



Indian Pharma Sector

For Prelims: Indian pharmaceutical industry, Active Pharmaceutical Ingredients.

For Mains: India's Pharma Sector - associated challenges and steps that can be taken to boost the sector, Making India the world's pharmacy in terms of value.

Why in News?

Recently, the Ministry of Chemical & fertilizers released guidelines on pharmaceutical innovation and entrepreneurship for academic institutions to Catalyze [Indian Pharma Sector](#).

- The Department of Pharmaceuticals has established NIPERs (National Institutes of Pharmaceutical Education and Research) as institutes of national importance for providing quality education and conducting high-end research.
- The Department is also soon coming up with a 'Policy to catalyze Research & Development and Innovation in the Pharma- MedTech Sector in India'.

What Do the Policy Guidelines Seek?

- These policy guidelines **aim to transform academic research into innovative and commercially applicable technologies**.
- It seeks to **build a strong ecosystem for entrepreneurial activities** and contribute to a [Self-Reliant India Mission](#).
- The policy guidelines will **encourage faculty, staff and students to pursue entrepreneurship**.
- The **availability of resources needs** to be ensured for pre-incubation and providing common facilities for prospective inventors and entrepreneurs.
 - Budgetary provisions should be available in terms of allocation of a fixed percentage (such as not less than 1%) of institute's annual budget for funding, promoting and supporting innovation and startup-related activities.
 - In return for the services and facilities provided, an institute may take a fixed percentage of (2 - 9.5%) equity in the startup/spin-off company, based on employee contribution, support provided and use of the institute's Intellectual Property.
- The entrepreneurial initiatives shall be evaluated on a regular basis using well-defined impact assessment parameters such as [IP \(Intellectual Property\)](#) filed, products developed and commercialized and number of employments generated, and startups created.
- To encourage students, **relaxation in attendance should be provided** to enable them to dedicate time for entrepreneurial activities, and they should be allowed to sit for the examination, even if their attendance is less than 75 %, adding institutes should provide relaxation to the PhD students in terms of a semester/year break or more, if needed, to devote time on startup ventures.

What is the Status of the Indian Pharma Sector?

- India is the **largest provider of generic drugs globally**. It supplies over 50% of global demand

- for various vaccines, 40% of generic demand in the US and 25% of all medicine in the UK.
- The **Indian pharmaceutical market is estimated at USD 40 billion** and pharma companies export another USD 20 billion.
 - However, this is a miniscule portion of the USD 1.27-trillion global pharmaceutical market.
 - Globally, **India ranks 3rd in terms of pharmaceutical production by volume and 14th by value.**
 - India has more than 30% share in the global generic market but less than 1% share in the new molecular entity space.
 - **New Molecular Entity:** A novel compound that has not previously been approved for use in humans.
 - According to the [Economic Survey 2021](#), the domestic market is expected to grow three times in the next decade.

What are the Issues with the Indian Pharma Sector?

- **Lack of Capabilities in Innovation Space:** India is rich in its manpower and talent but still lags in innovation infrastructure. The government needs to invest in research initiatives and talent to grow India's innovation.
 - The government should support the clinical trials and subjectivity in certain regulatory decision-making.
- **Effect of External Markets:** Reports comments that India is heavily dependent on other countries for [Active Pharmaceutical Ingredients \(API\)](#) and other intermediates. 80% of the APIs are imported from China.
 - So India is, therefore, at the mercy of supply disruptions and unpredictable price fluctuations. Implementation of infrastructure improvement in the field of internal facilities is necessary to stabilize supply.
- **Quality compliance inquiry:** India has undergone the highest number of Food and Drug Administration (FDA) inspections since 2009; therefore, continuous investment for upgrading quality standards will distract the capital away from other areas of development and growth is reduced.
- **Lack of Stable Pricing and Policy Environment:** The challenge created by unexpected and frequent domestic pricing policy changes in India. It has created a vague environment for investments and innovations.

What is the Need for Innovation in the Pharma Sector?

- Changing perspective and increasing the use of technology were the need of the hour. But now it is essential that innovation is at the core of business, and there is a dire need to embrace it if India wants to continue to be of relevance in the global pharmaceutical space.
- India playing at scale in the innovation space will not just help the country but will create a source of sustainable revenues, bringing new solutions to unmet healthcare needs.
 - In India, this would lead to reduction in disease burden (development of drugs for India-specific concerns like [tuberculosis and leprosy](#) does not get global attention), creation of new high-skilled jobs, and probably around USD 10 billion of additional exports from 2030.
 - Countries like China have already leapfrogged ahead, skipping the generic medicine based development.

What are Government Initiatives?

- [Strengthening of Pharmaceutical Industry Scheme:](#)
 - A total financial outlay of Rs. 500 crore (USD 665.5 million) for the period FY 21-22 to FY 25-26 were announced under the Scheme.
- **First Global Innovation Summit of the pharmaceuticals sector:**
 - In November 2021, Indian PM inaugurated the first Global Innovation Summit of the pharmaceutical sector, where national and international speakers deliberated on a range of subjects including regulatory environment, funding for innovation, industry-academia collaboration and innovation infrastructure.
- **Production Linked Incentive (PLI) Scheme:**

- The PLI scheme aims to promote domestic manufacturing of critical Key Starting Materials (KSMs)/Drug Intermediates and Active Pharmaceutical Ingredients (APIs) in the country.
- **Promotion of Bulk Drug Parks Scheme:**
 - The government aims to develop 3 mega Bulk Drug parks in India in partnership with States to reduce manufacturing cost of bulk drugs in the country and dependency on other countries for bulk drugs.

Way Forward

- Medicine spending in India is projected to grow 9-12% over the next five years, leading India to become one of the top 10 countries in terms of medicine spending.
- Going forward, better growth in domestic sales would also depend on the ability of companies to align their product portfolio towards chronic therapies for diseases such as cardiovascular, anti-diabetes, anti-depressants and anti-cancers, which are on the rise.
- The Indian Government has taken many steps to reduce costs and bring down healthcare expenses. **Speedy introduction of generic drugs into the market has remained in focus and is expected to benefit the Indian pharmaceutical companies.**
- In addition, the thrust on rural health programmes, lifesaving drugs and preventive vaccines also augurs well for the pharmaceutical companies.

Source: PIB

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