Kingdom of Swaziland

Ministry of Health

National Pharmaceutical Policy

2nd Edition

March 2011

World Health Organization

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Ministry of Health
P. O. Box 5
Mbabane

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FOREWORD

The Government of Swaziland adopted the first Swaziland National Pharmaceutical Policy (SNPP) in October 2000. The Policy was adopted at a time when the country's health sector was facing a lot of challenges particularly in relation to ever increasing emerging diseases and the policy was intended to help in effecting strategies that would help the acquisition of quality and safe pharmaceuticals at affordable cost for the population of Swaziland.

While the current policy provided essential orientations for the development of various aspects of the Swaziland pharmaceutical sector, most of them were not been implemented. In addition, new challenges facing the country's health sector in general, and the pharmaceutical sector in particular, have made it necessary to review the policy.

Of particular concern is the lack of appropriate legislation and regulations to control the pharmaceutical sector, the level of performance of the country's national medicine supply system in the face of the HIV and AIDS pandemic, and the need to ensure a regular supply of good quality medicines, (including anti-retrovirals) at affordable cost to the population of Swaziland, and the critical shortage of pharmaceutical personnel at all levels.

The present revised Swaziland National Pharmaceutical Policy, which was developed through a consultative process with all stakeholders, provides policy orientations susceptible to provide solutions to the pressing problems of the Swaziland pharmaceutical sector. It charts the way forward to address problems in the provision of pharmaceutical services in Swaziland. The second edition SNPP is therefore a commitment to a goal and a guide for action.

The key policy areas addressed in this document include the following:

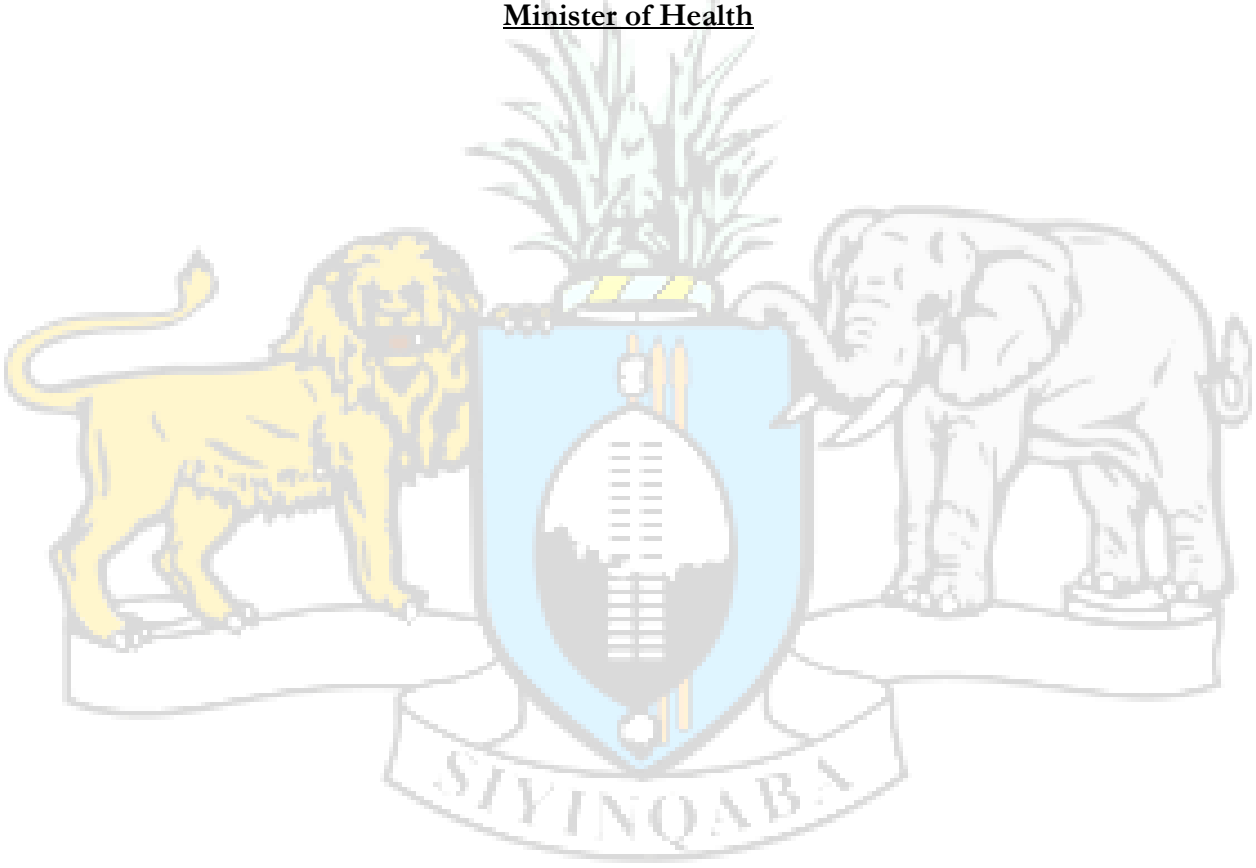
- Strengthening the central pharmaceutical administration;
- Developing and enacting enabling pharmaceutical legislation and regulations;
- Strengthening the national medicine supply system;
- Pharmaceutical human resources development;
- Establishment of a Pharmacy Council and a Medicines Regulatory Authority;
- Quality assurance;
- HIV and AIDS;
- Rational medicine use;
- Local Production and Patents and;
- Traditional medicine.

This policy shall be accompanied by an implementation plan, namely the Swaziland National Pharmaceutical Strategic Plan which shall, amongst others, set out objectives, strategies, activities and expected results after the implementation of all identified and prioritized policy components.

The MOH shall regularly promote the review of relevant laws to consolidate gains from this policy and its predecessor.

The Ministry of Health is committed to implementing the policy and urges all parties concerned to fully participate in its implementation in order to improve the quality of pharmaceutical services in Swaziland, as a contribution to the attainment of the goal of the Swaziland National Health Policy.

Honourable Bennedict Xaba
Minister of Health



ACKNOWLEDGEMENTS

The Ministry of Health is very grateful for the support received from all those who have contributed to the development of the present policy and in particular the members of the Swaziland National Pharmaceutical Policy Working Group as well as other officials from the Ministry of Health and other Government ministries.

The Ministry of Health acknowledges the financial support and technical assistance provided by the World Health Organization in the development of the present revised Swaziland National Pharmaceutical Policy. Sincere gratitude also goes to Management Sciences for Health, Strengthening Pharmaceutical Systems program for the technical assistance and support in the finalisation of this policy.

The Ministry of Health also acknowledges the contribution of bilateral and multilateral partners, non-governmental organizations, civil society representatives and the private sector towards the development of the present pharmaceutical policy.

Dr. Steven V. Shongwe
Principal Secretary

LIST OF ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
ANC	Ante-Natal Care
API	Active Pharmaceutical Ingredient
ART	Anti-Retroviral Therapy
ARV	Anti-Retroviral
CMS	Central Medical Stores
DHS	Demographic and Health Survey
EML	Essential Medicines List
EPI	Expanded Program on Immunization
GMP	Good Manufacturing Practices
HIV	Human Immuno-deficiency Virus
INN	International Non-Proprietary Name
MOH	Ministry of Health
MMAC	Ministerial Medicines Advisory Committee
MRA	Medicines Regulatory Authority
MSH	Management Science for Health
NERCHA	National Emergency Response Council on HIV and AIDS
NGO	Non-Governmental Organization
NF	National Formulary
NPP	National Pharmaceutical Policy
PLWHA	People Living with HIV and AIDS
PTC	Pharmacy and therapeutics Committee
RMU	Rational Medicines Use
SACU	Southern Africa Customs Union
SADC	Southern Africa Development Community
SNPP	Swaziland National Pharmaceutical Policy
SPS	Strengthening Pharmaceutical Systems
STG	Standard Treatment Guidelines
TRIPS	Trade Related Intellectual Property Rights
WHO	World Health Organization

1. Introduction

The Kingdom of Swaziland is a mountainous landlocked country covering 17,364 square kilometres in the south-eastern corner of Africa. Three quarters of its area is bordered by South Africa and one quarter by Mozambique. The country's national per capita income is USD 2,470 (World Bank, 2009) but 69% of the population lives below the poverty line, subsisting on USD 0, 60 per day (World Food Programme, 2009). The country is facing increasing levels of poverty, persistent drought and food insecurity. Poverty reduction is one of the priorities that is being addressed by government. The major economic sectors are agriculture, manufacturing, mining and tourism.

According to the 2007 population census, the population of Swaziland is 1,018 449 inhabitants with about 78.9% residing in rural areas. 52% of the population is under the age of 20 years. The capital is Mbabane (population 69 000) and the largest city is Manzini (population 75 000) (Central Statistics Office, 2007). The country is divided into four administrative regions: Hhohho (where the capital, Mbabane, and government ministries are located), Manzini (which contains the largest industrial site in the country), Lubombo and Shiselweni. The country is further subdivided into 55 constituencies which operate as administrative centres and 360 chiefdoms.

The Government, private sector, non-governmental organizations (NGOs), faith based organisations and traditional healers are involved in the provision of health services. There are 8 government hospitals, 2 mission hospitals, 1 industry supported hospital, 8 public health units, 5 health centres, and 218 clinics (type A+ B). In addition there are 73 mission health facilities (health centres, clinics and outreach sites), 62 private clinics and 22 industry-supported health centres and clinics (MOH Essential Health Care Package, 2010). The referral system is not functional leading to congestion of referral facilities with patients that could have been attended to at lower levels (MOH National Health Policy, 2007).

The Swaziland health system has an acute shortage of health staff, complicated by the burden of disease due to HIV and AIDS, migration of skilled health workers and the imbalance of staff in favour of the private sector and urban areas. According to the National Health Policy (2007), in 2004 there were 184 medical doctors, 3070 staff nurses, 275 nurse assistants, 46 pharmacists, 2 pharmacy technicians, 18 dispensers and a number of allied health professionals whose work is supplemented by approximately 4000 rural health motivators, home based care givers and community birth attendants.

Health sector funding is limited and has declined over time, and it falls short of the 15% of the national budget recommended by the Abuja Declaration of April 2001 on HIV and AIDS, Tuberculosis, and other related infectious diseases. It had gone down from 9.4% in the eighties to an average of 7.1% in the past five years. However, the 20010/2011 Financial year Health budget was increased to 13.7% (Ministry of Finance Budget Speech, 2010). Between 2000 and 2007 the per capita Government health spending has appreciated from USD 46 to USD 95 (World Health Organisation, 2010).

Communicable diseases continue to be a major challenge for the country. According to health statistics report, respiratory conditions account for more than a quarter of all out-patients visits, increasing from 25.3% in 1995 to 26.6% in 2002. The reasons for admissions included pulmonary tuberculosis, malaria, gastro enteritis and colitis and pneumonia. HIV and AIDS is one of the biggest challenges facing Swaziland (National Health Policy, 2007). The HIV prevalence in women attending ante-natal services has gone up from 3.9% in 1992 to 41.1% in 2010 (ANC Sentinel Surveillance report, 2010). According to DHS conducted in 2006/2007 the HIV prevalence in the general population of two years and older was 19% (22% in women and 15% in men). It is estimated that about 184 116 people are living with HIV and of these, about 86 220 are in need for anti-retroviral therapy (Ministry of Health Swaziland HIV Estimates and Projections report, 2010). HIV and AIDS is the single highest cause of death in both adults and children. The demand for health services is therefore very high and there is need to increase delivery of all services including pharmaceuticals.

2. Pharmaceutical Situation Analysis

The Department of Pharmaceutical Services is located within the Directorate of Health Services of the Ministry of Health. It is headed by the Chief Pharmacist who is responsible for organizing and directing all pharmaceutical activities in the country **(National Pharmaceutical Services Administration)** as well as formulating and providing policy advice and guidance to the MOH. Other functions include ensuring regular medicine supply to the public sector, technical supervision of national referral and regional hospitals and the overall implementation of the Swaziland National Pharmaceutical Policy.

The Chief Pharmacist is also secretary to the Ministerial Medicines Advisory Committee (MMAC) which has the role of setting specifications for medicine tenders, adjudication and site inspections. A special substance abuse program is also placed within the pharmaceutical services department since 2002 but it has no dedicated staff. The Chief Pharmacist also plays the role of regulatory authority, an unsatisfactory situation which requires the urgent creation of a formal regulatory body. The national pharmaceutical services administration needs strengthening with adequate human and other resources to enable it to effectively fulfil its multiple functions.

Legislation and regulations: The Pharmacy Act of 1929 which has been in use in the country is outdated. It does not provide for the licensing of pharmaceutical outlets, medicine scheduling and regulatory functions such as site inspections and medicine registration. In the absence of a regulatory body, pharmaceutical personnel is registered by the Medicines and Dental Council, licensing of premises and registration of medicines is not done, trading licenses are issued by the Ministry of Commerce, Industry and Trade upon receipt of an authorisation letter from the Ministry of Health. Import permits for medicines are issued by the Ministry of Finance upon receipt of an authorisation letter from the Ministry of Health. A new Pharmacy Bill and a new Medicines and Related Substances Control Bill are being drafted. They provide for the establishment of a Pharmacy Council and a Medicines Regulatory Authority.

Supply: Central Medical Stores (CMS) is responsible for the **procurement**, **storage** and **distribution** of all medicines and medical supplies and devices to all government, parastatal and

mission hospitals, clinics and health centres. Procurement of anti-retrovirals (ARVs) is done through the National Emergency Response Council on HIV and AIDS (NERCHA). Nevertheless, CMS is responsible for their storage and distribution to accredited treatment centres.

CMS storage space is still inadequate even after the extension of the old warehouse, it is about 3500 cubic meters, just enough for 6 months supply. This requires more frequent procurement and over burdens the existing inventory system. Currently there are four distribution trucks at CMS and four regional trucks. Nine additional storage and dispensing facilities have been constructed. Most medicines are imported from outside Swaziland in countries such as India and South Africa. Vaccines are also procured by CMS and distributed by the Extended Program on Immunization (EPI).

Procurement is in principle restricted to items on the **Swaziland National Essential Medicines List**. However revision of the list is seldom done and there are more items from outside the list being requested. Record keeping and stock management both at the CMS and health facilities require improvement. A routine national quantification exercise for medicine requirements is also required.

The tender process and the content of tender documents are constantly under review and updated. A comprehensive review of the country's medicine procurement and supply and management system is necessary.

CMS Human Resources: The current CMS technical staff compliment is inadequate (5 pharmacists and 8 pharmacy technicians) given the current work load and in the context of ART scale up. In a new structure under discussion, it is expected to have 2 additional pharmacists.

Access: Medicines are provided free of charge in all public health facilities. However it should be noted that in hospitals, a nominal user fee E10 is charged for consultation, as well as E5 for radiology and E3 for laboratory test. In health centres the overall fee is E4. No fees are charged in public health units and clinics.

Medicine Donations contribute to the supply of medicines in Swaziland. According to existing national medicine donation guidelines which have never been adopted, all donations should be notified through the Chief Pharmacist for clearance. However, this is seldom done and various problems are encountered with donations: poor quality medicines, items outside the essential medicines list as well as obsolete medicines.

Local Production contributes to improving availability and accessibility to essential medicines. There is one privately owned production unit in Swaziland, producing a range of solid and liquid formulations and participates in national tenders floated by the MOH. A Good Manufacturing Practice (GMP) inspection of the premises and processes should be undertaken. There is a 15% local preference provision in tenders floated by MOH but does not distinguish between manufacturers and wholesalers.

Pharmaceutical Quality Assurance: There are no established quality assurances procedures for pharmaceuticals imported into or manufactured in the country. There is no medicine

inspectorate, registration, adverse reaction monitoring and pharmacovigilance. A Pharmaceutical product quality control laboratory was established in 1993 within the CMS premises. In March 1996, a WHO consultant made recommendations in order to make it fully functional but most of the recommendations have not been implemented. The laboratory is currently not operational due to lack of qualified staff, equipment and resources. Quality control and monitoring of medicines is therefore not done.

Financing: About 15% of the MOH budget is spent on medicines and medical supplies and devices. Government Treasury allocates the funds in the local currency. This limits procurement of these commodities within the Southern African Customs Union (SACU) region where local currency is accepted. Procurement is through open tender coordinated by a tender board, and with advice from the Ministerial Medicines Advisory Committee. Funding for ARVs has been from the Global Fund and managed by NERCHA. However in 2006, government made available funds (E45 Million, which was more than the total provided to CMS) which were used to procure ARVs pending approval of funds from the Global Fund. Substantial funding from Government and other donors will be required to sustain the on-going ART scale up efforts. NERCHA and CMS are working together to move towards the integration of ARV procurement into the CMS system.

Human Resources: There is a critical shortage of qualified pharmaceutical personnel. Currently there are 48 registered pharmacists but most of them are in the private sector. There is need for training of more pharmaceutical personnel (pharmacists, pharmacy technicians) and putting in place incentives to attract and retain them in the public sector. In addition, the required number of posts needs to be created. Existing incentives for retaining government health staff (overtime payment, call allowance, standby allowance, retention allowances) do not apply to pharmaceutical personnel.

Rational Medicine Use: There are no mechanisms for monitoring medicine use by health workers and the general public mainly due to lack of the necessary tools, staff and resources. The clinical reference manual for Clinics and Health Centres published in 1986 is outdated, the National Essential Medicine List is not reviewed regularly, and there are no National Comprehensive Standard Treatment Guidelines and no National Formulary. Current prescribing and dispensing practices need to be rationalized and streamlined through the development of various rational medicine use tools and staff training.

Anti-retroviral Therapy: The current HIV prevalence in the country of 41.1% of pregnant women, (ANC Surveillance Report, 2010) is one of the highest in the world. National response to the epidemic has been guided by the National Multi-Sectorial HIV and AIDS Policy of 2006. Government has further established NERCHA to coordinate and facilitate the national response to the epidemic. One of the objectives of the HIV and AIDS policy is to improve the provision of treatment, care and support. About 184 116 people are living with HIV and about 86 220 of them are eligible for ART (Ministry of Health Swaziland HIV Estimates and Projections report, 2010). Currently there are 33 ART initiating sites in addition to 63 refill and roll out sites. More efforts are still needed to respond to the ART needs in the country.

Traditional Medicine and Complementary Medicine: There is no policy on traditional and complementary medicine (s) but their use is wide spread in the country. Patients often visit a

traditional health practitioner and a health care facility for the same illness. There are no mechanisms for collaboration with traditional health practitioners, to ensure the efficacy of their preparations. There is a need to encourage collaboration between traditional health practitioners and health workers and establish mechanisms for monitoring their activities in the community.

No **Research** is undertaken, even though some small scale research on traditional medicine is being carried out at the University of Swaziland. However, the current situation pleads for more operational research on the country's pressing pharmaceutical sector problems.

Given the numerous challenges within the pharmaceutical sector, there is need for close **Technical**, **Inter-sectorial Cooperation and Co-ordination** between the MOH on one hand, other government ministries, bi-lateral and multi-lateral partners on the other, in order to establish partnerships, mobilize resources and technical assistance.

Appropriate **Monitoring and Evaluation** mechanisms are also necessary to ensure that set objectives within existing policies are being achieved and the necessary adjustments are made in case of deviation.

3. Priority Challenges faced by the Swaziland Pharmaceutical Sector

The preceding overview of the Swaziland pharmaceutical sector highlights the following priority problems for which policy orientations are required so that appropriate interventions can be undertaken to resolve them.

3.1 **National Pharmaceutical Services Administration**: Insufficient resources and capacity in the Chief Pharmacist's office to enable effective policy guidance and coordination of all activities of the Swaziland Pharmaceutical Sector.

3.2 **Legislation and Regulations**: Inadequacy of existing laws and regulations for the control of medicines and the practice of pharmacy.

3.3 **Medicine Supply**: Limited capacity and resources for the Central Medical Stores to ensure regular supply of essential medicines and other medical supplies and devices.

3.4 **Pharmaceutical Quality Assurance**: Absence of established quality assurance procedures to ensure the quality of pharmaceuticals, including anti-retrovirals, used in the country.

3.5 **Medicine Financing**: Inadequate financing for medicines and other supplies and activities of the national pharmaceutical sector.

3.6 **Human Resources**: Critical shortage of qualified pharmaceutical human resources particularly in the context of the on-going ART scale-up.

3.7 **Rational Medicine Use**: Absence of a framework and appropriate tools for the promotion of rational medicine use by health workers and the public.

3.8 **Anti-retroviral Therapy:** Insufficient resources to provide anti-retroviral therapy and associated services to all eligible patients in Swaziland.

3.9 **Traditional Medicine**: Inadequate collaboration between traditional health practitioners and health workers despite wide spread use of traditional medicine by the population.

3.10 **Local Production**: Small scale local production takes place without sufficient capacity and incentives.

3.11 **Patents and Global Trade Agreements:** Limits access to essential medicines.

3.12 **Research**: Absence of a framework for carrying out operational research into priority problems affecting the Swaziland pharmaceutical sector.

4. Overall Goal of the Swaziland National Pharmaceutical Policy.

The goal of the Swaziland National Pharmaceutical Policy is to contribute to improving the health of the Swaziland population by ensuring equitable access to, and rational use of efficacious, high quality essential medicines, and medical supplies and devices at affordable cost particularly for vulnerable populations.

5. General Objectives of the Swaziland National Pharmaceutical Policy

In order to go towards the fulfilment of the overall goal for the Swaziland National Pharmaceutical Policy, the following general objectives will be pursued:

5.1 Provide the **National Pharmaceutical Administration** with the necessary human and other resources to carry out all its functions and oversee the effective implementation of the Swaziland National Pharmaceutical Policy.

5.2 Enact the necessary **Pharmaceutical Laws and Regulations** for the proper monitoring and control of the national pharmaceutical sector.

5.3 Establish a functional **Medicines Regulatory Authority** and a **Pharmacy Council** responsible for the regulation of all aspects of medicines and the pharmaceutical profession respectively.

5.4 Establish **Quality Assurance** mechanisms and procedures for all medicines imported into and exported out of or manufactured in Swaziland.

5.5 Improve the capacity and performance of the C**entral Medical Stores and health facilities** for efficient procurement, storage and distribution of essential medicines, including anti-retrovirals, and other medical supplies and devices.

5.6 Increase current **Public Funding for Medicines** to meet current and future demands and in support of on-going national anti-retroviral therapy scale up efforts.

5.7 Provide sufficient and qualified pharmaceutical **Human Resources** for the implementation of the Swaziland National Pharmaceutical Policy.

5.8 Develop tools and initiatives for the promotion of **Rational Medicine *Use*** among health workers and the general public.

5.9 Promote collaboration between **Traditional Healers, *Complementary medicines practitioners and*** health Workers.

6. Policy Orientations / Strategies

6.1 National Pharmaceutical Services Administration

The objective of the Swaziland National Pharmaceutical Policy in relation to National Pharmaceutical Services Administration is to ensure effective provision of policy advice to the MOH and overseeing implementation of the Swaziland National Pharmaceutical Policy.

To achieve this objective, the Government of Swaziland is committed to:

6.1.1 Provide the National Pharmaceutical Services with adequate resources to enable it carry out all its functions and oversee the implementation of the Swaziland National Pharmaceutical Policy.

6.1.2 Establish appropriate technical committee (s) responsible for establishing and regular reviewing of the national essential medicine list, national formulary and standard treatment guidelines, as well as advising the MOH on relevant pharmaceutical matters.

6.1.3 Develop and maintain a data base of public and private sector medicines and medical supply related information in Swaziland.

6.1.4 Ensure that licensed pharmaceutical outlets such as retail pharmacies and wholesales are owned by and licensed to registered pharmacists. In the case of pharmaceutical manufactures the majority shareholding should be held by a pharmacist or a group of pharmacists.

6.1.5 Implement a national quantification exercise for the estimation of medicine requirements at national and various levels of the health care delivery system.

6.1.6 The SADC harmonization guidelines on the regulation of medicines be adopted. Legislation and policies relating to the regulation of medicine be aligned as far as possible with these guidelines.

6.2 Legislation and Regulations

In relation to legislation and regulations, the objective of the Swaziland National Pharmaceutical Policy is to develop and implement the necessary pharmaceutical legislation and regulations, to enable effective control of medicines, the pharmaceutical profession and establishment of a medicines regulatory body.

To achieve this objective, the Government of Swaziland is committed to:

6.2.1 Enact and maintain two Acts relating to the control of the profession of pharmacy and the control of medicines and related substance in order to establish a Pharmacy Council and a Medicines Regulatory Authority respectively.

6.2.2 Review the current provisions relating to the control of Opium and other Habit Forming substances and incorporate the regulation thereof into the Act relating to the control of medicines and related substances.

6.2.3 Facilitate harmonization of all regulations controlling medicines and related substances that are subject to abuse

6.3 Medicine Supply

The objective of the Swaziland National Pharmaceutical Policy in medicine supply is to ensure efficient procurement, storage and distribution of sufficient quantities of quality essential medicines and other medical supplies and devices.

To achieve this objective, the Government of Swaziland is committed to:

6.3.1 Strengthen the capacity (staff, storage capacity, logistics, capacity, management) and performance of the CMS and other health facilities to enable it carry out its functions efficiently.

6.3.2 Integrate ARV procurement under the new MOH procurement reforms.

6.3.3 Ensure that CMS procurement is principally by tender to pre-qualified suppliers and limited to items on the Swaziland National Essential Medicine List.

6.3.4 Ensure that procurement of medicines for the public and private sector is restricted to products registered for use in the country of manufacture (or acceptable reasons given for non-registration in that country) and registered for use in Swaziland.

6.3.5 Ensure the provision of good quality, safe and efficacious medicines at affordable prices to the Government and the individual.

6.3.6 Establish and enforce the necessary control and monitoring mechanism for accountability and transparency in the use of medicines.

6.3.7 Adopt SADC & WHO donation guidelines and procedures for the donation of medicines and medical supplies and devices to Swaziland.

6.3.8 Extend the exemption of duties and taxes applied to medicines to other medical supplies and devices such as condoms, other sexual and reproductive health commodities and raw materials (APIs).

6.4 Quality Assurance

The objective of the Swaziland National Pharmaceutical Policy with regard to quality assurance is to ensure that only those medicines that are safe, efficacious and of assured quality are used in Swaziland.

To achieve this objective, the Government of Swaziland is committed to:

6.4.1 Provide the necessary equipment and resources for the resumption and continuation of activities at the Pharmaceutical product Quality Control Laboratory.

6.4.2 Control the quality of all medicines, medical supplies and devices imported into or manufactured in or exported from Swaziland before their use. A procedure for fast tracking the process should be in place in case of emergencies.

6.4.3 Establish procedures for the registration of medicines.

6.4.4 Develop mechanisms for controlling and combating substandard and counterfeit medicines.

6.4.5 Establish a national pharmacovigilance program to monitor and report adverse medicine reactions.

6.4.6 Apply the WHO Certification Scheme for Pharmaceutical Products Moving in International Commerce as one among other safeguards against sub-standard medicines.

6.4.7 Establish procedures and guidelines for the disposal of expired, unwanted and undesirable pharmaceuticals in collaboration with all relevant agencies. Establish adequate national capacity to efficiently dispose of undesirable medicinal products and medical supplies using the relevant waste disposal technology.

6.5 Medicine Financing

The objective of the Swaziland National Pharmaceutical Policy in medicine financing is to provide adequate public funding to ensure regular supply of sufficient essential medicines and medical supplies and devices.

To achieve this objective the Government of Swaziland is committed to:

6.5.1 Aligning the government medicine budget to the results of the national quantification of medicine requirements in Swaziland.

6.5.2 Establish and enforce the necessary control and monitoring mechanism for accountability in the use of funds for medicines.

6.5.3 Establish a pricing policy for medicines and medical supplies and devices in Swaziland.

6.5.4 Carry out a medicine financing study to examine various options for financing medicines in Swaziland.

6.5.5 Establish a donor coordination mechanism to capture and document all finances used to procure medicines in the country

6.6 Human Resources

The objective of the Swaziland National Pharmaceutical Policy in relation to human resources is to provide sufficient qualified pharmaceutical personnel for the efficient running of pharmaceutical services in Swaziland.

To achieve this objective, the Government of Swaziland is committed to:

6.6.1 Develop and implement a national pharmaceutical human resources plan, in line with the health sector Human Resource development plan.

6.6.2 Introduce the training of pharmacists and pharmacy support staff in the Kingdom of Swaziland.

6.6.3 Work towards the creation of sufficient pharmaceutical personnel posts within the ministry of health and enforce incentives, including rural retention schemes, for retaining them in the public sector.

6.7 Rational Medicine Use

In relation to rational use of medicines, the objective of the Swaziland National Pharmaceutical Policy is to ensure the rational use of medicine by both health workers and patients in order to maximize their therapeutic benefit.

To achieve this objective, the Government of Swaziland is committed to:

6.7.1 Ensure that a component on rational medicine use is included to existing training curricula for all health workers to ensure sufficient exposure to the essential medicines concept.

6.7.2 Provide continuing education on relevant aspects of medicine use to all health workers: prescribing, dispensing, advice to patients, anti-retroviral therapy, medicine administration.

6.7.3 Develop and implement information, education and communication campaigns on rational medicine use for the public.

6.7.4 Establish a medicines information service to generate and disseminate independent information for the promotion of rational medicine use for health workers and the public.

6.7.5 Enforce generic prescribing and dispensing in the public sector, and encourage it in the private, and establish regulatory measures to allow generic substitution.

6.7.6 Put in place measures to monitor and control advertising and promotion of medicines.

6.7.7 Enforce the creation of Pharmacy and Therapeutics Committees (PTC) to ensure rational and cost effective use of medicines by health facilities.

6.7.8 Review and enforce the use of the Essential Medicine List of Swaziland

6.7.9 Develop and enforce the use of National Comprehensive Standard Treatment Guidelines and National Formulary in the public sector, and encourage the same in the private sector.

6.7.10 Provide guidelines and legal provisions for the issuing of licenses to dispensing health professionals.

6.8 Anti-retroviral Therapy

The objective of the Swaziland National Pharmaceutical Policy in relation to anti-retroviral therapy is to support national ART scale-up efforts and ensure constant availability of ARVs and medicines for opportunistic infections and palliative care.

To achieve this objective, the Government of Swaziland is committed to:

6.8.1 Strengthening collaboration between CMS/MOH and NERCHA and provide sufficient resources (financial, human, material, logistic) to enable CMS meet the challenges of the ART scale-up drive.

6.8.2 Ensure the exposure of all pharmaceutical personnel to ART training.

6.8.3 Establish and regularly review national HIV and AIDS guidelines.

6.8.4 Ensure availability of sufficient quantities of first, second and salvage therapy line ARVs in line with national ART guidelines.

6.9 Traditional and Complementary Medicine

In relation to traditional and complementary medicine, the objective of the Swaziland National Pharmaceutical Policy is to maximize the use of positive aspects and minimize the negative consequences of traditional and complementary medicine in the provision of health care services.

To achieve this objective, the Government of Swaziland is committed to:

6.9.1 Initiate consultations with traditional health practitioners and other interested parties for the development of a traditional and complementary medicine policy.

6.9.2 Establishing mechanisms for collaboration between traditional health practitioners and conventional health workers in the delivery of health services.

6.9.3 Establish mechanisms for overseeing the activities related to the safety and efficacy of traditional and complementary medicines, as well as therapeutic claims made by traditional and complementary health practitioners.

6.10 Local Production

The objective of the Swaziland National Pharmaceutical Policy in relation to local production is to encourage local production as one way of improving access to medicines.

To achieve this objective the Government of Swaziland is committed to:

6.10.1 Provide incentives such as the removal of taxes and duties on raw and packaging materials, for the establishment of local production units for essential medicines.

6.10.2 Support local production units in upgrading their GMP status to ensure the production of good quality medicines.

6.11 Patents and Global Trade Agreements

The objective of the policy in relation to patents is to ensure that legislation and regulations maintain a balance between the minimum standard for intellectual property rights protection and the public health interest.

6.11.1 Review the local patent laws to be in conformity with international property provisions including the protection of traditional medical knowledge.

6.11.2 Protect public health by taking advantage of all the flexibilities within the Trade Related Intellectual Property Right (TRIPS) Agreement that promote public health and ensure access to affordable quality medicines.

6.12 Research

The objective of the Swaziland National Pharmaceutical Policy is to encourage research aimed at resolving pressing problems of the Swaziland Pharmaceutical Sector.

To achieve this objective the Government of Swaziland is committed to:

6.12.1 Establishing a research unit within the Ministry of Health.

6.12.2 Promote operational research and establish a framework for undertaking it in collaboration with training and other institutions in Swaziland.

6.12.3 Identify priority areas for research such as rational medicine, traditional and complementary medicine, socio-cultural aspects of medicine use and the impact of the present policy on pharmaceutical services delivery.

6.12.4 Ensure that all medicines and medical supplies and devices used in clinical trials have been duly authorized for that purpose by the Medicines Regulatory Authority.

6.12.5 Promote adherence to clinical trials guidelines and ensure that the Ethics Committee monitors and evaluates the proceedings of the investigations in accordance with the regulations.

6.13 Technical, Inter-sectoral Cooperation and Co-ordination

The objective of the Swaziland National Pharmaceutical Policy with regard to technical and inter-sectoral cooperation is to strengthen technical, inter-sectoral cooperation and co-ordination between the MOH and other government ministries as well as bi-lateral and multilateral partners, on matters concerning the national pharmaceutical sector.

To achieve this objective, the Government of Swaziland is committed to.

6.13.1 Ensuring inter-ministerial consultation and collaboration on national pharmaceutical matters, in particular with the Ministry of Agriculture with regard to veterinary medicines.

6.13.2 Involvement of civil society, professional associations, non-governmental organizations on national pharmaceutical matters as and when the need arises.

6.13.3 Strengthen collaboration with bi- and multi-lateral partners, sub-regional and regional organization particularly in relation to technology transfer, mobilization of financial resources and technical assistance for policy implementation.

6.13.4 Encourage collaboration and coordination with development partners in relation to donations.

7. Implementation of the Swaziland National Pharmaceutical Policy

7.1 A National Pharmaceutical Strategic Plan and yearly Priority Action Plans will be developed for the implementation of the present policy.

7.2 The MOH will be responsible for the effective implementation of the present policy.

7.3 A fund raising strategy will be established to source funding for those elements of the policy that cannot be funded from public funds.

8. Monitoring and Evaluation

8.1 A multi-disciplinary monitoring and evaluation committee will be established to follow progress and final evaluation of policy implementation.

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