Indian Pharma Industry - Need for Innovation Focus

What is the issue?

Despite being a leading player, the Indian pharma industry needs a relook in the age of innovation and emerging challenges.

How significant is the Indian pharma industry?

- Leads in the global generic world.
- Indian pharmaceutical market is estimated at $40 billion.
- Pharma companies export another $20 billion.

What are the shortcomings?

India has more than 30% share in the global generic market but less than 1% share in the new molecular entity space.

- India’s pharma industry is just a miniscule portion of the $1.27-trillion global pharmaceutical market.
- It ranks third worldwide for pharmaceutical production by volume, but only 14th by value.
- India is only the 12th largest exporter of medical goods.

What are the priorities now?

- Changing perspective and increasing the use of technology.
- Going beyond generics.
- Focusing on innovation.
- Creating and developing breakthrough products for Indian pharma companies to have a dominant global presence.

How significant is innovation in pharma industry?

- Bring new solutions to unmet healthcare needs.
- Reduction in disease burden through development of drugs for India-specific concerns like TB and leprosy.
- Creation of new high-skilled jobs.
- Facilitate probably around $10 billion of additional exports from 2030.
- Create a source of sustainable revenues.
- Stay relevant in the global pharmaceutical space. Countries like China have already leapfrogged ahead, skipping the generic chapter altogether.

What are the limitations?

- **Complex and delayed approval processes** - Nod for development of new drugs in India takes 33-63 months versus 11-18 months in developed countries.
- **Lack of robust process guidelines** - Indian websites list 24 guidelines compared to over 600 at the U.S. Food and Drug Administration.

- **Lack of transparency** - The US has an established pre-submission process and a time bound stage-gate process.
- **Inadequate capacity**/capability across regulatory bodies in India.
- **Limited governance** - Indian authorities currently only track the number of applications and approvals.
- **Limited innovation mindset** - India is risk averse compared to most global bodies. E.g., in the approval of clinical trials.

What are the measures to be taken?

- An enabling regulatory structure with simplified processes, robust guidelines, predictability, increased capacity and strong governance. India needs a 60% reduction in the approval timeline to be competitive.
- Funding support through policies/incentives, direct government investment, and significant Private Equity/Venture Capital investment.
- [The 'Make in India' campaign has played a small positive role in this regard.]
- Offering an attractive set of benefits for countries looking for innovation - Weighted R&D deduction, additional patent box benefits, progressive policies to increase innovation funding.
- Strong linkages between academia and industry, industry-oriented research.
- E.g., The US created the Bayh-Dole Act encouraging academics to set up independent companies.
- World-class centres of excellence to attract global talent and support cutting-edge research.
- A favourable policy landscape across research, technology commercialization and Intellectual Property.
- Innovation hubs to accelerate collaboration - Co-locating academia, public R&D centres, industry, start-ups and incubators.
- Policy support by way of R&D tax breaks, patent law tweaks and research talent.

Source: Business Line

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