



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

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Introduction

- Developed and 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
- Covers
 - Scope of the guidelines
 - Objectives of the veterinary drugs regulation guidelines
 - Regional policy guidelines
 - Context for the design of national veterinary drugs legislation in the SADC region
 - Legislative framework and key issues for the SADC region
 - A proposed framework for registration and quality control of veterinary drugs at national and SADC regional level

Definition in the guidelines

“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.”

Objectives

- Overall objective
 - 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
- Specific objectives
 - Provision of appropriate health care to animals
 - Provision to the regional market of 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.

Regional policy guidelines

- Basis is the SPS Annex to the SADC Protocol on Trade which is based on the WTO Agreement on the Application of Sanitary and Phytosanitary Measures or the WTO SPS Agreement for short. The SPS Annex objectives are to:
 - facilitate the protection of human, animal or plant life or health in the territory of the Member States;
 - enhance Member States' implementation of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures;
 - enhance technical capacity to implement and monitor SPS measures including promoting greater use of international standards and other matters concerning SPS;
 - provide a regional forum for addressing sanitary and phytosanitary matters; and
 - provide a regional forum for resolving trade related sanitary or phytosanitary issues.

Context for the design of national veterinary drugs legislation in the SADC region

- Key aspects to be covered in the veterinary drugs legislation based on OIE Codes, FAO code of practice for control of Vet drugs and International cooperation on harmonization of technical requirements for registration of veterinary medicinal products (VICH)
 - Veterinary drugs management
 - Testing of veterinary drugs
 - Reducing health and environmental risks
 - Regulatory and technical requirements
 - Availability and use
 - Information exchange
 - Information exchange

Legislative framework and key issues for the SADC region

- SADC Member States shall therefore revise and update their existing veterinary drugs legislation to bring it in line with international requirements
- key issues to be considered for the regulation of veterinary drugs in the SADC Region include
 - Objectives, Scope and Definitions of the Legislation
 - Administration
 - Registration procedures
 - New and Generic veterinary drugs
 - Confidentiality
 - Labelling
 - Review of Dossiers
 - Production of Veterinary Drugs
 - Procurement, fees etc. etc.

A proposed framework for registration and quality control of veterinary drugs

Considering constraints at MS which includes;

- policy and legislation issues,
- capacity issues relating to registration, surveillance testing and inspection facilities as well as HR, and
- Importation controls

Members could agree on a number of principles

- Harmonisation of policies, legislation and actions of Member States with regard to veterinary drugs
- Harmonised Registration Procedures for veterinary drugs
- Reciprocal recognition and equivalence
- Recognition of international standards
- Participation and information

What next

- This meeting
- Swaziland meeting in August 2015
 - Member States to take inventory of gaps in the Regional Guidelines on Regulation of Veterinary Drugs and national livestock policies through national consultative meetings with support from SADC Secretariat, OIE and AU-IBAR;
 - SADC Secretariat in collaboration with AU-IBAR to identify reference laboratories in the region to be used for testing medicines and biologicals;
 - SADC Secretariat in collaboration with AU-IBAR, WHO, OIE sub-regional office and other relevant organisations to facilitate training in quality control of veterinary medicines and biologicals being regulated;
 - SADC Secretariat in collaboration with AU-IBAR to facilitate accreditation of veterinary medicines and biologicals registration bodies;
 - SADC Secretariat in collaboration with AU-IBAR and OIE sub-regional to facilitate twining process with OIE reference laboratories and other accredited laboratories;
 - Facilitate development of a regional Agreement on registration processes of veterinary medicines and biological through endorsement by the relevant SADC structures;
 - Member States were urged to ensure that the veterinarians participate at all levels in the registration, control and management of veterinary medicines and biologicals.
- SADC M&E framework

THANK YOU
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