FOOD SAFETY – CAPACITY BUILDING ON RESIDUE CONTROL

Experience with Developing Veterinary Drugs Guidelines in the SADC Region

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Content

- Introduction
- Purpose
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- Agreed template
- Expected outcome

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Introduction

- By consuming animal and animal products humans are susceptible to consume what the animal has eaten or exposed to especially residues build-up in livestock and livestock products
- Drug of unknown quality or counterfeit can be introduced in the SADC Region
- Drugs withdrawn from other countries and be dumped in SADC Member States
- Veterinary drugs with misleading labelling can enter the SADC Region
- SADC Member States variable system to address veterinary drugs registration

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Purpose

- Harmonise food safety control regulations, guidelines and procedures through institutional strengthening in the SADC Region
- Promote exports through compliance with international requirements in order to increase exports while complying with food safety
- Provide a framework upon which each Member State can base its legally supported procedures for the Registration of Veterinary Drugs
- It is imperative that national governments meet obligations for the purposes of food security and safety, human and environmental health

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Process

- The guidelines were expected to take into account provisions and general framework developed by international organisations such as the OIE and FAO and other regions of the world
- The process to develop Veterinary Drugs Registration Guidelines started in August 2009
- The first draft of the guidelines was reviewed by SADC Member States during a Technical Workshop held in October 2009 and rejected
- A second consultant was hired in August 2010 to develop a new draft Veterinary Drugs Registration Guidelines

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Process

- The second draft was reviewed during a Technical Workshop held in September 2010
- The second draft outlined the scientific principles, biochemical characteristics, scientific tests, labelling, and MRLs that need to be assessed and complied with prior to registration
- SADC Member States provisionally accepted content but requested reformatting in technical language
- Member States also expressed concern that the scope was limited to one aspect of the registration process
- Most of the SADC Member States also raised concern of the lack of capacity to implement procedures outlined in the draft
- Recommended the designation of a reference institution to undertake some of the processes on behalf of the Region

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Core of the regulation

- Research, Development, Manufacturing, Importing, Marketing, Retailing and Use
  - Research and Development
    - Good Clinical Practices certification
    - Good Laboratory Practices certification
  - Manufacturing
    - Good Manufacturing Practices certification as the prerequisite for manufacturing license
    - Licensing
    - Label and leaflets
  - Distribution
    - Licensing
  - Training (etc…)

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Agreed format for Veterinary Guidelines

- Executive Summary
- Scope of veterinary medicine and products guidelines
- Terms and Definitions
- Regional Policy Guidelines
- Context for the deign of National Veterinary Medicines and products
- Legislative framework and key issues for the SADC
- Objectives, scope and definitions of the Legislation of Veterinary Medicines and Products
- Administration
- Registration procedures
- Labelling

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Agreed format for Veterinary Guidelines

- Review of the dossier
- Production of veterinary products
- Import, export and transit
- Storage, distribution and transportation
- Use, best practices e.g. GCP, GLP and application equipment
- Disposal, obsolete products, banning and restrictions
- Inspection, monitoring and enforcement
- Testing and certification
- Collaboration in the SADC region – two or three laboratories that have the capacity should be assigned to do the registration of veterinary drugs/products on behalf of SADC

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Agreed format for Veterinary Guidelines

- Information exchange
- Environmental considerations
- Training
- Emergency use
- Promotion and advertising
- Occupational safety
- Offences and penalties
- Fees
- Supply chain of Veterinary drugs/products in SADC member states (Sales and marketing)

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Agreed format for Veterinary Guidelines

- A proposed framework for harmonised registration and quality control of veterinary medicines and products at SADC Regional level
- The terms of reference for a SADC Committee for the registration of Veterinary Drugs and products
- Conclusion
- References
- Appendix 1: SADC Application Form

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Expected output

- Serve to to regulate matters pertaining to drugs (pharmaceuticals, biologicals)
- Facilitate the circulation of safe drugs in the region
- Facilitate the safe use of Veterinary drugs in the SADC region
- No need to re-register drugs that have already been registered in a Member States
- Compliance with MRLs

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Thanks for your attention