



# ICH/GCG MEETING

Portland Marriott Downtown waterfront  
Hotel, Portland, Oregon, USA

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2<sup>nd</sup> RHI representative from SADC Medicines Regulators Forum



# Southern African development Community (SADC) Member states... (14)

Angola, Botswana, Democratic Republic of  
Congo, Lesotho, Madagascar, Malawi,  
Mauritius, Mozambique, Namibia, South  
Africa, Swaziland, Tanzania, Zambia,  
Zimbabwe



# Historical perspective...

Founded in 1980 as Southern African Development coordinating conference by 9 member states

Windhoek Summit in Namibia in 1992 – became known as SADC and 5 other member states joined the grouping i.e. Madagascar, Mauritius, SA, DRC and Namibia



# SADC Protocol on health...

Article 29: provides for a SADC Pharmaceutical Programme which among other issues deals with:

- Harmonisation of procedures for pharmaceutical QA and registration;
- Availability of affordable essential medicines and promotion of rational use of medicines;
- Development and strengthening EDPs
- Promotion of R&D of ATMs

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## The Medicines Regulatory Authorities Forum

- established as an international technical working group comprising of SADC Regulatory Authorities, with a shared commitment to harmonise the regulatory framework in the SADC region.
- brings together representatives of SADC Medicines Regulatory Authorities to among other things, develop a strong regional quality assurance infrastructure supported by the coordinated information network and harmonized policies, medicines regulations and guidelines.



## SADC Pharmaceutical Programme...

The Programme has since developed a Pharmaceutical Business Plan that addresses issues that concern access to quality medicines in all Member States:

- aims at improving the availability of affordable, safe, efficacious and effective essential medicines of acceptable standard of quality.
- enhanced regional capacity for pharmaceutical manufacturing as well as the conduct of research in medicines and other pharmaceutical products including African Traditional Medicines that are relevant to local health problems.



## Pharmaceutical Business plan

The Pharmaceutical Business Plan strategic actions include:

- Harmonisation of standard treatment guidelines and essential medicine lists;
- Rationalisation and maximising the research and production capacity of local and regional pharmaceutical industry of generic essential medicines and African Traditional Medicines;
- Strengthening regulatory capacity, supply and distribution of basic pharmaceutical products through ensuring a fully functional regulatory authority with an adequate enforcement infrastructure;
- Promoting joint procurement of therapeutically beneficial medicines of acceptable safety, proven efficacy and quality;
- Establishing a regional databank of traditional medicine, medicinal plants and procedures in order to ensure their protection in accordance with regimes and related intellectual property rights governing genetic resources, plant varieties and biotechnology
- Developing and retaining competent human resources for the pharmaceutical programme within the SADC Human Resources for Health Strategic Framework; and
- Coordinate the implementation of TRIPS flexibilities to improve access to essential medicines within the SADC region.



## Development of guidelines ...

- In view of the above mentioned strategic actions, the Integrated Committee of Ministers (ICM) directed medicines regulators in the region to develop harmonised guidelines for registration and control of medicines as a way to facilitate the pooled/joint procurement.
- In 2000, The SADC Medicines Regulatory Authorities Forum started the process of developing the guidelines most of which have been approved.



# Approved guidelines...

- Guidelines for submitting application for registration of a medicine
- Guideline for Bioavailability and bioequivalence
- Guidelines for Stability Studies
- Guideline for regulating the conduct of clinical trials in human participants
- Advertising of medicines guidelines
- Guidelines for drug donations
- GMP guidelines



## Approved guidelines cont...

- Guidelines on import and export procedures for pharmaceutical products
  - Guideline for registration of Nutritional Supplements
  - Pharmacovigilance guidelines
  - Guideline for Recall /withdrawal of medicines
  - Guidelines for Retail Pharmacy
  - Guidelines for HIV Vaccine trials in human participants
  - Guidelines for pharmaceutical Wholesale dealing
- Yet to be finalised are Guidelines for ATMs and disposal of pharmaceutical waste



## Next steps:

- Implementation of guidelines at national levels
- Developed shared network for regulators and training is underway for effective utilisation of the network
- Assessment of Regional Capacities to identify centres of excellency
- Training and capacity building in the region

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