

poisons, stocks of Part II poisons which are found to be surplus to requirements, or for a person whose licence has been revoked or has expired to sell the poisons in his possession at the time of revocation or expiry, if the sale takes place within three months after the time of revocation or expiry or such longer time as the Board may allow.

(3) A person who sell a Part II poison except in accordance with the provisions of this section shall be guilty of an offence and liable to a fine not exceeding twenty thousand shillings, or to imprisonment for a term not exceeding one year, or to both.

[Act No. 3 of 1968, ss. 8, 11, Act No. 2 of 2002, Sch.]

34. Labelling of containers

(1) It shall be an offence for any person to supply any poison unless the container of the poison is labelled in the prescribed manner—

- (a) with the name of the poison; and
- (b) in the case of a preparation which contains a poison as one of the ingredients thereof, with the prescribed particulars as to the proportion which the poison contained in the preparation bears to the total ingredients; and
- (c) with the word “Poison” or other prescribed indication of the character of the article; and
- (d) if supplied on sale (other than wholesale), with the name of the seller and the address of the premises on which it is sold; and
- (e) if supplied otherwise than on sale, with the name and address of the supplier:

Provided that the provisions of paragraph (a), (b) and (c) of this section shall not apply in respect of a poison made up and supplied for the use of a particular person being a poison prescribed by reference to the needs of that person.

(2) The provisions of paragraphs (a), (b) and (c) of subsection (1) shall not apply in respect of a poison made up and supplied for the use of a particular person being a poison prescribed by reference to the needs of that person.

(3) Any person who commits an offence under this section shall be liable to a fine not exceeding twenty thousand shillings, or to imprisonment for a period not exceeding one year or to both.

[Act No. 2 of 2002, Sch.]

35. Prohibition on sale of poisons in automatic machines

A person exposing or causing to be exposed for sale any poison in or by means of an automatic machine shall be guilty of an offence and liable to a fine not exceeding twenty thousand shillings or to imprisonment for a period not exceeding one year or to both.

[Act No. 2 of 2002, Sch.]

PART IIIA – MANUFACTURE OF MEDICINAL SUBSTANCES

35A. Licence to manufacture medicinal substances

(1) No person shall manufacture any medicinal substance unless he has been granted a manufacturing licence by the Board.

(2) Each manufacturing licence shall expire on the 31st December of every year and the renewal thereof shall be subject to compliance with conditions prescribed by the Board.

(3) No person shall manufacture any medicinal substance for sale unless he has applied for and obtained a licence from the Board in respect of each substance intended to be manufactured.

(4) Any person who intends to manufacture a medicinal substance shall make an application in the prescribed form for the licensing of the premises; and the application shall be accompanied by the prescribed fee.

(5) The Director of the National Drug Quality Control Laboratory or any member of the Laboratory staff authorized by him shall have power to enter and sample any medicinal substance under production in any manufacturing premises and certify that the method of manufacture approved by the Board is being followed.

[Act No. 12 of 1992, s. 3.]

35B. Compliance with good manufacturing practice

Every person who is granted a manufacturing licence under section 35A shall comply with the good manufacturing practices prescribed by the Board.

[Act No. 12 of 1992, s. 3.]

PART IIIB – NATIONAL QUALITY CONTROL LABORATORY

35C. Interpretation of Part

In this Part, unless the context otherwise requires—

“**Director**” means the Director of the National Quality Control Laboratory appointed under section 35H;

“**Laboratory**” means the National Quality Control Laboratory established under section 35D.

[Act No. 12 of 1992, s. 3.]

35D. Establishment of the National Drug Quality Control Laboratory

(1) There shall be established a National Quality Laboratory which shall be used as a facility for—

- (a) the examination and testing of drugs and any material or substance from or with which and the manner in which drugs may be manufactured, processed or treated and ensuring the quality control of drugs and medicinal substances;
- (b) performing chemical, biological, bio-chemical, physiological and pharmacological analysis and other pharmaceutical evaluation; and
- (c) testing, at the request of the Board and on behalf of the Government, of locally manufactured and imported drugs or medicinal substances with a view to determining whether such drugs or medicinal substances comply with this Act or rules made thereunder.

[Act No. 12 of 1992, s. 3.]

35E. Incorporation of the Laboratory

The Laboratory shall be a body corporate with perpetual succession and a common seal and shall have power to sue and be sued in its corporate name and to acquire, hold and dispose of movable and immovable property for its own purposes.

[Act No. 12 of 1992, s. 3.]

35F. Board of Management

(1) There shall be a Board of Management for the Laboratory, which shall consist of nine members to be appointed by the Pharmacy and Poisons Board.

(2) A member of the Board of Management appointed under subsection (1) shall hold office for three years but shall be eligible for re-appointment.

(3) A quorum of the Board of Management shall be five members.

(4) The Board of management shall meet not less than four times each calendar year.

(5) The Director shall be the secretary of the Board of Management.

(6) Subject to this subsection, the Board of Management may regulate its own procedure.

[Act No. 12 of 1992, s. 3.]

35G. Functions of the Board of Management

The functions of the Board of Management shall be—

- (a) to administer the property and funds of the Laboratory in such manner and for such purposes as shall, in the opinion of the Board of Management, promote its best interests;
- (b) to receive, on behalf of the Laboratory, grants-in-aid, gifts, donations, fees, subscriptions or other moneys and make disbursements therefrom;
- (c) to make regulations governing the appointment, conduct and discipline of employees of the Laboratory;
- (d) in consultation with the Minister, to draw up a scheme of service for employees of the Laboratory;
- (e) to administer the approved terms and conditions of service, including appointments, dismissals, remuneration and retiring benefits of employees of the Laboratory; and
- (f) to appoint such employees upon terms and conditions to be laid down by the Board of Management, after consultation with the Minister, as it considers necessary for the proper and efficient administration of the Laboratory.

[Act No. 12 of 1992, s. 3.]

35H. Director

(1) The Board of Management shall appoint a Director who shall be the chief executive of the Laboratory responsible to the Board of Management for the day to day management of the Laboratory.

(2) The Director shall hold office on such terms and conditions of service as may be specified in the instrument of his appointment.

[Act No. 12 of 1992, s. 3.]

35I. Powers of the Director

The Director shall have power—

- (a) to develop and administer a data bank on quality assurance on behalf of the Board of management;
- (b) to inspect premises and issue certificates of compliance; and
- (c) to advise and obtain advice from the Board of Management in regard to any matter within his purview under this Act.

[Act No. 12 of 1992, s. 3.]

35J. Financial provisions

(1) The funds to be used for the management of the Laboratory shall consist of all moneys received or recovered under this Part and moneys provided by Parliament.

(2) The Laboratory may accept gifts, donations, subscriptions, fees and other moneys for the implementation of approved programmes.

(3) The financial year of the Laboratory shall be the same as the Government financial year.

(4) The estimates for the expenditure of the Laboratory shall be submitted through the Minister for approval by the Treasury and shall make provisions for—

- (a) the payment of salaries, allowances and all other charges in respect of the employees of the Laboratory;
- (b) the payment of pensions, gratuities and all other charges in respect of retirement benefits payable out of the funds of the Laboratory;
- (c) the procurement, proper maintenance, repair and replacement of equipment and other immovable property of the Laboratory;
- (d) the proper maintenance of the buildings and grounds of the Laboratory;
- (e) the creation of such reserve funds to meet future or contingent liabilities in respect of retiring benefits, insurance or replacement of building, or equipment or in respect of such other matters as the Board of Management may think fit;
- (f) the cost of Board of Management meetings; and
- (g) capital expenditure.

(5) The Board of Management shall cause to be kept and the Director shall keep all proper books of accounts of the Laboratory.

(6) The accounts of the Laboratory shall be audited by the Auditor-General (Corporations).

(7) The disposal of fixed assets by the Board of Management shall be subject to the approval of the Treasury.

[Act No. 12 of 1992, s. 3.]

35K. Certificate of analysis

(1) A certificate of analysis shall be issued and signed by the Director for every analysis done.

(2) The certificate of analysis issued under subsection (1) shall be in the prescribed form.

[Act No. 12 of 1992, s. 3.]

PART IV – MISCELLANEOUS PROVISIONS**36. Advertisement of drugs**

(1) Subject to the provisions of this Act, no person shall advertise any drug or poison except with the written permission of the Board.

(2) Applications for the advertisement of any drug or poison shall be made to the Board in the prescribed form and shall be accompanied by the prescribed fee.

[Act No. 7 of 1990, Sch.]

37. Prohibition of advertisements as to certain diseases, etc.

(1) Subject to the provisions of this Act, no person shall take part in the publication of an advertisement referring to a drug, appliance or article of any description in terms which are calculated to imply that such drugs, appliances or articles may be effective for any of the purposes specified in the Schedule to this Act.

(2) In any proceedings for contravention of the foregoing provisions of this section, it shall be a defence for the person charged to prove that the advertisement to which the proceedings relate was published only so far as was reasonably necessary to bring it to the notice of one or more persons of the following classes—

- (a) members of the National Assembly;
- (b) members of the governing body of a voluntary hospital;
- (c) duly qualified medical practitioners, dentists and veterinary surgeons;
- (d) registered pharmacists, authorized sellers of poisons and licensed wholesale dealers;
- (e) persons carrying on a business which includes the sale or supply of surgical appliances,

or that the said advertisement was so published in connection with an application for a patent submitted to the appropriate authority so far only as was requisite for the purpose of the application.

(3) The Minister may from time to time, by notice in the *Gazette*, amend or vary the Schedule to this Act.

[L.N. 365/1964.]

38. Prohibition of advertisements as to abortion

Subject to the provisions of this Act, no person shall take any part in the publication of any advertisement referring to any drug, appliance or article of any description, in terms which are calculated to lead to the use of such drugs, appliance or article for procuring the miscarriage of women.

39. Prohibition of misleading advertisements

Subject to the provisions of this Act, no person shall take any part in the publications of any advertisement referring to a drug, medicine, medical appliance or similar article in terms which in the opinion of the Board are considered to be extravagant and to bear little or no relation to the pharmacological properties and action of the ingredients or components thereof.

40. Offences and penalties in respect of advertisements

(1) A person who contravenes any of the provisions of sections 36, 37, 38 and 39 shall, subject to this Act, be liable—

- (a) in the case of a first conviction, to a fine not exceeding twenty thousand shillings or to imprisonment for a term not exceeding one year, or both;
- (b) in the case of a subsequent conviction, to a fine not exceeding thirty thousand shillings or to imprisonment for a term not exceeding two years or to both.

(2) Where, in proceedings for contravention of any of the provisions of sections 37 and 38, it is proved—

- (a) that an advertisement was published referring to any drug, appliance or article of any description, in terms calculated to lead to the use of such drugs, appliance, or article—
 - (i) in the case of a contravention of section 37 of this Act, for the treatment of any of the human ailments referred to in subsection (1) of that section; or
 - (ii) in the case of a contravention of section 38 of this Act, for procuring the miscarriage of women; and
- (b) that the advertisement also referred to the drug, appliance or article in terms calculated to indicate that it was manufactured, produced, imported, sold or offered for sale by the person charged,

then, unless the contrary is proved, it shall be presumed for the purpose of those proceedings that that person took part in the publication of the advertisement, but without prejudice to the liability of any other person.

(3) In any proceedings for contravention of any of the provisions of sections 36, 37, 38 and 39, it shall be a defence for the person charged to prove—

- (a) that the advertisement to which the proceedings relate was published in such circumstances that he did not know and had no reason to believe that he was taking part in the publication thereof; or
- (b) that the advertisement was published only in a publication of a technical character intended for circulation mainly amongst persons of the following classes, or of one or some of them that is to say—
 - (i) duly qualified medical practitioners, dentists and veterinary surgeons;
 - (ii) registered pharmacists and authorized sellers of poisons;

- (iii) persons undergoing training with a view to becoming duly qualified medical practitioners, dentists or veterinary surgeons, or registered pharmacists;
- (iv) persons carrying on a business which includes the sale or supply of surgical appliances.

(4) No prosecution for a contravention of any of the provisions of sections 37, 38 and 39 of this Act shall be instituted without the consent of the Attorney General.

[Act No. 7 of 1990, Sch., Act No. 2 of 2002, Sch.]

41. Labelling of articles containing medicine

(1) Subject to the provisions of this Act, no person shall sell by retail any article consisting of or comprising a substance recommended as a medicine unless there is written so as to be clearly legible on the article or on a label affixed thereto, or, if the article is sold or supplied as aforesaid in a container, on the container or on a label affixed thereto, or, if the article is sold or supplied as aforesaid in more than one container, on the inner container or on a label affixed thereto—

- (a) the appropriate designation of the substance so recommended or of each of the active constituents thereof, or of each of the ingredients of which it has been compounded; and
- (b) in a case where the appropriate designation of each of the active constituents or ingredients is written as aforesaid, the appropriate quantitative particulars of the constituents or ingredients:

Provided that this sub-section shall not apply to any article made up and supplied for the use of a particular person, being an article prescribed by reference to the needs of that person.

(2) In preceding sub-section (1)—

- (a) **“appropriate designation”**, in relation to a substance, constituent or ingredient, means—
 - (i) in a case where the substance, constituent or ingredient is a poison included in the Poisons List, the name with which the container of the poison is for the time being required to be labelled in pursuance of section 34 of this Act;
 - (ii) in a case where the substance, constituent or ingredient is not such a poison and is described in any of the monographs contained in the edition of the British Pharmacopoeia or the British Pharmaceutical Codex or the International Pharmacopoeia or the British Veterinary Codex which was last published before the date on which the article was sold or supplied, the description set out at the head of that monograph;
 - (iii) in a case where the substance, constituent or ingredient is not such a poison and is not so described, the accepted scientific name, or other name descriptive of the true nature of the substance, constituent or ingredient, and in all cases the appropriate name of the substance shall be written in English or in Latin;

- (b) the expression “**appropriate quantitative particulars**”, in relation to the active constituents or the ingredients of a substance, means—
- (i) the approximate percentage of each of those constituents or ingredients contained in the substance or the approximate quantity of each of those constituents or ingredients contained in the article sold or supplied; or
 - (ii) in a case where the article consists of or comprises a number of separate portions of the substance, either the approximate percentage or quantity aforesaid or the approximate quantity of each of the constituents or ingredients contained in each portion; and
- (c) the expression “**container**” includes a wrapper.

(3) If any person sells or supplies an article in contravention of this section, he shall, subject to the provisions of this Act, be liable—

- (a) in the case of a first conviction, to a fine not exceeding ten thousand shillings;
- (b) in the case of a subsequent conviction, to a fine not exceeding twenty thousand shillings or to imprisonment for a term not exceeding one year or to both such fine and such imprisonment.

[Act No. 3 of 1968, s. 12, Act No. 2 of 2002, Sch.]

42. Proceedings on charge concerning labelling

(1) It shall be a defence for a person charged with selling or supplying, in contravention of any of the provisions of section 41 of this Act, an article consisting of or comprising a substance recommended as a medicine to prove—

- (a) that he did not know, and had no reason to believe that the article consisted of or comprised such a substance; or
- (b) that, in relation to the matter in respect of which he is charged, he acted in the course of his employment as a servant or agent of another person on the instructions of his employer or of some other specified person.

(2) In any proceedings for contravention of any of the provisions of section 41 of this Act a document purporting to be a certificate signed by a public analyst within the meaning of the Food and Drugs (Adulteration) Act (Cap. 127) or by an officer authorized in writing by the Minister to perform such analysis, and stating the result of an analysis made by him, shall be admissible as evidence of the matters stated therein, but any party to the proceedings may require the person by whom the analysis was made to be called as a witness.

[Cap. 254.]

42A. Proceedings on charge of selling poisons, etc.

Where a person is charged with an offence under section 26, section 29 or section 33 of this Act by reason of his having sold or been in possession of a container labelled as containing poisons, and the container appears to have been packed by the manufacturer of the contents and to be intact, the container shall be presumed to contain poisons of the description specified on the label, until the contrary is proved.

[Act No. 3 of 1968, s. 13.]

42B. Appeals

An appeal under any of sections 27(2), 28(3), 32(5) and 50(2) of this Act shall be in writing, and shall be lodged within thirty days after the date of the act appealed against.

[Act No. 3 of 1968, Section 13.]

43. Power to prohibit or control certain medicines

(1) The Minister, on the recommendation of the Board, may, by order, prohibit or control the manufacture, sale, advertisement or possession of any secret, patent, proprietary or homoeopathic medicine, preparation or appliance.

(2) Any person who contravenes or fails to comply with any order made by the Minister under sub-section (1) of this section shall be guilty of an offence.

44. Rules

(1) The Minister may, after consultation with the Board, make rules with respect to any of the following matters or for any of the following purposes—

- (a) prohibiting the sale by retail of a specified Part I poison except on a prescription duly given by a duly qualified medical practitioner, dentist or veterinary surgeon and for prescribing the form and regulating the use of those prescriptions;
- (b) prohibiting, regulating or restricting the sale of Part II poisons or of any specified Part II poisons by any of the persons licensed under section 28 or section 32 of this Act or by any class of such persons;
- (c) exempting from any of the provisions of this Act relating to the sale of poisons any article or substance containing poison or any class of such articles or substances or for dispensing with or relaxing with respect to poisons any of the provisions contained in Part III of this Act;
- (d) prohibiting, regulating or restricting the manufacture, sale or advertising of drugs, pharmaceutical preparations and therapeutic substances;
- (e) the safe custody and storage of poisons;
- (f) the importation, exportation, transport and labelling of poisons;
- (ff) the importation and exportation of drugs;
- (g) the containers in which poisons may be supplied;
- (h) the addition to poisons of specified ingredients for the purpose of rendering them readily distinguishable as poisons;
- (i) the compounding and dispensing of poisons;
- (j) the period for which any books or registers required to be kept for the purposes of this Act are to be preserved;
- (k) the fees to be paid for anything to be done under this Act;
- (l) the procedure to be observed by the Board;
- (m) the conduct of inquiries by the Board under section 12 of this Act and the attendance of witnesses and the production of evidence thereat;

(mm) prescribing the qualification for registration of pharmaceutical analysts;

(n) anything which is by this Act required or authorized to be prescribed.

(2) The power to make rules under this section with respect to poisons or drugs includes the power to make rules with respect to any class of poisons or drugs or any particular poison or drug.

(3) All rules made under this section shall be laid before the Legislative Council as soon as may be after they are made, and if a resolution is passed within the next twenty days on which the Council sits after any such rule is laid before it that the regulation be annulled, it shall thenceforth be void, but without prejudice to the validity of anything done thereunder or to the making of any new rule.

[Act No. 39 of 1956, Sch., Act No. 3 of 1968, s. 14, Act No. 13 of 1980, Sch., Act No. 12 of 1992, s. 4.]

45. Power to enter and search premises, etc.

(1) If a magistrate is satisfied by information on oath that there is reasonable ground for suspecting that an offence against any of the provisions of this Act has been or is being or is about to be committed and that evidence of the commission of the offence is to be found on or in any premises, vehicle or vessel specified in the information, he may grant a search warrant authorizing any police officer to enter and search any such premises or to detain, enter and search any such vehicle or vessel, and to seize any drugs, articles or documents which the officer has reasonable cause for believing to be evidence of the commission of the offence.

(2) An authorized officer, if he has reasonable cause to believe that an offence against any of the provisions of this Act is being or has been committed on or in any premises, vehicle or vessel, or that any drug, article or document in respect of which there is reasonable ground for suspecting that such offence has been or is being committed is on or in any premises, vehicle or vessel, and if the delay which would occur in obtaining a search warrant as hereinbefore provided would, or would tend to, defeat the purposes of this Act, may without such warrant enter and search any such premises or may detain, enter and search any such vehicle or vessel, and may seize any drugs, articles and documents which he has reasonable cause to believe to be evidence of the commission of any such offence.

(3) Where any drug, article or document has been seized under the provisions of this section the person who has seized it shall forthwith report to a magistrate the fact of such seizure.

46. Retention and disposal of goods seized

(1) Any drug, article or document seized under the provisions of section 45 of this Act may be retained for a period not exceeding one month or if within that period proceedings are commenced for an offence under this Act in respect of such drug, article or document, until the final determination of those proceedings.

(2) Where a magistrate is satisfied that any such drug or article is of a perishable nature or that by reason of the fact that the market for any such drug or article is seasonal, or for any other reason, any delay in disposing of the drug or article would unduly prejudice the owner thereof, he may authorize the sale or other disposal of such drug or article.

(3) Where proceedings are taken for any offence against this Act the court by or before which the alleged offender is tried may make such order as to the forfeiture or other disposal of any drug or article in respect of which such offence was committed as the court shall see fit.

(4) In this section references to a drug or article shall be construed as including the proceeds of any sale effected in accordance with the provisions of sub-section (2) hereof.

47. Inspection of licences and books

(1) Every authorized or licensed seller of poisons shall, on the demand of an authorized officer, produce for inspection his certificate of registration or his licence, as the case may be.

(2) All books kept by any seller of poisons, medical practitioner, dentist or veterinary surgeon, or by any hospital, dispensary or similar institution, in accordance with the provisions of this Act, shall be open for inspection by an authorized officer at all reasonable times.

48. Obstruction of authorized officers

Any person who obstructs or hinders an authorized officer in the lawful exercise of the powers conferred by section 45 or section 47 of this Act shall be guilty of an offence.

49. Vicarious criminal responsibility

(1) An act which if done by an individual would be an offence against this Act or any rules made thereunder shall, if done by a body corporate, be an offence by every director, secretary and manager thereof unless he proves that the offence was committed without his consent or connivance and that he exercised all such diligence to prevent the commission of the offence as he ought to have exercised having regard to the nature of his functions in that capacity and to all the circumstances.

(2) If an offence against this Act or any rules thereunder has been 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 capacity, shall be deemed to be guilty of that offence unless he proves that the offence was committed without his consent or connivance and that he exercised all such diligence to prevent the commission of the offence as he ought to have exercised having regard to the nature of his functions in that capacity and to all the circumstances.

50. Penal sanctions with regard to bodies corporate

(1) If—

- (a) a body corporate has been convicted of an offence under this Act or any rules made thereunder; or
- (b) any member of the Board or any officer of a body corporate, or any person employed by a body corporate in carrying on a business, has been convicted of any such criminal offence, or been guilty of such misconduct as in the opinion of the Board renders him, or would if he were a registered pharmacist render him, unfit to be on the register,

then, whether the body corporate was or was not an authorized seller of poisons at the time when the offence or misconduct was committed, the Board may inquire into the case and may, subject to this Act, direct—

- (i) that the body corporate shall, in a case where it is an authorized seller of poisons, cease to be a seller and, in any case, be disqualified for such period as may be specified in the directions from being an authorised seller of poisons; or
- (ii) that all or any of the premises of the body corporate shall, in a case where they are registered in the register of premises kept in pursuance of section 23 of this Act, be removed from that register and in any case be disqualified for such period as may be specified in the directions from being registered therein.

(2) Any body corporate may appeal to the Minister against a direction given under this section, and the decision of the Minister on any such appeal shall be final.

[Act No. 15 of 1961, Sch.]

51. Penalties

Any person guilty of an offence under the provisions of this Act shall, except as otherwise provided, be liable on conviction to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both such fine or imprisonment, and in addition to any penalty imposed under this Act the court may order any article in respect of which the offence has been committed or which has been used for the commission of such offence to be forfeited.

[Act No. 3 of 1968, s. 15, Act No. 14 of 1991, Sch., Act No. 2 of 2002, Sch.]

52. Repeal

The Pharmacy and Poisons Ordinance (Cap. 128) is hereby repealed:

Provided that all licences, certificates, registrations, authorizations and approvals made under any of the provisions of the said Ordinance and in force immediately prior to the repeal thereof shall, so far as similar provision exists in this Ordinance, be deemed to have been made under such provision, and shall have effect accordingly.

SCHEDULE

[Section 37.]

PURPOSES FOR WHICH DRUGS, ETC., MAY NOT BE ADVERTISED

1. The cure of syphilis, gonorrhoea or soft chancre in any of their forms.
2. The prevention, relief or cure of Bright's disease, schistosomiasis, cancer, consumption or tuberculosis, leprosy, lupus, diabetes, epilepsy or fits, locomotor ataxy, paralysis, or infantile paralysis.

3. The cure of arterio-sclerosis, septicaemia, diphtheria, dropsy, erysipelas, gallstones, kidney stones and bladder stones, goitre, heart disease, tetanus or lockjaw, pleurisy, pneumonia, scarlet-fever, smallpox, trachoma, amenorrhoea, hernia or rupture, blindness, or any structural or organic ailment of the auditory system.

4. The cure of any habit associated with sexual indulgence, or of any ailment associated with those habits; or the restoration or stimulation of the sexual functions.

NO. 17 OF 1956

PHARMACY AND POISONS ACT

SUBSIDIARY LEGISLATION

List of Subsidiary Legislation

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POISONS LIST CONFIRMATION ORDER

ARRANGEMENT OF RULES

Rule

1. Citation.
2. Poisons List confirmed.

SCHEDULE – POISONS LIST

POISONS LIST CONFIRMATION ORDER

[L.N. 168/1961, Corr. No. 66/1961, L.N. 250/1961, L.N. 423/1961, L.N.146/1963, L.N. 242/1963, L.N. 93/1964, L.N. 150/1968, L.N. 15/2002.]

[Section 25.]

1. Citation

This Order may be cited as the Poisons List Confirmation Order.

2. Poisons List confirmed

The Poisons List prepared by the Pharmacy and Poisons Board and set out in the Schedule to this Order is confirmed as the list of substances which are to be treated as poisons for the purposes of the Act.

SCHEDULE

[Paragraph 2]

POISONS LIST

[Corr. No. 66/1961, L.N. 150/1968, L.N. 15/2002, s. 2.]

PART I

1. Acetanilide; alkyl acetanilides.
2. Acetohexamide.
3. Acetylcarbromal.
4. Acetyldihydrocodeine; its salts.
5. Acocanthera, glycosides of.
6. Adenium, glycosides of.
7. Alkali fluorides other than those specified in Part II of this List.
8. Alkaloids, the following; their salts, simple or complex; their quaternary compounds—
 - Aconite, alkaloids of.
 - Atropine.
 - Belladonna, alkaloids of.
 - Brucine.
 - Calabar bean, alkaloids of.
 - Coca, alkaloids of.
 - Cocaine.
 - Codeine.
 - Colchicum, alkaloids of.
 - Coniine.
 - Cotarnine.
 - Curare, alkaloids of; curare bases.
 - Ecgonine; its esters.
 - Emetine.
 - Ephedra, alkaloids of.
 - Ergot, alkaloids of, homologues and hydrogenated.
 - Gelsemium, alkaloids of.

[Subsidiary]

SCHEDULE—*continued*

- Homatropine.
 Hyoscine.
 Hyoscyamine.
 Jaborandi, alkaloids of.
 Lobelia, alkaloids of.
 Morphine.
 Papaverine.
 Pomegranate, alkaloids of.
 Quebracho, alkaloids of, other than the alkaloids of red quebracho.
 Rauwolfia, alkaloids of; their derivatives.
 Sabadilla, alkaloids of.
 Solanaceous alkaloids not otherwise included in this List.
 Stavesacre, alkaloids of.
 Strychnine.
 Thebaine.
 Veratrum, alkaloids of.
 Yohimba, alkaloids of.
9. Allylisopropylacetylurea.
 10. Allylprodine; its salts.
 11. Alphameprodine; its salts.
 12. Alphaprodine; its salts.
 13. Amidopyrine; its salts; amidopyrine sulphonates; their salts.
 14. Amino-alcohols esterified with benzoic acid, phenylacetic acid, phenylpropionic acid, cinnamic acid or the derivatives of these acids, their salts.
 15. p-Aminobenzenesulphonamide; its salts, derivatives of p-amino-benzenesulphonamide having any of the hydrogen atoms of the p-amino group or of the sulphonamide group substituted by another radical; their salts.
 16. p-Aminobenzoic acid, esters of; their salts.
 17. B-Aminopropylbenzene and B-aminoisopropylbenzene and any compound structurally derived from either of those substances by substitution in the chain or by ring closure therein (or by both such substitution and such closure), except ephedrine, N-methylephedrine, N-diethylaminoethylephedrine, phenylpropanolamine, and prenylamine; any substance falling within this item.
 18. p-Amino-salicylic acid; its salts; any preparation of p-Amino salicylic acid; its salts.
 19. Amitriptyline; its salts.
 20. Amyl nitrite.
 21. Androgenic, oestrogenic and progestational substances, the following—
 - Benzoestrol.
 - Derivatives of stilbene, dibenzyl or naphthalene with oestrogenic activity; their esters.
 - Steroid compounds with androgenic or oestrogenic or progestational activity; their esters.
 22. Anileridine; its salts.
 23. Antibiotics, that is to say any substances produced by a living organism and which have a suppressive or destructive action on other organisms; their synthetic equivalents; their salts; preparations of such substances and their salts.
 24. Anti-histamine substances, the following; their salts; their molecular compounds—
 - Antazoline.
 - Bromodiphenhydramine.
 - Bucizine.

SCHEDULE—*continued*

- Carbinoxamine.
 Chlorcyclizine.
 Chlorpheniramine.
 Cinnarizine.
 Clemizole.
 Cyclizine.
 Cyproheptadine.
 3-Di-n-butylaminomethyl-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 ethylene-diamine or propylenediamine.
25. Antimony, chlorides of; oxides of antimony; sulphides of antimony; antimonates; antimonites; organic compounds of antimony.
 26. Apomorphine; its salts.
 27. Arsenical substances, the following, except those specified in Part II of this List; halides of arsenic; oxides of arsenic; arsenates; arsenites; organic compounds of arsenic.
 28. Azacyclonol; its salts.
 29. Barbituric acid; its salts; derivatives of barbituric acid; their salts; compounds of barbituric acid, their salts, their derivates, their salts, with any other substances.
 30. Barium, salts of, other than barium sulphate and the salts of barium specified in Part II of this List.
 31. Benactyzine; its salts.
 32. Benzethidine; its salts.
 33. Benzhexol; its salts.
 34. Benzoylmorphine, its salts.
 35. Benztropine and its homologues; their salts.
 36. Benzylmorphine; its salts.
 37. Betameprodine; its salts.
 38. Betaprodine; its salts.
 39. Bromvaletone.
 40. Busulphan; its salts.
 41. Butylchloral hydrate.
 42. Cannabis (the dried flowering or fruiting tops of *Cannabis sativa* Linn); the resin of cannabis; extracts of cannabis; tinctures of cannabis; cannabin tannate.
 43. Cantharidin; cantharidates.

[Subsidiary]

SCHEDULE—*continued*

44. Captodiame; its salts.
45. Carbachol.
46. Carbromal.
47. Carisoprodol.
48. Carperidine; its salts.
49. Chloral; its addition and its condensation products; their molecular compounds.
50. Chlordiazepoxide; its salts.
51. Chlormethiazole; its salts.
52. Chloroform.
53. Chlorothiazide and other derivatives of benzo-1, 2, 4-thiadiazine-7-sulphonamide 1, 1-dioxide, whether hydrogenated or not.
54. Chlorphenoxamine.
55. Chlorphentermine; its salts.
56. Chlorpropamide; its salts.
57. Chlorprothixene, and other derivatives of 9-methylenethioxanthen and their salts.
58. Chlorthalidone.
59. Clonitazene; its salts.
60. Clorexolone.
61. Creosote obtained from wood.
62. Croton, oil of.
63. Cyclarbamate.
64. Cycrimine; its salts.
65. Dehydroemetine; its salts.
66. Demecarium bromide.
67. Desipramine; its salts.
68. Desomorphine; its salts.
69. Dextromethorphan; its salts.
70. Dextromoramide; its salts.
71. Dextrorphan; its salts.
72. Diacetylmorphine; its salts.
73. Diacetylnalorphine; its salts.
74. 4-4-Diamidino-diazoaminobenzene; its salts.
75. Diampromide, its salts and other compounds containing the chemical structure of 1:4 benzodiazepine substituted to any degree; their salts.
76. Diazepam.
77. Diethylcarbamazine.
78. Digitalis, glycosides of; other active principles of digitalis.
79. Dihydrocodeine; its salts.
80. Dihydrocodeinone; its salts; its esters; their salts.
81. Dihydromorphine; its salts, its esters; their salts.
82. Dimenoxadole; its salts.
83. Dimepheptanol; its salts.
84. Dinitroresols (DNC); their compounds with a metal or a base.
85. Dinitronaphthols; dinitrophenols; dinitrothymols.
86. Dinosam; its compounds with a metal or a base.
87. Dinoseb; its compounds with a metal or a base.
88. Dioxaphetyl butyrate; its salts.

SCHEDULE—*continued*

89. Diphenoxylate; its salts.
90. Dipipanone; its salts.
91. Disulfiram.
92. Dithienylallylamines; dithienylalkylallylamines; their salts.
93. Dyflos.
94. Ecothiopate iodide.
95. Ectylurea.
96. Elaterin.
97. Emylcamate.
98. Ergot (the sclerotia of any species of *Claviceps*); extracts of ergot; tinctures of ergot.
99. Erythrityl tetranitrate.
100. Ethchlorvynol.
101. Ethinamate.
102. Ethionamide.
103. Ethoheptazine; its salts.
104. Ethylmorphine; its salts.
105. Etonitazene; its salts.
106. Etoxidine; its salts.
107. Fentanyl; its salts.
108. Fluoroacetamide.
109. Fluoroacetanilide.
110. Furethidine; its salts.
111. Gallamine; its salts, its quaternary compounds.
112. Glutethimide; its salts.
113. Glyceryl trinitrate.
114. Guanidines, the following—
 polymethylene diguanidines; di-p-anisyl-p-phenetylguanidine.
115. Haloperidol, and other 4-substituted derivatives of N-(3-P. fluorobenzoylpropyl) piperidine.
116. Hexapropymate.
117. Hormones; natural and synthetic; any preparations, admixture, extract or other substance containing any proportion of any substance having the action of any hormone.
118. Hydrazines, benzyl, phenethyl and phenoxyethyl; their α -methyl derivatives; acyl derivatives of any of the foregoing substances comprised in this item; salts of any compounds comprised in this item.
119. Hydrocyanic acid; cyanides; double cyanides of mercury and zinc.
120. Hydromorphanol; its salts.
121. Hydromorphone; its salts; its esters; their salts.
122. Hydroxy-N-N-dimethyltryptamines, esters or ethers of these; salts of any of the foregoing.
123. Hydroxypethidine; its salts.
124. Hydroxyzine; its salts.
125. Imipramine; its salts.
126. Indomethacin; its salts.
127. Insulin.
128. Isomethadone (isoamidone); its salts.
129. Isoniazid; its salts, derivatives; their salts.
130. Ketobemidone; its salts.

[Subsidiary]

SCHEDULE—*continued*

131. Laudexium; its salts.
132. Lead acetates; compounds of lead with acids from fixed oils.
133. Levomethorphan; its salts.
134. Levomoramide; its salts.
135. Levophenacilmorphan; its salts.
136. Levorphanol; its salts.
137. Mannityl hexanitrate.
138. Mannomustine; its salts.
139. Mephenesin; its esters.
140. Meprobamate.
141. Mercaptopurine; its salts; derivatives of mercaptopurine; their salts.
142. Mercury, oxides of; nitrates of mercury; mercuric ammonium chlorides; potassio-mercuric iodides; organic compounds of mercury which contain a methyl (CH₃) group directly linked to the mercury atom; mercuric oxycyanides; mercuric thiocyanate.
143. Metaxalone.
144. Metazocine; its salts.
145. Metformin; its salts.
146. Methadone (amidone); its salts.
147. Methadyl acetate; its salts.
148. Methaqualone; its salts.
149. Methixene; its salts.
150. Methocarbamol.
151. Methoxsalen.
152. Methyldesorphine; its salts.
153. Methyldihydromorphine; its salts.
154. Methylpentynol; its esters and other derivatives.
155. 1-Methyl-4-phenylpiperidine-4-carboxylic acid.
156. Methypylone.
157. Metopon; its salts.
158. Monofluoroacetic acid; its salts.
159. Morpheridine; its salts.
160. Mustine and any other N-substituted derivatives of di-(2-chloroethyl) amine; their salts.
161. Myrophine; its salts.
162. Nalorphine; its salts.
163. Nicocodine; its salts.
164. Nicotine; its salts.
165. m-Nitrophenol; O-nitrophenol; p-nitrophenol.
166. Noracymehadol; its salts.
167. Norcodeine; its salts.
168. Norlevorphanol; its salts.
169. Normethadone; its salts.
170. Normorphine; its salts.
171. Norpipanone.
172. Nortryptiline; its salts.
173. Nux Vomica.
174. Opium.
175. Orphenadrine; its salts.

SCHEDULE—*continued*

176. Orthocaine; its salts.
177. Ouabain.
178. Oxalic acid.
179. Oxazepam.
180. Oxethazaine.
181. Oxycinchonic acid, derivatives of; their salts; their esters.
182. Oxycodone; its salts, its esters; their salts.
183. Oxymorphone; its salts.
184. Oxyphenbutazone.
185. Paramethadione.
186. Pargyline; its salts.
187. Pemoline; its salts.
188. Phenacemide.
189. Phenadoxone; its salts.
190. Phenamidine; its salts.
191. Phenaglycodol.
192. Phenampromide; its salts.
193. Phenanthridinium and its derivatives.
194. Phenazocine; its salts.
195. Phenbutrazate.
196. Phencyclidine; its salts.
197. Phenetidylphenacetin.
198. Phenformin; its salts.
199. Phenols (any member 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 sixty percent, weight in weight, of phenols; compounds of phenol with a metal, except in substances containing less than the equivalent of sixty percent, weight in weight, of phenols.
200. Phenorphan; its salts.
201. Phenoperidine; its salts.
202. Phenothiazine, derivatives of; their salts; except dimethoxanate, its salts and promethazine, its salts and its molecular compounds.
203. Phenylbutazone.
204. Phenylcinchoninic acid; salicylcinchonic acid; their salts.
206. Pholcodine; its salts.
207. Phosphorus, yellow, except as provided in Part II of this List.
Phosphorous compounds, the following—
Amiton, azinphos-ethyl, azinphos-methyl, demeton-O, demeton-S, demeton-O, methyl, demeton-S-methyl, diethyl 4-methyl-7-coumarinyl phosphorothionate, diethyl p-nitrophenyl phosphate, dimefox, disulfoton, ethion, ethyl p-nitrophenyl phenyl-phosphonothionate, mazidox, mecarbam, mevinphos, mipafox, oxydemeton-tmethyl, parathion, phenkapton, phorate, phosphamidon, schradan, sulfotep, TEPP (HETP), thionazin, triphosphoric pentadimethylamide, vamidothion.
208. Picric acid.
209. Picrotoxin.
210. Piminodine; its salts.
211. Pituitary gland, the active principles of.
212. Polymethylenebis(trimethylammonium salts).
213. Procyclidine; its salts.

[Subsidiary]

SCHEDULE—*continued*

214. Proheptazine; its salts.
215. Promoxolan.
216. Propoxyphene; its salts.
217. Propylhexedrine; its salts.
218. Prothionamide.
219. Prothipendyl; its salts.
220. Quinapyramine and analogous substances; their salts.
221. Quinuronium; its salts.
222. Quinethazone.
223. Racemethorphan; its salts.
224. Racemoramide; its salts.
225. Racemorphan; its salts.
226. Savin, oil of.
227. Strophanthus: glycosides of strophanthus.
228. Styramate.
229. Sulphinpyrazone.
230. Sulphonal; alkyl sulphonals.
231. Sulphones; their salts, their derivatives.
232. Suprarenal gland medulla, the active principles of; their salts.
233. Syrosingopine.
234. Tetrabenazine; its salts.
235. Thalidomide; its salts.
236. Thallium, salts of.
237. Thebacon; its salts; its esters; their salts.
238. Thiacetazone; its salts; its derivatives.
239. Thyroid gland, the active principles of; their salts.
240. Tolbutamide.
241. Toxaphene.
242. Tretamine; its salts.
243. Triaziquone.
244. Tribromethyl alcohol.
245. 2,2,2-Trichloroethyl alcohol, esters of; their salts.
246. Trimeperidine; its salts.
247. Trimipramine; its salts.
248. Troxidone.
249. Zoxazolamine.

PART II – GROUP A

1. Ammonia.
2. Barium carbonate, if in the form of preparations for the destruction of rats and mice.
3. Barium silicofluoride.
4. Barium sulphide when contained in depilatories.
5. Formaldehyde.
6. Formic Acid.
7. Hydrochloric acid.
8. Hydrofluoric acid; potassium fluoride; sodium fluoride; sodium silicofluoride.

SCHEDULE—*continued*

9. Metallic oxalates, other than potassium quadroxalate, if in the form of photographic solutions.
10. Nitric acid.
11. Phenols as defined in Part I of this list in substances containing less than sixty per cent., weight in weight, of phenols; compounds of phenol with a metal in substances containing less than the equivalent of sixty per cent., weight in weight, of phenols.
12. Phenylene diamines; toluene diamines; other alkylated-benzenediamines; their salts.
- 12A. Phosphorous compounds, the following—
Endosulfan, ethion, mecarbarn, phenkapton.
13. Phosphorous, yellow, when contained in rat poison.
14. Potassium hydroxide.
15. Potassium quadroxalate.
16. Sodium hydroxide.
17. Sodium nitrite.
18. Sulphuric acid.
19. Zinc Phosphide.

GROUP B

1. Aconite, alkaloids of, in preparations containing less than 0.02 per cent of the alkaloids of aconite.
2. Arsenic in preparations containing less than the equivalent of 0.01 per cent of arsenic trioxide, and dentifrices containing less than 0.5 per cent of acetarsol.
3. Belladonna, alkaloids of, in preparations containing less than 0.15 per cent of the alkaloids of belladonna calculated as hyoscyamine.
4. Chloral hydrate in preparations intended—
 - (a) for internal consumption containing less than 2.3 per cent chloral hydrate; and
 - (b) for external application containing less than 10.1 per cent chloral hydrate.
5. Codeine, when contained in any substance in a proportion of less than 1.5 per cent and also when contained in Compound Tablets of Codeine B.P., or tablets of a similar composition each containing not more than 1/6th grain of Codeine.
6. Coniine in preparations containing less than 0.02 per cent.
7. Ethylmorphine in preparations containing less than 0.2 per cent.
8. Hyoscyamine in preparations containing less than 0.15 per cent.
9. Lobelia, alkaloids of, in preparations containing less than 0.25 per cent.
10. Mercuric ammonium chloride when contained in an ointment not exceeding 15 per cent.
11. Mercury oxide when contained in yellow oxide of Mercury Ointment.
12. Morphine in preparations containing less than 0.2 per cent of anhydrous morphine.
13. Morpholinylethylmorphine in preparations containing less than 1 per cent.
14. Nux vomica, in preparations containing less than 0.2 per cent of alkaloids calculated as strychnine.
15. Opium when in preparations for external use containing less than 2 per cent (opium).
16. Stramonium, in preparations containing less than 0.15 per cent of alkaloids calculated as hyoscyamine.
17. Strychnine in preparations containing less than 0.2 per cent of strychnine.
18. Deltamethrine.

PHARMACY AND POISONS (PROHIBITED MEDICINES) ORDER

[L.N. 36/1963, L.N. 526/1997, L.N. 128/1998.]

[Section 43.]

1. This Order may be cited as the Pharmacy and Poisons (Prohibited Medicines) Order.
2. The manufacture, sale, advertisement or possession of the proprietary medicine and the poison set out in the Schedule is prohibited.

SCHEDULE

1. Nu-cell.
 2. Part I poison known as Thalidomide which is marketed under the names Distaval or Contergan or Softenon and which is an ingredient of Asmaval, Tensival, Valgis and Valgraine.
 3. Pearl Omega.
 4. Polyatomic Oxygen (Ozone)
-

PHARMACY AND POISONS RULES

ARRANGEMENT OF RULES

Rule

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9. Labelling of containers.
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11. Directions as to use.
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20. Forms.
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SCHEDULES

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SCHEDULE II	–	ARTICLES EXEMPTED FROM PART III OF THE ACT AND THESE RULES
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[Subsidiary]

SCHEDULE IX

- PERMIT AUTHORISING FARMERS AND OTHER PERSONS TO BE IN POSSESSION OF SUBSTANCES SPECIFIED IN GROUP II OF SCHEDULE IV TO THE RULES
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PHARMACY AND POISONS RULES

[L.N. 186/1957, L.N. 443/1957, L.N. 332/1958, L.N. 426/1958, L.N. 498/1958, L.N. 550/1959, L.N. 114/1960, L.N. 587/1961, L.N. 242/1963, L.N. 631/1963, L.N. 92/1964, L.N. 365/1964, L.N. 115/1968, L.N. 125/1969, L.N. 248/1969, L.N. 41/1971, L.N. 120/1984, Corr. No. 52/1984, L.N. 51/1985, L.N. 61/2002, L.N. 91/2004, L.N. 191/2010.]

RULES UNDER SECTION 44**1. Citation**

These Rules may be cited as the Pharmacy and Poisons Rules.

2. Interpretation

(1) In these Rules, unless the context otherwise requires—

“**animal**” includes bird;

“**antimonial poisons**” means chlorides of antimony, oxides of antimony, sulphides of antimony, antimonates, antimonites, and organic compounds of antimony;

“**arsenical poisons**” means halides of arsenic, oxides of arsenic, sulphides of arsenic, arsenates, arsenites, copper acetoarsenites, sodium thioarsenates, and organic compounds of arsenic;

“**British Pharmaceutical Codex**”, “**British Pharmacopoeia**” and “**British Veterinary Codex**” include supplements;

“**food**” includes drink;

“**medicine for the internal treatment of ailments**” includes any medicine to be administered by parenteral injection but does not include any mouth-wash, eye drops, eye lotion, ear drops, douche or similar article;

“**poison**” means a poison included in Part I or Part II of the Poisons List as the case may be;

“**Poisons List**” means the Poisons List for which provision is made in section 25 of the Act;

“**sell**” includes an agreement to sell and an offer to sell or any other act whatsoever by which willingness to enter into any transaction of sale is expressed, and an offer to sell includes the exposing of goods for sale.

(2) A reference to the percentage of a poison contained in a substance shall, unless otherwise expressly provided, be construed so that a reference to a substance containing 1 percent of a poison means—

(a) in the case of a solid, that one gramme of the poison is contained in every hundred millilitres of the substance or preparation;

(b) in the case of a liquid, that one millilitre of the poison, or, if the poison itself is a solid, one gramme of the poison, is contained in every hundred millilitres of the substance or preparation,

and so in proportion for any greater or lesser percentage.

(3) For the purposes of these Rules—

(a) a poison shall not be taken to be sold, issued or supplied otherwise than in accordance with a prescription or other order by reason only that the prescription or order specifies a quantity of the poison in terms of the imperial system and the quantity sold, issued or supplied is the equivalent of that amount in the metric system, or by reason only that the prescription or

[Subsidiary]

order specifies a quantity of the poison in terms of the metric system and the quantity sold, issued or supplied is the equivalent of that amount in the imperial system; and

- (b) the quantity of a poison in the imperial system which is the equivalent of a particular quantity in the metric system, and the quantity of a poison in the metric system which is the equivalent of a similar quantity in the imperial system, shall be deemed to be that set out as such in the Tables of Equivalents contained in the *British Pharmacopoeia*, the *British Pharmaceutical Codex* or the *British Veterinary Codex*.

3. Importation of drugs and Part I poison

(1) Any person, other than a person issued with an import licence in form 17 set out in Schedule VIII, who imports any drug or Part I poison from any place outside Kenya shall be guilty of an offence.

(2) The Board may issue an import licence authorizing the importation of any drug cosmetics, herbals, medical devices, technologies upon payment of two per cent Freight on Board value or Part I poison to the following persons—

- (a) an authorized seller of poisons;
- (b) persons licensed under the provisions of sections 27 and 28 of the Act, in accordance with the terms of such licence;
- (c) the Government or a local authority and its institutions for public purposes;
- (d) a person requiring to import poisons for industrial purposes;
- (e) any *bona fide* tourist or visitor having in his possession, on his arrival in Kenya, any drug or poison for the medical treatment or any other lawful use by himself or any other member of his party;
- (f) any duly qualified medical practitioner, dentist or veterinary surgeon who satisfies the Board that he is urgently in need of a drug or poison which he is unable to obtain in Kenya;
- (g) a hospital at and of which a medical practitioner registered under the Medical Practitioners and Dentists Act (Cap. 253), is resident and in direct control.

(3) A person requiring to import Part I poison under the provisions of paragraph (2) (d) shall indicate in his application for an import licence the purpose for which the poison is required and, if the importer is not the person who will use the poison, the name or names of the person or persons to whom the poison will be sold.

(4) The Board may, without assigning any reason therefor, refuse an application for a licence to import any drug or Part I poison; and any person aggrieved by the decision of the Board may appeal to the Minister whose decision shall be final.

(5) A person issued with an import licence under these Rules shall comply with the rules and regulations of the Central Bank of Kenya which may be in force from time to time.

(6) A person, issued with an import licence under these Rules who imports any drug or Part I poison from any place outside Kenya shall keep a full, accurate and separate record of such importation.

(7) A person referred to in paragraph (2) and a licensed seller of Part II poison shall not import Part II poison without an import licence issued under these Rules.

[Corr. No. 52/1984, L.N. 120/1984, L.N. 191/2010, r. 3.]

3A. Restriction on the importation or manufacture of specified drugs

(1) No person, shall, without the approval of the Registrar, in writing import or manufacture any of the following drugs—

- (a) amphetamine;
- (b) amobarbital;
- (c) amferpramone;
- (d) barbital;
- (e) dexamphetamine;
- (f) cyclovarbital;
- (g) ethinamate;
- (h) lysergide, or its salts;
- (i) glutethimide;
- (j) methamphetamine;
- (k) methyphenidate;
- (l) meprobamate;
- (m) methaqualone, or its salts;
- (n) methylphenobarbital;
- (o) methylprylon;
- (p) psilocin;
- (q) psilocybine;
- (r) phencyclidine;
- (s) phenmetrazine;
- (t) phenobarbital;
- (u) pentobarbital;
- (v) pipradrol;
- (w) secobarbital;
- (y) medroxyprogesterone and its salt; and
- (z) foreign traditional medicine of any description.

(2) A person who contravenes paragraph (1) shall be guilty of an offence.

[L.N. 125/1969, L.N. 191/2010, r. 2.]

4. Exportation of drugs and poisons

(1) A person, other than a person, issued with an export licence in form 23 set out in Schedule VIII, who exports any drug or poison to a destination outside Kenya shall be guilty of an offence.

(2) The Board may issue an export licence authorizing the exportation of any drug or poison to an authorized seller of poisons or other person licensed to deal in poisons under section 27 or section 28 of the Act.

(3) The Board may, without assigning any reason therefor, reject an application for a licence to export drugs or poisons to any destination outside Kenya; and a person who is aggrieved by the decision of the Board may appeal to the Minister whose decision shall be final.

(4) A person issued with an export licence under these Rules shall comply with the rules and regulations of the Central Bank of Kenya which are in force from time to time.

[Subsidiary]

(5) Every authorized seller of poison and any other person licensed to deal in poisons under section 27 or section 28 of the Act who exports any drugs or poisons to a destination outside Kenya shall—

- (a) keep a full and accurate record of those exports; and
- (b) if the drug or poison is sent by post, send the export by registered or parcel post; and
- (c) comply with the requirement of rule 15 relating to the transportation of poisons.

(6) A person who fails to comply with the provisions of paragraph (5) shall be guilty of an offence.

5. Exemptions

(1) A person who imports a Part I poison for industrial purposes in accordance with the provision of rule 3 may, notwithstanding the provisions of section 26 of the Act—

- (a) lawfully possess the Part I poison in the quantity authorised to be imported;
- (b) sell the poison so imported to the person named in the application as the purchaser, and the purchaser may, notwithstanding the provisions of section 26 of the Act, lawfully possess the poison.

(2) An authorised seller of poisons shall not be required to comply with the provisions of section 29 (2) and section 30 of the Act in the case of—

- (a) substances specified in Schedule I if the sale is effected by, or under the supervision of, a registered pharmacist; and
- (b) machine-spread plaster;
- (c) surgical dressings;
- (d) articles containing barium carbonate and prepared for the destruction of rats and mice;
- (e) corn paints in which the only poison is a poison included in the Poisons List under the heading of "Cannabis".

(3) Nothing in Part III of the Act or in these Rules shall apply to—

- (a) an article in Group I of Schedule II;
- (b) a poison specified in the first column of Group II of Schedule II to these Rules if contained in or in the form of any of the articles or substances specified in the second column.

(4) The requirements of subrule (c) of section 34 (1) of the Act shall not apply to any substance specified in Schedule III.

6. Poisons to be supplied only upon prescription

(1) Subject to subrule (2), no person shall sell by retail a Part I poison specified in Schedule IV except on and in accordance with a prescription given by a duly qualified medical practitioner, dentist or veterinary surgeon in the form provided by this rule.

(2) Where an authorised seller of poisons has reasonable cause to believe that a person ordering a Part I poison is a duly qualified medical practitioner, dentist or veterinary surgeon and who is by reason of some emergency unable to furnish such a prescription immediately, he may, notwithstanding that no such prescription has been given, if the person undertakes to furnish him with such a prescription within the twenty-four hours next following, deliver the poison ordered in accordance with the directions of the person, so, however, that notwithstanding anything in the directions, the supply shall not be repeated unless the prescription has been given.

(3) A person by whom any such undertaking has been given who fails to deliver to the seller a prescription in accordance with the undertaking, or who, for the purpose of obtaining delivery of a poison under subrule (2), makes a statement which is to his knowledge false, shall be guilty of an offence.

(4) The provisions of this rule shall not apply to—

- (a) a sale referred to in section 29 (1) of the Act;
- (b) the sale by an authorised seller of poisons of a substance specified in Group II of Schedule IV to a farmer or other person concerned with the welfare of animals as a regular part of the exercise of his trade, business or profession who is in possession of a permit issued by a duly qualified veterinary surgeon;
- (c) the sale of strychnine, in quantities not exceeding four ounces at any one time to persons authorised by the District Commissioner to obtain this substance for the purposes of poisoning vermin.

(5) For the purposes of this rule a prescription shall—

- (a) be in writing and be signed by the person giving it with his usual signature and be dated by him;
- (b) specify the address of the person giving it;
- (c) specify the name and address of the person for whose treatment it is given or, if the prescription is given by a veterinary surgeon, of the person to whom the medicine is to be delivered;
- (d) have written thereon, if given by a dentist, the words “for dental treatment only” or, if given by a veterinary surgeon, the words “for animal treatment only”;
- (e) specify the total amount of the medicine to be supplied and, except in the case of a preparation which is to be used for external treatment only, the dose to be taken.

(6) The person dispensing the prescription shall comply with the following requirements—

- (a) the prescription shall not be dispensed more than once unless the prescriber has directed thereon either that it may be dispensed a stated number of times or that it may be dispensed at stated intervals;
- (b) if the prescription contains a direction that it may be dispensed a stated number of times or at stated intervals it shall not be dispensed otherwise than in accordance with the direction;
- (c) a prescription which contains a direction that it may be dispensed a stated number of times but no direction as to the intervals at which it may be dispensed shall not be dispensed more often than once in three days, and a prescription which contains a direction that it is to be dispensed at stated intervals but no direction as to the number of times that it may be dispensed shall not be dispensed more often than three times;
- (d) at the time of dispensing or, where a poison has been delivered in accordance with subrule (2), on the subsequent receipt of the prescription there shall be noted on the prescription above the signature of the prescriber the name and address of the seller and the date on which the prescription was dispensed;
- (e) except in the case of a prescription which may be dispensed again, the prescription shall, for a period of two years, be retained and kept on the premises on which it was dispensed so as to be readily available for inspection.

[Subsidiary]

(7) For the purposes of subrule (4) (b) a permit—

- (a) shall be in the form set out in Schedule IX; and
- (b) shall be produced on every occasion when supplies are required; and
- (c) on every occasion the supplier shall endorse the permit with his name and address and the date.

(8) A person who fails to comply with the provisions of subrule (6) shall be guilty of an offence.

7. Restriction of sales by licensed sellers of Part II poisons

(1) No person may, by virtue of being a licensed seller of Part II poisons, sell or offer for sale a poison otherwise than in accordance with the provisions of his licence.

(2) A licensed seller of Part II poisons shall not sell a poison, other than ammonia, hydrochloric acid, nitric acid, potassium quadroxalate and sulphuric acid, except in a closed container as closed by the manufacturer or other person from whom the poison was obtained.

(3) A person who fails to comply with the provisions of subrule (2) shall be guilty of an offence.

8. Restriction of sales by person licensed to deal in poisons for mining, agricultural or horticultural purposes

(1) No person may, by virtue of being licensed to deal in poisons for mining, agricultural or horticultural purposes, sell or offer for sale a poison otherwise than in accordance with the provisions of his licence.

(2) A person licensed to deal in poisons for mining, agricultural and horticultural purposes shall not sell—

- (a) a poison, other than ammonia, hydrochloric acid, nitric acid, potassium quadroxalate and sulphuric acid, except in a closed container as closed by the manufacturer or other person from whom the poison was obtained;
- (b) a Part I poison unless—
 - (i) the purchaser thereof is a person engaged in the trade, business or profession of mining, agriculture or horticulture and requires the poison for the purposes of his trade, business or profession; and
 - (ii) the sale is made by one of the persons named in the application for the licence to sell the poisons; and
 - (iii) the poison, if it be one of the substances referred to in Schedule V, shall, in addition to any other requirements of the Act and these Rules, be labelled in the manner described in that Schedule; and
 - (iv) the requirements of section 30 of the Act are complied with.

(3) A person who fails to comply with the provisions of subrule (2) shall be guilty of an offence.

9. Labelling of containers

(1) A container of poison required to be labelled in accordance with section 34 of the Act shall be labelled clearly and distinctly in the English language with the required particulars and in the following manner—

- (a) the name of the poison shall be the term by which the poison is specified in the Poisons List:

Provided that—

- (i) where the term describes a group of poisons and not the poison specifically, the name of the poison shall be—
 - (A) if the poison is the subject of a monograph in either the *British Pharmacopoeia* or the *British Pharmaceutical Codex* or the *British Veterinary Codex* one or other of the names, synonyms or abbreviated names set out at the head of the monograph; and
 - (B) in any other case, the accepted scientific name or name descriptive of the true nature and origin of the poison, and in such cases the appropriate name of the poison shall be written in English or in Latin;
 - (ii) in the case of a preparation in the *British Pharmacopoeia* or the *British Pharmaceutical Codex* or the *British Veterinary Codex* or a dilution or admixture of such a preparation, or a surgical dressing for which a standard is described in the *British Pharmaceutical Codex* it shall be sufficient to state the name, synonym or abbreviated name used to describe the preparation or surgical dressing in the *British Pharmacopoeia* or the *British Pharmaceutical Codex* or the *British Veterinary Codex* with the addition of the letters B.P. or B.P.C or B.Vet.C., as the case may be;
- (b) the particulars as to the proportion which a poison contained in a preparation bears to the total ingredients shall be expressed as the percentage which the poison bears to the total ingredients:

Provided that—

- (i) in the case of a preparation containing a poison specified in the first column of Schedule VI, it shall be sufficient to state on the label the particulars specified in the second column of that Schedule against the description of the poison;
 - (ii) in the case of a preparation or surgical dressing which is named in accordance with the provisions of proviso (ii) to subrule (1) (a), it shall not be necessary to state on the label the proportion of the poison contained in the preparation, and in the case of any dilution or admixture of such a preparation, it shall be sufficient to state the proportion which the preparation bears to the total ingredients of the dilution or admixture;
 - (iii) where the poison is in tablets, pills, cachets, capsules, lozenges or similar articles, or in ampoules, it shall be sufficient to state on the container thereof the number of the articles, and the amount of the poison or the amount of the preparation contained in each tablet, pill, cachet, capsule, lozenge or other similar article;
- (c) the word "Poison" or the alternative indication of character specified in rule 10, as the case may be, shall—
- (i) in the case of a poison not specified in Schedule I or in Group B of Part II of the Poisons List, either be printed in red letters on a contrasting background or in letters of some other colour set against a red background;
 - (ii) in all cases be easily legible and either on a separate label or surrounded by a line within which there must be no other words.

(2) Where a proportion is stated as a percentage, the statement shall indicate whether the percentage is calculated on the basis of weight in weight, weight in volume or volume in volume.

[Subsidiary]

(3) Directions for the use of a poison shall be given in the English language, in addition to any other language.

(4) Where poison is contained in an ampoule, cachet or other similar article the box or receptacle containing the ampoules, catchets or other articles only need be labelled in pursuance of the provisions of section 34 of the Act and these Rules.

(5) Where the container of a poison or the container of an ampoule, cachet or other similar article is labelled in accordance with the provisions of the Act and these Rules, an outer cover or wrapper to that container used only for the purpose of delivery or transport need not be similarly labelled if it complies with the provisions of rule 15.

(6) A person who sells a poison not labelled in accordance with the provisions of these Rules shall be guilty of an offence.

10. Indication of character of poison

(1) A poison specified in Schedule V shall be labelled with the words and in the manner specified in that behalf in Schedule V.

(2) The words specified in Schedule V shall not be modified in meaning by the addition of other words or marks and shall—

- (a) in the case of a poison not specified in Schedule I or in Group B of Part II of the Poisons List, be printed in red letters on a contrasting background or in some other colour on a red background;
- (b) in all cases be easily legible on a separate label or surrounded by a line within which there must be no other words.

11. Directions as to use

(1) No person shall sell liquid poison in bottles of more than 120 fluid ounces capacity unless the bottle is labelled with the words "NOT TO BE TAKEN".

(2) No person shall sell embrocation, liniment, lotion, liquid or antiseptic, or other liquid medicine for external application, which contains poison, unless the container is labelled with the name of the article and the words "FOR EXTERNAL USE ONLY".

(3) No person shall sell hydrocyanic acid or cyanide unless the container is labelled with the words "WARNING. This container holds a poisonous substance and should be opened and used by persons having expert knowledge of the precautions to be taken in its use."

(4) A person who fails to comply with any provision of this rule shall be guilty of an offence.

12. Containers for poisons

(1) No person shall keep, sell or consign for transport a poison unless—

- (a) it is contained in a container impervious to the poison and sufficiently strong to prevent leakage arising from the ordinary risks of handling and transport; and
- (b) in the case of a liquid contained in a bottle of capacity of not more than 120 fluid ounces, not being a medicine made up ready for the internal treatment of human ailments, the outer surface of the bottle is fluted vertically with ribs or grooves recognisable by touch.

(2) The provisions of subrule (1) (b) shall not apply to the sale or the keeping of poisons for the purposes of education, research or analysis by a person or institution concerned with scientific education, research or chemical analysis.

13. Safe custody of poisons

(1) No person engaged in a trade, business or profession shall knowingly have in his possession or under his control a poison, unless the following conditions are complied with at all times when the poison is not in actual use—

- (a) the poison shall be kept under lock and key—
 - (i) in a separate room or compartment specially reserved for keeping poisons and partitioned off from the rest of the premises; or
 - (ii) in a cupboard, box or other receptacle specially reserved for keeping poisons, clearly marked with the words "Poisons Only", and kept in a place apart from anything containing food or drink.
- (b) the poison shall be kept in a place ordinarily accessible only to persons lawfully having access thereto;
- (c) the key of the room, compartment, cupboard, box or other receptacle in which poisons are kept shall be retained under the control of the person in charge of the poison.

(2) The provisions of subrule (1) of this rule shall not apply to the possession of—

- (a) a substance specified in Schedule I;
- (b) a substance specified in Group B of Part II of the Poisons List;
- (c) medicines prescribed for the personal use of the person having possession or control thereof.

(3) A person in possession of a container or other receptacle which has been used for containing a poison and which is no longer required for that purpose shall by destruction or other means render that container or receptacle innocuous.

(4) Poisons for the treatment of human ailments shall be kept entirely separate from other poisons.

(5) A person who fails to comply with any provisions of this rule shall be guilty of an offence.

13A. Pharmaceutical representative's permit

(1) A representative of a person engaged in the sale and supply of pharmaceuticals containing a poison may, in the course of business, give free samples of such products to persons who may lawfully possess Part I poisons if he—

- (a) is in possession of a permit issued by the Board in that behalf; and
- (b) enters the following particulars, at the time of issue, in a book used regularly for the purpose—
 - (i) the date on which the poison was issued;
 - (ii) the name and quantity of the poison given; and
 - (iii) the name and address and signature of the person to whom the poison was given.

(2) Every application for a permit under paragraph (1) of this rule shall be made to the Board in form 18 in Schedule VIII and shall be accompanied by a fee of twenty-five shillings in respect of the issue of the permit.

(3) Every permit under paragraph (1) of this rule—

- (a) shall be in form 19 in Schedule VIII to these Rules;
- (b) shall expire on the 31st December of the year of issue or on the earlier termination of the employment by the person concerned of the person in respect of whom the permit is issued.

[L.N. 41/1971.]

[Subsidiary]

14. Special provisions with respect to hospitals

(1) All poisons not in actual use in any hospital, infirmary, dispensary, clinic, nursing home or other similar institution at which human ailments are treated shall be kept under the control of the person in charge of the institution or some fit and proper person specially detailed for that purpose and shall only be issued for use as required.

(2) In any such institution, at which medicines are dispensed in a dispensing or pharmaceutical department in charge of a person appointed for that purpose, no medicine containing a poison shall, except in a case of emergency, be supplied from that department for use in the wards, operating theatres or other sections of the institution except upon a written order signed by a duly qualified medical or dental practitioner or by a sister or nurse in charge of a ward, theatre or other section of the institution; and the person supplying the medicine shall label the container with the words describing its contents and, in the case of medicines containing poisons other than poisons specified in Schedule I to these Rules or in Group B of Part II of the Poisons List, in addition thereto, an indication that the poison is to be stored in a cupboard reserved solely for the storage of poisons.

(3) Any poison, other than a poison specified in Schedule I or in Group B of Part II of the Poisons List, issued for use in any ward, theatre or other section of the institution shall, at all times when not actually in use, be stored in a cupboard reserved solely for the storage of poisons.

(4) The person in charge of the institution shall, not less than once in every three months, carry out, or arrange and be responsible for the carrying out by a medical practitioner, a pharmacist or some other person appointed for the purpose by the person in charge, of an inspection of—

- (i) all stores, cupboards and other places where poisons are kept in the institution;
- (ii) the methods by which poisons are issued, dispensed and used in the institution; and
- (iii) all books and other records whatsoever kept in the institution for the purpose of recording the purchase, issue and use of poisons.

(5) The person carrying out the inspection shall submit copies of his report in form 20 in Schedule VIII to these Rules—

- (i) to the person in charge of the institution, if that person has not himself carried out the inspection; and
- (ii) to the registrar.

(6) A person who fails to comply with any provision of this rule shall be guilty of an offence.

[L.N. 41/1971.]

15. Transport of poisons

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

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

(3) A person who fails to comply with any provision of this rule shall be guilty of an offence.

16. Manufacture of drugs

(1) No person shall manufacture for sale any drug which is or may be used for the treatment of any human or animal ailment unless he is in possession of a licence for that purpose issued by the Board.

(2) Every application for a licence under paragraph (1) of this rule shall be made to the Board in Form 21 in Schedule VIII to these Rules and shall be accompanied by a fee of one hundred shillings in respect of the issue of the licence, which shall be refundable if the licence is not granted.

(3) Upon an application for a licence under this rule, the Board may, in its absolute discretion, refuse to grant the licence, or may grant the licence either unconditionally or subject to conditions as it may think fit.

(4) A licence under this rule shall be in form 22 in Schedule VIII to these Rules.

(5) In an establishment in which drugs are manufactured, whether for sale or otherwise, for the purpose of the treatment of any human or animal ailment, such manufacture shall be carried out by, or under the supervision of—

- (a) a registered pharmacist; or
- (b) a person having a Fellowship or Associateship of the Royal Institute of Chemistry or an equivalent qualification recognized by the Board.

(6) The Board may, by notice in the *Gazette*, exempt any establishment or class of establishment from any or all of the provisions of this rule.

(7) A person who contravenes any of the provisions of this rule, or who fails to comply with any condition of a licence issued thereunder, shall be guilty of an offence.

[L.N. 41/1971.]

17. Restriction on sale of mepacrine and bisulphate tablets

(1) A person who sells mepacrine tablets containing less than 95.0 percent or more than 105.0 percent of 100 milligrams of Mepacrine Hydrochloride as described in the *British Pharmacopoeia* shall be guilty of an offence and liable to a fine not exceeding five hundred shillings or to imprisonment for a term not exceeding one month or to both, and in addition to any penalty imposed under these Rules the Court may order any article in respect of which the offence has been committed or which has been used for the commission of the offence to be forfeited.

(2) A person who sells quinine bisulphate tablets containing less than 95.0 per cent or more than 105.0 per cent of 5 grains of Quinine Bisulphate as described in the *British Pharmacopoeia* and containing any colouring matter shall be guilty of an offence and liable to a fine not exceeding five hundred shillings and to imprisonment for a term not exceeding one month or to both such fine and such imprisonment, and in addition to any penalty imposed under these Rules the court may order any article in respect of which such offence has been committed or which has been used for the commission of the offence to be forfeited.

18. The Poisons Book

(1) The Poisons Book shall be in the form set out in Schedule VIII.

(2) In the case of a person licensed under the provisions of section 27 of the Act as a wholesale dealer in poisons or an authorised seller of poisons having a wholesale section distinct and separate from any retail shop in which complete and detailed records of the receipts and disposals of all poisons are regularly maintained, the Board may, upon such conditions as it may deem fit to impose, relieve that person of the necessity to record sales by way of wholesale in the Poisons Book.

[Subsidiary]

19. Fees

The following fees shall be paid in connection with matters arising under the Act—

	Annual Amount (KSh.)
(a) For a certificate of registration as a pharmacist/ Pharmaceutical Technologist	5,000
(b) For the restoration of name to the register	5,000
(c) Professional Practice	5,000
(d) For the registration of premises	10,000
(e) For a wholesale dealer's license per annum	30,000
(f) For a license to deal in mining, agricultural and horticultural Poisons per annum	5,000
(g) For a license to sell Part II poisons per annum	5,000
(h) For a license to manufacture drugs per product	5,000
(i) Advertisement per product	5,000
(j) Pharmaceutical representative permit	5,000
(k) For application approval for import permit 2% value Freight on Board.	
(l) Good Manufacturing Practice Audit per site—	
(i) Foreign manufacturing site	USD 4,000
(ii) Local manufacturing site	USD 1,000
(m) Training and Assessment/Evaluation fees for pharmacists and pharmaceutical technologists	
	Kenyan Citizen Foreigners
Stage/Level I	9,500/= 22,000/=
Stage/Level II	7,000/= 20,000/=
(n) New application, inspection and course approval fees for pharmacy training institutions	
	KSh.
(i) Degree programmes	400,000
(ii) Diploma programme	210,000
(o) Renewal of Annual course approval fees (sect 8)	
	KSh.
(i) Degree programmes	60,000
(ii) Diploma programme	30,000
(p) Indexing of students in the pharmacy training institutions in Kenya	
	KSh.
(i) Degree programmes	1,000
(ii) Diploma programme	1,000

[L.N. 191/2010, s. 4.]

20. Forms

The forms to be used under the Act and these Rules shall be those set out in Schedule VIII.

21. Preservation of books

All books and other prescribed records for the purposes of Part III of the Act shall be preserved on the premises on which the sales recorded therein were made for a period of two years from the date on which the last entry was made therein.

SCHEDULE I

[Rule 5.]

SUBSTANCES EXEMPTED FROM THE PROVISIONS OF SECTION 29(2) AND
SECTION 30(1)(A) AND (B) OF THE ACT

GROUP I

A substance containing any of the poisons specified in the first column below if the poison content is less than the percentage specified in the second column.

<i>Poison</i>	<i>Percentage of poison content below which substance is exempted</i>
1. Alkaloids, including their salts simple or complex:—	
2. Aconite, alkaloids of	0.02 percent.
3. Apomorphine	0.20 percent.
4. Atropine	0.15 percent.
5. Belladonna, alkaloids of	0.15 percent, calculated as hyoscyamine.
6. Brucine	0.20 percent.
7. Coca, alkaloids of	0.10 percent.
8. Cocaine	0.10 percent.
9. Codeine	1.50 percent.
10. Colchicum, alkaloids of	0.50 percent, calculated as colchicine.
11. Coniine	0.10 percent.
12. Cotarnine	0.20 percent.
13. Ecgonine and its esters	0.10 percent.
14. Emetine	1.00 percent.
15. Ethylmorphine	0.20 percent.
16. Gelsemium, alkaloids of	0.10 percent.
17. Homatropine	0.15 percent.
18. Hyoscine	0.15 percent.
19. Hyoscyamine	0.15 percent.
20. Jaborandi, alkaloids of	0.50 percent.
21. Lobelia, alkaloids of	0.50 percent.
22. Morphine	0.20 percent, calculated as anhydrous morphine.
23. Morpholinylethylmorphine	1.50 percent.
24. Papaverine	1.00 percent.
25. Pomegranate, alkaloids of	0.50 percent.
26. Sabadilla, alkaloids of	1.00 percent.
27. Solanaceous alkaloids, not otherwise included in this Schedule	0.15 percent, calculated as hyoscyamine.
28. Stavesacre, alkaloids of	0.20 percent.
29. Strychnine	0.20 percent.
30. Thebaine	1.00 percent.
31. Veratrum, alkaloids of	1.00 percent.
32. Adrenalin, its salts, in preparations for external use only	0.10 percent.

Pharmacy and Poisons

[Subsidiary]

SCHEDULE I—*continued*

<i>Poison</i>	<i>Percentage of poison content below which substance is exempted</i>
33. Amino-alcohols, esterified with benzoic acids, phenylacetic acid, phenylpropionic acid, cinnamic acid or the derivatives of these acids	10.00 percent of esterified amino-alcohols.
34. Antimonial poisons	Equivalent of 1.00 percent of antimony trioxide.
35. Arsenical poisons	Equivalent of 0.01 percent of arsenic trioxide and dentifrices containing less than 0.50 percent of acetarsol.
36. Butyl chloral hydrate	10.00 percent.
37. Cantharidin	0.01 percent.
38. Cantharidates	Equivalent of 0.01 percent of cantharidin.
39. Chloral formamide	10.00 percent.
40. Chloral hydrate	10.00 percent.
41. Digitalis, glycosides and other active principles of	One unit of activity (as defined in the <i>British Pharmacopala</i>) in two grams. of the substance.
42. Dinitrocresols (DNC), their compounds with a metal or a base .	Equivalent of 5.00 percent of dinitrocresols.
43. Hydrocyanic acid	0.15 percent weight in weight of hydrocyanic acid (HCN).
44. Insulin	Not exceeding 80 units in 1 mil.
45. Cyanides	Equivalent of 0.10 percent weight in weight of hydrocyanic acid (HCN).
46. Mercuric chloride	1.00 percent.
47. Mercuric iodide	2.00 percent.
48. Nitrates of mercury	Equivalent of 3.00 percent weight in weight of mercury (Hg).
49. Potassio-mercuric iodides	Equivalent of 1.00 percent of mercuric iodide.
50. Organic compounds of mercury	Equivalent of 0.20 percent weight in weight of mercury (Hg).
51. Nux vomica	0.20 percent of strychnine.
52. Opium	0.20 percent of morphine calculated as anhydrous morphine.
53. Para-amino-benzoic acid, esters of; their salts	1.00 percent.
54. Para-aminobenzenesulphonamide; its salts; derivatives of para-aminobenzenesulphonamide having any of the hydrogen atoms of the para-substituted group or of the sulphonamide group substituted by another radical; their salts; when incorporated in a base for external application only	50 percent.

SCHEDULE I—*continued*

GROUP II

Antibiotics, the following—

Bacitracin

Gramicidin

Neomycin

Polymyxins

when incorporated in a base for treatment of the skin.

Chloramphenicol

when incorporated in a special base for the treatment of the feet of animals.

Anti-histamine substances, the following; their salts; their molecular compounds—

Antazoline.

Bromodiphenhydramine.

Buclizine.

Carbinoxamine.

Chlorcyclizine.

Chlorpheniramine.

Cinnarizine.

Clemizole.

Cyclizine.

Cyproheptadine.

3-Di- n-butylaminomethyl-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 propylenediamine.

[Subsidiary]

SCHEDULE II

[Rule 5.]

[L.N. 92/1964, L.N. 125/1969.]

ARTICLES EXEMPTED FROM PART III OF THE ACT AND THESE RULES

GROUP I

Adhesives, anti-fouling compositions; builders' materials; ceramics; distempers; electrical valves; enamels; explosives; fillers; fireworks; fluorescent lamps; glazes; glue; inks; lacquer solvents; loading materials; matches; medicated soaps; motor fuels and lubricants; paints other than pharmaceutical paints; photographic paper; pigment; plastics; propellants; rubber; varnishes; tyrothricin, framycetin.

GROUP II

<i>Poison</i>	<i>Substance or article in which exempted</i>
1. Acetanilide; alkyl acetanilides	Substances not being preparation for the treatment of human ailments.
2. Brucine	Surgical spirit containing not more than 0.015 percent of brucine.
3. Emetine	Ipecachuana; extracts and tinctures of ipecachuana; substances containing less than 0.05 percent of emetine.
4. Ephedra, alkaloids of	Substances containing less than 1 percent of the alkaloids of ephedra.
5. Formic acid	Substitutes containing not less than 5 percent weight in weight formic acid (HCOOH).
6. Jaborandi, alkaloids of	Substances containing less than 0.025 percent of the alkaloids of jaborandi,
7. Lobelia, alkaloids of	Preparations for the relief of asthma in the form of cigarettes, smoking mixtures or fumigants, substances containing less than 0.1 percent of the alkaloids of lobelia.
8. Nicotine	Tobacco.
9. Pomegranate, alkaloids of	Pomegranate bark.
10. Solanaceous alkaloids	Stramonium contained in preparations for the relief of asthma in the form of cigarettes, smoking mixtures or fumigants.
11. Stavesacre, alkaloids of	Soaps; ointments; lotions for external use.
12. Ammonia	Substances not being solutions of ammonia or preparations containing solutions of ammonia substances containing less than 5 percent weight in weight of ammonia (NH ₃); refrigerators; smelling bottles.
13. Antibiotics as defined in the Poisons List	Preparations or concentrates for animal feeding.
14. Antihistamine substances as defined in the Poisons List	Preparations intended for external application only.
15. Antimony, chlorides of	Polishes.
16. Arsenical poisons	Pyrites ores or sulphuric acid containing arsenical poisons as naturaimpurities.
17. Barium, salts of	Witherite other than finely ground witherite.

SCHEDULE II—continued

<i>Poison</i>	<i>Substance or article in which exempted</i>
18. Beta-aminopropylbenzene; its salts; its N-alkyl derivatives; their salts; beta-aminoisopropylbenzene; its salts; its Nalkyl derivatives; their salts	Appliances for inhalation in which the poison is absorbed in inert solid material.
18A. Carbarsonne	Poultry feeding stuffs containing not more than 0.0375 percent Carbarsonne.
19. Chloroform	Substances containing less than 10 percent of chloroform.
20. Creosote obtained from wood	Substances containing less than 50 percent of creosote obtained from wood.
21. Formaldehyde	Substances containing less than 5 percent weight in weight of formaldehyde (HCHO); photographic glazing or hardening solutions.
22. Hormones as defined in the Poisons List	Cosmetic preparations for external applicaton and plant hormones.
23. Hydrochloric acid	Substances containing less than 9 percent weight in weight of hydrochloric acid (HCL).
24. Lead acetate	Substances containing less than 4 percent of lead acetate.
25. Lead, compounds of	Machine-spread plasters.
26. Mercuric chloride	Batteries.
27. Mercuric chloride; mercuric iodide; organic compounds of mercury	Dressings on seeds or bulbs.
28. Mercury, nitrates of	Ointments containing less than the equivalent of 3 percent weight in weight of mercury (Hg).
29. Nitric acid	Substances containing less than 9 percent weight in weight of nitric acid (HNO ₃).
30. Nitrobenzene	Substances containing less than 0.1 percent of nitrobenzene; soaps containing less than 1 percent of nitrobenzene; polishes.
31. Oxalic acid; metallic oxalates	Laundry blue; polishes.
32. Oxycinchonic acid; derivatives of their salts; their esters	Preparations for external applications only containing not more than the equivalent of 3 percent oxycinchonic acid.
33. Paranitrobenzylcyanide	Photographic solutions containing less than the equivalent of 0.1 percent of HCN.
34. Paranitrophenol	Preparations for use in agriculture and horticulture containing not more than 0.5 percent of paranitrophenol as a preservative.
34A. Phenylcinchoninic acid	Preparations for external application only containing not more than the equivalent of 10.1 % of phenylcinchoninic acid.
35. Phenols	Carvacrol; creosote obtained from coal tar; essential oils in which phenols occur naturally; medicines containing less than 1 percent of phenols; nasal sprays, mouth washes, pastilles, lozenges, capsules,

[Subsidiary]

SCHEDULE II—*continued*

<i>Poison</i>	<i>Substance or article in which exempted</i>
	pessaries, ointments or suppositories containing less than 2.5 percent of phenols; paratertiaryamyl phenol; smelling bottles; soaps for washing; solid substances other than pastilles, lozenges, capsules, pessaries, ointments and suppositories, containing less than 60 percent of phenols; tar (coal or wood), crude or refined; tertiary butylcresol; thymol; animal dips containing less than 6 percent of phenols.
36. Phenylene diamines; toluene diamines; other alkylatedbenzene diamines; their salts	Substances other than preparations for the dyeing of hair.
37. Phenylmercuric salts	Toilet, cosmetic and therapeutic preparations containing not more than 0.01 percent of phenylmercuric salts as a preservative, and textiles containing not more than 0.01 %, as a bacteriostat and fungicide.
38. Picric acid	Substances containing less than 5 percent of picric acid.
39. Potassium hydroxide	Substances containing less than 12 percent of potassium hydroxide; accumulators; batteries.
40. Procaine	Combined with antibiotics when contained in preparations or concentrates for animal feeding.
41. Sodium ethyl mercurithiosalicylate	Therapeutic substances containing less than 0.1 percent of sodium ethyl mercurithiosalicylate as a preservative.
42. Sodium fluoride	Substances containing less than 3 percent of sodium fluoride as a preservative.
43. Sodium hydroxide	Substances containing less than 12 percent of sodium hydroxide.
44. Sodium silicofluoride	Substances containing less than 3 percent of sodium silicofluoride as a preservative.
44A. Sulphone	Substance containing a mixture of dapsone and pyrimethamine, recommended for use as an antimalarial.
45. Sulphuric acid	Substances containing less than 9 percent weight in weight of sulphuric acid (H ₂ SO ₄); accumulators, batteries; fire extinguishers.

SCHEDULE III

[Rule 5.]
[L.N. 248/1969.]

SUBSTANCES EXEMPT FROM CERTAIN LABELLING REQUIREMENTS

1. Antibiotics.
2. Hormones; natural and synthetic; any preparations, admixture, extract or other substance containing any proportion of any substance having the action of any hormone.
3. Isoniazid; its salts, derivatives of isoniazid; their salts.
4. Para-amino-salicylic acid; its salts; any preparation of para-amino-salicylic acid; its salts.
5. Sulphones; their salts; their derivatives.
6. Thiacetazone; its salts; its derivatives.
7. Drugs as defined in the Pharmacy and Poisons (Control of Drugs) Rules, 1969, which are not specifically named in the Schedule to the Poisons List Confirmation Order.

SCHEDULE IV

GROUP I

Substances required to be sold by retail only upon a prescription given by a duly qualified medical practitioner, dentist or veterinary surgeon.

1. Acetanilide; alkyl acetanilides.
- 2A. Acetohexamide.
3. Acetylcarbromal.
4. Allylisopropylacetylurea.
5. Amidopyrine; amidopyrine sulphonates; their salts.
6. Amitriptyline; its salts.
7. Antibiotics.
8. Antimony, organic compounds of, for injection.
9. Arsenic, organic compounds of, for injection.
10. Azacyclonal; its salts.
11. Barbituric acid; its salts, derivatives of barbituric acid; their salts; compounds of barbituric acid, its salts, its derivatives, their salts, with any other substance.
12. Benactyzine; its salts.
13. Benztropine and its homologues; their salts.
14. Benzhexol; its salts.
15. Bromvaletone.
16. Busulphan; its salts.
17. B-Aminopropylbenzene and B-aminoisopropylbenzene and any compound structurally derived from either of those substances by substitution in the side chain or by ring closure therein (or by both such substitution and such closure), except ephedrine N-methylephedrine, N-diethylamioethylephedrine, phenylpropanolamine and prenylamine; any salt of any substance falling within this item.
18. Captodiame; its salts.
19. Carbromal.

[Subsidiary]

SCHEDULE IV—*continued*

20. Carisoprodol.
21. Chlordiazepoxide; its salts.
22. Chlormethiazole; its salts.
23. Chlorothiazide and other derivatives of benzo-1, 2, 4-thiadiazine-7-sulphonamide 1, 1-dioxide, whether hydrogenated or not.
24. Chlorphenoxamine.
25. Chlorphentermine.
26. Chlorpropamide; its salts.
27. Chlorprothixene, and other derivatives of 9-methylenethioxanthen; and their salts.
28. Chlorthalidone, and other derivatives of O-Chlorobenzene sulphonamide.
29. Chlorexolone.
30. Curare; alkaloids of; curare bases and salts.
31. Cyclarbamate.
32. Cycrimine; its salts.
33. Demecarium bromide.
34. Desipramine; its salts.
35. 4; 4-diamidino-diazoamino-benzene; its salts.
36. Diazepam, and other compounds containing the chemical structure of 1:4 benzodiazepine substituted to any degree; their salts.
37. Dinitrocresols (DNC); their compounds with a metal or a base, except preparations for use in agriculture or horticulture.
38. Dinitronaphthols; dinitrophenols; dinitrothymols.
39. Disulfiram.
40. Dithienylallylamines; dithienylalkylallylamines; their salts except diethylthiambutene, dimethylthiambutene and ethylmethylthiambutene.
41. Ectylurea.
42. Emylcamate.
43. Ergot; alkaloids of; homologues of; their salts.
44. Ethchlorvynol.
45. Ethinamate.
46. Ethionamide.
47. Ethoheptazine; its salts.
48. Gallamine; its salts; its quaternary compounds.
49. Haloperidol, and other 4 substituted derivatives of N-(3-p. fluorobenzoylpropyl) piperidine.
50. Hexapropymate.
51. Hormones, adrenal cortical, natural and synthetic; any preparations, admixture, extract or other substance containing any proportion of any substance having the action of any adrenal cortical Hormone.
52. Hormones, sex, natural and synthetic and analogous substance, except when in the form of avian implants.
53. Hydrazines, benzyl phenethyl or phenoxyethyl; their a-methyl derivatives; acyl derivatives of any of the foregoing substances comprised in this item; salts of any compounds comprised in this item.
54. 4-Hydroxymethyl-2, 2-diisopropyl-1, 3-dioxolan.
55. Hydroxy N-N-dimethyl tryptamines, esters or ethers of these; salts of any of the foregoing (Psilocin and Psilocybe).
56. Hydroxyzine; its salts.
57. Imipramine; its salts.
58. Indomethacin; its salts.

SCHEDULE IV—*continued*

59. Isoniazid; its salts, derivatives of isoniazid; their salts.
60. Mannomustine; its salts.
61. Mephesisin; its esters.
62. Meprobamate.
63. Mercaptopurine; its salts, derivatives and their salts.
64. Metaxalone.
65. Metformin; its salts.
66. Methaqualone; its salts.
67. Methixene; its salts.
68. Methocarbamol.
69. Methoxsalen.
70. Methylpentynol; its esters and other derivatives.
71. Mustine and any other N-substituted derivatives of di-(2 Chloroethyl) amine; their salts.
72. Nortryptiline; its salts.
73. Orphenadrine; its salts.
74. Oxethazaine.
75. Oxyphenbutazone.
76. Para-aminobenzenesulphonamide; its salts; derivatives of para-aminobenzenesulphonamide having any of the hydrogen atoms of the para-amino group or of the sulphonamide group substituted by another radical; their salts, except when contained in ointments or surgical dressings or in preparations for the prevention and treatment of diseases in poultry.
77. Para-amino-salicylic acid; its salts; any preparation of para-aminosalicylic acid, its salts.
78. Paramethadione.
79. Pargyline; its salts.
80. Pemoline; its salts.
81. Phenacemide.
82. Phenaglycodol.
83. Phenanthridinium and its derivatives.
84. Phenbutrazate.
85. Phenetidylphenacetin.
86. Phenformin; its salts.
87. Phenothiazine, derivatives of; their salts; except dimethoxanate, its salts and promethazine, its salts and its molecular compounds.
88. Phenylbutazone; its salts.
89. Phenylcinchoninic acid; salicylcinchoninic acid; their salts, their esters.
90. Phenylhydantoin; its alkyl and aryl derivatives; their salts.
91. Pituitary gland, the active principles of; except when contained in preparation intended for external application only or, except in the case of lysinevasopressin or oxytocin, in inhalants.
92. Polymethylenebis(trimethylammonium) salts.
93. Procyclidine; its salts.
94. Promoxolan.
95. Propylhexedrine; its salts; except when contained in inhalers.
96. Prothionamide.
97. Prothipendyl.
98. Quinapyramine and analogous substances; their salts.
99. Quinethazone.

[Subsidiary]

SCHEDULE IV—*continued*

100. Rauwolfia, alkaloids of; derivatives of; their salts.
101. Strychnine except in preparations included in Part II of the Poisons List.
102. Styramate.
103. Sulphinpyrazone.
104. Sulphonals; alkyl sulphonals.
105. Sulphones; their derivatives; their salts.
106. Suprarenal gland medulla, the active principles of; their salts; except when contained in preparations intended for external application only or in inhalants, rectal preparations or preparations intended for use in the eye.
107. Syrosingopine.
108. Tetrabenazine; its salts.
109. Thalidomide; its salts.
110. Thiacetazone; its salts; its derivatives.
111. Thyroid gland, the active principles of; their salts.
112. Tolbutamide.
113. Tretamine; its salts.
114. Triazi quone.
115. Tribromethyl alcohol.
116. Trimipramine.
117. Troxidone.
118. Zoxazolamine; its salts.

GROUP II

SUBSTANCES TO WHICH RULE 6(3)(B) APPLIES

1. Antibiotics.
2. Arsenic, organic compounds of, for injection.
3. 4:4'-diamidino-diazoaminobenzene; its salts.
4. Phenanthridinium and its derivatives.
5. Para-aminobenzenesulphonamide; its salts; derivatives of para-aminobenzene-sulphonamide having any of the hydrogen atoms of the para-substituted group or any of the sulphonamide group substituted by another radical; their salts.
6. Quinapyramine; its salts.

SCHEDULE V

[Rules 8 and 10.]

INDICATION OF CHARACTER OF POISON

1. To be labelled with the words "Caution. It is dangerous to take this preparation except under medical supervision"—

Medicines made up ready for the internal treatment of human ailments if the poison is one of the following—

Beta-aminopropylbenzene; its salts; its N-alkyl derivatives; their salts.

SCHEDULE V—*continued*

Beta-aminoisopropylbenzene; its salts; its N-alkyl derivatives; their salts.

Insulin.

Phenylethylhydantoin; its salts; its acyl derivatives; their salts.

Pituitary gland, the active principles of.

Thyroid gland, the active principles of; their salts.

2. To be labelled with the words "Caution. It is dangerous to exceed the stated dose"—

Medicines (other than medicines mentioned in paragraph 1 of this Schedule) made up ready for the internal treatment of human ailments except in the case of a substance included in the First Schedule.

3. To be labelled with the words "Poison. For animal treatment only"—

Medicines made up ready for the treatment of animals.

4. To be labelled with the words "Caution. This preparation may cause serious inflammation of the skin in certain persons and should be used only in accordance with expert advice"—

Preparations for the dyeing of hair containing phenylene diamines, toluene diamines or other alkylated-benzene diamines or their salts.

5. To be labelled with the words "Caution. This substance is caustic"—

Potassium hydroxide, sodium hydroxide, and articles containing either of those substances.

6. To be labelled with the words "Caution. This substance is poisonous. The inhalation of its vapour, mist, spray or dust may have harmful consequences. It may also be dangerous to let it come into contact with the skin or clothing"—

Dinitrocresols (DNC), their compounds with a metal or a base, except preparations for the treatment of human ailments and except winter washes containing not more than the equivalent of five percent of dinitrocresols.

Dinosam, its compounds with a metal or a base.

Dinoseb, its compounds with a metal or a base.

Fluoroacetamide; Fluoroacetanilide.

Phosphorus compounds, the following—

Diethyl thiophosphate of ethyl-mercapto-ethanol, dimefox, ethyl-p-nitrophenyl-benzene thiophosphonate, hexaethyl tetraphosphate (HETP), 4-methyl hydroxy-coumarin-diethyl thiophosphate, mipafox, parintrophenyl-diethyl phosphate, parathion, schradan, tetraethyl pyrophosphate (TEPP), triphosphoric pentadimethylamide, di-isopropyl fluorophenate, demeton, mazidox, methyl demeton, sulphotepp, amiton, demeton-O, demeton-S, demeton-O-methyl, demeton-S-methyl, diethyl 4-methyl-7-coumarinyl phosphorothionate, diethyl p-nitrophenyl phosphate, ethyl p-nitrophenyl phenyl-phosphonothionate.

7. To be labelled with the words "Caution. This preparation should be administered only under medical supervision. The vapour is dangerous"—medicines made up ready for the internal or external treatment of human ailments and containing di-isopropyl fluorophosphonate.

8. To be labelled with the words "Caution. This may cause drowsiness"—

Anti-histamine substances, the following; their salts; their molecular compounds—

Antazoline.

[Subsidiary]

SCHEDULE V—continued

- Bromodiphenhydramine.
- Buclizine.
- Chlorcyclizine.
- (p-Chlorophenylpyrid-2-ylmethyl) 2-dimethylaminoethyl ether 1-(4-p-Chlorophenyl-3-phenyl-but-2-enyl)-pyrrolidine.
- Chlorpheniramine.
- Clemizole.
- Cyclizine.
- 3-Di-n-butylaminomethyl-4:5:6-trihydroxyphthalide.
- 1-Dimethylamino-3-phenyl-3-(2-pyridyl)-propane.
- Diphenhydramine.
- Diphenylpyraline.
- Doxylamine.
- Isothipendyl.
- Mebhydrolin.
- Meclozine.
- Phenindamine.
- Promethazine.
- Thenalidine.
- Tripolidine.
- Substances being tetra-substituted N derivatives of ethylenediamine or propylenediamine.

SCHEDULE VI

[Rule 9 (1) (b).]

STATEMENT OF PARTICULARS PERMITTED IN CERTAIN CASES AS TO PROPORTION OF POISON

<i>Name of poison</i>	<i>Particulars</i>
1. Alkaloids.	
2. Aconite, alkaloids of	The proportion of any one alkaloid of aconite that the preparation would be calculated to contain on the assumption that all the alkaloids of aconite in the preparation were that alkaloid.
3. Belladonna, alkaloids of	} The same as above, with the substitution for the reference to aconite of a reference to belladonna, calabar bean or such other of the said poisons as the case may require.
4. Calabar bean, alkaloids of	
5. Coca, alkaloids of	
6. Ephedra, alkaloids of	
7. Ergot, alkaloids of	
8. Gelsemium, alkaloids of	
9. Jaborandi, alkaloids of	
10. Lobelia, alkaloids of	
11. Pomegranate, alkaloids of	

SCHEDULE VI—continued

<i>Name of poison</i>	<i>Particulars</i>
12. Quebracho, alkaloids of, other than the alkaloids of red quebracho	}
13. Sabadilla, alkaloids of	
14. Solanaceous alkaloids not otherwise included in the Poisons List	
15. Stavesacre, alkaloids of	
16. Veratrum, alkaloids of	
17. Yohimba, alkaloids of	
18. Colchicum, alkaloids of	
19. Antimonial poisons	
20. Arsenical poisons	The proportion of arsenic trioxide (As ₂ O ₃) or arsenic pentoxide (As ₂ O ₅) that the preparation would be calculated to contain on the assumption that the arsenic (As) in the poison had been wholly converted into arsenic trioxide or arsenic pentoxide as the case may be.
21. Barium, salts of	The proportion of one particular barium salt which the preparation would be calculated to contain on the assumption that the barium (Ba) in the poison had been wholly converted into that salt.
22. Digitalis, glycosides of; other active principles of digitalis	The number of units of activity as defined in the <i>British Pharmacopoeia</i> contained in a specified quantity of the preparation.
23. Hydrocyanic acid; cyanides, double cyanides of mercury and zinc	The proportion of hydrocyanic acid (HCN) that the preparation would be calculated to contain on the assumption that the cyanides in the poison had been wholly converted into hydrocyanic acid.
24. Insulin	The number of units of activity as defined in the <i>British Pharmacopoeia</i> contained in a specified quantity of the preparation.
25. Lead, compounds of, with acids from fixed oils	The proportion of lead oxide (PbO) that the preparation would be calculated to contain on the assumption that the lead in the poison had been wholly converted into lead oxide.
26. Mercury, organic compounds of	The proportion of organically combined mercury (Hg) contained in the preparation.
27. Nux vomica	The proportion of strychnine contained in the preparation.
28. Opium	The proportion of morphine contained in the preparation.
29. Phenols	The proportion of phenols (added together) contained in the preparation.

[Subsidiary]

SCHEDULE VI—*continued*

<i>Name of poison</i>	<i>Particulars</i>
30. Compounds of a phenols with a metal	The proportion of phenols (added together) that the preparation would be calculated to contain on the assumption that the compounds of phenols with a metal had been wholly converted into the corresponding phenols.
31. Pituitary gland, the active principles of	<p>Either—</p> <p>(a) the number of units of activity as defined in the <i>British Pharmacopoeia</i> contained in a specified quantity of the preparation; or</p> <p>(b) the proportion of pituitary gland, or of anterior or of posterior lobe of the gland, as the case may be, contained in the preparation; or</p> <p>(c) the amount of pituitary gland or of anterior or of posterior lobe of the gland, as the case may be, from which a specified quantity of the preparation was obtained, together with an indication whether the amount relates to fresh or to dried gland substance.</p>
32. Potassium hydroxide	The proportion of potassium monoxide (K ₂ O) which the preparation would be calculated to contain on the assumption that the potassium hydroxide in the preparation had been wholly converted into potassium monoxide.
33. Sodium hydroxide	The proportion of sodium monoxide (Na ₂ O) which the preparation would be calculated to contain on the assumption that the sodium hydroxide in the preparation had been wholly converted into sodium monoxide.
34. Strophanthus, glycosides of	The amount of Standard Tincture of Strophanthus as defined in the <i>British Pharmacopoeia</i> which possesses the same activity as a specified quantity of the preparation when assayed by the method described in the said <i>Pharmacopoeia</i> .
35. Suprarenal gland, the active principles of; their salts	<p>Either—</p> <p>(a) the proportion of suprarenal gland or of the cortex or of the medulla of the gland, as the case may be, contained in the preparation; or</p> <p>(b) the amount of suprarenal gland or of the cortex or of the medulla of the gland, as the case may be, from which a specified quantity of the preparation was obtained, together with an indication whether the amount relates to fresh or to dried gland substance.</p>
36. Thyroid gland, the active principles of; their salts	<p>Either—</p> <p>(a) the proportion of thyroid gland contained in the preparation; or</p>

SCHEDULE VI—*continued**Name of poison**Particulars*

- (b) the amount of thyroid gland from which a specified quantity of the preparation was obtained, together with an indication whether the amount relates to fresh or to dried gland.

SCHEDULE VII

[Rule 15.]

POISONS REQUIRED TO BE SPECIALLY LABELLED FOR TRANSPORT

1. Arsenical poisons.
2. Barium, salts of.
3. Dinitrocresols (DNC), their compounds with a metal or a base when contained in preparations for use in agriculture or horticulture, except winter washes containing not more than the equivalent of 5 percent of dinitrocresols.
4. Dinitrophenols when contained in preparations for use in agriculture or horticulture.
5. Dinosam, its compounds with a metal or a base, when contained in preparations for use in agriculture or horticulture.
6. Dinoseb, its compounds with a metal or base, when contained in preparations for use in agriculture or horticulture.
- 6A. Endosulfan.
7. Fluoroacetamide; Fluoroacetanilide.
8. Hydrocyanic acid; cyanides.
9. Nicotine.
10. Phosphorus compounds, the following:—
Diethyl thiophosphate of ethyl-mercapto-ethanol, dimefox, ethyl-paranitro-phenyl-benzene thiophosphonate, hexaethyl tetraphosphate (HETP), 4-methyl-hydroxy-coumarin-diethyl thiophosphate, mipafox, parantrophenyl-diethyl phosphate, parathion, schradan, tetraethyl pyrophosphate (TEPP), triphosphoric pentadimethylamide, di-isopropyl-fluorophenate, demeton, mazidox, methyl demeton, sulphotepp, amiton, demeton-O, demeton-S, demeton-O-methyl, demeton-S-methyl, diethyl 4-methyl-7-coumarinyl phosphorothionate, diethyl p-nitrophenyl phosphate, ethyl p-nitrophenyl phenylphosphonothionate, ethion, mecarbam, phenkapton.
11. Strychnine.
12. Thallium, salts of.

SCHEDULE VIII

[L.N. 365/1964, L.N. 41/1971, Rule 20, L.N. 61/2002, s. 2, L.N. 91/2004, s. 2.]

FORMS

1. Application for registration as a pharmacist (section 7).
2. Register of pharmacists (section 6).
3. Certificate of registration as a pharmacist (section 9).
4. Application for registration of premises (section 23).
5. Register of premises (section 23).
6. Application for wholesale dealer's licence (section 27).

Pharmacy and Poisons

[Subsidiary]

SCHEDULE VIII—continued

- 7. Wholesale dealer's licence (section 27).
- 8. Register of wholesale dealer's licences (section 27).
- 9. Application for licence to deal in poisons for mining, agricultural and horticultural purposes (section 28).
- 10. Licence to deal in poisons for mining, agricultural and horticultural purposes (section 28).
- 11. Register of dealers in mining, agricultural and horticultural poisons (section 28).
- 12. Certificate for purchase of poison (section 29).
- 13. Application for licence to sell Part II poisons (section 32).
- 14. Licence to sell Part II poisons (section 32).
- 15. Register of licences issued to sellers of Part II poisons (section 32).
- 16. Poisons Book (section 30).
- 17. Permit to import Part I poisons (rule 3).
- 18. Application for pharmaceutical representative's permit (rule 13A).
- 19. Pharmaceutical representative's permit (rule 13A).
- 20. Institution inspection report (rule 14).
- 21. Application for licence to manufacture drugs for sale (rule 16).
- 22. Licence to manufacture drugs for sale (rule 16).
- 23. Application for licence for the exportation of drugs and poisons.
- 24. Annual professional practise licence as a pharmacist (section 9A).
- 25. Roll of Pharmaceutical Technologists (section 6(2)).
- 26. Application for enrolment as a pharmaceutical technologist (section 7(2)).
- 27. Application for annual practice licence for a pharmacist (section 9A).
- 28. Certificate of enrolment as a pharmaceutical technologist (section 9(2)).
- 29. Application for licence as a pharmaceutical technologist (section 20(1A)).
- 30. Application for registration of premises for a pharmaceutical technologist (section 20(1A)).
- 31. Certificate for registration of premises for a pharmaceutical technologist (section 20(1A)).
- 32. Annual licence to practice as a pharmaceutical technologist (section 20(2A)).
- 33. Certificate of registration of premises for pharmacist (section 23(c)).

Form 1

APPLICATION FOR REGISTRATION AS A PHARMACIST

The Registrar, Pharmacy and Poisons Board,
Afya House, P.O. Box 30016, Nairobi.

I, of
hereby make application for registration as a pharmacist.

I hereby declare that to the best of my knowledge and belief I am not aware of any circumstances which would disqualify me for registration.

My qualifications are

I enclose the following certificates/diplomas:—

Date

Signature

SCHEDULE VIII—continued

Form 2

REGISTER OF PHARMACISTS

REGISTRATION		Name of Applicant	Address	Qualification	Date of Qualification	Registration Fee
No.	Date					

Form 3

CERTIFICATE OF REGISTRATION AS A PHARMACIST

.....
is hereby registered as a pharmacist in accordance with the provisions of Part II of the Pharmacy and Poisons Act.

Given at Nairobi on the, 20

.....
Registrar, Pharmacy and Poisons Board

Form 4

APPLICATION FOR REGISTRATION OF PREMISES

The Registrar, Pharmacy and Poisons Board,
Afya House, P.O. Box 30016, Nairobi.

In accordance with the provisions of section 23 of the Pharmacy and Poisons Act, I/We

.....
wishing to carry on the business of a pharmacist, do hereby apply for registration of premises situated at

in the town of

The business, in so far as concerns the retail sale of drugs, will be under the control of

..... a pharmacist registered in accordance with Part II of the Act.

Date

Signature of Applicant

N.B.—Any change of pharmacist under whose control the business is carried on must be notified to the Registrar within seven days.

Fee: Sh. 100.

Pharmacy and Poisons

[Subsidiary]

SCHEDULE VIII, Form 4—continued

Form 5

REGISTER OF PREMISES

REGISTRATION		Name(s) of owner(s) of the business	Address of premises where business of a pharmacist is carried on (give name of minor settlement/town)	Name of pharmacist under whose control the business of a pharmacist is carried on
No.	Date			

Form 6

APPLICATION FOR WHOLESALE DEALER'S LICENCE

The Registrar, Pharmacy and Poisons Board,

Medical Headquarters, P.O. Box 30016, Nairobi.

I/We of
 wishing to carry on business as a wholesale dealer in poisons at
 in the town of
 hereby apply for the issue/renewal of a wholesale dealer's licence.

The registered pharmacist in control of the distribution of poisons is
, resident in

Date

Signature of Applicant

N.B.—Any change of registered pharmacist under whose control the distribution of poisons is effected must be notified to the Registrar within seven days.

Form 7

WHOLESALE DEALER'S LICENCE

Messrs of
 carrying on business at are hereby authorised
 to sell poisons by way of wholesale dealing.

Date

Registrar, Pharmacy and Poisons Board

Note.—This licence expires on the 31st day of December, 20.....

Fee: Sh. 400.

SCHEDULE VIII—continued

Form 8

REGISTER OF WHOLESALE DEALERS

REGISTRATION		Name(s) of owner(s) of the business	Address of premises where business is carried on	Name of pharmacist in control of the distribution of poisons
No.	Date			

Form 9

APPLICATION FOR LICENCE TO DEAL IN POISONS FOR MINING, AGRICULTURAL AND HORTICULTURAL PURPOSES

The Registrar, Pharmacy and Poisons Board,
Medical Headquarters, P.O. Box 30016, Nairobi.

I/We of
carrying on a regular business in *mining/agricultural/and/or horticultural accessories at
..... in the town of , hereby apply for the
issue/renewal of a licence to deal in the following poisons

I/We hereby nominate the following person(s)
.....
who may sell in accordance with the provisions of rule 10 of the Pharmacy and Poisons Rules.

Date

.....
Signature of Applicant

* Delete as necessary.
Note.—Not more than two persons may be nominated.

Form 10

LICENCE TO DEAL IN MINING, AGRICULTURAL OR HORTICULTURAL POISONS

Messrs. of
carrying on business at are hereby
licensed to deal in the following poisons

Pharmacy and Poisons

[Subsidiary]

SCHEDULE VIII, Form 10—*continued*

The following person(s) are hereby authorised to sell these poisons in accordance with the provisions of rule 10 of the Pharmacy and Poisons Rules.

.....

Date

.....
Registrar, Pharmacy and Poisons Board

N.B.—Any change in persons authorised to sell must be notified to the Registrar within seven days.

Note.—This licence expires on the 31st day of December, 20.....

Fee: Sh. 50.

Form 11

REGISTER OF DEALERS IN MINING, AGRICULTURAL AND HORTICULTURAL POISONS

REGISTRATION		Name of owner(s) of the business	Address of premises where business is carried on	Name(s) of person(s) authorised to sell poisons
No.	Date			

Form 12

CERTIFICATE FOR PURCHASE OF POISON

For the purposes of paragraph (b) of subsection (2) of section 29 of the Pharmacy and Poisons Act, I, the undersigned, hereby certify from my knowledge of (a)

..... of (b), that he is a person to whom

(c) may properly be supplied.

I further certify that (d) is the signature of the said (a)

Date

.....
Signature and designation of officer giving certificate

- (a) Insert full name of intending purchaser.
- (b) Insert full postal address.
- (c) Insert name of poison.
- (d) Intending purchaser to sign his name here.

SCHEDULE VIII—continued

Form 13

APPLICATION FOR LICENCE TO SELL PART II POISONS

To the Civil Secretary,

I/We , being engaged in the business of , hereby apply to sell poisons by wholesale/retail in Group A/Group B of Part II of the Poisons List or specified poisons, on the following premises

I/We hereby nominate the following person(s)

who will sell such poisons in accordance with the provisions of the Pharmacy and Poisons Act and the Pharmacy and Poisons Rules.

Date

Signature of Applicant

Form 14

LICENCE TO SELL PART II POISONS

..... , of , carrying on the business

at , is hereby licensed to sell the following

Part II Poisons

Insert here either

Group A,

Group B, or

specified poisons

as the case may

be and whether

by wholesale or

retail sale.

The following person(s) are hereby authorised to sell these poisons in accordance with the provisions of the Pharmacy and Poisons Act and the Pharmacy and Poisons Rules.

Date

Civil Secretary

N.B.—Any change of persons authorised to sell must be notified to the Civil Secretary within seven days.

Note.—This licence expires on 31st December, 20

Fee: Sh. 40.

Pharmacy and Poisons

[Subsidiary]

SCHEDULE VIII—continued

Form 15

REGISTER OF LICENCES ISSUED TO SELLERS OF PART II POISONS

REGISTRATION		Name of licensee	Address of premises where business is carried on	Class of licence	Name(s) of person(s) authorised to sell poisons
No.	Date				

Form 16

POISONS BOOK

Date of sale	Name and quantity of poison supplied	PURCHASER'S			Purpose for which stated to be required	Date of certificate (if any)	Name and address of person giving certificate (if any)	Signature of purchaser, or where a signed order is permitted the date of the signed order
		Name	Address	Business trade or occupation				

Form 17

MINISTRY OF HEALTH AND CENTRAL BANK OF KENYA

FOR EXCHANGE CONTROL USE No.

APPLICATION FOR IMPORT AND/OR FOREIGN EXCHANGE ALLOCATION

IMPORTER'S FULL NAME AND ADDRESS:	NOTE.—Applicant to attach sellers Proforma Invoice. Proforma Invoice No. Date: Reference:
IMPORTER'S BANK AND BRANCH:	TOTAL AMOUNT IN FOREIGN CURRENCY: In Figures: In Words: Exchange rates: Kenya Currency equivalent Sh.
SELLER'S FULL NAME AND ADDRESS:	APPLICABLE SCHEDULE:
	COUNTRY OF ORIGIN:

Pharmacy and Poisons

[Subsidiary]

SCHEDULE VIII—continued

Date of Shipment:			Terms of Payment (State commission rate if applicable):			
Mode of Transport Port of Loading			F.O.B.	Freight	Insurance	
Port of Discharge:						
S.I.T.C. Code	Generic Name	Trade Name	Package Size	Quantity	Reg. No.	Unit price

Signature of Applicant: Date:

FOR OFFICIAL USE OF MINISTRY OF HEALTH

Valid up to

Replacement

Extended to

FOR USE OF CENTRAL BANK OF KENYA

Replacement

Exchange Control Authorization Stamp and Signature

SPECIAL INSTRUCTIONS:

Approved subject to clean report of finding by general superintendence company limited as to: quality and quantity inspection and Price comparison:

To be contacted at:

FOR USE BY REMITTING BANK
PAYMENTS MADE

Date	Foreign Currency Remitted	Exchange Rate	Kenya Currency Equivalent	Branch Stamp and Authorized Signature

Pharmacy and Poisons

[Subsidiary]

SCHEDULE VIII—continued

Form 18

APPLICATION FOR PHARMACEUTICAL REPRESENTATIVE'S PERMIT

I/We of (postal address) being engaged in the sale and supply of pharmaceutical goods, hereby make application that our representative Mr. be permitted to possess pharmaceutical goods containing Part I poisons as scheduled below, for the purpose of giving free samples to persons who may lawfully possess such goods.

SCHEDULE

.....
.....
.....

Date (Signature of Applicant)

Form 19

PHARMACEUTICAL REPRESENTATIVE'S PERMIT

Mr. as representative of is hereby permitted to possess and supply free samples of pharmaceutical goods containing Part I Poisons, as scheduled below, to persons who are authorized to use them in their trade, business or profession as laid down in the Pharmacy and Poisons Act, subject to maintenance of records as required by rule 13A(1)(b) of the Pharmacy and Poisons Rules.

SCHEDULE

.....
.....
.....

Date The Pharmacy and Poisons Board, P.O. Box 30016, Nairobi.

Note.—This permit expires on 31st December, 20....., or upon the person named ceasing to be employed as a pharmaceutical representative of the firm stated above. FEE: Sh. 25.

Form 20

INSTITUTION INSPECTION REPORT

I, the undersigned of (postal address) have today carried out an inspection of as required by rule 14 of the Pharmacy and Poisons Rules.

SCHEDULE VIII, Form 20—continued

The following defects are reported—

- 1. Storage
-
-
-
- 2. Methods of Handling
-
-
-
- 3. Records
-
-
-

I have the following recommendations to make—

.....
.....
.....

The previous inspection was carried out on

Signature

Designation

Date

- To: 1. (person in charge of the Institution).
- 2. The Registrar, Pharmacy and Poisons Board.

Form 21

APPLICATION FOR A LICENCE TO MANUFACTURE DRUGS FOR SALE

The Registrar, The Pharmacy and Poisons Board

I/We
of (postal address)
having premises situated at
and being engaged in the business of

hereby apply to manufacture for sale the following drug(s) medicine(s)

This/These drug(s)/medicine(s) has/have the following composition

The manufacture of the above drug(s)/medicine(s) will be carried out under the direct personal supervision ofwho has the following qualifications

The manufacture of the above drug(s)/medicine(s) will be carried out at

Date

(Signature of Applicant)

Pharmacy and Poisons

[Subsidiary]

SCHEDULE VIII, Form 21—continued

Note.—Any change of the person under whose direct personal supervision the manufacture is carried out, whether temporary or permanent, must be notified to the Registrar immediately.

Form 22

LICENCE TO MANUFACTURE DRUGS FOR SALE

.....
of (postal address)
and having premises situated at
is hereby licensed to manufacture for sale the following drug(s)/medicine(s)
under the direct personal supervision of
at
Note—The licence expires on 31st December, 20
Registration No.

Registrar,
Pharmacy and Poisons Board,
P.O. Box 30016,
Nairobi.

Any change of the person under whose direct personal supervision the manufacture is carried on, whether temporary or permanent, must be notified to the Registrar immediately.

Form 23

MINISTRY OF HEALTH

APPLICATION FOR LICENCE FOR THE EXPORTATION OF DRUGS AND POISONS

EXPORTER'S NAME AND ADDRESS CODE No.						
CONSIGNEE'S NAME AND ADDRESS:				INVOICE No.:		
				CD3 No.		
				Country of origin:		Destination of goods:
DATE OF SHIPMENT:				Terms of delivery and payments:		
Mode of transport: Port of loading				F.O.B. Value:		
Port of discharge:						
Generic Name	Trade Name	Pack Size	Unit Price	Quantity	Batch No.	Country of Manufacture

Pharmacy and Poisons

[Subsidiary]

SCHEDULE VIII, Form 23—continued

I declare that the particulars which I have given are true and accurate to the best of my knowledge and belief.

Date Signed
Applicant

This document will be effective as an Export Licence only when it has been validated by the Chief Pharmacist.

FOR OFFICIAL USE ONLY: EXPORT LICENCE: NUMBER
Export of goods described above is approved, subject to

Date
for Chief Pharmacist

This licence is not transferable.

FORM TO BE FULLY COMPLETED IN TRIPLICATE (PREFERABLY TYPEWRITTEN) BY APPLICANT:
PHARMACY AND POISONS ACT, (CAP. 244) RULE

Form 24

(L.N. 61/2002, s. 2.)

ANNUAL PROFESSIONAL PRACTICE LICENCE AS A PHARMACIST

Serial No.
Prof./Dr.
(Full names in block letters)

is hereby licensed by the Pharmacy and Poisons Board to render pharmaceutical services in Kenya.

Dated the day of 20

Registrar, Pharmacy and Poisons Board

Licence No.
This Licence expires on 31st December, 20
Fee: KSh. 2,500

[Subsidiary]

SCHEDULE VIII—continued

ROLL OF PHARMACEUTICAL TECHNOLOGISTS

Form 25

ENROLMENT	NAME OF APPLICANT	ID No.	ADDRESS	QUALIFICATION	DATE OF QUALIFICATION	TRAINING INSTITUTION

SCHEDULE VIII—continued

Form 26

APPLICATION FOR ENROLMENT AS A PHARMACEUTICAL TECHNOLOGIST

The Registrar,
Pharmacy and Poisons Board,
P.O. Box 27663-00506,
Nairobi

I
of P.O. Box

ID No. do hereby apply to be enrolled as a
Pharmaceutical Technologist in accordance with the Pharmacy and Poisons Act.

Qualification

Institution

Date of Qualification

Period of Internship: From to

(Attach proof of Internship*)

.....

Signature of Applicant

* Applicants are advised to attach genuine evidence from recognized institution of attachment. Any false information given may lead to prosecution.

Form 27

APPLICATION FOR ANNUAL PRACTICE LICENCE FOR A PHARMACIST

The Registrar,
Pharmacy and Poisons Board,
P.O. Box 27663-00506,
Nairobi

I
of P.O. Box

Registration No. do hereby apply for a Practice
licence as a pharmacist.

.....

Date

.....

Signature of Applicant

[Subsidiary]

SCHEDULE VIII—continued

Form 28

SERIAL No.

CERTIFICATE OF ENROLMENT AS A PHARMACEUTICAL TECHNOLOGIST

The Registrar,
Pharmacy and Poisons Board,
P.O. Box 27663-00506,
Nairobi

.....
(Name and Address)

ID/No.

Having duly satisfied the Pharmacy and Poisons Board is hereby enrolled as a Pharmaceutical Technologist in accordance with the Pharmacy and Poisons Act.

Given on the day of in the year 20

Enrolment No.

.....
(Registrar, Pharmacy and Poisons Board)

Fee: KSh. 500

Form 29

APPLICATION FOR LICENCE AS PHARMACEUTICAL TECHNOLOGIST

The Registrar,
Pharmacy and Poisons Board,
P.O. Box 27663-00506,
Nairobi

Dear Sir/Madam

I,

of P.O. Box

ID/No. do hereby apply for a licence as a pharmaceutical technologist.

Enrolment No. Date of enrolment

Name of premises

Plot No. Road

Town

.....
Signature of Applicant

.....
Date

SCHEDULE VIII—continued

Form 30

APPLICATION FOR REGISTRATION OF PREMISES FOR A PHARMACEUTICAL TECHNOLOGIST

The Registrar,
Pharmacy and Poisons Board,
P.O. Box 27663-00506,
Nairobi

I/We

wishing to carry on the business of a Pharmaceutical Technologist, do hereby apply for registration of premises situated at

in the township of

The business in so far as concerns the retail sale of drugs will be under the control of

..... a Pharmaceutical Technologist enrolled in accordance with Part II of the Act.

Date

Signature of the Applicant

Note.—Any change of premises of a Pharmaceutical Technologist under whose control the business is carried on must be notified to the Registrar within seven days.

Form 31

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

PREMISES REGISTRATION CERTIFICATE FOR PHARMACEUTICAL TECHNOLOGIST'S PRACTICE

SERIAL No.

Name of Premises

Registration No. of premises

Location of premises

Town Street

Plot No.

Name of pharmaceutical technologist

ID No. Enrolment No.

Has met the necessary conditions for the business of a pharmaceutical technologist to be carried therein.

(Registrar, Pharmacy and Poisons Board)

Date

Pharmacy and Poisons

[Subsidiary]

SCHEDULE VIII , Form 31—continued

- Note: (a) This registration expires on 31st December, 20
- (b) No change of premises is permitted without the authority of the Board.
- (c) This registration shall become void upon expiration of 30 days from any change of ownership of the business.

Fee: KSh. 5,000

Form 32

SERIAL NO.

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

ANNUAL LICENCE TO PRACTICE AS A PHARMACEUTICAL TECHNOLOGIST

.....
(Name and Address)

is hereby licensed to practice as a pharmaceutical technologist in accordance with the Pharmacy and Poisons Act.

Name of Premises

Plot No. Road

Town

Given at Nairobi on the day of of the year 20

.....
(Registrar, Pharmacy and Poisons Board)

.....
Date

This licence expires on the 31st December, 20

Fee: KSh. 2,500

Form 33

SERIAL No.

CERTIFICATE FOR REGISTRATION OF PREMISES

Messrs.

of

Plot No. is registered to carry on business of a pharmacist as provided for by section 23.

Date

.....
Registrar, Pharmacy and Poisons Board.

SCHEDULE VIII—continued

- Note: (a) This registration expires on 31st December, 20
- (b) No change of premises is permitted without the authority of the Board.
- (c) This registration shall become void upon expiration of 30 days from any change of ownership of the business.

Fee: KSh. 5,000

SCHEDULE IX

[Rule 6.]

PERMIT AUTHORISING FARMERS AND OTHER PERSONS TO BE IN POSSESSION OF SUBSTANCES SPECIFIED IN GROUP II OF SCHEDULE IV TO THE RULES

For the purposes of rule 6 of the Pharmacy and Poisons Rules, I, the undersigned, of

 hereby authorise
 of to purchase and possess the
 following substances in Group II of Schedule IV to the Rules—

1. If any quantity is specified against any or all of the items listed above the permit holder may not purchase or possess more than that quantity at any time.
2. This permit is valid for a period of six months from date of issue.
3. This permit must be produced to the authorised seller of poisons on each occasion when supplies are purchased.

Date

Signature

PHARMACY AND POISONS (CONTROL OF DRUGS) RULES, 1969

[L.N. 180/1969, L.N. 247/1969, L.N. 228/1974.]

1. These Rules may be cited as the Pharmacy and Poisons (Control of Drugs) Rules, 1969.
 2. In these Rules, “**drug**” means a medicine, medicinal preparation or therapeutic substance which is contained in an ampule or capsule or in a form in which the drug may be used for injection.
 3. No person other than those authorized to import, possess, distribute, sell or purchase Part I poisons under the Act shall import, possess, distribute, sell or purchase any drug.
 4. A person who is authorized to import, possess, distribute, sell or purchase drugs shall do so subject to the conditions governing the importation, possession, distribution, sale and purchase of Part I poisons under the Act.
 5. A person who fails to comply with paragraphs 3 and 4 of these Rules shall be guilty of an offence and shall be liable to a fine not exceeding two thousand shillings or to a term of imprisonment not exceeding two months or both such fine and such imprisonment.
-

PHARMACY AND POISONS (REGISTRATION OF DRUGS) RULES

ARRANGEMENT OF RULES

Rule

1. Citation.
2. Interpretation.
3. Control of the manufacture, etc., of drugs.
4. Application for registration of drug.
5. Fees.
6. Issue of certificate of registration.
7. Duration, etc., of certificate of registration.
8. Suspension or revocation of certificate of registration.
9. Conditions for registration of a new drug.
10. Inspection of premises.
11. Offences and penalties.

SCHEDULE – FORMS

[Subsidiary]

PHARMACY AND POISONS (REGISTRATION OF DRUGS) RULES

[L.N. 147/1981, L.N. 142/1991, L.N. 192/2010.]

1. Citation

These Rules may be cited as the Pharmacy and Poisons (Registration of Drugs) Rules.

2. Interpretation

In these Rules, “**drug**” means a substance or mixture of substances which can be used for any of the following purposes—

- (a) treating, preventing or alleviating symptoms of disease;
- (b) diagnosing disease or ascertaining the existence, degree or extent of a physiological condition; or
- (c) otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily and whether by way of terminating, reducing, postponing or increasing or accelerating the operation of that function,

in human beings and animals and includes a substance which can be used as a contraceptive or for the purpose of inducing anaesthesia; but does not include a product prepared by a pharmacist in his pharmacy and dispensed by him without promotion, blood, blood plasma and blood preparations containing cellular elements of blood, or substances such as dental fillings and plates, or surgical preparations such as catgut and plaster of Paris bandages.

“**cosmetics**” includes any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair, eyes or teeth, and includes deodorants and perfumes;

“**import**” includes parallel importation; and

“**parallel importation**” means the importation into Kenya of patented drugs under section 58(2) of the Industrial Property Act, 2001.

[L.N. 192/2010, r. 3.]

3. Control of the manufacture, etc., of drugs

No person shall import, manufacture for sale or sell any drug in Kenya unless that drug has been registered and listed in accordance with the provision of these Rules.

[L.N. 192/2010, r. 4.]

4. Application for registration of drug

(1) An application for registration of a drug shall be in Form 1 in the Schedule.

(1A) An application for registration of parallel imported drugs, poisons, listing of herbal, complementary medicines and cosmetics shall be in form 1 in the Schedule.

(2) In addition to the information required to be furnished in the prescribed form the applicant shall furnish such further information and material as may be required by the Board for the proper evaluation of the drug in respect of which the application is made.

(3) An application for renewal of registration of a drug under rule 7 shall be in Form 1A set out in the Schedule.

[L.N. 142/1991, r. 2, L.N. 192/2010, r. 5.]

5. Fees

(1) An application made under rule 4 shall be accompanied by the following fees—

- (a) five thousand shillings if the drug required to be registered has been manufactured outside Kenya; and
- (b) one thousand shillings if the drug required to be registered has been manufactured in Kenya.

(2) If the registration is being renewed the applicant shall pay the following fees—

- (a) one thousand shillings in respect of a drug manufactured outside Kenya; and
- (b) five hundred shillings in respect of a drug manufactured in Kenya.

(3) A fee of five hundred shillings shall be paid for a duplicate copy of the certificate of registration if the original is defaced, damaged or lost and such copy shall bear the words "DUPLICATE COPY".

6. Issue of certificate of registration

(1) The Board shall consider the application made under rule 4, and, if it is satisfied of the safety, efficacy, quality and economic value of the drug, shall register the drug and issue a certificate of registration which shall be in Form 2 in the Schedule.

(1A) The Board shall consider the application made under sub-rule 4(1)(a) and may, if it is satisfied of the safety, quality, efficacy and economic value of the drugs, register the same, and issue a certificate of registration which shall be in Form 2.

(2) The Board may, while considering a drug for registration under paragraph (1), approve the details as supplied by the applicant or approve it with such amendments as it may deem appropriate in respect of the following particulars—

- (a) the name under which the drug may be sold;
- (b) the labelling;
- (c) the statement of the representations to be made for the promotion of the drug in respect of—
 - (i) the claim to be made for the drug;
 - (ii) the route of administration;
 - (iii) the dosage;
 - (iv) the contra-indications, the side effects and precautions, if any; and
 - (v) the package size.

(3) If the Board is not satisfied as to the safety, efficacy, quality or economic value of the drug, it may, after providing an opportunity to the applicant to be heard, reject the application for the registration of the drug and inform the applicant the reasons for rejection in writing.

[L.N. 192/2010, r. 6.]

7. Duration, etc., of certificate of registration

(1) A certificate of registration issued under these Rules shall, unless earlier suspended or revoked, be in force for a period of five years from the date of issue and may thereafter be renewed for periods not exceeding five years at any one time.

(2) If an application for renewal is made before the expiration of the period of validity of a certificate of registration the certificate shall remain in force until the application is

[Subsidiary]

approved; except that where the application for renewal is made after the expiration of the period of validity of the certificate of registration the application shall be considered as a fresh application and the provision of rule 6 shall apply accordingly.

8. Suspension or revocation of certificate of registration

(1) The Board may suspend or revoke a certificate of registration issued under these Rules for such period as the Board may determine.

(2) The powers conferred by subrule (1) shall not be exercised by the Board in respect of any certificate of registration except on one or more of the following grounds—

- (a) the matters stated in the application on which the certificate of registration was granted were false or incomplete in a material particular;
- (b) that a provision of the certificate of registration has to a material extent been contravened by the holder of the certificate; or
- (c) that the premises on which, or on part of which, drugs are manufactured, assembled or stored by or on behalf of the holder of the certificate of registration are unsuitable for the manufacturing, assembling or storage of drugs; or
- (d) that new information has been discovered by the Board which renders the drugs unsafe or dangerous.

9. Conditions of registration of a new drug

(1) The Board shall, before registering a new drug for which the research work has been conducted in another country and its efficacy, safety, and quality established in that country, require an investigation on the pharmaceutical, pharmacological and other aspects of the drug to be conducted and clinical trials to be made which are necessary to establish its quality and where applicable the biological availability and its safety and efficacy to be established under local conditions.

(1A) Any person wishing to carry out a clinical trial in the country shall apply to the Board for approval before engaging in such study involving investigational products.

(1B) An application under paragraph (1A) shall be accompanied by the fees set out in Part B of the Second Schedule.

(2) Notwithstanding subrule (1), the Board may register a new drug and require the investigations and clinical trials specified in subrule (1) to be conducted after its registration.

(3) The Board may, if in its opinion it is necessary to do so in the interests of public health, register a new drug for a period of two years.

[L.N. 192/2010, Section 7.]

9A. (1) The Board shall maintain a register containing a record of all the drugs registered.

(2) There shall be payable by entities whose drugs are registered a retention fee in the amount specified in Part A of the Second Schedule.

[L.N. 192/2010, Section 8.]

10. Inspection of premises

The Board may, before issuing a certificate of registration under these Rules, cause the premises in which the manufacturing of the drug is proposed to be conducted to be inspected by inspectors appointed for that purpose, and the inspectors shall have powers to enter the premises and inspect the plant and the process of manufacture intended to be employed in the manufacturing of the drug and make a report to the Board.

11. Offences and penalties

A person who contravenes any of the provisions of these Rules shall be guilty of an offence and shall be liable to a fine not exceeding six thousand shillings or to a term of imprisonment not exceeding six months or to both such a fine and such imprisonment.

FIRST SCHEDULE

[L.N. 147/1981, L.N. 192/2010, r. 9.]

Form 1

(r. 4)

APPLICATION FOR REGISTRATION OF A DRUG

(to be submitted in sextuplicate)

CONFIDENTIAL

PART 1

The Registrar,
Pharmacy and Poisons Board,
P.O. Box 30016,
NAIROBI.

- 1. Name of Applicant
- Business Address
-
- Telephone Number
- 2. Name of product to be registered
- Type of formulation to be registered
- Presentation of the product
- 3. Identification (physical appearance of the product)
-
-
- 4. Therapeutic classification
- 5. (a) Name and business address of manufacturer
-
-
- (b) Country of origin
- 6. Registration Number of the product in country of origin and all other countries where it is marketed
-
- 7. Is the product authorized to be on the market in the country of origin? If yes, attach a legal certificate of free sale from the registering Authority.
- If no, state the reasons below:
-
-
-
-

Pharmacy and Poisons

[Subsidiary]

FIRST SCHEDULE , Form 1—continued

PART II

8. Pharmaceutical Formula of the Product

CONSTITUENT		Quantity	Active or non-Active
Chemical Name	Approved Name (if any)		

PART III

9. The names and structural formula of the active ingredients are as follows:

Approved or Chemical Name	Structural Formula

PART IV

10. Specifications for all the active and non-active raw materials used in the manufacturing process are as follows—

PART V

11. Analytical control procedures which are performed on all active and non-active materials before they are used in the manufacturing process are as follows—

PART VI

12. Analytic control procedures and the frequency with which they are performed during the manufacturing process are as follows—

PART VII

13. Full specifications of final manufactured product are as follows—

PART VIII

14. The analytic control procedures which are performed on the final manufactured product are as follows—

PART IX

15. The inferred shelf-life of the product is as follows—

PART X

16. Summaries of the method of manufacture and packaging are as follows—

PART XI

17. A summary of the experimental details and results of the tests performed on the drug to confirm its pharmacological effects—

PART XII

18. Summary of the experiments and results performed on the drug to confirm its physiological availability.

FIRST SCHEDULE , Form 1—continued

PART XIII

19. Particulars of clinical tests conducted with reference to the efficacy of the use of the drug, with a summary of the nature of the tests, by whom conducted and where, results etc., and with special reference to comparative of controlled clinical tests, double blind tests etc.—

The undersigned declares that all the information contained herein is correct to the best of his knowledge and belief.

.....
Date of application

.....
Signature of applicant

Note:

- 1. A separate application is required for each drug.
- 2. A dosage form in a specified strength shall be considered as a drug.
- 3. Application fees are not refundable.

—————
SCHEDULE

Form 1A

APPLICATION FOR RE-REGISTRATION OF A DRUG

(to be submitted in sextuplicate)

The Registrar,
Pharmacy and Poisons Board,
P.O. Box 30016,
Nairobi

- 1. Name of Applicant (manufacturer)
Registered physical business address
(See note 1)
.....
Telephone no. (office)
- 2. Name of product to be re-registered
.....
Type of formulation (see note 2)
.....
Presentation of the product
- 3. Identification physical appearance of the product
- 4. (a) Therapeutic classification(s)
-
(b) Specific indication(s).....
.....
.....

[Subsidiary]

FIRST SCHEDULE—continued

- (c) Category (see note 3)
 - 5. Name and business address of manufacturer
 - 6. Registration number of the product in Kenya
Date of first registration
 - 7. Has the product been discontinued in any country?
 - If yes, why?
 - 8. Have you changed the pharmaceutical formula?
 - If yes, state changes and provide the new formula
 - 9. Have you changed the manufacturing procedures?
 - If yes, state the new changes
 - 10. Have you made any other changes in quality control of finished products, analytical procedures and packaging specifications?
 - If yes, state new specifications
 - 11. Provide recent (5-10 years) pharmacological, physiological, clinical, toxilological and bioavailability data (see note 4)
 - 12. We the undersigned hereby declare that all the information contained herein is correct to the best of our knowledge:
- | | Name | Signature | Qualifications | Date |
|-----------------------------|-------|-----------|----------------|-------|
| (a) Quality Control Manager | | | | |
| (b) Production Manager | | | | |
| (c) Registration Officer | | | | |
- (see note 5)

Notes—

- (1) for foreign manufacturers give your local agents contacts;
- (2) tablet, capsule injections;

FIRST SCHEDULE—continued

- (3) prescription only medicine (POM), over the counter medicine (OTC), pharmacy medicine (P), general sales (GS);
- (4) for veterinary products, provide residue levels in milk and meat;
- (5) for (c) local manufacturers, local agents — the company pharmacist is to sign;
- (6) a separate application is required for each drug;
- (7) reapplication fee is not refundable;
- (8) a dosage form in a specific strength shall be considered as a drug;
- (9) applicants are notified that any false information given in the application may lead to fines and refusal of subsequent registration of products;
- (10) each reapplication must be accompanied by six samples of the smallest commercial pack.

Date
 Signature of Applicant

Form 2

(r. 6.)

PHARMACY AND POISONS (REGULATION OF DRUGS) RULES

REGISTRATION OF DRUGS CERTIFICATE

Number

It is hereby certified that the medicine (drug) as described hereunder has been registered subject to the conditions indicated hereunder—

- 1. Approved name
- 2. Trade name under which marketed
- 3. Registration No.
- 4. Active ingredients and quantities per unit
- 5. Form of preparations
- 6. Condition under which medicine is registered
- 7. Name and business address of manufacturer
- 8. Registered in the name of
- Business address
- 9. Date of registration
- 10. Expiry date of registration

.....
 Date Registrar, Pharmacy and Poisons Board

Pharmacy and Poisons

[Subsidiary]

SECOND SCHEDULE

[L.N. 192/2010, Rule 52(b), 9(1B).]

	Fees (USD)
A	
Imported product (s)	300
Locally Manufactured products(s)	300
Late application for retention penalty	100
Appeal for rejected application of registration	300
B	
Application for clinical trials	1000

PHARMACY AND POISONS (CONDUCT OF INQUIRIES) RULES, 1985

[L.N. 52/1985.]

1. These Rules may be cited as the Pharmacy and Poisons (Conduct of Inquiries) Rules, 1985.
2. In these Rules, unless the context otherwise requires—
 - “**chairman**” means the chairman of the Board;
 - “**charge**” means a charge or charges specified in a notice of inquiry;
 - “**complainant**” means a person or body of persons who makes a complaint to the Board;
 - “**inquiry**” means an inquiry held by the Board under these Rules.
3. An inquiry into the conduct of a registered pharmacist may be instituted by the Board on its own initiative or upon a complaint addressed to the Board by or on behalf of any person alleging professional misconduct on the part of the registered pharmacist.
4. A person who lodges a complaint of professional misconduct against a registered pharmacist shall furnish an affidavit detailing the specific acts complained of to the registrar and the complainant must be prepared to give evidence before the Board in the event of an inquiry being held.
5. (1) The registrar shall, in accordance with the circumstances and if necessary in consultation with the chairman, on receipt of a complaint under these Rules—
 - (a) seek further information from the complainant; or
 - (b) advise the registered pharmacist of the nature of the complaint against him and ask him for an explanation warning him that the explanation may be used in evidence if an inquiry into his conduct is held in accordance with these Rules; or
 - (c) place the matter before the Board with the relevant documents.(2) The Board may, after giving the matter due consideration—
 - (a) cause further investigation of the complaint to be made; or
 - (b) seek legal advice or such other assistance as it may deem necessary; or
 - (c) if it is of the opinion that the complaint, even if substantiated, would not be held to constitute professional misconduct or if, for any other reason it considers that an inquiry should not be held, take such action as it deems fit; or
 - (d) if it is the opinion that the evidence furnished in support of the complaint discloses *prima facie* evidence of professional misconduct, hold an inquiry in accordance with these Rules.
6. (1) The registrar shall, if an inquiry is to be held—
 - (a) submit to the Board all documents and other material having bearing on the inquiry; and
 - (b) send to the registered pharmacist against whom the complaint relates a notice of inquiry which shall—
 - (i) state the nature of the charge preferred against him giving full particulars of such a charge, including copies of any relevant documents;
 - (ii) specify the date, time and venue of the inquiry;

[Subsidiary]

- (iii) inform the registered pharmacist that he may submit further statements to the Board prior to the inquiry, which statements may be used as evidence; and that he shall be afforded the opportunity, by himself or through his legal representative, of answering the charge or being heard in his defence.

(2) The notice of inquiry sent to a registered pharmacist under paragraph (1) shall be in the form set out in the Schedule and shall be sent by registered post to his last known address as notified to the registrar or by other means approved by the Board.

7. (1) The Board may make such order as to costs as it deems fit; and such costs shall be recoverable as a civil debt.

(2) In cases where a complainant or the registered pharmacist against whom the complaint is made requests that witnesses be summoned to give evidence, the Board may require the complainant or the registered pharmacist to deposit a sum of money sufficient to cover the costs of bringing the witness to the place where the inquiry is being held.

8. A person who fails when summoned by the Board to attend as a witness or to produce any books or documents which he is required to produce shall be guilty of an offence and liable to a fine not exceeding two thousand shillings or in default, to imprisonment for not more than three months.

9. In a case where the registered pharmacist against whom a complaint has been made appears personally or is represented by an advocate, the following procedure shall be followed—

- (a) the registrar shall read the notice of the inquiry addressed to the registered pharmacist;
- (b) the complainant shall be invited to adduce evidence in support of the complaint;
- (c) the registered pharmacist shall then be asked to state his case, either personally or through his legal representative and to produce evidence in support of his case, or in the event of deciding to produce a written statement in his defence, that statement shall be read;
- (d) at the conclusion of the case of the accused person, the Board shall, if he has adduced evidence, hear the complainant or his legal representative on the case generally but the Board shall not at this stage hear further evidence unless there are, in the opinion of the Board, special reasons for hearing such further evidence;
- (e) if the registered pharmacist does not adduce any evidence, the complainant shall not be heard in reply;
- (f) when a witness appears before the Board he shall be examined by the person at whose request he was summoned, then cross-examined by the person against whom the complaint is made or his representative and finally re-examined by the person who requested that he should be summoned to give evidence at the inquiry.

10. In a case where the registered pharmacist is not present, the following procedure shall be followed—

- (a) the registrar shall read the notice of inquiry addressed to the registered pharmacist under rule 5;
- (b) the complainant shall then be asked to state his case and to produce his evidence in support of it.

[Subsidiary]

- 11. In a case in which neither the complainant nor the registered pharmacist appears, the Board shall consider and decide what further action, if any, may be taken.
- 12. (1) Members of the Board may, with the permission of the chairman, put such questions to witnesses as they deem necessary.
 (2) All oral evidence shall be taken on oath and the Board may decline to admit the evidence of any witness or deponent to a document who is not present for, or declines to submit to, cross-examination.
 (3) Upon the conclusion of the case, the Board shall deliberate upon the evidence *in camera*, and the judgment and verdict shall be communicated in open meeting or at a later date, in writing, as the Board may direct.
- 13. Any decision of the Board in regard to any point arising in connection with, or in the course of, an inquiry may be arrived at *in camera* but shall be communicated to the persons concerned in open meeting.
- 14. The Board may, upon a finding of guilty as charged, administer one or other of the following penalties—
 - (a) a reprimand or a caution or reprimand and a caution; or
 - (b) the penalties specified in section 12 of the Act.
- 15. The Board may at any stage during an inquiry under these Rules adjourn its proceedings as it thinks fit.
- 16. Any party to the proceedings shall, on application, be furnished with a transcript of the shorthand notes or a certified copy of the proceedings or determination or finding of the Board on the payment of a fee of five shillings for every page of the shorthand notes or certified proceedings or determination or finding of the Board.
- 17. Meeting of the Board for purposes of an inquiry under these Rules, except so far as the chairman may otherwise direct, shall be held at the offices of the Board and may be held as regularly as circumstances require.

SCHEDULE

[Rule 6(2).]

FORM OF SUMMONS TO ATTEND AN INQUIRY UNDER THE PHARMACY AND POISONS (CONDUCT OF INQUIRIES) RULES

Dear Sir/Madam,

Disciplinary Inquiry

I have been directed to inform you that the following charge which has been preferred against you will be considered at a meeting of the Pharmacy and Poisons Board, to be held at
....., on at

That you, being a registered pharmacist

and that in relation to the facts alleged you have been guilty of professional misconduct.

You are requested to appear before the Board to establish any defence which you may wish to offer, but if you should decide not to do so, the Board may consider and deal with the charge in your absence.

Pharmacy and Poisons

[Subsidiary]

SCHEDULE—*continued*

If you wish your letter of , or any other letter you may address to me to constitute your defence, please advise me of this in writing not later than 14 days before the date set down for the inquiry.

.....
Registrar
