



Need for Relook on Indian Medical Devices Industry

What is the issue?

\n\n

\n

- The International Consortium of International Journalists (ICIJ) recently published the 'Implants Files investigation' on medical devices. Click [here](#) to know more.

\n

- In this backdrop, the Indian medical devices industry is in serious need of examination.

\n

\n\n

What are the concerns highlighted?

\n\n

\n

- The investigation has revealed multiple signs of danger in regards with the medical devices industry.

\n

- The number of “medical device adverse events” has gone up from 40 in 2014 to more than 550 in 2018.

\n

- One instance would be the deaths after the installation of a stent.

\n

- Then there is the question of devices that have been recalled elsewhere.

\n

- E.g. As many as 117 devices have been recalled over the past two years by the United States Food and Drug Administration (or USFDA) because they have led to adverse events.

\n

- But half, perhaps more, of these devices are still on the market in India.

\n

- Medical device manufacturers are not following up on their responsibility to

track down the recipients of medical devices that have been withdrawn.

\n

- They also do not pay the compensation that is consequent upon such withdrawals.

\n

\n\n

What are the drawbacks in India?

\n\n

\n

- The global withdrawals are not being followed through in India.
- There is not even a public list maintained by the regulator of devices that have been recalled from the global or Indian markets.
- In this case, the Central Drugs Standard Control Organisation (CDSCO) has the responsibility.
- Even if regulators are not willing to take action, they must at least serve as information clearinghouses and broadcasters.
- By this, at least, the recipients, their relatives, or citizens concerned can take action on their own.
- The data maintained by the Indian Pharmacopoeia Commission, or IPC, is also worryingly incomplete.
- This is likely because the reporting standards are too low.
- In general, the incentive structure for doctors and medical centres, particularly in metropolitan cities, are not supportive.
- So they do not react appropriately to a troublesome medical device and thus problems may not be reported.
- The close links between medical device companies and medical professionals are widespread, a variant of those between pharmaceutical companies and doctors.

\n

\n\n

What does it call for?

\n\n

\n

- The medical device industry is a unique blend of engineering and medicine.
- It involves the creation of machines that are then used to support life within the human body.
- Given this, it needs not only careful regulation but also the highest ethical standards.
- Certainly, major changes are needed in the sector.
- It is up to the government to reinvigorate both the IPC and the CDSCO, and to give them more resources and a clearer mandate.
- The issue of the trustworthiness of the private sector to be relied for the tertiary health care system also needs attention.
- A large and vibrant public sector in tertiary health care is essential.
- This is possibly the way to counteract the hurtful consequences of information asymmetries and poor regulation.
- The government should re-examine its plan for universal health care, at this juncture.

\n

\n\n

\n\n

Source: Business Standard

\n



IAS PARLIAMENT
Information is Empowering
A Shankar IAS Academy Initiative