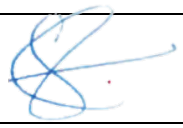
Standard Operating Procedure
HANDLING QUALITY COMPLAINTS

HQ_SOP_QA_03

Department/Unit: HQ/BOS/SUP

Document Specification

Version	V0	**Date**	01/07/2025
	Prepared by	Reviewed by	Endorsed by
Name	Jean Michel Cann	Sophie Laroche	Angela Kastner
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 procedure is to describe the process to manage the product quality complaints (PQCs). The process includes the steps to receive, register, acknowledge, investigate, implement corrective and/or preventive actions, close and respond to the complainant.

1.2. Scope

1.2.1. This procedure is applicable for the management of all alerts and the product complaints procured or supplied by WHO internally (form another WHO office) or externally (from a supplier, or partner)

1.2.2. The product complaint can be received from multiple sources, including but not limited to, customers/clients, patients, healthcare professionals, wholesalers, distributors, retailers and/or regulatory agencies

1.3. Objectives / aims

1.3.1. Address any suspected quality concerns related to health products using established best practices

1.3.2. Conduct thorough investigations to determine root causes and implement appropriate corrective actions

1.3.3. Maintain complete traceability by ensuring accurate recording and comprehensive documentation

2. Definitions and acronyms

2.1. **Alert**: An alert is any information shared by a National Regulatory Authority (NRA), the World Health Organization (WHO), or any other organization (e.g., donor, partner, supplier) to notify about a potential risk to patients or public health linked to a specific health product.

2.2. **Quality Issue/ complaint** : A quality issue is a defect, deficiency, or a significant variation in a product's expected appearance or performance. It refers to a concern that may compromise the safety, efficacy, or quality of a health product, potentially impacting the health of patients

and end users. This includes the physical defects, packaging defects, labelling errors, temperature excursions, as well as reports of suspected counterfeit/falsified product.

2.3. **Critical or Serious Complaint**: Any complaint that may result in potentially life threatening or could pose a serious risk to patient. This ultimately leads to product recall or/and need to inform the relevant health authority.

2.4. **Major Complaint**: Any complaint which could cause illness or mistreatment but are not critical. It causes serious impairment of product quality and efficacy, but without safety/medical risk.

2.5. **Minor Complaint**: All other non-critical complaints which have no important effect upon the therapeutic activity of the product and do not present an efficacy, safety or medical risk.

2.6. **Health products** : Products include, but are not limited to, finished pharmaceutical products (FPPs), medical devices (MD), including in vitro diagnostic (IVD) tests, and vaccines. In the context of this document, "health products" include FPPs, MDs, IVDs, vector control products (VCP), medical gases, medical gas supply systems, and personal protective equipment (PPE) intended to protect patients and medical staff while carrying out their duties.

3. Responsibilities

3.1. HQ/QA focal point:

3.1.1. Ensure that all the relevant staff is trained on complaint handling procedure

3.1.2. Receives, acknowledges and log the complaint in SOP XXX- Form 02 and subsequently handle the complaints as described in this procedure. Request for complaint sample, photograph or any other additional information from the complainant.

3.1.3. Conduct initial assessment, complaint classification and assign the criticality of the complaint. Forwards the complaint to for investigation. Escalate the critical complaints to top management if necessary.

3.1.4. Receive and review the complaint investigation report, closes the complaint, reply to complainant as needed and follow up on CAPAs. Maintains complaint documentation and making a final decision regarding the use of the product

3.1.5. Inform relevant stakeholders of the outcome of the case

3.2. Country / HUB Warehouse /logistic team:

3.2.1. Report the suspected quality issue using the SOP XXX - Form 01 and place the product in quarantine

3.2.2. Provides necessary information required to ensure compliance to the complaint handling process such as but not limited to additional information, pictures as requested, and sampling products, as per instructions, for Quality Control

3.2.3. Support in root cause analysis, identification of appropriate corrective and preventive actions (CAPAs) and implement related to specific functional domains

3.2.4. Raise Shipping Insurance Claim using the link https://who.service-now.com/self_service?id=sc_cat_item&sys_id=a320806f97969610a035f0b6f053afb3

3.2.5. Complete the training of this procedure and ensures that all relevant WCO staff in the specific function are trained on the complaint handling procedure

3.3. HQ Shipping team :

3.3.1. Follow up on the insurance claim process with the relevant departments

3.3.2. Inform the procurement team of any decision regarding the insurance claim for potential replacement of the product

3.3.3. Complete the training of this procedure and ensures that all relevant WCO staff in the specific function are trained on the complaint handling procedure

4. **Reference Material**

4.1. Guidelines

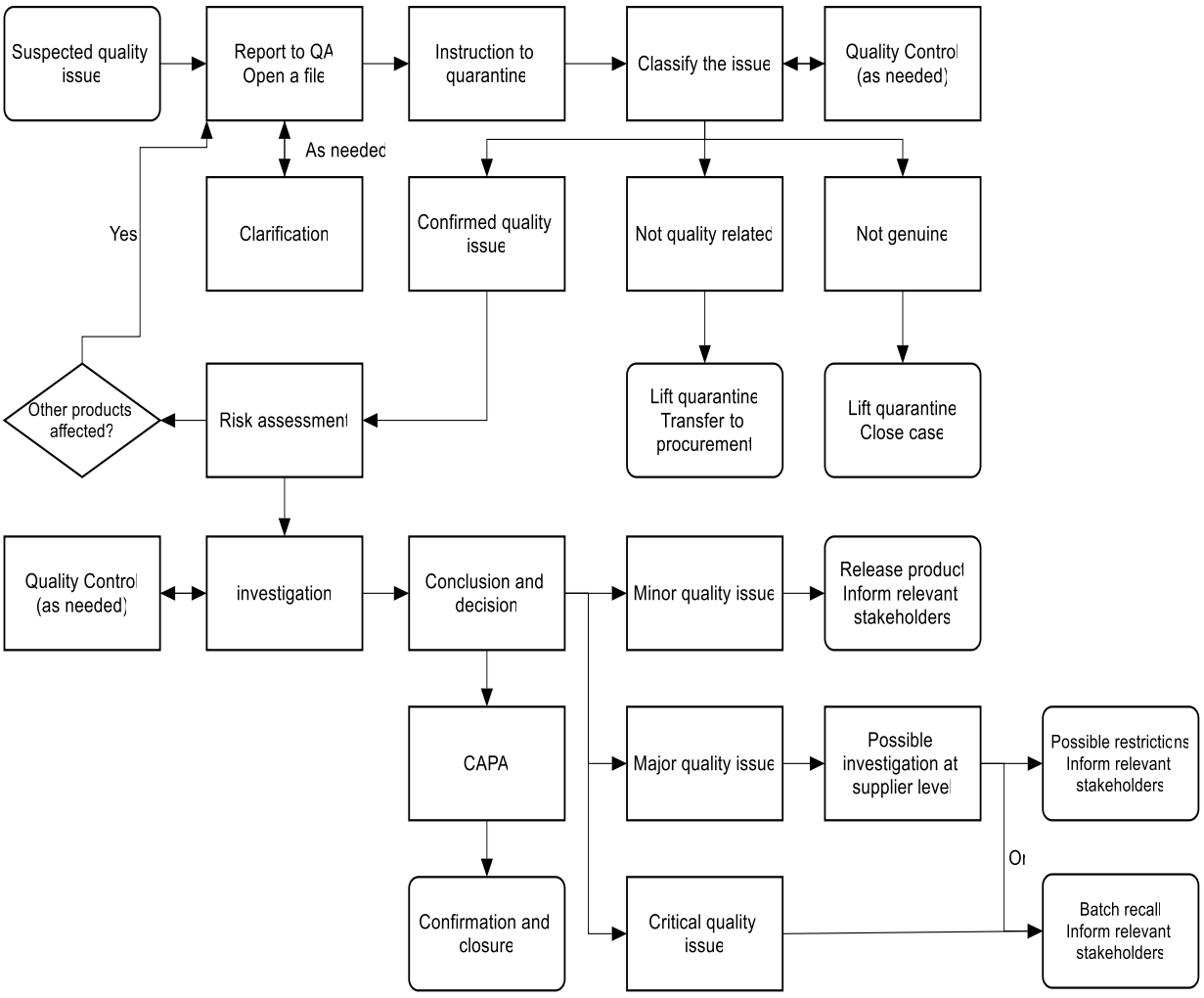
- WHO Technical Report Series, No. 986, annex 3 who-model-quality-assurance-system-for-procurement agencies
- WHO Technical Report Series, No.961, 2011 annex 9, Model guidance for the storage and transport of time- and temperature–sensitive pharmaceutical products

- WHO Technical Report Series, no. 1025, Annex 7: Good storage and distribution practices for medical products
- WHO Technical Report Series, No. 929, 2005, Annex 4 WHO guidelines for sampling of pharmaceutical products and related materials

4.2. Related SOPs

- BMS_SOP_QA_04_Recall

5. Process Flow



6. Procedure

6.1. General requirements

6.1.1. All complaints or alerts received through any source and any means shall be handled following this procedure. The complaint timeline starts with notification date i.e. when first WHO staff gets aware of the complaint or an alert.

6.2. Receipt of a product quality complaint

6.2.1. Complaints should be reported to HQ focal point at HQQAteam@who.int, using HQ_SOP_ QA_03 Appendix Form 01: Reporting Quality issue. The form needs to be careful completed (pictures, data loggers report…). The Subject of the email must be formatted as follows: "PO number -QA complaint – Country — Product" .

6.2.2. The complainant place the product in quarantine until further notice by the HQ/QA focal point.

6.2.3. HQ/QA focal point shall acknowledge the complaint and contact the complainant to gather additional information as and if required.

6.2.4. HQ/QA focal point when receiving the complaint assign a quality issue number and record the incident in the quality issues logbook on the share drive.

6.3. Initial assessment of the complaint and classification

6.3.1. HQ/QA focal point shall decide on the relevance of the complaint

- Not quality related: the issue reported pertain to compliance issue , the case is sent back with the complainant to proceed as per procedure and the case is closed, and quarantine lifted.
- Not genuine: the quality complaint could not be verify by HQ/QA focal point (reading error by the complainant, false alert, etc) the case is sent back with the complainant to proceed as per procedure and the case is closed and quarantine lifted.
- Confirmed quality issue: HQ/QA focal point launches the investigation using the HQ_SOP_ QA_03 Appendix Form 02 Quality issue assessment and decision.

6.3.2. If the complaint is related to quality, HQ/QA focal point shall decide on quarantine or not of the product and inform the complainant of the decision.

6.3.3. HQ/QA focal point shall assess the criticality of the complaint and adverse event as applicable referring to the definitions given in section 2.

6.3.4. To support the classification decision the HQ/QA focal point shall contact the manufacturer or initiate quality control using an approved quality control laboratory

- Minor risk: does compromise users' health, community and does not impact healthcare workers
- Major risk: likely to compromise users' health community and/or to impact healthcare workers
- Critical risk: might seriously compromise users' health, community

6.4. complaint evaluation and investigation

6.4.1. HQ/QA focal point shall perform a risk assessment on the complaint and classify it as critical , major or minor.

6.4.2. For all critical complaints, HQ/QA focal point shall retrieve the complaint sample. Instruction should be given on sampling procedure, as well as consideration of storage condition (e.g. cold chain), nature of product (e.g. hazardous, dangerous goods), packaging (e.g. glass bottles, ampoules, vials) and other factors as applicable shall be taken to ensure the sample and the handler are both safe.

6.4.3. If the investigation confirms more than one product / batch may be impacted, then the investigation shall be extended to all the associated products / batches. HQ/QA focal point shall inform the different recipients and open additional Form 02 linked with reference to the current complaint.

6.4.4. The marketing authorization holder of product and applicable regulatory authorities shall be informed in case of confirmed counterfeit.

6.4.5. The complaint investigation could lead to a recall procedure. Recall procedure shall be handled as per HQ_SOP_QA_04 Handling Recalls

6.4.6. HQ/QA shall inform the complainant of the final decision, next step to proceed including the release or not from quarantine. The complainant shall acknowledge reception of the email

and confirm implementation of the HQ/QA final decision on the product by email. Any misunderstanding shall be clarify quickly.

6.4.7. If the product need to be disposed, complainant shall share the disposal certificate with HQ/QA.

6.5. Root cause analysis (RCA) for complaint

6.5.1. The root cause analysis is the systematic procedure to identify the underlying cause of the complaint. The root cause analysis shall be comprehensive to ensure that actual / most probable root cause is identified.

6.5.2. Based on the root cause, the final evaluation shall be done, and appropriate corrective and preventative actions shall be identified by HQ/QA focal point and shared with the supplier, partner.

6.6. Complaint conclusion

6.6.1. HQ/QA focal point shall follow up on CAPAs

6.6.2. HQ/ QA focal point to decide when to close the case and archive the form 02 dinge including all supporting documents in the share drive. The tracking log shall also be updated.

6.6.3. Complaint conclusion may lead to procurement decision, relevant complaints shall be share with BOS/SUP/SHQ for supplier performance evaluation.

6.6.4. Insurance claim should be raised by the WCO/HUB warehouse team when needed.

7. Appendices

7.1. Appendix 01 : FORM 1: Reporting a quality issue

7.2. Appendix 02 : FORM 2 : Quality complaint/alert assessment and decision form

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