SITUATION ANALYSIS STUDY ON

MEDICINES REGISTRATION HARMONISATION IN AFRICA

FINAL REPORT FOR THE SOUTHERN AFRICAN DEVELOPMENT COMMUNITY (SADC)

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NEPAD
TRANSFORMING AFRICA

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ACRONYMS

AIDS	Acquired immunodeficiency syndrome
AMRH	African Medicines Regulatory Harmonisation
API	Active pharmaceutical ingredient
BMGF	Bill and Melinda Gates Foundation
CIA	Central Intelligence Agency (USA)
CPP	Certificate of Pharmaceutical Product
DDA	Dangerous Drugs Act (Zimbabwe)
DFID	Department for International Development (UK)
DNME	National Directorate of Medicines and Equipment (Angola)
DRC	Democratic Republic of Congo
EAC	East African Community
EMEA	European Medicines Agency
EML	Essential Medicines List
EU	European Union
FDA	Food and Drug Administration (US)
FFSAPS	Agence Française de Sécurité Sanitaire des Produits de Santé (French Agency for the Safety of Health Products)
FPP	Finished Pharmaceutical Product
GDP	Gross domestic product
GMP	Good manufacturing practice
GNP	Gross national product
GPA	Global Pharma Analytics
HIV	Human immunodeficiency virus
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
IMSA	View of Innovative Medicines South Africa
LDC	Least developed country
M&E	Monitoring and evaluation
PMPB	Pharmacy Medicines and Poisons Board (Malawi)
MASCA	Medicines and Allied Substances Control Act (Zimbabwe)
MASCAR	Medicines and Allied Substances Control (General) Regulations (Zimbabwe)

MCAZ	Medicines Control Authority of Zimbabwe
MCC	Medicines Control Council (South Africa)
NAFDAC	National Agency for Food and Drug Administration and Control
NAPM	National Association of Pharmaceutical Manufacturers
NCE	New chemical entity
NEPAD	New Partnership for Africa's Development
NMRA	National medicines regulatory authorities
PAP	Pan-African Parliament
PIASA	Pharmaceutical Industry Association of South Africa
PIC/S	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme
PMPB	Pharmacy Medicines and Poisons Board (Malawi)
REC	Regional economic community
RISDP	Regional Indicative Strategic Development Plan
SADC	Southern African Development Community
SADCC	Southern African Development Coordination Conference
SAGMA	Southern African Generic Medicines Association
SMASA	Self Medication Association of South Africa
SRA	Stringent Regulatory Authority
SWOT	Strengths, weaknesses, opportunities and threats
TFDA	Tanzania Food and Drug Authority
US/ USA	United States of America
US$	Unites States Dollar
WHO	World Health Organisation
WHO-PQ	World Health Organisation Prequalification of Medicines Programme

FOREWORD

This Situation Analysis Report on Medicines Registration Harmonisation for the Southern African Development Community (SADC) has been prepared following rigorous scientific and participatory methods. Assessment instruments consisting of three separate structured questionnaires were administered at the levels of the African regional economic community (REC), regional/national associations of pharmaceutical manufacturers and national medicines regulatory authorities (NMRAs) to gather information from a representative cross-section of stakeholders. The data were analysed to reflect the status of medicines registration harmonisation. In addition, focus group discussions and key informant interviews were conducted in order to collect both qualitative and quantitative data.

The purpose of the situation analysis was to establish the status of medicines regulation capacity, harmonisation efforts and challenges in SADC and member states with a view to enhancing better understanding of the situation in the region, learning from past experience and developing appropriate interventions to facilitate African Medicines Regulatory Harmonisation (AMRH). The report has been prepared by the consultant with invaluable support received from SADC, heads of national medicines regulatory authorities, and pharmaceutical manufacturers and their associations. The report serves among other things as a baseline on the status of medicines regulatory harmonisation in the region, and focuses efforts towards responding to identified gaps, while capitalising on existing strengths.

SADC has identified the need to develop and implement a Pharmaceutical Programme in line with the SADC Health Protocol and the SADC Health Policy. The purpose of the programme is to enhance the capacities of member states to effectively prevent and treat diseases that are of major concern to public health in the region. Encouraging though this may be, the data reveal that there are discrepancies in capacity levels for medicines regulation among the countries of the region, presenting challenges to harmonisation efforts. For instance, the human capital resources, in terms of both skills and numbers, of the SADC Secretariat and in respective member states are limited; physical facilities vary between member states and require expansion to cater for the full functions of medicines regulation; and information and communication systems also vary among member states and are inadequate to facilitate the full harmonisation of medicines regulation systems. Furthermore, existing legislation does not legally or mutually recognise each member state's decisions or procedures for medicines registration.

This situation analysis report and the important data it provides will offer very relevant information to guide and support efforts to improve legal frameworks, information sharing, capacity building and the institutionalisation and fast-tracking of the harmonisation of medicines regulation in the SADC region.

ACKNOWLEDGEMENTS

The team would like to acknowledge with gratitude the invaluable support received from regional economic communities, heads of national medicines regulatory authorities, and pharmaceutical manufacturers and their associations. This substantial support facilitated the collection and verification of data for this report. We would also like to thank Professor Aggrey Ambali, Mrs Mercy Fomundam and several other staff members of the New Partnership for Africa's Development (NEPAD) Office of Science and Technology in Pretoria, South Africa for providing extensive logistical and technical advice on this work. Finally, we would like to thank Mr Massy Chiocha for data entry and clean-up, and Mrs Jane Makhambera for secretarial services. We thank them for their professionalism.

EXECUTIVE SUMMARY

The constant availability of affordable pharmaceuticals is an important aspect of any national health system. Providing quality, low-priced pharmaceuticals to the population is a complicated undertaking, ranging from the identification and selection of drugs to the procurement and quality assurance of medicines circulating on the market. Regional and national registration of medicines is one way to ensure the quality, safety and efficacy of the medicines provided to the population. However, the registration of medicines is cumbersome, requiring considerable information from applicants. As a result, it is sometimes difficult to get companies to comply fully with the registration process, as the cost may outweigh the benefits. Over the years, international organisations have been supporting African countries to establish and strengthen medicines regulatory authorities by providing the technical and financial resources needed for the African Medicines Regulatory Harmonisation (AMRH) initiative.

Cognisant of the importance of the AMRH initiative, the New Partnership for Africa's Development (NEPAD) commissioned a consultancy to conduct a situation analysis of medicines regulation harmonisation in the Southern African Development Community (SADC). The aim of the study was to establish the status of medicines regulation capacity, harmonisation efforts and challenges in SADC and member states with a view to enhancing better understanding of the situation in Africa, learning from past experience and developing appropriate interventions to facilitate the AMRH initiative. The collection of data involved:

a) the administration of three separate structured questionnaires to the regional economic community (REC), pharmaceutical manufacturers and national medicines regulatory authorities (NMRAs);

b) a review of documents from the REC and NMRAs, including reports of the World Health Organisation (WHO) on medicines regulatory harmonisation in Africa; and

c) discussions with key people from the REC and NMRAs. The data were analysed to realise the stated objectives.

The data presented in this report cover all the NMRAs and some pharmaceutical industries in SADC. The results show that SADC has provisions in its Treaty as well as the SADC Protocol on Health to cater for the harmonisation of medicines regulation. However, the laws do not legally or mutually recognise each member state's decisions or procedures for medicines registration. Generally, the decision-making process in SADC involves the Heads of State or Government of Member States, the Integrated Council of Ministers, ministers of health, permanent secretaries, technical subcommittees, national health ministries and stakeholders. The SADC Secretariat coordinates the activities of the health section through the senior programme officers for health and pharmaceuticals.

Although the mission of SADC is clear, some member states do not have well-articulated mission statements for their NMRAs. Moreover, some legislation is outdated, and some NMRAs do not have a national medicines policy or implementation strategies for their policies.

Most of the NMRAs are involved in regulatory functions such as the licensing of pharmaceutical manufacturers, importers and retailers; good manufacturing practice (GMP) inspections of pharmaceutical manufacturers and distribution channels; quality control; regulation of the distribution of generic medicines; control of prescribing; and coordination of medicines regulation. Some are also involved in controlling the pharmacy profession.

Most countries have explicit provision in their legislation for registering medicines. Countries such as Angola, Lesotho, the Seychelles, the Democratic Republic of Congo (DRC) and Swaziland do not actively register medicines. Registration may be waived under various conditions in some countries, including medicines for

clinical trials or medicines in the public interest, as well as medicines required to combat an epidemic, to mention just a few. Registration guidelines are available, and most cover generic medicines, new chemical entities (NCEs) and renewals. The Certificate of Pharmaceutical Product (CPP) is required for registration in most countries, while other countries require the registration of a product by a Stringent Regulatory Authority (SRA) before it can be considered for marketing authorisation. The legislation of some countries provides for the registration of other products such as vaccines, traditional medicines, pre-packaged food and medical devices. In some cases, information on fast-tracking registrations is made available to the public. The medicines concerned generally include those for treating HIV/AIDS, malaria and tuberculosis. The average registration times are six months for fast-tracked medicines and 24 months for normal registrations. The final registration decision is made by a board, director-general or technical registration committee, depending on the particular NMRA.

The information provided on financial and human resources was scanty, probably because record-keeping is not automated in most NMRAs. The sources of funding for NMRAs include government, donors and industry fees. It is worth noting that government financing is on the decline, while donor support and industry fees are increasing. Human resources are generally inadequate, and this situation is particularly acute in the Seychelles.

The pharmaceutical industry is more developed in South Africa than in other SADC member states, where the industry is generally weak. National associations exist in some countries, but only one regional association, the Southern African Generic Medicines Association (SAGMA), operates in SADC. The industry has a moderate to excellent sense of what is required to apply for registration. However, respondents considered some aspects of the registration process to be superfluous, such as the need to include the manufacturing route for the synthesis of the active pharmaceutical ingredient (API) during dossier submissions, and the payment of fees in US dollars. The bottlenecks in getting medicines registered include long registration time, unclear guidelines, weak feedback mechanisms, administrative delays and poor record-keeping. Nevertheless, the industry is very supportive of the African Medicines Regulatory Harmonisation (AMRH) initiative.

Sharing information with stakeholders is crucial to the success of the harmonisation process. Although websites do exist, they are generally not updated frequently. Furthermore, these websites have not been regionally networked. Information is shared through various methods, including television, radio and print media. Most NMRAs also share information when they participate in the various activities of the AMRH initiative.

The REC, NMRAs and the pharmaceutical industry are enthusiastic about, and committed to, the implementation of a harmonised medicines regulatory system. The key stakeholders and partners are aware of and recognise the benefits of drug harmonisation, namely:

a) Communities and patients will enjoy increased availability of safe, effective, quality medicines for neglected and priority diseases. There will be safer, higher-quality medicines circulating on the market in the long term.

b) Harmonisation will help to facilitate the availability of safe and effective essential medicines at affordable prices. In doing so, it will contribute to achieving the Millennium Development Goals related to health (goals 4, 5, 6 and 8).

c) NMRAs 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 medicines.

d) Pharmaceutical companies will benefit from simplified and standardised regulatory approval processes, which may translate into the simultaneous submission of dossiers for much-needed medicines in multiple countries, as well as improved evaluation turnaround times.

SADC faces several challenges, however, in taking the medicines regulation harmonisation agenda forward, the most important of which include:

a) The Seychelles does not have an NMRA and thus carries out medicines regulatory functions within the National Ministry of Health.

b) The human capital resources, in terms of both skills and numbers, of the SADC Secretariat and in respective member states are limited.

c) Physical facilities vary between member states and require expansion to cater for the full functions of medicines regulation.

d) There is a shortage of quality control laboratories in most NMRAs, and very few of them have been prequalified by the WHO.

e) Information and communication systems vary among the member states and are generally inadequate.

f) There is inadequate financial support, especially for small medicines regulatory authorities.

g) Regional decisions remain undomesticated by member states, and hence decisions made by individual members are rarely recognised by others.

In view of the above, the following recommendations are made:

Legal framework

SADC and its member states should consider the following:

a) Each NMRA should fast-track the enactment of policies and legislation that mutually recognise the persuasive role of regulatory decisions made by the NMRAs of other member states. These policies and legislation must be consistent with decisions made under the SADC Treaty and must be passed by the national assemblies of member states.

b) In implementing recommendation (a) above, the laws or statutes passed regarding the registration of medicines must provide for uniform or approximate procedures for approving medicines registration in member states. This would facilitate the decision of a member state to approve a medicine to take precedence over subsequent applications for similar medicines within the region.

c) The Seychelles should enact medicines legislation that clearly provides for medicines regulatory functions and establish a national body corporate for medicines regulation (an NMRA). This legislation should facilitate the platform for implementing medicines registration harmonisation in the region.

d) The SADC Secretariat should take the administrative lead in preparing a roadmap for the implementation of recommendations (a), (b) and (c), or alternatively and preferably, draft a protocol to compel each state's legislative machinery to domesticate its national laws timeously so that the decisions made by other member states are mutually recognised, implemented and/or regularised.

e) SADC should facilitate the development of a framework for mutual recognition based on the Treaty and ensure the implementation of functions for controlling pharmacy practice and moulding professional pharmacists, whether government employed or private (namely, those regulating the safety, quality and efficacy of medicines), in order to achieve the comprehensive control of medicines.

f) The lack of articulated mission statements for the national regulation of medicines in some countries should be rectified. NMRAs that do not have in place mission statements drawn from existing legislation and policies for regulating medicines should be encouraged to put mission statements in place to

set the broad direction for achieving the goal of making safe and quality medicines available. Such mission statements should emphasise the serious intent and commitment of governments to fulfilling the obligation of protecting the public.

g) The Seychelles should develop a national medicines policy that complies with WHO recommendations and provides uniform obligations to other SADC member states. The Seychelles should incorporate in the policy the obligation for harmonisation initiatives for medicines registration, as agreed under the Treaty. Since national medicines policies provide a broad outline of how the pharmaceutical sector is governed and managed in a country, there is need for the Seychelles to enact medicines legislation assigning a mandate and clear functions to an NMRA.

h) South Africa and Mozambique should develop implementation plans for their national medicines policies that, among other things, take into consideration the domestication of the ongoing harmonisation of medicines registration in the SADC region, as agreed under the Treaty.

Registration of medicines

SADC and its member states' NMRAs should:

a) tighten the conditions guiding waivers in the various NMRAs to avoid abuse;

b) encourage and reward countries that adhere to guidelines for the registration of medicines. The scope, frequency of revision of guidelines, and dissemination of such information using websites and government gazettes need special attention;

c) shorten registration times in all NMRAs to no more than 12 to 18 months for most medicines;

d) develop and implement a framework for the joint evaluation of dossiers for the registration of medicines;

e) develop and implement a framework for joint inspection of manufacturing sites for compliance with GMP requirements;

f) establish a comprehensive information management system for tracking and recording information, including financial data; such information will be important for reference, forecasting and decision-making; and

g) undertake pre- and post-marketing surveillance programmes.

Sharing of information and stakeholder consultation

SADC and its member states' NMRAs should:

a) develop and execute strategies for sensitising regional and national parliaments to the need to fast-track the domestication of decisions on medicines regulatory harmonisation;

b) strengthen the SADC Secretariat for improved coordination and networking;

c) develop and implement a clear roadmap for the harmonisation of medicines registration;

d) create awareness among all stakeholders of the benefits and value of harmonisation;

e) engage the SADC Integrated Council of Ministers to direct and concretise regional pharmaceutical policies;

f) implement a robust roadmap for engaging the pharmaceutical industry;

g) ensure that information-sharing options such as websites are kept as up to date as possible; and

h) encourage and support regional and national associations.

Capacity building

SADC and its member states' NMRAs should:

a) strengthen the capacity and capability of the NMRAs to enable them to fulfil their legal and regulatory functions. This requires implementing the following activities:

   i. utilising pooled regional capacity;

   ii. developing a regional human resource training programme;

   iii. fostering staff exchange programmes;

   iv. establishing regional centres of excellence for training and research; and

   v. introducing incentives for better staff retention in various NMRAs; and

b) mobilise adequate financial resources for regulatory functioning.

It is important for SADC and NMRAs to take this agenda forward. It is therefore strongly recommended that a medicines regulatory harmonisation strategy for SADC be developed and that this strategy includes outcomes, objectives, measurable indicators and a monitoring and evaluation (M&E) framework The REC and NMRAs should also agree on an effective M&E strategy for medicines registration harmonisation projects.

1. BACKGROUND TO THE STUDY

The constant availability of favourably priced pharmaceuticals is an important aspect of any national health system. Providing quality, low-priced pharmaceuticals to the population is a complicated undertaking, ranging from the identification and selection of drugs to the procurement and quality assurance of medicines circulating on the market.

The national registration of medicines is one way to assure the quality, safety and efficacy of medicines provided to the population. However, the registration of medicines can be cumbersome, requiring considerable information from applicants. As a result, it is sometimes difficult to get companies to comply fully with the registration process, as the cost may outweigh the benefits. In recognition of the challenges of medicines registration, the New Partnership for Africa's Development (NEPAD), the World Health Organisation (WHO), the Pan-African Parliament (PAP), the Bill and Melinda Gates Foundation (BMGF), the UK's Department for International Development (DFID) and the Clinton Foundation have formed a consortium, and together they have developed a strategic approach to mobilising technical and financial resources to advance the African Medicines Regulatory Harmonisation (AMRH) initiative. The overall objective of the AMRH initiative is to improve the health of the people in the region by improving the availability of safe, efficacious and good quality essential medicines for the treatment of neglected and priority diseases. This will be achieved through the harmonisation of medicines regulations and standards, starting with medicines registration, within and across African regional economic communities (RECs) and organisations.

As a means of building upon and strengthening plans that already exist in sub-regional groupings, the consortium has invited RECs to submit project proposals for medicines registration harmonisation. NEPAD and the members of the consortium are working with RECs to ensure complementarities in their efforts; enable continent-wide communication, coordination and technical consistency; and mobilise donor support.

Having a better understanding of ongoing efforts and related barriers to the harmonisation process is an essential ingredient for succeeding with harmonisation. In order for NEPAD, PAP and the WHO to effectively execute their strategic roles in supporting RECs to harmonise their medicines regulations, it is important that the existing information regarding the capacity for medicines regulation in RECs and their national medicines regulatory authorities (NMRAs) is updated to reflect the realities on the ground. For instance, according to the report presented by the WHO at the 1st African Medicines Regulatory Authorities Conference held in Addis Ababa, Ethiopia from 31 October to 3 November 2005, only about 7% of the 46 sub-Saharan African countries had moderately developed medicines regulatory capacity. Of the remaining countries, about 63% had minimal capacity, and 30% did not have an NMRA in place.

Over the years, the WHO and other international organisations and donor countries have been supporting African countries to establish and strengthen their NMRAs. Various assessments of medicines regulatory systems have been undertaken using the WHO Data Collection Tool for the Review of Drug Regulatory Systems. However, the information collected in these assessments needs to be updated to take into account various developments over the years and to collect legislative and institutional information that will support the advocacy role of the AMRH initiative. This information is also essential for establishing benchmarks that could be used to assess the efficiency and effectiveness of the harmonisation process.

The need for a situation analysis was reiterated during the 2nd African Medicines Regulatory Authorities Conference held in Maputo, Mozambique from 24–26 November 2009. The conference recommended among other things that NEPAD should develop a specific tool to obtain information on legislative and institutional frameworks that would assist with advocacy and coordination with respect to medicines regulation harmonisation on the continent.

Against this background, NEPAD commissioned a consultancy to conduct a situation analysis of medicines regulation harmonisation on the African continent. The aim of the assessment was to provide useful information for developing a strategy to support RECs in their ongoing medicines regulation harmonisation initiatives.

1.1 OBJECTIVES

The aim of the study was to establish the status of medicines regulation capacity, harmonisation efforts and challenges in RECs and member states with a view to enhancing better understanding of the situation in Africa, learning from past experience and developing appropriate interventions to facilitate the AMRH initiative.

The specific objectives were:

a) critical analysis of legislative and legal frameworks governing the harmonisation of medicines policies and regulations at national, sub-regional and regional levels with a focus on medicines registration harmonisation;

b) evaluation of the status of human capital and infrastructure needs and challenges;

c) evaluation of structures, systems and institutional frameworks as they relate to the harmonisation of medicines regulation at national, sub-regional and regional levels;

d) assessment of funding and financing mechanisms for national medicines agencies and their operations;

e) identification of challenges, barriers and constraints regarding the harmonisation of medicines policies and regulations and exploration of opportunities for effective harmonisation;

f) delineation of views, perceptions and needs for regulatory harmonisation; and

g) establishment of logical steps towards medicines regulation harmonisation in Africa.

1.2 METHODOLOGY

Assessment instruments consisting of three separate structured questionnaires were administered at the levels of the REC, regional/national associations of pharmaceutical manufacturers and NMRAs to gather information, which was analysed to reflect the situation of medicines registration harmonisation. In addition, checklists were used during focus group discussions, and key informant interviews were conducted in order to collect both qualitative and quantitative data.

The assessment instruments were piloted in the East African Community (EAC), taking into account a recent assessment of medicines regulatory capacities in the five partner states, which was conducted using the WHO Assessment Tool. During the second week of May 2010, the assessment team conducted discussions with the EAC Secretariat, industry and heads of NMRAs with a view of identifying gaps in the assessment instruments and gathering inputs from stakeholders. Input from the EAC pre-testing was used to review the assessment instrument with a view to replicating the exercise in the remaining RECs. The assessment team reviewed various documents, including the latest WHO reports on medicines regulatory harmonisation in Africa and other relevant papers, as an input in the assessment exercise.

Data were collected and analysed to realise these objectives. Where no assessment had been done using the WHO Assessment Tools, the assessment team followed these steps: conducted a thorough review of all laws, regulations, forms and instructions pertaining to drugs regulatory systems in all partner states/member states; collected new data; analysed processes and systems; evaluated institutional capacity; and provided a qualitative and quantitative assessment using the data collected. The team has made recommendations and proposed strategies to address the needs and gaps identified at both national and regional levels.

2. SOUTHERN AFRICAN DEVELOPMENT COMMUNITY

2.1 BACKGROUND

The Treaty of the Southern African Development Community (SADC), whose headquarters are in Gaborone, Botswana, was signed by the Heads of State and Government on 17 August 1992. SADC currently comprises 15 members states, with an estimated population of 267.58 million, occupying 9.9 million square kilometres. The current member states are Angola, Botswana, the Democratic Republic of Congo (DRC), Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, the Seychelles, South Africa, Swaziland, Tanzania, Zambia and Zimbabwe. SADC originated from the Southern African Development Coordination Conference (SADCC), which was formed on 1 April 1980. The demographic, social, health and economic data for the region are provided in Table 1. The DRC is the largest and most populous member state, while Mauritius is the smallest. Average life expectancy in the region is estimated at 53.5 years, ranging from 74.25 in Mauritius to 38.5 in Angola. Average infant mortality rates are estimated at 63.1 per 1000 live births, and average maternal mortality rates at 354.6 per 100,000. However, these figures vary widely between countries, with Angola performing poorly on both indices, as shown in Table 1. Overall, real GDP growth rates averaged 1%, but 40% of the countries are estimated to have registered negative growth rates in 2009. There are large variations in the economies of member states; for example, Mauritius and the Seychelles have a gross national product (GNP) per capita of over US$10,000, while Zimbabwe's GNP per capita is less than US$100. The data presented in Table 1 are estimates obtained from the US Central Intelligence Agency (CIA) website. The list of respondents to the assessment instruments is provided in Appendix 1.

At its inception, SADC aimed to coordinate development projects in order to lessen economic dependence on South Africa, which was then under the apartheid regime. Currently, the SADC Common Agenda is based on principles such as development orientation, subsidiary market interaction and development, facilitated by the promotion of trade and investment. The SADC Common Agenda includes:

a) the promotion of sustainable and equitable economic growth and socio-economic development that will ensure poverty alleviation, with the ultimate objective of poverty eradication;

b) the promotion of common values, systems and other shared values, transmitted through institutions that are democratic, legitimate and effective; and

c) the consolidation and maintenance of democracy, peace and security.

In pursuit of this agenda, SADC has adopted milestones to facilitate the attainment of the SADC free trade area by 2008, customs union by 2010, common market by 2015, monetary union by 2016 and single currency by 2018. The free trade area was launched in South Africa on 17 August 2008 during the 28th Summit of Heads of State and Government. In its programmes and operations, SADC is guided by a clear mission statement: "To promote sustainable and equitable economic growth and socio-economic development through efficient productive systems, deeper co-operation and integration, good governance, and durable peace and security, so that the region emerges as a competitive and effective player in international relations and the world economy."

It is worth noting that SADC's integration agenda accords priority to social and human development, including fostering cooperation in addressing health challenges, reflected in the high burden of both communicable diseases such as HIV/AIDS, tuberculosis and malaria, and non-communicable diseases such as diabetes, hypertension and cancer. In order to address these challenges, the region

has adopted a collective approach and identified health as one of the priority areas in its regional cooperation and integration agenda. To this end, a SADC Health Programme was developed in 1997. The region also prioritised the development of a Protocol on Health, as this was considered to be critical for enhancing regional integration within a legally enforceable framework. Three key policy documents have been developed to underpin the implementation of the Health Programme, namely: a) the Health Policy Framework, b) the SADC Protocol on Health and c) the Regional Indicative Strategic Development Plan (RISDP). The SADC Health Programme has been developed taking into account global and regional health declarations and targets. SADC has identified the need to develop and implement a Pharmaceutical Programme in line with the SADC Protocol on Health and SADC Health Policy. The purpose of the programme is to enhance the capacities of member states to effectively prevent and treat diseases that are of major concern to public health in the region. The programme mainly addresses issues that concern access to quality medicines in all member states. The SADC Pharmaceutical Business Plan has been developed within the context of global, continental and regional policy frameworks, protocols and commitments. Based on an analysis of strengths, weaknesses, opportunities and threats (SWOT analysis), the plan identifies priority areas, objectives and major activities that will be implemented both at regional and national levels to improve access to quality and affordable essential medicines, including African traditional medicines.

Table 1: Demographic, social, health and economic data for SADC

Country	Land area of country (million km^2)	Population (million)	Life expectancy (years)	Infant mortality rate per 1000 live births	Maternal mortality rate per 100,000	Real GDP growth rates (%)	Gross national product (GNP billion US$)	Gross national product per capita (GNP million US$)
Angola	1.25	13.07	38.5	178.13	1400	-0.6	114.4	8900
Botswana	0.58	2.03	60.93	11.79	NA	-5.2	26	13,100
Democratic Republic of Congo	2.34	70.9	54.8	79.4	NA	2.7	21.3	300
Lesotho	0.03	1.9	50.67	56.42	762	-2	3.273	1700
Madagascar	0.59	21.3	63.29	52.84	NA	0.4	20.5	1000
Malawi	0.12	15.5	50.93	83.5	801	5.9	12.81	900
Mauritius	0.002	1.3	74.25	11.85	NA	2.1	15.9	12400
Mozambique	0.80	22.1	41.37	103.82	NA	4.3	20.17	900
Namibia	0.82	2.1	51.95	45.52	449	0.7	13.58	6400
South Africa	1.22	49.32	55.25	46	150	-1.8	495.1	10100
Seychelles	0.0046	0.88	73.35	11.97	NA	-8.7	1.682	19400
Swaziland	0.02	1.4	47.97	66.71	589	-0.4	5.882	4400
Tanzania	0.95	41.9	52.51	68.13	577	4.9	57.89	1400
Zambia	0.75	12.05	38.86	99.92	591	8.5	18.5	1500
Zimbabwe	0.39	11.7	47.55	30.9	NA	3.7	0.332	<100
Average	0.7	17.8	53.5	63.1	354.6	1.0	55.2	5493.3

NA: data not available

Source: Estimates obtained from CIA website (except for maternal mortality data, which were provided by NMRAs)

The overall goal of the SADC Pharmaceutical Business Plan is to ensure the availability of essential medicines, including African traditional medicines, in order to reduce the disease burden in the region. Its main objective is to improve sustainable availability and access to affordable, quality,

safe, efficacious essential medicines, including African traditional medicines. In order to achieve the overall goal and the main objective, the business plan specifies the following strategies to be pursued:

a) harmonise standard treatment guidelines and lists of essential medicines;

b) rationalise and maximise the research and production capacity of the local and regional pharmaceutical industry for generic essential medicines and African traditional medicines;

c) strengthen regulatory capacity, as well as the supply and distribution of basic pharmaceutical products, by ensuring a fully functional regulatory authority with adequate enforcement infrastructure;

d) promote joint procurement of therapeutically beneficial medicines of acceptable safety, proven efficacy and quality, at affordable prices, for the people who need them most;

e) establish a regional databank of traditional medicines, medicinal plants and procedures in order to ensure their protection in accordance with regimes and related intellectual property rights governing genetic resources, plant varieties and biotechnology;

f) develop and retain competent human resources for the pharmaceutical programme;

g) develop mechanisms to respond to emergency pharmaceutical needs of the region; and

h) facilitate trade in pharmaceuticals within SADC.

In line with the SADC Protocol on Health, the Implementation Plan for the Protocol and the SADC Health Policy Framework, the SADC Pharmaceutical Business Plan will be coordinated and implemented through the approved SADC structure. The business plan defines clear roles and responsibilities for all the stakeholders that will be involved in the implementation process. At the political level, the implementation of the business plan will be monitored through the established institutional framework. The implementation of the business plan will require substantial resources, including human, material and financial resources, from different sources. The estimated cost of implementing the business plan is US$16 million. To ensure ownership and sustainability, member states will be required to budget for the implementation of some of the interventions that need ongoing financial support. The SADC Secretariat will make efforts to mobilise resources from key stakeholders, including international cooperating partners. A monitoring and evaluation framework has been included in order to review activities during the implementation process. The Secretariat will facilitate capacity building for monitoring and evaluation. Appropriate technical and financial reports will be produced during and after the implementation of programme-specific activities outlined in the business plan.

2.2 OVERVIEW OF LEGAL ISSUES AFFECTING MEDICINES REGULATION

2.2.1 National medicines policies (NMP)

With the exception of the Seychelles, which has no policy, it has been found that the medicines regulatory framework that is reflected in various laws in SADC countries is backed by national medicines policies. These policies are in line with the recommendations of the WHO, and hence the components of those policies fall within the medicines policy framework that is similar in all member states. These components include provisions for the safety, quality and efficacy of medicines. With the exception of South Africa and Mozambique, the countries have policy implementation plans in place. The second common element of all the national medicines policies is that they vest the obligation to regulate medicines with governments.

2.2.2 Legislation, regulation and mission

One of the most significant determinants of safe, quality and efficacious medicines within the regulatory legal framework is the existence of legislation, regulations and policies that aim to ensure comprehensive control of medicines. This section intends to identify the status quo of the current medicines regulatory framework in each country in the SADC region. The ultimate goal is to link the countries' legal frameworks to the regional harmonisation initiatives for the control of medicines in order for the region to have access to safe, quality and efficacious medicines.

This study has established that medicines in each of the 15 SADC member states are controlled under various pieces of legislation passed by the member states' national legislative assemblies. The legislation is territorial, in that it can only bind obligations with the relevant country. The legislation in any one country is neither uniformly applicable between countries, nor does it take precedence over any prior decision regarding the regulation of medicines within other member states.

Within the SADC Treaty, however, provisions exist that may pave the way for regional harmonisation of the laws that regulate medicines. For example, according to Article 2 of the Treaty, SADC derived its legitimacy of existence when it was established by member states represented by their respective Heads of States and Government, or duly authorised representatives, to spearhead the economic integration of Southern Africa on 17 August 1992 in Windhoek, Namibia when the Declaration and Treaty were signed. Among the objectives of Article 5 of the SADC Treaty is to promote the interdependence of member states. In order to achieve this objective, Articles 21 and 22 of the SADC Treaty provide for areas of cooperation that become operational through concluding a protocol. In order to achieve this objective, SADC member states have in place under the Treaty a Protocol on Health that includes the harmonisation of the regulation of medicines in the region, which was strongly supported by the SADC Health Ministers' Declaration of 1999. Articles 3(h) and 29 of the Protocol on Health support the harmonisation of medicines registration, committing member states to progressively achieve equivalence harmonisation and standardisation in the provision of health services in the region.

Article 29 of the Protocol on Pharmaceuticals, in particular, states categorically: "Parties shall co-operate and assist one another in the:

a) harmonisation of procedures of pharmaceuticals, quality assurance and registration;

b) production, procurement and distribution of affordable essential drugs;

c) development and strengthening of an Essential Drugs Programme and the promotion of the rational use of drugs;

d) development of mechanisms for quality assurance in the supply and conveyance of vaccines, blood and blood products;

e) research and documentation on traditional medicine and its utilisation; and

f) establishment of a regional databank of traditional medicine, medicinal plants and procedures in order to ensure their protection in accordance with regimes and related intellectual property rights governing genetic resources, plant varieties and biotechnology."

There are also key policy documents such as the SADC Health Policy Framework, the SADC Trade Protocol, national medicines policies for each member state, as well as medicines legislation and regulations. All these confirm the existence of an enabling environment, in terms of both political will and legal framework, to ensure that medicines regulation laws are harmonised.

Like many other international treaties, the Treaty of the Southern African Development Community, which established SADC, is non-self-executing and requires implementing legislation, namely, amendments to the domestic legislation of a member state that will direct or enable it to fulfil

its treaty obligations. Most such treaties make provision for a penalty on a defaulting party that fails to fulfil an obligation under the Treaty. However, a member state that does not, or that delays in domesticating the obligations, may not be penalised. The challenges to the domestication of legislation are the varying degrees of determination and commitment of member states. This has rendered most of the obligations agreed at regional level either impossible to implement, or delayed and implemented at different times by member states. Even if treaties do provide sanctions on a defaulting party, imposing sanctions on defaulting member states for non-compliance regarding harmonisation initiatives is a complex and difficult matter, since sanctions can only be imposed once the obligations under the Treaty have been endorsed by the country. The obligation to enact national implementing statutes to bind SADC countries to fulfil their agreements in terms of the Treaty is indeed primary and requires a roadmap by the SADC Secretariat. This roadmap should guide member states to fast-track amendments to national legislation so as to implement timeous harmonised medicines registration. Another legal option would be to draft a protocol under the Treaty with a view to compelling member states to amend their domestic legislation within specific timeframes and provide guidance to counter all impediments that could hinder or delay the implementation of national laws regarding the harmonisation of medicines registration, or making the respective laws equivalent by minimising their differences.

The study has identified several pieces of legislation related to the control and regulation of medicines by each member state. Excluding international conventions that are equally binding on all signatory member states that ratified them, the common shortfall of all the various pieces of national legislation is that they are neither uniformly applicable to other member states, nor do they take precedence over any obligation to bind or be used as a reference for the approval of the registration of medicines already circulating within some SADC member states. This legal framework runs contrary to the purpose of facilitating the availability of safe, quality and efficacious medicines within the region. That being the case, it is indeed paramount for the region to embark on harmonising the legal framework so that the circulation of medicines within the region is applied uniformly, and so that nations will recognise decisions made in any member state without compromising their own safety and quality standards or diminishing state sovereignty. The various laws and regulations that are used to regulate medicines in SADC member states are listed in Table 2.

Table 2: List of legislation and regulations for regulating medicines in SADC member states

Country	Description/Title and year of enactment
South Africa	Medicines and Related Substances Control Act 101 of 1965 (1966) Pharmacy Act 53 of 1974 as amended (1975) Nursing Act 33 of 2005 (2006) Health Professions Act 56 of 1974 as amended (1975) Single Convention on Narcotic Drugs 1961 (1968) Convention on Psychotropic Substances 1971 (1972) United Nations Convention against Illicit Trafficking in Narcotic and Psychotropic Substances (1988) Pharmaceutical Inspection Cooperation Scheme (2007)
Zimbabwe	Medicines and Allied Substances Control Act (MASCA) Medicines and Allied Substances Control (General) Regulations (MASCAR) (1991) Dangerous Drugs Act (DDA) Dangerous Drugs Regulations

Country	Description/Title and year of enactment
DRC	Administrative Order on the Regulation of Pharmaceutical Sector of DRC (18/03/2000) Decree of 19 March 1952 concerning generics (19/03/1952) Pharmacy activities (Ordinance no. 27) (15/03/1933) Ordinance no. 91-018 Creating the Association Of Pharmacists (30/03/1991) Pharmaceutical Policy (December 2008) Registration and Market Sales Authorisation of Medicines (09/12/2001) Administrative order no. 1250/cab/mins/AZ/MS013/2001 National List of Medicines (November 2007) Decree Regulating the Pharmaceutical Sector Decree on the Granting of Marketing Authorisation National Pharmaceutical Policies
Zambia	Pharmaceutical Act No. 14 (2004) Dangerous Drug Act Health Professional Act (31/08/2009)
Malawi	Pharmacy Act (1988) Pharmacy Regulations (1998) Strategic Plan 2006–2011 Dangerous Drug Act (1956)
Madagascar	Decree establishing the Agency of Medicines of Madagascar (27/01/1998) Order on Pricing (17/12/2004) Order concerning the distribution of pharmaceuticals (15/03/2010) Decree on the establishment of medical stores (17/01/2006) Decree on the Substitution of Medicines (12/01/2007) Decree on Medicines Advertising (05/11/2009) Decree on Medical Devices (20/07/2001) Decree on Medicines Containing Mercury (19/06/2000)
Seychelles	Pharmacy Act (1996)
Namibia	Medicines and Related Substances Control Act, 13 of 2003 (25/07/2009) Medicines and Related Substances Control Amendment Act, 7 of 2008 (1/08/2009) Regulations to the Medicines Act (25/07/2009) Single Convention on Narcotic Drugs, 1961
Swaziland	Convention on Psychotropic Substances (1971) Pharmacy Act, updated to Medicines and Related Substance Bill (2009. 1929) WHO Certificate scheme, 1995 UN Convention on Narcotics, 1961 UN Convention on Psychotropic Substances, 1971 UN Convention against Illicit Traffic in Narcotic Drug and Psychotropic Substances, 1988
Angola	(in Portuguese to be translated into English)
Lesotho	Drugs of Abuse Act (3/2008)
Tanzania	Tanzania Food, Drugs and Cosmetics Act, 2003 Client Service Charter, 2005 Tradition and Alternative Medicines Act, 2002
Botswana	Drug and Related Substances Act, 1992 Drug and Related Substances Act Regulations, 1993
Mozambique	Law 4/98 – Medicines Law (14/01/1998) Decree 21/99 – Regulament of the exercise of the pharmaceutical profession (04/05/1999) Decree 22/99 – Regulament for the registration of medicines (04/05/1999) Law 3/97 – Narcotic and Psychotropic Substances (13/03/1997) Pharmacy Act, 1983

Country	Description/Title and year of enactment
Mauritius	Single Convention on Psychotropic Substances, 1971 Pharmacy Regulations, 1985 Dangerous Drugs Act, 2000 Illicit Traffic Against Narcotics and Psychotropic, 1988 Substances Convention, 1988

2.2.3 Comprehensiveness of legislation

This study has identified in each country the scope of the components that are regulated in order to determine whether the laws for regulating medicines provide for comprehensive control of all the key components of the medicines regulatory framework. It is important for the legislation to be able to cater for new ground and address practices that may compromise public health relating to licensing manufacturers, importers, wholesalers, distributors and retailers, and various dispensing outlets.

The key components that are regulated include marketing authorisation (registration of medicines), inspection of manufacturing premises, establishment of quality control laboratories, and control of clinical trials. These laws provide for the control of counterfeit medicines, import and export, safety monitoring of medicines, and control of promotion and advertisement. Some of the laws control other products that are not medicines, such as narcotics and psychotropic substances, as well as controlling medicines distribution schedules. Where necessary, there is provision for ministerial sanctions and powers to make regulations. Table 3 shows countries whose laws do not provide for some of the key regulatory functions.

Table 3: Comprehensiveness of legislation with respect to key regulatory functions

Key regulatory function/provision		Countries whose legislation does not provide for the key regulatory function/provision	Comments
Establishment of a body responsible for medicines regulation		Seychelles, Botswana	At present, this is the responsibility of Pharmaceutical Services, where a Medicines Regulation Unit has been established to ensure adherence to pharmacy legislation. (the Seychelles is currently revising its Pharmacy Act.)
Licensing of:			
1.	Manufacturers	None	
2.	Importers	None	
3.	Wholesalers	None	
4.	Distributors	None	
5.	Retailers/dispensing outlets	None	
6.	Other product licensing	Zambia, Malawi, Seychelles	
7.	Market authorisation/registration of medicines	Seychelles	
8.	Inspection of premises and manufacturing sites	None	
9.	Establishment of quality control laboratory	Malawi, Seychelles, Angola, Namibia and Botswana	
10.	Control of clinical trials	Seychelles, Namibia	

Key regulatory function/provision		Countries whose legislation does not provide for the key regulatory function/provision	Comments
11.	Control of counterfeit medicines	Botswana, Malawi, Seychelles	
12.	Control of imports and exports	DRC, Malawi, Seychelles	
13.	Safety monitoring of products	DRC, Malawi, Tanzania, Seychelles	
14.	Control of product promotion and advertisement	Madagascar and Seychelles	
15.	Control of other products	Botswana, Zambia, Malawi, Seychelles	
16.	Provision for medicines distribution schedules/ categories	Zambia	
17.	Control of narcotics and psychotropic substances	None	
18.	Administrative and legal sanctions (e.g. suspension or revocation of licences or fines/ imprisonment)	None	
19.	Authority to make regulations	Seychelles	

2.2.4 Mission and functions of the National Medicines Regulatory Authorities

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

While the mission of the SADC Pharmaceutical Business Plan is clear, mission statements for the regulation of medicines in nine of the SADC member states are not clearly established.

Four SADC countries (DRC, Malawi, Madagascar and Tanzania) have well-articulated mission statements on the control and regulation of medicines:

a) Malawi's mission hinges on promoting and improving the health of Malawians.

b) Madagascar has mandatory registration of medicines, pharmaceutical market surveillance, and measures to grant marketing authorisation and ensure the quality of the medicines available on the market.

c) Tanzania protects and promotes public health by ensuring the quality and safety of food, drugs, cosmetics and medical devices.

d) The DRC has decrees in place regulating the pharmaceutical sector and granting marketing authorisation in addition to national pharmaceutical policies.

The lack of clearly articulated mission statements for national regulation in the nine countries is indeed a curable pitfall. NMRAs that do not have in place mission statements drawn from existing legislation and policies that regulate medicines should be encouraged to develop such mission statements. Such an undertaking would emphasise the serious intent and commitment of governments to fulfilling their obligations to protect the public. The absence of mission statements for national medicines regulation should not compromise the role of governments to regulate medicines. The need to draw up mission statements as soon as possible should not be underestimated.

2.2.5 Decision-making process of SADC

The SADC Protocol on Health is implemented within the approved institutional framework under Article 4 of the Protocol. The SADC Committee of Ministers of Health (constituted as a subcommittee of the Integrated Council of Ministers, to which it reports) proposes, reviews and approves implementation plans for adoption by the Integrated Council of Ministers and monitors the implementation of the Protocol. All meetings of the Committee of Ministers of Health are preceded and supported by a meeting of senior officials, preferably at the level of at least permanent secretaries or directors-general of health services. These officials report to the Ministers of Health.

2.2.5.1 Technical subcommittees

Technical subcommittees or task teams are sanctioned by the SADC Committee of Ministers of Health as and when required. They have clear terms of reference for the tasks to be undertaken, and the duration of their assignment is stipulated. Technical subcommittees are required to assist with developing detailed programmes and project plans and monitoring their implementation. They report to the Committee of Ministers of Health through senior officials.

2.2.5.2 Directorate of Social and Human Development and Special Programmes

The Directorate of Social and Human Development and Special Programmes is responsible for overseeing SADC's response to social and human developmental issues. The Health Unit within the directorate coordinates the implementation of the Protocol on Health. The functions of the Health Unit include: a) developing annual plans; b) organising technical subcommittee meetings; c) drafting terms of reference for consultancies and studies; d) disseminating information to all stakeholders on the implementation of the Protocol; e) compiling reports to the Integrated Council of Ministers on progress made in implementing the Protocol; and f) mobilising technical and financial resources.

The Health Unit is headed by the Senior Programme Officer for Health and Pharmaceuticals, who reports to the Director of Social and Human Development and Special Programmes. The Director reports to the Executive Secretary through the Deputy Secretary-General. The Senior Programme Officer for Health and Pharmaceuticals and the Director also service the meetings of the Committee of Ministers of Health and implement their decisions. The institutional framework for the management and coordination of medicines regulation in SADC and in the Malawian Pharmacy Medicines and Poisons Board (PMPB) are provided Appendix 2.

2.2.5.3 National health ministries

National health ministries in the member states support the implementation of the SADC Protocol on Health through timely responses to requests by the SADC Health Unit. They lead the implementation of programmes at national level and support the process by assigning resources, including human resources when appropriate. The national health ministries report progress in implementing the Protocol through their SADC National Committees.

2.2.5.4 Stakeholders

All stakeholders (including research institutions, teaching/training institutions, non-governmental organisations and community-based organisations, professional councils and associations, regulatory authorities, communities and international cooperating partners) are essential for the successful implementation of the various provisions of the Protocol on Health. Their role is to identify areas of cooperation that require their expertise and competency and to assist with implementation.

Stakeholders may offer advice, technical assistance, coordination in a specialist area, and material and/or financial resources. To facilitate the timely engagement of reputable technical experts, the Secretariat uses stakeholders to establish a network of approved technical experts.

2.2.6 Organisation and management of regulatory functions

Since national medicines policies provide for the obligation to regulate medicines to be vested in the government, the regulatory functions are executed by National Medicines Regulatory Authorities (NMRAs) that are established through legislation to discharge day-to-day duties in terms of the government's obligations. In countries where such agencies have not been established, the functions are executed by departments or ministries responsible for health.

Fourteen of the 15 countries license the pharmaceutical wholesale trade and medicine-dispensing outlets. Twelve countries carry out medicines assessment (evaluation and registration/marketing authorisation) as well as inspections for good manufacturing practice (GMP). Thirteen countries inspect distribution channels, carry out medicines quality tests and operate quality control laboratories. The regulation of generic substitution and control of prescriptions is done by ten of the countries, while nine countries coordinate medicines regulation centrally at national level. Table 4 summarises the specific functions that each member state carries out. The names of the authorities responsible for each function are listed in Appendix 3.

Table 4: Summary of functions executed by NMRAs in SADC member states

Function	Country													
	ANG	BOT	DRC	MDG	MW	MAU	MOZ	NB	RSA	SCY	SW	TZ	ZA	ZIM
Licensing of pharmaceutical manufacturers	✓	✓	✓	✗	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓
Licensing of pharmaceutical imports	✓	✓	✓	✓	✓	✗	✓	✓	✓	✗	✓	✓	✓	✓
Licensing of pharmaceutical wholesale trade	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Licensing of medicine retail/ dispensing outlets	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Product assessment and registration/ marketing authorisation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✓	✓	✓
Good manufacturing practice (GMP) inspection	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✓	✓	✓
Inspection of distribution channels	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓
Performing medicine quality tests/ quality control laboratory	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓
Regulating generic substitution	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗	✗	✓	✓
Control prescribing	✗	✓	✗	✓	✓	✓	✓	✓	✗	✓	✗	✗	✓	✓
Coordination of medicines regulation centrally at national level	✗	✓	✗	✓	✓	✓	✓	✓	✓	✗	✗	✗	✓	✓

Note: In countries where an NMRA not been established, the functions are executed by department or ministry responsible for health

ANG=Angola; BOT=Botswana; DRC=Democratic Republic of Congo; LE=Lesotho; MDG=Madagascar; MW=Malawi; MAU=Mauritius; MOZ=Mozambique; NB=Namibia; RSA=South Africa; SCY=Seychelles; SW=Swaziland; TZ=Tanzania; ZA=Zambia; ZIM=Zimbabwe

To create a better and more conducive environment for the harmonisation of regulatory functions, it is recommended that all NMRAs within the SADC region should execute similar basic/primary functions. Governments are encouraged to establish NMRAs in each of the 15 SADC countries with more or less similar basic/primary functions. This would establish a standardised platform for implementing obligations under the Treaty in domestic legislation.

Angola, Malawi, Mozambique, Namibia, Tanzania and Zimbabwe have organisational structures that chart the medicines regulatory system in the country from central to local government, while South Africa, the Seychelles, Botswana, Swaziland and the DRC do not. The regulatory systems of Angola, Malawi, Mozambique, Mauritius, Namibia, Swaziland, South Africa, Zambia, Zimbabwe and Tanzania use various external experts/committees for advice. The use of different external experts makes the process of harmonisation more difficult, as they may have different approaches to it. While the functions of such external expert committees are advisory and their life span is limited, as determined by the respective NMRA, their impacts on the harmonisation process have to be carefully considered.

The functions of the expert groups include, but are not limited to: a) assessment and registration, b) legal advice, c) monitoring of safety and efficacy of biological medicines, d) quality control, e) risk assessment and determination, f) approval and monitoring of clinical trials, g) development of assessment guidelines, h) training of professionals involved in fields of registration, licensing of medicines and pharmacovigilance, i) harmonisation of registration procedures and j) licensing of products.

Terms of reference for expert committees are available in most countries with the exception of the DRC. Written procedures are available in South Africa, Zimbabwe, Zambia and Tanzania, while codes of conduct are available only in Zimbabwe, Zambia and Tanzania.

2.2.7 Recommendations

The obligation to enact national implementing statutes to bind SADC countries to fulfil what was agreed under the Treaty may require the SADC Secretariat to develop a roadmap to be adopted by the Integrated Council of Ministers. Such a roadmap would guide partner states to fast-track amendments to national legislation for the timely harmonisation of medicines registration.

It is therefore recommended that:

a) There should be an option to draft a protocol under the Treaty with a view to compelling the partner states to amend domestic legislation within a specified time. Guidance should be provided in overcoming challenges that could hinder or delay the domestication of national laws regarding the harmonisation of medicines registration so as to attain the regional goal of accessing safe, quality and efficacious medicines.

b) The REC should embark on harmonising the legal framework so that the circulation of medicines within the region is applied uniformly. To facilitate this, the laws should be amended so that the decisions of member states are recognised by others without compromising the safety and quality of medicines or diminishing state sovereignty.

c) The nine member states whose NMRAs do not have a mission statement on the national regulation of medicines should be encouraged to draw up such mission statements to set the broad direction for the goal of facilitating the availability of safe and quality medicines. This would emphasise the commitment of governments to fulfil the obligation of protecting the public.

d) The Seychelles should be encouraged to develop a national medicines policy. The policy should be compliant with WHO recommendations so as to provide uniform obligations to other

SADC member states. During the implementation of this recommendation, the Seychelles may be privileged to incorporate in the policy the entire obligation for harmonisation initiatives of medicines as agreed under the Treaty.

e) South Africa and Mozambique should develop an implementation plan for their national medicines policies that, among other things, takes into consideration the domestication of the ongoing harmonisation of the registration of medicines in the SADC region as agreed under the Treaty.

f) A better and more conducive environment for the harmonisation of regulatory functions should be created, so that all NMRAs within the SADC region strive to execute key regulatory functions. The governments of all 15 SADC member states should establish operational NMRAs with more or less similar functions in order to implement obligations under the Treaty in a standardised manner through their domestic legislation.

2.3 MEDICINE REGULATORY HARMONISATION AND REGISTRATION SYSTEMS

This section deals with the following aspects of harmonisation: legal and regulatory requirements, guidelines for the registration of medicines, registration times and processes, assessment of applications for pharmaceutical products, factory inspections and testing of medicine samples for registration.

2.3.1 Legal and regulatory requirements

Data from the respondent countries regarding the legal and regulatory requirements for the harmonisation process were reviewed and analysed.

The survey revealed that only ten countries (Zimbabwe, Zambia, Namibia, Swaziland, South Africa, Angola, Malawi, Mozambique, Mauritius and Tanzania) have explicit legislative provisions for the legal mandates of NMRAs to register medicines. The Seychelles and Botswana do not have such provisions, while the other three countries did not respond in this regard. Ten of the 15 countries (South Africa, Zimbabwe, Zambia, Namibia, Madagascar, Botswana, Mozambique, Mauritius, Angola and Tanzania) reported that they actively register medicines, and that this process covers the procurement and distribution of products in both the private and public sectors. The remaining countries (Lesotho, Malawi, Seychelles, DRC and Swaziland) do not have an active registration process in place.

According to the survey responses, provisions for waivers in the registration process exist in 11 of the countries, while Lesotho, Namibia and the Seychelles did not respond to this question. The reasons for waivers vary from country to country. In South Africa, waivers are subject to the issuing of a permit by the Medicines Control Council (MCC) based on a request by a medical practitioner. In the DRC, waivers are granted in the event of a disaster or epidemic, while Angola has similar conditions to the DRC but includes the possibility of waivers for orphan drugs. In Tanzania and Botswana, a waiver will be considered for importation if there is no registered alternative that is therapeutically equivalent, or there is an inadequate supply of the registered medicine, especially in the case of orphan drugs such as anti-cancer drugs. In Zimbabwe, the granting of waivers may arise when manufacturers deem that it is not viable to manufacture the drug in the country. In such cases, practitioners can apply for a waiver. Authorisation may also be granted in cases of national disaster or where a medicine is deemed a priority. In Malawi, if a drug is deemed to be in the public interest, or if it is a vaccine intended for combatting an epidemic, a waiver can be granted. In Zambia, products that are not licensed with the authority and that are imported for personal use, products

that are donated, as well as unlicensed products meant for disease outbreaks or pandemics, can be considered for a waiver. Madagascar will consider a waiver for medicines of public utility in health (for example, anti-HIV, anti-cancer, anti-tuberculosis and anti-malarial products). Medicines for clinical trials, special importation use and those of public health interest can receive a waiver in Mozambique.

2.3.2 Guidelines for registration of medicines

The relevant guidelines and reference standards for the registration of medicines in SADC were reviewed and analysed.

Twelve countries (Zimbabwe, DRC, Zambia, Malawi, Namibia, Madagascar, South Africa, Botswana, Angola, Tanzania, Mozambique and Mauritius) have guidelines for the registration of medicines, while the Seychelles and Swaziland do not have guidelines. The reference guides used for the reviews are WHO (used by the DRC and Tanzania), WHO-PQ and ICH (used by Zambia, Mozambique and Tanzania) and SADC registration guidelines and WHO guidelines (used by Zimbabwe), while Namibia uses its own guideline. The reference guide for South Africa is from the relevant NMRA.

The relevant guidelines and reference standards are shown in Table 5.

Table 5: Guidelines for the registration of medicines

Country	Name of guideline	Reference standard
Botswana	Guideline for Variations Guideline for Registration of Medicines 2009 Guideline for Bioequivalence and Bioavailability Guideline for Stability Testing Guideline for Validation	WHO-PQ
DRC	Standard Operational Procedures (9/2009)	WHO
Madagascar	Manual of Registration Procedures	WHO
Malawi	Guide to Registration, Licensing and Scheduling of Medicinal Products of Malawi	Own guidelines
Namibia	Guidelines of Registration of Medicines (2008)	Own guidelines
Tanzania	Guidelines of Registration of Medicines (2008)	WHO, WHO-PQ, ICH
Zambia	Guidelines on the Submission of Veterinary Products Guidelines on the Submission of Medicinal Products for Human Use Guidelines for the Submission of Herbal Medicines Guidelines for the Submission of Biological Products Guidelines on the Advertising of Medicinal Products	WHO-PQ, ICH, SADC
Zimbabwe	Draft MCAZ guidelines on the Submission of Documentation for Registration of Multi-Source (Generic) Finished Pharmaceutical Products (FPPs) (1998)	SADC
Mozambique	Manual of Procedures for the Registration of Medicines	WHO-PQ, ICH
Mauritius	WHO-PQ, SADC Guidelines	WHO SADC
South Africa		Relevant NMRA
Angola		

The scope of the guidelines covers generics in Namibia, South Africa, Malawi and Tanzania; new chemical entities (NCEs) in Namibia, Malawi and Tanzania; and renewals only in Tanzania. In Mozambique, the scope covers procedures for medicines registration, variation and renewal of registered medicines. The frequencies of reviews also vary from country to country. Namibia had not

yet reviewed its guidelines (as at the date of submission), while the DRC reviews its guidelines every two years. South Africa reviews its guidelines as required, while Tanzania and Zambia have yet to determine the frequency of reviews (Table 6).

Table 6: Scope and frequency of revision of guidelines

Country	Scope of guideline	Frequency of revision
Namibia	NCEs Generics	Not yet reviewed
Malawi	NCEs	Waiting
Mozambique	Procedures for medicines registration , variation and renewal of registered medicines	Waiting
DRC	WHO	2 years
Zambia	WHO-PQ, ICH	Not yet determined
South Africa	Generics	As required
Tanzania	WHO	Not defined

2.3.3 Registration times and processes

This section deals with the process leading to the registration of a product and the turnaround time for registration to be undertaken. The details of the requirements for marketing authorisation are considered, which is an essential aspect of medicines registration.

2.3.3.1 Requirements for registration and marketing authorisation

Marketing authorisation involves the assessment of scientific information submitted by applicants, including GMP inspection of manufacturing sites for the pharmaceutical product. Applicants are required to submit pharmaceutical information, clinical and non-clinical data so that the quality, safety and efficacy of a pharmaceutical product can be ascertained. Depending on the information submitted and the capacity of the particular NMRA, additional reference information, such as the Certificate of Pharmaceutical Product (CPP) or reference data from a Stringent Regulatory Authority (SRA), may be requested by the assessing NMRA.

A CPP is required for registration in 11 countries (Botswana, Angola, Zimbabwe, DRC, Mozambique, Mauritius, Zambia, Malawi, Madagascar, South Africa and Tanzania), while none is required in Namibia. For those countries that require a CPP, it must be submitted at the time of dossier submission, apart from in Zambia where the time was not stated (Table 7).

Table 7: Requirements and times for registration and marketing authorisation of medicines

Country	Reference document used for assessment	Timing	Type of products
Zimbabwe	CPP	At dossier submission	All medicines/products
DRC	CPP	At dossiersubmission	All medicines/products
Zambia	CPP	-	All medicines/products
Malawi	CPP	At dossier submission	All medicines/products
Madagascar	CPP	At dossier submission	All medicines/products
Tanzania	CPP	At dossier submission	-

Country	Reference document used for assessment	Timing	Type of products
Botswana	CPP	At dossier submission	All medicines/products
Angola	CPP	At dossier submission	All medicines/products
Mozambique	CPP	At dossier submission	All medicines/ products
Mauritius	CPP	At dossier submission	All medicines/ products
South Africa	CPP	At dossier submission	All medicines/products
Namibia	No CPP	-	-

Stringent Regulatory Authority (SRA) approval is required for marketing authorisation in all the 12 countries reviewed. In addition to an SRA reference, WHO-PQ is also required in nine countries (Angola, Botswana, Zimbabwe, Namibia, Zambia, Madagascar, Mauritius, Tanzania and DRC). In the other three countries (South Africa, Mozambique and Malawi), only SRA approval is required (Table 8).

Table 8: Countries requiring an SRA reference as the basis for marketing authorisation

Country	Reference requirement
Angola	WHO-PQ, SRA
Botswana	WHO-PQ, SRA
Zimbabwe	SRA, WHO-PQ
Namibia	WHO-PQ, SRA
Zambia	SRA, WHO-PQ
Madagascar	WHO-PQ, SRA
South Africa	SRA
Mauritius	WHO-PQ SRA
Tanzania	WHO-PQ, SRA
DRC	WHO-PQ, SRA
Mozambique	SRA
Malawi	SRA

The authorities that constitute an SRA, when SRA approval is required, include authorities in regions governed by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (PIC/S), the US Food and Drug Administration (FDA), the National Agency for Food and Drugs Administration and Control (NAFDAC), the Medicines Control Council of South Africa (MCC), the European Medicines Agency (EMEA), the European Union and the French Agency for the Safety of Health Products (AFFSAPS), depending on the requirements of the particular country. In six of the countries (Zimbabwe, DRC, Namibia, South Africa, Angola and Tanzania), the decisions of other regulatory authorities are taken into account if a factory inspection is not required. No such consideration is taken into account in Mozambique, Mauritius, Malawi and Zambia. In Mauritius and Namibia, an evaluation decision is accepted without the need to perform a separate review, while in nine of the countries (Zimbabwe, DRC, Zambia, Tanzania, Malawi, Angola, Botswana, Mozambique and South Africa), this is not the case. In Angola, Mozambique, Mauritius, Tanzania and the DRC, an abbreviated review is performed when there is a difference with the local

evaluation, while this is not the case in the remaining countries.

In Zimbabwe, the statute requires that medicines be registered in their country of origin. Marketing authorisation is therefore recognised for that purpose only. The product will still have to undergo the same rigorous evaluation process. Marketing authorisation granted in another country can be recognised in the DRC in the case of innovative medicines and also for specialist medicines from ICH regions. In Malawi, recognition is given when the drug is in the public interest and there is a need to expedite action. In Namibia, marketing authorisations from the regulatory bodies listed in the previous paragraph are formally accepted as supporting documentation in the dossier evaluation process. Botswana does not recognise marketing authorisation granted in another country, but does accept an evaluation decision taken in another country without the need to perform a standard evaluation.

In nine of the countries (Angola, Botswana, Zimbabwe, Zambia, Malawi, Madagascar, Mozambique, Namibia and Tanzania), a generic manufacturer can register a product even when the innovator product is not registered. However, South Africa, the DRC, Mauritius and the Seychelles do not allow such products to be registered. In countries that permit such registration, the manufacturer needs to provide a bio-equivalence study using an innovator product approved by an SRA as the reference point. In addition, Zimbabwe, Zambia, Angola, Malawi and Madagascar request the right to reference the clinical data used in the innovator's SRA filing. All the countries also require published clinical data on the safety and efficacy of the innovator product to be submitted if the innovator drug is not registered.

The law also provides for the registration of other products in ten of the countries (Botswana, Zimbabwe, Zambia, Angola, Malawi, DRC, Madagascar, Namibia, South Africa and Tanzania). Such products include vaccines/biologicals in nine countries (Angola, Malawi, Botswana, Zimbabwe, Zambia, Madagascar, Namibia, South Africa and Tanzania); traditional medicines in four countries (Angola, Madagascar, Namibia and Tanzania); cosmetics in two countries (Madagascar and Tanzania); pre-packaged food in Tanzania; and medical devices in seven countries (Angola, Zimbabwe, Zambia, Madagascar, Namibia, South Africa and Tanzania).

2.3.3.2 Assessment of applications for the registration of pharmaceutical products

The roles of various committees, both administrative and technical, that assess the applications for medicines registration are analysed in this section, which also deals with the process for fast-tracking applications for the registration of medicines for various diseases.

In ten of the countries (Mozambique, Mauritius, Zimbabwe, Zambia, Malawi, Madagascar, Namibia, Tanzania, Angola and South Africa), there are technical committees responsible for assessing applications for the registration of pharmaceutical products. There is no such committee in Botswana, while the committee in the DRC is not functional. These committees have various different names, such as the Registration Technical Committee, the Medicines Committee and the Technical Committee for Registration, to mention just a few, but they all have similar functions. The frequency of meetings varies from monthly to quarterly. In Zimbabwe and Madagascar, the final registration decision is made by the Registration Technical Committee, while the Board/Council makes the decision in Mauritius, Botswana, Zambia, Malawi, Namibia and South Africa. In Tanzania, the decision is made by the relevant director-general based on the advice of the technical committee, while in Angola the decision is made by other unspecified bodies. In Mozambique, the Director of the Ministry of Health makes the final registration decision.

Apart from Malawi, all the other 11 responding countries have a fast-track policy in place for high-priority medicines. In Botswana, Zimbabwe, the DRC, Zambia, Angola, Madagascar, South Africa,

Mauritius and Tanzania, medicines for treating HIV/AIDS are considered high priority. Anti-malarial and anti-tuberculosis drugs are considered high priority in the above countries with the exception of the DRC. In the DRC, Angola and Mauritius, generic products for all diseases and conditions are considered high priority. In South Africa, Namibia, Angola, Mozambique, Mauritius and Tanzania, drugs for other neglected diseases and the treatment of unmet medical needs are also considered high priority.

Public information regarding the fast-tracking of applications is published on the website in Namibia and through the media in Angola. Such information is included in the registration guidelines in Tanzania, Angola and Mauritius, while South Africa employs other means to disseminate the information. In those countries where public dissemination is not done, information is shared in various ways: in Malawi this done verbally; in the DRC by means of the compilation of a condensed version of the authorised medicines; and in Zambia, upon submission of the product dossier. Applicants are notified if they qualify for fast-track review only in Angola, Mauritius, Malawi and South Africa, while the other six countries reviewed (Botswana, Mozambique, Zimbabwe, Zambia, Namibia and Tanzania) do not notify applicants.

For countries that have fast-track mechanisms for HIV/AIDS medicines (Tanzania, Malawi, Madagascar, Zambia and DRC), the target time varies from 24 days to four months. The standard review times for these medicines are between three and 12 months in Malawi, Tanzania and the DRC. For anti-tuberculosis medicines, fast-track times vary from 24 days to six months in Tanzania and Malawi. The standard review time for anti-tuberculosis medicines in Tanzania is 12 months. Fast-tracking for malaria drugs varies from 24 days to 12 months in Malawi, the DRC and Tanzania. The standard times for the same drugs in Malawi and Tanzania are three and six months respectively. The fast-track review times for NCEs and generic products are between 24 days and 12 months in Malawi and Tanzania, while the standard review times are between three and 12 months. The South African MCC cannot meet the nine-month timeline for fast-tracking due to the volume of multisource products on the Essential Medicines List (EML).

2.3.3.3 Average registration times

In this section, data for each country for three years (2007–2009) are reviewed with respect to the registration times for medicines for the treatment of different diseases. The average registration times for the approval of applications, rejections and backlogs were determined.

For HIV/AIDS drugs, 541 applications were received, 243 were approved for registration, and there were 136 backlogs; the average registration time was three months for Malawi and 18 months for Tanzania. In South Africa, the registration of generics takes an average of 18 to 24 months, NCEs take 24 to 36 months, and products for use in addressing public health threats take three months. The data from Zambia were incomplete. With respect to anti-tuberculosis drugs, 125 applications were received, 52 were approved and there were 26 backlogs; the average registration time was three months for Malawi and 18 months for Tanzania. Over the three-year period, 186 applications were received for anti-malarial drugs, 115 of which were approved, and there were 11 backlogs; the average registration times were three months for Malawi and 18 months for Tanzania. There were 130 applications for NCEs, 66 of which were approved, with 57 backlogs; the average registration time was three months for Malawi and 24 months for Tanzania. The largest number of applications was for generic products, at 12,517, of which 3002 were approved, with 2290 backlogs; the average registration time was three months for Malawi and 18 months for Tanzania. However, there were many gaps in reporting on this section. Many of the countries did not fill in the average registration times, with the notable exception of Malawi and Tanzania. The responses to backlogs were also omitted by many countries. This makes analysis difficult, and accurate analysis of the data may not be possible. This problem could be avoided if each NMRA had a reliable information management system.

2.3.3.4 Factory inspection

The inspection of factories where the manufacturing of medicines is undertaken is an important aspect of the medicines registration process. Such inspections depend on the availability of technical experts, who may not be available in all countries. Joint inspections can be undertaken to minimise the cost of undertaking the exercise.

Nine of the countries (Angola, Malawi, Mozambique, Mauritius, Zimbabwe, DRC, Madagascar, South Africa and Tanzania) have factory inspection policies, while three of the countries (Zambia, Seychelles and Namibia) have no such policy. The policy was freely available to applicants in seven of the nine countries, with the exception of Angola and Zimbabwe. The policy is published on the NMRA website in South Africa, and included in guideline or policy documents in Malawi, Zimbabwe, Mauritius, Madagascar, Tanzania and South Africa. The DRC and Mozambique use other means to disseminate the information.

In nine of the countries (Angola, Malawi, Zimbabwe, Madagascar, DRC, South Africa, Namibia, Botswana and Tanzania), the authorities inspect factories outside their own borders as part of the registration process, but the authorities in Zambia, Mozambique and Mauritius do not perform extra-territorial inspections.

Product risk is a strong indication necessitating factory inspection, and this is done in Zambia, South Africa, Angola, Zimbabwe, Madagascar, Botswana and Namibia. Botswana, Zimbabwe, Madagascar, Tanzania, Angola and South Africa consider the manufacturer's track record in the process. Approval of a product by another competent authority is taken into consideration by Angola, Zimbabwe, Tanzania and the DRC. WHO-PQ, approval by an SRA or PIC/S, and factory approval by a recognised competent authority are taken into consideration by Zimbabwe, the DRC, Angola, Namibia, Madagascar and South Africa. In Malawi, inspections are conducted for all new products for registration, and no exemptions are granted. In Zimbabwe, possession of a GMP certificate grants exemption. In Namibia, an exemption is granted if the facility is prequalified by the WHO or approved by an SRA. In South Africa, if the site is approved by a PIC/S member country and by the US FDA, no inspection is done. In Tanzania, inspection is not performed if the facility is in a country with an NMRA that applies stringent standards and there is documentary proof to support compliance with GMP, as submitted by the applicant at the time of registration. In Botswana, new inspections are not performed if the facility has been inspected in the past five years.

2.3.3.5 Samples tested for medicines registration

An important aspect of medicines registration is testing medicine samples to ensure their efficacy. This is done both before and after marketing of the approved medicines.

Eight of the countries, (Zimbabwe, Madagascar, Namibia, Malawi, DRC, Botswana, South Africa and Mozambique) carry out post-marketing surveillance to test medicine samples. Zambia, Tanzania and Mauritius do not test medicine samples prior to registration.

The sample requirements in terms of number, type of batches and packaging vary from country to country, but ultimately depend on the dossier submitted for registration. The laboratories where these tests are done include the national quality control laboratories in Botswana, Malawi, Zimbabwe, Madagascar, Namibia and South Africa; government analysts in Botswana and Tanzania; local academic institutions and private laboratories in the DRC; and mini-laboratories at district and regional level in Zambia and Tanzania. In addition, quality control laboratories abroad are used by Angola, Zambia, the DRC, Botswana and Tanzania. South Africa also outsources the testing of samples to quality control laboratories.

2.3.3.6 Recommendations

A major problem identified in this report is that NMRAs in only nine of the 15 countries responded to most of the questions in the questionnaires. Thus, with only about 60% participation, inferences become difficult to make. This failure to provide information may be due to a lack of capacity in participating NMRAs and creates problems in tracking and recording all the regulatory processes. The following recommendations are made:

a) The capacity of NMRAs needs to be improved to enable them to fulfil their legal and regulatory functions. In particular, the backlogs in approving the registration of drugs for treating HIV/AIDS and TB are high, and only about 50% of applications for such drugs are approved. It should be determined whether the low approval rate is due to lack of capacity, and if so, the problems should be addressed.

b) Countries where the fast-tracking process for registration is longer than six months should be encouraged to shorten the processes. The same observation applies to countries where the normal registration time is 24 months. It is recommended that the standard registration time should be 12 months, while fast-tracking should take no longer than six months.

c) The countries without factory inspection policies should be made to comply. In order to use the limited available resources cost effectively, it is recommended that joint inspections should be encouraged as a way of solving the problem of limited expertise to conduct GMP inspections.

2.4 BENEFITS AND CHALLENGES OF REGIONAL MEDICINES REGULATORY HARMONISATION IN SADC

SADC NMRAs appreciate and are aware that the development and implementation of a regionally harmonised medicines regulatory system will have the following benefits, drawbacks and challenges.

2.4.1 Benefits

SADC and its NMRAs are expected to benefit from the medicines registration harmonisation initiative through:

a) Better regulatory systems facilitating rapid registration. This will catalyse the development and utilisation of joint GMP inspections and reviews of the more complex dossiers. The use of a single set of documents for the dossier, harmonised guidelines and the application of recognition will speed up registration systems across countries and allow industries more readily to make medicines available on the market. This will also facilitate agreements on the development of pool procurement and the use of common guidelines and common registration and regulation technical tools by member states, and thus improve the affordability of essential medicines in the region.

b) Communities in the REC accessing essential medicines that are safe, good quality and efficacious. Harmonised medicines registration processes will facilitate the availability to communities and patients of safer, good quality and efficacious medicines on the market. Medicines registration harmonisation will reduce the time for processing registrations and thus facilitate more rapid availability of medicines to the population. This will be enhanced by the utilisation of common technical tools for registration and regulation.

c) Industry accessing larger and diverse markets in the region. This system will minimise the duplication of efforts and facilitate pooled procurement initiatives in the region, thus allowing the pharmaceutical industry to access a larger market share and higher population than at present in individual countries. The use of common guidelines will ensure that the industry can make more medicines available to communities much faster.

d) Efficient and effective utilisation of technical and financial services. The region and its member NMRAs will be able to utilise pooled capacity across the region. This will benefit those countries with limited human capital and financial resources. The complementarity of skills and competencies will add further value to regional initiatives. It is also envisaged that countries with weak regulatory capacity will benefit by relying on regional efforts.

e) Greater networking and sharing of information. Strengthening networking will enhance the exchange and flow of information among NMRAs, and both industries and the population will be able to access information more readily using information and communication technology systems. Sharing information will also reduce the duplication of effort and save on some resources, especially finances. This will be further enhanced by the full exploitation of the computerisation of registration tools (such as the Pharmadex software in Namibia). Networking will also allow coordinated use of the limited human capital and the establishment of centres of excellence. It is also expected that the outcomes of regulatory decisions will be shared more efficiently.

2.4.2 Challenges

The main challenges faced and envisaged are:

a) Differences in levels of economic development among SADC member states. The member states in the region include both least developed countries (LDCs) and non-LDCs, which are at different levels of economic development. For example, the Seychelles has not established an NMRA. The country is under-resourced and lacks access to the high-level of expertise needed to manage an NMRA. Levels of maturity differ between countries, and there are limited and declining financial and human resource bases. This is exacerbated by human resource development plans that are either absent or weak. Countries also have variable local manufacturing potential.

b) Weak institutional frameworks at the regional level. Despite the existence of the Health Unit at the SADC Secretariat, concerted efforts to draw NMRAs together are weak, largely because of the lack of a dedicated focal person at the regional office to drive the process. There is also variable interest among member states with respect to the harmonisation process. The presence of a strong centre to drive the harmonisation process would be desirable.

c) Limited networking and information sharing. There is ineffective coordination within partner states, and information exchange is very weak.

d) Multiple membership of NMRAs in RECs. Most of the countries in SADC belong to more than one REC, and may thus have variable commitments to initiatives. The implementation of these various commitments may be characterised by conflicts.

e) Variations in national policies and legislation frameworks. NMRAs are at different levels of development. The Seychelles, for example, has not established an NMRA, given its small size and a population of only 85,000. Furthermore, no regional legal framework exists to facilitate medicines registration harmonisation or develop harmonised requirements for medicines registration, and medicines registration guidelines are not being developed.

2.4.3 Recommendations

In order to achieve the harmonisation of medicines registration, member states should:

a) develop a harmonised legislative framework that is acceptable to all member states;

b) build human and financial capacity for medicines regulation;

c) implement mechanisms to retain trained staff in various NMRAs;

d) develop comprehensive guidelines;

e) establish focal points in NMRAs and at the REC to improve coordination;

f) develop computerised information management systems that link the region and ensure transparency; and

g) sensitise and involve all stakeholders in the process.

2.5 STATUS OF FINANCIAL AND HUMAN RESOURCES IN NMRAs

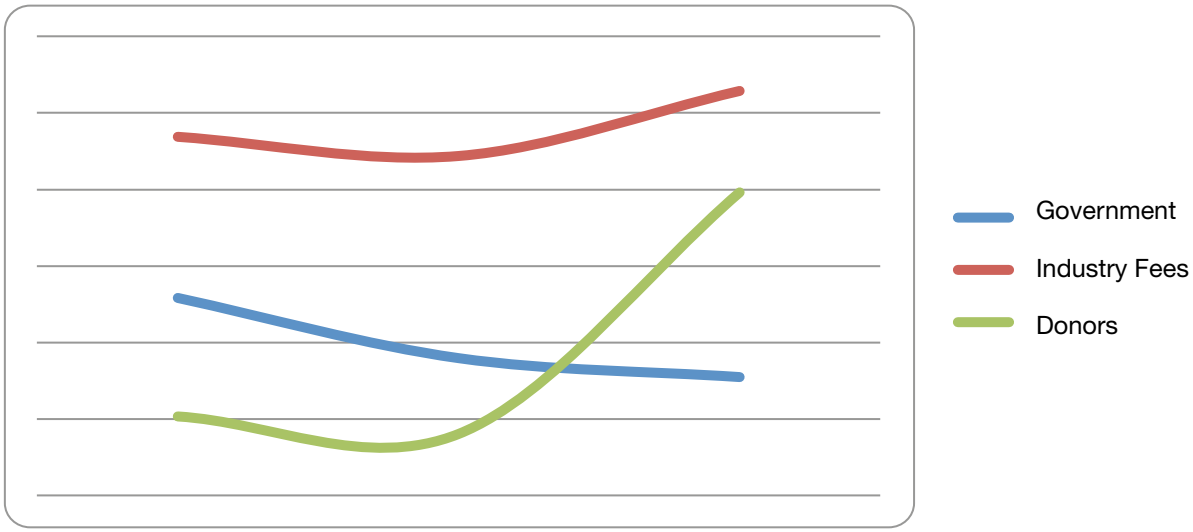
2.5.1 Sources and level of funding

The financing of NMRAs is a crucial factor in ensuring robustness in implementing a harmonised registration system. NMRAs were therefore requested to provide information on levels of funding from government, industry fees and donors for the years 2007, 2008 and 2009. The data received are shown in Table 9. The governments of Lesotho and Namibia fund their NMRAs fully, while in Malawi, Tanzania, Zambia and Zimbabwe, most of the funds come from industry fees. Only Tanzania is funded significantly (22.2%) by donors. It is evident from Figure 1 that government financing in Tanzania has been decreasing, while industry fees and donor support increased steadily between 2007 and 2009.

Table 9: Contribution to financing NMRAs in some SADC countries

Country	Contribution to financing (%)			
	Government	Industry	Donors	Total
Lesotho	100	0	0	100
Malawi	1	97	2	100
Namibia	100	0	0	100
Tanzania	22.65	55.15	22.2	100
Zambia	17	80	3	100
Zimbabwe	0	100	0	100

Figure 1: Tanzania Food and Drug Authority (TFDA) financing trends (2007–2009) (US$)



The NMRAs in some countries (Zimbabwe, Zambia, Tanzania, Malawi, Madagascar and DRC) retain industry fees to implement regulatory functions. Mauritius, South Africa, Lesotho, Namibia and Botswana do not utilise such fees to support regulatory functions, while Mozambique partly retains fees. The functions requiring financing are shown in Table 10.

Table 10: Functions requiring financing in NMRAs

Country	Functions
Zimbabwe	Full operation of the agency, including salaries, repairs, maintenance and the acquisition of capital items, working tools and consumables
Malawi	Salaries, inspections, clinical trial evaluations, meetings of expert committees and the board
Madagascar	Procurement of reagents and consumables for quality control Operating budget for the agency, various missions and training of personnel
DRC	Payment of fees to agents Running of the Department of Pharmacy and Medicines Furnishing of offices
Mozambique	Training, incentives, missions to provinces; 40% to Finance Ministry and 60% for the Pharmaceutical Department

In Botswana, activities of the Drug Regulatory Unit are funded through the Department of Clinical Services of the Ministry of Health, including staff salaries. Almost 40% of the funds for various other activities were obtained from donors.

2.5.1.1 Recommendation

SADC and its NMRAs need to keep comprehensive financial information, which is critical for the sustainable implementation of NMRA activities and in order to clearly inform the resource base. An effective and efficient information management system should be implemented to keep track of financial records.

2.5.2 Health and pharmaceutical human resources in NMRAS and RECS

The number of medical schools in SADC member states is limited, which consequently limits the number of health personnel that can be trained to serve the region. South Africa leads with eight medical and eight pharmacy schools, followed by the DRC, with seven medical and four pharmacy schools; Mozambique with four medical and three pharmacy schools; and Angola with four medical and two pharmacy schools. Other member states have one, two or no medical or pharmacy schools. Similarly, South Africa leads in terms of numbers, with a combined total of 69,069 physicians, dentists, other medicine prescribers, pharmacists and other formally trained pharmacy support staff. Although the data were incomplete for most countries, Angola ranked second with 38,221 such personnel; Mozambique third with 19,914; Zambia fourth with 5,331 and the DRC fifth with 3250. Inaccuracies in responding to the questionnaires make it difficult to know the actual number of health personnel in the respective countries. Botswana, for example, recorded zero in all respects, when this is actually not the case. Furthermore, it cannot be true, as stated in the questionnaire response, that Angola with 38,221 health workers does not have a single dentist. Detailed information on health and pharmaceutical institutions and human resources in all SADC member states is provided in Table 11.

Table 11: Health and pharmaceutical institutions and human resources for SADC

Country	ANG	BOT	DRC	LE	MDG	MW	MAU	MOZ	NB	RSA	SCY	SW	TZ	ZA	ZIM	TOTAL
No. of medical schools	4	0	7	0	2	1	2	4	1	8	0	0	0	1	1	31
No. of pharmacy schools	2	0	4	1.0	1	1	1	3	0	8	0	0	0	2	1	24
No. of other related schools	1	0	4	1	0	0	0	11	1	0	1	1	0	11	0	31
No. of physicians	2 342	0	700	0	0	300	1 500	796	774	33 534	124	181	0	1729	0	41 980
No. of dentists	0	0	250	0	0	4	250	206	90	4 890	16	27	0	65	0	5 798
No. of other medicines prescribers	34 892	0	300	0	0	0	0	17151	0	14 799	0	0	0	2 748	0	69 890
No. of pharmacists	137	0	1700	0	250	32	340	121	239	11 899	8	44	918	277	0	15 965
No. of pharmacy technicians	478	0	300	0	0	193	0	447	0	0	72	8	505	512	0	2 515
No. of other formally trained pharmacy support staff	372	0	0	0	0	30	250	1193	137	3947	0	15	378	0	0	6 322

ANG=Angola; BOT=Botswana; DRC=Democratic Republic of Congo; LE=Lesotho; MDG=Madagascar; MW=Malawi; MAU=Mauritius; MOZ=Mozambique; NB=Namibia; RSA=South Africa; SCY=Seychelles; SW=Swaziland; TZ=Tanzania; ZA=Zambia; ZIM=Zimbabwe

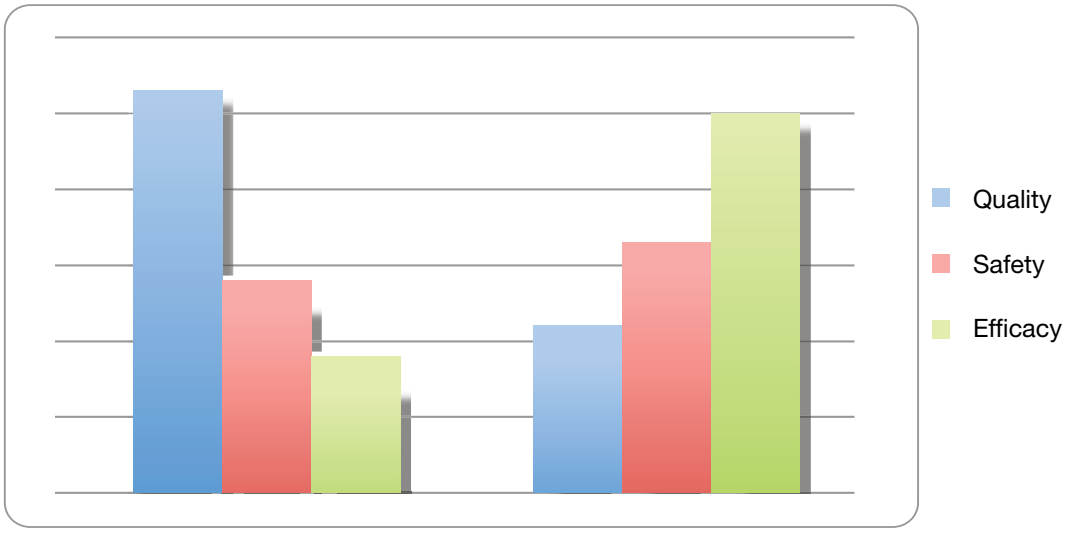
The human resources available in SADC to facilitate medicines regulatory activities (evaluators, inspectors and laboratory analysts) are shown in Table 12 and Appendix 4. Botswana, for example, has 12 pharmacists who conduct both inspections and evaluations of dossiers. Two of these have a masters degree and one is enrolled for a doctorate. There are also 18 officers (four pharmacists and 14 scientists) working in the quality control laboratory: all the pharmacists have a masters degree; one of the scientists has a masters degree; four are enrolled for a masters degree and one for a doctorate. Six of the scientists have undergone two-month attachments to reference laboratories in Zimbabwe and Kenya. Within the NMRAs, local and external expertise has been used to evaluate data on the quality, safety and efficacy of medicines submitted for registration, as shown in Figure 2. A large number of external staff are also used to evaluate safety and efficacy data. NMRAs in Angola, Lesotho, Mozambique and Tanzania have human resource development plans in place, while Botswana, the DRC, Namibia, South Africa, Zimbabwe and Mauritius do not have such plans.

Table 12: Human resource capacity for facilitating medicines regulatory activities in SADC

Regulatory function	No. of established posts	No. of filled posts	No. of qualified personnel and level of qualification				No. of personnel with specialised training
			Diploma	Bachelor degree	Masters degree	Doctorate	
Evaluators	133	64	13	51	9	9	20
Inspectors (total)	112	115	13	68	19	1	30
Distribution chain	80	64	13	44	5	0	0
GMP	32	51	0	24	14	1	30
Laboratory analysis	38	31	5	7	7	-	9
Total	283	210	31	126	35	10	59

Note: The number of filled posts may in some instances be higher than the number of established posts due to development partners supporting some of the positions.

Figure 2: Number of local and external evaluators of data on medicines quality, safety and efficacy in SADC



2.5.2.1 Recommendations

Strengthening human resources, as well as efficient and effective utilisation of such resources, will inform better delivery of the harmonisation of medicines registration. To this end, RECs and NMRAs should:

a) implement harmonisation processes that include modalities for utilising pooled regional capacity;

b) agree on and implement regional human resource development planning, such that adequate and skilled human capacity is available at both regional and national levels for various specific needs;

c) include staff exchange programmes in the harmonisation initiative such that the better-capacitated NMRAs can support the development of NMRAs in sister countries;

d) establish regional centres of excellence in training in order to train NMRA staff locally and thereby reduce the cost of training; and

e) decide on an optimum ratio for the number of pharmacists per population for SADC member states.

2.6 PHARMACEUTICAL MANUFACTURING SECTOR IN SADC

2.6.1 Preamble

Table 13 depicts the pharmaceutical production status of the SADC member states that provided such data. South Africa has the largest number of manufacturing plants (112), followed by the DRC (90) and Zimbabwe (32). The same countries also have the highest number of manufacturing plants for generic products. It is interesting to note, however, that locally owned companies exist in the DRC (with 30 such companies), Zambia (with six) and Tanzania (with three). The distribution of pharmaceutical industries is more diverse in South Africa, Tanzania, Mozambique and Angola (Table 14). Despite providing this information, most respondents were not able to provide information on the number of pharmaceutical products registered for human use; the number of pharmaceutical products marketed; the percentage of generic products registered; or the type of manufacturing facilities available (for example, facilities for manufacturing active ingredients or finished products, or for packaging finished products).

The total pharmaceutical market in the SADC region was estimated in 2000 at US$2.5–3 billion, with approximately one-third being public sector expenditure and two-thirds being private sector expenditure. Approximately half of this market is in South Africa (SADC 2006).

National associations of pharmaceutical manufacturers exist in the DRC, South Africa, Zimbabwe and Tanzania. In Botswana, the Botswana Pharmaceutical Association (BoPharma) is being formed, and its membership is open to all companies legally registered to manufacture and/or trade in pharmaceuticals in Botswana. Respondents indicated that there are no such associations in Malawi, Lesotho, Mozambique, the Seychelles, Swaziland or Zambia. The established associations of pharmaceutical manufacturers in SADC are the Pharmaceutical Manufacturers of the Congo; Tanzania Pharmaceutical Manufacturers Association; three associations in Zimbabwe, namely the Pharmaceutical Manufacturers Association (to which all local manufacturers belong), Ethical Drug Association for Wholesalers, and Retail Pharmacists' Association; and five associations in South Africa. Details of the pharmaceutical industry associations and their membership are provided in Appendix 5.

The Southern African Generic Medicines Association (SAGMA) is a new regional body with ten board members (two from Botswana, two from Zimbabwe, two from South Africa, one from Malawi, one from Zambia, one from Tanzania and one from the DRC). Its membership is open to all trade associations and pharmaceutical companies involved in the promotion and production of generic medicines. Its current membership includes companies and associations drawn from the countries represented on the board. The association sends out regular e-mails; has monthly teleconference and quarterly face-to-face meetings for the board of directors; and plans to have an annual general meeting.

Table 13: Pharmaceutical production status as provided by NMRAs in SADC (2009/10)

Country	ANG	BOT	DRC	LE	MDG	MW	MAU	MOZ	NB	RSA	SCY	SW	TZ	ZA	ZIM	Total
Total no. of pharmaceutical manufacturing plants	2	0	30	-	0	4	2	1	1	56	0	1	7	6	16	126
Total no. of research based pharmaceutical industries	0	0	-	-	2	0	0	0	0	10	0	0	0	0	0	12
Total no. of generic pharmaceutical products (including branded generics) manufacturers	0	0	30	1	0	4	2	1	1	46	0	1	7	6	16	115
Total no. of pharmaceutical plants owned by nationals (government and private)	0	0	30	0	0	2	0	1	1	-	0	0	3	6	-	43

ANG=Angola; BOT=Botswana; DRC=Democratic Republic of Congo; LE=Lesotho; MDG=Madagascar; MW=Malawi; MAU=Mauritius; MOZ=Mozambique; NB=Namibia; RSA=South Africa; SCY=Seychelles; SW=Swaziland; TZ=Tanzania; ZA=Zambia; ZIM=Zimbabwe

Table 14: Distribution of pharmaceutical companies in SADC

Country	ANG	BOT	DRC	LE	MDG	MW	MAU	MOZ	NB	RSA	SCY	SW	TZ	ZA	ZIM	TOTAL
Importers	120	-	23	3	38	42	29	90	10	165	11	-	310	75	-	916
Wholesalers	120	-	80	3.0	-	42	29	90	10	159	-	-	310	8	80	931
Government hospital pharmacies	152	-	-	9	-	39	10	1277	30	384	16	6	111	9	-	2043
Private for-profit pharmacies in 2010	1020	-	120	9	200	52	264	376	44	3115	5	-	830	86	-	6121
Private not-for-profit pharmacies	-	-	-	0	-	8	0	0	-	0	-	5	108	0	-	121
Retail pharmacies	-	-	-	-	-	400	142	6	12	7471	6	-	1652	45	-	9734

ANG=Angola; BOT=Botswana; DRC=Democratic Republic of Congo; LE=Lesotho; MDG=Madagascar; MW=Malawi; MAU=Mauritius; MOZ=Mozambique; NB=Namibia; RSA=South Africa; SCY=Seychelles; SW=Swaziland; TZ=Tanzania; ZA=Zambia; ZIM=Zimbabwe

2.6.2 Benefits, drawbacks and challenges experienced by pharmaceutical industry

Various stakeholders identified the benefits of medicines registration harmonisation in SADC. The pharmaceutical industry in the region identified the following potential benefits, drawbacks and challenges:

2.6.2.1 Potential benefits

The potential benefits include:

a) Faster and more efficient medicines registration processes in the region. The industry expects more efficient processes, which will bring about better regulatory control of medicines and reduce the risk of counterfeit medicines. There will be improved standards and quality of medicines and supply systems. Furthermore, mutual understanding of authorisation between countries will promote the accessibility of essential drugs for populations.

b) Expanded regional market and thus better income returns for investments by industries. It is expected that having more medicines on the market will increase competition and international trade in the region. There will be reduced imports of goods from outside regions. This will also enhance the availability of medicines on the market and serve to reduce costs.

c) Communities accessing safe, efficacious and affordable medicines. Quality of life depends on the quality and safety of medicines. Communities will be able to access safe, quality and efficacious medicines, including those licensed in other countries.

d) Better standards and application of a minimum standard for medicines. It is important that the health and safety of patients is assured. The development and implementation of regional standards, and adherence to such standards, will ensure better health among populations. The elimination of counterfeit drugs on the market will improve the standards and quality of medicines.

e) Application of common guidelines, technical documents and procedures. NMRAs are expected to agree on a standard dossier that could be submitted in any member state and be applicable to several countries. This would facilitate timely reviews and early registration, and reduce the duplication of effort.

2.6.2.2 Challenges and drawbacks

Stakeholders identified several drawbacks and challenges to the process of harmonisation, including:

a) Differences in economic development among SADC member states. The region has both LDCs and non-LDCs, which are at different levels of economic development. It is feared that harmonisation might favour selected countries and manufacturers to the detriment of others. This is exacerbated by the inability to secure and maintain political will to implement the harmonisation initiative.

b) Weak institutional capacity. Capacity varies considerably between NMRAs in the different countries in terms of human resources, financial capacity, infrastructure, information technology, information capacities and associated equipment. This situation is exacerbated by declining and erratic political commitment. The regulatory authorities have limited trained quality assurance inspectors and technicians to attend to equipment, as well as limited training facilities to train operators and officers with respect to the harmonised system.

c) Variation in national policies and legislative frameworks. Countries in the SADC region have different pharmaceutical policies and medicines legislative frameworks. This has led to some regulatory bodies in the region being set up without the competency to review the information requested. For example, the Seychelles has not established an NMRA, given its small size and total population of only 85,000.

d) Human resource development plans either absent or weak. The region is not well endowed; it is under-resourced, and some countries lack access to the high-level expertise needed to manage an NMRA. Some NMRAs have inadequate capacity to review bioequivalence and clinical data. This is also the case for inspectors and regulatory staff.

e) Variations in pharmaceutical capacities. There are differences in local production capacities between the different countries. It is thus feared that harmonisation might favour selected manufacturers to the detriment of others, and that big industries in countries with stronger economies would dominate the trade.

f) Weak coordinating mechanisms at regional level. SADC has a Health Unit for health matters and programmes, but the Secretariat currently has weak capacity to bring stakeholders together to agree on certain minimum standards. Some member states consider themselves superior to others. Differences in infrastructure development abound among countries, and this situation is worsened by huge differences in infrastructure capacities among countries.

The experiences of the industry with respect to medicines regulatory harmonisation initiatives in the region have generally been negative, despite industry working very closely and fruitfully with SADC at a meeting in 2002, at which it was agreed that expert groups be formed with representatives from different countries to make policy decisions and conduct reviews. Although the SADC committee tasked with responsibility for this initiative changed its approach, stopped communicating with the industry and stalled the implementation of the guidelines that had been prepared, the initiative was driven by only a few countries, such as Zimbabwe and South Africa, while the other countries were battling to set up proper regulatory authorities. At the meeting of the Drug Information Association in February 2010, industry and the SADC regulators engaged on this issue again. Clear commitment to the need for cooperation emerged again. However, it is not clear whether this could be done on a regional basis or a country-by-country basis. There is obviously a need for greater commitment and political will by stakeholders and governments. The industry is generally supportive of these initiatives. The survey showed that a broad range of stakeholders, including industries, have high levels of commitment to the harmonisation of medicines registration. However, industries do not have sufficient information, and most of them are not engaged in real discussions, although they are willing to do so. It seems that the REC does not always have an in-depth understanding of issues, the resources required or the practical aspects of implementing regulatory changes. Furthermore, some governments such as South Africa argue that such a move would undermine their own local industry as competition increases. In most countries, while commitment exists, the necessary personnel for effective harmonisation are either lacking or available only in limited numbers.

Industries in each country have expectations, which are shown in Table 15.

Table 15: Expectations of industry with respect to the medicines regulatory process

Country	Expectations
DRC	Creation of a mixed committee composed of all economic operations, regulatory authorities and technocrats
Lesotho	Training of regional officers together to bring them to a similar level of understanding for meaningful implementation of the process
Malawi	Having one uniform set of requirements for drug registration
South Africa	View of Pharmaceutical Industry Association of South Africa (PIASA): An EU-type model that encompasses the harmonisation of regulatory requirements as well as mutual recognition, with due consideration of widely accepted international standards for improvement View of Innovative Medicines South Africa (IMSA): Establishment of a unified approach to standard-setting and enforcement between and within regions, and sharing of resources, including with industry. Initially this should involve the promulgation of laws and establishment of controlling authorities that could establish minimum standards for registration and deliberately move towards harmonisation at global level. This does not imply mutual recognition View of National Association of Pharmaceutical Manufacturers (NAPM): Pooling of resources to ensure timely registration of safe, quality and efficacious medicines and proper enforcement of set standards, and in so doing improve medicine access in Africa and self-sufficiency in medicines registration
Swaziland	Improved information sharing, quality and supply systems and regional medicine evaluations and recognition of products between countries

Country	Expectations
Tanzania	Single registration for local manufacturers across the region
Zambia	Increased quality of medicines on the market, accessibility and affordability of medicines and pharmaceutical free trade
Zimbabwe	Joint evaluations need to start, because many disparities exist in the way countries approach registration. The few existing competent bodies should start the initiative; others should join later as they develop
Mozambique	Enhanced interaction with other regional industries

There is a moderate to excellent sense within the industry in Malawi, South Africa, Zambia, Zimbabwe and Tanzania of what is required to comply with registration requirements. The need to submit information on the manufacturing route synthesis of active pharmaceutical ingredients during dossier submission to the regulatory authority in Malawi, and US$-based fees in most countries, are considered to be superfluous aspects of the registration process. Longer registration times, unclear guidelines, high staff turnover, weak feedback mechanisms, administrative delays due to lack of financial and human resources, and poor record-keeping were cited as the causes of bottlenecks in getting a medicine registered.

2.6.3 Effectiveness of medicines registration processes and areas requiring improvement

Table 16 shows that the important factors required to support effective medicines registration processes in SADC and its NMRAs exist in some countries, namely: strong regulatory systems in member states; transparent and open registration systems; available and regularly updated information and guidelines; continual dialogue among stakeholders including government, consumers and industry; continuing national and regional political will and commitment; adequate, qualified and committed personnel for regulation; and regional commitment to medicines registration harmonisation. Table 16 also shows the factors that impede effective registration systems, including lack of autonomy of the agency; undue influence (political and otherwise); erratic dialogue systems with industry; inadequate financial and human capital; weak legal power to enforce regulations; and weak or absent testing facilities and thus over-dependence on outsourcing. Table 16 lists success factors, impeding and required factors identified by the various countries for catalysing better registration processes in SADC.

Table 16: Factors influencing medicines registration in SADC

Country	Factors		
	Success factors	Negative	Required
Botswana	Transparency Adequate capacity and skill to review applications Clear set timelines and processes Consistent application of procedures and guidelines Clear and open communication between industry and regulatory bodies Clear and consistent site inspection protocols and processes	Lack of autonomy of the agency/ undue influence, political and otherwise Limited knowledge among available personnel Lack of transparency in application processing and review Inadequate financial and other resources Lack of legal power to enforce regulations Inefficient communication between industry and regulator	

Country	Factors		
	Success factors	Negative	Required
DRC			Composition of a technical dossier Stabilisation conditions Documentation on the validation of active ingredients (toxicology)
Lesotho			Current system is good, quick and efficient
Malawi	Clear guidelines on the submission of dossiers Timeous response/feedback on shortfalls in dossier Forty-five to 60 days to respond to shortfalls Issuing conditional approvals on minor non-conformances Six months' accelerated stability data should be considered for the initial registration	Inability among regulators to focus on essential medicines Stringent requirements (e.g. route of synthesis on pharmaceuticals) Lack of testing facilities/reagents and consequent outsourcing to other countries Incomplete dossier submission to regulators	Increased frequency of meetings on evaluation of medicines from once a month to twice a month Acceptance of the same documentation approved by other regulatory bodies Harmonisation of labelling requirements within countries
South Africa	Transparency throughout the process by applying evaluation steps and standards Harmonised regulatory processes that are aligned to recognised international authorities Predictable timelines for review of applications for registration of medicines Appropriate fees, including but not limited to registration fees, retention fees and GMP inspection fees Open, consistent and regular dialogue between industry and government on health and medicines policy issues Adequate number of trained and qualified staff Ability to discuss unusual situations with regulator ahead of data generation and submission Application of guidelines as appropriate at time of submission, especially where review is delayed	Lack of transparency with respect to timelines and processes Lack of public consultation process and communication when implementing new policies and requirements Lack of harmonisation of requirements across markets and lack of clarity on the rationale for country-specific requirements Inappropriate fee structures (e.g. GMP inspection fees) Focus on non-value added regulatory requirements, which hinders medicines access Repeating assessments/evaluations where credible reports exist and can be used in the review process Poor communication within the regulatory authority, and between the regulatory authority and industry Poor databases and scant availability of information on the medicines register Lack of adequately qualified staff Poor administration and control Inconsistent application of requirements	Open channels of communication with the regulating body for local industry-related issues
Tanzania	Strength with clear guidelines Process is strictly followed and adhered to	Lack of technical personnel and resources at regulatory body Time taken is too long for registration, especially for local manufacturers Bureaucracy, which causes unnecessary delays No open channels for communication with the regulating body for local industry-related issues	

Country	Factors		
	Success factors	Negative	Required
Zambia	Adequate staffing in department of product registration Having defined timeframes for product registration Having more frequent medicines approval meetings Manufacturers should also have regulatory departments to help formulate decent dossiers for products to be submitted for registration NMRA to help facilitate regulatory training on product registration	Inadequate manpower Undefined registration timeframes Lack of national quality control laboratories	
Zimbabwe	Registration of quality and efficacious products, as opposed to opportunist products being 'dumped' in the country	It takes too long to communicate to applicants after decisions have been reached	Authority needs to publicise all its policies and develop guidelines to cover all areas (e.g. pharmaceutical development) Phased implementation of new requirements to allow the industry to recover from economic downturn

2.6.4.1 Recommendation

Pharmaceutical industries and NMRAs should keep records of their various operations. To facilitate this, training in record-keeping, as well as the implementation of effective information management systems, should be prioritised.

2.6.5 Information sharing and stakeholder engagement

The SADC health sector recognises that stakeholders are essential for the successful implementation of various provisions of the SADC Protocol on Health. Their role is to identify areas of cooperation that require their expertise and competency, and to participate in the implementation of the Protocol. To facilitate full engagement of stakeholders, SADC, with the support of the WHO, has established the Shared Network Point, which is an internet-based programme for discussions between and/or among regulators. The details of this arrangement were not accessible during this study.

Only eight of the countries (Botswana, Mozambique, Mauritius, Namibia, Zimbabwe, South Africa, Angola and Tanzania) have mechanisms for engaging stakeholders in decision-making regarding medicines regulatory processes, while the DRC does not have such mechanisms. The procedures used for consultation also varied. The aim of consultation is to reach consensus on key issues by involving stakeholders, including industry and lay members of the community, in the decision-making process. In Zimbabwe, Mozambique and Mauritius, the NMRA uses consultative meetings to engage with stakeholders, while in Angola there is an exchange of information. In South Africa, meetings with national ethical committees are held, and the draft and final guidelines are placed on a website for comment. The Tanzanian NMRA uploads draft documents on the TFDA website, or these are sent directly to stakeholders on request. In Botswana, stakeholders are involved in the development and revision of guidelines.

Seven of the countries have websites (Malawi: www.pmpb.mw; Zimbabwe: www.mcaz.co.zw;

Zambia: www.pra.gov.zm; Madagascar: not indicated, Namibia: www.nmrc.com.na; South Africa: www.mccza.com; and Tanzania: www.tfda.or.tz), while three countries do not (Seychelles, DRC and Lesotho). The websites of the seven countries are easy to access, and the South African website appears to be the most comprehensive. However, all the various websites carry important information related to legislation, guidelines, registration or application forms and process, fee structures, lists of registered products, lists of rejected products, lists of banned products, lists of authorised manufacturers, recent news and or updates, and a window for giving or receiving feedback. Interestingly, the Tanzania Food and Drug Authority (TFDA) website provides for Swahili language text. Other notable features are that the Zambian website features the director-general, and some of the websites, such as the South African one, display the board and committee structure. Some of the information on the websites was out of date: the Malawian and Namibian websites, for example, featured information related to job vacancies dating back to 2007, and the Namibian website featured the appointment of members of the Namibia Medicines Regulatory Council on 9 December 2009.

Information on medicines regulation is also shared with the public using newspapers, television and radio, periodical publications in the official gazette, a register for licensed medicine, mailed information, e-mails, workshops, circulars and free provision of information requested by interested parties. For example, six of the countries (Zimbabwe, Zambia, Malawi, Namibia, South Africa and Tanzania) publish various pieces of information on their NMRA websites. Seven of the countries (Zimbabwe, DRC, Zambia, Malawi, Madagascar, Namibia and South Africa) make information freely available to applicants on request at NMRA offices. It is interesting that Angola makes full use of the media, while Tanzania sells materials to applicants on request.

Most of the SADC countries participate in initiatives for the harmonisation of medicines regulation driven by other RECs. Madagascar and Angola, for example, have country policy and legal frameworks that provide for the NMRA to recognise regulatory decisions made by other RECs. For Madagascar, this is through the French Agency for the Safety of Health Products (AFFSAPS), the European Medicines Agency (EMA), the US Food and Drug Administration (FDA) and the European Commission.

2.6.5.1 Recommendations

To enhance information sharing and engagement with various stakeholders for better harmonisation of medicines regulations, the following recommendations are made:

a) strengthening and capacitating regional and national associations for better networking and information sharing;

b) developing and implementing a functional regionally linked information management system and fully functional websites, which should be updated regularly;

c) full exploitation of REC memberships where multiple memberships for countries can be obtained;

d) establishment of a forum between regulators and industry, including consumer groups; and

e) strengthening the SADC Shared Network Point for links among the regulators.

2.7 CONCLUSIONS AND RECOMMENDATIONS

2.7.1 Conclusions

NMRAs in ten of the SADC member states participate actively in various initiatives towards medicines registration harmonisation. Several countries are involved in activities in RECs other than SADC and therefore participate in medicines harmonisation in those RECs. Concerted efforts and consolidation of regional medicines harmonisation initiatives are required to achieve access to safer, quality, more affordable and highly efficacious medicines for communities. The following section provides a summary of recommendations from the situation analysis study.

2.7.2 Recommendations

To facilitate greater harmonisation of medicines registration, the region needs to address various issues relating to the legislative framework, registration of medicines, information sharing and capacity building, namely:

2.7.2.1 Legal framework

SADC and its member countries should:

a) develop and implement a roadmap for ensuring that national legislative bodies fulfil their commitments under the SADC Treaty;

b) work proactively towards concluding a protocol under the Treaty that requires partner states to amend their domestic legislation within specified timeframes. The protocol should provide guidance in removing all impediments to the domestication of national laws regarding the harmonisation of medicines registration;

c) ensure that all NMRAs have mission statements in place on the national regulation of medicines. Such mission statements should emphasise the serious intent and commitment of governments to fulfilling the obligation of protecting the public;

d) support the Seychelles in developing a national medicines policy that complies with WHO recommendations and informs the enactment of legislation. The policy should incorporate obligations with respect to initiatives for the harmonisation of medicines registration as agreed under the Treaty; and

e) encourage South Africa to develop an implementation plan for national medicines policy that, among other things, takes into consideration the domestication of the ongoing harmonisation of medicines registration in the SADC region, as agreed under the Treaty.

2.7.2.2 Registration of medicines

SADC and its member states' NMRAs should:

a) as a matter of urgency, reduce the backlogs in registering drugs for treating priority diseases such as HIV/AIDS and tuberculosis;

b) reduce the registration processing times to no more than six months for HIV/AIDS and anti-tuberculosis medicines, and promote registration times of no more than 12 to 18 months for most medicines in all NMRAs;

c) undertake pre- and post-marketing surveillance programmes as well as GMP inspections; and

d) support some member states in developing and implementing comprehensive guidelines for medicines registration.

2.7.2.3 Sharing of information and stakeholder consultation

SADC and its member states should:

a) strengthen mechanisms for sharing information, including the implementation of a regionally linked website based on a regionally linked information management system;

b) engage and sensitise all stakeholders, including the private sector, with respect to the process for the harmonisation of medicines registration;

c) strengthen the SADC Health Unit for enhanced coordination and networking;

d) create awareness among all stakeholders of the benefits and value of harmonisation using various forums and information dissemination tools;

e) ensure that the SADC Integrated Council of Ministers directs and concretises a regional pharmaceutical policy; and

f) endeavour to use a variety of information sharing options, including websites, which should be kept up to date.

2.7.2.4. Capacity building

SADC and its member states should:

a) build capacity and capability among NMRAs to enable them to fulfil their legal and regulatory functions; and

b) mobilise and efficiently utilise financial resources for the sustainability of NMRA activities.

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APPENDIX 1: CONTACT DETAILS OF RESPONDENTS TO THE ASSESSMENT INSTRUMENT FROM SADC

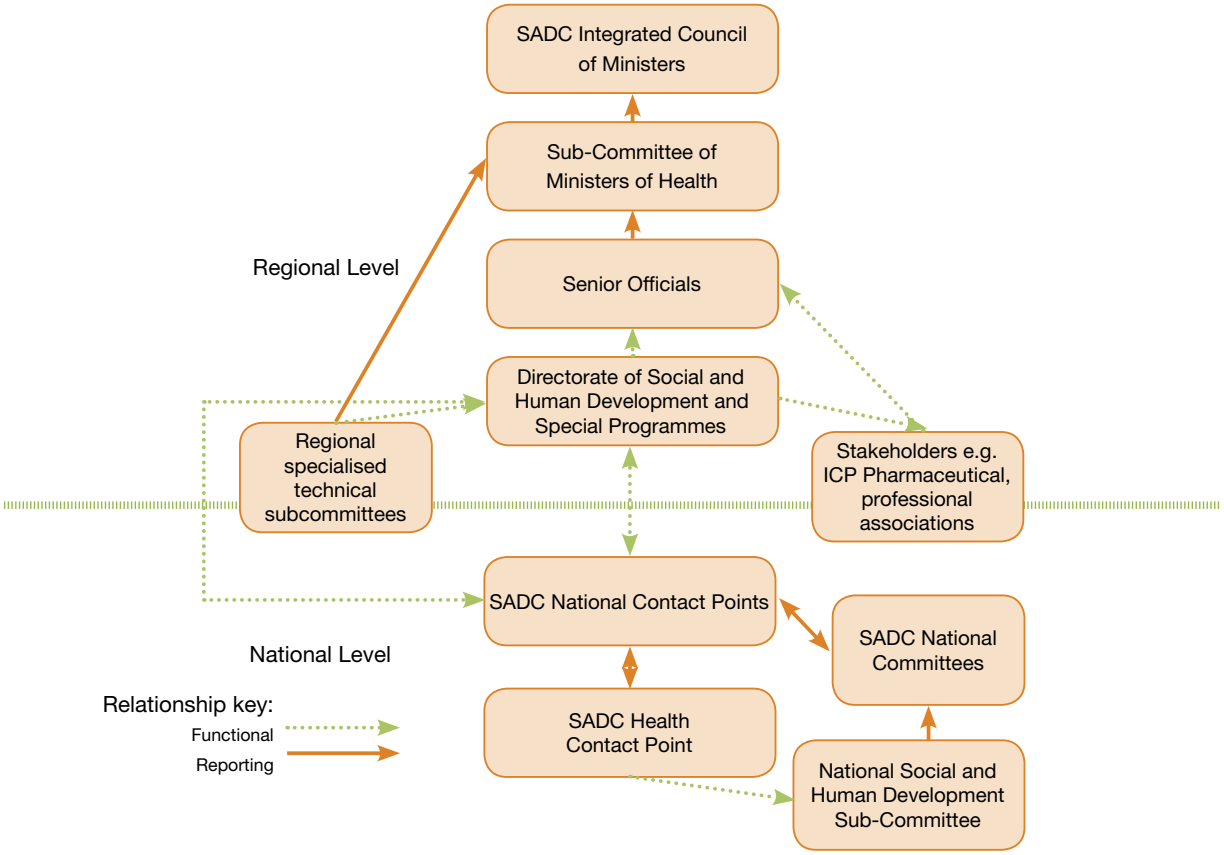
Country/ Region	Affiliation	Name of institution	Head of institution	Position	Contact details			
					Address	Telephone/Cell	Email	Website
Angola	NMRA	National Directorate of Medicines and Equipment	Boaventura Moura	National Director	Rua Ché Guevara nº 86/86A Maculusso - Ingombota, Luanda, República de Angola	+244-926731474 +244-222-320030 Fax +244-222-328166	dnmedicamentos@ebonet.net/ boaventura.ao@gmail.com	
	Pharmaceutical manufacturers							
DRC	NMRA	PMMP	Bitibiri Bitilon Jean-Pierre	Chief Registration Officer	Dept of Pharmacy, Medicines & Medicinal Plants, 36, Av De la Justice Kinshasa Gombe	+243999913490	Jpbitibilon2005@yahoo.fr	
	Pharmaceutical manufacturers	APM	Amir Surani	President	5 Bis Basisa, Kinshasa/ LIMETE	+243999947060 +243819904650	Promedlabo@gmail.com, /Amirsurani@hotmail.com	
Lesotho	NMRA							
	Pharmaceutical manufacturers	Tripharm Manufacturing	M. Khohlokwane	Director of Operations	23 Moshoeshoe Rd, Industrial Area, Maseru	+266 2232 7928 +266 5885 9333	mthi@tripharm.co.ls	
Madagascar	NMRA	MAM	Rabenandrianina Solofomboahangy Harisoa	Doctor, Assistant at the Registration Services		+360 020 22 365 22 +361 34 564 06	Harisoa.agmed@gmail.com	
	Pharmaceutical manufacturers							
Malawi	NMRA	Pharmacy, Medicines and Poisons Board	Aaron Glyn Sosola	Acting Registrar	Area 44, Near State House	+265 1755634 +265 888202930	sosola@malawi.net	www.pmpb.mw
	Pharmaceutical manufacturers	Kentam Products Limited	Alfred Edwin	Quality Assurance Manager	P.O. Box 898, Luwinga, Mzuzu, Malawi	+265 1 320 643 +265 88 407 6686	aedqin@kentam.co.mw	www.pmpb.mw
Namibia	NMRA	MoHSS MRC	Johannes Gaeseb	Registrar of Medicines	Harvey street, Windhoek North, Windhoek, Namibia	+246 61 203 2403	regmeds@nmrc.com.na	www.nmrc.com.na
	Pharmaceutical manufacturers							

Country/ Region	Affiliation	Name of institution	Head of institution	Position	Contact details			
					Address	Telephone/Cell	Email	Website
RSA	NMRA	Medicines Control Council National Department of Health	Mandisa Hela assisted by Dr Joel Gouws	Registrar of Medicines	Struben Street, Pretoria	+012 312 0285 +27827748966	helam@health.gov.za	www.mccza.com
	Pharmaceutical manufacturers							
Seychelles	NMRA	MoHSD	Lucile de Comarmond	Director of Pharmaceutical Services	Victoria Hospital, Mnt Fleuri, Mahe, Seychelles	+248 388074 +248 722100	Lucile.de comarmond@gov.sc	
	Pharmaceutical manufacturers							
Swaziland	NMRA	Ministry of Health	Thulie P. Magagula	Pharmacist	Mbabane Govt. Hospital, Hospital Hill, Mbabane, Swaziland	+268 40402111 extn 2136 +268 76030772	Tpmag91@yahoo.com	
	Pharmaceutical manufacturers	Ministry of Health	Thulie P. Magagula	Pharmacist	Mbabane Govt. Hospital, Hospital Hill, Mbabane, Swaziland	+268 40402111 extn 2136 +268 76030772	Tpmag91@yahoo.com	
Tanzania	NMRA	TFDA	Hiiti B. Sillo	Acting Director General	External Mabibo, Along Mandela Road, P.O. Box 77150, Dar es Salaam	+255222450512 +255754307179	info@tfda.or.tz/hiiti.sillo@tfda.or.tz	www.tfda.or.tz
	Pharmaceutical manufacturers	Zanzibar (ZFDB)	Simai Burhani Othman	Registrar	Zanzibar, Tanzania, Kaunda Road, Mnazi Mmoja Area,	+255242233959 +255777414455	bsimai@yahoo.com	www.zanhealth.info/zdfb
Zambia	NMRA	PRA	Caroline Yeta	Director, Inspectorate & Licensing	Tuleteka Road, Plot Number 6903, Rhodes Park	+260 211 22 04 29	cyeta@pra.gov.zim	www.pra.gov.zm
	Pharmaceutical manufacturers	Pharmanova Zambia Ltd	Alagappan Murugappan	General Manager	7328, Moobola Road, P.O. Box 35722, Lusaka, Zambia	286926 287926 286001 287977 0966431687	murugappan@zamnet.zm	www.pra.gov.zm
Zimbabwe	NMRA	MCAZ	S. Muengwa, T Ganga, L. Dzimbanhete, J. Chideme, T. Chizanga	Pre-registration Pharmacists	106 Baines Avenue, Harare	+263 4 736981 -5, 708255/792165	mcaz@africaonline.co.zw	www.mcaz.co.zw

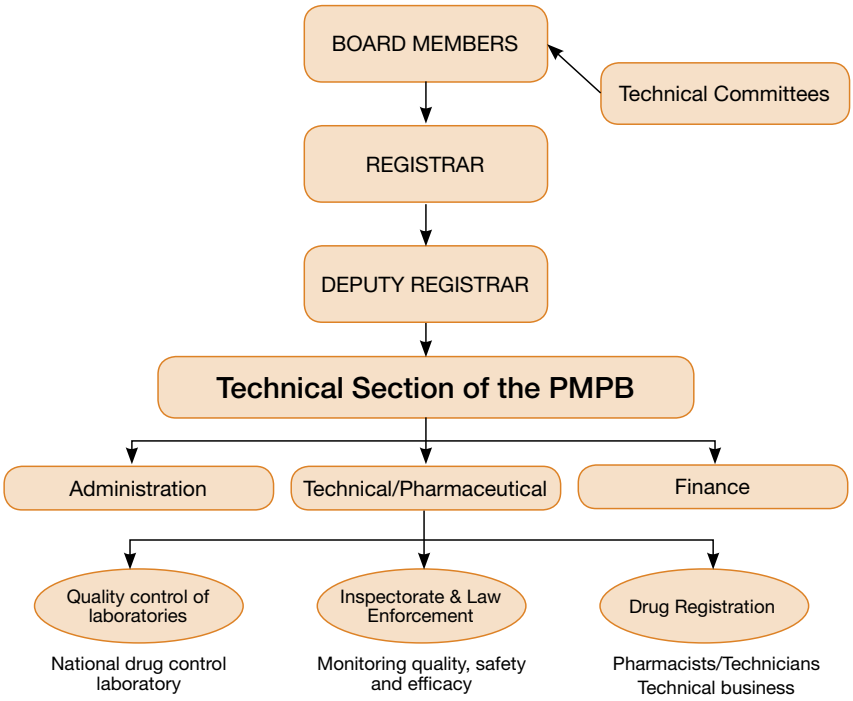
Country/ Region	Affiliation	Name of institution	Head of institution	Position	Contact details			
					Address	Telephone/Cell	Email	Website
	Pharmaceutical manufacturers	Datalabs (Pvt Limited)	Victor Basopo	Business Development Manager	45 Falcon Street, Belmont, Bulawayo	+263 9 470092/5 +263 9 12633633	Victor.Basopo@ datalabs.co.zw	www.mcaz.co.zw
Mauritius	NMRA		Mrs Sheesha Jankee	Director	Pharmaceutical Services, Ministry of Health and Quality Life, 5th Floor, Emmanuel Anqueth Building, Port Louis, Mauritius	2543498 2011334	sjankee@mail.gov. mu	
Mozambique	NMRA		Tania Vuyeya Sitoie	Director	Pharmaceutical Department AV. Agostinho Neto, R/C Maputo	+25821303473 +258826337199	Vuyeya78@yahoo. com	
	Pharmaceutical manufacturers		Santos Conzaga Jeque	General Director	Sociedade Mocambicana de Medicamentos, Rua da Uniqo Africana, SA, Maputo Provincia	+258823010240 +258822153240	Sg_jeque@yahoo. com	

APPENDIX 2: ORGANISATIONAL STRUCTURE FOR SADC AND MALAWI

Institutional framework for implementing the SADC Protocol on Health



Organisational chart of the Pharmacy Medicines and Poisons Board (PMPB) (Malawi)



APPENDIX 3: NAME OF AUTHORITY CARRYING OUT VARIOUS REGULATORY FUNCTIONS IN THE NMRAs

Function	NMRA
Licensing of pharmaceutical imports	Medicines Control Authority of Zimbabwe (MCAZ) Department of Pharmacy, Medicines and Medicinal Plants (DRC) Medicines Control Council (MCC) (South Africa) Pharmacy Medicines and Poisons Board (Malawi) Namibia Medicines Regulatory Council Medicines Agency and DPM (Madagascar) Pharmacy Regulatory Authority (Zambia) Ministry of Finance, after consultation with Ministry of Health (Swaziland) Tanzania Food and Drug Authority (TFDA) Ministry of Health (Botswana) National Directorate of Medicines and Equipment (DNME)/Commerce (Angola)
Licensing of pharmaceutical wholesale trade	Medicines Control Council (MCC) (South Africa) Medicines Control Authority of Zimbabwe (MCAZ) Department of Pharmacy, Medicines and Medicinal Plants (DRC) Pharmacy Regulatory Authority (Zambia) Pharmacy Medicines and Poisons Board (Malawi) Medicines Agency (Madagascar) Seychelles Licensing Authority Pharmacy Council, Department of Health (South Africa) Tanzania Food and Drug Authority (TFDA) Ministry of Health (Botswana) National Directorate of Medicines and Equipment (DNME)/Commerce (Angola)
Licensing of medicine retail/ dispensing outlets	Pharmacy Council, Department of Health (South Africa) Medicines Control Authority of Zimbabwe (MCAZ) Department of Pharmacy, Medicines and Medicinal Plants (DRC) Pharmacy Regulatory Authority (Zambia) Pharmacy Medicines and Poisons Board (Malawi) Medicines Agency and DPM (Madagascar) Seychelles Licensing Authority Tanzania Food and Drug Authority (TFDA) Ministry of Health (Botswana) National Directorate of Medicines and Equipment (DNME)/Commerce (Angola)
Product assessment and registration/marketing authorization	Medicines Control Council (MCC) (South Africa) Medicines Control Authority of Zimbabwe (MCAZ) Department of Pharmacy, Medicines and Medicinal Plants (DRC) Pharmacy Regulatory Authority (Zambia) Pharmacy Medicines and Poisons Board (Malawi) National Commission on Registration, Medicines Agency (Madagascar) Namibia Medicines Regulatory Council Tanzania Food and Drug Authority (TFDA) Drugs Regulatory Unit/Drugs Advisory Board (Botswana) National Directorate of Medicines and Equipment (DNME) (Angola)
Good manufacturing practice (GMP) inspection	Medicines Control Council (MCC) (South Africa) Medicines Control Authority of Zimbabwe (MCAZ) Department of Pharmacy, Medicines and Medicinal Plants (DRC) Pharmacy Regulatory Authority (Zambia) Pharmacy Medicines and Poisons Board (Malawi) Medicines Agency, Inspection Services (Madagascar) Namibia Medicines Regulatory Council Tanzania Food and Drug Authority (TFDA) Drugs Regulatory Unit/ Drugs Advisory Board, Ministry of Health (Botswana) National Directorate of Medicines and Equipment (DNME)/General Health Inspection (Pharmaceutical Inspection) (Angola)

Function	NMRA
Inspection of distribution channels	Medicines Control Council (MCC) (South Africa) Medicines Control Authority of Zimbabwe (MCAZ) Department of Pharmacy, Medicines and Medicinal Plants (DRC) Pharmacy Regulatory Authority (Zambia) Pharmacy Medicines and Poisons Board (Malawi) Medicines Agency, Inspection Services (Madagascar) Pharmaceutical Services (Seychelles) Namibia Medicines Regulatory Council Tanzania Food and Drug Authority (TFDA) DNME/ General Health Inspection (Pharmaceutical Inspection) (Angola) Drugs Regulatory Unit/ Drugs Advisory Board (Botswana)
Performing medicine quality tests/ quality control laboratory	Medicines Control Council (MCC) (South Africa) Medicines Control Authority of Zimbabwe (MCAZ) State laboratories (OCC, LAPHARI, LACOLIN, LACOMEDA) Pharmacy Regulatory Authority (Zambia) Pharmacy Medicines and Poisons Board (Malawi) Medicines Agency, Control Services (Madagascar) Pharmaceutical Services (Seychelles) Namibia Medicines Regulatory Council Tanzania Food and Drug Authority (TFDA) National Quality Control Laboratory, Botswana National Directorate of Medicines and Equipment (DNME) (Angola)
Regulating generic substitution	Medicines Control Authority of Zimbabwe (MCAZ) Department of Pharmacy and Medicines (DRC) Pharmacy Regulatory Authority (Zambia) Pharmacy Medicines and Poisons Board (Malawi) Medicines Agency of Madagascar, Registration Services Namibia Medicines Regulatory Council Director of Health Services, Ministry of Health, Botswana National Directorate of Medicines and Equipment (DNME)/Association of Doctors (Angola)
Control of prescribing	Medicines Control Council (MCC) (South Africa) Medicines Control Authority of Zimbabwe (MCAZ) Health Professions Council (Zambia) Pharmacy Medicines and Poisons Board (Malawi) National Association of Doctors (Madagascar) Namibia Medicines Regulatory Council Director of Health Services, Ministry of Health (Botswana)

APPENDIX 4: DETAILS OF NMRA HUMAN RESOURCE CAPACITY FOR MEDICINE REGULATORY ACTIVITIES IN SADC

a) Number of full-time evaluators, inspectors and laboratory analysts and their qualifications

Regulatory post	Country	No. of established posts	Total no. of filled posts	No. of qualified personnel and level of qualification				No. of personnel with specialised training
				Diploma	Bachelor degree	Masters degree	Doctorate	
Evaluators	Zimbabwe	8	8	-	7	1	-	4
	DRC	1	4	1	-	-	-	-
	Zambia	6	4	2	2	-	-	1
	Malawi	6	2	2	-	-	-	-
	Madagascar	-	-	-	-	-	2	7
	Seychelles	-	-	-	-	-	-	-
	Namibia	2	3	-	3	-	-	-
	South Africa	63	36	8	20	5	3	-
	Angola	8	1	-	8	-	-	-
	Lesotho	-	-	-	-	-	-	-
	Tanzania	31	8	-	6	2	-	8
Distribution chain inspectors	Zimbabwe	7	4	2	2	-	-	-
	DRC	2	-	-	-	-	-	-
	Zambia	-	6	4	2	-	-	-
	Malawi	9	4	3	1	-	-	-
	Madagascar	-	-	-	-	-	-	-
	Seychelles	-	-	-	-	-	-	-
	Namibia	-	-	-	-	-	-	-
	South Africa	-	-	-	-	-	-	-
	Angola	4	6	-	4	-	-	-
	Lesotho	-	-	-	-	-	-	-
	Tanzania	49	35	4	26	5	-	-
GMP inspectors	Zimbabwe	2	1	-	1	-	-	-
	DRC	7	-	-	-	-	-	-
	Zambia	-	3	-	3	-	-	-
	Malawi	7	1	-	1	-	-	-
	Madagascar	-	-	-	-	-	-	-
	Seychelles	-	-	-	-	-	-	-
	Namibia	1	1	-	1	-	-	-
	South Africa	14	10	-	8	1	1	10
	Angola	-	6	-	-	-	-	-
	Lesotho	-	-	-	-	-	-	-
	Tanzania	-	23	-	10	13	-	20
Laboratory analysts	Zimbabwe	-	-	-	-	-	-	-
	DRC	-	-	-	-	-	-	-
	Zambia	-	-	-	-	-	-	-
	Malawi	7	2	-	2	-	-	-
	Madagascar	-	-	-	-	-	-	-
	Seychelles	6	4	3	-	-	-	-
	Namibia	2	3	1	1	1	-	-
	South Africa	-	-	-	-	-	-	-
	Angola	2	5	-	2	-	-	-
	Lesotho	-	-	-	-	-	-	-
	Tanzania	17	9	1	2	6	-	9

Botswana: There are 12 pharmacists employed who do both inspections and evaluation of dossiers. Two have a masters degree and one is enrolled for a doctorate. There are also 18 officers, four pharmacists and 14 scientists working in the quality control laboratory. All the pharmacists have a masters degrees, one scientist has a masters degree, four are enrolled for a masters degree and one for a doctorate. Six of the scientists have undergone attachments of approximately two months at reference laboratories in Zimbabwe and Kenya.

b) Number of local and external evaluators with specialised expertise in each NMRA

Number of evaluators with specialised expertise in the following areas			
Area of specialisation	**Country**	**NMRA staff**	**External evaluators/ assessors**
Evaluation of quality data	Zimbabwe	9	-
	DRC	8	-
	Zambia	1	-
	Malawi	0	-
	Madagascar	2	-
	Seychelles	-	-
	Namibia	0	-
	Lesotho	0	-
	Angola	3	-
	South Africa	18	22
	Swaziland	-	-
	Tanzania	7	0
	Botswana	0	0
Evaluation of safety data	Zimbabwe	4	-
	DRC	3	-
	Zambia	0	-
	Malawi	0	-
	Madagascar	2	-
	Seychelles	-	-
	Namibia	0	-
	Angola	2	-
	Lesotho	0	-
	South Africa	15	29
	Swaziland	-	-
	Tanzania	2	5
	Botswana	0	0
Evaluation of efficacy data	Zimbabwe	4	-
	DRC	3	-
	Zambia	0	-
	Malawi	0	-
	Madagascar	0	-
	Seychelles	-	-
	Namibia	0	-
	Angola	2	-
	Lesotho	0	-
	South Africa	7	41
	Swaziland	-	-
	Tanzania	2	5
	Botswana	0	0

APPENDIX 5: COMPOSITION OF PHARMACEUTICAL ASSOCIATIONS IN SOME SADC NMRAS

Country	Associations	Membership
Zambia	Zambia Pharmaceutical Business Forum	Four manufacturers and 36 retailers and wholesalers
DRC	APHARCO, AFEPHAC, APPO, APHAC, UAPHARCO, SYNAPHACO	
Zimbabwe	Zimbabwe Pharmaceutical Manufacturers Association	
South Africa	Pharmaceutical Industry Association of South Africa (PIASA)	18 membership companies, representing multinational, local, innovator and generic companies on a South African and African level and globally through the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)
	Innovative Medicines South Africa (IMSA)	represent research-based manufacturers at regional level globally through IFPMA and through PhRMA in the Middle East and African Region
	Innovative Medicines South Africa (IMSA)	Diverse membership of 24 local and generic companies with representation at local and regional levels through the Southern African Generic Medicines Association (SAGMA) and at international level through Global Pharma Analytics (GPA)
	Self Medication Association of South Africa (SMASA)	Representation in excess of 90% of self-medication pharmaceutical industries
	PHARMSA	Seven member companies representing mainly empowered local manufacturers, who mainly manufacture for South Africa and export markets
Botswana	Pharmaceutical Association of Botswana	Membership composed of pharmacists and pharmacy technicians
Tanzania	Tanzania Pharmaceutical Manufacturers Association	Local manufacturers

For more information on African Medicines
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