Deloitte.

US-INDIA
STRATEGIC PARTNERSHIP FORUM

Strenghtening the pharmaceutical and medical devices manufacturing ecosystem in India

September 2020

Preamble

The pandemic has highlighted the importance of healthcare and medical supplies across the world. As a result, countries are now re-evaluating their capabilities to make available timely, quality medical supplies. This includes developing indigenous manufacturing competencies or restructuring the procurement supply chain. In the succeeding paragraphs, we have attempted to provide an overview of the size and capabilities of the Indian market to cater to the local as well as global demand alongwith the steps Government is taking to encourage manufacturing in India.

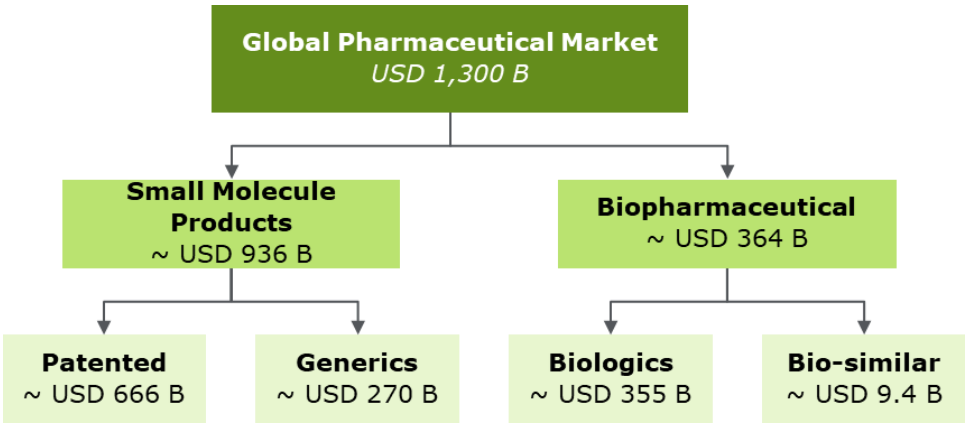
Current market dynamics

Pharmaceutical drugs/supplies

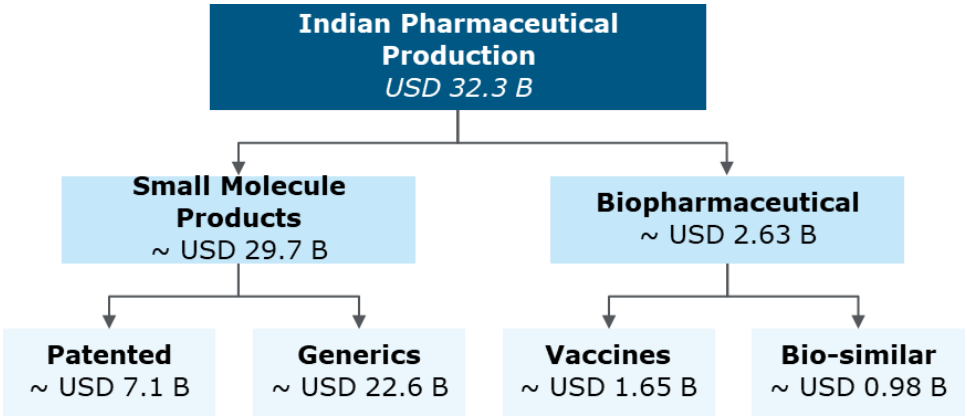
Across the three broad segments—generics, bio-similars, and biologics—the pharmaceutical manufacturing value chain comprises three key elements, namely Active Pharmaceutical Ingredients (API)/excipient manufacturing, KSM/intermediates manufacturing, and formulations/finished dosage.

The global pharmaceutical industry is estimated at US$1.3 trillion with generics contributing to ~US$270 billion. India accounts for 3 percent of the global pharma market, at US$40 billion, while being a large exporter of generics with imports comprising ~US$2 billion.

Global pharmaceutical market, FY19



Indian pharmaceutical production, FY19



Medical equipment

The medical devices industry can be classified into four broad segments—consumables and implants, diagnostic imaging, instruments and appliances, and patient aids and others. Each segment has distinct characteristics, such as players, usage of technology, and target markets.

Segments	Key products	Technology	Industry structure
Consumables and implants	Stents, syringes, needles, catheters, suturing materials, bandages and dressing, implants	Low-medium technology segment	Domestic and MNC players
Patient aids and other devices	Hearing aids, prosthetics and orthotics, pacemakers, and others	Medium-high technology segment	Mix of MNC and domestic Players
Diagnostic imaging	Electro-diagnostic apparatus, radiation apparatus, imaging parts and accessories	Medium-high technology segment	Mainly MNC players with a few domestic players with “local innovation”
Instruments and appliances	Surgical and non-surgical equipment, other instruments and supplies	Medium technology segment	Mostly MNC players

The Indian context

Pharmaceutical drugs/supplies

API and intermediates: India relies on imports to meet roughly two-thirds of its intermediates and more than one-fifth of its API requirements. There is an absence of an integrated and resilient supply base.

India currently imports most of its intermediates requirements from China. While the US is the largest API consumption market, China is the leading global API supplier. In 2018, China's API exports stood at ~US$30 billion (~9 million tons); India exported only ~US$3.5 billion, in comparison.

Most APIs imported by India are utilised to make formulations for the domestic market. The locally manufactured APIs are primarily used for exports and roughly, two-thirds of API production in India is for captive consumption.

Of the 373 essential drugs, more than 200 are imported as API/intermediates from China, especially for disease categories such as cardiovascular, antibiotic, diabetes, anti-inflammatory, and anti-tuberculosis. Given the significant cost differential between India and China, coupled with the need to meet Drug Pricing Control Order (DPCO)-related requirements, Indian pharmaceutical companies are compelled to import specific APIs (products such as Gabapentin) from China, although significant API capacity is available within the country.

Medical equipment

The medical devices industry is highly capital intensive with a long gestation period and dependent on imports in major-mid to high-tech segments.

The Indian medical devices market, which accounted for more than 13 percent of the Asia-Pacific (APAC) medical devices market in 2019, is expected to grow at a compound annual growth rate (CAGR) of 7.5 percent through 2025.

To cater to this demand, domestic manufacturing of medical devices in India is inadequate, as it is a small and fragmented industry with the presence of both domestic and MNC players. While most domestic players operate largely in the low-tech and high-volume segments, the high-end segments are catered to, a large extent, by MNCs. Currently, there is a significant import dependency in the mid- to high-tech segment of medical devices—diagnostic imaging, instruments and appliances, patient aids, and others. Further, India imports a variety of consumables, disposables and capital equipment, including orthopedic implants, gloves, syringes, bandages, computed tomography, and magnetic resonance imaging devices from China.

Medical devices have several components, which require a manufacturing ecosystem of their own. Lack of local and immature ancillary industry acts as a hurdle in the medical devices industry. Further, the lack of trained professionals and clinical staff required for installing, operating, servicing, and repairing medical devices is a critical limiting factor. Thus, requiring an impetus from the government.

Government's push to make an "Atmanirbhar Bharat"

India is now seen as a trusted partner by corporates looking to expand their manufacturing footprint in sectors such as automotive, pharmaceuticals, chemicals, and garments. The Indian pharmaceutical industry is the third-largest in the world by volume and fourteenth in terms of value. As mentioned earlier, India contributes ~3.5 percent of the total drugs and medicines exported globally. However, despite these achievements, India is significantly dependent on the import of basic raw materials, viz., bulk drugs that are used to produce finished dosage formulations, largely due to economic considerations. Bulk drugs accounted for 63 percent of the total pharmaceutical imports in the country during FY 2018–19.

With a view to attain self-reliance and reduce import dependence in critical APIs, a scheme to promote domestic manufacturing of critical Key Starting Materials (KSMs)/Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) In India has been approved by the government.

On the other hand, the medical device manufacturing industry is still in its development stages. Most high-tech innovative products originate from a well-developed ecosystem and innovation cycle, which is yet to fully develop in India. Since the creation of testing and laboratory facilities requires huge investment, a scheme for setting up of bulk drug parks and medical device parks has been approved by the government.

The growth of the healthcare sector is contingent on our ability to ensure uninterrupted supply of quality bulk drugs and our capacity to upscale their manufacturing during emergency situations. Self-reliance in manufacturing of bulk drugs, medical devices, is therefore, highly desirable.

1. **The Government of India has announced incentives to boost API manufacturing in India and build resilience in the pharma value chain. A USD1.3 billion fund was announced to encourage companies to manufacture pharma ingredients, which includes a Production Linked Incentive (PLI) scheme for manufacture of identified KSMs/intermediates/APIs for up to six years.**

Objective	The scheme intends to boost domestic manufacturing of identified Key Starting Material (KSMs), Drug Intermediates (DIs), and Active Pharmaceutical Ingredients (APIs) by attracting investments in the sector, and thereby reducing India's import dependence in critical APIs.
Scope	Financial incentives will be given based on the sales made by selected manufacturers for 41 products. These 41 products cover all the identified 53 APIs.
Quantum of incentive	Incentive would range from 5–20% of incremental sales depending on the type of KSMs/DIs/APIs manufactured in India and covered under "target segments".
Period of incentive	Six years, i.e., fy 2023–24 to 2028–29 for fermentation-based products and fy 2022–23 to 2027–28 for chemical-synthesis-based products.
Application window	Online application to be filed within 120 days after the release of guidelines, i.e., by 24 November 2020.

Target segments and threshold limit

S. no.	Target segment	Threshold investment (US$ million)
1.	Fermentation-based 04 KSMs/drug intermediates (e.g., Penicillin G, Clavulanic Acid)	53.33
2.	Fermentation-based 10 niche KSMs/drug intermediates/APIs (e.g., Vitamin B, Rifampicin)	6.66
3.	Key chemical synthesis-based 04 KSMs/drug intermediates (e.g., Para amino phenol)	6.66
4.	Other 23 chemical-synthesis-based KSMs/drug intermediates/APIs (e.g., Valsartan, Aspirin)	2.66

Quantum of incentive

Proposed incentive rate (on incremental sales of fermentation based products)	Proposed incentive rate (on incremental sales of Chemically synthesis based products)	Basis of computation
FY 2023–24 to FY 2026–27: 20% FY 2027–28 : 15% FY 2028–29 : 05%	FY 2022–23 to FY 2027–28: 10%	Assessment of incremental investments and sales of KSMs/DIs/APIs will be based on the details provided to the department and statutory auditor's certificate

2. To promote domestic manufacturing of medical devices in India and curb imports of medical devices, the government has announced a US$4.56 billion fund to encourage companies to manufacture certain specified segment of medical devices in India for five years.

Objective	The scheme aims to boost investments in domestic manufacturing of medical devices in India and curb dependence on imports in this sector.
Scope	Financial incentives given to selected companies based on "threshold investment" and "incremental sales" (over base year, i.e., FY 2019–2020) of medical devices covered under "target segments".
Quantum of incentive	5% of incremental sales (over base year, i.e., FY 2019–2020) of goods manufactured in India and covered under "target segments".
Period of incentive	Five years i.e., from FY 2021–22 to FY 2025–26.
Application window	Online application to be filed within 120 days post release of guidelines, i.e., by 24 November 2020.

Target segments

Target segments	Description of medical devices covered under target segment
Target segment 1	**Cancer care/radiotherapy medical devices** (e.g., proton therapy system)
Target segment 2	**Radiology and imaging devices** (both ionising and non-ionising radiation products) and nuclear imaging devices (e.g., CT scan, MRI, X-Ray equipment)
Target segment 3	**Anesthetics and cardio-respiratory medical devices,** including catheters of cardio respiratory category and renal care medical devices (e.g., biopsy renal kits, anesthesia kits)
Target segment 4	**All implants** including implantable electronic devices like cochlear implant and pacemakers (e.g., heart valves, stents)

Eligibility threshold criteria

Proposed incentive rate (on incremental sales of manufactured goods)	Incremental investment (US$ million)	Incremental sales of manufactured goods (US$ million)
FY 2021–22 to FY 2025–26: 5%	US$24 Mn over three years Cumulative minimum: • Year 1: US$8 Mn • Year 2: US$16 Mn • Year 3: US$24 Mn	FY 2021–22: US$16 Mn FY 2022–23: US$32 Mn FY 2023–24: US$48 Mn FY 2024–25: US$61.33 Mn FY 2025–26: US$74.66 Mn

3. **The Government of India has announced a US$0.53 billion fund to encourage companies to set up bulk drug parks and medical devices parks in India, respectively.**

Objective	The scheme of **"bulk drug park"** is meant to provide easy access to world-class common infrastructure facilities for bulk drug units located in such parks. Further, the scheme for promotion of **"medical devices park"** shall provide common testing and laboratory facilities/centres (which involves significant costs) at one place. This will help create a robust ecosystem for healthcare manufacturing in the country.
Scope	Financial assistance under the scheme will be provided to create common infrastructure facilities across four medical device parks and three bulk drug parks selected under the scheme.
Period of incentive	Five years, i.e., from FY 2020–2021 to FY 2024–2025.
Benefits	Aid would be given to selected bulk drug parks and medical devices parks, to the extent of 70% of the project cost of common infrastructure facilities, while it will be 90% in case of North Eastern states and hilly states. The total outlay for one medical device park shall be limited to US$0.13 billion, while for one bulk drug park shall be limited to US$1.33 billion.

With the government's announcement of the above schemes to make the Indian Healthcare industry attractive, self-reliant, and competitive, it will be interesting to see whether the industry players are fully ready to take this shot in the arm. The intriguing question is whether this potentially game changing vaccine is perfect the way it is or does it still need some fine-tuning before it can be realistically and seamlessly availed by the national and global players who stand to benefit. .

Sources and references

1. Invest India, Sector Pharmaceuticals, 2019
2. Pharmexcil
3. Global / US Generics and Biosimilars: Trends, Issues and Outlook, IQVIA, 2019
4. Economist Intelligence Unit, 2019
5. Indian Pharmaceutical Outlook, Crisil, 2019
6. Overview of India's pharma raw material imports, Crisil, 2018
7. Biopharmaceutical industry service report, Crisil, 2020
8. Biopharmaceuticals – Review and Output, Crisil, 2017
9. Indian Pharmaceutical Industry, IBEF, 2020
10. WHO, China policies to promote local production of pharmaceutical products and protect public health, 2017
11. The Indian pharmaceutical industry – the way forward, IPA, 2019
12. Evaluate Pharma World Preview, 2019
13. International Generics and Biosimilars Medicines Association
14. BCC research
15. News articles and company annual reports
16. Perspectives on clinical research, ISCR (Mar 17), PMC 5299798
17. Impact of Chinese Goods on Indian Industry, Parliament of India Report,2018
18. China Chamber of Commerce for Import & Export of Medicines and Health Products, 2018
19. Unforeseen Chinese API problems opportunity for Indian companies, ICICI Securities, 2019
20. Deloitte Analysis
21. https://timesofindia.indiatimes.com/business/india-business/india-us-trade-deal-what-both-sides-want/articleshow/74228132.cms
22. https://economictimes.indiatimes.com/news/economy/indicators/us-fdi-to-india-crosses-usd-40-bn-us-india-strategic-and-partnership-forum/articleshow/77029989.cms?from=mdr
23. https://www.mea.gov.in/Portal/ForeignRelation/India_U_S_Bilateral.pdf
24. https://www.outlookindia.com/website/story/india-news-donald-trump-india-visit-us-india-should-enhance-nuclear-space-cooperation-to-further-ties/347710
25. https://www.forbes.com/sites/meghabahree/2020/07/15/google-joins-facebook-in-billionaire-mukesh-ambanis-jio-juggernaut/#27b431e81990
26. https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/eight-global-pharmaceutical-firms-evince-interest-in-indias-plan-to-ramp-up-api-production-mansukh-mandaviya/articleshow/76201809.cms?from=mdr
27. https://economictimes.indiatimes.com/markets/stocks/news/carlyle-picks-up-20-stake-in-piramal-pharma-biz-for-490-mn/articleshow/76656364.cms?from=mdr

Contacts

Mahesh Jaising
Partner and Leader - Indirect Tax
mjaising@deloitte.com

P. S. Easwaran
Partner and Leader - Supply Chain
pseaswaran@deloitte.com

Deloitte.