Draft Medical Devices Bill

For Prelims: Drugs Medical Devices and Cosmetics Bill 2022, Medical Devices Technical Advisory Board, E-pharmacy

For Mains: Drugs Medical Devices and Cosmetics Bill 2022, E-pharmacy

Why in News?

Recently, the **Union Health Ministry** released a draft of the proposed **Drugs Medical Devices and Cosmetics Bill, 2022** which would replace the existing Drugs and Cosmetics Act,1940, and other several rules.

- It focuses on creating a **separate regulation for medical devices**, which makes provision for fines and imprisonment for injury and death related to **clinical trials or investigations and seeks to regulate e-pharmacies.**

What are Medical Devices?

- The medical device industry is a **unique blend of engineering and medicine.** It involves the creation of machines that are used to support life within the human body.
- Medical devices include Surgical Equipment, Diagnostic equipment like Cardiac imaging, CT scans, X-ray, Molecular Imaging, MRI and Ultrasound-imaging including hand - held devices, Life Support equipment like ventilator, etc. as well as Implants and Disposables.

What are the key Highlights of the Draft Bill?

- **Provisions for the Clinical Trials and Investigations:**
  - **Compensation to Heir:** It makes provisions for **compensation to participants or their legal heirs for injury or death suffered in clinical trials and investigations** for drugs and medical devices.
    - The draft also lays the onus on providing medical management for any injury arising due to the trial of the investigators.
  - **Penalty & Fines:** Provision for **imprisonment, and fines** amounting to double the compensation amount **if the compensation is not paid.**
  - **Prohibition of Clinical Trials: It prohibits clinical trials or clinical investigations** of drugs and medical devices **without permission from the central licensing authority.**
    - It provides for debarring the investigators and sponsors of a trial or investigation if the laid-down provisions are not followed.
- **Medical Devices Technical Advisory Board:** The draft bill provides for the creation of a **Medical Devices Technical Advisory Board on the lines of the existing drugs technical advisory board,** with people who have technical knowledge of the engineering of these devices,

and members of the industry.
    - Other than officials of the Health Ministry, the board will have officials from the Department of Atomic Energy, Department of Science and Technology, Ministry of Electronics and Information Technology, Defense Research and Development Organization, and experts from the fields of Biomedical Technology, Biomaterials, and Polymer Technology.

What are the Issues Related to it?

- The draft mainly confronted the issues of **E-pharmacy** and how they violate the existing regulations as follows:
- There is hardly any provision for the regulation of online pharmacies exist in the 1940 law.
    - At present all these **online pharmacies are working outside the law, most of them have licenses for physical shops or storage units.**
    - They deliver medicines without any prescription.
    - In case of violation regulatory authorities don't know under which provision of law to file suit against these companies.
    - Sometimes these **companies held licenses from another state and operate in other states.**

What is the Present Status of Medical Devices Industry of India?

- **About:**
    - The current market size of the medical devices industry in India is estimated at USD 11 bn, represents a sunrise sector of the Indian economy.
    - The medical devices industry in India consists of large multinationals as well as **Small and Medium Enterprises (SMEs)** growing at an unprecedented scale.
    - The medical device sector has been growing steadily at a **CAGR of 15% over the last 3 years.**
    - The medical devices industry in India is poised for significant growth with the market size expected to reach USD 50 bn by 2025.
    - **100% FDI is allowed under the automatic route** for both brownfield and greenfield setups. Strong FDI inflows reflect the confidence of global players in the Indian market.
- **Initiatives:**
    - **Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices:**
        - **The Production Linked Incentives Scheme (PLI)** Scheme for Medical Devices manufacturing proposes a **financial incentive to boost domestic manufacturing and attract large investment** in medical devices segments such as cancer care devices, radiology and imaging devices, anesthetics devices, implants, etc.
    - **Promotion of Medical Device Parks:**
        - Promotion of **Medical Device Parks aims to strengthen the infrastructure base and develop a robust manufacturing ecosystem** for medical devices in the domestic market.
        - Grants under the Scheme for development of **world-class standard testing and infrastructure facilities** will build momentum for domestic production and deepen the value chain of Medical Devices in India.
            - Additionally, these are expected to **reduce the cost of manufacturing significantly,** leading to better accessibility and affordability of medical devices in the country.
    - Medical devices have been recognised as a **sunrise sector** under the **'Make in India' campaign** in 2014.

What was the Need to Bring this Bill?

- Almost **80% of the medical devices currently sold in the country are imported,** particularly high-end devices.
- Indian players in the space have so far typically focussed on low-cost and low-tech products, like

consumables and disposables, leading to a higher value share going to foreign companies.

- It aims to **reduce India's import dependence from 80% to nearly 30% in the next 10 years** and become one of the top five global manufacturing hubs for medical devices by 2047.
- It is also aimed at **increasing India's per capita spend on medical devices.**
    - India has **one of the lowest per capita spend on medical devices at USD 3,** compared to the global average of per capita consumption of USD 47, and significantly lower than the per capita consumption of developed nations like the USA at USD 415 and Germany at USD 313.

Way Forward

- There is a need for either law or, more simply, a change in the current Rules to regulate e-pharmacies.
- There is a need for creating a deterrent against big Pharma companies as there are rules for clinical trials but it's not enough.
- There should also be provisions for recalling medicines or devices if any issues are detected.
- Increase access and improve the rational use of essential medicines.

Source: IE