# SADC REGIONAL GUIDELINES FOR VETERINARY DRUGS

VMP FP TRAINING CASABLANCA, DECEMBER 2011

# RATIONAL

- Harmonisation of VMP registration will contribute to implement the

  SPS Annex to the SADC Trade Protocol
- Will contribute to create a functioning regional market with free movement of animals and animal products
- Legislation and regulations dealing with registration of VMPs are not in accordance with international requirements in all SADC MS

# STRUCTURE

- Overseeing body:

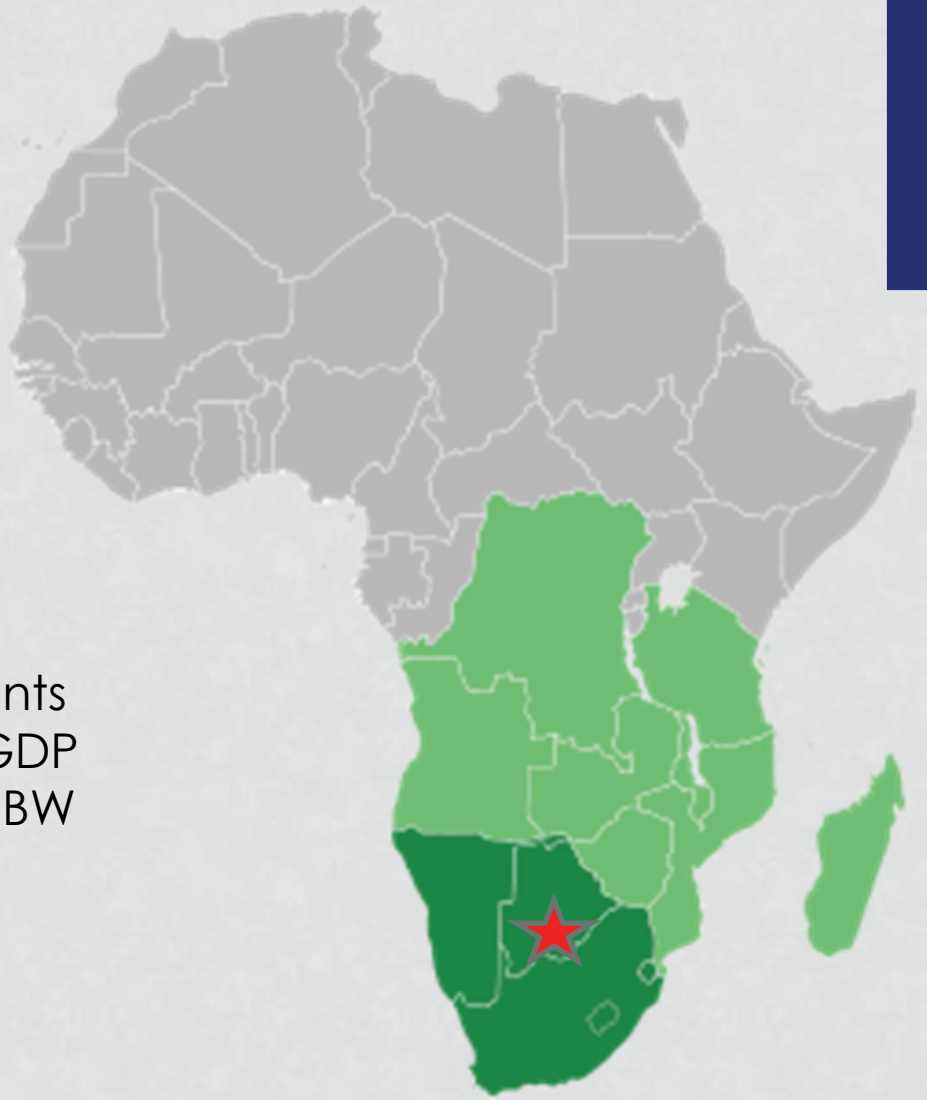
  Regional SPS Committee (SADC based)

- Coordination at national level:

  national Coordination Committees

  - Shall work together
  - Shall cooperate with private sector, academia and research institutions

# The 15 Member States of the SADC region



257.7 Mill inhabitants
471.1 US $ Billion GDP
HQ in Gaborone, BW

# REFERENCES FOR GUIDELINES

- Recommended International Code of Practices for Control of the Use of Veterinary Drugs (FAO, CAC/RCP 38,1993)
- Legislation of Veterinary Drugs Control (FAO. 2004)
- VICH Guidelines
- OIE Guidelines

# LEGISLATION SHOULD COVER

- VMP management
  - Regulation of the availability, distribution and use
  - Licensing of distributors, retailers and transporters
- Testing of VMPs
  - At national OR regional level, labs should be ISO 17025 accredited
- Health and environment
  - VMP registration scheme
  - Drug residue monitoring scheme
  - Manufacturing plants control
  - Waste and effluent control
  - Production quality assurance scheme

- Regulatory & technical requirements
  - Inspection of the registration scheme
  - Equivalence principle (VICH GL) of VMP
  - Harmonise registration requirements by groups of countries or the entire SADC region
  - Control illegal trade
- Availability and use of VMPs
  - Packaging and labeling
  - Classification regarding use
  - Prohibition of importation of non-registered VMPs
- Distribution and trade
  - Prevention of repackaging
- Confidentiality
- Information exchange

- This legislation should have provision to take legal action in case of non-adherence to it and prescribe appropriate penalties
- This legislation should also include a fee structure

# APPLICATION OF THE GL

- SADC registration application form
- Procurement of drugs following the *Practical Guidelines on Pharmaceutical Procurement for Countries with Small Procurement Agencies (WHO, 2002)*
- Only officially licensed/authorised drugs shall be marketed
  - Inspection at the point of entry
- Principle of mutual recognition and equivalence

# Thank you for your attention