

**MINISTRY OF HEALTH
GOVERNMENT OF SOUTHERN SUDAN**



Southern Sudan Pharmacy Protocol



**Southern Sudan
Pharmacy Protocol**

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Preface

The Southern Sudan Pharmacy Protocol has been developed to provide a broad guide and reference document in the subsequent laws and regulations or other specific guidelines with a view to ensuring successful attainment of quality health care. It relates to the mission of the Ministry that strives to improve the health status of the population and ensure a sector wide quality health care to all the people of Southern Sudan, especially the most vulnerable, women and children.

The protocol draws from experiences dating back to the period before the signing of the Comprehensive Peace Agreement (CPA), as well as the current status of the pharmaceutical sector. It seeks to ensure that all aspects of pharmaceutical services, including medicines supply management that takes into account procurement, storage, distribution, as well as quality assurance and rational use, are adequately addressed. It seeks to ensure effective medicines regulations and control to minimize entry and circulation of substandard and counterfeit products, including veterinary medicines and supplies in the Southern Sudan pharmaceutical market. Furthermore, recognizing the contribution of Traditional Medicine practice in the overall health care delivery service of Southern Sudan, the protocol makes provision for the harnessing the benefits of traditional medicines with due consideration to safety and efficacy.

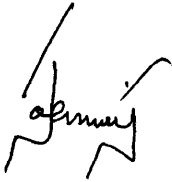
At the moment, laws governing the practice are in the formative stages. The country does not have the requisite infrastructure and human resource base to move at a comparative speed with distribution lines. This may cause an impediment in regulating the sector. However, if the attitudes are developed to harness ethical practices, this policy will find a solid base to cultivate the realities of rational medicine use, quality, safety and efficacy of pharmaceutical products and other medical appliances.

The Southern Sudanese people deserve to get quality health care in a uniform approach that is beneficial to all. Pharmaceuticals and other medical supplies are important in restoring good health. Pharmaceutical services are therefore vital in measuring the success, or improvement in the delivery of health services. Most other health delivery avenues will depend on efficient and sustainable pharmaceutical services.

It will be realised that there will be many players interested in providing health services from all over the world, different disciplines and beliefs, on humanitarian or commercial basis. The aim is to fully

utilize the potential of these good intentions to improve the health status of the people of Southern Sudan in the most beneficial and cost effective way. It is therefore incumbent upon all stakeholders, both in the public and private sectors to fully embrace this protocol and participate in its effective implementation.

This First Edition of the Southern Sudan Pharmacy Protocol is a step forward in the delivery of health care and I wish to congratulate and sincerely thank all those who contributed to the development of this Protocol.



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This Southern Sudan Pharmacy Protocol has been produced with collective inputs of many health professionals, development partners and individuals within and outside the Ministry of Health at various stages of its development. The first draft of this protocol was developed prior to the Comprehensive Peace Agreement (CPA) by the former Secretariat of Health (SOH) of the Sudan Peoples Liberation Movement (SPLM). It was then reviewed and adopted to address the current situation of the pharmaceutical sector in 2006 by the Ministry of Health, Government of Southern Sudan (MOH-GOSS), in consultation with various development partners and individual experts and consultants. The Ministry of Health is, therefore, indebted to a host of contributors to this protocol and wishes to register special thanks and appreciation to all, without whom this document would have been incomplete, especially the following individuals who have been involved at one stage or another in the development of the first edition of Southern Sudan Pharmacy Protocol.

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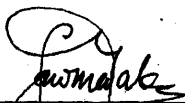
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AIDS	Acquired Immune Deficiency Syndrome
ARVs	Anti-Retroviral Medicines
CMS	Central Medical Stores
CPA	Comprehensive Peace Agreement
COA	Certificate of Analysis
IEC	Information, Education and Communication
QA	Quality Assurance
GMP	Good Manufacturing Practices
RMS	Regional Medical Stores
SMS	State Medical Stores
HIV	Human Immunodeficiency Virus
INN	International Non-Proprietary Name
MOH	Ministry of Health
GOSS	Government of Southern Sudan
NGO	Non-Governmental Organizations
NMP	National Medicine Policy
NPMP	National Pharmaceutical Master Plan
PHCU	Primary Health Care Units
PHCC	Primary Health Care Centre
SOPs	Standard Operating Procedures
SSPQCL	Southern Sudan Pharmaceutical Quality Control Laboratory
TRIPs	Trade Related aspects of Intellectual Property
WHO	World Health Organization

1 Introduction

Since the signing of the Comprehensive Peace Agreement in January 2005, the Government of Southern Sudan has instituted the Interim National Constitution, which has decentralized Government into four levels, i.e. Central, State, County and Community levels. The Constitution recognizes the provision of health care services in the country, through promotion of public health and guarantees equal access to Primary Health Care Services.

The Ministry of Health developed an Interim Health Policy for Southern Sudan 2007-2011. The Policy has a statement on Pharmaceutical Medical Supplies. The statement reads:

“ The Ministry of Health shall ensure only products of quality, safety, and efficacy is availed to the people of Southern Sudan. Therefore, the Ministry shall establish an autonomous Southern Sudan Pharmaceutical Quality Control Laboratory (SSPQCL) to conduct routine quality control testing of pharmaceuticals and veterinary drugs.

“Rational drug use is of paramount importance to the Ministry to ensure that health care is evidence based and affordable. The Ministry shall also develop, promulgate and enforce a Southern Sudan Pharmacy and Drugs Act and related regulations/Standard Operating Procedures (SOPs) for the regulation of the pharmaceutical business and other transactions and movement. This will include: registration and regular licensure of all pharmacy professionals by the Southern Sudan Pharmacy Council; ensuring pharmacy professionals adhere to the standards and code of ethics of practice stipulated by the Southern Sudan Pharmacy Council; regular inspections of pharmacy outlets/businesses and pharmaceutical manufacturers and pharmacovigilance”.

“The Ministry is also exploring options to ensure the most efficient procurement and distribution systems for Southern Sudan. Drugs or other medical supplies should not be donated to Southern Sudan without prior consultation with the Ministry of Health. Donated drugs with expiry date of less than 12 months will not be accepted”.

This protocol document is therefore a means to expound on this commitment and guide health service providers and users, both in the public and private sectors on effective implementation of the pharmaceutical aspects of the overall health policy. The process of developing this policy started before the signing of the CPA, and draws experiences and expertise of a wide range of experts at various times,

professionals. The World Health Organization guidelines for the development of National Medicines Policies were also extensively referred to in the process of the development. In this document considerations have been made to the current situation of the pharmaceuticals sector, the opportunities, challenges and constraints, as well as, possible future scenarios. At times therefore, reference is made to institutions that are yet to be established. To ensure effective implementation of this Policy, a comprehensive Pharmaceutical Master Plan will be developed shortly after its adoption. Moreover, applicable laws, regulations and guidelines, such as the Southern Sudan Pharmacy and Drugs Act and respective regulations, Essential Medicines List for Southern Sudan and a proposal for the establishment of autonomous Central Medical Stores are already in the final stages of development. These documents will augment and elucidate this policy further.

2.1 Country Profile

Southern Sudan is part of the Republic of Sudan, covering an area of 610,175 square kilometres. The capital is Juba and consists of ten states. Following the signing of the Comprehensive Peace Agreement (CPA) on January 2005, an autonomous Government of Southern Sudan was established that has taken into consideration one country with two systems.

The Ministry of Health, Government of Southern Sudan comprise of twelve Directorates, one of which is the Directorate of Pharmaceutical services and supplies. It is headed by the Minister of Health, assisted by an Undersecretary and twelve Director Generals. At the State level, each Ministry of Health is headed by a State Minister of Health, assisted by one Director General and eight Directors heading departments. One of the newly established departments at the State level is the department of Pharmaceutical Services.

2.2 Legislation

The Ministry of Health, Government of Southern Sudan has developed a Health Policy for the Government of Southern Sudan, through extensive consultation with stakeholders. The Ministry has also drafted various protocols, guidelines and laws for the different programmes, some of which are being used as references for implementation.

2.3 Pharmaceutical Services Administration

Before the CPA, the Pharmaceutical Services Administration was under the responsibility of the Directorate of Curative and Pharmaceutical Services. With the formation of the Ministry of Health, Government of Southern Sudan, it is now under the Directorate of Pharmaceutical Services and Supplies. It is important to note that a Southern Sudan Pharmaceutical Society has been formed.

2.4 Financial Resources

Currently, the Government of Southern Sudan and its development partners, through the Multi Donor Trust Fund (MDTF), have budgeted for pharmaceutical and medical supplies. The World Health Organisation, other UN agencies, the European Union, other

outside the country or in Northern Sudan. In the private sector, the professionals have made an expressed need for the establishment of regulatory mechanisms that will ensure internationally acceptable practice standards. The main challenges are the shortage of qualified pharmacy professionals and inadequate regulatory mechanisms that has left the handling of pharmaceuticals to untrained persons and unlicensed premises. The poor infrastructure and porous borders with the neighbouring countries are also contributing to the availability of substandard medicines in the country.

3 Vision

The vision of the Government of Southern Sudan (GOSS) is to pursue the ideals of the right to health and access to essential medicines so that everyone may attain full benefit of quality of life, which will result into the economic development and prosperity of the nation.

4 Mission Statement

The GOSS through the implementation of the Southern Sudan Pharmacy Protocol (SSPP) is to use available resources to develop and provide pharmaceutical products and services on a sustainable basis to meet the requirements of Sudanese in the prevention, diagnosis and treatment of diseases using safe, quality, efficacious, and cost-effective pharmaceutical products.

5 The Goal and Objectives of the Pharmacy Protocol

5.1 Goal

The goal of the Southern Sudan Pharmacy Protocol is to ensure that every person in the Southern Sudan has equal opportunity and access to quality, safe, effective pharmaceutical products and medical supplies, which are continuously available, affordable and put into rational use.

5.2 Objectives

The following are the main objectives of the Southern Sudan Pharmacy Protocol

- a) To ensure the constant availability of quality, safe and efficacious medicines according to international standards to all segments of the population
- b) To monitor and ensure equitable distribution, storage affordability of medicines to all areas of the country whether by the Government, private or Non-Governmental Organizations
- c) To facilitate and actively promote rational use of medicines through sound prescribing, good storage/dispensing practices and appropriate training of health professionals and suitable public education
- d) To encourage self sufficiency, self reliance and capacity building through technical, economic and commercial facilitation of local

manufacture of pharmaceuticals which meet GMP standards for domestic use and export

- e) To encourage and promote evidence-based use of traditional and herbal medicines, with due consideration to quality and safety
- f) To ensure that the provision and access of medicines for veterinary services are consistent with this policy
- g) To ensure that sound and effective pharmaceutical regulatory mechanisms and quality assurance systems are maintained at all levels.
- h) To encourage and support scientific research and development in pharmaceuticals, traditional medicines or alternative medicines and other medicinal products used in the country.
- i) To ensure allocation of sufficient Government budget and material and human resources to implement, monitor, evaluate and sustain this policy.

6 Policy Components

6.1 Legislation

The Government of Southern Sudan (GOSS) shall develop a sound pharmaceutical regulatory system and enact laws to ensure the timely implementation and enforcement.

6.2 Institutional Framework

The MOH-GOSS shall ensure effective and efficient implementation, monitoring and evaluation of the Southern Sudan Pharmacy Protocol at all levels. The following institutions shall be established and provided with the required financial, material and human resources to carry out their functions as appropriate:

- a. The Southern Sudan Pharmacy Council shall be responsible for the development and review of standards for the education, registration and licensing, standards of practice and Code of Ethics for pharmacy professionals.
- b. The Directorate of Pharmaceutical Services shall be responsible for: Monitoring, evaluation and periodic review of the Southern Sudan Pharmacy Protocol, Providing the Secretariat for the Southern Sudan Pharmacy Council, establishing a Secretariat to coordinate and document the bureaucratic activities and achievements of the committees under this Directorate, Ensuring access and availability of

medicines and medicines for human and veterinary use, Implementation and enforcement of pharmaceutical laws and regulations. This role shall be taken over by an autonomous Southern Sudan Pharmacy Regulatory Authority in due course.

- c. Management and supervision of the Central Medical Stores and Regional Medical Stores for the procurement, warehousing and distribution of pharmaceuticals for the public sector: This function shall be taken over by an autonomous Central Medical Stores and Regional Medical Stores in due course.
- d. Establishment and implementation of pharmaceutical quality control system and establishment of an autonomous Southern Sudan Pharmaceutical Quality Control Laboratory.
- e. State Departments of Pharmaceutical Services to carry out implementation of the Southern Sudan Pharmacy Protocol and the Pharmacy Laws and regulations, as appropriate
- f. The Government shall support and promote the establishment of structures for the administration, regulation and development of traditional medicines.

6.3 Financial Resources

The Government will ensure that adequate funding is made available and efficiently managed to implement the Southern Sudan Pharmacy Protocol and related laws and regulations, and in particular to provide the required quantity of essential medicines in the most cost-effective and sustainable way.

- a. Bearing in mind the annual budgetary allocation, adequate allocation will be made by MOH towards the implementation the Southern Sudan Pharmacy Policy.
- b. The MOH will work in close collaboration with all interested and pertinent parties, to ensure that due priority are given to the financing and importation of essential medicines.
- c. National requirements for financial resources will be based on the careful estimation of the total quantity of medicines and medical supplies needed in the country using data from all available reliable sources.

- d. In the funding of medicines supplies, MOH-GOSS shall seek and encourage inputs from different partners, including governmental, non-governmental and parastatal organizations, bilateral and multilateral agencies, the private sector and individuals.

6.4 Medicines Supply Management System

The Government shall establish a medicines supply management system that will ensure that sufficient quantities of medicines and medical supplies of the required standards of safety, quality and efficacy are available in all public health institutions at all times.

6.4.1 Procurement

Medicines and other medical supplies for the public sector shall be procured according to public procurement guidelines, which included the following key elements:

- a. The Southern Sudan Essential Medicines List shall be the basis for the selection of medicines for procurement
- b. Medicines will be procured by generic name (INN), and the products must be registered in Southern Sudan as well as country of origin
- c. Selection and Quantification of Pharmaceutical requirements will be done annually and updated periodically throughout the year, based on demand by the SSNPTC.
- d. An annual procurement plan and schedule will be made according to actual resources available and realistic delivery times.
- e. Pre-qualification of suppliers shall be open to international bidding. Medicines will be purchased through competitive tender from suppliers who have been pre-qualified by a technical evaluation committee composed of members from the MOH, NMS.
- f. The Southern Sudan Pharmaceutical Quality Control Laboratory (SSPQCL) will regularly test the quality of products procured by the NMS. In addition, other data generated by the SSPQCL will be used in the supplier pre-qualification process.

- g. A formal supplier monitoring system will be established by NMS with objective standards for medicine quality and services performance. Suppliers whose product quality or service falls below standards will be notified and eventually deleted from the list of approved suppliers.
- h. Supply terms will be specific to pharmaceutical products, particularly with respect to specifications, manufacturing site, Active Pharmaceutical Ingredient (API), shelf life, and labelling, packaging and related issues as originally submitted to SSPRA in the dossier for registration.
- i. Medicines not listed on the SSEDL will be allowed on exceptional basis for procurement only if they fit into one of the following categories and provided SSPRA has given its permission:
 - Medicines for emergency situations/diseases not catered for by the SSEDL or SSVEDL.
 - Specifically requested medicines not catered for by the SSEDL or SSVEDL for use in institutions with specialized medical personnel and expertise.
 - Orphan medicines
- j. A list of suppliers of pharmaceutical products and medical equipment will be established. The list will be reviewed annually.

6.4.2 Distribution

The MOH-GOSS shall ensure that distribution of medicines and medical supplies is done in such a way as to maintain the quality and constant availability of the products.

- a. The Central Medical Stores, under the MOH shall be responsible for public medicine distribution to reach all government stores and health institutions fast, efficiently and for appropriate storage in the pharmaceutical county stores.
- b. Medicines will be distributed according to established clinical needs, workload and institutional capacity to diagnose in order to enhance rational medicine use.
- c. Members of the Pharmaceutical Inspectorate will perform periodic inspections of the distribution channels, availability of medicines, and levels of rational medicine use.

- d. Private sector involvement in administration, storage or transport will be encouraged with the aim to improve efficiency and enhance cost-effectiveness as well as fill gaps in the distribution line.

6.4.3 Storage

The MOH-GOSS shall ensure that medicines in storage are secured and that their quality, safety and efficacy are maintained until delivery to the end user.

- a. It shall facilitate and mobilize resources for the provision of suitably designed, equipped and well-maintained storage facilities at all levels of the public sector medicines distribution system.
- b. In order to promote the correct organisation and maintenance of medical stores throughout the country, it shall develop a Stores Procedures Manual.

6.4.4 Inventory Control

The Government will ensure that accurate and systematic recording, monitoring and reporting system is maintained at all levels.

6.4.5 Donations

The MOH-GOSS will continue to encourage and welcome donation of medicines and medical supplies by interested partners that can augment government's efforts in the overall health care delivery. In this regard, the Government recommends the use of the World Health Organisation Guidelines for Donation of Medicines by all parties intending to donate medicines and medical supplies to Southern Sudan, which includes the following, until guidelines for Southern Sudan are developed and issued:

- a. Medicine donations should benefit the recipients to the maximum extent possible and be based on an expressed need.
- b. Donations should be supportive, complementary, and conform to existing government health policies and programme, including the Essential Medicines List.
- c. Medicine donations from both international and local sources must comply with the provisions governing pharmacy practice and the Southern Sudan Pharmacy Policy.

6.4.6 Local Production and Self-sufficiency

The government shall encourage the establishment of local pharmaceutical industry to ensure self-sufficiency and sustainability in the supply of essential medicines for both human and veterinary use. Manufacturers will be required to adhere to internationally accepted standards for Quality Assurance (QA) and Good Manufacturing Practices (GMP).

6.4.7 Pharmaceutical Regulatory System

The Government shall develop, promulgate and enforce a Southern Sudan Pharmacy and Drugs Act for the regulation of the pharmaceutical business and other transactions and movement. The MOH-GOSS shall develop regulations and Standard Operating Procedures (SOPs) for the implementation of the Pharmacy Act to ensure transparency to the public and applicants.

6.4.8 Registration and Licensing of Pharmacy Professionals

Anyone who intends to practice Pharmacy shall seek registration and licensing from the Southern Sudan Pharmacy Council and shall practice in accordance with the Standards and Code of Ethics of Practice, as stipulated by the Council:

6.4.9 Pharmaceutical Inspectorate

The Pharmaceutical Inspectorate shall be responsible for the following functions:

- a. Inspection of pharmaceutical trade outlets, including importers, exporters, wholesalers and distribution channels, for compliance with the Pharmacy and Drugs Act and regulations thereof for the purposes of licensing.
- b. Inspection of pharmaceutical businesses to ensure compliance with the provisions of the Pharmacy and Drugs Act and regulations thereof, including compliance with current Good Pharmacy / Distribution Practices.
- c. Inspections of manufacturing premises for compliance with the provisions of the Pharmacy and Drugs Act and current Good Manufacturing Practices (GMP) for the purposes of licensing.

- u. inspections of manufacturing operations for compliance with the provisions of the Pharmacy and Drugs Act and current Good Manufacturing Practices (GMP).
- e. Routine market surveillance to monitor the quality of medicines and to detect and remove from the market sub-standard medicines, counterfeit products or medicines of spurious quality.

6.4.10 Marketing Authorization (Registration) of Medicines

Pharmaceutical products intended for the Southern Sudan market as well as products intended for export may be given marketing authorisation based on the following requirements:

- a. Inclusion in the Southern Sudan Essential Medicine List (SSEDL).
- b. Pre-qualification of sources and products through a system of scientific review of:
 - GMP status of existing manufacturers (site inspections or collaboration with partner regulatory authorities).
 - Notification of existing medicines in the market for efficacy, safety, rationality and availability.
 - Registration of newly submitted dossiers based on quality, safety, efficacy and 'established need' criteria.
- c. Notification of herbal medicines and existing alternative therapies based on safety and current therapeutic value
- d. Unique characteristic of the medicine product such as life-saving and orphan medicines.
- e. New investigational medicines after scientific and ethical consideration by the responsible government institute for granting approval for specific clinical trials (involving human subjects) with that product.

6.4.11 Import and Export of Medicines

- a. Import or export authorisation shall be given by SSPRA to licensed importers/exporters and for registered products only with a minimum of two thirds remaining shelf life at arrival to ensure traceability and full accountability of all products within the Southern Sudan territory. Ports of Entry will be defined.

- b. Pharmaceutical imports/exports will be inspected by the SSPRA Pharmaceutical Inspectorate or authorised officers at these ports of entry before release to the market i.e. packing list: product description and strength, source, presence of release certificate/Certificate of Analysis (COA).
- c. Unauthorized or incomplete consignments shall be considered as prohibited and destroyed at the port of entry having certified and fulfilled custom regulations and other government regulations.

6.4.12 Scheduling of Medicines

The Pharmacy Council shall make medicine schedules that will enable handling commensurate with the training of the health care provider. In general the international criteria POM, P & OTC will be used, but adopted to local needs as deemed necessary to ensure relevant medicines reach the official retail and community outlets according to the level of competence of the health care provider.

6.4.13 Drug Abuse

Legislation shall be enacted to control the manufacture and distribution of narcotic, psychotropic and other chemical substances with known or potential for illicit use and abuse. Any existing legislation shall be amended to incorporate prohibition of manufacture and distribution and trafficking for illicit use, which shall be under the control of Narcotic Bureau (International Bureau). Chemicals likely to be used in the manufacture of drugs of abuse shall be controlled similarly. The medicinal use in appropriate dosage forms shall be controlled like other pharmaceutical products.

6.4.14 Fees and other Charges

The regulatory authorities may charge fees and other charges for various activities within their mandate. In determining the fees payable, consideration will be given for waivers for orphan medicines and pharmaceutical products necessary and essential to manage public health problems during emergencies and national disasters.

6.5 Quality Control

The Government shall establish an independent Southern Sudan Pharmaceutical Quality Control Laboratory (SSPQCL) to carry out testing of medicines and other medical products moving through the medicines supply system.

- a. Functions of the Southern Sudan Pharmaceutical Quality Laboratory shall include:
- b. To support the registration and the marketing authorization of products.
- c. To support the pharmaceutical inspectorate in the routine surveillance of pharmaceutical products manufactured, imported, exported or distributed in the pharmaceutical supply chain.
- d. To monitor and randomly verify the quality of pharmaceuticals manufactured, imported or to be exported and advise the Directorate of Pharmaceutical Services on the quality observed.
- e. The SSPQCL shall be of WHO Level I standard and shall gradually be upgraded to level II.
- f. A Laboratory Quality Assurance System will be instituted in the SSPQCL that will involve collaboration with internationally recognised laboratories.
- g. The SSPQCL shall be subject to local or international technical auditing periodically. In the interim, the SSPQCL shall have a coordinating role and shall utilize the services of recognized Pharmaceutical Quality Control Laboratories in the region and Standard Mini-Labs to carry out the required tests.
- h. Other quality control testing facilities of internationally recognised standards shall be identified and used as and when necessary to augment the effectiveness of SSPQCL.

6.6 Rational Medicines Use

The Ministry of Health shall institute mechanisms and guidelines to ensure that medicines are prescribed, dispensed and used rationally in order to optimise the therapeutic benefit to the patient, reduce loss and/or wastage and any hazards arising from irrational practices.

6.7 Southern Sudan Pharmacy and Therapeutic Committee

A multi-disciplinary Southern Sudan Pharmacy and Therapeutics Committee shall be established to formulate policies and advise the government on rational use of medicines.

6.8 The Essential Medicines Concept

The Government shall adopt and implement the Essential Medicines Concept that incorporates the selection of medicines that are required to satisfy the priority health needs of the majority and to be made accessible at all times in adequate quantities, at the appropriate dosage forms, and at prices that the individual and the community can afford.

- a. The Government of Southern Sudan shall formulate and adopt the following for use in the public sector:
 - A Southern Sudan Essential Medicines List
 - A Southern Sudan Essential Veterinary Medicines List for use in the public sector.
 - An Essential Medical Supplies and Appliance List
- b. Non-Governmental Organizations (NGOs), Faith-Based Organizations (FBOs) and the private sector shall be encouraged to adopt and use the above-mentioned lists.

6.9 Labelling

Labelling for both produced and imported pharmaceutical products shall carry the generic names (INN - International Non-proprietary) in letters at least two-thirds the size of the brand name. Labelling will be in English language

6.10 Prescribing

Prescribers in the public sector shall be required to prescribe by generic name, based on the Essential Medicines List. Prescribers in the private sector shall be encouraged to do the same.

6.11 Dispensing

The MOH-GOSS shall ensure that medicines are dispensed correctly and efficiently in accordance with current Good Dispensing Practices and Southern Sudan Pharmacy and Drugs Act.

6.12 Standard Treatment Guidelines

Standard Treatment Guidelines incorporating the Essential Medicines List for use in public health facilities in Southern Sudan shall be developed, adopted and widely disseminated.

Non-Governmental Organizations (NGOs), Faith-Based Organizations and the private sector shall be encouraged to adopt and use the Guidelines.

6.13 Training

The MOH-GOSS shall ensure that all health workers involved in diagnosis, prescribing and dispensing of medicines, receive adequate and relevant theoretical and practical training to enable them perform their functions efficiently.

- a. The concept of rational medicines use will be incorporated into the training curricula of all health professional categories.
- b. MOH-GOSS shall develop and implement a comprehensive Continuous Professional Development Programme for all health professionals

6.14 Medicines Information

The MOH-GOSS shall ensure the provision of correct, practical and unbiased information on the handling and rational use of medicines to health workers at all levels as well as community leaders, patients and the general public.

- a. Product inserts shall be required to accompany all products with adequate information as to the indications, pharmacology/literature side effects, toxicology, special precautions, and contra-indications.
- b. The MOH-GOSS shall develop and implement a comprehensive Information, Education and Communication (IEC) programme to ensure adequate dissemination of information to the public on rational medicines' use.

6.15 Hospital Pharmacy and Therapeutic Committees

The MOH-GOSS shall promote and support the establishment and effective functioning of Therapeutic Committees in all hospitals to ensure correct, efficient and cost effective handling and use of medicines' in hospitals.

6.16 Medicines Advertisement and Promotion

The MOH-GOSS shall ensure that advertising and promotion of medicines is professional and of high standards to conform to rational medicines' use as provided in the provisions of the current Pharmacy and Drugs Act.

- a. Promotion and advertising of medicines to health professionals shall be ethical, factual, educational, balanced in approach and designed to impart non-exaggerated information to prescribers. These principles apply equally to symposia and other scientific meetings.

6.17 Veterinary Medicines and Medical Supplies

The Government shall ensure that veterinary pharmaceutical services are subject to the provisions of the Pharmacy Policy and the regulatory laws and regulations of Southern Sudan, to ensure continuous availability of quality veterinary medicines for the animal husbandry and health

- a. An Essential Veterinary Medicines List for use at all levels of veterinary services shall be developed and regularly updated by Southern Sudan Pharmacy and Therapeutic Committee in collaboration with the Ministry responsible for veterinary services.
- b. The Ministry responsible for Veterinary services shall liaise with the Pharmacy Regulatory Authorities for proper control and marketing authorization of Veterinary medicines.
- c. The MOH-GOSS shall support the Ministry responsible for veterinary services in the implementation of the SSPP and in respect of veterinary products.

6.18 Traditional Medicines

The Government shall promote the potential of traditional medicines as an essential cultural heritage and support efforts for the investigation and development of indigenous traditional medicines, with due consideration for quality and safety.

- a. The Government shall develop policy and legal framework for the practice of traditional medicine.
- b. The Government shall encourage the sharing of information on efficacy and safety by the traditional healers, with due consideration to the protection of intellectual property rights.
- c. The Government shall encourage and support research in traditional medicines with a view to identifying the most useful remedies for treatment of common diseases, bearing in mind safety and quality.
- d. The Government shall support and facilitate efforts to protection indigenous medicinal plants of Southern Sudan.

6.19 Human Resource Development

The MOH-GOSS shall support efforts to ensure that sufficient numbers of suitably qualified and motivated personnel are available for the effective implementation of this Policy and related laws and regulations.

The Pharmacy Council shall ensure that curricula for the training and continuing education programmes for all health professionals involved in prescribing and dispensing of medicines are in conformity with this Policy and related laws and regulations.

- a. The Ministry shall support efforts to build the capacity for the training of pharmacy professionals.
- b. It shall support and facilitate the development and implementation of continuing professional development programmes for health professionals.
- c. It shall support the development of suitable career structures for pharmaceutical professionals, so as to attract and retain suitably qualified personnel in the public sector.

- d. It shall support and facilitate efforts to provide health professionals access to current literature on medicines.
- e. It shall continue to support and facilitate pre-service training of middle-cadre pharmacy personnel.
- f. It shall support and facilitate efforts for the training of, and information sharing among, traditional healers.

6.20 Research and Development

The MOH-GOSS shall support research and developmental activities, which will facilitate the achievement of the objectives of the Southern Sudan Pharmacy Protocol.

- a. The Ministry, in collaboration with other stakeholders, shall identify and support priority areas of health research, which have a bearing on finding cost effective solutions for treatment of neglected diseases.
- b. It shall support and facilitate collaboration between training and research institutions in and outside the country in pharmaceutical research and development.
- c. It shall register protocols for clinical trials for new medicines and establish guidelines for clinical trials involving medicines already registered.
- d. It shall implement their programmes taking into consideration international accords on Intellectual Property Rights suitable to the country, and with due consideration to its sovereign right to provide health services to the people of Southern Sudan and in accordance with the applicable flexibilities in the Trade Related aspects of Intellectual Property (TRIPs) agreements.

6.21 Monitoring and Evaluation

The MOH-GOSS will institute mechanisms for monitoring and evaluation to ensure the successful implementation of the Southern Sudan Pharmacy Policy.

- a. The Ministry will develop a Pharmaceutical Master Plan, with indicators for monitoring progress of achievement of policy objectives.
- b. It shall establish and maintain a monitoring and evaluation capability at all levels.

6.22 Linkages

The MOH-GOSS shall maximise inter-sectoral cooperation and collaboration and actively pursue all relevant forms of technical cooperation with other countries in order to optimise the use of limited resources.

6.23 Inter-sectoral Cooperation

The MOH-GOSS shall spearhead the promotion of the cooperation between various sectors to maximize achievement of the objectives of the Southern Sudan Pharmacy Policy.

6.24 International Cooperation

The MOH-GOSS shall encourage technical cooperation with other countries in the implementation of the Southern Sudan Pharmacy Policy

6.25 The Role of the Pharmaceutical Society of Southern Sudan

The MOH-GOSS shall encourage and facilitate the participation of the Pharmaceutical Society of Southern Sudan and other health Professional Associations in the implementation and promotion of this Policy.

6.26 Miscellaneous Issues

The MOH-GOSS shall develop policies to provide for any other relevant matter that may not be wholly covered by this policy but may become urgent with the changing times