

ICH GLOBAL COOPERATION GROUP MEETING
“SADC MEDICINES HARMONIZATION
AND STANDARDIZATION PROCESS”

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SADC - TOWARDS A COMMON
FUTURE

BACKGROUND

- SADC Member States are at various levels of pharmaceutical sector development and obviously pharmaceutical services delivery.
- There are those where the entire population have relatively good access to medicines, fairly advanced medicines quality assurance systems and relatively less challenging human resources constraint in the areas of pharmaceutical and medical personnel and have up-to-date legislation.
- There are others that are struggling to deliver good quality medicines to patients through their public health facilities and do not have a well developed private sector that serves the entire country; there are also those others whose situation is between the two extremes.

- The total pharmaceutical market in the SADC region is estimated at U\$2.5 to US\$3 billion per year with approximately one third being public sector expenditure and two thirds private sector expenditure
- Around half of this market being the Republic of South Africa alone

The disparities in the 14 SADC Member States is follows:

- 7 low-income countries (Lesotho, Malawi, Madagascar, Mozambique, Tanzania, Zambia and Zimbabwe),
- 5 middle income countries with high levels of inequity (Botswana, Mauritius, Namibia, South Africa, Swaziland), and
- 2 low income countries – despite being resource-rich – seriously affected by conflict (Angola and Democratic Republic of Congo).

- Reducing child mortality, improving maternal health and combating HIV and AIDS, TB, malaria and other diseases are some of the objectives of the Millennium Development Goals.
- Such goals cannot be achieved without well-regulated and organized supply and management systems for essential medicines.

The ultimate objective of SADC is:

“to build a Region in which there will be a high degree of harmonization and rationalization to enable the pooling of resources to achieve collective self-reliance in order to improve the living standards of the people of the region”.

- The SADC Health Protocol, the draft Protocol implementation plan and the draft SADC Health Policy are already comprehensive in relation to covering the issues identified by the World Health Organization as necessary to expand the access to quality essential medicines
- Regional cooperation can be useful in assisting individual countries in implementing their national drug policies, sharing information and technical expertise can be particularly effective if the policies and strategies are mutually relevant and easy to adapt.
- Thus the importance and aim of harmonization is to eliminate duplication and to ensure the efficient use of resources in order to allow faster access to safe and effective medicines of good quality.

- The challenge for SADC is therefore to determine which issues in addition to those issues which must be taken at the country level, that can be strategically helpful and synergistic if tackled at the sub-regional level.
- Significant progress has been made by SADC Member States in the harmonization of medicine regulation guidelines and there have been notable achievements on wider medicines access and quality issues in a number of Member States.

SADC has developed a Pharmaceutical Programme Business Plan which takes into account:

1. The SADC Health Protocol,
2. The draft Protocol implementation plan,
3. The draft SADC Health Policy, and
4. Other international, regional commitments and SADC's general prioritization areas of cooperation.

It is also comprehensive when measured against the WHO and other Medicines Strategies

Strategic priorities for the SADC Pharmaceutical Business Plan

- Access to and use of affordable essential medicines
- Quality of medicines, vaccines and blood products
- Traditional Medicine research and development
- Human resource development in medicines management
- Ethics in the medicines supply chain
- Clinical trials and other research
- Financing a sustainable pharmaceutical sector and delivery

**SADC MEDICINES REGULATORY AUTHORITY
FORUM STRATEGIC PLAN:
2006 – 2010**

GOAL

“To enhance the capacities of Member States to continually and consistently improve the quality, safety and efficacy of the medicines marketed in the region”

OBJECTIVES

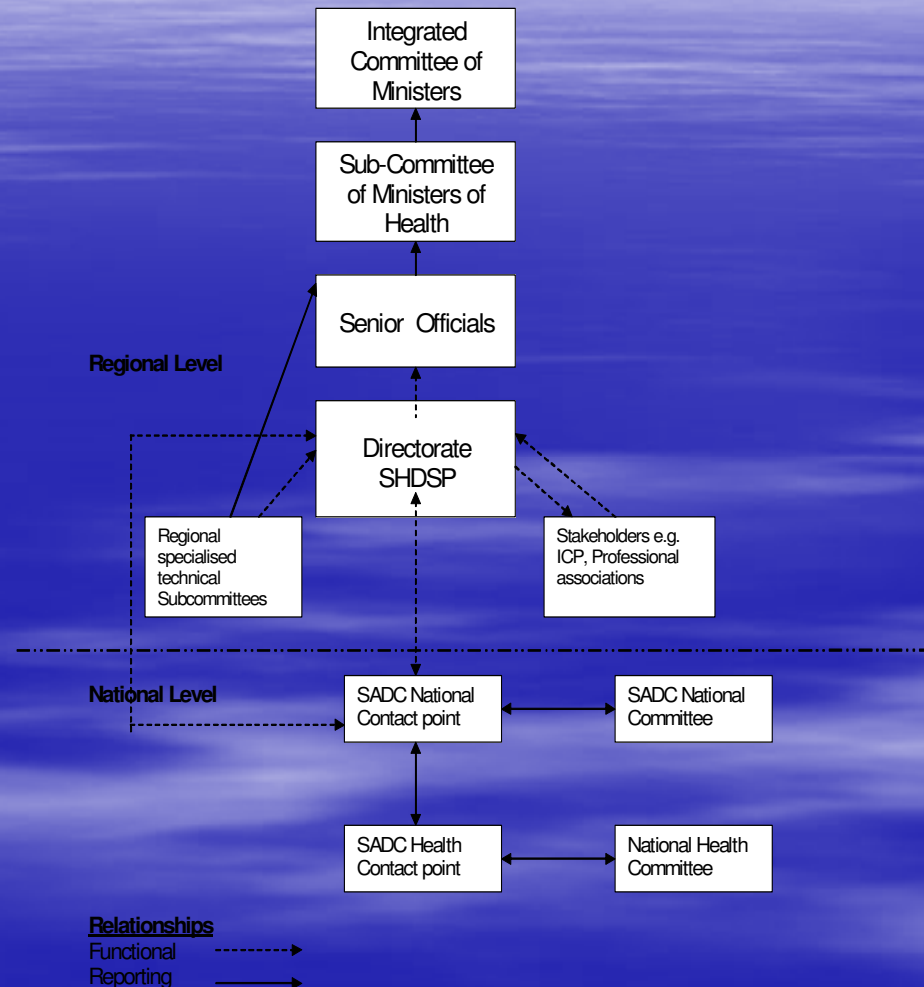
- To finalize harmonization of policies and medicine regulatory guidelines
- To facilitate the assessment of medicine regulatory capacities, including quality control infrastructure, of the Member States
- To develop a regional training programme for the implementation and sustainability of the harmonization process
- To promote collaboration in terms of quality control infrastructure, equipment, and/or supplies required for implementing the harmonized standards
- To establish regional centers of excellence in Member States on medicine regulation and quality control matters
- To establish and maintain a regional shared network system for regulatory authorities

EXPECTED OUTCOMES, INDICATORS AND TARGETS

- Harmonization of policies and medicine regulatory guidelines finalized and operational by November 2006
- Assessment of medicine regulatory capacities, including quality control infrastructure, of the Member States completed by 2007
- Regional training programme for the implementation and sustainability of the harmonization process developed and operational by 2007
- Strengthened capacity of Member States in terms of quality control infrastructure, equipment, and/or supplies required for implementing the harmonized standards by 2010
- Regional centers of excellence in Member States on medicine regulation and quality control matters established and operational by 2010
- Regional shared network system for regulatory authorities established and operational by 2008.

INSTITUTIONAL FRAMEWORK

- The Regional Medicine Regulation Implementation Plan will be implemented within the current institutional framework at the SADC Secretariat
- The implementation of the plan will require that clear roles and responsibilities be assigned to the different stakeholders
- The following institutional framework will facilitate the implementation of the plan



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RESOURCE MOBILISATION

- ❖ The implementation of the plan will require resources.
- ❖ These will be in the form of human, material and financial resources.
- ❖ Member States will contribute in the form of staff time and by financing their attendance at meetings where funds have not been secured.
- ❖ The cost effectiveness of the strategies should be measured to encourage Member States to budget for the implementation of some of the interventions that need ongoing financial support.

- The SADC Medicine Regulatory Authority Forum in collaboration with the Health Desk at SADC Secretariat will be responsible for ensuring that funds are mobilized from all parties, including co-operating partners.
- Substantial resources will have to be mobilized for implementation of programmes and projects and this can only be done through co-operating partners and multilateral and bilateral agencies and organizations.
- Some stakeholders in the health sector, e.g. research organizations can also support the plan by undertaking to lead, coordinate and/or fund specific tasks for the sector.

MONITORING & EVALUATION

- An evaluation and monitoring plan will be developed to define in detail the activities to be undertaken in support of the Strategic Plan for Medicine Regulatory Authority.
- This will include establishing benchmarks to assess the performance and relevance of the activities being undertaken by the SADC to respond to the improvement of the quality, safety and efficacy of the medicines marketed in the region.
- Existing WHO tools and indicators will also be used as the basis for monitoring of the impact of the plan.
- Capacity development is central to the improvement of the quality, safety and efficacy of medicines and it is essential that the SADC Monitoring and Evaluation Plan address this key concern.

CRITICAL ASSUMPTIONS

- Experienced and skilled governance and management in place to drive and manage the implementation plan
- Committed and political will from all Member States
- Availability of resources from all levels
- Commitment of partners including International Cooperating Partners, research institutions, and industries

BUDGET

- The proposed duration of this plan is five (5) years from the date of approval and resource allocation.
- The total cost over the 1 year will be approximately US\$150,000, which would include 5% from SADC Secretariat and 5% from member States.

THANK YOU

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