

[Chap3501]CHAPTER 35:01

PHARMACY, MEDICINES AND POISONS

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15 of 1988

30 of 1991

19 of 1995

21 of 1996

G.N. 9/1991

An Act to provide for the establishment of the Pharmacy, Medicines and Poisons Board, the registration and disciplining of pharmacists, pharmacy technologists and pharmacy assistants, the training within Malawi of pharmacists, pharmacy technologists and pharmacy assistants, the licensing of traders in medicines and poisons and generally for the control and regulation of the profession of pharmacy in Malawi and for matters incidental to or connected therewith

[15TH JANUARY 1991]

PART I

PRELIMINARY

[Ch3501s1]1. Short title

This Act may be cited as the Pharmacy, Medicines and Poisons Act.

[Ch3501s2]2. Interpretation

(1) 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 dispensed in, or diluted or mixed with, some other substance used as a vehicle for such administration;

“animal test certificate” has the meaning assigned to it by section 43 (c) (ii);

“assemble”, in relation to a medicinal product, means—

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

(b) where the product, with or without other medicinal products of the same description, is already enclosed in the container in which it is to be sold or supplied, labelling the container before the product is sold or supplied in it; and

“assembly” has a corresponding meaning;

“authorized seller of poisons” is a person, other than a person lawfully conducting a retail pharmacy business, who may sell Part II poisons pursuant to section 55 (2) (b);

“Board” means the Pharmacy, Medicines and Poisons Board established by section 3;

“business” includes a professional practice and any activity carried on by a person or a body of persons, whether corporate or unincorporate;

“clinical officer” means a person duly registered as such under the Medical Practitioners and Dentists Act; Cap. 36:01

“clinical trial” and “clinical trial certificate” have the meaning assigned to them by section 42;

“composition”, in relation to a medicinal product, means the ingredients of which it consists and the proportions, and the degree of strength, quality and purity, in which those ingredients are contained in it;

“container” in relation to a medicinal product, means a bottle, jar, box, packet or other receptacle which contains or is to contain it, not being a capsule, cachet or other article in which the product is or is to be administered, and, where any such receptacle is or is to be contained in another such receptacle, includes the former but does not include the latter receptacle;

“dentist” or “dental assistant” means a person registered as such under the Medical Practitioners and Dentists Act; Cap. 36:01

“dispensing” means selling or supplying a medical product;

“dispensing licence” has the meaning assigned to it in section 35 (4);

“hospital” includes a clinic, dispensary or similar institution;

“ingredients” in relation to the manufacture or preparation of a substance, includes anything which is the sole active ingredient of that substance as manufactured or prepared;

“inspector” means a person appointed under section 59;

“labelling”, in relation to a container or package or medicinal products, means affixing to or otherwise displaying on the container or package a notice describing or otherwise relating to the contents thereof, and “label” has a corresponding meaning;

“leaflet” includes any written information;

“licensing authority” means the authority upon which responsibility for licensing has been conferred by section 34;

“manufacture”, in relation to a medicinal product, includes any process carried out in the course of making the medicinal product but does not include dissolving or dispensing the medicinal product in, or diluting or mixing it with, some other substance used as a vehicle for the purpose of administering it or the incorporation of the product in any animal feed;

“manufacturer’s licence” has the meaning assigned to it in section 35 (2);

“medical practitioner” or “medical assistant” means a person registered as such under the Medical Practitioners and Dentists Act; Cap. 36:01

“medicinal product” means any substance or article which is manufactured, sold, supplied, imported or exported for use wholly or mainly in either or both of the following ways—

- (a) use by being administered to a human being or an animal for a medicinal purpose;
- (b) use as an ingredient in the preparation of a substance or article which is to be administered to a human being or an animal for a medicinal purpose,

but it shall not include an instrument, apparatus or appliance;

“medicinal purpose” means any one or more of the following purposes—

- (a) treating or preventing diseases;
- (b) diagnosing disease or ascertaining the existence, degree or extent of a physiological conditions;
- (c) contraception;
- (d) inducing anaesthesia;
- (e) otherwise preventing or interfering with the normal operation of a physiological function whether permanently or temporarily and whether by way of terminating, reducing or postponing, or increasing or accelerating, the operation of that function or in any other way;

“nurse” or “midwife” means a nurse or midwife registered in any category of nurses or midwives under the Nurses and Midwives Act: Cap. 36:02

“package”, in relation to any medicinal products, means any box, packet or other article in which one or more containers of the medicinal products are or are to be enclosed, and where any such box, packet or other article is or is to be enclosed in one or more other boxes, packets or articles in question, the collective number thereof;

“pharmacist” means a person registered as such under Part III;

“pharmacy technologist” means a person registered as such under Part III;

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

“poison” means a substance specified in the Poisons List prescribed under section 55 (1);

“product licence” has the meaning assigned to it in section 35 (1);

“Registrar” means the Registrar of the Board appointed under section 13 and includes any person duly acting as, or on behalf of, the Registrar;

“retail pharmacy business” means a business which consists of or includes the retail sale of medicinal products but does not include a professional practice carried on by a pharmacist;

“substance” means any natural or artificial substance, whether in solid or liquid form or in the form of a gas or vapour;

“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 cure or not;

“veterinary surgeon” means a person registered as such under the Veterinary Surgeons Act; Cap. 53:04

“wholesale dealer’s licence” has the meaning assigned to it in section 35 (3);

(2) In this Act, any reference to a sale of medicinal products or poisons by way of wholesale dealing is a reference to the sale of medicinal products or poisons to a person who buys medicinal products or poisons for the purpose of—

- (i) selling or supplying medicinal products or poisons; or
- (ii) administering or causing to be administered any medicinal products or poisons to a human being or an animal,

in the course of business carried on by that person but it shall not include any such sale by the manufacturer of medicinal products or poisons.

(3) In this Act, any reference to a retail sale of medicinal products or poisons is a reference to the sale of medicinal products or poisons to a person who buys medicinal products or poisons otherwise than for a purpose specified in subsection (2).

PART II

ADMINISTRATION

[Ch3501s3]3. Establishment of a pharmacy, medicines and poisons Board

30 of 1991There is hereby established a board to be known as the Pharmacy, Medicines and Poisons Board (in this Act referred to as the "Board") which shall be a body corporate having perpetual succession and a common seal and shall under that name, be capable of suing and being sued and of purchasing or otherwise acquiring, holding and alienating moveable or immoveable property and, subject to the provisions of this Act, of doing or performing all such acts and things as bodies corporate may by law perform.

[Ch3501s4]4. Composition of the Board

(1) Subject to subsection (3), the Board shall consist of the following eight members appointed by the Minister each of whom shall, except in case of an ex officio member, be a citizen of Malawi—

- (a) the Chief of Health Services, who shall be a member ex officio whether or not he is a citizen of Malawi;
- (b) the Chief Pharmacist, who shall be a member ex officio whether or not he is a citizen of Malawi;
- (c) three members, representing pharmacists;
- (d) one member, representing medical practitioners;
- (e) one member, representing veterinary surgeons; and
- (f) one member, representing nurses and midwives.

(2) A member of the Board, not being a member ex officio, shall hold office for three years.

(3) The Minister may appoint to the Board, for a period not exceeding three years, such other persons not exceeding three in number, as he considers suitably qualified to assist the Board in its work and deliberations and such persons shall not have the right to vote at any meeting of the Board.

(4) Upon the appointment to the Board of any member, the Minister shall cause notice of such appointment to be published in the Gazette and shall in such notice specify the current membership of the Board resulting upon such appointment.

(5) Members of the Board shall not, by virtue only of their appointment to the Board, be deemed to be officers of the public service.

[Ch3501s5]5. Vacation, etc., of members from office

(1) The Minister may require a member of the Board to vacate his office if the Minister is satisfied that the member—

(a) has become insolvent or has assigned his estate for the benefit of, or made a composition or other arrangement with, his creditors; or

(b) has been absent from three consecutive meetings of the Board, of which he has had notice, without the leave of the Chairman of the Board; or

(c) has been disqualified under this Act from carrying on his profession or calling; or

(d) has been convicted of an offence under this Act or the Act repealed by this Act or any law relating to drugs; or

(e) has been convicted—

(i) within Malawi of a criminal offence; or

(ii) outside Malawi of an offence by whatever name called which, if committed within Malawi, would have been a criminal offence, and sentenced to imprisonment for a term of six months or more without the option of a fine, whether or not such sentence has been suspended, and has not received a free pardon; or

(f) is mentally or physically incapable of efficiently performing his duties as a member of the Board.

(2) The Minister may suspend from office a member of the Board 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 Board has instituted an inquiry into his professional conduct or considers the removal of his name from the register under section 24 (1);

and while that member is so suspended he shall not carry out any duties as a member.

(3) A member of the Board may resign his office by notice in writing to the Minister and if the Minister accepts such resignation.

[Ch3501s6]6. Filling of vacancies on the Board

(1) On vacation of office by a member of the Board, the vacancy shall be filled by a person appointed in accordance with section 4 (1) under which the former member was appointed:

Provided that if the remaining period is less than six months the Minister may decide not to have the vacancy filled until the expiry of the period.

(2) If any member of the Board is granted leave of absence by the Board, the Board may, if it sees fit, co-opt a person who belongs to the same profession or calling as the member who has been granted leave to fill the vacancy during the absence of the member.

[Ch3501s7]6. Co-opted persons

The Board may in its discretion at any time and for any length of period invite any person, and the Minister may in like manner nominate any officer in the public service, to attend any meeting of the Board and take part in the deliberations of the Board, but such person or officer shall not be entitled to vote at that meeting.

[Ch3501s8]8. Chairman and ViceChairman

(1) The Minister shall, by writing under his hand, designate one member of the Board who is a pharmacist to be the Chairman thereof.

(2) The Board shall elect a Vice-Chairman from amongst its members who are pharmacists. The Vice-Chairman shall, subject to subsection (3), hold office for the duration of his membership on the Board.

(3) The office of the Vice-Chairman shall become vacant—

- (a) if the holder resigns his office by notice in writing to the Board; or
- (b) if the holder of the office ceases to be a member of the Board; or
- (c) if the Board so determines.

(4) Whenever the Chairman is absent or is for any reason unable to discharge the functions of his office, the Vice-Chairman shall discharge the functions of the Chairman.

[Ch3501s9]9. Meetings of the Board

(1) Subject to this Act, the Board shall hold ordinary meetings for the dispatch of business at least four times in each year.

(2) An extraordinary meeting of the Board—

- (a) may be convened by the Chairman at anytime;
- (b) shall be convened by the Chairman within twenty-one days of the receipt by him of a request in writing signed by not less than any three members of the Board and specifying the purpose for which the meeting is to be convened.

(3) At any meeting of the Board—

- (a) the Chairman or, in his absence the Vice-Chairman, shall preside;

(b) in the absence of both the Chairman and the Vice-Chairman the members present and forming the quorum shall elect one of their number to preside; and

(c) the quorum shall be formed by any five members.

(4) At any meeting the decision of the Board on any matter shall be that of the majority of the members present and voting at that meeting, and in the event of an equality of votes, the Chairman or the person presiding shall have a casting vote in addition to his deliberative vote.

(5) Subject to this Act, the Board may make standing orders for the regulation of its proceedings and business and may vary, suspend or revoke any such standing orders.

[Ch3501s10]10. Functions of the Board

The Board shall be the sole registering authority of all persons required to be registered under this Act and shall have the following further functions—

(a) to assist in the promotion and improvement of the health of the population of Malawi;

(b) to exercise discipline and control over the professional conduct of all persons registered under this Act and practising in Malawi;

(c) to control and exercise authority affecting the training of persons in the profession of pharmacy;

(d) to promote liaison in the field of training in the profession of pharmacy both within Malawi and elsewhere and to promote the standards of such training in Malawi;

(e) to advise the Minister on any matter falling within the scope of this Act.

[Ch3501s11]11. Powers of the Board

30 of 1991For the better performance of its functions, the Board shall, subject to this Act, have power—

(a) to remove any name from any register or, subject to such conditions as the Board may impose, restore it thereto;

(b) to approve of institutions in Malawi and of the curriculum for the training of pharmacists, pharmacy technologists and pharmacy assistants;

(c) to acquire, hire or dispose of property, and borrow money on the security of the assets of the Board and accept and administer any trust or donation;

(d) to consider any matter affecting the profession of pharmacy and make representations thereon to the Minister or take such action in connexion therewith as the Board considers necessary;

(e) to keep and maintain separate registers in the prescribed form—

- (i) of all pharmacists registered under this Act;
- (ii) of all pharmacy technologists registered under this Act;
- (iii) of all pharmacy assistants registered under this Act;
- (iv) of all pharmacy premises registered under this Act;
- (f) to advise the licensing authority on matters relating to medicinal products and poisons;
- (g) upon application by any person, to recognize any qualifications held by that person (whether such qualifications have been obtained in Malawi or elsewhere) as being equal, either wholly or in part, to any prescribed qualifications, whereupon such person shall, to the extent to which the qualifications have been so recognized, be deemed to hold such prescribed qualifications;
- (h) to perform such other functions as may be assigned to the Board by the Minister; and
- (i) generally, to do and perform all such acts or things as the Board deems necessary or expedient to achieve the objects of this Act.

[Ch3501s12]12. Committees of the Board

(1) In addition to the Pharmacy Committee, Medicines Committee and Poisons Committee and save as otherwise provided in relation to those three committees, the Board may establish any number of other committees to carry out any special or general functions determined by the Board and may delegate to any such committee such of the functions of the Board as the Board may consider expedient.

(2) The Chairman of the Board shall by reason of his office be a member of every committee established under subsection (1).

(3) The chairman of each committee shall be appointed by the Board from amongst the members of the Board.

(4) Each committee may co-opt as members of such committee persons who are not members of the Board and any of such members so co-opted may or may not be officers in the public service.

(5) The chairman of a committee may, at any time and place, convene a meeting of the committee of which he is chairman.

(6) The Board may, at any time, direct the chairman of any committee to convene a meeting of such committee and such chairman shall, as soon as is practicable, comply with such direction.

(7) Every committee shall keep minutes of its meetings and shall inform the Board of its activities and shall conduct its proceedings in such manner as the Board may direct.

(8) A member of a committee who is not an officer in the public service shall, in respect of expenses incurred by him in travelling and subsistence while discharging his duties as member of that committee, be paid out of the funds of the Board, such allowances as the Board may determine.

[Ch3501s13]13. Appointment of Registrar and other staff

(1) Subject to this section, the Board—

- (a) shall appoint a Registrar upon terms and conditions approved by the Minister; and
- (b) may appoint assistant registrars and such other employees as it considers necessary or desirable in the discharge of its duties and upon such terms and conditions as it may determine.

(2) The Registrar, after consultation with the Chairman of the Board, may appoint temporary employees at such daily rates of pay, not below the minimum rates otherwise prescribed by law, as he may consider appropriate and shall, after he has appointed any such employee, report the fact thereof to the Board at its next meeting.

(3) The Registrar shall be the secretary to the Board and to every committee thereof.

(4) If the Registrar is absent or unable to carry out any of his functions under this Act or any other enactment, an assistant registrar or any officer of the Board shall exercise, during the period that the Registrar is so absent or unable to act, such of the functions of the Registrar as the Chairman of the Board may designate.

(5) Subject to any general or special directions of the Board, the Registrar shall be the chief executive officer of the Board and as such he shall be responsible to the Board for the administration and management of its affairs, including the supervision of other staff of the Board.

[Ch3501s14]14. Funds, accounts and audit

(1) The funds of the Board shall consist of—

- (a) such sums as may be appropriated by Parliament for the purposes of the Board;
- (b) all fees payable under this Act;
- (c) such other moneys and assets as may vest in or accrue to the Board, whether in the course of its functions or otherwise;
- (d) the levy imposed under section 15.

(2) The Board shall keep proper accounts and other records relating thereto in respect of its funds and shall in every respect comply with the provisions of the Finance and Audit Act. Cap. 37:01

(3) The accounts of the Board shall be examined and audited annually by auditors appointed by the Board and approved by the Minister.

[Ch3501s15]15. Levy

The Minister may from time to time, by order published in the Gazette, impose a levy on gross or net income accruing to any person or class of persons registered under this Act and such levy shall be appropriated for the general operations of the Board or for such operations of the Board as the Minister may specify in the order.

[Ch3501s16]16. Remuneration and expenses of members of the Board

Members of the Board shall be paid from the funds of the Board such allowances as the Minister may determine and in determining the allowance the Minister may make provision for the reimbursement of any reasonable expenses incurred by a member of the Board or of a committee in connexion with the business of the Board or the committee.

PART III

PHARMACY

[Ch3501s17]17. No person to carry on pharmacy business unless registered

(1) Except as is provided by this Act, no person other than a person registered as a pharmacist under this part shall—

- (a) conduct a retail pharmacy business;
- (b) in the course of any trade or business prepare, mix, compound or dispense any medicinal product or poison except under the supervision of a registered pharmacist; and
- (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.

[Ch3501s18]18. Persons registered under the repealed Act

(1) Every person who, immediately before the commencement of this Act, was registered in the register of pharmacists under the Act repealed by this Act and is resident in Malawi, shall be deemed to have been registered under this Act in that register.

(2) Every person deemed by subsection (1) to be registered under this Act shall submit to the Registrar 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 certificate of registration under this Act.

[Ch3501s19]19. Residence of registered persons

(1) Subject to subsection (2), an applicant for registration as a pharmacist, pharmacy technologist or pharmacy assistant shall not be registered unless at the time of his application—

- (a) he resides in Malawi; or
- (b) he intends, if he is registered, to take up residence in Malawi within six months of the date of his registration.

(2) Any person who resides in and is lawfully practising his profession or calling in such country as the Board may from time to time specify for the purposes of this subsection by notice in the Gazette, may be registered if, but for residing outside Malawi, he is otherwise qualified for registration.

[Ch3501s20]20. Persons eligible to be registered as pharmacists, pharmacy technologists or pharmacy assistants

(1) Subject to this section, a person shall be eligible for registration under this Act as a pharmacist or pharmacy technologist or pharmacy assistant if he is a holder of a degree, diploma, certificate or other qualification which is recognized by the Board as making him eligible for registration and he satisfies the Board that he—

- (a) has acquired sufficient knowledge of science and pharmacy;
- (b) has an adequate knowledge of the English language; and
- (c) is, in all respects as to character and otherwise, a fit and proper person to be registered.

(2) No qualification from an examination authority outside Malawi shall be recognized or accepted under subsection (1) as a qualification for registration of the holder, unless the qualification entitles the holder to registration in the country, state or territory in which the examination authority has jurisdiction.

(3) In any case where the Board 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 Board may take steps to assess his suitability for registration and for the purpose of so doing may require him to attend an interview or to undergo any oral or written examination.

(4) The Board may, where it considers it expedient so to do, delegate the assessment of suitability for registration under subsection (3) to a committee of the Board which shall, after making such assessment, make such recommendations to the Board as it considers appropriate.

[Ch3501s21]21. Procedure for registration

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

- (a) the prescribed fee; and

(b) a certificate of any qualification on which he relies for registration or a certified photocopy thereof: Provided that a certificate showing his registration in the country, state or territory in which he qualified is submitted and that such a certificate contains details of the qualifications on which registration was based; and

(c) if other practical experience or training is required in the country, state or territory in which he qualified before registration in that country, state or territory—

(i) evidence that such experience has been acquired or that such training has been obtained; and

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

(d) save in case of a person referred to in section 19 (2), evidence that he resides or intends, if he is registered, to reside in Malawi.

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

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

[Ch3501s22]22. Certificate of registration

30 of 1991 Upon registration by the Board of the applicant in—

(a) the register of pharmacists;

(b) the register of pharmacy technologists;

(c) the register of pharmacy assistants.

the Board shall issue an appropriate certificate of registration in the prescribed form.

[Ch3501s23]23. Application for retention of name on register

30 of 1991 (1) Every registered pharmacist, registered pharmacy technologist and registered pharmacy assistant shall, before the 31st January in each year, make application to the Board for the retention of his name on the appropriate register.

(2) An application made under subsection (1) shall be accompanied with the prescribed fee.

(3) The Board may, by its resolution, strike off from the appropriate register the name and other particulars of any registered pharmacist, registered pharmacy technologist or registered pharmacy

assistant who does not make application to the Board for the retention of his name on the appropriate register as required by subsection (1).

[Ch3501s24]24. Removal of name of registered pharmacist, etc., from the register

30 of 1991(1) Subject to paragraph (3), the Board may remove from the appropriate register the name of a pharmacist or a pharmacy technologist or a pharmacy assistant who—

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

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

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

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

(c) is dead.

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

(3) The Board 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 Board may consider necessary to impose.

[Ch3501s25]25. Notification of registration and of removal from register

The Board shall, from time to time and not less frequently than once every year, cause to be published in the Gazette a notification of all registrations effected under this Act and of all removals from any register.

[Ch3501s26]26. Appeals against refusal to register or against removal from register

(1) A person aggrieved by—

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

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

may after giving written notice to the Board and within three months after the date on which notice is given to him by the Board of the fact of refusal or removal, as the case may be, appeal to the High Court in such manner as may be prescribed or as may be considered appropriate by the High Court.

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

- (a) dismiss the appeal; or
- (b) if it is of the opinion that the Board 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; or
- (c) refer the matter back to the Board for further consideration, and may make such other order 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 Board by reason only of an informality or irregularity in the proceedings of the Board, 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.

[Ch3501s27]27. Display of certificate of registration on premises where pharmacy business is carried on

No person shall carry on a retail 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.

[Ch3501s28]28. Registration of premises where pharmacy business is to be carried on

30 of 1991(1) A person carrying on manufacturing pharmacy business, a wholesale pharmacy business or a retail pharmacy business in accordance with this Act shall cause each set of premises where such business is being carried on to be registered.

(2) An application for registration of premises under this section shall be made to the Board in the prescribed form and such application shall be accompanied with the prescribed fee.

(3) The registration of any premises under this section shall become void upon the expiry of thirty days from the date of any change in the ownership of the business carried on therein.

(4) The Board may, for good cause to be stated in writing, refuse to register or in like manner remove from the register any premises which in its opinion are or have become unsuitable for the purpose of carrying on manufacturing pharmacy business, a wholesale pharmacy business or a retail pharmacy business.

[Ch3501s29]29. Company may carry on a retail pharmacy business upon certain conditions

(1) Notwithstanding anything contained in the foregoing provisions of this Act, a company may carry on a retail pharmacy business if—

- (a) it is registered by the Board under this Act;
- (b) it is shown to the satisfaction of the Board that the business is under the personal management and control of a registered pharmacist;

- (c) a copy of the certificate of incorporation of the company is lodged with the Board; and
- (d) the other provisions of this Act are complied with.

(2) A company carrying on a retail pharmacy business in accordance with this section shall be an authorized seller of poisons within the meaning of this Act and may use the description of chemist and druggist, or of dispensing chemists or dispensing druggist and may use the description “pharmacy” in connexion with the registered premises.

(3) 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.

[Ch3501s30]30. Representatives of deceased or insolvent pharmacists

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 representative may, with the permission of the Board and subject to such directions and conditions as the Board may in its discretion deem fit to impose, carry on the business, and 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 Board may decide;

(b) the representative of a pharmacist carrying on a business in accordance with paragraph (a) shall be the authorized seller of poisons within the meaning of this Act and it shall be lawful for him to use any title, emblem or description which might have been lawfully used by the pharmacist whose representative he is.

[Ch3501s31]31. Exemptions from this Part

(1) This Part shall not apply to medicinal products supplied by—

- (a) a medical practitioner or dentist in the ordinary course of his practice;
- (b) a veterinary surgeon in the ordinary course of his practice;
- (c) any hospital which the Minister may, by order published in the Gazette, exempt;
- (d) any sale of poisons in Part II of the Poisons List by an authorized seller of poisons pursuant to section 55 (2) (b); and
- (e) any transaction mentioned in section 35 (2) and (3).

[Ch3501s32]32. Pharmacy Committee

19 of 1995(1) There shall be a Pharmacy Committee (in this section referred to as the "Committee") of the Board which shall consist of a chairman and not less than two and not more than four other persons, at least two of whom shall be pharmacists, specially appointed by the Chairman of the Board for any particular business or function of the Committee.

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

21 of 1996(3) Without prejudice to the generality of subsection (2) the Committee shall, where it is assigned by the Board so to do, deal with all matters relating to—

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

(b) regulate the training of pharmacists, pharmacy technologists and pharmacy assistants; and

(c) the control and regulation of any pharmacy business.

(4) In any disciplinary inquiry before the Committee, the Board may request the Attorney General to nominate a legally qualified person serving in the public service to assist the Committee in the proceedings of the inquiry.

(5) At any meeting of the Committee the Chairman and two other members shall form a quorum.

(6) For the purposes of any disciplinary inquiry before the Committee, the Chairman of the Board may appoint to the Committee, in addition to the members by virtue of subsection (1), any other person he considers reasonably qualified to assist the Committee in the conduct of the inquiry.

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

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

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

[Ch3501s33]33. Pharmacy Committee to be the disciplinary committee of the Board

30 of 1991, 21 of 1996(1) Subject to subsection (2), the Pharmacy Committee shall perform the functions of a disciplinary committee of the Board and for that purpose it shall have power to inquire into any matter or question referred to it by the Board pursuant to sections 24 (1) and 32 (3) (a) alleging that a pharmacist, pharmacy technologist or pharmacy assistant—

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

(b) has been guilty of improper or disgraceful conduct or conduct which, when due regard is had to 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) Before 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 chairman or the Registrar 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—

(a) in the form prescribed; and

(b) signed by the Chairman of the Board or Registrar.

21 of 1996(5) Any person who has been summoned under subsection (4) and who—

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

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

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

(d) 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; or

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

shall be guilty of an offence and liable to a fine of K5,000 and to imprisonment for six months.

(6) The Pharmacy Committee shall, as soon as practicable after the close of the inquiry, consider the evidence adduced and the representations made thereat, and shall, without undue delay complete and deliver to the Board its report thereon together with such documents as were produced and are relevant to the matters inquired into, and shall make its recommendations as to whether the allegation should be dismissed, or the pharmacist, or pharmacy technologist, or pharmacy assistant, as the case may be, should be reprimanded, or his registration should be suspended or cancelled.

PART IV

MEDICINAL PRODUCTS

[Ch3501s34]34. Licensing authority

19 of 1995The Board shall be the licensing authority responsible for the granting, renewal, variation, suspension and revocation of licences and certificates under this Part.

[Ch3501s35]35. Classes of licences

21 of 1996(1) Subject to the provisions of this Act and except in accordance with a licence granted under this section (hereinafter referred to as a "product licence"), no person shall, in the course of a business carried on by him—

- (a) sell, supply, export or import any medicinal product;
- (b) procure for sale, supply or exportation of any medicinal product; and
- (c) procure the manufacture or assembly or for the manufacture or assembly of any medicinal product for sale, supply or export.

(2) No person shall, in the course of any business carried on by him, manufacture or assemble any medicinal product except in accordance with a licence granted for that purpose (hereinafter referred to as a "manufacturer's licence").

(3) No person shall, in the course of any business carried on by him, 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").

(4) No person other than a person lawfully carrying on a retail pharmacy business shall sell or supply any medicinal product by way of dispensing except in accordance with a licence granted for that purpose (hereinafter referred to as a "dispensing licence").

21 of 1996(5) Any person who contravenes subsection (1) shall be guilty of an offence and shall be liable to a fine of not less than ten thousand Kwacha and not exceeding one hundred thousand Kwacha.

21 of 1996(6) Any person who contravenes subsection (2) shall be guilty of an offence and shall be liable to a fine of not less than twenty thousand Kwacha and not exceeding two hundred thousand Kwacha, and to imprisonment for five years.

21 of 1996(7) Any person who contravenes subsection (3) shall be guilty of an offence and shall be liable to a fine of not less than fifty thousand Kwacha and not exceeding five hundred thousand Kwacha, and to imprisonment for ten years.

21 of 1996(8) Any person who contravenes subsection (4) shall be guilty of an offence and shall be liable to a fine of not less than ten thousand Kwacha and not exceeding one hundred thousand Kwacha.

[Ch3501s36]36. Exemptions

The provisions of section 35 shall not apply to—

- (a) anything done by a medical practitioner or dentist which—
 - (i) relates to a medicinal product specially prepared, or specially imported by him or to his order, for administration, sale or supply to his particular patient; or
 - (ii) relates to a medicinal product specially prepared by a medical practitioner or dentist at the request of another medical practitioner or dentist for administration, sale, or supply to a particular patient of that other medical practitioner or dentist; or
- (b) anything done by a veterinary surgeon which—
 - (i) relates to a medicinal product specially prepared for administration, sale, or supply for a particular animal or herd which is under his care; or
 - (ii) relates to a medicinal product specially prepared by a veterinary surgeon at the request of another verteinary surgeon for administration, sale or supply to a particular animal or herd which is under the care of that other veterinary surgeon;
- (c) anything which is done in a registered pharmacy or a hospital and is there done by or under the supervision of a pharmacist and consists of preparing, dispensing, assembling or procuring a medicinal product in accordance with a prescription given by a medical practitioner or dentist;
- (d) anything which is done in a registered pharmacy by or under the supervision of a pharmacist and consists of—
 - (i) preparing or dispensing a medicinal product for administration to a person where the pharmacist is requested by or on behalf of that person to do so in accordance with the

pharmacist's own judgment as to the treatment required, and that person is present in the pharmacy at the time of the request in pursuance of which that product is prepared or dispensed; or

(ii) preparing a stock of medicinal products with a view to dispensing them as mentioned in paragraph (c) or in paragraph (d) (i); or

(e) anything which is done in a hospital by or under the supervision of a pharmacist and consists of preparing a stock of medicinal products with a view to dispensing them as mentioned in paragraph (c); or

(f) the assembly of any medicinal products by a person in the course of that person's profession as a nurse or midwife; or

(g) the importation of a medicinal product by any person for administration to himself or to any persons who are members of his household, or the importation of a medicinal product where it is specially imported by or to the order of a medical practitioner or dentist for administration to his patient provided that in either case the quantity so imported shall be no greater than is reasonably necessary for that purpose and is not of commercial value; or

(h) the importation of a medicinal product in such circumstances as may be specified by the Minister in the notice published in the Gazette.

[Ch3501s37]37. Application for licences

(1) Any application for a licence under this Part shall be made to the licensing authority in the prescribed form.

(2) Any application referred to in subsection (1) shall contain a description of medicinal products to which the licence will relate.

[Ch3501s38]38. Matters to be considered before issuing a licence

Where an application is made for a licence under this Part, the licensing authority shall, before issuing the licence to which the application relates, consider the following—

(a) in the case of an application for a product licence—

(i) the safety of medicinal products of each description to which the application relates;

(ii) the efficacy of medicinal products of each such description for the purposes for which the medicinal products are proposed to be administered; and

(iii) the quality of medicinal products of each such description, according to the specification and the method or proposed method of manufacture of the medicinal products, and the provisions proposed for securing that the medicinal products when sold or supplied will be of that quality;

- (b) in the case of an application for a manufacturer's licence—
 - (i) the operations proposed to be carried out pursuant to the licence;
 - (ii) the premises in which those operations are to be carried out;
 - (iii) the equipment which is or will be available on those premises for carrying out those operations;
 - (iv) the qualifications of the person under whose supervision those operations will be carried out; and
 - (v) the arrangements made or to be made for securing the safekeeping of, and the maintenance of adequate records in respect of, medicinal products manufactured or assembled in pursuance of the licence;
- (c) in the case of an application for a wholesale dealer's licence—
 - (i) the premises on which medicinal products of the description to which the application relates will be stored;
 - (ii) the equipment which is or will be available for storing medicinal products on those premises;
 - (iii) the equipment and facilities which are or will be available for distributing medicinal products from those premises;
 - (iv) the qualifications of the persons under whose supervision those operations will be carried out; and
 - (v) the arrangements made or to be made for securing the safekeeping of, and the maintenance of adequate records in respect of, medicinal products stored on or distributed from those premises.

[Ch3501s39]39. Issue of licences

(1) If the licensing authority is satisfied that the applicant is a fit and proper person to carry on any business set out in section 35, he may issue to the applicant the licence appropriate to such business subject to such general or special conditions as the licensing authority may consider appropriate to impose.

(2) A licence issued under subsection (1) shall be in the form, and shall be for such duration, as may be prescribed.

(3) Where the licensing authority, after consultation with the Board, considers that the applicant is not a fit and proper person to whom a licence should be issued for the carrying on of any business specified in section 35, he shall refuse to issue a licence and such refusal shall not be subject to appeal

to, or question in or by, any court, and the licensing authority shall not be required to assign any reasons therefor.

[Ch3501s40]40. Suspension and revocation of a licence

(1) Subject to this Part, the licensing authority may suspend a licence for such period as he may determine, or may revoke, or vary the provisions of such licence.

(2) The suspension or revocation of a licence under this section may be limited to medicinal products of one or more descriptions, or to any particular premises or to a particular part of any premises.

[Ch3501s41]41. Variation of a licence

Subject to section 37, the licensing authority may, on the application of the holder of a licence under this Part, vary the provisions of the licence in accordance with any proposals contained in the application, if the licensing authority is satisfied that the variation will not adversely affect the safety, quality or efficacy of medicinal products.

[Ch3501s42]42. Clinical trial

(1) In this Part “clinical trial” means an investigation or series of investigations consisting of the administration of one or more medicinal products of a particular description by, or under the direction of, a medical practitioner or dentist to his patient where there is evidence that medicinal products of that description have effects which may be beneficial to the patient in question and the administration of the medicinal product is for the purpose of ascertaining to what extent the product has any other effects whether beneficial or harmful.

(2) Subject to the provisions of this Part, no person shall, in the course of a business carried on by him—

- (a) sell or supply any medicinal product for the purpose of a clinical trial; and
- (b) procure the sale or supply of any medicinal product for the purpose of a clinical trial; or
- (c) procure 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,

unless the following conditions are fulfilled by that person—

(aa) that he is the holder of a product licence which authorizes the clinical trial in question, or he does it to the order of the holder of such a licence, and, in either case, he does it in accordance with that licence; and

(bb) that a certificate for the purpose of this section (in this Act referred to as a “clinical trial certificate”) has been issued to him certifying that, subject to the provisions of the

certificate, the licensing authority has authorized the clinical trial in question and that a certificate is for the time being in force and the trial is to be carried out in accordance with that certificate.

(3) Subsection (2) shall not apply to—

(a) anything which is done in a registered pharmacy or a hospital by or under the supervision of a pharmacist in accordance with a prescription given by a medical practitioner or dentist; or

(b) anything done by or under the supervision of a pharmacist which consists of procuring the preparation or dispensing of a medicinal product in accordance with a prescription given by a medical practitioner or dentist.

(4) Any person who contravenes the provisions of this section shall be guilty of an offence.

[Ch3501s43]43. Animal test

(1) Subject to this Part, no person shall, in the course of a business carried on by him—

(a) sell or supply any medicinal product for the purposes of a medicinal test on animals; or

(b) procure the sale or supply of any medicinal product for the purposes of medicinal test on animals; or

(c) procure the manufacture or assembly or for the manufacture or assembly of any medicinal product for sale or supply for the purposes of medicinal test on animals,

unless the following conditions are fulfilled by that person—

(i) that he is the holder of a product licence which authorizes the test in question, or he does it to the order of the holder of such a licence, and, in either case, he does it in accordance with that licence;

(ii) that a certificate for the purpose of this section (in this Act referred to as an “animal test certificate”) has been issued to him certifying that, subject to the provisions of the certificate, the licensing authority has authorized the test in question and that a certificate is for the time being in force and the test is to be carried out in accordance with that certificate.

(2) Any person who contravenes the provisions of this section shall be guilty of an offence.

[Ch3501s44]44. Clinical trial and animal test certificates

(1) Subject to the provisions of this section, every clinical trial certificate or animal test certificate, unless previously renewed or revoked, shall expire at the end of the period of one year from the date on which it was issued or from the date specified in the certificate as issued or renewed.

(2) Any certificate, if it has not been revoked, may, on the application of the holder of the certificate be renewed by the licensing authority for a further period of one year from the date on which it would otherwise expire.

(3) The licensing authority may suspend, for such period as he may determine, a clinical trial certificate or animal test certificate, or he may revoke or vary the provisions of, any such certificate.

PART V

PROVISIONS RELATING TO DEALINGS IN MEDICINAL PRODUCTS

[Ch3501s45]45. Restrictions on sale of medicinal products

(1) Subject to any exemption conferred by or under this Part, no person shall sell by retail, offer or expose for sale by retail or supply any medicinal product on a pharmacy list unless—

- (a) the person is lawfully conducting a retail pharmacy business; or
- (b) the product is sold or supplied on premises which are a registered pharmacy; or
- (c) the person is a pharmacist, or, if the transaction is carried out on his behalf by another person, then that other person is, or acts under the supervision of a pharmacist; or
- (d) the product 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) No person shall sell or supply any medicinal product unless such sale or supply is made from premises capable of being closed so as to exclude the public.

(3) Any person who contravenes the provisions of this section shall be guilty of an offence.

[Ch3501s46]46. Circumstances in which restrictions on sale of medicinal product may not apply

(1) The restrictions imposed by section 45 shall not apply to—

- (a) the sale or supply of a medicinal product—
 - (i) by a medical practitioner or dentist who holds a dispensing licence; or
 - (ii) in the course of the business of a hospital where the product is sold or offered for sale or supplied for the purpose of being administered, whether in the hospital or elsewhere, in accordance with the directions of a medical practitioner or dentist;
- (b) the sale or supply of a medicinal product of a description or class specified by Order made by the Minister and published in the Gazette where such medicinal product is sold or supplied—
 - (i) by a nurse in the course of her professional practice; or

- (ii) by a midwife in the course of her professional practice; or
- (iii) by a clinical officer in the course of his professional practice and where he holds a dispensing licence; or
- (iv) by a medical assistant or dental assistant in the course of his professional practice and where he holds a dispensing licence; or
- (v) a veterinary surgeon who holds a dispensing licence.

[Ch3501s47]47. Sale and administration of medicinal product to be subject to prescription by appropriate practitioner

(1) Subject to the provisions of this section, no person shall sell by retail, or supply in circumstances corresponding to retail sale or administer, other than to himself, a medicinal product of a description or a class specified by Order made by the Minister and published in the Gazette except in accordance with a prescription given by an appropriate practitioner.

(2) Subsection (1) shall not apply if—

- (a) the sale or supply or administration of a medicinal product to a patient is by a medical practitioner or dentist who holds a dispensing licence; or
- (b) the sale or supply of a medicinal product is for administration to an animal or herd by a veterinary surgeon who holds a dispensing licence.

(3) In this Part “appropriate practitioner” means a medical practitioner, dentist, veterinary surgeon and any person as the Minister may specify in the Order made under subsection (1).

(4) Any person who contravenes the provisions of this section shall be guilty of an offence.

[Ch3501s48]48. Restrictions on wholesale dealings

The Minister may by Order published in the Gazette provide for restrictions on the sale or supply of medicinal products by way of wholesale dealing.

[Ch3501s49]49. Prohibition of adding to or abstraction of any substance from medicinal products

30 of 1991(1) No person shall—

- (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; or
- (b) sell or supply, or offer or expose for sale or supply, or have in his possession for the purpose of sale or supply, any medicinal product whose composition has been adversely affected by the addition thereto or abstraction therefrom of any substance; or

(c) sell or supply any medicinal product which is not of the nature or quality demanded by the purchaser.

(2) Subsection 1 (c) shall not be taken 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, subsections (1) and (2) shall have effect as 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) for the words “demanded by the purchaser” there were substituted the words “specified in the prescription”.

(4) Any person who contravenes the provision of this section and regulations made under section 66 shall be guilty of an offence.

PART VI

CONTAINERS, PACKAGE, AND IDENTIFICATION OF MEDICINAL PRODUCTS

[Ch3501s50]50. Medicinal product to be in labelled containers or packages

(1) No person shall, in the course of a business carried on by him, sell or supply or have in his possession for the purpose of selling or supplying any medicinal product in a container or package which is not labelled in accordance with regulations made under section 66.

(2) Without prejudice to subsection (1), no person shall, in the course of a business carried on by him, sell or supply, a medicinal product of any description in a container or package which is labelled 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) Any person who contravenes this section shall be guilty of an offence.

[Ch3501s51]51. Leaflets

(1) No person shall, 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, a leaflet relating to such medicinal products which does not comply with regulations made under section 66.

(2) Without prejudice to subsection (1), no person shall, in the course of a business carried on by him, supply together with a medicinal product or have in his possession for the purpose of so supplying a leaflet 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.

(3) Any person who contravenes this section shall be guilty of an offence.

PART VII

PROMOTION OF SALES OF MEDICINAL PRODUCTS

[Ch3501s52]52. Regulations for advertising of medicinal products

The Minister may make regulations which may prohibit any issue of advertisements—

- (a) relating to medicinal products 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 treating or preventing a disease so specified or of ascertaining the existence, degree or extent of a physiological condition so specified or of permanently or temporarily preventing or otherwise interfering with the normal operation of a physiological function so specified or for the purpose of artificially inducing a condition of body or mind so specified;
- (c) likely to lead to the use of medicinal products of a particular description or class specified in the regulations or the use of any other substance or article of a description or class so specified for any such purpose as is mentioned in paragraph (b); and
- (d) relating to medicinal products and containing 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 products or as to any condition of body or mind in connexion with which the medicinal product might be used.

[Ch3501s53]53. Meaning of advertisement

(1) In this Part “advertisement” includes every form of advertising, whether in a publication, or by the display of any notice or by means of any catalogue, price list, letter, whether circular or addressed to a particular person, or by the exhibition of a photograph or a cinematograph film, or by way of sound recording, sound broadcasting or television.

(2) Notwithstanding anything contained in subsection (1), “advertisement” does not include spoken words except—

- (a) words forming part of a sound recording or embodied in a sound-track associated with a cinematograph film;

(b) words broadcast by way of sound broadcasting or television or transmitted to subscribers to a diffusion service; and

(c) anything spoken in public.

(3) Save as regulations made under section 52 may otherwise provide, for the purposes of this Part, the following shall not constitute an advertisement—

(a) the sale or supply, or offer or exposure for sale or supply, of a medicinal product in a labelled container or package; and

(b) the supply, together with a medicinal product, of a leaflet relating solely to the use of the medicinal products supplied.

[Ch3501s54]54. Medicines Committee

19 of 1995(1) There shall be a Medicines Committee of the Board (in this section referred to as the "Committee") which shall consist of a chairman and not less than two and not more than four other persons appointed by the Board.

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

(3) Without prejudice to the generality of subsection (2), the Committee shall—

(a) advise the Board on all matters covered in Parts IV to VII; and

(b) advise the Board on the safety, quality or efficacy of medicinal products.

(4) Section 12 shall apply to the Committee to the extent possible.

PART VIII

POISONS

[Ch3501s55]55. Preparation of poisons list

(1) The Minister shall, after consultation with the Board, prescribe a list of non-medicinal poisons (hereinafter referred to as the "Poisons List").

(2) The Poisons List shall be divided into two parts, as follows—

(a) Part I shall consist of those substances which, subject to the provisions of this Act, are prohibited from being sold except by a person who is lawfully conducting a retail pharmacy business; and

(b) Part II shall consist of those substances which, subject to the provisions of this Act, are prohibited from being sold except by a person who is an authorized seller of Part II poisons.

[Ch3501s56]56. Prohibition of, and conditions with respect to, sale of poisons

(1) Subject to the provisions of this Act, no person shall—

(a) sell or supply any poison which is a substance included in Part I of the Poisons List, unless—

- (i) he is a person lawfully conducting a retail pharmacy business;
- (ii) the sale or supply is effected on premises which are a registered pharmacy; and
- (iii) the sale or supply is effected by, or under the supervision of, a pharmacist;

(b) sell or supply any poison which is a substance included in Part II of the Poisons List, unless—

(i) he is a person lawfully conducting a retail pharmacy business and the sale or supply is effected on premises which are a registered pharmacy; or

(ii) he is a person who is an authorized seller of Part II poisons;

(c) sell or supply any poison, whether it is a substance included in Part I or in Part II of the Poisons List, unless the container of the poison is labelled in the prescribed manner—

(i) with the name of the poisons;

(ii) in the case of a preparation which contains a poison as one of its ingredients, with the prescribed particulars as to the proportion which the poison contained in the preparation bears to the total ingredients;

(iii) with the word “poison” or other prescribed indication of the character of the article; and

(iv) with the name of the seller of the poison and the address of the premises on which it is sold.

(2) Subject to the provisions of this Act—

(a) no person shall sell or supply any poison which is a substance included in Part I of the Poisons List to any person unless that person is either—

(i) certified in writing in the prescribed manner by a person authorized in that behalf by the Minister; or

(ii) known by the seller or by a pharmacist in the employment of the seller at the premises where the sale is effected to be a person to whom the poison may properly be sold;

(b) the seller of any poison shall not deliver it until—

(i) he has made or caused to be made an entry in a book to be kept for that purpose stating the date of the sale, the name and address of the purchaser and of the person by whom the certificate required under paragraph (a) was given, the name and quantity of the article sold, and the purposes for which it is stated by the purchaser to be required; and

(ii) the purchaser has signed for the entry.

(3) Subject to the provisions of this Act, a poison shall not be exposed for sale in, or be offered for sale by means of, an automatic machine.

(4) Any person who contravenes this section shall be guilty of an offence.

[Ch3501s57]57. Poisons Committee

(1) There shall be a Poisons Committee of the Board (in this section referred to as the "Committee") which shall consist of a chairman and not less than two and not more than four other persons appointed by the Board.

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

(3) Without prejudice to the generality of subsection (2), the Committee shall, where it is assigned by the Board so to do—

(a) advise the Board on all matters covered under this Part; and

(b) assist the Board in the preparation of the Poisons List.

(4) Section 12 shall apply to the Committee to the extent possible.

PART IX

PROVISIONS FOR NON-MEDICINAL PRODUCTS

[Ch3501s58]58. Provisions relating to substances which are not medicinal products

(1) The Minister may by regulations specify any descriptions or classes of articles or substances which—

(a) are manufactured, sold, supplied, imported or exported in a manner similar to medicinal products; or

(b) are used as ingredients in the manufacture of a medicinal product; or

(c) if used without proper safeguards, are likely to be a risk to public health or to be dangerous or injurious to animals, and he may provide that, subject to such exceptions and modifications as may be specified, the provisions of this Act including those relating to offences and

penalties shall have effect to such descriptions or classes of articles or substances as those provisions apply to medicinal products.

PART X

INSPECTION

[Ch3501s59]59. Inspectors

21 of 1996(1) The Board shall, for the purposes of enforcing the provisions of this Act, appoint such number of inspectors as it considers appropriate and shall issue to them, in writing or in such form as may be prescribed, certificates of authority to act as such inspectors.

21 of 1996(2) A person shall not be qualified for appointment as an inspector unless he is a pharmacist or pharmacy technologist.

21 of 1996(3) A person appointed by the Board as an inspector under this section shall hold office subject to such conditions as the Board may determine, and the Board shall, in the case of an inspector who is a pharmacy technologist, determine the premises which may be inspected by such inspector.

[Ch3501s60]60. Entry into premises

21 of 1996(1) Subject to the provisions of this section and section 59 (3), an inspector may, at any reasonable time and on production of his certificate of authority, enter any premises—

(a) for the purpose of ascertaining whether there is or has been, on or in connexion with those premises, any contravention of this Act; and

(b) generally for the purposes of discharging his functions under this Act.

(2) An inspector may, at any reasonable time and on production of his certificate of authority—

(a) enter any ship, aircraft or any vehicle for the purpose of ascertaining whether there is in the ship, aircraft or vehicle any substance or article imported in contravention of this Act; or

(b) enter any ship, aircraft or any vehicle for any purpose for which the inspector is authorized to enter any premises under subsection (1).

[Ch3501s61]61. Mode of inspection

(1) For the purpose of ascertaining whether there is or has been a contravention of this Act an inspector may inspect—

(a) any substance or article appearing to him to be a medicinal product or a poison;

(b) any article appearing to him to be a container or package used or intended to be used to contain any medicinal product or poison or to be a label or leaflet used or intended to be used in connexion with a medicinal product or poison; or

(c) any plant or equipment appearing to him to be used or intended to be used in connexion with the manufacture or assembly of medicinal products or poisons and the means employed, at any stage of the processes of manufacture or assembly, for testing the materials after they have been subjected to those processes.

(2) Where an inspector requires a sample of any substance or article appearing to him to be—

(a) a medicinal product or poison sold or supplied or intended to be sold or supplied; or

(b) a substance or article used or intended to be used as an ingredient in the manufacture of a medicinal product or poison,

he shall, if he does not obtain the sample by purchase, obtain the sample of that substance or article from the person by whom the medicinal product or poison is sold and supplied or intended to be sold, supplied or manufactured.

(3) For the purposes of this section, an inspector may—

(a) require any person carrying on a business which consists of, or includes, the manufacture, assembly, sale or supply of medicinal products or poisons, and any person employed in connexion with such a business, to produce any books or documents relating to the business which are in his possession or under his control; and

(b) take copies of, or of any entry in, any book or document produced in pursuance of paragraph (a).

(4) An inspector may seize and detain any substance or article which he has reasonable cause to believe to be a substance or article in relation to which, or by means of which, an offence under this Act is being or has been committed, and any document which he has reasonable cause to believe to be a document which may be required as evidence in proceeding under this Act.

(5) In exercising the powers under this section, an inspector may, in order to secure that the provisions of this Act are observed, require any person who owns the substance or article or has authority over the substance or article which is contained in a container or package or a vending machine, to break open any container or package or open any vending machine or to permit the inspector to do so.

(6) Where an inspector seizes any substance or article, including any document pursuant to subsection (4), he shall inform of that fact the person from whom it is seized and, in the case of anything seized from a vending machine, the person whose name and address are stated on the machine as being

those of the owner of the machine or, if no name and address are so stated, the occupier of the premises on which the machine stands or to which it is affixed.

(7) An inspector entering any premises, ship, aircraft or vehicle, pursuant to section 60 may take with him such other persons and such equipment as may appear to him to be necessary, and on leaving any such premises, ship, aircraft or vehicle, he shall, if the premises are unoccupied or the occupier, or in the case of a ship, aircraft, vehicle, the master, commander or other person in charge of it is temporarily absent, leave it as effectively secured against trespass as he found it.

(8) Any person who—

(a) wilfully obstructs an inspector in the discharge of his duties; or

(b) wilfully fails to comply with any requirement properly made to him by an inspector; or

(c) without reasonable cause fails to give to the inspector any assistance or information which the inspector may reasonably require of him for the purpose of the performance of his duties under this Act,

shall be guilty of an offence.

(9) If any person, in giving any such information as is mentioned in subsection (8) (c), makes any statement which he knows to be false or which he does not believe to be true, he shall be guilty of an offence.

(10) Nothing in this section shall be construed as requiring a person to answer any question or give any information if to do so might incriminate that person or, where that person is married, the husband or wife of that person.

[Ch3501s61A]61A. Closure of premises and seizure of equipment, etc.

21 of 1996(1) Where the Board believes, on reasonable grounds, that this Act or any regulations made thereunder have been contravened, the Board may, subject to subsection (2), order—

(a) the closure of any premises; and

(b) the seizure of any equipment, instrument or any other thing,

by means of, or in relation to which, the Board reasonably believes the contravention was committed.

(2) The closure of any premises shall cease, and any equipment or any other thing seized shall not be detained, after the provisions of this Act or any regulations made thereunder have, in the opinion of the Board, been complied with, unless before that time disciplinary or court proceedings, as the case may be, have been instituted in respect of the contravention, in which event the premises shall remain closed and the equipment, instrument or other thing may be detained until the proceedings are finally concluded.

(3) Where a person has been found guilty of an offence or disciplinary misconduct under this Act or any regulations made thereunder, any equipment, instrument or other thing by means of or in relation to which the offence or misconduct was committed may, in addition to any other penalty imposed by the court or the Board, be forfeited to such person, and may be disposed of in such manner and at such time and place, as the court or the Board, as the case may be, may direct; but no equipment, instrument or other thing shall be disposed of pending an appeal against the decision of the court or the Board or before the time within which the appeal may be taken has expired.

[Ch3501s62]62. Non-disclosure of information

(1) If any person discloses to any other person—

(a) any information with respect to any manufacturing process or trade secret obtained by him in premises which he has entered pursuant to this Act;

(b) any information obtained by or furnished to him pursuant to this Act,

he shall, unless the disclosure was made in the performance of his duty and to an authorized person therefor, be guilty of an offence and shall be liable to a fine not exceeding K200 and to imprisonment for a term not exceeding three months.

[Ch3501s63]63. Inspectors not to be personally liable for acts done by them under the Act

An inspector shall not be personally liable in respect of any act done by him in the course of his employment and in the execution or purported execution of any duty under this Act.

[Ch3501s64]64. Offences by a corporate body

Where under this Act, an offence committed by a body corporate is proved to have been committed with the consent and connivance of, or to be attributable to any neglect on the part of, any director, manager, secretary or other similar officer of the body corporate or any person who was supposed to act in any capacity, such officer and the body corporate shall severally and jointly be guilty of an offence.

[Ch3501s65]65. Penalty

(1) Any person who is guilty of an offence under this Act for which a specific penalty has not been provided shall be liable to a fine not exceeding K50,000 and to imprisonment for a term not exceeding five years.

21 of 1996(2) Upon conviction of any person for an offence under this Act, the court may, in addition to any other penalty imposed, declare any substance or article seized and detained by an inspector and found to have been used in, or in connexion with, the commission of that offence to be forfeited, and may order it to be destroyed, without compensation.

PART XI

REGULATIONS AND SAVINGS

[Ch3501s66]66. Regulations

The Minister may, with the advice of the Board, make regulations for carrying out or giving effect to the provisions of this Act and, without prejudice to the generality of the foregoing, such regulations may—

- (a) specify descriptions or classes of medicinal products or poisons or of any articles or substances required to be specified under this Act;
- (b) control, regulate or prohibit the sale or supply, export or the importation, of medicinal products or poisons or any articles or substances of any specified description or class;
- (c) provide for the manner in which containers and packages or medicinal products or poisons may be labelled;
- (d) provide for the manner in which leaflets relating to the advertisement of medicinal products or poisons may be made;
- (e) prescribe such requirements as may be necessary with respect to—
 - (i) the manner in which, or persons under whose supervision, medicinal products or poisons may be prepared or may be dispensed;
 - (ii) the amount of space to be provided in any premises for persons preparing or dispensing medicinal products, the separation of any such space from the remainder of the premises, and the facilities to be provided in any premises for such persons;
 - (iii) the accommodation to be provided in any premises for the sale or supply of medicinal products or poisons;
 - (iv) the accommodation to be provided in any premises for members of the public to whom medicinal products or poisons are sold or supplied or for whom medicinal products or poisons are being prepared or assembled;
 - (v) the amount of space to be provided in any premises for members of the public and storage of medicinal products or poisons;
 - (vi) the safekeeping of medicinal products or poisons;
 - (vii) the disposal of medicinal products or poisons which have become unusable or otherwise unwanted;
 - (viii) precautions to be observed before medicinal products or poisons are sold or supplied;

(ix) the keeping of records relating to the sale or supply of medicinal products or poisons;

(x) the supply of medicinal products or poisons distributed as samples;

(xi) sanitation, cleanliness, temperature, humidity or other factors relating to the construction, location and use of automatic machines for the sale of medicinal products;

(f) prescribe forms of any register required to be kept by the Board under this Act;

(g) prescribe forms of any applications, notices, licences, certificates and any other documents required to be prescribed under this Act;

(h) prescribe forms of any book or record to be kept for the purposes of this Act;

(i) prescribe the fees payable upon registration or renewal of registration and upon application for a licence or certificate or renewal of licence or certificate; and

(j) prescribe anything to be prescribed under this Act.

[Ch3501s67]67. Repeal and savings

(1) The Pharmacy and Poisons Act is hereby repealed. Cap. 35:01

(2) Any subsidiary legislation made under the Pharmacy and Poisons Act in force immediately before the commencement of this Act—

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

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

SUBSIDIARY LEGISLATION

PHARMACY, MEDICINES AND POISONS (FEES AND FORMS) REGULATIONS

under s. 66

G.N. 65/1991

14/1995

82/1995

7/1997

87/1998

49/2000

1. Citation

These Regulations may be cited as the Pharmacy, Medicines and Poisons (Fees and Forms) Regulations.

2. Fees

The Fees specified in the First Schedule shall be payable in respect of the matters correspondingly specified herein.

3. Forms

The forms set out in the Second Schedule shall be used for the purposes of the Act, and such particulars as are contained in these forms and not particularly prescribed by the Act are hereby prescribed as particulars required under the Act.

FIRST SCHEDULE reg. 2

G.N. 14/1995

G.N. 82/1995

G.N. 87/1998

G.N. 49/2000

FEES

ItemMatterKt1.On application for—(a) registration as a pharmacist—(i) for a Malawian50000(ii) for a newly qualified Malawian25000(iii) for a Non-MalawianUS\$ 10000(b) registration as a pharmacy technologist—(i) for a Malawian20000(ii) for a newly qualified Malawian10000(iii) for a non-MalawianUS\$ 5000(c) registration as—(i) a pharmacy assistant10000(ii) a newly qualified pharmacy assistant5000(d) registration of premises where a retail pharmacy business is to be carried on—(i) by a company5,00000(ii) by an individual5,00000(e) registration of premises where—(i) a prescription wholesale pharmacy business is to be carried on12,00000(ii) a non-prescription wholesale pharmacy business is to be carried on10,00000(f) registration of premises where a manufacturing pharmacy business is to be carried on10,00000(g) registration of premises where a medicine store business is to be carried on3,000002.(a) Upon issue of a certificate of registration as a pharmacist—(i) for a Malawian50000(ii) for a newly qualified Malawian10000(iii) for a non-MalawianUS\$ 10000(b)Upon issue of a certificate of registration as a pharmacy technologist—(i) for a Malawian20000(ii) for a newly qualified Malawian10000(iii) for a non-MalawianUS\$ 5000(c) Upon issue of a certificate of registration as—(i) a pharmacy assistant10000(ii) a newly qualified pharmacy assistant5000(d) Upon registration of premises where a retail pharmacy business is to be carried on7,00000(e) Upon registration of premises where—(i) a wholesale pharmacy business is to be carried on15,00000(ii) a non-prescription wholesale

business is to be carried on7,00000(f) Upon registration of premises where a manufacturing pharmacy business is to be carried on12,00000(g) Upon registration of premises where a medicine store business is to be carried on4,000003.(a) On application for—(i) product licence for products manufactured within Malawi1,00000(ii) product licence for products manufactured outside MalawiUS\$ 5000(iii) manufacturer's licence1,00000(iv) wholesale dealer's licence2,00000(v) non-prescription wholesale dealer's licence1,00000(vi) dispensing licence50000(vii) medicine stores licence2,00000(b) Upon issue of—(i) a product licence for products manufactured within Malawi1,50000(ii) a product licence for products manufactured outside MalawiUS\$ 15000(iii) a manufacturer's licence5,00000(iv) a wholesale dealer's licence15,00000(v) a non-prescription wholesale dealer's licence10,00000(vi) a dispensing licence to—00(A) a medical practitioner, dentist or veterinary surgeon practising within the Cities of Blantyre, Lilongwe, Mzuzu and the Municipality of Zomba2,00000(B) a medical practitioner, dentist or veterinary surgeon practising at a place other than any of the places referred to in subparagraph (A)50000(C) any appropriate practitioner other than those referred to under subparagraphs (A) and (B) practising at any place in Malawi30000(vii) a medicine store licence4,000004.Retention fees—(a) On application for retention of name on the register of—(i) (A) a Malawian pharmacist50000(B) a non-Malawian pharmacistUS\$ 10000(ii) (A) a Malawian pharmacy technologist200(B) a non-Malawian pharmacy technologistUS\$ 5000(iii) a pharmacy assistant10000(b) Upon approval for retention of names of register of—(i) (A) a Malawian pharmacist40000(B) a non-Malawian pharmacistUS\$ 8000(ii) (A) a Malawian pharmacy technologist20000(B) a non-Malawian pharmacy technologistUS\$ 5000(iii) a pharmacy assistant7500(c) a retail pharmacy business7,00000(d) a wholesale dealer's licence15,00000(e) a non-prescription wholesale dealer's licence10,00000(f) a medicine store business3,50000(g) a manufacturer's licence5,00000(h) a dispensing licence—(i) to a medical practitioner, dentist or veterinary surgeon practising within the cities of Blantyre, Lilongwe and Mzuzu and the Municipality of Zomba2,00000(ii) to a medical practitioner, dentist or veterinary surgeon practising in any other district50000(iii) to any appropriate practitioner other than those referred to under subparagraphs (i) and (ii) practising at any place in Malawi30000(i) a product licence—(i) where the product is manufactured in Malawi1,00000(ii) where the product is manufactured outside MalawiUS\$ 150 00

SECOND SCHEDULE

FORM No. 1

FORMS

PHARMACY, MEDICINES AND POISONS ACT

(CAP. 35:01)

PHARMACY, MEDICINES AND POISONS (FEES AND FORMS) REGULATIONS

APPLICATION FOR REGISTRATION AS A PHARMACIST, PHARMACY TECHNOLOGIST OR PHARMACY ASSISTANTDelete whatever is not applicable*

(section 21 (1))

To: The Registrar Pharmacy, Medicines and Poisons Board P.O. Box 30377 Lilongwe 3

1. Name and address of applicant (in block letters) Surname First Names Address

Telephone Number 2. Date of birth

3. Sex (male/female)

4. Nationality 5. Application for registration in the register of 6. Academic qualifications (certificates, diplomas, degrees) and institutions attended (school, university, college)—

Qualification Year Institution and Country.....

7. Professional qualifications (with dates and institutions attended)—

Qualifications Year Institution/Body.....

8. Present employer and address:.....

9. I, the above-mentioned applicant, hereby apply for registration on the aforementioned register and submit herewith— NOTE: 1. Fee must be payable only by cheque or postal order made in favour of the Pharmacy, Medicines and Poisons Board.

2. Application fee is not refundable, but registration fee shall be refunded where application for registration has not been accepted.]*(a) the prescribed application fee of K NOTE: 1. Fee must be payable only by cheque or postal order made in favour of the Pharmacy, Medicines and Poisons Board. NOTE: 1. Fee must be payable only by cheque or postal order made in favour of the Pharmacy, Medicines and Poisons Board.

2. Application fee is not refundable, but registration fee shall be refunded where application for registration has not been accepted.]*(b) the prescribed registration fee of K, and NOTE: 1. Fee must be payable only by cheque or postal order made in favour of the Pharmacy, Medicines and Poisons Board.

2. Application fee is not refundable, but registration fee shall be refunded where application for registration has not been accepted.]*(c) the following documents in support of my application:

..... 10. Declaration— I, the above-mentioned applicant, hereby solemnly and sincerely declare that the information I have given above is true in every

respect to the best of my knowledge and belief and that I have read the Act and the Regulations made under the Act and understand that, if registered, I shall be bound thereby and by any amendments thereto, for as long as my name shall remain on the aforementioned register. Declared at by

Signature of Applicant before me at on this day of, 19

Commissioner of Oaths 11. FOR OFFICE USE ONLY— (a) Date of approval of application (b) Registration No.

Certificate No. (c) Receipt Nos. of application and registration fees (d) Remarks

..... Date Signature

Registrar

Pharmacy, Medicines and Poisons Board

FORM No. 2

PHARMACY, MEDICINES AND POISONS ACT

(CAP. 35:01)

PHARMACY, MEDICINES AND POISONS (FEES AND FORMS) REGULATIONS

REGISTER OF PHARMACIST, PHARMACY TECHNOLOGIST OR PHARMACY ASSISTANT (Delete whatever is not applicable)*

(Sections 21 (3) and 66 (f))

Qualifications	Name of Registered person	Date of Registration	Registration Number	Expiry Date	Address	Nationality	Date of Birth	Upon registration	Subsequent to registration	University, College, School or other institution	Date of cancellation of registration, if any	Remarks, if any
----------------	---------------------------	----------------------	---------------------	-------------	---------	-------------	---------------	-------------------	----------------------------	--	--	-----------------

FORM No. 3

PHARMACY, MEDICINES AND POISONS ACT

(CAP. 35:01)

PHARMACY, MEDICINES AND POISONS (FEES AND FORMS) REGULATIONS

CERTIFICATE OF REGISTRATION OF A PHARMACIST, PHARMACY TECHNOLOGIST OR PHARMACY ASSISTANT(*Delete whatever is not applicable)*

(Section 22)

Registration No Certificate No This is to certify that is this day of, 19 registered on the register of kept and maintained by the Pharmacy, Medicines and Poisons Board in accordance with the provisions of the Pharmacy, Medicines and Poisons Act, 1988, and the Regulations made thereunder. Valid until, 19

Dated

.....

Registrar.....

ChairmanCommon Seal of the Board

FORM No. 4

PHARMACY, MEDICINES AND POISONS ACT

(CAP. 35:01)

PHARMACY, MEDICINES AND POISONS (FEES AND FORMS) REGULATIONS

APPLICATION FOR RETENTION OF NAME OF REGISTERED PHARMACIST, REGISTERED PHARMACY TECHNOLOGIST, OR REGISTERED PHARMACY ASSISTANT(*Delete whatever is not applicable)* ON APPROPRIATE REGISTER

(Sections 23 (1) and 66 (g))

To:The Registrar Pharmacy, Medicines and Poisons Board P.O. Box 30377 Lilongwe 3

1. Surname 2. First names
..... 3. Address 4. Date of Birth
5. Sex (male/female)
6. Nationality 7. Registration No. dated
....., 19 8. Certificate No. dated , 19 9. Application for retention of name on the in respect of
.....(name of registered Pharmacist, registered Pharmacy

Technologist or registered Pharmacy Assistant) 10. I, the above-mentioned applicant, hereby apply for retention of my name on the aforementioned register and submit therefor— (a) [NOTE:

1. Fees must be payable only by cheque or postal order made in favour of the Pharmacy, Medicines and Poisons Board.

2. Application fee is not refundable, but retention fee shall be refundable where application for retention has not been accepted].*application fee of K and (b) [NOTE:

1. Fees must be payable only by cheque or postal order made in favour of the Pharmacy, Medicines and Poisons Board.

2. Application fee is not refundable, but retention fee shall be refundable where application for retention has not been accepted].*retention fee of K..... Dated this day of, 19

Signature of Applicant 11. FOR OFFICE USE ONLY— (a) Date of approval of application (b) Registration No. Certificate No. (c) Receipt Numbers of application and retention fees (d) Remarks

..... Date

Registrar Pharmacy, Medicines and Poisons Board

FORM No. 5

PHARMACY, MEDICINES AND POISONS ACT

(CAP. 35.01)

PHARMACY, MEDICINES AND POISONS (FEES AND FORMS) REGULATIONS

APPLICATION FOR REGISTRATION OF PREMISES WHERE A RETAIL PHARMACY BUSINESS IS TO BE CARRIED ON

(Section 28)

To:The Registrar Pharmacy, Medicines and Poisons Board P.O. Box 30377 Lilongwe 3

1. Name of applicant 2. Address 3. Location of premises on which a retail pharmacy business it to be carried (Town, Street, Plot No.)
.....

4. Where the applicant is a company— (a) state registration number of company under the Act (b) state name and Certificate No. of registered pharmacist under whose personal management and control the affairs of the company would be subject to (c) attach a copy of the certificate of incorporation of the company 5. Name and number of certificate of registration of a registered pharmacist having control of the premises referred to in paragraph 3

6. I, the above-mentioned applicant, submit herewith application fee of K

and registration fee of K

Date

Signature of Applicant

[*NOTE 1. Fees must be payable only by cheque or postal order made in favour of the Pharmacy, Medicines and Poisons Board.

2. Application fee is not refundable whereas registration fee is refundable where the application is not accepted]

7. FOR OFFICE USE ONLY— (a) Date of inspection of premises (b) Remarks (c) Date of approval of application (d) Registration No. (e) Receipt Nos. of application and registration fees \ Date Signature

Registrar Pharmacy, Medicines and Poisons Board

FORM No. 6

PHARMACY, MEDICINES AND POISONS ACT

(CAP. 35:01)

PHARMACY, MEDICINES AND POISONS (FEES AND FORMS) REGULATIONS

CERTIFICATE OF REGISTRATION OF PREMISES WHERE A RETAIL PHARMACY BUSINESS IS TO BE CARRIED ON

(Sections 28 and 66)

REGISTRATION No.

.....CERTIFICATE No.

.....

THIS IS TO CERTIFY that the Premises situated at

.....

.....(state location of premises, namely town, street and plot No.)where is authorized to carry out a(Name of business owner)retail pharmacy business are this day of, 19 registered on the register of premises where retail pharmacy business is to be carried on, kept and maintained by the Pharmacy, Medicines and Poisons Board in accordance with the provisions of the Pharmacy, Medicines and Poisons Act and the Regulations made thereunder.

Date

Registrar.....

ChairmanCommon Seal of the Board

FORM No. 7

PHARMACY, MEDICINES AND POISONS ACT

(CAP. 35:01)

PHARMACY, MEDICINES AND POISONS (FEES AND FORMS) REGULATIONS

REGISTER OF PREMISES WHERE A RETAIL PHARMACY BUSINESS IS TO BE CARRIED ON

(Sections 28 and 66 (f))

Location of Registered PremisesDate of RegistrationRegistrationName, Registration and Certificate No.
of Registered Pharmacist in Control of BusinessRemarks, if anyTownStreetPlot No.

FORM No. 8

PHARMACY, MEDICINES AND POISONS ACT

(CAP. 35:01)

PHARMACY, MEDICINES AND POISONS (FEES AND FORMS) REGULATIONS

APPLICATION FOR A PRODUCT LICENCE

(Sections 35 (1) and 37 (1))

To: The Secretary for Health Ministry of Health P.O. Box 30377 Lilongwe 3 Malawi

NOTES—1. Application for a product licence in respect of established medicinal products may be exempted from submission of information normally required for certain parts of the application at the discretion of the licensing authority. Exemption claims may be submitted along with the application with reasons for the request. Application for a product licence in respect of new medicinal products, however, will normally have to comply in full with the requirements of all relevant parts of the application form.

2. Before completing each part of the form, please read any notes on the application form.

3. Samples and printed matter should be sent by post or other means, postage prepaid by the applicant.

4.—(a) Written evidence of application fee of K and product licence fee of K as having been paid to the Board should be submitted together with this application, to the Secretary for Health. The application fee and product licence fee shall be paid to the Board in the form of postal order or cheque.

(b) The application fee shall not be refundable whereas the product licence fee shall be refundable where the applicant is not accepted.

SUMMARY OF APPLICATION FORM FOR PRODUCT LICENCE

PART 1: General Information
1.1 Particulars of Applicant
1.2 Particulars of Medicinal Product
PART 2: Pharmaceutical Data (Formulation)
PART 3: Chemical Data (Active and Inactive Ingredients)
3.1 Chemical Detail
3.2 Outline Synthesis
PART 4: Manufacturing Data
4.1 Summary of Procedures
4.2 In-process Controls
PART 5: Raw Materials Data
5.1 Specifications
5.2 Control Procedures
PART 6: Final Product Data
6.1 Specifications
6.2 Control Procedures
6.3 Product Information
PART 7: Container and Packaging Data
7.1 Primary Container
7.1.1 Specifications
7.1.2 Control Procedures
7.2 External Packaging
PART 8: Stability Data
8.1 Active Ingredient(s)
8.2 Analytical Procedures
8.3 Experimental Results
8.4 Shelf Life
8.5 Degradation Products
8.6 Deterioration Evidence
8.7 Stability Testing
PART 9: Package Insert and Labelling Data
9.1 Package Insert
9.2 Product Label
9.3 Outer Package Label
PART 10: Foreign Registration Data
10.1 Country of Origin
10.2 Other Countries
10.3 Non-acceptance Details
PART 11: Distribution and Promotion Data
11.1 Distribution
11.2 Promotion/Advertising
PART 12: Pharmaceutical and Biological Availability Data
12.1 Pharmaceutical Data
12.2 Biological Data
PART 13: Toxicological Data
13.1 Preclinical
13.2 Clinical
PART 14: Efficacy Data
14.1 Preclinical
14.2 Clinical
PART 15: Pharmacological Data
15.1 Pharmacodynamic Data
15.2 Pharmacokinetic Data
15.3 Adverse Reaction Data
15.4 Overdosage Data
15.5 Interaction Data
15.6 Biological Assay Data
PART 16: Veterinary Medicine Clinical Studies Data
16.1 Toxicological Data
16.2 Efficacy Data
16.3 Pharmacological Data
16.4 Data on Residues
PART 17: Additional Document Requirements

PART 11.1 Particulars of Applicant (2) Name
Business address

..... Postal address
.....

..... Telephone number Telex
number Telefax number1.2 Description of
medicinal product to which the product licence relates

..... Approved name (3)
..... Proprietary name (4) Dosage
form and presentation (5) Pharmacological classification (6)
..... Country of origin (7) Principal's
name and address

.....
Manufacturer's name and address

.....
The medicinal product (*delete as appropriate)*has/has not been available in Malawi/ before

....., 19 I, the undersigned, hereby solemnly and sincerely declare that the
information I have given above is true in every respect to the best of my knowledge and belief and that I
have read the Act and any Regulations or Rules made under the Act and understand that, if issued with
the product licence, I shall be bound thereby for so long the product licence is valid.....

Signature of Applicant Declared at by

(State name of applicant) before me this

day of, 19Signature

(Commissioner of Oaths)

PART 1—NOTES

(1) For office use only.

(2) Application for product licence shall be made—

(a) in case of an individual, by a registered pharmacist who is himself the applicant;

(b) in case of a company, by a registered pharmacist under whose _ personal management
and control the business of the company is carried on.

(3)(a) This shall be the international non-proprietary name or approved generic name in the
country of origin.

(b) If an approved name has not yet been allocated to the medicinal product by an appropriate international or national body, the name which has been or will be submitted for approval shall be stated here.

(4) This is the trade name which is unique to the particular medicinal product and by which it is generally identified for commercial purposes.(5)

(a) The dosage form namely, capsule, eye-drops, injection vial, ointment, solution, suppository, tablet and the presentation, including a brief description of the physical characteristics of the medicinal product and the strength of its active ingredient(s) shall be stated here. Examples:

(i) dispersible greenish-yellow round scored tablets containing

(ii) injection, powder for reconstitution as a solution/suspension, 2 g vial

(iii) suspension (=mixture), granules for reconstitution with water for preparations, 100 ml bottle. When reconstituted contains/5m

(b) Each different dosage form or presentation of a medicinal product will be construed as requiring a separate product licence.

However applications for product licence in respect of medicinal products which vary only in strength may be made on the same form.

(6) The pharmacological classification or therapeutic group into which the medicinal product falls should be stated.

Examples—stimulant laxativenon-steroidal anti-inflammatoryanti-epileptictopical antifungalanti-tuberculosis drug, etc.

(7) This is the country of original development of the medicinal product.

PART 2: PHARMACEUTICAL DATA (FORMULATION)

Name of applicant: Name of medicinal product—(a) Approved: (b) Proprietary:

Dosage Form:

Listed below are details of the active and inactive ingredients contained in the medicinal product.

Approved name (1)Chemical name (2)Quantity (3)Active or inactive (4)Reasons for inclusion if inactive

PART 2—NOTES

(1) This will be the international non-proprietary name or a national generic name. If no such approved name exists, the name which has been submitted for approval should be stated.

(2) This shall, wherever possible, be given in terms of the published list of an appropriate international body. If none exists, the chemical nature of the ingredient should be described.

(3) This should be stated in terms of a dosage unit or, where none exists, in terms of a suitable unit of mass or volume of the medicinal product.

(4) Inactive ingredients include all ingredients other than the active ingredient(s), including pharmaceutical additives, necessary for formulation purposes.

PART 3: CHEMICAL DATA (ACTIVE AND INACTIVE INGREDIENTS)

Name of Applicant: Name of Medicinal product—(a) Approved: (b) Proprietary:

Dosage Form:

3.1 Chemical details of the active and inactive ingredients are as follows:

Approved name	Chemical name and structural formula	Specifications (1)	Physical Characteristics (2)
---------------	--------------------------------------	--------------------	------------------------------

3.2 Outline synthesis procedures for each active ingredient with side-product limits is as follows:

Active ingredient	Outline synthesis	Side-product limits
-------------------	-------------------	---------------------

PART 3—NOTES

(1) Where applicable, reference to internationally recognized publications e.g. BP, BPC, Eur.P, IP, USP, etc., will be acceptable.

(2) These should include where relevant—

- (a) Melting point
- (b) Boiling point
- (c) Optical rotation
- (d) Water solubility (according to BP terminology)
- (e) Crystal form
- (f) Particle size

together with any other physical properties which characterize the ingredient.

PART 4: MANUFACTURING DATA

Name of Applicant: Name of Medicinal product—(a) Approved: (b) Proprietary:

Dosage Form:

4.1 Summary of Manufacturing Procedure (1)–(3). 4.2 Analytical, microbiological or other in-process control procedures (2).

PART 4—NOTES

(1) This should cover the various stages of manufacturing and packaging and should include types of equipment and process durations.

(2) The frequency with which and sequence in which in-process controls are carried out should also be indicated here.

(3) The name and address of each pharmaceutical manufacturing facility which carries out any of the above procedures should be indicated, together with particulars of the procedures.

PART 5: RAW MATERIALS DATA

Name of Applicant: Name of Medicinal product—(a) Approved: (b) Proprietary:

Dosage Form:

5.1—Specifications Summarized below are the specifications of all active and inactive raw materials used in the manufacturing process of the medicinal product. The names of the tests, limits and criteria of acceptance of each parameter in the specifications are given (1)–(4).

PART 5.1—NOTES

(1) Where the stated specification tests correspond to a recognized pharmacopoeia, this should be stated.

(2) Specifications should be as in the latest editions of such pharmacopoeia and any departure from these should be fully substantiated.

(3) Approved or chemical names only should be used.

(4) Those raw materials not present in the final product should be indicated.

5.2—Control Procedures

Following is a description of the analytical and other control procedures performed on each of the raw materials, in order to confirm the specifications stated in Part 5.1 (1)–(3). This should include microbiological procedures where applicable.

PART 5.2—NOTES

(1) Reference only to standard texts will not be sufficient and full details should therefore be given.

(2) Release criteria should be stated for each raw material.

(3) The name of the laboratory carrying out each control procedure should be given.

PART 6: FINAL PRODUCT DATA

Name of Applicant: Name of Medicinal Product—(a) Approved: (b) Proprietary:

Dosage Form:

6.1 Specifications Summarized below are the specifications of the final product in terms of the name of the specification and the limits and criteria of acceptance of the physical, chemical and microbiological parameters where applicable.

PART 6.1—NOTES

(1) Analytical procedures should not be given here but in the next section, part 6.2.

(2) Control Procedures

Following is a description of analytical and other control procedures performed on the final product in order to confirm the specifications stated in Part 6.1. This should include microbiological procedures where relevant (1)–(4).

PART 6.2—NOTES

(1) Reference only to standard texts will not be sufficient and full details should therefore be given.

(2) Where an analytical procedure has been fully described in another part of the application reference to the relevant page may be made.

(3) Lot release requirements for the final product should be stated.

(4) The name of the laboratory carrying out each control procedure should be given.

6.3 Product Information (1)

- (a) Name of medicinal product (2) and dosage form
 - (b) Content of active ingredient(s) (3)
 - (c) Summary of pharmacological effects
 - (d) Indications (4)
 - (e) Contra-indications
 - (f) Dose information (5)
 - (g) Cautions (6)
 - (h) Side-effects (7)
 - (i) Interactions and incompatibilities with other medicinal products and other substances
- (8)
- (j) Treatment of overdose (9)

- (k) Presentation and pack size(s) of the medicinal product (10)
- (l) Other dosage forms of the same medicinal product available (11)
- (m) Storage requirements of the medicinal product (11)
- (n) Scheduling status (12)
- (o) Proposed retail price per unit pack.

PART 6.3—NOTES

(1) All the information given here (with the exception of (1)), should appear on the data sheet package insert together with other details as specified in Part 9.

(2) The international non-proprietary name or nationality approved generic name should be given together with the proprietary name, where this exists.

(3) This should be expressed as the amount per unit dose or per suitable unit mass or volume. The name and quantity of any added preservative should be given. Inactive ingredients may be specified as “excipients” except where they have special significance, e.g. sugar in preparations likely to be used by diabetics.

(4) These will be the indications for which a product licence is being sought.

(5)(a) Dose information should be given in the form of average doses or dose ranges and normal, maximum single and total daily doses for adults, children and infants.

(b) This should be accompanied by information on routes of administration, dose frequencies and normal duration of treatment with the medicinal product. Where relevant, the above information should be given for each therapeutic indication of the medicinal product.

(c) Doses for children and infants should be expressed as mg/kg, mg/m² or for specified age ranges.

(6) Cautions should include—

(a) Specific information on conditions or patients where the medicinal product should be used with particular care, e.g. in pregnancy, in renal or hepatic impairment, in elderly or young patients, during lactation, etc.

(b) Other specific warnings on use of the medicine, i.e. if liable to cause drug dependence, the statement “may be habit forming”; if a prescription only medicinal product, the statement “consult your physician before use of this medicine” or similar warnings.

(c) Warnings of potential drug interactions and incompatibilities (to be detailed in section (i)).

(7) (a) Details of all major and minor side-effects should be given together with an indication of the likely frequency of occurrence, e.g. common, occasional, rarely with all patients, etc.

(b) Also whether such side-effects are related to high or low doses and short or prolonged courses of treatment with the medicine should be stated, together with information on the reversibility or otherwise of the side-effect(s).

(8) All potential interactions and incompatibilities with other medicinal products should be given together with any involving alcohol, tobacco, foodstuffs, etc., where relevant.

(9) Information on both general measures for treatment of overdose and use of specific antidotes should be given where available.

(10) Presentation should be described in terms of the macroscopic characteristics of the product together with details of any distinguishing features, e.g. colour, flavour, scoring, distinguishing marks, etc.

(11) Refers to other products made by the company manufacturing the medicinal products for which application for registration is being submitted.

(12) i.e. CD = controlled drug POM = prescription medicinal product OMP = other medicinal product GSL = general sales list medicinal product, etc.

PART 7: CONTAINER AND PACKAGING DATA

Name of Applicant: Name of Medicinal product—(a) Approved: (b) Proprietary:

Dosage Form:

7.1 Primary Container 7.1.1 Specifications The following are the detailed specifications of the type, nature, size and grade of the primary container, i.e. that which is in direct contact with the medicinal product. Details of the type and method of closure together with those of any internal wadding or packing materials should also be stated. (1)

PART 7.1.1—NOTES

(a) The physical characteristics of the material(s) of construction of the container and closure should be given.

(b) In the case of plastics, names and percentages of any supplementary substances should be indicated.

- (c) With metals, information on any interior lacquer coating substance should be given.
- (d) For all materials, possible interactions with the medicinal product should be described.
- (e) Where specifications for a container material do not exist, this should be stated.

7.1.2 Control Procedures Following are the analytical and any other control procedures carried out on the primary container by or on behalf of the applicant, in order to confirm the requirements of the specification detailed in Part 7.1.1.

PART 7.1.2—NOTES

(1) Reference only to standard reference texts will not be sufficient and full details should therefore be provided.

(2) The laboratories in which the control procedures are carried out should be stated, and where a laboratory other than that of the applicant or manufacturer is used, the applicant should confirm that the relevant tests are being carried out.

(3) Release criteria for the primary container and the closure should be stated.

7.2 External Packaging(s)

A brief description of any outer packaging(s) together with specifications, where relevant, is given below.

PART 8: STABILITY DATA (1) (6)

Name of Applicant: Name of Medicinal product—(a) Approved: (b) Proprietary:

Dosage Form: 8.1 Following is a description of active ingredient(s) characteristics regarding— (a) normal degradation patterns (where known) resulting from hydrolysis, photolysis, oxidation and other processes: (b) identity of known degradation products:

.....; and (c) storage conditions currently used to maintain the quality of each

.....

..... 8.2 Following is a description of analytical procedures used to determine the stability of the medicinal product as packaged with the reasons for assuming that these methods can indicate stability. (2)

(3)..... 8.3 Following are tabulated experimental results of the above stability tests carried out on the final product, together

with the interpretation of the results and an explanation of the basis on which the shelf-life is deduced.
(4)..... 8.4 The shelf-life claimed for the final packaged product
under specified storage conditions is as
follows.....

8.5 The methods employed and results obtained for determination of the presence of
degradation products after a period of storage under specified conditions are as
follows.....

8.6 Physical characteristics of the final product during storage under specified normal conditions
and evidence indicating deterioration are as
follows.....

8.7 Following is a programme of stability testing which is used to monitor and confirm the
deduced shelf-life.
(5).....

PART 8—NOTES

(1)(a) No application for a product licence in respect of any medicinal product shall be
submitted without inclusion of stability data indicating a shelf-life of twenty-four months for the final
packaged medicinal product.

(b) This requirement will not apply to medicinal products with inherently unstable
ingredients.

(2) As temperatures up to 40 degrees centigrade may be reached during storage in Malawi,
testing should simulate these condition.

(3) Stability tests should include monitoring of the continued preserving ability of any
antimicrobial preservative in the product.

(4) Tabulated results of stability tests should include—

(a) stability results obtained in respect of all specification tests listed in Part 6.2.;

(b) full details of environmental conditions e.g. temperature, humidity, light, duration of
storage, used in shelf-life studies.

(c) batch numbers and dates of manufacture of the samples' examined; and

(d) confirmation that the packaging used is the same as described in Part 7.1.

(5) The programme shall include details of frequency of testing, proposed environmental
conditions, acceptance criteria and parameters to be tested.

(6)(a) Informing on the batch number code must be given to the licensing authority so that it
will be possible to judge the age of the product.

(b) Alternatively the date of manufacture should be declared on the label of the primary container and on any other packaging.

PART 9: LABELLING AND PACKAGE INSERT DATA

Name of Applicant: Name of Medicinal product—(a) Approved: (b) Proprietary:

Dosage Form: 9.1 Package Insert The following information shall appear on the package insert/data sheet of the product, six specimens of which should be submitted— (a) scheduling status; (b) generic name; (c) proprietary name; (d) dosage form; (e) composition; (f) pharmacological/therapeutic classification; (g) summary of pharmacological action; (h) indications; (i) contra-indications; (j) dosages and directions for use; (k) side-effects; (l) interactions and incompatibilities; (m) symptoms and treatment of overdose; (n) cautions/warnings; (o) storage instructions; (p) presentation/identification; (q) name and address of manufacturer; (r) product licence number and date of issue; and (s) date of publication.

PART 9.1—NOTES

As for Part 6.1 where applicable

9.2 Product label.

The following information should be included on the label of the primary container which is in direct contact with the medicine, six specimens of which should be submitted—

- (a) scheduling status;
- (b) generic and proprietary names;
- (c) dosage form;
- (d) composition;
- (e) doses and routes of administration/directions for use;
- (f) any necessary warnings e.g. “keep away from children” “read package insert carefully before use”;
- (g) date of manufacture;
- (h) batch number;
- (i) date of expiry; and
- (j) name and address of manufacturer.

PART 9.2—NOTES

As for Part 6.3 where applicable

9.3 Outer Package Label The following information should be included on the label of any outer package of the product, six specimens of which should be submitted—

- (a) scheduling status;
- (b) generic and proprietary names;
- (c) dosage form;
- (d) composition;
- (e) doses and routes of administration/directions for use;
- (f) any necessary warnings;
- (g) manufacturing date;
- (h) batch number;
- (i) expiry date;
- (j) date and number of product licence;
- (k) for introductory samples, the statement "SAMPLE";
- (l) name and address of manufacturer; and
- (m) indications (in the case of over-the-counter products).

PART 9.3—NOTES

As for Part 6.3 where applicable

PART 10: FOREIGN REGISTRATION DATA

Name of Applicant: Name of Medicinal product—(a) Approved: (b) Proprietary:

Dosage Form:

10.1 Product licence/registration number in country of origin (1).10.2 Summary of other countries of registration with product licence/registration numbers, name and presentation of the medicinal product

and prescription status (2) in these countries. (Copies of the registration certificates and product licences should be submitted.)

CountryLicence/ RegistrationName of Medicinal ProductPresentationPrescription

10.3—Countries in which registration of the medicinal product has not been accepted with reasons for non-acceptance are as follows—

PART 10—NOTES

(1) If registration has not been authorized details as to progress made with the registration application should be given.

(2) i.e. PO (prescription only), P (pharmacy only), GSL (general sales list), CD (controlled drug) or other as specified.

PART 11: DISTRIBUTION AND PROMOTION DATA

Name of Applicant:Name of Medicinal product—(a) Approved:(b) Proprietary:

Dosage Form:

11.1 How it is proposed to distribute the medicinal product (1)

(a) under controlled drug (narcotics) regulations (b) on prescription only (c) recorded purchase through pharmacies only (d) on sale through pharmacies only (e) for general sale (f) for veterinary use only11.2 How will the medicinal product be advertised/ promoted ? (1) (a) to the medical/pharmacy professions only (b) to the general public by point-of-sale displays in pharmacies (c) to the general public

PART 11—NOTES

(1) Please tick the appropriate boxes

PART 12: PHARMACEUTICAL AND BIOLOGICAL AVAILABILITY DATA

Name of Applicant:Name of Medicinal product—(a) Approved:(b) Proprietary:

Dosage Form:

Following are experimental details and results of tests performed on the medicinal product to confirm its pharmaceutical and biological availability (bioavailability). 12.1 Pharmaceutical Availability

(1) 12.2 Biological Availability (2)

PART 12—NOTES

(1) These are IN VITRO tests (commonly dissolution rate studies) designed to illustrate the rate of release of active ingredient(s) from the dosage form.

(2) These are IN VIVO tests designed to show the characteristics of release of the active ingredient(s) from the dosage form into body fluid (usually blood plasma).

(3) Confirmation must be given that such tests were carried out on the medicine formulation for which registration is being sought. If the product formulation with which clinical trials were conducted is not identical to that of this application, any differences must be clearly indicated.

(4) The applicant should state whether any correlation exists between the in vitro and in vivo data obtained using the methods described above.

(5) Full details of any standard reference substances used in the tests should be given, e.g. supplier, composition, batch number.

PART 13: TOXICOLOGICAL DATA

Name of Applicant:Name of Medicinal product—(a) Approved:(b) Proprietary:

Dosage Form:

Following are details of methods used in, results obtained and conclusion drawn from tests performed on the medicinal product to demonstrate all aspects of its toxicity and to prove the safety of its use. These should include (1–6) (11)— 13.1 Pre-clinical studies with special reference to—

(a) single dose studies to investigate acute toxicity and determine the average lethal dose (7). (b) multiple dose studies to investigate sub-acute and chronic toxicity (8); (c) teratogenicity studies and other reproduction studies (9); (d) mutagenicity studies (10); (e) carcinogenicity studies (10); and (f) other studies to substantiate the safety of the medicinal product, including studies investigating drug-dependence potential and histopathological investigations.

PART 13.1—NOTES

(1) Where well known active ingredients are concerned, the licensing authority may grant exemption from the submission of some of the above information.

(2) The route of administration used in the tests should generally be the same as that intended for clinical use.

(3) Control groups should always be included in the tests. These controls would usually be given a place but otherwise treated and observed like the test groups.

(4) Data provided should be concise, relevant and provide adequate proof that the requirements of this part have been met.

(5) The following information must be supplied—

- (a) animal strain;
- (b) method of administration and dosage;
- (c) solvents or suspending agents used;
- (d) numbers, sexes, ages and weights of animals used; and
- (e) numbers and composition of control groups.

(6) Results of investigations and observations carried out should be reported both individually for each animal and collectively for each group. The arithmetic means for each test and control group should be specified.

(7)(a) Data on acute toxicity, stated as LD₅₀ with confidence limits and preferably LD₉₅ also, should be expressed as units of weight or volume per kg of body weight.

(b) This data should generally be available for at least two animal species and in respect of different administration methods.

(c) Observation periods and survival times of the animals tested should be stated.

(d) Data on acute toxicity in newborn animals should be provided for medicines to be used in the prenatal period.

(8) Reference here is to toxicity following different forms of repeated administration of the medicine. Such tests should be conducted with at least two animal species, one of which should normally be a non-rodent.

(9) These should include—

- (a) embryotoxicity (death of foetus or reduced foetal weight);

(b) peri- and post-natal actions (effects arising just prior to, during and after parturition;
and

(c) fertility studies.

(10) These tests are generally required if any ingredient of the medicine or metabolite are allied to known carcinogenic and/or mutagenic substances, and also in general if the medicine is intended to be used over prolonged periods.

(11) Where certain tests have not been performed, the reasons for this should be stated which the medicinal product is intended to be used and with regard to the dosage and method of administration of the medicinal product—

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

14.2 Clinical studies, with special reference to comparative or controlled clinical tests, double blind tests, etc.—

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

PART 14.2—NOTES

(1) Proof of all information relating to efficacy as contained in the package insert should be substantiated here.

(2) By whom, when and where the studies were carried out should be stated.

PART 15: PHARMACOLOGICAL DATA

Name of Applicant:

Name of Medicinal product—(a) Approved:(b) Proprietary:

Dosage Form:

The pharmacological properties of the medicinal product are summarized below in terms of its pharmacodynamic and pharmacokinetic characteristics.

15.1 Pharmacodynamic data (1).

15.1.1 Pre-clinical data on primary pharmacodynamic effects:

A summary of studies in animals of the pharmacological effects forming the basis for therapeutic use of the medicinal product, with particular reference to quantitative aspects is given below—

.....

.....

15.1.2 Pre-clinical data on other pharmacodynamic effects:

(a) Studies of other pharmacological effects of the medicinal product in animals, which though not relevant to its therapeutic use are relevant to assessment of its clinical use and risks, are summarized below—

.....

(b) Interactions of the medicinal product with other compounds where relevant to the proposed therapeutic use should be indicated.

15.1.3 Clinical data on primary pharmacological effects (2):

A summary of studies in humans of the pharmacological effects forming the basis for the therapeutic use of the medicinal product, with particular reference to quantitative aspects is given below—

.....

.....

15.1.4 Clinical data on other pharmacodynamic effects (3):

(a) Studies of such effects in humans, which though not relevant to the therapeutic use of the medicine are relevant to assessment of its clinical use and risks, are summarized below—

.....

.....

(b) Any interactions of the medicinal product with other compounds where relevant to its proposed therapeutic use should also be stated.

PART 15.1—NOTES

(1) In the case of new drugs which are similar to others in the same pharmacological category, clinical trials should if possible be planned so that comparison with an established drug in the category can be made.

(2) Dose-response curves and dose duration should be given.

(3) Any effect of the medicinal products on the CNS, including respiratory system, cardiovascular system, blood, hepatic and renal function, details of development of tolerance to the medicinal products should be described, in relation to doses intended for clinical use.

15.2 Pre-clinical Pharmacokinetic Data (1).

The pattern and time course of absorption (2), distribution (3), biotransformation (4) and elimination (5) of active constituents of the medicinal product and important metabolites, in at least one animal species are described below:

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

15.2.1 Clinical Pharmacokinetic Data.

As in 15.2 above but in human volunteers

PART 15.2—NOTES

(1) To facilitate assessment of information obtained in these investigations, certain relevant chemical and physical chars of the active ingredients should be stated in this part including pka values, partition coefficients at various pHs.

(2)(a) Absorption should be documented preferably on a quantitative basis and with the intended route of administration, Particulars should be given for those concentrations in the blood, plasma or serum at which pharmacological and toxicological effects are obtained.

(b) Any physico-chemical properties influencing absorption should be stated.

(3)(a) Primary distribution should be outlined by specifying concentrations in the various tissues. It is important to indicate individual organs having particularly high concentrations of the drug(s) or metabolites or risks of retention of these. Protein binding characteristics should be detailed.

(b) Penetration characteristics of the drug across the blood-brain and placental barriers should be described, preferably quantitatively.

(c) It should also be established whether the drug(s) is secreted in breast milk and what concentrations may be reached.

(d) Any physico-chemical properties affecting distribution should be stated.

(4) Studies of metabolism of the drug(s) in several species of animal and in humans should be described together with investigation into biologically active metabolites and including at test for

chemical toxicity.(5) The main routes of excretion of the drug(s) and its main metabolites should be stated. Data on the rate of elimination (half-life) from the blood, plasma or serum, should be stated including if possible the most important factors affecting elimination rate, including biotransformation, renal excretion and urinary pH.

15.3 Adverse Reaction Data (1).

Incidence and nature of adverse reactions to the medicine in therapeutic doses, together with descriptions of individual cases with particularly toxic or hypersensitivity reactions are stated below—

15.4 Overdosage

Toxic effects of overdosage with recommended treatment of such intoxication are detailed below—

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

PART 15.3—NOTES

(1) If available, information regarding the origin and biochemical mechanisms of adverse effects should be given, together with advice on how the effects may be minimized.

(2) All indications of development of tolerance, dependence or habitation to the medicinal product should be stated, including the appearance of withdrawal symptoms.

15.5 Interaction Data

All interactions with other drugs and in particular those likely to be used concurrently should be stated together with the likely effects of such an interaction.

15.5.1 Animal Studies

Interaction data observed in animal studies is summarized below (with references). Mechanisms of interaction aetiology should be explained.

15.5.2 Clinical Investigations

Interactions of the medicinal product observed in humans with other drugs, foods or other agents including alcohol, tobacco, together with a description of the effects of such interactions, are as follows (with references):

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

15.6 Biological Assay Data

Details of assay methods for the drug within body fluids including blood, urine, saliva are as indicated below. Experimental details of tests performed and results obtained to establish correlation between physiological levels of the drug and pharmacological action are as indicated.

PART 16: VETERINARY MEDICINE CLINICAL STUDIES DATA

Name of Applicant:

Name of Medicinal product—

(a) Approved:

(b) Proprietary:

Dosage Form:

16.1 Toxicological Data

Tests performed on different animal species regarding safety of the medicinal product are as follows—

16.1.1 Acute Toxicity

Studies are described below and the maximum tolerated doses and minimum lethal doses indicated:

Clinical tests performed regarding the efficacy of the

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

16.1.2 Chronic Toxicity

Field use studies involving sufficiently large groups of animals of both sexes and different ages are described below and results and conclusions are summarized:

.....
.....

.....

PART 16.1—NOTES

(1) All supporting data should be concise, relevant and sufficient to provide proof that the requirements of this part have been fulfilled.

(2) Proof of all information relating to toxicity and efficacy as contained in the package insert should be provided.

(3) For each species, the doses administered, route of administration used and side-effects observed, clinical tests performed regarding the efficacy of the medicinal products are described below and the results and conclusions of these are summarized:

.....

.....

.....

.....

PART 16.2—NOTES

(1) By whom, when and where the tests were conducted should be stated.

(2) Special reference should be made to comparative and controlled clinical trials.

16.3 Pharmacological Data

(a) Tests performed to establish correlation between physiological levels of the medicinal products and claimed pharmacological action are as described below:

.....

.....

.....

(b) Experimental details and results are specified and conclusions summarized:

.....

.....

.....

16.4 Data on Residues

(a) Tests conducted to determine the presence of residues of active ingredients of the medicinal product or their metabolites in the eggs, milk and tissues of food animals are described below:

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

(b) Experimental details and results are specified and conclusions summarized (1)
.....

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

PART 16.4—NOTES

(1) The recommended withdrawal period for the medicinal product should be stated.

PART 17: ADDITIONAL DOCUMENT REQUIREMENTS

Name of applicant:

Name of Medicinal product—

(a) Approved:

(b) Proprietary:

Dosage Form:

Listed below are the additional documents required to be submitted along with the application for product licence. Numbers of copies are indicated and reference is made to the relevant part of the application form where applicable—

(1) medical literature references regarding therapeutic use of the medicinal product, published within the last 10 years—one copy of each;

(2) package insert (Part 9.1)—6 copies;

(3) product label (Part 2)—6 copies;

(4) outer package label (Part 9.3)—6 copies;

(5) all proposed advertising and promotional materials (Part 11)—6 copies of each;

(6) product information summary (Part 6.3)—6 copies;

(7) product formula (Part 2)—6 copies;

(8) all manufacturing records and batch data relating to a particular batch, preferably that of the sample submitted, including—

(a) raw material analytical reports;

(b) manufacturing and packaging master sheets;

(c) in process control records;

(d) final product analytical reports;

(e) authorization for release;

(f) any other appropriate records, one copy of each;

(9) five sealed samples of the smallest commercial pack, to enable analytical tests to be performed.

FORM No. 8A

PHARMACY, MEDICINES AND POISONS ACT

(CAP. 35:01)

PHARMACY, MEDICINES AND POISONS (FEES AND FORMS) REGULATIONS

APPLICATION FOR A PRODUCT LICENCE (SUMMARY SHEET)

(sections 35 (1) and 37 (1))

A. Product Identification1. PMPB Ref. No.(for office use only) 2. Proprietary name 3. Non-proprietary name (INN)4. Dosage form5. Strength6. Route of administration7. Suggested Price USB. Applicant details1. Name of Applicant2. Address of Applicant3. City/town 4. Country5. Tel. No.6. Fax. No.7. Telex8. E-mail addressC. Manufacturer details1. Name of manufacturer2. Address3. City/town4. Country9. Manufacturing licence No.10. Licence date5. Tel. No.6. Fax No.11. Name and address of licensing authority7. Telex8. E-mail address12. Date of last GMP inspectionD. Product details1. Therapeutic category2. Main indication(s)3. Dosage details and method of use4. Stability data (on first 3 batches)5. Shelf-life6. Storage conditions7. Complete quantitative formula (per dose form)(a) Substance(b) Function(c) Amount (d) QC specifications(i)(ii)(iii)(iv)(v)(vi)(vii)(viii)8. Total weight or volume of dose form

E. Active ingredient details

9. Active ingredients

(a) Active ingredient(b) Source(c) Standard e.g. USP, BP(d) In-process controls (Optional)(i)(ii)(iii)(iv)

F. Manufacturing and Quality Control Information

10. (a) Method of manufacture of dosage form

10 (b) In process control measures

11. QC specifications of the final product12. Validated analytical method for final product13. Batch No.14. Date of manufacture15. Expiry date16. Results of batch testing

(attach additional information if necessary)

G. Equivalence data (Optional)Comparative bioavailability, pharmacodynamic or clinical studies and comparative in vitro dissolution testsH. Container information(a) Size (number of dose units)(b) Description of container and closure(i)(ii)(iii)

I. Distribution and Promotion Information

1. What is the intended scheduling status of the product? (tick appropriate box)

(a) CD Controlled(b) POM Prescription only medicine(c) PIM Pharmacist initiated medicine(d) P Pharmacy only medicine(e) GSL General sales list medicine(f) Veterinary use only

2.How is it proposed to promote the medicinal product? (tick appropriate box)(a)to the medical and pharmacy professions only(b)to the general public b point-of-sale displays in pharmacies(c)to the general public(d)other (please specify)

J. Current Regulatory Status of Product (Please attach relevant documents)

(a) Country(b) Product Licence No.(c) Date of First Registration(i) Country of manufacture(ii)(iii)(iv)(v)

K. Date and Signature

(a) Date of application(b) Signature of registered pharmacist (c) Applicant official seal

L. Registration Information (for office use only)

(a) Application Fee(b) App. Fee No.(c) Registration Fee(d) Reg. Fee Receipt No.(e) Reg. Date(f) Reg. expiry date(g) Registration No.(h) Full name and signature

Registrar

Pharmacy, Medicines and

Poisons Board

FORM No. 9

PHARMACY, MEDICINES AND POISONS ACT

(Cap. 35:01)

G.N. 7/1997

PHARMACY, MEDICINES AND POISONS (FEES AND FORMS) REGULATIONS

PRODUCT LICENCE

(section 39)

Product Licence No. issued at under section 39 of the Pharmacy, Medicines and Poisons Act

to

(name of person or firm to whom licence is issued)

of

(state city, street, plot number and postal address)

who is hereby licensed to engage in any or all of the business activities outlined under section 35 (1) of, and subject to, the Act in regard to the following medicinal product(s) in accordance with the special conditions specified hereunder—

(a) Medicinal product identity—

(i) name.....

(ii) generic form

(iii) dosage form

(iv) strength.....

(v) manufacturing

- (vi) manufacturing country.....
- (b) Year and therapeutic category of the medicinal product
- (c) Scheduling status
- (d) Declaration of content—
 - (i) active ingredient
 - (ii) content per unit dose
- (e) Package—
 - (i) type of package
 - (ii) size of package
 - (iii) initial retail price per package

Further conditions of this Product Licence are—

Valid until 20

Date

(Official Stamp)

.....

Registrar.....

Chairman

FORM No. 10

PHARMACY, MEDICINES AND POISONS ACT

(CAP. 35:01)

PHARMACY, MEDICINES AND POISONS (FEES AND FORMS) REGULATIONS

REGISTER OF PRODUCT LICENCES

(section 66)

Product licenceDescription of Medical Products to which licence relatesName and address of licence holderNo.Date issued

FORM No. 11

PHARMACY, MEDICINES AND POISONS ACT

(CAP. 35:01)

PHARMACY, MEDICINES AND POISONS (FEES AND FORMS) REGULATIONS

APPLICATION FOR A MANUFACTURER'S LICENCE

(sections 35 (2) and 37 (1))

To: The Secretary for Health

P.O. Box 30377

Lilongwe 3

Malawi

1. Name of applicant

2. Address

.....

.....

3. List of products to be manufactured (name, form, dosage and strength) (submit formula for each product):

.....

.....

.....

4. Location of business premises:

.....

(state city, street and plot number)

5. Manufacturing equipment to be used—

Name

/typeCapacity.....

.....

6. Name and registration number of supervising pharmacist:

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

7. Qualifications and experience of supervising pharmacist:

.....
.....

8. Other key officers:

Name	Qualification	Experience	Production Officer(s)	Quality Control Officer(s)	Maintenance Officer(s)
.....

9. Arrangements made or to be made for securing safekeeping of, and the maintenance of adequate records in respect of medicinal products stored on or distributed from premises specified under paragraph 4

.....
.....

10. Brief description of manufacturing process (may be attached separately)

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

11. Proposed source(s) of raw materials.

12. I submit herewith written evidence that application fee of K and manufacturer's fee of K have been paid to the Board.

Date

.....

Signature of Applicant

13. FOR OFFICE USE ONLY

- (a) Date of inspection
- (b) Date of approval
- (c) Licence No.
- (d) Receipt No. of application fees
- (e) Remarks
- Date

.....

Registrar Pharmacy, Medicines and Poisons Board

[NOTE: 1. Fees shall be payable to the Board in the form of postal order or cheque.

2. Application fee shall not be refundable whereas manufacturer's licence fee shall be refundable where the application is not accepted.]

FORM No. 12

PHARMACY, MEDICINES AND POISONS ACT G.N. 7/1997

(CAP. 35:01)

PHARMACY, MEDICINES AND POISONS (FEES AND FORMS) REGULATIONS

MANUFACTURER'S LICENCE

(section 39)

Manufacturer's Licence No. issued at under section 39 of
Pharmacy, Medicines and Poisons Act to

.....

(name of person or firm to whom licence is issued)

of

(state city, street, plot number and postal address)

who is hereby licensed to manufacture, subject to the Pharmacy, Medicines and Poisons Act and to the special conditions set out hereunder, the following medicinal products—

Special conditions of this Licence are—

.....

.....

Valid until 20

Date

(Official Stamp)

.....

Registrar.....

Chairman

FORM No. 13

PHARMACY, MEDICINES AND POISONS ACT

(CAP. 35:01)

PHARMACY, MEDICINES AND POISONS (FEES AND FORMS) REGULATIONS

APPLICATION FOR A WHOLESALE DEALER'S LICENCE

(sections 35 (3) and 37 (1))

To: The Secretary for Health

P.O. Box 30377

Lilongwe 3

Malawi

1. Name of applicant:

2. Postal address:

3. Residential address:

(state city, street, plot number)

4. Medicinal products to which this application relates:

.....

.....

5. Location of premises on which medicinal products specified under paragraph 4 will be stored:

.....

.....

.....

(state city, street, plot number)

6. Specify equipment which is or will be available for storing the medicinal products at the premises referred to under paragraph 5:

.....

.....

7. Specify equipment and facilities which are or will be available for distributing the medicinal products from the premises referred to under paragraph 5:

.....

.....

.....

8. Specify qualifications including the registration number of the pharmacist under whose supervision the wholesale dealer's business will be carried out:

.....

.....

.....

9. Specify the arrangements made or to be made for securing the safekeeping of and the maintenance of adequate records of the medicinal products stored on or distributed from the premises referred to under paragraph 5:

.....

.....

10. I submit herewith written evidence that application fee of K and wholesale dealer's licence fee of K have been paid to the Board.

Date

.....

Signature of Applicant

FOR OFFICE USE ONLY

(a) Date of inspection

(b) Remarks

(c) (i) Application fees K Receipt No. (ii) Licence fees K
..... Receipt No.

(d) Date of approval Licence No.

Date

.....

Secretary for Health

[NOTE:1. Fees shall be payable to the Board in the form of postal order or cheque.

2. Application fee shall not be refundable, whereas registration fee shall be refundable where application for licence has not been accepted.]

FORM No. 14

PHARMACY, MEDICINES AND POISONS ACT G.N. 7/1997

(CAP. 35:01)

PHARMACY, MEDICINES AND POISONS (FEES AND FORMS) REGULATIONS

WHOLESALE DEALER'S LICENCE

(section 39)

Wholesale Dealer's Licence No. issued at under section 39 of
the Pharmacy, Medicines and Poisons Act to

(name of person or firm to whom the licence is issued)

of

(state city, street, plot number and postal address)

who is hereby licensed to carry on business as a wholesaler of medicinal products, subject to the
Pharmacy, Medicines and Poisons Act and to the special conditions set out hereunder.

Special Conditions of this Licence are—

.....

.....

Valid until, 20

Date

(Official Stamp)

.....

Registrar.....

Chairman

FORM No. 15

PHARMACY, MEDICINES AND POISONS ACT G.N. 7/1997

(CAP. 35:01)

PHARMACY, MEDICINES AND POISONS (FEES AND FORMS) REGULATIONS

DISPENSING LICENCE

(section 39)

Dispensing Licence No issued at under section 39 of the Pharmacy,
Medicines and Poisons Act to

(name of person or firm to whom licence is issued)

of

(state city, street, plot number and postal address)

who is hereby licensed to dispense medicinal products, subject to the Pharmacy, Medicines and
Poisons Act, and to the special conditions set out hereunder.

Special conditions of this licence are—

.....

.....

Valid until, 20.....

Date

(Official Stamp)

.....

Registrar.....

Chairman

FORM No. 16

PHARMACY, MEDICINES AND POISONS ACT

(CAP. 35:01)

PHARMACY, MEDICINES AND POISONS (FEES AND FORMS) REGULATIONS

APPLICATION FOR A DISPENSING LICENCE

(sections 35 (4) and 37 (1))

To: The Secretary for Health

P.O. Box 30377

Lilongwe 3

Malawi

1. Name of Applicant:

2. Address:

3. Location of business premises:

.....

(state city, street, and plot number)

4. Name and registration number of supervising Pharmacist

.....

.....

5. Qualifications and experience of supervising pharmacist

.....

.....

.....

6. Medicinal products to which this application relates

.....

.....

7. I submit herewith written evidence that application fee of K and dispensing licence fee of K have been paid to the Board.

Date

.....

Signature of applicant

8. FOR OFFICE USE ONLY—

(a) Date of inspection

(b) Remarks

(c) Receipt of application fees

(d) Date of approval

(e) Licence No.

Date

.....

Secretary for Health

[Note: 1. Fees shall be payable to the Board in the form of postal order or cheque.

2. Application fee shall not be refundable whereas dispensing licence fees shall be refundable where the application is not accepted.]

FORM NO. 17

PHARMACY, MEDICINES AND POISONS ACT G.N. 87/1998

(CAP. 35:01)

PHARMACY, MEDICINES AND POISONS (FEES AND FORMS) REGULATIONS

MEDICINES INSPECTORATE

C.G.M.P. Inspection Report

(section 60)

MANUFACTURING

1. Name of Manufacturer: Date:

Owner: Individual/Partnership/Company

Address:

Tel. No. Fax No.

Name of Production Pharmacist/Manager.....

Registration Number.....

Complies Default Not Applicable

2. PREMISES:

2.1 Constructed and maintained to protect against weather, ground seepage, pests, vermins, etc.

2.2 Sited to avoid external contamination

2.3 Surrounding environment pleasant

2.4 Good state of repair of walls, floors and ceiling (no cracks, etc.)

2.5 Premises clean and tidy

2.6 Walls and floor cleanable

3. SERVICES PROVIDED:

3.1 Adequate lighting

3.2 Temperature controller/Air conditioner

3.3 Acceptable ventilation and humidity

3.4 Filtered air in sterile suites

3.5 Water supply (hot and cold)

3.6 Distilled water supply

3.7 Disposal of waste, receptacles provided

4. SECURITY:

4.1 Restricted entry into drug production and storage areas to authorized personnel only

4.2 Burglar bars provided

4.3 Adequate locking system

4.4 Security watchmen deployed

4.5 Burglar alarm installed

5. SAFETY:

5.1 Fire fighting equipment, e.g. hose pipes, fire extinguishers

5.2 Fire exits clearly marked

5.3 Fire alarm/smoke detectors

6. LAYOUT OF WAREHOUSE:

Adequate space to allow logical flow of materials and activities and to allow easy communication and supervision of operations in each of the following sections—

6.1 Receipts and quarantine section (raw materials store)

6.2 Weighing section (raw materials)

6.3 Production suites

6.4 In houses QC laboratory

6.5 Packing and labelling sections

6.6 Quarantine areas (finished products)

6.7 Rejected products area

6.8 Warehouse for finished products

6.9 Dispatch section (finished products)

6.10 Recalled products area

6.11 Retained samples area

6.12 Materials and finished products stored to minimize mix-up errors or cross contamination

6.13 All storage areas clearly labelled

6.14 Animal houses completely separated from production areas

6.15 Changing or cloakrooms suitably located and separated from production areas

6.16 Toilet facilities adequate and provided with running water, hand wash basin and other facilities

6.17 Toilets not opening directly to manufacturing areas

6.18 Air lock system on entering into the main production areas

6.19 Microbiological contamination monitoring and validation

7. EQUIPMENT:

7.1 General layout of equipment including segregation and spacing

7.2 State of repair and functioning of each equipment

7.3 Maintenance schedule and/ or service contracts

7.4 Written SOPs and other operating instructions available

7.5 Calibration methods and validation SOPs available

7.6 Cleaning SOPs to avoid cross contamination and their validation

7.7 Suitability of equipment in relation to the production activities

8. HUMAN RESOURCES:

8.1 Production Manager: a fulltime supervisor of production activities who is a registered pharmacist

8.2 Name and registration number given

8.3 Relevant experience related to manufacturing noted and satisfactory

8.4 Other supporting staff in production suitably

qualified(1)(2)(3)(4)(5)8.5Written job descriptions and areas of responsibilities for all support staff available and well defined8.6Formal preliminary and continuous educational program given to staff8.7Quality assurance manager available8.8QA manager separate from production manager8.9Relevant qualifications and experience noted and satisfactory8.10Other supporting staff in QC suitably trained(1)(2)(3)(4)8.11Written job descriptions and areas of responsibility available and well defined for all QC support staff8.12Personal Hygiene:8.12.1Instructions to personnel on hygiene8.12.2Adequate facilities for washing8.12.3Adequate toilet facilities8.12.4Adequate changing room 8.13 Health:8.13.1Pre-employment medical check-up policy in place8.13.2Periodic medical check-up during employment and records kept8.13.3Provision of protective clothing, headgear, marks boots, gloves, ear plugs, etc.9.DOCUMENTATION:Are documents available in the following areas and are they adequate?9.1Starting materials testing and specifications9.2Packaging materials testing and specifications9.3Intermediate and bulk material specifications9.4Finished products specifications9.5Sampling and approved documentation9.6Master formula and production methods9.7Inventory records for starting materials9.8Inventory records for packing materials including printed labels9.9Production: Yield reconciliation9.10Batch manufacturing records9.11Intermediate and bulk release records9.12Complaints, recalls and returned goods records and SOPs9.13Documented analytical methods for raw materials9.14Documented analytical methods for finished products9.15Product stability data and its conformity to labelling and packing instructions of final product10.MANUFACTURING PROCESS10.1Compliance with written specifications for raw materials including the following main areas—10.1.1Physical description of material10.1.2Safety precautions on handling10.1.3Approved supplier(s) of material10.1.4Storage conditions of material10.1.5Details of tests for identity, limits of purity, physical and chemical properties and microbiological standards (where applicable)10.1.6Method of assay of material10.1.7Re-examination and retesting program10.2Weighing and measuring records for all raw materials for the production process10.3Labelling and batch numbering10.4Batch manufacturing methods specify the following—10.4.1Specific equipment used and the cleaning, assembly, calibration, sterilization, etc.10.4.2Detailed stepwise processing instructions including the following—10.4.2.1Sequence of adding materials10.4.2.2Mixing and other processing times10.4.2.3Working temperature10.4.2.4Authorization and checking on each process10.4.2.5Format for presentation of data acceptable11.IN-PROCESS ACTIVITY AND PACKING11.1Facilities and personnel for in-process activities adequate11.2Sampling testing, recording and checking processes adequate11.3Contamination and product mix-up minimized11.4Storage and security of labels and their release procedure adequate11.5Reconciliation of yields done11.6Quarantine and release procedures for finished products in place11.7Storage facility and conditions of storage for finished products acceptable11.8Tests for quality of finished product including assay methods11.9Stability evaluation (records for accelerated stability tests and tests on samples at room temp).12.QUALITY CONTROL12.1Laboratory premises: cleanliness and layout acceptable12.2Ventilation adequate12.3Temperature and humidity controlled12.4Equipment adequate for the product list12.5Equipment in good working order12.6Maintenance, calibration and standardization program for equipment available12.7Sampling and handling of samples acceptable12.8Written specifications and methods of analysis available12.9Validation of methods of analysis done12.10Retention and storage of test samples adequate12.11Written reports and raw data presentations acceptable13.SELF AUDIT13.1All items on product list are registered13.2Final product specifications and monographs

available13.3Written, authorized and checked SOPs for all processes and procedures in manufacture, in
processes control and quality control available13.4Continued R&D to improve available
formulations14.REFERENCE BOOKS AND OTHER PUBLICATIONS14.1Current Edition
Martindale14.2Current GMP manuals (e.g. British, American or other)14.3United States
pharmacopoeia14.4British Pharmacopoeia14.5BPC14.6Remington Pharmaceutical
Sciences14.7Pharmacy, Medicines and Poisons Regulations14.8Others

INSPECTION REPORT: COMMENTS AND RECOMMENDATION

(attach additional sheet if necessary)

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Inspector's NameNumberSignatureDate

FORM No. 18

PHARMACY, MEDICINES AND POISONS ACT G.N. 87/1998

(CAP. 35:01)

PHARMACY, MEDICINES AND POISONS (FEES AND FORMS) REGULATIONS

MEDICINES INSPECTORATE

Wholesale inspection Report

(section 60)

WHOLESALE

1. Name of Wholesale:..... Date:

Owner: Individual/Partnership/Company

Address:

Tel. No Fax No

Name of Pharmacist/Manager:

Registration Number:

Complies Default Not Applicable

2. PREMISES:

2.1 Constructed and maintained to protect against weather, ground seepage, pests, vermins, etc.

2.2 Sited to avoid external contamination

2.3 Surrounding environment pleasant

2.4 Good state of repair of walls, floors and ceiling

2.5 Premises clean and tidy, walls and floor cleanable

3. SERVICE PROVIDED:

3.1 Adequate lighting

3.2 Temperature controlled

3.3 Acceptable ventilation and humidity

3.4 Water supply (hot and cold)

3.5 Disposal of waste; receptacles provided

4. SECURITY:

4.1 Restricted entry into drug storage areas to authorized personnel only

4.2 Burglar bars provided

4.3 Adequate locking systems

4.4 Security watchmen deployed

4.5 Burglar alarm installed

5. SAFETY:

5.1 Fire fighting equipment, e.g. hose pipes, fire extinguishers

5.2 Fire alarm/smoke detector

6. LAYOUT OF WAREHOUSE:

6.1 Adequate space to allow logical flow of goods in receipt, dispatch and storage sections

6.2 Space adequate enough to allow easy communication and supervision of various operations

6.3 Warehouse layout and shelving orderly to eliminate mix-up errors or cross contamination during handling

6.4 Quarantine area for inspection of incoming goods provided

6.5 Segregated storage for rejected goods

6.6 Segregated areas for product recalls

6.7 Segregated area for expired medicines

6.8 Pharmacist's office, tea/rest room for other staff available

6.9 Properly located toilet facilities with running water, hand wash basin and other facilities available

7. FACILITIES/EQUIPMENT:

7.1 Adequate shelving, racks and pallets

7.2 Refrigerator with freezer in good working order with temperature monitoring device

7.3 Goods assembly benches and trolleys

7.4 Cartons, seal tapes, etc.

8. HUMAN RESOURCES:

8.1 Full-time supervision by a registered pharmacist

8.2 Name and registration number given

8.3 Relevant experience noted and satisfactory

8.4 Other adequately trained support staff (1)(2)(30(4)

9. RECORDS:

9.1 Records for receipt of goods, delivery notes and invoices available on file

9.2 Purchase orders (for stock) and other supplies logistics activities authorized signed/countersigned by pharmacist

9.3 Expiry dates indicated on inventory records

9.4 Batch numbers recorded on inventory records

9.5 All sources of received goods identified and indicated on inventory records

9.6 Sales records: Details of clinics, hospitals and individuals supplied indicated on inventory records

9.7 Are the clients supplied bona fide registered persons? And is this requirement adequately verifiable?

9.8 Quantities sold tally with requisitions and sales invoices.

10. OTHER REQUIREMENTS:

10.1 No unregistered medicines sold in the premises (contrary to PMPB Act)

10.2 All medicines comply with labelling and other presentation requirements

10.3 No secondary production

activities such as repacking and re-labelling take place10.4Dispatch records and delivery notes (to be countersigned by pharmacist10.5Records for stock balances available for each item10.6Stock verification done on regular basis and shown on records10.7Records able to trace specific batches delivered for product recall purposes10.8Orders (requisitions) for supply from wholesale verified and countersigned by known (authorized) persons11.CONTROLLED DRUGS: (CD Schedule):11.1Transaction records kept in accordance with the provision of Dangerous Drugs Act11.2Storage in accordance with the Dangerous Drugs Act11.3Supplies sold to authorized clinics or individuals (verified)11.4Other controlled medicines stored securely under lock and key12.REFERENCE BOOKS:12.1Current Edition martindale12.2United States pharmacopoeia12.3British Pharmacopoeia12.4Pharmacy, Medicines and Poisons Board Act and Regulations12.5PMPB Schedules of Registered Medicine (POM, PIM, P, GSL)

COMMENTS AND RECOMMENDATIONS

(attach additional sheet if necessary)

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Inspector's NameNumberSignatureDate

FORM No. 19

PHARMACY, MEDICINES AND POISONS ACT G.N. 87/1998

(CAP. 35:01)

PHARMACY, MEDICINES AND POISONS (FEES AND FORMS) REGULATIONS

MEDICINES INSPECTORATE

Dispensing Practitioner Inspection Report (Clinic, Surgery or Private Hospital)(section 60)

1. PREMISES OWNED BY:

Individual/Partnership/Company

Address:

Tel. No

Available practitioner in-charge:

.....

.....

Other dispensing staff members (nurses, pharmacy assistants, etc.)

Practitioner's registration certificate displayed YES/No.

Dispensing licence displayed YES/No.

Distance from nearest Pharmacy Km

CompliesDefaultNot Applicable2.DISPENSARY LAYOUT2.1Constructed and maintained to protect against weather, ground seepage, pests, vermins, etc.2.2Sited to avoid contamination2.3Separate from Clinical Area (room)2.4Good state of repair of walls, floors and ceiling2.5Adequate ventilation2.6Lighting satisfactory2.7Security satisfactory2.8Wash-hand basin with cold and hot water2.9Toilet facilities satisfactory2.10Adequate seat for waiting area for patients3.STOREROOM:3.1Adequate lighting3.2Temperature controlled3.3Acceptable ventilation and humidity3.4Disposal of waste; receptacles provided3.5Orderly arrangement of medicines; external and internal medicines separated3.6Medicines protected from direct sunlight3.7Medicines protected from heat3.8Medicines protected from moisture3.9Medicines out of reach of patients4.SECURITY AND SAFETY:4.1Restricted entry into storeroom to authorized staff only4.2Adequate locking systems4.3Security watchmen deployed4.4Burglar alarm installed4.5Fire fighting equipment, e.g. hose pipes, fire extinguishers5.DISPENSING PROCEDURES:5.1Dispensed product label to comply with the following:5.1.1Name and strength of the medicine5.1.2Directions for use of medicine5.1.3Name of patient on label5.1.4Quantity dispensed indicated5.1.5Label legible5.1.6Name and address of surgery5.1.7Date of dispensing6.EQUIPMENT:6.1Measuring cylinders for dispensing reconstituted

powders6.2Refrigerator in good working condition6.3Medicines counting tray6.4Washable formica dispensing bench6.5Dispensing packs/containers/ glass bottles/vials, etc.6.6Adequate shelves, fans, air conditioner7.HUMAN RESOURCES.7.1Full-time supervisor who is a registered health professional in the medical, nursing or pharmacy field7.2Name and registration number given7.3Relevant experience noted and satisfactory8.RECORDS:8.1Receipt of goods delivery notes and invoices available8.2All sources of received goods indicated on inventory records8.3All documents, e.g. invoices, delivery notes for all receipts carefully filed8.4No unregistered medicines sold in the premises contrary to PMPB Act unless exempted8.5Records for stock movement and balances available for each item8.6Stock verification done on regular basis and shown on records8.7Expired medicines not on shelf and disposed off according to procedure8.8Transaction records for narcotics maintained satisfactorily and according to the provisions of the Controlled Substances Act (DDA)8.9Storage of narcotics in accordance with the Controlled Substances Act (DDA)8.10Other controlled medicines stored securely under lock and key8.11Records for ALL dispensed medicines available; computer, patient cards, etc.9.REFERENCE BOOKS:9.1Current Edition Martindale9.2Pharmacy, Medicines and Poisons Board Act and Regulations9.3PMPB Schedules of Registered Medicines (POM, PIM, P, GSL)9.4Malawi National Formulary9.5Malawi Standard Treatment Guidelines

COMMENTS AND RECOMMENDATIONS

(attach additional sheet if necessary)

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Inspector's NameNumberSignatureDate

FORM No. 20

PHARMACY, MEDICINES AND POISONS ACT G.N. 87/1998

(CAP. 35:01)

PHARMACY, MEDICINES AND POISONS (FEES AND FORMS) REGULATIONS

MEDICINES INSPECTORATE

Medicine Store Inspection Report

(section 60)

1. MEDICINE STORE

Name of Medicine Store: Date:

Owner: Individual/Partnership/Company

Address:

Tel. No Fax No

Complies Default Not Applicable

2. PREMISES:

2.1 Constructed and maintained to protect against weather, ground seepage, pests, vermins, etc.

2.2 Sited to avoid external contamination

2.3 Surrounding environment pleasant

2.4 Good state of repair of walls, floors and ceiling

2.5 Premises clean and tidy, walls and floor cleanable

3. SERVICES PROVIDED:

3.1 Adequate lighting

3.2 Temperature controlled

3.3 Acceptable ventilation and humidity

3.4 Water supply

3.5 Disposal of waste; receptacles provided

4. SECURITY AND SAFETY:

4.1 Adequate locking systems

4.2 Security watchmen deployed

4.3 Burglar bars/alarm installed

4.4 Fire fighting equipment available

5. LAYOUT OF DRUG STORE:

5.1 Space adequate to allow easy communication and supervision of operations

5.2 Medicines stored to minimize errors or contamination during sale

5.3 Quarantine area for inspection of incoming goods available

5.4 Properly located toilet facilities with water, hand wash basin and other facilities available

6. EQUIPMENT:

6.1 Adequate shelving, racks and pallets

6.2 Refrigerator, if needed, in good working order

7. HUMAN RESOURCES:

7.1 Full-time supervision by a registered health professional approved by the Pharmacy Board

7.2 Name and registration number of supervisor given

7.3 Relevant experience noted and satisfactory

7.4 Other support staff

(1)(2)(3)

8. RECORDS:

8.1 Receipt of documentation such as goods delivery notes and invoices available

8.2 All sources of received goods identified and indicated on inventory records

8.3 All documents, e.g. invoices, delivery notes for all receipts carefully filed

8.4 No unregistered medicines sold in the premises contrary to PMPB Act

8.5 Only P and GSL medicines found on premises

8.6 No secondary production activities such as re-packing and re-labelling or dispensing taking place

8.7 Expired medicines not on shelves and disposed off according to procedure

9. REFERENCE BOOKS:

9.1 Pharmacy, Medicines and Poisons Board Act and Regulations

9.2 PMPB Schedules of Registered Medicines (POM, PIM, P, GSL)

9.3 Malawi National Formulary

9.4 Guidelines Malawi Standard Treatment

COMMENTS AND RECOMMENDATIONS

(attach additional sheet if necessary)

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Inspector's NameNumberSignatureDate

FORM No. 21

PHARMACY, MEDICINES AND POISONS ACT G.N. 87/1998

(CAP. 35:01)

PHARMACY, MEDICINES AND POISONS (FEES AND FORMS) REGULATIONS

MEDICINES INSPECTORATE

Retail Pharmacy Inspection Report

(section 60)

RETAIL PHARMACY

1. Name of Owner: Date:

Owner: Individual/Partnership/Company

Address:

Tel. No. Fax No. Name of
Pharmacist/Manager Registration Number:

CompliesDefaultNot applicable2. PREMISES:2.1 Constructed and maintained to protect against weather, ground seepage, pests, vermins, etc.2.2 Sited to avoid external contamination2.3 Surrounding environment pleasant2.4 Good state of repair of walls, floors and ceiling2.5 Premises clean and tidy, walls, floors and shelves cleanable3. SERVICES PROVIDED:3.1 Adequate lighting3.2 Temperature controlled3.3 Acceptable ventilation and humidity3.4 Water supply (hot and cold)3.5 Disposal of waste, receptacles provided4. SECURITY:4.1 Restricted entry into drug storage areas to authorized personnel only4.2 Burglar bars provided4.3 Adequate locking systems4.4 Security watchmen deployed4.5 Burglar alarm installed5. SAFETY:5.1 Fire fighting equipment, e.g. hose pipes, fire extinguishers5.2 Fire

alarm/smoke detector6. LAYOUT OF WAREHOUSE:6.1 Suitable lockable room allocated for dispensing POM preparations out of reach of clients. Dispensing counter provided marked "Prescriptions" for serving clients, elevated in relation to the rest of the pharmacy front shop6.2 Dispensing counter clean and tidy with white smooth finish preferably formica6.3 Space (shelving) allocated for PIM preparations behind the dispensing counter with no public access6.4 Small room allocated for private consultations with patients next to the dispensary6.5 Space for the front shop for P and GSL medicines and other merchandise6.6 Medicines stored in all sections in an orderly manner to minimize mix-up errors or contamination during handling6.7 Quarantine area for inspection of incoming goods provided6.8 Segregated storage for rejected goods6.9 Segregated areas for product recalls6.10 Segregated area for expired medicines6.11 Pharmacist's office, tea/rest room for other staff available6.12 Properly located toilet facilities with running water, hand wash basin and other facilities available7. FACILITIES/EQUIPMENT:7.1 Adequate shelving, racks white smooth finish or formica in all sections7.2 Refrigerator with freezer in good working order with temperature monitoring device7.3 Dispensing counter (see 5.2)7.4 Measuring cylinders for up to 200 ml volume7.5 Balance in metric system7.6 Dispensing counting trays7.7 Fixed double lockable cupboard for Narcotics7.8 Other controlled substances such as psychotropics under lock and key8. HUMAN RESOURCES:8.1 Full-time supervision by a registered pharmacist8.2 Name and registration number given8.3 Relevant experience noted and satisfactory8.4 Other adequately trained support staff(1)(2)(3)(4)9. RECORDS:9.1 Records for receipt of goods such as delivery notes and invoices available on file9.2 Purchase orders (for stock) and other supplies logistics activities authorized, signed/ countersigned by pharmacist9.3 All sources of received medicines identified and recorded on inventory records9.4 Dispensing records:9.4.1 Patient profile cards9.4.2 Dispensed prescriptions filing system in place9.4.3 Labelling of dispensed prescriptions according to guidelines9.4.4 Patient counselling according to guidelines10. OTHER REQUIREMENTS:10.1 No unregistered medicines handled in the premises10.2 No expired medicines in the premises. Expired medicines disposed off according to procedure10.3 Stock verification done on regular basis and shown on records11. CONTROLLED DRUGS: (CD Schedule)11.1 Transaction records kept in accordance with the provision of Dangerous Drugs Act11.2 Storage in accordance with the Dangerous Drugs Act (see 6.7)11.3 Supplies sold to authorized clinics or individuals (verifiable)11.4 Other controlled medicines such as psychotropics stored securely under lock and key and sold to bona fide individuals12. REFERENCE BOOKS:12.1 Current Edition Martindale12.2 United States Pharmacopoeia12.3 British Pharmacopoeia12.4 Pharmacy, Medicines and Poisons Regulations12.5 PMPB Schedules of Registered Medicines (POM, PIM, P, GSL)

COMMENTS AND RECOMMENDATIONS

(attach additional sheet if necessary)

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Inspector's NameNumberSignatureDate

PHARMACY, MEDICINES AND POISONS REGULATIONS

ARRANGEMENT OF REGULATIONS

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G.N. 88/1998

PHARMACY, MEDICINES AND POISONS REGULATIONS

under s. 66

PART I

PRELIMINARY

1. Citation

These Regulations may be cited as the Pharmacy, Medicines and Poisons Regulations.

2. Interpretation

In these Regulations, unless the context otherwise requires—

“batch number” means the number or other cipher allocated to medicinal product by a manufacturer, by which the origin of raw materials and the complete process of manufacture of the medicinal product can be determined;

“business address” in relation to a business, means the full address of the premises where that business is carried on or any abbreviated address approved by the Board;

“country of origin” in relation to a medicinal product, means the country where the manufacture of that medicinal product was undertaken;

“dangerous drug” or “Controlled Drugs” or “(CD)” means a drug—

- (a) controlled in terms of the Dangerous Drugs Act;
- (b) listed in the Tenth Schedule; or
- (c) registered as such by the Board;

“expiry date”, in relation to any batch of a medicinal product, means the date on which the shelf-life of such medicinal product will expire;

“general sales list medicine” or “GSL” means a medicinal product to which Division 3 of Part VI applies or a medicinal product registered as such by the Board;

“logo” means the mark, device, design, letter, word, name or numeral or any combination thereof which is used in, or proposed to be used, in relation to, any medicinal product for the purpose of indicating a connexion with the principal manufacturer of the medicinal product and the medicinal product itself;

“institution” means a hospital, dispensary, clinic, nursing home or other institution at which human ailments are treated;

“label”, in relation to a package of a medicinal product, means any written, pictorial or other matter marked on or affixed to the package;

“package insert” means a pamphlet on which is printed the particulars prescribed in regulation 15;

“patent” means a patent registered in terms of the Patents Act and which is of full force and effect;

“pharmacist initiated medicine” or “PIM” means a medicinal product listed in the Sixth Schedule or registered as such by the Board;

“pharmacy medicine” or “(P)” means a medicinal product listed in the Seventh Schedule or registered as such by the Board;

“prescriber” means a medical practitioner, a dentist, or a veterinary surgeon or any other person who is lawfully authorized to prescribe any medicinal product;

“prescription” means an order, in writing or orally by a prescriber for the supply of a medicinal product or combination of medicinal products, for the treatment of a person or animal specified therein;

“prescription only medicines” or “POM” means a medicinal product listed in the Fifth Schedule, or registered as such by the Board;

“shelf-life”, in relation to any batch or a medicinal product, means the period up to which a medicinal product in that batch will retain the potency and properties stated on the label as fixed by the manufacturer.

PART II

FORMS

3. Particulars, etc., on forms

(1) Every person who is required to make an application under the Act shall complete the prescribed form and pay the prescribed fees, and shall furnish to the Registrar with such further information or particulars as may be prescribed.

(2) All forms shall be completed in English.

4. Illegible or incomplete forms

The Registrar may reject any form if any part of the form is illegible or not properly completed.

PART III

LICENSING OF PREMISES AND PERSONS

5. Minimum requirements for premises, etc.

Any person who applies for registration under the Act shall ensure that the premises comply with—

(a) in the case of manufacturing pharmacy business, the minimum requirements set out in Part I of the First Schedule;

(b) in the case of wholesale pharmacy business, the minimum requirements set out in Part II of the First Schedule;

(c) in the case of retail pharmacy business, the minimum requirements set out in Part III of the First Schedule;

(d) in the case of an institution, the minimum requirements set out in Part III of the First Schedule;

(e) in the case of a registered dispensing practitioner, the minimum requirements set out in Part IV of the First Schedule; and

(f) in the case of a medicine store, the minimum requirements set out in Part V of the First Schedule.

6. Dispensing licences

An application for a dispensing licence to dispense medicinal products from any premises in accordance with section 35 (4) of the Act shall not be granted where such premises are situated within five kilometres of a pharmacy:

Provided that the Board may waive this requirement where the Board considers it in the public interest so to do.

7. Duration of licences

Every licence which is issued in respect of premises or to any person pursuant to the Act shall be valid for a period of one year from the date of issue, and may be renewed annually thereafter.

8. Display of licences

(1) Subject to subregulation (2), every licensee shall ensure that his licence is prominently displayed at all times upon the licensed premises to which it relates.

(2) Subregulation (1) shall not apply in respect of any period during which the licence is necessarily removed from the licensed premises for the purposes of doing anything in terms of the Act or for any other lawful purpose the proof thereof, in any proceedings against any person for contravention of subsection (1), shall lie upon that person.

9. Production and return of licences

(1) Whenever the Board—

- (a) cancels any licence;
- (b) varies or amends the conditions of any licence; or
- (c) imposes any new condition in respect of or on the renewal of any licence,

the Registrar shall request the holder of the licence to produce such licence within such period as the Registrar may specify, and the holder thereof shall produce such licence within the specified period.

(2) Any person who fails to comply with a request made in accordance with subregulation (1) shall be guilty of an offence.

(3) Whenever the Board varies, amends or imposes any new condition in respect of a licence, the Board shall return such licence duly endorsed to the holder thereof within a reasonable time.

10. Application for renewal of licences

(1) Every application for the renewal of a licence shall be—

- (a) in the prescribed form;
- (b) lodged with the Registrar at least two months before the expiry of the licence; and
- (c) accompanied by the appropriate fee in respect of the licence.

(2) If an application for the renewal of a licence is lodged with the Registrar after the time limit as specified in subregulation (1) there shall be paid in addition to the renewal fee an appropriate penalty fee in respect of the licence as determined by the Board.

PART IV

CLASSIFICATION, REGISTRATION AND RETENTION OF REGISTRATION OF MEDICINAL PRODUCTS

11. Categories for registration

For the purpose of registration, the Board shall divide medicinal products into the categories specified in the Second Schedule.

12. Application for registration and retention of registration of medicinal products

(1) An application for the registration of a medicinal product may be made by—

- (a) the person who owns the medicinal product; or
- (b) any other person registered by the Board.

(2) Every application for the registration of a medicinal product shall be submitted to the Registrar in the prescribed form and shall be accompanied by—

(a) a sample of the medicinal product in the smallest of each of the package forms available for distribution to the public, including the identification marks on such product where appropriate, or if the package forms are not yet available, a sample in a package in which the applicant intends to make the medicinal product available for distribution to the public;

(b) detailed information of all advertising material and package inserts which the applicant intends to use;

(c) such samples of the medicinal product or the raw materials thereof as the Board may request for analysis;

(d) a copy of any literature in support of the application:

Provided that the Board may require additional copies of such literature;

(e) twenty additional package inserts and twenty labels or copies of the package;

(f) at least three copies of all records and batch data relating to a particular batch, which shall include raw material analytical reports, master sheets relating to manufacture and packaging in process control records, final product analytical records and authorized for release, and any other relevant records; and

(g) the prescribed fee, together with such additional fees as the Board may require for the purpose of analysing the medicinal product.

(3) Every applicant shall, without delay, inform the Board either before or after the registration of a medicinal product—

(a) of any alteration of the information or particulars furnished by him in applying for registration in terms of subsection (2); and

(b) whether the medicinal product is to be imported as a finished product into, or relabelled or repackaged or dealt with in any other manner, in Malawi.

(4) For the purposes of paragraph (b) of subsection (3), "finished product", in relation to a medicinal product, means a medicinal product which is wholly manufactured outside Malawi and is imported into Malawi ready for sale without having to be relabelled or repackaged.

(5) An application for the retention of the registration of a registered medicinal product shall be submitted to the Registrar, in prescribed form at least two months before the expiry of the licence and shall be accompanied by the prescribed fee.

13. Labelling and marking of medicinal products

(1) Subject to regulation 29, every medicinal product shall, unless otherwise directed by the Board, bear or incorporate a label on the package in which the medicinal product is sold, on which is printed in clear and indelible letters in the English language and any other language as may be directed or approved by the Board the following particulars which relate to that medicinal product—

- (a) the name and address of the person who owns the medicinal product;
- (b) the name and address of the manufacturer;
- (c) the approved name of the medicinal product and the proprietary name or trade mark, if any, of the medicinal product;
- (d) the logo, if any, of the person who owns the medicinal product or manufacturer of the medicinal product;
- (e) the name and percentage of any bacteriostatic or bactericidal agent which is added to the medicinal product as a preservative;
- (f) the date of manufacture and the expiry date of the medicinal product;
- (g) the batch number of the medicinal product;
- (h) the quantity of the medicinal product, in the package;
- (i) the strength of the medicinal product;
- (j) the required storage conditions or other necessary precautions for the preservation of the medicinal product;
- (k) the category of distribution of the medicinal product which may be represented by words or symbols as set out in the Third Schedule;
- (l) the dosage of the medicinal product and the directions for use;

(m) any warning notices which shall be in a colour or print other than the colour or print of the particulars referred to in subparagraphs (a) to (l); and

(n) any other particulars as may be directed by the Board:

Provided that in the case of a small package containing a medicinal product, it shall be adequate to record the information required by paragraphs (c), (f), (g), (h), and on the outer label.

(2) Every medicinal product shall where possible be marked with the logo of the owner of the medicinal product or manufacturer of the medicinal product, as the case may be, and such other distinguishing mark for the purpose of identifying such medicinal product.

14. Package inserts

Every package of a medicinal product shall, unless otherwise directed by the Board, contain a package insert on which is printed in clear and indelible letters in the English language and any other language as may be directed or approved by the Board the following particulars which relate to medicinal product—

(a) the name and address of the owner of the medicinal product;

(b) the name and address of the manufacturer of the medicinal product;

(c) the approved name of the active ingredient of the medicinal product and the proprietary name or trade mark, if any, of the medicinal product;

(d) the logo, if any, of the owner of the medicinal product or manufacturer of the medicinal product;

(e) the name and percentage of any bacteriostatic or bactericidal agent which is added to the medicinal product as a preservative;

(f) the strength of the medicinal product, where applicable;

(g) the required storage conditions or other necessary precautions for the preservation of the medicinal product;

(h) the category of distribution of the medicinal product which may be represented by words or symbols as set out in the Third Schedule;

(i) the pharmacological classification of the medicinal product determined in accordance with regulation 11;

(j) the dosage of the medicinal product and the directions for use;

(k) the description of the pharmacological action of the medicinal product;

(l) indications of the medicinal product;

- (m) contra-indications of the medicinal product;
- (n) warnings relating to the use of the medicinal product;
- (o) the side-effects and special precautions of the medicinal product;
- (p) known symptoms of over-dosage and particulars of its treatment;
- (q) the identification of the medicinal product;
- (r) the form in which the medicinal product is presented, whether tablet, capsule or liquid and the colour thereof;
- (s) the date of publication of the package insert;
- (t) any necessary warning concerning the administration or use of the medicinal product by children, old people, pregnant women or patients suffering from certain diseases, or the use of the medicinal product in conjunction with the consumption of alcohol or any particular food or any other medicinal product;
- (u) a summary of relevant information concerning the purpose and the beneficial, detrimental, injurious or other effects of the medicinal product, and the possible dangers that may arise from the prolonged use of the medicinal product;
- (v) relevant information, including particulars in regard to a specific medicinal product as an antidote (if known), concerning the treatment of a patient in cases where an overdose of the medicinal product has been administered or where a patient reacts adversely to the medicinal product; and
- (w) any other particulars or warning notices as may be directed by the Board.

15. Categories for distribution

(1) Where the Board approves the registration of a medicinal product it shall fix, as a condition of registration, the appropriate category for distribution of that medicinal product, prescribed in the Third Schedule.

(2) The same categories for distribution of a medicinal product shall apply to veterinary medicines and shall be identified by the suffix “(VET)”.

16. Medicinal products register

The Registrar shall enter in the register in respect of each medicinal product registered by the board—

- (a) the date of the application for registration of the medicinal product;
- (b) the number allocated to the application for registration;

- (c) the proprietary name or trade mark of the medicinal product, if any;
- (d) the logo of the owner of the medicinal product or manufacturer of the medicinal product, if any;
- (e) the particulars of the patent of the medicinal product, if any;
- (f) the approved name of the medicinal product;
- (g) the form in which the medicinal product is presented, whether tablet, capsule or liquid and the colour thereof;
- (h) the strength of the medicinal product;
- (i) the qualitative and quantitative details of every ingredient in each dosage unit of the medicinal product;
- (j) the name and business address of the owner of the medicinal product;
- (k) the name and business address of the manufacturer of the medicinal product;
- (l) the country of origin of the medicinal product;
- (m) the name and address of the applicant;
- (n) the number allocated to the inspection report of the place of manufacture, if applicable;
- (o) the date of registration of the medicinal product;
- (p) the registration number of the medicinal product;
- (q) the shelf-life of the medicinal product;
- (r) the category for distribution of the medicinal product fixed in accordance with regulation 15 and any other conditions of registration;
- (s) the pharmacological classification of the medicinal product determined in accordance with regulation 11;
- (t) the date and particulars of any variation in the conditions of registration of the medicinal product;
- (u) the payment of any fee for the retention or registration of the medicinal product; and
- (v) where applicable, the date of the cancellation of the registration of the medicinal product.

17. Certificate of registration for medicinal products

After registering a medicinal product, the Registrar shall issue a certificate of registration in the prescribed form.

18. Production and return of registration certificate for medicinal products

(1) Whenever the Board—

- (a) cancels the registration of any medicinal product;
- (b) varies or amends the conditions of registration of any medicinal products; or
- (c) imposes any new conditions on the registration of any medicinal product,

the Registrar shall request the holder of the registration certificate concerned to produce such certificate within a reasonable period as the Registrar may specify and the holder thereof shall produce such certificate within the specified period.

(2) Any person who fails to comply with a request made in accordance with subsection (1) shall be guilty of an offence.

(3) Whenever the Board varies, amends or imposes any new condition on any registration certificate, the Board shall return such certificate, duly endorsed, to the holder thereof within a reasonable period.

PART V

GENERAL, CONDITIONS FOR SALE OF MEDICINAL PRODUCTS

19. Importation of medicinal products with less than one-half of shelf-life

No person shall, without the prior written approval of the Board, import into Malawi any medicinal product which has less than one-half of its shelf-life remaining upon arrival in Malawi.

20. Delivery and sale of medicinal products with less than one-half of shelf-life

No person shall, without the prior written approval of the Board, deliver, receive, accept or sell any medicinal product whose shelf-life is less than one-half.

21. Sale of expired medicinal products

No person shall sell any medicinal product on a date later than the expiry date which appears on the package of such medicinal product.

22. Medicinal products to be sold from licensed premises

No person shall sell any medicinal product unless the sale is effected on premises—

- (a) licensed under the Act; or

(b) authorized in terms of these Regulations:

Provided that this regulation shall not apply to the sale of general sales list medicines.

23. Conditions of sale of medicinal products

No person shall sell any medicinal product unless—

(a) he is authorized to do so; or

(b) the sale is effected by or under the continuous personal supervision of an authorized person.

24. Disclosure of composition of medicinal product

No person shall sell any of the medicinal product which is not labelled in accordance with the requirements of regulation 13.

25. Safe-keeping of certain medicinal products

(1) No person who sells any medicinal products listed in the Fifth, Sixth or Seventh Schedule shall keep such medicinal products on an open shelf in a part of his premises to which members of the public have access.

(2) Any person who has in his possession or under his control or uses any medicinal product shall exercise all reasonable care in the custody, safe-keeping and use thereof.

26. Return of medicinal products three months before expiry

(1) Any person who practices or carries on the business of a pharmacy or dispenses any medicinal product may, where a medicinal product is due to expire, return such medicinal product, not less than three months before the expiry date of such medicinal product, to the manufacturer, agent or distributor, as the case may be:

Provided that the medicinal product shall be returned in its original unbroken package, as sealed by the manufacturer.

(2) On receipt of medicinal products returned pursuant to subparagraph (1), the manufacturer, agent or distributor, as the case may be—

(a) shall store such medicinal product in a quarantine area of his premises; and

(b) may reimburse the person who returned the medicinal products by—

(i) awarding a credit, or

(ii) replacing such surrendered or returned medicinal products,

to the person concerned.

27. Return of expired medicinal products

(1) Any person who practises or carries on the business of a pharmacist or dispenses any medicinal product shall, where a medicinal product has expired—

(a) return such expired medicinal product to the manufacturer, agent or distributor, as the case may be; or

(b) destroy such expired medicinal product on site in accordance with standard operating procedures.

(2) On receipt of an expired medicinal product the manufacturer, agent or distributor, as the case may be, shall destroy the medicinal product in accordance with standard operating procedures.

28. Dispensing of medicinal products

(1) No person shall dispense any medicinal product in or from an area to which members of the public have access.

(2) No person shall own, install or use or cause or permit the installation of, any machine designed or intended to be used to supply any medicinal product.

29. Labels for dispensed prescription only medicinal products

Every person who dispenses a prescription only medicine shall label such medicinal product with—

(a) the registered name, strength and form of the medicinal product;

(b) the total quantity of the medicinal product;

(c) the directions for use;

(d) any warnings;

(e) the name of the patient;

(f) the name of the prescriber;

(g) the prescription reference number allocated to the prescription by the person dispensing the medicinal product;

(h) the date on which the prescription only medicine is supplied; and

(i) the name and address of the supplier.

30. Limit of validity of prescription

No person shall dispense any prescription for the first time later than one month after the date of issue of the prescription.

31. Copy of prescription

A copy of a prescription marked “copy—for information—not to be dispensed” may be given to the patient by the person who dispenses the prescription.

32. Records of Prescription

The supplier of a prescription shall, on the day of which a prescription is dispensed or, if that is not reasonably practicable, on the business day next following that day, record in a manner acceptable to the Board, a complete copy of the prescription.

33. Preservation of records of prescription

Every person who dispenses any medicinal product shall keep or cause to be kept a record of such dispensing for a period of two years and shall preserve such record on the premises in which the dispensing takes place:

Provided that where the premises cease to be used or licensed such person shall make arrangements, acceptable to the Board, for the preservation or destruction of such records.

34. Restriction on advertising medicinal products

(1) No person shall advertise any medicinal product without the prior written approval of the Board.

(2) No person shall advertise or sell any medicinal product to the public in connexion with any bonus offer or discount.

(3) No person shall advertise any medicinal products to members of the public in terms calculated to lead to its use for the treatment of human beings for any of the conditions set out in the Fourth Schedule.

PART VI

SPECIAL CONDITIONS OF SALE FOR PRESCRIPTION ONLY MEDICINES, PHARMACIST INITIATED MEDICINES AND PHARMACY MEDICINES, GENERAL SALES LIST MEDICINES AND VETERINARY MEDICINES

Division 1—Prescription only Medicines (POM)

35. Possession of prescription only medicine

(1) No person shall possess a prescription only medicine unless, in accordance with subregulation (2), he is a member of a class of persons authorized to be in possession thereof.

(2) The classes of persons who are authorized to be in possession of a prescription only medicine shall be—

(a) in the case of a dangerous drug, any person who is authorized or licensed in terms of the Dangerous Drugs Act; Cap. 35:02

(b) in the case of a prescription only medicine other than a dangerous drug—

(i) prescriber;

(ii) any person in the employ and acting under the personal supervision of a prescriber in so far as is necessary in the execution of his duties; and

(iii) any person to whom the prescription only medicine has been supplied in accordance with a prescription by a prescriber.

36. Supply of prescription only medicine

(1) Subject to this regulation and regulation 37, no person shall supply any prescription only medicine listed in the Fifth Schedule otherwise than in accordance with the written prescription of a prescriber:

Provided that where it is not reasonably practicable for a prescriber to furnish to the supplier such written prescription immediately, the prescription only medicine may be supplied on the oral direction of the prescriber on one occasion only, and the prescriber shall furnish to the supplier a written prescription within three days.

(2) For the purpose of this regulation, a prescription shall—

(a) bear the name, address and qualifications of the prescriber;

(b) specify the name and address of the person for whom it is given or, if the prescription is issued by a veterinary surgeon, of the person for whose animal the prescription is issued; and

(c) have written thereon—

(i) if issued by a dentist, the words “for dental treatment only”; or

(ii) if issued by a veterinary surgeon, the words “for animal treatment only”; or

(iii) if issued for topical application, the words “for external use only”;

(d) if the person for whom the prescription is being issued is under the age of twelve years, state the person’s age;

(e) be legibly written, in the handwriting of the prescriber, and contain the following particulars—

(i) the date on which the prescription is issued; (ii) the registered name, strength and form of the medicinal product;

(iii) the total daily dose of the medicinal product; (iv) the total quantity of the medicinal product; and (v) the directions for use;

(f) where the medicinal product is packed otherwise than in ampoules, indicate the total amount to be supplied and, except in the case of a medicinal product which is to be used for external treatment only the dose to be taken;

(g) where the medicinal product is packed in ampoules, indicate either the total amount to be supplied or the total amount it is intended should be administered or injected and, in either case, the amount it is intended should be administered or injected in each dose;

(h) not be for more than thirty days' supply at the dosage indicated, and not authorize more than five further supplies of thirty days each: Provided that nothing in this paragraph shall apply to the supply of reasonable quantities of medicinal product to persons who intend to depart temporarily from Malawi; and

(i) be signed in full by the prescriber issuing it.

(3) In an emergency any pharmacist may sell any medicinal product listed in the Fifth Schedule at the request of any person, subject to the following conditions—

(a) that the pharmacist by, or under whose supervision the medicinal product is to be sold, has satisfied himself—

(i) that there is an immediate need for the medicinal product requested and that it is impracticable in the circumstances to obtain a prescription without undue delay; and

(ii) that the medicinal product requested has on a previous occasion been prescribed by a medicinal practitioner, dentist or veterinary surgeon, as the case may be, for the person requesting it;

(b) that not more than three days quantity of the medicinal product is sold: Provided that—

(i) where a public holiday falls within the three-day period, a sufficient quantity of such medicinal product may be sold; and

(ii) where the medicinal product is in a composite pack which exceeds three days supply a single pack may be sold;

(c) that the pharmacist by or under whose supervision the medicinal product is sold, before he delivers such medicinal product makes an entry in his records stating—

(i) the date on which the medicinal product is sold;

- (ii) the registered name, quantity, form and strength of the medicinal product;
 - (iii) the name and address of the person requesting the medicinal product;
 - (iv) the nature of the emergency; and
 - (v) the name of the medicinal practitioner, dentist or veterinary surgeon, as the case may be, if ascertainable; and
- (d) that the medicinal product is labelled—
- (i) in accordance with regulation 29; and
 - (ii) with the words “Emergency Supply”.

37. Dispensing of prescription only medicines

Every person who dispenses a prescription only medicine shall ensure that—

- (a) the prescription is not dispensed more than once, unless the prescriber has directed otherwise and in such event the lawful instructions of the prescriber shall be complied with; and
- (b) at the time of dispensing, or where a prescription preparation has been supplied in accordance with the proviso to regulation 36 (1), on the subsequent receipt of the prescription, there is noted on the prescription the name and address of the supplier and the date on which the prescription is dispensed.

38. Storage and safe custody of prescription only medicine

(1) Every person who is authorized under regulation 35 (2) (b) to be in possession of a prescription only medicine keep such medicinal product in a place to which members of the public do not have access, and in a cupboard or drawer, or on a shelf reserved solely for the storage of such medicinal products.

(2) Any person who is in possession of a prescription only medicine shall keep such medicinal product in a place to which children do not normally have access.

Division 2—Pharmacist Initiated Medicines (PIM) and Pharmacy Medicines (PM)

39. Sale of pharmacist initiated and pharmacy medicines

(1) No person other than a pharmacist shall sell a pharmacist initiated medicine listed in the Sixth Schedule at the request of any person, and every such sale shall be subject to the following conditions—

- (a) that the pharmacist by or under whose supervision the medicinal product is sold, before he delivers such medicinal product, makes an entry in his records stating—

(i) the name and address of the person requesting the medicinal product and the person for whom it is intended;

(ii) if the person is under the age of twelve years, the age of the person;

(iii) the date on which the medicinal product is sold;

(iv) the registered name, quantity, form and strength of the medicinal product;

(v) the total daily dose of the medicinal product; and

(vi) the directions for use; and

(b) that the medicinal product is labelled in accordance with regulation 13 as may be appropriate.

(2) No person other than a pharmacist, or a person acting under the continuous personal supervision of a pharmacist, shall sell a pharmacy medicine listed in the Seventh Schedule.

Division 3—General Sales List Medicines (GSL)

40. Sale of general sales list medicines

Any person may, subject to any other written law relating to the sale of goods, sell any general sales list medicine:

Provided that such medicinal product is labelled in accordance with regulation 13 and is sold in original unbroken packs.

Division 4—Veterinary Medicines

41. Sale of veterinary medicines

The provisions of Division 1, 2 and 3 shall apply, *mutatis mutandis*, to the sale of veterinary medicines.

42. Conditions of sale of veterinary medicines

The sale of veterinary medicines by an authorized dealer shall be in original unbroken packs, sealed by the manufacturer.

43. Use of veterinary medicines

No person shall use any veterinary medicine for the treatment of human beings.

PART VII

SPECIAL PROVISIONS FOR INSTITUTIONS

44. Supply of medicinal products from institutions to out-patients

The provisions of Division 1 of Part VI shall apply to any medicinal product dispensed from an institution to an outpatient.

45. Supply of medicinal products for use within institutions

(1) In any institution in which medicinal products are dispensed in a dispensary or pharmaceutical department, no medicinal products shall be supplied from that dispensary or pharmaceutical department, except in cases of emergency, for use in wards, operating theatres or other sections of the institution, unless such medicinal product is supplied on the directions of a prescriber.

(2) Every package of a medicinal product supplied under subsection (1) shall be labelled with—

- (a) the registered name, form, strength and quantity of the medicinal product;
- (b) the directions for use;
- (c) the name of the patient;
- (d) the date on which such medicinal product is supplied; and
- (e) the name of the prescriber.

46. Storage and handling of medicinal products in institutions

(1) Every medicinal product in an institution shall be stored in place to which no unauthorized person has access.

(2) Every person who handles or distributes medicinal products in an institution shall ensure that no unauthorized persons have access to such medicinal products during the handling or distribution of such medicinal products.

PART VIII

MISCELLANEOUS PROVISIONS

47. Withdrawal of medicinal products

(1) Where the Board is of the opinion that the withdrawal of any medicinal product is necessary for the protection of the public, the Board may require any person to withdraw such medicinal product in accordance with such procedures as the Board may determine.

(2) Every person who is in possession of a medicinal product required to be withdrawn under subregulation (1) shall comply with the procedure for the withdrawal of such medicinal product as determined by the Board.

48. Report of loss or theft of medicinal products

Any person, other than a person to whom a prescription preparation is lawfully dispensed, who is in possession of any medicinal product and who misplaces or loses such medicinal product or from whom such medicinal product is stolen, shall report such loss or theft, as the case may be, to a police officer and to the Registrar as soon as is reasonably practicable, and in any case within twenty-four hours of the occurrence of the loss or theft.

49. Disposal of existing stocks of prohibited medicinal products

If at any time any medicinal product becomes prohibited any person other than a person to whom a medicinal product is lawfully dispensed who is in possession of such medicinal product at the time shall inform the Board of his possession, and shall dispose of such medicinal product in such manner as the Board may direct.

50. Availability of Act and regulations

A copy of the Act and these Regulations shall be available at all premises licensed under the Act.

FIRST SCHEDULE

PART I

MINIMUM REQUIREMENTS FOR PREMISES USED FOR MANUFACTURING PHARMACY BUSINESS

1. Premises 1.1 Premises should be sited to avoid contamination from the external environment or from other nearby activities and in existing premises, effective measures should be taken to avoid such contamination. 1.2 Animal houses should be well isolated from manufacturing areas. 1.3 Premises should be constructed and maintained so as to be protected against weather, ground seepage and the entrance and harbouring of vermin, birds and pests. 1.4 Premises should be designed and laid-out in such a way that the risk of mix-up or contamination of one product or material by another is minimized. This especially applies to premises for the handling of highly toxic or sensitizing materials such as hormones, cytotoxic agents and antibiotics. 1.5 Protection from the weather should be provided for receiving and despatch areas and for materials and products in transit. 1.6 Premises should be maintained in a good state of repair. The condition of buildings should be reviewed regularly and repairs effected where necessary. Special care should be exercised to ensure that buildings and repair or maintenance operations do not hazard products. 1.7 Premises should have sufficient space to suit the operations to be carried out, allow an efficient flow of work, and permit effective communication and supervision. 1.8 The processing of materials for non-medicinal use should be separated from the processing of medicinal products. 1.9 Cloakrooms should be separate from, or partitioned from processing areas. Toilets should be well ventilated and should not open directly to manufacturing areas. 1.10 Premises in which medicinal products are manufactured or stored should be made secure, with access restricted to authorized personnel. 1.11 Floors in processing areas should be made of impervious materials, laid on an even surface, free from cracks and open joints, and should allow prompt and efficient removal of any spillages. Walls should be sound and finished with a smooth, impervious and washable surface. Ceilings should be so constructed and finished that they can be maintained in a clean condition. 1.12 Pipework,

light fittings, ventilation points and other services in manufacturing areas should be sited to avoid the creation of uncleanable recesses; and should be sealed into any walls and partitions through which they pass service should preferably be run outside the processing areas.1.13Drains should be of adequate size, and should have trapped quellies and proper ventilation. Open channels should be avoided where possible, but if they are necessary, they should be shallow to facilitate cleaning and disinfection.1.14Buildings should be effectively lit and properly ventilated, with air control facilities including temperature, humidity and filtration facilities appropriate both to the operations undertaken within them and to the external environment.1.15Air intakes and exhausts, and associate pipework and trucking should be sited to avoid product contamination hazards.1.16Manufacturing areas should not be used as a general right of way for personnel or except of materials used in the manufacturing process, for storage of materials.1.17All premises, including processing areas, laboratories, stores, passage ways, external surroundings should be maintained in a clean and tidy condition.1.18Waste material should not be allowed to accumulate but should be collected in suitable receptacles for removal to collection points outside the building, and disposed of at regular and frequent intervals. Special care is necessary over the disposal of waste containing dangerous, highly toxic or sensitizing materials such as hormones, cytotoxic agents, sensitizing antibiotics. Disposal of raw materials, printed packing materials and rejected products should be carefully controlled and documented.1.19There should be made available written cleaning procedures and schedules for manufacturing and storage areas.1.20Adequate space, preferably separated from processing areas, should be provided for cleaning and storing equipment, and the storage of cleaning materials.2.Storage areas2.1Storage areas should be designed, laid-out and be of sufficient capacity to permit effective and orderly segregation of the various categories of material stored and allow rotation of stock.2.2Segregated storage should be provided for rejected, recalled, expired or returned goods. Where the maintenance quarantine status depends upon storage in separate areas, such areas should be provided with restricted access.2.3Labels and other printed packaging materials, including labels for starting materials and for bulk and intermediate products, should be stored in a secure manner that will permit issue only to authorized person in accordance with formal documented procedures. Storage arrangements should permit separation of different labels and other printed materials and avoidance of mix-up.2.4Goods should be stored off the floor. Provision should be made for shelving, racking and pelleting and in a manner that will permit easy cleaning and the use of pest control agents by trained personnel without risk of contamination.2.5All goods should be stored under cover.2.6All materials containers should be clean before they are admitted to stores and checked again for cleanliness before issued to manufacturing areas.2.7Where special storage conditions such as temperature, humidity and security are required, these should be provided, checked and monitored.3.Equipment3.1Equipment should be designed and located to suit the process and products for which it is to be used. Equipment should be maintained so as to be fit to perform contemplated functions and present no hazard to the product and personnel.3.2Manufacturing equipment should be easily and conveniently cleanable, both inside and outside. There should be available written instructions for cleaning of equipment and suitable cleaning facilities should be provided.3.3Equipment should not be a hazard to products through leaking joints, lubricant drips, or through inappropriate modifications or adaptations.3.4Equipment used for weighing, measuring, testing and recording should be subject to regular recorded checks for accuracy and working order, in accordance with a written planned maintenance schedule.4.Qualifications of personnel4.1The key personnel are the person

responsible for production and the person responsible for quality control, who should be different persons, neither of whom should be responsible to the other, but who should both have a responsibility for achieving the requisite quality.4.2Manufacturing operations shall be carried out under the supervision of a registered pharmacist with adequate relevant postgraduate training with the support of suitably qualified personnel such as a pharmacy technologist or pharmacy assistant.4.3All quality control operations shall be carried out under the supervision of an appropriately trained pharmacist or chemist with relevant postgraduate training with the support of suitably qualified personnel such as pharmacy technologist, laboratory technologist or chemist.4.4All manufacturing and quality control processes should be done in accordance with Good Manufacturing Practices (GMP) as approved by Board.

PART II

MINIMUM REQUIREMENTS FOR PREMISES FOR WHOLESALE PHARMACY BUSINESS (reg. 5)

1.Premises and equipment1.1Premises should be sited to avoid contamination from the external environment or from the nearby activities and in existing premises, effective measures should be taken to avoid such contamination.1.2Premises should be constructed and maintained so as to be protected against weather, ground seepage and the entrance and harbouring of vermin, birds, pests and pets.1.3Protection from the weather should be provided for receiving and dispatching areas and for materials and products in transit.1.4Premises should be maintained in good state of repair. The condition of buildings should be reviewed regularly, and repairs effected where necessary. Special care should be exercised to ensure that buildings, repair and maintenance operations do not hazard products.1.5Premises should provide sufficient space to suit the operations to be carried out, allow an efficient flow of work, and permit effective communication and supervision.1.6Cloakrooms should be separate from or partitioned from processing areas. Toilets should be well ventilated and should not open directly to storage areas.1.7Premises in which medicinal products are stored should be secure, with access restricted to authorized personnel.1.8Floors in processing areas should be made of impervious materials, laid on an even surface, free from cracks and open joints and should allow prompt and efficient removal of any spillages. Walls should be sound and finished with a smooth, impervious and washable surface. Ceilings should be so constructed and finished that they can be maintained in a clean condition.1.9Buildings should be effectively lit and properly ventilated, with air control facilities including temperature and humidity appropriate both to operations undertaken within them and to the external environment.1.10All premises, including processing areas, stores, passage ways and external surroundings, should be maintained in a clean and tidy condition.1.11Waste material should not be allowed to accumulate, but it should be collected in suitable receptacles for removal to collection points outside the building and disposed of at regular and frequent intervals. Special care is necessary over the disposal of waste containing dangerous, highly toxic or sensitizing materials such as hormones, cytotoxic agents, sensitizing antibiotics.1.12Segregated storage should be provided for rejected, expired or returned goods.1.13Goods should be stored off the floor. Provision should be made for shelving, racking and pelleting, and in a manner that will permit easy cleaning and the use of pest control agents by trained personnel without risk of contamination.1.14Where special storage conditions such as temperature, humidity and security are required; these should be provided, and checked and monitored regularly. In particular, controlled temperature environments should be equipped with temperature

recorders.1.15Van selling should be restricted to items on the general sales list.2.Qualifications of personnel2.1Wholesale operations shall be carried out under the direct full-time supervision of a registered pharmacist, with the support of a suitably qualified personnel such as a pharmacy assistant or pharmacy technologist, who shall be responsible for the funding, procurement, clearing, receipting, storage, distribution and documentation relating to medicinal products.2.2The services of a locum may be used.3.Records3.1Adequate records shall be maintained for— (a) receipts source, quantity, expiry dates and batch number of medicinal products; (b) sales (source, quantity, expiry dates and batch number of medicinal products) despatches shall be countersigned by a pharmacist. Orders shall be signed by authorized persons known to the wholesaling unit; (c) stock (balances) of each batch and consignment; (d) disposal of rejected or/expired products and records shall be kept for a minimum period of 2 years. All expired products must be notified to the Board when destroyed plus method of destruction used.

PART III

MINIMUM REQUIREMENTS FOR PREMISES USED FOR RETAIL PHARMACY BUSINESS (reg. 5)

1.Premises1.1Premises shall be constructed and maintained so as to be protected against weather, ground seepage and the entrance and harbouring of vermin, pest and pets.1.2Premises should be maintained in a good state of repair. The condition of buildings should be reviewed regularly, and repairs effected where necessary. Special care should be exercised to ensure that buildings, and repair or maintenance operations do not hazard products.1.3Premises should provide sufficient space to suit the operations to be carried out, allow an efficient flow of work, and permit effective communication and supervision.1.4Toilets should be well ventilated and should not open directly to storage areas.1.5Floors should be made of impervious materials, laid to an even surface, and should be free from cracks and open joints. If not carpeted floors should have tiles to facilitate easy cleaning. Walls should be sound and finished with a smooth, impervious and washable surface. Ceilings should be so constructed and finished that they can be maintained in a clean condition.1.6Buildings should be effectively lit and properly ventilated with air control facilities.1.7All premises, including stores, passage ways and external surroundings, should be maintained in a clean and tidy condition.1.8Premises in which medicinal products are stored should be made secure, with access restricted to authorized personnel.1.9Waste material should not be allowed to accumulate, but it should be collected in suitable receptacles for removal to collection points outside the building and disposed of at regular and frequent intervals.1.10The dispensary should be separate and independent from other operations, and should be locked when the pharmacist is not present. The dispensary should have running water (cold and warm) and adequate working and cleaning benches with formica tops and adequate shelving.1.11The dispensary and consulting room should be elevated overlooking pharmacy and medicine counter.2.Equipment and reference books 2.1A Pharmacy shall, where relevant, have measuring cylinders, a stirring rod, counting trays, balance, fridge, a fixed lockable DDA cupboard, current edition of Martindale and other books such as British National Formulary (BNF). United States Pharmacopoeia (USP) and Malawi National Formulary (MNF).3.Records 3.1Patient profile cards should be kept where possible.3.2Prescriptions should be kept for a minimum period of two years and should be numbered and filed chronologically.3.3Record of receipts with expiry dates and Lot. No. should be kept for a

minimum of two years.4. Labelling 4.1 Labelling of dispensed medicine products should include— (a) name of patient; its strength and quantity dispensed; (b) name of medicine, (c) directions for use; (d) date of dispensing; and (e) name of pharmacy or dispensing unit. The Pharmacist shall communicate to the patient any other pertinent information.5. Prescription 5.1 A prescription should have— (a) name of patient; (b) name of medicine, its strength and quantity dispensed; (c) directions for use; and (d) signature, date and address of the prescriber.5.2 A prescription should be checked and endorsed after dispensing.6. Personnel 6.1 A retail pharmacy should be under the direct supervision of a full-time registered pharmacist assisted by appropriately trained personnel approved by the Board.

PART IV

MINIMUM REQUIREMENTS FOR REGISTERED DISPENSING PRACTITIONER (reg. 5)

1. Dispensary layout 1.1 Dispensary shall be separated from the clinical areas.1.2 Dispensary should be maintained in good state of repair. The general condition of the building should be reviewed regularly and repairs effected where necessary.1.3 Dispensary should be clean and tidy at all times.1.4 Floors and walls should be free from cracks and made of impervious material for easy cleaning.1.5 Dispensary should be effectively lit and properly ventilated.1.6 Dispensary should be made adequately secure with no access to unauthorized persons.1.7 Dispensary should have running water (cold and warm), adequate shelving for medicines and other supplies, adequate patient waiting area with seats.1.8 A toilet for staff with running water, must be provided but should not open directly to the dispensing area.2. Storage room (if separated from dispensary)2.1 The main storeroom for medicines should have adequate lighting and ventilation.2.2 Medicines and other supplies should be arranged on shelves in an orderly manner.2.3 Medicines should be protected from direct sunlight and excess heat and kept well out of reach of patients.2.4 Storeroom should be provided with adequate security measures including adequate locking system, burglar bars and there shall be restricted entry into storeroom.3. Dispensing requirements 3.1 Labelling of dispensed medicinal products must be legible and should include—Name of patient;Name of medicine, its strength and quantity dispensed;Directions for use of medicine;Date of dispensing;Name of surgery or clinic or dispensing unit.4. Equipment and reference books 4.1. Measuring cylinders for dispensing reconstituted powders must be made available.4.2 Refrigerator in good working condition must be provided.4.3 Medicine counting trays for tablets and capsules must be provided.4.4 Dispensing packs or containers must be available.4.5 A fixed lockable cupboard for controlled medicines, including narcotics must be provided.4.6 Current editions of the following publications must be made available—Current edition martindale;Pharmacy, Medicines and Poisons Board Act and Regulations;Pharmacy, Medicines and Poisons Board schedules of registered medicines;Mala???i National Formulary;Mala???i Standard Treatment Guidelines.5. Records 5.1 Patient profile cards should be maintained.5.2 Dispensed prescriptions should be kept for a minimum of 2 years and should be filed orderly.5.3 Records of sources of medicinal products, receipt of goods, stock movement, should be available and kept for a minimum of 2 years.6. Human Resources 6.1 A dispensary should be managed and supervised by a fulltime registered health professional in the medical, nursing or pharmacy field.6.2 Other suitably qualified staff may also be employed to assist the supervisor.

PART V

MINIMUM REQUIREMENT FOR OPERATION OF A MEDICINE STORE

1. Premises 1.1 Premises should be constructed and maintained so as to be protected against weather, ground seepage and the entrance and harbouring of vermin and pests. 1.2 Premises should be maintained in a good state of repair. The condition of the buildings should be reviewed regularly, and repairs effected where necessary. Special care should be exercised to ensure that building, repair or maintenance operations do not hazard the products. 1.3 Premises should provide sufficient space to suit the operations to be carried out, allow an efficient flow of work and permit effective communication and supervision. 1.4 Toilets should be well ventilated and should not open directly to the medicine store. 1.5 Floors should be made of impervious material and should be free from cracks and open joints. Walls should be sound and finished with a smooth, impervious and washable surface. Ceilings should be so constructed and finished that they can be maintained in a clean condition. 1.6 The building should be effectively lit and properly ventilated. 1.7 All premises, including stores, passage ways and external surroundings, should be maintained in a clean and tidy condition. 1.8 Premises in which medicinal products are stored should be made secure, with access restricted to authorized personnel. 1.9 Waste material should not be allowed to accumulate, but should be collected in suitable receptacles for removal to collection points outside the building and disposed of at regular and frequent intervals. 1.10 Adequate shelving should be provided.

SECOND SCHEDULE (reg. 11)

PHARMACOLOGICAL CLASSIFICATION CATEGORIES OF MEDICINAL PRODUCTS

PART I

HUMAN CLASSIFICATION

1. Anaesthetics 1.1 General anaesthetics and medical gases 1.2 Local anaesthetics 1.2.1 Injectable 1.2.2 Topical 1.3 Cholinesterase inhibitors and muscle relaxants used in anaesthesia 2. Analgesics and antipyretics 2.1 Single ingredient products 2.2 Compound products 3. Drugs used in rheumatism and gout 3.1 Nonsteroidal anti-inflammatory drugs 3.2 Drugs for gout 3.3 Special antirheumatic drugs 4. Narcotic analgesics/Narcotic Antagonists 4.1 Narcotic analgesics 4.2 Narcotics antagonists 5. Antihistamines 6. Antidotes 6.1 General 6.2 Specific 6.3 Drugs used in the treatment of addictions—6.3.1 Alcohol 6.3.2 Nicotine 6.3.3 Narcotics 6.3.4 Psychotropics 6.3.5 Others 7. Anti-infective drugs 7.1 Penicillins 7.1.1 Non beta-lactamase resistant 7.1.2 Beta-lactamase resistant 7.2 Other antibacterials 7.2.1 Aminoglycosides 7.2.2 Cephalosporins 7.2.3 Sulphonamides (including combinations with trimethoprim) 7.2.4 Tetracyclines 7.2.5 Others 7.3 Antituberculars 7.4 Antileprotics 7.5 Antimalarials 7.6 Antiprotozoals (other than antimalarials) 7.7 Anthelmintics 7.8 Antischistosomes 7.9 Antitrypanosomes 7.10 Leishmanicides 7.11 Antiflarials 7.12 Antifungals (systemic) 7.13 Antivirals 7.14 Urinary antiseptics 8. Antimigraine drugs 9. Antineoplastic and immunosuppressive drugs 9.1 Alkylating agents—9.1.1 Nitrogen mustard 9.1.2 Alkyl sulphonates 9.1.3 Nitrosureas 9.1.4 Triazines 9.2 Antimetabolites—9.2.1 Folic acid analogues 9.2.2 Pyrimidine

analogues9.2.3 Purine analogues9.3Natural products and their derivatives—9.3.1 Vinca alkaloids9.3.2 Antibiotics9.3.3 Enzymes9.4Miscellaneous cytotoxic agents9.5Hormones and hormone inhibitors—9.5.1 Hormones9.5.2 Hormones inhibitors9.6Immunosuppressive agents10.Drugs affecting the blood10.1Anti-anaemia preparations—10.1.1 Iron10.1.2 Folates10.1.3 Vitamin B1210.1.4 Combinations10.2Anticoagulants10.3Anticoagulant antagonists10.4Haemostatics10.5Drugs modifying platelet function10.6Drugs altering blood viscosity11.Blood production/blood substitutes11.1Plasma substitutes and expanders11.2Plasma fractions for specific uses12.Cardiovascular drugs12.1Antianginal drugs12.2Antiarrhythmic drugs12.3Antihypertensive drugs—12.3.1 Vasodilators12.3.2 Beta blockers12.3.3 Centrally acting antihypertensives12.3.4 Ganglion blockers12.3.5 Others12.4Cardiac glycosides12.5Diuretics and antidiuretics12.6Calcium antagonists12.7Sympathomimetic cardiac stimulants12.8Drugs modifying serum lipids12.9Other cardiovascular drugs13.Central nervous system drugs13.1Anticonvulsants13.2Psychotherapeutic drugs—13.2.1 Antidepressants13.2.2 Anxiolytics13.2.3 Antipsychotics13.3Hypnotics13.4Antiparkinsonian drugs13.5Drugs for myaesthesia gravis13.6Muscle relaxants, centrally acting13.7CNS stimulants13.8Drugs improving cerebral blood flow or metabolism13.9Respiratory stimulants, centrally acting14.Dermatological and topical preparations14.1Topical anti-infectives14.1.1 Antibiotics14.1.2 Sulphonamides14.1.3 Antifungals14.1.4 Antiseptics and disinfectants14.1.5 Scabicides and pediculocides14.2Topical corticosteroids—14.2.1 Plain14.2.2 Combinations14.3Topical antihistamines14.4Topical local anaesthetics14.5Acne preparations—14.5.1 Topical14.5.2 Systemic14.6Preparations for psoriasis—14.6.1 Topical14.6.2 Systemic14.7Anti-dandruff preparations14.8Keratolytic14.9Topical cytotoxic14.10Sunscreen agents14.11Melanin inhibitors14.12Melanin stimulants14.13Astringents14.14Emollients14.15Rubefacients14.16Medicated dressings14.17Vaginal preparations14.18Heavy metal preparations14.19Others15.Diagnostic agents15.1Miscellaneous—15.1.1 Serological15.1.2 Skin tests15.1.3 Blood grouping15.1.4 Others15.2Radiocontrast media15.3Reagent strips and tablets16.Gastrointestinal drugs16.1Antacids16.2Antiemetics16.3Antihemorrhoidals16.4Antispasmodics16.5Laxatives—16.5.1 Lubricants and softeners16.5.2 Stimulants16.5.3 Bulking agents16.5.4 Osmotic agents16.5.5 Combinations16.5.6 Others16.6Antidiarrhoeals16.7Gastric/peptic ulcer drugs16.8Gastrointestinal enzymes16.8.1 Pancreatic enzymes16.8.2 Other Glanzymes16.9Appetite depressants—16.9.1 Centrally acting16.9.2 Locally acting17.Endocrine system drugs17.1Corticosteroids17.2Androgens17.3Oestrogens17.4Progestogens17.5Sex hormones combinations (excluding contraceptive preparations)17.6Insulins17.7Oral antidiabetic drugs17.8Thyroid hormones/inhibitors—17.8.1 Thyroid hormones17.8.2 Thyroid inhibitors17.9Parathyroid hormones/inhibitors—17.9.1 Parathyroid hormones17.9.2 Parathyroid inhibitors17.10Pituitary hormones/inhibitors—17.10.1 Pituitary hormones17.10.2 Pituitary inhibitors17.11Tropic hormones17.12Hormone inhibitors (other than the above)17.13Fertility stimulants17.14Others18.Immunologicals18.1Sera/immunoglobulins—18.1.1 Antitoxins18.1.2 Antivenoms18.1.3 Immune globulins18.1.4 Others18.2Vaccines19.Ophthalmic drugs19.1Anti-infective19.1.1 Antibiotics19.1.2 Sulphonamides19.1.3 Antivirals19.1.4 Antiseptic19.1.5 Others19.2Corticosteroids—19.2.1 Without antibiotics19.2.2 With antibiotics19.3Local anaesthetics19.4Miotics19.5Mydriatics19.6Diagnostics19.7Systemic19.8Contact lens preparations19.9Topical decongestants and anti-allergies19.10Others20.Ear, nose, throat and mouth

preparations20.1Ear—20.1.1 Anti-infective20.1.2 Anti-inflammatory20.1.3 Analgesic20.1.4 Wax removers20.1.5 Others20.2Nose—20.2.1 Anti-infective20.2.2 Corticosteroid (plain and combination)20.2.3 Antihistamines (plain and combination)20.2.4 Other decongestants and anti-allergics20.2.5 Cauterising preparations20.2.6 Others20.3Throat and mouth—20.3.1 Special dental preparations20.3.2 Mouth ulcer preparations20.3.3 Local analgesics/anaesthetics (including toothache and teething preparations)20.3.4 Antiseptic mouthwashes, gargles, sprays, paints, etc.20.3.5 Antiseptic lozenges20.3.6 Others21.Drugs used in labour, delivery and contraception21.1Labour and delivery—21.1.1 Pre-partum uterine contraction stimulants21.1.2 Post-partum uterine contraction stimulants21.1.3 Uterine contraction inhibitors21.2Hormonal contraceptives—21.2.1 Combined oral contraceptives21.2.2 Progesterone-only oral contraceptives21.2.3 Injectables21.2.4 Others21.3Spermicides21.4Intrauterine devices21.5Barrier devices22.Drugs acting on the respiratory tract 22.1Anti-asthmatic drugs—22.1.1 Systemic bronchodilators22.1.2 Inhalation bronchodilators22.1.3 Inhalation corticosteroids22.1.4 Other inhalation products22.1.5 Other systemic products22.2Cough and cold preparations—22.2.1 Antitussives22.2.2 Expectorants22.2.3 Decongestants22.2.4 Mucolytics22.2.5 Combination products22.3Inhalations and vapour rubs23.Agents correcting or modifying body fluid composition23.1Oral—23.1.1 Oral rehydration products23.1.2 Oral electrolyte replacement23.2Parenteral—23.2.1 Large volume infusions23.2.2 Injections 23.3Dialysis products—23.3.1 Peritoneal dialysis solutions23.3.2 Peritoneal dialysis solutions23.4Ion exchange resins23.5Agents modifying urinary pH23.6Haemoperfusion products24.Vitamins, minerals and tonics24.1Vitamins (excluding combinations)—24.1.1 Vitamin A and analogues24.1.2 Vitamin B group (single compounds, except B12, see 10.1.3)24.1.3 Vitamin C24.1.4 Vitamin D and analogues24.1.5 Vitamin E and analogues24.1.6 Vitamin K and analogues24.1.7 Other preparations of single vitamins (except folate, see 10.1.2)24.2Vitamin B compound preparations24.3Multivitamins (excluding vitamins plus minerals)24.4Minerals (except iron, see 10.1.1, and electrolytes, see 13.1.2)—24.4.1 Single minerals24.4.2 Compound preparations24.5Vitamins plus minerals24.6Tonics—24.6.1 Tonics with vitamins24.6.2 Tonics with minerals24.6.3 Tonics with vitamins and minerals24.6.4 Others25.Nutritional agents25.1Intravenous nutrition preparations25.2Milk substitutes25.3Special oral foods26.Enzymes (excluding gi tract)27.Enzymes inhibitors28.Homeopathic, Herbal and dutch remedies28.1Homeopathic remedies28.2Herbal remedies28.3Dutch remedies29.Radioactive isotopes, and kits for their preparations29.1Diagnostic29.2Therapeutic30.Environmental disinfectants and decontaminants

THIRD SCHEDULE (regs. 11,12 and 13)

CATEGORIES FOR THE DISTRIBUTION OF MEDICINAL PRODUCTS

Prescription only Medicines (POM) are medicinal products controlled under Division 1 of Part VI.

Pharmacist Initiated Medicines or (PIM) are medicinal products controlled under Division 2 of Part VI.

Pharmacy Medicines are medicinal products controlled as such under Division 2 of Part VI.

General Sales List Medicines (GSL) are medicinal products suitable for self medication and which are controlled under Division 3 of Part VI.

Controlled Drugs (CD) are medicinal products listed in the Tenth Schedule.

FOURTH SCHEDULE (reg. 34 (3))

CONDITIONS FOR WHICH ADVERTISING IS PROHIBITED

Alcoholism

Appendicitis

Arteriosclerosis

Cardiovascular disease

Cataract

Diabetes

Hernia

Kidney stone

Pneumonia

Prostate gland disorders

Epilepsy

Gallstones

Gangrene

Glaucoma

Hypertension

Hypotension

Tuberculosis

HIV/Aids related diseases

FIFTH SCHEDULE (regs. 2 and 36)

PRESCRIPTION ONLY MEDICINES (POM)

Human Medicines

Acebutolol

Acetanilide

Acetazolamide

Acetohexamide

Acetylcarbromol

Acetylcysteine

Acetyldigoxin

Actinomycin-D

Acyclovir (excluding topical preparations)

Aescin, other than preparations for external use

Alclofenac

Alcuronium

Alfacalcidol

Alfadolonum

Alfaxalonum

Allopurinol

Alseroxylon

Amantadine

Amidopyrine

Amilorideaminocarproic acid

Amineptile

Amitriptyline

Amoxapine

Amoxycillin

Amphotericin

Ampicillin

Anaesthetic agents (including local anaesthetics for oral inhalation and injection excluding preparations for local use and procaine for oral use).

Anti-microbial substances (including those synthesized naturally or in the laboratory for treatment of specific infections except when used topically and for application into eye/ear).

Antimony

Apronal

Atenolol

Atracurium

Atropine

Aurothiomalate

Azacyclonal

Azapropazone

Azathioprine

Baclofen

Beclomethasone

Benactyzine

Benzatropine

Benzoctamine

Benzydamine

Betahistine

Betamethasone

Betanidine

Biperiden

Bromocriptine

Bromvaletone

Brucine

Bumadizon
Bumetanide
Bupivacaine
Buserelin
Busulfan
Butriptyline
Calcitonin
Calcium dobesilate
Cantharidates (excluding for topical use)
Cantharidin
Captodiamine
Captopril
Carbamazepine
Carbenicillin
Carbidopa
Carbimazole
Carbochol
Caribromal
Carisoprodol
Ceftriaxone
Cefuroxime
Cephalosporins (all generations)
Cetirizine
Chlorambucil
Chloramphenicol

Chlormethiazole

Chlorotrianisene

Chlorpromazine

Chlorpropamide

Chlorprothixene

Ciclosporin

Cilazapril

Cimetidine

Cinchophen

Cisapride

Clavulanic acid

Cifibrate

Clindamycin

Clioquinol

Clobetasol

Clofazimine

Clomifene

Clomipramine

Clonidine

Clopamide

Cloreolone

Clothiapine

Clotiapine

Clotrimazole

Cloxacillin

Clozapine

Colestyramine

Conjugated oestrogens

Corticosteroids (excluding hydrocortisone 1 per cent)

Cortisone acetate

Cotarnine

Co-trimoxazole

Cromoglycic acid

Curate

Cyclandelate

Cyclarbamate

Cyclopentolate

Cyclofenil

Cyclopenthiazine

Cyclophosphamide

Cycrimine

Cyproterone

Cytarabine

Dacarbazine

Danazol

Dapsone (except in combination with pyrimethamine for malaria prophylaxis)

Daunorubicin

Deanol

Debrisoquine

Demecarium bromide

Desferrioxamine

Desipramine

Desmopressin acetate

Dexamethasone

Dibenzepin

Dichloralphenazone

Diethylcarbamazine

Digitalis digoxin and other cardiac glycosides

Dihydralazine

Dihydroergocristine

Diloxanide furoate

Diltiazem

Dimercaprol

Dimetotiazine

Dinoprost

Dinoprostone

Dioxyanthanol (dithranol)

Diphenidol

Diprocetyl

Dipyridamole

Dipyrocetyl

Disopyramide

Disulfiram

Diuretics

Dobutamine

Domperidone

Dopamine

Dosulepin

Doxapram

Doxazosin

Doxepin

Doxorubicin

Doxycycline

Droperidol

Dyflos

Ectylurea

Edrophonium

Emetine

Emylcamate

Enalapril

Enzymes (for injection)

Erythrityl tetranitrate

Erythromycin

Ethacrinic acid

Ethambutol

Ethchlorvynol

Ethinamate

Ethoheptazine

Ethosuximide

Etomidate

Famciclovir
Famotidine
Fenbufen
Fencamfamin
Fenfluramine
Fenlofenac
Fenoprofen
Flucloxacillin
Fluconazole
Flucytosine
Fludrocortisone
Flufenamic acid
Flumazenil
Fluocinolone
Fluorouracil
Fluoxetine
Fluphenazine
Flurbiprofen
Fluticasone
Folic acid
Folinic acid
Framycetin (other than topical)
Furazolidine
Furosemide
Fusidic acid

Gallamine

Gamolenic acid

Gelsenium

Gemfibrozil

Gentamicin

Gilibornuride

Glafenine

Glibenclamide

Griseofulvin

Guanethidine

Guanidine

Halofantrine

Halometasone

Haloperidol

Halothane

Hapatitis-B vacc

Heparin

Hexamethonium

Hexapropymate

Hormones natural or synthetic

Human chorionic gonadotropin

Hyaluronidase

Hycanthone

Hydralazine

Hydrochlorthiazide

Hydroxyprogesterone

Hydroxyzine

Hyoscine

Imipramine

Indapamide

Indinavir

Indomethacine

Indoprofen

Insulin

Iodozuridine

Iron injectabler preparations

Isoconazole

Isoetarine

Isoflurane

Isoniazid

Isopyrine

Isosorbide

Isradipine

Ketaconazole (except topical)

Ketamine

Ketoprofen

Ketorolac

Ketotifen

Labetalol

Lamivudine

Lanatoside
Laudezium
Levallorphan
Levobunolol
Levocastine
Levodopa
Levonorgestrel
Lidoflazine
Lincomycin
Lisinopril
Lithium
Lobella
Loratidine
Loxapine
Lucanthone
Maprotiline
Mazindol
Medroxyprogesterone
Mefloquine
Meglumine
Melphalan
Mephenesin
Mephenytoin
Mephonoxalone
Mercaptopurine

MersalylMesna

Mesuximide

Metaraminol

Methamine

Methacarbamol

Methoxamine

Metformin

Methapyrilene

Methohexitone

Methofrexate

Metipranolol

Metoprol

Metrifonate

Metronidazole

Metyldopa

Metylsergide

Mexiletine

Mianserin

Milrinone

Minoxidil

Mitoxantrone

Moclobemide

Molindone

Monoamine oxidase inhibitors

Moxisylate

Mupirocin
Nadolol
Nalidixic acid
Naloxone
Natamycin
Neostigmine
Nicotine
Nifedipine
Niflumic acid
Niridazole
Nitrofurantoin
Nizatidine
Nomifensine
Norfloxacin
Nux vomica
Nystatin (for intra-oral use only)
Oestradiol
Ofloxacin
Olanzapine
Omeprazole
Orphenadrine
Oxamniquine
Oxolinic acid
Oxprenolol
Oxyphenisatin

Oxytetracycline

Oxytocin

Pancuronium

Paraldehyde

Pargyline

Pefloxacin

Penbutolol

Penciclovir

Penicillins

Penterythritol tetranitrate

Perhexiline

Phenacaine

Phenacemide

Phenacetin

Phenaglycodol

Phenbutrazate

Phenindione

Phenothiazines (except promethazine, anthelmintics)

Phensuximide

Phentolamine

Phenytoin

Physostigmine

Phytomenadione

Picrotoxin

Pimozide

Pindolol

Piracetam

Piroxicam

Pituitary gland extracts intended for topical use and inhalants

Pizotifen

Poldine

Plasma expanders

Potassium chloride (only injection)

Practolol

Pravastatin

Praziquantel

Praxosin

Prednisolone

Prednisone

Prenylamine

Primidone

Probenecid

Procaine hydrochloride

Procainamide

Procarbazine

Procaterol

Prochlorperazine

Procycline

Prolintane

Propanidid

Propofol

Propranolol

Propylthiouracil

Protamine

Prothipendyl

Protryptiline

Pyrazinamide

Pyridostigmine

Pyritinol

Quinapril

Quinethazone

Quinidine

Quinine

Ranitidine

Rauwolfia

Reserpine

Rifampicin

Ritodrine

Rosoxacin

Roxithromycin

Sabadilla

Seriraline

Sodium calcium edetate

Sodium pentosan polysulphate

Sotalol

Spectinomycin

Spirolactone

Streptodornase and other similar enzymes

Streptokinase

Strophathus

Styramate

Sulfinpyrazone

Sulfiram

Sulindac

Sulphinpyrazone

Sulphonal

Sulphonamides (including combinations with other active ingredients) except in combination with pyrimethamine for treatment of malaria and for topical use and ophthalmic use.

Sulpiride

Sulthiamine

Sumatriptan

Suxamethonium

Syrosingopine

Talozamide

Talozoline

Tamoxifen

Tenoxicam

Terfenadine

Tetrabenazine

Tetracycline

Thiacetazone

Thiamphenicol

Thioguanine

Thionamide

Thiopentone

Thioridazole

Thiotepa

Thiothixine

Thymoxamine

Thyroid gland extract

Thyroxine

Tiaprofenic acid

Timolol

Tinidazole

Tolbutamide

Tolfenamic acid

Tolmetin

Tranexamic acid

Tranlycypromine

Tretamine

Tretion

Triamcinolone

Triamterene

Tribromomethyl alcohol

Trichlorethyl alcohol

Trifluoperidol

Trihexyphenidyl (benzhexol)

Trimethadion

Trimethaphan

Trimethoprim

Trimipramine

Trioxsalen

Tubocurarine

Turpicamide

Vaccines, Sera and Antigens

Valacyclovir

Valproic acid

Vancomycin

Vasopressin

Verapamil

Veratrum

Viloxazine

Vinblastine

Vincristine

Vindesine

Warfarin

Xameterol

Zidovudine

SIXTH SCHEDULE (regs. 2 and 39)

PHARMACIST INITIATED MEDICINES (PIM)

Human Medicines

Acetarsol

Acyclovir (topical use only)

Alimezamine

All topical anti-fungal medicines (excluding whitfields, undecylenic acid)

All vaginal anti-fungal medicines

Astemisole

Belladonna

Bismuth suppository (in combination with steroids)

Caramiphen

Cetirizine

Chloral all salts and derivatives

Chloramphenicol (topical use)

Chlorbenoxamine

Chlormezanone

Chloroquin

Chlorphenoxamine

Cinnarizine

Codeine (less than 10 mg per unit dose)

Colchicin

Crotamiton

Cyanocobalamine (except injection)

Cyproheptadine

Diclofenac (except injectable form)

Diclofenamide

Ephedrine (containing less than 30 mg per unit dose)

Fenoterol

Glyceryl trinitrate

Hexachlorophene

Ibuprofen (more than 200 mg per unit dose)

Kaolin/pectin (oral preparations)

Loperamide

Mefenamic acid

Methenamine (hexamine)

Nephenesin

Orciprenaline

Pholcodine

Pirbuterol

Podophyllin

Potassium chloride (for oral use)

Povidone-iodide pessary

Pyrental pamoate

Rimiterol

Salbutamol (except injectable forms but including for inhalation)

Salmeterol

Sodium aescinate (topical use only)

Sulphomamides (including those in combinations for intra-vaginal and ophthalmic use)

Sucralfate

Terbutalin (except injection but including inhalation)

Terfenadine

Tetracycline (topical only)

Theophylline (except injectable forms)

Thiabendazole Vitamin E (more than 100 mg per unit dose)

Yohimbine

SEVENTH SCHEDULE (regs. 2 and 39)

PHARMACY MEDICINES

Human Medicines

The salts, preparations and admixtures of the following—

aconite

aescin, preparations intended for topical use only

albendazole

alkali fluorides other than dentifrices containing not more than 0.3 per centum of the alkali salts of hydrofluoric acid

Aloxiprin

Aminopentamidine

Amino-alcohols, esterified with benzoic acid, phenylacetic acid, phenylpropionic acid, cinnamic acid, or the derivatives of these acids, their salts, being preparations for oral use only.

P-Aminobenzoic acid

Ammonia (see H.S.A)

Amyl nitrate

Anethole trithione

Anthraquinones

Antimicrobial substances (chemotherapeutic substances) synthesized in nature or a laboratory, for use as eye ointment containing 1 per cent chloramphenicol tetracycline or oxytetracycline for use in eye infections other than eye ointments containing 1 per centum tetracycline or oxytetracycline for the use in trachoma. Antihistamine substances, the following—

Antazoline

Bromazine

Bucizine

Carbenoxolone

Calamine (topical use)

Chlorphenamine

Chlorphenoxamine, preparations containing 10 mg or less per unit dose

Clemastine

Clemizole

Cyclizine

Dexchlorpheniramine

Diphenhydramine

Diphenylpyraline

Doxylamine

Isothipendyl

Mebhydrolin

Meclozine

Phenindamine

Pheniramine

Promethazine containing 25 mg or less per unit dose

Propylenediamine

Pyrrhobutamine

Thenalidine

Topropamine

Triprolidine

Tetra substituted N derivatives of ethylenediamine or propylenediamine

Apomorphine

Atropine for oral treatment and in combination with other active ingredients

Arsenic

Barium

Belladonna and the alkaloids thereof

Bemegride

Benzyl Benzoate (topical use)

Benzoyl peroxide

Benzoic acid (topical use)

Bephenium

Bisacodyl

Bitolterol mesylate

Bismuth subgallate

Bromelains

Bromhexine

Calciferol

Camylofin

Carbocysteine

Carbuterol

Cetrimide

Cetylpyridinium chloride

Chlorbutol, except when intended for use as a preservative

Chlormezanone, preparation containing 100 mg or less in combination with an analgesic or anti-asthmatic drug

Chloroform, other than preparations containing less than 10 per centum chloroform

Chlorhexidine

Chlorphenesin

Chlorphenoxamine

Choline theophyllinate

Chrysarobin

Clioquinol (Iodochlorhydroxyquinoline)

Clobutinol

Colocynth

Creosote, obtained from wood, other than substances containing less than 50 per centum creosote

Dapsone, preparations in combination with pyrimethamine and intended for prophylaxis of malaria

Dequalinium

Dextromethorphan

Detrophan

Dibromopropamide

Dicycloverine (Dicyclomine)

Diethylamine salicylate

Dimethicon

Diloxanide

Diphenoxylate, preparations containing 2.5 mg or less per unit dose in combination with other active ingredients

Domiphen bromide

Enzymes, except those intended for injection

Etafedrine

Ethylchloride

Fedrilate

Ferric and ferrous salts, and combinations

Floctafenine

Fluoride sodium, excluding dental pastes and gels
Folic acid

Formaldehyde, other than when used as a preservative

Gamma benzene hexachloride

Glucuronic acid

Halquinol (Chlorhydroxyquinoline) (Di-iodohydroxyquinoline)

Hexachlorophene, preparations containing less than 1 per centum hexachlorophene

Hexetidine

Hexoprenaline

Hydrochloric acid, as diluted solution for achlorhydria

Hydrotalcitelozone, iodides/isoaminile

JalapLead, salts, other than preparations for hair containing less than 0.5 per centum of lead

Mebendazole

Mefenamic acid

Mepyramine maleate

Methoxyphenamine

Myrtecarine

Naphazoline

Niclosamide

Nicotinic acid

Nitric acid (see H.S.A.)

Noscapine

Oxalic acid

Oxetacaine

Oxyphencyclimine

Oxymetazoline

Pancreatin

Pantothenic acid

Pentiyllin

Pentoxyverine

Phenazone

Phenindamine

Phenolphthalcin

Phenylephrine, other than preparations containing less than 0.2 per centum phenylephrine intended for topical use

Phenylpropanolamine

Povidone iodine, other than preparations intended for topical application

Potassium hydroxide

Promethazine, preparations containing 25 mg or less

Proguanil

Propamidine

Propantheline bromide

Pyridoxine

Pyrimethamine

Selenium

Sodium hydroxide

Stavesacre (Staphisagria) and alkaloids thereof, other than in soaps, ointments and lotions

Sulphuric acid (see H.S.A.)

Terpine hydrate

Tolazoline (intended for topical use)

Tribenoside

Trichloroacetic acid

Vitamin A other than preparations containing 10 thousand units or less of Vitamin A activity per unit dose

Xylometazoline

Zinc Sulphate

Any substance derived from any other substances referred to in any of the items in this Schedule unless expressly excluded therefrom.

EIGHTH SCHEDULE

GENERAL SALES LIST MEDICINES

Human Medicines

Acetylsalicylic acid (packs of less than 20 including strip or blister pack)

Aluminium hydroxide

Ascorbic acid (less than 500 mg per unit dose)

Caffeine

Camphor

Chlorinated xyleneol

Dequalinium

Hexetidine

Hydroquinone (for external use only containing 2 per centum or less hydroquinone)

Ipecacuana

Liquid paraffin

Magnesium hydroxide

Magnesium sulphate

Magnesium Trisilicate

Menthol

Methyl salicylate (in liniments only)

Paracetamol (packs of less than 20 including strips or blister packs)

Piperazine

Psyllium

Sulphomanide (only in combination with pyramethamine for treatment of malaria)

NINTH SCHEDULE (reg. 2)

PROHIBITED SUBSTANCES (PS)

Bufotenine

Glutethimide

Lysergamide

Lysergide and other N-alkyle derivatives of lysergamide which includes the drug commonly known as L.S.D., but not including methaergide maleate

Mescaline

Methaqualone

Methypylon

Psilocin

N.N-Diethyltryptamine

N.N. Dimethyltryptamine

2,5-Demethoxy-4, a, dimethylphenthylamine

Any stereoisomerio form, ester, ether or salt of a substance prohibited and any preparation containing any proportion of the abovementioned drugs.

TENTH SCHEDULE (reg. 2)

CONTROLLED DRUGS (CD)

PART I

NARCOTICS

Acetyldihydrocodeine

Alfentanil

Cocaine

Codeine

Dextropropoxyphene

Dihydrocodeine

Diphenoxylate

Fentanyl

Hydrocodon

Methadone

Morphine

Opium

Pethidine

Pholcodine

Tilidine

PART II

PSYCHOTROPIC SUBSTANCES

Alprazolam

Bromazepam

Buprenorphine

Chlordiazepoxide

Clobazam

Clonazepam

Clorazepate

Diazepam and other compounds containing the chemical structure of dihydro-1, 4-Benzo-diazepine substituted to any degree

Dipotassium Clonazepate

Flunitrazepam

Flurazepam

Ketazolam
Lorazepam
Lormetazepam
Medazepam
Meprobamate
Methylphenidate
Midazolam
Nitrazepam
Oxazepam
Pentazocin
Pentobarbitone
Phenobarbitone
Phentermine
Prazepam
Temazepam
Triazolam