Medical Equipment Notified as 'Drugs'

Why in News

The Ministry of Health and Family Welfare has notified that **medical equipment** would qualify as **'drugs'** under Section 3 of the **Drugs and Cosmetics Act (D & CA), 1940** from 1st April, 2020.

- The **Medical Devices Amendment Rules, 2020** were also released. The rules will also come into force from 1st April, 2020.
    - The Rules state that the medical devices shall be registered with the Central Licensing Authority through an identified online portal established by the Central Drugs Standard Control Organisation (CDSCO).
    - Such registration is voluntary for a period of 18 months, after which it will be mandatory.
- The move comes in the wake of years of controversy about faulty hip implants of J&J. DePuy, a subsidiary of Johnson & Johnson (J&J), engineered a hip replacement device that used metal in prosthetic components, commonly called "Articular Surface Replacement or ASR hip implant".

Section 3 of the Drugs and Cosmetics Act, 1940

The Central Government, after consultation with the Drugs Technical Advisory Board (DTAB), specifies the devices intended for **use in human beings or animals as drugs.**

Drugs Technical Advisory Board

- Drugs Technical Advisory Board is a **statutory body** constituted under the **Drugs and Cosmetics Act, 1940.**
- The function of DTAB is to advise the Central government and State government on technical matters related to drugs and cosmetics.

Key Points

- At present, only **23 medical devices** have been classified as drugs. The latest notification gives a wide definition of the term medical devices.
    - The devices used for diagnosis, monitoring, treatment, assistance for any injury or disability, investigation, replacement or modification or support of the anatomy or of a physiological process will come within the scope of the definition of 'Drugs'.
    - Medical equipment under this definition include **implantable medical devices** such as **knee implants, CT scan, MRI equipment, defibrillators, dialysis machine, PET equipment, X-ray machine** etc.
    - Primary intended action of the device in or on human body or animals should not be pharmacological or immunological or metabolic.
- The aim is to regulate all medical devices so that they meet certain standards of quality. Besides it will also make medical device companies accountable for quality and safety of their products

    The manufacture, import and sale of **all medical devices** will now **need to be certified** by the **Central Drugs Standard Control Organisation.**
- **Possible Impact**
    - The decision is going to have a major impact on the small and marginal players, largely **unorganised,** in the low-value high volume segment of the medical devices industry.
    - The hi-tech diagnostic imaging sector is dominated by large players and will be the least impacted.
- **Concerns:** Concerns are being raised that the rules are very rigid and any non-conformity can be treated as a **criminal offence** by any drug inspector under the Act at his **discretion.**

Way Forward

Merely expanding the scope of regulation to all devices is not enough in a moment of growing number of safety disasters involving devices. Hence,there is a pressing need for framing of a new medical devices act.

Source:IE