DRAFT REGULATIONS IN TERMS OF ACT 101 OF 1965, AS AMENDED

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

GENERAL REGULATIONS

The Minister of Health intends, in terms of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965), as amended, in consultation with the Medicines Control Council, to make the regulations in the Schedule.

Interested persons are invited to submit, within three months after the date of publication of this notice, substantiated comments on or representations regarding the proposed regulations to the Minister of Health, Private Bag X828, PRETORIA (for the attention of the Chief Director: Pharmaceutical Services)

SCHEDULE

DEFINITIONS

1. In these Regulations any expression defined in the Act bears that meaning and, unless the context otherwise indicates –

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

"adulterated medicine" means a medicine that consists in whole or in part of any substance that is poisonous, harmful, toxic or the medicine's physical attributes are not the same as those approved by the Council during registration of such medicine;

"**adverse drug reaction**" means a response to a medicine which is noxious 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.

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

"holder of a certificate of registration" means a person who holds a registration certificate authorising the registration and marketing of a medicine.

"minimum legibility" means a writing 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 under patent in the Republic that has been put onto the market outside the Republic by or with the consent of the patent holder in respect of such medicine.

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

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

REQUIREMENTS FOR THERAPEUTIC EQUIVALENCE

2. (1) A medicine shall be regarded as therapeutically equivalent to another medicine if both medicines:

(a) show no significant difference, as determined by Council, in the rate and extent to which their active moieties, which must be the same, become absorbed and available at the site of drug action when administered at the same molar dose under similar conditions;

(b) are intended to be administered by the same route, and

(c) have essentially the same efficacy and safety profile.

(2) The standards to be met and the studies to be performed in establishing efficacy and safety contemplated in subregulation (1) are as determined by the Council.

THE MANNER AND CONDITIONS FOR ALLOWING INTERNATIONAL TENDERING

3. (1) The State may procure a medicine by international tender if such a medicine:

(a) is registered in terms of the Act; and

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

(c) in the opinion of the Minister, is 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.

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 or any other person licenced to compound a medicine for sale in the retail trade 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 OF MEDICINES

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

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

b) for medicines that are considered essential for national health, written notification to that effect from the Minister must be submitted with the application;

c) with regard to new medicines or chemical entities which do not appear on the Essential Drug List, the application must state whether or not-

(i) such a medicine is for the treatment of life threatening or severely debilitating disease; and

(ii) there is currently no available treatment for such a disease,

and written motivation in this regard, where applicable, must be submitted to the Registrar.

(2) Applications in respect of new medicines or new chemical entities must be accompanied by a Summary Basis for the Registration Application (SBRA) which contains data as determined by 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 new medicines or new chemical entities to an abbreviated medicine review process as determined by the Council, where registration has been granted by not less than four 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 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 determined by Council, failing which the Council may reject an application.

(7) The Council shall, within six months of receipt of an application referred to in subregulation (1), make a decision with regard to the application and inform the applicant of such decision.

PARTICULARS TO BE PUBLISHED IN THE GAZETTE IN RESPECT OF A MEDICINE

6. The following particulars shall be published in the *Gazette* in terms of section 15(11) of the Act:

(a) The proprietary name of the medicine;
(b) the generic or 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; and
(e) indications for use of such medicine.

PARALLEL IMPORTATION

7. (1) A medicine under patent in the Republic may be imported into and disposed of in the Republic if such medicine has been put onto the market outside the Republic by or with the consent of the patent holder of the medicine in the Republic subject to the provisions of the Act and these Regulations.

(2) A holder of a certificate of registration for a medicine in the Republic shall not be entitled, on account of such registration, to prevent the parallel importation of such medicine into the Republic and the disposal thereof within the Republic

(3) A person desiring to parallel import a medicine into the Republic shall apply to the Minister for a licence to parallel import such a medicine.

(4) The application to the Minister shall be accompanied by-

(a) the price at which the medicine is sold in the Republic by the holder of the certificate of registration;

(b) the price at which the medicine is intended to be sold in the Republic by the parallel importer;
(c) a declaration by the parallel importer that the medicine to be parallel imported is a medicine under patent in the Republic;
(d) any other information the Minister deems necessary.

(5) After being issued with a licence to parallel import a medicine the parallel importer shall apply to the Council to register the medicine.

(6) The Council shall only register the medicine if the parallel importer
(a) has been licenced by the Minister to parallel import the medicine;
(b) has a registered office in the Republic;
(c) has a storage facility approved by the Council for such medicine;
(d) has a responsible pharmacist as required in terms of the Pharmacy Act, 1974;
(e) undertakes to be responsible for ensuring that such medicine meet the safety, quality and efficacy standards as determined by the Council;
(f) has in place recall procedures as determined by Council, and
(g) complies with any other conditions as the Council may determine.

(7) An application referred to in subregulation (5) shall be-

(a) submitted to the Registrar;
(b) made on a form and accompanied by information as determined by the Council;
(c) accompanied by a fee determined by the Council; and
(d) considered and a decision made within the period(s) as determined by the Council.

(8) An application for the registration of a medicine to be parallel imported must be accompanied by:

(a) proof of registration of the medicine in the country of export;
(b) copies of the package insert, where applicable, for approval by the council translated into English and verified;
(c) copies of the sample with appropriate labelling and scheduling of such medicine;
(d) proof that the final product is safe, efficacious and complies with all quality requirements and specifications as determined by council;
(e) certificate of supplier accreditation in the country of export;
(f) information on the exporter's status, whether it is the original manufacturer, broker, packer, re-packer; and

(g) identity and assay of the medicine.

(9) The Council may require a person who applies for the registration of a medicine in terms of this regulation to submit to it relevant test data or samples in respect of such medicine.

(10) Medicines that are parallel imported shall be labelled, packaged and have package inserts and patient information leaflets as prescribed in terms of regulations 9 and 10.

(11) The person parallel importing a medicine into the Republic shall, in the interest of public health, be entitled to use the South African name and trademark of such medicine, even though the medicine was marketed outside the Republic under a different name or trademark: Provided that the name is approved by the Council.

(12) Council may, if it is satisfied with an application in terms of this regulation, approve the registration of such medicine as a parallel imported medicine.

(13) A person issued with a licence to parallel import a medicine in terms of this regulation shall within 14 days after such medicine has been registered, inform the holder of a certificate of registration in the Republic of such fact.

(14) The registrar shall keep a separate register of medicines registered in terms of this regulation.

(15) The registrar shall publish in the Gazette the names of persons issued with a license to be a parallel importer, and any other information as the Council may determine.

(16) A licence issued in terms of this regulation is valid for a period not exceeding one year and may be renewed if an application for renewal is approved by the Minister.

(17) A parallel importer of a medicine shall-

(a) not sell or dispose of such medicine unless such medicine is registered in the Republic;
(b) only parallel import the medicine from manufacturers; distributors or wholesalers who are duly licensed in the country of exportation by the medicines regulatory authority that is recognised by the Council;
(c) inform the Council within 30 days of any change of conditions under which the licence was issued, including any material changes to storage conditions, any change to the particulars of the medicine, and the cessation of parallel import activities;

(d) ensure that person(s) in charge of premises where the medicine is stored are appropriately qualified;

(e) maintain proper transaction records;

(f) report to the Council any adverse drug reactions or any other risks associated with such medicine that might affect its quality, safety or efficacy; and

(g) maintain emergency action plans for addressing any adverse drug reactions.

(18) The Minister may, on good cause shown, revoke the licence to parallel import a medicine.

(19) The Council may, on good cause shown, revoke the registration of a parallel imported medicine.

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 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 in at least one other official language :

(a) a distinct boxed signal word indicating the Schedule number;

(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 parental administration, the quantity of sugar or 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) the indications for use of the medicine;

(k) the recommended dosage of the medicine;

(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) 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;

(o) the lot number of the medicine;

(p) the expiry date of the medicine;

(q) the name of the applicant for registration of the said medicine;

(r) 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;

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

(t) the warning: 'Keep out of reach of children';

(u) in the case of a medicine intended for oral or parental administration which contains aspirin or paracetamol the warning: 'Do not use continuously for more than 10 days without consulting your doctor';

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

(w) in the case of a medicine for oral administration which contains an antihistamine, the warning: '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';

(x) 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';

(y) 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.

(z) 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), (o), (p) and (q) 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), (o), (p), (q) and (u) 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), (o), (p), (q) and (y) 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 (a) and (o) of sub-regulation (1);

(v) in the case of a medicine packed in blister or similar packaging, the details prescribed in paragraphs (b), (o), (p) and (q) of sub-regulation (1), repeated as frequently as its 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 prescribe 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 name of the medicine or the name of each active ingredient or constituent medicine;

(ii) the name of the person for whose treatment such medicine is sold;

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

(iv) the name and business address of the medical practitioner, dentist, pharmacist, pharmacy or hospital selling such medicine;

(v) date of dispensing;

(vi) reference number.

PACKAGE INSERTS FOR MEDICINES FOR HUMANS

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, that is the scheduling status of the medicine as determined from time to time by the Minister;

(b) Proprietary name (and dosage form)

(c) Composition, that is 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, as well as the approved name and quantity of any bactericidal or bacteriostatic agent included in the medicine as a preservative (expressed as a percentage) and the quantity of ethyl alcohol included in a preparation for oral or parenteral administration (if such quantity exceeds two per cent by volume) and the words " contains TARTRAZINE" should the medicine contain such ingredient;.

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

(e) Pharmacological action, that is a description of the pharmacological action of the medicine; The pharmacokinetic properties of the medicine shall be described, where applicable under a sub heading written in bold type: **PHARMACOKINETICS.**

(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 overdosage and particulars of its treatments;

(n) Conditions of registrations

(o) Identification;

(p) Presentation;

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

(r) Registration number, that is –

(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"

(s) name and business address of the applicant for registration of the medicine and 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 license;

(t) date of publication of this package insert: Provided that –

(i) If the Council determines 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 to it by an applicant, authorise the deviation from the format and content of a package insert prescribed as a condition of registration of a medicine; and

(iii) The Council may, on application by an applicant. Authorise the inclusion on a package insert of any specified information not required by this regulation to be so included.

(2) The requirements of subregulation (1) shall not apply in the case of medicines in respect of which exclusion from the operation the Act has been 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 or pharmacist in the course of his professional activities for the treatment of a particular patient; or

(c) any medicine sold by a pharmacist or by a hospital 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.

PATIENT INFORMATION LEAFLET

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

(a) Scheduling status;

(b) proprietary name and dosage form;

(c) what the medicine contains, which includes-

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

(ii) all inactive ingredients that must be listed qualitatively;

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

"Do not share medicines prescribed for you with other persons."

"In the event of overdosage, 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, blisterpack, 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 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)

PRESCRIPTION BOOK

11. (1) A prescription book or other permanent record in respect of schedules 2, 3, 4 and 5 medicines or substances shall be kept on all premises where prescriptions 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.

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

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

(b) the name of the pharmacist or intern pharmacist or pharmacist assistant who sold the substance; and

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

(4) The manufacturer or wholesaler shall keep a written 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 batchnumber; and

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

(5) The written 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 COUNTRY

12. (1) No person shall import any medicine or scheduled substance, including medicines imported in terms of section 15C, read together with regulation 7, of the Act, 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.

EXPORTATION OF MEDICINES, SCHEDULED SUBSTANCES AND MIXTURES CONTAINING SCHEDULED SUBSTANCES

13. (1) Medicines, scheduled substances and mixtures containing scheduled substances-

(a) intended for exportation-

(i) must be registered in terms of the Act or as determined by the Council;

(ii) shall comply with the Council's requirements for quality, purity and safety; and

(iii) shall not be exported without authorisation by the Council

(b) that are transmitted through the Republic shall

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

(ii) not be manipulated while in the bonded warehouse unless authorised by the Council; and

(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(9) OF THE ACT

14. (1) A medical practitioner or veterinarian desiring to be provided with a schedule 7 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 (a) 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 in the case of a particular patient; and

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

(3) A permit referred to in subregulation (1) may not be issued if 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 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) Any person desiring to manufacture a Schedule 6 substance, shall apply to Director-General for a permit to manufacture such substance.

(7) An application referred to in subregulation (6) 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) 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.

(8) A permit referred to in subregulation (6) may not be issued if the Director-General is of the opinion that-

(i) the applicant is not capable of keeping or storing the substance in a manner so as to prevent the loss thereof;

(ii) the annual quota for such substances has been exceeded or will be exceeded; or

(iii) such substance is already available in the Republic.

(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 statutory council;
(d) qualification 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 in the case of a particular patient; and
(h) in the case of veterinarian, the name and address of the owner, diagnosis, dosage and period of treatment in the case of a particular animal or group of animals.

(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 SCHEDULES 6 AND 7 SUBSTANCES

15. (1) Any person desiring to import or export Schedules 6 or 7 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 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 not exceeding one year.

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

16. (1) 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 2, 3, or 4, substance or medicine, which shall not exceed a quantity required for use for a period of three months.

(2) 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 5 or 6 substance or medicine, which shall not exceed a quantity required for use for a period of two weeks.

(3) A person referred to in subregulations (1) or (2) must have -

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

(b) a certificate by a pharmacist to the effect that the Scheduled substance or medicine concerned including its quantity was prescribed by an authorised prescriber 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 ANUALLY TO THE REGISTRAR BY THE HOLDER OF A PERMIT ISSUED IN TERMS OF REGULATION 15

17. (1) A person issued with a permit in terms of regulation 15 shall furnish the registrar 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 22(A)(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 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;

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

LICENCE TO COMPOUND AND/OR DISPENSE MEDICINES

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

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

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

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

(iv) telephone and fax numbers of the applicant;

(v) proof of registration with a statutory council;

(vi) a copy of the notice to other health facilities referred in subregulation 4.;

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

(viii) any other information that the Director-Ggeneral may require.

(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/or dispensing of medicines is intended to be carried out;
(b) representations 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 of his or her intention to apply for a licence to all health care facilities and providers in the immediate vicinity to be served by the applicant.

(6) Any person may support or oppose an application referred to in subregulation (1) by making representations to the Director-General.

(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 3 years from the date of sale;
(b) ensure that the premises and dispensary where medicines are kept are clean, secure and suitable for compounding and dispensing, with enough lighting and ventilation;
(c) keep the medicines under the manufacturer's recommended 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;
(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 proper diagnosis and prescribing for a particular patient by the license holder, his or her partner, associate or assistant in practice;
(g) not keep expired medicines on the premises;
(h) lock the premises where the compounding and dispensing is carried out whenever he or she is not physically present at the place where medicines are kept;

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

(j) keep a system capable of tracing all dispensed medicines;

(k) conspicuously display the licence in the practice; and

(l) comply with the conditions of his licence and inform his or her partner, associate or assistant referred to in paragraph (f) of the conditions under which the licence was granted.

(8) For the purposes of this regulation, " compounding and dispensing" does not refer to medicines compounded and used for the purposes of administration or injection thereof to a patient in the consulting rooms.

LICENCE TO MANUFACTURE, ACT AS A WHOLESALER OR DISTRIBUTE MEDICINES

19. (1) A person desiring to manufacture medicines, act as a wholesaler or distributor of medicines shall apply to the Council for a licence to manufacture, act as a wholesaler or distributor of medicines.

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

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

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

(b) the exact location of the premises where the manufacturing, wholesale or from which the distribution will be carried out;

(c) the name of the responsible pharmacist who will be responsible for managing the pharmaceutical aspects of the applicant;

(d) in the case of a manufacturer or importer authorised to import medicines in terms of section 15C of the Act, the physical address of the quality assurance laboratory to be used by the applicant;

(e) registration number of the applicant, in the case of-

(a) a natural person, with a statutory body; and

(ii) a juristic person, with the relevant registering authority;

(f) In the case of a juristic person, the name and title of the person responsible for the application; and

(g) any other information that the Council may deem necessary.

(4) A person issued with a licence in terms of this regulation shall:

(a) comply with the requirements and guidelines as determined in the latest edition of the South African Guide to Good Manufacturing Practice or any other guide as determined by the Council;

(b) in the case of the wholesaler or distributor, purchase Scheduled substances from a licensed pharmaceutical manufacturer or a licensed importer only;

(c) keep a record of medicines recalled or withdrawn;

(d) store medicines under their recommended storage conditions;

(e) employ only properly trained employees;

(f) have a system in place for detecting expired medicines from the wholesaler's shelves and such medicines shall be removed from the shelves;

(g) keep a secured area for Schedules 5 and 6 substances;

(h) have a pest and rodent control system in place;

(i) keep the premises clean, dust free, insect-free and in a bird-free condition;

(j) have a decontamination procedure for spillage's of hazardous substances;

(k) keep the premises in a secure condition; and

(l) have in place a disposal system for unwanted and expired medicines.

(5) The person issued with a licence shall inform the Council of any changes with regard to information furnished in terms of subregulation (3).

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

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

(2) A licence referred to in subregulation (1) and 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 referred to in regulations 18(3) and 19(3), as the case may be;

(b) be accompanied by a fee as determined from time to time by notice in the *Gazette* by the Director-General or the Council, as the case may be; and

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

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

21. (1) An appeal in terms of Section 24(1) of the Act shall be lodged within 21 days from the date on which the decision appealed against was communicated to the appellant.

(2) In noting the appeal, the appellant shall send a notice by registered mail to the Minister 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 appealed against.

(3) The notice referred to in sub-regulation (2) shall set out clearly and succinctly the grounds on which the appeal is based.

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

(5) The appeal committee -

(a) shall determine the procedure for its hearings;

(b) may, if it deems necessary-

(i) call for oral evidence or argument or summon any person who-

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

(bb) 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 or the Director-General, as the case may be.

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

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

(7) The appeal committee shall consider the appeal and make a decision in regard thereto within a period of one month from the date-

(i) on which it was appointed; or,

(ii) 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) In case the person referred to in subregulation (1) is not a pharmacist or veterinarian, the application must be co-signed by a responsible pharmacist or veterinarian, as the case may be.

(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 latest inspection report that is not more than two (2) years old, from the regulatory authority of the medicine's country of origin;
(d) in the case of Schedules 6 and 7 substances, a copy of a permit to manufacture such substances;
(e) all relevant data on the medicine, whether positive or negative;
(f) proof of the existence of a manufacturing site; and

(g) any other information as the Council may from time to time, by guidelines for the registration of medicines, determine.

(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:
- (i) Name
- (ii) Business Address
- (iii) Postal Address
- (iv) Telephone Number
- (v) Fax Number
- (vi) e-mail address
- (vii) Contact details of the responsible pharmacist 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, registration status outside the Republic and the medicine's history;
- (vi) pharmacological classification and data where applicable; and
- (vii) the name of the manufacturer(s).

(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 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; and
(c) conditions of registration;

(d) any other information as required per registration guidelines

(9) The provisions of regulation 22 shall, with the necessary changes, apply to the application for the registration of:
(a) veterinary medicines,
(b) biological medicines, and
(c) complementary medicines

INFORMATION THAT MUST APPEAR IN THE REGISTER FOR MEDICINES

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

(a) the name of the medicine approved by the Council, which must be the proprietary name;
(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);
(g) in the case of a medicine, the name of the packer(s);
(h) in the case of a medicine, the name of the final product release control (FPRC);
(i) in the case of a medicine, the name of the final product release responsibility (FPRR);
(j) the date of registration of the medicine;
(k) the conditions of sale of the medicine determined in terms of section 15(7) of the Act

APPLICATION FOR AN AMENDMENT TO A MEDICINE REGISTRATION

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

(2) The application referred to in subregulation (1) shall be accompanied by a fee as determined by Council from time to time and must contain the following information:

(i) the name of applicant;
(ii) business address of the applicant;

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

(iv) the details of the amendment applied for; and

(v) any other information that the Council may from time to time determine for the amendment of registration of medicines.

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;

(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; and

(d) Category D = Medicines which are Complementary Medicines of the various categories

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

1. Central nervous system stimulants

1.1 Central analeptics

1.2 Psycho analeptics (antidepressants)

1.3 Special antidepressant combinations

1.4 Respiratory stimulants

1.5 Hallucinogenic medicines

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

2.11 Connective tissue medicines

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

4. L**ocal anaesthetics**

5. Medicines affecting autonomic functions

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

6. C**ardiac medicines**

6.1 Cardiac stimulants

6.2 Cardiac depressants

6.3 Cardiac glycosides

7. V**ascular 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

8. M**edicines acting on blood and haemopoietic system**

8.1 Coagulants, haemostatics
8.2 Anticoagulants
8.3 Erythropoietics (haematinics)
8.4 Plasma expanders

9. M**edicines 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

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

14. Preparations for treatment of wounds
14.1 Wound disinfectants
14.2 Wound dressings

15. Ophthalmic preparations
15.1 Ophthalmic preparations with antibiotics and/or sulphonamides
15.2 Ophthalmic preparations with corticosteroids

15.3 Combination antibiotics

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

17. Medicines acting on muscular system

17.1 Peripherally acting muscle relaxants

17.2 Muscle activators

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

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

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

21.8.1Oestrogens
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

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

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 repellants

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

(3) Medicines in Category D are subdivided into the following classifications:

(a) African traditional medicine;
(b) Anthroposophical medicine;
(c) Aromatherapy medicine;
(d) Ayurvedic medicine,
(e) Chinese traditional medicine;
(f) Energy substances;
(g) Homeopathic medicine;
(h) Nutritional supplements;
(i) Urani-Tibb medicine;
(j) Western herbal medicine;
(k) Combination complementary medicine; and
(l) Combination homeopathic medicine / Flower essence.

REGISTRATION CERTIFICATE

26. A certificate of registration 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 CONTROL 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. Registered 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 (applicant) ……...

7. Date of registration ……...

……

Registrar of Medicines

Issued at Pretoria on ……... 20……..

DISPOSAL OF MEDICINES AND RECORDS OF SUCH MEDICINES

27. **(1)** A medicine may be destroyed as follows:

(a) in the case of Schedules 5 and 6 substances, only in the presence of an inspector designated in terms of Section 26 of the Act or any other person authorised by the Council and such inspector or person, as the case may be, shall issue a certificate confirming the destruction of the medicine;

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

(c) in the case of Schedules 1, 2, 3 and 4 substances, a pharmacist in charge of the pharmacy where the medicines or substances are kept, may destroy such medicines or substances and that pharmacist shall issue a certificate confirming such destruction.

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

(3) The destruction and disposal of medicines must be conducted in such a manner as determined by the Council and to ensure that the medicine 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 and must at least state the following:

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

(ii) the approved name and the quantity of the medicine or Scheduled substance to be supplied;

(iii) the name and address of the patient or, in the case of a prescription or order issued by a veterinarian, the name and address of the person to whom the medicines or Scheduled substances must be sold;

(iv) the name, qualification, practice number and address of the prescriber, and such particulars may be printed on the prescription or order;

(v) the dosage form;

(vi) the strength of the dosage form;

(vii) complete instructions for the administration of the dosage and frequency of administration;

(viii) the age, sex, height and weight of the patient; and

(ix) 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 SCHEDULE 6, 7 AND SPECIFIED SUBSTANCES

29. (1) No person must 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) and (b) 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) 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 SCHEDULES 5 OR 6 MEDICINES OR SUBSTANCES

30. (1) A person importing, exporting, manufacturing or using a Schedule 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;
(f) the quantity of the medicine or substance manufactured or used during the manufacturing process; and
(g) any other information as the Council may from time to time 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 and 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 designated in terms of Section 26 of the Act 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 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 in charge 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 by their authors to the Council 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) is adulterated;

(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 in possession by an unauthorised person; or

(h) is used in unauthorised clinical trial.

(2) Medicines or substances seized in terms of subregulation (1) must be removed from the premises by an inspector who shall record such seized medicines or substances.

(3) Seizure of larger batches shall be effected by any suitable means.

(4) In the event that a whole warehouse is to be seized, a police seal may be used to seal the whole warehouse and access to this area may be restricted.

(5) Seized medicines or substances must be stored at the premises approved by the Council or at a police station and a record shall be kept of such storage at such premises or police station by the person receiving such medicines or substances.

(6) A record referred to in sub-regulation (5) kept at a police station shall be submitted to the Council by the police concerned.

PRE-PACKING OF MEDICINES INTO PATIENT READY PACKS

33. The pre-packing of medicines into patient ready packs must –

(a) be carried out by a pharmacist or a veterinarian or under the supervision of a pharmacist or veterinarian;

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

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

(e) be carried out in accordance with any requirements as determined by the Council.

CONDUCT OF MEDICINE CLINICAL TRIALS

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

(2) An application referred to in subregulation (1) shall be accompanied by a fee determined from time to time by the Council and shall contain at least the following information:

(a) trial protocol;
(b) investigator's brochure or relevant pharmacological and toxicological data and human experience with the substance concerned;
(c) Curriculum Vitae of all investigators;
(d) signed declaration by the applicant and all investigators;
(e) patient information leaflet with regard to the substance;
(f) informed consent document(s); and,
(g) 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 patients to be involved in the trial; [and]
(b) the name of an investigator who shall be a medical or dental practitioner, 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 approval of the Council.

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 immediately after the completion or termination of the clinical trial.

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

SKILLS OF MEMBERS OF THE COUNCIL AND ITS COMMITTEES

35. The Council shall consist of the following:

(a) at least three (3) 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 Adverse Drug Events; and

(h) an expert in Virology and Microbiology;

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

(m) (j) two veterinarians, one of whom shall be a veterinary surgeon and the other an expert in veterinary clinical pharmacology;one person with knowledge of medicines under category D; and

(m) a person with expertise in law.

CONTROL OF MEDICINES IN HOSPITALS

36. (1) The responsible pharmacist as required under the Pharmacy Act, 1974, shall be responsible for the safe and secure keeping, purchase, storage, and dispensing of medicines in a hospital.

(2) The Council shall from time to time determine the manner in which the distribution, labelling, dispensing by nursing staff and pre-packing of medicines in a hospital shall be carried out.

ADVERSE DRUG REACTION

37. (1) The holder of a certificate of registration in respect of a medicine or Scheduled substance shall inform the Council of any serious or unexpected adverse drug reactions reported to him, her or it occurring as a result of the use of such a medicine.

(2) Subregulation (1) also applies in the case of unregistered medicines used in terms of section 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) as soon as the report referred to in subregulation (1) is received, 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;

(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 the Council:

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

(b) other pharmaco-vigilance data such as drug usage figures, periodic safety update reports, pharmacoepidemiology studies, etc;

(c) keep and maintain 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.

SMALL SCALE MANUFACTURE OF ADMIXED PARENTERAL MIXTURES

38. (1) No person may compound an admixed parenteral solution unless such person is a pharmacist or is the holder of a licence issued in terms of section 22C of the Act

(2) An intravenous admixture can only be compounded or prepared under conditions, specifications and standards as determined by the Council.

(3) The shelf life of the product referred to in subregulation (1) shall not exceed seven days.

PRICING COMMITTEE

39. (1) The pricing committee contemplated in section 22G of the Act shall consist of no more than fifteen members, including

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

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

(c) one person 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.

INVESTIGATIONS

40. 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

41. (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 English and in legible lettering:

(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;
(h) contra-indications;
(i) warnings;
(j) side-effects and special precautions;
(k) known symptoms 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, by guidelines, determine.

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

PHARMACOLOGICAL CLASSIFICATION OF VETERINARY MEDICINES

42. The following is a pharmacological classification of veterinary medicines:

(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 Buterophenone 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 Steroidal
- 3.1.2 Non-steroidal anti-inflammatory drugs (NSAIDs)
  - 3.1.2.1 Non selective COX_2 inhibitors
  - 3.1.2.2 Selective COX_2 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) Autocoids

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

85.1 Lubricants and Faecal softeners
85.2 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 rument

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 & Progestagens
11.2.4 Combinations

11.3 Prostaglandins

11.4 Tropic 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

13.6 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 Dichloroacetic acid derivatives
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 Organophosphors
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 Modulating 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

USE OF MEDICINES FOR THE PREVENTION OF MALARIA

43. (1) Any person who is employed by-

(i) the National Parks Board;
(j) the Board of Public Resorts;
(k) the National Parks, Game and Fish Preservation Board; or
(l) the department of nature conservation of any provincial administrations

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 displayed, in a prominent manner, a poster which has been approved by the Council and 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 be tablets and liquids containing chloroquin 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 hydrocholide in packs, the contents of which do not exceed 100 tablets.

OFFENCES AND PENALTIES

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

(a) Sub-regulations (5) and (17) of Regulation 7 with regard to the parallel importation of medicines;
(b) Regulation 8 with regard to the labelling of medicines;
(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) Regulation 12 with regard to the importation of medicines;

(g) Regulation 14 with regard to the permits applied for and issued in terms of s 22A(9) of the Act;

(h) Regulation 15 with regard to the importation or exportation of Schedule 6 and Schedule 7 substances;

(i) Regulation 16 with regard to the possession of specified quantities of Schedules 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 disposal 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 schedule 6 & 7 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 41 with regard to the package inserts for veterinary medicines;

(s) Regulation 45 with regard to compliance with these regulations.

shall upon conviction be liable to a fine, or to imprisonment for a period not exceeding 10 years.

COMPLIANCE WITH REQUIREMENTS

45. (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.

SAMPLES WITH APPLICATION FOR REGISTRATION

46. 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 lot, together with six copies of the protocols of testing of the bulk lot and filling lot 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 lot release condition.

ADVERTISING OF MEDICINES INTENDED FOR ADMINISTRATION TO HUMANS

47 (1) The undermentioned requirements shall apply to any advertisement of a medicine intended for administration to humans.

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

(b) Medicines which contain a substance appearing in Schedule 3, Schedule 4, Schedule 5, Schedule 6 or Schedule 7 may be advertised only for the information of medical practitioners, dentists, veterinarians and pharmacists or in a publication which is normally or only made available to members of the said professions.

(c) Paragraph (b) shall not be so construed as to prohibit the announcement to the public of the prices of medicines which contain a substance appearing in Schedule 3, Schedule 4, Schedule 5, Schedule 6 or Schedule 7.

(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 1o the safety of the use of the ingredients in human beings or the efficacy of such ingredients in relation to the purpose for which it is intended that they should be used, 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 a minimum legibility as defined in regulation I (vi) of the regulations: 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;

(c) in the case of-

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

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

(d) in any case 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.

(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 orally for the first time by or on behalf of the applicant to any member of the medical or dental profession or the pharmaceutical profession, written information, which shall include at least the information called for in terms of regulation 10, shall simultaneously be given 1o 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

48. 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 ten (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 rule.

(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 motion, and the notice of his 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 (I) (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, *mutatis mutandis,* 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 rdsum6 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) corespondence;

(f) general.

It shall, however, be competent 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 mover, 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"; or

(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 is in its fervour. 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 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 OR ADMIXTURES THEREOF BY REGISTERED MIDWIVES

49. (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 in a midwifery case, the scheduled substances set out on a list as determined by Council 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; and

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

(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 from the said pharmacy.

(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) If the applicant is for one reason or another not able to hand over the 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 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 qualities, and
(e) the name, address of the supplier of such scheduled substance who shall be a pharmacist.

LABELLING FOR VETERINARY MEDICINE

50. (1) Save as provided in subregulations (2), (3) and (4) of this regulation, 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 English and at least one other 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 the provisions and requirements of regulation 39 (I) (a) or (2), the reference number allocated to such application by the Registrar, followed by the words '(Wet/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;
(iii) in the case of a medicine containing more than six active ingredients, the minimum type size permitted by this regulation: Provided that such lettering shall have a minimum legibility as defined in regulation (1) (vi) of the regulations;

(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;

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

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

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

(j) 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;

(k) 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;

(l) the lot number of the medicine;

(m) the expiry date of the medicine;

(n) the name of the applicant for the said medicine as contemplated in regulation 2;

(o) 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 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, to be approved by the Council, 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 mil, the details prescribed in paragraphs (a), (b), (e), (k), (/) (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), (i), (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 I 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 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 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 of pharmacist who has sold such medicine;

(v) the reference number allocated to the sale of the medicine as referred to in

regulation 28 (1) (e); and

if applicable, the warning, referred to in paragraph (s) of subregulation (1), regarding the withdrawal period of such medicine.

REPEAL

51. 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; Nos R2311 and R2312 in Government Gazette 8942 of 21 October 1983 9as amended by No 2619 in Government in Government Gazette No 8985 of 2December 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 9as 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 127726 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; No R189 in Government Gazette No 16254 of 10 February 1995 are hereby repealed.

ME TSHABALALA-MSIMANG
MINISTER OF HEALTH