



Strategy for Pooled Procurement of Essential Medicines and Health Commodities, 2013-2017

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ACRONYMS AND ABBREVIATIONS

AfDB	African Development Bank
AIDS	Acquired Immunodeficiency Syndrome
CHAI	Clinton Health Access Initiative
DRC	Democratic Republic of Congo
FOB	Free-on-Board
GDP	Gross Domestic Product
HIV	Human Immunodeficiency Virus
LMIS	Logistics Management Information System
M&E	Monitoring and Evaluation
MSH	Management Sciences for Health
NEPAD	The New Partnership for Africa's Development
NGO	Nongovernmental organisation
PSM	Procurement and supply management
SADC	Southern African Development Community
SHD&SP	Directorate of Human and Social Development and Special Programmes
SOP	Standard operating procedure
SPPS	SADC Pharmaceutical Procurement Services
RISDP	Regional Indicative Strategic Development Plan
TB	Tuberculosis
TIFI	Trade Industry Finance and Investment
TRIPS	Trade Related Aspects of Intellectual Property Rights
UNICEF	United Nations Children's Fund
UNDP	United Nations Development Programme
USD	US dollar
WHO	World Health Organization



DEFINITION OF TERMS

Group contracting	A type of procurement whereby Member States jointly conduct and negotiate tender processes. They establish specifications, quantification, sourcing of suppliers, competitive bidding, technical and financial evaluations and adjudication, and contract awards. Member States agree to purchase from the selected suppliers, but they place purchase orders separately (in other words, the commitment is between the individual Member State and supplier).
Harmonisation	The name given to the efforts of Member States to replace the variety of national pharmaceutical policies, practices and standards currently adopted in favour of uniform regional policies, “good practices” and standards, which are at an internationally acceptable level.
Information sharing	Member States share information about products and suppliers (such as prices, quality, source and suppliers’ performances).
Coordinated informed buying	A type of procurement where Member States undertake joint market research, share suppliers’ performance information and monitor prices. Member States conduct procurement separately.
Good practices	The agreed description of the pharmaceutical organisation, procedures and standards that enable the required quality of service to be delivered, including criteria for organisational structures, personnel, facilities, equipment, materials, all kinds of operations, and quality control.
Pooled procurement	Pooled procurement (also know as joint procurement or procurement cooperation) is the overarching term for procurement where part or all of the procurement processes of different procurement entities (agencies or departments of bigger entities) are jointly executed by either one of those procurement entities or by a third party procurement entity.
Prequalification	An initial evaluation of the capabilities of suppliers (technical and financial) and of the quality of their products to allow them to participate in the procurement process.
Public procurement prices	Free-on-Board (FOB) prices contracted by National Medicines Procurement Agencies in Member States. It is recommended that the public procurement agency knows the FOB prices of the products that are being procured. Only FOB prices allow for analysis of logistics costs (freight, insurance, clearing, etc.), as well as for international benchmarking and comparison within the region. Actual supply contracts may still specify any other INCOTERM that includes freight and other costs, as long as FOB prices are also documented in the supplier’s tender submission and in the procurement agency’s information management system.
Pharmaceutical procurement and supply management system	The pharmaceutical procurement and supply management system is composed of all steps in the procurement and supply system: selection, quantification, shopping, tendering, negotiation, ordering, storing, selling, distributing and dispensing of essential medicines and medical supplies.
Orphan drugs	Medicines used for the diagnosis and/or treatment of rare diseases or conditions.



Quality assurance	The quality assurance of pharmaceutical products is a wide-ranging concept that covers all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made to ensure that pharmaceutical products are of the quality required for their intended use.
Quality control	The quality control of pharmaceutical products is a concept that covers all measures taken—including the setting of specifications, sampling, testing and analytical clearance—to ensure that the raw materials, intermediates, packaging materials and finished pharmaceutical products conform with established specifications for identity, strength, purity and other characteristics.
Tracer medicines	Medicines selected by the surveyors in the 2010 Pharmaceutical Marketing Analysis study, of which the assembled data form the baseline for measuring implementation of the Strategy.
Standardisation	Standardisation is the process of establishing a technical standard, which could be a standard specification, standard test method, standard definition, or standard procedure. Standardisation means that there is a standard specification, unit, instruction or characteristic that is understood globally.
Work sharing	The sharing of “good practices”, as laid down in guidelines, standard operating procedures (SOPs), standard bidding documents, tender adjudication reports, storage conditions, distribution schedules, etc.



EXECUTIVE SUMMARY

One of the priority objectives for the SADC region is “to improve sustainable availability and access to affordable, quality, safe, efficacious essential medicines.” The development of the SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities represents an important step towards that objective.

Studies done in the SADC region between 2009 and 2011 found considerable differences in Member States’ practices of pharmaceutical procurement and supply management (PSM), as well as in the application of regulations and procedures (such as for quality assurance and public procurement). While some Member States comply with a number of internationally accepted principles of procurement, most struggle to do so due to insufficient financial and human resource capacities.

There are opportunities for increasing market efficiencies by using regional approaches to procurement, such as pooled procurement and applying “good practices” in the pharmaceutical PSM systems. With pooled procurement, considerable savings can be made when procurement agencies in Member States practice information and work sharing. The savings release more funds for procurement, which can increase availability of and access to essential medicines and health commodities. Information sharing on product quality and supplier performance can also improve market regulation.

Implementation of the Strategy will follow the principles and approach of results-based management, with a focus on achieving specific outputs and outcomes, timely and efficiently. The proposed entity, the SADC Pharmaceutical Procurement Services (SPPS), will manage implementation of the Strategy while relying on the guidance from relevant SADC structures for policy development, monitoring and evaluation (M&E) functions, general oversight and implementation processes.

Initial funding for implementation of the Strategy will come from Member States and international cooperating partners. The SPPS shall charge a fee for managing regional pooled procurement. The fees, along with the results-based monitoring mechanisms, will strengthen the sustainability of the initiative.

Consensus on the development of the Strategy was achieved through consultations with Member States, partners, the SADC Secretariat, the private sector and civil society, where the following major issues were addressed ahead of presentation to SADC Joint Ministers of Health and HIV and AIDS meeting in 2012:

- Situation analysis of current procurement practices in Member States;
- Goal, principles and models of regional pooled procurement; and
- Structure and scope of the SADC Pharmaceutical Procurement Services.



INTRODUCTION

The SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities provides an overall mechanism for achieving one of the key priorities of the SADC Pharmaceutical Business Plan, which was approved in 2007.

The aim of the Strategy for Pooled Procurement of Essential Medicines and Health Commodities, 2013-2007 is to facilitate regional cooperation in the procurement of essential medicines and health commodities, thus ensuring access to affordable, safe, effective and quality-assured products.

The Southern African Development Community's (SADC) common agenda includes promoting: "sustainable and equitable economic growth and socio-economic development that will ensure poverty alleviation with the ultimate objective of its eradication, enhance the standard and quality of life of the people of Southern Africa and support the socially disadvantaged through regional integration".

SADC's integration agenda prioritises social and human development, including fostering cooperation, in addressing health challenges that are influenced by the high burden of communicable diseases such as HIV and AIDS, tuberculosis (TB) and malaria. Prevalence of non-communicable diseases such as cardiovascular diseases, cancer and diabetes is rapidly increasing.

Global and regional health declarations and targets informed the development of the SADC Health Programme, which was developed in 1997. The Programme is underpinned by three key policy documents:

- *The Health Policy Framework,*
- *The SADC Protocol on Health, and*
- *The Regional Indicative Strategic Development Plan (RISDP).*

Equitable access to adequate healthcare services remains a challenge in the region. SADC has identified the need to develop and implement a Pharmaceutical Programme in line with the SADC Protocol on Health and the SADC Health Policy. The purpose of this 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 specific objective of the Pharmaceutical Programme is to improve "sustainable availability and access to affordable, quality, safe efficacious essential medicines".

The *SADC Pharmaceutical Business Plan* was approved in 2007. The plan sets out the priorities and focus for the SADC Pharmaceutical Programme, a unit within the SADC Social and Human Development and Special Programmes (SHD&SP) Directorate.

The priorities of the *SADC Pharmaceutical Business Plan* includes:

- Strengthening and harmonisation of medicines regulatory systems;
- Undertaking pooled procurement of essential medicines;
- Supporting the local production of essential medicines;
- Supporting and retaining human resources for the pharmaceutical sector;
- Undertaking research into the availability and use of African traditional medicines; and
- Addressing Trade-Related Intellectual (TRIPS) issues to ensure that essential medicines remain available, safe, effective and affordable.

The Strategy for Pooled Procurement reflects issues that go beyond the mandate of the health sector. Issues relating to trade (customs procedures and tariffs, for example), legislation, procurement, financing and investments must also be addressed to facilitate the movement of essential medicines and health commodities across the region. In this regard, a combined effort is needed across SADC to include the relevant sectors and Ministries (such as Health, Trade, Finance, etc.) in order to enhance the seamless circulation of essential medicines within SADC.

The process for developing this Strategy dates back to 1999. In 2010, a drafting team was established to finalise the drafting of the Strategy. The team completed an assessment of pharmaceutical procurement systems across SADC Member States in August 2011. The findings, together with a desk review of the SADC pharmaceutical marketplace, were used to draft the SADC Pooled Procurement of Essential Medicines and Medical Supplies Situational Analysis and Feasibility study. This study forms the basis of the recommended options for the SADC Pooled Procurement Strategy for



Essential Medicines and Health Commodities.

The outputs of the drafting team have been reviewed by technical teams in the SADC Secretariat, including consultations with programme officers from the Directorates of Trade, Industry, Finance and Investment; Policy Planning and Resource Mobilisation; Procurement as well as other regional projects, such as the Communicable Diseases Project and the HIV and AIDS and Malaria programmes. Consensus on the development of the Strategy was achieved through consultations with Member States, partners, private sector and civil society.

This publication presents the proposed Strategy under a series of headings, starting with the Introduction, which is followed by the findings of the Situational Analysis. The Rationale for the proposed mechanism for pooled procurement is then presented together with a section on the expected benefits for SADC. The Values and Principles, Vision, Purpose, Strategic Objectives, and Results Framework are then outlined, and include an indicative budget and Institutional Arrangements for Implementation of the Strategy. The final sections concern Monitoring & Evaluation and Resource Mobilisation.

2. SITUATIONAL ANALYSIS

2.1 Introduction and approach

It is generally acknowledged that SADC Member States face challenges in ensuring the availability of quality and affordable essential medicines. The economies of SADC Member States differ in size, with GDP per capita ranging from USD 291 (in the DRC) to USD 10 818 (in Seychelles) in 2010. The sizes of Member States' populations also vary, from just over 72 million in the DRC to 87,000 in Seychelles, while the burdens of disease also differ in the region. These differences lead to various types of strain on pharmaceutical markets, and on the availability and affordability of essential medicines.

There is a paucity of information in the region on the full extent of these challenges. Data gathering can be difficult in some Member States, due to limitations in information management systems, a lack of harmonisation regarding treatment guidelines, and a lack of standardisation in terms of procurement and payment systems. However, regional policies, strategic interventions and decisions towards ensuring sustainable access to essential medicines must be evidenced-based. Using the available information from desk reviews and key information interviews with staff from pharmaceutical policy, regulatory and central procurement agencies, the situational analysis was able to provide some information on the availability of medicines, the products that are circulating in the region, current manufacturers and suppliers, prices that Member States are paying for procurement, as well as on the registration and regulation of some medicines.

Information on the availability, prices and registration status of medicines was summarised from the 2010 Pharmaceutical Market Analysis. It identified 50 tracer medicines and included medicines to treat malaria, TB, and HIV and AIDS, and medicines for child and maternal health and non-communicable diseases. These tracer medicines are presented in the Annex.

2.2 Problem analysis

From the situational analysis, eight key challenges in SADC PSM systems were identified.

1. Information on pharmaceutical procurement is not easily accessible in the SADC region. The level of transparency in public and private pharmaceutical markets is also rather low:
 - Little information was available in the public domain, and almost all information had to be collected from primary sources;
 - Public procurement agencies could not easily provide price and other purchase information; and
 - Private sector information was either very difficult or expensive to obtain. Namibia and South Africa provided this information at a price.
2. The average duration for which tracer items were found to be out of stock during a recent 12 months period varied between 3% and 70%, which indicates that the availability of essential medicines varies considerably between Member States. This information was available for Botswana, DRC, Lesotho, Seychelles, Zambia and Zimbabwe.



3. The lack of standardisation regarding procurement and price information made it difficult to compare information. Public sector procurement prices (using FOB prices where those were available, or estimating FOB prices where they were not available) were compared to the international benchmark price stated as FOB. For the majority of products in a group of 50 tracer items, the ratio between the highest and lowest prices among 13 SADC Member States was greater than 5—i.e. the prices varied up to five-fold between the countries. For 8% of the items, prices varied more than 50-fold, i.e. the highest price paid was more than 50 times more than the lowest price.
4. Data on pharmaceutical budgets and expenditure is hard to obtain. In addition, most Member States rely considerably on donor support for purchasing essential medicines, especially for HIV and AIDS, malaria and TB.
5. SADC Member States are at various levels of pharmaceutical sector development and pharmaceutical services delivery, as well as in the application of regulations and procedures, such as for quality assurance and public procurement.
6. Four Member States do not have a medicines regulatory authority that is responsible for regulating the quality of medicines on the market. Five countries do not actively register medicines (Angola, DRC, Lesotho, Seychelles and Swaziland). The capacities of Member states' regulatory authorities that are responsible for assessing and approving medicines are severely limited. Medicines allowed in one Member State are not automatically allowed for use in other Member States.
7. The median number of available pharmaceutical personnel (defined as pharmacists, pharmacy assistants, pharmacy technicians and related occupations) is 0.7, and varies from 0.3 to 7 per 10,000 inhabitants. Although there is no international recommended ratio for pharmaceutical human resources, these figures suggest that there are serious shortages of qualified personnel in a number of SADC countries.
8. No information was provided on the use of Trade Related Intellectual Property (TRIPS) flexibilities in national legislation to increase access to essential medicines. While the SADC Directorate for Trade, Industry, Finance and Investment (TIFI) is working with the Ministries of Finance, Trade and Industry, there is little coordination between these Ministries and the Health Ministries, both at national and regional levels.

2.3 Response analysis

The response analysis identified strategies that have been adopted regionally and nationally to improve the availability, affordability and quality of essential medicines:

- National medicines policy and regulations are fairly similar in all SADC Member States. All have a National Medicines Policy and Essential Medicines List in place, and all but one (South Africa) have a Public Procurement Act;
- SADC Member States were found to apply most of the internationally accepted Operational Principles for Good Pharmaceutical Procurement;
- There are three WHO pre-qualified quality control laboratories among the 42 laboratories in SADC—one is in Tanzania and two are in South Africa;
- While there appears to be no common approach from Member States toward duties and taxes on pharmaceutical products or the raw materials needed to produce pharmaceutical products, import duties are harmonised in the International Customs Code. The SADC Directorate of TIFI maintains a regional database of duties, taxes and tariffs; and
- Overall, there are also 14 approved regional guidelines that support regulatory harmonisation in medicines registration.

3. RATIONALE AND FEASIBILITY

From the situational analysis it is clear that progress has been made across the SADC region in improving access to essential medicines. However, limited resources, a lack of standardisation in approaches to PSM systems, and a lack of regional pharmaceutical market intelligence hamper further progress. Market intelligence is critical for improved decision-making, increased efficiency, good governance and transparency, all of which ultimately facilitate SADC's objectives of



ensuring that all citizens have equitable access to affordable, safe and effective essential medicines. In such a context the rationale for the pooled procurement of essential medicines and health commodities is there. This will be implemented in a phased approach, beginning with information and work sharing, and progressively moving towards group contracting, as PSM systems across Member States reach the required minimum standards of good practice.

3.1 Understandings and models of pooled procurement

Pooled procurement is the overarching term used where part or all of the procurement processes of different procurement entities (agencies or departments of bigger entities) are jointly executed by either one of those procurement entities or a third party procurement entity.

Successful procurement depends on technical capacity, financial resources, good information systems, efficient management and availability of suppliers. Effective policies, legislation, regulations and guidelines underpin the processes. Strong political will and economic commitment are needed to support pooled procurement.

Table 1: Four models of pooled procurement

MODEL	DESCRIPTION
Informed buying	Member States share information about prices and suppliers, but undertake individual procurement.
Coordinated informed buying	Member States undertake joint market research, share supplier performance information and monitor prices. Countries undertake individual procurement.
Group contracting	Member States jointly negotiate prices and select suppliers. Countries agree to purchase, individually, from selected suppliers.
Central contracting and purchasing	Member States jointly conduct tenders and awards contracts through an organisation acting on their behalf. A central buying unit manages the purchase on behalf of countries.

Source: Adapted from MSH, 2012.

3.2 Pooled procurement for SADC

The recommended option for pooled procurement of essential medicines for SADC is the group-contracting model, delivered incrementally through a staged approach that starts with coordinated information exchange and work sharing.

This strategy allows for all Member States to reach minimum standards of acceptable PSM systems, while allowing those Member States that have attained higher PSM standards to move towards more rapidly adopting group contracting.

The staged approach is in accordance with the principles of regional integration, as espoused by the RISDP. Implementation will follow progressive stages and build upon them. The expected results of this approach, together with implementation timeframes and responsibilities, are shown in Table 2.



Table 2: SADC pooled procurement option with stages, benefits and timelines

STAGE	BENEFITS/RESULTS	TIME FRAMES
1. Coordinated information sharing on medicines quality, prices, suppliers, availability and registration.	<ul style="list-style-type: none"> Increased suppliers base per Member State with resulting increased competition (more sources per product) Increased transparency Joint monitoring of quality Lower prices 	Initiated in year one; ongoing
2. Development and implementation of agreed regional “good practices”	<ul style="list-style-type: none"> Standardisation and harmonisation of “good practices” Decreased risk of quality problems 	Year 1 – Development; Year 2 – Implementation; ongoing
3. Coordinated work sharing through exchange of existing “good practices” among Member States	<ul style="list-style-type: none"> Increased professional experts base Increased performance of pharmaceutical procurement agencies 	Year 2 – Identify good practices Year 3 – Undertake exchange programmes
4. Establishment of the Coordination Entity: SPPS	<ul style="list-style-type: none"> Independent entity to coordinate and manage the Pooled Procurement Strategy. 	Year 2-3
5. Regional tendering for prequalification of regional suppliers and products.	<ul style="list-style-type: none"> Regional market for quality suppliers and products Increased market per supplier 	Year 2 – Development of tender documents, pre-qualification guidelines. Year 3 – Implementation; ongoing
6. Regional framework contracts with suppliers under which Member States purchase directly from suppliers (group contracting).	<ul style="list-style-type: none"> Increased efficiency and cost-effectiveness Increased availability and access 	Year 3 – Development of guidelines for contracting Year 4 – Implementation of guidelines; ongoing

3.3 Benefits of pooled procurement

The rationale for pooled procurement is to have quality essential pharmaceutical products available in the market at lower costs. With pooled procurement, considerable savings can be expected at the stage of information and work sharing by procurement agencies in Member States. The development and implementation of regional standards and procedures will lead to increased efficiency and more rapid procurement cycles, which in turn will lead to increased availability.

Pooled procurement will lead to savings and more affordable medicines. With a total population of just under 300 million and an anticipated SADC pharmaceutical market in the region of USD 4.1 billion, annual price reduction savings in the region of hundreds of millions of USD can be achieved with successful pooled procurement. The savings would enable greater access to essential medicines. Products with high inter-country maximum/minimum variations for procurement prices are expected to have the biggest potential for price reductions. From the situational analysis, products that show the highest maximum/minimum ratios for common Top 50 items were observed for anti-infectives and paracetamol



tablets.

Through the regional pharmaceutical procurement agency, improvements will be achieved in PSM systems. Member States with small populations will benefit from the economies of scale that are generated through joint procurement. There will also be increased availability of orphan drugs, which are otherwise hard to obtain due to the small quantities that individual Member States require.

The SADC regulatory harmonisation initiatives will facilitate access to quality-assured, safe and effective medicines.

4. VALUES AND PRINCIPLES

The core values and principles that guide the regional integration and cooperation agenda of SADC, as stated in the SADC Treaty and the RISDP, shall underpin the Strategy for Pooled Procurement:

- Human rights,
- Transparency,
- Equity,
- Gender,
- Sustainable ownership,
- Efficiency and quality, and
- The principle of subsidiarity.

5. VISION

The vision underpinning the SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities is that of a Southern African region that is able to maintain the highest standards of health for all.

6. PURPOSE

The purpose of the SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities is to contribute to improving the availability of, and access to affordable, quality, safe and efficacious essential medicines.

7. STRATEGIC OBJECTIVES

The following strategic objectives will allow SADC to achieve the vision and purpose of the SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities:

- Establish a mechanism for regional procurement of medicines and related health commodities;
- Mobilise and coordinate resources for the SADC regional procurement for essential medicines and health commodities;
- Develop and harmonise policies, guidelines and legislation for procurement of essential medicines and health commodities; and
- Facilitate trade and movement of essential medicines and health commodities in the region.

In line with the strategic objectives, the key outcomes of the Strategy will be:

- Improved coordination of regional activities;
- Improved capacity for procurement of essential medicines and health commodities;
- Improved resources for the SADC regional procurement of essential medicines and health commodities;
- Developed and harmonised SADC policies, guidelines and legislation for the procurement of essential medicines; and
- Enhanced trade facilitation and movement of essential medicines and health commodities.

The corresponding major outputs, key performance indicators, time frame and indicative costs for the realisation of the stated outcomes or results are described in the Results Framework below.



8. RESULTS FRAMEWORK

Outcomes	Outputs	Activities	Key performance indicators	Means of verification	Timeframe					Responsible	Indicative budget	Risks and Assumptions
					Y 1	Y 2	Y 3	Y 4	Y 5			
Strategic Objective 1: To establish a mechanism for regional procurement of essential medicines and health commodities												
1.1 Improved coordination of regional procurement activities	1.1.1 Mechanism for the coordination of pooled procurement established and operational	SADC Secretariat to facilitate the coordination of the first phase of the Pooled Procurement Strategy, i.e. information and work sharing.	Level of participation by Member States Information and worksharing platforms established	Implementation progress reports Progress reports	x	x	x	x	x	SADC Secretariat and Member states, international cooperating partners	1 500 000	Key risks or assumptions for realisation of the agreed activities include: 1. Level of buy-in from Member States. 2. Willingness to exchange information by all stakeholders. 3. ICT infrastructure (availability of off-the-shelf customisable software and suitability of the application for the low internet bandwidth environment of SADC) 4. Commitment to approve policy-related documents timely 5. Adherence to regulatory requirements
		Establish an oversight mechanism for coordination of Pooled Procurement activities.	Oversight mechanism established			x	x	x	x	SADC Secretariat and Member states	50 000	
	Establish an entity, SADC Pharmaceutical Procurement Services (SPPS), for managing the regional Pooled Procurement Services through principles of subsidiarity	Entity established Number of contracts signed through the entity					x		SADC Secretariat and Member States	To be determined part of above		
	1.1.2 Resources for proposed regional procurement mechanism, system or model mobilised	Mobilise resource for establishment of mechanism, system or model for procurement of essential medicines and health commodities	Amount of funds mobilised from Member States and relevant stakeholders	Report on resource mobilisation for proposed mechanism, system or model	x	x				SADC Secretariat and Member States		
	1.1.3 Inventory of major suppliers and prices of essential medicines done	Conduct an inventory of major suppliers and prices of essential medicines	A comprehensive list of major suppliers and prices of essential medicines prepared and distributed in Member States	List of major suppliers and prices		x	x			SADC Secretariat and Member States		



Outcomes	Outputs	Activities	Key performance indicators	Means of verification	Timeframe					Responsible	Indicative budget	Risks and Assumptions
					Y 1	Y 2	Y 3	Y 4	Y 5			
	1.1.4 Electronic database for the exchange of information on major suppliers and prices of essential medicines developed and operational information sharing platform in Member States conducted	Create electronic database to facilitate information exchange on major suppliers and prices of essential medicines information sharing platform	Type of information available on the database Number of Members States accessing and using the database sensitised on the information sharing platform Number of public procurement entities using the available information	Functional database	x	x				SADC Secretariat and Member States		
	1.1.5 Sensitisation on information sharing platform in Member States conducted	Sensitise Member States on the information sharing platform	Number of Members States sensitised on the information sharing platform Number of public procurement entities using the available information	Progress reports	x	x				SADC Secretariat	40 000	
	1.1.6 Business plan (including systems, Standard Operating Procedures, SOPs, for work-sharing) produced and operational	Develop a business plan (including systems and SOPs for work-sharing)	Business plan and SOPs developed and validated	Business plan and SOPs	x	x				SADC Secretariat and Member States		
	1.1.7 SADC Framework for group contracting developed and functional	Develop a SADC framework for group contracting	SADC framework for group contracting developed	Progress reports Transaction records	x	x				SADC Secretariat	40 000	
1.2 Improved capacity for procurement of essential medicines and health commodities			Extent of improvement in efficiency in procurement practices	Mini survey report								
	1.2.1 PSM capacity plan developed and available	Develop PSM capacity plan	PSM capacity plan prepared and approved	Capacity plan		x	x			SADC Secretariat Member States	40 000	
	1.2.2 Logistics Management Information System (LMIS) developed and functional	Develop and implement LMIS	Number of Member States submitting progress reports in accordance with agreed standards and formats	Information clearing-house Database	x	x	x	x		SADC Secretariat Member States	20 000	



Outcomes	Outputs	Activities	Key performance indicators	Means of verification	Timeframe					Responsible	Indicative budget	Risks and Assumptions
					Y 1	Y 2	Y 3	Y 4	Y 5			
Strategic objective 2: To mobilise and coordinate resources for the SADC regional procurement of essential medicines and health commodities												
2.1 Improved resources for the SADC regional procurement of essential medicines and health commodities			% of national budget allocated for pooled procurement of essential medicines and health commodities	Budget reports								
	2.1.1 Needs identification on existing resources (financial, human and IT resources) conducted	Conduct an inventory and needs identification, mapping on existing resources	Number and type of resources identified	Needs identification report	x	x				SADC Secretariat	200 000	
	2.1.2 Resources to support pooled procurement mobilised and available	Mobilise resources to support pooled procurement	% of budget allocated to pooled procurement Number of personnel recruited Type of equipment purchased % of resources raised from partners	Inventory report Budget document	x	x	x	x	x	SADC Secretariat and Member States		
Strategic objective 3: To develop and harmonise policies, guidelines and legislation for procurement of essential medicines and health commodities												
3.1 Developed and harmonise SADC policies and guidelines and legislation for procurement of essential medicines			Types of SADC policies and guidelines developed and approved Number of Member States that have domesticated the policies and guidelines	Progress reports MTR and ETE reports								
	3.1.1 Internationally accepted standards for good pharmaceutical procurement identified and disseminated	Identify internationally accepted standards for good pharmaceutical procurement that may be applicable at SADC and Member State levels	Number and types of standards for good pharmaceutical procurement identified	Inventory report	x					SADC Secretariat	20 000	
	3.1.2 International principles and standards selected and available	Select the required international principles and standards for good pharmaceutical procurement	Number and type of principles and standards selected	Inventory report	x	x				SADC Secretariat Member States	40 000	
	3.1.3 National PSM structures in Member States reviewed	Conduct an assessment on existing PSM structures in Member States	Disparities in PSM structures in Member States identified	Assessment report	x					SADC Secretariat Member States	15 000	



Outcomes	Outputs	Activities	Key performance indicators	Means of verification	Timeframe					Responsible	Indicative budget	Risks and Assumptions
					Y 1	Y 2	Y 3	Y 4	Y 5			
	3.1.4 SADC Pharmaceutical procurement policy and guidelines developed and available, including promotion of regional pharmaceutical manufacturing (allowing domestic preference)	Develop or prepare SADC Pooled Pharmaceutical Procurement Policy Guidelines	Policy guidelines developed and approved according to standards	Policy guidelines document	x	x	x	x		SADC Secretariat and Member States	40 000	
	3.1.5 Awareness campaigns on SADC Pooled Pharmaceutical Procurement Policy Guidelines conducted in Member States	Conduct awareness-creation campaigns in Member States on approved Pooled Pharmaceutical Procurement Policy Guidelines	Number of Member States sensitised on policy guidelines	Sensitisation reports	x	x	x	x	x	SADC Secretariat	50 000	
	3.1.6. Policy guidelines domesticated	Implement the developed policy guidelines	Number of Member States that have domesticated the policy guidelines Level of implementation of policy guidelines	Progress reports			x	x	x	SADC Secretariat and		
	3.1.7 Policy guidelines monitored	Monitor implementation of policy guidelines using agreed M&E tools	Level of implementation of policy guidelines	Progress reports MTR and ETE Reports	x	x	x	x	x	SADC Secretariat and Member States		
	3.1.8 Treatment protocols harmonised	Support to harmonisation of treatment protocols	Number of Member States with harmonised treatment protocols	Progress reports, Member State treatment protocol publications	x	x	x	x	x	SADC Secretariat and Member States		
Strategic Objective 4: To facilitate trade and movement of essential medicines and health commodities within the region												
4.1 Enhanced trade facilitation and movement of essential medicine and health commodities			Number of days and documentation required for clearance of essential medicines and health commodities reduced at Customs Number of non-tariff barriers reduced	Progress reports MTR and ETE reports								
	4.1.1 List of essential medicines and health commodities and respective tariff information identified and available	Identify list of essential medicines and health commodities and respective tariff information	Types of essential medicines and tariff information identified	Draft list		x				SADC Secretariat	10 000	



Outcomes	Outputs	Activities	Key performance indicators	Means of verification	Timeframe					Responsible	Indicative budget	Risks and Assumptions
					Y 1	Y 2	Y 3	Y 4	Y 5			
	4.1.2 Inventory of existing tax and duties conducted	Conduct a comprehensive inventory of existing tax and duties, and analyse their effect	Type of duties and taxes identified	Rates of duties and taxes analysis report	x	x				SADC Secretariat (Customs)	20 000	
	4.1.3 Various regulatory requirements other than Customs for import and export of essential medicines and health commodities identified	Identify and facilitate simplification of various regulatory requirements other than Customs for import and export of essential medicines and health commodities	Number and type of regulatory requirements identified	List of regulatory requirements	x	x	x			SADC Secretariat and Member States	20 000	
	4.1.4 Regulatory requirements for import and export of essential medicines and health commodities disseminated	Disseminate or publish identified list of Customs and regulatory requirements for import and export of essential medicines and health commodities to Member States	Type of regulatory requirements disseminated	SADC website			x			SADC Secretariat and Member States	5 000	
	4.1.5 Non-tariff barriers for essential medicines and health commodities using the online mechanism (www.tradebarriers.org) identified	Identify and resolve non-tariff barriers for essential medicines and health commodities using the online mechanism (www.tradebarriers.org)	Number of non-tariff barriers resolved	Tripartite NTB online mechanism website	x	x	x	x	x	Member States and SADC Secretariat	5 000	
	4.1.6 Legislation on PSM in Member States reviewed	Conduct assessment to determine relevant legislation PSM in Member States	Disparities in legislation on PSM in Member States identified	Assessment report				x		SADC Secretariat and Member States	20 000	
	4.1.7 Regional assessment of intellectual property and medicines conducted	Conduct a regional assessment of intellectual property and medicines legislation in countries to determine their TRIPs and adaptability	Number of Member States participated in the assessment	Assessment report	x	x				SADC Secretariat	20 000	
	4.1.8 Tender for prequalification of suppliers and products conducted	Ensure quality assured medicines through regulatory harmonisation to allow for a SADC prequalification system	List of prequalified SADC suppliers and products prepared and updated	List of prequalified SADC suppliers and products published on SADC website	x	x	x	x	x	Member States SADC Secretariat Regulatory Forum	50 000	



Outcomes	Outputs	Activities	Key performance indicators	Means of verification	Timeframe					Responsible	Indicative budget	Risks and Assumptions
					Y 1	Y 2	Y 3	Y 4	Y 5			
	4.1.9 TRIPS exemptions available to SADC for medicines implemented	Provide support to fully utilise TRIPS exemptions available to SADC Member States	Number of Member States that fully utilise TRIPS exemptions	Review reports	x	x	x	x		Member States	140 000	
Total											2 550 000	

9. COORDINATION AND IMPLEMENTATION OF THE STRATEGY

9.1 Institutional arrangements

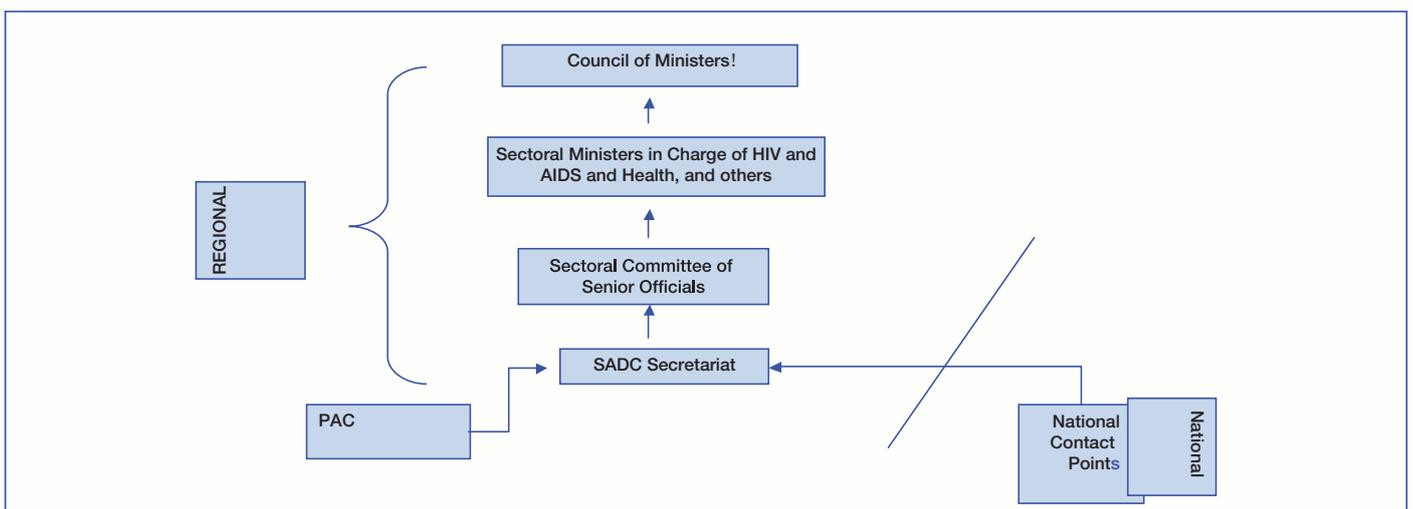
The SADC Council of Ministers will address major policy and budgetary issues that affect implementation of the Strategy. The Strategy involves issues that go beyond the mandate of the health sector. Implementation will therefore occur in collaboration between multiple ministries, including the Health, Trade, Finance, Justice and Industry ministries. The forum of Ministers for Health and HIV and AIDS will approve the Strategy, as well as facilitate implementation at the national level.

Under the leadership of the Director of the Directorate of Human and Social Development and Special Programmes of the SADC Secretariat, the Senior Programme Officer for Health and Pharmaceuticals will coordinate activities related to the implementation, monitoring and evaluation of the Strategy as part of the SADC Pharmaceutical Programme. This will be done with financial and technical assistance provided by international cooperating partners and Member States.

The existing forum of the Pharmaceutical Advisory Committee (consisting of representatives from Member States, UN partners, civil society and professional associations) will oversee implementation of the Strategy.

Activities in the first phase will mainly involve information and work sharing, as well as preparations to set up the SADC Pharmaceutical Procurement Services (SPPS). Management and coordination in this phase will be coordinated by the Senior Programme Officer for Health and Pharmaceuticals of the Directorate of Human and Social Development and Special Programmes (SHD&SP) in the SADC Secretariat. The SPPS is expected to be established at the beginning of the third year of implementation and will take full responsibility for all executive tasks from that point onwards. The SPPS will manage the daily operations of the services. In order to ensure the independence of the services, a Board shall be appointed; SPPS will report to it.

Figure 1: Institutional arrangements for the SADC Strategy for Pooled Procurement of Essential Medicines and Commodities





9.2 Operational arrangements

The SHD&SP Senior Programme Officer in the SADC Secretariat will coordinate the activities relating to information and work sharing, as well as the necessary preparations for setting up the SPPS planned for the first phase of implementation. Initially, information and work sharing electronic platforms will be tested in a pilot among a few Member States, after which these platforms are expected to become fully operational.

After its establishment in the Strategy's second year of implementation, the SPPS will coordinate and manage the pooled procurement process.

The SPPS will be established under the principle of subsidiarity. Its functions will be to:

- Technically coordinate the information and work sharing via shared electronic platform;
- Monitor, support and assure adherence to SADC Pharmaceutical Pooled Procurement Policy Guidelines in the Member States;
- Implement and adhere to good pharmaceutical procurement practices for essential medicines, especially for HIV and AIDS, TB and malaria;
- Reconcile needs and funds for pooled pharmaceutical procurement;
- Specify contractual terms and conditions;
- Tender/competitive bidding for medicines on behalf of Member States in accordance with the best public procurement principles. Negotiate affordable prices with pre-qualified suppliers and manufacturers on behalf of Member States;
- Monitor framework contracts and resolve issues related to orders placed by Member States;
- Perform any other activity needed in order to ensure the efficient pooled pharmaceutical procurement;
- Provide (e-)procurement services; and
- Ensure sustainability by generating revenue from fees for procurement services (including e-services) and technical assistance performed for Member States and other interested parties.

10. MONITORING AND EVALUATION

The Results Framework of the Strategy will form the main M&E tool, which is guided by the principles of results-based management, and by the SADC Policy on Strategy Development, Planning, Monitoring and Evaluation. The objectives of the M&E mechanism of the Strategy are to:

- Ensure that the outputs and outcomes are being achieved as planned; and
- Provide regular information to all stakeholders on progress to inform any reviews.

10.1 Output monitoring

In line with the Results Framework of the Strategy, the SADC Secretariat and the SPPS will put in place the following measures to ensure implementation of the planned activities and delivery of outputs:

- Set baselines and targets on availability and affordability of essential medicines and health commodities in the region;
- Develop relevant M&E tools and templates (such as M&E plans at national level, field monitoring visit reports and standard progress reports) that will guide the collection, analysis, dissemination and utilisation of data on key indicators and targets;
- Carry out active pharmaceutical surveillance in Member States through annual field visits to review the PSM systems;
- Conduct periodic review meetings of relevant stakeholders to assess progress; and
- Produce standard progress reports twice a year. These will be specifically produced by the SPPS through the SADC Pharmaceutical Advisory Committee to the SADC Secretariat, which will submit an annual report to the SADC Ministers of Health.



10.2 Outcome and impact evaluation

The SADC Secretariat will facilitate an external mid-term review for 2015 and an end-term evaluation for 2017. Both reviews will provide feedback on the efficiency, effectiveness and relevance of the Strategy in achieving the strategic objectives. The report of findings and recommendations of the mid-term review will be widely shared with all stakeholders and shall be used to modify outputs, as necessary. The outcome of the end-term evaluation will be used to design and inform future interventions.

The SADC Secretariat will work closely with Member States and key partners to ensure continuous collection and analysis of data in order to facilitate M&E as described above. At national level, access to data on essential medicines and health commodities from sources such as central medical stores and health care facilities will be facilitated by Heads of Pharmaceutical Services with support from a assigned personnel who are conversant with M&E.

11. RESOURCE MOBILISATION

The key to successful implementation of this Strategy is the availability of financial, technical and human resources. Limited technical assistance may be required in the form of intermittent technical support or secondment of staff from Member States when required.

Initial support for the establishment of the SPPS, and the work and information sharing platforms shall come from Member States, the AfDB-funded Communicable Disease Project and the UKAID-funded Southern African Regional Programme on Access to Medicines and Diagnostics project. At the national level, Member States will be urged to increase budgetary allocations for pooled procurement. These funds will be used to both purchase medicines through this Strategy, as well as pay the agreed fees to the SPPS for managing the services. This will ensure sustainability and ownership of the services.

The SADC Secretariat will make available financial resources to monitor and evaluate the Strategy.



REFERENCES

DFID-SA. *Southern African Regional Programme on Access to Medicines: Pharmaceutical Market Analysis*, Pretoria: DFID-SA;2010.

SADC. *SADC Protocol on Health*. Gaborone: SADC Secretariat; 1999.

SHD&SP. *Directorate Report of the Situational Analysis and Feasibility Study*. Gaborone: SADC; 2011.

SHD&SP Directorate. *SADC Pharmaceutical Business Plan 2007–2013*. Gaborone: SADC; 2007.

TIFI Directorate. *Review of Economic Performance*. Gaborone: SADC; 2010.

WHO. *Baseline Assessment of the Pharmaceutical Situation in Southern African Development Community Countries, Fact Book 2009*. Geneva: WHO; 2010.

WHO. *Operational Principles for Good Pharmaceutical Procurement*. Geneva: WHO; 1999. Available at www.who.int/3by5/en/who-edm-par-99-5.pdf



ANNEX: LIST OF MEDICINES ASSESSED IN THE FEASIBILITY STUDY

aciclovir 200mg tablet
albendazole 400mg tablet
amitriptyline 25mg tablet
Amodiaquine 150-200mg tablet
amoxicillin 125mg/5ml suspension
amoxicillin 500mg tablet/capsule
artemether + lumefantrine 20+120mg tablet
bleomycin 15iu inj
captopril 25mg tablet
carbamazepine 200mg tablet
ceftriaxone 250mg pwd for injection
cephalexin 250mg tablet
chloramphenicol 250mg capsule
chlorpheniramine 4mg tablet
chloroquine 150mg tablet
ciprofloxacin 500mg tablet
clotrimazole 100mg pessary
cotrimoxazole 240mg suspension
cotrimoxazole 480mg tab
diazepam 5mg tablet
diclofenac 50mg tablet
DPT vaccine injection
erythromycin 250mg tablet
ferrous sulfate/ folic acid 200-0.40mg tablet
glibenclamide 5mg tablet
insulin isophane 100IU/ml injection
Lamivudine/Stavudine/ Nevirapine 30+6+50mg dispersible tablet
levonorgestrel 0.75 mg tablet
lopinavir/ritonavir 200+50mg tablet heat-stable
magnesium sulphate 500mg/ml injection
measles vaccine
medroxyprogesteron acetate 150mg/ml injection
metformin 500mg tablet



metronidazole 200mg -250mg tablet
nystatin 100,00 IU pessary
omeprazole 20mg tablet
oral rehydration salts (WHO formulation) sachet
oxytocin 10IU/ml injection
paracetamol 120mg/5ml suspension
penicillin benzathine 2.4 MU powder for injection
rifampicin/isoniazid (150 + 75)mg tablet adults
rifampicin/isoniazid/ pyrazinamid 60+30+150mg dispersible tablet
salbutamol 100mcg/dose inhaler
simvastatin 20mg tablet
sodium valproate 200mg/5ml syrup
sulfadoxine + pyremethamine 500+25mg tablet
tamoxifen 20mg tablet
Tetracycline 1% eye ointment
Zidovudine 300mg + Lamivudine 150mg (3TC) tablet
zinc sulfate 20mg dispersable tablet





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