

# SADC HARMONISATION UPDATE

**MAY 10, 2005 ICH-GCG**

**BRUSSELS MEETING**

# ACTIVITIES NOV 2004-APRIL 2005

**Issues cleared at Jan 25-26, 2005**

**SADC Harmonisation meeting:**

- Standardization of recording and archiving of MRAs Forum meetings minutes**
- re affirming the official name of the harmonisation initiative as the SADC MRAs Forum**

## **Guidelines approved**

- Bioavailability and Bioequivalence studies**
- Clinical trials of drugs in human participants**

## Future planned activities

- **Guidelines undergoing in country consultations 2005 meeting**
  - ❖ **HIV vaccine trials in human participants**
  - ❖ **Harmonised glossary**

# Future planned activities.....

- **Guidelines under drafting..**
  - ❖ **Guidelines for registration of vaccines**
  - ❖ **Complementary medicines**
  - ❖ **Pharmacovigilance, adverse drug reactions and post-marketing surveillance**

# Future planned activities

- **Guidelines undergoing drafting**
  - ❖ **Nutritional supplements**
  - ❖ **Licensing of premises**
  - ❖ **Advertising**

## Reports Presented

- ICH-GCG Washington June 2004 and November 2004  
Yokohama meetings Reports-  
by SADC ICH-GCG  
Permanent representative.
- Implementation of  
harmonized guidelines- ICH  
Speaker.

# Technical Meetings

- **The next SADC-MRAs Forum meeting is planned for September 2005 agenda:**
  - ❖ **HIV vaccine trials in human participants**
  - ❖ **Guidelines for registration of vaccines**
  - ❖ **Complementary medicines**

# Cooperation for mutual benefits

