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بسم الله الرحمن الرحيم

Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

Guideline on Transparency and Dissemination of Information

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Republic of Maldives

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1 INTRODUCTION

Communication with stakeholders plays an important part of public health protection as the information conveyed can be related to product safety, quality, or its safe use. Maldives Food and Drug Authority (MFDA) strongly recognises the right of individuals and organisations to accurate information in respect to medications and therefore, takes a proactive, open, and transparent approach to communication.

Effective communication also helps to build public trust and transparency. Through effective communication, by communicating clear, concise and accurate and timely information with the stakeholders, MFDA aims to strengthen the credibility among stakeholders, and ensure the role of national pharmaceutical regulatory authority as the protector and regulator of pharmaceuticals is fulfilled.

2 PURPOSE

This guideline is aimed at informing the public and stakeholders of the established communication strategies for disseminating information to stakeholders.

3 SCOPE

The communication strategies outlined in this guideline is limited to information regarding medicines/pharmaceuticals which will be communicated by the Medicine and Therapeutic Goods (MTG) division of MFDA to the relevant stakeholders.

4 What information do we share?

4.1.1 The Medicine and Therapeutic Goods division of MFDA shares information on a number of issues related to pharmaceuticals. These topics include:

- Product safety and quality
- Product recalls and withdrawals
- Product information
- Changes to services, forms, etc.
- Rational use of medicines
- Awareness, e.g. Antibiotic resistance awareness
- Services

- Legal framework, legislations, standards, guidelines, etc.
- Policies and procedures
- Statistics, annual reports, monthly and quarterly reports, etc.
- Newsletter
- National programs, workshops, trainings, etc.

4.1.2 This information may at times be only relevant to specific groups of people in the community.

4.1.3 In addition to this, information specified in Act No. 1/2014 (Right to Information Act) will be disseminated to ensure transparency and accountability. However, third party information and Intellectual Property Rights are respected and strictly confidential.

5 Who do we communicate with?

5.1.1 There are several groups of stakeholders with regard to regulation of medicines. The following are some of the stakeholder groups identified by MTG/MFDA.

- Consumers/ general public
- Healthcare Professionals: Doctors, nurses, Community health workers
- Healthcare professionals: Pharmacists, Pharmacy Assistants, Assistant pharmacists
- Importers, distributors, retailers, manufacturers of Pharmaceuticals
- Government agencies (E.g. Ministry of Health, Ministry of Marine Resources, Fisheries and Agriculture)
- WHO
- Other regulators

6 What are the established Information sharing mechanisms?

6.1.1 In determining the most appropriate modes of communication MFDA/MTG recognizes the differences in stakeholder groups, timeliness, and urgency of the information. MTG currently utilizes several mechanisms for communication including the following.

- Newsletters
- Public Announcements/Government Gazette
- Press briefings
- General Media/TV/Radio
- Email
- Phone calls
- Surveys
- Trainings

- Awareness sessions
- Workshops
- Meetings (individually and in groups)
- Website
- Social Media platforms
- Stakeholder consultations

7 Target groups for information sharing

MFDA identifies the following target groups and utilizes the below listed modes of communication to disseminate information.

Target groups/stakeholders	Modes of Communication
Public	▪ Newsletters ▪ Public Announcements /Government Gazette ▪ Press briefings ▪ General Media/TV/Radio ▪ Website ▪ Social Media platforms
Health Professionals (Doctors, nurses, community health workers)	▪ Email ▪ Surveys
Pharmacists/Assistants	▪ Email ▪ Surveys ▪ Trainings ▪ Awareness sessions ▪ Workshops ▪ Website ▪ Social Media platforms ▪ Meetings (individually and in groups)
Importers, distributors, retailers, manufacturers of Pharmaceuticals	▪ Stakeholder consultations ▪ Trainings ▪ Awareness sessions ▪ Workshops ▪ Website ▪ Social Media platforms ▪ Meetings (individually and in groups)
Ministry of Health and other government agencies	▪ Meetings (individually and in groups)

Non-government agencies	▪ Website ▪ Social Media platforms ▪ Meetings (individually and in groups)
WHO	▪ Stakeholder consultations ▪ Meetings (individually and in groups)

8 Stakeholder consultation

8.1.1 As a proactive mode of communication and participative mode of governance, MFDA/MTG seeks stakeholder input for finalizing policies, regulations, laws, guidelines, except internal procedures. MTG will communicate the draft documents for feedback via email. The stakeholders will be given two weeks for commenting, and their comments and feedback will be analyzed by MTG. In return, MTG will inform whether their input is accepted or rejected and provide justifications or reasons for rejections.

9 Reference documents:

- Medicine Regulation 2014/R-46
- Right to Information Act (Act No: 1/2014)

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