



ICH GCG Meeting  
7<sup>th</sup> Nov – 10 Nov 2005

Regional Harmonisation Update -  
SADC  
8 NOV 2005  
Chicago – USA



# PURPOSE OF THE MEETING

- To implement the SADC approved Pharmaceutical Programme and implement the plan on the SADC Protocol on Health which was approved by the integrated committee of ministers (ICM) in June 2005, the Secretariat organised this first meeting of the proposed Core Task Force on SADC Pharmaceutical Programme to discuss the issue, in Gaborone on 1<sup>st</sup> September 2005.




## Purpose of the meeting continued...

- The overall focus of the meeting was to provide SADC with direction and the possible ways for the implementation process of the pharmaceutical programme initiative.
- The goal was to develop a Business plan as stipulated in the approved Multidisciplinary and Multi Agency Task Force Terms of reference. The meeting was expected to come up with a draft of action to direct SADC in drafting a Business Plan for the Pharmaceutical Programme.



# Participants

- SADC Secretariat
- ICP:WGO, UNICEF, UNAIDS, UNFPA, UNDP
- Private/ Public sector, DBSA
- Trade Union
- EQUINET/SEATINI

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- The chairperson reviewed the SADC Pharmaceutical Programme which was approved in 2004.
  - He pointed out that it is an important programme with ultimate goal of providing access to treatment for ALL citizens in need in the southern region.



# Meeting Progress

- The meeting identified main activities to be executed in the short, medium and long term. (refer to annex 1)
- The meeting agreed that it would be beneficial for SADC to send out brief notification to all international Cooperating Partners (ICPs) in order to help prepare the ICPs for whatever requests for support SADC might have on this subject at a later stage.



## Meeting Progress Continued.....


- The meeting also agreed that there was need to appoint a Project Manager who would be responsible for the overall coordination of the development of Business Plan.
- It was further agreed that a clear Project Proposal should be developed based on the Draft Action Plan. The proposal will then be used to mobilise resources for the implementation of the Business Plan.



# Draft Business Plan

- A Business Budget from EQUINET/SEATINI was presented and it was agreed that comments could only be submitted after a Project Manager is recruited.
- Inclusion of Business People, NGOs, Consultants was considered for the TASK Force efficiency.

# Draft Action Plan (annex 1)



Activities	Short Term (< 1yr)	Medium (1-3yrs)	Long Term (>3yrs)	Responsible/ Resources
1. Trade/ legal Framework - country Assessment And other Regions	Country assessment Of TRIPS, other trade/ Legal frameworks  Assistance to protect Existing flexibilities  Assess availability of Expertise	Analyse and identify gaps And make proposals for Corrective measures  Provide TA for SADC Countries to address Trade/ legislative Frameworks	Change trade/ legislative Frameworks Where appropriate	WHO has tool and some data Need some expansion UNDP has experience And technical Expertise MS

# Status of approved guidelines and proposed next steps

- Extract of Southern African Development Community (SADC) Medicines Regulatory Authorities Forum Held At the Paradise Holiday Resort, Bagamoyo – Tanzania (Jan 2005)
- After reviewing status of all the guidelines which were identified for harmonisation in the previous SADC harmonised meetings, members who have not been able to attend the meeting for a long time, were reassigned some of the guidelines .
- They agreed on specific actions to be taken either to implement or complete all guidelines.

## Continued...

- On the completed guidelines, it was noted that there is a need to define the implementation roadmap which would include official notification from SADC Secretariat, internationalisation of the guidelines in member states legislations and putting in place transitional arrangements.
- It was therefore recommended that the completed document be edited and printed. After they have been printed and bound the SADC Secretariat should officially notify the member states who will then take the necessary steps to implement them.
- On the outstanding guidelines it was resolved that member states should adhere to the agreed timeframes

# Status of approved guidelines and proposed next steps

<i>S/n</i>	<i>Guidelines</i>	<i>Status</i>	<i>Remark</i>
1	Application form for registration of a medicine	Approved	Already edited. secretariat Awaiting printing from to member state implementation
2	Guidelines for registration of medicines	Approved	Already edited. secretariat Awaiting printing from to member state implementation
3	Stability guidelines	Approved	Awaiting editing
4	Good Manufacturing Practice (GMP)	Adopted and Approved WHO guidelines	
	Validation		
	. 1 Analytical method validation		
5	. 2 Process validation	Adopted and Approved WHO guidelines	Preparing adoption document p.. from secretariat to member state implementation
6	Bioequivalence / Bioavailability	Approved	Awaiting editing Awaiting editing
7	Clinical trials	Approved	
8	HIV vaccine trials in human participants	pending	In country consultations should .... end of June 2005
9	Guidelines for registration of vaccines	pending	To be drafted by South Africa