بسم الله الرحمن الرحيم

Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

Guideline on Controlled Drug Monitoring and Evaluation

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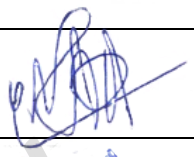
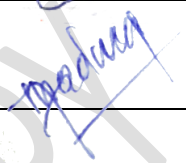
Approved By	Aishath Mohamed, Deputy Director General, Pharmaceuticals	
Authorized by	Thooma Adam, Deputy Director General, Laboratory Services (Acting Head of MFDA)	

Summary of Changes

Version No.	Issued Date	Section/Clause	Summary of Change	Changes Made by
1	23.07.2026	-	Creation of the document	Aminath Jihan, Medicine Regulatory Officer

ABBREVIATIONS

MTG – Medicine and Therapeutic Goods Division, MFDA

MoH – Ministry of Health

QARD – Quality Assurance Regulation Division, MoH

MoFAOR – Ministry of Fisheries, Agriculture and Ocean Resources

WHO – World Health Organization

INCB – International Narcotics Control Board

MPS – Maldives Police Service

MCS – Maldives Customs Service

ADL – Approved Drug List

NEML – National Essential Medicines List

SOP – Standard Operating Procedure

STG – Standard Treatment Guideline

DEFINITIONS

Term	Definition
Controlled Drugs	Substances classified as narcotic or psychotropic under national legislation and international conventions applicable in the Maldives.
Narcotic Drugs	Medicines used to relieve severe pain or treat certain medical conditions that have a high potential for dependence and misuse.
Psychotropic Drugs	Medicines used to treat certain mental, neurological, or behavioral conditions that affect the way the brain works and have the potential for dependence and misuse.
International Narcotics Control Board (INCB)	An independent body established under the United Nations drug control conventions that monitors compliance and manages the international estimates and quota system for narcotic drugs and psychotropic substances.
Nationally Controlled Drugs	Controlled drugs regulated under national laws and regulations. due to their potential for misuse, dependence, or abuse.
Internationally controlled drugs	Narcotic and psychotropic substances regulated under the United Nations drug control conventions to prevent misuse while ensuring availability for medical and scientific purposes.
Control Drug Annual Quota	The maximum quantity of controlled drugs allowed to be imported into the Maldives each year based on medical and scientific needs and approved through the quota system managed by the International Narcotics Control Board (INCB).
Controlled Drug Import and Sale License	License issued to registered importers to authorize the import and sale of controlled drugs in the Maldives.

Controlled Drug Storage Permit	Permit issued by the MFDA authorizing a facility to store controlled medicines in a registered health facility, pharmacy, or other authorized facility.
Import certificate	A certificate issued by the MFDA authorizing the import of a specific consignment of controlled drugs into the Maldives.
Export Certificate	Official authorization issued by the exporting country permitting the export of controlled drugs.
Dhirithi Portal	The MFDA online platform used for the electronic submission, processing, and management of applications and related services.
Medicine Importer	A business entity holding a valid MFDA medicine import permit.
Authorized Premises	A health facility, pharmacy, veterinary facility, rehabilitation treatment center, or any other organization that holds a valid controlled drug storage permit issued by MFDA.
Pharmaceutical Port Control Unit	An MFDA unit stationed at the borders responsible for inspecting and the clearance of pharmaceutical imports.
Responsible Personnel	A person formally appointed by a premises and authorized to perform activities related to controlled drugs, including receipt, storage, dispensing, administration, transportation, and management.
Controlled Drug Prescription	A prescription printed on blue-coloured paper in the MFDA-approved prescription format, designated exclusively for prescribing controlled drugs by authorized prescribers.
Controlled Drug Register	A paper-based or electronic register maintained by a premises to record controlled drug stock movements, daily stock counts, and stock reconciliation, ensuring accurate inventory management and compliance.

Prescription Data Sheet	A standardized record sheet used to document the details of an individual controlled drug prescription, including patient information, prescribed medication, dispensing details, and administration records where applicable.
Stock Reconciliation	The process of comparing the physical quantity of controlled drugs with recorded inventory balances to identify and investigate discrepancies.
Stock Status Report	A standardized report maintained by a premises to document-controlled drug stock movements and usage during a specified reporting period to support monitoring of stock levels, consumption trends, and supply planning.
Nil Report	A report submitted by an authorized premises confirming that no controlled drug transactions or activities occurred during the reporting period.
Drug Rehabilitation Treatment Service Provider	Any authorized organization responsible for managing opioid dependence and treatment in the Maldives, including opioid-substitution therapy, rehabilitation, patient monitoring, and programs that prevent misuse and support safe, regulated recovery.
Prescription Audit	A systematic review of controlled drug prescriptions to assess compliance with regulatory and prescribing requirements.
Incident	Any event involving loss, theft, damage, diversion, medication error, security breach, discrepancy, or suspected misuse involving controlled drugs.
Diversion	The unauthorized movement of controlled drugs outside approved channels.
Chain of Custody	A documentation that ensures the traceability and accountability of controlled drugs throughout handling.

Access-controlled	A restricted area designated for the secure storage and management of controlled drugs.

CONTENTS

1 Introduction

The Maldives Food and Drug Authority (MFDA), as the national regulatory authority, oversees all activities involving controlled drugs, including importation, storage, distribution, prescribing, dispensing, blue-prescription management, and disposal. Controlled drugs are classified under national legislation and international conventions into narcotic and psychotropic substances based on their medical use, dependence potential, and risk of misuse.

MFDA regulates every stage of handling-controlled drugs to ensure compliance with national laws, MFDA directives, and international obligations. As part of these obligations, the International Narcotics Control Board (INCB) assigns annual national quotas for narcotic and psychotropic substances, based on consumption and requirement data submitted by the National Regulatory Authority. This quota system ensures the availability of controlled drugs for legitimate medical and scientific use while reducing the risk of diversion and misuse.

This guideline sets the mandatory standards, responsibilities, and operational requirements for all stakeholders in the controlled-drug supply chain. It establishes the regulatory controls necessary to ensure that controlled drugs are imported, stored, managed, and used in a manner that safeguards public health, protects patient safety, and prevents unauthorized access.

2 Purpose

This guideline provides the regulatory framework for the safe, compliant, and controlled management of narcotic and psychotropic substances in the Maldives. It sets mandatory requirements to ensure consistent national compliance with international drug-control treaties and to safeguard public health through strong oversight, accountability, and risk-mitigation measures.

Specifically, this guideline:

- Establishes the national framework for management of narcotic and psychotropic substances.
- Ensures alignment with international drug-control conventions.
- Strengthens oversight, accountability, and risk-management practices.

3 Scope

This guideline applies to all entities and stakeholders involved in the controlled-drug regulatory chain in the Maldives, including:

- Registered controlled drug importers authorized by the MFDA.
- Registered pharmacies holding an MFDA controlled drug storage permit.
- Healthcare facilities, including hospitals, health centers, and private clinics, holding an MFDA controlled drug storage permit.
- Veterinary service providers authorized to store and manage controlled drugs.
- Drug rehabilitation treatment service providers authorized to manage controlled drugs.
- Authorized prescribers and licensed healthcare professionals involved in the prescribing, dispensing, administration, or management of controlled drugs.

4 Responsibility and Accountability

Medicine Regulatory Officer of Monitoring and Surveillance Unit (MTG)	MFDA is authority responsible for coordinating and overseeing all control drug related activities. Key responsibilities include: ✓ *Reviewing and verifying applications for Controlled Drug Import and Sale License, import certificates and storage permits* ✓ *Monitoring the importation, prescribing, dispensing, and consumption of controlled drugs.* ✓ *Maintaining clear communication with applicants and relevant stakeholders.* ✓ *Assessing controlled-drug reports and evaluating prescriptions to ensure compliance with regulatory requirements.* ✓ *Coordinating inspections or investigations related to controlled drugs.* ✓ *Initiating enforcement actions such as warnings, or penalties when required.* ✓ *Ensuring adherence to national legislation and international conventions governing narcotic and psychotropic substances.*

Director, Pharmaceuticals (Enforcement Section)	Responsible for ensuring regulatory compliance and enforcement in drug safety and quality, including: ✓ *Supervising controlled-drug oversight activities and issuing recommendations or approvals for permits.* ✓ *Approving controlled-drug, Controlled Drug Import and Sale License, storage permits and verifying controlled-drug import certificates.* ✓ *Ensuring adherence to national legislation and international conventions governing narcotic and psychotropic substances.* ✓ *Making regulatory decisions related to controlled drugs.* ✓ *Directing compliance monitoring, enforcement actions, for implementation of necessary corrective measures.*
Deputy Director General (MTG), Director General (MFDA)	A senior official providing strategic leadership and oversight of national controlled-drug regulation, including: ✓ *Authorizing import certificates and related permits for controlled drugs.* ✓ *Providing strategic direction for the national controlled-drug management and monitoring.* ✓ *Overseeing the monitoring and evaluation of controlled-drug surveillance systems.* ✓ *Coordinating with national and international partners to strengthen regulatory control, compliance, and enforcement activities.*
Medicine Regulatory Officer of Port Control Unit (MTG)	Responsible for clearing all controlled-drug shipments at ports, ensuring compliance with national and international regulations. Key duties include: ✓ *Conduct 100% inspection and verification of all controlled-drug shipments.* ✓ *Ensure shipment compliance by confirming that required security measures are in place.* ✓ *Update the shared data sheet with controlled-drug release details within 72 hours of clearance.*

	✓ *Ensure the signed release sheet is shared with the Controlled Drug Unit.*
Importers and Warehouse Personnel	Responsible for the safe and compliant handling of controlled drugs throughout storage and transport. Key responsibilities include: ✓ *Ensure secure transport and proper storage of controlled drugs to prevent loss, damage, or unauthorized access.* ✓ *Maintain complete, accurate records and reports of all inventory movements and transactions.* ✓ *Comply with MFDA inspections and reporting requirements to support regulatory oversight and accountability.* ✓ *Report any suspicious requests, irregularities, or potential misuse to relevant authorities.* ✓ *Update controlled drug distribution data in the shared sheets provided by MTG within forty-eight (48) hours of each sale or transaction to ensure continuous, near real-time monitoring of controlled drug distribution.* ✓ *Provide a dedicated official email address to the MTG to facilitate access to the reporting platform and for all communications related to controlled drug distribution.* ✓ *Submission of monthly controlled drug import and distribution sales report shall be submitted by the 5th day of each month.*
Border Control Agencies (Ports of Entry)	Key Responsibilities include: ✓ *Ensure secure storage of controlled drugs before and during the clearance process to prevent loss, damage, or unauthorized access.* ✓ *Comply with MFDA requirements to support regulatory oversight and accountability.* ✓ *Report any suspicious activities or irregularities to the MFDA if identified.* ✓ *Maintain proper documentation to ensure full traceability of controlled drugs.*

Health Facilities, Pharmacies and Other Authorized Premises	Key responsibilities include: ✓ *Designate a focal point to ensure oversight, safety, and regulatory compliance in the management of controlled drugs.* ✓ *Ensure the focal point's responsibilities are documented in writing and formally shared with the MFDA.* ✓ *Provide secure, access-controlled storage to prevent loss, theft, or diversion of controlled drugs.* ✓ *Establish mechanisms for accurate up-to-date inventory records.* ✓ *Ensure controlled drugs are dispensed or administered appropriately, in accordance with valid prescriptions and clinical guidelines.* ✓ *Maintain accurate records of all prescriptions issued to support audits, monitoring, and regulatory compliance.* ✓ *Ensure accurate submission of stock status reports in accordance with MFDA-defined timelines to support regulatory compliance monitoring.* ✓ *Proper dispose of unused, expired, or damaged controlled drugs in accordance with MFDA medicine disposal guidelines.* ✓ *Report any suspicious requests, irregularities, or potential misuse to relevant authorities.*

Prescribers	Responsible for the safe, appropriate, and compliant prescribing of controlled drugs. Key responsibilities include: ✓ *Conduct and document appropriate clinical assessment before prescribing controlled drugs.* ✓ *Prescribe controlled drugs only when clinically indicated and in line with applicable treatment guidelines.* ✓ *Consider patient history, current treatment, and risk of misuse or dependence prior to prescribing.* ✓ *Prescribe the minimum necessary quantity for the shortest appropriate duration, not exceeding three (3) months' supply.* ✓ *Avoid unnecessary duplication of opioids, sedatives, or other controlled drugs unless clinically justified and documented.* ✓ *Ensure prescriptions are issued only to eligible patients and are authentic to prevent misuse or diversion.* ✓ *Report any suspicious requests, irregularities, or suspected misuse or diversion to relevant authorities.*
Dispensing and administration personnel	Key responsibilities include: ✓ *Verify that prescriptions are valid, complete, authentic, and issued by authorized prescribers prior to dispensing or administration.* ✓ *Ensure controlled drugs are dispensed and administered strictly in accordance with prescriptions and applicable protocols or guidelines.* ✓ *Confirm patient identity and eligibility before dispensing or administering controlled drugs.* ✓ *Ensure secure storage and handling of controlled drugs with appropriate access controls to prevent loss, theft, or diversion.* ✓ *Maintain accurate inventory and patient-related records to support audit and regulatory requirements.* ✓ *Ensure compliance with approved policies, procedures, and internal controls governing controlled drugs.*

	✓ *Maintain up-to-date controlled drug records and submit timely stock reports to the MFDA.* ✓ *Investigate, document, and report discrepancies, losses, suspicious activities, errors, or suspected misuse to the MFDA.* ✓ *Ensure proper documentation and disposal of returned, unused, expired, damaged, or wasted controlled drugs in accordance with MFDA disposal guidelines.*
Drug rehabilitation service provider	Exclusively authorized agency or centers responsible for the management of opioid dependence medicines in the Maldives. Key responsibilities include: ✓ *Designate a focal point responsible for the oversight, safe management, and regulatory compliance of controlled drugs.* ✓ *The designated responsible personnel shall be appointed in writing, sign a declaration confirming understanding of the controlled drug guideline and internal SOPs, and a copy of this shall be submitted to the MFDA.* ✓ *Maintain secure, access-controlled storage and inventory management systems to prevent loss, theft, diversion, and stock discrepancies.* ✓ *Ensure controlled drugs are prescribed, dispensed, administered, and used in accordance with treatment guidelines and applicable regulatory requirements.* ✓ *Maintain accurate records of prescriptions, stock movements, administration, and consumption to support traceability, audits, and regulatory compliance.* ✓ *Submit accurate consumption and usage reports to the MFDA within the prescribed timelines.* ✓ *Implement and maintain SOPs, and guidelines for the safe management of opioid dependence medicines and other controlled drugs.* ✓ *Ensure the proper disposal of controlled drugs in accordance with the MFDA Medicine Disposal Guideline.* ✓ *Report any suspicious requests, irregularities, losses, theft, diversion, or suspected misuse to the MFDA without delay.*

	✓ *Conduct prescription audits at least once every twelve (12) months* ✓ *Document and implement corrective and preventive actions for any deficiencies identified through audits or monitoring.*
Blue Prescriptions Printing Party	The contracted printing party shall be responsible for the following: ✓ *Print and supply controlled drug blue prescription books in the MFDA-approved format and ensure timely delivery to requesting entities.* ✓ *Ensure all printed materials are clear, legible, and meet high-quality standards.* ✓ *Implement and maintain strict security measures to prevent unauthorized access, duplication, loss, or misuse of prescription books.* ✓ *Submit detailed monthly sales and distribution reports (Annex 5) to the MFDA by the 5th of each month, including quantities printed, distributed, and any discrepancies identified.* ✓ *Accept requests for prescription books with the approved request form and verify the eligibility of requesting entities prior to issuance.* ✓ *Immediately report any lost, stolen, or compromised prescription books to the Maldives Police Services and the MFDA via email.* ✓ *Develop, implement, and maintain a Standard Operating Procedure (SOP) covering all responsibilities related to the printing, distribution, and security of prescription books, and submit any updates or amendments to the MFDA for approval.*

5 Controlled Drug Import

5.1 Controlled drug quota allocation

5.1.1 Controlled drug quota refers to the maximum annual quantity of controlled drugs and substances permitted for import into the Maldives.

5.1.2 The International Narcotics Control Board (INCB) allocates the annual import quota for controlled drugs and substances to the Maldives.

5.1.3 The annual quota is determined based on national consumption data and estimates submitted by the Maldives Food and Drug Authority (MFDA).

5.1.4 The allocated quota defines the maximum quantities of controlled drugs and substances permitted for import into the country within a calendar year.

5.1.5 The MFDA shall publish the allocated annual import quotas for controlled drugs and substances on its official website by 15th January of each calendar year.

5.1.6 The MFDA shall update and publish quota utilization status every three (3) months, indicating quantities imported against each allocated quota and the remaining balance for the respective calendar year.

5.2 Process for obtaining controlled drug import and sale license

5.2.1 Controlled drug import and sale license is a license issued by the MFDA, in addition to the medicine import permit, authorizing a pharmaceutical importer to import and distribute controlled drugs in accordance with applicable regulatory requirements.

5.2.2 Any pharmaceutical importer holding a valid MFDA-issued pharmaceutical import license with a minimum validity of six (6) months shall apply for a controlled drug import and sale license.

5.2.3 Interested importers shall submit their request via email to mtg.controldrugs@mfda.mv, along with supporting documentation demonstrating compliance with the minimum requirements specified below:

a) *The applicant shall have secure storage facilities with lockable, access-controlled areas to ensure the safe storage of controlled drugs and prevent loss, theft, unauthorized access, or diversion.*

b) *A responsible pharmacist or pharmacy assistant holding a valid registration certificate shall be designated and available on-site to oversee the receipt, storage, handling, and distribution of controlled drugs.*

c) *At the time of application, the applicant shall have a minimum of six (6) months of continuous engagement in pharmaceutical import operations.*

d) *Controlled drug storage areas shall maintain temperature conditions in accordance with manufacturer specifications and shall be equipped with appropriate temperature monitoring systems.*

e) *The applicant shall maintain standard operating procedures (SOPs) detailing the management, handling, storage, transportation, and documentation of controlled drugs.*

5.2.4 The MFDA shall review submitted requests and conduct an on-site inspection of the premises to confirm compliance with the applicable requirements within seven (7) working days from the date of receipt of the application.

5.2.5 Upon completion of the inspection, the controlled drug import and sale license shall be issued within five (5) working days from the date of inspection.

5.2.6 A controlled drug import and sale license shall be granted only where the applicant fully meets the applicable requirements.

5.2.7 If any request is incomplete or additional documentation is required to confirm eligibility, the importer shall be given three (3) working days to provide the required document. Failure to submit the documents within this time frame shall result in rejection of the request.

5.2.8 The controlled drug import and sale license shall be issued in alignment with the validity period of the medicine import permit

5.2.9 The issuance of a controlled drug import license does not exempt importers from obtaining an import certificate, which is mandatory prior to each shipment.

5.2.10 Authorized importers shall ensure compliance with the Approved Drug List (ADL) and obtain all required approvals prior to import, as specified by the ADL.

5.3 Procedure for obtaining a controlled drug import certificate

5.3.1 An import certificate is an authorization issued by the MFDA to licensed controlled drug importers for each shipment, permitting the import of a specific consignment of controlled drugs into the Maldives.

5.3.2 Authorized controlled drug importers shall apply for import certificates through the Dhirithi portal by submitting all required information and supporting documents as specified below.

a) *Exporter details*
b) *Information about the specific controlled drug(s) being imported.*
c) *A product image displaying the ingredient list of the medication.*
d) *Pre-authorization (if the medication is categorized as PA product in ADL)*
e) *A sample import certificate (if importing a sample medication*

5.3.3 Upon receipt, the request shall be reviewed and verified to ensure that all required information and supporting documentation have been provided.

5.3.4 If the application is complete, the import certificate shall be issued within seven (7) working days.

5.3.5 If any required information or documentation is missing, the application shall be marked “needs clarification,” and the applicant shall submit the required details within three (3) working days.

5.3.6 Once the applicant submits the required clarification, the application shall undergo re-verification, and the import certificate shall be issued.

5.3.7 If the applicant fails to provide the required clarification within three (3) working days, the application shall be rejected, in such cases, a new application shall be submitted.

5.3.8 Once the request status update to “approved”, the import certificate shall be accessible digitally via the Dhirithi portal. If a hard copy is required, the applicant shall collect the certificate from MFDA.

5.3.9 Import certificates shall remain valid for six (6) months from the date of issuance. Certificates shall not be applicable to shipments that have been imported prior to issuance, ensuring compliance with import authorization requirements.

5.4 Cancellation of Import Certificates

5.4.1 An import certificate shall be automatically cancelled if the controlled drugs are not imported within its validity period.

5.4.2 An issued import certificate shall not be amended. Where changes are required, the importer shall submit a cancellation request via email, accompanied by a written justification.

5.4.3 Where a replacement import certificate is required, the importer shall submit a new application through the Dhirithi portal with the required supporting documents.

5.4.4 Where the MFDA identifies an error requiring cancellation of an issued import certificate, the importer shall be notified via official email, stating the reason for cancellation and, where applicable, the status of any replacement certificate.

5.4.5 Upon cancellation of an import certificate, the Controlled Drug Unit shall immediately notify both the port of entry and the importer via official email. The status of the certificate shall also be updated to “Cancelled” in the Dhirithi portal.

5.4.6 A cancelled import certificate shall not be used for the importation of controlled drugs. Where importation is still required, a new valid import certificate shall be obtained prior to shipment.

5.4.7 Upon issuance of a replacement import certificate, the importer shall ensure that all previously issued copies of the cancelled certificate, including the original hard copy, are discarded and not used for any purpose.

5.4.8 Any misuse of a cancelled or replaced import certificate shall result in regulatory action by the MFDA.

5.5 Import and clearance of controlled drugs

5.5.1 All importers shall comply with the Guideline for Health Clearance of Pharmaceuticals at Ports of Entry (MTG/QA-HC/GLN-TE 011) and shall fulfill all procedural and documentation requirements specified therein.

5.5.2 All controlled drug shipments shall be imported with a corresponding valid import certificate.

5.5.3 Where a medicine is listed as an internationally controlled substance in the approved drug list, the importer shall submit the export certificate to the port of entry along with the import certificate and other required documents for shipment clearance, as per the clearance guideline.

5.5.4 Storage areas for controlled drug shipments at border control inspection points shall be secure and access-restricted to prevent loss, theft, diversion, or tampering until clearance and release.

5.6 Import of Controlled Drugs under Special Circumstances

Category	Requirements
Personal Use and Travelers	Individuals importing controlled drugs for personal use, including traveler's carrying Schedule II medicines under Drug Act 17/2011, shall not require prior MFDA approval if below provided conditions are met: • *Prescription and/or medical records issued by the attending physician shall be presented covering the treatment period.* • *Quantity shall not exceed one (1) month supply based on prescribed dose. Prescription shall be issued within the last three (3) months.* • *For long-term or specialized treatment, up to three (3) months' supplies shall be allowed with supporting medical documentation.* • *Valid patient identification and relevant medical records (not older than 3 months) shall be presented at clearance.* • *Travelers shall carry medical documents confirming diagnosis and treatment.* • *Medicines shall not be sold, distributed, or transferred within the Maldives under any circumstances.*

Category	Requirements
Foreign Vessels and Authorized Operations	Client shall complete the following requirements: • *Prior MFDA approval shall be obtained before import via email submission with supporting documents (Product details including quantity and vessel name or project details, Duration)* • *Controlled drugs shall be delivered directly to the vessel or authorized location and shall not be stored or used other than authorized activities and location.* • *Medicines shall not be sold, distributed, or transferred within the Maldives under any circumstances.*
Drug Rehabilitation Treatment Programs	• *Controlled drugs shall be imported exclusively for MFDA-approved rehabilitation and treatment facilities for substance dependency disorders.* • *The contracted importer shall obtain all required import certificates prior to import.* • *The service provider shall hold a valid MFDA controlled drug storage permit before requesting imported quantities.* • *Medicines shall not be transferred to service providers without valid storage authorization and MFDA approval.* • *Any discrepancy or incident shall be reported immediately by the contracted importer to both MFDA and the service provider.* • *Medicines shall be used strictly within approved rehabilitation programs.*

6 Transportation Requirements

6.1 Strict requirements for the transportation of controlled drugs are essential to ensure regulatory compliance and to prevent loss, theft, diversion, or misuse. As controlled drugs have a high potential for abuse, dependence, and illicit distribution, robust security and monitoring measures are required throughout the entire supply chain. These safeguards help maintain product integrity, ensure accurate traceability, and protect both public safety and institutional accountability.

6.2 Transportation from Port of Entry to Authorized Warehouse

6.2.1 Upon port clearance, controlled drugs shall be transported directly from the port of entry to the authorized controlled drug import warehouse under the supervision of the designated responsible personnel. Transit, temporary storage, or unloading at any other location is strictly prohibited.

6.2.2 Vehicles used for transporting controlled drugs shall be suitable for this purpose and shall ensure adequate security, safety, and protection of the shipment.

6.2.3 All personnel involved in the handling and transport of controlled drugs are responsible for ensuring security, accuracy, and regulatory compliance throughout the process.

6.2.4 Upon receipt the responsible personnel from warehouse shall immediately verify, physically count, and reconcile the shipment against clearance documents, ensuring full quantity is received and stored.

6.2.5 All shipment-related records, including receipt, counting, and reconciliation, shall be completed by the designated responsible personnel and shall include the name, signature, date and time of receipt and verification, and the condition of the shipment upon receipt.

6.2.6 Any discrepancy, shortage, excess, damage, or deviation identified during receipt and counting of a controlled drug shipment shall be reported to MFDA by email within 48 hours of arrival.

6.2.7 All shipment-related records shall be retained at the licensed warehouse in a traceable and readily accessible manner for inspection by MFDA.

6.3 Distribution from warehouse to facilities / pharmacies

6.3.1 The warehouse shall issue controlled drugs only to facilities holding a valid controlled drug storage permit issued by the MFDA.

6.3.2 The MFDA shall publish a list of premises authorized to store controlled drugs (MTG/QA-SP/Li 0062) monthly.

6.3.3 Facilities holding a valid MFDA issued controlled drug storage permit are not required to obtain individual purchase authorization for each purchase. They shall procure controlled drugs directly from authorized warehouses.

6.3.4 Prior to issuing controlled drugs, the warehouse shall confirm that the recipient facility holds a valid controlled drug storage permit by referring to the latest MFDA published list of premises authorized to store controlled drugs.

6.3.5 For controlled drug storage permits issued after publication of the list of premises authorized to store controlled drugs, the MFDA shall notify authorized controlled drug importers by email. Until the facility is included in the next published list, the importer shall verify the facility's authorization using the MFDA email notification.

6.3.6 The warehouse shall pack controlled drugs in secure, tamper-evident packaging to maintain the integrity of the products during transport. If any package is opened prior to delivery, the receiver shall be notified, and appropriate corrective actions shall be implemented.

6.3.7 All controlled drug transactions shall be recorded. The importer shall submit a monthly sales report detailing receipts and issues to the MFDA at the end of each month in the format provided in Annex 4.

6.3.8 Transportation of controlled drugs from the importer warehouse to authorized premises shall comply with strict security, documentation, and regulatory requirements for land or sea transport.

6.3.9 Transportation of controlled drugs from the authorized warehouse to health facilities, pharmacies, warehouses, or other authorized locations shall comply with strict security, documentation, and regulatory requirements, whether via land or sea transport.

6.3.10 The warehouse pharmacist or designated responsible staff shall prepare and verify the order, ensuring quantities, batch numbers, and expiry dates match the requisition before dispatch.

6.3.11 Each shipment shall be accompanied by a complete chain-of-custody record, including:

a) Name and signature of the person who verified the order, dispatch, and final quantity check at the warehouse.
b) Date and time of dispatch
c) Vehicle or vessel identification (vehicle number or vessel name)
d) Transport personnel details (Name, Id card number, and Contact number)
e) Handover details at the receiving facility, signed by authorized receiving personnel.

6.3.12 For land-based transport, vehicles used for controlled drug delivery shall be suitable for such purpose. Distribution shall be conducted in a manner that ensures full traceability from the dispatch point (warehouse) to the receiver.

6.3.13 Any incident during the transportation of controlled drugs shall be reported immediately to the MFDA via email (mtg.controldrugs@mfda.mv). The email shall include incident details, the impact on the shipment, and any immediate corrective actions implemented.

6.3.14 Upon receipt of controlled drugs, the pharmacist or authorized staff at the receiving premises shall inspect the received items and verify them against the accompanying documentation.

6.3.15 Any discrepancies, damage, suspected tampering, or irregularities identified during transport or upon arrival shall be reported to the MFDA in writing within 48 hours.

6.3.16 All transportation and receipt records shall be securely archived by both the warehouse and the receiving facility or pharmacy.

6.3.17 Inter-Facility Transfers: Refers to the movement of controlled drug stock between authorized entities, including health facilities, pharmacies, and licensed warehouses. Any such transfer shall require prior MFDA approval via email (mtg.controldrugs@mfda.mv) and shall comply with the following requirements:

a) Transfers shall occur between health facility to health facility, pharmacy to pharmacy, or pharmacy to licensed warehouse.
b) Prior approval shall be obtained from the MFDA before any transfer is carried out.
c) The transfer request shall include details of the sender and receiver.
d) Product details shall be provided, including name, batch number, expiry date, and quantity.
e) Both the sending and receiving parties shall maintain complete records of the transfer.
f) All transfers shall be reflected in the stock status reports of both parties.

7 Procedure for obtaining controlled drug storage permit

7.1 Controlled Drug Storage Permit is an authorization issued by the MFDA to a premises, upon request, permitting the storage of controlled drugs in accordance with applicable regulatory requirements.

7.2 Any registered service provider intending to store controlled drugs, including health facilities, pharmacies, veterinary clinics, and other licensed parties, shall obtain a controlled drug storage permit from the MFDA.

7.3 In addition to point 7.2, medical camps, training centers, airline and air ambulance services, and other entities requiring storage of controlled drugs but not covered under point 7.2 shall also obtain a Controlled Drug Storage Permit.

7.4 All requests under points 7.2 and 7.3 shall be submitted via email to mtg.controldrugs@mfda.mv accompanied by the supporting documents demonstrating compliance with the requirements specified below:

a) Photographic evidence of the secure controlled drug storage facility, including lockable and access-controlled areas, and evidence that storage conditions meet required temperature specifications with appropriate temperature monitoring systems in place.
b) Details of the designated responsible personnel on-site, assigned to oversee the receipt, storage, handling, and distribution of controlled drugs.

7.5 The MFDA shall review the submitted documents to confirm compliance with applicable requirements within five (5) working days from receipt of the application and issue the controlled drug storage permit upon satisfactory compliance.

7.6 A controlled drug storage permit shall be granted only where the applicant fully meets all applicable requirements.

7.7 If an application is incomplete or additional documentation is required, the MFDA shall allow three (3) working days for submission of the required information. Failure to provide the requested documents within this timeframe shall result in rejection of the application.

7.8 The validity of the controlled drug storage permit shall align with the validity of the underlying registration issued by the relevant regulatory authority. Where no such validity applies, the permit shall be issued for a maximum period of five (5) years.

8 Storage and handling requirements

8.1 Controlled drugs shall only be stored by authorized premises holding a valid controlled drug import and sale license or controlled drug storage permit issued by the MFDA.

8.2 Each authorized premises storing controlled drugs shall designate a responsible personnel or licensed healthcare professional (e.g., pharmacist, pharmacy assistant, medical practitioner, or nurse), to oversee the secure storage, handling, and records of controlled drugs.

8.3 Controlled drugs shall be kept in a secure, locked storage area. Only responsible personnel shall have access, and the area shall be labeled “Responsible personnel Only.”

8.4 Keys or access codes for controlled drug storage shall be securely maintained, and any handover of keys shall be properly documented.

8.5 All entities shall implement access control, surveillance, and 24-hour monitoring where applicable.

8.6 Controlled drugs shall be stored in accordance with manufacturer-specified storage conditions. The storage area temperature shall be maintained and continuously monitored using a temperature monitoring device.

8.7 Standard Operating Procedures (SOPs): All authorized premises storing controlled drugs shall maintain written Standard Operating Procedures (SOPs) covering all aspects of controlled drug management including.

a) Receipt and verification of controlled drugs
b) Security measures for controlled drug storage
c) Sale or distribution procedures
d) Stock counting and inventory record management
e) Dispensing or administration procedures
f) Incident reporting (including loss, theft, diversion, or discrepancy)
g) Disposal of expired or damaged stock
h) Staff training on handling, security, and regulatory compliance

8.8 A controlled drug management system shall be in place to track the distribution and sale of controlled drugs in accordance with applicable guidelines.

9 Requirements for prescription and prescribing of controlled drugs.

9.1 Blue prescription requirements for controlled drug

9.1.1 A prescription printed on blue colored paper in the MFDA approved prescription format, designated exclusively for prescribing controlled drugs by authorized prescribers.

9.1.2 The MFDA shall appoint a printing contractor for the production of Controlled Drug Blue Prescription books through a competitive procurement process in accordance with applicable government procurement requirements.

9.1.3 The successful bidder shall be selected following the evaluation process and a contract shall be executed for a period of five (5) years.

9.1.4 The MFDA-approved Controlled Drug Blue Prescription format shall be provided to the contracted printing contractor and shall not be modified without prior written approval from the MFDA.

9.1.5 The MFDA shall conduct audits and inspections of the contracted printing contractor to verify compliance with this guideline, contractual obligations, and applicable security requirements.

9.1.6 The following entities shall be eligible to request Controlled Drug Blue Prescription books:

a) Health facilities registered and licensed by the Ministry of Health.

b) Registered veterinary clinics and project-based veterinary facilities.

c) Registered Drug Rehabilitation Treatment centers

9.1.7 The contracted printing contractor shall verify the eligibility of the requesting entity before issuing controlled drug blue prescription books.

9.1.8 Within seven (7) working days of each issuance, the contracted printing contractor shall submit a data to the MFDA containing:

a) The quantity of prescription books issued; and

b) The details of the recipient.

9.1.9 A controlled drug blue prescription book shall remain valid for three (3) calendar years from the year of printing. After the expiry of the validity period, the prescription book shall not be used for prescribing controlled drugs.

9.1.10 All expired prescription pad shall be discarded or removed from the facility and notify the MFDA with prescription pad's serial number and quantity.

9.2 Controlled drug prescribing requirements

9.2.1 Controlled drugs shall only be prescribed by healthcare professionals authorized under national legislation and within their approved scope of practice.

9.2.2 Prescriber shall:

a) Perform and document an appropriate clinical assessment before initiating treatment with a controlled medicine.

b) Prescribe controlled drugs only where there is a clear clinical indication and in accordance with treatment guidelines.

c) Consider the patient's medical history, current medicines, allergies, contraindications, risk factors for substance misuse or dependence, and potential drug interactions before prescribing.

d) Prescribe the lowest effective dose and the minimum quantity necessary for the shortest appropriate duration consistent with the patient's clinical needs.

e) Ensure that the quantity prescribed at a single consultation does not exceed a three (3) month dose.

f) Avoid unnecessary duplication of opioid, sedative, or other controlled medicine therapy unless clinically justified and documented.

9.2.3 Controlled drugs used in veterinary services shall be prescribed only by licensed veterinarians holding a valid certificate issued by the Ministry of Fisheries, Agriculture and Ocean Resources (MoFAOR), within their authorized scope of practice.

10 Requirements for dispensing, administration and patient counselling

10.1 Dispensing of controlled drug

10.1.1 Only licensed pharmacists or pharmacy assistants holding a valid MAHC registration and a valid pharmacist identification card issued by the MFDA shall perform the dispensing of controlled drugs.

10.1.2 Controlled drugs shall only be dispensed in accordance with a valid prescription and for the prescribed duration. A prescription shall be considered valid for dispensing for up to thirty (30) days from the date of issuance.

10.1.3 Prior to dispensing, the person responsible shall ensure that the prescription is fully completed and shall verify the following details:

a) Patient identity (all fields in the controlled drug prescription shall be completed)

b) Drug name, strength, and dosage

c) Diagnosis

d) Quantity or duration of treatment

e) Prescriber's full details as required in the controlled drug prescription format

f) Prescribing facility information.

10.1.4 Upon completion of dispensing, the dispensing personnel shall record their name, signature, the date of dispensing, the quantity dispensed, and the official pharmacy stamp on the prescription.

10.1.5 During dispensing patients or caregivers shall be counseled on the proper use, storage, and potential risks associated with the controlled drug.

11 Administration of controlled drug

11.1 Controlled drugs shall be administered only by authorized healthcare professionals acting within their professional scope of practice.

11.2 Prior to administering a controlled medicine, the healthcare professional shall:

a) Verify and confirm the patient's identity using established patient identification methods.

b) Confirm the validity of the prescription and medication order.

c) Verify the medicine, strength, dose, dosage form, route, frequency, and timing of administration.

d) Perform visual inspection of medicine to ensure it has not expired, been damaged, or otherwise compromised.

e) Confirm that the medicine has been stored under appropriate conditions.

11.3 Healthcare professionals administering controlled drugs shall:

a) Apply the principles of safe medication administration, including verification of the right patient, right medicine, right dose, right route, right time, and appropriate documentation.

b) Monitor patients for therapeutic response, adverse reactions, oversedation, respiratory depression, or other clinically significant effects where applicable.

c) Document administration immediately after the medicine is given, including the date, time, dose administered, batch number where required, and the identity of the administering professional.

d) Document any omitted, refused, delayed, partially administered, or wasted doses, together with the reason and, where applicable, witness verification.

e) Report medication errors, adverse events, discrepancies, suspected diversion, theft, or loss in accordance with MFDA incident reporting requirements.

f) Ensure that unused portions of controlled drugs are managed, witnessed where required, documented, and disposed of in accordance with MFDA procedures.

g) Ensure that when an injection vial is used for more than one patient, its use is properly documented and that each patient has a prescription issued in their name.

11.3.1 Healthcare facilities shall establish systems to monitor patients receiving controlled drugs, particularly those receiving long-term opioid therapy or other medicines associated with dependence. Monitoring shall include:

a) Assessment of treatment effectiveness.

b) Monitoring for adverse drug reactions.

c) Evaluation of signs of tolerance, dependence, misuse, or diversion.

d) Review of continued clinical need for therapy.

e) Documentation of all clinical decisions within the patient's medical record.

11.4 Patient Counselling

11.4.1 Patients and caregivers receiving controlled drugs shall receive counselling appropriate to the medicine prescribed, including:

a) The purpose of treatment and expected therapeutic outcomes.

b) Instructions for correct use, dosage, and duration of therapy.

c) Possible adverse effects and when to seek medical attention.

d) Risks of dependence, misuse, overdose, and sharing medicines with others.

e) Safe storage in a secure location to prevent unauthorized access.

f) Safe disposal of unused or expired controlled drugs.

g) The importance of adhering to the prescribed treatment regimen and

h) attending scheduled clinical reviews.

11.5 Management of Patients' Own Controlled Drugs During Admission and Discharge

11.5.1 All healthcare facilities shall develop, implement, and maintain written internal Standard Operating Procedures (SOPs) for the management of patients' own controlled drugs during admission and discharge. These SOPs shall align with the requirements outlined in this guideline and shall define the processes for assessment, use, storage, return, discontinuation, disposal, and incorporation of patient-leftover controlled medicines into facility stock where applicable.

11.5.2 Upon admission, where the treating doctor authorizes the continued use of a patient's own controlled medicine brought from home, the medicine may be used for the patient's treatment.

11.5.3 If the treating physician subsequently changes, discontinues, or substitutes the patient's own controlled medicine during admission or before discharge, such medicines shall not be incorporated into the healthcare facility's-controlled drug inventory and shall be managed and disposed of in accordance with the applicable medicine disposal guideline by health facility.

11.5.4 At discharge, a patient's own controlled drugs may only be returned if they remain clinically indicated, are within their expiry date, and are authorized for continued use by the prescribing clinician.

11.5.5 Unused and unopened controlled drugs deemed suitable for continued use that were purchased during a patient's admission shall return to the facility's-controlled drug stock. The return shall be documented in the controlled drug inventory records.

11.5.6 The healthcare facility shall ensure that:

a) The medicine is verified to be within its expiry date, suitable for use, and acceptable for inclusion in the facility's-controlled drug stock.
b) The medicine is entered into the controlled drug inventory records as patient-leftover stock incorporated into facility stock.
c) The medicine is included in daily controlled drug counting and reconciliation records.
d) The medicine is included in the quarterly controlled drug stock status report submitted to the MFDA, with the source clearly recorded as patient-leftover stock received into facility stock.

11.5.7 Any controlled medicine identified within the healthcare facility that has not been incorporated into the approved inventory records, controlled drug stock status report, and controlled drug counting records shall be considered unauthorized stock and shall be managed in accordance with applicable regulatory requirements.

11.6 Management of narcotic drugs in outpatient services for palliative and long-term illnesses

11.6.1 This applies to narcotic medicines prescribed by an authorized prescriber for the management of severe pain and other approved medical conditions requiring long-term outpatient treatment.

11.6.2 Apart the general prohibition on the storage and sale of narcotic medicines in pharmacies, public-owned pharmacies authorized by the MFDA shall store and dispense these medicines for outpatients in accordance with this guideline.

11.6.3 Applications for a permit to store and dispense narcotic medicines from pharmacies shall only be accepted from State Pharma Public Limited company pharmacies. The MFDA shall issue a permit to store narcotic medicines only to approved public-owned pharmacies.

11.6.4 The MFDA published list of premises authorized to store controlled drugs shall clearly specify the categories of controlled drugs that each authorized premises is permitted to store, including pharmacies authorized to store and dispense narcotic medicines.

11.6.5 Prior to selling any narcotic drugs to pharmacy, authorized importers shall verify the authorization status of the purchasing pharmacy against the latest MFDA published list.

11.6.6 Narcotic medicines shall only be sold to pharmacies specifically identified in the published list as authorized to store and dispense narcotic medicines.

11.6.7 All authorized pharmacy shall maintain an uninterrupted supply of approved narcotic medicines to ensure continuity of treatment for eligible patients.

11.6.8 Narcotic medicines shall only be dispensed against a valid prescription issued by an authorized prescriber.

11.6.9 Authorized pharmacies shall maintain complete records of the receipt, storage, dispensing, returns, losses, and disposal of narcotic medicines in accordance with this guideline.

11.6.10 Authorized pharmacies shall submit stock status reports required by the MFDA within the specified reporting period.

11.6.11 The sale and distribution records submitted by importers and wholesalers shall clearly identify all supplies of narcotic medicines made to authorized pharmacies.

11.6.12 Narcotic medicines dispensed under this section shall be used solely for the treatment of the patient for whom they were prescribed and shall not be transferred, resold, or supplied to any other person.

12 Management of controlled drugs in drug rehabilitation treatment service

12.1.1 Controlled drugs *in drug rehabilitation treatment services* refers to the safe, accountable, and regulated processes governing the importation, receipt, storage, prescribing, dispensing, administration, monitoring, auditing, and continuous quality improvement of controlled drugs used in the treatment of opioid dependence and other substance use disorders within licensed rehabilitation treatment program, in accordance with MFDA requirements and applicable national and international standards.

12.1.2 Drug rehabilitation treatment service providers shall ensure that the designated or contracted party responsible for importing medicines used in treatment holds a valid controlled drug import and sale license issued by the MFDA.

12.1.3 Drug rehabilitation treatment service providers shall ensure that the entire shipment imported for their use is received from the designated or contracted importer.

12.1.4 Drug rehabilitation treatment service providers shall develop, implement, and maintain a Standard Treatment Guideline (STG) for the management of opioid dependence and other conditions requiring the use of narcotic medicines.

12.1.5 The Standard Treatment Guideline shall:

a) Be evidence-based and consistent with recommendations issued by the World Health Organization (WHO), the International Narcotics Control Board (INCB), and other internationally recognized clinical guidelines and national standards.

b) Include standardized protocols for patient assessment, diagnosis, treatment initiation, dose titration, maintenance therapy, management of missed doses, overdose management, discontinuation of therapy, referral, and follow-up.

c) Be reviewed and updated at least every three (3) years or earlier where new evidence, national policy, or regulatory requirements become available.

d) Be readily accessible to all authorized professionals involved in the prescribing, dispensing, administration, and monitoring of narcotic medicines.

12.1.6 All authorized prescribers shall prescribe controlled drugs in accordance with the Standard Treatment Guideline.

12.1.7 Any deviation from the Standard Treatment Guideline shall:

a) Be clinically justified.

b) Be documented in the patient's medical record.

c) Include the reason for deviation.

d) Be subject to clinical review during prescription audit.

12.1.8 Drug rehabilitation treatment programs shall establish a system of regular clinical supervision to ensure safe and appropriate prescribing practices.

12.1.9 Each drug rehabilitation treatment service provider shall establish a documented prescription audit program. Prescription audits shall:

a) Be conducted at least once every twelve (12) months.

b) Be performed by an independent senior clinician or person designated by management.

c) Evaluate compliance with the approved Standard Treatment Guideline.

d) Assess the appropriateness of prescribing, dose adjustments, treatment duration, monitoring, documentation, and take-home dose decisions.

e) Identify inappropriate prescribing, prescribing trends, and medication errors.

f) Include recommendations for corrective and preventive actions where deficiencies are identified.

12.1.10 The prescription audit report shall be documented and retained for inspection by the MFDA and shall be submitted to the MFDA on 1st Quarter together with a stock status report.

12.1.11 Drug rehabilitation treatment programmes shall implement a continuous quality improvement programme based on audit findings, incident reports, patient outcomes, and clinical performance indicators.

12.1.12 Corrective and preventive actions (CAPA) shall be implemented, monitored, and periodically reviewed to improve the quality, safety, and effectiveness of opioid dependence treatment services.

12.1.13 The MFDA shall conduct regular or unannounced audits in drug rehabilitation care to verify controlled drug use against approved treatment guidelines. Service providers shall facilitate such audits in regional facilities upon request.

12.1.14 Any regulatory non-compliance with this guideline or the treatment guideline shall be subject to enforcement action under applicable legal frameworks.

12.1.15 Healthcare professionals involved in prescribing, dispensing, administration, or monitoring of controlled drugs used in rehabilitation treatment services shall receive regular training on:

a) Opioid dependence treatment.
b) Rational prescribing.
c) Overdose recognition and management.
d) Applicable national legislation.
e) The Standard Treatment Guideline.
f) Updates to evidence-based clinical practice.

13 Management of controlled drugs in Veterinary Services

13.1 Veterinary facilities shall hold valid permits issued by the Ministry of Fisheries, Agriculture and Ocean Resources. A registered veterinarian shall work in the facility.

13.2 Controlled drugs shall be prescribed only by licensed veterinarians holding a valid certificate issued by the Ministry of Fisheries, Agriculture and Ocean Resources (MoFOAR), within their authorized scope of practice.

13.3 Service providers shall obtain a controlled drug storage permit from the MFDA prior to requesting the purchase of any controlled drugs from importer in accordance with section 3.

13.4 The veterinary service provider shall submit the standard treatment guideline (STG) with the application. The Standard Treatment Guideline shall:

a) Cover all the services which include controlled drugs.

b) Be evidence-based and aligned, where applicable, with internationally recognized veterinary clinical guidelines and relevant national regulatory requirements.

c) Include standardized protocols for animal assessment, diagnosis, treatment initiation, dose calculation (based on species and weight), dose adjustment, and maintenance therapy.

d) Address the management of missed doses, overdose, discontinuation of therapy, referral, and follow-up through standardized protocols.

e) Be reviewed and updated at least every three (3) years or earlier when required by new scientific evidence or national policy.

f) Be readily accessible to all authorized personnel involved in controlled medicine use.

13.5 The steps outlined in sections 12.1.6 to 12.1.14 shall be followed in this procedure.

13.6 Veterinary facilities shall ensure that all controlled drug administrations are carried out for valid prescriptions, which shall include required details such as animal identification, owner name, species, dosage, and diagnosis, and administered amounts and the details of the administering professional are accurately documented.

13.7 All veterinary professionals involved in prescribing, dispensing, administering, or monitoring controlled drugs shall receive regular training to maintain competency in their safe and rational use, compliance with applicable legislation and regulatory requirements, implementation of relevant clinical guidelines and updates to evidence-based veterinary practice.

14 Management of Controlled Drugs in Mobile Health Camps and Mobile Hospitals

14.1 Mobile Hospitals or Medical Camps shall refer to temporary or mobile healthcare service units, including field hospitals, outreach services, medical camps, or training centers.

14.2 Such service providers shall obtain prior approval from the MFDA by submitting an official request via email at least ten (10) days prior to the commencement of the activity.

14.3 Facilities intending to use controlled drugs during a mobile service shall submit a request to MFDA for prior approval. The request shall include the following information:

a) Name of the island/location where the mobile service shall be conducted.
b) Scope of service and duration
c) Number of patients (or estimated number of cases, if applicable).
d) Name, strength, and quantity of each controlled medicine requested for use.

14.4 Upon receipt of the email request, the MFDA shall process the request within seven (7) working days.

14.5 In addition, the facility shall maintain proper records of all controlled drugs used during the mobile service or camps and submit a summary of drug utilization immediately after completion of the project or camp. The summary shall be submitted via email and shall include:

a) Opening stock.
b) Quantity used/dispensed.
c) Remaining balance stock (including decision taken with balance)
d) Any unused medicines returned to the health facility, where applicable.

14.6 Upon receipt of the summary, the MFDA shall review the information and inform the facility of the appropriate action to be taken regarding any unused or remaining balance of controlled medicines.

14.7 Based on the nature of the product or project, the MFDA shall require on-site process verification or participation. The project organizer shall ensure full facilitation of such requests.

15 Discarding and Disposal of Controlled Drugs

15.1 All healthcare facilities shall document details of controlled drugs that are discarded and shall maintain internal Standard Operating Procedures (SOPs) for the discarding and disposal process.

15.2 All expired and damaged controlled drugs disposal shall be done as per the Medicine Disposal Guideline (MTG/RE-MD/GLN-TE 004).

15.3 If any controlled drugs are disposed of within a reporting quarter, a copy of the corresponding disposal form shall be submitted together with the stock status report for applicable reporting period.

16 Controlled Drug Reporting

16.1 Controlled drug reporting is the systematic submission of information to the MFDA on the procurement, storage, distribution, dispensing, administration, use, loss, disposal, and balance of controlled drugs by authorized entities in accordance with this guideline.

16.2 All premises authorized to handle controlled drugs shall maintain complete and accurate records of all controlled drugs procured, received, stored, distributed, dispensed, administered, used, lost, or disposed of, using the approved formats.

16.3 All controlled drug data sheets shall be maintained using the formats approved and provided by the MFDA. The required data sheets shall be maintained as follows:

a) Sales and Distribution Data Sheet for controlled drug importers (Annex 4).
b) Prescription Data Sheet for pharmacies (Annex 5).
c) Consumption Data Sheet for health facilities and other premises (Annex 6).

16.4 Any modification or alteration to the approved formats shall require prior approval from the MFDA.

16.5 All controlled drug data sheets, including Sales and Distribution Data Sheets, Prescription Data Sheets, and Consumption Data Sheets, shall be maintained electronically using Google Sheets. The respective data sheets shall be shared with the designated MFDA controlled drug reporting email address (MTG control drug email - mtg.controldrug@mfda.gov.mv) to facilitate monitoring, review, and verification.

16.6 Controlled drug import and sale license holders shall maintain a Sales and Distribution Data Sheet (to record all controlled drug transactions, including procurement, importation, supply, distribution, and stock movement details.

16.7 Pharmacies authorized to handle controlled drugs shall maintain a Prescription Data Sheet to record all controlled drug dispensing transactions, including prescription details and dispensing information.

16.8 Health facilities and all relevant other premises authorized to handle controlled drugs shall maintain a Consumption Data Sheet to record all controlled drugs received, stored, administered, used, and remaining in stock across all relevant service areas.

16.9 The responsible personnel shall ensure that all controlled drug transaction records are entered into the relevant data sheet upon completion of each transaction or shift, as applicable.

16.10 Controlled drug stock counting shall be performed at the start of each shift before assuming duty. The stock balance shall be reconciled against recorded transactions, prescription records, consumption records, and stock records to verify accuracy and identify any discrepancies.

16.11 All controlled drug stock counting and reconciliation records shall be maintained in either paper-based or electronic format for verification or inspection purposes.

16.12 Personnel performing stock counts shall record their signature, together with the date and time of verification. All records shall be securely maintained to enable timely identification and investigation of discrepancies.

16.13 Any discrepancy identified during stock counting or reconciliation shall be reported to MFDA via email within twenty-four (24) hours. A root cause analysis shall be conducted, and appropriate corrective and preventive actions shall be implemented to prevent recurrence.

16.14 All authorized premises shall submit consolidated controlled drug stock status reports to MFDA based on the following reporting requirements:

a) Controlled drug importers shall submit a consolidated Stock Status Report on a monthly basis, supported by the Sales and Distribution Data Sheet.
b) Pharmacies shall submit a consolidated Stock Status Report every three (3) months, supported by the Prescription Data Sheet.
c) Health facilities and all other premises shall submit a consolidated Stock Status Report every three (3) months, supported by the Consumption Data Sheet.

16.15 All authorized premises shall ensure that submitted reports are complete, accurate, current, and supported by the relevant electronic records maintained for verification, compliance monitoring, and inspection purposes.

16.16 The quarterly stock status report from health facilities shall include all controlled drugs used or stored across all service areas, including operating theatres, treatment rooms, labour rooms, and other relevant units. The reported closing balance shall reflect the consolidated stock balance from all departments.

16.17 Reports shall be submitted to MFDA through the designated reporting channel by the applicable deadline:

a) Monthly reports submitted by importers: by the 15th day of the following month.

b) Quarterly reports submitted by pharmacies, health facilities and other premises:

- ✓ First Quarter - Q1 (January–March): 15 April
- ✓ Second Quarter - Q2 (April–June): 15 July
- ✓ Third Quarter - Q3 (July–September): 15 October
- ✓ Fourth Quarter - Q4 (October–December): 15 January (following year)

16.18 The MFDA shall review submitted reports and electronic records to verify compliance with reporting requirements. Any discrepancies identified shall be communicated.

16.19 Facilities with no procurement, distribution, dispensing, administration, use, or other controlled drug activity during a reporting period shall submit a nil report to the MFDA.

16.20 Where a facility intends to discontinue the storage and use of controlled drugs, it shall notify the MFDA in writing within fourteen (14) working days.

16.21 Upon notification under Clause 16.7, the controlled drug storage permit shall be cancelled, and the facility shall be removed from the authorized list. Any remaining stock shall be appropriately dispensed, transferred, or used within three (3) months, and a final report shall be submitted to MFDA.

16.22 Failure to comply with reporting requirements shall result in regulatory action as follows:

a) Failure to submit required reports for two (2) consecutive reporting periods shall result in removal from the MFDA authorized list.

b) Facilities with outstanding reports shall be suspended from the MFDA authorized list until all pending reports are submitted. Upon submission of all outstanding reports, the suspension shall be lifted, and the facility reinstated on the MFDA authorized list.

c) Failure to submit required reports for one (1) continuous year shall result in revocation of the controlled drug storage permit and removal from the authorized list.

d) Importers shall be liable for regulatory action if controlled drugs are supplied to any facility not included in the MFDA-published list of authorized premises to store controlled drugs without prior written authorization from the MFDA.

17 National Reporting to INCB

17.1 National Reporting to the INCB refers to the systematic collection, consolidation, verification, and submission of controlled drug data by the MFDA as the national competent authority to the International Narcotics Control Board (INCB), in accordance with the requirements of the 1961 Single Convention on Narcotic Drugs and the 1971 Convention on Psychotropic Substances, to support international monitoring, control, and quota allocation.

17.2 All entities authorized to store controlled drugs shall provide accurate, complete, and timely data to the MFDA to support national reporting obligations.

17.3 INCB reports shall be prepared based on consolidated data from importers, health facilities, pharmacies, and other relevant entities to ensure comprehensive national reporting on controlled drug consumption and requirements.

17.4 The MFDA shall prepare INCB reports using the following forms and data sources:

a) Form B – Annual Estimates of Requirements for Narcotic Drugs: Form B is prepared to estimate the Maldives' yearly requirement for narcotic drugs. It is based on information from relevant stakeholders, including the number of doctors and dentists, veterinarians, registered pharmacies, hospitals, hospital beds, and the annual narcotic quota given to the Maldives by the International Narcotics Control Board (INCB).

b) Form BP – Psychotropic Substances Requirements shows the estimated annual medical and scientific needs for psychotropic substances for the upcoming year.

c) **Form C – Narcotic Drugs Statistics** includes annual data on narcotic drugs in the Maldives, covering import and consumption data, as well as seized drug data provided by the Maldives Police Service and Maldives Customs Service for the previous year.

d) **Form P – Psychotropic Substances Statistics**: Form P includes annual import and consumption data for psychotropic substances for the previous year.

17.5 All data submitted for INCB reporting shall be verified, consolidated, and validated by the MFDA prior to submission.

17.6 Based on submitted data, the International Narcotics Control Board (INCB) allocates controlled drug quotas to the Maldives, reflecting national consumption needs and requirements. Details of allocated quotas are available on the INCB website (https://www.incb.org/) and MFDA website (https://mfda.gov.mv/dv)

18 Controlled drug records and documents management

18.1 Each authorized premises shall maintain documented roles and responsibilities for the responsible personnel and any authorized healthcare professional involved in controlled drug management. The document shall be signed by both parties and kept readily accessible at the premises.

18.2 All records and documentation related to controlled drugs shall be complete, accurate, up to date, and securely maintained in either hard copy or digital format.

18.3 All records and reports related to the import, distribution, and management of controlled drugs shall be retained for a minimum of five (5) years at the authorized premises and be readily available for inspection by MFDA officials during audits or regulatory inspections.

18.4 All controlled drugs importers shall maintain records of:

a) Import and export certificates.
b) Controlled drug release sheets issued by the MFDA Port Control Unit.
c) Controlled drug import and distribution stock status reports.
d) Approved invoices for all incoming and outgoing controlled drugs.

18.5 Healthcare facilities shall maintain records relating to patients' own controlled drugs, including:

a) Declaration, receipt, and details (medicine name, strength, form, quantity).

b) Any changes to therapy, including discontinuation or substitution with reasons.

c) Return of medicines at discharge or transfer.

d) Consent for destruction, where applicable.

e) Disposal or destruction details, including date and witness.

18.6 All authorized premises shall maintain complete, accurate, and up-to-date records of:

a) Purchase records

b) Stock received, dispensed, issued, and balances.

c) Internal distribution between departments

d) Disposal of expired or damaged controlled drugs

e) Copies of blue prescriptions

f) Inter facility transfer data.

19 Controlled Drug Compliance Monitoring and Inspection

19.1 The MFDA shall conduct inspections of all authorized facilities, pharmacies, and licensed importers handling controlled drugs on a routine, periodic, or unannounced basis to verify compliance with applicable laws, regulations, and guidelines.

19.2 All facilities involved in the handling of controlled drugs shall be subject to MFDA compliance monitoring and inspection and shall fully cooperate with MFDA inspectors during inspections, including provision of access to premises, records, personnel, and controlled drug storage areas.

19.3 For private clinics and hospitals outside the Greater Malé Area, the initial inspection for controlled drug storage permit approval shall be conducted collaboratively with the Ministry of Health's Quality Assurance and Regulation Division (QARD) during the facility's registration inspection. Inspection related logistical arrangements shall be required to be accommodated by the premise owner.

19.4 The following violations shall result in appropriate regulatory action by the MFDA:

a) Prescription-related violations, including forging, altering prescriptions.

b) Failure to submit required reports.

c) Incorrect dispensing or administration contrary to prescriptions.

d) Failure to provide requested information, data, or documentation to the MFDA.

e) Loss, misplacement, or negligent handling of controlled drugs.

f) Failure to maintain required security measures.

g) Any other breach of this guideline or related regulatory requirements governing controlled drugs.

19.5 All facilities located outside the Greater Malé Region shall facilitate MFDA inspection visits upon request, including ensuring access to premises and records. Inspection-related logistical arrangements shall be required to be accommodated by the facility, where applicable.

19.6 Non-compliant facilities shall be subject to increased inspection frequency, mandatory corrective action plans with defined timelines, suspension, or revocation of authorization, and legal action in accordance with applicable laws and regulations.

19.7 Repeated or serious violations shall result in permanent revocation of authorization and referral to law enforcement or other competent authorities.

19.8 Theft, diversion, or unauthorized distribution of controlled drugs shall result in immediate suspension of authorization and referral to law enforcement authorities.

19.9 Upon identification of non-compliance, the MFDA shall notify the facility of the violation and specify the required corrective actions and timeframe for implementation.

19.10 The facility shall implement the corrective actions within the specified timeframe and provide evidence of compliance, and failure to do so may result in escalated penalties, including suspension or revocation of authorization.

20 Legal Basis

This guideline is issued under the authority of the following national laws and international conventions:

National Legislation:

- Health Services Act (29/2015)
- Masthuvaa Thakehchaa Behey Gaanoon (Drug Act – 17/2011)
- Medicines Regulation (2014/R-46) and Amendment (R-49, 2016)

International Conventions:

- 1961 Single Convention on Narcotic Drugs
- 1971 Convention on Psychotropic Substances

21 Annexes

a) Annex 1: Controlled Drug Import and sales license

b) Annex 2: Import Certificate

c) Annex 3: Controlled Drug Storage Permit

d) Annex 4: Sales and Distribution Data Sheet

e) Annex 5: Prescription Data Sheet

f) Annex 6: Consumption Data Sheet

g) Annex 7: Stock Status Report Format

h) Annex 8: Reporting Guide

Annex 1: Controlled Drug Import and Sales License

بسم الله الرحمن الرحيم

Maldives Food and Drug Authority
Ministry of Health
Male', Republic of Maldives

Controlled Drug Import and Sales License

Permit Number:

Premises Information

Name of the Premises:	
Premises Address:	
Name of the person responsible for Controlled drugs	

Valid from:

Notes: Any changes to the information provided in this authorization must be officially communicated to this Authority in writing
An application for renewal must be submitted to this Authority at least 30 days prior to the expiration of this authorization

Signature:
Thooma Adam
Health Laboratory Specialist
Maldives Food and Drug Authority

Maldives Food and Drug Authority www.health.gov.mv Tel: 3014322, 3014317
Sosun Magu / Male',Republic of Maldives Fax: 3014315

Annex 2: Import Certificate

بسم الله الرحمن الرحيم

Maldives Food and Drug Authority
Ministry of Health
Male', Republic of Maldives

Date:

No:

IMPORT CERTIFICATE

I hereby certify that the Maldives Food and Drug Authority of Ministry of Health, Male' Republic of Maldives charged with the administration of law relating to drugs to which the single Convention on Narcotic Drugs 1961, and 1971 convention on psychotropic substances applies has approved the importation: -

By:

Address:

Name of Exporter:

The following drugs:

Serial No	Brand Name	Generic Name	Strength	Quantity Approved	Manufacture
1.					

Subject to the following conditions:

- The consignment shall be imported through the port of Male'.
- The consignment may not be delivered to post office box.
- The imported drugs shall be utilized for medical and / or scientific purpose only.
- This authorization is not transferable.
- This authorization is not applicable to shipments that have been imported to Maldives. The shipment of controlled drugs as per this authorization shall be accompanied by the proper documentation as specified by Maldives Food and Drug Authority (MFDA)
- This consignment shall be imported as full shipment through a single port.

Validity from:

Annex 3: Controlled Drug Storage Permit

بسم الله الرحمن الرحيم

Maldives Food and Drug Authority
Ministry of Health
Male', Republic of Maldives

Controlled drugs storage permit

Permit number:

Permit type

☐ Store and dispense (pharmacy)

☐ Store and administration (Health facility/other facilities)

Premises Information

Name of the Premises:	
Premises Address:	
Name of the person responsible for Controlled drugs	

Valid from:

Notes:
Any changes to the information provided in this authorization must be officially communicated to this Authority in writing (Facility address and Name of the person in responsible of Controlled drugs)
An application for renewal must be submitted to this Authority at least 30 days prior to the expiration of this authorization

Annex 4: Sales and Distribution Report Format

Sales and Distribution Data

Name of Presmises: **Controlled Drug Import & Sale License Number:**

Reporting Period:From: ___/___/_____ **To:** ___/___/_____

S.No	Purchased By: (Name)	CD Storage Permit No.	PO Number	Generic Name	Brand Name	Strength / Volume	Dosage form	Batch No	Expiry Date	Quantity Issued	Issued Date	Remarks

Annex 5: Prescription Data Sheet

Prescription Data Sheet For Pharmacies

Premise Name: Quarter: MFDA CD Storage Permit Number:

Beginning Balance												MFDA USE ONLY	
Purchased Qty													
Dispensed Qty													
Expired /Damaged Qty													
Ending Balance													
Dosage form / Generic Name / Brand Name/ Strength / Volume									Tab.Alprazolam (Alprax) 0.5mg	Tab.Alprazolam (Alzolam) 0.5mg	Inj Diazepam (Lori) 10mg/2ml	Syp Phenobarbital (Neobital) 200mg/5ml	Prescriptions evaluated by	Comment
S.No	Dispensed Date	Prescription Serial Number	Patient Full Name	NID/Passport No.	Precsribed By	Data Entered by	Batch Number	Dispensed Qty					

Annex 6: Consumption Data Sheet

Consumption Data Sheet

Name of Presmises: MFDA CD Storage Permit Number:

Reporting Period: From: ____ / ____ / ______ To: ____ / ____ / ______

Beginning Balance																		MFDA USE ONLY	
Received Qty																			
Administered Qty																			
Expired /Damaged Qty																			
Ending Balance																			
Dosage form / Generic Name /Brand Name / Strength/ Volume									Inj Fentanyl Citrate (Opifen) 100mcg/ 2 ml			Inj Morphine (Rumorph) 15mg/ml							
Prescribed Qty Administered amount & Balance									Prescribed Qty	Administered Strength	Balance	Prescribed Qty	Administered Strength	Balance					
S.NO	Prescribed Date	Prescription Serial Number	Patient Details	NID/Passport No.	Prescribed By	Administered Date	Administered By:	Issued Batch	Issued / Administered amount to the patient						Department	Balance Discarded Yes / No	*If NO Please provide the reason (If balance used for another patient provide all the details in next row and put 0 in amount column)*	Prescriptions evaluated by	Comment
				Total					**0**	**0**	**0**								

Annex 7: Stock Status Report Format

بسم الله الرحمن الرحيم

Controlled Drug Stock Status Report

MTG/QA-CD/Fo 0013

Maldives Food and Drug Authority
Male'

Name and Address of Premises:

Reporting Period: From: ____ / ____ / _____ To: ____ / ____ / _____

Note: In the Document Number and Quantity Received columns, warehouses shall record the applicable Import Certificate (PI/NI) Number and the corresponding quantity received. All other premises shall record the applicable Purchase Order (PO) Number and the corresponding quantity received.

S.No	Generic Name Brand Name	Strength / Volume	Dosage form Batch No	Expiry Date	(1) Beginning Balance	(2) Quantity Received	Document No.	(3) Quantity Issued	Quantity Expired, Damage & Discard	Ending Balance Remarks

NOTE : PLEASE FILL EACH AND EVERY COLUMN

Responsible Person

Name:
Designation:

Contact Number:
Official Seal of Presmises:
Signature:

Key:

1. Total quantity in stock at the first day of the reporting first month.
2. Total quantity received during ,monthly period.
3. Total quantity issued during monthly period.
4. Total quantity in stock at end of the month: = (1+2) –(3)

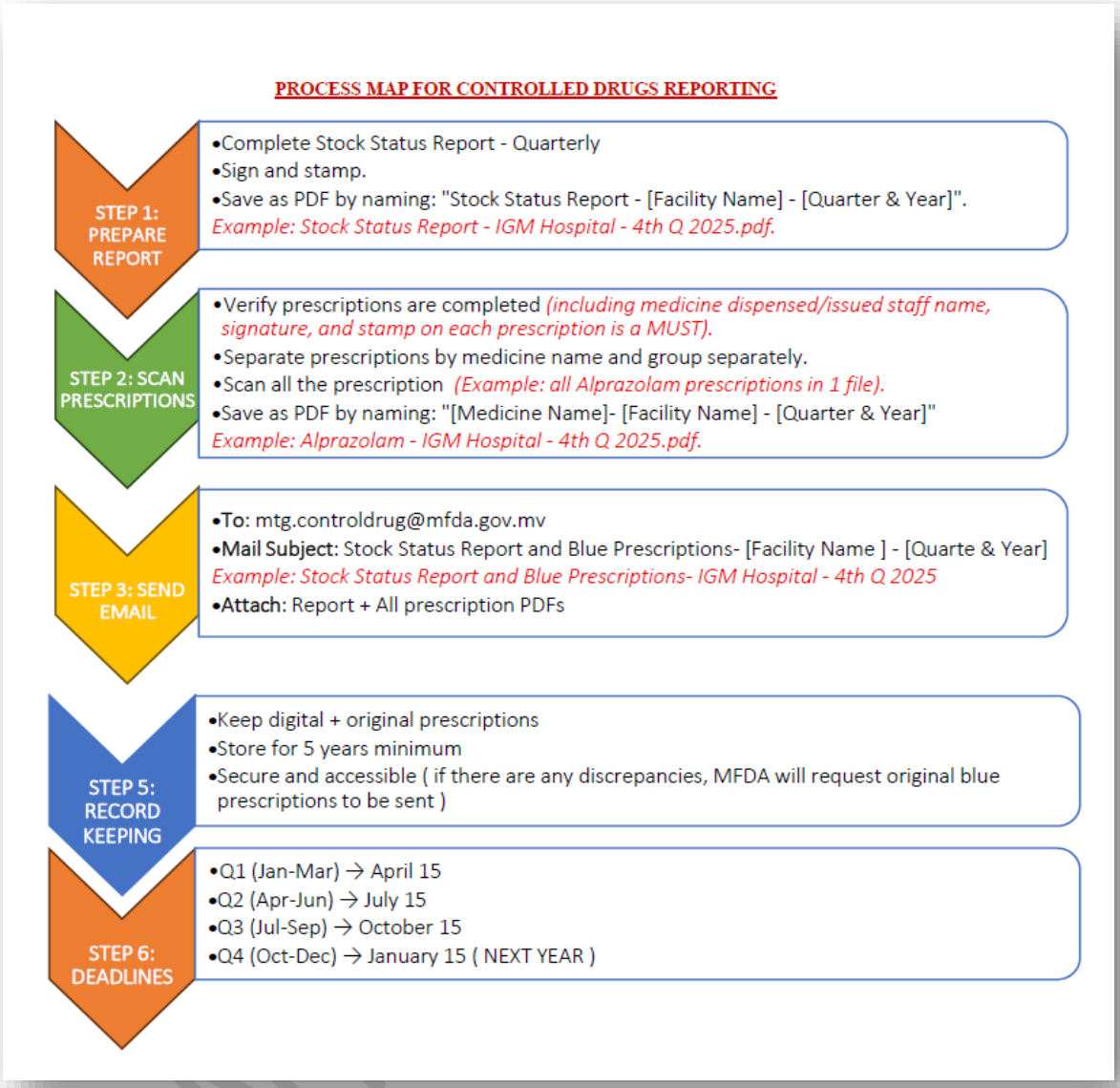
Annex 8: Controlled Drug Reporting Guide

CONTROLLED DRUG REPORTING GUIDE

Accurate monitoring and reporting of controlled drugs are important to ensure safe and appropriate use of these medicines and to maintain effective regulatory control. **The original hard copy of the manual prescription is not required for submission. A clear scanned copy of the prescription shall be submitted via email to mtg.controldrugs@mfda.mv.**

Accurate reporting helps to:

- *Prevent misuse, abuse, and trafficking of controlled drugs.*
- *Ensure compliance with national and international requirements.*
- *Monitor prescribing and usage patterns.*
- *Support effective regulatory monitoring and action.*


PROCESS MAP FOR CONTROLLED DRUGS REPORTING
STEP 1: PREPARE REPORT
•Complete Stock Status Report - Quarterly
•Sign and stamp.
•Save as PDF by naming: "Stock Status Report - [Facility Name] - [Quarter & Year]".
Example: Stock Status Report - IGM Hospital - 4th Q 2025.pdf.
STEP 2: SCAN PRESCRIPTIONS
•Verify prescriptions are completed (including medicine dispensed/issued staff name, signature, and stamp on each prescription is a MUST).
•Separate prescriptions by medicine name and group separately.
•Scan all the prescription (Example: all Alprazolam prescriptions in 1 file).
•Save as PDF by naming: "[Medicine Name]- [Facility Name] - [Quarter & Year]"
Example: Alprazolam - IGM Hospital - 4th Q 2025.pdf.
STEP 3: SEND EMAIL
•To: mtg.controldrug@mfda.gov.mv
•Mail Subject: Stock Status Report and Blue Prescriptions- [Facility Name] - [Quarte & Year]
Example: Stock Status Report and Blue Prescriptions- IGM Hospital - 4th Q 2025
•Attach: Report + All prescription PDFs
STEP 5: RECORD KEEPING
•Keep digital + original prescriptions
•Store for 5 years minimum
•Secure and accessible (if there are any discrepancies, MFDA will request original blue prescriptions to be sent)
STEP 6: DEADLINES
•Q1 (Jan-Mar) → April 15
•Q2 (Apr-Jun) → July 15
•Q3 (Jul-Sep) → October 15
•Q4 (Oct-Dec) → January 15 (NEXT YEAR)