SADC HARMONIZATION INITIATIVES

Tania V. Sitoie
Ministry of Health - Mozambique
Member of SADC Regulator Forum
OUTLINE

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- GUIDELINES DEVELOPMENT FOR MEDICINES REGULATION
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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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