



የኢትዮጵያ ግብርና ባለስልጣን
ETHIOPIAN AGRICULTURAL AUTHORITY



Impact
that matters

የኢትዮጵያ ግብርና ባለስልጣን ETHIOPIAN AGRICULTURAL AUTHORITY

GUIDELINE ON THE DOSSIER REQUIREMENTS FOR RENEWAL REGISTRATION OF VETERINARY DRUG IN ETHIOPIA

JUNE 2025
ADDIS ABABA, ETHIOPIA



ETHIOPIAN AGRICULTURAL AUTHORITY

የኢትዮጵያ ምርርና ባለስልጣን

Guideline on the Dossier Requirements for Renewal Registration of Veterinary Drug in Ethiopia

First Edition

Document No.:	VDR/GL/003
Approval Date:	02/06/2025

June 2025

Addis Ababa, Ethiopia

TABLE OF CONTENTS

FOREWORD	3
ACKNOWLEDGMENT	4
LISTS OF ACRONYMS	5
INTRODUCTION	6
SCOPE OF THE GUIDELINE	7
OPERATIONAL DEFINITIONS	8
1. GENERAL REQUIREMENTS AND APPLICATION PROCEDURES.....	10
2. ADMINISTRATIVE AND PRODUCT INFORMATION	12
2.1. Administrative Documents	12
2.2. Product Information	17
3. TECHNICAL DOCUMENTATION REQUIREMENTS.....	20
4. ASSESSMENT PROCESS.....	20
5. SUBMISSION OF LABORATORY SAMPLES	21
6. PERIODIC SAFETY UPDATE REPORTS (PSURS)	22
ANNEXURES.....	23

FOREWORD

Ethiopian Agricultural Authority (EAA) is a government institution established by Proclamation No.1263/2021 and Council of Minister Regulation No. 509/2022 mandated to ensure the quality, safety and efficacy of imported and locally produced agricultural inputs and products. Based on the regulatory mandates given, the Authority has issued this guideline on submission of dossier for renewal registration of veterinary drugs. This guideline provides guidance to applicants on documents and information required for submission of applications to renew their products' market authorizations. It also guides the authority in evaluating applications submitted for renewal of registrations. Applicants and assessors are encouraged to familiarize themselves with this guideline while compiling and reviewing applications. Applicants are required to carefully read this guideline together with relevant Ethiopian and international regulations, directives, guidelines and other references related to the market authorization of veterinary drugs.

Hamid Jemal (PhD)

Deputy Director General, Ethiopian Agricultural Authority

ACKNOWLEDGMENT

Ethiopian Agricultural Authority (EAA) would like to acknowledge the **Food Systems Resilience Program (FSRP)** for its financial support in the development of this guideline. We also thank the Ethiopian Agricultural Authority (EAA) technical staff and all participants of the consultative and validation workshops for their valuable contributions.

LISTS OF ACRONYMS

cGMP	Current Good Manufacturing Practice
EAA	Ethiopian Agricultural Authority
MA	Marketing Authorization
CPP	Certificate of Pharmaceutical Product
NRA	National Regulatory Authority
PSURs	Periodic Safety Update reports
SPC	Summary of Product Characteristics
SRA	Stringent Regulatory Authority
VICH	Veterinary International Cooperation on Harmonisation
VPP	Veterinary Pharmaceutical Products

INTRODUCTION

Ethiopian Agricultural Authority (EAA) is a government organization established by Proclamation No.1263/2021 and Council of Minister Regulation No. 509/2022 mandated to ensure the quality, safety and efficacy of imported and locally produced agricultural inputs and products. Article 4 of the veterinary drugs and animal feed administration and control proclamation no. 728/2012 states that no veterinary drug may be produced locally or imported and put in use unless it is registered by the Authority after being evaluated for its safety, efficacy and quality. Veterinary Drugs Registration Directive No. 1036/2025 article 17 (1) also states that any market authorization holder shall apply for renewal of veterinary drugs registration certificate to continue marketing of its product. Article 17(4) of this directive also promulgates that an application submitted for renewal of registration shall be compiled as per the technical guidelines for re-registration of veterinary drug. Pursuant to these mandates and provisions, the authority has developed and endorsed this guideline to inform applicants on the requirements for renewal registration application of veterinary drugs. This guideline is intended to provide guidance to applicants on the conditions to be fulfilled and the type of documentation to be submitted for renewal of market authorization to be approved by the authority.

Veterinary drugs registration certificate is valid for five years only. It is, therefore, mandatory for market authorization holders to apply for renewal of the certificate by submitting the required documents for re-registration entailed in this guideline. Adherence

to this guideline by the applicants will ensure consistency and transparency throughout the evaluation process, facilitating timely assessments and approvals of application dossiers for renewal of marketing authorization. Therefore, applicants are strongly advised to thoroughly review this guideline in conjunction with other relevant legislation, directives, and related guidelines.

Revision to this guideline can be made if the Authority finds it necessary to amend any of the requirements in the guideline for some valid reasons. In such case, the Authority will notify all applicants with the amendments made to comply with the revised requirements. Therefore, as an input for revision comments and suggestion from stakeholders are welcomed and can be sent to EAA by email through vdrcd@eaa.gov.et or by postal to the Ethiopian Agricultural Authority P.O. Box 31303, Addis Ababa, Ethiopia.

SCOPE OF THE GUIDELINE

This guideline shall apply to the renewal process for all veterinary drugs (pharmaceutical and immunological products) that have been previously registered and are due renewal in accordance with applicable national veterinary drug regulatory framework.

OPERATIONAL DEFINITIONS

“Agent” means a person authorized by marketing authorization holder by law to carry out matters on his behalf.

“Applicant” means the manufacturer or/and the license holder of the Veterinary pharmaceutical Products (VPP)

“Authority” means the Ethiopian Agricultural Authority (**EAA**)

“Certificate of pesticide products for ectoparasitic products” means an official document issued by the relevant regulatory authority that confirms a pesticide/insecticide product has been evaluated, approved and registered for veterinary use in a specific country or region against ticks, fleas, lice, mites

“Dossier” means a comprehensive collection of technical and administrative documents submitted to a regulatory authority as part of the application for the approval, renewal, or variation of a veterinary pharmaceutical product for market authorization.

“Market Authorization Holder” means a company by whose name the registration certificate has been granted and is responsible to monitor compliance with the conditions accepted during registration.

“Pharmacovigilance” means the science of activities relating to the detection, assessment, understanding and prevention of adverse effects or any other related problem

“Registration Certificate” means an official document granted to a veterinary drug after ensuring the fulfillment of registration requirements.

“Re-registration” Means to the renewal of the market authorization of a previously registered veterinary pharmaceutical product after five years of validity period.

“Stringent Regulatory Authority (SRA)” means regulatory authorities of other countries responsible for veterinary drugs regulation which are recognized as a stringent by the World Organization of Health (WHO).

“Veterinary drug” means any substance specifically formulated to diagnose, treat, prevent or control animal diseases that includes pharmaceutical and immunological veterinary products.

1. GENERAL REQUIREMENTS AND APPLICATION PROCEDURES

The application procedures for the renewal of a veterinary drug registration certificate must meet the following general requirements:

- a) The applicant should submit all kind of documentation in need to renewal of veterinary drug registration certificate through online application system (<https://www.eservices.gov.et/>) at the service name of **“Veterinary Drugs Re-Registration Service”**.
- b) The agent involved in handling the re-registration of veterinary drug should have a valid certificate of competence issued by the EAA and Trade License issued by Ministry of Trade and Regional Integration
- c) A veterinary product authorized for marketing in Ethiopia will be issued a registration certificate valid for five years and must be renewed upon expiration.
- d) Any marketing authorization holder shall apply for renewal of veterinary drugs registration certificate 90 days before or 90 days after the expiry date of the validity period.
- e) If the market authorization holder doesn't submit his application 90 days before or 90 days after the expiry date of the validity period, a renewal application can only be accepted within additional 90 days by paying a penalty of half of the service fee for renewal registration.

- f) However, if the applicant fails to submit the application within this due date for renewal, it will be considered as revoked with the chance for the applicant may reapply as a new veterinary drug registration application.
- g) If the applicant declares variation during the re-registration application, the variation application is treated first and renewal application will be followed up on approval of application. In such cases the applicant is required to make separate payments for the renewal and variation applications.
- h) If a variation has not been priorly notified to the authority and is identified during the re-registration evaluation, the applicant shall submit all required documents and pay service fees for both renewal and variation registrations and registration will be conducted together for both applications by taking administrative measure.
- i) A declaration statement by the applicant regarding the correctness, completeness and accuracy of all the documents should be submitted during the renewal procedure.
- j) All application and supporting documents shall be in English; if some or all section of the document is prepared in a foreign language other than English language, official English or Amharic translation of such document bearing official stamps of the translator shall be presented.

2. ADMINISTRATIVE AND PRODUCT INFORMATION

2.1. Administrative Documents

a) Cover Letter

An application for the registration of a veterinary pharmaceutical product, whether locally manufactured or imported, shall be submitted in writing through a cover letter and a completed application form. The cover letter accompanying the dossier must include a declaration by the applicant affirming that all submitted information is true and correct.

b) Application form for Renewal of Registration Certificate

The applicant shall submit a duly completed application form, as specified in **Annex I** of this guideline, with a signed, sealed, or otherwise verified signature, through the online application system.

c) Agency Agreement

- i. The applicant is required to submit a declaration letter if the agent responsible for the previous market registration remains unchanged.
 - ii. However, if the authorized local agent has changed or a third party has been introduced into the business relationship, the applicant must submit an agency agreement that meets the following requirements;
- a) All veterinary drug manufacturers or market authorization holders distributing veterinary drugs into the Ethiopian

market must appoint a local agent to initiate the renewal of the registration certificate. The local agent or representative must be physically located in Ethiopia and will serve as the primary and/or default point of contact between the Ethiopian Agricultural Authority (EAA) and the applicant.

- b) An agency agreement should be made between the applicant or manufacturer of the product and the agent responsible for submission of application in Ethiopia
- c) When the manufacturer has authorized a third party for the renewal of registration certificate, the agreement can be between the local agent and the authorized third party provided that a valid agreement between the a manufacturer and a third party is submitted.
- d) The agreement must be signed, sealed, and stamped by both parties, with all marks affixed to the document, and this fully executed agreement is what must be submitted.
- e) The agreement must specify the local agent or representative responsible for handling the veterinary drug registration process. If the manufacturer intends to appoint more than one distributor, this must be clearly stated in the other agreements. The appointed agent(s) or representative(s) will be responsible for all correspondence and ensuring full compliance with regulatory requirements throughout the product's distribution lifecycle in the country. However, applications for renewal of the registration certificate and related communications shall be conducted exclusively through a single appointed agent for this purpose.

- f) The agreement should specify that importation, distribution and post approval issues including safety and quality monitoring will be the responsibility of all parties (manufacturer or license holder and the local agents).
- g) The agreement should specify that both parties are responsible for pharmaco-vigilance and post-marketing reporting of the product safety, quality, and efficacy follow-up. Therefore, the agreement should also include the post market risk management plan of the parties signing the agreements.
- h) The agreement should state that if quality defect on the product or any fraud or unsuspected and unacceptable adverse event occurs to the consumer under normal utilization, all the party's (local agents, manufacturer, and/or market authorization holder) mentioned in the agreement will be responsible for the product recall and for substantiating any related consequences.

d) Certificate of Good Manufacturing Practice (GMP)

- i. For all veterinary medicinal products, key manufacturing steps and analytical procedures must be carried out in facilities that comply with GMP guidelines recognized by the EAA (e.g., WHO or PIC/S). A valid GMP certificate issued by the competent authority in the country of origin must be submitted. As a standard practice, all manufacturing sites are subject to EAA GMP inspection.
- ii. Re-inspection of the manufacturing site (by the Authority) may not be pre-request for submission of

application for renewal of the marketing authorization. However, valid GMP compliance letter or report issued by the Ethiopian Agricultural Authority shall be requested prior to issuing the renewal of registration certificate.

- iii. For applicants with manufacturing facilities in Stringent Regulatory Authority (SRA) countries, an authenticated GMP certificate issued by the competent authority in the country of origin must be submitted. The certificate must be valid and comply with the WHO GMP format requirements.

e) Certificate of Pharmaceutical Product (CPP)

The applicant must submit a Certificate of Pharmaceutical Product (CPP) that meets the following requirements, along with the product dossier.

- i. An original CPP or (*equivalent certificate*) and *certificate of pesticide products for ectoparasitic products* issued by competent authority and authenticated by the Ethiopian Embassy or Consulate in the country of origin.
- ii. If there is no Ethiopian Embassy or Consulate in the country of origin, authentication may be done by the Ethiopian Embassy in a neighboring country or by the Ethiopian Ministry of Foreign Affairs.
- iii. If authentication is not possible due to the absence of an Ethiopian Embassy or Consulate, and this is confirmed by the Authority, the applicant must

submit the original CPP along with a registration certificate proving the product's registration in the country of origin and/or other countries.

- iv. The CPP (or equivalent certificate) and the certificate of pesticide for ectoparasitic products must be consistent with the explanatory notes and the Summary of Product Characteristics (SPC) as outlined in **Annex III** of this guideline.
- v. The certificate of pesticide products for ectoparasitic (acaricide or insecticide) products must include at least the following details:
 - a. Product name and registration number
 - b. Active and inactive ingredients with their strengths
 - c. Dosage form (e.g., spray, pour-on, dip, spot-on, powder)
 - d. Target species (e.g., cattle, sheep, dogs, cats, poultry)
 - e. Toxicity classification (e.g., WHO hazard class)
 - f. Manufacturer's name and address
 - g. Certifying authority's name, official seal, and address

f) Manufacturing License

The applicant must submit a copy of the valid manufacturing license for the finished product, issued by the NRA or relevant regulatory authority of the exporting country.

g) Previous Registration Certificate

At the renewal, the applicant is required to submit the existing market authorization or product registration certificate.

h) Evidence for an application fee

- i. Applicant should pay a non-refundable service fee according to the currently effective service fee regulation and a receipt of this shall be attached.
- ii. If payments are made for more than one application, a tabular listing of the application numbers and payments for each application shall be prepared and submitted along with the attachment for the total payment.

2.2. Product Information

Product information including package insert, labeling, and Summary of Product Characteristics (SPC) must be included in the dossier and be scientifically justified. A declaration letter confirming no changes to this section may be submitted. The approved package label and leaflet design should be uploaded to the e-service. If labels are printed directly on plastic bottles via silk screen, colored photos of the labels will be accepted for approval.

a) Summary of Product Characteristics (SPCs)

The applicant shall submit a summary of the product characteristics, in accordance with the template in **Annex II** of this guideline.

b) Labelling (immediate and outer label)

i. Proposals for Packaging, Labelling, leaflet

All labeling information must be in English and in a language easily understood by the layperson. Pictorial signs on the package should correspond to the product's indication and visual features. One or two original samples of each package, label, and leaflet must be submitted. The label on the immediate container and closure system, Outer or secondary package and package leaflet must include the following requirements.

Immediate Container and Closure system

- a) The name of the product; brand and generic/INN
- b) Name and quantitative composition of the active substance
- c) Target species
- d) Indication(s)
- e) Pharmaceutical form and method of administration
- f) Pack size
- g) Contraindications, warnings, and precautions
- h) Handling and storage requirements
- i) The titles for batch number and manufacturing and expiry dates (the actual dates are not required)
- j) Name and address of the manufacturer
- k) A claim stating **“For Veterinary Use Only”** should be stated
- l) Must indicate the **“withdrawal period”** when applicable

- m) Must describe the residual resistance time in case of drugs to be used for ectoparasites.

If the product is presented **in a blister or strip packages** the following information printed direct on the blister or strip should be included as a minimum:

- a) Name, strength and pharmaceutical form of the VMP.
- b) Name of the manufacturer
- c) The batch number
- d) The manufacturing and expiry dates.

Outer or secondary package

The outer package shall bear all of the information required to appear on the label of the immediate container itself or else the wording on the label of the immediate container must be legible through the outer wrapper or carton.

The titles for batch number, manufacturing and expiry dates should be part of the printing (type written materials, stickers, etc. are not acceptable). If the labelling technology of the manufacturer is such that this information is to be printed on the label on production line using ink jet, laser printing, rubber stamp, etc, a written commitment to show all the required information on the label of the finished product must be submitted.

Package Leaflet

The general content of the package leaflet should be prepared in line with the content of the SPCs. It should not be described or

presented in a manner that is false, misleading, or deceptive or is likely to create an erroneous impression regarding its use in any respect, either pictorially or in words.

3. TECHNICAL DOCUMENTATION REQUIREMENTS

The applicant must submit the following technical documents for renewal of registration certificate:

- a) The applicant must submit a declaration stating that the manufacturing process, the type of packaging materials, and container closure remain unchanged from the previous registration. The product must also comply with current monographs and quality standards accepted by the Authority.
- b) The specification, method of analysis, certificate of analysis (CoA) for the finished product, and, if applicable, the analytical method validation report must be submitted.
- c) Unit composition and batch formula of the product
- d) If there are any changes, the applicant must submit all required documents for the API(s) and finished product in accordance with the relevant guidelines for veterinary pharmaceutical and immunological product registration in Ethiopia.

4. ASSESSMENT PROCESS

- a) Veterinary drug registration applications submitted via e-Service will be verified and acknowledged within 10 working days. Applications will then enter a queue before being assigned for assessment.

- b) Submitted data will be assessed for compliance with safety, efficacy, and quality standards. Any potential serious risk to animal health, human health, or the environment must be addressed during the renewal process.
- c) If assessors identify missing information or require clarification, a clock-stop period will be initiated until the applicant provides the necessary details.
- d) The Authority will evaluate the renewal application within 30 working days and issue the re-registration certificate within 5 working days after receiving a positive laboratory test result and confirmation that the manufacturer is approved to produce the product.

5. SUBMISSION OF LABORATORY SAMPLES

- a) For re-registration laboratory analysis is mandatory
- b) Sample of actual products, reference standard and working standard shall be submitted either during dossier evaluation or after completion of dossier evaluation.
- c) An adequate quantity of sample shall be submitted for quality control analysis as stipulated on **annex V**.
- d) Approved Certificate of Analysis, Method of analysis and analytical method validation shall be presented
- e) Sample should be identical to the actual commercial product
- f) The sample should be presented in an approved original label and package.
- g) Sample must be of the same batch

6. PERIODIC SAFETY UPDATE REPORTS (PSURS)

Periodic safety update reports are pharmacovigilance documents required to ensure the veterinary medicinal products are ongoing safety after authorized for use. The PSUR provides comprehensive and objective periodic assessment of a product's **risk- benefit balance** based on updated safety data. Therefore, Market Authorization Holders (MAHs) are required to submit Periodic safety updates of products that can be obtained from different sources such as from the periodic safety review conducted by EAA, periodic safety updates provided from the MA holder or relied reference authorities. When the **PSURs** indicate that there is tangible safety concern of the product under renewal application, the authority may not issue renewal for the marketing authorization and such application should be consulted for further investigation of the noted concern.

ANNEXURES

Annex I: APPLICATION FORM FOR RE-REGISTRATION OF VETERINARY DRUGS

1. Particulars of the applicant

Name: _____

Address: _____

Phone Number: _____ Fax: _____

Email: _____

1.1 Name and address of the manufacturer (if different from the applicant): _____

1.2 Name and address of the local agent or technical representative: _____

2. Particulars of the Product

Name of the product: _____

International Non-proprietary Name (INN) of the Active substance or immunogenic substance: _____

Product strength: _____

Dosage form: _____

The route and method of administration _____

Pack size(s): _____

Description of container closure: _____

Visual description of the product: _____

Proposed shelf life (months) and storage condition: _____

Main indication(s): _____

Proposed distribution category: _____

Product Composition (give the composition of the product in terms of units per dose)

S/N	Name of active and inactive ingredients	Quantity per unit dose	Specification or reference text
1			
2			
3			

3. Previous registration No. in Ethiopia

4. Declaration by applicant

I the undersigned hereby apply for registration of the product detailed above and declare that all the information herein and in the appendices is correct and true.

Full name and position of signatory: _____

Signature: _____

Date: _____

Annex II: SUMMARY OF PRODUCT CHARACTERISTICS

- 1. NAME OF THE VETERINARY PHARMACEUTICAL PRODUCT**
- 2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Active substance(s):

Excipient(s):

- 3. PHARMACEUTICAL FORM**

The description of pharmaceutical form should include visual appearance of the product (colour, markings, etc.)

- 4. CLINICAL PARTICULARS**

- 4.1. Target species:
- 4.2. Indications for use, specifying the target species
- 4.3. Contraindications:
- 4.4. Special warnings for each target species
- 4.5. Special precautions for use
 - i. In animals
 - ii. Person administering the veterinary medicinal product to animals
- 4.6. Adverse reactions (frequency and seriousness)
- 4.7. Use during pregnancy, lactation or lay
- 4.8. Interaction with other Pharmaceutical products and other forms of interaction
- 4.9. Amounts to be administered and administration route
- 4.10. Overdose (symptoms, emergency procedures, antidotes), if necessary
- 4.11. Withdrawal period(s)
Meat and offal, Milk, Eggs: {X} hours, day

5. PHARMACOLOGICAL PROPERTIES

5.1. pharmacodynamic properties of the product

5.2. pharmacokinetic properties of the product

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

6.2. Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3. Shelf life

- i. Shelf-life of the veterinary Pharmaceutical product as packaged for sale
- ii. Shelf-life after first opening the immediate packaging
- iii. Shelf-life after dilution or reconstitution according to directions where applicable
- iv. Shelf life after incorporation into pelleted feed where applicable

6.4. Special precautions for storage

Do not store above

Store below

Store in a refrigerator (2 °C – 8 °C)

Store and transport refrigerated (2 °C – 8 °C)

Protect from light

6.5. Nature and composition of immediate packaging

6.6. Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such product. Any unused veterinary medicinal product or waste materials

derived from such veterinary medicinal products should be disposed of in accordance with local requirements.>

7. MARKETING AUTHORISATION HOLDER

{Name and address}

Tel: _____ Fax: _____ E-mail: _____

8. MARKETING AUTHORISATION NUMBER(S)

9. Date of first Authorization/ Renewal of the

Authorization; {DD/MM/YYYY},{DD month YYYY}

10. Date of REVISION of the text {MM/YYYY} or month /YYYY

Annex III: Certificate of Pharmaceutical Products

This certificate conforms to the format recommended by the
World Health Organization

(General instructions and explanatory notes attached)

No. of Certificate

Exporting (certifying country):

Importing (requesting country):

1. Name and dosage form of the product:

1.1. Active ingredient(s) and amount(s) per unit dose

For complete composition including excipients, see
attached:

1.2. Is this product licensed to be placed on the market for
use in the exporting country? Yes No (Key in as appropriate)

1.3 Is this product actually on the market in the exporting
country? (Key in as appropriate) yes No unknown, If the
answer to 1.2. Is yes, continue with section 2A and omit section
2B.

If the answer to 1.2 is no, omit section 2A and continue
with section 2B:

2. A.1. Number of product license and date of issue:

2. A.2. Product license holder (name and address):

2. A.3. Status of product license holder: a/b/c (Key in appropriate category as defined in note 8)

2. A.3.1. For categories (b) and (c), provide the name and address of the manufacturer producing the dosage form:

2. A.4. Is a summary basis for approval appended? Yes No (Key in as appropriate)

2. A.5. Is the attached, officially approved product information complete and consonant with the license? Yes No not provided (Key in as appropriate) 2.A.6. Applicant for Certificate, if different from license holder (name and address):

2. B.1. Applicant for Certificate (name and address):

2. B.2. Status of applicant: a b/c (Key in appropriate category as defined in footnote 8)

2. B.2.1. For categories (b) and (c), provide the name and address of the manufacturer producing the dosage form:

2. B.3. Why is marketing authorization lacking?

Not required/not requested/under consideration/refused (Key in as appropriate)

2. B.4. Remarks:

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?

If not or not applicable, proceed to question 4.

Yes/no/not applicable (Key in as appropriate)

3.1. Periodicity of routine inspections (years):

3.2. Has the manufacture of this type of dosage form been inspected? Yes No

3.3. Do the facilities and operations conform to good manufacturing practices (GMP) as recommended by the World Health Organization (WHO)?

Yes/no/not applicable (Key in as appropriate)

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product: yes No (Key in as appropriate?)

If no, explain:

Address of certifying authority:

Telephone:

Fax no.:

E-mail:

Name of authorized person:

Signature:

Stamp and date:

Annex V: Sample Size & related materials requirement for lab quality Analysis

<i>S.No.</i>	<i>Dosage form</i>	<i>Unit</i>	<i>Sample size per batch of the product</i>	<i>Primary standard (USP, BP, EP)</i>	<i>Secondary reference Materials/Working standard</i>	<i>Internal standard(method dependant)</i>
	Bolus	Boli	140	≥ 200mg	≥500mg	≥ 200mg
	Tablet for injection	Tablet	120			
	Granule or powder for injection	Sachet	80			
	Powder for injection	Vial	40			
	Solution for injection	Vial	40			
	Powder for oral solution/suspension	Sachet/bag				
	• <50g		60			
	• 50-100g		30			
	• 500g		20			
	• 100-500g		6			
	• 1kg	3				
	Oral solution/suspension	Bottle				

500 ML		6			
1L		3			
Topical spray (acaricide /insecticide)	Liter	2			
Ointment	Tube	10			
Wound spray	Tin	5			
Intra mammary infusion	Syringe	20			
Intravenous/Electrolyte/supportive fluid	Vial/bag/bottle				
• <100		20			
• 100-500		10			
• >500		6			
Hormones	Vial	10			
Disinfectant/Sanitizers	Vial	2			
Freeze-dried pellet/lyophilized vaccine	Vial	35			
Liquid vaccines	Vial	20			
Toxoids	Vial	20			
Medical Supplies					
• Gloves		2			
• Surgical Blade	Pack	2			

	• Needles		2	
	• Syringe		10	
	• Cotton		2	
	• Gauze		2	
	• Suturing Material		2	

Annex VI: PSUR Standard Format (VICH GL29 (R1))

1. Introduction

- Product name(s)-----

- Active substance(s)-----

- Dosage form(s)-----

- Indications-----

- Marketing authorization details (countries, dates,
etc.)-----

2. Worldwide Marketing Authorization Status

- Overview of current marketing status globally-----

- List of countries where product is authorized, dates, and
changes since last PSUR-----

- -----

3. Update of Regulatory Authority or Market Authorization Holder (MAH) Actions Taken for Safety Reasons

- Actions such as recalls, withdrawals, suspensions, labeling changes, etc.-----

4. Changes to Reference Safety Information

- Include changes in Company Core Data Sheet (CCDS), if applicable
- Explanation of changes and justification-----

5. Patient Exposure

- Quantitative estimates of exposure (sales, number of animals treated, doses administered)
- Include data by species and indication

6. Presentation of Individual Case Histories

- Summary tabulation of adverse event reports
- Description of serious and/or unlisted events-----

7. Studies

- Clinical or non-clinical studies (completed or ongoing) relevant to safety
- Summaries and interpretations

8. Other Information

- Safety-related findings from literature, non-interventional studies, or other sources

9. Conclusion

- Final evaluation
- Recommendations for product safety profile

10. Appendices

- Line listings of adverse events
- Full study reports or literature references (if needed)

List of Contributors:

- 1 Dr. Solomon Kebede(DVM, MVSc): Lead Executive Officer, Veterinary Drug Regulatory, WOA National Focal Point for Veterinary products
- 2 Segedu Shiferaw(AHP, B.Pharm, MSc in Regulatory Affairs of Medicine): Veterinary Drug & Institution Registration & Licensing Manager
- 3 Dr. Teshome Habtamu(DVM): Veterinary Drug and Institution Registration & licensing Expert
- 4 Dr. Tigist Kabtyemer (DVM): Veterinary Drugs and Institutions Registration and Licensing Expert
- 5 Dr. Walie Zegeye(DVM): Veterinary Drugs and Institutions Registration and Licensing Expert
- 6 Dr. Fetene Demissie(DVM): Veterinary Drugs and Institutions Registration and Licensing Expert