Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

Guideline for Regulation of Veterinary Medicines import and Pharmacy registration

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Guideline for Regulation of Veterinary Medicines Import and Pharmacy registration is released under the authority of

Ms. Thooma Adam
Deputy Director General

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Maldives Food and Drug Authority
Male'
Republic of Maldives

Prepared by:
Pharmaceutical Officer
Fathimath Azma Ismail

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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Guideline for Regulation of Veterinary Medicines import and Pharmacy registration

1 INTRODUCTION

This procedure establishes the manner in which the Medicine and Therapeutic Goods Division (MTG) of Maldives Food and Drug Authority (MFDA) processes registration of veterinary pharmacies and approval of Veterinary medicines to ensure that the veterinary pharmacies are registered, and the medicines are approved before the product is imported to Maldives.

2 PURPOSE

This guideline is aimed to inform public and stakeholders of the process, and requirements for approval of Veterinary Medicines for sale and use in the Maldives also, to ensure veterinary pharmacies in the Maldives are registered.

I. Ensure approval of Veterinary medicines for animals before import to ensure the safety, efficacy and quality of the products imported

II. Ensure that veterinary medicines imported and sold within the Maldives are registered and included in the Approved Veterinary Medicines List of the Maldives Food and Drug Authority

II. Ensure that the Vet pharmacies are registered and licenced and operates as per the regulation and the guideline.

III. Ensure that the Veterinary medicines imported, sold and used in the Maldives are approved and updated in the Veterinary Medicines List of Maldives Food and Drug Authority.

IIII. Ensure medicine is sold by pharmacies in the Maldives are registered, licensed and operates in accordance with the regulation

3 Scope

This guideline applies to the process for veterinary medicine registration, from submission of application, evaluation and issue of permit.

4 Responsibility and Accountability

- Director General shall be responsible for authorizing the addition or modification of medicines and deletion of medicines from the VET LIST.
- Deputy Director General (DDG), Pharmaceuticals shall be responsible for approving documents submitted for approval to import Veterinary medicines.
- Director, Pharmaceuticals of Regulation section shall be responsible for verification of Product checklists and approving of veterinary approvals.
- Pharmaceutical Officers of MTG involved in veterinary approval process shall be responsible for following the procedure and preparing the documents and updating the records.

5 Guideline Contents

5.1 What are Veterinary Medicines?

5.1.1 Veterinary Medicines are medicines which have therapeutic indications based on clinical research and are used in veterinary, concerned with the prevention, control, diagnosis, and treatment of diseases affecting the health of domestic and wild animals and with the prevention of transmission of animal diseases.

5.2 Who can apply to import Veterinary Medicines?

5.2.1 Veterinary Medicines shall be imported by a Registered Veterinary Medicine importer.

5.3 Procedure to Import Veterinary Medicine

5.3.1 New Veterinary Medicine Importer Registration

5.3.1.1 The application form "Veterinary Medicine Importer Registration "shall be completed and submit along with all the required documentations and to MFDA via email to mfda.admin@health.gov.mv and cc: to mtg@health.gov.mv

a. Registration of Business Activity from Ministry of Economic and Development
b. Copy of National ID card (if an individual)
c. Company registration certificate of Ministry of Economic Development (if applicant is a company)
d. Copy of Medicine warehouse registration certificate (from City Council / Respective government authority)
e. Floor plan of the storage with the below requirements
    - All Measurements of the warehouse including square feet of the premises
    - Details of the exact location of the warehouse (example: which floor of the building, which building and located in which area etc.)
    - The floor area of medicine storage shall be minimum (size?) square feet.

5.3.1.2 Incomplete applications will be rejected within working 05 days

5.3.1.3 Application for renewal shall be submitted before 14 working days of the expiry of the registration.

- Previously issued medicine warehouse registration to import medicine issued by this Authority with the documents mentioned in 5.11

5.3.1.4 If all the documents are completed the inspection will be scheduled and inspection to be completed within 05 working days.

5.3.1.5 If requirements are fulfilled from the inspection Medicine Importer Registration permit will be issued within 05 working days.

5.4 Requirements for importing veterinary medicine.

5.4.1 Request to Import Veterinary Medicine with the documentation shall email to mfda.admin@health.gov.mv and cc: to mtg@health.gov.mv with product information requesting to import any veterinary product. This shall include the following detailed information of the product.

a. Product information (including generic name, brand, indication, strength, volume, dosage form, and side effects) shall be submitted.

b. GMP (Good Manufacturing Practice)/ Veterinary medicine registration certificate

c. **Product label:** The label information should be English. The following minimum information should be available on the label:

- Brand Name
- Generic Name/ Active ingredient
- Dosage Form
- Strength
- Batch or Lot Number
- Storage condition
- Full address of manufacturing site
- Pack Size
- Warning/precaution if any

d. Veterinary medicine importer's registration certificate

5.5 Evaluation process

5.5.1 If the required information is complete, the application is complete it shall be processed for as below:

- Verification (within 02 working days)
- Evaluation (within 08 working days)
- Approval (within 02 working days)

5.5.2 If the application or the documentations are incomplete or illegible, the request will be rejected, and the importer shall make a new request with complete documents.

5.5.3 If the importer wishes to include the medicine in approved veterinary medicine list GMP (Good Manufacturing Practice) and Veterinary medicine registration certificate shall be submitted.

5.5.4 If GMP / medicine registration certificate is unavailable one-time approval will be issued

5.5.5 Based on the evaluations and technical advice approval will be issued for a period of one year.

5.5.6 Permit for approving the import of Veterinary Medicine shall be issued to the client within 10 working days from the request submission.

5.5.7 A copy of authorization shall be sent to client and MFDA port control unit via email.

5.6 Approved veterinary medicine list

5.6.1 If the products are in the Approved Veterinary List, it can be imported without further authorization, hence invoice shall be submitted prior to 72hours to MFDA port control unit.

5.6.2 Products which have a valid Good Manufacturing Practice GMP / medicine registration certificate are added to Approved Veterinary List

5.6.3 If the requested product is not included in the Approved Veterinary List, MFDA shall do further evaluations and get technical advice from relevant authorities.

5.6.4 Technical Committee of Medicine and Therapeutic Goods will make the final decision for the product to be added to Approved veterinary medicine list

5.7 Add new products to veterinary medicine list

5.7.1 MFDA shall do product evaluation and verify the documents mentioned in 7.0.

5.7.2 If the required documents (Good Manufacturing Practice GMP / medicine registration certificate) is submitted, permit will be issued for 01 year validity and the product will be added to the Approved Veterinary Medicine List.

5.7.3 Approved Veterinary medicine list shall be updated and published on every 06 months

5.8 Veterinary Pharmacy Registration

5.8.1 This is to ensure veterinary medicine is sold by authorized parties and pharmacies in the Maldives are registered, licensed, and operates in accordance with the regulation.

5.9 New applications

5.9.1 To register a Veterinary pharmacy, "Application Form for Veterinary Pharmacy registration" (available on ministry of health website), shall be submitted together with the below supporting documents:

a. Floor plan of the **pharmacy** with the following details:
   - All Measurements of the pharmacy including square feet of the premises**, owner signature and seal of pharmacy/ company**

- Details of the exact location of the pharmacy (example: which floor of the building, which building and located in which area etc.)

(Note: Pharmacy floor area shall be minimum ----- square feet, and that of a pharmacy within a medical facility shall be minimum ---- square feet)

b. Copy of registration certificate issued by (**Ministry of Fisheries Marine resources and Agriculture**), to prospective Veterinary Doctors/ pharmacists, pharmacy assistants or dispensers, to be employed at the pharmacy.

c. Submit the Permit to Sell Imported Goods issued in the name of the Pharmacy address, by Ministry of Economic Development or relevant Government authority or relevant authority

d. **If application is tendered by a company,** a copy of company registration certificates from relevant authorities shall be submitted

e. If application is tendered by an individual, a copy of the National Identification card

5.9.2 "Application Form for Veterinary Pharmacy registration and Permit for Dispensing Medicines in Pharmacy along with a copy of "Veterinary Pharmacy Registration", shall be submitted for modification where there is any change to the information below:

- Location or name of the pharmacy
- Ownership of pharmacy
- Pharmacist/Dispenser, or any other information

5.10 Application for renewal of Veterinary Pharmacy Registration

5.10.1 Application for license renewal shall be submitted before 14 working days of the expiry of the Permit for Dispensing Medicines in Pharmacy.

5.10.2 The following shall be submitted for renewal:

- Completed application form "Application Form for Veterinary Pharmacy registration
- List of documents mentioned **5.9.1**
- Previously issued Permit for Veterinary Pharmacy Registration, issued by this Authority

5.11 Procedure after processing accepted the application form

5.11.1 If the application form is completed with all the requirements inspection will be scheduled and to complete within 05 working days.

5.11.2 Based on the inspection report, the registration and license is issued accordingly within 05 working days

5.11.3 A scan copy of authorization shall be sent to client and MFDA port control unit via email.

6 Legal basis and references

a. Medicine regulation R-46 (2014)

b. Medicine regulation amendment R-49 (2016)

c. Health service act (29/2015)