LAWS OF SOUTHERN SUDAN

THE SOUTHERN SUDAN MEDICINE CONTROL AUTHORITY BILL, 2010

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GENERAL PROVISIONS

LAWS OF SOUTHERN SUDAN
The Southern Sudan Medicine Control Authority Bill, 2010

In accordance with the provisions of Article 59(2) (b) read together with Article 85(1) of the Interim Constitution of Southern Sudan, the Southern Sudan Legislative Assembly, with the assent of the President of the Government of Southern Sudan, hereby enacts the following:

Chapter I

Preliminary Provisions

1. Title and Commencement

This Bill may be cited as the "Southern Sudan Medicine Control Authority Bill, 2010," 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Any provisions of the existing Legislation which are governed by this Bill are hereby repealed; provided that, all proceedings, orders and regulations taken or made thereunder, except to the extent they are cancelled by or are otherwise inconsistent with the provisions of this Bill, shall remain in full force or effect, until they are repealed or amended in accordance with the provisions of this Bill.

3. Purpose

The purpose of this Bill is to cover all matters concerned with establishment of an independent medicine control authority in Southern Sudan and to provide an appropriate and effective independent regulatory mechanism to control and regulate the manufacture, supply, marketing and distribution of medicines, pharmaceutical products and drugs.

4. Authority and Application

This Bill is drafted in accordance with the provisions of Article 55 read together with Article 35 as well as paragraphs 4, 24 and 31 of Schedule D of the Interim Constitution of Southern Sudan, 2005, which grants Southern Sudan authority over health and the co-ordination of services or the establishment of minimum Southern Sudan standards or the establishment of Southern Sudan uniform norms in respect of any matter or service referred to in Schedule C and D of the ICSS, 2005.

5. Interpretation.

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

"*Applicant*" means a person or company submitting an application for a license to practice, to open premises, to obtain Authorisation to market a new Pharmaceutical Product, to update or modify an existing Marketing Authorisation, or to obtain any other form of Licence or Authorisation required under the this Bill;
"*Appointed Date*" means the date specified under section 30(1) of the Bill;
"Authority" means the Southern Sudan Medicine Control Authority;
"*Board*" means the Southern Sudan Medicine Control Board;
"Clinical Trial" means a systematic study in human beings or animals in order to establish the efficacy of, or to discover or verify the effects or adverse reactions of Medicines, and includes a study of the absorption, distribution, metabolism and excretion of Medicines;
"Director" means a Director of the Authority appointed pursuant to this Bill;
"*Dispense*" in relation to a Medicine and Pharmaceutical Product, means to supply a Medicine or Pharmaceutical Product on and in accordance with a prescription duly given by a duly qualified medical practitioner, dentist or veterinary surgeon;
"***Generic Name***" is a term in common usage for any name applied to 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" and ***"GoSS"*** means the Government of Southern Sudan (GoSS);
"*International Non-Proprietary Name (INN)*" means the name allocated to a medicine by the World Health Organization and eligible for use by any manufacturer, as opposed to the "commercial name" or "brand name" which may be allocated to a medicine by a particular firm;
"*Inventory*" refers to the listing of Provisionally Registered/Authorized Pharmaceutical Products under section 33(2) of the Bill and related regulations issued by the Minister;
"Inspector" means a person appointed in terms of Section 38 of this Bill;
"Licence" is any form of Authorisation required under the present Bill;
"Manufacture" or ***"Manufacturing"*** is understood to mean the process by which Medicines or Pharmaceutical Products are produced serially for sale or distribution;
"*Marketing Authorisation*" is a Licence issued by the competent regulatory authority as designated under this Bill, signifying that a medicine has been evaluated as regards quality, safety and efficacy and the adequacy of the information accompanying it, and that the Licence 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 in possession of a licence or marketing authorization issued by the Board for a Pharmaceutical Product to be marketed in Southern Sudan
"*Medicine*" means any substance or preparation used or intended to be used for internal or external application to the human or animal body either in the treatment 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 Bill, and unless the context requires otherwise shall include the Chairperson;
"*Minister*" means the minister responsible for matters relating to health;

"Ministry" means the ministry responsible for matters relating to health;
"*Narcotic Medicine*" means any medicine or preparation controlled under the *Single Convention on Narcotic Drugs of 1961* or any subsequent version of that Convention;
"Pharmacist" or means the owner of the business on those premises is, or purports to be, a Registered Pharmacist
"*Pharmaceutical Product*" means any Medicine, intended for human or veterinary use, presented in its finished dosage form or as a starting material for use in such dosage form;
"*Promotion*" means all informational and persuasive activities by manufacturers, distributors or the holders of Marketing Authorisations, whether directed towards health professionals or the public generally;
"*Provisionally Authorized/Registered*" is used in relation to a Pharmaceutical Product which has been listed in the Inventory under section 33 of the Bill and which has not been screened for purposes of a product Licence/Marketing Authorisation under section 32 of the Bill;
"Psychotropic Substances" means any substance or preparation controlled under the *Convention on Psychotropic Substances of 1971* or any subsequent version of that Convention;
"*Register*" means the register of Pharmaceutical Products for which a Marketing Authorisation has been issued in terms of sections 32 and 33 of this Bill;
"*Registered Pharmacist*" means pharmacist whose name is entered in the Register under the *Health Professions Bill, 2010*;
"Registrar" means the Registrar of the Authority appointed under this Bill;
"Restricted Medicine" comprises a Psychotropic substance or a Narcotic Medicine as defined above or any other medicine on which the Medicines Control Authority has imposed corresponding restrictions;
"Secretariat" means the secretariat to the Authority created pursuant to this Bill;
"Secretary-General" means the Secretary-General of the Authority appointed pursuant to this Bill who shall also serve as Registrar;
"Society" means Pharmaceutical Society of Southern Sudan;
"SPLA" means the Sudan Peoples' Liberation Army.

Chapter II

Southern Sudan Medicine Control Authority

6. Establishment of Southern Sudan Medicine Control Authority

(1) There shall be established a body to be called the Southern Sudan Medicine Control Authority.

(2) The Authority shall be an autonomous body corporate, with perpetual succession and shall, subject to the provisions of this Bill, be capable in its corporate name of-
  (a) suing and being sued;
  (b) taking, purchasing or otherwise acquiring, holding, changing and disposing of property, movable or immovable;
  (c) borrowing and lending money;

(d) doing or performing all such other things or acts for the proper performance of its functions under this Bill, which may lawfully be done or performed by a body corporate.

(3) The main objective for which the Authority is established is to exercise general supervision and co-ordination over all matters relating to the drug industry and to be the principal instrument of Government in the implementation of all policies relating to drugs.

(4) The Authority shall consist of-
(a) the Board
(b) the Secretariat.

(5) Until such time as the Authority is created, the duties and functions of the Authority shall be delegated to the Ministry.

7. Membership of the Southern Sudan Medicine Control Board

(1) The Board shall consist of fourteen (14) Members as may from time to time be appointed in the following manner-
(a) Chairperson, appointed by the President of Government of Southern Sudan upon recommendation by the Minister three names of prominent South Sudanese nationals including at least one Pharmacist,
(b) Secretary-General who shall be appointed by the Minister,
(c) The following members, appointed by the Minister-
(i) One pharmacist with hospital pharmacy practice background upon nomination by the Society;
(ii) One pharmacist with community pharmacy practice background upon nomination by the Society;
(iii) One pharmacist from industry or with industrial/manufacturing knowledge and/or research background upon nomination by the Society;
(iv) One medical practitioner who is a specialist physician;
(v) One pharmacist from a recognized national and southern school, college or university of Pharmaceutical studies upon nomination by the Society;
(vi) One Pharmacist from the Ministry who is responsible for pharmaceutical services;
(vii) One physician from one of the Referral Teaching Hospitals in Southern Sudan
(viii) One registered dentist upon nomination by the Southern Sudan Medical and Dental Practitioners Council
(ix) One Registered Veterinary Surgeon, upon nomination by the ministry responsible for veterinary affairs in Southern Sudan and by the Veterinary Board of Southern Sudan;
(x) One legal counsel, upon nomination by the Ministry of Legal Affairs & Constitutional Development,
(xi) One financial expert, upon nomination by the Ministry of Finance and Economic Planning,

(xii) One representative from the Ministry of Commerce, Trade & Supply;
(xiii) One representative from the Medical Corps of Sudan Peoples' Liberation Army.
(xiv) One representative from the Directorate of Customs

(2) The Secretary-General shall have no voting rights.

(3) Tenure at the Board shall be for a term of three (3) years. Members may be re-appointed for a similar term.

8. Functions and Powers of the Chairperson of the Board

The Chairperson of the Board shall have the following functions and powers to –
(i) preside over the Board, call for meetings, determine the agenda of Board meetings in consultation with the Secretary-General;
(ii) supervise the performance of the Secretary-General;
(iii) represent the Board inside and outside Southern Sudan;
(iv) delegate his powers to any of the Board members and
(v) any other functions as the Board may entrust him therewith.

9. Application of the Seal

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 or other member of the Board and be deemed official.

10. Functions of the Board

(a) To advise the Minister on matters concerning control and regulation of pharmaceutical products;
(b) To ensure that all Pharmaceutical Products manufactured in, imported into or exported from the country conform to prescribed standards of quality, safety and efficacy, and that the personnel, premises and practices employed to manufacture, promote, procure, store, distribute and sell such products comply with defined codes of practice and other requirements;
(c) To ensure continued conformity of Pharmaceutical Products with such standards until their delivery to the end user;
(d) To ensure that Pharmaceutical Products are imported, manufactured, exported, stocked, sold, distributed or otherwise dealt with by duly authorized persons;
(e) To inspect and license all manufacturing premises, importing agents, wholesalers, distributors, hospital dispensaries, pharmacies and retail outlets;
(f) To grant, after due assessment, Marketing Authorisation licences or registration status for Pharmaceutical Products, whether locally manufactured or imported, and whether destined for the national market or export;

(g) cancel the Authorisation /registration of, or cause to be recalled from the market, such pharmaceutical products, the continued use of which may be detrimental to public health;
(h) maintain an Inventory of Provisionally Authorised/Registered Pharmaceutical Products;
(i) publish lists of Provisionally Authorised/Registered Pharmaceutical Products and of products with Marketing Authorisations from time to time for public information;
(j) ensure that dossiers for Marketing Authorisation of Pharmaceutical Products are kept up to date by the applicants and to approve alterations/changes thereto;
(k) provide for sampling and analytical and other testing of finished Pharmaceutical Products released into the distribution chain to assure their compliance with labeled specifications;
(l) To monitor and inspect the market for the presence of illegal, counterfeit or substandard pharmaceutical products;
(m) To ensure that the promotion and marketing of Pharmaceutical Products is in accordance with product information approved by the Board;
(n) To approve the use of unregistered / authorized Pharmaceutical Products for clinical trial purposes or for compassionate use and to regulate clinical trials on pharmaceutical products;
(o) To disseminate information on Pharmaceutical Products to health professionals and the public in order to promote their rational use;
(p) To levy marketing Authorisation/registration, application, retention and renewal fees;
(q) To monitor and review the implementation of the Bill;
(r) To review and amend the rules, guidelines and regulations pertaining to implementation of this Bill as deemed necessary to keep pace with time demands.

10. Meetings of the Board

(1) The Board shall meet regularly for the discharge of its functions at least six (6) times per year.

(2) Meetings of the Board shall be guided by the following procedures:
  (a) The Chairperson shall preside at all meetings. In his/her absence, the members present shall appoint a chair for that meeting.
  (b) Decisions of the Board meeting shall be by simple majority vote. In event of a tie, the Chairperson shall have a casting vote on the matter.
  (c) Any Member objecting to the decision of the majority shall have the reasons thereof recorded.
  (d) The venue, date and time for any meeting of the Board shall be determined by the Chairperson after consultation with the Secretary-General.
  (e) The notice for any Board meeting shall be issued by the Secretary-General not less than fourteen (14) days prior to the date of the meeting and the agenda together with other Board

papers (documents relevant to the meeting) shall reach Members not less than seven (7) days before the meeting.

(f) Quorum for Board meetings shall be not less than two thirds.

(g) Where a Member is absent, an apology may be recorded but shall not constitute an additional to make a quorum.

(h) The quorum of a postponed meeting shall be fifty (50%) percent of Board membership.

(i) All decisions of the Board shall be binding on all Members unless an objection is raised and recorded in the minute book

(j) A meeting postponed due to lack of a quorum shall be reconvened within fourteen (14) days with the same agenda.

(k) Any other person invited to guide the Board on a specific agenda or matter shall be recorded as in attendance and will not have voting powers.

(l) Any decision taken in a meeting where there are alternate members shall be binding to the substantive member unless at variance or conflict with public policy. The Chairperson shall seek concurrence on such matters as soon as it is practicable and present it to the next Board meeting for ratification.

(3) The Board's decisions, records, transactions materials made or availed shall be strictly confidential.

11. Disclosure of General Interest

The Chairperson of the Board or any of its members having a direct or indirect interest in any matter or proposal before the Board for consideration thereon, shall disclose to the Board the nature of the interest that connects him to such matter, or proposal, and shall not participate in deliberation, or decision passed by the Board concerning the same. This provision shall apply to members of Board Committees as well.

12. Committees of the Board

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

(2) The Chairman of the Board or of the committee may, at any time and at any place, convene a meeting of that committee.

(3) On the establishment of a committee, the Board shall appoint thereto one member of the Board who will be the Chairperson of that committee; and may appoint thereto persons who are not members of the Board.

(4) The procedure of the committee shall be fixed by the Board.

13. Appeals against decisions of the Board

Unless otherwise expressly provided in this Bill--

(a) where this Bill empowers the Authority or any of its organs to make a decision, the decision may be subject to appeal within the structure of the Authority in accordance with such administrative procedures as may be established for the purpose, and the decision shall not be called into question by any court;
(b) nothing provided for in this section impairs the court in the exercise of its supervisory jurisdiction.

14. Remuneration and expenses of members of the Board or committee

A member of the Board or of a committee of the Board shall be paid such allowances from the funds of the Authority such allowances as the Minister, after consultation with the Board, may fix.

Chapter III

Finance, Audit and Reporting

15. Operational Principle

The Authority shall manage its finances in accordance with sound financial principles and best practices and shall in that respect ensure that its revenues are sufficient to meet its expenditures, including payment of operational costs.

16. Sources of Funding

(1) The Authority's operations shall be funded by an approved and allocated budget approved in accordance with the ***Public Finance Management and Accountability Bill, 2010*** and other sources and shall include, but not limited to:
(a) grants, donations and bequests from local or foreign bodies;
(b) financial support from international donor agencies;
(c) Drug Registration Fees (80% to be committed to Authority activities);
(d) Licence Fees from pharmaceutical manufacturers, wholesale & retail pharmacies and community medicine shops (30% of fees from licensing of retail pharmacies and community medicine shops to be remitted by the states to the Authority), and
(e) any other source that may be approved by the President.

(2) Each year, the Authority shall prepare and submit for approval a budget proposal, in accordance with the GoSS budget process, for the following financial year. Such budget proposal shall be subject to review, revision and approval by the Minister.

17. Borrowing Powers

(1) The Authority may obtain loans or other credit facilities from any person, organisation or institution for the purposes of meeting its obligations.

(2) No loan or credit facility shall be obtained by the Authority pursuant to the provisions of subsection (1) above, without the prior approval of the Ministry of Finance and Economic Planning.

(3) Loan and credit facilities shall be on terms and conditions which are commensurate with sound financial practices and any regulations or policies governing borrowing by Government entities.

(4) The provisions of this section do not relieve the Authority or lender from obtaining any other approvals that may be required under any other applicable law.

18. Bank Accounts

The Authority shall open and maintain bank accounts as may be necessary for the performance of its functions and duties in accordance with the ***Public Finance Management and Accountability Bill, 2010.***

19. Surplus Funds

Funds belonging to the Authority, not immediately required for any purpose provided for in this Bill, may be invested in a manner which the Authority may decide after consultation with the Ministry of Finance and Economic Planning, subject to any rules and regulations governing the reversion of surplus funds in accordance with the provisions of the ***Public Finance Management and Accountability Bill, 2010.***

20. 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. The report 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.

21. 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 firm approved by the Auditor-General in writing and authorised by the Board.

(2) The Board shall ensure that within four (4) 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 20 above, is submitted to the Ministry of Finance and Economic Planning.

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

22. Annual and Other Reports

(1) In addition to the Financial Audit Report, required by section 20(2)(c) above, within four (4) months after the end of each financial year, or such other period as designated by the Government in writing, the Authority shall also prepare an Annual Report of its activities during that financial year.

(2) The Annual Report shall, *inter alia*, include the following information:

(a) A copy of the auditor's report;
(b) A statement of financial performance and of cash flows;
(c) The budget for the coming financial year;
(d) A description of the activities of the Authority during the previous year;
(e) An analysis of the extent to which it has met its objectives of the previous year;
(f) An evaluation as to the extent to which the advice and directives of the Board have been complied with;
(g) Its objectives for the coming year; and,
(h) Any recommendations on the matters governed by this Bill.

(3) The Authority shall publish and disseminate widely the Annual Report, along with its audited accounts. In the event the Authority fails to distribute the Annual Report, it shall be distributed by the Ministry of Finance and Economic Planning.

(4) The Secretariat shall submit to the President and the Assembly such other reports on its activities or any other matter that may from time to time be required.

Chapter IV

Secretariat

23. Secretariat of the Southern Sudan Medicine Control Authority

(1) The Authority shall establish a secretariat hereinafter referred to as the Secretariat of the Medicine Control Authority. The Secretariat shall be responsible for the day-to-day operations of the Authority.

(2) The Secretariat shall consist of professional cadre experienced in Pharmaceutical matters and be composed of:

(a) the Secretary-General;
(b) the Deputy Secretary-General;
(c) Directors;
(d) other employees of the Authority.

(3) Directors shall perform such functions as are conferred by this Bill and such additional duties as may be assigned by the Secretary-General.

24. Appointment of Secretary-General and Deputy Secretary-General

(1) The Secretary-General shall be appointed by the Minister upon recommendation of the Board. The nominee shall be a Registered Pharmacist who has specialized knowledge of the actions and applications of medicines. All other members of the Secretariat shall be appointed in accordance with the provisions of the Public Service Regulations.

(2) The Secretary-General, Deputy 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 pharmaceuticals.

(3) Without prejudice to the generality of subsection (1) above, a person shall be eligible for appointment to serve as the Secretary-General, Deputy Secretary-General and Director if he meets the following additional requirements:

(a) a Sudanese citizen;
(b) be of sound mind and high character;
(c) be at least thirty years of age;
(d) not a holder of an official office in, or is an employee of a political party;
(e) not a holder of an elected position at any level of government;
(f) possesses the skills and knowledge relevant to the work of the Authority or qualifications deemed relevant to the position;
(g) not an undischarged bankrupt or insolvent; and,

(h) not been convicted of an offence involving dishonesty or moral turpitude.

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

25. Functions of the Secretary-General

The Secretary-General shall have the following functions:

(1) Management of the Authority shall be the direct responsibility and duty of the Secretary-General as its Chief Executive. The Secretary-General shall be assisted in his day-to-day management functions and duties by the Deputy Secretary-General and the Directors.

(2) Without prejudice to the generality of subsection (1) above, the Secretary-General shall have administrative, financial and technical powers required for the performance of the work of the Authority, including, but not limited to:

(a) representing the Authority in official functions and occasions, in Southern Sudan, nationally, regionally and internationally;
(b) initiating policies and framework documents of the Authority;
(c) approving project and program activities proposed by the committees and/or directorates;
(d) overseeing the use of the funds of the Authority;
(e) providing periodic reports to the President, the Assembly, the Council and to the Minister;
(f) appointing, within budget limitations, the officers and support staff of the Authority in accordance with Public Service laws and regulations;
(g) initiating internal policies and procedures including job-descriptions of the support staff and the organisational chart;
(h) Monitoring and evaluating the performance of the Authority; and,
(i) Performing any other functions and duties as may be prescribed by any other law.

26. Declaration of Assets

The Secretary-General, Deputy Secretary-General, Secretaries, and any senior public service officials employed by the Authority shall, upon assumption of their offices, make confidential declaration of their assets and liabilities including those of their spouses and children in accordance with the applicable law.

27. Tenure, Resignation and Removal

(1) The tenure of office of the Secretary-General and Deputy Secretary-General and a Director shall be five (5) years, subject to renewal.

(2) A member of the Secretariat may resign by a letter addressed to the

Board through the Secretary-General. In case of the Secretary-General he or she shall submit his or her letter of resignation directly to the Minister.

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

(4) Reasons for removal under subsection (3) above shall include:
- (a) ineligibility for appointment under section 24(3) above of this Bill;
- (b) inability to perform the functions of his or her office due to mental or physical infirmity;
- (c) gross misconduct;
- (d) incompetence and inefficiency;
- (e) absence without permission or sufficient cause from five consecutive meetings of the Board; and,
- (f) conviction of an offence involving dishonesty, fraud or moral turpitude; and/or,
- (g) death.

(5) Where the Secretary-General, Deputy Secretary-General or a Director is removed from office, resigns or dies, he or she shall be duly replaced under the same conditions, and in the same manner, as he or she was appointed under section 24 above, of this Bill.

28. Restriction on Outside Employment

The Secretary-General, Deputy Secretary-General, Directors and staff of the Authority shall not practice any private profession, transact commercial businesses, or receive remuneration or accept employment of any kind from any other source other than the Authority.

29. Oath

The Secretary-General and other employs of the Authority shall, before assuming their duties, take the following oath or affirmation before the relevant appointing authority:

> *"I……., do hereby swear by the Almighty God/solemnly affirm that as the Secretary-General of the Southern Sudan Medicine Control Authority, I 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 Southern Sudan Medicines Control Authority Bill, with integrity and dignity in the best interest of the people of Southern 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 employment in the Authority so help me God/God is my witness".*

Chapter V

Registration of Medicines and Marketing Authorisation

30. Provisional Registration

(1) The Board shall, by order published in the gazette or through other means of notification, require manufacturers, importers and exporters of Pharmaceutical Products to notify the Board of such particulars as are specified in the order concerning the Pharmaceutical Products which such manufacturers, importers, or exporters wish to continue to Manufacture, import, export or sell after the Appointed Date as be specified in the order.

(2) Pharmaceutical Products in 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 and other considerations, before listing in Provisionally Registered Pharmaceutical Products Inventory and until granted a product Marketing Authorisation license or ordered by the Board not to be manufactured, imported, exported or sold, such products shall have the status of Provisionally Authorised/Registered Pharmaceutical Products.

(3) After the Appointed Date no person shall import, Manufacture, export or sell a Pharmaceutical Product not listed in the Inventory without the prior written permission of the Board, unless after a product Marketing Authorisation Licence has been granted in respect of such product under section 32 above, of this Bill.

(4) The Inventory format may be determined by regulations in accordance with the provisions of this Bill, shall be made available for inspection at such place and 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.

(5) The Inventory shall be revised accordingly as and when Provisionally Authorised/Registered products listed therein have been granted a Marketing Authorisation license under section 32(1) above, or the Board has ordered under section 34(3) above, of this Bill, that any such Provisionally Registered Pharmaceutical Product should not be manufactured, imported, exported or sold from such date as is specified in the order.

31. Application for Marketing Authorisation

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

(2) The Authority shall request for additional information, take samples or request for samples from the applicant within a certain period of time in order to complete the dossier or clarify any issues regarding the product. Where such a request has been made it shall be the duty of the applicant to avail the information until the evaluation is fully satisfied that the safety, quality and efficacy are established.

(2) The Authority may at any time, after evaluation, determine that an authorized or registered product is not eligible for Marketing Authorisation and that such product should not be manufactured, imported, sold or exported either with immediate effect or from such a date as is specified in an order made by the Board.

(4) Immediately following an order made under subsection (3) above, the Inventory and/or the Register of Authorised Pharmaceutical Products shall be accordingly revised with respect to the entry in relation to the relevant product.

(5) Any Manufacturer, importer or exporter who fails, without genuine reason, to 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, sell or export such pharmaceutical product from such date specified by the Board in a communication addressed to such manufacturer, importer or exporter.

(6) In determining whether a product Marketing Authorisation should be granted or not, the Board shall consult relevant authorities and health professionals and may take into account regulatory information from other countries and relevant international organizations.

32. Evaluation and Issuance of Marketing Authorisation

(1) The Board shall make, after considering product quality, safety and efficacy, an order as to whether a Provisionally Authorised or Registered product 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 Southern Sudan has been filed after the Appointed Date, should be granted a Marketing Authorisation license.

(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 Registered product or a product sought to be manufactured, imported or exported after the Appointed Date, to be evaluated and assessed.

(3) If, in the opinion of the Board, a medicine should be registered only if it is 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 to be necessary or desirable.

33. Register of Authorised Medicines and Pharmaceutical Products

(1) The Authority shall maintain a Register of Authorised Pharmaceutical Products for which Marketing Authorisation licenses have been issued and shall make this register, 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 Authorisation licenses, the format of the register, and the particulars to be furnished to obtain a product Marketing Authorisation license for Provisionally approved/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 promulgated in accordance with this Bill.

34. Revocation and suspension of Marketing Authorisation Licence and obligations of a Licence holder

(1) The Board may revoke, or suspend, the Marketing Authorisation for importation, Manufacture, sale or exportation of Pharmaceutical Products, or take samples for analysis or order recall of a Pharmaceutical Product if it appears or there is a reason to suspect that the conditions for the licence are no longer fulfilled. In event this happens, the Registrar shall within reasonable time, inform in writing the reason to the applicant and manufacturer.

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

(3) The order of the Board may specify the period within or up which it commence, how the order is to take effect, particularly with regard 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 Medicine shall be immediately reported to the Authority. An adverse drug reaction event reported to a License or Marketing Authorisation holder shall be conveyed to the Authority by the Licence holder within three days of the initial report.

35. Obligations of Market Authorisation Licence Holders

(1) A Marketing Authorisation Holder shall not deviate from the particulars submitted in the drug registration dossier, unless authorized thereto by the Board.

(2) The Marketing Authorisation holder of any Pharmaceutical Product shall be responsible for the product safety, quality and efficacy throughout the shelf life.

(3) The holder of the Marketing Authorisation shall be liable for any technical failure and errors in relation to safety, efficacy, and quality of the authorised Pharmaceutical Product whether the information was submitted in the application dossier or not.

36. Information Confidential

(1) The Secretary-General and any authorized officer of the Board shall keep all information regarding Pharmaceutical Product registration dossier confidential.

(2) Anyone who releases confidential or information considered prejudicial to the applicant without express written authority of the Board shall be in breach of the confidentiality clause provision and shall be liable for prosecution unless it is in the best interest of public health.

Chapter VI

Licensing and Control of Pharmaceutical Premises

37. Licensing of Pharmaceutical Premises

(1) The Authority shall issue a licence to the applicant, having evaluated and satisfied with the suitability of premises and the applicant to carry on business of manufacturing, importing, exporting, selling, supplying or distributing Pharmaceutical Products and undertake to ensure compliance with all applicable legislations, regulations and professional obligations.

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

(3) The Authority shall maintain a Register of pharmaceutical premises. The application for licensing of pharmacy or drug shop or community Medicine shop premises under this section shall be made in accordance with regulations issued by the Minister and in accordance with the provisions of the *Health Professions Bill, 2010*.

(4) The Board shall specify particulars to be furnished by applicants for a licence, in accordance with the regulations made under the Bill.

(5) The Minister, by Regulation, may fix fees for the initial registration of pharmaceutical premises, issuance of licenses and import/export permit. Annual fees may also be payable to retain the names of premises on the respective registers.

Chapter VII

Inspection

38. Appointment of Inspectors

(1) The Board, in consultation with the Minister, may appoint such persons as inspectors as it may be necessary for the proper enforcement of this Act.

(2) The Inspector must meet the rigorous training and educational requirements to be determined by regulations in order to perform his duties skillfully.

(3) Every person appointed as an inspector in terms of subsection (1) above shall be furnished with a certificate of appointment signed by the Secretary-General.

(4) An inspector shall, on demand by any person affected by the exercise or performance by him of any power or function under this Bill, exhibit the certificate issued in terms of subsection (2) above.

39. 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 used for or in connection with the manufacture, import, export, distribution, storage, sale, supply, dispensing or use of any Pharmaceutical Product.

(2) An Inspector may enter at all reasonable times any premises in respect of which an application for issue of a Licence has been made in terms of this Bill or a licence issued under this Bill is in force or on which any person is required to carry out any functions regulated in terms of this Bill.

(3) An Inspector may at any time enter any premise on or in relation to which he or she has reasonable cause to suspect that an offence under this Bill 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 Narcotic Medicine is carried on.

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

40. Powers of Investigation

(1) An Inspector is empowered under this Bill to enter any premises, vehicle or other means of transport 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 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 Medicine, substance, device, Pharmaceutical Product 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 under this Bill is being or has been committed.

(2) Where a Pharmaceutical Product is taken away pursuant to this section, reasonable payment thereof shall be tendered by the inspecting officer, but-

(a) no payment need be tendered in respect of a Pharmaceutical Product if the inspecting officer suspects that the Pharmaceutical Product is unfit for its purpose by reason of deterioration, impurity, adulteration or other defect but if the drug is later found on analysis to be fit for use, reasonable payment shall be tendered by the Inspector in respect of the Medicine or Pharmaceutical Product which is not returned to its owner in good condition;

(b) no payment shall be made in respect of a Pharmaceutical Product if the Inspector anticipates that proceedings for an offence under this Bill will be brought in respect of the Pharmaceutical Product; but if the proceedings are not commenced within six (6) months, reasonable payment shall be tendered in respect of the Medicine or Pharmaceutical Product which is not returned to its owner in good condition.

41. Proper Identification and Authority to be shown

An Inspector exercising any powers conferred by this Bill shall produce on demand a duly authenticated identification showing that he is competent to exercise those powers.

42. Obstruction

No person shall obstruct an Inspector exercising powers under this Bill or fail to comply with a requirement made by him in exercise of those powers.

Chapter VIII

Control of Transport, Import and Export of Medicines

43. Importation of Pharmaceutical Products

(1) No person shall import or transport Pharmaceutical Products for commercial and or public use purposes into Southern Sudan without having a Licence in relation to their import by the Board.

(4) The Licence shall be valid for the period specified by the Board and shall state the range of preparations to be imported during that period.

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

44. Exportation of Pharmaceuticals

(1) No person shall export any Pharmaceutical Products or preparation without having a Licence in relation to that export issued by the Board.

(2) The Licence shall be valid for the period specified by the Board and shall specify the Pharmaceutical Products range to be exported.

(3) A person who exports any Narcotic Medicines shall keep a record in the prescribed form of all exports.

45. Import and Export Licences

(1) The Authority may grant a Licence for the import or export of a Pharmaceutical Product if:
   (a) the application for the Licence is submitted in the prescribed form and accompanied by the prescribed fee; and
   (b) the Board is satisfied that the applicant is a person to whom the Licence can properly be granted.

(2) No Licence shall be granted for the import or export of any Narcotic Medicine or Psychotropic Substances under international control, other than for medical, dental or veterinary use.

(3) A Licence granted under this section may be granted generally for the import or export of classified drugs or limited to specified Pharmaceutical Products.

Chapter IX

QUALITY CONTROL OF MEDICINES

46. Establishment of the Southern Sudan Pharmaceutical Quality Control Laboratory

(1) The Government shall establish an independent Southern Sudan Pharmaceutical Quality Control Laboratory to carry out the required tests and analysis and conduct research to ensure that Medicines and medical devices meet quality requirements so as to contribute towards attainment of patient safety.

(2) The laboratory shall support the pharmaceutical inspectorate in the routine surveillance of Pharmaceutical Products manufactured, imported, exported or distributed in the pharmaceutical supply chain.

47. Functions of the Laboratory

The laboratory shall be responsible for

(a) Examination and testing of Pharmaceutical Products and material or substance from which or with which and the manner in which Pharmaceutical Products may be manufactured, processed or tested and ensuring the quality control of Pharmaceutical Products and medical devices;

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

(c) Testing, at the request of the Board and on behalf of the Government, of locally manufactured and imported drugs or Pharmaceutical Products with a view to determine whether such drugs or Pharmaceutical Products comply with this Bill and the regulations there under.

Chapter X

Scheduling of Medicines

48. Medicine nomenclature

(1) All Medicines imported, exported or manufactured in Southern Sudan shall in addition to the proprietary name be labeled, known and prescribed by their Generic Names except where evidence has been provided that no such name has been allocated and a non-proprietary alternative name exists.

(2) The size of the International Non-Proprietary Name shall be no less than two-thirds (2/3) the size of the proprietary name

49. Scheduling of Medicines

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

(2) In general the international criteria for scheduling of medicines will be used, but adapted to local needs as deemed necessary to ensure relevant medicines reach the official retail and community outlets according to the level of competence.

Chapter XI

Restricted Medicines

50. Supply and Dispensing of Restricted Medicines

(1) Subject to this section, no person shall mix, compound, prepare, supply or Dispense any Restricted Medicine unless that person is a Registered Pharmacist, medical practitioner, dentist or veterinary surgeon under this Bill.

(2) No person shall supply or Dispense 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 wholesale by 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 legislation or any other authorised person may supply or dispense Restricted Medicines in accordance with regulations made by the Minister in that behalf.

(5) The supply or dispensing of restricted Medicines under subsections (3) and (4) above shall be subject to the following: -
- (a) The Restricted Medicine shall be distinctly labeled with the name and address of the person by whom it is supplied or dispensed;
- (b) The following particulars shall, within 24 hours after the Restricted Medicine has been supplied or dispensed, be entered in a book used regularly for the purpose, which shall be known as the prescription book:

(i) The date on which the Restricted Medicine was supplied or dispensed
(ii) The ingredients and quantity supplied
(iii) The name and address of the person to whom the Restricted Medicine was supplied
(iv) The name and address of the person by whom the prescription was given,
(v) The name of the person who dispensed

(c) Except that paragraph (a) shall not apply in case where any Restricted Medicine is administered by a medical practitioner, dentist, veterinary surgeon or midwife, or under his or her direct supervision and in his or her presence.

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

Chapter XII

Clinical Trials and Advertisement of Medicines

51. Conduct of Clinical Trials

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

52. Application for conduct of Clinical Trials

(1) Any person wishing to conduct a Clinical Trial of a Medicine shall submit to the Secretary-General an application in the prescribed form, signed by him and accompanied by such fee as may be prescribed.

(2) In the case of a Medicine for the treatment of animals, the application referred to in subsection (1) above, shall specify the kinds of animals that will take part in the Clinical Trial, and the names and addresses of the owners thereof.

(3) Where a clinical trial is to be conducted in a hospital or other medical institution, the application referred to 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.

53. Secretary-General to submit applications to Authority

(1) Upon receipt of applications in terms of subsection 52(1) above, the Secretary-General shall submit it to the Board for consideration, together with his comments thereon, as soon as possible.

(2) If, after due consideration, the Board is satisfied that the application should be granted, it shall consult with, and obtain from, the Minister

written approval for the Clinical Trial, and thereafter issue written authorization in the prescribed form to the applicant to conduct the trial.

54. Conditions for conduct of clinical trials

Any Clinical Trial of any Medicine authorized in terms of subsection 53(2) above, shall be subject to such specific and general conditions as the Board may, with the approval of the Minister, impose and, for the safety 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.

55. Contents for Clinical Trials

(1) Where the Board grants written authorization under subsection 53(2) above, for the conduct of a Clinical Trial of a Medicine, no such trial shall take place until—

(a) In the case of a Medicine for the treatment of adult persons, the voluntary written consents of all such persons taking part in the clinical trial have been freely obtained;

(b) In the case of a Medicine for the treatment of 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 the case of a Medicine for the treatment of animals, the voluntary written consents of the owners of all animals taking part in the clinical trial have been freely obtained by the person conducting the trial.

56. Supply of information prior to Clinical Trials, etc.

(1) Whenever a clinical trial of any Medicine is authorized in terms of section 51 above, the person conducting the trial shall, before commencing the trial—

(a) Inform all persons taking part in the trial or persons whose animals will take part in the trial about—

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

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

(b) Insure in such amount as may be prescribed from time to time all persons or animals taking part in 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 GoSS, 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.

57. Board's power to stop or suspend Clinical Trials

If at any stage during the Clinical Trial of any Medicine authorized in terms of section 53 above, 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 seek and obtain forthwith the Minister's written approval to stop or suspend the trial immediately, and, if such approval is obtained, the Board shall not notify in writing the person conducting the trial accordingly.

58. Monitoring of Clinical Trials by Board

To ensure adequate protection of the general public against any risks or adverse effects from the clinical trial of any Medicine authorized in terms of section 53 above, the Board shall monitor such Clinical Trial from the beginning to the end so as 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 to all intents and purposes the trial will achieve its aims and objectives.

59. Reports on clinical trials

(1) Not later than thirty (30) days after the completion of a clinical trial authorized in terms of section 53 above, the person who conducted the trial shall compile and submit to the Minister through the Board a preliminary report on the ethical evaluation of the trial.

(2) In addition to the report referred to in subsection (1) above, the person who conducted the trial, not later than ninety (90) days after the completion of the trial, compile and submit to the Minister through the Board a comprehensive report on any serious or adverse effects or reaction established by the trial.

(3) Pursuant to the duty imposed upon it in terms of section 58 above, the Board shall, not later than ninety (90) days after the satisfactory completion of a Clinical Trial, 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 wish to make.

60. Control of Advertisement of Medicines

(1) No person shall publish, distribute or in any other manner whatsoever bring to the notice of the public or cause or permit to be published or distributed or to be so brought to the notice of the public any false or misleading advertisement concerning a Medicine.

(2) If any Medicine has been registered—

(a) Subject to the condition that it shall be available to the public only on the direction of a medical practitioner or veterinary surgeon no person shall advertise that medicine otherwise 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 fixed in terms of subsection 32(2) above, no person shall advertise that Medicine-
  (i) in a manner of inconsistent with such condition; or
  (ii) so as to indicate or imply that the Medicine may be used or sold in a manner inconsistent with such condition.

(3) It shall be sufficient in any prosecution for an offence involving a contravention of subsection (1) above if it is proved to the satisfaction of the court that the accused, not being a person selling the medicine to which the false or misleading advertisement which is the subject of the prosecution relates, did not know and could not reasonably be expected to have known that the advertisement was in any respect false or misleading unless it is proved that the accused failed on demand by the Secretary-General, an inspector or a police officer to furnish the name and address of the person at whose instance the advertisement was published or distributed or was brought to the notice of the public.

Chapter XIII

General Provisions

61. Prohibitions

(1) It shall be an offence under this Bill for any person to Manufacture, import, sell or export a product after the Appointed Date unless such product at the time of Manufacture, import, distribution or export has the status of a Provisionally Authorised/Registered Pharmaceutical Product under section 30(2) above, or has received a product Licence/Authorisation under section 31(1) above.

(2) After the Appointed Date, it shall be an offence for any person to engage in any of the activities mentioned in that section, unless such person holds a valid licence granted by the Board or is otherwise legally entitled to engage in any such activity.

(3) No person shall Manufacture, import, export, compound, store, sell, promote or distribute a Pharmaceutical 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 and/or unfavourable conditions; or

(e) has been labeled, 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 materials;

(5) No person shall manufacture a pharmaceutical product using any counterfeit starting materials or without taking reasonable measures to ensure that the starting materials used or employed in the manufacture of such Pharmaceutical Products are not counterfeit or of suspect quality;

(6) 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 Pharmaceutical Product which is a counterfeit or known or suspected to be a counterfeit.

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

(8) The provision of this Bill shall extend to all persons, both public and private sector engaged in manufacturing, importing, exporting, compounding, storing, distributing, promoting, selling or in any other way dealing with Pharmaceutical Products.

62. Prohibition of sale of sale of undesirable Medicines

(1) If the Authority is of the opinion that it is in the public interest that a specified Medicine shall 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 such Medicine or supply or deliver such Medicine to any person for any reason whatsoever:

(ii) Provided that a notice in terms of this subsection shall not prevent the person concerned from returning the Medicine to the manufacturer thereof or, in the case of an imported Medicine, to the importer concerned or from supplying or delivering such Medicine to a person approved by the Board for the purpose.

(2) The Board, with the approval of the Minister and the Minister OF Finance and Economic Planning, may, if it deems fit, on the application of a person who has sustained any loss by reason of compliance with a

notice issued in terms of subsection (1), grant to that person from the funds of the Authority such amount as compensation for such loss as the Authority considers to be reasonable in the circumstances.

63. Penalties

Any person who contravenes or fails to comply with any provision of this Bill or any regulation or any order made under this Bill shall be guilty of an offence, and on conviction shall be liable to a fine, withdrawal of licence, and or imprisonment for a period to be determined by the courts having regard to the provisions of the ***Penal Code Act, 2008.***

64. Exemption from Liability

No liability shall attach to the Board or any committee or any member of the Board or any committee or any officer of the Authority, for any act or omission committed by him in the *bona fide* exercise or performance of his functions and in terms of this Bill; provided that, such acts or omissions were committed in good faith.

65. Exemptions

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

66. Regulations

The Minister shall make such rules, regulations and procedures as may be necessary for the effective and efficient implementation of the provisions of this Bill.