بسم الله الرحمن الرحيم

Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

Guideline on Crisis Management

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Male'
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CONTENTS

Guideline on Crisis Management

1 INTRODUCTION

A crisis is any unplanned event or a series of events that triggers a threat to the public health safety and has a potential to affect the normal operations for public health safety. Maldives Food and Drug Authority (MFDA) as the regulatory body endeavours to ensure that policies and procedures are in place in an event of a crisis related to a pharmaceutical product. Although the likelihood of an emergency is low, MFDA strives to assess the risks, and ensure appropriate actions to mitigate the risks are in place and can be implemented.

2 PURPOSE

This guideline is aimed at informing the public and stakeholders of the roles and responsibilities of stakeholders to prevent a crisis and actions to be taken during a crisis, and the system for crisis management of pharmaceuticals in the Maldives.

3 SCOPE

The procedure and responsibilities outlined in this guideline is applicable for crises related to pharmaceuticals, or other medicines (alternative medicines, herbal, traditional and complementary medicines, etc.), and biologics.

4 Guideline Content

4.1 What could trigger a pharmaceutical crisis?

4.1.1 Possible crises of pharmaceuticals can be triggered by:

- Safety issues related to a medicine which is deemed to be harmful to the health and well-being of the consumers,
- Unexpected or sudden nationwide shortage or stock-outs or non-availability of essential medicines or lifesaving medicines,
- Nationwide product recalls due to product contamination,

- Counterfeit products,
- Safety issues related to active ingredients/excipients/ raw materials/packaging, etc.,
- Any other condition that warrants a nationwide recall or withdrawal of a pharmaceutical product.

4.2 Who are the stakeholders?

- Patients
- Manufacturers
- Healthcare professionals: Doctors, nurses, community health workers, healers,
- Marketing Authorisation holders, parallel importers
- Medicines importers, distributors, and retailers
- Health facilities, hospitals, etc.
- Pharmacies, pharmacists, pharmacy assistants
- Ministry of Health
- Media

4.3 What is your role?

4.3.1 Marketing authorisation holders, pharmaceutical importers, distributors, and retailers

4.3.1.1 Before a crisis happens, it is vital to be prepared for one. Hence, all marketing authorisation holders, pharmaceutical importers, distributors, and retailers shall identify persons to be responsible in case of a pharmaceutical crisis. All entities shall ensure to inform MFDA of any changes to the contact persons or their contact numbers or emails.

4.3.1.2 Ensure all records are maintained in accordance with Good Distribution Practices.

4.3.1.3 Ensure to fulfil legal and other responsibilities if a recall is authorised (refer to Guideline for quality defects and product recall).

4.3.2 Ministry of Health and other health facilities:

4.3.2.1 Contact persons from the Ministry of Health and other health facilities shall be assigned and identified and this list will be maintained by MFDA. All health facilities shall ensure to inform MFDA of any changes to the contact persons or their contact numbers or emails.

4.3.2.2 Ensure that all the relevant actions are implemented at the health facility level.

4.3.2.3 If the crisis is due to a shortage of an essential medicine, then the Ministry of Health and MFDA shall work together with local and international agencies to resolve the crisis.

4.3.3 Patients

4.3.3.1 If a crisis has been determined, relevant Information and directions will be disseminated to the public through mass media as well as through official social media accounts of MFDA and Ministry of Health.

4.3.3.2 Patients and other consumers are required to follow the directions given by MFDA or the crisis management team.

4.3.4 Media

4.3.4.1 Media contact points are established between Public Relations Officers at Ministry of Health and Journalists. Media and MFDA shall be connected by the Ministry or as decided by the crisis management team. Information will be disseminated by the MFDA or relevant officials of Ministry of Health.

4.3.4.2 MFDA and the crisis management team will inform the public regarding the crisis and its management. This information and information related to the products and crisis shall be responsibly published for the public.

4.4 What are the preventive actions taken by MFDA?

4.4.1 MFDA is the responsible government agency for implementing, coordinating, overseeing, monitoring and evaluating the situation in order to avert a pharmaceutical crisis and/or prevent a crisis from worsening.

4.4.2 MFDA also monitors and inspects all medicine warehouses and pharmacies to ensure Good Distribution Practices are followed.

4.4.3 Undertake regular monitoring and post market surveillance activities to prevent or minimise the likelihood of crisis related to a pharmaceutical.

4.4.4 MFDA has established good relationships with other national regulatory authorities, and the World Health Organisation, which facilitates easy and quick access to information.

4.4.5 A crisis management plan (Annex I) is developed for effective and smooth operation of the tasks.

4.5 How is a crisis managed?

4.5.1 MFDA shall be informed of a possible risk to the safety of public health in relation to a pharmaceutical (refer to Guideline for Pharmacovigilance and ADR Reporting). A crisis will be declared by the MFDA in consultation with the National Pharmaceutical Board and Ministry of Health.

4.5.2 The crisis management team shall be led by the MFDA in consultation with the National Pharmaceutical Board and Ministry of Health.

4.5.3 The crisis management team is composed of the members of Technical Committee of MTG. Where it is deemed appropriate, the team can also include the Ministry of Health's Policy level, Health Protection Agency or any other relevant divisions of the ministry that are directly involved in the crisis or its management.

4.5.4 The crisis management team will:

a. properly assess the crisis,

b. share information with stakeholders

c. manage the crisis to mitigate the risks/ eliminate or minimise the risk to public health,

d. make necessary regulatory decisions as appropriate and inform the public or stakeholder.

e. communicate information accurately and honestly to relevant parties in a timely manner, and

f. close the crises or bring an end to the crises timely.

4.5.5 During a crisis, the crisis management team's main priority will be to resolve the crisis.

4.5.6 The crisis management team may seek assistance and cooperation from relevant government and non-governmental organisations as appropriate.

4.5.7 After a crisis, the crisis management team shall compile a report based on the complaint or trigger, actions and decisions taken with rationale, and the outcomes and effectiveness of action taken, and if any, recommendations or areas of improvement for the future.

5 Reference documents:

- Medicine Regulation 2014/R-46
- Guideline for Quality Defects and Product Recall
- Guideline for Pharmacovigilance and ADR reporting

Contact

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Annex I – Crisis Management Plan

Crisis Management Plan

Crisis:

Task:

Aim:

Detail of the plan:

#	Work	Minimum staff required	Services to be continued or discontinued	Reason for service continuation
1	Medicine import authorizations (pre authorizations, donation , etc)			
2	Controlled drug purchase authorizations and import license			
3	Port clearance			
4	Renewal of Pharmacy and medicine warehouse license			
5	Inspection of pharmacies and medicine warehouse			
6	New pharmacy and medicine warehouse registration			
7	Product registration and medicine approvals			