بسم الله الرحمن الرحيم

Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

Guideline for Rational Use of Controlled Drugs

Guideline for Rational Use of Controlled Drugs is released under the authority of

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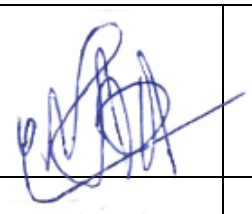
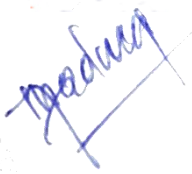
Approved by: **Ms.Aishath Mohamed** **Deputy Director General, Pharmaceuticals** **Maldives Food and Drug Authority**		13.02.2020
Authorised by: **Ms.Thooma Adam** **Deputy Director General, Laboratory Services** **Maldives Food and Drug Authority**		13.02.2020

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Guideline for Rational Use of Controlled Drugs

1 Introduction

In the Republic of Maldives, controlled drugs are imported and distributed by the State Trading Organization to Grade I pharmacies with prior authorization from the Ministry of Health. These drugs are dispensed to patients with a medical prescription.

Despite all the collaborative efforts made by the government and non-government organizations, available statistics indicates that drug abuse is becoming a growing problem in the Maldives and needs to be addressed urgently. With reference to the Health Master Plan (1996-2005), the issue of substance abuse, including misuse of prescription drugs (narcotics and psychotropics) will be dealt with through and prolonged approach, demand reduction through public awareness campaigns, establishment of a drug rehabilitation center and supply reduction through strict enforcement of law.

2 Purpose

The main objective of introducing this guideline is to advocate for the rational use of drugs with high misuse and abuse potential and thereby facilitate good prescribing and dispensing practice, better handling and management of controlled drugs in health institutes and pharmacies in public and private sectors.

Strategies have been recommended in order to accomplish this task and meet the ultimate goal, improvement of quality of health care through effective and safe use of pharmaceuticals, in this case, controlled drugs. Psychotropic and narcotic drugs, here in after called controlled drugs currently included in the list of drugs approved for the Republic of Maldives will be dealt in this guideline.

3 Scope

This document provides guidance on the procedures for controlled drugs including import, port clearance, storing, sale, use and reporting at pharmacies and health service providers, good prescribing system, sending of the quarterly and annual report to International Narcotics Control

Board (INCB), dispose, displacement, taking of action, reporting to Maldives Food and Drug Authority and monitoring of the said drugs. It is a practical guideline, a standard prescription format as well as providing training for physicians, pharmacists and health workers in general is essential to promote the rational use of controlled drugs all over the country.

4 Guideline Content

4.1 Procurement and Supply of Controlled Drugs

4.1.1 Drugs classified under Schedule I, II, III, and IV of the 1961 single convention on narcotics and 1971 convention on psychotropic substances and its addendum are under international control.

4.1.2 The 1961 single convention on narcotics and 1971 convention on psychotropic substances and its addendum emphasize on restriction of such substances to legitimate purposes and prevent and combat abuse of such substances and the illicit traffic to which it gives rise.

4.1.3 Physicians, pharmacists and all concerned health care personnel should therefore play active roles in rational use of controlled drugs by facilitating good prescribing, good dispensing practice and ensuring security of controlled drugs that comply with international conventions as recommended by INCB, WHO and national regulations.

4.1.4 The Ministry of Health through the State Trading organization (STO) has been doing an enormous amount of work to streamline procurement and make available generally recognized quality, effective and safe drugs including controlled drugs required for medical and scientific purposes.

4.2 Import Procedures

4.2.1 All controlled drugs are imported only through STO. In consultation with STO and Narcotic Control Board, the Ministry of Health prepares annual national requirements of controlled drugs and submits to INCB. Based on these, INCB notifies the Ministry of Health and subsequently authorization is given to import controlled drugs by STO.

4.3 Security of Controlled Drugs

4.3.1 **Minimum Storage Facilities**

4.3.1.1 Every establishment handling controlled drugs should ensure safe custody of the stocked drugs in the premises such that they are not easily accessible to persons likely to steal or divert them. The security provided should be sufficient to protect the controlled drugs and the personnel working in the establishment.

4.3.1.2 In pharmacies, hospitals, clinics and health centers metal safes or cabinets with suitable locks should be placed such that they are not readily accessible to casual visitors.

4.3.1.3 Necessary security measures should also be considered during international and local transport

4.3.2 **Record Keeping Procedures**

4.3.2.1 Accurate records should be maintained for controlled drugs purchased, distributed, prescribed and dispensed. They should be made available for inspection by an authorized officer of MFDA.

4.3.2.2 All establishments handling controlled drugs should ensure that the stock records are checked against actual stock on a regular basis.

4.3.2.3 All blue prescriptions must be collected and maintained for quarterly submission to MFDA.

4.3.2.4 All records and files related to controlled drugs such as purchase invoices, prescriptions, registers; disposal certificates should be kept at least for two years.

4.3.3 **Disposal Procedure**

4.3.3.1 The person assigned as the in-charge of the institution is responsible to inform the Ministry of Health whenever controlled drug (s) expire or are or withheld from use for any reason.

4.3.3.2 When the pharmacy ceases to operate as a business or closes, all records, files and stock of drugs for disposal or transfer to a third party shall be made in accordance with the directions of the Ministry of Health.

4.3.3.3 Pharmacies and health institutes in the islands should send list of expired controlled drugs to the nearby regional hospital or health center.

4.3.3.4 The regional hospital or health center will assign its staff (CHW) to attend to the proper disposal of expired controlled drugs. The staff must ensure that the quantities disposed off tallies with the list received from the respective pharmacy or institute.

4.3.3.5 After completing disposal, copy of list of expired drugs will be retained at the regional hospital or health center and a disposal certificate signed by the head of the institution will be issued.

4.3.3.6 Expired controlled drugs at regional hospital level should be reported to the Ministry of Health, Male' and will be disposed as per the instruction from the pharmaceutical section.

4.3.3.7 The standard reporting form (Medicine Disposal Form (MTG/RE-DF/Fo 0007)) should be used at all times (Annex 1).

4.3.4 **Reporting System**

4.3.4.1 On a form provided by the Ministry of Health (attachment form 2), the person in-charge of the health institution or pharmacy shall submit an inventory of controlled drugs in his/her possession to the Ministry of Health, Male' once every three-month.

4.3.4.2 While carrying out a physical check of stock, if any stock discrepancy is observed, the source of such discrepancy should be immediately investigated and reported to the Ministry of Health.

4.3.4.3 In the event that drugs are stolen, the case has to be reported immediately to the police and to the Atoll, island office and the Ministry of Health. Necessary legal documents have to be submitted to MTG for verification.

4.3.4.4 STO shall prepare report every three months and submit to the Ministry of Health on import, distribution and consumption of controlled drugs at its custody as per INCB and national standard forms.

4.4 Rational Use of Controlled Drugs

4.4.1 Generally rational drug use is judicious, appropriate and safe use of medicines. Rational drug use includes prescribing suitable drugs for patient with respect to the diagnosis, making them available at all times at affordable prices, ensuring their safety and quality, dispensing them correctly, taking them in the right doses and right interval for the right period of time.

4.4.2 At this point in time, drugs with high misuse and abuse potential i.e. controlled drugs are considered and given more emphasis. To curtail the major problems associated with the misuse, abuse of permitted psychotropic and narcotic drugs, inter-disciplinary collaboration involving physicians, pharmacists and other health professionals is of paramount importance.

4.4.3 As mentioned earlier in this document, the following strategies have been recommended to promote the rational use of controlled drugs and thereby minimize their misuse and abuse.

4.5 Good Prescribing Practice

4.5.1 Physicians play a decisive role:

- In ensuring that safe and cost-effective medicines are prescribed to patients,
- In providing sufficient information and educating patients and
- In improving the quality of patient care.

4.5.2 **Approved Drugs List**

4.5.2.1 Drugs required to treat the most prevalent diseases are included in the approved drugs list. On the basis of constant review of the approved drugs list and existing regulation governing pharmaceuticals, the Ministry of Health may propose addition or deletion of products to and from this list as necessary.

4.5.2.2 Single ingredient preparations containing controlled drugs are recommended to be on the list of approved drugs.

4.5.2.3 To ensure quality and safety, import of controlled drugs by various agents from undesignated sources is not permitted and sole import by the State Trading Organization from reputable manufacturers or their accredited agents. All manufacturers must comply with Standards for Good Manufacturing Practices (WHO) and all suppliers shall adhere to Standards for Good Distribution Practices (WHO).

4.5.3 Standard Prescription Format

4.5.3.1 A prescription is a written instruction for the pharmacist to supply a specified drug(s) to a patient. Apart from this, a prescription can be a source of information and a legal document when an issue arises and needs to be justified.

4.5.3.2 Therefore, necessary care should be taken while writing prescriptions. A standard prescription format is developed with a guideline to facilitate good prescribing practice and to minimize the occurrence of forged prescriptions and misuse of drugs for potential abuse.

4.5.3.3 The standard prescription format is printed in two copies, blue and white colored, while the blue color (original) should be given to the patient, the white copy should remain with the pad retained by the prescriber.

4.5.4 Principal Requirements for Prescriptions

4.5.4.1 The physician has to make sure that:

- Prescriptions ordering controlled drugs are signed and dated by the prescriber, and the prescriber's address is specified
- The written prescription order is precise and distinctly legible to enhance effective communication between the physician and the pharmacist.
- The prescription is stated in prescriber’s own handwriting in ink, or so as to make it permanent.

4.5.4.2 A Prescription Ordering Controlled Drugs Shall Bear:

a. serial number and date

b. name, age, sex, hospital / health center / clinic registration number, address of the patient and diagnosis
c. generic names of prescribed drugs (writing brand names in parenthesis is optional)
d. dosage form and strength of the preparation
e. total quantity of prescribed drug in words and figures in order to discourage alterations in written prescription orders
f. the dose, only official abbreviations should be used.
g. the interval between doses (frequency of administration)
h. duration of treatment
i. validity period of ***maximum one week*** from the date stated thereon
j. Doctor's name, registration number, signature and official seal of the institution.

4.5.5 **Responsibilities of The Prescriber**

4.5.5.1 The authorized prescriber for controlled drugs is a **physician registered** by the Ministry of Health to practice medicine in the Republic of Maldives.

4.5.5.2 The physician shall write a separate prescription in duplicate for controlled drugs on each occasion and issue only the original to the patient.

4.5.5.3 The physician has to sign and receive prescription pads. The physician is responsible to keep used copies of prescriptions and make a request to the hospital / health center / clinic administration unit for supply of new prescription pads. All used pads must be handed to the administration.

4.5.5.4 The physician shall neither introduce controlled drugs to patients without sound medical reasons nor prescribe routinely and indiscriminately.

4.5.5.5 Controlled drugs should be prescribed to patients with the **possible smallest effective dose** to minimize tolerance and dependence.

4.5.5.6 The physician should be vigilant not to be used as an unintentional source of supply for controlled drugs for any potential abuser.

4.5.5.7 The physician shall not sign prescription in advance and leave blank prescriptions unattended; should rather keep them in a safe place under locked drawer when not in use.

4.5.5.8 Missing prescription pads with specific serial numbers should be reported to the administration unit of the establishment and to the Ministry of Health immediately. Such events must be investigated thoroughly.

4.5.5.9 The physician shall provide complete information to the patient about the drug he /she is prescribing including cautions, warnings and clear direction for use.

4.5.5.10 The physician shall assist the pharmacist who calls to verify information about a written prescription order.

4.5.6 **Prescribing During Emergencies**

4.5.6.1 Prescriptions containing controlled drugs from other prescribers are not accepted except for medicines required for emergency situations such as epilepsy.

4.5.6.2 Except for treating disease conditions, prescribing controlled drugs greater than 48 hours for known cases of drug addicts should only be done by a consultant psychiatrist or in his / her absence the prescribing physician should get prior authorization from the Ministry of Health.

4.5.7 **Referral System**

4.5.7.1 Known cases of patients under controlled drug therapy can be followed up at primary and secondary level of health care, however, the examining physician should refill the prescription or be consulted through appropriate means of communication as regards to previous medication history of the patient.

4.5.7.2 Junior prescribers are allowed to prescribe a limited number of drugs in emergency situations only for 24 - 48 hours use, any extension requires the authorization of a physician or a specialist if applicable, if not the patient should be referred to the nearby health center or hospital.

4.6 Good Dispensing Practice and Management

4.6.1 **License Requirements**

4.6.1.1 Distribution of controlled drugs should be undertaken from licensed premises. In order to handle and dispense controlled drugs, the personnel should also be licensed by the Ministry of Health and registered as the in-charge for the establishment.

4.6.2 **Good Dispensing Practice**

4.6.2.1 Good dispensing practice should ensure that an effective form of the correct drug is delivered to the right patient, in the prescribed quantity, with appropriate information, clear instructions and in proper packaging that maintains the potency of the drug.

4.6.2.2 The pharmacist plays an important role to ensure that all these activities are properly done.

4.6.3 **Responsibilities of the Pharmacist**

4.6.3.1 The Pharmacist shall keep all controlled drugs in a locked cabinet under his/her own direct supervision and control.

4.6.3.2 The Pharmacist must check validity **of the prescription and identity of the patient** before dispensing

4.6.3.3 The Pharmacist shall consult the prescribing doctor if there is any doubt about the prescription or if pharmacist suspects any fraudulent activity.

4.6.3.4 The Pharmacist shall only dispense controlled drugs if the prescription provided by the physician is complete and valid.

4.6.3.5 Dispensing part of a controlled drug prescription is not permitted.

4.6.3.6 The Pharmacist shall properly label and mark containers to avoid undue intermixing that may cause harm to the patient.

4.6.3.7 The Pharmacist shall provide complete information to the patient about the prescribed drug he /she is dispensing including cautions, warnings and clear direction for use.

4.6.3.8 Under the current regulation, the pharmacist is not permitted either to refill or substitute a generically equivalent controlled drug unless instructed by the physician.

4.6.3.9 The Pharmacist shall retain prescriptions containing controlled drugs after dispensing the medication.

4.6.3.10 The Pharmacist shall keep retained prescriptions containing controlled drugs in a separate file and submit these prescriptions for the Ministry of Health

4.6.4 **Handling of Controlled Drugs in the Absence of a Pharmacist**

4.6.4.1 In institutions where there is no pharmacist / pharmacy assistant, only drugs required to manage emergencies will be kept in stock under the direct supervision of the physician or if not available, the in-charge of the health institute shall be responsible to keep them in a locked cabinet with appropriate records. However, special care should be exercised in the selection of staff that would handle controlled drugs in any establishment.

4.7 Educating The Patient and the Public

4.7.1 In general, the physician, the pharmacist and health workers have a responsibility to educate the patient and the public regarding the risk and benefits of medicines prescribed and dispensed to them.

4.7.2 Effective education requires a commitment to, and an understanding of the need for, improved communication between the health care provider and the patient.

4.7.3 At large, consumers will be provided with basic health education through appropriate media to understand better what controlled drugs are and how they act in the body, their risks and benefits, and their impact on the community development. In order to reduce the demand for controlled drugs, proper counseling and more clinical psychology and social services shall be sought.

4.8 Monitoring System for Controlled Drugs

4.8.1 Distributing and Supply of Prescriptions

4.8.1.1 Standard, model self-carbon, double prescription pads with codes and serial numbers have been printed by the Ministry of Health through WHO assistance.

4.8.1.2 A limited number of these prescriptions shall be initially issued to all authorized public and private health institutions free of charge. The Ministry of Health will print similar type of prescription pads and issue to health institutions with minimal charges.

4.8.1.3 The health institute in public or private sector shall send a written request including their estimated three months' requirement for controlled drugs prescription in advance and collect it when ready from the Ministry of Health.

4.8.1.4 A register shall be maintained at central level stating the serial number and quantities of controlled drug prescriptions distributed to each facility.

4.8.1.5 The cost of printing of these prescriptions shall be recovered from charges collected from clinics, health center and hospital both in public and private sectors.

4.8.2 Monitoring Implementation

4.8.2.1 On a form provided by the Ministry of Health, the person in-charge of the health institution or pharmacy shall submit an inventory of controlled drugs in his/her possession to the Ministry of Health, Male' once every three-months along with retained copies of prescriptions.

4.8.2.2 A prescription audit and feedback system will be developed to monitor and improve the drug prescribing practice.

4.8.2.3 The Ministry of Health in collaboration with other concerned government and non-government organizations will strictly enforce pertinent rules and regulations and promote the rational use of controlled drugs.

4.8.2.4 Strict action in accordance to current regulations will be taken against individuals or institutions that fail to comply with the set rules for the import, distribution and sale of controlled drugs in Maldives.

5 Annex

- Annex I – Medicine Disposal Form (MTG/RE-DF/Fo 0007)

بسم الله الرحمن الرحيم

MEDICINE DISPOSAL FORM

Maldives Food and Drug Authority
Ministry Of Health
Male, Maldives

Form No: MTG/RE-DF/Fo 0007 / ---------- / ----------

Name of Applicant: .....
Name of Pharmacist in Charge: .....

Date: .....
Contact No:.....

Brand Name	Generic Name	Strength	Dosage form	Manufacturer	Country of Origin	Batch No.	Mf. Date	Ex. Date	Unit	Quantity	Unit. Price	Total Price	Remarks
										Total Price:			

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Authorized by: Director General, MFDA		
Rec. No: DF/Fo 0007-MTG/RE	Rec. Name: **Medicine Disposal form**			
Issue No: 03	Issue Date: 21.2.2019	Prepared by: Director, Pharmaceuticals	Approved by: Deputy Director General, Pharmaceuticals	
Revision No:01	Revised Date: 5.12.2019	Verified by: Technical Committee of MTG		Page No: Page 1 of 2

To be filled by Applicant :	
Name & Sign	
Designation	
Date and Seal	

For office use only

Received by:

Name: **Designation:** **Signature:** **Date:**

The above drugs were found to be unusable anymore, after being duly checked and supervised by our inspectors. We hereby certify that these drugs have been safely disposed on __ /__ /_____

Name and Signature of Pharmaceutical Officers / Public Health Officers **Name:** _____ _____ **Signature:**

Division Head: **Name** _____ **Signature** _____

Note: Please complete two copies of this form for the pharmaceutical products whose shelf life has expired, is banned or damaged and send it to the Regulation Section of the Maldives Food and Drug Authority or to the Regional/ Atoll Hospitals or Health Centres in order to get certified for proper disposal

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Authorized by: Director General, MFDA		
Rec. No: DF/Fo 0007-MTG/RE	Rec. Name: **Medicine Disposal form**			
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