India: PHARMACY OF THE WORLD

India's pharmaceutical industry has played a crucial role during the COVID-19 pandemic and the country has cemented its position as a "dependable nation" when it comes to health crises. This burgeoning sector, often termed a "sunrise industry," is witnessing steep growth, with lots of innovation and employment generation. Yet, it grapples with challenges such as quality control, regulatory compliance, and inadequate infrastructure. However, the rising need for life-saving medicines and vaccines present new opportunities for India to not only meet global healthcare needs but also fortify its position as a pharmaceutical leader on the world stage.

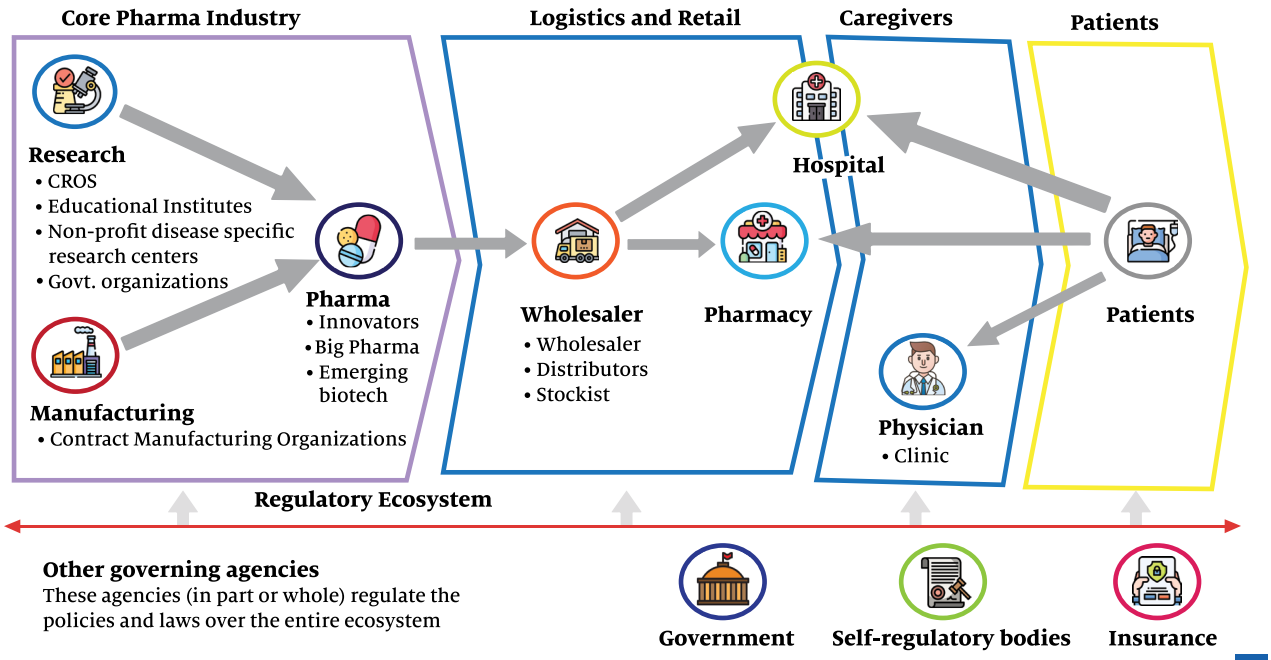
IN THIS DOCUMENT

1. How does India's pharmaceutical ecosystem function?

The Indian pharmaceutical industry is dedicated to the research, development, manufacturing, and distribution of various drugs and medications.

- **Key segments** include generic drugs, OTC medicines, bulk drugs, vaccines, contract research, biologics(medications made from living organisms), and biosimilars (biologic drugs that are highly similar to existing approved biologics).
- The sector has **evolved from ancient practices like Ayurveda,** with over 5,000 years of history, **to the modern pharmaceutical industry** taking shape in the early 20th century.

Figure 1.1. Pharmaceutical Ecosystem in India



Box 1.1. Evolution of India's pharma industry post-independence

1947-1970: (Prior to Process Patent Regime)	➢ **India relied mostly on imports** for many drugs consumed in the country. ➢ The Indian government started **regulating the industry and promoting the development of local manufacturing capabilities.** ➢ The first central **Pharmacy Council of India** was constituted in 1948 to regulate the educational requirements of the pharmaceutical sector.
1970-2005: (Post Implementation of Process Patent)	➢ The Indian pharma industry worked on the basis of **reverse-engineering and process innovation,** achieved technological self-sufficiency and ability to develop generic drugs and strengthened its export orientation. ⊳ **Patent Act, 1970** allowed Indian pharmaceutical companies **to produce alternative processes for drugs** that were not patented in India. ⊳ The basic objective of the **Drug Policy, 1978 was to achieve self-sufficiency in drug production.**
2005-2020: (Post Implementation of Product Patent)	➢ India **amended the Patent Act** to comply with the WTO's agreement on TRIPS, **introducing pharma product patents** and patent protection. ➢ After some initial challenges, Indian pharmaceutical companies **joined the global pharmaceutical value chain (GVC)** through alliances with global firms, enabling **technology transfers and technological upgrades.** ➢ **R&D shifted focus to product innovation,** novel drug delivery systems (NDDS), new drug development research (NDDR), and bio-pharmaceutical research.

2. How is the pharmaceutical industry in India faring at present?

Figure 2.1. Trends in India's Pharma Industry

Pharmaceutical Sector: An Overview

Over 65%
of WHO Demand for DPT & BCG and
90%
measles vaccines supplied by India

FDI Inflows
USD 21.46 Bn
(April 2000 - March 2023)

Contributes
1.72%
of the India's
GDP

Largest
generic provider size globally-exports 20%
20%
generics by volume

Pharma Exports:
USD 25.26 Bn
(FY 22-23)

Over 80%
of the antiretroviral drugs used globally to combat
AIDS
supplied by India.

Sector Ranking: India Rank

1ST
Largest supplier of low cost Generics, 20% 60% Vaccines and Affordable HIV medicines 80%

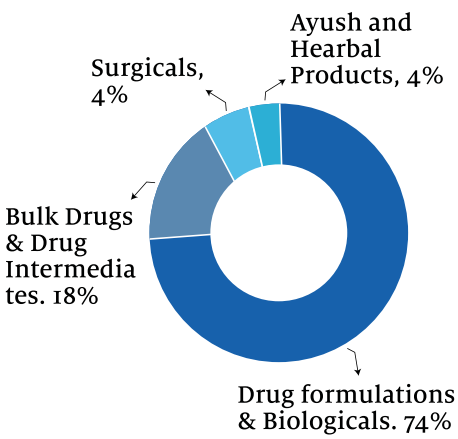
2nd
Highest FDA approved plants outside USA

3rd
Largest producer to API

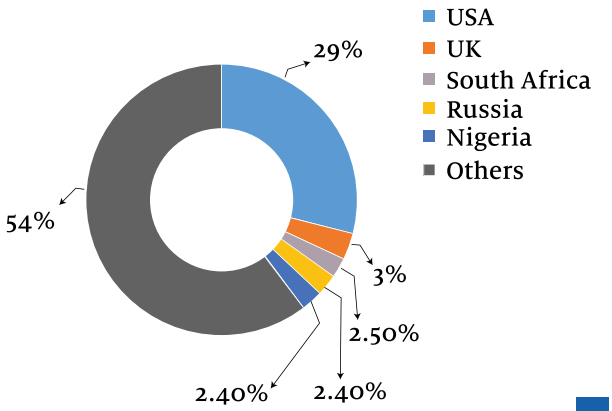
3rd
Largest in terms of volume

14th
Largest in terms of value

Key Pharma Exports from India



Key Export Destinations for India's Pharma Products

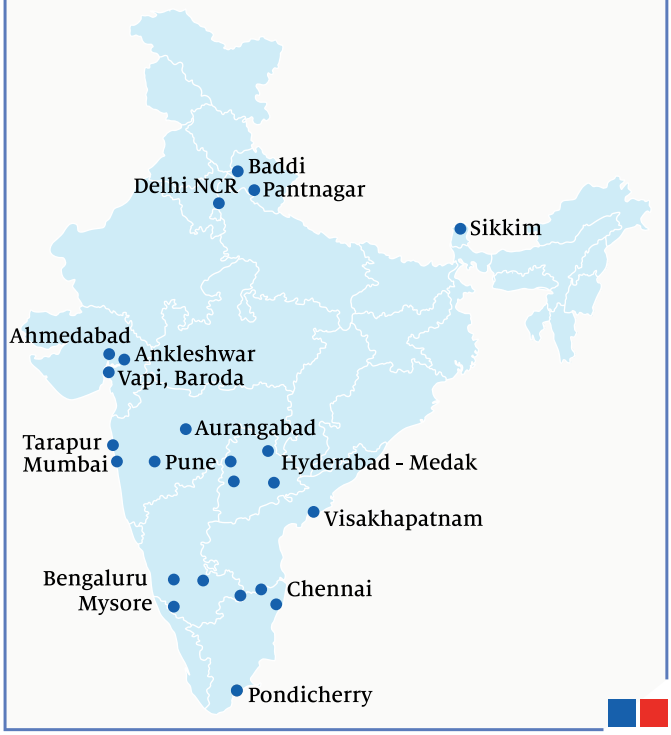


3. What are the key factors driving India to become Pharmacy of the World?

India's transformation into the "Pharmacy of the World" is a result of several pivotal factors that have propelled its pharmaceutical industry to international prominence. These include:

- **Industry Foundations and Strengths contributing to Affordable Healthcare:**
  - **Robust Generic Drug Industry:** India's robust generic drug industry plays a **pivotal role in enhancing global access to essential medicines.**
    - For instance, the generic version of Paracetamol 500 mg (10 tablets) costs Rs 6 in India, compared to the branded version, which can be priced between Rs. 28-72.
  - **Production Cost Efficiency:** India's cost of production is nearly **33% lower than that of the US** with labour costs 50–55% lower than western countries.
  - **Leading Vaccine Supplier:** India is a major contributor to affordable global vaccine coverage, producing vaccines like the recombinant Hepatitis B vaccine and COVID-19 vaccines.
  - **Abundant Talent Pool:** India is the **2nd largest provider of pharma and biotech professionals** globally, after China.
  - **Regulatory Compliance:** Regulatory bodies such as CDSCO ensure strict adherence to international quality and safety standards.
  - **Export Dominance:** Having the largest number of US-FDA compliant pharmaceutical plants, India **exports** pharmaceutical products **to more than 200 countries** (developed as well as developing), contributing significantly to the global healthcare supply chain.
- **Intellectual Property and Innovation:**
  - **Pre-2005 Product Patents Regime:** India's approach of not granting product patents on medicines before 2005 allowed the production of affordable generic versions of patented drugs through reverse engineering.
    - Notably, India introduced cost-effective HIV drugs (Zidovudine) and life-saving cancer medication (Imatinib) shortly after their US launch.
  - **Research and Development (R&D):** India's significant investments in pharmaceutical R&D focus on innovative drug discovery, biosimilars, and biotechnology.
    - This capacity was instrumental in manufacturing COVID-19 vaccines like Covaxin and Covishield during the pandemic.
- **Infrastructure, Government Support, and Other Growth Factors:**
  - **Infrastructure and Manufacturing Facilities:** India has established pharmaceutical hubs, clusters, and specialized SEZs, promoting world-class manufacturing and export capabilities.
  - **Government Support:** The Indian government offers tax incentives, subsidies, and research and development investments to foster sector growth and innovation.
  - **Booming Domestic Market:** India's expanding healthcare sector and large domestic market drive demand for pharmaceuticals and medical devices, both domestically and internationally.
    - India's reputation **attracts medical tourists to India** promoting a positive image of the country world-wide.
  - **Global Collaborations:** Collaborations between India and global pharmaceutical companies and research institutions facilitate the exchange of knowledge, expertise, and research findings.
    - For instance, Serum Institute of India (SII) partnered with US-based Codagenix Inc. to produce a live-attenuated vaccine (LAV) for COVID-19.
  - **Prompt response during crisis situation (COVID):** The pharma industry has brought path-breaking innovations and rapidly improved its global potential for distributing time-critical drugs to every corner of the world.
    - Under **Vaccine Maitri initiative** and **Neighbourhood First Policy,** India has supplied more than 150 nations with medicines and vaccines. Ex: **Hydroxychloroquine (HCQ) to USA.**

Figure 3.1. Pharmaceuticals Clusters in India



Box 3.1. Major Drivers of Growth in the Future

The Indian pharma sector is at the cusp of its next revolution. Future is underpinned by several signicant drivers and trends. These include:

- **Artificial Intelligence:** New and automated algorithms will help the industry to tackle dicult diseases, monitor drug adherence and comprehend complex data.
- **Small molecule patented drugs:** The Indian pharmaceutical industry is eyeing an opportunity in the small molecule patented drugs segment, with a potential upcycle (patent cli) from 2023 to 2026.
- **Patent cliff** refers to a sharp decline in revenue or protability when a rm's patents expire, opening them up to competition.
- **Rare and neglected diseases:** Research on drugs or medicines for **treating rare diseases and neglected diseases** will see a rise.
- **Demand for digital therapeutics:** This involves the use of high-quality evidence to oer optimal therapeutic interventions through automated programs. This will enable pharmaceutical companies to turn to service providers in therapeutics from simple medicine manufacturers.

3.1. What are the key initiatives taken by the Government of India to make India as Pharmacy of the world?

The Government of India has undertaken several key initiatives that are pivotal to the growth and global prominence of India's pharmaceutical sector. These include:

Table 3.1. Government Measures to support the development of harma Industry

Regulation of Pharma products	**Drugs and Cosmetics Act, 1940** regulates the import, manufacture, distribution and sale of drugs in India. **Central Drugs Standard Control Organization (CDSCO)** approves new drugs, clinicaltrials, and the regulation of pharmaceuticals in India. **Drug Controller General of India (DCGI)** grants approvals for the import andmanufacture of drugs and pharmaceuticals in India. **State Drug Regulatory Authorities** for granting licenses, conducting inspections, and ensuring compliance with drug laws at the state level.
Promoting Pharmaceutical Research and Innovation	**Pharma Vision 2020** to make India a drug discovery and innovation powerhouse in end-to-end drug manufacturing. **National Policy on Research and Development and Innovation in Pharma-MedTech Sector 2023 and Scheme for promotion of Research and Innovation in Pharma MedTech Sector (PRIP).**
Quality and Standards	**National Good Laboratory Practices (GLP) Compliance Monitoring Authority (NGCMA) to** monitor the implementation of GLP standards in various laboratories involved in pharmaceutical research. The **OECD Principles of Good Laboratory Practices (GLP)** ensure the generation of high quality and reliable test data related to the safety of industrial chemical substances and preparations. **Indian Pharmacopoeial Commission (IPC)** under MOHFW works to harmonize pharmacopeial standards for the quality and purity of pharmaceutical substances and dosage forms used in India. **Ayush Oushadhi Gunvatta evam Uttpadan Samvardhan Yojana (AOGUSY)** of Ministry of Ayush for augmenting quality of Ayush drugs. **The Department of Pharmaceuticals' Central Sector Schemes,** such as Consumer Awareness, Publicity and Price Monitoring (CAPPM) for ensuring quality, education, and growth in the pharmaceutical sector.

Affordable Medicines	➢ **National Pharmaceutical Pricing Policy 2012** creating a regulatory framework for drug pricing. ➢ **National Pharmaceutical Pricing Authority (NPPA)** regulates, monitors and controls the prices of essential medicines. ➢ **Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)** ensures the availability of aordable medicines.
Pharmaceutical Industry Development	➢ **Strengthening of Pharmaceutical Industry (SPI) Scheme** to address the requirements of pharmaceutical clusters and manufacturing facilities to improve productivity, quality and sustainability. ➢ **Production Linked Incentive (PLI) Schemes for promoting Domestic Manufacturing** of Key Starting Materials (KSMs), intermediates and APIs. ➢ **Scheme for Promotion of Bulk Drug Parks** to provide common infrastructure facilities. Approved in three States-**Himachal Pradesh, Gujarat and Andhra Pradesh.** ➢ **The Indian Pharmaceutical Alliance (IPA)** of 24 leading research-based pharmaceutical companies in India for promoting high standards in pharmaceutical production and quality assurance.
Foreign Direct Investment (FDI)	➢ **100% Foreign Direct Investment (FDI)** is allowed under the automatic route for **Greeneld** pharmaceuticals. ➢ **100% FDI** is allowed in **brownfield** pharmaceuticals;**(74% is allowed under the automatic route** and thereafter through the government approval route).
Export Promotion	➢ **Pharmaceutical Export Promotion Council of India (Pharmexcil)** was set up by the Ministry of Commerce & Industry.
Promoting Ethical Behaviour	➢ **Indian Medical Council Act, 1956,** prohibits physicians/medical practitioners from committing unethical acts. ➢ **Voluntary Uniform Code for Pharmaceutical Marketing Practices (UCPMP)** for Pharmaceutical companies to prevent unethical practices by the pharmaceutical companies. ➢ **Setting up a high-level committee** to examine the need for a legally enforceable mechanism to regulate pharmaceutical marketing practices. ➢ **Amendment of the New Drugs and Clinical Trial Rules (2023)** to promote ethical research practices and innovation.

Box 3.2: In Conversation! Compulsory Licensing for Affordable Healthcare

Vinay

Vini

Vinay, I've heard about something called "compulsory licensing" in India's pharmaceutical industry. Can you explain what that's all about?

Of course, Vini. Compulsory licensing is like a legal tool that India uses to ensure that essential medicines are available, especially when they are still under patent protection.

And how does it work?

Well, if a patented medicine is too expensive or in short supply, the Indian government can issue a compulsory license. This allows other manufacturers to produce the same medicine, even without the patent holder's consent.

So, it's a way to make sure that life-saving drugs are more aordable and accessible to people?

Exactly, Vini. India granted a compulsory license once in 2012 to the company Natco Pharma for the generic production of costly drug Nexavar which is used for treating cancer.

That's impressive. It's a powerful tool to balance the need for innovation and public health.

Indeed. It shows how India is contributing to global healthcare and access to medicines.

4. What challenges stand in the way of India's Pharma Sector's growth and global prominence?

The Indian pharmaceutical industry's journey to global prominence is marked by remarkable achievements, but it also faces several complex challenges that demand careful consideration. These include:

- **Regulatory Challenges:**
  - **Quality and Safety Challenges:** Frequent FDA inspections and the need for ongoing quality upgrades divert capital from development and growth, while safety concerns can lead to product safety alerts in international markets, impacting India's pharmaceutical image.
    - For example, **past incidents of ethylene glycol contamination with Indian cough and cold syrups in Gambia.**
  - **Challenges in Good Manufacturing Practices (GMP) Compliance:** GMP compliance adds to manufacturing costs, estimated to be about 25% more for regulated markets like the US.
    - GMP ensures consistent production and quality control.
  - **Challenges regarding Intellectual Property Rights(IPR):** This includes the lack of protection for intellectual property, the slow pace of the Indian patent oce to grant patents, and generic versions of patented drugs being produced and sold in the country.
  - **Delay in Implementing Mandatory Recall Law:** India has contemplated a mandatory recall law for substandard drugs since 1976, with no such law in existence today. Ineective enforcement was seen when **CDSCO failed to recall ranitidine contaminated with the carcinogen N-Nitrosodimethylamine (NDMA).**
    - This law compels pharmaceutical companies to recall substandard drug batches.
- **Systemic Challenges:**
  - **Overreliance on Foreign Raw Materials:** India heavily depends on China for bulk drugs or Active Pharmaceutical Ingredients (APIs) requirements (approximately 70%), leading to vulnerability when supply chains are disrupted.
  - **Unstable Pricing and Policy Environment:** Frequent changes in the **GoI's Drug Price Control Order** create industry uncertainty, deterring production expansion and new investments.
  - **Counterfeit Drug Problem:** Counterfeit drugs continue to pose risks to patient safety and public health, reecting systemic issues in monitoring and regulation.
- **Structural Challenges:**
  - **Limited Infrastructure:** Inadequate infrastructure facilities, including storage, **hindered the timely availability of critical drugs** like Remdesivir and Hydroxychloroquine during the pandemic.
  - **Intense Global Competition:** Indian pharmaceutical companies face competition from global counterparts like China, Israel, and Japan, impacting their competitiveness.
  - **Digitalization and Automation Lag:** The industry excels in producing quality drugs but lags in adopting digitalization and automation, **potentially affecting efficiency and quality control.**
- **Ethical Challenges**
  - **Unethical marketing tactics:** Pharmaceutical companies often adopt unethical practices to promote their products/brands by providing freebies for doctors and medical professionals.
    - This **increases the chances of the patient consuming irrational and/or unnecessary medicines.**
  - **Unregulated Innovation:** Large number of antibiotics are consumed in the form of xed-dose combinations (FDCs). But **many antibiotic FDCs sold in India are of unknown effectiveness** and have **not been approved by CDSCO**.
    - This increases their potential to **accelerate antibiotic resistance.**
  - **Lack of Transparency:** The Pharma ecosystem does not actively communicate the manufacturing processes and the side-eects of drugs to patients.

5. What strategies and actions should India pursue to strengthen Its position as the Pharmacy of the World?

Securing the future of India's pharmaceutical industry demands a concerted eort to build resilient and sustainable global supply chains. This necessitates the following measures:

- **Focus on Quality Control and Transparency:**
  - **Quality control:** India should harmonize its regulations with international standards like ICH/PIC(s). The enactment of the New Drugs, Medical Devices, and Cosmetics Bill in 2022 marked a positive stride in this direction.
  - **Conducive Policies:** Regulatory Reforms with focus on quality, Self-reliance in APIs, Thrust of R&D through incentivizing innovation and industry-academia collaboration.
  - **Enhancing Drug Regulation:** Implementation of the Malshekar committee's recommendations on drug regulation, including the establishment of a National Drug Authority and strengthening State Drug Control Organizations.
  - **Introducing Bar Code for all the drugs- Drugs Technical Advisory Board (DTAB)** has recommended that barcodes or QR codes be introduced to help track and trace drugs. It will help to reduce the threat of counter feit drugs.
  - **Self-regulation:** Promotion of self-regulation by pharma companies as a low-cost, eective measure for quality control.
- **Technological Advancements for Pharmaceutical Industry:**
  - **Emerging Technologies:** Leveraging cloud-based intelligent systems, AI, ML, and robotics to automate manufacturing and packaging processes, improving productivity, reducing costs, and minimizing errors.
    - » Encouraging **computer simulation and test tube studies to reduce reliance on animal testing of drugs.**
  - **Digital Therapeutics:** Embracing digital therapeutics to provide evidence-based therapeutic interventions through automated programs.
- **Infrastructure Development:**
  - **Boost Production:** Streamlining pharmaceutical manufacturing, implementing policies for the movement of manufacturing personnel across states, and supporting ancillary suppliers such as packaging material and solvents for pharmaceutical manufacturers.
  - **Strengthening Supply Chain and Logistics:** Integration of land, air, waterway, maritime, and port facilities to strengthen supply chain and logistics infrastructure.
  - **Digital Track and Trace System** to combat counterfeit drugs.
- **Research and Innovation:** Allocation of resources for **research on Rare and Neglected Diseases,** developing **next-generation molecules**, including **gene therapy, stem cell therapy**, and biosimilars.
- **Ethical Policy Framework:** Clear statutory framework is necessary to review marketing practices of pharmaceutical companies and dene penalties for transgressions by drug companies.
  - Framework should revolve around four **universally accepted principles of medical ethics – Autonomy, Justice, Benecence and Non-malecence.**

Conclusion

India's pharmaceuticals sector has grown in condence with India emerging as a global '**medical superpower**'. To harness the pharma industry's full potential, the stability, predictability and coherence of policy are fundamental. The sector's transformation from **volume to value leadership** will rely on a robust regulatory ecosystem that prioritizes patient-centricity while striking an optimal balance between access, aordability and innovation.

TOPIC AT A GLANCE

India: Pharmacy of the World

India's pharmaceutical industry played a crucial role during the COVID-19 pandemic and the country has cemented its position as a "dependable nation" amid a health crisis. Indian Pharma industry covers research, development, manufacturing, and distribution of drugs and medications.

Overview of Indian Pharmaceutical Sector

Leading global supplier of aordable medicines and vaccines.

Second highest FDA approved plants outside USA.

3rd in terms of volume and **14th largest in terms of value.**

Key factors Driving India's 'Pharmacy of the World' Status

- **Robust generic drug industry and cost efficiency in production.**
- **Leading vaccine supplier**
- **Abundant talent pool**
- **Strict regulatory compliance**
- **Extensive export dominance** (pharma products are exported to more than 200 countries)
- **Focus on research and development** leading to innovative drug discovery and biotechnology.
- **Government support in the form of** tax incentives, subsidies, and R&D investments.
- **World class Infrastructure and Manufacturing Facilities.**
- **Global collaborations** facilitating the exchange of knowledge and expertise.
- **Proactive response during Covid-19** under Vaccine Maitri initiative and Neighbourhood First Policy.

Government Measures to Support the Pharma Industry

- **Regulatory frameworks:** Drugs and Cosmetics Act, CDSCO, DCGI etc.
- **Promotion of research and innovation:** Pharma Vision 2020, National Policy on R&D and Innovation.
- **Quality standards and compliance monitoring:** National Good Laboratory Practices, Compliance Monitoring Authority.
- **Affordable medicines and pricing regulation:** National Pharmaceutical Pricing Authority, National Pharmaceutical Pricing Policy etc.
- **Industry development schemes:** Strengthening of Pharmaceutical Industry Scheme, Production Linked Incentive Schemes for promoting Domestic Manufacturing etc.
- **FDI policies:** 100% FDI under the automatic route for **Greenfield** pharmaceuticals and **100% FDI** in **brownfield** pharmaceuticals.
- **Ethical behaviour regulations:** Uniform Code for Pharmaceutical Marketing Practices.

Major Challenges Hindering Growth and Global Prominence:

- **Regulatory Challenges** such as quality and safety concerns, Intellectual Property Rights (IPR) etc.
- **Systemic Challenges** such as overreliance on foreign raw materials, counterfeit drugs etc.
- **Structural Challenges** such as Infrastructure limitations, Digitalization and Automation Lag and Intense global competition.
- **Ethical concerns** in marketing and innovation.

Key Strategies to Strengthen India's Position as Pharmacy of the World

- **Focus on Quality Control and Transparency through** conducive Policies, enhancing drug regulation.
- **Adopt emerging technologies and digital therapeutics** to automate manufacturing and packaging.
- **Infrastructure Development** and Strengthening Supply Chain and Logistics.
- **Invest in research and innovation including** research on Rare and Neglected Diseases, Gene therapy.
- **Establish an ethical policy framework** to uphold **principles of medical ethics.**

Boxes, Figures and Tables