Product Recall Norms

What is the issue?

- There is a debate on the cause for delay in identifying unsafe products in the Johnson and Johnson (J&J) hip implant case.
- This gave rise to a bigger question on how we should ensure the safety of consumer.

What is the current situation?

- Governments and businesses are dealing with the reality that given global supply chains and increased product complexity, recalls are inevitable.
- Whether it is recalls by automobile majors or food and drug manufacturers, safety issues are widespread.
- As these occurrences escalate in India, there is an urgent need to build systems, regulation and map data which can mitigate such events.

What is the global disparity?

- 2008 Sanlu milk scandal (China) - Infant formula adulterated with melamine led to infant deaths, resulted in a blanket ban on Chinese milk products and the final execution of the accused.
- However, the difference in safety regulations worldwide is stark.
- The J&J recalls took place in Australia and the US in 2010 but the Indian response began only in 2017.
- It began when the Drug Controller General of India set up a committee to probe the issue.
- Indian patients were eligible for revision surgeries but most were ignorant of this information.

What does their research reveal?

- **As per the research**, in India, there were around **29 recall events** across the automobile, drugs and food sectors.
- But, the US Food and Drug Administration's (**FDA**) import refusal list for India across food, drug and cosmetic products, in 2019 alone reveals an average of **162 refusals/month**.
- The **reasons** mentioned were ranging from mislabelling, adulteration and being unsafe for consumption to poor manufacturing practices.

- Research suggests that firm-initiated preventive recalls are indicative of mature internal quality control systems which may be the case in automobiles.

What are the regulations?

- The consumer protection laws have existed in India but an **integrated regulatory framework** for product recalls has been largely **absent**.
- However, the factors like **increasing consumer awareness, high profile recalls** and the **attention of policy-makers** are helping the product safety movement gain momentum.
- This is done through regulators such as the FSSAI, Central Drugs Standard Control Organisation (CDSCO) and the Society of Indian Automobile Manufacturers (SIAM).
- The FSSAI and SIAM introduced the recall process draft and code in 2011 and 2012, respectively, but there is a need for stronger enforcement of safety standards and recall data.

What could be done?

- **Standards systems** and **recall data** can mitigate the impact of a recall and enable faster tracking of unsafe products.
- In India, efficient response to safety events is critical.
- Standardised **information mapping** of recalls across sectors, stringent **regulation** and systemic **accountability** are essential for quick information dissemination to affected consumers.

Source: Business Line

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