



drishti

Medical Devices In India- Issues and Challenges

 drishtiias.com/printpdf/medical-devices-in-india-issues-and-challenges

This article is based on **“Medical devices are not drugs”** which was published in The Indian Express on 25/10/2019. It talks about the proposed regulatory framework for medical devices.

The Ministry of Health and Family Welfare is going to set up a **regulatory framework** for **medical devices** and aims to implement this new framework **without moving a new law in Parliament** to regulate the medical device industry.

Highlights

- The Ministry of Health and Family Welfare is creating an entire **regulatory framework** out of **notifications and rules**, using **powers delegated to it under the Drugs and Cosmetics Act, 1940**.
- The **first step** towards this framework was made in 2017 when the ministry notified the **Medical Device Rules, 2017**. At that time, only a few medical devices were notified as “drugs” but now all are intended to put in the category.
- This means that **all medical devices** would be **placed within the framework of the Medical Device Rules, 2017**.
- The **medical industry has been very irresponsible** towards patients in India which became evident by **the hip-implant scandal**.

The Drugs and Cosmetics Act, 1940

- It is a **pre-independence legislation** that was enacted almost 80 years ago.
- It is an act of Parliament which **regulates the import, manufacturing and distribution** of drugs in India.
- Its objective is to ensure that the drugs and cosmetics sold in India are **safe, effective and fulfills the safety standards and parameters**.

The Medical Device Rules, 2017

- It came into effect from **January, 2018** and is **applicable to medical devices and in-vitro diagnostic medical devices**.
- It made **licensing application process online**.
- It made **medical devices novel to Indian market subject to special regulations**.

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**.

Challenges

- It will **lead to a toothless regulatory framework for devices**, similar to what exists for drugs today.
- The **ministry cannot create new offences or penalties through its rule-making authority**.
 - Only laws enacted by Parliament create new offences and penalties. As a result, the Medical Device Rules 2017 contains no penal provisions.
 - The **Drugs and Cosmetics Act does contain a penal provision for the manufacture of sub-standard drugs** but it cannot be used to penalise manufacturers of sub-standard medical devices because legally binding standards recognised in the **Second Schedule to the Drugs and Cosmetics Act covers only pharmacopeias for drugs** which means no standards for medical devices and no prosecution of a manufacturer of sub-standard medical devices.
- If the current proposal is adopted, the **situation will be similar to that of substandard drugs**. Companies that make defective products will order devices from foreign markets and will continue to sell them in India, and comply with the law.

The **sale of substandard drugs can be prosecuted** under the current law but most manufacturers who make poor quality drugs stay free due to **poor surveillance and lack of political will and unity**.

- In the recent hip-implant scandal, **one of the main challenges** faced by the government in securing justice for faulty hip-implants **was to secure a list of patients who had received the implant through surgery.**
 - The manufacturer sold devices to doctors and hospitals instead of patients directly so it did not have a list of patients who had these devices implanted.
 - Doctors and hospitals lack incentives to share the patient list and even if they want to, legal liability for surgically implanting faulty devices in the patient's body, would stop them in doing so.
- More importantly **medical devices**, because of their nature, **are far more difficult to standardise** when compared to drugs.
- There are **no tools available** to Indian regulators under the proposed framework to hold makers of sub-standard medical device manufacturers to account for their actions. At most, the **ministry can prohibit the manufacture and sale of certain medical devices under Section 26A or cancel a license to prevent** future harm.
- **Penalties or prosecution to punish for the harm already inflicted on patients due to negligence or intentional wrongdoing are not figured** yet and it remains an important challenge.

Solution

- One of the solutions to solve this information deficit is to **create a confidential patient register** that should be maintained by the government to record all details of implants.
 - This register **could be used to notify patients** in the case of malfunctioning devices. But the proposed regulatory framework does not offer any such provision.
- The government **must rethink this toothless framework and instead enact a new law through Parliament.** While medical devices have tremendous potential to revolutionise healthcare, the hip-implant scandals in India and abroad have shown us the dark side of this industry.

Way Forward

- There is a difference between medical devices and drugs so it would be a grave mistake to apply the same regulatory framework for both of them. A **targeted and different approach is needed to regulate** these complex devices.
- **New and innovatives ideas are needed** to regulate this industry in the Indian context especially when the government bodies and the judiciary lack the capacity to handle such difficult and multilayered issues.

Drishti Mains Question

Examine the challenges and issues with respect to the medical device industry of India.