

## Medical Devices Authority

### Why in news?

The government is in the process of formulating a Medical Devices Authority (MDA) for the vast range of products in the sector.

### What is the proposal?

- The MDA would function as a regulator for India's semi-regulated medical devices industry.
- There is now a dichotomy between *CDSCO* (Central Drugs Standard Control Organisation) and BIS (Bureau of Indian Standards).
- Reportedly, the BIS will continue to frame guidelines but these would be regulated by MDA.
- Also, the proposed body will be separate from CDSCO, which will continue to be the regulator for drugs.

### What are the concerns with the proposal?

- Seemingly, the decision goes against the international norms.
- E.g. in the US, the FDA (Food and Drug Administration) is the agency under which medical devices are controlled.
- The FDA's Center for Devices and Radiological Health regulates firms that manufacture, repackage, relabel, and/or import medical devices sold.
- Similarly, the European Medicines Agency has a medical devices agency.
- Given these, a separate agency to regulate medical devices will be unique to India and may pose its own challenges.
- Non-compliance with global standards and safety guidelines on the domestic front is a major loophole in ensuring the quality of locally-manufactured medical devices.
- India lacks infrastructure to test the quality of such devices.
- Given this, the new mechanism and multiple layers of a separate MDA might lead to more confusion amongst manufacturers.

### What could have been done?

- There are already policy mechanisms and regulatory practices to compare India's domestic produce.
- The true testament of quality can only be attributed to adoption and

implementation of international harmonised standards.

- So, aligning with international standards would be better than coming up with a new mechanism altogether.
- Instead of forming a new body, it would be better to have the powers and working invested in a self-contained division within CDSCO.
- This would save costs and, more importantly, be within a regulatory system to share expertise.

### **What is the priority now?**

- India has not been able to develop itself as a strong manufacturing base for medical technology.
- The industry remains dependent on imports for meeting its domestic requirements.
- The ongoing US-India trade talks and speculations around the pricing mechanism remains another concern.
- This highlights the need for a scientific and promising alternative that goes beyond capping prices of select devices (cardiac stents, knee implants).
- Another problem to be addressed is the human resource crunch at multiple levels.
- A shortage of inspectors to carry out quality assessments, crippling state of manufacturing units and poor regulatory environment are other major challenges.
- So, the government needs to create a holistic environment that supports the establishment of a new regulatory regime.
- This would facilitate realising the need of wider accessibility of healthcare services.
- Any new mechanism should also be able to fill in the gaps in the fields of R&D, manufacturing and testing facilities.

**Source: Financial Express**

### **Quick Facts**

#### **Central Drugs Standard Control Organisation (CDSCO)**

- CDSCO functions under the Ministry of Health and Family Welfare.
- It is the Central Drug Authority for discharging functions assigned to the Central Government under the Drugs and Cosmetics Act.
- Major functions of CDSCO are:
  - i. regulatory control over the import of drugs
  - ii. approval of new drugs and clinical trials
  - iii. meetings of Drugs Consultative Committee (DCC) and Drugs Technical

### Advisory Board (DTAB)

- iv. approval of certain licenses as Central License Approving Authority
- It regulates the safety, efficacy and quality of notified medical devices under the provisions of Drugs and Cosmetics Act, 1940 and the rules made thereon.

### **Bureau of Indian Standards (BIS)**

- BIS is the National Standard Body of India established under the BIS Act 2016.
- The aim is the harmonious development of the functions of standardization, marking and quality certification of goods and for matters connected therewith or incidental thereto.

