الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Content analysis of drug recall announcements in Saudi Arabia: between 2016 and 2022

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Background

Poor-quality medicines are a significant public health problem primarily affecting developing countries and their emerging market economies. The most common reason that might contribute to the widespread of substandard medicines is inadequate regulation and governance of regulatory authorities of unethical practices by wholesalers. Therefore, drug regulatory authorities and pharmaceutical companies deal with poor-quality medicines through drug recalls to ensure the safety and efficacy of drugs and medical products for consumers. To our knowledge, no studies have analyzed drug recall announcement reports regarding patterns of requesting voluntary drug recalls by pharmaceutical companies.

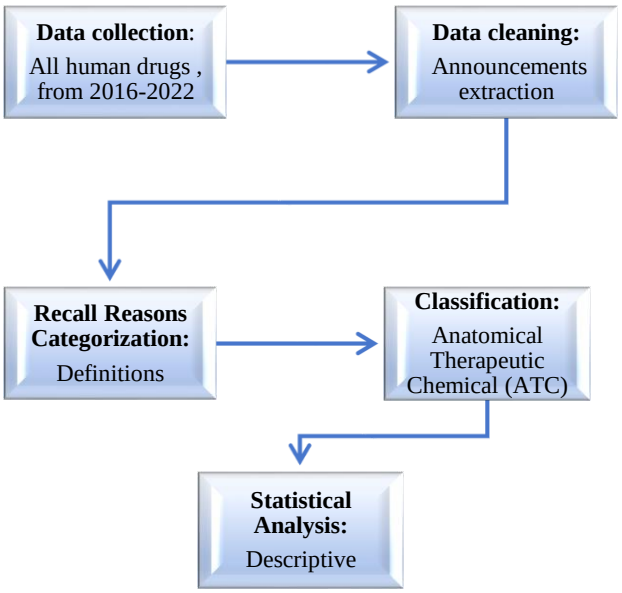
Objective

- Explore the characteristics of drug recalls announcements issued over seven years by the SFDA in Saudi Arabia.
- Examine the patterns of voluntary drug recall requests by pharmaceutical companies (both innovator and generic) in response to product defects.

Results

A total number of 375 products were recalled during the study period. The majority of recalls were involuntary [310, (82.7%)]. The most common reasons for recalls were; non-compliance with manufacturer's specifications [125,(33.3%)], contamination [89, (23.7%)], and violations [77, (20.5%)]. Antacid was reported as the highest-recalled therapeutic class in three different years (2017, 2019 and 2020). A total of 109 pharmaceutical companies were associated with recalled products, of those, [93 ,(85.3%)] companies were generic pharmaceutical companies. [11, (68.8%)] of innovator pharmaceutical companies requested voluntary drug recalls.

Methods



Conclusion

- Innovator pharmaceutical companies tend to request voluntarily recall when drug defect occurs compared to generic pharmaceutical companies.
- Results suggest that the SFDA might increase its efforts to tighten regulations on generic pharmaceuticals practices in terms initiating of recall request with listing the reasons of drug recalls.