Medical Device Rules, 2020

Why in News?

The Medical Devices (Amendment) Rules, 2020 was notified by the Government of India to make changes in the Medical Devices Rules, 2017 that regulates medical devices.

What are the notified changes?

- The 2020 rules are applicable to devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals.
- It requires online registration of these devices with the Central Licensing Authority through the online portal of the Central Drugs Standard Control Organisation (CDSCO).
- Manufacturer has to upload certificate of compliance along with other details like name and address in the portal.
- Manufacturer shall mention the registration number, which is generated after the above information online, on the label of the medical device.
- The notification calls for a voluntary registration within a period of 18 months from April 2020.
- It also calls for obtaining manufacturing/import licence under the Medical Device Rules within 36 months for some devices and 42 months for others.

What are the items covered under these rules?

- A large number of commonly used items including hypodermic syringes and needles, cardiac stents, lenses, sutures, etc are covered under the new rules will have to comply starting April 2020.
- For items such as sphygmomanometers, thermometers and glucometers deadlines for compliance have been set from January 2021.
- For CT scan and MRI equipment, dialysis and X-ray machines, implants etc, deadlines for compliance have been set from April 2021.
- For ultrasound equipment, it is November 2020.

Why was the move required?

- The Indian health sector has been at the centre of attention following the faulty hip implants marketed by Johnson & Johnson (J&J).

- This has exposed the lack of regulation when it came to medical devices.
- The matter dragged on, exposing the regulatory loopholes until finally the company agreed in court to pay compensation to those who had to undergo revision surgeries because of the defective implants.
- J&J had for a very long time maintained that it had not received any adverse events report in the product, but had given compensation in other countries where people were impacted due to their implants.
- That is really where the discussion started about regulation of medical devices.

What are the penal provisions under Indian law?

- There are various penal provisions under the Drugs and Cosmetics Act, 1940 for various kinds of offences.
- Manufacture or sale of substandard items is punishable with imprisonment of 10 years, which may extend to imprisonment for life.
- There is also a provision for fine that will not be less than Rs 10 lakh rupees or three times value of the confiscated items.

How has the industry reacted to the government move?

- **Welcomed move** - The industry has so far reacted positively.
- But doubts remain about the ability of the CDSCO to effectively regulate both drugs and medical devices.
- The Chairman of CII's Medical Technology Division said that this move will ensure that all medical devices available will be safe and effective.
- **Temporary registration** - The temporary registration application for devices that are currently unregulated will require basic administrative documents and basic product information.
- The registration process carries no government processing fees.
- This registration may be cancelled or suspended by the CDSCO for product safety concerns, or when superseded by an Import/ Manufacturing License.
- Once registered the local registration holder will be required to notify the CDSCO and Materiovigilance Programme of India (MvPi) of Serious Adverse Events (SEA) occurring in India.

Source: The Indian Express