Standard Operating Procedure
HANDLING RECALLS

HQ_SOP_QA_04

Department/Unit: HQ/BOS/SUP

Document Specification

Version	V0	**Date**	01/07/2025
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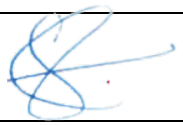
Signature			

Disclaimer

Standard Operating Procedures (SOPs) provide a step-by-step guide for staff directly involved in the processing of administrative actions to support and facilitate the implementation of WHO policies and procedures. The SOPs are for guidance only; they are neither authoritative nor binding. The SOPs reflect the policies and procedures of WHO at the time of writing; however, policies and procedures change from time-to-time. In the case of a conflict between the SOPs and the WHO eManual provisions, the WHO eManual provisions take precedence.

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1. Introduction

1.1. Purpose

1.1.1. The purpose of this SOP is to ensure that appropriate instructions and measures are in place in order to effectively recall a product or a batch, thereby mitigating risks to patients' health.

1.1.2. The purpose of this SOP is also to ensure proper documentation and recording of any recall process and to assess its effectiveness

1.1.3. A recall can be initiated by a health authority, a supplier (distributor or manufacturer) or by WHO itself.

1.2. Scope

1.2.1. This procedure applies to the management of recalls of health products procured by World health organisation (WHO) at HQ level, regional level or country level**.**

1.2.2. This procedure is applicable to a product or a batch does not meet its specifications and is deemed defective, appropriate arrangements should be made to stop distribution and initiate potential withdrawal. In such case, it is essential that prompt and well-coordinated actions are taken to quarantine existing stock, discontinue further distribution and initiate product recall.

2. Definitions and acronyms

2.1. **Recall:** A process for withdrawing or removing a pharmaceutical product from the pharmaceutical distribution chain because of defects in the product, complaints of serious adverse reactions to the product and/or concerns that the product is or may be counterfeit. The recall might be initiated by the manufacturer, importer, wholesaler, distributor or a responsible agency.

2.1.1. Class I recall: is for defective, dangerous or potentially life-threatening unfit products that predictably or probably could result into serious health risk or adverse events or death. Examples include but not limited to:

- Wrong product (label and content are different products);
- Wrong strength;
- Microbial contamination of sterile product;
- Contamination with another chemical with serious health consequences
- Wrong active ingredient;
- Product mix up.

2.1.2. Class II recall: is for unfit products that possibly could cause temporary or medically reversible adverse health problem or mistreatment; Examples include but not limited to:

- Mislabelling e.g. wrong or missing text or figures;
- Missing or incorrect information- leaflets or inserts with packing;
- Microbial contamination of non-injectable, non-ophthalmic sterile product with medical consequences;

- Chemical/ physical contamination (significant impurities, cross contamination, particulates);
- Mix up of products in containers;
- Non-compliance with specification (e.g. assay, stability, fill/ weight or dissolution);
- Insecure closure with serious medical consequences (e.g. cytotoxins, child resistant containers, potent products, toxic chemicals).

2.1.3. Class III recall: is for unfit products that are defective and are unlikely to cause any adverse health reaction or which do not comply with the requirements for the printed packaging material, product specification or labelling. Examples include but not limited to:

- Faulty packaging e.g. wrong or missing batch number or expiry date
- Faulty closure not resulting in any medical consequences
- Contamination with no medical consequences (e.g. dirt or detritus among others)

2.2. **Reconciliation:** Reconciliation is the process of collecting the data related to the delivered and recovered quantities of the concerned products/batches to assure that the total quantity initially delivered could be traced back. The final reconciliation must include the following minimum information: Quantity received, quantity quarantined, quantity distributed, quantity used and quantity returned/destroyed.

3. SOP Roles

3.1. **HQ QA is responsible for:**

3.1.1. Launching a recall
3.1.2. Documenting the process
3.1.3. Ensuring final reconciliation
3.1.4. Centralizing communication related to the recall

3.2. **QA pharmacists in Hubs and QA focal points in warehouses are responsible for:**

3.2.1. Implementing the recall in their facility
3.2.2. Ensuring downstream traceability
3.2.3. Facilitating data collection and reporting to HQ QA

3.3. **QA Focal point in Regional offices are responsible for:**

3.3.1. Ensuring downstream traceability
3.3.2. Informing relevant stakeholders
3.3.3. Making sure partners implement the recall
3.3.4. Facilitating data collection and reporting to HQ QA

3.4. **WR in Country offices are responsible for:**

3.4.1. Identifying a QA focal point

3.4.2. Ensuring implementation of this procedure at country level

3.5. **Country Office QA focal points are responsible for:**

3.5.1. Ensuring downstream traceability

3.5.2. Informing relevant stakeholders

3.5.3. Making sure partners implement the recall

3.5.4. Facilitating data collection and reporting to HQ QA

4. Reference Material

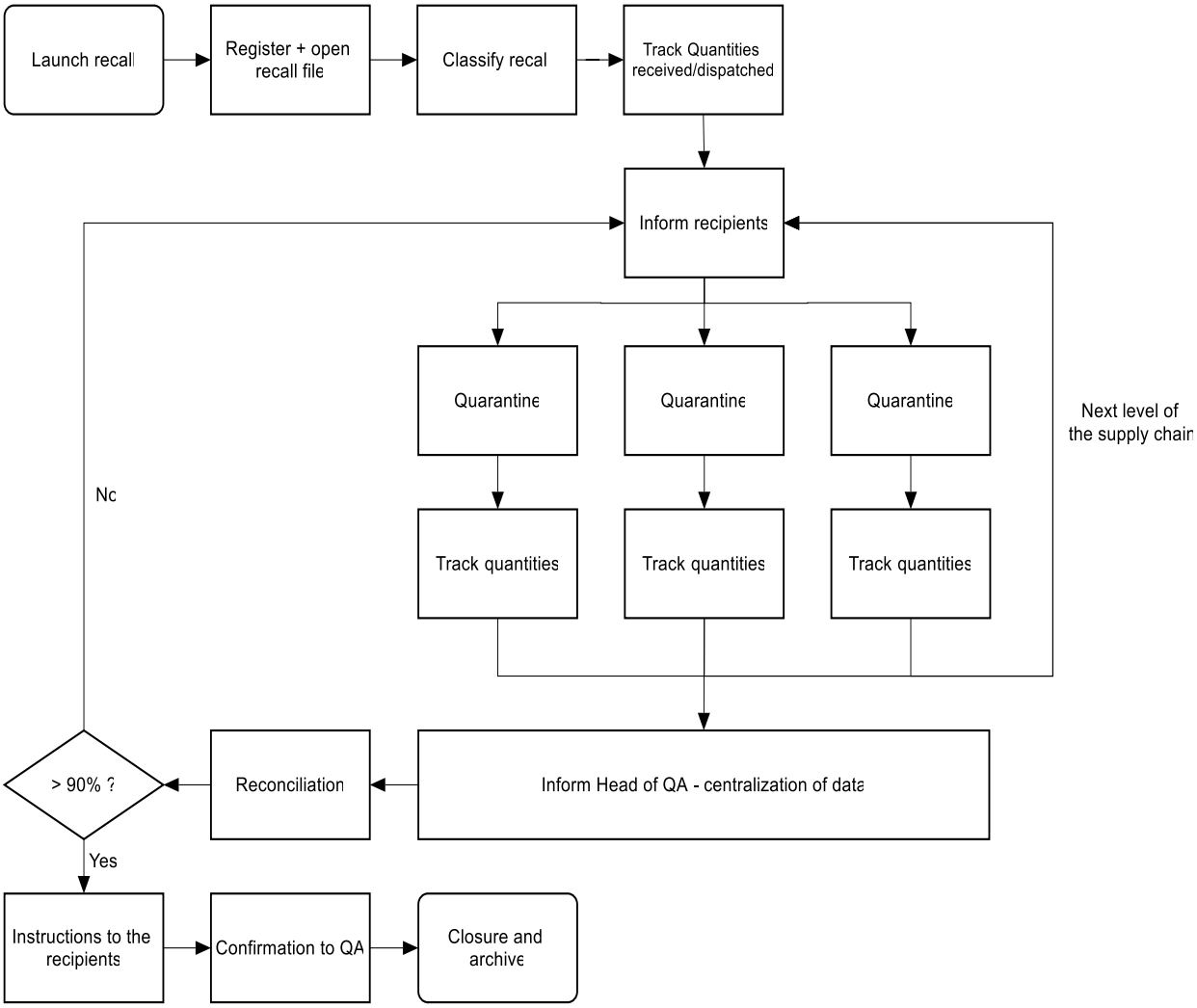
4.1. Guidelines

- WHO Technical Report Series, No. 957

4.2. **Related SOPs**

- BMS_SOP_QA_003_complaints

5. Process Flow



6. Process Steps

6.1. Reception of the Recall Notice HQ/QA :

6.1.1. Registers the recall in the "recall logbook" in share point and assigns a recall number which will be used in all further communication

6.1.2. Records the available information using FORM 01 and asks for clarification as needed Classify the recall in order to determine the timeframe:

- class I: recall should be initiated immediate, less than 24
- class II : recall should be initiated in 24 hours
- class III : recall should be initiated in less than 3 working days

6.1.3. Tracks quantities received and dispatched Informs all recipients using FORM 02 or supplier recall notice (if any) and requests confirmation that recall is initiated at their level

6.1.4. If traceability cannot be confirmed, recall notice is shared with all possible recipients (hubs, warehouses, regional offices, country offices)

6.1.5. Requests feedback on quantities remaining in stock and quantities already used / dispatched

6.2. Country / HUB follow up of the recall

Each country / HUB recipient contacted assigns a person to be in charge of the recall, this person will:

6.2.1. Checks if the product is still in stock and immediately organizes quarantine of the remaining stock

6.2.2. Tracks dispatched products to lower level of the supply chain and/or to local partners and complies information to be share with QA/HQ

6.2.3. Informs all in country recipients by forwarding the received FORM 02 and requests confirmation that recall is initiated at their level

6.2.4. Collects and tracks information on quantities quarantined at each level and quantities already used and reports accordingly to recall requester using FORM 02

6.2.5. Reports to HQ QA

6.3. **Aggregation of the information received HQ/ QA**

6.3.1. Makes sure that every recipient responded

6.3.2. Completes the reconciliation part in addendum 01 and calculates reconciliation rate

6.3.3. Verifies that reconciliation rate is above 90% to consider the recall efficiently managed (if not, sends a reminder to relevant recipients)

6.3.4. Informs recipients about actions to be taken with the product (return or destruction)

6.3.5. Requests confirmation that actions are in process

6.3.6. Records confirmations once actions are complete (return or destruction)

6.3.7. Closes the recall process and if the recall was requested by a health authority or a supplier, shares the reconciliation report and/or any requested specific document accordingly

7. Appendices

7.1. Appendix 01 : FORM 1 : Main Recall Report HQ/QA

7.2. Appendix 02 : FORM 2: Country/HUB Recall Report

8. Revision/ document History

Version	Date	Author	Reviewer	Description of Change	Approved by
V0	01/07/2025	Cann JM	Laroche S.	Initial	Kastner A.

***Minor Version Number**: Minor changes made to a document, such as grammatical or spelling errors. Increase the decimal number to signify minor modifications to a document. (0.1, 0.2, and so on);*
***Major Version number**: Major modifications are alterations to a document that necessitate its re-approval. Major changes are expressed by increasing the full number by one. (1.0, 2.0,*

8.1. **Version Numbering:** Use semantic versioning (e.g., 1.0, 1.1, 2.0) where:

- **Major changes** → increment the first digit (e.g., 1.0 → 2.0).

- **Minor changes** → increment the second digit (e.g., 1.0 → 1.1).

8.2. **Date:** will Always format consistently (e.g., YYYY-MM-DD or DD-MM-YYYY).

8.3. **Author:** will be the person who made the update.

8.4. **Description:** need to Be brief but specific (what was added, removed, or changed).

8.5. **Approved By** :will be the WHO/QA