Healthcare Update

Promotion for Research and Innovation in Pharma-MedTech

The Government of India (GoI) has focused on encouraging manufacturing in India and introducing innovative technologies. It has been instrumental in encouraging industries to 'Make in India' for domestic consumption and the world at large. The GoI has been regularly taking policy and regulatory interventions to help the industry manufacture and innovate in India. The AtmaNirbhar Bharat initiative, Production Linked Incentive Schemes, National Medical Device Policy, and New Drugs and Cosmetics Act (Draft) are examples of such initiatives. Taking forward this approach, the GoI last month announced the Promotion of Research and Innovation in Pharma-MedTech (PRIP) Scheme 2023. Under this scheme, the GoI has allocated USD 600 million over a five-year span for research and innovation activities in the field of Pharmaceuticals and Medical Devices.

Pharmaceuticals is a research-intensive industry and requires continued Research and Development (R&D) to not only remain competitive but also to grow the industry further. The Indian Pharmaceutical industry has accomplished significant milestones over the past four decades, the biggest of them being dubbed as the 'Pharmacy of the World'.

Over this period, Indian pharmaceutical companies have focused on generic drugs and held leadership for over two decades. The generic drug industry, while being complex, does not require R&D in comparison to patented drugs or creating New Chemical Entities (NCEs). Hence, the R&D spend has hovered around 3-5% of sales at industry levels which rises up to 7% for the Top 10 companies. There is an urgent need to increase this spending significantly to not only remain competitive but also to take the next step in the value chain. Recognizing this need, the GoI has identified five priority areas that hold the potential for the future and will help the industry leapfrog into the future.

The PRIP scheme also covers the Medical Devices industry. Along with the Pharmaceuticals industry, Medical Devices are an integral part of the Healthcare sector. The industry currently has a market size of around USD 11 billion and is expected to reach USD 50 billion by 2047. The industry has witnessed sustained growth if we exclude the COVID years. It is expected to continue to grow in the range of 15-18% CAGR for the next decade. It is an import-dependent industry with more than 70% of devices being imported even now.

To help reduce this number, the GoI has taken several steps as they did for pharmaceuticals (devising New Medical Devices Rules, 2017 and the Medical Device Policy, 2023, and topping it up with Production Linked Incentives (PLIs) to encourage domestic manufacturing. The missing piece in this reform was R&D. With the PRIP scheme, the government is addressing that need while also providing the industry with an opportunity to lead the world in affordable but innovative technologies in the field of Medical Devices.

We have compiled a list of key features of the scheme below:

Sr. No.	Scheme Features	Promotion of Research and Innovation in Pharma-MedTech Sector
1	**Release Date**	16 August 2023 The scheme was notified vide Gazette Notification No. 50018/2/2022-NIPER — Scheme for Promotion of Research and Innovation in Pharma-MedTech Sector (PRIP)
2	**Scheme Objectives**	The objective of the scheme is to transform the Indian Pharma-MedTech sector from cost-based to innovation-based growth by strengthening the research infrastructure in the country. The aim of the scheme is to promote industry academia linkage for R&D in priority areas, inculcate a culture of quality research, and nurture our pool of scientists. This will lead to a sustained global competitive advantage and contribute to quality employment generation in the country.
3	**Components**	Component A - Strengthening the research Infrastructure Component B - Promotion of research in the Pharma-MedTech sector
4	**Total Funding Outlay**	Component A • Strengthening the research infrastructure – Setting up Centers of Excellence (CoEs) at National Institutes of Pharmaceutical Education & Research (NIPERs) – USD 84 million Component B • Category B I – USD 136 million • Category B II – USD 360 million • Category B III – USD 15 million
5	**Features of Component A**	It is proposed to establish Centers of Excellence (CoEs) in the seven existing NIPERs at Mohali, Ahmedabad, Hyderabad, Guwahati, Kolkata, Hajipur, and Raebareli over a period of five years in the following specializations: • NIPER Mohali - Anti-Viral and Anti-Bacterial Drug Discovery and Development • NIPER Ahmedabad - Medical Devices • NIPER Hyderabad - Bulk Drugs • NIPER Kolkata - Flow Chemistry and Continuous Manufacturing • NIPER Raebareli - Novel Drug Delivery System • NIPER Guwahati - Phyto-pharmaceuticals • NIPER Hajipur - Biological Therapeutics

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6	**Eligible Areas / Products under Component B**	Area/Product 1 • New Chemical Entity (NCE) • New Biological Entity (NBE) • Phyto-pharmaceuticals (natural product) Area/Product 2 - Complex Generics: Products with • A complex active ingredient(s) (e.g. peptides, polymeric compounds, complex mixtures of APIs, naturally sourced ingredients, etc.) • A complex formulation (e.g. liposomes, colloids) • A complex formulation technology and manufacturing processes permeation enhancers with continuous flow manufacturing • A novel route of delivery (e.g. locally acting drugs such as dermatological products, complex ophthalmological products and optic dosage forms that are formulated as suspensions, emulsions, or gels) • A complex/novel dosage form (e.g. modified release formulations, transdermal, metered dose inhalers, extended-release injectables, etc.) • Innovative drug-device combination products (e.g. medicated catheters, auto-injectors, metered doses, inhalers, etc.) Area/Product 3 - Precision Medicine (targeted innovative therapeutics): • Any approach that uses information about a person's genes or proteins to prevent, diagnose, or treat a disease • Stem cell therapy, gene therapy • Bio-markers Area/Product 4 – Medical Devices: • AI/ML based Medical Devices with software development, Software as Medical Devices (SaMD) and Software in Medical Devices (SiMD) • Medical diagnostics and screening devices with genetic technology • Robotic medical devices for surgical procedures • Medical devices with telemedicine facilities Area/Product 5 - Orphan Drugs: • Medicinal products intended for diagnosis, prevention, or treatment of life-threatening, very serious diseases, or disorders that are rare (about 450 rare diseases are recorded in India in tertiary care hospitals) Area/Product 6 - Drug Development for Antimicrobial Resistance (AMR) • Prioritization will be done within and among categories based on future potential, opportunities, and national importance
7	**Duration of Scheme**	The tenure of the scheme is from FY 2023-24 to FY 2027-28

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<tr><th>Sr. No.</th><th>Scheme Features</th><th>Promotion of Research and Innovation in Pharma-MedTech Sector</th></tr>
<tr><td>8</td><td>Scheme Financial Details</td><td>
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<tr><th>Group of Participants</th><th>No. of projects to be selected</th><th>Funding (over five years)</th></tr>
<tr><td>Category B I</td><td>9</td><td>• Nine established pharma companies who are willing to carry out research in six priority areas will be selected for academic collaboration in GoI institutes of national repute
• The companies would avail the facilities of the research infrastructure (lab, equipment, support staff, etc.) available at national institutes. In addition, the company must provide training to a selected number of students/scientists of the institutes
• Investments made by the companies on the projects at the institutes would be supported with financial support at the rate of 35% of the total cost incurred or USD 15 million, whichever is less on a milestone basis (from TRL 1 to reach TRL 9) over a period of five years under the benefit-sharing principle</td></tr>
<tr><td>Category B II</td><td>30</td><td>• Funding would be provided to thirty research projects in six priority areas that are at successfully validated level (TRL 5 and above) to reach TRL 9 at the rate of 35% of the cost or USD 12 million, whichever is less over a period of five years under the benefit-sharing principle
• The projects would be selected on the basis of TR level
<table>
<tr><th>Sr. No</th><th>TRL Level</th><th>Percentage of Funding</th></tr>
<tr><td>1</td><td>5 to 7</td><td>30%</td></tr>
<tr><td>2</td><td>7 to 9</td><td>40%</td></tr>
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<tr><td>Category B III</td><td>125</td><td>• Funding would be provided to research projects in six priority areas to help Indian start-ups and MSMEs reach TRL 4
• Funding up to USD 120,000 would be provided per project over a period of five years in a milestone manner from ideation to proof of concept on a royalty-sharing basis</td></tr>
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<tr><td>9</td><td>Benefit-Sharing for Category B I & II</td><td>• The funding disbursed for the projects will be recovered through benefit-sharing (excluding refunded funding, if any) either through royalty or equity in the following ways:
• 10% royalty on the net sale of the product/technology till the patent is effective or</td></tr>
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Sr. No.	Scheme Features	Promotion of Research and Innovation in Pharma-MedTech Sector
9	**Benefit-Sharing for Category B I & II**	• Equity (not less than 100% of the Department of Pharmaceuticals (DoP) support provided) • The DoP may seek payment by way of a one-time transaction in the occurrence of events as under: • The fund recipient entity successfully commercializes the product/technology supported through the DoP-PRIP scheme • Licensing/assignment/technology-transfer of the project developments to any third party where the 'Fund Recipient' is not undertaking direct market reach which also be treated as successful Commercialization and the Fund Recipient shall be liable for benefit-sharing with the DoP • If the 'Fund Recipient' intends to transfer or sell/assign the interest of project developments, it shall take prior written permission from the DoP before doing so. The DoP reserves the right to realize benefit-sharing in case of a one-time transaction as will be mutually agreed while granting such permission • If the 'Fund Recipient' licenses the interest of project developments for periodical payments including royalty, then the 'Fund Recipient' can also continue to share the benefits as prescribed by the DoP to be met from the periodical proceeds received from licensees/sub-licensees • In cases of significant changes such as public offering of shares, raising of venture funds, change in shareholding pattern, change in the legal entity status, merger and acquisition, etc., the DoP reserves the right to enforce the benefit-sharing obligation or the 'Surety Bond' and recover the remaining benefit-sharing committed for the project through the resolution or liquidation process as a receivable in favor of the DoP. Payment of royalty shall be applicable with the first sale of the product(s) and the liability to pay royalty will terminate upon the first of any of the following two events to occur: • 10% royalty has been paid till the patent is effective or in the form of equity or • In case of foreclosure or termination of the project • In case the project is declared unsuccessful/commercially unviable, the remaining assistance would not be released and any unutilized amount as on date would be refunded to the Department of Expenditure within 30 days of the declaration
10	**Project Appraisal and Approval Committee**	A committee under the chairpersonship of the Secretary of the Department of Pharmaceuticals will be set up with representatives (not below the level of Joint Secretary) from DST, DSIR, DBT, DGHS, DHR, AYUSH, and CDSCO, which will examine and approve the projects, consider and approve claims for disbursements, and take appropriate steps to contain the expenditure within the prescribed outlay
11	**Implementation Agency**	The PMA would be responsible for the receipt of applications, appraisal of the applications, verification of eligibility threshold criteria, and examination of claims for disbursement of incentives. Compilation of the data regarding the progress and performance of the scheme, including cumulative investment in research and investment in priority areas of research in Pharma MedTech, is to be done by selected applicants
12	**Eligible Applicants**	Application under the scheme can be made by any company registered in India

Conclusion

Any nation's development is built on foundations of innovation. A nation that does not encourage research and development will not climb the development ladder quickly. While India has been conducting R&D at its own pace considering the restraints of resources and knowledge, it needed a catalyst to accelerate development. The PRIP scheme will act as catalyst that will expedite R&D in the country and more importantly, build a culture of sustained research and innovation. This also marks a paradigm shift in the Healthcare sector from a foundation of cost-centric competitiveness to one that will progress on innovation-driven growth. The policy takes a first principles approach of understanding the basics of Pharmaceuticals and Medical Devices products in an academic environment and then building on that knowledge by collaborating with the industry, leading to innovative commercial products. Establishing specific CoEs at NIPERs with in-house research graduates will also assist the Pharmaceutical and Medical Devices industry with skilled manpower for continuing R&D efforts. Component B of the scheme covers everything from complex generics to NCEs, providing ample opportunities to organizations from across the spectrum to participate and innovate in India.

The PRIP scheme in conjunction with the Bulk Drug and Medical Device Parks alongside PLI schemes will augment the entire value chain of the domestic manufacturing industry. The GoI has provided the Healthcare sector with a strong base to not only maintain its leadership position in Pharmaceuticals but also emerge as a strong player in Medical Devices industry. It is crucial to mention that such initiatives open India to the world in the form of skilled labor, increased capital inflows, and shifting manufacturing bases as over the next few years, India will have a complete ecosystem for healthcare.

About Nexdigm

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