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MALAWI GOVERNMENT

(Published 22nd Februay, 2019)

Act

No. 9 of 2019

I assent

PROF. ARTHUR PETER MUTHARIKA
PRESIDENT
19th February, 2019

ARRANGEMENT OF SECTIONS

SECTION

An Act to establish the Pharmacy and Medicines Regulatory Authority; provide for the functions and powers of the Authority; and to provide for matters connected therewith and incidental thereto

ENACTED by the Parliament of Malawi as follows—

PART I—PRELIMINARY

Short title and commencement

1. This Act may be cited as the Pharmacy and Medicines Regulatory Authority Act, 2019 and shall come into force on a date to be appointed by the Minister, by notice published in the *Gazette*.

Interpretation

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

"administer" means administer to a human being or an animal, whether 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 in this Act to administering a substance or article is a reference to administering it either in its existing state or after it has been dissolved or dispersed in, or diluted or mixed with, some other substance used as a vehicle for such administration;

"active drug substance or active pharmaceutical ingredient" means any substance or mixture of substances intended to be used in the manufacture of medicine and that, when used in the production of a pharmaceutical product, becomes an active ingredient of the pharmaceutical product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body;

"adulterated medicine" means any medicine—

(*a*) consisting in whole or in part of any filthy, putrid, decomposed, deleterious or foreign substance;

(*b*) that is prepared or stored under unsanitary conditions;

(*c*) whose container is composed of any poisons or deleterious substance;

(*d*) that contains a colouring agent that is not prescribed; or

(*e*) that contains any harmful or toxic substance;

"advertisement" in relation to a medicine, includes a representation by any means for the purpose of promoting, directly or indirectly, the sale or disposal of a product regulated by this Act; and "advertise" has a corresponding meaning, which may include pictorial, visual or otherwise descriptive matter or verbal statements or references appearing in a newspaper, a magazine, a pamphlet or other publication; the promotion may be by—

(*a*) broadcast on television or radio;

(*b*) distributed to members of the public; or

(*c*) brought to the notice of members of the public in any manner, which is intended to promote the sale of that medicine;

"allied substances" include acaricides, cosmetics, disinfectants, food supplements, feed additives and supplements, traditional medicines, medical and surgical sundries, medical devices, reagents and condoms;

"analytical test certificate or certificate of analysis" means a certificate of analysis issued after testing a sample by the National Medicines Quality Control Laboratory or by another laboratory hired or recognized by the Authority;

"assemble" in relation to a medicine, means enclosing the medicine or allied substance of the same description in a container before the medicine or allied substance is sold or supplied;

"Authority" means the Pharmacy and Medicines Regulatory Authority established under section 3 of this Act;

"authorized prescriber" means a medical doctor, a dental surgeon, a veterinary surgeon, clinical officers and medical officers registered with the Medical Council of Malawi and trained nurses and midwives registered with the Nurses and Midwives Council of Malawi;

"biological product" includes a vaccine, immune sera, anti-toxin, anti-venom, toxoid, blood and blood components, allergy products used in the prevention, treatment or cure of disease or condition in human beings and animals synthesized from living organisms or other product;

"business" includes a professional practice and any activity carried out by a person or body of persons, whether corporate or unincorporated;

"certificate of registration" means the certificate of registration of a pharmacy business premises and pharmacy personnel;

"Clinical Officer" has the same meaning as given under the Medical Practitioners and Dentists Registration Act; Cap. 36:01

"clinical trial" means the systematic study involving human participants or animal subjects that serves to answer the safety and efficacy of a medicine, biological products or method of prevention or treatment;

"committee" means a committee of the Authority established under section 17;

"container" in relation to a medicinal product, means a bottle, jar, box, packet, or other receptacle which contains or is meant to contain it, but not being a capsule, sachet, or other article in which the product is or is to be administered;

"cosmetic" means any substance manufactured or sold for use in cleansing, beautifying or altering the hair, eyes, teeth, nails, or complexion of the skin, and includes deodorants and perfumes;

"deal" means to sell or offer for sale or trade by wholesale;

"dental surgeon" means a person registered as such under the Medical Practitioners and Dentists Registration Act; Cap. 36:01

"Director General" means the person appointed as Director General of the Authority under section 18;

"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;

"dispensing licence" means a licence granted under section 52;

"distribute" means the division and movement of pharmaceutical products from the premises of the manufacturer of the products or from another central point or to an intermediate point or to the end user by means of any method of transport;

"export" includes delivering or supplying within the country for dispatch to a destination outside of the country;

"falsified medicine or allied substance" means medical product which is deliberately or fraudulently misrepresented with respect to it's identity, composition or source;

"harmonization" means adjustment of differences and inconsistencies among different laws, regulations, methods, procedures, schedules, specifications, or systems of medical products regulation to make them uniform or mutually compatible among different national or regional regulatory authorities;

"health facility" means an institution that provides health care and is registered or recognized by the Medical Council of Malawi, the Nurses, Midwives Council of Malawi or the Authority;

"health product" means any product used in the management of health care and includes medicines, allied substances, cosmetics, herbs, herbal products, traditional medicines;

"hospital pharmacy" means a type of pharmacy practice and premises in a hospital;

"import" means bringing into the national territory whether on one's body by land, sea or air with the intent to distribute, dispense and retail and consume;

"import permit" means an official document issued by the Authority for importation of particular consignment prior to shipment into Malawi;

"importer" means a person or organization bringing medicine or allied substance into the national territory or causing the medicine or allied substance to be brought into the national territory, and includes a person who—

(*a*) owns the goods brought into the country;

(*b*) carries the risk for the goods brought into the country;

(*c*) represents to be the one who brought the goods into the country or who owns those goods;

(*d*) actually brings the goods into the country;

(*e*) is beneficially interested in any way in the goods brought into the country; or

(*f*) acts on behalf of a person referred to in paragraphs (*a*) to (*e*), and "import" and "importation" have a corresponding meaning;

"ingredient" means any substance included in the formulation of a medicinal product. Ingredient can be active or inactive;

"inspector" means a person appointed by the Authority as an inspector under section 80;

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

"Laboratory" means the National Medicines Quality Control Laboratory established under section 79 and any other laboratory recognized or hired by the Authority;

"licence" means a certificate issued for a person, premises and activities under this Act in the prescribed form; required for the fulfillment of the mandate of the Authority;

"manufacture" in relation to 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 the product in any animal feed;

"manufacturer" means any person who converts raw materials, components or parts by the use of tools, machines and labour to produce finished medicinal products and allied substances for sale and or use in humans and animals, and it includes a person under whose direction and control such manufacturing takes place;

"manufacturer's licence" means an official document issued by the Authority to manufacture medicines in Malawi;

"marketing authorization" means the authorization granted, under section 62, for the placement of a medicine or allied substance on the market;

"medical device" includes an instrument, apparatus, component, part or accessory manufactured or sold for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or the symptoms of the disease, or abnormal physical state in human beings or animals;

"medical practitioner" means—

(*a*) a medical doctor, or other health personnel who is licensed to examine and diagnose the disease of humans and treat them with medicinal products; and

(*b*) the meaning of the term as defined in the Medical Practitioner and Dentist Registration Act; Cap. 36:01

"medical representative" means a person trained in health sciences with adequate knowledge of the medicine that he is to promote or that he promotes;

"medicine" means—

(*a*) a substance or a mixture of substances used or purported to be suitable for use or manufactured or sold for use in—

(i) the diagnosis, treatment, mitigation, modification or prevention of a disease, abnormal physical or mental state, or the symptoms thereof, in humans or in animals; or

(ii) restoring, correcting or modifying any somatic, psychic or organic function in humans or in animals; or

(*b*) allied substances such as traditional medicines, herbs and herbal substances;

"medicinal product" means any substance or combination of substances which may be administered to human beings or animals in order to make a medical diagnosis or to restore, correct or modify the physiological functions in human beings or animals;

"medicine store" means a place or premises for pharmacy business permitted by the Authority to sell a prescribed list of medicines under the control of an authorized person as determined by the Authority;

"midwife" means a person registered as a midwife under the Nurses and Midwives Act; Cap. 36:02

"narcotics" means—

(*a*) any medicinal product subject to control according to the Single Convention on Narcotic Drugs adopted and opened for signature by the United Nations Conference for the Adoption of a Single Convention on Narcotic Drugs, held at United Nations Headquarters, New York, from 24 January to 25 March 1961 and acceded by Malawi on 8th June, 1965; or

(*b*) a drug that is categorized as a narcotic drug by the Authority;

"package" means anything in or by which any medicine, herbal medicine, therapeutic substance or allied substance is enclosed, covered or contained, and includes primary and secondary packaging;

"package insert or leaflet" means information printed and placed inside the pack containing a medicinal product meant to provide all the necessary information on safety, dosage, storage conditions and other useful information to the user;

"person" means any natural or juridical person;

"pharmaceutical licence" means the licence issued, under this Act to a person to manufacture, distribute or deal in a medicine or allied substance;

"pharmacist" means a person registered as a pharmacist under this Act;

"pharmacist intern" means a pharmacy intern to be registered as a pharmacist upon successful completion of the internship;

"pharmacovigilance" means the science and activities relating to the detection, assessment, understanding and prevention of adverse effects of drugs or any other drug-related problem;

"pharmacy" means a drugstore, druggist, chemist or any business or premises registered or to be registered as such under this Act;

"pharmacy assistant" means a person registered as such under Part III;

"pharmacy practice" means any business activity authorized by the Authority whether for profit or non-profit and carried out in premises and by personnel registered under this Act;

"pharmacy practice premises" means any premises where pharmacy practice is conducted or is to be conducted and includes hospitals, clinics, pharmaceutical warehouses, medical product

depots, retail pharmacies, medicine stores, veterinary shops, pharmaceutical wholesales, and health product manufacturing premises;

"pharmacy student" means a person who is being trained in pharmacy at an institution recognized by the responsible authority that is recognized by the Authority;

"pharmacy technologists or technician" means a person registered as such under Part III;

"post-marketing surveillance" means the set of activities carried out by the Authority to monitor quality of medicines and allied substances when they are in distribution, warehouses, pharmacies, clinics, medicine stores, and hospitals;

"premises" includes a building, hut, shed, kiosk, or tent together with the land on which it is situated and an adjoining land used in connection with it, and a vehicle, conveyance or vessel;

"prescription" means a written direction given by an authorized prescriber directing that a stated amount of a medicine specified in the direction be dispensed for the person or animal named in the direction at a given time, for a given duration and a given manner;

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

"product licence" means an official document issued by the Authority as mark authorization;

"promote" in relation to medicine or allied substances, means all information and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase or use of medicinal product to health care professionals or the general public;

"psychotropic substance" means any substance subject to control according to the Convention on Psychotropic Substances, adopted and opened for signature by the United Nations Conference for the Adoption of a Protocol on Psychotropic Substances, held at Vienna from 11 January to 21 February 1971, acceded by Malawi on 9th April, 1980. This shall also include a substance that is categorized as psychotropic substance by the Authority;

"register" means the act of recording in writing the medicines, allied substances and any other articles or activities under this Act and includes the records kept in terms of this Act;

"regulation" means a law, policies, directives and guidelines made under this Act;

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

"substance" means any natural or artificial material, whether in the form of solid, liquid, gas, vapour or any active or inactive substance or pharmaceutical ingredient;

"substandard medicine" (also known as "out of specification") means an authorized medical product which fail to meet either its quality standards or its specifications or both;

"supply" includes having in possession for the purpose of supply;

"supplying" anything in circumstances corresponding to retail sale is a reference to supplying it, otherwise than by way of sale, to a person as being a person who receives it for a purpose other than that of selling or supplying;

"traditional medicines" (also known as complementary or alternative medicine) includes plant or herbal material, non-human animal material, minerals including mineral salts and naturally occurring minerals, microorganisms (whole or extracted) except vaccines;

"treatment" in relation to disease, includes anything done or provided for alleviating the effects of the disease, whether it is done or provided by way of a cure or not;

"veterinary practitioner" means a person registered a veterinary surgeon or a para-veterinary surgeon under the Veterinary and Para-Veterinary Practitioners Act; Cap. 53:04

"veterinary shop" means a place or premises permitted to sell prescribed veterinary medicinal products and allied substances under the control of a relevant veterinary professional as determined by the Authority; and

"veterinary surgeon" and para-veterinary surgeon shall have the meanings respectively ascribed to the terms under the Veterinary and Para-Veterinary Practitioners Act. Cap. 53:04

Part II—The Pharmacy and Medicines Regulatory Authority

Establishment of the Authority

3.—(1) There is hereby established an Authority known as the Pharmacy and Medicines Regulatory Authority (in this Act otherwise known as the "Authority").

(2) The Authority 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.

(3) The Authority shall seek the general direction of the Minister as to the manner in which it is to carry out its duties under this Act.

Functions of the Authority

4. The Authority shall—

(*a*) grant pharmaceutical licences and marketing authorizations;

(*b*) inspect any premises used for the purpose of manufacturing, distribution, sale, importation or exportation of medicines or allied substances or for any other purposes regulated under this Act;

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

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

(*e*) register and regulate pharmacy practice premises and personnel and their training;

(*f*) in consultation with the relevant professional bodies, establish, maintain and develop standards for the operation of pharmacy practice premises and the pharmacy profession in general;

(*g*) serve and protect the public interest in all matters relating to the sale of medicines and allied substances;

(*h*) (*i*) issue clinical trial licences;

(*ii*) monitor the conduct of clinical trials;

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

(*j*) approve the use of unregistered and unauthorized medical products for trial or for compassionate use;

(*k*) establish a functional system for pre- and post-marketing surveillance of safety, quality, efficacy and effectiveness of medical products and to optimize the risk-benefit balance.;

(*l*) establish, maintain and enforce standards for medicine quality control laboratories;

(*m*) formulate, disseminate, and advise the Minister on, policies relating to the regulation and control of medicines and allied substances;

(*n*) collaborate with corresponding medicines regulatory authorities in other countries;

(*o*) continuously review rules, regulations, guidelines and procedures pertaining to the implementation of this Act and make amendments where necessary in order to keep pace with changing times and pharmaceutical industry demands;

(*p*) in consultation with relevant research institutions, determine national priorities in pharmaceutical research;

(*q*) share data on pharmacy practice or medicine with other countries:

Provided that the Authority shall ensure that such data is protected; and

(*r*) perform all such things as are connected with, or incidental to, the functions of the Authority under this Act.

Powers of the Authority

5. The Authority shall have powers to—

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

(*b*) require any pharmacy practice premises, 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 the pharmacy practice premises, manufacturer, wholesale dealer, distributor, importer or exporter;

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

(*d*) declare certain substances as medicine;

(*e*) determine the method of sale of medicines;

(*f*) review the policy and strategic plan of the Authority;

(*g*) oversee the implementation and successful operation of the policy and functions of the Authority;

(*h*) approve the annual budget and plans of the Authority;

(*i*) monitor and evaluate the performance of the Authority against budgets and plans;

(*j*) establish and issue guidelines and standards for purposes of this Act;

(*k*) establish and approve rules and procedures for the appointment, discipline, termination and terms and conditions of service of the staff of the Authority;

(*l*) recommend to the Minister for amendments to this Act or the making of regulations under this Act; and

(*m*) exercise any other powers conferred or imposed on the Authority by, or under, this Act.

Members of the Authority

6.—(1) The Authority shall consist of the following part-time members appointed by the Minister—

(*a*) three registered pharmacists preferably who are also members of the Pharmaceutical Society of Malawi;

(*b*) one member, who is Medical Practitioner nominated by the Medical Council of Malawi;

(*c*) one member nominated by the Board of Veterinary Surgeons;

(*d*) one member nominated by the Nurses and Midwives Council;

(*e*) one member representing groups of advocates of patients' rights;

(*f*) the Secretary for Health or his representative;

(*g*) one person nominated by public institution of higher learning in health sciences;

(*h*) the Solicitor General or his representative; and

(*i*) the Comptroller of Statutory Corporations or his representative.

(2) The Minister shall cause to be published in the *Gazette* names of all members of the Authority, and every change of membership.

(3) The Minister shall appoint one of the members of the Authority, who is a pharmacist, as Chairperson.

(4) The members shall elect the Vice-Chairperson of the Authority from amongst themselves.

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

(*a*) is an undischarged bankrupt;

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

(*c*) has been convicted of an offence under any written law and sentenced to imprisonment for a period exceeding six months without the option of a fine;

(*d*) has been found guilty of professional misconduct; or

(*e*) is an employee of the Authority.

(6) The Minister may suspend from office a member of the Authority against whom—

(*a*) criminal proceedings have been instituted for an offence in respect of which a sentence of imprisonment for a term of six months or more without the option of a fine may be imposed; or

(*b*) the Authority has instituted an inquiry into his professional conduct:

Provided that while such member is so suspended he shall not carry out any duties as member.

Tenure of office and vacancy

7.—(1) A member of the Authority, other than an *ex-officio* member, shall hold office for a period of three years and shall be eligible for reappointment for one further term.

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

(3) The office of a member shall become vacant where—

(*a*) the member is absent, without reasonable excuse, from three consecutive meetings of the Authority of which the member has had notice;

(*b*) the member is adjudged bankrupt;

(*c*) the member has, within the last three years, been convicted by a competent court of a crime which is punishable with imprisonment without an option of a fine;

(*d*) the member ceases to be a representative or member of the institution which recommended the member;

(*e*) if the member is found guilty of professional misconduct;

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

(*g*) upon the member's death.

(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 vacancies

8. The Minister may, where the office of a member becomes vacant before the expiry of the term of office, appoint another member from the same body in place of the member who vacates office but that member shall hold office only for the unexpired part of the term.

Proceedings during meetings of the Authority

9.—(1) Subject to the other provisions of this Act, the Authority may regulate its own procedure.

(2) The Authority shall meet to transact its business at least once in every three months at such places and times as the Authority may determine.

(3) A meeting of the Authority may be called by the Chairperson, upon giving notice of not less than fourteen days, and shall be called by the Chairperson if not less than one-third of the members so request in writing, except that if the urgency of any particular matter does not permit the giving of the notice, a special meeting may be called upon giving a shorter notice.

(4) The Chairperson, or in the absence of the Chairperson, the Vice-Chairperson, with five other members shall constitute a quorum at any meeting of the Authority.

(5) The Chairperson of the Authority shall preside at any meeting of the Authority, and in his absence, the Vice chairperson shall preside at the meeting.

(6) In the absence of the Chairperson and the Vice-Chairperson, the members present may elect a person to preside at the meeting.

(7) A decision of the Authority 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 that person's deliberative vote.

(8) The Authority may invite any person, whose presence is in its opinion desirable, to attend and to participate in the deliberations of the meeting of the Authority, but that person shall not have any vote.

(9) Where a member is for any reason unable to attend a meeting of the Authority, the member may, in writing, nominate another person from the same organization to attend the meeting in that member's stead and that person shall be deemed to be a member for the purpose of that meeting.

(10) The validity of any proceedings, acts or decisions of the Authority shall not be affected by any vacancy in the membership of the Authority 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.

Honoraria of members

10. A member of the Authority or its committee shall be paid such allowances or other benefits as the Minister may determine.

Confidentiality

11.—(1) A person shall not publish or disclose to any entity, other than in the course of the entity's duties, the contents of any document, communication or information which has come to the person's knowledge in the course of his duties under this Act.

(2) A person who contravenes subsection (1) commits an offence.

(3) A person who, having any information which to the knowledge of that person has been published or disclosed in contravention of subsection (1), unlawfully publishes or communicates the information to any other person, commits an offence.

Disclosure of interest

12.—(1) Any member of the Authority or its committee who is present at a meeting of the Authority at which any matter in which he has an interest or may have an interest is being considered, shall disclose such interest as soon as is practicable after the commencement of the meeting and he shall not take part in any consideration or discussion of, or vote on, any question touching on such matter.

(2) The Director General shall disclose to the Chairperson of the Authority any interest he has in any matter that is under consideration by the Authority, and shall not attend any meeting of the Authority or of any committee of the Authority while any question touching the matter is being discussed.

(3) Any employee of the Authority or any consultant, adviser or sub-contractor of the Authority shall disclose to the Derector General any interest that he has or that may arise in the course of duties related to the operations of the Authority, and the Director General or the Authority, shall make decisions considered appropriate in each case and submit a report thereon to the Authority.

(4) The Authority shall promulgate regulations and guidelines for declaration of conflict of interest that shall be applicable to all members of the Authority, Committees and employees of the Authority

(5) A person who contravenes this section commits an offence and shall, upon conviction, be liable to a fine of K250,000.

Funds of the Authority

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

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

(*b*) 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, subject to the approval of the Minister—

(*a*) accept moneys by way of grants from any source within or outside Malawi; and

(*b*) raise, by way of loans or otherwise, such moneys as it may require for the discharge of its functions.

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

(*a*) the salaries, allowances, loans, gratuities and pensions of members of staff of the Authority;

(*b*) such reasonable travelling and other allowances for the members of the Authority and of any Committee of the Authority when engaged on the business of the Authority, at such rates as the Minister may determine; and

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

Cap. 37:02

(4) Subject to the Public Finance Management Act, the Authority may invest in such manner as it considers appropriate such funds of the Authority which it does not immediately require for the discharge of its functions.

(5) The moneys of the Authority which, at the end of each financial year, are in excess of the Authority's budgetary requirements for that year shall be paid into the Consolidated Fund, but the Authority may be entitled to retain such sums as it reasonably requires for its operations.

Financial year of the Authority

14. The financial year of the Authority shall be the same as the financial year of Government.

Accounts and audit

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

(2) The Authority shall, as prescribed, submit to the Government a report concerning its activities during the financial year.

(3) The report referred to in subsection (2) shall include statements of income and expenditure and a statement of affairs or balance sheet.

(4) The accounts of the Authority shall be audited annually as prescribed by Government.

Annual report

16. As soon as practicable, but not later than six months after the end of a financial year, the Authority shall submit to the Minister a report concerning its activities during that financial year.

Committees of the Authority

17.—(1) The Authority shall, for the purpose of performing its functions under this Act, establish—

(*a*) the Pharmacy Committee;

(*b*) the Medicines Committee;

(*c*) the Medicines Safety and Quality Monitoring Committee; and

(*d*) any other such committees as it considers necessary for implementing the powers and functions of the Authority under this Act.

(2) The Authority may delegate such of its functions as it considers fit, to any committee established under subsection (1).

(3) The Authority may appoint any person, irrespective of whether he is a member of the Authority or not, to be a member of a committee established under subsection (1):

Provided that at least one member of a committee shall be a member of the Authority.

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

Director General and other staff

18.—(1) The Authority shall appoint a Director General who shall be responsible for the day-to-day administration of the Authority.

(2) The Director General shall be—

(*a*) a registered pharmacist with a post graduate qualification in pharmaceutically related field; and

(*b*) a person with a minimum of seven years' senior management experience.

(3) The Director General shall report to the Authority.

(4) The Director General shall attend meetings of the Authority and of any committee of the Authority and serve as Secretary of the meetings.

(5) The Director General may delegate to any senior member of staff to attend and serve as Secretary at the meetings of Authority or any of its committee.

(6) The Authority may, whenever the Director General is for any reason unable to discharge the functions of the Director General, appoint an acting Director General to discharge the Director General functions.

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

Delegation to the Director General

19. The Authority may, by direction in writing, and subject to any terms and conditions as it considers necessary, delegate to the Director General any of its functions under this Act.

Seal of the Authority

20.—(1) The seal of the Authority shall be such device as may be determined by the Authority and shall be kept by the Director General.

(2) The affixing of the seal shall be authenticated by the Chairperson or the Vice Chairperson of the Authority, on the one hand, and the Director General or any other person authorized on that behalf by a resolution of the Authority, on the other hand.

(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 Director General or any other person generally or specifically authorized by the Authority 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.

Immunity

21. An action or other proceeding shall not lie or be instituted against the Director General or a member of staff for, or in respect of, any act or thing done in good faith in the exercise of, or performance of or purported exercise of, or performance of, any of the powers, functions or duties conferred under this Act.

Part III—Registration and Regulation of Pharmacists, Pharmacy Technologists, Pharmacy Assistants and Medical Representatives

Registration of persons under this Act

22.—(1) Except as is provided under this Act, a person, other than a person registered as a pharmacist, pharmacy technologist and pharmacy assistant under this Part shall not—

(*a*) conduct a pharmacy practice;

(*b*) in the course of any trade or business, prepare, mix, compound or dispense any medicinal product except under the 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 he 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 deemed to suggest that the owner of the business or the person having control of the business on those premises is, or purports to be, a registered pharmacist.

Residential requirements of applicants

23.—(1) Subject to subsection (2), an application for registration as a pharmacist, pharmacy technologist or pharmacy assistant shall only be accepted if, at the time of his application, the applicant is resident in Malawi.

(2) Notwithstanding subsection (1), any person who resides in and is lawfully practising his profession or calling in such country as the Authority may specify by notice published in the *Gazette*, may be registered if, but for residing outside Malawi, he is otherwise qualified for registration.

Persons eligible to be registered under this Act

24.—(1) Subject to subsection (2) and (3), a person shall be eligible for registration under this Act as a pharmacist, pharmacy technologist or pharmacy assistant if he is a holder of a degree, diploma, certificate or other qualification which is recognized by the Authority and he satisfies the Authority through written and oral internship examinations that he—

(*a*) has acquired sufficient knowledge of science and pharmacy; and

(*b*) has an adequate knowledge of the English language ;

(*c*) is, in all respects as to character and otherwise, a fit and proper person to be registered.

(2) A qualification from an examination authority outside Malawi shall only be recognized or accepted under subsection (1) as a qualification for registration if—

(*a*) the qualification entitles the holder to registration in the country, state or territory in which the examination authority has jurisdiction; and

(*b*) the holder has passed oral interview and a written internship examination set by the Authority.

(3) In any case where the Authority does not recognize a degree, diploma, certificate or other qualification, relating to the profession of pharmacy held by any person, as making him eligible for registration, the Authority shall reject the application.

Procedure for registration

25.—(1) A person desiring to be registered under this Act may make application, in the prescribed form, to the Authority, and shall submit with his application—

(*a*) a certificate of any qualification on which he relies for registration or a certified copy thereof:

Provided that a certificate showing his registration in the country, state or territory in which he qualified shall be submitted and that such certificate shall contain details of the qualifications on which registration was based; and

(*b*) documentary evidence of other practical experience or training that was required in the country, state or territory in which he qualified before registration in that country, state or territory;

(*c*) documentary evidence that such experience has been acquired or that such training has been obtained in that country;

(*d*) certificate of registration in that country, state or territory or a certified copy thereof;

(*e*) in case of a person referred to in section 23 (2), evidence that he resides or intends, if he is registered, to reside in Malawi; and

(*f*) the prescribed fee.

(2) The Authority may require any statement in connection with an application under subsection (1) to be supported by a solemn or statutory declaration.

(3) If the Authority is satisfied that the qualification and the particulars or documents submitted under subsection (1) are in accordance with the requirements of this Act, the Authority shall, upon payment by the applicant of the prescribed fee and passing the written internship examinations and oral interviews, register the applicant in the appropriate register.

Certificate of registration

26.—(1) Upon registration, the Authority shall issue an appropriate certificate of registration to—

(*a*) the pharmacist;

(*b*) the pharmacy technologist; or

(*c*) the pharmacy assistant.

(2) A person registered under section 25 shall not be allowed to practise without a practising licence issued at a fee as may be prescribed by the Authority.

(3) A practicing licence shall be valid from the time of issuance up to the end of the financial year.

(4) The Authority may index pharmacy students in colleges in Malawi on the basis of their proven enrollment and keep a separate register of pharmacist interns.

Application for retention of name on register

27.—(1) Every registered pharmacist, pharmacy technologist and pharmacy assistant shall, within the period specified by the Authority, annually make application to the Authority for the retention of his name on the appropriate register.

(2) An application made under subsection (1) shall be accompanied by a prescribed fee and late applications received after period specified in subsection (1) shall attract a penalty as prescribed by the Authority.

(3) The Authority may, by its resolution, strike off from the appropriate register the name and other particulars of any registered pharmacist, pharmacy technologist or pharmacy assistant who do not make application to the Authority for the retention of his name on the appropriate register as required by subsections (1) and (2).

(4) The Authority may retain a name on the register of the person by way of assessment through continuous professional development.

Removal of name from the register

28.—(1) Subject to paragraph (3), the Authority may remove from the appropriate register the name of a pharmacist or pharmacy technologist or a pharmacy assistant who—

(*a*) is convicted of an offence under this Act or any other written law which in the opinion of the Authority renders him unfit to be on the appropriate register; or

(*b*) is judged by the Authority after due inquiry, at which such person shall have an opportunity of being heard—

(i) to have been guilty of conduct which when due regard is had to his profession or calling, is improper or disgraceful; or

(ii) to have performed any act pertaining to his profession or calling in a grossly incompetent manner.

(2) Every pharmacist, technologist or pharmacy technician whose name is removed from the register under this section shall surrender the certificate of registration to the Director General for cancellation.

(3) The Authority may, instead of removing the name of a person registered under this Act from an appropriate register, reprimand such person or suspend his registration subject to such conditions as the Authority may consider necessary to impose.

Notification of registration and removal from register

29. The Authority shall, at least once every year, cause to be published in the *Gazette* a notification of all registrations effected under this Act and of all removals from the register.

Appeals against refusal to register or against removal from register

30.—(1) A person aggrieved by—

(*a*) the refusal of the Authority to enter his name in an appropriate register; or

(*b*) the removal by the Authority of his name from an appropriate register,

may, after giving written notice to the Authority, appeal to the High Court against the decision to refuse or the decision to removal him from the register.

(2) A notice of appeal under this section shall be filed within three months of the date on which a notice is given to him by the Authority of the fact of refusal or removal, as the case may be.

(3) On an appeal under subsection (1), the High Court may—

(*a*) dismiss the appeal; or

(*b*) if it is of the opinion that the Authority has not acted in accordance with the Act, make an order that the name of the appellant be entered or retained in the appropriate register on such conditions as the Court considers appropriate; or

(*c*) refer the matter back to the Authority for further consideration, and may make such other orders as to costs of the appeal or otherwise as it may deem just:

Provided that the High Court shall not set aside any finding or penalty imposed by the Authority by reason only of an informality or irregularity in the proceedings of the Authority, or where the matter was referred to the Pharmacy Committee, the proceedings of that Committee which did not embarrass or prejudice the appellant in answering the charge or in the conduct of his defence.

Display of certificate in practice premises

31. A person shall not carry on a pharmacy business 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 therein.

Registration of premises

32.—(1) A registered person carrying on a pharmacy business in accordance with this Act shall cause each set of premises where such business is being carried on to be registered.

(2) The Authority may, for good cause to be stated in writing, refuse to register or in like manner remove from the register any premises which do not have a suitable registered person under this Act.

Company conducting wholesale or retail pharmacy business

33.— (1) Notwithstanding anything contained in the foregoing provisions, a company may carry on a wholesale or retail pharmacy business where—

(*a*) majority shareholder of at least fifty one percent is a citizen of Malawi;

(*b*) it is registered under this Act;

(*c*) it is shown to the satisfaction of the Authority that the business is under the personal management and control of a registered pharmacist;

(*d*) a copy of the certificate of incorporation of the company is lodged with the Authority; and

(*e*) the other provisions of this Act are complied with.

(2) Any act which if done by an individual would be an offence against this Act shall, if done by a company, be an offence committed by every director, secretary and manager thereof unless he proves that the act or omission constituting the offence took place without his knowledge or consent.

Representatives of deceased or insolvent pharmacists

34. Notwithstanding anything contained in the foregoing provisions of this Part—

(*a*) if a pharmacist dies, or becomes of unsound mind or is adjudged bankrupt or enters into an arrangement with his creditors, his personal representative may, with the permission of the Authority and subject to such directions and conditions as the Authority may in its discretion deem fit to impose, carry on the business; and

(*b*) it shall be necessary for such representative to be registered in relation to the premises where such business is carried on, and such business shall be continued only under the personal management and control of a pharmacist and for such period not exceeding five years as the Authority may decide.

Exemptions from this Part

35. This Part shall not apply to medicinal products supplied by—

(*a*) a medical practitioner or a dentist in the ordinary course of his practice;

(*b*) a veterinary surgeon in the ordinary course of his practice; and

(*c*) any hospital which the Minister may, by order published in the *Gazette*, exempt.

Pharmacy Committee

36.—(1) The Authority shall, in accordance with section 17, establish a Pharmacy Committee which among other functions shall act as a disciplinary committee of the Authority.

(2) The Pharmacy Committee shall perform such functions and exercise such powers as the Authority may from time to time assign to the Committee.

(3) The Chairperson of the Pharmacy Committee shall be appointed by the Authority from amongst the members of the Committee.

(4) Without prejudice to the generality of subsection (2) the Pharmacy Committee shall, where it is assigned by the Authority so to do, deal with all matters relating to—

(*a*) the registration and discipline of pharmacists, pharmacy technologists or pharmacy assistants; and

(*b*) the registration, control and regulation of any pharmacy practice premises.

(5) In any disciplinary inquiry before the Pharmacy Committee, the Authority may request the services of a legal counsel to assist the Committee in the proceedings of the inquiry.

(6) At any meeting of the Pharmacy Committee, the Chairperson and two other members shall form a quorum.

(7) For the purposes of any disciplinary inquiry before the Pharmacy Committee, the Chairperson of the Authority may appoint to the Committee, in addition to the members of the Committee, any other person who the Chairperson considers reasonably qualified to assist the Committee in the conduct of the inquiry.

(8) All facts, matters or things authorized or required to be done by the Pharmacy Committee shall be decided by a majority vote at a meeting of the Committee at which a quorum is present.

(9) At all meetings of the Pharmacy Committee, each member present by virtue of subsection (1), shall have one vote on a question before the Committee and, in the event and equality of votes, the Chairperson shall, in addition to a deliberative vote, have a casting vote.

(10) The Pharmacy Committee shall have power to regulate its own procedure.

(11) Without prejudice to the generality of subsection (10), the Pharmacy Committee shall, as soon as practicable after the close of the inquiry—

(*a*) consider the evidence adduced and the representations made thereat, without undue delay complete;

(*b*) deliver to the Authority its report thereon together with such documents as were produced and are relevant to the matters inquired into; or

(*c*) make its recommendations as to whether—

(i) the allegation should be dismissed;

(ii) the person whose case was being heard be reprimanded; or

(iii) the registration of the person whose case was being heard be suspended or cancelled.

Performance of disciplinary function

37.—(1) Where the Pharmacy Committee shall perform the functions of a disciplinary committee, it shall have power to inquire into any matter or question referred to it by the Authority according to this Act when there is a report that a pharmacist, pharmacy technologist or pharmacy assistant—

(*a*) has been guilty of an offence which in the view of the Authority renders him unfit to be on the appropriate register; or

(*b*) has been guilty of conduct which, considering his profession or calling, is improper or disgraceful; or

(*c*) is grossly incompetent or has performed any act pertaining to his profession or calling in a grossly incompetent manner.

(2) In exercising its function under subsection (1), the Pharmacy Committee shall—

(*a*) cause to be served upon a registered pharmacist or registered pharmacy technologist or registered pharmacy assistant, a notice setting out the allegations against him; and

(*b*) afford him a reasonable opportunity of being heard either by himself or, if he so wishes, by a legal representative.

(3) For purposes of any inquiry, the Pharmacy Committee may take evidence and may—

(*a*) under the hand of the Chairperson, summon witnesses and require the production of any book, record, document or thing;

(*b*) administer oath or affirmation to any person; and

(*c*) examine any book, record, document or thing which a witness has been required to produce.

(4) A summons for attendance before the Pharmacy Committee or for the production to it of any book, record, document or thing shall be in the form prescribed by the Authority.

Loss of certificate of registration

38.—(1) A holder of a licence who loses the licence may apply to the Authority for a duplicate licence in the prescribed manner and form upon payment of the prescribed fee.

(2) The Authority shall within fourteen days of the receipt of an application under subsection (1) issue a duplicate licence if the applicant meets the requirements of this Act.

Registration of medical representatives

39.—(1) The Authority may maintain a register of medical representatives based on their approved applications.

(2) A person shall not be registered as a medical representative unless—

(*a*) he is trained in health sciences; and

(*b*) he has adequate knowledge of the medicine being promoted or to be promoted.

(3) A person shall only conduct himself as medical representative if he is registered as such by the Authority.

(4) The Minister may, on the recommendation of the Authority, make regulations for medical representatives.

(5) A person who contravenes this section commits an offence.

Part IV—Registration and Regulation of Pharmacy Practice Premises

Prohibition of unregistered pharmacy practice premises

40.—(1) A person shall not—

(*a*) operate, either on that person's own behalf or on behalf of another person, a pharmacy practice premises that is not registered under this Act; or

(*b*) assume, take, exhibit or in any way make use of any title, emblem, description or addition reasonably calculated to suggest that a pharmacy practice premises is registered.

(2) A person who contravenes this section commits an offence.

Application for a licence

41.—(1) A person who intends to operate pharmacy practice premises shall apply to the Authority for an appropriate licence, as the case may be, in the prescribed manner and upon payment of the prescribed fee.

(2) A separate application shall be made in respect of each pharmacy practice premises to be operated.

(3) The Authority shall—

(*a*) request an applicant to furnish any other information in relation to an application, within such period as it may determine; and

(*b*) inspect the premises in respect of which an application is made before the issuance of the licence.

Issuance of a licence

42.—(1) The Authority shall, within sixty days of receipt of an application made under section 41, issue to the applicant a licence if—

(*a*) the application meets the requirements of this Act;

(*b*) the premises to be used are suitable for conducting pharmacy practice;

(*c*) the pharmacy practice premises is under the management and control of an appropriate registered person as prescribed by this Act at all times; and

(*d*) the activity or business to be carried out does not contravene any other written law.

(2) Subject to the other provisions of this Act, a licence issued under this section shall be subject to such terms and conditions as the Authority may determine.

Rejection of application

43.—(1) The Authority shall reject an application for a licence if—

(*a*) the activity or business to be carried out contravenes any written law;

(*b*) the premises in respect of which the application is made are not suitable for pharmacy practice and do not comply with prescribed standards of pharmacy practice;

(*c*) the licence previously held by the applicant was cancelled by the Authority; or

(*d*) the applicant submits false information in relation to the application.

(2) The Authority shall, where it rejects an application under subsection (1), inform the applicant, in writing, and give the reasons for the rejection.

Display of a licence

44. A holder of licence shall display the licence in a conspicuous manner at the place of pharmacy practice premises.

Retention fees

45.—(1) A holder of a licence shall pay to the Authority annual retention fees in a prescribed manner.

(2) A licensee who fails to pay the annual retention fee within the period prescribed by the Authority shall be liable to a penalty as prescribed by the Authority.

Surrender of a licence

46.—(1) Where the holder of a licence decides not to continue with the business to which the licence relates, the holder shall notify the Authority, in writing, and shall agree with the Authority on the terms and conditions of the surrender of the licence.

(2) Where a licence is surrendered under subsection (1), the licence shall lapse and be cancelled.

Transfer of a licence

47.—(1) Any licence granted under this Act shall only be transferred to a third party with prior written approval of the Authority.

(2) An application for approval to transfer a licence shall be made to the Authority in the prescribed manner and form.

(3) The Authority may, within fourteen days of receipt of an application to transfer a licence, determine the application in accordance with this Act.

Amendment of a licence

48.—(1) Subject to subsection (2), a holder of a licence shall notify the Authority in writing, in the prescribed manner, where a change occurs in any of the following registered particulars—

(*a*) the business name;

(*b*) the physical address of the pharmacy;

(*c*) the structure of the place of business;

(*d*) ownership or control of the business; or

(*e*) name of the registered and designated person responsible for the pharmacy practice premises.

(2) The notification referred to in subsection (1) shall be made within fourteen days of the occurrence of the change of the registered particulars.

(3) The Authority shall, upon receipt of the notice referred to in subsection (1), amend the licence accordingly.

(4) The Authority shall, where it identifies an error on the Register relating to any particulars of a licence, inform the holder of the licence and amend the licence accordingly.

(5) A person who contravenes subsection (1) commits an offence.

Loss of a licence

49.—(1) A holder of a licence of registration who loses the certificate may, upon payment of the prescribed fee, apply to the Authority for a duplicate certificate of registration in the prescribed manner and form.

(2) The Authority shall, within fourteen days of the receipt of an application under subsection (1), issue a duplicate certificate of registration if the applicant meets the requirements of this Act.

Standard of pharmacy practice

50. For the purposes of this Part, the Minister may, on the recommendation of the Authority, by notice published in the *Gazette*, provide for standards for the practice of pharmacy in pharmacies and hospital pharmacies.

Management of hospital and retail pharmacies

51.—(1) Subject to subsection (3), a hospital pharmacy shall be managed by a pharmacist.

(2) A pharmacist shall always be present when a pharmacy is open and medicine is being dispensed.

(3) The Minister may, on the recommendation of the Authority, by notice published in the *Gazette*, provide for circumstances under which a hospital pharmacy may be operated by a pharmacy technologist or such other person as the Authority may determine, under the supervision of a pharmacist.

Dispensing licence

52.—(1) The Authority may, upon application by a person, issue a dispensing licence to a health facility or a veterinary clinic to dispense medicines and allied substances to patients in accordance with the categories prescribed by the Authority.

(2) The Minister may, on the recommendation of the Authority, by notice published in the *Gazette,* provide for—

(*a*) the criteria and procedure for applying for a dispensing licence and the grant, amendment, renewal, transfer and revocation of a dispensing licence;

(*b*) the terms and conditions attaching to an application, grant, amendment, refusal, renewal, transfer or revocation of a dispensing licence;

(*c*) the exemption of certain categories of persons from any provision of this section; and

(*d*) any other matters that are necessary or incidental to the effective regulation of a dispensing licence under this Act.

Veterinary shop licence

53.—(1) The Authority may, upon application by a person, issue veterinary shop licence to the person to sell a prescribed list of veterinary medicinal products, under the control and management of such persons as the Authority may authorize.

(2) The Minister may, on the recommendation of the Authority, by notice published in the *Gazette*, provide for—

(*a*) the criteria and procedure for applying for veterinary shop licence and the grant, amendment, renewal, transfer and revocation of a veterinary shop licence;

(*b*) the terms and conditions attaching to an application, grant, amendment, refusal, renewal, transfer or revocation of veterinary shop licence; and

(*c*) any other matters that are necessary or incidental to the effective regulation of veterinary shop licences under this Act.

Register of pharmacy practice premises

54.—(1) The Authority shall keep and maintain a register of all pharmacy practice premises that include retail pharmacy, manufacturer, wholesale dealer, and medicine store, registered under this Act in which shall be entered the names and other details relating to the premises.

(2) The register referred to in subsection (1) shall be kept at the offices of the Authority and shall be open to inspection by the public at such times and on such conditions, including the payment of a fee for inspection, as the Authority may determine.

(3) A person may, upon payment of the prescribed fee, require a copy of the register.

(4) Any document purporting to be an extract or copy of any entry in the register and duly certified to be a true copy or extract under the hand of the Director General shall be received in evidence as to the matters stated therein in any legal proceedings.

Publication of premises

55. The Authority shall publish annually the names of all the pharmacy practices premises registered under this Act on its website and a daily newspaper of wide circulation in Malawi.

Part V—Licences, Import and Export Permits

Prohibition of certain operation without a licence

56.—(1) A person shall not manufacture, distribute or deal in any medicine or allied substance without an appropriate pharmaceutical licence.

(2) A person who contravenes subsection (1) commits an offence.

(3) The Authority may adopt measures that promote local production of medicines and allied substances.

(4) All dealers shall be required to keep traceable records of the source of products sold or under their custody at all times.

Pharmaceutical manufacturing licence

57.—(1) A person who intends to manufacture, distribute or deal in any medicine or allied substance shall apply to the Authority for an appropriate pharmaceutical manufacturing licence in the prescribed manner and upon payment of the prescribed fee.

(2) The Authority shall, within ninety days of the receipt of an application under subsection (1), issue a pharmaceutical manufacturing licence to the applicant if the applicant meets the requirements of this Act.

(3) The Authority shall reject an application which does not meet the requirements of this Act and inform the applicant of the reasons for the rejection.

(4) The Minister may, on the recommendation of the Authority, by notice published in the *Gazette*, provide for—

(*a*) the criteria for the licensing of persons under subsection (1);

(*b*) the procedure for applying for a pharmaceutical manufacturing licence and the grant, amendment, renewal, transfer, surrender or revocation of a pharmaceutical manufacturing licence;

(*c*) the terms and conditions attaching to an application, grant, amendment, refusal, renewal, transfer, surrender or revocation of a pharmaceutical manufacturing licence; and

(*d*) such other matters as are necessary or incidental to the effective regulation of licences under this Part.

(5) The Minister may, on the recommendation of the Authority, and for the purposes of facilitating the effective implementation and enforcement of this Act—

(*a*) exempt certain categories of persons from the application of some or all of the provisions of this section; and

(*b*) provide that some or all of the provisions of this section shall not apply in certain circumstances.

Import permit

58.—(1) A person shall not import any medicine or allied substance without an import permit.

(2) This section shall not apply to any medicine or allied substance imported by a traveler entering Malawi for the traveler's use as may be prescribed as long as supply is for personal use for a period not exceeding six months.

(3) A person who contravenes subsection (1) commits an offence.

(4) The Minister may, on the recommendation of the Authority, by statutory instrument, provide for—

(*a*) the criteria for the regulation of persons under subsection (1);

(*b*) the procedure for applying for an import permit and the grant, amendment, renewal, transfer, suspension and revocation of an import permit;

(*c*) the terms and conditions attaching to an application, grant, amendment, refusal, renewal, transfer, suspension or revocation of an import permit; and

(*d*) such other matters as are necessary or incidental to the effective regulation of import permits under this Part.

Export permit

59.—(1) A person shall not export any medicine or allied substance without an export permit.

(2) A person who contravenes subsection (1) commits an offence.

(3) The Minister may, on the recommendation of the Authority, by notice published in the *Gazette*, provide for—

(*a*) the criteria for the regulation of persons under subsection (1);

(*b*) the procedure for applying for an export permit and the grant, amendment, renewal, transfer, suspension and revocation of an export permit;

(*c*) the terms and conditions attaching to an application, grant, amendment, refusal, renewal, transfer, suspension or revocation of an export permit; and

(*d*) such other matters as are necessary or incidental to the effective regulation of export permits under this Part.

Additional permit requirements for narcotics, etc.

60. Where a person intends to import or export a narcotic drug, psychotropic substance or precursor for medical or scientific use, the person shall—

(*a*) in addition to obtaining an import or export permit, obtain additional authorization from the Authority; and

(*b*) comply with additional requirements as may be provided for under the Dangerous Drugs Act, the International Conventions to which Malawi is a signatory and any other written laws.

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Register of licences and permits

61. The Authority shall maintain a register of licences and permits, which shall contain such particulars as the Authority may consider necessary for purposes of this Act.

Part VI—Regulation and Registration of Medicines and Allied Substances

Marketing authorization

62.—(1) A person who intends to place on the market, advertise, market, manufacture, sell, import, supply, administer or deal in any manner with any medicine or allied substance shall apply to the Authority for a marketing authorization in the prescribed manner.

(2) A person shall not place on the market, advertise, market, manufacture, sell, import, supply, administer or deal in any manner with any medicine or allied substance without a marketing authorization issued by the Authority.

(3) A person who contravenes subsection (2) commits an offence.

(4) This section shall not apply to—

(*a*) donated medicines and allied substances that shall comply with specific guidelines prescribed by the Authority and approved by the Minister;

(*b*) a person importing medicine for that person's use or for the use of that person's relative, if the quantity of the imported medicine is based on a prescription;

(*c*) a physician, dentist or veterinary surgeon importing medicine on the physician's, dentist's or veterinary surgeon's order for

administration to a person or animal, if the quantity of the imported medicine is based on a prescription;

(*d*) medicine manufactured under the supervision of a pharmacist or by a pharmacist—

(i) for sale in the pharmacist's own pharmacy; or

(ii) in a hospital for its use;

(*e*) medicine imported or exported in response to a declared health emergency;

(*f*) any medicine or allied substance used for purposes of a clinical trial; and

(*g*) the importation of a medicine or medicinal product and allied substance in such circumstances as the Minister may, specify by notice published in the *Gazette*.

(5) The Minister may, on the recommendation of the Authority, by notice published in the *Gazette*, provide for—

(*a*) the criteria for the regulation of persons under subsection (1);

(*b*) the procedure for applying for a marketing authorization and the grant, amendment, renewal, transfer and revocation of a marketing authorization;

(*c*) the terms and conditions attaching to an application, grant, amendment, refusal, renewal, transfer or revocation of a marketing authorization; and

(*d*) such other matters as are necessary or incidental to the effective regulation of marketing authorizations under this Part.

(7) A holder of a product licence shall obtain a marketing authorization and shall pay such annual retention fee as the Authority, with approval of the Minister, may determine.

(8) The product licence shall show—

(*a*) the categorization of the medicine by the Authority such as prescription only medicine;

(*b*) any other conditions of registration; and

(*c*) shall maintain the registration status of the medicine as per the requirements stated in the registration guidelines.

(9) A product licence which is annually retained shall remain valid for three years and shall require renewal of registration of the medicine registered pursuant to this Act.

(10) Any registered medicine shall be presented for re-licensing at least one hundred and twenty days prior to the end of the prescribed validity of the product licence.

(11) The Authority may, with approval of the Minister, provide a list of persons allowed to deal in allied substances under this Act. Such substances shall include food supplements, herbs and traditional medicines.

Categories of medicines

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

(*a*) prescription only medicine;

(*b*) controlled drugs and psychotropic substances;

(*c*) pharmacy initiated medicine;

(*d*) pharmacy medicine; and

(*e*) general sale or over the counter medicine.

(2) Medicines shall be dispensed in accordance with the respective requirements applicable to the categories specified in subsection (1) and as shall be prescribed notice published in the *Gazette*.

Medicines list

64. The Minister may, on the recommendation of the Authority, by notice published in the *Gazette*, provide for a list of substances to be considered as medicines.

Prohibition of sale of prescription only medicines without prescription

65.—(1) A person shall not sell or supply medicine which is required to be sold by prescription only to any person without a prescription.

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

(3) Unless otherwise provided, all prescriptions shall specify the medicine to be administered by reference to the generic name of that medicine.

(4) A prescription signed by an authorized prescriber authorizing the sale or supply of a medicine shall not be dispensed on more than one occasion, except if the prescription expressly directs that it may be dispensed on a specified number of occasions or at specified intervals in a specific period, and it may be dispensed in accordance with that direction:

Provided that the number of additional occasions shall not exceed three times.

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

(6) A person who contravenes this section commits an offence.

(7) The Minister may, for the purpose of preventing the improper use of prescription only medicines, and on the recommendation of the Authority, by Order published in the *Gazette*—

(*a*) provide for the control of the importation, exportation, sale, possession, distribution, use and labeling of prescription only medicines; and

(*b*) prohibit, regulate or restrict the manufacture and distribution of prescription only medicine.

Labelling of medicine

66. Medicines shall be labeled in such manner as the Minister may, on the recommendation of the Authority, provide by notice published in the *Gazette*.

Sale of medicine, etc.

67.—(1) A person shall not sell by retail or otherwise supply medicine in a place other than a registered pharmacy practice premises, health facility or an animal health facility, except with the written approval of the Authority.

(2) Any medicine sold in a place other than those prescribed under subsection (1), shall be sold in the original package labelled by the manufacturer with—

(*a*) full instructions for use;

(*b*) indications, contra indications, warnings and precautions; and

(*c*) any other information as the Minister may provide, by notice published in the *Gazette*, on the recommendation of the Authority.

(3) Such places and list of the categories of products under subsection (2) may be published by the Authority from time to time.

(4) An authorized prescriber shall not sell any medicine to any person unless—

(*a*) it is in a package for an individual patient's use only; and

(*b*) the health facility from which the medicine is sold has a dispensing licence issued under this Act.

(5) A registered wholesaler, manufacturer or importer shall not sell any medicine to any person unless that person is duly authorized to handle medicines and allied substances under this Act.

Advertising of medicines

68.—(1) Advertisement of any medicine or allied substance shall conform to the information relating to the medicine or allied substance approved by the Authority and as specified in the marketing authorization.

(2) Advertisement of any medicine or allied substance shall require prior screening and approval by the Authority.

(3) A medicine or allied substance which is sold by prescription only shall not be advertised to the general public.

(4) 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 or allied substance.

(5) A person who contravenes this section commits an offence.

Recall of medicine etc., from circulation

69.—(1) The Authority may, where it determines that it is not in the public interest that any medicine or allied substance should be made available to the public, recall the medicine or allied substance which the person has possession of.

(2) The Authority shall determine the manner in which the medicine or allied substance, recalled under subsection (1) shall be disposed.

(3) A person shall not dispose of any medicine or allied substance contrary to the manner prescribed by the Authority under subsection (2).

(4) The cost of recalling and disposing the medicine or allied substance under this section shall be borne by—

(*a*) a local manufacturer, in the case of a locally manufactured product;

(*b*) an importer, in the case of a foreign manufactured product; or

(*c*) any other person as the Authority may determine on case by case basis, in the case of a situation other than in paragraphs (*a*) and (*b*).

(5) A person who contravenes this section commits an offence.

(6) Where the Authority has recalled a medicine or an allied substance under this section, it may, where it deems fit, cause to be published in a newspaper of wide circulation—

(*a*) name of the recalled product;

(*b*) batch details of the product;

(*c*) name of the manufacturer of the product;

(*d*) direction to consumers on how to handle the product;

(*e*) any other matter which the Authority may deem necessary.

Medicines Safety Monitoring and Quality Committee

70.—(1) The Authority shall, in accordance with section 17, establish a Medicines Safety and Quality Monitoring Committee.

(2) The Committee shall comprise not more than nine members which shall consist of experts in —

(*a*) human medicine;

(*b*) clinical pharmacy;

(*c*) toxicology;

(*d*) pharmaceutical analysis;

(*e*) pathology;

(*f*) veterinary medicine;

(*g*) epidemiology; or

(*h*) biologicals.

(3) The Minister may, on the recommendation of the Authority, make regulations for monitoring the safety and quality of medicines and allied substances including regulations on pharmacovigilance and medicinal poisons.

(4) When making regulations under this section, the Minister shall have regard to the provisions of section 72.

Register of marketing authorizations

71.—(1) The Authority shall keep and maintain a register of marketing authorizations issued under this Act.

(2) The register referred to in subsection (1) shall be kept at the offices of the Authority and shall be open to inspection by the public at such times and on such conditions, including the payment of a fee for inspection as the Authority may determine.

Establishment of national pharmacovigilance system

72.—(1) The Authority shall establish and maintain a national pharmacovigilance system with which all marketing authorizations, as determined by and Authority, shall comply.

(2) The Authority shall, using the system referred to under subsection (1) be responsible for the following—

(*a*) monitoring and analysis of adverse effects or events for products regulated under this Act;

(*b*) collaborating with other local and international institutions on pharmacovigilance issues;

(*c*) taking appropriate regulatory action when necessary;

(*d*) monitoring of clinical trials, identify and report adverse effect or events; and ensure that they conform with ethical principles for medical research involving human subjects;

(*e*) providing for the means of establishing causality, taking remedial actions and reporting to international safety monitoring systems;

(*f*) categorize medicinal poisons into parts based on criteria to be determined by the Authority.

(3) The Minister shall make regulations to provide for mandatory reporting by the industry, particularly, manufacturers and distributors and health care professionals, and submission of periodic safety updates.

Medicine Committee

73.—(1) The Authority shall, in accordance with section 17, establish a medicines Committee which shall consist of a maximum of seven members who shall be experts in human medicine, veterinary medicine, pharmacology, other experts that may be deemed necessary by the Authority and allied substances.

(2) The Medicine Committee shall—

(*a*) advise the Authority on—

(i) licensing of medicines and allied substances;

(ii) monitoring advertisement on medicines and allied substances;

(iii) monitoring the standards relating to medicines and allied substances; and

(iv) monitoring the conduct of clinical trials;

(*b*) provide technical and scientific advice on any aspect of medicines and allied substances;

(*c*) review risk assessment and risk management measures relating to medicines and allied substances;

(*d*) recommend containment measures, reporting mechanisms, remedial measures, monitoring procedures and other appropriate conditions for medicines or allied substances; and

(*e*) perform any other function conferred on the Medicine Committee by the Authority for purposes of this Act.

(3) Subject to any specific or general directive of the Authority, the Medicine Committee may regulate its own procedure.

(4) The Authority shall appoint the Chairperson of the Medicine Committee and the members of the Medicine Committee shall elect the Vice-Chairperson from among themselves.

(5) The Minister may, by Order published in the *Gazette*, determine the composition and tenure of the Medicine Committee.

Part VII—Regulation of Clinical Trials

Prohibition of conducting clinical trial without certificate

74.—(1) A person shall not conduct a clinical trial involving any medicine or allied substance without a clinical trial certificate.

(2) A person who contravenes this section commits an offence.

Application for clinical trial certificate

75.—(1) A person who intends to conduct a clinical trial shall apply to the Authority for a clinical trial certificate in the prescribed manner upon payment of the prescribed fee.

(2) The Authority shall reject an application for a clinical trial certificate if—

(*a*) the application does not meet the requirements of this Act;

(*b*) the activity to be carried out contravenes any written law of Malawi;

(*c*) the applicant submits false information in relation to the requirements for the application;

(*d*) the premises to be used for the clinical trials is not suitable for the intended purpose; or

(*e*) there is some risk to the health or well-being of a participant and the potential benefit of the clinical trial does not significantly outweigh that risk.

(3) The Authority shall, where it rejects an application under subsection (1), inform the applicant accordingly and give the reasons thereof.

(4) The Minister may, on the recommendation of the Authority, by notice published in the *Gazette*, provide for—

(*a*) the criteria for the regulation of persons under subsection (1);

(*b*) the procedure for applying for a clinical trial certificate and the grant, amendment, renewal, transfer and revocation of a clinical trial certificate;

(*c*) the terms and conditions attaching to an application, grant, amendment, refusal, renewal, transfer or revocation of a clinical trial certificate; and

(*d*) such other matters as are necessary or incidental to the effective regulation of clinical trials under this Part.

Granting of clinical trial certificate

76.—(1) The Authority shall, within ninety days of receipt of an application under this Part, issue the applicant with a clinical trial certificate if—

(*a*) the application meets the requirements of this Act;

(*b*) the clinical trial does not contravene any other written law;

(*c*) appropriately qualified persons are available to handle the medicine or allied substance for purposes of the clinical trial; and

(*d*) the premises on which the applicant proposes to conduct the clinical trials are suitable for the intended purpose.

(2) A certificate granted under this Part shall be valid for such period as shall be specified in the certificate.

(3) The Minister may, on the recommendation of the Authority, by notice published in the *Gazette*, provide for a list of registered clinical trials.

Monitoring, inspection and reporting of clinical trial

77.—(1) The Authority shall monitor and inspect clinical trial sites during the course of the trial and at such intervals as it may determine.

(2) A principal investigator of clinical trial under this Part shall, at the end of the clinical trial, submit to the Authority a copy of prescribed reports of the clinical trial.

(3) The Minister, on recommendation of the Authority, by notice published in the *Gazette*, may prescribe the contents, format and other details of the report submitted under this section.

Register of clinical trial certificates

78.—(1) The Authority shall keep and maintain a register of clinical trial certificates issued under this Act in which it shall enter the names and other details relating to clinical trials.

(2) The Register referred to in subsection (1) shall be kept at the offices of the Authority and shall be open to inspection by the public at such times and on such conditions, including the payment of a fee for inspection, as the Board may determine.

Part VIII—The National Medicines Quality Control Laboratory

Establishment of National Medicines Quality Control Laboratory

79.—(1) There is hereby established the National Medicines Quality Control Laboratory (in this Act otherwise referred to as the "Laboratory") which shall—

(*a*) embrace good laboratory practices;

(*b*) be managed by the Authority; and

(*c*) facilitate the regulation of medicines and allied substances under this Act.

(2) The Authority shall use the laboratory to—

(*a*) verify the safety, quality and efficacy of medicines and allied substances which are manufactured in or imported into the country by persons who are authorized or licensed under this Act;

(*b*) provide laboratory services to the general public;

(*c*) provide practical training for personnel in the analysis of medicines and allied substances; and

(*d*) perform such other functions relating to the analysis of medicines and allied substances as it considers necessary.

(3) The Authority shall charge such fees for the analysis of medicines and services provided by the laboratory as it may determine.

(4) The Authority shall appoint a head for the Laboratory on such terms and conditions as it may determine, who shall be responsible for the day-to-day administration of the Laboratory.

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

(6) A laboratory or pharmaceutical analyst shall, as soon as is practicable, analyze or examine medicines or allied substances sent to the laboratory and issue a certificate of analysis in such form as may be prescribed.

(7) The Authority may use any approved laboratory to verify the quality, efficacy and safety of medicines and allied substances and the laboratory shall, upon analysis or examination of the medicines or allied substances, issue a certificate of analysis.

(8) The Authority shall conduct post marketing surveillance activities in Malawi and ensure that—

(*a*) testing of collected samples is done by the laboratory;

(*b*) there is in place, throughout the supply chain in the country, a testing scheme consisting of sampling of high risk medical products, from private and public pharmaceutical premises; and

(*c*) appropriate action is taken to protect public health through enforcement action under this Act.

(9) For the purpose of maximizing protection of public health, the Authority shall implement a programme of risk-based inspection of medical products throughout the manufacturing, distribution, compounding, dispensing, clinical trials activities and pharmacovigilance by among other things—

(*a*) assessing the risk of any scientific data presented to it and make an informed decision on whether that product will be recalled or withdrawn from circulation or not; or

(*b*) taking appropriate enforcement action upon determining that compliance is not being achieved or cannot be achieved or that an unacceptable risk to public health exists.

(10) Whenever the Authority finds that any portion of any medical product does not conform to the standards of identity, strength, quality and purity, or any other requirement specified in the documentation for registration, the Authority shall—

(*a*) instruct the licensee to discontinue the sale of the remainder of the batch and, so far as is practicable; and

(*b*) recall any portion of the batch already sold.

(11) The Authority shall, by order published in the *Gazette*, its website and local print media, issue notices withdrawing from the market in the country any medical products stocked or retailed but which on the latest available scientific evidence are shown to be hazardous to public health and welfare or are unsafe, inefficacious or of unacceptable quality.

(12) A certificate of analysis (analytical certificate) issued under this section shall be received in evidence and shall be deemed to be so issued as the case may be, without further proof, unless the contrary is proved.

(13) Whenever the Authority is of the opinion that it is not in the public interest that a medicine be made available to the public, the Authority may, following quality control test—

(*a*) by notice in writing handed or transmitted by registered post or electronically to any person direct that person; or

(*b*) by notice published in the *Gazette*, direct any person, to—

(i) return any quantity of that medicine in his possession to the manufacturer, supplier or importer of that medicine or scheduled substance; or

(ii) deliver or send that medicine to any other person designated by the Authority.

(14) The Authority may, by notice in writing, direct—

(*a*) any manufacturer, supplier or importer of a medical product who has any quantity of that medical product, including any quantity returned to him in pursuance of a direction made under subsection (13)(*a*); or

(*b*) any other person to whom any quantity of a medical product has been delivered or sent to dispose of that quantity in such manner, subject to regulations made, as the Authority may determine.

(15) A person may not dispose of a medicine which is the subject of a notice under subsection (13), unless the notice has been withdrawn by the Authority or set aside on appeal.

(16) A person who contravenes this section commits an offence.

Part IX—Inspections

Inspectors and inspections

80.—(1) The Authority may appoint any suitably qualified pharmacist, pharmacy technologist or quality assurance personnel and pharmaceutical manufacturing experts to be an inspector for the purposes of ensuring compliance with this Act, on such terms and conditions as it may determine.

(2) The Authority shall in the case of an inspector, who is a pharmacy technologist or quality assurance personnel, determine the premises which may be inspected by such inspector.

(3) The Authority shall provide an inspector with an identification card, in the prescribed form, which shall be *prima facie* evidence of the inspector's appointment as such.

(4) An inspector shall, in performing any function under this Act—

(*a*) be in possession of the identification card referred to in subsection (2); and

(*b*) show the identification card to any person who requests to see it or is subject to an inspection or investigation under this Act.

(5) An inspector may, for the purpose of enforcing the provisions of this Act, at any reasonable time, and on the authority of a warrant, enter any premises including pharmacy practice premises, container, vessel, vehicle, aircraft or other conveyance that the inspector has reasonable grounds to believe is used for the commission of an offence or purposes contrary to the provisions of this Act, and—

(*a*) search the premises, container, vessel, vehicle, aircraft or other conveyance, or the premises of a manufacturer, importer, exporter, seller or distributor of any medicine or allied substance or any person licensed or regulated under this Act, including a private dwelling, where information or documents which may be relevant to an inspection may be kept or which are being used for the commission of an offence under this Act;

(*b*) search any person on the premises if the inspector has reasonable grounds to believe that the person has possession of an

article, document, record, medicine or allied substance that has a bearing on an investigation, except that a person shall only be searched by a person of the same sex;

(*c*) examine any document, record, book, article, medicine or allied substance found on the premises that has a bearing on an inspection or investigation;

(*d*) require information to be given about any document, record, book, article, medicine or allied substance in any premises by—

(i) the owner of the premises;

(ii) the person in control of the premises;

(iii) any person who has control of the document, record, book, article, medicine or allied substance; or

(iv) any other person who may have the information;

(*e*) seize any document, book, record, article, computer or other electronic storage device, medicine or allied substance that has a bearing on an inspection or investigation or is used for purposes contrary to the provisions of this Act;

(*f*) take samples of any medicine or allied substance as may be necessary for the purposes of testing, examination or analysis;

(*g*) take extracts from, or make copies of, any book, record or document found on the premises that has a bearing on an inspection or investigation;

(*h*) use any computer system or any other electronic device on the premises, or require the assistance of any person on the premises to use that computer system or electronic device, to—

(*i*) search any data contained in, or available to the computer system or electronic device;

(ii) reproduce any record from the data; or

(iii) seize any output from the computer or electronic device for examination and copying; and

(*i*) attach and, if necessary, remove from the premises for examination and safeguarding any document, record, book or article that has a bearing on an inspection or investigation.

(6) An inspector who removes any document, book, record or article from any premises under subsection (5) shall—

(*a*) issue a receipt for the document, book, record or article to the owner of, or person in control of, the premises; and

(*b*) return the document, book, record or article as soon as practicable after achieving the purpose for which it was removed.

(7) An inspector may—

(*a*) for the purpose of the execution of his duties under this Act, take with him a police officer if he has reasonable cause to believe that he will meet any serious obstruction in the execution of his duty; and

(*b*) for the purpose of enforcing the provisions of this Act, at any reasonable time, and production of a certificate of authority signed by the Director General, temporarily close pharmacy premises pending completion of investigation, disciplinary procedure or legal proceedings where gross violation of provisions of this Act is reasonably suspected to have been committed.

(8) A person who—

(*a*) assaults, threatens or obstructs an inspector in the performance of the inspector's functions;

(*b*) refuses to give an inspector such reasonable assistance as the inspector may require for the purpose of exercising the inspector's powers;

(*c*) gives an inspector false or misleading information in answer to an inquiry made by the inspector; or

(*d*) impersonates an inspector or presents oneself to be an inspector,

commits an offence.

(9) For the purpose of this section, a person shall be deemed to have obstructed an inspector in the execution of his duties under this Act if he—

(*a*) willfully delays an inspector in the exercise of any power under this Act;

(*b*) fails to comply with the requisition of an inspector in pursuance of this Act;

(*c*) fails to produce any register, certificate, notice or documents which he is required, in pursuance of this Act, to produce;

(*d*) withholds a commodity, or method or procedure for the manufacture of a commodity; or

(*e*) conceals or prevents, or attempts to conceal or prevent a person from appearing before or being interviewed by an inspector.

(10) An inspector shall furnish the Authority with a written report and any other information relating to an inspection, as the Authority may require.

(11) Nothing in this section shall require a person to disclose or produce information or a document, if the person would in an action in a court be entitled to refuse to disclose or produce the information or document.

(12) An inspector may issue an improvement or prohibition notice in the manner prescribed in the Schedule.

Part X—Offences and Penalties

Contempt of the Pharmacy Committee

81. A person who has been registered under this Act, who has been summoned by the Pharmacy Committee and who—

(*a*) refuses or fails without sufficient cause to attend and give evidence relevant to the case or inquiry at the time and place specified in the summons; or

(*b*) refuses to be sworn or to affirm;

(*c*) attends as a witness before the Pharmacy Committee and refuses to answer or to answer fully and satisfactorily to the best of his knowledge and belief any question properly put to him;

(*d*) refuses or fails without sufficient cause to produce any book, record, document or thing which he has been required by that summons to produce;

(*e*) gives false evidence on oath at an enquiry before the Pharmacy Committee knowing such evidence to be false or not believing it to be true,

commits an offence and shall, upon conviction, be liable to a fine of K1,000,000 and to imprisonment for twelve months.

Theft of medicines or allied substance

82.—(1) A person who steals medicines or allied substances from a public health facility commits an offence and shall, upon conviction, be liable to a fine of K20,000,000 and to imprisonment for twenty years.

(2) Notwithstanding the penalty imposed under subsection (1), the Court may, on application, order that—

(*a*) the medicines or allied substance in issue be restored to the public health facility concerned upon certification by the Authority; and

(*b*) any gain which has accrued to the offender be paid to the public health facility concerned.

(3) The penalty under subsection (1) shall also apply to any health worker such as a medical doctor, clinical officer, nurse or midwife, pharmacist, pharmacy technician, pharmacy assistant, medical assistant, laboratory technician, health surveillance assistant who manages medicines and allied substances in a public health facility and has been found not to keep proper records of medicines and allied substances under his or her charge; to have stolen the medicines and allied substances; and or to have issued a false prescription in order to have medicines dispensed or used in the dispensing of medicines.

(4) This section shall also apply to—

(*a*) institutions that are not health facilities but do handle medicines and allied substances;

(*b*) a person who steals medicines and allied substances from a health facility or any institution, which is not public but handles medicine or allied substances.

Failure to keep proper records

83. A person who is in charge of managing medicines and allied substances in a public health facility and fails to keep proper records including its source of the medicines and allied substances under his charge, commits an offence and shall, upon conviction, be liable to a fine of K1,000,000 and imprisonment for twelve months.

Issuing false prescription of medicines

84. A person who is in charge of managing medicines and allied substances in a public health facility and who knowingly issues a false prescription in order to have medicines dispensed or used in the dispensing of medicines, commits an offence and shall, upon conviction be liable to a fine of K1,000,000 and imprisonment for twelve months.

Unregistered dealer, product or premises

85. Except as is provided in this Act, a person other than a person registered under this Act shall not—

(*a*) conduct a pharmacy practice;

(*b*) in the course of any trade or business, prepare, mix, compound or dispense any medicinal product except under the 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 he is registered under this Act.

Conducting pharmacy business on unlicensed premises

86. A person shall not conduct pharmacy practice from unregistered premises.

Assembling, importing, selling, etc., medicinal product without product licence

87. Subject to the provisions of this Act and except in accordance with a licence granted under this Act (hereinafter referred to as a "product licence"), a person shall not, in the course of a business carried on by him, possess, assemble, sell, import or export any medicinal product without a product licence.

Penalty for contravening sections 85, 86 and 87

88. A person who contravenes sections 85, 86 and 87 commits offence and shall, upon conviction, be liable to a fine of K5, 000,000 and to imprisonment for five years.

Failure to comply with a manufacture's licence

89.—(1) A person shall not, in the course of any business carried on by him, manufacture or assemble any medicinal product or medical device except in accordance with a licence granted for that purpose (hereinafter referred to as a "manufacturer's licence").

(2) A person who contravenes this section commits an offence and shall, upon conviction, be liable to a fine of K10,000,000 and imprisonment for ten years.

Failure to comply with a wholesale dealer's licence

90.—(1) A person shall not, in the course of any business carried on by him, possess, sell, supply any medicinal product by way of wholesale dealing except in accordance with a licence granted for that purpose (hereinafter referred to as a "wholesale dealer's licence").

(2) A person who contravenes this section commits an offence and shall, upon conviction, be liable to a fine of K10,000,000 and to imprisonment for ten years.

Managing retail pharmacy practice without a licence

91.—(1) A person, other than a person with a retail pharmacy practice licence, shall not manage any retail pharmacy practice.

(2) A person who contravenes this section commits an offence and shall, upon conviction, be liable to a fine of K5,000,000 and to imprisonment for five years.

Failure to comply with a dispensing licence

92.—(1) A person, other than a person lawfully carrying on a retail pharmacy practice, shall not possess, sell or supply any medicinal product or medical device by way of dispensing except in accordance with a licence granted for that purpose (hereinafter referred to as a "dispensing licence").

(2) A person who contravenes this section commits an offence and shall, upon conviction, be liable to a fine of K5,000,000 and to imprisonment for five years.

Failure to comply with a medicine store licence

93.—(1) A person shall not, in the course of any business carried on by him possess, sell, or supply any medicinal product from a medicine store or veterinary shop except in accordance with a licence granted for that purpose (hereinafter referred to as a "medicine store licence" or "veterinary shop licence", respectively).

(2) A person who contravenes this section commits an offence and shall, upon conviction, be liable to a fine of K2,000,000 and to imprisonment for two years.

Clinical trial without protocols and regulatory approvals

94.—(1) A person commits an offence who, in the course of business and in violation of this Act-—

(*a*) conducts or commissions clinical trials without local ethical and regulatory protocols' approvals by the relevant authority;

(*b*) sells or supplies any medicinal product for the purpose of a clinical trial;

(*c*) procures the sale or supply of any medicinal product for the purpose of a clinical trial; or

(*d*) procures the manufacture or assembly or for the manufacture or assembly of any medicinal product for sale or supply for the purpose of a clinical trial.

(2) Any person who contravenes this section commits an offence and shall, upon conviction, be liable to a fine of K15,000,000 and to imprisonment for fifteen years.

Non compliance with requirements on medicine schedules

95.—(1) Subject to any exemption granted under this Act, a person shall not possess or sell by retail, offer or expose for sale by retail or supply, any medicinal product and medical device on all scheduled medicines and devices other than general sales list, unless—

(*a*) the person is lawfully conducting a retail pharmacy practice;

(*b*) the product is sold or supplied on premises registered under this Act;

(*c*) the person is registered under this Act or, if the transaction is carried out on his behalf by another person recognized under this Act, then that other person is or acts under the supervision of a pharmacist; or

(*d*) the product is general sales medicine and has been made up for sale in a container or package elsewhere than at the place at which it is sold or supplied and the container has not been opened since the product was made up for sale in it.

(2) A person shall not sell or supply any medicinal product and medical device unless such sale or supply is made from premises capable of being closed so as to exclude the public.

(3) Any person who contravenes this section commits an offence and shall, upon conviction, be liable to a fine of K5,000,000 and to imprisonment for five years.

Import or export without permit

96.—(1) Subject to any exemption granted under this Act, a person shall not import and or export any medicinal product and medical device unless—

(*a*) the person is lawfully conducting a pharmacy business;

(*b*) the person is in possession of a valid import permit or export permit issued by the Authority;

(*c*) the medicinal product being imported or exported is currently registered.

(2) Any person who contravenes this section, upon conviction, be liable to a fine of K5,000,000 and to imprisonment for five years.

Modification of a product without approval

97.—(1) A person shall not—

(*a*) add any substance to, or abstract any substance from, a medicinal product so as to affect adversely the composition of the product with intention of selling the product in that changed state;

(*b*) sell or supply, or offer or expose for sale or supply, any medicinal product whose composition has been adversely affected by the addition thereto or there from of any substance; or

(*c*) sell or supply any medicinal product, medical device or herbal substance which is not of the nature or quality demanded by the purchaser.

(2) Subsection (1) (*c*) shall not be considered to have been contravened by reason only that a medicinal product contains some extraneous matter, if it is proved that the presence of that matter was an inevitable consequence of the process of manufacture of the product.

(3) Where a medicinal product is sold or supplied pursuant to a prescription given by an appropriate practitioner, subsection (1) and (2) shall not have effect if—

(*a*) any reference to the "purchaser" included a reference to the person for whom the medicinal product was prescribed by an appropriate practitioner; and

(*b*) the words "demanded by the purchaser", were substituted by the words "specified in the prescription".

(4) A person who contravenes this section shall, upon conviction, be liable to a fine of K10,000,000 and to imprisonment for ten years.

Sale of falsified or substandard medicine

98.—(1) A person shall not, in the course of any business carried on by him, manufacture, import, assemble, dispense, sale any medicinal product or medical device which is falsified or substandard.

(2) A person who contravenes this section shall, upon conviction, be liable to a fine of K10,000,000 and to imprisonment for ten years.

No labeling of product

99.—(1) A person shall not, in the course of a business carried on by him, sell any medicinal product, medical device and herbal substance in an appropriate container or package which is not labeled in accordance with this Act.

(2) Without prejudice to subsection (1), a person shall not, in the course of a business carried on by him, sell or supply, a medicinal product, medical device and herbal substance of any description in a

container or package which is labeled or marked in such a way that the container or package—

(*a*) falsely describes the product; or

(*b*) is likely to be misleading as to the nature, efficacy or quality of the product or as to the uses or effects of medicinal products of that description.

(3) A person who contravenes this section commits an offence and shall, upon conviction, be liable to a fine of K10,000,000 and to imprisonment for ten years.

Sale of product with wrong leaflet or package insert

100.—(1) A person shall not, in the course of a business carried on by him, supply or have in his possession for the purpose of supplying together with medicinal products, medical devices and herbal substance, a package insert relating to such medicinal products or medical devices or herbal substances, which does not comply with regulations made under this Act.

(2) Without prejudice to subsection (1), a person shall not, in the course of a business carried on by him, supply together with a medicinal product and herbal substance or have in his possession for the purpose of so supplying a package insert which—

(*a*) falsely describes a medicinal product to which it relates; or

(*b*) is likely to be misleading as to the nature, efficacy or quality of such medicinal product;

(*c*) is in a language other than the language prescribed by the Authority.

(3) Any person who contravenes this section commits an offence and shall, upon conviction, be liable to a fine of K5,000,000 and to imprisonment for five years.

Disregard for prohibited advertise-ments

101.—(1) The Minister may, on recommendation of the Authority, make regulations which may prohibit any issue of advertisements—

(*a*) relating to medicinal products, medical devices or supplies and herbal substances of a description or a class specified in the regulations;

(*b*) likely to lead to the use of any medicinal product, or any other substance or article, for the purpose of–

(i) treating or preventing a disease so specified;

(ii) ascertaining the existence, degree or extent of a physiological condition so specified;

(iii) permanently or temporarily preventing or otherwise interfering with the normal operation of a physiological function so specified; or

(iv) artificially inducing a condition of body or mind so specified;

(*c*) likely to lead to the use of—

(i) medicinal products, medical devices or supplies and herbal substances of a particular description or class specified in the regulations;

(ii) any other substance or particle of a description or class so specified for any such purpose referred to in paragraph (*b*); and

(*d*) relating to medicinal products, medical devices or supplies and herbal substances and maintaining a word or phrase specified in the regulations, as being a word or phrase which, in the opinion of the Minister, is likely to mislead the public as to the nature or effects of the product or as to any condition of body or mind in connection with which the medicinal product might be used.

(2) Any person convicted of contravention of the regulations made under this section may, be liable to a fine of not more than K5,000,000 and imprisonment for not more than five years.

Miscellaneous offences and penalties

102.—(1) A person who—

(*a*) deals in unregistered medicines or allied substances;

(*b*) tampers with any sample taken for purposes of this Act;

(*c*) obtains medicines or allied substances from unauthorized suppliers;

(*d*) contravenes or fails to comply with any provision of this Act, or any directive, regulation, order, condition, requirement or request made there under;

(*e*) refuses or fails to pay any money levied under this Act;

(*f*) falsely represents any material or substance to be reference material supplied by the Authority;

(*g*) falsely holds himself out to be an inspector for the purposes of this Act;

(*h*) makes any statement to an inspector which is false in any material respect, knowing it to be false;

(*i*) refuses or fails to answer to the best of his knowledge any relevant question which an inspector has in the exercise of his powers put to him;

(*j*) refuses or fails to comply to the best of his ability with any lawful requirements, demand or order of an inspector;

(*k*) who fraudulently obtains a licence, permit, authorization or registration under this Act;

(*l*) hinders or obstructs an inspector in the exercise of his powers;

(*m*) makes any false or misleading statement in connection with any medicine or allied substance,

commits an offence and shall, upon conviction, be liable to—

(i) in the case of a first offence, to a fine of K2,000,000 and to imprisonment for two years; and

(ii) in the case of a subsequent offence, to imprisonment for six years.

(2) Any person who indulges in acts or omissions proscribed under section 81 which, if the person was a registered person under this Act, would have amounted to an offence of contempt of the Pharmacy Committee, commits an offence and shall, upon conviction, be liable to the same penalties under section 81.

Additional penalties

103. Upon conviction of any person of an offence under this Act, the court may in addition to any other penalty imposed—

(*a*) order that any medicine or allied substance or article seized and detained by an inspector and found to have been used in, or in connection with, the commission of that offence be—

(i) forfeited to the Government; or

(ii) destroyed or be disposed of in the manner considered appropriate by the Court at the cost of the offender and without compensation;

(*b*) cancel any licence permit, certificate or authorization issued to that person under this Act;

(*c*) order that any licence, permit, certificate or authorization issued to that person be cancelled; and

(*d*) summarily enquire into, and assess, the effect on human life and the monetary value gained or likely to be gained by such person in consequence of that offence and impose on that person a fine equal to the amount so assessed and imprisonment for not less than five years.

Manufacture, import, export, etc., of substandard substances

104.—(1) A person shall not manufacture, import, export, distribute, sell, store or deal in any manner with substandard and falsified medicines or allied substances.

(2) A person shall not import any medicine or allied substance without an import permit:

Provided that this subsection shall not apply to any medicine or allied substance imported by a traveler entering Malawi for the traveler's use as may be prescribed.

(3) A person who contravenes subsections (1) and (2) commits an offence and shall, upon conviction, be liable to a fine of K5,000,000 and to imprisonment of five years.

(4) In addition to the penalty imposed under subsection (3), 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 Government to be destroyed in the manner prescribed by the court.

Sale of expired medicines

105.—(1) A person shall not supply or sell expired medicine or allied substance.

(2) A person who contravenes this section (1) commits an offence and shall, upon conviction, be liable to a fine of K5,000,000 and to imprisonment for five years.

Misleading information

106.—(1) A person shall not label, package, alter expiry date, process, sell or advertise any medicine or allied substance 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 provision of this Act.

(2) A person who contravenes subsection (1) commits an offence and is liable, upon conviction, to a fine of K10,000,000 and to imprisonment for ten years.

Sale of dangerous cosmetics

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

(*a*) contains any substance that is likely to 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; or

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

(2) A person shall not manufacture, import, export, sell or supply any cosmetic that does not meet the standards of quality prescribed by the Authority.

(3) Where a standard has been prescribed for a cosmetic, any person who labels, packages, sells or advertises any article in such a manner that it is likely to be mistaken for a cosmetic of the prescribed standard commits an offence.

(4) A person who contravenes subsections (1), (2) and (3) commits an offence and shall, upon conviction, be liable to a fine of K5,000,000 or to imprisonment for five years.

Sale of certain cosmetics without Authority

108.—(1) A person who sells, prepares, packages or stores for sale, any cosmetic with medicinal substance or claim without authorization from the Authority commits an offence and shall, upon conviction, be liable to a fine of K1,000,000 and to imprisonment for twelve months.

(2) For the purpose of this section, "medicinal claim or substance" means—

(*a*) any substance or combination of substances presented for treating or preventing disease in human beings or in animals; or

(*b*) Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or animals is likewise considered a medicinal substance.

Dealing in dangerous medical devices

109.—(1) A person shall not sell any medical device that may cause injury to the health of the user when the medical device is used—

(*a*) according to the direction on the label of, or accompanying, that medical device; or

(*b*) for such purposes and by such methods of use as are customary or usual.

(2) A person shall not manufacture, import, sell or supply any medical device that does not meet the standards of quality prescribed by the Authority.

(3) A person who contravenes subsection (1) or (2) commits an offence and shall, upon conviction, be liable to a fine of K5,000,000 and to imprisonment for five years.

Unregistered medical representative

110.—(1) A person shall not conduct himself as medical representative unless he is registered as such by the Authority.

(2) Any person who contravenes subsection (1) commits an offence and shall, upon conviction, be liable to a fine of K1,000,000 and to imprisonment for twelve months.

Disclosure of information without consent

111.—(1) A person who, without the written consent given by, or on behalf of, the Authority, publishes or discloses to any unauthorized person, otherwise than in the course of duties of that person, the contents of any document, communication, or information whatsoever, which relates to or which has come to the knowledge of that person in the course of that person's duties under this Act, commits an offence and shall, upon conviction, be liable to a fine of K1,000,000 and to imprisonment for twelve months.

(2) A person who, having any information which to the knowledge of that person has been published or disclosed in contravention of subsection (1), publishes or communicates the information to any other person, commits an offence and shall, upon conviction, be liable to a fine of K1,000,000 and to imprisonment for twelve months.

Conducting clinical trial without certificates

112. A person who conducts a clinical trial involving an allied substance without, or in breach of, a clinical trial certificate conditions commits an offence and shall, upon conviction, be liable to a fine of K5,000,000 and to imprisonment for five years.

Sale of recalled or substandard medicines

113. A person who sells or makes available to the public any medicine or allied substance which—

(*a*) is determined by the Authority not to be in the public interest and which by notice, in writing, served on any person or published in the *Gazette*, the Authority has directed the person to return the medicine or allied substance to—

(i) the manufacturer of the medicine or allied substance;

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

(iii) deliver it or send it to the Authority or such other person as the Authority may designate; or

(*b*) in respect of which the Authority may, by notice in writing, direct the manufacturer or importer of the medicine or allied substance referred to in paragraph (*a*), who has in his possession any quantity of the medicine or allied substance, including the returned quantity to deal with or dispose of that quantity in such manner as the Authority may determine,

commits an offence and shall, upon conviction, be liable to a fine K10,000,000 and to imprisonment for ten years.

Dispensing medicine without a dispensing licence

114. A person who dispenses any medicine or allied substance to a patient without a dispensing licence commits an offence and shall, upon conviction, be liable to a fine of K1,000,000 and to imprisonment for twelve months.

Non adherence to advertising conditions

115. A person who—

(*a*) advertises any medicine or allied substance without conforming to the information relating to the medicine or allied substance approved by the Authority and as specified in the marketing authorization;

(*b*) advertises to the general public a medicine or allied substance which is sold by prescription only without the prior written approval of the Authority,

commits an offence and shall, upon conviction, be liable to a fine of K2,000,000 and to imprisonment for two years.

Sale of "prescription only" medicine without prescription

116.—(1) A person shall not sell or supply a "prescription only" medicine to any person without a prescription.

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

(3) Unless otherwise provided, all prescriptions shall specify the medicine to be administered by reference to the generic name of that medicine.

(4) A prescription signed by an authorized prescriber authorizing the sale or supply of a medicine shall not be dispensed on more than one occasion, unless the prescription expressly directs that it may be dispensed on a specified number of occasions or at specified intervals in a specific period.

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

(6) A person who contravenes this section commits an offence and shall, upon conviction, be liable to a fine of K1,000,000 and to imprisonment for one year.

Suspension or cancellation of licence

117.—(1) Subject to the other provisions of this Act, the Authority may suspend or cancel a licence if—

(*a*) the holder obtained the licence by fraud or deliberate or negligent submission of false information or statements;

(*b*) the holder operates a pharmacy under unsanitary conditions;

(*c*) the pharmacist or responsible person obtains medicines and allied substances from unauthorized suppliers or deals in unauthorized products;

(*d*) the pharmacy in respect of which it was issued is not compliant with prescribed standards of pharmacy practice or is not managed or controlled by a registered pharmacist or authorized person as determined by the Authority;

(*e*) the pharmacist fails to maintain the required records on medicines and allied substances;

(*f*) the holder fails to submit annual retention in accordance with this Act; or

(*g*) the holder contravenes the terms and conditions of the certificate of registration under this Act or any other relevant written law.

(2) The Authority shall, before suspending or cancelling a certificate of registration in accordance with subsection (1), give written notice to the holder thereof of its intention to suspend or cancel the certificate and shall give the reasons for the intended suspension or cancellation and require the holder to show cause, within a period of not more than thirty days, why the certificate should not be suspended or cancelled.

(3) The Authority shall not suspend or cancel a certificate of registration under this section if the holder takes remedial measures to the satisfaction of the Authority within the period referred to in subsection (2).

(4) Where a holder who is notified under subsection (2) fails to show cause to the satisfaction of the Authority, or does not take any remedial measures to the satisfaction of the Authority within the time specified in that subsection, the Authority shall suspend or cancel the certificate of registration.

(5) Where a certificate of registration is cancelled, the holder of the certificate shall return it to the Authority and the Authority shall cancel the name and the particulars relating to the pharmacy practice premises from the register.

(6) Subject to subsection (5), a person whose certificate of registration is cancelled may re-apply for registration in the prescribed manner and form, if that person takes remedial measures to the satisfaction of the Authority.

(7) An application for re-registration may be made after one year from the date of the cancellation of the registration.

Closure of pharmacy practice premises

118.—(1) The Authority may order the closure of a pharmacy practice premises where—

(*a*) the premises contravene the terms and conditions of registration in a manner that presents danger or imminent harm to members of the public;

(*b*) the premises are not registered under this Act; or

(*c*) the premises contravene the provisions of this Act or any other relevant law.

(2) The Authority shall, where it receives an inspection report indicating that a pharmacy practice premises—

(*a*) is not compliant with the requirements of this Act or its certificate of registration; or

(*b*) is offering services in excess of those permitted to the premises,

give the person responsible a written notice of the violation.

(3) The person responsible for pharmacy practice premises shall, within fourteen days of receiving the notice under subsection (2), provide the Director General a written plan of remedying the violation, indicating a schedule of dates by which remedial action shall be taken.

(4) A person responsible for a pharmacy practice premises shall, where the plan of remedy submitted by the pharmacy under subsection (3) is accepted by the Director General, comply with the schedule contained in the plan.

(5) The Authority shall, where the remedial plan submitted under this section is rejected by the Director General, revoke the certificate of registration and order the closure of the pharmacy.

Offence by body corporate

119. Where an offence under this Act is committed by a body corporate, every director or manager of the body corporate shall be liable as if the director or manager had personally committed the offence, unless the director or manager proves to the satisfaction of the court that the act constituting the offence was done without the knowledge, consent or connivance of the director or manager or that the director or manager took reasonable steps to prevent the commission of the offence.

Offence against an inspector

120. A person who—

(*a*) delays, assaults, threatens or obstructs an inspector in the performance of the inspector's functions;

(*b*) refuses to give an inspector such reasonable assistance as the inspector may require for the purpose of exercising the inspector's powers;

(*c*) gives an inspector false or misleading information in answer to an inquiry made by the inspector;

(*d*) impersonates an inspector or presents oneself to be an inspector; or

(*e*) tampers with a seal of closure affixed by an inspector,

commits an offence and shall, upon conviction, be liable to a fine of K3,000,000 and to imprisonment for three years.

Failure to display practice or premises licence

121. A person who fails to display a practice licence or a premises licence commits an offence and shall, upon conviction, be liable to a fine of K250,000.

General penalty

122. A person who commits an offence under this Act for which no punishment has been provided for in this Act shall, upon conviction, be liable to a fine of K1,000,000 and to imprisonment for twelve months.

Part XI—Harmonization of Regulation of Medical Products and International Cooperation

Harmonization and international cooperation

123. The Authority may participate and cooperate with any regional or continental medical products regulatory agencies and take such measures to share summary evaluation and inspection reports in order to—

(*a*) provide for harmonization of the data requirements for evidence of quality, safety, and efficacy of medical products;

(*b*) harmonize registration of medical products, inspections, quality management system, information management systems, joint evaluations, joint inspections and any other regulatory activities as may be appropriate; and

(*c*) provide for the use of accredited quality control laboratories within the harmonization framework.

Promotion of transparency

124. The Authority may put in place mechanisms that will promote transparency and information sharing through—

(*a*) the establishment of a Quality Management System based on common regional requirements;

(*b*) the establishment of paper and electronic web based copies including but not limited to regulations, laws, forms, applications, list of registered medicines.

Monitoring and Evaluation Unit

125. The Authority may create a monitoring and evaluation unit charged with reviewing and assessing the performance of the regulatory system.

Part XII—General Provisions

Appeals

126.—(1) A person aggrieved with a decision of the Authority may appeal to the Minister within thirty days from the date of service of the decision.

(2) The Minister shall make a decision on the appeal lodged under subsection (1) within ninety days of receiving the appeal.

(3) A person aggrieved with the decision of the Minister under subsection (2) may appeal to the High Court within thirty days from the date of service of the decision.

Authorizations and patents Cap. 49:02

127. The provisions of the Patents Act on compulsory licensing shall apply *mutatis mutandis* to this Act in respect of pharmacy and medicine.

Guidelines

128.—(1) The Authority may make guidelines for the better carrying out of the provisions of this Act.

(2) The guidelines referred to in subsection (1) shall be published in the *Gazette* and shall be binding on all persons regulated under this Act.

Regulations

129.—(1) The Minister may make regulations for the better carrying out of the provisions of this Act.

(2) Without prejudice to the generality of subsection (1), regulations under that subsection may make provision for—

(*a*) the prohibition, regulation or restriction of the manufacture or importation of pharmaceutical preparations and prescription only medicines;

(*b*) the required standards for pharmacy practice premises, including their operation and the maintenance, space, equipment and facilities required for such premises;

(*c*) the required standards for the manufacture, supply, dispensing and the distribution of medicines and allied substances;

(*d*) the compounding of prescriptions and the dispensing of medicines or allied substances by medical doctors, dental surgeons, veterinary surgeons and the conditions under which the compounding and dispensing of medicines may be earned out;

(*e*) the records to be kept by pharmacy practice premises;

(*f*) the advertising, promotion and labeling of medicines and allied substances;

(*g*) the recall or withdrawal of medicines and allied substances that do not meet the prescribed standards of quality, efficacy and safety;

(*h*) the handling of donated medicines;

(*i*) the disposal of obsolete, expired or unwanted medicines or allied substances, in consultation with the Malawi Government agency responsible for environmental management;

(*j*) the storage and standards for medicines and allied substances;

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

(*l*) the fees to be paid for certificates, permits, authorizations and licences under this Act;

(*m*) the restriction of the number and location of entry points through which medicines, herbal medicines or allied substances may be imported or exported;

(*n*) the categorization of methods of sale for medicines and allied substances; and

(*o*) any matter that the Minister considers necessary or expedient to give effect to the objectives of this Act.

(3) Notwithstanding section 21(*e*) of the General Interpretation Act, the regulations made under this Act may create offences in respect of any contravention to the regulations, and may for any such contravention impose a fine of up to K20,000,000 and to imprisonment for up to twenty years.

Repeal and savings Cap. 35:01

130.—(1) Subject to subsection (2), the Pharmacy, Medicines and Poisons Act is hereby repealed.

(2) Any subsidiary legislation made under the Pharmacy, Medicines and Poisons Act repealed by subsection (1), in force immediately before the commencement of this Act—

(*a*) shall remain in force, unless in conflict with this Act and shall be deemed to be subsidiary legislation made under this Act; and

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

Part XIII—Transitional Provisions

Status of existing assets, funds, liabilities, etc

131.—(1) All property, assets, funds, liabilities, obligations, agreements and other arrangements which, immediately before the commencement of this Act were vested in, acquired by, incurred by, entered into by, and on behalf of, the Pharmacy, Medicines and Poisons Board established under the repealed Act shall, on the commencement of this Act, be deemed to have vested in or to have been acquired, incurred or entered into by or on behalf of the Authority, and shall become enforceable by or against the Authority to the same extent as they were enforceable by or against the Board.

(2) Where the transfer of any property, assets, funds, liabilities, obligations, agreements and other arrangements referred to in subsection (1) is required by any written law to be registered, the Authority shall, within twelve months of the commencement of this Act or within such other period as the written law may prescribe, apply to the appropriate registering authority for the registration of the transfer and thereupon the registering authority shall, at no cost to the Authority or any person by way of registration fees, stamp or other duties—

(*a*) make such entries in the appropriate register as shall give effect to the transfer;

(*b*) where appropriate, issue to the Authority a certificate of title or other statutory evidence or ownership of the property or make such amendments on such certificates or in the appropriate register as may be necessary; and

(*c*) make any necessary endorsement on such deeds or other documents as may be presented on such registering authority relating to the title, right or obligation concerned.

Existing members and employees

132.—(1) Members of the Pharmacy, Medicines, and Poisons Board, as constituted immediately before the coming into force of this Act, shall continue to hold office as members until the appointment of new members in accordance with this Act.

(2) Any person who immediately prior to the commencement of this Act is employed by the Pharmacy, Medicines and Poisons Board established under the repealed Act, shall be deemed to have been transferred to the employment of the Authority on terms and conditions of service not less favourable than the terms and conditions of service with the Board and, for the purpose of determining his rights thereunder, his service shall be regarded as continuous from the time he was appointed by the Board.

Existing registrations

133.—(1) Subject to subsection (2), every person who, immediately before the commencement of this Act, was registered in the register of pharmacists, pharmacy technologist and pharmacy assistant under the repealed Act and is resident in Malawi shall be deemed to have been registered under this Act in that register on such conditions as the Authority may impose.

(2) Every person deemed by subsection (1) to be registered under this Act shall submit to the Director General particulars of his registration in such form as may be prescribed and, subject to payment of the prescribed fee, shall be entitled to be issued with a practising licence under this Act.

(3) Every premises that, immediately before the commencement of this Act, were registered in the register of premises under the Act repealed by section 130, shall be deemed to have been registered under this Act in that register.

(4) Every permit or licence issued, immediately before the commencement of this Act, under the Pharmacy, Medicines and Poisons Act repealed by this Act, shall be deemed to have been issued under this Act. Cap. 35:01

Clinical trial certificates

134. Every clinical trial that, immediately before the commencement of this Act, was issued a clinical trial certificate under the Act, shall be deemed to have been certified under this Act in that register.

Legal proceedings

135. Any legal proceedings commenced immediately before the commencement of this Act by or against the Pharmacy, Medicines and Poisons Board established under the repealed Act, shall be deemed to have been commenced by or against the Authority.

SCHEDULE (s 80(12))

IMPROVEMENT AND PROHIBITION NOTICES

Circumstances and manner of service

1. Where an inspector is of the opinion that a person—

   (*a*) is contravening a provision of this Act or regulations made thereunder; or

   (*b*) has contravened a provision of this Act in circumstances that make it likely that the contravention will continue or be repeated,

   he may serve on him a notice (referred to as "an improvement notice") stating that he is of that opinion, specifying the provision in respect of which he is of that opinion, giving particulars of the reasons why he is of that opinion and requiring that person to remedy the occasioning within a period within which an appeal against the notice can be brought under section 5 as may be specified in the notice.

Application of this Schedule

2. (1) This Schedule shall apply to an activity which is being or are about to be carried on by or under the control of any person, being activities to or in relation to which this Act or the regulations made thereunder apply or will, if the activities are so carried on, apply.

   (2) If as regards any activity to which this clause applies an inspector is of the opinion that, as carried on or about to be carried on by or under the control of the person in question the activity involve or, as the case may be will involve a risk or serious personal injury, the inspector may serve on that person a notice (in this part referred to as "a prohibition notice").

Contents of prohibition notice

3. (1) A prohibition notice shall—

   (*a*) state the opinion of the inspector;

(*b*) specify the matters which, in his opinion, give or as the case may be, will give rise to the said risk;

(*c*) where in his opinion any of those matters involve or, as the case may be, will involve a contravention of any provision of this Act or the regulations made thereunder, state that he is of that opinion, specify the provision or provisions in respect of which he is of that opinion and give particulars of the reasons why he is of that opinion; and

(*d*) direct that the activities to which the notice relates shall not be carried on by or under the control of the person on whom the notice is served unless the matters specified in the notice in pursuance of paragraph (*b*) and any associated contravention of provisions so specified in pursuance of paragraph (*c*) have been remedied.

(2) A direction given under subsection (1) (*d*) shall take immediate effect if the inspector is of the opinion, and states it, that the risk of safety, health or environment as related to the commodity, is or, as the case may be, will be imminent, and shall have effect to the end of a period specified in the notice in any other case.

(3) A notice may contain directions as to the measures to be taken to remedy any contravention or matter which the notice relates and any such directions—

(*a*) may be framed to any extent by reference to any regulation or technical specification approved by the Authority; and

(*b*) may be framed so as to give the person on whom the notice is served a choice regarding ways of remedying the contravention or matter.

Withdrawal or extension of notice

4. Where an improvement notice or prohibition notice which is to take immediate effect has been served—

(*a*) the notice may be withdrawn by an inspector at any time before the end of the period specified therein in pursuance of section 5, if the risk to safety, health or environment has been remedied; or

(*b*) the period so specified may be extended by an inspector at any time when an appeal against the notice is not pending.

Appeal against a notice

5. (1) A person on whom a notice is served may, within fourteen days from the date of its service, appeal to the Minister and on such appeal the Minister may either cancel or affirm the notice and, in affirmation the Authority, may do so either in the notice's original form or with such modification as the Minister may in the circumstances deem fit.

(2) Where an appeal under this clause is brought against a notice within the period allowed under subsection (1) then—

(*a*) in the case of an improvement notice, the lodging of the appeal shall have the effect of suspending the operation of the notice until the appeal is finally disposed of or, if the appeal is withdrawn, until the withdrawal of the appeal; or

(*b*) in the case of a prohibition notice, the lodging of the appeal shall have the like effect if, but only if, on the application of the appellant, the Authority so directs; and then only from the giving of the direction.

Passed in Parliament this eleventh day of December, two thousand and eighteen.

FIONA KALEMBA
Clerk of Parliament