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GUIDELINE ON THE DOSSIER REQUIREMENTS FOR IMMUNOLOGICAL VETERINARY PRODUCTS REGISTRATION IN ETHIOPIA

JUNE 2025
ADDIS ABABA, ETHIOPIA



ETHIOPIAN AGRICULTURAL AUTHORITY

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**Guideline on the Dossier Requirements for
Immunological Veterinary Products Registration
in Ethiopia**

First Edition

Document No.:	VDR/GL/002
Approval Date:	02/06/2025

June 2025

Addis Ababa, Ethiopia

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FOREWORD

Ethiopian Agricultural Authority (EAA) is a government organization established by Proclamation No.1263/2021 and Council of Minister Regulation No. 509/2022 mandated to ensure the quality, safety and efficacy of imported and locally produced agricultural inputs and products. The authority has issued this guideline on submission of dossier for new immunological veterinary product registration based on the given mandates. This guideline provides guidance to applicants on documents and information required for application to get market authorization of new veterinary immunological product. It also guides the authority in evaluating applications for new immunological veterinary product registration. 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 for registration of veterinary immunological products.

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Deputy Director General, Ethiopian Agricultural Authority

ACKNOWLEDGMENT

Ethiopian Agricultural Authority (EAA) would like to acknowledge the World Bank for its financial support in the development of this guideline. The Authority would also like to thank the United Kingdom Veterinary Medicine Directorate (UK-VMD) for their technical support in drafting this guideline. Appreciations also go to all technical staff of the authority who contributed to this guideline and all participants of the consultative and validation workshops for their valuable inputs during the development of the guideline.

INTRODUCTION

The provision of veterinary medicines including immunological products of proven safety, efficacy and quality is indispensable to provide appropriate health care to animals in the country. One important method of ensuring the safety, efficacy and quality of these products is thorough evaluation and authorisation of veterinary immunological products, which are to be imported or locally produced before they are available for use in the country.

Ethiopian Agricultural Authority (EAA) is a government organization established by Proclamation No.1263/2021 and Council of Minister Regulation No. 509/2022 mandated to ensure the quality, safety and efficacy of imported and locally produced agricultural inputs and products. Article 4 of the veterinary drugs and animal feed administration and control proclamation no. 728/2012 states that no veterinary drug may be produced locally or imported and put in use unless it is registered by the Authority after being tested for its safety, efficacy and quality. Veterinary Drugs Registration Directive No. 1036/2025 article 5(1) also states that any application dossier for veterinary drug registration shall be submitted as per the relevant and current veterinary drug registration guideline issued by the Authority. Pursuant to these mandates and legal provisions, the authority developed and endorsed this guideline to inform applicants on the requirements for veterinary immunological products registration application.

This guideline is issued with the objective of providing applicants with information concerning the scientific documentation required for the authorisation of veterinary immunological products in Ethiopia. The information provided in this document

is intended to provide guidance to the applicant in generating the appropriate data for inclusion in a registration application dossier. This guideline provides details about the type of Quality information concerning the Manufacture and Control of veterinary immunological products that the applicant should present in the registration dossier. It also describes the data required to support the Safety and Efficacy of the product.

Separate guidelines will be issued addressing application to make change(s) to existing authorisations (variation), application for re-registration, application for veterinary pharmaceutical products, application for veterinary instruments and application for minor use and minor species products. Following the granting of a new marketing authorisation and in order to monitor the risk/benefit assessment, any new information not in the original application and all pharmacovigilance information shall be submitted to EAA.

This guideline is subject to revision whenever the Authority is forced to make changes to 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 to vdrcd@eaa.gov.et or by post to the Ethiopian Agricultural Authority P.O. Box 30313, Addis Ababa, Ethiopia.

OPERATIONAL DEFINITIONS

Active Immunogen: is the unformulated active substance or organism that provokes an immune response (produces immunity), which may be subsequently formulated with excipients to produce the immunological veterinary product. It may be whole bacterial cells, viruses, or parasites (live or killed), crude or purified antigens isolated from killed or living cells; crude or purified antigens secreted from living cells, toxins, recombinant or synthetic carbohydrate, protein or peptide antigens, polynucleotides (as in plasmid DNA vaccines) or conjugates.

Applicant: the person, persons or company that applies for a Marketing Authorisation to sell an immunogenic veterinary product in Ethiopian market. This applicant will become the Marketing Authorisation Holder for that particular product after the registration certificate is granted.

Authority: refers to Ethiopian Agricultural Authority (EAA).

Excipient: any pharmacologically inert substance used for combining with an active immunogen to achieve the desired bulk, consistency, etc.

Finished Product: the formulated immunological veterinary product containing the active immunogen(s) that has undergone all stages of production, including packaging in its final container and labelling, intended for marketing and ready for administration either alone or after reconstitution with the relevant diluents.

Immunological Veterinary Product: A veterinary medicinal product administered to animals to produce active or passive immunity or to diagnose the state of immunity or a veterinary medicinal product containing a biological active substance that is produced by or extracted from a biological source.

License Holder: a company in whose name the product is registered and authorised to supply products to Ethiopia. This company may or may not be the manufacturer of the product.

Master Seed (MS): a collection of aliquots of a preparation, for use in the preparation and testing of a product, distributed into containers in a single operation and processed together in such a manner as to ensure uniformity, and processed and stored in such a manner as to ensure stability.

Stringent Regulatory Authority countries (SRA countries): United States of America (USA), European Union member countries, Australia, Canada, Japan, Switzerland, Norway, Iceland and Liechtenstein.

Vaccine: A preparation of a weakened (attenuated) or killed pathogen, such as a bacterium or virus, or of a portion of the pathogen's structure, that stimulates immune cells to recognize and attack it, especially through the production of antibodies.

Working Seed Lot: a collection of aliquots of a preparation consisting of a passage level between MS and the last passage, which forms the finished product, for use in the preparation of finished product, distributed into containers in a single operation and processed together in such a manner as to ensure uniformity, and processed and stored in such a manner as to ensure stability.

SCOPE OF THE GUIDELINE

This guideline is applicable to dossier assessment and market authorization of immunological veterinary products.

EAA GENERAL REGULATORY FRAMEWORK AND GUIDING PRINCIPLES

I. General Format and Organization of the Dossier

The Immunological Veterinary Products Dossier shall be organized basically in Common Technical Document (CTD) module format of the VICH.

MODULE 1: ADMINISTRATIVE AND PRODUCT INFORMATION

MODULE 2: QUALITY

MODULE 3: SAFETY TESTES

MODULE 4: EFFICACY TESTES

Module one is about administrative documents which are specific requirements by EAA and product information. Modules 2-4 are technical and scientific requirements. Detail contents of each module will be described below in this guideline. Organizing and compilation of dossiers in this format will facilitate the evaluation process and decrease the delay in the screening time. In contrast, badly compiled documents may lead to unnecessary wastage of time both for the applicant and the Authority. Therefore, documents should be outlined in accordance with the EAA format and shall have unambiguous contents: title, nature and purpose should be clearly stated.

A) Requirements For Marketing Authorisation Applications for Multi-Strain Immunological Products

For certain immunological veterinary medicinal products (e.g., foot-and-mouth disease, avian influenza and bluetongue) the concept of the use of a multi-strain dossier can be used. A multi-strain dossier means a single dossier containing the relevant data for a unique and thorough scientific assessment of the different options of strains/combinations of strains permitting the authorisation of vaccines against antigenically variable viruses. Dossier of such products shall be compiled according to the scientific guidelines called “[Data requirements for multi-strain dossiers for Inactivated vaccines against avian influenza \(AI\), blue tongue \(BT\) and foot-and-mouth disease \(FMD\)](#)” issued by EMA.

II. Application of the Dossier and Evaluation Procedure by the Authority

- a) The applicant should submit all kind of documentation in need to new registration of veterinary drug through online application system (<https://www.eservices.gov.et/>) at the service name of “*Veterinary immunological Products New Registration Service*”.
- b) All applications must be submitted in the English language. When any part of the dossier is originally written in another language, a legalised translation into the English language must be submitted along with the original version.
- c) Any abbreviation in the Application Dossier should be clearly defined.

- d) Applications are acceptable if only the active immunogens is listed on the national veterinary drugs list. For those antigens which are not included in the list, application for inclusion should first be made by providing appropriate documents. The choice of antigens or vaccine strains shall be justified on the basis of epidemiological data of the country. The first and the last three letters of any trade name should not be identical with a registered veterinary immunological product in Ethiopia. All information which is relevant to the evaluation of the veterinary immunological product concerned shall be included in the application, whether favourable or unfavourable to the product. In particular, all relevant details shall be given of any incomplete or abandoned tests or trials relating to the veterinary immunological product.
- e) Where available, reference should be made to the scientific guidelines published by International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products ([VICH](#)), European Medicines Agency (EMA), United States Department of Agriculture (USDA) and other SRAs.
- f) The applicant shall provide true (genuine) information in the dossier whether favourable or not. Any change that might be made after the registration of the product based on the original (submitted) dossier and affect the quality of the product or not shall be reported or/and approved to/by the Authority

- g) Applications submitted for registration will be evaluated chronologically according to date of submission to the Authority. However, veterinary immunological products with a market shortage and locally manufactured veterinary immunological products will be registered by fast-track registration and Market shortage veterinary immunological products shall be evaluated based on minor use and minor species registration guideline. The authority will update the list of market shortage veterinary immunological products as necessitates and provide upon request.
- h) Requested supplementary information should be submitted (Further Information Request Response) within six months of notification to the missing elements and/or clarification. Applicants who fail to respond within the given time shall respond within 15 working days. Failure to act accordingly results in rejection unless the Authority considers the application with the provision of adequate justification for the non-compliance.

III. Labelling Regulation

Picture

If the label has any picture it shall be in line with its targeted species indication and dosage administration.

IV. Validity of Registration Certificate and Conditions for Cancellation

The registration certificate and purchase order approval is valid for five years from the approval date in the registration certificate. However, the Authority may suspend or revoke (cancel) the market authorization certificate, if the product is found non-

compliant following consignment testing, post-marketing surveillance (PMS). The Authority decision scheme in such non-compliance is as shown in the table below.

Table 1: Authority decision scheme following product quality defect

S/No	Frequency of product quality defect reported	Decision
1	One time QC defect	Purchase order approval of the product will be blocked and the registration certificate will be nullified. Product license holder can apply for new registration if the company has submitted root cause analysis and CAPA report and when the Authority confirms that the defective product is recalled from the market and disposed and/or returned to the country of origin.
2	Two QC defects reported on the same product	Purchase order approval of the product will be blocked and the registration certificate will be nullified. Applicant can apply for new registration of the product after 3 years of notification of the QC defect. This will also be applied when the Authority confirms that the defective product is recalled from the

		market and/or returned to the country of origin.
3	Three QC defect from the same or different lines or one purity defect of product(s) with in one GMP validity period.	The Authority will initiate full or partial GMP inspection. The licence holder or manufacturer will be responsible to pay the inspection fee according to the service fee regulation schedule.

V. Good Manufacturing Practice (GMP) Inspection

All companies involved in veterinary immunological manufacturing who want to enter the Ethiopian market shall comply with at least WHO GMP principles. All veterinary immunological products manufacturers found in non-stringent regulatory authority countries are subjected to initial and every five years cGMP inspection by the Authority.

The authority accepts a maximum of two contractual manufacturing application for already registered manufacturer (GMP inspected company by EAA). The applicant is expected to apply for new GMP inspection with the necessary applicable fees.

VI. Clinical Trial

Applicant shall communicate the authority with letter and study protocol before commencement of any clinical trial and get approval from the authority. Any clinical trial shall be conducted with reference to EAA acceptable guidelines such as VICH,

EMA and USDA. And any clinical trial shall be conducted with reference to product with known safety or placebo.

A reference to OIE standard monograph (annex 3) shall be made for Immunological Veterinary Products.

The Authority also considers the following guidelines official: ***VICH, USDA (9 CFR) and EMA***. Justification with reference to these guidelines is valid unless specifically addressed in this guideline differently.

VII. Sample Requirements for Quality Control (QC) Test

a) General

The Authority complements dossier assessment with quality test result to register products. The applicant shall submit sample of the product according to the sample requirements set by the Authority.

Sample size required will be available on EAA website and provided upon request.

VIII. Bibliographical References

Any bibliographical references cited in the dossier shall be listed in detail and copies shall be provided.

MODULE ONE: ADMINISTRATIVE AND PRODUCT INFORMATION

Module one, has two sections, Section A, Administrative information (1. A.1 to 1. A. 6) and Section B (1. B. 1 to 1. B. 5), Product information. This module is specific to the Ethiopian Agricultural Authority

1. A. Administrative Information

The administrative information shall include:

1. A.1 Cover letter

An application for the registration of a veterinary immunological product, either locally manufactured or imported, shall be made in writing via a cover letter. The cover letter submitted with the dossier should be signed by authorized person and have official stamp of the applicant and includes a clear statement by the applicant indicating that the information submitted is true and correct.

1. A.2 Application form

The application form shall only be filled by the manufacturer or license holder of the product. The application form should be signed by authorized person and have official stamp of the applicant or digitally signed. The application form to be used is annexed in this guideline (**annex I**) and also available for downloading from EAA website (www.eaa.gov.et).

1. A. 3. Table of Contents of the Dossier

Table of contents of module 1 through module 4 shall be provided here.

1. A.4 Agency agreement

An applicant can be represented by registered local agent or registered country representative. The applicant can appoint local agents to distribute its products. The decision to include or exclude agent is purely the Applicant choice. The applicant shall notify its decision in letter to the Authority through carrier and get letter of registration of the notification from the Authority.

An agency agreement made between the applicant of the veterinary immunological product for registration and the agent responsible for the import, distribution and sale of the product in Ethiopia shall be submitted. The agreement should be signed by both parties and such is what is to be presented. The seal/stamp of both parties should also be affixed to the agreement document.

The agent representing the manufacturer should be registered by EAA and hold certificate of competence.

The manufacturer or license holder can have additional agents. All agreements shall be valid for at least one year. All agency agreements shall be directly sent to Veterinary Drug Regulatory executive office of EAA.

The agreement should state that both parties (the supplier and importer of the specific batch of product) are responsible to collect the product from the market and substantiating any related consequences, if any quality defect is confirmed during

inspection of the consignment and by PMS and/or if any fraud or unsuspected and unacceptable adverse event occurs to the consumer under normal utilization.

1. A.5. Contractual agreement

A signed and stamped contract agreement should be submitted if the applicant is different from the manufacturer. The agreement should clearly state the duties and responsibilities of both parties.

If the applicant has multiple manufacturing sites the relationship and responsibility of each site should be clearly described. The agreement should specify who will be responsible to handle product related defects.

If manufacturing steps of the finished products is conducted at different manufacturing sites, an agreement clearly stating the responsibilities of the parties and manufacturing process(s) conducted at each site should be submitted.

1. A.6. Receipt of registration fee

Evidence of payment of a registration fee paid according to the Authority's service fee regulation regimen. This can be found on the authority website and can be provided upon request. Payment shall be made in foreign currency (USD, GBP, Euros) or in an equivalent bank's selling rate of Ethiopian Birr on the date of deposit to the account of the Authority. The details of the bank account of the Authority can be provided upon request.

1. B. Product Information

1. B.1 Manufacturing License

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

1. B.2 Certificate of Good Manufacturing Practice (GMP)

For all veterinary immunological products, irrespective of the country of origin, all key manufacturing and/or processing steps in the production of finished veterinary immunological products must be performed in plants that comply with PIC/S GMP guidelines accepted by EAA. Certificate of GMP issued by competent Authority in the country of origin shall be attached. As a principle of the Authority all manufacturing facilities are subjected to EAA GMP inspection

For those applicants where the manufacturing facility resides in stringent regulatory authority (SRA) countries, an authenticated GMP certificate issued by competent authority in the country of origin should be submitted as the Authority is not practicing GMP inspection in manufacturers residing in these countries. The certificate should meet the validity period and the requirements of WHO GMP format.

1. B.3 Certificate of Pharmaceutical Product (CPP)

Original Certificate of Pharmaceutical Product (CPP) or an equivalent certificate issued by competent authority in the country of origin as per WHO format should be submitted. The certificate should be original and authenticated by the Ethiopian embassy in the country of origin. If the applicant is unable to authenticate the certificate 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 certificate of pharmaceutical product.

1. B.4 Summary of Product Characteristics (SPC)

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

1. B.5 Proposals for Packaging, Labelling and Leaflet

All of the labeling information required must be in English and/or Amharic and must appear conspicuously so that it will be read and understood by the ordinary individual.

The pictorial signs used in the package label should match with the product indication and its visual characteristics.

The label of the immediate container should at least include:

- The name of the product
- Dosage form and route of administration
- Pack size
- Handling and storage requirements
- The titles for batch number and expiry date
- Name and/or logo of the manufacturer
- A claim stating “*For Veterinary use only*” should be stated

Outer or secondary package

The outer package must bear all of the information required to appear on the label of the immediate container itself or else the

wording on the label of the immediate container must be legible through the outer wrapper or carton. It should also contain the following information;

- Indication of the product
- Target species
- Shelf-life

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

Package Leaflet

The general content of the package leaflet should be prepared in line with the content of the SPC. It should not be described or presented in a manner that is false, misleading, or deceptive or is likely to create an erroneous impression regarding its use in any respect, either pictorially or in words.

In addition to the name of the product and its manufacturer or license holder, handling, transportation and storage precautions shall also be indicated on the outer tertiary packaging of the product.

MODULE TWO: QUALITY DOCUMENTATION

General Information

All test procedures shall fulfil the necessary criteria for analysis and control of the quality of the starting materials and the finished product and shall be validated procedures. The results of the validation studies shall be provided. Any special apparatus and equipment which may be used shall be described in adequate detail, possibly accompanied by a diagram. The formulae of the laboratory reagents shall be supplemented, if necessary, by the manufacturing method.

In the case of test procedures included in the pharmacopoeia acceptable by EAA (USP, BP, Eur Ph and OIE), this description may be replaced by providing the copy of the pharmacopoeia in question.

Where available, chemical and immunological reference material of the Pharmacopoeia accepted by EAA shall be used. If other reference preparations and standards are used, they shall be described in detail and submit its copy.

2. A. Qualitative and Quantitative Composition of the Product

A tabulated list of all components of the immunological veterinary product and diluents (if applicable) should be given as per table 1 below. The quantities per dose should be stated. A clear description of the active immunogenic substance including the name(s) or designation of the strain of organism used to produce the active immunogenic substance should be provided. The reason(s)

for inclusion of each excipient and a justification for overages should also be stated. The constituent(s) of the excipients, whatever their nature or the quantity used, including preservatives, stabilisers, emulsifiers, colouring matter, flavouring, aromatic substances, markers, etc., should be indicated. The type of water (e.g purified, demineralised), where relevant, should be indicated. If diluents are part of the market authorization application, detailed composition of it shall be indicated.

Table 1: Composition of the Immunological Veterinary Product

Name	Grade or reference text	Quantity/ unit dose	Function
Active Immunogen(s)			
Inactive ingredients (Excipients/Adjuvant)			
Diluents (if any)			

2. B. Production and Control of Starting Materials

For the purposes of this paragraph “starting materials” means all components used in the production of the immunological veterinary product. Culture media consisting of several

components used for production of the active substance shall be regarded as one starting material. Nevertheless, the qualitative and quantitative composition of the any culture media shall be presented in so far as the authorities consider that this information is relevant to the quality of the finished product and any risks that might be posed. If materials of animal origin are used for preparation of these culture media, the animal species and the tissue used have to be included.

The dossier shall include the specifications, information on the tests to be conducted for the quality control of all batches of starting materials and results for a batch for all components used and shall be submitted in accordance with the following provisions.

2. B.1. Starting materials listed in pharmacopoeias

The monographs of the *Pharmacopoeia* accepted by EAA, shall be applicable to all starting materials appearing in them.

Constituents fulfilling the requirements of the pharmacopoeias accepted by EAA shall be deemed to comply sufficiently with the following requirements: description of the control testing methods employed by the manufacturer (qualitative and quantitative analysis of the constituents and the finished product, specific tests e.g. sterility tests, test for the presence of pyrogens, for the presence of heavy metals, stability tests, immunological and toxicity tests, tests on intermediate products). In this case the description of the analytical methods may be replaced by a detailed reference to or copy of monograph of the pharmacopoeia in question.

Colouring matter shall, in all cases, have the designation of an “E” code assigned to them and also stating the name of the authority that gave the designation and the legal basis.

In cases where a specification or other provisions contained in a monograph of the pharmacopoeias accepted by EAA might be insufficient to ensure the quality of the substance, EAA may request more appropriate specifications from the applicant for marketing authorisation.

When starting materials of animal origin are used, they shall comply with the relevant monographs including general monographs and general chapters of the Pharmacopoeia accepted by EAA. The tests and controls conducted shall be appropriate to the starting material.

The applicant shall supply documentation to demonstrate that the starting materials and the manufacturing of the veterinary immunological product is in compliance with the requirements of the corresponding monograph of the Pharmacopoeia accepted by EAA. Certificates of Suitability issued by competent body, with reference to the relevant monograph of the Pharmacopoeia accepted by EAA, may be used to demonstrate compliance.

2. B.2. Starting materials not listed in a pharmacopoeia

2. B.2.1. *Starting materials of biological origin*

The description shall be given in the form of a monograph.

Whenever possible, vaccine production shall be based on a seed lot system and on established cell seeds. For the production of

immunological veterinary products consisting of serums, the origin, general health and immunological status of the producing animals shall be indicated and defined pools of source materials shall be used.

The origin, including geographical region and history of starting materials shall be described and documented.

Seed materials, including cell seeds and raw serum for anti-serum production shall be tested for identity and extraneous agents.

Information shall be provided on all substances of biological origin used at any stage in the manufacturing procedure. The information shall include:

- Details of the source of the materials,
- Details of any processing, purification and inactivation applied, with data on the validation of these process and controls during production,
- Details of any tests for contamination carried out on each batch of the substance.

If the presence of extraneous agents is detected or suspected, the corresponding material shall be discarded or used in very exceptional circumstances only when further processing of the product ensures their elimination and/or inactivation; elimination and/or inactivation of such extraneous agents shall be demonstrated.

When cell seeds are used, the cell characteristics shall be shown to have remained unchanged up to the highest passage level used for the production.

For live attenuated vaccines, proof of the stability of the attenuation characteristics of the seed has to be given.

Documentation shall be supplied to demonstrate that the seed materials, cell seeds, batches of serum and other material originating from animal species relevant for the transmission of TSE/BSE comply with the corresponding monograph accepted by EAA. Certificates of Suitability issued by Competent Body, with reference to the relevant monograph of the Pharmacopoeias accepted by EAA, can be used to demonstrate compliance.

2. B.2.2. Starting materials of non-biological origin

The description shall be given in the form of a monograph under the following headings:

- the name of the starting material shall be supplemented by any trade or scientific synonyms,
- the description of the starting material, set down in a form similar to that used in a descriptive item in the *Pharmacopoeia* accepted by EAA,
- the function of the starting material,
- methods of identification,
- any special precautions which may be necessary during storage of the starting material and, if necessary, its storage life shall be given.

2. C. Method of Manufacture

2. C.1 Flow chart

A complete visual representation of the manufacturing process flow shall be provided for each active immunogenic substance and the immunological veterinary product. Show the steps in

production, including incubation times and temperatures, equipment and materials used the area where the operation is performed and a list of the in-process controls and finished product tests performed at each step. In-process holding steps should be included with time and temperature limits indicated.

2. C.2 Detailed description of the manufacturing process

Provide a description of manufacturing starting with the Working Seed, and including any steps in which the bulk of the active immunogenic substance is further processed (e.g separated from the cells, concentrated). List all the components used in the manufacturing process including media, solvents or solutions etc. A description shall be provided for:

i) Propagation and Harvest

For each antigen production method or combination of methods, a growth curve or tabular representation of growth characteristics for each propagation step shall be provided. Include a table showing yield, purity and viability (if applicable) of the crude harvest.

ii) Attenuation (if appropriate)

iii) Inactivation (if appropriate)

Inactivation kinetics or killing curves, or a tabular representation shall be provided. Validation of the titration method used to measure residual live organisms, including the sensitivity of the method in a background of inactivating agents, shall be provided. The following information shall be provided:

- a) How culture purity is verified before inactivation
- b) The method(s) and agent(s) used for inactivation
- c) The method(s) undertaken to prevent aggregation and assure homogeneous access of inactivating agent(s) to the

culture

- d) The stage in production where inactivation or killing is performed
- e) The parameters which are monitored

iv) Detoxification (if appropriate)

For toxoid or toxoid-containing vaccines, the detoxification procedures should be described in detail for the toxin component(s):

- a) The method(s) and agent(s) used for detoxification
- b) The stage in production where detoxification is performed and the parameters, which are monitored, must be described.

v) Purification (if appropriate)

Describe any purification methods used, including specialised equipment such as columns, ultracentrifugation, ultra-filtration, and custom reagents such as monoclonal antibodies. State the process parameters monitored and the process for determination of yields. For each purification method or combination of methods used, a tabulation of yields, purity and biological activity shall be provided. Verification of the removal or dilution of product related and non-product related impurities, e.g. processing reagents, endotoxin contaminating cell proteins or nucleic acids, and other residual contaminants shall be included. A standard denominator (e.g. international units) shall be used to facilitate comparison through processing, concentration, or dilution. If the purified substance is held prior to further processing, a description of the storage conditions and time limits shall be included.

vi) Stabilisation process (if applicable)

A description shall be provided for any post-purification steps

performed to produce a stabilised antigen (e.g. adsorption, addition of stabilisers, addition of preservatives), and the objectives and rationale for performing each process. A description of precautions taken to monitor bio-burden and prevent contamination during these processes shall also be given. If the antigen is held prior to further processing, a description of storage conditions and time limits should be included. Verification of the stability of the active immunogenic substance under the conditions described shall be provided.

vii) Provide the criteria for pooling more than one batch (if applicable)

The reuse and/or regeneration of columns and adsorbents and monitoring for residual impurities and leachable reagents should be provided. Consistency of the manufacturing process for each antigenic component shall be demonstrated by manufacturing at least three, preferably consecutive, batches of active immunogenic substance of a size corresponding to that for routine production.

viii) Formulation of the finished product

Include a detailed description of the further manufacturing process flow of the formulated bulk up to the filling of the finished product. This should include the sterilisation operations, aseptic processing procedures, filling, lyophilisation (if applicable), and packaging.

2. C.3. Control Tests during the Manufacturing Process

The dossier shall include particulars relating to the control tests, which are carried out on intermediate products with a view to verifying the consistency of the manufacturing process and the final product. For inactivated or detoxified vaccines, inactivation

or detoxification shall be tested during each production run as soon as possible after the end of the inactivation or detoxification process and after neutralisation if this occurs, but before the next step of production.

2. C.4. Process Validation

The validation of key stages in the production process shall be demonstrated and the validation of the production process as a whole shall be demonstrated with provision of results of three consecutive batches produced using the method described. It has to be supported with statistical analysis with acceptable criteria. In the case of continuous manufacture, full details concerning precautions taken to ensure the homogeneity and consistency of each batch of the finished product.

2. C.5. Container and Closure

Details of the container and closure system, and its compatibility with the immunogenic veterinary product shall be submitted. Detailed information concerning the supplier(s), address (es), and the results of any relevant information on compatibility, toxicity and biological tests shall be provided for containers of novel origin. For sterile product, evidence of container and closure integrity shall be provided for the duration of the proposed shelf life.

The finished product immediate containers packaging materials shall comply with the requirements of the appropriate pharmacopoeias of those accepted by EAA. In the absence of a pharmacopoeial monograph accepted by EAA, a specification shall be proposed and justified for the packaging material. Indicate how the containers are sterilised and if the method is

appropriate.

2. C.6. Batch Manufacturing Record

Batch Manufacturing Record of at least one production batch of the product shall be submitted.

2. D. Control Tests on the Finished Product

For all tests, the description of the techniques for analysing the finished product shall be set out in sufficiently precise detail for quality assessment.

The dossier shall include particulars relating to control tests on the finished product. Where appropriate monographs exist, if test procedures and limits other than those mentioned in the monographs of the Pharmacopoeias accepted by EAA, are used, proof must be supplied that the finished product would, if tested in accordance with those monographs, meet the quality requirements of that pharmacopoeia for the pharmaceutical form concerned. The application for marketing authorisation shall list those tests, which are carried out on representative samples of each batch of finished product. The frequency of the tests, which are not carried out on each batch, shall be stated. Release limits shall be indicated.

Where available, chemical and immunological reference material of the Pharmacopoeias accepted by EAA shall be used. If other reference preparations and standards are used, they shall be identified and described in detail.

2. D.1. General characteristics of the finished product

The tests of general characteristics shall, wherever applicable, relate to the control of average masses and maximum deviations, to mechanical, physical or chemical tests, physical characteristics such as density, pH, viscosity, etc. For each of these characteristics, specifications, with appropriate confidence limits, shall be established according to “*VICH GL40 Test procedures and acceptance criteria for new biotechnological/biological veterinary medicinal products*” by the applicant in each particular case.

2. D.2. Identification of active immunogenic substance(s)

A specific test for identification shall be carried out.

2. D.3. Batch titre or potency

A quantification of the active substance shall be carried out on each batch to show that each batch will contain the appropriate potency or titre to ensure its safety and efficacy.

2. D.4. Identification and assay of adjuvants

Insofar as testing procedures are available, the quantity and nature of the adjuvant and its components shall be verified on the finished product.

2. D.5. Identification and assay of excipient components

Insofar as testing procedure available, the excipient(s) shall be subject to identification, limit solvent level, relevant impurities and quantitative tests. The specification method of analysis and Certificate of analysis thereof shall be presented. An upper and lower limit test shall be obligatory in respect of preserving agents.

An upper limit test for any other excipient components liable to give rise to an adverse reaction shall be obligatory.

2. D.6. Safety tests

Apart from the results of tests submitted in accordance with Part 3 of this guideline (Safety Tests), particulars of the batch safety tests shall be submitted. These tests shall preferably be overdosage studies carried out in at least one of the most sensitive target species and by at least the recommended route of administration posing the greatest risk. Routine application of the batch safety test may be waived in the interests of animal welfare when a sufficient number of consecutive production batches have been produced and been found to comply with the test. “*VICH GL50 on Harmonisation of criteria to waive target animal batch safety testing for inactivated vaccines for veterinary use*” and “*VICH GL55 Harmonisation of criteria to waive target animal batch safety testing for live vaccines for veterinary use*” shall be referenced to waive target animal batch safety testing.

2. D.7. Sterility and purity test

Appropriate tests to demonstrate the absence of contamination by extraneous agents or other substances shall be carried out according to the nature of the immunological veterinary medicinal product, the method and the conditions of manufacture.

If fewer tests than required by the relevant Pharmacopoeia accepted by EAA are routinely employed for each batch, the tests carried out shall be critical to the compliance with the monograph. Proof must be supplied that the immunological veterinary medicinal product would meet the requirements, if

fully tested according to the monograph.

2. D.8. Residual moisture

Each batch of lyophilised and effervescent products shall be tested for residual humidity according to “*VICH GL26 Biologicals: testing of residual moisture*”.

2. D.9. Inactivation

For inactivated vaccines, a test to verify inactivation shall be carried out on the product in the final container unless it has been conducted at a late stage in-process.

2. D.10. Batch-to-Batch Consistency

In order to ensure that quality of the product is consistent from batch to batch and to demonstrate conformity with specifications a full protocol of three consecutive batches giving the results for all tests performed during production and on the finished product shall be provided. It shall be supported with statistical analysis with acceptable criteria.

2. D.11. Stability Studies

The particulars and documents accompanying the application for marketing authorisation pursuant to proposed shelf life and description of the testing methods employed by the manufacturer shall be submitted in accordance with the following requirements.

The stability study should be conducted according to “*VICH GL17 Stability testing of biotechnological/biological veterinary medicinal products*”.

A description shall be given of the tests undertaken to support the shelf life proposed by the applicant. These tests shall always be real-time studies; they shall be carried out on at least three batches produced according to the described production process and on products stored in the final container(s); these tests include immunological and physicochemical stability tests.

The conclusions shall contain the results of analyses, justifying the proposed shelf life under all proposed storage conditions.

In the case of products administered in feed, information shall also be given as necessary on the shelf life of the product, at the different stages of mixing, when mixed in accordance with the recommended instructions.

Where a finished product requires reconstitution prior to administration or is administered in drinking water, details of the proposed shelf life are required for the product reconstituted as recommended. Data in support of the proposed shelf life for the reconstituted product shall be submitted.

2. E. Documents on Diluents

Information relating to the composition, method of manufacture, container-closure, pack sizes, labelling information, quality specification and certificate of analysis of the diluent should be included here if diluent is required to reconstitute the immunological veterinary product before administration. If the manufacturer of the diluent is different from the manufacturer of the immunological veterinary product, details of the manufacturer, including name and address, manufacturing license, and cGMP certificate, should be submitted.

MODULE THREE: SAFETY TESTS

3. A. Introduction and General Requirements

The safety tests shall show the potential risks from the immunological veterinary medicinal product, which may occur under the proposed conditions of use in animals: these shall be evaluated in relation to the potential benefits of the product.

Where immunological veterinary medicinal products consist of live organisms, especially those, which could be shed by vaccinated animals, the potential risk to unvaccinated animals of the same or of any other potentially exposed species shall be evaluated.

The safety studies shall be carried out in the target species. The dose to be used shall be the quantity of the product to be recommended for use and the batch used for safety testing shall be taken from a batch or batches produced according to the manufacturing process described in Part 2 of this guideline.

In the case of an immunological veterinary medicinal product containing a live organism, the dose to be used in the laboratory tests described in Laboratory Trials section below (Sections B.1 and B.2) shall be the quantity of the product containing the maximum titre. If necessary the concentration of the antigen may be adjusted to achieve the required dose. For inactivated vaccines the dose to be used shall be that quantity recommended for use containing the maximum antigen content unless justified.

The safety documentation shall be used for assessment of the

potential risks which may result from the exposure of human beings to the immunological veterinary medicinal product, for example during its administration to the animal.

All tests are recommended to be conducted in accordance to [VICH GL44 Target Animal Safety for Veterinary Live and Inactivated Vaccines](#).

3. B. Laboratory Tests

3. B.1. Safety of the Administration of One Dose

The immunological veterinary medicinal product shall be administered at the recommended dose and by each recommended route of administration to animals of each species and category in which it is intended for use, including animals of the minimum age of administration. The animals shall be observed and examined for signs of systemic and local reactions. Where appropriate, these studies shall include detailed post-mortem macroscopic and microscopic examinations of the injection site. Other objective criteria shall be recorded, such as rectal temperature and performance measurements.

The animals shall be observed and examined until reactions may no longer be expected, but in all cases, the observation and examination period shall be at least 14 days after administration.

This study may be part of the repeated dose study required under point 3 or omitted if the results of the overdose study required under point 2 have revealed no signs of systemic or local reactions.

3. B.2. Safety of one Administration of an Overdose

Only live immunological veterinary medicinal products require overdose testing.

An overdose of the immunological veterinary medicinal product shall be administered by each recommended route(s) of administration to animals of the most sensitive categories of the target species, unless the selection of the most sensitive of several similar routes is justified. In the case of immunological veterinary medicinal products administered by injection, the doses and route(s) of administration shall be chosen to take account of the maximum volume, which can be administered at any one single injection site. The animals shall be observed and examined for at least 14 days after administration for signs of systemic and local reactions. Other criteria shall be recorded, such as rectal temperature and performance measurements.

Where appropriate, these studies shall include detailed post-mortem macroscopic and microscopic examinations of the injection site if this has not been done under point 1.

3. B.3. Safety of the Repeated Administration of One Dose

In the case of immunological veterinary medicinal products to be administered more than once, as part of the basic vaccination scheme, a study of the repeated administration of one dose shall be required to reveal any adverse effects induced by such administration. These tests shall be carried out on the most sensitive categories of the target species (such as certain breeds, age groups), using each recommended route of administration.

The animals shall be observed and examined for at least 14 days

after the last administration for signs of systemic and local reactions. Other objective criteria shall be recorded, such as rectal temperature and performance measurements.

3. B.4. Examination Of Reproductive Performance

Examination of reproductive performance shall be considered when data suggest that the starting material from which the product is derived may be a potential risk factor. Reproductive performance of males and non-pregnant and pregnant females shall be investigated with the recommended dose and by the most sensitive route of administration. In addition, harmful effects on the progeny, as well as teratogenic and abortifacient effects, shall be investigated. These studies may form part of the safety studies described in points 1, 2, 3 or of the field studies provided for in Section C.

3. B.5. Examination of Immunological Functions

Where the immunological veterinary medicinal product might adversely affect the immune response of the vaccinated animal or of its progeny, suitable tests on the immunological functions shall be carried out.

3. B.6. Special Requirements for Live Vaccines

3. B.6.1. Spread of the vaccine strain

Spread of the vaccine strain from vaccinated to unvaccinated target animals shall be investigated, using the recommended route of administration most likely to result in the spread. Moreover, it may be necessary to investigate the spread to non-target animal species which could be highly susceptible to a live vaccine strain.

3. B.6.2. Dissemination in the vaccinated animal

Faeces, urine, milk, eggs, oral, nasal and other secretions shall be tested for the presence of the organism as appropriate. Moreover, studies may be required of the dissemination of the vaccine strain in the body, with particular attention being paid to the predilection sites for replication of the organism. In the case of live vaccines for zoonoses (any disease and/or infection which is naturally transmissible directly or indirectly between animals and humans) to be used for food producing animals, these studies must take particularly into account the persistence of the organism at the injection site.

3. B.6.3. Reversion to virulence of attenuated vaccines

Reversion to virulence shall be investigated with the master seed. If the master seed is not available in sufficient quantity the lowest passage seed used for the production shall be examined. Use of another passage option shall be justified. The initial vaccination shall be carried out using the route of administration most likely to lead to reversion to virulence. Serial passages shall be made in target animals through five groups of animals, unless there is justification to make more passages or the organism disappears from the test animals sooner. VICH GL41 shall be used as a reference for the Examination of Live Veterinary Vaccines in Target Animals for Absence of Reversion to Virulence.

3. B.6.4. Immunological properties of the vaccine strain

Other tests may be necessary to determine as precisely as possible the intrinsic immunological properties of the vaccine strain (e.g. neurotropism).

3. B.6.5. Recombination or genomic reassortment of strains

The probability of recombination or genomic reassortment with field or other strains shall be discussed.

3. B.7. User Safety

This section shall include a discussion of the effects found in the preceding sections, which shall relate those effects to the type and extent of human exposure to the product with a view to formulating appropriate user warnings and other risk management measures.

3. B.8. Study of Residues

For immunological veterinary medicinal products, it will normally not be necessary to undertake a study of residues. However, where adjuvants and/or preservatives are used in the manufacture of immunological veterinary medicinal products, consideration shall be given to the possibility of any residue remaining in the foodstuffs. If necessary, the effects of such residues shall be investigated. A proposal for a withdrawal period shall be made and its adequacy shall be discussed in relation to any residue studies which have been undertaken.

3. B.9. Interactions

If there is a compatibility statement with other veterinary immunological products in the summary of product characteristics the safety of the association shall be investigated. Any other known interactions with veterinary medicinal products shall be described.

3. C. Field Studies

Unless justified, results from laboratory studies shall be supplemented with data from field studies, using batches according to the manufacturing process described in the marketing authorisation application. Both safety and efficacy may be investigated in the same field studies.

3. D. Environmental Risk Assessment

The purpose of the environmental risk assessment is to assess the potential harmful effects, which the use of the product may cause to the environment and to identify any precautionary measures, which may be necessary to reduce such risks.

This assessment shall normally be conducted in two phases. The first phase of the assessment shall always be performed. The details of the assessment shall be provided in accordance with established guidance. It shall indicate the potential exposure of the environment to the product and the level of risk associated with any such exposure, taking into account in particular the following items:

- the target animal species and the proposed pattern of use,
- the method of administration, in particular the likely extent to which the product will enter directly into the environmental system,
- the possible excretion of the product, its active substances into the environment by treated animals, persistence in such excreta,
- the disposal of unused or waste product.

In the case of live vaccine strains which may be zoonotic, the risk

to humans shall be assessed.

Where the conclusions of the first phase indicate potential exposure of the environment to the product, the applicant shall proceed to the second phase and evaluate the potential risk(s) that the veterinary medicinal product might pose to the environment. Where necessary, further investigations on the impact of the product (soil, water, air, aquatic systems, non-target organisms) shall be carried out.

MODULE FOUR: EFFICACY TESTS

CHAPTER ONE

General principles

The purpose of the trials described in this Part is to demonstrate or to confirm the efficacy of the immunological veterinary medicinal product. All claims made by the applicant with regard to the properties, effects and use of the product, shall be fully supported by results of specific trials contained in the application for marketing authorisation.

Performance of trials

All efficacy trials shall be conducted in accordance with a fully considered detailed protocol, which shall be recorded in writing prior to commencement of the trial. The welfare of the trial animals shall be subject to veterinary supervision and shall be taken fully into consideration during the elaboration of any trial protocol and throughout the conduct of the trial.

Field trials shall be conducted in accordance with established principles of good clinical practice, unless otherwise justified.

A written agreement shall be submitted if the applicant and investigator of the trial are different.

Before the commencement of any field trial, the informed consent of the owner of the animals to be used in the trial shall be obtained and documented. In particular, the animal owner shall be informed in writing of the consequences of participation in the trial for the subsequent disposal of treated animals or for the

taking of foodstuffs from treated animals. A copy of this notification, countersigned and dated by the animal owner, shall be included in the trial documentation.

In all cases, the words “for veterinary field trial use only” shall appear prominently and indelibly upon the labelling.

4. A. General Requirements

1. The choice of antigens or vaccine strains shall be justified on the basis of epizootological data.
2. Efficacy trials carried out in the laboratory shall be controlled trials, including untreated control animals unless this is not justified for animal welfare reasons and efficacy can be otherwise demonstrated. In general, these laboratory trials shall be supported by trials carried out in field conditions, including untreated control animals. All trials shall be described in sufficiently precise details so as to be reproducible in controlled trials, carried out at the request of the National Regulatory Authority. The investigator shall demonstrate the validity of all the techniques involved. All results obtained, whether favourable or unfavourable, shall be reported.
3. The efficacy of an immunological veterinary medicinal product shall be demonstrated for each category of target animal species recommended for vaccination, by each recommended route of administration and using the proposed schedule of administration. The influence of passively acquired and maternally derived antibodies on the efficacy of

a vaccine shall be adequately evaluated, if appropriate. Unless justified, the onset and duration of immunity shall be established and supported by data from trials.

4. The efficacy of each of the components of multivalent and combined immunological veterinary medicinal products shall be demonstrated. If the product is recommended for administration in combination with or at the same time as another veterinary medicinal product, they shall be shown to be compatible.
5. Whenever a product forms part of a vaccination scheme recommended by the applicant, the priming or booster effect or the contribution of the veterinary immunological product to the efficacy of the scheme as a whole shall be demonstrated.
6. The dose to be used shall be the quantity of the product to be recommended for use and the batch used for efficacy testing shall be taken from a batch or batches produced according to the manufacturing process described in Part 2 of the dossier.
7. If there is a compatibility statement with other immunological products in the summary of product characteristics, the efficacy of the association shall be investigated. Any other known interactions with any other veterinary medicinal products shall be described. Concurrent or simultaneous use may be allowed if supported by appropriate studies.
8. For diagnostic immunological veterinary medicinal products administered to animals, the applicant shall indicate how

reactions to the product are to be interpreted.

9. For vaccines intended to allow a distinction between vaccinated and infected animals (marker vaccines), where the efficacy claim is reliant on in vitro diagnostic tests, sufficient data on the diagnostic tests shall be provided to allow adequate assessment of the claims related to the marker properties.

4. B. Laboratory Trials

1. In principle, demonstration of efficacy shall be undertaken under well-controlled laboratory conditions by challenge after administration of the immunological veterinary medicinal product to the target animal under the recommended conditions of use. Insofar as possible, the conditions under which the challenge is carried out shall mimic the natural conditions for infection. Details of the challenge strain and its relevance shall be provided. For live vaccines, batches containing the minimum titre or potency shall be used unless justified. For other products, batches containing the minimum active content shall be used unless otherwise justified.
2. If possible, the immune mechanism (cell-mediated/humoral, local/general classes of immunoglobulin) which is initiated after the administration of the immunological veterinary medicinal product to target animals by the recommended route of administration shall be specified and documented.

4. C. Field Trials

1. Results from laboratory trials shall be supplemented with data from field trials, using batches representative of the manufacturing process described in the marketing authorisation application. Both safety and efficacy may be investigated in the same field study.
2. Where laboratory trials cannot be supportive of efficacy, the performance of field trials alone may be acceptable.

CHAPTER II: PRESENTATION OF PARTICULARS AND DOCUMENTS

A. INTRODUCTION

The dossier of the safety and efficacy studies shall include an introduction defining the subject and indicating the tests which have been carried out in compliance with Parts 3 and 4 as well as a summary, with detailed references to the published literature. This summary shall contain an objective discussion of all the results obtained and lead to a conclusion on the safety and efficacy of the immunological veterinary medicinal product. Omission of any tests or trials listed shall be indicated and discussed.

B. LABORATORY STUDIES

The following shall be provided for all studies:

1. a summary;
2. the name of the body having carried out the studies, if

different from the applicant;

3. a detailed experimental protocol giving a description of the methods, apparatus and materials used, details such as species or breed of animals, categories of animals, where they were obtained, their identification and number, the conditions under which they were housed and fed (stating, inter alia, whether they were free from any specified pathogens and/or specified antibodies, the nature and quantity of any additives contained in the feed), dose, route, schedule and dates of administration, a description and a justification of the statistical methods used;
4. in the case of control animals, whether they received a placebo or no treatment;
5. in the case of treated animals and where appropriate, whether they received the test product or another product authorised in the study area.
6. all general and individual observations and results obtained (with averages and standard deviations), whether favourable or unfavourable. The data shall be described in sufficient detail to allow the results to be critically evaluated independently of their interpretation by the author. The raw data shall be presented in tabular form. By way of explanation and illustration, the results may be accompanied by reproductions of recordings, photomicrographs, etc;
7. the nature, frequency and duration of observed adverse reactions;
8. the number of animals withdrawn prematurely from the studies and reasons for such withdrawal;
9. a statistical analysis of the results, where such is called for

- by the test programme, and variance within the data;
10. occurrence and course of any intercurrent disease;
 11. all details concerning veterinary medicinal products (other than the product under study), the administration of which was necessary during the course of the study;
 12. an objective discussion of the results obtained, leading to conclusions on the safety and efficacy of the product.

C. FIELD STUDIES

Particulars concerning field studies shall be sufficiently detailed to enable an objective judgement to be made. They shall include the following:

1. a summary;
2. name, address, function and qualifications of the investigator in charge;
3. place and date of administration, identity code that can be linked to the name and address of the owner of the animal(s);
4. details of the trial protocol, giving a description of the methods, apparatus and materials used, details such as the route of administration, the schedule of administration, the dose, the categories of animals, the duration of observation, the serological response and other investigations carried out on the animals after administration;
5. in the case of control animals, whether they received a placebo or no treatment;
6. identification of the treated and control animals (collective or individual, as appropriate), such as species, breeds or strains, age, weight, sex, physiological status;

7. a brief description of the method of rearing and feeding, stating the nature and quantity of any additives contained in the feed;
8. all the particulars on observations, performances and results (with averages and standard deviation); individual data shall be indicated when tests and measurements on individuals have been carried out;
9. all observations and results of the studies, whether favourable or unfavourable, with a full statement of the observations and the results of the objective tests of activity required to evaluate the product; the techniques used must be specified and the significance of any variations in the results explained;
10. effects on the animals' performance;
11. the number of animals withdrawn prematurely from the studies and reasons for such withdrawal;
12. the nature, frequency and duration of observed adverse reactions;
13. occurrence and course of any intercurrent disease;
14. all details concerning veterinary medicinal products (other than the product under study) which have been administered either prior to or concurrently with the test product or during the observation period; details of any interactions observed;
15. an objective discussion of the results obtained, leading to conclusions on the safety and efficacy of the product.

ANNEXES

Annex I

APPLICATION FORM FOR REGISTRATION OF IMMUNOLOGICAL VETERINARY PRODUCTS IN ETHIOPIA

1. Particulars of the applicant

Name: _____

Address: _____

Phone Number: _____ Fax: _____

Email: _____

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

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

2. Particulars of the Product

Name of the product: _____

Name of active immunogenic substance(s): _____

Source of master seed: _____

Product strength: _____

Dosage form: _____

Target species: _____

The route and method of administration _____

Pack size(s): _____

Description of container closure: _____

Visual description of the product: _____

Proposed shelf life (months) and storage condition: _____

Main indication(s): _____

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

Name	Grade or reference text	Quantity /unit dose	Function
Active Substance(s)			
Inactive ingredients (Excipients/Adjuvant)			
Diluents (if any)			

3. Current Registration and Licensing Status

3.1 Registration status in the country of manufacture
(Registered Not Registered)

3.2 If the product is registered in the country of origin attach the MA certificate.

3.3 If not registered in the country of origin, justify the reason_____

3.4 List of countries where the immunological Product is already registered_____

4. Declaration by applicant

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

Signature: _____

Full name and position of signatory: _____

Date: _____

Annex II
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance(s):

Adjuvant(s):

Excipient(s):

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

4.2 Indications for use, specifying the target species

4.3 Contraindications

4.4 Special warnings <for each target species>

4.5 Special precautions for use

- i. Special precautions for use in animals
- ii. Special precautions to be taken by the person administering the product to animals

4.6 Adverse reactions (frequency and seriousness)

4.7 Use during pregnancy, lactation or lay

4.8 Interaction with other pharmaceutical products and other forms of interaction

4.9 Methods of preparation, Amounts to be administered and administration route

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

4.11 Withdrawal period(s)

Meat and offal> <Milk> <Eggs>: {X} <hours><days>

5. IMMUNOLOGICAL PROPERTIES

Brief description of the immunological properties and characteristics of the active substance(s)

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

6.2 Incompatibilities

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

6.3 Shelf life

Shelf-life of the veterinary immunological product as packaged for sale

Shelf-life after first opening the immediate packaging

Shelf-life after dilution or reconstitution according to directions where applicable

Shelf life after incorporation into pelleted feed where applicable

6.4. Special precautions for storage

Do not store above

Store below -20 °C

Store in a refrigerator (2 °C – 8 °C)

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

Protect from light

6.5 Nature and composition of immediate packaging

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

<Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.>

7. MARKETING AUTHORISATION HOLDER

{Name and address }

Tel:

Fax:

E-mail:

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<{DD/MM/YYYY}><{DD month YYYY}>...

10. DATE OF REVISION OF THE TEXT

{MM/YYYY} or <month YYYY>

ANNEX III: LIST OF CONTRIBUTORS

1. Solomon Kebede (DVM, MSc)
2. Hamid Jemal (DVM, MVSc, PhD)
3. Yohannes Abebe (BSc, B.Pharm, MSc in
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