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ETHIOPIAN AGRICULTURAL AUTHORITY

E Ethiopia
F Food
S System
R Resilience
P Program

SNV Impact that matters

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ETHIOPIAN AGRICULTURAL AUTHORITY

GUIDELINE ON THE DOSSIER REQUIREMENTS FOR VARIATION REGISTRATION OF VETERINARY DRUGS IN ETHIOPIA

JUNE 2025

ADDIS ABABA, ETHIOPIA

ETHIOPIAN AGRICULTURAL AUTHORITY

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Guideline on the Dossier Requirements for Variation Registration of Veterinary Drugs in Ethiopia

First Edition

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FOREWORD

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 Authority has issued this guideline on submission of dossier for variation registration of veterinary drugs. This guideline provides guidance to applicants on documents and information required for submission of variations applications on the previously approved market authorizations. It also guides the authority in managing applications submitted for variation registration. 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

ACKNOWLEDGEMENT

The Ethiopian Agricultural Authority appreciates the financial support received from Food Systems Resilience Program (FSRP) of the Ministry of Agriculture in the development of this guideline. The Authority would also like to thank the technical working team who drafted the guideline. Appreciation also goes to all participants of the validation workshop for sharing their technical comments to enrich the guideline.

LIST OF ABBREVIATIONS

API	Active Pharmaceutical Product
BMR	Batch Manufacturing Record
CEP	Certificate of Suitability
EAA	Ethiopian Agricultural Authority
CPP	Certificate of Pharmaceutical Product
FVP	Finished Veterinary Product
GMP	Good Manufacturing Practice
MAH	Market Authorization Holder
NRA	National Regulatory Authority
SmPC	Summary of Product Characteristics
TSE	Transmissible Spongiform Encephalopathy
FIFO	First-in-First-out

INTRODUCTION

The Ethiopian Agricultural Authority (EAA) is a government institution established by Proclamation No.1263/2021 and Council of Minster Regulation No. 509/2022 mandated to regulate the quality, safety and efficacy of veterinary drugs among other agricultural inputs and products. One important method of ensuring the safety, quality and efficacy of these veterinary drugs is thorough evaluation and authorization before they are placed for use in the country. Any changes to a registered veterinary drug, i.e., variations, whether administrative or substantial, are also subject to approval by the authority. It's provisioned on article 18(1) of the Veterinary Drugs Registration Directive No. 1036/2025 that any marketing authorization holder shall not make change on the authority approved product labelling, packaging and other conditions of registered veterinary drugs unless notified to and get approval from the authority. Article 18(2) of this directive also promulgates the marketing authorization holder shall apply any variations to registered veterinary drugs as per the Authority's current guideline on variation applications to the registered veterinary drugs.

Pursuant to these mandates and provisions, the authority has developed and endorsed this guideline to inform applicants on the requirements for variation 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 before a variation can be approved by the authority. Guidance for the implementation of

the different types of variations (notification, minor and major variations) is set out in this document to facilitate the task of both the MAHs and the Authority, and to guarantee that variations to the veterinary product do not give rise to negative effects on animal health as well as public health concerns.

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 applicants intending to make changes to a registered veterinary drug, including pharmaceutical and immunological products, approved by the authority. It's not applicable on products that are under assessment process for new registration. This guideline should be read in conjunction with other applicable guidelines including guideline for veterinary pharmaceutical products registration and guideline for veterinary immunological products registration.

OPERATIONAL DEFINITIONS

Applicant is a company who applies for variation registration of a veterinary drug, this might be the manufacturer or market authorization holder of the product.

Authority refers to the Ethiopian Agricultural Authority.

Active Pharmaceutical Product: is the unformulated active substance or organism that is responsible for the pharmacological, physiological, or immunological action of the product, which may be subsequently formulated with excipients to produce the finished veterinary product.

Finished Veterinary Product means a medicinal product that has undergone all stages of production, including packaging in its final container and labeling.

Local Agent means a company registered in Ethiopia and certified by EAA to run a veterinary drug business, that has

received a mandate from the applicant to handle registration issues on his/her behalf.

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.

Major variation means a significant change to the registered finished veterinary drug that has major effect on the overall quality, safety and efficacy of the finished product.

Minor variation means a change to the registered finished veterinary drug that have minimal or no effects on the overall quality, safety and efficacy of the finished product.

Variation means a post-registration change to any aspect of a veterinary drug, including but not limited to a change to formulation, method and site of manufacture, specifications for the finished product and ingredients, container and container labelling and product information.

Veterinary Drug means medicines which includes veterinary pharmaceutical, biological and immunological products.

1. GENERAL PRINCIPLES AND GUIDANCE

A) Principles

i) Any marketing authorization holder shall not make change on the approved product labelling, packaging and other conditions of registered product unless notified and get approval from the Authority.

ii) The marketing authorization holder shall apply any variations to registered veterinary drug as per this guideline.

iii) Any variation made on the pre-approved product registration shall be notified before implementation to get an approval from the Authority.

iv) The marketing authorization holder shall re-submit all parts of the dossier that are affected by a variation based on the type of variation as listed on sections 2 of this guideline.

v) The Authority will evaluate applications chronologically based on the principle of first-in-first-out (FIFO) procedure.

vi) 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.

vii) The issue date of the registration certificate will remain the same after approval of the variation(s).

B) Categorization of Changes

Categorization of the variations is essential to evaluate the implementation of changes made on the veterinary drug. It also provides guidance to the applicants with respect of classification of the changes made and the submission of relevant documents to the authority.

i) Notification

Notifications are changes that could have minimal or no adverse effects on the overall safety, efficacy, and quality of the finished veterinary drug. Such notifications must be notified to the Authority and get written approval from the Authority before implementation of the change.

ii) Minor Variation

Minor variations are changes that may have minor effects on the overall safety, efficacy, and quality of the finished veterinary drug. Applicants must satisfy themselves that they meet all of the prescribed conditions for the change and submit all required documentation with the variation application.

iii) Major Variation

Major variations are changes that could have major effects on the overall safety, efficacy, and quality of the finished veterinary drug. The documentation required for the changes included in this reporting type should be submitted.

C) Application Procedures

i) Applicants shall submit their application through an online application system (https://www.eservices.gov.et/) at the service name of "*Veterinary Drugs Variation Registration*".

ii) Individual changes shall be submitted in separate variation applications.

iii) If multiple variations are made on a single product registration scheme, a single application should be made by compiling the required documents for each variation and paying the service fee.

iv) A variation consisting of both a minor and major variations will be classified as a major variation.

v) A notification or minor variation that affects multiple market authorizations and submitted as grouped variation application may be approved accordingly. A service fee set for a single minor variation shall be paid for such applications. However, any major variation that affects multiple market authorizations should be applied separately for each product.

vi) Applicants shall submit the following documents along with the technical documents required for each type of variation stated under sections 2.2 & 2.3 of this guideline.

a) Application form (Annex I)
b) Registration certificate of the product
c) Agency agreement signed between the marketing authorization holder and local agent and/or agency agreement approval letter issued by the Authority

d) Description of the change made
e) Confirmation letter that declares there is no other change except for the proposed variation
f) Proof of service fee payment

D) Changes that cannot be Considered as Variation and Need New Registration

The following changes are not acceptable for variation registration. These changes require registration of the product as new.

i) Change of active ingredient
ii) Inclusion of an additional active ingredient to the existing composition
iii) Removal of active ingredient from a combination drug
iv) Change of strength
v) Change of dosage form
vi) Change of route of administration

2. DOCUMENT REQUIREMENTS AND CONDITIONS TO BE FULFILLED FOR SUBMISSION OF VARIATIONS

2.1. Notifications

S/N	Description of Variation	Conditions to be Fulfilled	Documents Required	Sample Submission Requirement
1	Change of graphic design of the package and label of the product (change in color of the packaging, change in the layout of information or pictures without altering the meaning, and addition/ deletion/ replacement of pictures, diagrams, bar code, or logos)	No change on the main content of prescribing information of the label and leaflet	• The new proposed package and label design • Description of the reason for change	No
2	Change in the name or address of a manufacturer of an API	No change in the location of the manufacturing site and in the manufacturing operations	• A formal document from a relevant official body in which the new name and/or address is mentioned.	No
3	Change of the shape, dimension, or color of the container closure of the FVP	No change in the type of the primary packaging material	• Description of the change • Specification and method of analysis of the container/closure	No
4	Change in the unit of expression of the composition of the product on the package, leaflet and label of the product	• No change in the qualitative and quantitative composition of the product • The ratio between the new and previous unit expressions should be the same.	Newly proposed and old designs of the package, label and leaflet of the product.	No

5	Addition of site of products distribution	• The manufacturing site and MAH are not changed	• Formal document from a national competent body that shows the new distribution site is legal entity. • A document that clearly shows the distribution channel and the relationship between the MAH and the distribution center.	No

2.2. Minor Variations

S/N	Description of Variation	Conditions to be Fulfilled	Documents Required	Sample Submission Requirement
1	Change of the name and/or address naming of the manufacturer and/or Marketing Authorization Holder (MAH) of the registered product	• The manufacturer and/or MAH of the product remains the same legal entity • No change in the location of manufacturing site and in the manufacturing operations	• A formal (legal) document from a competent body in which the new name and/or address is mentioned. • Revised package, label and leaflet of the product(s).	No
2	Change of MAH from one company to another	• The manufacturer of the product remains the same legal entity • All legal requirements for change of MAH have been met & Legal transfer of change has been completed	• Notarized transfer documents • A certified copy of company registration certificate from the relevant jurisdiction • Letter of cessation from previous/current MAH • Letter of acceptance from proposed MAH	No

3	Deletion of a manufacturing site or manufacturer involving production, packaging or testing of the intermediate or finished veterinary product	• At least one other site continues to perform the same function(s) as the site(s) intended to be deleted. • The deletion of site is not a result of critical deficiencies in manufacturing.	• Clear identification of the manufacturing, packaging and/or testing site to be deleted, in the letter accompanying the application. • Documents that support the deletion of the mentioned site doesn't affect the manufacturing activity.	No
4	Replacement or addition of a new manufacturing site or manufacturer of an API	• The profile, manufacturing process and specification of the API are verified as equivalent to that previously accepted and have no effect on the release and end-of-shelf-life specifications of the finished product (quality, safety & efficacy). • The new site is cGMP certified by competent authority.	• Name, address, and responsibility of the proposed site or facility involved in manufacture or testing (including block(s) and unit(s). • A valid certificate of GMP compliance. • A side-by-side comparison of the manufacturing flowcharts for production of the API, intermediate, or API starting material (as applicable) at the parent and proposed sites. • Copies or summaries of validation reports or method transfer reports, which demonstrate equivalency of analytical procedures to be used at the proposed testing site. • Description of the batches, copies of certificates of analysis and batch analysis data (in a comparative tabular format) for at least two (minimum pilot scale) batches of the	No

			API from the currently accepted and proposed manufacturers/sites. • Stability study report of the API • A copy of the finished product manufacturer's API specifications. • A discussion of the impact of the new API on the safety, efficacy, and quality of the veterinary product. • Declaration that the specification, method of analysis and certificate of analysis of the finished product is not changed.	
5	Changes to the test parameters, acceptance criteria, or analytical procedures of the API manufacturer that do not require a change to the FVP manufacturer's API specifications	• The revised test parameters, acceptance criteria, or analytical procedures have been submitted as amendments to the associated regulatory body and accepted. • The API manufacturer has provided the relevant documentation to the FVP manufacturer. The FVP manufacturer has considered the API manufacturer's revisions and determined that no consequential revisions to the FVP manufacturer's API test parameters, acceptance criteria, or analytical procedures are required	• Copy of the current and proposed API specifications dated and signed by the API manufacturer. • Copies or summaries of analytical procedures if new analytical procedures are used. • Copies or summaries of analytical validation reports for new or revised analytical procedures, if applicable. • Certificate of analysis of the API • Justification as to why the change does not affect the FVP manufacturer's specifications.	No

		to ensure that adequate control of the API is maintained.		
6	Change of product name	• The product name should not have been accepted for another product. • The product name should not bear close resemblance to that already registered by the authority (pronunciation and spelling) • There is no change to the product (formulation, release & shelf-life specifications, manufacturing source & process) except for the product name change.	• Revised summary of product characteristics, label, package and leaflet. • A declaration from the marketing authorization holder that there is no other changes to the product except for the product name change.	No
7	Change of shape & appearance of boluses (addition or deletion of embossing, imprints and score lines and change in dimensions) without change in qualitative & quantitative composition	• Specifications for the FVP are updated only with respect to dimensions of the FVP. • Multipoint in vitro dissolution profiles of the current and proposed versions of the product (determined in the release medium, on at least one batch of pilot or production scale), are comparable.	• For scored tablets/boli where the scoring is intended to divide the FVP into equal doses, demonstration of the uniformity of the tablet/bolus portions. • Discussion on the differences in manufacturing process (es) between the currently accepted and proposed products and the potential impact on product performance. • Comparative multipoint in vitro dissolution profiles in the release medium, on at least one batch of pilot or production scale of the current and proposed products.	No

			• Copies of revised FVP release and shelf-life specifications. • Copies of relevant sections of blank BMR with changes highlighted as well as relevant pages of executed BMR for one batch and confirmation that there are no changes to the production documents other than those highlighted.	
8	Change in the package size of the finished veterinary product	• The change is consistent with the posology and treatment duration accepted in the SmPC. • No change in the primary packaging material.	• Revised draft of packing inserts and labelling incorporating the proposed variation. • Justification for the new pack-size, showing that the new size is consistent with the dosage regimen and duration of use as registered in the SmPC. • A written commitment that stability studies will be conducted • In case of outer carton pack size change, letter of declaration stating that no other changes except for the change of outer carton pack sizes for finished product.	No

2.3. Major Variations

S/N	Description of Variation	Conditions to be Fulfilled	Documents Required	Sample Submission Requirement
1	Change in the composition of a solution and suspension dosage forms	• The affected excipient(s) does/do not function to affect the solubility and/or the absorption of the API. • The affected excipient(s) does/do not function as a preservative or preservative enhancer. • No change in the specifications of the affected excipient(s) or the FVP. • No change in the physical characteristics of the FVP (e.g., viscosity, osmolality, pH). • The excipients are qualitatively the same. The change in the amount (or concentration) of each excipient is within ±10% of the amount (or concentration) of each excipient in the originally registered product.	• Description and composition of the FVP • Discussion on the components of the proposed product (e.g., choice of excipients, compatibility of API and excipients, preservative effectiveness, suitability studies on the packaging system for the changed product). • Batch formula, description of manufacturing process and process controls, controls of critical steps and intermediates, process validation protocol and/or evaluation. • Control of excipients if new excipients are proposed. • For any new component of animal origin susceptible to TSE risk, documented evidence that the specific source of the TSE risk material is free of TSE or BSE. • Copies of FVP release and shelf-life specifications and certificates of analysis for a minimum of three pilot or production scale batches.	**Yes**

			• Evidence to demonstrate that the new excipient does not interfere with the analytical procedures for the FVP. • Results of stability testing generated on at least three pilot or production scale batches with a minimum of six (6) months of accelerated and six (6) months of long-term testing. • Copies of relevant pages of blank batch manufacturing record (BMR) with changes highlighted, as well as relevant pages of the executed BMR for one batch and confirmation that there are no changes to the BMR other than those highlighted. • Certificate of pharmaceutical product (CPP)	
2	Change in the composition of solid oral dosage forms including: • replacement of a single excipient with a comparable excipient at a similar level • quantitative changes in excipients	• No change in functional characteristics of the pharmaceutical form. • Only minor adjustments are made to the quantitative composition of the FVP; any minor adjustment to the formulation to maintain the total weight is made by an excipient which currently makes up a major part of the FVP formulation.	• Description and composition of the FVP. • Supporting clinical or comparative bioavailability data or justification for not submitting a new bioequivalence study according to the current requirements. • Discussion on the components of the proposed product (e.g., choice of excipients, compatibility of API and excipients)	**Yes**

		• Stability studies have been started • The dissolution profile of the proposed product determined on a minimum of two pilot scale batches is similar to the dissolution profile of the old composition. • The change is not the result of stability issues and/or does not result in potential safety concerns i.e., differentiation between strengths.	• Batch formula, description of manufacturing process, controls of critical steps and intermediates, and process validation protocol and report. • Control of excipients if new excipients are proposed. • For any new component of animal origin susceptible to TSE risk, documented evidence that the specific source of the TSE risk material is free of TSE or BSE. • Copies of FVP release and shelf-life specifications and certificates of analysis for a minimum of two pilot or production scale batches. If applicable, data to demonstrate that the new excipient does not interfere with the analytical procedures for the FVP. • Results of stability testing generated on at least three pilot or production scale batches with a minimum of six (6) months of accelerated and long-term testing. • Copies of relevant sections of blank BMR with changes highlighted as well as relevant pages of the executed BMR for one batch, and confirmation that there are no changes to the production documents other than those highlighted.	

			• Certificate of pharmaceutical product (CPP)	
3	Change in the colouring system or the flavouring system currently used in the FVP involving: • Reduction or increase of one or more components of the colouring or the flavouring system • deletion, addition or replacement of one or more components of the colouring or the flavouring system	• No change in the functional characteristics of the pharmaceutical form e.g. disintegration time or dissolution profile. • Any minor adjustment to the formulation to maintain the total weight is made using an excipient which currently makes up a major part of the FFVP formulation. • Specifications for the FFVP are updated only with respect to appearance, odour and/or taste or if relevant, deletion or addition of a test for identification.	• Discussion on the components of FVP (e.g. compatibility of the API, qualitative composition of colouring and flavouring system if purchased as mixture, with specifications, if relevant). • TSE/BSE free certificate of the newly added coloring/flavoring agent • Copies of revised FVP release and shelf-life specifications and certificates of analysis • If applicable, data to demonstrate that the new excipient does not interfere with the analytical procedures for the FVP. • Results of stability testing generated on at least three pilot or production scale batches with a minimum of 6 months of accelerated and long-term testing. • Certificate of pharmaceutical product	**Yes**
4	Addition or replacement of a manufacturing site for part or all the manufacturing process for a FVP involving: • Secondary packaging of all types of FVPs	• No change in the batch formula, description of manufacturing process and process controls, equipment class and process controls, controls of critical steps and intermediates, or FVP specifications.	• A copy of the current manufacturing authorization, a GMP certificate or equivalent issued by the NRA in the country of origin. • GMP certificate issued by the Authority • For solid dosage forms, data on comparative dissolution tests in the routine release medium, with	**Yes**

	• primary packaging site of FFVP • all other manufacturing operations except batch control/release testing	• Satisfactory joint inspection in the last three years by the authority. • Site appropriately authorized by national regulatory authority (to manufacture the pharmaceutical form and the product concerned). • Validation protocol is available or validation of the manufacturing process at the new site has been successfully carried out on at least three production scale batches in accordance with the current protocol.	demonstration of similarity of dissolution profiles with those of the biobatch, performed on one (1) production scale batch each from current and proposed manufacturing sites and comparison with the biobatch results, with commitment to generate dissolution profiles on two (2) more production scale batches. • Process validation protocol and reports for three (3) batches of the proposed batch size. • Copies of FVP release and shelf-life specifications from the proposed manufacturing site. • Batch analysis data on one production scale batch from the proposed site and comparative data on the last three batches from the previous site. • Stability study data report of at least six (6) months of accelerated and long-term data of three batches and a commitment letter to continue the stability study. • Executed batch manufacturing record for one batch of the FVP manufactured at the new site. • Certificate of pharmaceutical product (CPP)	

5	Change in the manufacturing process of the FVP	• The change does not require supporting in vivo data. • No change in qualitative and quantitative impurity profile or in physico-chemical properties; dissolution profiles are similar with those of the biobatch. • The manufacturing processes for the currently accepted and proposed products use the same principles (e.g., a change from wet to dry granulation, from direct compression to wet/dry granulation or vice versa would be considered a change in manufacturing principle), same processing intermediates and there are no changes to any manufacturing solvent used in the process. • The same classes of equipment, operating procedures, in-process controls (no widening or deleting of limits) are used for the currently accepted and proposed products, no change in critical process parameters. • No change in the specifications of the intermediates or the FVP.	• Discussion on the development of the manufacturing process. • Comparative in vitro testing, e.g., multipoint dissolution profiles in the release medium for solid dosage units (one production batch and comparative data of one batch from the previous process and the biobatch results). • Batch formula, manufacturing flow chart, description of manufacturing process and process controls, controls of critical steps and intermediates, process validation protocol and/or report. • Specification(s), certificate of analysis for one production scale batch each manufactured according to the currently accepted and the proposed processes. • Results of stability testing generated on at least three pilot batches with a minimum of six (6) months of accelerated and six (6) months of long-term testing. • Stability protocol and stability commitment to place the first production scale batch of the proposed product into the long-term stability programme. • Batch manufacturing record of at least one batch executed according to the new process.	**Yes**

		• The change is not necessitated by unexpected events, resulting in failure to meet specifications, arising during manufacture or because of stability concerns. • The change does not involve packaging or labeling where the primary packaging provides a metering and/or delivery function. • The change does not affect the sterilization parameters of a sterile FVP.		
6	Change in the standard claimed for the FVP from an in-house to an officially recognized pharmacopoeia standard. Update to the specifications to comply with an officially recognized pharmacopoeia monograph because of an update to this monograph to which the FVP is controlled.	• The change is made exclusively to comply with the officially recognized pharmacopoeia. • No change to the specifications that result in a potential impact on the performance of the FVP (e.g., dissolution test). • No deletion of or relaxation to any of the tests, analytical procedures, or acceptance criteria of the specifications.	• Copy of the proposed FVP specifications dated and signed by authorized personnel and copy of the claimed official monograph. • Where an in-house analytical procedure is used and a pharmacopoeial standard is claimed, results of an equivalency study between the in-house and pharmacopoeial methods. • Description of the batches, certificates of analysis for at least one batch (minimum pilot scale) and comparative summary of results, in tabular format, for one batch using current and proposed procedures, if new analytical procedures are implemented.	**No**

			• Justification for the proposed FVP specifications. • Demonstration of the suitability of the monograph to control the FVP.	
7	Change in the specifications of the FVP involving test parameters and acceptance criteria	• The change is within the range of currently accepted limits. • The change is not necessitated by unexpected events, resulting in failure to meet specifications, arising during manufacture or because of stability concerns. • Any new analytical procedure does not concern a novel, non-standard technique or a standard technique used in a novel way. • No additional impurity found over the VICH identification threshold. • The deleted test has been demonstrated to be redundant with respect to the remaining tests. • The change to the specifications does not affect the stability and the performance of the product. • The change does not concern sterility testing.	• Copy of the proposed FVP specifications dated and signed by authorized personnel and a comparative table of currently accepted and proposed specifications. • Copies of analytical procedures, if new analytical procedures are used. • Copies of analytical validation reports, if new analytical procedures are used. • Where an in-house analytical procedure is used and a pharmacopoeial standard is claimed, results of an equivalency study between the in-house and pharmacopoeial methods. • Description of the batches, certificates of analysis for at least one batch (minimum pilot scale) and comparative summary of results, in tabular format, for one batch using currently accepted and proposed procedures, if new analytical procedures are implemented. • Justification for the proposed FVP specifications.	**Yes**

8	Change in the analytical procedures for the FVP	• The method of analysis is based on the same analytical technique or principle (e.g., changes to the analytical procedure are within allowable adjustments to column length, etc., but do not include variations beyond the acceptable ranges or a different type of column and method), and no new impurities are detected. • Comparative studies demonstrate that the proposed analytical procedure is at least equivalent to the currently accepted analytical procedure. • Any new analytical procedure does not concern a novel, non-standard technique or a standard technique used in a novel way. • The change does not concern sterility testing. • The change is not necessitated by unexpected events, resulting in failure to meet specifications, arising during manufacture or because of stability concerns.	• A copy of the proposed FVP specifications dated and signed by authorized personnel and a comparative table of currently accepted and proposed specifications. • Copies of analytical procedures if new analytical procedures are used. • Copies of analytical validation reports, including verification data for assay or purity methods, if new analytical procedures are used. • Where an in-house analytical procedure is used and a pharmacopoeia standard is claimed, results of an equivalency study between the in-house and pharmacopoeia methods. • Description of the batches, certificates of analysis for at least one batch (minimum pilot scale) and comparative summary of results, in tabular format, for one batch using currently accepted and proposed analytical procedures. • Justification for the deletion of the analytical procedure, with supporting data.	**Yes**

		• No new impurities have been detected.		
9	Replacement or addition of a primary packaging type	The change does not include any change on the qualitative and quantitative composition of the product.	• Data on the suitability of the container closure system (e.g., extractable/leachable testing, permeation testing, light transmission) demonstrating equivalent or superior protection compared to the current packaging system. • For changes to functional packaging, data to demonstrate the functioning of the new packaging. • For sterile FVPs, process validation and/or evaluation studies. • Information on the proposed primary packaging type (e.g., description, materials of construction of primary packaging components, specifications, results of transportation studies, if appropriate). • Stability summary and conclusions, results for a minimum of three (3) batches of pilot or production scale of at least six (6) months of accelerated and six (6) months of long-term testing. • A stability commitment to place the proposed product into the long-term stability programme, unless full data is provided.	**Yes**

10	Change in the shelf-life of the FVP (as packaged for sale)	• No change to the primary packaging type in direct contact with the FVP and to the recommended condition of storage. • Stability data was generated in accordance with the currently accepted stability protocol. • The change is not necessitated by unexpected events arising during manufacture or because of stability concerns.	• Copy of the currently accepted shelf-life specifications. • Full long-term stability study data report of three commercial batches conducted for at least the period of claimed shelf-life.	**No**
11	Change in the labelled storage conditions of the veterinary drug (as packaged for sale), the product during the in-use period or the product after reconstitution or dilution.	• The change is not necessitated by unexpected events, resulting in failure to meet specifications, arising during manufacture or because of stability concerns.	• Stability and/or compatibility test results to support the change to the storage conditions. • Justification for the proposed change of the storage condition.	**No**
12	Change and/or additional • Indications • Dosing regimen • Target animals • Inclusion of clinical information extending the	Potential benefits of the product, when used to treat the identified disease or condition, outweigh the known and potential risks of the product.	• Currently approved product labelling. • Proposed product labelling, a clean and annotated version highlighting the change made • Approved SmPC from an approved reference regulatory authority or the country of origin containing the proposed changes (where applicable) • Justification for the change proposed.	**Yes**

	usage of the product		• Data on safety and effectiveness for recommended indication under the recommended conditions of use such as dosage, status and age of patients and others. • Clinical trial reports (where applicable) • Efficacy document as per module 4 of the guideline for registration of veterinary pharmaceutical products.	

Annex I

APPLICATION FORM FOR VARIATION REGISTRATION

1. Particulars of the applicant

Name: _____

Address: _____

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 in Ethiopia: _____

_____

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: _____

Pack size(s): _____The route and method of administration _____

Description of container closure: _____

3. Previous registration No. of the product in Ethiopia _____

4. Description of the change(s) made from previous market authorization (description of the variation application) _____

_____

_____

_____

5. Category of the change: Major Variation ☐ Minor Variation ☐

6. 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: _____

List of Contributors

1. **Dr. Hailu Zeru**: Veterinary Drugs and Institutions Registration and Licensing Expert
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3. **Dr. Abdisa Hunduma**: Veterinary Drugs and Institutions Registration and Licensing Expert
4. **Dr. Hamid Jemal:** Deputy Director General, Ethiopian Agricultural Authority
5. **Dr. Solomon Kebede** : Veterinary Drug Regulatory, Lead Executive Officer