Draft Notification for Medical Implants

Recently, a draft notification issued by the **Ministry of Health and Family Welfare** has proposed to **bring "all devices" used for medical application,** under the purview of Drugs and Cosmetics Act, 1940. This will make “all devices” to be termed as “drugs” .

- **All devices** will include medical instruments, apparatus, appliance, implant, material or other article, whether used alone or in combination, including software or an accessory, to be used especially for human beings or animals.
- Manufacturers and importers of most of these devices will have at least 1.5 years to voluntarily register with the **Central Drugs Standard Control Organisation.**

The Rationale Behind the Draft Notification

Defective implants can cause crippling pain and even death. For example, **Johnson and Johnson’s faulty hip implants.**

Johnson and Johnson’s faulty hip implants case

- In 2018, **Johnson and Johnson’s hip implant called Pinnacle** was found to be leaking the **cobalt-chromium ions into the body,** leading to serious health complications, including metal poisoning of the blood, debilitating pain, and damage to the body organs.
- Further, **Johnson and Johnson have paid compensations to US patients** who had received the defective implants. However, In India, the company has **challenged government orders** to compensate 4,700 patients who had undergone hip replacement surgeries.
- Therefore, the Johnson and Johnson continue to **exploit the regulatory deficit** in India.

Impact

If implemented, the country's drug regulator will enforce standards to ensure the safety and effectiveness of these products while its pricing regulator will monitor the prices.

- **Central Drugs Standard Control Organisation (CDSCO)** is drug regulator in India.
  - It applies the provisions of the Drugs and Cosmetics Act, as well as the Medical Devices Rules 2017 on all medical devices.
  - It can also punish for violations as per the Act.
- While, **the National Pharmaceutical Pricing Authority (NPPA),** monitor the prices of drugs and ensure that they don't raise it more than 10% every year.

Way Forward

- The application of these medical regulations is marred by **inordinate delays.**
  - For example, the Food and Drug Administration of Maharashtra had directed to stop the import of Johnson and Johnson's hip implants, few months after Johnson and Johnson withdrew the product from the global market.
  - However, it took another year for the Central Drugs Standard Control Organisation to ban the import.
- Therefore, merely expanding the scope of regulation to all devices is not enough in a moment of growing number of safety disasters involving devices.
- So, there is a pressing need for framing of a **new medical devices act.**

Central Drugs Standard Control Organisation (CDSCO)

- **The CDSCO is the Central Drug Authority for discharging functions assigned to the Central Government under the Drugs and Cosmetics Act.**
- **Major Functions:**
  - **Regulatory control over the import of drugs, approval of new drugs and clinical trials.**
  - **Approval of certain licences as Central Licence Approving Authority**

National Pharmaceuticals Pricing Authority

- NPPA is an organization under **Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers** which was **set up in 1997** to revise the prices of controlled bulk drugs and formulations and to enforce prices and availability of medicines in the country, under the Drugs (Prices Control) Order (DPCO), 1995.
- The prices are **now fixed/revised** under **Drugs (Prices Control) Order (DPCO), 2013.**
- It also monitors the prices of decontrolled drugs in order to keep them at reasonable levels.

Source: IE