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Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

Guideline on Management of Appeals, Incidents, and Complaints

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Guideline on Management of Appeals, Incidents, and Complaints is released under the authority of

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Director General
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Abbreviations

FCD: Food Control Division

MFDA: Maldives Food and Drug Authority

MTG: Medicine and Therapeutic Goods Division

NHL: National Health Laboratory

Definitions

Appeal: Is a stakeholder's request for MFDA to reconsider a decision or an agreement.

Complaint: It is an expression of dissatisfaction with the services provided, employee conduct, policies, and regulations.

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, or an alleged or evident deviation from established procedures and services. A complaint or incident does not include requests or queries regarding services provided.

Whistleblower: A person who has the knowledge of wrongdoings within an organization and reports or exposes it to an authority or to the public.

Content

1 Introduction

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

As a regulatory authority MFDA receives complaints regarding its services, regulated products and parties, and legal appeals regarding regulatory actions. Management of incidents reflects on the reputation and credibility of the organization and has been shown as a keystone of public confidence in regulatory authorities. The effective implementation of Appeals, Incidents, and Complaints (AICOM) management system would contribute 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, it is crucial to have a systematic approach to management of complaints, incidents, and appeals.

1.1 Purpose

The purpose of this guideline is to:

1. Harmonise the management of complaints and incidents within the divisions of MFDA.
2. To take prompt and appropriate regulatory actions to prevent negative impacts on public health.
3. Resolve individual complaints and identify areas for systemic and continuous improvement.

1.2 Scope

The scope of this guideline is defined by the subject of the complaints, incidents, and appeals as defined in the guideline, and is applicable to the Maldives Food and Drug Authority. It includes

submissions by external stakeholders and public as well as internal submissions by the staff.

1.3 Outcomes

The Appeals, Incidents, and Complaints (AICOM) management system is aimed at

1. Improving the standard of services provided,
2. Sustaining a quality management system
3. Building public trust and confidence
4. Increasing transparency and accountability

2 Management commitment

The top management of MFDA and all staff should commit to continuous improvement of the complaints, incidents, and appeals management system.

2.1 Responsibilities and accountability

It is the responsibility of division heads:

1. In collaboration with the Senior Management Committee (SMC) of MFDA, to develop and implement processes and procedures in compliance with this guideline
2. Ensure that all employees of the respective divisions are aware of and comply with the guideline and procedures necessary for Appeals, Incidents, and Complaints (AICOM) management
3. Facilitate trainings for employees to comply with this guideline and related procedures
4. Monitor and conduct audits of compliance with this guideline and related procedures
5. Ensure that appeals, incidents, and complaints are managed, investigated, and corrective actions, preventive actions, and regulatory actions are implemented in a timely and cost-effective manner, according to established laws and regulations
6. To follow all relevant laws, regulations, and rules in management of complaints, incidents and appeals, and freedom of information in attending to queries and briefings communication.

The Quality Manager of MFDA should conduct weekly progress checks/evaluation of appeals, incidents, and complaints to report to SMC and ensure timely management by divisions.

2.2 Distribution

A copy of this guideline and associated Standard Operating Procedures (SOPs) should be made available at all units of MFDA for all employees. All new staff should be trained to the procedures during induction.

2.3 Document review

The Guideline and associated SOPs should be reviewed every two (2) years for continuous improvement. The documents can be revised anytime based on systemic improvements identified.

2.4 Evaluation

Incident management procedures should be evaluated every two years to identify areas of strengths, weaknesses, opportunities, and threats, and further increase the efficiency of operations.

3 Management of Appeals, Incidents, and Complaints

3.1 General principles

As a general principle, internally documented and recorded information, and evidence brought to MFDA, such as products with quality defects, should be regarded as confidential information and should not be disseminated to the public, complainants, appellants, or stakeholders directly related to safety incidents. This is necessary to control documented information, prevent dissemination of unauthorized documents, information, and prevent creation of unnecessary alarm and rumors among public.

The identity of whistleblowers shall be confidential and shall not be disclosed.

Information on third parties cannot be disclosed without their consent.

However, regarding issues directly concerning an individual(s) or company, the individual(s) or company have the right to know internal procedures, observe the investigations carried out, etc. directly concerning them. Hence, to ensure transparency, such information can only be shown to those who are directly involved, upon visiting MFDA; taking pictures, soft copies or hard copies shall not be allowed under such circumstances.

When product defects are apparent, pictures shall only be released officially approved by the Technical Committee of MFDA/Divisions, only to help public identify the defected products.

Only information classified as public information can be disseminated to the public or interested parties who are not directly involved in the issue.

3.2 Defining appeals, incidents, and complaints

All employees should be aware of what constitutes an appeal, incident, or complaint.

A complaint or incident does not include requests or queries regarding services provided.

3.3 Structures for management

At MFDA level and division levels, relevant structures (eg: a task force or technical committees) for incident management and their role should be developed and approved by the Director General of MFDA and documented in the respective SOPs. The structures related to safety incidents of food and medicinal products should include a representative from the National Health Laboratory for any testing that maybe required.

In case an incident needs multi-sectorial coordination, focal points (coordinators) should be identified from relevant departments or organisations, communication channels and a contact list should be maintained (These focal points may be chosen from the Ministry of Health, Health Protection Agency, Dhamanaveshi, Regional and Atoll Health Services (RAHS), WHO-Maldives, Ministry of Fisheries and Agriculture, Ministry of Economic Development, etc.).

3.4 Continuous monitoring

Continuous monitoring of incidents is crucial for prompt actions to prevent adverse impacts on public health. There are various sources of information from which an incident notice may be received through continuous monitoring. These sources of information can be alerts from international competent authorities, and relevant organisations and networks on product safety (eg: WHO, INFOSAN, RASSF, etc), information from government organisations, consumers, media, and general public. Continuous monitoring of these sources for incidents in other countries, related to products imported to Maldives would enable pro-active incident management.

A list of trusted sources of information should be identified in relation to various types of

products. Respective divisions should have efficient procedures for collecting and filtering information from the trusted sources.

Whether the notice given is official or non-official, it is crucial that incidents are attended promptly.

3.5 Mechanisms for filing complaints, appeals, and notifying incidents

Mechanisms for filing complaints, appeals, and notifying incidents should be established as simple as possible and communicated to the public. Complaints can be filed and incidents notified face-to-face at the offices of MFDA, via telephone, e-mails, or in writing to the MFDA. Appeals filed to MFDA should be in writing or email. Details of these mechanisms are outlined in Annex 1. Any appeals, incidents, and complaints containing confidential information should be submitted in sealed envelopes to the MFDA counter.

3.6 Receiving complaints, incident notification, and evidence/samples

A complaint form should be developed, published on MFDA website, and a minimum number of ten copies retained at the reception and divisions of MFDA. This form has to be filled for complaints or incidents received through any mechanism for complaints and incidents. Any evidence or sample with regard to a complaint shall be forwarded to and received by the relevant division.

Documents submitted as appeals, incidents, and complaints to MFDA should be processed according to established administrative process. To maintain confidentiality and prevent disclosure, sealed documents addressed to the Director General of MFDA (DG, MFDA) shall not be opened except by the DG, MFDA or a staff assigned by the DG, MFDA.

Incidents and complaints received to the hotlines during unofficial hours should be noted by the receiver, and officially documented at the earliest when office resumes. These incidents and complaints should be reported and investigated similar to those received during office hours. Depending on the urgency and public health risk perceived, complaints and incidents should be addressed at the earliest and even during unofficial hours,

Once a complaint is received, or incident is notified, employees should log the complaint or incident on complaint forms. To ensure that the information collected can be used to investigate

or trace a problem, the complaint record should have description of the relevant product, service, or incident, and contact details of the complainant. The complaint forms should have similar format for general information and may be customized for products.

All appeals, incidents, and complaints should be submitted to MFDA main entry and routed to the Director General, MFDA and forwarded to divisions and Quality Manager, MFDA to take necessary actions. Complaints regarding food products and water should be directed to Food Control Division. Complaints regarding medicines, medical devices and other health products should be directed to Medicine and Therapeutic Goods division. Complaints regarding testing should be directed to National Health Laboratory. Complaints regarding administrative services should be directed to the Administration unit. Complaints regarding services, staff conduct, policies and regulations should be directed to the SMC for management and reported to administration section/Quality Manager of MFDA.

3.7 Management of Complaints and incidents

Once a complaint/incident has been received to MFDA and respective divisions, it should be assessed by SMC to determine jurisdictional issues, whether the problem should be referred to other departments and divisions of Ministry of Health, or other organisations, or higher levels of the Ministry of Health.

The complainants should be informed about the resolution or progress of the issue within three working days according to the established administrative process.

Complaints should be investigated and resolved within a maximum of two weeks, and necessary actions should be taken and recorded. Refer to 3.8 for guidance on management of safety incidents related to products regulated by MFDA. Division heads should ensure that open complaints cases are updated as its management proceeds. Once a case is closed, the complaint should be filed indicating the nature of the problem, actions taken or resolutions reached, recommendations, etc. If any changes to services, policies, regulations, etc are necessary, it should be brought according to established procedures to sustain a quality management system.

Quality Manager of MFDA shall do a weekly evaluation of complaints received and report to the Director General of MFDA, and SMC.

Each division of MFDA should have documented procedures for management of complaints.

3.8 Management of Safety incidents

For any safety incident, a preliminary investigation should be done and relevant information should be gathered. During preliminary investigation information can be collected regarding:

- Effects on consumer health (severity of effect ranging from no effect to hospitalization to death)
- Number of affected people
- Risk assessment (potential for causing harm based on scientific evidence)
- Public perception of risk
- Impact on the media (how long and widely the incident has been reported in local, regional and international media)
- Distribution chain (product identification, traceability, recall and withdrawal results)
- Extension or complexity (range of products and batches affected)
- Economic impact
- Reputation of the organization (extent to which the credibility of MFDA is at risk)
- Other information deemed as necessary

An information file of the safety incident should be maintained, and procedures for safety incident management should be documented.

3.8.1 Assessment and classification of safety incidents related to food, medicine, and other health products

Safety incidents regarding food, medicines, and other products regulated by MFDA can be assessed and classified based on the information collected during preliminary and follow-up investigations.

A matrix of these factors (Annex 2) can be used to classify incidents into three levels. Classification exercise should be reviewed and reclassified as necessary as and when the incident escalates or is controlled.

Classification of safety incidents aids in maintaining the consistency in responding to the incidents. Based on the levels of incidents, MFDA and divisions should take management actions and implement communication strategies appropriate to the level.

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3.8.2 Management strategies

Level I incidents often require routine management within MFDA.

Level II incidents may require product analysis, detention and seizure, product recalls, etc.

Level III incidents may require product detention, seizure, destruction, recalls, bans, additional investigations to identify potential products with similar issues, cooperation and coordination with other agencies, community outreach activities, etc.

Each division should establish and document a strategy for recall and destruction of products. Recall strategies should be risk-based and identify the circumstances for product recalls, depth of recalls, communication strategies, and methods for effectiveness checks. Each recall should be followed up with a report that may be combined with the incident report.

Guidelines for importers, exporters, distributors, etc, on how to handle a recall including disposal/destruction should be documented and shared with relevant stakeholders.

Further, a rapid alert procedure should be established using the fastest mode of communication to circulate alerts of utmost urgency and seriousness which cannot permit delays in transmission to alert appropriate levels of distribution and supply chain, relevant communities, islands, organisations, and other stakeholders. Communication modes include email, telephone, fax, SMS, etc. These systems should also include a confirmation and feedback mechanism between MFDA and relevant stakeholders to inform and report necessary information to MFDA.

3.8.3 Communication strategy

Communication strategy for various levels of incidents differs. The incident management committees shall decide the communication strategy for an incident based on the classification of the incident.

Incident Level I incidents do not require active communication with the public, but requires adherence to principles of transparency and freedom of information. These incidents pose minimal risk to organisation's credibility, public confidence, public health, and have lower chances of escalation of the incidents.

Incident Level II incidents require active communication strategies by the established incident

management structure. These strategies could include press releases, alerts, etc.

Incident Level III incident communication should start with the declaration of a level III critical incident. These incidents require frequent and regular communication to relevant organisations, the public, media, and consumers. Two-way communication channels should be established. These channels include:

- Active postings on website
- Official press release or press conferences
- Use of multiple media (radio, television, social media)
- Using hotlines

3.8.4 Communiqué content

The communiqué is any information officially issued in any format by MFDA. The communiqué should balance transparency and confidentiality. It should be aimed at creating awareness among consumers without creating alarm. In case of product safety incidents, the communiqué should provide sufficient information for consumers to make the right choices. This could include:

- Description of the risk, health effects on consumers, risk groups/population involved, etc
- Description of the product affected
- Measures taken and planned
- Directions to consumers if they possess, used, or consumed the product
- Contact information for exchange of information

3.8.5 Evaluation

For incidents of level II and level III, an evaluation should be undertaken to review and analyse the process of incident management. This evaluation should be reported with recommendations for any necessary improvements identified. The evaluation could be based on:

- Information file:
  - Accuracy of information sources
  - Timeliness of information
  - Sufficiency of information
  - Types of information sources

- Risk assessment, whether it was based on sufficient scientific sources, or similar cases

- Assessment of incident management
  - Accuracy of classification and usefulness
  - Timeliness and efficacy of information flow

3.9 Management of Appeals:

Appeals can be submitted at MFDA, MoH, Courts, legislative bodies, etc. However, this guideline defines how to handle appeals filed at MFDA and those appeals requested by the Minister of Health. Appeals requested by the Minister may be filed by and documented by MFDA indicating the nature of the appeal.

Appeals regarding MFDA's regulatory decisions that are filed at MFDA should be submitted in writing with signature of the appellant, to the MFDA counter or sent electronically to the designated email. Once an appeal has been filed, it will be directed to the relevant division of MFDA. The designated committee/responsible staff of the division shall assess the details of the appeal and the technical committee shall finalise a decision in consultation with the Division Head and Director General of MFDA.

Appeals can be managed through negotiation, mediation, arbitration, directed to MoH, etc. Each division shall document the procedure for handling appeals. Legal advice shall be sought as necessary from the legal unit of Ministry of Health.

The decision made and any further information that needs to be given to the appellant shall be given formally in writing. All relevant information regarding the appeals process should be documented and filed.

The Quality Manager of MFDA shall evaluate the appeals process weekly.

4 ANNEXES

4.1 Annex 1: Mechanisms for filing complaints, appeals, and notifying incidents

Mechanisms for filing complaints, appeals, and notifying incidents		
Complaints and Incidents	Telephone	3014322 (Maldives Food and Drug Authority reception number) 3014303 (Food Control Division) 3014361 (Food Control Division) hotline 3014316 (Medicine and Therapeutic Goods Division) hotline 3014346 (National Health Laboratory)
	Email	mfda.admin@health.gov.mv mtg@health.gov.mv nhl@health.gov.mv foodsafetydivision@health.gov.mv
	At MFDA offices	▪ Roashanee Building 2nd Floor
Appeals	E-mail	aicommfda@health.gov.mv
	At MFDA	Roashanee Building 2nd Floor, Sosun Magu

4.2 Annex 2: Classification Matrix

Item	Levels					
Health effect	No effect	No doctor appointment	Doctor appointment	Hospital appointment	Hospitalization	Death
Affected people	0	1-5	Few (5-10)	>10-50	>10 Vulnerable population	All consumers
Risk assessment	No risk	Minimal risk	Medium Risk Short term effects. Mitigation measure feasible	High Risk Long term potential effects	High Risk Long term confirm effects	High Risk Acute effect
Risk perception	No risk	Very low risk	Low risk	Medium risk	High risk	Very high risk
Media impact	No impact	Very Low Impact (1-2 days, only in specialized media, regional-national)	Low impact (>2 days, restricted media sources, national)	Medium impact (<1 week, several media sources, national)	High impact (1-2 week, all general sources, national- Asia region)	Very high impact (>2 week, all general media sources, wide world)
Distribution within consumer chain	No health effect. Distribution not relevant	All products identified, not in the market or withdrew	All Products identified, presence in the market, traced, withdrawal in process	All Products identified, presence in the market, incomplete traceability data, incomplete withdraw,	Products not completely identified, incomplete traceability data, incomplete withdraw,	Products not identified or widely distributed. Lack of traceability, no withdrawal
Extension/ complexity	Single product/ Single location/ single business operator	Single product/ multiple locations	Single batch/ multiple business operators	Multiple batches	Multiple products/ single batch	Multiple products/ multiple batches
Economic impact	None	Very low	Low	Medium	High	Very high

- ***Level I incidents***: when **all** the factors are **within the blue zone**
- ***Level II incidents***: When there are **no level III** incident factors, but factors escalated **out of level I blue zone**
- ***Level III incidents***: When **any factor reaches the red zone**

4.3 Annex 3: Process Diagrams

Figure 1: Complaints management process

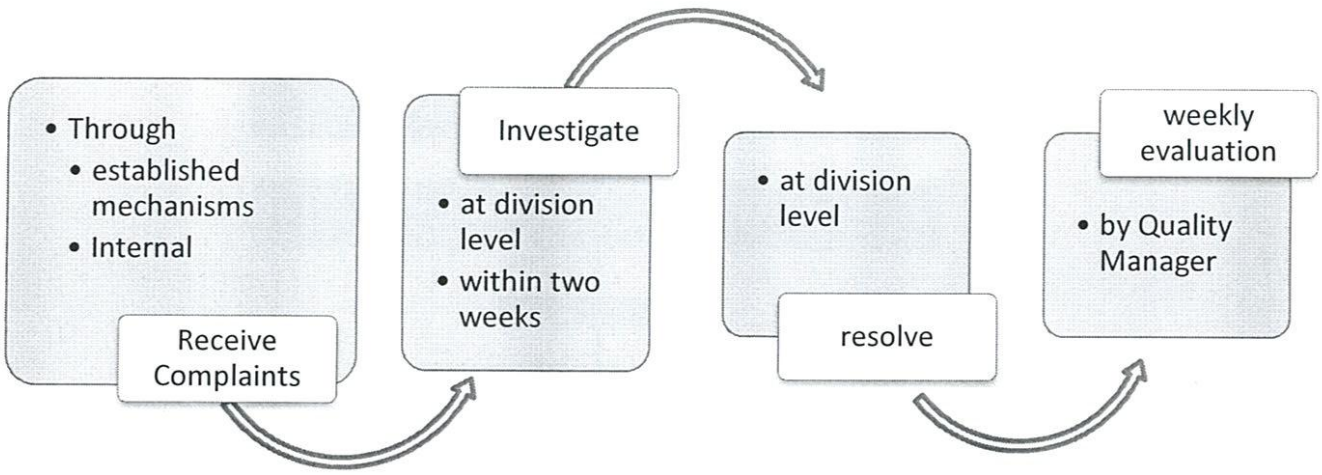

Figure 2: Appeals management process

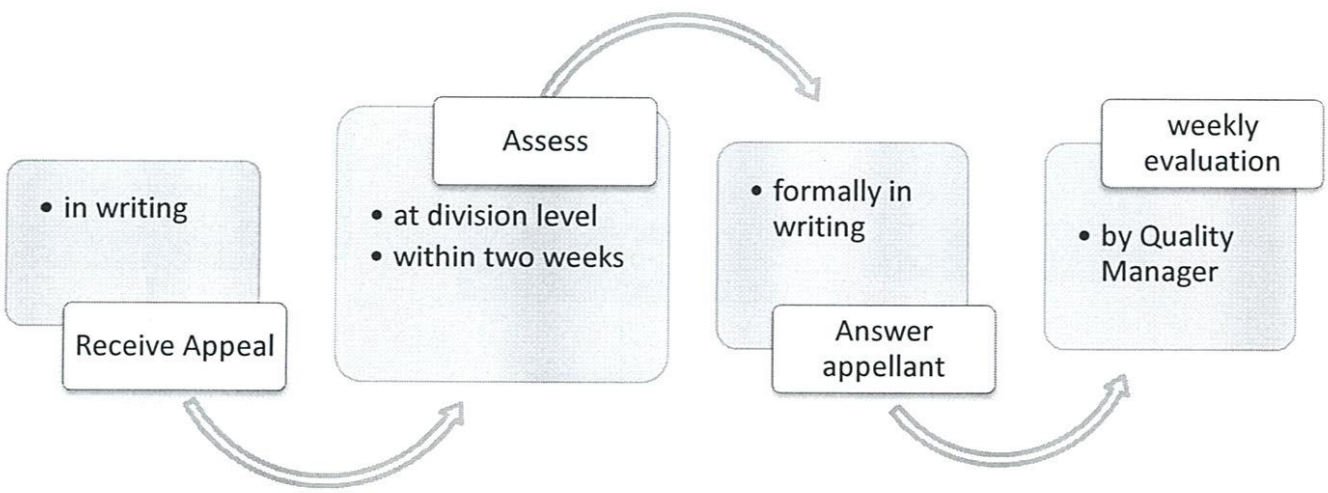

Figure 3: Incident management process