Review Article

Recall act in South Africa: An overview

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ABSTRACT

The pharmaceutical industry is making every effort to meet all current requirements in terms of quality. However, in recent times, due to drastic increase in recalls of pharmaceutical product, major challenges such as increasing complexities of design and manufacturing processes, intensive globalization processes, more stringent inspection procedures, and manufacturer's product liability and regulatory burdens have risen dramatically. Product recall could greatly damage the reputation, profitability, and brand integrity of a company, and therefore, the industry needs to deal with effective tactics for recall. In addition, safety must always be a concern of the people who manufacture these pharmaceuticals and are associated with them. The recall is usually due to company's discovery, customer's complaint, or regulatory board observation. The recall process involves a specific plan of action that addresses the complexity of the recall, the need for public warning, and the extent to which the recall will be checked for effectiveness. The regulatory board will review and/or recommend changes, as relevant, to the recall strategy of the firm. The critical recall information list includes product identity, brief description of the failure, product quantity produced in the distribution chain, and direct account. Product recall clashes affecting thousands of businesses each year: Sales, testing customer relationships, and disrupting supply chains.

KEY WORDS: Recall Process, Recall strategies, Recalls

INTRODUCTION

A drug recall is an instance, whereby a batch or a whole production run of a drug product is returned to the manufacturer, usually due to the detection of safety problems or the defect of the drug product. When drug products are known to have potential adverse effects on users due to their deficient quality, safety, or efficacy, they may be subject to a recall and all related information will be reported to the drug office. When a regulatory authority finds a breach of the laws, it issues a recall order by which a company removes or corrects the market product. If the orders are not followed, the agency would initiate legal action. A team is responsible for coordinating all aspects relating to the recall of products. The team consists of endeavor to design, manufacture, and sell safe and reliable products. No matter how best a company exists, dangerously defective drug product can reach the customers. These products may cause disasters, leading to adverse verdicts in litigations involving liability for drug products.[1]

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Quality management of complaints and recalls of drug products is needed to ensure customer safety. Recalls may either be unconstrained by the manufacturer or regulatory board injunctions occasionally. Recalls vary in severity and in the action required to be taken. Factors such as product returns and recalls are giving the companies new challenges, such as litigation problems, negative publicity, loss of patent protection for many major drugs, and widespread efforts to contain drug spending. A recall is a serious process. It illustrates a dangerous situation that needs swift and immediate intervention to avoid harm to the public. Drug recalls are increasingly widespread and have dramatically increased.

There is continuous upsurge in the growth of product recall that is being noticed somewhere across the globe accompanied with safety issues of the product. The product present in numerous jurisdictions requires to recall the product based on the response evaluated from each country. Outbreak of product recall could result in the following:

- A crisis of consumer confidence
- An onslaught of adverse media publicity
- Multiple product liability claims
- Irreparable reputation and brand damage

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- Plummeting profits and stock price
- Substantial regulatory fines and business interruption
- And criminal penalties [Figure 1].

SOUTH AFRICA

The development of guideline for recall/withdrawal of medicines, medical devices, and *In-vitro* diagnostic product (IVDs) is a contract between the certificate holder of registration (HCR)/parallel importer (PI)/distributor of the medicine/medical device/IVDs, and the department of health: Medicines Control Council (MCC) in South Africa. When the safety and quality of the three (medicines, medical devices, and IVDs) are intentionally or unintentionally compromised, then the latter three should be picked out of the market for which cluster: Food control, pharmaceutical trade, and product regulation: Directorate: Inspectorate and law enforcement and the holder of the certificate of registration/PI of the medicine/medical device/IVDs have to take the action against the compromised product [Table 1].

The responsibility for removal of the product from the market lies with the Registrar of Medicines, the director and deputy director: Inspectorate and law enforcement, and the medicines who will evaluate the measures taken by the holder of the registration certificate/PI's/distributors to recall the product and provide scientific, technical, and operational guidance.

Any quality defects observed should be reported by the HCR/PI/distributor, the outcome of which may be a recall of the product together with coordination of regulatory authority. The two personnel shall be appointed by the HCR/PI/distributor who have the charge to talk on the recall, if necessary execute a recall and such information of two persons with their names and telephone number should be provided to the regulatory authority of medicines.

The HCR/PI/distributor should ensure that the recall is promptly done with regular follow-up for a successful removal of the product from the market and hence the regulatory authority – MCC keeps high expectation that the HCR/PI/distributor will do their work properly.

Table 1: Country profile of South Africa

Country profile	
Country name	Republic of South Africa
Capital	Pretoria
Population	50.7 million
Area	1.22 million sq. km
Major language	11 official languages including English, Afrikaans, Sesotho, Setswana, Xhosa, and Zulu
Major religion	Christianity, Islam, indigenous beliefs
Life expectancy	53 years (men), 54 years (women)
Currency	Rand (1 Rand = 5 INR)
Government	Unitary dominant-party parliament constitutional republic
President	Cyril Ramaphosa
Regulatory authority	SAHPRA

SAHPRA: South African Health Products Regulatory Authority

Majority of the recalls are directed on voluntary basis. The withdrawal or removal of the product from the marketplace may fall into following mentioned reasons:

- Cancellation of registration
- Illegally present in the market
- Comprising the quality or safety of the product

If needed, MCC will take appropriate steps when the recall of the product performed is not adequate.

Provisions of the Act

The provision of the act is explained in the Figure 2.

NOTIFICATION/INITIATION OF THE RECALL

The reports on the deficiency of the product are obtained from manufacturers, wholesalers, retail and hospital pharmacists, and doctor which are provided to HCR/PI/distributor or MCC to initiate the recall. The report of the deficient product may contain: The adverse drug reactions, deficiency in quality, complaints on technical aspects, for example, in print wrapping material, errors in labeling, not maintaining cleanliness (contamination), and bogus medicines that could be adulterated.[2]

The range at which the public is warned about the deficient product and the effectiveness of the recall are the following aspects to be considered before the recall is being initiated by the HCR/PI/distributor.

The Registrar of Medicines or the designee in the absence of latter should be informed before beginning a recall as well as it is obligatory to consult with MCC irrespective of the level of recall. In case of weekend or public holidays, the HCR/PI/distributor can circulate the information of recall within 24 h along with the precautionary steps to be applied to quarantine stock pending the initiation of the recall.

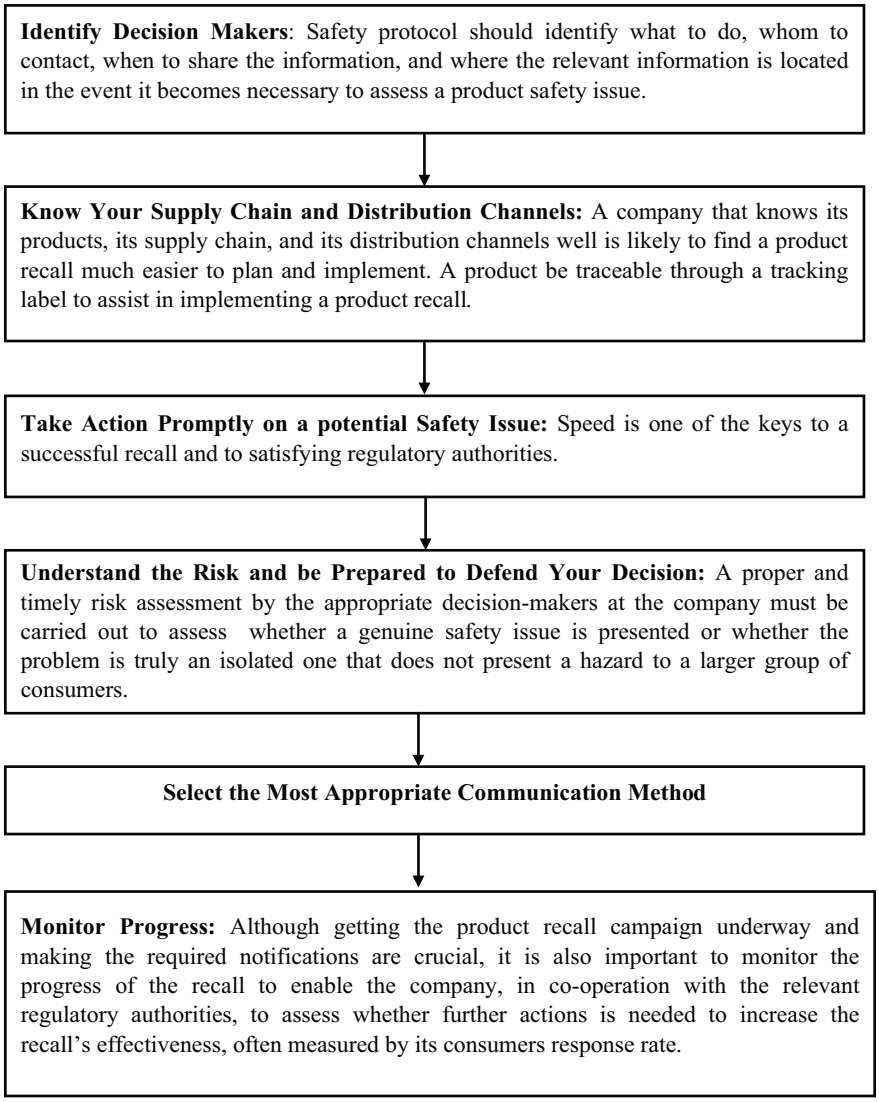

Figure 1: Understanding of recall steps

INFORMATION REQUIRED FOR THE ASSESSMENT OF A RECALL

The recall of each product is differently characterized and exercised. It is acceptable to set a recall strategy, wherein most of the factors will remain same in the recall of different products. In most of the cases, the report should be validated, in turn, the assessment of the same should be performed when the product is associated with potential risk of danger to public. The HCR/PI/distributor should collect all the appropriate information about recall and the same about the recall should be informed to the MCC which is provided in Annex1 of the guideline.[3]

Stages of Product Recall

The stages of recall are explained in the Figure 3.

CLASSIFICATION OF RECALLS

Recall Letter Contents

The reason of the recall should be mentioned with the facts with some unique data on the product that will help discriminate the product from others. This recall letter is sent (post and e-mail, or facsimile) to the office of the inspectorate and law enforcement for the purpose of approval and once the approval is obtained, the dispatchment should be done within 24 h [Table 2].[4,5]

A signed copy of the authorized consumer recall letter (or fax) shall be sent to the office of the inspectorate and law enforcement. The regulatory authorities of other countries should be informed when the product is placed internationally in the respective countries by the responsible applicant/distributor [Table 3].

The following directive should be obeyed while writing a recall letter by the HCR/distributor to the distribution:

- The company's letter head shall be used and the accountable pharmacist or authorized person should sign the same
- "Urgent Medicine" should be the indicative heading
- The classification and the type of the recall should also be indicated in the heading

- Where appropriate the following information should be provided:
    - Product name
    - Dosage form
    - Strength
    - Registration number
    - Size of the pack
    - Batch number(s)
    - Expiry date
    - Other relevant information
- Shall brief the nature of defect

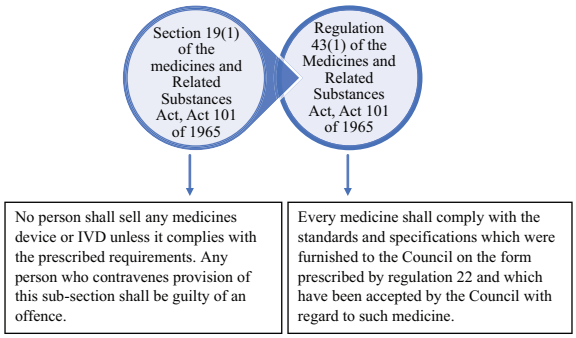

Figure 2: Provisions of the act undertaken by Medicines Control Council

- The action taken depending on the urgency
- The action to be taken should be provided with reason
- Risk to the health should be stated such as indication and side effects
- Steps taken to correct the product or recover the product that has been recalled from the market should be provided
- A message of follow-up will be sent when no response is observed for initial recall message
- Telephone number and fax number should be provided
- A request to retain the letter in a prominent position for 1 month in case stock is in transit (where applicable)
- Where recalled stock has been distributed to a limited number of hospitals and the recall letter is not to be sent to all hospitals in the province, the letter should include the following:

"If any of the recalled stock could have been transferred from your hospital to another, please let that hospital know or alternatively inform our company so that we can make contact with the hospital supplied from your hospital."

Table 2: Recall classification in South Africa

Recalls are classified into both the classes according to the level of health hazard involved (risk to the patient) and type which denotes the depth or extent to which the product should be recalled from the distribution chain, for example, Class I, type C recall, etc. Class I or Class II recalls are considered to be urgent safety-related recalls. Class III recalls are considered to be routine non safety-related recalls.	
Classification	**Description**
Class I (safety related)	Product defects are defective/dangerous/potentially life-threatening that predictably or probably could result in serious health/adverse events or even death and could cause permanent debilitating health issues
Class II (Safety related)	Product defects could cause illness, temporary or medically reversible adverse health problem, or mistreatment and the recovery of the patient is likely
Class III (Non-safety related)	Product defects may not pose a significant hazard to health, but is defective and is unlikely to cause any adverse health reaction, withdrawal may be initiated for other reasons, or which do not comply with requirements of Act 101 of 1965 in terms of the requirements of printed packaging material, product specification, labeling, etc.

Table 3: Type of recall in South Africa

Type of recall	Action
Type A recall is designed to reach all suppliers of medicines/medical devices/IVDs (all distribution points), that is, wholesalers throughout the country, directors of the hospital services (private as well as state hospitals), retail outlets, doctors, nurses, pharmacists, authorized prescribers and dispensers, and individual customers or patients through media release (radio, television, regional, and national press)	Recall letter to all distribution points plus media release
Type B recall is designed to reach wholesalers throughout the country, directors of the hospital services (private as well as state hospitals, retail outlets, doctors, nurses, pharmacists, authorized prescribers, and dispensers)	Recall letter to all distribution points
Type C recall is designed to reach wholesale level and other distribution points (e.g., pharmacies, doctors, and hospitals) this can be achieved by means of a representative calling on wholesalers and/or retail outlets. If it is known where the product in question had been distributed to, specific telephone calls or recalls letter to arrange for the return of the product could be made	Specific telephone calls, recall letter to/representatives calling at distribution points if known where medicines

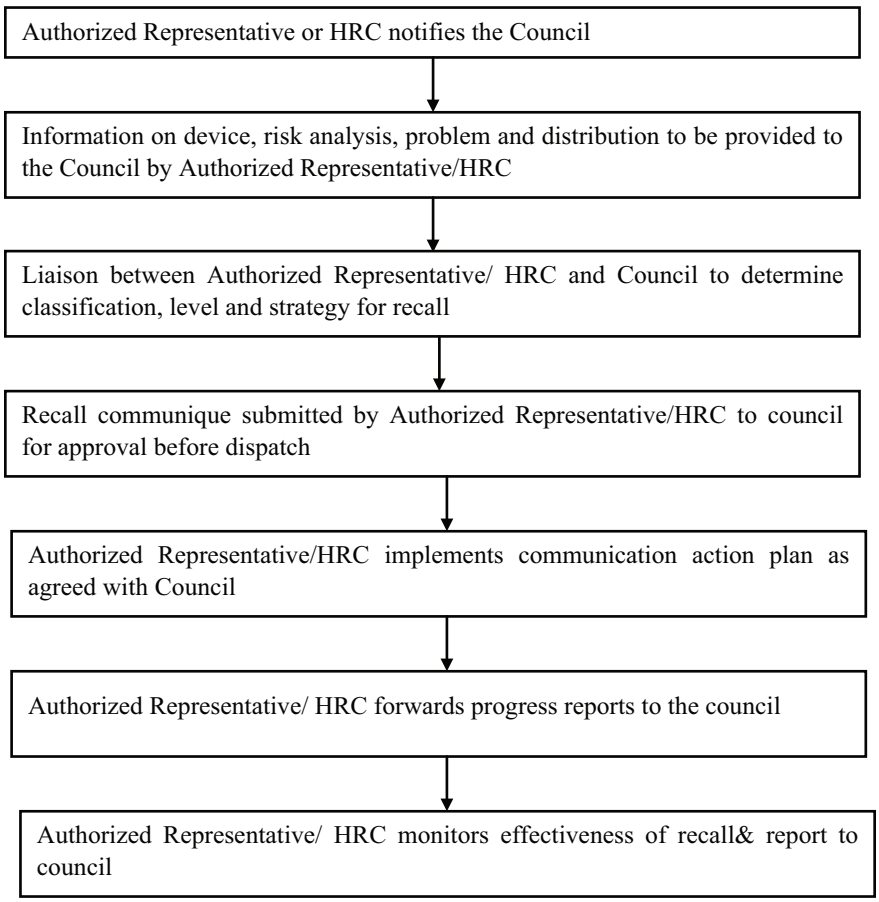

Figure 3: Stepwise approach to recall in South Africa

NB: The recall communication shall not contain any material that can be viewed as promotional in nature.

The letter and the envelope shall indicate in bold red type "MEDICINE" and be marked "URGENT."

MEDIA RELEASE

The text for the media release will be made by the HCR/distributor and MCC in coordination with expert advice jointly. For Class 1 or customer level, recalls require HCR/distributor in coordination with MCC should give the statement for media release. This media release should contain all the appropriate data that differently identify the product, the problem associated with the product, and the response given by the consumer/client. A 24 h service telephone number will be provided to contact the HCR/distributor to obtain more information. In case, the media release is rejected then the communication or message is sent through the department of health.

FOLLOW-UP ACTION

- The follow-up activities include an assessment of the efficiency of the recall and an examination into why the recall was done and improvements to deter recurrence[6]
- The Medicines Control Officer assesses the information obtained from the reports of the recall site and an assessment of the efficacy of the recall action
- After completing a recall or during a recall, the reminder site is asked to include specifics of the necessary correction measures and timescales to avoid a relapse of the issue that prompted the wakeup call
- If the essence of the issue and the necessary remedial steps are not obvious, a pharmacovigilance analysis and/or a good manufacturing practice audit may be required in certain cases
- The MCC or, as ordered by the council, the directorate of inspectorate and law enforcement, on behalf of the MCC, will take clear follow-up steps. The medicine dossier should be reviewed and any action taken by the MCC in response to the results of the analysis of the report relevant
- The MCC decides the recall termination until the recall is processed satisfactorily.

CONCLUSION

Recall is the opposite of what a manufacturer who is conscious of quality seeks to achieve. Recalls happen,

but an increasing and repeated occurrence may be expensive, can cause a company's short-term failure, and is not good for society as a whole, but in the long run, it increases the product and helps the customer. In today's world, a manufacturer is technologically able to take advantage of the opportunity of a new kind of innovation in healthcare. The vital recall information list contains product identity, description of the failure, product quantity generated in the distribution chain, and direct account. Drug recall is failure for pharmaceutical firms, as it affects the company's reputation. The most common reason for product recall is connected to manufacturing. This assumption that development sequel was not meeting the existing standards for good manufacturing practise. Another reason involves safety/efficacy that suggests that the safety data were not adequate or that some sort of bias was involved during the time of drug development.

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