National Policy on Research & Development and Innovation in the Pharma-Med Tech Sector in India

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1. Preamble

1.1. Indian pharmaceutical industry is the 3rd largest pharmaceutical industry in the world by volume with a current market size of around USD 50 Billion (approximately ₹ 4,10,000 crores) and is widely known as 'Pharmacy of the World'. Going forward, the Indian pharma industry could potentially grow to USD 120-130 Billion (₹ 9,84,000 to ₹10,66,000 crores) over the next decade, increasing its contribution to the GDP by about 100 basis points.

1.2. The Indian pharmaceutical industry has played a key role in driving better health outcomes across the world by being a large and reliable supplier of affordable and high-quality generics drugs. The sector has contributed significantly in increasing the accessibility of affordable drugs in India and thereby substantially reducing the disease burden in the country. Over the years, Bio-pharmaceuticals are becoming a key driver for growth in global Pharmaceuticals, with the increasing emergence of biologics and biosimilars. The vaccine industry in India has proven its capacity for manufacturing at scale (catering to more than 60% of global vaccine demand). The medical devices sector is an essential and integral constituent of the Indian healthcare sector and forms an important pillar in the healthcare delivery system along with healthcare providers, pharmaceuticals and healthcare insurance industry. As India is a bio-diverse country, rich in flora and fauna. In recent years, efforts have been initiated by M/o AYUSH to integrate traditional medicines and phyto-pharmaceuticals into the mainstream public dialogue and practice.

1.3 In order to encourage R&D in pharmaceuticals, including traditional medicines & phyto-pharmaceuticals and medical devices, and to create an ecosystem for innovation in this sector in order for India to become a leader in drug discovery and innovative medical devices, a 'National Policy on R&D and Innovation in the Pharma- MedTech Sector in India' is the need of the hour. The proposed policy acknowledges the need for greater emphasis on encouraging R&D, through indigenously developed cutting- edge products and technologies across the value chain so as to sustain global competitiveness while meeting Health Goals. The policy is built upon three focus areas, namely, strengthening the regulatory framework, incentivizing investments in innovation and creating a facilitatory ecosystem for Innovation.

2. Need for the Policy

2.1. Despite strong fundamentals, there are areas of concern that need to be addressed for the sustained growth of the Pharma-MedTech sector. These challenges are, (i) the high degree of import dependence on Active Pharmaceutical Ingredients (API) and Key Starting Materials (KSMs) (ii) the relatively low pace of development of biologics, biosimilars and other emerging products/ trends (iii) low technological capabilities in high-end scanning and imaging equipment; and (iv) need to generate acceptable scientific evidence for mainstreaming of Traditional medicines.

2.2. While giving a clarion call for '*Atmanirbhar Bharat*', the Prime Minister highlighted that India can only achieve self-reliance in pharmaceuticals and medical devices by strengthening its R&D infrastructure that would drive the expansion of access to life-saving medicines and drugs and help India to become a global pharmaceuticals and medical devices exports hub.

2.3 Over past few decades, disease profile and demographic profile has been evolving in India and new therapies are emerging globally. These include Precision medicines, cell and gene

therapy, greater reliance on biological products and use of Digital tools. Most of the medicines in these categories are imported. A policy to foster Research and innovation in a focused manner would help enhance domestic availability and affordability of these categories of new age therapeutics. At the same time, development of affordable and high quality innovative drugs and devices would enable India to enhance its contribution to Global Health goals as part of the philosophy of Vasudaiva Kutumbakam.

2.4. The COVID-19 pandemic has brought to the forefront the role of innovation in expanding the scale, access and affordability of healthcare products. The role of innovation in providing vaccines and medical equipment at scale and of quality that can work in countries at different stages of development has been critical to the management of the pandemic. The benefits of repurposing drugs and the proliferation of Monoclonal antibodies (MABs) have also highlighted the role of innovation in tackling global emergencies. A cogent policy is needed to shape the transformation of the experience of the COVID Pandemic into a broader and more systematic approach for improving preparedness of the Indian Pharma MedTech sector to meet medical emergencies.

2.5. At a global level, Pharma and MedTech innovators are moving toward the application of telemedicine, Artificial Intelligence (AI) & Machine Learning (ML), Virtual Reality (VR), Internet of Medical Things (IoMTs), nanotechnology, robotics & 3D printing, as well as big data and advanced analytics for aided diagnosis. Several enablers including a strong local industry, export experience, and depth of technical capabilities can help Pharma and MedTech sectors work towards the vision of 'Discover in India' and build a strong ecosystem for healthcare innovation. Achieving this vision will not only help India maintain its global relevance but also drive significant health and economic benefits for the country by meeting the current unmet needs in India. A policy direction to focus efforts on such drug discovery can generate substantial health benefits for India by enabling the development of drugs for India-specific ailments, which do not get adequate attention globally.

2.6. About 70% of human pathogens in last three decades globally have animal origin. Animal disease outbreak leads not only to mortality and morbidity but also directly and indirectly impact economy through loss of productivity. It is estimated that India has lost upwards of USD 40-45 Bn (Rs 3,28,000-Rs 3,69,000 crores) due annual disease outbreak. Most of the drugs developed are similar for human and animal health albeit with different dosage forms. A policy which promotes R&D in pharmaceutical sector will also benefit animal health care market thus aligning with the vision of "ONE HEALTH".

2.7. A larger share of global value capture (40% of a market of 6.65 trillion USD) in the pharmaceutical sector lies in innovation- based products. A policy to promote drug discovery and innovation will unlock this value and will also enhance the industry's contribution to Indian economy (additional USD 10-12 Bn ((₹ 82,000 to ₹ 98,400 crores) in exports every year) and create a large pool of white-collar jobs to enhance India's differentiation vis a vis other developing economy.

2.8. The increased spending on healthcare globally, the increase in the size of the Indian middle class, the commitment to Universal Healthcare and the attention to schemes such as *Ayushman Bharat – Pradhan Mantri Jan Arogya Yojana* (PM- JAY) and *Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana* (PMBJP), etc. have created a sustained demand trajectory for Pharma and MedTech sectors. The demand for better therapeutic outcomes, the trends in in-home treatment, personalized diagnostics, wearables, telemedicine, etc. have created scope for differentiated product and service offerings. In order to capture these opportunities, the Pharma-MedTech sectors would have to move out of their comfort zone and to adopt innovation as a driving feature of their business strategies.

2.9. The R&D in Pharma and MedTech in the public institutions is currently spread over various research departments/ institutions. A policy guidance encouraging the coordination among these departments and Institutions would also contribute to optimizing existing Research resources for efficiency, prioritization and alignment with national health priorities.

2.10. The Policy aims to address the above-mentioned needs including strengthening the innovation ecosystem by focusing on key areas, such as drug discovery programs to be built on National Health priorities based on the burden of disease, promoting discovery-based research to build a pipeline of new molecules, novel drug delivery systems, development & standardization of phyto-pharmaceuticals and evaluation of drugs for repurposing, and boost core technologies in medical devices.

3. Objectives of the Policy

3.1 The objective of the policy is to achieve *Atmanirbharata* in Pharma- MedTech sector through measures to accelerate R&D and innovation. The specific objectives of the Policy are as under:

i. To enable rapid drug discovery and development and innovation in medical devices by streamlining of regulatory processes;

ii. To incentivize private sector investment in research and explore various funding mechanisms – Budgetary support, Venture capital, CSR funding, etc. and fiscal incentives to support innovation;

iii. To strengthen R&D ecosystem through increased collaboration between Industry and Academia;

iv. To enable coordination among the existing policies and programs of various departments/ agencies/ institutes in order to develop mechanisms to dovetail research as per the requirement of the sector; and

v. To facilitate the rapid development and availability of innovative drugs and medical devices in India.

4. Focus areas of the Policy

4.1. The Policy postulates three main areas for focus to achieve the above objectives. The first is to create a regulatory environment that facilitates innovation and research in product development, expanding the traditional regulatory objectives of safety and quality. The second focus area would be to incentivize private and public investment in Innovation through a mix of fiscal and non-fiscal measures, thereby matching risks with remunerative financing options. The third area of focus will be to build an enabling ecosystem designed to support innovation and cross-sectoral research as a strong institutional foundation for sustainable growth in the sector. The following paragraphs, based on the recommendations in the Report to Catalyze R&D and Innovation in Pharma- MedTech sector describe how the measures proposed under these three focus areas meet the policy objectives.

A. Regulatory Framework: Streamlining Processes / Approvals

4.2. Regulatory frameworks are currently geared towards assuring safety and efficacy and do not necessarily differentiate in favour of innovation. The Drug Controller General of India in the Central Drug Standards Control Organization (CDSCO) is the licensing authority, but there are multiple agencies with different mandates and expertise that an Innovator firm has to navigate, particularly for research in biologics and medical devices. Indian regulators are now working towards establishing global harmonization in this regard, with modifications in the Clinical Trial Rules, 2019 and introduction of the Medical Devices Rules. Another major challenge lies in building regulatory capacity within the government to keep up with the latest advances in science and technology and reduce dependence on ad-hoc external inputs. All of this contributes to long timelines for grant of approval to innovative products, which has been identified as an area of concern.

Therefore, the following measures are contemplated to create a regulatory bias in favour of Innovation and original research:

i. **Process optimization:** A mechanism will be explored by the government that will mandate all the regulators to work together to reduce process overlapping and establish timelines for requisite approvals. Data protection and time bound processing of regulatory approvals will be an important aspect to be followed by the regulators. It will aim to bring down the current time taken for regulatory approvals for innovative products by at least 50% within the next two years.

ii. **Technology based platform:** Creation of a single end to end digital portal which

would be used by different departments/ regulators will offer a single interface between Innovator and Regulator and would potentially align with Ease of doing Business and reduce Compliance Burden, both being stated goals of Government. The technology based single point of interaction shall aim to bring transparency, timeliness and predictability to processes and outcomes around regulation.

iii. **Regulatory Capacity:** Various measures to strengthen the existing institutional capacity of the regulatory bodies, will be explored which would include building in-house expertise in respect of New Biological Entities and New Chemical Entities, Biologics, Imaging medical technologies, New Materials, tele - diagnostics, AI/ML based innovations, Sensors, etc. National Pharmaceutical Pricing Authority (NPPA) would work to develop greater expertise in the pricing of new innovative products while pursuing affordability as an overall objective. Collaboration with relevant international regulatory agencies and capacity building of regulators will enable them to introduce benchmarked best practices, stay ahead of the curve and add value to the expansion of the Pharma- MedTech sectors through Innovation.

iv. **Legislation:** A review of the multiple legislation impacting research and development in Pharmaceuticals and Medical Devices could be undertaken to identify areas of friction and design tenable solutions. Some of the areas indicated for such effort include differentiated handling of research in products that are cultured and cultivated artificially, increasing the number of bodies that can approve pre-clinical trials, enabling joint inspections and licensing mechanisms for traditional medicinal products.

B. Incentivizing investment in Innovation

4.3. The Pharmaceutical and Medical Devices sectors are being encouraged to build global champions by enhancing domestic manufacturing capacities. Production Linked Incentive (PLI) Schemes cover investments and production of biopharmaceuticals, patented drugs, complex generics, specific high-end segments of medical devices such as Cancer care/ Radiotherapy, Radiology & Imaging, Anaesthetics & Cardio-respiratory equipment etc.

4.4 However, private investment in innovation is challenging given the long gestation, technological and regulatory complexity and external uncertainties associated with research in Pharmaceuticals including biologics, the interdisciplinary nature of innovation in medical devices, and the capital & resource intensive Bioequivalence Studies and Clinical Trials in Pharmaceutical & MedTech research. Specifically, there is a need for access to finance to enable investment through the research life cycle, consistent policies across schemes for assessment of innovation, and financing support for late-stage research. The policy focuses on the provision of appropriate fiscal and non-fiscal incentives for Pharmaceuticals/ MedTech innovations by introduction of direct/ indirect funding support to promote India as an innovation hub. The interventions would be in compliance with multiple treaties with foreign countries wherein inter alia the Government of India has committed to non-discriminatory treatment of foreign investments in the country.

4.5 The Union Budget 2022-23 has indicated the proposal to explore Blended Finance products for Pharmaceuticals sector and an Innovation Fund for the promotion of Pharma-MedTech start-ups focusing on new-age technologies will be explored by the government within the extant SEBI regulations. There is also a need to look at a range of interventions that would facilitate funding support for innovation such as schemes to support investments into R&D/ innovation, reimbursement of R&D spending and appropriate fiscal incentives, review of scope of the patent box etc.

4.6 Funding support can also be explored from the existing and future government programs and schemes to aid R&D based innovation in the sector such as National Research Foundation (NRF) and Biotech Innovation Fund and leveraging the existing available fund support available with various Ministries and departments for focused outcome-oriented Pharma and MedTech research. Thus, a compelling 'Discover

in India' vision is to be created as a message to be actively disseminated across stakeholders.

C. Enabling ecosystem for Innovation and Research

4.7 The industry and individual institutes working on Pharma-MedTech research are largely working independently or through informal ad-hoc cooperation. There is a need to support the creation of a wider ecosystem that systematically recognizes, facilitates and rewards innovation and research. The policy, therefore, proposes to address the following three areas for building a robust enabling ecosystem:

4.7.1 Industry-academia linkages: Innovation and Research would be benefited by strengthening the academic infrastructure and its subsequent integration into a coherent framework for building skilled manpower for the Pharma and MedTech sectors. Currently, pharmaceutical education is governed by the Pharmacy Council of India. In addition, NIPERs work as Institutes of national importance for postgraduate and doctoral study. Considerable effort is also warranted to modernize and diversify the curriculum in pharmaceutical education, institutionalize industry engagement, covering a holistic approach to prepare manpower to navigate and lead the technology changes in research and manufacturing. This would be in line with the National Education Policy, 2020.

4.7.2. The multidisciplinary nature of the medical devices sector covering material science, electronics, sensors, biochemistry, etc. requires the sector to draw upon talent from a wide range of academic institutions including the Indian Institutes of Technology (IITs). Developing a talent ecosystem that supports the medical device sector by a steady supply of skilled work force across the innovation value chain (e.g., scientists, regulators, health experts, managers, technicians, etc.) is necessary for the growth of the sector which will be done in collaboration with ministry of skill development. Further, the setting up Institutes of National Importance (INIs) in the area of MedTech education and research in line of NIPERs would enhance the development of talent pool with academic and research skills.

4.7.3. The capacity building programs should adequately factor in skill development to build next generation inter- disciplinary skills for product innovation, knowledge of navigating regulatory policies, business development capabilities, better management of IPR systems and practices for building effective workforce and next generation leaders. Efforts would be made to attract global educational institutions of eminence to create centres in India, leveraging the provision in the National Education Policy (NEP) allowing foreign universities to open campuses in India.

4.7.4. The importance of setting up a strong governance framework will also be key to build trust and accountability to ensure accountability, strong program management to monitor and report progress and a robust performance framework with the upfront alignment of objectives and funding linked to outcomes.

4.8. Collaborating across institutions and sectors: While a great deal of the R&D and Innovation that leads to the launch of innovative medical products takes place in the Industry, a number of Research centres are also operating in the Government sector on various aspects of Pharmaceuticals and Medical Technology and associated fields. The multiplicity of institutions and programmes supporting research and innovation in the Pharma- Med-Tech space makes articulation as well as the implementation of research on priority areas challenging. Collaboration is also required across the entire product development cycle due to its multi- disciplinary nature, covering drug discovery, drug delivery, device design, clinical trials, therapeutic and incremental innovations etc., There is also a need to align current pharmaceutical R&D focus in line with the disease burden of the country and meet evolving priorities such as drug security, resilience in value chains and building domestic capacities.

The broader objectives of the R&D Policy for Pharmaceuticals and Medical Devices have been aligned with the Science, Technology and Innovation Policy (STIP) of the Department of Science & Technology (DST) to build a nurtured ecosystem that promotes research and innovation for India to march ahead on a sustainable development path for achieving an 'Aatmanirbhar Bharat'.

4.9 A number of steps are proposed to be taken to integrate the existing policies and programs of various departments to develop mechanisms to dovetail research as per dynamic requirements in healthcare through the setting up of an Inter-Departmental Research Council namely the Indian Council of Pharmaceuticals and Med-tech Research and Development to facilitate, strengthen outreach mechanisms, and promote collaboration across industry, academia and research institutions across Departments for domestic and international collaboration in R&D in Pharma MedTech sectors. The Council would have an agile and slim structure with a focus on prioritizing areas for research based on national healthcare priorities, building synergies, strengthening outreach mechanisms, convergence with various schemes of the Government of India and promoting the sharing of information among these research bodies, for Resource Optimization. The proposed Council would also lead the Drug Discovery Mission as a multi- institutional initiative by pooling the strengths and talents of research institutions under DoP, DHR, DBT and CSIR, educational institutions such as IITs, IISc, IISERs, etc. and Public- Private Partnerships (PPPs).

4.10 Taking forward the compelling lesson learned from Covid-19 to showcase India's strength and prowess in recent times, the government will pursue the promotion of "Innovate in India" concept. To achieve this and to promote India as an "innovation hub", in line with the Atal Innovation Mission., various interventions will be explored to build a strong brand along with effective dissemination of the same among target investors looking at making R&D investments in India in the Pharma-MedTech sector.

4.11. **Building Innovation infrastructu**re: While research institutions in the Government sector have an important role in promoting basic and applied research, much of the innovation that leads directly to patient benefits take place through private entrepreneurs and innovator firms. Under the Atal Innovation Mission, Government is setting up Atal Incubation Centres (AICs), in the public and private sectors as well as scaling up Established Incubation Centres (EICs). A number of Startup Incubators are already functioning in life sciences, biotech, medical devices and MedTech space under Start up India. However, the current infrastructure is limited and concentrated in a few nascent innovation hubs in the country, emphasizing the need for more high-quality infrastructure. Measures will be explored for strengthening the infrastructure for innovation in Pharma MedTech Sectors in India, including scaling up, creating sub-sector specific hubs, integrating Centres of Excellence with Innovation hubs.

5.0 Implementation and Monitoring

A. Implementation Framework

5.1 A High-level Task Force will be set up in the Department of Pharmaceuticals under the Minister for Chemicals and Fertilizers to guide and review the implementation of the Policy. The Task Force will draw upon resource persons from Departments and Organizations related to the implementation as the success of the policy requires coordinated action by several agencies.

5.2 The Policy will be supported by a ten-year Strategy and action plans that will spell out the policy and programmatic interventions required from time to time within the Policy.

B. Monitoring and evaluation:

5.3. A Monitoring and Evaluation Framework would be designed with the help of Development Monitoring and Evaluation Office (DMEO) NITI with rational Target setting, resource optimization, and a portal-based reporting mechanism. Risk to implementation would be defined and risk management plans would be devised for consideration by the High-Level Task Force. Industry-led Advisory Committee would be set up for continuous feedback on the implementation and monitoring. Independent evaluation would be carried out at the prescribed periodicity against the defined outcomes.

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