

SADC HARMONISATION

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MEMBER OF THE SADC MEDICINES REGULATORS' FORUM

SADC MEMBER COUNTRIES

- ANGOLA
- BOTSWANA
- DEMOCRATIC
REPUBLIC OF
CONGO
- LESOTHO
- MALAWI
- MAURITIUS
- MADAGASCAR
- NAMIBIA
- SEYCHELLES
- SOUTH AFRICA
- SWAZILAND
- TANZANIA
- ZAMBIA
- ZIMBABWE

BRIEF HISTORY

- In 1999 SADC undertook to embark on a bulk purchasing initiative for TB medicines.
- However, before this could be done there was a need to harmonise medicine registration and control requirements within member States.
- Ministers of health then took a decision to harmonise this requirements within the region.
- This started with several activities being coordinated by the Medicines Control Council of South Africa.

GUIDELINE DEVELOPMENT

- Regulators Discussion Forums (RDF)
- Allocation of responsibilities
- Drafts presented to RDF
- Country consultations
- Recommendation for Approval of guideline by RDF
- Approval of guideline by the SADC Integrated Committee of Ministers
- Implementation

LIST OF GUIDELINES APPROVED

- **Application Form and its guidelines**
- Stability Guideline
- Bio-availability/Bio-equivalence studies 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
- Licensing of Pharmacies and Wholesalers
- Marketing Surveillance
- **Nutritional Supplements**
- Recalls

OUTSTANDING GUIDELINES

- Complementary Medicines
- African Traditional Medicines
- Clinical Trials for HIV Vaccines
- Registration of Vaccines
- Destruction of Unwanted Medicines
- Terminology/Glossary

THANK YOU FOR YOUR ATTENTION

- Acknowledgments:
SADC Secretariat
WHO
ICH-GCG Secretariat
Ministry of Health and Social Services,
Namibia
- SADC websites: www.sadc.int
www.ecs.sadc