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GENERAL REGULATIONS MADE IN TERMS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965(ACT NO. 101 OF 1965), AS AMENDED

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MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965), AS AMENDED.

GENERAL REGULATIONS

The Minister of Health has, in terms of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), in consultation with the Medicines Control Council, made the regulations in the Schedule.

SCHEDULE

DEFINITIONS

1. In these Regulations any word or expression defined in the Act and not defined herein bears the same meaning as in the Act and unless the context otherwise indicates-

"the Act" means the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), as amended;

"adverse drug reaction" means a response in human or animal to a medicine which is harmful and unintended and which occurs at any dosage and can also result from lack of efficacy of a medicine, off-label use of a medicine, overdose, misuse or abuse of a medicine;

"applicant" means a person who submits an application for the registration of a medicine, an update or amendment to an existing registration;

"as determined by council" means as determined by Council in the guidelines as published in the *Gazette* from time to time;

"authorised prescriber" means any person authorised by the Act to prescribe any medicines;

"batch" or "lot" in relation to a medicine means a defined quantity of a medicine manufactured in a single manufacturing cycle and which has homogeneous properties;

"batch number" or "lot number" means a unique number or combination of numbers or cyphers allocated to a lot or a batch by the manufacturer;

"bioequivalence" means the absence of a significant difference in the bioavailability between two pharmaceutically equivalent products under similar conditions in an appropriately designed study;

"bonded warehouse" means a customs and excise warehouse licenced in terms of section 19 of the Customs and Excise Act, 1964 (Act No. 91 of 1964);

"clinical trial" means an investigation in respect of a medicine for use in humans that involves human subjects and that is intended to discover or verify the clinical, pharmacological or pharmacodynamic effects of the medicine, identify any adverse events, study the absorption, distribution, metabolism and excretion of the medicine or ascertain its safety or efficacy;

"counterfeit medicine" means a medicine in respect of which a false representation has been made with regard to its contents, identity or source by any means including its labelling and packaging;

"compound" means to prepare, mix, combine, package and label a medicine for dispensing as a result of a prescription for an individual patient by a pharmacist or a person authorised in terms of the Act;

"dispense"-

(a) in the case of a pharmacist, means dispense as defined in the Regulations Relating to the Practice of Pharmacy made in terms of the Pharmacy Act, 1974; and

(b) in the case of a medical practitioner, dentist, practitioner, nurse or any authorised prescriber to dispense medicines, means-

(i) the interpretation and evaluation of a prescription;
(ii) the selection, reconstitution, dilution, labelling, recording and supply of the medicine in an appropriate container; or
(iii) the provision of information and instructions to ensure safe and effective use of a medicine by a patient;

"expiry date" means the date up to which a medicine will retain the strength and other properties which are mentioned on the label which strength and other properties can change after the lapse of time and after which date the medicine shall not be sold to the public or used;

"holder of a certificate of registration" means a person in whose name a registration certificate has been granted and who is responsible for all aspects of the medicine, including quality and safety and compliance with conditions of registration;

"manufacture" means all operations including purchasing of material, processing, production, packaging, releasing, storage and shipment of medicines and related substances in accordance with quality assurance and related controls;

"manufacturer" means a person manufacturing a medicine and includes a manufacturing pharmacy;

"minimum legibility" means a printing in 6-point Helvetica, typeface in black ink on white cartridge paper or the equivalent thereof;

"parallel importation" means the importation into the Republic of a medicine protected under patent and/or registered in the Republic that has been put onto the market outside the Republic by or with the consent of such patent holder;

"parallel importer" means a person who parallel imports a medicine into the Republic on the authority of a permit issued in terms of regulation 7(3);

"person" means both a natural and a juristic person;

"proprietary name", "brand name" or "trade name" means the name which is unigue to a particular medicine and by which the medicine is generally identified and which in the case of a registered medicine is the name approved in terms of section 15(5) of the Act;

"responsible pharmacist" means a responsible pharmacist as defined in the Pharmacy Act, 1974, (Act No. 53 of 1974);

"Site Master File" means a document prepared by the manufacturer containing specific and factual good manufacturing practice information about the production and/or control of pharmaceutical manufacturing operations carried out at a named site and any closely integrated operations at adjacent and nearby buildings; and

"trademark" means a trademark as defined under section 2 of the Trade Marks Act, 1993 (Act No. 194 of 1993).

"wholesaler" means a dealer who purchases medicines from a manufacturer and sells them to a retailer and includes a wholesale pharmacy;

REQUIREMENTS FOR THERAPEUTIC EQUIVALENCE

2. (1) A medicine is considered therapeutically equivalent to another medicine if both medicines-

(a) are pharmaceutically equivalent, i.e., contain the same amount of active substances in the same dosage form, meet the same or comparable standards and are intended to be administered by the same route; and

(b) after administration in the same molar dose, their effects with respect to both efficacy and safety are essentially the same.

(2) Therapeutic equivalence is determined from comparative bioavailability, pharmacodynamic, clinical or in vitro studies which meet the requirements and accepted criteria for bioequivalence as determined by the Council.

THE MANNER AND CONDITIONS FOR ALLOWING INTERNATIONAL TENDERING

3. (1) The State may tender for a medicine internationally if such a medicine-

(a) can be obtained at a lower price outside of the Republic; or

(b) is, in the opinion of the Minister, essential for national health.

(2) A medicine referred to in subregulation (1), which at the time of request for tenders is not registered, may be subjected to an expedited registration process in terms of regulation 5.

(3) A medicine cannot be procured by international tender unless such medicine is registered in terms of the Act.

THE CONDITIONS FOR AND THE QUANTITY NOT TO BE EXCEEDED BY A PHARMACIST IN COMPOUNDING A MEDICINE FOR SALE IN THE RETAIL TRADE

4. A pharmacist compounding a medicine for sale in the retail trade in terms of section 14(4)(b) of the Act, must only compound a quantity that is -

(a) related to a treatment regimen of a particular patient; and

(b) to be used by the patient for not more than 30 consecutive days from the date of dispensing.

EXPEDITED REGISTRATION PROCESS FOR MEDICINES FOR HUMAN USE

5. (1) Expedited registration process for medicines for human use shall be as follows:

(a) an application for medicines that appear on the Essential Drugs List shall be accompanied by declaration by the applicant that such a medicine appears on such a list; and

(b) for any medicines containing new chemical entities that are considered essential for national health but do not appear on the Essential Drugs List, written notification to that effect from the Minister must be submitted with the application.

(2) Applications in respect of medicines referred to in (1)(b) must be accompanied by a Summary Basis for the Registration Application (SBRA) which contains such information as determined by the Council.

(3) The format of the summary referred to in subregulation (2) and the details to be contained therein shall be as determined by the Council.

(4) The Council may subject certain applications in respect of medicines containing new chemical entities to an abbreviated medicine review process as determined by the Council, where registration has been granted by other medicines regulatory authorities recognised by the Council for the purpose applied for.

(5) The applicant shall be notified by the registrar within 30 days of the date of receipt of the application whether or not the application is to be subjected to expedited registration process.

(6) The Council may request any information with respect to an application under consideration and such information shall be furnished by the applicant within a period indicated by Council, failing which the Council may reject an application.

(7) The Council shall, within nine months from the date of receipt of the application by the registrar, make a decision with regard to the application and inform the applicant of such decision.

(8) Notwithstanding the above subregulations, an application for an expedited registration process must still comply with regulation 22.

PARTICULARS TO BE PUBLISHED IN THE GAZETTE

6. The following particulars with regard to applications for registration referred to in section 15(11) shall be published in the Gazette:

(a) The proprietary name of the medicine;

(b) the approved name and quantity of each active ingredient of the medicine;

(c) the dosage form of the medicine;

(d) the name of the applicant who lodged the application for registration;

(e) the number allocated to it in terms of section 15 of the Act;

(f) the name and address of the manufacturer and manufacturing facilities; and

(g) the name of the final product release control.

IMPORTATION OF MEDICINES IN TERMS OF SECTION 15C

7. (1) A medicine referred to section in 15C(b) of the Act may be sold if:

(a) the medicine is being sold outside the Republic with the consent of the holder of the patent of such medicine;

(b) the medicine is imported from a person licenced by a regulatory authority recognised by the council;

(c) the person desiring to import such medicine is in possession of a permit issued by the Minister; and

(d) the medicine is registered in terms of the Act.

(2) A person desiring to import a medicine referred to in subregulation (1) must submit to the Minister:

(a) a duly completed application on a form approved and provided by the Minister;

(b) a certified copy of his or her identity document or in the case of a juristic person, a certificate of registration as such in the Republic;

(c) a certified copy of his, her or its registration in terms of the Pharmacy Act, 1974, where applicable;

(d) a certified copy of a licence in respect of premises in terms of-

(i) section 19 of Customs and Excise Act, 1964 (Act No. 91 of 1964); and
(ii) section 22 of the Pharmacy Act, 1974;

(e) documentary proof-

(i) that the medicine is under patent in the Republic;

(ii) that the medicine is registered in its country of export by a regulatory authority recognised by the council;

(iii) regarding the lowest price at which the medicine is sold in the Republic;

(iv) regarding the price at which the medicine will be sold in the Republic;

(v) that he, she or it is able to comply with good manufacturing and distribution practices as determined by the council; and

(f) an undertaking that he, she or it will ensure the continued safety, efficacy and quality of the medicine.

(3) The Minister-

(a) may approve the application referred to in subregulation (2) with or without conditions;

(b) must if he or she approves the application, issue the applicant with a permit, which is valid for a period of two years;

(c) may cancel the permit if the holder thereof fails to comply with the conditions of the permit or on any other good cause shown.

(4) The permit issued in terms of subregulation (3) may only be transferred with the approval of the Minister.

(5) A person issued with a permit in terms of subregulation (3) must apply to the council for the registration of the medicine specified in the permit by submitting to the Registrar-

(a) a certified copy of that permit;

(b) a duly completed application form approved and provided by the council; and

(c) an application fee as determined by the council.

(6) The council-

(a) must, if satisfied that the application referred to in subregulation (5) complies with the requirements of the Act and these regulations and those of the council regarding the safety, efficacy

and quality of the medicine, and that its registration is in the public interest, approve the application with or without conditions; and

(b) may issue the person referred to in subregulation (5) with a certificate of registration in respect of such medicine under the name approved by the council.

(7) The certificate of registration referred to in subregulation (6) may only be transferred with the approval of the council.

(8) A person importing a medicine in terms if this regulation shall in writing inform-

(a) the Minister of any change of facts in relation to the application for a permit issued in terms of subregulation (5)or conditions under which such permit was issued;

(b) the council of any amendments to the application for the registration of medicines or the conditions for the registration of such medicine;

(c) the holder of a certificate of registration in the Republic of the registration of the medicine in terms of this regulation.

(9) A medicine registered in terms of this regulation may only be sold to the State or a person authorised to sell medicines in terms of the Act or any other legislation.

LABELLING OF MEDICINES INTENDED FOR ADMINISTRATION TO HUMANS

8. (1) Save as provided in sub-regulations (2), (3) and (4), the immediate container of every medicine in which a medicine intended for administration to humans is sold shall have a label attached to it on which only the following particulars shall appear in clearly legible indelible letters in English and at least one other official language:

(a) in the case of a medicine listed in any Schedule made in terms of the Act, the letter 'S' followed by the number of the relevant Schedule, in a prominent type size and face and surrounded by a square border, immediately preceding the proprietary name of such medicine;

(b) the proprietary name of the medicine;

(c) the registration number of the medicine allocated in terms of section 15(6) of the Act;

(d) the dosage form of the medicine;

(e) the approved name of each active ingredient of the medicine and the quantity thereof contained in a dosage unit, or per suitable mass or volume or unit, starting with an active ingredient of a high Schedule, in lettering which has minimum legibility;

(f) the name and percentage of any bacteriostatic or bactericidal agent which has been added to the medicine as a preservative;

(g) the approved name of any anti-oxidant contained in the medicine;

(h) in the case of a medicine for oral or parenteral administration, the quantity of-

(i) sugar contained in the medicine; or

(ii) ethyl alcohol contained in the medicine, expressed as a percentage of the total volume of the medicine, if such quantity exceeds two per cent by volume;

(i) the content of the medicine package expressed in the appropriate unit or volume of the medicine;

(j) approved indications where practical, for use of the medicine;

(k) the recommended dosage of the medicine, where practical;

(l) where applicable, the instruction 'Shake the bottle before use';

(m) in the case of a medicine intended for injection by a particular route of administration only, that route of administration by means of suitable words or abbreviations;

(n) the lot number of the medicine;

(o) the expiry date of the medicine;

(p) the name of the holder of certificate of registration of the said medicine;

(q) the requirements regarding the manner in which the medicine shall be stored with specific reference to the applicable storage temperature and other precautions required for the preservation of the medicine;

(r) where applicable, the statement: 'For external use only';

(s) the warning: 'Keep out of reach of children';

(t) in the case of a medicine which contains aspirin or paracetamol the warning:

'Do not use continuously for more than 10 days without consulting your doctor';

(u) in the case of a medicine for oral administration which contains fluorides, the warning: "Contains fluoride;

(v) in the case of a medicine for oral administration which contains an antihistamine, the warnings:

'This medicine may lead to drowsiness and impaired concentration, which may be aggravated by simultaneous intake of alcohol or other central nervous system depressant agents';

(w) in the case of eye drops or artificial tear solutions in respect of which evidence concerning the self-sterilising ability of the medicine has not been approved by the Council, the warning 'Do not use more than 30 days after opening';

(x) any specified warning required in terms of section 15(7) to be given on the label of the medicine as a condition of registration thereof;

(y) in the case of a medicine that contains TARTRAZINE, the warning:
'Contains TARTRAZINE.'

(2) If the medicine package bears both an immediate container label and an outer label, the requirements of sub-regulation (1) shall apply to the outer label as well: Provided that it shall be sufficient to give on the immediate container label -

(i) in the case of medicines intended for administration by injection and having a total volume not exceeding 5 ml, the details prescribed in paragraphs (b), (e), (m), (n), (o) and (p) of sub-regulation (1);

(ii) in the case of an ointment, cream, gel or powder having a net mass not exceeding 10 grams, the details prescribed in paragraphs (b), (c), (e), (f), (n), (o), (p) and (x) of sub-regulation (1);

(iii) in the case of liquid, solution or suspension having a total volume of more than 1 ml, but not exceeding 15 ml, the details prescribed in paragraphs (b), (c), (d), (e), (n), (w), (o), (p), and (x) of sub-regulation (1);

(iv) in the case of a liquid, solution or suspension having a total volume not exceeding 1 ml, the details prescribed in paragraphs (b) and (n) of sub regulation (1);

(v) in the case of a medicine packed in blister or similar packaging, the details prescribed in paragraphs (b), (n), (o) and (p) of sub-regulation (1), repeated as frequently as is practicable.

(3) The Council may authorise the inclusion on the label of a medicine of any special information that is not required by this regulation to be so included.

(4) The requirements of sub-regulation (1) shall not apply to

(a) any medicine sold in accordance with section 14(4) of the Act;

(b) any medicine sold by a person authorised to dispense in terms of section 22C or a pharmacist in the course of his or her professional activities for the treatment of a particular patient; or

(c) any medicine sold by a pharmacist, a person authorised to compound and dispense, or in a hospital pharmacy in accordance with a prescription issued by a medical practitioner or dentist for the treatment of a particular patient: Provided that such medicine shall be sold in a package to which is attached a label containing the following information:

(i) the proprietary name, approved name, or the name of each active ingredient of the medicine, where applicable, or constituent medicine;
(ii) the name of the person for whose treatment such medicine is sold;

(iii) the directions in regard to the manner in which such medicine should be used;

(iv) the name and business address of the person authorised to sell such a medicine;

(v) date of dispensing; and

(vi) reference number.

PACKAGE INSERTS FOR MEDICINES FOR HUMAN USE

9. (1) Save as provided in subregulations (2) and (3), each package of a medicine shall be accompanied by a package insert, either as a separate entity or as an integral part of the package, on which are printed in English and at least one other official language and in type having a minimum legibility as defined in regulation 1, under the headings and in the format specified in this regulation, and which shall contain the following particulars -

(a) Scheduling status, i.e the scheduling status of the medicine as determined from time to time by the Minister;

(b) Proprietary name and dosage form;

(c) Composition, i.e-

(i) the approved name of each active ingredient and the quantity thereof contained in a dosage unit or per suitable mass or volume or unit of the medicine;

(ii) the approved name and quantity of any bactericidal or bacteriostatic agent included in the medicine as a preservative , expressed as a percentage;

(iii) the quantity of ethyl alcohol included in a preparation for oral or parenteral administration, if such quantity exceeds two per cent by volume;

(iv) the words " contains TARTRAZINE" should the medicine contain such ingredient; and

(v) in the case of a medicine, for oral administration, which contains or does not contain sugar, the warning: "contains sugar" or "sugar free", whichever is applicable.

(d) pharmacological classification, i.e. the category, the number and the description of the classification as stated in regulation 25;

(e) pharmacological action, i.e. a description of the pharmacological action of the medicine, and where applicable, under a sub-heading: Pharmacokinetics, pharmacodynamics; summary of clinical studies.

(f) Indications;

(g) Contra-indications;

(h) Warnings;

(i) Interactions;

(j) Pregnancy and lactation;

(k) Dosage and directions for use;

(l) Side effects and special precautions;

(m) Known symptoms of over dosage and particulars of its treatments;

(n) Identification;

(o) Presentation;

(p) Storage instructions that are practically formulated and which indicate storage temperatures;

(q) Registration number, i.e

(i) the number allocated in terms of section 15 (6) of the Act; or

(ii) in the case of a medicine the registration of which has been applied for, the reference number allocated to such application, followed by the expression " Act 101/1965"

(r) name and business address of the holder of the certificate of registration, or in case of a parallel imported medicine, the name and business address of the holder of the parallel importer permit;

(s) date of publication of the package insert: Provided that -

(i) if the Council decides that there is no applicable information to be furnished under a particular heading, such heading may be omitted with the approval of Council;

(ii) the Council may on application authorise the deviation from the format and content of a package insert prescribed as a condition of registration of a medicine;

(iii) the Council may on application authorise the inclusion on a package insert of any specified information not required by this regulation to be so included; and

(iv) the council may on application determine under a particular heading the information to be furnished in respect of an interchangeable multisource medicine.

(2) The requirements of subregulation (1) shall not apply in the case of medicines in respect of which exclusion from the operation the Act hasbeen granted by the Minister in terms of section 36 of the Act.

(3) The requirements of subregulation (1) shall not apply to -

(a) any medicine sold in accordance with the provisions of section 14 (4);

(b) any medicine compounded and/or sold by a medical practitioner, dentist, pharmacist or any other person who is authorised to dispense medicines in the course of his or her professional activities for the treatment of a particular patient;

(c) any medicine sold by a pharmacist or by a hospital pharmacy in accordance with a prescription issued by a medical practitioner or dentist for the treatment of a particular patient.

(4)Nothing contained in subregulation (2) and (3) shall be construed as prohibiting the inclusion of a package insert in the medicine.

(5) The council may withdraw any indication if it is of the opinion that the risk and benefit profile of the medicine for the approved indications for which they have been registered is not in the public interest.

PATIENT INFORMATION LEAFLET

10. (1) Each package of a medicine shall have a patient information leaflet that must contain the following information with regard to the medicine in at least English and one other official language:

(a) Scheduling status;

(b) proprietary name and dosage form;

(c) the composition of the medicine i.e information contemplated in regulation 9(1)(c);

(d) the approved indications and use;

(e) instructions before taking the medicine, which include -

(i) contra-indications;

(ii) precautions;

(iii) warnings e.g. concerning sedative properties of the medicine or risks involved with sudden withdrawal of the medicine;

(iv) interactions;

(v) the following general statements:

"If you are taking medicines on a regular basis, using the medicine at the same time with another medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice."

"If you are pregnant or breast feeding your baby while taking this medicine please consult your doctor, pharmacist or other health care professional for advice. "

(f) instructions on how to take the medicine, including the following statements:

"Do not share medicines prescribed for you with any other person. "

"In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre";

(g) side effects, including the following general statement:

"Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice";

(h) storage and disposal information, including the following general statement:

"store all medicines out of reach of children."

(i) presentation, which includes the number, volume or mass per package

unit and a description of the packaging material, e.g. bottle, blister pack, etc;

(j) identification of the medicine, i.e. the description of its physical appearance as tablet, capsule, etc;

(k) registration number of the medicine;

(l) the name, business address and telephone number of the holder of the certificate of registration; and

(m) the date of publication of the patient information leaflet;

(2) The Council may authorise a deviation from sub-regulation (1)

(3) A person dispensing or administering a medicine must ensure that a patient information leaflet is made available at the point of such dispensing or administration.

(4) The council may, on application, in respect of an interchangeable multisource medicine determine additional information to be furnished under a particular heading.

PRESCRIPTION BOOK

11. (1) A prescription book or other permanent record in respect of schedule 2, 3, 4, 5 and 6 medicines or substances shall be kept on all premises where prescribed medicines are dispensed or sold and shall contain the following details:

(a) the name of the medicine or scheduled substance;

(b) the date on which the prescription was dispensed;

(c) the dosage form and quantity of the medicine or scheduled substance;

(d) the name and address of the patient, or, in the case of a prescription issued by a veterinarian, the name and address of the person to whom the medicine or scheduled substance was sold;

(e) where applicable the name of the medical practitioner, dentist, veterinarian or any other authorised person who issued the prescription; and

(f) prescription reference number.

(2) In the case of Schedule 1 medicine sold without a prescription in terms of section 22A(4) of the Act, the following shall be recorded:

(a) the name of the person to it was sold;

(b) its name and quantity; and

(c) the name of the pharmacist or intern pharmacist or pharmacist assistant who sold it.

(3) A prescription record shall be retained at the business address of the seller for a period of at least five years after the date of the last entry made therein.

(4) The manufacturer or wholesaler shall keep a record of Schedule 2, 3, 4 and 5 medicines and substances in the form of invoices that will reflect:

(a) the date and transaction of every sale;

(b) the name of the medicine;

(c) the name and address of every purchaser;

(d) the quantities sold;

(e) the batch number; and

(f) the price at which the medicine was sold.

(5) A record referred to in subregulation (4) shall be kept for a period of five years from the date of sale.

IMPORTATION OF MEDICINES INTO THE REPUBLIC

12. (1) No person shall import any medicine or scheduled substance, including medicines imported in terms of section 15C of the Act, read together with regulation 7, into the Republic except through one of the following ports of entry:

(a) Cape Town Airport or harbour;

(b) Port Elizabeth Airport or harbour;

(c) Durban Airport or harbour; and

(d) Johannesburg international airport

(2) A person can only import a medicine or scheduled substance if such person:

(a) is licensed in terms of the Act to import medicines; and

(b) in the case of unregistered medicines, is authorised by the Council to import such unregistered medicines.

TRANSMISSION OF MEDICINES THROUGH THE REPUBLIC

13. (1) Medicines, scheduled substances and mixtures containing scheduled substances that are transmitted through the Republic shall-

(a) while in the Republic be stored in a bonded warehouse which is registered with the Council; and

(b) not be manipulated while in the bonded warehouse unless authorised by the Council.

(2) A bonded warehouse referred to in subregulation (1) must comply with good storage conditions as determined by the Council.

PERMITS IN TERMS OF SECTION 22A OF THE ACT

14. (1) A medical practitioner or veterinarian desiring to be provided

with a schedule 8 substance for the treatment or prevention of a medical condition in a particular patient, shall apply to the Director-General for a permit to use such substance.

(2) An application referred to in subregulation (1) shall contain at least the following information:

(a) name and address (both physical and postal) of applicant;

(b) identification number of the applicant;

(c) registration number of the applicant with statutory council;

(d) qualifications of the applicant;

(e) telephone and facsimile numbers of applicant

(f) purpose for which the application is made;

(g) in the case of a medical practitioner, the name and address of the patient, diagnosis, dosage and period of treatment; and

(h) in the case of a veterinarian, the name and address of the owner of the animal, diagnosis, dosage and period of treatment.

(3) A permit referred to in subregulation (1) may not be issued if the Director-General is of the opinion that the applicant is not capable of keeping or storing the substance in a manner so as to prevent the loss thereof.

(4) An analyst or researcher, desiring to be provided with a Schedule 6 or Schedule 7 substance for the purpose of education, analysis or research, shall apply to the Director-General for a permit to use such substance.

(5) An application referred to in subregulation (4) shall contain at least the following information:

(a) name and address (both physical and postal) of applicant;

(b) identification number of applicant;

(c) name and address of employer;

(d) qualifications of the applicant;

(e) telephone and facsimile numbers of applicant;

(f) particulars of the research project;

(g) address at which research will be undertaken;

(h) estimated duration of project;

(i) total quantity of scheduled substances to be kept in stock per annum;

(j) source of supply; and

(k) the place where and the manner in which the scheduled substances shall be stored safely.

(6) The Director-General may grant or refuse an application referred to in subregulation (4).

(7) Any person desiring to manufacture a Schedule 6 substance, shall apply to Director General for a permit to manufacture such substance.

(8) An application referred to in subregulation (7) shall contain at least the following information:

(a) name and address (both physical and postal) of the applicant;

(b) registration number of applicant with the South African Pharmacy Council;

(c) a certified copy of a manufacturing licence issued by the Council;

(d) telephone and facsimile numbers of applicant;
(e) address at which manufacturing is to be undertaken; and

(f) estimated quantity of Schedule 6 substance that will be manufactured.

(9) Any person desiring to manufacture, use or supply a Schedule 5 or

Schedule 6 substance for other than medicinal purposes, shall apply to the Director-General for a permit to manufacture such substance.

(10) An application referred to in subregulation (9) shall contain at least the following information:

(a) name and address (both physical and postal) of applicant;

(b) identification number of the applicant;

(c) registration number of the applicant with a statutory council;

(d) qualification of the applicant;

(e) telephone and facsimile numbers of applicant; and

(f) purpose for which the application is made.

(11) A medical practitioner or veterinarian shall not be authorised to administer a scheduled substance or medicine for other than medicinal purposes for administration outside any hospital for the satisfaction or relief of a habit or craving unless he or she complies with the conditions as determined by the Director-General.

(12) The Director-General may issue a permit referred to in subregulation (9) only after consultation with the Drug Advisory Board and the Council.

(13) The medical practitioner or veterinarian referred to in this regulation is subject to regular inspections in terms of the Act.

(14)The permit may be withdrawn, revoked or suspended by the Director-General if the person issued with such a permit fails to comply with the conditions or requirements for issuing the permit.

IMPORTATION OR EXPORTATION OF SPECIFIED SCHEDULE 5, SCHEDULES 6, 7 AND 8 SUBSTANCES

15. (1) Any person desiring to import or export specified schedule 5, Schedules 6, 7 or 8 substances shall apply to Director-General for a permit to import or export such substances.

(2) An application referred to in subregulation (1) shall contain at least information referred to in regulation 14(2)

(3) The applicant must submit with the application a certified copy of the permit for importation issued by the country to which the substance is to be exported.

(4) A permit issued in terms of subregulation (1) shall be valid for a period of six months.

POSSESSION OF SPECIFIED QUANTITIES OF SCHEDULED SUBSTANCES FOR PERSONAL MEDICINAL USE BY PERSONS ENTERING OR DEPARTING FROM THE REPUBLIC

16. (1) Notwithstanding regulation 12 and subject to subregulation (3) any person entering or departing from the Republic may be in possession, for personal medicinal use, of a quantity of a Schedule, 3, 4, 5 or 6 substance, which shall not exceed a quantity required for use for a period of one month.

(2) A person referred to in subregulation (1) must have -

(a) a valid prescription for such Scheduled substance or medicine; or

(b) a certificate by an authorised prescriber or a person dispensing such Scheduled substance or medicine to the effect that the Scheduled substance or medicine concerned including its quantity was prescribed for the person including the name and address of such authorised prescriber; and

(c) his or her particulars of residence in the Republic, in the case of the person entering the Republic, recorded at the port of entry.

INFORMATION TO BE FURNISHED ANNUALLY TO THE DIRECTOR-GENERAL BY THE HOLDER OF A PERMIT

17. (1) A person issued with a permit in terms of regulation 15 shall furnish the Director-General with the following information with regard to the substances referred to in that regulation:

(a) the quantity of the substance, as a raw material or as contained in a preparation, which was held in stock on 1 January of the preceding calendar year;

(b) the quantity of such substance acquired during the preceding calendar year by -

(i) importation of the substance, as a raw material or as contained in a preparation;

(ii) local production of the raw material;

(iii) local purchasing of the raw material, in which case the name of the supplier shall also be furnished;

(c) the quantity of such substance, as a raw material or as contained in a preparation, which was disposed of during the preceding year through exportation or other means;

(d) the quantity of such substance used during the preceding calendar year in the production of any other Schedule 6 or Schedule 7 substance or a specified substance referred to in section 22A(12)(a)(ii) and (iii) of the Act;

(e) the quantity of such substances and preparations containing such substances remaining in stock on 31 December of the preceding year.

(2) The information referred to in sub-regulation (1) shall comply with the following requirements:

(a) quantities shall be expressed in metric units or as a percentage of the relevant substance;

(b) in the case of opium and any preparations containing opium, quantities shall be expressed in terms of opium containing 10 per cent of anhydrous morphine;

(c) preparations not obtained directly from opium but from a mixture of opium alkaloids shall be expressed in terms of morphine;

(d) quantities of coca-leaves shall be expressed in terms of coca-leaves containing 0,5 percent of cocaine; and

(e) where stocks are held or manufacture has been undertaken on behalf of another person, this fact shall be indicated.

LICENCE TO DISPENSE OR COMPOUND AND DISPENSE MEDICINES

18. (1) As contemplated in section 22C(1) of the Act, a medical practitioner, dentist or any other person registered in terms of the Health Professions Act, 1974 (Act No. 56 of 1974), practitioner or nurse desiring to dispense or compound and dispense medicines shall apply to the Director-General for a licence to dispense or compound and dispense medicines.

(2) An application referred to in subregulation (1) shall be accompanied by an application fee as determined by the Director-General.

(3) The application shall contain at least the following information:

(a) the name and both residential and business addresses (both physical and postal) of the applicant;

(b) the exact location of the premises where compounding and/or dispensing will be carried out;

(c) proof of completion of a supplementary course contemplated in section 22C(2) of the Act;

(d) telephone and fax numbers of the applicant, where available;

(e) proof of registration with the relevant statutory council;

(f) proof of publication of the notice contemplated in subregulation (5);

(g) motivation, as to the need for a licence in a particular area;

(h) any other information that the Director-General may require; and

(i) proof of ability to supply a patient information leaflet.

(4) In considering an application referred to in subregulation (1), the Director-General shall have regard to the following:

(a) the existence of other licensed health facilities in the vicinity of the premises from where the compounding and dispensing of medicines is intended to be carried out;

(b) representations, if any, by other interested persons as to whether a licence should be granted or not;

(c) the geographic area to be served by the applicant;

(d) the estimated number of health care users in the geographic area referred to in paragraph (c);

(e) demographic considerations including disease patterns and health status of the users to be served; and

(f) any other information that he or she deems necessary.

(5) At the same time when an application referred to in subregulation (1) is made, the applicant must also give notice by publication in a newspaper circulating in the area where the applicant intends to conduct his or her practice of his or her intention to apply for a licence.

(6) Any person may support or oppose an application referred to in subregulation (1) by making written representations to the Director-General within 30 days of publication of the notice contemplated in subregulation (5).

(7) A person referred to in subregulation (1) who has been issued with a licence shall:

(a) keep sales records either in hard copy or electronically relating to medicines compounded and dispensed for a period of 5 years from the date of sale;

(b) ensure that the dispensary and any premises where medicines are kept are suitable for dispensing or compounding and dispensing in accordance with good pharmacy practice;

(c)keep the medicines under the manufacturer's recommended storage conditions as specified on the medicines label and or package insert;

(d) not pre-pack medicines at the premises unless authorised to do so by the Director-General and in terms of regulation 33(a)(ii);

(e) label medicines properly with the name of the patient and a reference number linking the patient to a patient record;

(f) not compound and dispense medicines to patients unless the sale is

preceded by a proper diagnosis and a prescription for a particular patient;

(g) not keep expired medicines on the premises other than in a demarcated area in a sealed container clearly marked: EXPIRED MEDICINES and such expired medicines shall be destroyed in terms of regulation 27;

(h) secure the premises where the compounding and dispensing is carried out whenever he or she is not physically present at those premises;

(i) in the event of a recall of a medicine, withdraw the medicine;

(j) conspicuously display the licence in the premises referred to in paragraph(b); and

(k) comply with the conditions of his or her licence.

(8) For the purposes of this regulation, "compounding and dispensing" does not refer to a medicine requiring preparation for a once-off administration to a patient during a consultation.

LICENCE TO MANUFACTURE, ACT AS A WHOLESALER OR DISTRIBUTE MEDICINES

19 (1) A person referred to in section 22C(1)(b) of the Act-

(a) must prior to commencing business as such-

(i) apply to the Council for a licence to manufacture, import or export, act as wholesaler or distribute medicines, Scheduled substances or medical devices;

(ii)appoint, and designate as such a pharmacist who will control the manufacturing or distribution of medicines, Scheduled substances or medical devices;

(iii) appoint and designate a natural person who resides in the Republic, who shall be responsible to Council for compliance with the Act;

(b) must submit to the registrar an application, on a form approved and provided by the Council, for a licence as contemplated in sub-regulation (1) (a) (i);

(c) must as part of the application in sub-regulation (1)(b) provide acceptable documentary proof of:

(i) the particulars of the owner of the business;

(ii)registration of the responsible pharmacist;

(iii) qualifications of staff to manufacture, store, distribute and sell medicines, Scheduled substances or medical devices in terms of the Act;

(iv) the ability to comply with good manufacturing or distribution practices as determined by Council, which must include:

(aa) a copy of a local area plan of the location of the business premises indicating all adjacent properties and the nature of the business being carried on, on such properties;

(bb) a floor plan of the building in which the business premises are situated;

(cc) a plan of the actual layout of the business premises;

(dd) an inventory of equipment to be used in conducting the business;

(ee) a manual of procedures and practices to be implemented to ensure the safety, efficacy and quality of medicines, or Scheduled substances or medical devices to be manufactured or distributed and sold;

(d) must specify the medicines, Scheduled substance or medical devices to be manufactured or distributed and sold;

(e) must pay the application and inspection fees as determined by the Council.

(2) The registrar may give the person referred to in sub-regulation (1) written notice to furnish the Council with such additional documentation or information as the Council may require, within a reasonable time, specified in the notice.

(3) The Council must inspect the business premises specified in the application.

(4) If the Council is satisfied that:

(a) the person referred to in subregulation (1)complies with the prescribed requirements;

(b) the application for a licence to manufacture, act as wholesaler, or distribute medicines, Scheduled substances, or medical devices complies with the prescribed requirements;

(c) the applicant is able to comply with good manufacturing or distribution practices,

then the Council must approve, with or without conditions, the application and issue such person with a licence.

(5) The registrar must:

(a) keep a separate register for each of the categories of licensees referred to in sub-regulation (1)(a)(i); and

(b) enter the licence number, the name of the licensee and his or her physical and postal addresses, in such register.

(6)Notwithstanding the period of validity of the licence the licensee shall pay the annual fee for continued registration as determined by the Council.

(7)A licensee must notify the registrar in writing of any change to any of the particulars furnished in the application or entered in the register, which occurs after the issue of the licence.

(8)Any entry into the register which is proved to the satisfaction of the council to have been made in error or through misrepresentation or in circumstances not authorised by the Act, may be removed from the register.

(9)A person in respect of whose entry a removal as contemplated in sub-regulation (8) has been made, must be notified of such removal and any certificate issued in respect of the registration in question shall be deemed to be cancelled as from the date on which notice has so been given.

(10)The Council may direct the registrar to remove from the register the name of the licensee-

(a)who does not comply with the Act or the conditions of a licence;

(b)if the responsible pharmacist fails to control the manufacturing or distribution of medicines, Scheduled substances, or medical devices;
and the licensee has failed to furnish written reasons within 21 days after the date upon which a notice is given of the Council's intention to remove the name of the licensee from the relevant register and to close such business why the licensee's name should not be removed or the

business should not be closed: Provided that if the Council is of the opinion that it is in the interest of the public, it may dispense with the required notice.

PERIOD OF VALIDITY OF A LICENSE ISSUED IN TERMS OF REGULATIONS 18 AND 19 AND RENEWAL OF LICENCES

20. (1) A licence issued in terms of regulation 18 shall be valid for a period of 3 years whereas a licence issued in terms of regulation 19 shall be valid for a period of 5 years from the date of issue.

(2) A licence referred to in subregulation (1) which has expired may be renewed upon application to the Director-General or the Council, as the case may be.

(3) An application referred to in subregulation (2) shall -

(a) contain at least the information or documentation referred to in regulations 18(3) and 19(1)(c), as the case may be;

(b) be accompanied by a prescribed fee; and

(c) be made at least 90 days before the expiry of the existing licence.

APPEAL AGAINST THE DECISION OF THE DIRECTOR-GENERAL OR THE COUNCIL

21. (1) An appeal to be lodged or representations to be made in terms of Section 24 of the Act shall be lodged or made within 30 days from the date on which the decision appealed against or in respect of which representations are made was communicated to the appellant or person making representations.

(2) In lodging the appeal or making representations, the appellant or person making representations shall send a notice by registered mail to the Minister or the Director-General, whatever the case may be, and-

(a) in the case of a decision of the Council, to the Registrar of Medicines, Medicines Control Council, Private Bag X828, Pretoria, 0001, or

(b) in the case of a decision of the Director-General, to the Director-General, Department of Health, Private Bag X828, Pretoria, 0001, stating the decision in respect of which representations are made.

(3) The notice referred to in sub-regulation (2) shall set out clearly and succinctly the basis for the appeal or representations.

(4) The Minister shall within 30 days of receipt of notice of appeal, appoint an appeal committee to decide the appeal.

(5) The Director-General shall within 15 days of receipt of the notice referred to in subregulation (2), submit such notice to the Minister and the Minister shall make a decision on the decision of the Director-General within 30 days from the date on which-

(a) the notice was received; or
(b) the consideration of the representations was completed; whichever is the later.

(6) The appeal committee -

(a) shall determine the procedure for its hearings;

(b) may, if it deems necessary call for oral evidence or argument or summon any person who-

(i) in its opinion may be able to give information concerning the subject of the appeal; or

(ii) it believes has in his or her possession or under control any document which has a bearing on the subject of the appeal, to appear before it at a time and place specified in the summons, to be asked questions or to produce any document; and

(c) shall, if it calls for oral evidence or argument,

(i) determine the date, time and place for the appeal and shall communicate these in writing to the appellant and the Council;

(ii) administer an oath to or accept an affirmation from any person called as a witness at the appeal..

(7) Persons appearing before the Appeal Committee may be represented by a legal practitioner.

(8) The appeal committee shall consider the appeal and make a decision in regard thereto within a period of 30 days from the date-

(a) on which it was appointed; or,

(b) when the appeal hearing was completed,

whichever is the later.

APPLICATION FOR THE REGISTRATION OF A MEDICINE

22. (1) Any person residing and doing business in the Republic may make an application for the registration of a medicine.

(2) The application referred to subregulation (1) shall include the particulars of the person with appropriate knowledge of all aspects of the medicine who shall be responsible for communication with the council.

(3) An application referred to in subregulation (1) shall be made on the appropriate form obtainable from the Registrar and shall be accompanied by:

(a) a properly completed screening form obtainable from the Registrar;

(b) a proposed label for use on the medicine;

(c) where applicable, a copy of the manufacturing licence together with the current Good Manufacturing Practice certificate from the regulatory authority of the medicine's country of origin;

(d) in the case of specified Schedule 5, Schedules 6, 7 and 8 substances, a certified copy of a permit to manufacture such substances;

(e) data on the safety, efficacy and quality of the medicine, whether positive or negative, as may be determined by the Council;

(f) proof of the existence of a manufacturing site, ie a Site Master File;

(g) any other information as the Council may determine; and

(h) an application fee.

(4) The information referred to in subregulation (3) shall be in English and at least one other official language.

(5) The application form referred to in subregulation (3) shall contain at least the following information:

(a) Particulars of the Applicant and the prospective holder of certificate of registration:

(i) Name

(ii) Business Address

(iii) Postal Address

(iv) Telephone Number

(v) Fax Number

(vi) e-mail address

(vii) Contact details of the person referred to in subregulation (2)in the case of a juristic person.

(b) Particulars of a medicine:

(i) proprietary name

(ii) dosage form;

(iii) strength per dosage unit;

(iv) route of administration;

(v) country of origin and registration status outside the Republic;

(vi) category and pharmacological classification;

(vii) the name of the manufacturer(s); and

(viii) approved name.

(6) A medicine in respect of which an application for registration is made must comply with the technical requirements as determined by the Council.

(7) An application must be made in respect of each individual dosage form and strength of a medicine.

(8) In an instance where a medicine in respect of which an application is made is or was registered with any regulatory body outside the Republic,

the following information in respect of such medicine must accompany the application:

(a) a copy of the certificate of registration;
(b) package insert;
(c) conditions of registration; and
(d) any other information as determined by Council.

(9) The provisions of this regulation shall, with the necessary changes, apply to the application for the registration of veterinary medicines.

INFORMATION THAT MUST APPEAR IN THE REGISTER FOR MEDICINES

23. The medicines register must, in respect of any registered medicine, contain the following information:

(a) the proprietary name of the medicine;

(b) the registration number allocated to the medicine;

(c) the approved name of each active ingredient of the medicine and the quantity thereof contained in a dosage unit or per suitable mass or volume or unit of the medicine;

(d) the dosage form of the medicine, where applicable;

(e) the name of the holder of the certificate of registration;

(f) the name and address of the manufacturer(s) and the manufacturing facilities;

(g) the name of the final product release control (FPRC);

(h) the name of the final product release responsibility (FPRR);

(i) the date of registration of the medicine; and

(j) the conditions of registration of the medicine determined in terms of section 15(7) of the Act.

APPLICATION FOR AN AMENDMENT TO THE MEDICINES REGISTER

24. (1) A holder of a certificate of registration may submit to the Registrar an application on a form as determined by Council to amend an entry made into the medicines register with regard to a particular medicine.

(2) The application referred to in subregulation (1) shall be accompanied by a prescribed fee and must contain the following information:

(a) the registration number of the medicine;

(b) business address of the applicant;

(c) declaration by the applicant that the information furnished is complete and accurate;

(d) the details of the amendment applied for;

(e) any other information as determined by the Council; and

(f) the name of applicant.

CATEGORIES AND CLASSIFICATION OF MEDICINES

25. (1) The following are the basic categories of medicines:

(a) Category A = Medicines which are intended for use in humans and which are, without manipulation, ready for administration, including packaged preparations where only a vehicle is added to the effective medicine;

(b) Category B = Medicines which can not normally be administered without further manipulation; and

(c) Category C = Medicines intended for veterinary use which are, without further manipulation, ready for administration, including packaged preparations where only vehicle is added to the effective medicine.

(2) Medicines in category A are subdivided into the following pharmacological classes:

1. Central nervous system stimulants

1.1 Central analeptics

1.2 Psychoanaleptics (antidepressants)

1.3 Special antidepressant combinations

1.4 Respiratory stimulants

1.5 Hallucinogenic medicines and

1.6 Other central nervous system stimulants

2. Central nervous system depressants

2.1 Anaesthetics

2.2 Sedatives, hypnotics

2.3 Barbiturates

2.4 Non-barbiturates

2.5 Anticonvulsants, including anti-epileptics

2.6 Tranquillisers

2.6.1 Phenothiazines and their derivatives

2.6.2 Rauwolfia: Alkaloids and combinations

2.6.3 Diphenylmethane and its derivatives

2.6.4 Alkyl diols and their derivatives

2.6.5 Miscellaneous structures

2.7 Antipyretics or antipyretic and anti-inflammatory analgesics

2.8 Analgesic combinations

2.9 Other analgesics

2.10 Centrally acting muscle relaxants and

2.11 Other central nervous system depressants.

3. Connective Tissue Medicines

3.1 Antirheumatics (anti-inflammatory agents)

3.2 Non-hormonal preparations

3.3 Anti-gout preparations

3.4 Combinations with corticosteroids and

3.5 Others

4. Local anaesthetics

5. Medicines affecting autonomic function

5.1 Adrenomimetics (sympathomimetics)

5.2 Adrenolytics (sympatholytics)

5.3 Cholinomimetics (cholinergics)

5.4 Cholinolytics (anticholinergics)

5.4.1 Anti-Parkinsonism preparations

5.4.2 General

5.5 Ganglion blockers

5.6 Histamine

5.7 Antihistaminics, anti-emetics and antivertigo preparations

5.7.1 Antihistaminics

5.7.2 Anti-emetics and antivertigo preparations

5.8 Preparations for the common cold including nasal decongestants

5.9 Hydroxytryptamine (serotonin)

5.10 Serotonin antagonists and
5.11 Others

6. Cardiac medicines

6.1 Cardiac stimulants
6.2 Cardiac depressants

6.3 Cardiac glycosides and
6.4 Others

7. Vascular medicines

7.1 Vasodilators, hypotensive medicines

7.1.1 Rauwolfia and combinations

7.1.2 Rauwolfia: Diuretic combinations

7.1.3 Other hypotensives

7.1.4 Vasodilators - coronary and other medicines used in angina pectoris

7.1.5 Vasodilators - peripheral

7.2 Vasoconstrictors, pressor medicines

7.3 Migraine preparations

7.4 Lipotropic agents

7.5 Serum-cholesterol reducers and

7.6 Others

8. Medicines acting on blood and haemopoietic system

8.1 Coagulants, haemostatics

8.2 Anticoagulants

8.3 Erythropoietics (haematinics)

8.4 Plasma expanders and

8.5 Others

9. Medicines against alcoholism

10. Medicines acting on respiratory system

10.1 Antitussives and expectorants

10.2 Bronchodilators

10.2.1 Inhalants

11. Medicines acting on gastro-intestinal tract

11.1 Digestants

11.2 Gastro-intestinal antispasmodics and cholinolytics (anticholinergics)

11.3 Anorexigenics

11.4 Antacids

11.4.1 Acid neutralisers

11.4.2 Acid neutralisers with antispasmodics

11.4.3 Other

11.5 Laxatives

11.6 Lubricants and faecal softeners

11.7 Cholagogues

11.8 Suppositories and anal ointments

11.9 Antidiarrhoeals

11.9.1 Antidiarrhoeals in combination with anti-infective agents

11.9.2 Special combinations and

11.10 Others

12. Anthelmintics, bilharzia medicines, filaricides, etc.

13. Dermatological preparations

13.1 Antiseptics, disinfectants and cleansing agents

13.2 Antiscabies medicines

13.3 Surface anaesthetics

13.4 Antipruritics

13.4.1 Corticosteroids with or without anti-infective agents

13.4.2 Emollients and protectives

13.5 Rubefacients

13.6 Counterirritants

13.7 Keratolytics

13.8 Special combinations

13.8.1 Preparations for psoriasis

13.8.2 Fungicides

13.9 Radiation protectants

13.10 Melanin inhibitors and stimulants

13.11 Acne preparations and
13.12 Others

14. Preparations for treatment of wounds

14.1 Wound disinfectants
14.2 Wound dressings and
14.3 Others

15. Ophthalmic preparations

15.1 Ophthalmic preparations with antibiotics and/or sulphonamides

15.2 Ophthalmic preparations with corticosteroids

15.3 Combination antibiotics and
15.4 Others

16. Ear, nose and throat preparations

16.1 Nasal decongestants

16.2 Aural preparations

16.3 Surface anaesthetics
16.4 Naso-pharyngeal and bucco-pharyngeal antiseptics and

16.5 Others

17. Medicines acting on muscular system

17.1 Peripherally acting muscle relaxants

17.2 Muscle activators and

17.3 Others

18. Medicines acting on genito-urinary system

18.1 Diuretics

18.2 Antidiuretics

18.3 Ion-exchange preparations

18.4 Urolitholytics

18.5 Urinary tract antiseptics

18.6 Vaginal preparations

18.7 Contraceptive preparations

18.8 Ovulation controlling agents

18.9 Uterine antispasmodics and

18.10 Others

19. Oxytocics

20. Antimicrobial (chemotherapeutic) agents

20.1 Antibiotics and antibiotic combinations

20.1.1 Broad and medium spectrum antibiotics

20.1.2 Penicillins

20.1.3 Penicillin-streptomycin combinations

20.1.4 Antibiotic-sulphonamide combinations

20.1.5 Streptomycin and combinations

20.1.6 Topical antibiotics

20.1.7 Antifungal antibiotics

20.2 Other than antibiotics

20.2.1 Sulphonamides

20.2.2 Fungicides

20.2.3 Tuberculostatics

20.2.4 Leprostatics

20.2.5 Germicides

20.2.6 Medicines against protozoa

20.2.7 Spirochaeticides

20.2.8 Antiviral agents and

20.3 Others

21. Hormones, antihormones and oral hypoglycaemics

21.1 Insulin preparations

21.2 Oral hypoglycaemics

21.3 Thyroid preparations

21.4 Parathyroid preparations

21.5 Corticosteroids

21.5.1 Corticosteroids and analogues

21.5.2 Analgesic combinations

21.5.3 Anti-infective combinations

21.6 Anabolic steroids

21.7 Male sex hormones

21.8 Female sex hormones

21.8.1 Oestrogens

21.8.2 Progesterones with or without oestrogens

21.9 Androgen-oestrogen combinations

21.10 Trophic hormones

21.11 Hyperglycaemic hormones

21.12 Hormone inhibitors and

21.13 Others

22 Vitamins

22.1 Multivitamins and multivitamins with minerals

22.1.1 Vitamins for paediatric use

22.1.2 Vitamins for prenatal use

22.1.3 Vitamins for geriatric use

22.1.4 Vitamin B-complex with Vitamin C and

22.2 Others

23. Amino-acids

24. Mineral substitutes, electrolytes

25. Special foods

25.1 Infant foods and other formulae, excluding foods used solely as a substitute for human milk

26. Cytostatic agents

27. Chelating agents (versenates) as heavy metal antidotes

28. Contrast media

29. Diagnostic agents

30. Biologicals

30.1 Antibodies

30.2 Antigens

30.3 Blood fractions

31. Enzymatic preparations

32. Other substances or agents

32.1 Tonics

32.2 Other

32.3 Slimming preparations

32.4 Water for injection

32.5 Artificial tear and contact lens solutions

32.6 Preparations of boracic acid, borax and zinc, starch and boracic powder

32.7 Topical applications of delousing agents

32.8 Topical applications of insect repellents

32.9 Intra-uterine devices

32.10 Dental preparations

32.11 Solutions for haemo- or peritoneal dialysis

32.12 Preparations for which the expressions "medicated", "medicinal", "for medical use" or expressions with similar connotations are used

32.13 Preparations intended to promote hair growth

32.14 Sales packs containing two or more medicines with different indications

32.15 Radiopharmaceuticals and

32.16 Others

25(3) Medicines in category C are subdivided into the following pharmacological classes:

1. Central And Peripheral Nervous System

1.1 Central nervous system stimulants

1.1.1 Central analeptics

1.1.2 Respiratory Stimulants

1.2 Anaesthetics

1.2.1 Inhalation anaesthetics

1.2.2 Parenteral anaesthetics

1.2.3 Local anaesthetics

1.3 Narcotic analgesics

1.3.1 Opioid agonists

1.3.2 Opioid antagonists

1.4 Sedatives

1.4.1 Sedative hypnotics

1.4.2 Sedative analgesics

1.4.3 Sedative antagonists

1.5 Anticonvulsants including anti-epileptics

1.6 Tranquillisers

1.6.1 Phenothiazine derivatives

1.6.2 Butyrophenone derivatives

1.7 Neuroleptanalgesics

1.8 Analgesic antipyretics

1.9 Drugs used for euthanasia

2. Autonomic Nervous System

2.1 Sympathomimetics

2.2 Sympatholytics

2.3 Cholinergics

2.4 Antimuscarinics

3. Musculo-Skeletal System and Joints

3.1 Anti-inflammatory

3.1 .1 Steroidals

3.1.2 Non-steroidal anti-inflammatory drugs (NSAIDs)

3.1.2.1 Non selective COX2 inhibitors

3.1.2.2 Selective COX2 inhibitors

3.1.3 Topical agents

3.1.4 Combinations

3.1.5 Other

3.2 Analgesics

3.2.1 Opioids

3.2.2 NSAIDs

3.2.3 Topical agents

3.2.4 Combinations

3.3 Muscle relaxants

3.3.1 Centrally acting

3.3.2 Peripherally-acting

4. Autacoids

4.1 Histamine inhibitors

4.1.1 Antihistamines

4.1.2 Histamine release inhibitors

4.2 Serotonin antagonists

4.3 Others

5. Cardio-Vascular System

5.1 Positive inotropic agents

5.1.1 Cardiac glycosides

5.1.2 Methylxanthines

5.1.3 Others

5.2 Anti-arrhythmics

5.3 Vasodilators

5.3.1 Peripheral-acting vasodilators

5.3.2 Angiotensin inhibitors

5.3.3 Calcium channel inhibitors

6. Blood And Haemopoeitic System

6.1 Coagulants, haemostatics

6.2 Anticoagulants

6.3 Haematinics

6.4 Plasma expanders

7. Respiratory System

7.1 Antitussives and expectorants

7.2 Mucolytics

7.3 Bronchodilators

7.4 Combinations

8. Gastro-Intestinal System

8.1 Mouth washes

8.2 Emetics

8.3 Anti-emetics

8.4 Acid-reducers

8.4.1 Antacids and combinations

8.4.2 Histamine-2 receptor antagonists

8.4.3 Proton pump inhibitors

8.4.4 Cytoprotective agents

8.5 Motility enhancers

8.5.1 Lubricants and Faecal softeners

8.5.2 Laxatives and Purgatives

8.6 Antispasmotics

8.7 Antidiarrhoeals

8.7.1 Plain

8.7.2 With anti-microbial agents

8.7.3 Antimicrobial agents

8.7.4 Biologicals

8.8 Analgesics

8.9 Digestants

8.10 Preparations used in the rumen

8.10.1 Ruminotorics

8.10.2 Anti-bloat remedies

8.10.3 Others

9. Hepatic System

9.1 Cholagogues and cholerectics

9.2 Liver protectants and lipotropics

10. Urinary System

10.1 Diuretics

10.2 Urolitholytics and antispasmodics

10.3 Urinary tract antiseptics

10.4 pH modifiers

10.4.1 Urinary acidifiers

10.4.2 Urinary alkalinisers

10.5 Others

11. Reproductive System

11.1 Intravaginal and intra-uterine preparations

11.2 Sex hormones

11.2.1 Testosterone

11.2.2 Oestrogens

11.2.3 Progesterones & Progestogens

11.2.4 Combinations

11.3 Prostaglandins

11.4 Trophic hormones

11.5 Myometrial stimulants (Ecbolics)

11.6 Myometrial relaxants (Tocolytics)

11.7 Ovulation controlling agents

12. Endocrine System

12.1 Insulin preparations

12.2 Thyroid preparations

12.3 Corticosteroids

12.4 Growth Hormone

12.5 Anabolic steroids

13. Dermatologicals

13.1 Disinfectants and cleaning agents

13.2 Antiseptic and antimicrobial preparations

13.3 Antipuritics

13.3.1 Topical corticosteroids with or without anti-infective agents

13.3.2 Topical antihistamines with or without anti-infective agents

13.4 Emollients and protectives

13.5 Rubefacients and counter irritants

1 3.6 Keratolytics

13.7 Antifungals

13.8 Anti-parasitics

14. Ophthalmic And Aural Preparations

14.1 Anti-infectives

14.2 Corticosteroids

14.3 Combinations (anti-infective with corticosteroids)

14.4 Others

15. Wounds

15.1 Wound antiseptics

15.2 Wound dressings

15.3 Desloughing agents

16. Mammary Gland

16.1 Intra-mammary preparations

16.2 Preparations for the care of teats and udders

17. Antimicrobials

17.1 Antibacterials

17.1.1 Beta-lactams

17.1.1.1 Penicillins

17.1.1.2 Cephalosporins

17.1.2 Tetracyclines

17.1.3 Aminoglycosides

17.1.4 Macrolides and Lincosamides

17.1.5 Amphenicol

17.1.6 Quinolones

17.1.7 Sulphonamides and potentiators

17.1.8 Nitrofurans

17.1.9 Polypeptides

17.1.10 Other

17.1.11 Antibacterial combinations

17.2 Antifungals

17.3 Antivirals

17.4 Anti-protozoals

17.4.1 Anticoccidials

17.4.2 Antibabesials

17.4.3 Spirochaeticides

17.4.4 Others

18. Antiparasitic Agents

18.1 Endoparasiticides

18.1.1 Benzimidazoles and Probenzimidazoles

18.1.2 Macrocyclic lactones

18.1.3 Halogenated salicylanilides and Nitrophenols

18.1.4 Imidazoles

18.1.5 Tetrahydropyrimidines

18.1.6 Piperazines

18.1.7 Organophosphores

18.1.8 Others

18.1.9 Combinations

18.2 Endectocides

18.3 Ectoparasiticides

18.3.1 Organochlorines

18.3.2 Organophosphores

18.3.3 Pyrethrin and Pyrethroids

18.3.4 Formamidines

18.3.5 Nitroquanidines

18.3.6 Phenylpyrazoles

18.3.7 Insect growth hormones

18.3.8 Chitin inhibitors

18.3.9 Others

18.3.10 Combinations

19. Vitamins, Minerals And Geriatric Preparations

19.1 Vitamins only

19.2 Vitamin and mineral combinations

19.3 Minerals and electrolytes

19.4 Vitamins, electrolytes and aminoacid combinations

20. Cytostatic Agents

21. Immune Modulating Agents

22. Chelating Agents

23. Contrast Media

24. Biologicals

24.1 Dogs vaccines

24.2 Cats vaccines

24.3 Poultry vaccines

24.4 Other vaccines

24.5 Other biologicals

25 Production Enhancers

25.1 Antimicrobials

25.2 Hormones

25.2.1 Sex hormones

25.3 Beta agonists

25.4 Other

26. Fish Medicines

CERTIFICATE OF REGISTRATION

26. A certificate of registration substantially in the form shown below shall be issued by the Registrar in terms of section 15(4) after a medicine has been registered.

MEDICINES AND RELATED SUBSTANCES ACT 1965, (ACT 101 OF 1965)
MEDICINE REGISTRATION CERTIFICATE

It is hereby certified that registration of the medicine described below has been approved by the Medicines Control Council in terms of Section 15(3)(a) of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965), subject to the conditions indicated.

1. Proprietary name .....

2. Registration number .....

3. Approved name of every active ingredient and quantities thereof per dosage unit or per suitable mass or volume or unit of the medicine .....

4. Dosage form .....

5. Conditions under which the medicine is registered .....

6. Registered in the name of (holder of certificate of registration) .....

7. Name and address of the manufacturer and the manufacturing facility.....

8. Name of the final product release control.....

9. Name of the final product release responsibility.....

10. Conditions of registration.....

11. Date of registration .....

.....
Registrar of Medicines

Issued at .....on..... 20 .....

DESTRUCTION OF MEDICINES

27. (1) A medicine or scheduled substance may be destroyed as follows:

(a) A medicine containing a Schedule 5, 6, 7 or 8 substance may only be destroyed in the presence of an inspector, an officer of the South African Police Service or any other person authorised by the Director-General. Such inspector, person or officer, as the case may be, shall issue a certificate confirming the destruction of the medicine and in the case of an officer, the case number must be entered in the register;

(b) notwithstanding paragraph (a), the Council may authorise the destruction of Schedules 5 or 6 substance by a manufacturer of such substances in the absence of an inspector;

(c) in the case of Schedule 1, 2, 3 and 4 substance or medicine, a pharmacist or an authorised person in charge of a place where medicines or substances are kept may destroy such medicines or substances. Such pharmacist or authorised person shall certify such destruction.

(2) No medicines may be disposed of into municipal sewerage systems.

(3) The destruction or disposal of medicines or scheduled substances must be conducted in such a manner as determined by the Council to ensure that they are not retrievable.

PARTICULARS WHICH MUST APPEAR ON A PRESCRIPTION OR ORDER FOR A MEDICINE

28. (1) Every prescription or order for a medicine must be written in legible print, typewritten or computer generated and signed in person by a medical practitioner, dentist, veterinarian or authorised prescriber or in the case of an order, an authorised person, and must at least state the following:

(a) the name, qualification, practice number and address of the prescriber or authorised person placing the order;

(b) the name and address of the patient in the case of a prescription or the name and address of the person to whom the medicines are delivered in the case of a prescription issued by a veterinarian;

(c) the date of issue of the prescription or order;

(d) the approved name or the proprietary name of the medicine;

(e) the dosage form;

(f) the strength of the dosage form and the quantity of the medicine to be supplied;

(g) in the case of a prescription, instructions for the administration of the dosage, frequency of administration and the withdrawal period in the case of veterinary medicines for food producing animals;

(h) the age and sex of the patient and in the case of veterinary medicine, the animal species; and

(i) the number of times the prescription may be repeated.

(2) In the case of a faxed, e-mailed, telephone or electronic transmission by other means of a prescription or order, the pharmacist must verify the authenticity of the prescription or order.

(3) A permanent copy of the faxed, e-mailed, telephone or other electronic transmitted prescription or order referred to in subregulation (2) must be made for record purposes;

(4) The faxed, e-mailed, telephone or other electronic transmitted prescription or order should be followed by the original prescription or order within 7 working days.

(5) The prescriber must keep records of the diagnosis relevant to the prescription and where the patient consents, indicate the diagnosis on the prescription.

RETURNS TO BE FURNISHED IN RESPECT OF SPECIFIED SCHEDULE 5, SCHEDULES 6, 7 AND 8 SUBSTANCES

29. (1) No person shall import, export, sell by wholesale, produce, manufacture, or use in the manufacture of any medicine or substance, any substance referred to in section 22A(12) of the Act unless the Council is supplied with a return reflecting the following information on or before 28 February of each year-

(a) the quantity of such substance, as a raw material or as contained in a preparation, which was held in stock on 1 January of the

preceding calendar year;

(b) the quantity of such substance acquired during the preceding calendar year by -

(i) importation, as a raw material or contained in a preparation;

(ii) production of the raw material in the Republic;

(iii) purchasing of the raw material in the Republic and the name of the supplier must be stated;

(c) the quantity of such substance, as a raw material or as contained in a preparation, which was disposed of during the preceding calendar year through -

(i) exportation; or

(ii) destruction thereof;

(d) the quantity of such substance used during the preceding calendar year in -

(i) the production of any other Schedule 6 or Schedule 7 substance or a specified substance referred to in section 22A(12) of the Act; and

(ii) the production of any other chemical substance not included in Schedule 6 or Schedule 7 or specified in section 22A (12)(a) of the Act;

(e) the quantity of such substance and preparations containing such substance remaining in stock on 31 December of the preceding year.

(2) Notwithstanding sub-regulation (1), the Council may exempt an importer or exporter from furnishing a return, if the particular return is not necessary in determining the consumption of any of the substances included therein.

(3) The return referred to in sub-regulation (1) must comply with the following requirements:

(a) all quantities must be expressed in metric units as a percentage base of the relevant substance;

(b) in the case of opium and any preparations containing opium, quantities must be expressed in terms of opium containing 10% of anhydrous morphine;

(c) preparations obtained not directly from opium itself but by mixing opium alkaloids must be expressed in terms of morphine;

(d) in the case of any preparations of coca-leaves, quantities of coca-leaves must be expressed in terms of coca-leaves containing 0,5% of cocaine; and

(e) where stocks are held or manufacture has been undertaken on behalf of another applicant, this fact must be indicated.

REGISTER OF SPECIFIED SCHEDULE 5, SCHEDULES 5 OR 6 MEDICINES OR SUBSTANCES

30. (1) A person importing, exporting, manufacturing or selling specified Schedule 5, Schedules 5 or 6 medicines or substances shall keep a register of such medicines or substances.

(2) The register referred to in subregulation (1) must indicate the quantity of every such medicine or substance remaining in stock on the last day of March, June, September and December of each year and must also contain the following information:

(a) the date on which the medicine or substance was received or supplied;

(b) the name, business address of the person from whom the medicine or substance was received or sent and in the case of imported medicine or substance, the import permit number;

(c) the name and address of the person who purchased the medicine or substance;

(d) the quantity, in words and figures, of such medicine or substance indicated per dosage unit, mass or volume;

(e) in the case of the supply of the medicine or substance on prescription, the name and address of the authorised prescriber unless such prescription was issued at a hospital in which case the name of the authorised prescriber shall be recorded;

(f) the quantity of the medicine or substance manufactured or used during the manufacturing process; and

(g) any other information as the Council may determine.

(3) The register referred to in subregulation (1) must be kept for a period of five years after the date of the last entry made therein.

(4) In a case where the register is kept by computer, a computer print out must be made monthly, dated, signed and filed.

(5) Records must be stored in an orderly manner so that they can be accessed easily.

METHOD OF TAKING SAMPLES DURING AN INVESTIGATION, THE CERTIFICATE TO BE ISSUED AND THE REPORTING OF ANALYSIS RESULTS

31. (1) An inspector may take a sample or any quantity of samples of a medicine or Scheduled substance for purposes of testing, examination or analysis in terms of the Act by a person designated as an analyst, pharmacologist or pathologist.

(2) The sample or samples contemplated in subregulation (1) must -

(a) be taken in the presence of the person who is in charge of such medicine or substance, or in the absence of such person, in the presence of any witness present;

(b) be taken and stored in such a manner as to ensure its integrity during the entire examination process of the sample;

(c) be packed and sealed and suitably labelled or marked in such a manner as its nature may permit and must be transmitted by any suitable means to an analyst, pharmacologist or pathologist together with the certificate signed by the inspector, a copy of which must be issued to the person contemplated in paragraph (a) by the inspector at the earliest possible time.

(3) An analyst, pharmacologist or pathologist referred to in subregulation (1) must as soon as possible after receipt of the sample, test, examine or analyse the sample and report the results thereof.

(4) An inspector referred to in subregulation (1) may take a sample during a routine inspection from a manufacturer, a wholesaler or retailer for testing, examination or analysis in terms of these regulations.

(5) Notwithstanding subregulation (1), the Council may require any holder of a certification of registration to supply the Council with a sample of a particular medicine or substance in order to test, examine or analyse such sample.

(6) Certificates or reports issued in terms of this regulation must be submitted to the registrar within 7 days from the date of issue.

SEIZURE OF MEDICINES

32. (1) A medicine may be seized if it-

(a) is unregistered and sold in contravention of the Act;

(b) is suspected counterfeit;

(c) is misbranded;

(d) has expired

(e) is suspected stolen;

(f) is Scheduled and is possessed by an unauthorised person or by an authorised person but in unauthorised quantities;

(g) has been declared undesirable in terms of the Act;

(h) belongs to the State and is found possessed by an unauthorised person; or

(i) is used in unauthorised clinical trial.

(2) An inspector seizing any item in terms of section 28 (1) (c) of the Act shall as soon as possible and at the scene of seizure make a written inventory of all items seized and the inventory shall include:

(a) the date, place and time of seizure;
(b) the name and personal details of the person from whom the items were seized;
(c) the name and quantity of every item seized; and
(d) the name of the inspector conducting the seizure.

(3)An item contemplated in section 28 (1) (c) of the Act may be used as evidence in any criminal proceedings in terms of this Act.

(4) An inspector taking any sample in terms of section 28 (1) (d) shall make a written inventory of all samples taken which shall include:

(a) the date on which, the place where and time when the sample was taken;
(b) a description of nature and size of each sample taken;
(c) the personal details of the person in whose presence the samples were taken; and
(c) the name of the inspector taking the sample.

REPACKING OF MEDICINES INTO PATIENT READY PACKS

33. The repacking of medicines into patient ready packs-

(a) may only be carried out by-

(i) a pharmacist or under the supervision of a pharmacist; or

(ii) any other person authorised in terms section 29(4)of the Pharmacy Act, 1974

(b) must have a batch numbering system which contains all the information relating to the ingredients and the procedures used in preparing the patient ready pack;

(c) must be carried out under the required temperature and humidity conditions;

(d) must be carried out in an area of the premises specially used for pre-packing only; and

(e) must be carried out in accordance with good manufacturing and distribution practices.

CONDUCT OF CLINICAL TRIALS FOR HUMANS

34. (1) A person desiring to initiate or conduct a clinical trial in respect of an unregistered medicine, a new indication or new dosage regimen of a registered medicine or substance, shall apply to the Council on a form determined by the Council for authority to conduct such a clinical trial.

(2) An application referred to in subregulation (1) shall be accompanied by a fee as determined in the Regulations Relating to Fees Payable to the Council and shall contain at least the following information:

(a) trial protocol;

(b) investigator's brochure containing relevant chemical, pharmaceutical, pre-clinical pharmacological and toxicological data and where applicable, human pharmacological and clinical data with the substance concerned;

(c) Curriculum Vitae of all investigators;

(d) signed declaration by the applicant and all investigators that they are familiar with and understand the protocol and will comply with Good Clinical Practice as determined by the council in the conduct of the trial; and

(e) informed consent document and endorsement by any ethics committee recognised by the Council.

(3) The clinical trial protocol referred to in paragraph (a) of subregulation (2) shall contain at least the following information:

(a) number of human subjects to be involved in the trial;

(b) the name of an investigator who shall be an appropriately qualified and competent person approved by the Council, resident in the Republic, and must be
in charge of the site where trials are conducted; and;

(c) any other information as determined by the Council.

(4) Clinical trials must be conducted in accordance with guidelines for good clinical practice as may from time to time be determined by the Council.

(5) No person shall conduct clinical trials referred to in subregulation (1) without the authorisation of the Council.

(6)The person conducting the clinical trial must submit progress reports to the Council after every six months from the date when the clinical trial was started and 30 days after the completion or termination of the clinical trial.

(7) The Council may request additional information, inspect a clinical trial or withdraw the authorisation to conduct a clinical trial if the council is of the opinion that the safety of the subjects of the trial is compromised, or that the scientific reasons for conducting the trial have changed.

(8) A medicine referred to in subregulation (1) must be properly labelled and the package must sufficiently identify the-

(a) clinical trial to be carried out;
(b) medicine to be used;
(c) person to whom the medicine is to be administered; and
(d) name and address of the premises where the clinical trial is to be carried out.

SKILLS OF MEMBERS OF THE COUNCIL AND ITS COMMITTEES

35. The Council shall include the following:

(a) At least three persons who shall be medical practitioners and one such person shall be a paediatrician, another a specialist in internal medicine and another a specialist in public health;

(b) an expert in clinical pharmacology;

(c) an expert in pharmaceutical chemistry;

(d) an expert in toxicology and drug safety;

(e) an expert in biotechnology;

(f) a pharmacist who is an expert in pharmaceutics;

(g) one person with knowledge in the study of Adverse Drug Reactions; and

(h) an expert in virology and microbiology;

(i) one person with specialised knowledge in veterinary clinical pharmacology;

(j) one veterinarian designated by the Minister of Agriculture;

(k) one person with knowledge of complementary medicines and

(l) a person with expertise in law.

CONTROL OF MEDICINES IN HOSPITALS

36. The responsible pharmacist or any other person licensed in terms of section 22C(1)(a)of the Act shall supervise the safety, security, purchasing, storage, and dispensing of medicines in a hospital.

ADVERSE DRUG REACTION

37. (1) The applicant or holder of a certificate of registration in respect of a medicine or Scheduled substance shall inform the Council, in the manner and within the time frame as determined by the Council, of suspected adverse drug reactions reported to him, her or it occurring as a result of the use of such a medicine or scheduled substance.

(2) Subregulation (1) also applies in the case of unregistered medicines used in terms of sections 14(4), 15C and 21 of the Act.

(3) The holder of the certificate referred to in subregulation (1) or the applicant with regard to medicines referred to in subregulation (2), as the case may be, shall-

(a) within the time frame determined by the Council after receipt of the report referred to in subregulation (1) inform the Council of the steps to be taken to address the adverse drug reactions;

(b) whenever requested by the Council, conduct a concise critical analysis of the safety and efficacy profile of the medicine concerned and submit the results thereof to the Council within a specified time frame; and

(c) in the case where, after receipt of the results referred to in paragraph (b), the Council determines that the medicine may not be safe to use, submit, if required to do so to the Council:

(ii) case reports of all suspected adverse drug reactions in respect of the medicine; and

(ii) other pharmacovigilance data such as drug usage figures, periodic safety update reports, pharmacovigilance studies, etc;

(d) keep and maintain or have access to records of all adverse reaction data in respect of his, her or its medicines.

(4) Nothing in this regulation shall be interpreted as prohibiting any person from reporting any adverse drug reaction to the Council.

PRICING COMMITTEE

38. (1) The pricing committee contemplated in section 22G of the Act shall consist of no more than eighteen members, but shall include-

(a) one person nominated by the Minister of Finance;

(b) one person nominated by the Minister of Trade and Industry;

(c) one or more persons representing the Department of Health;

(d) at least one person with background in pharmacology;

(e) at least one person with background in the law;

(f) at least one person with background in academic medical research;

(g) at least two persons with economics background, one of whom must be a health economist; and

(h) at least one person representing independent patient or consumer groups.

(2) The Committee shall determine the procedure for the conduct of its business.

(3) The Committee may appoint, subject to the approval of the Minister, subcommittees as it may deem necessary, to investigate and report to it any matter within the purview of the Committee in terms of the Act.

(4) The Director-General may designate employees of the Department to serve as the secretariat of the Committee.

INVESTIGATIONS

39. The Council may conduct an investigation with regard to a medicine if-

(a) such a medicine is recalled in South Africa or any other country;

(b) adverse reaction is reported;

(c) the medicine is suspected or found not to comply with the requirements of the Act;

(d) there is an international alert with regard to such a medicine; or

(e) for any other reason, the Council deems it fit to conduct an investigation on the medicine.

PACKAGE INSERTS FOR VETERINARY MEDICINES

40. (1) The immediate container of a veterinary medicine that is sold must have the following information with regard to the medicine which is in

at least one official language and in minimum legibility:

(a) the proprietary name;

(b) scheduling status;

(c) dosage form;

(d) composition, using generic or approved names;

(e) pharmacological classification;

(f) pharmacological action;

(g) pharmacokinetic properties and pharmacodynamic properties;

(h) contra-indications;

(i) warnings or withdrawal period in the case of food producing animals;

(j) side-effects and special precautions;

(k) known signs of overdose and particulars of its treatment;

(l) quantity and strength of active ingredients per dosage unit;

(m) storage instructions;

(n) registration number;

(o) name and business address of holder of certificate of registration; and

(p) any other information as the Council may from time to time determine.

(2) The Council may, upon application, authorise a deviation from subregulation (1).

USE OF MEDICINES FOR THE PREVENTION OF MALARIA

41. (1) Any person who is employed by any department responsible for environmental affairs and tourism at a provincial government may acquire, keep and use for the purpose of preventing malaria, the medicine referred to in sub-regulation (4).

(2) At the place where such medicine is kept and used there shall be freely available a supply of pamphlets concerning the use of such medicine, which pamphlets shall be approved by the Council.

(3) Every employer referred to in sub-regulation (1) who implements the provisions of this regulation, shall-

(a) before the end of March of every year, furnish the Council with a statement reflecting the names and location of every place where such medicine is kept and used; and

(b) permit an inspector who has been duly authorised in terms of the Act to inspect such a place.

(4) The medicine referred to in this regulation shall-

(a) be tablets and liquids containing chloroquine sulphate, pyrimethamine and dapsone or combinations thereof in packs, the contents of which do not exceed 20 tablets or 50ml when in liquid form, or tablets which contain proguanil hydrochloride in packs, the contents of which do not exceed 100 tablets; or

(b) be any other anti-malaria medicine and in a quantity as may be determined by the Director-General from time to time.

OFFENCES AND PENALTIES

42. Any person who fails to comply with, contravenes the provisions of or wilfully furnishes incorrect information in respect of -

(a) Regulation 7(1)(c) or (d) with regard to the parallel importation of medicines;

(b) Regulation 8 with regard to the labelling of medicines for human use;

(c) Regulation 9 with regard to the package inserts;

(d) Regulation 10 with regard to the patient information leaflet;

(e) Regulation 11 with regard to the prescription book;

(f) Regulations 12 or 13 with regard to the importation or transmission of medicines;

(g) Regulation 14 with regard to the permits issued in terms of section 22A(9) of the Act;

(h) Regulation 15 with regard to the importation or exportation of specified Schedule 5, Schedules 6, 7 or 8 substances;

(i) Regulation 16 with regard to the possession of specified quantities of Schedule substances for personal medicinal use by persons entering or departing from the Republic;

(j) Regulation 17 with regard to the information to be furnished annually to the Registrar by the holder of a permit to import or export Schedules 6 & 7 substances;

(k) Regulation 18 with regard to the licence to compound and dispense medicines;

(l) Regulation 19 with regard to the licence to manufacture, act as a wholesaler or distributor of medicines;

(m) Regulation 27 with regard to the destruction of medicines;

(n) Regulation 28 with regard to the particulars which must appear on a prescription or order for medicine;

(o) Regulation 29 with regard to the returns to be furnished in respect of specified Schedule 5, Schedules 6, 7 and 8 medicines and specified substances;

(p) Regulation 30 with regard to the register of schedule 5 & 6 medicines

(q) Regulation 34 with regard to the conduct of clinical trials;

(r) Regulation 40 with regard to the package inserts for veterinary medicines;

(s) Regulation 45 with regard to the advertising of medicines; or

(t) Regulation 48 with regard to the labelling of veterinary medicines; or

sells a medicine that has expired, shall be guilty of an offence and upon conviction be liable to a fine, or to imprisonment for a period not exceeding 10 years.

COMPLIANCE WITH REQUIREMENTS

43. (1) Every medicine shall comply with the standards and specifications which were furnished to the Council on the form prescribed by regulation 22 and which have been accepted by the Council with regard to such medicine.

(2) Any proposed deviation from accepted standards and specifications as intended in subregulation (1) shall be submitted to the Council for prior approval and such deviation shall not be introduced before the said approval has been granted.

BATCH RELEASE FOR BIOLOGICAL MEDICINES

44. The council may, with regard to the registration of biological medicines, require, in terms of section 15 (7) of the Act, that six samples of every batch, together with six copies of the protocols of testing of the bulk batch and filling batch and six copies of the certificate of release issued by the competent authority in the country in which the product was manufactured, be submitted to the council as a batch release condition.

ADVERTISING OF MEDICINES

45 (1) The under mentioned requirements shall apply to any advertisement of a medicine.

(2) (a) Medicines which do not contain a scheduled substance and medicines which contain a substance appearing in Schedule 0 or Schedule 1 may be advertised to the public; and

(b) Medicines which contain a substance appearing in Schedule 2,

Schedule 3, Schedule 4, Schedule 5 or Schedule 6 may be advertised only for the information of medical practitioners, dentists, veterinarians
pharmacists and other persons authorised to prescribe or in a publication which is normally or only made available to persons referred to therein;

(c) Paragraph (b) shall not be so construed as to prohibit informing the public of the prices, names, pack sizes and strengths of medicines which contain a substance appearing in Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6.

(3) No advertisement for a medicine may contain a statement which deviates from, is in conflict with or goes beyond the evidence submitted in the application for registration of such medicine with regard to its safety, quality or efficacy where such evidence has been accepted by the Council in respect of such medicine and incorporated into the approved package insert of such medicine.

(4) A written advertisement for a medicine shall contain-

(a) the proprietary name of such medicine;

(b) the approved name and quantity of each active ingredient of such medicine in lettering having minimum legibility: Provided that, in the case of a medicine containing only one active ingredient, such lettering shall be not less than one half the size of the largest lettering used for the said proprietary name; and

(c) in the case -

(i) of a registered medicine, the registration number allocated to it in terms of section 15 (6);

(ii) of a medicine in respect of which an application for registration has been submitted in terms of section 14 of the Act, the reference number allocated to such application by the Registrar, followed by the words 'Act 101/1965)';

(iii) where a name other than the proprietary name is also used, such other name in lettering one half the size of the largest type size in which the proprietary name appears in such advertisement;

(iv) of a veterinary medicine, an indication that the medicine is for veterinary use; and

(v) of a homeopathic medicine, an indication that the medicine must be used in accordance with homeopathic principles.

(5) In the case of an advertisement for a medicine which contains more than one active ingredient, no specific reference shall be made to the specific properties of any individual active ingredient unless a reference of this nature has been approved by the Council for inclusion in the package insert of such medicine.

(6) When a medicine is advertised verbally for the first time to persons referred to in subregulation 2(b), written information, which shall include at least the information referred to in regulation 9 or regulation 40, shall simultaneously be given to the person to whom the oral advertisement is directed, and when the medicine is advertised orally on subsequent occasions such information shall be available on request.

RULES RELATING TO THE CONDUCT OF BUSINESS OF THE COUNCIL

46. In addition to the provisions concerning the conducting of the business of the Council as prescribed in the Act, the following additional rules shall apply:

(1) Notices convening ordinary and special meetings of the Council shall be signed by the Registrar, and shall specify the business to be transacted at the meeting. They shall be sent by post or by hand to each member and issued, in the case of ordinary meetings, at least 10 days before the date for which the meeting is convened. In the case of special meetings such notice shall be given as the Chairperson may deem sufficient, and, if necessary, may be given by telegram or telephone. If all members agree, a specific meeting can be convened at shorter notice, or without written notice.

(2) No business shall be transacted at a meeting other than that specified in the notice relating thereto, except matters which the Council shall resolve to deal with as urgent.

(3) The Council may adjourn a meeting to any day or hour, but no business shall be transacted at an adjourned meeting except such as was set out in the notice convening the meeting of which it is an adjournment, other than matters which are brought forward in accordance with the preceding subregulation.

(4) An attendance register of any members attending a meeting shall be kept by the Registrar.

(5) Any member desirous of bringing any matter before the Council shall forward in writing to the Registrar at least 30 days before the date for which a meeting is to be convened, a written notice of his or her motion, and the notice of his or her motion shall appear in the notice convening the meeting and shall be considered with the other business to be brought before the Council in the order indicated.

(6) No matter shall be considered unless due notice has been given in accordance with the preceding rule, unless permission is obtained from the meeting to bring it forward as a motion. Should the motion find no seconder, it shall not be further considered.

(7) The quorum of any committee established under section 9 (l) (b) of the Act and of the Executive Committee shall consist of the majority of the members of the relevant committee.

(8) The Registrar shall, when the Council is not sitting, refer, as far as possible, all matters within the terms of reference of a committee to such committee, and such committee shall, if possible, report thereon to the next meeting of the Council. This rule shall not apply to matters of ordinary routine or such matters, the principle of which has already been laid down by regulation or resolution of the Council.

(9) The rules of procedure laid down herein for the conduct of ordinary and special meetings of the Council shall apply to meetings of committees.

(10) Copies of reports of committees shall, whenever practicable, be forwarded to each member of the Council with the notice convening the meeting at which such reports are to be considered.

(11) The proceedings of meetings of the Council shall be preserved in the form of typewritten minutes authenticated, after confirmation, at the next meeting by the signature of the Chairperson.

(12)(a) The minutes of each meeting of the Council and the Executive Committee shall contain a resume of the subject matter dealt with, and such

motions and amendments as have been proposed and adopted or rejected, with the names of the proposer and seconder, but without any comment or observation of the members.

(b) The minutes of all meetings of committees of the Council established under section 9 (1) (b) of the Act shall contain a resume of the subject matter dealt with and resolutions adopted, but without any comment or observation of the members.

(13) The Registrar shall forward a copy of the minutes of each meeting of the Council and of any committee to all members of the Council as soon as reasonably possible after the meeting has been held.

(14) The minutes may be taken as read: Provided that any member may move that a particular minute should be read with a view to such correction therein or addition thereto as may be found necessary.

(15) At the opening of each separate session of the Council, opportunity shall be given to members to put questions with regard to the work of the Council, which questions shall be answered forthwith, if possible, or if not, at a later session by the Chairperson or by such office-bearer or official as the Chairperson may direct. No discussion thereon shall be permitted.

(16) The agenda for every meeting of the Council or of a committee of the Council shall be compiled by the Registrar in consultation with the Chairperson and shall include the following:

(a) Confirmation of the minutes of the previous meeting;

(b) matters arising from the minutes of the previous meeting;

(c) reports of standing committees;

(d) motions

(e) correspondence;

(f) general.

It shall, however, be permissible for a member of the Council to move at a particular meeting that any item appearing on the agenda for that particular meeting of the Council be advanced in the agenda.

(17) All motions and amendments shall, unless otherwise permitted by the Chairperson, be committed to writing and signed by the proposer, and, before they are spoken to by other members, shall be read by the Chairperson or by the Registrar under the authority of the Chairperson, and seconded. All formal amendments shall be so framed that they may be read as independent motions. An amendment shall be relevant to the motion it is intended to amend, and shall not alter the original motion in such a way as to make it virtually a new motion. It shall be so framed as

(a) to add or insert certain words; or

(b) to omit certain words; or

(c) to omit certain words and add or insert others.

(18) No motion or amendment shall be withdrawn after having been read by the Chairperson or by the authority of the Chairperson unless by permission of the Council.

(19) The seconder of a motion or of an amendment may reserve his speech until any period of the debate.

(20) If an amendment be proposed, it may be followed by other amendments, and the last amendment shall be considered first.

(21) Should every amendment be rejected, the original motion shall then be put to the vote.

(22) If an amendment be carried, it shall then be regarded as a substantive motion and, as to further amendments, in all other respects be treated as an original motion.

(23) When a motion is under debate, no further proposal shall be received except one of the following:

(a) An amendment, namely, "that the motion be amended as follows:

(b) the postponement of the question, namely, "that the meeting do proceed to the next business".';

(c) the closure, namely, "that the question be now put";

(d) the adjournment of the debate, namely, "that the debate on the motion be adjourned"; or

(e) the adjournment of the Council, namely, "that the Council do now adjourn'.

(24) When an amendment is under debate, no further proposal shall be received except one of the following:

(a) An amendment, namely, "that the motion be amended as follows: ;

(b) the closure, namely, "that the question be now,. put";

(c) the adjournment of the debate, namely, "that the debate on the motion be adjourned";

(d) the adjournment of the Council, namely, "that the Council do now adjourn".

(25) The proposal for the postponement of the question (which may specify a date for the further consideration of the question) shall be made and seconded without debate, and may be moved at any time, even during debate on an amendment. If the proposal is carried, the question shall be dropped from the programme of business. If it is lost, the debate shall proceed.

(26) The proposal for the closure shall be made and seconded without debate and shall be put forthwith. Should the proposal be carried, the motion or amendment under debate shall at once be voted on by the Council.

(27) If the proposal for the adjournment of the debate is carried, the Council shall pass to the next item on the programme of business and the debate shall be resumed at the next ordinary meeting of the Council. The proposer of the adjournment shall, on the resumption of the debate, be

entitled to speak first.

(28) If the proposal for the adjournment of the Council is proposed and seconded, it shall be competent for the Chairperson, before putting the question, to take the opinion of the Council as to whether it shall, before rising, proceed to the transaction of unopposed business.

(29) A motion to rescind a resolution, which has been passed at a previous meeting, shall be considered only if notice thereof has been given in terms of rule (6). It shall be passed if a majority of the votes recorded are in its favour. A motion to rescind a resolution which has been passed during a session of the Council may, however, notwithstanding what is prescribed above, be considered at the same session of the Council, provided that written notice thereof is given that the matter be considered on a subsequent day of that session. It shall be passed only if two thirds of the votes recorded are in its favour.

(30) The Registrar shall embody in the minutes any rulings of the Chairperson as to the interpretation of these rules, if so requested by a member at the time of the ruling.

(31) Notice may be given of a motion to review any ruling of the Chairperson as to the interpretation of these rules, if so requested by a member at the time of the ruling.

(32) Notice may be given of a motion to review any ruling of the Chairperson, and when given shall constitute an instruction to the Executive Committee to consider and report to the Council on such ruling and shall be placed on the Council agenda.

(33) The ruling of the chairperson of any committee on a point of order may, on the request of any two members of the committee present at the meeting at which such ruling was given, be reviewed by the Executive Committee, which may, if it thinks fit, direct that such ruling shall be cancelled or amended, and the decision of the Executive Committee shall be acted on by the chairperson of the committee whose ruling is called in question unless and until reversed by the Council. If any ruling of the Chairperson of the Executive Committee is called in question, the Chairperson shall vacate the chair while the matter is under discussion: Provided, however, that no ruling may be discussed or reviewed during the

meeting of the committee at which it has been given.

(34) If any member dissents from the opinion of the majority and wishes to have his dissent recorded, he shall state so forthwith; such dissent shall then be entered in the minutes.

OBTAINING OF PETHIDINE OR PREPARATIONS THEREOF BY REGISTERED MIDWIVES

47. (1) Any person registered as a midwife, in terms of the Nursing Act. 1978 (Act 50 of 1978), who wishes to purchase, acquire or keep for administration to patients Scheduled substances appearing on a list published by the Council in the *Gazette* shall apply in writing to the Director-General for a permit.

(2) An application referred to in subregulation (1) shall contain the following information:

(a) the type of midwifery service for which the scheduled substances are required;

(b) the name, in full, of the applicant, together with proof of current registration with the South African Nursing Council;

(c) the registered name and address of the pharmacy from which the applicant intends to obtain the scheduled substances;

(d) the name, strength, and quantity of every scheduled substance required;

(e) the precise quantities of the maximum supply of all scheduled substances for which the permit is requested; and

(f) the physical address of the premises where the midwifery services are intended to be rendered.

(3) The Director General may, upon receipt of such application and after making such enquiries as he or she may deem necessary, issue a permit authorising the applicant to purchase, acquire, keep or administer the requested scheduled substances.

(4) The permit shall be issued in a form as determined by the Director-General and in triplicate, and the original shall be sent to the Pharmacy, the duplicate to the applicant (registered midwife) and the third copy shall be retained by the Director General.

(5) A permit referred to in subregulation (3) shall be issued subject to the following conditions:

(a) the applicant shall keep a register of scheduled substances in the form as determined by Council, in which shall be entered the following particulars with regard to scheduled substances in Part (a):

(i) Schedule number;
(ii) name of substance;

(iii) Strength; and

(iv) maximum supply.

(b) the pharmacist supplying the scheduled substances shall enter the following particulars in Part (b) in the register of scheduled substances kept by the midwife:

(i) date of supply;

(ii) number of permit;

(iii) quantity of medicine supplied;

(iv) name and address of pharmacy; and

(v) the pharmacist's signature.

(c) The midwife shall sign in the presence of the pharmacist for receipt of the scheduled substances in the register of scheduled substances.

(d) The registered midwife shall enter the following particulars in

Part (c) of the register or scheduled substances after administration of the scheduled substances:

(i) date and time of administration;

(ii) name and address of patient;

(iii) quantity administered;

(iv) full signature;

(v) qualifications;

(vi) reason for administration; and

(vii) the balance on hand.

(6) The applicant shall be personally responsible for keeping all scheduled substances purchased or acquired in terms of a permit in safe-keeping.

(7) The holder of a permit shall at all times, at the request of any person duly authorised by the Director-General for purposes of inspection, produce the said permit, register of scheduled substances and quantity of scheduled substances in his or her possession.

(8) The Director General may at any time, by notice to the applicant cancel or withdraw the permit.

(9) On receipt of notification of cancellation or withdrawal, the applicant shall personally hand over the permit and register of scheduled substances, together with any scheduled substances still in his or her possession, to the Director General for disposal.

(10)1f the applicant is for one reason or another not able to hand over me items referred to in subregulation (9) in person, the items may be collected from the applicant by the Director General or a duly authorised representative of the Director-General.

(11)The Director General shall:

(a) keep a register of all permits issued to midwives;

(b) Inform the Registrar of the South African Nursing Council-

(i) before the end of February of each year of the full names and addresses of all persons to whom permits have been issued;

(ii) of the full name and address of every midwife whose permit has been cancelled or withdrawn, together with the reasons for such action.

(12) A permit issued in terms of this regulation shall be valid for a period of two years and may be renewed.

(13) A permit shall contain the following information:

(a) permit number;

(b) the name, qualifications and official designation of the authorised official who issued such a permit, in an instance where the Director-General has delegated the power to issue such a permit;

(c) the name, and address of the registered midwife;

(d) scheduled substances to be purchased, and their strength, dosage form and quantities, and

(e) the name and address of the supplier of such scheduled substance who shall be a pharmacist.

LABELLING FOR VETERINARY MEDICINE

48. (1) Save as provided in subregulations (2), (3) and (4), the immediate container of every package in which a veterinary medicine is sold shall have a label attached on which only the following particulars pertaining to the contents of such package shall appear, such particulars to be stated in clearly legible, indelible lettering in at least one official language:

(a) The words 'Veterinary Medicine';

(b) the proprietary name of such medicine;

(c) the registration number allocated to such medicine under section 15 (6) of the Act or, in the case of a medicine in respect of which an application for registration has been submitted in accordance with regulation 22, the reference number allocated to such application by the Registrar, followed by the words '(Act 101/1965)';

(d) the dosage form of the medicine;

(e) the approved name of each active ingredient of the medicine and the quantity thereof contained in a dosage unit or per suitable mass or volume or unit in lettering which shall not be less than-

(i) in the case of a medicine containing only one active ingredient, one half the size of the largest lettering which is used for the said proprietary name;

(ii) in the case of a medicine which contains more than one but less than six active ingredients, one-quarter the size of the largest lettering which is used for the said proprietary name; and

(iii) in the case of a medicine containing six and more active ingredients, the minimum type size permitted by this regulation: Provided that such lettering shall have a minimum legibility.

(f) the name and percentage of any bacteriostatic or bactericidal agent which has been added to the medicine as a preservative;

(g) the content of the medicine package expressed in the appropriate unit or volume of the medicine;

(h) where practicable, the indications for use of the medicine;

(i) where practicable, the recommended dosage of the medicine;

(j) where applicable, the instruction 'Shake the bottle before use';

(k) in the case of a medicine intended for injection by a particular route of administration only, that route of administration by means of suitable words or abbreviations;

(l) in the case of a medicine listed in any Schedule to the Act, the letter 'S' followed by the number of the relevant Schedule, in a prominent type size and face and surrounded by a square border, immediately preceding the proprietary name of such medicine;

(m) the lot number of the medicine;

(n) the expiry date of the medicine;

(o) the name of the holder of certificate of registration of the said medicine;

(p) the requirements regarding the manner in which the medicine shall be stored with specific reference to the applicable storage temperature and other precautions required for the preservation of the medicine;

(q) where applicable, the statement: 'For external use only';

(r) the warning: 'Keep out of reach of children and uninformed persons';

(s) in the case of any medicine intended to be used in food producing animals and involving the possibility of the ingredients of such medicine or metabolites thereof being present in the eggs, milk or tissue of such animals, a warning regarding the withdrawal period of such medicine; and

(t) any specified warning which, in terms of the provisions of section 15 (7), has to be included on the label of a particular medicine as a condition of registration of that medicine.

(2) If the medicine package bears both an immediate container label and an outer label, the requirements of subregulation (1) shall apply to the outer label as well: Provided that it shall be sufficient to give on the immediate container label-

(i) in the case of medicines intended for administration by injection and having a total volume not exceeding 5 ml, the details prescribed in paragraphs (a), (b), (e), (k), (l) (m) and (n) of subregulation (1);

(ii) in the case of an ointment, cream, gel or powder having a nett mass not exceeding 10 grams, the details prescribed in paragraphs (a), (b), (c), (e), (m), (n) and (o) of subregulation (1);

(iii) in the case of a liquid, solution or suspension having a total volume more than 1 ml but not exceeding 15 ml, the details prescribed in paragraphs (a), (b), (c), (d), (e), (l), (m), (n), and (o) of subregulation (1);

(iv) in the case of a liquid, solution or suspension having a total volume not exceeding 1 ml, the details prescribed in paragraphs (a), (b) and (o) of subregulation (1);

(v) in the case of a medicine packed in blister or similar packaging, the details prescribed in paragraphs (a), (b), (m), (n) and (o) of subregulation (1), repeated as frequently as is practicable.

(3) The Council may, on application to it by an applicant, authorise the inclusion on the label of a medicine of any specified information, which is not required by this regulation to be so included.

(4) The requirements of subregulation (1) shall not necessarily apply to a medicine excluded therefrom by the Minister in terms of section 36 of the Act or to-

(a) any medicine sold in accordance with the provisions of section 14 (4) for the treatment of a specific animal;

(b) any medicine sold by a veterinarian or pharmacist in the course of his or her professional activities for the treatment of a particular animal; or

(c) any medicine sold by a pharmacist in accordance with a prescription issued by a veterinarian for treatment of a particular animal:

Provided that such medicine shall be sold in a package to which is

attached a label containing the following information:

(i) The name of the medicine or the name of each active ingredient or constituent medicine, unless the relevant prescription issued by the veterinarian concerned has been clearly marked with the words *'non nomen propium'*;

(ii) the name of the person to whom such medicine has been sold and a description, as accurate as possible, of the animals for which the treatment is intended;

(iii) the directions for the use of such medicine;

(iv) the name and address of the veterinarian or pharmacist who has sold such medicine;

(v) the reference number allocated to the sale of the medicine as referred to in regulation 11(1) (f); and where applicable, the warning, referred to in paragraph (s) of subregulation (1), regarding the withdrawal period of such medicine; and

(vi) date of dispensing;

REPEAL

49. The regulations published under Government Notice No R352 in Government Gazette No. 4594 (Regulation Gazette No. 2117) of 21 February 1975 and amended by the following Government Notices: No R1188 in Government Gazette No 5209 of 9 July 1976; No R1195 in Government Gazette No 5631 of 1 July 1977; No R538 in Government Gazette No 5936 of 17 March 1978; No R2030 in Government Gazette N 6654 of 14 September 1979; No R384 in Government Gazette No 6867 of 29 February 1980; No R777 in Government Gazette No 7542 of 10 April 1981; No R2311 and R2312 in Government Gazette 8942 of 21 October 1983 9as amended by No 2619 in Government in Government Gazette No 8985 of 2 December 1983); No 2086 in Government Gazette No 9428 of 21 September 1984; No 2217 in Government Gazette No 9952 of 4 October 1985; No R524 in Government Gazette No 10152 of 21 March 1986; No 617 in Government Gazette No 10172 of 4 April 1986; No 1134 in Government Gazette No 10269 of 13 June 1986 as amended by No 1763 of 29 August 1986); No 2098

in Government Gazette No 10476 of 3 October 1986; No R 2311 in Government Gazette No 10988 of 16 October 1987; No R 2346 in Government Gazette No 10996 of 23 October 1987; No R2466 in Government Gazette No 11021 of 6 November 1987; No R1001 in Government Gazette No 11318 of 27 May 1988; No R1088 in Government Gazette No 11333 of 10 June 1988; No R236 in Government Gazette No 11699 of 17 February 1989; No R2108 in Government Gazette No 12726 of 7 September 1990; No R113 in Government Gazette No 12986 of 25 January 1991; No R2316 in Government Gazette No 14220 of 7 August 1992; No R3123 in Government Gazette No 14395 of 13 November 1992; No R621 in Government Gazette No 15596 of 31 March 1994; No R1833 in Government Gazette No 16040 of 28 October 1994; and No R189 in Government Gazette No 16254 of 10 February 1995 are, with the exception of regulation 35, hereby repealed.

COMMENCEMENT

50. These regulations come into operation on 2 May 2003.

ME TSHABALALA-MSIMANG
MINISTER OF HEALTH