JOSEPH MTHETWA
SENIOR PROGRAMME OFFICER
FOR HEALTH AND
PHARMACEUTICALS

SADC PHARMACEUTICAL
HARMONIZATION
PROGRAMME
SADC PHARMACEUTICAL PROGRAMME
Priority Areas in Harmonization

- Assessment of NMRA to identify critical areas of weakness;
- Development of Strategies to strengthen the NMRAs;
- Identify and strengthen region training centres;
- Facilitate the exchange of information on the safety, quality and efficacy of medicines;
- Ascertain capacity of laboratories and facilitate access and testing of essential medicines and African Traditional Medicines;
- Develop and Review regulatory Environment and Strengthen capacity to ethically review and Monitor Clinical Trials.
RISDP • 1999: APPROVED AND SIGNED BY HEADS OF STATE

PROTOCOL ON HEALTH • 2000 APPROVED BY ALL SADC HEADS OF STATE AND GOVERNMENT

SADC HEALTH POLICY • APPROVED BY SADC COUNCIL OF MINISTERS IN 2000

IMPLEMENTATION PLAN FOR THE PROTOCOL ON HEALTH • APPROVED BY SADC MINISTERS OF HEALTH IN 2007

SADC PHARMACEUTICAL BUSINESS PLAN
HARMONIZATION

REGISTRATION OF MEDICINES

CLINICAL TRIALS

CONTROL OF MEDICINES

REGIONAL REGULATORY GUIDELINES
CHALLENGES OF HARMONIZATION

- POLICIES
- LEGISLATION
- GOVERNANCE
- POLITICAL WILL
- COMMITMENT
STEPS TO SADC REGIONAL HARMONIZATION

- NEPAD PROJECT ON REGISTRATION OF MEDICINES
- WHO GUIDELINES
- ICH Guidelines
- FDA Guidelines
- cGMP and GCP
REMAINING GUIDELINES

- CONTROL OF COUNTERFEIT MEDICINES
- DISPOSAL OF UNWANTED AND SUBSTANDARD MEDICINES
- REGISTRATION OF AFRICAN TRADITIONAL MEDICINES
TRAINING 2011 - 2012

- GOOD MANUFACTURING PRACTICES ICH Q7
- FDA - GOOD CLINICAL PRACTICE
- FDA - GOOD CLINICAL PRACTICE - Inspection Clinical Trials Sites
- HARVARD INSTITUTE PHARMACEUTICAL REFORMS COURSE
TRAINING TO BE UNDERTAKEN 2013 - 2014

- Quality Assurance
- Good Manufacturing Practices
- Good Laboratory Practices
- Good Clinical Practices:
  - Inspection of Clinical Trials Sites
  - Ethical review
PROPOSAL FOR PARTICIPATION TO INCREASE FROM 2 TO 3

PARTICIPATION IN EWG

FOLLOW-UP OF ICH ISSUES
HARMONIZATION OF REGISTRATION OF MEDICINES – NEPAD AGENCY
Thank You