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GUIDELINE ON THE DOSSIER REQUIREMENTS FOR REGISTRATION OF VETERINARY INSTRUMENTS IN ETHIOPIA

JUNE 2025

ADDIS ABABA, ETHIOPIA

ETHIOPIAN AGRICULTURAL AUTHORITY

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Guideline on the Dossier Requirements for Registration of Veterinary Instruments in Ethiopia

First Edition

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FORWORD

Ethiopian Agricultural Authority (EAA) is a government institution established by Proclamation No.1263/2021 and Council of Minster 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 Aauthority has issued this guideline on submission of dossier for registration of veterinary instruments. This guideline provides guidance to applicants on documents and information required for submission of new, renewal and variations registration applications of instruments and devices used for veterinary purpose. It also guides the authority in evaluating applications submitted for registration of these products. Applicants and assessors are encouraged to familiarize themselves with the 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 instruments (medical devices).

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Deputy Director General, Ethiopian Agricultural Authority

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ABBREVIATIONS

EAA	Ethiopian Agricultural Authority
ISO	International Organization for Standardization
QC	Quality Control
QMS	Quality Management System
FSC	Free Sale Certificate
FIFO	First-in-First-out

INTRODUCTION

The Ethiopian Agricultural Authority (EAA) is a government regulatory body established by Proclamation No.1263/2021 and Council of Minster Regulation No. 509/2022 mandated to ensure the quality, safety, and efficacy of imported and locally produced agricultural inputs and products. The provision of veterinary instruments of proven safety, performance and quality is crucial to provide appropriate health care to animals in the country. One important method of ensuring the safety, performance and quality of these products is thorough evaluation and authorization, which are to be imported or locally produced before they are available for use in the country. It's also provisioned on article 4 of the Veterinary Drugs and Animal Feed Administration and Control Proclamation no. 728/2012 and the Veterinary Drugs Registration Directive No. 1036/2025 that no veterinary drug, including veterinary instruments, may be produced locally or imported for use unless registered by the Authority after being evaluated for its safety, performance, and quality.

Pursuant to these mandates and provisions, the Authority has developed and endorsed this guideline to inform applicants on the technical requirements for veterinary instruments registration application. Adherence to this guideline by the applicants will ensure consistency and transparency throughout the evaluation process, facilitating timely assessments and approvals of veterinary instruments application dossiers for marketing authorization.
Veterinary instrument registration certificate is valid for five years only. It is, therefore, mandatory for manufacturers and/or license holders to apply for re-registration by submitting the required

dossier for re-registration mentioned under section 2(c) of this guideline. Additionally, any variation to registered veterinary instruments shall be applied to the Authority and registered by submitting appropriate dossier for variation mentioned under section 2(b) of this guideline.

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 applies to veterinary instruments which are specifically intended to be used in animal health (clinical, diagnostic, research, and other practices) and claimed for registration to enter the Ethiopian market. This applies to new registration, re-registration and variation applications of veterinary instruments.

OBJECTIVE

The objective of this guideline is to provide a guidance and requirements for submission of registration applications of veterinary instruments to assist applicants to compile and submit a complete and consistent registration dossier to facilitate the registration process of the products.

OPERATIONAL DEFINITIONS

Authority: The Ethiopian Agricultural Authority (EAA)

Applicant: Means the manufacturer or/and the market authorization holder of the veterinary instrument.

Local Agent: means a company registered in Ethiopia and certified by EAA to run a veterinary drugs business that has received a mandate from the applicant to act on his/her behalf with regard to matters relating to the registration of veterinary instruments.

Veterinary Instrument: means any device that may be used for diagnosis, treatment, or prevention of animal diseases, and includes but not limited to laboratory, artificial insemination and castration

instruments, machines and reagents. But does not achieve its primary intended use in or on the animal body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

Label: means any tag, brand, mark, pictorial or other descriptive matter, written, printed, marked, embossed or impressed on or attached to a container of any veterinary instrument and includes an informational sheet or user manual or leaflet that accompanies the instrument when its being supplied.

Manufacture: means all operations that involve preparation, processing, filling, transforming, packaging, repackaging and labelling of veterinary medical devices.

Manufacturer: means a person or a firm that is engaged in the manufacture of veterinary instruments.

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.

Documentation: a compilation of required information for registration including samples and any other additional information requested for registration.

Certificate of Registration (Market Authorization): means an official document granted to a veterinary instrument to enter the market after ensuring the fulfilment of registration requirements.

Intended use or purpose: The objective intent of the manufacturer regarding the use of a veterinary instrument, process or service as reflected in the specifications, instructions and information provided by the manufacturer.

Packaging material: means any material, including printed material, employed in the packaging of a veterinary medical device, excluding any outer packaging used for transportation or shipment.

Quality Management System: means a management system to direct and control an organization with regard to quality, from establishing quality policy, quality objectives and implementing and maintaining a quality system.

Registered Veterinary Instrument: means veterinary instrument that has been granted market authorization.

Technical Documentation: means documented evidence, normally an output of the Quality Management System that demonstrates compliance of a device to the Essential Principles of Safety and Performance of veterinary medical devices.

Shelf-life: The period during which a veterinary instrument maintains its intended performance and safety under a specified storage condition.

1. GENERAL GUIDANCE, PROCEDURES AND REQUIREMENTS

a) Any veterinary instrument(s) manufacturer or market authorization holder shall not sell, manufacture, import or export, distribute, provide as a gift or offer for sale any veterinary instrument unless it is registered by the Authority.

b) Applicants shall submit their application to the Authority to register their veterinary instruments according to this guideline.

c) Applicants shall submit their application through an online application system (https://www.eservices.gov.et/) at the service name of "*Veterinary Medical Devices Registration Service"* and all the required documents shall be attached at its respective attachment spaces in PDF format.

d) All applications shall be submitted in English language. If some or all section of the document is prepared in a foreign language other than English language, an official English translation of such document bearing official stamps of the translator shall be presented.

e) All applications pass through two stages of review process. The first stage is screening (validation of application), which occurs before the scientific review with the aim of ensuring completeness & eligibility of the application for the approval pathway in order to facilitate the subsequent scientific review. Documents indicated on section 3 (b, d & e) of this guideline shall be submitted for this stage. The second stage is evaluation which includes the detail assessment of the submitted administrative and technical documents against the requirements stipulated in this guideline. The documents

indicated under sections 3 (a, c, f, g & h) and 4 (a, b & c) shall be submitted for the second stage of evaluation.

f) Applications can be submitted by the manufacturer, market authorization holder, or a local agent assigned by the manufacturer and/or market authorization holder of the veterinary instrument(s).

g) Applications for registration of veterinary instruments can be submitted as a single instrument or listed group of veterinary instruments.

h) Every application shall be accompanied by appropriate service fees as specified in the Service Fees Regulation currently in force at the time of application.

i) Evaluation of the applications by the Authority will be conducted chronologically based on the principle of first-in-first-out (FIFO) procedure.

j) During the review, additional data and/or samples may be requested. Once a query has been raised, the evaluation processing will halt until the applicant responds to the query. If the applicant doesn't submit a query response within 6 months, it will be deemed as the application has been withdrawn by the applicant. If not able to respond within 6 months due to reasonable scientific or technical issues, the applicant shall submit such justifications within 15 working days.

k) When a veterinary instrument is found to have complied with all the prescribed registration requirements, a registration certificate will be issued to the applicant.

l) The certificate of registration is valid for a period of five (5) years unless suspended or revoked by the Authority or terminated by the registrant.

m) It is, therefore, mandatory for manufacturers and/or market authorization holders to apply for re-registration by submitting the required dossier. Any variation to registered veterinary instrument shall also be applied to the Authority by submitting appropriate dossier for variation.

2. TYPES OF APPLICATIONS

For the purpose of submission to EAA, applications are categorized as:

a) New Applications

These are applications for registration of veterinary instruments that are intended to be placed on the Ethiopian market for the first time.

The following documents shall be submitted for the new registration application;

i. All administrative documents mentioned under **section 3** of this guideline
ii. All technical documentation mentioned under **section 4** of this guideline
iii. Sample(s) of the product(s) for QC test (*as required*)

b) Applications for Variation of a Registered Veterinary Instrument(s)

The Authority should be informed on any change(s) that could reasonably be expected to affect the safety, quality or performance of the veterinary instrument(s).

If the proposed change affects the content of registration certificate issued by the Authority, the Authority will issue amended certificate. However, if the change does not result in the change of the content of marketing authorization certificate issued by the Authority, acceptance letter will be issued as evidence of approval.

The issue date of the registration certificate will remain the same after approval of the variation.
Any application for variation to a registered veterinary instrument shall be accompanied with the following documents: -

i. Dully filled in application form for variation (**Annex III**)
ii. Covering letter
iii. Re-submission of all parts of the dossier that are affected by the variations according to the structure of this guideline.
iv. A non-refundable service fee for variation as prescribed in the EAA Fees and Charges Regulation currently in force.
v. A detailed documentation along with samples (*if applicable*).

c) Applications for Renewal of Registration

Applications for renewal of registration shall be made at least 90 days before and 90 days after the expiry date of the validity period. If the market authorization holder doesn't submit according to the above specified days, a renewal application can only be accepted within additional 90 days by paying a penalty of half of the service fee for renewal registration. The registration certificate is considered as cancelled if the market authorization holder doesn't apply for renewal according to the above specified days and an applicant may

apply as a new veterinary instrument registration application. The following documents shall be submitted for re-registration of the veterinary instruments: -

i. A dully filled in application form for renewal of registration (**Annex II**)
ii. Original and authenticated free sale certificate as per 3(h) of this guideline.
iii. Valid manufacturing license
iv. Certificate of quality management system (QMS) as specified on section 3(g) of this guideline.
v. Specifications of the device along with certificates of analysis (*if applicable*)
vi. Artwork or mock-up of package and label of the instruments (*if applicable*)
vii. A non-refundable application fee for renewal registration of veterinary instruments in Ethiopia as prescribed in the EAA Fees and Charges Regulation currently in force.
viii. Confirmatory letter that declares no change is made on the manufacturing method, quality specification and package & label of the veterinary instrument(s) since the previous registration.
ix. A detailed documentation along with sample(s) of the instrument(s) (*as required*).

3. ADMINISTRATIVE DOCUMENTATION

a) Cover letter

An application for the registration of a veterinary instrument shall be made in writing via a cover letter. The cover letter submitted with

the dossier shall include a declaration statement by the applicant indicating that the information submitted is true and correct.

b) Application form

The application form (**Annex I, II & III**) shall only be filled by the applicant, signed by an authorised person and have an official stamp of the applicant.

c) Fee payment receipt

Evidence of payment of a registration fee paid according to the Authority's service fee regulation regimen currently in force.

d) Manufacturing license

A copy of valid manufacturing license issued by the competent body in the country of origin shall be submitted.

e) Agency agreement

A signed agency agreement made between the manufacturer and/or market authorization holder of the veterinary instrument and the local agent in Ethiopia shall be submitted. The agreement shall clearly state that both parties are responsible on all issues of quality of the products, to collect the product from the market and substantiating any related consequences, if any quality defect is confirmed during inspection of consignment of the product and by post-marketing surveillance and/or if any fraud or unsuspected and unacceptable adverse event occurs to the animal or user under normal usage.

f) Company profile (Manufacturer)

The applicant should submit background information about the manufacturer indicating the year of establishment, development

since establishment, ownership, organogram (organizational chart of the company), financial capacity, and total working force. Additionally, documents about the production unit, quality control system, and research & development shall be submitted.

g) Certificate of Quality Management System (QMS)

A valid QMS certificate for medical device manufacturing (ISO 13485 or any other parallel quality standard) issued by a recognized certifying body shall be submitted. This certificate should be traceable at the national database or website of the certifying body.

h) Free Sale Certificate

Original Free Sale Certificate (FSC) issued by competent authority in the country of origin should be submitted. The list of all instruments claimed for the registration shall be clearly indicated on the FSC. The FSC shall be authenticated by Ethiopian embassy in the country of origin or neighbouring country or by Ethiopian Ministry of Foreign Affairs. If the applicant is unable to authenticate the certificate in accordance with the above points, due to non-existence of the Ethiopian embassy in the area and this is confirmed by the Authority, a registration certificate confirming the registration of the product in the country of origin and/or other countries shall be submitted along with the original FSC.

4. TECHNICAL DOCUMENTATION

a) Veterinary Instrument Details

i. Name of the instrument(s)
ii. Labelled pictorial representation of the instrument(s) in the form of diagrams, photographs or drawings with sufficient explanation should be provided.

iii. Details about components, parts, spares, and accessories which are intended to be presented with the veterinary instrument(s)
iv. Intended use/indication
v. Instruction for use
vi. Warning, precaution, contraindication (*if necessary*)
vii. Storage condition and shelf-life (*if necessary*)

b) Safety and Performance Documents

i. Materials from which the instrument is made and description of its suitability for the intended purpose
ii. Specification of the instrument (*if necessary*)
iii. Manufacturing process
iv. Certificate of analysis (*if applicable*)
v. Device verification and validation (*if applicable*)
vi. Risk analysis of the instrument (*if applicable*)

c) Labelling Requirements

Artwork or mock-up of package and label of the instruments shall be submitted. Labelling information on the veterinary instruments should be provided in English in which the labelling shall be expressed in a legible, permanent, and prominent manner that can be easily understood by the intended user.

The label shall include the following information:

i. Name of the veterinary instrument
ii. Batch or lot or serial or model number of the instrument(s)
iii. Name and address of the manufacturer and/or market authorization holder of the instrument
iv. Manufacturing and expiry date of the instrument (*if applicable*)
v. The words “Sterile” and “For Single Use Only” should be written on the label if the veterinary instrument is intended

to sell in a sterile condition and intended for single use respectively.

vi. For those veterinary instruments that do not have immediate packaging, the instrument shall have a unique permanent mark directly embossed or written on the instrument. The marks could be letters and/or symbolic figures.

vii. Where applicable, veterinary medical devices should be accompanied with device user manual. The user manual may be presented as a soft copy and/or a hard copy.

Annexes

Annex I: Application form for New Registration of Veterinary Instruments

1. Applicant name and address: _____
   _____
   _____
2. Name and address of the manufacturer (if different from the applicant): _____
   _____
3. License number of the manufacturer in the country of origin _____
4. Name and address of the local agent or technical representative in Ethiopia: _____
   _____
5. List of veterinary instruments for registration

S/N	Name of the instrument	Purpose/Use
1		
2		
3		
4		
5		
	Add new row option needed	

6. Current registration and licensing status of the products in the country of origin and other countries _____
   _____
   _____
   _____

7. 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.

Signature: _____
Full name and position of signatory: _____
Date: _____

_____

Annex II: <u>Application form for Re-registration of Veterinary Instruments</u>

1. Applicant name and address: _____
   _____
   _____
2. Name and address of the manufacturer (if different from the applicant): _____
   _____
   _____
3. License number of the manufacturer in the country of origin _____
4. Name and address of the local agent or technical representative in Ethiopia: _____
   _____
5. List of veterinary instruments for re-registration

S/N	Name of the instrument	Purpose/Use
1		
2		
3		
4		
5		
	Add new row option needed	

6. Previous registration number in Ethiopia _____
7. 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.

Signature: _____
Full name and position of signatory: _____
Date: _____

Annex III: <u>Application form for Variation Registration of Veterinary Instruments</u>

1. Applicant name and address: _____
   _____
2. Name and address of the manufacturer (if different from the applicant): _____
   _____
3. License number of the manufacturer in the country of origin _____
4. Name and address of the local agent or technical representative in Ethiopia: _____
   _____
5. Previous registration number in Ethiopia _____
6. Description of the change(s) made from previous market authorization (description of the variation application) ____
   _____
   _____
7. 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.

Signature: _____
Full name and position of signatory: _____
Date: _____
_____

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