Need for Relook on Indian Medical Devices Industry

What is the issue?

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- The International Consortium of International Journalists (ICIJ) recently published the 'Implants Files investigation' on medical devices. Click here to know more.
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- In this backdrop, the Indian medical devices industry is in serious need of examination.
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What are the concerns highlighted?

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- The investigation has revealed multiple signs of danger in regards with the medical devices industry.
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- The number of “medical device adverse events” has gone up from 40 in 2014 to more than 550 in 2018.
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- One instance would be the deaths after the installation of a stent.
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- Then there is the question of devices that have been recalled elsewhere.
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- 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.
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- But half, perhaps more, of these devices are still on the market in India.
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- Medical device manufacturers are not following up on their responsibility to track down the recipients of medical devices that have been withdrawn.
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- They also do not pay the compensation that is consequent upon such withdrawals.

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What are the drawbacks in India?

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

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

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