Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

Guideline on Pharmaceutical Inspection

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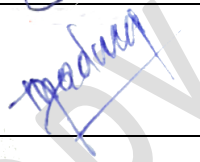
Authorized by	Thooma Adam, Deputy Director General, Laboratory Services (Acting Head of MFDA)	

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 point have been added for better tracking and reporting. amended based on the outcomes of new process changes.	Bishara Ahmed A. Pharmaceutical Officer

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Guideline on Pharmaceutical Inspection

1 INTRODUCTION

The Maldives Food and Drug Authority (MFDA) is responsible for regulating all pharmaceuticals used in the Maldives to ensure public safety. This guideline outlines the measures used in the inspection of pharmacies and medicine warehouses for pharmaceutical products. The criteria in this guideline are based on the requirements of Medicine Regulation No: 2014/R-46 and its first amendment (2016/R-49), ensuring that facilities holding pharmaceuticals operate in accordance with the regulations.

2 PURPOSE

This guideline aims to establish a consistent, risk-based, and transparent approach to pharmaceutical inspections. It assists pharmacy and warehouse management in understanding inspection processes, criteria, and enforcement actions. The primary goal is to ensure high-quality pharmacy practice for the benefit of patients. For the purpose of these guidelines, a pharmacy is defined as premises licensed by the MFDA for the retail sale of medicines. Inspections also serve to enhance systems, services, and patient outcomes.

3 SCOPE

The requirements specified in this guideline are applicable to all pharmacies and medical warehouses that are licensed by the Maldives Food and Drug Authority (MFDA).

4 DEFINITIONS

Pharmaceutical Inspection	A systematic process 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.
Pharmacy	Premises holding a license issued by the Maldives Food and Drug Authority (MFDA) for the sale of medicines by retail.
Warehouse	A facility where pharmaceuticals are stored prior to distribution or sale. It must meet specific regulatory criteria to ensure the safety and efficacy of the stored medicines.
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.
Permit	An official authorization issued by the MFDA allowing a pharmacy or warehouse to operate legally under specified conditions.
Corrective Action Notice	A document issued by inspectors listing the non-compliance issues identified during an inspection and specifying the required corrective actions and timelines.

Self-Assessment Checklist	A tool provided by the MFDA for pharmacy and warehouse owners to assess their own compliance with regulatory requirements prior to registration.
Temperature-Controlled Medicines	Pharmaceuticals that must be stored within a specific temperature range to maintain their efficacy and safety, often requiring refrigeration.
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.
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.
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 Matric	Inspection Metrics are quantitative data points or measurements used to assess the performance, compliance, and quality of inspections across all premises. Tool developed to monitor the effectiveness of inspection processes, identify areas for improvement, and ensure that standards and regulations are being met.
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.
Pharmacist ID Card	An official identification card issued to pharmacists, validating their qualification and authorization to practice in a specific pharmacy.
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.

5 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. Medicine Regulation R-46 (2014)

b. Medicine Regulation Amendment R-49 (2016)

c. Health Service Act (29/2015)

6 RESPONSIBILITY & ACCOUNTABILITY

Pharmaceutical officers of Registration	Responsible for verifying and accepting the documents submitted for registration or renewal of pharmacies and warehouses. They are also responsible for effective communication with the applicant in a timely manner.
Pharmaceutical officers of Inspection	Responsible for conducting inspections to ensure pharmacies and medical warehouses maintain ongoing compliance with relevant regulations. They are responsible for checking and verifying the self-inspection checklist and inspection-related documents submitted by clients before approval. Additionally, they are responsible for effective communication with the applicant in a timely manner.
Health Professionals from atoll health facilities (Regional Inspectors)	Responsible for conducting inspections to ensure that pharmacies and medical warehouses in the atolls maintain ongoing compliance with relevant regulations. They are also responsible for effective communication with the applicant in a timely manner.
Senior Pharmacist (Enforcement Section) & Pharmaceutical Specialist (Medicine Therapeutic Goods Division)	Responsible for approving the pharmacy and warehouse inspection checklists before issuing permits.

7 AIM OF INSPECTION PROCESS

7.1.1 Inspections are intended to help pharmacies and medicine warehouses improve their systems, services, and the quality of care and outcomes for patients and the public using their services. Consistently carrying out these procedures can ensure quality and safety.

7.1.2 To ensure that pharmacies and medicine warehouses operate in accordance with Medicine Regulation No: 2014/R-46 and its first amendment, Medicine Regulation No: 2016/R-49.

7.1.3 To ensure that pharmaceuticals are sold only by authorized entities.

7.1.4 To ensure that pharmaceuticals sold in these facilities are either registered or imported by persons licensed by the Maldives Food and Drug Authority (MFDA).

7.1.5 To ensure that pharmaceuticals and vaccines are stored in accordance with established standards in the Maldives.

Standardizing the actions taken for non-compliance.

8 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.

- **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.
- **Routine Inspections:** These are scheduled inspections carried out to ensure the compliance of pharmacies, and institutions.
- **Follow up Inspections:** It is carried out to double check if the establishment has taken corrective measures for the violations identified during the routine inspections.
- **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 spotted.

All criteria are same for private and government entities in correspondingly.

9 GENERAL PROCEDURES FOR INSPECTIONS

All inspections must follow the procedures outlined below. Specific processes shall be detailed in the relevant procedures.

9.1.1 Upon arrival at the premises, the inspector shall present their identity card to verify their status as an MFDA staff member/inspector and provide a brief explanation of the purpose of the visit.

9.1.2 Pharmacy/warehouse staff shall introduce themselves and provide their pharmacist identification card for further verification.

9.1.3 After completing the inspection, the inspector shall brief the findings to the staff present at the time of inspection and obtain the signature of the pharmacy or warehouse staff on the checklist.

9.1.4 If low-risk issues are identified, it shall be highlighted in the checklist, and the pharmacy/warehouse staff shall be advised to address any issues that can be corrected immediately during the inspection.

9.1.5 Corrective Action Notice (MTG/QA-CN/Fo 0029) shall be issued for the High-risk issues identified during the inspection or major non-compliance. The notice shall specify a time limit for resolving the issues, based on the significance of the non-compliance

10 NEW REGISTRATION INSPECTION PROCEDURE

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

10.1.1 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.

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

10.1.3 Checklist signed by authorized manager or owner should be uploaded to the Dhirithi portal along with relevant documents, while submitting the new request.

10.1.4 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

10.1.5 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.

10.1.6 Upon confirmation of compliance with the submitted checklist and readiness of the premises for operations, the inspection unit shall forward the checklist to the regulation section registration unit within **three working days** to facilitate permit issuance.

10.1.7 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 three working days** and provide clarification for the request to proceed further.

10.1.8 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

10.1.9 The MFDA inspection team shall conduct an unannounced inspection of the premises within 30 days after starting operations.

10.1.10 Owner of the pharmacy or warehouse must send and official email to inspection unit email mtg.inspection@health.gov.mv within **three working days** after starting pharmacy or warehouse operations.

11 PERMIT RENEWAL INSPECTION PROCEDURE

11.1 GREATER MALE' AREA PHARMACIES AND WAREHOUSE PERMIT RENEWAL PROCESS

This process shall be followed for pharmacies and warehouses in the greater male' area only,

11.1.1 The client is required to download the self-assessment checklist (**Checklist 2)** from the Dhirithi portal and complete it for pharmacy and warehouse permit renewals.

11.1.2 The steps outlined in sections **10.1.1 to 10.1.9** must be followed in this procedure.

11.2 ATOLL PHARMACIES & WAREHOUSES PERMIT RENEWAL PROCESS

This process shall be followed in the atoll pharmacies and warehouses

11.2.1 Inspections at the atoll level are carried out by registered health professionals from the public health unit under the Ministry of Health.

11.2.2 Upon receiving a request from the licensing unit, the inspection team shall send an inspection request, checklist, and required documents to atoll health facilities within **three working days.**

11.2.3 Atoll health facilities shall email the completed inspection checklist to the MTG with in **ten working days** after completing the inspection process.

11.2.4 The Inspection unit shall review the checklist. If compliant, MTG inspectors shall finalize the checklist with written approval and forward it to the regulation section within **three working days** to process permit.

11.2.5 If any non-compliances are mentioned in the checklist, the Inspection unit staff shall issue a Corrective Action Notice (MTG/QA-CN/Fo 0029) for the non-compliance identified within **three working days.**

11.2.6 Upon receiving the notice from the Inspection unit, the responsible regional inspector shall deliver the notice to the pharmacy or warehouse.

11.2.7 A follow-up inspection shall verify if corrective actions were taken.

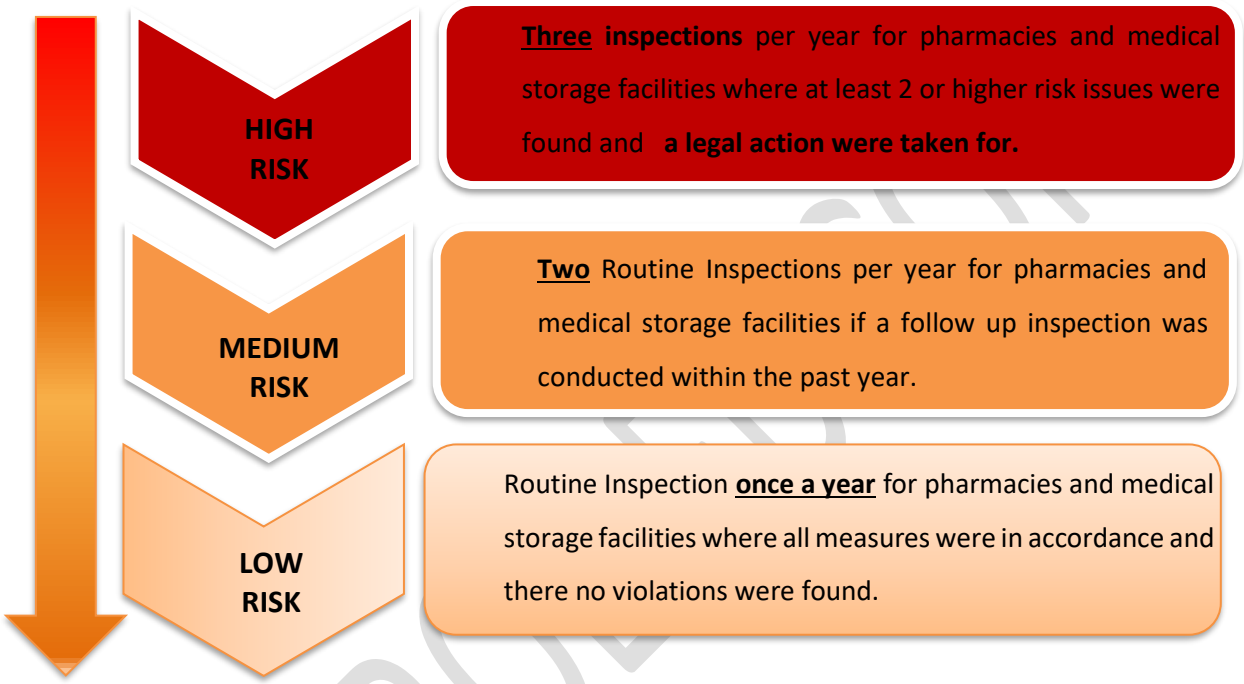
11.2.8 If everything is in compliance during the follow-up inspection, the Inspection unit shall evaluate and hand over the inspection checklist to the regulation section within **three working days** to issue the permit.

11.2.9 If corrective actions are not completed by the time of the follow-up inspection, the owner shall be notified via the Dhirithi portal. The registration unit shall also be informed to reject the request.

11.2.10 The owner must then address the non-compliance issues, implement the necessary corrections, and submit a new registration request

12 ROUTINE INSPECTION PROCEDURE

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



12.1.1 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.

12.1.2 The inspection teams do not need to provide prior notice for pharmacy/warehouse inspections. However, the warehouse in-charge can be contacted to open the warehouse at the time of the visit.

12.1.3 At the end of the inspection, if any major non-compliance is identified, inspectors shall provide a Corrective Action Notice (which shall specify the time allotted for correcting the issues based on their severity) to the person in charge who is present during the inspection. Minor issues shall be communicated for immediate correction without the need for a corrective action notice.

12.1.4 If the premises are found unsatisfactory during the routine inspection, a follow-up inspection shall be carried out according to the procedure.

13 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.

13.1.1 After addressing non-compliances listed in the Corrective Action Notice, pharmacy and warehouse owners must notify MTG of the completion of corrective actions via email or through portal.

13.1.2 Follow-up inspections should be conducted within **seven working days** upon receipt of the confirmation email from the pharmacy and warehouse owner.

13.1.3 If the client fails to inform MTG after taking corrective action, an inspection shall be scheduled within **seven days** of the initial inspection.

13.1.4 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.

13.1.5 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.

13.1.6 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.

14 PROCEDURE FOR IMMEDIATE CESSATION OF PHARMACY AND WAREHOUSE PERMITS

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

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

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

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

14.1.4 If any premise condition is found to pose a high risk that could impact the public health of patients. In this situation inspectors shall obtain approval from the Section/Division Head.

15 TAKING LEGAL ACTIONS

15.1.1 Below are the legal actions that could be taken:

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.

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

15.1.3 The inspection unit shall conduct a meeting with pharmacy and warehouse owners or pharmacists to discuss the violations and outline the proposed legal actions.

15.1.4 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.

15.1.5 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.

15.1.6 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.

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

15.1.8 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.

15.1.9 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.

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

Non-compliance risk level correlation to public health risk

- Inspectors use a risk-based approach to assess pharmacy compliance against each inspection criterion. Risk levels correlate with the potential risk to the efficacy and safety of medicines, arising from non-compliance.
- Enforcement action shall be taken when there is a risk of harm to people or when registered pharmacies repeatedly fail to meet regulatory standards.

Level of Risk	Description
Low Risk	Does not pose an imminent risk of harm to patient safety and efficacy of medicine, but does require correction (may become an imminent public health risk if not corrected within specified timeframes). **Based on the risk of harm to patient, the responsible person shall be penalized with a fine of 500 MVR.**
Medium Risk	May cause harm to patient safety and efficacy of medicine in relation to public health and requires immediate rectification. **Based on the risk of harm to patient, the responsible person shall be penalized with a fine of 1000 MVR.**
High Risk	Poses an imminent, serious public health risk that requires immediate rectification and may require immediate enforcement action. **Based on the risk of harm to patient, the responsible person shall be penalized with a fine of 2000 MVR, and based on repetitiveness, the permit may be suspended for a period not exceeding 14 (fourteen) days.**

16 COMPLETION OF INSPECTIONS

16.1.1 The inspection is considered complete when no issues are identified, or all identified issues have been corrected.

16.1.2 If the inspection findings are in compliance with applicable regulations, no formal report shall be prepared. Instead, the inspection shall be marked as complete by finalizing the verification and authorization sections of the checklist.

16.1.3 At the beginning of each calendar year, the inspection unit shall prepare and publish inspection metrics based on the findings from the previous year's inspections. These metrics shall be made publicly available to ensure transparency, while adhering to national confidentiality requirements.

CRITERIA FOR NEW REGISTRATION

REQUIREMENTS FOR NEW PHARMACY REGISTRATION

1. Floor Plan Submission: A detailed floor plan of the pharmacy/warehouse is required for approval. The premises must accurately match the submitted drawing.
2. The floor plan of the pharmacy should include the following details:
   a. All measurements, including square footage
   b. Locations of key features such as the counter, air conditioning unit, main door, windows, partitions, etc.
   c. Exact location of the pharmacy (e.g., floor number, building name, area).
3. Floor Area Requirements
   a. Minimum 100 square feet for pharmacies located outside health facilities.
   b. Minimum 75 square feet for pharmacies located inside health facilities.
   c. Minimum 200 square feet for medicine warehouses.
4. Pharmacy Name Board: The pharmacy name must be clearly displayed outside in both Dhivehi and English. If the name does not indicate that it is a pharmacy, the word "pharmacy" or "chemist" must be included in either language.
5. The premises must be air-conditioned, with a system adequate to maintain a temperature below 25°C for the entire floor area.
6. The pharmacy must have a functioning refrigerator to store temperature-controlled medicines in accordance with the manufacturer's recommended temperature.
7. A functioning thermometer must be available to monitor both the room temperature of the premises and the temperature inside the refrigerator.
8. Adequate counter space must be provided for dispensing medicines, with a design that prevents customers from accessing medicines stored on shelves.
9. The counter area must be restricted to owners and authorized staff only.
10. The premises should have sufficient racks for medicine storage. These racks must be easily cleanable and well-organized.
11. As per Act No. 15/2010 (Tobacco Control Act), a "No Smoking" sign, including the act number, must be prominently displayed in the premises.
12. Adequate lighting (lights or bulbs) must be installed to ensure sufficient illumination throughout the premises.

13. The premises should be constructed in a manner that prevents the entry of rodents such as rats and mice.
14. The walls, ceiling, and floor of the premises should be constructed with materials that do not promote moisture buildup.
15. The stamp used on prescriptions must clearly display the pharmacy's name.

REQUIREMENT FOR WAREHOUSE REGISTRATION

1. A detailed floor plan of the warehouse is required for approval. The premises must accurately match the submitted drawing.
2. The floor plan of the pharmacy should include the following details:
    a. All measurements, including square footage
    b. Locations of key features such as the medicine racks, main door, windows, partitions, etc.
    c. Exact location of the warehouse (e.g., floor number, building name, area).
3. Floor Area Requirements: Minimum 200 square feet for medicine warehouses.
4. warehouse premise must be fully access-controlled, permitting entry only to owners and authorized staff, except when necessary for item handling.
5. The warehouse should have sufficient racks for medicine storage. These racks must be easily cleanable and well-organized
6. No Smoking Sign: As per Act No. 15/2010 (Tobacco Control Act), a "No Smoking" sign, including the act number, must be prominently displayed in the premises
7. A fire extinguishing system must be installed in the warehouse.
8. The premises must be air-conditioned, with a system adequate to maintain a temperature below 25°C for the entire floor area.
9. A functioning thermometer must be available to monitor both the room temperature of the premises and the temperature inside the refrigerator.
10. The warehouse must have the following Standard Operating Procedures (SOPs):
    a. Stock Record Management: SOP for managing the storage and distribution of medicines.
    b. Expired Drug Segregation and Disposal: SOP for timely segregation, storage, and disposal of expired drugs.
    c. Warehouse Cleaning and Pest Control: SOP for maintaining cleanliness and pest control.
    d. Drug Recall Procedures: SOP for managing product drug recall processes.
    e. Temperature Management Protocols: SOP for managing temperature control and reporting deviations promptly.

CRITERIA FOR PERMIT RENEWAL & ROUTINE INSPECTIONS

FOR PHARMACIES

1. No changes should be made to the floor plan approved by the relevant authority, as submitted with the Pharmacy Authorization Permit.
2. The non-expired Pharmacy Authorization Permit shall be prominently displayed within the pharmacy.
3. The name on the Pharmacy Authorization Permit must match the pharmacy name displayed as name board of the pharmacy.
4. The pharmacy counter area must be access-controlled, and not accessible to customers without authorization.
5. A visible notice must be displayed inside the pharmacy indicating that the counter area is for authorized personnel only.
6. The pharmacist must possess a valid (non-expired) pharmacist ID card. The pharmacist's ID card must be visibly displayed on their clothing or uniform.
7. The pharmacist working in the pharmacy must have Pharmacy-Specific ID card.
8. A translator must be present during the shift of a foreign pharmacist or when a Dhivehi competency exam completion certificate is required.
9. The stamp used on prescriptions must clearly display the pharmacy's name.
10. The latest approved drug list should be easily accessible to pharmacists, who must be able to verify medicines from the list.
11. Unapproved medicines that are not listed in the Approved Drug List shall not be stored or sold in the pharmacy.
12. All medicines categorized as essential for pharmacies must be available.
13. When selling prescribed medicines, the attached label must include all required mandatory information.
14. A designated area must be allocated for storing damaged and expired medicines until disposal, and it must be appropriately labeled.
15. The air conditioning system must be in proper working condition to maintain a temperature below 25°C.
16. Medicines requiring temperature control should be stored in a refrigerator at the manufacturer's recommended temperature.
17. The pharmacy and refrigerator temperatures should be maintained and recorded daily. These records must be reviewed monthly by the responsible person in the pharmacy, and the records should be sent via mail every 3 months.

18. Medicines on the counter and shelves must not be accessible to customers.
19. Adequate number of shelves must be available for storing medicines. No medicines should be stored directly on the floor.
20. Medicines stored on shelves should not touch the walls or ceiling.
21. Regular maintenance and renovation of the pharmacy building must be conducted, ensuring the absence of pests or signs of pest activity.
22. The pharmacy's floor, walls, and ceiling must be free from any water leakage or damage.
23. Medicines must be arranged according to their therapeutic class, and medicines intended for long-term storage should be kept in airtight containers.
24. Loose, cut pieces of medicines or those kept outside their original packaging must be properly labeled, including the medicine name, strength, batch number, and expiry date.
25. The prices of medicines must be clearly displayed, and a payment receipt must be issued after each purchase.
26. A dustbin with a lid must be available for waste, and waste disposal must be kept separate from medicine stock.
27. In accordance with the Tobacco Control Act (Act No. 15/2010), a "No Smoking" sign, including the Act number, must be displayed in the pharmacy.
28. Appropriate measures must be taken to protect medicines stored on shelves from direct sunlight.

Controlled Drug Requirements:

a. Purchase Authorization: A valid "Purchase Authorization" for controlled drugs must be obtained.
b. Separate Storage: Controlled drugs must be stored separately in a lockable cupboard or drawer.
c. Controlled Drug Register: A separate register (book) must be maintained for controlled drugs records.
d. Stock Status Report: A controlled drugs stock status report must be submitted every 3 months.
e. Storage of Expired or Damaged Controlled Drugs: Expired and damaged controlled drugs must be stored separately in locked cupboards.
f. Responsible Person for Controlled Drugs: There must be a designated registered person responsible for managing controlled drugs.

FOR WAREHOUSE

1. The warehouse should have the following Standard Operating Procedures (SOPs):

    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.

2. No changes should be made to the floor plan approved by the relevant authority, as provided with the Authorization Permit.
3. Warehouse access must be restricted, and a "No Admittance Without Permit" notice should be prominently displayed
4. Documents such as invoices and sales receipts must be maintained for a minimum of 2 years and should be readily available for inspection upon request.
5. The air conditioning system must be in proper working condition and should maintain a temperature below 25°C.
6. Temperature-sensitive medicines should be stored in a refrigerator at the manufacturer's recommended temperature. The refrigerator must be equipped with at least 1 hour of backup power.
7. Warehouse and refrigerator temperatures must be recorded daily. These records should be reviewed and verified monthly by the responsible person.
8. Temperature records must be submitted every 3 months via email to the relevant authorities.
9. A designated area should be available for storing damaged and expired medicines, clearly labeled, until they are disposed of properly.
10. Shelves should be organized to allow easy access to medicines and avoid overcrowding.
11. Medicines should never be stored directly on the floor. Sufficient shelves or pallets should be provided to ensure proper storage.
12. Separation from Walls and Ceiling: Medicines stored on shelves or pallets must not come into direct contact with the walls or ceiling to allow proper air circulation.
13. Regular maintenance and renovation of the warehouse building should be carried out to ensure it remains in optimal condition.
14. The floor, walls, and ceiling of the warehouse should be free from any water damage or leaks.
15. Pest Control: The warehouse should be constructed and maintained to prevent any pest entry.
16. There should be no visible signs of pest infestation or pest entry on the warehouse premises.
17. In compliance with Act No. 15/2010 (Tobacco Control Act), a "No Smoking" sign must be clearly displayed in the warehouse.
18. Fire prevention measures, including fire extinguishers and evacuation plans, must be established and clearly communicated within the warehouse.