

Pharmaceutical sector in India

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With the outbreak of COVID-19 and its origin traced to China, the production of bulk drugs or APIs took a hit. India should use this situation of a possible shortage in Chinese medicinal raw materials to its advantage. The proposed bulk drug parks are seen as a good opportunity to harness India's potential in the pharma sector.

In news: Bulk drug parks to be setup in states

Placing it in syllabus: Industries

Dimensions

- Factors for concentration in a few pockets
- Indian pharmacy place in global supply chain
- Government initiatives for pharmacy sector
- Regulation of pharmaceutical sector
- Challenges faced by the sector

Content:

Factors for concentration of pharma industries in few pockets:

It is the west coast of India which concentrates this sector.



- Large sea ports available since ancient times like Kandla, Bhavnagar and Mumbai had been important trading

centres.

- Larger exports to western world including Africa, Europe and the USA.
- Availability of huge capital in alignment with trade culture and Bombay high which completes energy requirements.
- Availability of skilled labour due to number of pharmaceutical colleges as well as early introduction of western scientific education.
- Better connectivity of roads and airports.
- Early introduction of advanced technology owing to economic capital as well as moderate climatic conditions

Now Benglauru, NCR, Sikkim as well as Himachal Pradesh also have industries. Himachal has Asia's largest pharma manufacturing hub, the **Baddi-Barotiwala-Nalagarh industrial belt**, and the state produces around half of India's total drug formulations.

Indian pharmacy place in global supply chain:

- India is the **largest provider of generic medicines globally**, occupying a 20% share in global supply by volume.
- It supplies 62% of global demand for vaccines.
- India **ranks 3rd worldwide for production by volume and 14th by value.**
- India is the **only country with the largest number of US-FDA compliant Pharma plants** (more than 262 including APIs) outside of the USA.
- India has more than 2000 WHO-GMP approved Pharma Plants, 253 European Directorate of Quality Medicines (EDQM) approved plants with modern state of the art Technology.
- India is the source of 60,000 generic brands across 60 therapeutic categories and manufactures more than 500 different Active Pharmaceutical Ingredients (APIs).
- The API industry is **ranked third largest in the world contributing 57% of APIs to the WHO prequalified list.**

- From 2018-19, India's pharmaceutical exports were worth \$19.3 bn with a growth of 10.72% year on year.
- Indian pharmaceutical sector is expected to grow to \$ 65 billion industry by 2024.

Government initiatives for pharmacy sector:

- The government has allowed **100% FDI in Greenfield pharmaceutical projects and 74% FDI in brownfield pharmaceutical** projects.
- The government had launched the **Pharma Vision 2020** with the following objectives: Transform India into a global leader in low-cost generics and end-to-end drug discovery and development.
- The government had launched the **Pradhan Mantri Bhartiya Janaushadhi Pariyojana** to supply low-cost pharma drugs to the economically weaker sections.
- The government, in 2019, released draft rules for regulating the e-pharmaceutical companies.
- In March, the Union Cabinet approved the establishment of mega '**Bulk Drug Parks**' in association with state governments.

Bulk drug parks:

- The park will have a designated contiguous area of land with common facilities like solvent recovery, effluent treatment, distillation, etc.
- These parks are expected to bring down manufacturing costs of bulk drugs in the country and increase competitiveness in the domestic bulk drug industry.
- The **Centre's scheme will support three selected parks in the country by providing a one-time grant-in-aid** for the creation of common infrastructure facilities.
- The **grant-in-aid will be 70 percent** of the cost of the common facilities but in the case of Himachal Pradesh and other hill states, it will be 90 per cent.
- The **Centre will provide a maximum of Rs 1,000 crore per**

park.

- A state can only propose one site, which is not less than a thousand acres in area, or not less than 700 acres in the case of hill states.
- The proposals should contain the estimated cost, feasibility studies, environmental risk assessment etc.
- A **project management agency**, nominated by the department of pharmaceuticals, will examine these proposals and make recommendations to a scheme steering committee, which will then approve the proposals.
- Several states including Andhra Pradesh, Maharashtra, Gujarat, Haryana, Punjab, Tamil Nadu and Telangana have expressed interest in the scheme.

Regulation of pharmaceutical sector:

- India has some of the toughest legislation in the world for drug regulation.
- According to the **Drugs and Cosmetics Act, 1940**, in case any substandard drugs are detected, the remaining stocks are to be recalled.
- The manufacturing, sale and distribution of drugs are regulated mainly by the state authorities under the states' health departments.
- Other aspects like licensing, approval, regulation of clinical trials and the quality assurance are handled by the **Drugs Controller General of India** at the central level.
- The office of DCGI functions under the **Central Drugs Standard Control Organisation (CDSCO)**.
- The ultimate implementation and regulation of the drug manufacturers are carried out by drug inspectors.
- The drug inspectors can label the drugs as 'spurious' (involving criminal intent) or simply 'not-of-standard quality'.
- Based on this, the state authority can decide on the prosecution, license cancellation or simply recall.

- The **centre notified medical devices as 'drugs' according to the Medical Devices (Amendment) Rules, 2020.**
- This means that these devices will be regulated under the Drugs and Cosmetics Act, 1940.

Challenges faced by the sector:

- Lack of research components and real time good manufacturing practices. This has always been a difficulty for the pharma industry.
- Indian pharma companies are not getting proper profits, their earnings are basically very low as compared to their counterparts in other countries such as the US.
- Their income is not sufficient enough to invest money on research components.
- The pharma industry is dependent on China for the supply of raw material for generic medicines production.
- Raw material produced from small scale units are not properly validated in the testing laboratory of the state to ascertain their quality specifications.
- This year, drug manufacturers in India suffered repeated setbacks due to disruption in imports due to China shut down.

Mould your thought:

1. Why are the pharma industries concentrated in few pockets in India? What measures the government has taken to boost the pharma sector?

Approach to the answer:

- Write about the status of India in pharma sector briefly
- Write factors for concentration
- Measures taken by the government
- Conclusion