SADC HARMONISATION INITIATIVES

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OUTLINE

• INTRODUCTION
• BRIEF HISTORY
• OBJECTIVES
• GUIDELINES DEVELOPMENT FOR MEDICINES REGULATION
• PLAN OF ACTION
• TRAINING
• CHALLENGES
INTRODUCTION

• Regulatory challenges and imperatives
• National Medicines Regulatory Authorities
• Legislative framework
• Technical guidelines and requirements
• Human, physical and financial resources
• Processes and systems
SADC MEMBER COUNTRIES

- ANGOLA
- BOTSWANA
- DEMOCRATIC REPUBLIC OF CONGO
- LESOTHO
- MALAWI
- MAURITIUS
- MADAGASCAR

- NAMIBIA
- SEYCHELLES
- SOUTH AFRICA
- SWAZILAND
- TANZANIA
- ZAMBIA
- ZIMBABWE
BRIEF HISTORY

- SADC Health Protocol for regional cooperation and integration
- Protocol Implementation Plan
- Priority areas: TB, Malaria and HIV and AIDS
- Program on pharmaceuticals: regulation, availability and access
OBJECTIVES

- Promotion of access to essential medicines of quality, safety and efficacy by
- Development of standards for the quality, safety and efficacy of medicines in the region
- Establishment of a structure for harmonisation
- Establishment of Centre of excellence
GUIDELINES DEVELOPMENT

- Discussion Forums
- Representation
- Allocation of responsibilities
- Process and Progress
LIST OF GUIDELINES APPROVED

- Application Form
- Guideline to Apply for Registration of Medicine
- Stability Guideline
- Biostudies Guideline (BA/BE)
- GMP Guideline
- Clinical Trials for Human Participants
- Licensing for Export/Import of Medicines
- Validation (Analytical and Process)
LIST OF GUIDELINES
APPROVED CONT’D

- Clinical Trials for HIV Vaccines
- Advertising Code
- Donation of Medicines
- Destruction of Unwanted Medicines (For comment by member states)
- Licensing of Pharmacies and Wholesalers
- Marketing Surveillance
- Nutritional Supplements
- Recalls
OUTSTANDING GUIDELINES

- Complementary Medicines
- African Traditional Medicines
- Clinical Trials for Human Participants
- Clinical Trials for HIV Vaccines
- Registration of Vaccines
- Terminology/Glossary
SADC PROJECTS

- Project on Pharmacovigilance
- Project on Combating Counterfeit Medicines
- Project on Pooled Procurement of Medicines
PLAN OF ACTION

• Two-year plan (2007 – 2009)
• Implementation of regulatory guidelines
• Assessment of NRAs
• Strengthening capacity of NRAs
• Regional training program
• Strengthen QA/QC laboratories in the region
• Identify and develop Centres of Excellence
• Combat counterfeit medicines in the region (IMPACT)
• Establish SADC Shared Network
• Establish Prequalification system for Pooled Procurement of Medicines in the Region
TRAINING PROGRAMME

• Evaluation of application dossiers for medicines regulation and authorisation
• Qualification and accreditation of QA/QC laboratories
• Development and implementation of Quality Management Systems (QMS)
• Market surveillance and monitoring
REGULATORY CHALLENGES

- Enabling legislation
- Common technical requirements
- Technical regulatory expertise
- Availability of resources
- Effective implementation of common guidelines
- Availability of laboratory services
- Communication and exchange of information
- Availability of training facilities and resources
THANK YOU FOR YOUR ATTENTION

• Acknowledgments:
  SADC Secretariat
  WHO
  ICH-GCG Secretariat
  Ministry of Health (SA)

• SADC websites: www.sadc.int
  www.ecs.sadc