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India's pharma sector should go from volume to value leadership

We should simplify and strengthen our regulatory system for this industry to fulfil its potential

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The Indian pharmaceutical industry is a formidable global force today, shaping global health outcomes. During the covid pandemic, the sector showed its manufacturing resilience by ensuring uninterrupted supply of quality-assured medicines to more than 150 countries across the world. Today, the industry ranks third worldwide in terms of production volume and 14th in overall value. Globally, the innovation space accounts for two-thirds of the value in this sector. By leveraging its inherent strengths in manufacturing, digital talent and favourable demographics (in terms of a youth preponderance), India has the potential to become a global life-sciences innovation hub and grow its market to $120-130 billion by 2030 and $400-450 billion by 2047.

Compared to global pharma firms that typically spend around 20-25% of their revenues on research and development (R&D), Indian companies spend approximately 8% of their revenues on the same. The government has recently announced a package of ₹5,000 crore in funds under its Promotion of Research & Innovation Scheme. These funds will be allocated to create a centre of excellences and promote research in the private sector, a much-needed step for the industry to move up the value chain and become competitive globally.

Here is how the country could strengthen the regulatory framework to achieve the ends outlined:

Refocus the emphasis on innovation: Today, the regulatory landscape that the Indian pharma industry operates under is one of the most complex ecosystems when it comes to R&D. The existing regulatory framework involves multiple agencies, which often leads to lengthy approval timelines for companies. Simplifying these processes is crucial not only to speed up the journey from the laboratory to the market and foster sustainable growth, but also for the purpose of nurturing innovation.

The recent amendment of the New Drugs and Clinical Trial Rules (2023) underscores India's commitment to ethical research practices and innovation. Encouraging alternative methods such as computer simulation and test tube studies reduces reliance on animal testing, while better aligning Indian practices with global trends and fostering innovation. These rules prioritize patient safety and aim to enhance clinical research in India, supporting the industry's growth and innovation. These rule revisions are therefore welcome. But various other simplifications are needed too.

Double down on quality assurance: In terms of quality, India should align its regulations with global standards such as ICH/PIC(s) to establish itself as a global quality benchmark. The introduction of the New Drugs, Medical Devices, and Cosmetics Bill, 2022, was a step in the right direction, demonstrating India's commitment towards quality. This bill emphasizes the importance of safety, effectiveness and compliance with international standards, and also of aligning with global best practices. Harmonization with international regulatory bodies will help our producers command greater trust globally and encourage international collaborations, which are vital for the sector to reach its next level.

Keep pricing policy on an even keel: India has among the lowest priced medicines in the world, given the intensity of competition. The market can be broadly classified into 1,800+ subgroups, encompassing a staggering 55,000 odd brands, with each subgroup consisting of approximately 30 different brands on an average. Over the past three years, the annual price increase of medicines has been around 5%, lower than the Wholesale Price Index and Consumer Price Index increases. Despite a permissible 10% price increase for non-scheduled pharmaceutical products, high competition has kept it at 5% on average. The thrust of regulations should be on affordability and accessibility of medicines as well as the cost viability of products needed by the market. The pricing ecosystem plays a crucial role in attracting investments and fostering a greater emphasis on innovation and quality.

Encourage the sector to go from 'Make in India' to 'Discover and Make in India for the world': The Indian pharma industry is a knowledge-driven sector and of strategic importance for the nation. Today, India is regarded in many places as a 'pharmacy of the world,' with a focus on high quality but affordable medicines.

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, affordability and innovation. An enabling regulatory framework and stable policy environment will favour long-term investment decisions in research and innovation. Collaborations among key stakeholders—the government, regulators, industry and academia—will help India realize this vision and meeting the unmet needs of patients globally will have a positive impact on the nation's economy.