وزارة الصحة
Ministry of Health

DSC
مركز سلامة الدواء
Drug Safety Center

Guideline on the Management of Complaints and Appeals

Drug Safety Center

2026

First Edition

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Acronyms:

CAPA	Corrective and Preventive Action
DSC	Drug Safety Center
GBT	Global Benchmarking Tool
MOH	Ministry of Health
QA	Quality Assurance
WHO	World Health Organization

7 Definitions

Appeal	A formal request to reconsider a specific Violation Committee or DSC regulatory decision.
Appeal Database	The controlled master record used to register, track, document, and close appeals.
Appellant	A person, Pharmaceutical Establishment, or authorized representative submitting an appeal.
Complaint	An expression of dissatisfaction about a service, conduct, communication, process, or other DSC activity for which a response or resolution is expected, without necessarily seeking reconsideration of a regulatory decision.
Complaint Database	The controlled master record used to register, assess, investigate, track, and close complaints.
Complainant	A person, organization, Pharmaceutical Establishment, or authorized representative submitting a complaint.
Concerned Department	The DSC department responsible for investigating a complaint or reviewing an appeal against its regulatory decision.
Pharmaceutical Establishment	An establishment licensed under the Law Regulating the Practice of Pharmacy and Pharmaceutical Establishments.
Regulatory Decision	A formal decision issued by DSC while exercising its regulatory functions.
Violation Committee	The committee authorized to consider violations and issue decisions under the applicable Law and Executive Regulation.

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CHAPTER ONE

Introduction

This guideline provides a standardized framework for receiving, documenting, evaluating, and resolving complaints and appeals. It ensures that the services and regulatory decisions of the Drug Safety Center (DSC) are managed with transparency, impartiality, and in compliance with applicable legal requirements.

Legal basis

This guideline is developed in accordance with the Law Regulating the Practice of Pharmacy and Pharmaceutical Establishments, promulgated by Royal Decree No. 35/2015, and its Executive Regulation issued by Ministerial Decision No. 113/2020.

Purpose

The purpose of this guideline is to establish an effective and transparent process for the management of complaints and appeals. It ensures that all concerns raised by stakeholders are handled in a consistent manner and that decisions are reviewed fairly.

Scope

This guideline applies to all complaints and appeals received by the Ministry of Health and DSC related to regulatory, administrative and technical activities or decisions.

Structure

This is the first version of this guideline and is organized into four chapters. CHAPTER ONE covers the Introduction, Purpose, Scope, and Structure. CHAPTER TWO outlines the detailed procedures and methods. CHAPTER THREE defines responsibilities in relation to this guideline. CHAPTER FOUR includes the document history and version control table, references, and the Annex.

CHAPTER TWO

Methods and Procedures

2.1 Complaints and Appeals Distinguished

- **A complaint** concerns dissatisfaction with the DSC's service, conduct, communication, or the process followed in reaching a decision, and does not by itself require reconsideration of the decision's substance.
- **An appeal** is a formal request to reconsider the substance of a specific regulatory decision on defined grounds. Where a complaint, on examination, is found in substance to challenge a regulatory decision, the DSC focal point should redirect it to be handled as an appeal under this guideline and should inform the complainant accordingly.

2.2 Complaint Handling

- QA should record all complaints received through Tajawob, the MOH portal or email, telephone, call center, or written correspondence in the controlled Complaint Database under a unique reference number.
- Pharmaceutical Establishments should complete and submit the Complaint Submission Form. Complaints from other stakeholders may be submitted through the available channels and are not required to use the Complaint Submission Form. Regardless of the submission channel, all complaints should be recorded and managed in the controlled Complaint Database by authorized DSC personnel.
- QA should assess completeness, jurisdiction, conflicts of interest, and risk. Complaints should be classified as Minor, Major, or Critical based on their potential impact. Critical complaints require immediate escalation and containment.
- Complainants should receive acknowledgment within five (5) working days. The database should flag approaching and overdue deadlines for acknowledgment, investigation, response, CAPA, and closure.
- QA should refer complaints to the concerned department. The database should record the evidence reviewed, findings, and recommendations, with supporting records filed under the complaint reference number.

- Identified systemic causes or nonconformities should undergo root cause analysis. Required CAPAs should be assigned, implemented, monitored, and verified for effectiveness.
- The complainant should receive the outcome and actions in writing. QA should record the outcome, completed actions, communication and closure dates, and approval in the Complaint Database.
- Database access should be role-based and limited to authorized personnel. Confidential information should be protected, with an audit trail maintained where available.
- QA should periodically review trends, repeat and overdue complaints, root causes, and CAPA effectiveness, and report key volumes, risks, timeliness, outcomes, and CAPA status.
- The submitted form, database entries, evidence, correspondence, investigation records, approvals, and reports should be securely retained for at least five (5) years under applicable record-control requirements.

2.3 Appeal Handling

2.3.1 Appeals against decisions of the Violation Committee: The Pharmaceutical Establishment may appeal a Violation Committee decision to the Minister of Health, as the competent authority, in accordance with Article 40 of the Law.

- **Submission:** The appellant should submit a signed written appeal to the Minister of Health within sixty (60) days from the date of notification of the Violation Committee decision. The appeal should include the appellant's details; the decision number and date; the date of notification; the findings or sanctions contested; the grounds for appeal; the requested outcome; and supporting documents and evidence.
- **Review:** If the Minister forwards the appeal to DSC for technical review, QA shall register and acknowledge it and check its timeliness, completeness, jurisdiction, and admissibility. The designated DSC department or committee shall objectively review the complete case file, including the contested decision, inspection or investigation records, evidence considered by the Violation Committee, applicable legal requirements, and the appellant's submissions. Persons with a conflict of interest shall not participate, and additional information may be requested where necessary. DSC shall submit its findings and recommendations to the Minister for decision.

- **Decision:** The Minister of Health should decide the appeal within thirty (30) days of submission, assessing its legality, procedural fairness, proportionality, and evidence. The Minister may confirm, amend, cancel, or return the decision for reconsideration, as legally permitted. If no decision is made within this period, the appeal is deemed rejected.

- **Feedback and closure:** The appellant should be notified in writing of the Minister's decision, its reasons, effective date, and any required action. Where the appeal is deemed rejected because the thirty-day period expired without a decision, this status should be recorded and communicated. The concerned DSC department should implement the outcome, update the appeal status, and retain the complete appeal record in the controlled Appeal Database.

2.3.2 **Appeals against DSC regulatory decisions:** These appeals should be handled as follows:

- **Submission:** The appellant submits the appeal and supporting information to the concerned department.
- **Investigation:** The concerned department reviews the appeal, investigates the grounds raised, and assesses the relevant records and evidence.
- **Decision:** The concerned department issues a decision within the specified timeframe.
- **Feedback:** The decision and its outcome are communicated in writing to the appellant.

CHAPTER THREE

Responsibilities:

- **Quality Assurance (QA):**
  Responsible for receiving, logging, and tracking all complaints and appeals, ensuring proper investigation, and maintaining the CA Database within DSC
- **Appeal Committee / Independent Committee:**
  Reviews appeals referred by the Minister and conducts technical assessments with written recommendations.
- **Minister of Health:**
  Reviews and approves final decisions related to appeals.
- **Appellant / Complainant:**
  Submits the complaint or appeal with the required information within the specified timelines and responds to requests for clarification.

CHAPTER FOUR

Document History and Version Control

Version	Description	Review Date
1	Initial Release	
2		
3		

References:

Sultanate of Oman (2015) Royal Decree No. 35/2015 Promulgating the Law Regulating the Practice of Pharmacy and Pharmaceutical Establishments, see in particular Article (40) (right of grievance against committee decisions). Muscat: Official Gazette.

Ministry of Health, Sultanate of Oman (2020) Ministerial Decision No. 113/2020 Issuing the Executive Regulation of the Law Regulating the Practice of Pharmacy and Pharmaceutical Establishments. Muscat: Ministry of Health.

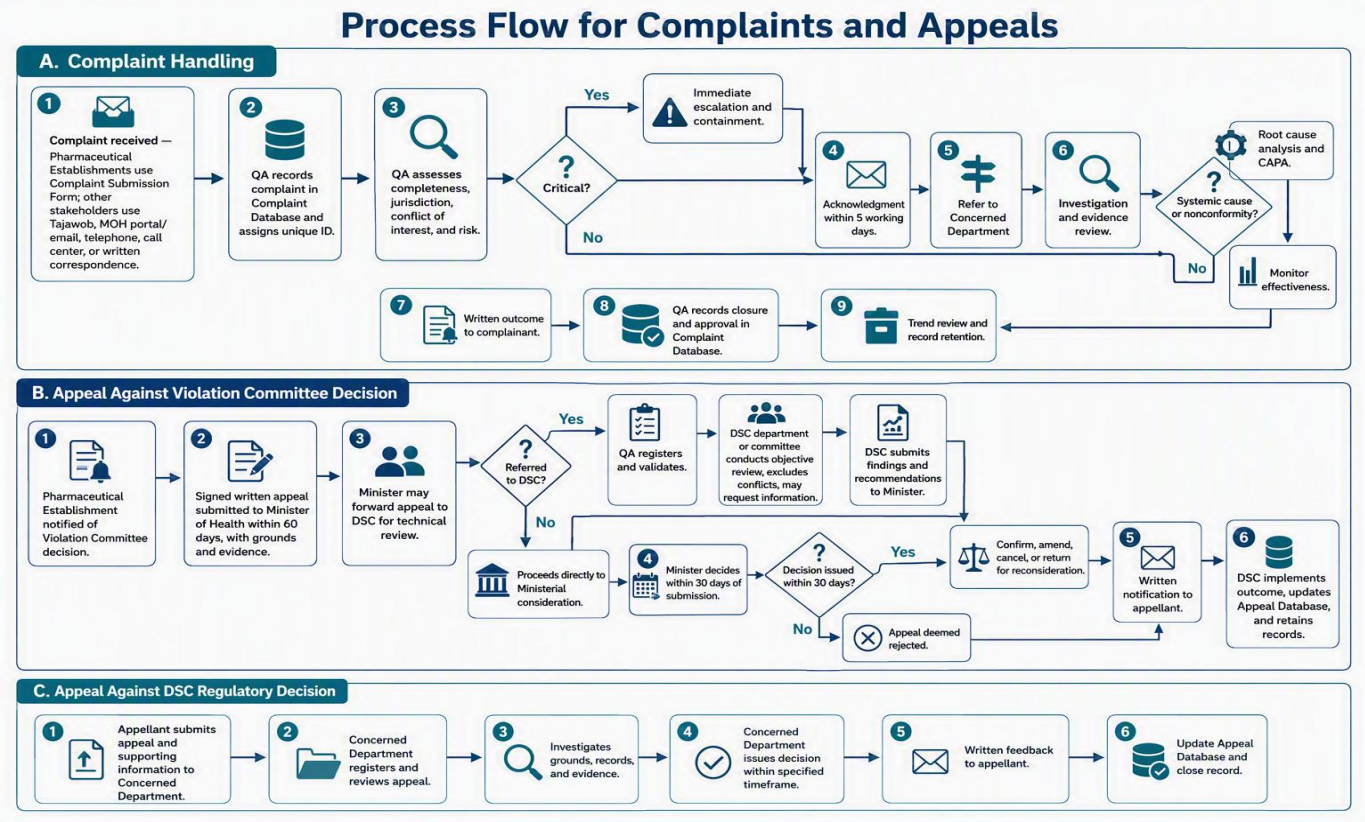
World Health Organization (2021). *Global Benchmarking Tool (GBT) for Evaluation of National Regulatory Systems of Medical Products, Revision VI.* Geneva: World Health Organization.

World Health Organization (2013). *WHO Good Regulatory Practices for National Regulatory Authorities of Medical Products,* in WHO Technical Report Series, No. 981, Annex 11. Geneva: World Health Organization.

Ministry of Health, Sultanate of Oman (2025) Ministerial Decision No. 252/2025 on the Drug Safety Center's Departmental Roles and Responsibilities. Muscat: Ministry of Health.

Annexes

Appendix 1 Process Flow for Complaint and Appeals



Appendix 2 Complaint and Appeal Form

Type of submission	☐ Complaint ☐ Appeal
Full name of complainant / appellant	
Organization / establishment (if applicable)	
Contact details (address, phone, email)	
License / registration / reference number (if applicable)	
Regulatory decision being appealed (reference number and date) -- leave blank for a complaint	
Date of notification of the decision	
Grounds for appeal (see paragraph 2.4 of this guideline)	
Detailed statement of the complaint / grounds for appeal (attach additional sheets if necessary)	
Supporting documents attached (list)	
Outcome sought	
Declaration	I confirm that the information provided is true and complete to the best of my knowledge.
Signature	
Date submitted	
For DSC use only	Date received: Reference number assigned: Focal point:

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Appendix 3 Complaint Database Field Structure

Column Name	Purpose / Expected Entry
Complaint ID	Unique controlled reference number
Date Received	Date the complaint was first received
Receipt Channel	Tajawob, MOH portal, email, phone, call center, or letter
Complainant Name	Name of complainant or authorized representative
Organization / Establishment	Affiliated entity, if applicable
Contact Details	Telephone and email address
Confidentiality Level	Record-access classification
Complaint Category	Service, conduct, communication, process, safety, quality, or compliance
Complaint Subject	Brief descriptive title
Complaint Description	Complete summary of the concern
Department / Entity Concerned	Responsible DSC department, service, product, or regulated entity
Risk Classification	Potential impact assessment
Assigned To	Responsible department and investigator
Acknowledgment Due Date	Calculated deadline for acknowledgment
Acknowledgment Date	Date acknowledgment was issued
Investigation Due Date	Approved target date for completion
Status	Current workflow stage
Investigation Findings	Summary of verified findings
Root Cause Category	Confirmed or probable cause
CAPA Reference	Linked corrective and preventive action number
CAPA Status	Implementation and effectiveness status

Outcome	Substantiated, partially substantiated, unsubstantiated, referred, or withdrawn
Response Date	Date final written response was issued
Closure Date	Date formal closure was approved
Closure Approved By	Name and designation of approving person
Overdue Status	Automatic indication against applicable due dates
Repeat / Linked Complaint ID	Related complaint reference, if any
Supporting Records Location	Controlled folder or record reference
Retention / Disposal Date	Minimum five-year retention control

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Appendix 4 — Appeal Database Field Structure

Column Name	Purpose / Expected Entry
Appeal ID	Unique controlled appeal reference
Date Received	Date the appeal was received by MOH or DSC
Appeal Type	Decision under challenge
Appellant Name	Name of appellant or authorized representative
Pharmaceutical Establishment	Name of establishment, where applicable
License / Registration Number	Applicable establishment or product reference
Contact Details	Telephone and email address
Contested Decision Number	Reference number of the appealed decision
Contested Decision Date	Date the appealed decision was issued
Notification Date	Date the appellant was notified of the decision
Appeal Submission Deadline	Applicable statutory or specified deadline
Submitted Within Timeframe	Timeliness assessment
Grounds for Appeal	Summary of the grounds raised
Outcome Sought	Remedy requested by the appellant
Supporting Documents	Evidence or document list
Referred by Minister	Whether a Violation Committee appeal was forwarded to DSC
Ministerial Referral Date	Date the appeal was forwarded to DSC
Concerned Department / Committee	DSC unit assigned to review or investigate
Assigned To	Responsible reviewer or focal point
Completeness and Admissibility	Administrative validation outcome
Conflict of Interest Check	Confirmation that reviewers are independent
Review / Investigation Start Date	Date substantive assessment began
Additional Information Requested	Whether further documents or clarification were requested
Additional Information Due Date	Deadline given to the appellant or concerned party
Review Findings	Summary of assessment or investigation findings

Column Name	Purpose / Expected Entry
DSC Recommendation	Recommendation submitted to the Minister, where applicable
Recommendation Date	Date DSC submitted its recommendation
Decision Due Date	Applicable statutory or specified decision deadline
Status	Current appeal stage
Decision Authority	Minister of Health or concerned DSC department
Final Decision	Outcome of the appeal
Decision Reasons	Summary of reasons supporting the outcome
Decision Date	Date the decision was issued
Feedback Date	Date the appellant was notified in writing
Implementation Action	Action required to implement the outcome
Implementation Status	Progress of required action
Closure Date	Date the appeal record was formally closed
Overdue Status	Automatic indication against applicable deadlines
Supporting Records Location	Controlled folder or record reference
Retention / Disposal Date	Record-retention control date

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