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.

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