SADC GCG MEETING PRESENTATION

FORTUNATE FAKUDZE
GCG Meeting
13th November 2012
Hilton Hotel, San Diego, California, USA

ICH Meeting San Diego California USA
Membership

• The Southern African Development Community (SADC) was launched in 2002. SADC consist of 15 member states namely:
  • Republic Angola, Republic Botswana, Democratic Republic of the Congo, Republic Lesotho, Republic Malawi, Republic Madagascar (currently suspension) Republic Mauritius, Republic Mozambique, Republic Namibia, Republic South Africa, Republic Seychelles, Kingdom of Swaziland, United Republic of Tanzania, Republic Zambia and Republic Zimbabwe, with an estimated total population of 220 million people.
  • The SADC Secretariat is based in Botswana
The SADC Pharmaceutical Programme

- SADC developed and implemented a Pharmaceutical Programme in 2004 within the SADC Health Programme; in line with the SADC Protocol on Health and the SADC Health policy.

- The purpose of the SADC Pharmaceutical Programme is to enhance the capacity of Member States to effectively prevent and treat diseases that are of major concern to public health in the region by addressing issues of access to quality medicines.

- The SADC Pharmaceutical Business Plan was developed to operationalize the SADC Pharmaceutical Programme, it was approved in 2007
Priority Strategic Action Areas of the Pharmaceutical Business Plan

• Harmonization of STGs and EMLs;
• Rationalization and maximization of research and production capacity of generic essential medicines;
• **Strengthening of regulatory capacities of member states;**
• Promotion of joint procurement of quality essential medicines;
• Establishment of regional databank of traditional medicines and medicinal plants;
• Development and retention of competent human resource for the pharmaceutical programme;
• Developing mechanisms to respond to emergency pharmaceutical needs of the region; and
• Coordination of the implementation of TRIPS flexibilities to improve access to medicines
SADC/ICH GMP TRAINING FOR ACTIVE PHARMACEUTICAL INGREDIENTS (ICH Q7 GUIDELINES)

NAURA SPRING HOTEL, ARUSHA, UNITED REPUBLIC OF TANZANIA
27TH – 30TH JUNE 2011
ICH Q7 Guidelines Training

• The Training Workshop was attended by 12 (twelve) Member States (out of the 14 SADC Countries) comprising of Pharmaceutical Regulators & Inspectors and MOH Pharmacists.

• Facilitators for the Training came from the European Medicines Agency through the European Federation of Pharmaceutical Industries and Associations (EFPIA).

• The four days training workshop was funded by the African Development Bank Support Project for the Control of Communicable and the UK-DFID-Southern African Regional Programme for improving Access to Medicines and Diagnostics (SARPAM).

• Both projects support the operationalization and implementation of the SADC Pharmaceutical Business Plan.
Training Outcomes

• Regulators with a basic, common core of knowledge and skills in GMP for APIs and Inspections
• Skilled Inspectors: for Infrastructure review of (processes and procedures) of a GMP Inspection program
• Skilled trainer of Trainers Current GMP
• Skilled Inspectors and Assessors in Good Manufacturing Practices for Active Pharmaceutical Ingredients.
• Collaboration skills: Knowledge about each others’ organizations and operations with respect to the oversight of GMP and sharing information.
Implementation Challenges

• Inadequate capacity (financial, human and systems) within regulatory authorities in the region to implement the ICH Q7 guidelines.

• Disparities in Regulatory Capacity across the Region.

• Non of the member state within the region has either adopted nor adapted the ICH Q7 guidelines.

• The region heavily relies on the WHO pre-qualification program to carry out most of the work.
FUTURE TRAINING REQUESTS

1. • Pharmaceutical Quality Systems Q8/Q9/Q10 (2013)

2. • Validation of Analytical Procedures: Text and Methodology Q2 (R1) (2014)

3. • Good Clinical Practice (GCP) IV: FOR Inspection Of Ethical Review Committee (2013,US-FDA)
SADC REGIONAL TRAINING PLANS

ESTABLISHMENT OF REGIONAL TRAINING CENTRE
FOR REGULATORY AFFAIRS

Twinning and Work Sharing

Short Term Courses in Regulation

Centres of Excellence

Sustainable Training in Regulation

UNIVERSITY OF THE WITWATERSRAND

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