

SADC HARMONIZATION INITIATIVES

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OUTLINE

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

INTRODUCTION

- Regulatory challenges;
- National Medicines Regulatory Authorities;
- Legislative framework;
- Technical Guidelines and requirements;
- Human, physical and financial resources;
- Process and systems;

SADC MEMBER COUNTRIES

- Angola
- Botswana
- Democratic Republic of Congo
- Lesotho
- Malawi
- Mauritius
- Madagascar
- **Mozambique**
- Namibia
- Seychelles
- South Africa
- Swaziland
- Tanzania
- Zambia
- Zimbabwe

BRIEF HISTORY

- SADC Health Protocol for Regional Cooperation and Integration – Adopted on 1999;
- Protocol Implementation Plan;
- Priority areas: TB, Malaria and HIV/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

(17 guidelines approved and 5 outstanding)

SADC PROJECTS

- Project on Pharmacovigilance;
- Project on Combating Counterfeit Medicines;
- Project on Pooled Procurement of Medicines

PLAN OF ACTION

- Two-years plan;
- Implementation of Guidelines;
- Assessment of NRAs;
- Strengthening capacity of NRAs;
- Regional training program;
- Identify and develop centres of excellence;
- Combat counterfeit medicines;
- Establish SADC shared network;
- Establish Prequalification system for Pooled Procurement ;

TRAINING PROGRAMME

- Evaluation of application dossiers for medicines authorisation;
- Qualification and accreditation of QA/QC laboratories;
- Development and implementation of Quality Management Systems (QMS);
- Market surveillance and monitoring.

Experience of Mozambique

- New Legislation, Regulation and Procedures that came up;
- Approval of an independent and autonomous NRA;
- External evaluation of the sector and implementation of a roadmap;
- Sharing expertise within the region;
- Development of tools in order to improve the availability of good quality and efficacious medicines.

CHALLENGES

- Enabling legislation (regional);
- Common technical requirements;
- Technical regulatory expertise;
- Availability of resources (including training facilities);
- Exchange of information.

Thank You

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