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A Statute to establish a National Drug Policy and a National Drug Authority to ensure the availability, at all times, of essential, efficacious and cost-effective drugs to the entire population of Uganda, as a means of providing satisfactory health care and safe-guarding the appropriate use of Drugs.


Date of commencement: 3rd December, 1993.

BE IT ENACTED by the President and the National Resistance Council as follows:

PART I PRELIMINARY PROVISIONS.
1. Short title
This Statute may be cited as the National Drug Policy and Authority Statute, 1993.
2. Interpretation
In this Statute, unless the context otherwise requires:

"advertisement"
includes any notice, circular, label, wrapper or other document, and any announcement made orally or by means of producing or transmitting light or sound;

"approved institution"
includes gazetted hospitals, health centres, dispensaries, aid posts, registered medical clinics and nursing homes;

"authorised person"
means a person authorised under this Statute;

"authorised pharmacopoeia"
means the current edition for the time being of any of the following, namely, the International Pharmacopoeia, the British Pharmacopoeia, the British Pharmaceutical Codex, the European Pharmacopoeia, the United States Pharmacopoeia and the British Veterinary Codex;

"class A drug", "class B drug" and "class C drug"
shall be construed in accordance with section 13 of this Statute;

"classified drug"
means a class A, B, or C drug;

"Commission"
means the National Drug Authority Commission;

"descriptive matter"
means any statement, whether written or oral, which purports to describe the composition or effect of any drug; and references to the publication of descriptive matter shall be references to its publication by way of advertisement, or on or with the container in which the drug is supplied, or in any other manner;

"disease"
includes injury and bodily or mental deficiency or abnormality;

"dispense"
, in relation to a medicine or poison, means to supply a medicine or poison on and in accordance with a prescription duly given by a duly qualified medical practitioner, dentist or veterinary surgeon;

"drug"
means any substance or preparation used or intended to be used for internal or external application to the human or animal body either in the treatment or prevention of disease or for improving physiological functions; or for agricultural or industrial purposes;

"Drug Authority"
"duly qualified"
used in relation to a medical practitioner, dentist, or veterinary surgeon, means a person recognised by law to practise medicine, surgery, dentistry and midwifery or, as the case may be, veterinary surgery;

"Generic name"
means the International Non-proprietary, name (INN) established by a body of the World Health Organisation;

"Indian hemp"
includes the dried flowering or fruiting tops of the pistillate plant known as cannabis sativa or cannabis indica from which the resin has not been extracted, by whatever name such tops are called and resins obtained from such tops, all preparations of which such resins form the base, and all extracts or tinctures obtained from such tops;

"inspecting officer"
means a person empowered under Part VII of this Statute to enter any premises;

"International Control"
means the International conventions on the control of narcotic drugs and psychotropic substances;

"International Non-proprietary Name (INN)"
means the official name of a drug, regardless of the manufacturer;

"licensed person"
means a person licensed under section 15 of this Statute;

"licensed seller"
means a person licensed under section 16 of this Statute;

"manufacture"
includes any treatment of a plant, mineral or other substance for the purpose of extracting a drug;

"Minister"
means Minister responsible for health;

"narcotic drug"
means a class A drug or preparation;

"pharmacist"
means pharmacist under the Pharmacy and Drug Act, 1970;

"prepared opium"
means opium prepared for smoking and includes dross and any other residues remaining after opium has been smoked, and also includes any opium for whatever purpose prepared which is capable of being smoked;

"proprietary drug"
means a drug distributed for sale by retail under a brand name or other proprietary
description and in a form ready for use;
"register"
means the register of specialities maintained under the Drug Authority;
"restricted drug"
means a classified drug or any other drug which is not an exempted drug;
"substance"
includes a preparation;
"supply"
with its grammatical variations and cognate expressions includes in relation to a
drug the administration of any such drug.
PART II NATIONAL DRUG POLICY AND AUTHORITY.
3. National Drug Policy
(1) The National Drug Policy shall be—
(a) to ensure that essential, safe, efficacious and cost-effective drugs are made
available to the entire population of Uganda to provide satisfactory health care;

(b) to make a continuous review of the needs knowledge and resources of essential
drugs;

(c) to promote the rational use of drugs both in the public and private sector;

(d) to improve Government regulation and control on manufacture, production,
importation, exportation, marketing and use of drugs;

(e) to provide systematic public information, professional training and re-training of
health workers;

(f) to improve the registration of drugs and licensing of pharmaceutical premises;
(g) to intensify research in all types of drugs including traditional medicines;

(h) to comply with the international regulations on drugs including the conventions on Narcotic drugs and Psychotropic substances under international control; and

(i) to fight against drug and substance abuse.

(2) The National Drug Policy shall relate to the regulation of the importation, production, distribution, marketing, exportation and use of pharmaceuticals in the public as well as in the private sector and to any matter related to the above.

4. Establishment of the National Drug Authority

(1) There is established a National Drug Authority which shall be a body corporate with perpetual succession and a common seal and may sue or be sued in its corporate name.

(2) The Drug Authority shall consist of the Chairman and the following other persons—

(a) the Director of Medical Services;

(b) the Commissioner for Veterinary Services;

(c) the Commissioner for Commerce;

(d) the Director, Criminal Investigation Department;
(e) the Chief of Medical Services, Ministry of Defence;

(f) the Chief of Pharmaceuticals and Health supplies;

(g) the Head of Natural Chemotherapeutics laboratory;

(h) the Director, Mulago Hospital;

(i) a representative of each of the following—

(i) National Medical Stores,
(ii) the Uganda Medical Association,
(iii) the Pharmaceutical Society of Uganda
(iv) the Uganda Veterinary Association,
(v) the Head of the School of Pharmacy Makerere University,
(vi) the Uganda Herbalists,
(vii) the Uganda Dental Association; and
(viii) the Joint Medical Stores:

(j) the Director-General of Uganda Aids Commission;

(k) two other persons appointed from the public.

(3) The Chairman and the members under paragraph (2) (k) shall be appointed by the Minister.
(4) The members appointed under subsection (3) shall be in office for three years but shall be eligible for reappointment.

5. Application of the Seal

(1) The common seal of the Drug Authority shall be as the Drug Authority may determine and shall be kept by the Secretary.

(2) The common seal shall, when affixed into any document, be authenticated by any two signatures of the Chairman, the Secretary and any other member of the Commission as may be authorised by the Drug Authority.

(3) A contract or instrument which if entered into or executed by a person not being a body corporate would not be required to be under seal may be entered into or executed without seal on behalf of the Drug Authority by the Secretary or any other person authorised by the Drug Authority.

(4) Every document purporting to be—

(a) an instrument issued by the Drug Authority and sealed with the common seal of the Drug Authority and authenticated in the manner prescribed in subsection (2); or

(b) a contract or instrument entered into or executed by the Drug Authority shall be received in evidence without further proof as that instrument dully issued or a contract dully entered into or executed unless the contrary is proved

6. Functions of the Drug Authority

The Drug Authority shall be charged with the implementation of the National Drug Policy and in particular, but without derogation of the foregoing, shall—

(a) deal with the development and regulation of the pharmacies and drugs in the country;

(b) approve the National List of Essential Drugs and supervise the revisions of the list in a manner provided by the Minister;
(c) estimate drug needs to ensure that the needs are met as economically as possible;

(d) control the importation, exportation, and sale of pharmaceuticals;

(e) control the quality of drugs;

(f) promote and control local production of essential drugs;

(g) encourage research and development of herbal medicines;

(h) promote rational use of drugs through appropriate professional training;

(i) establish and revise professional guidelines and disseminate information to health professionals and the public;

(j) provide advice and guidance to the Minister and bodies concerned with drugs on the implementation of the National Drug Policy; and

(k) perform any other function that is connected with the above or that may be accorded to it by law.

7. Commission and other bodies of the Authority
There shall be a National Drug Authority Commission which shall consist of the Chairman and four other members appointed by the Drug Authority from among themselves.

The Chairman of the Drug Authority shall be the Chairman of the Commission.

The functions of the Commission shall be—

(a) to exercise the functions of the Drug Authority which may require exercising when the Drug Authority is not sitting;

(b) to monitor and supervise the implementation of the decisions of the Drug Authority;

(c) to establish and revise from time to time, the working procedure of the Drug Authority;

(d) to perform any other functions relating to the functions of the Drug Authority as the Authority may direct.

There shall be the following committees of the Drug Authority—

(a) the Committee on Essential Drugs; and

(b) the Committee on National Formulary.

(1) The membership of the Committee on Essential Drugs shall be as follows—

(a) a Chairman appointed by the Drug Authority;
(b) the Commissioner Curative Services of the Ministry of Health;

(c) the Chief of Pharmaceuticals and Health Supplies;

(d) the Chief of Medical Services, Ministry of Defence;

(e) the Head of School of Pharmacy;

(f) a representative of each of the following specialities—

(i) Physician;
(ii) Pediatrician;
(iii) Gynaecologist/Obstetrician;
(iv) Surgeon;
(v) Psychiatrist;

(g) a member from the Private Medical Practitioners Association;

(h) a Non-Government Organisation pharmacist from the Joint Medical Stores.

(2) The Committee on Essential Drugs shall have power to co-opt members deemed necessary.
(6) The membership of the Committee on the National Formulary shall be as follows—
(a) a Chairman appointed by the Drug Authority on the recommendation of the appropriate professional bodies;

(b) a member of the faculty of medicine of the Universities in Uganda;

(c) a member of the faculty of Veterinary Sciences;

(d) a member from the school of Pharmacy;

(e) a member from the Pharmaceutical Society of Uganda;

(f) a member from the Private Medical Practitioners Association;

(g) a member from the Uganda Medical Association;

(h) the Executive Director of the National Bureau of Standards;

(i) a representative of each of the following specialities—

(i) Physician;
(ii) Surgeon;
(iii) Paediaetrician;
8. Meetings of the Drug Authority

(1) The Drug Authority shall meet for the discharge of its functions at least six times a year.
(2) The National Drug Authority Commission shall establish the working procedure for the Drug Authority.

PART III CONTROL OF DRUG SUPPLY.

9. National list of Essential Drugs

(1) There shall be a National List of Essential Drugs which shall be revised from time to time.
(2) There shall be a National Formulary made of the National List of Essential Drugs and such other drugs as the Authority may, from time to time, approve.
(3) No person shall import or sell any drug unless it appears on the National Formulary.
(4) Notwithstanding subsection (3), a drug not appearing on the National Formulary may be imported and sold after authorisation by the Drug Authority to meet emergency or extraordinary circumstances.

10. Selection of Drug items

The Drug Authority shall receive from the Committee on Essential Drugs the proposals of the revised list which shall be made in accordance with the available resources and existing diagnostic and therapeutic capacity.

11. Estimation of Drug needs

(1) The Commission shall ensure regular assessment and estimation of the National Drug needs both in the public and private sectors.
(2) Estimates of the national drug needs shall be expressed both in unit (quantity) and financial cost.
(3) For the purposes of providing accurate estimates of drug needs, the Commission shall promote and encourage investigations, including studies of current morbidity patterns, drug utilization and available diagnostic and therapeutic resources.

12. Drug Nomenclature

All drugs imported in Uganda shall be labelled, known and prescribed by their International Non-proprietary Names (generic names) except where no such name has been allocated and no satisfactory non-proprietary alternative exists.

13. Restricted drugs

(1) For the purpose of this Statute and subject to the provisions of this section—
(a) the drugs specified in Schedules 1, 2, and 3 to this Statute shall be classified drugs;

(b) the drugs and articles specified in Schedule 4 to this Statute shall be exempted drugs and articles; and

(c) any classified drug or any other drug which is not exempted shall be deemed to be a restricted drug.

(2) Subject to subsection (3) where a preparation contains any quantity of a drug which is included in Schedules 1, 2, or 3 the preparation shall be deemed to be a classified or restricted drug of the same class as the drug which it contains.

(3) Where an entry in Schedules 1, 2, or 3 to this Statute defines the proportions of a drug which brings a preparation containing it within the list of restricted drugs, sub-section (2) shall not apply to that preparation.

(4) Where, apart from the provisions of this subsection, a preparation would fall to be treated as a class A drug and also as a class B or class C drug or both, it shall be treated as a class A drug only.

(5) Where, apart from the provisions of this subsection, a preparation would fall to be treated as a drug of both class B and class C, it shall be treated as a class B drug only.

14. Supply and dispensing of restricted drugs

(1) Subject to the provisions of this section no person shall mix, compound, prepare, supply or dispense any restricted drug unless that person is a registered pharmacist, medical practitioner, dentist, veterinary surgeon, or a licensed person.

(2) The provisions of subsection (1) shall not prevent—

(a) the supply of any drug, other than a drug of class A or B, by a licensed seller;

(b)
the mixing, compounding or preparing of a drug under the immediate supervision of a registered pharmacist;

(c) the supply or dispensing of a restricted drug by a member of staff of a hospital, dispensary or similar institution which has been authorised to do so by a general or special order of the Drug Authority;

(d) the supply of restricted drugs subject to regulations made by the Minister after consultation with the Drug Authority, by a representative of a person engaged in the sale and supply of pharmaceutical goods for the purposes of giving free samples of the drugs to persons who may lawfully possess restricted drugs.

(3) A person registered or enrolled under the Nurses, Midwives and Nursing Assistants Act or any other authorised person may supply or dispense restricted drugs in accordance with regulations made by the Minister in that behalf.

(4) The supply or dispensing of restricted drugs under subsections (2) and (3) shall be subject to the following—

(a) the restricted drugs shall be distinctly labelled with the name and address of the person by whom it is supplied or dispensed;

(b) the following particulars shall, within twenty-four hours after the restricted drug has been supplied or dispensed, be entered in a book used regularly for the purpose, which shall be known as the Prescription Book—

(i) the date on which the restricted drug was supplied or dispensed;
(ii) the ingredients and the quantity supplied;
(iii) the name and address of the person to whom the restricted drug was supplied;
(iv) the name and address of the person by whom the prescription was given,
except that the provisions of paragraph (a) shall not apply in any case where any restricted drug is administered by a medical practitioner, dentist, veterinary surgeon, or midwife, or under his direct supervision and in his presence.

(5) Any record under the provisions of this section shall be open to inspection by an inspector of drugs.

15. Lecensed Persons

(1) If, on application made in the prescribed form by any person, the Authority is satisfied —

(a) that the applicant is fit to carry on a business of mixing, compounding and preparing and supplying restricted drugs by retail;

(b) that the business, so far as concerns restricted drugs, will be carried on under the immediate supervision of a pharmacist in each set of premises where the business is to be carried on;

(c) in the case of a body corporate, that at least one of the directors is a pharmacist resident in Uganda; and

(d) in the case of a partnership, that at least one of the partners is a pharmacist resident in Uganda,

the Authority may, on the payment of a prescribed fee, issue a licence to the applicant to carry on the business required at the premises and on conditions specified in the licence.

(2) A licence issued under this section shall be valid for a period specified in the licence, but the Drug Authority may revoke the licence if, at any time, it is satisfied that the licensed person has contravened any provision of this Statute or any condition specified in the licence, or has ceased to be fit to carry on the business.
(3) A person who carries on the business of a pharmacist without a licence issued under this section commits an offence and is liable to a fine not exceeding one million shillings or imprisonment not exceeding five years or both.

16. Licensed sellers

(1) If, on application made in the prescribed form by a person other than a pharmacist or a licensed person, the Authority is satisfied—

(a) that the applicant is fit to carry on a business of supplying by retail restricted drugs, other than drugs of class A or B;

(b) that the area in which the applicant proposes to carry on that business is not sufficiently served by existing facilities for the retail supply of the drugs; and

(c) an authorised person,

the Authority may issue to the applicant a licence authorising him, subject to any conditions specified in the licence, to carry on the business required from the premises specified in the licence.

(2) A licence issued under this section shall be valid for a period specified in the licence, but the Authority may revoke the licence if, at any time, it is satisfied that the holder of the licence has contravened any provision of this Statute or any condition specified in the licence, or has ceased to be fit to carry on the business.

17. Places from which restricted drugs may be supplied

(1) No person shall carry on the business of supplying restricted drugs from any premises—

(a) if restricted drugs including drugs of class A or B are supplied, unless either a general or a limited certificate is issued under this Statute for the purpose;

(b)
if restricted drugs not including drugs of class A or B are supplied, unless either a
general or a limited certificate issued under this Statute is in force.

(2) No person shall supply any drug by means of an automatic machine.

18. Certificates of suitability of premises

(1) If on application made in the prescribed form for certificate in relation to any
premises, the Authority is satisfied, that the accommodation, fixtures, equipment
and other physical attributes of those premises render those premises suitable for
the supply of restricted drugs or for the supply of restricted drugs excluding drugs
of classes A and B it may issue in respect of those premises either a general or
limited certificate.

(2) Every person carrying on the business of supplying restricted drugs from the
premises in respect of which a certificate issued under this section is in force shall
notify the Authority of any alteration in the physical attributes of the premises, or
if no alteration occurs in any calendar year, shall notify the Authority of that fact
before the end of January in the following year.

(3) A certificate issued under this section shall remain in force until a date
specified in the certificate, but the Authority may revoke the certificate if, at any
time, it is satisfied, on the recommendation of the Inspector of Drugs, that, owing
to an alteration or deterioration in the physical attributes of the premises, the
premises have ceased to be suitable for the supply of the restricted drugs, or of
restricted drugs other than drugs of classes A and B, as the case may be.

(4) The Authority shall keep a register in the prescribed form of the premises in
respect of which a certificate is issued under this section.

19. Loss of class A or B Drugs

(1) Any person entitled under this Statute to supply or dispense class A or B drug
shall, upon the loss of that drug in his possession or control or of any records kept
under this Statute in relation to that drug, report that loss to the Inspector of
Drugs, within seven days of the loss, giving particulars of the ingredients and
quantities of the drugs or the particulars of the records lost.

(2) A person contravening any provision of section commits an offence and shall
be liable to a fine not exceeding one million shillings or to a term of
imprisonment not exceeding five years or to both.

PART IV SPECIAL PROVISIONS RELATING TO CLASSIFIED DRUGS.

20. Classified Drugs
The Minister on the advice of the Authority may, by statutory instrument, declare a drug to be a classified drug.

21. Need for prescription for Classified drugs

(1) A pharmacist or licensed person shall not supply a class A or class B Group I drug unless it is under prescription reasonably believed by the person supplying the drug to be valid.

(2) A prescription shall be valid only if—

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

(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 or, if signed by a veterinary surgeon, of the person in charge of the animal to which the drug is to be administered;

(d) it is signed by a dentist, and bears the words "for dental treatment only" or, if signed by a veterinary surgeon, and bears the words "for animal treatment only";

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

(f) it has not previously been fully dispensed.

(3) A prescription shall be fully dispensed if the drug prescribed has been supplied 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 the stated number of times.

(4) This section shall not apply—
( a) if the drug is supplied, whether personally or on a signed order, to a medical practitioner, dentist, veterinary surgeon, pharmacist or licensed pharmacy for the purpose of being subsequently dispensed or supplied or used for purposes of scientific education or research; or

( b) if the drug is supplied from the dispensing department of an approved institution in accordance with regulations made by the Minister in that behalf.

22. Action to be taken in relation to prescription
Where a classified drug is supplied under a prescription—
( a) the person supplying the drug shall enter on the prescription in indelible writing the date on which it is supplied and the name and address of the supplier;

( b) if the prescription is fully dispensed it shall be retained by the supplier and, for the period of two years thereafter, shall be kept on the premises at which it was dispensed in such a manner as to be readily available for inspection.

23. Classified drugs to be supplied to responsible persons
A pharmacist or licensed pharmacy shall not supply a Class A or B drug to a person who is not reasonably believed by the supplier to be a person to whom the drug may properly be supplied.

24. Supply to conform to prescription
No person shall supply any classified drug which does not conform to the prescription or order under which it is supplied.

25. Classified drug book

(1) Every person who supplies class A, B, or C Group II drugs shall keep in all premises from which the drugs are supplied by him a book of the prescribed description to be known as the Classified Drugs Book.

(2) Subject to the provisions of subsection (3) of this section, before any person supplies class A, B or C Group II drugs, he shall enter or cause to be entered in the Classified Drugs Book the following particulars, namely—

(a) the name and quantity of the drug to be supplied;

(b) the name and address of the person who requires the drug;

(c) the purpose for which the drug is stated to be required;

(d) the signature of the person to whom the drug is delivered; and

(e) the date of the delivery.

(3) Where any classified drug is sold in the presence of an agent or servant of the person by whom it is to be used or where sale is effected by post, the following provisions shall apply—

(a) before the sale is completed, the seller shall obtain an order in writing, signed by the purchaser showing—

(i) the purchaser's name, address and occupation;
(ii) the name and the quantity of drug to be purchased; and
(iii) the purpose for which it is required;
but where a person represents that he urgently requires a classified drug for the purpose of his trade, business or profession, and satisfies the seller that, by reason of some emergency, he is unable before delivery to furnish the order in writing, the seller may, deliver the drug to the purchaser who shall, within twenty-four hours of the sale, furnish the seller with a written order.

(b) before the sale is completed, the seller shall satisfy himself that the signature on the order is that of the person by whom it is supposed to be signed and that person carries on the occupation stated in that order, being an occupation for which the drug is properly required;

(c) the requirements of subsection (2) of this section as to the making of entries in the Classified Drugs Book shall be complied with except that in place of the signature of the person to whom the drug is delivered, it shall be sufficient to record "signed order" giving a reference by which the particular signed order may be readily identified;

(d) all signed orders and prescribed records of transactions to which this subsection applies shall be retained on the premises where the sales were made for a period of two years.

(4) Any person who contravenes any of the provisions of this section commits an offence and shall be liable to a fine not exceeding two million shillings or to imprisonment for a term not exceeding five years or to both.

26. Containers and labels
No person shall supply any classified or restricted drug unless —

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

(b)
the container bears a label giving the prescribed particulars of its contents.

27. Further restrictions on the supply of narcotics

(1) The Minister may, by statutory instrument, make regulations further restricting the persons who may supply narcotic drugs, and otherwise controlling the supply of such drugs.

(2) No person shall supply any narcotic drugs under International Control other than for medical, dental or veterinary purposes.

28. Possession of classified drugs

(1) It shall be lawful for the following persons to be in possession of classified drugs, but to the extent only and subject to the limitations prescribed below—

( a) any person specified in section 15 for the purposes of that section;

( b) a licensed person or seller of classified drugs, on premises registered under this Statute;

( c) a wholesale dealer licensed under this Statute for the purposes of the licence and on the premises so licensed;

( d) any person, institution or department, to whom a classified drug has been lawfully sold in accordance with the provisions of this Statute, for the purpose for which the sale was made;

( e) any person for whom the classified drug has been lawfully supplied or dispensed by a duly qualified medical practitioner, dentist or veterinary surgeon or by an approved institution.
(2) Any person who is in possession of a classified drug otherwise, than in accordance with the provisions of this section commits an offence and is liable to a fine not exceeding two million shillings or to imprisonment for a term not exceeding five years or to both.

29. Withdraw of authority

(1) Where any person authorized to obtain or supply narcotics under the provisions of this Statute is convicted of any offence under this Statute, if the Minister is of the opinion that that person ought not to be allowed to obtain, possess or supply drugs, he may, acting in accordance with the recommendation of the Authority by notice published in the Gazette, withdraw the authority of that person.

(2) Where the person whose authority is withdrawn under subsection (1) is a registered or licensed medical practitioner or dentist, or a duly qualified veterinary surgeon, the Minister may, by notice published in the Gazette, direct that it shall not be lawful for that person to give prescriptions or orders for the purposes of this Statute.

30. Drug addicts

(1) Every medical practitioner or dentist shall keep a record in the prescribed form of all persons who are addicted to any drug specified in Schedule 1 or 2 to this Statute and shall at least every year make a report to the Minister specifying the names of such persons and the drugs to which they are addicted.

(2) Notwithstanding any other provision of this Statute, no person may prescribe or supply any drug specified in Schedule 1 or 2 to this Statute for the use of a person whom he knows or has reason to believe is addicted to any such drug, unless he is authorised in writing to do so by the Minister and in a manner and subject to conditions that may be prescribed.

Drugs Generally

31. Impure drugs not to be supplied

Any person who—

( a) sells any drug, medical appliance or similar article which is not of the nature, substance and quality demanded or which, unless otherwise agreed at the time of demand, does not conform to the standards laid down in the authorised pharmacopoeia; or

( b)
supplies any drug which is unwholesome or adulterated or which does not conform to the prescription under which it is supplied,

commits an offence and is liable to a fine not exceeding five million shillings or to imprisonment for a term not exceeding ten years or both.

32. Power to call for information as to proprietary drugs

(1) Where the Authority has reason to believe that any person is proposing to sell any proprietary drug by retail or to procure, whether directly or indirectly, its sale by retail, the Authority may require that person to furnish to it—

(a) details of the composition of the drug;

(b) copies of any descriptive matter published or proposed to be published in relation to the drug; and

(c) any other information that the Authority may require.

(2) No disclosure of information furnished under this section shall be made without the consent of the person by whom it was furnished.

33. Power to prohibit retail sale of proprietary drugs

The Authority may prohibit the sale by retail of a proprietary drug if, in the opinion of the Authority—

(a) claims are made for the drug, whether or not in a statement furnished under section 32, which are unjustified; or

(b) the use of the drug may endanger the health of the user or there may be other undesirable effects in the use of the drug; or

(c)
details of the composition of the drug furnished under section 32 differ substantially from those disclosed on an analysis of samples of the drug obtained from retail suppliers; or

(d) descriptive matter published in relation to the drug differs substantially from that, whether or not in the same language, contained in copies furnished to the Authority in relation to the drug under the last preceding section.

34. Control of publication of descriptive matter

(1) Subject to the provisions of this section, no person shall, by way of advertisement, publish in whatever manner, in relation to any drug descriptive matter calculated to lead to the use of that drug—

(a) for prevention or treatment of any disease specified in Schedule 5 to this Statute; or

(b) for the purpose of termination or influencing the course of human pregnancy; or

(c) for any purpose relating to enhancing human potency.

(2) Subject to the provisions of this section, the Authority may, with the approval of the Minister, serve on any person a notice prohibiting him from publishing in relation to any drug descriptive matter referred to in the notice.

(3) This section shall not apply to the publication of descriptive matter—

(a) by direction of the Minister; or

(b)
in a document intended for persons whose profession or employment calls for a
knowledge either of drugs generally or of drugs of the description to which the
matter in question relates; or

( c)
for the purposes of an application for the grant of a patent.

35. Return of details of pharmacy business

(1) Every person carrying on a pharmacy business on any premises shall, within
twenty-one days after the commencement by him of that business on those
premises and annually in the month of January thereafter, send to the Authority
returns in the prescribed manner, stating—

( a)
the location and postal address of the premises;

( b)
the name and principal postal address of the person carrying on the business; and

( c)
the name of the pharmacist supervising the sale of drugs at those premises.

(2) If any alteration occurs in the particulars stated in the last return made the
person carrying on the business shall, within twenty-one days of the alteration
send notice in writing to the Authority.

36. Drug Regulation and registration of specialities

(1)

( a)
The Drug Authority may scientifically examine any drug for the purposes of
ascertaining efficacy, safety and quality of that drug;

( b)
the Drug Authority shall institute a system for the approval of drugs or drug
combinations not included in the National List of Essential Drugs.
(2) The Drug Authority shall keep a register of specialities in the prescribed form.

(3) If, on application made in the prescribed manner and on payment of the prescribed fee, the Authority is satisfied—

(a) that the drug or preparation in respect of which the application is made has not previously been registered; and

(b) that the use of the drug or preparation is likely to prove beneficial,

the Authority shall register the name and description of that drug or preparation.

(4) Where, an application so made, the Authority is not satisfied as aforesaid, it shall notify the applicant that the application is dismissed on the grounds which shall be specified.

(5) The Authority may direct at any time for the deletion of any drug or preparation from the register.

(6) The register shall, at all reasonable times be open for public inspection on payment of such fee, as may be prescribed.

37. Drug quality

(1) The Drug Authority shall advise the Minister on measures to be taken to ensure the quality of drugs imported into or held in stock in the country.

(2) The execution of the measures prescribed shall be entrusted to bodies charged with the importation and distribution of drugs.

(3) The inspection of drugs and measures prescribed may be delegated to the Chief of Pharmaceuticals and Health Supplies or any other person properly qualified in Pharmaceuticals and Health Supplies.

38. Licence required for wholesale supply of restricted drugs

(1) No person shall carry on a business of supplying restricted drugs by wholesale unless he is authorised to carry on that business by a licence granted under this section.

(2) The Authority may, on application made in the prescribed form and upon payment of the prescribed fee, grant a licence for the carrying out of a business of supplying restricted drugs by wholesale, if the Authority is satisfied—
(a) that the applicant is a person to whom the Licence can properly be granted;

(b) that the business will be carried on in separate premises apart from any other business;

(c) that the business will be carried on in premises under the immediate supervision of a pharmacist;

(d) in the case of a company, that at least one of the directors is a pharmacist resident in Uganda; and

(e) in the case of a partnership, that at least one of the partners is a pharmacist resident in Uganda.

(3) Licence granted under this section may include a condition prohibiting or limiting the supply of restricted drugs of a description specified in the condition, and shall be deemed to include a condition prohibiting the supply of any prepared opium or Indian hemp which is prepared for smoking.

(4) A licence granted under this section shall be valid for a period specified in the licence but the Authority may revoke the licence if, at any time it is satisfied that the holder of the licence has contravened any provision of this Statute or any condition contained in the licence, or has ceased to be fit to carry on the business.

Control of Manufacture and Storage of Drugs.

39. Restriction of manufacture of classified drugs

(1) No person shall manufacture any drug or preparation which is not included on the National Formulary unless such a drug or preparation is approved by the Authority.

(2) No person, unless approved by the Authority in that behalf, shall manufacture a speciality.
(3) No person shall manufacture any classified drug unless the processes of manufacture are carried out or supervised by a pharmacist.

(4) Subsection (3) shall not apply to the manufacture of preparations mentioned in Schedule 6 to this Statute if the processes of manufacture are carried out or supervised by a medical practitioner.

40. Further restrictions on the manufacture of drugs

(1) The Minister may, by statutory instrument, make regulations further limiting the persons who may manufacture any drug or preparation and the premises in which they may be manufactured, and otherwise controlling their manufacture.

(2) No person shall manufacture any narcotic drug or psychotropic substances under International Control for purposes other than for medical, dental or veterinary use.

41. Clinical trials

(1) The Authority may issue a certificate to any person for the purpose of carrying out clinical trials in respect of a drug that may be specified in the certificate.

(2) No person may carry out any clinical trial in respect of any drug unless he is in possession of a certificate issued under subsection (1).

42. Local research and production

(1) The National Drug Authority shall encourage research by persons carrying on research and development in herbal and other medicines and where appropriate take such medicines into production as a component of the drug supply.

(2) Where the Drug Authority considers it economically advantageous and it is in the interest of the development of a National Drug Industry, it shall encourage and develop national production of essential drugs.

43. Storage

(1) Where restricted or classified drugs are kept on any premises, they shall be kept in accordance with the provisions of Schedule 7 but that Schedule shall not apply to drugs supplied to an individual for the treatment of himself or another individual residing with him or an animal in his possession or control.

(2) If an act is done on any premises in contravention of the above subsection then—

(a) in a case where the act constitutes a breach of a duty imposed by or under the terms of his employment upon a person employed on the premises, that person shall be deemed to have committed an offence;
(b) in any other case, the occupier of the premises shall be deemed to have committed an offence.

(3) Nothing contained in subsection (2) of this section shall prevent any person who wilfully removes or alters the label on any container, or does any other act, as opposed to an omission, in respect of a restricted drug, from being treated as having committed an offence under subsection (1).

PART V CONTROL OF TRANSPORT, IMPORT AND EXPORT OF DRUGS.

44. Transportation of drugs
The Minister may, on the advice of the Drug Authority, make regulations for the control of the transportation of any drug or class of drugs.

45. Importation of pharmaceuticals
(1) No person or body shall import any drugs into Uganda without having a licence in relation thereto from the Drug Authority.
(2) The licence shall be valid for one year and shall state the range of preparations to be imported during that period.

46. Exportation of drugs
(1) No person or body shall export any drug or preparation without having a licence in relation thereto from the Drug Authority.
(2) The licence shall be valid for one year and shall specify the drug to be exported.
(3) A person who exports any classified drugs shall keep a record in the prescribed form of all exports.

47. Import and Export licences
(1) The Authority may grant a permit for the import or the export of a classified drug if—
(a) an application for the permit is made in the prescribed form and the applicant pays the prescribed fee; and

(b) the Authority is satisfied that the applicant is a person to whom the permit can properly be granted.
(2) No permit shall be granted for the import or export of any narcotic drugs or psychotropic substances under International Control, other than for medical, dental or veterinary use.

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

PART VI FURTHER RESTRICTIONS ON NARCOTICS.

48. Possession of narcotics
(1) No person shall have in his possession without lawful excuse, the proof whereof shall lie on him, any narcotic drug or psychotropic substance under International Control.
(2) The Minister may, by statutory instrument, make regulations applying subsection (1) to such other narcotic drugs as are specified in the regulations.

49. Smoking of Opium or Indian hemp
No person shall—
(a) smoke Opium or Indian hemp or frequent any place used for the smoking thereof; or

(b) permit premises owned or occupied by him to be used by persons smoking Opium or Indian hemp; or

(c) have in his possession pipes or other utensils for use in connection with the smoking of Opium or Indian hemp.

50. Cultivation of plants yielding narcotics
(1) No person shall, without the written consent of the Minister, the proof whereof shall lie on him, cultivate any plant from which a narcotic drug can be extracted.
(2) The Minister shall, before giving his consent under this section, consult with the Authority and he may give his consent subject to such conditions as he may specify.

PART VII POWERS OF ENTRY AND INVESTIGATIONS.

51. Powers of entry
(1) An inspector or assistant inspector of drugs may enter—
(a)
at all reasonable times, any premises in respect of which a certificate issued under this Statute is in force or on which any person is required to carry out any functions imposed under this Statute;

(b) at any time, any premises on or in relation to which he has reasonable cause to suspect that an offence under this Statute has been or is being committed;

(c) at any reasonable time, any premises on which a business relating to the manufacture or supply of narcotic drugs is carried on;