Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

Guideline on Pharmaceutical Inspection

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Issued Date	03.08.2026	
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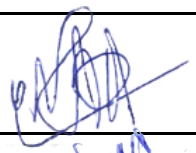
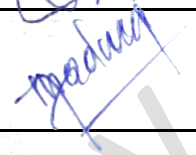
Approved By	Aishath Mohamed, Deputy Director General, Pharmaceuticals	
Authorized by	Thooma Adam, Deputy Director General, Laboratory Services (Acting Head of MFDA)	

SUMMARY OF CHANGES

Version No.	Issued Date	Section / Clause	Summary of Change	Changes Made by
1	23.06.2022	-	Creation of the document	Bishara Ahmed A. Pharmaceutical Officer
2	23.05.2024	-	Revised and updated Process for Implementation of Self-Inspection Procedure	Bishara Ahmed A. Pharmaceutical Officer
3	14.11.2024	-	Criteria's have been amended based on the outcomes of the new process changes. Inspection matrix and data publication requirement added to improve tracking and reporting, updated in line with new process changes.	Bishara Ahmed A. Pharmaceutical Officer
4	05.10.2025	-	Minimum criteria for warehouse SOPs included as ANNEX 4.	Bishara Ahmed A. Medicine Regulatory Officer
5	03.08.2026	-	Replaced Corrective Action Notices with Inspection Post inspection Notices to enhance transparency, consistency, and clarity in communicating inspection findings. Risk levels are integrated into the inspection checklist in accordance with the detailed risk classifications outlined in Guideline Annex 4. The requirements for monthly temperature monitoring sheet submissions have been revised.	Bishara Ahmed A. Medicine Regulatory Officer

CONTENTS

ABBREVIATION

MFDA	Maldives Food and Drug Authority
MTG	Medicine and Therapeutic Goods Division
SOP	Standard Operating Procedure
CA	Corrective Action
RCA	Root Cause Analysis
GDP	Good Distribution Practice
GPP	Good Pharmacy Practice
QMS	Quality Management System
CAPA	Corrective and Preventive Action
QA	Quality Assurance
FEFO	First Expired, First Out
FIFO	First In, First Out
MAHC	Maldives Allied Health Council
ID	Identification
HR	High Risk
MR	Moderate Risk
LR	Low Risk
WHO	World Health Organization

DEFINITIONS

Pharmaceutical Inspection	A systematic and risk-based assessment carried out by regulatory authorities to assess compliance with legal and regulatory requirements related to the storage, handling, and sale of pharmaceuticals in pharmacies and medical warehouses.
Registered Pharmacy	A pharmacy licensed by the MFDA to procure, store, dispense medicines in accordance with regulatory requirements.
Authorized Importer	A license holder authorized by MFDA to import and distribute medicines within the Maldives.
Registered Warehouse	A warehouse licensed by the MFDA to receive, store, and distribute medicines in accordance with regulatory requirements.
Permit	An official authorization issued by the MFDA allowing a pharmacy or warehouse to operate legally under specified conditions.
Routine Inspection	Scheduled inspections conducted to ensure ongoing compliance of pharmacies and medical warehouses with relevant regulations.
Follow-up Inspection	An inspection conducted to verify that corrective actions have been taken to address non-compliance issues identified in a previous inspection.
Spot Inspection	Unannounced inspections conducted in response to public complaints or observed irregularities to ensure immediate compliance.
Risk-Based Inspection	An approach to inspection where the frequency and thoroughness of inspections are determined based on the potential risk to public health and safety posed by non-compliance.
Self-Inspection	Inspection conducted by pharmacy and warehouse owners to assess their own compliance with regulatory requirements using tool provided by MFDA.
Inspection Checklist	MFDA official assessment tool used by inspectors to evaluate compliance with regulatory requirements during inspections.
Self-Inspection Checklist	A tool provided by the MFDA for pharmacy and warehouse owners to assess their own compliance with regulatory requirements prior to registration.
Post Inspection Notice	An official notice issued following an inspection that communicates the compliance level of a pharmacy or warehouse and is accompanied by a checklist outlining observations and necessary corrective measures.
Non-compliance	Failure to comply with applicable legislation, regulations, licensed conditions, guidelines, or approved procedures.
Observation	A condition identified during inspection that may require correction or further assessment.
Public Health Risk	The potential harm to the health of the population that can arise from non-compliance with pharmaceutical regulations, including issues related to the safety, efficacy, and quality of medicines.

High Risk	Critical deficiencies posing a serious public health risk and potentially compromising medicine safety, quality, efficacy, patient safety, controlled drug security, or regulatory oversight.
Level 2 – Moderate Risk	Deficiencies that may significantly impact storage conditions, operational controls, traceability, environmental conditions, or compliance systems without posing an immediate critical risk to patient safety.
Level 1 – Moderate Risk	Deficiencies affecting operational practices, documentation, medicine handling, or issues with limited impact on medicine quality or patient safety.
Low Risk	Minor deficiencies that do not pose an immediate risk to patient safety or medicine efficacy but require correction. If not addressed within the specified timeframe, they may escalate to higher risk categories.
Enforcement Action	Legal or administrative steps taken by regulatory authorities to address and rectify non-compliance, which may include fines, suspension of permits, or legal proceedings.
Inspection Metrics	Inspection Metrics are quantitative indicators used to assess inspection performance, compliance, and quality across all premises.
Quality Management System (QMS)	A documented management system that directs and controls quality-related activities to ensure consistent compliance with regulatory requirements.
Standard Operating Procedure (SOP)	A set of step-by-step instructions compiled by an organization to help workers carry out complex routine operations, ensuring consistency and compliance with regulations.
Critical Control Points	Specific stages, steps, or processes in warehouse operations where control can be applied and is essential to prevent, eliminate, or reduce significant risks (such as temperature excursions or mismanagement of stock).For e.g.: maintenance of logs, calibration of devices /equipment's.
Deviation	Any instance where an approved procedure, regulatory requirement, established standard, or specified condition is not followed.
Corrective and Preventive Action (CAPA)	A systematic approach used to identify the root cause of non-compliance, implement corrective actions, and establish preventive measures to avoid recurrence.
Root Cause Analysis (RCA)	A structured process used to determine the underlying cause of a non-compliance or incident.
Temperature-Controlled Medicines	Pharmaceuticals that must be stored within a specific temperature range to maintain their efficacy and safety, often requiring refrigeration.
Temperature Excursion	Any temperature measurement outside the approved storage conditions specified by the manufacturer.
Traceability	The ability to track the receipt, storage, movement, distribution, and disposition of medicines throughout the supply chain.
Validation	Documented evidence demonstrating that a process, system, or equipment consistently performs as intended.

Responsible Pharmacist	The pharmacist designated by the license holder to supervise pharmacy operations and ensure compliance with regulatory requirements.
Pharmacist ID Card	An official identification card issued to pharmacists, validating their qualification and authorization to practice in a specific pharmacy.
Approved Drug List	An official list of medicines approved and published by the MFDA for importation, distribution, dispensing, sale, and use in the Maldives in accordance with applicable regulatory requirements.
National Essential Medicine List	List that identifies the critical medicines required to be available in registered pharmacies.
Therapeutic Class	A classification of medicines based on their therapeutic use and mechanism of action.
Controlled Drugs	Pharmaceuticals that are regulated under strict legal and administrative controls due to their potential for abuse and dependency.
Bandeyri Pay Portal	An online payment system used for processing fines and fees related to pharmaceutical regulatory compliance in the Maldives.
Dhirithi Portal	An online platform used by the MFDA to facilitate communication, documentation, and self-assessment processes for pharmacies and warehouses.

1 INTRODUCTION

The Maldives Food and Drug Authority (MFDA) is the national regulatory authority responsible for ensuring that pharmaceutical products available in the Republic of Maldives consistently meet the required standards of quality, safety, and efficacy, thereby protecting public health. In carrying out this mandate, the MFDA regulates pharmaceutical products throughout their lifecycle, including their importation, storage, distribution, and dispensing, to ensure that medicines remain safe, effective, and of assured quality until they reach patients.

Inspection of pharmacies and medicine warehouses is a key regulatory activity that enables the MFDA to assess compliance with applicable legal and regulatory requirements and to verify that pharmaceutical products are stored, handled, and distributed under conditions that preserve their quality and integrity. Effective inspections contribute to the prevention of product deterioration, contamination, diversion, and other risks that may compromise patient safety or the effectiveness of medicines.

This guideline has been developed to provide a standardized framework for the inspection of pharmacies and medicine warehouses and to promote a consistent and transparent approach to regulatory oversight. The inspection requirements and criteria contained in this guideline are based on the provisions of the Medicine Regulation No. 2014/R-46 and its First Amendment (2016/R-49), together with recognized principles of good pharmaceutical practice. The guideline supports the implementation of appropriate quality systems and regulatory controls that contribute to maintaining the integrity of the pharmaceutical supply chain and ensuring public confidence in the quality of medicines available in the Maldives.

2 PURPOSE

This guideline establishes the requirements and procedures for the inspection of pharmacies and medicine warehouses licensed by the Maldives Food and Drug Authority (MFDA). It provides a standardized framework for conducting consistent, objective, and risk-based inspections and serves as a reference for licensed establishments to assess and maintain compliance with applicable regulatory requirements.

The objectives of this guideline are to:

- Verify compliance with the Medicine Regulation (No. 2014/R-46), its First Amendment (No. 2016/R-49), and other applicable MFDA regulatory requirements.
- Ensure that pharmaceutical products are sold, supplied, or distributed only by MFDA-licensed establishments.

- Verify that pharmaceutical products are registered with the MFDA or legally imported by MFDA-authorized importers.
- Ensure that pharmaceutical products, including temperature-sensitive medicines, are stored and handled under conditions that maintain their quality, safety, and efficacy.

3 SCOPE

This guideline applies to all pharmacies and medicine warehouses licensed by the Maldives Food and Drug Authority (MFDA) that are engaged in the storage, handling, distribution, supply, or dispensing of pharmaceutical products within the Republic of Maldives.

For the purpose of this guideline, all references to licensed establishments include pharmacies and medicine warehouses licensed by the Maldives Food and Drug Authority (MFDA).

The requirements contained in this guideline shall be used by the MFDA when conducting pre-licensing, routine, follow-up, complaint-driven, and risk-based inspections, and by licensed establishments as a reference for maintaining compliance with the Medicine Regulation No. 2014/R-46, its First Amendment (2016/R-49), and other applicable regulatory requirements issued by the MFDA.

4 LEGAL CONTEXT

These guidelines shall be read in conjunction with the other applicable legislations on drug product (pharmaceutical and biological products) which include but not limited to:

a. Health Service Act (29/2015)
b. Medicine Regulation R-46 (2014)
c. Medicine Regulation Amendment R-49 (2016)

5 RESPONSIBILITY & ACCOUNTABILITY

Medicine Regulatory Officers (Registration Section)	Responsible for registration and permit renewal of pharmacy and warehouses. Key responsibilities include: ✓ *Responsible for ensuring regulatory compliance related to the registration, renewal, and authorization of pharmacies and medical warehouses. Key responsibilities include:* ✓ *Reviewing and verifying applications submitted for the registration or renewal of pharmacies and medical warehouses.*

	✓ *Ensuring that all submitted documentation complies with applicable requirements before forwarding applications to inspection unit.* ✓ *Communicating with applicants in a timely manner regarding deficiencies and requests for clarification prior to submit for inspection unit.* ✓ *Issuing authorization permits based on compliance reports provided by the Inspection Unit.* ✓ *Maintaining and publishing an up-to-date list of authorized pharmacies and medical warehouses.*
Medicine Regulatory Officer (Inspection Unit)	Responsible for monitoring ongoing compliance of pharmacies and warehouses. Key responsibilities include: ✓ *Preparing annual and routine inspection schedules based on risk classifications.* ✓ *Conducting inspections of pharmacies and medical warehouses in accordance with approved MFDA inspection procedures and risk-based inspection criteria.* ✓ *Reviewing and verifying self-inspection checklists, supporting documents, and evidence submitted by premises.* ✓ *Assessing compliance with requirements related to storage conditions, documentation, personnel, security and distribution or dispensing practices.* ✓ *Documenting inspection findings, assigning risk levels, and recommending appropriate regulatory actions.* ✓ *Conducting follow-up inspections or compliance verification activities when required.* ✓ *Maintaining effective communication with applicants and license holders regarding inspection requirements, findings, and corrective actions.* ✓ *Conduct training or refresher sessions for regional inspectors towards inspection guideline checklist and all regulatory requirement.*

Director Pharmaceuticals (Enforcement Section)	Responsible for providing regulatory oversight and ensuring effective implementation of compliance monitoring activities. Key responsibilities include: ✓ *Reviewing and approving inspection findings, compliance assessments, and recommendations prior to issuance of regulatory decisions.* ✓ *Ensuring inspection checklists and assessment tools remain aligned with applicable laws, regulations, and international standards.* ✓ *Ensuring risk-based inspection approaches and enforcement criteria are appropriately implemented.* ✓ *Providing regulatory direction on compliance actions, corrective measures, warnings, restrictions, or other enforcement actions when required.* ✓ *Ensuring consistency, integrity, and quality of regulatory inspection and enforcement processes.*
Deputy Director General (MTG) Director General (MFDA)	Responsible for providing strategic leadership and oversight of pharmaceutical regulatory activities. Key responsibilities include: ✓ *Providing strategic direction for regulatory systems related to pharmacy and medical warehouse regulation.* ✓ *Reviewing and endorsing regulatory decisions related to licensing, inspection outcomes, and compliance actions.* ✓ *Ensuring effective implementation of regulatory frameworks, policies, and guidelines.* ✓ *Supporting continuous improvement of inspection, monitoring, and enforcement systems.*
Premise owners and License Holders (Pharmacies and Medical Warehouses)	Responsible for ensuring continuous compliance with all applicable pharmaceutical regulations, MFDA requirements, and conditions of authorization. Key responsibilities include: ✓ *Maintaining compliance of the premises, facilities, operations, and pharmaceutical activities.* ✓ *Maintaining required records and documentation and making them available during MFDA inspections.* ✓ *Facilitating inspections by providing access to the premises, personnel, records, and relevant information.* ✓ *Cooperating with MFDA inspectors and responding to inspection findings.* ✓ *Implementing corrective and preventive actions (CAPA) within the specified timelines.* ✓ *Notifying the MFDA of significant changes affecting the licensed establishment.* ✓ *Ensuring pharmaceutical products are stored, handled, and distributed under appropriate conditions to maintain their quality, safety, and efficacy.*

Regional Inspectors (Registered Health Professionals from atoll Health Facilities)	Responsible for conducting inspections of atoll-based pharmacies and medical warehouses on behalf of MFDA. Key responsibilities include: ✓ *Conduct inspections of atoll pharmacies and medicine warehouses as requested by the MTG Inspection Unit to assess compliance with regulatory requirements.* ✓ *Record inspection observations, evidence, and required corrective actions using the approved inspection checklist.* ✓ *Identify, document, and classify inspection findings according to MFDA risk classification criteria.* ✓ *Communicate inspection findings and required corrective actions to the establishment representative.* ✓ *Submit completed inspection reports and supporting documents to the MTG Inspection Unit within the specified timeframe.* ✓ *Conduct follow-up inspections, when requested, to verify implementation of corrective actions.* ✓ *Immediately report critical or high-risk non-compliances to the MTG Inspection Unit.* ✓ *Maintain confidentiality, impartiality, and integrity throughout inspection activities.* ✓ *Maintain accurate inspection records and ensure secure retention of inspection documents.* ✓ *Participate in MTG Inspection Unit training and maintain knowledge of applicable regulations, guidelines, and inspection procedures.*

6 TYPES OF INSPECTION

Inspectors from the MFDA conduct a range of regulatory inspections to ensure that medicines are stored and supplied in accordance with relevant legislation.

a) **Authorization Inspections:** It is an inspection required before issuing permit for selling pharmaceuticals. This may include opening of new pharmacies, permit renewals, change of premises and issuing permit for control drugs etc.

b) **Routine Inspections:** These are scheduled inspections carried out to ensure the compliance of pharmacies, and institutions.

c) **Follow up Inspections:** It is carried out to verify if the establishment has taken corrective measures for the violations identified during the routine inspections.

d) **Spot Inspection:** Spot Inspections are instantaneous inspections conducted without any schedule. These inspections are carried out in conjunction with public complaints or when a problem or irregularity has been identified.

All criteria apply equally to both private and government entities.

7 GENERAL PROCEDURES FOR INSPECTIONS

All physical inspections shall be conducted in accordance with the procedures outlined below. Specific inspection activities and processes shall be detailed in the applicable procedures.

7.1.1 Upon arrival at the premises, the inspector shall present their identification card to verify their status as an MFDA inspector and provide a brief explanation of the purpose of the inspection.

7.1.2 The pharmacy or warehouse representative shall introduce themselves and provide their pharmacist identification card, where applicable, for verification.

7.1.3 The inspector shall conduct the inspection in accordance with the approved inspection checklist. The checklist shall include assigned risk levels for each inspection criterion to ensure consistent assessment, classification, and regulatory decision-making.

7.1.4 During the inspection, all observations, supporting evidence, and identified non-compliances shall be documented in the inspection checklist.

7.1.5 All high-risk and Moderate Risk Level 2 findings identified during the inspection shall be documented through photographs as supporting evidence.

7.1.6 Upon completion of the inspection, the inspector shall explain the inspection findings to the representatives present at the premises and obtain the signature of the pharmacy or warehouse representative on the completed inspection checklist.

7.1.7 The inspector shall issue a post-inspection notice and provide the completed inspection checklist to the inspected premises to communicate the inspection outcome and compliance status.

7.1.8 Where low-risk findings are identified, the pharmacy or warehouse representative shall be advised to correct deficiencies that can be immediately resolved during the inspection.

7.1.9 Where inspection findings are categorized as Level 1 (Moderate Risk) and can be resolved through submission of supporting evidence without a follow-up inspection, the pharmacy or warehouse shall submit the required corrective action evidence within five (5) working days.

7.1.10 Inspection findings categorized as Level 2 (Moderate Risk) shall be formally notified for corrective action. A follow-up inspection shall be conducted to verify implementation of corrective actions and achievement of compliance. Further regulatory action shall be initiated based on the risk level and recurrence of the non-compliance.

7.1.11 For all high-risk findings, the pharmacy or warehouse representative shall submit a written statement within three (3) working days. The statement shall clearly describe the identified non-compliance, explain the reason for the occurrence, and include the following information:

a) The pharmacist's statement shall include the pharmacist's full name, Allied Health Council registration number, National ID card number or passport number, contact number, premises name and address, and signature.

b) The pharmacy owner's statement shall include the owner's full name, National ID card number, contact number, premises name and address, and signature.

c) *Statements shall be submitted by all pharmacists working at the pharmacy, together with a statement from the pharmacy management or owner, as applicable. Submission of all required statements shall be mandatory.*

7.1.12 Upon receipt of all required statements, the Inspection Unit shall review the submitted information and initiate necessary regulatory or legal actions within seven (7) working days, where applicable.

7.1.13 Failure to submit the required statements within the specified timeframe shall result in the Inspection Unit finalizing the inspection outcome based on the identified high-risk findings and proceeding with the necessary regulatory actions.

7.1.14 If the inspection concludes with a follow-up requirement an inspection report shall be prepared by the inspector and issued to the inspected premises via email or the dhirithi Portal within five (5) working days following completion of the inspection. For inspections conducted in atolls, the timeline shall commence from the date the completed inspection documents are received by the Inspection Unit.

7.1.15 All inspections resulting in high-risk findings shall only be considered closed upon completion of all required regulatory and legal actions.

7.1.16 All legal actions shall be initiated and implemented in accordance with Sections 15.1.1 to 15.1.10 of this guideline.

8 AUTHORIZATION INSPECTION

8.1 New Registration Inspection Procedure

This process shall be followed across all areas, including Greater Malé and Atolls.

8.1.1 The client is required to download the self-assessment checklist (Checklist 1) from the Dhirithi portal and complete it for new registrations of pharmacies and warehouses.

8.1.2 The inspection should be conducted by management to assess the condition of the premises.

8.1.3 The applicant shall upload the completed checklist signed by the authorized manager or owner, to the Dhirithi Portal when submitting a new application request, together with all relevant supporting documents and photographic evidence in accordance with the requirements specified below.

8.1.3.1 All submitted photographs shall be captured and provided in a manner that enables inspectors to verify the authenticity, location, and current condition of the premises and facilities.

8.1.3.2 Photographs shall clearly demonstrate that they are taken from the premises under application and shall enable inspectors to verify the location, context, and current condition of the premises and facilities. Wide-angle photographs shall be provided to establish the premises context and confirm that the submitted evidence relates to the specific premises under application.

8.1.3.3 Close-up photographs shall be provided where detailed verification of specific requirements is necessary. Close-up photographs alone shall not be considered sufficient where they do not provide adequate context or confirmation that the evidence belongs to the premises under application.

8.1.3.4 Applicants shall ensure that each photograph is clearly identifiable and corresponds to the relevant inspection point or requirement. Unclear, incomplete, excessively close-up, or otherwise unverifiable photographs that do not provide adequate location context or demonstrate compliance with applicable requirements may not be accepted as valid evidence.

8.1.4 If the authorized manager signing the checklist is a foreigner, an additional signature from a local representative of the premise management must be included on the checklist. The inspection must be conducted in the presence of the local representative, as their signature is required

8.1.5 Inspection unit staff shall evaluate and verify the client-submitted checklist to confirm that all requirements are fully compliant, and the premises are deemed ready for operations.

8.1.6 Upon completion of document verification, inspectors have the authority to determine whether a physical inspection of the premises is required to verify compliance based on the information and evidence provided.

8.1.7 Following verification of compliance with the submitted checklist and readiness of the premises for operations, the Inspection Unit shall forward the inspection documents to the Registration Unit within three (3) working days to proceed with permit issuance

8.1.8 If any corrections are identified in the completed checklist or the submitted supporting documents, the client shall be notified via the Dhirithi portal, with the request status updated to "Need Clarification." In such cases, the client must make the necessary corrections or upload the required documents within 03 (three) working days and provide clarification for the request to proceed further.

8.1.9 If the premises do not meet compliance standards, the owner shall be informed through the Dhirithi portal, and the request shall be rejected. The owner shall be required to make the necessary preparations to the premises and resubmit the registration request

8.1.10 An unannounced inspection shall be carried out by the MFDA following the start of operations, to verify that the premise is operating in accordance with approved standards and submitted documentation.

8.1.11 The owner of the pharmacy or warehouse shall send an official email to inspection unit email within three working days after starting pharmacy or warehouse operations. mtg.inspection@health.gov.mv.

8.2 Permit Renewal Inspection Procedure

The permit renewal inspection process shall be conducted based on the location of the pharmacy or warehouse as follows:

8.2.1 For pharmacies and warehouses located in the Greater Malé Area, the applicant shall download and complete the self-assessment checklist (Checklist 2) available through the Dhirithi Portal for permit renewal.

8.2.2 The steps outlined in 8.1.2 to 8.1.10 shall be followed for permit renewal inspections of pharmacies and warehouses located in the Greater Malé Area.

8.2.3 For pharmacies and warehouses located in the atolls, inspections shall be conducted by registered health professionals from public health units under the Ministry of Health.

8.2.4 For atoll premises, permit renewal below mentioned procedure shall be followed:

8.2.4.1 Upon receiving a request from the Licensing Unit, the Inspection Unit shall send the inspection request, checklist, and required documents to the relevant atoll health facility within five (5) working days.

8.2.4.2 The atoll health facility shall complete the inspection within ten (10) working days and provide the post-inspection notice and completed inspection checklist to the inspected premises.

8.2.4.3 Following completion of the inspection, the atoll health facility shall submit the completed inspection documents to the MTG Inspection Unit via email within five (5) working days.

8.2.4.4 The MTG Inspection Unit shall review the submitted inspection documents. Where all requirements are compliant, the checklist shall be finalized with written approval and forwarded to the Regulation Section within five (5) working days for permit processing.

8.2.4.5 Where moderate non-compliances requiring verification are identified, the Inspection Unit shall update the application status to "Need Clarification" in the Dhirithi Portal. The applicant shall submit evidence of correction and required clarification within five (5) working days.

8.2.4.6 Where follow-up action is required, the Inspection Unit shall prepare and upload the inspection report to the Dhirithi Portal within five (5) working days from receipt of the completed inspection documents. The application status shall be updated to "Need Clarification."

8.2.4.7 If a high-risk issue is identified, the client shall submit a statement outlined in 7.1.6.

8.2.4.8 Upon receipt of statements, the MTG Inspection Unit shall initiate legal action and issue the "Advice Notice to Personnel for Non-Compliance Identified During Inspection" (MTG/QA-VR/Fo 0033). The notice shall be uploaded to the Dhirithi Portal within five (5) working days.

8.2.4.9 Failure to submit the required statements within the specified timeframe shall result in the Inspection Unit finalizing the inspection based on the identified high-risk findings and issuing the Advice Notice accordingly.

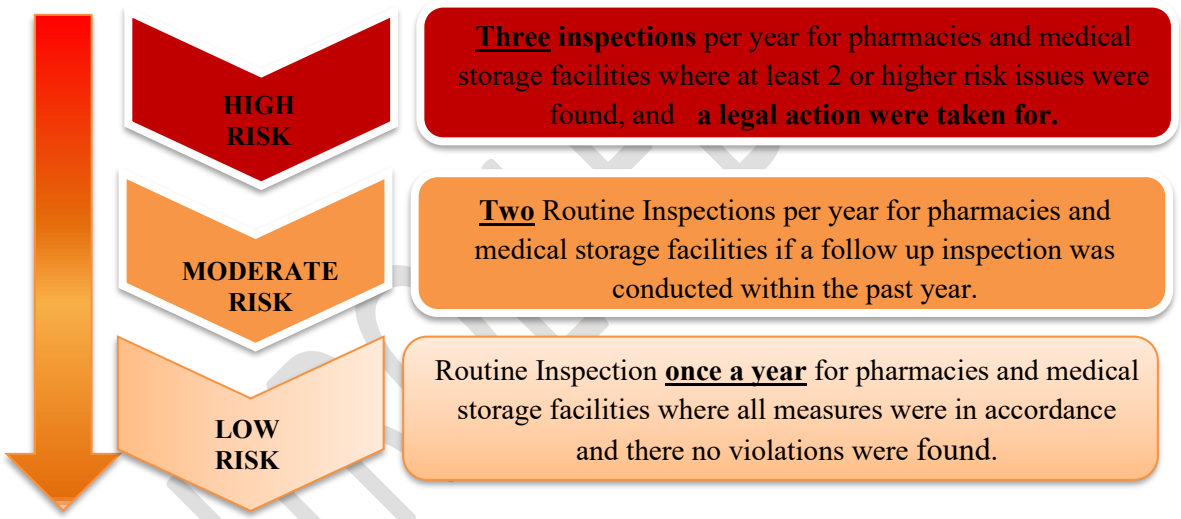
8.2.4.10 Inspections that conclude with high-risk issues shall only be closed upon full accomplishment of all legal actions specified in the issued advice notice.

8.2.4.11 The client shall complete all required corrective actions within the specified timeframe and submit a follow-up inspection request. Upon submission of the request, the status shall be updated to "Clarified."

8.2.4.12 The procedures outlined in Sections 13.1.1 to 13.1.19 of this guideline shall apply to the follow-up inspection process.

9 ROUTINE INSPECTION PROCEDURE

Routine Inspections carried out by MFDA shall be based on Risks. The following measures shall be taken into consideration while carrying out Risk-based Inspections; reference shall be given to the past years Inspection Report



9.1.1 Routine inspections shall be conducted according to the schedule approved by the section head at the beginning of the year, and all registered pharmacies and warehouses shall be inspected.

9.1.2 Inspection teams are not required to provide prior notice for pharmacy or warehouse inspections. However, the warehouse in-charge may be contacted to facilitate access during the visit.

9.1.3 Inspectors shall apply a risk-based approach when assessing pharmacy compliance against each inspection criterion. Risk levels shall correspond to the potential impact of non-compliance on the safety and efficacy of medicines.

9.1.4 At the end of inspection, the inspectors shall hand over a post-inspection notice and checklist which states the inspection outcome and compliance status.

9.1.5 If the inspection concludes with a follow-up requirement, the inspectors shall prepare an inspection report and issue it to the client via email within five (5) working days.

9.1.6 For all high-risk issues, the client shall submit a written statement via email within three (3) working days from the date of inspection, in accordance with Point 7.1.6.

9.1.7 The client shall complete all required corrective actions within the specified timeframe and submit follow up inspection request.

10 PROCEDURE FOR FOLLOW UP INSPECTION

During this inspection, the primary purpose is to verify if the issues identified in the initial inspection have been corrected within the specified timeframe. However, inspectors are also responsible for checking for any ongoing visible violations.

10.1.1 After all corrective actions for high-risk issues or moderate-risk issues requiring follow-up have been completed, the pharmacy or warehouse owner shall inform the Inspection Unit via email or the portal within three (3) working days.

10.1.2 The Inspection Unit shall conduct follow-up inspections within seven (7) working days from receipt of the confirmation email or notification of the status update through the Dhirithi Portal by the pharmacy or warehouse owner.

10.1.3 If the client fails to notify within given timeframe, a follow-up inspection shall be performed within seven (7) working days from the initial inspection date.

10.1.4 If issues are not corrected, the inspection team shall not provide a second opportunity and shall close the inspection with the necessary regulatory action, potentially initiating a full inspection based on the severity of the unresolved issues.

10.1.5 If the current condition is found to be worse than during the previous inspection, the process shall restart with a full inspection, and immediate action shall be taken for any identified issues.

10.1.6 The Inspections Unit shall collaborate with regional health facilities to conduct follow-up inspections of atoll pharmacies and warehouses. This includes providing the necessary checklists and required documents for the inspection process.

11 PROCEDURE FOR IMMEDIATE CESSATION

Inspectors issue a post inspection notice to inform the pharmacy or warehouse to immediately halt operations under the following conditions:

11.1.1 Pharmacist working without valid identity card: Exceptions may be considered if the card is under renewal.

11.1.2 No Valid Permit: Exceptions may be considered if the permit is under renewal or extension.

11.1.3 Unapproved Operations: If the pharmacy or warehouse is found conducting operations outside of what was permitted.

11.1.4 If any critical deficiencies posing a serious public health risk and potentially compromising medicine safety, quality, efficacy, patient safety, controlled drug security, or regulatory oversight. In this situation inspectors shall obtain approval from the Section/Division Head.

12 INITIATION OF LEGAL ACTIONS

12.1.1 The following regulatory actions may be taken based on the nature and severity of the non-compliance:

a. *Advice and giving a period for rectification.*

b. *Imposing a fine between MVR 500 (five hundred Maldivian Rufiyaa) and MVR 2000 (two thousand Maldivian Rufiyaa).*

c. *Suspension of the permit for a period not exceeding 14 (fourteen) days.*

d. *Filing the case at court*.

12.1.2 Depending on the severity of the violations of the medicine regulations, further legal actions shall be taken immediately following the final report.

12.1.3 The inspection unit shall conduct a meeting with premise owners along with pharmacists to discuss the violations and outline the proposed legal actions.

12.1.4 An "Advice Notice to Personnel for Non-Compliance Identified During Inspection" (MTG/QA-VR/Fo 0033) shall be issued in writing, in addition to any fines imposed.

12.1.5 If a fine is imposed, the personnel must make the payment within 3 (three) working days through the Bandeyri Pay portal, using the reference number from the Advice Notice. The fine amount shall be specified on the Advice Notice.

12.1.6 If the client fails to pay the fine within the specified timeframe, a reminder shall be issued. Should payment remain unpaid after the reminder, further legal actions shall be taken.

12.1.7 If legal action is taken against a registered pharmacist, the relevant details shall be shared with the Maldives Allied Health Council.

12.1.8 In the event of a permit suspension, a letter outlining the violations, along with a copy of the inspection report, shall be issued to the pharmacy/warehouse owner. The letter shall instruct them to cease all services during the suspension period.

12.1.9 The pharmacy or warehouse owner must take corrective actions and notify MTG in writing. An inspection unit shall then conduct an inspection before the suspension period ends. If all regulations are complied with, a letter shall be issued allowing the pharmacy or warehouse to resume services once the suspension period has concluded.

12.1.10 If the pharmacy or warehouse continues to operate during the suspension period, the suspension shall be extended accordingly, depending on the circumstances.

12.1.11 Enforcement action shall be initiated in all cases where non-compliance presents a risk of harm to public health. In addition, regulatory enforcement measures shall be applied where registered pharmacies demonstrate repeated failure to meet established regulatory standards.

13 COMPLETION OF INSPECTIONS

13.1.1 An inspection shall be considered complete where no non-compliances are identified or where all identified deficiencies, including low-risk findings corrected during the inspection, have been resolved.

13.1.2 Where moderate-risk issues are identified that do not require follow-up, the inspection shall be closed upon submission of sufficient supporting evidence confirming correction.

13.1.3 For inspections meeting the conditions specified in Points 13.1.1 and 13.1.2, a formal inspection report shall not be required, and the inspection shall be closed upon completion of the verification and authorization sections of the inspection checklist.

13.1.4 If the inspection concludes with a follow-up requirement, the inspectors shall prepare an inspection report and issue it to the client within five (5) working days.

13.1.1 All inspections resulting in high-risk findings shall only be considered closed upon completion of all required regulatory and legal actions.

13.1.2 At the beginning of each calendar year, the Inspection Unit shall prepare and publish annual inspection metrics based on the previous year's inspection findings

14 ANNEXES

Annex 1: Criteria and Requirements for New Registration

Annex 2: Criteria for Permit Renewal

Annex 3: Criteria for Warehouse Sop

Annex 4: Risk Categorization of Non-Compliances

ANNEX 1 - CRITERIA AND REQUIREMENTS FOR NEW REGISTRATION

A. FOR NEW PHARMACY REGISTRATION

1. A detailed floor plan of the pharmacy premises shall be submitted for approval and shall accurately reflect the actual premises.

2. The floor plan shall include all measurements (including floor area), locations of key features such as dispensing counter, air-conditioning unit, doors, windows, partitions, and the exact premises location (including floor number, building name, and area).
3. The minimum required floor area shall be:
    a) *100 sq. ft. for pharmacies located outside health facilities.*
    b) *75 sq. ft. for pharmacies located within health facilities.*
4. The premises shall be maintained in a clean, hygienic, and suitable condition to support the safe storage and handling of medicines and maintain their quality and safety.
5. The premises shall be constructed and maintained to prevent entry of rodents and pests.
6. Walls, ceilings, and floors shall be constructed using materials that minimize moisture accumulation.
7. Adequate lighting shall be provided throughout the premises.
8. A suitable dispensing counter shall be provided to restrict public access to medicines.
9. Adequate, cleanable, and organized storage racks shall be available to ensure proper storage of medicines. **(Medicines shall not be stored at the premises until the pharmacy permit has been issued by MFDA)**
10. The pharmacy name board shall be displayed in both Dhivehi and English and shall include the term “Pharmacy” or “Chemist” where the nature of the premises is not clearly identifiable.
11. The premises shall be air-conditioned and maintained at a temperature below 25°C.
12. Adequate refrigeration facilities shall be available for storage of temperature-sensitive medicines in accordance with manufacturer requirements.
13. Functional thermometers shall be available for monitoring room and refrigerator temperatures.
14. A no smoking sign, including reference to Tobacco Control Act No.15/2010, shall be prominently displayed within the premises.
15. A prescription stamp shall be available and shall clearly display the pharmacy name.
16. Compliance with the applicable Essential Medicines List requirements specified in the Guideline on Minimum Requirement of Essential Medicines in Pharmacies (MTG/RE-EM/GLN-TE 025) shall be verified prior to issuance of the pharmacy permit.
17. The pharmacy shall maintain at least 80% availability of medicines included in the applicable Essential Medicines List.

B. NEW WAREHOUSE REGISTRATION

1. A detailed warehouse floor plan shall be submitted for approval and shall accurately represent the actual premises.

2. The floor plan shall include measurements, storage arrangements, key features (including racks, pallets, doors, windows, and partitions), and exact location details of the premises.
3. The minimum required warehouse floor area shall be 200 sq. ft.
4. The warehouse shall have access controls to restrict entry to authorized personnel only.
5. The premises shall be maintained in a clean, hygienic, and suitable condition to support the safe storage and handling of medicines and maintain their quality, safety, and integrity.
6. Adequate, cleanable, and well-organized storage racks or pallets shall be provided.
7. A no smoking sign, including reference to Tobacco Control Act No. 15/2010, shall be prominently displayed within the premises.
8. A functional fire extinguisher with a valid service status shall be available within the premises.
9. The warehouse shall be air-conditioned and maintained at a temperature below 25°C.
10. Functional thermometers shall be available for monitoring room and refrigerator temperatures, where applicable.
11. Documented SOPs shall be available and implemented for warehouse operations in accordance with Annex 3 of this guideline. The SOPs shall cover, at a minimum:
    a) *SOPs for storage, handling, and distribution of medicines.*
    b) *SOPs for the segregation, storage, and timely disposal of expired drugs.*
    c) *SOPs for regular warehouse cleaning and pest control management.*
    d) *SOPs outlining procedures for recalling products, if necessary.*
    e) *SOPs for maintaining temperature controls, with procedures for reporting temperature deviations promptly.*

ANNEX 2 - CRITERIA FOR PERMIT RENEWAL

A. FOR PHARMACIES

1. No changes shall be made to the approved floor plan submitted with the Pharmacy Authorization Permit.
2. A valid Pharmacy Authorization Permit shall be prominently displayed.
3. The permit name shall match the pharmacy name board.
4. The dispensing counter shall be access-controlled and restricted to authorized personnel.
5. A notice shall be displayed stating the counter area is for authorized personnel only.
6. Pharmacists shall hold a valid pharmacist ID, visibly displayed during duty.
7. A pharmacy-specific ID card shall be used by the pharmacist on duty.
8. A translator shall be present for foreign pharmacists or where required for competency verification.
9. Prescription stamps shall clearly display the pharmacy name.
10. The approved drug list shall be readily accessible for verification.
11. Only medicines listed in the approved drug list shall be stored or sold.
12. All essential medicines shall be available in the pharmacy.
13. Dispensed medicines shall include labels with mandatory information.
14. A designated, clearly labeled area shall be provided for expired/damaged medicines.
15. Air-conditioning shall maintain temperature below 25°C.
16. Temperature-sensitive medicines shall be stored at manufacturer-recommended conditions.
17. Room and refrigerator temperatures shall be recorded daily and reviewed monthly.
18. All temperature records shall be retained on-site and latest 3 months records shall be submitted along with renewal application.
19. Medicines on counters/shelves shall not be accessible to customers.
20. Adequate shelving shall be provided; medicines shall not be stored on the floor.
21. Medicines shall not be stored in direct contact with walls or ceilings.
22. Premises shall be regularly maintained and kept free from pests.
23. Floors, walls, and ceilings shall be free from leaks or damage.
24. Medicines shall be arranged by therapeutic class.

25. Medicines removed from their original packaging or dispensed as loose or cut pieces shall be properly labeled.
26. Prices shall be clearly displayed, and receipts shall issue for all sales.
27. Covered waste bins with lid shall be available; waste shall be segregated from stock.
28. A “No Smoking” sign with Act No. 15/2010 shall be displayed.
29. Medicines shall be protected from direct sunlight.
30. Compliance with the applicable Essential Medicines List (EML) requirements specified in the Guideline on Minimum Requirement of Essential Medicines in Pharmacies (MTG/RE-EM/GLN-TE 025).
31. The pharmacy shall maintain a minimum availability of 80% of the medicines included in the relevant EML, in accordance with the minimum quantity requirements specified in the applicable guideline.
32. All facilities with controlled drugs shall comply with the requirements specified in the Guideline on Controlled Drug Monitoring and Evaluation (MTG/QA-ME/GLN-TE 011).

B. FOR WAREHOUSE

1. SOPs shall be maintained for storage, handling, distribution, expiry management, cleaning, pest control, recalls, and temperature monitoring (Annex 3 compliant).
2. No changes shall be made to the approved floor plan.
3. Access shall be restricted with a “No Admittance Without Permit” notice displayed.
4. Records (invoices/receipts) shall be retained for at least 2 years.
5. Temperature shall be maintained below 25°C via functional air-conditioning.
6. Temperature-sensitive medicines shall be stored under recommended conditions with at least 1-hour backup power.
7. Room and refrigerator temperatures shall be recorded daily and reviewed monthly.
8. All temperature records shall be retained on-site and latest 3 months records shall be submitted along with renewal application.
9. A clearly labeled area shall be provided for expired/damaged medicines.
10. Storage shall ensure proper organization and accessibility without overcrowding.
11. Medicines shall not be stored directly on the floor; shelving or pallets shall be used.
12. Medicines shall not contact walls or ceilings to ensure airflow.
13. Premises shall be maintained in good condition, free from leaks or damage.

14. Pest prevention measures shall be in place with no signs of infestation.
15. A “No Smoking” sign (Act No. 15/2010) shall be displayed.
16. Fire safety measures, including extinguishers and evacuation plans, shall be in place.
17. All facilities with controlled drugs shall comply with the requirements specified in the Guideline on Controlled Drug Monitoring and Evaluation (MTG/QA-ME/GLN-TE 011).

ANNEX 3 - CRITERIA FOR WAREHOUSE SOP

STANDARD REQUIREMENTS FOR PHARMACEUTICAL WAREHOUSE SOP SUBMISSION

To ensure consistency, regulatory compliance, and operational clarity, all SOPs must comply with the Minimum Requirements for Pharmaceutical Warehouse SOPs outlined below.

Each SOP must include the following components:

1. Title – Clearly state the subject matter (eg: SOP for Receiving Medicines)
2. SOP Number – Unique identifier for tracking and version control
3. Version & Date – Indicate the version number and effective date.
4. Prepared, Reviewed and Approved person's names, designation, and signatures.
5. Purpose – Describe the main objective of the SOP.
6. Scope – Define the departments, areas, or facilities where the SOP applies.
7. Responsibilities – Assign specific roles (e.g., Pharmacist, QA)
8. Procedure – Describe the process steps, including applicable timelines, frequency, and completion requirements for each activity.
9. Records - Maintained in each process.

All warehouses must provide an operational process flow of their warehouse activities. This may be submitted either as a single compiled flow covering all procedures or as separate flows for each individual process. The document must clearly highlight the critical control points and outline how associated risk factors are identified and managed.

Name of SOP	Minimum Criteria
1. SOP for Receiving Medicines	Physical condition of goods verifying process.
	specify how and where inspections are carried out.
	Labeling and expiry date verification protocol
	Process in place for confirmation of correct product name, strength, and batch number
	Temperature Control Checks: Procedures for verifying the temperature of cold-chain or temperature-sensitive products at the time of receipt.
	Quarantine Process: Steps for handling and isolating non-conforming or suspect items.
	Documentation and System Entry: Describe how information is recorded and entered into the inventory system.
	Deviation and Discrepancy Handling: Outline how any variances or issues are reported, investigated, and resolved.
2. SOP for Storing and Distribution of Medicines	Access Control and Security Measures - Brief the procedures in place to restrict unauthorized access and ensure the security of stored medicines.
	Outline storage condition monitoring procedures, including temperature monitoring methods, equipment used (e.g., thermometers, data loggers), monitoring frequency, and documentation requirements.
	shelving and segregation procedures to ensure proper stock management.
	Inventory Control Principles used, such as FIFO (First-In, First-Out), FEFO (First-Expired, First-Out), or other applicable systems.
	Packing and dispatch process
	Document Management Process (e.g., delivery notes, batch numbers, receiving confirmation)

	The process for receiving, inspecting, and managing returned medicines to ensure they are properly handled and documented.
3. SOP for Disposal of Expired and Damaged Medicines	Procedure for identifying expired or damaged medicines and separating them from usable stock.
	Labeling: Specify how expired or damaged medicines are labeled and stored securely to prevent accidental use or dispatch.
	Disposal Procedures: Outline the process followed in disposal of expired and damaged medicines, in compliance with regulatory guidelines.
	Disposal frequency and recordkeeping process
4. SOP for Cleaning Process and Pest Control	Cleaning Procedures and Schedules: define the cleaning process, including Daily, weekly, and monthly cleaning tasks.
	Identify who is responsible for performing and supervising the cleaning activities, including their roles and training requirements.
	Cleaning methods and frequency (floors, shelves etc.) including areas to be cleaned (e.g., floors, walls, ceilings, shelves, equipment).
	Pest control measures in place, including whether pest control is managed internally or through an external service provider
	Types of pest control activities conducted and frequency of pest control inspections and treatments
5. SOP for Product Recall	Recall initiation process covering criteria, roles and responsibilities, and internal communication and documentation.
	The product recall process, including batch identification, stakeholder notification, and market retrieval coordination.
	Tracking and accounting of recalled products, including secure storage and investigation of return discrepancies.
	Recall closure procedure, including root cause analysis, CAPA, recordkeeping, and final report submission (if required).
	Retention of recall documents and duration per regulatory requirements.
6. SOP for Temperature Management and Deviation Handling	Temperature monitoring procedures, including acceptable ranges, monitoring methods, frequency, and data recording.
	Types of monitoring devices used and procedures for their calibration, maintenance, and replacement.
	Temperature deviation handling: define deviations, immediate actions, notification process, and impact assessment.
	Procedures for identifying, isolating affected products, and assessing disposition (release, rework, or disposal).
	Conduct root cause analysis, implement corrective actions and evaluate the effectiveness of the corrective action.
	Backup power for refrigeration and emergency response plans for failures or outages.
	Maintain records of temperature data, deviations, investigations, and corrective actions.

ANNEX 4 - RISK CATEGORIZATION OF NON-COMPLIANCES

This Risk categorization defines the criteria for classifying non-compliances identified during inspections of pharmacies, medicine warehouses, and facilities handling controlled drugs. The framework is integrated into the official inspection checklist, where each inspection point is assigned a corresponding risk level to ensure uniform assessment and consistent regulatory response in the event of non-compliance.

Risk Level Descriptive Table

Risk Level	Description & Corresponding Action
High Risk	Critical deficiency posing a serious public health risk and potentially compromising medicine safety, quality and efficacy, patient safety, controlled drug security, or regulatory oversight. Immediate corrective action shall be required, and a follow-up inspection shall be conducted. Legal action shall be initiated as per applicable regulations. All responsible persons shall be subject to a fine of up to MVR 2,000. The MFDA permit may be suspended for up to 14 days depending on severity and conditions of non-compliance.
Level 2 – Moderate Risk	Deficiency that may significantly impact storage conditions, operational controls, traceability, environmental conditions, or compliance systems, without posing an immediate critical risk to patient safety. Corrective action shall be required, and a follow-up inspection shall be conducted. Legal action may be initiated as per applicable regulations. Enforcement measures, including a fine of up to MVR 1,500, may be applied based on risk and recurrence.
Level 1 – Moderate Risk	Non-compliances affecting operational practices, documentation, medicine handling, or routine compliance requirements with limited impact on medicine quality or patient safety. Corrective action supported by documentary or photographic evidence shall be required. A follow-up inspection shall not be routine; however, the Authority shall conduct one based on the nature or recurrence of the issue. A fine of MVR 500–1,000 may be imposed depending on recurrence.
Low Risk	Minor deficiencies that do not pose an immediate risk to patient safety or medicine efficacy but require correction. If not addressed within the specified timeframe, they may escalate to higher risk categories. Corrective action shall be required. Follow-up inspection shall not be routine; however, the Authority reserves the right to conduct one based on the nature or recurrence of the issue.

1. HIGH RISK

The following activities, conditions, practices, or observations identified during inspection shall be categorized as High-Risk, as they may directly compromise medicine quality, patient safety, regulatory control, or public health.

Risk Level	Non-Compliance	Applicable Premise
HR-01	Operating a pharmacy or medicine warehouse without a valid MFDA permit.	Pharmacy & Warehouse
HR-02	Failure to maintain required hygiene standards, including the presence of mold, fungal growth, or other unsuitable conditions for the storage of medicines.	Pharmacy & Warehouse
HR-03	Medicines stored in unapproved areas outside the authorized premises layout.	Pharmacy & Warehouse
HR-04	Expired medicines stored together with non-expired stock.	Pharmacy & Warehouse
HR-05	Storage, sale, or supply of unauthorized or unapproved medicines.	Pharmacy & Warehouse
HR-06	Required air-conditioning or environmental control systems not maintained.	Pharmacy & Warehouse
HR-07	Cold chain products not maintained within 2°C–8°C or temperature monitoring systems not implemented.	Pharmacy & Warehouse
HR-08	Pharmacy operating without an authorized pharmacist, pharmacy assistant, or dispenser on duty.	Pharmacy Only
HR-09	Valid pharmacist identity card not available or pharmacist working with an expired identity card.	Pharmacy Only
HR-10	Dispensing prescription medicines without valid prescriptions or conducting unauthorized medicine-related activities.	Pharmacy Only
HR-11	No minimum 1-hour backup power system for refrigerators storing temperature-controlled medicines	Warehouse Only
HR-12	Required authorization for handling controlled drugs or hospital-use medicines not available or maintained	Controlled Drug Handling Facilities
HR-13	Designated responsible person for controlled drug handling not available	Controlled Drug Handling Facilities
HR-14	Controlled drugs not secured in a lockable or restricted-access storage area	Controlled Drug Handling Facilities

2. MODERATE RISK - LEVEL 2

The following activities, conditions, practices, or observations identified during inspection shall be categorized as Moderate Risk Non-Compliances – Level 2, as they may compromise storage conditions, environmental controls, access restrictions, operational procedures, medicine traceability, or regulatory compliance, without presenting an immediate critical risk to patient safety.

Risk Level	Non-Compliance	Applicable Premise
MR2-01	The premises layout is not in accordance with the MFDA-approved floor plan, and unauthorized modifications have been made	Pharmacy & Warehouse
MR2-02	Evidence of pests, insects, rodents, or related conditions is observed within the premises.	Pharmacy & Warehouse
MR2-03	Water damage, leakage marks, cracks, or other structural defects are observed within the premises.	Pharmacy & Warehouse
MR2-04	Adequate shelving and pallet arrangements for medicine storage are not in place	Pharmacy & Warehouse
MR2-05	Medicines are stored directly on the floor without proper pallets, shelving, or protective measures.	Pharmacy & Warehouse
MR2-06	Medicines are stored in direct contact with walls, ceilings, or other unsuitable surfaces.	Pharmacy & Warehouse
MR2-07	Adequate measures are not implemented to protect medicines from direct sunlight, excessive heat, or other environmental exposure.	Pharmacy & Warehouse
MR2-08	Functional thermometers or temperature monitoring devices required for room and refrigerator storage are not available or not in working condition.	Pharmacy & Warehouse
MR2-09	Temperature monitoring activities are not performed, recorded, or maintained in accordance with regulatory requirements.	Pharmacy & Warehouse
MR2-10	The responsible pharmacist or pharmacy assistant specified in the permit is not working at the premises and no amendment request has been submitted.	Pharmacy Only
MR2-11	Pharmacist identity cards are not visibly displayed during dispensing activities	Pharmacy Only
MR2-12	Foreign pharmacists are working without a translator during duty hours or without a valid Dhivehi competency certificate.	Pharmacy Only
MR2-13	The pharmacy nameboard is not displayed or is not clearly readable from outside the premises.	Pharmacy Only
MR2-14	The pharmacy counter entrance allows unauthorized access to the inside of the dispensing counter area, or adequate access control measures are not implemented.	Pharmacy Only
MR2-15	Prescription-only medicines are displayed or stored in areas easily accessible to customers, resulting in a risk of unauthorized access, misuse, or improper handling of medicines. (Applicable for pharmacy only)	Pharmacy Only
MR2-16	Leftover tablets from cut blister strips, as well as medicines stored outside their original packaging, are not adequately labelled with essential information.	Pharmacy Only
MR2-17	Loose tablets intended for long-term storage are not kept in airtight containers	Pharmacy Only
MR2-18	Standard Operating Procedures (SOPs) related to warehouse operational activities are not readily accessible to warehouse personnel	Warehouse Only
MR2-19	Warehouse operational activities are not performed in accordance with Standard Operating Procedures (SOPs).	Warehouse Only

MR2-20	Adequate access control measures are not implemented within the warehouse, and required signage restricting entry of unauthorized persons is not displayed.	Warehouse Only
MR2-21	A functional fire extinguishing system is not available within the warehouse, or fire extinguishers are expired	Warehouse Only
MR2-22	Controlled drug records are not properly maintained, or no dedicated registry or recording sheet is maintained for controlled drug transactions.	Controlled Drug Handling Facilities
MR2-23	Required stock status reports, sales reports, and supporting blue prescription copies are not properly documented or submitted to the Authority.	Controlled Drug Handling Facilities

3. MODERATE RISK– LEVEL 1

The following activities, conditions, practices, or observations identified during inspection shall be categorized as Moderate Risk Non-Compliances Level 1, as they may affect operational compliance, medicine handling practices, documentation standards, or routine regulatory requirements.

Risk Level	Non-Compliance	Applicable Premise
MR1-01	Minor deviations from the approved floor plan or authorized operational layout are observed within the premises without affecting designated medicine storage areas.	Pharmacy & Warehouse
MR1-02	Lighting within medicine storage or dispensing areas is insufficient to ensure clear visibility and readability of medicine labels and related information.	Pharmacy & Warehouse
MR1-03	There is no designated area for segregation of expired and damaged medicines from non-expired stock, and these medicines are not properly labelled.	Pharmacy & Warehouse
MR1-04	General waste is not properly separated from medicines at an adequate distance.	Pharmacy & Warehouse
MR1-05	The pharmacy name displayed at the premises does not correspond with the name stated on the valid permit issued by the MFDA.	Pharmacy Only
MR1-06	Handwashing or hand sanitization facilities are not available within the pharmacy premises.	Pharmacy Only
MR1-07	Essential medicines required for the applicable level of care are not adequately available within the pharmacy.	Pharmacy Only
MR1-08	Labels attached to medicines during dispensing do not contain essential information including medicine name, strength, dosage instructions, duration of use, and expiry date.	Pharmacy Only
MR1-09	Prescription stamps used during dispensing do not clearly indicate the pharmacy name or are not easily readable.	Pharmacy Only
MR1-10	The latest Approved Drug List is not readily accessible to pharmacists.	Pharmacy Only
MR1-11	Pharmacists are not aware of, or do not use, the Approved Drug List for verification of medicine information.	Pharmacy Only
MR1-12	Adequate patient counselling and provision of necessary medicine information during dispensing are not consistently provided.	Pharmacy Only
MR1-13	Temperature monitoring records are not reviewed and verified monthly by the responsible person as required.	Pharmacy Only
MR1-14	A designated area for segregation of expired controlled drugs pending disposal is not maintained, and appropriate warning notices are not displayed.	Controlled Drug Handling Facilities

4. LOW RISK NON-COMPLIANCES

The following activities, conditions, practices, or observations identified during inspection shall be categorized as low risk, as they are unlikely to immediately compromise medicine quality, patient safety, or regulatory control, but require corrective action to maintain acceptable operational and compliance standards.

No.	Inspection Issue / Non-Compliance	Applicable Location
LR-01	Lighting units within the premises are not maintained in fully functional condition.	Pharmacy & Warehouse
LR-02	Shelves and pallets used for medicine storage are not maintained in a condition that is easily cleanable.	Pharmacy & Warehouse
LR-03	Required “No Smoking” signage is not displayed within the premises.	Pharmacy & Warehouse
LR-04	The pharmacy nameboard does not clearly identify the premises as a pharmacy, as it does not include the terms “Pharmacy” or “Chemist”.	Pharmacy Only
LR-05	The valid MFDA permit is not displayed in a prominent and visible location within the pharmacy premises.	Pharmacy Only
LR-06	Covered dustbins are not available for general waste within the pharmacy premises.	Pharmacy Only
LR-07	No mechanism is in place for medicine price verification, and receipts or bills are not issued with medicines supplied to customers.	Pharmacy Only
LR-08	Medicines are not arranged according to therapeutic classification	Pharmacy Only
LR-09	Documents such as invoices and sales receipts are not maintained for the required retention period or are not readily available during inspection	Pharmacy Only
LR-10	Shelves are not arranged to allow easy access to medicines and appropriate space allocation.	Pharmacy Only
LR-11	The assignment of responsibility for controlled drugs has not been formally documented or notified to the Authority.	Controlled Drug Handling Facilities
LR-12	Import, sales, and stock records of controlled drugs for the required retention period are not properly maintained or readily accessible.	Controlled Drug Handling Facilities

Note:

Risk levels in this guideline are assigned based on the nature, severity, and potential impact of non-compliances. However, the final risk categorization may vary depending on inspection findings, recurrence of violations, public health impact, and the overall compliance status of the premises.

In addition, any non-compliance, condition, practice, or observation identified during inspection that is not specifically listed under the defined risk categories may also be assessed and categorized by the MTG inspection unit based on its potential risk to medicine quality, patient safety, regulatory control, or public health. Appropriate regulatory or enforcement actions may be taken accordingly.