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SADC Pooled Procurement of Essential Medicines and Medical Supplies Situational Analysis and Feasibility Study

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ENGLISH

Acknowledgements

This situational analysis and feasibility study was undertaken as part of the development of the SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities. This report was informed by a desk review, survey and telephonic interviews with the officials in charge of pharmaceutical services in SADC Member States.

The work was carried out by the consultant, Mr Rob Verhage, under the general direction of the SADC Secretariat. The consultant's findings guided the discussions of the drafting team which comprised experts from the Ministries of Health in Angola, Botswana, Democratic Republic of Congo (DRC), Namibia, South Africa, Swaziland, Zambia and Zimbabwe, as well as partners and SADC Secretariat staff. Two regional workshops were held to provide Member States with opportunities to comment on various drafts of this report.

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ACRONYMS AND ABBREVIATIONS

AU/NPCA	African Union/NEPAD Planning and Coordinating Agency
CHAI	Clinton Health Access Initiative
CIF	Cost, insurance, freight
CMAM	Central de Medicamentos e Artigos Medicos
CMS	Central medical stores
COMESA	The Common Market for Eastern and Southern Africa
DFID	Department for International Development
DRC	Democratic Republic of Congo
ECSA	The East, Central and Southern African Health Community
FOB	Free on board
GCC/GPP	Gulf Cooperation Council/Group Purchasing Program
GDP	Gross domestic product
GFATM	Global Fund to fight AIDS, Tuberculosis and Malaria
GMP	Good manufacturing practices
GNI	Gross national income
HAI	Health Action International
ICP	International Cooperating Partners (similar to DP)
IDPIG	International Drug Price Indicator Guide
INCOTERMS	International Commerce Terms
IPC	Interagency Pharmaceutical Coordination Group (with representation from UNICEF, UNFPA, WHO and World Bank)
LDC	Least-developed countries
LMIS	Logistics Management Information Systems
MSD	Medical Stores Department
MSH	Management Sciences for Health
MSL	Medical Stores Limited
NATPHARM	National Pharmaceutical Company of Zimbabwe
NEPAD	The New Partnership for Africa's Development
NMP	National Medicines Policy
NMPA	National Medicines Procurement Agency
NMRA	National Medicines Regulatory Authority
OCEAC	Organisation de Coordination pour la lutte contre les Endémies en Afrique Centrale
OECS/PPS	Pharmaceutical Procurement Services of the Organization of Eastern Caribbean States
PAC	Pharmaceutical Advisory Committee
PAHO	Pan-American Health Organization
PCP	Pharmaceutical Country Profile
PMA	Pharmaceutical Market Analysis
PSM	Procurement and Supply Management
REC	Regional Economic Community
SACU	Southern Africa Customs Union
SADC	Southern African Development Community
SARN	Southern African Regional Network for Malaria
SARPAM	Southern African Regional Program on Access to Medicines and Diagnostics
SOPs	Standard Operating Procedures
SPS	Strengthening Pharmaceutical Systems programme
SPPPS	SADC Pharmaceutical Pooled Procurement Secretariat
SwAp	Sector-wide Approach
TB	Tuberculosis
UNDP	United Nations Development Programme
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
USD	United States Dollar
TRIPS	(Agreement on) Trade-Related aspects of Intellectual Property Rights
VAT	Value-added tax
WHO	World Health Organization
WHO/PCP	Pharmaceutical Country Profiles of the SADC Member State published by the World Health Organization
WTO	World Trade Organization
ZAR	South African Rand

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EXECUTIVE SUMMARY

The situational analysis and feasibility study presented in this report reflects the situation in the pharmaceutical sectors in the 14 Member States of the Southern African Development Community (SADC).[11][12] [13]

The purpose of the study is to collate available information and data, analyse the actual situation and explore the feasibility of options for the SADC Pharmaceutical Business Plan 2007-2013 Objective 4: "Procurement Cooperation" strategy.[14] [15]

The study considers findings of several earlier studies by the Southern African Regional Programme on Access to Medicines and Diagnostics (SARPAM), the World Health Organization (WHO), the African Union / NEPAD Planning and Coordinating Agency, and others conducted between 2009 and 2011. That information was complemented with data obtained through a Member State survey, conducted in August 2011. A desk review, the gathering of new data and information using a questionnaire (see Annex 9), follow-up telephone interviews, analysis and report writing were completed within three weeks. In September 2011, Member States were given the opportunity to submit comments and corrections. The Feasibility Study for Pooled Procurement in the SADC Region, prepared by AMPROC Inc. and commissioned by the SADC Secretariat in 2009, did not feature among the resource materials because that study had not been finalised.

Rationale for pooled procurement and regional standardisation

The rationale for pooled procurement is that the pooling of resources (technical, financial and information) will increase the availability and reduce the cost of quality, essential products in the market. Through information and work sharing (the first stage of pooled procurement), the procurement agencies in Member States can already expect considerable savings. The development and implementation of regional standards and procedures will in turn lead to increased efficiency and standardisation. These are pre-conditions for group contracting, which represents an advanced stage of pooled procurement.

Findings

There are considerable cultural, demographic and economic differences between SADC Members States. Some Member States have small populations (Mauritius with 1.2 million inhabitants and Seychelles with 87,000, for example), while others have much larger populations (the Democratic Republic of Congo (DRC), South Africa and the United Republic of Tanzania with a total of 155 million people, or 60% of the total SADC population), and some countries are large but sparsely populated like Botswana and Namibia.

Member States' Gross National Income (GNI) per capita ranges from USD 140 in the DRC to USD 8,960 in Seychelles. South Africa (with a population of about 50 million or one-fifth of the total SADC population) contributes about two-thirds of the region's total GDP. [16]

However, the main causes of morbidity in the SADC region are generally similar across countries, which is relevant for the types of essential medicines that are likely to be most in demand. In addition to HIV and AIDS, and Malaria[17], the most common disease categories are acute respiratory infection, respiratory infection, pneumonia, pulmonary tuberculosis (TB), intestinal infection, diarrhoea, and trauma and accidents. The prevalence of non-communicable diseases, such as cardiovascular diseases, cancer and diabetes, is rapidly increasing.

11 *Many of the documents referred to in this report are available on the website of the Southern African Regional Programme on Access to Medicines and Diagnostics, at http://www.sarpam.net/.*

12 *SADC. Final record of the Southern African Development Community Workshop on the Development of the SADC Regional Strategy for Pooled Procurement of Essential Medicines and Commodities. Gaborone, Botswana, 24 to 26 August 2011*

13 *Angola, Botswana, Democratic Republic of Congo, Lesotho, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, Tanzania, Zambia and Zimbabwe. Madagascar was excluded from this study because it was suspended from SADC at the time of the study.*

14 *SADC. Pharmaceutical business plan 2007-2013: Operational plan. 2010 (Annex C1_a of the SARPAM Inception Report of 20 October 2010)*

15 *"Pooled procurement" refers to the full range of options for working together on procurement systems t, from information and work sharing to pooled procurement in the form of group or central contracting. See also Annex 2. The terms joint procurement or procurement cooperation may be used.*

16 *TIFI Directorate. Review of economic performance. SADC, December 2010.*

17 *Malaria is not endemic in Lesotho and the Seychelles.*

In general, pharmaceutical market information is not easily accessible in the SADC region, and a lack of standardisation makes it difficult to compare the information that is available. This lack of transparency can result in higher transaction costs, and creates opportunities for suppliers to diversify their prices, to the disadvantage of purchasers.

Considerable differences exist between Member States regarding pharmaceutical procurement and supply management (PSM) practices as well as regarding the application of regulations and procedures, such as for quality assurance and public procurement. Despite the similarities in National Medicines Policies (NMPs) and public procurement legislation, SADC Member States are at different levels of pharmaceutical sector development and pharmaceutical services delivery. In some respects, a majority of countries comply with internationally accepted principles, but in others they do not.

Application of the internationally accepted Interagency Pharmaceutical Coordination (IPC) Group Operational Principles for Good Pharmaceutical Procurement[18] is under way in most Member States. However, most of them struggle with inadequate financial and human resources. Few Member States apply output-based financing with regard to their National Medicines Procurement Agency (NMPA).

There are other important differences between Member States, as well. The median number of pharmaceutical personnel (defined as pharmacists, pharmaceutical assistants, pharmaceutical technicians and related occupations) in Member States is 0.7 (range 0.3-7.0) per 10,000 inhabitants.[19] Although there is no internationally recommended ratio for pharmaceutical human resources, these figures suggest that there are serious shortages of qualified personnel in a number of SADC countries. In two-third of Member States, the state official responsible for the overseeing the pharmaceutical sector is not positioned at the required level in the Ministry of Health hierarchy, which may reflect the "low profile" of this sector within the overall health system management field.

Almost all Member States have ongoing programmes for strengthening PSM systems and quality assurance systems, most of them supported by development partners. Few countries have mapped these programmes, and all Member States indicated that more coordination was required, nationally and regionally.

Data on pharmaceutical budgets and expenditure was hard to obtain in most Member States. Assuming that 10% of total health expenditure[20] is used for pharmaceutical expenditure, the estimate of total annual pharmaceutical expenditure for the SADC region would be approximately USD 4.1 billion, or USD 15.90 per capita, with per capita expenditure ranging between USD 1.18 and USD 56.50, depending on the country.

Public sector procurement prices for essential medicines differ significantly between SADC Member States. For the majority of 50 tracer items, the ratio between the highest and the lowest price reported by study countries was greater than 5. This meant that some countries were paying five times as much as others for the same products. For 8% of the items, the high/low ratio exceeded 50. This meant that the highest price paid by one country A was more than 50 times higher than the lowest price paid by another country. These findings indicate that there is clear potential for cost savings in individual study countries through information exchange and price reduction.

Four Member States do not register medicines, but in three other Member States the National Medicines Regulatory Authority (NMRA) operates at internationally acceptable levels. The capacity of most Member States' regulatory authorities, which are responsible for assessing and approving medicines, is severely limited. This carries the risk of inflows of substandard and/or inappropriate medicines and, consequently, wasteful expenditures. Furthermore, while fast-track registration mechanisms exist, there are still delays and backlogs in the registration of essential medicines in almost all Member States, which also hinders access.

A five-year programme, "Harmonisation of Medicines Registration in the SADC Region" (which is guided by the African Medicines Registration Harmonization Initiative), will allow for the development and implementation of new or more developed legislation, and standardised sets of guidelines, processes and procedures. This would facilitate medicines registration across SADC and ensure intensified market surveillance. Regional regulatory harmonisation—including mutual recognition of registration—can improve the availability of quality-assured medicines, especially for priority products with small sales volumes, since the increased market size will offer better incentives for suppliers to register such products.

18 *See http://apps.who.int/medicinedocs/en/d/Jwhozip49e.*

19 *WHO. Baseline assessment of the pharmaceutical situation in Southern African Development Community Countries; Fact Book 2009 (WHO/EMP/MPC/2010.3), 2010.*

20 *As found by WHO/PCP in 2009; the total health expenditure includes both the public and private sectors.*

Feasibility and conclusions

The implementation of internationally accepted principles is expected to yield quick gains in the form of savings stemming from information sharing on prices and suppliers. Regionally, price reductions of 10% might be achievable, which would save hundreds of millions of USD in the current market. Although there are substantial differences and weaknesses in Member States, it is believed that the existing commitment and similarities of Member States' PSM and quality assurance systems justify the proposed steps of the SADC Pharmaceutical Pooled Procurement Strategy. However, study results also reveal gaps in information for certain areas, which require further study. This is especially the case for financial resources and systems, and the existing programmes for strengthening PSM systems (including Logistics Management Information Systems, LMIS, and quality assurance systems).

Recommendations

The following recommendations are addressed to the SADC Secretariat, which has a mandate to facilitate regional pharmaceutical pooled procurement. Implementation of the recommendations will require approval and close cooperation with Member States.

Continue investing in regional procurement cooperation by:

- Supporting countries to actively participate in the approval and implementation of the regional pharmaceutical pooled procurement strategy;
- Facilitating the establishment and maintenance of regional pharmaceutical information and work sharing platforms foreseen in the regional pooled procurement strategy;
- Facilitating the establishment of a SADC Pharmaceutical Pooled Procurement Institute;
- Facilitating the establishment of successful cooperation models for possible application in SADC (such as with the CHAI, Management Sciences for Health/Strengthening Pharmaceutical Systems, Association des Centrales d'Achats Africaines des Médicaments Essentiels, World Bank Initiatives/East Africa Community programme and other SADC regional programmes) to identify joint procurement opportunities in multi-country programmes, such as the cross-border clinics funded by the Global Fund to fight AIDS, Tuberculosis and Malaria (Global Fund).

Commission follow-up research, including:

- An assessment of the financial resources and systems in the pharmaceutical sector in Member States. Among other things, the assessment should include payment mechanisms, duties and taxes with:

- A comprehensive inventory of existing tax and duties instruments; and
- Analysis of the effects of these instruments on purchasing behaviour and pricing.

The study should also identify the options, benefits and challenges of price regulations. Those should cover the use of price regulations as policy instruments to increase access to medicines, show how price regulations may interact with other policy instruments, and indicate which conditions are needed to achieve the desired effects.

- A mapping study of existing programmes for strengthening PSM systems and/or quality assurance systems in Member States. The "map" will be the starting point for regional work sharing so that Member States can share PSM tools, and benefit from potential support from Member States with more advanced PSM systems.
- A study to assess the user level demand side in the region to generate information that can inform policies that directly address patients' access to medicines. This should be preceded and informed by an assessment of the WHO/Health Action International price and availability surveys already conducted in the DRC, Malawi, Mauritius, Tanzania and South Africa.

Support medicines regulatory harmonisation by:

- Facilitating the process of harmonising medicines registration requirements and processes in the region (including updating of standardised guidelines and capacity building plans for implementers), which are to lead to mutual recognition of medicines registration.

The SADC Secretariat, and Trade and Health Ministries of Member States should optimise the use of the TRIPS agreement by:

- Maximising “TRIPS flexibilities” in national intellectual property legislation and by avoiding “TRIPS+” pressures in bilateral negotiations, Free Trade Agreements and Economic Partnership Agreements.

Developing a regional strategy for regional development, production, distribution and procurement of generic copies of newly patented medicines within SADC.

1. Introduction

1.1 Background and purpose

Southern African Development Community (SADC) Member States are at various levels of pharmaceutical sector development and pharmaceutical services delivery.[11] In some Member States, the entire population has relatively good access to medicines with quality assurance systems that are fairly advanced. Other Member States, however, are struggling to deliver quality medicines through public health facilities and do not have a well-developed private sector that serves the entire country. The situation in most Member States places them between those two extremes.

The purpose of the SADC Pharmaceutical 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. One of the priority objectives for SADC is "to improve sustainable availability and access to affordable, quality, safe, efficacious essential medicines."[12] Pooled procurement is one of the priorities in the SADC Pharmaceutical Business Plan 2007-2013. The legitimacy of the Pharmaceutical Business Plan is firmly based on the SADC Health Sector Policy Framework and the SADC Protocol on Health. As in the Regional Indicative Strategic Development Plan, these documents clearly express the political commitment for pooled procurement among SADC Member States.

1.1.1 Member States' Malawi meeting

In December 2010, a Member States meeting was held in Malawi on the development of the SADC pooled procurement strategy.[13] The Member States reviewed the 2009 feasibility study for pooled procurement that had been commissioned by the SADC Secretariat. The Member States rejected the findings of that study. Delegates made detailed recommendations and mandated the SADC Secretariat to appoint a drafting team to address the issues that were identified, and produce a draft Strategic Framework for regional pooled procurement of medicines and commodities (see Annex 9 for details).

1.1.2 Technical Briefing Report and Strategic Framework

The drafting team met in late February and early March 2011 in Johannesburg, South Africa, together with representatives from the SADC Secretariat, WHO, UNICEF and SARPAM. The resulting Technical Briefing Report[14] and draft Strategic Framework[15] have informed this study report.

1.1.3 Pharmaceutical Advisory Committee

The Technical Briefing Report and draft Strategic Framework were discussed at the meeting of the SADC's Pharmaceutical Advisory Committee (PAC) in March 2011, where they were accepted with some amendments. However, it was also acknowledged that the pooled procurement strategy has to be based on a situational analysis and feasibility report that reflects the current state of affairs with regard to existing regional pharmaceutical procurement and supply systems and the opportunities to strengthen them. SARPAM offered to assist in compiling such a study, using available data as well as conducting its own survey to fill gaps.

1.1.4 SADC Regulatory Forum

The Technical Briefing Report and draft Strategic Framework were also presented at the meeting of the SADC Regulatory Forum in May 2011.[16] In order to provide baseline data pertaining to the medicines regulation and harmonisation situation in the SADC region, the African Union NEPAD Planning and Coordinating Agency (AU/NPCA) commissioned a situational analysis. This in-depth report provided vital information on the status and functionality of National Medicines Regulatory Authorities across the region.[17] A subsequent five-year project proposal was prepared for the "Harmonisation of Medicines Registration in the SADC Region". Both documents, in combination with some findings in the PMA, provided the inputs for section 3.5, as well as the subsequent conclusions and recommendations that affect pooled procurement.

11 *SADC. Pharmaceutical business plan 2007-2013. Gaborone: SADC; 2007.*
12 *SADC. Pharmaceutical business plan 2007-2013. Gaborone: SADC; 2007.*
13 *SADC. Final record Southern African Development Community Workshop on the Development of the SADC Regional Strategy for Pooled Procurement and Strategic Framework for Regional Production of Essential Medicines and Commodities for HIV and AIDS, TB and Malaria. Lilongwe, 13-17 December 2010.*
14 *Verhage R. Technical briefing report on regional pooled procurement within SADC. SARPAM, March 2011.*
15 *SADC Drafting Team. SADC strategic framework for pooled procurement of essential medicines and medical supplies, March 2011*
16 *Convened by the SADC Secretariat with support from the African Medicines Regulatory Harmonization Initiative Consortium, and held in Malawi on 2-6 May 2011.*
17 *AU/NPCA. Situational analysis study on medicines registration harmonization in Africa, final report for the Southern African Development Community (SADC), November 2010*

1.1.5 Purpose of the study

The purpose of this study is to collate available information and data pertaining to regional pooled procurement, analyse the situation, and explore the feasibility of various options for the SADC Pharmaceutical Business Plan 2007-2013 Objective 4 "Procurement Cooperation"[18] strategy.[19]

1.1.6 Content of the study report

This study report begins with sections on the study's Methodology and Challenges. Chapter 2 discusses the Rationale for SADC regional pooled procurement, as well as relevant global and regional initiatives. Chapter 3 describes the overall context, and provides findings and analysis in the areas of political and organisational commitment, procurement policies and legislation, medicines regulatory harmonisation, medicines supply chain systems, and financial resources and systems. The Feasibility of SADC pooled procurement is discussed in Chapter 4, which is followed by Conclusions and Recommendations.

1.2 Methodology

1.2.1 Analytical framework

This study is a compilation of results of studies done during 2009 and 2010. It is complemented by a desk review of available documentation on the national situations in SADC Member States, as well as with information and data assembled during a SARPAM survey (assembly of data and information from the questionnaire and the follow-up telephonic interviews). The study was prepared in August 2011.

1.2.2 Existing information sources

The most up-to-date information and data were found in the report on the Pharmaceutical Market Analysis (PMA) done by SARPAM[20]; the summary report of the pharmaceutical country profiles of SADC Member States, published by WHO[21]; and the report of the Situational Analysis Study on Medicines Registration Harmonisation for SADC[22], done by a study team of AU/NPCA, all published in 2010. The recommendations of the Malawi Meeting in 2010 (see above) were taken into account for this study. The draft AMPROC Feasibility Study for Pooled Procurement in the SADC Region, commissioned by the SADC Secretariat in 2009, which has not been finalised, was not included in the study.

These data sources were supplemented with country-specific documents, such as National Medicines Policies.

1.2.3 Survey 2011

In August 2011, a questionnaire (Annex 8) was developed and distributed to the officials in the Ministries of Health of Member States responsible for the pharmaceutical sector. This was done to address issues raised in the Malawi meeting, and which had been insufficiently covered in subsequent studies and meetings. Responses to the questionnaire were analysed, and follow-up telephonic interviews were conducted. The survey was done in August 2011.

1.2.4 Survey results

Questionnaires were sent to all 14 Member States via the SADC Secretariat's official channels, with support from SARPAM administrative staff. By end-August 2011, 12 completed questionnaires had been returned and interviews with stakeholders in 10 Member States[23] had been conducted (see Table 1).

18 *Pooled procurement implies the full range of collaboration options on procurement systems–from information sharing and work sharing to pooled procurement in the forms of group or central contracting. See also Annex 2. The terms "joint procurement" or "procurement cooperation" are sometimes used interchangeably with "pooled procurement".*

19 *SADC. Pharmaceutical business plan 2007-2013: Operational plan. 2010 (Annex C1_a of the SARPAM Inception Report of 20 October 2010).*

20 *SARPAM. SADC pharmaceutical market analysis (2010 baseline) volume 1: Summary of findings, conclusions & recommendations. Volume 2: annexes. Final draft, January 2011.*

21 *WHO. Baseline assessment of the pharmaceutical situation in Southern African Development Community countries; Fact book 2009 (WHO/EMP/MPC/2010.3), 2010. The individual pharmaceutical profiles for 14 Member States (Angola, Botswana, Democratic Republic of Congo, Lesotho, Malawi, Mozambique, Namibia, Seychelles, South Africa, Swaziland, Tanzania, Zambia and Zimbabwe; Madagascar is suspended) are available at http://www.who.int/medicines/areas/coordination/coordination_assessment/en/index1.html.*

22 *AU/NPCA. Situational analysis study on medicines registration harmonization in Africa, final report for the Southern African Development Community (SADC). November 2010*

23 *See Annex 3 for details.*

Table 1: Questionnaires returned and telephonic interviews done (August, 2011)

SADC Member States	Questionnaire returned	Interviews
Angola	1	0
Botswana	1	1
DRC	1	1
Lesotho	1	1
Malawi	1	0
Mauritius	1	1
Mozambique	1	1
Namibia	1	1
Seychelles	1	1
South Africa	1	1
Swaziland	1	1
Tanzania	0	0
Zambia	0	0
Zimbabwe	1	1
Total	12	10

1.2.5 Member States Botswana meeting

A Member States meeting was held in Botswana on 24-26 August, 2011, to present and discuss the draft situational analysis and feasibility report[24], as well as approve the draft SADC Strategy on Pooled Procurement of Essential Medicines and Commodities.[25] At the meeting, two additional countries submitted data based on the questionnaire. Those data and the corrections and comments made by Member States were incorporated in the final draft of the study report.

1.2.6 Member States' consensus-building meeting, South Africa

Delegations from all 14 Member States unanimously adopted the report of the Situational Analysis and Feasibility Study at the SADC Member States Consensus-Building Meeting, which was held on 17-21 September 2012 in Johannesburg. Adoption occurred with the proviso that Member States could provide corrections, along with updated data and information up to two weeks after the Meeting. [26] Three countries did so, and those data and corrections were incorporated in this final draft of the study report.

1.3 Study challenges

The unavailability of the main respondent (or a deputy) was the main reason why not all questionnaires and interviews were completed. In cases where the questionnaires were returned, Member States indicated that not all data were available to fully answer some of the questions. This was especially the case for data on funding sources and external support.

The PMA study report mentioned the following challenges:

- Lack of availability of reliable contextual information, including health financing and epidemiological data;
- Reluctance of private sector stakeholders to make sales information available, despite guarantees of confidentiality;

24 *SARPAM. SADC pooled procurement of essential medicines and medical supplies situational analysis and feasibility study (Compilation of available data and information). August, 2011*
25 *SADC. Final record of the Southern African Development Community Workshop on the Development of the SADC Regional Strategy for Pooled Procurement of Essential Medicines and Commodities. Gaborone, Botswana, 24 to 26 August 2011*
26 *SADC. Final record of the Southern African Development Community Member States consensus-building meeting. Johannesburg, South Africa, 17-21 September 2011*

- Difficulty of a number of public sector procurement agencies to produce all the requested information—either because it was not routinely recorded, information systems were not up to date, or the responsible person was not available at the time of the survey; and

- Not all tracer items were usually included amongst stock items for the public sector, and information on tracer items was therefore often incomplete. This decreased sample size and the representativeness of some findings where tracer items were used.

It should also be taken into account that the information in the PMA and WHO Pharmaceutical Profiles is somewhat dated, as it was assembled during 2009-2010. However, it is believed that the trends have become sufficiently clear to serve as basis for the SADC Pooled Procurement Strategy. At the Botswana meeting, Member States confirmed that "this report presented a good reflection of the situation in the region".

2. Rationale for pooled procurement, and global and regional developments

2.1 Introduction

This chapter is based on the Technical Briefing Report, which was prepared in March 2011.[27] It discusses the rationale and inspiration for new ideas for regional pooled procurement in the SADC region, as well as major pertinent initiatives at global and regional levels.

SADC is not the only regional economic community considering pooled procurement The East African Community, the Organisation of the Eastern Caribbean States and the Pacific Islands Forum have undertaken similar initiatives. Overall, however, there has been limited progress.

Putting policies into practice is a challenge. Differences between country systems and insufficient human resource capacities in countries and at the health units of regional economic community secretariats have been major obstacles.

Linking regional economic community activities with other global and regional initiatives to foster complementarity has been another challenge. Examples of complementarity include collaboration with the New Partnership for Africa's Development (NEPAD) and WHO on multi-stakeholder partnerships in the Medicines Transparency Alliance[28], and pooled procurement initiatives for the faith-based sector coordinated by the Ecumenical Pharmaceutical Network[29].

2.2 Rationale

The main rationale for pooled procurement is to increase the availability of affordable, quality essential pharmaceutical products in the market. Pooled procurement enables considerable savings, even at the limited stage of information and work sharing between Member States' procurement agencies. The development and implementation of regional standards and procedures will lead to increased efficiency and harmony, which are preconditions for group contracting. Group contracting involves Member States establishing joint tenders for contracting suppliers, but purchasing items individually.

In the longer term, potential benefits for Member States include:

- Improved pharmaceutical PSM systems in Member States (in line with internationally accepted standards) through regional standardisation, work sharing[30] and inter-Member State cooperation;
- The services of a state-of-the-art regional pharmaceutical procurement agency, which can offer quality procurement services, ranging from information sharing and coordination of work sharing to actual (e-) procurement services.

Usually, four forms of pooled procurement can be distinguished (see Annex 2):

- Informed buying and coordinated informed buying, both based on information exchange between the participating partners; and
- Group and central contracting, also termed "joint procurement".

27 *Verhage R. Technical briefing report on regional pooled procurement within SADC. SARPAM, March 2011.*
28 *See http://www.medicinestransparency.org/*
29 *See http://www.epnetwork.org/Home*
30 *Work sharing is the sharing of procurement and supply management system "good practices", as set out in guidelines, standard operating procedures, standard bidding documents, tender adjudication reports, storage conditions, distribution schedules, monitoring and evaluation reports, etc.*

Inter-country pooled procurement is challenging because of the systems differences between countries. Pooled procurement within individual countries is less complicated because common policies, legislation and regulations, language and financing modalities are usually in place (see Table 2).

Table 2: Some conditions for the success of pooled procurement schemes for medicines

Conditions for the success of pooled procurement schemes
Homogeneity of members: size, range of needs, economic development, culture, political traditions, languages.
Harmonised requirements: drug regulation, taxes, import duties.
Financial stability: stable currencies, members able to pay for pooled services and for supplies received.
A common approach to quality: agreed quality standards, agreed procedure for control of suppliers and batches.
Reasonably accurate prediction of needs.
Competent and stable central staff.
Reliable data on the patent situation of medicines.
Loyalty of members: members' procurement agencies must not compete with the pool.
Monitoring performance at pool and national level.

Source: UN Millennium Project[31]

2.3 Global and regional initiatives

The strategies that organisations use to influence the health product markets are important when considering global and regional initiatives around pooled procurement. As a report of the Global Fund to fight AIDS, Tuberculosis and Malaria (Global Fund) has noted:

"At one end of the spectrum are 'market takers' which participate in marketplaces but do not actively seek to shape the marketplace and simply try to optimise the outcomes they obtain within the constraints of what the marketplace currently offers. On the other end of the spectrum are 'market shapers', which seek to use their influence and market power to deliberately reshape marketplaces (e.g., enhancing competition, changing procurement practices) in ways that produce outcomes such as lower prices, improved quality of products, and greater and more timely product availability." [32]

The value of the pharmaceutical market in the SADC region is estimated at about USD 4 billion. It therefore is worthwhile to explore opportunities for market- shaping in order to make more efficient use of the available resources. An example of a global initiative that operates on both the supply and demand sides is the Clinton Health Access Initiative (CHAI).

There are several global and regional initiatives for pooled procurement. They range from information exchanges (for example, on product prices, quality and suppliers) to sharing "best practices" (in the form of guidelines, SOPs, standard bidding documents and evaluation forms) to actually conducting joint procurement (through group or central contracting). In general, recent initiatives for inter-country regional pooled procurement have not been very successful. Despite extensive investments in studies and meetings in Africa (including in the SADC region), the Caribbean and the Pacific over the past decade, and support from WHO and other partners, little progress has been made beyond policy development and information sharing.

The main reason appears to the lack of similarity in countries' legal, regulatory, financial and pharmaceutical procurement systems. The required similarities are present in the two successful regional pooled procurement initiatives that have been in operation:

- The Gulf Cooperation Council/Group Purchasing Program (GCC/GPP) which has been operating since 1978; and
- The Pharmaceutical Procurement Services of the Organization of Eastern Caribbean States (OECS/PPS), which has been operating since 1987.

31 *UN Millennium Project. Prescription for healthy development: Increasing access to medicines. Report of the Task Force on HIV/AIDS, Malaria, TB, and Access to Essential Medicines. Sterling: Earthscan; 2005*

32 *The Global Fund. Report of the Market Dynamics and Commodities ad hoc Committee. Twenty-second board meeting. Sofia, 13-15 December 2010.*

While the focus in the East African Community and SADC has been on joint procurement, a recent European Commission-funded study recommended that inter-country work sharing should be promoted instead, since "work sharing between the agencies of various countries seems more likely to prove acceptable than any imposition of supranational services or structures."[33]

Work sharing has been developed the most in francophone Africa, with the establishment of the Association des Centrales d'Achats Africaines des Médicaments Essentiels (African Association of Essential Medicines Purchasing Centres).[34]

One of the programmes supported by the World Bank Institute involves learning and knowledge sharing events in three East African Community countries. This enables procurement practitioners and other stakeholders to learn about various country experiences with transparency and accountability mechanisms that can improve procurement. It also introduces them to existing cutting-edge tools and approaches for improving governance in procurement, and networks them with counterparts from other countries.[35]

In the Caribbean region, a procurement and supply management assessment tool was developed in 2007 by the Caribbean Procurement and Supply Management Network. However, it is currently only used by the procurement and supply agency in Haiti.[36] It is suspected that discrepancies between countries prevented wider use of the tool. In order to overcome such differences, a Caribbean Pharmaceutical Policy was drafted in 2010, with support from the Pan American Health Organization. The Policy is to serve as basis for a Caribbean Pharmaceutical Program, and includes activities to standardise and harmonise systems.

PAHO regards support (such as technical assistance and procurement of essential medicines) via its Strategic Fund as vital for strengthening PSM in the Americas. Countries' actual use of the PAHO Strategic Fund as a pooled procurement mechanism has been limited since it was set up in 2000. On the other hand, the PAHO Revolving Fund for Vaccine Procurement, established in 1979, remains a successful mechanism. Its success may be explained by the fact that member countries waived some of their regulations (such as the requirement for market authorisation) as confidence grew that the PAHO mechanism could guarantee the best prices for quality vaccines.

Other initiatives, described in the Technical Briefing Report on Regional Pooled Procurement among SADC Member States[37], include Global Fund Voluntary Pooled Procurement, the Global Drug Facility, Roll Back Malaria, and the Partnership For Supply Chain Management / Supply Chain Management System, among others.

No studies were identified that include a cost-benefit analysis of existing pooled procurement mechanisms. In addition, no recent study was found showing how the procurement prices obtained by functional regional pooled procurement organisations relate to the international reference prices. Some prices for the Pharmaceutical Procurement Services of the Organization of Eastern Caribbean States (which are published in the MSH/WHO International Drug Price Indicator Guide) appear to be lower and others appear to be higher than the median tender prices. Considering the small size of the market, that would be a fairly good outcome.[38] The Gulf Cooperation Council / Group Purchasing Program does not make prices available for the MSH/WHO International Price Indicator Guide. SADC-based National Medicines Procurement Agencies in Lesotho, Namibia, South Africa and Tanzania did contribute that Guide.[39]

In addition to the MSH/WHO International Price Indicator Guide, there are several other sources for procurement information (including prices, quality, quantities and suppliers), including:

- The Global Fund Price and Quality Reporting tool, which has restricted access for registered users only;
- The Price Information Exchange website[40], which contains public sector procurement prices and suppliers for selected medicines that participating countries in the Western Pacific Region have shared voluntarily;
- The global price reporting mechanism provided by the WHO AIDS Medicines and Diagnostics Service[41];
- Médicine Sans Frontières' Untangling the Web of Antiretroviral Price Reductions[42];
- Suppliers catalogues; and
- Numerous government and health insurance pricing mechanisms.

33 *Gruppo Soges Spa. Procurement policies and practices for drugs in sub-Saharan Africa: Report on a study for the European Commission and recommendations of a workshop held jointly with WHO, June 2008.*
34 *See www.acame.org*
35 *See http://wbi.wordbank.org*
36 *See http://www.paho.org/Spanish/AD/THS/EV/acceso-cariprosum.htm*
37 *See http://www.sarpam.net/*
Management Sciences for Health/WHO. International drug price indicator guide 2009. 2010. Available at http://erc.msh.org/dmpguide/pdf/DrugPriceGuide_2010_en.pdf
39 *Ibid.*
40 *Copied from http://www.piemeds.com/users/page/AboutRmpies*
41 *See http://www.who.int/hiv/amds/gprm/en/*
42 *See www.msfaccess.org*

3. Findings and Situational Analysis

3.1 Introduction

This chapter presents and discusses the findings that are most relevant for SADC pooled procurement. The focus is on the conditions that are required for successful pooled procurement (see Table 2) and the actual compliance of pharmaceutical PSM systems in Member States with internationally accepted standards. The issues raised in the December 2010 Malawi meeting have been taken into account.

3.1.1 Findings from the 1999 study

In 1999, SADC commissioned a study to identify opportunities for increased practical co-operation in the procurement of anti-TB medicines.[43] The study did "not find a positive correlation between current buying leverage and low price levels of anti-TB drugs", and added that "competitive national price levels seem to be a result of proper, open international bidding procedures rather than sheer buying volume."

That important finding was confirmed in 2010 by the PMA study, which found that the country with the largest market—South Africa—was one of the countries with the highest price levels in the SADC region for a sample of 50 tracer medicines.[44] This suggested that prices would not decrease simply because of larger procurement volumes.

The 1999 study recommended "a cautious, gradual approach towards greater procurement coordination in the region, given the paramount importance of an uninterrupted supply of anti-TB drugs, the relative wide variety in national buying practices and the considerable, practical, mostly new implications of running a Bulk Purchasing Scheme."

That recommendation still seems valid.

3.1.2 The Pharmaceutical Business Plan 2007-2013 and zero-draft of the Regional Pooled Procurement Strategy

Pooled procurement was declared a priority in the SADC Pharmaceutical Business Plan 2007-2013, and related activities began in 2009. Supported by the European Union and the WHO African Regional Office in Brazzaville, a zero-draft Regional Pooled Procurement Strategy was prepared.[45] That Strategy contained a short situational analysis along with a rationale for pooled procurement. It also focussed on central contracting for health supplies for the priority diseases HIV and AIDS, Malaria and TB, which would be managed by a new Directorate in the SADC Secretariat. Important elements in that draft, such as the structure of a regional strategy, have been used for this study and in the SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities, 2013-2017. Also in 2009, a feasibility study on pooled procurement was commissioned with the support of the African Development Bank. However, that study was not completed following discussion of the draft at the Member States' meeting in Lilongwe in December 2010.[46]

3.1.3 Standards

The aim of pharmaceutical public procurement is to procure quality-assured medicines and medical supplies based on the lowest evaluated bid. This means that only qualified products from qualified suppliers and qualified manufacturers may be regarded for price comparison.

Currently, different Member States apply different methods and criteria in the qualification process. Products that are allowed in one Member State may not be allowed in others. A similar situation exists for the pre- or post-qualification of suppliers. Standardisation (i.e. agreeing on the quality, technical and financial capacity criteria for suppliers and products) is a pre-condition for successful pooled procurement and has been included as one of the objectives in the SADC Strategy for Pooled Procurement.

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43 *Van de Gronden JA, et al. A bulk purchasing study on the procurement of anti-TB drugs among 11 SADC countries: Procurement consulting services for the Southern African Development Community Secretariat in Gabarone, Botswana, through the SADC Health Sector Coordinating Unit in Pretoria, South Africa, in the framework of the Southern African Tuberculosis Control Initiative (SATCI) (Final Report). Irene, South Africa: International Procurement Agency SA (Pty) Ltd.; 1999.*

44 *SARPAM. SADC Pharmaceutical market analysis (2010 Baseline) Volume 1: Summary of findings, conclusions & recommendations. Volume 2: Annexes. Final Draft – January 2011.*

45 *SADC. SADC regional pooled procurement strategy (zero draft). Johannesburg, 18th April 2009.*

46 *SADC. Final record of the Southern African Development Community Workshop on the Development of the SADC Regional Strategy for Pooled Procurement and Strategic Framework for Regional Production of Essential Medicines and Commodities for HIV and AIDS, TB and Malaria. Lilongwe, Republic of Malawi, 13-17 December 2010.*

Similarly, there is a need for standardisation of public procurement legislation and regulations that affect the procurement of medicines. For example, legislation and regulations should allow pre-qualification, framework contracts, exclusion of non-registered medicines and special bidding documents for health products.

The IPC Operational Principles for Good Pharmaceutical Procurement[47] (presented in Table 3) are internationally regarded as the basis for sound pharmaceutical procurement. They could serve as minimum standards for "best practices" in PSM systems in all Member States.

Table 3: IPC operational principles for good pharmaceutical procurement in SADC Member States

	Operational principles for good pharmaceutical procurement
1	Proper division of functions
2	Transparent, clear procedures and criteria for award
3	Proper planning, M&E including external audit
4	Procurement limited to essential items
5	Use International Non-proprietary Name or generic name
6	Proper quantification
7	Ensure reliable financing and financial procedures
8	Promote economies of scale
9	Use competitive procurement methods
10	Sole-source commitment
11	Pre-qualification of suppliers
12	Quality-assured products

3.2 The SADC context

SADC comprises 15 Member States (Angola, Botswana, DRC, Lesotho, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, Tanzania, Zambia and Zimbabwe). Madagascar was excluded from this study because the country is currently suspended from SADC.

The SADC region has 257.7 million inhabitants and a Gross Domestic Product (GDP) of USD 471.1 billion.[48] There are considerable cultural, demographic and economic differences between SADC Member States.

Official languages differ, but English is one of the official languages in 11 of the 14 Member States, with Portuguese (Angola and Mozambique) and French (DRC) also official languages. This is not expected to affect regional trade cooperation, since English is commonly used for trade in all Member States.

Member State populations range from 87,000 (Seychelles) to 65.8 million (DRC). Three Member States (DRC, South Africa and United Republic of Tanzania) together have 155 million inhabitants, or 60% of the total SADC population. Some Member States are large and sparsely populated (Botswana and Namibia).

47 *Interagency Pharmaceutical Coordination Group. Operational principles for good pharmaceutical procurement. (WHO/EDM/PAR/99.5). WHO, 1999.*

48 *www.sadc.int/# [accessed 19 August 2011]*

Table 4: Demographic, economic and health data for the SADC region

	Total population (000s)	Population < 15 years	GDP USD billions, current exchange rates	GDP growth	GNI per capita, USD current exchange rates	Population living < PPP int. USD1 a day	Adult literacy rate, 15+ years	Maternal mortality ratio, per 100 000 live births	Infant mortality rate per 1,000
Angola	17,024	46%	61.4	6%	2,540	43%	67%	1,400	116
Botswana	1,882	35%	12.3	8%	6,120	23%	81%	193	33
DRC[49]	65,800	50%	9.0	6%	140	59%	72%	549	92
Lesotho	2,506	40%	1.6	3%	1,030	39%	82%	762	91
Malawi	13,925	47%	3.6	7%	250	40%	72%	807	71
Mauritius	1,262	24%	6.8	4%	5,580	Na	84%	15	15
Mozambique	20,531	44%	7.8	8%	330	68%	44%	520	108
Namibia	2,190	39%	6.3	5%	4,704	44%	80%	449	46
Seychelles	87	23%	0.7	6.3%*	8,960	Na	96%	1	13
South Africa	49,321	31%	362.8	3%	5,720	21%	98%	124	46
Swaziland	1,018	39%	2.89	2%	2,560	62%	80%	589	85
Tanzania	40,454	44%	16.2	7%	410	82%	72%	578	58
Zambia	11,992	46%	11.4	7%	770	64%	na	830	103
Zimbabwe	12,225	40%	12.0	8%	340	Na	90%	880	59

Legend: na = not available

Sources: WHO/PCP; AU/NPCA report; on GDP growth, TIFI Directorate[50] except for Seychelles where the data for maternal and infant mortality rate were provided by the delegate at the Member States Consultation Meeting in Gaborone on 26 August, 2011.

South Africa alone (with a population of about 50 million or one-fifth of the total SADC population) contributes about two-third of the region's GDP. South Africa also has developed strong protective measures for its manufacturers, which might affect regional pooled procurement.

Member States' GNI per capita range from USD 140 in DRC to USD 8,960 in Seychelles. SADC Member States recorded an average real GDP growth of 5.9% in 2010, 2.9% higher than the 2009 growth. The average inflation rate was 7.9% in 2010, compared with 10.1% in 2009.[51]

With the exception Mauritius and Seychelles, all Member States report shortages of qualified staff in general. Only Mauritius reported sufficient qualified staff in the public sector. The main causes of morbidity in the SADC region are broadly similar across countries, which is relevant for which essential medicines are likely to be needed. In addition to HIV and AIDS and Malaria[52], the most commonly recorded disease categories were acute respiratory infection, respiratory infection - non-pneumonia, pulmonary TB, intestinal infection, diarrhoea, and trauma & accidents. Prevalence of non-communicable diseases—such as cardiovascular diseases, cancer and diabetes—is rapidly increasing.

Some Member States have adopted strong health reforms and sector-wide approaches (SWAp). Implementation of the WHO Essential Medicines Policy has been generally accepted for several decades.

Markets may be affected by historical networks, such as the Southern Africa Customs Union (SACU), which includes Botswana, Lesotho, Namibia, South Africa and Swaziland. For example, procurement in Swaziland is biased towards suppliers in neighbouring South Africa, due to the possibility of paying in local currency.

49 *According the draft Document de stratégies et de croissance pour la réduction de la pauvreté, May 2011, GDP growth in DRC for 2010 was 7.2%, the population living on "PPP int. 1 a day" was 70% and the "infant mortality rate per 1,000" was 97.*
50 *TIFI Directorate. Review of economic performance. Gaborone: SADC, December 2010.*
51 *TIFI Directorate. Review of economic performance. Gaborone: SADC, December 2010.*
52 *Malaria is not endemic in Lesotho and the Seychelles.*

Most countries are dependent on development partners (or international cooperating partners) for part of the funding of their health services, including medicines purchases.

3.3 Political and organisational commitment

Table 5 provides an overview of official policy statements related to pooled procurement, drawn from SADC policy documents and plans. The fact that joint procurement has been on the SADC agenda for more than 10 years reflects strong commitment, both at policy and executive level.

However, commitment to pooled procurement of medicines is insufficiently reflected in the National Health Policies and National Medicines Policies (NMPs) of several Member States (South Africa is among the exceptions). Tanzania is also involved in the regional pooled procurement initiative of the East African Community.

Table 5: Statements on pooled procurement in official SADC documents

Year	*Document*	*Statement*
1998	Terms of Reference for the Establishment of the Health Sector[53]	[objective 15 out of 23 objectives] Harmonise the legislation and practice regarding pharmaceuticals, including their registration, procurement and associated quality assurance
2000	Health Sector Policy Framework[54]	Reform of drug supply systems in the Member States presents opportunities for the possible improvement of efficiencies and waste reduction to ensure access to essential medicines. Limited and partial data are a concern and may impact on attempts to improve these systems.[55] [objective b out of 6 main objectives] Promote joint procurement of therapeutically beneficial medicines of acceptable safety, proven efficacy and quality to the people who need them most at affordable prices. [priority ii out of 5 priorities] Promote a regional essential medicines and supplies service, and technical and administrative support for the procurement, supply and distribution services. [priority iii out of 5 priorities] Establish a regional drug procurement unit for carefully selected, high-priority essential drugs, and coordinate regional procurement and distribution activities so as to bulk purchase and achieve economies of scale. [strategy 4 out of 7 strategies] Promote economic evaluation to ensure the best optimal therapy at the best possible price for the region. [indicator i out of 4 indicators] Regional drug procurement unit established.
No date [but current framework for 15 years]	Regional Indicative Strategic Development Plan[56]	[as one of 4 strategies under 'Combating of the HIV and AIDS Pandemic'] Coordinate and harmonise the development of policies and strategies in major intervention areas, including prevention, care and treatment, provision of antiretrovirals, nutrition, traditional medicines, procurement and manufacturing of essential drugs and medical supplies for HIV and AIDS. [under Human and Social Development and area of focus 4.13] Establish centres of specialisation and excellence for the training and development of strategic interventions and programs on priority human development, such as high-level and critical skills development (including vocational training), and productivity (including science and technology, ICT, joint procurement and manufacturing of essential educational materials and health services, including essential drugs and antiretrovirals). Design and coordinate mechanisms for the joint procurement and production of essential drugs for the combating of HIV and AIDS, TB and major diseases.

53 *SADC. The health sector policy framework document. Mauritius 2000; 4-5*
54 *SADC. The Health sector policy framework document. Mauritius 2000; pp 98-99.*
55 *SADC. The Health sector policy framework document. Mauritius 2000; p 20.*
56 *SADC. Regional indicative strategic development plan; pp 57, 73, 138.*

No date [but currently valid]	Protocol on Health[57]	State Parties shall cooperate and assist one another in the: a) Harmonisation of procedures of pharmaceuticals, quality assurance and registration; and b) Production, procurement and distribution of affordable essential drugs.
No date [currently valid]	Implementation Plan for the Protocol on Health[58]	[Second of five milestones, 2008-2013] Mechanisms for improving sustainable availability and access to Essential Medicines effectively implemented by 2013 (local production &joint procurement & distribution) [Second of six objectives] Promote local production, joint procurement and distribution of affordable essential drugs;
2007	SADC Pharmaceutical Business Plan 2007-2013[59]	[One of seven strategies] Promote joint procurement of therapeutically beneficial medicines of acceptable safety, proven efficacy and quality to the people who need them most at affordable prices. [Opportunity five out of nine] Improve efficiency in supply chain management systems through regional collaboration and sharing of best practices in public sector procurement.
2009	Zero Draft SADC Regional Pooled Procurement Strategy[60]	For policy statements reference is being made to the Protocol on Health, which describes the establishment of a permanent SADC Procurement Directorate, a Central Fund and a regional Reference Medicines Regulatory Authority (TORs included).

With the exception of Mauritius (which follows WHO guidelines as policy), all SADC Member States have established NMPs, and 10 have a related NMP implementation plan. There is strong similarity between the NMPs, which may be explained by the fact that they are all based on WHO's Essential Medicine Policy principles. Although SADC Member States are at various levels of pharmaceutical sector development and pharmaceutical services delivery, the objectives set out in their NMPs are broadly similar.

The telephone interviews with the in-charges of the pharmaceutical sector revealed that there are no doubts related to the current commitment at political and operational level to pooled procurement. The inclusion of regional pooled procurement in the national policy documents may therefore be regarded as a necessary formality.

There is no SADC Regional Medicines Policy at the moment. However, with the SADC Pharmaceutical Business Plan in place and almost all Member States having NMPs, preparation of a regional pharmaceutical policy is expected to be relatively straightforward.

Experts envision a Regional Medicines Policy containing overarching guidance for the development of the regional pharmaceutical sector, both public and private, as a pre-condition for successful realisation of regional pooled procurement.[61] Such a Regional Medicines Policy would also offer guidance to investments in systems strengthening by funding entities such as the Global Fund, and to other interventions by development partners working in the region.

This study included an attempt to develop an inventory of funding agencies and development partners supporting pharmaceutical PSM systems in the Member States, but too little information was available to present detailed results. However, it appears that (with the exception of Mauritius) all Member States receive some support for improving pharmaceutical PSM systems and/or quality assurance. More than 20 different development partners appear to be working in the pharmaceutical sector in the region.

The Global Fund finances health programmes in all Member States except the Seychelles. The Global Fund has disbursed a total of USD 3.1 billion out of the USD 4.8 billion approved funds for all SADC countries, of which an estimated 47% was for essential medicines and supplies.[62]

57 *SADC Protocol on health; Article 29.*
58 *SADC. Implementation plan for the protocol on health; p 39.*
59 *SADC. Implementation plan for the protocol on health; p 39.*
60 *SADC Secretariat/SADC Pharmaceutical Programme. SADC pharmaceutical business plan 2007-2013, 27 June 2007.*
61 *As realised in the Caribbean, where the CARICOM Ministers of Health approved the Caribbean Pharmaceutical Policy as a tool to guide the development of the pharmaceutical sector in the region.*
62 *See http://www.theglobalfund.org/en/activities/psm [accessed 03 Aug 2011]: "An estimated 47% of Global Fund grants has been used on procurement."*

Three SADC countries and several development partners are committed to the harmonisation of health systems[63] and public procurement practices.[64] A study mapping donor assistance to the pharmaceutical sector in DRC listed 17 development partners active in supporting this sector in that country. In this case, however, coordination is an issue, since international pharmaceutical procurement is divided across three procurement groups, while the national plan is left underfunded.[65] Development partners should be much more involved in a regional approach to strengthening health systems, in general, and the pharmaceutical sector, in particular. Regional mapping of the activities of development partners may be seen as a first step toward better regional coordination.

The Global Fund's quality assurance policy no longer allows procurement of medicines marketed in countries with regulatory authorities' membership of the PIC/S[66] or registered by local Member States' regulatory authorities. When working on regional standards (including accepting the marketing status in Member States), the Global Fund needs to be convinced to accept these standards in the spirit of international harmonisation efforts.

A review of the officials managing the pharmaceutical subsector in Member States' Ministries of Health indicates that a minority are at the required highest technical level in the Ministry: only 4 of 14 officials are at the Directorate level (Level 1 in Table 6). Their tasks are multiple (on average eight key tasks have been identified), and range from guiding and supervising the subsector to executive tasks, such as budget preparation. In 10 of 12 Member States, the officials are involved in resource allocation decision-making. The role can be regarded as a key function, since the pharmaceutical budget is the second biggest budget in the public health sectors of almost all Member States (the personnel budget being the largest).

An evaluation of the EU/ACP/WHO programme 2006-2010 revealed that the involvement of other key stakeholders (such as professionals, NGOs and the public) is weak in the pharmaceutical subsector. This is due to several factors, including a technocratic approach that overshadows a more developmental approach, the fact that strategic issues take precedence (such as broader health system development, capacity building, SWAP processes, etc.), and the variable position of Chief Pharmacists in the health hierarchy. There is a need to "re-profile" the pharmaceutical subsector in the wider health system, so as to ensure that priorities are properly addressed in broader national health policies and plans.[67]

Table 6: Positions and tasks of officials managing the pharmaceutical sections in SADC Member States' Ministries of Health

	Ministry of Health level	# of supervisory tasks	# of executive tasks	Total # of tasks
Angola	1[68]	4	3	7
Botswana	3	3	3	6
DRC	1	4	3	7
Lesotho	2	5	3	8
Malawi	2	6	4	10
Mauritius	1	5	6	11
Mozambique	*2*	*3*	*0*	*3*
Namibia	*2*	*4*	*3*	*7*
Seychelles	*1*	*5*	*5*	*10*
South Africa	*2*	*4*	*4*	*8*

63 *For example, the International Health Partnership and related initiatives seek to achieve better health results by mobilising donor countries and other development partners around a single, country-led national health strategy, guided by the principles of the Paris Declaration on Aid Effectiveness and the Accra Agenda for Action (see http://www.internationalhealthpartnership.net/en/home). DRC, Mozambique and Zambia are country partners of the International Health Partnership.*

64 *Developing countries, and bilateral and multilateral donors worked together in 2003-2004 using a round table process to develop an integrated set of tools and good practices to improve developing country public procurement systems and their contribution to development outcomes. The work of the round table on procurement is an integral component of the agenda for aid effectiveness, harmonisation, alignment and results set out in the Paris Declaration. The results are contained in good practice papers. In view of the importance of sound procurement systems for aid effectiveness, the papers are being published as Volume 3 of the DAC Guidelines and Reference Series on Harmonizing Donor Practices for Effective Aid Delivery.*

65 *Mulangu/Vreeke. Mapping donor assistance in the pharmaceutical sector in the Democratic Republic of the Congo. 2010. Draft version.*

66 *Pharmaceutical Inspection Convention-Scheme (http://www.picscheme.org/), which includes South Africa's regulatory authority, the Medicines Control Council, as a member.*

67 *Dubbeldam/Verhage. End-of-programme evaluation: EU/ACP/WHO partnership on pharmaceutical policies. AEDES Consortium, 2010*

68 *Levels: 1 = Directorate; 2 = Sub-directorate; 3 = lower than sub-directorate*

Swaziland	2	3	5	8
Tanzania	2	Ne	Ne	ne
Zambia	2	Ne	Ne	ne
Zimbabwe	2	8	3	11
Average	na	4.3	3.5	7.8

Legend: na = applicable; ne = not established; Ministry of Health Level 1 = Directorate responsible to Permanent Secretary; Level 2 = Sub-directorate or Department responsible to Director; Level 3 < level 1 or 2; Source: August 2011 SARPAM Questionnaire

The median number of available pharmaceutical personnel (defined as pharmacists, pharmaceutical assistants, pharmaceutical technicians and related occupations) is 0.7, and varies from 0.3 to 7 per 10,000 inhabitants in the SADC region.[69] Although there is no international recommend ratio for pharmaceutical human resources, these figures suggest that there are serious shortages of qualified personnel in a number of SADC Member States. The questionnaire responses indicated shortages of pharmacists in five Member States and shortages of procurement staff at central level in three Member States (see Table 7). However, several Member States pointed out that the data were assembled by comparing the actual number of pharmacists and procurement officers to the number of established posts. Often the latter were established longer than 10 years ago and no longer reflect the real needs. Indeed, the officials in-charge of the pharmaceutical sector in nine Member States confirmed serious shortages of qualified staff (see last column of Table 7).

Although further study is needed, it may be concluded that a programme for strengthening staff numbers should be a priority. A Regional Institute that can provide pooled procurement services would be especially useful to Member States that are experiencing the most serious shortages of qualified personnel.

The data shown in Table 7 do not compare shortages of qualified staff in the public and private sectors. However, two countries attributed their shortages of pharmacists in the public sector to the differences in remuneration between the public and private sectors. South Africa has taken steps to counteract that situation.

The matter of migration of qualified staff within the region is also an issue. Several Member States employ pharmacists from other SADC countries, both in the private and public pharmaceutical sectors. However disadvantageous this may be for the respective countries, this practice may also facilitate greater conformity in line with commonly agreed standards. Some officials recommended a regional agreement on qualifications, and minimum terms and conditions for pharmaceutical staff.

Table 7: Pharmacists and procurement staff in SADC Member States

	Population (1000s)	# of pharmacists in-country	# of pharmacists (10,000's)	Regional or provincial pharmacists shortage[70]	NMPA[71] procurement officers shortage[71]	Pharmaceutical staff shortage confirmed by in-charge
Angola	17 024	127	0.07	88%	33%	Yes
Botswana	1 882	125[72]	0.66	na	na	Yes
DRC	65 800	1,144	0.17	80%	na	Yes
Lesotho	2 506	31	0.12	0%	0%	No
Malawi	13 925	136	0.10	100%[73]	0%	Yes
Mauritius	1 262	354	2.81	0%	na	No
Mozambique	20 531	111	0.05	na	na	Yes
Namibia	2 190	285	1.30	15%	na	Yes

69 *WHO. Baseline assessment of the pharmaceutical situation in Southern African Development Community countries. Fact book 2009 (WHO/EMP/MPC/2010.3), 2010.*

70 *The figures were established by comparing the number of posts filled with the number of established posts.*

71 *NMPA = National Medicines Procurement Agency, i.e. the government agency that procures, stores and distributes essential medicines and commodities. It can be a Ministry of Health structure or a more autonomous entity that is controlled by the government.*

72 *In September 2012, the Botswana delegation at the SADC Member State Consensus-Building Meeting indicated that this number relates only to pharmacists working in the public sector.*

73 *In Malawi, pharmacy technologists are used instead of pharmacists (at regional and district levels).*

Seychelles	87	10[74]	1.14[73]	na	50%	Yes
South Africa	49,321	11,833	2.40	na	na	No
Swaziland	1,018	44	0.43	17%	20%	Yes
Tanzania	40 454	639	0.16	ne	ne	No
Zambia	11 992	243	0.20	ne	ne	Yes
Zimbabwe	12 225	550	0.45	0%	0%	No
Average			0.70			

Legend: na = not available; ne = not established
Source: WHO/PCPs and August 2011 SARPAM Questionnaire

In 8 of the 14 Member States, the operational functions of pharmaceutical PSMs form part of the Ministry of Health, and in 5 Member States this is the case also for regulatory functions. This renders these functions more vulnerable to direct political influence than if they were organised outside the Ministry of Health, with a clear distinction between supervisory and executive functions in order to comply with the first principle in the IPC Operational Principles for Good Pharmaceutical Procurement . In this respect, too, outsourcing operational procurement functions to a Regional Institute may benefit the countries that are prepared to efficiently re-organise their national pharmaceutical PSM systems. Supervisory and executive functions in procurement can be separated by setting up a Procurement Unit and a Tender Committee or Board, each with distinct responsibilities. As shown in Annex 5, almost all Member States already do so.

3.4 Procurement policies and legislation

With the exception of South Africa, all Member States have formal public procurement legislation in place. The procurement legislation, supplemented with procurement regulations, applies to the public procurement of medicines and medical supplies in all Member States (except in the Seychelles, where medicines procurement is exempted).

Responses to the questionnaire indicated that the public sector procurement regulations apply to pharmaceutical procurement in 10 of the 12 responding Member States. In Seychelles, the procurement of medicines is not subject to the public sector procurement regulations (unlike the procurement of other medical commodities). On request, Member States indicated the key steps in pharmaceutical procurement that their procurement legislation allows, as well as the application of these steps by their NMPA (regardless of whether the agency forms part of the Ministry of Health or is autonomous). The results are summarised in Table 8 and the details are presented in Annex 4.

Table 8: Summary of steps in procurement of pharmaceuticals allowed in existing public procurement legislation, and overview of steps actually applied by NMPAs in Member States

	Member States where procurement steps are in listed in the Act	Member States where procurement steps are applied by NMPA	Respondents
Pre-qualification of suppliers	7	6	12
Pre-qualification of products	6	9	12
Framework contracts	8	6	12
Standard Bidding Document for Pharmaceuticals	8	12	12
Public Bid Opening	9	10	12
Waivers from international competitive tendering (i.e. using alternative procurement methods)	4	6	12
Negotiation	6	7	12
Publication of awards	8	10	12
Outsourcing of procurement	1	2	12
e-Procurement	1	0	12

Source: August 2011 SARPAM Questionnaire

74 *Updated from 3 to 10 pharmacists by the Chief Pharmacist of Seychelles, August, 2012.*

As Table 8 shows, almost all Member States use a Standard Bidding Document for Pharmaceuticals and the majority employ Public Bid Openings and publish the awards—all of which is supported by current legislation. These features are important benchmarks for good procurement practices.

Four Member States indicated that they procure products that are not pre-qualified by being included in the National Medicines Regulatory Authority Register. This may indicate that those medicines are to be registered after awards are made (but before contracting), or that unregistered medicines are being allowed on the market. Indeed, one country indicated that the registration of medicines applied only to the private sector. The PMA found that in 7 of the 9 study countries that do issue marketing authorisations, only registered medicines were allowed to be procured for the public sector. Related findings from the 2009 WHO Assessment of the Pharmaceutical Situation in SADC Member States can be summarised as follows:

- 12 of the 15 [the WHO/PCP includes Madagascar] responding countries' procurement agencies used the WHO Prequalification of Medicines Programme[75] to identify suppliers;
- 11 of the 15 responding countries' procurement agencies used the WHO Certification Scheme on the quality of pharmaceutical products circulating in international commerce[76];
- 13 of the 14 responding countries' procurement agencies confirmed that a functioning process existed to ensure the quality of other procured products, and in 11 countries this included pre-qualification of products and suppliers, as well as explicit criteria and procedures for pre-qualification of suppliers.

However, the current survey found only 6 of the 12 Member States where pre-qualification of suppliers by NMPAs is applied, even though this pre-qualification is one of the Principles for Good Pharmaceutical Procurement (see Table 3). Half of the 12 Member States apply framework contracts—an important feature with considerable advantages compared to traditional tenders.

Waivers on tendering (i.e. using alternative procurement methods) and negotiation seem to be a common practice in half of the Member States. The recent South African antiretroviral tender experience used a pooled procurement mechanism operated by the National Department of Health on behalf of provinces. It demonstrated the potential for pricing information (through negotiations supported by CHAI) and smarter tender specifications and procedures to dramatically impact on procurement prices and other terms. Recently, the Minister for Health in South Africa announced an 18% aggregate reduction in the cost of anti-TB medication and antibiotics, which translated to a saving of ZAR 242 million. Other Member States could benefit from this kind of specific experiences if they are shared via a regional pooled procurement platform.

Only two Member States reported outsourcing of procurement. This might be because Member States did not regard the use of third party agencies by development partners as outsourced procurement. Alternatively, it might indicate that experiences in the region with outsourced procurement are limited. All Member States laws have provisions that allow for engagement of third party procurement services.

None of the Member States apply e-procurement, but all showed a keen interest.

Differences in the public procurement legislation and regulations do exist, but are not expected to have a major impact on a SADC Pooled Procurement Strategy, possibly with the exception of domestic preferences. The PMA reported that 8 of the 13 study Member States add a preference for locally manufactured products in their tenders. In most cases, the preference is applied as a percentage deduction from the quoted price during financial evaluation. The study interviews also revealed that 6 Member States apply preferences for products that are offered by local wholesalers. The range of preferences given was between 5% and 30%, and is set out in Member State legislation and regulations.

75 *This is the United Nations Prequalification Programme, managed by WHO; see http://apps.who.int/prequal/: "The list of prequalified medicinal products used for HIV/AIDS, Malaria, tuberculosis and for reproductive health produced by the Programme is used principally by United Nations agencies, including UNAIDS and UNICEF, to guide their procurement decisions. But the list has become a vital tool for any agency or organization involved in bulk purchasing of medicines, be this at country level, or at international level, as demonstrated by the Global Fund to Fight AIDS, Tuberculosis and Malaria."*

76 *"The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce guarantees, through the issue of a WHO-type certificate by the certifying authority, "the quality of pharmaceutical products entering international commerce. It is a simple administrative procedure that enables importing countries to obtain information on whether a product has been authorized to be placed on the market in the exporting country, and assure that the manufacturer has been found to comply with WHO standards of good manufacturing practices." See WHO. Operational package for assessing, monitoring and evaluation country pharmaceutical situations (Guide for coordinators and data collectors), December 2007, p 52. Available at http://apps.who.int/medicinedocs/documents/s14877e/s14877e.pdf [accessed 19 September, 2011]*

This implies that domestic producers and wholesalers can be awarded a contract even if their price is higher than that of competitors. Existing domestic preference arrangements may impede regional joint contracting, but should not be a problem as long as pooled procurement is in the phase of information and work sharing.

In most Member States, the procurement legislation includes a clause that allows the use of development partners' procurement guidelines when those partners are funding procurement. Some development partners prefer to use the existing national procurement regulations and structures as long as they comply with the internationally accepted "good practices". The World Bank has been supporting procurement reforms in most Member States for some time and regularly assesses progress. Public procurement in most Member States has developed considerably in compliance with "good practices", although irregularities may still occur in some Member States and remain a concern. The use of NMPAs by development partners is being recommended in order to promote NMPAs' "good practices".

The questionnaire enabled a closer look at the status and functioning of NMPAs in Member States, especially where there is a proper distinction between functions.

In several countries, public procurement reforms have taken place or are ongoing. Public procurement legislation and regulations affect the procurement of medicines. The Common Market for Eastern and Southern Africa (COMESA), runs a regional public procurement programme, Enhancing Procurement Reforms and Capacity Project (EPRCP), which seeks to harmonise public procurement rules and regulations.[77] This procurement project (funded by the African Development Bank, until the end of 2011) has developed a website where information on existing procurement legislation in the COMESA countries are published, as along with procurement opportunities (tenders).[78]

The agreement on Trade Related Intellectual Property Rights (TRIPS) of the World Trade Organization (WTO) obliges all SADC member states to provide a certain minimum level of intellectual property protection in their national patent, trademark and copyright legislation. The same TRIPS agreement and the 2001 Doha Declaration, however, incorporate flexibilities that allow governments to bypass patents in the interest of public health, under certain conditions. Member States that lack these flexibilities in their national intellectual property laws can find that their abilities to procure more affordable generic versions of patented medicines are severely limited. This is important not only for HIV and AIDS, TB and Malaria, but for all diseases, including non-communicable diseases, A 2007 survey[79] showed that the level of incorporation into law and the use of these flexibilities were very low in Eastern and Southern Africa.[80] Procurement of affordable medicines thus requires maximising the use of these flexibilities and avoiding unnecessary conditions, including the so-called TRIPS+ pressures, in Free Trade Agreements and/or Economic Partnership Agreements.

SADC Member States in recent years have relied heavily on affordable generics from India for their HIV treatment programmes. The TRIPS agreement, however, makes it very difficult for India to manufacture generic copies of medicines patented after 1 January 2005. "Least Developed Countries" (LDCs) are exempted from the TRIPS obligations for pharmaceuticals until at least 2016, and therefore are the only countries that can legally make generic copies of post-2005 patented medicines.[81] Since a majority of countries in the SADC region are classified as LDCs, they can benefit from article 32bis in the TRIPS agreement, which allows for the (re)exportation of such generics to other countries in the SADC region. If the SADC region wishes to benefit from this possibility, serious joint planning, transfers of technology, financing and a regional strategy will be needed, involving the Health and Trade Ministries in the region.

3.5 Medicines regulatory systems

3.5.1 Medicines regulatory harmonisation

The SADC Pharmaceutical Programme has organised the National Medicines Regulators regionally in a regulators' forum, which holds regular meetings. In addition, using support from WHO, a shared regulators' platform has been created which allows for virtual communication and email discussions among the regulators and the SADC Secretariat Senior Programme Officer for Health and Pharmaceuticals. Activities related to harmonisation of registration guidelines as part of the regulatory harmonisation process led to development of this infrastructure. The SADC Secretariat Senior Programme Officer, with support from international cooperating partners facilitated the development of 17 regional guidelines for registration of medicines.[82]

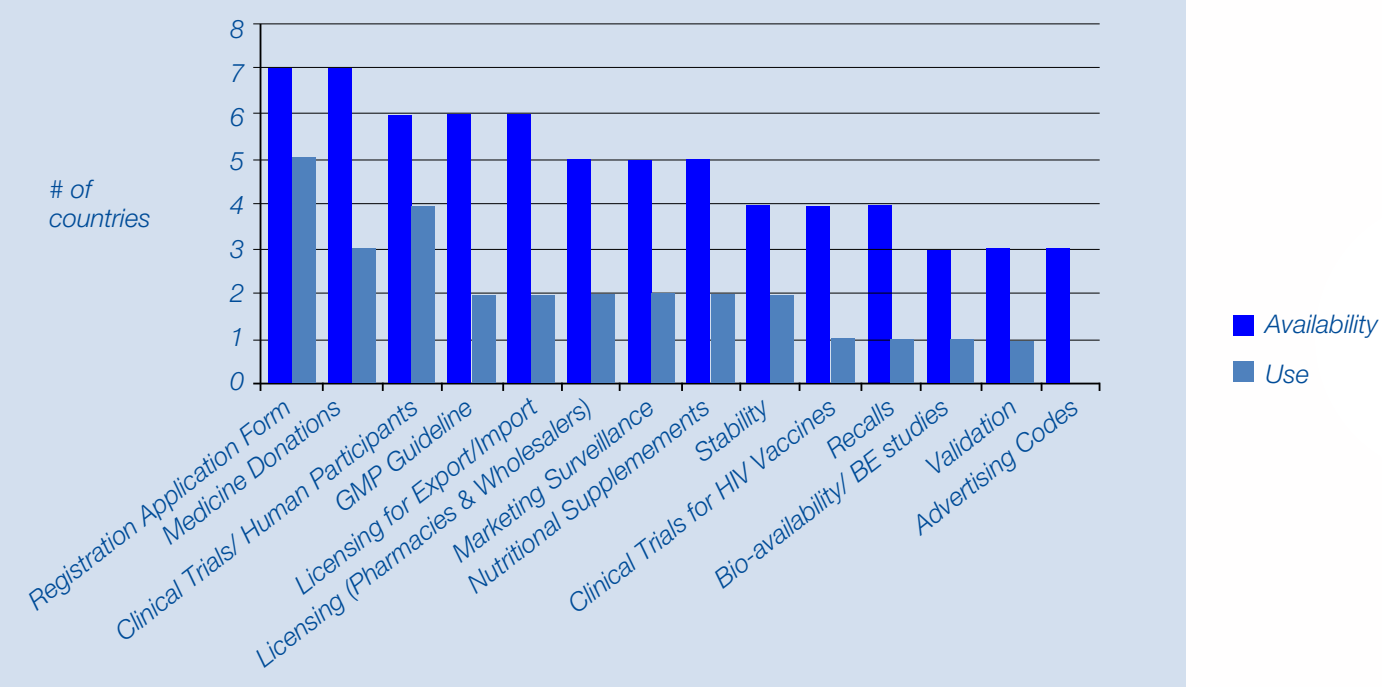
77 *See http://programs.comesa.int/index.php?option=com_content&view=article&id=21&Itemid=23&lang=en and http://promis.comesa.int/*
78 *See http://promis.comesa.int*
79 *Currently being updated by SARPAM.*
80 *Musungu SF. Access to ART and other essential medicines in sub-Saharan Africa: Intellectual property and relevant legislations. UNDP, September 2007.*
81 *If patented before expiry of the patent, but not necessarily so, because least-developed countries are not obliged to grant patents under TRIPS.*
82 *SADC registration guidelines.*

The guidelines were developed by the SADC regulators and approved by the SADC Ministers of Health. SADC is therefore well placed to participate in the African Medicines Registration Harmonization Initiative for the SADC Regional Economic Community as an initial step towards regulatory harmonisation.[83]

The PMA found that few of the existing SADC medicines regulatory guidelines are actually available or used in the Member States (Figure 1). Only one country reported that the current national guidelines of the Medicines Regulatory Authority had incorporated SADC harmonised guidelines.

In line with the African Medicines Registration Harmonisation Initiative and in order to provide baseline data concerning the medicines regulation and harmonisation situation in the SADC region, the African Union NEPAD Planning and Coordinating Agency commissioned a Situational Analysis of Medicines Regulation and Harmonisation in the region. This in-depth report provided baseline information on the status and functionality of National Medicines Regulatory Authorities across the region.[84] A subsequent five-year project proposal was prepared for the Harmonisation of Medicines Registration in the SADC Region.

Figure 1: Availability and use of SADC harmonised medicines regulatory guidelines in 12 study countries[85]



Source: PMA

The African Union NEPAD Planning and Coordinating Agency assessment report summarised the medicines regulatory arrangements in Member States as follows:

- Some Member States do not have well-articulated mission statements for their National Medicines Regulatory Authorities. In addition, some laws are outdated and some of those Authorities lack implementation strategies for their policies.

- Most of the National Medicines Regulatory Authorities are involved in regulatory functions such as licensing of pharmaceutical manufacturers, importers and retailers; inspections of Good Manufacturing Practices (GMP) and distribution channels; quality control; regulating generic distribution; controlling prescribing; and coordinating medicine regulation. In addition, some are also involved in the control of pharmacy practice.

- Most countries have explicit provisions in their legislation for registering medicines. Angola, DRC[86], Lesotho, Seychelles, and Swaziland currently are not actively registering medicines.

83 *SADC. Harmonization of medicines registration in the SADC region, July 2011.*
84 *AU/NPCA. Situational analysis study on medicines registration harmonization in Africa. Final report for the Southern African Development Community (SADC), November 2010.*
85 *Information for Lesotho was not available.*
86 *This information was not confirmed when SARPAM checked: active registration of medicines does take place in DRC. WHO/ PCP also reports that DRC has registration of medicines.*

- In some countries, registration may be waived under certain conditions including medicines for clinical trials, medicine of public interest, and in case of an epidemic.[87]

- Registration guidelines are available and most cover generics, new chemical entities, and renewals. The Certificate of Pharmaceutical Products is required for registration in most countries, while some countries require registration with another stringent regulatory authority.

- Information on fast tracking registrations is made available to the public. The medicines concerned generally include those for HIV and AIDS, Malaria and TB. Average registration times are six months for fast-tracked medicines and 24 months for normal registrations. The final registration decision is made by Boards, Directors-General or Technical Registration Committees, depending on the National Medicines Regulatory Authority

- The pharmaceutical industry is most developed in South Africa, while remaining comparatively weak in other Member States. National manufacturer associations exist in some countries, and one regional association (SAGMA) is operating in the region. The industry has a moderate to excellent sense of what is required to apply for registration. However, some aspects of the registration process are considered superfluous. These include the need to include manufacturing route synthesis of API during dossier submission and payment of fees in US dollars. Difficulties mentioned in registering medicines include lengthy registration periods, confusing guidelines, weak feedback mechanisms, administrative delays and poor record keeping. The industry is highly supportive of the medicine registration harmonisation initiative.[88]

- Sharing of information with stakeholders is crucial for the success of the harmonisation process. Although websites do exist, information is not updated or uploaded regularly and the websites are not networked regionally. Information is shared in various ways including television, radio and print media. Most NMRAs share information when participating in the activities of the African Medicines Registration Harmonisation programmes.

- There is enthusiasm and commitment in the SADC Secretariat, National Medicines Regulatory Authorities and the pharmaceutical industry for implementing a harmonised medicine regulatory system. The key stakeholders and partners recognise the benefits of regulatory harmonisation.

The PMA found that there is no common regional approach to fast-track applications for medicines registration. Opinions most frequently expressed in interviews conducted with public and private sector stakeholders on medicines regulatory harmonisation were as follows:

- Harmonisation of registration procedures could do much to facilitate registration of products in a larger number of markets.

- Registration in one Member State should facilitate registration in other Member States. Whether this would mean direct, full acceptance of the product or the skipping of one or more steps in the registration process is to be decided.

- For mutual recognition of registration among all SADC Member States there is a risk that countries with an underperforming regulatory authority might negatively affect the quality of medicines on the markets in other Member States. This could be addressed by only accepting registration with those regulatory authorities that have reached a certain level of performance.

Additional information was captured from the WHO Pharmaceutical Country Profiles and from the questionnaire (see Annex 6 for more detail):

- Of the 11 Member States that register medicines, only Botswana lacks explicit provision in its legislation granting a legal mandate to its National Medicines Regulatory Authority to register medicines.

- Legal provisions for market authorisation exist in all Member States, but are still in draft in four of them.

87 *Waivers could potentially be applied to medicines acquired through regional initiatives such as pooled procurement arrangements, but this would not be the preferred method. Mutual recognition of medicines registration based on agreed common standards would be a better option.*

88 *The Pharmaceutical Industry Association of South Africa reports a clear link between access to markets and regulatory requirements. For example, life-saving essential medicines for rare diseases often are not considered commercially attractive enough to justify the efforts and costs involved in registering them, especially when markets are relatively small. A number of countries reported that they have problems sourcing these medicines.*

- WHO advises National Medicines Regulatory Authorities to be independent. However, five of the 11 Authorities in Member States fall under the Ministry of Health. The African Union / NEPAD Planning and Coordinating Agency identified only two National Medicines Regulatory Authorities that are largely financially independent from government (Malawi and Zimbabwe).

- At least three National Medicines Regulatory Authorities require applicants (local agents) to be resident in the country in order to register medicines, while one (Zimbabwe) reported that this was not a legal requirement. Although it is generally deemed important for quality assurance, the local residency requirement may impede access to Member State markets.

- Only one Member State (Mauritius) stated that its National Medicines Regulatory Authority product license numbers are not required on labels of imported medicines. However, such labeling was a legal obligation in four Member States. The requirement for local product license number labeling of imported products increases costs (especially in smaller markets) and may impede access to products. Alternatively, requiring the country of origin on the label may improve quality standards.

The African Union / NEPAD Planning and Coordinating Agency reported that six National Medicines Regulatory Authorities in 14 Member States have websites.[89] All feature important information related to legislation, guidelines, registration or application forms, and process and fee structure, as well as lists of rejected products, banned products, authorised manufacturers, and other information. However, only two Member States reported that a list of registered products is being maintained on the website (Namibia and South Africa). In Namibia this list includes the name and address of the manufacturer.

The African Union / NEPAD Planning and Coordinating Agency assessment report listed the following benefits of regional regulatory harmonisation:

- Communities and patients will enjoy increased availability of safe, effective, quality medicines for neglected and priority diseases. Safer, higher-quality medicines will circulate in the market in the long-term.

- It will facilitate improved availability of safe and effective essential medicines at affordable prices. This will contribute to the achievement of the Millennium Development Goals relating to health (Goals 4, 5, 6 and 8).

- National Medicine Regulatory Authorities will be better equipped to register medicines in a cost-effective and timely manner, by improving regulatory processes and making better use of technical skills. They will enjoy greater technical capacity, improved quality of inspections, and more effective control over registered, unregistered and counterfeit or substandard medicines.

- Pharmaceutical companies will benefit from simplified and standardised regulatory approval processes, including faster processing times. This is expected to lead to the simultaneous submission of dossiers for much-needed medicines in multiple countries.

However, the same report identified the following challenges as SADC pursues the medicines regulation harmonisation agenda:

- Seychelles does not have a National Medicine Regulatory Authority and thus carries out medicines regulatory functions within its Ministry of Health.

- Human resources capacity (in terms of both skills and numbers) is limited at the SADC Secretariat and in Member States.

- Physical facilities vary in Member States and need to be expanded to cater for the full functions of medicines regulation.

89 *Malawi – www.pmpb.mw; Zimbabwe – www.mcaz.co.zw; Zambia –www.pra.gov.zm; Namibia – www.nmrc.com.na; South Africa – www.mccza.com; and Tanzania – www.tfda.or.tz.*

- There is a shortage of quality control laboratories in most National Medicine Regulatory Authorities. In addition, few are pre-qualified by WHO or have been certified as an ISO-17025 compliant laboratory.[90]
- There is inadequate financial support, especially for small medicines regulatory authorities.

3.5.2 Availability of registered products for tracer items

Information in this section has been extracted from the 2010 PMA study report.

One of the PMA's objectives was to establish commonalities of product registration in the SADC region. This was done by using a list of 50 tracer items.

Four of the SADC Member States do not currently register medicines (Angola, Lesotho, the Seychelles and Swaziland). Information on the number of registered products per tracer item is based on nine study countries and is shown in Figure 2.

Medicines Regulatory Authorities were requested to provide information for up to three registered products for each tracer item, including the originator brand where applicable. Information about the registered product's name, manufacturer and name of applicant (where available) was sourced from the Medicines Regulatory Authorities' official register.

Some priority medicines for children (paediatric formulations) or maternal health (such as magnesium sulphate injection) have very few products registered in countries and in the region as a whole. Therapeutic alternatives do not exist for all of them. This might not have been captured by the survey, and the low number of registrations indicates restriction of access to adequate treatment.

During a consultative meeting in September 2010, Member States provided some updated information on the number of products registered. Although not reflected in Figure 2, the updated information does not alter the overall picture.

90 *See also section 3.5.4. The number of ISO-17025 certified quality control laboratories was not ascertained, but it may be substantial as this is a requirement under cGMP standards for manufacturers. The Global Fund has a (incomplete) list of ISO-17025 certified quality control labs. The MCAZ quality control lab is listed.*

Figure 2: Number of product registrations per tracer item and study country[11]

		Columns blocked for [illegible]							
[illegible]	27	3+	[illegible]	3+	3+	3+	3+	3+	3+
[illegible]	27	3+	[illegible]	3+	3+	3+	3+	3+	3+
amoxicillin 500mg tablet/capsule	26	3+	3	3	3+	3	3	3	3
[illegible]	26	3+	[illegible]	3+	2	3+	3+	3+	3+
[illegible]	26	3	[illegible]	3+	3+	3+	3+	3+	3+
[illegible]	26	3+	2	3+	3+	3+	3+	3+	3+
[illegible]	26	3+	3	3	3+	3+	3+	3+	2
[illegible]	26	3+	3	3+	3+	3	3+	3	3
[illegible]	26	3+	[illegible]	3+	3+	3+	3+	3+	3
[illegible]	26	[illegible]	3	3+	3+	3+	3+	3	3
amoxicillin 125mg/5ml suspension	25	3+	3	3	3+	3	3+	3	3
[illegible]	25	3+	3	3+	3+	3	3+	3	3
[illegible]	25	3+	3	3	3+	3+	3+	3+	3+
[illegible]	25	3+	3	3+	3	3	3+	3	3
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[illegible]	18	3	[illegible]	3	3	3	3	3	[illegible]
[illegible]	18	[illegible]	[illegible]	3+	[illegible]	3+	[illegible]	3+	3
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[illegible]	13	[illegible]	3	3	3	3	3	3	[illegible]
[illegible]	12	3+	3	[illegible]	[illegible]	3	3	3	3
[illegible]	11	[illegible]	3	[illegible]	3	3	3	3	3
[illegible]	11	3	[illegible]	3	[illegible]	3+	[illegible]	3	3
[illegible]	10	[illegible]	3	3	[illegible]	[illegible]	3+	3	[illegible]
[illegible]	9	3	[illegible]	3	[illegible]	3+	[illegible]	[illegible]	3
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[illegible]	8	3+	[illegible]	[illegible]	[illegible]	3	[illegible]	3	3
[illegible]	8	[illegible]	3	[illegible]	3	3+	[illegible]	[illegible]	3+
[illegible]	7	3	[illegible]	[illegible]	3	3	3	[illegible]	[illegible]
[illegible]	6	3	[illegible]	[illegible]	[illegible]	[illegible]	3	3	[illegible]
[illegible]	3	[illegible]	3	[illegible]	3	[illegible]	3	[illegible]	[illegible]

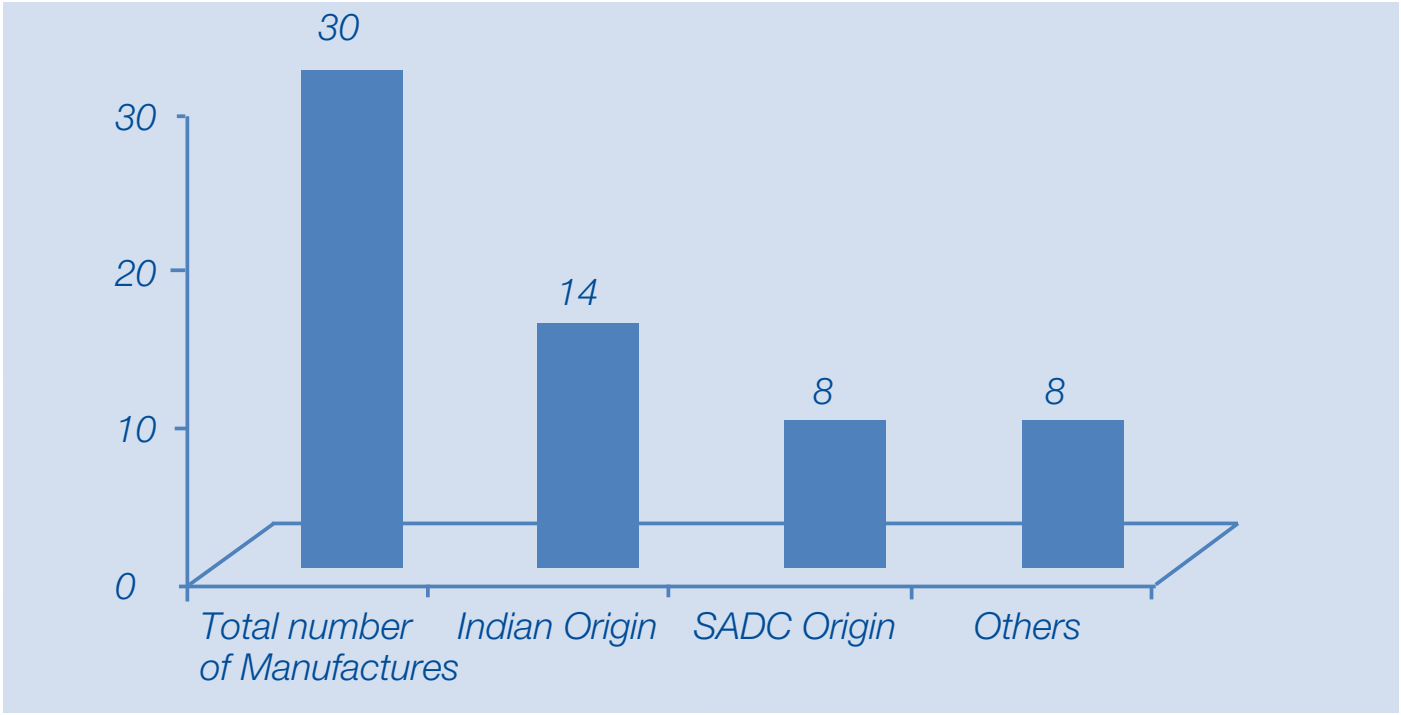
11 *Tracer items are ranked in descending order according to the total number of products registered in the region (second column). The actual numbers could be higher, because the study only captured up to three registered products per tracer item per country (indicated by 3+ in the respective country fields). The same applies to the overall total in the second column.*

3.5.3 Similarity of registered products in the region

Information in this section has been extracted from the 2010 PMA study.

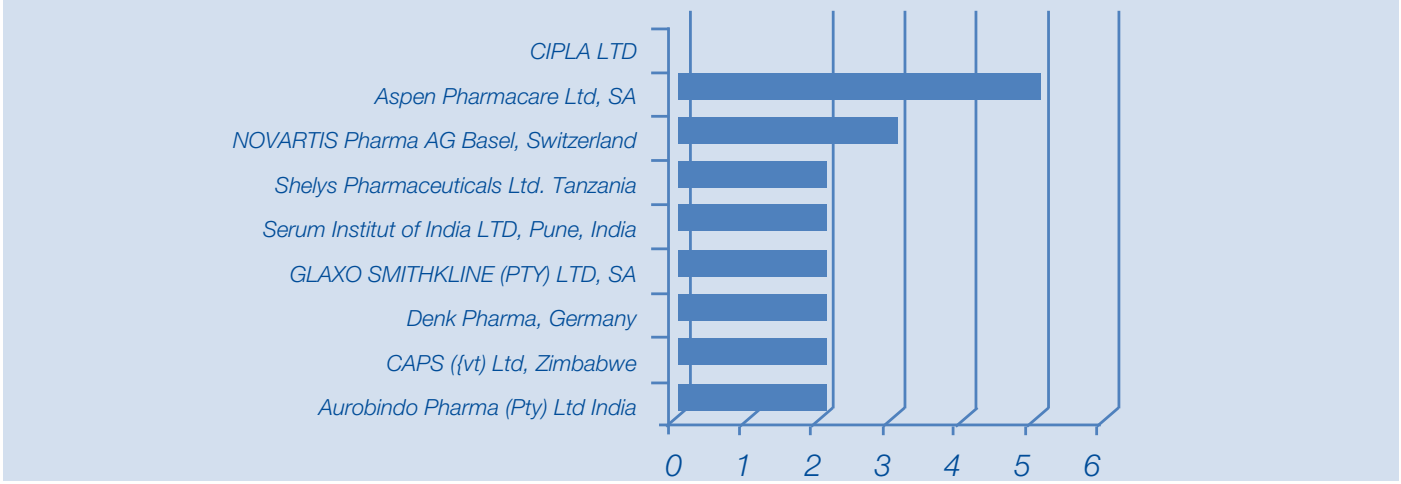
- For 30 of the 50 tracer items, the same product (i.e. manufactured by the same company) is registered in at least three study countries.
- 30 different manufacturers have one or more tracer item products registered in at least three countries. Eight of these manufacturers are based in the SADC region and 14 are based in India (see Figure 3).

Figure 3: Number of manufacturers with one or more tracer item products registered in at least three countries



Manufacturers that have more than one tracer item product registered in at least three countries are shown in Figure 4. CIPLA has registered products in at least three countries for six different tracer items. Since CIPLA is supplying a number of WHO pre-qualified antiretrovrials and all countries that register medicines have HIV treatment programmes, CIPLA has greater access to the markets (global funders restrict procurement to WHO pre-qualified products where they exist). However, we could not identify one dominant player in the SADC pharmaceutical market.

Figure 4: Manufacturers with tracer item products registered in at least three countries



3.5.4 Quality control laboratories

Information in this section has been extracted from the 2010 PMA study.

There are 42 quality control laboratories in the SADC region that are not linked to a manufacturing unit. Fourteen of them are public and 28 are private. There are two WHO pre-qualified quality control laboratories among the 42 identified laboratories—both are in South Africa.

Table 9: Public and private sector medicine quality control laboratories

Country	Public sector quality control laboratories	Private sector quality control laboratories	Total
Angola	0	0	0
Botswana	1	0	1
DRC	3	1	4
Lesotho	1	0	1
Malawi	1	0	1
Mozambique	1	0	1
Namibia	1	0	1
Seychelles	1	0	1
South Africa	4	27	31
Swaziland	1	0	1
Tanzania	1	0	1
Zambia	1	0	1
Zimbabwe	1	0	1
TOTAL	14	28	45

Source: PMA

3.6 Medicines supply chain systems

3.6.1 National Medicines Procurement Agencies

All National Medicines Procurement Agencies (NMPAs) are listed in Annex 5. About half of the NMPAs operate as autonomous entities owned by the Government, while the others operate under the Ministry of Health, except in the DRC. The FEDECAME in the DRC is an association comprising Government, development partners, NGOs and others. The non-autonomous NMPAs that are departments of Ministries of Health are more vulnerable to political influence and budgetary problems (see Section 3.7).

Nine of the 13 NMPAs have an NMPA procurement manual that guides their operations, and three of these take the form of Standard Operating Procedures (SOPs). With the exception of the Seychelles, these are based on the actual procurement legislation and regulations, and are important tools for ensuring that proper procedures are applied.

With the exception of Mozambique, the existence of a procurement unit and separate tender committee or board has been confirmed, which is important for achieving a clear distinction of functions.
The frequency of tenders varies from once every two years to three times a year. Tenders for framework contracts are firmly established in six countries and explain the overall low tender frequency (an average of 1.3/year).

Several Member States use tender documents based on the World Bank's Standard Bidding Document for Health Sector Goods[91] or use important clauses from that document. However, the World Bank has not yet developed a standard document for framework contracts for pharmaceuticals.

All Member States reported that their NMPAs use software for inventory control. Namibia and Zimbabwe reported that their NMPAs use special tender management software. There is considerable variation in the software packages being used. Two NMPAs use the same software packages—MACS and Rx Solutions (adapted). All other NMPAs use different software packages (such as Exact, Navision, Apisoft, etc). The availability of a comprehensive software package for NMPAs is still a challenge and needs to be addressed.

All Member States reported that they have up-to-date documentation of the availability of medicines at central level. However, only three reported that this was the case at health facility level. This indicates the serious weaknesses confirmed by most Member States in their Logistics Management Information Systems (LMIS). More generally, quantification and procurement planning was mentioned as an area that needs improvement.

Table 10: Overview of National Medicines Procurement Agencies in SADC Member States

	Number of Member States	Number of respondents	Remarks
Autonomous	6	14	In Zambia procurement is done by the Ministry of Health Procurement Unit, while storage and distribution is handled by the autonomous Medical Stores Limited.
Procurement manual	9	13	No information was available for one Member State.
NMPA includes executive Procurement Unit[93]	10	14	In Seychelles, procurement is done by the Ministry of Health Department of Pharmaceutical Services, and storage and distribution by the Ministry of Health-CMS. In Mauritius, Swaziland and Zambia, pharmaceutical procurement is done by the Ministry of Health Procurement Unit, in addition to other Ministry of Health procurement. The Units operate separately from the other NMPA functions, such as storage and distribution.
Tender committee[94]	13	14	Mozambique reported that it had no Tender Committee
Average tender frequency (per year)	1.3	8	No information was available for five Member States. Due to limited funding, NatPharm in Zimbabwe was not able to plan for tenders and was not considered here.
Available PSM software	14	14	All Member States use different inventory control software. Namibia and Zimbabwe had software for tender management.
Overview stocks at NMPA always available	14	14	
Overview stocks at health facilities always available	3	12	No information was available for two Member States. Angola, Malawi and South Africa were confident that health facilities could produce reliable reports on stocks, pipeline status and costs of all essential pharmaceuticals at any given time.

Source: August 2011 SARPAM Questionnaire

The PMA includes a short description of each Member State NMPA, which has been complemented using the Member State information provided through the questionnaire. Public sector procurement systems in SADC countries differ in terms of scope and organisation:

- In Angola, the Central de Compras de Medicamentos de Angola, CECOMA, autonomous medical store, performs centralised procurement, storage and distribution.

91 *World Bank. Standard bidding document procurement of health sector goods. May 2004 (revised August 2008). See http://web.worldbank.org/WBSITE/EXTERNAL/PROJECTS/PROCUREMENT/0,,contentMDK:21890171~menuPK:84284~pagePK:84269~piPK:60001558~theSitePK:84266~isCURL:Y,00.html*

92 *An executive Procurement Unit is dedicated to the execution of pharmaceutical procurement as part of the functions of an NMPA.*

93 *The Tender Committee (or Board or Procurement Committee) has guiding and supervisory tasks in relation to pharmaceutical procurement that are independent from those of the executive Procurement Unit.*

- In Angola, the Central de Compras de Medicamentos de Angola, CECOMA, autonomous medical store, performs centralised procurement, storage and distribution.
- In Botswana, the Central Medical Stores forms part of the Ministry of Health, but management is contracted to Crown Agents as part of support by SCMS.[94] After extensive discussions, Botswana Cabinet decided that Central Medical Stores will remain part of the Ministry of Health.
- In the DRC, the national-level procurement agency FEDECAME is an autonomous association of several stakeholders and is responsible for both tendering and purchasing, and distribution to district stores. However, it covers only 19% of the country. Two other groups of procurement Agents are responsible for 81% of all international procurement. Better coordination and support for the Système National d'Approvisionnement en Médicaments Essentiels is needed.[95]
- In Lesotho, the National Drug Supply Organisation is a semi-autonomous body, wholly owned by the government. It was not established by an Act of Parliament, but via a Government circular. It operates as a commercial entity, and is expected to procure, store and distribute medicines and medical supplies for public and faith-based health facilities run mainly by the Ministry of Health and Church Health Association Lesotho.
- In Malawi, the Central Medical Stores was made autonomous (in the form of a trust) in July 2011.
- The Central Medical Stores in Mauritius is part of the Ministry of Health. However, it is only tasked with storage and distribution, while pharmaceutical procurement, along with other procurement, is done by the Ministry of Health Procurement Unit.
- In Mozambique, the Central de Medicamentos e Artigos Médicos (CMAM), the Central Medical Stores, is a sub-directorate of the Directorate of Medical Assistance of the Ministry of Health. Currently, CMAM is under review.
- In Namibia, the Central Medical Stores is a sub-division of the Ministry of Health and is responsible for procurement, storage and distribution for the entire country.
- In the Seychelles, procurement is done by the Directorate of Pharmaceutical Services, based on information provided by the sub-department Central Medical Stores, which stores and distributes medicines.
- In South Africa, the Directorate of Affordable Medicines and National Treasury manage tendering jointly at the national level, with the participation of all provinces. Once contracts are awarded, the provinces are responsible for their procurement and payment of accounts. The establishment of a Central Procurement Unit is in process; it has been tasked with managing three priority contracts (Antibiotics, TB and Family Planning). The unit should play a key role in supporting the implementation of the National Health Insurance system. The Strengthening Pharmaceutical Systems Programme[96] and CHAI have been providing technical support for the planning and implementation of the Central Procurement Unit.
- In Swaziland, the Central Medical Stores under the Ministry of Health is responsible for storing and distributing medicines, and medical supplies and devices to all Government, parastatal and mission hospitals, clinics and health centres. Procurement is done by the Ministry of Health Procurement Unit. Procurement of antiretrovirals is done through the National Emergency Response Council on HIV and AIDS. Nevertheless, the Central Medical Stores is responsible for storage and distribution to accredited treatment centres.
- In Tanzania, the procurement agency Medical Stores Department is Government- owned and responsible for procurement and distribution for the entire country. It has autonomously managed and operates on a commercial basis, as it is required to be financially self-sustaining.
- In Zambia, tendering and ordering is the responsibility of the Ministry of Health procurement unit while storage and distribution is the responsibility of the autonomous Medical Stores Limited.
- In Zimbabwe, the National Pharmaceutical Company (NatPharm) is a corporation with all shares owned by the Government. Due to a lack of public funding, NatPharm has not been able to perform significant public sector procurement since 2007. Support to the Ministry has been in the form of medicines and medical supplies procured through partners such as UNICEF, with external funding from various development partners. NatPharm remains responsible for logistics (storage and distribution) for all commodities, including donated stocks.

94 *In September 2012, the Botswana delegation at the Member State consensus-building meeting informed the report that the number of 125 pharmacists only refers to the number of pharmacists working in the public sector.*

95 *FEDECAME = Fédération Des Centrales d'Achats en Médicaments Essentiels. The other procurement groups are the Government of the DRC (44%) and external procurement agents (37%).*

96 *See http://www.msh.org/global-presence/sps.cfm.*

The WHO Pharmaceutical Country Profiles of the SADC Member States reported that eight of the 14 Member States based their procurement on the national Essential Medicines List. The questionnaire revealed that Essential Medical Supplies lists and Laboratory lists exist in Angola, Botswana, the DRC and Malawi. Lesotho has an Essential Medical Supplies List along with an Essential Medicines List.

Overall, there is a reasonable amount of similarity in the medicines on the Essential Medicines Lists of the various Member States.[97] However, not all items found on those lists were of the same dosage form or formulation as described in the PMA tracer list (see Annex 1). In most Essential Medicines Lists a number of items lack exact specifications for dosage form, strength and unit size. Harmonisation of evidence-based Standard Treatment Guidelines and Essential Medicine Lists is not necessarily a precondition for pooled procurement; pooled procurement may prompt countries to harmonise Essential Medicines Lists and Standard Treatment Guidelines in cases where alternatives are more cost-effective.[98] The PMA recommended that the NMPAs should always be informed on the FOB prices of procured products. 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. Only three of the 13 Member States could provide FOB prices for some or all of the tracer items, and only one Member State consistently uses FOB.

Table 11 shows the diversity of INCOTERMS that are in use, and lists the INCOTERMS that were reported for procurement of the top 50 (by value) products in the surveyed countries.

Table 11: INCOTERMS used in surveyed Member States and number of items for which the specific INCOTERM is being used

Country	Local supply (no INCOTERM)	FOB	CFR	CIF	DDU	DDP	Not known or a mix
Angola						50	
Botswana				40			
DRC		50					
Lesotho					50		
Malawi [100]				50			
Mozambique				29		21	
Namibia						50	
Seychelles							
South Africa	All						
Swaziland				49			
Tanzania	10		37				
Zambia				47			
Zimbabwe							45

Legend: INCOTERM = International commerce terms; FOB = Free On Board; CFR = Cost and Freight; CIF = Cost, Insurance, Freight; DDU = Delivered Duty Unpaid; DDP = Delivered Duty Paid.

97 *This was, however, not the case with the top 50 items (annual procurement value) according to the PMA study SARPAM. SADC pharmaceutical market analysis (2010 Baseline) Volume 2: Annexes, January 2011.*

98 *SARPAM. Southern African regional programme on access to medicines and diagnostics SARPAM harmonisation of standard treatment guidelines and essential medicine lists study report. Final draft, September 2010.*

99 *The Central Medical Stores Malawi agreed to use FOB INCOTERMS in 2002 following a consultant's recommendation, but this was never implemented (Nancollas & Kumwenda, June 2002).*

In Zimbabwe, where the bulk of public sector procurement is being done by international organisations (UNICEF, UNDP and others), no information on INCOTERMS was available. There is no ongoing procurement coordination between Member States. Four Member States participate in the Global Fund Voluntary Pooled Procurement Initiative, but experiences are not yet conclusive as the initiative is still new. Most principal recipients in the HIV and AIDS programmes funded by the Global Fund are eligible for the Clinton Health Access Initiative (CHAI) negotiated prices (13 of the 15 SADC Member States are members of the CHAI procurement consortium).[100]

3.6.2 Profile of domestic market suppliers

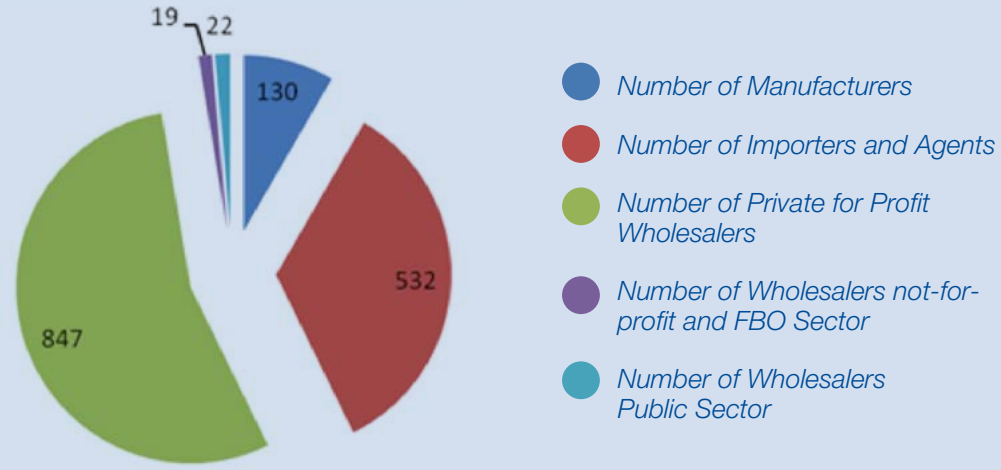
This section has been largely extracted from the 2010 PMA study.

The PMA collected information on the number and types of supply-side organisations in the study countries: licensed public, private for-profit and not-for-profit wholesalers; importers; and manufacturers. Findings are presented in Figure 5.

Unlike importers, wholesalers are defined as carrying and owning the stock they sell. However, in South Africa distributors who provide logistics services (storage and distribution) to their principals and do not own stock are also licensed as wholesalers. While South African medicines law provides for different licenses for importers and/or exporters and wholesalers, this is not the case in the majority of other Member States, where wholesalers can also act as importer and/or importers do not require a specific pharmaceutical license.

The PMA found 847 licensed pharmaceutical private for-profit wholesalers[101], with the highest number in Tanzania (243), followed by Angola (199) and South Africa (163). The number of public sector wholesalers is limited to one per country[102], except in South Africa where 11 (mainly provincial) organisations are identified as public sector wholesalers. The DRC has no public sector wholesaler; all regional medical stores contracted to supply the public sector are private, not-for-profit wholesalers.[103]

Figure 5: Categories and numbers of pharmaceutical suppliers in the SADC region



Source: 2010 PMA study report

The WHO Pharmaceutical Country Profiles of the SADC Member States reported that there were 100 pharmaceutical manufacturers in 10 Member States, of which 67 were GMP compliant. The PMA found 130 and the African Union / NEPAD Planning and Coordinating Agency assessment 126. Details are presented in Table 12. The majority of the manufacturers are situated in South Africa.

100 *See http://www.clintonfoundation.org/what-we-do/clinton-health-access-initiative/information-center-resources [accessed 10 October 2010]. CHAI UNITAID ARV supplier letter. RE: Supply of UNITAID-financed paediatric and/or adult second-line antiretrovirals for period of March 2010 - February 2011.*

101 *Aggregate for the 12 study countries; information for Lesotho was not available.*

102 *These public sector wholesalers usually operate different branches across the country.*

103 *Figures for wholesalers and manufacturers for South Africa are sourced from the official Medicines Control Council Register (February 2010). Wholesalers and manufacturers are currently also registered with the South African Pharmacy Council, and the numbers differ from those on the Medicines Control Council Register: 285 "wholesale pharmacies" and 251 "manufacturing pharmacies" are registered with the Pharmacy Council (May 2010).*

The PMA reported that only South Africa provided comprehensive information on the export of pharmaceutical products. During 2009, pharmaceutical products with a value of ZAR 1.3 billion (USD 154 million at 2009 average exchange rate) were exported from South Africa. The top five destinations were Zambia, Kenya, Zimbabwe, Ghana and United States. Neither the extent of all intra-SADC trade in pharmaceutical products nor the value of the total export market (SADC internal and external) could be established.

The African Union / NEPAD Planning and Coordinating Agency described the Southern African Generic Medicines Association as a new regional body with 10 Board members (two each from Botswana, South Africa and Zimbabwe, and one each from the DRC, Malawi, Tanzania and Zambia). Membership is open to all trade associations and pharmaceutical companies that are involved in the promotion and production of generic medicines. Current membership includes companies and associations drawn from countries represented on the Board. The Association has regular emails discussions, monthly teleconference and quarterly face-to-face meetings for the Board of Directors and holds one annual general meeting per year.

Table 12: Number of pharmaceutical manufacturers per Member State

Country	Number of domestic manufacturers according to WHO/PCP	Number of domestic manufacturers according to AU/NPCA	Number of GMP compliant domestic manufacturers according to WHO/PCP[105]	Remarks
Angola	0	2	0	
Botswana	0	0	0	
DRC	22	30	8	
Lesotho	0	-	0	
Malawi	4	4	0	
Mauritius	2	2	2	One manufacturer for export only
Mozambique	1	1	0	The Director of CMAM reported zero manufacturers in an August 2011interview
Namibia	1	1	0	
Seychelles	0	0	0	
South Africa	42	56	39	Six are affiliates of multinational pharmaceutical companies
Swaziland	1	1	0	
Tanzania	7	7	2	
Zambia	6	6	2	
Zimbabwe	14	16	14	
Total	**100**	**126**	**67**	

AU/NPCA = African Union / NEPAD Planning and Coordinating Agency
WHO/PCP = WHO Pharmaceutical Country Profiles of the SADC Member States
Source: WHO/PCP

104 Local regulatory authorities issue a "certificate of pharmaceutical product" for the products of these manufacturers, under the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce: "The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce guarantees, through the issue of a WHO-type certificate by the certifying authority, the quality of pharmaceutical products entering international commerce. It is a simple administrative procedure that enables importing countries to obtain information on whether a product has been authorized to be placed on the market in the exporting country, and assure that the manufacturer has been found to comply with WHO standards of good manufacturing practices." From WHO. Operational package for assessing, monitoring and evaluation country pharmaceutical situations (guide for coordinators and data collectors), December 2007; p 52. See http://apps.who.int/medicinedocs/documents/s14877e/s14877e.pdf

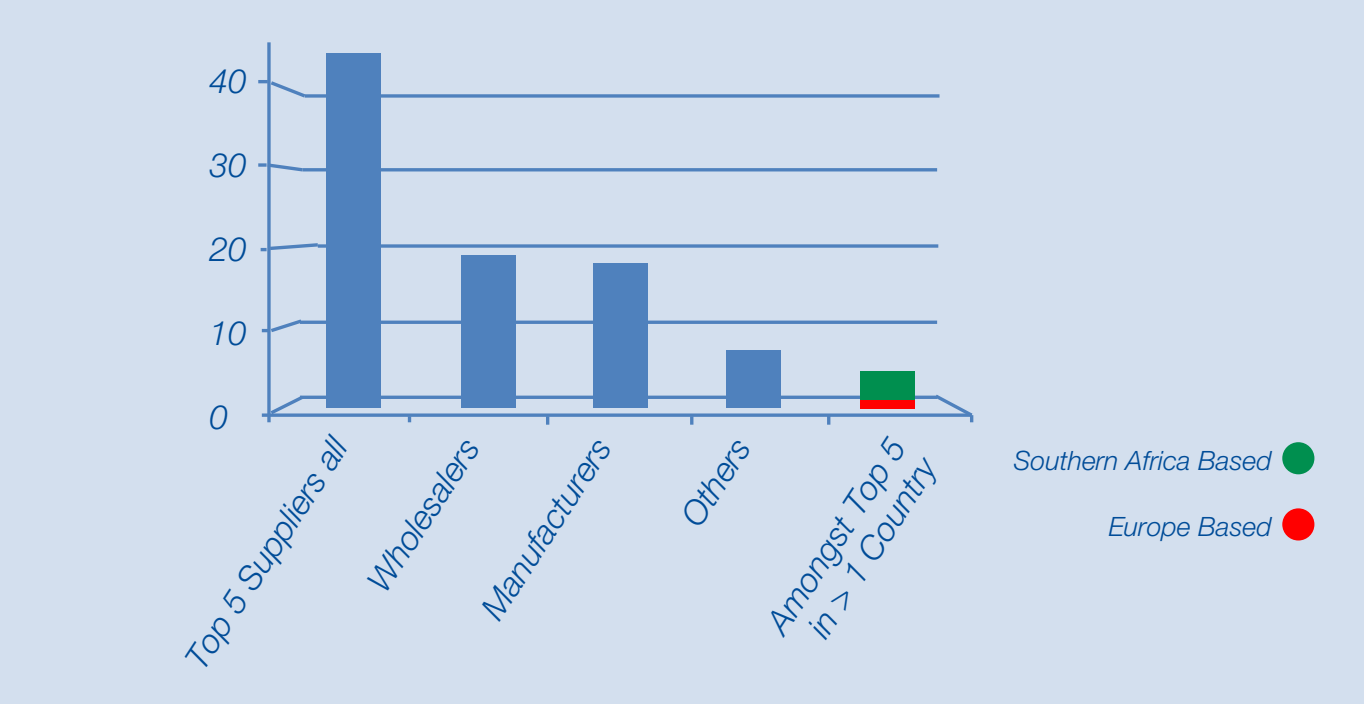
3.6.3 Diversity of suppliers to the public sector

This section has been extracted from the 2010 PMA study.

The PMA tried to ascertain whether the same suppliers—domestic or international—are active in more than one study country by asking the public procurement agencies to list their Top 5 suppliers (in value).

A total of 44 companies were listed as Top 5 suppliers. National and international wholesalers and manufacturers were identified as suppliers (the type of supplier could not be identified in the case of seven suppliers). Although available data are incomplete, it appears that there are few countries in the region that share the same major suppliers. Supplier types and diversity are shown in Figure 6.

Figure 6: Type and distribution of the Top 5 pharmaceutical suppliers to the public sector in study countries



Six of the main supplier organisations were "not-for-profit" organisations (such as UNFPA and UNICEF), while the remaining 38 were "for-profit" private sector suppliers. Not-for-profit suppliers in most cases act as procurement agencies on behalf of the public sector.

Similar diversity in suppliers was found for the tracer list items (see Figure 7). A total of 85 different suppliers were identified as sources for tracer items, but only nine of them supplied to more than one country.

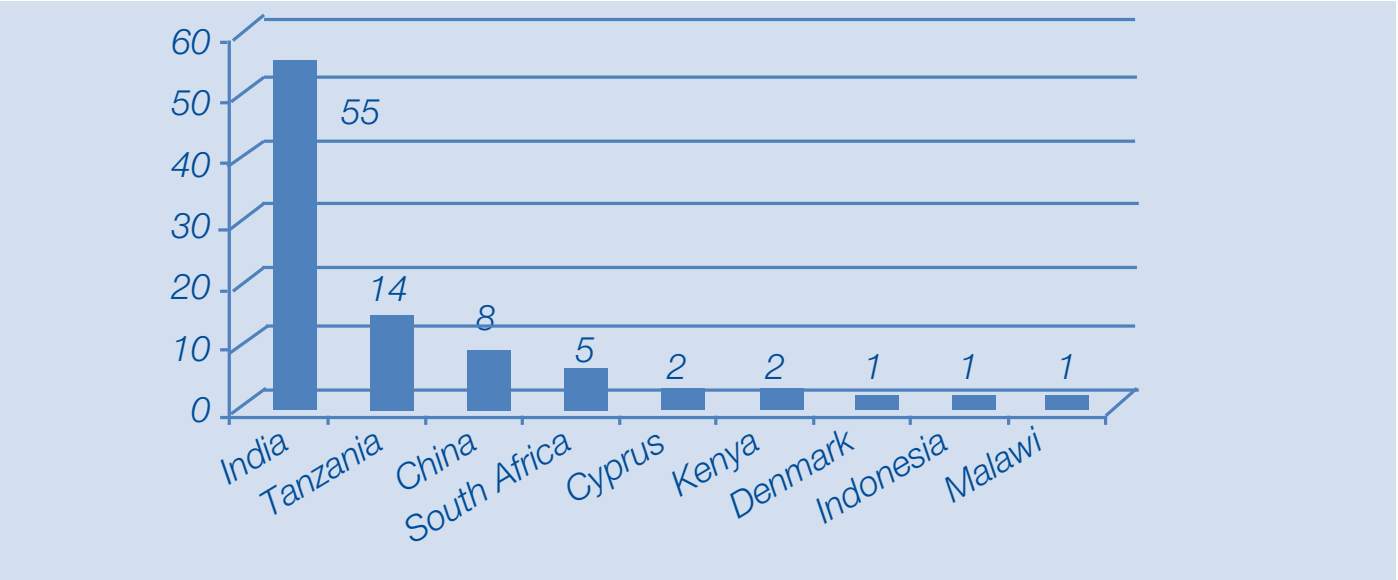
Possible reasons for both findings include:

- Procurement agencies follow different contracting strategies (for example, contracting manufacturers directly, focusing on bigger international wholesalers and/or contracting through locally-based agents). However, the study did not assess this possibility;
- Local private sector wholesalers are small businesses that lack the capacity (including logistic and market intelligence) to supply beyond the borders of their countries;
- Local regulations do not allow wholesalers to export (for example, in South Africa); and
- Suppliers have difficulties or lack incentives to participate in procurement agencies' calls for pre-qualification.

Figure 7: Suppliers for tracer list items to the public sector

Only in four countries could data be obtained on the country of manufacture of tracer item products (see Figure 8). The information covers a limited sample of 89 products: one fifth (21%) of these tracer item products were manufactured in the SADC region, and 62% of them were manufactured in India.

Figure 8: Countries of origin for products procured (tracer list items)



3.6.4 Availability of tracer items at central level in the public sector

This section has been extracted from the 2010 PMA study.

Only six medicines from the list of 50 tracer items were usual stock items with the public procurement agencies in the eight study countries that provided the required information. Expressed as a median, 65% of tracer items were usual stock items in those countries.

This finding does not necessarily indicate a general lack of availability or access to essential priority medicines; for many of the tracer items, acceptable alternatives were available, and those might be stocked instead. For future studies of this type a review of the tracer list might be warranted.

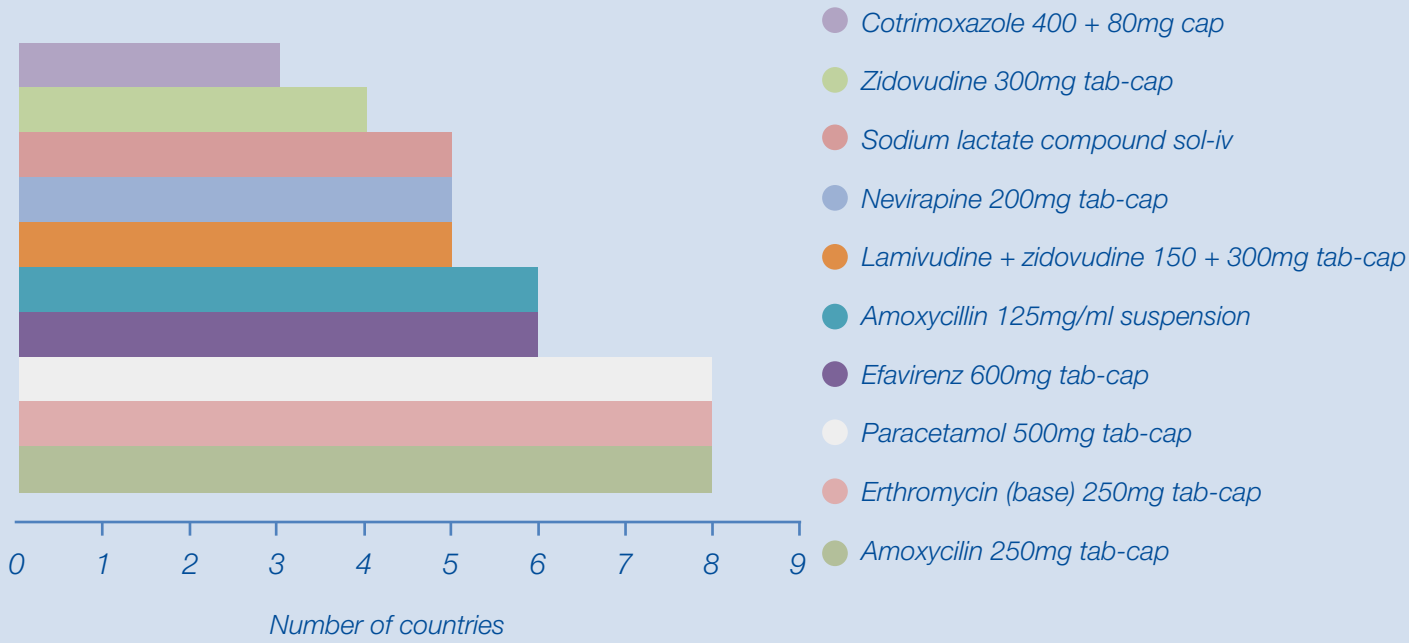
The average time tracer items were out of stock during a recent 12-month period varied between 3% and 70% (based on six countries that could provide the relevant information). No trend or similarities could be identified among the products that were out of stock.

3.6.5 Similarity of medicines procured in the public sector

This section has been extracted from the 2010 PMA study.

Aggregation of the top 50 medicines (Top 50 in terms of value) procured per country showed a total of 334 different items that featured in any of the Top 50 lists. The ten that occurred most frequently on the Top 50 lists of different countries are presented in Figure 9. Amoxicillin 250mg tablet/capsule, Erythromycin 250mg tablet/capsule and Paracetamol 500mg tablets were on the Top 50 lists of procured medicines in eight countries.

Figure 9: Number of countries in which the specified medicine is included among the "Top 50 medicines procured"



3.6.6 Regional pharmaceutical market: demand side

This section has been extracted from the 2010 PMA study.

Medicines retail sector

A total of 5,244 licensed pharmacy outlets were documented in the 12 study countries.[105] The highest number of licensed community pharmacies was found in South Africa (2,869), and the lowest in the Seychelles (5). Population per licensed pharmacy varied between 16,400 and more than 450 000.

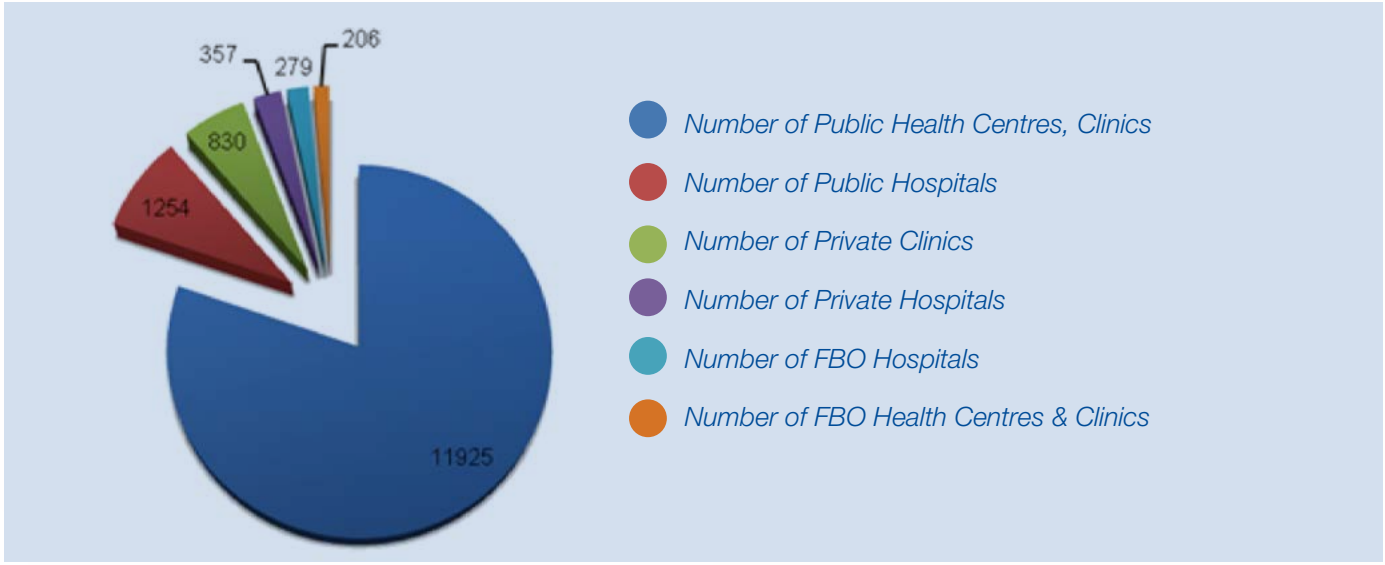
Five countries provided information on the number of other licensed drug outlets, with an overall total of 922. The highest number of licensed drug outlets was reported for Tanzania (662) and the lowest was in the Seychelles (2). The types of licensed drug outlets included Accredited Drug Dispensing Outlets (Tanzania), Medicines Shops (Malawi), or dispensing doctors (Zimbabwe)[106].

105 *Information for Lesotho was not available.*
106 *As stated in Chapter 2, it was beyond the scope of this study to further analyse the type and specific licensing conditions for retail sector medicines outlets.*

Findings indicate inequity in populations' access to professional pharmacy services within and between study countries.

Health products are also dispensed to the public through health services delivery institutions (Figure 10). However, the study focussed on the high-level wholesale demand side, and data on value of pharmaceuticals dispensed through retail pharmacies and through public and private health institutions was not collected.

Figure 10: Number of public and private health facilities



In addition to formal dispensing outlets, the retail market includes informal medicines sellers or shops and unlicensed establishments. Investigation of this market segment was not part of this study, but there is evidence that the importance of the informal market increases when public sector performance and coverage is inadequate, capacity for enforcement of regulations is weak, and purchasing power of the population is low.[107]

Total market size

There are not enough data to determine the size of the regional pharmaceutical sector market in terms of sales volume or value (see also Section 3.7.1). Only in six of the 13 countries did private sector wholesalers provide data on the sales prices of the tracer items, and some confidentiality provisions had to be taken into account in those countries. The private sector was not willing to share volume data.

Reliable data was obtained on the size of the private pharmaceutical market in South Africa.[108] This translated to approximately USD 57 per capita in 2009, with an expected growth to USD 64 per capita in 2010 (ZAR 23 billion, or more than USD 3 billion in total). In the South African market, medicine sales for five therapeutic classes accounted for 70% of the market:[109]

- Nervous system,
- Systemic anti-infectives,
- Alimentary tract and metabolism,
- Cardiovascular system, and
- Respiratory system.

Public sector sales

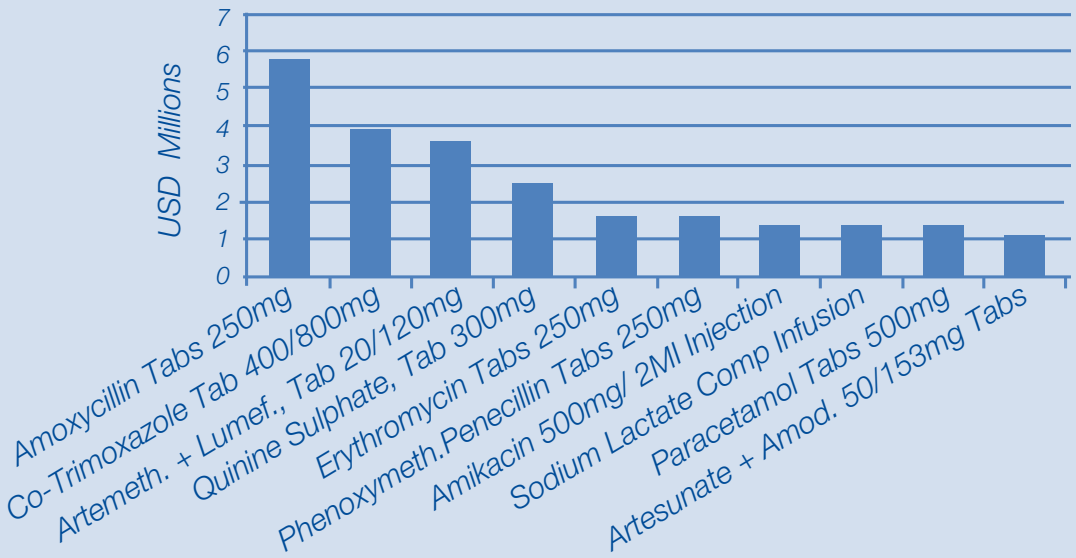
The Top 10 products sold in the public sector (ranked by 2009 USD) are presented in Figure 11. Antiretrovirals have been excluded from the comparison because of inconsistencies in responding countries' information management systems (some respondents could not provide lists of Top 50 items sold that include antiretrovirals). Information is based on eight countries, excluding South Africa.

107 *For example, Ministère de la Sante Publique. Enquête sur les prix des médicaments en République Démocratique du Congo (July 2007); Ministère de la Sante, République d'Angola. Evaluation du secteur pharmaceutique de l'Angola (Accès, qualité et usage rationnel des médicaments (August 2007); Ariane McCabe. Private sector pharmaceutical supply and distribution chains: Ghana, Mali and Malawi; Health Systems for Outcome publication, December 2009.*

108 *IMS Health South Africa.*

109 *IMS health data, 2010.*

Figure 11: Top 10 products sold, in millions USD



The information shown in Figure 11 represents a relatively small share of the regional public sector market for these products, covering approximately 30% of the SADC population. It therefore provides only an indication of the medicines that are most commonly sold or distributed.

Three procurement agencies provided information on calculation of sales prices (mark-ups). We compared sales and procurement prices, but could only verify for one country that the mark-up as stated was consistently applied. It might be that for the other two countries procurement price information was not necessarily identical to that used to calculate current sales prices. The latter might be based on an earlier procurement or on a mixed landed cost price resulting from different procurements.

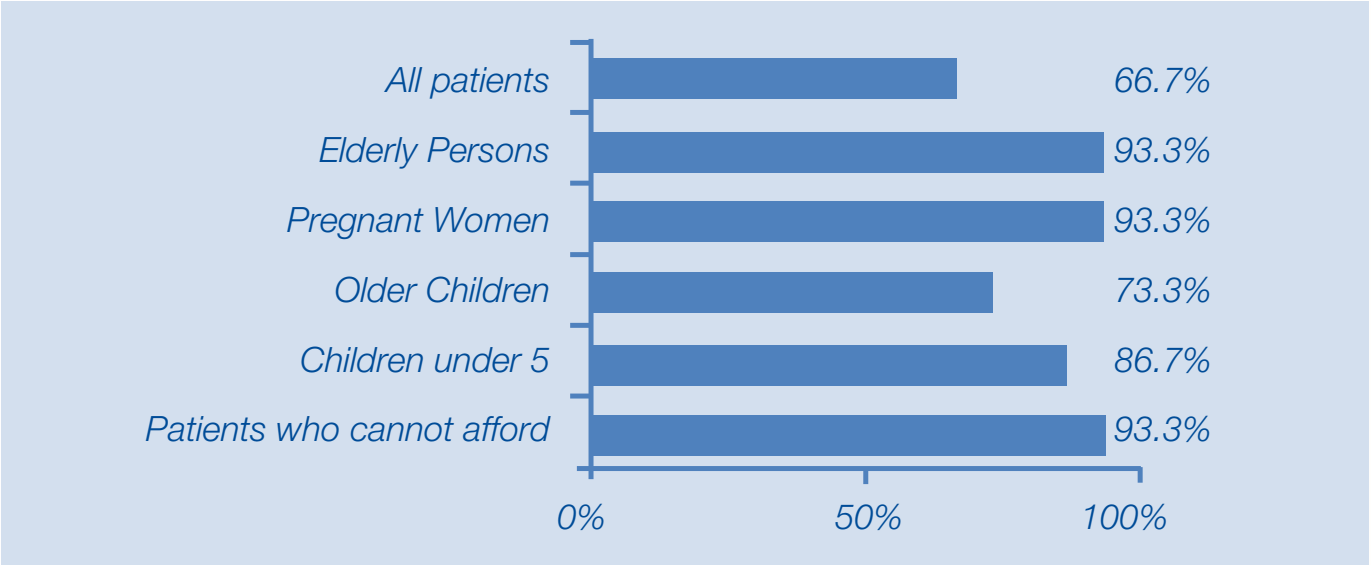
The private sector median sales price was higher than the public sector median sales price for 26 of the 50 tracer items.

It is to be expected that sales prices in the private sector are higher than in the public sector, given the profit incentive in the private sector. However, public sector procurement procedures are more likely to apply more stringent quality standards for medicines purchased, which can increase the procurement and sales prices. These quality standards are also supposed to be applied in the private sector, but regulatory authorities do not always have adequate capacity to regulate the entire market. Very low sales prices in the private sector may therefore indicate quality deficiencies.

The sales prices that were compared were intermediate wholesale level sales prices. Considerable mark-ups on these intermediate sales prices are often applied by the private retail sector.[110] In the public sector, health facilities may or may not add a percentage to their purchasing price before selling the medicine to the patient. Health facilities may also distribute medicines for free. In fact, all SADC Member States reported having programmes providing free medicines in the public sector. Figure 12 shows the beneficiaries of these programmes, and the percentage of Member States implementing them. In addition, treatment for TB and HIV and AIDS is officially provided for free to all patients in all Member States.

110 *In South Africa, the "single exit price" is supposed to be applied also at retail level. Instead of retail mark-ups, regressive dispensing fees are prescribed.*

Figure 12: Categories of patients receiving free medicines in SADC Member States' public sectors[111]



3.7 Financial resources and systems

3.7.1 Pharmaceutical budgets & expenditures

Comprehensive and reliable information on SADC public sector pharmaceutical total budgets and expenditure, and on sources of funding (for example, government, global initiatives or private sector) could not be obtained by the PMA. The WHO Assessment of the Pharmaceutical Situation in SADC Member States[112] experienced similar difficulties in obtaining these kinds of data.

Available information suggests that there are huge intra-regional differences regarding per capita budgets and expenditures, as well as funding sources for pharmaceuticals.

111 *Assessment of the pharmaceutical situation in SADC Member States, including pharmaceutical profiles for each SADC Member State. Available at http://www.who.int/medicines/areas/coordination/coordination_assessment/en/index1.html.*

112 *Ibid.*

Table 13: WHO/PCP health financing data in SADC Member States

Country	Total annual expenditure on health (USD)	Total annual per capita expenditure on health (USD)	Health expenditures as percentage of GDP	Government annual expenditure on health (USD millions)	Government expenditure on health as percentage of total government budget	Annual per capita government expenditure on health (USD)	Government annual expenditure on health as percentage of total
Angola	1 176	71	2.6%	1 021	5.0%	62	86.8%
Botswana	704	296	7.1%	279	18.0%	148.20	76.5%
DRC	775	11.80	8.4%	84	3.6%	1.30	10.8%
Lesotho	125	50.10	6.9%	80	12.5%	32.20	64.2%
Malawi	279	21	12.9%	193	17.1%	14	69.0%
Mauritius	275	230	3.9%	141	9.4%	118	51.1%
Mozambique	387	19	9.0%	309	12.5%	15	80.0%
Namibia	549	252	8.3%	249	11.3%	114	45.5%
Seychelles	37	565	6.3%	27	14.5%	316	75.1%
South Africa	34 525	425	8.0%	13 029	9.1%	160	37.7%
Swaziland	175	155	6.3%	115	11.2%	102	65.8%
Tanzania	910	23	6.4%	526	13.7%	13	57.8%
Zambia	678	38	6.2%	412	16.4%	18	60.7%
Zimbabwe	502	38	9.3%	245	8.9%	18	48.7%
Total	41 097						

Results from the questionnaire and the follow-up interviews revealed that information on pharmaceutical budgets and expenditures is hard to obtain for most financing sources. For example, several Member States failed to mention the Global Fund as a funding source (yet it funded programmes in all the Member States except the Seychelles) and most of those who did mention it were unable to stipulate the amount of funding (since its launch in 2002 the Global Fund disbursed about USD 3.1 billion in the SADC Member States, of which an estimated 47% was used for supplies).[113]

Although specific data on pharmaceutical expenditure are hard to obtain, health expenditure data for Member States are available (see Table 13). In order to estimate the total pharmaceutical expenditure (public and private sector) for all SADC Member States, it was assumed that the total annual pharmaceutical expenditure for the 14 Member States was 10% of total health expenditure. This was a modest assumption; the actual percentage was found to range between 6.3% and 32.0% for the seven Member States that provided data to the WHO Pharmaceutical Country Profiles of the SADC Member States in 2009.

Using the 10% estimate, the total annual pharmaceutical expenditure would be USD 4.1 billion or USD 15.90 per capita. Per capita pharmaceutical expenditure for each Member State (using the same data and method) would range from USD 1.18 in the DRC to USD 56.50 in the Seychelles. The 2008 National Health Accounts found an annual per capita pharmaceutical expenditure of USD 2.50 or 28% of total health expenditure (which is close to the 30% of total expenditure on health).

More data and information could probably be obtained from the "mapping" and other studies that have been done in several Member States by WHO and others.[114] Due to limited time, however, those studies were not all reviewed for the current study. It is clear that further investigation study is needed to achieve a fuller assessment of financial resources and pharmaceutical expenditure in the SADC region. Such a study could also devote attention to the possible wastage of funds due to inefficient procurement methods.

113 *See "An estimated 47% of Global Fund grants has been used on procurement" at http://www.theglobalfund.org/en/activities/psm [accessed 3 Aug 2011]*

114 *WHO mapping studies have been done in the DRC, Tanzania and Zambia.*

Table 14: Financing of pharmaceutical procurement and NMPAs

Country	Procurement by NMPA (NMPA is being pre-funded before procurement takes place, i.e. input financing)	Operational costs for NMPA (operational costs are carried by government, i.e. input financing)	Payment of NMPA for deliveries of products to health facilities (including mark-up from which operational costs NMPA are to be paid, i.e. output financing)	Payment of suppliers (other than NMPA) for deliveries of products to health facilities (output financing)	Remarks
Angola	1	1	0	1	
Botswana	1	1	1	1	
DRC	0	0	1	0	
Lesotho	1	1	1	1	
Malawi	1	1	1	1	
Mauritius	1	1	0	0	USD 20 million public market and USD 100 million private market
Mozambique	1	1	0	0	
Namibia	1	1	1	1	
Seychelles	1	1	0	0	
South Africa	1	1	0	1	Provincial stores being paid from budget to pay for suppliers' deliveries; problems with their quantification and monitoring stocks
Swaziland	1	1	0	0	
Tanzania	ne	ne	ne	Ne	
Zambia	ne	ne	ne	Ne	
Zimbabwe	1	1	1	1	

Legend: 1 = yes; 0 = no; ne = not established

Table 14 depicts the mode of financing of pharmaceutical procurement and operational costs of NMPAs. Input financing dominates in the Member States: only six of the 12 Member States who responded applied output financing, and in three of them output financing was applied alongside input financing.

Payment for deliveries of pharmaceuticals is regarded as a form of output financing. This method for earning revenue generally provides incentives to NMPAs to be more efficient and cost-effective. Input financing, on the other hand, involves making funds available before procurement takes place to cover supplier payments and NMPA operational costs. Input financing makes NMPAs more vulnerable to Government budgetary issues and poor payment discipline.

Output financing payment for medicines deliveries is funded from Government budgets, which are either administered centrally or made available to districts or health facilities (decentralised). Payments are made from those budgets to the NMPAs (as is usually done with suppliers other than NMPAs) against proof of deliveries and invoices.

With the exception of the DRC, all Member States apply input financing, while eight Member States reported some form of output financing. The high level of input financing reported could be an important factor in the challenges NMPAs face in some Member States. Further study into its possible effects is deemed necessary.

One Member State reported that a lack of foreign currency affected international procurement. For that reason, procurement was often done from South African suppliers within the Southern Africa Customs Union (SACU), although this resulted in higher prices.

The current gap in information and data on financial resources and system needs to be addressed, and should be subject to further study.

3.7.2 Public sector procurement prices

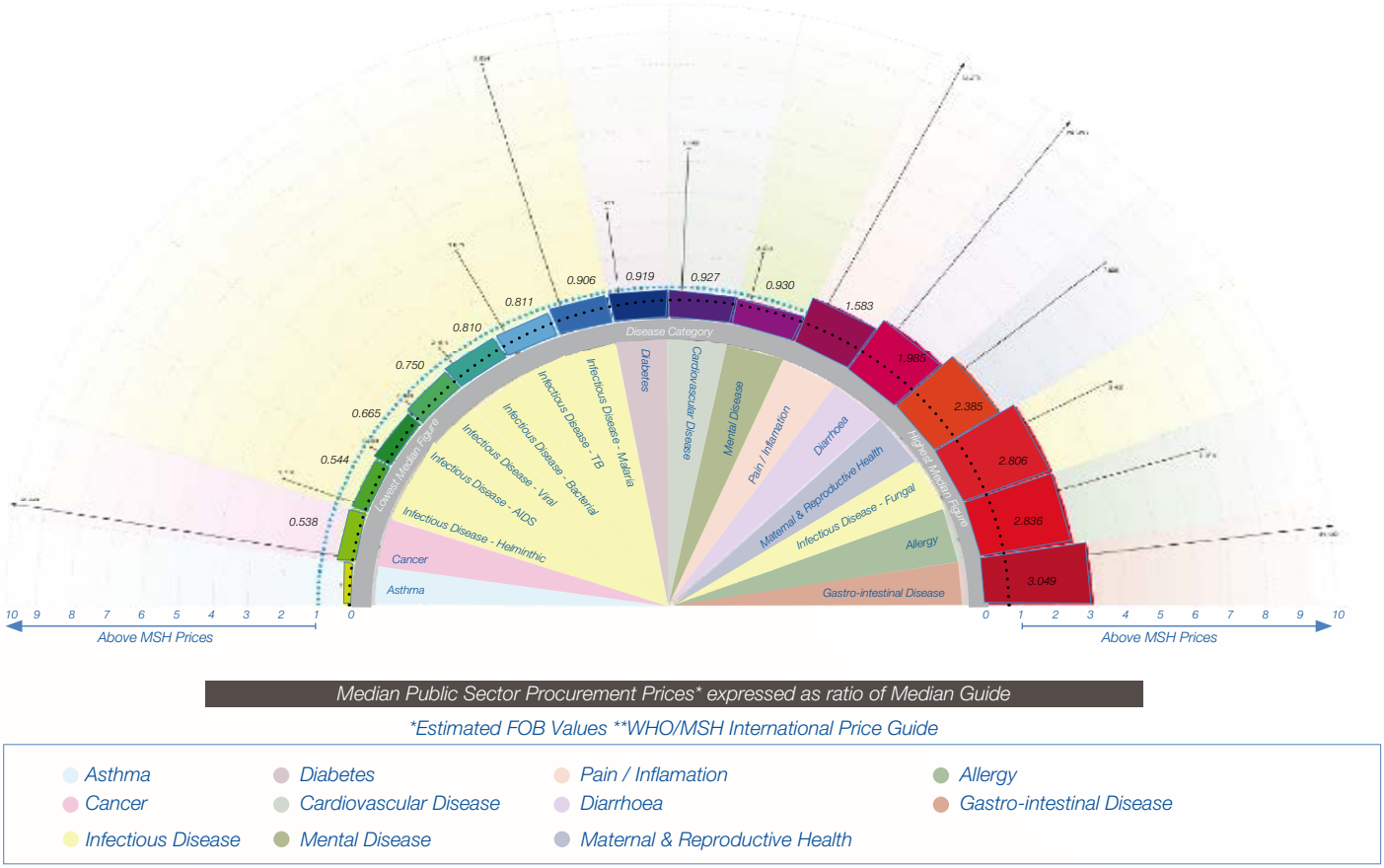
This section has been extracted from the 2010 PMA study.

Public sector procurement prices
Analysis of tracer item prices revealed that half of the SADC median prices compared favourably to the international benchmark prices (i.e. yielding a SADC/benchmark price ratio of below 1).

In Figure 13, the tracer items are grouped according to disease categories.[115] The SADC median price ratio was calculated per disease category (shown as coloured blocks at the top of the half circle) and plotted against the international benchmark (shown as turquoise dotted line at a ratio value of 1). Minimum and maximum price ratios for the different products in each disease category are represented by the black lines leading out of the circle.

Some disease categories show an acceptable price ratio, as well as little variation between tracer items included in that category (for example, "infectious disease-AIDS"), while other disease categories show a high price ratio and large variation (for example, "gastro-intestinal disease"). This indicates that there is room for price gains.

Figure 13: The range of SADC median public sector procurement prices for each disease category expressed as a ratio of Management Sciences for Health median supplier prices



However, there are significant differences between SADC Member States' public procurement prices for tracer items (see Figure 14). For the majority of products, the ratio between the highest price among the study countries and the lowest price was greater than five, meaning that the "worst" performer paid more than five times as much as the "best" performer. For 8% of the items, the high/low ratio exceeded 50. This means that the highest price paid was more than 50 times higher than the lowest price paid. In individual countries, there was a clear potential for cost savings through information exchange and consequent price reduction.

115 *For example, antibiotics grouped under "infectious disease-bacterial", and antiretrovirals grouped under "infectious disease-AIDS".*

Figure 14: Variation of tracer item procurement prices between Member States (expressed as ratio of highest/lowest price, and grouped in four high/low categories)

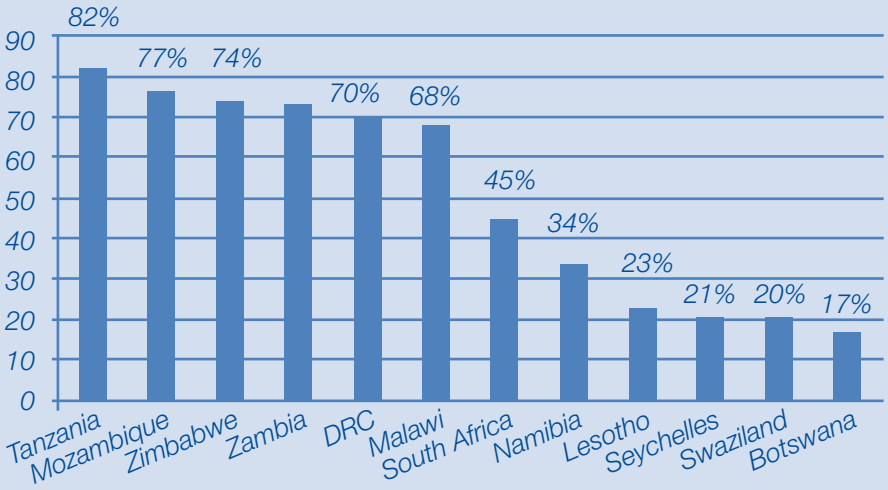
Figure 15 indicates that some Member States perform better overall than others in terms of procurement prices obtained. Tanzania paid less than the international benchmark for 82% of the tracer items procured, while Botswana, Lesotho the Seychelles[116] and Swaziland paid more than the benchmark for most of tracer items procured. No reliable information on procurement prices could be obtained from Angola.

We tried to establish a correlation between prices and procurement volumes, but lacked sufficient data to arrive at valid conclusions. Figure 15 suggests that higher volumes may yield lower prices, as the countries with the smallest populations and procurement volumes seemed to obtain the worst prices. Stakeholders from the Seychelles Ministry of Health confirmed that small volume was the main reason suppliers gave for their relatively high prices. However, the same figure also shows that the median procurement prices in SADC's largest market, South Africa, are not necessarily always the best.

As noted, price comparisons did not consider possible differences in the quality of procured products. However, countries such as Tanzania and Zimbabwe (which have well-developed Medicines Regulatory Authorities that do assess the quality of products procured by the public sector) were also among the "good" performers in terms of prices obtained.

116 *This remained the case after corrections were made for Seychelles in September 2012.*

Figure 15: Percentage of public sector procurement prices for medicines on the tracer list that are below the international benchmark



3.7.3 Duties and taxes

This section is adapted from the similar section in the 2010 PMA study.

Member States do not take a common approach towards duties and taxes on pharmaceutical products or the raw materials needed to produce pharmaceutical products. Duties and taxes appear to be used rarely as an instrument to support the local pharmaceutical industry. The DRC has a special rate for customs duties and taxes incentives that benefits the pharmaceutical industry. These rates are in the order of 8%, while similar rates for consumer goods and mass luxury goods are 27% and 38%. Besides duties and taxes, other costs (administrative, economic and social) negatively affect the costs of pharmaceuticals.

Several SADC member states belong to more than one regional economic community. Harmonisation of import duties and taxes within regional economic communities is difficult and is especially challenging when more than one regional economic community is involved. Disparities in duty and tax regimes between the study countries continue to exist.

The Trade, Industry, Finance and Investment Directorate at the SADC Secretariat maintains a tax database for the SADC Member States at: http://www.sadc.int/english/regional-integration/tifi/tax/.

Table 15: Membership of study countries in regional organisations

Country	SADC	COMESA	CEPGL	EAC	ECCAS	SACU	OCEAC	ECSA (health only)
Angola	x							
Botswana	x					x		
DRC	x	x	x		X		x	
Lesotho	x					x		x
Malawi	x	x						x
Mozambique	x					x		
Namibia	x					x		
Seychelles	x	x						x
South Africa	x					x		
Swaziland	x	x				x		x
Tanzania	x			x				x
Zambia	x	x						x
Zimbabwe	x	x`						x

SADC = Southern African Development Community; COMESA = Common Market for Eastern and Southern Africa; CEPGL = Communauté Economique des Pays des Grands Lacs; EAC = East African Community; ECCAS = Economic Community of Central African States; SACU = Southern Africa Customs Union; OCEAC = Organisation de Coordination pour la lutte contre les Endémies en Afrique Centrale; ECSA = East, Central and Southern African Health Community.

Import duties

Customs tariffs for essential medicines are classified and harmonised as per the Harmonised Commodity Description and Coding Systems (generally referred to as Harmonised System). The Harmonised System is a multi-purpose international product nomenclature developed by the World Customs Organization. It is arranged in six digit codes, and allows all participating countries to classify traded goods on a common basis. Beyond the six-digit level, countries are free to introduce national distinctions for tariffs and many other purposes. Codes that apply to pharmaceutical products are reproduced in Box 1. By virtue of belonging to a free trade area, SADC Member States benefit from the gradual elimination of customs tariffs and non-tariff barriers. No customs duties are imposed on Member States that are party to the free trade area. However, Member States have not yet adopted a Common External Tariff, because the status of a Customs Union has not yet been achieved.

Box 1: International customs code for pharmaceutical products

The duties that can be imposed have been standardised and fit under any of the following categories:	
30.03	Medicaments (excluding goods of 3002, 3005 or 3006) consisting of two or more constituents, which have been mixed together for therapeutic or prophylactic uses, not put up in measured doses or in forms or packings for retail sale
3003.10	Containing penicillins or derivatives, with a penicillanic acid structure, orstreptomycins or their derivatives
3003.20	Containing other antibiotics
3003.31	Containing insulin
3003.39	Other
3003.40	Containing alkaloids or derivatives thereof, but not containing hormones or other products of 2937 or antibiotics
3003.90	Other
30.04	Medicaments (excluding goods of 3002, 3005 or 3006) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retails sale.
3004.10	Containing penicillins or derivatives thereof, with a penicillanic acid structure, orstreptomycins or their derivatives
3004.20	Containing other antibiotics
3004.31	Containing insulin
3004.32	Containing adrenal corticosteroid hormones, their derivatives and structural analogues
3004.39	Other
3004.40	Containing alkaloids or derivatives thereof but not containing hormones, other products of 2937 or antibiotics
3004.50	Other medicaments containing vitamins or other products of 2936
3004.90	Other
3002.20	Vaccines for human use

Only three study countries reported that they imposed import duties on medicines (as shown in Table 16. The public sector procurement agency in Zimbabwe was exempt from paying such duties. In Angola and the DRC, the public sector did have to pay duties. In Angola, payment obligations were included in the Ministry of Health's budget, while in the DRC, NGOs were exempted in case the pharmaceuticals were to be used by the poor.

Table 16: Import duties on pharmaceutical products

Code	Angola	DRC	Zimbabwe
3003.10	2%	27%	10%
3003.20	2%	27%	10%
3003.31	2%	27%	
3003.39	2%	27%	
3003.40	2%	27%	10%
3003.90	2%	27%	10%
3004.10	2%	38%	
3004.20	2%	38%	
3004.31	2%	27%	
3004.32	2%	27%	
3004.39	2%	27%	
3004.40	2%	27%	
3004.50	2%	27%	
3004.90	2%	38%	10%
3002.20	2%	27%	

Source: PMA

According to the WHO Pharmaceutical Situation Assessments[117], 12 of the 13 surveyed countries impose duties on the import of raw materials, and eight countries impose duties on the import of finished products.

117 *WHO. Assessment of the pharmaceutical situation in SADC Member States, 2009. Available at http://www.who.int/medicines/areas/coordination/coordination_assessment/en/index1.html.*

Table 17: Duties on raw materials and on imported finished products (comparison of WHO Assessment and PMA findings)

	WHO: Duty on imported raw materials	WHO: Duty on imported finished products	PMA: Duty on imported raw materials	PMA: Duty on imported finished products
Angola	Yes	Yes		Yes
Botswana	Yes	Yes		
DRC	Yes	Yes	No	Yes
Lesotho		Yes		
Malawi	Yes	No	Yes	
Mozambique	Yes	No	Yes	
Namibia	Yes	Yes		
Seychelles	No	No		
South Africa	Yes	Yes		
Swaziland	Yes	No	(Yes)	(Yes)
Tanzania	Yes	No	(Yes)	(Yes)
Zambia	Yes	No		
Zimbabwe	Yes	No	Yes	Yes

Note: (Yes) signifies that according to our findings, import duties are imposed, but specific information on the type of product as per international customs code could not be obtained.

Inconsistencies between the WHO Assessments and PMA findings indicate that the respondents in the surveys might not always have been aware of the existing regulations, or that definitions were not clear. Triangulation of information for Tanzania, using the "Harmonized customs, excise, value added tax (VAT) and East Africa tariffs" downloaded from the website of the Tanzania Revenue Authority, shows that responses received in both surveys were incorrect. Tanzania applies import duty on finished products (10% in general, 2% for the East African Community) and none on starting materials; 20% of VAT is charged on imports of starting materials, while finished products are exempt.

Other taxes

Where VAT does exist, it is applied at retail level for all types of medicines. However, the public sector is exempt from VAT in three countries (Botswana, the Seychelles and Swaziland). In the DRC, the VAT imposed in accordance with Ordinance Law No. 10/001 of 20 August 2010 was scheduled to enter into force on 1 January 2012. It provides for the exemption from import and local purchase of pharmaceutical products and inputs and medical devices.

Taxes and duties do not seem to be used as an incentive to favour the purchasing of locally manufactured products or the importation of products that originate from the SADC region. There is also no differentiation between the rates that are imposed on originator or multi-source products or on products on the Essential Medicines Lists.

Free Trade Area

Within the framework of the SADC Regional Indicative Strategic Development Plan, trade is seen as a catalyst for deeper regional integration. The SADC Protocol on Trade, as amended, which came into force on 25 January 2000, envisaged the establishment of a Free Trade Area in the region by 2008, with the following main objectives:

- Further liberalise intra-regional trade in goods and services;
- Ensure efficient production; and
- Enhance economic development, diversification and industrialisation of the region.

The main, relevant strategies adopted to achieve those objectives are:

- The gradual elimination of tariffs;
- Adoption of common rules of origin;
- Harmonisation of customs rules and procedures;
- Attainment of internationally acceptable standards; quality; accreditation and metrology;
- Harmonisation of sanitary and phyto-sanitary measures; and
- Elimination of non-tariff barriers.

On the other hand, in June 2011, Heads of State and Government of the Common Market for Eastern and Southern Africa, the East African Community and SADC tripartite launched the negotiations for the establishment of an integrated market of 26 countries. The Heads of State also adopted a developmental approach to the tripartite integration process that will be anchored on three pillars namely:

- Market integration based on the Tripartite Free Trade Area;
- Infrastructure development; and
- Industrial development.

These initiatives are expected to have a positive impact on the movement and availability of essential medicines in the region. The consolidations of SADC's own free trade area is equally important. Not only would it result in improved access (due to lower costs), but it would also favour the Regional Pooled Procurement initiative.

4. Feasibility

4.1 Potential savings

The PMA identified the therapeutic groups where the highest price reductions may be achieved. The PMA also looked at possible product groups with the best potential to benefit from regional procurement cooperation. Anticipated benefits from regional procurement cooperation include lower prices and increased availability of commonly used priority medicines.

The PMA found that the best potential for lower prices is likely for those products that show high inter-country maximum or minimum ratio variations for procurement prices. The highest maximum or minimum ratios for common Top 50 items were observed for anti-infectives and paracetamol. This is similar to the findings of the 2007 Situational Analysis and Feasibility Study on Regional Pooled Procurement of Medicines, which was conducted on behalf of the East African Community.[118]

In addition, even small gains will have a large impact on monetary savings if they are realised for high-volume items. Procurement cooperation might also be beneficial for product groups that show a high rate of stock outs across the region. However, no specific group was identified in this study.

The median prices found in Member States for the top six disease categories that were higher than the median international reference prices, as found by the PMA (see Figure 13), represent the best opportunities for price savings. Given the estimated SADC pharmaceutical market of USD 4.1 billion, price reductions in the range of hundreds of millions USD could be achieved. Such savings could be used to increase access to essential medicines.

Member States were requested to indicate the disease categories they preferred to be included in a SADC pooled procurement arrangement. Their responses have been compared with the disease categories that have the highest potential for medicines price savings as found by the PMA (see Annex 7). One Member State indicated that it had no preference and preferred to see pooled procurement be applied to all essential medicines and medical supplies. Between one and five Member States were found to prefer the top six categories The preferred disease categories mentioned by six to nine Member States were cardiovascular diseases, diabetes, Malaria, TB, AIDS and cancer.

118 *East African Community Secretariat. A situational analysis and feasibility study on regional pooled procurement in the East African Community partner states, September 2007. Available at* http://apps.who.int/medicinedocs/en/m/abstract/Js18414en/

It would be unrealistic to expect price savings in one country to result in similar savings in all Member States. It is therefore recommended to include an inventory of the items with the highest potential for savings in relation to their current procurement prices. This list should be included in the study on financial resources and systems, and the mapping of ongoing PSM strengthening programmes.

4.2 Potential barriers

The PMA noted that "in interviews it was indicated that national laws and regulations may not permit a country to use public money to fund regional level pooled procurement."[119] National procurement policies that are focussed on encouraging procurement from domestic sources may hinder regional cooperation. South Africa has a Preferential Procurement Policy Framework Act that is the foundation on which all procurement activities are to be based.[120] One cannot expect other SADC Member States to follow this policy and it may potentially constitute a barrier to regional cooperation. However, the PMA noted that "it was also mentioned in interviews that SADC could develop initiatives towards harmonised preferential treatment for regionally manufactured products".

Each Member State employs its own methods to support domestic industry, but not all of them have pharmaceutical manufacturers that comply with Good Manufacturing Practices. In the latter instances, some Member States prefer importing medicines from low-cost quality producers outside the region. Other countries, which have more developed industry, may wish to continue protecting their own industry even though this may render the medicines more expensive.

4.3 Options for procurement cooperation, and their advantages and disadvantages in the SADC context

Options for procurement cooperation are usually grouped according to four models with increasing levels of organisational integration (see Annex 2). The stakeholders that were interviewed preferred informed buying or coordinated, informed buying over group or central contracting which were regarded as the most feasible and practical options, since implementation costs are relatively low. They could serve as a test of the level of regional collaboration that the Member States are prepared to engage in. Another advantage would be that Member States and their civil societies could compare (albeit to a limited extent) their own performances with that of neighbouring countries.

4.4 Phased approach

In the draft Strategic Framework for Pooled Procurement, Member States agree to a phased approach.[121] This would commence with information exchange and work sharing of PSM systems in the Member States, which would then be upgraded at the policy, legal and regulatory, and PSM management levels to promote informed buying. A next phase would involve group contracting for those countries where the systems have reached the required standards.

4.5 SADC Pooled Procurement Secretariat

Member States also opted for a SADC Strategic Pooled Procurement Secretariat that would be established with the task, amongst others, of coordinating information and work sharing, and providing procurement services. When asked, eight of ten Member States indicated that they would prefer the establishment of a Regional Pooled Procurement Institute over other possible organisational forms of regional level collaboration. Three Member States preferred for such an institute to be part of the SADC Secretariat. Five Member States favoured an independent entity, while two of those five wished to see it partner with an existing, strong NMPA.

Member States' NMPAs are expected to contribute a membership fee that could be funded from the savings that they are expected to make through the implementation of the Pooled Procurement Strategy. The Institute should offer state-of-the-art procurement services and should aim to achieve a preferred status of procurement agent for development partners (which is also another opportunity to increase revenues).

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119 *PMA, Vol 2, page 40.*

120 *The aim is to: (a) advance the development of SMMEs and HDIs; (b) promote women and physically handicapped people;(c) create new jobs;(d) promote local enterprises in specific provinces, in a particular region, in a specific local authority, or in rural areas; and (e) support the local product.*

121 *SADC Drafting Team. SADC Strategic Framework for Pooled Procurement of Essential Medicines and Medical Supplies. March 2011.*

5. Conclusions

The situational analysis and feasibility study presented in this report is the accepted reflection of the situation in the pharmaceutical sector in the 14 SADC Member States that were studied.[122]

The fact that 10 of the 14 Member States returned the questionnaire within two weeks is a sign of the commitment of public officials managing the pharmaceutical sectors to the process of regional pooled procurement.

The PMA correctly concluded that, in general, pharmaceutical market information is not easily accessible in the SADC region and a lack of standardisation makes it difficult to compare the information that is available. Furthermore, the overall level of transparency in public and private pharmaceutical markets appears to be 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. Most of them did not seem used to sharing or analysing this information;
- Getting private sector information was either very difficult or expensive. Only in Namibia and South Africa could the information be purchased.

This lack of transparency can result in higher transaction costs, and creates opportunities for suppliers to diversify their prices to the disadvantage of purchasers. There are several possible reasons for lack of transparency—ranging from little or no local demand for the information, or a lack of standard performance indicators, to the absence of appropriate management information systems, cultural factors, or different legal requirements in national procurement legislation.

The PMA study noted a number of findings that indicate opportunities for increasing market efficiencies through a regional approach. Potentially beneficial regional activities include further in-depth studies, technical and policy advice and a push towards standardisation. This may in the long term produce tangible results in the Member States' pharmaceutical sectors.

Considerable differences exist in Member State pharmaceutical PSM practices, as well as in the application of regulations and procedures, such as for quality assurance and public procurement. Despite the similarities in the National Medicines Policies and in public procurement legislation, SADC Member States are at different levels of pharmaceutical sector development and pharmaceutical services delivery. A small majority of countries comply with internationally accepted principles in some respects. Most countries struggle with shortages of financial and human resources.

The findings described in Section 3 have been compared with the IPC Operational Principles for Good Pharmaceutical Procurement. The results are presented in Table 18. They indicate that application of these internationally accepted principles is underway in most Member States, with results regarding prices and quality that are good enough to justify investments in information and (south-south) work sharing. This would allow for countries that are not (yet) applying those principles to be assisted through regional facilitation or support from better performing agencies. However, it should be noted that, although the principles are a good starting point for developing regional standards and "good practices" for pharmaceutical PSM, they are not sufficiently detailed to serve as regional standards.
The results in Table 18 also show that gaps exist in certain areas and that further study is required, especially regarding:

- The financial resources and systems; and
- The existing programmes for strengthening PSM and/or quality assurance systems with or without support from development partners.

122 *SADC. Final record of the Southern African Development Community (SADC) Workshop on the Development of the SADC Regional Strategy for Pooled Procurement of Essential Medicines and Commodities. Gaborone, 24-26 August 2011.*

In the majority of the Member States, country-specific programmes for strengthening PSM and/or quality assurance systems are ongoing, mostly supported by development partners. A regional mapping study could establish who is working on which (sub-) areas in pharmaceutical PSM systems and in which Member States, as well as enhance information about the available resources, and promote regional coordination, harmonisation and synergies. Although most of the programmes apply existing WHO standards, it would be ideal if they could also comply with agreed regional or SADC standards and good practices for pharmaceutical PSM.

Table 18: Member States scores for application of Interagency Pharmaceutical Coordination Group Operational Principles for Good Pharmaceutical Procurement

	Operational principles for good pharmaceutical procurement	Number of Member States applying the principle	Explanation
1	**Proper division of functions**	14	With the exception of the Seychelles, all Member States pharmaceutical procurement comply with national procurement legislation and regulations that are based on internationally accepted "good practices". All apply tender boards or procurement committees for supervisory functions distinct from executive functions.
2	**Transparent, clear procedures and criteria for award**	7-12	Needs further study for the four Member States that have not replied yet and requires strengthening in some Member States. See principle 1 above. Procurement legislation and regulations allow for pharmaceutical procurement to use: · Standard Bidding Document for Health Sector Goods (similar to the World Bank's Standard Bidding Document)[124]—8 out of 10 Member States · Pre-qualification of suppliers and their products—7 out of 10 Member States (see principles 11 and 12 below) · Framework contracts—8 out of 10 Member States · Publication of awards—8 out of 10 Member States · Public Bid Opening—9 out of 10 Member States Further assessment of additional benchmarks is needed. For example, do Member State pharmaceutical procurement agencies implement public bid openings and do they publish details of the awards.
3	**Proper planning, monitoring and evaluation, including external audit**	9-13	Only one of the10 Member States that responded to the questionnaire indicated that no support for proper planning and quantification is needed. Most countries struggle with planning and monitoring of procurement of supplies, especially when resources are limited. Most medical stores have difficulties in sourcing and applying appropriate software with integrated modules for inventory control, procurement, distribution (sales), financial administration and management information.[125]
4	**Procurement limited to essential items**	8	The WHO/PCP reports that 8 of the 14 Member States base their procurement on the national Essential Medicines List.
5	**Use INN or generic name**	14	All NMPAs use generic names in public procurement. However, this is often not so in the for-profit private sector
6	**Proper quantification**	9	See principle 3.

123 *See, for example, the OIG Global Fund programmes audit reports for DRC, Tanzania and Zambia at http://www.theglobalfund.org/en/oig/reports/?lang=en*

124 *See http://web.worldbank.org/WBSITE/EXTERNAL/PROJECTS/PROCUREMENT/0,,contentMDK:20062006~menuPK:84284~pagePK:84269~piPK:60001558~theSitePK:84266,00.html*

	Operational principles for good pharmaceutical procurement	Number of Member States applying the principle	Explanation
7	**Ensure reliable financing and financial procedures**	1-4	Needs further study and strengthening in all Member States. Insufficient data and information available on financial resources and systems. Most countries apply input financing. This is problematic in most countries. In several countries the Government budget and funds from international cooperating partners are used for input financing for the procurement by and operational costs for Medical Stores, instead of for payment for the delivery of products to the health facilities (i.e. output financing). With input financing, there is little incentive for the Medical Stores to perform. Problems with payments. Several countries struggle to ensure sufficient financial resources for the supply of essential medicines and supplies. One Member State has price controls. Price regulations have not been implemented in Member States, with the exception of South Africa. Price controls on essential medicines exist in most high-income countries as one of the methods to ensure access in the private sector.
8	**Promote economies of scale**	13	With the exception of the DRC, all Member States procure most pharmaceuticals for public sector centrally through NMPA or a Ministry of Health structure.
9	**Use competitive procurement methods**	13	Most Member States apply International Competitive Bidding will do need to confirm with the consultant] or another competitive procurement method or at least agree that ICB is the standard (the exception is the Seychelles, where shopping is used).
10	**Sole-source commitment**	14	In most countries, Government health facilities (and provincial stores) are obliged to order products from the NMPA or the centrally contracted supplier.
11	**Pre-qualification of suppliers**	5	Needs strengthening in about half of the Member States. Minimum requirement is pre-qualification based on technical and financial capacities of all suppliers by the central medical stores or procurement agency.
12	**Quality assured products**	10	Needs strengthening in some Member States. Angola, Lesotho, the Seychelles and Swaziland do not currently register medicines (market authorisation is not required). These countries use different criteria for quality assurance. For example, Lesotho is relying on market authorisations issued by member countries of PIC/S[126] and Zimbabwe and Tanzania, which are regarded as countries with well-functioning medicines regulatory authorities. In the countries where those authorities do issue market authorisations, different methods and criteria are used.

The capacity and capability of NMRAs in the region for the assessment and approval of medicines products is limited. As a consequence, there is a substantial risk of inflows of substandard medicines with a negative impact on public health and budgets. Furthermore, while fast-track registration mechanisms exist, there are still delays and backlogs in the registration of essential medicines in almost all Member States, which also hinders access.

The project proposal for the "Harmonisation of Medicines Registration in the SADC Region", submitted in July 2011 with guidance from the African Medicines Registration Harmonisation Initiative, will allow for the development and implementation of new or more developed legislation, standardised sets of guidelines, processes and procedures. These would facilitate medicines registration across SADC and lead to intensified market surveillance.

125 *Pharmaceutical Inspection Cooperation Scheme; see http://www.picscheme.org/members.php*

Regional regulatory harmonisation—including mutual recognition of registration—can improve the availability of medicines, especially for priority products with small sales volumes, since the increased market size will offer bigger incentives for applicants to register such products.

6. Recommendations

The following recommendations are addressed to the SADC Secretariat, which is mandated to facilitate regional pharmaceutical pooled procurement. Implementation of the recommendations will require close cooperation with Member States and their prior approval. Recommendations from the 2010 PMA study are incorporated where appropriate.

6.1 Continue investing in regional procurement cooperation

Countries should be supported so they can actively participate in the approval and implementation of the regional Pharmaceutical Pooled Procurement Strategy that aims for:

- All SADC Member States to commit to the Strategy and include it in their National Medicines Policies (NMP);
- All Member States to agree on SADC pharmaceutical PSM standards at policy level;
- All Member States to agree on models for sustainable human resources for regional Pooled Pharmaceutical Procurement;
- All Member States to agree on models for sustainable financing for SADC Pooled Pharmaceutical Procurement;
- All Member States to have legal instruments in line with the SADC Protocol on Health to support SADC Pooled Pharmaceutical Procurement; and
- All Member States to have pharmaceutical PSM systems in place that operate according to agreed standards at management level.

The establishment and maintenance of regional pharmaceutical information and work sharing platforms should be facilitated. Among other things these platforms should provide:

- A public sector procurement database with prices (preferably standardised FOB prices), sources and quality information. Links could be established with other price information sites (such as Management Sciences for Health, WHO, the Global Fund and Price Information Exchange;
- Names and contact details of pre-qualified public sector suppliers (importers, wholesalers and manufacturers) including pre-qualification criteria;
- Performance ratings of suppliers;
- Information on accessibility, conditions, capacities and fee levels of quality control laboratories in the region;
- Price and availability reporting mechanisms; and
- Sharing of PSM tools and standards.[126]

126 *For more details, see Schürmann M. Using a multi-stakeholder approach to improve governance in pharmaceutical procurement: Methodology for procurement information exchange platform embedded in the electronic network for procurement practitioners (e-NePP). Final draft. WBI, 28 April 2011; and Verhage R. Notes on pooled procurement information and work sharing e-platforms, 23 May 2011.*

The establishment of a SADC Pharmaceutical Pooled Procurement Institute with the following tasks should be facilitated:

- Technically coordinate the information and work sharing via shared electronic platforms;
- Monitor, support and assure adherence to SADC Pooled Pharmaceutical Procurement Policy Guidelines in Member States;
- Implement and adhere to good pharmaceutical procurement practices of essential medicines, especially for HIV and AIDS, TB and Malaria;
- Reconcile needs and funds for pooled pharmaceutical procurement;
- Negotiate affordable prices with pre-qualified suppliers and manufacturers on behalf of Member States;
- Specify contract terms and conditions;
- Monitor framework contracts and resolve issues related to orders placed by Member States; and
- Perform any other activity needed in order to ensure efficient pooled pharmaceutical procurement.

The establishment of successful cooperation models for possible application in SADC should be facilitated (models such as CHAI, the Management Sciences for Health / Strengthening Pharmaceutical Systems programme, the Association des Centrales d'Achats Africaines des Médicaments Essentiels, and the World Bank Institute/East African Community programme). There should be linkages to existing SADC programmes such as the Malaria and HIV and AIDs cross-border initiatives that are funded by the Global Fund.

6.2 Commission follow-up research

Follow-up research could include:

- An assessment of financial resources and systems in the pharmaceutical sector in Member States. Among other things, the assessment should review payment mechanisms and duties and taxes with:

- A comprehensive inventory of existing tax and duties instruments, and
- Analysis of the effects of these instruments on purchasing behaviour and pricing.

The study should also identify the options, benefits and challenges of price regulations. It should cover the use of price regulations as policy instruments to increase access to medicines, show how price regulations may interact with other policy instruments, and indicate the conditions that are needed to achieve the desired results.

- A mapping study on existing programmes for strengthening PSM and/or quality assurance systems in Member States. The "map" would constitute a starting-point for regional work sharing so that Member States can share PSM tools and benefit from potential support by those Member States that have more advanced PSM systems.
- A study to assess the user level demand side in the region to generate information that can inform policies that directly address access to medicines for patients. This should be preceded and informed by an assessment of the WHO / Health Action International price and availability surveys that already have been done in the DRC, Malawi, Mauritius, Tanzania and South Africa.

6.3 Support medicines regulatory harmonisation

Medicines regulatory harmonisation should be supported by facilitating the process of harmonising medicines registration requirements and processes in the region (including updating of standardised guidelines and capacity building plans for implementers).

6.4 Optimise use of the TRIPS agreement

Member States must maximise “TRIPS flexibilities” in their national intellectual property legislation and avoid “TRIPS+” pressures in bilateral negotiations, Free Trade Agreements and Economic Partnership Agreements.

A regional strategy for regional development, production, distribution and procurement of generic copies of newly-patented medicines within SADC the region should be developed.

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Annex 1: PMA List of Tracer Items

This section has been extracted from the 2010 PMA study.

Criteria for the inclusion of items in the list were:

- Included in the list of Top 50 items by thee or more countries (as submitted by countries in the context of the WHO Assessment of Pharmaceutical Situations in SADC Member States);
- Included in the original draft of the SARPAM tracer list (which included all medicines from the WHO / Health Action International and AFRO regional core lists);
- Included in the latest WHO Essential Medicines List; and
- Used to address regional priority diseases (burden of disease, public health relevance, specific focus on maternal and reproductive health and child health).

	Item	Basic unit
1	aciclovir 200mg tablet	tablet
2	albendazole 400mg tablet	tablet
3	amitriptyline 25mg tablet	tablet
4	amodiaquine 150-200mg tablet	tablet
5	amoxycillin 125mg/5ml suspension	ml
6	amoxycillin 500mg tablet/capsule	tablet
7	artemether + lumefantrine 20+120mg 12 tablets*	tablet
8	bleomycin 15iu inj	vial
9	captopril 25mg tablet	tablet
10	carbamazepine 200mg tablet	tablet
11	ceftriaxone 250mg pwd for injection	vial
12	cephalexin 250mg tablet	tablet
13	chloramphenicol 250mg capsule	capsule
14	chloropheniramine 4mg tablet	tablet
15	chloroquine 150mg tablet	tablet
16	ciprofloxacin 500mg tablet	tablet
17	clotrimazole 100mg pessary	pessary
18	cotrimoxazole 240mg/5ml suspension	ml
19	cotrimoxazole 480mg tab	tablet
20	diazepam 5mg tablet	tablet
21	diclofenac 50mg tablet	tablet
22	DPT vaccine injection	dose
23	erythromycin 250mg tablet	tablet
24	ferrous sulfate/ folic acid 200-0.40mg tablet	tablet
25	glibenclamide5mg tablet	tablet

	Item	Basic unit
26	insulin isophane 100IU/ml inj.	ml
27	Lamivudine/Stavudine/ Nevirapine 30+6+50mg dispersible tablet	tablet
28	levonorgestrel 0.75 mg tablet	tablet
29	lopinavir/ritonavir 200+50mg tablet heat-stable	tablet
30	magnesium sulphate 500mg/ml injection	ml
31	measles vaccine	dose
32	medroxyprogesteron acetate 150mg/ml injection	ml
33	metformin 500mg tablet	tablet
34	metronidazole 200mg -250mg tablet	tablet
35	nystatin 100,00 IU pessary	pessary
36	omeprazole 20mg tablet	tablet
37	oral rehydration salts (WHO formulation) sachet for 1L	
38	oxytocin 10IU/ml injection	ml
39	paracetamol 120mg/5ml suspension	ml
40	penicillin benzathine 2.4 MU powder for injection	vial
41	rifampicin/isoniazid (150 + 75)mg tablet adults	tablet
42	rifampicin/isoniazid/ pyrazinamid 60+30+150mg dispersible tablet	tablet
43	salbutamol 100mcg/dose inhaler	dose
44	simvastatin 20mg tablet	tablet
45	sodium valproate 200mg/5ml syrup	ml
46	sulfadoxine + pyremethamine 500+25mg tablet	tablet
47	tamoxifen 20mg tablet	tablet
48	Tetracycline 1% eye ointment	g
49	Zidovudine 300mg + Lamivudine 150mg (3TC) tablet	tablet
50	zinc sulfate 20mg dispersible tablet	tablet

Annex 2: Models for Procurement Cooperation[127]

	Information exchange		Pooled procurement	
	Informed buying	**Coordinated informed buying**	**Group contracting**	**Central contracting**
Description	Member States share information about suppliers	Member States undertake joint market research, share supplier performance information, and monitor prices	Member States jointly negotiate prices and select suppliers	Member States jointly conduct tenders and award contracts through an organisation acting on their behalf
	Member States conduct procurement individually	Member States conduct procurement individually	Member States agree to purchase from selected suppliers	Central buying unit manages the purchase on behalf of member countries
			Member States conduct procurement individually	
Regional group roles and responsibilities	Facilitate the gathering and dissemination of supplier and price information among Member States	Forum for harmonisation of information requirements and systems, mechanism for market research and disseminating findings among Member States, and potentially, providing drug information	Member State delegates meet to jointly negotiate prices and select suppliers	Contracts with a jointly designated central buying unit/ agency to conduct and adjudicate tenders
	Simple sharing of information	Focus on coordination of information gathering and sharing	Alternatively, an agency may be contracted for this purpose	

127 *Onyango C. 2003. Readiness for regional pooled procurement of HIV/AIDS-related drugs and commodities in sub-Saharan Africa: An assessment of 11 member countries of the Commonwealth Regional Health Community Secretariat, 2002.*

	Information exchange		Pooled procurement	
	Informed buying	**Coordinated informed buying**	**Group contracting**	**Central contracting**
Country roles and responsibilities	Share procurement information on selected items	Collect information related to pricing and supplier performance based on harmonised requirements	Provide accurate and reliable quantification of need for selected terms	Provide accurate and reliable quantification of need for selected items
		Provide resources to conduct market research activities for selected items	Provide timely payment to suppliers	Provide funds to procurement unit/ agency for supplier payment
			Provide accurate and reliable information on supplier performance and product quality monitoring	Provide accurate and reliable information on supplier performance and product quality monitoring

Annex 3: Member States stakeholders interviewed

Name (country)	Position
Jennie Lates (Namibia)	Deputy-Director Pharmaceutical Services (and chair PAC up to August 2011)
Thamizhanban Pillay (South Africa)	Cluster Manager of Financial Planning & Health Economics (Manager Pharmacy & Policy), Ministry of Health
Helecine Zeeman (South Africa)	Director Affordable Medicines, Ministry of Health
Lucile de Comarmond (Seychelles)	Director Pharmaceutical Services, Ministry of Health
Ropah Hove (Zimbabwe)	Director Pharmacy Services
Paulo Fernando Nhaducue (Mozambique)	Director Central Medical Stores (CMAM)
Muhammad Farooq Chohan (Botswana)	Principal Pharmacist, CMS
Daniel Ngeleka Mutolo (DRC)	Director of Pharmacy and Medicines Department
Sheesha Jankee (Mauritius)	Acting Director Pharmaceutical Services
Fortunate Fakudze (Swaziland)	Senior Pharmacist, Ministry of Health
Kelita Kamoto (Malawi)	Director Health Technical and Support Services
Tlai-Tlai Paul Sepetla (Lesotho)	Pharmacist, Ministry of Health

Annex 4: Overview of steps in procurement of pharmaceuticals allowed in existing public procurement legislation, and overview of steps actually applied by the NMPA

Country	Act/NMPA applied	Public procurement legislation applies to pharmaceutical procurement	Pre-qualification of suppliers (1)	Pre-qualification of products (2)	Framework contracts (3)	Standard Bidding Document for pharma-ceuticals (4)	Public bid opening (5)
Angola	Act	1	1	0	0	1	1
	NMPA	1	1	0	0	1	0
Botswana	Act	1	1	1	1	1	1
	NMPA	1	0	1	1	1	1
DRC	Act	1	1	1	1	1	1
	NMPA	1	0	1	1	1	1
Lesotho	Act	1	1	1	1	1	1
	NMPA	1	1	1	1	0	1
Malawi	Act	0	1	0	1	0	1
	NMPA	0	1	1	0	1	1
Mauritius	Act	1	1	1	1	1	1
	NMPA	1	1	1	0	1	1
Mozambique	Act	1	0	0	0	0	0
	NMPA	1	0	1	0	1	1
Namibia	Act	1	1	0	1	0	1
	NMPA	1	0	0	1	1	1
Seychelles	Act	0	na	na	na	na	na
	NMPA	0	0	0	0	0	0
South Africa	Act	1	0	1	1	1	1
	NMPA	1	0	1	1	1	0
Swaziland	Bill	1	0	0	1	1	1
	NMPA	1	0	0	1	1	1
Tanzania	Act	ne	ne	ne	ne	ne	ne
	NMPA	ne	ne	ne	ne	ne	ne
Zambia	Act	ne	ne	ne	ne	ne	ne
	NMPA	ne	ne	ne	ne	ne	ne
Zimbabwe	Act	1	1	1	1	1	1
	NMPA	1	1	1	1	1	1

Legend: 1 = yes; 0 = no; na = not applicable; ne = not established
Source: August 2011 SARPAM Questionnaire

	Waivers from inter-national compet-itive tendering (6)	Negotiation (7)	Publication of awards (8)	Outsourcing of procurement (9)	e-Procurement (10)	Remarks
	0	1	1	0	0	
	0	1	1	0	0	
	1	1	1	0	0	
	1	0	1	0	0	
	1	1	1	1	0	
	1	1	1	1	0	
	0	0	1	0	0	
	0	0	1	0	0	
	1	1	1	1	0	
	1	0	1	0	0	
	0	0	1	0	0	
	0	0	1	0	0	Expressed interest in (4)
	0	0	0	0	0	
	0	0	1	0	0	
	1	1	0	0	0	
	1	1	0	0	0	(1) not applied; (2) actually applied
	na	na	na	na	na	Applies for medical supplies only; not for medicines (further study needed)
	0	1	0	0	0	
	0	1	1	0	1	
	0	1	1	0	0	
	0	0	1	0	0	
	0	0	1	0	0	
	ne	ne	ne	ne	ne	
	ne	ne	ne	ne	ne	
	ne	ne	ne	ne	ne	
	ne	ne	ne	ne	ne	
	1	1	1	0	0	
	1	1	1	0	0	

Annex 5: Overview of NMPAs in Member States

Country	NMPA name	Under Ministry of Health	Autonomous	Procurement manual	Name procurement manual	Exec Procurement Unit
Angola	CECOMA	0	1	1	Caderno de Encargos para aquisições	1
Botswana	CMS	1	0	1	SOPs 2009 1st edition	1
DRC	MOH-PCU/ Donor-Pas/ FEDECAME (BCAF/ ASRAMES)	0	1	1	FEDECAME SOPs based on MSP. Manuel de procédures d'approvisionnement de gestion des medicament essentiels, Mai 2010	1
Lesotho	NDSO	0	1	1	NDSO Procurement Procedures Manual, January 2008 + SOPs	1
Malawi	CMS	0	1	0	Procurement Manuals developed by the Office of the Director of Public Procurement (ODPP)	1
Mauritius	MOH-PU/ MOH-CMS	1	0	1	The World Bank Procurement Manual is being prepared	0
Mozambique	CMAM	1	0	0	Na	1
Namibia	CMS	1	0	1	SOP Manual for Managing Pharmaceutical Supplies at the Central Medical Stores – DRAFT 2006 October 2006, MoHSS	1
Seychelles	MOH-DPS/ MOH-CMS	1	0	1	Internal document, not formalised	1
South Africa	DOH	1	0	0	In process	1
Swaziland	MOH-PU/ MOH-CMS	1	0	0	Na	1
Tanzania	MSD	0	1	ne	Ne	Ne
Zambia	MOH-PU/ MSL[129]	1	0	1	Ne	1
Zimbabwe	NATPHARM	0	1	1	SOPs	1
Total		**7**	**6**	**9**		**11**

Legend: na = not applicable; ne = not established; SOP = Standard Operating Procedures; MOH = Ministry of Health; MSL = Medical Stores Limited; CMS = Central Medical Stores
Source: August 2011 SARPAM Questionnaire

128 *The PU in the MOH procures medicines and the autonomous Medical Stores Limited (MSL) stores and distributes*

	Tender committee	Frequency (per year)	Overview stocks etc. at NMPA	Overview stocks etc at Health Facilities	Software NMPA	Remarks
	1	ne	1	1	UniLog / UniHealth	
	1	1	1	0	Pulse/Oracle	
	1	3	1	0	APISOFT/EXACT	Three procurement groups have been identified. The stores in the health zones or districts, CDRs, deliver to health facilities. The DRC is working on common standards in PSM; aims for this in two years time.
	1	1	1	0	Rx Solutions (adapted)	
	1	ne	1	1	Channel/ACCPAC	The CMS Trust became official in July 2011
	1	1	1	0	Oraclesun	
	0		1	0	MACS	Currently CMAM is under review by development partners
	1	0.5	1	0	Syspro	Draft 2006; places frequently orders under framework contracts; has functioning tender management system
	1	2	1	0	Trifour-Health	MOH-CMS for storage and distribution only. Data from clinics on requisitions (stock, consumption and order qty). Monthly Statements for all clinics/hospitals are sent by CMS to DPS and regular audits, stock outs sometimes due to stock management problems; need higher level pharmacy personnel
	1	0.5	1	1	0	DOH pharmaceutical PU only exists for some months
	1	ne	1	0	Rx Solutions	Software adapted for CMS/ govt software for MOF procurement monitoring. NERCHA as GFATM Principal Recipient for procurement of antiretrovirals
	ne	ne	ne	ne	ne	
	1	ne	1	ne	MACS	Autonomous MSL for storage and distribution only; had procurement also < 2000
	1	na	1	0	Navision	
	11	**na**	**12**	**2**		

Annex 6: Overview of NMRAs in Member States

	Legal provision exists establishing Medicine Regulatory Authority	Formal Medicines Regulatory Authority exists	NMRA name	Under MOH	Autonomous	Legal provisions exist for market authorisation	Local agents required
Angola	1	1	DNME	1	0	draft	ne
Botswana	1	0	DAB	1	0	1	ne
DRC	1	1	DPM	1	0	1	ne
Lesotho	0	0	na	na	na	draft	na
Malawi	1	1	PMPB	0	1	1	ne
Mauritius	1	1	DPS	1	0	1	1
Mozambique	1	1	DP	1	0	1	1
Namibia	1	1	NMRC	1	0	1	1
Seychelles	0	0	na	na	na	draft	na
South Africa	1	1	MCC	0	1	1	ne
Swaziland	0	0	na	na	na	draft	na
Tanzania	1	1	TFDA	0	1	1	ne
Zambia	1	1	PRA	0	1	1	ne
Zimbabwe	1	1	MCAZ	0	1	1	0
Total	10	11	Proposed	5	6	10	3

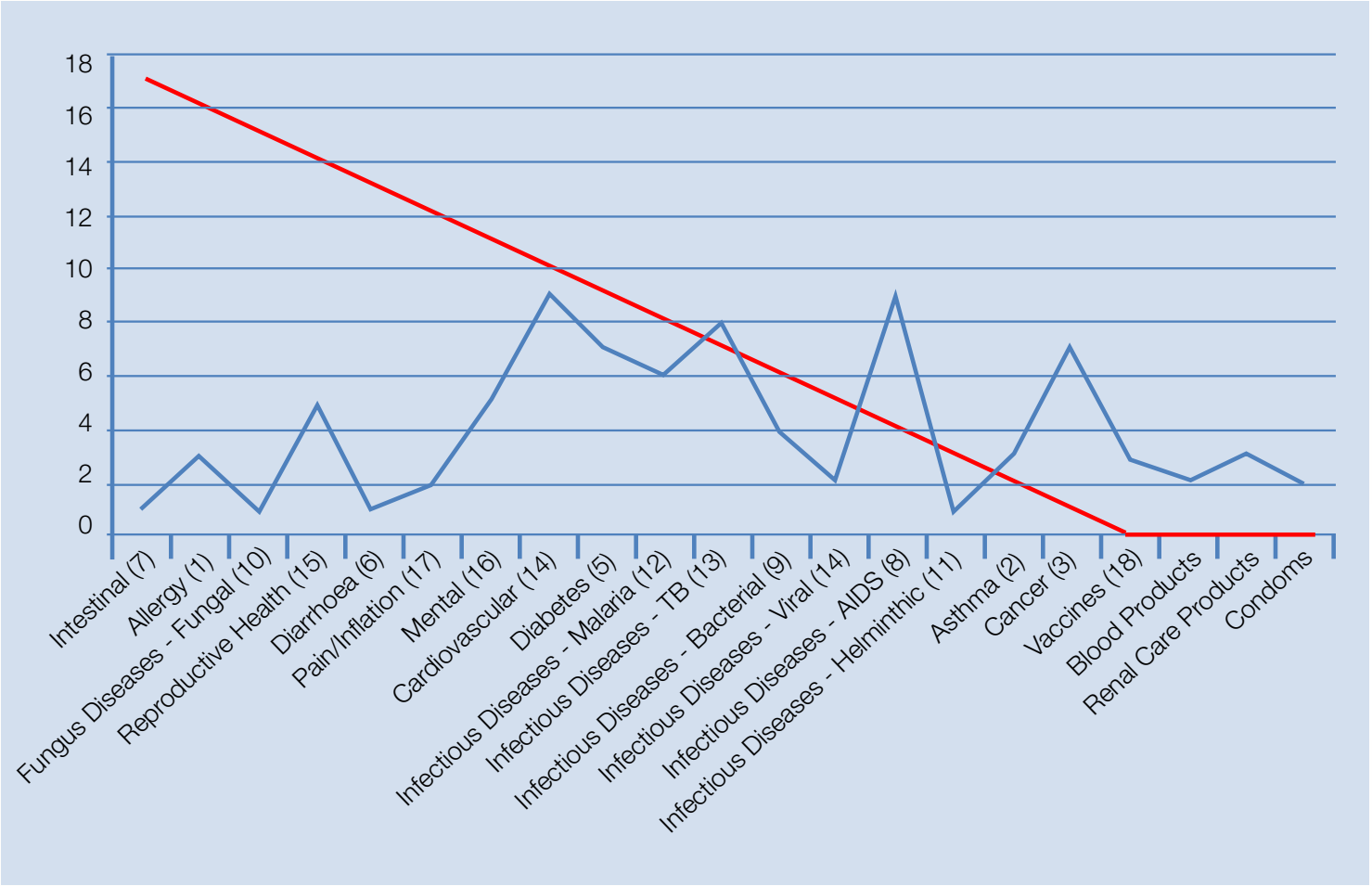
Legend: na = not applicable; ne = not established
Source: August 2011 SARPAM Questionnaire

129 *"The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce guarantees, through the issue of a WHO-type certificate by the certifying authority, the quality of pharmaceutical products entering international commerce. It is a simple administrative procedure that enables importing countries to obtain information on whether a product has been authorized to be placed on the market in the exporting country, and assure that the manufacturer has been found to comply with WHO standards of good manufacturing practices." From WHO. Operational package for assessing, monitoring and evaluation of country pharmaceutical situations (guide for coordinators and data collectors), December 2007; p 52.*
See http://apps.who.int/medicinedocs/documents/s14877e/s14877e.pdf.

130 *MCC website was down in 2011-2012*

	WHO Certification Scheme[130] may be part of the marketing authorisation process	Product license # required on label	Regulatory agency has website	Registered medicines published	Does publication include manufacturer?
	1	ne	0	0	na
	1	ne	0	1	1
	1	ne	0	0	na
	na	na	0	na	na
	1	1	1	0	na
	1	0	0	0	na
	0	ne	0	0	na
	1	1	1	1	1
	na	na	0	na	na
	1	1	1	1	ne[131]
	na	na	0	na	na
	1	ne	1	ne	ne
	0	ne	1	ne	ne
	1	1	1	0	na
	9	4	6	2	1

Annex 7: PMA Disease categories with highest to lowest price gains against the number of Member States which preferred THE same categories to be part of SADC pooled procurement



Source: PMA and August 2011 Questionnaire

Annex 8: Questionnaire for SADC ministry of health pharmaceutical in-charges

QUESTIONNAIRE FOR SADC MINISTRY OF HEALTH PHARMACEUTICAL IN-CHARGES

Questionnaire to identify information and data needed for the finalisation of the situational analysis for the SADC Strategy on Pooled Procurement of Essential Medicines.

SADC/SARPAM
18 July 2011

PLEASE RETURN FILLED QUESTIONNAIRE TO THE EMAIL ADDRESSES BELOW BEFORE 6 AUGUST 2011

The Questionnaire has been designed to be filled in electronically in MS Word. Where requested, be so kind as to type the information or applicable numbers on the dotted lines (...) by putting your cursor on the dotted line, then double-click and start typing. Pre-testing this questionnaire showed that it takes about 20 to 30 minutes to complete it. In the week of 1 August, Rob Verhage will call you to inquire about the progress you made and to assist where required.

For any questions or remarks please contact Rob Verhage, SARPAM consultant at
verhager@gmail.com
Mobile: +5978888647
Skype-name: verhager

AND

Aarti Patel, SARPAM Technical Advisor for SADC Secretariat
aarti@sarpam.net
Mobile: +27725874397 (SA); +26774551802 (Botswana)
Skype-name: Aarti.patel67

GENERAL SECTION	
A. Country	
B. Name In-Charge of MOH Pharmaceutical Sector	
C. E-mail address In-Charge	
D. Mobile number In-Charge	
E. Designation In-Charge of Pharmaceutical Sector	
F. Please indicate how your Directorate, Department or Section is located in the MOH hierarchy (1,2, 3 or 4) and to whom you report. [Please, fill in function of your direct supervisor on dotted line in 1st column and state applicable number in 2nd column (you can use one number only!)]	
1. Directorate, reporting to ……	...
2. Sub-Directorate or Department, reporting to ……..	
3. Section or Unit, reporting to ……	[Fill one number only]
4. Other …… [state formal name of unit],reporting to ……	
G. Please indicate your responsibilities in pharmaceutical Procurement & Supply Management (PSM) [Please, state applicable number in last column; more than one number is possible!]	

Supervisory responsibilities:

1. Participates in decision-making at highest level in resource allocation for public health (including budget for pharmaceuticals)
2. Member of Committee coordinating implementation of National Medicines Policy (NMP)
3. Member of Tender Board that includes responsibility for pharmaceutical tenders
4. Member of National (Medicines) Pricing Committee
5. Member of Board of Medicines Regulatory Authority
6. Member of National Pharmacy Council
7. Member of Board of Directors of (semi-)autonomous public National Medicines Procurement Agency (NMPA)
8. Direct supervisor of NMPA (where NMPA is within MOH structure)
9. Participates in Medicines Regulatory Authority
10. Other supervisory responsibilities, i.e …… [state responsibility related to pharmaceutical PSM]

Executive responsibilities:

11. In charge of implementation of National Medicines Policy (NMP)
12. Member of National Therapeutics Committee or equivalent (in charge of the selection of essential medicines)
13. In charge of Pharmaceutical Inspection
14. Prepares budgets for pharmaceuticals
15. Procurement of pharmaceuticals [is doing actual pharmaceutical procurement]
16. Storage & Distribution of pharmaceuticals [is doing actual storage and distribution of pharmaceuticals;] of …… [state categories of products]
17. Other executive responsibilities, i.e …… [state responsibility related to pharmaceutical PSM]

H. Staff

[Please, fill appropriate numbers]

	MOH pharmacists	NMPA pharmacists	NMPA qualified procurement officers	Regional or provincial pharmacists	District pharmaceutical staff
# established posts					
# posts filled					
Balance					

I. Development Partners Support for pharmaceutical PSM

[Please, fill "Yes/No" where appropriate and period in years and approximate value in USD]

Development Partner	Technical assistance (Yes/ No)	Funding of medicines supply (Yes/ No)	In-kind donations of medicines (Yes/No)	Period (YY to YY)	Approximate value (USD)
Bill Gates Foundation					
Clinton Foundation					
European Union					
DfID					
Dutch Government					
GFATM					
Pharmaceutical Industry					
USAID					
WHO					
Other, i.e. ……					
Other, i.e. ……					

J. Continuous technical assistance (TA) for pharmaceutical PSM

[Please fill in behind the appropriate PSM area from who TA is being received, such as from Clinton Foundation, Crown Agents, JSI and MSH (i.e. TA provider) and who is funding this support (i.e.Funding agency]

PSM area	TA received (Yes/No)	TA provider	Funding agency	Remarks
Selection				
Quantification				
Tendering				
Outsourced procurement				
NMPA management				
Storage				
Distribution				
Rational Use				
Other, i.e. ……				

SECTION ON PHARMACEUTICAL PROCUREMENT & SUPPLY MANAGEMENT LEGISLATION, REGULATIONS AND GUIDELINES		
J. Is there a Public Procurement Act?	1. Yes 2. No	... [1→K 2→L; fill one number only]
K. Procurement Act		
K1. State full reference of Act and website or email-address were Act and related Regulations/ Guidelines and Standard Bidding Documents may be obtained	Act: …… …… [Author. Title, Place and Date of Publication] Website: …… [where Act may be downloaded] Email address: …… [from which Act may be obtained]	
K2. Does the Procurement Act apply to the National Pharmaceutical Procurement Agency (NMPA)?	1. Yes 2. No	... [Fill one number only]
K3. The Procurement Act allows for procurement of pharmaceuticals:	1. Pre-qualification of suppliers 2. Pre-qualification of products [i.e. actual excluding of pharmaceuticals that have no market authorisation from the National Medicines Regulatory Authority (NMRA)] 3. Framework contracts [i.e. contracts for a longer period under which call-off orders are being placed] 4. Standard Bidding Document for Pharmaceuticals 5. Public Bid Opening 6. Waivers from international competitive tendering; 7. Negotiation 8. Publication of Awards 9. Outsourcing of procurement 10. e-Procurement	... ... [Please, state applicable number; more than one number is possible!]

L. Which of the procedures are actually applied by the NMPA?	1. Pre-qualification of suppliers 2. Pre-qualification of products [i.e. actual excluding of pharmaceuticals that have no market authorisation from the NMRA] 3. Framework contracts [i.e. contracts for a longer period under which call-off orders are being placed] 4. Standard Bidding Document for Pharmaceuticals 5. Public Bid Opening 6. Waivers from international competitive tendering; 7. Negotiation 8. Publication of Awards 9. Outsourcing of procurement 10. e-Procurement	... ... [Please, state applicable number; more than one number is possible!]
M. Which of the procedures are actually applied by others than NMPA (for example in vertical programmes)	1. Pre-qualification of suppliers 2. Pre-qualification of products [i.e. actual excluding of pharmaceuticals that have no market authorisation from the NMRA] 3. Framework contracts [i.e. contracts for a longer period under which call-off orders are being placed] 4. Standard Bidding Document for Pharmaceuticals 5. Public Bid Opening 6. Waivers from international competitive tendering; 7. Negotiation 8. Publication of Awards 9. Outsourcing of procurement 10. e-Procurement	... ... [Please, state applicable number; more than one number is possible!]

N. Which of the following arrangements are in place at the NMPA?	1. Procurement Manual for Pharmaceutical Procurement 2. Procurement Unit (or similar) charged with executive procurement 3. Tender/Procurement Board/Committee charged with guiding and supervisory responsibilities NMPA Procurement Manual Reference: …….. …… ..... …….. [Author. Title, Place and Date of Publication] Website: …… [where Manual may be downloaded] Email address: …… [from which Manual may be obtained]	... ... [Please, state applicable number; more than one number is possible!]
O. Which of the following arrangements are in place at others than NMPA (for example at vertical programmes?	1. Procurement Manual for Pharmaceutical Procurement 2. Procurement Unit (or similar) charged with executive procurement 3. Tender/Procurement Board/Committee charged with guiding and supervisory responsibilities NMPA Procurement Manual Reference: …… …… …… [Author. Title, Place and Date of Publication] Website: …… [where Manual may be downloaded] Email address: …… [from which Manual may be obtained]	... ... [Please, state applicable number; more than one number is possible!]
P. Can the NMPA <u>at any given time</u> produce a <u>reliable</u> report on stocks, pipeline status and costs of all essential pharmaceuticals?	1. Yes 2. No Remarks: …… …… ……	

Q. What software is being used in NMPA for inventory control, procurement and /or accounting?	1. Exact 2. MACS 3. mSupply 4. Navision 5. Sage 6. Other …… [state name]	... ... [Please, state applicable number; more than one number is possible!]
R. Are all medicines registered by the NMRA being published on a website?	1. Yes, namely ……[website address] 2. No Remarks: …… ……	
S. Can health facilities produce a <u>reliable</u> report on stocks, pipeline status and costs of all essential pharmaceuticals at <u>any given time</u>?	1. Yes 2. No Remarks: …… …… ……	
T. Which of the following tools are used for selection in pharmaceutical PSM:	1. Essential Medicines List 2. Therapeutic Guidelines 3. Essential Medical Supplies List 4. Essential Laboratory Supplies List Other; i.e. …….. …… ……	... ... [Please, state applicable number; more than one number is possible!]

U. Which of the disease categories would best benefit from SADC pooled procurement (for medicines and other supplies) in your country?	1. Allergy 2. Asthma 3. Cancer 4. Cardiovascular 5. Diabetes 6. Diarrhoea 7. Gastro-intestinal 8. Infectious diseases - AIDS 9. Infectious diseases – Bacterial 10. Infectious diseases – Fungal 11. Infectious diseases – Helminthic 12. Infectious diseases – Malaria 13. Infectious diseases – TB 14. Infectious diseases – Viral 15. Maternal & Reproductive Health 16. Mental 17. Pain/Inflation 18. Other…… 19. All 20. None	... ... [Please, state applicable number in order of importance; more than one number is possible!]
V. Please state products or groups of products (medicines or other commodities), which could best be acquired using SADC pooled procurement.	1. …… 2. …… 3. …… 4. …… 5. …… 6. …… 7. …… 8. …… 9. …… 10. ……	

W. MOH budgets for pharmaceuticals are used for:	1. Procurement by NMPA (input financing) 2. Operational costs for NMPA (input financing) 3. Payment of NMPA for deliveries to health facilities (output or performance financing) 4. Payment of other suppliers (including NMPA) for deliveries to health facilities (output or performance financing)	... ... [Please, state applicable number; more than one number is possible!]
X. Which PSM indicators are used for M&E at national level? **[Circle the appropriate answers; more than one answer is possible]**	1. Availability of key essential medicines (please attach file with key items when applicable) 2. Value-for-Money (e.g. ratio between median price of number of key products procured and the international median reference value; please attach file with key items when applicable) 3. Other: i.e. …… …… 4. Other: i.e. …… …… Reference for reports including national health indicators: …… …… …… [Author. Title, Place and Date of Publication] Website: …… [where national indicators may be downloaded] Email address: …… [from which national indicators may be obtained]	... ... [Please, state applicable number; more than one number is possible!]

Y. Please indicate need for improvement in each sub-area of pharmaceutical PSM in your country. **[Circle the appropriate answers; more than one answer is possible]**	1. Selection 2. Planning and quantification 3. Stock control at central level 4. Stock control at user level 5. Procurement and budget monitoring at central level 6. Pre-qualification of suppliers 7. Pre-qualification of products [i.e. actual excluding of pharmaceuticals that have no market authorisation from the MRA] 8. International tendering for framework contracts [i.e. contracts for a longer period under which call-off orders are being placed] 9. International trade agreements 10. Price negotiations 11. Medicines financing 12. Rational use of medicines 13. Other; i.e. ……	... ... [Please, state applicable number; more than one number is possible!]
Z. What is your preferable option for the SADC Pooled Procurement Secretariat?	1. Department within the SADC Secretariat 2. Independent institute with specific tasks[132], its own budget and qualified staff to be based in one of the SADC countries 3. Institute as in 2. above, but attached to one of the better functioning Medical Stores in one of the SADC countries 4. Other; i.e. ……	... ... [Please, state applicable number; only <u>one number</u> is possible!]

THANK YOU!

131 *See SADC Strategic Framework for Pooled Procurement of Essential Medicines and Medical Supplies. 2011*

Annex 9: Malawi Member States' Meeting 2010 detailed recommendations on situational analysis study

The December 2010 Member States meeting in Malawi on the development of the SADC Pooled Procurement Strategy[132] made the following detailed recommendations with regard to further study of the regional situational analysis:

- In-depth discussion on pooled procurement to:

- Cover the experiences of the Member States;
- Discuss benefits and challenges of pooled procurement;
- Provide experiences from other countries (what has worked, what did not work); and
- Literature review on pooled procurement to provide adequate background.

- Evidence for consultation with high-level policy makers, and existing protocols and ministerial decisions;
- Analysis of private sector systems;
- The need for an inclusive meeting with all stakeholders to address discrepancies in the situational analysis;
- Assessment of sustainability;
- WHO to facilitate prequalification of regional manufacturers and products; and
- WHO to assess Member States' adherence to SADC Harmonised Regulation.

The Malawi meeting felt that a situation analysis should include:

- Description of products to be included in pooled procurement activities (especially regarding HIV and AIDS, TB and Malaria; STIs; reproductive health);
- Description of commodities;
- Annual procurement volumes;
- Procurement price in FOB;
- Price of locally manufactured product if applicable;
- Frequency of tenders;
- Pre-qualification of suppliers;
- Suppliers selection;
- Tender dossier;
- Information on requirements for minimum shelf life;
- Contract details;
- Methods of payment;

132 *SADC. Final Record Southern African Development Community (SADC) Workshop on the development of the SADC Regional Strategy for Pooled Procurement and Strategic Framework for Regional Production of Essential Medicines and Commodities for HIV and AIDS, TB and Malaria. Cross Roads Hotel, Lilongwe, Republic of Malawi, 13 to 17 December 2010*

- Management of supplier performance;
- Registration requirements;
- Service level general;
- Order fulfillment rate for the selected medicines;
- Constraints and challenges;
- Government budget for medicines;
- Donor budget for medicines;
- Value of donated medicines; and
- Release of budget to procurement entity.

The meeting mandated the SADC Secretariat to appoint a drafting team to address these issues and produce the draft *Strategic Framework for Regional Pooled Pharmaceutical Procurement.*

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