



Impact of the pharma industry on the Indian economy in the post-COVID era

A report by KPMG in India and FICCI

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and Chemicals & Fertilizers
Government of India

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FOREWORD

The Indian pharmaceutical industry is at the cusp of transformation. The COVID-19 pandemic provided just the right impetus for India to introspect on its global leadership position.

A unique opportunity awaits the Indian pharmaceutical industry to reflect on innovation, scale, and impact; and transition from being a volume player to a significant value player in a post-pandemic world in the global arena. With several policy boosts by the Indian government, the stage is ready for the Indian pharma industry to move up the value chain and stamp its presence in the innovation space.

The government's focus on promoting biopharmaceuticals and complex generic drugs manufacturing is in perfect alignment with the rapidly evolving strengths of the Indian pharmaceutical industry. India's strategic advantage lies in its manufacturing capabilities, scientific talent pool and strong technology infrastructure which can easily help India create the highest impact in the global pharma space.

A concerted push towards the Indian pharmaceutical industry through initiatives such as Make in India, Ayushman Bharat Scheme, National Digital Health Mission etc. has positioned India as the leading global capital market. With an increase in pharma R&D facilities, access to large consumer markets, generation of new employment opportunities and rise in net foreign exchange earnings, not only Indian but also global pharma companies can look forward to claiming higher stakes in the success of the industry. The rising FDI inflows to the industry reflect the firm belief of the global investors that India will spearhead the next wave of global pharma growth engines.

On the eve of Annual India Pharma and India Medical Devices 2022 event, between 25-27th April 2022, I appreciate the Industry in bringing out a knowledge paper namely "*Impact of Pharma Industry on the Indian economy in a Post-COVID era*"

I wish huge success to all the stakeholders of the Indian pharmaceutical industry on this journey of future excellence and hope our readers enjoy this insightful report.

(Dr. Mansukh Mandaviya)

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BHAGWANTH KHUBA



रसायन एवं उर्वरक एवं
नवीन एवं नवीकरणीय ऊर्जा राज्य मंत्री
भारत सरकार
Minister of State
Chemicals & Fertilizers and
New & Renewable Energy
Government of India



FOREWORD

India has been truly leading the global pharmaceutical and healthcare industry's fight against the COVID-19 pandemic.

The industry has shown exemplary resilience in its recovery from the pandemic and delivering essential medicines and critical medical supplies to countries across the globe, deserving the title of 'pharmacy of the world'.

Indian drug makers have also demonstrated excellent proactiveness in ramping up COVID-19 medicines and COVID-19 vaccine production. While the pandemic brought to surface potential systemic gaps in the industry, it also highlighted numerous opportunities in the space of raw material sourcing, boosting domestic manufacturing and creating a more collaborative pharma ecosystem.

With exports gradually witnessing a record high, foreign investments in the sector are likely to gain momentum.

The government's Production Linked Incentive (PLI) and Bulk Drug & Medical Devices Park schemes can significantly strengthen domestic Pharma manufacturing and help accomplish its Atmanirbhar vision.

With a strong public-private collaborative ecosystem, India is well on its way to not only become self-reliant for its sourcing needs but also becoming the global Pharma capital.

I appreciate the Industry in bringing out a knowledge paper namely "*Impact of Pharma Industry on the Indian economy in a Post-COVID era*" on the occasion of Annual India Pharma and India Medical Devices 2022 event.

(Bhagwanth Khuba)

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Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals

Dated:-20th April, 2022

FOREWORD for the Knowledge Paper

India is the third largest player globally in Pharmaceuticals in terms of volume and is the largest supplier of low cost generics and vaccines to the world. The sector has immense growth potential in the sphere of generics, bulk drugs, vaccines and bio-similar.

The Indian pharmaceutical industry has contributed in numerous ways during the pandemic. The industry provided cooperation to societal as well as national needs by ensuring adequate and regular supply of quality and affordable medicine, and despite several constraints, the industry helped to fulfil the healthcare needs of India and the globe, especially, over 120 countries.

The pandemic has also been an inflection point for India to focus on some grassroot level issues and introduce long-term sustainable changes to the sector. While the government has launched several schemes to attract investments and strengthen manufacturing, the industry's strength lies in its generics and vaccine manufacturing capabilities.

Department of Pharmaceuticals is implementing three PLI schemes {viz PLI scheme for Bulk Drugs, PLI scheme for Medical Devices and PLI scheme for Pharmaceuticals and Two Park Schemes {one for Bulk Drugs and another for Medical Devices} to increase the domestic manufacturing of Bulk Drugs, pharmaceuticals and Medical Devices. Besides, seven NIPERs under the Department are closely interacting with the Industries in facilitating Research and Innovation under the Academia-Industry Collaboration.

It is time for the country to focus to become a quality-value player by strengthening its scientific capabilities and promoting innovation through R&D. In a post pandemic world, it is imperative for India to explore avenues of growth, bring in strong policy frameworks and implement best practices that make it an indispensable choice for the global pharma market.

On the eve of Annual India Pharma and India Medical Devices 2022 event, between 25-27th April 2022, I appreciate the Industry in bringing out a knowledge paper namely "*Impact of Pharma Industry on the Indian economy in a Post-COVID era*"

The Department of Pharmaceuticals will strive to enable the policy environment to facilitate the India Pharma Industry's vision for transformative manufacturing and contributing as the leader for global medical needs.


(S. Aparna)

Foreword by FICCI

Technology transfer and collaboration – an important tool in enhancing the healthcare ecosystem

We witnessed a collective global response to COVID-19 pandemic achieved by, amongst other important elements, the fast-tracking of 'technology transfers' (the sharing of how to manufacture certain vaccines from vaccine providers to contract manufacturers, around the globe) and value of collaborations/partnerships.

The onset of pandemic brought to light the importance of collaboration & partnership not just between governments and companies, but also amongst companies in the industry. A number of deals were struck between local companies and MNCs to bring in innovation and increase supply of life-saving medicines. Leading U.S. drug maker entered into a non-exclusive voluntary licensing agreements with multiples local companies for its patented product, used in the treatment on COVID-19. Similarly, another leading U.S. pharma company entered into a licensing agreement with Indian pharma companies for its patented product, which is an antiviral drug used for treating COVID-19 infection. Amidst meeting the domestic needs during the pandemic, by 2021, India also ensured supply of medicines to 123 partner countries and exported a total of 587 lakh doses of COVID-19 vaccines across the world¹, living up to its name of being the 'pharmacy of the world'.

On the technology transfer front in India specifically, there is this multi-level partnership which is a significant example of why technology transfers and collaborative thinking is essential in the times to come if we have to respond strongly to the gaps as we see in the healthcare ecosystem currently. Similarly, multiple other companies have entered into deals with local companies for manufacturing & distribution of their COVID-19 vaccines. Taking our cue, we all must continue to propel innovation and innovative approach to tackle the disease burden.

Pharma companies have the wherewithal to augment a solution led approach to most of the areas where there is a felt need of enhancement in both communicable and non-communicable disease areas. Access and adherence to treatment for many non-communicable diseases was impacted during the pandemic-cancer was one of them. According to a prominent study conducted in December 2020, there was a drop of 25 per cent in the weekly patient load due to COVID-19. Out of the 50 oncologists surveyed in public and private practice, 70 per cent of the physicians advised their patients to postpone the appointments. This was mostly done for older patients, routine follow-up patients, patients

with non-aggressive stage of cancer and patients with respiratory co-morbidities. Many other aspects of cancer care were either postponed or dropped during these times.

It is clear from these developments that there is a virtual ecosystem of care that was needed to ensure a smooth interaction between patients and HCPs and this is now prioritized by many healthcare delivery partners and pharmaceutical companies to be able to save lives. We saw multiple new age solutions creating an online ecosystem for diagnosis, treatment and wellness of patients. Such initiatives saw a whooping success and has indicatively touched over +3 lakh lives over a short period.

"Patient First" being the motto of healthcare providers, we need to chart out a plan to feed the future of all the new capabilities that emerged during the lockdown and enhance the point of care with sustainable solutions!

Gagandeep Singh

Chair, FICCI Pharmaceutical Committee

Managing Director, AstraZeneca Pharma India Limited

1. Industry estimates

Foreword by KPMG in India

The coming decade is extremely critical for the Indian pharmaceutical sector. India has shown incredible resilience in meeting not only the domestic demand but also catering to the global pharma needs, ensuring accessibility of critical medications. However, with its disruptions, the pandemic has also shed light on the emerging opportunities that lie ahead for the sector. The paper talks about the creation of an integrated ecosystem that focuses on accelerating research & innovation, strengthening manufacturing and supply chains and improving access to medicines. R&D and technology have been key catalysts driving industry-academia collaborations, which are expected to foster innovation and benefit the sector through transformation across the value chain. As regulatory bodies and government work towards streamlining the regulatory processes and making it more comprehensive, the industry hopes to create a holistic pharma landscape that aids affordable and accessible healthcare for all. The future of pharma sector would heavily rely on its stakeholders working collectively towards the common goal of making India the pharmacy of the world.

This report is a collaborative effort by FICCI and KPMG, bringing together insights and knowledge from sector stakeholders – the government, leading pharmaceutical and medical

device industry leaders — and complemented with extensive secondary research.

While the industry sets out to bring the intended aims to reality, we hope this study will serve as a springboard for discussion and a roadmap for all stakeholders envisioning a stronger Indian pharma sector.

Vijay Chawla

Partner and Head – Risk advisory
Head – Life Sciences
KPMG in India



Executive summary

The contribution of the Indian pharmaceutical industry to the country's economy is immense. Over 2.7 million people are employed by the industry either directly or indirectly and contributes about 2 per cent to India's gross domestic product (GDP)¹. Over the last two decades, it has taken phenomenal strides in improving public healthcare in India and the world. With the COVID-19 pandemic, it displayed extraordinary resilience as it was quick to mobilise its resources and fix the logistics and supply chain disruptions despite the nationwide imposition of lockdowns and restrictions.

The Indian pharmaceutical industry is likely to reach USD130 billion by 2030², growing at a CAGR of 12.3 per cent³ from USD40.8 billion in 2020. The current market size of the pharmaceutical industry in India is estimated to be valued above USD50 billion (2020-21) with a growth rate of 10-12 percent⁴. The impressive growth is despite the COVID-19 pandemic and may be attributed to the industry's strong credentials in formulation development capabilities, trained workforce, and reputation in international markets such as North America and Europe.

The Indian government has taken a slew of initiatives to support the Indian pharmaceutical industry. Initiatives such as the production linked incentive (PLI) schemes, medical device and bulk drug parks are likely to boost domestic production of active pharmaceutical ingredients (APIs), biopharmaceuticals, complex generics, patented drugs, and various medical devices and transform India as the global manufacturing hub. This is a major step towards realizing its vision of "Aatmanirbhar Bharat".

It is imperative for the Indian pharmaceutical industry to leverage the momentum already gained and work on making its way to becoming a force to reckon with in the global pharma market.

1. Draft Policy - Department of Pharmaceuticals; accessed on 7th March 2022
2. "Indian Pharmaceutical Industry", IBEF, March 2021; accessed on 7th March 2022
3. KPMG in India analysis 2022
4. Industry estimates

Attracting foreign investments



- Favourable provisions may be developed by the government which would support greater influx of foreign investments and at the same time benefit local pharma and medical device companies. For instance, currently it is not compulsory for the foreign investor to make a technology transfer, which restricts the development of technological capabilities of local pharma companies.

Streamlining the regulatory framework



- Create a central overarching regulatory body, infusing efficiency and effectiveness at governance
- Collaborations with global regulatory bodies to build expertise of Indian regulators on new drug approvals
- A single end to end digital platform that connects different regulatory departments is likely to fast track the drug approval processes.

Fostering an eco-system of research and innovation



- A research linked incentive (RLI) scheme would incentivise risk-taking for carrying out drug discovery research in the country
- Suitable tax incentives by the government for R&D spending would encourage the Indian pharma players to invest more on R&D
- Major Indian pharma players may sponsor research in the prominent pharma academic institutions of the country.

Boosting data privacy and data security



- Secure platforms for seamless sharing of data from different sources such as epidemiological databases, patient registries and historical clinical trial data would significantly aid medical research
- A strong healthcare data protection law is much needed to protect the privacy and security of certain health information.

Promoting the growth of domestic manufacturing



- India supplies low-cost generic drugs globally, however, nearly 70 per cent of all APIs are imported from China. Any disruption in China's bulk drugs market has a direct influence on the Indian pharma industry
- To overcome this challenge, government can form a taskforce which devises strategies for attaining self-reliance and reduce import dependency for APIs thereby, enhancing the sector's manufacturing capabilities to move up the value chain.

Enhanced insurance penetration



- Schemes such as Ayushman Bharat, PM-JAY can act as a good demand creator, but it is yet to achieve the desired goal. There still lies a huge challenge to reduce the out-of-pocket expense and enhance Universal Health Coverage especially among the rural population
- Furthermore, payer groups (government, private insurance players), health providers and pharma players can strategically team up to strengthen India's position to have access to quality healthcare at affordable costs.

Digital technology disruption



- With government's focus on Ayushman Bharat Digital Mission (ABDM) to boost the digitization of Indian healthcare system, it is important to simplify the user interface and have unified platform for all healthcare applications ranging from teleconsultation to e-pharmacy. This will enhance access to medical services
- Promoting integration of digitalization in the pharma units and discussing its benefits among manufacturers will also lead to increased productivity and value generation.

Boosting supportive infrastructure



- Promoting setting up of pharma equipment manufacturing plants would help substantially in lowering installation costs, cut down on imports, save time to set up additional facilities and commissioning machinery
- Additionally, streamlining temperature-controlled shipping of vaccines, and cold-chain facilities for storage nationwide will enhance exports, reduce losses due to expiry of shelf-life and strengthen overall supply chain capabilities.

Although unprecedented, but COVID-19 crisis showcased exemplary resilience of the Indian healthcare system and collectively as a nation. It acted as a catalyst to bring the focus of the Indian population towards being more health conscious and government towards the importance of boosting pharma sector and strengthening healthcare. Going forward, the responsibility lies with the pharma stakeholders (government, industry, and academia) to continue stepping forward with similar momentum towards the journey of transforming Indian healthcare ecosystem. Hence, with the implementation of these steps, India can not only continue being pharmacy of world, but the leading choice for the global pharma market.

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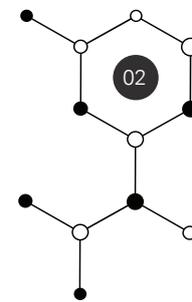
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01

The Indian pharma industry

**A view of the pre-pandemic times
and COVID-induced challenges**





Indian pharmaceutical industry - 'Pharmacy of the world'

India's booming pharmaceutical industry is truly hailed as the 'pharmacy of the world' as the country is the leading source of path-breaking innovations and has the ability to provide essential medicines and offer medical support to countries across the globe. This is further aided by India's 'Neighbourhood First Policy'

and 'Vaccine Maitri' initiative. The COVID-19 pandemic underlined India's position not only as an innovator but also as a supplier of essential and life-saving drugs to every part of the world wherever required. The industry's global contribution was amply evident in 2020 as the country led from the front in the global

crusade against the pandemic by providing critical drug supplies to over 120 countries⁵. India is one of the largest suppliers of low-cost vaccines to countries all over the globe and India's Serum Institute is the world largest vaccine manufacturer by the number of production of doses and global sales⁶.

Indian pharma companies had a 5 per cent share of the Indian market while global pharma companies had a 95 per cent share in 1969. The situation has reversed with Indian pharma companies occupying 85 per cent and global pharma 15 per cent of the market in 2020⁷. Globally the country is the largest provider of generic medicines with a 20 per cent share by volume⁸.

The current market size of the pharmaceutical industry in India is estimated to be valued above USD50 billion (2020-21) with a growth rate of 10-12 per cent.⁹ The industry ranks third worldwide for production by volume and 14th by value¹⁰.

With the highest number of FDA compliant pharmaceutical plants, more than 3,000 pharma companies¹¹ and a strong network of over 10,500 manufacturing facilities¹² the industry provides high optimism for the years to come.

The Indian pharmaceutical industry has a strategic importance in terms of economic contribution and foreign trade

The Indian pharmaceutical industry, over the years has significantly contributed to India's economic growth. According to the Department of Pharmaceuticals¹³, over 2.7 million people are employed by the industry either directly or indirectly in high-skill areas like research and development (R&D) and manufacturing.

The pharma industry is well-positioned to contribute to India's economic prosperity in a notable way. The strong belief stems from the industry's impressive net foreign exchange revenues of USD11 billion in 2021 which the industry can clock to USD30-40 billion annually by 2030¹⁴. Within the same period, the industry has got the wherewithal to boost

consumption in the local economy by creating 1-2 million additional jobs¹⁵. A great opportunity awaits the Indian pharma companies to leverage the 'China plus one' strategy and attract significant global investments as India has a huge competitive advantage in pharmaceuticals.

5. "India supplied paracetamol, hydroxychloroquine to over 120 countries in last 2 months: Piyush Goyal", The Economic Times, May 2020; accessed on 6th April 2022.

6. "About us", Serum Institute of India Pvt. Ltd.; accessed on 6th April 2022

7. "India: Pharmacy to the World", Invest India, July 2020; accessed on 6th April 2022

8. "Pharmaceuticals", Invest India; accessed on 23rd March 2022

9. Industry estimates

10. "Indian pharmaceuticals - a formula for success", Invest India, March 2022; accessed on 6th April 2022

11. "Indian pharmaceuticals - a formula for success", Invest India, March 2022; accessed on 6th April 2022

12. "Indian pharmaceuticals - a formula for success", Invest India, March 2022; accessed on 6th April 2022

13. Draft Policy - Department of Pharmaceuticals; accessed on 7th March 2022

14. "IBEF" website. Accessed on 6th April 2022

15. "IBEF" website. Accessed on 6th April 2022

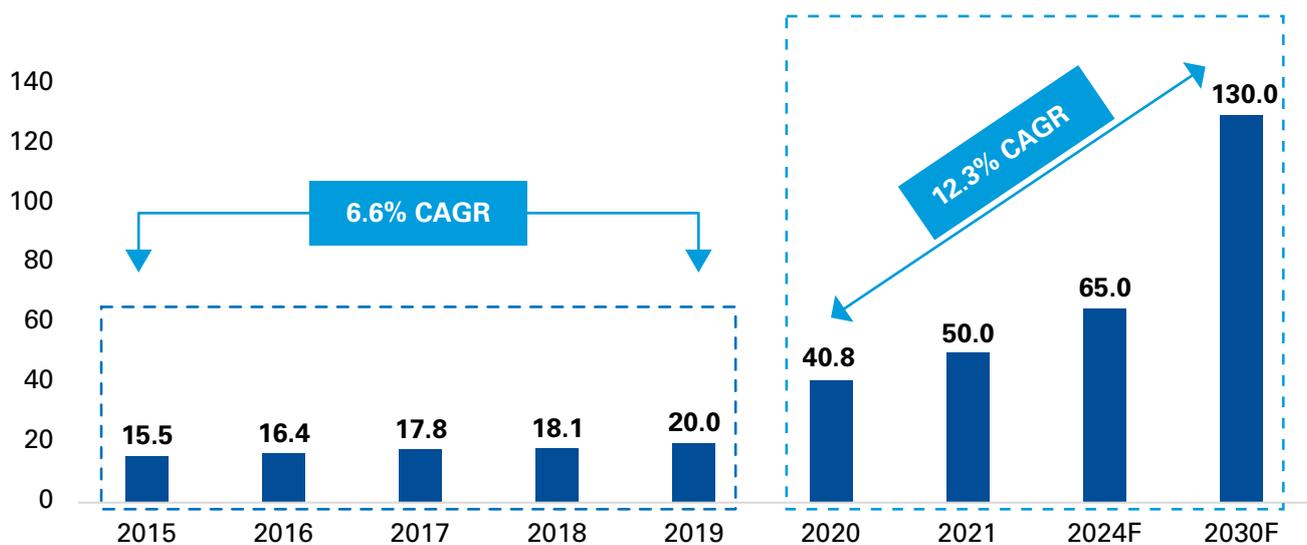
The Indian pharmaceutical industry is poised to experience high growth

The Indian pharmaceutical industry grew at a modest CAGR of 6.6 per cent to reach USD20 billion in 2019 from USD15.5 billion in 2015¹⁶. At the onset of the COVID-19 pandemic, the industry witnessed a slump but recovered soon after to register a phenomenal growth starting from early 2021.

Domestic pharma market was hit at the onset of COVID-19 in 2020	Why growth picked up in 2021?
The pharmaceutical units were severely impacted due to stringent lockdown measures, with companies facing challenges in distribution, manufacturing, and logistics	In the first half of 2021, there was a reasonable demand for COVID related products like Remdesivir, vitamins and minerals kind of supplemental products
The prescriptions for anti-infectives, pain, gastro and vitamins were down	The second wave of the pandemic boosted the sales of drugs having a direct/indirect role in the treatment of COVID. Anti-infectives and nutraceuticals witnessed impressive growth
The sales of drugs used to treat acute medical conditions and elective procedures hit a slump following reduced doctor visits owing to travel restrictions and hospitals' increased priorities towards COVID treatment over elective procedures	The sales of drugs used to treat acute medical conditions and elective procedures recovered in 2021 as travel restrictions were lifted and doctor visits restarted

In the 2020-30 period, it is expected that the Indian pharmaceutical industry will grow at a CAGR of 12.3 per cent¹⁷ to reach at USD130 billion¹⁸. To achieve this ambitious target, a collaborative effort is required from all the industry stakeholders – the healthcare providers, physicians, payers, policymakers, pharma companies, academic institutions and a range of service providers offering solutions pertaining to logistics and distribution, packaging, and other ancillary services.

Figure 1: Indian pharmaceutical market, (USD billion), 2015-30F

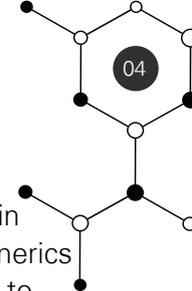


Source: IBEF reports, Invest India, Department of Pharmaceuticals, KPMG in India analysis 2022

16. KPMG in India analysis 2022

17. KPMG in India analysis 2022

18. Indian Pharmaceutical Industry, IBEF, March 2021; accessed on 6th April 2022



Small and medium enterprises (SMEs) are one of the significant contributors to the growth of the Indian pharmaceutical industry. There are more than 24,000 registered pharma SMEs, which meet around 70 per cent of the country's pharmaceutical needs¹⁹. They provide a huge advantage in terms of costs in the manufacturing of high-quality pharmaceutical products not only for the Indian pharma companies but also leading global pharma players. The SMEs account for 30-40 per cent of the Indian pharmaceutical industry's production with a turnover

of around USD4,581 million (INR35,000 crore)²⁰. These are expected to clock 8-10 per cent growth in 2021-22 after exhibiting an impressive 8-9 per cent growth in 2020-21²¹.

Indian pharmaceutical industry takes a big leap in exports

The Indian pharmaceutical firms are successful not only in catering to its domestic needs but also in achieving the position of a leading exporter of pharmaceutical products. At a time when the global pharma market was negatively growing by 1-2 per cent

in 2020²², there was a surge in demand for made in India generics and vaccines primarily owing to its quality and affordability. India's pharma exports clocked an impressive growth of over 18.2 per cent in FY21 as compared to the last fiscal. This was the highest export growth rate in the last eight years for the Indian pharma industry²³. The exports touched USD24,469.8 million in 2020-21 and USD20,254.4 million in 2021-22 (Apr-Jan) across product categories of drug formulations and biologicals, bulk drugs and drug intermediaries, vaccines, surgicals, ayush and herbals.

Table 1: Pharma exports from India across different product categories, (USD million), FY2017-21 (Apr-Jan 2021)

Product Category	2016-17	2017-18	2018-19	2019-20	2020-21	% growth
Drug Formulations & Biologicals	11,966.1	12,203.8	13,648.8	15,049.4	17,959.3	19.3%
Bulk Drugs & Drug Intermediates	3,383.5	3,525.7	3,895.4	3,867.8	4,405.5	13.9%
Vaccines	679.3	696.5	719.9	878.7	887.8	1%
Surgicals	354.4	399.8	425.3	479.5	677.1	41.2%
Ayush & Herbals	401.7	456.1	448.1	428.1	539.9	26.1%
Total exports	16,785.0	17,281.8	19,137.4	20,703.5	24,469.5	18.2%

Source: Trade statistics, Pharmaceutical Export Promotion Council of India (Pharmexcil), Ministry of Commerce and Industry, Government of India

- Primary factors that make India a leading exporter include low capital requirements, economical innovations, operating facilities with minimal expenses along with well-established manufacturing processes and R&D infrastructure
- Countries rely heavily on India to solve their rising healthcare expenses as India is a leading provider of affordable medicines

19. "Research portal on Pharma to benefit MSME sector: Union Minister Mandaviya", KNN, January 2022; accessed on 6th March 2022

20. "Research portal on Pharma to benefit MSME sector: Union Minister Mandaviya", KNN, January 2022; accessed on 6th March 2022

21. "Domestic demand to drive pharma SMEs' growth in FY22: Crisil SME Tracker", Business Standard, January 2022; accessed on 6th March 2022

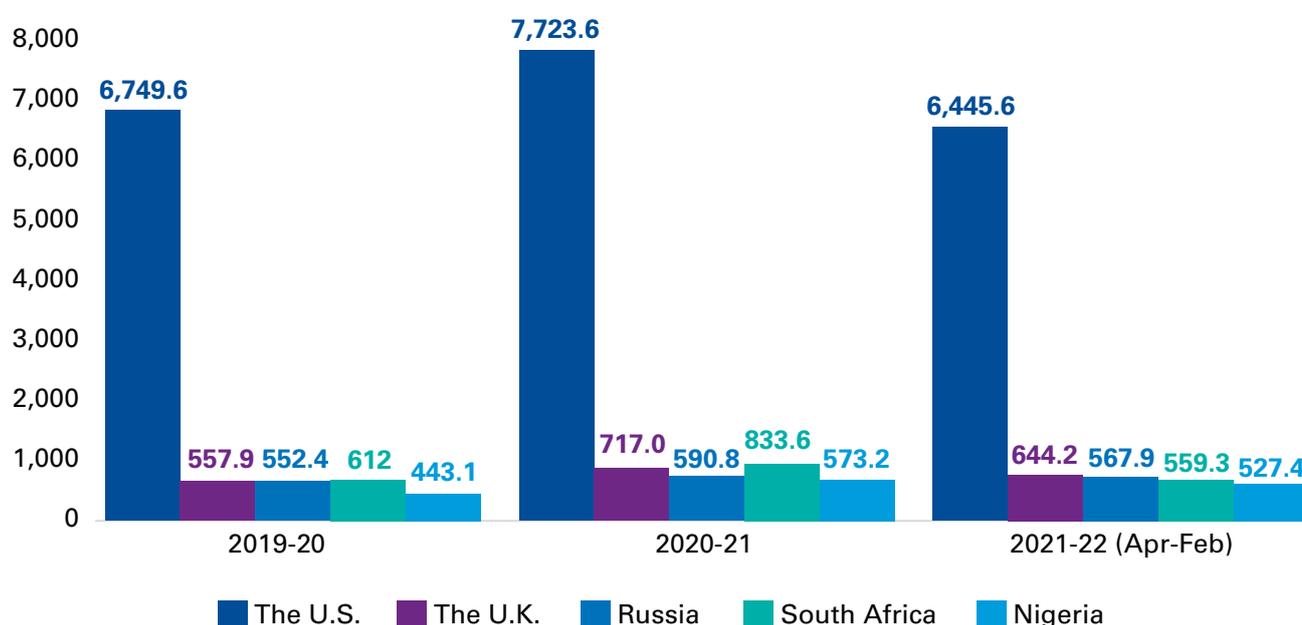
22. "Indian pharma exports grow at 18% to \$24.44 billion in FY 21 from \$20.58 bn", Business Standard, April 2021; accessed on 6th March 2022

23. KPMG in India analysis 2022

The top export destinations for the Indian pharmaceutical industry

The U.S., the U.K., Russia, South Africa, and Nigeria form the top five export destinations for the Indian pharmaceutical products. The U.S. is the largest importer of Indian pharmaceuticals with pharmaceuticals comprising more than 33 per cent of the total exports to the country consistently throughout the years from 2017-18 to 2021-22²⁴. Exports to the U.S. have grown in the last two decades mainly driven by the cost advantage that India offers.

Figure 2: The top five export destinations of Indian pharmaceutical products by value (USD million), FY2020-22 (Apr-Jan 2022)



Source: Trade statistics, Pharmaceutical Export Promotion Council of India (Pharmexcil), Ministry of Commerce and Industry, Government of India

The demand for Indian pharmaceutical products increased in non-traditional markets²⁵ such as Latin America (growth of 14.5 per cent), Commonwealth of Independent States (CIS) countries (23.5 per cent growth) and Middle East (17.5 per cent growth) during the pandemic year 2020-21. Also, impressive growth rates were observed in exports to previously unexplored countries such as Australia (growth of 21 per cent)

UAE (growth of 43 per cent), Uzbekistan (growth of 125 per cent) and Ukraine (growth of 40.6 per cent).

FDI in the Indian pharma sector shoots up by more than 200 per cent in 2020-21

The Indian pharmaceutical industry witnessed record FDI inflows worth USD1,441 million (INR11,015 crore) for the financial year 2020-21. The record influx of

foreign investments during the pandemic period was driven by a need to meet COVID-induced demands for therapeutics and vaccines. The FDI inflows into the drugs and pharmaceuticals sector in FY 2021-22 during the six months from April to September, was USD559 million (INR4,143 crore). This is higher than the USD518 million (INR3,650 crore) registered during the 12-month period from April 2019 to March 2020.

24. "Exports", Ministry of Commerce and Industry, Government of India; accessed on 6th April 2022

25. "Indian pharma exports up 18% to a record \$24.44 bn in pandemic year", Business Today; accessed on 12th March 2022

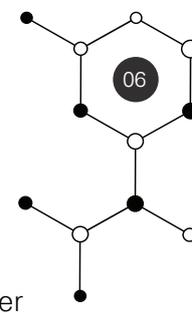
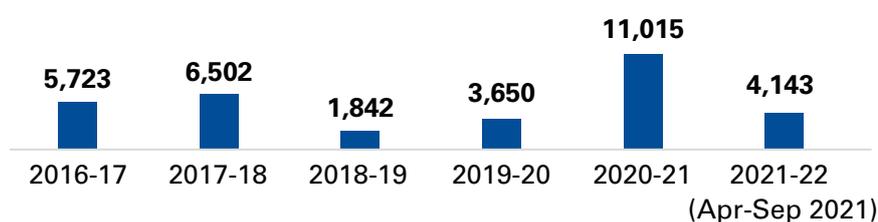


Figure 3: FDI inflows to the Indian pharmaceutical sector (INR crore), FY2017-22 (Apr-Sep 2021)



Source: FDI statistics, Department for Promotion of Industry and Internal Trade, Ministry of Commerce and Industry, Government of India

The Indian Government has allowed 100 per cent FDI in pharmaceuticals in India under the automatic route for greenfield pharma²⁶. 100 per cent FDI in drugs and pharmaceuticals is allowed in brownfield pharma, wherein 74 per cent FDI is permitted under the automatic route and after that through Government's approval.

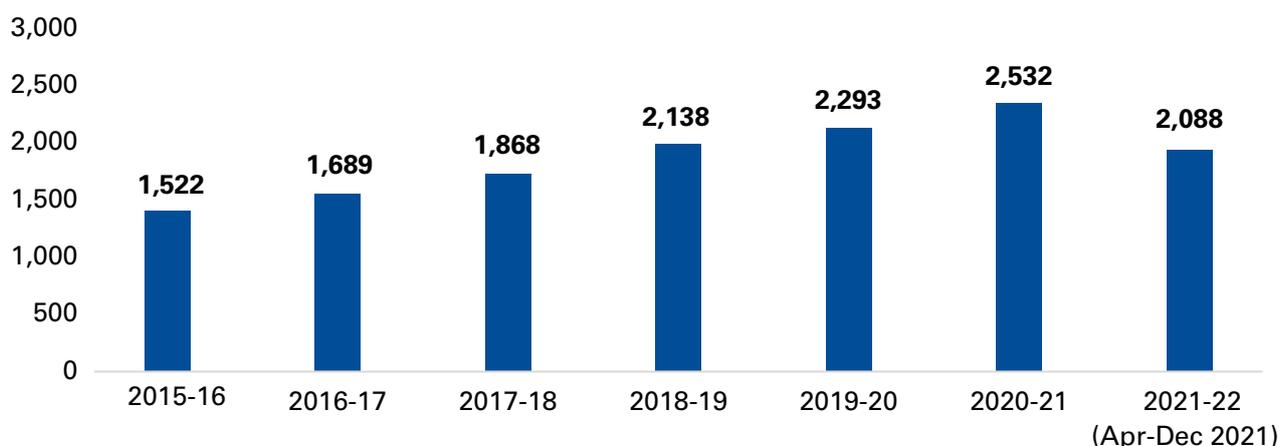
Indian medical device manufacturing industry is at the cusp of a great opportunity

On account of various geopolitical reasons, global investors have begun to show a renewed interest in Indian medical devices. India's commitment for self-reliance i.e., Atmanirbhar Bharat will not only see India emerge as a superpower in medical devices manufacturing but will also strengthen India's quest for a position of a reliable manufacturer of quality products on a global scale.

The exports of medical devices grew by 10.4 per cent in 2020-21 as the Indian Government heavily trusted the Indian manufacturers to meet the rising demand not only for the country but also for exports. Before the outbreak of the pandemic, there were a mere 20 firms manufacturing 62 lakh PPEs per year²⁷. However, within a short period of just two-three months, the number

of manufacturers listed with the Association of Indian Medical Device Industry (AiMeD) increased to 140 firms with an added annual capacity of USD3.3 million (INR25.55 crore)²⁸.

Figure 4: Exports of medical devices from India (USD million), FY2016-22 (Apr-Dec 2021)



Source: Engineering Export Promotion Council of India (EEPC), Ministry of Commerce, Government of India

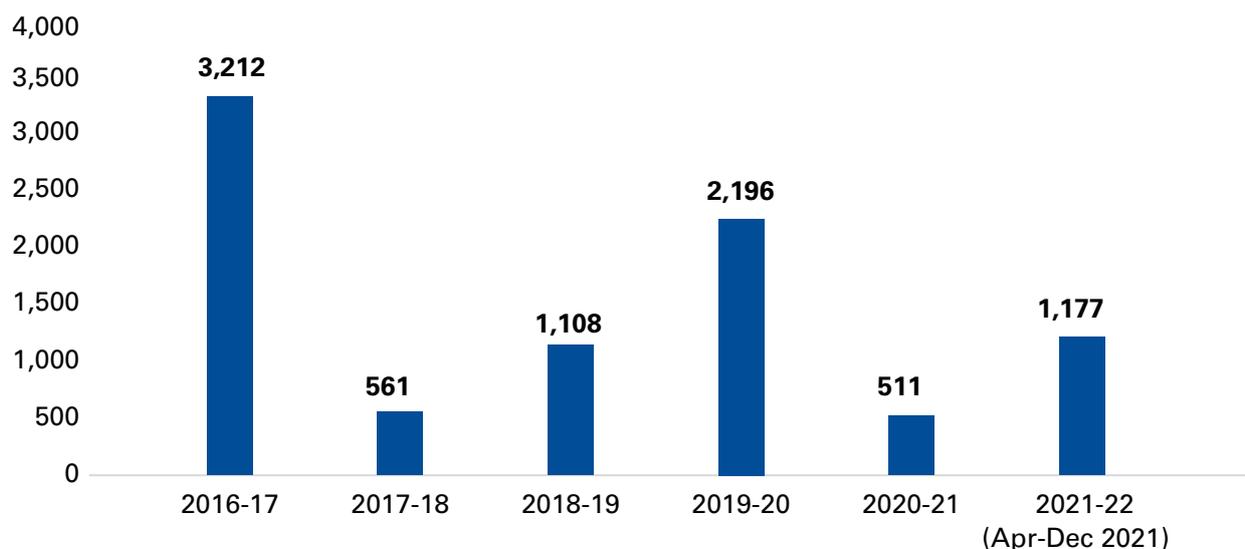
26. "Pharmaceuticals", Invest India. January 2022; accessed on 7th March 2022

27. "AiMeD reports increased growth rate of Indian medical device industry during Covid-19", Medical Dialogues. November 2021; accessed on 26th April 2022

28. "AiMeD reports increased growth rate of Indian medical device industry during Covid-19", Medical Dialogues. November 2021; accessed on 26th April 2022

The Indian government has commenced various initiatives to strengthen the medical and surgical appliances sector. It has emphasised on various Research and Development (R&D) initiatives and has allowed 100 per cent FDI for medical devices to boost the sector. Currently, the FDI inflows in the medical and surgical appliances sector stands at INR1,177 crore (USD158.77 million) in April 2021-Dec 2021. The need of the hour is more proactive efforts to ensure that India transitions its position from a net importer to an exporter of medical devices.

Figure 5 : FDI inflows in the Indian medical and surgical appliances industry (INR crore), FY2017-22 (Apr-Dec 2021)



Source: FDI statistics, Department for Promotion of Industry and Internal Trade, Ministry of Commerce and Industry, Government of India

The Indian government has taken significant measures to ensure the growth of the dynamic medical device ecosystem of the country^{29,30,31}

Medical Devices Rules 2017:

The Medical Devices Rules (MDR), 2017 regulates Clinical Investigation, Manufacture, Import, Sale, and Distribution of Medical Devices. The government is also advocating to align the New Drugs, Cosmetics and Medical Devices Bill with MDR 2017 for a streamlined regulatory ecosystem.

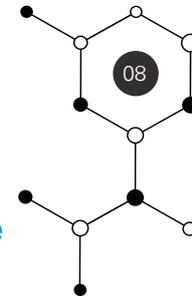
- This streamlining would enable Indian manufacturers to receive greater acceptability of their products in global markets, bolstering the Make in India objective of the government and keeping India competitively aligned to the global market.



29. "Medical devices", Invest India, March 2022; accessed on 10th March 2022.

30. "New Drugs, Cosmetics and Medical Devices Bill should be aligned with MD Rules 2017 for effective regulation: Experts", Financial Express, October 2021; accessed on 10th March 2022.

31. "Medical device manufacturing", Invest India, 2021; accessed on 10th March 2022.



The Indian pharmaceutical industry has been quick to bounce back from the pandemic lows

It has been two years since the COVID-19 pandemic first struck but the global economy continues to be haunted by varied uncertainties such as constant fears of new variants, logistics and supply chain disruptions, inflation in both developed and emerging economies. The Indian pharmaceutical industry bounced back from the lows of the COVID-induced lockdown-hit months of April-June 2020 and maintained a

strong growth momentum starting September 2020.

The Indian pharmaceutical companies experienced robust sales in 2021-22 as sales normalised in the pharmaceutical segments affected by the pandemic in the previous year. Most Indian pharmaceutical companies witnessed strong operating performance in 2020-21, as they were largely benefitted by

gradual stabilisation after Q1FY21, geographical diversification and sales of COVID-19 related drugs. There was a fall in the sales in these categories in 2020-21 as doctor visits reduced owing to travel restrictions and hospitals used to accord highest priority to COVID-19 treatment over elective procedures.

COVID-19 pandemic brought to light systemic gaps for the Indian pharmaceutical industry

With the Indian pharmaceutical industry's primary focus on large-scale, high-quality manufacturing of generic medicines and essential medical products, it is expected to be ready for future pandemics. This is quite evident from the numerous vaccines, therapeutics and diagnostics that were developed and approved during

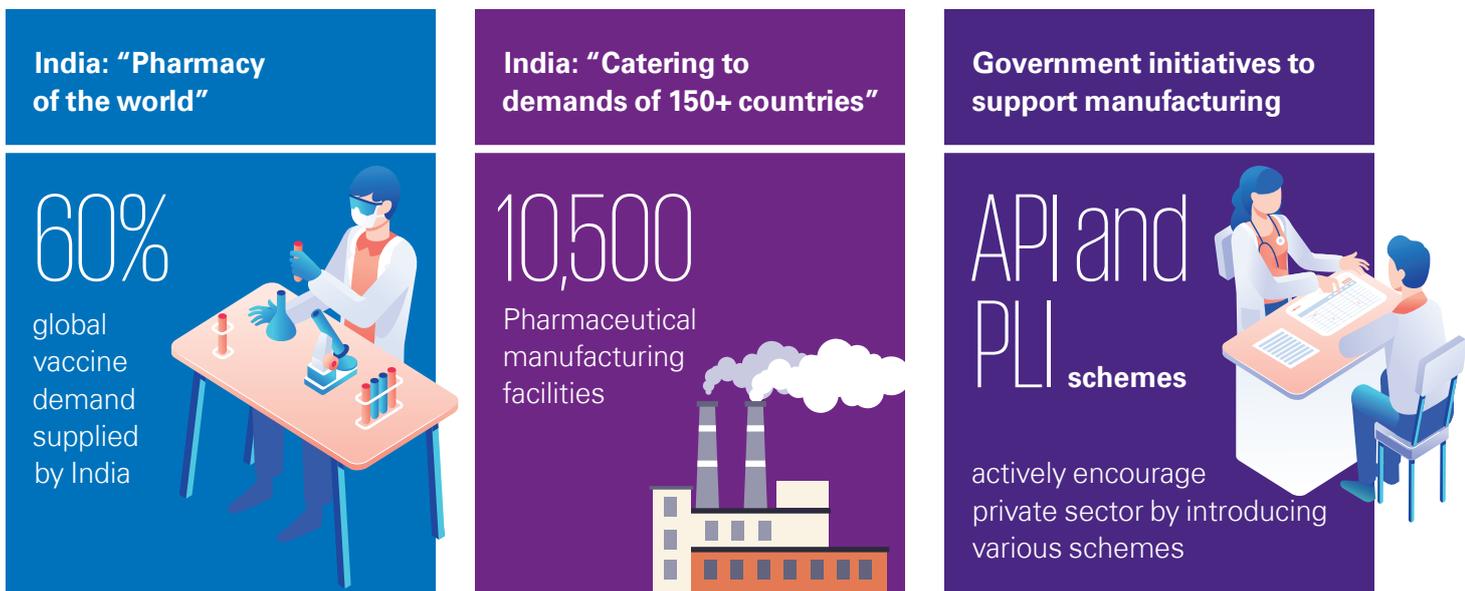
the pandemic. The India-made products have made a significant and lasting impact on lives and livelihoods, not just within India but globally. Notwithstanding the recent successes, the pandemic also brought to the fore certain systemic gaps in the sector and has necessitated the need to bridge these gaps. To emerge as

an absolute winner in the post-pandemic times and achieve the ambitious target of a USD130 billion industry by 2030, it should find strong and lasting solutions to fill these gaps.



Systemic gaps in the Indian pharmaceutical sector'

Manufacturing and supply chain are vital components of the pharmaceutical value chain. In this era of competition, it is significant to manage optimal cost for manufacturing and supply chain as well as to keep the cost to consumers and inventory levels also at the lowest while maintaining quality in service .



Source: "Not without India: World's pharmacy gears up for vaccine race" - Retuers.com; "Invest India" - official website, accessed on 16th March 2022

Thus, as Indian pharmaceutical industry aspires to grow, there is a need to revamp the infrastructure for logistics, movement and storage of raw materials including finished products across the country. Certain pharmaceutical products such as injectables, vaccines, or complex drugs require specialised transportation and storage facilities during shipment with temperature and humidity requirements monitored, according to guidelines framed by regulatory authorities.

In comparison to the west and emerging markets of China and South Korea there remains scope to improve storage and transportation facilities. There still lies a huge gap to be filled in Indian ports, airports, railways, roads, and waterways to meet the global standards of facilities, automation and time-taken/speed, thus impacting supply chain.

Thus, as pharmaceutical industry grows in value and volume in the coming years, it places

a huge demand on various elements of the supply chain. COVID-19 pandemic created enormous disruptions in the demand and supply sides of pharma supply chain. Below is the timeline of COVID-19 restrictions implemented by Indian government and its effect on pharma productions during 2019-end to July 2020³²:

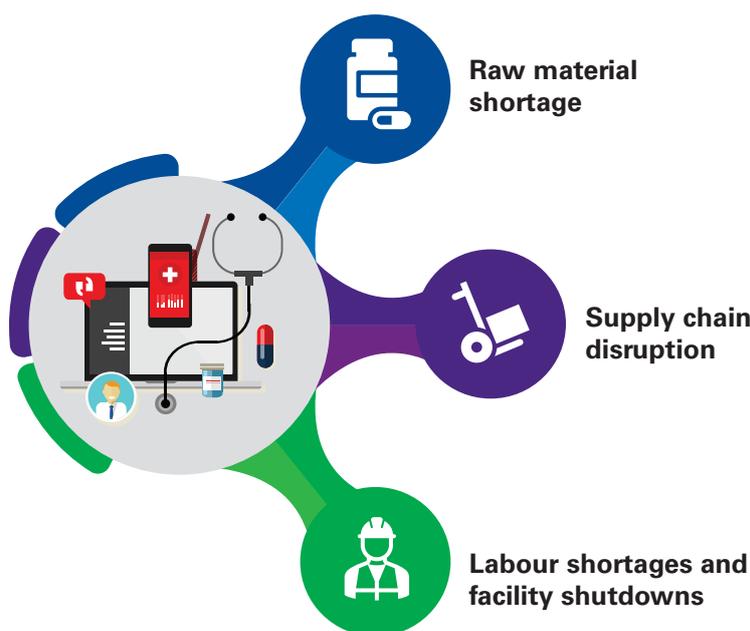
32. "Essential-medicines-supply-chains-press-scan-India-manufacturing" - CGDEV.com, accessed on 16th March 2022

Figure 6: Timeline of COVID-19 restrictions and pharma production during first half of 2020



Source: "Essential-medicines-supply-chains-press-scan-India-manufacturing"-CGDEV.com, accessed on 16th March 2022

Thus, COVID-19 pandemic highlighted some of the major gaps to be addressed in Indian pharmaceutical industry, primarily in terms of availability of manpower, ancillary materials such as packaging and continuity of logistics. Among these issues, there were three most pertinent issues which have been highlighted further in the subsequent subsections, namely: raw material shortages due to disruption in import of APIs, supply chain disruption, facility shutdowns and labour shortages.



Raw material shortages—disruption in import of APIs

As COVID-19 outbreak was gripping the global trade, many sectors in India were also facing a shortage in supply of raw materials. Indian pharmaceutical sector was among one of the worst hit sectors. As the factories in China were hit by lockdown, India was facing challenges to maintain continuous supply of active pharmaceutical ingredients (APIs), a primary raw material for drugs.

India is a leader in supplying low-cost generics, both domestically and globally. However, nearly 70 per cent of all APIs are imported from China; which is the global leader in producing and exporting, by volume- for antibiotics (especially penicillin, cephalosporins, and macrolides).^{33,34,35}

Table 2: Over 70 per cent of all APIs imported from China, (in %)

API	Proportion
Oxytetracycline (antibiotic)	100%
Paracetamol	100%
Metformin	100%
Ampicillin	100%
Ciprofloxacin	100%
Tetracycline	99.8%
Azithromycin	99.4%

Source: "Relief for Pharma firms as govt starts clearing API imports from China", Business Standard, accessed on 9th March 2022, "Indian API industry reaching the full potential Thought Leadership", KPMG in India, accessed on 9th March 2022

Thus, the dependence is substantial on imports, especially for antipyretics, cardiovascular, respiratory and diabetics medicines. Further, India's raw material demand for paracetamol and other major antibiotics is primarily relied upon imports from China, up to 100 per cent, as listed above.



33. "Key COVID-19 drugs to be hit by customers"- Times of India, accessed on 9th March 2022

34. "Indian API industry reaching the full potential Thought Leadership", KPMG in India, accessed on 9th March 2022

35. "Coronavirus-impact-on-India's-pharma sector"- Economic times, accessed on 9th March 2022

For most Indian pharma companies, a major portion of their raw material sourcing is imported from China. For instance³⁶:

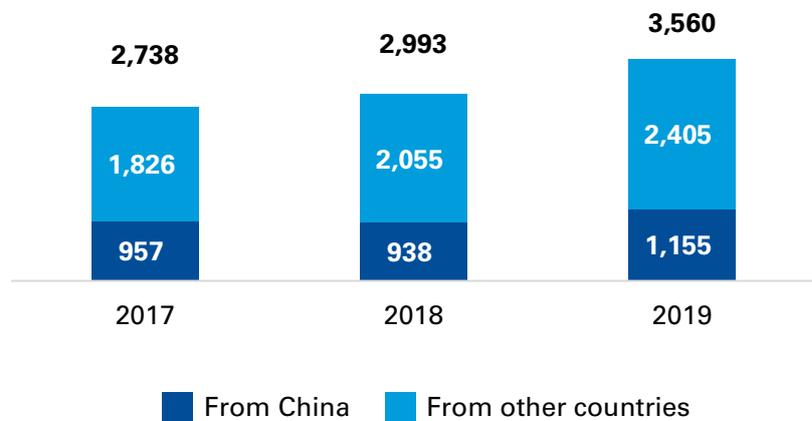
- Companies such as Cipla are significantly dependent on China. Around 30-35 per cent of sales were affected due to paracetamol import disruption for this company.

Most Indian pharma companies have their stockpile lasting for two-three months, while small and medium-sized companies had stock that could last only for 20-25 days.

- For instance, Cipla mentioned that it stored two months stock of APIs and intermediates as part of inventory holding norms.

China constitutes the largest share in the overall bulk drugs and drug intermediate imports by India.

Figure 7: Dependency upon China on bulk drugs imports, (USD billion), 2017-19



Source: "India's increased dependence on Chinese APIs causing concern" - Directorate General of Commercial Intelligence and Statistics

It was observed during the first half of FY 2022 (April-September 2021) that China accounted for more than 65 per cent³⁷ of the total bulk drugs and drug intermediate imports by India. This high import dependency is majorly due to availability of APIs and bulk drugs in China at low prices.

Any disruption in China's bulk drugs market has a direct influence on the Indian pharma industry. A considerable increase in the prices of raw materials was recorded due to traffic restrictions and staff shortages, as listed below:

Table 3: Rise in prices of raw materials*

API	Old price per kg (in USD) (pre-pandemic)	New price per kg (in USD) (post-pandemic)	% change in price
Paracetamol	4.8	10.9	127.1%
Propylene glycol	1.92	5.5	186.5%
Ivermectin	248.0	717.0	189.1%
Doxycycline	82.7	165.3	99.9%
Azithromycin	110.0	165.0	50.0%
Loratadine	303.0	503.0	66.0%
Desloratadine	41.3	52.0	25.9%

Source: "Pharma raw material shortage pushing India to regulate bulk drug prices" - the Pharma Letter, accessed on 10th March

*Note: pre and post pandemic dates not available. Hence, data considered as Yo-Y growth



³⁶. "Indian APIs & Formulations for Global Healthcare-IDMA Bulletin 2020"; accessed on 10th March 2022

³⁷. "India - Pharmaceuticals Industry-CMIE, accessed on 10th March 2022

Thus, prices of some of the vital drugs such as Nimesulide increased by 189 per cent, from INR450 to INR1,300 per kg between January and April 2020 whereas, 6APA (a chemical used to manufacture antibiotics) prices increased by more than 360 per cent, from INR400 to INR1,875 per kg from January to February³⁸.

- On an average, the industry was facing a price rise of around 20-700 per cent in APIs imported from China.³⁹
 - Furthermore, pharma companies increased prices of the products that led to a shortage of pertinent medicines. Medicines that helped to mitigate COVID-19 effect attained a substantially higher price, driven by the demand surge.⁴⁰

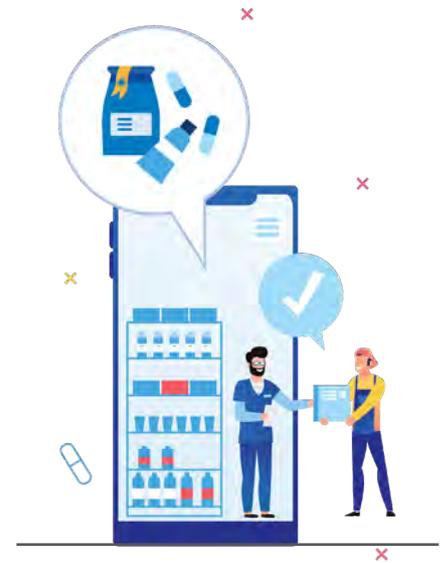
However, government authorities such as Department of Pharmaceuticals (DoP) and Drugs Controller General of India (DCGI) were actively monitoring the scenario and were striving to tackle the raw material crisis.

Assessment of availability and ensuring adequate stock of essential items were monitored by DoP. For instance:⁴¹

- National Pharmaceutical Pricing Authority (NPPA), DCGI, and various state governments were directed by DoP to ensure adequate supply of APIs and formulations in the market
- Prevention of black-marketing, illegal hoarding, and artificial shortages were checked by DoP

- Restricted export of around 13 APIs and their associated formulations

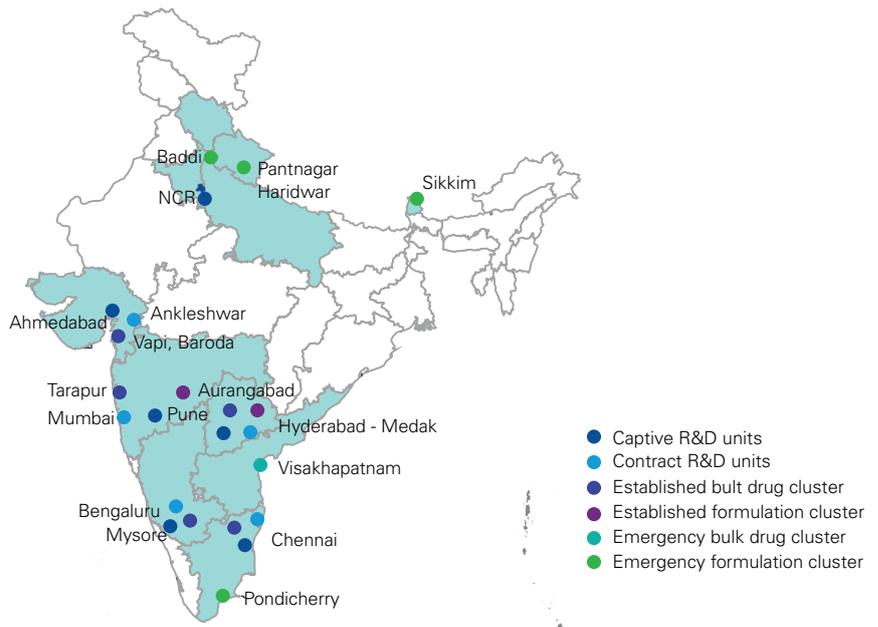
Hence, challenges with shortage of APIs and key starting raw materials led to shortfall in pharmaceuticals production which certainly had a direct impact on the country's export of generic medicines worldwide.



Labour shortages and facility shutdowns⁴²

Most Indian pharma companies were affected by the lockdown primarily due to facility shutdowns and labour shortages. Asia's largest pharmaceutical hub, situated in Baddi-Barotiwala-Nalagarh, Himachal Pradesh, producing several primary lifesaving, anti-inflammatory, antiviral, and COVID-19 drugs, were also battling this new crisis of procuring raw materials and limited operations. Members of the industrial belt asked the government to intervene to streamline the availability and transportation of raw materials.

Figure 8: Major pharmaceutical clusters in India



Source: FDI India; Foreign Investment facilitators

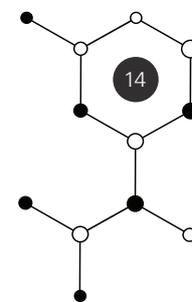
38. "Prices-of-some-medicines-could-go-up-as-cost-of-chinese-bulk-drugs-import-surges"- the Print, accessed on 9th March

39. "Pharma raw material shortage pushing India to regulate bulk drug prices"- the Pharma Letter, accessed on 10th March

40. Utilisation, Availability and Price Changes of Medicines and Protection Equipment for COVID-19 Among Selected Regions in India: Findings and Implications

41. "Annual Report 2020-21"- Department of Pharmaceuticals, Government of India, accessed on 14th March

42. "Annual Report 2020-21"- Department of Pharmaceuticals, Government of India, accessed on 14th March 2022



Reduced availability of workers⁴³

- Restriction of movement of labourers inside plants. Some of these labourers travelling across states were also restricted at borders
- Contractual workers involved in loading, unloading and material movement belonged to states like UP, or Bihar, so, they left for their home states. Apart from this, announcement by Government of India that labourers would get their compensations during lockdown made workers hesitant to turn up for work
- Housing societies resided by employees of pharma units created ruckus due to fear of contracting infection.

Production trends during lockdown of major pharmaceutical manufacturing hubs^{44,45}

Baddi, Himachal Pradesh

- Accounts for 35-40 per cent of the nation's pharma output and ~35 per cent of pharma formulation demand of Asia
- Consists of over 750 pharma units in the Solan and Sirmaur area of the state
- Around 80 per cent of production was hampered during the lockdown periods, due to 50 per cent workforce allowed till April 2020
- Government allowed movement of pharma workers from Chandigarh to Baddi and resumption of intra-district movement within the state to keep the facilities running

Telangana

- Bulk drug capital of India, which accounts for 40 per cent of the country's total bulk drug production
- Telangana is the home to around 800 life sciences companies and employs about 1.20 lakh people
- Bulk drug and pharmaceutical production mainly take place in Hyderabad and surrounding districts of Rangareddy, Medchal, and Sangareddy
- Bulk drug manufacturers in the hub were reported to be functioning at 50 per cent capacity from March till May 2020

Gujarat

- Accounts for 35 per cent of India's pharma production and exports
- Many facilities halted its operations due to its employees' contracting COVID-19 infection:
 - In the first week of May, Cadila Pharmaceuticals shut down its operations for about 15 days after 26 employees tested positive
 - In mid-July, Lupin Ltd shut down at least one of its 11 manufacturing sites in Gujarat after 18 workers tested positive for COVID-19

Thus, restrictions on public transportation and interstate or inter-district travels, or as well as requirement of passes for the same affected the movement of labourers, making it difficult for the workforce to reach manufacturing plants.

Furthermore, most Indian pharma manufacturing units were operating at 40–50 per cent of their capacities because of unavailability of workforce, and due to curtailment of operations at various plants to only one shift. Consequently, this led to losses amounting to approximately USD776-866 million due to COVID-19, when extrapolated to normal circumstances⁴⁶.

43. Annual Report 2020-21 - Department of Pharmaceuticals, Government of India, accessed on 14th March 2022

44. "COVID-19: Implications on Regional Industry and Economy" - FICCI, April 2020, accessed on 15th March 2022

45. "12-employees-test-positive-for-covid-at-lupins-ankleshwar-facility" - The Hindu Business Line, accessed on 15th March 2022

46. "Essential-medicines-supply-chains-press-scan-India-manufacturing" - CGDEV, accessed on 15th March 2022

Supply chain disruptions⁴⁷

Nationwide lockdown during COVID-19 pandemic led to supply chain disruptions although healthcare industry was exempted from lockdown restrictions under essential services.

- However, major challenges were faced due to restrictions on inter-state movement of medicines, other essentials, and movement of labourers

- In addition, non-availability of ancillary services such as packing materials, courier services.

Furthermore, even though supply of raw materials from China resumed after lockdowns from January to March 2020, input costs rose steeply for many chemicals (APIs and key starting

materials (KSMs)) due to increased freight costs

- For instance, air freight charges increased from USD2 per kg to USD5- USD6 per kg. The average cost of shipping a container from China to India increased from USD750 to USD1,200- USD1,300 during the first and second waves of pandemic.

Listed below are some of the major challenges faced due to supply-chain disruptions:

Challenges in transportation:

The non-availability of local transportations for dispatching materials led to retailers, wholesalers and distributors being unable to receive their consignments. Some associated factors are as follows:

- Unavailability of trucks due to reluctance of truck operators caused by manhandling by police, unavailability of food, or fuel on the run.
- Lockdown restrictions were not uniform countrywide- COVID-19 restrictions varied across states
- Additionally, secondary transportation of drugs from drug forwarding agencies to stockists was hampered due to mobility restrictions during the pandemic.

Due to disruption of connectivity from office to warehouse and warehouse to stockists, there was a severe disruption in delivery of medicines across India.

In case of air transport, there was an impact on cargo movement from key international hubs due to restrictions on passenger flights and limited availability

- Due to impact on air transport, critical drugs were getting piled up at various hubs, movement of goods to India being slow



47. "Annual Report 2020-21"- Department of Pharmaceuticals, Government of India, accessed on 14th March

Challenges in logistics



A

Courier services disrupted

- Courier services were largely not operational during the lockdown, especially in Tier 1 and Tier 2 cities

B

Black marketing and hoarding of medicines

- Huge demand for medicines, and medical devices resulted in hoarding and black marketing by a few
- Rural markets were more susceptible at many cases- duplicate Remdesivir was sold.

C

Limited cooperation from local administration

- Some of the allied industries to pharma sector related to packaging materials for medicines, were not brought under the umbrella of essential services in most states
- This posed a challenge to the packaging vendors to source their raw materials for preparing medicine packages and in storage of materials.

Thus, supply chain disruption of critical bulk drugs led to price surge and shortage in supply of raw materials. This highlighted the need for India to attain a sufficient degree of self-reliance in bulk drugs, thereby, driving the attention of various government authorities.

Government initiatives helped minimise the disruptions in the Indian pharma industry amid the COVID-19 crisis

Although pharmaceutical manufacturing and supply chain operations underwent disruptions during COVID-19 outbreak, it was timely intervention by the

government which helped the country tide over the challenges. The strategies adopted by the government, at operational and policy levels helped the industry cater to domestic and global market demands. This included augmenting manufacturing capacity and supply of COVID-19 vaccines or other medical supplies. Thus, pandemic served an opportune time for the government to focus on making India self-reliant in pharmaceutical manufacturing.



Government's support to the pharma sector during the COVID-19 pandemic

The Indian government has been a major stakeholder in making the Indian pharmaceutical industry globally competitive through the provision of world class manufacturing capabilities along with production capacities which are of top-notch quality and are also cost-efficient. The government has also helped in the comprehensive upgradation of research and development capabilities for new drugs and

allied activities like contract manufacturing and clinical trials.

As the spread of the pandemic ceases, the Indian economy is expected to be on a faster road to recovery. Vaccination is one of the critical factors helping India regain the momentum of economic recovery and India has proved its leadership status to the world in terms of COVID-19 vaccine development and its rollout.

India's pragmatic vaccine strategy against COVID-19⁴⁸

India set out on a challenging path of vaccinating its massive 1.38 billion-strong population against COVID-19 in January 2021. The success of the world's largest vaccination drive is the direct outcome of the Indian government's robust strategy built on a strong footing of R&D, manufacturing, and administration.



R&D

COVID-19 Research Consortium Program: With a focus on developing affordable vaccines in quick time, the Department of Biotechnology (DBT) and the Biotechnology Industry Research Assistance Council (BIRAC) invited proposals from the industry players and academia.

Sequencing of local COVID-19 strain: A memorandum issued by the government's empowered committee on COVID-19 allowed Indian scientists to collect blood, throat, and nasal samples from the infected persons to enable sequencing of the local COVID-19 strain.



Manufacturing

Covid Suraksha: This was announced under Aatmanirbhar Bharat 3.0 mission with a view to accelerate the development and production of indigenous COVID-19 vaccines. The Indian government provided financial support as grants to vaccine manufacturing facilities.

Facility augmentation: Capacities of Bharat Biotech Limited, Hyderabad as well as other public sector pharma manufacturers were upgraded with required infrastructure and technology.



Administration

Creation of National Expert Group on Vaccine Administration (NEGVAC): NEGVAC was created under the chairpersonship of Member (Health) NITI Aayog and co-chairpersonship of Secretary, Ministry of Health and Family Welfare (MoHFW). Its primary responsibility was to guide all phases of COVID-19 vaccination drive in India.

Training and capacity building: Extensive training and skill-building programs were conducted for different vaccination officers.

Technology integration: An end-to-end mobile app platform (CO-WIN) handles the registration and tracking of beneficiaries, listing of facilities and session sites, and monitoring of vaccine doses and wastages at regional and national levels.

48. "India's COVID-19 vaccination administration journey, An overview", Institute for Competitiveness; accessed on 30th March 2022

The Government of India (GoI) adopted a comprehensive five-point communication strategy for an effective COVID-19 vaccine rollout⁴⁹

The Indian government designed and implemented an inclusive and responsive communication strategy for awareness building and facilitating access to real-time information for the citizens of India. This helped encourage the eligible citizens to come forward and register themselves for vaccination.

Advocacy



- Steps were taken to gain social trust, commitment, and support for rolling out the vaccine for the masses
- Involved engaging the influencers, leading voices, and celebrities for removing vaccine hesitancy and motivating people for vaccine registrations

Capacity building



- Training and skill enhancement of the resources involved in the vaccination drive at state, district, and block levels across the country
- The resources included administrators, program officers, healthcare workers (HCWs), frontline workers (FLWs), doctors, nurses, volunteers, leading development organisations and other individual as well as institutional partners

Media engagement



- Focused on promoting the evidence-based narrative regarding the benefits of vaccination among the masses
- Different media channels (print, TV, billboards, radio, word of mouth, social media) were engaged to connect with the people and address their vaccine hesitancy, vaccine refusal and rumors

Community engagement



- Last-mile partners like NGOs, civil society organisations, ASHA workers, regional volunteers and local community members were engaged in creating awareness and trust among the people
- This helped in building momentum and bringing out a systemic behaviour change among the people towards the vaccination drive

Adverse event following immunisation (AEFI) management



- NGOs, civil society organisations, community-based organisations and doctors were trained and engaged to reach out to people in case of any adverse event faced by a vaccinated person at home
- AEFI teams were created which interacted with the vaccination teams across the states regularly for analysing the cause of adverse events reported by the vaccinated people

49. "India's COVID-19 vaccination administration journey, An overview", Institute for Competitiveness; accessed on 30th March 2022

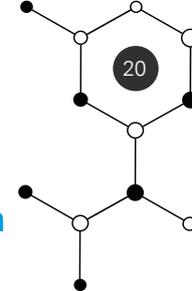
Strengthening the transportation and storage facilities

- The MoHFW released a detailed cold chain management and logistics guidelines in advance even before the launch of the vaccination drive
 - Government of India (GoI) procured cold-chain equipment such as walk-in freezers, walk-in coolers, refrigerators and deep freezers as per the demand and supply estimates and distributed the same to the states for allocation to the districts and blocks
 - The CO-WIN platform played a crucial role in the capacity of a technology handler for real-time tracking of the vaccine stocks, storage information and keeping a count of vaccinated people at state, district, and block levels
-

The private sector participation scaled up the vaccination drive

- The private sector stepped-up the vaccination drive, especially in towns and villages with vaccination camps and community engagement initiatives
 - Many private companies in India came forward to cover the cost of the vaccines for eligible employees and their dependents in India
 - The government enabled the integration of the CO-WIN technology platform with third-party applications. This allowed the private sector stakeholders to offer a host of services related to vaccination; develop and execute software solutions compatible with the national vaccination portal; and offer a seamless customer experience and a way of easy access to COVID-19 vaccination drive
-





India's schemes for pharmaceutical manufacturing are a push to accomplish its vision of self-reliance^{50,51}

The production linked incentive (PLI) schemes

In the wake of the COVID-19 pandemic causing large scale supply chain disruptions and escalating costs, especially for APIs, KSMs and DIs, the government approved the first Production Linked Incentive (PLI 1.0) scheme in March 2020 aimed at attaining self-reliance and reduce import dependencies in critical APIs. Based on 'Aatmanirbhar Bharat' strategies for enhancing India's manufacturing capabilities and enhancing exports in this sector, another Production Linked Incentive Scheme for pharmaceuticals was approved in 2021 with a financial outlay of USD1,963 million (INR15,000 crore)⁵².



Production Linked Incentive scheme for Bulk drugs (PLI 1.0)

Domestic manufacturing of 53 KSMs/Drug intermediates and APIs

Objective

Boost investments thereby reducing India's import dependence on critical APIs

Financial assistance

A funding of approximately USD908 million (INR6,940 crore) to eligible applicants with greenfield projects and includes minimum annual production amounts for the targeted products

Economic impact



INR1,96,000 crore (USD25,654 million)

Expected export generation potential over 6 years



Production Linked Incentive scheme for pharmaceuticals (PLI 2.0)

Domestic manufacturing of high value products

Objective

Enhance India's manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification to high value goods in the pharmaceutical sector. One of the further objectives of the scheme is to create global champions out of India who have the potential to grow in size and scale using cutting edge technology and thereby penetrate the global value chains

Financial assistance

Total financial outlay of the scheme is USD1,963 million (INR15,000 crore). The annual incentive outlay is estimated based on projected incremental sales of the identified pharmaceutical goods by the selected participants



INR15,000 crore (USD1,963 million)
Estimated investment potential



Production Linked Incentive scheme for domestic manufacturing of medical devices

Domestic manufacturing of medical devices

Objective

Intends to boost domestic medical devices manufacturing and attract large investments into the sector

Financial assistance

The financial outlay of the scheme is INR3,420 crore (USD464 million) under four segments of medical devices viz.

- Cancer care/radiotherapy medical devices
- Radiology and imaging medical devices and nuclear imaging devices
- Anaesthetics, Cardio-respiratory medical devices including catheters of cardio-respiratory category and renal care medical devices
- All implants including implantable electronic devices



20,000 direct jobs

80,000 indirect jobs

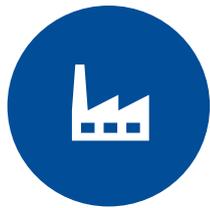
Source: "Schemes for Pharmaceuticals Manufacturing", Invest India; "Notification", Ministry of Chemicals and Fertilizers, July 2020; accessed on 7th April 2022

50. "Schemes for Pharmaceuticals Manufacturing", Invest India; accessed on 7th March 2022
51. Notification, Ministry of Chemicals and Fertilizers, July 2020' accessed on 15th March 2022
52. "Second PLI scheme worth Rs 15, 000 crore incentives for pharma sector to benefit 55 qualified pharma cos: Centre", Financial express, November 2021; accessed on 5th March 2022

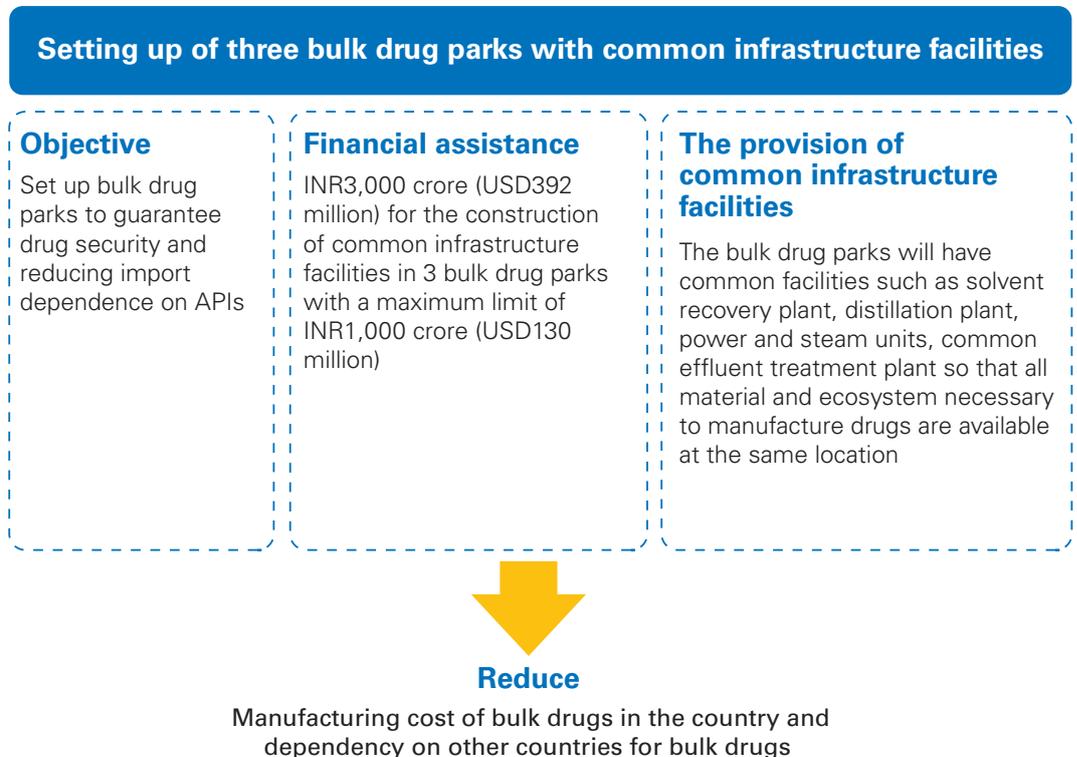
The domestic medical devices market in India is increasingly reliant on imports which contribute to more than 85 per cent of the market. The medical devices manufacturing sector traditionally suffers from specific challenges such as high cost of finance, lack of sufficient infrastructure, bottlenecks pertaining to domestic supply chain and logistics, limited design capabilities and minimal focus on R&D and skill development. With the production linked incentive scheme for domestic manufacturing of medical devices, India is expected to become self-reliant in the medical devices sector as well.

The bulk drug park scheme

The Department of Pharmaceuticals (DoP), in June 2020 announced the bulk drug park scheme for the promotion of three bulk drug parks in India. With this, the competitiveness of the Indian pharmaceutical industry is expected to increase and facilitate easy access to standard testing and infrastructure facilities. A bulk drug park is slated to have a designated contiguous area of land with common infrastructure facilities for the exclusive manufacture of APIs, DIs or KSMs, and also a common waste management system.



Bulk drugs park scheme



Source: "Schemes for Pharmaceuticals Manufacturing", Invest India

Many Indian states have expressed interest in setting up a bulk drug park⁵³ and have also sent proposals to the central government. A state can propose only one site, which is not less than 1,000 acres in area, or not less than 700 acres in the case of hilly states. Each proposal contains the estimated cost, feasibility studies, environmental risk assessment etc. A Project management agency, nominated by the Department of Pharmaceuticals, is currently examining these proposals and will make recommendations to a scheme steering committee, which will then approve the proposals.

53. "Explained: What is a bulk drug park, and why does Himachal want one?", The Indian Express, November 2020; accessed on 24th March 2022

Scheme for promotion of medical device parks

The Department of Pharmaceuticals had approved the proposal of Andhra Pradesh Medtech Zone Ltd. (AMTZ), Andhra Pradesh for establishment of Common Facility Centre for testing & research of Superconducting Magnet Coils of MRI under the sub-scheme termed as 'Assistance to Medical Device Industry for Common Facility Centre'. Recognising the need for higher levels of investments for the creation of testing and laboratory facilities, the sub-scheme 'Assistance to Medical Device Industry for Common Facility Centre' has been revised and renamed as 'Promotion of Medical Device Parks' which has been approved by the Government of India on 20 March 2020.

Proposals from 16 States/UTs were received under the scheme based on which Himachal Pradesh, Tamil Nadu, Madhya Pradesh, and Uttar Pradesh have been given 'final' approval under the scheme.

Promotion of medical device parks



Scheme for promotion of medical device parks

Objective

- Creation of world class infrastructure facilities in order to make Indian medical device industry a global leader
- Easy access to standard testing and infrastructure facilities through creation of world class Common Infrastructure Facilities for increased competitiveness will result into significant reduction of the cost of production of medical devices leading to better availability and affordability of medical devices in the domestic market
- Exploit the benefits arising due to optimisation of resources and economies of scale

Financial assistance

The total financial outlay of the scheme is INR400 crore (USD54 million) for a period of FY 2020-21 to FY 2024-25

Source: "Schemes for manufacturing medical devices", Make in India; accessed on 17th April 2022

Schemes for 'Strengthening of Pharmaceuticals Industry' (SPI)

On 11th April 2022, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers released guidelines for 'Strengthening of Pharmaceutical Industry (SPI)' scheme aimed at supporting existing pharma clusters and Micro, Small and Medium Enterprises (MSMEs) across the country to improve their productivity, quality, and sustainability. The Indian government has assigned a financial outlay of USD654 million (INR500 crore) for the period of FY2022-26.

The scheme will provide financial assistance to pharma clusters for the establishment of common facilities. It will improve the quality and ensure the sustainable growth of clusters.⁵⁴

The recent trends in the Indian pharmaceutical industry coupled with the government initiatives are vastly encouraging the Indian pharmaceutical companies to innovate their practices and build on their strengths. It is imperative for the industry to transition itself to a global pharma innovation player and address several growth challenges.



54. "Guidelines for the Scheme - Strengthening of Pharmaceuticals Industry (SPI)" - Pharmaceuticals.gov; accessed on 20th April 2022

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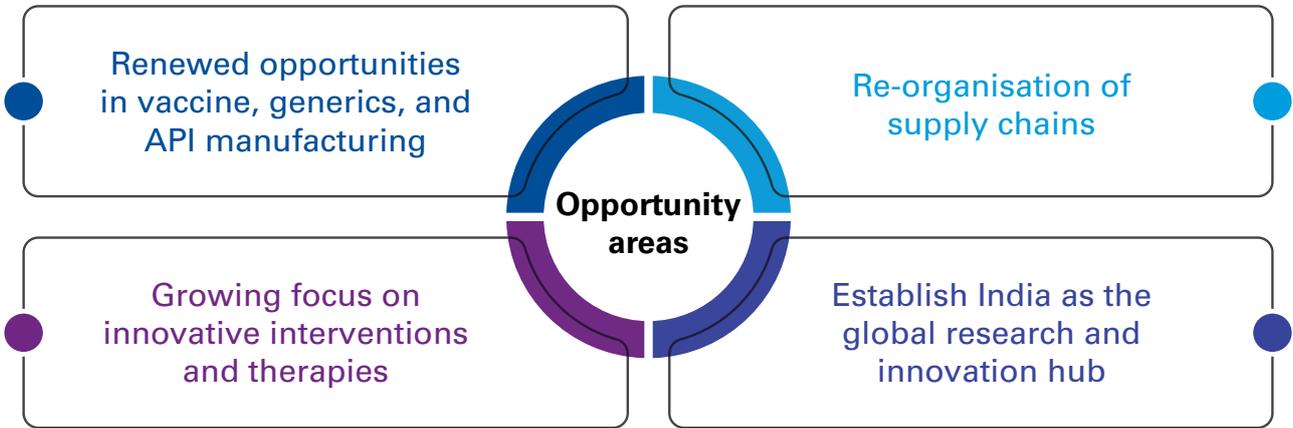
COVID-triggered transformation and emerging opportunities for the pharma sector



The disruption caused by the COVID-19 pandemic across industries and economies is unprecedented and the pharma industry was no exception.

However, with ever crisis and setback that the pharma industry faced, there emerged a learning and opportunity for growth. The last two years of the pandemic

highlighted some key areas of continued strength and some emerging areas of growth opportunities for the sector.



While it is difficult to fully assess the impact of disruption caused by the pandemic, what can be seen is the continued focus by industry

stakeholders in augmenting the growth of the sector by leveraging its existing capabilities in pharma production and supply chain and

focusing on developing new interventions and therapies through R&D and innovation.

Renewed opportunities in vaccine, generics, and API manufacturing

India has emerged as a prominent player in the global vaccines market. The next focus for India is to focus on research and development (R&D) of novel vaccines, and this has become more necessary since the onset of COVID-19 pandemic. Unlike R&D for medicines, involving novel drug development undertaken by global pharma players, opportunity for developing indigenous preventive vaccine/ drug to combat COVID-19 was open to all.^{55,56}

Thus, Indian companies such as Zydus Cadila, and Bharat Biotech embarked on this journey to develop indigenous COVID-19 vaccines. Consequently, as on 19 April 2022, under the Vaccine Maitri scheme, India has exported 178 million doses of COVID-19 vaccines to over 96 countries and two UN entities (this includes 14.9 million doses supplied as grant; 121.2 million doses commercially exported and approximately 42.5 million doses supplied to COVAX').⁵⁷

- Largest volume supplier to public market of vaccines
- Supplies over 62 per cent of global vaccine requirements-
- Supplies 1.5 billion doses of vaccines every year, exports amounting to USD410 Million to 150+ countries

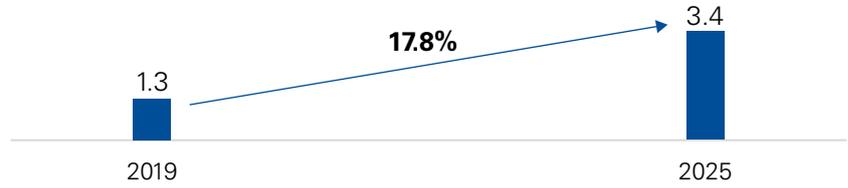
55. "Investment Opportunities in Healthcare Sector"- NITI Aayog report, accessed on 23rd March 2022
56. "Riding the vaccine wave"-Business Today, accessed on 23rd March 2022

57. "PIB press release"- Ministry of Health and Family Welfare; accessed on 20th April 2022

India's vaccine market projected to triple to USD3.4 billion by 2025^{58,59}

An immensely promising picture of India's vaccine market as one of the leading manufacturers of vaccines worldwide has emerged over the years on the global platform. This growth can be primarily attributed to vaccine manufacturers, vial and syringe makers ramping up capacity due to surge in demand.

Figure 9: India vaccine market, (USD billion), 2019-25



Source: "Ancillary firms look to tap USD6 billion vaccine business" - Ministry of External Affairs;

- Indian pharma sector observed a 200 per cent rise in foreign direct investment (FDI) in 2020-21, according to the Economic Survey 2021-22
- During 2020-21, total pharma exports were USD24.4 billion, while imports were USD7.0 billion, thus, generating a trade surplus of USD17.5 billion

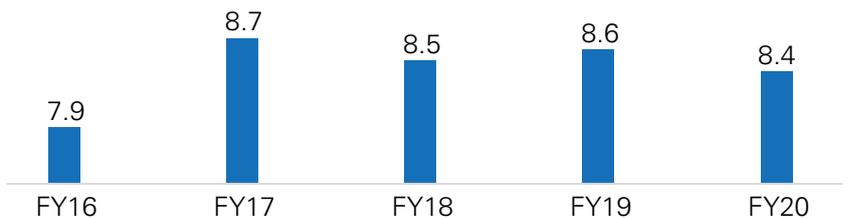


Source: "Economic Survey: FDI in pharma sector shot up by 200% in 2020-21" - Economic Times, "Eco Survey 20-21: Foreign direct investment in pharma sees 'sudden spurt'" - Business Standard; accessed on 6th April 2022

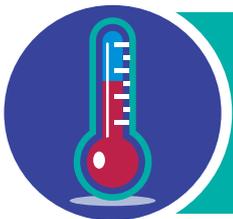
Investment opportunities in vaccines

Some of the leading Indian players are investing significantly in R&D. As depicted in Figure 10, leading Indian players have increased their R&D budgets by ~30 per cent over the last few years, indicating a good launch pipeline of these players. This indicates the market holding a strong potential for future growth and drug development opportunities.

Figure 10: R&D investment by key Indian pharma companies* (% of sales), FY16-20



*Top 10 companies as per research by HDFC securities; Source: IPA- Indian Pharmaceutical Alliance

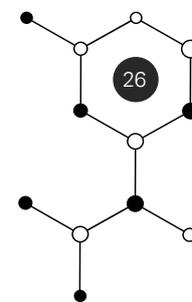


Streamlining temperature-controlled shipping of vaccines opens opportunities

- Maintaining correct vaccine storage temperature during transport is vital. Optimizing temperature-controlled storage will enhance exports, reduce losses due to expiry of shelf-life of vaccine shipments

58. "Ancillary firms look to tap USD6 billion vaccine business" - Ministry of External Affairs, accessed on 6th April 2022

59. "Economic survey fdi in pharma gets pandemic boost up 200 in FY21", accessed on 6th April 2022

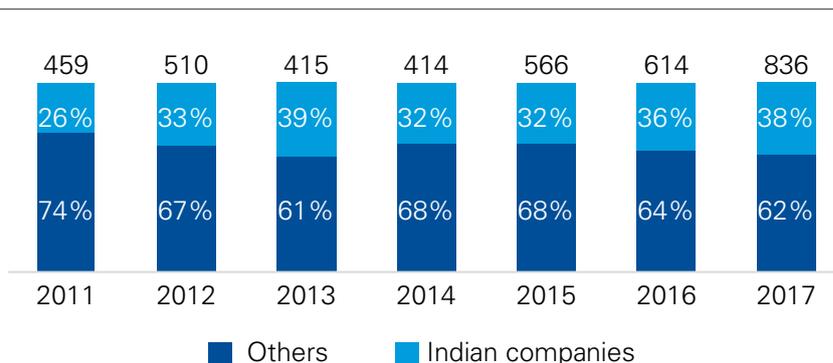


33 per cent of all ANDA Applications were filed by Indian companies in FY20⁶⁰

India is the largest provider of generic medicines globally. Indian companies overtaken the generics firms in the U.S. to receive highest first-time ANDA approvals. Out of the total ANDA approvals in 2016-17, Indian players constituted the highest share of approximately 40 per cent.

The growing number of product approvals and filings implies competitiveness in the U.S., a major market for many Indian companies. There is also continuous pressure on pricing. Cost of production in India is 33 per cent lower than the U.S., which is a key reason that India houses nearly 12 per cent of manufacturing sites globally, serving the U.S.

Figure 11: Growing share of ANDA approvals over the years



Source: FDA ANDA approval data

- Accounts for 20 per cent of global generic drugs exports (in volume)
- 8 out of the top 20 global generic companies are from India- around 60,000 generic brands across 60 therapeutic categories
- India contributes 57 per cent of APIs to the prequalified list of WHO.

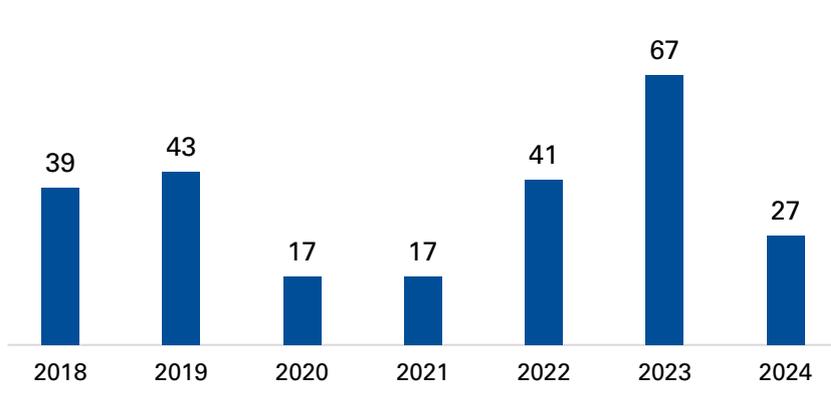
Source: Invest India.gov, accessed on 23rd March 2022, Indian API Industry – Reaching the full potential, KPMG in India, CII report, April 2020

Investment opportunities in generics

Leveraging the patent cliff, patent for drugs worth USD251 billion are set to get expired

Figure 12 depicts year-on-year sales risk globally due to patent expiration. It is anticipated that patents worth USD251 billion are expiring globally between 2018-24. This presents a lucrative opportunity for the Indian pharmaceutical sector. Indian generics industry can benefit substantially from the patent cliff. The industry may take steps to formulate a sharp strategy, coupled with favourable regulatory and market-tapping execution initiatives.

Figure 12: Total sales at risk worldwide due to patent expiration, USD billion, 2018-24



Source: Evaluate Pharma 2018 report

60. "Investment Opportunities in Healthcare Sector"- NITI Aayog report, accessed on 23rd March 2022

Imports have led to a gradual erosion of India's manufacturing capacity of many bulk drugs

In the past, India had the capacity and capability to manufacture many APIs locally (that are imported today), however, most were discontinued due to availability of low-cost imports. Imports have led to a gradual erosion of India's manufacturing capacity of many bulk drugs. In addition, Indian API producers are battling higher operating costs due to various factors including inadequate infrastructure support.

- As of July 2019, only 11 out of the 232 Special Economic Zones (SEZ) operational in India were dedicated to the pharmaceutical sector.⁶¹ The scarcity of SEZs leads to higher land acquisition operational and utility cost

Owing to multiple factors, such as inadequate infrastructure support and due to competitive pricing strategy, manufacturers are reluctant to use their idle capacity or restart closed plants despite manufacturing capacity for many imported APIs existing in India. Cheaper imports further lead to reduction in employment opportunities and tax revenue loss to the Government.

Many domestic firms are initiating backward integrating into manufacturing of APIs. However, the dependency on imports can be reduced only if India is able to manufacture the APIs/ intermediates in a cost

efficient and sustainable manner. Government's intervention and support is immensely significant for this. With the onset of pandemic and several factors such as higher labour costs, stringent environment, compliance costs, and other challenges, there is a recent decline in Chinese manufacturing output and capabilities. Thus, Indian companies holds a promising opportunity to act as a potential alternative for China.

With nearly 20 per cent rise in API costs during the COVID-19 lockdown, India's plans to diversify risk and boost domestic API production are growing rapidly

With most Indian API plants having a much larger capacity than at which they currently operate, and certain states such as Telangana providing high incentives and strong infrastructure to cater to the global demand, there exists plethora of growth potential. The pandemic, combined with government response to infuse growth into the industry, would encourage manufacturers to fully leverage their capacity and serve as a strong alternative to countries looking to diversify supply out of China. Thus, with respect to APIs, India holds a strong avenue to strengthen domestic manufacturing which is supported by recent Government schemes such as production-linked incentives (PLIs)- part of 'Aatmanirbhar Bharat' or 'self-reliant India' initiative.



61. "Lok Sabha starred question no. 243 to be answered" - Ministry of Commerce and Industry", accessed on 23rd March 2022

Investment opportunities in APIs

Key measures to boost domestic pharmaceutical production and export^{62,63}

 Drug Parks	 China plus one policy	 Production Linked Incentive (PLI) schemes	 Biotechnology-related: Bio-NEST, BioTech Science clusters
<ul style="list-style-type: none"> • One-time grant was announced for three bulk drug parks with a maximum limit of USD140 million per park during FY2021–25 • This will include infrastructure facilities, solvent storage systems, logistics, and effluent treatment plant facilities • Further, “Ind-CEPI” mission, and the COVID Suraksha Mission (financial outlay INR900 crore or USD117 million approximately) have been launched by the government to boost the development and testing of indigenous vaccine candidates 	<ul style="list-style-type: none"> • With the onset of pandemic, companies are contemplating on reducing their dependence on China. • MNCs are augmenting their operations in other countries, including India, thus, making India the potential candidate for manufacturing opportunities • ‘China plus one’ policy is being adopted by companies to move production facilities to more lucrative markets such as India, and other ASEAN countries 	<ul style="list-style-type: none"> • Production Linked Incentive (PLI) schemes announced for Key Starting Materials (KSMs) and APIs to boost domestic manufacturing of 53 bulk drugs, with a financial outlay of INR6,940 crore (USD908 million) • It includes financial incentives to eligible manufacturers of identified 41 products on incremental sales over base year FY2019-2020 for six years • Domestic manufacturing and exports of APIs, KSMs, and other drugs is set to be implemented at a cost of INR15,000 crore (USD1,963 million) 	<ul style="list-style-type: none"> • Biotechnology- For strengthening biotechnology sector, initiatives such as Bio-NEST and BioTech Science Clusters were implemented by the government • Four bio-clusters have been established at Faridabad, Bangalore, Kalyani, and Pune. focused on bridging industry-academia research and innovation gaps, incubation space to start-ups, and bio-clusters for catalysing R&D and entrepreneurship activities



Domestic players into development of oral pills for COVID-19

- There is a major shift towards treatment using oral pills for COVID-19, with domestic pharma players such as Cipla and Dr. Reddy’s eyeing on domestic production of these pills.
- These products are expected to be available at a fraction of the global price

Pharma companies need to get a clear understanding of the ecosystem and the latest technologies. It is necessary to have the resources, including a team of experts and adequate capital for the required investments. Thus, there exists renewed opportunities of growth for Indian pharma players to restructure and revamp their supply chain process by implementing advanced technologies.

62: “Investment Opportunities in Healthcare Sector”- NITI Aayog report, accessed on 23rd March 2022

63. “As focus shifts to Covid pills Indian companies eye affordable antiviral medicine- Times of India”, accessed on 25th March 2022

Re-organisation of supply chains

With the onset of COVID-19 pandemic, many pharma companies retooled manufacturing to produce high in demand. Repurposing capacity highlights the company's potential in terms of business agility for the future. However, accelerating innovation in product development requires engineering, design, production, and supply of resources. Rapid digitisation enabled business to survive during the pandemic and especially for the supply chains. Digitising the supply chain helps organisation make data-driven decisions, ideally

real-time which eliminates scope for human error. It also prepares companies well for crisis, helping them manage their inventory better, and plan for the demand, supply situations.⁶⁴

- It is essential to have end-to-end visibility across production process and distribution such as Systems to monitor production in real-time, Tools enabling advanced planning and scheduling in manufacturing, tracking and tracing of products as it moves along the supply chain, from materials to final product.

Digital supply chain can lower procurement costs by 20 per cent, reduce supply chain process costs by 50 per cent, and increase revenue by 10 per cent (According to study by Centre for Global Enterprise (CGE) research)



Application areas of digital supply chain⁶⁵

- With data available from every node of the supply chain, analytics tools process to develop better insights on operations and supply chain

Virtual supply-chain processes

Automation in manufacturing

- Used in manufacturing of medicines- equipment effectiveness and downtime is improved
- Robots are replacing human tasks like packaging or mixing chemicals, and reducing human errors

- Enables rapid computing of data across all nodes of the supply chain
- Collecting, storing, and translating data in the cloud ensures accessibility to all via multiple databases

Cloud-based IT architecture

Digitally-enabled warehousing and distribution facilities

- RFID tags in warehouse allows automated picking systems and scanning drones provides inventory information.
- For distribution, RFID-tagged storage cabinets and pillboxes enables automated re-stocking of drugs

64. "Impact of digitalization on the pharma-supply chain"- Medibox, accessed on 29th March 2022

65. "Digitisation-is-key-for-pharmaceutical-companies-to-transform-market-engagement"- Times of India, accessed on 28th March 2022

Furthermore, digitising the end-to-end supply chain allows pharma companies to operate with cost-efficiency, agility, and control to transform their market engagement. Some of the benefits are listed as follows⁶⁶:



Thus, with an improved business forecasting, planning of demand and supply improves. There was always a need for better planning of supply chain process, but post-pandemic, global companies having a large product mix, are facing a lot of complexities. Therefore, most companies are emphasizing on making digitised supply chain crucial to attain an enhanced greater operational efficiency.

However, government’s interventions will help India to cater to both the domestic and the global pharmaceutical market with emerging opportunities related to novel drug development and new biological or chemical entities, i.e., NBEs or NCEs. Pandemic has created immense pressure for both government and the corporate sector. There are several initiatives taken by both sectors to strengthen the overall supply chain of Indian pharma sector⁶⁷



66. "Need-for-real-time-data-is-driving-indian-pharma-to-digitise-supply-chains"- Financial Express, accessed on 29th march 2022

67. Department of Pharmaceuticals Annual report 2020-21; accessed on 28th March 2022

Furthermore, digitising the end-to-end supply chain allows pharma companies to operate with cost-efficiency, agility, and control to transform their market engagement. Some of the benefits are listed as follows :



Public sector initiatives

Implementation of IT Enabled warehousing/ supply chain system under Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)

- End-to-end supply chain system (IT-enabled) was implemented and one central warehouse at Gurugram, three regional warehouses at Chennai, Bengaluru, and Guwahati has been established during the pandemic
- Further, two warehouses in Western and Central India are also planned
- Appointment of distributors in states/UTs is envisioned to strengthen the supply chain system

Implementation of POS system

- A single IT enabled system was launched in 2017 that monitors every process from placing the order of medicines to manufactures till the supply of drugs to Store's doorstep
- During pandemic, the National Pharmaceutical Pricing Authority (NPPA) developed IT platform to track hydroxychloroquine (HCQS) stock.
- State drug controllers were directed by the Drug Controller General of India (DCGI) to make drugs available



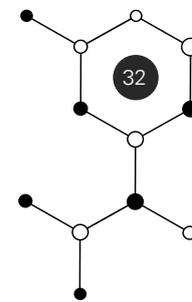
Private sector initiatives

There is rising collaborations between industry players and IT solution providers to develop integrated end-to-end supply chain solutions, either in the form of acquisitions or collaborations (Dr. Reddy's) to leverage services and solutions

Strategic partnerships with tech firms:

Pharma companies are digitising their supply chain supported by the leading IT companies providing solutions in this space

- Post-pandemic, Cipla has undergone complete digital transformation of its value chain and across business verticals – from supply chain, manufacturing, R&D, finance, and human resources, etc.
- Acquired 21.8 per cent stake in GoApptiv, an end-to-end solution provider, focused on healthcare companies and expert in digitising supply chains



Indian pharma sector's growing focus on innovative interventions and therapies

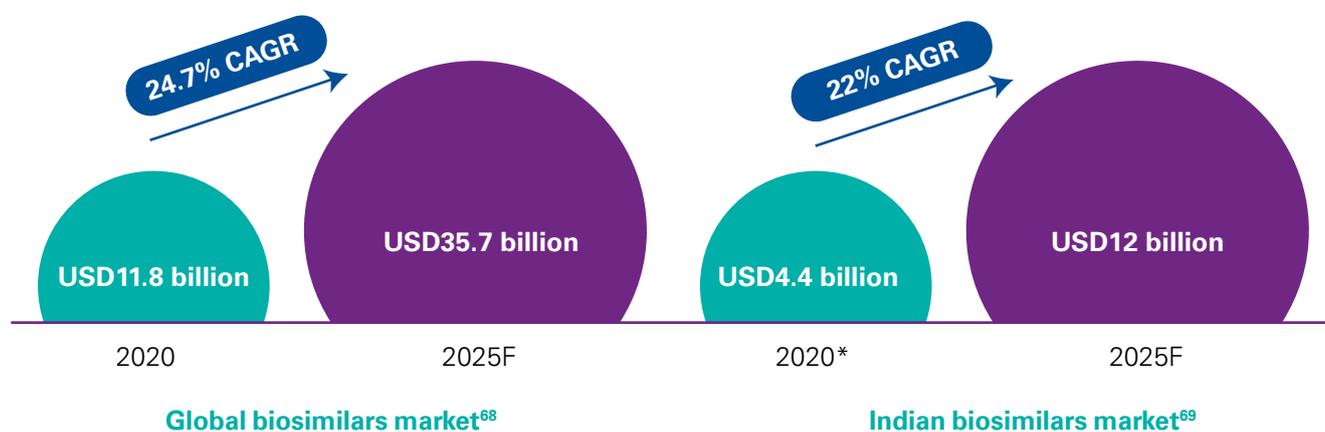
The Indian pharmaceutical industry is already a market leader in the field of generics. However, the U.S., considered India's largest pharma market is witnessing a drop in the generic drug prices amid increased competition, distributor consolidation, and government push. At a global level, increased competition and pricing pressures are also affecting the revenues of India's

generics players. The pertinent question that emerges is how can the Indian pharmaceutical industry grow beyond generics and move up the pharma value chain.

India to capitalise on the global biosimilar opportunity

Biosimilars refer to a biotherapeutic product which is similar to a reference biologic drug. It is produced using living

organisms or cells and has a complex molecular structure. When the patent of a biologic drug expires, manufacturers resort to the approval from the regulatory authorities to start the production of biosimilars. For being labelled as a biosimilar, a biological drug should be proved similar in terms of quality, safety, and efficacy.



*The market size for 2020 has been manually calculated on the basis of the available CAGR and market size value for 2025

68. "The Opportunities & Challenges of India's Biologics Market", Biosimilar Development, January 2021; KPMG in India analysis 2022

69. "The Opportunities & Challenges of India's Biologics Market", Biosimilar Development, January 2021; KPMG in India analysis 2022

India already has a significant share of the global biosimilars market, and the segment is set to become mainstream of the Indian pharmaceutical industry. The Indian biosimilars market is expected to account for 34 per cent share of the global biosimilars market by 2025⁷⁰. India has already approved about 100 biosimilars till October 2020 with another 40+ in the clinical development stage⁷¹. This is in stark contrast to just 26 approved biosimilars in the U.S. and 61 in the European Union (EU) by August 2019⁷². India offers an advantage in terms of lower cost of Research and Development, and this has promoted the increased development of

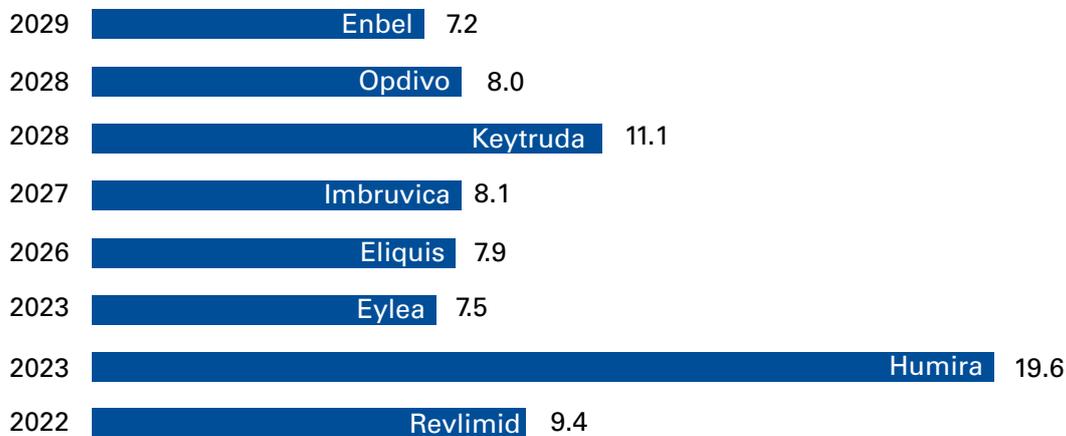
biosimilars in the country. The cost of developing a biosimilar in the EU or the U.S. ranges between USD100-200 million, while in India it costs 90 per cent lesser, at USD10-20 million⁷³. This lower cost of development may be attributed to several factors, including the lower cost of recruiting patients, fewer labour and service fees, as well as less stringent regulatory approval criteria.

Patents for eight out of the top ten biologics are set to expire over the next decade

Over the current decade, the patents of some of the best-selling biologic drugs in the

global pharmaceutical market are expected to expire. The top selling drugs include Humira, Keytruda, Revlimid and Eliquis. Nearly USD100 billion worth (by sales) of biologic drugs are set to go off patent by 2030⁷⁴ thereby creating a massive opportunity for their biosimilar counterparts to find a way to the market. Indian pharmaceutical companies actively focusing on the biosimilars market are expected to be among the biggest beneficiaries of this opportunity.

Figure 13: Sales opportunity in the U.S. owing to the patent expiry of top biologics, USD billion, 2022-29



Source: Pharma Intelligence, Informa

70. KPMG in India analysis 2022

71. Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India, October 2021; accessed on 24th March 2022

72. "The regulatory landscape of biosimilars: WHO efforts and progress made from 2009 to 2019", Science Direct, May 2020; accessed on 24th March 2022

73. "The Opportunities & Challenges of India's Biologics Market", Biosimilar Development, January 2021; accessed on 24th March 2022

74. "Vaccines, Biologics: Indian Pharma's New Temptations", Fortune India, February 2022; accessed on 24th March 2022

Emerging strategic collaborations between Indian and international pharmaceutical players for biosimilars

With biosimilars grabbing an increasing share of the global biologicals market and with India providing a cheaper place to carry out research and development, more international players are partnering with Indian pharma companies.

The biosimilars segment is expected to generate a great deal of interest in the global market over the next decade. A global consensus has been building over the years on the need to reduce the cost of treatment, something which the biosimilars may be able to address.

New chemical entities (NCEs) and New biological entities (NBEs) offer an opportunity for the Indian pharma sector to build expertise in drug discovery

Novel drugs undergoing clinical development are innovative new entities that have not been approved by the U.S. Food and Drug Administration (FDA) in the past. These drugs are generally divided into two main classes and are identified as either a new chemical entity (NCE) or a new biological entity (NBE). These products have been receiving

a significant attention from the leading multinational pharma players. For the Indian pharma industry to be future secured and sustainable, it must leverage its expertise in chemistry and biologics and put concerted efforts into new drug discovery.

New chemical entities (NCEs)

India's association with NCEs dates to 2013, when Zydus Cadila became the first Indian pharma company to indigenously develop a new chemical entity, Lipaglyn (saroglitazar). The drug that helps in lowering cholesterol in diabetic patients and in glycemic control, is already an USD6.5 million (INR50 crore) drug in Indian market and growing at 30 per cent⁷⁵.

Recently, India's Alembic Pharmaceuticals and its Swiss-based associate received the drug regulatory approval for the sales of a NCE in the U.S. market. The drug is said to be the first NCE discovered by Indian scientists to secure a U.S. FDA approval. It is a novel, next generation, oral drug for adult patients with relapsed or refractory lymphoma and relapsed or refractory marginal zone lymphoma (MZL) that resists treatments and drugs. These cancers affect over 3-4 lakh patients in the U.S. every year. The drug is estimated to have a global market worth USD1-1.5 billion⁷⁶.

A leading U.S.-based pharma firm established a partnership with a leading Indian firm to produce a drug for decreasing febrile neutropenia for cancer patients going through chemotherapy.

The drug is U.S.FDA approved



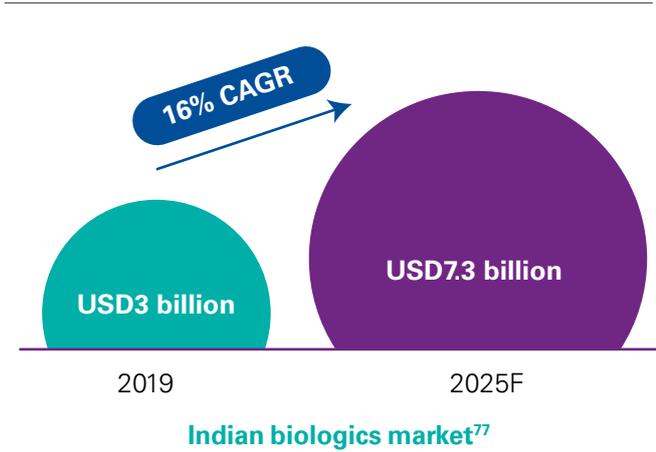
New biological entities (NBEs)

Biologic drugs include a wide variety of products derived from human, animal or microorganisms using biotechnology. The biologics market of India is primarily dominated by simple biologics such as insulin, erythropoietin, drugs for cardiovascular and autoimmune diseases, monoclonal antibodies among others. Biologics have a certain advantage with less likelihood of adverse side effects as associated with small molecule therapeutics and invasive surgeries and can also treat a wide range of conditions. These can reach targets, otherwise considered undruggable for small molecule therapeutics.

The Indian biologics market is expected to grow at a CAGR of 16 per cent to reach USD7.3 billion in 2025.

75. "Cadila Healthcare to focus on innovation and IP creation: Sharvil Patel", Moneycontrol, March 2020; accessed on 24th March 2022

76. "First new chemical entity discovered by Indian scientists gets USFDA approval", Business Today, February 2021; accessed on 10th March 2022



Patent expiry of a range of biologics in the upcoming years



Increasing incidence of chronic heart and vascular diseases, cancer, and diabetes



Rise in the number and quality of tertiary care facilities



Offer a significant cost advantage (priced 25-40 per cent lesser than the original branded products)

India occupies only 8 per cent share of the global biopharmaceuticals market. However, the opportunity is huge given that India adopts a strategic approach to access mature markets such as the U.S. and Europe.



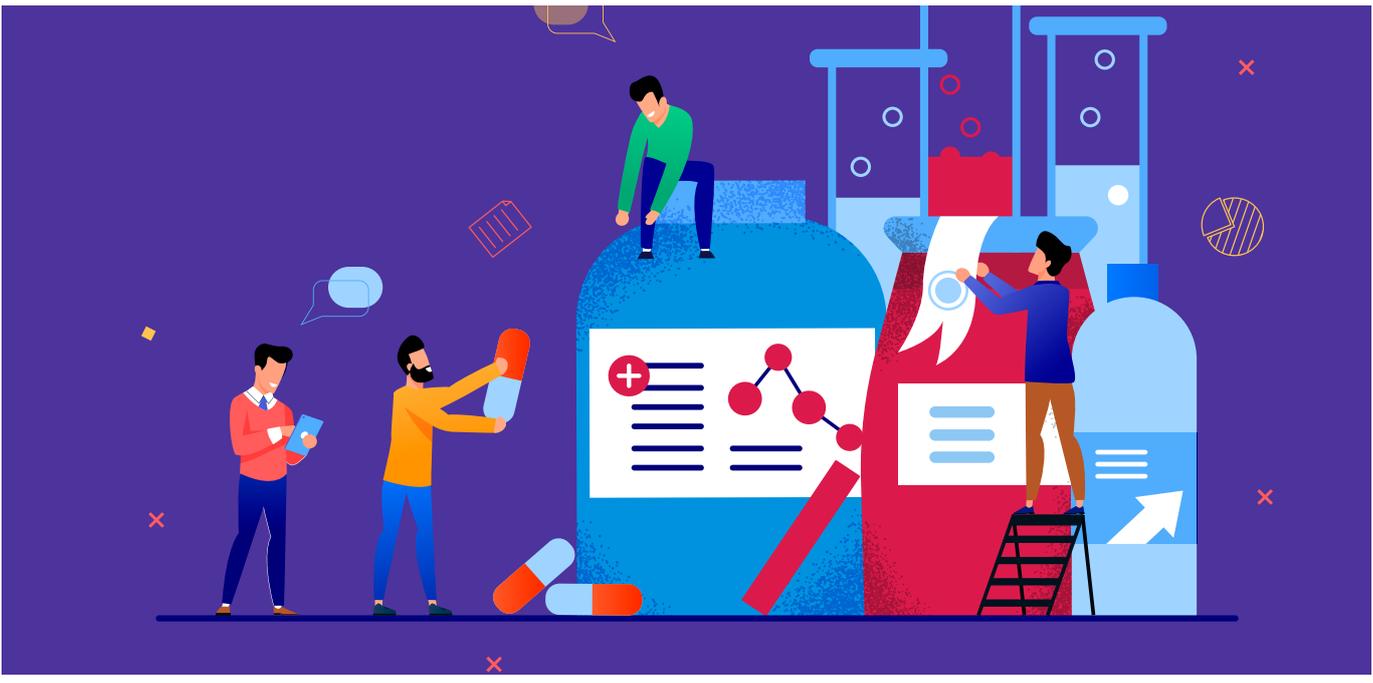
⁷⁷."India: The emerging hub for biologics and biosimilars", BIRAC, ABLE, November 2019; accessed on 10th March 2022.

Figure 14: Concentration of global biopharmaceutical manufacturing (% share by volume), 2018-19



Source: Pharma Intelligence, Informa

The Indian pharmaceutical industry has successfully made COVID-19 vaccines. Now, it is the time for the industry to foray into novel drug development. It is also important to consider that the return on investment will not be easy given that it takes seven to eight years for biosimilars development and involves high costs of the order of US\$100-250 million⁷⁸. Therefore, creating an innovation mindset, achieving cost leadership, and developing go-to-market excellence are the key pre-requisites for India to win in the mature markets.



78. Indian pharmaceutical industry, Alpha Invesco, October 2018; accessed on 14th April 2022

Establish India as the global research and innovation hub

The Hon'ble Prime Minister of India has given a clarion call for a self-reliant India and has highlighted that the way to achieving this in the pharmaceuticals space passes through a strong R&D infrastructure. This would also drive expansion of access to life-saving medicines within the country and at the same time help India become a

global pharmaceuticals exports hub. During the COVID-19 pandemic, many of the leading Indian pharma companies invested heavily in R&D and manufacturing of different COVID-19 vaccine technologies, either in partnership with the government, or with global counterparts or on their own. The Department of Pharmaceuticals (DoP) has prepared a draft policy

to catalyse R&D and innovation in pharmaceutical and medical devices sectors in India.

India's pursuit of establishing itself as the global pharma research and innovation hub should be built on 3 pillars – strengthening the regulatory framework, incentivizing investments, and creating a facilitatory innovation ecosystem.

1. Strengthening the regulatory framework

The current Indian regulatory framework is traditionally geared towards safety and efficacy. However, it should also differentiate in favor of innovation. The Drug Controller General of India in the CDSCO is the licensing authority, but there are multiple agencies with different mandates and expertise that a pharma innovator must navigate.

Future considerations in accelerating research and innovation from a regulatory standpoint:

<p>Process optimization</p>	<ul style="list-style-type: none"> • There should be a central overarching regulatory body (such as the U.S. FDA) • A collaborative approach followed by different regulators will reduce overlaps and establish predictable timelines for requisite approvals • Faster approval and response time (bring down the current time taken for regulatory approvals for innovative products by at least 50 per cent)
<p>Technology usage</p>	<ul style="list-style-type: none"> • A single end-to-end digital platform connecting different departments/regulators and offering a single interface between a pharma innovator and regulator • Automated transfer of data across multiple departments and agencies for facilitating clearance by reducing time and efforts
<p>Building expertise on innovative drugs</p>	<ul style="list-style-type: none"> • Building regulatory expertise in emerging areas such as NCEs, NBEs, biosimilars etc. to build a strong reputation of the quality of Indian products in the international markets • Collaborations with relevant international regulatory agencies to build expertise of Indian regulators on new drug approvals

3. Creating a facilitatory innovation ecosystem

The industry and individual institutes working on pharmaceutical research largely work in silos or informal ad-hoc cooperation. This need to change and instead be supported with a wider enabling ecosystem.

Future considerations in accelerating research and innovation by creating a facilitatory innovation ecosystem:

<p>Building industry-academia linkages</p>	<ul style="list-style-type: none"> • Strengthen academic curriculum to make it dynamic and contemporary to meet current needs of the industry • Institutionalise industry representation in the NIPERs with multiple channels of financial and managerial involvement • Focused investment in few priority institutes to build 'Pharma centres of excellence' • Encourage industry to fund cutting edge research in academic institutions
<p>Collaborations across institutions and sectors</p>	<ul style="list-style-type: none"> • Increase collaboration across research institutions to encourage innovation at scale and integrate research work across different pharma sectors • Collaboration across the entire product development cycle – drug discovery, drug delivery, clinical trial design, clinical trials etc.
<p>Building infrastructure</p>	<ul style="list-style-type: none"> • Identification and scaling of existing innovation hubs ensuring co-location of academia, R&D centres, startups, and incubators • Establish sub-sector wise new hubs; each with a network of academic institutions, startups, funding agencies (VCs), business schools, and clinical settings • Provide plug and play infrastructure at the hubs and ensure requisite financial and regulatory support
<p>Research linked incentive scheme</p>	<ul style="list-style-type: none"> • The current Production Linked Incentive scheme may be expanded to link it to research • This will incentivise and offer benefits to all the pharma innovators, be it an individual scientist, a startup, or an established company



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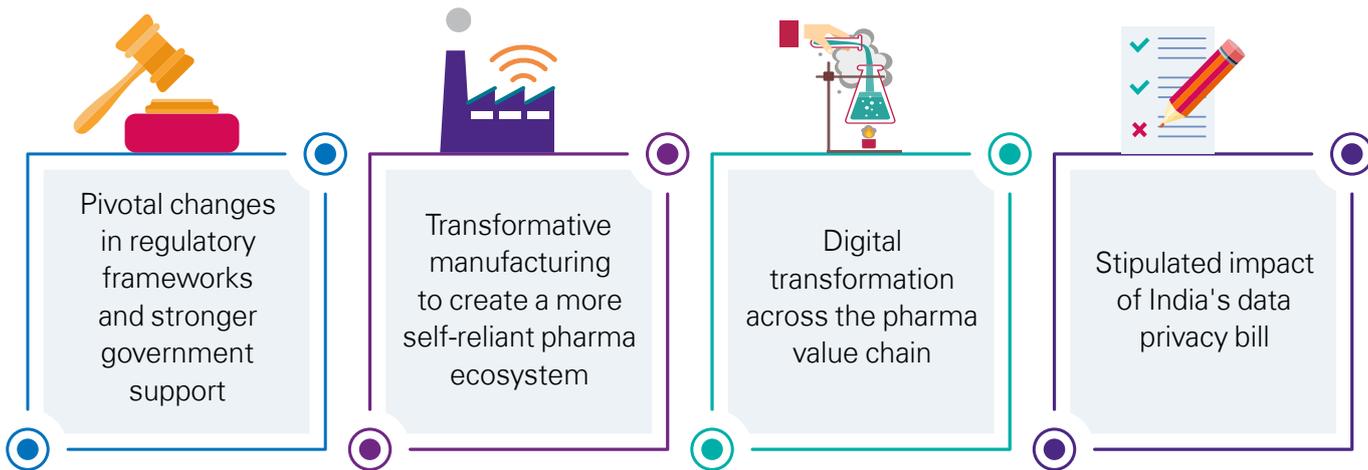
The road ahead



The Indian pharmaceutical sector has played a significant role in improving healthcare and economic outcomes of the country. As the reliance on China for pharmaceuticals widens, it creates significant opportunities for the Indian market from countries looking to diversify their

sourcing. It is important to realise that the growth of pharmaceutical sector relies heavily on the harmonised functioning of its stakeholders. This means, streamlining the regulatory network, developing robust infrastructure, fostering innovation, and promoting a

collaborative environment. The industry needs strong investment from domestic and international markets to build on its strengths while also taking a great leap forward in innovation. Key focus areas going forward:



Pivotal changes in regulatory frameworks and stronger government support

The Indian government along with the regulatory bodies have a bigger than ever role to play in driving the next wave of growth for the pharmaceutical industry in a post-COVID world. Enabling and supportive policies and stronger government support would help the industry achieve its vision of a truly global pharma leader.

Conducive regulatory landscape will pave the way for growth and innovation

A revamp of the country's pharmaceutical regulatory norms is expected to not only expedite the drug approval process but also promote innovation.

Strengthening Central Drugs Standard Control Organisation (CDSCO) and creating a stable and supportive regulatory environment		
Action item	The necessity	Way forward
Create project management roles	<ul style="list-style-type: none"> The future of the Indian pharma industry lies in moving up the pharma value chain and innovate in complex generics, specialty drugs, NBEs and NCEs. The country needs to build regulatory expertise in these domains 	<ul style="list-style-type: none"> The CDSCO having dedicated, and specialised teams can provide in-house regulatory guidance to the pharma innovators working on complex generics, specialty drugs, NBEs and NCEs
Collaboration with global regulatory bodies	<ul style="list-style-type: none"> It is important for the Indian pharmaceutical industry to grow and expand in markets beyond the U.S. and the EU, such as China and Japan Collaboration with global regulatory bodies helps the Indian counterparts enhance their expertise on the approval of new drugs and medical devices and ensures a globally consistent regulatory regime 	<ul style="list-style-type: none"> India should strengthen the exchange of regulatory best practices with international regulatory bodies. The Pharmaceutical Inspection Co-operation Scheme (PICS) has regulatory bodies from across the globe. Indian regulatory bodies can strive to be a part of this consortium Closely work with the U.S. FDA and other regulatory bodies to communicate issues faced by the Indian pharma companies and drive the requisite regulatory changes Communicate the contributions of the Indian pharmaceutical products on shaping public health outcomes to the global healthcare and pharmaceutical markets and regulators
Creation of a single unified interactive digital platform hosted by CDSCO	<ul style="list-style-type: none"> The regulatory approvals of innovative pharmaceutical products take about 18-24 months at present⁸¹. From a pharma and medical device company's viewpoint, the current regulatory structure appears complicated with a web of entities at the central and state levels having the responsibility of monitoring the sector The currently operational SUGAM portal* has certain limitations such as there is no provision of adding multiple files greater than 10 MB and no automated document management workflows 	<ul style="list-style-type: none"> There can be an integrated portal enabling automated data transfer between different regulatory departments. Use of artificial intelligence (AI) and natural language processing (NLP) can ensure faster document review and deficiency identification leading to enhanced efficiency and reduction of human interface A single overarching regulator like the U.S. FDA, if created can jointly oversee the functioning of food, drugs, and medical devices

*Note: SUGAM is an online licensing portal of the CDSCO which enables online submission of applications requesting for permissions related to drugs, clinical trials, ethics committee, medical devices, vaccines and cosmetics, launched on 14th November 2015

81. "Department of Pharmaceuticals proposes to reduce time for regulatory approvals by 50%", Business Today, October 2021; accessed on 14 March 2022

Create regulatory cells in academic institutes	<ul style="list-style-type: none"> • Help the academic institutes orient themselves with the regulatory aspects of pharmaceuticals 	<ul style="list-style-type: none"> • Collaborations with global regulatory institutes such as Centre for Innovation in Regulatory Sciences U.K., DIA (U.S.), Centre for Regulatory Excellence at the Duke- NUS Graduate Medical School (Singapore) etc.
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Stronger government support

The Indian government has a prominent role to play in nurturing the country's pharmaceutical sector – be it reinforcing manufacturing and supply chains for domestic as well as global pharmaceutical markets or expanding and upskilling the talent pool.

Reinforcing manufacturing and supply chains for domestic as well as global pharmaceutical markets		
Action item	The necessity	Way forward
Improving the ease of doing business	<ul style="list-style-type: none"> • Ease of doing business is one of the important factors to help setting up world class manufacturing facilities in India. In the pharma sector, India has improved its ease of doing business ranking to 63⁸² 	<ul style="list-style-type: none"> • Build capabilities in APIs and high-end specialised pharmaceutical products such as biologics, complex generic drugs and gene and cell therapy drugs. The government's ambitious PLI and bulk drug parks schemes are an important push in this direction
Setting up of pharmaceutical equipment manufacturing facilities	<ul style="list-style-type: none"> • This would help in lowering fixed costs, cutting down imports and reducing the amount of time required to set up additional facilities 	<ul style="list-style-type: none"> • Setting up medical equipment and pharmaceutical machinery manufacturing parks in different parts of the country
Boost the infrastructure pertaining to logistics to connect India's key pharma hubs	<ul style="list-style-type: none"> • This will help enhance supply chain efficiencies (including cold chain facilities), improve accessibility, control costs, and generate employment 	<ul style="list-style-type: none"> • Set up dedicated logistics clusters and primary warehousing hubs across the country and develop the requisite infrastructure across these • Impart specific training programmes for pharma logistics as it involves specialised knowledge and skill to handle and deliver drugs
Expanding and upskilling the talent pool		
Strengthen the pharma higher education system and build industry-academia linkages	<ul style="list-style-type: none"> • India may be lacking in talent to cater to the entire pharma product life cycle ranging from drug discovery to go-to-market • Disconnect between academia and industry is resulting in students missing out on market-relevant skills and knowledge 	<ul style="list-style-type: none"> • The government may set up some grants especially for funding research and innovation activities at the academic institutes • The industry may be incentivised to collaborate with the academia on certain complex drug development research

82. "Govt working to improve ease of doing biz in pharma sector: Minister", Business Standard, February 2021; accessed on 30th March 2022

Transformative manufacturing to create a more self-reliant pharma ecosystem

It is important that manufacturing operations are managed optimally including product quality, compliance to regulatory frameworks, safety, affordable cost, and inventory levels at lowest while maintaining service. COVID-19 crisis has caused disruptions in the pharma value

chain. Key impacts were felt in material availability- raw material packaging and ancillary, along with manpower availability in the manufacturing sector. Indian pharma industry is witnessing substantial growth and has achieved a good scale and competitive cost to serve within

the global industry. However, there still exists scope for scaling up existing manufacturing capabilities and achieve excellence in manufacturing operations in terms of productivity and the need for an enhanced regulated government guideline.⁸³

Automation



- Automation technologies are evolving, it can improve processes, and disrupt the traditional, stringent chain of processes.
- Advanced automation forms, like robotic process automation and cognitive technologies used in high throughput screening methods for research allows testing of thousands of compounds against a specific model of disease
 - Robotic platforms or modular systems can cover the entire development process, pilot design, processing of samples to evaluation and data analysis

Industry 4.0 and digitising manufacturing



- Industry 4.0 and automation is evolving into a revolution in manufacturing, with pharma companies adopting digital technologies, virtual and mixed reality, among others
- Digitalisation can make tremendous strides in improving speed to market, and providing better flexible manufacturing
- Use of technologies such as Big Data and AI in manufacturing aids in process optimisation that leads to improved productivity and lower costs , thus, building a future-forward framework for pharma manufacturing

83. "Department of pharmaceuticals, Annual report 2020-21"; accessed on 6th April 2022

Upgrading existing manufacturing capabilities



- Setting up additional infrastructure in pharmaceutical industry is time consuming and cost intensive. It is of paramount importance to upgrade the existing pharma units thus, allowing ramped up productions and increased productivity
- Although India has the second-highest number of U.S. FDA approved plants outside the U.S., largest provider of generic drugs globally, India is still a high-volume, low-value market
- This can be done by setting up of Special Economic Zones (SEZs) or drug parks, providing cost efficient utilities, public-private partnerships, industry-academia partnerships, and incentivising through schemes.

Government initiatives can aid in fueling manufacturing growth

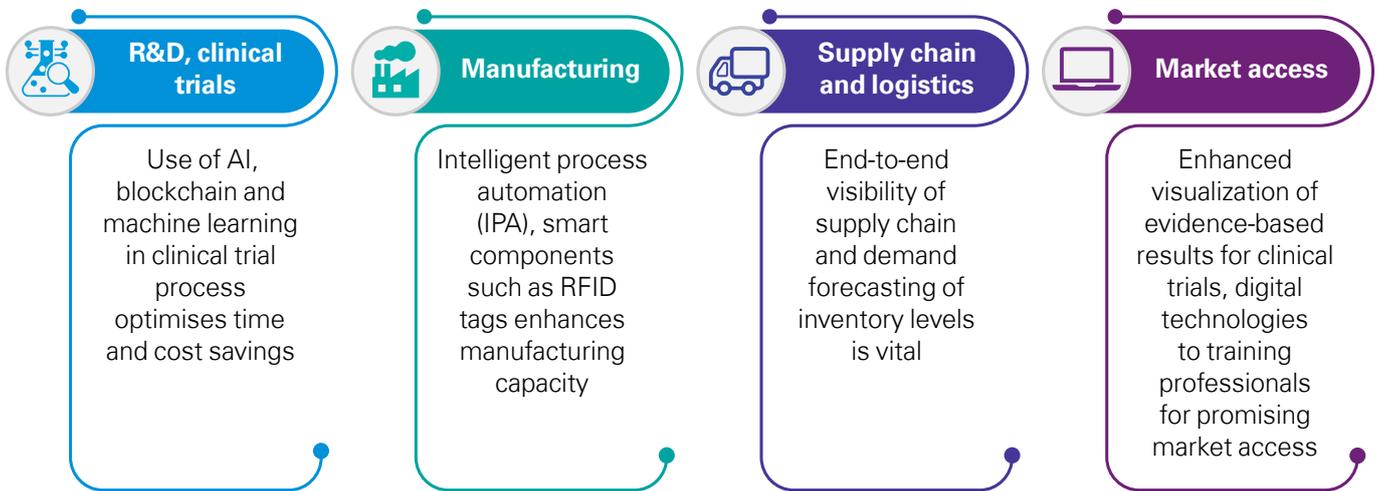


- Exports can also be included in PLI scheme as India holds around USD100 billion export potential. Scaling up productions and incentives such as PLI should make India compete globally and not limit to boosting domestic market
- Some initiatives such as simplifying tendering, transparency in government tendering process can aid in attracting global firms to get R&D investments in India. There exists a gap to showcase potential business opportunities and return on investment (ROI) to global MNCs for attracting investments in India



Digital transformation across the pharma value chain

Digital evolution has led to a fundamental shift in the way pharmaceutical organisations conduct business with a focus on patient experience across all the stages of value chain. India's pharmaceutical industry is estimated to reach USD65 billion by 2024⁸⁴, according to the Indian Economic Survey 2021. Technology disruption is helping organisations to improve patient interactions and experience, gain greater visibility, innovation of improved drug, cost-effectiveness, rebuild the business model and aim for upgraded production processes.



Digital transformation in R&D and clinical trials

Development time and risk of failure are the major factors for increasing cost of pharmaceutical research. In the entire R&D process, clinical trials, (primarily the third phase) drives the

cost upward. Thus, reducing complexity of these processes and optimizing the time taken is of utmost importance. Through the application of data and analytics technologies, return on

investments can be improved. However, it is also vital to ensure faster, and safer treatments for diseases.

84. "Digital-transformation-pharmas-pivot-for-post-pandemic-success"- Express Pharma, accessed on 6th April 2022

Use Cases

Drug molecule developed by AI put into clinical trials

- This compound is designed to help patients with obsessive-compulsive disorder, and consequently it reached human clinical trials in 12 months, compared to the 4-6 years typically taken for drug candidates
- In 2020, an Oxford-based company collaborated with a Japanese pharmaceutical firm to put a drug molecule developed by artificial intelligence into clinical trials.



Artificial Intelligence

- Artificial intelligence is used to structure and classify data saving time and allowing the researcher to focus on other important tasks
- Data and analytics can be used to find the right patients for a given study, thereby increasing safety and cost efficiency, In the case of clinical trials
- Companies are also using digital platforms to communicate with patients and doctors



Blockchain Technology

- Blockchain uses a highly secure, distributed database technology- includes smart contracts that are distributed around all involved parties. It enhances security while lowering transaction costs.
- The trial protocol (part of every clinical trial) ensures adherence and timelines are distributed as a smart contract and can be checked constantly by CROs. Hence, every participating party will have information about the progress of trials
- Blockchain technology makes online transactions secured, allowing patient data to be circulated in a reliable manner



Cloud computing

- Cloud-based solutions can improve the quality of data and their availability while meeting security and regulatory requirements
- Life sciences enterprises can use enhanced version, i.e., cloud-based analytics. These cognitive technologies can support in decision-making process for day-to-day life in decentralised organisation

Digital transformation in manufacturing

Manufacturers face the challenge of optimizing maintenance costs and duration of time-sensitive repairs, while maintaining operations efficiently. It is estimated that around 60 to 73 per cent of all manufacturing data is under-utilised or analysed.^{85,86,87} Use of advanced technologies such as AI, transforms data into relevant insights related to operations and equipment performance, as well as identify patterns or complex relationships between variables, and their forecasting errors, etc.

 <p>Intelligent process automation</p>	<ul style="list-style-type: none"> • Industry 4.0 aims to encourage the digitalisation and automation of manufacturing processes. IoT generates a vast amount of data, that can be optimised using advanced analytics with AI capabilities. IoT uses chips, sensors, and networks to integrate 'digital' and 'physical' assets • IPA combines Robotic process automation (RPA) and machine learning to deliver tools that directs to make advanced decisions and mimic human interactions • RPA refers to the automation of process based on a combination of process automation software and artificial intelligence.
 <p>Cloud-based solutions for digital sourcing and procurement</p>	<ul style="list-style-type: none"> • The digitisation of sourcing and procurement impacts interaction of companies with their suppliers and internal sourcing management processes • These cloud-based procurement solutions allow touchless order processes, alerts, mobile approval of purchase orders, automatic invoice creation thus allowing seamless procurement • Cloud-based solutions offer spend-related analytics that provide valuable insights into all procurement activities contained in the user friendly dashboards enabling smarter procurement decisions
 <p>Optimizing preventive maintenance</p>	<ul style="list-style-type: none"> • Preventive maintenance includes routine asset monitoring and visual inspection, to obtain regular information on the condition of the different system component • Machine learning (ML) helps manufacturing assets available when needed, by preventing unplanned downtime
 <p>RFID chips in smart factories</p>	<ul style="list-style-type: none"> • RFID chips are integrated with the production process and move independently to individual units for various functions like filling, closing, labeling • Humans, machines, and resources are connected via cyber-physical systems in smart factories that communicates like that of a social network

85. How Cipla is embedding digital into its business planning and execution - Express Computer, accessed on 7th April 2022

86. "Getting ready for pharma 4.0", Pharmaceutical Engineering, accessed 6th April 2022

87. "Up to 73 Per cent of Company Data Goes Unused for Analytics", accessed 6th April 2022

Use Cases



A leading U.S.-based vaccines player leveraging digital technologies in its business strategies

- A leading U.S.-based clinical stage biotechnology company pioneering the development of messenger RNA (mRNA) therapeutics and vaccines is a fully digital company having digitisation as a part of its business strategy
- It uses robotics and automation to increase operation accuracy and throughput, while reducing human errors and improving quality and compliance



Cipla's vision to unleash the power of digital integration

- Cipla targets to reduce their downtime by 20 to 30 per cent at their global manufacturing base by using a cloud-based architecture supporting commercial and portfolio decisions
- Use of Manufacturing Execution System (MES) automates material flow and accurately captures cost-information with a paperless workflow. This information helps to increase the volume while maintaining quality

Digital transformation in supply chain and logistics

While a lot has been discussed on how technology is innovating drug discovery and patient access to treatments, the bridge connecting the two, i.e., the pharmaceutical supply chain is also experiencing a technological revolution rapidly.

With new market requirements, increasing complexity and value of the supply chain ecosystem, there is a growing adoption of digitisation of supply chain management. With rise in novel therapeutics, (biologics, vaccines,

including COVID-19 vaccine), there is a requirement for specialised materials, and temperature conditions for packaging and transport.





Demand forecasting using machine learning

- Optimising inventory levels are important for insights on value of the supply chain and for patients to obtain timely, reliable access to their therapies
- Demand forecasting is an essential aspect of logistics and supply chain management, which leverages various AI tools such as machine learning (ML)
- Predictive analytics can analyse, and interpret data collected from various sources to detect patterns, anomalies and generate demand forecast accurately.



Digitally-enabled physical supply chain

- Devices, storage, and logistics can be digitally turned into system's "smart" components, exchanging real-time data via IoT sensors, Radio Frequency Identification (RFID) tags, wireless transmitters, and other technologies
- For instance, there are smart storage cabinets and refrigerators in hospitals and pharmacies to track and report consumption of data and replenishment requirements
- There are scanning drones, packing robots, and automatically guided vehicles to perform highly automated work in warehouses



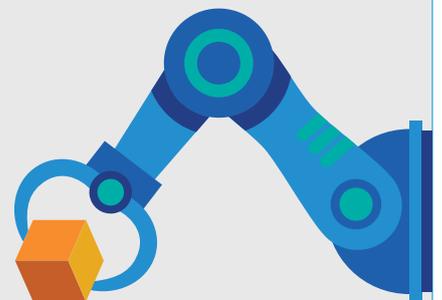
End-to-end visibility in supply chain

- A leading tech giant launched supply chain insights solution integrated with Watson AI to help companies with a control tower that leverages AI and ML in achieving end-to-end visibility and connects data across systems.
- Watson AI processes data from both internal and external sources, thus enabling analysis of 80 per cent of unstructured data that includes digital media and weather reports

Use Cases

Cipla integrating production machines to collect real-time feedback

- Transformed their supply chain by integrating its machines at production facility to collect real-time feedback
- There are automated workflows for inventory reserve calculation for GAAP accounting filings
- Robotic Process Automation: enhanced security and accuracy of problem-solving as it is powered with analytics and cloud-based solution



Digital transformation in market access^{88,89}

It is estimated that 50-80 per cent of Indian population is unable to access medicines they need. Although, there are 850,000 retailers approximately, 60 per cent of Indian market remain underserved. In rural areas, there is lack of medicines to treat even mild conditions like common cold.

However, manufacturers can leverage digital innovation in the following attributing segments in the product's market access journey:



Evidence-based results

- Payers want evidence-based results between therapies for formulary decision-making, so, a systemic literature review (SLR) is conducted by manufacturers which includes hundreds of studies, extracting relevant secondary data
- Creating a digital repository for the SLR data, using advanced digital tools generating data visualisation and graphs that can be easily incorporated into modeling and presentations, can further help to demonstrate the value of a therapy



Using digital tools for efficient marketing

- It is vital for manufacturers to identify the most effective messaging to communicate the value of their products. Digital tools enable manufacturers to effectively compile and incorporate feedback from a vast variety of stakeholders
- There is need for a set of legally bound guidelines for drug promotion, advertising, and marketing. Currently, the pharma companies are voluntarily required to follow "Uniform Code of Pharmaceutical Marketing Practices" (UCPMP)



Training staff to facilitate market access and product success

- Pharmaceutical companies train field associates to understand challenges of prescribers and patients and give potential solutions. Physicians may find it challenging to prescribe and patients may encounter hurdles to access especially for new therapies
- Increasingly, companies are turning to digital technologies to teach new concepts in a more engaging way, prompt players to use problem-solving skills to address challenges in a virtual realm, thus, leading to success of the product

- On September 27, 2021, "Ayushman Bharat Digital Mission (ABDM)" was launched, giving a boost to the digitisation of Indian healthcare system
- ABDM focusses on improving the quality, affordability, and accessibility of healthcare in India by bringing various stakeholders such as patients, doctors, and hospitals under a digital ecosystem.
- It will facilitate safe and secure flow of health information such as medical bills, prescriptions, within stakeholders with the consent of the owner of the health data.

88. "How-digital-innovation-drives-improved-market-access-strategies"- Amerisource Bergen, accessed on 6th April 2022

89. "India-lead-next-century-healthcare-digitisation"- Yourstory, accessed on 6th April 2022

Use Cases⁹⁰

Dr Reddy's develops its digital service platform to build successful customer engagement

- The company leverages its digital service platform Dr. Reddy's XCEED to help customers manage their business interactions with the company in real time ranging

from sample ordering to submitting and tracking orders. It also allows customers to interact with interdisciplinary support team of Dr. Reddy's.



Additionally, increasing digitisation has led to an increasing e-commerce adoption due to consumer preferences inclined towards online shopping post-pandemic has led to a widespread penetration of various e-commerce channels, and subsequent popularity of e-pharmacies.

E- pharmacy^{91,92}

E-commerce is witnessing substantial growth due to increasing internet penetration and smart phone availability. Additionally, growing awareness among the population about counterfeit drugs is driving people towards digital and organised channels which are offering medicines. Market size of global e-Pharmacy market was estimated to be USD 0.8 Billion in 2020, prescription drugs constituting 68 per cent and over the counter (OTC) drugs constituting 32 per cent revenue share.

- India E pharmacy market was valued at USD344.8 million in 2021 growing at a robust growth rate of 21.28 per cent CAGR during 2021-2027

45 per cent internet penetration rate in India in January 2021:

- Internet users in India grew by 47 million to reach 624 million in January 2021

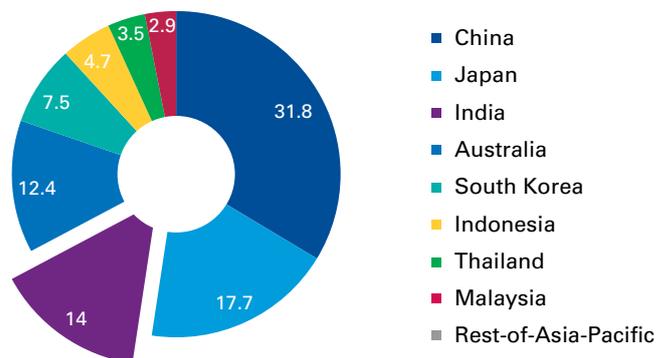


90. "COVID-19 and What's Next for API Sourcing?"- Dr. Reddy's official website, accessed on 7th April 2022

91. "E-pharmacy, Pharma retail blog- KPMG", accessed on 7th April 2022

92. "Global E-Pharmacy Market, Mordor Global Industry Reports"- EMIS, accessed on 7th April 2022

Figure 18: Revenue share of Asia-Pacific countries in e-pharmacy market, (in %), 2020



- The Indian E-Pharmacy market was operating with ~50 e-pharmacies in 2020
- It accounted for 14 per cent share of the total revenue share of e-Pharmacies market in the Asia Pacific Region in 2020.

Source: Global E-Pharmacy Market, Mordor Global Industry Reports

Note: *- Market value for India e-pharmacy market and revenue share in figure for APAC market are from different sources. Hence, market values can vary

Country's largest conglomerates and multinational e-commerce companies investing and get a foothold in this sector:

- One of the leading global e-commerce firms is eyeing a partnership for enhancing its omnichannel focus of pharmacy business
- In April 2020, Reliance Retail invested approximately USD81 million (INR620 crore) to get a majority stake in Chennai-based e-pharmacy company Netmeds.com⁹³
- In December 2020, U.S.- based private equity firm acquired a 7 per cent stake in the parent company of Mumbai-headquartered online pharmacy brand



93. "Reliance Retail buys majority stake in online pharmacy Netmeds for Rs 620 crore- Indian Express", accessed on 7th April 2022

Thus, there is an explosion in teleconsultation platforms by health-tech start-ups, and e-pharmacy companies, etc. In the future, multiple agencies are likely to play the role of platform providers. Some of the attributing factors impacting the growth of e-pharmacies are illustrated below:



Growth Drivers

- Unorganised traditional pharma retail:
 - E-pharmacy allows consumers to purchase from an organised online platform, contradictory to traditional retailers having price wars and availability challenges
- Rising government support
 - Classified as an essential service during pandemic
 - Schemes like Aarogya Setu App, Digital India and NDHM promotes e-pharmacies and enhances ease of doing business
- Immense potential in tier II and tier III cities
 - Large untapped potential in tier II and tier III cities, which can be catered by investments for improvement of logistics channels.



Challenges

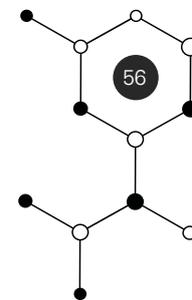
- Cyberthreats and data security
 - Potential risk of data breaches as online platforms depends heavily on valuable insights derived from customer's personal data
- Lack of strong legal and regulatory framework
 - There is a need to establish a legal framework for e-pharmacies, distinctive from legal regime for offline sales
- Need for technology upgradation
 - E-Pharmacies need to constantly focus on utilizing latest technologies (AI, ML, AR/VR) to deliver the best services



Future Outlook

- E-pharmacy market in India is expected to increase at a higher CAGR of around 40-45 per cent
- E-Pharmacies would continue to grow in India, with increase in internet and mobile phone penetration (Internet users rose by around 47 million to reach 624 million in January 2021)
- The sector is attracting huge investments from national and international market leaders
- Medicine spending in India is expected to grow between 9-12 per cent over the next five years

It is anticipated that e-pharmacies holds tremendous growth potential and will continue growing in India. Some of the key factors such as growing internet penetration and digital payments infrastructure, rise in industry investments and medicine spending, as well as government initiatives will fuel growth of this sector.



Stipulated impact of India's data privacy bill

With the outbreak of novel coronavirus pandemic, India is undergoing a digital revolution. Under Digital India Mission, government is also emphasising on the importance of cyber security and robust laws protecting digital data. Certain laws aimed at electronic health data privacy, data security, Health Information Exchanges have been proposed.

Specific laws to protect personal health information related data are enacted under various jurisdictions. For instance, Health Insurance

Portability and Accountability Act, 1996 (HIPAA) in the U.S. establishes legal framework for data security of health information ensuring patient's control over their health data. DISHA can be considered as the Indian counterpart to HIPAA.^{94,95}

However, India does not have any specific data protection law in force like HIPAA in the U.S. to develop regulations protecting the privacy and security of certain health information. There are two draft legislations in this regard:

- India stands amongst the fastest growing data generating nations in the world
- Around 4.6 billion internet users and new data being added at the rate of 2.5 quintillion bytes per day.



Personal Data Protection Bill 2019 (PDP)

- The PDP Bill, 2019 implies to "processing of personal data by the state, any Indian company, any Indian citizen or any person or body of persons incorporated or created under Indian law"
- It also applies on international companies that processes personal data for any business operations in India
- It was reviewed by the Joint Parliamentary Committee Report and presented on 29 November 2021. The final report suggested around 93 changes and amendments.

DISHA by Health Ministry

- Digital Information Security in Healthcare Act (DISHA) regulates the generation, collection, access, storage, transmission and use of Digital Health Data (DHD) and associated personally identifiable information (PII)
- It states that health data including physical, physiological, sexual orientation, medical records, and biometric data can only be the property of the person it pertains to.

94. "Data privacy day 2022 Indian personal data protection bill 2019s- benefits and effect on the industry"- Financial express, accessed on 30th March 2022

95. "DISHA-india's-probable-response-to-the-law-on-protection-of-digital-health-data- Mondaq, accessed on 31st March 2022

NDHM⁹⁶

- Central Government and the Ministry of Health and Family Welfare (MOHFW) announced the National Digital Health Mission (NDHM) in late 2019
- It includes a national health ecosystem that allows for interoperability of digital health systems at cross levels (patient, hospital, etc.).
- On 14 December 2020, a Health Data Management Policy (HDM Policy) was approved from the MOHFW aimed at governing data in the ecosystem and majorly based on the PDP Bill. The HDM Policy establishes framework for consent to process personal data.

Potential challenges in telehealth due to privacy concerns

In case of teleconsultation, doctors look for platforms that follow ethical practices as they are not able to maintain patients' data privacy and confidentiality in an appropriate manner. There can be potential lack of trust on virtual care and data privacy issues. These barriers require advanced and secure teleconsultation platforms as well as policy interventions.

The HDM Policy will have potential impact on the telemedicine and e-pharmacy segments upon implementation. This will lead to healthcare institutions having

enhanced compliance obligations, thereby driving the growth of telemedicine sector. However, some of the overlaps of the HDM Policy with PDP Bill may cause some conflicts between the two.

Data security challenges in clinical trials

CDSCO made changes in regulations governing clinical trials in India, with the implementation of new rules. It is anticipated that the newly implemented regulations provide simplified and transparent system for regulation of clinical trials. Waiving local clinical trials under the new rules will help early access to drugs for patients in India. However, there still lies challenges in terms of timelines.

Extended approval timelines- While timelines are specified for various activities in the drug / clinical trial approval process, such timelines are not usually met. This is typically due to additional documentation requested by the regulatory authority

Thus, there exists certain gaps in interpretation and implementation of regulations. However, the regulatory system or guidelines requires effective implementation on the ground.

Along with patient data, there is a requirement of huge amount of data for medical research as well. Thus, governments can also play a pivotal role in providing these

data required for research. The government can offer platforms for secured data sharing, such as epidemiological databases, patient registries, and historical clinical trial data, among others.

Similarly, pharma companies can equally contribute to historical data on drug discovery and chemical libraries in the form of open repositories without compromising intellectual property.

Indian pharma sector's promising future transformation

India showed great resilience collectively to bounce back during the pandemic. Rightly called as 'pharmacy of the world', India supplied PPE kits, ventilators, and other medical essentials to over 123 countries, including 178 million doses of COVID-19 vaccines to over 96 countries, as on 19 April 2022, under the Vaccine Maitri scheme.^{97,98,99}

Furthermore, healthcare sector also showcased remarkable integrated response. The industry managed the crisis in an exemplary manner and went into global collaborations to ramp up production for emergency medicines such as Remdesivir. The healthcare workforce stepped up to ensure continued service delivery to patients suffering from chronic diseases such as oncology, diabetes, for last mile delivery healthcare at home, and remote patient monitoring services were practiced by health professionals.

96. "Privacy-and-data-protection-india-wrap-2020"- NTLA review, accessed on 31st March 2022

97. "71 countries, 58 million doses, India's vaccine diplomacy gets Quad booster"- Indian Express, accessed on 1st April 2022

98. "India's medical diplomacy during COVID19 through South Cooperation"-Observer Research Foundation, accessed on 1st April 2022,

99. "PIB press release"- Ministry of Health and Family Welfare; accessed on 20th April 2022

In addition, government's response was agile towards the health sector. For instance, fast-track approval process for testing kits and other essential medical devices. Also, a robust supply chain system coupled with continuous supply of essential medical equipment such as ventilators nationwide was remarkable. India still can continue with such exports to attract foreign investments and domestic manufacturing. As a

country, India can continue taking these breakthrough steps to attract foreign investments and to promote domestic manufacturing.

However, there still lies certain gaps in the healthcare sector at elementary level pertaining to universal health coverage, R&D initiatives, availability of skilled workforce, access to health services among rural population, and a favourable regulatory ecosystem for the manufacturers.

With COVID, we believe India has realised its potential of what can be achieved in case, there is concerted action across all the stakeholders such as industry, government, regulators.

If India continues to leverage this opportunity, then it can realise its ambitions of moving up the value chain and truly becoming the pharmacy to the world, in volume and value terms.



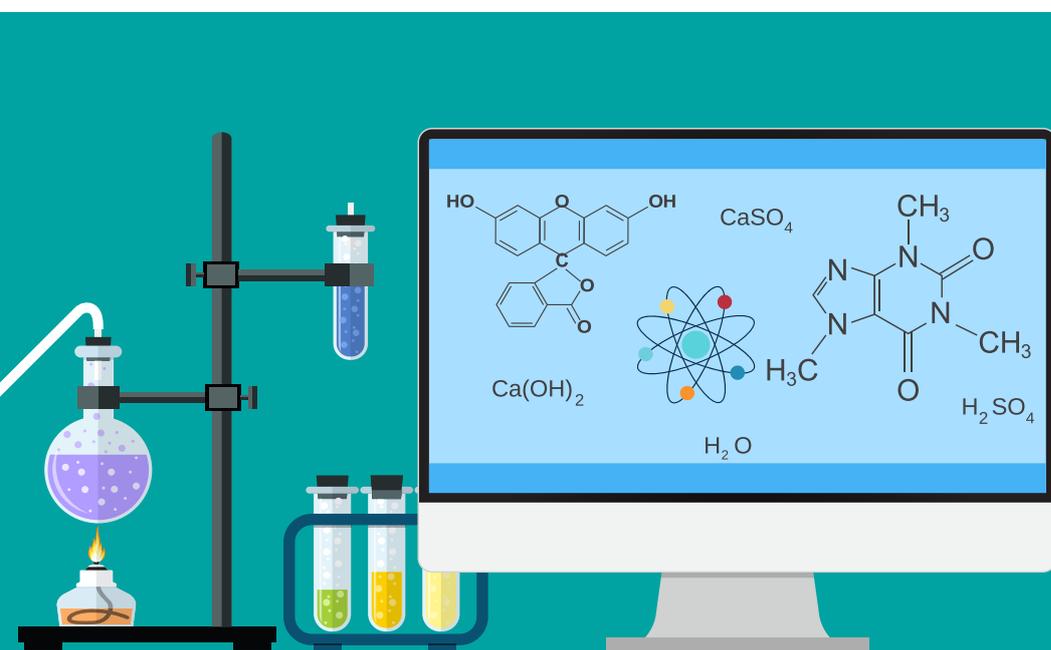
List of abbreviations

ABDM	Ayushman Bharat Digital Mission
AEFI	Adverse Event Following Immunization
AI	Artificial Intelligence
AiMeD	Association of Indian Medical Device Industry
API	Active Pharmaceutical Ingredients
ANDA	Abbreviated New Drug Application
BIRAC	Biotechnology Industry Research Assistance Council
CAGR	Compound Annual Growth Rate
DCGI	Drugs Controller General of India
DHD	Digital Health Data
DIs	Drug Intermediaries
DoP	Department of Pharmaceuticals
EU	European Union
FDA	Food and Drug Administration
FDI	Foreign Direct Investment
FWs	Frontline workers
GDP	Gross Domestic Product
GoI	Government of India
HCQ	Hydroxychloroquine
HCWs	Healthcare Workers
HDM	Health Data Management
HIPAA	Health Insurance Portability and Accountability Act
IP	Intellectual Property
IPA	Intelligent Process Automation



List of abbreviations

KSMs	Key Starting Materials
MES	Manufacturing Execution System
ML	Machine Learning
MoHFW	Minister of Health and Family Welfare
MZL	Marginal Zone Lymphoma
NBEs	New Biological Entities
NCEs	New Chemical Entities
NDHM	National Digital Health Mission
NEGVAC	National Expert Group on Vaccine Administration
NLP	Natural Language Processing
NPPA	National Pharmaceutical Pricing Authority
OTC	Over the Counter
PICS	Pharmaceutical Inspection Co-operation Scheme
PII	Personally Identifiable Information
PLI	Production Linked Incentive
R&D	Research and Development
RFID	Radio Frequency Identification
RLI	Research Linked Incentive
ROI	Return On Investment
RPA	Robotic Process Automation
SEZ	Special Economic Zones
SLR	Systemic Literature Review
SMEs	Small and Medium Enterprises
UCPMP	Uniform Code of Pharmaceutical Marketing Practices



About KPMG in India

KPMG entities in India are professional services firm(s). These Indian member firms are affiliated with KPMG International Limited. KPMG was established in India in August 1993. Our professionals leverage the global network of firms, and are conversant with local laws, regulations, markets and competition. KPMG has offices across India in Ahmedabad, Bengaluru, Chandigarh, Chennai, Gurugram, Hyderabad, Jaipur, Kochi, Kolkata, Mumbai, Noida, Pune, Vadodara and Vijayawada.

KPMG entities in India offer services to national and international clients in India across sectors. We strive to provide rapid, performance-based, industry-focused and technology-enabled services, which reflect a shared knowledge of global and local industries and our experience of the Indian business environment.

KPMG International

KPMG is a global network of professional firms which provides Audit, Tax and Advisory services.

We operate in 155 countries and have more than 162,000 people working in member firms around the world. The KPMG Audit practice endeavours to provide robust and risk-based audit services that address member firms' clients' strategic priorities and business processes. KPMG's Tax services are designed to reflect the unique needs and objectives of each client, whether firms are dealing with the tax aspects of a cross-border acquisition or developing and helping to implement a global transfer pricing strategy. In practical terms that means, KPMG firms work with their clients to assist them in achieving effective tax compliance and managing tax risks, while helping to control costs. KPMG Advisory professionals provide advice and assistance to help enable companies, intermediaries and public sector bodies to mitigate risk, improve performance, and create value. KPMG firms provide a wide range of Risk Consulting, Management Consulting, and Transactions and Restructuring services that can help their clients respond to immediate needs as well as put in place the strategies for the longer term.

About FICCI

KPMG entities in India are Established in 1927, FICCI is the largest and oldest apex business organization in India. Its history is closely interwoven with India's struggle for independence, its industrialization, and its emergence as one of the most rapidly growing global economies.

A non-government, not-for-profit organization, FICCI is the voice of India's business and industry. From influencing policy to encouraging debate, engaging with policy makers and civil society, FICCI articulates the views and concerns of industry. It serves

its members from the Indian private and public corporate sectors and multinational companies, drawing its strength from diverse regional chambers of commerce and industry across states, reaching out to over 2,50,000 companies.

FICCI provides a platform for networking and consensus building within and across sectors and is the first port of call for Indian industry, policy makers and the international business community.

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