Medical Devices Under Drugs Law: RSTV – Big Picture

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What's in the News?

- The Union Health Ministry has notified that the medical equipment used on humans or animals, will be classified as "drugs" under Section 3 of the Drugs and Cosmetics Act, with effect from April 1, 2020.
- The Ministry, through a gazette notification, also released the Medical Devices Amendment Rules, 2020, for mandatory registration of medical devices.
    - This is to ensure that all medical devices meet certain standards of quality and efficacy.

Larger Background:

- Drugs fall under the Concurrent List and the definition of medical devices was introduced in 1982, under the definition of drugs under the **Drugs and Cosmetics Act,1940.**
- A majority of medical devices and their sale is unregulated in India.
- At present, only 24 high-risk medical devices, including cardiac stents, are regulated as drugs by the Central Drugs Standards Control Organisation.
    - The **Medical Devices Rules** were introduced in 2017, and the Centre has also formulated a report on a **roadmap to medical devices**. It has been formulated in consultation with all the stakeholders, such as AiMED, NITI Aayog, etc.
        - The AiMeD is an Umbrella Association of Indian Manufacturers of Medical Devices.
- **The Central Drugs Standards Control Organisation (CDSCO) is the apex drug regulator in India.**
- The Health Ministry notification has said that all medical device manufacturers will also have to register themselves on a centralized online portal for the purposes of quality control and assurance.
- The decision to include all the medical devices under the ambit of the Drugs and Cosmetics Act,1940 was taken in consultation with the **Drugs Technical Advisory Board (DTAB)**.

About DTAB:

- The DTAB is the highest statutory decision-making body on technical matters related to drugs.
- It is constituted as per the Drugs and Cosmetics Act,1940 and is a part of the CDSCO under the Ministry of Health and Family Welfare.

Drugs and Cosmetics Act, 1940

- The Act regulates the import, manufacture, and distribution of drugs in India.
- The primary objective of the act is to ensure that the drugs and cosmetics sold in India are safe, effective and conform to state quality standards.
- It was initially known as the Drug Act and was passed in 1940 and after several amendments is known as the Drugs and Cosmetics Act, 1940.

Classification of medical devices:

- The classification of the medical device rules along with the regulatory approval and registration by the CDSCO is under the control of the Drug Controller General of India (DCGI).

- All medical devices in India follow a regulatory framework based on the drug regulations under the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetic Rules, 1945.
- The newly notified rules further classify medical devices in four categories, Class A, Class B, Class C, and Class D.

Sl. No	Classes of Medical Device	Type of Medical Device	Examples
1.	Class A	Low-risk	absorbent cotton balls, alcohol swabs, etc.
2.	Class B	Moderate-low risk	thermometer, BP monitoring device, etc.
3.	Class C	Moderate-high risk	Implants, etc.
4.	Class D	High-risk	heart valve, etc.

- **Class A** and **Class B** would have 36 months, while **Class C** and **Class D** will have 42 months to subject themselves to strict quality control mechanisms and come under the compliance regime.
- The regulatory requirements for the approval of the license for drugs and medical devices are completely different.

The objective of the Union Health Ministry notification:

- The objective of the notification released by the Union Health Ministry is that all the medical devices should be brought under regulations, such that India could rise to international standards.

What is the need to bring the medical devices under the ambit of the Drugs Law?

- The total import of medical devices is more than 75% of the total medical device sales in India.
- The regulations imposed would help Indian companies to raise up to the International standards and integrate with global standards.
- There was a dire need to include all of the medical devices under the ambit of the Drugs Law, as the regulation of medical devices has been a problem in the past.
- The regulations on the Medical Devices would also provide an assurance of safety to the customers.
- Accountability has to be created, as medical devices play a key role in the medical field. Thus it could save or take away a person's life. Thus, a compromise in the quality of the devices could have tragic repercussions.

Apprehensions:

- The AiMED has placed forth a few apprehensions regarding this notification, such as:
    - Medical devices need to be regulated as medical devices or as engineering products and not as drugs/medicines.
    - The low-risk medical device manufacturers should be allowed to continue without regulations if they are not producing devices that have cost lives.
    - The law needs to be appropriate and specific to the medical devices and their uses.
    - The manufacturers coming under the ambit of the law should be trained for capacity building, as the changes shouldn't be disruptive.

What are the operational difficulties and concerns associated with the notification?

- India depends a lot on the import of medical devices and exports a lot of consumables.
- A lot of the equipment and medical devices have not been mentioned.
- The industries would seek a lot of clarifications from the DCGI and the Health Ministry in terms of the definitions of importers and manufacturers, Low risk and high-risk devices, etc.

How does the consumer benefit from these regulations?

- The consumer gets an assurance that the devices sold or used are of the proper quality due to the regulations imposed.
- The regulations are dynamic in nature. These are formulated keeping in mind the latest technology and current needs of the public. The regulations include the manufacturer, the distributor, and the consumer's roles and responsibilities.
- Regulations will ensure the safety and equality of medical devices to the patients.
- The devices exported did not have a license earlier, thus under the new notification, the exported devices will be getting a license or a certificate.

Way Forward:

- A separate lawbook that had been promised by NITI Aayog has to be formulated.
- A separate regulatory framework with specialists and adequate manpower to control and handle medical devices has to be formulated.
- The regulatory framework must be given the power to make decisions when in need, such that the burden on the courts also reduces.