LAWS OF SOUTH SUDAN

DRUG AND FOOD CONTROL AUTHORITY ACT, 2012

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LAWS OFSOUTH SUDAN

THE DRUG AND FOOD CONTROL AUTHORITY ACT, 2012

In accordance with the provisions of Article 55 (2) (3) (b) read together with Article 85(1) of the Transitional Constitution of the Republic of South Sudan, 2011, the National Legislature with the consent of the President of the Republic of South Sudan hereby enacts the following:

CHAPTER I

PRELIMINARY PROVISIONS

1. Title and Commencement.

This Act may be cited as the "Drug and Food Control Authority Act 2012" and shall come into force on the date of its signature by the President.

2. Repeal and Saving.

Any provisions of the existing legislation which are governed by this Actare hereby repealed; provided that, all proceedings, orders and regulations taken or made thereunder, except to the extent they are cancelled by or are otherwise inconsistent with provisions of this Act shall remain in full force and effect, until they are repealed or amended in accordance with the provisions of this Act.

3. Purpose.

The purpose of this Actis to provide for the establishment of an independent Drug and Food Control Authority in South Sudanand to provide an appropriate and effective independent regulatory mechanism to control and regulate the manufacture, supply, promotion, marketing, advertising, distribution and use of drugs, poisons, chemicals, cosmetics, medical devices and food for human or animal use.

4. Authority and Application.

(1) This Actis drafted in accordance with the provisions of Schedule (C) (26) read together with Schedule (D) and Article 31 of the Transitional Constitution of the Republic of South Sudan, 2011, which confer concurrent legislative competence on matters of human and animal drug quality and residual powers upon the National Legislature to legislate on national matters requiring a national standard.

(2) The provisions of this Act shall apply to any person who is involved in manufacturing, selling, distributing, marketing, supplying, advertising for sale or use of drags drugs, poisons, chemicals, medical devices or foods for human or animal use.

5. Interpretation.

In this Act, unless the context otherwise requires, the following words and expressions shall have the meanings assigned to them respectively:

"Advertisement"* or *"Advertise" means any written, pictorial, visual or other descriptive matter or verbal statement or reference appearing in any newspaper, magazine, pamphlet or other publication or which is distributed to members of the public or brought to the notice of members of the public in any manner whatsoever, which is intended to promote the sale of a regulated product;

"***Adulterated***" when used in relation to a product, means one that is tampered with in such a way as to affect the authenticity of the original product;

"Applicant" means a person or company submitting an application for a licensefor premises or to obtain authorisation to market a new drug, poison, chemical, cosmetic, medical device or food, to update or modify an existing Marketing Authorisation, or to obtain any other form of Licence or Authorisation required by provisions of this Act;

"Appointed Date" means a date set by the Board and published in the gazette as the deadline for applicants to submit notification requests for regulated products;

"Authority"means the South Sudan Drug and Food Control Authority;

"Biologics" means medicinal products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins created by biological processes;

"Board"means the Board ofDrug and FoodControl Authority;

"Chairperson" means the Chairperson of the Board**;**

"Chemical"means any organic or inorganic substance listed as a regulated product in a schedule issued by the Minister in accordance with provisions of this Act;

"Clinical Officer" means a person who has completed a course of training in a recognized institute either with a Diploma or a Bachelor Degree**;**

"Court" means the High Court or any court of competence;

"Clinical Trial" means a systematic study of human beings or animals in order to establish the efficacy of, or to discover or verify the effects or adverse reactions of drugs, poisons, chemicals, cosmetics, medical devices or foods, and includes a study of their absorption, distribution, metabolism and excretion;

"Committee" meansany of a Committee of the Board constituted in accordance with the provisions of section 17 of this Act;

"Cosmetic" means any preparation intended to be applied to the human body for cleansing, beautifying, promoting attractiveness or altering the appearance without affecting the body's structure or functions. This term includes any article intended for use as component of a cosmetic;

"Counterfeit"when used in relation to a product, means one that is deliberately and fraudulently mislabelled with respect to identity or source. Counterfeit can apply to brand or generic regulated products and may include products with correct ingredients, with the wrong ingredients, without ingredients, with insufficient active ingredients, or with fake package;

"Dentist" means a person who holds a Bachelor Degree in Dentistry from a recognized university, and under applicable laws is duly registered or holds a valid license to practice dentistry in South Sudan;

"Director" means a Director of the Authority appointed pursuant to provisions of this Act;

"Dispense" in relation to a drug, means to supply a drug in accordance with a prescription duly written by a duly qualified medical practitioner, pharmacist, dentist or veterinary surgeon or any other competent person authorized by this Act;

"***Drug***"means any substance or mixture of substances used for diagnosis, treatment, mitigation or prevention of disease, disorder, abnormal physical or mental state, or symptoms, in man or animal, or for restoring, correcting, or beneficial modification of organic or mental functions in man or animal. This phrase includes traditional/herbal medicines, narcotic and psychotropic substances, biologics, vaccines, and radiopharmaceuticals;

"***Food***" means any article other than drugs, cosmetics and tobacco typically used as or in food or drink for human consumption, but on which a medical or therapeutic claim is being made. This shall include, but not be limited to, food supplements , nutritional additives, infant or child feeding preparations, dietary supplements for diabetics and any substance used in the manufacture or treatment of foods construed to have a medical or therapeutic effect or purpose;

"***Generic Name"***means the term in common usage for describing a drug that is not a "commercial" or "brand name" and is not a legally protected trade mark. The term covers both International Non-Proprietary Names and other unprotected names;

"Government"means the Government of the Republic of South Sudan;

"Traditional or herbalmedicine" means any preparation in a form that contains as active ingredients one or more substances of natural origin that are derived from plants or animals;

"International Non-Proprietary Name (INN)" means the name assigned to a drug by the World Health Organization and eligible for use by any manufacturer, as opposed to the "commercial name" or "brand name" which may be assigned to a drug by a particular firm;

"Inventory" refers to the listing of Provisionally Registered/Authorized drugs, poisons, chemicals, cosmetics, or foodsin accordance withsection 34(2) of this Act and related regulations issued by the Minister;

"Inspector"means a person appointed in accordance with section 43 of this Act;

"License" is any form of Authorisationrequired in accordance with provisions of this Act;

"Manufacture"and its grammatical variations, mean the preparation, compounding, mixing or making of a drug, poison, chemical, cosmetic or food for sale or distribution but does not include the dispensing of a pharmaceutical preparation for a particular individual;

"Marketing Authorisation"is a License issued by the competent authority as designated under this Act, signifying that a drug, poison, chemical, cosmetic orfood has been evaluated as regards quality, safety and efficacy and the adequacy of the information accompanying it, and that the License holder is authorized to sell or market it, subject to such conditions as the Authority may specify;

"Marketing Authorisation Holder"means a natural or legal person or corporate body in possession of a License or marketing authorization issued by the Board for a drug, poison, chemical, cosmetic or food to be marketed in South Sudan;

"Medical Assistant" means a person who has complete a course in nursing in a recognized institute, either with a Certificate of Nursing or a Diploma;
"Medical Practitioner" means a person who holds a Bachelor Degree in Medicine and Surgery from a recognized University, and under applicable laws in dully registered or holds a valid license;
"Medical device"means any instrument, appliance, material, machine, apparatus, implant or diagnostic reagent, including any part or an accessory, used or purporting to be suitable for use or manufactured or sold for use in: a) the diagnosis, treatment, mitigation, modification, monitoring or prevention of disease, abnormal physical or mental states or the symptoms thereof, or b) restoring, correcting or modifying any somatic or psychic or organic function or c) the diagnosis or prevention of pregnancy, and which does not achieve its purpose through chemical, pharmacological, immunological or metabolic means in or on the human body but which may be assisted in its function by such means. A product may also be considered a medical device if declared as such by the Minister by notice published in the Gazette;
"*Medicine*" means any substance or preparation derived from animal, plant, inorganic or organic sources used or intended to be used for internal or external application to the human or animal body either in the treatment, diagnosis, mitigation or prevention of disease or for improving physiological functions, or for agricultural or industrial purposes;
"*Member*" means a member of the Board appointed in accordance with the provisions of this Act, and unless the context requires otherwise shall include the Chairperson;
"*Minister*" means the minister responsible for health in the Government of the Republic of South Sudan;
"Midwife" means an individual who holds a suitable qualification as determined by the relevant authority regulating midwifery practice and has a current, valid license that authorizes him or her to practice midwifery in South Sudan;
"Ministry" means the ministry responsible for health in the Government of South;
"National Legislature" means the South Sudan National Legislature comprised of the National Legislative Assembly and the Council of States;
"*Narcotic Medicine*"means any drug or preparation controlled under the *Single Convention on Narcotic Drugs of 1961* or any subsequent version of that Convention;
"***Nutritionist***"means a person who holds a Bachelor's degree in Food Science, Nutrition or a related field from a recognized university;
"**Nurse**" means an individual who holds a suitable qualification as determined by the relevant authority regulating nursing practice and has a current, valid license that authorizes him or her to practice nursing in South Sudan;
"***Other Medical Corps''*** means the medical and health institutions of the South Sudan Armed Forces\ Defence, Police Service, Prison, Security and other organized Services;
"Pharmacist"means a person who holds a Bachelor Degreeof Pharmacy from a recognized university or college;
"*Poison*"means any substance listed as a poison in a schedule or Poison List issued by the Minister in accordance with provisions of this Act;
"*President*"means the President of the Republic of South Sudan;
"Premises" includes land, building, structures, basements and vessels and in relation to any building includes a part of a building any cartilage, forecourt, yard, or place of storage used in connection with building or part of that building, and in relation to "**vessel**" means ship, boat, air craft and includes a carriage or receptacle of any kind, whether open or closed;

"*Promotion*"means all informational and persuasive activities on regulated productsby manufacturers, distributors,holders of Marketing Authorisations or any other person, whether directed towards health professionals or the public generally;
"Pharmacy Technician" means a person who holds a Diploma of Pharmacy from recognized College or Training Institute, and whose name has been duly entered in the Registry of Pharmacy Technicians in accordance with pharmacy Profession and Practitionersregulations as shall be determined by Law;

"*Provisionally Authorized/Registered*" is used in relation to a regulated product which has been listed in the Inventory in accordance with section 34 of the Act and which has not been screened for purposes of a product Licence/Marketing Authorisationin accordance with section35 of the Act;
"Psychotropic Substances"means any substance or preparation controlled under the *Convention on Psychotropic Substances of 1971* or any subsequent version of that Convention;
"*Registry*"means the registry of Pharmaceutical Products for which a Marketing Authorisationhas been issued in accordance with sections 35 and 36 of this Act;
"*Registered Pharmacist*" means pharmacist whose name is entered in the Registry of Pharmacistsin accordance with thePharmacy profession and practitioners regulations as shall be determined by law;
"Regulated product"means any product such as drug, poison, chemical, cosmetic or food, including allprocesses involved in the production or manufactureof such products thatare subject to the provisions of this Act;
"Restricted Medicine"means a Psychotropic substance or a Narcotic Medicine as defined in this section or any other medicine on which the Authority has imposed corresponding restrictions;
"Secretariat" means the Secretariat to the Authority created pursuant to this Act;
"Secretary-General"means the Secretary-General of the Authority appointed pursuant to this Act as the Chief Executive of the Authority;
"Society" means the Pharmaceutical Society of South Sudan;
"Substandard" when used in relation to a product means one that does not comply with the quality standards adopted by the Authority;
"State Ministry" means the state Ministry of health, in any state of South Sudan; and
"Veterinary Surgeon" means a person who holds a Bachelor Degree in Veterinary Science and under applicable laws is duly registered or holds a valid license to practice Veterinary Medicine in South Sudan.

CHAPTER II

DRUG AND FOOD CONTROL AUTHORITY

6. Establishment of the Authority.

(1) There shall be established in South Sudan a corporatebody to be known as the South SudanDrug and Food Control Authority hereinafter referred to as the Authority.

(2) The Authority shall be an autonomous body, with perpetual succession and shall, subject to the provisions of this Act, be capable in its name to:
   (a) sue and be sued;
   (b) take, purchase, acquire, hold, and dispose of property whether movable or immovable;
   (c) borrow or lend money; or
   (d) Performing such other things or acts, which may lawfully be performed by a corporate body, for the proper performance of its functions andin accordance with provisionsof this Act,.

7. The Objective of the Authority.

The main objective for which the Authority is established is to exercise general supervision, control and co-ordination over all matters relating to the pharmaceutical industry and to be the principal instrument of Government in the implementation of all policies relating to drugs, poisons, chemicals, cosmetics, and foodsmeant for human or animal use.

CHAPTER III

GOVERNANCE OF THE AUTHORITY

8. Structure of the Authority.

The Authority shall consist of the following management structures:
(a) the Board;
(b) the Secretariat.

9. Establishment of the Board

(1) The Authority shall establish its Board which shall be entrusted with supervision of the activities and affairs of the Authority and to exercise all functions and powers conferred under provisions of this Act.

(2) The Board shall discharge its functions and powers under supervision of the Minister

10. Composition and Tenure.

(1) The Board which shallconsist of twenty one (21) members shall be appointed and removed by the President upon recommendation of the Minister, as follows:
   (a) Chairperson, appointed by the Presidentfrom amongstthree names of prominent South Sudanese nationals, including at least one Pharmacist, upon the recommendation of the Minister,
   (b) Secretary-General who shall be appointed by the Minister as an ex-officio member subject to the provisions of section 22of this Act,

(c) The following members, shall be appointed by the Minister:-

(i) One Registered Pharmacist with hospital pharmacy practice background who shall be nominated for appointment by the Society;

(ii) One Registered Pharmacist with community pharmacy practice background who shall be nominated for appointment by the Society;

(iii) OneRegistered Pharmacist from industry or with industrial/manufacturing knowledge and/or research background who shall be nominated for appointment by the Society;

(iv) One Registered Pharmacist from a recognized School or College of Pharmaceutical Studies or a University,who shall be nominated for appointment by the School, the College or the University;

(v) One Registered Pharmacist who shall be nominatedby the Directorate responsible for pharmaceutical services in the Ministry;

(vi) One Registered Physician who shall be selected from one of the Referral Teaching Hospitals in South Sudan;

(vii) One Registered Medical Practitioner who shall be a practicingpaediatricianand shall be nominated by the South Sudan Doctors Association/ Union.

(viii) One Registered Dentistwho shall be nomination by the South Sudan Dentists Society/Doctors Association or Union

(ix) One Registered veterinarysurgeon,who shall be nominatedby the Ministry responsible for veterinary affairs in South Sudan;

(x) One nutritionist, who shall be nominated by the Directorate of Nutrition in the Ministry ofHealth;

(xi) One environmentalist or public health officerhaving knowledge and experience in industrial and general chemical pollutants, who shall be selected by the Ministry responsible for environment;

(xii) One legal counsel, who shall be nominated by the Ministry of Justice.

(xiii) One financial expert who shall be nominated by the Ministry of Finance and Economic Planning;

(xiv) One representative from the Ministry of Commerce, Industry and Investment;

(xv) One representative from the Medical Corps of the South Sudan Armed Forces;

(xvi) One representative from the Police Servicewho shall be nominated by the Ministryof Interior;

(xvii) One representative from the Directorate of Customs, who shall be nominated by the Director of Customs and Excise Duty;

(xviii) One Veterinary Surgeon who shall be nominated by Ministry of Animal Resources and Fisheries;

(xix) One expert in plants protection, who shall be nominated by Ministry of Agriculture; and

(xx) One expert in Medical Engineering.

(2) The term of office of members of the Board shall be five (5) years; provided that members shall be eligible for re-appointment.

11. Eligibility for Appointment.

In addition to the requirements provided in the above section, each person who serves as a member of the Board shall:

(a) be aSouth Sudanese national;
(b) be of sound mind;
(c) notbe an un-dischargedbankrupt or insolvent;
(d) not have beenconvicted by a court in any legal jurisdiction of anoffenceinvolvingfraud, dishonesty or moral turpitudeover the past five years; and
(e) have attained the age of 30 years or above;

12. Loss of Membership of the Board.

(1) Membershipto the Board may be lost when:
   (a) any member fails to meet the eligibility requirements referred to undersection 11 of this Act;
   (b) a member resigns or isincompetent to carry out the duties of a Board member;
   (c) a member has been absent for more than three consecutive meetings of the Board without the leave of theChairperson;
   (d) a member is deemed by the appointing authority to have violated the standards of conduct, code of ethics or other internal rules of the Board that is published by notice in the Gazette; and
   (e) a member dies.

(2) If the position of any member becomes vacant before the expiration of the period for which he or she was appointed, the appointing authority may appoint another person with similar qualifications andmeetingthe eligibility requirements referred to under section 11 above,to hold the position for the unexpired term of office for which his or her predecessor was appointed.

13. Functions of the Board.

(1) The Board shall have the following powers and functions:
   (a) advise the Government on matters concerning control and regulation of Regulated Products;
   (b) regulate, monitor and enforce the use, manufacture, import and export, distribution and sale of all Regulated Products for human or animal use;.
   (c) regulate and enforceconformancewith prescribed standards of quality, safety and efficacy;
   (d) regulate, monitor and inspect personnel, premises and practices that areinvolved inthe manufacture, promotion, procurement, storage, distribution and sale of such products for compliance withdefined codes of practice and other requirements;

(e) publish, apply and enforce the standards of professional conduct and code of ethics related to drugs, poisons, chemicals, cosmetics or foods for human and or animal use and monitor compliance

(f) provide regulations for controlling the manufacture, import and export, distribution and use of Regulated Products and necessary steps to prevent misuse and abuse;

(g) take necessary steps to prevent importation, distribution or sell to the public of counterfeit, substandard or adulterated drugs, cosmetics, medical devicesor foods;

(h) take reasonable steps to ensure that only duly authorized persons are involved in importing, exporting manufacturing, stocking, selling, distributing or otherwise dealingin the Regulated Products;

(i) inspect and license all manufacturing premises, importing agents, wholesalers, distributors, transport vessels, medical stores and dispensing areas within health facilities, pharmacies and retail outlets dealing in the Regulated Products;

(j) maintain an Inventory of Provisionally Authorised/Registered regulated products;

(k) grant, after due assessment, Marketing Authorisation licenses or registration status for Regulated Products meant for humanor animal use , whether locally manufactured or imported, and whether destined for the national market or export;

(l) cancel the Authorisation/Registration licenses of, or cause Regulated Products that are detrimental to public health to be recalled from the market;

(m) regulate the maintenance of proper books and recordsof Marketing Authorisation of Regulated Productsfor human and or animal use are kept up to date by the applicants;

(n) levy fees for Marketing Authorisationand other authorisation related to Regulated Products;

(o) publish lists of Provisionally Authorised Regulated Products meant for human or animal use and provide public information from time to time about products that have been issued with Marketing Authorisations;

(p) monitor and inspect the market for presence of illegal, counterfeit, substandard or adulterated Regulated Products meant for human or animal use;

(q) provide a process for sampling,analysingand testing Regulated Products that includes processes for production and manufactureand distribution and monitor and enforce compliance with labellingrequirements;

(r) ensure that the promotion, advertising and marketing of Regulated Products meant for human and or animal use is in accordance with the product information approved by the Board;

(s) approve the use of unregistered and unauthorized Regulated Products for clinical trial purposes or for compassionate use, oversee clinical trials on regulated products;

(t) to establish a functional system for pre- and post-marketing surveillance of safety, quality, efficacy, and effectiveness of regulated products and to optimize the risk-benefit balance;

(u) to disseminate information on Regulated Products for human or animal use to health professionals and to the public in order to promote their rational use;
(v) to maintain a system of consultation and cooperation with line Ministries and institutions on proper implementation of this Act;
(w) to monitor and review implementation of thisAct; and
(x) to continuously review rules, guidelines and regulations pertaining to implementation of this Actand make amendments when necessary in order to keep pace with changing times and industry demands.

14. Functions and Powers of the Chairperson of the Board.

The Chairperson of the Board shall perform and exercise the following functions and powers, to:
(a) preside over the Board, call for meetings, determine the agenda of Board meetings in consultation with the Secretary-General;
(b) supervise the performance of the Secretary-General;
(c) represent the Board inside and outside South Sudan;
(d) delegate his powers to any of the Board members; and
(e) performany other such functions assigned and or delegated thereto by the Board.

15. Meetings of the Board.

(1) The Board shall convene its ordinary meeting every two months at the seat ofthe Authority upon the invitation of the chairperson and may convene extraordinary meeting at any time on special matters of emergency and disaster; provided that sufficient notice and a reasonable period of time for such extraordinary meeting shall havebeen given.

(2) The Quorum to convene meetings of the Board shall be of a simple majority(fiftyper centplus one) of the Board members.

(3) If the required quorum referred toin subsection (2) of this section cannot be attained, then the meeting shall be adjourned and a subsequent meeting shall be scheduled within the period of one week from the date of the adjourned meeting which shall convene with any number of Board members present.

(4) Decisions and resolutions of the Board shall be passed by a simple majority of the members present, and in the event ofa tie, the chairperson shall have casting vote.

(5) Notice for any Board meeting together with the agenda and other relevant documentsshall be issued by the Secretary-General not less than fourteen (14) days prior to the date of the meeting.

(6) The Board shall develop its own business code of conduct and procedures governing meeting, and its decisions, records, transactions, and materials made available at meetings of the Board shall be strictly confidential.

16. Declaration of Assets and disclosure of Interest.

(1) All Board Members, Secretary General, Directors and other senior employees of the Authority shall make confidential declaration of their assets and liabilities including those of their spouses and children in accordance with the applicable law.

(2) The Chairperson of the Board or any of its Members, the Secretary General, Directors and senior employees of the Authority having a direct or indirect interest in any matter or proposal before the Board for consideration, shall disclose to the Board the nature of interest they may havein the matter, or proposal and they shall not participate in the deliberation, or participate in the decision of the Board concerning the same subject-matter. This provision shall apply to members of Board and members of Committees of the Board.

17. Committees of the Board.

(1) The Board shall constitute and determine the number and size of Committees of the Board with specific functions and powers as may be deemed necessary.

(2) The Board's business code of conduct and procedures referred to in section 15 above, shall apply and regulate the meeting of the committees.

(3) Upon establishment of a committee, the Board shall appoint one Member of the Board who shall be the Chairperson of that committee; and may appoint other persons who may not be members of the Board.

18. Appeals againstthe Decisions of the Board.

(1) The decision of the Board may be contested before an impartial and independent Appeal Panel within the Authority to be determined by the Minister.

(2) The functions, powers and procedures of the Appeal Panel shall be determined by the Minister and its decisions shall be final and binding.

(3) Notwithstanding the provisions of subsection (1) above, a decision of the Appeal Panel shall not exclude the jurisdiction of a court of competent jurisdiction or preclude it from making any determination on the same matter.

19. Remunerationsof the Board and or Committee Members.

A Member of the Board or of a Committee shall be paid such allowances and expenses from the funds of the Authority as may be approved by the Minister after consultation with the Board.

20. Oath of Office for Board and Committee Members.

Board and Committee Members of the Authority shall, before assuming their duties, take the following oath or affirmation before the relevant appointing authority:

"I……., do hereby solemnly swear by the Almighty God that as a Board/Committee Member of the South Sudan Drug and Food Control Authority, shall be faithful, and shall diligently and honestly discharge my functions and duties and shall strive to exercise the powers vested upon me by the South Sudan Drug and Food Control Authority Act, with integrity and dignity in the best interest of the people of South Sudan; and that I shall respect and abide by all the rules, regulations and instructions thereunder; and that I shall not, without due authority, disclose or make known any information, matter or thing that comes to my knowledge by reason of my role in the Authority, so help me God".

CHAPTER IV

SECRETARIAT

21. Secretariat of the Authority.

(1) The Authority shall establish a Secretariat to be known as the Secretariat of the South Sudan Drug and Food Control Authoritywhich shall be responsible for the daily management and operations of the Authority.

(2) The permanent staff of the Secretariat shall be comprised of persons experienced in the pharmaceutical industry as follows:
(a) the Secretary-General;
(b) Directors; and
(c) Support staff and other employees of the Authority.

(3) Directors shall perform such functions as may be conferred upon them by the provisions of this Act and or such additional duties as may be assigned by the Secretary-General thereof.

22. Appointment of Secretary-General and Directors.

(1) The Secretary-General and Directors shall be appointed by the Ministerupon recommendation of the Boardin conformity with the provisions of the Civil ServiceAct 2011, and Regulations. The nominee shall be a Registered Pharmacist with specialized knowledge ofapplication, usage and dispensing of regulated products.

(2) The Secretary-General and Directors shall be selected from persons of high moral reputation and integrity and shall possess the necessary qualifications, expertise and experience in matters related to regulated products.

(3) Without limiting the generality of subsections (1) and (2) above, a person shall be eligible for appointment to serve as the Secretary-General, or a Director if he or shemeets the following additional requirements:
(a) be a South Sudanese citizen;
(b) be of sound mind and of high moral character;
(c) be at least thirty years of age;
(d) not be a holder of an office in, or employed byany political party;
(e) not bein an elected position at any level of government;

(f) possess the skills and knowledge relevant to the work of the Authority or qualifications deemed relevant to the position;
(g) not an un-discharged bankrupt or insolvent; and,
(h) not been convicted by a competent court in any legal jurisdiction of an offence involving fraud, dishonesty or moral turpitude for the last five years

(4) Any person appointed to serve as the Secretary-General, or Director while in another service shall be given a reasonable opportunity to take necessary steps to fulfil the eligibility requirements of this section.

(5) All members of the Secretariat shall be appointed in accordance with provisions of the CivilService Act 2011, andapplicable regulations.

(6) The Secretary-General,in consultation with the Chairperson of the Board, may delegate any of the Directors to act in his or her capacity, provided that the Director so delegated shall be a Registered Pharmacist.

23. Functions of the Secretary-General.

The Secretary-General shall perform the following functions:
(a) Management of the day-to-day affairs of the Authorityas its chief executive and shall be assisted as, necessary, by Directors.

(b) Without limiting the generality of subsection (1) of this section, the Secretary-General shall exercise administrative, financial and technical powers necessary for proper performance of all functions of the Authority whichinclude, but are not limited to the following:
(i) to represent the Authority at official functions and occasions, nationally, regionally and internationally;
(ii) to initiate policies and framework documents of the Authority;
(iii) to approve project and program activities proposed by the committees and/or directorates;
(iv) to oversee the use of the funds of the Authority;
(v) to provide periodic reports to the Minister and the Board.
(vi) to appoint, within budget limitations, officers and support staff of the Authority in accordance with applicable public service laws and regulations;
(vii) to initiate internal policies and procedures including jobdescriptions of support staff and the organisational structures of the Authority;
(viii) to monitor and evaluating performance of the Authority; and
(ix) toperformsuch other functions and duties as may from time-to-time be prescribed by law.

24. Tenure.

The Secretary General shall serve for a term of five (5) years and shall be eligible to serve for a subsequent five year term of office.

25. Resignation and Removal.

(1) A member of the Secretariat may resign by a letter addressed to the Board through the Secretary-General. If it is the Secretary-General the letter of resignation shall be addressed to the Ministerthrough the Board.

(2) The Secretary-General may be removed from office upon a resolution passed by a two-thirds (2/3) majority vote of the Board, after a hearing.

(3) Without limiting the generality of subsection (2) of this section, the Secretary General and anyDirector may be removed for any one or more of the following reasons:
(a) is no longer compliant with the eligibility requirements of this Act;
(b) is unable to perform his or her duties due to mental or physical infirmity;
(c) is guilty of gross misconduct;
(d) has demonstrated repeated incompetence to fulfil his or her duties;
(e) has been absent from five consecutive meetings of the Board without permission or sufficient cause;
(f) has been convicted by a competent court in any legal jurisdiction of an offence involving fraud, dishonesty or moral turpitude; or
(g) death.

(4) When the Secretary-General is removed from office, resigns or dies, he or she shall be duly replaced under the same conditions and in the same manner as provided for appointment into that position.

(5) Prior to the formal replacement of the Secretary-General, the Board shall appoint any senior Director, who shall be a registered pharmacist, to act in his or her capacity until the formal recruitment process is finalized.

26. Restriction on Outside Employment.

The Secretary-General, Directors and staff of the Authority shall not engage in private profession practice or enter into commercial businessesor activities that are regulated under this Act, or receive remuneration or accept employment by regulated entities without the expressedauthorization of the Authority.

27. Oath ofSecretariat Staff.

The Secretary-General, Directors and other employees of the Authority shall, before assuming their duties, take the same oath or affirmation asrequired to be taken bymembers of the Board under section 20 of this Act.

CHAPTER V

FINANCE, ACCOUNTS AND AUDIT

28. Operational Principle.

The Authority shall manage its finances in accordance with sound financial and accounting principles and best practices and shall in that respect ensure that its revenues are sufficient to meet its expenditures, including payment of operational costs. All fees collected shall be reported and submitted to theMinistry of Finance and Economic Planning in accordance with requirements of the Public Finance Management and Accountability Act, 2011.

29. Sources of Funding.

(1) The operations of the Authority shall be funded by an allocated budget approved in accordance with the Public Financial Management and Accountability Act, 2011and other sources and to include, but not limited to the following:

(a) grants, donations and bequeath from local or foreign bodies;
(b) financial support from international donor agencies;
(c) drug registration fees (80% to be committed to the activities of the Authority;
(d) Fees from license to retail pharmacies and community medicine shops;and
(e) Any other source thatmay be approved from time-to-time by the Board or the Minister.

(2) The Authority shall prepare and submit an annual budget proposal for approval by the Minister in accordance with the Government budget process, for each financial year. The budget proposal shall be open to review, revision and approval by the Minister.

30. Bank Accounts.

(1) The Authority shall open and maintain bank accountswith the Central Bank of South Sudan or with any other recognised commercial bank in South Sudan as may benecessary for proper performance of its functions and duties in accordance with the Public Financial Management and Accountability Act, 2011.

(2) The Secretary General shall adopt measures to ensure withdrawal or payment out of any of the bank accounts of the Authority are made with his expressed authorization of that of a Director who is duly delegated to act on his behalf.

(3) The Secretary General shall be the primary signatory to all cheques, other financial documents and receipts of the Authority.

31. Accounts.

(1) The Secretary-General shall maintain comprehensive books of accounts and records of all funds received and spent by the Authority during the financial year.

(2) The Secretary-General shall prepare and submit a financial report to the Board not later than three months from the end of the previous financial year which shall include:
- (a) a financial statement of income and expenditure during the financial year;
- (b) a statement of assets and liabilities of the Authority for the financial year prepared in accordance with generally accepted accounting principles;
- (c) a Financial Audit Report; and
- (d) any other reports as needed by the Board.

32. Audit.

(1) The Secretary-General shall ensure that, for each financial year, the accounts of the Authority are audited by the Auditor-General or such other audit firms approved by the Auditor-General in writing and authorised by the Board.

(2) The Board shall ensure that within four months from the end of the financial year, or such other period as the Government may require in writing, an audited statement of accounts in accordance with the provisions of section 31(2) (c) is submitted to the Ministry of Finance and Economic Planning.

(3) The Auditor-General shall have access to all books of accounts, vouchers and other records and shall be entitled to any information and explanation required in relation to any other records of the Authority

33. Annual and Other Reports.

(1) In addition to the Financial Audit Reports required undersection 32(1) the Authority shall also prepare an annual report of its activities within four months of the end of such financial year or within such other period provided by law.

(2) The Annual Report shall include:
- (a) a copy of the financial audit report;
- (b) a copy of the report of the auditor;
- (c) a statement of financial performance and of cash flows, budget performance and balance sheet;
- (d) a description of the activities of the Authority during the previous year;
- (e) an analysis of the extent to which the Authority has met its objectives in the previous year;

(f) an evaluation of the extent to which advice and directives of the Board have been complied with;
(g) the Authority's strategic goals and objectives for the following year; and
(h) any recommendations on the matters related to implementation ofthis Act.

(3) The Authority shall publish and widely disseminate itsannual report, along with its audited accounts. The reports shall be archived in accordance with applicable law. The Minister of Finance and Economic Planning shall also be authorized to disseminate the Authority's reports.

(4) The Authority shall submit to the Minister, the President andthe National Legislature such other reports on its activities or any other matter that may from time-to-time be required.

CHAPTER VI

REGISTRATION OF REGULATED PRODUCTS AND MARKETING AUTHORISATION

34. Provisional Registration.

(1) The Board shall, by order published in the gazette or through other means of notification require manufacturers, importers and exporters of regulated productsto notify it of particulars specified in any order concerning drugs, poisons, chemicals, cosmetics, medical devices and foods which such manufacturers, importers, or exporters wish to continue to manufacture, import, export or sell after the Appointed Date specified in the order.

(2) Drugs, poisons, chemicals, cosmetics, medical devices and foodsin respect of which a notification has been received by the Board on or before the Appointed Date shall be evaluated for safety, efficacy, cost effectiveness and public health benefits or other considerations before listing them in theProvisionally Registered Inventory; and, until granted a product Marketing Authorisationlicense or ordered by the Board not to be manufactured, imported, exported or sold, such products shall have the status of ProvisionallyAuthorised or Registered drugs, poisons, chemicals, cosmetics, medical devices and foods for human or animal use.

(3) After the Appointed Date, no person shall import,manufacture, export or sell anydrug, poison, chemical, cosmetic, medical device or food not listed in the Inventory, without the prior written permission of the Board or until after a product Marketing AuthorisationLicence has been granted in respect of such product in accordance withthe provisions of section 36of this Act.

(4) The Inventory format may be determined by regulations issued in accordance with provisions of this Act whichshall be made available for inspection at such placesand times as shall be specified by the Board in an order published in the Gazette or one or more newspapers as required by regulations.

(5) The Board may take into consideration available evidence of safety, efficacy and qualityin granting theProvisional Marketing Authorization for a new drug to be used in an epidemic or as an orphan drug.

(6) The Inventory shall be revisedwhenever Provisionally Authorised or Registered drugs, poisons, chemicals, cosmetics, medical devices or food listed therein have been granted a Marketing Authorisationlicense in accordance withthe provisions of section 36 of this Actor whenever the Boardorders, in accordance withthe provisions ofsection 38 of this Act,that any such Provisionally Registered drugs, poisons, chemicals, cosmetics, medical devices and foodsfor human or animal useshall not be manufactured, imported, exported or sold from such date as specified in the order.

35. Application for Marketing Authorisation.

(1) An application for Marketing Authorisation shall be submitted to the Secretary-General in the prescribed form and shall be accompanied by the prescribed fee.

(2) The Authority may request additional information, take samples or request for samples from the applicant within a specified period of time in order to complete the dossier or to clarify issues related to the drug, poison, chemical, cosmetic, medical device orfood. Where such a request has been made it shall be the duty of the applicant to avail the information to the satisfaction of the Authority, that safety, quality and efficacy are assured.

(3) The Authority may at any time after evaluation, determine that an authorized or registered drugs, poisons, chemicals, cosmetics, medical devices or food is not eligible for Marketing Authorisation and that such drugs, poisons, chemicals, cosmetics, medical devices or foods shall not be manufactured, imported, distributed, sold or exported either with immediate effect or from such a date as specified in an order issued by the Board.

(4) After an order made in accordance with the provisions of subsection (3) above, the Inventory and or the Registry of Authorised drugs, poisons, chemicals, cosmetics, medical devices orfoods shall be revised accordingly with respect to the entry in relation to the particular product(s).

(5) Any manufacturer, importer or exporter who, without genuine reasons, failsto furnish such particulars within the stipulated time-limit or within an extended time-limit as may have been granted by the Authority, shall not be entitled to manufacture, import, distribute, sell or export such drug, poison, chemical, cosmetic, medical device or food from such date as shall be specified by the Board in a notification addressed to such manufacturer, importer or exporter.

(6) In determining whether or not to grant a product Marketing Authorisation license, the Board shall first consult relevant authorities including health professionals, and may take into account regulatory information from other countries as well as pronouncements by international organizations.

36. Evaluation and Issuance of Marketing Authorization.

(1) The Board shall make an order after considering product quality, safety and efficacy, as to whether a Provisionally Authorised or Registered drug, poison, chemical, cosmetic, medical device orfood or a product which is not listed in the Inventory but in respect of which an application for its manufacture, import, export or sale in South Sudan has been filed after the Appointed Date, shall be granted a Marketing Authorisationlicense.

(2) The Authority may at any time call upon any manufacturer, importer or exporter to furnish such information as is required in order to enable a Provisionally Authorised or Registereddrug, poison, chemical, cosmetic, medical device or food or a regulated productsought to be manufactured, imported or exported after the Appointed Date to be evaluated and assessed.

(3) If, in the opinion of the Board, a drug, poison, chemical, cosmetic, medical device or food shall be registered only if it is promoted, distributed or advertised in a particular manner or distributed subject to certain safeguards, it shall, in approving the registration of that medicine, fix such conditions as it considers necessary or desirable.

37. Registry of AuthorisedRegulated pharmaceuticalProducts.

(1) The Authority shall maintain a registry of Regulated Products for which Marketing Authorisationlicenses have been issued and shall make thisregistry or extracts from it available at such times as specified by the Board in an order published in the gazette or one or more newspapers as may be specified in the regulations.

(2) The terms, conditions and validity of product Marketing AuthorisationLicenses, the format of the Registry, and the particulars to be furnished to obtain a product Marketing AuthorisationLicense for Provisionally approved or Authorised products or for products not listed in the Inventory and other requirements, including the payment of fees for applications for a product Marketing Authorisation, shall be determined and specified in the regulations issuedin accordance with the provisions of this Act.

38. Revocation and Suspension of Marketing Authorisation License and Obligations of a License holder.

(1) The Board may revoke, or suspend the Marketing Authorisation for importation, manufacture, sale or export of Regulated Products or take samples for analysis or order recall of a RegulatedProduct if it appears or if there is a reason to suspect that the conditions for the License are no longer complied with.Upon revocation or suspension of the Marketing Authorization, the Secretary-General shall, within fifteen (15) days, give reasons for such revocation or suspension to the applicant, manufacturer, importer or exporter, as the case may be

(2) The Board may vary the provisions of the Marketing AuthorisationLicense provided that it is satisfied that such variation does not adversely affect the safety, quality or efficacy of the Regulated Product.

(3) The order of the Board may specify the period within or upon which it commences, how the order is to take effect, particularly with respect to recalling the product from the market, and the procedures, if any, for notifying health professionals and the public.

(4) A formulation or other error pertaining to a Regulated Product shall be immediately reported to the Authority by the Marketing Authorization License Holder. An adverse drug reaction event reported to a Licensee or Marketing Authorisation License Holder that exceeds lower toxicity or severity limits set by the Board shall be disclosed to the Authority by the Marketing Authorization License Holder within three (3) days of filing the report.

39. Obligations of Market AuthorisationLicense Holders.

(1) A Marketing AuthorisationLicense Holder shall not deviate from the particulars submitted in the regulated product registration dossier unless prior authorization is granted by the Board.

(2) The Marketing Authorisation License Holder of any drug, poison, chemical, cosmetic, medical device or food shall be responsible for the product safety, quality and efficacy throughout its shelf-life and product life cycle.

(3) The holder of the Marketing Authorisation License shall be liable for any technical failure and errors in relation to safety, efficacy, and quality of the authorised drug, poison, chemical, cosmetic, medical device or food whether the information was submitted in the application dossier or not.

40. Information Confidentiality.

(1) The Secretary-General and any authorized officer of the Authority shall keep all information regarding Regulated Products and allproduct registers confidential.

(2) Anyone who discloses confidential information of the Authority without the expressedwritten consent of the Board shall be liable to prosecution at the discretion of the Board.

CHAPTER VII

LICENSING AND CONTROL OF PHARMACEUTICAL PREMISES

41. Categories of Licenses for Pharmaceutical Premises.

(1) The Board may issue the following Licenses for purposes of this Act:
   (a) License A issued in the name of a Registered Pharmacist to manufactureRegulated Productsor the raw materials for manufacturing such productsin a dulylicensed premises;
   (b) License B issued in the name of a Registered Pharmacist to import, store, distribute and deal generally in Regulated Products or raw materials in a duly licensed premises such as sale and distribution houses, stores or warehouses for temporary storage of regulated products that are in transit; and
   (c) the Board may issue an import or export License only to a holder of a License A or B; provided the application for license shall be in accordance with the provisions of section 50 of this Act.

(2) Each stateministry in South Sudan may issue Licenses for operation of retail pharmacies (License C) or drug stores and community medicine shops (License D).

(3) Licenses issued in accordance with the provisions of subsection (2) of this section shall be in the name of a Registered Pharmacistfor License C and in the name of a Registered Pharmacy Technician for License D.

(4) In exercise of provisions of subsections (1) or (2), no Registered Pharmacist or Registered Pharmacy Technician shall be entitled to more than one License at any given time.

(5) The Board shall retain its supervisory role over Licenses issued pursuant to the provisions of subsection (2) of this section.

(6) Private clinics shall only be allowed to store and supply life-saving medicines as defined in the schedules, ordersor regulations issued in accordance withprovisions of this Act.

(7) Private hospitals may be issued with License C, provided, they meet the requirements of subsection (2) of this section

(8) Licenses issued in accordance with provisions of this Act shall be for conducting the stated businessin licensed premises by the specified person or under his or her direct supervision and shall not be transferable to another person.

(9) Where the Board or the state ministry refuses to grant a License, it shall give written reasons to the applicant within fourteen (14) days.

(10) The Board and or a state ministry may amend a Licence or changethe address of the premises at which the licensed person is authorized to carry on the business or profession in respect of which he or she is licensed.

(11) A License issued under provisions of this section shall be valid for the prescribed period and may be renewed on application by the License holder in the prescribed manner and duration granted, and upon payment of the prescribed fee.

42. Licensing of Pharmaceutical Premises.

(1) On or after such date as specified in a notice published in the Gazette or in any official publication as may be specified in the regulation, any person carrying on the business of manufacturing, importing, exporting, compounding, storing, dispensing, selling, supplying or otherwise distributing Regulated Products shall possess a valid Licence issued by the Authority in order to carry out that activity in the specified premises.

(2) The Authority shall issue a License to the applicant, after having evaluated and becomingsatisfied that the premises are suitable and the applicant can safely and effectively carry on business of manufacturing, importing, exporting, selling, supplying or distributing Regulated Products in compliance with all applicable law, regulations and ethical standards.

(3) The Authority shall maintain a Registry of pharmaceutical premises.

(4) Applications for License of retail pharmacy, drug store, community medicine shop,or premises under the provisions of this section shall comply with regulations issued by the respective state ministry and shall bein accordance with the *Pharmacy Professionand Practitioners*Regulations as shall be determined by law.

(5) The Minister shall, by regulationsprescribeparticulars that are to be furnished by applicants for a LicenseunderthisAct.

(6) The Minister, by Regulation, mayset the fees payable in respect of application for initial registration of pharmaceutical premises, issuance of operatingLicenses, licenses for import or export and Annual fees for retaining names of premises on the Registry.

CHAPTER VIII

INSPECTION

43. Appointment of Inspectors.

(1) The Board, in consultation with the Minister may appoint, as necessary,Inspectorswho shall enforceprovisions of this Act and state ministries shall have delegated powers to appoint Inspectors with respect to License C and License D premises.

(2) Inspectors appointed by the state ministries,under subsection (1) of this section,shall inspect health facilities, retail pharmacies and drug store premises within the administrative jurisdiction of the state.

(3) The Inspector shallcomply with requirements for education and training prescribed by regulations.

(4) Every Inspector appointedin accordance with the provisions of subsection (1) of this sectionshall be issued with an Inspector's Badge and formal identificationthat shall be signed by the Secretary-General or the designated authority in the state.

(5) Upon request by a person affected by the Inspector's exercise of powers conferred by this Act, theInspector shall exhibit the Inspector's Budge and identification issued in accordance with provisions of subsection (4)of this section.

44. Powers of Entry.

(1) The Board or any authorized officer shall have the power to visit and inspect any manufacturing plant, processing unit, business establishment, warehouse, office or any premises, transportation vessel or vehicle used for or in connection with the manufacture, importation, export, distribution, storage, sale, supply, dispensing or use of anyregulated products.

(2) An Inspector may, during reasonable time, enter any premises in respect of which an application for issuance of a License has been made in accordance with provisions of this Act or any licensed premises where any person is authorized to carry out any functions or activities that are regulated byprovisions of this Act.

(3) An Inspector may, at any time, enter any premises in relation to which he or she has reasonable cause to suspect that an offence in accordance withprovisions of this Act has been or is being committed.

(4) An Inspector may enter, at any reasonable time, any premises on which a business relating to the manufacture or supply of Restricted Medicine is carried on.

(5) An Inspector may enter, at any time, any vehicle or vessel which he or she reasonably suspects of being used or which is about to be used in the commission of an offence in accordance with provisions of this Act.

45. Powers of Investigation.

(1) An Inspector is empowered,in accordance with theprovisions of this Act, to enter any premises, vehicle or other mode of transportation,and may:

(a) inspect the premises, vehicle or vessel and any articles found in the premises, vehicle or vessel;

(b) require any person on or in the premises, vehicle or vessel to furnish any information in his or her possession as to the activities carried on or taking place in the premises and the person by whom they are carried on or the purposes for which the vehicle or vessel is being used,

(c) seize any drug, poison, chemical, cosmetic, medical device,food or records and other documents found on or in the premises, vehicle or vessel; or

(d) seize any substance, article or document which he or she has reasonable cause to believe to be a substance, article or document in which or by means of which an offence in accordance with provisions of this Act is being or has been committed.

(2) Whenany Regulated Product is seizedpursuant to provisions of this section a claim for reasonablepayment may be made in accordance with regulation

(3) The Inspector shall report to the Authority any act which contravene any provision of this Act or other applicable laws or practice that he or she finds while visiting any premises.

46. Proper Identification and Authority to be shown.

An Inspector exercising any powers conferred by provisions of this Act shall produce on demand a duly authenticated identification showing that he or sheis duly authorized to exercise the powers of inspection.

47. Obstruction.

No person shall obstruct, intimidate, threaten, or cause harm to an Inspector exercising powers vested in him or her by the provisions of this Act or fail to comply with directivesmade by him or her in exercise of such powers.

CHAPTER IX

CONTROL OFIMPORT, EXPORTAND TRANSPORTATION

48. Importation of Regulated Products.

(1) No person shall import or transport regulated productsfor commercial or public use into South Sudan without having a valid Licenseissued by the Authority in relation to such import or transportation.

(2) The Licence shall be valid for the period specified by the Board and shall state the range of authorized Regulated Products to be imported during thevalidity period of such Licence.

(3) Any person who imports any regulated product shall keep a record in the prescribed form of all imports.

49. Exportation of Regulated Products.

(1) No person shall export any Regulated Product without having a valid Licenseissued by the Authority in relation to that export.

(2) The License shall be valid for the period specified by the Board and shall specify the authorizedregulated product range and types that are to be exported.

(3) A person who exports any regulated product shall keep a record, in the prescribed form, ofall exports made in a particular year.

50. Import and Export Licenses.

(1) The Authority may grant a License for the import or export of a Regulated Productfor human and or animal use,if:
   (a) the application for the License is submitted in the prescribed form and accompanied by the prescribed fee; and
   (b) theBoard is satisfied that the applicant is a person to whom the License may properly be granted.

(2) No License shall be granted for the import or export of any Restricted Medicinesunder international control other than for medical, dental or veterinary use.

(3) The Authority shall review and issue Verification Certificate to an Import or Export License Holder for Regulated Products, for each consignment being imported or exported by the License holder.

51. Donations of Regulated Products.

(1) Only the RegulatedProducts registered in accordance withprovisions of section 36of this Act shall be accepted as donation to South Sudan,

(2) The Board in coordination with the Minister may issue additional guidelines, orders or regulations to control import or export of donations of regulated products.

52. Transportation of Regulated Products.

(1) No person shall transport, consign for transport or clear for passage within South Sudan or at ports of entry, any Regulated Product contrary to the provisions of this Act.

(2) Vessels or vehicles used for transporting Regulated Productsshall comply with the procedures and or guidelines for good distribution practices issued in accordance with the provisions of this Act.

CHAPTER X

QUALITY CONTROL OF REGULATED PRODUCTS

53. Establishment of the South Sudan Pharmaceutical Quality Control Laboratory.

(1) The Board shall establish Pharmaceutical Quality Control Laboratory to carry out the required tests and analysis and conduct research to ensure that Regulated Productsmeet quality requirements as to contribute towards assuring quality, safety and wellbeing of the public.

(2) The laboratory shall support the pharmaceutical inspectorate in routine monitoring, inspection and supervision of the Regulated Products that aremanufactured, imported, exported or distributed in the pharmaceutical supply chain.

54. Functions of the Laboratory.

The laboratory shall be responsible for:-

(1) Examining and testing Regulated Productsand material or substance from which or with which and the manner in which any Regulated Productmay be manufactured, processed or tested and ensuring the quality of Regulated Products;

(2) Performing chemical, biological, biochemical, physiological and pharmacological analysis and other pharmaceutical evaluation;

(3) Testing, at the request of the Board and on behalf of the Government, of locally manufactured and or imported Regulated Products to determine if they comply with the provisions of thisAct and the regulations issued thereunder.

55. Disposal of Regulated Products.

(1) Regulated Products that fail to meet quality and safety standards at any stage of the supply chain shall be denied entry into South Sudan or removed from active inventory and destroyed.

(2) Regulated Products that are expired, damaged, obsolete, substandard, counterfeit, adulterated, mislabelled, unregistered or in a state deemed unsuitable for use shall be disposed of in an environmentally friendly manner consistent with international best practices and regulations to be issued in accordance with the provisions of thisAct.

CHAPTER XI

NOMENCLATURE, LABELLING AND SCHEDULINGOFREGULATED PRODUCTS

56. Nomenclature, Labelling and Generic Substitution.

(1) All Regulated Productsimported, exported or manufactured in South Sudan shall in addition to the proprietary name be labelled, known and prescribed by their Generic or International Non-Proprietary Names except where evidence has been provided that no such name has been allocated and a non-proprietary alternative name does notexist.

(2) No person shall import, distribute or sell any Regulated Product unless the immediate, primary container or package bears a tamperproof and anindelible imprint of the manufacturing and expiry dates and batch or lot number or other additional labelling requirements prescribed by regulations issued in accordance with provisions of this Act.

(3) In the event a drug is prescribed by its brand or proprietary name, a generic substitution may be dispensed subject to the regulations issued in accordance with the provisions of this Act.

57. Scheduling of Drugs.

(1) The Board shall determine which drugs shall be placed under the various schedules of this Act.

(2) In general the international criteria for scheduling of drugs may be used but they shall be adapted to local needs as deemed necessary to ensurethatrelevant

medicines reach the public and private facilities includingretail and community outlets as needed.

CHAPTER XII

SUPPLY AND DISPENSING OF RESTRICTEDMEDICINES

58. Restricted Medicines.

(1) Subject to the provisions of this section, no person shall mix, compound, prepare, supply or dispense any Restricted Medicine unless that person is a Registered Pharmacist, Registered Medical Practitioner, Registered Dentist or Registered Veterinary Surgeon as defined under the provisions of this Act.

(2) No person shall supply ordispense Restricted Medicines as free samples.

(3) Without prejudice to the provisions of subsection (1) above, exceptional permission may be granted for:
- (a) the supply of Restricted Medicine by way of wholesaleby a licensed person;
- (b) the mixing, compounding or preparing of a Medicine under the immediate supervision of a Registered Pharmacist;
- (c) the supply or dispensing of a Restricted Medicine by a member of the staff of a hospital, dispensary or similar institution which has been authorised to do so by a general or special order of the Board;

(4) A person registered or enrolled under the nurses and midwives laws or any other authorised person may supply or dispense Restricted Medicines in accordance with the regulations issued by the Board and the Ministry

(5) The supply or dispensing of restricted Medicines referred to under the provisions of subsections (3) and (4) of this section shall be subject to the following:
- (a) the Restricted Medicine shall be dispensed only upon receipt of a valid prescription issued by a medical practitioner, dentist, veterinary surgeon or other person authorized to practice as such by relevant applicable laws or regulations.
- (b) the dispensed Restricted Medicine shall be distinctly labelled with the name and address of the person by whom it is supplied or dispensed;
- (c) the following particulars shall, immediately after the Restricted Medicine has been supplied or dispensed, be entered into a book that shall be used regularly for that purpose. The book shall be known as the “Restricted Medicine Prescription Book”andshall contain the following particulars:
  - (i) The date on which the Restricted Medicine was supplied or dispensed;
  - (ii) The ingredients, concentration, strengths and quantity supplied Or dispensed;

(iii) The name and address of the patient to whom the Restricted Medicine was supplied;

(iv) The name and address of the person under whose authority the prescription was given; and

(v) The name and signature of the person who dispensed the Restricted Medicine;

(d) Without limiting the generality of paragraph (a) of this section, the requirements of paragraph (c) of this section, shall not apply where the Restricted Medicine is administered by a medical practitioner, dentist, veterinary surgeon or midwife, or under his or her direct supervision and in his and or her presence.

(6) Any record kept under provisions of this section shall be open to inspection by an Inspector of medicines or an authorized officer.

(7) Due care shall be exercised to ensure security and proper accountability of stock of all Restricted Medicines under the care of a pharmacist, doctor, dentist, veterinary surgeon or any other authorized person.

CHAPTER XIII

CLINICAL TRIALS AND ADVERTISEMENT OF MEDICINES

59. Conduct of Clinical Trials.

No person shall conduct a Clinical Trial of any Medicine without the prior written authorisation of the Authority granted with approval of the Minister.

60. Application for Conduct of Clinical Trials.

(1) Any person who desires to conduct a Clinical Trial with respect to aRegulated Product shall submit to the SecretaryGeneral an application in the prescribed form, signed by him or her and accompanied by such fees as may be prescribed.

(2) In case of a Regulated Product used for the treatment of animals, the application shall specify the kindsof animals that will take part in the Clinical Trial, and the names and addresses of the owners of such animals.

(3) Where a clinical trial is to be conducted in a hospital or other medical institutions, the application referred in subsection(1) above, shall be countersigned by the medical superintendent or a senior medical officer of a comparable rank of such hospital or medical institution.

61. Secretary-General to Submit Application to Board.

(1) Upon receipt of the applications accordingto the provisions ofsection 60(1) above, the Secretary-General shall, within a reasonable time, submit it together with his or her comments to the Board for consideration.

(2) If, after due consideration, the Board is satisfied that the application shall be entertained, it shall consult with and obtain from the Minister written approval for the intended Clinical Trial, and shall issue written authorization in the prescribed form to the applicant to conduct the trial.

62. Conditions for Conducting Clinical Trials.

Any Clinical Trial in relation to a Regulated Product that is authorized in accordance with the provisions of section 60of this Act,shall be subject to such specific and general conditions as the Board may, with the approval of the Minister, impose in the interestof safety and wellbeing of all persons or animals taking part in such trial. The person conducting the trial shall observe strictly all the conditions subject to which the trial is authorized.

63. Conditions for Clinical Trials.

(1) Where the Board grants written authorization under the provisions of section60 (2)of this Act for the conduct of a Clinical Trial pertaining to a Regulated Product, no such trial shall take place until:

(a) in case of a drug, poison, chemical, cosmetic, medical device or food for use by persons of adult age, the voluntary written consents of all such persons taking part in the clinical trial have been freely obtained;

(b) in case of a Regulated Productfor use in minors or persons under legal disability, the voluntary written consents of their parents or legal guardians, as the case may be, have been freely obtained; and

(c) in case of a drug, poison, chemical, medical device or food for use in animals, the voluntary written consents of the owners of all such animals taking part in the clinical trial have been freely obtained by the person conducting the trial.

64. Supply of Information Prior to Clinical Trials.

(1) Whenever a clinical trial of any Regulated Productis authorized in accordance with the provisions ofsection 60 of this Act, the person conducting the trial shall, before commencing the trial:

(a) inform all persons taking part in the trial or persons whose animals may take part in the trial about:

(i) the aims and objectives of the Clinical Trial and the way in which it may be conducted; and

(ii) the possible benefits, risks, discomforts and other adverse effects that may result therefrom;

(b) maintain insurance, in such amount as may be prescribed from time to time, covering all persons or animals taking partin the trial against any injury or risk of injury that may be sustained during the trial; and

(c) sign an indemnity, in such form as may be prescribed, indemnifying the Government, the Minister and the Board from liability in respect of any injury or adverse effect whatsoever which may be sustained by any person or animal, directly or indirectly, as a result of the conduct of the

trial and which occurs or reveals itself at the time of the trial or subsequently.

65. Power of the Board to stop or suspend Clinical Trials.

If at any stage during the Clinical Trial authorized in accordance with the provisions of section 60 of this Act, relating to a Regulated Product, the Board is satisfied that having due regard to the initial risks, discomforts or other adverse effects caused to persons or animals taking part in the Clinical Trial it is in public interest to stop or suspend the trial, it shall notify in writing the person conducting the trial accordingly.

66. Monitoring of Clinical Trials by the Board.

To ensure adequate protection of the general public against any risks or adverse effects from the clinical trial of any Medicine authorized in accordance with the provisions of section 60 of this Act,the Board shall monitor such Clinical Trial from the beginning to the endin order to satisfy itself that all the specific and general conditions subject to which the trial was authorized are being strictly observed by the person conducting the trial and that for all intents and purposes the trial is likely to achieve its purposes.

67. Reports on Clinical Trials.

(1) Not later than thirtydays after the completion of a clinical trial authorized in accordance with provisions of section 60 of this Act, the person who conducted the trial shall compile and submit to the Minister through the Board a preliminary report on the scientific and ethical evaluation of the conduct of trial.

(2) In addition to the report referredto under the provisions of subsection(1)of this section, the person who conducted the trial shall, not later than ninety(90) days after completion of the trial, compile and submit to the Minister, through the Secretary General, a comprehensive report on any serious or adverse effects or reaction established by the trial.

(3) In exercise of the powers conferred under the provisions of section 65 of this Act, the Board shall compile and submit to the Minister an independent comprehensive report giving its factual assessments and findings on the trial as a whole, together with any recommendations that it may desire to make within ninety (90) days following satisfactory completion of the Clinical Trial,.

68. Control of Advertisement of Regulated Products and Pharmaceutical Premises.

(1) No person shall publish, distribute or in any manner whatsoever bring to the notice of the public or cause or permit to be published or distributed, any false or misleading advertisement concerning a drug, poison, chemical, cosmetic, medical deviceor food.

(2) The Board shall regulate the advertisement of pharmaceutical premises, and or any business conducted therein.

(3) If any drug, poison, chemical, cosmetic,medical device or food has been registered:

(a) Subject to the condition that it shall be available to public only on the direction of a medical practitioner or veterinary surgeon, no person shall advertise that drug, poison, chemical, cosmetic,medical device or food other than:

(i) in medical, dental or veterinary or pharmaceutical journal approved by the Board; or

(ii) to members of the medical, dental, veterinary or pharmacy profession;

(b) Subject to any condition set forthunder provisions of subsection (2)of this section,, no person shall advertise that drug, poison, chemical, cosmetic, medical device or food:

(i) in a manner inconsistent with such condition; or

(ii) to indicate or imply that the drug, poison, chemical, cosmetic, medical device or food may be used or sold in a manner inconsistent with such a condition.

CHAPTER XIV

MISCELLANEOUS PROVISIONS

69. Prohibitions.

(1) It shall be an offence under the provisions of this Act for any person to manufacture, import, sell or export a Restricted Product after the Appointed Date, unless such product at the time of Manufacture, importation, distribution or export, has the status of a Provisionally Authorised or Registered regulated productas provided under provisions of section 34 of this Act or where such product has received a productLicence orAuthorisation under provisions of section 36 of this Act.

(2) After the Appointed Date, it shall be an offence for any person to engage in any of the activities referred to insections 35 and 36 of this Act, unless such person holds a valid Licence granted by the Board or is otherwise legally entitled to engage in such activity.

(3) No person shall manufacture, import, export, compound, store, sell, promote or distribute a Regulated Product that:

(a) is unfit for use in humans or in animals;

(b) is adulterated;

(c) has upon it any natural or added deleterious substance which renders it injurious to health;

(d) has been manufactured, prepared, preserved, packaged or stored for sale under unsanitary or unfavourable conditions; or

(e) has been labelled, packaged or promoted in a manner that is false, misleading, deceptive or likely to create an erroneous impression

regarding its source, character, value, quality, composition, potency, merit or safety.

(4) No person shall manufacture, import, export, distribute, sell, supply or use any counterfeit starting or intermediate materials for manufacturing regulated products;

(5) No personshallstock, distribute or supply for sale in the private sector,drugs that are packaged and intended to be used in public hospitals and clinics.

(6) No person shall manufacture Regulated Products using any counterfeit starting or intermediate materials without taking reasonable measures to ensure that the startingor intermediate materials used or employed in the manufacture of such Regulated Products are not counterfeit or of suspected quality;

(7) No manufacturer, importer, exporter, distributor, pharmacist, health practitioner, health worker or other person shall manufacture, import, export, compound, prepare, promote, sell, supply, obtain, display, dispense or otherwise distribute, for a fee or by way of sample or gift any Regulated Product which is a counterfeit or known or suspected to be a counterfeit.

(8) Where any standard is prescribed for any RegulatedProduct, no person shall label, package, sell, offer for sale, distribute or promote any such product which does not conform to such standard in such manner as is likely to be mistaken for the Regulated Product for which the standard has been prescribed.

(9) The provisions of this Act shall extend to all persons, both public and private, engaged in manufacturing, importing, exporting, compounding, storing, distributing, promoting, and sellingor in any way dealing with Regulated Products.

70. Prohibition of Sale of Undesirable Regulated Products.

(1) If the Authority is of the opinion that it is in the public interest that a specifiedRegulated Productshall not be available to the public it may: –

(a) By notice in writing transmitted by registered post to any person, direct that person; or

(b) by notice in the Gazette, direct all persons;

(i) not to sell, supply or deliver such Regulated Productto any person for any reason whatsoever:

(ii) Provided that a notice in accordance withthe provisions of this subsection shall not prevent the person concerned from returning theRegulated Product tothe manufacturer or, in the case of an imported Regulated Product, to the importer concerned or from supplying or delivering such Regulated Product to a person approved by the Board for that purpose.

(2) The Board, with approval of the Ministerand the Minister forFinance and Economic Planning, may, if it deems fit andupon application by a person who has sustained any loss by reason of compliance with a notice issued in accordance with the provisions ofsubsection (1)of this section, grant to that

person from the funds of the Authority, such an amount as compensation for his or her loss as the Authority considers reasonable in the circumstances.

71. Official Seal and Logo.

The Authority shall have a common seal and logo that shall be kept by the Secretary-General. The common seal, when affixed onto any document shall be authenticated by two signatures of the Chairperson, the Secretary-General ora Member of the Board who is duly authorised

72. Offences and Penalties.

whoever contravenes or fails to comply with any provisions of this Act or any regulation or order made under provisions of this Act shall be guilty of an offence and upon conviction shall be liable to punishment that may include withdrawal of the license, imprisonment, or fine or both as determined by a court of competent jurisdiction authorised to hear the matter.

The penalties prescribed under this Actarein addition to and do not exclude any of the penalties provided for under provisions of the *Penal Code 2008*

73. Authority to Institute Legal Proceedings.

The Public Prosecutor shall institute Legal Proceedings relating to violations of provisions of this Act

74. Penalties.

(1) The court of competent jurisdiction to hear and decidecases of violation of provisions of this Act shall be the High Court.

(2) .Any person violating the provisions of this Actcommits an offence.

75. **Exemption from Liability.**

The Authority and personnel of the Authority or any member of the Board shall not be liable foracts or omissionsdone while discharging their official functions, duties orpowers conferred under this Act, provided thatsuch acts or omissionsare done in good faith.

76. Exemptions.

The Board may exempt in writing any person, medicine or therapeutic substance from application of any or all of the provisions of this Act exempt, subject to such conditions as it may specify.

77. Regulation.

The Minister shallissue regulations, orders and procedures for implementation of provisions of this Act.

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ASSENT OF THE PRESIDENT OF THE REPUBLIC OF SOUTH SUDAN

In accordance with the provision of Article 85 (1) of the Transitional Constitution of the Republic South Sudan, 2011, I, Gen. Salva Kiir Mayardit, President of the Republic of South Sudan, hereby Assent to the Drug and Food Control Authority Act, 2012 and sign it into law.

Signed under my hand in Juba, this 24th day of the month of MAR. in the year 2012.

Gen. Salva Kiir Mayardit
President
Republic of South Sudan
RSS/ Juba.