

Medicines and Allied Substances Control (General) Regulations, 1991.

S.I. 150 of 1991

[amended by S.I.'s 298/93, 61/94, 319/94, 199/98, 256/98, 36/99, 24/2001 and 257/2002, 105 and 222 /2004]

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IT is hereby notified that the Minister of Health and Child Welfare has, in terms of section 74 and after consultation with the Authority in terms of section 38 of the Medicines and Allied Substances Control Act [Chapter 15:03], made the following regulations:—
[amended to comply with the 1996 Revised Edition of the Acts, and related legislation.]

PRELIMINARY

Title and date of commencement

1. (1) These regulations may be cited as the Medicines and Allied Substances Control (General) Regulations, 1991.

[amended by S.I. 199 of 1998 with effect from 7 August, 1998.]

(2) These regulations shall come into operation on the 1st, July, 1991.

Interpretation

2. In these regulations—

“**allied substances**” means any substance, which is prohibited, controlled or restricted in terms of section 38 of the Act;

“**applicant**” means the person by, or on whose behalf, an application for registration is made;

“**appropriate fee**” means the fee prescribed in the First Schedule;

“**batch number**” means the number or other cipher allocated to a medicine by a manufacturer, by which the origin of all raw materials and the complete process of manufacture of the medicine 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 Authority;

“**competent authority**” means the authority of a foreign country, which is authorized in terms of its law to control and regulate medicines and drugs;

[amended by S.I. 256 of 1998 with effect from 11 September, 1998.]

“**country of origin**” in relation to a medicine, means the country where the basic research in connexion with the manufacture of that medicine was undertaken;

“**dangerous drug**” or “**Narcotic**” or (N.) means a medicine –

- (a) controlled in terms of the Dangerous Medicines Act [Chapter 15:02]; or
- (b) listed in the Fourteenth Schedule; or
- (c) registered as such by the Authority;

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

“**form**” means the appropriate form set out in the Second Schedule;

“**household remedy**” or “**(H R)**” means a medicine to which Part D of Part VII applies or a medicine registered as such by the Authority;

“**housemark**” or “**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 medicine for the purpose of indicating a connexion with the principal or manufacturer of the medicine and the medicine itself;

“**label**” in relation to a package of a medicine, 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 section 38;

“**patent**” means a patent registered in terms of the Patents Act [Chapter 26:03] and which is of full force and effect;

“**pharmacist initiated medicine**” or “**(P. I. M.)**” means a medicine listed in the Eleventh Schedule or registered as such by the Authority;

[amended by S.I. 257 of 2002 with effect from 27 September, 2002.]

“**pharmacy medicine**” or “**(P.)**” means a medicine listed in the Twelfth Schedule or registered as such by the Authority ;

[amended by S.I. 257 of 2002 with effect from 27 September, 2002.]

“**prescriber**” means a medical practitioner, a dental practitioner, or a veterinary surgeon who is lawfully authorized to prescribe any medicines;

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

“**prescription preparation**” or “**(P. P.)**” means

- (a) a dangerous medicine; or
- (b) a medicine listed in the Ninth Schedule; or
- (c) a medicine listed in the Tenth Schedule; or
- (d) a medicine registered as such by the Authority;

“psychotropic substance” means a substance listed in the Eighth A Schedule.
[amended by S.I. 256 of 1998 with effect from 11 September, 1998.]

“shelf life” in relation to any batch of a medicine, means the period up to which a medicine in that batch will retain the potency and properties stated on the label as fixed by the Authority;

“specially restricted preparation” or (S R)” means a medicine listed in Part I of the Eighth Schedule or a medicine registered as such by the Authority.

Exemption of hazardous substances

3. These regulations shall not apply to substances controlled by the Hazardous Substances and Articles Act [Chapter 15:05]

[This Act is replaced by Section 144 of the Environmental Management Act No.13 of 2002, Chapter 20:27, with effect from a date to be gazetted.-Editor.]

PART I FORMS

Particulars

4. Any person who is required to make an application shall complete the appropriate form and shall furnish the Director-General, or some other person appointed by him, with such further information or particulars as may be required.

Forms to be completed in English

5. All forms shall be completed in the English language

Illegible or incomplete forms

6. The Director-General may reject any form if any part of such form is illegible or not properly completed

PART II LICENSING OF PREMISES AND PERSONS

Minimum requirements of premises

7. Any person who wishes to obtain a licence for his premises shall ensure that such premises comply with the minimum requirements set out in the Third Schedule: Provided that the Authority may exempt any person from any of the requirements set out in the Third Schedule.

Application for the issue of a licence for premises and persons

8. An application for the issue of a licence in terms of subsection (1) of section 57 of the Act shall be made to the Director-General, in triplicate –
[amended by S.I. 257 of 2002 with effect from 27 September, 2002.]

- (a) in the case of an application for the licensing of premises, in Form M.C. 1 and shall be accompanied by—
 - (i) the appropriate fee; and
 - (ii) three copies of a plan of the premises proposed to be licensed which shall comply with the requirement specified in the Fourth Schedule;

- (iii) in the case of an individual, proof of citizenship or proof of being ordinarily resident in Zimbabwe or proof of an exemption by the Minister; or
- (iv) in the case of a company, proof of citizenship or proof of being ordinarily resident in Zimbabwe of the majority of directors or proof of an exemption by the Minister;
- (b) in the case of an application for the licensing of a person, in Form M.C. 2 and shall be accompanied by –
 - (i) the appropriate fee; and
 - (ii) proof of citizenship or proof of being ordinarily resident in Zimbabwe, or proof of an exemption by the Minister; and
 - (iii) proof of registration by the Health Professions Authority or the Council of Veterinary Surgeons.

Requirements for the issue of a licence to a person

9. (1) Subject to subsection (2), no person shall be issued with a licence unless such person –
- (a) has passed the forensic examination set by the Authority; or
 - (b) satisfies the Authority that he is familiar with the regulations relating to the custody and dispensing of medicines and such other matter as the Authority may determine from time to time.
- (2) The Authority may exempt any person from any of the requirements referred to in subsection (1) if it is satisfied that such person has –
- (a) passed other examinations in the course of such person's studies; or
 - (b) has such other practical experience:
- as the Authority considers justifies the grant of such exemption.

Special requirements for medical practitioners

10. An application by a medical practitioner for a licence to dispense medicines from any premises in terms of section 55 of the Act shall not be granted where such premises are situated within five kilometres of a pharmacy;
[amended by S.I. 298 of 1993 with effect from 1 October, 1993.]
 Provided that the Authority may waive this requirement where the Authority considers it necessary or desirable to do so.

Duration of licences

11. Any licence, which is issued in respect of premises or persons, shall be valid for a period of one year from the date of its issue and may be renewed annually thereafter.

Form of licences

12. A licence issued in terms of —
- (a) subparagraph (iii) of paragraph (a) of subsection (4) of section 57 of the Act for premises shall be in Form M.C. 12 and
 - (b) subparagraph (ii) or paragraph (a) of subsection (3) of section 58 of the Act for a person shall be in Form M.C. 13.

Display of licences

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

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

Production and return of licences

14. (1) Whenever the Authority—

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

the Director-General shall request the holder of the licence to produce such licence within such period as he may specify and the holder thereof shall produce such licence within the specified period.

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

(3) Whenever the Authority varies, amends or imposes any new conditions on any licence, the Authority shall return such licence duly endorsed to the holder thereof within a reasonable time.

Application for renewal of licences

15. (1) An application for the renewal of a licence in terms of subsection (2) of section 60 of the Act shall be lodged with the Director-General, in triplicate, in Form M.C. 3 for the renewal of a licence for premises and in Form M.C. 4 for the renewal of a licence for a person—

- (a) before the expiry of such licence; and
[amended by S.I. 61 of 1994 with effect from 25 March, 1994.]
- (b) shall be accompanied by the appropriate fee in respect of each licence

(2)

[repealed by S.I. 61 of 1994 with effect from 25 March, 1994.]

(3) Where an application for the renewal of a licence has been lodged with the Director-General, the validity of the licence shall, where the applicant has not been given notice of the renewal or refusal of the application by the date of expiry of such licence, continue after the date of expiry until the decision of the Authority on the application is notified to the applicant by the Director-General.

Fee payable for temporary renewal of licences

16. (1) The fee payable for the temporary renewal of a licence shall be the appropriate fee prescribed in the First Schedule

(2) The fees specified in terms of this section shall not be payable by any person or institution that has been exempted, in writing, by the Authority.
[amended by S.I. 24 of 2001, with effect from 26 January 2001.]

PART III

WHOLESALE DEALERS' AND SALES REPRESENTATIVES' PERMITS

Sale of medicines

17. (1) No person shall sell any medicine –
- (a) from any premises unless such premises are licensed in terms of Part VI of the Act; or
[amended by S I. 257 of 2002, with effect from 27 September, 2002.]
 - (b) from any premises by wholesale unless –
 - (i) such person holds a wholesale dealer's permit issued by the Authority in terms of section 23 in respect of those premises; and
 - (ii) such premises are under the continuous personal supervision of a registered pharmacist or registered pharmacy technician approved by the Authority.
[amended by S I 199 of 1998, with effect from 7 August, 1998.]
- or
- (c) by soliciting or receiving orders for the sale of any medicines on behalf of an employer unless such person holds a sales representative's permit issued by the Authority in terms of section 23 in respect of such person.

Purchase of medicines

- 17A. No person shall purchase or receive any medicines from an unauthorized person or source.
[inserted by S I. 319 of 1994, with effect from 23 December, 1994.]

Wholesaler dealer's permits

18. (1) A wholesale dealer's permit shall authorize the sale of medicines supplied from premises specified in such permit to the holder of a licence, permit or any person authorized by the Authority, at any time on any day.
- (2) No medicine, the sale of which is authorized under a wholesale permit, may be supplied directly to the holder of a licence, other than those specified in such permit.

Minimum requirements for wholesale premises

19. No person shall sell any medicines by wholesale from his premises unless such premises comply with the minimum requirements set out in the Third Schedule; Provided that the Authority may exempt any person from any of the requirements set out in the Third Schedule.

Application for wholesale dealer's permits

20. Any person who wishes to obtain a wholesale dealer's permit for his premises for the sale of medicines by wholesale shall make an application to the Director-General, in triplicate, in Form M.C. 5, and such application shall be accompanied by—
- (a) three copies of a plan of the premises which shall comply with the requirements specified in the Fourth Schedule: and
 - (b) the appropriate fees

Sales representatives' permits

21. (1) A sales representative's permit shall authorize the holder thereof to –

- (a) solicit and receive, on any day and at any time, from the holder of a licence, permit or any person authorized by the Authority, orders for the sale of medicines on behalf of any person who carries on the business inside or outside Zimbabwe of selling medicines;
- (b) keep medicines on his person or within his reach for the purposes of soliciting orders for the sale of such medicines to person referred to in paragraph (a).

(2) A person who is employed by the holder of –

- (a) a licence issued in terms of Part VI of the Act for the manufacture of medicines; or
- (b) a wholesale dealer's permit; shall not solicit or receive order for the supply of medicines on behalf of his employer unless such person holds a sales representative's permit.

(3) A sales representative's permit, which has been issued to a person who is employed by the holder of a licence issued in terms of Part VI of the Act for the manufacture of medicines or a wholesale dealer's permit, shall expire simultaneously with the termination of such person's employment by such holder.

Application for sales representatives' permits

22. Any person who wishes to obtain a sales representative's permit for the sale of medicines shall make an application to the Director-General, in triplicate, in Form M.C. 6 and such application shall be accompanied by the appropriate fee.

23. The Authority may issue a wholesale dealer's permit or a sales representative's permit to any person who makes application in terms of section 20 or 22 and in issuing such permit the Authority may impose such conditions, as it may consider necessary or desirable.

Refusal of permits

23A (1) Where the Authority intends to refuse to grant a permit in respect of an application submitted in terms of section 20, 22 or 29 the Authority shall notify the Director - General thereof, together with its reasons.

(2) The Director-General shall, upon receipt of the Authority's notification in terms of subsection (1), inform the applicant in writing of the Authority's intention and the reasons therefor and request the applicant to submit to him, within thirty days, any representations he may wish to make on the matter.

(3) If

- (a) No representations are submitted in terms of subsection (2); or
- (b) after considering any representations submitted in terms of subsection (2), the Authority is of the opinion that a permit should not be issued;

the Authority may direct the Director-General to notify the applicant of its refusal.

[inserted by S.I. 199 of 1998, with effect from 7 August, 1998.]

Validity of permits

24. Any permit, which is issued in terms of section 23 or renewed in terms of section 29, shall be valid for a period of one year from date of its issue or renewal, as the case may be.

Form of permits

25. A permit issued in terms of section 23 shall –

- (a) in the case of a wholesale dealer's permit, be in Form M.C. 14;
- (b) in the case of a sales representative's permit, be in Form M.C. 15;

Display of permits

26. (1) Subject to subsection (2), a holder of a permit issued or renewed in terms of this Part shall ensure that his permit is prominently displayed at all times upon the premises to which it relates:

Provided that a holder of a sales representative's permit shall carry on his person and produce such permit to any person while soliciting or receiving orders for the sale of any medicines or when requested to do so by any authorized person.

(2) Subsection (1) shall not apply in respect of any period during which the permit is necessarily removed from the premises or person concerned for the purposes of doing anything in terms of these regulations or any lawful purpose the proof whereof, in any proceedings against any person for contravention of subsection (1), shall lie upon that person.

Variation, amendment and revocation of permits

27. (1) The Authority may in its discretion, vary or amend the conditions of, or revoke any permit issued in terms of section 23 at any time.

[amended by S.I. 298 of 1993 with effect from 1 October, 1993.]

(2) Where the Authority varies or amends the conditions of, refuses to renew or revokes any permit, the decision shall have immediate effect notwithstanding the noting of an appeal against the decision of the Authority:

Provided that where a permit has been varied, amended or its renewal has been refused the Authority may, subject to such conditions as it may specify, authorise the person concerned to continue to operate under the original permit until the appeal is determined or has been abandoned, as the case may be.

[inserted by S I 257 of 2002, with effect from the 27th of September 2002.]

Production and return of permits

28. (1) Whenever the Authority—

- (a) revokes any permit;
- (b) imposes new conditions on the renewal of any permit;

issued in terms of section 23, the Director-General shall request the holder of such permit to produce such permit within such period as he may specify and the holder thereof shall produce such permit within the specified period.

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

(3) Whenever the Authority varies, amends or imposes any new conditions on any permit, the Authority shall return such permit duly endorsed to the holder thereof within a reasonable time.

Renewal of permits

29. (1) A permit issued in terms of section 23 may be renewed before its expiry.

(2) Any person who wishes to renew his permit issued in terms of section 23 shall make an application to the Director-General, in triplicate, in Form M.C. 7 and such application shall be accompanied by the appropriate fee.

[amended by S.I. 61 of 1994 with effect from 25 March, 1994.]

(3) Upon receipt of an application to renew a permit the Authority may renew such permit if it is satisfied that the applicant has observed the conditions subject to which the permit was issued.

(4) Where the Authority refuses to renew a permit the Authority shall inform the applicant of such refusal, in writing, and the reasons therefore.

(5) Where an application for the renewal of a permit has been lodged with the Director-General, the validity of the permit, shall, where the applicant has not been given notice of the renewal or refusal of the application by the date of expiry of such permit, continue after the date of expiry until the decision of the Authority on the application is notified to the applicant by the Director-General.

[inserted by S.I. 199 of 1998 with effect from 7 August, 1998.]

Storage of medicines

30. A holder of a wholesale dealer's permit shall store any medicines on the premises in such area approved by the Authority.

Storage of medicines by sales representatives

31. A holder of a sales representative permit shall, where he leaves his vehicle unattended, keep any medicines in his possession in a locked compartment of a motor-vehicle, the key to which is kept on his person.

Samples

32. (1) No person shall sell for gain any samples of any medicine.

(2) Every sales representative who supplies any samples of any medicine to any authorized person, shall keep and maintain a record showing –

- (a) the name of such sample: and
- (b) the amount of such sample; and
- (c) the date of supply of such sample: and
- (d) the name of the person to whom the sample of the medicine is supplied to: and
- (e) the signature of the recipient: and
- (f) his signature.

PART IV CLASSIFICATION, REGISTRATION AND RETENTION OF REGISTRATION OF MEDICINES

Interpretation of term in Part IV

33. In this Part –
“**principal**” means the person who owns the medicine.

Categories for registration

34. For the purposes of registration, the Authority shall divide medicines into the categories specified in the Fifth Schedule.

Application for the registration and retention of medicines

35. (1) An application for the registration of a medicine may be made by –
- (a) the principal; or
 - (b) any other person acceptable to the Authority.

2) Every application for the registration of a medicine shall be submitted in Form M.C. 8 and shall be accompanied by –

- (a) a sample of the medicine in the smallest of each of the package forms available for distribution to the public including the identification marks on such medicine where appropriate; or
- (b) if such package forms are not yet available a sample in a package, in which the applicant intends to make the medicine available for distribution to the public; and
- (c) detailed information of all advertising material and package inserts which the applicant intends to use; and
- (d) such samples of the medicine or the raw materials thereof as the Authority may request for analysis; and
- (e) a single copy of any literature in support of the application:
Provided that the Authority may require additional copies of such literature; and
- (f) twenty additional package inserts or, where there is no package inserts, twenty labels or copies of the package; and
- (g) 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 authorization for release, and any other relevant records; and
- (h) the appropriate fee, together with such additional fee as may be fixed by the Authority for the purpose of analysing such medicine.

(3) Every applicant shall, without delay, inform the Authority either before or after the registration of a medicine –

- (a) of any alteration from the information or particulars furnished by him in applying for registration in terms of subsection (2); and
- (b) whether the medicine is to be imported as a finished product into, or relabelled or repackaged or dealt with in any other manner in Zimbabwe,

(4) For the purposes of paragraph (b) of subsection (3) –
“finished product”, in relation to a medicine, means a medicine which is wholly manufactured outside Zimbabwe and is imported into Zimbabwe and is ready for sale without have to be relabelled or repackaged.

(5) An application for the retention of the registration of a registered medicine shall be submitted to the Director-General, in duplicate in Form M.C. 9, and shall be accompanied by the appropriate fee which shall be payable on or before the 1st April annually.
[amended by S. I. 257 of 2002, with effect from the 27th September 2002.]

Fee payable for retention of right to sell unregistered specified medicines

36. The fee payable for the retention of the right to sell an unregistered specified medicine shall be the appropriate fee prescribed in the First Schedule which shall be payable on or before the 1st April, annually.
[amended by S. I. 257 of 2002, with effect from the 27th September 2002.]

37. (1) Subject to section 60, every medicine shall, unless otherwise directed by the Authority, bear or incorporate a label on the package in which such medicine 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 Authority, in addition to the registration number required by subsection (1) of section 36 of the Act, the following particulars which relate to the medicine only –

[amended by S. I. 257 of 2002, with effect from the 27th September 2002.]

- (a) the name and address of the principal;
- (b) the name and address of the manufacturer;
- (c) the approved name of the medicine which shall be of greater size and prominence than the proprietary name (trade mark), if any, of the medicine;
- (d) the housemark, if any, of the principal or manufacturer of the medicine;
- (e) the quantity and strength of the active ingredient of the medicine;
- (f) the name and percentage of any bacteriostatic or bactericidal agent which is added to the medicine as a preservative;
- (g) the date of manufacture and expiry date of the medicine;
- (h) the batch number of the medicine;
- (i) the quantity of the medicine in the package;
- (j) the strength of the medicine (where applicable);
- (k) the requirements for the method of storage or other necessary precautions for the preservation of the medicine;
- (l) the category of distribution of the medicine which may be represented by words or symbols as set out in the Sixth Schedule;
- (m) the dosage of the medicine and the directions for use;
- (n) any warning notices which shall be in a colour other than the colour of the particulars referred to in paragraph (a) to (m);
- (o) any other particulars as may be directed by the Authority:

Provided that in the case of a package containing a medicine of a quantity of five millilitres or less, it shall be adequate to record the information required by paragraphs (a), (b), (c), (d), (e), (f), (g), (h), (l) and (o) on the outer label.

(2) Notwithstanding subsection (1), the Authority may, if it deems it expedient, direct that the name and address of the manufacturer of a particular medicine, shall not appear on the packages.

(3) Every medicine shall, where possible, be marked with the housemark of the principal or manufacturer of the medicine, as the case may be, and such other distinguishing mark for the purpose of identifying such medicine.

Package inserts

38. Every package of a medicine shall, unless otherwise directed by the Authority, 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 Authority the following particulars which relate to that medicine only –

- (a) the information, which is required to be included on a label in terms of section 36 of the Act;

[amended by S. I. 257 of 2002, with effect from the 27th September 2002.]

- (b) the name and address of the principal;
- (c) the name and address of the manufacturer;
- (d) the approved name of the active ingredient of the medicine which shall be of greater size and prominence than the proprietary name (trade mark), if any, of the medicine;
- (e) the housemark, if any, of the principal or manufacturer of the medicine;
- (f) the quantity and strength of the active ingredient of the medicine;

- (g) the name and percentage of any bacteriostatic or bactericidal agent which is added to the medicine as a preservative;
- (h) the strength of the medicine where applicable;
- (i) the requirements for the method of storage or other necessary precautions for the preservation of the medicine;
- (j) the category of distribution of the medicine which may be represented by words or symbols as set out in the Sixth Schedule;
- (k) the pharmacological classification of the medicine determined in terms of section 34;
- (l) the dosage of the medicine and the directions for use;
- (m) the description of the pharmacological action of the medicine;
- (n) indications of the medicine;
- (o) contra – indications of the medicine;
- (p) warnings relating to the use of the medicine and such warning shall be printed in a colour as approved by the Authority;
- (q) the side-effects and special precautions of the medicine;
- (r) known symptoms of overdosage and particulars of its treatment;
- (s) the identification of the medicine;
- (t) the form in which the medicine is presented, whether tablet, capsule, liquid, etc., and the colour thereof;
- (u) the date of publication of the package insert;
- (v) any necessary warning concerning the administration or use of the medicine by children, old people, pregnant women or patients suffering from certain diseases, or the use of the medicine in conjunction with the consumption of alcohol or any particular food or any other medicine;
- (w) a summary of relevant information concerning the purpose and the beneficial, detrimental, injurious or other effects of the medicine, and the possible dangers that may arise from the prolonged use of the medicine;
- (x) relevant information, including particulars in regard to a specific medicine as an antidote (of known), concerning the treatment of a patient in cases where an overdose of the medicine has been administered or where a patient reacts adversely to the medicine;
- (y) any other particulars or warning notices as may be directed by the Authority.

Categories for distribution

39. (1) Where the Authority approves the registration of a medicine, it shall fix as a condition of registration the appropriate category for distribution of the medicine, prescribed in the Sixth Schedule.

(2) The same categories for distribution of a medicine shall apply to veterinary medicines and shall be identified by the suffix (VET):
 Provided that the veterinary medicines referred to in section 80 shall be identified by the suffix (V.M.G.D.).

Medicines register: information to be recorded

40. The Director-General shall enter in the register in respect of each medicine registered by the Authority –

- (a) the date of the application for registration of the medicine; and
- (b) the number allocated to the application for registration; and
- (c) the proprietary name (trade mark) of the medicine, if any; and
- (d) the housemark of the principal or manufacturer of the medicine, if any; and
- (e) the particulars of the patent of the medicine, if any; and
- (f) the approved name of the medicine; and

- (g) the form in which the medicine is presented, whether tablet, capsule, liquid, etc., and the colour thereof; and
- (h) the strength of the medicine; and
- (i) the qualitative and quantitative details of every ingredient in each dosage unit of the medicine; and
- (j) the name and address of the principal; and
- (k) the name and address of the manufacturer; and
- (l) the country of origin of the medicine; and
- (m) the name and address of the applicant; and
- (n) the number allocated to the inspection report of the place of manufacture, if applicable; and
- (o) the date of registration of the medicine; and
- (p) the registration number of the medicine; and
- (q) the shelf life of the medicine; and
- (r) the category for distribution of the medicine fixed in terms of section 39 and any other conditions of registration; and
- (s) the pharmacological classification of the medicine determined in terms of section 34; and
- (t) the date and particulars of any variation in the condition of registration of the medicine; and
- (u) the payment of any fee for the retention or registration of the medicine; and
- (v) where applicable, the date of the cancellation of the registration of the medicine.

Certificate of registration

41. After registering a medicine, the Director-General shall issue a certificate of registration in Form M.C. 16 required in terms of subparagraph (iii) of paragraph (a) of subsection (2) of section 33 of the Act.

Production and return of registration certificates

42. (1) Whenever the Authority—

- (a) cancels the registration of any medicine; and
- (b) varies or amends the conditions of registration of any medicine; and
- (c) imposes new conditions on the registration of any medicine;

the Director-General shall request the holder of the registration certificate concerned, to produce such certificate within a reasonable period as may be specified and the holder thereof shall produce such certificate within the specified period

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

(3) Whenever the Authority varies, amends or imposes any new conditions on any registration certificate, the Authority shall return such certificate, duly endorsed, to the holder thereof within a reasonable period.

PART V CLINICAL TRIALS

Application for a clinical trial

43. An application for the purpose of conducting a clinical trial of a medicine shall be made to the Director-General, in duplicate, in Form M.C. 10 and shall be accompanied by –

- (a) the appropriate fee; and

- (b) the consent of persons who, or the owners of animals which, will participate in such trial in Form M.C. 17 or Form M.C. 18, as may be appropriate.

Authorization to conduct clinical trials

44. An authorization granting an application for authority to conduct a clinical trial in terms of section 18 of the Act shall be issued in Form M.C. 19.

Consent of person or owner of animal

45. A person or the owner of an animal who consents to –
(a) himself; or
(b) his minor child or a person under legal disability; or
(c) his animal
participating in a clinical trial shall complete Form M.C. 17 or M.C. 18, as may be appropriate.

Insurance

46. For the purposes of paragraph (b) of section 21 of the Act, a person conducting a clinical trial shall insure the persons or animals participating in such trial for the sum of not less than one hundred thousand dollars in respect of each person or animal or such other amount as the Authority may direct.

Indemnity forms

47. An indemnity form required to be signed by an applicant in terms of paragraph (c) of section 21 of the Act shall be in Form M.C. 20.

**PART VI
GENERAL CONDITION OF SALE**

Importation of medicines with less than one-half of shelf life prohibited

48. (1) Subject to subsection (2), no person shall, without the approval of the Authority, import into Zimbabwe any medicine, which has less than one-half of its shelf life remaining.

(2) Subsection (1) shall not apply to any person who imports a medicine for his personal use.

[amended by S. I. 319 of 1994, with effect from the 23 December 1994.]

Delivery and sale of medicines with less than one-half of shelf life prohibited

49. No person shall deliver, receive, accept or sell any medicine, without the approval of the Authority, whose shelf life is less than one-half :
Provided that this section shall not apply to a person who sells or dispenses any medicine as a retailer to members of the public.

Medicines to be sold from licensed premises

50. No person shall sell any medicine unless the sale is effected on premises –
(a) licensed in terms of Part VI of the Act; or
(b) authorized in terms of these regulations;
(c) authorized by a general dealer's licence issued in terms of the Shop Licences Act.
[Chapter 14:17]

[proviso repealed and new subs. inserted by S. I. 199 of 1998, with effect from the 7th August, 1998.]

Sales of expired medicines prohibited

51. No person shall sell any medicine on a date later than the expiry date, which appears on the package of such medicine.

Conditions of sale

52. (1) No person shall sell any medicine unless –

- (a) he is authorized thereto; and
- (b) the sale is effected by or under the continuous personal supervision of an authorized person.

(2) No person shall sell any medicine to any person apparently under the age of sixteen years —

- (a) in the case of a household remedy or a medicine listed in Part I of the Twelfth Schedule, except upon production of a written order signed by the parent or guardian of the child known to such person;
- (b) in the case of any other medicine not referred to in paragraph (a) except upon production and in terms of a prescription issued by a medical practitioner, dental practitioner or veterinary surgeon.

[amended by S. I. 199 of 1998, with effect from the 7th August, 1998.]

Record-keeping of medicines by wholesalers

52A(1) This section shall not apply to a wholesale dealer who does not hold a wholesale dealers permit issued in terms of section 23 or who is not otherwise authorized in terms of the Act to sell medicines by wholesale.

(2) Every person who is engaged in the wholesale dealing of medicines shall keep a record of –

- (a) every quantity of a medicine –
 - (i) acquired by him;
 - (ii) supplied by him;
- (b) in respect of each acquisition and disposal of a medicine—
 - (i) details of the quantity;
 - (ii) the date of the transaction;
 - (iii) the supplier;
 - (iv) the person to whom the medicine is supplied;
 - (v) the batch number of such medicine;
 - (vi) the expiry date of the medicine;

(3) Every person who keeps a record in terms of subsection (2) shall make every entry required to be made in terms of subsection (2) on the day on which the medicine is received, or on which the transaction with respect to the supply of the medicine takes place, or if that is not reasonably practicable, on the next day following that day.

[inserted by S. I. 199 of 1998, with effect from the 7th August, 1998.]

Exemption for wholesale dealing

53. Subsection (1) of section 52 shall not apply to the sale of medicines by way of wholesale dealing where such sale is made—

- (a) by or under the continuous personal supervision of a person acceptable to the Authority; and

(b) to a medical practitioner, dental practitioner, veterinary surgeon or pharmacist for the purpose of carrying on his profession or for use in any hospital or clinic:
Provided that this section shall not apply to household remedies.

Disclosure of composition of medicines: labels

54. Subject to section 60, no person shall sell any medicine unless the medicine is labelled in accordance with the requirements of section 37.

Safe keeping of medicines

55. (1) No person who sells any medicines listed in the Ninth, Tenth or Eleventh Schedule, shall keep such medicine on an open shelf in a part of his premises to which members of the public have access.

(2) Any person who keeps in his possession or has under his control or uses any medicine shall exercise all reasonable care in the custody, safe keeping and use thereof.

Return of medicines three months before expiry

56. (1) Any person who practises or carries on the business of a pharmacist or dispenses any medicines may, where a medicine is due to expire, return such medicine not less than three months before the expiry date of such medicine to the manufacturer, agent or distributor, as the case may be:
Provided that a person shall return such medicine in its original unbroken package, as sealed by the manufacturer.

(2) On receipt of such medicine the manufacturer; agent or distributor, as the case may be—

- (a) shall store such medicine in a quarantine area of the premises; and
- (b) may reimburse the person who returned such medicine by –
 - (i) awarding a credit; or
 - (ii) replacing such surrendered medicine; or
 - (iii) where the Authority extends the expiry date of such medicine in terms of subsection (2) of section 58, returning such medicine duly relabelled; to the person concerned.

[amended by S. I. 319 of 1994, with effect from the 23 December, 1994.]

Return of expired medicines

57. (1) Any person who practises or carries on the business of a pharmacist or dispenses any medicine shall, where a medicine has expired –

- (a) return such expired medicine to the manufacturer, agent or distributor, as the case may be; or
- (b) keep a record or cause a record to be kept of such returned expired medicine; and
- (c) send a copy of such record to the Director-General.

(2) On receipt of an expired medicine, the manufacturer, agent or distributor, as the case may be –

- (a) shall store such medicine in a quarantine area of the premises;
- (b) may reimburse the person who returned such expired medicine by –
 - (i) awarding a credit; or
 - (ii) replacing such surrendered medicine; or

- (iii) where the Authority extends the expiry date of such medicine in terms of subsection (2) of section 58, returning such medicine duly relabelled; to the person concerned.

Extension of expiry date

58. (1) Every manufacturer, agent or distributor, as the case may be, may, on receipt of a medicine in terms of section 56 or an expired medicine, apply to the Authority for an extension to the expiry date of such medicine.

(2) On receipt of an application in terms of subsection (1), the Authority may approve or refuse an extension to the expiry date of such medicine.

(3) Where the Authority approves an extension to the expiry date of a medicine, the manufacturer, agent or distributor, as the case may be, shall –

- (a) relabel such medicine in a manner approved by the Authority; and
- (b) replace a similar quantity of such medicine to the person who surrendered such medicine to him.

(4) Where the manufacturer, agent or distributor, as the case may be, does not apply to the Authority for an extension to the expiry date of a medicine, or where the Authority does not approve an extension to the expiry date of a medicine on application being made to it in terms of subsection (1), the manufacturer, agent or distributor, as the case may be, shall, within thirty days of the receipt of such medicine, destroy such medicine and inform the Authority, in writing of –

- (a) the manner in which he destroyed such medicine; and
- (b) the date of such destruction.

Dispensing of medicines

59. (1) No person shall dispense any medicine 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 medicine.

Labels for dispensed medicines

60. Every person who dispenses a prescription preparation shall label such prescription preparation with—

- (a) the registered name, strength and form of the medicine;
Provided that this shall not apply where the prescriber has indicated that the prescription preparation shall not be so labelled: and
- (b) the total quantity of the medicine; and
- (c) the directions for use; and
- (d) any warnings; and
- (e) the name of the patient; and
- (f) the name of the prescriber;
- (g) the name of the manufacturer; and
- (h) the prescription reference number allocated to the prescription by the person dispensing the medicine; and
- (i) the date on which the prescription preparation is supplied; and
- (j) the name and address of the supplier.

Limit of validity

61. No person shall dispense any prescription for the first time later than three months after the date of issue thereof.

Copy of prescription

62. 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.

Records to be kept

63. On the day on which a prescription preparation is supplied or dispensed or, if that is not reasonably practicable, on the business day next following that day, the supplier shall record in a manner acceptable to the Authority, a complete copy of the prescription.

Preservation of records

64. Every person who dispenses any medicine shall keep or cause to be kept a record of such dispensing for a period of five years and shall preserve such record on the premises in which the dispensing takes place:

[amended by S. I. 256 of 1998, with effect from the 11th September, 1998.]

Provided that where the premises cease to be used or licensed such person shall make arrangements, acceptable to the Authority, for the preservation or destruction of such records.

Restriction on advertising medicines

65. (1) No person shall advertise codeine or any medicine which contains codeine.

(1a) No person shall advertise any psychotropic substance.

(1b) No person shall advertise any other medicine without the approval of the Authority in writing.

[amended and extended by S. I. 256 of 1998, with effect from the 11th September, 1998.]

(2) No person shall advertise or sell any medicine in connection with any bonus offer or discount to the public.

[amended by S. I. 298 of 1993, with effect from the 1 October, 1993.]

Provided that this subsection shall not apply to a medicine which is a personal hygiene product and is registered as a house-hold remedy.

[amended by S. I. 257 of 2002, with effect from the 27th September, 2002.]

(3) No person shall advertise any medicine 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 Seventh Schedule:

Provided that this subsection shall not apply to advertisements published by any local authority, or by or with the consent of the Minister.

PART VII SPECIAL CONDITIONS OF SALE

PART A SPECIALLY RESTRICTED PREPARATIONS (S.R.)

Import and export

66. No person shall import into or export from Zimbabwe any specially restricted preparation, except with the written permission of the Authority and subject to such conditions as the Authority may impose.

Possession

67. (1) No person shall acquire or possess a specially restricted preparation other than—
- (a) a pharmacist who controls, or is employed at premises where –
 - (i) the manufacturer of specially restricted preparation is authorized in terms of subsection (2) of section 68; or
 - (ii) the storage and distribution of specially restricted preparations is authorized in terms of section 69:

Provided that such person may possess a specially restricted preparation solely for the purposes of and to the extent that is necessary for the execution of his duties on such premises; or

- (b) a person for whom a specially restricted preparation has been prescribed by a medical practitioner in a prescription issued to him in terms of section 70 to the extent permitted by such prescription; or
- (c) any person authorized by the Authority in terms of subsection (2).

(2) Notwithstanding subsection (1), the Authority may authorize in writing, any person to acquire, possess, administer and distribute a specially restricted preparation and may impose such conditions as it considers fit.

Manufacture

68. (1) No person shall manufacture or carry out any process in the manufacture of a specially restricted preparation unless he is authorized to do so in terms of subsection (2)

(2) The Authority may, subject to such conditions as it considers fit, authorize, in writing, any person who is licensed in terms of Part VI of the Act to manufacture a specially restricted preparation on the licensed premises.

[amended by S. I. 257 of 2002, with effect from the 27th September, 2002.]

Storage

69. (1) Subject to subsection (2), no person shall store or dispense a specially restricted preparation in or from any premises other than premises specified in Part II of the Eighth Schedule.

(2) The Authority may, subject to such conditions as it considers fit, authorize, in writing, any person to store for distribution a specially restricted preparation on premises licensed in terms of Part VI of the Act.

Prescriptions

70. (1) No medical practitioner shall prescribe a specially restricted preparation for his own use or for the use of any member of his family.

(2) Every medical practitioner shall, before prescribing a specially restricted preparation for any person, take all reasonable steps to ascertain –

- (a) the identity of such person; and
- (b) whether such person has previously received a specially restricted preparation.

(3) A prescription for a specially restricted preparation shall bear the words “dispense once only”.

(4) No person shall supply a specially restricted preparation to any person more than once on the authority of any one prescription.

Countersignature

71. (1) Every prescription for a specially restricted preparation shall be submitted to one of the persons specified in Part III of the Eighth Schedule.

(2) A person specified in Part III of the Eighth Schedule to whom a prescription has been submitted in terms of subsection (1) shall—

- (a) if he is satisfied that –
 - (i) there is no suitable alternative treatment; and
 - (ii) the treatment is necessary; and
 - (iii) all the provisions of these regulations have been, or are likely to be, complied with; and
 - (iv) the prescription complies with subsection (2) of section 74;
record the particulars of the prescription and countersign the prescription;
- (b) if he is not satisfied, refuse to countersign the prescription.

Dispensing

72. No person shall dispense a specially restricted preparation unless it is apparent from such prescription that subsection (2) of section 74 and subsections (1) and (3) of section 70 have been complied with and that such prescription has been countersigned in terms of section 71.

PART A PSYCHOTROPIC SUBSTANCES

[inserted by S. I. 256 of 1998, with effect from the 11th September, 1998.]

Import and export of psychotropic substances

72A. (1) Any person who wishes to

- (a) import a psychotropic substance shall submit an application to the Director-General in Form M.C. 10A;
- (b) export a psychotropic substance shall submit an application to the Director-General in Form M.C. 10B.

(2) Any person who imports or exports a psychotropic substance shall, for every import and export, as the case may be, whether such import or export consists of one or more substances, obtain a separate licence from the Authority for such importation or exportation.

(3) An import or export licence granted by the Authority shall state—

- (a) the name and address of the importer or exporter, as the case may be;
- (b) the international non-proprietary name of the psychotropic substance or if there is no such name, the appropriate name set out in Part I of the Eighth A Schedule;
- (c) the quantity to be exported or imported;
- (d) the pharmaceutical form;
- (e) the period within which the import or export shall be effected;
- (f) where the substance is imported or exported in the form of a preparation, the name of the preparation;

- (4) An export licence shall state—
- (a) the number and date of the import authorization; and
 - (b) the authority by whom it is issued.

(5) No export licence shall be granted in respect of a psychotropic substance by the Authority unless the exporter produces to the satisfaction of the Authority proof of an import authorization issued by a competent authority of the importing country confirming the approval of the proposed importation.

(6) A copy of the export licence shall accompany each consignment of a psychotropic substance, which is to be exported.

(7) Where any psychotropic substance is imported into Zimbabwe, the Director—General shall return authorization of the government of the exporting country and shall endorse on such authorization the amount of such substance, which has been actually imported.

(8) No psychotropic substance, which is in transit through Zimbabwe being exported from a destination outside Zimbabwe to another destination, shall be permitted to pass through Zimbabwe unless a copy of the export authorization is presented to and approved by the Director-General.

(9) Every consignment of a psychotropic substance whether imported or exported shall be accompanied by an export licence or similar authorization.

(10) Any consignment referred to in subsection (9) which is not accompanied by an export licence or similar authorization shall be detained by a customs officer until such licence or authorization is presented to and approved by the Director-General.

(11) No person shall mislabel any psychotropic substance intended for export.

(12) No psychotropic substance shall be imported or exported by ordinary or registered letter post.

- (13) A licence granted by the Authority in term of subsection (1) shall –
- (a) in the case of an import licence, be in Form M.C. 27;
 - (b) in the case of an export licence, be in Form M.C. 28.

Export of certain psychotropic substances

72B. (1) Any person who exports a psychotropic substance set out in Part II of the Eighth A Schedule shall state in a declaration in Form M.C. 29, in triplicate, the following information –

- (a) the names and addresses of the exporter and importer;
- (b) the international non-proprietary name of the substance and if there is no international non-proprietary name, the designation of the substance in Part II of the Eighth A Schedule;
- (c) the quantity and pharmaceutical form in which the substance is exported and if the substance is in the form of a preparation, the name of the preparation, if any;
- (d) the date of dispatch;

(2) Every exporter shall –

- (a) furnish the Authority with two copies of the declaration;
- (b) attach the third copy of the declaration to the consignment being exported.

(3) Upon receipt of the copies of a declaration in terms of subsection (2) the Director-General shall, within ninety days, send one copy by registered mail, to the competent authority of the importing country requesting such authority to return the receipt thereof.

(4) Every importer shall, upon receipt of any substance set out in Part II of the Eighth A Schedule; send a copy of the consignment, duly endorsed, to the Director-General.

(5) No exporter of any psychotropic substance set out in Part II of the Eighth A Schedule shall export such substance to a bank to the account of a person other than the person named in the export authorization.

Diversion of certain psychotropic substances prohibited

72C. If a psychotropic substance, which is permitted under the law of any country outside Zimbabwe to be exported therefrom to any destination outside Zimbabwe, is brought into Zimbabwe, no person shall cause such substance to be diverted to any other destination unless an export licence has been issued by the Authority to such other destination.

Alteration of psychotropic substances in bonded warehouses

72D. No psychotropic substance which is stored in a bonded warehouse or whilst in transit shall be subjected to any process which would change the nature of such substance.

Alteration of packaging prohibited

72E. No packaging of a psychotropic substance which is stored in a bonded warehouse or whilst in transit shall be altered without the approval of the Authority.

Keeping of registers in respect of psychotropic substance

72F. (1) Any person who is authorized or licensed to manufacture or supply a psychotropic substance set out in Parts I and II of the Eighth A Schedule or who imports or exports such substance shall keep a register and shall enter therein, in chronological sequence, true particulars with respect to such substance—

- (a) every quantity of such substance manufactured by him;
- (b) every quantity of such substance acquired by him;
- (c) every quantity of such substance supplied by him;
- (d) every quantity of such substance used by him;
- (e) in respect of each acquisition and disposal of such substance details of the quantity, the date, the supplier and the person to whom the substance is supplied; and the provisions of section 42 of the Dangerous Drugs Regulations, 1975, shall apply, mutatis mutandis.

(2) Subsection (1) shall apply to any hospital, clinic, dispensary, wholesaler or similar institution administered by the State.

(3) Every manufacturer, importer and exporter of a substance set out in Parts II and III of the Eighth A Schedule shall keep a record showing the quantities of such substance manufactured, imported or exported, as the case may be.

(4) The records required to be kept in terms of subsections (1) and (3) shall be kept for a period of five years.

PART B

PRESCRIPTION PREPARATIONS (P. P.)

Possession of prescription preparations

73. (1) No person shall possess a prescription preparation unless he is a member of a class of persons authorized in terms of subsection (2) to be in possession thereof.

(2) The classes of persons who are authorized to be in possession of a prescription preparation shall be –

- (a) in the case of a dangerous drug, any person who is authorized or licensed in terms of the Dangerous Drugs Act [Chapter 15:02];
- (b) in the case of a prescription preparation other than a dangerous drug –
 - (i) any medical practitioner, dental practitioner, pharmacist or veterinary surgeon; or
 - (ii) any person in the employ and acting under the personal supervision of a medical practitioner, dental practitioner, pharmacist or veterinary surgeon in so far as is necessary in the execution of his duties; or
 - (iii) any registered nurse or registered pharmaceutical technician employed at a hospital or clinic in so far as is necessary in the execution of his duties; or
 - (iv) any person to whom the medicine has been supplied in accordance with a prescription by a medical practitioner, dental practitioner or veterinary surgeon; or
 - (v) any person who has obtained a permit in writing, upon payment of the appropriate fee, from the Director General to procure, possess, administer or distribute medicines subject to any conditions laid down by the Authority for the storage, safe custody, supply and sampling of such medicines.

Supply of prescription preparations

74. (1) Subject to this section and section 75, no person shall supply any medicine listed in the Ninth Schedule otherwise than in accordance with the written prescription of a medical practitioner, dental practitioner or veterinary surgeon, as the case may be:

Provided that where it is not reasonably practicable for a prescriber to furnish to the supplier such written prescription immediately, the 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 seven days.

(2) For the purposes of this section, a prescription shall –

- (a) bear the name, address and qualifications of the prescriber; and
- (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, if issued –
 - (i) by a dental surgeon, the words “for dental treatment only”; or
 - (ii) by a veterinary surgeon, the words “for animal treatment only”; or
 - (iii) in respect of a specially restricted preparation, the words “S R”, or
 - (iv) for topical application, the words “for external use only”; and
- (d) if the person for whom the prescription is being issued is under the age of twelve years, state the person’s age; and
- (e) be legibly written and contain the following particulars—
 - (i) the date on which the prescription is issued; and
 - (ii) the registered name, strength and form of the medicine; and
 - (iii) the total daily dose of the medicine; and
 - (iv) the total quantity of the medicine; and
 - (v) the directions for use; and

- (f) where the medicine is packed otherwise than in ampoules, indicate the total amount to be supplied and, except in the case of a medicine which is to be used for external treatment only, the dose to be taken; and
 - (g) where the medicine 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; and
 - (h) not be for more than thirty days' supply at the dosage indicated, and shall not authorize more than five further supplies of thirty days each:
- Provided that nothing in this paragraph shall apply to –
- (i) medicines listed in the Tenth Schedule; or
 - (ii) the supply of reasonable quantities of medicines to persons who intend to depart temporarily from Zimbabwe; and
 - (iii) be signed in full by the prescriber issuing it.

(3) In an emergency any pharmacist may sell any medicine listed in the Tenth Schedule at the request of any person, subject to the following conditions—

- (a) that the pharmacist by, or under whose supervision the medicine is to be sold, has satisfied himself –
 - (i) that there is an immediate need for the medicine requested and that it is impracticable in the circumstances to obtain a prescription without undue delay; and
 - (ii) that the medicine requested has on a previous occasion been prescribed by a medical practitioner, dental practitioner or veterinary surgeon, as the case may be, for the person requesting it; and
- (b) that not more than three days quantity of the medicine is sold:

Provided that—

 - (i) where a public holiday falls within the three day period, a sufficient quantity of such medicine may be sold; and
 - (ii) where the medicine is in a composite pack which exceeds three days supply a single pack may be sold; and
- (c) that the pharmacist, by or under whose supervision the medicine is sold, before he delivers such medicine makes an entry in his records stating:
 - (i) the date on which the medicine is sold; and
 - (ii) the registered name, quantity, form and strength of the medicine; and
 - (iii) the name and address of the person requesting the medicine; and
 - (iv) the nature of the emergency; and
 - (v) the name of the medical practitioner, dental practitioner or veterinary surgeon, as the case may be, if ascertainable; and
- (d) that the medicine is labelled –
 - (i) in accordance with section 60; and
 - (ii) with the words “Emergency Supply”.

Dispensing

75. Every person who dispenses a prescription preparation shall ensure that –
- (a) the prescription is not dispensed more than once, unless the prescriber has directed otherwise and in such event the prescriber's lawful instructions shall be complied with; and
 - (b) at the time of dispensing, or where a prescription preparation has been supplied in terms of the proviso to subsection (1) of section 74 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.

Storage and safe custody

76. (1) A person who is authorized in terms of subparagraph (i), (ii) or (iii) of paragraph (b) of subsection (2) of section 73 to be in possession of a prescription preparation, shall keep such medicine 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 medicines.

(2) Any person who is in possession of a prescription preparation shall keep such medicine in a place where children do not normally have access to the medicine

Application of Dangerous Drugs Regulations

77. Part II of the Dangerous Drugs Regulations, 1975, published in Rhodesia Government Notice 1111 of 1975 shall, mutatis mutandis, apply to any medicine specified in the Fourteenth Schedule.

[amended by S. I. 319 of 1994, with effect from the 23 December, 1994.]

Undesirable medicines or substances

77A. (1) No person shall sell, supply or deliver any of the medicines specified in Part I of the Fifteenth Schedule intended for use as a medicine to any person for any reason whatsoever.

(2) No person shall include any of the medicines or substances specified in Part I of the Fifteenth Schedule as an ingredient in any preparation or in any medicine.

(3) With effect from the 1st January 2000 no person shall include any of the medicines or substances specified in Part II of the Fifteenth Schedule as an ingredient in any medicine.

[inserted by S. I. 199 of 1998, with effect from the 7th August, 1998.]

PART C PHARMACY MEDICINES (P.) AND PHARMACIST INITIATED MEDICINES (P.I.M.)

Persons who may sell

78. (1) No person shall sell a pharmacy medicine other than –

- (a) a pharmacist, or a person acting under his continuous personal supervision, from premises licensed in terms of Part VI of the Act; or
- (b) a wholesale dealer.

(2) A pharmacist may sell any medicine listed in the Eleventh Schedule at the request of any person, subject to the following conditions –

- (a) that the pharmacist, by or under whose supervision the medicine is sold, before he delivers such medicine, makes an entry in his records stating—
 - (i) the name and address of the person requesting the medicine and the person for whom it is intended; and
 - (ii) if the person is under the age of twelve years, the person's age; and
 - (iii) the date on which the medicine is sold; and
 - (iv) the registered name, quantity, form and strength of the medicine; and
 - (v) the total daily dose of the medicine; and
 - (vi) the directions for use; and
- (b) that the medicine is labelled in accordance with section 37 or 60 as may be appropriate.

PART D
HOUSEHOLD REMEDIES (H.R.)

Conditions of sale

79. Any person may, subject to any other law relating to the sale of goods, sell any household remedy:

Provided that such household remedy is –

- (i) labelled in accordance with section 37; and
- (ii) sold in original unbroken packs.

PART E
VETERINARY MEDICINES (GENERAL DEALER) (V.M.G.D.)

Sale of veterinary medicines by general dealers

80. No general dealer shall sell any veterinary medicine listed in Part II of the Twelfth Schedule unless he is authorized thereto by the Authority.

Permits

81. The Authority may issue a permit to sell veterinary medicines to a general dealer if

- (a) an application is made in Form M.C. 11; and
- (b) the premises from which it is proposed to sell the veterinary medicines meet the requirements of the Authority.

Form and validity of permits

82. A permit issued in terms of section 81 shall be in Form M.C. 21 and shall expire on the 31st December of the year of issue.

Record of issue of permits

83. A record of the issue of permits to sell veterinary medicines shall be kept by the Authority.

Revocation

84. The Authority may in its discretion revoke at any time a permit to sell veterinary medicines.

General dealer may appoint agents

85. An authorized general dealer who holds a permit to sell veterinary medicines may appoint not more than two persons to be his agents and shall, upon appointment, notify the Director-General of such appointment and any changes thereto.

Conditions of sale

86. The sale of veterinary medicines by an authorized general dealer shall—

- (a) be in original unbroken packs, sealed by the manufacturer; and
- (b) be effected by the dealer or his appointed agent.

Storage

87. An authorized general dealer shall store the veterinary medicines listed in Part II of the Twelfth Schedule in a locked receptacle on the premises specified in the permit or in any other manner required or authorized by the Authority,

Use of veterinary medicines on humans prohibited

88. No person shall use any veterinary medicine for the treatment of humans.

PART VIII ADDICTS

Supply to addicts

89. (1) No medical practitioner shall, otherwise than in accordance with this section prescribe any medicine to any person whom he has reasonable grounds for believing is addicted to such medicine.

(2) Any medical practitioner who considers the issue of any medicine to be necessary for treatment or care of the person whom he has reasonable grounds for believing is addicted to any medicine may apply to the Secretary for permission to prescribe such medicine for the use of such person.

(3) An application made by a medical practitioner in terms of subsection (2) shall be accompanied by such information as the Secretary may require.

(4) Where an application has been made to him by a medical practitioner in terms of section (2), the Secretary may authorize, in writing, such medical practitioner to prescribe such quantities of such medicine as the Secretary considers necessary in the circumstances.

(5) Notwithstanding subsection (2), every medical practitioner or pharmacist who has reasonable grounds for believing that any person is addicted to any medicine shall forthwith report the matter to the Secretary and shall provide the Secretary with such information concerning his belief as the Secretary may require.

PART IX SPECIAL PROVISIONS FOR INSTITUTIONS

Interpretation of term in Part IX

90. In this Part –
“institution” means a hospital, dispensary, clinic, nursing home or other institution at which human ailments are treated.

Supplies from institutions to outpatients

91. The provision of Part B of Part VII shall apply to any medicine dispensed from an institution to an outpatient.

Supply of medicines for use within institutions

92. (1) In any institution in which medicines are dispensed in a dispensary or pharmaceutical department no medicine shall be supplied from that dispensary or department, except in cases of emergency, for use in wards, operating theatres or other sections of the institution unless such medicine is supplied on the directions of a medical practitioner, dental practitioner or any other person designated by the Authority.

(2) Every package of a medicine supplied in terms of subsection (1) shall be labelled with —

- (a) the registered name, form, strength and quantity of the medicine; and
- (b) the directions for use; and
- (c) the name of the patient; and
- (d) the name of the manufacturer; and
- (e) the date on which such medicine is supplied; and
- (f) the name of the prescriber.

Storage and handling

93. (1) Every medicine in an institution shall be stored in a place to which no unauthorized person has access.

(2) Every person who handles or distributes medicines in an institution shall ensure that no unauthorized persons have access to such medicines during the handling or distribution of such medicines.

PART X PROHIBITED MEDICINES (P.M.)

Prohibited medicines

94. The medicines specified in the Thirteenth Schedule are declared to be prohibited medicines.

Form to be attached to prohibited medicines

95. Where—

- (a) a court has ordered the forfeiture of any prohibited medicines to the State in terms of section 49 or 51 of the Act the appropriate Registrar of the High Court or the Clerk of the Magistrate Court;
 - (b) any prohibited medicines are forfeited to the State in terms of section 52 of the Act the police officer or the public officer concerned;
- shall complete Form M.C.22 or Form M.C.23, as may be appropriate, and attach such form to the prohibited medicines delivered to the Director-General in terms of section 49 of the Act.

Confirmation of forfeited medicines

96. (1) On receipt of any medicine in terms of section 49 or section 52 of the Act, the Director-General shall refer a sample of such medicine and record the amount thereof to an analyst to confirm that such medicine is the medicine so forfeited to the State.

[amended by S. I. 257 of 2002, with effect from the 27th September, 2002.]

(2) On receipt of any medicine in terms of subsection (1) an analyst shall record the amount—

- (a) so received; and
- (b) used for analysis; and
- (c) retained as a specimen sample, if any.

(3) On completion of the analysis the analyst shall forward a certificate to the Director-General stating therein the information referred to in subsection (2) and the result of the analysis carried out.

Information on appeals

97. The appropriate Registrar of the High Court or the Clerk of the Magistrate's Court shall—

- (a) within seven days of an appeal being noted against a decision of a Court in respect of a case involving prohibited medicines, inform the Director-General that an appeal has been noted;
- (b) within seven days of the expiry of the period for the noting of an appeal, inform the Director-General that no appeal has been noted;
[amended by S. I. 298 of 1993, with effect from the 1 October, 1993.]
- (c) where a late appeal is noted, inform the Director-General that an appeal has been noted.

Joint declaration

98. The joint declaration to be subscribed to and signed in terms of subsection (4) of section 50 of the Act shall be in Form M.C. 24.

Delivery of joint declaration

99. Within fourteen days of the destruction of any forfeited prohibited medicines in terms of section 50 or 52 of the Act, the Director-General shall, in addition to complying with subsection (5) of section 50 of the Act, cause a copy of the joint declaration of destruction of such medicines to be delivered to the appropriate Registrar of the High Court or Clerk of the Magistrates Court and to the officer in charge of the appropriate police station or the public officer concerned, as the case may be.

PART XI GENERAL

Sampling and testing of medicines

100. (1) When taking a sample of any medicine or substance in terms of subsection (3) of section 66 of the Act, an inspector, customs officer or police officer above the rank of sergeant shall issue a certificate in Form M.C. 25, to the analyst and shall hand or transmit a copy of such certificate to the owner, or seller of the medicine or substance or to his agent.

(2) After analysing, testing or examining a sample of any medicine or substance in terms of subsection (4) of section 66 of the Act, the analyst shall issue a certificate in Form M.C. 26.

(3) The Authority may require the owner, principal or agent of any medicine or any other person to supply, free of charge, within a period stipulated by the Authority such number of samples of any medicine and the working standards of the active ingredients and excipients of such medicine, as it considers necessary for the purposes of testing, examining or analysing such medicine.

Fees

[inserted by S. I. 61 of 1994, with effect from the 25th March, 1994.]

100A. The fees payable in terms of these regulations shall be the appropriate fees opposite the appropriate item specified in the first column of the First Schedule and shall—

- (a) in the case of an applicant whose medicine is wholly manufactured in Zimbabwe or is relabelled or repackaged in Zimbabwe, be paid in Zimbabwe dollars and shall be the amount specified in the second column of the First Schedule;
- (b) in the case of an applicant whose medicine is imported into Zimbabwe as a finished product, be paid in United States dollars and shall be the amount specified in the third column of the First Schedule.

(2) For the purposes of paragraph (b) of subsection (1) “finished product”, in relation to a medicine, means a medicine, which is wholly manufactured outside Zimbabwe and is imported into Zimbabwe and is ready for sale without having to be relabelled or repackaged.

(3) The fees specified in terms of this section shall not be payable by any person or institution that has been exempted, in writing, by the Authority.

[inserted by S I 24 of 2001, with effect from the 26th day of January 2001.]

Import and export of certain substances

[inserted by S. I. 256 of 1998, with effect from the 11th September, 1998.]

100B. (1) No person shall export a substance listed in Table I of the Sixteenth Schedule without obtaining an export licence granted by the Authority.

[amended by S.I. 257 of 2002, with effect from 27 September 2002]

(2) Any person who wishes to export a substance listed in Table I of the Sixteenth Schedule shall submit an application to the Director-General in Form M.C. 11A and such application shall be accompanied by the appropriate fee.

[amended by S.I. 257 of 2002, with effect from 27 September 2002]

(3) An Export Licence referred to in subsection (1) shall state—

- (a) the names and addresses of the exporter and importer;
- (b) the name and address of the consignee, if any;
- (c) the name of the substance in Table I of the Sixteenth Schedule;
- (d) the quantity to be exported;
- (e) the expected point of entry in the importing country;
- (f) the expected date of dispatch;
- (g) any other details as may be required by the importing country.

[amended by S.I. 257 of 2002, with effect from 27 September 2002]

(4) Where the Authority grants the issue of an export licence the Director-General shall send a copy of such licence to the competent authority of the importing country prior to the intended exportation.

(5) An Export Licence granted in terms of this section shall be in Form M.C. 30.

(6) Any person who imports or exports a substance set out in the Sixteenth Schedule shall state on any invoice, cargo manifest or similar document—

- (a) the names and addresses of the importer and exporter;
- (b) the name and address of the consignee, if any;
- (c) the quantity to be imported or exported, as the case may be;

and such invoice, cargo manifest or similar document shall be kept for a period of five years.

[amended by S.I. 257 of 2002, with effect from 27 September 2002]

Returns to Authority

[inserted by S. I. 256 of 1998, with effect from the 11th September, 1998.]

101C. Any person who imports or exports a substance set out in Table I of the Sixteenth Schedule shall, before the 31st March in each year, submit a return to the Authority stating the amounts so imported or exported from January to December in the previous year.

[amended by S.I. 257 of 2002, with effect from 27 September 2002]

Withdrawal of medicines

101.(1) Where the Authority is of the opinion that the withdrawal of any medicine is necessary for the protection of the public, the Authority may require any person to withdraw such medicine in accordance with the procedure for the withdrawal of any medicine as determined by the Authority from time to time.

(2) Every person who is in possession of a medicine required to be withdrawn in terms of subsection (1) shall comply with the procedure for the withdrawal of any medicine as determined by the Authority from time to time.

Report of loss or theft

102. Any person other than a person to whom a prescription preparation is lawfully dispensed, who is in possession of a prescription preparation and who misplaces or loses such medicine or from whom such medicine is stolen, shall report such loss or theft, as the case may be, to a police officer and to the Director-General as soon as is reasonably practicable, and in any case within twenty-four hours of the occurrence of the loss or theft.

Liability of carrier

103. No provision of these regulations relating to the possession of any medicine other than section 102 shall apply to a carrier, his agent or employee who is in possession of a medicine in the ordinary course of the carrier's business.

Disposal of existing stocks

104. If at any time any medicine becomes a prohibited or specially restricted medicine, any person other than a person to whom a medicine is lawfully dispensed who is in possession of such medicine at the time shall inform the Authority of his possession and shall dispose of such medicine in such manner as the Authority may direct.

Availability of Act and Regulations

105. A copy of the Act and these regulations shall be available at all premises –

- (a) Licensed in terms of Part VI of the Act; and
- (b) for which a permit is issued in terms of section 23.

Penalties

106. Any person who contravenes the provisions of these regulations, other than a provision for the contravention of which a penalty is provided by subsection (3) of section 38 or subsection (2a) of section 39 of the Act, shall be guilty of an offence and liable to a fine not exceeding level seven or to imprisonment for a period not exceeding six months or to both such fine and such imprisonment.

[amended by S.I. 105 of 2004 with effect from 9 April, 2004.]

Repeals

107. The regulations specified in the Seventeenth Schedule are repealed.
[amended by S.I. 257 of 2002, with effect from 27 September 2002]

FIRST SCHEDULE (Sections 2, 16 And 100A)

FEEs

In this Schedule--

“finished product” in relation to a medicine, means a medicine which is wholly manufactured outside Zimbabwe and is imported into Zimbabwe ready for sale without having to be relabelled or repackaged;

“line extension of a medicine” means any additional strength or pharmaceutical forms excluding novel dosage forms or delivery systems;

“orphan medicine” means a medicine which is used in low volumes and is intended for the treatment of conditions of low morbidity as determined from time to time by the Authority.

Item		Z\$	Fees US\$
1.	Application for the issue of a licence for-		
(a)	premises other than a pharmaceutical manufacturer's premises	16 000 000	---
(b)	premises for a dispensary of a local Authority clinic	3 000 000	---
(c)	a pharmaceutical manufacturer's premises	70 000 000	---
(d)	a person other than a pharmacist	2 000 000	---
(e)	a pharmacist	1 500 000	---
2.	Application for the renewal of a licence for-		
(a)	a person other than a pharmacist	1 500 000	---
(b)	a pharmacist	1 000 000	---
(c)	a premises other than a pharmaceutical manufacturer's premises lodged at least two months before the expiry of such licence but within one month before the expiry of such licence	10 500 000	---
(d)	a pharmaceutical manufacturer's premises at least two months before the expiry of such licence but within one month before the expiry of such licence	50 000 000	---
(e)	a premises other than a pharmaceutical manufacturer's premises lodged within the last month of the expiry date	15 500 000	---
(f)	a pharmaceutical manufacturer's premises lodged within the last month of the expiry date	54 000 000	---
3.	Application for an inspection of-		
(a)	premises other than the initial inspection and other than a pharmaceutical manufacturer's premises	9 000 000	---
(b)	a pharmaceutical manufacturer's premises other than the initial inspection	57 500 000	---
4.	Application for the temporary renewal of a licence in terms of section 60(7) of the Act	2 000 000	---
5.	Application for the issue of a permit for a		
(a)	a wholesale dealer	25 000 000	---
(b)	a sales representative	1 500 000	---

Item		Z\$	Fees US\$
6.	Application for the renewal of a permit for a -		
(a)	a wholesale dealer	16 500 000	—
(b)	a sales representative	600 000	—
7.	Application for the registration of a medicine		
(a)	in the case of a medicine imported into Zimbabwe as a finished product for –		
	(i) a new chemical entity including novel dosage form or delivery system	—	2 000
	(ii) a generic medicine	—	1 500
	(iii) a line extension of a medicine	—	1 000
	(iv) an orphan medicine	—	500
(b)	in the case of a medicine imported into Zimbabwe and which is relabelled or repackaged before being sold as –		
	(i) human medicine	18 500 000	—
	(ii) veterinary medicine	11 000 000	—
(c)	in any other case as –		
	(i) human medicine	11 000 000	—
	(ii) veterinary medicine	7 500 000	—
8.	Retention of a registered medicine, annually		
(a)	in the case of a medicine for imported into Zimbabwe as a finished product for use as –		
	(i) human medicine	500	—
	(ii) veterinary medicine	300	—
	(iii) orphan medicine	300	—
(b)	in the case of a medicine imported into Zimbabwe and which is relabelled and repackaged before being sold		
	(i) human medicine	10 000 000	—
	(ii) veterinary medicine	5 500 000	—
(c)	in any other case –		
	(i) human medicine	6 000 000	
	(ii) veterinary medicine	3 000 000	
9.	Retention of the right to sell an unregistered specified medicine, annually		
(a)	in the case of a medicine for imported into Zimbabwe as a finished product for use as –		
	(i) human medicine	—	500
	(ii) veterinary medicine	—	300
(b)	in the case of a medicine imported into Zimbabwe and which is relabelled and repackaged before being sold as –		
	(i) human medicine	10 000 000	—
	(ii) veterinary medicine	5 500 000	—
(c)	in any other case		
	(i) human medicine	6 000 000	—
	(ii) veterinary medicine	3 000 000	—

Item		Z\$	Fees US\$
10.	Application to export or import an unregistered medicine in terms of section 75 of the Act		
(a)	individual prescription	100 000	—
(b)	Institutions per medicine	800 000	—
(c)	Clinical trials per medicine	800 000	—
11.	Any amendment to the original application for the registration of a medicine and registration certificate		
(a)	indications	7 600 000	400
(b)	category for distribution	6 500 000	400
(c)	formulation	6 000 000	300
(d)	stability data	5 500 000	200
(e)	change of manufacturer	5 600 000	200
(f)	batch data	5 500 000	200
(g)	bioavailability/bioequivalence	6 000 000	300
(h)	any other matter	5 000 000	100
12.	Application to conduct a clinical trial of a medicine -		
(a)	by a local sponsor	30 000 000	
	(i) human medicine	12 500 000	
	(ii) veterinary medicine	12 500 000	
	(iii) Sub-study		
(b)	by a non-resident		3 000
(c)	operational	12 500 000	1 000
	bioequivalence/bioavailability	12 500 000	500
	observational	3 000 000	100
	in any other case	3 000 000	100
13.	Application to import psychotropic substances	600 000	
14.	Application to export psychotropic substances	600 000	
15.	Application to manufacture a medicine on contract for export	25 000 000	500
16.	Application for a permit to procure, possess, administer or distribute medicines	2 000 000	
17.	Application for a permit to supply veterinary medicines	2 000 000	
18.	Application for any copy of a current licence or permit	200 000	50
19.	Any amendment to the original application, licence or permit Additional information:		
	(i) Initial	400 000	50
	(ii) Subsequent	300 000	50
	(iii) Any other	200 00	50
20.	Application for a copy of a certificate of registration	200 000	
21	Analysis of a medicine	Costs incurred on analysis	

Notes

Inspection fees for new premises are part of the application fee.

Second and subsequent inspections carried out due to unsuccessful initial inspections will attract an inspection fee.

Incomplete applications will attract an amendment fees as stipulated.

The fees specified herein shall not apply to any person or institution exempted by the Authority.

SECOND SCHEDULE (Section 2)
FORMS

PART I
APPLICATION FORMS

Form M.C. 1

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]
APPLICATION FOR ISSUE OF A LICENCE FOR PREMISES
(To be submitted in triplicate)

(Pharmacy, dispensing medical practitioner, veterinary surgeon, manufacturer, clinic, other*)

PART A (To be completed by all applicants)

1. Particulars of proposed licensee-

If an individual: Full names
Date and place of birth
Qualifications.....
Number of registration with the Health Professions Authority*
or the Council of Veterinary Surgeons*.....
Address (Home).....
.....
.....

If a company: Name of company:.....
Physical address:.....
.....
.....

Registered Office:
.....
.....
State shareholders or distribution of shares or nominees:

PARTICULARS OF DIRECTORS:

Name	Address	Citizenship
.....		
.....		
.....		

If any director is registered with the Health Professions Authority* or the Council of Veterinary Surgeons*, state the registration number:
.....

Position of applicant in the company:
.....

2. Name under which business is conducted:
.....
Address:.....

-

3. Physical address of premises to be licensed:

 4. Postal address of business:

 5. Telephone number:

 6. Purposes for which premises to be licensed (e.g. manufacture of medicines, dispensing, packing etc.)

 7. Have you previously held a licence to manufacture, pack or sell medicines? YES / NO*
 If YES, give details:

 8. Has any application made by you for a licence been refused or cancelled? YES/NO*
 If YES, give details:

 9. Name and address of nearest police station:

 10. Name and approximate distance of nearest pharmacy from premises to be licensed:

 11. Particulars and date of any trading or other licence held by the applicant or business:

 12. State the name of the person under whose personal supervision the premises will be for the purposes of section 55 (1) (b) of the Act and the registration number of that person with the Health Professions Authority* or the Council of Veterinary Surgeons* and the practising certificate number thereof.

Name	Numbers
------	---------

 13. If an individual:-
 (a) are you a citizen of, or ordinarily resident in Zimbabwe? YES/NO*;
 if YES supply proof thereof;
 If NO have you been exempted by the Minister in terms of the proviso, to paragraph (a) of subsection (2) of section 59 of the Act? YES/NO*
 If YES supply proof thereof.

- (b) have you within the preceding three years of this application been convicted inside or outside Zimbabwe of an offence involving the wrongful dealing in or supply or possession of medicines, or of an offence involving dishonesty? YES/NO*
If YES state details
.....
.....
14. If a company –
- (a) are the directors of the company or a majority thereof citizens or ordinarily resident in Zimbabwe?
If YES supply proof thereof;
If NO, has the company been exempted by the Minister in terms of the proviso to paragraph (a) of subsection (1) of section 59 of the Act? YES/NO*
If YES, supply proof thereof;
- (b) has the company or any of the directors of the company within the preceding three years of this application been convicted inside or outside Zimbabwe of an offence involving the wrongful dealing in or supply or possession of medicines, or of an offence involving dishonesty? YES/NO*
If YES state details:
.....
Date:
Signature of applicant:
- *Delete the inapplicable

NOTE:

- Plans of the premises in accordance with the Fourth Schedule, the appropriate fee, proof of citizenship, residency or an exemption by the Minister, etc, are required to be attached to the application. Copies of original documents must be properly certified.
If any plan document or fee required to be attached is not attached, the application cannot be accepted.
- A person who wishes to obtain a licence for pharmaceutical premises need only complete Part A
- If insufficient space is provided in the application, attach a sheet of paper with the additional information.

PART B

This Part shall also be completed by persons applying for the issue of a licence for the manufacture of medicines and allied substances.

Application to manufacture medicines and allied substances

I hereby make application for a licence to manufacture the medicines* and allied substances* listed below (attach extra list if insufficient space provided here).

Indicate by reference to one of the following paragraphs which of the following classes the medicines and allied substances* come within -

- antibiotics, or preparations of antibiotics;
- vaccines and sera;
- sterile preparations;
- hormones and steroid preparations;
- vitamin preparations;
- antineoplastic agents and immunosuppressant agents other than steroid preparations;
- narcotic medicines;
- psychotropic substances;

- (i) genetic engineering;
- (j) other medicines not included in paragraph (a) to (i) above;
- (k) allied substances (specify type of substance).

Appropriate designation/Trade mark of medicine or allied substance Class

.....

Premises where manufacture (including packing and labelling) of the medicines and allied substances* will be carried out :

.....

I enclose the fee of :

Date:

Signature of applicant:

*Delete the inapplicable

PART C

This part shall also be completed by persons applying for the issue of a licence to pack medicines and allied substances.

Application to pack medicines and allied substances

I hereby make application for a licence to pack the medicines* and the allied substances* listed below (attach extra list if insufficient space provided here).

Indicate in the third column the category for distribution as per the Fifth Schedule

Appropriate designation/Trade mark of medicine or allied substance Category for distribution

Premises where packing and labelling will be carried out

.....

I enclose the fee of :

Date

.....
 Signature of applicant

**Delete the inapplicable*

Form M.C. 2

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]
APPLICATION FOR ISSUE OF A LICENCE FOR A PERSON

(To be submitted in triplicate)

(pharmacist, dispensing medical practitioner, veterinary surgeon, other*)

1. Full names
2. Date and place of birth
3. Qualifications
4. Number of Registration with the Health Professions Authority* or the Council of Veterinary Surgeons*

Number of Practising Certificate with the Health Professions Authority

5. Address (Home)

(Business)

6. Telephone number (Home)

(Business)

7. Present place of employment

8. Position of applicant at place of employment (e.g. owner, manager, etc

9. Have you worked in a designated health institution? (This item should be completed by medical practitioners only) YES/ NO*

If YES, state details and length of service

10. If NO, attach exemption issued by the Minister in terms of the proviso to section 59 of the Act

11. Name and approximate distance of nearest pharmacy from premises to be licensed. (This item should be completed by medical practitioners only)

12. Will you undertake locum tenens on a full time basis ? YES/NO*

13. Are you a citizen of, or ordinarily resident in Zimbabwe?

If YES, supply proof thereof.

If NO, have you been exempted by the Minister in terms of the proviso to paragraph (a) of subsection (2) of section 59 of the Act ?

14. Have you within the preceding three years of this application been convicted inside or outside Zimbabwe of an offence involving the wrongful dealing in or supply or possession of medicines, or of an offence involving dishonesty ?

YES/NO ?

If YES, state details

Date

.....
Signature of applicant

**Delete the inapplicable*

Note: The appropriate fee, proof of citizenship or ordinary residency or an exemption by the Minister, etc., are required to be attached to the application. Copies of original documents must be properly certified.
 If any document or fee required to be attached is not attached, the application cannot be accepted.
 If an applicant's Practising Certificate is not renewed by the Health Professions Authority for any reason any licence issued in terms of this Act will immediately become invalid.

Form M.C. 3

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]
APPLICATION FOR THE RENEWAL OF A LICENCE FOR PREMISES
 (To be submitted in triplicate)

(Pharmacy, dispensing medical practitioner, veterinary surgeon, manufacturer, clinic, other*)

1. Type of licence held (state whether for pharmacy, dispensing medical practitioner, veterinary surgeon, manufacturer, clinic, etc)

2. Name and address of applicant, in full

3. Location of premises

4. Name of practice or business on the premises

5. Names of person (s) under whose supervision the premises will be for the purposes of section 55 of the Act.

Name	Licence number
.....	
.....	
6. Have any particulars contained in the original application for the licence changed ?
 YES/NO*
 If YES, give details

7. If an individual –
 - (a) are you a citizen of, or ordinarily resident in Zimbabwe? YES/NO*
 If YES, supply proof thereof
 If No, have you been exempted by the Minister in terms of the proviso to paragraph (a) of subsection (2) of section 59 of the Act? YES/NO*
 If YES, supply proof thereof.
 - (b) Have you within the preceding three years of this application been convicted inside or outside Zimbabwe of an offence involving the wrongful dealing in or supply or possession of medicines, or of any offence involving dishonesty? YES/NO*
 If YES, state details

8. If a company –
- (a) are the directors of the company or a majority thereof citizens or ordinarily resident in Zimbabwe?
If YES, supply proof thereof;
If NO, has the company been exempted by the Minister in terms of the proviso to paragraph (a) of subsection (1) of section 59 of the Act? YES/NO*
- (b) has the company or any of the directors to the company within the preceding three years of this application been convicted inside or outside Zimbabwe of an offence involving the wrongful dealing in or supply or possession of medicines, or of an offence involving dishonesty? YES/NO*
If YES, state details
.....

Date

.....
Signature of applicant

**Delete the inapplicable*

Form M.C. 4

**MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [[CHAPTER 15:03]
APPLICATION FOR THE RENEWAL OF A LICENCE FOR PERSONS**

(To be submitted in triplicate)

(Pharmacist, dispensing medical practitioner, veterinary surgeon, other*)

1. Name and address of applicant, in full
.....
2. Number of licence
.....
3. Name and address of employer
.....
4. Location of place of employment
.....
5. State whether any particulars contained in the original application for the issue of the licence or the application for the last renewal of the licence have changed
.....
6. Will you undertake locum tenens on a full time basis? YES/NO* -
 - (a) are you a citizen of, or ordinarily resident in Zimbabwe? YES/ NO*
If YES, supply proof thereof.
If NO, have you been exempted by the Minister in terms of the proviso to paragraph (a) of subsection (2) of section 59 of the Act? YES/NO*
If YES, supply proof thereof.
 - (b) have you within the preceding three years of this application been convicted inside or outside Zimbabwe of an offence involving the wrongful dealing in or supply or possession of medicines, or of an offence involving dishonesty ? YES/NO*
If YES, state details
.....

I enclose the fee of

Date

.....
Signature of applicant

**Delete the inapplicable*

Form M.C. 5

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]
APPLICATION FOR THE ISSUE OF A WHOLESALE DEALER'S PERMIT
(To be submitted in triplicate)

1. Particulars of proposed permit holder:
If an individual: Full names
Date and place of birth
Qualifications
Address (Business)
.....
(Home)
.....
Telephone numbers; (Business).....
(Home).....
If a company: Name of company
Physical Address
.....

Registered office
.....

Main object of the company
.....
.....

State shareholders and distribution of shares or nominees
.....

Particulars of Directors:

Name	Address
1.	
2.	
3.	
4.	

2. Position of applicant in the company

-
3. Name under which business is conducted
.....
 4. Name and address of nearest Police Station
.....
 5. Particulars and date of any trading licence or other licence relating to the business held by the applicant or business
.....
.....
 6. State the name of the person (s) under whose personal supervision the premises will be
.....
 7. Have you or any of the directors of the company, or the person under whose control the premises will be, been convicted of any offence relating to medicines? YES/NO*
If YES, state details
.....

Date

.....
Signature of applicant

**Delete the inapplicable*

Form M.C. 6

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]
APPLICATION FOR THE ISSUE OF A SALES REPRESENTATIVE'S PERMIT
 (To be submitted in triplicate)

1. Full name
.....
2. Date and place of birth
.....
3. Qualifications
.....
4. If registered with the Health Professions Authority or the Council of Veterinary Surgeons, registration number
If you hold a Health Professions Authority practising certificate, state the number thereof.....
5. Address
(Business).....
(Home).....
6. Telephone number (Business)
(Home).....
...
7. Name and address of employer or principal or any company you are representing
.....
8. Position of applicant at place of employment

-
9. Have you been convicted of any offence relating to medicines? YES/NO*
If YES, state details

-
10. State the medicines you intend to sell (attach extra list if insufficient space is provided here)

.....

Date

.....
Signature of applicant

**Delete the inapplicable*

Form M.C. 7

**MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]
APPLICATION FOR RENEWAL OF A WHOLESALE DEALER'S PERMIT OR A
SALES REPRESENTATIVE'S PERMIT**

(To be submitted in triplicate)

1. Type of permit held
.....
2. Name and address of applicant
.....
3. Name of business on the premises
.....
4. Number of permit
.....
5. Location of premises +
.....
6. Name of business on the premises +
.....
7. Name of person (s) under whose supervision the premises will be +
.....
8. Have any particulars contained in the original application for the permit or the application for the last renewal of the permit changed? YES/NO*
If YES, give details

.....

Date

.....
Signature of applicant

**Delete the inapplicable*

+ Items 5, 6 and 7 must be completed by holders of wholesale dealer's permits.

Form M.C. 8

**MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]
APPLICATION FOR REGISTRATION OF A MEDICINE**

(To be submitted in duplicate)

To be sent to the Director-General, Medicines Control Authority, P O Box UA 559, Union Avenue, Harare, or to be lodged at the offices of the Director-General, Medicines Control Authority, 106 Baines Avenue, Harare.

Samples and printed matter to be forwarded by post or by other means and carriage, customs duty and clearance to be paid and effected by the applicant in all instances.

PARTICULARS OF APPLICANT:—

Name

.....

Business address

.....

Postal address

.....

Telephone number

.....

PARTICULARS OF MEDICINE

Approved name (if any) (1)

.....

Proprietary name (Trade mark) (if any) (2)

.....

Title of patent (registered in terms of the Patents Act [Chapter 26:03], if any

.....

Name of proprietor of patent

.....

Number of patent

.....

Is the patent still in force? YES/NO*

The form in which the medicine is presented, and the colour thereof (3)

.....

Name and address of principal

.....

Name and address of manufacturer

.....

Country of origin

.....

The strength of the medicine

.....

Classification (4)

.....

Will the medicine be manufactured, partially manufactured, repacked or relabelled in Zimbabwe?

.....

State who will complete the process of manufacture

.....
State address at which the certificate will be kept
.....

I enclose the fee of
.....

I, the undersigned, hereby declare that all the information contained herein and in the appendices is correct and true

Date.....

.....
Signature of applicant

**Delete the inapplicable*

NOTES

General information

1. If no name has been allocated to the medicine by an appropriate international body, the name, which has been or will be submitted for approval must be mentioned here
2. Medicines which are not identical in composition or strength are not regarded as the same medicine, but application for registration of medicines, which vary only in strength, may be made on the same form
3. The form of preparation, i.e. capsules, ear drops, emulsions, eye drops, injections, ointments, solutions, suppositories, suspensions, tablets, etc. and the colour thereof must be mentioned here
4. The classification of the medicine as described in the Fifth Schedule of the Medicines and Allied Substances Control (General) Regulations, 1991, as amended.

Form M.C. 8

APPENDIX I

Name of applicant
.....

Name of medicine
.....

The form in which the medicine is presented and the colour thereof
.....

The following is a schedule of the

- (a) active ingredients, giving their approved names, chemical names, structural formulae, specifications and quantity in a dosage unit of the medicine;
- (b) inactive ingredients giving specifications and quantity and reason for inclusion, e.g. preservative, antioxidant;
- (c) specification of any raw materials used in the manufacturing process and not present in the finished medicine; and
- (d) specification of the packaging material in immediate contact with the medicine.

Approved name	Chemical name and	Quantity per dosage unit	Active or non - active	Specifications (2)	Reason for inclusion of
---------------	-------------------	--------------------------	------------------------	--------------------	-------------------------

	structural formula (1)				ingredient

Specifications of additional raw material (if any) (2) used in the manufacturing process and not in the final product

.....

Specification of packaging material (3)

.....

Notes

1. The chemical name must, where possible, be given in terms of the published list of an appropriate international body.
2. Reference to the following publications will, where applicable, be acceptable,
 - (a) British Pharmacopoeia;
 - (b) European Pharmacopoeia;
 - (c) Pharmacopoeia of the United States of America;
 - (d) Pharmacopoeia of Japan;
 - (e) International Pharmacopoeia;
 - (f) Such other works of reference as may be approved by the Authority.
3. Where no specifications for raw materials and packaging materials exist this must be mentioned

Form M.C. 8

APPENDIX II

Name of applicant

.....

Name of medicine

.....

The form in which the medicine is presented and the colour thereof

.....

(a) A summary of the manufacturing procedure

.....

(b) The analytical control procedures performed on raw materials including the microbial status where applicable

.....

(c) The analytical control procedures performed during the manufacturing process

.....

- (d) The analytical control procedure used to determine the compliance with specifications.....
- (e) The full specifications of the medicine including microbial limits
.....
- (f) Data and reasoning on which the stability of the medicine is predicted (a minimum of three batches is required)
.....
- (g) The shelf life claim
.....
- (h) Copies of all records and batch data relating to a particular batch (preferably that of the sample submitted). This includes raw material analytical reports, manufacturing and packaging master sheets, in process control records, final product analytical report and authorization for release and any other appropriate records.

Where appropriate references to the publications mentioned in the notes to Appendix I, will be acceptable.

Form M.C. 8

APPENDIX III

Name of applicant
.....
Name of medicine
.....
The form in which the medicine is presented, and the colour thereof
.....

1.—

- (a) has the medicine been registered in the country of origin? YES/NO*
(if YES, a valid certificate of registration in respect of such medicine issued country of origin must accompany this application);
 - (b) has an application for the registration of the medicine been made in any other country? YES/NO*
if YES, state full details
.....
.....
 - (c) has the registration of the medicine been rejected, refused, deferred or cancelled in any country? YES/NO*
if YES, state full details
.....
.....
- do you intend to advertise the medicine? YES/NO*
if YES, state how and give details of proposed advertising and promotional materials.....
.....

2. Under what category do you envisage distributing the medicine?

.....

* Delete the inapplicable

Form M.C.8

APPENDIX IV

Name of applicant

.....

Name of medicine

.....

The form in which the medicine is presented and the colour thereof

.....

(a) the following particulars refer to the toxicological trials undertaken

.....

(b) the following particulars refer to therapeutic effects of the medicines

.....

(c) the following particulars refer to the tests which have been performed on animals regarding the efficacy of the medicine and the purposes for which it will be promoted, with special reference to the dosage and method of administration (pharmacological trials)

.....

(d) the following particulars refer to the tests, which have been performed as in (c) above on humans:

.....

(e) the following are particulars of the purpose, mode of action, side effects, contra – indications of the medicine:

.....

(f) the following data relating to the pharmacokinetics and the bioavailability of the medicine in humans and animals is attached .

.....

(g) state details of medicine residue in species intended for human consumption:

.....

(h) state details of withdrawal periods for species intended for human consumption

Form M.C.8

APPENDIX V

Name of applicant

.....

Name of medicine

.....
The form in which the medicine is presented and the colour thereof
.....

(a) the following are references to literature about the medicine:
.....
.....

(b) the attached are relevant documents concerning the medicine:
.....
.....

(c) twenty copies of the package inserts or draft package inserts and twenty labels or copies
of packages are attached:
.....
.....

(d) all proposed advertising and promotional material is attached :
.....
.....

(e) samples have been submitted by registered post/by hand* to the Director-General .
.....
.....

*Delete the inapplicable

Form M.C.9

**MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]
APPLICATION FOR RETENTION OF REGISTRATION OF A REGISTERED
MEDICINE**

(To be submitted in duplicate)

To be sent to the Director-General, Medicines Control Authority P O Box UA 559, Union
Avenue, Harare, or to be lodged at the offices of the Director-General, Medicines Control
Authority, 106, Baines Avenue, Harare, annually, on or before the 1st July.

PARTICULARS OF APPLICANT AND MEDICINE

Name of applicant
.....

Postal address
.....

Name of distributor
.....

Postal address
.....

Registered name of medicine
.....

Registration number of medicine
.....

The form in which the medicine is presented and the colour thereof

.....
Date of original registration
.....

Have any alterations taken place in the information submitted in the original application for the registration of the medicine and/or since the last renewal of the retention of the registration of the medicine? YES/NO*

If YES, state details
.....

Has the country of origin of the medicine cancelled or modified in any way the registration of the medicine? YES/NO

If YES, give details
.....

Is the medicine manufactured, partially manufactured, repacked or relabelled in Zimbabwe?
.....
.....

Address where registration certificate will be kept

I enclose the fee of

Date

.....
Signature of applicant

**Delete the inapplicable*

Form M.C. 10

**MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]
APPLICATION FOR AUTHORIZATION TO CONDUCT A CLINICAL TRIAL**

(To be submitted in duplicate)

1. Particulars of applicant
.....

If an individual: Full names
.....

Date and place of birth
.....

Qualifications
.....

Address (Home)
.....

(Business)
.....

If a company: Name of company
.....

Physical address
.....
.....

Registered Office
.....
.....

Postal address

.....
.....

Telephone number

.....

Position of person in the company who is making the application on behalf of the

.....

State the main field of manufacture of the company, if applicable

.....
.....

2. State the name of the medicine, its chemical composition, graphic and empirical formulae, animal pharmacology, toxicity and teratology as well as any clinical or field trials in humans or animals, or any other relevant information and supply reports, if any

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

3. State any adverse or possible reactions to the medicine

4. State therapeutic effects of the medicine.

5 —

- (a) has the medicine been registered in the country of origin? YES/NO*

if YES, a valid certificate of registration in respect of such medicine issued by the appropriate authority established for the registration of medicines in the country of origin shall accompany this application;

if NO, state details

.....
.....

- (b) have clinical trials been conducted in the country of origin? YES/NO*

If YES, state details

.....
.....

If NO, give reasons why

.....
.....

- (c) has an application for the registration of the medicine been made in any other country? YES/NO*

If YES, state details including the date on which the application was lodged

.....
.....

- (d) has the medicine been registered in any other country? YES/NO*

if YES, state details

.....
.....

- (e) has the registration of the medicine been rejected, refused, deferred or cancelled in any country? YES/NO*

if YES, state details

.....
.....

(f) What is the status of the medicine in Zimbabwe?

*Tick (✓)
whichever is
appropriate*

Registered _____

Unregistered..... _____

Application for registration has been submitted..... _____

6. State the names (s), address (es) and telephone number (s) and qualifications of the person(s) who will conduct the trial
.....
.....

7. State the name, physical address and telephone number of the institution or the places where the trial will be conducted

Name	Qualifications	Address and telephone number (Business)	Address and telephone number (Home)
.....			
.....			
.....			

8. State the purpose of the trial and the reasons therefor
.....
.....

9. State the time period of the trial
.....

10. Description of the type of trial (e.g. controlled, open) trial design (e.g. parallel groups, crossover technique), blind technique (e.g. double blind, simple blind) randomisation (e.g. method and procedure) or any other type of trial
.....

11. Description of participants (e.g. age group of persons or animals, type or class of persons or animals, sex, etc.)
.....

12. Criteria for inclusion or exclusion of participants
.....

13. Number of participants expected to take part in the trial and a justification thereof (e.g. based on statistical considerations)
.....

14. Administration route, dosage, dosage interval and period for the medicine being tested and the medicine being used as a control
.....
- 15 Control groups (placebo, other therapy, etc.)
.....
- 16—
 - (a) state whether any other medicine will be given concomitantly. YES/NO*; if YES, state the name of the medicine
.....
 - (b) state whether a person already on another medicine will be given the experimental medicine at the same time or whether the participant will be taken off the other medicine
.....
- 17 Recording of effects: Give a description of the methods of recordings and times of recordings
.....
- 18 State clinical and laboratory tests, pharmacokinetic analysis etc. that are to be carried out
.....
- 19 State the method of recording adverse reactions and provisions for dealing with same and other complications
.....
- 20 State antidote
.....
- 21 State the procedure for the keeping of participant lists and participant records for each participant taking part in the trial†
.....
- 22 State where the trial code will be kept and how it can be broken in the event of an emergency
.....
.....
- 23 State the measures to be implemented to ensure the safe handling of medicines and to promote and control compliances with the prescribed instructions
.....
.....
- 24 Evaluation of results, state the description of methodology (e.g. statistical methods)
.....
.....
- 25 State how the persons or owners of animals are to be informed about the trial
.....
.....
- 26 State how the staff involved are to be informed about the way the trial is to be conducted and about the procedures for medicine usage and administration and what to do in an emergency
.....
.....

.....
27 State whether there are any ethical or moral considerations relating to the trial, giving details

.....
28 State the name and address of the company who will insure all the participants in the proposed trial††
.....
.....
.....

29 State the amount of insurance in respect of each participant
.....

30 State the quantity of the medicine for which exemption is required if the medicine is not registered
.....

31 Particulars of persons who will take part in the clinical trial†††

	Name	Occupation	Address	Date and place of birth
1.				
2.				
3.				

32 .Particulars of animals that will take part in the clinical trial—

Kind and breed of animal
.....

Age of animal, if known.....

Name and addresses of owners of animals

	Name	Address
1.		
2.		
3.		

33 Attached is a sample of the medicine, together with methods of analysis and storage conditions

Date.....

.....
Signature of applicant

Countersignature of medical superintendent or senior medical officer if the clinical trial is to be conducted in a hospital or a medical institution ††††

Date.....

NOTES

**Delete the inapplicable*

† item 21: Records should permit easy identification of individual participants.

- †† item 28: A letter from the insurance company shall be attached to the application. indicating the insurance company's consent to the proposed insurance and a copy of the proposed insurance policy.
- ††† item 31: The consent of each person or the guardian of such person who will participate in the trial is required to be attached to the application in Form M.C. 17. The consent of each owner of an animal which will participate in the trial is required to be attached to the application in Form M.C. 18.
- †††† this item should be countersigned by a veterinary surgeon if the trial is to be conducted in a veterinary hospital.

FOR OFFICAL USE ONLY

1 Director-General's comments on the application

.....

2 Authority's comments on the application

.....

3 Application approved/disapproved by the Secretary.
Comments

.....
.....

Date

.....
Secretary for Health

Form M.C. 10A
Licence No.....
File No.....

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03] APPLICATION FOR LICENCE TO IMPORT PSYCHOTROPIC SUBSTANCES AND CORRESPONDING IMPORT CERTIFICATE

(Medicines and Allied Substance Control (General) Regulations 1991)

Attention is drawn to the instructions appearing overleaf. Delay will be caused if these instructions are not followed, or if any of the questions below are not answered or if the declaration is not signed.
(See Instruction 7.)

SEPARATE APPLICATIONS MUST BE SUBMITTED IN RESPECT OF EACH CONSIGNMENT TO BE IMPORTED

(a) Full name and address of Importer (see Instruction 1):

.....

(b) Full name and address of Consignor in exporting country:

.....
.....

- (c) Substances are to be imported * by sea and /or rail via
 * by road via
 *by air-freight via
 and will be imported throughCustoms Office (State port of entry)

*Delete the inapplicable words

- (d) Approximate date of arrival

- (e) State the purpose for which the substances are required

.....

(if vague reasons only are given, further inquiries may be necessary, see Instruction 5)

- (f) Particulars of each item to be imported (see Instruction 6)

Item No	Quantity	Full Description of each item	Active principal content (in grammes)	Stocks on hand

I hereby declare that to the best of my knowledge and belief all the particulars in this application are correctly stated, and in particular that the substances, if their importation is allowed, will not be used for any purposes other than stated in paragraph (e)

Signed (see Instruction 7)

Status

If on behalf of a company, state position in company

NB – This form must be signed in accordance with Instruction 7 and your attention is particularly drawn to section 68 (1) (b) of the Medicines and Allied Substances Control Act [Chapter 15:03]

ON REVERSE SIDE OF FORM INSTRUCTIONS FOR COMPLETING THIS FORM

Non- compliance with these instructions will involve delay

Note— An Import Licence is an authority solely for the importation of a particular consignment, and must be produced to the Customs Officer at the time of importation.

An Importation Certificate is for transmission to the consignor in the exporting country, for submission to his Government in support of his application for authority to export the consignment . It is not authority for the admission of the consignment into Zimbabwe.

1. An application will, in ordinary circumstances, be entertained only if made by a person or company resident in Zimbabwe. They must always be made by the actual importer and not be a forwarding agent (i.e. shipping agent or other such person) on his behalf.
2. Import Licences under the Medicines and Allied Substances Control Act [Chapter 15:03]. are required for psychotropic substances to which the Act applies.
 Copies of the Act and Regulations made thereunder may be obtained from the Publications Office, Department of Printing and Stationery, Cecil House, Jason Moyo Avenue, Harare, P O Box CY 341, Causeway, Harare, Zimbabwe; or from Zxnet, 5,

Maasdorp Avenue, Belgravia, Harare, P.O.Box CY 1030, Causeway. Phones 2634 - 252785-7.

- 3 A separate licence is required in respect of each consignment.
- 4 The appropriate application fee must be forwarded with the application. Cheques, postal orders and money orders must be made payable to the Medicines Control Authority of Zimbabwe.
- 5 Paragraph (e). The applicants should state the exact use for which the importation is required, e.g. for medicinal, dental or veterinary use or for the purpose of being sold or supplied to some other person in accordance with the provisions of the Act.
- 6 Paragraph (f) The following should be carefully observed:
 - (a) not more than one item should appear on each line provided in this space. Preparations of the same psychotropic substance should be grouped together. Where the details of the items exceed ten lines of typing, six copies of a schedule giving the requisite particulars should be furnished instead of including them in the table.
 - (b) each item should be described fully. In the case of ampoules, the total quantity of the psychotropic substances and volume of liquid in each ampoule, and not the quantity intended to be administered, must be stated.
 - (c) the official conversion factors must be used in determining the active principal content, the name of which must be stated.
- 7 Signing of form. The declaration on the front page must be signed by the actual importer, or in the case of a company, by a person authorized under the Act to procure medicines. In either case, the person signing must insert under " status " the class of authorized person to which he belongs.

All application must be addressed to :
The Director-General
Medicines Control Authority of Zimbabwe
P O Box UA 559
Union Avenue
Harare
Zimbabwe.

Form M.C. 10B
Licence No.....
File No

**MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]
APPLICATION FOR EXPORT LICENCE OR MOVEMENT LICENCE OF
PSYCHOTROPIC SUBSTANCES**

(Medicines and Allied substances Control (General) Regulations, 1991)

Attention is drawn to the instructions appearing overleaf.
It is requested that the form be filled in legibly, preferably typewritten.

(a) Full name and address of supplier

.....

(b) State method by which the psychotropic substances are to be exported

Rail

Air Freight.....

Road

Sea

(c) State port or customs office through which the psychotropic substances are to be exported
.....

(d) Full name and address of person to whom the psychotropic substances are to be supplied
(as stated in Import Certificate, if any)
.....
.....

(e) State whether the psychotropic substances are to be dispatched alone, or form part of
miscellaneous order
.....

(f) Particulars of each item to be supplied (See Instruction 3)

Item No	Quantity	Full Description of each item	Active principal content (in grammes)	Stocks on hand

I hereby declare the to the best of my knowledge and belief all the particulars in this application are correctly stated, and I undertake that if this licence is granted to me, it shall be used solely for the supply of psychotropic substances being my own property or the property of a person or company for whom I am authorized to act in this transaction as the sole responsible representative.

Signed.....

Status.....

Date

If on behalf of a company, state position in company.....

NB - This form must be signed in accordance with Instruction 4 and your attention is particularly drawn to Section 68 (1) (b) of the Medicines and Allied Substances Control Act [Chapter 15:03]

**ON THE REVERSE SIDE OF FORM
INSTRUCTIONS FOR FILLING IN THIS FORM**

Non – compliance with these instructions will involve delay

- 1 Export Licences and Movement Licences under the Medicines and Allied Substances Control Act [Chapter 15:03], are required for all psychotropic substance to which the Act applies
- 2 The appropriate application fee must accompany each application. Cheques, postal orders and money orders must be made payable to the Medicines Control Authority of Zimbabwe (No fee is charged for Movement Licences)

- 3 Paragraph (f) The following should be carefully observed :—
 - (a) not more than one item should appear on each line proved in this space. Preparations of the same psychotropic substance should be grouped together. Where the details of the item exceed ten lines of typing, six copies of a schedule giving the requisite particulars should be furnished instead of including them in the table.
 - (b) each item should be described fully. In the case of ampoules, the total quantity of the psychotropic substances and volume of liquid in each ampoule, and not the quantity intended to be administered, must be stated.
 - (c) the official conversion factors must be used in determining the active principal content, the name of which must be stated.
- 4 Signing of form. The declaration on the front page must be signed by a person authorized under the Act to supply medicines and domiciled in Zimbabwe, otherwise the application cannot be accepted. The person signing must insert under: “ status ” the class of authorized person to which he belongs.
- 5 The consignment must be addressed exactly as stated in the licence.

All applications must be addressed to :—
 The Director-General
 Medicines Control Authority of Zimbabwe
 P O Box UA 559
 Union Avenue
 Harare
 Zimbabwe

Form M.C. 11

**MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]
 APPLICATION FOR THE ISSUE OF A PERMIT TO SELL VETERINARY**

MEDICINES

- 1 Particulars of proposed permit holder –
 - If an individual: Full names
 - Address (Business).....
 -
 - Telephone number (Business).....
 - If a company : Name of company
 - Address.....
 -
 - Telephone number.....
 - Registered office
 - Main object of the company
 -
- State shareholders and distribution of shares or nominees.....

PARTICULARS OF DIRECTORS

Name	Address
1.	
2.	
3.	
4.	

Position of applicant in the company

3 Name under which business is conducted
.....

4 Name (s) of agents, if any
1.....
2.....

5 Applicant's general dealer's licence receipt number.....

6 Local authority

I am familiar with the regulations and conditions relating to the sale of veterinary medicines
Date.....

.....
Signature of applicant

Form M.C. 11A

Licence No.....

File No

**MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]
APPLICATION FOR LICENCE TO EXPORT TABLE I SUBSTANCE**

(Medicines and Allied Substances Control (General) Regulations 1991)

1.-
(a) Full name and address of applicant
.....
Telephone and Fax numbers
.....

2. Name of Table I substance and amounts to be exported

3. State method by which the Table I substance(s) are to be exported:
(Rail, Road, Air Freight).....

4. State port or customs office through which the Table I substances are to be exported:
.....

5. Expected date of dispatch.....

6. Expected point of entry in importing country.....

I hereby declare that to the best of my knowledge and belief all the particulars in this
application are correctly stated, and I undertake that if this licence is granted to me, it shall be
used solely for the supply of Table I substances.

Signed..... Status.....

Date.....

If on behalf of a company, state position in company.....

Notes:

- 1 The appropriate application fee must be forwarded with the application.
Cheques, postal orders and money orders must be made payable to the Medicines Control Authority of Zimbabwe.
- 2 All applications must be addressed to:—
The Director-General
Medicines Control Authority of Zimbabwe
P O Box UA 559
Union Avenue
Harare
Zimbabwe

PART II
FORMS OF LICENCES, PERMITS, CERTIFICATES, ETC.

Form M.C. 12

MEDICINES AND ALLIED CONTROL ACT [CHAPTER 15:03]
LICENCE FOR PREMISES

(Specify type of licence)

(Pharmacy, dispensing medical practitioner, veterinary surgeon, manufacturer, clinic, other*)

Licence Number.....

- 1 Licensee
.....
- 2 In the case of a company –
Names of Directors Citizenship
.....
.....
.....
- 3 Type of premises licensed
.....
- 4 Description of licensed premises
.....
- 5 Location of premises
.....
- 6 Name of person practising or carrying on business on licensed premises
.....
- 7 Name of business
.....
- 8 Conditions of issue/renewal* imposed by the Authority
.....
.....
- 9 The premises shall, for the purposes of section 55 of the Act, be under the personal supervision of the following person (s) –
Name Licence number
.....
.....

**MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]
LICENCE FOR PERSONS**

(Pharmacist, dispensing medical practitioner, veterinary surgeon, other*)

Licence number.....

1. Licensee
.....
2. Place of employment
.....
3. Type and name of business
.....
4. Conditions of issue/renewal* imposed by the Authority
.....
5. Date of issue/renewal* of licence
.....

Code area

Code type

.....
Director-General of Medicines

*Delete the inapplicable

**MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]
WHOLESALE DEALER'S PERMIT**

Permit number.....

1. Name of permit holder
.....
2. Location of premises
.....
3. Name of person (s) under whose personal supervision the premises will be
.....
4. Conditions of issue/renewal* imposed by the Authority
.....

Date of issue/renewal* or permit.....

Expiry date of permit.....

Code area

Code type

.....
Director-General of Medicines

*Delete the inapplicable

**MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]
SALES REPRESENTATIVE'S PERMIT**

Permit number

- 1 Name of sales representative
.....
 - 2 Employer's or principal's name
.....
 - 3 Conditions of issue/renewal* imposed by the Authority
.....
.....
 - 4 Date of issue/renewal of permit
.....
 - 5 Expiry date of
permit.....
- Code area
- Code type

This permit authorizes the holder to solicit and receive orders for medicines and to procure, possess and distribute the medicines listed herein .

.....
Director-General of Medicines

*Delete the inapplicable

In terms of subsection (3) of section 21 of the Medicines and Allied Substances (General) Regulations, 1991, this permit expires simultaneously with the termination of employment with

.....
.....
.....
the person specified in item 2 of the permit.

**MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]
REGISTRATION CERTIFICATE**

Number.....

It is hereby notified that a medicine has been registered as follows:

1. Approved name of medicine

-
2. Trade mark of medicine
.....
3. The form in which the medicine is presented and the colour thereof
.....
4. Approved name and active ingredient(s) and strength
.....
5. Registration number of medicine
.....
6. Shelf life of medicine in months
7. Category for distribution of medicine
8. Name and address of manufacturer (s)
.....
.....
.....
9. Name and address of principal
.....
10. Name and address of applicant
.....
11. Address at which certificate will be kept
.....
12. Date of original registration
.....
13. The medicine will be.....Zimbabwe
14. Conditions of registration imposed by the Authority
.....
.....
15. Date of issue of certificate

Issued at Harare this day of 20...

.....
Director-General of Medicines

*Delete the inapplicable

This certificate must be returned to the Authority if cancelled, invalidated or if the registration of the medicine is withdrawn or when requested to do so by the Director-General. Failure to do so is an offence.

**MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]
CONSENT OF PERSON WHO WILL PARTICIPATE IN A CLINICAL TRIAL**

I, (state full name)

born on the 20 , of (state address)

do hereby confirm that I have freely consented to participating in this clinical trial to be conducted by

(state name of institution or place where the trial is to be conducted)

for the purpose of

Date.....

Signature of person

Guardian's signature, if necessary

Form M.C. 18

**MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]
CONSENT OF OWNER OF ANIMAL WHICH WILL PARTICIPATE IN A
CLINICAL TRIAL**

I, (state full names)

of (state address)

do hereby confirm that I have freely given my consent for my (state kind of animal)

to participate in the clinical trial to be conducted by

at (state name of the institution or place where the trial is to be conducted)

for the purposes of

Date

.....
Signature of owner of animal

Form M.C. 19

**MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]
AUTHORIZATION TO CONDUCT A CLINICAL TRIAL IN RESPECT OF**

IT is hereby notified that the Medicines Control Authority has, in term of subsection (2) of section 18 of the Medicines and Allied Substances Control Act [Chapter15:03], with the approval of the Secretary for Health, authorized

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

to conduct a clinical trial in respect of

subject to the contents of the application and subject to the following conditions:—

- 1.
- 2.
- 3.

Date :

.....
for: Medicines Control Authority

Form M.C. 20

**MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]
INDEMNITY FORM FOR CONDUCTING CLINICAL TRIALS**

I/We

.....
to whom authority has been granted in terms of section 18 of the Medicines and Allied Substances Control Act [Chapter 15:03] to utilize the medicine for the purpose of conducting a clinical trial therewith upon persons/animals, declare that I/We have read and understood the conditions contained in such authority and hereby indemnify the State, the Secretary for Health and the Authority (and any committee thereof) from liability in respect of any injury or adverse effect whatsoever which may be sustained by any person or animal, directly or indirectly, as a result of the conduct of the trial and which occurs or reveals itself at the time of the trial or subsequently (at any time) and further indemnify the aforementioned against any claim for damages, howsoever arising, notwithstanding the proviso to section 64 of the said Act.

Dated at this day of 20...

Form M.C. 21

**MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]
PERMIT TO SELL VETERINARY MEDICINES**

1. Name of permit holder
.....
.....

2. Address of premises
.....
.....
.....

The holder of this permit is authorized to sell veterinary medicines from the above – mentioned premises

This permit, unless revoked earlier is valid until the 31st December 20....

Date of issue.....

Director-General of Medicines

Form M.C. 22

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]
INFORMATION RELATING TO FORFEITED PROHIBITED MEDICINES
(To be submitted in duplicate)

To be sent to the Director-General, Medicines Control Authority P. O. Box UA 559, Union Avenue, Harare or to lodged at the offices of the Director-General, Medicines Control Authority, 106, Baines Avenue, Harare.

PARTICULARS OF CRIMINAL PROCEEDINGS:

1. Name(s) of accused person(s)
2. Court
3. Court Record Book No
4. CR No
5. Results of case – Convicted/Acquitted*
Sentence, if applicable

PARTICULARS OF MEDICINES

- 1 Name (s) of medicine (s)
.....
- 2 Form in which medicine is presented
.....
- 3 Quantity
.....

Date

.....
Signature of Registrar of the High Court
/Clerk of the Magistrate's Court*

* Delete the inapplicable

**MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]
INFORMATION RELATING TO SEIZED PROHIBITED MEDICINES
(To be submitted in duplicate)**

To be sent to the Director-General, Medicines Control Authority, P O Box UA 559, Union Avenue, Harare or to be lodged at the offices of the Director-General, Medicines Control Authority, 106, Baines Avenue, Harare.

**PARTICULARS OF PERSON WHO HAS SEIZED PROHIBITED MEDICINES
FORFEITED IN TERMS OF SECTION 52 OF THE ACT**

1. Name of police officer or other public officer :
.....
2. Name and address of employer:
.....
3. State circumstances on seizure of medicines:
.....
.....

PARTICULARS OF MEDICINES SEIZED

1. Name of medicine:
.....
2. Form in which medicine is presented:
.....
3. Quantity :
.....

Date:

.....
Signature of police officer or other
public officer*

* Delete the inapplicable

**MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]
JOINT DECLARATION OF DESTRUCTION OF FORFEITED PROHIBITED
MEDICINES**

WE the undersigned, being members of the panel constituted in terms of section 50 (3) of the Medicines and Allied Substances Control Act [Chapter15:03], hereby declare that we have today in the full view and presence of each other at

.....
.....
assisted

Director-General of Medicines in the destruction of the under-mentioned forfeited prohibited medicines and that the said medicines have been totally destroyed by incineration in accordance with the provisions of section 50 of the said Act.

PARTICULARS OF MEDICINES DESTROYED

Name of medicine:

.....

Form in which medicine is presented.....

Quantity

*1 Particulars of criminal proceedings resulting in forfeiture of medicines —

Court

Court Record Book No.

Name (s) of accused person(s)

.....

.....

Date medicines received by Director-General from court

Police Station and C.R. No

*2. Particulars of forfeiture of medicines in terms of section 52 of the Act —

Name of police officer or other public officer:

State circumstances on how medicines were seized:.....

.....

.....

Subscribed to and signed at

this day of 20

.....
(Name, rank and force number)

Designated by Commissioner of Police.

.....
(Name and post held)
Designated by Commissioner of
Customs and Excise

.....
(Name and post held)
Designated by Attorney-General

Countersigned by:

Director-General of Medicines.....

*Delete the inapplicable item

Form M.C. 25

**MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]
CERTIFICATE OF INSPECTOR, CUSTOMS OFFICER OR POLICE OFFICER
TAKING A SAMPLE OF A MEDICINE OR SUBSTANCE**

I hereby certify that the accompanying is (are) a sample (s) of a medicine or substance* taken
on

.....
at (1)

.....
in the presence of (2)

.....
being the owner/seller/person in charge of the medicine/substance*/witness.

PARTICULARS IN CONNEXION WITH THE SAMPLE(S)

- (a) Name of medicine or substance
.....
- (b) Name and business address of manufacturer of sample
.....
- (c) Name and business address of owner or seller of sample
.....
- (d) Estimated quantity of sample
.....
- (e) Batch number appearing on label of sample
.....
- (f) Expiry date appearing on label of sample
.....
- (g) Other particulars appearing on label of sample.....
- (h) Sample marked or labelled as follows
.....
- (i) Type of seal used
.....
- (j) Any other appropriate particulars (e.g. package insert)
.....
.....

I.....
being the owner/seller/person in charge of the medicine/substance*/witness confirm that the particulars contained herein are correct and the sample was divided into three samples and sealed in accordance with the provisions of subsection (3) of section 64 of the Act.

.....
Owner/seller/Person in charge/witness* (3)

.....
Inspector, customs officer, police officer*

Date:.....

*Delete the inapplicable

Notes (1), (2) and (3)

1. Full address.
2. Name and full address of owner/seller/person in charge/witness*.
3. This form is not an admission of guilt.

A copy of this certificate together with a part of the sample shall be handed or forwarded by registered post to the owner or seller of the medicine or substance, or to his agent.

**MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]
CERTIFICATE BY ANALYST OR RESULTS OF TEST OR EXAMINATION OR
ANALYSIS OF A MEDICINE OR SUBSTANCE**

I, (full name):

.....

a duly appointed analyst in terms of paragraph (b) of subsection (1) of section 65 of the
Medicines and Allied Substances Control Act [Chapter 15:03], hereby declare that on
(date)

.....

I received a sample of (1)

.....

quantity (2)

.....

from (3)

.....

for (4) test, examination, analysis; that sample was marked as follows: (5)

.....

and sealed as follows (6)

.....

that I have (4) tested, examined and/or analysed the sample and found the results, which are
annexed hereto.

Summary of results:

.....

.....

Date:

Analyst:

Notes: (1), (2), (3), (4), (5) and (6)

1. Name of contents as described on the label.
2. Quantity.
3. Name of person from whom sample was received.
4. Delete whichever is not applicable.
5. Name of manufacturer, batch number and any other particulars on the label.
6. Manner of seal.

**MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]
LICENCE TO IMPORT PSYCHOTROPIC SUBSTANCES**

- 1 Name of importer :
.....
- 2 Address:
.....
.....
- 3 Telephone and Fax numbers:
.....
4. Name of psychotropic substance to be imported:
.....
5. International non-proprietary name of psychotropic substance:
.....
6. Quantity to be imported:
.....
7. Dosage form of psychotropic substance:
.....
8. Name of preparation (finished product):
.....
9. Name of country from which psychotropic substance is being imported:
.....
- 10 Name and address of person, company organization etc, from whom psychotropic substance is being obtained (exporter):
.....
.....
.....
- 11 Period within which importation must be effected:
.....
- 12 Port of entry:
.....
- 13 The psychotropic substances stated herein have been*/have not been* approved for importation to a bonded warehouse:
.....
- 14 Date of issue of licence:
.....

Director-General of Medicines
Control Authority of Zimbabwe

*Delete the inapplicable

ON REVERSE SIDE OF FORM CONDITIONS

1. The licence does not in itself authorize the licensee to be in possession of or to supply the psychotropic substance imported.
2. The licence does not relieve the licensee from compliance with any Customs regulations in force for the time being relating to the importation of goods into or trans-shipment of goods in Zimbabwe.
3. The licence is valid only for the licensee and may be revoked at any time by the Medicines Control Authority of Zimbabwe, in which event it shall be immediately surrendered. It shall be produced for inspection when required by any person duly authorized under the Act.

4. Unless the licence is sooner revoked, it shall be produced to the Customs Officer at the time of importation, or, if the importation is not effected before the date specified overleaf, the licence shall immediately after that date be surrendered to the Director-General of the Medicines Control Authority of Zimbabwe.

ENDORSEMENT BY CUSTOMS OFFICER AT TIME OF IMPORTATION

I hereby certify that the person named overleaf has imported the consignment thereon specified* by**sea or rail/air freight/road transport.

Signature of Customs Officer:

Rank:

Port:

Date:

OFFICE STAMP

*if the whole consignment for which the licence has been granted is not imported the Customs Officer should suitably amend the certificate above, and insert below the actual amount or item imported.

**Delete whichever is inapplicable

Amount	Description of items
--------	----------------------

This licence when completed, must be returned immediately by the Customs Officer to:
The Director-General
Medicines Control Authority of Zimbabwe
P O Box UA 559
Union Avenue
Harare
Zimbabwe.

Form M.C. 28
Licence No
File No

**MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]
LICENCE TO EXPORT PSYCHOTROPIC SUBSTANCES**

- 1 Name of exporter :
.....
- 2 Address:
.....
.....
.....
- 3 Telephone and Fax numbers:
.....
4. Name of psychotropic substance to be exported:
.....
5. International non-proprietary name of psychotropic substance:
.....

6. Quantity to be exported:
.....
7. Dosage form of psychotropic substance:
.....
8. Name of preparation (finished product):
.....
9. The substance will be exported through the Customs Office at:
.....
10. Name of country to which export is being made:
.....
11. Name and address of person, company, organization etc, to whom export is being made:
.....
.....
.....
12. Port of entry in importing country:
.....
13. The psychotropic substances stated herein have been*/ have not been* approved for importation to a bonded warehouse/free zone*:
.....

Item No	Description	Quantity and Active principal content in (grammes)
---------	-------------	--

FOR OFFICIAL USE ONLY

14. Number of Import Certificate:
.....
15. Date of Import Certificate :
.....
16. Name of authority, which has issued Import Certificate :
.....
17. Date of issue of licence:
.....

*Delete the inapplicable

CONDITIONS OF LICENCE

- (a) The psychotropic substance must be exported within three months of the date of issue of this licence.
- (b) The licence is valid only for the psychotropic substances of the exact quantity, kind and form specified.
- (c) The consignment shall be addressed exactly as stated in the licence.
- (d) The duplicate copy sent to the exporter (or supplier) shall be placed inside the outer wrapper of the parcel containing the psychotropic substances. If the psychotropic substances are contained in more than one parcel, the duplicate copy shall be placed inside the wrapper of one of them, the parcels shall be consecutively numbered on the outer wrapper, and on each parcel there shall be legibly stated the number of the parcel in which the duplicate copy is to be found.
- (e) No psychotropic substance to which this licence refers, may be exported or supplied by ordinary or registered letter post.
- (f) The licence is not transferable.

Director-General of Medicines
Control Authority of Zimbabwe
Medicines Control Authority of Zimbabwe

P O Box UA 559
Union Avenue
Harare
Zimbabwe.

Note;

1. If any alteration is desired in this licence it must be returned with a request for amendment and a statement of the reasons therefor. No unauthorized alteration is permissible.
2. Failure to comply with paragraph (d) may lead to delay or confiscation of the consignment in the country of destination.

Form M.C. 29
Licence No
File No

**MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]
Declaration Relating to Certain Psychotropic Substances in
Part II of the Eighth A Schedule**

1. Name and address of exporter:

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

Telephone and Fax Numbers:

2. Name and address of person to whom the psychotropic substance is being exported to:

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

Telephone and Fax numbers:

3. International non-proprietary name of psychotropic substance or other designation of such substance:

.....

4. Quantity being exported:

5. Dosage form of psychotropic substance or name of preparation if the substance is being exported in the form of a finished product:

6. Date of dispatch:

I/We the undersigned confirm that the particulars contained herein are correct and true.

Date Signature of exporter

Form M.C. 30
Licence No
File No

**MEDICINES AND ALLIED SUBSTANCES CONTROL ACT[CHAPTER 15:03]
Licence to Export Table I Substances
(Table I Substances of the Sixteenth Schedule to the Medicines and Allied Substances
Control (General) Regulations, 1991)**

1. Name of exporter:
2. Address:
3. Telephone and Fax numbers:
4. Name of substance to be exported:
5. International non-proprietary name of substance:
6. Active principal content (in grammes):
7. Quantity to be exported:
8. Name of country to which export is being made:
9. Name and address of person, company, organization etc, to whom export is being made:
10. The substance will be exported through the Customs Office at:
11. Name and address of consignee, where appropriate:
12. Name of expected point of entry in importing country:
13. Expected date of dispatch of substances:

Director-General of Medicines
Control Authority of Zimbabwe

FOR OFFICIAL USE ONLY

Date of issue of licence:

Third Schedule (Section 7) **MINIMUM REQUIREMENTS FOR PREMISES**

1 Manufacturing Premises—

An applicant shall comply with the requirements set out in the Good Manufacturing Practice (G.M.P.) which may be obtained at the offices of the Director-General, Medicines Control Authority, 106 Baines Avenue, Harare, or P.O. Box UA 559 Union Avenue, Harare, and any other requirements as may be required by the Authority.

2 All other premises—

- (a) satisfactory cleanliness, lighting, ventilation, tidiness, security, toilet facilities, washable impervious floor, washable painted walls and shelves;
- (b) wash hand basin and sink with hot and cold water;
- (c) storage of medicines; adequate protection from light, heat, moisture; prescription preparations to be out of reach of public; special storage place for dangerous medicines, namely fixed and lockable cupboards;

- (d) equipment; sufficient and adequate measures, balance and weights*; adequate refrigeration, mortar and pestle*, counting tray spatulas, sterilizing facilities;
- (e) prescription recording system: satisfactory prescription record (e.g. microfilm, computer, photocopy or patient profile cards or other approved recording system);
- (f) reference books: satisfactory reference books (e.g. latest Martindale, or British National Formulary, or next to latest British Pharmacopoeia or latest Pharmaceutical Codex or other approved references);
- (g) legislation: Medicines and Allied Substances Control Act [Chapter 15:03] as amended and up to date regulations made thereunder; Dangerous Drugs Act [Chapter 15:02] as amended and up to date regulations made thereunder;
- (h) containers: cardboard cartons, vial, bottles (plastic/glass) and no other containers whatsoever unless approved by the Authority in writing; stock bottles for tablets, capsules and liquids;
- (i) any other requirements as may be required by the Authority.

*Medical practitioners, veterinary surgeons and clinics may be exempted from obtaining these items.

FOURTH SCHEDULE (Section 8 (a) (ii))

REQUIREMENTS OF PLANS ACCOMPANYING APPLICATIONS TO AUTHORITY

- A. Every plan or set of plans of premises proposed to be licensed shall—
 - (a) show the premises in plan, section and elevation;
 - (b) be to a scale of 1:100 (metric);
 - (c) have figures thereon the sizes of rooms, passages and stairways (if any), the position and types of windows, and the means of external and internal communications;
 - (d) have indicated thereon the use to which rooms are to be put, with particular reference to store rooms showing in details the types and positions of fittings and equipment;
 - (e) be amplified by notes explaining the systems of ventilation and lighting, and the finishing of roofs, ceilings, walls and floors, and any other relevant information;
 - (f) have indicated thereon the layout of the premises, including the designation of areas for use (e.g. dispensing area, location of shelves for cosmetic, hazardous substances, etc, store rooms or cupboards for storing dangerous medicines, cupboards to be used for storing medicines to be destroyed etc.);
 - (g) have indicated thereon security of the premises against entry and theft (e.g. burglar bars, alarms, etc.).

- B. Every site of premises proposed to be licensed shall be shown clearly on a plan to a scale of not less the 1:500 (metric), which plan shall also show—
 - (a) the north point;
 - (b) the area, in square metres, of the site;
 - (c) the development on the site, including, particularly, the position of every existing building and of any proposed new building and the use to which such buildings are being, or are proposed to be put;
 - (d) the drainage arrangements, sewerage-disposal system and the nature and situation of the water-supply;
 - (e) the developments, particularly buildings, on all neighbouring sites which abut the site of the premises to be licensed;
 - (f) the surrounding streets in urban areas, or the roads in rural areas (indicating the places to which they lead and the relevant road distances therefrom), and the position and form of access from such streets or roads to the premises proposed to be licensed.

FIFTH SCHEDULE (Section 34)

PHARMACOLOGICAL CLASSIFICATION CATEGORIES OF MEDICINES

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
 - 1.4 Others *[inserted by S.I. 199 of 1998 with effect from 7 August, 1998.]*
2. Analgesics and antipyretics
 - 2.1 Single ingredient products
 - 2.2 Compound products
 - 2.3 Others *[inserted by S.I. 199 of 1998 with effect from 7 August, 1998.]*
3. Medicines used in rheumatism and gout
 - 3.1 Nonsteroidal anti-inflammatory medicines
 - 3.2 Medicines for gout
 - 3.3 Special antirheumatic medicines
 - 3.4 Others *[inserted by S.I. 199 of 1998 with effect from 7 August, 1998.]*
4. Narcotic analgesics/narcotic antagonists
 - 4.1 Narcotic analgesics
 - 4.2 Narcotic antagonists
5. Antihistamines
6. Antidotes
 - 6.1 General
 - 6.2 Specific
 - 6.3 Medicines used in the treatment of addictions:
 - 6.3.1. Alcohol
 - 6.3.2. Nicotine
 - 6.3.3. Narcotics
 - 6.3.4 Psychotropic
 - 6.3.5 Others
7. Anti – infective medicines
 - 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 Antifilarials
- 7.12 Antifungals (systemic)
- 7.13 Antivirals
- 7.14 Urinary antiseptics
- 7.15 Others *[inserted by S.I. 199 of 1998 with effect from 7 August, 1998.]*
- 8. Antimigraine medicines
- 9. Antineoplastic and immunosuppressive medicines
 - 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 analogues
 - 9.2.3 Purine analogues
 - 9.3 Natural products and their derivatives:
 - 9.3.1 Vinca alkaloids
 - 9.3.2 Antibiotics
 - 9.3.3 Enzymes
 - 9.4 Miscellaneous cytotoxic agents
 - 9.5 Hormones and hormone inhibitors
 - 9.5.1 Hormones
 - 9.5.2 Hormone inhibitors
 - 9.6 Immunosuppressive agents
 - 9.7 Others *[inserted by S.I. 199 of 1998 with effect from 7 August, 1998.]*
- 10. Medicines affecting the blood
 - 10.1 Anti-anaemia preparations:
 - 10.1.1 Iron
 - 10.1.2 Folates
 - 10.1.3 Vitamin B12
 - 10.1.4 Combinations
 - 10.2 Anticoagulants
 - 10.3 Anticoagulant antagonists
 - 10.4 Haemostatics
 - 10.5 Medicines modifying platelet function
 - 10.6 Medicine altering blood viscosity
 - 10.7 Others *[inserted by S.I. 199 of 1998 with effect from 7 August, 1998.]*
- 11. Blood products/blood substitutes
 - 11.1 Plasma substitutes and expanders
 - 11.2 Plasma fractions for specific uses
 - 11.3 Others *[inserted by S.I. 199 of 1998 with effect from 7 August, 1998.]*
- 12. Cardiovascular medicines
 - 12.1 Antianginal medicines
 - 12.2 Antiarrhythmic medicines
 - 12.3 Antihypertensive medicines
 - 12.3.1 Vasodilators

- 12.3.2 Beta blockers
 - 12.3.3 Centrally acting antihypertensives
 - 12.3.4 Ganglion blockers
 - 12.3.5 Others
 - 12.4 Cardiac glycosides
 - 12.5 Diuretics and antidiuretics:
 - 12.5.1 Diuretics
 - 12.5.2 Antidiuretics
 - 12.6 Calcium antagonists
 - 12.7 Sympathomimetic cardiac stimulants
 - 12.8 Medicines modifying serum lipids
 - 12.9 Other cardiovascular medicines
- 13. Central nervous system medicines
 - 13.1 Anticonvulsants
 - 13.2 Psychotherapeutic medicines
 - 13.2.1 Antidepressants
 - 13.2.2 Anxiolytics
 - 13.2.3 Antipsychotics
 - 13.3 Hypnotics
 - 13.4 Antiparkinsonian medicines
 - 13.5 Medicines for myaesthesia gravis
 - 13.6 Muscle relaxants, centrally acting
 - 13.7 CNS stimulants
 - 13.8 Medicines improving cerebral blood flow or metabolism
 - 13.9 Respiratory stimulants, centrally acting
 - 13.10 Others *[inserted by S.I. 199 of 1998 with effect from 7 August, 1998.]*
- 14. Dermatological and topical preparations
 - 14.1 Topical anti-infectives
 - 14.1.1 Antibiotics
 - 14.1.2 Sulphonamides
 - 14.1.3 Antifungals
 - 14.1.4 Antiseptics and disinfectants
 - 14.1.5 Scabicides and pediculocides
 - 14.2 Topical corticosteroids
 - 14.2.1 Plain
 - 14.2.2 Combinations
 - 14.3 Topical antihistamines
 - 14.7 Anti-dandruff preparations
 - 14.8 Keratolytics
 - 14.9 Topical cytotoxics
 - 14.10 Sunscreen agents
 - 14.11 Melanin stimulants
 - 14.12 Melanin inhibitors
 - 14.13 Astringents
 - 14.14 Emollients
 - 14.15 Rubefacients
 - 14.16 Medicated dressings
 - 14.17 Vaginal preparations
 - 14.18 Heavy metal preparations
 - 14.19 Others
- 15. Diagnostic agents
 - 15.1 Miscellaneous

- 15.1.1 Serological
- 15.1.2 Skin tests
- 15.1.3 Blood grouping
- 15.1.4 Others
- 15.2 Radiocontrast media
- 15.3 Reagent strips and tablets
- 15.4 Others *[inserted by S.I. 199 of 1998 with effect from 7 August,1998.]*

16. Gastrointestinal medicines

- Antacids
- Antiemetics
- Antihaemorrhoidals
- Antispasmodics
- Laxatives
- Lubricants and softeners
 - 16.5.2 Stimulants
 - 16.5.3 Bulking agents
 - 16.5.4 Osmotic agents
 - 16.5.5 Combinations
 - 16.5.6 Others
- 16.6 Antidiarrhoeals
- 16.7 Gastric/peptic ulcer medicines
- 16.8 Gastrointestinal enzymes
 - 16.8.1 Pancreatic enzymes
 - 16.8.2 Other GI enzymes
- 16.9 Appetite depressants:
 - 16.9.1 Centrally acting
 - 16.9.2 Locally acting
- 16.10 Others *[inserted by S.I. 199 of 1998 with effect from 7 August,1998.]*

17. Endocrine system medicines

- 17.1 Corticosteroids
- 17.2 Androgens
- 17.3 Oestrogens
- 17.4 Progestogens
- 17.5 Sex hormone combinations (excluding contraceptive preparations)
- 17.6 Insulins
- 17.7 Oral antidiabetic medicines
- 17.8 Thyroid hormones/inhibitors
 - 17.8.1 Thyroid hormones
 - 17.8.2 Thyroid inhibitors
- 17.9 Parathyroid hormones/inhibitors
 - 17.9.1. Parathyroid hormones
 - 17.9.2. Parathyroid inhibitors
- 17.10 Pituitary hormones/inhibitors
 - 17.10.1 Pituitary hormones
 - 17.10.2 Pituitary inhibitors
- 17.11 Trophic hormones
- 17.12 Hormone inhibitors (other than the above)
- 17.13 Fertility stimulants
- 17.14 Others

18. Immunologicals

- 18.1 Sera/immunoglobulins
 - 18.1.1 Antitoxins

- 18.1.2 Antivenoms
- 18.1.3 Immune globulins
- 18.1.4 Others
- 18.2 Vaccines
- 18.3 Others *[inserted by S.I. 199 of 1998 with effect from 7 August, 1998.]*

19. Ophthalmic medicines

- 19.1 Anti- infective
 - 19.1.1 Antibiotics
 - 19.1.2 Sulphonamides
 - 19.1.3 Antivirals
 - 19.1.4. Antiseptic
 - 19.1.5 Others
- 19.2 Corticosteroids
 - 19.2.1 Without antibiotics
 - 19.2.2 With antibiotics
- 19.3 Local anaesthetics
- 19.4 Miotics
- 19.5 Mydriatics
- 19.6 Diagnostics
- 19.7 Systemic
- 19.8 Contact lens preparations
- 19.9 Topical decongestants and anti- allergics
- 19.10 Others

20. Ear, nose, throat and mouth preparations

- 20.1 Ear:
 - 20.1.1 Anti – infective
 - 20.1.2 Anti – inflammatory
 - 20.1.3 Analgesic
 - 20.1.4 Wax removers
 - 20.1.5 Others
- 20.2 Nose:
 - 20.2.1 Anti – infective
 - 20.2.2 Corticosteroid (plain and combination)
 - 20.2.3 Antihistamines (plain and combination)
 - 20.2.4 Other decongestants and anti-allergics
 - 20.2.5 Cauterising preparations
 - 20.2.6 Others
- 20.3 Throat and mouth
 - 20.3.1 Special dental preparations
 - 20.3.2 Mouth ulcer preparations
 - 20.3.3. Local analgesics/anaesthetics (including tooth ache and teething preparations)
 - 20.3.4 Antiseptic mouthwashes, gargles, sprays, paints etc.
 - 20.3.5 Antiseptic lozenges
 - 20.3.6 Others
- 20.4 Others *[inserted by S.I. 199 of 1998 with effect from 7 August, 1998.]*

21. Medicines used in obstetrics, gynaecology and urinary tract disorders

[amended by S.I. 199 of 1998 with effect from 7 August, 1998.]

- 21.1 Labour and delivery
 - 21.1.1 Pre-partum uterine contraction stimulants
 - 21.1.2 Post–partum uterine contraction stimulants
 - 21.1.3 Uterine contraction inhibitors

- 21.2 Hormonal contraceptive:
 - 21.2.1 Combined oral contraceptives
 - 21.2.2 Progesterone – only oral contraceptives
 - 21.2.3 Injectables
 - 21.2.4 Others
- 21.3 Spermicides
- 21.4 Intrauterine devices
- 21.5 Barrier devices
- 21.6 Prostaglandins *[inserted by S.I. 199 of 1998 with effect from 7 August, 1998.]*
- 21.7 Urinary tract disorders *[inserted by S.I. 199 of 1998 with effect from 7 August, 1998.]*
- 21.8 Others *[inserted by S.I. 199 of 1998 with effect from 7 August, 1998.]*
- 22 Medicines acting on the respiratory tract
 - 22.1 Anti-asthmatic medicines:
 - 22.1.1 Systemic bronchodilators
 - 22.1.2 Inhalation bronchodilators
 - 22.1.3 Inhalation corticosteroids
 - 22.1.4 Other inhalation products
 - 22.1.5 Other systemic products
 - 22.2 Cough and cold preparations
 - 22.2.1 Antitussives
 - 22.2.2 Expectorants
 - 22.2.3 Decongestants
 - 22.2.4 Mucolytics
 - 22.2.5 Combination products
 - 22.3 Inhalations and vapour rubs
 - 22.4 Others *[inserted by S.I. 199 of 1998 with effect from 7 August, 1998.]*
- 23. Agents correcting or modifying body fluid composition
 - 23.1 Oral:
 - 23.1.1 Oral rehydration products
 - 23.1.2 Oral electrolyte replacement
 - 23.2 Parenteral
 - 23.2.1 Large volume infusions
 - 23.2.2 Injections
 - 23.3 Dialysis products
 - 23.3.1 Peritoneal dialysis solutions
 - 23.3.2 Haemodialysis solutions
 - 23.4 Ion exchange resins
 - 23.5 Agents modifying urinary pH
 - 23.6 Haemoperfusion products
 - 23.7 Others *[inserted by S.I. 199 of 1998 with effect from 7 August, 1998.]*
- 24. Vitamins, minerals and tonics
 - 24.1 Vitamins (excluding combinatins);
 - 24.1.1 Vitamin A and analogues
 - 24.1.2 Vitamin B group (single compounds, except B12, see 10.1.3)
 - 24.1.3 Vitamin C
 - 24.1.4 Vitamin D and analogues
 - 24.1.5 Vitamin E and analogues
 - 24.1.6 Vitamin K and analogues
 - 24.1.7 Other preparations of single vitamins (except folate, see 10.1.2)
 - 24.2 Vitamin B compound preparations
 - 24.3 Multivitamins (excluding vitamins plus minerals)
 - 24.4 Minerals (except iron, see 10.1.1, and electrolytes, see 23.1.2);

- 24.4.1 Single minerals
 - 24.4.2 Compound preparations
- 24.5 Vitamins plus minerals
- 24.6 Tonics
 - 24.6.1 Tonics with vitamins
 - 24.6.2 Tonics with minerals
 - 24.6.3 Tonics with vitamins and minerals
 - 24.6.4 Others
- 24.7 Others *[inserted by S.I. 199 of 1998 with effect from 7 August, 1998.]*
- 25. Nutritional agents
 - 25.1 Intravenous nutrition preparations
 - 25.2 Milk substitutes
 - 25.3 Special oral foods
 - 25.4 Others *[inserted by S.I. 199 of 1998 with effect from 7 August, 1998.]*
- 26. Enzymes (excluding GI tract)
- 27. Enzyme inhibitors
- 28. Medicines used in complementary medicine
[amended by S.I. 199 of 1998 with effect from 7 August, 1998.]
 - 28.1 Homeopathic remedies
 - 28.2 Herbal remedies
 - 28.3 Dutch remedies
 - 28.4 Ayurvedic remedies
 - 28.5 Traditional remedies
 - 28.6 Others
- 29. Radioactive isotopes, and kits for their preparations
 - 29.1 Diagnostic
 - 29.2 Therapeutic
 - 29.3 Others *[inserted by S.I. 199 of 1998 with effect from 7 August, 1998.]*
- 30. Environmental Disinfectants and Decontaminants
- 31. Miscellaneous *[inserted by S.I. 199 of 1998 with effect from 7 August, 1998.]*

PART II

VETERINARY CLASSIFICATION

- 800100 Central nervous system stimulants
- 800110 Respiratory stimulants
- 800120 Narcotic analgesic antagonists
- 800200 Central nervous system depressants
- 800210 Anaesthetics
- 800211 Inhalants
- 800212 Injections
- 800220 Narcotic analgesics
- 800230 Non-narcotic analgesics and antipyretics
- 800240 Soporifics, sedatives and hypnotics
- 800250 Anticonvulsants, anti-epileptics

800260 Tranquillizers and neuroleptics
800261 Phenothiazine derivatives
800262 Butyrophenone derivatives [amended by the Director-General.]
800270 Central acting muscle relaxants
800280 Special agents and medicine combinations used for game immobilization.
800290 Agents for euthanasia
800300 Medicines acting on the muscular system
800310 Peripherally acting muscle relaxants
800400 Local anaesthetics
800410 Injections
800411 Topical
800500 Connective tissue medicines
800501 Anti-inflammatory agents (anti-rheumatics and anti-arthritis)
800511 Non-hormonal preparations
800512 Combinations with corticosteroids
800600 Medicines affecting autonomic functions
800610 Adrenomimetics
800620 Adrenolytics
800630 Cholinomimetics
800640 Cholinolytics
800650 Antihistamines
800700 Cardiac medicines
800710 Cardiac stimulants
800720 Cardiac depressants
800730 Cardiac glycosides
800800 Medicines acting on the blood and the haemopoietic system
800810 Haemostatics and coagulants
800820 Anticoagulants
800830 Haematinics
800900 Medicines acting on the respiratory system
800910 Nasopharyngeal and laryngeal preparations
800920 Expectorants, bronchodilators
800930 Antitussives
801000 Medicines acting on the gastro-intestinal tract
801020 Anti-emetic
801030 Antispasmodics and spasmolytic preparations
801040 Anorexigenics
801050 Antacid preparations
801060 Lubricants, laxatives, purgatives and faecal softeners
801070 Antidiarrhoeals
801071 Plain
801072 Combinations with antimicrobial agents
801080 Digestants
801090 Rumatorics and other preparations used in the ruminant
801100 Medicines acting on the liver
801110 Cholagogues and choleretics
801120 Liver protectants and lipotropic agents
801200 Anthelmintics
801210 Anthelmintics used in livestock
801211 Trematocides
801212 Cestocides
801213 Nematocides
801220 Anthelmintics used in small animals
801221 Cestocides
801222 Nematocides

801300 Dermatological preparations
801310 Antiseptic and antibiotic preparations
801320 Cleaning agents
801330 Surface anaesthetics
801340 Antipruritics
801341 Corticosteroids with or without antimicrobial agents
801342 Others
801350 Emollients and protectants
801360 Keratolytics
801370 Topical fungicides
801400 Wound and burn preparations
801410 Wound disinfectants
801420 Wound dressings
801430 Desloughing agents.
801500 Disinfectants
801510 Environmental disinfectants
801520 Instrument disinfectants
801600 Pesticides and control of external parasites
801601 Dusts
801612 Dips
801613 Others
801620 Pesticides used on small animals
801621 Dusts
801622 Dips
801623 Others
801700 Ophthalmic preparations
801710 With antibiotics and/or sulphonamides
801720 With corticosteroids
801730 Combinations of antibiotics and/or sulphonamides with corticosteroids
801740 Others
801800 Aural preparations
801810 With antibiotics and/or sulphonamides
801811 Combinations of antibiotics and/or sulphonamides
801900 Medicines acting on the urinary system
801910 Diuretics
801920 Urolitholytics and urinary tract antispasmodics
801930 Urinary tract antiseptics
801940 Others
802000 Medicines acting on the genital system
802010 Vaginal preparations
802020 Uterine preparations
802030 Uterine antispasmodics
802040 Oxytoxics
802050 Ovulation controlling agents
802060 Prostaglandins
802100 Intramammary preparations
802200 Antimicrobial (chemotherapeutic agents)
802210 Antibiotics and antibiotic combinations
802211 Broad and medium spectrum
802212 Narrow spectrum
802213 Penicillins
802214 Penicillin – streptomycin combinations
802215 Antifungal antibiotics
802216 Topical antibiotics
802220 Sulphonamides and sulphonamide combinations

802230 Nitrofurans and other antibacterial agents
 802240 Fungicides
 802250 Protozoacides
 802251 Coccidiostats
 802252 Babesiocides
 802253 Others
 802300 Biologicals
 802310 Vaccines
 802311 Horse diseases
 802312 Cattle diseases
 802313 Sheep diseases
 802314 Pig diseases
 802315 Dog diseases
 802316 Cat diseases
 802317 Other species
 802400 Hormones, antihormones and oral hypoglycemics
 802410 Insulin preparations
 802420 Oral Hypoglycaemics
 802430 Thyroid preparations
 802440 Corticosteroids
 802441 Corticosteroids and analogues
 802442 Combinations with antimicrobial agents
 802443 Others
 802450 Anabolic steroids
 802460 Male sex hormones
 802470 Female sex hormones
 802471 Oestrogens
 802472 Progestogens
 802480 Androgen-oestrogen combinations
 802490 Tropic hormones
 802500 Vitamin preparations
 802510 Fat-soluble vitamin preparations
 802520 B-Complex vitamin preparations
 802530 Vitamin C preparations
 802540 Composite vitamin preparations
 802600 Amino acids and protein hydrolysates
 802700 Mineral and nutritional supplements
 802800 Tonics and geriatric preparations
 802900 Electrolytes and fluids for parenteral administration
 802901 Electrolytes and fluids for oral use
 803000 Cytostatic and immunosuppressant agents
 803100 Chelating agents, heavy metal antidotes and miscellaneous
 803200 Contrast media
 803300 Diagnostic agents
 803400 Enzyme preparations
 803500 Growth stimulants

SIXTH SCHEDULE (Section 39) **CATEGORIES FOR THE DISTRIBUTION OF MEDICINES**

Dangerous medicines or ("N.") are medicines subject to International control under the Single convention on Narcotic Medicines, 1961, signed in New York on the 30th March 1961, and to control by the Dangerous Drugs Act, [Chapter 15:02].

Prescription Preparations or ("P. P.") are medicines controlled in terms of Part B of Part VII.

Special Restricted preparations or ("S. R.") are medicines controlled in terms of Part A of Part VII.

Pharmacist Initiated Medicines or ("P. I. M.") are medicines controlled as such in terms of Part C of Part VII.

Pharmacy Medicines or ("P.") are medicines controlled as such in terms of Part C of Part VII.

Household Remedies or ("H. R. ") are medicines suitable for self medication and which are controlled in terms of Part D of Part VII.

Veterinary Medicines (General Dealer) or ("V. M. G. D.") are medicines for veterinary use and which are controlled in terms of Part E of Part VII.

Prohibited Medicines or ("P. M. ") are medicines controlled in terms of Part X.

SEVENTH SCHEDULE (Section 65 (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
Infantile diarrhoea
Plague
Pleurisy
Locomotor or any other ataxia
Meningitis (all types)
Nephritis
Osteoarthritis
Sexually transmitted disease
Pneumoconiosis
Multiple sclerosis
Rheumatic fever
Rheumatoid arthritis
Malignant disease
Thrombosis
Tuberculosis
Poliomyelitis
Parkinson's disease
Eighth Schedule (Sections 2, 69 (1) and 71.)

PART I

SPECIALLY RESTRICTED PREPARATIONS (S.R.)

Amphetamine type medicines in the form of -

(a) a -methylphenethylamine

- (b) b- methylphenethylamine
- (c) a- ethylphenethylamine
- (d) any synthetic compound structurally derived from any of the substances mentioned in items (a), (b), or (c) by any of the following methods
 - (i) by substitution in the aliphatic part;
 - (ii) by the ring enclosure in the aliphatic part;
 - (iii) by both substitution and ring enclosure in the aliphatic part;
 - (iv) by the substitution in the aromatic ring with or without substitution at the nitrogen atom and including any of the following synthetic substances
 - amphetamine;
 - benzphetamine;
 - chlorphetamine;
 - dexamphetamine;
 - methamphetamine;
 - fencamphamine;
 - phentermine;
 - phendimetrazine;
 - phenmetrazine;
 - pemoline;
 - prolintane;
 - propylhexedrine (except when absorbed in inert solid material for inhalation);
- (e) any substance derived from any of the medicines mentioned in terms of (a) – (d) other than –
 - (i) hydroxyamphetamine;
 - (ii) methoxyphenamine;
 - (iii) phenylpropanolamine;
 - (iv) pholedrine;
 - (v) isoprenaline;
 - (vi) orciprenaline sulphate;
 - (vii) phenylephrine;

Dipipanone hydrochloride;

Etretinate

Isotretinoin

[Zidovudine- deleted by S.I. 199 of 1998 with effect from 7 August, 1998.]

PART II

PREMISES WHERE SPECIALLY RESTRICTED PREPARATIONS MAY BE STORED, AND FROM WHICH THEY MAY BE DISPENSED

The Pharmacy Department at the following hospitals –

- (1) Bulawayo Central
- (2) Gweru General
- (3) Harare Central
- (4) Masvingo General
- (5) Mpilo Central
- (6) Mutare General
- (7) Parirenyatwa

PART III

PERSONS TO WHOM PRESCRIPTIONS SHALL BE SUBMITTED FOR COUNTER-SIGNATURE

The Medical Superintendent, or his Deputy at the following hospitals

- (1) Bulawayo Central
- (2) Gweru General

- (3) Harare Central
- (4) Masvingo General
- (5) Mpilo Central
- (6) Mutare General
- (7) Parirenyatwa

**EIGHTH A SCHEDULE
PSYCHOTROPIC SUBSTANCES**

[inserted by S.I. 25 of 1998 with effect from 11 September, 1998.]

**PART I
PSYCHOTROPIC SUBSTANCES**

Amphetamine
Dexamphetamine
Methamphetamine
Methylphenidate
Phencyclidine

**PART II
PSYCHOTROPIC SUBSTANCES**

Amobarbital
Cyclobarbital
Pentobarbital
Secobarbital

**PART III
PSYCHOTROPIC SUBSTANCES**

Amfepramone
Barbital
Ethinamate
Meproamate
Methylphenobarbital
Phenobarbital
Pipradrol

**NINTH SCHEDULE (Sections 2 and 74)
PRESCRIPTION PREPARATIONS (P.P.)**

PART I

The salts, preparations and admixtures of the following-

Acetanilide;
Acetylcarbromal;
Acetyldihydrocodeine;
Acetylcysteine;
Actinomycin – D;
Acyclovir;
Aescin other than preparations intended for topical use only;
Alcuronium;

Apronal;
Alfadolonum;
Alfaxalonum;
Alfentanil;
Allergy desensitisation treatment sets, in graded doses;
Alprazolam;
Amidopyrine;
Amineptile;
Amitriptyline;
Amoxapine;
Amoxycillin;
Amphotericin;
Ampicillin.

Anaesthetic agents, including local anaesthetics intended for injection, but excluding those preparations intended for topical use and procaine for oral use.

Antimicrobial substances (chemotherapeutic substances) synthesized in nature or laboratory, being substances used in the specific treatment of infection, including any preparations and admixtures, other than the following-

- (a) preparations for topical application, excluding chloramphenicol eye preparations;
- (b) penicillin, procaine penicillin (but excluding the semi-synthetic penicillins and cephalosporins), tetracycline and tylosin in any form when contained in unbroken packs and intended for the treatment of animals only;
- (c) streptomycin, when contained in preparations intended for intramammary application only;
- (d) eye ointments containing one per centum tetracycline or oxytetracycline which are for use in Trachoma.

Antimony

Atracurium

Aurothiomalate

Azacyclonal

Azathioprine

Azapropazone

Baclofen

Barbituric acid, other than preparations containing 15 mg or less in combination with other medicines per unit dose.

Beclomethasone

Benactyzine

Benzocetamine

Benzatropine

Betamethasone

Bromazepam

Bromvaletone

Brucine

Bumadizon

Bupivacaine

Buprenorphine

Buserelin

Busulfan

Butriptyline

Calcitonin

Cantharidates (except Cantharidin for topical use)

Captodiamine

Carbachol

Carbenicillin

Carbromal

Carisoprodol
Ceftazidine Pentahydrate
Ceftriaxone
Cefuroxime Acetate
Cephalosporins (all generations).
Chlorambucil
Chloramphenicol
Chlordiazepoxide
Chlorphenoxamine, other than preparations containing 10 mgm or less per unit dose.
Chlormethiazole
Chlorpromazine
Chlorprothixene
Chlortrianisene
Ciclosporin
Cinchophen
Clavulanic Acid
Clindamycin
Clioquinol
Clobazam
Clobetasol Propionate
Clobetasone Butyrate
Clofazimine
Clomifene
Clomipramine
Clorazepate
Clotiapine
Cloxacillin
Clozapine
Coca Alkaloids
Codeine
 (a) other than preparations in solid dosage or containing 15 mgm or less per unit dose in combination with other active ingredients;
 (b) other than liquid preparations containing 5 mgm or less per unit dose alone or in combinations with other active ingredients;
Co-Trimoxazole
Corticosteroids, other than in topical preparation containing 1 per centum or less of hydrocortisone
Cotarnine
Curare
Cyclarbamate
Cyclofenil
Cyclophosphamide
Cyrimine
Cytarabine
Dacarbazine
Danazol
Dapsone, other than preparations combined with pyrimethamine, and intended for the prophylaxis of malaria
Daunorubicin
Deanol
Demecarium Bromide
Desferrioxamine
Desipramine
Desmopressin Acetate
Dexamethasone

Diazepam and other compounds containing the chemical structure of dihydro – 1, 4
Benzodiazepine substituted to any degree
Dibenzepin
Dichloralphenazone
Diethylcarbamazine
Diethylpropion
Dihydrocodeine
Diloxanide Furoate
Diltiazem
Dimercaprol
Dinoprost
Dinoprostone
Diphenidol
Diphenoxylate, other than in preparations containing 2,5 mgm or less per single unit dose
Dipotassium Clorazepate
Diprocetyl
[Dipyrrone - repealed by S.I. 257 of 2002 with effect from 27 September, 2002.]
Disulfiram
Dobutamine
Dopamine
Dosulepin
Doxapram
Doxazosin
Doxepin
Doxorubicin
Droperidol
Doxycycline
Dyflos
Ectylurea
Edrophonium
Emetine, other than Tinct. Ipecacuanha
Emylcamate
Enzymes intended for injection
Etretinate *[inserted by S.I. 256 of 1998 with effect from 11 September, 1998.]*
Ethambutol
Ethchlorvynol
Ethinamate
Ethionamide
Ethoheptazine
Etomidate
Erythromycin
Famotidine
Fencamfamin
Fenfluramine
Fentanyl
Flucloxacillin
Flucytosine
Fludrocortisone
[Flunitrazepam- repealed by S.I. 257 of 2002 with effect from 27 September, 2002.]
Fluorouracil
Fluocinolone
Fluphenazine
Flumazenil
Flurazepam
Folinic Acid

Framycetin, other than topical
Fusidic Acid
Gallamine
Gamolenic Acid
Gelsemium
Gentamycin
Glafenine
Guanidine
Halofantrine
Haloperidol
Halothane
Heparin
Hepatitis – B vac.
Hexapropymate
Hormones, natural or synthetic, other than-
 (a) preparations not intended for systemic effect;
 (b) ampoules of Adrenalin (one part of adrenalin in ten thousand parts of solvent) used
 in the treatment of snakebite;
 (c) progestational and oestrogenic substances used for the control of ovulation in the
 human, supplied by a person authorized by the Authority;;
 (d) conjugated oestrogens
Human chorionic gonadotrophin
Hycanthone
Hydrocortisone, other than in topical preparations containing 1 per centum or less of
hydrocortisone
Hydrocyanic acid
Hydroquinone, other than preparations intended for external use containing 2 per centum or
less
Idoxuridine
Imipramine
Indapamide
Isoflurane
Isoniazid
Isopyrine
Isotretinoin [*inserted by S.I. 256 of 1998 with effect from 11 September, 1998.*]
Iron preparation intended for injection
Ketamine
Ketazolam
Laudexium
Levonorgestrel
Lincomycin
Lithium
Lobelia
Lorazepam
Lormetazepam
Loxapine
Lucanthone
Maprotiline
Mazindol
Medazepam
Medroxyprogesterone
Mefloquine
Meglumine
Melphalan
Mephensin

Mephenoxalone
Meproamate
Mercaptopurine
Mercury, other than solutions of mercurochrome for topical application containing less than 3
per centum mercurochrome
Mesna
Metaraminol
Methadone
Methapyrilene
Methohexitone
Methotrexate
Methylphenidate
Metrifonate
Metronidazole
Mexiletine
Mianserin
Midazolam
Milrinone Lactate
Minoxidil
Mitoxantrone
Molindone
Monoamine, oxidase inhibitors
Morphine, other than in the form of Gee's Lintus and Tinct. Camph. Co.
Nalorphine
Naloxone
Natamycin
Neostigmine
Nicotine, other than in tobacco
Niflumic Acid
Nimorazole
Niridazole
Nitrazepam
Nomifensine
Norfloxacin
Nux vomica
Ofloxacin
Opium, other than in the form of Gee's Linctus and Tinct. Camph. Co
Oxamniquine
Oxazepam
Oxyphenisatin
Oxtetracycline
Oxytocin
Pancuronium
Paraldehyde
Pargyline
Pentazocine
Pethidine
Phenacaine
Phenacemide
Phenacetin
Phenaglycodol
Phenbutrazate
Phentolamine
Phenothiazine, other than-
 (a) Anthelmintics;

(b) Promethazine containing preparations;
(c) Dimethoxanate in anti-tussive preparations containing 25 mgm or less per unit dose
Phenylbutazone (only for the treatment of Ankylosing Spondylitis)
Physostigmine
Pimozide
Pipradol
[inserted by S.I. 256 of 1998 with effect from 11 September, 1998.]
Piracetam
Pituitary Gland and the active principles thereof, except when intended for topical applications and inhalants
Plasma expanders
Practolol
Prazepam
Prednisolone
Procarbazine
Prochlorperazine
Prolintane
Propanidid
Propofol
Propoxyphene, including dextro-propoxyphene and its salts and preparations
Propylthiouracil
Protamine sulphate
Prothipendyl
Protryptiline
Proxymetacaine
Pyrazinamide
Pyridostigmine
Pyritinol
Quinine
Rifampicin
Rosoxacin
Sabadilla
Seriraldine
Sodium calcium edetate
SPA(-)-1-dimethylamino-1,2-diphenylethane
[inserted by S.I. 256 of 1998 with effect from 11 September, 1998.]
Spectinomycin
Streptokinase streptodornase and other emzymes obtained from microbiological cultures
Strophathus
Styramate
Sulfiram, other than for topical use.
Sulphinpyrazone
Sulphonal
Sulphonamides
Sulphonamides, including combinations with other active ingredients, other than for intra-vaginal ophthalmic and topical use, and for use in malaria prevention
Sulpiride
Suxamethonium
Syrotingopine
Tamoxifen
Temazepam
Tenoxicam
Tetrabenazine
Tetracycline
Theophylline Anhydrous

Thiacetone
 Thiamphenicol
 Thioguanine
 Thiopentone
 Thiotepa
 Thiothixine
 Thioridazine
 Tolazoline
 Tranlylcypromine
 Tretamine
[Triazolam –repealed by S.I. 319 of 1994.]
 Tribromomethyl alcohol
 Trichlorethyl alohol
 Trifluperidol
 Trimethaphan
 Trimethoprim
 Trimipramine
 Tubocurarine
 Turpicamide
 Vaccines, Sera, and Antigens other than for animal use and for oral or nasal administration in man.
 Vancomycin
 Vasopressin
 Veratrum
 Viloxazine
 Vinblastine
 Vincristine
 Vindesine
 Xamoterol
 Zidovudine *[inserted by S.I. 199 of 1998 with effect from 7 August, 1998.]*
 Any substance derived from any other substance referred to in any of the items in this Schedule, unless expressly excluded therefrom.
 All preparations in injectable form other than normal saline used for the purpose of maintaining contact lenses *[inserted by S.I. 199 of 1998 with effect from 7 August, 1998.]*

PART II **VETERINARY MEDICINES**

The salts, preparations and admixtures, including unregistered preparations, containing the following

acepromazine;
 acetazolamide;
 acetylpromazine;
 adrenaline;
 alclofenac;
 alphadolone ;
 alphaxalone;
 amantadine;
 amidopyrine;
 antimicrobial substances (chemotherapeutic substances) synthesised in nature or in the laboratory, being substances used in the specific treatment of infections, including any preparations and admixtures other than the following-
 (a) preparations for topical application;

- (b) penicillin and streptomycin when contained in preparations intended for intramammary application only (but excluding the semi-synthetic penicillins and cephalosporins);
- (c) tetracyclines injectable, other than for administration to cats, dogs and horses;
- (d) tetracyclines as dusting powder, and premix to food or water for poultry and pigs

Apomorphine

Atropine

Avoparcin

Azaperone

Azapropazone

Baclofen

Barbituric acid

Belladonna, and the alkaloids thereof

Bemegride

Benztropine

Betamethasone

[Buparvaquone- repealed by S.I. 257 of 2002 with effect from 27 September, 2002.]

Buserelin

Busulfan

Carbachol

Carbamazepine

Carbimazole

Carfentanyl

Carisoprodol

Cefoperazone

Cefuroxime

Cephalonium

Chloral, all salts and derivatives

Chloranbucil

Chlordiazepoxide

Chlorprothixine

Chlorothiazides

Clomifene

Clonazepam

Cloprostenol

Clotrimazole

Codeine

Corticosteroids

Cyclopenthiiazide

Cyclophosphamide

Cyrimine

Cyprenorphine

Dapsone

Demecarium Bromide Detomidine

Diazepam

Dichlorphenamide

Diclofenac

Digitalis, digoxin and other cardiac glycosides

Dimetridazole

Dinoprost tromethamine

Diphenidol

Dipsatin

Diphenoxylate other than preparations containing 2,5 mg or less per single dose

Diprenorphine

Doxapram

Droperidol
Dyflos
Edrophonium
Ephedra including natural or synthetic alkaloids thereof but excluding topical preparations
Etamiphylline camyslate
Etacrynic acid
Ethoheptazine
Ethosuximide
Etorphine
Fentanyl
Fluorouracil
Furosemide
Gallamine
Guaiphenesin
Haloperidol
Heparin
Heptaminol
Homatropine
Homidium
Hormones, natural or synthetic other than preparations not intended for systemic effect
Hydrochlorothiazide
Hyoscine
Idazoxan
Idoxuridine
Indometacin
Insulin
Isometadrin
Isopyrine
Ketamine
Ketoprofen
Levallorphan
Lincomycin
Local anaesthetics, intended for injection
Megestrol
Mephenesin
Mephenoxalone
Meprobamate
Methetharimide
Metimazol
Metronidazole
Morphine
Nalidixic acid
Nalorphine
Naloxone
Naltrexone
Neostigmine
Nitrofurantoia
Opium
Oxytocin
Pentolinium
Perphenazine
Phenacemide
Phenacetin
Phenamidine
Phenothiazine other than –

- (a) in anthelmintics; or
- (b) promethazine containing preparations; or
- (c) dimethoxanate in antitussive preparations containing 25 mg or less per dose.

Phentolamine
 Phenylbutazone
 Phenytoin
 Physostigmine
 Phytomenadione
 Pipothiazine
 Pituitary gland, and the active principles thereof except when intended for topical application
 Plasma expanders
 Potassium chloride in the form of mineral substituents and electrolytes
 Prednisolone
 Primidone
 Propiomazine
 Propionylpromazine
 Propoxyphene
 Propoxur
 Propranolol
 Propylthiouracil
 Prostigmine
 Pyrazinamide
 Sodium benzydazate
 Sodium valproate
 Sotalol
 Spectinomycin
 Spironolactone
 Strophanthus
 Sulphonamides other than the following -

- (a) those intended for topical application
- (b) those intended for injection
- (c) premix additives to water or feeds.

Suxamethonium
 Thyroid gland, natural and synthetic derivatives but excluding radio active derivatives
 Tiletamine
 Tolbutamide
 Tranexamic acid
 Trimethoprim and combinations with sulphonamides
 Tylosin
 Vaccines, sera and antigens other than those intended for use in livestock
 Xylazine
 Yohimbine
 Zeranol
 Zolazepam
 Zuclopenthixol
 All preparation in injectable form other than normal saline used for the purpose of maintaining contact lenses *[inserted by S.I. 199 of 1998 with effect from 7 August, 1998.]*

TENTH SCHEDULE (Sections 2 and 74 (2) (h) and (3)) PRESCRIPTION PREPARATIONS (P.P. 10)

Acebutolol
 Acetazolamide

Acrivastine *[Inserted by S I 257 of 2002, with effect from the 27th day of September 2002.]*
Acetohexamide
Acetyldigitoxin
Alclofenac
Alseroxylon
Amantadine
Amiloride
Aminocaproic Acid
Astemizole *[Inserted by S I 257 of 2002, with effect from the 27th day of September 2002.]*
Atenolol
Benzydamine
Betanidine
Betahistine
Biperiden
Bromocriptine
Bumetanide
Calcium dobesilate
Cantharidin for topical use
Carbamazepine
Carbidopa
Carbimazole
Cetirizine *[Inserted by S I 257 of 2002, with effect from the 27th day of September 2002.]*
Chlorpropamide
Chlorthalidone
Chlorotrianisene
Cimetidine
Clofibrate
Clonazepam
Clonidine
Clorexolone
Clopamide
Colestyramine
Conjugated oestrogens
Cortisone acetate for buccal use
Cromoglycic acid
Cyclopenthiazide
Cyproterone
Debrisoquine
Diclofenac
Diclofenamide
Dipitalis, dogoxing and other cardiac glycosides
Dihydralazine
Dihydroergocristine
Dimetotiazine
Dioxyanthanol (Dithranol)
Dipyridamole
Dipyrocetyl
Dispyramide
Diuretics, including all medicines that promote the excretion of water and electrolytes by the kidney
Ebastine *[Inserted by S I 257 of 2002, with effect from the 27th day of September 2002.]*
Enalapril
Erythrityl tetranitrate
Etarynic acid
Ethosuximide

Fenbufen
Fenprofen
Fenclofenac
Flufenamic acid
Flurbiprofen
Furosemide
Glibenclamide
Glibornuride
Griseofulvin
Guanethidine
Hexamethoinum bromide

Hormones

- (a) preparations not intended for systemic effect
- (b) ampoules of Adrenalin (one part of adrenalin in ten thousand parts of solvent) used in the treatment of snakebite
- (c) progestational and oestrogenic substances used for the control of ovulation in the human, supplied by a person authorized by the Authority
- (d) conjugated oestrogens

Hydralazine
Hydroxyprogesterone
Hydroxyzine
Hydrochlorothiazide
Indapamide
Indoprofen
Indometacin
Isoetarine
Isosorbide dinitrate
Ketoconazole
Ketoprofen
Ketotifen
Labetalol
Lanatoside
Levobunolol
Lidoflazine
Mephenytoin
Mersalyl
Mesuximide
Metformin
Methyldopa
Methysergide
Metoprolol
Moxisylyte
Nadolol
Naldixic Acid
Nifedipine
Nitrofurantoin
Non-steroidal anti-inflammatory agents, excluding phenylbutazone
Nystatin for intra-oral use only
Oestradiol in oestrogen deficiency states and menopause
Orphenadrine
Oxolinic Acid
Oxprenolol
Penbutolol
Penicillins in oral forms for the prophylaxis of rheumatic fever
Pentaerythritol tetranitrate

Pentolinium tartrate
Perhexiline
Phenacemide
Phenformin
Phenindione
Phenobarbital as anti-convulsant only
Phensuximide
Phenytoin
Pindolol
Piroxicam
Pizotifen
Prazosin
Prenylamine
Preparations containing corticosteroids for intra or peri-anal use
Primidone
Probenecid
Procainamide
Procyclidine
Propranolol
Quinethazone
Quinidine
Ranitidine
Rauwolfra
Reserpine
Salbutamol *[Inserted by S I 257 of 2002 with effect from the 27th day of September 2002.]*
Sodium cromoglycate, preparations intended for the treatment of asthma
[Inserted by S I 257 of 2002, with effect from the 27th day of September 2002.]
Sodium pentosan polysulphate
Sotalol
Sprironolactone
Sulfinpyrazone
Sulindac
Sulthiame
Terfenadine *[Inserted by S I 257 of 20002, with effect from the 27th day of September 2002.]*
Theophylline anhydrous
Thyroid gland natural and synthetic derivatives but excluding radio active derivatives
Thyroxine
Thymoxamine hydrochloride
Tiaprofenic acid
Timolol
Tinidazole
Tolazamide
Tolbutamide
Tolfenamic Acid
Tolnetin
Tranexamic Acid
Tretinoin
TriaM.C.inolone for buccal use
Triamterene
Tribexyphenidyl (benzhexol)
Trimethadion
Valproic Acid
Verapamil
Warfarin

Any substance derived from any other substances referred to in any of the items in this Schedule, unless expressly excluded therefrom.

**ELEVENTH SCHEDULE (Sections 2 and 78 (2))
PHARMACIST INITIATED MEDICINES (P.I.M.)**

The following medicines are medicines that do not require a medical practitioner's prescription, but may only be supplied on the recommendation of a pharmacist who shall maintain proper records relating thereto:

Acetarsol
Alimenzanine (trimeprazine)
All topical antifungal preparations (excluding whitfields, undecylenic acid)
All vaginal antifungal preparations
Allopurinol
[Astemizole- Repealed by S I 257 of 2002, with effect from the 27th day of September 2002.]
Atropine, including eye drops and ointment, but excluding combination with metrifphonate for treatment of worms in animals
Bellodonna
Calabar bean
Caramiphen
Chloral, all salts and deriviatives
Chlorbenoxamine
[Chlormezanone, - Repealed by S I 257 of 2002, with effect from the 27th September 2002.]
Chlorphenoxamine
Colchicum
Diclofenamide
Domperidone
Ephedra including natural or synthetic, preparations containing more than 30mgm per unit dose
Ergot
Glyceryk trinitrate
Hexachlorophene, preparations containing more than 1 per centum hexachlorophene
Homatropine
Hormones all oral contraceptives and vaginal preparations
Hyoscine
Ibuprofen
Insulin
Mannitol hexanitrate
Mathenamine
Methocarbamol
Metaclopramide
Naproxen
Pholcodine in the form of liquid preparations only
Phytomenadione
Potassium chloride
Povidone iodine pessaries
Praziquantel
Sodium aescinate for topical use
Sodium cromoglycate, for preparations other than those intended for the treatment of asthma-
[Inserted by S I 257 of 2002 with effect from the 27th September 2002.]
Solaneaceous alkaloids including hyoscyamine,
Sulphonamides including combinations with other active ingredients intended for intra-vaginal and ophthalmic use only
Yohimba

Zoxazolamine.

Twelfth Schedule (Sections 2, 78 and 89)

PHARMACY MEDICINES AND VETERINARY MEDICINES (GENERAL DEALER) (V.M.G.M.)

PART I PHARMACY MEDICINES

The salts, preparations and admixtures of the following -

aconite

aescin, preparations intended for topical use only;

albendazole

alfacalcidol

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

Aminophylline

Amodiaquine

Ammonia (see H S A)

Amyl nitrate

Anethole trithione

Anthraquinones

Antimicrobial substances (chemotherapeutic substances) synthesized in nature or a laboratory, being substances used in the specific treatment of infections, preparations and admixtures for topical use only other than -

- (a) penicillin, procaine penicillin, tetracycline and tylosin in any form contained in unbroken sealed containers intended for animal treatment only, not including semi-synthetic penicillins and cephalosporins.
- (b) streptomycin, contained in preparations intended for intra-mammary use in animals
- (c) eye ointments containing 1 per centum tetracycline or oxytetracycline for the use in trachoma.

Antihistamine substances, the following -

Antazoline

Bromazine

Bucizine

Carbinoxamine

Chlorcyclizine

Chlorphenamine

Chlorphenozamine, preparations containing 10mgm or less per unit dose

Cinnarizine

Clemastine

Clemizole

Cyclizine

Cyproheptadine

Dexchlorpheniramine

Diphenhydramine

Diphenylpyraline

Doxylamine

Isothipendyl
 Mebhydrolin
 Meclozine
 Phenindamine
 Pheniramine
 Promethazine containing 25 mgm or less per unit dose
 Propylenediamine
 Pyrrhobutamine
 Thenalidine
 Tolpropamine
 Triprolidine
 Tetra substituted N derivatives of ethylenediamine or propylenediamine
 Barbitol and barbiturates, in the form of preparations in combination with other active ingredients containing 15 mgm or less per unit dose
 Barium
 Belladonna and the alkloids thereof
 Bemegride
 Benzocaine *[inserted by S.I.199 of 1998 with effect from 7 August,1998.]*
 Benzoyl peroxide
 Bephenium
 Beta-carotene, preparations containing 10 000 iu or more per unit dose
[inserted by S.I.199 of 1998 with effect from 7 August,1998.]
 Bisacodyl
 Bitolterol mesylate
 Bismuth subgallate
 Bromelains
 Bromhexine
 Calciferol, preparations containing 10M.C.g or more per unit dose
[amended by S.I. 199 of 1998 with effect from 7 August,1998.]
 Camylofin
 Carbocisteine
 Carbuterol
 Cetrimide, excluding mouth washes
[amended by S.I. 199 of 1998 with effect from 7 August,1998.]
[Cetylpyridinium chloride -Repealed by S I 257 of 2002, with effect from the 27th day of September 2002]
 Chorbutol, except when intended for use as a preservative
[Chlormezanone, preparation containing 100 mgm or less in combination with an analgesic or anti-asthmatic medicine-Repealed by S I 257 of 2002, with effect from the 27th day of September 2002.]
 Chloroform other than preparations containing less than 10 per centum Chloroform
[Chlorhexidine, excluding mouth washes -Repealed by S I 257 of 2002, with effect from the 27th day of September 2002.]
 Chlorphenesin
 Chlorphenoxamine
 Choline theophyllinate
 Chrysarobin
 Cinchocaine hydrochloride *[inserted by S.I.199 of 1998 with effect from 7 August,1998.]*
 Clioquinol (Iodochlorhydroxyquinoline)
 Codeine
 (a) Preparations in solid dosage form containing 15 mgm or less per unit dose in combinations with other active ingredients;
 (b) liquid preparations containing 5 mgm or less per unit dose clone or in combinations with other active ingredients.
 Colocynth
 Corticosteroids, topical preparations containing one per centum or less of hydrocortisone

Creosote, obtained from wood, other than substances containing less than 50 per centum creosote
Crotamiton
[Cyanocobalamine-repealed by S.I. 199 of 1998 with effect from 7 August, 1998.]
Cyclandelate
Cyclopentolate
Damiana
Dapsone, preparations in combination with pyrimethamine and intended for prophylaxis of malaria
Dequalinium
Dextromethorphan.
Dextrophan
Dibromopropamidine
Dicycloverine (Dicyclomine)
Diethylamine salicylate
Diloxanide
Diphenoxylate, preparations containing 2,5 mgm or less per unit dose in combination with other active ingredients
Domiphen bromide
Enzymes, except those intended for injection
Ephedra including natural or synthetic derivatives –
preparation containing 30 mgm or less per unit dose alone or in combinations with other active ingredients
Etafedrine
Ethyl Nitrate
Fedrilate
Fenoterol
Ferric and ferrous salts and combinations, preparations containing 20mg or more per unit dose
[amended by S.I. 199 of 1998 with effect from 7 August, 1998.]
Floctafenine
Fluoride sodium excluding dental pastes and gels
Folic Acid, preparations containing 400 M.C.g or more per unit dose
[amended by S.I. 199 of 1998 with effect from 7 August, 1998.]
Formaldehyde, other than when used as a preservative
Forazolidine
Gamma benzene hexachloride
Glucuronic acid
Halquin (Chlorhydroxyquinoline) (Di-iodohydroxyquinoline)
Hexachlorophene, preparations containing less than 1 per centum hexachlorophene
Hexetidine, excluding mouth washes *[amended by S.I. 199 of 1998 with effect from 7 August, 1998.]*
Hexoprenaline
Hyaluronidase
Hydrochloric acid, as diluted solution for achlorhydria
Hydrocortisone, preparations intended for external use containing 1 per centum or less hydrocortisone
Hydrotalcite
Hydroxyamphetamine
Hydroquinone, preparations intended for external use containing 2 per centum or less of hydroquinone
Iodine, iodides, preparation containing 500 M.C.g or more per unit dose excluding mouth washes
[amended by S.I. 199 of 1998 with effect from 7 August, 1998.]
Isoaminile
Isoprenaline

Jalap

[Lead, salts, other than preparations for hair containing less than 0,5 per centum of lead. Repealed by S I 257 of 2002, with effect from the 27th September 2002.]

Levallorphan.

Loperamide

Mebendazole

Mefenamic acid

Mepyramine maleate

Mercury: solution of mercurochrome for topical application containing less than 3 per centum mercurochrome

Methemamine (hexamine)

Methoxamine

Methoxyphenamine

Morphine, only in the form of Gee's Linctus and Tinct. Camph. Co

Myrtecarine

Naphazoline

Niclosamide

Nicotinamide for preparations containing 100 mg or more per unit dose

[inserted by S.I.199 of 1998 with effect from 7 August, 1998.]

Nicotinic acid

Nitric acid (see H S A)

Noscapine

Opium only in the form of gee's Linctus and Tinct. Camph. Co

Orciprenaline

Ozalic acid

Oxetacaine

Oxyphencyclimine

Oxymetazoline

Pancreatin

[Pantothenic acid- Repealed by S I 257 of 2002, with effect from the 27th September 2002.]

Papaverine substances containing less than 1 per centum papaverine

Paracetamol—

(a) other than a preparation in solid dosage form containing 500 mg or less and in pack sizes of twenty or less per unit dose;

(b) other than liquid preparations intended for paediatric use of 100 ml or less.

[inserted by S.I. 105 of 2004—correcting 85/2004—with effect from 30th April, 2004.]

Paracetamol

Pentifyllin

Pentoxyverine

Phenazone

Phenindamine

[Phenolphthalein- Repealed by S I 257 of 2002, with effect from the 27th September 2002.]

Phenylephrine, other than preparations containing less than 0,2 per centum phenylephrine intended for topical use.

Phenylpropanolamine

Pholedrine

Piperazine

Pirbuterol

Podophyllum resin

Poldine metilsulfate

Povidine iodine, other than -

(a) preparations intended for topical application and for application to body cavities;

(b) mouth washes;

(c) Pyridoxine, preparations containing 50 mg or more per unit dose;

(d) Selenium, preparations containing 200 mg or more per unit dose;

(e) Zinc Sulphate, preparations containing 20 mg or more per unit dose;
[amended and extended by S.I.199 of 1998 with effect from 7 August,1998.]
 Potassium hydroxide
 Procaine hydrochloride
 Procaterol
 Promethazine preparations containing 2 mgm or less
 Proguanil
 Propamidine
 Propantheline bromide
 Propyhexedrine
 Propyphenazone
 Pyrantel
 Pyridoxine
 Pyrimethamine
 Rimiterol
 Ritodrine
[Salbutamol -Repealed by S I 257of 2002, with effect from the 27th day of September 2002.]
 Salmefamol
[Selenium-Repealed by S.I.199 of 1998 with effect from 7 August,1998.]
 Sodium hydroxide
 Stavesacre (Staphisagria) and alkaloids thereof, other than in soaps, ointments and lotions.
 Sucralfate
 Sulfiram, preparations intended for topical use only
 Sulphonamides including combinations with other active ingredients intended for topical use only and with pyrimethamine for the prevention of malaria
 Sulphuric acid (see H S A)
 Terbutaline
 Terpene hydrate
 Theophylline
 Tiabendazole
 Tolazoline intended for topical use
 Tribenoside
 Tricyclamol chloride
 Trichloroacetic acid
 Vitamin A other than preparations containing 10 thousand units or less of Vitamin A activity per unit dose.
 Vitamin K and analogues
 Xylometazoline
[Zinc sulphate-repealed by S.I.199 of 1998 with effect from 7 August,1998.]
 Any substances derived from any other substances referred to in any of the items in this Schedule unless expressly excluded therefrom.

PART II

VETERINARY MEDICINES (GENERAL DEALER) (V. M. G. D.)

The salts, preparations and admixtures of the following –

- aconite
- acriflavine
- albendazole
- amprolium
- antimicrobial substances (Chemotherapeutic substances) in the following forms –
 - (a) preparations for topical application;
 - (b) penicillin and streptomycin when contained in preparations intended for intramammary application only;
 - (c) tetracyclines injectable, other than for administration to cats, dogs and horses

(d) tetracyclines as dusting powder, and premix to food or water for poultry and pigs.

Arprinocid

Arsenic; preparations containing less than 0,01 per centum arsenic calculated as arsenic trioxide containing less than the equivalent of 0,5 per centum acetarsol

Asorbic acid, preparations containing less than 500 mg per single recommended dose.

Atropine

(a) for the treatment of Organo-Phosphate poisoning

(b) Combinations with Metrifonate for treatment of worms

Buparvaquone [Inserted by S I 257 of 2002, with effect from the 27th September 2002.]

Calciferol, preparations containing five hundred international units or more per single recommended dose

Calcium gluconate

Chloramine

Chlorbutol

Chorhexidine

Chlormethiuron

Chloroform, other than preparations containing less than 10 per centum

Clanobutin

Closantel

Cresol

Cyanocobalamin

Cymiazol

Dichlorophen

Dimercaprol

Dimtridazole

Diminazene aceturate

Etsazole

Febantel

Fenbendazole

Fenvalerate

Fornaldehyde

Furaltadone

Furazolidone

Gamma benzene hexachloride

Hexachlorophene

Imidocarb dipropionate

Iodine, iodides

Iron

Ivermectin

Lasalocid

Levamisole

Mebendazole

Metacresolsulphonic acid

Metrifonate

Monosulfiram

Morantel

Nicarbazine

Nitroxynil

Oxalic acid

Oxyclozanide

Permethrin

Piperonyl butoxide

Piperazine

Poloxalene

Praziquantel

Pyrantel
 Rafoxanide
 Resorantel
 Salinomycin
 Selenium
 Silicone
 Sulphonamides, only in the following form of -
 (a) those intended for topical application
 (b) those intended for injection
 (c) premix additives to water or feeds.
 Tetramisole
 Tiabendazole
 Thiasolucin
 Tryptan blue
 Undecenoic acid
 Vaccines, when intended for use in livestock only;
 Virginiamycin
 Vitamin preparations
 Zeranol

THIRTEENTH SCHEDULE (Section 94) **PROHIBITED DRUGS (P.D.)**

1. Bufotenine
- 1A. DMPH
[inserted by S.I. 256 of 1998 with effect from 11 September, 1998.]
2. Glutethimide
3. Lysergamide
4. Lysergide and other N-alkyle derivatives of lysergamide, which included the medicine commonly known as LSD, but not including methysergide maleate
5. Mescaline
6. Methaqualone
7. Methypylon
- 7A. Parahexyl *[inserted by S.I. 256 of 1998 with effect from 11 September, 1998.]*
8. psilocine, psilocin-*[amended by S.I. 256 of 1998 with effect from 11 September, 1998.]*
9. Psilocybine *[amended by S.I. 256 of 1998 with effect from 11 September, 1998.]*
10. DET N, N-diethyltryptamine
[amended by S.I. 256 of 1998 with effect from 11 September, 1998.]
11. N N-Dimethyltryptamine
12. 2,5-Dimethoxy-4, a, dimethylphenethylamine
- 12A. .STP, DOM *[inserted by S.I. 256 of 1998 with effect from 11 September, 1998.]*
- 12B. tetrahydrocannabinols, all isomers
[inserted by S.I. 256 of 1998 with effect from 11 September, 1998.]
13. Any stereoisomeric form, ester, ether or salt of a substance prohibited and any preparation containing any proportion of the above-mentioned medicines

FOURTEENTH SCHEDULE (Section 77) **NARCOTIC MEDICINES (N)**

1. Chlorphentermine
- 1A. Flunitrazepam *[Inserted by S I 257 of 2002, with effect from the 27th September 2002]*
2. Methylphenidate
3. Propoxyphene, including dextro-propoxyphene and its salts and preparations
4. Tilidine-*[inserted by S I. 319 of 1994, with effect from the 23 December, 1994.]*
5. Triazolam-*[inserted by S I. 319 of 1994, with effect from the 23 December, 1994.]*

FIFTEENTH SCHEDULE (Section 77A.)
UNDESIRABLE MEDICINES AND SUBSTANCES

[inserted by S.I. 199 of 1998 with effect from 7 August, 1998, amended by S.I. 256 with effect from 11 September, 1998, and substituted by S.I. 257 of 2002 with effect from 27 September, 2002.]

PART I

Benoxaprofen
Chlormezanone
Clioquinol (in medicines for oral administration)
Dipyrone
Lead and lead salts
Oxyphenbutazone
Phenacetin
Phenformin
Phenolphthalein
Ponceux Fx
Practolol
Zomiperac

PART II

Cholorform (in liquid oral medicines or preparations)
Tartrazine (in medicines intended for oral use).

SIXTEENTH SCHEDULE (Sections 100B and 100C.)
CERTAIN REQUIREMENTS FOR IMPORT AND EXPORT OF SUBSTANCES
LISTED HEREUNDER

[substituted by S.I. 257 of 2002 with effect from 27 September, 2002.]

TABLE I

N-Acetylanthranilic acid(2)
Ephedrine
Ergometrine
Ergotamine
Isosafrole (2)
Lysergic Acid
3,4 Methylenediooxyphenyl-2-propanone (2)
1-Phenyl-2-propanone
Piperonal (2)
Pseudoephedrine
Safrole (2)

TABLE II

Acetic anhydride
Acetone
Anthranilic acid
Ethyl ether
Hydrochloric acid (1) (2)
Methyl ethyl ketone (2)
Phenylacetic acid
Piperidine
Potassium permanganate (2)
Sulphuric acid(1)(2)
Toluene(2)

The salts of the substances listed in the Tables above whenever the existence of such salts is possible.

- (1) The salts of hydrochloric acid and sulphuric acid are specifically excluded from Table II.
- (2) Included by decision of the Commissioner on Narcotic Drugs on 9th April, 1992, and becoming effective on 23rd November, 1992.