Veterinary Drug and Animal Feed Administration and Control Authority

Veterinary Drug Registration and Market Authorization Process Guideline

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WORLD BANK GROUP

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Contents

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PREFACE

The guideline contains the process flow and requirements starting from application for Pre-registration Certificate of Competence (Pre-CoC) or Certificate of Competence (CoC) through agency agreement approval, veterinary drug registration application processes, storage facility approval, and purchase order approval to release permit approval.

It is hoped that the guideline together with process map for registration and market authorization of veterinary drugs would help veterinary drug importers and veterinary drug manufacturers to understand the process and requirements for each step and also to minimize the time needed to get market in Ethiopia by avoiding endless visits to the office. At the same time, it plays a role in increasing the availability of a variety of veterinary drugs, decreasing the cost of veterinary drugs and enhancing the quality of veterinary pharmaceutical services so as to decrease the economic losses and public health hazards due to diseases of livestock. Veterinary drug professionals and importers who work on the trade of veterinary drugs are encouraged to read this guideline and other guidelines annexed in the document to ease the process.

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VDFACA APPLICATION PROCEDURE FOR VETERINARY DRUGS

Importers or local manufacturers wishing to distribute and sell veterinary drugs in Ethiopia must have an authorisation from VDFACA. No veterinary drug may be produced locally or imported and put into use unless VDFACA approves it. This document explains the authorisation process and sets out the different steps and requirements as well as timelines for the different stages involved in the approval process.

Step 1: Pre-submission advice

Importers or local manufacturers of veterinary drugs should contact VDFACA, Veterinary Drug Quality and Standard Preparation and Distribution team to notify them of their intention to start trading and apply for a certificate of competence/veterinary drugs import permit. VDFACA, Veterinary Drug Quality and Standard Preparation and Distribution team will then provide applicants application pack (see Annexes) containing the following information. The information pack can be sent in hard copy or by email and will also be available on VDFACA's website.

Application Pack

1. Application forms and requirements for applying for Pre-CoC and CoC

- Requirements for obtaining pre-registration certificate of competence (Pre-CoC) for veterinary drug import (Annex 5)
- Requirements for obtaining a certificate of competence (CoC) for veterinary drug import (Annex 4)
- Certificate of competence (CoC) for veterinary drug import requisition application form (Annex 2)
- Pre-registration certificate of competence (CoC) for veterinary drug import requisition application form (Annex 3)
- Requirements to get professional licence (Annex 6)

2. Guidance/checklists

- Declaration template (for importer or to declare that office/site will be adequately furnished/staffed and that they will apply to VDFACA for the relevant permits) (Annex 9)
- Guidance for registering an Agency Agreement (Annex 8)
- Guidance/checklist for GMP inspection (Annex 10)
- Guidance/checklist for Certificate of Pharmaceutical Products (local manufacturers only) - Annex 8
- Guidance/checklist for the inspection of storage/office facility (Annex 9)
- Guidance/checklist for submitting product dossier and samples for testing (Annex 8)
- Service fee for registration and licensing of veterinary drugs and feed regulation No. 725/2014 (Annex 7)
- Timescales for each step

Step 2: Application for Pre-registration Certificate of Competence (Pre-CoC) or Certificate of Competence (CoC)

Individuals wishing to import veterinary drugs (applicants) should fulfil all the requirements for Pre-CoC or CoC. Completed pre-CoC or COC application forms and all the other relevant forms/checklists must be completed and submitted to VDFACA.

Pre-CoC is issued if the applicant has acquired office and employed technical manager but has not yet acquired a warehouse to store the imported/manufactured veterinary drugs. The importer is also not required to employ an assistant technical manager. The technical manager, who should be educated to at least a degree/ DVM level, should have a Professional Licence issued by VDFACA. It is no longer compulsory to acquire a warehouse at the early stage of application. This can be done later in the process during the dossier evaluation. It should be noted that the import permit will only be issued once the warehouse has been inspected and a CoC issued.

CoC is issued if the applicant has acquired a warehouse and employed both an assistant manager and Technical manager and the premises have been inspected and found to be acceptable by VDFACA. The assistant technical manager, who should be educated to at least a diploma level,

should have a Professional Licence issued by VDFACA. Professional Licence application will be considered within 3 days of submitting all the required information.

The inspection is conducted by at least 2 inspectors and will use the checklist given in the application pack. If the premises fail inspection, the inspectorate will inform the applicant of the reasons for failure within 2 working days following the inspection, in writing. If the rationale for failure could not be addressed, the applicant would be required to find another suitable premise that would pass the inspection. Once the notification of a positive inspection is received by VDFACA office, the CoC containing the name of the applicant and technical manager, address of the warehouse and a photo of the technical manager will be issued within 2 working days. The frequency of further inspections by VDFACA inspectorate is decided using a risk-based approach.

VDFACA will issue the Pre-CoC or CoC within 3 working days following receipt of a complete application. VDFACA will log application and applicant details in the database/spreadsheet and the CoC approval letter will be sent to the applicant by letter.

The importer should then submit an application together with a copy of the pre-CoC or CoC to the Ministry of Trade (MoT) in order to obtain a Trade Licence.

Step 3: Agency Agreement Approval

After obtaining a trade licence from MoT, the importer should then apply to VDFACA for the approval of their Agency Agreement. Agency Agreement is a document that sets out the agreement between the importer and the overseas supplier. Guidance/checklist is available on the requirements and the fee payable. VDFACA will then update the database/spreadsheet to record receipt of Agency Agreement related documents and will link it with previous pre-CoC or CoC application. This will be done within 24 hours and VDFACA will then assess the Agency Agreement documents and either request for additional or missing information from the importer (via email), giving them a deadline for response (3 months) in case of any missing information. VDFACA will complete the initial evaluation within 3 days. Once all the relevant information is submitted, VDFACA will approve the Agency Agreement within 3 days.

Step 4: Submission for Veterinary Drug Registration Application to VDFACA

Both importers and local manufacturers are required to submit the following:

- Completed application form for product registration
- Certificate of Pharmaceutical Products from a country of origin (importers only)
- GMP certificate (if available)
- Copy of trade licence awarded by Ministry of Trade

Upon receipt of an application, VDFACA will update the database/spreadsheet to record receipt of an application, linking it with previous Pre-CoC/CoC and Agency Agreement applications. VDFACA will then carry out validation of the submission by checking all forms and supporting data are provided. A validation check will be done within 3 working days. If the application fails validation, VDFACA will request further/missing information (by letter), giving a maximum deadline for a response of 3 months. If the information is not provided on time or is unsatisfactory, the applicant will be asked to withdraw the application and re-apply at a later date when all the information is available. If all the required information is submitted, then the application passes validation and the applicant is notified within 3 working days of receipt of response. VDFACA's validation pass letter will also indicate if the manufacturing site has a valid GMP certificate issued by a Stringent Regulatory Authority (SRA)[1] or if GMP inspection by VDFACA is required and the payments needed for the different stages. The applicant is required to make payment in the bank and send the bank receipt to VDFACA (in person or by email) as proof of payment. Once VDFACA verifies the receipt of payment (within 2 days), VDFACA will confirm the receipt of payment in a letter. If the product is deemed to require laboratory testing following VDFACA's risk-based determination, the letter will also include permission to import product test samples. A copy of this letter will also be sent to the relevant VDFACA Branch Office at the port of entry.

[1] Stringent Regulatory Authorities (SRAs) - The national drug regulatory authorities which are members or observers or associates of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) are considered as Stringent Regulatory Authority (SRA). These include all member countries of the European Union (EU), Japan, USA, Switzerland, Canada, Australia, Norway, Iceland and Liechtenstein.

Step 5: Assessment of Product Registration Application by VDFACA

The three processes: GMP inspection, dossier evaluation and laboratory testing take place simultaneously and the outcome of each process will be communicated to the applicant as soon as each process is completed. The applicant will also receive the collective final decision for the product once all the processes have been completed.

1. GMP Inspection

GMP inspection by VDFACA is required if the manufacturing site does not have a valid GMP certificate issued by an SRA or if VDFACA's GMP certificate has expired. The applicant (importer or manufacturer) will be asked to pay the inspection fee ($4000-$6500) depending on the location of the manufacturing site by letter (email) (Annex 7). The applicant should then make the payment at the bank and send VDFACA the receipt as proof of payment. Once receipt of payment is confirmed, VDFACA will contact the manufacturing site in order to arrange a date for the inspection[2]. The inspection will be conducted by 2-3 inspectors and a preliminary inspection report will be ready at the end of the inspection. The formal inspection report will then be prepared by VDFACA inspectors and presented to VDFACA's technical committee within 1 month. The technical committee will then decide on the outcome of the inspection within 3 days following the receipt of the Inspectors' report. If the outcome is positive, VDFACA will then issue the GMP certificate for the manufacturing site inspected and the applicant will then be sent a copy of the GMP certificate and report within 2 days. If the manufacturing site fails inspection, the applicant will be sent a report highlighting the deficiencies identified within 10 days. This will then be followed either by sending corrective action or another inspection once the shortcomings have been addressed and the applicant has made the application.

2. Dossier Assessment

Once the dossier passes validation, the safety, quality and efficacy aspects are assessed and list of questions drawn up and sent to the applicant within 60 working days following validation. The applicant (agent/importer) is given a deadline of not more than 6 months for a response. If a response is not received by the deadline, the applicant will be reminded of the outstanding request

[2] VDFACA will check if there is another company awaiting inspection in the same country so that costs can be shared.

by email. Once responses are received, VDFACA will assess the responses within 14 days of receipt and conclude on the evaluation and notify the applicant by email.

3. Laboratory Testing

VDFACA uses pre-defined criteria to decide if laboratory testing of a product sample is required or not by applying a risk-based approach in its decision. If laboratory testing is deemed necessary, VDFACA will identify the tests to be conducted and prepare a request form within 3 working days. Once the laboratory request form is ready, the applicant will be notified by email and is then required to collect the form from VDFACA and take the request form and the number of samples indicated in Annex 11 to the laboratory. The quality control laboratory may outsource some of its work to other recognised laboratories for some of the tests. In such situations, the applicant will be informed where the samples and the request form should be taken. The designated laboratory will analyze it within 7 days for physico-chemical tests and 16 days for microbiological tests of receipt of the samples and will notify the applicant of the outcome of the analysis by email.

Decision

Immediately the application is found to satisfy all the requirements of GMP, dossier evaluation and laboratory testing, the product will be approved and the registration certificate (product approval) will be prepared and sent to the applicant within 2 working days from approval. The registration certificate (approval) of the product will be valid for 5 years from the date of issue.

If the application is refused, VDFACA will notify the applicant of the reason(s) for refusal which can be:

1) GMP failure (one re-inspection allowed)
2) Dossier questions not resolved
3) Failure of laboratory analysis

If the applicant disagrees with the reasons for refusal, the applicant can appeal to VDFACA's Director General, giving their reasons for the appeal.

4. Storage Facility Approval

If the applicant succeeds in obtaining the registration certificate through the use of pre-CoC and not full CoC, the applicant will be required to obtain an appropriate storage facility and a CoC for the import permit (purchase order) to be issued. The process of obtaining a CoC is described in Step 2 of this document.

Step 6: Purchase Order Approval

Once all of the above procedures have been completed, the applicant requests the overseas manufacturer to send the Proforma Invoice. When this is received, the applicant prepares purchase order and Manufacturing Certificates and submits them online through the single window to VDFACA. Local manufacturers will also be required to have a Manufacturing Certificate. VDFACA will check if the product has a valid Registration Certificate, and if so, will issue the import permit on the same day free of charge. VDFACA approves advance purchase order (APO), and the branch office and the Bank are notified of approval by the system (Single Window). The applicant can also apply for hard currency from the banks and start importing veterinary drugs.

Step 7: Release Permit Approval

When the import permit is approved and the veterinary drugs reach to one of the legal ports of entry in Ethiopia, the importer is required to apply for a release permit online through the system (Single Window) by attaching all the required documents in the system (Annex 11).
VDFACA branch office will then assign a document verifier and consignment inspector through the system. If all the requirements are satisfied, the VDFACA branch office will then issue a 'Release Permit' to Customs online through single window.

Regulation of Veterinary Drug Trades and the Storage Facility

The frequency of storage facility re-inspections is decided using a risk-based approach by VDFACA's inspection directorate. Laboratory testing is also conducted from consignment samples and the marketplace randomly as part of the post-authorisation market surveillance. GMP inspection of manufacturing sites is performed every 5 years. Import permit/MA/Product registration is renewed every 5 years with laboratory testing on samples.

End

Local manufacturers should also fulfil all the requirements set out in this document. They are required to submit a CoC application and pay the appropriate fee, as indicated in the application pack. Local manufacturers should also obtain a manufacturing licence from the Ministry of Trade once VDFACA has issued the CoC.

APPLICATION PACK

ANNEX 1: Veterinary Medicine Screening Checklist

FEDERAL DEMOCRATIC REPUBLIC OF ETHIOPIA

MINISTRY OF AGRICULTURE

Veterinary Drug & Animal Feed Administration And Control Authority

Veterinary Medicine Validation Checklist

Product Name: _____ Active substance(s):_____

Strength: _____ Applicant: _____

Manufacturer: _____ Received Date: _____

	Description of topics			**Not applicable**
	Is the structure of dossier in CTD-format?			
	Is covering letter attached? (Both from local applicant & the manufacturer)			
	Does the manufacturing site have GMP Certificate issued by SRA?			
	Is the agency agreement /signed by the applicant and manufacturer attached? Is the local agent sole agent (1st agent)? If previously submitted, is it valid?			
	Is the product present in the national drug list (both in strength & dosage form)?			
	Are all sections in English language or has English translation been included in the case of other languages?			
	Is there an application form that is signed & dated by the applicant?			
	Is there a table of contents?			
	Is the original copy of the Certificate of Pharmaceutical Product (CPP) included?			
	Is the CPP authenticated by the Ethiopian Embassy in the country of origin?			
	Is the summary of the product characteristics attached?			
	Is there a raw materials specification & method of analysis?			
	Is there an API route of analysis? Is there an API stability study report?			

	Is there a method of manufacture or batch manufacturing record (BMR) for finished product?			
	Are there manufacturing process validations?			
	Is there finished product specifications & method of analysis?			
	Is there analytical method validation? (If the method is in house)?			
	Is there packaging material specification?			
	Is the FPP stability study report attached?			
	Is a Bioequivalence study report attached? (Optional)			
	Are there actual samples of packaging materials (immediate & outer part)? Is the leaflet submitted?			
	Is a copy of the appropriate registration fee receipt submitted (CPO or Bank transfer (special case)?			

Screened by: _____Signature:_____ Date:_____
Remark received: _____Not received:_____

Comment:_____
_____

ANNEX 2: Certificate of Competence for Veterinary Drug Import Requisition Application Form

<u>የእንስሳት መድኃኒትና የሕክምና መሣሪያ ንግድ ድርጅት ለማቋቋም የብቃት ማረጋገጫ ምስክር ወረቀት መጠየቂያ ማመልከቻ ቅጽ</u>

1. የአመልካች ስም ከነአያት_____

2. የአመልካች መኖሪያ አድራሻ ክልል _____ዞን _____ወረዳ _____ከተማ_____ክፍለ ከተማ _____ቀበሌ _____የቤት ቁጥር _____

3. ሊቋቋም የታሰበዉ የእንስሳትመድኃኒትና የሕክምና መሣሪያ ንግድ ድርጅት ዓይነት

ሀ. የእንስሳት መድኃኒትና የሕክምና መሣሪያ አስመጪ፣

ለ. የእንስሳት መድኃኒትና የሕክምና መሣሪያ ጅምላ አከፋፋይ፣

ሐ. የእንስሳት ሕክምና መሣሪያ አስመጪ

መ. የእንስሳት መድኃኒትና የሕክምና መሣሪያ ላኪ፣

4. ድርጅቱ የሚያስመጣቸዉ ወይም ጅምላ የሚያከፋፈላቸዉ ወይም የሚልካቸዉ'

ሀ. የእንስሳት መደኃኒትና የሕክምና መሣርያ ☐

ለ. የእንስሳት ሕክምና መሣርያ ☐

ሐ. ለሎች ካሉ ይጠቀስ .----------

5. የእንስሳት መድኃኒትና የሕክምና መሣሪያ ንግድ ድርጅቱባለቤትነት

ሀ. የግል

ለ. ኃላፊነቱ የተወሰነ የግል ድርጅት

ሐ. የአክሲዮን (አስረጂ መረጃዎች ይያያዝ)

6. የእንስሳት መድኃኒትናየሕክምና መሣሪያንግድ ድርጅቱ ሊቋቋም የታሰበበት አድራሻ፣

ክልል _____ዞን_____ከተማ_____ክፍል ከተማ_____ ወረዳ_____ ቀበሌ_____የቤ/ቁ_____

7.አመልካቹ/ቿ በድርጅቱ የሚኖረዉ/ራት ኃላፊነት፣

ሀ. ባለንብረት

ለ. ባለንብረትና ባለሙያ

8. ድርጅቱንየሚመራዉ ባለሙያ

ሀ. ስም ከነአያት _____

ለ. የሙያ ደረጃ _____

ሐ. የሙያ ምዝገባ ፈቃድ ቁጥር _____

መ. በባለሥልጣኑ ወይም አግባብ ባለዉ አካል

የተመዘገበ_____

(ባለሙያዉ ተቀጣሪ ከሆነ የዉል ስምምነት ይያያዝ)

ሠ. ባለሙያዉ በሙያዉ (በዘርፉ) ያለዉ የሥራ ልምድ (መረጃ ይያያዝ)

9. የቴክኒክ ረዳት/መጋዘን ኃላፊ ባለሙያ

ሀ. ስም ከነአያት _____

ለ. የሙያ ደረጃ _____

ሐ. የሙያ ምዝገባ ፈቃድ ቁጥር _____

መ. በባለሥልጣኑ ወይም አግባብ ባለዉ አካል የተመዘገበ _____

(ባለሙያዉ ተቀጣሪ ከሆነ የዉል ስምምነት ያያይዝ)

ሠ.ባለሙያዉ በሙያዉ (በዘርፉ) ያለዉ የሥራ ልምድ (መረጃ ይያያዝ)

10. የሚቋቋመዉ ድርጅት

ሀ. የዉሃ አገልግሎት

አለዉ ☐ የለዉም ☐

ለ. የኤሌክትሪክ መብራት አገልግሎት

☐ አለዉ ☐ የለዉም

ሐ. ለትራንስፖርት አገልግሎት ምቹ

☐ ነዉ ☐ አይደለም

መ. የስልክአገልግሎት

☐ አለዉ ☐ የለዉም

ሠ. የፖስታአገልግሎት

☐ አለዉ ☐ የለዉም

ረ. አረካካቢዉ ለእንስሳት መድኃኒት ወይም የሕክምና መሣሪያ ንግድ ተግባር ተስማሚ

ነዉ ☐ ☐ አይደለም

ሰ. ኢሜል አድራሻ አለዉ

☐ አለዉ ☐ የለዉም

11. ድርጅቱ፣

ሀ. የማረካከቢያክፍል ስፋት ☐

ለ. የማከማቻ ክፍል ስፋት ☐

ሐ. የማከማቻ ክፍሎች በቂ መደርደሪያ፣ ☐ አለዉ የለዉም ☐

መ. የማረካከቢያ ክፍል ማረካከቢያ ጠረጴዛ፣ ☐ አለው ☐ የለዉም

ሠ. ማቀዝቀዣ ከነሙቀት መቆጣጠሪያዉ ቴርሞሜትር፡

☐ አለዉ ☐ የለዉም

ረ. የእሳት አደጋ መከላከያ (ማጥፊያ)

☐ አለዉ ☐ የለዉም

ሰ. ለጽህፈት ሥራ የሚጠቀምበት ጠረጴዛና ወንበሮች

☐ አለዉ ☐ የለዉም

ሸ. የልብስ መስቀያ

☐ አለዉ ☐ የለዉም

ቀ. የሣይኮትሮፒክ መድኃኒቶች ማስቀመጫ ቁልፍ ያለዉ ካቢኔት

☐ አለዉ ☐ የለዉም

በ. መፀዳጃ ክፍል ከነዉሃ አገልግሎቱና የእጅ መታጠቢያ ሲንክ

☐ አለዉ ☐ የለዉም

ተ. ድርጅቱ ጎርፍ የማያስገባ

☐ ነዉ ☐ አይደለም

ቸ. ድርጅቱየሚቋቋምበት ቤት ቆሻሻ የሌለበት አካባቢ

☐ ነዉ ☐ አይደለም

ነ. ደረቅ ቆሻሻ ማስወገጃ

☐ አለዉ ☐ የለዉም

11. እኔ ከዚህ በላይ የዘረዘርኋቸዉ መረጃዎች ትክክለኛ መሆናቸዉን አረጋግጣለሁ

ስም_____

ፊርማ_____ቀን_____

ANNEX 3: Pre registration Certificate of Competence for Vet Drug Import Requisition Application Form

<u>የእንስሳት መድኃኒትና የሕክምና መሣሪያ አስመጪንግድ ድርጅት ለማቋቋም ቅድመ ምዝገባ ብቃት ማረጋገጫ ምስክር ወረቀት መጠየቂያ ማመልከቻ ቅጽ</u>

1. የአመልካች ሙሉ ስም _____

2. የአመልካች መኖሪያ አድራሻ

ክልል _____ዞን _____ወረዳ _____ከተማ_____ክፍለ ከተማ _____ቀበሌ _____የቤት ቁጥር _____

6. ሊቋቋም የታሰበዉ የእንስሳት መድኃኒትና የሕክምና መሣሪያ ንግድ ድርጅት ዓይነት

ሀ. የእንስሳት መድኃኒትና የሕክምና መሣሪያ አስመጪ

ለ. የሕክምና መሣሪያ አስመጪ

7. ድርጅቱ የሚያስመጣዉ

ሀ. የእንስሳት መድኃኒትና የሕክምና መሣርያ ☐

ለ. የሕክምና መሣሪያ ☐

ሐ. ለሎች ካሉ ይጠቀስ .----------

8. የእንስሳት መድኃኒትና የሕክምና መሣሪያ ንግድ ድርጅቱ ባለቤትነት

ሀ. የግል

ለ. ኃላፊነቱ የተወሰነ የግል ድርጅት

ሐ. የአክሲዮን (አስረጂ መረጃዎች ይያያዝ)

6. የእንስሳት መድኃኒትና የሕክምና መሣሪያ ንግድ ድርጅቱ ሊቋቋም የታሰበበት አድራሻ፣

ክልል _____ዞን_____ከተማ_____ ክፍልከተማ_____ ወረዳ_____ ቀበሌ_____የቤ/ቁ_____

7.አመልካቹ/ቿ በድርጅቱ የሚኖረዉ/ራት ኃላፊነት

ሀ. ባለንብረት

ለ. ባለንብረትና ባለሙያ

8. ድርጅቱን በቴክኒክ ኃላፊነትየሚመራዉ ባለሙያ

ሀ. ሙሉ ስም _____

ለ. የሙያ ደረጃ _____

ሐ. የሙያ ምዝገባ ፈቃድ ቁጥር _____

መ. በባለሥልጣኑ ወይም አግባብ ባለዉ አካል

የተመዘገበ_____

(ባለሙያዉ ተቀጣሪ ከሆነ የዉል ስምምነት ይያያዝ)

ሠ. ባለሙያዉ በሙያዉ (በዘርፉ) ያለዉ የሥራ ልምድ

_____(መረጃ ይያያዝ)

10. የድርጅቱ የቴክኒክ ኃላፊ ቢሮ

ሀ. ለጽሕፈት ሥራ የሚጠቀምበት ጠረጴዛ፣ወንበርና ኮምፒዩተር

አለዉየለዉም ☐ ☐

ለ. የተለያዩ መረጃዎች ማስቀመጫ ባለቁልፍ ቁምሳጥን /ካቢኔት

☐ አለው ☐ የለውም

ሐ. የልብስ መስቀያ

☐ አለው ☐ የለውም

እኔ _____ከዚህ በላይ የዘረዘርኳቸው መረጃዎች ትክክለኛ መሆናቸዉን አረጋግጣለሁ፡፡

ስም_____

ፊርማ_____ቀን_____

ANNEX 4፡ Requirements to get Certificate of competency for veterinary drug import

አዲስ የእንሰሳት መድኃኒት ተቋማት የብቃት ማረጋገጫ ለማውጣት ማሟላት ያለበቸው፡-

1. የብቃት ማረጋገጫ ማመልከቻ
2. የእንሰሳት መድኃኒት ባለሙያዎች (የቴክኒክ ኃላፊና የመጋዘን ኃላፊ)
3. የቅጥር ውል
4. የእንሰሳት መድኃኒት መጋዘን ኪራይ ውል ወይም የባለቤትነት ካርታ
5. የመመስረቻና መተዳደሪያ ደንብ ለኃላፊነቱ የተወሰነ የግል ማህበር
6. እዝዕል አንድን ቅጽ መሙላት
7. ክፍያ መፈፀም ይጠበቅባቸዋል

ተ.ቁ	መስፈርቶች	ቀርባል	አልቀረበም	አስተያየት
1.	የብቃት ማረጋገጫ ጥያቄ			
2.	የእንሰሳት መድኃኒት ባለሙያዎች የቴክኒክ ኃላፊና			
	የመጋዘን ኃላፊ			
3.	የቅጥር ውል			
4.	የእንሰሳት መድኃኒት መጋዘን ኪራይ ውል ወይም የባለቤትነት ካርታ			
5.	የመመስረቻና መተዳደሪያ ደንብ ለ ኃላ.የ. የግ . ማ			
6.	ቅጽ ሞልቶ ማቅረብ			
7	የአገልግሎት ክፍያ			

ANNEX 5፡ Requirements to get Pre-registration Certificate of Competency for Vet Drug Import

አዲስ የእንሰሳት መድኃኒት ተቋማት የቅድመ ምዝገባ የብቃት ማረጋገጫ ለማውጣት ማሟላት ያለበቸው፡-

1. የቅድመ ምዝገባ ብቃት ማረጋገጫ ማመልከቻ
2. የእንሰሳት መድኃኒት ባለሙያ (የቴክኒክ ኃላፊ)
3. የቅጥር ውል
4. የቢሮ ኪራይ ውል ወይም የባለቤትነት ካርታ
5. የመመስረቻና መተዳደሪያ ደንብ ለኃላፊነቱ የተወሰነ የግል ማህበር
6. እዝዕል አንድን ቅጽ መሙላት
7. ክፍያ መፈፀም ይጠበቅባቸዋል

ተ.ቁ	መስፈርቶች	ቀርባል	አልቀረበም	አስተያየት
1.	የቅድመ ምዝገባ ብቃት ማረጋገጫ ጥያቄ			
2.	የእንሰሳት መድኃኒት ባለሙያዎች የቴክኒክ ኃላፊና			
3.	የቅጥር ውል			
4.	የእንሰሳት መድኃኒት መጋዘን ኪራይ ውል ወይም የባለቤትነት ካርታ			
5.	የመመስረቻና መተዳደሪያ ደንብ ለ ኃላ.የ. የግ . ማ			
6.	ቅጽ ሞልቶ ማቅረብ			
7	የአገልግሎት ክፍያ			

ANNEX 6፡ Requirements to get Professional License

በእንሰሳት መድኃኒት የሙያ ምዝገባ ፍቃድ ለማውጣት፡-

1. የሙያ ምዝገባ ፍቃድ ማመልከቻ
2. የትምህርት ማስረጃ
3. አግባብ ያለው የስራ ልምድ(ግብር መክፈሉን የሚገልፅ)
4. የቅጥር ውል
5. ክሊራንስ
6. ፎቶ ለቴክኒክ ኃላፊው 4ፎቶ እና ለረዳት ባለሙያው 2 ጉርድ ፎቶ
7. የሙያ ፍቃድ ክፍያ መፈፀም ይጠበቅባቸዋል

ተ.ቁ	መስፈርቶች	ቀርባል	አልቀረበም	አስተያየት
1.	የሙያ ምዝገባ ፍቃድ ጥያቄ			
2.	የትምህርት ማስረጃ			
3.	የቅጥር ውል			
4.	አግባብ ያለው የስራ ልምድ(ግብር መክፈሉን የሚገልፅ)			
5.	ክሊራንስ			
6	የአገልግሎት ክፍያ			

ANNEX 7: Service Fee for Registration and Licensing of Veterinary Drugs and Feed Regulation No. 325/2014

SCHEDULE ONE
Service Fees for Veterinary Drug and Instrument Registration and Licensing

No	Type of Services	Fee (USD)	Ethiopian Birr
1	New registration requiring clinical data	800	15,600.00
2	New registration requiring bioequivalence data	700	13,650.00
3	New registration of not requiring bioequivalence data	500	9,750.00
4	Re- registration of veterinary drugs (every five years)	250	4,875.00
5	Variation to existing marketing authorization requiring sample analysis	200 /variation/	3,900.00 /variation/
6	Variation to existing marketing authorization not requiring sample analysis	100 /variation/	1,950.00 /variation/
7	New registration of veterinary instrument	500	9,750.00
8	Re- registration of veterinary instrument	250	4,875.00
9	Change in local agent (agency agreement) approval or request registration	50	975.00
10	New registration of miscellaneous veterinary drugs with market shortage	100	1,950.00
11	Re-registration of miscellaneous veterinary drugs with market shortage	75	1,462.50

SCHEDULE TWO

Service Fees for Veterinary Drug and Feed professionals Registration and Licensing, Commercial Advertisement Registration and licensing

No.	Type of Services	New (Birr)	Renewal (Birr)	Replacement (Birr)
1	Registration of veterinarian	54.00	27.00	18.00
2	Registration of animal health professionals BSC Degree	54.00	27.00	18.00
3	Registration of animal health pharmacist	54.00	27.00	18.00
4	Registration of assistant veterinarian	54.00	27.00	18.00
5	Registration of animal health laboratory professionals BSC Degree	54.00	27.00	18.00
6	Registration of Advanced Animal Health Services TVT level IV professionals	54.00	27.00	18.00
7	Registration of higher animal feed professional	54.00	27.00	18.00
8	Registration of medium animal feed professional	54.00	27.00	18.00
9	Registration of Animal Production and Marketing Management TVT level IV professionals	54.00	27.00	18.00
10	Issuing license for veterinary drug or instruments advertisement	400.00	200.00	133.3
11	Issuance of identity card for veterinary drug or instruments advertisement	200.00	100.00	66.7

SCHEDULE THREE
Service Fee for Inspection of Veterinary Drug Good Manufacturing Practice

No.	Subcontinent	Type of service	Fee (USD)	Ethiopian Birr
1	East Africa	full manufacturing site inspection of good manufacturing practice	4,ooo	78,000
2	East Africa	Partial manufacturing site inspection of good manufacturing practice	3,000	58,500
3	other Africa regions outside East Africa	full manufacturing site inspections of good manufacturing practice	4,500	87,750
4	other Africa regions outside East Africa	partial manufacturing site inspections of good manufacturing practice	4,000	78,000
5	Middle East	full manufacturing site inspections of good manufacturing practice	6,000	117,000
6	Middle East	partial manufacturing site inspections of good manufacturing practice	5,000	97,500
7	Far East and Asia	full manufacturing site inspections of good manufacturing practice	6,500	126,750
8	Far East and Asia	partial manufacturing site inspections of good manufacturing practice	6,000	117,000
9	Europe, South America and North America	For companies for which good manufacturing practice inspection is necessary	6,500	126,750

SCHEDULE FOUR

Service Fees for Veterinary Drug and Animal Feed Institutions Registration and Licensing

No	Types of Institution	For new certificate of competence (birr)	For renewal of certificate competence (birr)	For replacement (birr)	2nd round pre licensing inspection (birr)	3rd round pre licensing inspection (birr)	Change of professional (birr)	Change of place (birr)
1	Veterinary drug and instruments importer	720	360	120	720	1440	360	360
2	Veterinary drug and instruments exporter	720	360	120	720	1440	360	360
3	Veterinary drug and instruments whole seller	600	300	120	720	1440	360	360
4	Veterinary instrument importer	600	300	120	720	1440	360	360
5	Veterinary instrument whole seller	600	300	120	720	1440	360	360
6	License for local drug manufacturing company	800	400	200	800	1600	400	400
7	Local feed, feed additives, mixtures and feed processing facility	1820	910	303.3	1820	3640	910	910
8	Feed, feed additives, mixtures and feed instruments importer	1450	725	241.6	1450	2900	725	725
9	Feed, feed additives, mixtures exporter	885	442.5	147.5	885	1770	442.5	442.5
10	Feed, feed additives, mixtures and feed instruments whole seller	360	180	60	360	720	180	180

ANNEX 8: The Sample Size per Batch needed for Laboratory Analysis for each Dosage Form

1. Sample Size of Finished Product and Reference Standards

S. No	Dosage form	Unit	Sample size per batch of the product	Primary standard (USP, BP, EP)	Secondary reference Materials/Working standard	Internal standard(method dependant)
1	Bolus	Boli	140	≥ 200mg	≥ 500mg	≥ 200mg
2	Tablet for injection	Tablet	120			
3	Granule or powder for injection	Sachet	80			
4	Powder for injection	Vial	40			
5	Solution for injection	Vial	40			
6	Powder for oral solution/suspension	Sachet/bag				
	• <50g		60			
	• 50-100g		30			
	• 100-500g		20			
	• 500g		6			
	• 1kg		3			
7	Oral solution/suspension	Bottle				
	500 ML		6			
	1L		3			
8	Topical spray (acaricide /insecticide)	liter	2			
9	Ointment	Tube	10			
10	Wound spray	Tin	5			
11	Intra mammary infusion	Syringe	20			
12	Intravenous/Electrolyte/supportive fluid (Vial/bag/bottle)	<100	20			
		100-500	10			
		>500	6			
13	Hormones	Vial	10			
14	Disinfectant/Sanitizers	Vial	2			
15	Freeze-dried pellet/lyophilized vaccine	vial	35			
16	Liquid vaccines	Vial	20			
17	Toxoids	Vial	20			
18	Medical Supplies	Pack				
	• Gloves		2			
	• Surgical blade		2			
	• Needles		2			
	• Syringe		10			
	• Cotton		2			
	• Gauze		2			
	• Suturing material		2			

2. Documents

- Finished product (sample) specification and Certificate of Analysis
- Reference standard (USP, BP, EP) certificate of analysis.
- Working standard certificate of analysis
- Internal standards certificate of analysis if needed
- In house method of analysis with its validation report if needed

3. Remark
    - It should be noted that the type of reference standard is determined based on the pharmacopeia used by the manufacturer. If the product to be registered is not official in nationally accepted pharmacopeia, the laboratory will accept the manufacturer working standard.

Annex 9: Check list for renewal of veterinary drug establishment

የእንስሳት መድኃኒት ተቋማት የእድሳት ጥያቄ ማስተናገጃ ቼክሊስት -

የድርጅቱ ስምና የፈቃዱ አይነት፡_____

የባለንብረቱ ስም፡_____

የብቃት ማረጋገጫዉ

- የወጣበት የቴክኒክ ሃላፊ ስም፡ ----------
- ቀድሞ የተሰጠበት/የታደሰበት መለያ ቁጥር፡ ----------
- ቀድሞ የተሰጠበት/የታደሰባት ቀን : ----------
- አሁን ለ---------ዓ. ም. በማመልከቻ ለእድሳት ጥያቄ የቀረበበት ቀን ----------

*ለወደፊት የሙያ ደረጃና ፈቃድ ሰርተፊኬት አሰጣጥ ጠቃሚ ግብአት ስለሆነ

ተ.ቁ	ለእድሳቱ መረጋገጥ ያለባቸዉ ጉዳዮች	አግባብነት	አስተያየት
1	**የብቃት ማረጋገጫ እድሳት ጥያቄ/ማመልከቻ / ቀጥታ ለቡድኑ**	ቀርቧል / አልቀረበም	
2	**የኢንስፔክሽን ሪፖርት**	ቀርቧል/ አልቀረበም	
2.1.	በተቋሙ ላይ የተሰጠ ሁኔታ	አዎንታዊ/ አሉታዊ	
2.2.	ተቋሙ ዉስጥ በሚሰሩ የሙያ ፈቃድ ባላቸዉ ሙያተኞች ላይ	አዎንታዊ/ አሉታዊ	
3	**የሙያ ፈቃድ (የቴክኒክ ኃላፊዉ)**		
3.1	*ባወጡት የሙያ ፈቃድ በተቋሙ እየሰሩ መሆኑን የቅጥር ማስረጃ	ቀርቧል / አልቀረበም	
3.2	*የስራ ግብር ማስረጃ	ቀርቧል / አልቀረበም	
3.3	የሙያ ፈቃድ እድሳት ጥያቄ (በሙያተኛዉ የሚቀርብ)	ቀርቧል / አልቀረበም	
4	**የሙያ ፈቃድ (ረዳት ቴክኒክ/ መጋዘን ኃላፊዉ)**		
4.1	*ባወጡት የሙያ ፈቃድ በተቋሙ እየሰሩ መሆኑን የቅጥር ማስረጃ	ቀርቧል / አልቀረበም	
4.2	*የስራ ግብር ማስረጃ	ቀርቧል / አልቀረበም	
4.3	የሙያ ፈቃድ እድሳት ጥያቄ (በሙያተኛዉ የሚቀርብ)	ቀርቧል / አልቀረበም	
5	**ለእንስሳት መድኃኒት ማከማቻነት የዋለዉ መጋዘን**	የድርጅቱ የዞታ ነዉ / በኪራይ የተገኘ ነዉ	
	መጋዘኑ በኪራይ የተገኘ ከሆነ ዉሉ ስለመታደሱ	ታድሷል / አልታደሰም	
	የድርጅቱ ይዞታ ከሆነ የባለቤትነት ማረጋገጫ	ቀርቧል / አልቀረበም	
6	**የመመስረቻ ጽሁፍና መተዳደሪያ በማህደር ዉሰጥ ስለመኖሩ/ስለመቅረቡ**	ቀርቧል / አልቀረበም	
7	**የእድሳት ጠያቄ ማመልከቻ በጀነራል ማናጀሩ ስለመቅረቡ**	ቀርቧል / አልቀረበም	
8	**ከዚህ በፊት በወጣዉ የብቃት ማረጋገጫ ሰርተፊኬት በእንስሳት መድኃኒት ንግድ ዘርፍ የንግድ ፈቃድ የወጣ ኮፒ**	ቀርቧል / አልቀረበም	
10	**የዕድሳት ክፍያ**	ከፍሏል/ አልከፈለም	

የሙያተኞች ማጠቃለያ አስተያየት፡ ----------

ስምና ፊርማ፡---------- ስምና ፊርማ፡---------- ቀን ----------

የቡድን መሪዉ አስተያየት/ዉሳኔ፡----------

ስምና ፊርማ :---------- ቀን:----------

የዳይሬክተሩ አስተያየት/ዉሳኔ፡----------

ስምና ፊርማ :---------- ቀን:----------

ANNEX 10: Import Permit Requirements

1. Certificate of competency for veterinary drug import
2. Trade license for veterinary drug import
3. Agency agreement between importer and manufacturer
4. Valid Registration certificate for each veterinary drug
5. Performa invoices from the manufacturer
6. Pre import permit online application by single window

ANNEX 11: Release Permit Requirements

1. Certificate of competency for veterinary drug import
2. Trade license for veterinary drug import
3. Pre import permit approved by the authority
4. Registration certificate for each veterinary drug
5. Commercial invoice from the manufacturer
6. Certificate of origin
7. Packing list
8. Certificate of analysis of each of the goods
9. Airway bill/bill of loading
10. Release permit online application by single window

ANNEX 12: Veterinary drug registration guideline

ANNEX 13: Veterinary drug importer and wholesaler registration and licensing directives

ANNEX 14: Veterinary drug GMP inspection guideline