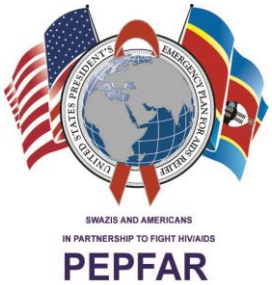
Swaziland Pharmaceutical Strategic Plan (2012-2016): Baseline Survey

January 2013



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Swaziland Pharmaceutical Strategic Plan (2012-2016): Baseline Survey

Pharmaceutical Services Department - Ministry of Health

January 2013

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The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, the SIAPS result areas include improving governance, building capacity for pharmaceutical management and services, addressing information needed for decision-making in the pharmaceutical sector, strengthening financing strategies and mechanisms to improve access to medicines, and increasing quality pharmaceutical services.

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Key Words

Pharmaceutical strategic plan, baseline assessment, pharmaceutical services monitoring and evaluation, Swaziland pharmacy sector

Systems for Improved Access to Pharmaceuticals and Services
Center for Pharmaceutical Management
Management Sciences for Health
4301 North Fairfax Drive, Suite 400
Arlington, VA 22203 USA
Telephone: 703.524.6575
Fax: 703.524.7898
E-mail: siaps@msh.org
Website: www.siapsprogram.org

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FOREWORD

The National Health Policy (NHP), 2007 raised key policy issues, including access to safe medicines and diagnostic technology. In response to this, the Ministry of Health developed the National Pharmaceutical Policy, 2011 – 2nd Edition (SNPP). In order to operationalize this Second Edition SNPP, the Ministry developed the Swaziland Pharmaceutical Strategic Plan, 2012-2016 (SPSP). The SPSP 2012 - 2016 serves as a roadmap for the SNPP implementation and charts the way forward in order to fully address the key policy orientations identified and prioritised in the Pharmaceutical Policy.

To measure and ensure the efficient implementation of the SPSP, a baseline survey of the pharmaceutical sector was conducted in July to August 2012. The Pharmaceutical Services Baseline Survey Report will facilitate the monitoring and evaluation (M&E) function of the implementation of the Pharmaceutical Strategic Plan. This report contains input from all the relevant pharmaceutical sector stakeholders. The Report is a reflection of the pharmaceutical sector situation that existed on the ground when the survey was conducted (July – August 2012). The survey identified a number of successes in the pharmaceutical sector, but also revealed gaps that can be addressed through implementation of the Strategic Plan.

The Ministry of Health reiterates its commitment to implementing the Pharmaceutical Policy, through the Strategic Plan, and monitoring the effectiveness of its implementation using this Baseline Survey Report as the M&E baseline. Thus, I urge all stakeholders to continue to work with the Ministry in implementing the Pharmaceutical Policy and Strategic Plan in order to improve delivery of pharmaceutical services in Swaziland.

Simon M. Zwane
Principal Secretary, Ministry of Health

ACKNOWLEDGEMENTS

The Ministry of Health extends its gratitude to all partners and stakeholders who provided baseline information on the pharmaceutical sector, which will be used to inform the implementation of the Swaziland Pharmaceutical Strategic Plan 2012-2016 (SPSP), including Officials of the Ministry of Health, other government ministries and organisations, partners, non-governmental organisations and the private sector. We particularly thank Management Sciences Health/Systems for Improved Access to Pharmaceuticals and Services program (SIAPS) for providing technical and financial support.

The Ministry also conveys its appreciation to the SPSP baseline survey working group, the pharmacy cadre, and the data collection team for their dedication and efforts to ensure this exercise was completed.

Below are the members of the baseline survey working group, whose contributions to this effort were invaluable:

Core Team

Fortunate Fakudze	Central Medical Stores
Ola Fatodu	Clinton Health Access Initiative
Khontile Kunene	Ministry of Health (Secretariat)
Felicity Magagula	Regional Pharmacist, Lubombo Region
Sbongile Mndzebele	Monitoring and Evaluation Unit
Kholiwe Shongwe	Raleigh Fitkin Memorial Hospital
Mavis Vilane	Central Medical Stores (Secretariat)

Extended Working Team

Sandile Dlamini	Monitoring and Evaluation Unit
Sihle Mabuza	Central Medical Stores
Bongiwe Malaza	Central Medical Stores
Maqhawe Sibandze	SIAPS Swaziland

Vusi Magagula
Director of Health Services

ACRONYMS

ART	antiretroviral therapy
cGMP	current Good Manufacturing Practices
CHAI	Clinton Health Access Initiative
CMS	Central Medical Stores
COMESA	Common Market for Eastern and Southern Africa
ECSA-HC	East, Central and Southern Africa Health Community
EGPAF	Elizabeth Glaser Pediatric AIDS Foundation
FBO	faith-based organizations
MCAZ	Medicines Control Authority of Zimbabwe
MOH	Ministry of Health
MOPSI	Ministry of Public Service and Information
MRA	Medicines Regulatory Authority
MSF	Medecins sans Frontieres
MSH	Management Sciences for Health
NDAC	National Drug Advisory Committee
NHP	National Health Policy
NPP	National Pharmaceutical Policy
NQE	National Quantification Exercise
PPP	public and private partnership
PTC	Pharmaceutical and Therapeutic Committee
RFM	Raleigh Fitkin Memorial
RMU	rational medicines use
SADC	Southern African Development Community
SANU	Southern African Nazarene University
SCTWG	Supply Chain Technical Working Group
SEC	Scientific and Ethics Committee
SIPA	Swaziland Investment Promotion Authority
SMO	senior medical officer
SOPs	standard operating procedures
SPSP	Swaziland Pharmaceutical Strategic Plan
SRA	Swaziland Revenue Authority
STG/EML	Swaziland Standard Treatment Guidelines/Essential Medicines List
SWASA	Swaziland Standards Authority
UN	United Nations
URC	University Research Council
USFDA	United States Food and Drug Administration
WHO	World Health Organisation

EXECUTIVE SUMMARY

Background

One of the fundamental policy objectives highlighted by the National Health Policy (NHP), 2007 was access to safe medicines and diagnostic technology. In an effort to address this, the Ministry of Health developed the National Pharmaceutical Policy, 2011 (SNPP). The Swaziland Pharmaceutical Strategic Plan, 2012-2016 (SPSP), was developed to operationalize the SNPP. The SPSP provides the overall roadmap for pharmaceutical services development in the health sector. To inform the monitoring and evaluation of the SPSP implementation plan, a baseline survey of the pharmaceutical sector was conducted from July to August 2012.

Methodology

The study was mainly qualitative in nature and used both primary and secondary data sources. Key informant interviews were conducted with targeted informants within the pharmaceutical sector. Face to face interviews were conducted by the monitoring and evaluation (M&E) and pharmaceutical services data collection team using a standard questionnaire. The questionnaire was structured in accordance with the 12 strategic objectives outlined in the SPSP. The components of the questionnaire targeted senior management within the Ministry of Health (MOH), health facility personnel in charge of the pharmacy, partners, and other pharmaceutical stakeholders.

The key respondents in health facilities were pharmacists, pharmacy technicians and senior nurses. In selecting the health facilities, stratified sampling was applied. The facilities were stratified according to three levels of health care: hospitals, health centres and clinics. A total of 20 public sector health facilities were selected to form the sample population. Seven hospitals, five health centres and eight clinics (two clinics per region) were selected using a convenience sampling method. The data collection process commenced in July 2012 and was completed at the end of August 2012. Due to the qualitative nature of the study, the data was compiled into summaries across the common themes of the questionnaire. This report will serve as a baseline for all activities within the SPSP action plan. The structure of the report is consistent with the data collection tool.

Findings

There is only one staff member, the Head of Pharmaceutical Services, at the level of Pharmaceutical Services Administration. This Office of the Head of Pharmaceutical Services does not have adequate human and other resources necessary for it to function efficiently. There are two functional technical committees supporting the national pharmaceutical services activities; the National Drug Advisory Committee and the Supply Chain Technical Working Group.

Swaziland participates in the Southern African Development Community (SADC), Common Market for Eastern and Southern Africa (COMESA) and East, Central and Southern Africa Health Community (ECSA) initiatives. It lacks a public-private partnership and a mechanism

for the coordination of Partner interventions in the pharmaceutical sector. However, all Partners have Memorandums of Understanding (MOUs) with the MOH.

The pharmaceutical sector is governed by the Pharmacy Act, 1929, which does not provide for adequate regulation of the pharmaceutical sector. The Pharmacy Bill, 2012 and the Medicines and Related Substances Control Bill, 2012 were developed to regulate the profession and practice of pharmacy; and to regulate the registration, importation and use of medicines and related substances, respectively, so as to fill the gaps identified in the Pharmacy Act, 1929. These Bills are currently awaiting enactment by the House of Parliament. Although a number of advocacy activities have been undertaken in support of enactment of the Bills, additional advocacy is needed in order for the Bills to be passed into law.

There is no medicines registration mechanism in Swaziland. The Medicines and Related Substances Control Act shall establish the Swaziland Medicines Regulatory Authority (MRA), which will be the Authority responsible for the registration and the regulation of medicines in the country. In the meantime, some activities have been conducted in preparation for the establishment of the MRA. While there is no Quality Control Unit and no Pharmacovigilance and Drug Information Unit within the Ministry, some measures are being taken to establish these Units. There is also no Pharmaceutical Inspectorate Unit in place. The Pharmacy Act shall establish the Pharmacy Council but no activities have been conducted in preparation for that. In the meantime, the Medical and Dental Council conducts the registration of pharmacy personnel.

The Central Medical Stores' (CMS) organizational structure has been reviewed to increase its supply chain management efficiency. The proposed structure was approved by the MOH and is presently awaiting approval by the Ministry of Public Service and Information (MOPSI). The CMS and National Procurement Unit require strengthening and capacity building to enhance their staffs' skills and their available resources, and thereby improve the units' effectiveness. A draft Procurement Manual and Procurement Standard Operation Procedures (SOPs) are under development. The security and storage capacity of pharmaceutical commodities is insufficient at both the central and facility levels.

Advocacy activities to support sufficient financing of pharmaceutical commodities have been conducted. Nonetheless, more advocacy activities are needed in order to achieve adequate pharmaceutical budget allocation. There is no mechanism in place to capture all of the sources of pharmaceutical services funding or a comprehensive mechanisms for the control and monitoring for accountability of the use of pharmaceuticals.

There are 20 public sector pharmacists and 44 pharmacy technicians. Swaziland is heavily reliant on outside countries for training pharmacy personnel and for a pool of pharmaceutically skilled personnel; all pharmacists are trained outside the country and 55% of the pharmacy technicians are expatriates. There is no orientation programme for newly recruited pharmacy personnel. There are no specific retention strategies for pharmacy personnel in the public sector and there are no minimum wage standards for those in the private sector.

The Standard Treatment Guidelines/Essential Medicines List (STG/EML) has been developed to promote rational medicines use. However, no STG/EML use enforcement activities have been taken because the document is awaiting launch by the Minister of Health.

Furthermore, the STG/EML coordinating mechanisms have not been put in place yet. Rational medicines use has not been incorporated into health professionals' pre-service curricula in the country but in-service training as well as public education exercises on rational medicines use have been conducted.

There is no collaborative framework between the MOH and traditional and complementary medicine practitioners. There is also no mechanism for the MOH to oversee the safety and efficacy of complementary medicines. No actions have been taken to stimulate local production and create an enabling and transparent production environment.

In addition, no activities have been conducted to ensure that clinical trials are well regulated and monitored, or to encourage pharmaceutical operational research. The MOH and other ministries and public institutions have engaged in some collaborative activities but they have not entered into MOUs. Stakeholders are involved in pertinent pharmaceutical matters, however. Although there is no established mechanism for information dissemination, relevant information is disseminated through various channels to stakeholders. There is also no coordination mechanism for the implementation of the SPSP and no monitoring and evaluation plan for the SPSP at present.

Conclusion

The SPSP action plan was developed to address gaps identified in the pharmaceutical sector. This baseline survey will serve as an indicator of the level and extent to which the proposed interventions should be implemented in order to adequately address the gaps and strengthen the quality, effectiveness and efficiency of the pharmaceutical services in Swaziland.

BACKGROUND

Introduction

The Swaziland National Health Policy (NHP), 2007 identified several crucial policy issues, among which health resources were viewed as a challenge, including access to safe medicines and diagnostic technology. In order to strengthen access to safe medicines, the Ministry of Health developed the second edition of the Swaziland National Pharmaceutical Policy (SNPP), 2011 – a review of the SNPP, 2000. The overall goal of the SNPP is to contribute towards improving the health of Swaziland's population by ensuring equitable access to, and rational use of efficacious, high quality essential medicines and medical supplies and devices at an affordable cost.

To operationalize the SNPP, the Ministry developed the Swaziland Pharmaceutical Strategic Plan (SPSP), 2012-2016. The SPSPS provides the overall roadmap for pharmaceutical services development in the health sector. The roadmap focuses on 12 priority areas, including national pharmaceutical service administration, the supply of medicines, pharmaceutical financing and quality assurance, traditional and complementary medicine and patents and global trade agreements.

To facilitate the monitoring of the implementation of the SPSP and to evaluate the National Pharmaceutical Policy's effectiveness, the Ministry of Health conducted a baseline survey of the pharmaceutical sector to assess the current situation across the 12 priority areas. The baseline study report will also serve as a frame of reference for subsequent comparisons on which evaluations of the implementation of the SPSP will be based. Furthermore, the baseline survey will assist the Ministry in identifying the appropriate scope of intervention required to improve pharmaceutical services delivery during the implementation of the SPSP.

The Pharmaceutical Strategic Plan's monitoring and evaluation plan is closely linked to each strategic objective of the log frame and includes indicators of achievement and means of verification. The baseline survey is an early component of the monitoring and evaluation plan and uses the log frame structure to systematically assess the circumstances in which the SPSP implementation commences.

Background

Geographic and Population Context

According to the 2007 census, the population of Swaziland is 1,018,449. About 77% of the population lives in rural areas and 27% in cities and townships. Regionally, the population is distributed as follows: Hhohho (331,734), Manzini (360,248), Shiselweni (241,365), and Lubombo (249,153).

Women of child-bearing age (15-19years), comprise 26.2% of the total population, while all females account for 53%. An estimated 4.6% of the population is 60 years of age and over. According to the Swaziland Demographic Health Survey (DHS 2006-2007), about 60% of the population are under 30, of which 39.6% are children under the age of 15. 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. The average life expectancy at birth has fallen from 60 years in 1997 to 43 years in 2007.

Socioeconomic Profile

Swaziland is classified as a lower middle-income country and its gross domestic product (GDP) per capita income is estimated at about US$2,533[1]. Income distribution is heavily skewed; 54.6% of the country's wealth is held by the richest 20% of the population compared to 4.3% of the wealth held by the poorest 20%. In addition, 63% of the population lives below the upper poverty line of E71.07 per capita per month.

In the wake of the global economic downturn, GDP growth for 2009 was estimated at 1.2% of GDP, which constitutes a decline of 2.4% from its level in 2008. Prospects for 2011 are less favorable, with GDP predicted to rise by 0.5% due to the need for fiscal adjustment. Swaziland's revenue has also been severely affected by the global downturn. While approximately 60% of government revenue consisted of SACU receipts in 2008, it is estimated at 9.3% in 2010.

Swaziland's middle income status is misleading from a human development perspective. The Human Development Index (HDI) rose from 0.535 in 1980 to 0.641 in 1995 but declined to 0.572 in 2007. Furthermore, the DHS reports that Swaziland is not on track to meet its Millennium Development Goal (MDG) targets, with its performance regarding MDGs four and five actually worsening. In addition, health outcomes are worsening due to high levels of HIV/AIDS and tuberculosis (TB) and the limited progress made regarding maternal, neo-natal and child health.

Health Sector Profile

Health Status

The country's investment in health, over several years, has not resulted in the expected improvement in some key health indictors. Both communicable and non-communicable 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 in-patient morbidity and mortality, with AIDS and TB together accounting for over a third of admissions and deaths.

Currently the most frequently cited reasons for admission include pulmonary diseases, malaria, gastro-enteritis, colitis and pneumonia. On the other hand, diabetic mellitus and non-communicable diseases were reportedly among the top ten leading causes of in-patient admissions in 2009. Others include cancers, cardio-vascular diseases, nutritional conditions and injuries or trauma.
In 2010, 11,057 new confirmed TB cases were reported, and the incidence of the disease 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), 88% of TB patients have been tested for HIV, of whom 82% tested positive.

[1] The World Bank, World Development Indicators 2009

Universal access to antiretroviral therapy is one of the goals of the response to the HIV and AIDS epidemic. By the end of September 2010, 55 296 (64.1%) people with HIV and AIDS were actively treatment, which consisted of 49 907 adults and 5 389 children. Using the eligibility criteria of CD4 cell count (a 350 cut-off point), approximately 77 156 require ART and a projected 97 108 will require ART by 2015.

The recent Demographic and Health Survey (Swaziland DHS 2006-07) reports that infant mortality is at 85 deaths per 1,000 live births, and under-five mortality at 120 deaths per 1,000 live births. Furthermore, 70% of all deaths are reported to have taken place during the first year of the child's life.

The crude death rate per 1,000 population increased from 13 in 1990 to 26.2 in 2005 (World Bank, 2006). Infant Mortality (IMR) per 1,000 live births increased from 94.4 per 1000 in 1990 to 108 in 2005 (World Bank, 2006). It is important to note that malnutrition is one of the major contributing factors to high infant mortality and high morbidity and mortality among children under five. Indeed, almost 20% of children in the country were found to be severely stunted and 5.1% severely underweight in 2004 (MOHSW & WHO, 2004).

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

Organization of the Health System

The Swaziland health system is based on the concept of primary health care, which consists of three main levels: primary, secondary and tertiary. The primary level involves clinics and outreach services. The secondary level is comprised of health care centres, which offer both outpatient and inpatient services; and serve as referral points for the primary level facilities. The tertiary level consists of regional hospitals, specialized hospitals and the national referral hospital. The health care system relies on both formal and informal sectors. The formal health service sector consists of both public and private health services providers including NGOs, mission, 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), National Clinical Referral Laboratory (NCRL), National Blood Transfusion Service, and 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.

Key Pharmaceutical Areas Assessed

The baseline survey assessed the following key pharmaceutical areas, as prioritised by the National Pharmaceutical Policy and Pharmaceutical Strategic Plan:

- National pharmaceutical services administration
- Pharmaceutical legislation and regulations
- National pharmaceutical supply chain system
- Pharmaceutical quality assurance
- Financing of pharmaceuticals
- Human resources development
- Rational medicine use
- Traditional and complementary medicine
- Local production (of pharmaceuticals to increase access to medicines)
- Pharmaceutical research
- Technical inter-sectorial cooperation and coordination; and
- Monitoring and evaluation

METHODOLOGY

Introduction

This chapter describes how the pharmaceutical services baseline survey was conducted. This includes the objectives of the baseline survey, the study design and the data collection process. The chapter also explains how the data was analysed and presented in this report.

Objectives of the Study

The objectives of this baseline survey were to:

- Gather information on the situation of the pharmaceutical sector at the start of the implementation of the Swaziland Pharmaceutical Strategic Plan, 2012-2016.

- Assess the pharmaceutical sector's situation at the beginning of the implementation period of the SPSP so that periodic evaluations can be made about the quality and development results achieved from implementing the SPSP.

- Develop a basis for subsequent measurement and assessment of the impact of the implementation of the SPSP and the eventual results achieved. Mid-term reviews, SPSP completion reports and other evaluations will judge progress, largely based on comparisons with the information obtained from the Baseline Survey Report.

Methodology

Study Design

The study was qualitative because qualitative research can offer insight into research problems during the initial stages when little is known about the research problem. Furthermore, qualitative research is somewhat unstructured and helps elicit responses that could be otherwise difficult to discover. Qualitative research also guards against a loss of understanding certain phenomena from the point of view of its participants within their environment, which occurs through the quantification of data.

The research design used in this study was the survey design because surveys provide quick, inexpensive, efficient, and accurate means of assessing information about the question under study. The research was a cross-sectional study, as the data was collected at one point in time.

Target Population

The target population for this research was senior management within the Ministry of Health (MOH) and other relevant government ministries, health facility personnel in charge of the pharmacy, development and implementation partners, tertiary training institutions, and other pharmaceutical stakeholders. The key respondents in health facilities were pharmacists, pharmacy technicians and senior nurses.

Sampling

A combination of non-probability and probability sampling was used in this study. Judgment sampling (non-probability sampling) was used in selecting key respondents (except for those in health facilities), whereby the key respondents were selected based on their knowledge of and role in the management of certain aspects affecting the pharmaceutical sector. In selecting the health facilities, stratified sampling (probability sampling) was applied. The facilities were stratified according to three levels of health care, namely; hospitals, health centres and clinics. A total of 20 public sector health facilities were selected to form the sample population. Seven hospitals, five health centres, and eight clinics (two clinics per region) were selected using a convenience sampling (non-probability sampling) method. Figure 1 below shows the distribution of the selected health facilities by type (or level of health care).

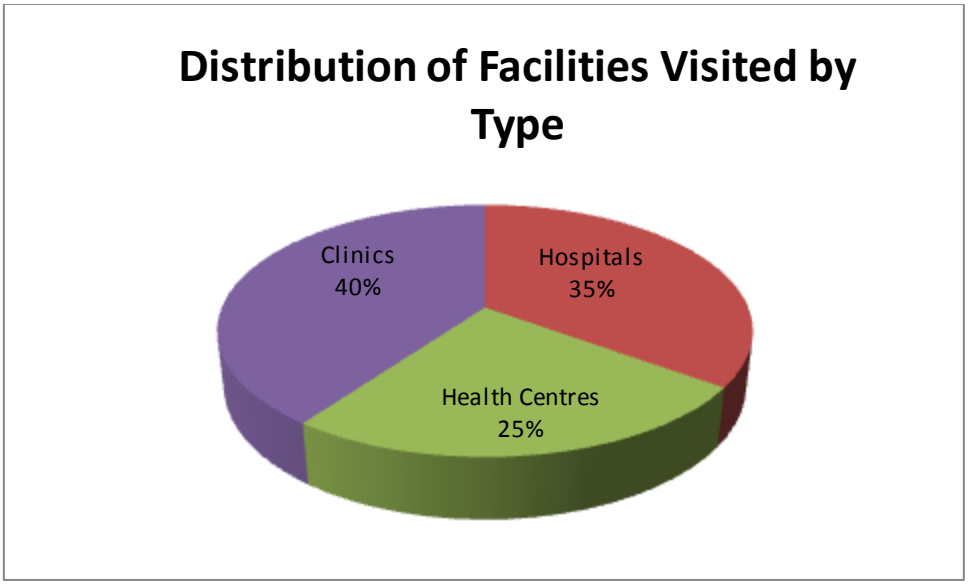

Figure 1. Proportion of selected health facilities

Data Collection

The data collection process used both primary and secondary data sources. Primary data was collected from key respondents and secondary data from relevant Ministry of Health documents.

Data Collection Tool

A standard questionnaire was developed using the means of verification from the SPSP logical framework as the starting point. The questionnaire was structured according to the twelve (12) strategic areas as outlined in the SPSP. The key informants for each question were then noted beside the questions.

Data Collection

Key informant interviews were conducted with targeted informants within the pharmaceutical sector. The M&E and pharmaceutical services data collection team conducted face to face interview using the standard questionnaire. Interviews were conducted mainly because they the researcher to adapt and change questions as the interview proceeds within the parameters set by the assigned questions.

Research Process

Data Collection Phase

The data collection process began in July 2012 and was completed at the end of August 2012.

Data Analysis

Since the study is of a qualitative nature, the data was compiled into summaries across the common themes of the questionnaire and the findings are presented according to the 12 strategic areas in this report.

Presentation of Findings

The baseline survey findings are presented in chapters 3 to 14. The findings are presented according to the 12 Strategic Areas. Under each area, an overview is provided to orient readers on the strategic orientation and direction of that area. The overview is followed by the presentation of the survey findings, which are then discussed and summarised under the 'discussion' sub-section.

NATIONAL PHARMACEUTICAL SERVICES ADMINISTRATION

Overview

The National Pharmaceutical Services Administration Unit is responsible for co-coordinating all functions and activities of the national pharmaceutical sector. This will be achieved through strengthening the capacity of the pharmaceutical services unit, ensuring continuous supply of essential medicines, aligning the strategic orientation of the national pharmaceutical services and administration with those of the sub-region and coordinating development partner support.

Findings

Number of Skilled Personnel and Required Resources

At the administration level, there is only one skilled staff member, and that is the chief pharmacist who sits at the Ministry of Health. In terms of other resources, currently there is one desktop computer, a direct phone line, and access to the government Internet. There is no vehicle assigned to this office and no government issued cell phone. There is also no fax machine, no laptop and no printer in this office.

Existence of Technical Committees

The only two technical committees are the Supply Chain Technical Working Group (SCTWG) and the National Drug Advisory Committee (NDAC). The SCTWG meets quarterly as planned, but can meet more often, as required. It contains representatives of the Directorate, CMS and all partners involved in pharmaceutical supply chain issues. The NDAC is supposed to meet quarterly, but currently meets once a year during the tender adjudication period. The NDAC constitutes of hospital pharmacists, National Procurement Unit, CMS, hospital Senior Medical Officers (SMOs) and the MOH Directorate.

Existence of Functional Central System for All Pharmaceutical Information

Pharmaceutical information is available at different sources and levels but is not centralized and is not coordinated.

National Quantification Exercises (NQEs)

There are currently no Standard Operating Procedures (SOPs) and no schedule for conducting NQEs. It has not yet been established when NQEs are to be conducted and how they are to be conducted.

Existence of Endorsed WHO/SADC Donation Guidelines

The World Health Organisation WHO/SADC donation guidelines are available and endorsed, but have not yet been adapted nor adopted in Swaziland.

Existence of a System and Guidelines for the Disposal of Obsolete Pharmaceuticals

A system previously existed for the disposal of obsolete pharmaceuticals using the SAPPI industrial incinerator. However, due to the closure of SAPPI, this incinerator is no longer operational. In March 2012, the Hlathikhulu government hospital negotiated with the Shiselweni Forestry Company for the disposal of the hospital's obsolete pharmaceuticals. However, the company does not have the capacity to dispose of the entire country's obsolete pharmaceuticals. Health facilities consequently will be overloaded with expired medicines and medical supplies until a new system of disposal can be established.

With regard to guidelines, there are SOPs to guide facilities on the handling of obsolete pharmaceuticals. The MOH Environmental Health Unit, however, has no specific guidelines for the destruction of obsolete pharmaceuticals. It is essential for the Unit to be involved when the obsolete pharmaceuticals disposal guidelines are developed to ensure compliance with environmental protection protocols.

Subregional Pharmaceutical Initiatives in which Swaziland Participates

The country participates in the SADC, Common Market for Eastern and Southern Africa-COMESA, East, Central and Southern Africa Health Community-ECSA-HC regional initiatives.

Coordinating Mechanisms to Guide Partner Interventions

The MOH holds monthly meetings with partners to discuss progress and other pertinent issues. Each of the identified partners has an MOU to guide their interventions with the MOH.

Public and Private Partnership (PPP) Framework

There is no specific PPP framework for the MOH due to inadequate funding, but there are on-going plans for this within the Planning Unit of the MOH. The Ministry of Finance (MOF) developed a national PPP framework for the whole public sector, which will guide the MOH's framework.

Discussion

The office of the chief pharmacist does not have sufficient resources to enable it to conduct its activities efficiently. Two technical committees exist within the public pharmaceutical sector that are tasked with monitoring the supply chain and providing technical advice on pharmaceuticals within the public sector. However, there is no centralized pharmaceutical information management system. Currently no national quantification exercise has been undertaken to inform the Ministry of the country's pharmaceutical requirements.

Even though the WHO/SADC donation guidelines are available, they have not been adopted for use in Swaziland. The pharmaceutical services department has also not developed the country's destruction guidelines for obsolete medicines and there is no national system developed to undertake these destructions. The country is a signatory and participates in the SADC, COMESA and ECSA-HC regional initiatives. In addition, the pharmaceutical services department cooperates with a number of Partners guided by the MOUs between the MOH and these partners. Presently, the Pharmaceutical Services Unit has no PPP but the MOF has developed a national PPP framework to guide the establishment of future PPP within the public sector.

LEGISLATION AND REGULATIONS

Overview

Pharmaceutical legislation and regulations shall be implemented to ensure the effective regulation of pharmaceuticals and the pharmacy profession. This will be done through strengthening the legislative framework of the pharmaceutical sector and ensuring prompt implementation of the Medicines and Related Substances Control Act and the Pharmacy Act.

Findings

Activities towards Advocacy for the Enactment of Pharmaceutical Bills

The Medicines Policy Advisor has primary responsibility to facilitate advocacy activities regarding the pharmaceutical bills. Since August 2011, there have been approximately 30 advocacy meetings which include the review of the bills, stakeholder meetings, and presentations to the MOH and to the Cabinet. The Pharmacy Bill and the Medicines and Related Substance Control Bill received cabinet approval in February 2012 and June 2012, respectively.

Stakeholder Sensitization

Since 2008, approximately eight stakeholder sensitization meetings have been conducted with 14 groups of stakeholders. These include the Ministry of Agriculture, Swaziland Pharmaceutical Association, Swaziland Pharmaceutical Wholesalers Association, Medical and Dental Council, Medical and Dental Association, Nursing Council, Ministry of Justice, Ministry of Trade and Industry, Ministry of Finance, Customs and Excise, Swaziland Standards Authority (SWASA), the Office of the Attorney General, and members of the general public.

Activities towards the Enforcement of Bills

No activities have been conducted towards the enforcement of the Medicines and Related Substances Control Bill and the Pharmacy Bill since the bills have not yet been enacted.

Activities towards the Establishment of the Medicines Regulatory Authority

Four (4) activities have been conducted regarding the establishment of the medicines regulatory authority (MRA). These include the development of the concept paper and its endorsement by the MOH, the Rapid Assessment of the national medicines regulatory systems with WHO technical assistance, the benchmarking study tour with the Medicines Control Council of Zimbabwe with assistance from SIAPS, and the development of the draft pharmaceutical import guidelines with the Swaziland Revenue Authority (SRA) using the SADC Import and Export Guidelines.

Activities towards the Establishment of the Pharmacy Council

There have been no activities conducted towards the establishment of the Pharmacy Council.

Discussion

The pharmaceutical sector is governed by the Pharmacy Act, 1929. This Act does not provide for the effective regulation of the practice and licensing of the pharmacy profession in Swaziland, which has led to poor regulation of the pharmaceutical sector. It is imperative for Swaziland to strengthen its regulatory and legislative framework to enable the Ministry of Health to carry out its mandate of assuring the nation's optimal health and safety. In 2009, the World Health Organisation (WHO) Maximizing Positive Synergies Collaborative Group found that most health sector interventions are undermined by poor governance and weak legislative frameworks in the pharmaceutical sector.

The Pharmacy Bill and Medicines and Related Substances Control Bill were developed through a widely consultative approach, with numerous stakeholders consulted during the development process. Considerable strides have been made regarding advocacy for the enactment of the pharmaceutical bills. The MOH, supported by the Strengthening Pharmaceutical Systems program, appointed a Medicines Policy Advisor who has primary responsibility for advocacy activities towards the enactment of the Bills. Consequently, the Pharmacy Bill, 2012 and the Medicines and Related Substances Control Bill, 2012 have received cabinet approval and are awaiting tabling before Parliament.

Some activities have also been conducted towards the establishment of the MRA, including an options analysis for Swaziland and a bench-marking study tour to the MCAZ. However, no measures have been taken regarding the enforcement of the Pharmaceutical Acts or the establishment of the Pharmacy Council because the bills have not yet been enacted.

SUPPLY OF PHARMACEUTICALS

Overview

Sufficient quantities of high-quality pharmaceuticals will be procured, stored, and distributed efficiently. This will be achieved by improving the procurement of pharmaceuticals in the country, optimizing and securing the storage and distribution of pharmaceuticals and promoting the use of appropriate technology to improve supply chain management.

Findings

CMS Organizational Structure

The process of reviewing the CMS organizational structure is underway. The proposed structure received MOH approval and is currently under review at the MOPSI.

CMS Organizational Structure Implementation

The implementation of the CMS organizational structure is pending MOPSI approval.

Availability of Procurement Standards, Guidelines and Procedures

There are no procurement standards, guidelines or SOPs. The procurement unit currently uses the Swaziland procurement regulations to guide its activities. A draft procurement manual is awaiting MOH approval and procurement SOPs are currently being developed.

Supplier Performance Assessment System

The Supplier Performance Assessment system is not yet in place except for the ART programme, where a contract management system has just been put in place. Generally, Supplier Performance Reviews are conducted on an ad-hoc basis during the tender adjudication process.

CMS and National Procurement Unit Capacity

The CMS does not have the human resources required to perform its procurement function. With regards to the National Procurement Unit, there is inadequate human resource capacity. The Unit's staff still requires skills development and the World Bank/EU project has been tasked with building the Unit's capacity. A training plan to achieve this is being finalized. In addition, the Unit does not have other necessary resources such as laptops, vehicle, landlines that can call cell phones, fax machine, and a printer.

Control and Monitoring Mechanisms for the Use of Pharmaceuticals

There are systems for ordering, receiving and dispensing pharmaceuticals, however, these systems are not validated. Most of the monitoring is done at central warehouse at CMS and bulk store room level at health facilities. The Swaziland Standard Treatment Guidelines/Essential Medicines List (STG/EML) was finalized by the end of March 2012.

The implementation of this STG/EML will guide the rational prescribing and use of pharmaceuticals. Pharmaceutical and Therapeutic Committees (PTCs) will facilitate the monitoring of adherence rational prescribing and correct medicine use.

Security of Pharmaceuticals at all Levels of the Supply Chain

Central Level

There is security from the CMS to facilities' bulk warehousing, nonetheless, this needs to be strengthened to minimize losses due to pilferage. At the CMS level, security needs to be reinforced both with physical security and surveillance cameras. There is no tracking system to monitor supplies while they are in transit from CMS to facilities.

Facility Level

At the facility level, there is inadequate access control both at the bulk storeroom and dispensary. Security is particularly lacking at the dispensary. At a majority of facilities, there are no controls at the facility main gate for incoming and outgoing traffic. In addition, there are no surveillance cameras in all facility storerooms in the country. The Mbabane government hospital is the only facility with a finger biometric access control system. Of the 18 facilities that were visited, 83% had burglar doors and 72% had burglars at the windows.

Pharmaceutical Storage Capacity

Central Level

At the main CMS, the storage capacity is 3,000m^2, while at the ART CMS the storage capacity is 1,900m^2.The capacity of storage spaces is not adequate at the CMS level so the CMS is also renting warehouses.

Facility Level

The warehouse space was improved at nine health facilities following the construction and shelving of nine regional/integrated warehouses. The space thus has been increased by 3,349m^2. Nevertheless, some facilities still have inadequate storage space, particularly the clinics. Hospitals and health centres have functional air-conditioning systems in their warehouse whereas a majority of the clinics visited have non-functional air-conditioning systems in their warehouses. Warehouse storage space across all health facilities is further decreased as a result of accumulating obsolete pharmaceuticals, due to the current lack of availability of an obsolete pharmaceuticals destruction mechanism. Some of the main ART facilities have limited space to keep both their supplies and satellite clinic supplies.

Good Storage and Distribution Guidelines

The Good Storage and Good Distribution guidelines are not yet in place but , there are Good Storage and Good Distribution SOPs for both the CMS and health facilities.

Technology for Supply Chain

Central Level

The CMS uses RxSolution® for inventory control and distribution of all pharmaceuticals.

Facility Level

Hospitals, health centres and some clinics use RxSolution for ART inventory control and dispensing. All health facilities use paper-based inventory management systems for Essential Medicines. RFM is currently the only hospital that uses RxSolution for the management of both Essential Medicines and ART Medicines.

Discussion

The organisational structure and work flow of the CMS has been reviewed in order to improve the CMS operational efficiency and promote functional synergies. The implementation of the proposed structure is still awaiting MOPSI approval.

Although the MOH Procurement Unit lacks standards, guidelines and SOPs, progress has been made with regard to strengthening the Unit. The Procurement Act, 2011, draft procurement manual and the on-going development of procurement SOPs for the Unit are evidence of that progress. However, some gaps still exist regarding supplier performance management and contract management (except for ART medicines), as well as the capacity and resources of the CMS and MOH Procurement Units to perform their functions.

The control and monitoring mechanisms for the use of pharmaceuticals require strengthening. Although there are some monitoring mechanisms at the central level and at facility storerooms, the control and monitoring mechanisms at the facility dispensing level are inadequate. The STG/EML and PTCs can be used to improve these mechanisms at the facility level. Similarly with commodity security; the available security is at the central and facility storeroom levels. There is no security during transportation from CMS to facilities or at the facility dispensaries. Consequently, pharmaceutical commodity security needs to be improved.

There are Good Storage and Good Distribution SOPs but not guidelines. The storage capacity is inadequate at both the central and facility level, despite the construction of nine (9) integrated pharmacies and warehouses. RxSolution is currently used for supply chain management at the central level. Facilities use this system for the management of ARVs, except RFM that uses the system for the management of all medicines.

QUALITY ASSURANCE

Overview

Medicines used in Swaziland shall be safe, efficacious and of assured quality. To achieve this, the MRA will be established and its regulatory capacity will be strengthened.

Findings

MRA Unit

The MRA unit has not been established and no resources have been allocated to it yet.

Collaborating Activities between the MRA and Other Regulatory Authorities

Although the MRA has not yet been established, a relationship has been established with the Medicines Control Authority of Zimbabwe (MCAZ).

Medicines Registration System

There is currently no medicines registration system in place.

Pharmacovigilance and Drug Information Unit

A pharmacovigilance and drug information unit is not in place, but some of its functions are taking place. These include the review and use of adverse drug reaction forms which are also analysed; a quarterly Medicines Safety Watch newsletter that is printed and disseminated; and drug information reference materials that are available at the CMS.

National Quality Control Laboratory

The National Quality Control Laboratory is not yet in place, but there is allocated space for it at the CMS. There are two Minilab testing kits which were donated by MSH/SIAPS for basic quality control tests. However, there is no other quality control equipment. A quality control pharmacist has been appointed for the laboratory and provision has been made for two laboratory technicians.

Pharmaceutical Inspectorate Unit

No Pharmaceutical Inspectorate Unit exists at present. There are plans to establish a joint Inspectorate Unit that will perform medicine regulatory activities and carry out the inspection functions of the Pharmacy Council. This will happen once the Medicines and Related Substances Control Bill and the Pharmacy Bill have been enacted.

Discussion

Based on the findings, it is evident that a large gap exists in the area of pharmaceutical quality assurance which is a very critical area for ensuring that medicines used in the country

are safe and quality assured. Unsafe medicines pose a big threat to those using them. Therefore, priority should be given to the employment of quality control procedures in the above mentioned areas.

FINANCING OF PHARMACEUTICALS

Overview

Adequate funding will be provided to ensure a consistent supply of sufficient pharmaceuticals. To achieve this, pharmaceutical financing and the coordination and monitoring of medicine financing in the country will be improved.

Findings

Advocacy for Adequate Budget Allocation

A procurement plan was developed in 2012. Although this plan was developed after the annual government budget allocation cycle, the intention is to use the annual procurement plans to inform and advocate for adequate budget allocation in the future. To ensure sustained availability of pharmaceuticals, ongoing meetings with the Ministry of Finance have been conducted and these include the submission of an annual purchasing plan and a presentation during the Smart Partnership dialogue.

Pricing Policy

There is no pricing policy in the country.

Pharmaceutical Financing Guidelines

Specific pharmaceutical financing guidelines are not available, however, a draft procurement manual is available to guide pharmaceutical financing.

Alternate Pharmaceutical Financing Approaches Report

The MOH has not yet identified other approaches to pharmaceutical financing; hence no report has been compiled on this subject.

Control and Monitoring of Pharmaceutical Funds

The segregation of duties amongst different staff members within the MOH Procurement Unit serves as one of the control mechanisms. The Government Commitment System is another control mechanism in that it imposes budgetary limits at the central level, however, its limitation is that it does not place budgetary limits at the facility level. RxSolution serves as a monitoring mechanism for the accountability of the use of pharmaceutical funds. There are annual audits conducted by the Auditor General Office that also serve as a monitoring mechanism.

Coordinating Mechanisms for Sources of Pharmaceutical Funding

Funding efforts and sources are not coordinated through a central system that informs the MOH about pharmaceutical budgeting.

Discussion

The MOH does not have a pricing policy in place. Pharmaceutical financing will be informed by the recently developed procurement plan for allocation of the pharmaceutical budget. The procurement manual draft contains a section on pharmaceutical guidelines. There is no report of other approaches that the MOH has identified towards pharmaceutical financing.

The MOH is using the RxSolution as one of the control measures for control and monitoring of pharmaceuticals usage. The Government Commitment System, which is another control measure, only has control at the central level and excludes the periphery/facility levels. Another control strategy that is used is the segregation of duties in the procurement of pharmaceuticals. The MOH currently does not have a coordination system for the sources of funding pharmaceuticals in the country.

HUMAN RESOURCES

Overview

Sufficient qualified pharmaceutical personnel will be provided to ensure the efficient provision of pharmaceutical services. Capacity building will be done in order to expand the local source of skilled pharmaceutical personnel. The recruitment, retention and working conditions for pharmaceutical personnel in the public and private sectors will be improved, and personnel handling pharmaceuticals will be capacitated in medicines supply management.

Findings

Human Resources Availability

There are 20 pharmacists in the public sector; 3 of whom are Global Fund supported, 1 who is seconded, 3 who are supported by faith-based organizations (FBOs) and the rest (13) are funded by the government of Swaziland. The percentage distribution of the sources of funding for the pharmacists is depicted in figure 2, below:

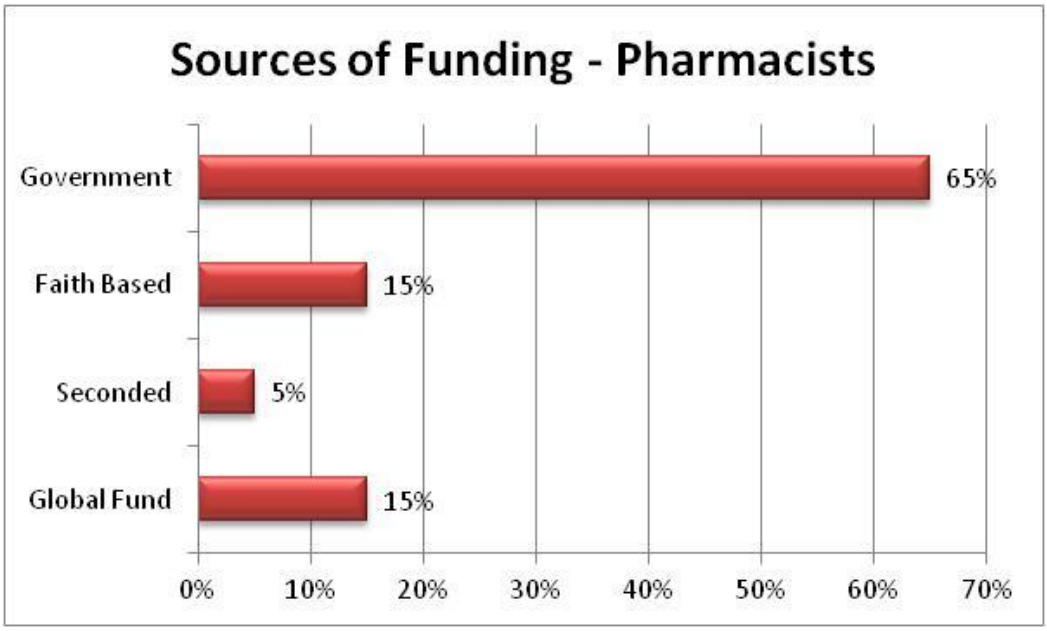

Figure 2. Public sector pharmacists' sources of funding by percentages

There are 44 pharmacy technicians in the public sector, of whom only 45% are Swazi nationals; 14 pharmacy technicians are supported by the Global Fund, 8 are supported by FBOs, and 22 are funded by the government (Figure 3).

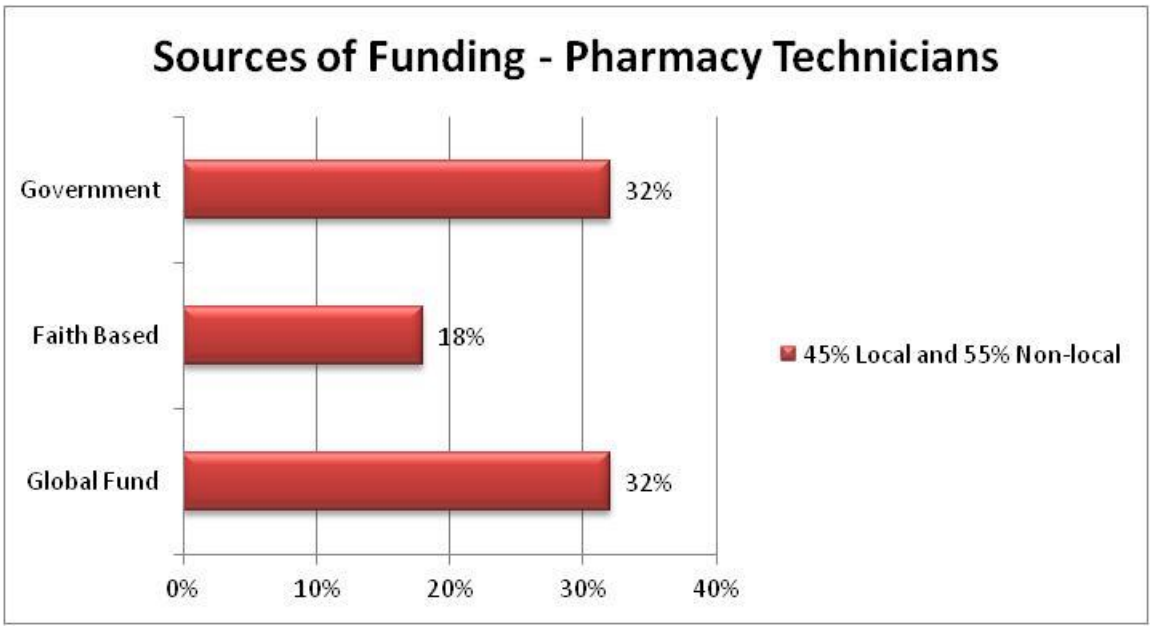

Figure 3. Public sector pharmacy technicians' sources of funding by percentages

Pharmaceutical Personnel Training Program

There is a two-year Certificate in Pharmacy training programme offered at Southern African Nazarene University (SANU). This programme commenced in August 2012.

Pharmaceutical Personnel Trained Externally

The Ministry of Labour does not maintain a database of trained personnel in the pharmaceutical sector in the country. The only information available is that of trainees who are currently enrolled in pharmaceutical studies and who are sponsored by the government.

Continuous Professional Development Records

Although there are continuous professional development activities at different levels; on an individual basis, those conducted by the government and those supported by Partners, there are no records kept of these.

Pharmaceutical Vacant Posts

There are 6 pharmacists' and 16 pharmacy technicians' posts that are still vacant within the public pharmaceutical sector.

Advocacy for the Creation of Pharmaceutical Posts within MOH

The on-going advocacy activity is that for the creation of posts for pharmacy assistants. There are no activities towards the creation of posts for pharmacists and pharmacy technicians.

Orientation of Newly Recruited Pharmaceutical Personnel

No orientation programme exists for newly recruited pharmaceutical personnel, but some orientation is conducted by individual facilities.

Retention Strategies for Public Sector Pharmaceutical Personnel

Retention strategies for the public sector are standard and include training opportunities, housing and transport benefits, and health coverage. Pharmaceutical personnel currently do not benefit from the scarce skills allowance.

Minimum Wage Standards for Private Sector Pharmaceutical Personnel

The Ministry of Labour does not set standards for professionals; they only set minimum standards for non-professionals. Thus, there are no minimum wage standards for private sector pharmaceutical personnel.

Non-Pharmaceutical Personnel Handling Pharmaceuticals Trained in Medicines Supply Management

The specific numbers of personnel trained in medicines supply management are not readily available, but the following partners offer training; Medicins Sans Frontieres (MSF), Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), University Research Council (URC), Clinton Health Access Initiative (CHAI) and MSH/SIAPS.

Discussion

Pharmaceutical personnel currently working in the public sector are largely supported by the government, Global Fund and FBOs. Most pharmacy technicians working in the public sector are expatriates, highlighting the need for the establishment of local training programmes for pharmacy personnel, the need for advocacy for the creation of additional posts for pharmacy personnel and the need to fill these posts within the Ministry. SANU has initiated the training of pharmacy assistants this year (2012) with support from SIAPS.

The Ministry of Labour does not keep a record of pharmacy personnel trained outside the country who receive a government scholarship but the information available is that of personnel currently undergoing trainings. Even though continuous professional development is taking place with the support of the government, Partners and personal initiatives, the records of these activities are not maintained. An orientation program for newly employed pharmacy personnel in the Ministry needs to be established. In Swaziland, the minimum wages for professionals are not set by the Ministry of Labour.

RATIONAL MEDICINE USE

Overview

Health outcomes will be optimized by ensuring the rational use of medicines by both health workers and patients. This will be achieved by promoting rational medicine use among health workers and members of the public as well as strengthening the use of the STG/EML and PTCs.

Findings

Rational Medicine Use in Health Professional Curricula

There is no rational medicine use component in health professionals' curricula in the country, at present.

Continuous Professional Development Training Programme on Rational Medicine Use

This rational medicine use training programme is not available; however, in-service training of this kind is provided.

Community Education Activities and Rational Use of Medicine

Community education activities conducted through the Swaziland Pharmacy Association include a pharmacy week which is a week dedicated to educating the public about pertinent pharmacy issues, including rational medicine use. During this week, a radio and a TV show are broadcast to inform the public, as well as a print advertisement in the national newspaper. The pharmacy week activities culminate in a lecture aimed at educating both the public and health professionals.

Meanwhile, the Health Promotion Unit conducts public education activities on rational medicines use (RMU) centered on the WHO 2011 theme of 'prevent antimicrobial resistance; promote rational medicines use'. This includes providing information on adherence to antiretroviral (ARV) and anti-tuberculosis (anti-TB) therapy as part of RMU. Patients are also encouraged to ensure that they get prescriptions before obtaining antibiotics from retail pharmacies. Health professionals are encouraged to engage in integrated disease management as a means of discouraging poly-pharmacy and encouraging prescribers to stick to treatment guidelines. No IEC material has been developed for these educational activities, which just rely on verbal messages.

Advertising and Promotion Regulations

There are no advertising and promotion regulations available.

Activities towards the Enforcement of the Use of the STG/EML

No activities have been conducted pending the launch of the STG/EML by the Minister of Health.

STG/EML Review and Update

No review mechanism exists yet as the STG/EML has just been printed.

Activities towards the Enforcement of Generic Prescribing and Dispensing

There have been no activities conducted towards the enforcement of generic prescribing and dispensing in the public sector at the facility level. At the central level, generic procurement is enforced through tender specifications. Similarly, the MOH has not conducted any activities regarding encouragement of generic prescribing and dispensing in the private sector, but medical aid companies encourage generic prescribing and dispensing in the private sector.

Coordinating and Monitoring Mechanisms for PTCs

No coordinating mechanisms exist for PTCs. The only monitoring mechanism is the review of minutes to ensure the functionality of PTCs.

Discussion

Health professionals' curricula in the country do not contain a rational medicine use component. Furthermore, no rational medicine use training programme is available, although in-service training of this kind is provided. Community education activities are conducted through the Swaziland Pharmacy Association, which include a pharmacy week that is dedicated to pharmacy issues and educating the public. Health professionals are encouraged to engage in integrated disease management is encouraged as a way of discouraging poly-pharmacy and encouraging prescribers to stick to treatment guidelines.

There are no advertising and promotion regulations available. In addition, no activities have been conducted regarding enforcement of use of STGs pending the launch of the STG/EML by the Minister of Health, and there is no STG/EML review mechanism yet. There have been no activities conducted regarding enforcement of generic prescribing and dispensing in the public sector, except for generic procurement at the central level. Medical aid companies encourage generic prescribing and dispensing in the private sector. There is no coordinating mechanism for PTCs except for the review of minutes to ensure functionality of PTCs in facilities.

TRADITIONAL AND COMPLEMENTARY MEDICINE

Overview

In order to maximize the positive aspects and minimize the negative consequences of traditional and complementary medicine in the provision of health care services, collaboration mechanisms between the MOH and traditional and complementary practitioners will be established. In addition, the practice of complementary medicines will be regulated by establishing a mechanism to oversee activities related to the safety and efficacy of complementary medicines.

Findings

Collaborative Framework between the MOH and Traditional and Complementary Practitioners

There is no collaborative framework between the MOH and traditional and complementary medicine practitioners. The process of creating a framework was initiated by the MOH but was not finalized. The Ministry then requested traditional healers to initiate the process of developing the framework in order to foster its ownership thereof.

Overseeing Mechanism for the Safety and Efficacy of Complementary Medicines

Currently no oversight mechanism for the safety and efficacy of complementary medicines is in place.

Discussion

The 2010 Multiple Indicator Cluster Survey revealed that 10% of men and 1% of women with an STI reported that they had sought advice on their STIs from a traditional health practitioner. This clearly demonstrates the need to foster collaborations within the various health practitioners to harmonize health care practices in the country.

The findings of the SPSP baselines assessment showed that there is currently no collaborative framework between the Ministry of Health and Alternative Health Practitioners, which poses a challenge to regulating activities related to the safety and efficacy of, and curbing the negative effects of traditional and complementary medicines. It was also ascertained that the Traditional Healers Organization (THO) was tasked with leading the process of developing the collaborative framework. However, the MOH needs to play a key and active role in this activity in order to be able to influence the inclusion of WHO standards.

The Ministry of Health is expected to therefore prioritize, guide and promote this collaboration for better health outcomes. Having the collaborative framework in place is also expected to guide the work of the MRA in overseeing the safety and efficacy of traditional and complementary medicines.

LOCAL PRODUCTION

Overview

Local production will be encouraged as a way of improving access to medicines by promoting the establishment of new local production units and strengthening their compliance with current Good Manufacturing Practices (cGMP).

Findings

Activities towards Advocating for Incentives to Stimulate Local Production

No activities have been conducted towards advocating for incentives to stimulate local production of pharmaceutical commodities. It is important to note that it is within the Swaziland Investment Promotion Authority's (SIPA's) mandate to attract investors for local production.

Activities Aimed at Creating an Enabling and Transparent Investment Environment

No activities to create an enabling and transparent investment environment were conducted.

Activities towards Encouraging Local Production Units to Upgrade their cGMP Status

No activities have been conducted regarding encouraging local production units to upgrade their cGMP status because as there are currently no active local production units.

Discussion

The availability and affordability of quality-assured medicines and the proper use of medicines is essential and can save many lives. The price of pharmaceuticals is one of the main barriers to accessing effective medicines in most developing countries, including Swaziland. One of the strategies that can lower prices is local production of essential medicines.

Currently, Swaziland procures all pharmaceutical products externally, which tends to drive up the procurement costs, including transit costs, taxations etc. The strategic direction outlined in the SPSP is to advocate and foster a mechanism for promoting local production of cGMP approved and compliant pharmaceutical production units. The pharmaceutical sector through the MOH and relevant partners will engage the Swaziland Investment Promotion Authority to work towards attracting foreign and local investors for local production of pharmaceuticals.

Moreover, the WHO's analyses suggest that the global share of counterfeit medicines is roughly 10%, but may be upwards of 40% in some developing countries (WHO-IMPACT, 2006; Rollings, 2007). Local production of pharmaceuticals can minimize the availability of counterfeit medicines imported into the country.

RESEARCH

Overview

To foster research aimed at resolving problems confronting the Swaziland pharmaceutical sector, the MOH Research Unit's capacity will be strengthened and research in pharmaceutical priority areas will be promoted.

Findings

Activities Conducted towards MOH Research Unit Capacity Building

Nothing specific has been done towards this activity. There is currently no head for the MOH Research Unit. MOH is in the process of filling vacant positions in the Research Unit so that it is a fully-functioning entity. There are also plans to provide research training to its officers. There has only been a capacity building exercise for the Scientific and Ethics Committee (SEC) as a whole, but this did not include specific activities regarding pharmaceutical research. The training only covered the role of the SEC in research and oriented the committee on the SEC guidelines.

Activities Aimed at Ensuring the Regulation and Monitoring of Clinical Trials

Although no clinical trials have been conducted, the Ministry has put in place the Scientific and Ethics Committee, which is responsible for the approval of any research that is conducted in the country. The committee also monitors research activities. In addition, the Ministry has participated in SADC/US-FDA Good Clinical Practice for clinical trials' training.

Pharmaceutical Research Priority Areas Identified and Documented

Currently no pharmaceutical research priority areas have been identified and documented, however, the SEC is planning a national health research priority areas meeting. Heads of departments and programmes, including pharmaceutical services, will be invited to the session to inform the prioritization of certain research areas and to develop a priority research plan.

Activities Conducted towards the Encouragement of Operational Research in the Pharmaceutical Sector

No activities have been conducted to encourage operational research in the pharmaceutical sector specifically. The SEC provides guidance to all operational research applicants on the scientific aspects of the protocol (study design) and the ethical components of the research.

Discussion

Operational and clinical research is key to improving the pharmaceutical sector. The limited functionality of the MOH Research Unit hinders progress towards the development of a research agenda that can address the gaps identified in the pharmaceutical sector. The scope and expertise of the SEC can also be broadened to enable the committee to regulate and monitor clinical trials.

TECHNICAL INTER-SECTORAL COOPERATION AND COORDINATION

Overview

Cooperation and coordination between the MOH and other government ministries, public institutions, and partners will be improved through strengthened collaboration between the MOH, relevant ministries, organizations and agencies, as well as by building consensus among all stakeholders.

Findings

Collaborative Activities between MOH and other Ministries and Public Institutions

Collaborative activities that have been conducted include those between the MOH and the Ministry of Education on training of pharmacy personnel and with the Ministry of Agriculture on veterinary medicine. In addition, a technical committee on taxation (VAT) was recently formed. In 2009 the MOH participated in operations Zambezi, which was conducted in conjunction with the Royal Swaziland Police, Interpol, Customs and Excise, SWASA, the Attorney General's office and the Environmental Health Unit. No MOUs have been signed with other ministries and public institutions.

Collaborative Activities between MOH and Partners, Non-Governmental Organisations (NGOs) and Regional Organizations

Collaborative activities that have been conducted include mobilizing partners to fund various portions of procurement of pharmaceuticals, the sector-wide approach that includes regular meetings with the United Nations (UN) bodies and other partners and the SADC standing committee on pharmaceuticals.

Mechanism to Ensure Effective Involvement of Relevant Stakeholders

There is no mechanism in place to ensure the effective involvement of relevant stakeholders in pharmaceutical issues. Nevertheless, stakeholders are involved on an ad-hoc basis, such as with respect to the preparation of the Pharmaceutical Strategic Plan.

Mechanism to Disseminate Pharmaceutical Information to Public and Private Stakeholders

There is no specific mechanism to disseminate pharmaceutical information to stakeholders. Information is presently disseminated through e-mails and stakeholder meetings. For large events such as document launches, print media is used to disseminate pharmaceutical information.

Activities towards Fostering Ownership among the Public and Private Sector

Stakeholders are involved in stakeholder consultation meetings on various pharmaceutical issues.

Discussion

The MOH collaborates with other ministries, public institutions, partners, NGOs, and regional organisations. However, it has not entered into any MOUs with the other Ministries, Public Institutions and Agencies on the terms of collaboration and cooperation.

Information is currently disseminated to stakeholders using the most convenient means of distribution. It is not governed by an information dissemination strategy and dissemination mechanism. In addition, there is no mechanism and mapping of stakeholder involvement in pertinent pharmaceutical issues; they are involved instead on an ad-hoc basic. It is essential to develop mechanisms for stakeholder involvement and information dissemination in order to foster a sense of ownership of pharmaceutical activities among stakeholders.

MONITORING AND EVALUATION

Overview

Effective monitoring and evaluation (M&E) of the implementation of the SPSP shall be achieved by establishing a SPSP monitoring and evaluating system.

Findings

Baseline Study

The baseline study report is not yet available because it is currently being finalized.

Monitoring and Evaluation Operational Plan

The M&E operational plan for the pharmaceutical sector is not available.

Coordinating Mechanism for the SPSP Implementation

There is no coordinating mechanism for monitoring and evaluating the implementation of the SPSP.

Activities Conducted Regarding towards Establishing the SPSP M&E Unit

No activities have been conducted towards establishing the SPSP M&E Unit.

Discussion

To effectively monitor and evaluate the implementation of the SPSP, a Pharmaceutical M&E Unit needs to be established. The absence of this Unit means there is no coordinating mechanism for all activities taken in the implementation of the Strategic Plan. In addition, the absence of such a Unit means there is no central point where all pharmaceutical information may be sourced. The immediate establishment of this unit would ensure that the SPSP activities are well monitored and documented.

CONCLUSION AND RECOMMENDATIONS

This Baseline Survey Report has highlighted the current achievements and shortcomings of the pharmaceutical sector. This report will facilitate the coordination of the implementation of the SPSP and the Plan's monitoring and evaluation activities.

Implementing the Pharmaceutical Strategic Plan will involve change, so the monitoring and evaluation system that will be informed by the Survey's findings will:

- Show whether change is occurring;
- Indicate the results of the implementation activity, including eventual impacts, whether these changes are intended or not, direct or indirect, positive or negative, and primary or secondary;
- Suggest how to improve the efficiency of the implementation;
- Reveal the nature, magnitude and severity of any successes and gaps

The Survey has also revealed the level at which proposed interventions should be implemented so that any interventions build on progress that has already been achieved rather than re-inventing the wheel and duplicating existing efforts.