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:**
  - **Central Drugs Standards and Control Organisation (CDSCO)** and the State Licensing Authorities (SLAs) provided updates for the **smooth transition to licensing of Class A and B Medical Devices w.e.f 1st October 2022.**
    - Medical devices under Medical Devices Rules, 2017 **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 National Accreditation Board for Testing and Calibration Laboratories (NABL) accreditation **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 e**nsure 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