

SADC PHARMACEUTICAL PROGRAMME



SADC PHARMACEUTICAL BUSINESS PLAN

2007-2013

**SADC SECRETARIAT
27TH JUNE 2007**

ACRONYMS

AIDS	:	Acquired Immunodeficiency Syndrome Antiretroviral
ARV	:	Antiretroviral
cGMP	:	Current Good Manufacturing Practice
GMP	:	Good Manufacturing Practice
HIV	:	Human Immunodeficiency Virus
HR	:	Human Resources
ICM	:	Integrated Committee of Ministers
ICPs	:	International Cooperating Partners
MDGs	:	Millennium Development Goals
NEPAD	:	New Economic Partnership for African Development
PPP	:	Public Private Partnerships
QA	:	Quality Assurance
RISDP	:	Regional Indicative Strategic Development Plan
SADC	:	Southern African Development Community
SADCC	:	Southern African Development Coordinating Conference
SWOT	:	Strength, Weakness, Opportunity and Threats
TB	:	Tuberculosis
TRIPS	:	Trade Related Aspects of Intellectual Property Rights
UNDP	:	United Nations Development Programme
UNGASS	:	United Nations General Assembly Special Session
WHO	:	World Health Organization
WTO	:	World Trade Organization

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EXECUTIVE SUMMARY

The Southern African Development Community (SADC) was formally launched on 17th August 2002 under a Treaty, and consists of 14 Member States with an estimated total population of 200 million people. In its programmes and operations, SADC is guided by a clear mission statement, which is "To promote sustainable and equitable economic growth and socio-economic development through efficient productive systems, deeper co-operation and integration, good governance, and durable peace and security, so that the region emerges as a competitive and effective player in international relations and the world economy".

It is worth noting that SADC's integration agenda accords priority to social and human development including fostering of cooperation in addressing health challenges which are reflected in the high burden of both communicable such as HIV and AIDS, Tuberculosis and Malaria and non-communicable diseases which include diabetes, hypertension and cancer. In order to address these challenges, the region has adopted a collective approach and identified health as one of the priority areas in its regional cooperation and integration agenda. To this end, a SADC Health Programme was developed in 1997. The region also prioritized the development of a Protocol on health matters as this was seen as critical for enhancing regional integration within a legally enforceable framework. Three key policy documents have been developed to underpin the implementation of the Programme, namely: Health Policy Framework, SADC Protocol on Health and the Regional Indicative Strategic Development Plan (RISDP). The SADC Health Programme has been developed taking into account global and regional health declarations and targets.

SADC has identified the need to develop and implement a Pharmaceutical Programme in line with the SADC Health Protocol and the SADC Health Policy. The purpose of the programme is to enhance the capacities of Member States to effectively prevent and treat diseases that are of major concern to public health in the Region. The Programme mainly addresses issues that concern access to quality medicines in all Member States. The SADC Pharmaceutical Business Plan has been developed within the context of global, continental and regional policy frameworks, protocols and commitments. Based on a SWOT analysis, the Plan identifies priority

areas, objectives and major activities that will be implemented both at regional and national levels to improve access to quality and affordable essential medicines including African Traditional Medicines.

The overall goal of the SADC Pharmaceutical Business Plan is to ensure availability of essential medicines including African Traditional Medicines to reduce disease burden in the region. Its main objective is to improve sustainable availability and access to affordable, quality, safe, efficacious essential medicines including African Traditional Medicines. In order to achieve the overall goal and the main objective, the following strategies will be pursued:

- i). Harmonizing standard treatment guidelines and essential medicine lists;
- ii). Rationalizing and maximizing the research and production capacity of local and regional pharmaceutical industry of generic essential medicines and African Traditional Medicines;
- iii). Strengthening regulatory capacity, supply and distribution of basic pharmaceutical products through ensuring a fully functional regulatory authority with an adequate enforcement infrastructure;
- iv). Promoting joint procurement of therapeutically beneficial medicines of acceptable safety, proven efficacy and quality to the people who need them most at affordable prices;
- v). 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;
- vi). Developing and retaining competent human resources for the pharmaceutical programme;
- vii). Developing mechanisms to respond to emergency pharmaceutical needs of the region; and
- viii). Facilitate the trade in pharmaceuticals within SADC.

In line with the SADC Protocol on Health, the Implementation Plan for the Protocol and the SADC Health Policy Framework, the SADC Pharmaceutical Business Plan will be coordinated and implemented through the approved SADC structure. The Business Plan has spelt out clear roles and responsibilities of all stakeholders that will be involved in the implementation process. At the political level, the implementation of the Plan will be monitored through the established institutional framework.

The implementation of the Plan will require substantial resources including human, material and financial from different sources. The Plan is estimated to cost US\$16 million. To ensure ownership and sustainability, Member States will be required to budget for implementation of some of the interventions that need ongoing financial support. The SADC Secretariat will make all efforts to mobilize resources from key stakeholders including International Co-operating Partners.

A monitoring and evaluation framework has been included in order to review activities during implementation process. The Secretariat will facilitate capacity building on monitoring and evaluation. Appropriate technical and financial reports will be produced during and after implementation of program specific activities outlined in the Pharmaceutical Business Plan.

1. INTRODUCTION AND BACKGROUND INFORMATION

The 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; Madagascar; Malawi; Mauritius; Mozambique; Namibia; Swaziland; United Republic of Tanzania; South Africa; Zambia; and Zimbabwe. 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, with an average annual population growth rate of 2.2 per cent.

In its programmes and operations, SADC is guided by a clear mission statement, which is "To promote sustainable and equitable economic growth and socio-economic development through efficient productive systems, deeper co-operation and integration, good governance, and durable peace and security, so that the region emerges as a competitive and effective player in international relations and the world economy.

1.1 SADC Health Programme

It is worth noting that SADC's integration agenda accords priority to social and human development including fostering of cooperation in addressing health challenges which are reflected in the high burden of both communicable such as HIV and AIDS, Tuberculosis and Malaria and non-communicable diseases which include diabetes, hypertension and cancer. In order to address these challenges, the region has adopted a collective approach and identified health as one of the priority areas in its regional cooperation and integration agenda. In order to address these challenges, the region has adopted a collective approach and identified health as one of the priority areas in its regional cooperation and integration agenda. To this end, a SADC Health Programme was developed in 1997. The region prioritized the development of a protocol on health matters as this was seen as critical for enhancing regional integration within a legally enforceable framework. Three key policy documents have been developed to underpin the implementation of the

programme, namely: Health Policy Framework, SADC Protocol on Health and the Regional Indicative Strategic Development Plan (RISDP).

The SADC Health Policy Framework aims to attain an acceptable standard of health for all citizens by promoting, coordinating and supporting the individual and collective efforts of Member States to increase access to evidence based high impact health interventions. The goal of the health policy is to reach specific targets of "Health for All in the 21st Century by 2020" in all Member States based on the primary health care strategy. The SADC Health Policy Framework Document was developed by the SADC Health Ministers and approved by the SADC Council of Ministers in September 2000.

The Protocol on Health was approved by the SADC Heads of State in August 1999 and entered into force in August 2004 after ratification by the requisite number of Member States. The Protocol on Health is premised on the belief that a healthy population is a prerequisite for sustainable human development and increased productivity in Member States. It recognizes that close co-operation in the area of health is essential for the effective control of communicable and non communicable diseases and for addressing common health concerns

In order to provide strategic direction to the organization and to operationalise the SADC Common Agenda, a 15 year Regional Indicative Strategic Development Plan (RISDP) was adopted in August 2003 and launched in March 2004. It reaffirms the commitment of SADC Member States to good political, economic and corporate governance entrenched in a culture of democracy, full participation by civil society, transparency and respect for the rule of law. In this Plan, health issues form part of priority areas.

1.2 Global and Regional Health Targets, Declarations and Commitments

The SADC Health Programme has been developed taking into account global and regional health declarations and targets. These include the Millennium Development Goals (MDGs); New Economic Partnership for African Development (NEPAD); Abuja Declaration on HIV/AIDS, Tuberculosis and Other Related Infectious Diseases

(2001); United Nations General Assembly Special Session on HIV and AIDS (UNGASS) 2001; The Maseru Declaration on HIV and AIDS (2003); Brazzaville Commitment on Scaling-up Towards Universal Access to HIV and AIDS prevention; treatment, care and support in Africa by 2010 (2006); and Lusaka Declaration on African Traditional Medicine (2001).

1.3 SADC Pharmaceutical Programme

1.3.1 SADC has identified the need to develop and implement a Pharmaceutical Programme in line with the SADC Health Protocol and the SADC Health Policy. The purpose of the programme is to enhance the capacities of Member States to effectively prevent and treat diseases that are of major concern to public health in the Region such as Human Immunodeficiency Virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS), Tuberculosis (TB), malaria and other communicable and non-communicable diseases. The SADC Pharmaceutical Programme was approved by the Integrated Committee of Ministers (ICM) at its meeting in June, 2004.

1.3.2 The Programme mainly addresses issues that concern access to quality medicines in all Member States. Therefore, it aims at improving the availability of affordable; safe; efficacious; and effective essential medicines of acceptable standard. This should be accompanied by 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. The pharmaceutical programme is one of the priorities under the RISDP.

1.3.3 It is against this background that a Business Plan has been developed in order to operationalize the Programme. The Plan has six main sections which include: Introduction and Background information; Situation Analysis of the Pharmaceuticals in the SADC region; Overall Goal and Main Objective; Institutional Framework; and Monitoring and evaluation.

2. SITUATION ANALYSIS OF PHARMACEUTICALS IN THE SADC REGION

This section analyses the Strengths, Weaknesses, Opportunities and Threats (SWOT) in SADC region on the state of improving access to affordable and quality essential medicines at both regional and national levels reveals the following:

2.1 Strengths

- i). Existence of an enabling strategic policy context and political will as reflected in key policy documents such as the SADC Health Policy Framework, SADC Protocol on Health, the SADC Trade Protocol, Pharmaceutical Programme and the RISDP;
- ii). All SADC Member States have an official or draft national medicines policy,
- iii). as well as medicines legislations and regulations;
- iv). Existence of the Pharmaceutical Regulatory Shared Network;
- v). The SADC region has developed pharmaceutical guidelines for medicines regulation and other strategies aiming to improve access to medicines; and
- vi). All countries in SADC region are members of the World Trade Organization (WTO), which automatically makes them signatory to the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).

2.2 Weaknesses

- i). outdated medicine laws and Intellectual Property Laws which are not TRIPS compliant;
- ii). Government expenditure on health is below the 15% of the total national budget as per Abuja Declaration for most Member States thereby hampering provision of adequate health care delivery;
- iii). weak regulatory systems leading to concerns on quality, safety and efficacy of medicines with many unregistered products on the market, and also the mushrooming of unlicensed wholesalers and retailers with instances of medicines being sold on street markets in some countries;
- iv). lack of regulatory capacities and abilities of medicines authorities in Member States to ensure the quality, safety and efficacy of medicines circulating in their markets;

- v). predominance of Private Sector expenditure on essential medicines in a region with high poverty levels and substantial price disparities which has implications on affordability particularly for the poor and disadvantaged population;
- vi). inadequate national and regional medicine quality control laboratories as reflected in the following: there is one WHO Pharmaceutical Reference Quality Control Laboratory in Zimbabwe and one WHO Collaboration Quality Control Laboratory in South Africa; lack of adequate capacity and properly trained laboratory personnel to conduct relevant tests; inability to access laboratory services due to the high cost of analysis of samples from member states;
- vii). Over dependence on imported medicines both patented and generics. For instance, about 85% of the generic ARV medicines used in the region are imported from India and 15% are manufactured within the SADC region;
- viii). Lack of research and development of medicines for diseases of public health importance and the selection of products is driven largely by market demand. As a result, medicines for some diseases and health conditions are neglected because no viable market exists for these products;
- ix). Inappropriate use of medicines in all SADC Countries. More than half of all medicines in the region are prescribed, dispensed or sold inappropriately, and half of all patients fail to take them correctly;
- x). Inconsistent medicine regulatory procedures and divergent treatment guidelines and essential drug lists;
- xi). Under utilization of installed manufacturing capacities and failure to comply with national medicines regulatory requirements including Good Manufacturing Practice Standards (GMP);
- xii). Unreliable medicine supply systems due to the following: insufficient procurement and supply management capacity; lack of established mechanisms for procurement quality assurance; lack of consumption data and inadequate estimation of needs and forecasting of medicine requirements;
- xiii). Lack of information on prices and use of medicines;
- xiv). Changing clinical needs;

- xv). Unpredictable rate of scaling-up and lack of effective management information systems to aid evidence based decision making;
- xvi). Lack of pricing policies and substantial variation in prices of essential medicines for the same or similar products both within and between countries; and
- xvii). Lack of adequate trained personnel and inappropriate use of available pharmaceutical professionals whereby these are usually tied up with activities that can be dealt with by other trained middle level health workers.

2.3 Opportunities

- i). The SADC region has developed pharmaceutical guidelines for medicines regulation and other strategies aiming to improve access to medicines;
- ii). Development of a policy and legislative framework for regulation and validation of the safety, quality and efficacy as well as appropriate use of African Traditional medicines is essential. Populations throughout the region are using traditional medicines to help meet their primary health care needs. Medicinal plants contain a wealth of active ingredients that are used in the production of essential medicines;
- iii). A large regional market for the pharmaceutical manufacturing industries, which was estimated in 2000 at U\$2.5 - 3 billion, 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 affordable essential medicines to meet public health objectives;
- iv). Advanced medicines quality assurance systems in some Member States can be used for building capacities in other Member States through training and exchange programmes;
- v). Improvement of efficiency in supply chain management systems through regional collaboration and sharing of best practices in public sector procurement. An estimated U\$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 U\$1 0 million; whilst an achievable efficiency gain of 5% can translate into U\$50 million savings per year;

- vi). The TRIPS agreement contains a number of flexibilities and safeguards that allow countries to import or manufacture pharmaceuticals that are still under patent without the consent of the patent holder. So far three Member States namely; Mozambique, Zambia, and Zimbabwe have issued either compulsory licenses or Government use orders to take advantage of the flexibilities to address public health emergencies. A second window of opportunity which could be exploited is contained in paragraph 6 of the WTO decision of August 30th of 2003, which allows regional economic blocs with at least half of its membership being LDCs to trade in pharmaceuticals within the bloc without restrictions. These opportunities can be an effective ways of improving accessibility and lowering medicine prices in the region;
- vii). Improvement of local research and development capacity through transfer of technology and improved public-private partnership. The WHO Commission on Intellectual Property and Public Health issued its final report in April 2006, calling for increased collaboration between industrialized and developing countries as well as South - South Collaboration to facilitate technology transfer in the manufacturing of pharmaceuticals;
- viii). There is great scope for strengthening the Public - Private - Partnership (PPP) given the important roles these sectors are already playing in the pharmaceutical industry; and
- ix). Increase in additional funding sources and mechanisms can continue to improve access to essential medicines.

2.4 Threats

- i). Implementation of approved guidelines will require substantial resources and continued effort both at regional and individual Member State level;
- ii). Current and future bilateral trading agreements could potentially impact negatively on public health concerns, especially on improving access to affordable and quality medicines, unless closely monitored;
- iii). The multiplicity of procurement agencies and unregulated donations with separate administrative and supply system management requirements are stretching the already overwhelmed public sector medicines supply systems;

- iv). Brain drain - Many of the pharmaceutical personnel migrate outside the region thereby aggravating the problem of inadequate human resource capacity to effectively implement the various components of national and regional medicine policies and programmes;
- v). Unethical promotional activities by pharmaceutical manufacturers and suppliers that aggressively promote their products through various means. These promotions entice health professionals including pharmacists and managers dealing within the medicine chain management to engage in unethical activities. These unethical activities include:
 - a) the production of substandard/counterfeit medicines;
 - b) conduct of unethical clinical trials;
 - c) unethical inspection and registration of medicines and premises;
 - d) corruption in the procurement processes;
 - d) distribution of unregistered medicines;
 - e) irrational prescribing practice; and
 - f) irrational dispensing practice.

3. STRATEGIC CONTEXT

The SADC Pharmaceutical Business Plan has been developed within the context of global, continental and regional policy frameworks, protocols and commitments. Based on a SWOT analysis the Plan identifies priority areas, objectives and major activities that will be implemented both at regional and national levels to improve access to quality and affordable essential medicines including African Traditional Medicines.

4. OVERALL GOAL AND MAIN OBJECTIVE OF PHARMACEUTICAL BUSINESS PLAN

The overall goal of the SADC Pharmaceutical Business Plan is to ensure availability of essential medicines including African Traditional Medicines to reduce disease burden in the region.

The main objective is to improve sustainable availability and access to affordable, quality, safe, efficacious essential medicines including African Traditional Medicines. In order to achieve the overall goal and the main objective, the following strategies will be pursued;

- i). Harmonizing standard treatment guidelines and essential medicine lists;
- ii). Rationalizing and maximizing the research and production capacity of local and regional pharmaceutical industry of generic essential medicines and African Traditional Medicines;
- iii). 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 to the people who need them most at affordable prices; 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;
- iv). Developing mechanisms to respond to emergency pharmaceutical needs of the region; and
- v). Facilitate the trade in pharmaceuticals within SADC.

4.1 Priority strategic actions of the Pharmaceutical Business Plan

4.1.1 Harmonizing standard treatment guidelines and essential medicine lists:

- i). Facilitate the review of existing treatment guidelines and essential medicine lists;

- ii). Formulate regional standard treatment guidelines and essential medicines lists; and
- iii). Develop regional guidelines on rational drug use.

4.1.2 Rationalizing and maximizing the research and production capacity of local and regional pharmaceutical industry of generic essential medicines and African Traditional Medicines;

- i). Undertake economic appraisal of existing production capacity and feasible local production for priority medicines and propose mechanisms to maximize those not fully utilized;
- ii). Strengthen local producers capacity to meet current Good Manufacturing Practices (cGMP);
- iii). Facilitate harmonization of fiscal measures and pricing policies on raw materials for producing essential medicines and imported medicines; and
- iv). Facilitate joint ventures and public-private partnership for regional research and production.

4.1.3 Strengthening regulatory capacity, supply and distribution of basic pharmaceutical products.

- i). Assess national medicine regulatory authorities to identify critical areas of weaknesses in control and registration of medicines including African Traditional Medicines;
- ii). Develop strategies to strengthen national medicine regulatory authorities capacity to implement harmonized SADC guidelines;
- iii). Identify and strengthen regional training centres on medicines regulation and quality control matters;
- iv). Facilitate the exchange of information on the safety, quality and efficacy of medicines, vaccines and blood products as well as joint action to control illegal and substandard medicines on the market including counterfeit medicines;
- v). Ascertain capacity of laboratories and facilitate access and testing of essential medicines and African Traditional Medicines;

- vi). Develop/review regulatory environment and strengthen capacity to ethically review and monitor clinical trials.

4.1.5 Promoting joint procurement of therapeutically beneficial medicines of acceptable safety, proven efficacy and quality.

- i). Evaluate the options for pooled procurement for priority medicines and harmonize procurement regulations;
- ii). Identify the priority essential medicines which can bring about the largest savings from pooled procurement or price negotiations;
- iii). Identify and facilitate access to funding sources and finance mechanisms for joint procurement;
- iv). Establish a regional mechanism for pooled procurement of medicines; and
- v). Assess and strengthen national procurement agencies and supply chain management systems.

4.1.6 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.

- i). Examine existing databases for traditional medicines in the region;
- ii). Develop/review policies and legal frameworks for the practice of traditional medicines, codes of ethics and practice for traditional health practitioners as well as protection of indigenous knowledge and practice (recipes);
- iii). Develop and document the knowledge base on traditional medicines and practices including inventories/catalogues of effective traditional medicines and practices, and the development of formularies on traditional medicines;
- iv). Research and documentation on traditional medicines to enhance the role of traditional medicines and promote cooperation with health systems;
- v). Formalize training on traditional medicines knowledge and practice for non traditional health practitioners.

4.1.7 Developing and retaining competent human resources for the pharmaceutical programme within the SADC Human Resources for Health Strategic Framework.

Developing mechanisms to respond to emergency pharmaceutical needs of the region within the framework of Emergency Health Services and Disaster Management.

- 4.1.8 Coordinate the implementation of TRIPS flexibilities to improve access to essential medicines within the SADC region.
- i). Conduct a regional assessment of intellectual property and medicines legislation in countries to determine their TRIPS compliance and adaptability;
 - ii). Identify reliable and specialized legal advice resources both within and outside the SADC region and maintain a roster of legal experts who are able to offer technical assistance on TRIPS;
 - iii). Collaborate with development partners to enable countries to protect, include and take advantage of the flexibilities that exist in the TRIPS Agreement as well as to assist countries in bilateral trade negotiations to conclude agreements that are not detrimental to public health.

5. INSTITUTIONAL FRAMEWORK FOR IMPLEMENTATION OF THE PHARMACEUTICAL BUSINESS PLAN

In line with the SADC Protocol on Health, the Implementation Plan for the Protocol on Health and the SADC Health Policy Framework, the SADC Pharmaceutical Business Plan will be coordinated and implemented through the SADC approved structure. The Business Plan has spelt out clear roles and responsibilities of all stakeholders that will be involved in the implementation process.

At the political level, the implementation of the Plan will be monitored through the established institutional framework. The SADC Ministers of Health, constituted as a subcommittee by the Integrated Committee of Ministers reviews, approves, proposes the Implementation Plan and monitors the implementation of the protocol. All meetings of Ministers of Health will be preceded and supported by a meeting of senior officials, from Departments responsible for health in Member States. Technical sub-committees or Task Teams will be constituted by as and when required. They will have clear terms of reference for the tasks to be undertaken, and

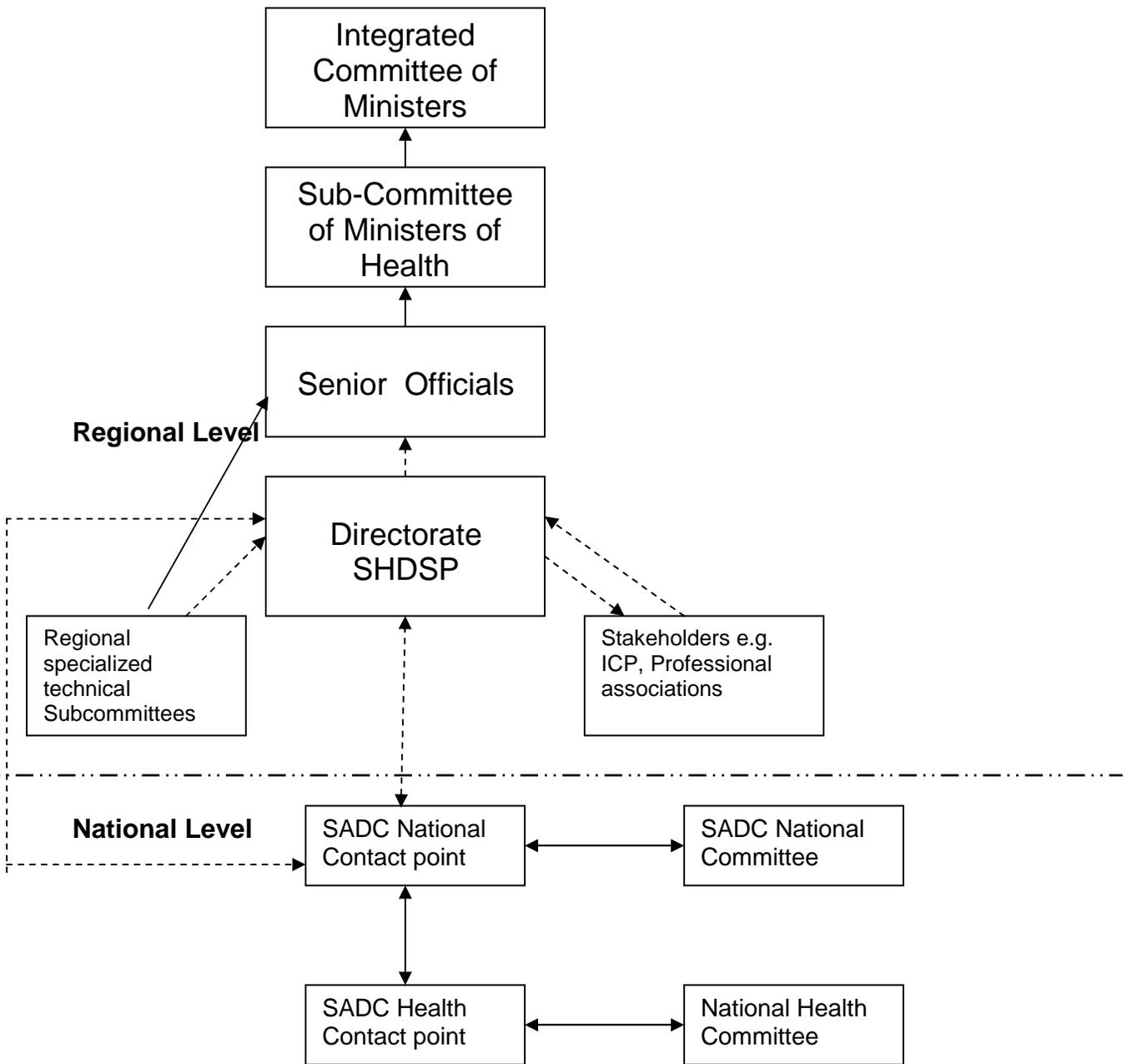
the duration of their assignment will be stipulated. The subcommittees will be required to assist with development of detailed programmes and project plans and to monitor the implementation of these.

The Directorate is responsible for overseeing SADC's response to social and developmental issues. Within the Directorate there is a Health Desk with clearly defined roles and functions in coordinating the implementation of the Plan. Some of these include: development of yearly plans; organizing technical subcommittee meetings; drafting terms of reference for consultancies and studies; dissemination of information to all stakeholders on the implementation of the Plan; compiling reports to ICM on progress made with implementation of the Plan; and mobilizing technical and financial resources.

6. LINKAGES WITH MEMBER STATES

National Health Ministries will support the implementation of the Plan through timely responses to requests by the SADC Health Desk. They will lead implementation of any programmes at a national level and will support the process through assigning resources, including human resources when appropriate. National Health Ministries will report on progresses made regarding the implementation of the Plan through their SADC National Committees.

The following diagram explains the linkages among the different actors in the Plan.



Stakeholders including research institutions, teaching institutions, NGOs, professional councils and associations, regulatory authorities and communities are essential for the successful implementation of the various provisions of the Business Plan. Their role will be to identify areas of co-operation that require their expertise and competency and to assist with implementation of the same. Stakeholders may offer advice, technical assistance, coordination in an area, and material and/or financial resources. Stakeholders will be invited to major fora that review progress with the implementation of the Plan.

7. FINANCING THE PLAN

The implementation of the Plan will require substantial resources including human, material and financial from different sources. The Plan is estimated to cost US\$16 million. The major expenditure items will cover:

- i). Harmonizing standard treatment guidelines and essential medicine lists;
- ii). Rationalizing and maximizing the research and production capacity of local and regional pharmaceutical industry of generic essential medicines and African Traditional Medicines;
- iii). Strengthening regulatory capacity, supply and distribution of basic pharmaceutical products through ensuring a fully functional regulatory authority with an adequate enforcement infrastructure;
- iv). Promoting joint procurement of therapeutically beneficial medicines of acceptable safety, proven efficacy and quality to the people who need them most at affordable prices; 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;
- v). Developing and retaining competent human resources for the pharmaceutical programme; and
- vi). Developing mechanisms to respond to emergency pharmaceutical needs of the region.

To ensure ownership and sustainability, Member States will be required to budget for implementation of some of the interventions that need ongoing financial support. The SADC Secretariat will make all efforts to mobilize resources 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 potential co-operating partners and multilateral and bilateral agencies and organizations. Some stakeholders in the health sector, e.g. research organizations will be approached to support the plan through undertaking specific activities within the plan and coordinate and/or funding specific tasks for the sector.

8. MONITORING AND EVALUATION OF THE BUSINESS PLAN

A monitoring and evaluation framework will be built in order to review activities during implementation. The Secretariat will facilitate capacity building on monitoring and evaluation. The main activities of monitoring and evaluation will include:

- i). reviewing and assessing progress in the implementation of the Plan;
- ii). assessing effective utilization of mobilized funds and other
- iii). resources;
- iv). producing Bi-annual Progress Report by Member States;
- v). reviewing the implementation of SADC Pharmaceutical Business Plan;
- vi). ensure adherence to international requirements for M&E; and
- vii). promoting the use of core indicators.

Appropriate technical and financial reports will be produced during and after implementation of program specific activities outlined in the Pharmaceutical Business Plan.

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Table: SADC Pharmaceutical Programme Matrix – Logframe

HIERARCHY OF OBJECTIVES	EXPECTED OUTCOME	RESPONSIBLE PARTY	PERFORMANCE INDICATORS BY 2013	INDICATIVE TARGETS BY 2015	COST OF ACTIVITY (US\$)	ASSUMPTIONS AND RISKS
<p>Overall Goal:</p> <p>To ensure availability of essential medicines including African Traditional Medicines in order to reduce disease burden in the region.</p>	<p>Long Term Outcome:</p> <p>Improvement in the availability and affordability of quality essential medicines, including African Traditional medicines.</p>	<p>SADC Secretariat and Member States, and key Stakeholders</p>	<p>50 % increase in local production and availability of essential medicines</p>	<p>100 % availability of essential medicines</p> <p>50% reduction in child and maternal morbidity and mortality</p>	<p>15,230,000</p>	<p>Commitment by all stakeholders and availability of resources for implementation of the Plan</p>

Main Strategic Action	Medium term Outcomes	Responsibility	Indicators			Assumptions and risks
Harmonising standard treatment guidelines and essential medicine lists	<p>Treatment guidelines and essential medicines lists developed</p> <p>Regional guidelines on rational drug use developed</p>	SADC Secretariat and Member States	Availability and use of harmonised guidelines and essential medicines lists	Use of standardised treatment guidelines and medicines lists in all member states	200,000	Commitment by Member States and availability of resources

Rationalising and maximising the research and production capacity of local and regional pharmaceutical industry of generic essential medicines and African Traditional Medicines	Economic and financial appraisal undertaken	SADC Secretariat and Member States	Appraisal report compiled and bankable financing proposals prepared	Up to date economic and financial evaluation reports on pharmaceutical industry	700,000	Commitment by Member States and availability of resources
	Capacity building programmes on cGMP developed and training conducted	SADC Secretariat, Member States and Development Partners	At least one training programme per year, at least 30 trainees per year, 2 technical assistance missions/attachme nts per year/Member State		500,000	
	Fiscal measures and pricing policies in place	Secretariat and Member States	Agreement and Government Gazettes on fiscal and pricing policies		700,000	
	Joint venture agreements signed and strategic partnerships formed	SADC Secretariat, Member States, Private Sector and Development Partners	At least one production facility established or strengthened per year		30,000	

Strengthening regulatory capacity, supply and distribution of basic pharmaceutical products.	Weaknesses for the national medicine regulatory authorities Assessed	SADC Secretariat and Member States	Availability of Assessment Report and information of all Member States finalized	Functional national regulatory authorities	400,000	
	Capacity for national medicine regulatory authorities and medicine laboratories ascertained and strengthened		At least one Regional Training Conducted per year.		400,000	
	Regional training centres on medicines regulation control Identified and strengthened		National Laboratories capacity strengthened		400,000	
			Regional Training Programme developed identified			

<p>Promoting joint procurement of therapeutically beneficial medicines of acceptable safety, proven efficacy and quality to the people.</p>	<p>Pooled procurement Evaluation conducted and completed</p> <p>Priority essential medicines for diseases of Public Health Importance listed</p> <p>Access to funding sources and finance mechanisms identified</p> <p>regional mechanism for pooled procurement of medicines Established</p>	<p>SADC Secretariat and Member States</p>	<p>Support Processes for Pooled procurement established</p> <p>Regional Policy on agreement for pooled procurement developed</p>	<p>Essential Medicines available at affordable prices</p> <p>Enhanced Pooled Procurement System</p>	<p>2,000,000</p>	
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<p>Establishing a regional databank of traditional medicine, medicinal plants and procedures.</p>	<p>National databases evaluated</p> <p>legal frameworks for the practice of traditional medicines developed</p> <p>Research and documentation on African Traditional Medicines conducted</p> <p>Training on traditional medicines Formalized</p>	<p>SADC Secretariat and Member States</p>	<p>National Data base on African Traditional Medicines in Place</p>	<p>Effective regulation of African Traditional Medicine in place</p>	<p>3,700,000</p>	
<p>Developing and retaining competent human resources for the pharmaceutical programme.</p>	<p>See SADC HR Strategy</p>	<p>SADC Secretariat and Member States</p>				

Developing mechanisms to respond to emergency pharmaceutical needs of the region.	See SADC Emergency and Disasters management strategy	SADC Secretariat and Member States				
Coordinate the implementation of TRIPS flexibilities to improve access to essential medicines within the SADC region	Regional assessment of intellectual property and medicines legislation in countries conducted Specialized legal advice resources on TRIPS Identified.	SADC Secretariat and Member States	Assessment Report developed Database for TRIPS legal experts developed	100% TRIPS Flexibilities implementation in the region	5,700,000 100,000	

Inputs:						
Grant of US\$15,230,000 million for goods, services and operating costs.	Project coordination in place at SADC	SADC Member States WHO	Grant agreement signed and made effective	Operating costs made available by 2006		