HARMONIZATION INITIATIVE FOR THE SADC REGION

Ms. Fortunate Fakudze
Senior Pharmacist
Ministry of Health
KINGDOM OF SWAZILAND
The Southern African Development Community (SADC) was formally launched in August 2001 under a Treaty.

Comprises of 15 member states with an estimated population of 220 million people.
New SADC headquarters building in Gaborone, Botswana
SADC has developed and implemented a Pharmaceutical 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 threat 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 then developed in order to operationalize the SADC Health Programme.
Priority Strategic Actions 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
- 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
- Coordination of the implementation of TRIPS flexibilities to improve access to medicines
SADC PHARMACEUTICAL PROGRAMME

Priority Areas in Medicines Regulation

- Assessment of NMRA to identify critical areas of weakness;
- Development of Strategies to strengthen the NMRAs;
- Identify and strengthen the region’s 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.
CREATION OF HARMONIZATION ENVIRONMENT

- Pharmaceutical Business Plan for 2007 – 2013 approved;

- 17 Guidelines (Minimum Standards) for Registration and Control of Medicines developed (2004 – 2007);

- Training Programme Started (FDA GCP Part I October 2010; ICH Q7 GMP for APIs June 2011; Flagship Course {Harvard University} July 2011; FDA GCP Part II September 2011);

- Development of Regional Strategic Framework for Regional Pooled Procurement of Medicines for HIV and AIDS, TB and Malaria;

- Development of Strategy for Regional Production of Generic Medicines for HIV and AIDS, TB and Malaria
PREVIOUS SUPPORT RECEIVED

- EC/ACP/WHO SUPPORT
- WHOA

UK-DFID (Southern African Regional Programme for Access to Medicines and Diagnostics Project)
Finalization of Guidelines for Disposal of unwanted Medicines;

Finalization of Guidelines for Control of Counterfeit Medicines;

Finalization of Guidelines for Substandard medicines;

Finalization of Guidelines for Regulation of Traditional Medicines
Swaziland is a landlocked country, it shares boarders with South Africa and Mozambique.

- Population: 1,018,449
- Area: 17,364 square KM
- Size: 193 KM from North to South
- Regions: 4 geographic regions
- Official Languages: 2 official languages, Siswati and England
THE KINGDOM OF SWAZILAND
REGULATION OF MEDICINES IN SWAZILAND

- The Pharmacy Act, 1929 is the legislation governing the regulation of medicines and the pharmacy profession in Swaziland.
- This Act does not make provision for the establishment of the NMRA nor the registration of medicines.
- There is no provision for the registration of pharmaceutical businesses and licensing of premises.
REGULATION OF MEDICINES IN SWAZILAND

- There is a National Pharmaceutical Policy (2nd Edition March 2011) that informs the two legislations
- The Pharmacy Bill and Medicines and Related Substance Control Bill have been developed and some sections from the Pharmacy Act of 1929 have been repealed
- The two Bills are currently in the office of the Attorney General before going to parliament for enactment
- The Medicines and Related Substance Control Bill once enacted will establish the NMRA
The Medicines and Related Substance Control Bill makes provision for the registration of medicines in country.

Currently all medicines coming into the country are not registered.

There is no database of medicines circulating in-country either.

Currently some of the functions of the NMRA are carried out by the office of the Chief Pharmacist in the Ministry of Health.
The Ministry of Finance in consultation with the Ministry of Health is responsible for issuing import permits for all pharmaceuticals coming in-country.

The absence of a current legal document and the NMRA poses challenges in the regulation on medicines.

There is need to expedite the enactment of the Medicines and Pharmacy Bills and the establishment of the NMRA.
Strengths:

- There is a political will
- Technical Support (SADC, WHO and MSH)
- Reviewed National Pharmaceutical Policy
- Medicines and Related Substance Control Bill and Pharmacy Bill
- Standard Treatment Guidelines and Essential Medical List currently under review (due for completion in September 2011)
REGULATION OF MEDICINES IN SWAZILAND

Weaknesses:

- Pharmacy Act 1929 – Required to be updated
- Lack of NMRA
- Lack on National Quality Control Laboratory
- No medicine registration and no technical skills for dossier evaluation
- No manufacturing sites inspections and no technical skills for cGMP site inspections
- Inadequate Human Resource
Regulation of Medicines in Swaziland

- Swaziland being a SADC Member State will benefit from the:
  - Harmonized guidelines for medicines registration, control of medicines, and other SADC guidelines
  - SADC Trainings for regulators (FDA GCP Part 1 October 2010; ICH Q7 GMP for APIs June 2011; Flagship Course {Harvard University} July 2011; FDA GCP Part II September 2011);
  - Information sharing, Shared Regulators Network
  - Use of accredited Quality Control Laboratories in the SADC region
  - Mutual recognition of NMRA
SADC

World Health Organization

Management Sciences for Health
CURRENT PLAN

- Establishment of a DRU in line with the Harmonization Processes
- Legislation enactment
- Human Resource development