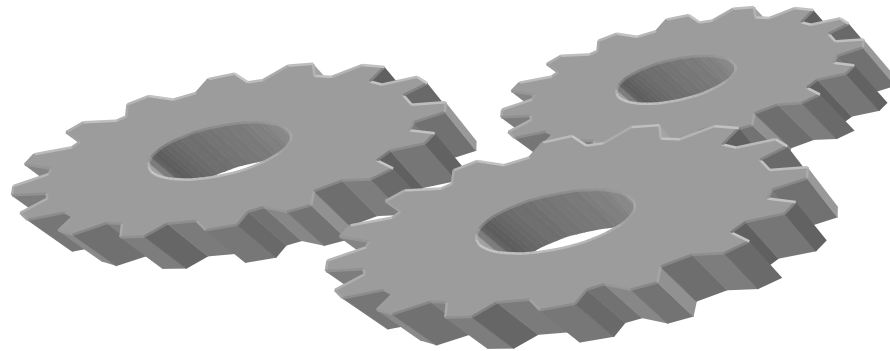


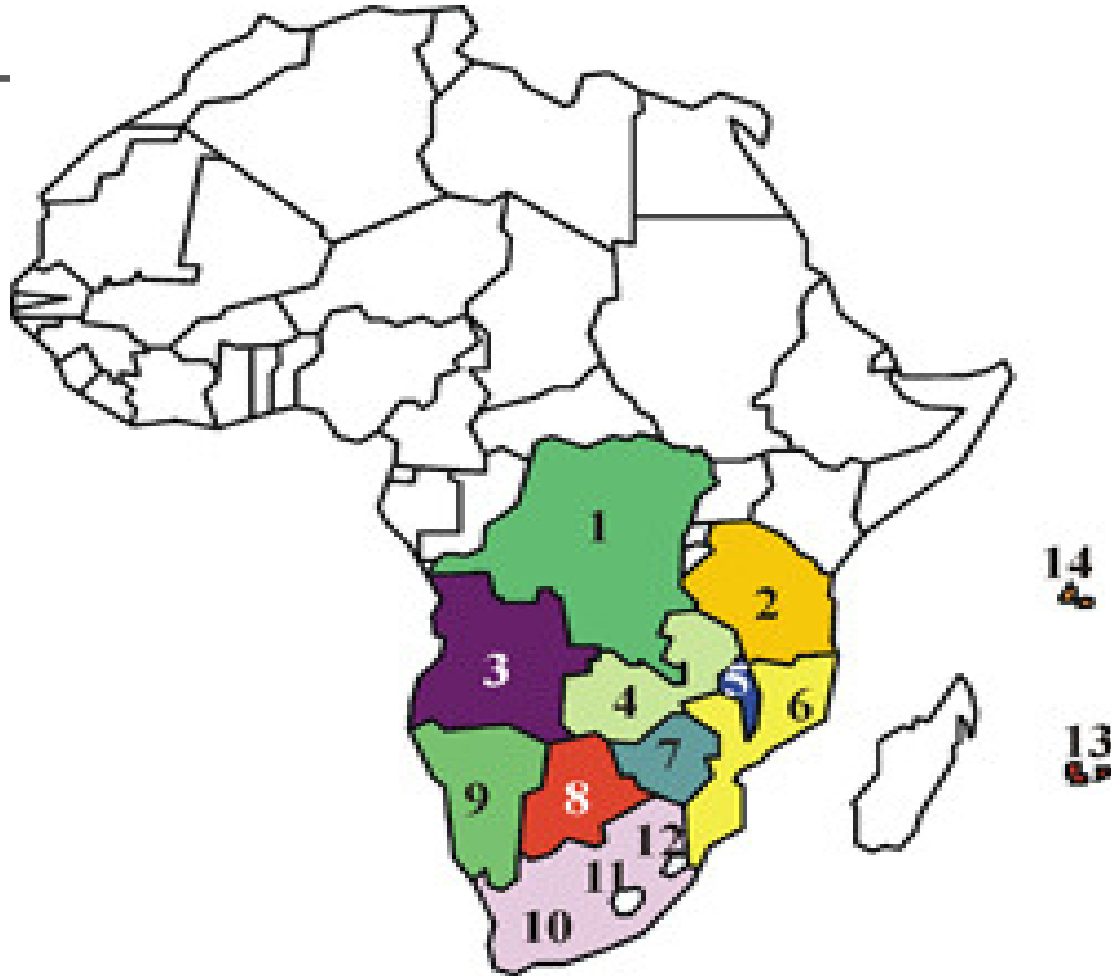
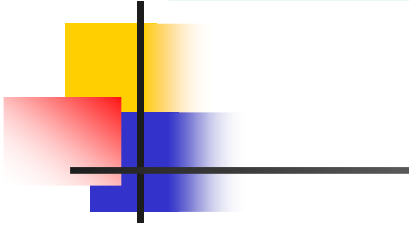


**HARMONIZATION PROCESS  
FOR MEDICINES  
REGULATION IN THE SADC REGION**

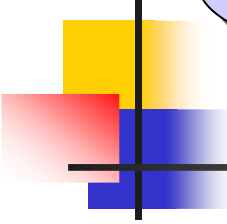


MANDISA HELA ON BEHALF OF  
SADC SECRETARIAT  
GABORONE, BOTSWANA

Map of SADC Member-States



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Southern African Development Community (SADC) was formally launched on 17th August 2002 under a Treaty

It consists of 14 Member States namely Angola, Botswana, Democratic Republic of Congo, Lesotho, Malawi, Madagascar, Mozambique, United Republic of Tanzania, Zambia and Zimbabwe, Mauritius, Namibia, South Africa, and Swaziland

SADC originated from the Southern African Development Coordination Conference (SADCC), which was formed in 1980. It has an estimated total population of 200 million people



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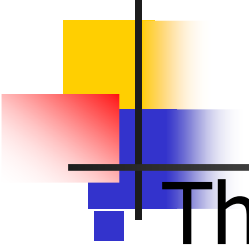
## Objective of SADC:

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“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”.



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The Common Agenda includes; the promotion of sustainable and equitable economic growth and socio-economic development that will ensure poverty alleviation with the ultimate objective of its eradication and the promotion of common political values, systems and other shared values.



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# HARMONIZATION

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- SADC identified the need to develop and implement a harmonized Pharmaceutical Programme in line with the SADC Health Protocol and the SADC Health Policy.



# HARMONIZATION TASKS THE SADC REGION HAS ACCOMPLISHED

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- Developed a pharmaceutical business plan focusing on regulation, availability & access
- Priority areas TB, Malaria, HIV and AIDS
- A well established Medicines Regulatory Forum
- Developed 14 guidelines for the Registration and Control of Medicines



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# LIST OF APPROVED GUIDELINES

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- Application for Registration of Medicines
- Stability Guideline
- Biostudies Guideline (BA/BE)
- Conduct of Clinical Trials in Human Participants
- Import & Export of Pharmaceutical Products
- Drug Donations



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# LIST OF APPROVED GUIDELINES

## cont.

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- Conduct of Clinical Trials for HIV vaccines in humans
- Pharmaceutical wholesaling
- Recall & withdrawal of medicines
- Nutritional supplements
- Pharmacovigilance
- Retail Pharmacy



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# GUIDELINES cont.

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## **APPROVED NOT YET PUBLISHED**

- Destruction of Unwanted Medicines
- GMP (adopted WHO)

## **OUTSTANDING**

- African Traditional Medicines
- Complementary medicines
- Post Marketing Surveillance

## **NEED FOR ASSESSMENT OF IMPLEMENTATION TARGET 2010**



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# ON THE VACCINE FRONT

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## **With the assistance of the WHO Global Training Network training conducted in :**

- Basic requirements for GCP inspections
- Evaluation of Clinical Trial data for Registration of a Vaccine.
- Planning joint inspections



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# PLANNED SUPPORTIVE ACTIVITIES

- Establishment of a structure for harmonisation
- Establishment of centre/s of excellence
- Strengthening capacity of NRAs



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# CHALLENGES

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- Capacity constraints (skills, numbers, financial)  
– threat to continuity & sustainability
- Varying individual country priorities & sovereignty issues
- Policy Environment – balancing Public Health, Trade & Treasury interests
- Pressure to approve products quickly from both industry & civic patient / pressure groups coupled with sub-optimal post -marketing & pharmacovigilance capacity



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# CHALLENGES cont.

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- African Traditional Medicines – different paradigm & need for extensive research on methodology to establish safety, efficacy & quality
- Biotechnologies (including biosimilars) – population specific needs: may require clinical studies in our populations
- Technologies with a small market – orphan status? Can we agree?



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# LESSONS LEARNT

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- Cooperation within SADC as well as with more mature authorities requires legislative processes (e.g. confidentiality wrt negative reports, Access to information Acts etc.)
- Current country to country agreements not very helpful in regional harmonisation arena
- Pace of adaptation of processes differs e.g. CTD format agreed to but not yet fully implemented. Some members already keen to migrate to eCTD format



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# CONCLUSION

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- Continuous Priority setting
- Attention to how new technologies will be handled (nanotechnologies, proteomics, etc.)
- Abraham Lincoln once said “You cannot strengthen the weak by weakening the strong. You cannot help men permanently by doing what they could and should do themselves. You cannot build character and courage by taking away man’s independence and initiative”.



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# THANK YOU

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