

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
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graph TD; A[Draft by working group/country] --> B[MRAs technical meeting]; B --> C[Integrated council of ministers]; C --> D[Adoption in national legislations];
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# *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<sup>th</sup> 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<sup>th</sup> Jan. 2005

SADC is glad to welcome a representative of the ICH Secretariat

*Thank you for your attention*

