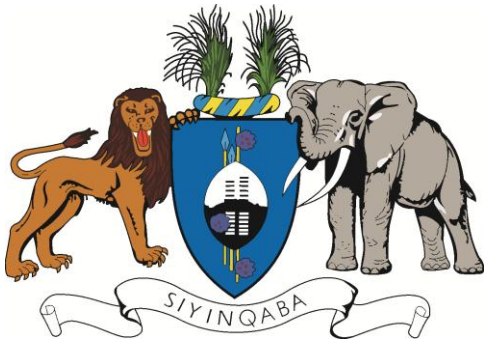
SWAZILAND PHARMACEUTICAL STRATEGIC PLAN

2012–2016



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ABBREVIATIONS AND ACRONYMS

AIDS	acquired immunodeficiency syndrome
ART	antiretroviral therapy
ARV	antiretroviral
AU	African Union
CDC	US Centers for Disease Control and Prevention
cGMP	current Good Manufacturing Practices
CHAI	Clinton Health Access Initiative
CMS	Central Medical Stores
DHS	Demographic Health Survey
E	Swaziland Lilangeni (currency of Swaziland)
EGPAF	Elizabeth Glaser Pediatric AIDS Foundation
EHCP	Essential Health Care Package
EML	essential medicines list
EU	European Union
FLAS	Family Life Association of Swaziland
FY	fiscal year
GDP	gross domestic product
HIV	human immunodeficiency virus
ICAP	International Centre for AIDS Care and Treatment Programs
IEC	information, education and communication
M&E	monitoring and evaluation
MCAZ	Medicines Control Authority of Zimbabwe
MoH	Ministry of Health
MoHSW	Ministry of Health and Social Welfare
MRA	Medicines Regulatory Authority
MSF	Médecins Sans Frontières (Doctors Without Borders)
MSH	Management Sciences for Health
MOU	memorandum of understanding
NGO	nongovernmental organisation
NHP	National Health Policy
NPP	National Pharmaceutical Policy
PEPFAR	US President's Emergency Plan for AIDS Relief
PMIS	pharmaceutical management information system
PPP	public-private partnership
PPSC	Partner Project Steering Committee
PSI	Population Services International
PTC	Pharmaceutical Therapeutic Committee
RHMT	Regional Health Management Team
ROC Taiwan	Republic of China Taiwan
SADC	Southern African Development Community
SANU	Southern African Nazarene University
SCTWG	Supply Chain Technical Working Group
SIAPS	Systems for Improved Access to Pharmaceutical Services

SID	Strategic Information Department
SNPP	Swaziland National Pharmaceutical Policy
SO	strategic objective
SOP	standard operating procedure
SPS	Strengthening Pharmaceutical Systems
SPSP	Swaziland Pharmaceutical Strategic Plan
SRA	Swaziland Revenue Authority
STG	standard treatment guidelines
SWAp	sector-wide approach to planning
TB	tuberculosis
TOR	terms of reference
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
UNISWA	University of Swaziland
URC	University Research Co.
USD	US dollar
WHO	World Health Organisation

FOREWORD

The second edition of the Swaziland National Pharmaceutical Policy (SNPP) was adopted by the Ministry of Health in 2011. The SNPP was developed in response to the need to review its predecessor, the National Pharmaceutical Policy of 2000, in view of the new challenges and changes in disease patterns facing the country's pharmaceutical sector. To implement the SNPP, the Swaziland Pharmaceutical Strategic Plan (SPSP) 2012–16 was developed.

The SPSP serves as a roadmap for SNPP implementation and charts the way forward to fully address the key policy orientations identified and prioritised in the SNPP, namely:

- Strengthening the National Pharmaceutical Services Administration
- Enacting enabling pharmaceutical legislation and regulations
- Strengthening the national pharmaceuticals supply chain system
- Strengthening pharmaceutical quality assurance
- Prioritising the financing of pharmaceuticals
- Developing pharmaceutical human resources
- Promoting rational medicine use
- Evaluating the use of traditional and complementary medicine
- Encouraging local production
- Promoting pharmaceutical research
- Facilitating technical intersectorial cooperation and coordination
- Monitoring and evaluation

The SPSP details the strategic objectives, strategies, activities and expected outcomes following the implementation of the identified priority strategic policy areas. The SPSP also includes a detailed and timed action plan to facilitate its operationalisation. The SPSP was developed through a widely consultative process involving all relevant stakeholders.

The Ministry of Health is committed to implementing the National Pharmaceutical Policy, through this strategic plan. I therefore encourage all stakeholders to fully participate in the successful implementation of this strategic plan, for the improvement of pharmaceutical services delivery in Swaziland.

Honourable Benedict Xaba
Minister of Health

ACKNOWLEDGMENTS

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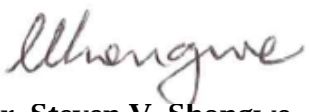

Dr. Steven V. Shongwe
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CHAPTER 1. INTRODUCTION

The Swaziland National Health Policy (NHP) 2007 raised key policy issues concerning the challenge of having adequate health resources, which includes access to safe medicine and diagnostic technology. To assure the quality of medicines and medical supplies, the NPH calls for the establishment of the Medicines Regulatory Authority (MRA) that will regulate the manufacture, importation, exportation, distribution and sale of pharmaceutical products and related commodities and ensure the quality and safety of medicines as well as their rational use.

Following this call, the Ministry of Health (MoH) developed the National Pharmaceutical Policy (NPP) in 2011. The overall goal of the NPP is to contribute towards improving the health of the Swaziland population by ensuring equitable access to and rational use of efficacious, high-quality essential medicines, medical supplies and devices at affordable cost.

To operationalise the NPP, the Swaziland Pharmaceutical Strategic Plan (SPSP), 2012–16, was developed. The SPSP provides the overall roadmap for pharmaceutical services development in the health sector. The roadmap focuses on priority areas including the National Pharmaceutical Services Administration, medicine supply, pharmaceutical quality assurance, traditional and alternative medicine, patents and global trade agreements.

1.1 Background

1.1.1 Geographic and Population Context

The population of Swaziland in 2007 was 1,018,449. About 77 percent of the population lives in rural areas and 23 percent in cities and townships. Regionally, the population is distributed as follows—Hhohho (331,734), Manzini (360,248), Shiselweni (241,365), Lubombo (249,153) (Central Statistics Office, 2007).

Women of childbearing age (i.e., 15–19 years) make up 26.2 percent of the total population; all females account for 53 percent. An estimated 4.6 percent of the population are 60 years of age or older. According to the Swaziland Demographic Health Survey 2006–07 (Ministry of Health, 2008), about 60 percent of the population are younger than 30 years, of which 39.6 percent are children under the age of 15 years. The total fertility rate is estimated at an average of 3.8 births in a woman's life compared to 6.4 births in 1986. Average life expectancy at birth has fallen from 60 years in 1997 to 43 years in 2007.

1.1.2 Socioeconomic Profile

Swaziland is classified as a lower middle-income country and has a gross domestic product (GDP) per capita income estimated at about USD 2,533 (World Bank, 2009). Income distribution is heavily skewed: 54.6 percent of the wealth is held by the richest 20 percent of the population, compared to 4.3 percent of the wealth held by the poorest 20 percent; 63 percent of the population lives below the upper poverty line of USD 8.80 per capita per month.

In the wake of the global downturn, GDP growth for 2009 is estimated to have been 1.2 percent of GDP, which represents a decline by 2.4 percent in 2008 (World Bank, 2011). According to the Ministry of Finance (Ministry of Finance, 2010), prospects for 2011 are less favourable, with GDP predicted to rise by 0.5 percent due to the need for fiscal adjustment. Swaziland's revenue has also been severely affected by the global downturn; approximately 60 percent of Government revenue was comprised of Southern African Customs Union receipts in 2008; it is estimated at 9.3 percent in 2010. Swaziland's middle-income status is misleading from a human development perspective. The DHS indicates that Swaziland is off-track to meet its Millennium Development Goal targets with goals 4 and 5 worsening.

The Human Development Index rose from 0.535 in 1980 to 0.641 in 1995, then declined to 0.572 in 2007 (World Health Organisation, 2010). Health outcomes are worsening due to high levels of HIV, AIDS and TB and limited progress with maternal, neonatal and child health.

1.1.3 Health Sector Profile

Health Status

The country's investment in health, over the years, has not resulted in expected improvement of some key health indictors. Both communicable and noncommunicable diseases continue to be a major challenge in the country. The situation has also been worsened by the advent of HIV and AIDS and the rising incidence of TB. The burden of communicable diseases is similarly reflected in the leading causes of inpatient morbidity and mortality, with AIDS and TB together accounting for over a third of admissions and deaths (Ministry of Health, 2010a).

The most cited reasons for admission include pulmonary diseases, malaria, gastroenteritis, colitis and pneumonia. Conversely, diabetes mellitus and noncommunicable diseases were reportedly among the top 10 leading causes of inpatient admissions in 2009. Others that have added in the burden include cancers, cardiovascular diseases, nutritional conditions and injuries or trauma.

In 2010, 11,057 new confirmed TB cases were reported, and the incidence has increased from 300 per 100,000 people in 1990 to 1,257 per 100,000 people in 2010. According to the National TB program's annual report 2010 (Ministry of Health, 2010c), 88 percent of TB patients have been tested for HIV and of these, 82 percent tested positive.

Universal access to antiretroviral therapy (ART) is one of the Millennium Development Goal's responses to the HIV/AIDS epidemic. By the end of September 2010, 55,296 (64.1 percent) people with HIV/AIDS were actively on treatment (49,907 adults and 5,389 children). Using the eligibility criteria of CD4 cell count, 350 cut-off point, approximately 77,156 are in need of ART and a projected 97,108 will be in need of ART by 2015 (Ministry of Health, 2010d).

The recent Swaziland DHS 2006–07 indicates that infant mortality is at 85 deaths per 1,000 live births, and under-five mortality is at 120 deaths per 1,000 live births; 70 percent of all deaths are reported to have taken place during the first year of the child's life.

Crude death rate per 1,000 population increased from 13 in 1990 to 26.2 in 2005 (World Bank, 2009). The infant mortality rate per 1,000 live births increased from 94.4 in 1990 to 108 in 2005 (World Bank, 2006). It is essential to note that malnutrition is one of the major factors contributing to high infant mortality, with high morbidity and mortality among children under five. Indeed, almost 20 percent of children in the country were found to be severely stunted and 5.1 percent severely underweight in 2004 (Ministry of Health, 2004).

The maternal mortality rate per 100,000 continued to increase in Swaziland from 229 in 2001 to 329 in 2005 and to 589 in 2007, despite high prenatal care attendance (97 percent), health facility–based delivery (74 percent) and skilled professional delivery (74 percent). The Maternal Death Review Audit of 2001 revealed that out of 16,898 live births that occurred between January and December 2000, there were 43 maternal deaths in four regional hospitals. Direct causes of maternal deaths accounted for 48.8 percent of all the deaths.

Organisation of the Health System

The Swaziland health system is based on the primary health care concept, consisting of three main levels: primary, secondary and tertiary. At the primary level are clinics and outreach services. The secondary level comprises health care centres, which offer both outpatient and inpatient services and serve as referral points for the primary level facilities. The tertiary level comprises regional hospitals, specialised hospitals and the national referral hospital. The health care system relies on both formal and informal sectors. The formal health service sector has both public and private health services providers including nongovernmental organisations (NGOs), missions and industrial and private practitioners. The informal sector consists mainly of traditional and other alternative health care providers.

In addition to the service delivery levels outlined above, the Central Medical Stores (CMS), the National Clinical Referral Laboratory, the National Blood Transfusion Service and the Biomedical Engineering Unit provide support services to clinical and public health programmes. CMS is responsible for the overall procurement, storage and distribution of all medicines, medical supplies and devices to public health institutions. For CMS to carry out its mandate effectively, nine regional pharmaceutical warehouses have been constructed in collaboration with development partners. These warehouses function as regional and facility storage and distribution centres to facility pharmacy units.

1.2 Situational Analysis

National Pharmaceutical Administration

The Pharmaceutical Services Department is located within the Directorate of Health Services in the MoH. It is headed by the chief pharmacist and tasked with numerous roles, which include organizing and directing all pharmaceutical activities.

Legislation and Regulation

Registration and regulation in Swaziland still refers to the Pharmacy Act of 1929. The main limitation of this act is that it does not provide for licensing of pharmaceutical outlets, scheduling of medicines, establishment of an MRA with all its functions, and registration of pharmaceutical businesses (professionals). A new Pharmacy Act and a Medicines and Related Substance Control Act have been drafted. They provide for the establishment of a pharmacy council and an MRA.

Supply

The country relies heavily on imports for medicines and medical supplies, with limited local production capacity. The Government uses the CMS as the main pharmaceutical warehouse mandated to manage the supply chain of medicinal commodities in the country. In this regard, it faces storage space constraints. The current warehouse, which is about 3,500 cubic meters, can only house six months' supply, so as a result, the existing inventory system is over-burdened.

Procurement of medicines and medical supplies is managed by the recently established procurement unit within the CMS. In principle, procurement is restricted to medicines and medical supplies listed in the national essential medicines list (EML).

Human Resources for Pharmaceutical Services

The human resources element has been recognised as the main challenge for pharmaceutical service provision in the country. In total, the country has 103 pharmacy personnel, of which 41 are pharmacy technicians (table 1).

Table 1. Breakdown of the Pharmaceutical Cadre

Paramedical or therapist categories	Swazi nationals	Facility category					
		Public	Private	Mission	NGO	Industrial	All
Pharmacists	35	17	39	3	3	0	62
Pharmacy technicians	17	31	5	3	2	0	41
Total	52	48	44	6	5	0	103

Access to Medicines

Medicines are provided free in all public health facilities with E 10 charged for consultation in hospitals, E 5 for radiology and E 3 for laboratory services. These charges may present a barrier for access to services for certain parts of the population, especially those with low or no income capacity. Currently, no regulation for medicine donations exists. It is important to note that the Office of the Chief Pharmacist is not notified of all donations to clear them. Local production is encouraged and promoted with certain conditions.

Quality Assurance

Quality assurance in the pharmaceutical services is almost non-existent (Prat, 2012; Ministry of Health, 1996). In addition to the absence of quality assurance procedures for imported and locally manufactured pharmaceutical products, no established quality assurance procedure for imported and manufactured pharmaceuticals, no registration of medicines, no adverse drug reaction monitoring (pharmacovigilance) and no functional quality control laboratory (personnel and equipment and reference standards) exists.

Financing

Procurement of pharmaceuticals, including antiretrovirals (ARVs) and medical products, is financed by Government. The budget allocated to pharmaceutical and medical supplies has been increasing over the years. The sustainability of the budget of pharmaceutical commodities is being threatened by the current fiscal crisis. Approximately 15 percent for the health sector budget is allocated to pharmaceutical and medical supplies.

Rational Use of Medicines

The rational use of medicine is compromised by the limited mechanisms for monitoring the use of medicine by health care workers and the general public. However, MoH developed and finalised the standard treatment guidelines and essential medicines list (STG/EML) in 2012 to address most of the gaps in the rational use of medicines in the country.

Traditional and Complementary Medicine

It remains a fact that a proportion of Swazis believe in, and use, traditional medicines. The absence of a traditional medicine policy inhibits collaboration between Western medicine and traditional medicine. The country is also faced with the emergence of complementary medicine marketing and supply, both of which are currently unregulated.

1.3 Core Pharmaceutical Issues to be Addressed by the SPSP

The SPSP aims to address the following core pharmaceutical issues as highlighted mainly in the situational analysis:

- Insufficiency of resources and capacity for pharmaceutical service provision
- Inadequacy of organizational structure of the pharmaceutical services
- Inadequacy of existing laws and regulations for the control of medicines and the practice of the pharmacy profession
- Limited management capacity of the supply chain

- Limited access to pharmaceuticals
- Absence of quality assurance systems
- Absence of an MRA
- Inefficient use of pharmaceutical medicines and medical supplies
- Inadequacy of collaboration between traditional health practitioners and health care workers
- Lack of incentives for local manufacturing in accordance with current Good Manufacturing Practices (cGMP)
- Lack of framework for operational research of priority areas or problem areas on pharmaceuticals

CHAPTER 2. OVERVIEW OF THE SPSP

2.1 Vision

SPSP's vision is to support the improvement of the health status of the Swazi population by ensuring equitable access to and rational use of quality essential medicines.

2.2 Mission

SPSP's mission is to provide efficacious quality and safe and cost-effective pharmaceuticals and services to the Swazi population.

2.3 General Objectives

SPSP's general objectives are to—

- Provide the National Pharmaceutical Administration with the necessary human and other resources to carry out all its functions
- Enact the necessary pharmaceutical laws and regulations for the proper monitoring and control of the national pharmaceutical sector
- Establish a functional MRA and a Pharmacy Council responsible for the regulation of all aspects of medicines and the pharmaceutical profession, respectively
- Establish quality assurance mechanisms and procedures for all medicines imported into, exported out of or manufactured in Swaziland
- Improve the capacity and performance of the CMS and health care facilities for efficient procurement, storage and distribution of essential medicines, including ARVs, and medical supplies and devices
- Increase current public funding for medicines to meet current and future demands and support ongoing national ART scale-up efforts
- Provide sufficient and qualified pharmaceutical human resources for the implementation of the SNPP
- Develop tools and initiatives for the promotion of rational medicine use among health care workers and the general public
- Promote collaboration between traditional healers, complementary medicines practitioners and health care workers

2.4 Scope

The SPSP will address the key issues and priority areas as elaborated in the pharmaceutical policy: the National Pharmaceutical Services Administration, legislation and regulations, medicine supply, pharmaceutical quality assurance, medicine financing, human resources, rational medicine use, traditional medicine, local production, research, patents and global trade agreements.

All the legislation, regulations and guidelines emanating from the implementation of the SPSP will be binding on all public and private sector pharmaceutical service providers.

2.5 Guiding Principles

The implementation of the SPSP will be guided by the following principles:

- **Human rights:** Respect for human dignity will be foremost, with specific focus on ensuring that the people are educated and the rights of the beneficiaries are guaranteed.

- **Ethics:** Confidentiality of intended beneficiaries will be maintained at all levels of service delivery.

- **Norms and standards:** Technical guidelines and protocols will be developed to ensure good management practices, rational use and quality assurance of pharmaceutical service delivery.

- **Equity:** Accessibility and affordability of quality pharmaceutical services at the point of demand for all clients, especially the vulnerable, marginalised and underserved, population irrespective of political or religious affiliation will be planned for.

- **Sustainability:** Sustainability and cost-effectiveness of all interventions in relation to pharmaceutical service delivery will be ensured.

- **Gender:** All pharmaceutical interventions will be gender sensitive at all levels of health service delivery.

- **Decentralization:** Decentralization of pharmaceutical services will be promoted and supported for efficient health care service delivery.

2.6 Planning Assumptions

The successful implementation of the SPSP will depend on the following assumptions:

- Availability of resources (human, financial and material) at all levels to support interventions as defined in the SPSP

- Political commitment from the Government of Swaziland

- Effective cooperation and collaboration among the public and private sectors and development partners

2.7 Pharmaceutical Strategic Plan Development Process

The SPSP has been developed through a participatory and extensive stakeholder consultation process. With technical support from development partners, MoH consulted widely internally and externally with health care professionals and other stakeholders. The process also involved extensive review and analysis of various policy documents and reports. To obtain a broad consensus on the plan, consultative workshops and sector technical working groups were involved in formulating, discussing, and adopting the pharmaceutical strategic plan.

2.8 Cost Implications of Implementation

The 2008–13 National Health Sector Strategic Plan identifies critical areas that require support and aims to improve poor health outcomes and inefficiencies. In addition, support for implementation comes from the highest level of the Government because the SPSP is considered a key sector in the country's plans for growth and development. With the assurance of the Government's commitment to prioritise and support health sector initiatives, pharmaceutical service development is likely to receive particular attention.

The costing of the SPSP has taken into account the current ongoing economic crisis that may last several years. The goal of costing the SPSP is to estimate the full cost of implementing the plan as well as all resource requirements in various service delivery levels, and to project future resource requirements for effective delivery of pharmaceutical services. The financial and technical support for the implementation of the SPSP will be provided mainly by the Government of Swaziland, with support from development partners and the private sector. In this regard, strong advocacy to development partners will be undertaken by the Government to ensure their support. (Annex A provides a summary of the costing assumptions used for planning.)

CHAPTER 3. KEY STRATEGIC AREAS FOR THE PHARMACEUTICAL SECTOR

To meet the overall goal of the SNPP, in line with the policy objectives, MoH has identified key strategic areas, which will be points of focus during the implementation of the SPSP. These strategic areas are—

1. National Pharmaceutical Services Administration
2. Legislation and regulations
3. Medicine supply
4. Quality assurance
5. Medicine finance
6. Human resources
7. Rational medicine use
8. Traditional and complementary medicine
9. Local production
10. Research
11. Technical, intersectorial cooperation and coordination
12. Monitoring and evaluation (M&E)

Each of these areas is outlined in this section in terms of expected outcomes, strategic objectives and strategies and interventions. A logic framework has been developed, which details the key interventions towards realizing the objectives as specified in the SNPP (annex B).

3.1 National Pharmaceutical Services Administration

Expected outcome: An efficiently managed pharmaceutical services sector in Swaziland

Strategic objective: To ensure an effective National Pharmaceutical Services Administration Unit to coordinate all functions and activities of the national pharmaceutical sector

Strategies and interventions

3.1.1 Strengthen the capacity of the National Pharmaceutical Services Unit to coordinate all pharmaceutical services in the country. Strengthening will entail the following:

- Capacitating the unit with appropriately skilled pharmaceutical personnel and other necessary resources
- Establishing the relevant technical committees to facilitate the achievement of the unit's mandate
- Establishing and maintaining a public and private sector pharmaceutical information system containing all medicine- and medical supply–related information in Swaziland to inform planning and decision making

3.1.2 Ensure continuous supply of essential medicines in Swaziland through the following:

- Institutionalising national quantification exercises for the estimation of medicine requirements at all levels of the health care delivery system
- Endorsing and implementing the WHO/Southern African Development Community (SADC) donation guidelines
- Establishing systems and guidelines for the disposal of expired, damaged and obsolete pharmaceuticals in collaboration with the relevant agencies

3.1.3 Ensure that the strategic orientation of the National Pharmaceutical Services Administration is aligned with those of the subregion, by maintaining Swaziland's participation in the on-going subregional initiatives, including the SADC and African Union (AU) harmonization processes.

3.1.4 Ensure the development partners provide coordinated support to the pharmaceutical sector through the following:

- Establishing and implementing a mechanism to coordinate and guide development partner interventions in the pharmaceutical sector
- Establishing and managing a public–private partnership (PPP) framework in the pharmaceutical sector.

3.2 Legislation and Regulations

Expected outcome: Effectively and efficiently regulated pharmaceutical sector services and products in Swaziland

Strategic objective: To enact and implement the necessary pharmaceutical legislation and regulations to ensure the effective control of pharmaceuticals and the pharmacy profession

Strategies and interventions

3.2.1 Strengthen the legislative framework of the pharmaceutical sector in Swaziland through the following:

- Advocating for the enactment of the Medicines and Related Substances Control Act and the Pharmacy Act
- Sensitising stakeholders on the Medicines and Related Substances Control Act and the Pharmacy Act
- Enforcing the Medicines and Related Substances Control Act and the Pharmacy Act

3.2.2 Ensure the prompt implementation of the Medicines and Related Substances Control Act and the Pharmacy Act through the following:

- Initiating the process for the establishment of the MRA by the Medicines and Related Substances Control Act
- Initiating the process for the establishment of the Pharmacy Council by the Pharmacy Act

3.3 Supply of Pharmaceuticals

Expected outcome: Availability of the right products, at the right time, in the right quantities and quality, at the right place and at the right cost

Strategic objective: To ensure efficient procurement, storage and distribution of sufficient quantities of quality pharmaceuticals

Strategies and interventions

3.3.1 Strengthen the procurement of pharmaceuticals in the country through the following:

- Reviewing the CMS structure to address its procurement, warehousing, distribution and quality assurance functions
- Advocating for the adoption and implementation of the new CMS organizational structure
- Developing and implementing standards, guidelines and procedures for the procurement of pharmaceuticals
- Developing and implementing a supplier performance assessment system
- Building capacity of the CMS and the national procurement units

3.3.2 Optimise and secure the storage and distribution of commodities within the supply chain through the following:

- Establishing and enforcing a control and monitoring mechanism for accountability in the management of pharmaceuticals
- Strengthening the security of pharmaceuticals at all levels of the supply chain
- Improving and expanding the pharmaceutical storage capacity across all levels within the supply chain
- Adopting, adapting and enforcing WHO guidelines on good storage and distribution practices

3.3.3 Promote the use of appropriate existing and emerging technology to improve supply chain management by strengthening of the use of technology in supply chain management in all levels of the supply chain.

3.4 Pharmaceutical Quality Assurance

Expected outcome: Good quality pharmaceuticals used in Swaziland

Strategic objective: To ensure that all medicines used in Swaziland are safe, efficacious and of assured quality

Strategies and main interventions

3.4.1 Establish the MRA through the following:

- Putting in place the MRA Unit with all necessary resources
- Fostering the formation of formal links between the MRA and other regulatory authorities in the region

3.4.2 Strengthen the regulatory capacity of the MRA through the following:

- Establishing the medicines registration system for all pharmaceuticals used in Swaziland
- Establishing a Pharmacovigilance and Drug Information Unit
- Establishing and capacitating a National Pharmaceutical Quality Control Laboratory
- Establishing the Inspectorate Unit for the pharmaceutical sector

3.5 Medicine Financing

Expected outcome: Efficient financing mechanisms for pharmaceuticals

Strategic objective: To provide adequate funding to ensure regular supply of sufficient pharmaceuticals

Strategies and main interventions

3.5.1 Improve pharmaceuticals financing in the country through the following:

- Advocating for adequate budget allocation for pharmaceuticals
- Establishing and implementing a pricing policy for pharmaceuticals in Swaziland

- Developing guidelines for pharmaceuticals financing in the country
- Examining alternative approaches to pharmaceuticals financing and implementing appropriate approaches

3.5.2 Strengthen coordination and monitoring mechanisms in medicine financing through the following:

- Establishing and implementing control and monitoring mechanisms for accountability in the use of pharmaceutical funds
- Defining and establishing a coordination mechanism for the MoH to capture and document all sources of finances for pharmaceuticals

3.6 Human Resources

Expected outcome: Availability of adequate and skilled pharmaceutical personnel in Swaziland

Strategic objective: To provide sufficient qualified pharmaceutical personnel for the efficient provision of pharmaceutical services

Strategies and main interventions

3.6.1 Build capacity and expand the local source of skilled pharmaceutical personnel through the following:

- Developing and implementing a National Pharmaceutical Human Resource Plan that is in line with the Health Sector Human Resource Development Plan
- Establishing training for pharmaceutical personnel in the institutions of higher learning in Swaziland
- Providing interim training of pharmaceutical personnel in institutions outside of Swaziland
- Ensuring continuous professional development

3.6.2 Improve the recruitment, retention and working conditions for pharmaceutical personnel in the public and private sectors through the following:

- Ensuring that all pharmaceutical personnel posts are filled with appropriately qualified personnel
- Advocating for the creation of sufficient pharmaceutical personnel posts within MoH

- Developing an orientation programme for newly recruited pharmaceutical personnel
- Developing and implementing retention strategies for pharmaceutical personnel in the public sector
- Establishing minimum wage standards for pharmaceutical personnel in the private sector

3.6.3 Ensure that all personnel handling pharmaceuticals are competent in drug supply management by capacitating the non-pharmaceutical personnel responsible for pharmaceuticals at lower levels of health care delivery

3.7 Rational Medicine Use

Expected outcome: Pharmaceuticals used rationally to improve therapeutic outcomes in patients in the country

Strategic objective: To ensure the rational use of medicines by both health care workers and patients to maximise the medicines' therapeutic benefits

Strategies and main interventions

3.7.1 Promote rational medicine use among health care workers and in the community through the following:

- Incorporating rational medicine use content into existing curriculum for all health care professionals
- Providing continuing education to staff on rational medicine use
- Educating the community on rational medicine use
- Regulating the advertising and promotion of pharmaceuticals

3.7.2 Strengthen the use of the STGs/EML and the Pharmaceutical Therapeutic Committees (PTCs) in the country through the following:

- Enforcing the use of STG/EML in the public sector and encouraging the private sector to comply
- Creating a mechanism to review the STG/EML
- Enforcing generic prescribing and dispensing and establishing regulatory measures to allow for generic substitution
- Establishing a mechanism that will enable MoH to coordinate and monitor the performance of PTCs

3.8 Traditional and Complimentary Medicines

Expected outcome: Collaboration between MoH and traditional and complementary practitioners in the provision of quality health care services

Strategic objective: To maximise the use of positive aspects and minimise the negative consequences of traditional and complementary medicine in the provision of health care services

Strategies and main interventions

3.8.1 Establish mechanisms for collaboration between traditional and complementary practitioners and MoH through developing a collaborative framework between MoH and traditional and complementary practitioners and coordinating services and activities between traditional and complementary practitioners and MoH

3.8.2 Regulate the practice of complementary medicine practitioners by establishing a mechanism for overseeing the activities related to the safety and efficacy of complementary medicines as well as claims made by the practitioners

3.9 Local Production

Expected outcome: Increase in the number of local production units and locally manufactured products

Strategic objective: To encourage local production as one way of improving access to medicines

Strategies and main interventions

3.9.1 Promote the establishment of new local production units through the following:

- Advocating for incentives to stimulate local manufacturing
- Creating an enabling and transparent environment to access the incentives

3.9.2 Strengthen the compliance of local production units to cGMP by encouraging local production units to upgrade their cGMP status

3.10 Research

Expected outcome: A pharmaceutical research program that is able to inform planning and decision making

Strategic objective: To foster research aimed at resolving problem areas of the Swaziland pharmaceutical sector

Strategies and main interventions

3.10.1 Improve the regulation of pharmaceutical research in Swaziland through the following:

- Building the capacity of MoH Research Unit
- Ensuring that clinical trials are well regulated and monitored by the relevant authorities

3.10.2 Promote research in pharmaceutical priority areas through the following:

- Identifying pharmaceutical priority areas for research in Swaziland
- Encouraging operational research in the pharmaceutical sector

3.11 Technical Intersectorial Cooperation and Coordination

Expected outcome: Coordinated efforts and resource maximization of pharmaceutical interventions

Strategic objective: To strengthen the cooperation and coordination between MoH and other Government ministries and development partners

Strategies and main interventions

3.11.1 Improve the collaboration between MoH and relevant ministries, organisations and agencies on pharmaceutical matters through the following:

- Collaborating with other ministries and public institutions on pharmaceutical issues
- Collaborating with development partners, NGOs and regional organisations on pharmaceutical matters

3.11.2 Build consensus amongst all stakeholders by—

- Establishing a mechanism for effective involvement of relevant stakeholders on pertinent pharmaceutical matters as required
- Establishing a mechanism for disseminating relevant pharmaceutical information to both the public and private sectors
- Fostering a sense of ownership amongst the public and private sector on pharmaceutical issues

3.12 Monitoring and Evaluation

Expected outcome: A fully functional M&E system for pharmaceutical services

Strategic objective: To ensure effective M&E of the implementation of the SPSP

Strategies and main interventions

3.12.1 Establish an M&E system for the SPSP through the following:

- Conducting a baseline study of pharmaceutical services in Swaziland
- Developing an M&E operational framework for the pharmaceutical sector
- Building the M&E capacity for the pharmaceutical sector across all levels of health service delivery
- Developing a coordinating mechanism for the implementation of the SPSP

CHAPTER 4. IMPLEMENTATION ARRANGEMENTS

The overall responsibility for implementing the SPSP lies with MoH. Using the sectorwide approach to planning (SWAp), MoH will coordinate the participation of all stakeholders in the pharmaceutical subsector. Implementation of the SPSP will be undertaken at all levels of decision making and service delivery with support from development partners.

The guiding principles of the SPSP will be adhered to in the private sector. The Pharmacy Council, MRA and technical committees will regulate and advise the private sector.

4.1 Central Level

The Office of the Director of Health Services is mandated to supervise the coordination and implementation of the SPSP. The Office of the Head of Pharmaceutical Services will be responsible for the technical coordination of the implementation of the SPSP, with guidance from the Pharmacy Council, the MRA and various technical committees at different levels. The representative from the Office of the Head of Pharmaceutical Services will be secretary of technical committees whose establishment may be deemed necessary for the implementation of the plan. Chairpersons of these committees will be appointed by MoH as recommended by the Head of Pharmaceutical Services. In addition, MoH will be responsible for resource mobilization and allocation of funds to implement the interventions outlined in the plan.

The coordination of pharmaceutical supply chain management and logistics, in the public sector, lies with the CMS. The Procurement Unit is responsible for purchasing all pharmaceutical and medical supplies.

4.2 Regional Level

The Regional Health Management Team (RHMT), which includes the regional pharmacists, is the decision-making body at regional level. This team is responsible for the implementation of the SPSP at the regional level, including M&E, supply chain coordination, mentoring and supervision.

4.3 Facility Level

The PTCs advise the facility practitioners on rational use of medicines and monitoring of adverse effects. Pharmacy personnel are responsible for quantification and forecasting of pharmaceutical requirements. Health facilities are required to provide necessary information to RHMTs for planning and decision making.

CHAPTER 5. MONITORING AND EVALUATION

The SPSP cannot be effectively implemented without an M&E framework. The M&E framework describes different structures and mechanisms for the monitoring and assessment of the SPSP. This framework will be accompanied by a costed road map outlining all M&E-related activities in line with the SPSP strategic objectives. A set of core indicators at all levels (i.e., inputs, process indicators, outputs, outcomes) will be defined to measure the extent of the SPSP interventions:

- **Inputs** will be applied to monetary assets, human resources (including building their capacity) and infrastructures.

- **Process indicators** will assess the degree of completion of each set of planned activities at all levels.

- **Outputs** will be assessed in terms of pharmaceutical service coverage, service delivery and the number of beneficiaries reached.

- **Outcomes** will be assessed in terms of the degree of meeting the specific objectives as outlined in the SPSP.

The implementation of the M&E framework of the SPSP will be coordinated by the National Health M&E Unit within MoH.

5.1 Routine Monitoring

Quarterly progress reports based on supervisory field visits and endorsed aggregated facility and program generated reports will inform decision making during the implementation time frame of the SPSP.

5.2 Evaluation

Before implementation, a baseline assessment will be carried out to enable measurement of performance indicators in the SPSP. The evaluation of the implementation of SPSP will be carried out at midterm as well as at the end of the five-year period. Midterm will offer the opportunity to learn from experience of the first two and a half years on the implementation, taking corrective measures where actions have not been effective, and to reorient parts of the plan in response to unforeseen challenges.

CHAPTER 6. COSTING THE SPSP

The final step of the development of the SPSP is costing the interventions outlined in the strategic plan. The costing of the SPSP aims at quantifying the total amount of resources required to effectively implement the SPSP. The costs are standardised and costing the strategic plan will assist in a phased implementation of the SPSP.

The 2008–13 National Health Sector Strategic Plan, a guiding document for the SPSP, aims to improve health outcomes and inefficiencies in the country and to identify critical areas that require support. The highest level of the Government supports health because it is considered a key sector in the country's plans for growth and development. With the assurance of the Government's commitment to prioritise and support health sector initiatives, pharmaceutical service development is likely to receive particular attention.

6.1 Methodology

The costing of the SPSP was carried out according to the strategies and interventions identified under each of 12 strategic objectives over the three-fiscal-year period 2012 through 2014 that begins in April 2012 and ends in March 2015. The SPSP costing exercise was conducted by MoH Pharmaceutical Services Department, the Planning Unit and the Directorate. The costing activity was carried out with technical assistance from SIAPS. Other partners that were consulted during the costing exercise include WHO, Médecins Sans Frontières (Doctors Without Borders) (MSF), the Clinton Health Access Initiative (CHAI), and the National Emergency Response Council on HIV and AIDS (Global Fund).

This SPSP is the first for Swaziland, and the purpose of the proposed interventions is to address the gaps identified and defined in the SNPP (second edition). Therefore, the SPSP is aimed at complementing the ongoing pharmaceutical services activities. Since the SPSP will be implemented for the first time, most of the interventions and activities defined in the action plans for the first three fiscal years (FYs) are mainly focused on the following:

- Staffing key pharmaceutical areas
- Capacity building of staff through trainings, workshops, meetings and technical support from partner organizations
- Capacitating various pharmaceutical units with the necessary resources to make them functional and efficient
- Using assessments and evaluations to identify effective and efficient approaches in implementing the plan in the later stages of SPSP

Interventions to be undertaken in years 4 and 5 will be dependent upon the findings from research and the milestones and accomplishments achieved in the first three-fiscal-year period. (See annex C for the SPSP action plan 2012–14.)

Therefore, the incremental costs of additional interventions and activities to be carried out from April 2012 to March 2015 were estimated during the costing exercise. The incremental costs are additional costs to MoH that would not have been incurred if the SPSP was not being implemented. Costing was based on a provider's perspective which means that only costs that providers pay were included. All costs have been presented in 2011–12 prices. The adjustment for salary has been made according to the current Government policy (i.e., no salary increments for the FYs 2012–13 to 2014–15 due to the prevailing fiscal situation).

Costs that have already been incurred, such as costs associated with existing staff and ongoing activities, were excluded. Costs for resources that will be shared across strategic objectives (SOs) will be allocated based on the projected use level. For newly recruited staff, however, who may spend time on more than one SO, the total costs associated with the staff will be fully assigned to the SO under which the staff were first recruited because each new staff is expected to be hired as a full-time employee. If staff costs were to be allocated to all SOs that staff will work on, the total costs required to implement the SPSP would be underestimated if some SOs were not prioritised for implementation.

The capital has to be acquired at the price of capital items. To present the investment required in implementing the SPSP, capital costs were estimated based on full costs with no depreciation or amortization. The costing, however, should be refined in accordance with the action plans and operational plans.

Costing data collection was based on the unit cost and quantity information. The costing emphasised the use of in-country sources of information and discussions with MoH officials. Unit costs for items that are currently available or in use in Swaziland, such as salaries, transport and meetings were based on the latest available data. When local data were not available, data were obtained through consultation with experts and neighbouring countries that had relevant similar experience. For new interventions that have not been introduced in Swaziland, data from neighbouring countries were used and adjusted to the context of the Swaziland pharmaceutical system. Unit costs were assumed to remain constant over the analysis period except for salaries, which were assumed to be fixed until 2014 and then increasing at 5 percent per annum from 2015 onwards. References and assumptions used in costing of SPSP are provided in annex A.

6.2 Cost Categories

The main cost components included are human resources, office supplies, communication, maintenance, capital, research and evaluation, development of printing materials, meetings and technical support through partner organizations (table 2).

Table 2. Cost Categories

Category	Item
Recurrent costs	
Human resources	Salaries and benefits of MoH staff
Office supplies	Paper, office materials
Fuel, communication and maintenance	Utility, telephones, Internet connection, maintenance of equipment
Capital	
Equipment	Computers, printers, laboratory equipment, incinerator
Vehicles	Vehicles
Implementation costs	
Meetings	Meeting venues, meals, coffee breaks, honoraria
Supervision	Activities to support and monitor implementation, transport costs
Recruitment	Job advertisement
Research and evaluation	Feasibility study, assessments, evaluation, research activities to generate data and evidence
Guidelines, standard operating procedures (SOPs) and materials	Development and printing of guidelines, SOPs, and information, education and communication (IEC) materials
Technical assistance	External assistance from technical experts or consultants

6.3 Cost of the SPSP

The implementation costs of the SPSP are estimated and presented for 12 SOs. Overall, approximately E 21 million will be required to implement the SPSP over the analysis period. Table 3 shows the annual costs associated with phased implementation of the SPSP by strategic objective. The annual cost is highest in the first year at E 10,587,759, decreasing to E 5,652,444 and E 4,801,010 in years 2 and 3, respectively.

Table 3. Implementation Costs per Year by Strategic Objective (E, millions)

Strategic objective	FY 2012	FY 2013	FY 2014	Total	% Y1	% Y2	% Y3	% Total
SO1: To ensure an effective National Pharmaceutical Services Administration Unit to coordinate all functions and activities of the national pharmaceutical sector	326,790	990,412	1,171,874	2,489,076	13.1	39.8	47.1	11.8
SO2: To enact and implement the necessary pharmaceutical legislation and regulations to ensure the effective control of pharmaceuticals and the pharmaceutical profession	64,800	347,590	142,880	555,270	11.7	62.6	25.7	2.6
SO3: To ensure efficient procurement, storage and distribution of sufficient quantities of quality pharmaceuticals	7,440,418	771,859	713,632	8,925,909	83.4	8.6	8.0	42.4
SO4: To ensure that all medicines used in Swaziland are safe, efficacious and of assured quality	940,447	2,003,315	1,660,655	4,604,417	20.4	43.5	36.1	21.9
SO5: To provide adequate funding to ensure regular supply of sufficient pharmaceuticals	164,295	156,240	23,800	344,335	47.7	45.4	6.9	1.6
SO6: To provide sufficient qualified pharmaceutical personnel for the efficient provision of pharmaceutical services	305,720	560,150	430,718	1,296,588	23.6	43.2	33.2	6.2
SO7: To ensure the rational use of medicines by both health care workers and patients to maximise their therapeutic benefit	1,110,043	463,549	386,749	1,960,341	56.6	23.6	19.7	9.3
SO8: To maximise the use of positive aspects and minimise the negative consequences of traditional and complementary medicine in the provision of health care services	7,500	19,400	3,000	29,900	25.1	64.9	10.0	0.1
SO9: To encourage local production as one way of improving access to medicines	38,390	11,700	4,800	54,890	69.9	21.3	8.7	0.3
SO10: To foster research aimed at resolving problem areas of the Swaziland pharmaceutical sector	22,500	42,900	16,000	81,400	27.6	52.7	19.7	0.4
SO11: To strengthen cooperation and coordination between the MoH and other government ministries and development partners	18,300	48,800	48,800	115,900	15.8	42.1	42.1	0.6
SO12: To ensure effective monitoring and evaluation of the implementation of the SPSP	148,556	236,529	198,102	583,187	25.5	40.6	34.0	2.8
Total	10,587,759	5,652,444	4,801,010	21,041,213	50.3	26.9	22.8	100

Figure 1 presents the total costs over the three-FY period by SO. SO3 (to ensure efficient procurement, storage and distribution of sufficient quantities of quality pharmaceuticals) is the largest cost component of the SPSP. SO3 includes strategies and interventions such as establishing network facilities for the use of Quantimed® and PipeLine® software systems, the development of the commodity tracking system and hiring a CMS pharmacist. SO3 requires approximately E 8.9 million, SO4 (to ensure that all medicines used in Swaziland are safe, efficacious and of assured quality) about E 4.6 million and SO1 (to ensure an effective National Pharmaceutical Services Administration Unit to coordinate all functions and activities of the national pharmaceutical sector) approximately E 2.4 million, which represent 42, 22 and 12 percent of the total cost, respectively. The remaining nine SOs are accountable for 24 percent (approximately E 5 million) of the overall cost.

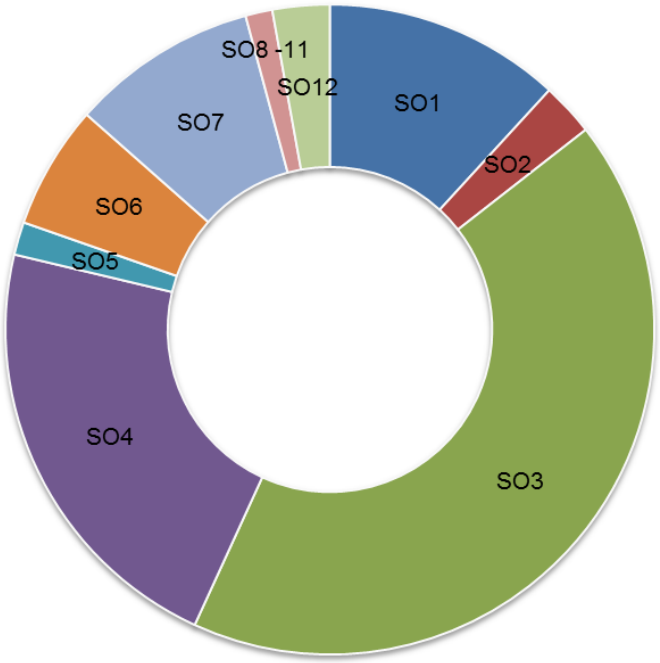

Figure 1. Cost of SPSP by SO, FY 2012–14

In figure 2 the costs are classified by SO and FY. Investment in SO3 and SO7 (to ensure the rational use of medicines by both health care workers and patients to maximise their therapeutic benefit) will require a large share of costs in the first year. Costs associated with SO1 are expected to increase from year 1 to year 3 as the Office of Pharmaceutical Services is capacitated with suitably skilled staff to coordinate and support pharmaceutical services activities.

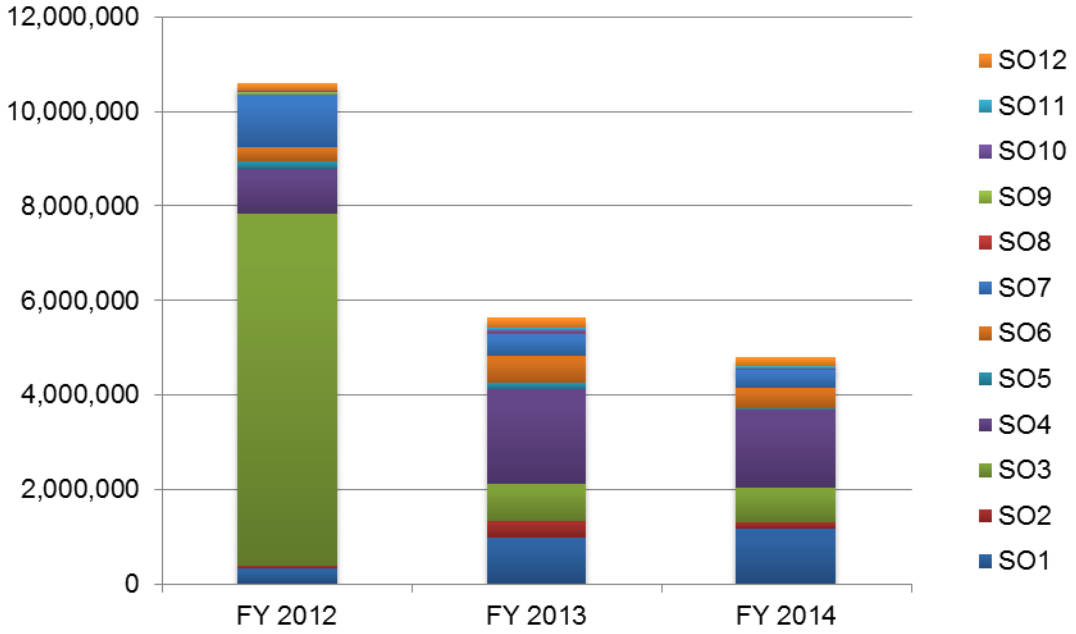

Figure 2. Cost of SPSP by strategic objective and FY

Because almost all strategies and interventions in the SPSP will be introduced in Swaziland for the first time, capacity building and a significant investment in capital and human resources are required. Various activities have to be activated in the first year to pave the way for other activities. In addition, a number of feasibility and situation analyses must be conducted to improve the understanding of the pharmaceutical systems in the country. Therefore, the total cost in year 1 of E 10,587,759 is highest, compared to the next two years, as depicted by figure 2. Experiences from neighbouring countries provide a threshold level of types and quantities of resources needed. Having adequate capacity and resources is essential in ensuring success in implementing the SPSP.

As demonstrated in table 4, when shown according to cost category, the costs in the first year are driven primarily by capital costs; research and evaluation; development of guidelines, SOPs and materials; and technical assistance. A financial commitment will be required in the first year to capacitate and prepare relevant MoH units for successful implementation of SPSP.

Table 4. Cost of SPSP by Category and FY (E, millions)

Cost category	FY 2012	FY 2013	FY 2014	Total	% Y1	% Y2	% Y3	% Total
Recurrent costs	547,786	3,101,607	3,297,779	6,947,172	7.9	44.6	47.5	33.0
Human resources	199,996	2,457,276	2,467,335	5,124,607	3.9	48.0	48.1	24.4
Office supplies	3,350	21,900	36,300	61,550	5.4	35.6	59.0	0.3
Fuel, communication and maintenance	344,440	622,431	794,144	1,761,015	19.6	35.3	45.1	8.4
Capital	7,167,909	86,000	100,000	7,353,909	97.5	1.2	1.4	35.0
Equipment	6,767,909	86,000	100,000	6,953,909	97.3	1.2	1.4	33.0
Vehicles	400,000	—	—	400,000	100.0	0.0	0.0	1.9
Implementation costs	3,307,453	2,029,447	1,403,231	6,740,131	49.1	30.1	20.8	32.0
Meetings	381,500	834,387	892,501	2,108,388	18.1	39.6	42.3	10.0
Supervision	3,000	27,000	30,600	60,600	5.0	44.6	50.5	0.3
Recruitment	81,000	90,000	—	171,000	47.4	52.6	0.0	0.8
Research and evaluation	183,715	43,400	—	227,115	80.9	19.1	0.0	1.1
Guidelines, SOPs and materials	792,450	230,010	107,850	1,130,310	70.1	20.3	9.5	5.4
Technical assistance	1,865,788	804,650	372,280	3,042,718	61.3	26.4	12.2	14.5
Total	11,023,148	5,217,054	4,801,010	21,041,213	52.4	24.8	22.8	100.0

(—) No costs are associated with that particular cost category for that fiscal year.

Figure 3 shows the cost breakdown by category over the three-FY period. Overall, capital costs are a little higher than the recurrent costs and implementation costs. A capital cost corresponds to an input to the SPSP that has a useful life of more than one year and that will not recur every year. A recurrent cost, conversely, corresponds to resources that will be consumed or replaced in one year or less. Equipment such as computers, printers, laboratory equipment and incinerators, all of which are capital costs, contributed about 35 percent to the total costs. Costs associated with human resources are the second largest cost driver representing 24.4 percent of the total costs. The third largest cost category is support and assistance from technical experts and consultants (14.5 percent) to build and strengthen the pharmaceutical services capacity.

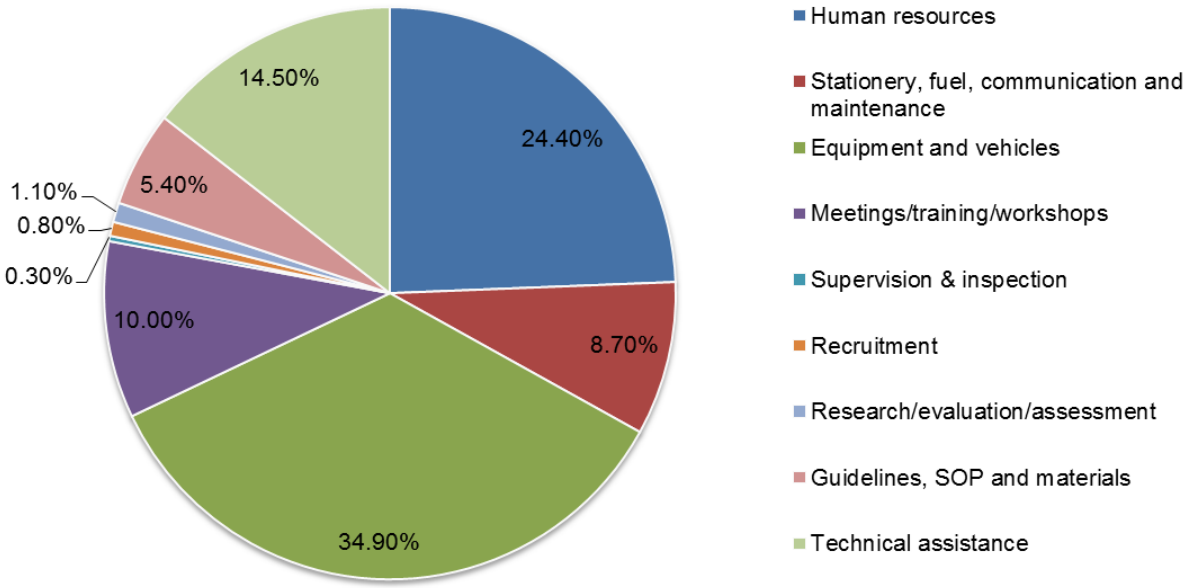

Figure 3. SPSP by cost category

6.4 Financing Gap Analysis

The financing component will focus on the incremental costs, that is, the additional costs that will be incurred as a result of implementing the SPSP activities. As such, the current MoH expenditure on pharmaceutical services of E 261,354,018.59 (pharmaceuticals and pharmaceutical personnel) will not be factored into the financial gap analysis because the new SPSP activities had not been included in the 2012–13 budget. The approved incremental costs associated with the SPSP activities will be known once the 2013–14 budget has been approved by Parliament.

In addition, it can be difficult for development partners to commit future funds for SPSP activities because budgets are reviewed and approved annually. Thus, the financing gap analysis could not be finalised at this point because it requires information that is not yet available. The

financing component, and financing gap of the SPSP, will be calculated before the SPSP's mid-term review.

6.5 Conclusion

Since costs are determined by available funds and activities, and costs in subsequent years depend on activities achieved in prior years, periodic review and evaluation of the SPSP and indicators are required to adjust the activities, interventions and costs and to determine the funds to be available and disbursed for subsequent years.

The cost estimates produced and presented in this report, however, do not represent the total amount required to implement all interventions for achieving all of the strategic goals primarily because the types of investment and interventions to be implemented beyond March 2015 and their costs will be determined by activities and outcomes in the first three fiscal years. In addition, the SPSP was developed to complement the ongoing activities to address the gaps in the pharmaceutical sector.

6.6 Next Steps

The costing chapter of the SPSP will inform the MoH budgeting process and shall be used for advocacy purposes for the allocation of adequate funds for pharmaceutical services by the Ministry of Finance.

The costing information will also be used to coordinate partner interventions, to ensure that there is no duplication of efforts and subsequent inefficient utilization of resources by partners in their support to the pharmaceutical services department.

The financing gap analysis will be conducted once the partner coordinating mechanism has been established to capture and coordinate partner financial contributions to the activities of the SPSP.

The SPSP as a whole shall guide partner interventions as it, along with the SNPP, gives the strategic position and orientation of MoH with regards to the pharmaceutical sector in country.

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ANNEX A. COSTING ASSUMPTIONS

Table A1. Summary of Unit Costs and Assumptions

Item	Unit cost (E)
SO1: To ensure an effective National Pharmaceutical Services Administration Unit to coordinate all functions and activities of the national pharmaceutical sector	
Senior pharmacist annual salary and benefits[a,b]	258,300
Principal pharmacist annual salary and benefits[a,b]	364,096
Data clerk annual salary and benefits[a,b]	48,750
Boiler attendant annual salary and benefits[a,b]	40,955
Meeting cost per day	5,300
Advertisement (3 days)	18,000
Cost per unit of laptop computer	17,000
Cost per unit of desktop computer	10,000
Annual maintenance cost for computers	10% of computer costs
Printing cost per document	38.8
Printing cost per IEC/campaign material	11.5
Cost per incinerator	72,909
Annual maintenance cost for incinerator	7,291
Cost per day TV broadcast	9,500
SO2: To enact and implement the necessary pharmaceutical legislation and regulations to ensure the effective control of pharmaceuticals and the pharmaceutical profession	
Meeting cost per day	5,300
Cost per road show event (2 days)	32,400
Advertisement (3 days)	18,000
Printing cost per IEC/campaign material	11.5
SO3: To ensure efficient procurement, storage and distribution of sufficient quantities of quality pharmaceuticals	
CMS pharmacist annual salary and benefits[a,b]	244,279
Advertisement (3 days)	18,000
Cost per unit of desktop computer	10,000
Annual maintenance cost for computers	10% of computer costs
Meeting cost per day	5,300
Printing cost per document	38.8
Installation of computer and network facilities for Quantimed and PipeLine	6,320,000
Annual cost of maintenance of network facilities	120,000
SO4: To ensure that all medicines used in Swaziland are safe, efficacious and of assured quality	
MRA registrar annual salary and benefits[b]	333,951
MRA pharmacovigilance annual salary and benefits[b]	244,279
Pharmacy technician annual salary and benefits[b]	107,267
Advertisement (3 days)	18,000
Cost per unit of laptop computer	17,000
Annual maintenance cost for computers	10% of computer costs
Cost per unit of printer	5,000
Cost per sedan vehicle	150,000
Cost per minivan vehicle	250,000
Meeting cost per day	5,300
WHO membership annual fee	14,420
Journal subscription	14,420–28,840

Item	Unit cost (E)
Laboratory equipment for quality control	350,000
Annual maintenance cost for laboratory equipment	10% of equipment costs
Annual pharmaceutical inspection activity fee	62,613
Annual cost of implementing active surveillance	197,500–316,000
SO5: To provide adequate funding to ensure regular supply of sufficient pharmaceuticals	
Meeting cost per day	5,300
Printing cost per document	38.8
SO6: To provide sufficient qualified pharmaceutical personnel for the efficient provision of pharmaceutical services	
Meeting cost per day	5,300
Costs of scholarship per student to be awarded by Ministry of Labour and Social Security	81,470
SO7: To ensure the rational use of medicines by both health care workers and patients to maximise their therapeutic benefit	
MRA inspectorate annual salary and benefits[b]	244,279
National Environment Management Council secretariat annual salary and benefits[b]	48,570
Meeting cost per day	5,300
Printing cost per IEC/campaign material	11.5
Printing cost per document	38.8
Cost per campaign	27,000
Advertisement (3 days)	18,000
SO8: To maximise the use of positive aspects and minimise the negative consequences of traditional and complementary medicine in the provision of health care services	
Meeting cost per day	5,300
Printing cost per document	38.8
SO9: To encourage local production as one way of improving access to medicines	
Meeting cost per day	5,300
Printing cost per document	38.8
SO10: To foster research aimed at resolving problem areas of the Swaziland pharmaceutical sector	
Meeting cost per day	5,300
Printing cost per document	38.8
Cost per unit of printer	5,000
Cost per unit of desktop computer	10,000
Annual maintenance cost for computers	10% of computer costs
SO11: To strengthen cooperation and coordination between MoH and other government ministries and development partners	
Meeting cost per day	5,300
Cost per conference package including materials	29,000
SO12: To ensure effective M&E of the implementation of the SPSP	
Pharmaceutical M&E officer annual salary and benefits[b]	197,102
Meeting cost per day	5,300
Cost per unit of printer	5,000
Cost per unit of desktop computer	10,000
Annual maintenance cost for computer	10% of computer costs
Printing cost per document	38.8

[a]Source is MoH

[b]Including the benefit of 15 percent pension and housing allowance of E 1,000; salary freeze until 2014 with a 5 percent increase in 2015

Medicines Regulatory Authority Establishment Assumptions

Building on intervention 2.4 (initiate the process for the establishment of the MRA by the Medicines and Related Substances Control Act) and 2.5 (initiate the process for the establishment of the Pharmacy Council by the Pharmacy Act) in the first three years, the main resources required for establishing and running the MRA are described. Because little information or data are available in Swaziland for conducting regulatory activities, data from neighbouring countries were used. The countries benchmarked against are included Namibia, Zimbabwe and Botswana. These factors considered in selecting these countries included; regional proximity, participation in SADC regional harmonization, population size and development status, among others (table A.2).

Table A2. Characteristics of Benchmarking Countries

Characteristic	Swaziland	Namibia	Botswana	Zimbabwe
Population size (year)	1 million (2007)	2 million (2009)	1.8 million (2007)	13 million (2007)
Gross national income per capita, USD (year)	2,560 (2007)	4,074 (2007)	6,120 (2007)	340 (2005)
Total annual per capita expenditure on health, USD (year)	155 (2006)	252 (2006–07)	296 (2006)	38 (2006)
Total number of physicians (year)	184 (2007)	1,200 (2009)	715 (2009)	2,086 (2004)
Total number of nursing and midwifery personnel (year)	3,070 (2007)	9,200 (2009)	6,075 (2009)	9,357 (2004)
Total number of pharmaceutical personnel (year)	81 (2007)	440 (2009)	401 (2009)	883 (2004)
Hospitals (year)	8 (2009)	47 (2009)	34 (2005)	N/A

Swaziland

According to the Medicines and Related Substances Control Act No. 8 of 2012, the Swaziland MRA shall consist of no fewer than five members and no more than nine members and shall consist of the following:

- The chief pharmacist in the Ministry of Health or a representative of that chief pharmacist
- A pharmacist engaged in the private sector
- A pharmacist engaged in the public sector
- A medical practitioner who is a specialist physician
- The Director of Health Services or a representative of that director

- A person with special knowledge of the action and application of medicines in the human body such as a pharmacologist or a pharmacist who holds a postgraduate qualification in pharmacology

- The Director of Veterinary Services or a representative of that director

- A registered nurse

- A representative appointed by the Minister of Finance

The Swaziland MRA shall meet quarterly. The day-to-day duties shall be performed by secretariat staff, under the supervision of the registrar. For the purposes of costing, the recommendations from a MRA establishment options analysis report (Prat, 2012) were used to estimate the number of secretariat staff required to undertake day-to-day regulatory functions. The MRA will begin with four pharmacists, each responsible for one of the four main units:

- Medicines Evaluation/Registration Unit
- Pharmacovigilance and Medicine Information Unit
- Quality Control Unit
- Inspectorate Unit

Four pharmacy technicians will support the activities of the MRA and the Pharmacy Council Inspectorate.

According to the Medicines and Related Substance Control Act (2003) in Namibia, the Council consists of the following members—

- Three medical practitioners

    - One of whom is registered as a medical specialist
    - One of whom is engaged in private medical practice
    - One of whom is employed by the MoH responsible for health

- Three pharmacists

    - One of whom is engaged in private pharmaceutical practice
    - One of whom is employed by the MoH responsible for health
    - Any other pharmacist

- Two veterinarians, nominated for appointment by the Minister of Health responsible for agriculture

    - One of whom is engaged in private veterinary practice

    - One of whom is employed by MoH and responsible for agriculture

- One legal practitioner nominated for appointment by the Minister of Health responsible for justice

- One registered nurse
- One practitioner who, in the opinion of the Minister of Health, has sufficient knowledge of medicines and related substances
- One other person

Namibia

According to the Namibia Medicines Regulatory Council (NMRC) consultancy paper, (Strengthening Pharmaceutical Systems, 2009) the NMRC requires at least 20 secretariat staff to perform day-to-day duties as follows:

- Registration Unit (7)
    - Reviewers/evaluators (4)
    - Evaluator for veterinarian (1)
    - Information systems (1)
    - Administrative assistant (1)
- Inspection and Licensing Unit (4)
    - Inspector (pharmacist) (1)
    - Inspection technician (1)
    - Lawyer for enforcement (1)
    - Licensor (1)
- Pharmacovigilance and Drug Information Unit (5)
    - Therapeutics, Information, and Pharmacovigilance Centre coordinator (pharmacist) (1)
    - Pharmaco-epidemiologist (1)
    - Medicine information specialist (pharmacist) (1)
    - Information systems specialist (1)
    - Administrative assistant (1)
- Quality surveillance unit (4)
    - Pharmacist (1)
    - Technician (2)
    - Work hand (1)

Zimbabwe

The medicines and allied substances control (chapter 15:03) provides legal basis on constitution of the Medicines Control Authority of Zimbabwe (MCAZ) as follows. The MCAZ shall consist of no fewer than eight and no more than 12 members. Of the members appointed—

- One shall be a medical practitioner engaged in general medical practice, chosen from a list of no fewer than three names submitted by the Zimbabwe Medical Association.
- One shall be a veterinary surgeon, chosen from a list of no fewer than three names submitted by the Council of Veterinary Surgeons of Zimbabwe.
- One shall be a pharmacist who is not an officer of the ministry for which the minister is responsible, chosen from a list of no fewer than three names submitted by the Pharmaceutical Society of Zimbabwe.
- One shall be a medical officer of health for a local authority, chosen from a list of no fewer than three names submitted by the Urban Councils Association.
- One shall be a registered legal practitioner of no fewer than five years' standing, chosen from a list of no fewer than three names submitted by the Law Society of Zimbabwe.
- One shall be a medical practitioner who is a specialist physician.
- One shall have a special knowledge of the action and application of medicines.
- One shall be an officer of the MoH for which the minister is responsible who is either a pharmacist or a medical officer.

The MCAZ according to the act has 8–12 members, but the secretariat has a staff complement of 89, 40 of whom are technical staff.

Botswana

The number of staff in Botswana Drug Regulatory Unit is 9 (WHO, 2009).

ANNEX B. SWAZILAND PHARMACEUTICAL STRATEGIC PLAN LOGIC FRAMEWORK

Expected outcome	Strategic objectives	Strategies	Main interventions	Time frame					Responsible	Collaborating partners	Indicators or means of verification
				2012	2013	2014	2015	2016			
Strategic area 1: National Pharmaceutical Services Administration											
Efficiently managed pharmaceuti-cal services in Swaziland	To ensure an effective National Pharmaceutical Services Administration Unit to coordinate all functions and activities of the national pharmaceutical sector	Strengthen the capacity of MoH Pharmaceu-tical Services Unit to coordinate all pharmaceuti-cal services	1.1 Capacitate the unit with appropriately skilled pharmaceutical personnel and other resources	X	X	X	X	X	Office of the Head of Pharmaceuti-cal Services	WHO, SIAPS	1.1.1 Number of additional skilled personnel 1.1.2 Additional required resources in place
			1.2 Establish relevant technical committees to facilitate the achievement of the unit's mandate	X	X	X	X	X		WHO, SIAPS	1.2.1 Existence of technical committees
			1.3 Establish and maintain a central system of public and private sector pharmaceutical information to inform planning and decision making	X	X	X	X	X		WHO	1.3.1 Existence of functional central system of all pharmaceutical information
		To ensure a continuous supply of essential medicines in Swaziland	1.4 Institutionalise national quantification exercises for the estimation of medicine requirements at all levels of the health care delivery system		X		X		Office of the Head of Pharmaceutic al Services, SCTWG	WHO, PEPFAR, SIAPS, CHAI, UNICEF, UNFPA, MSF, FLAS, CDC, URC	1.4.1 National quantification exercises conducted in a timely manner according to SOPs

Expected outcome	Strategic objectives	Strategies	Main interventions	Time frame					Responsible	Collaborating partners	Indicators or means of verification
				2012	2013	2014	2015	2016			
			1.5 Endorse and implement the WHO/SADC pharmaceutical donation guidelines	X	X	X	X	X	Office of the Head of Pharmaceutical Services	WHO, SADC, SIAPS	1.5.1 Existence of endorsed WHO/SADC donation guidelines
			1.6 Establish systems and guidelines for the disposal of obsolete pharmaceu-ticals in collab-oration with the relevant agencies	X	X				Office of the Head of Pharmaceuti-cal Services, MoH Environmental Unit	WHO, SIAPS, Treasury Department/ auditors	1.6.1 Existence of a system and guidelines for the disposal of obsolete pharmaceuticals
		To ensure that the strategic orientation of the National Pharmaceuti-cal Services Administra-tion is aligned with those of the subregion	1.7 Maintain Swaziland's participation in the ongoing subregional initiatives, including the SADC and AU harmonisation processes	X	X	X	X	X	Office of the Head of Pharmaceuti-cal Services	SADC, NEPAD	1.7.1 Number of subregional initiatives Swaziland participates in
		To ensure that development partners provide coordinated support to the pharmaceuti-cal sector	1.8 Establish and implement a mechanism to coordinate and guide development partner interventions in the pharmaceutical sector	X	X	X	X	X		WHO, PEPFAR, SIAPS, CHAI, UNICEF, UNFPA, MSF, FLAS, CDC, URC, ICAP, EGPAF	1.8.1 Coordinating mechanism in place to guide development partner interventions
			1.9 Establish and manage a PPP framework in the pharmaceutical sector	X	X	X	X	X		WHO, SIAPS, CHAI, EGPAF, UNICEF, UNFPA, MSF, FLAS, CDC, URC, ICAP,	1.9.1 PPP framework available

Expected outcome	Strategic objectives	Strategies	Main interventions	Time frame					Responsible	Collaborating partners	Indicators or means of verification
				2012	2013	2014	2015	2016			
Strategic area 2: Legislation and regulations											
Effectively and efficiently regulated pharmaceutical sector services and products in Swaziland	To enact and implement the necessary pharmaceutical legislation and regulations to ensure the effective control of pharmaceuticals and the pharmaceutical profession	Strengthen the legislative framework of the pharmaceutical sector in Swaziland	2.1 Advocate for the enactment of the Medicines and Related Substances Control Act and the Pharmacy Act	X	X				Office of the Head of Pharmaceutical Services	SIAPS	2.1.1 Number of activities conducted to advocate for the enactment of the pharmaceutical bills
			2.2 Sensitise stakeholders on the Medicines and Related Substances Control Act and the Pharmacy Act		X	X	X	X	Office of the Head of Pharmaceutical Services, MRA, Pharmacy Council	All stakeholders	2.2.1 Number of stakeholder sensitisation exercises conducted 2.2.2 Number of stakeholders sensitised
			2.3 Enforce the Medicines and Related Substances Control Act and the Pharmacy Act		X	X	X	X		Ministries of Justice and Agriculture, Royal Swaziland Police Force, Interpol, SRA	2.3.1 Number of activities conducted to enforce the pharmaceutical bills
		Ensure the prompt implementation of the Pharmacy Act and the Medicines and Related Substances Control Act	2.4 Initiate the process for the establishment of the MRA by the Medicines and Related Substances Control Act	X	X				Office of the Head of Pharmaceutical Services	WHO, SADC, SIAPS	2.4.1 Number of activities conducted to initiate the process of establishing the MRA
			2.5 Initiate the process for the establishment of the Pharmacy Council by the Pharmacy Act	X	X					SIAPS	2.5.1 Number of activities conducted to initiate the process of establishing the Pharmacy Council

Expected outcome	Strategic objectives	Strategies	Main interventions	Time frame					Responsible	Collaborating partners	Indicators or means of verification
				2012	2013	2014	2015	2016			
Strategic area 3: Supply of pharmaceuticals											
Availability of the right products, at the right time, in the right quantities and quality, at the right place and at the right cost	To ensure efficient procurement, storage, and distribution of sufficient quantities of quality pharmaceuticals	Strengthen the procurement of pharmaceuticals in the country	3.1 Review the CMS structure to address its procurement, warehousing, distribution, and quality assurance functions	X					Office of the Head of Pharmaceutical Services, SCTWG	SIAPS, CHAI, URC, UNFPA, EGPAF, PSI,	3.1.1 Review report of the CMS organisational structure
			3.2 Advocate for the adoption and implementation of the new CMS organisational structure	X	X				Office of the Head of Pharmaceutical Services	SIAPS, CHAI, URC, UNFPA, EGPAF, PSI	3.2.1 Reviewed CMS structure adopted
			3.3 Develop and implement standards, guidelines, and procedures for procurement of pharmaceuticals	X	X	X	X	X	Office of the Head of Pharmaceutical Services, SCTWG	SIAPS, CHAI, URC, UNFPA, EGPAF, PSI	3.3.1 Procurement standards, guidelines and procedures in place
			3.4 Develop and implement a supplier performance assessment system	X	X	X	X	X		SIAPS, CHAI, URC, UNFPA, EGPAF, PSI	3.4.1 Supplier performance assessment system available
			3.5 Build the capacity of CMS Procurement Section & MoH Procurement Unit	X	X	X	X	X	Office of the Head of Pharmaceutical Services	SIAPS, CHAI, URC, UNFPA, EGPAF, PSI	3.5.1 Activities conducted to build capacity of CMS and National Procurement Units

Expected outcome	Strategic objectives	Strategies	Main interventions	Time frame					Responsible	Collaborating partners	Indicators or means of verification
				2012	2013	2014	2015	2016			
		Optimise and secure the storage and distribution of commodities within the supply chain	3.6 Establish and enforce control and monitoring mechanisms for accountability in the management of pharmaceuticals	X	X	X	X	X	Office of the Head of Pharmaceutical Services	SIAPS, CHAI, URC, UNFPA, EGPAF, PSI	3.6.1 Control and monitoring mechanisms for the accountability of the management of pharmaceuticals in place
			3.7 Strengthen the security of pharmaceuticals at all levels of the supply chain	X	X	X	X	X	Office of the Head of Pharmaceutical Services, SCTWG	SIAPS, CHAI, URC, UNFPA, EGPAF, PSI	3.7.1 Activities conducted to improve the security of pharmaceuticals at all levels of the supply chain
			3.8 Improve and expand the pharmaceutical storage capacity across all levels within the supply chain	X	X	X	X	X		SIAPS, CHAI, URC, UNFPA, EGPAF, PSI	3.8.1 Activities conducted to improve pharmaceutical storage capacity at all levels of the supply chain 3.8.2 Increased pharmaceutical storage space across all levels of the supply chain
			3.9 Adopt, adapt, and enforce WHO guidelines on good storage and distribution practices	X	X	X	X	X		WHO, SIAPS, CHAI, URC, UNFPA, EGPAF, PSI	3.9.1 Good storage and distribution guidelines available
		Promote the use of appropriate existing and emerging technology to improve supply chain management	3.10 Strengthen the use of technology in supply chain management in all levels of the supply chain	X	X	X	X	X		WHO, SIAPS, CHAI, URC, UNFPA, EGPAF, PSI	3.10.1 Use of up-to-date technology used for supply chain at all levels

Expected outcome	Strategic objectives	Strategies	Main interventions	Time frame					Responsible	Collaborating partners	Indicators or means of verification
				2012	2013	2014	2015	2016			
Strategic area 4: Pharmaceutical quality assurance											
Good quality pharmaceuticals used in Swaziland	Ensure that all medicines used in Swaziland are safe, efficacious, and of assured quality	Establish the MRA	4.1 Put in place the MRA Unit with the necessary resources		X	X	X	X	Office of the Head of Pharmaceutical Services, MRA	WHO, SADC, SIAPS	4.1.1 MRA Unit established with necessary resources
			4.2 Foster the formation of formal links between the MRA and other regulatory authorities in the region		X	X	X	X		WHO, SADC	4.2.1 Collaborative activities undertaken between the MRA and other regulatory authorities in the region
		Strengthen the regulatory capacity of the MRA	4.3 Establish the medicines registration system for all pharmaceuticals used in Swaziland		X	X	X	X	MRA	MoH, WHO, SIAPS, URC, SWASA	4.3.1 Medicines registration system in place
			4.4 Establish Pharmacovigilance and Drug Information Unit			X	X	X		MoH, WHO, SIAPS	4.4.1 Functional Pharmacovigilance and Drug Information Unit in place
			4.5 Establish and capacitate a National Pharmaceutical Quality Control Laboratory			X	X	X		MoH, WHO, SADC, SIAPS	4.5.1 Capacitated and functional national quality control laboratory
			4.6 Establish the Inspectorate Unit for the pharmaceutical sector			X	X	X		MoH, WHO, SIAPS	4.6.1 Functional Pharmaceutical Inspectorate Unit in place
Strategic area 5: Financing of pharmaceuticals											
Efficient financing mechanisms for pharmaceuticals	To provide adequate funding to ensure a regular supply	Improve pharmaceuticals financing in the country	5.1 Advocate for adequate budget allocation for pharmaceuticals	X	X	X	X	X	Office of the Head of Pharmaceutical Services	MoH, Ministry of Finance	5.1.1 Advocacy activities towards adequate budget allocation

Expected outcome	Strategic objectives	Strategies	Main interventions	Time frame					Responsible	Collaborating partners	Indicators or means of verification
				2012	2013	2014	2015	2016			
	of sufficient pharmaceuti-cals		5.2 Establish and implement a pricing policy for pharmaceu-ticals in Swaziland	X	X	X	X	X	Office of the Head of Pharmaceuti-cal Services	Ministry of Finance, Medical Aids, Ministry of Commerce, Industry and Trade, MRA	5.2.1 Pricing policy available
			5.3 Develop guidelines for pharmaceuti-cals financing in the country		X					WHO, SIAPS	5.3.1 Pharmaceutical financing guidelines available
			5.4 Examine alternative approaches to pharmaceuti-cals financing and implement appropriate approaches	X	X	X	X	X		WHO, SIAPS	5.4.1 Alternate pharmaceutical financing approaches report available
		Strengthen coordination and monitor-ing mechan-isms in phar-maceutical financing	5.5 Establish and implement control and monitoring mechanisms for accountability in the use of pharmaceutical funds	X	X	X	X	X		SIAPS	5.5.1 Control and monitoring mechanisms for the accountability of the use of pharmaceuticals funds in place
			5.6 Define and establish a coordination mechanism for MoH to capture and document all sources of finances for pharmaceuti-cals	X	X	X	X	X		SIAPS	5.6.1 Coordinating mechanism to capture all sources of pharmaceutical funding in place

Expected outcome	Strategic objectives	Strategies	Main interventions	Time frame					Responsible	Collaborating partners	Indicators or means of verification
				2012	2013	2014	2015	2016			
Strategic area 6: Human resources											
Availability of adequate and skilled pharmaceutical personnel in Swaziland	To provide sufficient qualified pharmaceutical personnel for the efficient provision of pharmaceutical services	Build capacity and expand the local source of skilled pharmaceutical personnel	6.1 Develop and implement a National Pharmaceutical Human Resources Plan in line with the health sector human resources development plan	X	X	X	X	X	Office of the Head of Pharmaceutical Services, MoH Training Unit	WHO, SIAPS	6.1.1 Human resources available
			6.2 Establish training for pharmaceutical personnel in institutions of higher learning in Swaziland	X	X	X	X	X	Office of the Head of Pharmaceutical Services	UNISWA, SANU, SIAPS	6.2.1 Pharmaceutical personnel training programs available in institutions of higher learning
			6.3 Provide interim training of pharmaceutical personnel in institutions outside of Swaziland							Ministry of Labour and Social Security, Ministry of Public Service	6.3.1 Pharmaceutical personnel trained in institutions outside of Swaziland
			6.4 Ensure continuous professional development	X	X	X	X	X	Pharmacy Council	MoH	6.4.1 Continuous professional development records available
		Improve the recruitment, retention and working conditions for pharmaceutical personnel in the public and private sectors	6.5 Ensure that all pharmaceutical personnel posts are filled with appropriately qualified personnel	X	X	X	X	X	Office of the Head of Pharmaceutical Services	Civil Service Commission	6.5.1 Zero vacant pharmaceutical posts
			6.6 Advocate for the creation of sufficient pharmaceutical personnel posts within the MoH							Ministry of Public Service	6.6.1 Advocacy activities towards the creation of adequate pharmaceutical post within the MoH

Expected outcome	Strategic objectives	Strategies	Main interventions	Time frame					Responsible	Collaborating partners	Indicators or means of verification
				2012	2013	2014	2015	2016			
			6.7 Develop an orientation programme for newly recruited pharmaceutical personnel	X	X				Office of the Head of Pharmaceuti-cal Services, MoH Training Office	SIAPS, CHAI, ICAP	6.7.1 Orientation program for newly recruited pharmaceutical personnel in place
			6.8 Develop and implement retention strategies for pharmaceutical personnel in the public sector	X	X	X	X	X	Office of the Head of Pharmaceuti-cal Services	Ministry of Public Service	6.8.1 Retention strategies for public sector pharmaceutical personnel available
			6.9 Establish minimum wage standards for pharmaceutical personnel in the private sector	X	X					Ministry of Public Service	6.9.1 Minimum wage standards for private sector pharmaceutical personnel available
		Ensure that all personnel handling pharmaceuti-cals are competent in pharmaceuti-cal supply management	6.10 Capacitate nonpharmaceu-tical personnel responsible for pharmaceut-icals at lower levels of health care delivery	X	X	X	X	X		SIAPS, MSF, CHAI	6.10.1 Number of nonpharmaceutical personnel handling pharmaceuticals at lower levels of health care delivery trained in pharmaceutical supply management
Strategic area 7: Rational medicine use											
Pharmaceutic als are used rationally to improve therapeutic outcomes in patients in the country	Ensure rational use of medic-ines by health care workers and patients to maximise their therapeutic benefit	Promote rational medicine use among health care workers and in the community	7.1 Incorporate rational medicine use content into existing curricula for all health care professionals		X				Office of the Head of Pharmaceuti-cal Services	SIAPS	7.1.1 Rational medicines use incorporated into curricula for all health care professionals
			7.2 Provide continuing education to staff on rational medicine use	X	X	X	X	X		WHO, SIAPS, CHAI	7.2.1 Continuous professional development training program on rational medicines use in place

Expected outcome	Strategic objectives	Strategies	Main interventions	Time frame					Responsible	Collaborating partners	Indicators or means of verification
				2012	2013	2014	2015	2016			
			7.3 Educate the community on rational medicine use	X	X	X	X	X	Office of the Head of Pharmaceuti-cal Services	WHO, SIAPS, CHAI	7.3.1 Activities on educating the community on the rational use of medicines in place
			7.4 Regulate the advertising and promotion of pharmaceuti-cals	X	X	X	X	X	MRA	MoH	7.4.1 Advertising and promotion regulations available
		Strengthen the use of the STG/EML and the role of PTCs in the country	7.5 Enforce the use of STG/EML in the public sector and encourage the private sector to comply	X	X	X	X	X	Office of the Head of Pharmaceuti-cal Services	WHO, SIAPS	7.5.1 Activities conducted towards the enforcement of the use of STG/EML in the public sector 7.5.2 Activities towards the encouragement of compliance with the STG/EML for the private sector
			7.6 Create a mechanism to review the STG/EML	X	X	X				WHO, SIAPS	7.6.1 STG/EML review mechanism available 7.6.2 STG/EML updated periodically
			7.7 Enforce generic pre-scribing and dispensing and establish reg-ulatory mea-sures to allow for generic substitution in both the public and private sectors		X	X	X	X	MRA	MoH	7.7.1 Activities conducted towards the enforcement of generic prescribing and dispensing in the public sector 7.7.2 Activities towards the encouragement of compliance with generic prescribing and dispensing by the private sector

Expected outcome	Strategic objectives	Strategies	Main interventions	Time frame					Responsible	Collaborating partners	Indicators or means of verification
				2012	2013	2014	2015	2016			
			7.8 Establish a mechanism that will enable MoH to coordinate and monitor the performance of PTCs	X	X	X	X	X	Office of the Head of Pharmaceuti-cal Services	WHO, SIAPS	7.8.1 Coordinating mechanism for PTCs available 7.8.2 Monitoring mechanisms for PTC performance in place
Strategic area 8: Traditional and complementary medicine											
Collaboration between MoH and tradition-al and com-plementary practitioners in the provision of quality health care services	To maximise the use of positive aspects and minimise the negative consequences of traditional and complementary medicine in the provision of health care services	Establish mechanisms for collabora-tion between traditional and comple-mentary practitioners and MoH	8.1 Develop a collaborative framework between MoH and traditional and complementary practitioners and coordinate services and activities between traditional and complementary practitioners and MoH	X	X	X	X	X	Office of the Head of Pharmaceuti-cal Services	WHO, SIAPS	8.1.1 Existence of a collaborative framework between MoH and traditional and complementary practitioners
		Regulate the practice of complementa ry medicine practitioners	8.2 Establish mechanisms for overseeing the activities related to the safety and efficacy of complementary medicines as well as claims made by the practitioners	X	X	X	X	X	Office of the Head of Pharmaceuti-cal Services, MRA	WHO, SIAPS	8.2.1 Overseeing mechanism for the safety and efficacy of complementary medicines mechanism in place
Strategic area 9: Local production											
Increase in the number of local production units and	Encourage local production as 1 way of improve-ing access to medicines	Promote es-tablishment of new local production units	9.1 Advocate for incentives to stimulate local manufacturing	X	X				Office of the Head of Pharmaceuti-cal Services	WHO, SIAPS	9.1.1 Activities towards advocating for incentives to stimulate local production

Expected outcome	Strategic objectives	Strategies	Main interventions	Time frame					Responsible	Collaborating partners	Indicators or means of verification
				2012	2013	2014	2015	2016			
locally manufactured products			9.2 Create an enabling and transparent environment to assess the existing incentives			X			Office of the Head of Pharmaceuti-cal Services	Ministry of Trade and Industry, Ministry of Finance, SIPA	9.2.2 Activities aimed at creating an enabling and transparent environment conducted
		Strengthen compliance of local production units with cGMP	9.3 Encourage local production units to upgrade their cGMP status	X	X	X	X	X		WHO, SIAPS	9.3.1 Activities conducted towards encouraging local production units to upgrade their cGMP status
Strategic area 10: Research											
Pharmaceuti-cal research program that is able to inform planning and decision making	To foster research aimed at resolving problem areas of the Swaziland pharmaceutical sector	Improve the regulation of pharmaceuti-cal research in Swaziland	10.1 Build the capacity of the MoH Research Unit	X	X				Office of the Head of Pharmaceuti-cal Services, SID	WHO, SADC, URC	10.1.1 Activities conducted toward building the capacity of the MoH Research Unit
			10.2 Ensure that clinical trials are well regulated and monitored by the relevant authorities			X	X	X	Office of the Head of Pharmaceuti-cal Services, MRA	SID, SEC	10.2.1 Activities aimed at ensuring that clinical trials are well regulated and monitored
		Promote research in pharmaceuti-cal priority areas	10.3 Identify pharmaceutical priority areas for research in Swaziland	X	X	X	X	X	Office of the Head of Pharmaceuti-cal Services, SID	WHO	10.3.1 Pharmaceutical research priority areas identified and documented
			10.4 Encourage operational research in the pharmaceutical sector	X	X	X	X	X		WHO, UNISWA, SANU	10.4.1 Activities conducted towards the encouragement of operational research in the pharmaceutical area

Expected outcome	Strategic objectives	Strategies	Main interventions	Time frame					Responsible	Collaborating partners	Indicators or means of verification
				2012	2013	2014	2015	2016			
Strategic area 11: Technical intersectorial cooperation and coordination											
Coordinated efforts and resource maximisation of pharma-ceutical interventions	To strengthen cooperation and coordination between MoH and other government ministries and development partners	Improve the collaboration between MoH and relevant ministries, organisations and agencies on pharma-ceutical matters	11.1 Collaborate with other ministries and public institutions on pharmaceutical issues	X	X	X	X	X	Office of the Head of Pharmaceuti-cal Services	All government ministries and public institutions	11.1.1 Collaborative activities undertaken between MoH and other ministries and public institutions
			11.2 Collaborate with development partners, NGOs and regional organisations on pharmaceutical matters	X	X	X	X	X		WHO, PEPFAR, SIAPS, CHAI, UNICEF, UNFPA, MSF, FLAS, CDC, URC, ICAP, EGPAF, EU, World Bank, ROC Taiwan	11.2.1 Collaborative activities conducted between MoH and development partners, NGOs and regional organisations
		Building consensus among all stakeholders	11.3 Establish mechanisms for effective involvement of relevant stakeholders on pertinent pharmaceutical matters as required	X	X	X	X	X		All stakeholders	11.3.1 Existence of mechanisms to ensure effective involvement of relevant stakeholders in pharmaceutical matters
			11.4 Establish mechanisms for disseminating relevant pharmaceutical information to both the public and private sectors	X	X	X	X	X		MRA, Pharmacy Council	11.4.1 Existence of mechanisms to disseminate relevant pharmaceutical information to public and private sector stakeholders in pharmaceutical matters

Expected outcome	Strategic objectives	Strategies	Main interventions	Time frame					Responsible	Collaborating partners	Indicators or means of verification
				2012	2013	2014	2015	2016			
			11.5 Foster a sense of ownership among the public and private sector on pharmaceutical issues	X	X	X	X	X	Office of the Head of Pharmaceutical Services	All stakeholders	11.5.1 Activities carried out towards fostering a sense of ownership amongst the public and private sector on pharmaceutical issues
Strategic area 12: Monitoring and evaluation											
Fully functional M&E system for pharmaceutical services	To ensure effective M&E of the implementation of the SPSP	Establish an M&E system for the SPSP	12.1 Conduct a baseline study of pharmaceutical services in Swaziland	X					Office of the Head of Pharmaceutical Services	WHO, SIAPS, UNFPA, CMS Data Management Unit, MoH M&E Unit	12.1.1 Baseline study report available
			12.2 Develop an M&E operational framework for the pharmaceutical sector	X	X					WHO, SIAPS, UNFPA, CMS Data Management Unit, MoH M&E Unit	12.2.1 M&E operational plan available
			12.3 Build M&E capacity for the pharmaceutical sector across all levels of health service delivery	X	X	X	X	X		WHO, SIAPS, UNFPA, CMS Data Management Unit, MoH M&E Unit	12.3.1 Coordinating mechanisms for the SPSP implementation available
			12.4 Develop a coordinating mechanism for implementation of the SPSP	X	X	X	X	X		WHO, SIAPS, UNFPA, CMS Data Management Unit, MoH M&E Unit	12.4.1 Activities conducted towards establishing the SPSP M&E Unit

ANNEX C. SWAZILAND PHARMACEUTICAL STRATEGIC PLAN ACTION PLAN 2012–2014 (YEARS 1 AND 2)

Strategies	Main interventions	Activities	Timeline (2012−14)				Responsible	Resources	Indicators
			S1	S2	S3	S4			
Strategic objective 1: To ensure an effective National Pharmaceutical Services Administration Unit to coordinate all functions and activities of the national pharmaceutical sector									
Strengthen the capacity of the MoH Pharmaceutical Services Unit to coordinate all pharmaceutical services	1.1 Capacitate the unit with appropriately skilled pharmaceutical personnel and other resources	1.1.1 Develop job descriptions of the required pharmaceutical personnel according to the Human Resources Plan		X			Office of the Head of Pharmaceutical Services	Consultant, conferencing	1.1.1.1 Approved job descriptions available
		1.1.2 Recruit the necessary skilled pharmaceutical personnel				X		Advertising	1.1.2.1 Number of pharmaceutical personnel recruited
		1.1.3 Orient the newly recruited pharmaceutical personnel				X		Time	1.1.3.1 Register of oriented pharma-ceutical personnel
		1.1.4 Identify the required resources for the effective functioning of the unit		X				Time	1.1.4.1 Resource needs assessment plan available
		1.1.5 Motivate for the provision of adequate resources identified in 1.1.4		X	X	X		Time	1.1.5.1 Number of motivation activities carried out
		1.1.6 Equip the unit with the identified resources				X		Equipment	1.1.6.1 Inventory of resources
	1.2 Establish relevant technical committees to facilitate the achievement of the unit's mandate	1.2.1 Develop a concept note identifying all the different committees that need to be put in place	X					Time	1.2.1.1 Concept note available
		1.2.2 Develop TORs for each of the technical committees		X	X			Time	1.2.2.1 TORs available
		1.2.3 Establish the technical committees		X	X	X		Time, conferencing	1.2.3.1 List of committee members 1.2.3.2 Committee meeting minutes

Strategies	Main interventions	Activities	Timeline (2012−14)				Responsible	Resources	Indicators
			S1	S2	S3	S4			
	1.3 Establish and maintain a central system of public and private sector pharmaceutical information to inform planning and decision making	1.3.1 Develop a concept note for the system of pharmaceutical information to inform planning and decision making	X				Office of the Head of Pharmaceutical Services	Time	1.3.1.1 Concept note available
		1.3.2 Advocate for the establishment of the system based on the concept note		X	X	X		Time	1.3.2.1 Number of advocacy activities conducted
		1.3.3 Implement the system based on the concept note recommendations			X	X		Computer with Internet connection, stationery	1.3.3.1 System in place
		1.3.4 Maintain the efficiency of the system to ensure its continuous functionality				X		Time, computer with Internet connection, stationery	1.3.4.1 Availability of current information
To ensure a continuous supply of essential medicines in Swaziland	1.4 Institutionalise national quantification exercises for the estimation of medicine requirements at all levels of the health care delivery system	1.4.1 Conduct a situational analysis to guide the development of national quantification guidelines and SOPs	X				Office of the Head of Pharmaceutical Services, SCTWG	Transport, conferencing	1.4.1.1 Situational analysis report available
		1.4.2 Develop national quantification guidelines		X				Time, conferencing	1.4.2.1 Guidelines available
		1.4.3 Develop quantification SOPs		X	X			Time, conferencing	1.4.3.1 Existence of SOPs
		1.4.4 Print and disseminate the quantification guidelines and SOPs				X		Printing	1.4.4.1 Printed guidelines available at the end-users 1.4.4.2 Printed SOPs available at the end-users
		1.4.5 Train users on the quantification SOPs				X		Conferencing	1.4.5.1 Training report
	1.5 Endorse and implement the WHO/SADC pharmaceutical donation guidelines	1.5.1 Motivate for the adoption of the WHO/SADC pharmaceutical donation guidelines	X				Office of the Head of Pharmaceutical Services	Time	1.5.1.1 Number of activities carried out to motivate for adoption of the guidelines
		1.5.2 Adapt and implement the WHO/SADC donation guidelines		X	X			Time, conferencing	1.5.2.1 Swaziland donation guidelines available

Strategies	Main interventions	Activities	Timeline (2012−14)				Responsible	Resources	Indicators
			S1	S2	S3	S4			
		1.5.3 Print and disseminate and orient stakeholders on the donation guidelines			X	X	Office of the Head of Pharmaceutical Services	Printing	1.5.3.1 Printed Swaziland donation guidelines available at the end-users 1.5.3.2 Stakeholders have working knowledge of donation guidelines
	1.6 Establish systems and guidelines for the disposal of obsolete pharmaceuticals in collaboration with the relevant agencies	1.6.1 Identify and recruit a consultant to conduct an assessment on pharmaceutical waste management in Swaziland		X	X		Office of the Head of Pharmaceutical Services, MoH Environmental Unit	Consultant, conferencing	1.6.1.1 Consultant engaged
		1.6.2 Develop guidelines for the disposal of obsolete pharmaceuticals based on the assessment recommendations		X	X			Conferencing	1.6.2.1 Guidelines available
		1.6.3 Develop SOPs for the disposal of obsolete pharmaceuticals		X	X			Conferencing	1.6.3.1 SOPs available
		1.6.4 Print and disseminate, and train users on the disposal guidelines and SOPs				X	Office of the Head of Pharmaceutical Services	Printing	1.6.4.1 Printed guidelines available at end-users 1.6.4.2 Printed SOPs available at the end-users 1.6.4.3 End-users have working knowledge of guidelines and SOPs
To ensure that the strategic orientation of the National Pharmaceutical Services Administration is aligned with those of the subregion	1.7 Maintain Swaziland's participation in the ongoing subregional initiatives, including the SADC and AU harmonisation processes	1.7.1 Draw up an annual schedule of local and subregional pharmaceutical meetings	X					Time, stationery	1.7.1.1 Annual schedule available
		1.7.2 Attend scheduled and unscheduled subregional pharma-ceutical meetings	X	X	X	X		Travel, conferencing	1.7.2.1 Meeting reports available

Strategies	Main interventions	Activities	Timeline (2012−14)				Responsible	Resources	Indicators
			S1	S2	S3	S4			
		1.7.3 Provide feedback in departmental, direct-orate and ministerial or management meetings locally	X	X	X	X		Conferencing	1.7.3.1 Meeting minutes available
		1.7.4 Implement relevant action points and activity plans from all meetings attended	X	X	X	X		Activity resources	1.7.4.1 Implementation and activity plans 1.7.4.2 Progress report
To ensure that development partners provide coordinated support to the pharmaceutical sector	1.8 Establish and implement a mechanism to coordinate and guide development partner interventions in the pharmaceutical sector	1.8.1 Identify pharmaceutical sector needs that necessitate partner involvement	X					Time	1.8.1.1 Pharmaceutical needs assessment report
		1.8.2 Develop MOUs with development partners in collaboration with relevant ministerial units	X	X				Conferencing	1.8.2.1 MOUs available
		1.8.3 Establish a PPSC		X	X			Conferencing, time	1.8.3.1 PPSC membership list 1.8.3.2 PPSC meeting minutes
		1.8.4 Develop TORs for the PPSC		X	X			Conferencing	1.8.4.1 PPSC TORs available
	1.9 Establish and manage a PPP framework in the pharmaceutical sector	1.9.1 Conduct an assessment for needs in the pharmaceutical sector that can be addressed using the PPP framework	X					Transport, conferencing	1.9.1.1 PPP needs assessment report available
		1.9.2 Develop guidelines for the pharmaceutical sector PPP framework		X	X	X		Conferencing	1.9.2.1 PPP framework guidelines available
		1.9.3 Implement the guidelines of the pharmaceutical PPP				X		Time	1.9.3.1 Number of PPP activities carried out
Strategic objective 2: To enact and implement the necessary pharmaceutical legislation and regulations to ensure the effective control of pharmaceuticals and the pharmaceutical profession									
Strengthen the legislative framework of the pharmaceutical	2.1 Advocate for the enactment of the Medicines and Related Substances Control Act	2.1.1 Orient MoH senior management on the content and importance of the two bills	X				Office of the Head of Pharmaceutical Services	Conferencing	2.1.1.1 Orientation meeting minutes available

Strategies	Main interventions	Activities	Timeline (2012−14)				Responsible	Resources	Indicators
			S1	S2	S3	S4			
sector in Swaziland	and the Pharmacy Act	2.1.2 Orient the legislators on the relevance of the two bills	X	X			Office of the Head of Pharmaceutical Services	Conferencing	2.1.2.1 Orientation workshop report available
		2.1.3 Motivate for the tabling of the two bills before Cabinet	X	X				Time, Transport	2.1.3.1 Number of activities carried out toward the motiva-tion of the tabling of the bills
	2.2 Sensitise stakeholders on the Medicines and Related Substances Control Act and the Pharmacy Act	2.2.1 Launch the Medicines and Related Substances Control Act and the Pharmacy Act			X	X	Office of the Head of Pharmaceutical Services, MRA and Pharmacy Council	Conferencing	2.2.1.1 Launch report available
		2.2.2 Develop IEC materials to raise aware-ness of the two bills			X	X		Conferencing	2.2.2.1 IEC material developed
		2.2.3 Print and disseminate IEC material on the two bills				X		Printing	2.2.3.1 Printed IEC material on the bills available in community
		2.2.4 Conduct educational events through the media (radio, TV, print) to educate the public on both bills				X		Advertising	2.2.4 Number of media awareness events conducted
	2.3 Enforce the Medicines and Related Substances Control Act and the Pharmacy Act	2.3.1 Develop regulations for the enforcement of the Medicines and Related Substances Control Act				X	Office of the Head of Pharmaceutical Services, MRA	Conferencing	2.3.1.1 Regulations available
		2.3.2 Develop regulations for the enforcement of the Pharmacy Act				X	Office of the Head of Pharmaceutical Services, Pharmacy Council	Conferencing	2.3.2.1 Regulations available
Ensure the prompt implementation of the Pharmacy Act and the Medicines and Related Substances Control Act	2.4 Initiate the process for the establishment of the MRA by the Medicines and Related Substances Control Act	2.4.1 Develop a concept note for the establish-ment of the MRA	X	X	X		Office of the Head of Pharmaceutical Services	Time	2.4.1.1 Concept note available
		2.4.2 Appoint an interim MRA steering committee			X	X		Advertising	2.4.2.1 Interim MRA steering committee available
		2.4.3 Implement the recommendations of the concept note		X	X	X		Activity resources	2.4.3.1 Number of recommendations carried out

Strategies	Main interventions	Activities	Timeline (2012−14)				Responsible	Resources	Indicators
			S1	S2	S3	S4			
		2.4.4 Mobilise resources for the establishment of the MRA		X	X	X	Office of the Head of Pharmaceutical Services	Time	2.4.4.1 Number of resources available
		2.4.5 Utilise regional and international technical assistance to set up the MRA		X	X	X		Travel, unit set-up costs	2.4.5.1 Number of activities carried out to request technical assistance
		2.4.6 Benchmark against regional MRA best practices		X	X	X		Travel	2.4.6.1 Number of regional and international best practices carried out
		2.4.7 Build the capacity of the interim MRA committee			X	X		Activity resources	2.4.7.1 Number of activities carried out to build the capacity of the interim committee
		2.4.8 Develop a database of all pharmaceuticals imported into Swaziland			X	X	Office of the Head of Pharmaceutical Services, MRA	Advertising, database set-up costs	2.4.8.1 Database of all pharmaceuticals imported into Swaziland available
	2.5 Initiate the process for the establishment of the Pharmacy Council by the Pharmacy Act	2.5.1 Mobilise resources for the establishment of the Pharmacy Council	X	X	X		Office of the Head of Pharmaceutical Services	Time	2.5.1.1 Number of resources available
		2.5.2 Utilise regional technical assistance to set up the Pharmacy Council		X	X	X		Travel, consultant	2.5.2.1 Number of activities carried out to request technical assistance
		2.5.3 Benchmark against regional Pharmacy Council best practices		X	X	X		Travel, conferencing	2.5.3.1 Number of regional best practices carried out
		2.5.4 Build the capacity of the interim Pharmacy Council			X	X		Activity resources	2.5.4.1 Number of activities carried out to build capacity of interim committee
Strategic objective 3: To ensure efficient procurement, storage and distribution of sufficient quantities of quality pharmaceuticals									
Strengthen the procurement of pharmaceuticals in the country	3.1 Review CMS structure to address procurement, warehousing, distribution, and QA functions	3.1.1 Conduct an assessment on the functions and needs of the CMS	X	X			Office of the Head of Pharmaceutical Services, SCTWG	Consultant, conferencing	3.1.1.1 Assessment report available
		3.1.2 Review the current CMS structure to address identified needs			X	X		Consultant, conferencing	3.1.2.1 CMS organogram available

Strategies	Main interventions	Activities	Timeline (2012−14)				Responsible	Resources	Indicators
			S1	S2	S3	S4			
		3.1.3 Develop job descriptions of the required CMS personnel			X	X	Office of the Head of Pharmaceutical Services	Consultant, conferencing	3.1.3.1 Approved job descriptions available
	3.2 Advocate for the adoption and implementation of the new CMS organisational structure	3.2.1 Advocate for the adoption of the new CMS structure with the Ministry of Public Service	X	X	X			Conferencing, time	3.2.1.1 Number of advocacy activities conducted
		3.2.2 Motivate for the creation and grading of the required positions	X	X	X			Time	3.2.2.1 Number of motivation activities carried out
		3.2.3 Recruit the required personnel				X		Advertising	3.2.3.1 Number of recruited personnel
	3.3 Develop and implement standards, guidelines and procedures for the procurement of pharmaceuticals	3.3.1 Develop standards for the procurement of pharmaceuticals	X	X			Office of the Head of Pharmaceutical Services, SCTWG	Time, consultant	3.3.1.1 Pharmaceutical procurement standards available
		3.3.2 Print and disseminate standards for the procurement of pharmaceuticals			X	X		Printing	3.3.2.1 Printed pharmaceutical procurement standards available at the end-users
		3.3.3 Develop guidelines for the procurement of pharmaceuticals	X	X				Time, consultant	3.3.3.1 Existence of pharmaceutical procurement guidelines
		3.3.4 Print and disseminate guidelines for the procurement of pharmaceuticals			X	X		Printing	3.3.4.1 Printed pharmaceutical procurement guidelines available at the end-users
		3.3.5 Develop SOPs for the procurement of pharmaceuticals	X	X				Time, consultant	3.3.5.1 Existence of pharmaceutical procurement SOPs
		3.3.6 Print and disseminate SOPs for the procurement of pharmaceuticals			X	X		Printing	3.3.6.1 Printed pharmaceutical procurement SOPs available at the end-users
		3.3.7 Orient users on the standards, guidelines and SOPs for the procurement of pharmaceuticals			X	X	Office of the Head of Pharmaceutical Services	Travel, conferencing	3.3.7.1 Orientation plans available; 3.3.7.2 Orientation reports available

Strategies	Main interventions	Activities	Timeline (2012−14)				Responsible	Resources	Indicators
			S1	S2	S3	S4			
	3.4 Develop and implement a supplier performance assessment system	3.4.1 Develop guidelines for the assessment of supplier performance	X	X			Office of the Head of Pharmaceutical Services, SCTWG	Time, conferencing	3.4.1.1 Existence of supplier performance assessment guidelines
		3.4.2 Adopt the supplier performance assessment guidelines	X	X			Office of the Head of Pharmaceutical Services	Time, conferencing	3.4.2.1 Approved Swaziland supplier performance assessment guidelines
		3.4.3 Orient all stakeholders on the supplier performance assessment system		X	X	X	Office of the Head of Pharmaceutical Services, SCTWG	Time, conferencing	3.4.3.1 Orientation plan available; 3.4.3.2 Orientation reports available
		3.4.4 Enforce compliance with the supplier performance assessment system				X	Office of the Head of Pharmaceutical Services	Time, travel	3.4.4 Number of activities carried out to ensure compliance with supplier performance assessment system
	3.5 Build the capacity of the CMS Procurement Section and the MoH Procurement Unit	3.5.1 Develop TOR for the CMS Procurement Section and align them to the MoH Procurement Unit	X	X	X			Time, conferencing	3.5.1.1 CMS Procurement Section TORs
		3.5.2 Identify the procurement skill development needs of the CMS Procurement Section and MoH Procurement Unit	X	X	X			Transport, conferencing	3.5.2.1 Procurement training needs assessment report available
		3.5.3 Advocate for resources to be allo-cated to CMS Procure-ment Section and MoH Procurement Unit		X	X	X		Time	3.5.3.1 Number of advocacy activities carried out
		3.5.4 Provide necessary resources for the CMS Procurement Section and MoH Procurement Unit to perform their procurement functions efficiently		X	X	X		Activity resources	3.5.4.1 Number of resources available

Strategies	Main interventions	Activities	Timeline (2012−14)				Responsible	Resources	Indicators
			S1	S2	S3	S4			
Optimise and secure the storage and distribution of commodities within the supply chain	3.6 Establish and enforce control and monitoring mechanisms for accountability in the management of pharmaceuticals	3.6.1 Develop an M&E protocol for supply chain performance	X	X	X		Office of the Head of Pharmaceutical Services	Time, conferencing	3.6.1.1 Supply chain M&E protocol available
		3.6.2 Develop national stock-taking guidelines, including documentation of discrepancies and interventions	X	X	X			Time, conferencing	3.6.2.1 Existence of national stock-taking guidelines
		3.6.3 Print and disseminate national stock-taking guidelines			X	X		Printing	3.6.3.1 Printed stock-taking guidelines available at end-users
		3.6.4 Develop stock-taking SOPs	X	X				Time, Conferencing	3.6.4.1 Stock-taking SOPs available
		3.6.5 Print and disseminate stock-taking SOPs			X	X		Printing	3.6.5.1 Printed stock-taking SOPs available at end-users
		3.6.6 Orient users on the stock-taking guidelines and SOPs				X		Time, conferencing	3.6.6.1 Orientation plan available; 3.6.6.2 Orientation report available
		3.6.7 Conduct stipulated stock-taking exercises at all levels of the supply chain to inform the annual national pharmaceutical audit	X	X	X	X		Time, inventory system	3.6.7.1 Scheduled stock-taking reports available
	3.7 Strengthen the security of pharmaceuticals at all levels of the supply chain	3.7.1 Conduct a security needs assessment across all levels of the supply chain	X	X	X		Office of the Head of Pharmaceutical Services, SCTWG	Transport, conferencing	3.7.1.1 Security needs assessment report available
		3.7.2 Implement the recommendations of the assessment report				X		Activity resources	3.7.2.1 Number of recommendations implemented
		3.7.3 Develop the commodity tracking system	X	X	X			Consultant, conferencing	3.7.3.1 Commodity tracking system in place
		3.7.4 Enforce timely submission of required reports			X	X		Activity resources	3.7.4.1 Number of activities carried out to enforce timely submission of reports

Strategies	Main interventions	Activities	Timeline (2012−14)				Responsible	Resources	Indicators
			S1	S2	S3	S4			
		3.7.5 Produce quarterly data quality reports		X	X	X	Office of the Head of Pharmaceutical Services, SCTWG	Activity resources	3.7.5.1 Quarterly data quality reports available
	3.8 Improve and expand the pharmaceutical storage capacity across all levels within the supply chain	3.8.1 Conduct an assessment of the storage capacity needs across all levels of the supply chain	X	X				Consultant, transport, conferencing	3.8.1.1 Storage capacity needs assessment report available
		3.8.2 Develop a storage capacity expansion plan		X	X			Consultant	3.8.2.1 Storage capacity expansion plan available
		3.8.3 Advocate for the implementation of the storage capacity expansion plan			X	X		Time	3.8.3.1 Number of advocacy activities carried out
	3.9 Adopt, adapt and enforce WHO guidelines on good storage and distribution practices	3.9.1 Adapt WHO guidelines on good storage practices	X	X				Time	3.9.1.1 Swaziland good storage practices guidelines available
		3.9.2 Print and disseminate the guidelines on good storage practices			X	X		Printing	3.9.2.1 Printed Swaziland good storage practices guidelines available at end-users
		3.9.3 Adapt WHO guidelines on good distribution practices	X	X				Time	3.9.3.1 Swaziland good distribution practices guidelines available
		3.9.4 Print and disseminate the good distribution practices			X	X		Printing	3.9.4.1 Printed Swaziland good distribution practices guidelines available; 3.9.4.2 Swaziland good distribution practices guidelines available at end-users
		3.9.5 Orient users on the guidelines for good storage practices and good distribution practices				X	Office of the Head of Pharmaceutical Services	Transport, conferencing	3.9.5.1 Orientation plan available; 3.9.5.2 Orientation report available

Strategies	Main interventions	Activities	Timeline (2012−14)				Responsible	Resources	Indicators
			S1	S2	S3	S4			
Promote the use of appropriate existing and emerging technology to improve supply chain management	3.10 Strengthen the use of technology in supply chain management in all levels of the supply chain	3.10.1 Implement PipeLine monitoring tools	X	X	X	X	Office of the Head of Pharmaceutical Services, SCTWG	Activity resources	3.10.1.1 PipeLine monitoring tools in place
		3.10.2 Implement the Quantimed forecasting tool	X	X	X	X		Activity resources	3.10.2.1 Quantimed forecasting tool in place and in use
		3.10.3 Implement the commodity tracking system for selected program commodities	X	X	X			Activity resources	3.10.3.1 Commodity tracking system in place and in use for selected commodities
		3.10.4 Maximise the use of a computerised inventory and ware-house management system (RxSolution) across all levels of the supply chain	X	X	X	X		Activity resources	3.10.4.1 RxSolution reports available across all levels of the supply chain
Strategic objective 4: To ensure that all medicines used in Swaziland are safe, efficacious, and of assured quality									
Establish the MRA	4.1 Put in place the MRA Unit with the necessary resources	4.1.1 Appoint the MRA in accordance with the Medicines and Related Substances Control Act			X	X	Office of the Head of Pharmaceutical Services	Advertising, time	4.1.1.1 List of MRA members 4.1.1.2 Letters of appointment avail-able with members
		4.1.2 Provide the necessary resources for the MRA to function efficiently			X	X		Activity resources	4.1.2.1 Inventory of MRA resources available
	4.2 Foster the formation of formal links between the MRA and other regulatory authorities in the region	4.2.1 Identify regional and international regulatory authorities to collaborate with		X	X		Office of the Head of Pharmaceutical Services, MRA	Time	4.2.1.1 List of regional and inter-national regulatory authorities to collab-orate with available
		4.2.2 Develop MOUs with relevant regulatory authorities		X	X	X	Office of the Head of Pharmaceutical Services, MRA	Consultant, time	4.2.2.1 Existence of MOUs with relevant regulatory authorities
Strengthen the regulatory capacity of the MRA	4.3 Establish the medicines registration system for all pharmaceuticals used in Swaziland	4.3.1 Develop a registration system for pharmaceuticals in Swaziland	X	X	X		MRA	Advertising, computer with Internet connection, stationery	4.3.1.1 Pharmaceuticals registration system in place

Strategies	Main interventions	Activities	Timeline (2012−14)				Responsible	Resources	Indicators
			S1	S2	S3	S4			
		4.3.2 Adapt WHO/SADC guidelines for the registration of pharmaceuticals	X	X	X	X	MRA	Activity resources	4.3.2.1 Existence of Swaziland registration of pharmaceuticals guidelines
		4.3.3 Orient stakeholders on the pharmaceuticals registration system		X		X	Office of the Head of Pharmaceutical Services, MRA	Transport, conferencing	4.3.3.1 Orientation plan available; 4.3.3.2 Existence of orientation report
	4.4 Establish the Pharmacovigilance and Drug Information Unit	4.4.1 Appoint the focal person for the unit	X	X				Advertising, time	4.4.1.1 Pharmacovigilance and Drug Information Unit focal person in place 4.4.1.2 Focal person with formal letter of appointment
		4.4.2 Mobilise resources for the unit		X	X	X		Activity resources	4.4.2.1 Inventory of resources available for the unit
		4.4.3 Compile and disseminate the quarterly *Medicines Safety Watch* newsletter	X	X	X	X		Printing	4.4.3.1 Quarterly *Medicines Safety Watch* newsletter available
	4.5 Establish and capacitate a National Pharmaceutical Quality Control Laboratory	4.5.1 Appoint the focal person for the laboratory		X	X		MRA	Advertising, time	4.5.1.1 National Pharmaceutical Quality Control Laboratory focal person in place; 4.5.1.2 Focal person with formal letter of appointment
		4.5.2 Mobilise resources for the laboratory	X	X	X		Office of the Head of Pharmaceutical Services, MRA	Activity resources	4.5.2.1 Inventory of resources available for the laboratory
	4.6 Establish the Inspectorate Unit for the pharmaceutical sector	4.6.1 Appoint the inspectorate members		X	X		MRA	Advertising, time	4.6.1.1 Pharmaceutical Inspectorate Unit focal person in place 4.6.1.2 Focal person with formal letter of appointment

Strategies	Main interventions	Activities	Timeline (2012−14)				Responsible	Resources	Indicators
			S1	S2	S3	S4			
		4.6.2 Mobilise resources for the unit	X	X	X	X	Office of the Head of Pharmaceutical Services, MRA	Activity resources	4.6.2.1 Inventory of resources available for the unit
Strategic objective 5: To provide adequate funding to ensure a regular supply of sufficient pharmaceuticals									
Improve pharmaceuticals financing in the country	5.1 Advocate for adequate budget allocation for pharmaceuticals	5.1.1 Conduct a budgetary needs assessment for pharmaceuticals in the country	X	X			Office of the Head of Pharmaceutical Services	Consultant	5.1.1.1 Pharmaceuticals budgetary needs assessment report available
		5.1.2 Provide advocacy to the Ministry of Finance for necessary pharmaceutical budget	X	X	X	X		Time	5.1.2.1 Number of advocacy activities conducted
		5.1.3 Advocate to the Parliamentary Health Committee on issues of the pharmaceutical budget	X	X	X	X		Time	5.1.3.1 Number of advocacy activities conducted to Parliamentary Health Committee
	5.2 Establish and implement a pricing policy for pharmaceuticals in Swaziland	5.2.1 Conduct a survey of pricing of pharmaceuticals in Swaziland	X	X			Office of the Head of Pharmaceutical Services, MRA	Transport, conferencing	5.2.1.1 Swaziland pharmaceuticals pricing survey report available
		5.2.2 Develop the pricing policy based on the findings of the survey	X	X	X			Consultant	5.2.2.1 Swaziland pharmaceuticals pricing policy available
		5.2.3 Print and disseminate the pricing policy and regulations			X	X		Printing	5.2.3.1 Printed Swaziland pharmaceutical pricing policy 5.2.3.2 Printed Swaziland pharmaceutical pricing policy available at end-users
		5.2.4 Sensitise the stakeholders on the pricing policy and regulations			X	X		Conferencing	5.2.4.1 Stakeholder sensitisation plan available 5.2.4.2 Stakeholder sensitisation report available
	5.3 Develop guidelines for pharmaceuticals financing in the country	5.3.1 Create and adopt pharmaceutical financing guidelines	X	X			Office of the Head of Pharmaceutical Services	Time	5.3.1.1 Existence of Swaziland pharmaceutical financing guidelines

Strategies	Main interventions	Activities	Timeline (2012−14)				Responsible	Resources	Indicators
			S1	S2	S3	S4			
		5.3.2 Implement the pharmaceuticals financing guidelines			X	X	Office of the Head of Pharmaceutical Services	Activity resources	5.3.2.1 Implementation plan available 5.3.2.2 Swaziland pharmaceuticals financing in place and in use
	5.4 Examine alternative approaches to pharmaceuticals financing and implement appropriate approaches	5.4.1 Conduct a study on different approaches of pharmaceutical financing	X	X				Travel, consultant	5.4.1.1 Existence of pharmaceuticals financing approaches study report
Strengthen coordination and monitoring mechanisms in pharmaceutical financing	5.5 Establish and implement control and monitoring mechanism for accountability in the use of pharmaceutical funds	5.5.1 Generate monthly expenditure reports across all supply chain levels to inform the annual national pharmaceutical audit	X	X	X	X		Computerised inventory system, time	5.5.1.1 Monthly expenditure reports available across all levels of supply chain
		5.5.2 Disseminate the monthly expenditure reports to all relevant stakeholders	X	X	X	X		Computer with Internet connection, stationery	5.5.2.1 Monthly expenditure report available at all identified stakeholders
		5.5.3 Conduct an annual audit of pharmaceutical funds expenditure			X			Consultant	5.5.3.1 Annual audit report available
	5.6 Define and establish a coordination mechanism for MoH to capture and document all sources of finances for pharmaceuticals	5.6.1 Develop guidelines to coordinate the documentation of all sources of finances for pharmaceuticals	X	X				Time, conferencing	5.6.1.1 Pharmaceuticals financing sources guidelines available
		5.6.2 Implement the guidelines to capture all sources of finances of pharmaceuticals			X	X		Activity resources	5.6.2.1 Report of all sources of pharmaceuticals financing in Swaziland
Strategic objective 6: To provide sufficient qualified pharmaceutical personnel for the efficient provision of pharmaceutical services									
Build capacity and expand the local source of skilled pharmaceutical personnel	6.1 Develop and implement a National Pharmaceutical Human Resources Plan in line with the health sector	6.1.1 Conduct a pharmaceutical human resources needs assessment	X	X			Office of the Head of Pharmaceutical Services, MoH Training Unit	Consultant	6.1.1.1 Pharmaceuticals human resources needs assessment report available

Strategies	Main interventions	Activities	Timeline (2012−14)				Responsible	Resources	Indicators
			S1	S2	S3	S4			
	human resource development plan	6.1.2 Put together the National Pharmaceutical Human Resources Plan			X	X	Office of the Head of Pharmaceutical Services, MoH Training Unit	Conferencing	6.1.2.1 Existence of pharmaceutical human resources plan
		6.1.3 Inform the national staffing norms on pharmaceutical human resources		X	X		Office of the Head of Pharmaceutical Services	Conferencing	6.1.3.1 Number of activities conducted to inform the national staffing norms on pharmaceutical human resources
	6.2 Establish training for pharmaceutical personnel in institutions of higher education in Swaziland	6.2.1 Develop a training curriculum for pharmaceutical personnel	X	X				Consultant, conferencing	6.2.1.1 Existence of training curriculum for pharmaceutical personnel
	6.3 Provide interim training of pharmaceutical personnel in institutions outside of Swaziland	6.3.1 Identify training needs	X					Consultant	6.3.1.1 Training needs report available
		6.3.2 Advocate for the allocation of sponsor-ship based on training needs assessment and training plans	X		X		Office of the Head of Pharmaceutical Services, Ministry of Labour and Social Security	Time	6.3.2.1 Number of advocacy activities towards the allocation of sponsorships
	6.4 Ensure continuous professional development	6.4.1 Establish guidelines for continuous professional education	X	X			Pharmacy Council	Time, conferencing	6.4.1.1 Swaziland continuous profes-sional education guidelines available
Improve the recruitment, retention and working conditions for pharmaceutical personnel in the public sector and private sector	6.5 Ensure that all pharmaceutical personnel posts are filled with appropriately qualified personnel	6.5.1 Advocate for filling all pharmaceutical personnel posts with the Civil Service Commission	X	X	X	X	Office of the Head of Pharmaceutical Services	Time	6.5.1.1 Number of advocacy activities conducted for the filling of all pharmaceutical personnel posts
	6.6 Advocate for the creation of sufficient pharmaceutical personnel posts within the MoH	6.6.1 Motivate for the Ministry of Public Service to support the creation of additional pharmaceutical posts in line with the human resources plan			X	X		Time	6.6.1.1 Number of activities carried out to motivate for the creation of pharmaceutical posts

Strategies	Main interventions	Activities	Timeline (2012−14)				Responsible	Resources	Indicators
			S1	S2	S3	S4			
	6.7 Develop an orientation programme for newly recruited pharmaceutical personnel	6.7.1 Develop guidelines for the orientation of newly recruited pharmaceutical personnel	X	X			Office of the Head of Pharmaceutical Services, MoH Training Unit	Time, conferencing	6.7.1.1 Swaziland orientation of newly recruited pharma-ceutical personnel guidelines available
	6.8 Develop and implement retention strategies for pharmaceutical personnel in the public sector	6.8.1 Conduct job satis-faction survey to inform retention strategies	X	X			Office of the Head of Pharmaceutical Services	Transport, conferencing	6.8.1.1 Existence of job satisfaction survey report
		6.8.2 Conduct a survey of the staff turnover for the past five years	X	X				Transport, conferencing	6.8.2.1 Five-year staff turnover rate report available
		6.8.3 Identify retention strategies			X			Time	6.8.3.1 Retention strategies report available
	6.9 Establish minimum wage standards for pharmaceutical personnel in the private sector	6.9.1 Advocate for the Ministry of Labour and Social Security to establish minimum salary guidelines for the private sector	X	X	X	X		Time	6.9.1.1 Number of advocacy activities carried out with the Ministry of Labour and Social Security to establish minimum salary guidelines
Ensure that all personnel handling pharmaceuticals are competent in pharmaceutical supply management	6.10 Capacitate the nonpharmaceutical personnel responsible for pharmaceuticals at lower levels of health care delivery	6.10.1 Conduct a pharmaceutical skills needs assessment for nonpharmaceutical personnel handling pharmaceuticals	X	X				Transport, conferencing	6.10.1.1 Nonpharmaceutical personnel skills needs assessment report available
		6.10.2 Develop training plan to address training needs of nonpharma-ceutical personnel			X	X		Time	6.10.2.1 Nonpharmaceutical personnel training plan available
Strategic objective 7: To ensure the rational use of medicines by both health care workers and patients to maximise their therapeutic benefit									
Promote rational medicine use among health care workers and in the community	7.1 Incorporate rational medicine use content into existing curricula for all health care professionals	7.1.1 Assess the existing curricula to identify gaps with regards to rational medicines use	X	X			Office of the Head of Pharmaceutical Services	Time, conferencing	7.1.1.1 Existence of report on rational medicines use−re-lated gaps in health care professional training curricula in Swaziland
		7.1.2 Develop pharmaceutical training curriculum for nonpharmaceutical personnel			X	X		Time, conferencing	7.1.2.1 Pharmacy-related training curriculum for nonpharmaceutical personnel available

Strategies	Main interventions	Activities	Timeline (2012−14)				Responsible	Resources	Indicators
			S1	S2	S3	S4			
		7.1.3 Advocate for the inclusion of rational medicines use components from 7.1.2 into the curricula of all health care professionals to address gaps identified in 7.1.1				X	Office of the Head of Pharmaceutical Services	Time	7.1.3.1 Number of advocacy activities conducted towards the inclusion of rational medicines use components into all health care professionals' curricula
	7.2 Provide continuing education to staff on rational medicine use	7.2.1 Develop a system to link continuous professional education to registration renewal	X	X				Time	7.2.1.1 System linking continuous professional education to registration renewal in place
		7.2.2 Develop an in-service training module on rational medicines use for all health care professionals	X	X				Time, conferencing	7.2.2.1 In-service training module on rational medicines use available
		7.2.3 Sensitise all pharmaceutical stakeholders on the continuous professional education requirements			X	X		Time, conferencing	7.2.3.1 Pharmaceutical stakeholder senitisation plan on continuous professional education requirements 7.2.3.2 Pharmaceutical stakeholder sensitisation report
		7.2.4 Sensitise other health care professionals on the availability of rational medicines use training opportunities			X	X		Time, conferencing	7.2.4.1 Sensitisation plan for health care professionals on rational medicines use training opportunities 7.2.4.2 Health care professionals sensitisation report
		7.2.5 Develop a calendar of training activities for all facilities in the country			X	X		Time	7.2.5.1 Calendar for training activities available in health facilities
	7.3 Educate the community on rational medicine use	7.3.1 Develop IEC materials on rational medicines use	X	X				Designing	7.3.1.1 Rational medicines use IEC materials available

Strategies	Main interventions	Activities	Timeline (2012−14)				Responsible	Resources	Indicators
			S1	S2	S3	S4			
		7.3.2 Print and disseminate IEC materials and conduct community awareness activities on rational medicines use			X	X	Office of the Head of Pharmaceutical Services	Printing	7.3.2.1 Printed rational medicines use IEC materials available 7.3.2.2 Rational medicines use IEC materials available at community level 7.3.2.3 Number of community awareness activities on rational medicines use conducted
		7.3.3 Carry out media awareness campaigns on rational medicines use			X	X		Advertising	7.3.3.1 Number of media awareness campaigns on rational medicines use conducted
	7.4 Regulate the advertising and promotion of pharmaceuticals	7.4.1 Develop regulations on the advertising and promotion of pharmaceuticals	X	X			MRA	Time, conferencing	7.4.1.1 Swaziland regulations on the advertising and promotion of pharmaceuticals available
		7.4.2 Print and disseminate regulations to all stakeholders			X	X		Printing	7.4.2.1 Swaziland regulations on the advertising and promotion of pharmaceuticals printed 7.4.2.2 Swaziland pharmaceuticals advertising and promotion guidelines available at end-users
		7.4.3 Sensitise all stakeholders on the regulation of the advertising and promotion of pharmaceuticals			X	X		Conferencing	7.4.3.1 Stakeholder sensitisation plan available 7.4.3.2 Stakeholder sensitisation report available

Strategies	Main interventions	Activities	Timeline (2012−14)				Responsible	Resources	Indicators
			S1	S2	S3	S4			
		7.4.4 Enforce the regulation of the advertising and promotion of pharmaceuticals				X	MRA	Activity resources	7.4.4.1 Number of activities carried out to enforce regulation of the advertising and promotion of pharmaceuticals
Strengthen the use of the STG/EML and the role of Pharmacy & Therapeutic Committees in the country	7.5 Enforce the use of STG/EML in the public sector and encourage the private sector to comply	7.5.1 Develop the STG/EML	X				Office of the Head of Pharmaceutical Services	Consultant	7.5.1.1 STG/EML approved final draft available
		7.5.2 Print and disseminate the STG/EML		X				Printing	7.5.2.1 Printed STG/EML available 7.5.2.2 Printed STG/EML available at end-users
		7.5.3 Train public sector users on the STG/EML		X	X			Conferencing	7.5.3.1 STG/EML user training plan; 7.5.3.2 STG/EML user training report
		7.5.4 Develop a mechanism to monitor the compliance with the STG/EML		X	X			Time	7.5.4.1 Mechanism to monitor the compliance with STG/EML in place
		7.5.5 Implement the mechanism to monitor the compliance with the STG/EML				X		Activity resources	7.5.5.1 Number of activities conducted to monitor compliance with the STG/EML
		7.5.6 Build capacity within facility PTCs to ensure compliance with the STG/EML			X	X		Conferencing, training materials	7.5.6.1 Number of activities carried out towards building the capacity of facility PTCs with regards to ensuring STG/EML compliance
		7.5.7 Train the private sector users and encourage them to comply with the STG/EML			X	X		Conferencing, training material	7.5.7.1 STG/EML private sector user training plan 7.5.7.2 STG/EML private sector user training report
	7.6 Create a mechanism to review the STG/EML	7.6.1 Establish a National Essential Medicines Unit		X	X			Conferencing	7.6.1.1 Existence of National Essential Medicines Unit

Strategies	Main interventions	Activities	Timeline (2012−14)				Responsible	Resources	Indicators
			S1	S2	S3	S4			
		7.6.2 Capacitate the unit with the appropriate human resources		X	X	X	Office of the Head of Pharmaceutical Services	Advertising	7.6.2.1 Number of appropriately skilled personnel appointed to National Essential Medicines Unit
		7.6.3 Provide necessary resources for the unit to function effectively		X	X	X		Office space, supplies	7.6.3.1 Number of resources available for unit to function
		7.6.4 Establish linkages between the Unit and the facility PTCs			X	X		Conferencing	7.6.4.1 Number of meetings conducted between unit & PTCs
	7.7 Enforce generic prescribing and dispensing, and establish regulatory measures to allow for generic substitution in both the public and private sectors	7.7.1 Develop regulations on generic prescribing and dispensing and generic substitution	X	X			MRA	Time	7.7.1.1 Swaziland generic prescribing & generic substitution regulations available
		7.7.2 Print and disseminate regulations to all stakeholders			X	X		Printing	7.7.2.1 Printed Swaziland generic prescribing and generic substitution regulations available; 7.7.2.2 Swaziland generic prescribing and generic substitution regulations available at end-users
		7.7.3 Sensitise all stakeholders on regulation of generic prescribing and dispensing and generic substitution			X	X		Conferencing, transport	7.7.3.1 Stakeholder sensitisation plan; 7.7.3.2 Stakeholder sensitisation meeting report
		7.7.4 Enforce the regulation of generic prescribing and dispensing and generic substitution				X		Activity resources	7.7.4.1 Number of activities carried out to enforce generic prescribing and generic substitution regulations
	7.8 Establish a mechanism that will enable the MoH to coordinate and monitor the performance of PTCs	7.8.1 Revive and strengthen institutional PTCs	X	X	X	X	Office of the Head of Pharmaceutical Services	Transport, conferencing	7.8.1.1 Number of activities conducted to revive and strengthen institutional PTCs

Strategies	Main interventions	Activities	Timeline (2012−14)				Responsible	Resources	Indicators
			S1	S2	S3	S4			
		7.8.2 Train health care workers on PTCs	X	X	X	X	Office of the Head of Pharmaceutical Services	Conferencing, training material	7.8.2.1 PTC training for health care workers training plan 7.8.2.2 PTC training for health care workers training report
		7.8.3 Develop performance monitoring indicators for PTCs	X	X				Time	7.8.3.1 Performance monitoring indicators for PTCs available
		7.8.4 Establish linkages between the PTCs and the National Essential Medicines Unit and other relevant committees		X	X	X		Conferencing	7.8.4.1 Number of activities conducted to establish linkages between facility PTCs and other relevant committees
Strategic objective 8: To maximise the use of positive aspects and minimise the negative consequences of traditional and complementary medicine in the provision of health care services									
Establish mechanisms for collaboration between traditional and complementary practitioners and the MoH	8.1 Develop collaborative framework between MoH and traditional and complementary practitioners and coordinate services and activities between traditional and complementary practitioners and MoH	8.1.1 Engage the leaders of the traditional healers' associations to discuss issues of common concern (e.g., medicines safety, rational medicines use)	X		X		Office of the Head of Pharmaceutical Services	Conferencing	8.1.1.1 Number of activities conducted towards engaging traditional healers on discussion issues of common concerns
Regulate the practice of complementary medicine practitioners	8.2 Establish mechanisms for overseeing the activities related to the safety and efficacy of complementary medicines as well as claims made by the practitioners	8.2.1 Develop a register of all complementary medicines in the country		X	X	X	MRA	Advertising, computer with Internet, stationery	8.2.1.1 Swaziland register of complementary medicines available
		8.2.2 Develop guidelines governing the labeling, classification, advertising and promotion of complementary medicines	X	X				Consultant, time	8.2.2.1 Swaziland guidelines for label-ing, classification, advertising and promotion of complementary medicines available

Strategies	Main interventions	Activities	Timeline (2012−14)				Responsible	Resources	Indicators
			S1	S2	S3	S4			
		8.2.3 Print and disseminate the guidelines to all stakeholders			X	X	MRA	Printing	8.2.3.1 Printed Swaziland guidelines for labeling, classification, advertising, and promotion of complementary medicines 8.2.3.2 Complementary medicines guidelines available at end-users
		8.2.4 Sensitise all stakeholders on the complementary medicines guidelines			X	X		Conferencing	8.2.4.1 Stakeholder sensitisation plan on complementary medicines guidelines 8.2.4.2 Stakeholder sensitisation report
Strategic objective 9: To encourage local production as one way of improving access to medicines									
Promote establishment of new local production units	9.1 Advocate for additional incentives to stimulate local manufacturing	9.1.1 Lobby for the removal of import taxes on raw materials	X	X	X	X	Office of the Head of Pharmaceutical Services	Time	9.1.1.1 Number of activities carried out towards the lobbying for the removal of raw material import taxes
		9.1.2 Motivate for the restriction of the local preference government procurement price advantage to local manufacturing units	X	X	X	X		Time	9.1.2.1 Number of activities conducted to motivate for restriction of the local preference price advantage to local manufacturing units
	9.2 Create an enabling and transparent environment to access the existing incentives	9.2.1 Obtain information on the requirements for establishing a local pharmaceutical manufacturing unit and available incentives	X	X	X	X		Time	9.2.1.1 Information on requirements for establishing local pharmaceutical manufacturing unit and existing incentives available
		9.2.2 Avail this information to all interested parties	X	X	X	X		Time	9.2.2.1 Information accessible to all interested parties
Strengthen compliance of local production units	9.3 Encourage local production units to upgrade cGMP status	9.3.1 Develop Swaziland cGMP guidelines	X	X				Time, consultant	9.3.1.1 Swaziland cGMP guidelines available

Strategies	Main interventions	Activities	Timeline (2012−14)				Responsible	Resources	Indicators
			S1	S2	S3	S4			
with cGMP		9.3.2 Print and disseminate Swaziland cGMP guidelines to local production units			X	X	Office of the Head of Pharmaceutical Services	Printing	9.3.2.1 Printed Swaziland cGMP guidelines available at local production units
		9.3.3 Create a system for continuous information sharing on relevant updates		X	X			Time	9.3.3.1 System for continuous information sharing in place
		9.3.4 Conduct inspections to ensure cGMP compliance of local production units				X		Transport, time	9.3.4.1 cGMP inspection reports available
Strategic objective 10: To foster research aimed at resolving problem areas of the Swaziland pharmaceutical sector									
Improve the regulation of pharmaceutical research in Swaziland	10.1 Build the capacity of the MoH Research Unit	10.1.1 Conduct an assessment of the unit's capacity to regulate pharmaceutical research	X	X			Office of the Head of Pharmaceutical Services, SID	Conferencing	10.1.1.1 MoH Research Unit pharmaceutical research regulation capacity assessment report
		10.1.2 Develop guidelines on the regulation of pharmaceutical research	X	X			Office of the Head of Pharmaceutical Services	Conferencing, time	10.1.2.1 Swaziland pharmaceutical research regulation guidelines available
		10.1.3 Train the unit's staff on the regulation of pharmaceutical research			X	X	Office of the Head of Pharmaceutical Services, SID	Conferencing, training materials	10.1.3.1 MoH Research Unit training plan on pharmaceutical research regulation 10.1.3.2 MoH Research Unit training report on pharmaceutical research regulation
		10.1.4 Develop a plan to address any other gaps identified in 10.1.1		X	X			Time	10.1.4.1 Existence of implementation plan for MoH Research Unit pharmaceutical research regulation capacity assessment report
	10.2 Ensure that clinical trials are well regulated and monitored by the relevant authorities	10.2.1 Develop regulations for conducting and monitoring clinical trials	X	X			MRA	Conferencing	10.2.1.1 Swaziland clinical trials monitoring and regulation guidelines

Strategies	Main interventions	Activities	Timeline (2012−14)				Responsible	Resources	Indicators
			S1	S2	S3	S4			
		10.2.2 Print and disseminate the regulations governing clinical trials			X	X	MRA	Printing	10.2.2.1 Printed Swaziland clinical trials monitoring and regulation guidelines 10.2.2.2 Swaziland clinical trials monitoring and regulation guidelines available at end-users
		10.2.3 Sensitise all stakeholders on the regulation of clinical trials			X	X		Conferencing	10.2.3.1 Stakeholder sensitisation plan on the regulation of clinical trials 10.2.3.2 Stakeholder sensitisation report
		10.2.4 Appoint a focal person for Pharmaceutical Research and Development Unit		X	X		Office of the Head of Pharmaceutical Services	Advertising	10.2.4.1 Focal person formally appointed with written TORs
		10.2.5 Provide necessary resources for unit to function effectively		X	X			Office space, supplies	10.2.5.1 Inventory of resources available to the unit
		10.2.6 Foster linkages between the Pharmaceutical Research and Development Unit and the MoH Research Unit		X	X	X		Conferencing	10.2.6 Number of activities conducted to foster linkages between Pharmaceutical Research and Development and the MoH Research Unit
Promote research in pharmaceutical priority areas	10.3 Identify pharmaceutical priority areas for research in Swaziland	10.3.1 Conduct an assessment of areas for pharmaceutical research	X	X			Office of the Head of Pharmaceutical Services, SID	Conferencing	10.3.1.1 Pharmaceutical research areas assessment report
		10.3.2 Develop a plan to address the identified priority pharmaceutical research areas		X	X			Time	10.3.2.1 Pharmaceutical research implementation plan
		10.3.3 Mobilise resources to sponsor priority areas of pharmaceutical research			X	X	Office of the Head of Pharmaceutical Services	Time	10.3.3.1 Number of activities conducted to mobilise resources for priority research areas sponsorship

Strategies	Main interventions	Activities	Timeline (2012−14)				Responsible	Resources	Indicators
			S1	S2	S3	S4			
	10.4 Encourage operational research in the pharmaceutical sector	10.4.1 Create a mechanism for the dissemination of operational research findings		X	X		Office of the Head of Pharmaceutical Services, SID	Time	10.4.1.1 Mechanism for the dissemination of operational research findings available
		10.4.2 Establish a system for recognition of operational research work through the continuous professional education point system		X	X			Time	10.4.2.1 System for recognition of operational research work through continuous professional education point system in place
Strategic objective 11: To strengthen cooperation and coordination between the MoH and other government ministries and development partners									
Improve the collaboration between the MoH and relevant ministries, organisations and agencies on pharmaceutical matters	11.1 Collaborate with other ministries and public institutions on pharmaceutical issues	11.1.1 Identify pharmaceutical issues that necessitate the involvement of other ministries and public institutions	X				Office of the Head of Pharmaceutical Services	Conferencing	11.1.1.1 Existence of report of issues requiring other ministries and public institutions' involvement
		11.1.2 Develop MOUs with the other ministries and public institutions		X	X	X		Consultant, time	11.1.2.1 MOUs with other ministries and public institutions available
	11.2 Collaborate with development partners, NGOs and regional organisations on pharmaceutical matters	11.2.1 Identify pharmaceutical issues that necessitate the involvement of development partners, NGOs and regional organisations	X					Conferencing	11.2.1.1 Existence of report of issues requiring involvement of development partners, NGOs, and regional organisations
		11.2.2 Develop MOUs with the development partners, NGOs and regional organisations		X	X	X		Consultant, time	11.2.2.1 MOUs with relevant development partners, NGOs, and regional organisations available
Building consensus amongst all stakeholders	11.3 Establish mechanisms for effective involvement of relevant stakeholders on pertinent pharmaceutical matters as required	11.3.1 Identify pharmaceutical areas that necessitate stakeholder involvement	X					Conferencing	11.3.1.1 Existence of report of issues requiring stakeholder input

Strategies	Main interventions	Activities	Timeline (2012−14)				Responsible	Resources	Indicators
			S1	S2	S3	S4			
		11.3.2. Develop an activity mapping framework for all stakeholders	X	X	X	X	Office of the Head of Pharmaceutical Services	Time	11.3.2.1 Activity mapping framework for all stakeholders available
		11.3.3 Involve stakeholders on pharmaceutical issues as per the activity mapping framework	X	X	X	X		Conferencing	11.3.3.1 Number of activities conducted involving relevant stakeholders according to the activity mapping framework
	11.4 Establish mechanisms for disseminating relevant pharmaceutical information to both the public and private sectors	11.4.1 Conduct a stakeholder information needs assessment	X					Conferencing	11.4.1.1 Stakeholder information needs assessment report
		11.4.2 Develop a stakeholder information needs plan to address the needs identified in the assessment		X	X	X		Time	11.4.2.1 Stakeholder information needs plan available
		11.4.3 Develop process of disseminating information to all stakeholders according to their needs as identified in 11.4.1		X				Time	11.4.3.1. Process for disseminating information to stakeholders available with documentation
	11.5 Fostering a sense of ownership amongst the public and private sector on pharmaceutical issues	11.5.1 Develop system of input, review, & feedback among all pharmaceutical stakeholders	X	X				Time	11.5.1.1 Feedback system among pharmaceutical stakeholders available
		11.5.2 Conduct annual public-private pharmaceutical sector forum to discuss all pertinent issues			X			Conferencing	11.5.2.1 Public-private pharmaceutical sector forum report
Strategic objective 12: To ensure effective M&E of the implementation of the SPSP									
Establish an M&E system for the SPSP	12.1 Conduct a baseline study of pharmaceutical services in Swaziland	12.1.1 Identify areas of focus and indicators for the baseline study	X				Office of the Head of Pharmaceutical Services	Conferencing	12.1.1.1 Report of areas of focus and indicators for the baseline study
		12.1.2 Develop a protocol for conducting the baseline study	X					Time	12.1.2.1 Baseline study protocol available
		12.1.3 Develop the data collection tool	X					Time, Stationery	12.1.3.1 Baseline study data collection tool available

Strategies	Main interventions	Activities	Timeline (2012−14)				Responsible	Resources	Indicators
			S1	S2	S3	S4			
		12.1.4 Obtain approval from the Scientific and Ethics Committee to conduct the study	X	X			Office of the Head of Pharmaceutical Services	Time	12.1.4.1 Number of activities conducted towards obtaining Scientific and Ethics Committee approval 12.1.4.2 Scientific and Ethics Committee written approval
		12.1.5 Conduct the baseline study		X	X			Transport, Time	12.1.5.1 Baseline survey results available
		12.1.6 Compile the report and disseminate findings			X	X		Time	12.1.6.2 Baseline survey report available at stakeholders
	12.2 Develop an M&E operational framework for the pharmaceutical sector	12.2.1 Develop pharmaceutical sector performance indicators	X	X				Conferencing	12.2.1.1 PMIS indicators
		12.2.2 Develop tools for routine reporting and analysis of pharmaceutical sector information	X	X	X			Stationery, time	12.2.2.1 PMIS data collection tools
		12.2.3 Produce an annual supply chain performance report			X		Office of the Head of Pharmaceutical Services, SCTWG	Time	12.2.3.1 Annual supply chain performance report available
	12.3 Build the M&E capacity for the pharmaceutical sector across all levels of health service delivery	12.3.1 Develop training materials and guidelines on pharmaceutical M&E	X	X			Office of the Head of Pharmaceutical Services	Conferencing	12.3.1.1 Existence of training materials and guidelines for pharmaceutical M&E
		12.3.2 Train health care workers in pharmaceutical M&E			X	X		Conferencing	12.3.2.1 Training plan for training health care workers on pharmaceutical M&E available 12.3.2.2 Pharmaceutical M&E training report
	12.4 Develop a coordinating mechanism for the implementation of the SPSP	12.4.1 Appoint focal person for the Pharmaceutical M&E Unit		X	X			Advertising	12.4.1.1 Pharmaceutical M&E Unit focal person available 12.4.1.2 TORs available for focal person

Strategies	Main interventions	Activities	Timeline (2012−14)				Responsible	Resources	Indicators
			S1	S2	S3	S4			
		12.4.2 Provide necessary resources to enable the Pharmaceutical M&E Unit to function efficiently		X	X	X	Office of the Head of Pharmaceutical Services	Office space, supplies	12.4.2.1 Inventory of resources availed to the Pharmaceutical M&E Unit
		12.4.3 Establish and maintain linkages with the MoH M&E Unit		X	X	X		Conferencing	12.4.3.1 Number of activities carried out towards establishing and maintaining linkages with the MoH M&E Unit
		12.4.4 Ensure periodic reviews of the SPSP				X		Conferencing, Consultant	12.4.4.1 SPSP review plan

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