Government invites stakeholders for consultation on Draft National Medical Devices Policy 2022

Department of Pharmaceuticals (DoP), Ministry of Chemicals and Fertilizers, vide public notice dated 10.03.2022, has released on its website, an Approach Paper for the Draft National Policy for the Medical Devices, 2022. The Department has invited feedback and comments from the public, the medical device industry and stakeholders on the Draft Policy, to have the approach paper converted into a robust policy framework. The feedback/inputs may be provided at nmdp-2022@gov.in (in both PDF and Word document) by not later than 25.03.2022.

➢ **Objectives of the Draft policy:**

DoP as the nodal agency for promotion, production and manufacturing of medical devices in India, has formulated this Policy building upon a patient-centric approach and acknowledging the need to address structural challenges, enhance competitiveness of domestic manufacturers, increase private investments and innovate in technology through fundamental research and knowledge driven enterprise.

The Draft policy aims at addressing the core objectives of accessibility, affordability, safety and quality, focus on self-sustainability, innovation and growth in the medical devices sector and the salient features are as follows:

- **Regulatory streamlining** in order to optimize regulatory processes and multiplicity of agencies for enhanced ease of doing business, along with harmonization with global standards to ensure standardization.
- **Quality Standards and Safety of the Devices** in order to provide safe devices to the consumers, in harmony with the global standards.
- **Building Competitiveness through fiscal and financial support** for stimulating the development of the local manufacturing ecosystem with private sector investments.
- **Infrastructure Development** to provide best-in-class physical foundation, including medical devices parks with common facilities such as testing centres, to improve cost competitiveness and enhance attraction of domestic manufacturers.
- **Facilitating R&D and Innovation** with a focus on enhanced collaboration in innovation and R&D projects, global partnerships, and joint ventures among key stakeholders to bridge the gap between academic curriculum and industry requirements.
- **Human Resource Development** to ensure relevant curriculum at higher education level, skilling of various stakeholders, creation of future-ready HR with required skill sets across the innovation value chain.
- **Awareness Creation and Brand Positioning** in creating awareness and positioning India as a hub for manufacturing of medical devices as part of the "Make in India, Make for the World" initiative.

➢ **Vision of the Draft policy:**

This policy envisions that by 2047, India will:

- be one amongst Top 5 global manufacturing hubs in terms of value and technology for medical devices.
- be home to 25 MedTech $Bn companies and home & originator to 25 high-end futuristic technologies in MedTech.
- emerge as champion in critical components, cancer diagnostics, medical imaging, ultrasonic scans, molecular imaging & PCR technologies.
- have a MedTech industry of $100-300 billion size with 10-12% of global market share.
- have about 50 medical devices clusters across India for faster clinical testing of medical devices to boost production development and innovation.

➢ **Proposed Policy Interventions:**

The policy envisages to:

- Create an online system for medical devices, an online single window portal of CDSCO, for filing applications for medical device manufacturing license, import license and clinical investigation, which shall integrate all the key stakeholders involved with the regulatory processes associated with the medical device ecosystem.
- Enhance the level of standardization, certification and quality and enable indigenous industry to gain global competitiveness.
- Facilitate the establishment of the medical device parks with common infrastructure facilities in proximity to economic zones with requisite logistics connectivity as envisioned under the National Industrial Corridor programme and the proposed National Logistics Policy 2021, with the assistance and incentives from the State Governments.
- Develop additional NABL accredited laboratories for medical device testing to ensure quality, safety and efficacy of the medical devices marketed in the country and to provide low cost testing facility.
- Support for setting up of Common Infrastructure centers which would include Common Testing Labs & Tool room, Enterprise Software & shared hardware, shared service like Legal, Accounting, Technology, Patents, Investment Banking and entrepreneurship development cells.
- Encourage private investments in medical device sector by creating an ecosystem for risk-based financing through active outreach engagement such as inviting VCs for screening of start-ups to incubate.
- Engage, leverage, and systematically build upon the initiatives of Startup India initiated by DPIIT to actively participate in supporting startups in the medical devices sector.
- Setting up of National Institutes of MedTech (Medical Devices Education and Research) (NIMERs) on the lines of National Institutes of Pharmaceutical Education and Research (NIPERs), as Institutes of National Importance (INIs).
- Formulate a National Registry which will maintain a data bank having the details related to latest technology being used in medical device sector and the skill required to do the production with that specific technology.
- Finance such skills through hands-on trainings, internships/training in specialized industrial locations by all departments and ministries as par with Junior Research Fellow (JRF) stipends made available by UGC to Universities.