Implants File Investigation and Indian Regulations

Why in news?

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The International Consortium of International Journalists (ICIJ) recently published the 'Implants Files investigation' on medical devices.

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What is the Implants Files investigation about?

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- Implants Files investigation is a global examination of the medical device industry and its overseers.
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- According to India’s regulator Central Drugs Standard Control Organisation (CDSCO) broadly defines a medical device as any “instrument, apparatus, appliance, software, material, or other article” that is to be used, whether alone or in combination, for “diagnostic or therapeutic purposes”.
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- The International Consortium of International Journalists (ICIJ) and a team of more than 250 reporters examined hundreds of cases to investigate various aspects of the medical device industry regulation, faulty devices and corruption.
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- The ICIJ and its partners filed more than 1,500 public records requests and collected more than 8 million device-related records, including recall notices, safety warnings, legal documents and corporate financial filings.
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What are the significant findings of the investigation?

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- Governments in dozens of countries in Africa, South America and Asia don’t regulate medical devices, instead placing their trust in European authorities

or in the US FDA.
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- Medical devices that broke, misfired, corroded, ruptured or otherwise malfunctioned after implantation or use — despite assurances by regulators, the industry and doctors that they were safe were linked to 1.7 million injuries and nearly 83,000 deaths over the last decade.
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- Nearly 5,00,000 reports mentioned an explant a surgery to remove a device in connection with an adverse event.
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- Doctors and manufacturers often fail to report adverse events, and when they do the information can be unverified and incomplete.
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What are the laws governing medical devices in India?

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- Earlier, only 10 notified medical devices were regulated in India later this has since been broadened to 23 categories of devices.
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- These mainly include syringes, needles, perfusion sets, in-vitro devices for HIV treatment, catheters, intra-ocular lenses, cannulas, bone cements, heart valves, orthopedic implants, coronary stents, IUDs and condoms.
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- The important segments of medical devices in India are consumables and disposables that are mostly manufactured by Indian player, patients aids like hearing aids and pacemakers, various implants, and stents.
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- In India, medical devices continue to be regulated as “drugs” via the Drugs and Cosmetics Act, 1940, and that newly introduced Medical Device Rules, 2017, which came into effect on January 1, 2018.
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- New rules classify medical devices based on risk, as is done by the Global Harmonization Task Force.
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- The devices are classified as Class A (low risk), Class B (low moderate risk), Class C (moderate high risk) and Class D (high risk).
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1. An application for grant of a license to manufacture Class A medical devices

does not require prior audit by third party or official inspection.
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2. Class B medical devices require prior audit by a third party but do not require official inspection.
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3. Class C or Class D medical devices require prior official inspection.
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How medical device price regulation works in India?

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- The National Pharmaceutical Pricing Authority of India (NNPA) monitors the prices of medical devices.
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- The NPPA's Drug Price Control Orders (DPCO) 2013 apply only to medical devices.
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- Out of 23 medical devices listed as drugs, four cardiac stents, drug eluting stents, condoms and intra-uterine devices have been included in the National List of Essential Medicines and are under price control by virtue of being included in Schedule-I to DPCO 2013.
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- Their ceiling prices have been fixed, the government has also notified ceiling prices for orthopedic knee implants in DPCO 2013.
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- The maximum retail prices of other medical devices, being under the non-scheduled category, are monitored by the NPPA to ensure that no manufacturer increases the MRP by more than 10% of the price during the preceding 12-month period.
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What are few issues in Indian medical device regulation?

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- In India a device such as a pacemaker cost less in the market and much more when implanted in a hospital.
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- For instance, a US-based company buys an 'X' pacemaker for Rs 25,000.
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- The Indian subsidiary then increases the price, fixes the MRP at Rs 50,000,

and then sells it to a distributor at a “discounted price”, say Rs 46,000.
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- The distributor then sells it to a hospital at a price that is still discounted compared to the MRP, say at Rs 48,000.
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- Finally, the patient buys the device from the hospital at Rs 50,000, So within the chain all three make a profit.
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- Additionally, the patient pays the cost of the surgery, which varies from hospital to hospital.
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- Currently, there are no specific rules or a law that allows the government to direct a medical device company to give compensation to a victim after the device has been found faulty.
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What lies ahead?

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- Following the emergence of faulty hip implants from Johnson & Johnson, the Ministry of Health and Family Welfare is working on a formula for compensation. Click here to know more
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- There are proposals that the government might include a special clause under the Medical Device Rules to include compensation for patients.
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- But the patient can always approach a consumer court to seek damages from the device company.
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Source: Indian Express

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