Mains Practice Question

Q. The growing problems in the field of medical implants in India calls for regulatory overhaul of present structure. Discuss. (250 words)

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Approach

- Introduce the topic by giving data and ground reality of medical device industry in India.
- In body enumerate the reasons for regulation of the industry
- Conclude by giving a way forward or mentioning government interventions, if any.

Introduction:

- India’s medical device industry is estimated to be worth $5.2 billion – the **fourth largest in Asia**. Devices implanted into the human body, or used for life support or sustenance, may pose potential risk must be strictly controlled. As of now there is no safety check on the devices.

- However, the rigour of reporting faults in medical devices in India is shockingly low. In the last decade, the US had more than 26,700 product recalls. India, on the other hand, had not been disclosing this information up until 2014.

Need for regulatory overhaul

- **Non-existent Regulation:** The International Consortium of International Journalists (ICIJ) in a report titled "Implant Files" on the medical device industry found India’s regulatory system as effectively non-existent. India's Central Drugs Standard Control Organisation earlier notified only 10 medical devices for regulation, but the list has expanded to 23 categories of devices.
- **Lack of quality control:** Patients become test subjects for new medical technology following the trusted advice of their doctors; they have been injured, maimed and killed by poorly-tested implants. For Instance, case of J&J hip implants.
- **Lobbying and Corruption:** In absence of regulation serious problems, including companies lobbying and bribing doctors, and patients being duped into unnecessary operations exist and was confirmed by the ICIJ report.
- **Lack of accountability:** Doctors and manufacturers of medical devices often don't report untoward incidents caused by faulty implants, and when they do, the information is frequently unverifiable and incomplete.
- **Aggravating financial burden:** In case of failure of implant device the burden of corrective surgery as well as permanent damages is borne by patients themselves.
- **No provision for compensation:** India currently lacks a system to ensure compensation for a victim of faulty implants.
  Increasing cases of "medical device adverse events": In 2014, 40 such cases were reported in India , the figure spiked to 556 in 2018 alone. The coronary stents manufactured by Abbott accounted for 50 of these 556 cases.
- **Lack of regulation in Pricing:** The National Pharmaceutical Pricing Authority of India (NPPA) monitors the prices of medical devices in India, but it's the NPPA's Drug Price Control Orders 2013

that applies only to medical devices. Of these 23 implants listed as "drugs" only cardiac stents, drug eluting stents, condoms and intra-uterine devices are considered "essential" and have their ceiling prices fixed.

Conclusion:

A bill for regulating the medical devices industry was first drafted 12 years ago but has not yet been enacted. Due to significant consequences for patients health as well as financial loss there is need for a comprehensive law for regulation of medical implants.