Tanzania

Pharmaceutical and Poisons Act

Chapter 219

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Pharmaceutical and Poisons Act
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Chapter 219

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[Note: This legislation has been thoroughly revised and consolidated under the supervision of the Attorney General's Office, in compliance with the Laws Revision Act No. 7 of 1994, the Revised Laws and Annual Revision Act (Chapter 356 (R.L.)), and the Interpretation of Laws and General Clauses Act No. 30 of 1972. This version is up-to-date as at 31st July 2002.]

[Acts Nos. 9 of 1978; 1 of 1981; G.N. No. 19 of 1979]

An Act to provide for the control of the profession of pharmacy, and of matters relating to dealings in pharmaceuticals and poisons.

Part I – Preliminary provisions (ss. 1-2)

1. Short title

This Act may be cited as the Pharmaceutical and Poisons Act.

2. Interpretation

(1) In this Act, unless the context otherwise requires—

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

"**authorised seller of poisons**" means any of the persons declared by sections 34 and 35 to be authorised sellers of poisons;

"**Board**" means the Pharmacy Board established by section 3;

"**British Pharmaceutical Codex**" and "British Veterinary Codex" mean, respectively, the current edition, and any amendments made to them, of the books published by these names by the Pharmaceutical Society of Great Britain;

"**British Pharmacopoeia**" means the current edition, and any amendments made to it from time to time, of the book published by that name in pursuance of section 47 of the Medical Act, 1956, of the United Kingdom or any enactment replacing it;

"**certificate of registration**" means the certificate issued to a pharmacist under section 11 upon his being registered by the Board;

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

"**drug**" includes any medicine, medicinal preparation or therapeutic substance;

"**for use by man**" means for human consumption or for external application to the human body;

"**Government Analyst**" means the Government Chemist and any analyst appointed by the Minister for the purposes of this Act;

"**labelled**" means distinctly labelled in English or Latin and in Kiswahili;

"**manufacture**", with its grammatical variations 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 results in that article or substance being possibly of use by man as a pharmaceutical product or poison, whether or not on a lawfully given prescription;

"**medicine**" means any medicament or curative or preventive substance whether proprietary or in the form of a preparation;

"**member**" in relation the to 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 manufactured or prepared in any way and intended for use by man as a medicine or as a remedy used for the purposes of medical, dental or veterinary treatment;

"**pharmacist**" means a pharmaceutical chemist or a chemist and druggist who is registered under this Act;

"**Pharmacopoeia**" means the current edition, and any amendments made to it from time to time, of the book published by that name by the World Health Organisation;

"**poison**" means a pharmaceutical product included in the Poisons list referred to in section 33;

"**qualified**" in relation to a medical practitioner, dentist or veterinary surgeon, as the case may be, means a medical practitioner or dentist registered under the Medical Practitioners and Dentists Act[1] and a Veterinary Surgeon registered under the Veterinary Surgeons Act[2];

"**Registrar**" means the Registrar of the Board appointed under section 6;

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

"**sell**" with its grammatical variations and cognate expressions includes an 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;

"**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 or any wrapper or 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 exhibited at the place where the article is sold; or

(iii) in any advertisement published 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 the case where the article was sold, under a proprietary designation, the proprietor of the designation,

1 Cap. 152

2 Cap. 319

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 give a definite indication that 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 comprises.

Part II – Pharmacy (ss. 3-19)

The Pharmacy Board and registration of pharmacists (ss. 3-14)

3. Establishment of Board

(1) There is hereby established a Board to be known as the Pharmacy Board which shall, subject to this Act, be responsible for regulating the standards of conduct and activities of pharmacists and for the control of all dealings in pharmaceutical and in poisons.

(2) The First Schedule to this Act shall have effect as to the constitution and proceedings of the Board and otherwise in relation to it.

(3) The Minister may, by order in the *Gazette*, amend, vary or replace all or any of the provisions of the First Schedule to this Act.

4. Functions of Board

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 pharmacists 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 or facilities for the study of and training in pharmacy, and to promote the development of research and 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 pharmacists and between the Board and other institutions or organisations, whether or not concerned with the profession of pharmacy;

(h) to regulate, in accordance with this Act, the manufacture, importation, labelling, marking or identification, storage and sale of pharmaceutical or any substances used in the manufacture of pharmaceutical;

(i) to prescribe minimum standards of quality in respect of pharmaceutical manufactured or imported in or into the United Republic;

(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 laws or as are incidental to the performance of its functions under this Act.

5. Power of Board to cancel or suspend registration

(1) Subject to subsection (2), the Board may, after due inquiry and upon such grounds as may be prescribed by regulations made under section 71, 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.

6. Appointment and functions of Registrar

(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.

7. Register of pharmacists

(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 registration; 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.

8. Qualifications for registration

(1) Subject to any regulations made under section 71 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 8 of the Pharmacy and Poisons Ordinance[3]; or

(b) the holder of a pharmaceutical diploma recognised 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 71.

(2) The Board may require an applicant for registration under this section to satisfy it that his professional and general conduct render him a fit and proper person to be registered.

3 R.L. Cap. 416

9. Provisional registration

(1) Subject to any regulations made under section 71 providing for the suspension or cancellation of any licence issued or 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 8(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 purposes 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 purposes 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 8.

10. Temporary registration

(1) Where a person satisfies the Board—

(a) that he is not ordinarily resident in Mainland Tanzania;

(b) that he is or intends to be employed in Mainland Tanzania 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 Mainland Tanzania 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 as to the cessation 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 8, but in relation to other things shall be treated as not so registered.

11. Certificate of registration

(1) Subject to subsection (2), 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 the Pharmacy and Poisons Ordinance[4].

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12. Publication of registered particulars and lists of pharmacists

(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 directions of the Board, may cause to be so 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.

13. Publication sufficient evidence of registration

(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 authorised to receive evidence as sufficient evidence of the facts stated in them.

14. Registrar may call for information

The Registrar shall, if instructed by the Board, and may, if he 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.

Restriction on activities of pharmacists (ss. 15-19)

15. Restriction on use of certain titles

(1) Subject to section 16, no person other than a pharmacist shall, on or after the appointed day—

(a) carry on, either alone or in association with other persons, the business of a pharmacist;

(b) in the course of any trade or business, manufacture, or dispense any drug except under the immediate supervision of a pharmacist; or

(c) assume, take, exhibit, or in any way make use of any title, emblem, or description reasonably calculated to suggest that he is a pharmacist.

(2) Any person who contravenes this section commits an offence and on conviction is liable to a fine not exceeding five thousand shillings or to imprisonment for a term not exceeding two years, or to both.

(3) For the purpose of subsection (1)(c), the use of any of the titles "pharmacist", "druggist", "chemist", "pharmaceutist" or "pharmaceutical chemist", or any similar word or combination of words in any language, shall be deemed to be reasonably calculated to suggest that the owner of the business and the person having control of the business on the premises are pharmacists.

(4) Nothing in this section shall extend to or interfere with the supply of medicine to a particular person by a qualified medical practitioner, dentist or veterinary surgeon for the purpose of medical, dental or veterinary treatment.

(5) Nothing in this section shall be deemed to make it unlawful for any person to sell any non-poisonous drug provided that the drug is sold in its original condition as received by the seller, or to require that person to be registered as a pharmacist.

16. Bodies of persons operating as pharmacists

(1) No body of persons whether corporate or unincorporated shall carry on business or practise as pharmacists except in accordance with this section.

(2) Where the body is a body corporate—

(a) a copy of the certificate of its incorporation shall be lodged with the Board;

(b) the business shall be under the management of a superintendent who is a pharmacist and also a member of its board of directors who is not acting in a similar capacity for any other body corporate;

(c) in each set of premises for the retail sale of pharmaceutical, the business shall be carried on by the superintendent or by a manager or assistant who is a pharmacist and who is subject to the directions of the superintendent;

(d) the name and certificate of registration of the person in control of the shop or wholesale business shall be conspicuously displayed in each set of premises where the business is carried on.

(3) Where the body is a partnership—

(a) a copy of the certificate of its registration under the Business Names (Registration) Act[5], if any, shall be lodged with the Board;

(b) one or more of the partners shall be a pharmacist;

(c) it shall comply with the provisions of subsections (2)(c) and (d).

(4) Where a superintendent, a partner or member of a body of persons, whether corporate or unincorporated carrying on business or practising as a pharmacist dies, the body of persons may, notwithstanding the provisions of subsections (1), (2) and (3), continue to carry on business or practise until such time as the administration of the estate of the deceased is completed, as if such legal representatives were pharmacists.

(5) Nothing in this Act shall be construed as entitling any body of persons, whether corporate or unincorporated, to be registered as pharmacists.

(6) Any body of persons which carries on business or practises as pharmacists in contravention of this section commits an offence and on conviction is liable to a fine not exceeding thirty thousand shillings.

17. Definition of "carrying on business" or "practising as pharmacist"

For the purposes of this Act, a person shall be deemed to be carrying on business or practising as a pharmacist if, for a fee, reward or other valuable consideration, he offers or renders the services ordinarily offered or rendered by persons recognised as skilled in the science and art of preserving pharmaceutical and of compounding and dispensing medicines according to prescriptions of physicians.

18. Restriction on directions by Board

(1) Where an act or omission which, under this Part, may be made the ground of a direction by the Board involving the cesser or restriction of the right of a person to have his name registered, is

5 Cap. 213

an act or omission on the part of an employee of that person, the Board shall not give any such direction unless proof is given to its satisfaction of some one or more of the facts specified in subsection (2) and the Board is of the opinion that, having regard to the facts so proved, that person ought to be regarded as responsible for the act or omission.

(2) The facts someone or more of which the Board must be satisfied before giving the direction referred to in subsection (1) are—

(a) that the act or omission in question was instigated or connived at by that person;

(b) that person or his employee had been guilty, within twelve months immediately preceding the date when the act or omission concerned occurred, of a similar act or omission and that person had, or reasonably ought to have had, knowledge of that previous act or omission;

(c) if the act or omission concerned was a continuing act or omission, that the said person had, or reasonably ought to have had, knowledge of its continuance;

(d) in the case of a criminal offence which is an offence under this Act, that the person had not exercised due diligence to enforce the execution of the Act.

(3) In this section references to the responsibility, knowledge or diligence of the owner of the business shall, if the owner is a body corporate, be construed as references to the responsibility, knowledge or diligence of that body as a whole.

19. Control of recruitment and activities of medical representatives

(1) The Minister may, after consultation with the Board, by order in the *Gazette*, provide for the regulation of the recruitment and the activities of medical representatives.

(2) The Minister may, by an order made under subsection (1), provide for the licensing, registration and payment of fees on application, and may require that persons who may be recruited as medical representatives by any person, shall be persons who have attained a standard of academic education and a measure of practical knowledge of pharmacy, which the Minister, on the recommendation of the Board, may specify.

Part III – Manufacture of pharmaceutical (ss. 20-24)

Licensing of manufacturers (ss. 20-22)

20. Restriction on manufacture of pharmaceuticals

(1) No person shall, on or after the appointed day, manufacture pharmaceutical unless he is the holder of a licence issued by the Board under section 22 for that purpose.

(2) Any person who contravenes or fails to comply with subsection (1) commits an offence and on conviction is liable to a fine not exceeding twenty thousand shillings or to imprisonment for a term not exceeding five years or to both.

21. Register of manufacturers of pharmaceutical

As soon as practicable after the Board has accepted an application by a person for a licence to manufacture pharmaceutical, the Registrar shall enter in a register in relation to that person such particulars as the Board may, from time to time, direct.

22. Application for and grant of licence to manufacture pharmaceutical

(1) Subject to subsection (2), an application for a licence to manufacture pharmaceutical shall be made to the Board in the prescribed manner.

(2) A person shall be granted a licence to manufacture pharmaceutical, if, after satisfying the Board as to his fulfilment of such requirements as the Minister may prescribe by regulations made under section 71, he pays the prescribed fee.

Registration of premises (ss. 23-24)

23. Registration of premises for manufacture of pharmaceutical and for other business of pharmacists

(1) No person shall manufacture pharmaceutical or carry on business or practise as a pharmacist except in premises registered under this section.

(2) The Registrar shall keep a register in the prescribed form of all premises registered under this section.

(3) The Registration of any premises under this section shall cease to have effect upon the expiration of thirty days from the date of any change of the ownership of the business carried on in them.

(4) Any person who contravenes or fails to comply with this section commits an offence and is liable on conviction to a fine not exceeding five thousand shillings or to imprisonment for a term not exceeding twelve months or to both.

24. Application for registration

(1) Every application for registration of premises shall be made to the Board in the prescribed form, and shall be accompanied by such fee, not exceeding one hundred shillings, in respect of the registration of any set of premises, as may be prescribed.

(2) The Board may, for good and sufficient reason to be stated in writing, refuse to register, or may cause to be deleted from the register, any premises which are or have become unsuitable for the manufacture in them of pharmaceutical, or for the lawful carrying on in them of business or practice as a pharmacist.

Part IV – Dealings in pharmaceuticals and poisons (ss. 25-51)

Composition of pharmaceutical (ss. 25-27)

25. Regulations regarding the composition of pharmaceutical

(1) The Minister may, after consultation with the Board, make regulations prescribing minimum standards to be complied with by manufacturers with regard to the composition of pharmaceutical 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 pharmaceutical, or extraction from them, of any specified substance or any substance of any specified category, or the use of any substance as an ingredient in the manufacture or preservation of any pharmaceutical or poisons;

(b) prohibit, restrict or regulate the importation or manufacture, or the sale, possession for sale, or the consignment or delivery, of pharmaceutical, 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 pharmaceutical, 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 pharmaceutical 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.

26. Prohibition on preparation and sale of adulterated pharmaceutical

(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 that 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) commits an offence and on conviction is liable to a fine not exceeding five thousand shillings or to imprisonment for a term not exceeding three years or to both.

(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 publish or arrange for the publication of advertisements, he received the advertisement for publication in the ordinary course of business.

27. General protection for purchasers of pharmaceutical

(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 commits an offence.

(2) Where regulations made under section 25 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 prejudiced.

Pharmaceutical unfit for use by man (ss. 28-29)

28. Offences regarding sale of pharmaceutical unfit for use by man

(1) Any person who—

(a) sells, or offers or exposes for sale, or has in his possession for the purpose of sale or manufacture for sale; or

(b) deposits with, or consigns to, any person for the purpose of sale or of manufacture for sale,

any pharmaceutical product intended, but unfit, for use by man commits an offence.

(2) Where any pharmaceutical product in respect of which an offence under subsection (1)(a) 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 be deposited or to whom he consigned or sold, the pharmaceutical product concerned that it was not intended for use by man; or

(b) that at the time when he 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 diligence have known, that it was unfit.

29. Pharmaceutical offered as prizes

(1) Sections 28 and 58 shall apply in relation to—

(a) any pharmaceutical product intended for use by man, which is offered as a prize 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 had been, exposed for sale by each person concerned in the organisation of the entertainment;

(b) any pharmaceutical product intended for use by man which is offered as a prize or reward or given away for the purpose of advertisement, or in furtherance 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.

Importation of pharmaceutical (ss. 30-32)

30. Restriction on importation of pharmaceutical, etc.

(1) No person shall, engage in the importation of pharmaceutical, or of substances for the manufacture of pharmaceutical, unless he is registered by the Board under this section.

(2) The Registrar shall keep a register in the prescribed form in which he shall enter and maintain the following particulars—

(a) the name and address of every person registered for the purposes of this section;

(b) the date of registration;

(c) the names of the pharmaceutical which he is permitted to import;

(d) the bacteriological effects and chemical composition of the pharmaceutical in respect of which he has been registered as an importer;

(e) such other particulars as the Minister may, from time to time, determine.

(3) The provisions of section 31 shall be complied with by every person registered under this section on every occasion he proposes to import a pharmaceutical product or substance for the manufacture of pharmaceutical, which was not included in his original or, as the case may be, subsequent application for registration.

31. Application and conditions for registration

(1) Every application for registration under section 30 shall be addressed to the Registrar and shall be in the prescribed form.

(2) Upon receipt of an application for registration under section 30, the Board shall, as soon as may be practicable, proceed to consider the application and grant registration where it is due.

(3) The Minister may, by order in the *Gazette*, prescribe factors to which the Board shall have regard when considering applications for registration under section 30.

32. Publication of registered particulars of importers of pharmaceutical

The Registrar shall, at least once in each year, publish in the *Gazette* the particulars in respect of every person registered under section 30.

Poisons (ss. 33-46)

33. List of poisons for purposes of Act

(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—

(a) Part I of the list 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; and

(b) Part II of the list shall consist of poisons which, subject to this Act, shall not be sold except by a person entitled to sell Part I poisons and by persons licensed under section 43.

(3) In determining the distribution of poisons as between the two Parts of the List, regard shall be had to the desirability of restricting Part II 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 Part II if the public are to have adequate facilities for obtaining them.

(4) The Board may, subject to any directions of the Minister given in that behalf, amend or vary the List, from time to time, as it deems proper.

34. Conditions for pharmacist to become authorised seller of poisons

A pharmacist carrying on business comprising the retail sale of pharmaceutical shall be an authorised seller of poisons within the meaning of this Act if—

(a) in each set of premises for the retail sale of drugs, the business is carried on under the personal control of the pharmacist himself or of some other pharmacist; and

(b) the name and certificate of registration of the pharmacist having control of the business are conspicuously exhibited in the premises.

35. Conditions for body corporate to become authorised seller of poisons

(1) A body corporate carrying on business comprising the retail sale of pharmaceuticals shall be an authorised seller of poisons within the meaning of this Act if—

(a) with regard to the keeping, retailing dispensing and compounding of pharmaceutical the business is under the management of a superintendent who—

(i) is a pharmacist;

(ii) has signed, and sent to the Registrar, a statement in writing on behalf of the body corporate stating his name and specifying whether or not he is a member of that body;

(iii) is not at the time acting in a similar capacity for any other body corporate; and

(b) in each set of premises for the retail sale of pharmaceutical, the business is carried on either under the personal control of the superintendent or, subject to his directions, under the personal control of a manager or assistant who is a pharmacist; and

(c) the name and certificate of registration of the superintendent or of some other pharmacist having control of the business is conspicuously exhibited in the premises.

(2) If—

(a) a body corporate which is an authorised seller of poisons has been convicted of an offence under this Act; or

(b) any member of the body corporate or any of its officers, or any officer employed by it in carrying on the business, has been convicted of any criminal offence, or has been guilty of misconduct which, in the opinion of the Board renders him or would, if he were a pharmacist, render him, unfit to be on the register,

the Board may inquire into the matter and may, subject to this Act, direct that—

(i) the body corporate cease to be an authorised seller of poisons, and be disqualified, for a period specified in the direction, from being an authorised seller of poisons; or

(ii) any or all of the premises of the body corporate be removed from the register of premises and be disqualified, for a period specified in the direction, from being registered.

(3) The Board may in any fit case, either on its own motion or on the application of the body corporate concerned, direct the cessation of any disqualification imposed under this section.

36. List of shops and pharmacists in charge

(1) Every authorised 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 pharmaceutical and the name of the pharmacist having the personal control of the business in each set of premises.

(2) Any authorised seller of poisons who fails to comply with this section commits an offence and is 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.

37. Possession of Part I poisons prohibited in certain cases

(1) No person shall have any Part I poison in his possession unless—

(a) he is entitled under this Part to sell that poison or is a wholesale dealer licensed under section 38 to sell poisons; or

(b) the poison has been sold or supplied to him by an authorised seller of poisons in accordance with this Act.

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

38. Wholesale dealer's licence

(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) Subject to any regulations made under section 71, providing for the cancellation or suspension of any licence issued or registration granted under this Act, the Board may, if it is satisfied that the public interest so requires, and upon payment of the prescribed fee, issue to the applicant a licence, or renew the licence, permitting him to deal as a wholesale dealer in poisons.

(3) A separate licence under this section shall be required in respect of each set of premises in which the business of the licensee in the sale of poisons is carried on.

(4) Notwithstanding subsection (2), no licence shall be issued or renewed under this section unless the applicant is, or has a pharmacist who resides in the United Republic, in control of the distribution of the poisons.

(5) Every licence issued under this section shall expire on the 31st day of December of the year in which it is issued, and may be renewed.

(6) The Registrar shall keep a register of all licences issued by the Board under this section.

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

(1) Any person who wishes to carry on, or to continue carrying on, regular business in mining, agricultural or horticultural accessories shall apply to the Board in writing in the prescribed form for a licence authorising him to sell the poisons specified in the licence to persons who require them for a trade or business of mining, agriculture or horticulture.

(2) Subject to any regulations made under section 71 providing for the cancellation or suspension of any licence issued or any registration granted under this Act, the Board may, 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 on, and every such licence shall expire on the 31st day of December in the year in which it is issued, and may be renewed.

(4) The Registrar shall keep a register of all licences issued by the Board under this section.

40. Power to sell Part I poisons

(1) Subject to this Act, a person licensed under section 38 to deal as a wholesale dealer in poisons may sell Part I poisons—

(a) to another person so licensed;

(b) to an authorised seller of poisons;

(c) in respect of the poisons specified in the purchaser's licence, to a person licensed under section 39 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 from 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 or institution concerned with scientific education or research, where the hospital, dispensary, institution or person has been approved in that behalf by the Minister.

(2) Subject to this Act, an authorised seller of poisons may sell Part I poisons to any of the persons and institutions referred to in subsection (1), and may, in addition, sell the poisons to any person who is —

(a) in possession of a prescription of a duly qualified medical practitioner, dentist or veterinary surgeon, in accordance with the prescription; or

(b) in possession of a written certificate to the effect that he may properly be supplied with the poison, such certificate having been issued by a person authorised by the Board in that behalf, a list of which persons shall be published in the *Gazette* from time to time; or

(c) a person known by the seller to be a person to whom the poison may properly be sold.

(3) Subject to this Act, a personal licensed under section 39 to sell poisons for mining, agricultural or horticultural purposes may sell Part I poisons in accordance with that licence.

(4) Subject to subsection (5), any person who—

(a) being an authorised seller of poisons or a person licensed under section 38 or under section 39 to deal in poisons according to the terms of the licence, supplies any Part I poison to any person other than one to whom he is authorised by this section to sell that poison, or contrary to the provisions of this Act relating to the sale of Part I poisons; or

(b) sells any Part I poison in any other manner contrary to this Act,

commits an offence and shall be liable on conviction to a fine not exceeding five thousand shillings or to imprisonment for a term not exceeding twelve months, or to both.

(5) Nothing in this section shall make it illegal for any person to sell or resell to a wholesale dealer licensed under section 38 or to an authorised seller of poisons, any stocks of Part I poisons which are found to be surplus to requirements if—

(a) they are lawfully in the possession of that person under this Act; or

(b) they were lawfully in the possession of that person under the Pharmacy and Poisons Ordinance[6] and are sold by him within a period of six months from the commencement of this Act or such further time as the Minister may by notice in the *Gazette* allow.

41. Poisons Book

(1) Where any Part I 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 40(2)(b) 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 Part I 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 purchaser'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.

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(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 commits an offence and shall be liable on conviction to a fine not exceeding two thousand shillings or to imprisonment for a term not exceeding four months, or to both.

42. Supply and dispensing of Part I poisons by doctors and hospitals

(1) A qualified medical practitioner, dentist or veterinary surgeon, or a member of the staff of a hospital, dispensary or similar institution who has been authorised to do so by the general or special order of the Minister, may supply or dispense a Part I 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 distinctly labelled with the name and address of the person by whom it is supplied or dispensed;

(b) the following particulars shall, within twenty-four hours after the 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 authorised seller of poisons supplies a Part I poison, forming part of the ingredients of medicine for the internal or external treatment of human ailments, and where an authorised seller of poisons supplies a Part I poison on prescription, he shall enter its particulars in a 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 41.

(3) Any person to whom subsection (1) applies and who supplies or dispenses any Part I poison in a manner contrary to this section commits an offence and is liable on conviction to a fine not exceeding five thousand shillings or to imprisonment for a term not exceeding twelve months, or to both.

43. Licence to sell Part II poisons

(1) Every person who, not being otherwise empowered to do so, desires to sell Part II poisons, shall apply in writing in the manner prescribed to the Regional Commissioner in charge of the district in which he proposes to sell the poisons.

(2) If the Regional Commissioner, after consultation with the Regional Medical, Veterinary or Agricultural Officer, as the case may be, is satisfied that the national interest requires that a licence under this section be issued or renewed in order that the public may have adequate facilities for obtaining Part II poisons and that the applicant is a fit and proper person to sell those poisons, and that the premises in which the business is to be carried on are suitable, he may, on payment of the prescribed fee by the applicant, issue or renew the licence.

(3) A licence under this section may be issued in respect of all Part II poisons or in respect of the Part II poisons specified in the licence and the Regional Commissioner may impose on the licence such conditions as he may think fit.

(4) Every licence issued under this section shall be in the prescribed form and shall expire on the 31st December of the year in which it is issued, and may be renewed.

(5) A Regional Commissioner may, after consultation with the Regional Medical, Veterinary or Agricultural Officer, as the case may be, refuse to issue or renew a licence, or may revoke the licence of any person who, in his opinion is, for a reason relating either to the person or to his premises, not fit to hold the licence.

(6) Every Regional Commissioner shall cause to be kept a register in the prescribed form of all licences issued by him under this section, and shall forward to the Registrar a copy of each entry made in it.

(7) The Board may issue general or special directions to Regional Commissioners as to the exercise of the power conferred by this section and every Regional Commissioner to whom the instructions are addressed shall comply and give effect to them.

(8) Where any person aggrieved by an decision made under this section by a Regional Commissioner appeals in accordance with section 66, the decision shall not be quashed on the ground only that the Regional Commissioner failed to consult the Regional Medical, Veterinary or Agricultural Officer as required by subsection (2).

44. Power to sell Part II poisons

(1) Subject to this Act, Part II poisons may be sold by—

(a) a person licensed under section 38 to deal as a wholesale dealer in poisons, to the persons, departments and institutions to whom he is entitled under section 40 to sell Part I poisons, and to persons licensed to sell Part II poisons;

(b) an authorised seller of poisons;

(c) a person licensed under section 39 to sell poisons for mining, agricultural and horticultural purposes, in accordance with that licence; or

(d) a person licensed under section 43 to sell Part II poisons, in accordance with that licence.

(2) Subject to subsection (3), any person who sells Part II poisons in any manner contrary to this Act commits an offence.

(3) Nothing in this section shall make it illegal for any person to sell or resell any stocks of Part II poisons, found to be surplus to requirements, to a wholesale dealer licensed under section 38 or to an authorised seller of poisons.

45. Poisons not to be sold in automatic machines

(1) No poison 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 poison contrary to subsection (1), commits an offence.

46. Disposal of stocks by disentitled persons

(1) Any person who, having been permitted or licensed under this act to possess or sell any poison, becomes for any reason disentitled to possess or sell that poison may, with the consent of the Board and subject to any conditions or directions which the Board may impose, within ninety days from the date of his disentitlement, dispose of any stocks of poison lawfully acquired by him prior to the disentitlement.

(2) The personal representative of any deceased person who immediately before his death was lawfully in possession of any poison under this Act, and any lawfully appointed liquidator, receiver or other person dealing with the property of any person who has ceased to be entitled to possess any poison under this Act may, with the written permission, and subject to the directions of the Board, sell that poison to a licensed wholesale dealer or to an authorised seller of poisons.

Labelling and advertisement (ss. 47-51)

47. Labelling of containers

(1) Subject to subsection (2), every poison shall be supplied in a container labelled in the prescribed manner—

(a) with the name of the poison;

(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;

(c) with the word "Poison" or other prescribed indication of the character of the article;

(d) if supplied on retail or other 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, but not on sale, with the name and address of the supplier.

48. Labelling of articles containing medicine

(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 than 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 an article prescribed by reference to the needs of that person;

(b) for a period of six months from the commencement of this Act.

(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 47;

(ii) in case where the substance, constituent or ingredient is not that poison and is described in any of the monographs contained in the edition of the British Pharmaceutical Codes 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 relation to the active constituents of 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, or the approximate quantity, of each of those constituents or ingredients contained in each portion; and

(c) the expression "container" includes a wrapper.

(4) If any person sells or supplies an article in contravention of this section, subject to this Act, commits an offence and is liable on conviction—

(a) in the case of a first conviction, to a fine not exceeding five hundred shillings; and

(b) in the case of a subsequent conviction, to a fine not exceeding three thousand shillings or to imprisonment for a term not exceeding four months, or to both.

(5) 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 recommended as medicine to prove that—

(a) he did not know, and had no reason to believe, that the article consisted of or comprised such a substance; or

(b) 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.

49. Prohibition of advertisements as to certain diseases

(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) In any proceedings for a contravention of subsection (1), it shall be a defence for the accused person to prove that the advertisement concerned was published only so far as was reasonably necessary to bring it to the notice of one or more of the persons in the following categories—

(a) members of Parliament;

(b) qualified medical practitioners, dentists and veterinary surgeons;

(c) pharmacists, authorised sellers of poisons and licensed wholesale dealers;

(d) persons carrying on a business which includes the sale or supply of surgical appliances,

or that the 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 Second Schedule to this Act.

50. Prohibition of advertisements as to abortion

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 lead to the use of that product, appliance or article for procuring miscarriage by women.

51. False labelling and advertisement

(1) Any person who gives out or displays, 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;

(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 extravagant and bear little or no relation to the therapeutic properties and action of their ingredients or components,

commits an offence, unless he proves to the satisfaction of the court that he did not know, and could not with reasonable diligence have ascertained, that the label concerned was of the character it is alleged to be, and is liable on conviction to a fine not exceeding ten thousand shillings.

(2) Subject to subsection (3), any person who publishes, or is a party to the publication of an advertisement, not being a label given out or displayed by him, which has the same effects as those referred to in subsections (1)(a), (b) or (c), commits an offence and is 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 defendant to prove, either—

(a) that he did not know, and could not with reasonable diligence have known, that the advertisement was of the character described in that subsection; or

(b) that, being a person whose business is to publish or arrange for the publication of advertisement, he received the advertisement for publication in the ordinary course of business.

(4) In any proceedings under this part, 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.

Part V – Enforcement and legal proceedings (ss. 52-67)

Sampling and analysis (ss. 52-55)

52. Power to take samples

(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 pharmaceutical, which appears to him to be intended for sale or to have been sold for use by man, or which is found by him on or in any premises, stall, vehicle, vessel,

aircraft or place which he is authorised to enter for the purposes of ensuring compliance with this Act.

(2) The inspector shall pay or tender payment of the market price of the sample he takes or, if the market price is unknown or not readily ascertainable, a reasonable price, to the person appearing to him to have the lawful custody of the pharmaceutical product a sample of which the inspector takes.

(3) Where the pharmaceutical product or substance a sample of which the inspector intends to take, is kept for retail sale in unopened 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 commits an offence and conviction is liable to a fine not exceeding one thousand shillings or to imprisonment for a term not exceeding six months, or to both.

53. Right to have sample analysed

(1) Any inspector who has procured a sample of any pharmaceutical product or other substance for use in the manufacture of pharmaceutical 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 59 and to any regulations made under section 71, 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.

54. Provisions regarding the taking of samples for analysis

(1) Where any inspector who has taken a sample of any pharmaceutical product or other substance for use in the manufacture of pharmaceutical under section 52 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 parts of the sample, comply with subsection (3).

(2) (a) If the sample was obtained by purchase from a dealer in the pharmaceutical product or substance concerned, the inspector shall permit the vender 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 preceding paragraphs of this subsection 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 he 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 the sample is given that that sample was taken for analysis by the Government Analyst.

(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 that 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 manufactured 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.

55. Where division of sample into parts impracticable

Where an inspector procures a sample consisting of a pharmaceutical product or substance contained in unopened packages and the division into parts of the pharmaceutical product or substance in the packages —

(a) is not reasonable; or

(b) might affect the composition or impede the proper analysis of the contents,

the inspector shall be deemed to have complied with section 54(2) if he divides the containers into the requisite number of lots and deals with each lot as if it were a part in the manner provided by that section and reference in this Act to a part of a sample shall be construed accordingly.

Enforcement (ss. 56-58)

56. Appointment of inspectors

(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 authorise in writing any public officer to be an inspector for the purposes of this Act.

57. Power of inspectors

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

(a) at all reasonable times, enter—

(i) any premises which are 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, he 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 under 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,

commits an offence and is liable on conviction to a fine not exceeding two thousand shillings or to imprisonment for a term not exceeding twelve months or to both.

(3) Without prejudice to the generality of subsections (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 commits an offence and is liable on conviction to a fine not exceeding five hundred shillings.

58. Power to prohibit or control certain medicines

(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 homeopathic medicine, 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) commits an offence and on conviction is liable to a fine not exceeding five thousand shillings.

Legal proceedings (ss. 59-67)

59. Certificate of analysis

(1) In every case in which a sample for analysis is delivered to the Government Analyst under section 54, 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.

(2) Where a sample taken under section 52 has been analysed by the Government Analyst, any person to whom a part of the sample was given in accordance with section 54(2) shall, on payment of the prescribed fee, be supplied with a copy of the certificate by the Government Analyst.

(3) 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.

(4) Any person who, for the purpose of advertisement, uses any certificate of analysis obtained under this section commits an offence and is liable on conviction to a fine not exceeding one thousand shillings.

60. Evidence of analysis

(1) In any proceedings for an offence under this Act, the production by one of the parties of a document purporting to be a certificate of the Government Analyst given under section 59, or of a document supplied to him by the other party as being 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.

(2) In any proceedings for an offence under this Act, if a defendant intends to produce a certificate of the Government Analyst, or to require, under subsection (1), that the person who made the analysis be called as a witness, he shall give notice of that intention to the other party, together, in the former case, with a copy of the certificate, three days before the date fixed for hearing of the case and, if the notice is not given, the court may, if it thinks fit, adjourn the hearing on terms which it considers proper.

(3) If any relevant method of analysis has been prescribed under this Act, evidence of an analysis carried out by that method shall be preferred to evidence of any other analysis or test.

(4) In any proceedings under this Act, where a sample has been procured in circumstances which necessitate the requirement that it be divided into parts, the part of the sample retained by the person who took it shall be produced at the hearing.

61. Presumptions

(1) For the purposes of this Act—

(a) any pharmaceutical product commonly used by man shall, if sold or offered, exposed or kept for sale, be presumed until the contrary is proved, to have been sold or, as the case may be, to have been or to be intended for sale for use by man;

(b) any pharmaceutical product commonly used by man, or any article commonly used in the manufacture of pharmaceutical for use by man, which is found on any premises or in any vessel, vehicle, aircraft or container used for the manufacture, storage, transport or sale of that pharmaceutical product or article, shall be presumed, until the contrary is proved, to be intended for sale or as the case may be for the manufacture of pharmaceutical, for use by man;

(c) any substance capable of being used in the composition or manufacture of any pharmaceutical product commonly used by man which is found on any premises or in any vessel where that pharmaceutical product is manufactured shall be presumed to be intended for that use.

(2) Where any pharmaceutical product for use by man is sold, or deposited with or consigned to any person for the purpose of sale for use by man in an unopened package, any person who appears from any statement on or attached to the package to have enclosed it in that package shall, until the contrary is proved, be deemed to have imported, manufactured or enclosed that pharmaceutical product.

62. When warranty may be pleaded as defence

(1) In any proceedings for an offence which consists of selling, or offering, exposing or advertising for sale or having in possession for the purpose of sale, any pharmaceutical product or substance, it shall be a defence for the defendant to prove—

(a) that he purchased it as being an article or substance which could lawfully be sold or dealt with under the name or description or for the purpose under or for which he sold or dealt with it, and with a written warranty to that effect;

(b) that he had no reason to believe, at the time when the alleged offence was committed, that it was something other than what he said it was in paragraph (a); and

(c) that it was then in the same state as when he purchased it.

(2) A warranty shall only be a defence in proceedings under this Act if—

(a) the defendant—

(i) has, not later than three days before the date of the hearing, sent to the prosecutor a copy of the warranty with a notice that he intends to rely on it and specifying the name and address of the person from whom he received it; and

(ii) has also sent a like notice to that person; and

(b) in the case of a warranty given by a person resident outside the United Republic, the defendant proves that he had taken reasonable steps to ascertain, and did in fact believe in, the accuracy of the statement contained in it.

(3) A defendant who is an employee or agent of the person who purchased the article or substance under a warranty may rely on this section in the same way as his employer or principal would have done had he been the defendant.

(4) The person by whom the warranty is alleged to have been given may appear and give evidence at the hearing, and the court may, if it thinks fit, adjourn the hearing to enable him to do so.

(5) For the purposes of this section and of section 63, a name or description entered in an invoice shall be deemed to be a written warranty that the article or substance to which the entry refers can be sold or dealt with in any other way under that name or description by any person without contravening this Act.

63. Offences in relation to warranties or certificates of analysis

(1) A defendant who in any proceedings under this Act wilfully applies to any article or substance a warranty or certificate of analysis given in relation to any other article or substance commits an offence and on conviction shall be liable to a fine not exceeding one thousand shillings or to imprisonment for a term not exceeding six months, or to both.

(2) Any person who, having sold any article or substance in respect of which a warranty might be pleaded under section 62, gives to the purchaser a false warranty in writing commits an offence, unless he proves that when he gave the warranty he had reason to believe that the statements or description contained in it were accurate, and on conviction is liable to a fine not exceeding three thousand shillings.

64. Recovery of expenses incidental to taking of samples

(1) Where a person is convicted of an offence under this Act, the court may order that all expenses incidental to the taking of any sample or the making of any analysis of any pharmaceutical product in respect of which the conviction is obtained shall be paid by the person convicted.

(2) All expenses recoverable under this section shall be recovered in the same manner as a fine is recovered.

65. Forfeiture

(1) In any proceedings for an offence under this Act, the court before which the offence is tried may, 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.

66. Appeals

(1) Any person aggrieved by a decision of the Board relating to his licence or registration, or to a matter which affects or may affect the validity of his licence or registration, under this Act, may appeal to the High Court against that decision.

(2) The Board may appear as respondent and be heard on any appeal against its decision and, for the purposes of enabling directions to be given as to the costs of the appeal, the Board shall be deemed to be a party to the appeal, whether or not it appears at the hearing of the appeal.

(3) Appeals made under this section shall be regulated by written laws for the time being in force and rules of court made by the Chief Justice relating to the admission and disposal of appeals in criminal proceedings.

(4) Where on an appeal under this section the High Court varies or reverses any decision of the Board, the Board shall give effect to the order of the Court, and in particular, shall grant or renew the licence or registration concerned, as the case may be.

67. Right to carry on business pending appeal

When a decision of the Board or of a court in any proceedings of or an offence under this Act, makes it unlawful for a person to carry on any business which he was lawfully carrying on at the date when that decision was given or to use any premises for any purpose for which he was lawfully using them at that date, he may carry on that business and use the premises for that purpose until the time for appealing has expired, and if any appeal is lodged, until the appeal is finally disposed of or abandoned or withdrawn.

Part VI – Miscellaneous provisions (ss. 68-73)

68. Substances used in local system of therapeutics

(1) Subject to subsection (2), this Act shall not apply to—

(a) the possession, sale or manufacture, of any substance customarily used in a system of therapeutics according to local methods by a person to whom section 37 of the Medical Practitioners and Dentists Act[7] applies, who possesses, sells, prepares, mixes, compounds or in any other way manufactures the substance in a *bona fide* practice of the system; or

(b) the possession by any member of the community to which that person belongs of that substance received from that person.

7 Cap. 152

(2) Nothing in this section shall be construed as authorising any person—

(a) to sell or manufacture any substance to or for any person other than a member of the community to which he belongs; or

(b) to sell or supply that substance in quantities or preparations which are, or are likely to be, dangerous to life; or

(c) to add any substance manufactured by him to any pharmaceutical manufactured in a system of therapeutics other than his system.

69. Liability of members of Board

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.

70. Power to delegate

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.

71. Regulations

(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 Part I 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 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 39 or section 43, or 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 articles or substances or for dispensing with or relaxing any provision contained in Part IV of this Act with respect to poisons;

(d) providing for the better regulation of the manufacture, sale or advertising of pharmaceutical, poisons and therapeutic substances;

(e) the safe custody, storage and transport of pharmaceutical and poisons;

(f) the effective regulation of the importation, exportation, and labelling of pharmaceutical 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 8(1)(c);

(l) 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.

72. By-laws by Board

1 The Board may, with the consent of the Minister make by-laws 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 by-laws—

(a) prescribe diplomas which shall be recognised as entitling the holder to registration under this Act;

(b) prescribe ethics 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) By-laws made by the Board under this section shall be published in the *Gazette*.

73. General penalty

(1) Any person who commits an offence under this Act for which no specific penalty is provided, on conviction is liable, in the case of a first offence, to a fine not exceeding two thousand shillings or to a sentence of imprisonment for a term not exceeding six months and in the case of a second offence, to a fine not exceeding six thousand shillings, and in the case of a subsequent offence, to a fine not exceeding ten thousand shillings.

(2) Where the court is of the opinion, in the case of a second or subsequent offence, that a fine will not meet the circumstances of the case and that the offence was committed through the personal act, default or culpable negligence of the accused person, it may, in lieu of or in addition to any fine, impose a sentence of imprisonment for a term not exceeding four years.

[s. 72A]

Part VII – Repeal and consequential provisions (ss. 74-76)

74. Repeal of R.L. Caps. 93 and 416

(1) The Food and Drugs Ordinance[8], in so far as it relates to the regulation of the manufacture, importation and sale of pharmaceutical, is hereby repealed.

(2) *[Repeals the Pharmacy and Poisons Ordinance[9].]*

8

R.L. Cap. 93

9

(3) Subject to the provisions of this part, every licence or permit and every registration issued to or granted in respect of any person under the Food and Drugs Ordinance[10] or under the Pharmacy and Poisons Ordinance[11], entitling that person to deal in any manner with pharmaceutical and poisons, or to carry on business in any other way as a pharmacist, shall, from the commencement of this Act, be deemed to have been revoked.

[s. 73]

75. Savings

Notwithstanding the repeal of the Food and Drugs Ordinance[12] as it relates to pharmaceuticals, and that of the Pharmacy and Poisons Ordinance—[13]

(a) all subsidiary legislation made under the Food and Drugs Ordinance in relation to pharmaceutical, and all subsidiary legislation made under the Pharmacy and Poisons Ordinance, which is in force on the commencement of this Act, 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;

(b) all officers appointed under the Food and Drugs Ordinance or the Pharmacy and Poisons Ordinance to perform functions in relation to the control of the manufacture, importation or sale of pharmaceutical and poisons, and also in relation to the regulation of the profession of pharmacy, shall continue to perform those duties in so far 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.

[s. 74]

76. Transitional provisions

Notwithstanding any provision in this Act to the contrary, the Minister may, on the recommendation of the Board and upon being satisfied that special circumstances exist which make it just and equitable to do so, permit any person who was licensed, registered or permitted in any other way under the Food and Drugs Ordinance[14] or the Pharmacy and Poisons Ordinance[15] to deal in any manner with or in connection with pharmaceutical or poisons to continue doing so after the appointed day, upon conditions determined by the Minister.

[s. 75]

R.L. Cap. 416

10 R.L. Cap. 93

11 R.L. Cap. 416

12 R.L. Cap. 93

13 R.L. Cap. 416

14 R.L. Cap. 93

15 R.L. Cap. 416

First Schedule (Section 3(2))

1. **Composition of Board**

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 or his representative;

(d) the Chief Agricultural Officer;

(e) the Chief Pharmacist in the service of the Government;

(f) the Government Chemist;

(g) two pharmacists appointed by the Minister;

(h) one qualified medical practitioner appointed by the Minister;

(i) three other members appointed by the Minister.

2. **Vice-Chairman**

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

3. **Tenure of office**

A member appointed under paragraph 1(g), (h) and (i)—

(a) shall, unless his appointment is sooner terminated by the Minister, or he 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.

4. **Meetings of the Board**

(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.

5. **Quorum**

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

6. **Decisions of the Board**

(1) Subject to subparagraph (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 an 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.

7. **Minutes of meetings**

(1) The Board shall cause to be recorded and kept details of all business conducted or transacted at its meetings, and the minutes 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 that meeting.

(2) Any minutes 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 minutes they purport to be.

8. **Vacancies not to invalidate proceedings**

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.

9. **Board may regulate its own proceedings**

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

10. **Proof of documents**

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 authorised to receive evidence and shall, unless the contrary is shown, be deemed, without further proof, to be sufficient evidence of what is contained in the document.

Second Schedule (Section 49(1))

Purposes for which pharmaceutical 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 or bilharzia, ankylostomiasis or hookworm, cancer, consumption or tuberculosis, leprosy, lupus, diabetes, epilepsy or fits, locomotor ataxy, paralysis, or infantile paralysis.

3. The cure of arteriosclerosis, septicaemia, diphtheria, dropsy, erysipelas, gallstones, kidney stones and bladder stones, goitre, heart disease, tetanus or lockjaw, pleurisy, pneumonia, scarlet-fever, smallpox, tracheoma, 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 sexual functions.

Third Schedule

Forms

[Editorial note: The forms have not been reproduced]