



# PHARMACEUTICAL INDUSTRY -HOW BIG IS THE INDIA'S PHARMA MARKET? AN OVERVIEW.

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**CONTEXT:** an explosion tore through Sigachi Industries, a pharmaceutical factory, and flattened a three-storeyed building in Pashamylaram on the outskirts of Hyderabad raised concerns of safety and quality.

## Pharmaceutical Sector of India- current scenario:

The Indian pharmaceutical industry, often referred to as '**the pharmacy of the world**', contributes immensely to global public health and promoting universal healthcare access.

The pharmaceutical industry in India is currently valued at **\$50 Bn.**

- **Major segments of industry** include generic drugs, OTC medicines, bulk drugs, vaccines, contract research & manufacturing, biosimilars and biologics
- The Pharmaceutical industry in India is the **third largest** in the world in terms of volume and **14th largest** in terms of value
- The Pharma sector currently contributes to around **1.72% of the country's GDP.**
- India is the **3rd largest producer of API** accounting for an **8% share** of the Global API Industry



## Challenges Faced by the Indian Pharmaceutical Industry;

### 1. Quality Control Failures:

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- According to a report by Indian Pharmaceutical Alliance and McKinsey & Company in 2023, the [US Food and Drug Administration \(FDA\)](#) classified 13% of its 145 inspections of Indian facilities as Official Action Indication (OAI), which is lower than the global average of 15% OAIs.

## **2.Global Competition:**

oThe Indian pharmaceutical industry faces intense global competition, particularly from China, in the production of **Active Pharmaceutical Ingredients (APIs)**. APIs are the main components that make medicines effective.

oIndia relies heavily on imports from China for these ingredients(APIs).

## **3.Government Price Controls:**

The Indian government is often accused of controlling the prices of medicines, which critics argue limits the profitability of pharmaceutical companies

## **4.Patent Law Disputes:**

- Indian patent laws are designed to ensure the availability of affordable medicines, which sometimes leads to disputes with foreign governments and pharmaceutical companies
- The Indian government has enacted laws allowing the waiver of patent rights during emergencies to facilitate access to essential drugs. While this liberal policy aims to prioritise public health, it often leads to conflicts with global pharmaceutical companies and foreign governments

## **5.Lower R&D Investment:**

- Compared to global counterparts, Indian pharmaceutical companies invest less in Research and Development (R&D)
- This limited investment hampers innovation and the development of new medicines, affecting the industry's competitiveness on a global scale.

## **Steps taken to ensure the quality of manufacturing:**

### **1.Crack down by Indian Govt.**

§Indian government had taken steps on 18 drug companies for poor quality manufacturing.

§It had cancelled the licences of over 10 pharmaceutical companies as part of a crackdown on poor quality manufacturing.

### **2.Vision Pharma 2047**

§Make India a global leader in the manufacturing of affordable, innovative & quality pharmaceuticals & medical devices for the goal of **Vasudhaiva Kutumbakam**.

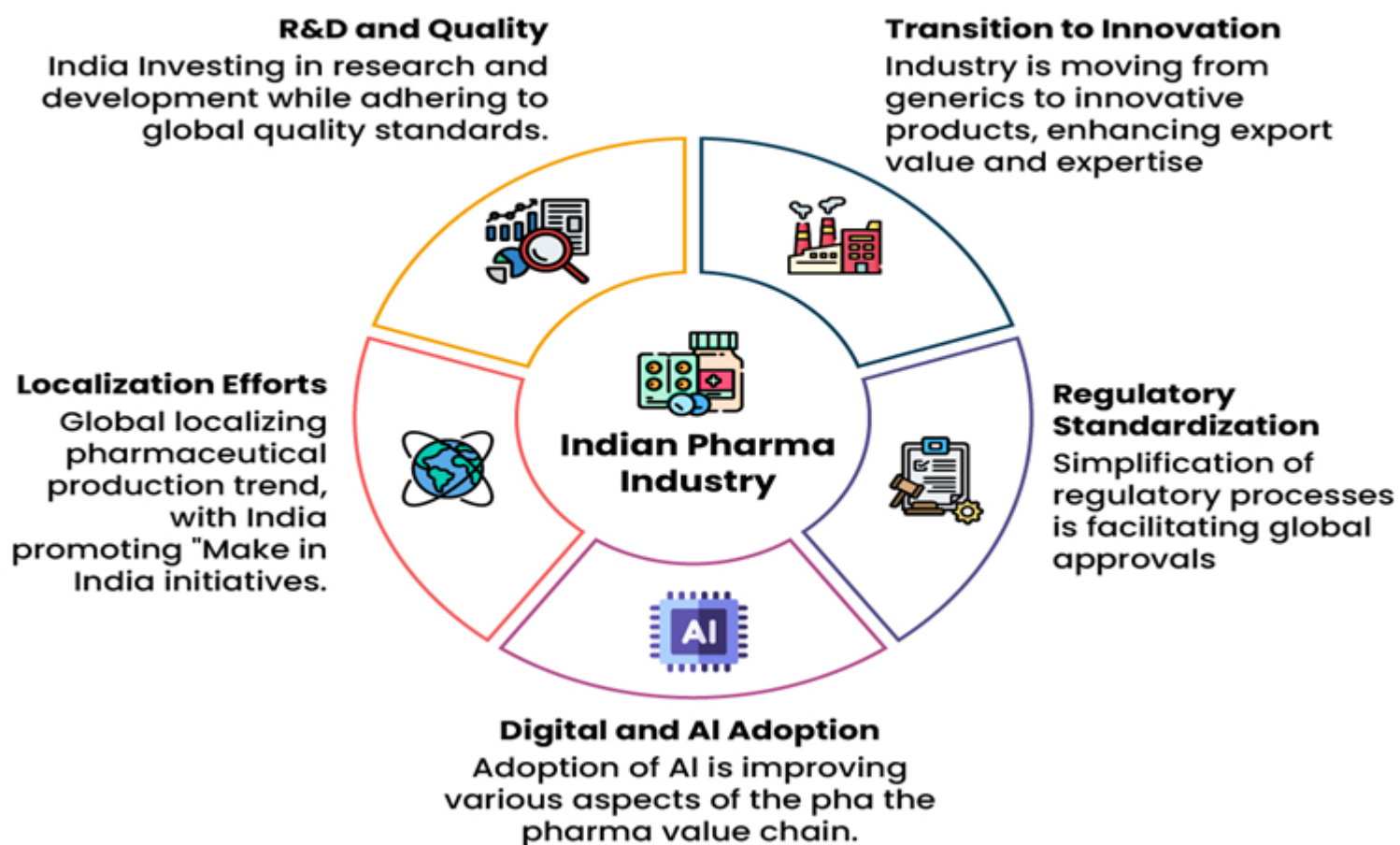
### **3.National Pharmaceutical Policy (2023)**

§The policy is being drafted to serve as a comprehensive framework to address the challenges faced by Indian Pharmaceutical industries.

### **The draft policy encompasses five key pillars:**

*Fostering Global Pharmaceutical Leadership, Promoting Self-Reliance, Advancing Health Equity and accessibility, Enhancing Regulatory Efficiency in the Indian Pharmaceutical Sector and Attracting investments.*

## Transformative Trends Shaping India's Pharmaceutical Future



### Recommendations and way forward:

- **Balancing Patent Protection and Accessibility:** India must strike a careful balance between protecting intellectual property rights and ensuring public access to affordable medicines. This involves closing loopholes that MNCs exploit to extend patent periods unjustifiably, thereby preventing the excessive pricing of essential drugs.
- **Encouraging Quality and Accountability in Pharmaceuticals:** In the light of recent incidents, pharmaceutical companies should be incentivized and encouraged to adopt rigorous **quality management systems and self-improvement initiatives**.
- Simultaneously, they must be held **accountable for any lapses through stringent enforcement of penalties and sanctions**, thereby fostering a culture of responsibility and compliance within the industry.
- **Strengthening Post-Market Surveillance:** A robust post-market surveillance system is essential to identify and address potential issues with pharmaceutical products early.
- This system should enable prompt investigations and the implementation of corrective actions, thereby safeguarding public health and maintaining trust in the pharmaceutical sector.
- **Global Market Penetration:** Expanding exports to Africa, Latin America, and [ASEAN](#) via trade deals and overseas manufacturing will overcome trade barriers and boost growth.