


F. No. 50020/5/2020-NIPER
Department of Pharmaceuticals
Ministry of Chemicals & Fertilizers

Janpath Bhawan, New Delhi

Dated 25th October, 2021

Subject: Circulation of Draft Policy to Catalyze Research & Development and Innovation in the Pharma- MedTech Sector in India through DoP's Website.

The Department has prepared a draft policy document to 'Catalyze Research & Development and Innovation in the Pharma- MedTech Sector in India' which has been hosted on the Department's website seeking comments thereon. The comments thereon may be sent to the undersigned by 6th November, 2021.


(Krishna Kumar P.)

Director, DoP

Tel: 011-23324930

Email: dir-pharma@gov.in

Draft Policy to Catalyze Research & Development and Innovation in the Pharma- MedTech Sector in India

1. Preamble

The pharmaceutical and medical devices sectors in India have shown impressive growth over the years. Globally, India Pharmaceutical sector has contributed significantly to improve health outcomes while the Indian Medical Devices sector is well poised to pursue its constant growing trajectory. The Government is committed to promote Indian Pharma-Medtech as globally competitive sectors to ensure availability, accessibility and affordability of drugs and medical devices in domestic and global markets. One of the key policy measures to achieve this objective is to increase attention in India to Research & Development and innovation, which accounts for 2/3rd of the global pharmaceutical opportunity.

This “Policy to Catalyze R&D and Innovation in the Pharma- MedTech Sector in India” is a commitment to encourage Research & Development (R&D) in pharmaceuticals and medical devices and to create an ecosystem for innovation in the sector in order for India to become a leader in drug discovery and innovative medical devices through incubating an entrepreneurial environment. It acknowledges the need for greater emphasis on encouraging R&D, through indigenously developed cutting-edge products and technologies across the value chain.

Recognizing that R&D is integral to enhance the benefits of the Pharma - Medtech sectors towards meeting the health care needs of the country, a comprehensive national policy framework is proposed to build a robust ecosystem to ensure the holistic development of R&D and Innovation. The sector objectives in turn, can contribute to achieving SDG 03 namely “*Ensure healthy lives and promote well-being for all at all ages*” and specifically the Target 3.8. “*Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all*”. The policy is built upon three focus areas, namely, strengthening the regulatory framework, incentivizing investments and creating a facilitatory ecosystem for Innovation.

2. Background to the Policy

2.1 India is well recognized as the pharmacy of the world. The 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. Increased accessibility to affordable drugs in India has helped reduce disease burden in the country by 36 percent between 1990 and 2016 and has also brought down treatment cost for several life-threatening diseases to <5% of its original cost. India has also helped improve access globally by supplying ~60% of global vaccine supply, 20-22% of generic exports, enabling access to AIDS treatment to 37% of patients in Africa in 2009 compared to just 2% in 2003 and by being the 2nd largest exporter of Ayurveda and alternative medicine in the world. The industry has also contributed significantly to India's economy by providing employment to 2.7 Mn people, generating USD 13 Bn in trade surplus every year, and USD 2 Bn in FDI inflows to pharmaceutical industry in the period 2015 to 2018. The focus on high quality is borne out by the presence of largest number of USFDA accredited manufacturing plants outside of the US. Indian pharmaceutical industry's contribution has become even more prominent in 2020 as India has supported the global battle against COVID-19 pandemic by maintaining drug supplies to about 200 countries even during the darkest days of the pandemic.

2.2. Over the years, Biopharmaceuticals is becoming a key driver for growth in global Pharmaceuticals, with increasing emergence of biologics and biosimilars. The global biosimilar market opportunity is expected to grow to USD 70 bn by 2027¹. In India the biopharmaceuticals sector is reported to have delivered a 5 year CAGR of 50% and likely to grow strongly. There are about 100 biosimilar approved in the Indian market till October 2020 and Industry reports another 40+ biosimilars in the clinical development stage. In the response to the pandemic, Indian industry has come forward to develop and manufacture bio-specific antibodies with some companies developing expertise in Antibody Drug Conjugate (ADC) and Monoclonal antibodies (MAB). The Vaccine sector in India with proven capacity for manufacturing at scale, (catering to 62% of global vaccine demand) is also benefitted by talented vaccine developers that have been at the forefront of the fight against COVID 19. Innovation and R&D will be key to retaining global leadership in vaccine sector and growing the biopharmaceuticals segment.

¹ Source: Association of Biotechnology led enterprises (ABLE)

2.3. The medical devices sector, is a sunrise segment in Indian manufacturing sector, with over 750-800 domestic medical devices manufacturers having an average investment of \$2.3-2.7 Mn and turnover of \$6.2-6.9 Mn. The sector itself is highly diversified as it covers a range of products from reagents to radiotherapy equipment. The Indian medical device Industry is heterogeneous, consisting of large multinationals as well as small and medium enterprises (SMEs) and is growing at an unprecedented scale. Around 65% of the medical device manufacturers in India are domestic players operating in the consumables segment and catering to local consumption with limited exports. In addition, there are notable private sector firms manufacturing stents, dialyzers, x ray machines etc. While currently there is a high degree of import dependence for high end equipment, yet, the Indian medical devices sector is playing a key role in driving better health outcomes by providing innovative and affordable products and solutions at scale. During the recent pandemic period, the industry demonstrated capacity for scale, innovation and cost efficiency in manufacture of ventilators, diagnostic kits, followed by pulse oximeters, oxygen concentrators and similar equipment. The well-developed IT ecosystem in India affords added advantage to diversification in the medical devices space.

2.4. Despite these strong fundamentals, there are areas of concern that need to be addressed for the sustained growth of the Pharma-Medtech sector with attendant benefits to Health care systems. On the Pharmaceuticals side, the strong presence in generics market is vulnerable to the high degree of import dependence in APIs and KSMs. The relatively low pace of development of Biologics and Biosimilars and other products that capture emerging trends in new generation therapeutics is also cause for concern. In the Medtech space, the low domestic manufacturing capabilities in High end scanning and imaging equipment needs to be addressed.

2.5. While giving a clarion call for 'Atmanirbhar Bharat', the Hon'ble Prime Minister highlighted that India can only achieve self-reliance in pharmaceuticals and medical devices by strengthening its R&D infrastructure that would drive expansion of access to life-saving medicines and help India become a global pharmaceuticals and medical devices exports hub. Also, the Parliamentary Standing Committee in its 46th Report on 'Promotion and coordination of basic, applied and other research in areas related to the Pharmaceutical Sector' in July, 2018 recommended for institutionalizing

inter-departmental coordination mechanism, enhancing academia-industry linkage, boosting infrastructure, enhancing budget allocation for Pharmaceuticals and medical devices Research & Development, concentrating on future areas of research, like biologics and re-adjusting policy, rules & regulations. In pursuance to the recommendations of the Committee, an Inter-Departmental Committee (IDC) was set up by the Department of Pharmaceuticals in January, 2019 to institutionalize a robust mechanism to ensure efficiency, effectiveness and transparency and coordinate research in a collaborative, synchronized and synergized way for optimum utilization of funds and to ensure no overlapping and duplication of efforts and resources.

2.6. More recently, the challenges faced in India and indeed globally during the pandemic years of 2020 and 2021 have generated insights that growth must also serve the aims to assure drug security, diversify supply chains, increase access and develop innovative solutions to meet health care needs at scale. Whereas other support, in the form of regulation for safety and quality, financing, manufacturing infrastructure, skilled manpower, and cross border cooperation will no doubt be necessary for achieving these multiple objectives, Innovation and Research will be important contributors for sustaining them.

3. Opportunities and Objectives

3.1. The COVID 19 pandemic has brought to the forefront the role of innovation in expanding scale, access and affordability of healthcare products. The role of innovations 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 management of the pandemic. The benefits of repurposing of drugs and the proliferation in monoclonal antibodies have also highlighted the role of innovation in tackling global emergencies.

3.2. At a global level, Pharma and Medtech innovators are moving towards application of telemedicine, Artificial Intelligence (AI) & Machine Learning (ML), Virtual Reality (VR), Internet of Medical Things (IoMTs), Nanotechnology, Robotics & 3D printing, Big data & advanced analytics for aided diagnosis, green technology, additive manufacturing, flexible production, mobile applications for chronic disease management, digital therapeutics, precision medicine, and Medical records etc.

3.3. 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 several health and economic benefits for the country. India although well placed in generics and certain medical devices, is yet to demonstrate sustained higher capabilities relating to drug discovery in pharmaceuticals, new products in biopharma and high-end medical devices. Building this presence can generate substantial health benefit for India by enabling development of drugs for India-specific ailments, which do not get adequate attention globally (e.g., drug-resistant infections like NDM-1; oral cavity cancer, where India accounts for ~30% of diseases burden). It will also enhance industry’s contribution to India’s economy (additional USD 10-12 Bn in exports every year) and create large pool of white-collar jobs to enhance India’s differentiation vis a vis other developing economies.

3.4. The increased spending on healthcare globally, the increase in the size of the Indian middle class, the commitment to Universal Health and the attention to schemes such as PM AY, Ayushman Bharat etc. have created a sustained demand trajectory for Pharma Medtech sectors. The demand for better therapeutic outcomes, the trends in in-home treatment, personalized diagnostics and wearables, telemedicine etc have created scope for differentiated product and service offerings. To capture these opportunities, the Pharma-Medtech sectors would have to move out of comfort zones and adopt innovation as a driving feature of their business strategies.

3.5. Objectives of the Policy: This policy aims to enable a conducive regulatory landscape to accelerate research & development and drive targeted funding, build strong industry-academia collaboration in line with the global best practices and create best-in-class infrastructure for Innovation in Pharma-Medtech sectors. The specific objectives of the Policy are listed below:

- 3.5.1 To simplify regulatory processes to enable rapid drug discovery and development and innovation in medical devices;
- 3.5.2 To explore mechanisms to incentivize private sector investment in research and evaluate various funding mechanisms - Budgetary support, Venture capital, CSR funding etc. and fiscal incentives to support innovation;
- 3.5.3 To identify mechanisms to strengthen the R&D ecosystem through increased collaboration between Industry and Academia; and

3.5.4 To enable integration of the existing policies and programs of various departments/ agencies/ institutes in order to develop mechanisms to dovetail research as per requirement of the Industry.

4. Focus Areas

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 describe how the measures proposed under these three focus areas to meet the policy objectives, largely based on the recommendations in the Report to Catalyse R&D and Innovation in Pharma-Medtech.

4.2 Regulatory Framework: Streamlining Processes/Approvals

4.2.1. 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 CDSCO is the licensing authority, but there are multiple agencies with different mandates and expertise that an Innovator firm has to navigate. In the case of bio-pharmaceuticals, the regulatory scrutiny of manipulation of the genetic material is an additional procedure. In the case of medical technology, a number of existing standards and licensing approvals apply to specific components especially in the electronic and radioactive spheres. As a result, clear processes to deal with new products and innovations that fall outside the existing standards may be absent. The Clinical Trial Rules have been modified in 2020 to deal with some of these issues and the Medical Devices Rules have been notified by MOHFW to guide the transition to a fully regulated regime. Another major challenge lies in building regulatory capacity within 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.

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

- a. Process optimization: All regulators will be mandated to work together to reduce process overlapping and establish timelines for requisite approvals. A Common Specific Procedure Pathway (CSPP) would be provided for each class of product, which would include checklists, prescribed timelines, parallel processing, joint inspections, automatic / deemed approvals, and sharing of data across regulators. It shall be the aim to bring down the current time taken for regulatory approvals for innovative products by at least 50% within the next two years.
- b. Technology based platform: Creation of a single end to end digital portal is proposed, which would be used by different departments/ regulators. The Portal (single window) to be hosted by CDSCO will offer a single interface between Innovator and Regulator. It will function through an interconnected system with automated transfer of data across departments and agencies and enable upload of all documents on the integrated portal. Artificial intelligence backed dossier review and deficiency identification using natural language processing (NLP) and automated document management workflows will be deployed to enhance efficiency and reduce human interface. The technology based single point of interaction shall aim to bring transparency, timeliness and predictability in processes and outcomes around regulation.
- c. Regulatory Capacity: The policy proposes to strengthen the existing institutional capacity of the regulatory bodies (CDSCO) by setting up of project management roles to provide dedicated support to the industry Innovators. The strengthening of the regulator's capabilities would include building in-house expertise in Biopharmaceuticals and high end medical devices. Specialisation will have to be created or in-sourced to handle oversight of regulatory functions in respect of New Biological Entities and New Chemical Entities, Biologics, Imaging medical technologies, New Materials, tele-diagnostics, AI/ML based innovations, Sensors, etc. NPPA will be supported to develop greater expertise in pricing of new innovative products, while pursuing affordability as an overall objective. The policy advocates collaboration with relevant international regulatory agencies to enhance expertise of Indian regulators for approval of new drugs and medical devices and

ensure a globally harmonized regulatory system; existing MoUs available with CDSCO will be reactivated and expanded for this purpose. The 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.

d. Legislation: A review of the multiple legislations impacting research and development in Pharmaceuticals and medical devices will be undertaken with a view to remove inconsistencies, and redundancies. An illustration of measures sought are listed as follows:

- Products that are cultured and cultivated artificially under controlled conditions are essentially not impacting natural resources and effectively the biodiversity of the country and hence should be exempted from the Biological Diversity Act.
- Institutional bodies need to be empowered for approving pre-clinical protocols, e.g., Institutional Animal Ethics Committee (IAEC) to be on par with Institutional Bio- Safety Committee (IBSC) to permit regulatory approvals for pre-clinical activities.
- Enable joint inspection by CDSCO and State FDA (which should be conducted only once), in parallel, in case of vaccines and biologics for a particular class of product, for marketing authorization
- Review legislation enabling regulation of all medical devices in a phased manner with lead time of 12 months to manufacture for each category of medical device - Class A, B, C & D.
- Create dedicated licensing provisions for Ayurveda, Siddha & Unani (ASU) drugs. Explore providing Ayurveda WHO licensing authority to have the power to issue WHO GMP certificate.
- Review DPCO 2013 to enable differential pricing for innovation with therapeutic benefits.

4.3 Funding of Innovation: Incentivizing investment

TO BE COVERED IN STAKEHOLDERS' CONSULTATIONS

4.4 Enabling ecosystem for Innovation and Research

The industry and individual institutes working on Pharma- MedTech research are largely working in silos or through informal ad-hoc cooperation and therefore need to be supported with a wider ecosystem that systematically recognizes, facilitates and rewards Innovation and research. Countries that have created such ecosystem are reaping the market benefits and financial rewards of innovation. Building Institutional ecosystem also creates a balance of equity with efficiency motivations that will align the market and societal forces towards the Goal of Universal Health care. The policy therefore proposes to address three components of building a robust enabling ecosystem including:

- Strengthening academic industry linkages
- Collaborating across institutions and sectors
- Building supporting infrastructure

4.4.1. Industry-academia linkages: Strengthen academic talent and infrastructure

The academic infrastructure will be strengthened and integrated into a coherent framework for building skilled manpower for the Pharma and Medtech sectors. Currently Pharmaceutical education is governed by Pharmacy Council of India. In addition, NIPERs work as Institutes of national excellence for post graduate and doctoral study. 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. Considerable effort is also warranted to modernize curriculum in pharmaceutical education to prepare manpower to navigate if not lead the technology changes in research and manufacturing. The following measures are proposed to be taken up in this respect:

- Strengthening academic curriculum to make it dynamic and contemporary to meet current needs of pharmaceutical and Medtech sector, with increased focus on future ready technologies (e.g. Biologics, continuous flow technology, use of AI and automation in manufacturing.)
- Institutionalize Industry representation in NIPERs and provide channels for varying degree of financial and managerial involvement

- Integrate pharmaceutical education at graduate, post graduate and doctoral levels under NIPERs and enhance expertise in Biopharmaceutical education
- 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
- Purposeful investment in few priority institutes to build 'Centres of excellence' focused on med-tech innovation and R&D in the country
- Programs to attract global talent and incentivize local talent in research areas through recognition (President's Award and equivalent), monetary awards, fellowships & grants, etc.
- Encouraging industry to fund research in academic institutions; Provision for companies to setup "research fund" for supporting research programs at academic institutions and laboratories with tax incentives
- Setup of entrepreneurship incubation centres in academic institutions with institutional linkage with Pharma and Med tech industry
- Design a Bayh Dole like policy to encourage academicians to setup independent companies (spin offs) to move academic discoveries into the commercial landscape, and ensure fair reward sharing between innovators, institutes and industry.
- Setup a strong governance framework to build trust and accountability; To ensure accountability, setup a strong program management to monitor and report progress, robust performance framework with upfront alignment of objectives and funding linked to outcomes

4.4.2. Collaborating across institutions and sectors

While a great deal of the R&D and Innovation that leads to 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 (an illustrative list is annexed). Apart from the NIPERs, the rest of them fall within the Council for Scientific and Industrial Research, Department of Biotechnology, Department of Health Research and Department of Higher education. There is scope to increase

collaboration across institutions so as to encourage innovation at scale and integrate research work across sectors and institutions. Collaboration is also required across the entire product development cycle covering drug discovery, drug delivery, device design, clinical trials, therapeutic and incremental innovations etc. The multiplicity of institutions and programmes supporting research and innovation in the pharma- Medtech space makes articulation as well as the implementation of research on priority areas challenging. 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 following steps are proposed to be taken to integrate the existing policies and programs of various departments in order to develop mechanisms to dovetail research as per dynamic requirements in healthcare:

- Identification of Partner Institutions / organizations that would adopt the policy through a formal mechanism; these Partner institutions may include Research Institutions under various Government departments, CoEs set up under various Programs, and Private Research Labs. Institutions operating in a wide range of subjects of research would be eligible including electronics, instrumentation, Sensors and IoT, Material Science, AI/ML, Pharmacology, Biotechnology, Human Genetics etc.
- Setting up of an Inter-Departmental Research Council on Pharma and MedTech to catalyze, facilitate 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 will have an agile and slim structure with a focus on prioritizing areas for research based on national healthcare priorities, building synergies and promoting the sharing of information among these research bodies, with following functions:
 - Resource Optimization by creating a strong project management structure, with representation from government, industry, academia to (i) focus on industry relevant research areas, (ii) decide priority areas for funding and incentives, and (iii) continuously monitor the program and project implementation.

- Create Provision for a Corpus fund for the council to be funded jointly by government and industry which can leverage existing sources such as NRF
 - Creation of Observatory for R&D prioritization in both communicable and non-communicable diseases areas through evaluation of disease burden and identification of knowledge gaps in disease areas; Observatory to work with regulatory agencies and keep them updated on new developments across disease areas
 - Leading the Drug Discovery Mission as a multi-institutional initiative by pooling the strengths and talents of research institutions under DoP, DHR, DBT and CSIR.
 - Supporting the Common Research Program of NIPERs and establishment of Centres of Excellence in selected disease areas.
- Building an ecosystem model to strengthen R&D establishments, that acts as a unique platform for innovation, integrates diverse skill sets, and brings together stakeholders of pharmaceuticals/ bio-pharmaceutical / biomedical innovation landscape, while ensuring synergy between stakeholders across the product innovation pipeline.
 - Taking forward the compelling lesson learnt from Covid-19 to showcase India's strength and prowess in recent times, the policy will promote the concept of "Innovate in India". To achieve this and to promote India as an "innovation hub", the following interventions will be undertaken to build a strong brand along with effective dissemination of the same among target investors looking at making R&D investments in India in this Pharma-Medtech sector:
 - Setting up innovation forums and awards to enable investors to have visibility and actively interact with the domestic innovation community
 - Encourage the participation of Indian innovation leaders in Global Forums to help Indian innovators to gain insights on global market access and showcase our country's strength on global platforms
 - Creating a compelling "Discover in India" vision and actively disseminate messages across community, by highlighting the initiatives and incentives offered by the Government of India.

4.4.3. Infrastructure: Creation of dedicated 'Innovation Hub'

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 takes place through private entrepreneurs and innovator firms. Under the Atal Innovation Mission, Government is setting up Atal Incubation Centres (AICs), in public and private sector 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. The following steps will be taken for strengthening the infrastructure for innovation in Pharma MedTech Sectors in India:

- Identification and Scale up of selected existing Innovation hubs to maturity ensuring co-location of academia, R&D Centers, industry, startups, incubators; provide "plug and play" infrastructure and ensure requisite financial and regulatory support
- Establish sub-sector specific new hubs with an anchor investor leading a consortium / network of academic institutions, universities, start-ups with industries, business schools, clinical settings, funding agencies (including VCs) to provide an integrated thrust to research in the country in 3-5 years' time frame
- Promote establishment of health-tech ecosystem within the innovation hubs with high end capabilities merging healthcare with the new age technologies such as artificial intelligence, digital and analytics, bringing together cross sectoral expertise
- Create a matrix of Therapeutic Segments, including vector borne diseases, infectious diseases, non-communicable diseases and lifestyle diseases and develop Centres of Excellence within the Innovation Hubs focusing on these verticals
- To ensure a faster availability of testing infrastructure, the empanelment of laboratories will be accelerated for testing medical devices, Biologics, vaccines, IVDs, diagnostic kits for various functionalities including reliability, biocompatibility, bioequivalence, transportation, vibration

and other relevant conformity requirements. NIPERs will be supported for increasing testing and certification functions.

- The establishment of IP Innovation and Patent Offices (IPO) or Technology Transfer offices (TTO) in academic institutions, industries and incubation centres will be considered in order to support innovators, entrepreneurs and start-ups with patent related policies and provisions. Patent offices would be attached to the Office of the Controller General of Patents, Designs and Trade Marks to bring clarity in patent application process, joint ventures and foreign collaborations.

5. Implementation Framework

A High-level Task Force will be set up in 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. The Implementation will be designed in the form of an Action Plan defining roles, responsibilities, activities, targets, and timelines. The Policy has a ten-year perspective, and the Action Plan will be broken down to five year and annual activities for ease of implementation including spending decisions. The Action Plan will list activities in four categories namely Policy decisions, Program execution, Collaboration and Communications. The Policy Action Plan will cover a Five-year period with Annual Plans with attendant Financing framework.

6. Monitoring and Evaluation

6.1 The Policy requires the Action Plan to determine the targets on the following indicators:

- i. Identification of Priority areas and Research problems measured in Share of Research by Identified Institutions in priority areas
- ii. R&D spending by Industry
- iii. New Drug Discovery (including Biopharmaceuticals) measured in number of NCE and NBE in the pipeline and approved.

- iv. Domestic manufacturing share in identified high end medical equipment
- v. Degree of Backward Integration in API, consumables and Components in domestic startups,
- vi. Number of Orphan Drugs introduced in Indian market
- vii. Increased availability of quality Research manpower in priority areas
- viii. Start Ups in Pharma Medtech space incubated by Partner Institutions
- ix. Share of Global exports in non-generics
- x. Share of imports in selected product segments of medical devices

6.2 A Monitoring and Evaluation Framework would be designed with the help of IEO NITI with rational Target setting, resource optimization, portal based reporting mechanism. Risk to implementation would be defined and risk management plans would be devised for consideration of 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 prescribed periodicity against the defined outcomes.

[1] Annexure 4

[2] Section 8 of R&D Global Best Practices Document

[3] Section 9 of R&D Global Best Practices Document

[4] Section 8 of R&D Global Best Practices Document

[5] Section 2 of R&D Global Best Practices Document

List of Central Institutes conducting research in Health Sciences

CSIR INSTITUTES	
1.	Centre for Cellular and Molecular Biology (www.ccmb.res.in)
2.	Central Drug Research Institute (www.cdriindia.org)
3.	Institute of Genomics and Integrative Biology (www.igib.res.in)
4.	CSIR-Institute of Himalayan Bioresource Technology (https://www.ihbt.res.in/en/)
5.	CSIR-Indian Institute of Chemical Biology (http://www.iicb.res.in)
6.	Indian Institute of Chemical Technology (www.iictindia.org)
7.	Indian Institute of Integrative Medicine (www.iiim.res.in)
8.	Indian Institute of Toxicology Research (www.iitrindia.org)
9.	CSIR-Institute of Microbial Technology (https://www.imtech.res.in/)
10.	National Chemical Laboratory (www.ncl.india.org)
DBT INSTITUTES	
1.	National Institute of Immunology (http://www.nii.res.in/)
2.	National Centre for Cell Science (https://www.nccs.res.in/)
3.	National Brain Research Centre (http://www.nbrc.ac.in/newweb/)
4.	Institute of Life Sciences (https://www.ils.res.in/)

5.	Rajiv Gandhi Centre for Biotechnology (https://www.rgcb.res.in/)
6.	Institute for Stem Cell Science and Regenerative Medicine (https://www.instem.res.in/)
7.	Translational Health Science and Technology Institute (https://thsti.res.in/newthsti/)
8.	National Institute of Biomedical Genomics (https://www.nibmg.ac.in/)
9.	Regional Centre for Biotechnology (https://www.rcb.res.in/)
10.	National Institute of Animal Biotechnology (http://niab.org.in/)

ICMR INSTITUTES

1.	National JALMA Institute for Leprosy & Other Mycobacterial Diseases (https://www.jalma-icmr.org.in/)
2.	National Institute of Cancer Prevention and Research (https://nicpr.icmr.org.in/)
3.	National Institute of Occupational Health (http://nioh.org/)
4.	National Centre for Disease Informatics and Research (https://ncdirindia.org/)
5.	Bhopal Memorial Hospital & Research Centre (http://bmhrc.ac.in/)
6.	National Institute for Research in Environmental Health (https://nireh.icmr.org.in/)
7.	National Institute for Research in Tuberculosis (http://www.nirt.res.in/)
8.	National Institute of Malaria Research (https://nimr.org.in/)

9.	National Institute of Pathology (http://instpath.gov.in/)
10.	National Institute of Medical Statistics (http://icmr-nims.nic.in/)
11.	National Institute of Nutrition (https://www.nin.res.in/index.html)
12.	National Institute of Cholera and Enteric Diseases (http://www.niced.org.in/)
13.	National Institute for Research in Reproductive Health (http://nirrh.res.in/)
14.	National Institute of Immunohematology (https://www.niih.org.in/)
15.	National Institute of Virology (https://www.niv.co.in/)
16.	National AIDS Research Institute (https://nari-icmr.res.in/)
17.	Rajendra Memorial Research Institute of Medical Sciences (http://www.rmrim.org.in/)
DRDO INSTITUTES	
1.	Defence Bio-engineering & Electro-medical Laboratory (https://www.drdo.gov.in/labs-and-establishments/defence-bio-engineering-electro-medical-laboratory-debel)
2.	Defence Institute of Bio-Energy Research (https://www.drdo.gov.in/labs-and-establishments/defence-institute-bio-energy-research-diber)
3.	Defence Institute of High-Altitude Research (https://www.drdo.gov.in/labs-and-establishments/defence-institute-high-altitude-research-dihar)

4.	Defence Institute of Physiology & Allied Sciences (https://www.drdo.gov.in/labs-and-establishments/defence-institute-physiology-allied-sciences-dipas)
5.	Defence Institute of Psychological Research (https://www.drdo.gov.in/labs-and-establishments/defence-institute-psychological-research-dipr)
6.	Institute of Nuclear Medicine and Allied Sciences (https://www.drdo.gov.in/labs-and-establishments/institute-nuclear-medicine-allied-sciences-inmas)
DOP INSTITUTES	
1.	National Institute of Pharmaceutical Education and Research, Mohali (http://www.niper.gov.in)
2.	National Institute of Pharmaceutical Education and Research, Hajipur (https://www.niperhajipur.ac.in)
3.	National Institute of Pharmaceutical Education and Research, Kolkata (http://www.niperkolkata.edu.in)
4.	National Institute of Pharmaceutical Education and Research, Hyderabad (http://www.niperhyd.ac.in)
5.	National Institute of Pharmaceutical Education and Research, Guwahati (https://niperguwahati.ac.in)
6.	National Institute of Pharmaceutical Education and Research, Ahmedabad (https://www.niperahm.ac.in)
7.	National Institute of Pharmaceutical Education and Research, Raebareli (http://niperraebareli.edu.in)