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(c) (d) (e) "authorised person" means a person authorised under this Act; "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 12; "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;

(i)

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

- (j) "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;
- (k) "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;
- (I) "drug authority" means the National Drug Authority;
- (m) "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;
- (n) "generic name" means the International Nonproprietary Name (INN) established by a body of the World Health Organisation;
- (o) "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 the tops are called, and resins obtained from those tops, all preparations of which those resins form the base and all extracts or tinctures obtained from those tops;
- (p) "inspecting officer" means a person empowered under Part VII of this Act to enter any premises;
- (q) "international control" means the international conventions on the control of narcotic drugs and psychotropic substances;
- (r) "International Nonproprietary Name (INN)" means the official name of a drug, regardless of the manufacturer;
- (s) "licensed person" means a person licensed under section 14;
- (t) "licensed seller" means a person licensed under section 15;
- (u) "manufacture" includes any treatment of a plant, mineral or other substance for the purpose of extracting a drug:
- (v) "Minister" means Minister responsible for health;
- (w) "narcotic drug" means a class A drug or preparation;
- (x) "pharmacist" means pharmacist under the Pharmacy and Drugs Act;
- (y) "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;

(z) "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; (aa) "register" means the register of specialties maintained under the

drug authority; (bb) "restricted drug" means a classified drug or any other drug which

is not an exempted drug; (cc) "substance" includes a preparation; (dd) "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 NATIONAL DRUG AUTHORITY.

2. National drug policy.

(1) The national drug policy shall be-

to ensure that essential, safe, efficacious and cost-effective drugs are made available to the entire population of Uganda to provide satisfactory health care;

to make a continuous review of the needs, knowledge and resources of essential drugs;

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

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

to provide systematic public information and professional training and retraining of health workers;

to improve the registration of drugs and licensing of pharmaceutical premises;

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.

3. Establishment of the National Drug Authority.

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.

The drug authority shall consist of the chairperson and the following other persons—
the director of medical services;
the commissioner for veterinary services;
the commissioner for commissioner for trade;
the director, criminal investigation department;
the chief of medical services, Ministry of Defence;
the chief of pharmaceuticals and health supplies;
(g) the head of the Natural Chemotherapeutics Laboratory;(h) the director, Mulago Hospital;(i) a representative of each of the following—
(i) the 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 the Uganda AIDS Commission; (k) two other persons appointed from the public.
The chairperson and the members appointed under subsection (2)(k) shall be appointed by the Minister.
The members appointed under subsection (3) shall be in office for three years but shall be eligible for reappointment. 4. 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

other member of the commission as may be authorised by the drug authority.

chairperson, the secretary and any

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)(a)Every document purporting to be 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 a contract or instrument entered into or executed by the drug authority shall be received in evidence without further proof as that instrument duly issued or a contract duly entered into or executed unless the contrary is proved. 5. Functions of the drug authority. (b) (c) (d) (e) (f) (g) (h) (i) (j) The drug authority shall be charged with the implementation of the national drug policy and, in particular, but without derogation of the foregoing, shalldeal with the development and regulation of the pharmacies and drugs in the country; approve the national list of essential drugs and supervise the revisions of the list in a manner provided by the Minister; estimate drug needs to ensure that the needs are met as economically as possible; control the importation, exportation and sale of pharmaceuticals;

(3) A contract or instrument which if entered into or executed by a person not being a body corporate would

control the quality of drugs;

promote and control local production of essential drugs;

encourage research and development of herbal medicines;

promote rational use of drugs through appropriate professional

training;

establish and revise professional guidelines and disseminate

information to health professionals and the public;

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.

6. Commission and other bodies of the authority.

There shall be a National Drug Authority Commission which shall consist of the chairperson and four other members appointed by the drug authority from among themselves.

The chairperson of the drug authority shall be the chairperson of the commission.

The functions of the commission shall be-

to exercise the functions of the drug authority which may require exercising when the drug authority is not sitting;

to monitor and supervise the implementation of the decisions of the drug authority;

to establish and revise from time to time, the working procedure of the drug authority;

to perform any other function relating to the functions of the drug authority as the authority may direct.

(4) There shall be the following committees of the drug authority—

the committee on essential drugs; and

the committee on the national formulary.

(5) The membership of the committee on essential drugs shall be as follows—
a chairperson appointed by the drug authority;
the commissioner of curative services of the Ministry of Health;
the chief of pharmaceuticals and health supplies;
the chief of medical services, Ministry of Defence;
the head of the School of Pharmacy;
a representative of each of the following specialities— (i) physician; (ii) paediatrician; (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.
(6) The committee on essential drugs shall have power to co-opt members deemed necessary.
(7) The membership of the committee on the national formulary shall be as follows—
a chairperson appointed by the drug authority on the recommendation of the appropriate professional bodies;
a member of the faculty of medicine of the universities in Uganda;
a member of the faculty of veterinary sciences;
a member from the School of Pharmacy;
a member from the Pharmaceutical Society of Uganda;
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) paediatrician;
(iv) gynaecologist/obstetrician;

(v) psychiatrist.

7. Meetings of the drug authority.

The drug authority shall meet for the discharge of its functions at least six times a year.

The National Drug Authority Commission shall establish the working procedure for the drug authority.

PART III—CONTROL OF THE DRUG SUPPLY.

8. National list of essential drugs.

There shall be a national list of essential drugs which shall be revised from time to time.

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.

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.

9. 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.

10. Estimation of drug needs.

The commission shall ensure regular assessment and estimation of the national drug needs both in the public and private sectors.

Estimates of the national drug needs shall be expressed both in unit (quantity) and financial cost.

For the purposes of providing accurate estimates of drug needs, the commission shall promote and encourage investigations, including studies of current morbidity patterns, drug utilisation and available diagnostic and therapeutic resources.

11. Drug nomenclature.

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

12. Restricted drugs.

(1) For the purpose of this Act and subject to this section—

the drugs specified in the First, Second and Third Schedules to this Act shall be classified drugs;

the drugs and articles specified in the Fourth Schedule to this Act shall be exempted drugs and articles; and

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

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

Where an entry in the First, Second or Third Schedule to this Act defines the proportions of a drug which bring a preparation containing it within the list of restricted drugs, subsection (2) shall not apply to that preparation.

Where, apart from 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.

Where, apart from 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.

13. Supply and dispensing of restricted drugs.

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

Subsection (1) shall not prevent—

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

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

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

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.

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

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

the restricted drug shall be distinctly labelled with the name and address of the person by whom it is supplied or dispensed:

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 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 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 or her direct supervision and in his or her presence.

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

14. Licensed persons.

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

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

that the business, so far as concerns the 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;

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

in the case of a partnership, that at least one of the partners is a pharmacist resident in Uganda, the authority may, on 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.

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 Act or any condition specified in the licence, or has ceased to be fit to carry on the business.

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 to imprisonment not exceeding five years or to both.

15. 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—

that the applicant is fit to carry on a business of supplying by retail restricted drugs, other than drugs of class A or 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) that the applicant is an authorised person, the authority may issue to the applicant a licence authorising him or her, 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 Act or any condition specified in the licence, or has ceased to be fit to carry on the business.

16. 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

Act 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 Act is in force.
- (2) No person shall supply any drug by means of an automatic machine.

17. Certificates of suitability of premises.

If on application made in the prescribed form for a 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.

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.

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.

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

18. Loss of class A or B drugs.

- (1) Any person entitled under this Act to supply or dispense a class A or B 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 inspector of drugs, 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 contravening any provision of this section commits an offence and is 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.

19. Classified drugs.

The Minister on the advice of the authority may, by statutory instrument, declare a drug to be a classified drug.

20. Need for prescription for classified drugs.

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.

A prescription shall be valid only if-

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

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

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;

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";

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

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—

the number of times it may be dispensed; and

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—

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

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

21. Action to be taken in relation to prescription.

Where a classified drug is supplied under a prescription—

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;

if the prescription is fully dispensed, it shall be retained by the supplier and, for 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.

22. 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.

23. 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.

24. Classified Drugs Book.

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 or her a book of the prescribed description to be known as the Classified Drugs Book.

Subject to subsection (3), before any person supplies class A, B or C Group II drugs, he or she shall enter or cause to be entered in the

Classified Drugs Book the following particulars—

the name and quantity of the drug to be supplied;

the name and address of the person who requires the drug;

the purpose for which the drug is stated to be required;

the signature of the person to whom the drug is delivered; and

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—

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 or she urgently requires a classified drug for the purpose of his or her trade, business or profession, and satisfies the seller that, by reason of some emergency, he or she 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;

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

the requirements of subsection (2) 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;

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 two years.

(4) Any person who contravenes any of 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. **25. Containers and labels.**

No person shall supply any classified or restricted drug unless—

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

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

26. Further restrictions on the supply of narcotics.

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

No person shall supply any narcotic drugs under international control other than for medical, dental or veterinary purposes.

27. Possession of classified drugs.

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

any person specified in section 14 for the purposes of that section;

a licensed person or seller of classified drugs, on premises registered under this Act;

a wholesale dealer licensed under this Act for the purposes of the licence and on the premises so licensed;

any person, institution or department to whom a classified drug has been lawfully sold in accordance with this Act, for the purpose for which the sale was made;

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 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.

28. Withdrawal of authority.

- (1) Where any person authorised to obtain or supply narcotics under this Act is convicted of any offence under this Act, if the Minister is of the opinion that that person ought not to be allowed to obtain, possess or supply drugs, he or she 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 Act.

29. Drug addicts.

Every medical practitioner or dentist shall keep a record in the prescribed form of all persons who are addicted to any drug specified in the First or Second Schedule to this Act and shall at least every year make a report to the Minister specifying the names of those persons and the drugs to which they are addicted.

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

Drugs generally.

30. Impure drugs not to be supplied.

Any person who—

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

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 to both.

31. 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—

details of the composition of the drug;

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

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.

32. 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—

claims are made for the drug, whether or not in a statement furnished under section 31, which are unjustified;

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;

details of the composition of the drug furnished under section 31 differ substantially from those disclosed on an analysis of samples of the drug obtained from retail suppliers; or

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 section 31.

33. Control of publication of descriptive matter.

(1) Subject to 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—

for prevention or treatment of any disease specified in the Fifth Schedule to this Act;

for the purpose of termination or influencing the course of human pregnancy; or

for any purpose relating to enhancing human potency.

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

(3) matter— (a) (b)

This section shall not apply to the publication of descriptive

by direction of the Minister;

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.

34. 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 or her of that business on those premises and annually in the month of January thereafter, send to the authority returns in the prescribed manner, stating—

the location and postal address of the premises;

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

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.

35. Drug regulation and registration of specialities.

(1) The drug authority—

may scientifically examine any drug for the purposes of ascertaining efficacy, safety and quality of that drug;

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-

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

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.

Where, on 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.

The authority may direct at any time for the deletion of any drug or preparation from the register.

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

36. Drug quality.

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.

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

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.

Wholesale trade.

37. Licence required for wholesale supply of restricted drugs.

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

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—

that the applicant is a person to whom the licence can properly be granted;

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

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

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

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

A 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.

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 Act 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.

38. Restrictions on manufacture of classified drugs.

No person shall manufacture any drug or preparation which is not included on the national formulary unless the drug or preparation is approved by the authority.

No person, unless approved by the authority in that behalf, shall manufacture a speciality.

No person shall manufacture any classified drug unless the processes of manufacture are carried out or supervised by a pharmacist.

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

39. Further restrictions on the manufacture of drugs.

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.

No person shall manufacture any narcotic drug or psychotropic substances under international control for purposes other than for medical, dental or veterinary use.

40. Clinical trials.

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.

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

41. Local research and production.

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.

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.

42. Storage.

- (1) Where restricted or classified drugs are kept on any premises, they shall be kept in accordance with the Seventh Schedule, but that Schedule shall not apply to drugs supplied to an individual for the treatment of himself or herself or another individual residing with him or her or an animal in his or her possession or control.
- (2) If an act is done on any premises in contravention of the above subsection then—

in a case where the act constitutes a breach of a duty imposed by or under the terms of his or her employment upon a person employed on the premises, that person shall be deemed to have committed an offence:

in any other case, the occupier of the premises shall be deemed to have committed an offence.

(3) Nothing contained in subsection (2) 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.

43. 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.

44. Importation of pharmaceuticals.

No person or body shall import any drugs into Uganda without having a licence in relation to their import from the drug authority.

The licence shall be valid for one year and shall state the range of preparations to be imported during that period.

45. Exportation of drugs.

No person or body shall export any drug or preparation without having a licence in relation to that export from the drug authority.

The licence shall be valid for one year and shall specify the drug to be exported.

A person who exports any classified drugs shall keep a record in the prescribed form of all exports. **46. Import and export licences.**

(1) The authority may grant a permit for the import or the export of a classified drug if—

an application for the permit is made in the prescribed form and the applicant pays the prescribed fee; and

the authority is satisfied that the applicant is a person to whom the permit can properly be granted.

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.

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.

47. Possession of narcotics.

No person shall 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 under international control.

The Minister may, by statutory instrument, make regulations applying subsection (1) to such other narcotic drugs as are specified in the regulations.

48. Smoking of opium or Indian hemp.

No person shall—

smoke opium or Indian hemp or frequent any place used for the smoking of opium or Indian hemp;

permit premises owned or occupied by him or her to be used by persons smoking opium or Indian hemp; or

have in his or her possession pipes or other utensils for use in connection with the smoking of opium or Indian hemp.

49. Cultivation of plants yielding narcotics.

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

PART VII—POWERS OF ENTRY AND INVESTIGATION. **50.** Powers of entry.

(1) An inspector or assistant inspector of drugs may enter—

at all reasonable times, any premises in respect of which a certificate issued under this Act is in force or on which any person is required to carry out any functions imposed under this Act;

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

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

at any time, any vehicle or vessel which he or she reasonably suspects is being or is about to be used in the commission of an offence under this Act.

(2) Any police officer not below the rank of assistant superintendent may enter, at any reasonable time, any premises or detain and enter any vehicle or vessel on or in relation to which he or she has reasonable cause to suspect that an offence under this Act has been or is being committed.

51. Powers of investigation.

(1) A drug inspector, assistant inspector of drugs or police officer of the rank of assistant superintendent empowered under this Act to enter any premises, vehicle or any other means of transport may—

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

require any person on or in the premises, vehicle or vessel to furnish any information in his or her possession as to the activities carried on or in the premises and the person by whom they are carried on or the purposes for which the vehicle or vessel

is being used; (c) take away any drug or records and other documents found on or in the premises, vehicle or vessel.

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

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

no payment shall be made in respect of a drug if the inspecting officer anticipates that proceedings for an offence under this Act will be brought in respect of the drug; but if the proceedings are not commenced within six months, reasonable payment shall be tendered by the inspecting officer in respect of the drug which is not returned to its owner in good condition.

52. Authority to be shown.

An inspecting officer exercising any powers conferred by this Act shall produce on demand a duly authenticated document showing that he or she is entitled to exercise those powers.

53. Obstruction.

No person shall obstruct an inspecting officer exercising powers under this Part of this Act or fail to comply with a requirement made by him or her in exercise of those powers.

PART VIII—THE SECRETARIAT AND FINANCIAL PROVISIONS.

54. Secretariat.

(1) The drug authority shall have a secretariat which shall be responsible for the day-to-day operations of the drug authority.

- (2) The secretariat shall be headed by the secretary to the drug authority who shall be appointed by the drug authority on terms and conditions that the drug authority may determine.
- (3) In addition to any other functions that may be conferred upon him or her by the drug authority, the secretary shall—

have custody of the seal of the drug authority;

be responsible for taking the minutes of the drug authority and the commission and for keeping the records of the transactions of the drug authority.

There shall be other officers and employees of the drug authority as the drug authority may determine.

An employee of the drug authority shall not, in his or her personal capacity, be liable to any civil or criminal proceedings in respect of any act done or omission made in good faith in the performance of his or her duties under this Act.

55. Funds of the drug authority.

(1) The funds of the drug authority shall consist of—

grants from the Government;

grants and loans from any body, organisation or person;

interest on savings made by the drug authority;

money that may accrue to the drug authority in the discharge of its functions; and

money from any other source as may be approved by the Minister.

(2) The drug authority shall possess a bank account in a bank approved by it.

56. Estimates.

The drug authority shall, within three months before the commencement of each financial year, prepare and submit to the Minister, estimates and expenditure for the drug authority for the next ensuing year; and any time before the end of a financial year, the drug authority may prepare and submit to the Minister for approval any estimates supplementary to the estimates of a current year.

The Minister shall notify the drug authority of his or her decision on the estimates submitted to him or her within one month of the submission of the estimates.

(3) No expenditure shall be made out of the funds of the drug authority unless that expenditure is part of the expenditure approved by the Minister under the estimates for the financial year in which the expenditure is to be incurred or in supplementary estimates for that year.

57. Accounts.

The drug authority shall keep proper books of account of all its income and expenditure and proper records in relation to those accounts.

Subject to any direction given by the Minister responsible for finance, the drug authority shall cause to be prepared in respect of each financial year, a statement of account which shall include—

a balance sheet, a statement of income and expenditure and a statement of surplus and deficit; and

any other information in respect of the financial affairs of the drug authority as the Minister responsible for finance may require.

58. Audits.

The accounts of the drug authority shall, in respect of each financial year, be audited by the Auditor General or an auditor appointed by him or her.

The drug authority shall ensure that within four months after the end of the financial year a statement of account is submitted to the Auditor General for auditing.

The Auditor General and any auditor appointed by him or her shall have access to all books of account, vouchers and other financial records of the drug authority and be entitled to have any information and explanation required by him or her in relation to those records.

The Auditor General shall, within two months after receipt of statements of accounts under this section, audit the accounts and deliver to the drug authority and the Minister a copy of the audited accounts and his or her report on those accounts.

PART IX -MISCELLANEOUS PROVISIONS.

59. Rational use of drugs.

The drug authority shall, in the interest of public health and the economical use of resources, and in consultation with the bodies concerned, promote the rational use of drugs both in the private and public sector.

In the implementation of subsection (1), the drug authority may adopt methods and materials which have proved effective in other countries and shall, among other methods, do the following—

develop basic and postgraduate training in the health sector;

promote public awareness and knowledge of the proper use of drugs; and

disseminate information on the purposes and progress of the national drug policy.

60. Offences and penalties.

(1) A person contravening a provision of this Act commits an offence and, where no punishment is provided, is liable—

to a fine not exceeding one million shillings;

to a withdrawal of the licence or permit for a period not exceeding five years;

to cause the items in contravention to be impounded, forfeited, destroyed or disposed of in a manner prescribed by the Minister;

to imprisonment not exceeding one year; or (e) to any two of the above punishments, and for any subsequent offence under this Act, a person is liable to a fine not exceeding two million shillings or to a term of imprisonment not exceeding five years or to both.

(2) A person who commits an offence under this Act and no other punishment is provided is liable—

where the offence relates to class A drugs, to a fine not exceeding two million shillings or to a term of imprisonment not exceeding five years or to both;

where the offence relates to narcotic drugs or psychotropic substances under international control and is a second or more subsequent offence, to a term of life imprisonment;

(c) where the offence relates to manufacturing, smoking or having possession of any narcotic drug or psychotropic substance under international control and is a second or more subsequent offence, to a term not exceeding ten years.

Where no case is proved in respect of any drug or article taken from an accused person, the court shall order reasonable payment to the owner in respect of the drug or article which is not returned to him or her in good condition.

No proceedings shall be instituted for an offence under section 35 without the consent of the Director of Public Prosecutions.

61. Vicarious criminal responsibility.

Any act or omission which if done by an individual would be an offence under this Act or any regulations made under it shall, if done by a body corporate, be deemed to be an offence committed by every director, secretary and manager of the body corporate, unless the director, secretary or manager 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.

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.

62. Evidence.

(1) In any proceedings under this Act—

any licence, permit or certificate purporting to have been issued under this Act; or

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—

the unlawful possession, sale or supply of any restricted drug and the drug is in a container; or

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.

63. Drugs bureau.

There shall be established a drugs bureau under the office of the inspector of drugs.

The drugs bureau shall—

keep and maintain a register in which shall be entered details of the composition of all drugs registered under section 35;

keep and maintain a list of all toxic substances, their composition, toxicity and antidotes;

supply such information to medical practitioners, dentists or veterinary surgeons in respect of drugs as may be in its possession in emergency cases of poisoning.

In order to discharge its functions under this section, the drugs bureau may require any person to give any information in his or her possession or control regarding any drug, and that person shall furnish the information within such period as may be specified by the drugs bureau.

Subject to subsection (2)(c), any information furnished to the drugs bureau under subsection (3) shall be kept confidential and shall not be published without the consent of the person furnishing the information.

64. Regulations.

- (1) The Minister may, on the advice of the drug authority, by statutory instrument, make regulations generally for better carrying into effect the provisions of this Act—
- (a) including the period within which all drugs imported—
- (i) should be labelled and prescribed by their International

Nonproprietary Names (INN) or generic names; and (ii) but not appearing on the national list of essential drugs or the national formulary may be off the market;

prescribing the procedure to be followed at meetings, inquiries and other proceedings of the authority and its committees;

prescribing conditions to be inserted in licences or permits granted under this Act, and otherwise prescribing things to be done in relation to such licences or permits;

laying down conditions in respect of supplies and issues of drugs by hospitals and the storage of drugs by hospitals and the records to be kept;

use of drugs in first-aid boxes notwithstanding any other enactment;

prohibiting, regulating or restricting the manufacture, sale or advertising of drugs, pharmaceutical preparations and therapeutic substances;

regulating, restricting or prohibiting the importation, sale or advertising of surgical instruments and appliances;

- (h) regulating and restricting the use of classified drugs for agricultural, horticultural, mining and industrial purposes, and the measures to be taken to protect the persons using such classified drugs, including the types and standards of protective clothing which shall be worn;
- (i) requiring the registration and treatment of persons addicted to drugs;
- (j) the registration and operation of authorised persons;
- (k) prescribing anything which under this Act may be prescribed.

65. Amendment of Schedules.

The Minister may, after consulting the authority, by statutory order, amend the First, Second, Third, Fourth, Fifth, Sixth, Seventh and Eighth Schedules to this Act.

SCHEDULES

First Schedule.

ss. 12 and 29.

Class A drugs or narcotics.

The drugs included in this class may only be imported, or exported, manufactured or used, under authority. They may be sold by retail only on the prescription of a duly qualified medical practitioner, dentist or veterinary surgeon, but only for medical, dental or veterinary purposes and may be supplied only by a registered pharmacist or licensed pharmacy.

registered pharmacist or lice
Acetorphine
Acetyl-alpha-methylfentanyl
Acetyldihydrocodeine
Acetylmethadol
Alfentanil
Allyprodine
Alphacetlylmethadol
Alphameprodine
Alphamethadol.
Alpha-methylfentanyl
Alphaprodine
Anileridine

Benzethidine Betacetylmethadol

Betameprodine Betamethadol

Betaprodine

Bezitramide Cannabis (Indian hemp) and

Cannabis resin (resin of Indian hemp) Clonitazene Coca leaf Cocaine Codeine Codoxime

Concentrate of poppy straw (the material arising when poppy straw has entered into a process for the concentration of its alkaloid when such material is made available in trade)

Desomorphine

Dextromoramide

Dextropropoxyphene

Diampromide

Diethylthiambutene

Difenoxin

Dihydrocodeine

Dimepheptanol

Dimethylthiambutene

Dioxaphetyl butyrate

Diphenoxylate

Dipipanone

Ecgonine, its esters and derivatives which are convertible to ecgonine and cocaine

Ethlymethylthiambutene

Ethylmorphine

Etonitazene

Etorphine	Noracymethadol
Etoxeridine	Norcodeine
Fentanyl	Norlevorphanol
Furethidine	Normethadome
Heroin	Normorphime
Hydrocodone	Norpipanone
Hydromorphinol	Opium
Hydroxypethidine	Oxycodone
Isomethadone	Oxymorphone
Ketobemidone	Para-fluorofentanyl

Levomethorphan			PEPAP
Levomoramide			Pethidine
Levophenacylmorphan			Pethidine-intermediate-A
Levorphanol			Pethidine-intermediate-B
Metazocine			Pethidine-intermediate-C
Methadone			Phenadoxone
Methadone-intermediate			Phenampromide
Methyldesorphine			Phenazocine
Methyldihydromorphine			Phenomorphan
3-methylfentanyl			Phenoperidine
Metopon			Pholcodine
Moraine-intermediate			Piminodine
Morpheridine			Piritramide
Morphine			Proheptazine
Morphine Methobromide	and	the	Properidine
pentavalent nitrogen morphine			Propiram
derivatives, including,		in	Racemethorphan
particular, the morphine-N-			Racemoramide
oxide derivatives,	one	of	Racemorphan

which is Codeine-N-Oxide

Morphine-N-Oxide

Thebacon

MPPP

Thebaine

Myrophine

Thiofentanyl

Nicodicodine

Trimeperidine

Nicomorphine

The isomers, unless specifically excepted, of the drugs in this Schedule whenever the existence of such isomers is possible within the specific chemical designation.

The salts of the drugs listed in this Schedule, including the salts of the

isomers as provided above whenever the existence of such salts is possible. The esters and ethers, unless appearing in another Schedule of the drugs in

this Schedule whenever the existence of such esters or ethers is possible. The salts of the drugs listed in this Schedule, including the salts of esters,

ethers and isomers as provided above whenever the existence of such

salts is possible.

Second Schedule.

ss. 12 and 29.

Class B drugs or controlled drugs.

GROUP I.

The following drugs may be supplied by retail only on the prescription of a duly qualified medical practitioner, dentist or veterinary surgeon, but only for medical, dental or animal treatment respectively.

Acetahexamide
Acetanilide; alkyl acetanilides (except as provided in Group II)
Acetazolamide
Acetylcarbromal
Acocanthera, glycosides of
Adenium, glycosides of
Alcuronium chloride

Allylisopropyl-acetylurea

Amidopyrine, its salts; amidopyrine sulphonates, their salts.

b-Aminopropylbenzene and b-aminoisopropylbenzene; their salts, synthetic compound structurally derived from either of those substances by substitution in the aliphatic part or by ring closure therein (or by both such substitution and closure except ephedrine, its optical isomers, N-substituted derivations oxethazaine, phenylpropanolamine, phenylamine and tropicamide), any salt of any substance falling within this item

p-Aminobenzenesulphonamide; its salts, derivatives of p-aminobenzenesulphonamide having any of the hydrogen atoms of the p-amino group or the sulphonamide group substituted by another radical; their salts (except as provided for in Group II of this class) Aminometradine p-aminosalicylic acid; its salts, any preparation of p-aminosalicylic acid; their salts Aminorex, its salts Aminosometradine. Amitriptyline, its salts Androgenic, oestrogenic and progestational substances, the following—

Benzoestral

Derivatives of stilbene, dibenzyl or naphthalene with oestrogenic activity; their salts; their esters

Steroid compounds with androgenic, oestrogenic or progestational activity; their esters (except as provided in Group II of this class) Antibiotics, the following (except as provided in Group II of this class) any

substance the chemical and biological properties of which are identical

with or similar to those antimicrobial substances but which is produced

by means other than living organisms Amphomycin and its salts; its esters and salts of such esters Amphotericins and their salts Bacitracin

Capreomycin and its salts, its esters and salts of such esters Cephaloridine and its salts; its esters and salts of such esters Chloramphenicol Chlortetracycline Cycloserine and its salts Demethylchlortetracycline and its salts Erythromycin; its salts; its esters and salts of such esters Framycetin and its salts

Fusidic acid and its salts, its esters and salts of such esters Gentamycin and its salts, its esters and salts of such esters Gramicidin

Griseofulvin and its salts Kanamycin and its salts

Lincomycins, their salts, their esters and salts of such esters Neomycin and its salts Novobiocin and its salts Oleandomycin and its salts; its esters and their salts Oxytretracycline and its salts

Paramomycin and its salts, its esters and salts of such esters Penicillin and its salts, derivatives and their salts

Polymyxins and their salts

Rifamycins, their salts, their esters and salts of such esters

Ristocetins and their salts

Spiramycins and its salts

Streptomycin, its salts, its derivatives and their salts

Sulphomycin

Tetracyclins and their salts

Tyrothricin

Vancomycin and its salts

Viomycin and its salts

Virgiamycin and its salts

Azacyclonol acid, its salts

Barbituric acid, its salts; derivatives of barbituric acid; their salts;

compounds of barbituric acid; their salts; their derivatives, their salts;

with any other substance (except as provided in Group II of this class) Benactyzine; its salts Benzhexol; its salts

Benztropine, its homologues; their salts Bromvaltene Busulphan, its salts Captodiame; its salts Caramiphen; its salts Carbromal Carisoprodal

Chlordiazepoxide; its salts Chlormethiazole Chlorophentermine; its salts

Chlorothiazide and other derivatives of Benzol 2:4-thiadiazine -7-sulphonamide 1:1-dioxide, whether hydrogenated or not Chlorphenoxmine; its salts Chlorpropamide; its salts Chlorprothixene, and other derivatives of 9-methylenethiazane-ther, their

salts Chlorthalidone, and other derivatives of o-chlorbenzene sulphonamide. Clorexolone, its salts Corticotrophinis, natural and synthetic Cycalrbamate Cycrimine, its salts Debrisoquine sulphate Demacarium bromide

Desipramine; its salts

Diazepam, and other compounds containing the chemical structure of

dihydro-1-4-benzodiazepine substituted to any degree; their salts Dinitrocresols (DNOC) their compounds with a metal or base, except when

in preparations especially formulated and approved for use in

agriculture or horticulture Dinitronaphthols dinitrophenols dinitrothymols Disulfiram Dithienylalkylamines; dithienylakylallylamines; their salts except

diethylthaimbutene Dyflos

Ecothiopate iodide Ectylurea Embutramide Emylcamate Ergot, alkaloids of, whether hydrogenated or not; their homologues; any salt

of any substance falling within this item (except as provided in Group

II of this class) Ethacrycin acid; its salts Ethchlorynol Ethinamate Ethionamide Ethoheptazine; its salts Fenfluramine; its salts

Flufenamic acid; its salts; its esters, their salts Gallamine; its salts; its quaternary compounds Glutethimide; its salts Guaiphenesin

Haloperidol; and other 4-substituted derivatives of N-(3-p-fluorobenzolpropyl) piperidine Hexapropymate Hydrazines, benzyl, phenethyl and phenoxythyl; their a-methyl derivates;

acyl derivatives of any of the foregoing substances comprised in this

item; salts of any compounds comprised in this item Hydroxy-N, N-dimethyltryptamines; their esters or ethers; any salt of any

substance falling within this item Hydroxyurea Hydroxyzine; its salts Imipramine; its salts Indomethacin; its salts Iprindole; its salts

Isoniazid; its salts; derivatives of isoniazid; their salts

Mafenamic acid; its salts; its esters, their salts

Mannomustine; its salts Mebezonium; its salts

Mebutamate

Meclofenokate; its salts Mephenesin; its esters

Meprobamate Meralluride

Mercaptopurine, its salts, derivatives of mercaptopurine, their salts

Mescaline, and other derivatives of phenethylamine formed by substitution

in the aromatic ring, their salts Metaxalone; its salts Metformin; its salts Methaqualone; its salts Methoxysalen Methoxysalen Methyldopa

Methylpentynol; its esters and other derivatives Methyprylone Metoclopramide; its salts Metronidazole Mitopodozide; its salts Mustine and any other N-substituted derivatives of di-(2-chloroethyl) amine; their salts Nortryptyline; its salts Orphenadrine Oxethazine Oxyphenbutazone Oxytocins, natural and synthetic Paramethadione Pargyline; its salts Pemoline, its salts Pentazocine; its salts Phenacemide Phenaglycodal Phenanthridinium; its salts; its derivatives; their salts; their compounds with other substancesPhenbutrazate Phencylidine; its salts Phenetidylphenacetin

other substances Phenbutrazate Phencylldine; its saits Phenetidylphenace

Phenformin; its salts

Phenothiazine; its salts; derivatives of; their salts; except dimethoxanate, its

salts and promethazine, its salts and its molecular compounds, except

also as shall be provided for in Group II of this class and class C Phenylbutazone; its salts

2-Phenylcinchoninic acid, 2-salicylcinchoninic acid; their salts; their esters 5-Phenylhydantoin; its alkyl and aryl derivatives; their salts Pituitary gland, the active principles of whether natural or synthetic except as provided for in Group II of this class Polymethylnebistrimethylammonium salts Procarbazine; its salts Procyclidine; its salts Promoxalan

Propylhexedrine; its salts Prothionamide Prothipendyl; its salts Quinapyramine; derivatives of

quinapyramine; their salts; compounds of

quinapyramine with other substances Quinethazone Rauwolfia; alkaloids of; their salts, derivatives of the alkaloids of rauwolfia;

their salts Spironolactone Strychnine (except in preparations included in Group II of this class and class C) Styramate Sulphinpyrazone Sulphonal, alkyl sulphonals Sulphones; their salts, their derivatives Suprarenal gland, the active principles of; whether natural or synthetic, their

esters and salts of such esters, provided for in Group II of this class Suramin

Syrosingopine; its salts Tetrabenazine; its salts Thalidomide; its salts Thiacetazone; its salts; its derivatives Thiocarlide; its salts

Thyroid gland; the active principles of; their salts Tolbutamide Tretamine; its salts Triaziquone; its salts Tribromethyl alcohol

2: 2: 2-Trichloroethyl alcohol; esters of; their salts

Trimipramine; its salts

Troxidone Tybamate

Vasapressins, natural and synthetic

Verapamil

Zoxazolamine; its salts

GROUP II.

The following drugs and preparations containing such drugs may be supplied by retail only by a registered pharmacist or licensed pharmacy.

Acetanilide, alkyl, acetanilides, when contained in preparations not intended for the treatment of human ailments Acetyldihydrocodeine; its salts, when contained in approved preparations

containing not more than 100 milligrammes of the drug per dosage unit

or 2.5 percent in individual preparations Alcuronium chloride Aldrin (except as provided in class C) Alkali fluorides (other than those specified in class C) Alkaloids and related substances; the following; their salts, simple or

complex; their quaternary compounds Aconite, alkaloids of (except as provided in class C) Atropine Belladonna, alkaloids of (except as provided in class C) Brucine (except as provided in class C) Calabar bean, alkaloids of Cocaine, but only in approved preparations containing less than 0.10 percent w/v of cocaine Codeine when contained in approved preparations containing not more than 2.5 percent of codeine Colchicum, alkaloids of Coniine (except as provided in class C) Cotarnine Curare, alkaloids of; curare bases, their salts and quaternary compounds Ephedrine, its optical isomers except as provided in class C Ergotamine tartrate but only when contained in oral preparations for the relief of migraine Gelsemium, alkaloids of Homatropine

Hyoscine (except as provided in class C)

Hyoscyamine (except as provided in class C)

Jaberandi, alkaloids of

Lobelia, alkaloids of (except as provided in class C)

Morphine, but only in approved preparations containing less than 0.20

percent w/v and as provided in class C Nicotine (except as provided in class C) Papaverine

Pomegranate, alkaloids of Quebracho, alkaloids of Sabadilla, alkaloids of

Salanaceous alkaloids not otherwise included in this list Stavesacre, alkaloids of

Stramonium, alkaloids of (except as provided in class C) Strychnine when contained in preparations containing not more than 1

percent of strychnine and as provided in class C Thebaine

Veratrum, alkaloids of Yohimba, alkaloids of

Allylisopropyl acetylurea Allylprodine; its salts Alphameprodine; its salts Alphaprodine, its salts Aluminium phosphide

Amino-alcohols esterified with benzoic, phenylacetic acid, phenylpropionic acid, cinnamic acid or the derivatives of these acids, their salts

p-Aminobenzenesulphonamide having any of the hydrogen atoms of the p-amino group or of the sulphonamide group substituted by another radical; their salts, but only when in the form of approved preparations containing not more than 50 percent of such drugs and intended for external use only; or in specifically formulated, labelled and approved preparations for the prevention and treatment of diseases in poultry, or in animal feeding stuff, containing not more than .5 percent of sulphonamides Amyl nitrite

Anileridine, its salts

Androgenic, oestrogenic and progestational substances as defined in Group I of this Schedule when contained in approved cosmetic preparations

Antibiotics as listed in Group I of this Schedule, when contained in

preparations or concentrates for animal feeding stuffs, as provided in class C Antihistamine substances; the following: their salts; their molecular compounds (except as provided in class C) Antazoline

Bromodinhenhydramine Rudizine Carbinovamine Chlorbeniramine Chlorovlizing

Bromodiphenhydramine Buclizine Carbinoxamine Chlopheniramine Chlorcylizine Cinnarizine Cyproheptadine

3-Di-n-bytylaminomethyl -4:5:6 trihydroxyphthalide Diphenhydramine Diphenylpyraline Doxylamine Isothipendyl Mebhydrolin Meclozine Phenindamine Pheniramine Phenyltoloxamine Promethazine Pyrrobutamine Thenalidine Tolpropamine Triprolidine Substances being tetra substituted N derivatives of ethylenediamine or

prophylendiamine

Antimonial substances; antimonates, antimonites, chlorides of; oxides of; sulphides of; organic compounds of antimony Apomorphine, its salts Arsenical substances; arsenates, arsenites, halides of arsenic, oxides of

arsenic, sulphides of arsenic, organic compounds of arsenic (except as provided in class C) Barium, salts of; (other than the salts of barium specified in class C) Butylchloral hydrate Calcium phosphide Cantharidin, cantharidates Carbachol Carperidine; its salts

Chloral; its addition and its condensation products, their molecular

compounds (except as provided in class C) Chloroform (except as provided in class C) Clorprenaline; its salts

Creosote obtained from wood (except as provided in class C) Dehydroemetine; its salts Dextromethorphan; its salts Dextrorphan; its salts Diacetylnalorphine; its salts Digitalis, glycodies and other active principles of Dihydrocodeinse when contained in approved preparation containing not

more than 2.5 1/5 of Dihydrocodeine Dimitrocresols (DNOC); their compounds with a metal or base when in

preparations specially formulated and approved for agricultural or

horticultural purposes Dinosam; its compounds with a metal or base Dinoseb; its compounds with a metal or base Diphenoxylate; its salts, when contained in approved formulation containing not more than 2.5 milligrammes of diphenoxylate base per dosage unit. Endosulfan (except as provided in class C) Endothal; its salts (except as provided in class C) Endrin (except as provided in class C) Ethylmorphine when contained in preparations containing not more than 2.5

of ethylmorphine Ethylnoradrenaline; its salts Etonitazene; its salts Etoxeridine; its salts Fenranyl; its salts Fluanisone

Fluoroacetamide; fluoroacetanilide Furethidine; its salts Glyceryl trinitrate Guanidines, the following—

Polymethylene diguanidines,

di-p-anizyl-p-phenethlauanidine Heparin and preparations thereof

Hydrocyanic acid, cyanides; double cyanides of mercury and zinc Hydroxycinchoninic acid; derivatives of, their salts, their esters 4-Hydroxy-3-nitrophenylarsonic acid Insulin

Iprindole, its salts

Isetharine, its salts

Isoaminile, its salts

Isoprenaline, its salts

Isoprophenamine, its salts

Isopropylarterenol, its salts
N-Isopropylethylnoradrenaline, its salts
Isopropylnoradrenaline, its salts
Isoproterenol, its salts
Laudexium, its salts
Lead; salts of; compounds of lead with acids from fixed oils
Levisoprendhine; its salts
Mannityl hexanitrate
Mercury, oxides of; nitrate of mercury, mercuric ammonium chlorides,

potassio-mecuric iodides, organic compounds of mercury; oxycyanides,

mercuric thiocyanates, mercuric chloride, mercuric iodide, mercurous chloride (except as provided in class C) Methoxiphenadrin; its salts Methoxyphenamine, its salts Methylaminoheptane; its salts Methylbromide

Monofluoroacetic acid; its salts Nalorphine; its salts Nialamide; its salts

Nitrobenzene (except as provided in class C) m-Nitrophenol; o-Nitrophenol; p-Nitrophenol Norcodeine; its salts when contained in approved preparations containing not

more than 2.5 percent of Norcodeine Nux Vomica (except as provided in class C) Opium, but only in preparation for external use and containing not more than

0.2½ of morphine, calculated as anhydrous morphine Orciprenaline; its salts

Organofentin compounds, that is compound of fentin Orthocaine; its salts Ouabain

Oxalic acid, salts of (except as provided in class C) Oxycinchoninic acid, its derivatives; their salts; their esters Pamaquine Phenamidine; its salts Phenobarbitone when contained in approved preparations containing

Theophylline, ephedrine and not more than 6 milligrammes of

phenobarbitone per dosage unit

Phenols (any members of the series of phenols of which the first member is phenol and of which the molecular composition varies from member to member by one atom of carbon and two atoms of hydrogen) except in substances containing less than 60.5 percent weight in weight of phenols; compounds of phenol with a metal; except in substances containing less than the equivalent of 60 percent weight in weight of phenols

Phenothiazine; its salts; when in approved preparations specially formulated and labelled for animal treatment (and as provided in class C)

Phenylene diamines, toluene diamines, other alkylated benzene diamines, their salts (except as provided in class C)

Phenylpropanolamine; its salts

Pholcodine, salts of, when contained in preparations containing not more than $2\frac{1}{2}$ 1/5 of pholcodine (and as provided in class C)

Phosphorous, yellow (except as provided in class C)

Phosphorus compounds, the following (except as provided in class C)

Amiton

Azniphos-ethyl

Azniphos-methyl

Cholorfenrinphos

Demeton-O

Demeton-O-methyl

Demeton-S

Demeton-S-methyl

Diazonon

Dichlorvos

Diethyl 4- methyl-7-courmarinyl phosphorothionate

Diethyl-p-nitrophenyl phosphate Dimefox Disulfotan Ethion Ethyl-p-nitrophenyl phenyphosophonothimate Maridox

Mecardbam

Merimphos

Mipafox

Oxydematon-methyl

Paralthion

Phenhaptan

Phosphamidan

Plorate

Schradan

Sulfotep

Tepp (Hepp)

Thionazin

Triphosporic pantadimethylamide

Vamidothion

Quinapyramine

Savin, oil of

Selenium; its compound (except as provided in class C)

Sodium chlorate

Strophanthus, glycodides of strophanthus

Suprarenal gland, the active principles of; their salts, but only when

contained in preparations for external application or in inhalants, rectal

preparations or preparations intended for use in the eye Schradan Tetrachloroethylene Thallium, salts of Toxaphene (except as provided in class C) Trichloroethyl phosphate Trimeperidine; its salts

Warfarin; its salts (except as provided in class C) Zinc phosphide (except as provided in class C) All radioactive materials

Hypodermic needles and hypodermic syringes used for injection Preparations of human blood Substances commonly known as vaccines, sera, toxin, antitoxins and

Antigens Substances known as stethoscopes Any other substance or preparation not otherwise specified if in a form

intended for, or suitable for, injection Surgical ligatures; any absorbent or protective material capable of being

absorbed by the body tissues offered or intended for use in surgical

operations

Third Schedule.

s. 12.

Class C licensed drugs.

Note—The following drugs, except such as are in a form suitable for administration by injection, are the drugs included in this Schedule. They may be sold by retail only by a person or company operating a licensed pharmacy or a licensed drug seller, but in the case of the latter, only in accordance with the terms of his or her licence.

GROUP I.

Any proprietary preparation which does not contain any class A or B drugs Aconite, alkaloids of, in preparations containing less than 0.02 percent of the alkaloids of aconite Antibiotics, when contained in preparations or concentrates for animal feeding stuffs Antihistamines as listed in class B, Group II, but only when contained in

preparations for external application only, other than for the eye or

nose, and in preparations containing not more than 1 percent of an

antihistamine substances intended for application only to the eye or nose Arsenic, in preparations containing less than the equivalent of 0.01 percent

of arsenic trioxide, and dentifrices containing less than .5 percent of acetarsol Barium sulphide when contained in depilatories Belladonna, alkaloids of, in preparations containing less than 0.15 percent of

the alkaloids of belladonna, calculated as hyscyamine Brucine, when contained in surgical spirit containing not more than 0.2

percent of brucine Chloroform, in preparations containing not more than 5 percent of chloroform Codeine, when contained in preparations in a proportion of less than 1.5

percent; and also when contained in compound tablets of Codeine B.P.,

or tablets of a similar composition each containing not more than 10

milligrammes of codeine; and being in sealed containers holding not more than twenty-five such tablets Coniine, in preparations containing less than 0.1 percent of coniine Creosote, preparations containing not more than 10 percent of creosote obtained from wood Emetine, preparations containing less than 1 percent of emetine Ephedrine salts when contained in preparations containing less than 1

percent of the alkaloids of ephedra; tablets of ephedrine hydrochloride

containing not more than 30 milligrammes of ephedrine hydrochloride

per tablet, and being in sealed containers holding not more than fifty such tablets Ethylrnorphine, in preparations containing less than 0.2 percent of ethylmorphine Hyoscine, when in preparations in the form of tablets and intended for use in travel sickness Hyoscyamine, in preparations containing less than 0.15 percent of hyoscyamine Lobelia, alkaloids of, in preparations for the relief of asthma or in substances containing less than 0.50 percent of the alkaloids of lobelia Mercuric ammonium chloride when contained in an ointment containing not

more than 5 percent of mercuric ammonium chloride or when contained in approved cosmetic preparations Mercuric oxide when contained in yellow oxide of mercury ointment Morphine in approved preparations containing less than 0.2 percent of anhydrous morphine Nux Vomica, alkaloids of; in preparations containing less than 0.2 percent of the alkaloids of Nux Vomica calculated as strychnine Ohenothiazine, when in approved preparations, specially formulated and

labelled for animal treatment Phenylene diamines, touene diamines, other alkylated benzene diamine; their salts, when contained in preparations intended for use as hair dyes Pholcodine in approved preparations containing not more than 1 percent of

pholcodine Solenium; its compounds when contained in hair lotions and similar preparations Stramonium, alkaloids of, in preparations for the relief of asthma or

substances containing less than 0.15 percent of alkaloids calculated as hyoscyamine Strychnine, in preparations containing less than 0.2 percent of strychnine Sulphadimidine, when contained in approved preparations formulated and

labelled for the treatment of poultry diseases containing not more than

16 percent w/v of sulphadimidine

GROUP II.

Aldrin, when contained in preparations for agricultural or horticultural purposes, and sold in the original container as supplied by the

manufacturer Ammonia Barium carbonate, when in preparations intended for the destruction of rats and mice Barium silico fluoride Chloralose, when contained in preparations for the destruction of rats and mice Chlordane, when contained in preparations for agricultural or horticultural purposes Dieldrin, when contained in preparations for agricultural or horticultural

purposes and sold in the original container as supplied by the manufacturer Endosulfan, when contained in preparations for agricultural or horticultural purposes Endothal, when contained in preparations for agricultural or horticultural purposes Endrin, when contained in preparations for agricultural or horticultural purposes Formaldehyde Formic acid Hydrochloric acid Hydrofluoric acid Metallic oxalates other than potassium quadroxalate in photographic solutions Nicotine, its salts; when contained in preparations intended for agricultural or horticultural purposes Nitric acid Nitrobenzene; when contained in agricultural or horticultural insecticides; in

substances for the treatment of bee disease and in ointments for animal treatment Paraquat; salts of Phenols as defined in class B, Group II of the Second Schedule to this Act in

substances containing less than 60 percent weight of phenols;

compounds of phenol with a metal in substances containing less than the equivalent of 60 percent weight of phenols Phosphoric acid Phosphorus, yellow, when contained in rat poisons Phosphorus compounds as listed in class B, Group II, but only when

contained in preparations specially formulated, packed and labelled for

agricultural or horticultural purposes and sold in the original container

as supplied by the manufacturer
Potassium fluoride
Potassium hydroxide
Potassium quadroxalate
Sodium fluoride
Sodium hydroxide
Sodium nitrate
Sodium solico fluoride
Sulphuric acid

Toxaphene, but only in preparations intended for use in agricultural or

horticultural purposes, and sold in the original container as supplied by the manfacturer Warfarin, its salts, when contained in preparations for the destruction of rats and mice Zinc phosphide when in preparations intended for the destruction of rats and

Fourth Schedule.

s. 12.

Exempted drugs and articles.

The following drugs and articles are known as exempted drugs and articles.

Adhesives

Ammonia, substances containing less than 5 percent of ammonia,

refrigerators. Antifouling compositions

Antimony, chlorides of, when contained in polishes Batteries and accumulators Builders' materials

Ceramics Chemicals not included in class A, B or C when packed and labelled for

culinary and cooking purposes Creasote, obtained from coal tar Dentrifrices Distempers

Dressings on seeds or bulbs Electrical valves Enamels Explosives

Fireworks

Fitters, fire extinguishers

Fluorescent lamps

Formaldehyde, when in photographic glazing or hardening solution

Glazes

Glue

Inks

Lacquer solvents

Laundry materials; blue, bleaches and starch

Loading materials

Matches

Medicated soap

Motor fuels and lubricants

Nitrobenzene, when contained in polishes

Oxalic acid and metallic ozalates when contained in polishes and cleaning powders Paints (other thin pharmaceutical paints)

Phenylmercuric salts, when used in a concentration not exceeding 0.01 per cent in toilet and cosmetic preparations as a preservative or in textiles or antiseptic dressings as a bacteriostat or fungicide Photographic paper

Pigments

Plastics

Propellants

Rubber

Tar (coal or wood)

Tobacco

Varnishes

Fifth Schedule.

s. 33.

Diseases as to which publication of descriptive matter is restricted or

prohibited.

- 1. Syphilis, gonorrhoea, soft chancre and any form of genitourinary disease or other diseases connected with the human reproductive functions.
- 2. Any of the following— Amenorrhoea Arteriosclerosis Bladder stones Blindness Brights' disease Cancer Cataract Deafness Diabetes Diphtheria Dropsy

Epilepsy or fits Erysipelas Gallstones Glaucoma Goitre

Heart disease Hernia or rupture

Kidney stones Leprosy
Locomotorataxy Lupus
Nephritis or Brights' disease Paralysis Pleurisy Pneumonia Poliomyelitis Scarlet fever Schistosomiasis
Septicaemia Smallpox
Tetanus or lockjaw Trachoma
Tuberculosis or consumption Any structural organic ailment of the auditory system

Sixth Schedule.

s. 38.

Preparations that may be manufactured by, or under the supervision of, a duly qualified medical practitioner.

Preparations containing extracts of pituitary, suprarenal, thyroid, liver, pancreas or parathyroid glands, or stomach.

Preparations containing the active principles of any of the aforesaid glands or the salts of the active principles of any of those glands.

Seventh Schedule.

s. 42.

Requirements as to the storage of classified drugs.

- 1. All class B and class C (Group II) drugs and preparations except when in use shall be kept— $\,$
- (a) under secure lock and key-
- (i) in a separate room or compartment specially reserved for

keeping these drugs and partitioned off from the rest of the premises; or (ii) in a suitable cupboard, box or other receptacle specifically reserved for keeping drugs, and kept in a place apart from anything containing food or drink; and

(b) the drugs shall be kept in a place ordinarily accessible only to the person in charge of the drugs, or to some person under his or her immediate supervision and control; and

the key of the room, compartment, cupboard, box or other receptacle in which these drugs are kept shall be retained under the control of the person in charge of the drugs.

All class A drugs and preparations shall, except when in use, be stored in a separate store or cupboard apart from all other drugs, in accordance with the requirements of paragraph 1 above, except that if stored in a cupboard or similar receptacle the cupboard or other receptacle shall be so fixed in position as to be immovable.

No class A, class B (Group I) or class C (Group II) drugs shall be kept in a part of any premises to which members of the general public

normally have access.

4. All drugs and preparations for external use shall be kept separate from drugs and preparations intended for internal use.

Eighth Schedule.

s. 43.

Consignment and transportation of classified drugs.

No person shall consign for transport any drug specified in this Schedule, unless the outside of the package is labelled conspicuously with the name or description of the drug and a notice indicating that it is to be kept separate from food and from empty food containers.

No person shall, knowingly, transport any drug specified in this Schedule in any vehicle in which food is being transported, unless the food is carried in a part of the vehicle effectively separated from that containing the drug, or is otherwise adequately protected from the risk of contamination.

Aldrin

Aluminium phosphide

Arsenical preparations

Barium, salts of

Dieldrin

Dinitrocresols (DNOC), their compounds with a metal or base when

contained in preparations for use in agriculture or horticulture Dinosam, its compounds with a metal or base when contained in

preparations for use in agriculture or horticulture Dinoset, its compounds with a metal or base when contained in

preparations for use in agriculture or horticulture Endosulfan Endrin

Endothal, its salts

Ethylene dibromide; ethylene dichloride Fluoroacetamide, fluoroacetanilide Hydrocyanic acid, cyanides Mercury, its halides when contained in preparations for use in

agriculture or horticulture

Methyl bromide

Monofluoroacetic acid; its salts

Nicotine; its salts

Organo tin compounds, the following compounds of gentin

Phosphorous compounds, the following—

Amiton, azinphos-ethyl, azinphos-methyl; chlorgenrinphos; demeton-O-methyl; demeton-O; demeton-S; demeton-S-methyl, diazinon, dichlorvos, diethyl 4-methyl-7-coumarinyl phosphorothianate, diethyl-p-nitrophenyl phosphate; dimefox; disulfotam ointment; disulfoton; ethion; ethyl-pitrophenyl, phenylphosphonothionate; mazidox, mecarbam, mevinphos, mipafox, oxydematon-methyl; parathon, phenkapton, photate, phosphamidon schradon, sulfetep, TEPP, HEPP, thionazin, triphosphoric pentadimethylamide; vamidothion

Selenium; its compounds when contained in preparations for use in agriculture or horticulture

Strychnine

Thallium, salts of

History: Statute 13/1993; S.I. 31/1999.

Cross References

Nurses and Midwives Act, Cap. 274. Pharmacy and Drugs Act, Cap. 280.