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India's pharma industry needs innovation-promoting and smart regulation to up its game

Certainly Worth the Shot

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The ongoing Covid-19 pandemic and the global race to develop a reliable vaccine, with attendant concerns about 'vaccine nationalism', reinforce the importance of investing in domestic research and development (R&D). Prime Minister Narendra Modi recognised the strategic importance of promoting indigenous innovation and entrepreneurship when he set up the Atal Innovation Mission (AIM). The cornerstone of an Atmanirbhar Bharat will have to be indigenous capacity and capability for R&D, innovation and translating ideas into globally competitive products and brands.

The Indian pharmaceutical industry is a fine example of how such investment in R&D, combined with supportive public policy, has created global players. However, the pharma, biology and healthcare industry needs a public policy framework that will support private investment in R&D and innovation to maintain India's pre-eminent position in this sector.

We have no dearth of scientific, academic and entrepreneurial talent in the industry. What we need are regulatory policies and institutions in step with the times, and sensitive to the needs of both research and business. The regulatory environment should be an enabling one based on the scientific competence of regulatory institutions.

The importance of intelligent — rather than mindless — regulation cannot be over-emphasised in the current context where the world is battling a deadly virus and seeking urgent solutions. Consider the fact that today Indian companies supply 60% of vaccines worldwide, and will emerge as important suppliers for a coronavirus vaccine too.

We have already seen how India emerged as a major source of HIV-Aids treatment, supplying vaccines and drugs at a fraction of the cost of drugs supplied by western firms. Accounting for 75% of the world market for HIV-Aids medicines, cost-effective Indian firms have helped save millions of lives around the world, especially in Africa.

The story of Indian generics increasing their share of the highly competitive US market, and capturing around 40% of the world market, is well known. Even with regard to active pharmaceutical ingredients (APIs), where China has emerged a major player, Indian companies remain competitive and capable of increasing their share of the world market. Indian pharma has also made its presence felt in biotech products and advanced insulin. For the industry to reach the next stage of development, it needs innovation-promoting and smart regulation.

Injecting a New Life

The experience of Indian firms operating in western and East Asian markets, including China, shows that there is significant scope for streamlining the regulatory and review process in India, in terms of timelines and simplification of processes. For patients, such changes would mean early access to new drugs, while innovators would also benefit from minimal loss of residual patent life.

Consider regenerative medicine. The existing regulatory framework in most countries was designed 30-40 years ago. While many western countries have persisted with old rules and regulations, countries like Japan and South Korea have updated their regulatory requirements and facilitated significant amount of research work. India, too, requires a smart regulatory environment for regenerative medicine.

Shall we proceed?

In the drug discovery space, our scientific regulations are in line with today's science. However, the process for approving various clinical trials is bureaucratic and time-consuming. Here, we must adopt the US and European model that focuses on safety in Phase 1 clinical trials, with government approving the laboratory areas where Phase 1 clinical trials are conducted, and not necessarily every stage of the clinical trial. Innovation and research should not be constrained by administrative processes.

AIM should undertake a forensic study of existing administrative processes that inhibit investment in R&D and weed out such constraints. Ensuring domain knowledge, and learning from industry experience within relevant institutions, would be a good first step for GoI to take.

Reform of regulation and of the review process pertaining to new drug development can go a long way in encouraging and sustaining research in new drug discovery. A reduction in time taken for securing clearances is very important. Delays in the review process cut into the products' patent life, and also delay patients' access to new medicines. Improved and efficient inter-agency and inter-departmental coordination in the review process can go a long way in ensuring ease of doing R&D.

The Wheels of Change

GoI may consider creating a separate and competent organisation equipped with domain knowledge for the approval of new chemical and biological entities. Indeed, some of the approval processes can be outsourced to experts within, and even outside, the country. This will reduce cost and time. Given the limitations imposed by the lifetime of patents, it is essential that Indian firms remain competitive even in doing R&D.

It is incumbent upon government to provide that competitive space to Indian firms by ensuring efficient regulation that is sensitive to cost and time requirements of firms investing in R&D. These initiatives will bolster GoI's 'Make in India-Make for the World' programme, and empower Atmanirbhar Bharat.

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