REGIONAL GUIDELINES FOR THE REGULATION OF VETERINARY DRUGS IN SADC MEMBER STATES

November 2011

REGIONAL GUIDELINES FOR THE REGULATION OF VETERINARY DRUGS IN SADC MEMBER STATES

Published by SADC through the Food Safety – Capacity Building on Residue Control Project, FANR

November 2011

SADC Secretariat
Private Bag 0095
SADC House, Plot 54385,
Central Business District
Gaborone West
Gaborone, Botswana

Tel: +267 395 1863
Fax: +267 397 2848
E-mail: registry@sadc.int
Website: www.sadc.int

Acknowledgements:

The FANR Directorate of the SADC Secretariat would like to thank all those who contributed to the development and production of these guidelines, through discussion and written inputs. The design and implementation of this programme was financed by the Southern African Development Community (SADC) Secretariat through the Food Safety – Capacity Building on Residue Control Project with support from the European Union. The SADC Secretariat is grateful to the European Union for the provision of financial support.

REGIONAL GUIDELINES FOR THE REGULATION OF VETERINARY DRUGS IN SADC MEMBER STATES

ABBREVIATIONS iv
TERMS AND DEFINITIONS iv
PREFACE viii
EXECUTIVE SUMMARY ix
1 INTRODUCTION 1
2 SCOPE OF THE VETERINARY DRUGS AND PRODUCTS GUIDELINES 1
3 OBJECTIVES OF THE VETERINARY DRUGS REGULATION GUIDELINES 1
4 REGIONAL POLICY GUIDELINES 2
5 CONTEXT FOR THE DESIGN OF NATIONAL VETERINARY DRUGS LEGISLATION IN THE SADC REGION 3
6 LEGISLATIVE FRAMEWORK AND KEY ISSUES FOR THE SADC REGION 6
7 A PROPOSED FRAMEWORK FOR REGISTRATION AND QUALITY CONTROL OF VETERINARY DRUGS AT NATIONAL AND SADC REGIONAL LEVEL 20
8 CONCLUSION 22
9 ANNEXES 23

ABBREVIATIONS

ADI: Average Daily Intake
AER: Adverse Event Report
CAC: Codex Alimentarius Commission
FAO: Food and Agriculture Organisation of the United Nations
GMP: Good Manufacturing Practices
ILO: International Labour Organisation
INN: International Non-Proprietary Name
ISO: International Standards Organisation
MRL: Maximum Residue Level
OIE: International Animal Health Organisation
PIC: Prior Informed Consent
POP: Persistent Organic Pollutants
SADC: Southern African Development Community
SPS: Sanitary and Phytosanitary
VICH: International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products
WCO: World Customs Organisation
WHO: World Health Organisation

TERMS AND DEFINITIONS

For the purposes of these guidelines, the following have the meanings hereby assigned to them.

Active Ingredient - A substance or mixture of substances with a therapeutic, diagnostic or prophylactic activity used in a pharmaceutical product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and the function of the body

Advertising - means the promotion for the sale and use of veterinary drugs by printed and electronic media, signs, displays, gift, demonstration or word of mouth

Bioavailability - The rate and extent to which the active ingredient is absorbed from a drug product and becomes available at the site(s) of action.

Bioequivalence - A high degree of similarity in the bioavailabilities of two pharmaceutical products (of the same generic form) from the same molar dose, that are unlikely to produce clinically relevant differences in therapeutic effects, or adverse effects or both.

Bioequivalent - Two products are considered to be bioequivalent when their active ingredient(s) is (are) equal in their rate and extent of absorption, and availability at the site(s) of action.

Generic Drug Product - means a pharmaceutical product, usually intended to be

interchangeable with the innovator product, which is usually manufactured without a license from the innovator company and marketed after expiry of patent or other exclusivity rights.

Container - is that which holds the drug and is or may be in direct contact with the drug.

Disposal means any operation to recycle, neutralize, destroy or isolate drug wastes, used containers and contaminated materials.

Distribution means the process by which veterinary drugs are supplied through trade channels to local or international markets.

Dosage Form - Formulation of an active ingredient(s) so that it can be administered to an animal in specified quantity/strength e.g. tablets, capsules, injection solution, syrups, ointments, suppositories, etc.

Environment means surroundings, including water, air, soil and their interrelationship as well as all relationship between them and any living organism.

Manufacturer means a corporation or other entity in the public or private sector or any individual engaged in the business or function (whether directly or through an agent or entity controlled by or under contract with it) of manufacturing a veterinary drugs active ingredient or preparing its formulation or product.

Innovator Drug - means a pharmaceutical product which was authorized for marketing (normally as a patented drug) on the basis of documentation of efficacy, safety and quality (according to contemporary requirements).

Labelling - All labels and other written, printed, or graphic matter upon an immediate container of a veterinary drug, any package or wrapper in which it is enclosed, except any outer shipping container.

Medicated premix (Feed additive) - A drug specifically formulated for blending into animal feed.

Marketing means the overall process of product promotion, including advertising, product public relations and information services as well as the distribution and sales on local and international markets.

Maximum Residue Limit (MRL) means the maximum concentration of a residue that is legally permitted or recognized as acceptable in or on a food or agricultural commodity or animal feedstuff.

New veterinary drug - One which has not been previously registered or marketed for veterinary purposes, including any new salts and esters of an active substance, new fixed combinations of substances previously marketed or any

veterinary drug previously marketed if its indication, mode of administration, or formulation are changed

Proprietary Product - A medicinal product sold or supplied under a special name (a brand or trade name) rather than the generic name of the ingredient alone.

Reference Standard/Substance - Authentic specimens that have been verified for suitability for use as comparison standards in compendia tests and assays.

Pharmaceutical product - Any preparation for veterinary use that is intended to modify or explore physiological systems or pathological states for the benefit of the recipient.

Pharmaceutical Equivalence - It refers to drug products, which contain the same active ingredient in the same strength (concentration) and dosage form, and is intended for the same route of administration. In general, it has the same labelling and meets compendia and other standards of strength, quality, purity, and identity but does not necessarily contain the same non-medicinal ingredients

Pharmacodynamics - The study of biochemical and physiological effects of drugs, their mechanisms of action, their structure activity relationships and their interaction with other drugs.

Pharmacokinetics - The study of the time course of drugs: absorption, distribution, metabolism and excretion.

Pharmacovigilance means adverse drug reaction reporting and post-market surveillance to monitor the safety and efficacy of veterinary drugs

Pivotal Trials - Studies providing the basic evidence to determine the efficacy, properties and conditions of use of the drug conducted by qualified investigators at the recommended doses with the proposed formulation and for indications which are being claimed.

Registration means the process whereby the responsible national government or regional authority approves the sale and use of a veterinary drug following the evaluation of comprehensive scientific data demonstrating that the product is effective for the intended purposes and does not pose an unacceptable risk to human or animal health or the environment.

Residue means any specific substance in or on food, agricultural commodities or animal feed resulting from the use of veterinary drugs. The term includes any derivatives of a drug such as conversion products, metabolites, reaction products and impurities considered to be of toxicological concern. The term "veterinary drug residue" includes residues from unknown as well as known uses of the drug.

Toxicity means a physiological or biological property, which determines the capacity of a chemical to do harm or produce injury to a living organism by other than mechanical means.

Submission - A submission is documentation consisting of data related to a drug product submitted by a named party and provided in response to a regulatory requirement. A submission is required for any substance or combination of substances that is manufactured, sold, offered for sale, or represented for use for medicinal purpose.

Veterinary drugs - any substance or combination of substances used for purpose of:

- Alleviating, treating, curing, or preventing a disease or pathological condition, or symptoms of a disease
- Diagnosing a disease or ascertaining the existence, degree or extent of a physiological pathological condition
- Contraception
- Inducing anaesthesia
- Maintaining mitigation, prevention, or diagnosis of disease, abnormal physical state, or the symptoms thereof in animal, or
- The restoration, correction, or modification of organic functions in animals
- Maintaining balance of vitamins, minerals, and other nutrients in animals, administered by injection and/or bolus dosage forms.

The term veterinary drugs is equivalent to veterinary medicines and medicinal products.

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 eggs, milk derived from the animal.

PREFACE

The development of these guidelines has involved extensive consultations processes which included Member States and relevant stakeholders. These have been recommended for use by Member States in developing their specific regulations by Ministers responsible for Agriculture and Food Security.

The implementation of these regional guidelines will help to harmonise the regulations for the registration and use of veterinary medicines and drugs across the region. This will promote safe use of effective and proven drugs for livestock which will contribute to increased regional food security and trade opportunities.

I, therefore, urge all relevant stakeholders to embrace the implementation of these guidelines, in order to take full benefit of the diverse livestock resources of the region.

Tomaz Augusto Salomão
Executive Secretary
SADC Secretariat

EXECUTIVE SUMMARY

The *Regional Guidelines for the Regulation of Veterinary Drugs* in *SADC Member States* are part of the process that is meant to promote regional trade and provide greater access to SADC Member States' exporters of agricultural products, including livestock and fisheries, to the EU and world markets.

In order to achieve this there is need to harmonise food safety control regulations, guidelines and procedures through institutional strengthening in the SADC region in conformity with international requirements in order to increase exports while complying with food safety requirements. These *Regional Guidelines for the Regulation of Veterinary Drugs in SADC Member States* were therefore developed through a participative approach with all stakeholders. The guidelines will assist Member States to strengthen the regulatory framework for registration and quality control of veterinary drugs at national and at regional levels.

The guidelines outline the obligations of Member States with regard to the registration of veterinary drugs. It is imperative that Member States meet these obligations for the purposes of food security and safety, human and animal health, and environmental safety, and meet the requirements for international trade in animal and animal products. To fulfil these obligations vast human and financial resources are required. Unfortunately these resources are lacking in the region. In order to overcome these constraints and to make the best possible use of expertise and resources available, the SADC Secretariat has embarked on the formulation of these *Guidelines for Veterinary Drugs.* These will provide ground for harmonising veterinary drugs policies, legislation, registration and control. The promotion of harmonization of the guidelines in the region will be addressed by the Regional SPS Committee as per the SADC SPS Annex to the Protocol on Trade.

These *Veterinary Drugs Guidelines* include the registration procedures, quality, safety, efficacy and environmental requirements, import and export control, compliance to the fact that only registered and correctly labelled dugs can be authorised for sale, and the accreditation of manufacturing premises, distributors and users. Member States, together with all stakeholders, shall ensure that the necessary programs are implemented with regard to training on the correct and safe use, as well as, the proper disposal of expired veterinary drugs and empty containers.

1 INTRODUCTION

These guidelines describe the information concerning the documentation to be supplied by manufacturers and importers for registration of veterinary drugs in the SADC Region. They also serve as a guide for veterinary drugs evaluators in assessing the acceptability of the applications submitted.

2 SCOPE OF THE VETERINARY DRUGS AND PRODUCTS GUIDELINES

SADC Member States are at different levels of technology development and implementation of various SPS related regulations. Therefore it is necessary to define sound scientific and technical framework that include the process, ethical principles and regulatory arrangements to authorise and control the use of veterinary drugs in Member States of the SADC Region.

The veterinary drugs guidelines are necessary to ensure appropriate health care to animals, in Member States of the SADC Region and to authorise only the use of veterinary drugs of proven safety, efficacy and quality.

One important method of ensuring the safety, efficacy and quality of these products is thorough evaluation and registration of veterinary drugs, which are to be imported or locally manufactured in Member States before they are offered for sale.

3 OBJECTIVES OF THE VETERINARY DRUGS REGULATION GUIDELINES

The Veterinary Drugs Registration Guidelines provide a general scientific framework including basic methodology, technical requirements, ethical principles as well as regulatory aspects for registration of veterinary drugs in SADC Member States with the following objectives:

- Provide appropriate health care to animals
- Provide the regional market with drugs that have proven safety, efficacy and quality
- Provide transparency in trade of agricultural products including animal and animal products within and outside the region
- Raise public awareness in the use of veterinary drugs
- Protect public health against zoonotic diseases
- Protect the environment
- Provide the regulatory basis for management and control of veterinary drugs
- Provide a relevant approach for the observance and compliance with Maximum Residues Limits.

The scope also includes the regulation of acaricides used in veterinary practice.

The guidelines for the registration of veterinary drugs provide the applicants with information concerning documentation to be submitted for registration of veterinary products. The present guidelines have been prepared taking into consideration the need for worldwide harmonization. This will assist the drug manufacturers in the preparation of a well-structured dossier to be submitted for the registration of veterinary drugs in order to facilitate their screening and subsequent review.

4 REGIONAL POLICY GUIDELINES

The livestock sector is a very significant contributor to food security in the SADC Region. However, animal production and trade is constrained by several factors including diseases, the control of which invariably involves in part, the use of veterinary drugs.

A policy to ensure that this area of the provision of veterinary services is adequately addressed is therefore vital.

The process of harmonizing SPS related policies within the SADC region is of paramount importance as it contributes to the building up of efficient SPS related control management system in Member States. The regional SPS policies provide also a framework on which national governments can develop their legal framework in line with international requirements for animal and animal products, and the associated production systems, achieve or contribute to the achievement of the protection of the health of consumers and ensure fair practices in the food trade. Furthermore, the harmonized guidelines provide an opportunity to increase the confidence among Member States SPS related control system.
Their implementation will ensure:

- A high level of protection of human life and animal health.
- The free movement of safe and wholesome animal and animal products as an essential aspect of a regional market.
- That the regional control management requirements do not differ significantly from Member State to Member State to the extent of impeding movement of animal and animal products within the region or internationally.
- That all the National Coordinating Committees and equivalent agencies in the Member States having mandates related to management of SPS matters work together and collaborate with the private sector, academia and other research organizations to ensure the coordination and long term sustainability of safety, quality and profitability of the animal and animal products produced in the region.

Veterinary drugs use and residues are some of the most important issues with regard to health, food safety and trade. Misuse of drugs in animal production, prohibited drugs residue levels on food of animal origin, agricultural commodities and feedstuffs can endanger human life and lead to constraints in trade within the region and internationally. To exercise the necessary

management and control over veterinary drugs it is necessary to have the relevant legislation in place to enable Member States to manage and control all aspects related to the registration, availability, use, labelling, marketing, manufacture, import, export, transport and disposal of these products. Therefore structures must also be put in place to ensure compliance to legislation and to monitor the use of veterinary drugs.

5 CONTEXT FOR THE DESIGN OF NATIONAL VETERINARY DRUGS LEGISLATION IN THE SADC REGION

The Recommended International Code of Practices for Control of the Use of Veterinary Drugs (FAO, CAC/RCP 38, 1993) and the Legislation for Veterinary Drugs Control (FAO, 2004) as well as the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) set out the guidelines on the prescription**,** distribution administration and control of drugs used for treating animals, preserving animal health or improving animal production. These codes of practices together with the OIE recommendations (OIE 2010) provide guidance to countries to achieve sound veterinary drugs management. In particular it addresses the responsibilities of national governments, the veterinary services, manufacturers, retailers and users of veterinary drugs.

The development and improvement of international and regional collaboration in the establishment and enforcement of legislation to harmonise the regulatory framework between Members so as to assist countries in need to effectively institute and maintain such mechanisms is cardinal to ensure the safe circulation and distribution of registered veterinary drugs.

Presently SADC Member States' legislations and regulations dealing with the registration of veterinary drugs are not in accordance with international requirements. In particular they do not take into account the transparency in the registration of veterinary drugs including licensing, labelling, efficacy, import/export procedures, good manufacturing processes, accreditation of foreign manufacturers, distribution, quality control, use, storage, disposal, training, and update of the legislation.

The implementation of these guidelines will promote the responsible and prudent use of veterinary drugs, in particular of antibiotics, used in veterinary medicine, which are responsible for antimicrobial resistance in humans. Indeed the current registration and distribution practices of veterinary drugs in some SADC Member States result in the proliferation of poor quality and counterfeit products in the Region.

Key aspects of the veterinary drugs legislation are summarised below:

5.1 Veterinary drugs management

- Member States shall regulate the availability, distribution and use of veterinary drugs and allocate adequate resources for this mandate.

- Countries exporting veterinary drugs shall provide technical assistance to other countries and ensure that good trading practices are ensured, especially to those countries with limited or no technical and regulatory schemes.

5.2 Testing of veterinary drugs

- Analytical laboratories shall be available on a national or regional basis to verify the quality of veterinary drugs offered for sale or export and to conduct residue and monitoring studies. These laboratories shall adhere to sound scientific procedures and guidelines for good laboratory practice and preferably be accredited by a designated authority according to ISO 17025 and participate to laboratory proficiency testing schemes related to veterinary drugs of concern.
- Where national laboratories are not available or are not in a position to carry out verifications on quality, adequate arrangements shall be agreed with other laboratories in the region to do it on their behalf.

5.3 Reducing health and environmental risks

- Member States shall implement a veterinary drugs registration scheme.
- Where necessary conduct periodic reviews of veterinary drugs available in the countries.
- Implement a program to monitor veterinary drugs residues in food and the environment.
- In cooperation with industry, ensure the proper location of drugs manufacturing plants, designing plants and storage facilities
- Adequately control wastes, effluents and the establishment of quality assurance procedures for compliance with the relevant standards of purity, performance, stability and safety according to Good Manufacturing Practices (GMP) and ISO 14000 standards.

5.4 Regulatory and technical requirements

- Introduce the necessary legislation for the regulation of veterinary drugs and make provisions for its effective enforcement.
- Establish veterinary drugs registration schemes and an inspectorate to ensure that only registered veterinary drugs can be produced, imported, sold and used.
- Conduct risk evaluations and risk management decisions based on available data or information.
- Use the principles described in the *VICH Guidelines* for Technical Harmonisation determining equivalence of veterinary drugs.
- Cooperate with other governments, Codex, OIE, VICH in the establishment of harmonized (regionally or by groups of countries) veterinary registration requirements, procedures and evaluation criteria.
- Detect and control illegal trade in veterinary drugs.

5.5 Availability and use

- All veterinary drugs made available to the general public must be packaged and labelled in a manner consistent with the appropriate national regulations.
- All veterinary drugs must be classified at the time of registration in the following categories
    - Prescription only
    - Pharmacy
    - Authorised dealer
    - General use
- Prohibition of the importation, sale and purchase of veterinary drugs of unknown quality, counterfeit, expired drugs, drugs withdrawn from sales from other countries
- Prohibition of the importation, sale and purchase of hazardous products may be desirable, if other control measures, such as restriction to certify users or similar measures are insufficient to ensure that the product can be handled with acceptable risk to the user.

5.6 Distribution and trade

- The necessary regulatory measures shall be available to prevent the repacking or decanting or misuse of any veterinary drugs into food or beverage containers.

5.7 Information exchange

- Facilitate the exchange of regulatory decisions (banning or severely restricting veterinary drugs, potential risks to human and animals, toxicological, environmental and safety data, availability of resources and expertise etc.) through national institutions, international, regional and sub regional organizations and public sector groups

- *Terrestrial Animal Health Code mammals, birds and bees*
- *Aquatic Animal Health Code fish, molluscs and crustaceans*
- *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*
- *Manual of Diagnostic Tests for Aquatic Animals*
- *The Basel Convention on the Control of Transboundary Movement of Hazardous Wastes and their Disposal (1989).*
- *Codex Alimentarius Commission/Joint expert committee on food additives*
- *International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products*
- *Legislation for veterinary drugs control, FAO, 2004.*
- *WCO Harmonized Commodity Description and Coding System.*
- *WHO good manufacturing practices: main principles for pharmaceutical products, WHO Technical Report Series, No. 908, 2003*

5.8 Regional Harmonisation

Regional cooperation is necessary for the development and implementation of common policies and legislation on veterinary drugs to facilitate the following in the SADC Region:

- The sharing of information.
- Harmonized registration requirements.
- Facilitation of trade.
- Optimum utilization and sharing of available expertise and facilities.
- Harmonized regional risk assessment, benefit/risk analysis and MRLs establishment for registration purposes in all the Member States.
- Concerted actions against substandard, unregistered and banned veterinary drugs and for specific uses

6 LEGISLATIVE FRAMEWORK AND KEY ISSUES FOR THE SADC REGION

National governments are responsible for the necessary policy and national legislation to control veterinary drugs including pesticides for animal uses) and the establishment of facilities and allocation of resources for this task. This includes regulations, directives and guidelines, with the necessary participation of all stakeholders (viz. industry, consumers, farmers, labour and environmentalists). According to the publication *Legislation for Veterinary Drugs Control* (FAO Legal Paper 38, 2004) a modern veterinary drugs legal framework must reflect a country's international obligations while effectively addressing the country's particular circumstances.
SADC Member States shall therefore revise and update their existing veterinary drugs legislation to bring it in line with international requirements:

- *Aquatic Animal Health Code fish, molluscs and crustaceans*
- *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*
- *Manual of Diagnostic Tests for Aquatic Animals*
- *The Basel Convention on the Control of Transboundary Movement of Hazardous Wastes and their Disposal (1989).*
- *Codex Alimentarius Commission/Joint expert committee on food additives*
- *International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products*
- *Legislation for veterinary drugs control, FAO, 2004.*
- *WCO Harmonized Commodity Description and Coding System*
- *WHO Good Manufacturing Practices: Main Principles for Pharmaceutical Products, WHO Technical Report Series, No. 908, 2003*

The legislation must also take into account arrangements applicable at the regional level e.g. registration harmonization. The legislation shall not only address the manufacturing, distribution and marketing but also the expiry period and actual use. The main law and its accompanying subsidiary instruments shall take into account the economic and social situation as well as

any specific technical requirements in the country, such livestock diseases and parasite problems, dietary patterns, livestock production system, the literacy level, climate and environmental concerns. With respect to the drugs themselves it is widely recognized that the goals of regulating the supply of veterinary drugs are to guarantee their quality, safety and efficacy at the time of administration to the animal. A number of key issues must therefore be considered for the regulation veterinary drugs in the SADC Region.

6.1 Objectives, Scope and Definitions of the Legislation

The national veterinary control law shall clearly indicate its objectives in the preamble or other introduction. The preamble serves as a policy statement capturing the purpose and objectives of the law. The scope describes what the law will cover or not cover viz. the products and substances to which the law applies and the targeted activities relating to veterinary drugs management. It must also include a section with updated definitions of all relevant terms
The main legal and institutional issues involved in the regulation of veterinary drugs arise with respect to the following:

- Scope of the law;
- Definition of the key concepts
- Drug administration
- Drug registration
- Classification of veterinary drugs
- Manufacture, import, distribution and sale;
- Enforcement.

The matters usually covered with regard to veterinary drugs are the introduction of drugs into the country (by manufacturers or by importation from outside the country), their circulation in the country, and their supply to the end-user. Each of these main activities can be divided into separate aspects,

6.2 Administration

- Member States must make resources and facilities available for the effective management and control of veterinary drugs in their countries.
- Each Member State shall establish a committee of experts from different Ministries, Departments and Institutions to deal with the registration applications.
- Each Member State shall designate a Registrar, Authorised Officers, Analysts, Technical Advisers and Inspectors to deal with veterinary drugs registration and to control the registration of veterinarians and licensing of dealers.

6.3 Registration procedures

The registration shall cover all categories of veterinary drugs viz, those that have not previously been registered or marketed and those that are already registered and provisionally approved. The authorization process is an exhaustive

investigation involving all aspects of the new product. It is based on trial results and data submitted by the applicant company.
The objectives of registration are to ensure:

- The veterinary drug is safe for the animal itself, the consumer of food derived from treated animals, those handling the drug, and the environment,
- The product is of consistently high quality, does not deteriorate and has the stability to last at least until the expiry date.
- The veterinary drug efficacy conforms to the claims made on its information leaflet and label.
- The veterinary drug itself and the excreta of treated animals do not have potential adverse impact on the environment

6.3.1 New veterinary drugs

All products that fall under the definition of veterinary drugs and are found or deemed acceptable are required to be registered before being marketed and distributed following the procedure and requirements stated in these guidelines.

- Harmonized veterinary drugs evaluation procedures.
- Dossier content requirements. These must be in line with the SADC registration application form and shall include the SADC Forms at Annex 10.1, 10.2, 10.3 and 10.4 according to the particular products

6.3.2 Generic veterinary drugs.

- These are products that are produced and sold without patent protection. Dossier content must be in line with the SADC registration application forms
- Dossier content document -SADC Forms Annex-10.1, 10.2, 10.3 and 10.4 according to the particular products

6.4 Confidentiality.

There must be clear rules and procedures to determine which information shall be considered to be confidential. This will include manufacturing process, formulation details and proprietary data such as efficacy, toxicological, safety and residues data. The rules and procedure must indicate how confidential records are to be maintained, stored and who shall have access to them. Penalties for breaches of confidentiality shall be set to act as a true deterrent.

6.5 Labelling

The label of the primary container for each pharmaceutical and vaccine products shall meet the WHO Good Manufacturing Practices: Main Principles for Pharmaceutical Products, (WHO Technical Report Series, No. 908, 2003). The label should include the SADC logo.
The W210 GMP standard and include:

- The International Non-Proprietary Name (INN) or generic name prominently displayed and above the brand name, where a brand name has been given. Brand names shall not be bolder or larger than the generic name;
- Dosage form, e.g. tablet, ampoule, etc.;
- The active ingredient "per unit, dose, tablet or capsule, etc.
- The applicable pharmacopoeia standard;
- The manufacturer's logo and code number and any specific colour coding if required;
- Content per pack;
- Instructions for use;
- Special storage requirements;
- Batch number;
- Date of manufacture and date of expiry (in clear language, not code);
- Name and address of manufacture; and
- Any additional cautionary statement.
- Registration number
- Registration authority

The outer case or carton shall also display the above information.
All cases shall prominently indicate the following:

- Manufacturer's line and code numbers;
- The generic name of the product;
- The dosage form (tablet, ampoule, syrup);
- Date of manufacture and expiry (in clear language not code);
- Batch number;
- Quantity per case;
- Special instructions for storage;
- Name and address of manufacture; and
- Any additional cautionary statements.
- Registration number
- Registration authority

6.6 Review of Dossiers

The legislation must indicate which application form shall be used and what information the applicant must include. This will include the proposed trade name of the product, the envisaged use, composition statement of the formulation

- General information
- Pharmaceutics study
- Pharmacological study
- Toxicological study
- Clinical study
- Residue study
- Ecological/environmental toxicity study

These studies include, physicochemical property, protocol of production, stability data, toxicity, pharmacological action, absorption distribution, metabolism and excretion, results of clinical trials, safety for target animals, residue reports.
In addition to the requirements laid down in the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (www.vichsec.org/en/guidelines.htm)
VICH Guidelines which include the validation of analytical procedures, stability testing, environmental impact assessment, studies to evaluate the safety of residues of veterinary drug in human food; reproduction studies, genotoxicity testing, carcinogenicity testing, marker residue depletion studies to establish product withdrawal periods, general approach to establish a microbiological Acceptable Daily Intake (ADI) pharmaco-vigilance of veterinary medicinal products: management of Adverse Event Reports (AERs); the procedures highlighted in the WHO Good Manufacturing Practices: Main Principles for Pharmaceutical Products, WHO Technical Report Series, No. 908, 2003 and the Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies Interagency Guidelines, (WHO,1999) and Recommended International Code of Practice for Control of the Use of Veterinary Drugs (FAO, CAC/RCP 38-1993) shall also be followed. The dossier requirements of all SADC Member States shall be harmonized in line with the requirements of the SADC registration application forms presented in Annex 10.

The registration decisions are to be made on a risk assessment including all available information and in accordance with FAO, WHO, OIE and VICH specifications for veterinary drugs. The following factors shall be taken into account:

Type of Data	Outline of Data for Major Studies
1. Data concerning the origin and background of the new product	Origin and background of new product Condition of use in foreign country Properties and comparative studies with other drugs
2. Data concerning physicochemical properties	Structural determination, Physicochemical constants, Biological properties and basic experimental data to support, Data to establish standards, and Test methods and actually measured values
3. Data concerning stability	Long-term storage tests of sample or stability tests under stress condition
4. Data concerning toxicity	Acute toxicity study Sub acute and chronic toxicity study Special toxicity studies such as inhalant toxicity
5. Data concerning target animal safety	Studies on safety using target animals
6. Data concerning pharmacological action	Studies on efficacy Studies on general pharmacological action
7. Data concerning absorption	Studies on absorption, distribution, metabolism and excretion of drug
8. Data concerning results of clinical trials	Studies on efficacy and safety of target animals in the field
9. Data concerning residue	Studies on residue of target animals

After reviewing the application, registration will be granted (full, provisional or conditional) or rejected. This may include banning a veterinary drug, severely restricting it or phasing it out. If the registration is refused then the applicant must receive a written explanation of such a refusal. The legislation must make provision for an appeal process. The legislation must also make provision to review the status of a product at any time or when new information becomes available.

6.7 Production of Veterinary Drugs

In order to ensure that only quality, safe and efficacious veterinary drugs will be available in the SADC region it will be necessary for all Member States to have a harmonised approach for the registration of veterinary drugs produced in and outside the Region. The following measures (Legislation for Veterinary Drugs Control, (FAO, 2004) shall therefore be adopted by Member States:

- Rules shall be established that are applicable to the manufacture of veterinary dugs in the region, including permissible locations, construction and operational requirements, occupational health conditions in accordance with the requirements of the International Labour Organisation (ILO, Safework Bookshelf Compendium, 4th ed., 2006)
- Safety guidelines, anti-pollution devices, quality control and provision for poisoning cases.
- A licensing scheme for veterinary drugs manufacturers shall be established, including criteria for the grant or denial of the licence, conditions of the grant and provisions for suspension or revocation.
- The facilities must adhere to good manufacturing requirements with the effective pharmaceutical quality assurance system, management of personnel, record keeping and prevention of pollution of the environment by hazardous waste.
- Good Manufacturing Practices; includes, suitable facilities, a validated manufacturing process, validated test procedure, raw material testing, in-process testing, stability testing, recall procedures, etc.
- If the necessary control measures to ensure compliance with good manufacturing practices are not feasible within the national context then the manufacture of veterinary drugs shall be banned.
- Countries shall also ensure that their lists of banned veterinary drugs for manufacture are in harmony with international obligations.
- Quality standards for manufactured veterinary drugs shall be set, based on international specifications (VICH Guidelines, Test Procedures for new Veterinary Drugs Substances and New Medicinal Products, 2005) WHO Technical Report Series, No. 908, 2003)
- Provision must also be made to inspect overseas manufacturers to ensure that they adhere to the principles of good manufacturing practice.

6.8 Procurement

In case of procurement of veterinary drugs by Member States Government or NGOs, strict rules shall be followed and only registered drugs can be procured. In this respect the requirements highlighted in the Practical Guidelines on Pharmaceutical Procurement for Countries with Small Procurement Agencies (WHO, 2002) shall be followed.

6.9 Import, Export and Transit Permits

It is important that all SADC Member States adopt the same import, export and transit requirements and procedures. This will ensure that only quality standards, safe and efficient veterinary drugs are available in the Region and prevent the importation of banned or obsolete products. Only officially licensed/authorized veterinary drugs shall be marketed, and that only through approved distribution systems and licensed establishments.
The following measures (Legislation for Veterinary Drugs Control, FAO, 2004) must therefore be implemented:

- The importation and exportation of defective or substandard products must be prohibited.
- Exported veterinary drugs shall meet the quality standards of the importing country and be equivalent to the required standards. A licensing scheme for importers and exporters shall be considered.
- Develop procedures and criteria for decisions on import, export and transit permits.
- Inspections must be carried out at the point of entry in the SADC Region/Member State.
- Ensure collaboration between the competent national authority/ veterinary authorities and custom department at points of entry/Member States/SADC Region.
- During movement of veterinary drugs from one Member States to another, the consignment must be accompanied by common transit documentation and a Safety Data Sheet in the official language (s) of the transit country.
- Adherence to the requirements of the Rotterdam Convention (PIC procedure), Stockholm Convention (POPs) and Basel Convention (hazardous waste) shall be ensured.
- A harmonised import/export and transit recommended by OIE shall be used by SADC Member States

6.10 Storage, Distribution and Transportation

Veterinary drugs are hazardous products. It is therefore imperative that all workers in the supply chain receive training on the correct and safe storage, handling and transport and administration requirements. Member States shall therefore implement the following:

- Distributors, retailers and transporters of veterinary drugs shall be licensed and requirements set for such licensing.

- The requirements would be training and sufficient knowledge in the management, storage and transport of veterinary drugs according to Good Manufacturing Practices: Main Principles for Pharmaceutical Products, WHO Technical Report Series, No. 908, 2003, Good Distribution Practices for Pharmaceutical Products, (WHO, 2002) and Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies Interagency Guidelines, (WHO, 1999) .
- Setting of storage and transport requirements for veterinary drugs based on the WHO Good Distribution Practices for Pharmaceutical Products, 2005.
- This would include choice of site, design and structure of buildings, stacking positions and heights, shelf life, refrigeration and ventilation, stock planning and recording systems, local transport of products, spills, leaks and disposal of containers and chemicals, decontamination, emergencies (fire, flooding, destruction) and personal safety and protective clothing (including the availability of Safety Data Sheets) in line with international guidelines (WHO, Quality Assurance of Pharmaceuticals, 2nd Ed., 2007).
- Expired stock shall be removed and dealt with as bulk quantities of expired veterinary drugs in keeping with the Guidelines on Disposal of Bulk Quantities of Obsolete Pesticides in Developing Countries (FAO, 1996).
- Good Manufacturing Practices (A Compendium of Guidelines and Related Materials Volume 2: Good Manufacturing Practices and Inspection QAS/04.068/Rev. 2, Good Distribution Practices for Pharmaceutical Products (WHO, 2006).

6.11 Use, Good Veterinary Practices

Member States shall ensure that:

- Veterinary drugs (including medicated feeds) be only handled by authorised persons excluding children, elderly persons, pregnant and breastfeeding women, in compliance with international occupational requirements.
- Drug administration is as per the labelling of the information leaflet. All Veterinary drugs shall be used strictly in accordance with their label recommendations and Good Veterinary Practice and as prescribed by the veterinarian.
- The health and safety of personnel working with veterinary medicine shall be protected and appropriate protective equipment shall be available.
- All application equipment must be correctly calibrated (on a regular basis) to ensure that the correct dosage is delivered.
- After use all equipment shall be thoroughly sanitised and well stored.
- Personnel working with veterinary drugs shall make sure that high standards of personal hygiene are observed.

- Keep records of all veterinary drugs used, animal treated, equipment repairs and maintenance and operator health surveillance.

6.12 Disposal

Member States must ensure that procedures, in cooperation with the pharmaceutical industry, farmers and other stakeholders are in place for the safe disposal of empty veterinary drugs containers, banned and expired products. All disposal actions shall take place in accordance with the Basel Convention and the following FAO guidelines:

- Guidelines for the Management of Small Quantities of Unwanted and Obsolete Pesticides (1999).
- Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies Interagency Guidelines, (WHO, 1999)
- Recommended International Code of Practice for Control of the Use of Veterinary Drugs (FAO, CAC/RCP 38-1993).

6.13 Inspection, Monitoring and Enforcement

Member States shall ensure the following:

-
- Inspection of veterinary drugs for compliance (registration, labelling, illegal decanting into smaller containers, storage, utilisation, disposal) and to take the necessary legal action in cases of non-compliance.
- Reporting of veterinary drug related incidents to the competent authorities.
- The collection of information on environmental contamination associated with veterinary drug .
- The collection of information on the use of antimicrobial drugs in animal production.
- Monitor and report on the management of hazardous veterinary products.

6.14 Testing

Member States must undertake regular sampling and testing of veterinary drugs and inspection of manufacturing premises to ensure compliance with good manufacturing practices, quality assurance systems, and quality of the products. The following shall be observed:

- Undertake the routine testing of veterinary drugs sampled on the market to ensure compliance to approved specifications and quality during the registration process.
- Undertake monitoring of the veterinary drug residues by use of designated/accredited laboratories to verify the compliance to the official Maximum Residue Limits (MRLs) in line with MRLs set by Codex.

- Products not in compliance with MRLs shall not be allowed in the consumer market and shall be destroyed
- Member States shall identify the laboratories presently available, their status with regard to accreditation according to ISO 17025, foster the establishment of more accredited laboratories in the region and participation in international proficiency testing schemes.
- Conduct inspections in manufacturing facilities to ensure that manufacturers adhere to the principles of Good Manufacturing Practice (GMP).
-

6.15 Collaboration in the SADC Region

To utilize the existing expertise and resources optimally in the region it is necessary for Member States to collaborate in the following areas:

- Harmonised procedures and standards for the registration of veterinary drugs in the region.
- A common registration application form would contribute towards the establishing of common and clear registration procedure in the region. Member States shall therefore consider the acceptance of a common registration application form as the first step towards harmonizing registration requirements and co-operation in the region.
- Harmonized guidelines on assessing the quality, safety and efficacy of veterinary drugs
- Harmonized guidelines for carrying out residue trials required for registration.
- Member States must accept the principle of mutual recognition and equivalence of registrations.

6.16 Information exchange

Member States must make information on veterinary drugs available to the SADC Secretariat regarding:

- Banned products, illegal and counterfeit veterinary drugs, and those severely restricted.
- Undesirable environmental consequences resulting from the use of veterinary drugs.
- Application safety and poisoning incidences.
- Annual quantities of veterinary drugs used.
- Research on effect of veterinary drugs on animals and the environment.
- Database of registered and approved veterinary drugs
- Results from routine residue monitoring of animal products and feeds.

6.17 Obsolete Products, Banning and Restrictions

All Member States shall institute the following:

- Adherence to international obligations, conventions and protocols outlined in The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (1989), The Rotterdam Convention on the Prior Informed Consent Procedure for certain Hazardous Chemicals and Pesticides in International Trade (1998), Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies Interagency Guidelines, (WHO, 1999), Good Manufacturing Practices (A Compendium of Guidelines and Related Materials Volume 2: Good Manufacturing Practices and Inspection QAS/04.068/Rev. 2 Good Distribution Practices for Pharmaceutical Products) , WHO, 2006.
- Confiscation of banned, illegal, counterfeit and expired veterinary drugs and disposal of these products according to the Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies Interagency Guidelines, (WHO, 1999) and the Recommended International Code of Practice for Control of the Use of Veterinary Drugs (FAO, CAC/RCP 38-1993).

6.18 Environmental considerations

Member States shall minimize the negative effect of veterinary drugs on the environment by taking the following measures:

- Withdrawing the registrations of the more hazardous veterinary drugs, if suitable less hazardous alternatives are available.
- Implementing good animal husbandry/production practices so as to minimise the use of veterinary drugs and restrict them to necessary cases.
- Avoiding the purchase and storage of excess veterinary drugs stock during the procurement process.

The impact of veterinary drugs on the environment shall be conducted in line with the VICH, Guidelines on Environmental Impact Assessment for Veterinary Medicinal Products, (VICH, 2000).

1.19 Training of users of veterinary products

All stakeholders shall be trained in the management, control, safe handling, transportation, use and disposal of veterinary drugs to ensure the safety to the consumer of animal derived food, the protection of public health and the environment.
Training shall involve all the relevant professional organizations, regulatory authorities, the pharmaceutical industry, veterinary schools, research institutes, professional associations and other approved users such as farmers and producers of food animals and focus on:

- Information on disease prevention and management strategies to reduce the need to use veterinary drugs;

- Relevant pharmacokinetic and pharmacodynamic information to enable the veterinarian to use veterinary drugs prudently;
- The possibility of veterinary drugs used in food producing animals that may have adverse effects on animal or human health;
- The need to observe the veterinarian's advice or recommendations for using drugs.

6.19 Promotion and Advertising

The legislation must make provision to control advertising as stipulated in Recommended International Code of Practice for Control of the Use of Veterinary Drugs (FAO, CAC/RCP 38-1993).
The advertising of veterinary drugs in all media must not be in conflict with label directions and precautions, particularly those related to dosage and animal species and appropriate personal protective equipment, special precautions for children and pregnant women or the dangers of re-using containers. All statements used in advertising must be technically and scientifically justified and no misleading statements shall be made.

6.20 Occupational safety

Member States must ensure the following:

- Promote the establishment of poison centres in their countries.
- All veterinary drugs must include an emergency telephone number (poison centres) on the central panel of the label.
- Adherence to the ILO Convention on Safety and Health in Agriculture, No. 184 (2001), especially with regard to pregnant and lactating women, and children.
- Adherence to the International Labour Organisation requirements Convention Concerning Safety in the Use of Chemicals at Work, No. 170 (1990). (ILO, Safework Bookshelf Compendium, 4th ed., 2006)

6.21 Offences and Penalties

All Member States must have provisions in their legislation to take the necessary legal actions against persons failing to adhere to the legislation. The legislation must also prescribe appropriate penalties for offenders as stipulated in the Legislation for Control of Veterinary Drugs (FAO, 2004). The offences are outlined below:

- The manufacture of veterinary drugs without a manufacturer's licence.
- The import or export of veterinary drugs without import/export permit.
- The publication or advertisement of false or misleading information relating to the use, usefulness or effectiveness of a veterinary drug.
- The sale or release for sale of a veterinary drug contrary to the requirements.

- The unauthorised disclosure of confidential business information gained as a result of carrying out a function.
- The storage or transport of veterinary drugs in a manner contrary to their labels or containers.
- Selling or distributing a veterinary drug that does not meet the specifications as stated when the product was registered or drug that is adulterated.
- The administration to animal of an unregistered veterinary drug.
- The sale of veterinary drugs by an unauthorised person/entity.
- The sale of expired veterinary drugs.
- Performing any function for which a licence is required without obtaining that licence.
- Failing to comply with any condition of registration or licensing.
- Violating the packaging, re-packaging, labelling, advertising, storage or disposal requirements.
- Supplying a veterinary drug in a container that is unsuitable, deteriorated or been damaged.
- Selling or distributing a veterinary drug without an approved label attached to it.
- Detaching, altering or destroying any label on the container of a veterinary drug.
- Using veterinary drugs in a manner that is not consistent with the approved label.
- Making false or misleading statements or providing false or misleading information in an application for registration or licensing or in required reports or records.
- Participating in the illegal traffic of veterinary drugs (including transporting acaricides related waste across an international border).
- Making shipments contrary to the import decisions of a country under the Rotterdam Convention or under the Basel Convention.
- Failing to report incidents related to veterinary drugs that are subject to mandatory reporting, or otherwise failing to keep required records.
- Hindering or impeding an inspection or assaulting an inspector.

Penalties could include fines, suspension or revocation of registration or licence as well as forfeiture of products. It may also include the cost of clean-up, disposal or other measures necessary to mitigate the damage caused by the offence. A term of imprisonment is permissible for criminal offences but not for administrative ones.

6.22 Fees

In order to ensure funds for activities regarding the registration and inspections of veterinary drugs Members States shall require fees for the services provided.

7 A PROPOSED FRAMEWORK FOR REGISTRATION AND QUALITY CONTROL OF VETERINARY DRUGS AT NATIONAL AND SADC REGIONAL LEVEL

To make optimum use of existing resources and expertise in the SADC region a harmonized approach will be necessary to address the following issues:

- Inadequate or non-existing policies and legislation regarding the veterinary drugs.
- Poor control of the importation, sale and distribution of veterinary drugs leading to the use of illegal, banned, obsolete and counterfeit products.
- Inadequate registration requirements viz. no clear directives on information necessary such as toxicological and clinical studies, manufacturing process, quality control, bioequivalence, efficacy data , safety residue data and labelling requirements.
- The lack of suitably trained, qualified and experienced personnel to evaluate registration applications, review the human and environmental toxicology and institute the necessary control measures.
- Inadequate surveillance and application of existing control measures.
- Poor enforcement of legislation leading to improper use of veterinary drugs with adverse effects to human health and the environment and resulting in microbial resistance. Ultimately this will also lead to the loss of export markets.
- Lack of facilities for the testing the quality of veterinary drugs and routine Maximum Residue Limits monitoring.
- Inadequate inspection and administration infrastructure to enforce regulatory control.
- Lack of training and experience in regulatory administration and control.

The above-mentioned problems can be addressed if SADC Members could agree on a number of principles. These are the following:

- **Harmonisation**. The SADC region must contribute to the reconciliation of the policies, legislation and actions of Member States with regard to veterinary drugs
- **Harmonised Registration Procedures for veterinary drugs**. In the interest of a regional market, the implementation of a regional agricultural policy and the free circulation of veterinary drugs it is vital that such products are suitable and effective for their intended use and conform to the required quality standards.
- **Reciprocal recognition and equivalence.** Member States shall implement the principle of mutual recognition of registrations based on the requirements of the registration procedures and guidelines including the principle of equivalence where applicable.

- **Recognition of international standards:** in order to ensure free movement of livestock and livestock products in the SADC region and to promote their interregional trade, SADC Member States shall base their technical regulations on standards, directives and international recommendations issued by OIE and Codex,.
- **Participation and information:** Member States subscribe to transparency in the decision-making processes regarding public decisions relating to veterinary drugs and to involve all stakeholders in such processes. The public shall also have access to information regarding registered veterinary drugs (with the exception of intellectual property). Member States shall also contribute towards the training and awareness of stakeholders from the Livestock and agriculture sectors.

To make optimum use of the available expertise and capacities in the SADC Region it is proposed that Member States develop harmonized national regional registration systems for veterinary drugs. This would include harmonized veterinary drugs policies, legislation, directives and guidelines. National governments would be responsible for harmonizing national legislation with the requirements of the SADC Region and the control of veterinary drugs at the national level.

To assist Member States with harmonization in the SADC Region it is proposed that the Livestock Technical Committee be tasked to facilitate the process, together with the existing structures within SADC that deals with SPS related matters as stated in the SPS Annex to Protocol of Trade. These structures shall be utilized to assist the Member States with the following:

- Development of common veterinary drug policies.
- Development and implementation of common legislation regulating veterinary drugs.
- Harmonized directives and guidelines on registration requirements in the SADC region. These shall be in line with WHO, VICH, OIE and Codex and other international requirements. This will include toxicology and ecotoxicology, bioequivalence, chemical, biological and physical specifications, safety, efficacy trials and residue trials according to Good Veterinary Practices. Pivotal studies shall be conducted for efficacy and Maximum Residue Limits throughout the SADC region and shall be divided into sub-regions with similar climatic/agro pastoral conditions and agricultural practices.
- Identify the need for and to promote the establishment of accredited laboratories in the region to undertake testing of veterinary drugs (quality assurance) and Maximum Residue Limits analysis and routine monitoring of agricultural commodities.
- Training programs for distributors, cooperative, farmers and extension officers.
- The establishment of a database on registered veterinary drugs in the region and the occurrence of Veterinary drugs related incidence

- Representation at the international level (e.g. committees of the Codex Alimentarius Commission, OIE, VICH) involving the participation of all stakeholders.

8 CONCLUSION

The proposed harmonization for the SADC regional veterinary drugs registration is in line with the *international requirements.* It will involve the development and implementation of common policies, a common legislative framework and harmonized registration requirements and procedures. The acceptance of a harmonised SADC registration application forms indicating the registration requirements and documentation needed to register veterinary drugs in the SADC Region would be an important starting point for regional harmonization.

A key aspect would be the acceptance by Member States of the principle of mutual recognition and equivalence. The existing structures within SADC that deals with SPS related matters as stated in the SPS Annex to Protocol of Trade shall be used to promote cooperation and harmonization between Member States regarding the regulation of veterinary drugs and facilitate the circulation of safe products.

9 ANNEXES

9.1 REGISTRATION FORM

APPLICATION FOR REGISTRATION OF VETERINARY DRUG	
To be filled by the Applicant	
A.	**COMPANY APPLICANT**
	Company Name:
	Complete Address:
	Contact Numbers:
	Type of establishment
	[ ] Manufacturer [ ] Trader [ ] Importer/Distributor/Wholesaler
	[ ] Importer in bulk &repacked locally
	[ ] Importer finished and packed locally
	[ ] Imported finished product
	LTO Number:
	Valid until:
	DATA ON [ ] MANUFACTURER [ ] REPACKER
	Complete Name:
	Complete Address:
B.	**TYPE OF APPLICATION**
	[ ] INITIAL REGISTRATION
	[ ] Established Drug
	[ ] New Drug (Monitored Release
	[ ] Fixed Dose Combination
	[ ] RENEWAL REGISTRATION
	[ ] MONITORED RELEASE EXTENSION
	Approved Extension [ ] 1yr [ ] 2yr [ ] 3yr Registration Number
	Valid Until:
C.	**COMPLETE INFORMATION REGARDING THE PRODUCT**
	1. Generic Name(s):
	2. Brand Name, if any:
	3. Dosage Strength:
	4. Dosage Form:
	5. Route of Administration
	6. Pharmacologic Category
	7. Classification [ ] Rx (Prescription Drug) [ ] OTC (Over - the Counter [ ] Restricted/ Regulated

	Essential Drug List (EDL) [ ] Yes [ ] No
	8. Claimed Shelf Life
	9. Storage Condition
	10. Primary packaging (Market/Commercial Presentation):
	11. Suggested Retail Price / Unit
	12. Reference Monograph:[1]
	[ ] Official [ ] Non Official

9.2 REQUIREMENTS FOR VETERINARY PHARMACEUTICALS

Section	Requirements	Generic	New
Module 1	Regional Administrative Information		
1.	Cover letter		
1.1	Comprehensive table of content		
1.2	Application form		
1.3	Product Information		
1.3.1	Summary of Product Characteristics (SPC)		
1.3.2	Labelling		
1.3.3	Package leaflet		
1.3.3.1	English/French/Portuguese		
1.3.4	Artwork (Mock-ups)		
1.3.5	Samples		
1.4	Information on the expert		
1.4.1	Quality		
1.4.2	Safety and Residues		
1.4.3	Efficacy		
1.5	Pharmacovigilance		
1.5.1	Pharmacovigilance system		
1.5.2	Risk Management Plan		
1.6	Certificates		
1.6.1	Certificate for Pharmaceutical Products or Free-sales		
1.6.2	Certificate of analysis - Drug Substance		
1.6.3	Certificate of analysis- Excipients		
1.6.4	Certificate of analysis- Finished goods		
1.6.5	The diluents and colouring agents in the product Formula		
1.6.6	Patent information		
1.7	Pricing		
1.7.1	Price list		
1.7.2	Other related documents		
1.8	Response to questions		
Module 2	**Common Technical Document Summaries**		
2.1	Quality overall Summary		
2.1.1	Composition of the product		
2.1.2	Description of the Manufacturing Method		
2.1.3	Control of starting Materials		
2.1.3.1	Active substance(s)		
2.1.3.2	Excipients		
2.1.3.3	Container/Closure System		
2.1.3.4	Substances of Biological Origin		
2.1.4	Control tests on Intermediate Products (if necessary)		
2.1.5	Control Tests on Finished goods		
2.1.6	Stability		
2.2	Safety and Residues Tests Overall Summary		
2.2.1	Safety documentation		
2.2.2	Residue documentation		
2.3	Efficacy Overall Summary		

Section	Requirements	Generic	New
2.2.3.1	Pre-clinical Documentation		
2.3.1.1	Phamacodynamics		
2.3.1.2	Phamacokinetics		
2.3.1.3	Target species tolerance		
2.3.1.4	Resistance		
2.	Clinical documentation		
Module 3	**Quality**		
3.1	Composition		
3.1.1	Composition of the veterinary medicinal products		
3.1.2	Container/Closure System		
3.1.3	Pharmaceutical Development		
3.2	Description of the Manufacturing method		
3.2.1	Manufacturing formula		
3.2.2	Manufacturing process		
3.2.3	Process validation		
3.3	Control of Starting Materials		
3.3.1	Active substance(s)		
3.3.1.1	Specification		
3.3.1.2	Justification of Specification		
3.3.1.3	Scientific Data		
3.3.1.3.1	Nomenclature		
3.3.1.3.2	Description		
3.3.1.3.3	Manufacture		
3.3.1.3.4	Quality control during manufacture		
3.3.1.3.5	Development chemistry		
3.3.1.3.6	Impurities		
3.3.1.3.7	Batch analysis		
3.4.2	Excipient(s)		
3.4.2.1	Specifications		
3.4.2.2	Justification of Specification		
3.4.2.3	Scientific data		
3.4.3	Container/ Closure System		
3.4.4	Substances of Biological Origin		
3,5	Control Tests on Intermediate Products		
3.6	Control Tests on the finished Products		
3.6.1	Product specification		
3.6.2	Justification of Specifications		
3.6.3	Control Methods		
3.6.3.1	Test procedures for identification and quantitative determination for the active substance(s)		
3.6.3.2	Identification and determination of excipient(s)		
3.6.4	Scientific data		
3.6.4.1	Validation of Analytical Procedures		
3.6.4.2	Batch analysis		
3,7	Stability		
3.7.1	Stability Tests on active substance(s)		
3.7.2	Stability Tests on the finished Product		
3.8	Other Related Documents		
3.9	Literature References		
Module 4	**Safety and Residues Tests**		

Section	Requirements	Generic	New
4.1	Safety documentation		
4.1.1	Precise identification of the product concerned by the application		
4.1.2	Pharmacological studies		
4.1.2.1	Pharmacodynamics		
4.1.2.2	Pharmacokinetics		
4.1.3	Toxicological studies		
4.1.4	Studies of other effects		
4.1.5	User safety		
4.1.6	Environmental risk assessment		
4.2	Residue documentation		
4.2.1	Precise identification of the product concerned by the application		
4.2.2	Residue Studies		
4.3.2.1	Pharmacokinetics		
4.3.2.2	Depletion of residues		
4.3.2.3	Maximum Residue Limits (MRL)		
4.3.2.4	Withdrawal periods		
4.3.3	Analytic methods		
4.3.3.1	Description of the method		
4.3.3.2	Validation of the method		
4,4	Other Related Documents		
4.5	Literature References		
Module 5	**Efficacy**		
5.1	Pre- clinical Documentation		
5.1.1	Pharmacodynamics		
5.1.2	Pharmacokinetics		
5.1.3	Target species tolerance		
5.1.4	Resistance		
5.2	Clinical documentation		
5.3	Other Related Documents		
5.4	Literature References		

9.3 REQUIREMENTS FOR VETERINARY IMMUNOLOGICALS

Section	Requirements	
Module 1	Regional Administrative Information	
1.	Cover letter	
1.1	Comprehensive table of content	
1.2	Application form	
1.3	Product Information	
1.3.1	Summary of Product Characteristics (SPC)	
1.3.2	Labelling	
1.3.3	Package leaflet	
1.3.3.1	English/French/Portuguese	
1.3.4	Artwork (Mock-ups)	
1.3.5	Samples	
1.4	Information on the export	
1.4.1	Quality	
1.4.2	Non Clinical	
1.4.3	Clinical	
1.5	Pharmacovigilance	
1.5.1	Pharmacovigilance system	
1.5.2	Risk Management Plan	
1.6	Certificates	
1.6.1	CPP or Free-sales	
1.6.2	Certificate of analysis - Drug Substance	
1.6.3	Certificate of analysis- Excipients	
1.6.4	Certificate of analysis- Finished goods	
1.6.5	Pork-free declaration	
1.6.6	The diluents and colouring agents in the product formula	
1.6.7	Patent information	
1.7	Pricing	
1.7.1	Price list	
1.7.2	Other related documents	
1.8	Response to questions	
Module 2	**Common Technical Document Summaries**	
2.1	Quality overall Summary	
2.1.1	Composition of the product	
2.1.2	Production and control of starting Materials	
2.1.3	Control Tests During Production	
2.1.4	Control tests on Finished Products (if necessary)	
2.1.5	Batch to Batch consistency	
2.1.6	Stability Tests	
2.1.7	Substances of Biological Origin	
2.2	Safety Overall Summary	
2.3.1	Laboratory Tests	
2.3.2	Field Studies	
Module 3	**Quality**	
3.1	Composition	
3.1.1	Composition of the immunological product	
3.1.2	Container/Closure System	

Section	Requirements	
3.1.3	Pharmaceutical Development	
3.2	Description of the Manufacturing method	
3.2.1	Manufacturing formula	
3.2.2	Manufacturing process	
3.2.3	Process validation	
3.3	Production and Control of Starting Materials	
3.4	Control Tests during Production	
3.5	Control Tests on the finished Products	
3.6.1	General Characteristics	
3.6.2	Identification of active substance(s)	
3.6.3	Batch titre or potency	
3.6.4 3.6.5	Identification and assay of adjuvants Identification and assay of excipient components	
3.6.6	Safety test	
3.6.7	Sterility and purity tests	
3.6.8	Residual humility	
3.6.9	Inactivation	
3,7	Batch to Batch Consistency	
3.8	Stability Tests	
3.9	Substances of Biological Origin	
3.10	Other Related Documents	
3.11	Literature References	
Module 4	**Safety**	
4.1	Laboratory Tests	
4.1.1 4.1.2	Safety of the administration of one dose Safety of one administration of an overdose	
4.1.3	Safety of the repeated administration of one dose	
4.1.4	Examination of reproductive performance	
4.1.5	Examination of immunological functions	
4.1.6	Special Requirements for live vaccines	
4.1.7	User safety	
4.1.8	Study of residues	
4.1.9	Interactions	
4.2	Field Studies	
4.3	Environmental Risk Management	
4.4	Other Related Documents	
4.5	Literature References	
Module 5	**Efficacy**	
5.1	Laboratory Trials	
5.2	Field Trials	
5.3	Other Related Documents	
5.4	Literature References	

9.4 REQUIREMENTS FOR VETERINARY ACARICIDES

Section	Requirements	
Module 1	Regional Administrative Information	
1.	Cover letter	
1.1	Comprehensive table of content	
1.2	Application form	
1.3	Product Information	
1.3.1	Labelling	
1.3.2	Package leaflet	
1.3.3.1	English/French/Portuguese	
1.3.3	Artwork (Mock-ups)	
1.3.4	Samples	
1.4	Certificates	
1.4.1	CCP or Free-sales	
1.4.2	Certificate of analysis- Active Constituents	
1.4.3	Certificate of analysis- Inactive Constituents	
1.4.4	Certificate of analysis-Finished product	
1.4.5	Patent Information	
1.5	Pricing	
1.5.1	Price list	
1.5.2	Other related documents	
1.6	Response to questions	
Module 2	**Common Technical Document Summaries**	
2.1	Quality overall Summary	
2.1.1	Description and Quantitative composition of the Product	
2.1.2	Control of starting Materials	
2.1.2.1	Specifications	
2.1.2.2	Analytic procedures	
2.1.2.3	Validation of Analytic procedures	
2.1.2.4	Batch Analysis	
2.2.3	Finished Product	
2.2.3.1	Specifications	
2.2.3.2	Analytical Procedures	
2.2.3.3	Validation of Analytical Procedures	
2.2.3.4	Batch Analysis	
2.2.3.5	Manufacture of the finished Product	
2.2.3.6	Container Closure system of the Finished Product	
2.2.5	Control Tests on Finished goods	
2.2.6	Stability	
2,3	Safety and Residues Tests Overall Summary	
2.3.1	Safety Tests	
2.3.1.1	Toxicology	
2.3.1.2	User Risk Assessment	
2.3.1.3	Environmental Risk Assessment	
2.3.2	Residue Tests	
2.3.2.1	Identification of the Product	
2.3.2.2	Metabolism and residue kinetics	
2.3.2.3	Residue analytic method	

Section	Requirements	
2.3.2.4	Maximum Residue Limits (MRLs) and withholding periods	
2.4	Efficacy Overall Summary	
2.4.1	Efficacy Studies	
2.4.2	Reports of Post-Marketing Experience	
Module 3	**Quality**	
3.1	General information	
3.1.1	Name of the Product	
3.1.2	Description and quantitative composition of the Product	
3.2	Control of Starting Materials	
3.2.1	Specification	
3.2.2	Analytical Procedures	
3.2.3	Validation of Analytical Procedures	
3.2.4	Batch Analysis	
3.3	Finished Product	
3.3.1	Specification	
3.34.2	Analytical Procedures	
3.3.3	Validation of Analytical Procedures	
3.3.4	Batch Analysis	
3.3.5	Manufacture of the finished Product	
3.3.5.1	Manufature(s)	
3.3.5.2	Description of Manufacturing Process and in Process Controls	
3.3.5.3	Batch Formula	
3.3.5.4	Controls of critical Steps and Intermediates	
3.3.5.5	Process Validation and /or Evaluation	
3.4.6	Container Closure System of the Finished Product	
3.4.7	Stability of the Finished Product	
3.4.7.1	Stability Summary and Conclusions	
3.4.7.2	Stability Data	
3.5	Other Related Documents	
3.6	Literature References	
Module 4	**Safety and Residues Tests**	
4.1	Safety Tests	
4.1.1	Toxicology	
4.1.2	User Risk Assessment	
4.1.3	Environmental Risk Assessment)	
4.2	Residue Tests	
4.2.1	Identification of Product	
4.2.2	Metabolism and residue kinetics	
4.2.3	Residue Analytical method	
4.2.4	Maximum Residue Limits (MRLs), and withholding periods	
4.3	Other Related Documents	
4.4	Literature References	
Module 5	**Efficacy**	
5.1	Efficacy Studies	
5.2	Target Species tolerance	
5.3	Reports of Post- Marketing Experience	
5.4	Other Related Documents	
5.5	Literature References	