AN ACT TO REPEAL THE DANGEROUS DRUGS DECREE TO MAKE PROVISIONS RELATING TO PHARMACEUTICAL AND DANGEROUS DRUGS AND TO PROVIDE FOR THE CONTROL OF THE PROFESSION OF PHARMACY AND OTHER MATTERS RELATING TO DEALINGS IN PHARMACETICALS, DRUGS AND POISONS

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PRESIDENT OF ZANZIBAR AND CHAIRMAN OF THE REVOLUTIONARY COUNCIL

2182 May , 1986

AN ACT TO REPEAL THE DANGEROUS DRUGS DECREE TO MAKE PROVISIONS RELATING TO PHARMACEUTICAL AND DANGEROUS DRUGS AND TO PROVIDE FOR THE CONTROL OF THE PROFESSION OF PHARMACY AND OTHER MATTERS RELATING TO DEALINGS IN PHARMACEUTICALS, DRUGS AND POISONS

ENACTED by the House of Representatives of Zanzibar.

## PART I

Short title and commencement.

1. This Act may be cited as Pharmaceuticals and Dangerous Drugs Act, 1986 and shall come into operation immediately upon being assented by the President.

Interpretation.

2. In this Act, unless the contrext otherwise requires -

"dangerous drug" means any of the drugs, preparation extracts or other substances declared to be dangerous in accordance with section 16 of this Act.

"diversion certificate" means a certificate issued
by the competent authority of a country through
which a dangerous drug passes in transit,
authorising the diversion of such drug to a
country other than that specified as the country
of ultimate destination in the export
authorisation, and containing all the particulars
required to be included in an export authorisation,
together with the name of the country from which
the consignment was originally exported;

"export" with its grammatical variations and cognate expressions, in relation to Zanzibar, means to

- take or cause to be taken out of Zanzibar by air or sea otherwise than in transit;
- "export authorisation" means an authorisation issued by a competent authority in a country from which a dangerous drug is exported, containing full particulars of such drug, and the quantity authorised to be exported, together with the names and addressed of the exporter and the person to whom it is to be sent, and stating the country to which, and the period within which, it is to be exported;
- "Government" includes any Ministry or department of Government charged with the administration of the law relating to any dangerous drugs to which this Act refers;
- "import" with its grammatical variation and cognate expressions, in relation to Zanzibar, means to bring or cause to brought by air or sea otherwise than in transit;
- "import authorisation" means a licence, issued by a competent authority, authorising the importation of a specified quantity of a dangerous drug and containing full particulars of the drug, together with the name and address of the person authorised to import the drug, the name and address of the person from whom the drug is to be obtained, and specifying the period within which the importation must be affected;
- "import certificate" means a certificate substantially in the form set out by a competent authority in a country into which its is intended to import dangerous drugs;
- "in transit" means taken or sent from any country and brought into Zanzibar by air or sea for purposes of being carried to another country either by the same or another conveyance;
- "certificate of refistration" means the certificate issued to a pharmacist under section 11 upon this being registered by the Board;
- "drug" includes any medicine, medicinal preparation or therapeutic substance in whatever form it may be;
- "for the use by man" means for human consumption or for external application to the human body;
- "Government analyist" means the Government Chemist and any analyist appointed by the Ministry or any other authority for the purposes of this Act;

- "labelled" means distinctly labelled in English or Latin and or in Kiswahili;
- "mamufacture" with its grammatical and cognate
  expressions, means to subject any physical
  article or substance commonly used to prepare
  drugs or other pharmaceutical products, to any
  process including preparation and compounding
  which result in that article or substance being
  possible of use by man as a pharmaceutical
  product or poison, whether or not on a lawful
  given prescription;
- "medicine" means any medicament or curative preventive substance whether proprietary or in the form of a preparation;
- "member" in relation to the Board means a member of the Pharmacy Board and includes the Chairman and the Vice-Chairman;
- "Minister" means the Minister for the time being responsible for matters relating to health and medical services;
- "Pharmaceutical" and "Pharmaceutical product" means any drug, substance or other article mamufactured or prepared in any way and intended for use by man as a remedy used for the pruposes of medical dental or veterinary treatment;
- "Pharmacist" means pharmaceutical Chemist or a Chemist and druggist who is registered under this Act;
- "poison" means a pharmaceutical product included in the poisons list referred to in section 41;
- "Registrar" means the Registrar of the Board appointed under section 7;
- "sell" with its grammatical variations and cognate expressions includes and agreement to sell and an offer to sell or any other act by which willingness to enter into any transaction of sale is expressed and an offer to sell shall be deemed to include the exposing of goods for sale:

"sale by way of wholesale" means sale to a person who buys for the purpose of selling again;

"substance" includes a preparation;

- "substance recommended as medicine" in relation to the sale of an article consisting of or comprising a substance so recommended means a substance which is referred to -
  - (i) on the article of any wrapper of container in which the article is sold, or any label affixed to or in any document enclosed in the article or that wrapper or container; or
  - (ii) in any placard or other document at the place where the article is sold; or
  - (iii) in any advetisement by or on behalf of the manufacturer of the article, or the person carrying on the business in the course of which the article was sold or, in case where the article was sold under a proprietary designation, the proprietor of the designation,

in terms which are calculated to lead to the use of the substance for the prevention or treatment of any ailment, infirmity or injury affecting human beings or animals, not being terms which given a definite indication that the substance is intended to be used as, or as part of, a food or drink, and not as, or as part of a medicine.

(2) In this Act reference to sale of an article includes reference to the supply of an article as a sample for the purpose of inducing persons to buy by retail the substance of which the article consists or which it comprise

#### PART II

ESTABLISHMENT OF THE ZANZIBAR PHARMACY
AND DANGEROUS DRUGS BOARD

Establishement of Board.

3. (1) There is hereby established a Board to be as the Zanzibar Pharmacy and Dangerous Drugs Board.

- (2) The Board shall, subject to this Act, be responsible -
  - (a) for regulating the standards of conduct and activities of pharmacists; and
  - (b) for the control of and dealing in pharmaceuticals and in poisons.

## First Schedule.

- 4. (1) The First Schedule to this Act shall have effect as to the constitution and proceedings of the Board and otherwise in relation to it.
- (2) The Minister may, in consultation with the Board and by order in the Gazette, vary or replace any of the provisions of the First Schedule to this Act.

#### Functions of the Board.

- 5. Subject to this Act, the functions of the Board shall be -
  - (a) to consider and decide upon applications for registration of pharmacists;
  - (b) to keep and maintain a register for the registration of pharmacist in accordance with this Act;
  - (c) to regulate the standards of conduct and activities of pharmacists and the practice of the profession of pharmacy;
  - (d) to promote interest in, and the advancement of, the profession of pharmacy;
  - (e) to provide opportunities of facilities for the study of and training in pharmacy, and to promote the development of research are the application of technical information relating to pharmacy;
  - (f) to evaluate academic and practical qualifications for the purposes of registration of pharmacists under this Act;
  - (g) to foster co-operation among pharmacis and between the Board and other institutuions or organizations, whether or not concerned with the profession of pharmacy;

- (h) to regulate, in accordance with this Act, the mamufacture, importation labelling, marking or identification, storage and sale of pharmaceutical or any substances used in the manufacture of pharmaceuticals;
- (i) to prescribe minimum standards of quality in respect of pharmaceuticals manufactures or imported in or into Zanzibar;
- (j) to assist members of the public in matters touching upon, ancillary or incidental or conducive to the practice of the profession of pharmacy;
- (k) to carry out such other functions as may be conferred upon the Board by any written law or as are incidental to the performance of its funtions under this Act.

Power of Board to cancel or suspend registration etc.

- 6. (1) Subject to subsection (2) of this section the Board may, after due inquiry and upon such grounds as may be prescribed by regulations made under section 67, cancel or suspend any registration made or any licence given under this Act.
- (2) In every inquiry conducted under this section the Board shall give the pharmacist, or other person concerned a reasonable opportunity to answer allegations made against him.

Appointment and functions of Registrar.

- 7. (1) The Minister shall appoint a public officer to be the Registrar of the Board, who shall also be Secretary to the Board.
- (2) The Registrar shall perform the duties prescribed in relation to his office under this Act and shall perform such other functions as the Minister or the Board may specify from time to time.

Register of pharmacists.

- 8. (1) The Registrar shall keep a register of pharmacists in the prescribed form.
- (2) As soon as practicable after the Board has accepted any person for registration as a pharmacist, the Registrar shall enter in the register in respect of that person the following particulars -

- (a) his name and address;
- (b) the date of registration;
- (c) his qualifications and the status of his registaration; and
- (d) such other particulars as the Board may, from time to time, direct.
- (3) All changes in the particulars registered under subsection (2), shall be entered in the register by the Registrar.
- (4) The Registrar may, with the general or specific approval of the Board, rectify any clerical errors in the register or other document containing extracts from the register.

Qualifications for registration.

- 9. (1) Subject to any regulations made under section 67 providing for the suspension or cancellation of any licence issued or registration granted under this Act, a person shall be entitled, on making an application to the Board in the prescribed manner, to be registered under this section and to offer his services for profit or gain if he is -
  - (a) immediately prior to the commencement of this Act, already registered as a pharmacist under section 69(4) of this Act;
  - (b) the holder of a pharmaceutical diploma recognized by the Board as furnishing a sufficient guarantee that he has the requisite academic knowledge of skill and practical experience in pharmacy; or
  - (c) a person who has, after obtaining a pharmaceutical diploma, complied with such additional requirements relating to the acquisition of practical experience as the Minister may, after consultation with the Board, prescribe by regulations made under section 67.
- (2) The Board may require an applicant for registration under this section to satisfy it that his professional and general conduct render him fit and proper person to be registered.

Provisional registration.

- 10. (1) Subject to any regulations made under section 67 providing for the suspension or cancellation of any licence issued ro registration granted under this Act, any person who is not entitled to be registered by reason only of the fact that he has not complied with the additional requirements referred to in section 9(1)(c) shall if, upon application in the prescribed manner, he satisfies the Board that he has secured an offer for employment or training in the public service or by a person or persons approved by the Board for the pruposes of complying with the additional requirements, be entitled to be registered under this section.
- (2) A person registered under this section shall be deemed to be registered as far as is necessary to enable him to be employed or trained for the pruposes stated in subsection (1) and while so employed or being trained, but not otherwise, may carry out the duties and responsibilities, exercise the rights and enjoy the privileges of a pharmacist.
- (3) The registration of a person under this section shall cease to have effect upon his being registered under section 9.

Temporary registration.

- 11. (1) Where a person satisfies the Board -
- (a) that he is not ordinarily resident in Zanzibar;
- (b) that he is or intends to be employed in Zanzibar in the capacity of a pharmacist for the express purpose of carrying out a specific assignment for which he has been engaged; and
- (c) that he is, or immediately before entering Zanzibar was, in practice as a pharmacist and that he is eligible for registration under section 8,

the Board may, if it is satisfied that his professional and general conduct renders him a fit and proper person to be registered, direct that he be registered under this section for the duration of the specific assignment or for the period which the Board may specify.

(2) The Board may require an applicant for registration under this section to appear before it or produce documents relating to his work or employment.

- (3) Registration of a person under this section shall continue only while he is engaged on the specific assignment or for the period specified by the Board and on his ceasing to be so engaged or on the expiry of the period, his registration shall cease to have effect. In case of doubt to the ceasation of his engagement on the specific assignment or as to the expiry of the period specified by the Board, the decision of the Board on the matter shall be final.
- (4) A pharmacist registered under this section shall, in relation to the duration of the specific assignment or the period specified by the Board, and to things done in the course of that assignment, be treated as registered under section 9, but in relation to other things shall be treated as not so registered.

Certificate of registration.

- 12. (1) Subject to subsection (2) of this section, upon the registration of a pharmacist and on payment of the prescribed fee, the Registrar shall issue a certificate of registration in the prescribed form.
- (2) No fee shall be payable in respect of a certificate of registration if the pharmacist was on the appointed day, already registered under section 69(4) of this Act.

Publication of registered particulars and lists of pharmacists.

- 13. (1) The Registrar shall cause to be published in the Gazette, as soon as may be practicable after registration, the particulars entered in the register in respect of each pharmacist and, subject to the direction of the Board, may cause to be published any amendment or deletion of the particulars in the register.
- (2) The Registrar shall cause to be published in the Gazette, at least once each year, a list containing the particulars entered in the register in respect of all pharmacists remaining on the register at the close of the previous year.

Publication sufficient evidence of registration.

- 14. (1) A publication under section 12 shall be sufficient evidence that the persons mentioned in it are registered under this Act, and the deletion from the register of the name of any person notified by the publication, or the absence of the name of any person from that publication, shall be sufficient evidence that that person is not registered or that the validity of his registration has ceased to have effect.
- (2) The register, lists and all their copies or extracts from them which purport to have been certified under the hand of the Registrar shall be receivable in all Courts and tribunals or other bodies authorized to receive evidence as sufficient evidence of the facts stated in them.

Registrar may call for information. Board, and may, if the considers it necessary for the furtherance of the objects and purposes of this Act require any pharmacist or other person, by a registered letter sent to the last known address of the pharmacist or the other person, to furnish any information relating to his practice or business as a pharmacist or any other matter, which may be specified in the letter.

## PART III

## CONTROL OF DANGEROUS DRUGS

Power to declare certain preparations to be dangerous drugs or pharmaceutical. 16. If it appears to the Minister that any new derivative of morphine or cocaine or of any salts of morphine or cocaine or other alkaloid of opium or any other drug of whatever kind is to be productive if improperly used, or is capable of being converted into a substance which is, or is likely to be productive, if improperly used, of ill effects substantially of the same character or nature as or analogous to those produced by morphine or cocaine, the Minister may by order published in the Gazette declare it as dangerous drug.

Cultivation and possession of bhang prohibited. grow bhang.

- 17. (1) It shall be unlawful to cultivate or grow bhang.
- (2) Any person who has in his possession bhang for purposes of sale or otherwise shall be guilty of an offence.

For the purpose of this section bhang includes cannables indica, cannables stiva, or the plant of the India hemp or any other leafs plants or seeds of the like character in effect by whatever name it is called.

Narcotics prohibited. (3) It shall be unlawful to possess, sale or use any narcotic unless otherwise lawfully permitted by the Board.

For the purpose of this subsection narcotic includes a dictable drugs of the nature of opium (paparer sommeferum) and related substances which are legally under International Control.

Mamufacture of dangerous drugs or poisons prohibited. 18. It shall be unlawful to manufacture, or carry on any business in the manufacture of dangerous drugs or poisons except with the possession of the valid licence issued in accordance with the requirements of this Act.

Prohibition of import or export drugs or poisons. him to do so.

- 19. (1) No person shall import or export dangerous drugs or poisons except with a valid licence committing him to do so.
- (2) Where any dangerous drug or poison is to be exported, exportation shall be done from the Port of Zanzibar only.

Application for export or import of dangerous drugs. 20. Any person who wishes to export or import dangerous drugs or poisons shall apply to the Board in the form specified by the Board.

Registrar to keep records of export or import of dangerous drugs or poisons.

- 21. The Registrar shall keep a register in which he shall enter the particulars of -
  - (a) every application made in pursuance of section 19;
  - (b) every import or export certificate produced in pursuance of section 19; and
  - (c) every import authorisation issued in pursuance of section 18.

Restriction on importation of drugs or poisons.

22. (1) No dangerous drugs or poisons shall be imported into Zanzibar except at the Port of Zanzibar and unless the person to whom the drug is consigned is in possession of a valid licence and import authorisation

granted in pursuance of this Act.

- (2) No person shall import, cause to be imported or take any steps preparatory to importing any dangerous drug into Zanzibar except in pursuance of and in accordance with the provisions of this Act.
- (3) No person shall bring any dangerous drugs to Zanzibar in transit unless -
  - (a) the drug in course of transit from a country from which it may lawfully be exported to another country into which such drug may lawfully be imported;
  - (b) where the dangerous drug in transit is accompanied by an export authorisation diversion certificate and the Controller of Customs has reasonable grounds for believing that such authorisation or certificate is false, or that it has been obtained by fraud or wilful misrepresentation of a material particular, it shall be lawful for the Controller of Customs to seize and betain the drug to which such authority or certificate relates. Upon being satisfied that such authorisation or certificate is valid or has not been obtained by fraud or misrepresentation as aforesaid the Controller of Customs shall release the drug.
- (4) Where the dangerous drug in transit is not accepted by an export authorisation or diversion certificate by reason of the fact that the drug comes from a country not a party to the Narcotic Convetion and the Controller of Customs has reasonable grounds for believing that such drug is being conveyed in an unlawful manner or for unlawful purpose of being imported into another country in contravention of the laws of that country it shall be lawful for the Controller of Customs to seize and detain the frug.
- (5) Where a dangerous drug brought into Zanzibar in transit is landed, or transhipped in to Zanzibar it shall be moved only under and in accordance with the removal licence granted in pursuance of section 19.

Provided that such dangerous drugs or poison shall remain in transit on a period of six months and no longer, and failure of which the Government shall dispose off such dangerous drugs or poisons.

- (6) Nothing in this section contained shall be deemed to apply to any dangerous drug in transit by port or in transit by air if the aircraft passes over Zanzibar without landing, or to such quantities of dangerous drugs may bona fide and reasonably form part of the medical stores of any ship or aircraft.
- (7) For the purpose of this section Port of Zanzibar includes both sea port and airport of Zanzibar Island and Pemba Island which are legally recognised as aither sea port or airport.

Restriction on possession of dangerous drugs.

- 23. No person shall be in possession or attempt to obtain possession of any dangerous drugs unless -
  - (a) he is authorised to import or export any such drug;
  - (b) he is authorised by this Act to be in possession of such drugs;
  - (c) he proves that the drugs were supplied for his own use by a registered or licensed medical pratitioner or dentist or on a prescription of such medical practitioner or dentist given in accordance with the provisions of this Act.

Sale and distribution of dangerous drugs.

24. No person shall supply or procure or offer to supply or procure any dangerous drugs to or for any person whether in Zanzibar or elsewhere or shall advertise any of such drugs for sale unless he is authorised by this Act to import, export or supply such drugs.

Supply of drugs on prescription.

25. Except when dangerous drugs are lawfully dispensed in pursuance of a prescription given by a registered or licensed medical practitioner, or dentist or duly qualified veterinary surgeon or are supplied by a registered or licensed medical practitioner or dentist who

dispenses his own medicines in accordance with the conditions hereinafter specified, no person shall supply or procure any dangerous drugs to or for any person in Zanzibar who is not licensed or otherwise authorised to be in possession of such drugs, nor to any person so licensed or authorised except in accordance with the terms and conditions of such licence or authority.

Provided that the administration of any such drugs by or under the direct personal supervision of a registered dentist in dental treatment or by or under the direct personal supervision of a veterinary surgeon in the treatment of any animal, shall not be deemed to be supplying drugs within the meaning of this Act.

Contitions as to prescription.

- 26. A prescription for the supply of dangerous drugs must comply with the following conditions -
  - (a) the prescription must be in writing, must be dated and signed by the medical practitioner or dentist or veterinary surgeon or as the case may be, with his full name and address and must specify the name and address of the person for whose use the prescription is given, and the total amount of the drug to be supplied on the prescription;
  - (b) a prescription shall only be given by a dentist for the purpose of dental treatment and shall be marked "For local dental treatment only";
  - (c) a prescription shall only be given by a veterinary surgeon for the purpose of treatment of animals and shall be marked "For animals treatment only".

Conditions as to dispensing prescriptions.

- 27. The following conditions shall be observed by person dispensing prescriptions for dangerous drugs -
  - (a) a prescription for any of the drugs shall only be dispensed if the person dispensing the prescription is acquainted with the signature of the medical practitioner or dentist or veterinary surgeon by whom the prescription purports to be given, or is acquainted with the person for whose use

the prescription is given, and has no reasons to suppose that the prescription is not genuine;

(b) the drugs shall not be supplied more than once in the same prescription:

Provided that if the prescription so directs, the drugs may be supplied on more than one but not exceeding three occasions, as directed in the prescription at intervals to be specified in the prescription;

- (c) the prescription shall be marked with the date on which it is dispensed, and shall be retained for a period of two years by the person by whom the prescription is dispensed and shall be kept on the premises where it is dispensed and shall be available for inspection;
- (a) a medical practitioner who dispenses his own medicines shall enter particulars thereof in his day book or in the register hereinafter specified.

Marking of package or bottles.

- 28. (1) No person shall supply any dangerous drug unless the package or bottle containing it is clearly labelled with the amount of the drug in the package or bottle.
- (2) No person shall supply any preparation add mixture, extract, or other substance containing any dangerous drug unless the package or bottles are clearly labelled -
  - (a) in the case of a powder, solution or ointment with the total amount thereof in the package or bottle and the percentage of the drug in the powder, solution or ointment;
  - (b) in the case of tablets or other article with the amount of the drug in each article and the number of articles in the package or bottle.

(3) This section shall not apply to any preparation dispensed by a registered or licensed medical practitioner or on the prescription of such medical practitioner.

Record to be kept.

- 29. Every person who supplies any dangerous drugs shall comply with the following provisions -
  - (a) he shall enter or cause to be entered in a register kept for the sole purpose as shall be prexcribed by the Board all supplies of dangerous drugs imported, purchased or otherwise obtained by him and shall have dealings in the drug affected by him;
  - (b) he shall make the entry with respect to any of the drugs imported, purchased or otherwise obtained by him on the day on which the drug is received, and with respect to any sale or supply by him of the drug on the day on which the transaction is effected;
  - (c) he shall keep the register in his shop, place of business or dispensary so that it shall at all times be available for inspection; and
  - (d) he shall not cancel, obliterate or alter any entry in the register or make therein any entry which is untrue in any particular manner. Any mistake in an entry may be corrected by a marginal note or footnote giving the correct particulars and date.
  - 30. Any person being -
  - (a) registered or licensed medical practitioner or dentist;
  - (b) a duly qualified veterinary surgeon;
  - (c) a registered druggist duly licensed to carry on business as such;

General authorisation to dispense, compound and supply dangerous drugs.

- (d) a registered druggist employed or engaged in compounding and dispensing medicines in a Government hospital or dispensary;
- (e) a Government chemist, pharmacist, pharmaceutical assistant, dispensing auxillaries or other public officer in charge of any Government laboratory; and
- (f) any person holding the authority of the Director of Medical Services under the provisions of any other law,

is hereby authorised so far as is necessary for the practice of his profession or employment in such capacity, to be in possession of and to dispense, compound, sell and dupply dangerous drugs, but subject always to the provisions of this Act and any Rules made thereunder.

Power of inspection.

Government medical officer or any other person duly authorised by the Director of Medical Services shall for the purpose of the execution of this Act have power to enter the premises of any registered or licensed medical practitioner, dentist, or druggist, and to demand the production of and to inspect the register referred to in section 29 or any other book or books or documents relating to dealings in any such drugs, and to inspect any stock of any such drugs.

Penalty.

- 32. (1) Any person who montravenes the provisions of this Part shall be guilty of an offence and shall on conviction be liable to be sent to an education centre for a period fo not less than three years or to a fine of fifty thousand shillings or to both such imprisonment and fine.
- (2) the penalty provided under subsection (1) shall not apply to section 17 to this Act.
- (3) Any person who is guilty of an offence under section 17 of this Act, shall on conviction be liable to be sent to an educational centre for a term of not less than five years, but not exceeding ten years with corporal punishment not exceeding six strokes.

#### PART IV

## DEALINGS IN PHARMACEUTICALSS

Prohibition on preparation and sale of adulterated pharmaceuticals.

- 33. (1) No person shall add any substance to, or abstract any constituent from, a pharmaceutical product so as to affect injuriously the quality, constitution or potency of the product, with intent that the pharmaceutical product shall be sold in that state.
- (2) Subject to this section, no person shall sell, offer, expose or advertise for sale, or have in his possession for the purpose of sale, any pharmaceutical product injuriously affected in its quality, constitution or potency by means of any operation referred to in subsection (1).
- (3) Any person who contravenes or fails to comply with subsection (1) or subsection (2) shall be guilty of an offence and shall be liable on conviction to a fine of not more than five thousand shillings or to imprisonment for a term not exceeding three years or to both that fine and imprisonment.
- (4) In any proceedings for an offence under subsection (2) consisting of the advertisement for sale of a pharmaceutical product, it shall be a defence for the defendant to prove that, being a person whose business it is to publishs or arrage for the publication of advertisements, he received the advertisement for publication in the ordinary course of business.

Regulations regarding the composition of pharmaceuticals.

- 34. (1) The Minister may, after consultation with the Board, make regulations prescribing minimum standards to be complied with by mamufacturers with regard to the composition of pharmaceuticals or their bacteriological or chemical standard.
- (2) Without prejudice to the generality of the power conferred by subsection (1), the Minister may in those regulations -

- (a) require, prohibit or regulate the addition to pharmaceuticals or extraction from them of any specified substance or any substance of any specified category, or the use of any substance as an igredient in the manufacture of preservation of any pharmaceuticals or poisons;
- (b) prohibit, restrict or regulate the importation or manufacture, or the sale, possession for sale, or the consignment or delivery, of pharmaceuticals, or the ingredients of any pharmaceutical product or products, which do not comply with those regulations;
- (c) prohibit or regulate the importation of any pharmaceutical product or category of pharmaceuticals, which, in his opinion, is or may be prejudicial to public health;
- (d) prohibit, restrict or regulate the importation or the use of any specified materials of any specified category, in the manufacture of apparatus or utensils designed for use in the preparation or preservation of pharmaceuticals for use by man;
- (e) prescribe or provide for methods of analysis for the purpose of ascertaining the presence in any pharmaceutical product, or the absence from it, of any specified substance, or the quantity of any substance, present in the drug.

ceneral protection for purchasers of pharmaceuticals.

- 35. (1) Any person who sells to the prejudice of a purchaser any pharmaceutical product which is not of the nature, substance or quality of the product demanded by the purchaser shall be guilty of an offence.
- (2) Where regulations made under section 34 contain provisions prescribing the composition of, or prohibiting or restricting the addition of any substance to, any pharmaceutical product a purchaser of that product shall, unless the contrary is proved, be deemed, for the purpose of subsection (1), to have demanded a pharmaceutical product complying with those provisions.
- (3) In any proceedings for an offence under subsection (1), it shall not be a defence for the defendant to allege that the purchaser bought for analysis or examination and therefore was not a prejudice to the purchaser.

Offences regarding sale, etc. of pharmaceuticals unfit for use by man.

- 36. (1) Any person who -
- (a) sells or offers or exposes for sale
  has in his possession for the purpose of
  sale or manufacture for sale; or
- (b) deposits with, or consigns to, any part for the purpose of sale or of mamufacture for sale,

any pharmaceutical product intended, but unfit, for use by man shall be guilty of an offence.

- (2) Where any pharmaceutical product in respect of which an offence under subsection (1) has been committed was sold to the defendant by some other person, that other person shall also be guilty of an offence.
- (3) Where a person is charged with an offence under subsection (1)(b), or under subsection (2), it shall be a defence for him to prove either -
  - (a) that he gave notice to the person with whom he deposited or to whom he consort or sold, the pharmaceutical product concerned that it was not intended to use by man; or
  - (b) that at the time when the delivered or dispatched it to that person, either the product was fit for use by man, or he did not know, and could not with reasonable deligence have known, that it was unfit.

Pharmaceuticals offered as prizes, etc.

to -

- 37. (1) Section 36 shall also apply in relation
- (a) any pharmaceutical product intended for use by man, which is offered as a price or reward in connection with any entertainment to which the public are admitted, whether or not on payment of money, as if the product were, or have been exposed for sale by each person concerned in the organization of the entertairment;
- (b) any pharmaceutical product intended for use by man which is offered as a price or reward or given away for the purpose of

advertisement, or in furthereance of any trade or business, as if the product were, or had been exposed for sale by the person offering or giving it away;

- (c) any pharmaceutical product intended for use by man which is exposed or deposited in any premises for the purpose of being so offered or given away, as if the product were, or had been, exposed for sale by the occupier of those premises.
- (2) In this section, the expression "entertainment" includes any social gathering, amusement, exhibition, performance, game, lottery or trial of skill.

Restriction on importation and exportation of pharmaceuticals etc. 38. No person shall engage in the importation or exportation of pharmaceuticals or of substance for the manufacture of pharmaceuticals unless -

- (a) be is registered by the Board; and
- (b) has a valid permit from the Board authorising him to import or export such pharmaceuticals.

Classification of 39. The Minister may, in consultation with the pharmaceuticals.

Board classify pharmaceuticals -

- (a) in order of their importance; or
- (b) in the manner which the Board shall deal with; or
- (c) in order of their composition and reaction to human consumption; or
- (d) on any other classification which the Minister may think fit.

Penalty.

40. Any person who is guilty of an offence under this part shall be liable to imprisonment for a period of not less than three years but not exceeding five years or to a fine of not less than fifty thousand shillings or to both such imprisonment and fine.

#### PART V

## DEALING IN POISONS

Mst of poisons for purposes of Act.

- 41. (1) The Board shall, with the consent of the Minister, by order in the Gazette, declare a list of substances which shall be treated as poisons for the purposes of this Act.
- (2) The list declared shall be divided into the following two parts -

List number one shall consist of poisons which, subject to this Act, shall not be sold except by an authorised seller of poisons or a licensed wholesale dealer in mining, agricultural or horticultural accessories;

List number two shall consist of poisons which, subject to this Act, shall not be sold except by a peron entitled to sell list number one poisons and by persons licensed under section 42.

- (3) In determining the distribution of poisons as between the two List, regard shall be had to the desirability or restricting List number two to articles which are in common use, or likely to come into common use, for purposes other than the treatment of human ailments and which it is reasonably necessary to include in that List number two if the public are to have adequate facilities for obtaining them.
- (4) The Board may, subject to any direction of the Minister given in that behalf, amend or vary the List, from time to time, as it deems proper.

Wholesale dealer's licence.

- 42. (1) Any person who wishes to deal, or to continue dealing, as a wholesale dealer in poisons shall apply in writing in the prescribed form to the Board.
- (2) A separate licence under this section shall be required in respect of each set of premises in which the business of licensee in the sale of poisons in carried on.

Conditions for seller of poisons.

- 43. A pharmacist carrying on business comprising become authorized the retail sale of pharmaceuticals shall be an authorized seller of poisons within the meaning of this Act if -
  - (a) in each set of premises for the retail sale of drugs, the business in carried on under the personal control of the pharmacist himself or of some other pharmacist;
  - (b) the name and certificate of registration of the pharmacist having control of the business are conspicuously exhibited in the premises; and
  - (c) is authorised by the Board to sell such poisons.

List of shops and pharmacists in charge.

- 44. (1) Every authorized seller of poisons shall in the month of January in each year send to the Registrar a list of all sets of premises where he carries on business in the retail sale of pharmaceuticals and the name of the pharmacist having the personal control of the business in each set of premises.
- (2) Any authorized seller of poisons who fails to comply with this section shall be guilty of an offence and shall be liable on conviction to a fine of one thousand shillings and to a further fine of two hundred shillings for every day subsequent to his conviction during which the default continues.

Possession of List number One poisons prohibited in certain cases.

- 45. (1) No person shall have any List Number One poisons in his possession unless -
  - (a) he is entitled under this List to sell that poison or is a wholesale dealer licensed under section 42 to sell poison; or
  - (b) the poison has been sold or supplied to him by an authorized seller of poisons in accordance with this Act.

(2) In any precedings for an offence under this section the burden to prove that the poison has been sold or supplied by an authorized seller of poisons in accordance with this Act shall lie upon the person in whose possession the poison was found.

Micence to deal in poisons for mining, agricultural or horticultural purposes.

- 46. (1) Any person who wishes to carry on, continue carrying on, regular business in mining, agricultural or horticultural accessories shall apply to the Board in writing in the prescribed form for licence authorizing him to sell the poisons specified in the licence to persons who require them for and or business of mining, agruculture or horticultural.
- (2) Subject to any regulations made under section 67 providing for the cancellation or suspension of any licence issued or any registration granted under this interest so requires, if it is satisfied that the public interest so requires, and upon payment of the prescribed fee by the applicant, issue or renew the licence.
- (3) A separate licence under this section shall be required in respect of each set of premises in which the business of the licensee is carried and every such licence shall expire on the 31st day of December in the year in which it is issued any may be renewed.
- (4) The Registrar shall keep a register of all licences issued by the Board under this section.

Power to sell List One poisons.

- 47. (1) Subject to this Act, a person licensed under section 42 to deal as a wholesale dealer in poisons may sell List One poisons -
  - (a) to another person so licensed;
  - (b) to an authorized seller of poisons;
  - (c) in respect of the poisons specified in the purchaser's licence, to a person licensed under section 46 to sell those poisons for mining, agricultural or horticultural purposes;

- (d) subject to a pharmacist being in direct control of the poisons at the premises which they are sold, to a duly qualified medical practitioner, dentist or veterinary surgeon for purposes of medical, dental or veterinary treatment respectively;
- (e) subject to a pharmacist being in direct control of the poisons at the premises from which they are sold, to a hospital, dispensary or similar institution or a person concerned with scientific education or research, where the hospital, dispensary, institution or person has been approved in that behalf by the Minister.

Poisons Book.

- 48. (1) Where any List One poison is sold in the presence of the person by whom it is to be used, the seller shall not deliver it until -
  - (a) he has made or caused to be made an entry in a book kept for that purpose to be called the Poisons Book, indicating in the form prescribed the date of the sale, the name and address of the purchaser and of the person if any, by whom the certificate required under section 42 was given, the name and quantity of the poison sold, and the purposes for which it is stated by the purchaser to be required; and
  - (b) the purchaser has affixed his signature to the entry made under paragraph (a).
- (2) Where any List One poison is sold in the presence of an agent or employee of the person by whom it is to be used, or where the sale is effected by post, the following provisions shall apply -
  - (a) subject to subsection (3), before the sale is completed the seller shall obtain an order in writing signed by the purchaser, showing the pruchaser's name, address and occupation, the name and quantity of the poison to be purchased and the purpose for which it is required;

(b) before the sale is completed the seller shall satisfy himself that the signature on the order is that of the person by whom it purports to be signed, and that that person carries on the occupation stated in the order, and in which the poison to be purchased is properly required;
(c) the requirements of subsection (1) as to the making of entries in the Poisons Book shall be complied with, except that in place of the purchaser's signature in the Poisons Book it shall be sufficient to enter in the space provided for the signature the words "signed order" together with a reference whereby the particular order may be readily identified;

- (d) if the poison is sent by post it shall be sent by registered post.
- (3) Where a person represents that he urgently requires a poison for the purpose of his trade, business or profession and satisfies the seller that by reason of some emergency he is unable before delivery to furnish such order in writing, the seller may forthwith deliver the poison to the purchaser who shall, within twenty-four hours of the sale, furnish the seller with the written order referred to in subsection (2)(a).
- (4) All signed orders and prescribed records of transactions to which this section applies shall be retained in the premises where the sales were made for a period of five years.
- (5) Any person who contravenes or fails to comply with this section shall be guilty of an offence and shall be liable on conviction to a fine not exceeding Five thousand shillings or to imprisonment for a term not exceeding Six months, or to both that fine and imprisonment.

Supply and dispensing List One poisons by doctors, hospitals, etc. 49. (1) A qualified medical practitioner, dentist of or veterinary surgeon, or a member of the staff of a hospital, dispensary or similar institution who has been authorized to do so by the general or special order of the Minister, may supply or dispense List poison for the purpose of medical, dental or Veterinary treatment, as the case may be, subject to the following provisions —

- (a) the poison shall be deistinctly labelled with the name and address of the person by whom it is supplied or dispensed;
- (b) the following particulars shall, within twenty-four hours after the poison has been supplied or dispensed, be entered in a book used regularly for the purpose, and which shall be called the Prescription Book -
  - (i) the date on which the poison was supplied or dispensed;
  - (ii) the ingredients and the quantity supplied;
  - (iii) the name and address of the person to whom the poison was supplied;
  - (iv) the name and address of the person by whom the prescription was given.
- (2) Where an authorized seller of poisons supplied a List One poison, forming part of the igredient of medicine for the internal or external treatment or human ailments, and where an authorized seller of poisons supplies a List One poison on prescription Book kept in accordance with this section but shall not in respect of that supply be required to make any entry in the Poisons Book in accordance with section 48.
- (3) Any person to whom subsection (1) applies and who supplies or dispenses any List One poison in a manner contrary to this section shall be guilty of an offence and shall be liable on conviction to a fine not exceeding Ten Thousand shillings or to imprisonment for a term not exceeding twelve months, or to both such fine and imprisonment.

# PART VI MISCELLANEOUS

Poisons not to be sold in automatic machines.

- 50. (1) No pison shall be exposed or offered for sale in or by means of an automatic machine.
- (2) Any person who exposes or offers, or causes to be exposed or offered, for sale, any poisons contrary to subsection (1), shall be guilty of an offence.

Labelling of containers.

- 51. Subject to section 52 every poison shall be supplied in a container labelled in the prescribed manner -
  - (a) with the name of the poison; and
  - (b) in the case of a pharmaceutical product which contains a poison as one of its ingredients, with the prescribed particulars as to the proportion which the poison contained in the product 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 retail or other sale other wholesale, with the name of the seller and the address of the premises on which it is sold; and
  - (e) if supplied, but not on sale, with the name and address of the supplier.

Labelling of articles containing madicine.

- 52. (1) Subject to this Act, no person shall sell by retail any article consisting of or comprising a substance recommended as a medicine unless there is legibly written on the article or on the label affixed to it, or, if the article is sold or supplied in a container, on the container or on the label affixed to it, or if the article is sold or supplied in more that one container, on the inner container or on a label affixed to it -
  - (a) the appropriate designation of the substance so recommended or of each of its active constituents, 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, the appropriate quantitative particulars of the constituents or ingredients.
  - (2) Subsection (1) shall not apply -

- (a) to any article made up and supplied for the use of a particular person being on article prescribed by reference to the needs of that person;
- (3) In subsection (1) -
- (a) the expression "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 51;
  - (ii) in case where the substance, contituent or ingredient is not that poison and not described in any of the monographs contained in the edition of the British Pharmaceutical Codex or the International. Pharmaceutical 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 that poison and is not described thus 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 Latin and in addition where it exists, in the official Kiswahili equivalent;

> (b) the expression "appropriate quantitative particulars", in red to the active constituents of the ingredients of a substance, means -

( 30 )

- (i) the approximate percentage 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 or the approximate quantity of each of those 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, be shall, subject to this Act, be guilty of an offence and shall be liable on conviction -
  - (a) in the case of a first conviction, to a fine not exceeding One thousand shillings; and
  - (b) in the case of a subsequent convict to a fine not exceeding Five thousand shillings or to imprisonment for a term not exceeding six months or both that fine and imprisonment.
- (4) It shall be a defence for a person charged with selling or supplying, in contravention of any of the provisions of this section, an article consisting of or comprising a substance recommends as 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 an employee or agent of another person on the instructions of his employer or of some other specified person.

Prohibition of advertisements as to certain diseases, etc. 53. (1) Subject to this Act, no person shall take any part in the publication of any advertisement referring to any pharmaceutical product appliance or article of any description in terms which are calculated

to imply that the product appliance or article may be effective for any of the purposes specified in the Second Schedule to this Act.

- (2) The Minister may, from time to time by notice in the Gazette, amend or vary the Second Schedule to this Act.
- (3) Subject to this Act, no person shall take any part in the publication of any advertisement referring to any pharmaceutical product appliance or article of any description, in terms which are culculated to lead to the use of that product, appliance or article for procuring miscarriage by women.

False labelling and advertisement.

- 54. (1) Any person who gives out or deals with any pharmaceutical product, medicine, medical appliance or similar article sold or exposed by him for sale, a label, whether or not attached to or printed on the container or wrapper, which -
  - (a) falsely describes the product, medicine, medical appliance or article; or
  - (b) is calculated to mislead as to the nature, substance or quality of the product, medicine, medical appliance or article; or
  - (c) refers to the product, medicine, medical appliance or similar article in terms which are extravagent and bear little or no relation to the therapeutic properties and action to their ingredients or components,

shall be guilty of an offence, unless the proves to the satisfaction of the court that he did not know, and could not with reasonable diligence be ascertained, that the label concerned was of the character it is alleged to be and shall be liable on conviction to imprisonment for a period of not less than one year but not exceeding two years or to a fine exceeding fifty thousand shillings or to both such fine and imprisonment.

- (2) Subject to subsection (3), any person who publishes, or is a party to the publication of advertisement, not being a label given out or dispatched by him, which has the same effects as those referred to in subsection (1)(a), (b) or (c), shall be guilty of an offence and shall be liable on conviction to a fine not exceeding ten thousand shillings.
- (3) In proceedings for an offence under subsection (2), it shall be a defence for a defender to prove, either -
  - (a) that he did not know, and could not with reasonable diligence have known, that the advertisement was of the character which described in that subsection; or
  - (b) that, being a person whose business is to publish or arrage for the publication of advertisements, he reads the advertisement for publication in the ordinary course of business.
- (4) In any proceedings under this Part, in the fact that a label or advertisement in respect of which the offence is alleged to have been committed contained an accurate statement of the composition of the pharmaceutical product shall not preclude the court from finding that the offence was committed.

Power to take samples.

- 55. (1) Subject to subsection (2) and to subsection (3), any inspector may take samples for analysis, or for bacteriological or other examination of any pharmaceutical product, or of any substance capable of being used in the manufacture of pharmaceuticals, which appears to him to be intend for sale or to have been sold for use by man, or which is found by him on or in any premises, store, vehicle, vessel, aircraft or place which is authorized to enter for the purposes of ensuring compliance with this Act.
- (2) The inspector shall take without payment to the person appearing to him to have the lawful custody of the pharmaceutical product a sample of which the inspector needs for analysis.

- (3) Where the pharmaceutical product or substance a sample of which the inspector intends to take, is kept for retail sale in unopended packages, the sample shall consist of the whole of any one package.
- (4) When taking any sample under this section, the inspector shall take any necessary measures to satisfy himself that the sample taken is a fair sample of the bulk of the pharmaceutical product.
- (5) Any person who fails to comply with any demand made by an inspector under this section shall be guilty of an offence and shall be liable on conviction to a fine not exceeding one thousand shillings or to imprisonment for a term not exceeding six months, or to both such fine and imprisonment.

Provisions regarding the taking of samples for analysis.

- 56. (1) Where any inspector who has taken sample of any pharmaceutical product or substance under section 55 considers that it should be analysed he shall divide the sample into three parts, each part to be marked and sealed or secured in the manner permitted by its nature and shall -
  - (a) with respect to one part of the sample comply with subsection (2); and
  - (b) with respect to the remaining part of the sample comply with subsection (3).
  - (2)(a) If the sample was obtained by purchasing from a dealer in the pharmaceutical product or substance concerned, the inspector shall permit the vendor to select and take one part from the three parts.
  - (b) If the sample is of any pharmaceutical product or substance consigned from outside the United Republic and was taken by that officer before delivery to the consignee, he shall give the one part of the sample to the consignee.

- (c) If the sample is of any pharmaceutical product or substance in transit from a consigner within the United Republic to a consignee within or outside the United Republic, the inspector shall give the one part of the sample to the consigner.
- (d) If none of the preceeding paragraphs of this subssection applies, the inspector shall give the one part of the sample to the person appearing to him to be the owner of the pharmaceutical product or substance from which the sample was taken.
- (3) The inspector shall unless the subsequently decides not to have an analysis made, submit to the Government Analyst one of the remaining two parts of the sample and retain the other for future comparison.
- (4) In every case to which subsection (2) applies, the inspector shall inform the person to whom the part of sample is given that that sample was taken for analysis by the Government Analysis.
- (5) Where any sample taken for analysis consists of the contents of an unopened package, the inspector shall retain the packing material and, if he decides to have an analysis made, deliver the sample together with the packing material and any label which may have been attached to it at the time when the sample was taken to the Government Analyst with the part of the sample submitted pursuant to subsection (3).
- (6) Any part of a sample which is to be given to any person under this section may be given either by delivering it to him or his agent, or by sending it to him by post in a registered packet, but if after reasonable inquiry the inspector is unable to find the person to whom the part of the sample is to be given or to ascertain his name and address, he may, in lieu of giving that part to that person, retain it.

(7) If it appears to the inspector that any pharmaceutical product or substance of which he has taken a sample for analysis was manufacture or put into a wrapper or container by a person other than one to whom any part of the sample is required to be given, having his name and an address in the United Republic displayed or written on the wrapper or container, the inspector shall, unless he subsequently decides not to have an analysis made, within three days after taking that sample, send to that person a notice informing him that the sample has been taken by him and where the sample was taken or, as the case may be, from whom it was purchased.

Right to have sample analysed.

- 57. (1) Any inspector who has procured a sample of any pharmaceutical product or other substance for use in the manufacture of pharmaceuticals shall, if he considers that it should be analysed, submit it to the Government Analyst for analysis; and any other person who has purchased any pharmaceutical product may submit a sample of it to the Government Analyst for analysis.
- (2) Subject to section 61 and to any regulations made under section 67, the Government Analyst shall analyse as soon as may be practicable any sample submitted to him in pursuance of this section, but shall, where a sample is submitted by a person other than an inspector, demand the prescribed fee to be paid prior to the analysis being done.

Appointment of inspectors.

- 58. (1) For the purposes of this Act, every member of the Board, and every Regional Medical Officer, shall be an inspector.
- (2) The Board may authorize in writing any public officer to be an inspector for the purpose of this Act.

Power of inspectors.

- 59. (1) For the purposes of ensuring compliance with this Act, an inspector may -
  - (a) at all reasonable time, enter -
    - (i) any premises which is on the register of premises;

- (ii) any premises in which any person whose name is entered in any register under this Act carries on any business; and
- (iii) any premises in respect of which any person is licensed under this Act;
- (b) At any time enter any premises in which he has reasonable cause to suspect that this Act has been, or is about to be, contravened in relation to any poison specified in the Poisons List;
- (c) examine or inspect any certificate of registration, licence book or other document in the premises and, for that purpose, be may do such other things, including the taking of extracts from documents in the possession of the pharmacist, as may be necessary to effectuate the examination or inspection;
- (d) seize and detain any pharmaceutical product, substance or article consisting of or containing any poison which he has reasonable cause to suspect is liable to forfeiture order this Act;
- (e) seize and detain any pharmaceutical product, article, record or other thing which appears to him to constitute or contain evidence of a contravention of any provision of this Act.
- (2) Any person who -
- (a) wilfully delays or obstructs an inspector in the exercise of his powers under this section; or
- (b) refuses or fails without reasonable excuse, to give any information which he is lawfully required under this section to give; or

(c) gives any information which is false in a material particular or which he reasonably believes to be untrue,

shall be guilty of an offence and shall be liable on conviction to a fine not exceeding two thousand shillings or to imprisonment for a term not exceeding twelve months or to that fine and imprisonment.

(3) Without prejudice to the generality of subsection (2) and (3), every person who appears to be conducting in any premises any business involving the retail sale of drugs shall, on being required to do so by an inspector, state who the owner of the business is, and if that person fails, without reasonable excuse, to comply with this subsection, he shall be guilty of an offence and shall be liable on conviction to a fine exceeding ten thousand shillings.

Power to prohibit or control certain medicines, etc.

- 60. (1) The Minister may, on the recommendation of the Board, by order in the Gazette, prohibit or control the manufacture, importation, sale, advertisement or possession of any secret, patent, proprietary or home-eopathic madeicine, preparation or appliance or any drug, pharmaceutical preparation or therapeutic substance.
- (2) Any person who contravenes or fails to comply with any order made under subsection (1) of this section shall be guilty of an offence.

Certificate of analysis.

- 61. (1) In every case in which a sample or analysis is delivered to the Government Analyst under section 56, the Analyst shall cause it to be analysed as soon as is practicable and shall give to the person who requested the analysis to be made a certificate specifying the result of the analysis in the form prescribed in the Third Schedule to this Act and such certificate shall judicially be noticed.
- (2) A certificate of the result of analysis given by the Government Analyst under subsection (1) shall be signed by him, but the analysis may be made by any person acting under his instructions.

Evidence of analysis.

62. In any proceedings for an offence under this Act, the production by one of the parties of document purporting to be a certificate of the Government Analyst given under section 61, or of document supplied to him by the other party as by a copy of that certificate, shall be sufficient evidence of the facts stated in it, unless, in the former case, the other party requires that the person who made the analysis be called as a witness.

Penalty.

63. Any person who contravenes the provision of this Part shall be guilty of an offence and shall on conviction be liable to imprisonment for a period of three years, or to a fine of fifty thousand shillings or to both such fine and imprisonment.

Forfeiture.

- 64. (1) In any proceedings for an offence under this Act, the court before which the offender is tried shall in addition to any order or sentence it makes or imposes, order that any pharmaceutical product, substance or other article with respect to which the offence was committed be forfeited to the Government of the United Republic.
- (2) An order of forfeiture may be made under this section whether or not any person has been convicted of the offence alleged to have been committed.
- (3) Any pharmaceutical product, substance or other article in respect of which an order for forfeiture is made under this section shall be deemed to be free from any rights of any person.

Liability of members of Board, etc. 65. No matter or thing done by any member of the Board, the Registrar, an inspector or any other person empowered to perform any function under this Act shall, if done in good faith in execution or purported execution of his function under this Act, render the member, the Registrar, the inspector or that other person personally liable for the matter or thing concerned.

Power to delegate.

66. The Minister may, by order in the Gazette empower the Board to delegate to any of its members or to the Registrar any function conferred upon the Board by this Act.

Regulations.

- 67. (1) The Minister may, after consultation with the Board, make regulations with respect to any of the following matters or for any of the following purposes -
  - (a) prohibiting the retail sale of any specified List One poison except on a prescription lawfully given by a qualified medical practitioner, dentist or veterinary surgeon, and for prescribing the form and regulating the use of those prescription;
  - (b) prohibiting, regulating or restricting the sale of List B poisons or of any specified List B poisons by any of the persons licensed under section 46 by any category of those 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 category of such article or substances of for dispensing with or relaxing any provision contained in Part V of this Act with respect to poisons.
  - (d) providing for the better regulation of the manufacture, sale or advertising of pharmaceuticals, poisons, and therapeutic substances;
  - (e) the safe custody, storage and transport of pharmaceuticals and poisons;
  - (f) the effective regulation of the importation, exportation, and labelling of pharmaceuticals and poisons;
  - (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) prescribing the forms the manner, the procedure and the fees payable in respect of applications for licences or registration under this Act;

- (k) prescribing, after consultation with the Board, the additional requirements relating to experience referred to in section 9(1)(c);
- the conduct of inquiries by the Board, and the attendance of witnesses and production of evidence at inquiries under this Act, including the power to take evidence on oath;
- (m) prescribing the grounds for suspension or cancellation of a licence issued or registration granted under this Act;
- (n) anything which is required or permitted to be prescribed or provided for under this Act.
- (2) The power to make regulations under this section in relation to poison includes the power to make rules in relation to any category of poisons or drug or any particular poison or drug.

Regulations by Board.

- 68. (1) The Board may, with the consent of the Minister make regulations for the better carrying out of its functions under this Act and without prejudice to the generality of the power conferred by this subsection, the Board may by such regulations -
  - (a) prescribe diplomas which shall be recognized as entitling the holder to registration under this Act;
  - (b) prescribe article for the practice of the profession of pharmacy;
  - (c) prescribe rules to regulate the standards of professional conduct of pharmacists;
  - (d) provide for and regulate the manner of giving assistance to members of the public on matters touching upon, ancillary or incidental to, the practice of the profession of pharmacy;
  - (e) prescribe anything which, in the opinion of the Board, is incidental or conducive to the exercise of its functions and powers under this Act.

(2) Regulations made by the Board under this section shall be published in the Gazette.

Repeal and savings.

- 69. (1) The Penicillin Decree, Cap. 75 and the Dangerous Drugs Decree, Cap. 76 of the Laws of Zanzibar are hereby repealed.
- (2) All subsidiary legislation made under that Decree, which is in force on the appointed day shall be deemed to be subsidiary legislation made under this Act and shall remain in force until revoked by regulations or rules made under this Act.
- Drugs Decree to perform functions in relation to the control of the manufacture, importation or sale of pharmaceuticals and poisons, and also in relation to the regulation of the profession of pharmacy, shall continue to perform those duties in so for as this Act relates to them unless their tenure of office expires or their appointments are sooner terminated or, as the case may be, they are reappointed and shall, for that purpose, be deemed to have been appointed under this Act.
- (4) Any person who before the commencement of this Act was registered as a pharmacist shall be deemed to have been registered under this Act.

#### FIRST SCHEDULE

### (Section 4(1)

Composition of Board.

- 1. The Board shall consist of -
- (a) the Director of Medical Services, who shall be the Chairman;
- (b) a legally qualified person holding office in the Attorney-General's Chambers, nominated in that behalf by the Attorney-General;
- (c) the Chief Veterinary Officer;
- (d) the Chief Pharmacist in the service of the Government;
- (e) the Government Chemist;
- (f) one pharmacists appointed by the Minister;
- (g) one qualified medical practitioner appointed by the Minister;
- (h) three other members appointed by the Minister.

Vice-Chairman.

2. The members shall elect one of their number to be the Vice-Chairman of the Board and any number elected as Vice-Chairman shall, subject to his continuing to be a member, hold office for a term of three years from the date of his election, but shall be eligible for re-election.

Appointment Office Registrar. 3. The Minister shall in consultation with the Board appoint a competant person who knowledgeable and fit to be the Registrar of the Pharmarcy and Poisons Board who shall also be the Secretary of the Board. Tenure of office.

- 4. A member appointed under paragraph 1(g),(h) and (i) -
  - (a) shall, unless his appointment is sooner terminated by the Minister, or be ceases in any other way to be a member, hold office for a period of three years but shall be eligible for re-appointment;
  - (b) may at any time resign his office by giving notice in writing addressed to the Minister, and from the date specified in the notice or, if no date is so specified, from the date of the receipt of the notice by the Minister, he shall cease to be a member.

Meetings of the Board.

- 5. (1) The Board shall ordinarily meet at such times and places as it deems necessary for the transaction of its business, but shall meet at least once every three months.
- (2) The Chairman or, in his absence, the Vice-Chairman, may at any time call a special meeting of the Board, and shall call a special meeting upon a written request by a majority of the members in office.
- (3) The Chairman or in his absence the Vice-Chairman, shall preside at every meeting of the Board. In the absence of both the Chairman and the Vice-Chairman, the members present shall appoint a member from amongst themselves to preside over the meeting.

Quorum.

6. The quorum at any meeting of the Board shall be five, of whom one shall be a pharmacist and one a qualified medical practitioner.

Decisions of the Board. 7. (1) Subject to sub-paragraph (2), questions proposed at a meeting of the Board shall be decided by a majority of the votes of members present and voting, and in the event of a equality of votes then the person presiding shall have a casting vote in addition to his deliberative vote.

(2) A decision may be made by the Board without a meeting by circulation of the relevant papers among the members and the expression of the views of the members in writing, but any member may require that the decision be deferred and the subject matter be considered at a meeting of the Board.

Minutes of meetings.

- 8. (1) The Board shall cause to be recorded and kept details of all business conducted or transacted at its meetings, and the mimutes of each meeting of the Board shall be read and confirmed, or amended and confirmed at the next meeting of the Board and signed by the person presiding at the meeting.
- (2) Any mimites purporting to be signed by the person presiding at a meeting of the Board shall, in the absence of proof of error, be deemed to be a correct record of the meeting whose mimutes they purport to be.

Vacancies, etc. not to invalidate proceedings. 9. The validity of any act or proceeding of the Board shall not be affected by any vacancy among its members or by any defect in the appointment of any of them.

Board may regulate its own proceedings. 10. Subject to the provisions of this Schedule the Board may regulate its own proceedings.

Proof of documents.

11. Any document purporting to be under the hand of the Registrar as to any resolution of the Board or as having been issued on behalf of the Board, shall be receivable in all courts or tribunals or other bodies authorized to receive evidence and shall, unless the contrary is shown, be deemed, without further proof, to sufficient evidence of what it contained in the document.

#### SECOND SCHEDULE

### (Section 53(1))

Purposes for which Pharmaceuticals etc., may not be Advertised.

- The cure of syphillis, gonorrhea or soft chancre in any of their forms.
- 2. The prevention, relief or cure of Britht's disease, schistosomiasis or bilharzia, ankylostomiasis or hookworms, cacer, consumption or tuberculosis, leprosy, lupus, diabetes, epilepsy of fits, locomotor ataxy, paralysis, or infantile paralysis.
- Jo The cure of arterio-sclerosis, septicaemia, diphtheris, dripsy, erysipelas, gallstones kidney stones, and bladder stones, goitrem heart disease, tetamus or lockjaw, pleurisy pneumonia, scarlet-fever, small pox, trachoma, amenorrhoea, hearnia or rupture, blindness, or any structure or organic ailment of the auditory system.

## THIRD SCHEDULE

# (Section 59 (1))

## CERTIFICATE OF ANALYSIS

The Pharmaceuticals and Poisons Act, 1986

# (Section 61 (1))

To:
I,, being the Government
Analyst for the purposes of the Pharmaceuticals and Poisons Act, 1978,
do hereby certify that I received on the day of 19
from a sealed packet marked
and said to contain a sample of; that
I found the seals intact and have analysed the contents of that packet,
and do hereby declare that the result of my analysis was as follows -
I am of the opinion that the sample contained parts as under or
the foreign ingredient as follows -
Observations
down of 19
As witness my hand this day of 19
Signature
Government Chemist (or as the case may be analyst)
Note:- All percentages given indefinitions or standards prescribed
are, unless otherwise specified, percentages by weight.

Passed in the House of Representatives on the

2nd day of April, 1986.

SALIM MZEE
ACTING CLERK TO THE HOUSE
OF REPRESENTATIVES