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Fostering R&D and innovation in pharma and medtech sector

The government pushes the frontier through an enabling policy and a novel scheme

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In the evolving tapestry of India's growth, few threads are as crucial as the pharmaceuticals and medical technology sector. These industries are not just economic pillars; they are also critical enablers of our nation's health and well-being. As we navigate the post-Covid complexities of the 21st century, it is imperative that we catalyse innovation in this sector, not just for realising the goal of Atmanirbhar Bharat, but also to meet the rising demand for conventional and novel medical products worldwide.

Prime Minister Narendra Modi's maxim of 'Jai Vigyan, Jai Anusandhan' has set the agenda for national progress powered by science, research and innovation. Nurturing research and development (R&D) and innovation are absolutely essential to make India a world leader.

The generics-driven pharmaceuticals industry must also emerge as a hub for drug discovery and development. The Indian pharmaceutical industry has the current market size of $50 billion, the third largest in the world by volume. Boosted by R&D and innovation, it could grow to $120-130 billion in ten years. Likewise, the med-tech sector should leapfrog from low-value products to cutting-edge devices and other medical technologies. The National Medical Devices Policy 2023, already in place, aims to propel the sector from the current $11 billion size to $50 billion by 2030 with R&D and innovation being the central lever.

To meet these aspirations, the central government has recently launched two complementary initiatives, namely, the National Policy on Research & Development and Innovation in the Pharma-MedTech Sector, and the scheme on Promotion of Research and Innovation in Pharmaceuticals and Medical Device (PRIP).

The need for robust R&D in the Pharma-MedTech sector cannot be overstated. The Covid-19 pandemic has brought to the fore the importance of innovation for healthcare products with speed, scale and affordability. Even as diseases of yore persist as challenges, new ones are emerging continuously necessitating improved medical counter-measures that are effective, affordable and safe. Advances in biotechnology, bio-engineering, digital technologies, artificial intelligence and regenerative science are opening pathways for new diagnostics, implants, therapies, monitoring devices, wearables, assistive appliances, imaging systems, medical robots, as well as primary health care products for Health and Wellness centres (such as a simple test for HbA1c to check blood sugar control).

Despite strong fundamentals, the Indian Pharma-MedTech sector is plagued by challenges such as a high degree of import dependence on Active Pharmaceutical Ingredients (APIs) and Key Starting Materials (KSMs), low technological capabilities in high-end scanning and imaging equipment, relatively low pace of development of biologics, biosimilars and other emerging products, among others. Our R&D investment in pharma and MedTech lags behind that of other nations. For instance, the US and China spend $50-60 billion and $15-20 billion, respectively, whereas India's investment is around $3 billion only. Our top ten pharma companies invest only around 7 per cent of their sales on R&D. This must change.

The policy: Creating a thriving ecosystem for R&D

In order to encourage R&D in pharmaceuticals and medical technologies, and create an ecosystem for innovation in this segment, a ‘National Policy on R&D and Innovation in the Pharma Med-Tech Sector in India’ has been launched. The objective of the scheme is to transform the Indian Pharma MedTech sector from cost-based to innovation-based growth. The policy serves as a blueprint to drive discovery and development of new drugs, vaccines, diagnostics and devices. It encourages collaboration and aims to elevate India's status as a global hub for cutting-edge healthcare solutions by creating a conducive ecosystem for innovation through stronger infrastructure, cross-sectoral research, enhanced public and private investments, and a streamlined regulatory framework.

At the heart of the policy lies the recognition that innovative products are critical to further improve health, wellness and longevity. The policy will promote collaboration between academia and industry, accelerate the development of groundbreaking treatments and technologies, and ensure that our healthcare system becomes a model of quality and effectiveness. This will guarantee that innovative drugs, devices, and diagnostics are not only accessible but also affordable for people. It is also proposed to set up an Indian Council of Pharmaceuticals and Med-tech Research and Development to facilitate and promote collaboration among industry, academia and research institutions, promoting domestic and international collaboration in R&D in Pharma-Med-tech sectors.

PRIP: A catalyst for delivery

The Promotion of Research and Innovation in Pharmaceuticals and Medical Device (PRIP) scheme is a new path-breaking intervention designed to promote R&D in the Pharma-MedTech sector in high-priority areas with a financial outlay of Rs 5,000 crore spread over 5 years. The PRIP scheme comprises two components.

Component A aims to strengthen research infrastructure by setting up seven centres of excellence (CoEs) in the National Institutes of Pharmaceutical Education and Research (NIPERs) with a Rs 700 crore investment. The scope of the CoEs would include anti-viral and anti-bacterial drug discovery and development, medical devices, bulk drugs, flow chemistry and continuous manufacturing, novel drug delivery system, phyto-pharmaceuticals and biological therapeutics. With generous funding through PRIP, these institutions will play

a more effective role in industry-academia collaboration and mentoring of scientific talent while simultaneously generating potentially viable products for greater public good.

Component B with an outlay of Rs 4,250 crore is targeted to specific projects in six priority areas. Some examples of the specified products in these areas include: new chemical/biological entities, complex generics and biosimilars, precision medicine, AI/ML-based devices, robotic surgical devices, orphan drugs and drugs against antimicrobial-resistant pathogens. In category BI, nine established pharma companies who are willing to carry out research in the priority areas with academic collaboration in government institutes of national repute will be provided support. In category BII, funding would be provided to 30 research projects in priority areas which are at successfully validated stage, namely, at technology readiness level (TRL) 5, to reach TRL 9, thus expediting their market launching and large-scale commercialisation process to take innovation to people. Under category BIII, funding would be provided to about 125 research projects in the priority areas to help Indian startups and SMEs/MSMEs to take products up to TRL 4 (ideation to proof-of-concept) stage.

This scheme recognises that innovation thrives when researchers have the resources and support they need. By funding research projects, supporting startups, industry and facilitating collaboration, the PRIP empowers innovators to turn their ideas into tangible solutions. It will also benefit animal health care science and market. Indeed, the scheme will help the Indian Pharma-MedTech sector transition to a high-value, high-volume enterprise in the near future.

The road ahead

These two initiatives will cultivate an R&D-friendly ecosystem within India. Their potential impact will be far-reaching and profound, extending beyond the realms of bolstering drug security and accessibility. They also hold the promise of generating high-end R&D manpower and employment opportunities while alleviating the burden of disease.

Simultaneously, the development of cost-effective and high-quality innovative pharma MedTech products of universal use would empower India to further its contribution to global health objectives, in alignment with the philosophy of ‘Vasudaiva Kutumbakam’.

As we embark on this journey of transformation, it is essential to recognise that innovation is not a one-time endeavour, but a continuous process. We must nurture a culture where

industry and academicians are encouraged to take risks in exploring new ideas, and failures are seen as opportunities to learn, and to do better next time.

The policy and scheme are ambitious steps to usher in an era of innovation-led growth of the Pharma-MedTech sector. To fully realise the potential of these initiatives, it is crucial that all stakeholders — government, industry, academia, startups and researchers — come together to capture the opportunity. This decade is decisive in this endeavour. We must change our approach, sharpen our priorities, align our efforts and work relentlessly in mission mode for the common goal of making India's pharmaceuticals and med-tech sector a global hub of innovation and of highest-value products.

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