

Pharmaceutical Programme Development in SADC Region

*MO. Nasiruddin Pawar, Darshil Shah, Dilip Maheshwari

Department of Quality Assurance & Pharm Regulatory Affairs, L. J. Institute of Pharmacy, Ahmedabad, Gujarat, India.

ABSTRACT

Southern African Development Community (SADC) comprises of 15 member states of Southern African region. SADC started the harmonization of policies and guidelines in 1992 through pharmaceutical programme for easily access to affordable and safe effective medicines. In SADC region major disease like AIDS, Ebola, Malaria and other blood related diseases are transforming to serious threat for public domain. SADC is concerned to cure and prevent these diseases, which is a major threat to public health of this region. In recent scenario generic medicines are overtaking the global pharmaceutical market as these drugs are easily available at affordable price. In this decade SADC has initiated health programmes based on the use of generic medicines, which are quite efficient for public domain and also for this organisation. SADC is also partner with ICH and WHO for development of policies and guidelines to provide effective and good quality of medicines. To acquire this goal SADC have developed and approved the 15 guidelines, which is mentioned in this article. The present article focuses on the pharmaceutical program development in SADC. The main objective of the present article is to describe in detail about the SADC organization and its structure and development of the harmonization guidelines by SADC through pharmaceutical programmes.

Keywords: Organization of SADC, SADC pharmaceutical programme, SADC pharmaceutical business plan, Structure of SADC, SADC region

Received 19 Jan 2015

Received in revised form 07 Feb 2015

Accepted 09 Feb 2015

*Address for correspondence:

MO. Nasiruddin Pawar,

Department of Quality Assurance & Pharm Regulatory Affairs, L. J. Institute of Pharmacy, Ahmedabad, Gujarat, India.

E-mail: nasir.pawar@gmail.com

INTRODUCTION [1-3]

The Southern African Development Community (SADC) launched in 1992 under a treaty. It was established in 1980 as Southern African Development Coordination Conference (SADCC) and later transform into SADC. It comprises of 15 member states namely Angola, Botswana, Democratic Republic of the Congo, Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, Tanzania, Zambia and Zimbabwe with an estimated population of 220 million people. SADC has developed the pharmaceutical programme in 2004 to prevent and treat diseases of major concern to public health in the region, especially like AIDS, malaria, and tuberculosis. In Southern Africa access to affordable, safe and quality-assured medicines is uneven. A lack of standardised legislation for pharmaceutical

product registration, usage and different treatment for diseases currently affect healthcare in the SADC region, and creating challenges. Due to these issues SADC created the Pharmaceutical Programme in 2004. Shortly after starting of the Pharmaceutical Programme, SADC established Protocol on Health in 2004 for improving access, affordability and effectiveness of pharmaceuticals within SADC region. The goal of the SADC is to ensure the accessibility of essential medicines as well as African Tradition Medicines to decrease disease load in the region.

The article provides the overview of the SADC organizational structure, process, development and harmonization of guidelines in SADC member states. This will help to understand the SADC function and

process of development of guidelines. The purpose of SADC Pharmaceutical Programme is to increase the capacity of member states to effectively prevent and treat diseases that are major concern to public health in the region by addressing issues of access to quality medicines.

SADC Institutional structure [4,5]

The SADC pharmaceutical programmes medicines regulation implementation plan is within the SADC institutional framework as describe below,

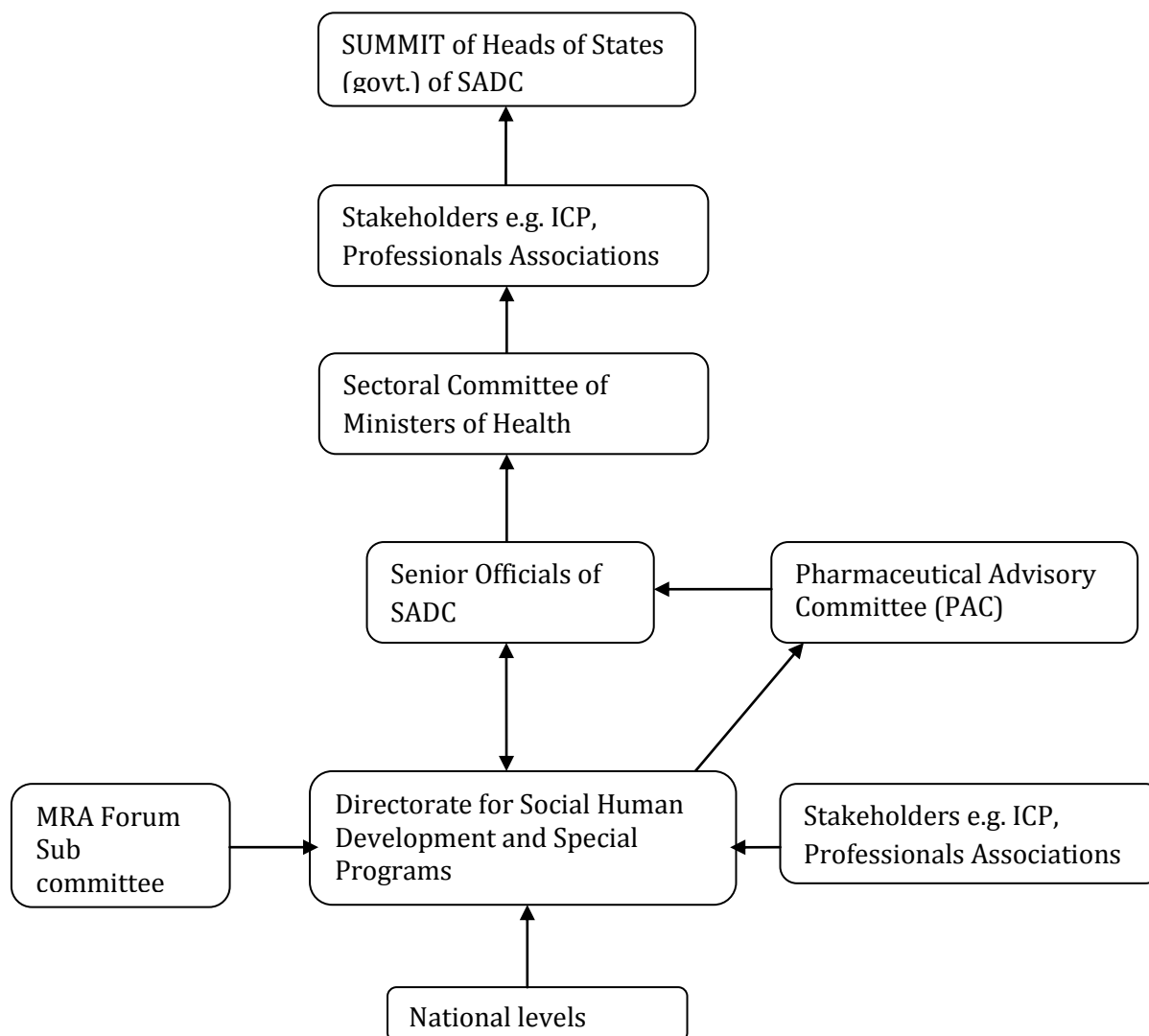


Figure 1: SADC Institutional Framework at National Level [4]

At national level there are Implementation Committees that work through SADC national contact points who have a direct link with the SADC Secretariat. SADC Secretariat is the responsible for the strategic planning, co-ordination, facilitation of all SADC programmes which is headed by the SADC executive secretary. The SADC Summit of Heads of states is responsible for the all policy track and directs the function of community which ultimately makes it the policy-making

organization of SADC. It is made up of the all SADC Heads of states or government. The Directorate of Social and Human Development and Special Programmes (SHDSP) are the one of the four programmes Directorates that is part of the SADC Secretariat. Pharmaceutical harmonisation initiative takes place under the Directorate for SHDSP. The Directorate is responsible for channelling the information between national and regional levels of SADC, and for co-ordinating the interface of

the Technical Committee which is applied to regulators is known as the SADC Medicines Regulatory Authority Forum (MRA), seniors Ministerial Health officials. The Secretariat main work is to increase the capacity of each member states of SADC to effectively treat diseases that are major public health concern and to harmonise policies and regulatory processes in SADC region.

The SADC Ministers of Health monitored the implementation of the protocol on health and reported to Integrated Committee of Ministers (ICM). The Pharmaceutical Programme, which is a part of SADC protocol is implemented within the approved institutional framework of SADC. The process of guidelines development involves each Member State. The member states are being assigned to a specific technical guideline to develop over a specific period of time. The assignment is based on the expertise and capacity, depending on their interest. Member state identifies the appropriate bodies to form the working group who will develop the draft guidelines. In cases where the required expertise is not available in member states which the topic is assigned can partner with another member states and develop the guideline.

Once the guidelines is developed the member state present the draft guidelines to the MRA forum for discussion at workshops. Then it is organised to debated the guidelines and request all input from partners and stakeholders. Once agreement has been reached the draft guidelines will be presented to Pharmaceutical Advisory Committee (PAC) through SHDSP for subsequent submission to senior officials for the clearance and to Sectoral Committee of Health Ministers for approval. The highest level of authority within the Harmonization initiative is the Summit for Heads of state and government preceded by the Council of Ministers.

Project "Registration Harmonization" [6-8]

SADC initiated its project Registration Harmonization in 2011 in the SADC region with help of Southern African Generic Medicines Association and other international agencies with intentions to improve public health by achieving rapid

and sustainable access to safe, effective and affordable essential medicines. A generic drug is a pharmaceutical product, usually intended to be interchangeable with an innovator product that is manufactured without a licence from the innovator corporation and marketed after the expiry date of the patent or other exclusive rights. This Harmonization project is based on the collective action, innovation which strengthens the SADC region's capacity to supply essential medicines and diagnostics. The SADC Pharmaceutical Harmonization project includes the activity of development of technical guidelines and policies, relating to the registration and control of medicines across the SADC region. The aim is to improve the quality, efficacy and safety of medicines circulating within the region and to established and maintain a regional shared network system for regulatory authorities.

SADC Pharmaceutical Business Plan

Essential medicines are those drugs that satisfy the health care needs of the majority of the population. That's why they should be available at all times in adequate amounts and in appropriate dosage forms at a reasonable price so community can afford them. SADC Pharmaceutical Business Plan (2007-2013) was published in the 2007 within the context of global, continental and regional policy frameworks, protocols and commitments. The overall goal is to ensuring availability of essential medicines to reduce the diseases in the region. The main objective is to improve sustainable availability and access to affordable, safe, quality, efficacious essential medicines. In order to achieve these goals, SADC have developed the strategies which are,

- ❖ Increasing the regulatory capacity, supply, and distribution of basic pharmaceutical products through assuring a fully functional regulatory authority which have adequate enforcement infrastructure.
- ❖ Establishing a regional databank consisting traditional medicine, medicinal plants, and procedures in order to ensure their safety, in harmony with regimes and related intellectual property rights prevailing genetic

resources, plant varieties and biotechnology.

- ❖ Providing the harmonising standard treatment guidelines and essential medicine lists.
- ❖ Justifying and maximising the research and production capacity of regional and local pharmaceutical industry of generic essential medicines and African Traditional Medicines.
- ❖ Enhancement and retaining capable human resources for the pharmaceutical programme.
- ❖ Endorsing combined procurement of therapeutically valuable medicines of acceptable safety, established efficacy, and quality to the people who at reasonable costs.
- ❖ Facilitates trade in pharmaceuticals inside SADC region.
- ❖ Development of mechanisms for responding to emergency pharmaceutical requirements of the SADC region.

Opportunities of SADC Pharmaceutical Market [9]

Development of a policy and legislative framework for regulation and validation of the safety, quality and efficacy as well as proper use of African Traditional medicines is essential.

Populations throughout the SADC region are using traditional medicines to help meet their principal health care needs. Medicinal plants contain riches of active ingredients that are used in the manufacture of essential medicines.

A large regional market for the pharmaceutical manufacturing industries, which was approximate in 2000 at US\$ 2.5 to 3 billion, which creates opportunities for regional investment and trade, growth of local entrepreneurship, creation of job opportunities as well as the development of viable pharmaceutical industries thus ensuring sustainable supply of quality and reasonable essential medicines to meet public health objectives.

Advanced medicines quality assurance systems in some Member States can be used for building capacities in other Member States through training and exchange programmes.

Improvement of efficiency in supply chain management systems through regional collaboration and sharing of best practices in public sector procurement. An estimated US\$ 1 billion per year is used in procurement and a 1 % improvement in efficiency could therefore translate into realization of savings in the region of US\$1 0 million; whilst an achievable efficiency gain of 5% can translate into US\$50 million savings per year.

Increase in additional funding sources and mechanisms can continue to improve access to essential medicines.

Development of Guidelines [10]

- ❖ The process of harmonisation is initiated through the SADC Secretariat who prepares and submits for decision an Agenda to the Ministers of health. WHO and ICH guidelines as well as other guidelines form the basis for reference materials for the development of regional guidelines, with agreement on the adoption of international guidelines whenever possible.
- ❖ The guidelines once complete will be available to all stakeholders and they have opportunities to comment on existing guidelines which being transmitted to MRA forum for consideration.

Topics under Harmonisation [11]

The topics under Harmonisation developed through active participation of Regulatory Representatives from Member States in Workshops guided by Technical Advisor from the Stakeholder and Partner.

CONCLUSION

The brief review of pharmaceuticals harmonization in the SADC region was not easily accessible. The regional and political differences among the member states and implantation of guidelines and policies are challenging in SADC region. This article gives brief overview about pharmaceutical program, process and development of policies and guidelines which are developed by SADC with the help of ICH and WHO and other international agencies. However, the implementation and development of guidelines is very slow process.

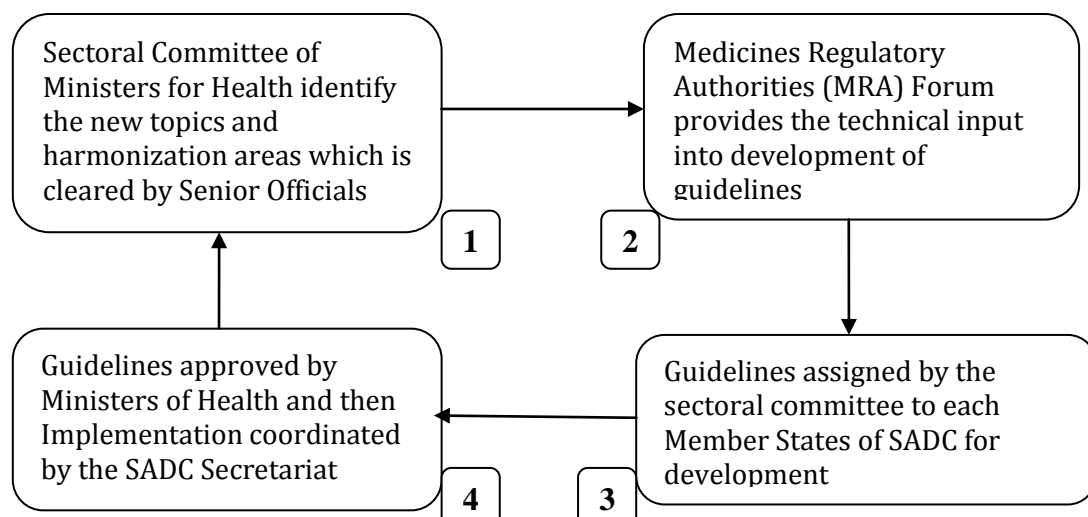


Figure 2: Flow chart for Process of development of guidelines [10]

Table 1: Topics under harmonisation

No.	Topics	Based on	Status
1	Application form for Registration of Medicinal Product	Adapted ICH Q1 F, Q1 C, E5 (R1) and WHO Guidelines	Approved by Sectoral Ministers of Health
2	Registration of Medicinal Product	Adapted ICH E2 C (R1) and WHO Guidelines	Approved by Sectoral Ministers of Health
3	Stability Studies	Adapted ICH (Q1A, Q1B, Q1C, Q1E, Q1F) and WHO Guidelines	Approved by Sectoral Ministers of Health
4	Good Manufacturing Practice	Adapted ICH Q7 and WHO Guidelines	Approved by Sectoral Ministers of Health
5	Bioequivalence/Bioavailability	Adapted WHO Guidelines	Approved by Integrated Committee of Ministers
6	HIV Vaccines Clinical Trails	Adapted ICH E1, E2A and E2B (R3) Guidelines	Approved by Sectoral Ministers of Health
7	Registration of Nutritional Supplements	Adapted WHO Traditional Medicines Guidelines	Approved by Sectoral Ministers of Health
8	Validation (Analytical Method & Process)	Adapted ICH E4 and WHO Guidelines	Approved by Sectoral Ministers of Health
9	Advertising	Adopted WHO Quality and Safety Guidelines	Approved by Sectoral Ministers of Health and endorsed by Council of Ministers
10	Licensing of Manufacturers	Adapted ICH Q7 and WHO Prequalification Guidelines and IPR	Approved by Sectoral Ministers of Health
11	Licensing of Wholesalers, Dispensaries and Pharmacies	Adapted WHO Prequalification Guidelines	Approved by Sectoral Ministers of Health
12	Licensing for Import/Export	Adapted ICH Q1D and WHO Guidelines	Approved by Sectoral Ministers of Health
13	Post-Marketing Surveillance	Adapted ICH E2E and WHO Guidelines	Approved by Sectoral Ministers of Health
14	Donations	Adapted WHO Guideline for Healthcare Equipment Donation and Guidelines for Drug Donations	Approved by Sectoral Ministers of Health
15	Recalls	Adapted ICH E2E and WHO Quality and Safety Guidelines	Approved by Sectoral Ministers of Health
16	Terms and Definitions	To be adopted ICH M1 Med DRA	Work in progress

17	Registration of Medicines	Adapted ICH E1, E2A, E2B (R3) and WHO Guidelines	Work in progress
18	Regulation of Traditional Medicines	Adapted WHO Traditional Medicines Guidelines	Work in progress
19	Disposal of Medicines	Adapted ICH E2D, E2C (R1) and WHO Safe Disposal of Unwanted Medicines Guidelines	Work in progress

ACKNOWLEDGEMENT

The Authors are thankful to Dr. K. Pundarikakshudu, Director of L. J. Institute of Pharmacy for providing us facilities and guidance.

REFERENCES

1. SADC Overview [online]. 2012 [cited 2014 Dec 21]; Available from: URL:<http://www.sadc.int/about-sadc/overview/>
2. SADC pharmaceutical business programme [online]. [cited 2015 Feb 04]; Available from: URL:https://www.unido.org/fileadmin/user_media/Services/PSD/BEP/SADC%20PHARMACEUTICAL%20BUSINESS%20PLAN%20-APPROVED%20PLAN.pdf
3. SADC Member states [online]. 2012 [cited 2014 Dec 23]; Available from: URL:<http://www.sadc.int/member-states/>
4. Organisation of SADC [online]. [cited 2014 Dec 29]; Available from: URL:<http://www.ich.org/about/organisation-of-ich/coopgroup/sadc/organisation-of-sadc.html>
5. SADC Secretariat [online]. 2008 [cited 2015 Feb 04]; Available from: URL:<http://www.sadc.int/sadc-secretariat>
6. SADC Pharmaceutical programme [online]. 2012 [cited 2014 Dec 27]; Available from: URL:<http://www.sadc.int/themes/health/pharmaceuticals/>
7. Generic Drugs [online]. 2015 [cited 2015 Feb 05]; Available from: URL:<http://www.who.int/trade/glossary/story034/en/>
8. Essential Medicines [online]. [cited 2014 Dec 25]; Available from: URL:http://www.who.int/medicines/services/essmedicines_def/en/
9. SADC Medicines Situation Analysis [online]. [cited 2015 Feb 06]; Available from: URL:http://medicines.sadc.int/?page_id=50#
10. Operating Procedure and Process [online]. [cited 2014 Dec 31]; Available from: URL:<http://www.ich.org/about/organisation-of-ich/coopgroup/sadc/operating-procedures-and-processes.html>
11. Topics under Harmonisation [online]. [cited 2015 Jan 2]; Available from: URL:<http://www.ich.org/about/organisation-of-ich/coopgroup/sadc/topics-under-harmonisation.html>