Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

Guideline on Pharmaceutical Inspection

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Ms. Thooma Adam
Deputy Director General

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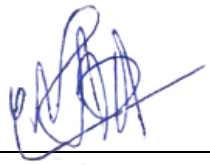
Prepared by:
Assistant Pharmaceutical Officer
Bishara Ahmed

Approved by: **Ms. Aishath Mohamed** **Deputy Director General, Pharmaceuticals** **Maldives Food and Drug Authority**		23.06.2022
Authorized by: **Ms. Thooma Adam** **Deputy Director General, Laboratory Services** **Maldives Food and Drug Authority**		23.06.2022

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1 INTRODUCTION

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

2 PURPOSE

This guideline has been developed to ensure a consistent, risk based and transparent approach to pharmaceutical inspections. The Guide is designed to assist management of pharmacies and medicine warehouse, about pharmaceutical inspection processes, criteria and enforcement actions.

Purpose of these guidelines is to ensure the quality of the pharmacy practice for the benefit of patients. For the purpose of these guidelines, pharmacy is defined as premises holding a license issued by the Maldives Food and Drug Authority (MFDA) for the sale of medicines by retail.

Inspections are also intended to help pharmacies and medical warehouse to improve their systems and services, the quality of care and the outcomes for patients and the public using their services.

3 SCOPE

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

4 RESPONSIBILITY AND ACCOUNTABILITY

1. Pharmaceutical Officers
2. Director, Pharmaceuticals (Enforcement Section)
3. Deputy Director General (Medicine Therapeutic Goods Division)
4. Director General (MFDA)

5 GUIDELINE CONTENT

5.1 TYPES OF INSPECTIONS CARRIED OUT

- 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 carried out in cases where prior inspection is 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.

5.2 NEW PHARMACY / WAREHOUSE REGISTRATION INSPECTION

5.2.1 AUTHORIZATION INSPECTION PROCEDURE

- Inspection shall be conducted within seven working days after receiving request with all relevant documents.
- Inspection should be conducted to verify the condition of the premises.
- If everything is in compliance during inspection and the premise is ready for services, Inspection unit shall handover inspection report to regulation section within 3 working days to issue permit.
- If not, the owner shall be informed through Dhirithi Portal to prepare the premises before inspection and once the owner informs the premise is ready, follow up inspection shall be conducted.
- Inspections at atoll level, is carried out through public health unit in health facilities under the Ministry of Health and Inspection unit shall coordinate and send request email to atoll health facilities with necessary check list and other documents required for inspection within 3 working days.

- For new permit approvals or permit renewals, a copy of the report shall be uploaded to the dhirithi portal.

5.2.2 CRITERIA FOR NEW PHARMACY / WAREHOUSE

a) Drawing (floor plan) which shows the floor area of the pharmacy / warehouse for approval and premise should align with submitted drawing.

b) Floor Area shall have minimum
   - ✓ Minimum 100 square feet if the pharmacy is located in outside the health facility.
   - ✓ Minimum of 75 square feet for the pharmacies located inside the health facilities
   - ✓ Minimum 200 square feet for medicine warehouse.

c) Pharmacy name board should be displayed on outside the pharmacy in Dhivehi and English language. ("pharmacy" or "chemist" shall be written either English or Dhivehi language If the name of the pharmacy does not evident, from the name itself that it is a pharmacy)

d) Premise should be air conditioned and air conditioner should adequate for floor area to maintain temperature below 25 (twenty five) degrees Celsius.

e) There must be a functioning thermometer that shows the temperature of the premise.

f) Adequate counter should be there to dispense medicine and counter should design in a way that prevents access to medicine displayed on shelves to customers.

g) Entrance to the counter shall be restricted for everyone except owners and staffs.

h) The premises shall have sufficient racks to keep medicine and racks shall be easily cleanable and in a manner

i) As per act no 15/2010 (Tobacco Control Act) "No Smoking" sign / notice with act number must be displayed in premise.

j) Should have enough lights or bulbs inside the premises for adequate lighting.

k) Premises should be in a manner that prevents entry of rodents such as rats and mice.

l) Walls and floor should be cemented and painted with a light color or something such as cladding used after constructed and cemented.

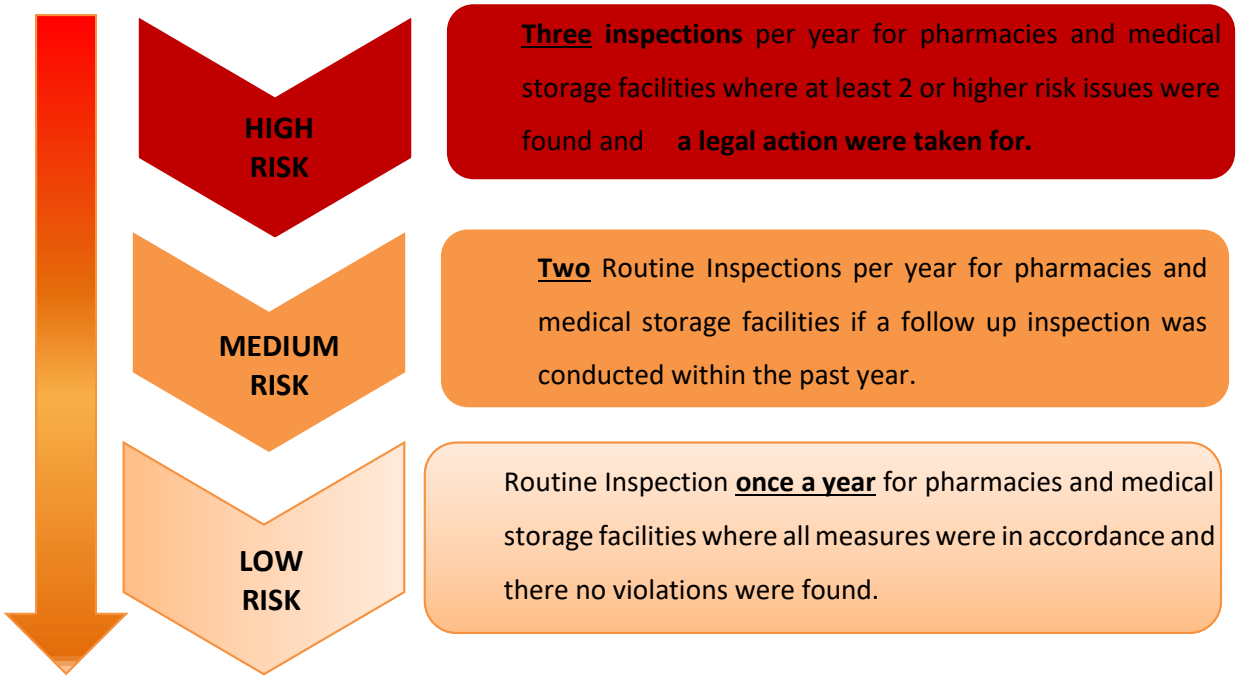
m) Premise walls, ceiling and floor of the premise should be prepare with material that does not cause moisture.

n) Warehouse should be fully access controlled and no one except the owners and staff of the warehouse shall be allowed inside the warehouse except to take items inside or outside the warehouse

o) A fire extinguishing technique should be installed in the warehouse.

5.3 ROUTINE INSPECTION PROCEDURE

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



5.3.2 Routine inspections shall be conducted as per the schedule approved by DDG at the start of the year and all registered pharmacies and warehouses shall be inspected .

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

5.3.4 At the end of the inspection, if any incompliance identified during the inspection inspector's shall provide Corrective Action Notice to the person in charge who is present in the time of inspection.

5.3.5 Time for correcting the issues shall be given depending on the severity of non-conformity.

5.3.6 If the premises were found to be unsatisfactory in the routine inspection, a follow up inspection shall be carried out as per the procedure.

5.4 PROCEDURE FOR FOLLOW UP INSPECTION

5.4.1 In this inspection the usual purpose is to verify if the issues identified in the initial inspection has been corrected within the time given in the notice. However, inspectors shall also take the responsibility to inspect for any ongoing visible violations.

5.4.1.1 After taking the corrective actions for non-compliances identified in Corrective Action Notice, pharmacy and warehouse owner should inform to MTG the completion of corrective actions through e-mail.

5.4.1.2 Follow up inspection should be completed within working 7 days upon after receiving confirmation e-mail from pharmacy and warehouse owner.

5.4.1.3 If client fails to inform after taking corrective action, inspection shall be carried out within 15 (fifteen) days after initial inspection.

5.4.1.4 If the issues were not rectified, if it is appropriate, the inspection team can allow the client a second chance to rectify the issues.

5.4.1.5 If the identified issues require immediate action to be taken, consider and take the appropriate action for the situation.

5.4.1.6 If inspection team finds the present condition worse than in the previous inspection, a 3rd follow up inspection shall not be conducted. The process shall be restarted with a full inspection.

5.4.1.7 Inspections unit shall coordinate with regional health facilities to conduct follow up Inspection of atoll pharmacies and warehouse, by providing required necessary check list and other documents required for inspection.

5.5 IMMEDIATE CESSATION OF PERMIT

5.5.1 Under the following conditions notice to immediately halt operations (shutdown) shall be issued if any of the following conditions are met.

5.5.1.1 Pharmacist found to be working without the identity card; exceptions can be considered if the card is under the process of renewal.

5.5.1.2 No permits for operations or invalid permit; exceptions can be considered if the permit is under process for renewal or extension.

5.5.1.3 If the pharmacy/warehouse is found conducting other operations other than what was permitted.

5.6 TAKING LEGAL ACTIONS

5.6.1 Below are the legal actions that could be taken:

- Advice and giving a period for rectification.
- Imposing a fine between MVR 500 (five hundred Maldivian Rufiyaa) and MVR 2000 (two thousand Maldivian Rufiyaa)
- Suspension of the permit for a period not exceeding 14 (fourteen) days.
- Filing the case at court.

5.6.2 Depending on the magnitude of the violations on the medicine regulation, further legal actions shall be taken against the violations immediately after the final report.

5.6.3 The legal can only be taken with the written approval of division head. **Procedure shall complete within 07 working days.**

5.6.4 If any legal action taken against registered pharmacist, his /her details will be shared with Maldives Allied Health Council.

5.6.5 Written advice note to Owner / Pharmacist / Pharmacy Assistant /Dispenser shall be issued.

5.6.6 If fine is issued the personnel has to complete the payment within 03 (three) working days, through Bandeyri Pay portal with the reference number of the Advice notice. The amount for pay is allocated on the advice notice.

5.6.7 If the client fails to pay the fine within the given time, client shall be reminded to complete the payment via email. If payment is not completed within 07 (seven) days further action will be taken.

5.6.8 Non-compliance risk level correlation to public health risk

5.6.8.1 Inspectors use a risk-based approach to assessing pharmacy compliance against each of the inspection criteria. Risk levels correlate with the potential risk to efficacy of medicine patient and safety arising from the non-compliance.

5.6.8.2 Enforcement action shall be taken when people are at risk of harm or registered pharmacies are repeatedly failing to meet regulation 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, advice is offered, and the responsible person shall penalize with a fine 500MVR.
Medium Risk	May cause harm to patient safety and efficacy of medicine in relate to public health and requires immediate rectification. Based on the risk of harm to patient, advice is offered and the responsible person shall penalize with a fine 1000MVR.
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 penalize with a fine 2000MVR and based on repetitiveness the suspension of the permit for a period not exceeding 14 (fourteen) days.

5.7 SUSPENSION OF PERMIT

5.7.1 A letter with details of the violations and a copy of inspection report shall be issued to pharmacy/warehouse owner to halt all services for the given suspension period.

5.7.2

5.7.3 Pharmacy or warehouse owner should take corrective measures and inform MTG in writing. Inspection unit shall then conduct an inspection before the end of the suspension period. If everything is in compliance pharmacy or warehouse will be informed through a letter to restart services once the suspension period is over.

5.7.6 If the pharmacy or warehouse provides service during the suspension period, the period shall be further extended depending on the case.

5.8 REQUIREMENTS FOR PERMIT RENEWAL & ROUTINE INSPECTIONS

5.8.1 FOR PHARMACIES

5.8.1.1 No changes should bring to the floor plan approved by this authority which was given with Pharmacy Authorization Permit.

5.8.1.2 Has displayed non-expired Pharmacy Authorization Permit shall be displayed.

5.8.1.3 Name in "Pharmacy Authorization Permit" and pharmacy name board matches and pharmacy name board shall be displayed and is visible from outside.

5.8.1.4 Pharmacy counter area shall be access controlled and is not accessible to customers without permit.

5.8.1.5 There should be a visible notice inside the pharmacy stating that counter area is only accessible to those with a permit.

5.8.1.6 Pharmacist shall have valid (not expired) pharmacist ID card.

5.8.1.7 Pharmacist ID card shall displayed on pharmacists clothes or uniform

5.8.1.8 Pharmacist working in pharmacy shall have ID card permitted to work in this pharmacy.

5.8.1.9 Translator shall present in pharmacy during the shift of a foreign pharmacist

5.8.1.10 Stamp used on prescription shall have pharmacy name clearly visible.

5.8.1.11 Latest approved drug list should be there in easily accessible manner to pharmacist and pharmacist shall aware how to check details of medicine from approved drug list.

5.8.1.12 Unapproved medicines which are not included in Approved Drug List shall not kept and sold in pharmacy.

5.8.1.13 All medicines which are categorized as essential for pharmacies shall be available in pharmacy

5.8.1.14 When selling prescribed medicine, the details on the attached label shall include all required mandatory information's

5.8.1.15 Designated area should be allocated for damaged and expired medicine until disposal time and shall label appropriately.

5.8.1.16 Air conditioner should be in proper working condition for maintaining temperature below 25 degree Celsius.

5.8.1.17 Temperature controlled medicines should be kept in refrigerator with manufacture's recommended temperature

5.8.1.18 Pharmacy temperature and refrigerators temperature should be monitored and recorded regularly.

5.8.1.19 Medicine kept in counter area and shelves should not be accessible to customers

5.8.1.20 Appropriate amount of shelves should be available to keep medicines and no medicines should kept on the floor

5.8.1.21 Medicine kept on the shelves should not touching against walls and ceiling

5.8.1.22 Maintenance and renovation should be done on pharmacy building regularly

5.8.1.23 Pharmacy floor, walls and ceiling should not have any sign of damage from water

5.8.1.24 Pharmacy building should not have any signs of pests.

5.8.1.25 Medicines should be arrange according to therapeutic class and medicines for long term storage should be stored in airtight containers

5.8.1.26 Loose and cut pieces of medicines and medicines kept out from original box should be labeled properly (with medicine name, strength, batch number and expiry date)

5.8.1.27 Price of medicines should be displayed and payment receipt should be issue after purchase

5.8.1.28 Dustbin with lid should be available and waste disposal should kept separately from medicine stock.

5.8.1.29 As per act no 15/2010 (Tobacco Control Act) "No Smoking" sign / notice with act number should displayed in pharmacy

5.8.1.30 Appropriate measures should take to protect medicines on shelves from direct sunlight

5.8.1.31 If pharmacy has controlled drugs, the below mentioned conditions must be met

a) Should have "Purchase Authorization" for controlled drugs
b) Controlled drugs must be stored separately in lockable cupboard / drawer.
c) Should have separate register (book) for controlled drugs records
d) Should submit controlled drugs stock status report every 3 months

e) Expired & Damaged controlled drugs should be keep separately in locked cupboards

f) Should have specific registered person to take responsibility for controlled drugs.

5.8.2 FOR WAREHOUSE

5.8.2.1 No changes should bring to the floor plan approved by this authority which was given with Authorization Permit.

5.8.2.2 Warehouse access should be controlled and “no admittance without permit” notice should be displayed.

5.8.2.3 Documents such as invoices and sales receipts shall be maintained for a period of not less than 2 (two) years should available.

5.8.2.4 The following standard operation procedure should be there in warehouse.

- S.O.P for receiving and storing (stock records) of medicine
- S.O.P for Storing expired and damaged medicine before disposal.
- S.O.P for cleaning and pest control.

5.8.2.5 Air conditioner should be in proper working condition for maintaining temperature below 25 degree Celsius.

5.8.2.6 Temperature controlled medicines should be kept in refrigerator with manufacture's recommended temperature and Refrigerator should have atleast 1 hour backup power.

5.8.2.7 Temperature of the warehouse and refrigerator should be maintained and recorded daily and these records should be checked and verified by the responsible person of the warehouse monthly.

5.8.2.8 Designated space should be available for damaged and expired medicine until disposal time and that space should be labeled appropriately

5.8.2.9 Shelves in the warehouse should be arranged in a way that medicine can be easily accessible.

5.8.2.10 There must be sufficient amount of shelves or pallets and no medicine should be kept on the floor.

5.8.2.11 Medicines kept on the shelves / pallets should not touch against walls and ceiling.

5.8.2.12 Maintenance and renovation should be done on warehouse building regularly.

5.8.2.13 Warehouse floor, walls and ceiling should not have any damaged or affected with water

5.8.2.14 Warehouse building is not accessible to pests

5.8.2.15 The warehouse premises shall not have any sign of entry of pests.

5.8.2.16 As per act no 15/2010 (Tobacco control act 15/2010) "No Smoking" sign is displayed in Warehouse

5.8.2.17 Fire prevention counter measures should be established in the warehouses

5.9 AIM OF INSPECTION PROCESS

5.9.1 Inspections are intended to help pharmacies / medicine warehouses to improve their systems and services, the quality of care and the outcomes for patients and the public using their service. Through consistently carrying out the procedure, it can guarantee the quality and safety.

5.9.2 To ensure that Pharmacies and medicine warehouse are operated in accordance to Medicine Regulation No: 2014/R-46 and first amendment to the Medicine Regulation No 2016/R-49.

5.9.3 To ensure that pharmaceuticals are sold by authorized persons (entities).

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

5.9.5 To ensure that pharmaceuticals and vaccines are stored in places and under conditions as per the established standards in Maldives.

5.9.6 Standardizing the actions undertaken for non-compliance.

6 References

- Health Service Act 29/2015
- Medicine Regulation R-46/2014
- Amendment of Medicine Regulation R-49/2016