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

Shastri Bhawan, New Delhi
Dated 2nd November, 2021

Subject: Circulation of Draft Policy to Catalyze Research & Development and Innovation in the Pharma- MedTech Sector in India - Regarding.

Draft policy to **'Catalyze Research & Development and Innovation in the Pharma- MedTech Sector in India'** has been hosted on the Department's website on 25th October, 2021

2. Subsequently, a presentation was made on the subject on 28th October, 2021. A copy thereof is **enclosed**.

3. Due to on-going festive season, some associations have sought extension of time limit for submission of their comments. Accordingly, the time limit is extended up to 10th **November, 2021.**

4. The comments on the draft policy may be sent on following email ids:

dir-pharma@gov.in

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(**Rajneesh Tingal**)
Joint Secretary to the Government of India

National Policy on R&D and Innovation in Pharmaceuticals and Medical Devices

Department of Pharmaceuticals
Ministry of Chemicals & Fertilizers
Government of India

OCTOBER 2021

Pharmaceuticals

India Ranks

#1 Supplier of low-cost generics, vaccines and HIV medicines

#1 Most US FDA approved plants outside the USA

#3 Industry size by volume

Exports to top 25 destinations

$11 Bn Annual trade surplus

2.7 Mn jobs created (Direct and Indirect)

Sector Highlights

60,000 generic brands

60 therapeutic categories

500 APIs manufactures

10-12% Growth rate

Major FDI Sources


UK


USA


JAPAN


FRANCE


SPAIN


GERMANY

MARKET SIZE (2020)	SIZE BY 2030	FDI (APR 00 - JUN 21)
$41 Bn	$130 Bn	$18.12 Bn

Opportunities

Generics	Bulk Drugs	Vaccines	Biosimilars
20% global generics supplied by India. **60,000** generics brands supplied covering 60 therapy areas. **33%** global ANDA approvals (2010-19).	**USD 2.98 Bn** Production Linked Incentive scheme for API and formulations. **3 dedicated bulk drug parks.** **3rd** largest market for APIs. **~ 57%** of APIs contributes to WHO's prequalified list.	**150+ countries** being catered for Vaccines. **USD 272 Mn** market size expected for Animal Vaccines by FY'28.	**200+** biosimilars in pipeline. **11%** Biosimilar market growth by FY'19. **~98** biosimilars approved in FY'19 more than US or EU.

Trends:

Competitive timelines for regulatory approvals and clinical trials

Other emerging areas: Precision medicine, AI adoption and 3-D printing technology

Medical Devices

4th

Largest Market in Asia

After Japan, China & South Korea

$11Bn

Current Market Size

Including implants, consumables, Medical Electronics

9-11%

CAGR Growth

Over the period of 5 years

$50Bn

Market Size By 2025

Poised to be the leader in Medical Devices

FDI

FDI Equity inflows from April 2000 to December 2020 - **USD 2.2 Bn**

Trade Scenario

Imports : **USD 5.8 Bn**, Exports : **USD 2.2 Bn**

Opportunities

A

Diagnostics

Rapid diagnostics to reach $1.230 Bn by 2024, growing at a CAGR of 10.81%

B

Exports

Consumables & Disposables account for 50% of the total exports, top exporting category

C

Startup Ecosystem

5000+ health-tech startups, $2 Bn raised b/w 2011-2020.
500+ investments into 340+ companies

C

Medical Tourism

22-25% growth in medical tourism; expected to contribute $152 Bn by 2029

Need of a dedicated R&D and Innovation Policy

1

Import Dependence

High degree of import dependence in Drugs and Medical devices

2

Development Cycle

Relatively low pace of development of Biologics & Biosimilars and other products capturing emerging trends in new generation therapeutics

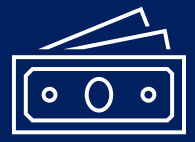
3

Infrastructural Challenges

Low domestic manufacturing capabilities in several medical equipment's

Objectives

Strengthening regulatory framework



Incentivizing investments

Creating facilitatory ecosystem for Innovation

Regulatory Framework: Streamlining Processes

Process Optimization

- Reduce process overlapping & establish timelines for approvals
- Common Specific Procedure Pathway for regulatory approvals
- **Aims to bring down current time taken for regulatory approvals for innovative products by ~50% within next 2 years**

Tech Based Platform

- Single end to end digital portal - interface between Innovator & Regulator
- AI backed dossier review & deficiency identification using natural language processing and automated document management workflows
- **Aims to bring transparency, timeliness and predictability in processes and outcomes**

Regulatory Capacity

- Dedicated support to industry Innovators
- In-house expertise in Biopharma & high-end medical devices
- Collaboration with International regulatory agencies
- **Aims to enable regulators to introduce global best practices**

Legislation

- Institutional bodies to be empowered for approving pre-clinical protocols
- Enabling joint inspections by CDSCO & State FDA
- Reviewing legislation enabling regulation of all medical devices in a phased manner
- Reviewing DPCO 2013 to enable differential pricing
- **Review of existing legislations impacting R&D to remove inconsistencies, & redundancies**

Incentivizing Investments (1/6)

Recent Government Initiatives

Pharmaceuticals (innovative products with the specific inclusion of biopharmaceuticals, patented drugs, complex generics, gene therapy drugs, orphan drugs, etc.)

INR 15,000 Cr
Scheme Outlay

Medical Devices (high-end segments of medical devices such as Cancer care/ Radiotherapy, Radiology & Imaging, Anesthetics & Cardio-respiratory and all Implants, etc.)

INR 3,420 Cr
Scheme Outlay

Measures to promote funding support to innovation

- Schemes/ tax policies to support investments
- Ensure improved ROI for innovation through reimbursement
- Increase scale of funding
- Create a compelling 'Discover in India' vision
- Harmonize multiple regulations (Single window clearance for external funding)
- Encourage investment in innovation through matching funds
- Enable alternate sources of funding

Incentivizing Investments (2/6)

Exploring Fiscal Support

- Programmatic support through tax and grant Incentives linked to R&D spending in priority areas
- Increase scope of patent box, Capital gains exemptions on research funds, Introduction of long-term-secure "innovation bonds" with income tax concessions
- Providing tax credits for donors, which are subtracted directly from an individual tax liability
- Introduction of a concessional rate of customs duty on import of specific goods and services for R&D
- Reviewing the Health Cess @5% Ad Valorem introduced in the Union Budget 2020-21, on import of specified medical devices
- Tax exemptions on research funds eg: Angel investment for start-ups

Incentivizing Investments (3/6)

Exploring Fiscal Support (SMEs)

- Introduction of an interest subvention scheme on loans availed through Public Sector Financial Institution for strengthening infra for global certifications
- Special Grants that focus on market-oriented tech and development project
- Assistance towards cost of filing and prosecution of patent application
- Drawing support from existing National Research Fund and Biotech Innovation Fund to aid innovations focused on drug discovery, promotion of Health startups and digital and analytics

Incentivizing Investments (4/6)

Exploring Fiscal Support (Start-ups)

- Dedicated seed capital fund to support start-ups in key emerging pharma & medical devices technologies
- Special fund - MD Innovation Development Fund, for promotion of Medtech start-ups
- Introduction of Pharma focused Cat – I Alternate Investment Funds (AIF)
- Creating provisions for Risk-based capital investments through equity funding
- Direct funding support for late-stage Clinical trials by industry through mile stone based payments

Incentivizing Investments (5/6)

Exploring Non-Fiscal Support

- Harmonization of multiple regulations for single window clearance for external funding
- Foreign Venture Capital Investors may be registered with SEBI & be allowed to freely invest and disinvest
- Considering the relaxation in norm of 3 years track record of profit for companies backed by registered VC Funds
- Evaluating options for allowing direct listing of companies with securities listed in other countries
- Considering developing accounts in consultation with SEBI, which can be linked to demat accounts to invest in cherry-picked stocks (significant revenue from advance drugs etc.)
- Collaboration with Biotechnology Industry Research Assistance Council (BIRAC) for expansion of Fund of Fund Biotech Innovation Fund- Accelerated Entrepreneurs (AcE) daughter funds to co-invest in Alternate Investment Funds (AIFs)
- Listing Innovation Bonds, which will match the cash flow from the market to R&D expenses of the company, with tax benefits to retail investors with aim to increase monetary liquidity for manufacturing

Incentivizing Investments (6/6)

Exploring Interventions to create Innovation Hub

- Setup Innovation forums and awards to enable investors to have visibility and actively intercat with domestic innovation community
- Encourage participation of Indian Innovation leaders in global forums to help gain insights on global market
- Create compelling “Discover India” vision and actively disseminate messages across community

Enabling ecosystem for Innovation & Research (1/2)

Strengthening academic industry linkages

- Strengthening academic curriculum, Institutionalize Industry representation in NIPERs, Setup of entrepreneurship incubation centers
- Attract global educational institutions to create centers in India
- Build 'Centers of excellence'
- Programs to attract global talent and incentivize local talent
- Provision for companies to setup "research fund"
- Setting up a strong program management to monitor and report progress, robust performance framework

Collaborating across institutions and sectors

- Identification of Partner Institutions/ organizations to adopt the policy through a formal mechanism
- Inter-Departmental Research Council – to catalyze, facilitate and promote collaboration across institutions
- Ecosystem model to strengthen R&D establishments

Building Infrastructure

- Identification and Scale up of selected existing Innovation hubs; Provide "Plug and Play" infra
- Establish sub-sector specific new hubs with an anchor investor
- Establishment of health-tech ecosystem within innovation hubs
- Create a matrix of Therapeutic Segments and develop CoEs

Enabling ecosystem for Innovation & Research (2/2)

Strengthening academic industry linkages

- Institutionalise Industry Representation in academic institutions
- Integrate governance of Pharmaceutical educational at levels of academic programs
- Setup Entrepreneurship Incubation Centres
- Design Bayh Dole like policy to encourage academicians to set up independent companies

Collaborating across institutions and sectors

- Resource Optimization- Strong project management structure with representation from relevant stakeholders
- Provision for corpus fund- Jointly funded by Govt. and Industry, which can leverage existing sources
- Observatory model: R&D prioritization in key area to identify knowledge gaps especially in disease areas; work in coordination with regulatory agency

Building Infrastructure

- Ensure a faster availability of testing infrastructure; specialized labs for MD and pharma
- Establishment of IP Innovation and Patent Offices or Technology Transfer offices in academic institutions, industries and incubation centres to support innovators, entrepreneurs and start-ups

Implementation Framework

Policy Duration: 10 years **Action Plan: 5 years (*2)**

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

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

Implementation will be designed in the form of an Action Plan defining roles, responsibilities, activities, targets, & timelines. Annual activities will be drawn down for ease of implementation including spending decisions

Action Plan will list activities in four categories namely Policy decisions, Program execution, Collaboration and Communications

Policy Action Plan will cover a Five-year period with Annual Plans with attendant Financing framework

Monitoring and Evaluation

- Identification of Priority areas & Research problems measured in Share of Research by Identified Institutions in priority areas
- R&D spending by Industry
- New Drug Discovery (including Biopharmaceuticals) measured in number of NCE and NBE in the pipeline and approved.
- Domestic manufacturing share in identified high end medical equipment
- Degree of Backward Integration in API, consumables and Components in domestic startups

- Number of Orphan Drugs introduced in Indian market
- Increased availability of quality Research manpower in priority areas
- Start Ups in Pharma Medtech space incubated by Partner Institutions
- Share of Global exports in non-generics
- Share of imports in selected product segments of medical devices

Monitoring and Evaluation Framework would be designed with 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.

Share your suggestions @

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