Botswana Medicines Regulatory Authority

BOMRA
MEDICINES REGULATORY AUTHORITY

Approved By:

Dr. P. Gurumurthy
Director
Pharmacovigilance and Clinical Trial

Date of Approval (DD/MM//YY)

Table of Contents

Revision status sheet

Page	Changes made	Issue No	Process owner's name	Date
8	Inclusion of the following; All recall communications that originate from BoMRA shall follow Safety Communication Policy V1 BOMRA/PCT/COM/P03/F01, BOMRA/PCT/COM/G01 and BOMRA/PCT/COM/P02.	1.0	Manager Pharmacovigilance	05/10/2022
7	Inclusion of Timelines	1.0	Manager Pharmacovigilance	05/10/2022

1 Purpose

The purpose of this guideline is to provide an analysis of the process relating to the recall of a medicinal product from the marketplace, and to provide guidance on the roles and responsibilities of the market authorisation holder, the manufacturer, and the wholesaler/importer in the recall process.

2 Scope

This guideline is applicable to recalling and/or withdrawal of human and veterinary medicines, cosmetics and medical devices that are registered or exempted from registration in Botswana.

This is not applicable to unauthorized medicinal products which may be on the Botswana market and are not authorised into the country in any shape or form. These products are handled by Department of Inspections and Licencing during inspections and Law Enforcement unit.

3 Definitions and abbreviations

3.1 Definitions

For the purpose of this document, the following definitions shall apply;

3.1.1 Recall - removal or correction of marketed products for the reasons relating to deficiencies in quality, safety, or efficacy, including labeling considered to be in violation of the laws.

3.1.2 Batch Recall - process for removal of selected batch/es of a product which are found to be defective and pose health risk to the consumers if left in the market.

3.1.3 Batch (Lot) - a specific quantity of material produced in a process or series of processes so that it is expected to be homogeneous within specified limits.

3.1.4 Customer - any person, firm or party buying/receiving goods from the company for storage, distribution, and sale.

3.1.5 Voluntary Recall - a recall initiated by the licensee (in case of loan licensee jointly the contract giver and contract acceptor) as a result of abnormal observation in any product quality during periodic review (Internal / External) or investigation of a market complaint or any other failures.

3.1.6 Statutory Recall - a recall directed by BoMRA after notifying that product does not meet the set standards for quality, efficacy, and safety.

3.2 Abbreviations

For the purpose of this document, the following abbreviations shall apply;

3.2.1 MAH – Marketing Authorization Holder

3.2.2 MRSA– Medicines and Related Substances Act 2013

4 Method

4.1 Overview of Product Recall/Withdrawal

4.1.1 The purpose of recalling and/or withdrawal is to effectively remove from the market products that do not meet the quality and safety requirements and hence may pose a health hazard to the public. Most recalls are conducted on voluntary basis, and it is the responsibility of the MAH to ensure that they invoke their recall process should the need arise. BOMRA expects MAHs to take full responsibility for medicines recalls, including follow-up checks to ensure that the recalls were successful.

4.2 What May Cause a Recall/Withdrawal of a Product?

4.2.1 The withdrawal/recall of a batch or batches of a product from the market may be occasioned by the following but not limited to;

a) Reports of serious adverse drug reactions not included in the package insert.
b) Increased frequency of occurrence of an adverse reaction.
c) Incorrect/inappropriate labelling or contamination of a product.
d) Unfavourable results of ongoing stability studies.
e) Quality of the product not meeting specifications including efficacy.

4.3 Recall Classification

4.3.1 General

Recalls are classified relative to the degree of health hazard presented by the product being recalled. The following aspects are taken into consideration.

a) reasonable probability that the use of or exposure to a suspect product will cause serious adverse health consequences or death

b) the use of or exposure to a suspect product will cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote.

c) the use of or exposure to a suspect product is not likely to cause any adverse health consequences

4.3.2 Classification Criterion

The following classification criterion is recommended:

4.3.2.1 Class I - is for defective/dangerous/potentially life-threatening products that predictably or probably could result into serious health risk/adverse events or even death.

4.3.2.2 Class II - is for products that possibly could cause temporary or medically reversible adverse health problem or mistreatment.

4.3.2.3 Class III - is for products that are defective and unlikely to cause any adverse health reaction or which do not comply with the requirements of the Medicines and Related Substances Act of 2013, in terms of the requirements of printed packaging material, product specification, labelling, etc.

4.4 Types of Recall

4.4.1 Type A - type A recall is designed to reach all suppliers of medicines (all distribution points) i.e., wholesalers throughout the country, hospitals (private and public), retail outlets, doctors, nurses, pharmacists, authorised prescribers and dispensers and individual customers or patients through media release (radio, television, regional and national press).

Action: Recall letter to all distribution points and media release.

4.4.2 Type B - type B recall is designed to reach wholesalers throughout the country, directors of hospital services (private as well as state hospitals), retail outlets, doctors, nurses, pharmacists, authorised prescribers and dispensers.

Action: Recall letter to all distribution points.

4.4.3 Type C - type C recall is designed to reach wholesale level and other distribution points (e.g., pharmacies, doctors, hospitals) that are known to have received the product in question. This can be achieved by means of representatives calling on wholesalers and/or retail outlets. Specific telephone calls or recall letters to arrange for the return of the product could be made.

Action: Specific telephone calls, recall letters to/representatives calling at distribution points if known where the medicines have been distributed.

4.5 Recall Notification

4.5.1 It is imperative that before or upon initiating a recall, the company immediately on becoming aware of the problem, notifies BoMRA and other stakeholders depending on class and type of recall.

4.5.2 Basic Information Required in the Notification

4.5.2.1 The following is required when a notification has been made;

a) The reason for initiating the recall - nature of defect/problem.
b) Name, strength, pack size, batch/lot number and any means of identification of the recalled product.
c) Total quantity of the product being recalled originally in possession of the company.
d) The date in which distribution of the product began.
e) The total quantity of the product being recalled that had been distributed up to

the time of the recall should be indicated.

f) Area of distribution of the product and, if exported, the country to where it was exported.
g) List of customers to whom product was issued.
h) The quantity of the recalled product still in the possession of MAH.
i) Suggested action to be taken and its urgency.
j) Indication of the health risk together with reasons.
k) Any adverse events observed/reported for the product being recalled.

4.6 Timelines

4.6.1 Based on the risk, type and class of the information received, a recall is instigated. The recall communication should not contain irrelevant information or any that may devaluate the message being communicated.

4.6.2 By nature of their type as prescribed in this guideline, Class I and Class II medicine recalls should always be treated as ***urgent*** and recalled within ***15 DAYS*** whilst for Class III medicine recalls, they should be instigated within ***30 days.***

4.6.3 Recall notification should be communicated to the Authority, which shall be followed by 4.6.2, thereafter a summary report on the events of the recall. A comprehensive Recall report by the MAH/Institution shall be submitted to the Authority within 90 days of instituting the recall.

4.7 Health Hazard Evaluation

4.7.1 Before initiating a recall, the MAH will gather, collate, and evaluate all known information on the nature and extent of the health risk.

4.7.2 The following aspects shall be taken into account;

a) Whether any disease or injuries have already occurred from the use of the product.
b) Hazard to various segments of the population e.g., children, surgical patients etc, who are expected to be exposed to the product, with particular attention to those individuals who may be at greatest risk.
c) The degree of seriousness of the health hazard to which the population at greatest risk would be exposed.
d) The likelihood of occurrence of that hazard.
e) The consequences (immediate or long-term) of occurrence of the hazard.

BoMRA will also conduct its own evaluation of the health hazard presented by a product being recalled or considered for recall.

4.8 Recall Strategy

In formulating a recall strategy, the following should be taken into consideration:

a) Result of health hazard evaluation

b) Ease in identifying the product

c) Extent to which the product deficiency is obvious to the consumer

d) Continued availability of essential products (risk: benefit)

4.8.1 Elements of a Recall Strategy

4.8.1.1 Depth of Recall

Depending on the product's degree of hazard and extent of distribution, the recall strategy must specify the level in the distribution chain in which the recall is to extend, as follows:

a) Consumer or user level including any intermediate wholesale and/ or distribution or retail level, and or all government facilities; or

b) Retail level, including any intermediate wholesale and/ or distribution level; or

c) Wholesale and/ or distributor level.

4.8.1.2 Recall notification from Recalling Company to all Affected Parties

A recalling MAH is responsible for promptly notifying involved parties about the recall and the same information be notified to BoMRA.

Recall notification should convey:

a) That the product in question is subject to recall

b) That further distribution or use of any remaining product should cease immediately

c) The instructions on what to do with the product

4.8.2 Communication

4.8.2.1 All recall communications that originate from BoMRA shall follow Safety Communication Policy V_1 ***BOMRA/PCT/COM/P03/F01, BOMRA/PCT/COM/G01*** and ***BOMRA/PCT/COM/P02.***

4.8.2.2 Success of a recall is dependent on the effectiveness of communication. Communication may be sent via but not limited to email, telephone, fax or in person.

4.8.2.3 Conspicuous marking e.g., "MEDICINE RECALL" in bold red on the letter and envelope, and, also "URGENT" for serious cases

4.8.2.4 A public warning may be necessary for products that pose serious health hazards. However, this should be reserved for urgent situations where other means of preventing use of the

recalled product appear inadequate. BOMRA to decide and who to issue such a warning.

4.8.2.5A recall communication should be brief and to the point yet containing relevant information; name of the product, strength, pack size, and any other pertinent descriptive information of the product; nature of the defect; Specify urgency of the action; reason for the action; potential health risk; and provide specific instructions on what should be done with the recalled product

Note: Where necessary, follow-up communication should be sent to those who fail to respond to the initial recall communication. This should be done within a reasonable time depending on the urgency of the recall.

4.9 Post Recall Procedures

4.9.1 BoMRA must be furnished with a final report within a specified period (12 weeks) of the recall or withdrawal being instituted. The report shall contain the following information:

a) Name of the product
b) Strength of the product
c) Pack size
d) Batch/ lot number
e) Nature of the defect
f) Action that was taken
g) Urgency of the action taken
h) Reason for the action
i) Indication of the health risk and reported clinical problems
j) Copies of all the recall correspondence
k) Steps taken to prevent re-occurrence of the problem
l) After termination of a recall and not later than 90 days after a recall has been instituted, a full reconciliation must be submitted.

4.9.2 A recall will be closed when BOMRA and the recalling company are in agreement that the non-compliant product has been removed and proper disposal or correction has been made. Where the outcome of the recall dictates that the product in question be disposed, guideline ***BOMRA/IL/IE/P05/G04*** shall be followed.