



Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

MTG Guideline for Appeals, Incidents and Complaints Management (AICOM)

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 30.09.2026	
Doc. No: MTG/QP-IC/GLN 008	Doc. Name: MTG Guideline for Appeals, Incidents and Complaints Management (AICOM)		
Version No: 01	Issued Date: 30.09.2026	Copy Letter:	Page No: Page 1 of 31

Version Number	1	
Issued Date	30.09.2026	
Prepared By	Mariyam Laisa, Quality Manager	
Approved By	Aishath Mohamed, Deputy Director General, Pharmaceuticals	
Authorized by	Thooma Adam, Deputy Director General, Laboratory Services (Acting Head of MFDA)	

SUMMARY OF CHANGES

Version No.	Issued Date	Section/Clause	Summary of Change	Changes Made by
1	30.09.2026	-	Creation of the document	Mariyam Laisa, Quality Manager

ABBREVIATIONS

MOHFW	Ministry of Health Family and Welfare
MFDA	Maldives Food and Drug Authority
MTG	Medicine and Therapeutic Goods Division
NHL	National Health Laboratory
AICOM	Appeals, Incidents and Complaints Management

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 30.09.2026	
Doc. No: MTG/QP-IC/GLN 008	Doc. Name: MTG Guideline for Appeals, Incidents and Complaints Management (AICOM)		
Version No: 01	Issued Date: 30.09.2026	Copy Letter:	Page No: Page 3 of 31

Definitions

Regulatory decision	They are individual legal acts undertaken by MTG to address those subject to the relevant laws and regulations and grant them rights or impose obligations.
Appeals	An appeal is a formal request to review and possibly revise a prior decision issued by MTG related to any of its regulatory activities. It plays a pivotal role in ensuring fairness and accountability of the Authority.
Appellants	Any client who presents an appeal against a regulatory decision made by MTG.
Complaint	An expression of dissatisfaction with the activities of the Authority, and may relate to services provided, employee conduct, policies, and regulations. It can also be a concern that provides feedback regarding some aspect of the service offered that identifies issues requiring a response. It does not include requests for services or information, explanations of policies or procedures.
Customer	A person or an organization that receives, or intends to receive, a service or authorization from MTG.
Incident	It can be an alleged or evident deficiency related to the identity, quality, durability, reliability, safety, effectiveness, or performance of products within the mandate of MFDA, or an adverse event i.e., any undesirable effect resulting from the use of any product within the mandate of MFDA. A complaint or incident does not include requests or queries regarding services provided.
Customer satisfaction	Refers to the perception of the degree to which the customer's expectations have been fulfilled
Risk	Risk revolves around calculating the difference in negative and positive features of a process.
Risk-based thinking	This method of thought is related to reflecting on how much risk is involved for a certain amount of gain. Typically, you'll want to find the best low-risk/high-reward ratio.
Whistleblower	A whistleblower is an employee who discloses information that they reasonably believe is evidence of misconduct or mismanagement.

1 Introduction

The Maldives Food and Drug Authority (MFDA) is the agency mandated by government to regulate and conduct quality tests to ensure the safety and quality of food, medicines, chemicals of public health significance, medical gases, vaccines, other biologicals, medical devices, diagnostic devices, and radiation emitting devices used in the Maldives, through established standards, product registrations, licensing, public awareness, and laboratory testing.

Within MFDA, the Medicine and Therapeutic Goods Division (MTG) is responsible for conducting regulatory and enforcement activities related to medicines, medical devices, and other health products within its regulatory mandate.

MTG is responsible for the management of appeals, incidents and complaints as per Clause 47 of Medicine Regulation R-64/2026. Management of appeals, incidents and complaints reflects on the reputation and credibility of the organization and has been shown to be a keystone of public confidence in regulatory authorities. It contributes to building public confidence and trust in the Authority. It also aims to improve internal management of such cases and improve the standard of our services to the community.

Hence, to enhance transparency and accountability, and sustain a quality management system with a customer focus, MTG has instituted this guide that outlines the systematic approach to management of complaints, incidents, and appeals.

2 Purpose

The purpose of this guideline is to:

1. Define the processes involved in managing appeals, incidents and complaints received in regards to its mandated regulatory activities.
2. Ensure that complaints, incidents and appeals are dealt with professionally, timeously and appropriately to prevent negative impacts on public health.
3. Ensure appropriate assessment, investigation, resolution and effectiveness implementation of action for appeals, incidents and complaints to reduce potential negative impact
4. Identify areas for systematic and continuous improvement

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 30.09.2026	
Doc. No: MTG/QP-IC/GLN 008	Doc. Name: MTG Guideline for Appeals, Incidents and Complaints Management (AICOM)		
Version No: 01	Issued Date: 30.09.2026	Copy Letter:	Page No: Page 5 of 31

3 Scope

This guideline outlines the procedure for managing appeals, incidents, and complaints received from external stakeholders, members of the public, and internally within MFDA, relating to the activities conducted by MTG under its regulatory mandate.

4 Management commitment

The top management of MFDA and its divisions are committed to continuous improvement of the complaints, incidents, and appeals management system.

4.1 Responsibilities and accountability

It is the responsibility of Division Heads:

RESPONSIBLE PERSONNEL	RESPONSIBILITIES
Division Head – MTG	• Provide overall oversight of the management of Appeals, Incidents and Complaints (AICOM) within MTG. • Ensure AICOM cases are managed in accordance with this guideline, relevant SOPs, applicable laws and regulations. • Ensure adequate resources and appropriate structures are available for effective AICOM management. • Review significant cases and ensure appropriate corrective, preventive and regulatory actions are implemented in a timely manner. • Ensure appropriate escalation of appeals and other matters requiring higher-level review.
Section Heads – MTG	• Monitor and guide the management of AICOM cases within their respective sections. • Ensure staff are aware of and comply with this guideline and relevant procedures. • Ensure cases assigned to their sections are appropriately assessed, investigated, documented and managed within established timeframes. • Review proposed actions and recommendations and ensure

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 30.09.2026	
Doc. No: MTG/QP-IC/GLN 008	Doc. Name: MTG Guideline for Appeals, Incidents and Complaints Management (AICOM)		
Version No: 01	Issued Date: 30.09.2026	Copy Letter:	Page No: Page 6 of 31

	appropriate follow-up Escalate matters requiring technical, managerial or higher-level consideration to the Division Head or relevant committee, as applicable.
Responsible Staff for handling individual case	- Receive and register assigned complaints, incidents and appeals and ensure that relevant information and evidence are documented. - Conduct the investigation and assessment of the case and obtain additional information or evidence where necessary. - Prepare the Corrective Action Request (CAR) / relevant case report, where applicable, and document the findings, actions and recommendations. - Coordinate with relevant sections, staff and stakeholders during the investigation and management of the case. - Submit cases requiring technical evaluation, recommendations or corrective actions to the MTG Technical Committee. - Communicate with the complainant or appellant regarding relevant updates, progress and the conclusion of the case, in accordance with applicable confidentiality requirements. - Follow up on the implementation and effectiveness of corrective, preventive and regulatory actions arising from the case. - Ensure that cases are managed and closed within the established or acceptable timeframe, with all required documentation and records completed and filed.
Quality Manager – MTG	- Coordinate and oversee the overall AICOM management system within MTG. Maintain and monitor AICOM records and the status of cases. - Generate periodic reports on AICOM cases and the performance of the AICOM management system. - Establish, monitor and periodically evaluate relevant AICOM performance indicators.

	• Conduct periodic evaluations of the effectiveness, timeliness and compliance of AICOM management. • Report AICOM monitoring and evaluation results to the relevant management structures. • Monitor the implementation and effectiveness of corrective and preventive actions arising from AICOM cases, where applicable. • Identify trends and opportunities for systematic and continual improvement.
MTG Technical Committee	• Provide technical advice and recommendations on corrective, preventive and regulatory actions arising from AICOM cases, as applicable. • Serve as the first level of evaluation for appeals received by MTG. • Review relevant information, evidence, findings and recommendations associated with appeals and provide technical advice on the appropriate resolution. • Escalate appeals requiring further consideration to the Senior Management Committee (SMC) of MFDA.
Senior Management Committee (SMC) – MFDA	• Provide technical and management advice and conduct the second-level evaluation of appeals escalated from the MTG Technical Committee. • Review relevant information, evidence and recommendations provided at the first level of appeal evaluation. • Provide recommendations on the appropriate resolution and further action required. • Escalate appeals to the National Pharmaceutical Board where further consideration is required.
National Pharmaceutical Board	• Serve as the third and final level of escalation for appeals • Review and evaluate appeals escalated by the SMC. • Provide advice and recommendations on the resolution and appropriate regulatory action arising from the appeal.

	Consider the potential impact on public health and provide recommendations to minimize potential negative impacts on public health.
--	---

5 General principles

Legal and Regulatory Compliance	All complaints, incidents, and appeals shall be managed in accordance with applicable laws, regulations, established MFDA procedures, and the regulatory mandate of MTG.
Commitment	MTG should actively commit to establishing and implementing an effective complaints-handling process.
Transparency	Sufficient resources should be available for the effective handling of AICOM system
Accessibility	The AICOM process should be easily accessible, understandable and easy to use. Information and assistance should be available in appropriate languages and formats so that complainants are not disadvantaged.
Responsiveness	MTG should address the needs and expectations of customers in relation to appeals, incidents and complaints handling.
Objectivity	Each appeal, incident and complaint should be handled in an equitable, objective and unbiased manner.
Charges	Access to the AICOM process should be free of charge to the relevant customer of stakeholder.
Information Integrity	Information about AICOM should be accurate and not misleading. Information collected should be relevant, correct, complete, meaningful and useful.
Confidentiality	Personally identifiable information should be protected and used only as necessary to address the case, unless disclosure is authorized by the customer/stakeholder or required by law and with the appropriate authorizations.
Customer-Focused Approach	MTG should maintain a customer-focused approach to appeals, incidents and complaints handling and remain open to feedback.
Accountability	Accountability should be established and maintained for decisions and

	actions relating to AICOM, including appropriate reporting.
Improvement	Improving the effectiveness and efficiency of the AICOM process should be a permanent organizational objective.
Competence	Personnel handling AICOM should have the appropriate attributes, skills, training, education and experience.
Timeliness	All appeals, incidents and complaints should be handled as promptly as reasonably practicable, considering the nature of the case and the process involved.

6 Risk-Based Thinking

- 6.1** MTG shall apply risk-based thinking throughout the management of appeals, complaints and incidents. Each case shall be assessed based on its nature, severity, likelihood of occurrence, potential impact on public health and safety, regulatory compliance, stakeholders, and the effectiveness of the QMS. The level of investigation, resources, corrective or regulatory actions, escalation, monitoring and follow-up shall be proportionate to the identified risk.
- 6.2** Where significant or emerging risks are identified, MTG shall take timely and appropriate action to control or mitigate the risk and shall consider whether similar risks may exist elsewhere. Risk information arising from appeals, complaints and incidents shall be used, where appropriate, to identify opportunities for improvement and inform changes to relevant processes, controls and the QMS.

7 Mechanisms For Filing Complaints, Appeals, and Notifying Incidents

- 7.1** Mechanisms for filing complaints, appeals, and notifying incidents shall be established and communicated to the public. The following mechanisms are available for customers/appellants to file appeals, incidents or appeals.
1. Complaints can be filed and incidents notified through:
 2. face-to-face communication at the offices of MFDA
 3. phone (detailed in Annex 2)
 4. e-mails (detailed in Annex 2)
 5. in writing to MFDA
 6. Appeals filed to MFDA should be in writing by email.

8 Management of complaints

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 30.09.2026	
Doc. No: MTG/QP-IC/GLN 008	Doc. Name: MTG Guideline for Appeals, Incidents and Complaints Management (AICOM)		
Version No: 01	Issued Date: 30.09.2026	Copy Letter:	Page No: Page 11 of 31

- 8.1** Complaints shall be viewed as valuable feedback on the effectiveness of the Quality Management System and shall be used to improve the system, focusing on customer satisfaction. All complaints shall be logged and resolved in a timely manner, and customers informed of the decisions or actions taken.
- 8.2** Complaint management ensures systematic handling of issues to maintain customer satisfaction, regulatory compliance, and operational efficiency.
- 8.3** Complaint or incident can be lodged by:
- (a) **Internal customer:** A complaint received from another division of Maldives Food and Drug Authority (that is within the organization), regarding any service provided by MTG.
 - (b) **External customer:** These are the customers or clients outside the organization of Maldives Food and Drug Authority.
 - (c) Staff of Medicine and Therapeutic Goods division
- 8.4** Customer Complaints can be classified as general, service/quality, product or statutory/regulatory complaints.
- 8.5** The following shall be considered examples of regulatory complaints and shall not be limited to the categories listed below. MTG may classify a complaint as a regulatory complaint based on its nature, subject matter, and applicability to the regulatory mandate of MTG:
- 1. Sale of unregistered medicines
 - 2. Sale of expired medicines
 - 3. Operating from unlicensed premises
 - 4. Complaints on registered medicines
 - 5. Failure to comply with labelling requirements.
 - 6. No package inserts
 - 7. Distribution outside approved category for distribution

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 30.09.2026	
Doc. No: MTG/QP-IC/GLN 008	Doc. Name: MTG Guideline for Appeals, Incidents and Complaints Management (AICOM)		
Version No: 01	Issued Date: 30.09.2026	Copy Letter:	Page No: Page 12 of 31

8. Illegible writing on package insert/label
9. Sale or advertising of complementary medicines with medicinal claims
10. Complaints involving persons-medical practitioner, pharmacist, nurse, pharmacy technician or veterinary in relation to sale or use of medicines and allied substances.
11. Complaints involving premises- dispensing practice, pharmacy, clinic, wholesale dealer, general dealer

8.5.1 The complaint record shall contain, where applicable:

- name and contact details of the customer or stakeholder
- date and method of receipt
- description and nature of the complaint
- person, organization, product, service or regulatory activity concerned
- relevant supporting documents or evidence
- any immediate risks or potential impact identified
- details of the staff member responsible for handling the complaint
- Reference number within the AICOM system.

8.6 Initial Assessment and Categorization

8.6.1 Upon receipt, MTG shall conduct an initial assessment to determine whether the matter falls within the mandate of MTG.

8.6.2 Complaints shall be categorized according to their nature and regulatory relevance. Categories may include:

- General complaint
- Service or quality complaint;
- Product-related complaint
- Regulatory complaint.

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 30.09.2026	
Doc. No: MTG/QP-IC/GLN 008	Doc. Name: MTG Guideline for Appeals, Incidents and Complaints Management (AICOM)		
Version No: 01	Issued Date: 30.09.2026	Copy Letter:	Page No: Page 13 of 31

8.6.3 The complaint shall also be assessed according to its severity, risk and potential impact to determine the appropriate level of investigation, action and escalation.

8.6.4 Where a complaint identifies an immediate or potential risk to public health, safety, product quality or regulatory compliance, appropriate action shall be initiated without undue delay.

8.7 Investigation and Root Cause Analysis

8.7.1 A responsible staff shall be assigned for each case as per the procedure of MTG and investigation shall be conducted to gather necessary evidence for analysis of root cause, determination of root cause analysis and effective resolution of the complaint. Investigations shall be conducted objectively and impartially based on the information and evidence available.

8.7.2 The investigation may include, as applicable:

- review of relevant regulatory decisions, records
- review of inspection, registration, licensing or authorization records
- review of previous complaints, incidents or related cases
- consultation with relevant MTG personnel or other MFDA divisions
- obtaining information or evidence from the customer or relevant external parties
- verification of information provided
- assessment of applicable laws, regulations, guidelines and procedures
- determination of whether similar or related issues exist or could potentially occur elsewhere

8.7.3 MTG shall conduct an appropriate root cause analysis to determine the underlying cause for each complaint.

8.7.4 Appropriate methods may include 5 Whys, cause-and-effect analysis or Ishikawa diagrams, depending on the nature and complexity of the complaint.

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 30.09.2026	
Doc. No: MTG/QP-IC/GLN 008	Doc. Name: MTG Guideline for Appeals, Incidents and Complaints Management (AICOM)		
Version No: 01	Issued Date: 30.09.2026	Copy Letter:	Page No: Page 14 of 31

8.7.5 The root cause analysis shall be supported by relevant evidence, which may include review of records, historical complaint data, regulatory or distribution information, interviews with involved persons or organizations, and verification of the information obtained.

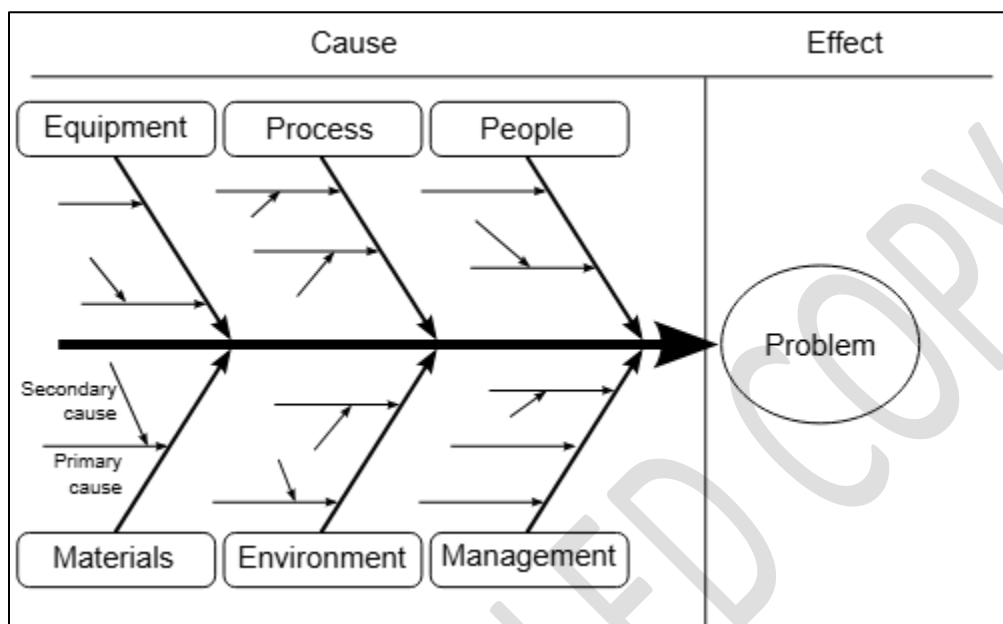


Figure 1 Ishikawa Diagram

8.8 Resolution of Complaint

8.8.1 With the conclusion of initial investigations and determination of root cause, the complaint is presented to the MTG Technical Committee for review. The role of the technical committee includes:

- Reviewing the complaint and relevant investigation findings
- Determining and assigning necessary corrective actions, including responsible persons and target timelines
- Requesting further investigation or additional evidence, where applicable
- Obtaining legal advice from MFDA legal personnel, where necessary
- Escalating the complaint to the Senior Management Committee (SMC) of MFDA, where deemed necessary
- Facilitating an effective and appropriate resolution of the complaint

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 30.09.2026	
Doc. No: MTG/QP-IC/GLN 008	Doc. Name: MTG Guideline for Appeals, Incidents and Complaints Management (AICOM)		
Version No: 01	Issued Date: 30.09.2026	Copy Letter:	Page No: Page 15 of 31

- 8.8.2** The assigned staff shall complete the necessary corrective actions within the given timelines and the case shall be closed under the authority of division head of MTG.
- 8.8.3** The customer or stakeholder shall be notified of the conclusion to the complaint through appropriate communication channel whether phone or e-mail.
- 8.8.4** All complaints shall be concluded within working 10 (ten) days. Feedback shall be provided to the customer or stakeholder within working 07 (days) providing necessary updates regarding the progression of the case. A maximum of 30 (thirty) days shall be taken under the direction of MTG Technical Committee if the extension of timeline is deemed necessary.
- 8.8.5** All documents and records, including all communications generated or received during the handling of a complaint, shall be retained in accordance with applicable document control requirements and kept confidential. Information relating to a complaint shall not be disclosed to persons or organizations not involved in the handling of the case without prior authorization from the Senior Management Committee (SMC) of MFDA, unless disclosure is required or permitted by applicable laws or regulations.

9 Management of Incidents

9.1 Incident Reporting and Registration

- 9.1.1** MTG shall maintain appropriate mechanisms for the reporting and notification of incidents. Any person or organization, including MFDA staff, external stakeholders, regulated entities and other relevant parties, may report an incident that falls within the mandate of MTG.
- 9.1.2** Upon receipt or identification of an incident, MTG shall record the available information and assign a unique reference number to ensure traceability throughout the incident-management process.
- 9.1.3** The incident record shall include, where applicable, the date and source of the notification, description of the incident, persons, products, premises or activities involved, available supporting evidence, immediate actions taken and any other information relevant to the assessment.

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 30.09.2026	
Doc. No: MTG/QP-IC/GLN 008	Doc. Name: MTG Guideline for Appeals, Incidents and Complaints Management (AICOM)		
Version No: 01	Issued Date: 30.09.2026	Copy Letter:	Page No: Page 16 of 31

9.2 Preliminary Assessment

9.2.1 Upon receipt or identification of an incident, MTG shall conduct a preliminary assessment to determine the nature, scope and potential impact of the incident and whether immediate action is required.

9.2.2 The preliminary assessment may consider, as applicable:

- actual or potential effects on the health and safety of patients, consumers or other affected persons
- severity and potential consequences of the incident
- number of persons potentially or actually affected
- likelihood and potential extent of harm
- products, batches, premises, persons or activities potentially affected
- geographical and distributional extent of the incident
- availability and reliability of information and evidence
- previous or similar incidents, complaints or regulatory findings
- potential impact on regulatory compliance and public confidence
- any other information considered necessary

9.2.3 Where an immediate risk to public health, safety or regulatory compliance is identified, MTG shall take appropriate immediate measures to control or mitigate the risk while further assessment is undertaken. (Refer to Guideline for Risk Mitigation and Crisis Management)

9.2.4 MTG shall assess the risk associated with each incident based on the available information, considering its potential impact and likelihood. The assessment shall be conducted in accordance with the applicable MFDA risk management framework. The outcome shall be used to determine the appropriate level of investigation, action, escalation and follow-up.

9.3 Incident Investigation

9.3.1 Incidents requiring investigation shall be investigated in a manner proportionate to their nature, severity and assessed risk.

9.3.2 The investigation may include, as applicable:

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 30.09.2026	
Doc. No: MTG/QP-IC/GLN 008	Doc. Name: MTG Guideline for Appeals, Incidents and Complaints Management (AICOM)		
Version No: 01	Issued Date: 30.09.2026	Copy Letter:	Page No: Page 17 of 31

1. verification of the information received
2. review of relevant regulatory records, correspondence and documented information
3. review of inspection, registration, licensing, authorization or surveillance records
4. review of previous complaints, incidents, adverse events or similar cases
5. collection and evaluation of scientific, technical and regulatory evidence
6. interviews or consultation with relevant persons or organizations
7. inspection, sampling or testing, where applicable
8. consultation with relevant MFDA divisions, committees or technical experts
9. assessment of whether similar or related incidents exist or could potentially occur elsewhere.

9.3.3 A root cause analysis shall be conducted based on the investigation. (refer to 7.7 of this guideline)

9.4 Risk Control and Regulatory Actions

9.4.1 Based on the outcome of the assessment and investigation, MTG shall determine and implement appropriate actions to control, mitigate or eliminate the identified risk.

9.4.2 Actions may include, as applicable:

1. requesting additional information or evidence
2. increased monitoring or surveillance
3. inspection, sampling or testing
4. product detention, withdrawal or recall in accordance with applicable procedures
5. regulatory or enforcement action
6. referral to the Pharmacovigilance process or another relevant MFDA process
7. notification or coordination with other competent authorities

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 30.09.2026	
Doc. No: MTG/QP-IC/GLN 008	Doc. Name: MTG Guideline for Appeals, Incidents and Complaints Management (AICOM)		
Version No: 01	Issued Date: 30.09.2026	Copy Letter:	Page No: Page 18 of 31

8. other actions necessary to protect public health, safety or regulatory compliance.

9.4.3 Actions shall be proportionate to the assessed risk and potential impact of the incident and shall be documented in the incident record.

9.5 Referral and Escalation

9.5.1 Where an incident falls within the scope of an established specialized regulatory process, the incident shall be referred to the relevant process or responsible unit for appropriate action.

9.5.2 This may include, as applicable, pharmacovigilance, product recall, inspection, laboratory testing, enforcement or other relevant regulatory procedures.

9.5.3 Where an incident presents a significant or escalating risk, MTG shall escalate the matter to the appropriate management level in accordance with the assessed risk and applicable MFDA procedures.

9.5.4 Where the incident meets the criteria for an emerging threat, declared health emergency or public health crisis, the applicable provisions of the Guideline on Risk Management and Crisis Mitigation in Public Health Emergencies shall be activated. The AICOM incident record shall continue to be maintained and relevant information shall be provided to the responsible emergency or crisis-management structure, as appropriate.

9.6 Communication and Information Sharing

9.6.1 Communication relating to an incident shall be proportionate to the nature, severity and assessed risk of the incident.

9.6.2 Where communication with affected persons, stakeholders, healthcare professionals, regulated entities, other authorities or the public is required, MTG shall ensure that information communicated is accurate, evidence-based, clear, appropriately authorized and consistent with the current assessment of the incident.

9.6.3 Communication shall be managed in accordance with applicable confidentiality, information-sharing and regulatory requirements.

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 30.09.2026	
Doc. No: MTG/QP-IC/GLN 008	Doc. Name: MTG Guideline for Appeals, Incidents and Complaints Management (AICOM)		
Version No: 01	Issued Date: 30.09.2026	Copy Letter:	Page No: Page 19 of 31

9.6.4 Where an incident is associated with or escalated to a public health emergency or crisis, communication shall be coordinated in accordance with the applicable emergency and crisis-management arrangements.

9.7 Resolution of Incident

9.7.1 An incident shall be closed when:

1. the required assessment and investigation have been completed
2. the identified risk has been adequately controlled or appropriately transferred for further management
3. required regulatory, corrective or other actions have been completed or appropriately assigned for follow-up
4. the outcome and decisions have been documented
5. no further action is required under the incident-management process.

9.7.2 Where ongoing monitoring or follow-up is required, the incident may be closed only after responsibility for such activities has been formally assigned and the required arrangements have been documented.

10 Management of Appeals

10.1 Eligibility and Grounds for Appeal

10.1.1 Appeals can be filed by any client directly affected by a regulatory decision made by MTG which causes direct impact material impact for the appellant. This may include pharmacies, importers, warehouse owners etc. Meaning the appellant shall demonstrate the specific material impact of the decision made by MTG.

10.1.2 Appeals may be submitted only after the relevant regulatory decision has been finalized and formally communicated to the client. An appeal may arise following the conclusion of a regulatory service or in response to a decision made in relation to a complaint or incident. Hence, MTG shall provide sufficient chances for appellant to clarify submitted documents and explain their perspective prior to the decision is made.

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 30.09.2026	
Doc. No: MTG/QP-IC/GLN 008	Doc. Name: MTG Guideline for Appeals, Incidents and Complaints Management (AICOM)		
Version No: 01	Issued Date: 30.09.2026	Copy Letter:	Page No: Page 20 of 31

10.1.3 Grounds of appeal are the specific reasons why an appellant contends the regulatory decision made by MTG was wrong and should be set aside or varied. Such grounds shall be precise with supporting evidence and vague assertion that the decision was wrong will not be accepted. The grounds must identify the particular error, whether of law, fact, or procedure, and explain why it made the decision wrong.

10.1.4 An appeal may be rejected where the appellant fails to provide sufficient and specific grounds for reconsideration and does not provide relevant information or evidence capable of supporting those grounds.

10.2 Filing an Appeal

10.2.1 Appeals can be formally submitted through an email or by letter along with the evidence to justify the grounds of the appeal. The information required for the filing is specified in Annex 1 of this guideline.

10.2.2 Before submission of an appeal, the appellant shall determine the following:

- If the decision is appealable and on what grounds: This shall help determine the extent and nature of resources required to prepare the appeal.
- Which points to be challenged: refer to point 10.1.3
- Investigate and assess the impact of the decision

10.2.3 Misinformation or falsified information submitted as evidence can directly result in regulatory actions. (Refer to Medicine Regulation R-64/2026 and Guideline for Regulatory Actions)

10.2.4 The window for filing an appeal is within maximum 15 (fifteen) days after a regulatory decision is formally issued and communicated. Adherence to this timeline is important for the certainty of the appeal process and to ensure appeals are made and dealt with promptly. It shall also allow for any quick corrections to be made or misunderstandings regarding the regulatory decision to be resolved.

10.3 Preliminary Screening of Appeals

10.3.1 Once a regulatory appeal has been submitted, the MTG shall check that if the appeal is made:

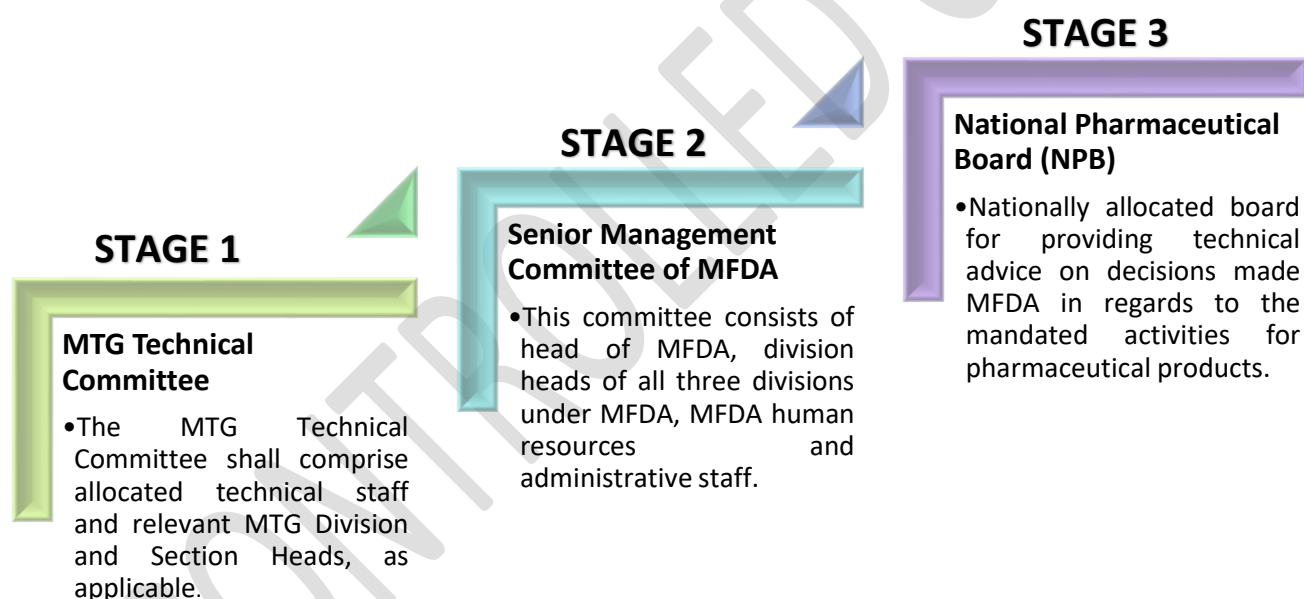
Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 30.09.2026	
Doc. No: MTG/QP-IC/GLN 008	Doc. Name: MTG Guideline for Appeals, Incidents and Complaints Management (AICOM)		
Version No: 01	Issued Date: 30.09.2026	Copy Letter:	Page No: Page 21 of 31

- against a formal regulatory decision,
- has been made by the right person
- that the appeal has been made within the correct timescale.
- If the grounds for appeal are specific and acceptable
- If there are complete and legible information and evidence provided

10.3.2 The screening shall be completed withing working 03 days and shall be submitted to MTG Technical Committee if accepted.

10.3.3 If the appeal is rejected, the appellant shall be notified in writing with the justification of the reject.

10.4 Stages for Review of Appeals



10.5 General Requirements Applicable at All stages

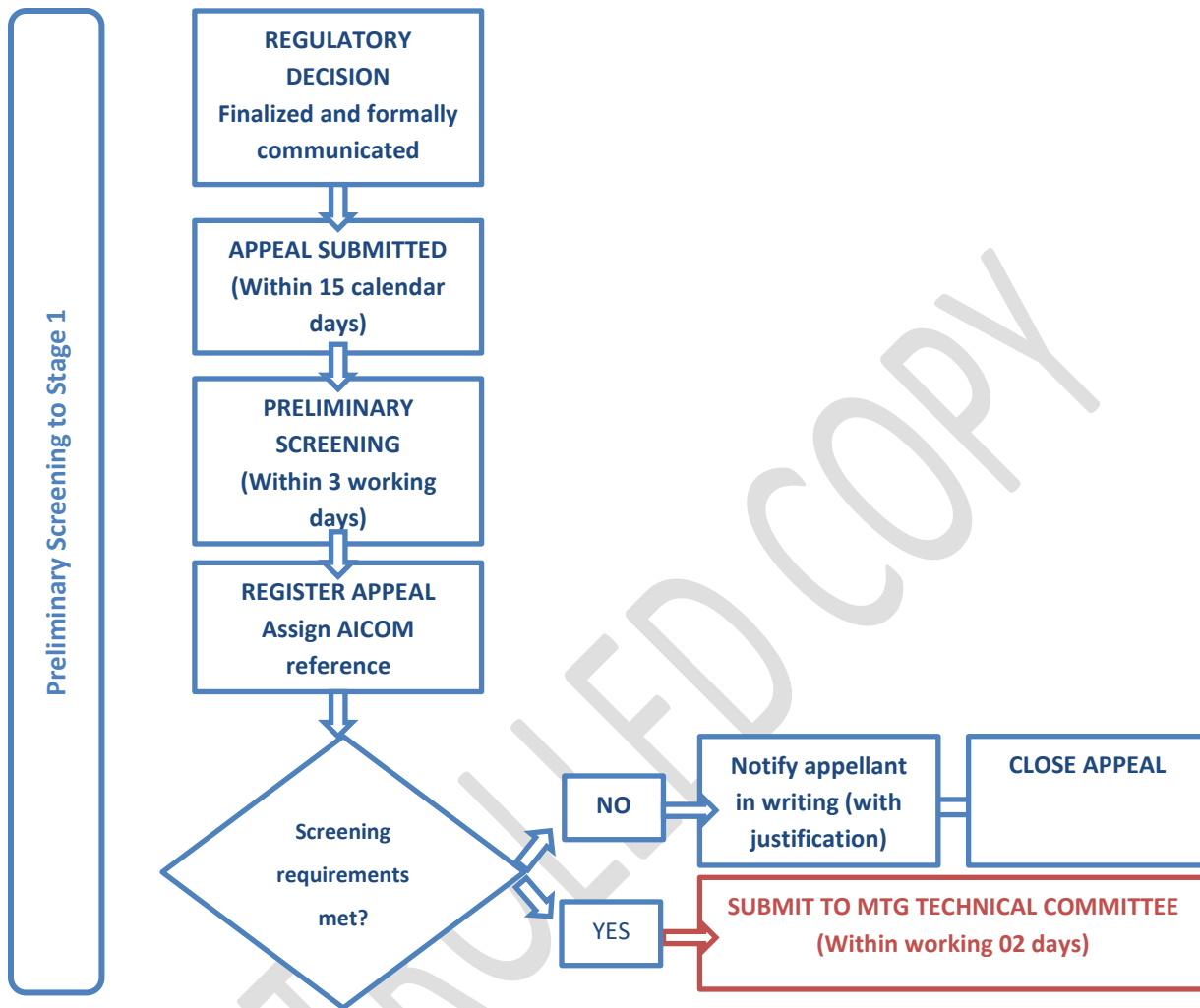
10.5.1 The committee/board members shall have the appropriate competence to evaluate the appeal, provide technical input and make reasoned and just decisions based on the available evidence.

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 30.09.2026	
Doc. No: MTG/QP-IC/GLN 008	Doc. Name: MTG Guideline for Appeals, Incidents and Complaints Management (AICOM)		
Version No: 01	Issued Date: 30.09.2026	Copy Letter:	Page No: Page 22 of 31

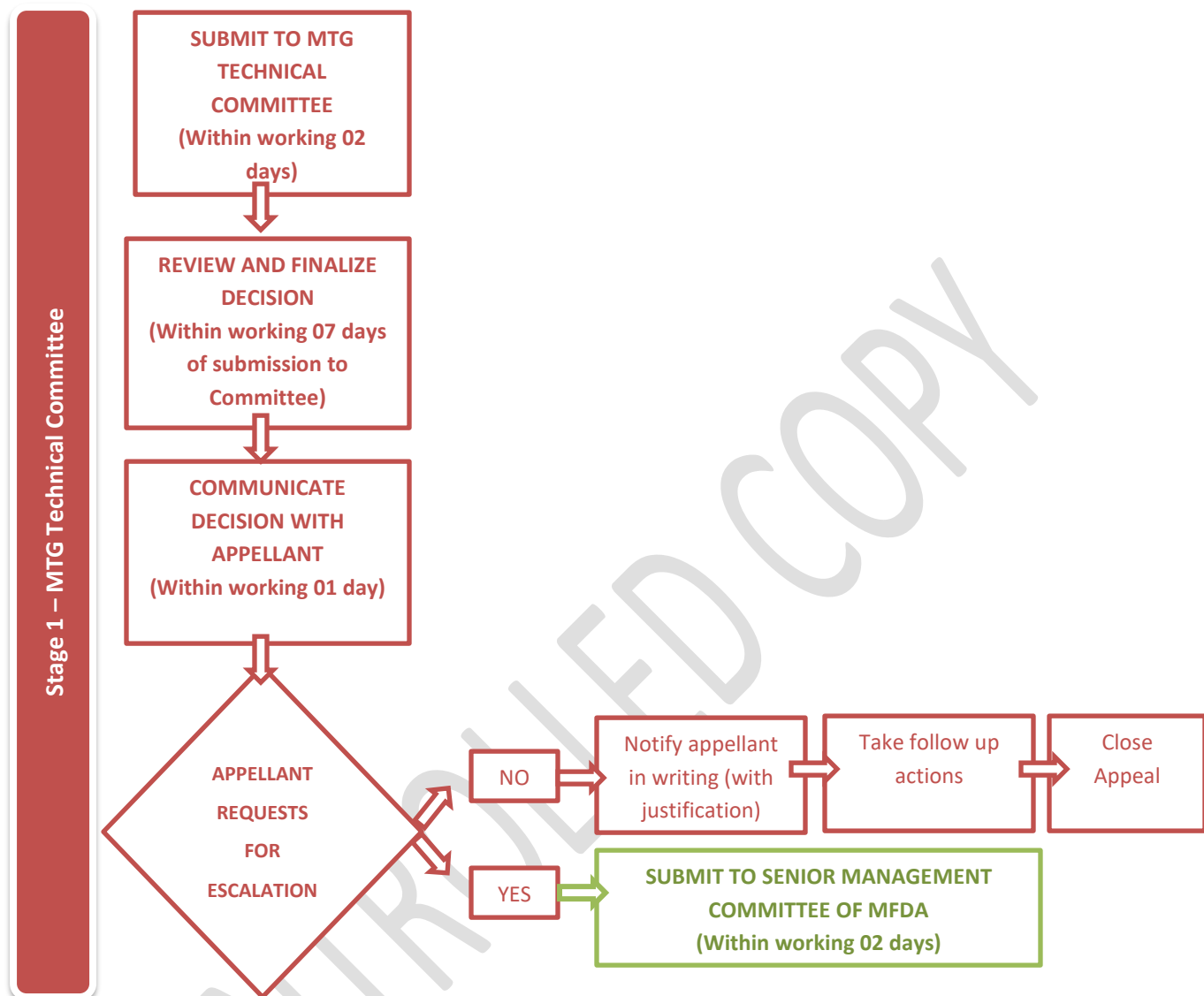
- 10.5.2** All appeals shall be objectively evaluated with impartiality based on the submitted evidence, related law, regulations, guidelines and with the application of a risk-based approach.
- 10.5.3** Members participating shall declare any actual, potential or perceived conflict of interest and where the conflict may affect their impartiality.
- 10.5.4** Decision shall be reached by consensus with the approval of the head of MFDA or the division head of MTG (in case of MTG Technical Committee)
- 10.5.5** A formal record shall be developed for each committee/board meeting held for appeals and this shall include appeal filing with supporting evidence, discussions made, decisions finalized, feedback provided to the appellant and follow up actions wherever applicable.
- 10.5.6** For Stage 1 and Stage 2, an appellant may request escalation of an appeal to the subsequent stage. Where escalation is requested, the appellant shall provide new and relevant information or evidence to justify further consideration of the appeal. Where sufficient new and relevant information or evidence is not provided, the appeal shall be closed and the decision of the preceding stage shall remain in effect.
- 10.5.7** The final stage for all appeals is the National Pharmaceutical Board (Stage 3). No further requests for escalation or review shall be accepted following the decision at Stage 3.

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 30.09.2026	
Doc. No: MTG/QP-IC/GLN 008	Doc. Name: MTG Guideline for Appeals, Incidents and Complaints Management (AICOM)		
Version No: 01	Issued Date: 30.09.2026	Copy Letter:	Page No: Page 23 of 31

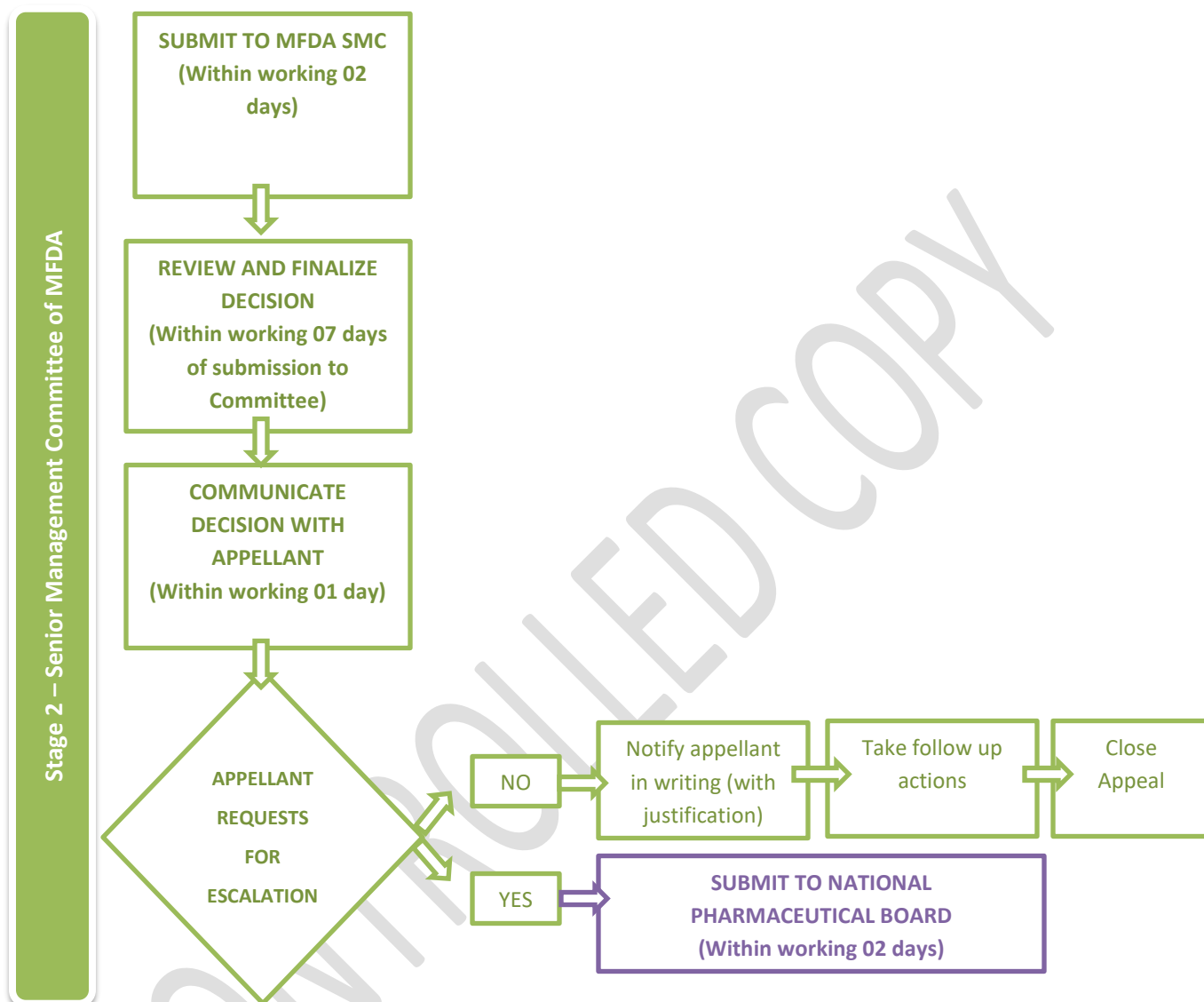
10.6 Procedure Outline for Appeals



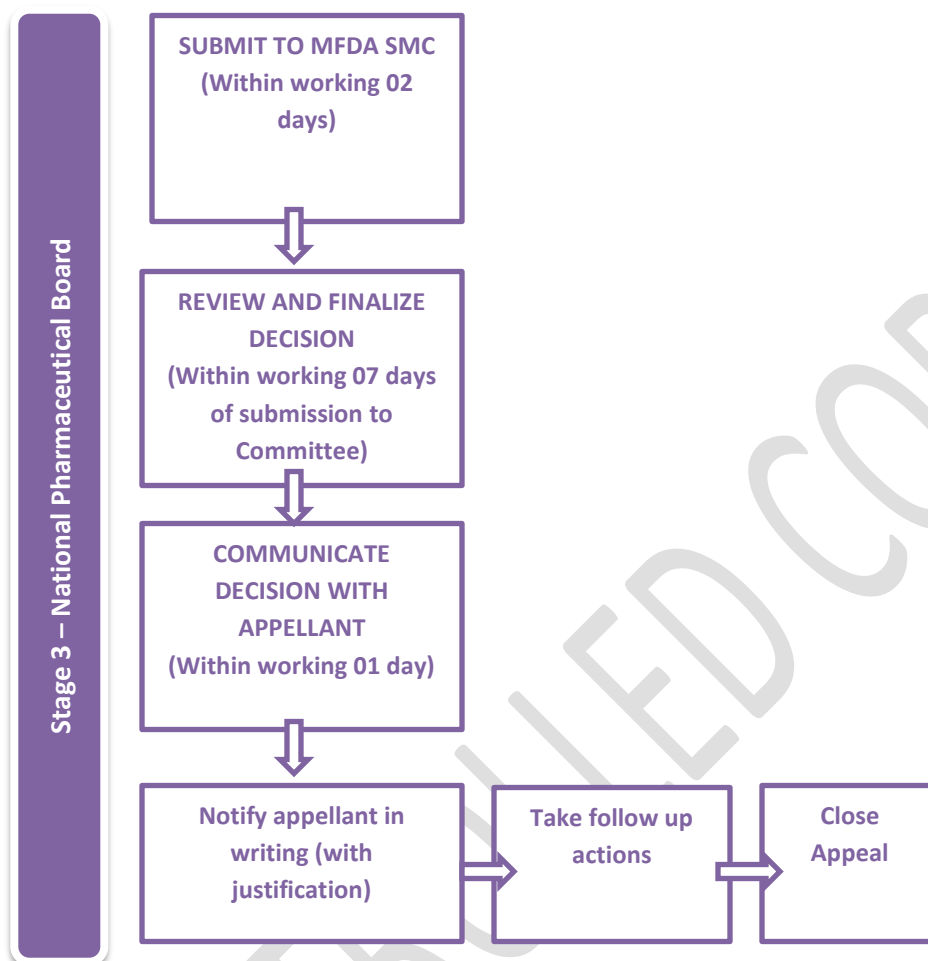
Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority			Document Created on: 30.09.2026
Doc. No: MTG/QP-IC/GLN 008	Doc. Name: MTG Guideline for Appeals, Incidents and Complaints Management (AICOM)		
Version No: 01	Issued Date: 30.09.2026	Copy Letter:	Page No: Page 24 of 31



Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 30.09.2026	
Doc. No: MTG/QP-IC/GLN 008	Doc. Name: MTG Guideline for Appeals, Incidents and Complaints Management (AICOM)		
Version No: 01	Issued Date: 30.09.2026	Copy Letter:	Page No: Page 25 of 31



Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 30.09.2026	
Doc. No: MTG/QP-IC/GLN 008	Doc. Name: MTG Guideline for Appeals, Incidents and Complaints Management (AICOM)		
Version No: 01	Issued Date: 30.09.2026	Copy Letter:	Page No: Page 26 of 31



11 Documentation and Record-keeping

- 11.1** All information and documented records relating to an appeal, complaint or incident shall be maintained in accordance with applicable document-control requirements.
- 11.2** The incident record shall, as applicable, contain the notification, preliminary assessment, risk classification, investigation findings, evidence, decisions, actions taken, communications, corrective actions, follow-up and closure information.
- 11.3** Records shall be retained for the period specified by applicable document-retention requirements and shall be protected against unauthorized access, alteration or disclosure.

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 30.09.2026	
Doc. No: MTG/QP-IC/GLN 008	Doc. Name: MTG Guideline for Appeals, Incidents and Complaints Management (AICOM)		
Version No: 01	Issued Date: 30.09.2026	Copy Letter:	Page No: Page 27 of 31

12 Monitoring and Continuous Improvement

- 12.1.1** MTG shall establish and monitor appropriate indicators to evaluate the effectiveness and timeliness of the AICOM process. Monitoring may include, as applicable, the number and type of cases received, processing and resolution times, overdue cases, recurring issues, escalation rates, corrective actions and stakeholder feedback.
- 12.1.2** MTG shall periodically monitor and review information arising from the management of appeals, complaints and incidents to identify trends, recurring issues, systemic issues, risks and opportunities for improvement.
- 12.1.3** The outcomes of monitoring and evaluation shall, where appropriate, be used to:
1. identify and address risks and opportunities
 2. improve regulatory processes, controls and services
 3. determine and implement corrective or improvement actions
 4. identify the need for changes to relevant guidelines, SOPs or other QMS processes
 5. identify training and competency needs
 6. inform management review and continual improvement of the QMS.

13 Legal Basis

- Medicine Regulation R-64/2026 – Clause 47

14 References

- International Organization for Standardization (ISO). ISO 9001:2015 Quality management systems — Requirements, including Amendment 1:2024.

15 Annex

1. ANNEX 1: Information Required for Filing an Appeal
2. ANNEX 2: Communication Channels for AICOM

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 30.09.2026	
Doc. No: MTG/QP-IC/GLN 008	Doc. Name: MTG Guideline for Appeals, Incidents and Complaints Management (AICOM)		
Version No: 01	Issued Date: 30.09.2026	Copy Letter:	Page No: Page 28 of 31

ANNEX 1: Information Required for Filing an Appeal

No.	Section	Information Required	Details / Requirement
1	Details of the Regulatory Decision	MTG reference/service/application number	Provide the relevant reference number associated with the regulatory decision.
		Date of the decision	Provide the date on which the regulatory decision was made.
		MTG section/unit	Specify the MTG section or unit that issued the decision, where applicable.
		Applicable law, regulation or guideline	Specify the relevant law, regulation, guideline or other regulatory provision under which the decision was made, where known.
		Details of the decision	Clearly state and describe the regulatory decision being appealed.
2	Grounds for Appeal	Specific grounds for appeal	Clearly state the specific grounds on which the regulatory decision is being challenged.
		Relevant facts and circumstances	Provide the relevant facts, circumstances and information supporting the grounds for appeal.
3	Material Impact of the Decision	Impact of the decision	Describe how the regulatory decision directly and materially affects the appellant, including any relevant impact on an authorization, registration, licence,

			importation, business activity or other regulatory matter, as applicable.
4	Outcome Sought	Requested outcome	Clearly state the outcome or regulatory action requested from MTG.
5	Supporting Documents and Evidence	Copy of the regulatory decision	Provide a copy of the regulatory decision being appealed.
		Supporting evidence	Provide relevant documents or evidence supporting the grounds for appeal.
		Relevant correspondence	Provide relevant correspondence with MTG relating to the decision, where applicable.
		New or relevant information	Provide any new or relevant information or evidence that was not previously considered by MTG, where applicable.
		Other relevant documents	Provide any other documents considered relevant to the appeal.
6	Declaration	Declaration* (Mandatory)	I/We confirm that the information and documents submitted in support of this appeal are true and accurate to the best of my/our knowledge. I/We understand that submission of false, misleading or falsified information or evidence may result in regulatory action as per the applicable laws and regulations.

ANNEX 2: Communication Channels for AICOM

MFDA Admin	3014322
MTG Hotline	7200321
E-mail	mtg@mfda.gov.mv
By letter	Maldives Food and Drug Authority, Roashanee Building, 2nd Floor, Sosun Magu, Malé, Maldives, Addressed to Head of MFDA
Face-to-face	MTG, MFDA, Roashanee Building, 2nd Floor, Sosun Magu, Malé, Maldives

***Note: For appeals submissions are only accepted through email and letter.**

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 30.09.2026	
Doc. No: MTG/QP-IC/GLN 008	Doc. Name: MTG Guideline for Appeals, Incidents and Complaints Management (AICOM)		
Version No: 01	Issued Date: 30.09.2026	Copy Letter:	Page No: Page 31 of 31