

India's Pharmaceutical Market for FY 2023-24 is Valued at USD 50 billion with domestic consumption valued at USD 23.5 billion and export valued at USD 26.5 billion



The Department of Pharmaceuticals has established seven National Institutes of Pharmaceutical Education & Research (NIPERs), recognized as institutes of national importance, to provide postgraduate and doctorate education and conduct high-end research in various pharmaceutical specializations.

To foster Research & Development (R&D) and innovation, the Department has introduced the “National Policy on Research & Development and

Innovation in the Pharma-MedTech Sector in India”, aimed at creating an ecosystem for innovation in pharmaceuticals and medical devices.

India’s pharmaceutical market for FY 2023-24 is valued at USD 50 billion, with USD 23.5 billion attributed to domestic consumption and USD 26.5 billion to exports. The Indian pharma industry is the third largest globally by volume and 14th by value of production, offering a diversified product range, including generic drugs, bulk drugs, vaccines, biosimilars, and biologics.

According to National Accounts Statistics 2024 (Ministry of Statistics and Programme Implementation), the total output of the pharmaceuticals, medicinal, and botanical products industry was valued at ₹4,56,246 crore for FY 2022-23, with a value addition of ₹1,75,583 crore. The industry engaged 9,25,811 people during this period.

Research & Development (R&D) and innovation in the Pharma Sector is done by several institutions and organizations under various scientific Ministries/Departments. The Department of Pharmaceuticals has set up seven National Institutes of Pharmaceutical Education & Research (NIPERs) as institutes of national importance, which besides imparting postgraduate and doctorate education, conduct high-end research in various pharma specializations. Further, the Department has framed a “National Policy on Research & Development and Innovation in Pharma-MedTech Sector in India” to encourage R&D in pharmaceuticals and medical devices and to create an ecosystem for innovation in the sector for India to become a leader in drug discovery and innovative medical

devices through incubating an entrepreneurial environment to build a robust ecosystem to ensure the holistic development of R&D and Innovation. The policy was notified on 18.08.2023.

Key Focus Areas of the Policy:

1. **Regulatory Environment:** Establishing a regulatory framework that facilitates innovation and product development while maintaining safety and quality standards.
2. **Incentives for Investment:** Encouraging private and public investments in innovation through fiscal and non-fiscal measures.
3. **Enabling Ecosystem:** Developing a strong institutional foundation to support cross-sectoral research and sustainable growth in the pharma and MedTech sectors.

The [full policy document](#) is available in the Gazette notification dated 18.08.2023.

Additionally, the Department has launched the Scheme for Promotion of Research & Innovation in the Pharma Sector (PRIP) with a financial outlay of ₹5,000 crore for the period 2023-24 to 2027-28, notified on 17.08.2023. The scheme aims to transform India's pharma and MedTech sector from a cost-based model to an innovation-driven model by enhancing research infrastructure.

Components of the PRIP Scheme:

Component A: Strengthening Research Infrastructure

- Establishing Centres of Excellence (CoEs) within the seven NIPERs to boost advanced research capabilities.

Component B: Promoting Research in the Pharma-MedTech Sector

- Providing financial assistance to companies and projects for in-house and academic R&D in six specified priority areas.

Further details of the scheme are available in the Gazette notification dated 17.08.2023 at: <https://pharmaceuticals.gov.in/schemes>.

The New Drugs and Clinical Trials Rules, 2019, notified on 19/03/2019, include provisions to encourage research, development, and innovation of new drugs in the country.

Key Features of the Rules

- Disposal of clinical trials and new drug applications, including approval, rejection, or requests for additional information, within 90 days.
- For applications to conduct clinical trials of new drugs or investigational new drugs as part of drug discovery and manufacture in India, disposal is required within 30 days.
- In cases where no communication is received from CDSCO within the prescribed timelines, the application is deemed approved.
- Provisions for accelerated or expedited approval processes for unmet medical needs, orphan drugs for rare diseases, and similar situations.

- Provisions for pre-submission and post-submission meetings with CDSCO for formal discussions and case-specific regulatory pathways.

For export, drugs must be manufactured under a valid manufacturing license as per the Drugs and Cosmetics Act and its rules, while also meeting the importing country's regulatory requirements.

The Department for Promotion of Industry & Internal Trade (DPIIT) has informed that no specific initiative has been taken exclusively for the pharmaceutical industry to strengthen its intellectual property (IP) regime. However, several broad-based initiatives have been undertaken to enhance the overall IP framework.

Key Initiatives

- Amendments to IP Rules:
 - Patent Rules: Since 2014, patent rules have been amended multiple times to streamline the filing and processing of patent applications, eliminate irregularities, address procedural delays, and simplify the patent-granting process. Key changes include:
 - Fee rebates of at least 80% for filing and maintaining patent applications for startups, small entities (MSMEs), and educational institutions.
 - Expedited examination facilities for startups, small entities, applicants electing India as the international

search authority, female applicants, and government institutions/departments.

- Mandatory electronic submission of documents by patent agents and streamlined timelines for procedural steps.
 - Simplification of requirements for filing priority documents and Form 27 (regarding the working of patents).
 - Reduction of the timeline for submitting a request for examination from 48 months to 31 months to fast-track the examination process.
 - A 10% reduction in patent renewal fees if fees for at least four years are paid in advance electronically.
- Start-Ups Intellectual Property Protection (SIPP) Scheme:
 - Launched in 2016 and extended until 31.03.2026, this scheme supports the protection of patents, trademarks, and designs for startups, Indian innovators, and educational institutions using services from Technology and Innovation Support Centers (TISCs) in India.
 - Over 2,700 impaneled facilitators assist startups with filing applications.
 - Recently revised, the scheme increased facilitation fees by at least 100%, making it more beneficial for applicants.

These initiatives collectively aim to enhance the IP ecosystem, promote innovation, and support startups and small businesses in protecting their intellectual property.

The revised applicable fee structure is as under:

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Stage of Payment		Patent Rupees	Trade Mark Rupees	Design Rupees
At the time of filing of applications		15000	3000	3000
At the time of final disposal of Applications	Without opposition	25000	5000	5000
	With opposition	35000	10000	10000

Reference: <https://pib.gov.in/PressReleasePage.aspx?PRID=2085345>

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