SADC HARMONISATION

MR J GAESEB

- 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