SADC HARMONISATION INITIATIVE REPORT

PRESENTED BY CHUKILIZO NB
(ALTERNATE TO THE SADC PERMANENT REPRESENTATIVE)

ICH –GCG MEETING

16TH NOVEMBER, 2004
YOKOHAMA, JAPAN
SADC decision tree

- Draft by working group/country
- MRAs technical meeting
- Integrated council of ministers
- Adoption in national legislations
Objectives

- Improved quality of medicines
- Optimizing utilization of resources
- Standardization of regulatory requirements
Harmonization Processes

• Development of common technical requirements for registration of medicinal products
• Adoption of common GMP requirements
• Development of common procedures for other medicines regulatory controls e.g. licensing of pharmaceutical dealers, advertising, product recalls, etc
Achievements

COMMON GUIDELINES APPROVED BY SADC INTEGRATED COUNCIL OF MINISTERS IN JUNE 2004 ARE:

• GENERAL INFORMATION ON REGISTRATION OF MEDICINAL PRODUCTS
• APPLICATION FORM FOR REGISTRATION OF MEDICINAL PRODUCTS
• STABILITY GUIDELINES
• WHO’S GOOD MANUFACTURING PRACTICES

MEMBER STATES TO ADOPT THEM IN NATIONAL LEGISLATIONS
Guidelines under preparation

Likely to be discussed at the 25-26\textsuperscript{th} January 2005 meeting of SADC-MRAs

- Terms and definitions
- Nutritional supplements
- Bioequivalence/bioavailability
- HIV Vaccine trials in human participants
- Clinical trials
Guidelines to follow

- Pre clinical pharmaco-toxicological
- Complementary medicines
- Adverse drug reaction
- Advertising
- Licensing of premises
Challenges

Implementation of adopted guidelines

- Regulatory capacities
- Medicines legislation
- Human resources
- Financial resources
- Infrastructure
**Strengths**

- Existence of political structure
- Political will
- Possibility of common market
Technical Meetings

SADC expects to hold a technical meeting of MRAs from 25-26\textsuperscript{th} Jan. 2005

SADC is glad to welcome a representative of the ICH Secretariat
Thank you for your attention