



GUIDELINES FOR CONDITIONAL APPROVAL OF VETERINARY PRODUCTS

MARCH, 2024

FOREWORD

Rwanda Food and Drugs Authority (Rwanda FDA) is a regulatory body established by the Law N° 003/2018 of 09/02/2018. One of the functions of the Rwanda FDA is to regulate matters related to the quality, safety, and efficacy of Veterinary Products to protect animal health and public health in general from falsified and substandard Products.

Considering the provisions of the technical regulations No. CBD/TRG/010 of 20 April 2020 governing the registration of medicinal products especially in its articles 15, 16, and 17, the Authority has issued Guidelines No DAR/VMDAR/GDL/074 for conditional approval of regulated veterinary products.

Rwanda FDA has developed these guidelines to provide guidance on submission of documentation for conditional approval to make available regulated veterinary products that can be used in situations of very limited alternatives. This alternative marketing authorization pathway is developed to cover circumstances in which routine marketing authorization procedures may not be followed to make veterinary products legally available to be used in minor animal species and for the control of uncommon diseases in the major animal species.

Rwanda FDA acknowledges the effort of staff who have contributed to the development of these guidelines and is grateful to all stakeholders who participated in the validation of this document.

Prof. Emile BIENVENU
Director General

DOCUMENT DEVELOPMENT HISTORY

| | |
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ACRONYMS AND ABBREVIATIONS

| | |
|----------------------|---|
| ATC vet codes | Anatomical Therapeutic Chemical code. |
| CTD | Common Technical Document |
| IRIMS | Integrated Regulatory Information Management System |
| IVD | In-Vitro Diagnostic |
| MA | Market Authorization |
| LTR | Local Technical Representative |
| PMA | Provisional Market Authorization |
| SmPC | Summary of Product Characteristics |
| VP | Veterinary Product |

GLOSSARY / DEFINITIONS

The definitions provided below apply to the terms used in these guidelines. They may have different meanings in other contexts and documents. For these guidelines, the following definitions shall apply:

Active Substance: The active substance in a veterinary pharmaceutical product is the biologically active component of a product that produces the intended effects.

Applicant: The person or company that apply for a Marketing Authorization (registration) or license to sell a veterinary pharmaceutical product, an update or amendment to existing marketing authorization. Once the marketing authorization is granted, the applicant becomes the Marketing Authorization Holder for that medicinal product.

Authority: Rwanda Food and Drugs or its acronym “Rwanda FDA”, established under Article 2 of Law 003/2018.

Finished Product: The formulated medicinal product containing the active ingredient(s) and ready for administration either alone or after reconstitution with the relevant diluents.

Major animal species: They include pet animals such as dogs and cats, Equidae such as horses and donkeys, and livestock such as cattle, swine, poultry, sheep, goat, and rabbit, among others.

Minor animal species: all animals other than humans that are not one of the major species. They include animals such as zoo animals, ornamental fish, parrots, ferrets, guinea pigs, catfish, game birds, and honeybees among others.

Minor use: refers to when drugs are used to treat one of the major species (horses, dogs, cats, cattle, pigs, turkeys and chickens) for a rare disease. A disease can be rare because it occurs only in certain areas of the country, or because it affects only a small number of animals each year.

Local Technical Representative (LTR): means any corporate body registered in Rwanda and authorized by Rwanda FDA to deal with pharmaceuticals, Medical Devices and In Vitro Diagnostics that has received a mandate from the Applicant to act on his/her behalf regarding matters pertaining to registration of pharmaceuticals and medical devices including IVDs.

Regulated veterinary products: These include veterinary pharmaceutical products, veterinary medical devices and veterinary In Vitro Diagnostics (IVDs).

Chemical immobilizing drugs: Chemical immobilizing drugs, also known as tranquilizers or immobilizing agents, are substances used to induce temporary paralysis or sedation in animals, often for medical procedures, transportation, or research purposes. These drugs typically act on the central nervous system, causing a reversible loss of consciousness or muscle control.

Veterinary Medical Device: any instrument, machine, appliance, material intended by the manufacturer to be used alone or in combination for the purpose of diagnosis, testing, vaccination, cure, surgery or for animal health protection.

Veterinary Pharmaceutical Products: Substances or compounds presented as possessing curative or preventative properties with respect to animal diseases, or that is administered to animals for establishing a medical diagnosis or restoring, correcting or modifying the organic functions of animals. They include veterinary immunological products such as vaccines, veterinary medicinal products such as anthelmintic, veterinary biological products such as hormones, and veterinary pesticides such as Ectoparasiticides.

Veterinary in vitro diagnostic device (IVD): A device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the animal body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles, used for diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction, and determination of physiological status.

Withdrawal period: The minimum time that must elapse between the cessation of treatment of a food-producing animal and either the slaughter of the animal for human consumption or the resumption of the supply for human consumption of products, such as meat, eggs, milk derived from the animal.

Zoonotic disease or zoonosis: infections that are shared between animals and humans.

INTRODUCTION

Rwanda FDA is mandated to ensure that all regulated veterinary products are properly and timely evaluated for quality, safety, and efficacy before being registered as authorized products on the Rwandan market. Marketing Authorization (MA) is issued after a thorough assessment of the application dossier to ensure the product's quality, safety, and efficacy of the product.

This alternative marketing authorization pathway is developed to cover circumstances in which routine marketing authorization procedures may not be followed. It allows the availability of certain veterinary products for serious or life-threatening diseases or conditions, unmet animal, or human health needs such as medicines for seriously debilitating diseases or life-threatening diseases, those used under an emergency situation, and orphan medicines. This pathway provides accessibility to veterinary products that can be used in situations of very limited alternative choices. In addition, the pathway is intended to make more veterinary products legally available to veterinarians and animal owners to be used in minor animal species and for the control of uncommon diseases in the major animal species.

These guidelines were developed to provide guidance to applicants and the Authority on conditional approval of regulated veterinary products. The guidelines were developed in reference to relevant regional and international guidelines or documents.

SCOPE

These guidelines apply to all regulated veterinary products intended to be marketed or used in Rwanda. They consist of veterinary immunological products, veterinary medicinal products, veterinary biological products, wildlife chemical immobilizing drugs, veterinary pesticides, and veterinary medical devices and IVDs.

These guidelines outline the required documents to support the quality, safety, and efficacy/performance of regulated veterinary products and eligibility criteria for conditional approval.

1. SUBMISSION OF APPLICATION

All applications for product registration for either locally manufactured or imported shall be submitted via Rwanda FDA Clients online portal Integrated Regulatory Information Management System (IRIMS CLIENTS) available on Rwanda FDA website. If the applicant is a foreign company, the applicant shall appoint a local technical representative who is a registered wholesale pharmaceutical company or an accredited manufacturer's representative.

2. ELIGIBILITY CRITERIA

To be eligible for conditional approval, veterinary products shall meet one of the following criteria:

2.1. The product is intended to treat a serious or life-threatening disease or condition:

A disease or condition that is associated with morbidity that has a substantial impact on day-to-day functioning or is associated with mortality in the target animal. Short-lived and self-limiting morbidity will usually not be sufficient unless the disease or condition is persistent or recurrent.

Whether a disease or condition is serious is a matter of clinical judgment, based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one.

A disease or condition may be considered serious based on the magnitude of its effect on the target animals that would receive the drug, its potential to affect humans if they were to contract the disease or condition from an affected target animal, or its potential to adversely impact the food supply.

The following are considered serious or life-threatening diseases or conditions:

- a) A disease or condition associated with mortality or morbidity that has a substantial impact on day-to-day functioning in the target animal;
- b) A disease or condition in animals that is zoonotic and that presents a risk of a serious or life-threatening disease or condition to human beings, whether or not it also presents a risk of harm to the target animal receiving the drug;
- c) A disease or condition that causes widespread morbidity in food-producing animals that presents a risk of regional or national disruption to food production, even if the effect of the disease or condition on an individual-animal basis is minor.

2.2. The product is intended to address unmet animal health need

Unmet animal health need mean a disease or condition whose treatment, control, or prevention is not adequately addressed by available therapy.

A disease or condition for which treatment, control, or prevention is not adequately addressed by therapy when:

- a) Available therapy does not exist for the same intended use proposed for the drug,
- b) Available therapy does exist for the same intended use but the drug for which conditional approval is sought is reasonably expected to provide a meaningful advantage over available therapy.

“Available therapy” means a product that is approved or registered by Rwanda FDA and is currently being marketed in Rwanda, for the same intended use in the same species as the proposed product for which conditional approval is sought.

Note: Conditionally approved veterinary products are not considered as available therapy because substantial evidence of effectiveness has not been demonstrated.

“Meaningful advantage” means that the drug for which conditional approval is sought is reasonably expected to provide one or more of the following advantages over available therapy:

- a) Provide clinically relevant improved effectiveness on an outcome of the involved disease or condition when compared to the available therapy.
- b) Provide a clinically relevant beneficial effect on the disease or condition that is not provided by available therapy for that disease or condition.
- c) Provide comparable effectiveness on an outcome of the involved disease or condition in animals that cannot tolerate the available therapy.
- d) Provide effectiveness comparable to available therapy, while improving safety. For example, avoiding serious toxicity that occurs with available therapy, avoiding serious toxicity that is common and causes discontinuation of treatment for a serious disease or condition, reducing the potential for harmful drug interactions.
- e) Provide for safe administration with other therapies that are necessary for an improved beneficial effect on an outcome of the involved disease or condition when available therapy cannot.

2.3. The product is intended to be used in minor animal species

Minor animal species are all animals other than the major animal species. They include animals such as zoo animals, wild animals, pets (such as dogs and cats), ornamental fish, parrots, ferrets, guinea pigs, catfish, game birds, equines (such as horses and donkeys) and honeybees among others.

2.4. The product is intended for minor use

Minor use refers to when drugs are used to treat one of the major species (horses, dogs, cats, cattle, swine, turkeys, and chickens) for a disease that is rare. A disease can be rare because it occurs only in certain areas of the country, or because it affects only a small number of animals each year.

2.5. Complex or particular case(s)

Rwanda FDA will handle a case-by-case basis by considering the extent to which one or more of the following factors apply to demonstrate substantial evidence of effectiveness:

- a) The nature of the disease or condition makes it unusually time consuming or difficult to enroll sufficient numbers of eligible animals to provide substantial evidence of effectiveness. Among other possible factors, there are the sporadic occurrence of the disease or the condition, the unpredictability of the occurrence or outcome of the disease or condition, the difficulty in diagnosing the disease or condition, and the lack of feasible alternatives such as induced disease model studies.
- b) The demonstration of effectiveness is unusually difficult or complex due to logistical challenges, such as needing an unusually large number of animals in the study or studies or the need for use of advanced or complicated tests.
- c) It is necessary to develop and qualify effectiveness endpoints (e.g., clinical endpoints, biomarkers) to conduct the study or studies.
- d) It is necessary to develop and validate or qualify novel methods to adequately evaluate effectiveness outcomes (e.g., complex animal models, technologies, or diagnostic tests).
- e) The endpoint being evaluated is a delay in progression of a chronically progressive disease or condition where evaluation of effectiveness for an individual animal will likely take an extended period of time (typically a year or more).
- f) There is a need to evaluate the treatment of a disease or condition over an extended period of drug administration where evaluation of effectiveness for an individual animal will likely take an extended period of time (typically a year or more).
- g) The drug will be indicated for mitigating transmission of a zoonotic disease from animals to humans and it is necessary to conduct a study (ies) to evaluate the human aspect of effectiveness.

2.6. The product is intended to be used in emergency animal health situation

Emergency health situations include, but are not limited to, a heightened risk of affliction or outbreak on the life, health, safety and security of the general animal health or public health, or else any incident with a significant potential to affect national security.

2.7. The Product is intended for wildlife immobilizations

Wildlife immobilization can be for translocation, relocation, treatment, collaring, Dehorning, application of transmitters, surgical purposes (spaying and castration) and research purposes (sampling).

3. ADMINISTRATIVE AND TECHNICAL REQUIREMENTS

3.1. Administrative and prescribing information

The following are administrative documents to be submitted to Rwanda FDA for conditional approval of regulated veterinary products:

- a) An application letter written in English that specifies why conditional approval is requested.
- b) Filled and signed application form (*Appendix 1, Appendix 2*).
- c) Filled checklist for conditional approval of veterinary products (*Appendix 3 and Appendix 4*).
- d) Letter of appointment of the local technical representative supported by the power of attorney notarized in the country of origin (if applicable).
- e) A copy of valid certificate of compliance to quality standards such as the current Good Manufacturing Practice (cGMP) certificate for medicinal products and the ISO certificate for medical devices including In-vitro diagnostics (or equivalent document).
- f) Copies of inner and outer Labeling. The content of the label should at least contain a minimum information as stipulated in *Appendix 4*.
- g) A copy of the Product Information Leaflet (PIL) or Package Insert (minimum information to be included highlighted in *Appendix 5*).
- h) A draft copy of the Summary of product characteristics (minimum information to be included highlighted in *Appendix 6*).
- i) List of countries in which the product is registered or authorized for use (if applicable) and provide proof/evidence to establish the fact.
- j) Proof of payment of the required application fees for **the registration of veterinary products for minor species and minor use** as per Rwanda FDA regulations related to regulatory service tariff for conditional registration. However, for the emergency use veterinary products there will be no application fees required.

3.2. Technical documentations

3.2.1. A description of the product and its intended use: justification that the product falls within the scope of the conditional marketing authorization.

3.2.2. Data to support quality, safety, and efficacy/performance of the product (if available):

3.2.2.1 For veterinary medicinal products, veterinary biological products, and immunological veterinary products:

a) Module 1: Administrative information

b) Module 2: Summary of submitted data

c) Module 3: Available information to support the quality of the product:

The active substance:

- i. General information on the active substance (nomenclature, structure and properties of the active ingredients)
- ii. Specifications of the active substance
- iii. Certificates of analysis of three batches of active substance
- iv. Stability data of the active substance

The finished product:

- i. General description of the finished product (appearance and composition)
- ii. Specifications of the finished product
- iii. Certificates of analysis of three batches of the finished product
- iv. Container Closure of the finished product
- v. Reference standard used in the manufacture of the finished product
- vi. Stability data of the finished products

d) Module 4: Available information to support the efficacy of the product:

Reports of conducted studies to establish the efficacy of the product.

e) Module 5: Available information to support the safety of the product:

Reports of conducted studies to establish the safety of the product.

3.2.2.2 For Veterinary Medical Devices and In-Vitro Diagnostics

- a) Description and Specifications of the Device
- b) Labels
- c) Device's Instructions for use

3.2.3. Commitment letter from the applicant to provide the comprehensive data to support quality, safety, and efficacy of the product once available (if applicable).

4. TIME PERIOD FOR CONDITIONAL APPROVAL

The time for Provisional Marketing Authorization (PMA) of regulated veterinary products under conditional approval is limited to a maximum of three years unless cancelled prior to this time due to different reasons such as serious safety and quality concerns on the product or end of the health emergency.

The PMA will automatically be discontinued at the end of the specified period.
Where applicable, if the veterinary product is still needed, the PMA may be renewed.

5. REVIEW PROCESS

Upon submission of the application dossier, a team of experts at Rwanda FDA will be designated to assess the information and data included in the application dossier to make recommendations to the Director General.

If the application is approved, a letter certifying the issuance of a PMA under conditional approval will be submitted to the applicant. The Letter will include a general description of the product, the intended use, as well as the indications and contraindications of the product (Appendix 7). The letter will be issued by the Director General.

The timelines for processing of a PMA through a conditional approval will depend on the following:


- a) Product profile
- b) The existing, if any, of pending applications
- c) The nature of the emergency situation
- d) Other relevant factors.

Although the length of time required for action will vary, Rwanda FDA recognizes that it is likely that, in an emergency situation that is occurring or believed imminent, a request for consideration for a conditional approval will be processed within 15 working days.

6. REFERENCES

1. EFDA. GUIDELINE FOR CONDITIONAL APPROVAL OF MEDICINES. Addis-Ababa: 2021.
2. CVM. Eligibility Criteria for Expanded Conditional Approval of New Animal Drugs Guidance for Industry. Maryland: 2021.
3. MOHM. Guidance and Requirements on Conditional Registration of Pharmaceutical Products during Disaster. Kuala Lumpur: 2021.
4. U.S Government. Minor Use and Minor Species Animal Health Act of 2004. Washington DC: 2004.
5. European Medicines Agency. Guideline on the scientific application and the practical arrangements necessary to implement commission Regulation (EC) No 507/2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC. Eur Med Agency 2006; 44:1–10.C

ENDORSEMENT OF THE GUIDELINES

| | Prepared by | Checked by | | Approved by |
|------------------|---|-----------------------------------|-------------------------------------|-------------------------|
| Title | Division Manager | Head of Department | QMS Division Manager | Director General |
| Names | Dr. Doreen INGABIRE | Dr. Védaste HABYALIMANA | Mr. Théogène NDAYAMBAJE | Prof. Emile BIENVENU |
| Signature |  | | | |
| Date | 12 th March, 2024 | | | |

APPENDICES

Appendix 1. Application form for registration of veterinary medicinal products



Doc No: DD/VMDR/FOM/002

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APPLICATION FORM FOR A NEW MARKETING AUTHORISATION FOR VETERINARY PHARMACEUTICAL, BIOLOGICAL AND IMMUNOLOGICAL PRODUCTS

(Application form Adopted from the Regional Regulatory Harmonization for Livestock
Products in Sub-Saharan Africa)

*A separate application form is required for each strength and/or pharmaceutical dosage form.
Different pack sizes of the same product can be included on the same form.*

SECTION 1 - PRODUCT NAME(s)

1.1. Proposed trade name of product

| |
|--|
| |
|--|

1.2. International Non-Proprietary Name (Generic Name)

| |
|--|
| |
|--|

SECTION 2 – APPLICATION DETAILS

2.1 Product Type

Please select either pharmaceutical OR Biological/Immunological

| | |
|--------------------------|---|
| <input type="checkbox"/> | Pharmaceutical |
| <input type="checkbox"/> | Biological A VMP sourced from a biological source that is not a vaccine |
| <input type="checkbox"/> | Immunological - vaccine. |

2.2 Type of Drug Substance

Please select only one

| | |
|--------------------------|---|
| <input type="checkbox"/> | Newly marketed Product with New Drug Substance |
| <input type="checkbox"/> | Newly marketed Product with New Combination of Drugs Substances |
| <input type="checkbox"/> | Newly marketed Product with Existing Drug Substance |
| <input type="checkbox"/> | Re-evaluation of an Existing Product |

SECTION 3 – PRODUCT DETAILS

3.1 Formulation *(provide the full formulation details)*

| | Name of the substance | Concentration in the final product | Description of Function <i>(example, active substance, attenuated virus, adjuvant, excipient)</i> |
|---|-----------------------|------------------------------------|--|
| 1 | | | |
| 2 | | | |

Please add extra rows, if required.

3.2 Therapeutic Subgroup Classification *(example, inactivated viral vaccine, diuretic drug)* and ATC Code (if applicable)

| |
|--|
| |
|--|

3.3 Dosage Form and Strength *(example, solution for injection)*

| |
|--|
| |
|--|

3.4 Visual appearance including colour *(example, clear, light yellow oily solution)*

| |
|--|
| |
|--|

3.5 Target Species and Route(s) of Administration

| | Target Species | Route of Administration | Food-producing? (tick as appropriate) |
|--|----------------|-------------------------|--|
| | | | |

| | | | |
|---|--|--|--|
| 1 | | | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| 2 | | | Yes <input type="checkbox"/> No <input type="checkbox"/> |

Please add extra rows, if required.

3.6 Do all active substances have the appropriate Maximum Residue Limits (MRLs) set in the species and for the route of administration(s) for which they are indicated? For example, from Codex, EU or other.

YES NO

If yes, states the MRLs

| Target Species | Tissue | MRLs | Reference (Codex, EU,...) |
|----------------|--------|------|---------------------------|
| | | | |
| | | | |

If no, please tell us what you are doing to obtain the appropriate MRL(s):

3.7 Pack type details

Please provide information of all pack types including their container and closures.

| | Pack Size <i>(example, 100 ml)</i> | Container <i>(example HDPE bottle)</i> | Closure <i>(example, polyethylene screw-cap)</i> |
|---|---------------------------------------|---|---|
| 1 | | | |
| 2 | | | |

Please add extra rows, if required.

3.8 Proposed shelf-life (if applicable also include the proposed shelf life after reconstitution or dilution or after first opening container)

SECTION 4 – CONTACT INFORMATION

4.1 Details of the proposed Marketing Authorization Holder (MAH) or Applicant contact:

Company Name:

Company Address:

Telephone No.

Email

4.2 Name, address and contact details of the proposed Manufacturers

4.2.1. Name, address and contact details of the proposed finished product manufacturer(s):

If the proposed named manufacturer is the same as the proposed MAH, simply enter 'same as MAH' in the field below.

| | Name, address and telephone number, Email | Brief description of functions performed (e.g. bulk manufacturing, batch release, primary or secondary packaging) |
|----------|--|--|
| 1 | | |
| 2 | | |

Please add extra rows, if required.

4.2.2. Name, address and contact details of the proposed manufacturer (s) of Active pharmaceutical ingredient (s) or active Immunogenic Substance(s):

| | Name, address and telephone number, Email | Brief description of functions performed (e.g. bulk manufacturing, batch release, primary or secondary packaging) |
|----------|--|--|
| 1 | | |
| 2 | | |

Please add extra rows, if required.

SECTION 5 – REGULATORY STATUS

5.1 Regulatory Status in Country of Origin. *Provide the regulatory status in the country of manufacture and the authorisation number/reference.*

| |
|--|
| |
|--|

5.2 Regulatory Status in Other Territories. *Regulatory status of the proposed product in other countries globally, including successful or pending, rejected, withdrawn, suspended or revoked applications.*

| Country/Region with successful authorisations |
|---|
| |
| |

Please add extra rows, if required.

| Country/Region where applications are pending |
|---|
| |
| |

Please add extra rows, if required.

| Country/Region where applications/authorisations have been rejected, withdrawn, suspended or revoked |
|--|
| |
| |

Please add extra rows, if required.

SECTION 6 – DECLARATION

Contact details of the person responsible for the application: *A legal representative of the applying company to take full responsibility for the application on behalf of the MAH and is answerable to the authority.*

Name:

Company
Name:

Address
(including
country):

Telephone
No.

Email Address:

Position and Affiliation:

I confirm that the information provided in support of this application is correct at the time of submission.

I understand that if any information provided in this application is later found to be false or incorrect, the authorization may be suspended or revoked.

| | |
|-------------------|----------------------|
| SIGNATURE: | <input type="text"/> |
| DATE: | <input type="text"/> |

**Note: - not signing this box will lead to your application being rejected at validation.*

- If fees have been paid, attach proof of payment

ANNEX 1: Rwanda Specific Information

If applications are being made to a number of countries, please provide the following details for each country (please replicate this annex for each country)

A.1 Contact details of in-country Local Technical Representative: *An in-country legal representative of the company holding the original authorization to take full responsibility for the product on behalf of the MAH and is answerable to the authority.*

Name:

Address (including country):

Telephone No.

Email Address:

A.2 Name and contact details of person responsible for pharmacovigilance:

Name:

Telephone No.

Email Address:

A.3 Proposed Distribution Category in country *(example, controlled drug, drug requiring prescription by veterinarian etc.)*

| |
|--|
| |
|--|

A.4 Proposed Storage Conditions (if applicable, also include the proposed storage condition after first opening and after reconstitution)

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| |
|--|

A.5 Intended Use

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|--|
| |
|--|

Appendix 2. Application form for registration of medical devices and In Vitro Diagnostics



Doc No: DD/VMDR/FOM/008

Revision No:0

Effective Date: 18/03/2024

Application Form for Market Authorization of Veterinary Medical Devices and /or In Vitro Diagnostics Devices (IVDDs)

| Application Number | Rwanda FDA use only | |
|--|--|--|
| Date of submission of dossier | Rwanda FDA use only | |
| 1.0 PARTICULARS OF THE MEDICAL DEVICE or IVDD (Bold or Tick the right type of application) | | |
| 1.1 | Type of application <ul style="list-style-type: none"> • New • Renewal • Variation* * If variation has been made, information supporting the changes should be submitted. | |
| 1.2 | Name: Brand Name of the Veterinary Medical Device or IVDD | |
| 1.2.1 | Common/generic Name of Veterinary Medical Device or IVDD | |
| 1.3 | Global Medical Device Nomenclature (GMDN) Name (Where Applicable) | |
| 1.3.1 | GMDN Code (Where applicable) | |
| 1.3.2 | GMDN Category (where Applicable) | |

Guidelines for conditional approval of veterinary products

| | | |
|-------|--|---|
| 1.4 | Category: Type of Device | <input type="checkbox"/> Veterinary Medical Device <input type="checkbox"/> Veterinary IVDD <input type="checkbox"/> Others, Specify..... |
| 1.4.1 | State the Class of the Medical Device or IVDD (Device Risk class) | <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D |
| 1.4.2 | State applicable Classification rule of the Medical Device or IVDD as appended in Annex IV and V of these guidelines | |
| 1.5 | Intended use of the Veterinary Medical Device or IVDD (i.e conditions that require its usage) | |
| 1.6 | Intended user of the Veterinary Medical Device or IVDD | <input type="checkbox"/> Veterinarian/Professional Vet Use <input type="checkbox"/> Herds man/Farmer /General use <input type="checkbox"/> Others (Specify;.....) |
| 1.7 | Targeted Species | |
| 1.8 | The number of unit products/devices in a commercial pack | |
| 1.9 | Any associated products/Devices that work together with the device (examples; reagents, controls, accessories etc) | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, specify: |
| 1.10 | Full Names, address and contact details (physical and postal) of Applicant | Name: Address: Country: Telephone: Telefax: E-Mail |
| 1.11 | Full Names, address and contact details (physical and postal) of the Local Technical Representative (LTR) (Attach a valid copy of a letter of appointment supported by original copy of power of attorney duly notarized in country of origin) | Names Address: Country: Telephone: Telefax: E-Mail |
| 1.12 | Manufacturer Information: Full Names, address and contact details (physical and postal) of veterinary Medical devices or IVDD manufacturer | Name: Address: Country: Telephone: Telefax: |

| | | |
|--------|---|---|
| | | E-Mail |
| 1.12.1 | Full Name(s) and physical address(es) of the manufacturing site(s) of the Medical Device or IVDD. Alternative sites/Contract Manufacturer (s) should be also declared here. All manufacturing sites involved in the manufacturing process of the device, stating the role of each including quality control / in-process testing sites should be listed. | Name: Address: Country: Telephone: Telefax: E-Mail |
| 1.13 | Visual description of the Medical Device or IVDD | |
| 1.14 | Proposed shelf life (in months) (where applicable). | |
| 1.15 | Proposed storage conditions (where applicable). | |
| 1.16 | Device's Serial Number (Where Applicable) | |
| 1.17 | Commercial Presentation (Number of Units Presented in Pack (Where applicable). | |
| 1.18 | Model/Series/Family of the Veterinary Medical device or IVDD (List all sizes applicable). | |
| 1.19 | Registration status in different countries along with supporting documents (marketing authorization approval, free sale certificate, etc.) | |
| 1.20 | Country of origin (where the device was manufactured). | |

1.21. DECLARATION BY THE APPLICANT

I, _____, the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge.

I further confirm that the information referred to in my application dossier is available for verification during Quality audit inspection. I also agree that I shall carry out Materiovigilance and Post Marketing Surveillance to monitor the safety, quality and performance of the device on the market and provide safety, quality and performance update reports to Rwanda FDA.

I further agree that I am obliged to follow the requirements of Rwanda Legislations and Regulations, which are applicable to Medical Devices and IVDDs. I also consent to the processing of information provided to Rwanda FDA. It is hereby confirmed that fees will be paid/have been paid according to the authority's rules*

Signature:

Date:

* **Note:** If fees have been paid, attach proof of payment

Appendix 3. Checklist for conditional approval of veterinary medical devices and IVDDs



Doc No: DD/VMDR/CKL/003

Revision No:0

Effective Date: 18/03/2024

Checklist for Conditional Approval of Veterinary Medical Devices and IVDDs

| <p>In case the expectation is that, the applicant for conditional approval will continue to submit required documents until full product registration, use this checklist to specify the available information provided in the application dossier. If some information will be provided in the future, indicate the estimated date of submission of additional data.</p> | | | | |
|---|---|-----|----|---------------------------|
| No. | Documents | Yes | No | Date of future submission |
| 1. Administrative Document | | | | |
| 1.1 | Signed and dated original copy of a cover letter | | | |
| 1.2 | Signed and dated and duly filled application form (Appendix II) | | | |
| 1.3 | Proof of payment of veterinary notification fees as per relevant regulations governing service tariff/fees and charges at the time of dossier submission. | | | |
| 1.4 | A copy of a free sale certificate or equivalent document | | | |
| 1.5 | Appointment letter of a Local technical representative (LTR) | | | |
| 1.6 | Certificate of conformity of the veterinary device | | | |
| 1.7 | Samples | | | |
| 2. Technical documents | | | | |
| 2.1 | The Device art works | | | |
| 2.2 | Instructions for Use (IFU) | | | |
| 2.3 | Statement of the intended use depending on the device | | | |
| 2.4 | Device manufacturer | | | |
| 2.5 | Device Description | | | |
| 2.6 | Certificate of compliance to quality standards | | | |
| 2.7 | Veterinary Medical device and/or IVDD Specification | | | |
| 2.8 | Device's Labels | | | |
| 3. Module 3: Quality Data | | | | |
| Other submitted documents | | | | |
| | | | | |

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Appendix 4. Checklist for conditional approval of veterinary Medical Products



Doc No: DD/VMDR/CKL/002

Revision No:0

Effective Date: 18/03/2024

Title: Checklist for Conditional Approval of Veterinary Medical Products

| <p>In case the expectation is that the applicant for conditional approval will continue to submit required documents until full product registration, the application should follow the CTD format as per the specific guidelines. Use this checklist to specify the available information provided in the application dossier. If some information will be provided in the future, indicate the estimated date of submission of additional data.</p> | | | | |
|---|--|-----|----|---------------------------|
| No. | Documents | Yes | No | Date of future submission |
| 4. Module 1 : Administrative Information | | | | |
| 1.1 | An application letter written in English | | | |
| 1.2 | Filled and signed application form (Appendix 1) | | | |
| 1.3 | Letter of appointment of the local technical representative | | | |
| 1.4 | Power of attorney notarized in the country of origin (if applicable). | | | |
| 1.5 | A copy of valid current good manufacturing practice (cGMP) certificate issued by national regulatory authority in the country of origin or Stringent Regulatory Authority. | | | |
| 1.6 | Copies of inner and outer Labeling. The content of the label should at least contain a minimum information as stipulated in Appendix 2. | | | |
| 1.7 | A copy of the Product Information Leaflet (PIL) or Package Insert (minimum information to be included highlighted in Appendix 3). | | | |
| 1.8 | A draft copy of the Summary of product characteristics (minimum information to be included highlighted in Appendix 4). | | | |
| 1.9 | List of countries in which the product is registered or authorized for use (if applicable) and provide proof/evidence to establish the fact. | | | |
| 1.10 | Evidence for payment of Service fees | | | |

| 5. Module 2. Summaries of submitted Data | | | | |
|---|--|--|--|--|
| 2.1 | Summary of module 3 | | | |
| 2.2 | Summary of module 4 | | | |
| 2.3 | Summary of module 5 | | | |
| 6. Module 3: Quality Data | | | | |
| 3.1 Active substance | | | | |
| 3.1.1 | General information on the active substance | | | |
| 3.1.2 | Information on the manufacture of the active substance | | | |
| 3.1.3 | Information on the characterization of the active substance | | | |
| 3.1.4 | Information on the control of the active substance (Specifications, analytical procedures, validation of analytical procedures, and batch analysis) | | | |
| 3.1.5 | Information on the reference standard | | | |
| 3.1.6 | Information on the container closure system | | | |
| 3.1.7 | Information on the stability of the active substance | | | |
| 3.2 Finished product | | | | |
| 3.2.1 | Description of the finished product | | | |
| 3.2.2 | Information on the Pharmaceutical Development | | | |
| 3.2.3 | Information on the manufacture process of the finished product | | | |
| 3.2.4 | Information on the control of excipients (Specifications, analytical procedures, validation of analytical procedures, and excipient of human or animal origin or novel excipient) | | | |
| 3.2.5 | Information on the control of the finished product (Specifications, analytical procedures, validation of analytical procedures, and batch analysis) | | | |
| 3.2.6 | Information on the reference standard | | | |
| 3.2.7 | Information on the container closure system | | | |
| 3.2.8 | Information on the stability of the finished product | | | |
| 7. Module 4: Efficacy Data | | | | |
| 4.1 | Reports of conducted studies to support efficacy of the product | | | |
| 4.2 | Literature Review | | | |
| 8. Module 5: Safety data | | | | |
| 5.1 | Reports of conducted studies to support safety of the product | | | |
| 5.2 | Literature Review | | | |
| Samples | | | | |
| | Commercial samples | | | |
| Other submitted documents | | | | |
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Appendix 5. Content of the container Labelling

Every immediate and outer container of any veterinary product shall be labeled in clearly legible indelible letters in English.

Particulars to appear on the primary package

1. Name of the veterinary product
2. Name and quantity of active substance(s)
3. Target species
4. Indication (s)
5. Dosage and administration
6. Contraindications
7. Content by volume or number of doses
8. Storage conditions
9. Date of manufacture, expiry, and batch number in an uncoded form
10. Name and physical address of the finished product manufacturer
11. For Veterinary Use only

For containers of less than or equal to 10 ml capacity that are marketed in an outer pack such as a carton, the outer packaging will bear all the required information while the immediate container will only contain items (1), (2), (3), (5), (7), (8), (9). Alternatively, a logo that unambiguously identifies the company or the name of the dosage form, or the route of administration can be used.

Particulars to appear on the secondary package

1. Name of the veterinary product
2. Name and quantity of active substance(s) and excipients
3. Target species
4. Indication(s)
5. Dosage and administration
6. Contraindications
7. Warnings and precautions, “for animal treatment only” “keep out of reach of children” are Mandatory.
8. Withdrawal Period (if applicable)
9. Content by volume or number of doses
10. Storage conditions
11. Date of manufacture, expiry, and batch number in an Uncoded form
12. Name and physical address of the manufacturer

Small packs container

As a minimum, the following information is printed directly on blister or/and strip:

1. Name, strength, and pharmaceutical form of the veterinary product.
2. Name of the manufacturer.

3. The batch number assigned by the manufacturer.
4. The manufacturing and expiry dates.

Appendix 6. Content of Product Information Leaflet

Particulars to appear on the package leaflet

1. Name of the veterinary product
2. Name and quantity of active substance(s) and excipients
3. Indication(s)
4. Contraindications, warnings and precautions
5. Adverse effects following the usage
6. Target species
7. Amount to be administered and administration route for each Species
8. Withdrawal period (where applicable)
9. Special storage precautions
10. Special warning(s)
11. Content of pack(s) by volume or number of doses
12. Special precautions for the disposal of unused product or waste materials, if any (dispose according to local regulations)
13. Name and physical address of the manufacturer and Marketing authorization holder, if different from the Manufacturer.
14. Date on which the package leaflet was last revised

Appendix 7. Summary of Product Characteristics (SmPCs) for a veterinary product

1. Name of the veterinary product

State the name under which the product will be marketed.

2. Qualitative and quantitative composition

Provide the qualitative and quantitative composition per unit dosage form in terms of the active substance(s) and excipients in a format as indicated below:

Each dose of (product name) contains:

- Active substance(s):
- Adjuvant(s) (if any):
- Excipient(s):

3. Product Dosage form

State clearly the dosage form of the product. Any descriptive terms to indicate the exact type of dosage form should also be included. The visual and physical characteristics of the product also should be stated.

4. Clinical particulars

4.1. Target species

State target species, including any sub-category where appropriate.

4.2. Indications for use

Provide information on indications of the product in the target species.

4.3. **Contraindications**

State the contraindications for the veterinary product e.g. not for use in pregnant animals, very young and old animals.

4.4. **Special warnings**

State any specific warnings associated with this product.

4.5. **Special precautions for use**

State precautions to be taken by the person administering the veterinary product (if any). State the precautions that should be taken for use in animals.

4.6. **Adverse effects following the usage (frequency and seriousness).**

State the side effects and adverse reactions of the product. Within each frequency grouping, undesirable effects should be presented in order of decreasing seriousness.

4.7. **Use during pregnancy, lactation or lay**

Provide information on the use of the product in pregnant, lactating animals or laying birds and the reasons for any relevant recommendation. Information about the use of the product during pregnancy or lactation may have been provided in the sections dealing with contraindications or special precautions for use. In such cases, a cross-reference to the relevant section will be sufficient. Information on the reasons for the relevant recommendation should be given.

4.8. **Interaction with other products and other forms of interaction**

State briefly the interactions of the product with other types of medicinal products, or state whether compatible with other products likely to be used at the same time.

4.9. **Amount to be administered and administration route**

State the dose, dosage schedule and route of administration.

4.10. **Overdose (symptoms, emergency procedures, if necessary)**

Describe symptoms observed at higher dose levels. Give the recommended management and emergency procedures.

4.11. **Withdrawal period**

State the withdrawal periods (if applicable)

5. Clinical / Therapeutic properties

State the clinical/therapeutic properties of the product e.g. active against gram negative bacterial infections.

6. Veterinary product particulars

6.1. **Incompatibilities**

Provide information on incompatibilities of the product with other products.

6.2. **Shelf life**

a) Shelf life (in months) of the veterinary product.

b) State the veterinary product shelf life after reconstitution (where applicable).

- c) For multi-dose packages state the in use shelf life after first opening (where applicable).

6.3. Special precautions for storage

State the recommended storage conditions (e.g. temperature, light) as established by stability studies. The storage temperature must be stated in figures.

6.4. Nature and composition of packaging

State briefly the type(s) of packing and pack size(s) being applied for registration. The pack sizes declared here should correspond with the samples submitted.

6.5. Special precautions for the disposal of unused products or waste

State Material derived from the use of such products. Provide practical instructions for the safe disposal of the medicinal product and waste materials derived from the used/unused product (if applicable).

7. Marketing Authorization holder/License holder

State the name and physical address of the registrant including telephone, fax number, and e-mail. In addition, provide the name and physical address of the manufacturer including telephone, fax number, and e-mail if different from the Marketing Authorization Holder.

8. Date of revision of the text

To be stated at the time of approval of changes to the SmPC

Appendix 8. Provisional Marketing Authorization



Kigali on .../.../...

Applicant Name

Address Details

Ref. N°: DD/VMDR/...../FDA/202..

Subject: Provisional Marketing Authorization (PMA)

Approval N°: Rwanda FDA-PMA of VP / 0000/202***

Applicant Name: *****

Product Name: *****

Manufacturer: *****

Product Description:

Indication for use:

Method of administration

Rwanda FDA Statement:

Rwanda Food and Drugs Authority (Rwanda FDA) supports the development of veterinary products that address serious or life-threatening disease or condition, unmet animal health need, and health emergency. In addition, provisional market authorization may be granted to applicant to make more veterinary products legally available to veterinarians and animal owners to be used in minor animal species, minor use animals and for the control of uncommon diseases in the major animal species.

The provisional marketing authorization is issued for veterinary products where the benefit of immediate availability outweighs the risk of less comprehensive data than normally required for full product review for product registration.

Conditions for Authorization:

- The holder of the provisional marketing authorization will report information related to quality, safety and efficacy in the ongoing studies on *****.
- The holder of Authorization will report to Rwanda FDA all serious adverse events associated with the use of *****.

- The holder of provisional marketing authorization should comply with Current Good Manufacturing Practice requirements.
- The product ***** shall only be used for the approved intended use: *****

- *****(other conditions, if applicable).

Rwanda FDA Decision:

Pursuant to Rwanda Food and Drugs Authority (Rwanda FDA) Law No 003/2018 especially in its Article 8 para12;

Pursuant to the Technical Regulation CBD/TRG/010 related to medicinal products registration;

Rwanda FDA upon:

- a) The comprehensive review of the data submitted by the Applicant,

- b) Consideration to its legal mandates, believes that, the known and potential benefits of ***** , when used in respect of approved indication outweigh its known and potential risks,

Grants a Provisional Marketing Authorization of *** to be used for *****.**
The ***** will be strictly used in accordance with official recommendations.

Duration of Authorization:

This Provisional Marketing Authorization is effective for ***** year from ***** until *****.

Sincerely,

Name of DG
Director General

Cc:
Local technical representative (if applicable)