Regulating Medical Devices

What is the issue?

- For a country with the fourth-largest medical devices foothold in Asia, India must aim to increase local investment and production.
- The success of India's aim to be self-reliant will be defined by the regulatory framework in medical devices.

What is the transition?

- Japan is paying its companies to shut their manufacturing plants in China.
- American companies are planning to shift their base from China.
- So, these are times of strategic transitions which India must use wisely.

What is the history?

- In 2017, voluntary certifications began in India with the Indian Certification for Medical Devices (ICMED) of Quality Council of India.
- The ICMED gave process certification to many medical devices using notified bodies.
- The industry couldn't understand the need for the voluntary certification scheme, and this was opposed by the CII and the FICCI.
- Medical device experts see it as a deviation from global practices.
- This indicates that the regulatory environment in India is complex.

What kind of reform is needed?

- Industry representatives recommended that any new legislation should be aligned with international regulatory best practices.
- They also suggested that the industry should be involved and consulted throughout the process.
- India aims to transform into a global manufacturing hub.
- So, the regulatory mechanism should be harmonised with the global best practices recommended by the International Medical Device Regulators Forum (IMDRF).

What are the global standards?

- Essential principles of **safety and performance** are important.

- To demonstrate compliance with essential principles, there are consensus standards developed by global standards bodies such as the ISO, and recognised by stringent regulatory authorities and the IMDRF.
- There are two kinds of standards:
    1. Horizontal (ones that describe the process or practice that is applied across a range of devices, like sterilisation, software, etc)
    2. Vertical (specific test methods or performance aspects of a specific grouping of devices).
- These standards have been segregated so that a manufacturer can develop a medical device in accordance with key elements of essential principles.

What is the problem?

- Procurement agencies have been procuring commodities complying with a specific standard.
- In the case of medical devices, they were faced with the challenge in procurement as the same product with different specifications and varying complexities was before them.
- This led to complexities in procurement.
- Hence, the Bureau of Indian Standards (BIS) was requested to develop standards to procure medical devices.

What could be done?

- The BIS must adopt international standards to encourage Indian manufacturers to conquer the global market.
- It should also help global players introduce new products and increase investments in India.
- The US, the EU, Japan and other IMDRF countries rely on these consensus standards to increase predictability, streamline premarket review and provide clearer regulatory expectations.

Source: Financial Express

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