GOVERNMENT OF ZAMBIA

ACT

No. 14 of 2004

Date of Assent: 2/9/04

An Act to establish the Pharmaceutical Regulatory Authority and to define its functions; to provide for the registration and regulation of pharmacies; to provide for the registration and regulation of medicines intended for human use and for animal use; to provide for the regulation and control of medicines, herbal medicines and allied substances; to provide for the regulation and control of the manufacture, importation, exportation, possession, storage, distribution, supply, promotion, sale and use of medicines, herbal medicines and allied substances; to repeal the Pharmacy and Poisons Act, 1940 and the Therapeutic Substances Act, 1968; and to provide for matters connected with or incidental to the foregoing.

[8th September, 2004

ENACTED by the Parliament of Zambia. Enactment

PART I
PRELIMINARY

1. This Act may be cited as the Pharmaceutical Act, 2004, and shall come into operation on such date as the Minister may, by statutory instrument, appoint. Short title and commencement

2. In this Act, unless the context otherwise requires— Interpretation

"administer" means to give a substance to a human being or an animal, orally, by injection or by introduction into the body in any other way, or by external application, whether by direct contact with the body or not, and any reference to administering a substance or article is a reference to administering it either in its existing state or after it has been dissolved or dispensed in, or diluted or mixed with, some other substance;

"allied substances" include cosmetics, disinfectants, food supplements, feed additives, medical and surgical sundries, medical devices, condoms and blood products;

"animal clinical trial" means an investigation consisting of the administration of a medicine under the direction of a veterinary surgeon;

"appointed date" means the date appointed under section *one;*

"assemble" in relation to a medicine means—

(a) enclosing the medicine, with or without other medicine of the same description, in a container which is labelled before the medicine is sold or supplied; or

(b) where the medicine, with or without other medicines of the same description is already enclosed in the container before the medicine is sold or supplied labelling the container before the medicine is supplied;

"Authority "means the Pharmaceutical Regulatory Authority established by section *four;*

"Board "means the Pharmaceutical Regulatory Authority Board constituted under section *eight;*

"Chairperson" means the person appointed as Chairperson of the Board under section *eight;*

"clinical trial" means an investigation consisting of the administration of a medicinal product under the direction of a medical practitioner or a dental surgeon;

"committee" means a committee of the Authority established under section *nine;*

Cap. 297 "dental surgeon" means a person registered as a dental surgeon under the Medical and Allied Professions Act;

"Director- General" means the person appointed as Director-General under section *eleven;*

"dispense" means to count, measure or decant a medicine from a bulk supply or to prepare, mix, dissolve or supply a medicine for the treatment of a person or animal but does not include the administration of medicine;

"herbal medicine" means any medicinal product that contains, as active ingredients, aerial or underground parts of plants, other plant materials or combinations thereof, whether in a crude state or as plant preparations and includes herbal medicines which contain natural, organic or inorganic active ingredients and are processed or packaged in such a manner that they appear like medicines under the western system but does not include medicines containing plant material combined with chemically defined active substances, or chemically defined isolated constituents of plants;

"hospital" means any institution established as a hospital and includes a clinic, nursing home, health centre, surgery, consulting room, hospice and any other facility authorised to dispense medicines and drugs;

THE PHARMACEUTICAL ACT, 2004

ARRANGEMENT OF SECTIONS

PART I

PRELIMINARY

Section

PART II

THE PHARMACEUTICAL REGULATORY AUTHORITY

PART III

REGISTRATION OF PHARMACIES

PART IV

LICENCES

Single copies of this Act may be obtained from the Government Printer, P.O. Box 30136, 10101 Lusaka. Price K10,000 each

" hospital pharmacy " means a pharmacy which is part of a hospital;

" import licence " means a licence issued under section *twenty-three* of this Act;

" ingredient " in relation to the manufacture or preparation of a substance, includes anything which is the sole active ingredient of that substance;

" inspector " means a person appointed as an inspector under section *fifty-nine;*

" label " means to affix to, or otherwise display on a container or package, a notice describing the ingredients and contents thereof;

" manufacture ", in relation to a medicine, herbal medicine or allied

substance includes any process carried out in the course of making that medicine or allied substance but does not include the process of—

(a) dissolving or dispensing a product in, or diluting or mixing it with some other substance for purposes of administering it; or

(b) the incorporation of a medicine in any animal feed;

" manufacturer's licence " means a manufacturer's licence issued under section *twenty-one;*

" Medicines Committee " means the Medicines Committee constituted under section *nine;*

" medicines list " means a list of medicines prepared pursuant to section *forty-one;*

" medical practitioner " means a person who is registered as a medical practitioner under the Medical and Allied Professions Act; Cap. 297

" medicine " means any substance or mixture of substances other than a herbal medicine intended to be used or manufactured for use for its therapeutic efficacy or for its pharmacological purpose in the diagnosis, treatment, alleviation, modification or prevention of disease or abnormal physical or mental state or the symptoms of disease in a person and includes a medicinal product, drug and veterinary medicine;

" member " means a person appointed as a member of the Board under section *eight;*

"package" means anything in or by which any medicine, herbal medicine, therapeutic substance or allied substance is enclosed, covered, contained or packed;

" pharmacy registration certificate " means a certificate of registration issued in respect of a pharmacy under section *thirteen;*

" poison " means any substance which is on the poisons list that is prepared pursuant to section *fifty-five;*

"preparation" includes compound, mixture and salt;

"prescription" means a written direction given by an authorised prescriber directing that a stated amount of a medicine specified in the direction be dispensed for the person or animal named in the direction;

" prescription only medicine "means a medicine dispensed only on prescription;

" product licence " means a licence issued under section *thirty-seven;*

Cap. 297 " registered pharmacist " means a person registered as a pharmacist under the Medical and Allied Professions Act;

" registered nurse " means a person registered as a nurse under
Act No. 31 of 1997 the Nurses and Midwives Act;

"registered pharmacy" means a business or premises registered as a pharmacy under section *thirteen* of this Act;

" registered midwife " means a person registered as a midwife
Act No. 31 of 1997 under the Nurses and Midwives Act;

"sell" means to offer for sale, expose for sale, have in possession for sale, or distribute whether or not the distribution is made for consideration;

Cap. 119 " Society " means the Pharmaceutical Society of Zambia which is registered under the Societies Act;

" substance " means any natural or artificial substance whether in solid or liquid form and shall include gasses or vapour;

" veterinary medicine " means any substance or mixture of substances, other than a stock remedy or farm feed, used, manufactured or sold for the treatment, diagnosis, prevention or cure of any disease, infection or other unhealthy condition or for the maintenance or improvement of health, growth, production or working capacity, or correcting or modifying behaviour in an animal;

"veterinary surgeon" means a person registered as a veterinary surgeon under the Veterinary Surgeons Act; Cap. 243

"veterinary surgery" means a facility for the diagnosis, treatment, mitigation, modification or prevention of disease or abnormal physical state or condition in an animal; and

"wholesale dealer's licence" means a wholesale dealers licence issued under section *twenty-two* of this Act.

Application

3. (1) This Act does not apply to a traditional health practitioner who practises traditional medicine in a traditional setting.

(2) In this section "traditional setting" means a village or rural setting and includes the practice of traditional medicine in an urban setting as long as the practice is restricted to the treatment of specific patients and is not done for commercial purposes.

PART II

THE PHARMACEUTICAL REGULATORY AUTHORITY

Establishment of Authority

4. (1) There is hereby established the Pharmaceutical Regulatory Authority which shall be a body corporate with perpetual succession and a common seal, capable of suing and of being sued in its corporate name, and with power, subject to the provisions of this Act, to do all such acts and things as a body corporate may by law do or perform.

(2) The provisions of the First Schedule shall apply to the Authority.

Functions of Authority

5. (1) The functions of the Authority shall be to—

(a) register medicines, herbal medicines and licence allied substances;

(b) register pharmacies and licence any premises used for purposes of manufacturing, importing, exporting, distribution and sale of medicines, herbal medicines and allied substances;

(c) regulate and control the manufacture, importation, exportation, distribution and sale of medicines, herbal medicines and allied substances;

(d) regulate and control the advertising and promotion of medicines, herbal medicines and allied substances;

(e) in consultation with the Society establish, maintain and develop standards for the operation of pharmacies;

(f) serve and protect the public interest in all matters relating to the sale of medicines, herbal medicines and allied substances;

(g) regulate and monitor the conduct of clinical trials on human beings and animals;

(h) establish, maintain and enforce standards relating to the manufacture, importation, exportation, distribution and sale of medicines, herbal medicines and allied substances;

(i) conduct postmarket surveillance and monitor adverse drug reactions;

(j) manage the National Drug Quality Control Laboratory;

(k) establish, maintain and enforce standards for privately owned drug quality control laboratories;

(l) coordinate and manage national drug formulary activities;

(m) advise the Government on policies relating to the regulation and control of medicines, herbal medicines and allied medicines;

(n) establish and maintain a relationship with corresponding pharmaceutical authorities in other countries;

(o) in consultation with the National Science and Technology Council and other relevantresearch institutions, determine national research and development priorities in pharmacy;

(p) administer this Act and perform duties and exercise powers which are imposed on the Authority by this Act; and

(q) do all such things as are connected with or incidental to the functions of the Authority under this Act.

(2) The Authority may, by direction, in writing and subject to such conditions as the Authority thinks fit, delegate to the Director-General or to any member or any committee any of its functions under this Act.

Powers of Authority

6. (1) The Authority shall have power to—

(a) direct any pharmacy or person providing services relating to the manufacture, importation, exportation, distribution and sale of medicines, herbal medicines and allied substances to deliver its services in such manner as to ensure compliance with this Act;

(b) require any pharmacy, manufacturer, wholesale dealer, distributor, importer, exporter or person to submit such information and records as may be necessary to enable the Authority to monitor the performance of such pharmacy, manufacturer, wholesale dealer, distributor, importer or exporter;

(c) consider any matter relating to the manufacture, importation, exportation, distribution and sale of medicines, herbal medicines and allied substances and make representations thereon to the Minister; and

(d) to require any person who is in control of a registered pharmacy to inform the Authority of the intention to move from the registered premises prior to relocating.

Authority may recall medicine, etc. from circulation

7. If the Authority is of the opinion that it is not in the public interest that any medicine, herbal medicine or allied substance should be made available to the public, the Authority may by notice in writing served on any person or in the *Gazette*, direct such person to return such medicine, herbal medicine or allied substance which the person has in that person's possession to—

(a) the manufacturer of the medicine, herbal medicine or allied substance; or

(b) in the case of any imported medicine, herbal medicine or allied substance, to the importer concerned; or

(c) deliver it or send it to the Authority or such other person as the Authority may designate.

(2) The Authority may, by notice in writing, direct any manufacturer or importer of the medicine, herbal medicine or allied substance referred to in subsection (1) or the person referred to in paragraph *(c)* of subsection (1) who has in their possession any quantity of such medicine, herbal medicine or allied substance, including the returned quantity to deal with or dispose of that quantity in such manner as the Authority may determine.

(3) A person shall not sell any medicine, herbal medicine, or allied substance which is the subject of a notice under subsection (1).

(4) Any person who contravenes subsection (3) commits an offence and is liable, upon conviction to a fine of not less than fifty thousand penalty units but not exceeding one hundred thousand penalty units or to imprisonment for a term of not less than six months but not exceeding five years, or to both.

Constitution of Board

8. (1) There is hereby constituted the Pharmaceutical Regulatory Authority Board which shall, subject to the provisions of this Act, perform the functions of the Authority under this Act.

(2) The Board shall consist of part-time members appointed by the Minister as follows:

(a) five representatives of the Pharmaceutical Society of Zambia;

(b) a representative of the Medical Association of Zambia;

(c) a representative of the Medical Council of Zambia;

(d) a representative of the Department of Pharmacy of the University of Zambia;

(e) a representative of the pharmaceutical manufacturers;

(f) a representative of the General Nursing Council;

(g) a representative of the consumer Association of Zambia;

(h) a representative of the ministry responsible for health;

(i) a representative of the Traditional Healers Association of Zambia;

(j) a representative of the ministry responsible for Veterinary Services;

(k) a representative of the ministry resonsible for local government;

(l) a representative of the Veterinary Association of Zambia;

(m) a representative of the School of Veterinary Sciences of the University of Zambia;

(n) a representative of the Environmental Council of Zambia;

(o) a representative of the Attorney General; and

(p) one other person.

(3) The members referred to in subsection (2) shall be nominated by the organisations or institutions which they represent.

(4) The Chairperson and the Vice-Chairperson shall be elected by the members of the Board from among their number.

(5) A person shall not be appointed as a member of the Board if the person—

(a) is an undischarged banlcrupt;

(b) has been convicted of an offence relating to medicines, drugs, pharmacy, dangerous drugs or poisons under this Act or any other written law;

(c) has been convicted of an offence involving fraud or dishonesty;

(d) has been convicted of an offence under any other written law and sentenced to a term of imprisonment of not less than six months without the option of a fine; or

(e) is an employee of the Authority.

Medicines Committee and other committees

9. (1) The Board shall constitute a Medicines Committee which shall consist of the following members:

(a) a clinical pharmacologist;

(b) two registered pharmacists with specialisation or experience in quality control of medicines or the formulation and manufacture of medicines;

(c) a person licensed to deal in herbal medicines or who has expertise relating to herbal medicines;

(d) a medical practitioner;

(e) a veterinary surgeon; and

(f) a senior member of staff of the Authority responsible for medicine control who shall be an *ex-officio* member.

(2) The senior member of staff referred to in paragraph *(f)* of subsection (1) shall be the Secretary to the Committee.

(3) The functions of the Medicines Committee shall be to advise the Board on—

(a) licensing of medicines or medicinal products;

(b) monitoring the advertisements and promotion of medicines, herbal medicines and allied substances;

(c) monitoring standards relating to medicines, herbal medicines and allied substances;

(d) monitoring the conduct of clinical trials and animal clinical tests; and

(e) any other matter referred to it by the Board.

(4) The Chairperson and the Vice-chairperson shall be elected by the members from among their number.

(5) Three members of the Medicines Committee shall form a quorum.

Provided that at least one of the members present shall be a registered pharmacist.

(6) The Board may, for the purpose of performing its functions under this Act, constitute such other committees as it considers necessary and may delegate to any such committee such of its functions as it considers fit.

(7) The Board may appoint as members of a committee, persons who are, or are not, members of the Board, except that at least one member of a committee shall be a member of the Board.

(8) A person serving as a member of a committee shall hold office for such period as the Board may determine.

(9) Subject to any specific or general direction of the Board, a committee may regulate its own procedure.

Constitution of Secretariat

10. There is hereby constituted the Secretariat of the Authority which shall have the function of implementing, on a day to day basis, the decisions of the Board.

Director-General and other staff

11. (1) Subject to subsection (2), the Board shall, with the approval of the Minister appoint a Director-General who shall be the chief executive officer of the Authority and who shall, subject to the control of the Board, be responsible for the day to day administration of the Authority.

(2) The Board shall with the approval of the Minister determine the terms and conditions for the Director-General.

(3) The Director-General shall be appointed for a term of four years and shall be eligible for re-appointment.

(4) A person shall not be appointed as Director-General unless the person is—

(a) a registered pharmacist; or

(b) holds such qualifications as the Board may determine.

(5) The Director-General shall attend meetings of the Board of the Authority and of any committee and may address such meetings, but shall have no vote.

(6) The Director-General shall be the Secretary to the Authority.

(7) The Authority may appoint, on such terms and conditions as it may with the approval of the Minister determine, such other staff of the Authority as it considers necessary for the performance of its functions under this Act.

PART III

REGISTRATION OF PHARMANCIES

No one to carry on the business of pharmacist unless registered

12. (1) Subject to the other provisions of this Part a person who is not a registered pharmacist shall not—

(a) carry on, either on that person's own behalf or on behalf of another person the business of a pharmacist;

(b) in the course of any trade or business—

(i) procure, supply, package, label, prepare, admix, compound, sell or dispense any medicine or allied substance or supply any poison; or

(ii) assure quality of medicines in practice;

except under the immediate supervision of a registered pharmacist;

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

(2) For the purpose of paragraph *(c)* of subsection (1), the use of the word "pharmacist" or "chemist" or "druggist" or any similar word or combination of words shall be considered to be reasonably calculated to suggest that the person having control of the business on those premises is a registered pharmacist.

Pharmacy registration certificate

13. (1) A person who wishes to operate a pharmacy shall, at least sixty days prior to the date the person intends to operate such pharmacy make an application for a pharmacy registration certificate in the prescribed form to the Director-General and provide evidence satisfactory to the Authority—

(a) regarding the ownership of the pharmacy;

(b) regarding the suitability of the premises for use as a pharmacy; and

(c) that a registered pharmacist will manage and control the pharmacy at all times that the practice of pharmacy is being engaged in.

(3) Where the applicant is not a registered pharmacist the application shall state the name of the registered pharmacist who is designated by the applicant as the manager of the pharmacy.

(4) Where the applicant is a corporation, the application shall state—

(a) the name of the registered pharmacist who is designated by the applicant as the manager of the pharmacy;

(b) the name of every director of the corporation who is a registered pharmacist if any; and

(c) the names and addresses of the directors of the corporation.

(5) The Authority shall, within sixty days of receipt of an application under subsection (1), issue a registration certificate, subject to such terms and conditions as the Authority may specify if the applicant and the pharmacy and its proposed operation satisfy the requirements of this Act.

(6) A registration certificate issued under this section shall be valid for such period as may be specified in the registration certificate and shall be renewable for a like period if the applicant has been complying with the provisions of this Act and upon payment of a prescribed fee.

(7) Where the Authority is not satisfied with an application to issue a pharmacy registration certificate the Authority shall within sixty days of receiving the application, refuse to issue the registration certificate to the applicant and shall state the reason for the refusal.

(8) Every person carrying on the business of a pharmacist shall cause each set of premises where such business is carried on to be registered in accordance with this section.

(9) The Authority shall keep a register of pharmacies registered under subsection (1).

(10) The Authority shall every year, publish in the *Gazette,* a list of all pharmacies registered under this Act.

Prohibition of operating pharmacy without registration

14. (1) No person shall establish or operate a pharmacy except under the authority of a pharmacy registration certificate issued under section *thirteen.*

(2) Any person who contravenes subsection (3) commits an offence and is liable, upon conviction to a fine of not less than fifty thousand penalty units but not exceeding two hundred thousand penalty units or to imprisonment for a term of not less than six months but not exceeding five years, or to both.

Name and certificate of registration to be exhibited on premises

15. A person shall not carry on the business of a pharmacist unless the name and certificate of registration of the person having control of the premises in which such business is carried on are conspicuously exhibited in the premises.

Practice in a registered pharmacy

16. A registered pharmacist may engage in the practice of retail pharmacy only in a registered pharmacy.

Management of hospital pharmacies

17. (1) Notwithstanding the provisions of any other written law, a hospital pharmacy shall be managed by a registered pharmacist:

Provided that the Minister may, on the recommendation of the Authority, by regulations provide for circumstances under which a hospital pharmacy may be operated by a pharmacy technician or such other person with the recognised health related qualifications and registered with a relevant registration body as the Authority may determine, under the supervision of a registered pharmacist.

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(2) In this section "pharmacy technician" means a person registered as a pharmacy technician under the Medical and Allied Professions Act.

Standards of pharmacy practice

18. For the purposes of this Part the Minister may, in consultation with the Society and on the recommendation of the Authority, by regulations, determine standards for the practice of pharmacy in pharmacies and hospital pharmacies.

Offences and penalties

19. Any person who contravenes the provisions of this Part commits an offence and shall be liable, upon conviction, to a fine not exceeding fifty thousand penalty units or to imprisonment for a term not exceeding five years, or to both.

PART IV

LICENCES

Prohibition of manufacture, etc. of medicines without licence

20. (1) No manufacturer, wholesale dealer, importer or distributor referred to in this Part shall manufacture, act as a wholesale dealer of, import or distribute, as the case may be, any medicines or allied substances unless that manufacturer, wholesale dealer, importer or distributor is a holder of a licence issued under this Part.

(2) Notwithstanding the provisions of subsection (1), a person may, subject to subsection (3), import medicines or allied substances for that person's own use but the amount so imported shall not exceed one year's supply.

(3) The Authority may require any person who imports medicines or allied substances for their own use to obtain clearance from the Authority at the port of entry of such medicines or allied substances.

(4) Any person who contravenes subsection (1) commits an offence and shall be liable, upon conviction, to a fine not exceeding twenty thousand penalty units or to imprisonment of a term not exceeding five years, or to both.

Manufacturer's licence

21. (1) Upon application by a manufacturer to the Director-General in the prescribed form and upon payment of the prescribed fee, the Authority may issue to such manufacturer a licence to manufacture medicine or allied substances upon such conditions as to the application of such acceptable quality assurance principles and good manufacturing practices as the Authority may determine.

(2) The Authority shall grant the licence referred to in subsection (1) if it is satisfied with—

(a) the proposed manufacturing operations to be carried out under the licence;

(b) the premises on which the medicines or allied substances shall be manufactured;

(c) the equipment available at the premises to be utilised for purposes of manufacturing the proposed medicines or allied substances;

(d) the qualifications of the persons employed to supervise the manufacturing or any medicines or allied substances; and

(e) the arrangements made for securing the custody of records on all medicines or allied substances manufactured by the applicant.

(3) An application under subsection (1) shall—

(a) specify the manufacturer's name, address and nationality and if the manufacturer is a company, its registered office and the names, addresses and nationalities of the directors and of any shareholder who is the beneficial owner of more than five per centum of the issued capital;

(b) give a full description of the medicines or allied substances which the manufacture intends to manufacture; and

(c) be accompanied by such documents, materials, samples and other information relating to the medicine or allied substances as the Authority may require.

Wholesale dealer's licence

22. (1) Upon application by a wholesale dealer to the Director-General in the prescribed form and upon payment of the prescribed fee, the Authority may issue to such wholesale dealer a wholesale dealer's licence where the Authority is satisfied with—

(a) the premises on, and the facilities in, which the medicines or allied substances shall be stored;

(b) the equipment available for storing the medicines or allied substances;

(c) the equipment and facilities available for distributing the medicines or allied substances from the premises;

(d) the qualifications of the persons under whose supervision the operations shall be carried out; and

(e) the arrangements for securing the records in respect of medicines or allied substances stored on, or distributed from, the premises.

(2) A wholesale dealer licenced under this section shall not supply medicines or allied substances to persons other than those persons specified by the Authority under the wholesale dealer's licence.

Import or export licence

23. Upon application by an importer or exporter to the Director-General in the prescribed form and upon payment of the prescribed fee, the Authority may issue to such importer or exporter a licence to import or export medicines or allied substances if the Authority is satisfied with—

(a) the quality, safety and efficacy of the medicines or allied substances to which the application relates; or

(b) in relation to the medicines or allied substances which are to be imported—

(i) the premises on, and the facilities in, which the medicines or allied substances shall be stored; and

(ii) the equipment and facilities available for distributing the medicines or allied substances.

Refusal to issue licence

24. (1) The Authority may refuse to issue a licence under this Part if—

(a) the applicant fails to comply with any prescribed conditions precedent to the issue of such licence;

(b) any licence formerly issued to the applicant under this Part has been revoked by the Authority;

(c) the applicant has been convicted of an offence under this Act; and

(d) the applicant has been convicted of an offence relating to the practice of pharmacy in Zambia or in any other country or the person's licence was withdrawn by the parmaceutical authority of another country.

(2) The Authority shall notify the applicant in writing of the refusal to issue a licence under this section and shall state the reasons for the refusal.

Appeal against refusal to issue licence

25. (1) Any person aggrieved by any refusal of the Authority to issue a licence to that person may appeal to the Minister not later than thirty days after the notification of such refusal.

(2) Where an appeal is made under subsection (1), the Minister may give such directions to the Authority as the Minister considers necessary to enable the Minister to determine the appeal.

(3) The Minister in determining the appeal may direct the Authority to issue the licence to the applicant or uphold the decision of the Authority and notify the appellant accordingly.

(4) Any person who is aggrieved by the decision of the Minister to uphold the Authority's decision under subsection (3) may appeal to the High Court within thirty days of the receipt of the notification of the Minister's decision.

Revocation of licence

26. (1) Subject to subsection (2), the Authority may suspend or revoke any licence issued under this Part if satisfied that the licensee has failed to comply with any of the conditions relating to the licence.

(2) Where the Authority intends to suspend the licence under subsection (1) the Authority shall, at least twenty-one days before suspending the licence, give notice in writing to the licensee of the intention to suspend the licence of such licensee.

(3) Where the Authority intends to revoke the licence under subsection (1), the Authority shall, at least two months before revoking the licence, give notice in writing to the licensee of the intention to revoke the licence of such licensee.

(4) The notice referred to in subsection (2) or (3) shall state the reasons for the intended suspension or revocation and require the licensee to show cause, within thirty days of receipt of the notice, why the licence should not be so suspended or revoked.

(5) If the Authority is not satisfied with the explanation given by the licensee, the Authority shall suspend or revoke, as the case may be, the licence and notify the licensee accordingly.

(6) Any person who is aggrieved by the decision of the Authority to suspend or revoke a licence under this section may within thirty days of receipt of the notice of the revocation under subsection (5) appeal to the High Court.

Duration of licences

27. (1) A licence granted under this Part shall authorise the licensee to sell, manufacture, distribute, import or export medicines or allied substances in accordance with the provisions of this Act upon the premises specified in the licence and shall—

(a) in the case of a wholesale dealer's licence, an export licence or an import licence be valid for a period of one year from the date of issue; or

(b) in the case of a manufacturing licence be valid for a period of five years from the date of issue.

(2) Upon the expiry of any licence issued under this Part, the holder of such licence may within sixty days before the expiry of such licence apply to the Authority for renewal.

(3) An application for renewal under subsection (2) shall be in the prescribed form and shall be accompanied by the prescribed fee.

Licence Register

28. The Authority shall maintain a register in the prescribed form of licences issued under this Act, which shall contain such particulars as the Authority may consider necessary.

Power of Minister to regulate

29. The Minister may, on the recommendation of the Authority, by statutory instrument, prescribe—

(a) the form of, and the terms and conditions attached to, each licence; and

(b) the appropriate fee payable in respect of each licence issued under this Part.

Licences not transferrable

30. (1) Except as otherwise provided by this Act, any licence issued under this Part shall be used solely by the licensee and shall not be transferable to any other person.

(2) Any person who transfers a licence issued to that person or accepts the transfer of any licence commits an offence and shall be liable, upon conviction, to a fine not exceeding twenty thousand penalty units or to imprisonment for a term not exceeding two years, or to both.

Exemption of qualified medical practitioners and other persons

31. The provisions of this Part with respect to licensing, shall not apply to medicines or allied substances supplied by—

(a) a duly qualified medical practitioner, dentist, veterinary surgeon, registered nurse and a registered midwife in the ordinary course of practice of that medical practitioner, dentist, veterinary surgeon, registered nurse or registered midwife;

(b) any employee of the Government in the course of that employee's duties; or

(c) any hospital, dispensary or similar institution exempted by the Minister, on the recommendation of the Authority, by statutory order, whether general or special.

Offences and penalties

32. (1) Any person who fraudulently obtains a licence under this Part commits an offence and shall be liable, upon conviction, to a fine not exceeding one hundred thousand penalty units or to imprisonment to a term not exceeding seven years, or to both.

(2) Any person who—

(a) deals in unregistered medicines or allied substances;

(b) fails to maintain records for medicines or allied substances registered under this Act; or

(c) obtains medicines or allied substances from unauthorised suppliers;

commits an offence and shall be liable, upon conviction, to a fine not exceeding three hundred thousand penalty units or to imprisonment to a term not exceeding ten years, or to both.

(3) In addition to the penalty provided in subsection (1) and (2) the court before which a person is convicted of an offence under this section may order that any medicines or allied substances in respect of which the offence is committed be forfeited to the State.

Prohibition of manufacture, etc. of substandard, counterfeit or adulterated medicines

33. (1) A person shall not manufacture, import, export, distribute or sell substandard, counterfeit or adulterated medicines or allied substances.

(2) A person who contravenes subsection (1) commits an offence and shall be liable, upon conviction, to a fine of not less than three hundred thousand penalty units but not exceeding five hundred thousand penalty units or to imprisonment for a term of not less than five years but not exceeding ten years, or to both.

(3) In addition to the penalty provided in subsection (2) the court before which a person is convicted of an offence under this section may order that any medicines or allied substances in respect of which the offence is committed be forfeited to the State to be destroyed.

Prohibition of supply of expired medicines

34. (1) A person shall not supply or sell an expired medicine or allied substance.

(2) A person who contravenes subsection (1) commits an offence and shall be liable, upon conviction, to a fine of not less than three hundred thousand penalty units but not exceeding five hundred thousand penalty units or to imprisonment for a term of not less than five years but not exceeding ten years, or to both.

(3) In addition to the penalty provided in subsection (2) the court before which a person is convicted of an offence under this section may order that any medicines or allied substances in respect of which the offence is committed be forfeited to the State to be destroyed.

Prohibition of deception in labelling of medicine, etc.

35. (1) A person shall not label, package, treat, process, sell or advertise any medicine in a manner that is false, misleading or deceptive in respect of its character, constitution, value, potency, quality, composition, merit or safety or in contravention of any regulations made under this Act.

(2) A person who contravenes subsection (1) commits an offence and shall be liable, upon conviction, to a fine not exceeding two hundred thousand penalty units or to imprisonment for a term not exceeding ten years, or to both.

PART V

REGISTRATION OF MEDICINES, HERBAL MEDICINES AND ALLIED SUBSTANCES

Categories of medicine

36. (1) The categories of medicines to which this Part applies are—

(a) prescription only medicine;

(b) pharmacy medicine; and

(c) general sale medicine.

(2) Medicines shall be dispensed in accordance with the respective requirements applicable to the categories specified in subsection (1).

(3) The Authority shall for purposes of this Part maintain a register of medicines registered under this Part.

Registration of medicines, etc.

37. (1) An application for the registration of a medicine, herbal medicine, or allied substance shall be made to the Authority in the prescribed form and shall be accompanied by the prescribed fee.

(2) The Authority may require an applicant referred to in subsection (1) to furnish such information in support of the application as the Authority may consider necessary.

(3) The Authority shall, upon receipt of an application under subsection (1) conduct an investigation into such medicine, herbal medicine or allied substance and if the Authority is satisfied—

(a) with the quality, safety and efficacy of the medicines or allied substances to be manufactured;

(b) that the medicine, herbal medicine or allied substance is suitable for the purpose for which it is intended;

(c) that the medicine, herbal medicine or allied substance complies with the prescribed requirements; and

(d) that the registration is in the public interest;

the Authority shall grant a product licence in the prescribed form.

(4) The holder of the product licence referred to in subsection (3) shall pay such annual retention fees as the Authority may determine.

(5) Where the Authority refuses to grant an application under this section the Authority shall inform the applicant, in writing, stating the reasons for such refusal.

Cancellation of product licence

38. (1) Subject to subsection (2), the Authority may cancel a product licence issued under section *thirty-seven* if the holder of the licence—

(a) has contravened the terms and conditions of the product licence;

(b) manufactures medicine that does not satisfy the required standards prescribed for that medicine; or

(c) in manufacturing the medicine has conducted oneself in a manner that does not conform with good manufacturing practice.

(2) Where the Authority intends to cancel a licence under subsection (1) the Authority shall, at least three months before cancelling the licence, give notice, in writing, to the licensee of the intention to cancel the licence of such licensee.

(3) The notice referred to in subsection (2) shall state the reasons for the intended cancellation and require the licensee to show cause, within thirty days of receipt of the notice, why the licence should not be so cancelled.

(4) If the Authority is not satisfied with the explanation given by the licensee the Authority shall cancel the licence and notify the licensee accordingly.

Appeals

39. (1) Any person aggrieved by any refusal of the Authority to issue a licence or to cancel a product licence may appeal to the Minister not later than thirty days after the notification of such refusal.

(2) Where an appeal is made under subsection (1), the Minister may give such directions to the Authority as the Minister considers necessary to enable the Minister to determine the appeal.

(3) The Minister in determining the appeal may direct the Authority to issue the licence to the applicant or uphold the decision of the Authority and notify the appellant accordingly.

(4) Any person who is aggrieved by the decision of the Minister to uphold the Authority's decision under subsection (3) may appeal to High Court with thirty days of the receipt of the notification of the Minister's decision.

Prohibition of manufacture, etc. of medicine without product licence

40. (1) A person shall not manufacture, import, export, supply or sell a medicine in respect of which a product licence has not been issued by the Authority under section *thirty-seven*.

(2) A person who contravenes subsection (1) commits an offence and shall be liable, upon conviction, to a fine not exceeding two hundred thousand penalty units or to imprisonment for ten years, or to both.

(3) In addition to the penalty provided in subsection (1) the court before which a person is convicted of an offence under this section may order that any medicines in respect of which the offence is committed be forfeited to the State for destruction.

Medicines list

41. (1) The Authority shall, with the approval of the Minister prepare a list of prescription only medicines which shall consist of those medicines which, subject to the provisions of this Act, may be supplied or dispensed only under a prescription issued by an authorised prescriber.

(2) The Authority shall, with the approval of the Minister prepare a list of pharmacy medicines which shall consist of those medicines which, subject to the provisions of this Act are not to be sold or supplied except by or under the supervision of a registered pharmacist.

(3) The Authority shall, with the approval of the Minister prepare a list of general sale medicines which shall consist of those medicines which, subject to the provisions of this Act, may be sold or supplied without a prescription or the supervision of a registered pharmacist.

(4) A person shall not dispense, administer, supply, sell or offer any medicines on the prescription only medicine list or the pharmacy medicine list unless that person is licensed, registered or exempted from the provisions of this Part by the Authority.

(5) The Minister may on the recommendation of the Board, by statutory order, amend or vary the prescription only medicines list, the pharmacy medicines list or the general sale medicines list referred to in this section.

Prescription only medicines not so be sold without prescription

42. (1) No medicine which is required to be sold by prescription only shall be sold or supplied to any person without a prescription.

(2) For the purposes of this section an authorised prescriber shall prescribe medicines which under this Act are required to be dispensed only under a prescription by issuing a prescription which shall be in the prescribed form.

(3) All prescriptions shall specify the medicine to be administered by reference to the generic, name of that medicine.

(4) Subject to subsection (5), a prescription signed by a an authorised prescriber authorising the sale or supply of a medicine shall not be dispensed on more than one occasion:

Provided that if the prescription expressly directs that it may be dispensed on a specified number of occasions or at specified intervals in a specific period, it may be dispensed in accordance with that direction.

(5) Notwithstanding the provisions of subsection (4), insulin and medicines for the treatment of asthma or other such diseases as the Minister may, on the advice of the Authority, by regulations specify, may be sold or supplied any number of times under an initial prescription of a medical practitioner.

(6) In this section " authorised prescriber " means a medical practitioner, a dental surgeon, a veterinary surgeon or such other person as the Minister may, on the advice for the Authority, by statutory order, designate.

(7) Where a generic medicine is prescribed under subsection (3) the registered pharmacist, or any person acting under the supervision of a registered pharmacist, to whom the prescription is presented shall dispense the generic medicine specified in that prescription unless such generic medicine is not available.

(8) Any person who contravenes the provisions of subsection (1) commits an offence and shall be liable on conviction to a fine not exceeding one hundred thousand penalty units.

Advertising of medicines

43. (1) A person shall not advertise medicines unless the advertisement conforms with the information submitted to obtain a licence under this Part.

(2) Medicine which is sold by prescription only shall not be advertised to the general public without the prior written authority of the Board.

(3) In this section " advertisement " means any representation by any means whatsoever for the purpose of promoting directly or indirectly the sale or disposal of any medicine.

(4) A person who contravenes subsection (1) or (2) commits an offence and shall be liable, upon conviction, to a fine not exceeding one hundred thousand penalty units or to imprisonment to a term not exceeding five years, or to both.

Labelling of medicines

44. Medicines shall be labelled in accordance with such regulations as the Minister may, on the recommendation of the Authority, prescribe.

Sale of medicine, etc.

45. (1) A person shall not sell by retail or otherwise supply medicine in a place other than a pharmacy except with the written authority of the Board.

(2) Where the medicine is to be sold under subsection (1) in a place other than a pharmacy—

(a) it shall be sold in the original package labelled with—

(i) full instructions for use;

(ii) contra-indications, warnings and precautions; and

(b) the package shall be marked in a conspicuous way with the letters " GS " representing general sale.

(3) A medical practitioner, dental surgeon or veterinary surgeon shall not sell any medicine or allied substance to any person unless it is in a package for an individual patients use only and under the supervision of a pharmacist.

(4) A wholesaler, manufacturer or importer shall not sell any medicine to any person other than a pharmacist unless the medicine is for general sale.

Regulations

46. For the purpose of preventing the improper use of prescription only medicines the Minister may, on the recommendation of the Authority, by regulations—

(a) provide for controlling the importation, exportation, sale, possession, distribution, use and labelling of prescription only medicines;

(b) excluding any prescription only medicine or preparation of such medicine from the operation of this Part;

(c) prohibiting, regulating or restricting the manufacture of prescription only medicine; and

(d) regulating the use by any medical practitioner, dental surgeon or veterinary surgeon of preparations containing a prescription only medicine and the dispensing of any such preparations.

PART VI
HERBAL MEDICINES

Restriction on importation, exportation, etc, of herbal medicines

47. (1) A person shall not manufacture, export, import, distribute or sell herbal medicine unless that person has a licence issued by the Authority.

(2) A person who intends to manufacture, export, import, distribute or sell herbal medicine may apply to the Authority for a licence.

(3) An application under subsection (1) shall—

(a) be accompanied by a prescribed fee;

(b) be in such form as the Minister may, by statutory instrument, prescribe;

(c) specify—

(i) the name of the applicant;

(ii) the principal place of business of the applicant;

(iii) the type of herbal medicines the applicant intends to manufacture, export, import, distribute or sell; and

(iv) such other details as the Minister may, on the advice of the Authority, by statutory instrument prescribe.

Power of Minister to regulate

48. The Minister may, on the recommendation of the Authority by statutory instrument, make regulations—

(a) for the issue, renewal and revocation of any licence issued under this part for the requirement of a herbal medicine product licence;

(b) the form of, and the terms and conditions attaching to a licence relating to herbal medicines;

(c) specifying the herbal medicines to which this part applies;

(d) for the prescription of herbal medicines;

(e) relating to the use of herbal medicines for clinical trials on human beings or animals;

(f) prescribing standards for herbal medicines;

(g) stipulating standards for the production, packaging, storage and distribution of herbal medicines;

(h) regulating the advertising, marketing and promotion of herbal medicines;

(i) prescribing standards for herbal medicines; and

(j) prescribing anything which may be prescribed under this section in relation to herbal medicines.

PART VII

CLINIC TRIALS AND ANIMAL TESTS

Clinical trials

49. (1) A person shall not sell, supply, assemble, manufacture or procure the sale, supply, manufacture or assembly of any medicine for purposes of a clinical trial unless that person is the holder of a product licence issued by the Authority, on such terms and conditions as the Authority may determine and which authorises that person to conduct clinical trials.

(2) This section shall not apply to—

(a) anything done in a registered pharmacy, hospital or health centre by or under the supervision of a pharmacist in accordance with a prescription issued by a medical practitioner, dental surgeon, registered nurse, midwife or such other person duly authorised by the Minister; or

(b) any person procuring, preparing or dispensing a medicine under the supervision of a pharmacist in accordance with a prescription issued by a medical practitioner.

(2) A person who contravenes subsection (1) commits an offence and shall be liable, upon conviction, to a fine not exceeding two hundred thousand penalty units or to imprisonment to a term not exceeding twenty-five years, or to both.

Animal clinical trials

50. (1) A person shall not sell, supply, manufacture or assemble or procure the sale, supply, manufacture or assembly of any medicine for purposes of animal clinical trials unless that person is the holder of a product licence issued by the Authority, on such terms and conditions as the Authority may determine and which authorises that person to conduct animal clinical trials.

(2) This section shall not apply to—

(a) anything done in a veterinary surgery, registered pharmacy, hospital or health centre by, or under the supervision of, a pharmacist in accordance with a prescription issued by a veterinary surgeon; or

(b) any person procuring, preparing or dispensing a medicine under the supervision of a pharmacist in accordance with a prescription issued by a veterinary surgeon.

(3) A person who contravenes subsection (1) commits an offence and shall be liable, upon conviction, to a fine not exceeding fifty thousand penalty units or to imprisonment to a term not exceeding five years, or to both.

Application for clinical trial or animal clinical trials certificate

51. An application for a clinical trial certificate or an animal test certificate shall be made to the Authority and shall be accompanied by such documents and information as the Minister may, on the recommendation of the Authority, prescribe.

Grant and refusal of certificate

52. (1) If the Authority is satisfied that the applicant is a fit and proper person to conduct clinical trials or animal clinical trials and that the premises in which the applicant proposes to carry on such trials or tests are suitable, the Authority may, upon payment of the prescribed fee, issue to the applicant a clinical trial certificate or an animal clinical trial certificate as the case may be.

(2) A certificate granted under this section shall authorise the applicant to conduct clinical trials or animal tests in accordance with the provisions of this Act upon the premises and shall be valid for a period of one year from the date of issue.

(3) A certificate granted under this section may be renewed upon application.

(4) The Authority may refuse to issue a certificate under this Part or may revoke such certificate granted if, in the opinion of the Authority the applicant is not fit to be granted a certificate or the Authority is not satisfied with the premises upon which the business will be carried on.

Appeals

53. (1) Any person aggrieved by the decision of the Authority not to grant the person a clinic trial certificate or an animal test certificate may, within thirty days of receiving the notification of refusal, appeal to the Minister.

(2) Any person aggrieved by the decision of the Minister not to grant the person a certificate under this section may, within thirty days of receiving the notification of refusal, appeal to the High Court.

Suspension and revocation of certificate

54. (1) The Authority may suspend or revoke a certificate issued under section *fifty-two*—

(a) if the person to whom such licence is issued conducts such clinical trial or animal test in a manner which poses a risk to public health;

(b) if for any other reason the Authority is not satisfied with the manner in which any clinical trial or animal test is conducted;

(c) if it is established that the medicine is toxic; or

(d) if the clinical trial results in loss of life.

PART VIII

POISONS

Poisons list

55. The Minister shall, on the recommendation of the Authority, by regulations, prepare a list comprising of substances which are to be treated as poisons under this Act.

Control of poisons

56. The Minister shall, on the recommendation of the Authority, by statutory instrument, make regulations for the control, manufacture, importation, exportation, storage, distribution, sale, supply and use of poisons.

PART IX

THE NATIONAL DRUG QUALITY CONTROL LABORATORY

Establishment of Laboratory

57. There is hereby established the National Drug Quality Control Laboratory which shall be managed by the Authority and which shall facilitate the regulation of medicines and allied substances under this Act.

Authority to verify safety, etc., of medicines

58. (1) The Authority shall use the Laboratory—

(a) to verify the safety, quality and efficacy of medicines, herbal medicine, allied substances and poisons which are manufactured or imported into the country by persons who are licenced under this Act;

(b) to analyse and conduct research on herbal medicines, allied substances and poisons;

(c) to provide laboratory services to the general public;

(d) to provide practical training for personnel in the analysis of medicines, herbal medicines, and allied substances;

(e) to perform such other functions relating to the analysis of medicines, herbal medicines, allied substances or poisons as it considers necessary.

(2) The Authority shall charge such fees for any analysis of medicines or services provided by the Laboratory as the Authority may determine.

(3) The Authority shall appoint a Director for the Laboratory who shall be responsible for the day to day administration of the Laboratory.

(4) The Authority shall appoint such number of pharmaceutical analysts as it may consider necessary for purposes of performing its functions under this section.

PART X

INSPECTIONS

Appointment of inspectors

59. (1) In order to ensure compliance with the provisions of this Act, the Authority shall appoint inspectors to monitor, inspect and enforce the provisions of this Act.

(2) The Authority shall issue an identity card to each inspector.

(3) Any inspector carrying out any function under this Act shall on demand by any person who is affected by the inspector's exercise of power, produce for inspection the identity card referred to in subsection (2).

Powers of entry and inspection

60. (1) An inspector shall have power on production of an identity card issued to the inspector under section *fifty-nine*, to enter the premises of a person carrying on the business of a manufacturer, seller or distributor of any medicines, herbal medicines or allied substances and to demand the production of, and to inspect, any books or documents relating to the manufacture, sale or distribution of such medicines, herbal medicines or allied substances and to inspect any stocks of any such medicines, herbal medicines or allied substances.

(2) An inspector may take as many samples of a medicine, herbal medicine, therapeutic substance or allied substances as may be necessary for the purpose of testing, examination or analysis, without payment and with or without a warrant.

(3) If a magistrate is satisfied by information on oath that there is reasonable ground for suspecting—

(a) that any medicines, herbal medicines or allied substances are in contravention of the provisions of this Act or any regulations made under the Act, in the possession or under the control of a person in any premises, place, aircraft, boat, train or other vehicle of whatever description; or

(b) that a document directly or indirectly relating to, or connected with, a transaction or dealing which would if carried out be, an offence under this Act, is in the possession, or under the control, of a person in any premises, place, aircraft, boat, train or other vehicle of whatever description;

the magistrate may grant a search warrant authorising any inspector, customs officer or police officer named in the warrant, at any time or times within one month from the date of the warrant, to enter, if need be by force, such premises, place, aircraft, boat, train or other vehicle, as the case may be, and to search the same and any persons found in such premises, place, aircraft, boat, train or other vehicle.

(4) If there is reasonable ground for suspecting that an offence under this Act has been committed in relation to any medicines, herbal medicines or allied substances which may be found in any premises, place, aircraft, boat, train or other vehicle entered under this section or in the possession of any persons, or that a document which may be found is a document referred to in paragraph *(b)* of subsection (2), to seize and detain those medicines, herbal medicines or allied substances or that document as the case may be.

(5) Any person who wilfully delays or obstructs an inspector or other person in the exercise of that inspector or other person's powers under this section or fails to produce or conceals or attempts to conceal, any books, stocks, medicines, herbal medicines or allied substances, commits an offence and shall be liable, upon conviction, to a fine not exceeding fifty thousand penalty units or to imprisonment for a term not exceeding three years, or to both.

Duty of inspector to report to Authority

61. Each inspector shall furnish the Authority with such reports and other information relating to an inspection as the Authority may direct.

PART XI

GENERAL PROVISIONS

Authority may authorise manufcature of patented medicine cap.400

61A. Notwithstanding the provisions of the Patents Act or of any other written law, where the Minister declares a national health disaster the Authority may authorise a manufacturer to manufacture, locally, a generic formulation of a medicine notwithstanding that a patent in respect of that medicine has been issued in Zambia or in another country.

Prohibition of sale of harmful cosmetics

62. (1) A person shall not sell any cosmetic that—

(a) has in or upon it any substance that may cause injury to the health of the user when the cosmetic is used—

(i) according to the direction on the label, of or accompanying, such cosmetic; or

(ii) for such purposes and by such methods of use as are customary or usual therefor; or

(b) consists in whole or in part of any filthy, rotten, decomposed or diseased substance or of any injurious foreign matter; or

(c) was prepared, preserved, packed or stored under insanitary condition.

(2) A person who contravenes subsection (1) commits an offence and shall be liable, upon conviction, to a fine not exceeding fifty thousand penalty units or to imprisonment to a term of not less than eighteen months but not exceeding five years, or to both.

Offence by corporation

63. Where an offence under this Act is committed by a corporation every director or senior officer of that corporation shall be liable, upon conviction, as if such director or senior officer had been personally guilty of the offence unless such director or senior officer proves to the satisfaction of the court that the act constituting an offence under

this Act was done without the knowledge, consent or connivance of that director or senior officer or that such director or senior officer took reasonable steps to prevent the commission of the offence.

Regulations

64. (1) The Minister may, on the recommendation of the Authority, by statutory instrument, make regulations for the proper carrying into effect of the provisions of this Act.

(2) In particular and without prejudice to the generality of the foregoing, the regulations under subsection (1) may make provision for—

(a) prohibiting, regulating or restricting the manufacture or importation of pharmaceutical preparations and prescription only medicines;

(b) prescribing standards for pharmacies, including their operation and the maintenance, space, equipment and facilities required for pharmacies;

(c) the safe custody and storage of medicines and allied substances;

(d) prescribing the conditions to be satisfied by an applicant for a pharmacy registration certificate;

(f) the compounding of prescriptions and the dispensing of medicines or allied substances by medical practitioners, dentists, veterinary surgeons and the conditions under which such compounding and dispensing of medicines may be carried out;

(g) prescribing the records to be kept by registered pharmacists and registered pharmacies and the length of time they shall be kept;

(h) the advertising, promotion and labelling of medicines and allied substances;

(i) the handling of donated medicines;

(j) the disposal of obsolete, expired or unwanted medicines in consultation with the Environmental Council of Zambia;

(k) prescribing standards for medicines and allied substances;

(l) prohibiting the supply or sale of counterfeit, adulterated or substandard medicines;

(m) prescribing the period for which any books or registers required to be kept for the purposes of this Act are to be preserved;

(n) prescribing the fees to be paid for registration certificates and licences under this Act;

(o) restrict the number and location of entry points through which medicines or allied substances may be imported or exported;

(p) schedules of medicines within categories; or

(q) for prescribing anything which is by this Act to be prescribed.

Repeal of Part IIB, C and D of the Food and Drugs Act Cap. 303

65. Divisions B, C and D of Part II of the Food and Drugs Act are hereby repealed.

Repeal of Pharmacy and Poisons Act and Therapeutic Substances Act and transitional provisions Cap.299 Cap. 310

66. (1) The Pharmacy and Poisons Act, 1940 and the Therapeutic Substances Act, 1968 are hereby repealed.

(2) Notwithstanding the repeal of the Pharmacy and Poisons Act and the Therapeutic Substances Act referred to in subsection (1), any subsidiary legislation made under those Acts in force immediately before the commencement of this Act—

(a) shall remain in force unless inconsistent with this Act and be deemed to be subsidiary legislation under this Act;

(b) may be replaced, amended or repealed by subsidiary legislation made under this Act;

(c) any regulation, order, notice or direction made or given and in force, immediately before the commencement of this Act, under those Acts shall, unless contrary to this Act, continue in force until revoked, as if made or given under this Act.

(3) Notwithstanding the repeal of the Pharmacy and Poisons Act, any pharmacy premises or medicine registered by the Pharmacy and Poisons Board under that Act shall continue to operate as though registered by the Authority under this Act.

(4) The Second Schedule shall have effect in relation to transitional provisions in respect of the Pharmacy and Poisons Board.

FIRST SCHEDULE
(Section 4 (2))
PART I
ADMINISTRATION OF AUTHORITY

Seal of Authority

1. (1) The seal of the Authority shall be such device as may be determined by the Authority and shall be kept by the Secretary.

(2) The affixing of the seal shall be authenticated by the Chairperson or the Vice-Chairperson and the Secretary or any other person authorised in that behalf by a resolution of the Board.

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

(4) Any document purporting to be a document under the seal of the Authority or issued on behalf of the Authority shall be received in evidence and shall be deemed to be so executed or issued, as the case may be, without further proof, unless the contrary is proved.

Tenure of office and vacancy

2. (1) Subject to the other provisions of this Act, a member of the Board shall hold office for a period of three years from the date of appointment and shall be eligible for re-appointment for one further term of three years.

(2) A member may resign upon giving one month's notice, in writing, to the organisation which nominated the member and to the Minister.

(3) The office of the member shall become vacant—

(a) upon the member's death;

(b) if the member is absent without reasonable excuse from three consecutive meetings of the Board of which the member has had notice;

(c) on ceasing to be a representative of the organisation which nominated the member;

(d) if the member becomes mentally or physically incapable of performing the duties of a member; or

(e) if the member is declared bankrupt.

(4) On the expiration of the period for which a member is appointed the member shall continue to hold office until a successor has been appointed but in no case shall the further period exceed four months.

Filling of casual vacancy

3. Whenever the office of a member becomes vacant before the expiry of the term of office the Minister may appoint another member in place of the member who vacates office but such member shall hold office only for the unexpired part of the term.

Proceedings of Board

4. (1) Subject to the other provisions of this Act, the Board may regulate its own procedure.

(2) The Board shall meet for the transaction of business at least once every three months at such places and times as the Chairperson may determine.

(3) The Chairperson may, upon giving notice of not less than fourteen days, call a meeting of the Board and shall call a special meeting to be held within fourteen days of receipt of a written request to the Chairperson by at least five members of the Board.

(4) If the urgency of any particular matter does not permit the giving of such notice as is required under subparagraph (3), a special meeting may be called by the Chairperson, upon giving a shorter notice.

(5) Nine members of the Board shall form a quorum at any meeting of the Board.

provided that at least one of the members present shall be a pharmacist.

(6) There shall preside at any meeting of the Board—

(a) the Chairperson; and

(b) in the absence of the Chairperson the Vice-Chairperson, and in the absence of the Chairperson and the Vice-Chairperson such member as the members present may elect for the purpose of that meeting.

(7) A decision of the Board on any question shall be by a majority of the members present and voting at the meeting and in the event of an equality of votes, the person presiding at the meeting shall have a casting vote in addition to the deliberative vote.

(8) The Board may invite any person, whose presence is in its opinion desirable, to attend and to participate in the deliberations of the meeting of the Board but such person shall have no vote.

(9) The validity of any proceedings, act or decision of the Board shall not be affected by any vacancy in the membership of the Board or by any defect in the appointment of any member or by reason that any person not entitled to do so took part in the proceedings.

Allowances for members

5. The members of the Board or any committee shall be paid such allowances as the Board may, with the approval of the Minister, determine.

Disclosure of interest

6. (1) If a member or person is present at a meeting of the Board or any committee of the Board at which any matter is the subject of consideration in which matter the member or person or the member or person's spouse is directly or indirectly interested in a private capacity the member or person shall as soon as is practicable after the commencement of the meeting, declare such interest and shall not, unless the Board or the committee otherwise directs, take part in any consideration or discussion of, or vote on, any question touching that matter.

(2) A declaration of interest made under this paragraph shall be recorded in the minutes of the meeting at which it is made.

Prohibition of disclosure of information

7. (1) A person shall not, without the consent in writing given by, or on behalf of, the Authority, publish or disclose to any person otherwise than in the course of duties, the contents of any documents, communication, or information which relates to, and which has come to that person's knowledge in the course of duties under this Act.

(2) Any person who knowingly contravenes the provisions of subsection (1) commits an offence and shall be liable, upon conviction, to a fine not exceeding ten thousand penalty units or to imprisonment for a period not exceeding three months, or to both.

PART II

FINANCIAL PROVISIONS

Funds of Authority

8. (1) The funds of the Authority shall consist of such moneys as may—

(a) be appropriated to the Authority by Parliament for the purposes of the Authority;

(b) be paid to the Authority by way of fees, grants or donations; and

(c) otherwise vest in or accrue to the Authority.

(2) The Authority may—

(a) accept moneys by way of grants or donations from any source in Zambia and subject to the approval of the Minister, from any source outside Zambia;

(b) subject to the approval of the Minister, raise by way of loans or otherwise, such moneys as it may require for the discharge of its functions; and

(c) in accordance with the regulations made under this Act, charge fees for services provided by the Authority.

(3) There shall be paid from the funds of the Authority—

(a) salaries, allowances, loans, gratuities and pensions of staff of the Authority and other payments for the recruitment and retention of staff;

(b) such reasonable travelling and subsistence allowances for members and members of any committee of the Authority when engaged on the business of the Authority and at such rates as the Authority may, with the approval of the Minister, determine; and

(c) any other expenses incurred by the Authority in the performance of its functions.

(4) The Authority may after the approval of the Minister invest in such manner as it thinks fit such of its funds as it does not immediately require for the discharge of its functions.

Financial year

9. The financial year of the Authority shall be the period of twelve months ending on 31st December of each year.

Accounts

10. (1) The Authority shall cause to be kept proper books of account and other records relating to its accounts.

(2) The accounts of the Authority shall be audited annually by independent auditors appointed by the Authority, subject to the approval of the Minister.

(3) The auditor's fees shall be paid by the Authority.

Annual report

11. (1) As soon as practicable, but not later than ninety days after the end of the financial year, the Authority shall submit to the Minister a report concerning its activities during the financial year.

(2) The report referred to in subsection (1) shall include information on the financial affairs of the Authority and there shall be appended to the report—

(a) an audited balance sheet;

(b) an audited statement of income and expenditure; and

(c) such other information as the Minister may require.

(3) The Minister shall not later than seven days after the first sitting of the National Assembly next after receipt of the report referred to in sub-paragraph (1), lay the report before the National Assembly.

SECOND SCHEDULE

(Section 66 (4))

SAVINGS AND TRANSITIONAL PROVISIONS IN RELATION TO THE PHARMACY AND POISONS BOARD

References to Pharmacy and Poisons Board

1. On the appointed date, reference in any written law or any other legal document to the Pharmacy and Poisons Board shall be read and construed as references to the Authority established by section *three* of this Act.

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2. The Pharmacy and Poisons Board constituted pursuant to section *three* of the Pharmacy and Poisons Act shall, pending the appointment of the Board under this Act, continue in office for a period of three months from the appointed date.

Vesting of assets of Pharmacy and Poisons Board

3. (1) On or after the appointed date, there shall be transferred to, and vest in, or subsist against, the Authority by virtue of this Act and without further assurance—

(a) the affairs of the Pharmacy and Poisons Board; and

(b) subject to this Act, all property, rights and obligations which immediately before the appointed date were the property, rights and obligations of the Pharmacy and Poisons Board.

(2) Except as provided in this Act, every deed, bond and agreement (other than an agreement for personal service) to which the Government was a party immediately before the commencement of this Act in respect of the Pharmacy and Poisons Board, whether in writing or not, and whether or not of such a nature that rights, liabilities and obligations thereunder could be assigned, shall, unless its subject-matter or terms make it impossible that it should have effect as modified in the manner provided by this subsection, have effect as from the date of the assignment thereof, as if—

(a) the Authority had been a party thereto;

(b) for any reference to the Government there were substituted, as respects anything falling to be done on or after the appointed date, a reference to the Authority; and

(c) for any reference to any officer of the Pharmacy and Poisons Board not being a party thereto and beneficially interested therein there were substituted, as respects anything falling to be done on or after commencement of this Act, or reference to such officer of the Authority as the Authority shall designate.

(3) Subject to the provisions of subsection (2), documents, other than those referred to therein, which refer specifically or generally to the Pharmacy and Poisons Board shall be construed in accordance with subsection (2) as far as applicable.

Registration of property to be transferred by Government

3. (1) Where under this Act, any property, rights, liabilities and obligations of the Government through the Pharmacy and Poisons Board are deemed transferred to the Authority in respect of which transfer a written law provides for registration, the Authority shall make an application in writing to the appropriate authority for registration of the transfer.

(2) The registration authority referred to in subsection (1) shall make such entries in the appropriate register as shall give effect to such transfer and, where applicable, issue to the transferee concerned a certificate of title in respect of the property or make necessary amendments to the register, as the case may be, and shall make endorsement on the deeds relating to the title, right or obligation concerned; and no registration fees, stamp duty or other duties shall be payable in respect thereof.

Legal proceedings

4. (1) Without prejudice to the other provisions of this Act, where any right, liability or obligation vests in the Authority by virtue of this Act, the Authority and all other persons shall, as from the commencement of this Act, have the same rights, powers and remedies (and in particular the same rights as to the instituting or defending of legal proceedings or the making or resisting of applications to any authority) for ascertaining, perfecting that right, liability or obligation as they would have had if it had at all times been a right, liability or obligation of the Authority.

(2) Any legal proceedings or application of any authority pending immediately before the commencement of this Act by or against the Government in respect of the Pharmacy and Poisons Board may be continued by or against the Authority.

(3) After the commencement of this Act, proceedings in respect of any right, liability or obligation which was vested in, held, enjoyed, incurred or suffered by the Government in respect of the Pharmacy and Poisons Board may be instituted by or against the Authority.

Terms of service of employees of Board

5. (1) On or after the appointed date, the Authority shall on such terms and conditions as it may, with the approval of the Minister, determine appoint as officers of the Authority such employees of, or public officers from, the Pharmacy and Poisons Board as may be necessary for the performance of the functions of the Authority.

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(2) Where an officer from the Public Service is appointed to the service of the Authority—

(a) the terms and conditions of service with the Authority shall not be less favourable than those the officer enjoyed in the Public Service; and

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(b) the officer shall be deemed to have retired under section *thirty-nine* of the Public Service Pensions Act.

(3) On or after the appointed date employees of the Pharmacy and Poisons Board who are not engaged by the Authority under subsection (2) shall be retained by the Government and shall—

(a) be redeployed in the service of the Government; or

(b) be retired under section *thirty-nine* of the Public Service Pensions Act.