

First Meeting of the Reconstituted National Medical Device Promotion Council (NMDPC)

For Prelims: National Medical Device Promotion Council (NMDPC), CDSCO, FDI, PLI, Medical Devices Park, NABL Accreditation, Medical Devices Rules, 2017, National Medical Devices Policy 2022.

For Mains: Challenges and Issues with respect to the Medical Device Industry of India, Government Initiatives to Promote the Medical Device Industry of India.

Why in News?

Recently, important issues of Medical Technology (MedTech) Industry were taken-up at the first meeting of the reconstituted National Medical Device Promotion Council (NMDPC).

What were the Key Highlights of the Meeting?

- Agenda:
 - <u>Central Drugs Standards and Control Organisation (CDSCO)</u> and the State Licensing Authorities (SLAs) provided updates for the <u>smooth transition to licensing of Class A</u> and <u>B Medical Devices w.e.f 1st October 2022.</u>
 - Medical devices under <u>Medical Devices Rules</u>, <u>2017</u> are classified as:
 - Class A (low risk): E.g., absorbent cotton balls, alcohol swabs.
 - Class B (low moderate risk): E.g., thermometer, BP monitoring device.
 - Class C (moderate high risk): E.g., implants.
 - Class D (high risk): E.g., heart valves.
 - Department of Pharmaceuticals provided the latest status of the various initiatives such as 100% Foreign direct Investment (FDI) in MedTech Sector on automatic route, Production-Linked Incentive Scheme (PLI) scheme for Medical Devices, Medical Devices Parks in four States (Himachal Pradesh, Tamil Nadu, Madhya Pradesh and Uttar Pradesh), etc.
 - The discussion regarding the requirement of <u>National Accreditation Board for Testing and Calibration Laboratories (NABL) accreditation</u> of In-House labs of the manufacturers of specific Medical Devices was taken-up during the meeting.
- Concerns Highlighted:
 - There is a regulatory burden of labelling requirements of Medical Devices.
 - There are only 18 certified Medical Device Testing Laboratories that have been approved by CDSCO and that is grossly insufficient keeping in view the size of the country.
 - Indian Medical Devices Industry presently lacks research ecosystem and infrastructure for manufacturing of high tech, advanced medical devices (Class C&D).

What were the Key Recommendations made by the NMDPC?

Harmonize the Labelling Provisions:

 There is a need to move forward to harmonize the provisions of labeling of Medical Devices under the Legal Metrology (Packaged Commodity) Rules, 2011 into Medical Device Rules, 2017, for licensed medical devices.

• Investment in the Medical Devices Park:

The Medical Devices Industry Associations representatives were encouraged to actively
engage with states, which were sanctioned Medical Devices Parks by the
Department for creating common infrastructure facilities and come forward to invest in
the proposed parks to boost domestic manufacturing.

Active Participation in the National MedTech Expo, 2022:

• The industry's support was also asked for the proposed National MedTech Expo, 2022 to showcase the strengths and capabilities of Indian Medical Devices Industry.

Need of More Certified Medical Devices Testing Laboratories:

 An adequate common infrastructure including accredited laboratories in various regions of the country for standard testing should be in place.

Post-market Surveillance system and Medical Device Registry:

 There must be a robust IT enabled feedback driven post-market surveillance system and medical device registry, particularly for implants to ensure traceability of patient who has received the implant in order to assess the performance of the implant.

New Legislation for a New Regulator:

- The Committee has recommended that the new legislation should set up a new set of regulators at different levels for regulating the medical devices industry.
 - The Ministry of Chemicals and Fertilizers should allow the new regulator to involve institutions such as Indian_Institute of Science (IISc), Council of Scientific and Industrial Research (CSIR), Defence Research and Development Organisation (DRDO) and network of Indian Institute of Technology (IITs) to test medical devices for safety and efficacy.
- Medical device regulations must be dispensed with by qualified and well-trained
 Medical Device Officers to give a boost to the Medical Device industry in the country.

Research Linked Incentive (RLI) Scheme:

• The Committee recommended the Department to start a **RLI Scheme** in Line with the PLI scheme.

Upskilling of the Medical Device Officers:

 The Ministry should work in synergy with State governments and impart the necessary skills to the local medical device officers.

A Single Window Clearing Platform:

- A single window clearing platform for application of license for manufacturing, export, import must be set up that shall also integrate all these bodies involved in the regulation of medical devices.
 - The Ministry must incorporate such an all-encompassing "single window clearing/approval system" in the proposed new separate Act for the regulation of Medical Devices.

What is NMDPC?

About:

- National Medical Device Promotion Council (NMDPC) is chaired by the Secretary,
 Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers.
 - It has **members from stakeholder departments/ organizations**, functions of which have a bearing on the growth of the sector.
 - Also, it has **representation from several medical device industry associations,** representing the sector in India.

Significance:

 NMDPC, going forward, is expected to become a vibrant forum for all issues relating to the medical devices sector, which is a sunrise sector with huge potential for social obligations and the economic aspirations of India.

Source: TH

 $\label{potential} \begin{tabular}{ll} PDF Referece URL: $https://www.drishtiias.com/printpdf/first-meeting-of-the-reconstituted-national-medical-device-promotion-council-nmdpc \end{tabular}$

