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Review Article

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Drug Recalls: Trend analysis of Recalls by Indian Pharmaceutical Industry during the period 2013-2023

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Abstract

With the advanced technologies, increasing complexities of the manufacturing processes, more stringent inspections, and dynamic regulatory environment under which manufacturers work, there are high possibilities that a pharmaceutical firm will undergo a recall of one of its products. A recall can impact a company in product exposure, sales, manufacturing costs, and patients trust. The study presented here explored the drug recalls made by Indian Pharmaceutical Industry during the period of 2013 – 2023 from US market. There is an increasing trend in number of recalls post 2017 which could be due to the new regulations and, scientific discoveries from USFDA. The major reasons for recalls primarily included cGMP deviations, failure to comply with the approved specification, labeling mix ups. The study enlists the expectations of US FDA from Indian Pharmaceutical sector. This will help Indian pharmaceutical manufacturers to adopt the strategies to minimize drug recalls from US.

Keywords: Drug Recall, Pharmaceutical, Indian Pharmaceutical Industry, Risk based classification, FDA (Food and Drug Administration)

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1. Introduction

Recalls are actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority. They have been classified by USFDA based on the level of hazard to patients:

Class I recall: a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

Class II recall: a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

Class III recall: a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

A drug recall is the most effective way to protect the public from a defective or potentially harmful product. FDA's role in a recall is to oversee a company's recall strategy, assess the adequacy of the company's action and classify the recall. Not all recalls are announced on FDA.gov or in the news media. Public notification is generally issued when a product that has been widely distributed or poses a serious health hazard is recalled. However, if a company does not issue public notification of a recall, FDA may do so if the agency determines it is necessary to protect patients and consumers. All recalls are posted weekly in the FDA enforcement report. (1-3)

2. Objective

The objective of the study presented in this paper, was to analyse the trend of recall events issued by USFDA to Indian Pharmaceutical Industry during the period 2013-2023. In addition, this paper also discusses the top reasons for recalls and strategies to overcome the same.

3. Methods

The method adopted in this research was exploratory, where the data about the recalls was extracted from US FDA compliance dashboard with the appropriate filters. An event is a firm's recall of one or more products. Filtering of database at the event level as well as at the

product level displays how many recalls have occurred voluntarily and category wise, respectively. FDA compliance dashboard is created by US FDA to increase transparency and accountability by displaying and allowing the analysis of public FDA data through easy to use, visually accessible, customizable, and understandable graphics.

Recalls data included in the dashboard is based on the FDA's Enforcement Reports and only includes recalls that have been classified. (4)

4. Results and discussion

4.1. Results

A total of 142 products (Figure 1) were recalled during the period of 2013–2023 by Indian Pharmaceutical Industry, out of which 123 (Figure 2) were of product category "drugs". FDA reviews the company's proposed strategy for carrying out the recall upon notification and assigns the recall a risk classification. Based on the data available by FDA, there has been a gradual increase in class II recalls from 2013 to 2023. However, in Fiscal year 2023, the number of recalls of Class I & Class II have been increased drastically (Figure 3). (5)

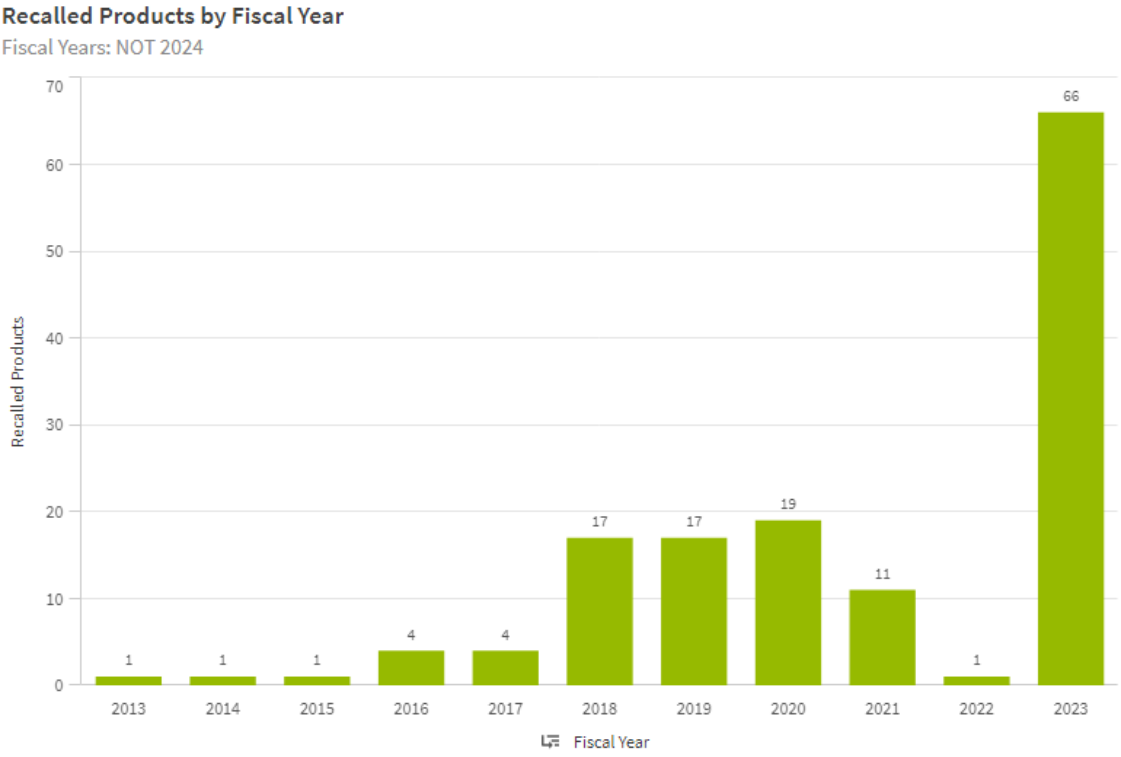

Figure 1. Recalled Products by Fiscal Years

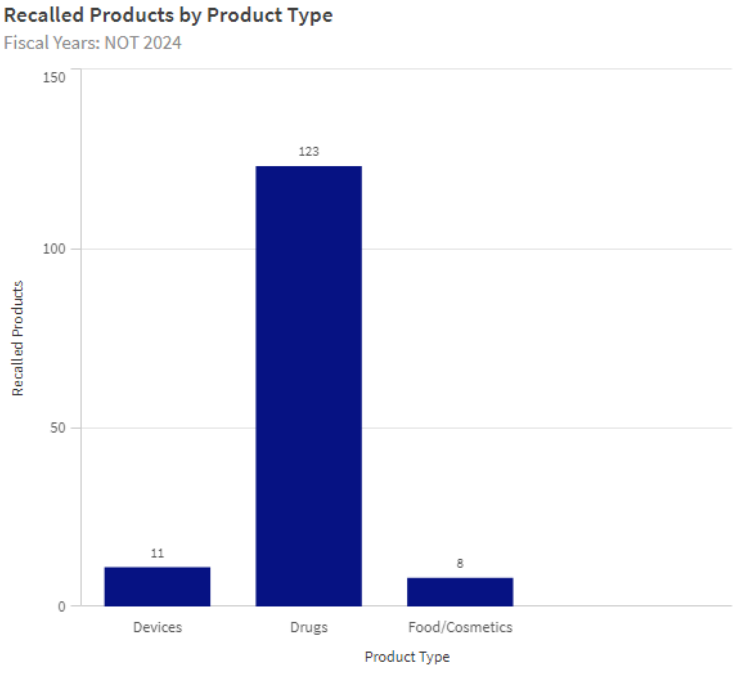

Figure 2. Recalled Products by Product Type

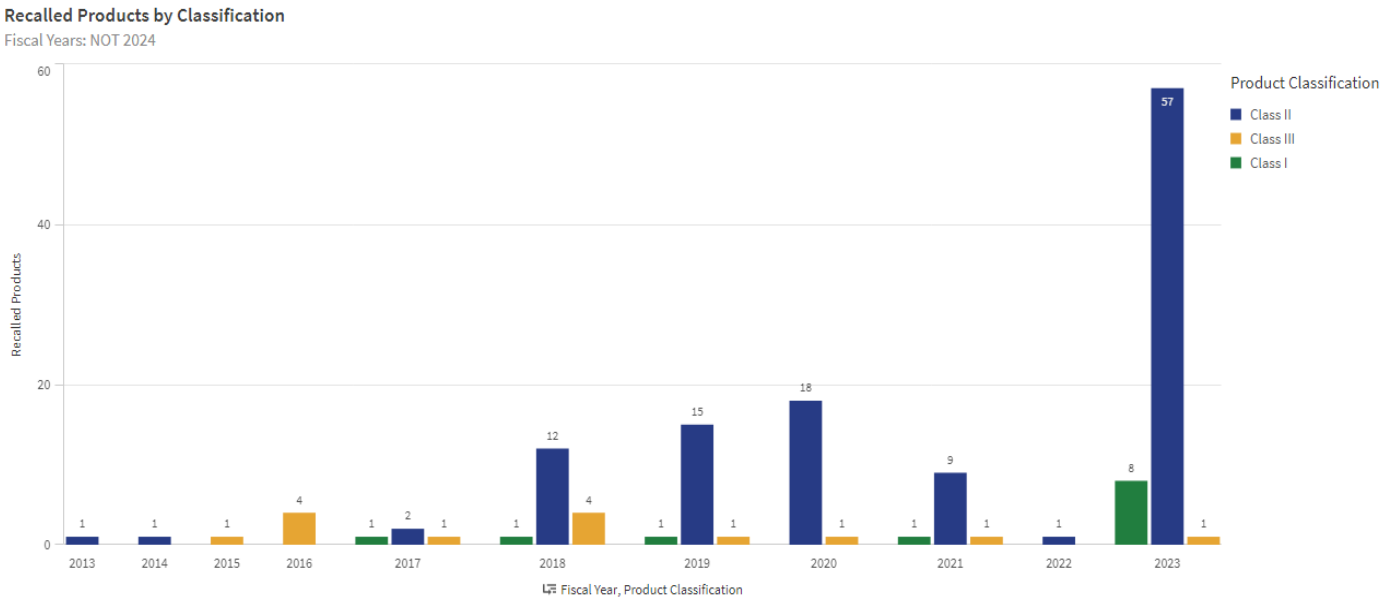

Figure 3. Recalled Products by Classification

Further targeting the product category "drugs", the overall recall trend based on classification in the last decade is as per Figure 4.

Based on the critical analysis of recall letters issued to Indian Pharmaceutical Industry, the top reasons for recalls are identified and tabulated in table 1.

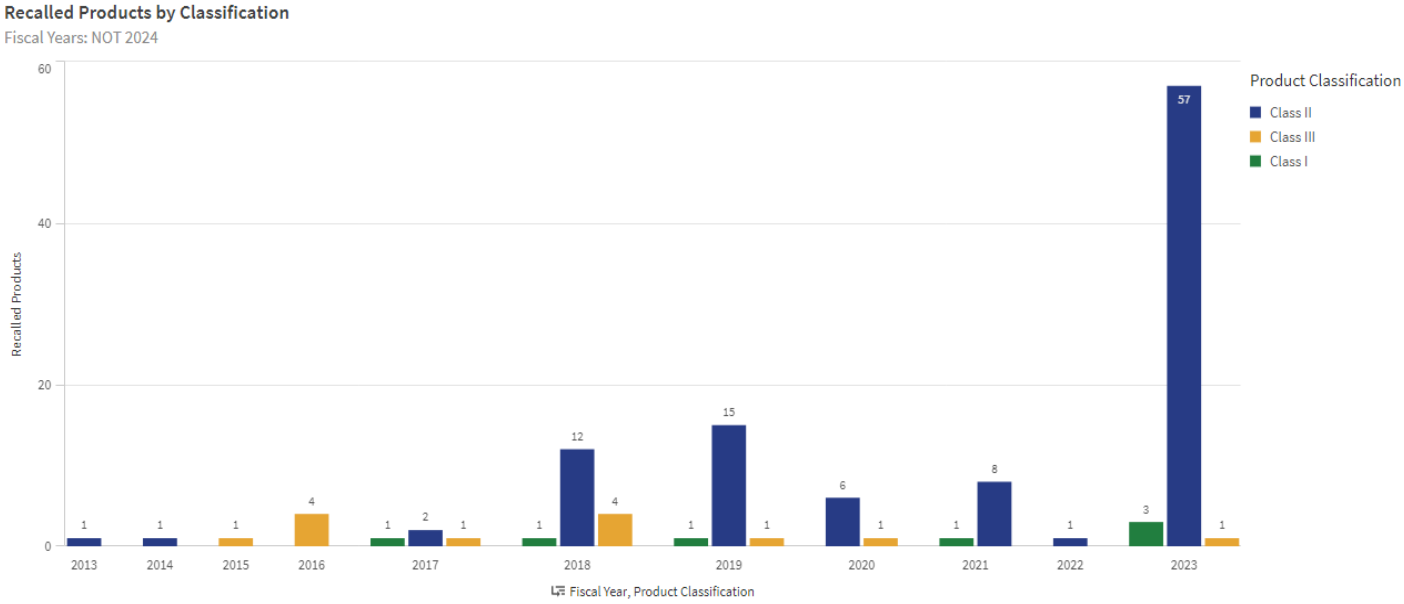

Figure 4. Recalled Products (Category: Drugs) by Classification

Table1. Reasons for Drug Recalls

Classification	Reasons for Recall
Class I	• cGMP deviations • Labeling mix-ups • Non-sterility • Presence of Particulate matter
Class II	• Lack of assurance of sterility • cGMP deviations including nitrosamines • Presence of foreign substances • Failed specification with respect to impurities, dissolution
Class III	• Failed specifications • Presence of foreign substances • cGMP deviations • Incorrect labelling

4.2. Discussion

According to figure 4, there has been an increase in the drug recalls by Indian Pharmaceutical and Manufacturing Industry. The sharp increase in the class II drug recalls in Fiscal Year 2018 was due to the discovery of presence of N-nitrosodiethylamine found in the API used to manufacture the product. Thereafter, the failure to the compliance to the approved specifications became another reason for recall. However, the drastic increase in class II drug recalls in the Fiscal Year 2023 is attributed to multiple reasons dominated by the non-compliance to sterility assurance in parenteral products.

As per table 1, the main reasons for the recall of the finished product batch after it has been commercialized in the market, included quality issues, labeling issues and/or GMP deviations during the manufacturing process. These issues are unacceptable to the FDA and pose consumer safety risks that could damage both profitability and reputation of the company.

To avoid and minimize the drug recalls, Industry should consider the setting up of following practices:

a) Focus more on compliance to regulatory guidelines : Regulatory requirements of batch testing and release prior to commercialization of products should be known to the entire team who is involved in the batch production and dispatch.

b) Managing strict quality control measures: Quality controls approved from FDA should be considered while testing the product.

c) Set-up a vigilant quality system: Multi-level quality checks during manufacturing of the batch.

d) Prevent labeling mix-ups: Automation of manufacturing lines, use of digital tools may minimize labeling mix-ups.

e) Personnel:

- Employ skilled workforce,
- Provide periodic training on regulatory guidelines
- Make them understand the impact of the recalls.

5. Conclusion

Drug Recalls are not a respectable sign for any company. The recall is usually due to company's discovery, customer's complaint, or FDA observation. (6) These recalls not only impact the overall trust of the regulatory agency but also of patients who are the ultimate user of the medicine. Indian Pharmaceutical industry should understand the expectations of Agencies and try to work on adapting the same while minimising the drug recalls. Employing a skilled workforce, well-trained personnel, creating a quality culture, if adequately put into practice, helps to prevent instances of contamination and mix-ups, thereby reducing the chances of drug recalls.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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