

SADC HARMONISATION INITIATIVES

MR FF HLANGWANE

DIRECTOR: MEDICINES EVALUATION AND RESEARCH –
MEDICINES CONTROL COUNCIL OF SOUTH AFRICA

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MEMBER OF THE SADC MEDICINES REGULATORS'
FORUM



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

