1. Medical Equipments Notified as Drugs

Prelims Level: Medicine and Pharmaceuticals.

Mains Level: GS-II Issues relating to development and management of Social Sector or Services relating to Health, Education, Human Resources.

Why in News?

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

What does Section 3 of the Drugs and Cosmetics Act, 1940 says?

- 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.**

About 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. It is a decision making body related to Drugs and Cosmetics in the country.
- It is also part of **Central Drugs Standard Control Organization (CDSCO)** in the **Ministry of Health and Family Welfare**.

About the News:

- The **Medical Devices Amendment Rules, 2020** were released recently which will 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 Johnson & Johnson (J&J).

- DePuy, a subsidiary of Johnson & Johnson, engineered a hip replacement device that used metal in prosthetic components, commonly called "**Articular Surface Replacement** or **ASR hip implant**".
- The manufacture, import and sale of all medical devices will now need to be certified by the Central Drugs Standard Control Organisation.

What is the Concern?

- 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.
- 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.

Why such Rules Initiated?

- 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.

What are the Possible Impacts?

- 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.

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.