.3
China	133.00	5.3
France	74.89	3.0
Singapore	74.8	3.0
Sub-Total	1016.4	40.15

Sources: EEPC, https://www.eepcindia.org/market-info/22/Export-Statistics, and Annual Report 2021-22, Ministry of Ministry of Chemicals & Fertilizers Department of Pharmaceuticals, Government of India, https://pharmaceuticals.gov.in/sites/default/files/English%20Annual%20Report%202021-22%20%281%29.pdf

India enjoys a consistent and long run revealed comparative advantage (RCA) in its pharmaceutical exports since 2009. However, in terms of a cross-country perspective, India's RCA stands at 12th spot. In addition, Indian pharmaceutical sector has high value of trade specialization coefficient (TSC), closer to one, consistently from FY 2014-15. The value of TSC lies between -1 and 1, wherein a higher TSC value denotes st$ronger export competitiveness of the country.

Import Data

During the COVID-19 pandemic, there was a spike in the demand for electronics equipment and consumables & disposables. This segment constituted respectively 57.18 per cent and 23.57 per cent in FY 2020-21 (see Table 5).

Table 5: Category wise Import Data

(In US$ million)

Segments	Imports 2019-20	Imports 2020-21	% Share (2019-20)	% Share (2020-21)
Consumables & Disposables	1076.23	1470.77	18.41	23.57
Surgical Instruments	180.10	103.62	3.08	1.66
Electronics Equipment	3646.53	3568.64	62.38	57.18
Implants	415.35	225.63	7.11	3.62
IVD Reagent	527.2	871.89	9.02	13.97
TOTAL	5845.41	6240.55		

Sources: EEPC, https://www.eepcindia.org/market-info/22/Export-Statistics, and Annual Report 2021-22, Ministry of Ministry of Chemicals & Fertilizers Department of Pharmaceuticals, Government of India, https://pharmaceuticals.gov.in/sites/default/files/English%20Annual%20Report%202021-22%20%281%29.pdf

China is amongst the largest trading partners of India. India has imported pharma related equipment and facilities of US$1110.9 million in FY 2020-21 constitutes 17.8 per cent of the total imports followed by USA and Germany (see Table 6).

Table 6: Top Import Destinations

(In US$ million)

Country	Imports 2020-21	% Share
World	6240.6	100.0
China	1110.9	17.8
USA	984.1	15.8
Germany	668.5	10.7
Singapore	517.8	8.3
Japan	237	3.8
Sub-Total	3518.26	56.38

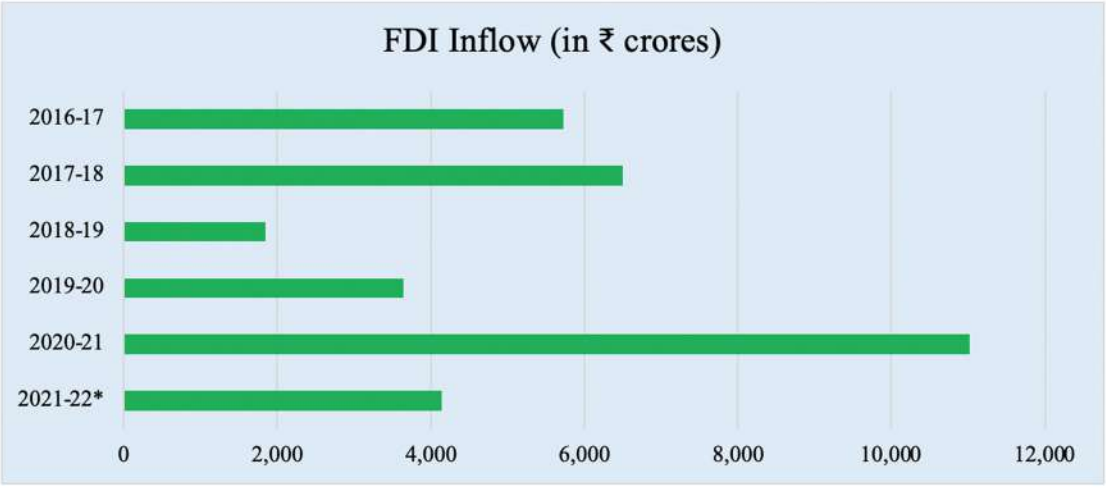
Sources: EEPC, https://www.eepcindia.org/market-info/22/Export-Statistics, and Annual Report 2021-22, Ministry of Ministry of Chemicals & Fertilizers Department of Pharmaceuticals, Government of India, https://pharmaceuticals.gov.in/sites/default/files/English%20Annual%20Report%202021-22%20%281%29.pdf

Foreign Direct Investment (FDI)

Pharmaceuticals constitute one of the top ten attractive sectors for foreign investment in India. Foreign investment to the extent of 100 per cent is allowed under automatic route in Medical Devices. Foreign investments in pharmaceuticals in greenfield projects are allowed up to 100 per cent under the automatic route and for brownfield pharmaceutical projects, foreign investment beyond 74 per cent to up to 100 per cent, Government approval is required.

FDI in the pharmaceutical sector suddenly spurted in FY 21 vis-a-vis the previous year showing a 200 per cent increase. In FY 2022 (April-September), the FDI inflows continued to be buoyant at ₹4413 crore, growing at the rate of 53 per cent over the corresponding period in FY 2020-21.[2] Recently, a significant growth of foreign investments in the Pharma sector was witnessed, which was mainly on account of investments to meet COVID-19 related demands for therapeutics and vaccines (see Table 2).

Chart 2: FDI Inflow Trend



* From April to September 2021
Source: Ministry of Commerce and Industry, Government of India

The Indian drugs and pharmaceuticals sector received cumulative FDIs worth US$ 19.19 billion between April 2000 and December 2021. The foreign direct investment (FDI) inflows in the Indian drugs and pharmaceuticals sector reached US$ 1.206 billion between April-December 2021.

The Department of Pharmaceuticals approved 10 FDI proposals worth ₹7,860 crore inflows under the brownfield pharmaceutical projects during the financial year 2021-22 (till December 2021).

Institutional Initiatives

The pharmaceutical sector has emerged as one of the critical sectors with significant policy-interventions from the government. The sector needs an enabling ecosystem, where more investment and innovation with efficient policy support is needed to foster steady growth of the sector. The government has successively implemented ground-level policies to ensure greater resilience to external shocks, enforce drug security and enhance capacity of domestic manufacturers of bulk drugs and high-valued pharmaceutical devices. The rising trend of budget allocations to the Department of Pharmaceuticals over the years is understandable in the wake of the devastating COVID-19 pandemic in the country and the crippling hit to lives and livelihoods. However, the trends vary in terms of the initial budget estimates and the actual expenditure over the years.

The Indian government's ambitious Pharma vision of making India a global leader in end-to-end drug manufacturing and the introduction of mechanisms, such as, the Drug Price Control Order and the National Pharmaceutical Pricing Authority to make drugs more affordable and easily available, competitively priced products, sustained macro-economic growth with rising insurance penetration, increased expenditures on healthcare and medicines augur well in the Pharma growth story. Other factors propelling the industry to a higher orbit include the relatively lower cost of manufacturing pharma products, a strong manufacturing base, highly skilled work force and effective marketing and distribution system.

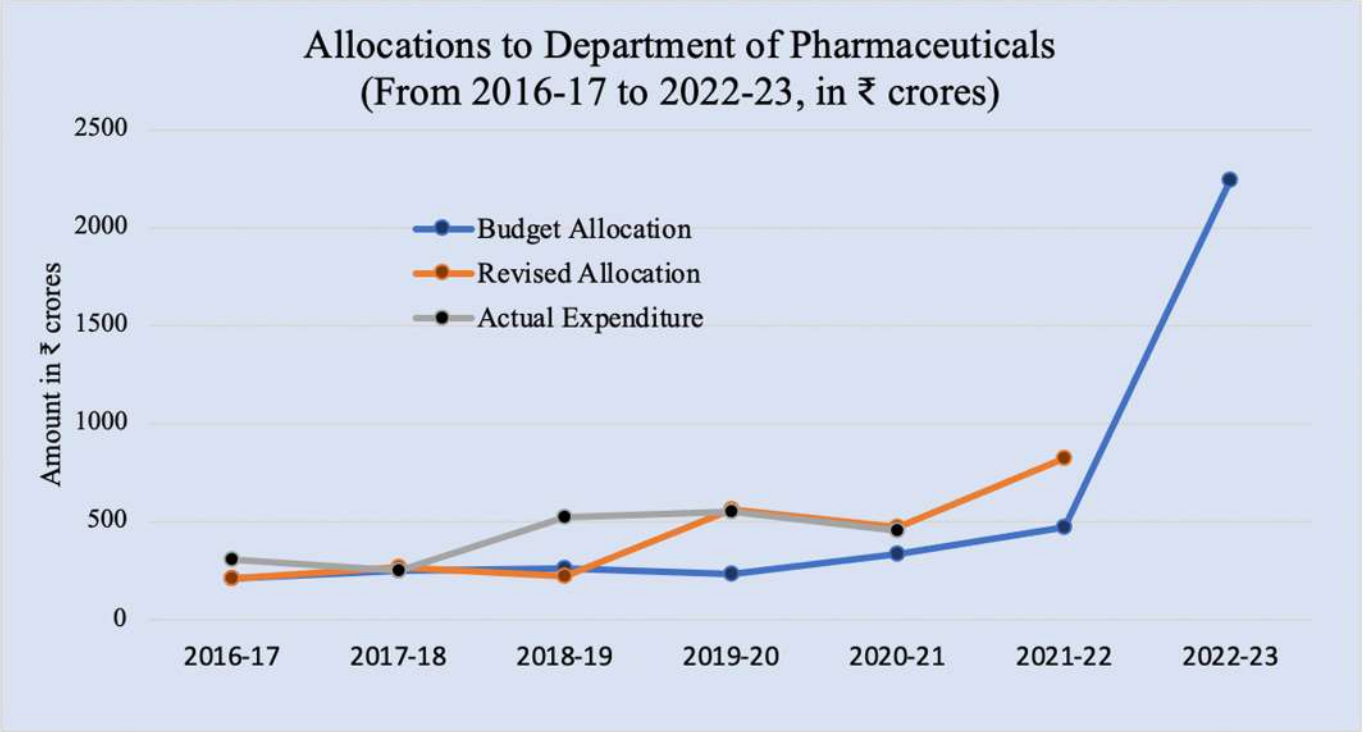
The thrust on rural health programmes, lifesaving drugs and preventive vaccines, synchronized efforts in the biologics market by leveraging the expertise of domestic companies, diverse ecosystem, rising private sector investments in research and development and acquisitions also provide an impetus to the growth and structural transformation of this sector. But there are headwinds of relatively lower investment in research in terms of global benchmarks, ineffective co-ordination between the industry and the academia, negligible expenditure on health care by households, and in some cases the manufacture of low and fake medicines. Therefore, zthe pathway to the future requires harnessing growth potential, greater export of generic drugs to the developed market, positioning India as a centre for international clinical trials and a key player in global pharmaceutical R&D. These and other developments require an incessant focus on operational efficiency and productivity. Strategic developments in health insurance, medical technology and mobile telephony are also salubriously influencing the transformation of the Pharma industry.

During FY 2018-19, the actual expenditure was twice the budget estimates. The budget estimates for the year were ₹261.53 crores, while the actual expenditure for the year was ₹523.46 crores. While the budget estimates for FY 2019-20 were on par with those of the previous year, they were revised to ₹562 crores, closer to the actual expenditure incurred in FY 2018-19 (see Chart 3).

During the pandemic hit FY 2020-21, the initial budget estimates for the Department of Pharmaceuticals were ₹333.58 crores, which the government revised to ₹470.4 crores. However, as per the details provided in the Budget documents, the actual expenditure for FY 2020-21 was ₹456.01 crores. This is not only slightly lower than the revised estimates but also lower than the actual expenditure for the previous two years.

The Budget also highlights the substantial increase in focus and allocation to the Department of Pharmaceuticals in FY 2022-23. The revised estimates for FY 2021-22 increased to ₹823.11 crores from the earlier budget estimates of ₹470 crores. However, a substantial increase was observed in the budget estimates for FY 2022-23. The Budget estimates for FY 2022-23 for the Department of Pharmaceuticals stand at ₹2244.15 crores, which marks an almost five-fold increase over the budget estimates of FY 2021-22. [3]

Chart 3: Allocations to Department of Pharmaceuticals



Sources: Union Budget 2022-23, https://www.indiabudget.gov.in/

The Production Linked Incentive (PLI) scheme with total financial outlay of ₹6,940 crore are aimed at boosting domestic manufacturing of identified KSMs, DIs and APIs by attracting large investments in the sector and thereby reduce India's import dependence in critical APIs. The scheme will be active for 10 years from 2020-21 to 2029-30. Under the scheme, 41 products have been identified and hence on their sales financial incentives will be provided for six years (see Table 7):

Table 7: Outlay under Production Linked Incentive (PLI) scheme

	FY 2023-24 to FY 2026-27	FY 2027-28	FY 2028-29
a) Fermentation-based products	20%	15%	5%
	FY 2022-23 to FY 2027-28		
b) Chemical synthesis-based products	10%		

Source: Annual Report 2021-22, Ministry of Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals, Government of India, https://pharmaceuticals.gov.in/sites/default/files/English%20Annual%20Report%202021-22%20%281%29.pdf

A total of 239 applications were received, out of which 49 applicants were selected for 32 products. The total committed investment of ₹3685.38 crore and actual investment of ₹774.88 crore took place by 49 approved applicants till December 2021 in all segments.

In June 2021, the Union Finance Minister announced an additional outlay of Rs. 197,000 crore (US$ 26,578.3 million) will be utilised over five years for the pharmaceutical PLI scheme in 13 key sectors such as active pharmaceutical ingredients, drug intermediaries and key starting materials.

Another 'PLI scheme for Pharmaceutical' sector has been launched to enhance the India's manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification leading to high value goods in the pharmaceutical sector. With a total financial outlay of ₹15,000 crore, the three categories of pharmaceutical goods will be incentivized under the scheme based on their incremental sale of 6 years. The tenure of the scheme is from FY 21 to FY 29. Promotion of innovation for development of complex and high-tech products, including products of emerging therapies and in-vitro Diagnostic Devices have been targeted under the scheme. A total of 278 applications were received by the Department of Pharmaceutical, out of which 55 applicants were selected.

The scheme named 'Promotion of Bulk Drug Parks' is setting up bulk drug parks in different parts of the country significantly providing financial assistance to the selected bulk drug units to access world class common infrastructure facilities. The scheme will be active for 5 years from FY 2020-21 to FY 2024-25. Out of the total outlay of ₹3000 crore for the scheme, 70 per cent of the project cost of common infrastructure facilities will be given to a selected Bulk Drug Park as a financial assistance. In case of North-eastern States and Hilly States (Himachal Pradesh, Uttarakhand, Jammu & Kashmir, and Ladakh) financial assistance would be 90 per cent of the project cost. Maximum assistance under the scheme for one Bulk Drug Park would be limited to ₹1000 crore.

The Government of India has recently announced instructions for "Strengthening of Pharmaceutical Industry (SPI)" and an outlay of ₹500 crore for the period FY 22 to FY 26 was also announced.

Industry Risks

The pandemic, however, exposed the fragility of the Indian pharmaceutical industry in terms of its excessive dependence on China for sourcing Active Pharmaceutical Ingredients (APIs) and Key Starting Materials (KSMs). Further, there is a disproportionate dependence of Indian pharma exports on USA and generics. To successfully overcome this "concentration risk" and make the sector more broad-based and resilient, pharmaceuticals drugs have been identified as one of the ten key sectors for introducing Production Linked Incentive (PLI) Scheme to enhance India's manufacturing capabilities and exports.

This is in addition to the already notified PLI schemes for bulk drugs and medical devices, which aim to provide a boost to domestic manufacturing for critical KSMs/ Drug Intermediates (DIs), APIs and medical devices. Both these schemes received an encouraging response from the pharmaceutical and the medical device industry. Further, a scheme for promotion of bulk drug parks and medical devices parks was also announced.

The recent unprecedented supply chain disruptions first caused by the pandemic and subsequently by Russia-Ukraine crisis hit the pharmaceutical industry. Russia is amongst the biggest importers of Indian generic medicines. A series of progressively stringent economic sanctions on Russia by the West were also worrisome for the Indian pharmaceutical manufacturers. The receivable amounts of Indian drug exporters were inordinately delayed. Also, stocks were stuck at Indian ports for long periods causing severe financial hardships and anguish to drug producers and exporters.

At the same time, the price of raw materials required for packaging drugs e.g., aluminium foil, has increased now. Ukraine is the major exporter of aluminium foil to Indian pharma industry which was priced at ₹250-Rs300/kg earlier now costs about ₹400-450/kg. [4]

The pharmaceutical industry needs a qualified workforce with significant knowledge, experience, and skills. Accordingly, a huge investment is still required in the industry to create the pool of highly qualified workforce with essential skills and training to meet the rising global demand.

As per the Statista, a market research firm, the pharmaceutical industry is expected to have almost $50 billion in prescription drug sales worldwide at risk due to patent expiration in 2022.[5] This makes it even more necessary for India to significantly upscale the capabilities of the Pharma industry in terms of innovation and R&D.

With fast receding pandemic, there has to be a sharper focus on medical diplomacy. There is an urgent need for exploring new avenues of trade agreements together with the existing ones with cross border demands. India needs to consolidate its capacity to meet rising global demand for API shortage globally being a leader in supplying generic medicines to the world.

The Road Ahead

The expenditure on social services (health, education and others) by Centre and States as a proportion of GDP increased from 6.2 per cent in 2014-15 to 8.6 per cent in 2021-22 (BE). More significantly, the BE for 2020-21 pegged the overall government expenditure on health as a share of GDP at 1.8 per cent up from 1.2 per cent in 2014-15 and 1.5 per cent in 2018-19. This is welcome and indeed is the way to go. But concerted efforts are necessary to ensure that such efforts do not remain a flash in the pan and are sustained over the medium-term.

Cataclysmic events, such as, the pandemic and Russia-Ukraine crisis have brought in its wake new opportunities. This is why the players in the Pharma industry should explore new business models and innovative ways of drug development. The Indian pharma industry has targeted annual revenue of US$130 billion by 2030 as against the present level of US$44 billion. [6]

In order to provide an impetus to exports and to make them more competitive in terms of price, quality and timelines, the major challenge for the Indian Pharma industry is to develop a cost-efficient mode of production with low cost of production and well-equipped R&D section.

India should minimise its dependence on China for Active Pharmaceutical Ingredients (APIs), or necessary bulk drugs required for manufacturing drugs. In addition to competitive exports, the Indian Pharma industry must explore the possibility of procuring raw materials from other countries and provide financial assistance to domestic manufacturers of medicinal raw materials.

According to Moody's recent report, a few bestselling drugs are going to lose exclusivity by 2030 and nearly a $100 billion worth of biologics drugs will go off by 2030. There is, therefore, a compelling necessity for the Indian Pharma industry to reorient itself to the needs and requirements of rapidly changing market dynamics.

ENDNOTES

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