BILLS SUPPLEMENT No. 11 **29th August, 2025**

BILLS SUPPLEMENT

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Bill No. 19 *National Drug and Health Products Authority Bill* **2025**

THE NATIONAL DRUG AND HEALTH PRODUCTS AUTHORITY BILL, 2025

MEMORANDUM

1. OBJECTIVE OF THE BILL

The object of the National Drug and Health Products Authority Bill, 2025 is to establish the National Drug and Health Products Authority, to provide for the functions and powers of the Authority, to regulate the manufacture, distribution, importation, exportation and supply of drugs, medical devices, cosmetic products, public health products and nutritional supplements, to provide for the administration and enforcement of the Act and to repeal the National Drug Policy and Authority Act and amend the Food and Drug Act.

2. DEFECTS IN THE NATIONAL DRUG POLICY AND AUTHORITY ACT

The National Drug Policy and Authority Act was enacted in 1993 and has not been directly amended since enactment. However, the health sector has evolved significantly over the years and the requirements of the World Health Organisation (WHO), the expansion of the health professions and the needs to regulate related health products all necessitate the need to overhaul mandate and functions of the National Drug Authority.

The National Drug Authority faces challenges during the execution of its mandate as the regulator of medicine and its usage in Uganda. This is due to the inadequacies of the Act and the narrow scope of the mandate of the Authority. The National Drug Policy and Authority Act, Cap. 198 does not regulate; pharmacies in health units, the distribution of drugs, the release of vaccines and biologicals by lots, the recall and withdrawal of drugs that are

determined to be unsuitable for use, amongst other matters. The Act does not provide for the testing and analysis by the laboratory of the Authority and does not give the Authority the mandate to seal off premises that are determined to be in contravention of the Act. These and other shortcomings of the current Act have curtailed the powers of the National Drug Authority in its regulation of medicine, which the Bill seeks to rectify.

The scope of the Bill has been expanded to provide for the regulation of medical devices, cosmetic products that contain parabens, phthalates, hydroquinone, retinoids or sunscreens, public health products and nutritional supplements, all which are directly related to the health and wellbeing of Ugandans.

3. PROVISIONS OF THE BILL

The Bill contains 14 Parts, 122 clauses and 1 Schedule, as follows-

Part I contains the preliminary provisions i.e. the commencement provision and the interpretation clause.

Part II establishes the National Drug and Health Products Authority and provides for its functions, establishes the Board of Directors and the tenure of office of members of the Board and the committees of the Board. The Part establishes the Secretariat of the Authority, the Office of the Executive Director and the other staff of the Authority and provides for the financial provisions to govern the Authority.

Part III provides for the registration, notification and listing of drugs, the manufacture and distribution of drugs and lot release of vaccines, biologicals and diagnostics, the importation and exportation of drugs, the regulation of pharmacies and drug shops and the general provisions on drugs in clauses 30 to 49.

Part IV of the Bill regulates clinical trials and **Part V** provides for the obligations of manufacturers, health care professionals and of the Authority with regards to pharmacovigilance.

Part VI provides for the regulation of medical devices, including the classification of medical devices and the registration, notification and listing

of medical devices. The licensing for the manufacture and distribution of medical devices and the regulation of the importation and exportation of medical devices and the requirement to report defects and adverse events arising from the usage of medical devices. to the Authority.

Part VII provides for the regulation of cosmetic products including the classification of cosmetic products and the registration, notification and listing of cosmetic products. The licensing for the manufacture and distribution of cosmetic products and the regulation of the importation and exportation of cosmetic products and the power of the Minister to prohibit the importation of certain cosmetic products.

Part VIII provides for the regulation public health products including the categorization of public health products and the registration, notification and listing of public health products. The licensing for the manufacture and distribution of public health products and the regulation of the importation and exportation of public health products.

Part IX provides for the regulation of nutritional supplements including the classification of nutritional supplements and the registration, notification and listing of nutritional supplements. The Part also provides for the licensing for the manufacture and distribution of nutritional supplements and the regulation of the importation and exportation of nutritional supplements.

Part X provides general regulation of medical devices, cosmetic products, public health products and nutritional supplements including the requirement to conformity to standards of the Uganda National Bureau of Standards Act. the obligation for manufacturers to establish monitoring systems and monitoring of regulated products by the Authority, the duty to maintain records of supply, the packaging and labelling of regulated products, compliance with good manufacturing practices in Uganda and good storage practices and good distribution practices. The requirement for authorisation to conduct clinical trials or field trials and compliance with good clinical practices. The Part also provides for the mandate to recall or withdraw defective product. The Part categories the prohibited activities including the prohibition to supply of regulated products in certain cases, the prohibition to falsify regulated products or to supply substandard regulated products.

Part XI establishes the National Drug and Health Products Laboratory and **Part XII** provides for the administration and enforcement of Act by the Authority including the appointment of inspectors and the power of the inspectors of the Authority. The Part also provides for the destruction of products that are not fit for their intended purpose.

Part XIII provides for legal proceedings including the evidence that is admissible in courts of law, the forfeiture and cancellation of licence by court, vicarious criminal responsibility and punishment without prosecution.

Part XIV provides the general provisions applicable to the products regulated under the Act including the requirement to ascertain the quality of the drugs of the National Medical Stores, the requirement to notify the Authority of amendment of particulars or persons regulated under the Act, the approved ports of importation and exportation, the protection of members of the Board and employees from personal liability, the repeal of the National Drug Policy and Authority Act and the continuance of the regulation of veterinary drugs, veterinary medical devices and field trials pending the enactment of a Bill to regulate these products.

The Bill contains a Schedule providing the value of the currency point.

HON. DR. ACENG JANE RUTH OCERO
Minister of Health.

THE NATIONAL DRUG AND HEALTH PRODUCTS AUTHORITY BILL, 2025

Arrangement of Clauses

Clause

PART XIV– GENERAL PROVISIONS

A Bill for an Act

ENTITLED

THE NATIONAL DRUG AND HEALTH PRODUCTS AUTHORITY BILL, 2025.

An Act to establish the National Drug and Health Products Authority; to provide for the functions and powers of the Authority; to regulate the manufacture, distribution, importation, exportation and supply of drugs, medical devices, cosmetic products, public health products and nutritional supplements; to provide for the administration and enforcement of the Act; to repeal the National Drug Policy and Authority Act, to amend the Food and Drug Act and for related matters.

PART I—PRELIMINARY

1. Commencement

(1) This Act shall come into force on a date appointed by the Minister by statutory instrument.

(2) The Minister may appoint different dates for the commencement of different provisions of this Act.

2. Interpretation

In this Act, unless the context otherwise requires—

"adverse event" means an unpleasant or an unexpected medical occurrence in a patient or a clinical trial subject to whom a drug, cosmetic product, public health product or nutritional supplement is administered or on whom a medical device is applied or used, which does not necessarily have a causal relationship with the treatment or clinical trial;

"adverse reaction" means the response to a drug or nutritional supplement which is noxious and unintended, for which a causal relationship between the drug or nutritional supplement and an adverse event is at least a reasonable possibility;

"advertisement" means any pictorial, visual or other descriptive matter, verbal statement or reference—

(a) appearing in a print or electronic publication or medium;

(b) appearing in a broadcast on television or radio; or

(c) brought to the notice of members of the public in any other manner,

which is intended to directly or indirectly advise on the existence and benefits of a drug, medical device, cosmetic product, public health product or nutritional supplement;

"authorised pharmacopoeia" means the current edition of the international pharmacopoeia, the British pharmacopoeia, the British pharmaceutical codex, the European pharmacopoeia and the United States pharmacopoeia;

"Authority" means the National Drug and Health Products Authority established under section 3;

"biological" means medicine that contains living organisms, or which is derived from living organisms or biological processes that is applicable to the prevention, treatment, or cure of a disease or condition of human beings and includes blood and blood products;

"Board" means the board of directors of the Authority;

"complementary medicine" means a drug consisting wholly or principally of one or more of the following ingredients, each of which has a clearly established identity and a traditional use—

(a) an essential oil;

(b) a plant or herbal material including plant fibers, enzymes, algae, fungi, cellulose and derivatives of cellulose and chlorophyll;

(c) a homoeopathic preparation;

(d) a mineral including a mineral salt and a naturally occurring mineral;

(e) non-human animal material including dried material, bone and cartilage, fats and oils; and

(f) a substance produced by or obtained from bees, including royal jelly, bee pollen and propolis;

"cosmetic product" means any substance or mixture intended to be placed in contact with the external parts of the human body such as the epidermis, the hair system, nails, lips or the external genital organs or with the teeth or the mucous membranes of the oral cavity of the human body,

for the exclusive or main purpose of cleaning those parts or for perfuming, changing the appearance, protecting or keeping in good condition those parts or for correcting body odours, where the cosmetic product contains –

(a) steroids;

(b) parabens;

(c) phthalates;

(d) hydroquinone;

(e) retinoids; or

(f) sunscreens;

"currency point" has the meaning assigned to it in the Schedule;

"drug" means any substance or mixture of substances used for—

(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical or mental state, or the symptoms of the disease, disorder or abnormality, in human beings;

(b) restoring, correcting or the beneficial modification of the organic or mental functions in human beings by exerting a pharmacological, immunological or metabolic action; or

(c) manufacturing as a component of any articles specified in paragraph (a) or (b), and includes biologicals, gene therapy, herbal medicine, complementary medicine, cosmeceuticals and nutraceuticals;

"drug shop" means an outlet licensed under section 29;

"emergency situation" means a circumstance which is urgent or unforeseeable or a situation which is not caused by dilatory conduct where—

(a) there is serious threat or actual confrontation with disaster, catastrophe, war or an act of God; or

(b) life or the quality of life or environment may be seriously compromised;

"health care professional" means a person who is regulated under the Medical and Dental Practitioners Act, the Pharmacy and Drug Act, the Nurses and Midwives Act or the Allied Health Professionals Act;

"herbal medicine" means any medicine that exclusively contains as active ingredients, one or more parts of natural organic or inorganic plant materials with or without animal or mineral materials in a form suitable for administration to human beings;

"inspection of premises" includes inspection of the land, courtyard and any other area to be used or used in connection to the area to be used for the business activity for which a licence or certificate is required this Act;

"lot release" means the process of evaluating each individual lot of vaccines, biological medicines and other medicinal products before giving approval for their release to the market;

"medical device" means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator,

software, material or other similar or related article including any component, part or accessory of it--

(a) used in human beings for—

(i) the diagnosis, prevention, monitoring, treatment or alleviation of a disease, a disorder or an abnormal physical state or an injury or a symptom of any of these, as the case may be:

(ii) supporting and sustaining life:

(iii) the diagnosis, monitoring, treatment or alleviation of, or compensation of an injury:

(iv) the diagnosis of a pregnancy;

(v) the control of conception:

(vi) investigation, replacement, modification or support of the anatomy or of a physiological process: or

(vii) providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; or

(b) used for the disinfection of a medical device,

which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means but which may be assisted in its intended action by such means;

"medicine" means drugs:

"Minister" means the Minister responsible for health:

"nutritional supplement" means any product or substance which supplements the normal diet and which is a concentrated

source of a vitamin or mineral or other substance with a nutritional or physiological effect, alone or in combination;

"pharmacist" means a person registered as such under the Pharmacy and Drugs Act;

"proprietary name" means the name of a drug under which the drug is distributed;

"public health product" means an item, instrument, apparatus, implement, machine, appliance, calibrator, software, material or other similar or related article, substance or mixture of substances intended for industrial or public health use, for the prevention of disease or promotion of health among the population;

"supply" with its grammatical variations and cognate expressions means, in relation to a product regulated under this Act, the administration or application of the product and includes the sale of the product;

"vessel" includes a ship, boat, aircraft or carriage of receptacle of any kind whether open or closed.

PART II—THE NATIONAL DRUG AND HEALTH PRODUCTS AUTHORITY

National Drug and Health Products Authority

3. Establishment of the National Drug and Health Products Authority

(1) The National Drug Authority in existence at the commencement of this Act, shall continue in existence under this Act as the National Drug and Health Products Authority.

(2) The Authority shall be a body corporate with perpetual succession and may, in the discharge of its functions under this Act—

(a) acquire, hold and dispose of moveable and immovable property;

(b) sue and be sued in its corporate name; and

(c) do all acts and things a body corporate may lawfully do.

4. Seal of the Authority

(1) The Authority shall have a seal which shall when affixed to any document be authenticated by the signature of the Chairperson to the Board and the Executive Director.

(2) A document issued by the Authority and sealed with the seal of the Authority and authenticated in the manner provided by this section shall be received and taken to be a true instrument duly issued by the Authority, without further proof unless the contrary is shown.

5. Functions of the Authority

(1) The functions of the Authority are

(a) with respect to drugs –

(i) to register or notify the drugs to be used in Uganda;

(ii) to regulate the manufacture, importation, exportation, distribution, transportation, advertisement, labelling, storage and supply or dispensing of drugs;

(iii) to regulate the disposal of falsified, adulterated, substandard, unwholesome and expired drugs;

(iv) to license premises on which drugs are manufactured, distributed, stored and supplied or dispensed;

(v) to test and analyse drugs;

(vi) to monitor the safety of drugs and where necessary conduct investigations on the quality or safety of drugs used in Uganda;

(vii) to maintain a system of lot release for vaccines, biologicals and diagnostics;

(b) with respect to medical devices, cosmetic products, public health products and nutritional supplements—

(i) as may be applicable, to register, notify or list the medical devices, cosmetic products, public health products and nutritional supplements to be used in Uganda;

(ii) to regulate the manufacture, importation, exportation, distribution, advertisement, labelling, promotion, storage and supply of the medical devices, cosmetic products, public health products and nutritional supplements in Uganda;

(iii) as may be applicable, to regulate the disposal of falsified, adulterated, substandard, unwholesome and expired drugs, medical devices, cosmetic products, public health products and nutritional supplements;

(iv) to license the premises on which medical devices are manufactured, distributed and supplied by wholesale;

(v) to test and analyse medical devices, cosmetic products, public health products and nutritional supplements, as may be applicable;

(vi) to monitor the safety and quality of the medical devices, cosmetic products, public health products and nutritional supplements, and where necessary conduct investigations on the quality or safety of drugs used in Uganda;

(c) to regulate clinical trials for drugs, medical devices, cosmetic products, public health chemicals and nutritional supplements and field trials for public health products;

(d) to provide to the public, information on the safety, quality and efficacy of drugs, medical devices, cosmetic products, public health products and nutritional supplements;

(e) to advise the Government on matters relating to the quality, safety and efficacy of drugs and the quality, safety and performance of medical devices, cosmetic products, public health products and nutritional supplements;

(f) to issue technical guidelines to persons regulated under this Act; and

(g) to perform any other function that is incidental to the performance of the functions of the Authority.

(2) In the performance of the functions under subsection (1), the Authority shall cooperate with other Government agencies and where necessary enter into agreements including agreements to combat the production, supply or use of substandard and falsified drugs, medical devices, cosmetic products, public health products and nutritional supplements.

(3) In the performance of the functions under subsection (1), the Authority may cooperate with the regulatory bodies of other

countries and similar regional and international regulatory agencies, on matters of common interest.

(4) For the purposes of subsection (3), the Authority shall—

(a) recognise, rely on or refer to decisions, reports, data and other information of regulatory bodies of other countries or of regional or international regulatory agencies;

(b) where applicable, adopt international technical guidelines;

(c) participate in regional, international and other regulatory initiatives for drugs and the other products regulated under this Act; and

(d) enter into agreements with other related regulatory bodies of other countries and similar regional and international regulatory agencies including agreements to combat the production, supply or use of substandard and falsified drugs medical devices, cosmetic products, public health products and nutritional supplements.

6. Directions of the Minister

(1) The Minister may, in writing, give policy directions to the Authority, and the Authority shall comply with the directions of the Minister.

(2) Notwithstanding subsection (1), where the Authority does not comply with the directions of the Minister, the Authority shall in writing, giving reasons, inform the Minister.

7. Board of Directors

(1) The Authority shall have a Board of Directors appointed by the Minister and which shall be the governing body, responsible for the policy, general direction and supervision of the Authority.

(2) The Board of Directors shall comprise nine members who shall include the chairperson of the Board.

8. Tenure of office of members of the Board

(1) A member of the Board shall be appointed for a term of four years on terms and conditions as shall be specified in the instrument of appointment and may at the expiry of the term, be reappointed as a member of the Board.

(2) A member of the Board may, at any time resign his or her office, by letter addressed to the Minister, giving notice of not less than one month.

(3) The Minister may, at any time, remove a member of the Board where—

(a) the member has a physical or mental incapacity that renders a person incapable of performing the duties of that office;

(b) the member is convicted of an offence punishable by imprisonment of more than three months or is convicted of an offence involving fraud or dishonesty;

(c) the member is convicted of the offence of abuse of office;

(d) in the case of a member regulated by a professional body, the member is disqualified or suspended from practicing his or her profession by a professional body or ceases to be a member of the profession otherwise than at his or her own request;

(e) the member is guilty of misbehavior or misconduct;

(f) the member is incompetent; or

(g) the member is adjudged bankrupt by a court of law.

9. Committees of the Board

(1) The Board may establish committees to perform such functions of the Board, as the Board may delegate or refer to the committee.

(2) A committee appointed under subsection (1) shall be chaired by a chairperson, who shall be a member of the Board and shall have other persons, whether members of the Board or not, as the Board may determine.

Secretariat of Authority

10. Secretariat

(1) The Authority shall have a Secretariat which shall be under the direction and supervision of the Board.

(2) The Secretariat shall implement the policies and programmes of the Authority, as may be determined by the Board.

11. Executive Director

(1) The Secretariat shall be headed by an Executive Director who shall be appointed by the Board for five years, on terms and conditions as shall be specified in the instrument of appointment, and the Executive Director may be re-appointed by the Board.

(2) The Executive Director shall be the chief executive officer and the accounting officer of the Authority, and shall be responsible for the day-to-day operations of the Authority including –

(a) the management of the funds, property and business of the Authority; and

(b) the administration, organisation and supervision of the officers and staff of the Authority.

(3) The Executive Director shall be an ex-officio member of the Board.

(4) The Executive Director shall be a person of high moral character and proven integrity, with qualifications and experience related to the functions of the Authority.

12. Staff of the Authority

(1) The Authority shall have other employees as may be necessary for the effective performance of the functions of the Authority, as may be determined by the Board.

(2) The employees appointed under this section shall hold office on terms and conditions as may be specified in their instruments of appointment, as may be determined by the Board.

(3) The Board shall regulate the appointment, terms and conditions of service and the discipline of the Executive Director and the employees of the Authority.

13. Rules to regulate staff

The Board shall make rules in conformity, as may be applicable, with the Uganda Public Service Standing Orders, to regulate-

(a) the appointment, remuneration, discipline and dismissal of the staff of the Authority; and

(b) the payment to the staff of the Authority, of gratuities and other like payments on retirement or on termination of service.

Financial provisions

14. Funds of the Authority

The funds of the Authority shall consist of -

(a) the fees payable to the Authority, as prescribed by this Act;

(b) money from any other source as may be determined by the Board; and

(c) grants and loans from the any organization or any other source, secured in accordance with the applicable laws.

15. Power to open and operate bank accounts

The Authority shall open and maintain such bank accounts as are necessary for the performance of the functions of the Authority.

16. Borrowing powers

The Authority may, with the approval of the Minister in consultation with the Minister responsible for finance, borrow money from any source as may be required for the discharge of the functions of the Authority.

17. Estimates

(1) The Executive Director shall, before the end of each year, cause to be prepared and submitted to the Board for approval, estimates of the income and expenditure of the Authority, for the following year.

(2) The Board shall, on approval, submit the estimates of income and expenditure to the Minister for approval.

18. Accounts

(1) The Executive Director shall cause to be kept in accordance with accepted accounting standards, proper books of accounts and records of the transactions of the Authority.

(2) Subject to any direction given by the Board, the Executive Director shall cause to be prepared and submitted to the Minister in respect of each year, and not later than two months after the end of the year, the annual statement of accounts of the Authority for the preceding year.

19. Audit

(1) The Auditor General or an auditor appointed by the Auditor General shall, for each year, audit the accounts of the Authority.

(2) The Board shall ensure that within two months after the end of each year, the annual statement of accounts of the Authority for the preceding year, is submitted to the Auditor General or to an auditor appointed by the Auditor General.

20. Annual report

(1) The Board shall submit to the Minister, as soon as practicable but not later than six months after the end of each year, a report of the activities and operations of the Authority conducted during the year to which the report relates.

(2) The report referred to in subsection (1) shall include the audited accounts of the Authority and any other information the Board may consider necessary.

PART III—REGULATION OF DRUGS

Registration, notification and listing of drugs

21. Registration, notification and listing of drugs

(1) A person shall not manufacture, import, export, distribute, supply or dispense a drug unless the drug is registered or notified by the Authority.

(2) Where the drug is a herbal medicine or a complementary medicine, a person shall not manufacture, import, export, distribute, supply or dispense the drug unless it is registered, notified or listed by the Authority, as the case may be.

(3) Subsections (1) and (2) shall not apply-

(a) where the drug is required by the Authority for purposes of registration, notification or listing under this Act;

(b) where the drug is required for purposes of conducting a clinical trial;

(c) with respect to importation, where the drug is imported for personal use; or

(d) where the manufacture or importation of the drug is required for an emergency situation.

(4) Any person that so wishes may, in the prescribed form and on payment of the prescribed fees, make an application to the Authority, for the registration, notification or listing of a drug.

(5) The requirements for registration, notification and listing of drugs, including any conditions for registration, notification and listing, shall be prescribed by regulations made under this Act.

(6) The Authority shall register, notify or list the drug that satisfies the requirements of this section and grant the person who makes the application a certificate of registration, notification or listing, as the case may be.

(7) A drug that is registered, notified or listed under this section shall for each financial year, be retained on the register on the payment of the prescribed fees, by the person that caused the registration, notification or listing or by any other person, except where the registration, notification or listing is cancelled or suspended by the Authority.

(8) A person that manufactures, imports, exports, distributes or supplies a drug which is not registered, notified or listed by the Authority commits an offence and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding three thousand currency points; and

(b) in case of an individual, to a fine not exceeding five hundred currency points or imprisonment not exceeding ten years, or both.

Manufacture and distribution of drugs and lot release

22. Licence for the manufacture of drugs

(1) A person shall not manufacture a drug in Uganda without a licence to manufacture the drug, issued by the Authority.

(2) A person that seeks to manufacture a drug shall in the prescribed form and on payment of the prescribed fees, make an application to the Authority for a licence.

(3) The requirements for the manufacture of drugs, including the requirement for inspection of premises to be used to manufacture drugs, shall be prescribed by regulations made under this Act.

(4) The Authority shall grant a person that satisfies the requirements of this section, a licence to manufacture the drugs specified in the licence.

(5) A person that manufactures drugs in Uganda contrary to this section commits an offence and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding ten thousand currency points; and

(b) in case of an individual, to a fine not exceeding five thousand currency points or imprisonment not exceeding five years, or both.

23. Licence for distribution of drugs

(1) A person shall not distribute a drug in Uganda without a licence to distribute the drug, issued by the Authority.

(2) A person that seeks to distribute drugs shall in the prescribed form and on payment of the prescribed fees, make an application to the Authority for a licence.

(3) An application to distribute drugs shall indicate the pharmacist responsible for the distribution of the drugs.

(4) The requirements for the distribution of drugs, including the requirement for inspection of premises to be used to distribute drugs, shall be prescribed by regulations made under this Act.

(5) The Authority shall grant a person that satisfies the requirements of this section, a licence to distribute drugs.

(6) A person that distributes drugs in Uganda contrary to this section commits an offence and is liable on conviction –

(a) in case of a corporate body, to a fine not exceeding five thousand currency points; and

(b) in case of an individual, to a fine not exceeding five thousand currency points or imprisonment not exceeding five years, or both.

24. Lot release of vaccines, biologicals and diagnostics

(1) The Authority shall maintain a system for the release of vaccines, biologicals and diagnostics by lot, by the manufacturers in Uganda and exporters from Uganda, of vaccines, biologicals and diagnostics.

(2) A manufacturer or an exporter of vaccines, biologicals or diagnostics who intends to release vaccines, biologicals or diagnostics into the market shall, have a certificate of lot release issued by the Authority, and the certificate may specify any conditions for the release as may be necessary.

(3) A manufacturer or exporter who contravenes this section commits an offence and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding three thousand currency points; and

(b) in case of an individual, to a fine not exceeding five hundred currency points or imprisonment not exceeding three years, or both.

Importation and exportation of drugs

25. Importation of drugs

(1) A person shall not import a drug into Uganda without a licence issued by the Authority prior to the importation.

(2) Notwithstanding subsection (1), the Authority may for a specified purpose, and subject to conditions the Authority may deem fit, authorise the importation of a drug which is not registered under this Act where the importation is for—

(a) conducting a clinical trial;

(b) personal use;

(c) an emergency situation; or

(d) purposes of registering or notifying the drug.

(3) Any person that seeks to import a drug into Uganda shall in the prescribed form and on payment of the prescribed fees, make an application to the Authority for a licence.

(4) The requirements for the importation of drugs, the conditions for importation and the approved shelf life of the drugs to be imported shall be prescribed by regulations made under this Act.

(5) The Authority shall grant a person that satisfies the requirements of this section, a licence to import the drugs specified in the licence.

(6) The Authority may, in public interest, authorise parallel importation of a drug.

(7) In subsection (6), "parallel importation" means the importation of a drug from a country other than the country where the drug is patented and the drug is legitimately placed in that other country by any other person, without the authorisation of the person in whose names the drug is patented.

(8) Where a drug is imported into Uganda contrary to the provisions of this Act, the Authority shall-

(a) order the person granted a certificate of registration, notification or listing, as the case may be, or the authorised representative of that person or the importer of the drug, to destroy the drugs, at their own cost; or

(b) order the person granted a certificate of registration, notification or listing, as the case may be, or the authorised representative of that person or the importer of the drug, to re-export the drugs to the country of import, at their own cost.

(9) Where a drug is imported into Uganda contrary to the provisions of this Act and the importer cannot be traced, the Authority shall destroy the drugs at its own cost.

26. Importation of drugs for donation

(1) Where a drug to be imported is for donation, the drug shall not be imported without the authorisation of the Authority.

(2) A person that seek to import a drug for donation shall upon payment of the prescribed fees, make an application to the Authority in a manner prescribed by regulations made under this Act.

(3) The Authority shall issue a certificate of donation in respect to the drug, which shall specify the conditions of the donation and the shelf life approved for the drug.

(4) The donations of drugs to Government shall be approved by the Minister before the drugs are delivered to Uganda.

(5) A person that imports drugs for donation contrary to this section commits an offence and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding three thousand currency points; and

(b) in case of an individual, to a fine not exceeding five hundred currency points or imprisonment not exceeding five years, or both.

27. Exportation of drugs

(1) A person shall not export drugs from Uganda without a licence issued by the Authority prior to exportation.

(2) Any person that wishes to export drugs from Uganda shall apply to the Authority for a licence to export the drugs specified in the licence.

(3) A person that seeks to export drugs shall, on payment of the prescribed fees, make an application to the Authority.

(4) The requirements for the exportation of drugs, including the persons authorised to export drugs, and conditions for exportation shall be prescribed by regulations made under this Act.

(5) The Authority shall grant a person that satisfies the requirements of this section, a licence to export the drugs specified in the licence.

(6) A person that exports drugs contrary to this section commits an offence and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding ten thousand currency points; and

(b) in case of an individual, to a fine not exceeding five thousand currency points or imprisonment not exceeding five years, or both.

Regulation of pharmacies and drug shops

28. Operation of wholesale or retail pharmacies

(1) A person shall not operate a wholesale or retail pharmacy unless the pharmacy is licensed by the Authority.

(2) A person that intends to operate a pharmacy shall in the prescribed form and on payment of the prescribed fees, make an application to the Authority for a licence to operate a pharmacy.

(3) An application to operate a pharmacy shall indicate the pharmacist responsible for the immediate supervision of the supply or dispensing of drugs within the pharmacy.

(4) A pharmacy to be licensed under this Act shall be–

(a) a corporate body incorporated under the Companies Act and shall in this case have a pharmacist regulated under the Pharmacy and Drug Act, as director;

(b) a sole proprietorship registered under the Business Names Registration Act and shall in this case have a pharmacist as the sole proprietor:

(c) a partnership registered under the Partnership Act and shall in this case have a pharmacist regulated under the Pharmacy and Drug Act, as one of the partners; or

(d) a pharmacy that is an integral part of a private hospital or private clinic and in this case the private hospital or private clinic shall be registered as a health unit under the Medical and Dental Practitioners Act.

(5) For purposes of subsection (4) (d), the health unit shall be licensed to operate the pharmacy.

(6) A person that operates a pharmacy in contravention of this section commits an offence, and is liable on conviction—

(a) in case of a corporate body or partnership, to a fine not exceeding five thousand currency points; and

(b) in case of an individual, to a fine not exceeding five hundred currency points or imprisonment not exceeding ten years, or both.

29. Operation of drug shops

(1) A person shall not operate a drug shop unless the drug shop is licensed by the Authority.

(2) A person that intends to operate a drug shop shall in the prescribed form and on payment of the prescribed fees, make an application to the Authority for a licence to operate a drug shop.

(3) The Authority shall be satisfied that the person that makes an application under subsection (2) is fit to carry on a business of operating a drug shop.

(4) A drug shop to be licensed under this section shall be located in an area that is not sufficiently served by existing retail pharmacy licensed under section 28 or another drug shop.

(5) A person that operates a drug shop in contravention of this section commits an offence, and is liable on conviction to a fine not exceeding fifty currency points or imprisonment not exceeding five years, or both.

General provisions on drugs

30. Inspection of premises by the Authority

(1) The Authority shall before issuing a licence under this Part, satisfy itself that the premises where business is to be carried out, are suitable for the business for which the licence is required.

(2) For the purposes of subsection (1), a person that intends to apply for a licence to manufacture, distribute, import, export, supply or dispense drugs shall, upon payment of the prescribed fees, make an application for a certificate of suitability of premises, in respect of the premises at which the business activity is to be carried out.

(3) The Authority shall, prior to issuing a certificate of suitability of premises, inspect the premises, fixtures, equipment and other physical attributes of the premises to determine that the premises are suitable for the purpose for which the certificate is to be issued.

31. Drugs to be manufactured under supervision of pharmacist

A person licensed to manufacture a drug in Uganda shall manufacture the drug under the direct supervision of a pharmacist.

32. Supply and dispensing of medicine to be under supervision of pharmacist

The supply and dispensing of drugs within a pharmacy, shall be under the immediate supervision of a pharmacist.

33. Drug nomenclature

(1) A drug manufactured, distributed, supplied or dispensed in, or a drug imported into Uganda shall be known and prescribed by the international non-proprietary name of the drug except where the drug does not have an allocated international non-proprietary name or where there is no satisfactory alternative nonproprietary name for the drug.

(2) A drug to which subsection (1) applies shall be labelled using the international non-proprietary name of the drug.

(3) Where a drug referred to in subsection (1), is a herbal medicine or complementary medicine and does not have an allocated international non-proprietary name, the Authority shall prescribe a nomenclature, that shall apply to the herbal medicine or complementary medicine.

(4) In this section, "international non-proprietary name" means the official name of a drug, regardless of the manufacturer of the drug.

34. Packaging and labelling of drugs

(1) A drug manufactured, distributed, supplied or dispensed in, or a drug imported into Uganda, shall be packaged and labelled as may be prescribed by regulations made under this Act.

(2) For avoidance of doubt, a person shall not supply or dispense any drug unless –

(a) the drug is placed in a container or package of the prescribed description; and

(b) the container or package in which the drug is placed bears a label, stating the prescribed particulars of the drug.

(3) The person to whom this section applies shall notify the Authority of any change of the label of the drug.

(4) A person shall not remove or alter the label on any container or package of a drug without the approval of the Authority.

(5) A person that manufactures, imports, exports, distributes or supplies any drug in contravention to this section commits an offence, and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding five thousand currency points; and

(b) in case of an individual, to a fine not exceeding three thousand currency points or imprisonment not exceeding five years, or both.

35. Classification of drugs

(1) For purposes of this Act, drugs shall be classified in regulations to be made under this Act, as specified in this subsection and shall when supplied or dispensed by retail, be supplied or dispensed as specified in this subsection—

(a) class AI drugs; narcotic drugs and psychotropic substances, which shall only be supplied or dispensed on the prescription of a medical practitioner or dental practitioner for medical or dental purposes and which shall be dispensed by a medical practitioner, dental practitioner or pharmacist;

(b) class AII drugs; other prescription-only drugs, which shall only be supplied or dispensed on the prescription

of a medical or dental practitioner, for medical or dental purposes and which shall be dispensed by a medical practitioner, dental practitioner or pharmacist;

(c) class B drugs; drugs, which may be supplied or dispensed without a prescription of a medical practitioner or dental practitioner, by a pharmacist;

(d) class C drugs; over-the-counter drugs, which may be supplied or dispensed without a prescription of a medical practitioner or dental practitioner, in a pharmacy or a drug shop;

(e) class D drugs; general sales drugs which may be supplied or dispensed without a prescription of a medical practitioner or dental practitioner, in a retail outlet; and

(f) class E drugs; precursor chemicals, used in the manufacture of narcotic drugs and psychotropic substances.

(2) Class A and class B drugs shall be restricted drugs.

36. Possession of drugs

(1) The following persons may be in possession of drugs, but to the extent only and subject to the limitations prescribed by this section—

(a) a pharmacist, for the purposes of section 28;

(b) a person who is licensed under section 29 to operate a drug shop;

(c) any person, institution or department to whom or to which drugs have been lawfully supplied or dispensed in accordance with this Act, for the purpose for which the supply or dispensing was made.

(2) A person shall not have in his or her possession without lawful excuse, the proof of which shall lie on him or her, any narcotic drug or psychotropic substance which is used for medical or dental purposes.

(3) A medical practitioner, dental practitioner or pharmacist shall not supply or dispense any narcotic drugs or psychotropic substance used for medical or dental purposes other than for medical or dental purposes.

(4) Any person who is in possession of drugs otherwise than in accordance with this section commits an offence and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding five thousand currency points; and

(b) in case of an individual, to a fine not exceeding three thousand currency points or imprisonment not exceeding five years, or both.

37. Need for prescription for restricted drugs

(1) A pharmacist shall not —

(a) dispense class AI and class AII drugs without a prescription of a medical or dental practitioner; or

(b) dispense a drug which does not conform to the prescription under which it is to be supplied or dispensed.

(2) For the purposes of subsection (1) (b), a pharmacist shall not dispense the drug except where he or she reasonably believes that the prescription is valid.

(3) A prescription is valid only if—

(a) it is in indelible writing, dated and signed with the usual signature of a medical practitioner or dental practitioner;

(b) it states the name, qualification and address of the person signing it;

(c) it states the name and address of the person for whose treatment it is given;

(d) in the case of a prescription of a dental practitioner, it bears the words "for dental treatment only";

(e) it indicates the total amount of the drug to be supplied or dispensed and the dose to be taken or the manner of its application or use; and

(f) it has not previously been fully dispensed.

(4) A prescription may be presented without the physical presence of the person to whom the drug may otherwise be lawfully supplied or dispensed.

(5) A prescription shall be fully dispensed if the drug prescribed has been supplied or dispensed once, unless it clearly states

(a) the number of times it may be dispensed; and

(b) the intervals at which it may be dispensed, and shall in that case, be fully dispensed if the drug prescribed has been supplied or dispensed the stated number of times.

(6) Subsection (1) (a) shall not apply-

(a) where the drug is supplied or dispensed, whether personally or on a signed order, to a medical practitioner, dental practitioner or pharmacist or to a pharmacy for the purpose of being subsequently supplied or dispensed or

for the purpose of being subsequently used for scientific education or research; or

(b) where the drug is supplied or dispensed from the dispensing department of an approved institution in accordance with regulations made under this Act.

(7) For the avoidance of doubt, class AI drugs, class AII drugs and class B drugs shall not be supplied or dispensed in the absence of a pharmacist.

(8) A pharmacist shall not supply or dispense a class AI drug, class AII drug or a class B drug to a person that the pharmacist does not reasonably believe is the person to whom the drug may properly be supplied or dispensed.

38. Supply, dispensing and mixing of restricted drugs by nurses, midwives and dispensers

(1) The Minister may by regulations, after consultation with the Authority, authorise a person registered or enrolled under the Nurses and Midwives Act or the Allied Health Professionals Act to supply or dispense restricted drugs.

(2) The supply and dispensing of restricted drugs under this section shall be subject to the following conditions —

(a) the restricted drug shall be distinctly labelled with the name and address of the person by whom it is supplied or dispensed except where the drug is supplied or dispensed under the direct supervision or in the presence of a medical practitioner, dental practitioner or pharmacist;

(b) the following particulars shall, within twenty-four hours after the restricted drug has been supplied or dispensed, be entered in a prescription drug record—

(i) the date on which the restricted drug was supplied or dispensed;

(ii) the ingredients and quantity supplied or dispensed;

(iii) the name and address of the person to whom the restricted drug was supplied or dispensed; and

(iv) the name and address of the person by whom the prescription was given.

(3) The prescription drug record kept under this section shall be open to inspection by the Authority.

(4) A nurse, midwife or dispenser may under the immediate supervision of a pharmacist, mix or compound a class AI drug, class AII drug or a class B drug.

(5) Notwithstanding subsection (4), a nurse, midwife or dispenser may compound drugs that he or she is licensed to supply or dispense in a drug shop under section 29.

39. Promotion of drugs

A drug registered under this Act may subject to regulations made by the Minister in consultation with the Authority, be promoted by giving free samples of the drug to persons who may lawfully possess the drug.

40. Loss of class AI drugs and class AII drugs

(1) A medical practitioner, dental practitioner or pharmacist who supplies or dispenses a class AI drug or a class AII drug shall, upon the loss of that drug in his or her possession or control or of any records kept under this Act in relation to that drug, report that loss to the Authority, within seven days of the loss, giving particulars of the ingredients and quantities of the drug or the particulars of the records lost.

(2) A person who contravenes this section commits an offence and is liable on conviction, to a fine not exceeding two hundred fifty currency points or to a term of imprisonment not exceeding seven years or to both.

41. Prescription drugs record

(1) A pharmacist in charge of a pharmacy and a person licensed under section 29 to operate a drug shop shall keep in respect to the drugs supplied or dispensed at the pharmacy or drug shop respectively, in the prescribed form, a prescription drugs record which shall indicate the drug supplied or dispensed.

(2) The prescription drugs record shall be open to inspection by the Authority.

(3) A pharmacist or person licensed to operate a drug shop who contravenes this section commits an offence and is liable on conviction to a fine not exceeding three hundred currency points or imprisonment not exceeding three years, or both.

42. Prohibition of supply or dispensing of drugs in certain cases

(1) The Authority may prohibit the supply or dispensing of a drug where —

(a) the information provided for purposes of registration of the drug is misleading;

(b) the use of the drug is likely to endanger the health of the users or cause other undesirable effects;

(c) the specifications of the drug, which were furnished to the Authority for purposes of registration of the drug, differ from the specifications of the analysis of the drug obtained from samples of the drug from the retail suppliers of the drug; or

(d) the descriptive matter published in relation to the drug, differs from that descriptive matter furnished to the Authority.

(2) In this section "sale" means sell by wholesale or retail and includes importation, advertising and delivering for sale.

43. Recall of drugs

(1) Where the Authority determines that a drug do not conform to the conditions of its registration or notification and where it is in public interest that the drug should not be made available to the public, the Authority shall—

(a) order the person granted a certificate of registration, notification or listing, as the case may be, or the authorised representative of that person or the importer of the drug, to recall and destroy the affected batches of the drug, at their own cost; or

(b) order that the supply of the affected batches of the drug be discontinued.

(2) A person shall not import, supply or dispense any drug or batch of a drug which is the subject of an order for recall made under subsection (1) (a).

(3) The Authority may order the destruction of a drug referred to in subsection (1).

(4) Notwithstanding this section, a manufacturer or person granted a certificate of registration, notification or listing of a drug, as the case may be, or the authorized representative of that person respectively, or the importer of a drug or batch of a drug, may upon notification to the Authority, as may be prescribed, recall the drug or batch of the drug from the market.

(5) A person that contravenes this section commits an offence and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding ten thousand currency points; and

(b) in case of an individual, to a fine not exceeding five thousand currency points or imprisonment not exceeding five years, or both.

44. Withdrawal of drugs

(1) A person granted a certificate of registration, notification or listing holder of a drug or the authorised representative of that person or the importer, may upon notification to the Authority, as may be prescribed, withdraw the drug from the market.

(2) The Authority may where it deems fit and on its own decision, withdraw a drug from the market.

(3) The Authority shall remove from the register, the drug that is withdrawn from the market under this section.

45. Deception of consumers

(1) A person shall not package, label, advertise, supply or dispense a drug in a manner that is false, misleading or deceptive or that misbrands the drug as to its character, constitution, value, potency, quality, composition merits or safety.

(2) For the purposes of subsection (1), a drug is "misbranded"—

(a) if the drug is made to appear to be of a better or greater therapeutic value than it really is;

(b) if the drug is not labelled in the prescribed manner, or

(c) if the label or the container of the drug or anything accompanying the drug bears a statement, design or device which makes a false claim for the drug, or which is false or misleading.

(3) A person that packages, labels, advertises, supplies or dispenses a drug contrary to this section commits an offence and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding ten thousand currency points; and

(b) in case of an individual, to a fine not exceeding five thousand currency points or imprisonment not exceeding five years, or both.

46. Advertisement of drugs

(1) A person that intends to advertise a drug shall, upon payment of the prescribed fees and using the procedure prescribed by regulations made under this Act, submit the advertisement to the Authority for approval.

(2) A person that intends to advertise a drug by-

(a) publication of information on the drug or by promotion or distribution of information on the drug;

(b) bringing to the notice of the public information on the drug by causing or permitting to be published, promoted, distributed, information on the drug; or

(c) bringing to the notice of the public, information on the drug in any other manner,

shall comply with the requirements prescribed by regulations made under this Act.

(3) Notwithstanding subsection (2), a person —

(a) shall not advertise or promote any drug or cause any product to be advertised or promoted as a drug if that product is not a drug; or

(b) shall not advertise or promote any drug or cause any drug to be advertised or promoted in such a way as to represent the drug as usable for any purpose other than that for which it has been registered.

(4) A person that advertises a drug contrary to this section commits an offence and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding five thousand currency points; and

(b) in the case of an individual, to a fine not exceeding three hundred currency points or imprisonment not exceeding five years, or both.

47. Manufacture, distribution, importation, exportation, supply and dispensing of falsified drugs prohibited

(1) A person shall not manufacture, distribute, import, export, supply, dispense or offer for sale any falsified drug.

(2) A drug shall be deemed to be falsified where it is deliberately and fraudulently mislabeled with respect to its identity or source.

(3) "Falsified drug" includes—

(a) a drug with incorrect ingredients;

(b) a drug with wrong ingredients;

(c) a drug without active ingredients;

(d) a drug with incorrect quantities of the active ingredients:

(e) an adulterated drug: and

(f) a drug whose packages are not as prescribed.

(4) For the purposes of subsection (3)(e), a drug shall not be deemed to be adulterated only by reason of the fact that—

(a) there is added to the drug some substance or ingredient which is required for the manufacture or carriage of the drug where the addition of the substance or ingredient is not intended to increase the bulk, weight or measure of the drug or to conceal the inferior quality or other defects of the drug: or

(b) in the process of manufacture, some extraneous substance unavoidably became intermixed with the drug.

(5) A person that contravenes this section commits an offence and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding twenty thousand currency points: and

(b) in case of an individual, to a fine not exceeding five thousand currency points or imprisonment not exceeding fifteen years, or both.

48. Supply or dispensing of substandard drugs prohibited

(1) A person shall not—

(a) supply or dispense a drug which is not of the nature, substance or quality specified in the prescription of the purchaser or which is not demanded by the purchaser;

(b) supply or dispense a drug which does not conform to the standards on efficacy, safety and quality provided in an authorised pharmacopoeia recognised by the Authority;

(c) supply or dispense a drug which is not wholesome or which does not conform to the prescription under which it is supplied or dispensed; or

(d) supply, dispense or offer or expose for supply or dispensing, or have possession of a drug for the purpose of supply or dispensing the drug, where the composition of the drug is affected by an addition to it or subtraction from it of any substance.

(2) A person shall not offer for sale or administer to any person any drug which is not fit for the intended purpose.

(3) A drug which is not fit for the intended purpose shall be kept in a separate place labelled with the words "not fit for intended purpose".

(4) For purposes of subsection (2) and (3) "not fit for intended purpose" means a drug which is not safe or efficacious or which is of an undesired quality or which is expired.

(5) A person that contravenes this section commits an offence and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding five thousand currency points; and

(b) in case of an individual, to a fine not exceeding three thousand currency points or imprisonment not exceeding five years, or both.

49. Monitoring of drugs for quality

(1) A person that manufactures, distributes or imports drugs shall, as may be prescribed by regulations made under this Act, establish a system for monitoring the drugs.

(2) The monitoring system referred to in subsection (1), shall be approved by the Authority and may be inspected by the Authority, as may be prescribed.

(3) The Authority may require a manufacturer or distributor of drugs to provide for the placement of a unique identifier on the package of each drug, as may be prescribed.

PART IV—CLINICAL TRIALS

50. Authorisation to conduct clinical trials

(1) A person shall not conduct a clinical trial without the authorisation of the Authority.

(2) A person that intends to conduct a clinical trial shall, upon payment of the prescribed fees, make an application to the Authority in a form prescribed by regulations made under this Act and the application shall include the protocol for the field trial.

(3) Where a clinical trial is for a drug which is registered under this Act, the clinical trial shall be for the aspects for which an amendment of the registration is necessary or for the aspects that are not included in the registration.

(4) A person that conducts a clinical trial shall carry out safety surveillance for the drug undergoing clinical trial.

(5) The Authority shall authorise the conduct of a clinical trial by issuing a clinical trial certificate and authorisation for a clinical trial may be subject to conditions, which shall be included in the clinical trial certificate.

(6) The Authority may—

(a) on application by the person to whom a certificate is granted under subsection (5) and upon payment of the prescribed fees, authorise any amendment to a clinical trial protocol; or

(b) at its instance, direct any amendments to the clinical trial protocol.

(7) The Authority may, on application by the person to whom a certificate is granted under subsection (5) and upon payment of the prescribed fees, extend the duration of a clinical trial.

(8) The Authority may by notice, in writing, to the person authorised to conduct a clinical trial, suspend or terminate a clinical trial, in accordance with regulations made under this Act.

(9) The Authority shall monitor a clinical trial to ensure that—

(a) the subjects of the clinical trial and the general public are protected against any risks that may result from the clinical trial; and

(b) the specific and general conditions of the clinical trial are adhered to.

(10) A person that conducts a clinical trial in contravention of this section commits an offence and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding ten thousand currency points; and

(b) in case of an individual, to a fine not exceeding five thousand currency points or imprisonment not exceeding fifteen years, or both.

51. Good clinical practices

(1) A clinical trial shall comply with good clinical practices, as may be prescribed by regulations made under this Act.

(2) The person in charge of a clinical trial shall—

(a) ensure that adequate protection, from the risks or adverse events of the clinical trial, is provided to the subjects of a clinical trial and the general public;

(b) ensure that the conditions of the clinical trial are adhered to by the person conducting the trial; and

(c) report to the Authority, all adverse reactions and adverse events, as may be prescribed by the regulations made under this Act.

(3) The Authority may, at any time, inspect the clinical trial site to assess compliance with good clinical practices.

(4) A person that conducts a clinical trial in contravention of this section commits an offence and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding ten thousand currency points; and

(b) in case of an individual, to a fine not exceeding five thousand currency points or imprisonment not exceeding fifteen years, or both.

PART V—PHARMACOVIGILANCE

52. Obligation for manufacturers *etc.* to establish pharmacovigilance systems

(1) A person that manufactures, distributes or imports drugs shall, in accordance with regulations made under

this Act. establish a pharmacovigilance system for the monitoring of the drugs.

(2) Where it is deemed necessary. the Authority may at any time. request the person referred to in subsection (1) to conduct for the drugs. a safety study or an efficacy study. or a safety study and an efficacy study.

(3) The pharmacovigilance system. shall be approved by the Authority and may be inspected by the Authority. as may be prescribed.

(4) Where a person referred to in this section does not establish a pharmacovigilance system. the Authority shall not issue a certificate of good manufacturing practices or may take any other action as may be prescribed by regulations made under this Act.

53. Obligation of health care professionals to report adverse reactions and adverse events of drugs

A health care professional shall. monitor the safety of the drugs supplied or dispensed to a patient and where that health care professional becomes aware of any adverse reaction or adverse event of drugs arising from the use of the drugs or which reveals any defect in the drugs. the health care professional shall using the prescribed format. make a report to the Authority.

54. Pharmacovigilance by the Authority

The Authority shall monitor and analyse the adverse reactions and adverse events of drugs through—

(a) monitoring and analysing the adverse reactions or adverse events of drugs;

(b) identifying the adverse events relating to clinical trials;

(c) establishing the causality of the adverse reactions or adverse events and ensure that remedial action is taken; and

(d) sharing with regional and international safety monitoring systems, information on adverse reactions and adverse events and the remedial action taken.

PART VI—REGULATION OF MEDICAL DEVICES

55. Classification of medical devices

For the purposes of this Act, medical devices shall be classified as shall be specified in regulations to be made under this Act.

56. Registration, notification and listing of medical devices

(1) A person shall not manufacture, distribute, import, export or supply by wholesale or retail, a medical device unless the medical device is registered, notified or listed, by the Authority, as the case may be.

(2) Subsection (1) shall not apply—

(a) where a medical device is required by the Authority for purposes of registration, notification or listing under this Act;

(b) where a medical device is required for purposes of conducting a clinical trial;

(c) with respect to importation, where a medical device is imported for personal use; or

(d) where the manufacture or importation of a medical device is required for an emergency situation.

(3) Any person that so wishes may, in the prescribed form and on payment of the prescribed fees, make an application to the Authority, for the registration, notification or listing of a medical device.

(4) The requirements for registration, notification and listing of medical devices shall be prescribed by regulations made under this Act and shall include—

(a) the classes of medical devices to be registered, notified and listed, respectively;

(b) the conditions for registration, notification and listing of medical devices; and

(c) the categories of businesses that may supply specified classes of medical devices and the premises at which specified classes of medical devices may be supplied.

(5) The Authority shall register, notify or list the medical device that satisfies the requirements of this section and grant the person who makes the application a certificate of registration, notification or listing, as the case may be.

(6) A medical device that is registered, notified or listed under this section shall for each financial year, be retained on the register on the payment of the prescribed fees, by the person that caused the registration, notification or listing or by any other person, except where the registration, notification or listing is cancelled or suspended by the Authority.

(7) A person that manufactures, distributes, imports, exports or supplies by wholesale or retail a medical device that is not registered, notified or listed by the Authority commits an offence and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding five thousand currency points; and

(b) in case of an individual, to a fine not exceeding five hundred currency points or imprisonment not exceeding ten years, or both.

57. Licence for the manufacture of medical devices

(1) A person shall not manufacture a medical device without a licence issued by the Authority.

(2) A person that seeks to manufacture a medical device shall, on payment of the prescribed fees, make an application to the Authority, in the format prescribed by regulations made under this Act.

(3) The requirements for the manufacture of medical devices including the requirement for inspection of the premises to be used for the manufacture of medical devices and the requirement to establish quality management systems shall be prescribed by regulations made under this Act.

(4) The Authority shall grant a person that satisfies the requirements of this section, a licence for the manufacture of the medical device specified in the licence.

(5) A person that manufactures a medical device contrary to this section commits an offence and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding five thousand currency points; and

(b) in case of an individual, to a fine not exceeding five thousand currency points or imprisonment not exceeding five years, or both.

58. Importation of medical devices

(1) A person shall not import a medical device without a licence issued by the Authority, prior to the importation.

(2) Subsection (1) shall not apply –

(a) where the importation of the medical device is required by the Authority for purposes of registration, notification or listing of the medical device under this Act;

(b) where the medical device is imported for purposes of conducting a clinical trial;

(c) where the medical device is imported for personal use; or

(d) where the importation of the medical device is required for an emergency situation.

(3) A person that seeks to import a medical device shall on payment of the prescribed fees, make an application to the Authority, in the format prescribed by regulations made under this Act.

(4) The requirements for the importation of medical devices, including the conditions for importation, shall be prescribed by regulations made under this Act.

(5) The Authority shall grant a person that satisfies the requirements of this section, a licence to import the medical device specified in the licence.

(6) Where a medical device is imported into Uganda contrary to the provisions of this Act, the Authority shall—

(a) order the person granted a certificate of registration, notification or listing for the medical device, as the case may be, or the authorised representative of that person or the importer of the medical device, to destroy the medical device, at their own cost; or

(b) order the person granted a certificate of registration, notification or listing for the medical device, as the case

may be, or the authorised representative of that person or the importer of the medical device, to re-export the medical device to the country of import, at their own cost.

(7) Where medical devices are imported into Uganda contrary to the provisions of this Act and the importer cannot be traced, the Authority shall destroy the medical devices at its cost.

(8) A person that imports medical devices contrary to this section commits an offence and is liable on conviction–

(a) in case of a corporate body, to a fine not exceeding five thousand currency points; and

(b) in case of an individual, to a fine not exceeding five thousand currency points or imprisonment not exceeding five years, or both.

59. Licence for the distribution of medical devices

(1) A person shall not distribute medical devices without a licence issued by the Authority.

(2) A person that seeks to distribute medical devices shall, on payment of the prescribed fees, make an application to the Authority, in the format prescribed by regulations made under this Act.

(3) The requirements for the distribution of medical devices including the requirement for inspection of premises to be used for the distribution of medical devices shall be prescribed by regulations made under this Act.

(4) The Authority shall grant a person that satisfies the requirements of this section, a licence to distribute the medical devices specified in the licence.

(5) A person that distributes medical devices contrary to this section commits an offence and is liable on conviction -

(a) in case of a corporate body, to a fine not exceeding five thousand currency points: and

(b) in case of an individual, to a fine not exceeding five thousand currency points or imprisonment not exceeding five years, or both.

60. Licensing of premises to be used for wholesale of medical devices

(1) The Authority shall license the premises to be used for the business of wholesale of medical devices.

(2) The requirements for the supply of medical devices by wholesale, including the requirement for inspection of premises to be used prior to licensing, shall be prescribed by regulations made under this Act.

(3) The Authority shall grant a person that satisfies the requirements of this section a licence to supply medical devices by wholesale.

(4) A person issued with a licence to operate a business of wholesale of medical devices shall be required to comply with good storage practices and good distribution practice guidelines approved by the Authority.

(5) A person that engages in the business of wholesale of medical devices contrary to this section commits an offence and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding five thousand currency points; and

(b) in case of an individual, to a fine not exceeding five thousand currency points or imprisonment not exceeding five years, or both.

61. Reporting of defects and adverse events to the Authority

(1) Where the person granted a certificate of registration, notification or listing for a medical device or the authorised representative of that person or the importer of a medical device becomes aware of any adverse event arising from the use of the medical device or where an adverse event reveals any defect in the medical device, that person shall, using the prescribed format, make a report to the Authority.

(2) A health care professional shall, monitor the safety of a medical device supplied to a patient and where a health care professional becomes aware of any adverse event arising from the use of a medical device or where an adverse event reveals any defect in a medical device, the health care professional shall, using the prescribed format, make a report to the Authority.

62. Exportation of medical devices

(1) A person shall not export a medical device without a licence issued by the Authority, prior to the exportation.

(2) A person that seeks to export medical devices shall, on payment of the prescribed fees, make an application to the Authority, in the format prescribed by regulations made under this Act.

(3) The requirements for the exportation of medical devices, including the conditions for exportation shall be prescribed by regulations made under this Act.

(4) The Authority shall grant a person that satisfies the requirements of this section, a licence to export the medical device specified in the licence.

(5) A person that exports a medical device contrary to this section commits an offence and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding five thousand currency points; and

(b) in case of an individual, to a fine not exceeding five thousand currency points or imprisonment not exceeding five years, or both.

PART VII—REGULATION OF COSMETIC PRODUCTS

63. Classification of cosmetic products

For the purposes of this Act, cosmetic products shall be classified as shall be specified in regulations to be made under this Act.

64. Registration, notification and listing of cosmetic products

(1) A person shall not manufacture, distribute, import, export or supply by wholesale or retail a cosmetic product unless the cosmetic product is registered, notified or listed by the Authority, as the case may be.

(2) Subsection (1) shall not apply-

(a) where a cosmetic product is required by the Authority for purposes of registration, notification or listing under this Act;

(b) where a cosmetic product is required for purposes of conducting a clinical trial;

(c) with respect to importation, where a cosmetic product is imported for personal use; or

(d) where the manufacture or importation of a cosmetic product is required for an emergency situation.

(3) Any person that so wishes may, in the prescribed form and on payment of the prescribed fees, make an application to the Authority, for the registration, notification or listing of a cosmetic product

(4) The requirements for registration, notification and listing of cosmetic products shall be prescribed by regulations made under this Act and shall include—

(a) the classes of cosmetic products to be registered, notified and listed, respectively;

(b) the conditions for registration, notification and listing of cosmetic products; and

(c) the categories of businesses that may supply specified classes of cosmetic products and the premises at which specified classes of cosmetic products may be supplied.

(5) The Authority shall register, notify or list the cosmetic product that satisfies the requirements of this section and grant the person who makes the application a certificate of registration, notification or listing, as the case may be.

(6) A person that manufactures, imports, exports, distributes or supplies a cosmetic product that is not registered, notified or listed by the Authority commits an offence and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding five thousand currency points; and

(b) in case of an individual, to a fine not exceeding five hundred currency points or imprisonment not exceeding ten years, or both.

65. Licence for the manufacture of cosmetic products

(1) A person shall not manufacture a cosmetic product without a licence issued by the Authority.

(2) Subsection (1) shall not apply for the manufacture of samples of a cosmetic product for purposes of registration, notification or listing of the cosmetic product or conducting a clinical trial for the cosmetic product.

(3) A person that seeks to manufacture a cosmetic product shall, on payment of the prescribed fees, make an application to the Authority in a format prescribed by regulations made under this Act.

(4) The requirements for the manufacture of cosmetic products including the requirement for inspection of the premises to be used for the manufacture of cosmetic products and the requirement to establish quality management systems shall be prescribed by regulations made under this Act.

(5) The Authority shall grant a person that satisfies the requirements of this section, a licence for the manufacture of the cosmetic products specified in the licence.

(6) A person that manufactures a cosmetic product contrary to this section commits an offence and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding five thousand currency points; and

(b) in case of an individual, to a fine not exceeding five thousand currency points or imprisonment not exceeding five years, or both.

66. Importation of cosmetic products

(1) A person shall not import a cosmetic product without a licence issued by the Authority, prior to the importation.

(2) Notwithstanding subsection (1), the Authority may for a specified purpose, and subject to conditions the Authority may deem

fit. authorise the importation of a cosmetic product which is not registered under this Act where the importation—

(a) is for purposes of conducting a clinical trial;

(b) is for personal use;

(c) is required for an emergency situation; or

(d) is required by the Authority for purposes of registering, notifying or listing the cosmetic product.

(3) A person that seeks to import cosmetic products shall, on payment of the prescribed fees, make an application to the Authority, in the format prescribed by regulations made under this Act.

(4) The requirements for the importation of cosmetic products, including the conditions for importation, shall be prescribed by regulations made under this Act.

(5) The Authority shall grant a person that satisfies the requirements of this section, a licence to import the cosmetic products specified in the licence.

(6) Where a cosmetic product is imported into Uganda contrary to the provisions of this Act, the Authority shall—

(a) order the person granted a certificate of registration, notification or listing for the cosmetic product, as the case may be, or the authorised representative of that person or the importer of the cosmetic product, to destroy the cosmetic product, at their own cost; or

(b) order the person granted a certificate of registration, notification or listing for a cosmetic product, as the case may be, or the authorised representative of that person or the

importer of the cosmetic product, to re-export the cosmetic product to the country of import, at their own cost.

(7) Where cosmetic products are imported into Uganda contrary to the provisions of this Act and the importer cannot be traced, the Authority shall destroy the cosmetic products at its cost.

(8) A person that imports a cosmetic product contrary to this section commits an offence and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding five thousand currency points; and

(b) in case of an individual, to a fine not exceeding five thousand currency points or imprisonment not exceeding five years, or both.

67. Power of Minister to prohibit importation of cosmetic products

The Minister may, on the advice of the Authority, by notice in three newspapers of nationwide circulation, prohibit the importation of a cosmetic product where—

(a) the Minister is satisfied that the use of the cosmetic product is likely to cause risk to human beings;

(b) the cosmetic product contains ingredients, in such quantity for which there is no justification and the ingredients are likely to cause risk to human beings,

and that in the public interest it is necessary or expedient to prohibit the importation of the cosmetic product.

68. Licence for the distribution of cosmetic products

(1) A person shall not distribute cosmetic products without a licence issued by the Authority.

(2) A person that seeks to distribute cosmetic products shall, on payment of the prescribed fees, make an application to the Authority in a format prescribed by regulations made under this Act.

(3) The requirements for the distribution of cosmetic products including the requirement for inspection of premises to be used for the distribution of cosmetic products shall be prescribed by regulations made under this Act.

(4) The Authority shall grant a person that satisfies the requirements of this section, a licence to distribute cosmetic products.

(5) A person that distributes cosmetic products contrary to this section commits an offence and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding five thousand currency points; and

(b) in case of an individual, to a fine not exceeding five thousand currency points or imprisonment not exceeding five years, or both.

69. Exportation of cosmetic products

(1) A person shall not export a cosmetic product from Uganda without a licence issued by the Authority, prior to the exportation.

(2) A person that seeks to export cosmetic products shall, on payment of the prescribed fees, make an application to the Authority, in the format prescribed by regulations made under this Act.

(3) The requirements for the exportation of cosmetic products, including the conditions for exportation shall be prescribed by regulations made under this Act.

(4) The Authority shall grant a person that satisfies the requirements of this section, a licence to export the cosmetic product specified in the licence.

(5) A person that exports cosmetic products contrary to this section commits an offence and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding five thousand currency points; and

(b) in case of an individual, to a fine not exceeding five thousand currency points or imprisonment not exceeding five years, or both.

PART VIII —REGULATION PUBLIC HEALTH PRODUCTS

70. Categories of public health products

For purposes of this Act, public health products shall be categorised in regulations to be made under this Act, as specified in this section—

(a) category 1 public health products, which shall comprise of public health products which require listing by the Authority prior to manufacture, importation, exportation, distribution or supply;

(b) category 2 public health products, which shall comprise of public health products which require notification by the Authority prior to manufacture, importation, exportation, distribution or supply and which include—

(i) cleaning products which contain as active ingredients, anionic or nonionic surfactants;

(ii) adhesives which contain as active ingredients, alkyl cyanoacrylate; and

(iii) swimming pool disinfectants which contain as active ingredients, calcium hypochlorite, sodium hypochlorite, dichloroisocyanuric acid and its salts or trichloroisocyanuric acid;

(c) category 3 public health products which shall comprise public health products which are required to be registered by the Authority prior to manufacture, importation, exportation, distribution or supply and which include—

(i) household pesticides or public health pesticides containing as active ingredients, chlorpyrifos or pyrethroids; and

(ii) cleaning products and disinfectants containing as active ingredients, acids, alkalines or aldehydes;

(d) category 4 public health products which shall comprise public health products whose importation, exportation and possession is prohibited, including dichlorodiphenyltrichloroethane (DDT), disulfoton, chlordane, dieldrin and neonicotinoids.

71. Registration, notification and listing of public health products

(1) A person shall not manufacture, distribute, import, export or supply by wholesale or retail a public health product unless the public health product is registered, notified or listed by the Authority, as the case may be.

(2) Subsection (1) shall not apply—

(a) where the public health product is required by the Authority for purposes of registration, notification or listing under this Act;

(b) where the public health product is required for purposes of conducting a clinical trial;

(c) with respect to importation, where the public health product is imported for personal use; or

(d) where the manufacture or importation of the public health product is required for an emergency situation.

(3) Any person that so wishes may, in the prescribed form and on payment of the prescribed fees, make an application to the Authority, for the registration, notification or listing of a public health product.

(4) The requirements for registration, notification or listing of a public health product shall be prescribed by regulations made under this Act and shall include—

(a) the categories of public health products to be registered, notified and listed;

(b) the conditions for registration, notification and listing of public health products; and

(c) the categories of businesses that may supply specified classes of public health products and the premises at which specified classes of public health products may be supplied.

(5) The Authority shall register, notify or list the public health product that satisfies the requirements of this section and grant the person who makes the application a certificate of registration, notification or listing, as the case may be.

(6) A person that manufactures, imports, exports, distributes or supplies a public health product that is not registered, notified or listed by the Authority commits an offence and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding five thousand currency points; and

(b) in case of an individual, to a fine not exceeding five hundred currency points or imprisonment not exceeding ten years, or both.

72. Licence for the manufacture of public health products

(1) A person shall not manufacture a public health product without a licence issued by the Authority.

(2) Subsection (1) shall not apply to the manufacture of samples of a public health product for purposes of conducting a clinical trial for the public health product.

(3) A person that seeks to manufacture a public health product shall, on payment of the prescribed fees, make an application to the Authority in a format prescribed by regulations made under this Act.

(4) The requirements for the manufacture of public health products including the requirement for inspection of the premises to be used for the manufacture of public health products and the requirement to establish quality management systems shall be prescribed by regulations made under this Act.

(5) The Authority shall grant a person that satisfies the requirements of this section, a licence for the manufacture of the public health products specified in the licence.

(6) A person that manufactures a public health product contrary to this section commits an offence and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding five thousand currency points; and

(b) in case of an individual, to a fine not exceeding five thousand currency points or imprisonment not exceeding five years, or both.

73. Importation of public health products

(1) A person shall not import a public health product without a licence issued by the Authority, prior to the importation.

(2) Subsection (1) shall not apply where the importation—

(a) is required by the Authority for purposes of registration, notification or listing under this Act;

(b) is for purposes of conducting a clinical trial for the public health product; or

(c) is required for an emergency situation.

(3) A person that seeks to import public health products shall, on payment of the prescribed fees, make an application to the Authority in the format prescribed by regulations made under this Act.

(4) The requirements for the importation of public health products, including the conditions for importation, shall be prescribed by regulations made under this Act.

(5) The Authority shall grant a person that satisfies the requirements of this section, a licence to import the public health products specified in the licence.

(6) Where a public health product is imported into Uganda contrary to the provisions of this Act, the Authority shall—

(a) order the person granted a certificate of registration, notification or listing for the public health product, as the case may be, or the authorised representative of that person or the importer of the public health product, to destroy the public health product, at their own cost; or

(b) order the person granted a certificate of registration, notification or listing, for the public health product, the case may be, or the authorised representative of that person or the importer of the public health product, to re-export the public health product to the country of import, at their own cost.

(7) Where a public health product is imported into Uganda contrary to the provisions of this Act and the importer cannot be traced, the Authority shall destroy the public health product at its cost.

(8) A person that imports a public health product contrary to this section commits an offence and is liable on conviction—
(a) in case of a corporate body, to a fine not exceeding five thousand currency points; and
(b) in case of an individual, to a fine not exceeding five thousand currency points or imprisonment not exceeding five years, or both.

74. Licence for the distribution of public health products

(1) A person shall not distribute public health products without a licence issued by the Authority.

(2) A person that seeks to distribute public health products shall, on payment of the prescribed fees, make an application to the Authority in a format prescribed by regulations made under this Act.

(3) The requirements for the distribution of public health products including the requirement for inspection of premises to be used for the distribution of public health products shall be prescribed by regulations made under this Act.

(4) The Authority shall grant a person that satisfies the requirements of this section, a licence to distribute public health products.

(5) A person that distributes public health products contrary to this section commits an offence and is liable on conviction

(a) in case of a corporate body, to a fine not exceeding five thousand currency points; and

(b) in case of an individual, to a fine not exceeding five thousand currency points or imprisonment not exceeding five years, or both.

75. Exportation of public health products

(1) A person shall not export a public health product from Uganda without a licence issued by the Authority, prior to the exportation.

(2) A person that seeks to export public health products shall, on payment of the prescribed fees, make an application to the Authority in the format prescribed by regulations made under this Act.

(3) The requirements for the exportation of public health products, including the conditions for exportation shall be prescribed by regulations made under this Act.

(4) The Authority shall grant a person that satisfies the requirements of this section, a licence to export the public health products specified in the licence.

(5) A person that exports public health products contrary to this section commits an offence and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding five thousand currency points; and

(b) in case of an individual, to a fine not exceeding five thousand currency points or imprisonment not exceeding five years, or both.

PART IX—REGULATION OF NUTRITIONAL SUPPLEMENTS

76. Classification of nutritional supplements

For the purposes of this Act, nutritional supplements shall be classified as may be specified in to be made regulations made under this Act.

77. Registration, notification and listing of nutritional supplements

(1) A person shall not manufacture, distribute, import, export or supply by wholesale or retail, nutritional supplements unless the

nutritional supplement is registered, notified or listed, by the Authority, as the case may be.

(2) Subsection (1) shall not apply—

(a) where the nutritional supplement is required by the Authority for purposes of registration, notification or listing of the nutritional supplement under this Act;

(b) where the nutritional supplement is required for purposes of conducting a clinical trial;

(c) with respect to importation, where the nutritional supplement is imported for personal use; or

(d) where the manufacture or importation of the nutritional supplement is required for an emergency situation.

(3) Any person that so wishes may, in the prescribed form and on payment of the prescribed fees, make an application to the Authority, for the registration, notification or listing of a nutritional supplement.

(4) The requirements for registration, notification and listing of nutritional supplements shall be prescribed by regulations made under this Act and shall include—

(a) the classes of nutritional supplements to be registered, notified and listed, respectively;

(b) the conditions for registration, notification or listing of nutritional supplements; and

(c) the categories of businesses that may supply specified classes of nutritional supplements and the premises at which specified classes of nutritional supplements may be supplied

(5) The Authority shall register, notify or list the nutritional supplement that satisfies the requirements of this section and grant the person who makes the application a certificate of registration, notification or listing, as the case may be.

(6) A person that manufactures, imports, exports, distributes or supplies nutritional supplements that is not notified or listed by the Authority commits an offence and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding five thousand currency points; and

(b) in case of an individual, to a fine not exceeding five hundred currency points or imprisonment not exceeding ten years, or both.

78. Licence for the manufacture of nutritional supplements

(1) A person shall not manufacture nutritional supplements without a licence issued by the Authority.

(2) Subsection (1) shall not apply to the manufacture of samples of a nutritional supplement for purposes of conducting a clinical trial for the nutritional supplement.

(3 A person that seeks to manufacture a nutritional supplement shall, on payment of the prescribed fees, make an application to the Authority in a format prescribed by regulations made under this Act.

(4) The requirements for the manufacture of nutritional supplements including the requirement for inspection of premises to be used for the manufacture of nutritional supplements and the requirement to establish quality management systems shall be prescribed by regulations made under this Act.

(5) The Authority shall grant a person that satisfies the requirements of this section, a licence for the manufacture of the nutritional supplements specified in the licence.

(6) A person that manufactures nutritional supplements contrary to this section commits an offence and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding five thousand currency points; and

(b) in case of an individual, to a fine not exceeding five thousand currency points or imprisonment not exceeding five years, or both.

79. Importation of nutritional supplements

(1) A person shall not import a nutritional supplement without a licence issued by the Authority, prior to the importation.

(2) Notwithstanding subsection (1), the Authority may for a specified purpose, and subject to conditions the Authority may deem fit, authorise the importation of a nutritional supplement which is not registered, notified or listed under this Act where—

(a) the importation is required for the purposes of conducting a clinical trial;

(b) the importation is for personal use;

(c) the importation is required for an emergency situation; or

(d) the importation is for purposes of registering, notifying or listing the nutritional supplement.

(3) A person that seeks to import a nutritional supplement shall, on payment of the prescribed fees, make an application to the Authority in the format prescribed by regulations made under this Act.

(4) The requirements for the importation of nutritional supplements, including the conditions for importation, shall be prescribed by regulations made under this Act.

(5) The Authority shall grant a person that satisfies the requirements of this section, a licence to import nutritional supplements.

(6) Where nutritional supplements are imported into Uganda contrary to the provisions of this Act, the Authority shall—

(a) order the person granted a certificate of registration, notification or listing for the nutritional supplement, as the case may be, or the authorised representative of that person or the importer of the nutritional supplement, to destroy the nutritional supplement, at their own cost; or

(b) order the person granted a certificate of registration, notification or listing for the nutritional supplement, as the case may be, or the authorised representative of that person or the importer of the nutritional supplement, to re-export the nutritional supplement to the country of import, at their own cost.

(7) Where nutritional supplements are imported into Uganda contrary to the provisions of this Act and the importer cannot be traced, the Authority shall destroy the nutritional supplements at its cost.

(8) A person that imports nutritional supplements contrary to this section commits an offence and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding five thousand currency points; and

(b) in case of an individual, to a fine not exceeding five thousand currency points or imprisonment not exceeding five years, or both.

80. Licence for the distribution of nutritional supplements

(1) A person shall not distribute nutritional supplements without a licence issued by the Authority.

(2) A person that seeks to distribute nutritional supplements shall, on payment of the prescribed fees, make an application to the Authority in a format prescribed by regulations made under this Act.

(3) The requirements for the distribution of nutritional supplements including the requirement for inspection of premises to be used for the distribution of nutritional supplements shall be prescribed by regulations made under this Act.

(4) The Authority shall grant a person that satisfies the requirements of this section, a licence to distribute nutritional supplements.

(5) A person that distributes nutritional supplements contrary to this section commits an offence and is liable on conviction –

(a) in case of a corporate body, to a fine not exceeding five thousand currency points; and

(b) in case of an individual, to a fine not exceeding five thousand currency points or imprisonment not exceeding five years, or both.

81. Exportation of nutritional supplements

(1) A person shall not export a nutritional supplement without a licence issued by the Authority, prior to the exportation.

(2) A person that seeks to export nutritional supplements shall, on payment of the prescribed fees, make an application to the Authority, in the format prescribed by regulations made under this Act.

(3) The requirements for the exportation of nutritional supplements, including the conditions for exportation shall be prescribed by regulations made under this Act.

(4) The Authority shall grant a person that satisfies the requirements of this section. a licence to export the nutritional supplements specified in the licence.

(5) A person that exports nutritional supplements contrary to this section commits an offence and is liable on convictionn—

(a) in case of a corporate body. to a fine not exceeding five thousand currency points; and

(b) in case of an individual. to a fine not exceeding five thousand currency points or imprisonment not exceeding five years. or both.

PART XII—GENERAL REGULATION OF MEDICAL DEVICES, COSMETIC PRODUCTS, PUBLIC HEALTH PRODUCTS AND NUTRITIONAL SUPPLEMENTS

82. Application of Part

This Part shall. except where specifically provided. apply to medical devices. cosmetic products. public health products and nutritional supplements. which shall in this Part be referred to as "regulated products".

83. Conformity to standards of the Uganda National Bureau of Standards Act, Cap. 210

(1) Prior to the application of this Act. a regulated product shall where applicable. conform to the standard prescribed under the Uganda National Bureau of Standards Act.

(2) The Authority shall inspect the premises where a regulated product is manufactured. distributed or supplied. for conformity of the regulated product to the standard referred to in subsection (1).

(3) A person that manufactures, imports, exports, distributes or supplies a regulated product that does not conform to the prescribed standard commits an offence and is on conviction liable ton—

(a) in case of a corporate body, to a fine not exceeding five thousand currency points; and

(b) in case of an individual, to a fine not exceeding five thousand currency points or imprisonment not exceeding five years, or both.

84. Obligation for manufacturers *etc.* to establish monitoring systems and monitoring of regulated products by the Authority

(1) A person that manufactures, distributes or imports a regulated product shall, as may be prescribed by regulations made under this Act, establish a system for monitoring the regulated product.

(2) The monitoring system referred to in subsection (1), shall be approved by the Authority and may be inspected by the Authority, as may be prescribed.

(3) The Authority may require a manufacturer or distributor of a regulated product to provide for the placement of a unique identifier on the package of each regulated product, as may be prescribed by regulations.

(4) The Authority shall—

(a) monitor and analyse the adverse events and as may be applicable, the adverse reactions of using a regulated product;

(b) establish the causality of the adverse events and as may be applicable, the adverse reactions and ensure that remedial action is taken; and

(c) share information on the matters specified in this subsection, with regional and international safety monitoring systems.

(5) A person that contravenes subsection (1) or (3) commits an offence and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding five thousand currency points; and

(b) in case of an individual, to a fine not exceeding five hundred currency points or imprisonment not exceeding five years, or both.

85. Duty to maintain records of supply

A person granted a certificate of registration, notification or listing for a regulated product or the authorised representative of that person or the importer, manufacturer, distributor or supplier or dispenser of a regulated product shall keep a record of the supply of the product, and where required, produce the records for inspection by the Authority.

86. Conditions for licences and certificates for drugs, medical devices, cosmetic products, public health products and nutritional supplements

(1) The Authority may attach any conditions to a licence or certificate that it thinks necessary, and may from time to time vary the conditions of a licence or certificate, as may be prescribed by the regulations made under this Act.

(2) A licence or certificate issued under this Act may be renewed, upon payment of the prescribed fees, using the procedure prescribed by regulations made under this Act.

(3) The Authority may suspend or cancel a licence or a certificate issued for a regulated product where the conditions subject

to which the licence or certificate was issued are not complied with or where a person does not comply with any provision of this Act or regulations made under this Act.

87. Packaging and labelling of regulated products

(1) A regulated product shall be packaged and labelled as may be prescribed by regulations made under this Act.

(2) A person that manufactures, exports, imports, distributes or supplies a regulated product that is not packaged or labelled as prescribed commits an offence and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding five thousand currency points; and

(b) in case of an individual, to a fine not exceeding three thousand currency points or imprisonment not exceeding five years, or both.

88. Compliance with good manufacturing practices in Uganda

(1) The manufacturers of drugs, medical devices, cosmetic products, public health products and nutritional supplements in Uganda shall comply with good manufacturing practices, prescribed by regulations made under this Act or approved by the Authority.

(2) A manufacturer that seeks to be issued with a certificate of compliance with good manufacturing practices shall, upon payment of the prescribed fees, make an application to the Authority in the form and manner prescribed by the Authority.

(3) For the avoidance of doubt, the Authority shall not issue a certificate of compliance with good manufacturing practices except where the person has a licence to manufacture drugs, medical devices, cosmetic products, public health products and nutritional supplements, as the case may be, issued under this Act.

(4) Where the drugs, medical devices, cosmetic products, public health products or nutritional supplements to be imported into Uganda, the manufacturer shall comply with the good manufacturing practices determined by the Authority.-

(5) A certificate of good manufacturing practice issued under this section, shall be valid for the period specified in the certificate and shall be subject to review, as may be prescribed by regulations made under this Act.

89. Compliance with good storage practices and good distribution practices

(1) A distributor of drugs, medical devices, cosmetic products, public health products or nutritional supplements in Uganda shall comply with good storage practices and good distribution practices, as may be prescribed by regulations made under this Act.

(2) A person that seeks to be issued with a certificate of compliance with good storage practices and good distribution practices shall, upon payment of the prescribed fees, make an application to the Authority in the form and manner prescribed by the Authority.

(3) For the avoidance of doubt, the Authority shall not issue a certificate of compliance with good storage practices and good distribution practices except where the person has a licence to distribute drugs, medical devices, cosmetic products, public health products or nutritional supplements, as the case may be, issued under this Act.

(4) A certificate of good storage practice and good distribution practice issued under this section, shall be valid for the period specified in the certificate and shall be subject to review, as may be prescribed by regulations made under this Act.

90. Authorisation to conduct clinical trials or field trials for regulated products

(1) A person shall not without the authorisation of the Authority—

(a) conduct a clinical trial for medical devices, cosmetic products or nutritional supplements; or

(b) conduct a field trial for public health products.

(2) A person that intends to conduct a clinical trial or field trial for a regulated product shall upon payment of the prescribed fee, make an application to the Authority in a form prescribed by regulations made under this Act.

(3) Where a clinical trial or field trial is for a regulated product which is registered, notified or listed under this Act, as the case may be, the clinical trial or field trial shall be for the aspect for which an amendment of the registration, notification or listing is necessary or for the aspect that was not included in the registration, notification or listing.

(4) The Authority shall authorise the conduct of a clinical trial or field trial by issuing a clinical trial certificate or field trial certificate and authorisation for a clinical trial or field trial may be subject to conditions, which shall be included in the certificate.

(5) The Authority may, on application by the person to whom a certificate is granted under subsection (4) or at the instance of the Authority, authorise or direct, as the case may be, any amendments to the clinical trial protocol or field trial protocol.

(6) The Authority may, on application by the person to whom a certificate is granted under subsection (4) and upon payment of the prescribed fees, extend the duration of a clinical trial or field trial.

(7) The Authority may by notice, in writing, to the person authorised to conduct a clinical trial or field trial, suspend or terminate a clinical trial or field trial, in accordance with regulations made under this Act.

(8) The Authority shall monitor a clinical trial or field trial to ensure that—

(a) the subjects of the clinical trial or field trial and the general public are protected against any risks that may result from the clinical trial or field trial; and

(b) the conditions of the clinical trial or field trial are adhered to.

(9) A person that conducts a clinical trial or field trial in contravention of this section commits an offence and is liable on conviction—

(a) in case of an individual, to a fine not exceeding five thousand currency points or imprisonment not exceeding fifteen years, or both; or

(b) in case of a corporate body, to a fine not exceeding ten thousand currency points.

91. Good clinical practice

(1) A clinical trial conducted under section 90 shall comply with good clinical practices, as may be prescribed by regulations made under this Act.

(2) The person in charge of a clinical trial shall—

(a) ensure that adequate protection, from the risks or adverse events of the clinical trial, is provided for the subjects of a clinical trial and the general public;

(b) ensure that the conditions of the clinical trial are adhered to by the person conducting the trial; and

(c) report to the Authority, all adverse reactions and any adverse events, as the case may be, using the procedures prescribed by regulations made under this Act.

(3) The Authority may, at any time, inspect the clinical trial site to assess compliance with the good clinical practices.

(4) A person that conducts a clinical trial in contravention of this section commits an offence and is liable on conviction-

(a) in case of a corporate body, to a fine not exceeding ten thousand currency points; or

(b) in case of an individual, to a fine not exceeding five thousand currency points or imprisonment not exceeding fifteen years, or both.

92. Recall of regulated products

(1) Where the Authority determines that a regulated product does not conform to the conditions of its registration, notification or listing, as may be applicable and where it is in public interest that the regulated product should not be made available to the public, the Authority shall—

(a) order the person granted a certificate of registration, notification or listing for the regulated product, or the authorised representative of that person or the importer of the regulated product, to recall and destroy the affected batches of the regulated product, at their own cost; or

(b) order that the supply of the affected batches of the regulated product be discontinued.

(2) A person shall not import or supply a regulated product or a batch of the regulated product which is the subject of an order for recall made under subsection (1) (a).

(3) The Authority may order the destruction of the regulated product referred to in subsection (1).

(4) Notwithstanding this section, the manufacturer of a regulated product or the person granted a certificate of registration, notification or listing for a regulated product, or the authorized representative of that person or the importer of a regulated product or of a batch of a regulated product, may upon notification to the Authority, as may be prescribed, recall from the market, the regulated product or the batch of the regulated product.

(5) A person that imports or supplies a regulated product contrary to subsection (2) commits an offence and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding ten thousand currency points: and

(b) in case of an individual, to a fine not exceeding five thousand currency points or imprisonment not exceeding five years, or both.

93. Withdrawal of regulated product

(1) A person granted a certificate of registration, notification or listing for a regulated product or the authorised representative of that person or the importer of a regulated product may upon notification to the Authority, withdraw the regulated product from the market.

(2) The Authority may where it deems fit and on its own decision, withdraw a regulated product from the market.

(3) A regulated product that is withdrawn under this section shall be removed from the register.

94. Prohibition of supply of regulated products in certain cases
The Authority may prohibit the supply of a regulated product where—

(a) the information provided for purposes of registration, notification or listing of the regulated product, as the case may be, is misleading;

(b) the use of the regulated product is likely to endanger the health of the users or cause other undesirable effects;

(c) the specifications of the regulated product, which were furnished to the Authority for purposes of registration, notification or listing of the regulated product, differ from the specifications of the analysis of the regulated product obtained from samples of the suppliers of the regulated product; or

(d) the descriptive matter published in relation to the regulated product differs from that descriptive matter furnished to the Authority.

95. Deception of consumers
(1) A person shall not package, label, advertise or supply a regulated product in a manner that is false, misleading or deceptive or that misbrands the regulated product as to its character, constitution, value, potency, quality, composition, merits or safety.

(2) For the purposes of subsection (1), a regulated product is "misbranded"—

(a) if the regulated product is not labelled in the prescribed manner; or

(b) if the label of the container of the regulated product or anything accompanying the regulated product bears a statement, design or device which makes a false claim for the regulated product, or which is false and misleading.

(3) A person that packages, labels, advertises or supplies a regulated product contrary to this section commits an offence and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding five thousand currency points; and

(b) in case of an individual, to a fine not exceeding five thousand currency points or imprisonment not exceeding five years, or both.

96. Advertisement of regulated products

(1) A person shall not advertise —

(a) a regulated product or cause any other product to be advertised as a regulated product; or

(b) a regulated product or cause a regulated product to be advertised in such a manner that represents the regulated product as being usable for a purpose other than the purpose for which it was been registered, notified or listed.

(2) A person shall not advertise a regulated product or cause a regulated product to be advertised in a false or misleading way.

(3) For the purposes of subsection (2), an advertisement of any regulated product is taken to be false or misleading if the advertisement —

(a) falsely describes the regulated product or gives any false information concerning the regulated product; or

(b) is likely to create an erroneous impression regarding the formulation, composition, design specification, quality, safety, efficacy or use of the regulated product.

(4) A person that advertises a regulated product in contravention of this section commits an offence and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding five thousand currency points; and

(b) in the case of an individual, to a fine not exceeding five hundred currency points or imprisonment not exceeding five years, or both.

97. Prohibition of falsified regulated products

(1) A person shall not manufacture, import, supply, possess or offer for sale any regulated product that is falsified.

(2) A regulated product shall be deemed to be falsified where—

(a) it is deliberately or fraudulently mislabeled with respect to its identity or source;

(b) it is likely to deceive, or bears on its label or container the name of another regulated product unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with any other regulated product;

(c) the label or container bears the name of an individual or a corporate body which is fictitious or that does not exist and purports that the individual or corporate body is the manufacturer of the regulated product;

(d) it purports to be a product of a manufacturer of which it is not; or

(e) it is a regulated product which or the container or labelling of which, without authorisation, bears a trademark, trade

name or any other identifying mark of another person, imprint, or device.

(3) A person that manufactures, imports, exports, distributes, supplies or offers for sale a regulated product that is falsified commits an offence and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding five thousand currency points; and

(b) in case of an individual, to a fine not exceeding five thousand currency points or imprisonment not exceeding fifteen years, or both.

98. Prohibition of supply of substandard regulated products

(1) A person shall not—

(a) supply a regulated product which is not of the nature, substance or quality specified in a prescription or which is not of the nature, substance or quality demanded by the purchaser;

(b) supply a regulated product which does not conform to the standards recognised by the Authority;

(c) supply any regulated product which is not wholesome or which does not conform to the prescription under which it is supplied; or

(d) supply or offer or expose for supply, or have in his or her possession for the purpose of supply, any regulated product whose composition is affected by an addition to it or subtraction from it of any component.

(2) A person shall not use or offer for sale or administer to any person or for any person a regulated product which is not fit for the intended purpose.

(3) For purposes of subsection (2) "not fit for the intended purpose" means a regulated product which—

(a) is malfunctional;

(b) is not safe or efficacious;

(c) is of an undesired quality; or

(d) is expired.

(4) A person that contravenes this section commits an offence and is liable on conviction—

(a) in case of a corporate body, to a fine not exceeding five thousand currency points; and

(b) in case of an individual, to a fine not exceeding three thousand currency points or imprisonment not exceeding five years, or both.

PART XI—THE NATIONAL DRUG AND HEALTH PRODUCTS LABORATORY

99. Establishment of the National Drug and Health Products Laboratory

(1) There is established the National Drug and Health Products Laboratory of the Authority to be used to test and analyse the products regulated under this Act.

(2) For the purposes of subsection (1), the Authority shall assign analysts to test and analyse the products regulated under this Act and to make reports of the tests and analyses.

(3) Any report of a test or analysis shall be prima facie evidence of the facts stated in it and may be used as evidence in court.

(4) Notwithstanding this section, the Authority may request another laboratory to test or analyse a product on behalf of the

Authority and where the Authority so requests, the report of the test or analysis shall be adopted by the Authority and shall be prima facie evidence of the facts stated in it and may be used as evidence in court.

PART XII—ADMINISTRATION AND ENFORCEMENT OF ACT BY THE AUTHORITY

100. Appointment of inspectors

(1) For purposes of ensuring compliance with this Act, the Authority shall appoint inspectors.

(2) A person appointed inspector shall be a person qualified in the field for which an inspection is to be conducted or is required.

(3) An inspector shall produce on demand, a duly authenticated document showing that the person is authorised to exercise the powers of inspector specified in the section 101.

101. Power of inspectors

(1) For the purposes of ensuring compliance with this Act, an inspector may at any time—

(a) enter any premises where a product regulated under this Act is manufactured, stored or supplied or enter any vessel where a product regulated under this Act is transported, and if satisfied that there is contravention of this Act—

(i) seize and retain the product which appears to the inspector to be unfit for the intended purpose; or

(ii) purchase or take a sample of the product or any substance capable of being used in the preparation of the product, for testing and analysis in accordance with section 99;

(b) refuse entry into Uganda of a product regulated under this Act, where that product is found to be in contravention of this Act; and

(c) enter any premises or vessel where the inspector reasonably suspects that the premises or vessel contains a product regulated under this Act and, require any person to furnish any information in his or her possession as to the activities carried on, on the premises or vessel and the person by whom the activities are carried on or the purposes for which the premises are being used or the vessel is being used.

(2) Where an inspector determines that the product to which subsection (1) (a) applies is likely to be harmful to the public, the Authority shall suspend the continued use of the product or close or seal off the affected premises.

(3) An inspector may be accompanied by a police officer and shall exercise his or her powers under subsections (1) and (2) in the presence of-

(a) the owner of the product regulated under this Act; or

(b) the person found in charge of the premises or vessel, as the case may be.

(4) Where the owner of a product regulated under this Act or the person in charge of the premises or vessel cannot be traced or is not available, the inspector shall exercise his or her powers under subsections (1) and (2), in the presence of a police officer.

(5) The premises that are closed and sealed off under this section shall be under the control of the Authority.

(6) A person that willfully delays or obstructs an inspector in the exercise of his or her powers, or that does not comply with any order or warrant made or issued under this Act commits an offence and is liable, on conviction to a fine not exceeding two thousand currency points or imprisonment not exceeding five years, or both.

(6) Where the court is satisfied that the person convicted of an offence under this section committed the offence with the intent of preventing the discovery of another offence under this Act, or where the person has within the last twelve months been convicted of an offence specified in this section, the person shall be liable to a fine not exceeding five thousand currency points of imprisonment not exceeding ten years, or both.

102. Appeal to the High Court

Any person aggrieved by a decision or action of the Authority under section 101, may appeal to the High Court against that decision or action.

103. Destruction of products not fit for intended purpose

(1) Where an inspector is satisfied that a product regulated under this Act, is on testing and analysis found to be unfit for the intended purpose, the Authority shall apply to court for an order for destruction of the product.

(2) Court may order for the destruction to be conducted by the Authority or by the person granted a certificate of registration, notification or listing, as the case may be, or by the authorised representative of that person, or by the importer or manufacturer, and the cost of destruct shall be borne by the person so ordered by court.

(3) The Authority shall supervise the destruction conducted by a person other than the Authority under a court order in subsection (2).

PART XIII—LEGAL PROCEEDINGS

104. Evidence

(1) In any proceedings under this Act—

(a) any licence or certificate purporting to have been issued under this Act; or

(b) any document purporting to state the results of an analysis carried out on behalf of the Authority for the purposes of this Act,

shall be prima facie evidence of the facts stated in it.

(2) Where, in any proceedings under this Act, a person is charged with—

(a) the unlawful possession, supply of any product regulated under this Act, where the product is in a container; or

(b) any other offence where the contents of a container are in issue in the proceedings, and the container appears to the court to be intact and in its original state of packing by its manufacturer,

the contents of the container shall be deemed, unless the contrary is proved, to be of the description specified on the label of the container.

(3) In any proceedings under this Act, a sample of a product regulated under this Act shall, unless the contrary is proved, be deemed to possess the same properties as the product to which the sample relates.

105. General offence

(1) A person that commits an offence for which no penalty is prescribed in this Act shall on conviction be liable to a fine not exceeding five hundred currency points or to imprisonment not exceeding four years, or both.

(2) A person convicted under this section is for any subsequent offence under this Act, liable to a fine not exceeding seven hundred currency points or to a term of imprisonment not exceeding five years, or to both.

106. Forfeiture and cancellation of licence

In any proceedings for an offence under this Act, the court may, in addition to the penalty imposed—

(a) order that the regulated product with respect to which the offence is committed be forfeited to the State; or

(b) order the Authority to suspend or cancel the licence or certificate related to the offence.

107. Vicarious criminal responsibility

(1) Where an act or omission which if done by an individual would be an offence under this Act, is done by a corporate body, the act or omission shall be deemed to be an offence committed by every director, secretary and manager of the corporate body, except where the director, secretary or manager proves that—

(a) the offence was committed without his or her consent or connivance; or

(b) he or she exercised due diligence to prevent the commission of the offence as he or she ought to have exercised, having regard to the nature of his or her functions in that capacity and to all the circumstances of the case.

(2) If an offence under this Act or any regulations made under it is committed by a partner in a firm, every person who at the time of the commission of the offence was a partner in that firm, or was purporting to act in that office, shall be deemed to have committed the like offence unless he or she proves that the offence was committed without his or her consent or connivance and that he or she exercised

all such diligence to prevent the commission of the offence as he or she ought to have exercised, having regard to the nature of his or her functions in that capacity and to all the circumstances of the case.

108. Punishment without prosecution

(1) The Minister may, with the approval of the Minister responsible for internal affairs, by statutory instrument, for the offences specified in this Act or in regulations made under this Act, prescribe the offences for which a person that commits the offence may be given notice in writing offering that person opportunity to discharge any liability to conviction for the offence by payment of a fixed penalty.

(2) The statutory instrument made under subsection (1) shall prescribe—

(a) the offences to which this section applies;

(b) the officers who may issue notice and the information to be supplied to them;

(c) the fixed penalty which shall not be more than two hundred currency points; and

(d) the format of the notice to be issued under this section.

PART XIV—GENERAL PROVISIONS

109. Authority to ascertain the quality of the drugs of the National Medical Stores

The Authority shall ascertain the quality of the drugs of the National Medical Stores.

110. Notification and amendment of particulars

If any alteration occurs in the particulars of registration, notification or listing of a product regulated under this Act, the person granted a certificate of registration, notification or listing for the product or the authorised representative of that person shall within twenty-one days of the alteration, in writing, notify the Authority.

111. Approved ports of import and export

(1) Drugs, medical devices, cosmetic products, public health products and nutritional supplements shall only be imported and exported through ports of entry approved by the Authority and shall be subject to inspection by the Authority at the port of entry or exit.

(2) The Authority shall by notice in the Gazette and a newspaper on nationwide circulation designate the ports of entry and ports of exit to be used for the importation and exportation of drugs, medical devices, cosmetic products, public health products and nutritional supplement.

112. Registers

(1) The Authority shall keep and maintain a register for each of the products regulated under this Act, in a manner prescribed by regulations made under this Act.

(2) A register shall, at all reasonable times, be accessible for inspection by the public at the prescribed fee.

113. Power to require information

(1) The Authority may direct any person that carries on a business related to a product regulated under this Act, to submit to the Authority any information within the period specified in the order.

(2) A person that—

(a) fails to give such information to the Authority as required in subsection (1); or

(b) gives information which is false in a material particular or which the person reasonably believes to be untrue in respect of the information required,

commits an offence and is liable on conviction to a fine not exceeding fifty hundred currency points or imprisonment not exceeding ten years, or both.

114. Technical committees

(1) With the approval of the Board, the Executive Director may, set up technical committees to facilitate the functions of the Authority, as may be necessary.

(2) The Authority may adopt the reports and recommendations of a technical committee.

115. Protection of members of the Board and employees from personal liability

A member of the Board and an employee of the Authority shall not be liable in civil or criminal proceedings for any act or omission done in good faith in the exercise of the functions of the Authority.

116. Local research and production

The Government shall encourage research by persons carrying on research and development in herbal and other medical products and where appropriate allow such medical products into production as a component of the medical product supply.

117. Non-application of the Industrial Licensing Act

The Industrial Licensing Act shall not apply to products regulated under this Act.

118. Regulations

(1) The Minister may, on recommendation of the Board, make regulations for the better carrying out of the functions of the Authority.

(2) Without prejudice to the generality of subsection (1), the Minister may make regulations—

(a) for the registration of the products regulated under this Act;

(b) for licensing the manufacture, importation, exportation, distribution and sale of the products regulated under this Act;

(c) for the licensing of pharmacies and drug shops, including the inspection and location of premises of pharmacies and drug shops;

(d) for the transportation of the products regulated under this Act;

(e) for the marketing of the products regulated under this Act;

(f) prescribing the conduct of clinical trials;

(g) for the certificates and licences to be granted by the Authority;

(h) for the lot release for vaccines, biologicals and diagnostics;

(i) for the sale of drugs where the request for supply is made electronically without the physical appearance at the pharmacy, of the person making the request;

(j) exempting any person from any of the provisions of this Act;

(k) prescribing the fees payable under this Act; or

(l) prescribing for any matter or thing which is required or permitted to be prescribed under this Act.

(3) Regulations made under this section may prescribe for a contravention of any of the provisions of the regulations, of a fine not exceeding—

(a) in case of a corporate body, to a fine not exceeding five thousand currency points; and

(b) in the case of an individual, to a fine not exceeding five hundred currency points or imprisonment not exceeding five years, or both.

119. Amendment of Schedule

The Minister may, by statutory instrument, with the approval of Cabinet amend the Schedule to this Act.

120. Repeals and savings

(1) The National Drug Policy and Authority Act, Cap 198 is repealed.

(2) All references to drugs in the Food and Drug Act, Cap 307 are repealed.

(3) Sections 14 and 82 (4) of the Narcotic and Psychotropic Substances (Control) Act are repealed.

(4) Any statutory instrument made under the National Drug Authority Act, Cap. 206 which is in force immediately before the commencement of this Act, shall remain in force, so far as it is not inconsistent with this Act, until the statutory instrument is revoked by a statutory instrument made under this Act and until that revocation, the statutory instrument shall be deemed to have been made under this Act.

(5) The Human Resource Manual of the National Drug Authority shall continue to apply until the Authority makes rules to regulate the staff of the Authority under in section 13, and the decisions and actions taken by the Board under the Human Resource Manual are valid.

121. Transitional provisions

(1) A member of the Board in office at the commencement of this Act shall be eligible for appointment under this Act.

(2) The Secretary to the Authority in office at the commencement of this Act shall at the expiry of his or her instrument of appointment, be eligible for appointment under section 11.

(3) The services of the employees of the National Drug Authority in office at the commencement of this Act shall be transferred to the Authority on similar terms.

(4) The licences issued and the registrations done by the National Drug Authority under the National Drug Policy and Authority Act shall remain valid for their duration, and shall only be modified, to the extent that the licences or registrations are inconsistent with this Act.

(5) The rights and liabilities of the National Drug Authority at the commencement of this Act, shall vest in the Authority.

(6) Any legal proceedings pending before court or a judgement which was enforceable by or against the National Drug Authority, immediately before the commencement of this Act, and connected with the assets vested in the Authority or the functions of the Authority, shall be enforceable by or against the Authority, as it would have been enforced by or against the National Drug Authority, before the commencement of this Act.

122. Regulation of veterinary drugs, veterinary medical devices and field trials

(1) Veterinary drugs, veterinary medical devices and field trials shall be regulated under this Act until the commencement of an Act enacted to regulate veterinary drugs, veterinary medical devices and field trials.

(2) For the purposes of subsection (1), in this Act—

(a) the definition of "authorised pharmacopoeia" and any reference to authorised pharmacopoeia includes the British Veterinary Codex;

(b) any reference to clinical trials includes field trials;

(c) the definition of "drugs" and any reference to drugs includes veterinary drugs;

(d) the definition of "drug shop" any reference to drug shops includes veterinary drug shops;

(e) the definition of "healthcare professionals" any reference to healthcare professionals includes veterinary practitioners:

(f) the definition of "medical devices" and any reference to medical devices includes veterinary medical devices:

(g) any reference to medical practitioner includes veterinary surgeon: and

(h) any reference to pharmacies includes veterinary pharmacies.

SCHEDULE

Section 2

CURRENCY POINT

A currency point is equivalent to twenty thousand shillings.