MINISTERIAL DIPLOMA No. XX/MAPPF/2024
Of XX
FOR THE CONTROL OF VETERINARY MEDICINES

Considering the importance of protecting Timor-Leste's livestock and animal population as well as veterinary public health, from diseases that may threaten animal and human health, livestock dependent economic activities and food security;

Considering the objective in Decree-Law No. 41/2023 on Animal Health and Quarantine to provide a clear, efficient and conducive framework for trade and business activities, facilitate private sector activities, empower public officials, support livestock production activities and prevent animal disease risks to public health and food security;

Considering the Decree-Law No. 41/2023 on Animal Health and Quarantine requires the development of procedural and technical requirements to give effect to its norms relating to regulation of veterinary products as per Article 83;

Considering that Decree-Law No. 77/2023 establishing the structure of the Ministry of Agriculture, Livestock, Fisheries and Forestry grants authority to the National Veterinary Directorate (hereafter DVN) on matters relating to the evaluation, authorization, control and inspection of the commercialization and use of veterinary medicines, pharmacological, immunological, homeopathic, and respective raw materials and medical premixes, grooming products, as well as other products for use veterinarian;

the Government, through the Minister of Agriculture, Livestock, Fisheries and Forestry, pursuant to Article 109 of Decree-Law on Animal Health and Quarantine No. 41/2023, shall publish the following Diploma:

CHAPTER I
GENERAL PROVISIONS

Article 1. Objective

1. The purpose of this Diploma is to establish measures and actions relating to the control of veterinary medicines, in particular those provided for in Chapter VII, Article 83 of the Decree-Law on Animal Health and Quarantine No. 41/2023.
2. The definitions contained in article 4 of the Decree-Law on Animal Health and Quarantine No. 41/2023 are applicable to this Diploma, in particular that
   a. <<Veterinary medicinal products>> means any product, including veterinary medicinal or biological products, which are proven to have a prophylactic, therapeutic, diagnostic effect or to modify physiological functions when administered or applied to an animal.

Article 2. Executing entity

1. The National Veterinary Directorate (hereafter DVN) shall be responsible for implementing this Diploma, under the supervision of the Chief Veterinary Officer (hereafter CVN).
2. Where required, the DNV will collaborate and coordinate with the Unit for Quarantine and Biosecurity (UQB), the Business Registration and Verification Service (SERVE), the Authority for Inspection of Economic, Sanitary and Food Activities (AIFAESA), and the Ministry of Health, to implement this Diploma.
3. The CVN shall report to the Minister.

CHAPTER II

REGISTRATION OF VETERINARY MEDICINES

Article 3. Registration – General Requirements

1. All veterinary medicinal products imported, sold or distributed in East Timor must be registered.
   a. This does not apply to traditional animal medicines produced and administered in small quantities in line with customary use.
2. The CVN, under specified conditions, may approve the following veterinary medicines for import without registration:
   a. To respond to animal health emergencies;
   b. When DVN determines that there is insufficient availability or accessibility of registered veterinary products to satisfy a veterinary need;
   c. For research or testing purposes.

Article 4. Registration – Imported Veterinary Medicines

1. All veterinary medicines imported into Timor Leste must be officially approved by a government authority in the country of manufacture.
   a. The government authority in the country of manufacture must be officially approved by the national government in the country of manufacture to assess and register veterinary medicines.
2. The CVN can recommend to the Minister to approve and publish a list of specific veterinary medicines or specific categories of veterinary medicines from specified countries; and/or specific countries in Annex 1 that will not be recognised as approved for import or registration in Timor Leste.
3. All veterinary medicines imported into Timor Leste meeting the conditions in number 1, and not listed in Annex 1, will be regarded as being registered in Timor Leste.

Article 5. Registration – Veterinary Medicines Produced in Timor Leste

1. DNV, in collaboration with the Ministry of Health, will develop a Manual of Registration for veterinary medicines produced in Timor Leste.
2. The Manual will
    a. include categorization of veterinary medicines by considering relevant information, including the following factors in relation to veterinary medicines:
        i. the risk to animals, humans and the environment from their use or disposal,
        ii. how they are produced and the complexity of the method,
        iii. their intended use.
    b. specify the information required to be provided for assessment of different categories of veterinary medicines.
    c. specify the conditions of registration applied to different categories of veterinary medicines.
        i. as a minimum all products must comply with the relevant requirements in this Diploma.
3. The Manual and any amendments to the Manual must be approved by the CVN and then submitted to the Minister for approval and publication.
4. To register a veterinary medicine produced in Timor Leste, an applicant must submit the required information, as specified in the Manual.
5. An application to register must be made to DNV using the form in Annex 2 with payment of the fee in Annex 9.

Article 6. Registration – The Label

1. All registered veterinary medicines must have a label.
    a. The label must include as a minimum;
        i. instructions for use and storage,
        ii. required warnings,
        iii. an expiry date,
        iv. the active constituent.
    b. The drug must be used according to their label, unless varied under a prescription.

CHAPTER III

IMPORTED VETERINARY MEDICINES

Article 7. Approval to Import Veterinary Medicines

1. Veterinary medicines can only be imported into Timor Leste with the approval of DNV.
2. A business importing restricted veterinary medicines must be licensed with SERVE and approved by DNV, as specified under article 11.
3. Any person who wishes to import veterinary medicines shall apply to DNV, using the form set out in Annex 3.
4. The application fee listed in Annex 9 shall be paid by the applicant together with the submission of the form referred to in number 3.
5. The DNV shall process the application within 5 working days of receipt of the application in number 3 and the fee in number 4 and if the application is approved, an approval certificate listed in Annex 4 will be provided to the importer.

Article 8. Clearance of Imported Veterinary Medicines

1. The approval certificate from DNV must be provided to UQB, for verification and clearance of the imported veterinary medicines, on entry to Timor.
2. Where, following an inspection, UQB finds that the certificate is incorrect or the veterinary medicines do not match the certificate, or a banned medicine is found, UQB shall place the shipment under detention, and shall issue a notice in writing to the importer.
3. UQB, under the previous number, shall inform the CVN of detention of the shipment.
4. Medicines detained under number 2 will be stored to maintain their viability and safety, including temperature control if needed.
5. Any action taken by the UQB under this article shall be at the expense of the importer.
6. Any medicine that is unclaimed at the border for a period exceeding 21 days may be seized by the UQB.
7. If after 21 days UQB has been unable to clear the detained medicines, or the importer has not paid the required fees or charges, or any medicine has been seized, UQB, following advice from the CVN, can destroy, sell or dispose of, the seized or detained medicines.

CHAPTER IV

VETERINARY MEDICINE CONTROLS

Article 9. Banned Ingredients and Substances

1. The CVN can recommend to the Minister to approve and publish a list of banned ingredients and/or substances that could be used in the production of veterinary medicines.

Article 10. Restricted Veterinary Medicines - General

1. Restricted veterinary medicines are products which can potentially cause significant harm to animals, humans or the environment.
2. The DNV, in collaboration with the Ministry of Health, will create a list of restricted veterinary medicines.
    a. these veterinary medicines will be listed in Annex 5.
3. Restricted veterinary medicines:
    a. can only be sold or supplied by prescription by approved persons.
    b. cannot be advertised.
    c. must be kept in a site that can be secured and be stored to comply with the label, including temperature requirements.
    d. can only be used to treat animals, without prescription, by approved persons.
    e. must be used according to the official label, unless off-label use is used or approved by an approved person, under a prescription

Article 11. Restricted Veterinary Medicines – Business License

1. Restricted veterinary medicines can only be imported, sold, handled, or distributed by a business licensed by SERVE and approved by DNV.
2. The conditions of approval by DNV will be based on ensuring the restricted veterinary medicines are imported, handled, stored, distributed or sold in a manner that ensures their safety and to meet the requirements of this Diploma.
3. The conditions of approval by DNV are set out in Annex 6.
4. The licensed business will be inspected by AIEFESA at least once per year to assess compliance with their license conditions and the requirements of this Diploma.
    a. Any potential breaches will be reported to the CVN for assessment of the application of sanctions or penalties.

Article 12 Approved Persons

1. An approved person is:
    a. a veterinarian,
        i. who must have a veterinary degree,
    b. an approved para-veterinarian,
        i. who must be approved by the CVN,
        ii. who must undertake specified training.
2. Approval criteria for para-veterinarians, including training specifications, and the application form are set out in Annex 7 and any associated fees in Annex 9.

Article 13. Prescribing

1. Prescriptions for veterinary medicines can only be issued by approved persons.
2. The prescription must include the following information, as a minimum:
    a. date,
    b. name and position of prescriber,
    c. directions for use and storage,
    d. active constituent,
    e. any required warnings.
3. A prescription can refer to the label to cover part of these requirements.
4. A prescription for a restricted veterinary medicine can only be issued where the animal is under the direct care of an approved person.
    a. Direct care means the approved person
        i. has responsibility for judging the health and welfare of the animal(s) and the need for treatment, with the owner's agreement.
        ii. has sufficient knowledge of the animal(s) to form a diagnosis of their medical condition.
        iii. is personally acquainted with the keeping and care of the animal(s) by examination, or by visits to the premises where the animal(s) are kept.
        iv. has assessed that the owner can understand instructions and can correctly administer drugs if required.

Article 14. Off-label Use of Veterinary Medicines

1. Off-label use is where a veterinary medicine is used without following some or all of the requirements specified by the legal label.
2. Off-label use can only be done or permitted by an approved veterinarian with a prescription.

Article 15. Off-label Use of Restricted Veterinary Medicines

1. Where an approved veterinarian uses or prescribes off-label use of a restricted veterinary medicine, as defined under article 14, they must provide a prescription with the following additional information.
   a. An appropriate withholding period (WHP).
      i. The WHP is the time between treatment of the animal with the veterinary drug and when the animal can be consumed for human consumption.

Article 16. Antibiotic Controls

1. Antibiotics can only be used for therapeutic purposes.
2. Reserved antibiotics listed in Annex 8 can only be used for individual treatment of animals.
3. The following records of antibiotic use or supply must be kept by the approved person or the licensed business for at least three years:
   a. active constituent, concentration and method of use,
   b. date and amount used or supplied,
   c. name and position of user or supplier.
4. Records of antibiotic use or supply must be made available for inspection by approved inspectors upon request.

Article 17. Labelling and Packaging

1. A registered veterinary medicine that is repackaged can only be sold, distributed, or supplied with the original label copied and attached, or as a minimum the following information is made available in writing or digital form to the purchaser.
   a. directions for use and storage,
   b. active constituent,
   c. expiry date,
   d. any required warnings.
2. Provided all other requirements under this Diploma are followed for the use or supply of veterinary medicines by approved persons, they are exempt from number 1.

Article 18. Animal Feeds

1. Veterinary medicines used in animal feeds must meet the requirements specified in this Diploma.

CHAPTER V
FINAL PROVISIONS

Article 19. Publication and communications

1. DNV shall disseminate the provisions of this Diploma, any changes thereto, and any modification of requirements relating to imports of veterinary medicines by the following means:
   a) on the relevant government website or other electronic means;
   b) during meetings of the Animal Health Advisory Committee established under article 20 of the Decree-Law; or
   c) through radio, newspaper or other media and at other public places as relevant.
2. This Diploma and any changes thereto shall be made available to trading partners, upon request.
3. Through the Animal Health Advisory Committee established under article 20 of the Decree-Law and other processes, DNV shall take steps to make information available to the public and affected businesses and persons regarding the requirements of this Diploma.

Article 20. Service costs

1. Pursuant to Article 107 of Decree-Law on Animal Health and Quarantine No. 41/2023, the cost of all fees, measures and actions and the methodology for calculations of the same, that are provided for in Annex 9 of this Diploma shall be determined in accordance with the Table of Fees published by Ministerial Order.
2. The service costs are payable on receipt of an invoice from the DNV and for which a receipt of payment of the fee shall be issued to the payee.

Article 21. Entry into force

The present Diploma enters into force XXX days after its publication.

____ of ____ of 2024.

The Minister of Agriculture, Livestock, Fisheries and Forestry

List of Annexes

Annex 1. List of veterinary products or categories of veterinary products from specified countries and/or specific countries not approved for registration in Timor Leste.
Annex 2. Application form for registration of veterinary medicines produced in Timor.
Annex 3. Application form to import veterinary medicines into Timor.
Annex 4 Approval certificate to import veterinary medicines into Timor.
Annex 5. List of Restricted veterinary medicines.
Annex 6 Conditions of approval for a business license for the importation, sale, handling, or distribution of restricted veterinary medicines.
Annex 7. Criteria for approving a para-veterinarian to prescribe veterinary medicines and application form for approval of para-veterinarian
Annex 8. List of reserved antibiotics
Annex 9. List of service fees

ANNEX 1

Veterinary products from countries not approved for registration in Timor Leste.

[no countries or veterinary products from specified countries are currently listed]

ANNEX 2

Application form for registration of veterinary medicines produced in Timor.

[to be developed]

ANNEX 3

Application form to import veterinary medicine into Timor Leste.

[to be developed]

ANNEX 4

Approval certificate to import veterinary medicines into Timor Leste.

[to be developed]

ANNEX 5

Restricted Veterinary Medicines

- Antibiotics
- Hormones
- Anaesthetics, tranquilizers, sedatives
- Pyschotropic medications
- Opioids or derivatives
- Anti-cancer treatments

[list to be verified and completed following consultation]

ANNEX 6

Conditions of approval for a business license for the importation, sale, handling, or distribution of restricted veterinary medicines.

[to be developed]

ANNEX 7

The criteria for approving a para-veterinarian to prescribe veterinary medicines.

Criteria

Must have a degree or equivalent qualification which is science based

- For example, UNTL Animal Health degree

Must pass a DNV approved training course that covers

- Anti-microbial Resistance (AMR),
- Risks and safe use of veterinary medicines
- Regulatory requirements relating to veterinary medicines

[criteria to be finalized following consultation]

The application form for approval of para-veterinarian.

[to be developed]

The approval certificate for para-veterinarians.

[to be developed]

ANNEX 8

Reserved Antibiotics

- Eg 3rd generation cephalosporins

[list to be verified and completed following consultation]

ANNEX 9

Service Fees

Application to register veterinary medicine made in Timor Leste (Article 5)

Amount *[to be determined]*

Application to import veterinary medicines into Timor Leste (Article 7)

Amount *[to be determined]*

Application to be approved as a para-veterinarian (Article 12)

Amount *[to be determined]*