



## Regulations for boosting the innovations

### What is the issue?

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Regulations are needed for the development of Pharma in India.

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### What are Indian measures to promote innovation?

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- India, recently signed an agreement with his Israel to create a \$40 million innovation fund to connect innovators from India and Israel with larger R&D opportunities.

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- Funds has been allocated for Impacting research innovation and technology (IMPRINT) initiative.

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- India Innovation Index to rank Indian states on their innovative spirit, to create an innovation-centric economy for India.

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### Why Indian market is averting innovations?

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- The ethos of innovation seem to lose with regulations prevailing in India.

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- Indian regulators routinely adopt strategies, including egregious 'price control' mechanisms which hinder the ability of the industry to innovate.

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- Price control measures deny an innovator the right to price goods in line with what the market will permit.

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## **What is the status of Indian Pharma device industry?**

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- India has a \$2.5 billion medical-device industry.
- The growth rate of India's medical-device industry is around 15% which is more than double of the global industry growth rate.
- It is expected to become a \$25-30 billion industry in India by 2025.
- But, India spends a woeful little of only 0.9% of its GDP in bio-pharma research.
- It is largely dependent on other countries for supply of pharmaceutical ingredients and medical devices.

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## **What are the issues with Pharma R&D?**

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- In February, the NPPA (National Pharmaceutical Pricing Authority), ventured from drug pricing into medical device pricing.
- It slashed prices of stents, a tube-like mesh placed to unblock arteries to maintain the heart's blood supply by about 85%.
- NPPA put all drug-eluting stents into a single category and price, with no consideration of innovations that have led the industry from first to the fourth generation of stents.
- NPPA disallowed stent manufacturers from withdrawing their loss-making products from the market for at least six months to avoid any shortage.
- This essentially means that stent manufacturers can neither decide the price nor the type of stents they can sell in India.

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## What is the need for moral regulatory practices?

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- The absence of robust medical devices regulations in India may be the reason for NPPA's current approach.

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- Price control is a blunt regulatory instrument and is not a substitute for genuine healthcare reform.

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- Regulatory trends by mandating price levels below market will cause such foreign suppliers to withdraw from the Indian market ultimately harming the Indian patients.

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- Countries like the US and the UK have their drug regulators.

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- They subject new devices to rigorous rounds of clinical trials, assessing their improvements and innovations before approving such devices.

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- NPPA need to re-imagine their regulatory strategies from policing price to that of nurturing innovation.

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**Source: Financial Express**

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