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.
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