Government Gazette
Staatskoerant

REPUBLIC OF SOUTH AFRICA
REPUBLIEK VAN SUID-AFRIKA

Regulation Gazette **No. 7636** *Regulasiekoerant*

Vol. 454 **Pretoria, 10 April 2003** **No. 24727**

PART 1 OF 2

AIDS HELPLINE: 0800-0123-22 Prevention is the cure

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GOVERNMENT NOTICES
GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF HEALTH
DEPARTEMENT VAN GESONDHEID

No. R. 509 **10 April 2003**

SCHEDULES

The Minister of Health has, in terms of section 22A(2) of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), on the recommendation of the Medicines Control Council, made the Schedules in the Schedule

SCHEDULE

In these Schedules, "the Act" means the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965)

SCHEDULE 0

(a) All substances referred to in this Schedule are excluded when specifically packed, labelled and used for -

(i) industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose, which are intended to be ingested by man or animals as food, or applied to the body as a cosmetic, and which are approved for such use in terms of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972) or registered in terms of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947); and

(ii) analytical laboratory purposes.

(b) All substances referred to in this Schedule include the following:

(i) The salts and esters of such substances, where the existence of such salts and esters is possible; and

(ii) All preparations and mixtures of such substances where such preparations and mixtures are not expressly excluded.

This Schedule includes all substances subject to registration in terms of the Act and which are not listed in any of the other Schedules.

SCHEDULE 1

(a) All substances referred to in this Schedule are excluded when specifically packed, labeled and used for –

(i) industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose; and

(ii) analytical laboratory purposes.

(b) All substances referred to in this Schedule include the following:

(i) The salts and esters of such substances, where the existence of such salts and esters is possible; and

(i) all preparations and mixtures of such substances where such preparations and mixtures are not expressly excluded.

(c) In terms of section 22A(4)(a)(v) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974 (Act No. 56 of 1974) other than a medical practitioner or dentist, may prescribe and supply to patients under their care, the Schedule 1 substances and medicines provided for in the Annexures, only within their scope of practice and subject to the conditions determined by the Medicines Control Council. The conditions and the Annexures will be published in the *Gazette*.

Acetanilide and alkyl acetanilides.

Acetarsol, when intended for human vaginal use.

Acyclovir, when intended for application to the lips in the early treatment of recurrent herpes simplex virus infections. (S4)

Anethole trithione.

Anticoagulants, when intended for application to the skin. (S4)

Antimalarials; chloroquine in combination with proguanil when intended specifically for malaria prophylaxis. (S4)

Antimicrobial substances, namely bacitracin, gramicidin, polymyxin B and tyrothricin,

when intended for application to the skin, nares and external ear, as excluded from the conditions of Schedule 4. (S2, S4)

Antimony potassium tartrate and antimony sodium tartrate; substances, preparations and mixtures containing 1,0 percent or more thereof.

Arsenic; substances, preparations and mixtures containing the equivalent of less than 0,01 percent of arsenic trioxide. (S2)

Azelaic acid.

Belladonna alkaloids; when specifically intended for topical application (S2).

Benzethonium chloride, when intended for human vaginal use.

Benzydamine; preparations and mixtures containing -

(a) 3 per cent or less of benzydamine when intended for application to the skin;

(b) 0,15 per cent or less of benzydamine when intended for use as a mouth rinse or for topical application in the mouth and throat: Provided that the total daily dose does not exceed 36 mg of benzydamine. (S3)

Beta-aminopropylbenzene and beta-aminoisopropylbenzene as excluded from the conditions of Schedule 5. (S5)

Bifonazole, when intended for application to the skin.

Bioallethrin.

Bitolterol.

Bufexamac, when intended for application to the skin.

Bunamidine.

Calcium salts; preparations thereof, when intended for injection, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Chlorhexidine, when intended for human vaginal use.

Chloroform, preparations and mixtures containing less than 20 percent of chloroform. (S5)

Clotrimazole, when intended for application to the skin and when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis. (S4)

Dialysate preparations.

Diclofenac, when intended for application to the skin. (S2, S3)

Diosmine.

Dithiazanine.

Econazole, when intended for application to the skin and when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis. (S4)

Enilconazole, when intended for application to the skin. (S4)

Ephedra alkaloids (natural or synthetic) except ephedrine preparations and mixtures intended for application to skin, eyes, ears and nares containing 1,0 per cent or less of ephedra alkaloids, and other preparations and mixtures containing not more than 30 milligrams of ephedrine or ephedra alkaloids per dose. (S2, S5)

Ephedrine contained in products registered in terms of the Act, preparations and mixtures intended for application to the skin, eyes, ears and nares containing 1,0 per cent or less of ephedrine, and other oral preparations and mixtures containing not more than 30 milligrams of ephedrine per dose. (S2, S5)

Escin (aescin); medicinal preparations and mixtures thereof intended for application to the skin and containing 1,0 per cent or less of escin. (S3)

Ether (diethyl ether); all substances, preparations and mixtures containing less than 20 per cent of ether. (S5)

Ethylphenylephrine.

Etofenamate, when intended for application to the skin.

Felbinac, when intended for application to the skin.

Fenbendazole, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Fenticonazole, when intended for application to the skin.

Flubendazole, except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Flufenamic acid, when intended for application to the skin. (S3)

Flurbiprofen, when intended for application to the skin, including by transdermal patch, provided that in the case of application by transdermal patch indications are for use by adults and children 12 years and older and the treatment period is limited to 4 weeks. (S2, S3, S4)

Fluorescein, when intended for ophthalmic use.

Fluorides; oral medicinal preparations and mixtures thereof containing 0,25 milligrams or more of fluorine as fluoride per recommended daily dose, unless listed in another Schedule. (S4)

Gamma benzene hexachloride human medicinal preparations and mixtures when intended for application to the skin.

Glycosaminoglycan polysulphate (previously mucopolysaccharide poly-sulphuric acid ester) when intended for application to the skin. (S4)

O- (β-hydroxyethyl)rutosides.

Ibuprofen, when contained in preparations intended for application to the skin (S2, S3)

Idoxuridine, when intended for application to the skin. (S4)

Indanazoline.

Indomethacin, when intended for application to the skin. (S2, S3)

Injections, unless listed in another Schedule, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Irrigation fluids.

Isoconazole, when intended for application to the skin and when intended for human vaginal use specifically for the treatment of recurrent vaginal candidiasis. (S4)

Ketoconazole, when intended for application to the skin, except preparations and mixtures containing not more than 1,0 percent of ketaconazole, when intended for the prevention and treatment of dandruff. (S0, S4)

Ketoprofen, when intended for application to the skin. (S2, S3)

Lactobacillus acidophilus and Lactobacillus bifidus, when intended for therapeutic purposes, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Local anaesthetics, except when intended for ophthalmic and for parenteral use. (S2, S4)

Lufenuron, except when intended and registered as a systemic preparation against fleas in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Luxabendazole, except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Lysozyme, when intended for application to the skin. (S4)

Malathion, except when intended and registered as an ectoparasiticide in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Manganese salts, preparations thereof for injection, when intended for veterinary use.

Mebendazole, except intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Methenamine (hexamine), except when intended for application to the skin and except when intended and registered as an urinary tract antiseptic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Methionine, when intended for medicinal purposes.

Miconazole when intended for application to the skin and when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis. (S2, S4)

Microfibrillar collagen hydrochloride.

Morantel citrate, except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

N-acetyl-aspartyl-glutamic acid.

Naphazoline, when intended for nasal use.

Naproxen, when intended for application to the skin (S2, S3)

Nicotine; when used as nicotine transdermal patches for continuous application to the skin in strengths up to and including 15mg/16 hours when these medicines are used for the relief of nicotine withdrawal symptoms as an aid to smoking cessation only. (S2)

except-

nicotine gum containing 4mg or less nicotine per piece where the pack size does not exceed 30 pieces per pack when these medicines are used for the relief of nicotine withdrawal symptoms as an aid to smoking cessation only (S0).

Nitrofurantoin, when intended for application to the skin. (S4)

Nitrofurazone, when intended for application to the skin. (S4)

Nystatin, when intended for application to the skin and when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis. (S4)

Ornidazole, when intended for application to the skin. (S4)

Orthodichlorobenzene, when intended for topical human medicinal use.

Oxibendazole, except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Oxymetazoline, when intended for nasal use.

Paracetamol -

(1) substances, preparations and mixtures, except -

(a) in tablets or capsules each containing 500 milligrams or less of paracetamol, when-

(i) packed in a primary pack containing not more than an aggregate of 12,5 grams of paracetamol in such tablets or capsules;

(ii) packed in blister strip packaging or in containers with child-resistant closures;

(iii) the primary pack is labeled with the following boxed warning, placed prominently on at least the main panel of the immediate container label and outer label (carton):

CONTAINS PARACETAMOL- READ THE PACKAGE INSERT;

(b) in individually wrapped powders or in sachets containing 1000 milligrams or less of paracetamol, when -

(i) packed in a primary pack containing not more than an aggregate of 12,5 grams of paracetamol in such powders or sachets;

(ii) the primary pack is labelled with the following boxed warning, placed prominently on at least the main panel of the immediate container label and outer label (carton):

CONTAINS PARACETAMOL- READ THE PACKAGE INSERT;

(c) in liquid or syrup dosage form containing 120 milligrams or less of paracetamol per 5 millilitres or in pediatric dosage form (drops) containing 120 milligrams or less of paracetamol per 1,2 millilitres, when -

(i) packed in a primary pack containing not more than 100 millilitres in the case of the liquid or syrup dosage form containing 120 milligrams or less of paracetamol per 5 millilitres;

(ii) packed in a primary pack containing not more than 20 millilitres in the case of the paediatric dosage form (drops) containing 120 milligrams or less of paracetamol per 1,2 millilitres;

(iii) the primary pack is labelled with the following boxed warning, placed prominently on at least the main panel of the immediate container label and outer label (carton):

CONTAINS PARACETAMOL- READ THE PACKAGE INSERT.;

(2) when contained in rectal suppositories. (S2)

Paradichlorobenzene, when intended for topical human medicinal use.

Penciclovir, when intended for application to the lips in the early treatment of recurrent Herpes simplex virus infections. (S4)

Pentosan polysulfate sodium, except when intended for the treatment of interstitial cystitis. (S3)

Phenylephrine, except ophthalmic preparations containing 0,2 per cent or less of phenylephrine.

Phospholipids, when applied for therapeutic purposes.

Procaine hydrochloride, when intended for oral administration.

Proguanil when used in combination with chloroquine when intended specifically for malaria prophylaxis. (S4)

Propentofylline, when intended for veterinary use.(S4)

Propylhexedrine, when used as a vasoconstrictor and decongestant in nose preparations and inhalants. (S4)

Proteolytic (fibrinolytic) enzymes for oral use and when intended for application to the skin, unless listed in another Schedule, and except when intended for soft contact lens cleaners and except when intended for injection (S0, S4)

Pyrantel pamoate, including veterinary use, except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Pyridoxilate.

Sertaconazole, when intended for application to the skin. (S4)

Sodium fluoride; preparations and mixtures thereof containing 40 milligrams or more per daily dose. (S4)

Terbinafine, when intended for application to the skin. (S4)

Tetrahydrozoline, when intended for nasal use.

Thiabendazole, when intended for application to the skin. (S4)

Thiram, except when intended and registered as a fungicide in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Ticlatone, when intended for application to the skin.

Tioconazole, when intended for application to the skin and when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis. (S4)

Tolmetin, when intended for application to the skin. (S3)

L-tryptophan when intended for medicinal use as supplementation for nutritional purposes. (S5)

Xylometazoline, when intended for nasal use.

Zinc salts, preparations thereof for injection, when intended for veterinary use. (S3)

- END SCHEDULE 1 -

Schedule 2

(a) All substances referred to in this Schedule are excluded when specifically packed, labelled and used for -

(i) Industrial purposes including the manufacture or compounding of consumer items or products, which have no pharmacological action or medicinal purpose; and

(ii) Analytical laboratory purposes.

(b) All substances referred to in this Schedule include the following:

(i) The salts and esters of such substances, where the existence of such salts and esters is possible; and

(ii) All preparations and mixtures of such substances where such preparations and mixtures are not expressly excluded.

(c) In terms of Section 22A(5)(f) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, may prescribe and supply to patients under their care, the Schedule 2 substances and medicines provided for in the Annexures, only within their scope of practice and subject to the conditions determined by the Medicines Control Council. The conditions and the Annexures will be published in the Government Gazette.

Acetylcysteine.

Acetyldihydrocodeine; preparations and mixtures when compounded with one or more therapeutically active substances and containing 20 milligrams or less of acetyldihydrocodiene (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of acetyldihydrocodeine (calculated as base) per 5 millilitre dosage unit. (S6)

Aconite alkaloids; substances, preparations and mixtures containing 0,02 percent or more thereof.

Acrivastine.

Adrenaline (epinephrine), except ophthalmic preparations when intended for glaucoma and except preparations for injection. (S3, S4)

Alkaloids and glycosides; all poisonous alkaloids and glycosides, and the salts of such poisonous alkaloids and glycosides not specifically named in any other Schedule.

Alverin.

Aminopentamide

Amorolfine.

Amyl nitrite

Antihistamines, irrespective of indication or dosage form, except-

(a) astemizole and terfenadine; (S4)

(b) when listed separately in these Schedules; (S2,S5) and

(c) except when registered in terms of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Antimicrobial substances, namely griseofulvin, mupirocin, natamycin , when intended for application to the skin, nares and external ear, as well as nystatin preparations intended for application to the oral cavity, nares and external ear and excluding nystatin when intended for application to the skin and for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis, as excluded from the conditions of Schedule 4. (S1, S4)

Apomorphine; preparations and mixtures thereof, except when indicated for the treatment of erectile dysfunction. (S4)

Aptocaine.

Arecoline.

Arsenic; substances, preparations and mixtures containing the equivalent of 0,01 percent or more of arsenic trioxide. (S1)

Atropine; substances, preparations and mixtures thereof, except ophthalmic preparations. (S3)

Azelastin.

Bambuterol.

Beclomethasone dipropionate, when intended for nasal administration (other than by aerosol), in the treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12, subject to-

(a) a maximum dose of 100 micrograms per nostril;

(b) a maximum daily dose of 200 micrograms per nostril;

(c) a pack size limit of 200 doses. (S3, S4).

Belladonna alkaloids; substances, preparations and thereof, except when intended for topical application (S1)

Benproperine.

Bevonium methylsulphate.

Biologicals, when intended for human medicinal use, including polyvalent snake antivenom, and except other injectable preparations thereof (S4).

Bismuth, when intended for oral use.

Bromhexine.

Bromides; preparations and mixtures thereof containing less than 80 milligrams of bromine as bromide per recommended daily dose. (S5)

Butinoline.

Calabar bean alkaloids; substances, preparations and mixtures thereof.

Camphorated Opium Tincture BP.

Camylofin.

Cantharidin

Canthaxanthin; when intended for medicinal purposes

Carbocisteine.

Carbuterol, except when contained in respirator solutions (S3) and except when intended for injection. (S4)

Carisoprodol.

Cathine ((+)-norpseudoephedrine); preparations and mixtures containing 50 milligrams or less of cathine per dosage unit. (S6)

Cetirizine.

Chlormezanone; mixtures thereof where the maximum recommended or prescribed dose does not exceed 100 milligrams of chlormezanone. (S5)

Chlorodyne (Chloroform and Morphine Tincture BP 1980); or any preparation or mixture thereof described as chlorodyne: preparations and mixtures containing 5,0 percent or less of chlorodyne in combination with other active medicinal ingredients. (S6)

Chlorprenaline.

Cholestyramine.

Chlorzoxazone.

Clonidine when intended for treatment of migraine. (S3)

Cimetidine, when intended for the short-term symptomatic relief of heartburn, dyspepsia and hyperacidity, subject to-

(a) a maximum dose of 200 milligrams;

(b) a maximum daily dose (per 24 hours) of 800 milligrams;

(c) a maximum treatment period of 2 weeks. (S3)

Clidinium bromide.

Codeine (methylmorphine); preparations and mixtures when compounded with one or more therapeutically active substances and containing 20 milligrams or less of codeine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of codeine (calculated as base) per 5 millilitre dosage unit. (S6)

Colchicine, in cases of emergency. (S3)

Contrast media

Cyclandelate.

Cyclopentolate, except ophthalmic preparations thereof. (S3)

Desloratidine.

Dextromethorphan.

Diclofenac, when intended for the emergency treatment of acute gout attacks, and when intended for the treatment of post traumatic conditions such as pain, swelling and inflammation, for maximum period of 5 days. (S1, S3)

Dicyclomine.

Difenoxin (or diphenoxylic acid); mixtures containing, per dosage unit, 0,5 milligrams or less of difenoxin, calculated as the base, and a quantity of atropine sulphate equal to at least 5,0 per cent of such quantity of difenoxin, calculated as the base, as is present in the mixture. (S6)

Dihydrocodeine; preparations and mixtures when compounded with one or more therapeutically active substances and containing 20 milligrams or less of dihydrocodeine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of dihydrocodeine (calculated as base) per 5 millilitre dosage unit. (S6)

Diphenoxylate; preparations containing not more than 2,5 milligrams of diphenoxylate, calculated as the base, and not less than 25 micrograms of atropine sulphate per dosage unit. (S6)

{D-norpseudoephedrine - see cathine}

Domperidone.

Emedastine.

Emepronium.

Ephedra alkaloids (natural or synthetic), other than ephedrine preparations and mixtures intended for application to the skin, eyes, ears and nares containing 1,0 per cent or less of ephedra alkaloids, and other preparations and mixtures containing not more than 30 milligrams of ephedrine or ephedra alkaloids per dose. (S1, S5)

Ephedrine contained in products registered in terms of the Act, except preparations and mixtures intended for application to the skin, eyes, ears and nares containing 1,0 per cent or less of ephedrine, and other oral preparations and mixtures containing not more than 30 milligrams of ephedrine per dose. (S1, S5)

Ergot alkaloids (natural or synthetic), when intended for the treatment of migraine. (S4)

Ethylmorphine; preparations and mixtures when compounded with one or more therapeutically active substances and containing 20 milligrams or less of ethylmorphine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of ethylmorphine (calculated as base) per 5 millilitre dosage unit. (S6)

Etilefrine.

Exalamide.

Famotidine, when intended for the short-term symptomatic relief of heartburn caused by excess acid, subject to-

(a) a maximum dose of 10 milligrams;

(b) a maximum daily dose (per 24 hours) of 20 milligrams;

(c) a maximum treatment period of 2 weeks. (S4)

Fedrilate

Fenoprofen, when intended for the emergency treatment of acute gout attacks and when intended for the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S3)

Fenoterol, except when contained in respirator solutions (S3) and except when intended for injection or for the prevention or delay of labour. (S4)

Flavoxate.

Flunisolide, when intended for nasal administration, other than by aerosol in a strength not exceeding 0,025 per cent (w/v), indicated for treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12, subject to-

(a) a maximum dose of 50 micrograms per nostril and a maximum daily dose of 100 micrograms per nostril in the case of adults and children over the age of 16 years;

(b) a maximum dose of 25 micrograms per nostril and a maximum daily dose of 75 micrograms per nostril in the case of children 12 to 16 years of age; and

(c) a pack size containing not more than 240 doses. (S3, S4)

Flurbiprofen, when supplied by a pharmacist to a patient and intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S1, S3, S4)

Fluticasone propionate, when intended for nasal administration (other than by aerosol), in the short-term (less than 6 months) prophylaxis and treatment of symptoms of allergic rhinitis (hay fever) in adults and children over 12, subject to-

(a) a maximum daily dose of 100 micrograms per nostril;

(c) a pack size limit of 120 doses. (S3).

Formoterol.

Fusafungine.

Gadopentetic acid

Gelsemium alkaloids; substances, preparations and mixtures thereof.

Glycopyrronium.

Halogenated hydroxyquinolines, when intended for application to the skin. (S4)

Hexametazine.

Hexoprenaline, except when contained in respirator solutions (S3) and except when intended for injection or for the prevention or delay of labour. (S4)

Homatropine; preparations and mixtures thereof, except ophthalmic preparations. (S3)

Hormones (Natural or synthetic, including recombinant forms), with either hormonal or anti-hormonal action, when intended for human vaginal use and oral contraceptives containing only progestogen and hormones when specifically intended for emergency postcoital contraception. (S3, S4, S5)

Hydrocortisone and hydrocortisone acetate, when used in a maximum concentration of 1,0 percent in preparations intended for application to the skin and hydrocortisone in

a maximum concentration of 1,0 percent used in combination with miconazole for topical application in the treatment of athlete's foot. (S4)

Hydroquinone; preparations and mixtures containing 2 percent or less thereof, when intended for application to the skin. (S3)

Hyoscine; substances, preparations and mixtures thereof, including transdermal preparations when intended for the prevention of the symptoms of motion sickness.

Ibuprofen when used in oral medicinal preparations –

a. where the recommended daily dose for adults does not exceed 1,2 grams and that for children up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight;
b. the emergency treatment of acute gout attacks;
c. when intended for the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days;

except when intended for treatment of inflammatory joint disease (S3)

Indomethacin, when intended for the emergency treatment of acute gout attacks. (S1, S3)

Iopromide

Ipratropium bromide.

Isoaminile.

Isoprenaline (isoproterenol), except when contained in respirator solutions (S3) and except when intended for injection. (S4)

Isopropamide.

Ketoprofen,

a) when intended for the short term management of headache, toothache, muscular ache, backache, minor pain associated with arthritis, pain associated with menstrual cramps (dysmenorrhoea), minor aches and pains associated with the common cold and fever, at a maximum dose of 75 milligrams of ketoprofen in 24 hours;
b) when supplied by a pharmacist to a patient and intended for the emergency treatment of acute gout attacks or for the treatment of post traumatic conditions such as pain, swelling and inflammation, at a maximum dose of 100mg of ketoprofen per day, for a maximum period of 5 days. (S1, S3)

Lansoprazole, when intended for the temporary short-term relief of heartburn and hyperacidity, subject to –

a) a maximum daily dose of 15mg

b) a maximum treatment period of 14 days. (S4)

Levocetirizine.

Lithium salts, when intended for application to the skin. (S5)

Lobelia alkaloids; substances, preparations and mixtures thereof.

Lodoxamide.

Loperamide

Loratadine.

Mebeverine.

Mefenamic acid, when intended for the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days; and preparations containing mefenamic acid as the only therapeutic active substance, when intended for the treatment of primary dysmenorrhoea where the maximum daily dose is 500 millligrams 3 times a day and the maximum treatment period is 3 days. (S3)

Mepenzolate bromide.

Mephenesin.

Mercuric ammonium chloride.

Mercuric chloride.

Mercuric iodide.

Mercuric oxides; substances, preparations and mixtures thereof, except those containing less than 3 per cent of mercury.

Mercury organic compounds; substances, preparations and mixtures in the form of aerosols, intended for application to the skin and mucous membranes and substances, preparations and mixtures containing the equivalent of 0,6 per cent or more of elemental mercury, intended for application to the skin and mucous membranes, except phenylmercuric nitrate when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947).

Mesna, except preparations intended for injection. (S4)

Metaproterenol (orciprenaline) except when contained in respirator solutions (S3) and except when intended for injection or for the prevention or delay of labour (S4)

Methixene

Methocarbamol, when intended for medicinal purposes

Methoxyphenamine

Miconazole, when intended for human use in preparations containing 2 percent or less of miconazole, for the topical treatment of fungal infections of the mouth (oral candidiasis). (S1, S4)

Minoxidil, when intended for application to the scalp. (S4)

Morphine; mixtures containing 0,2 percent or less of morphine, calculated as anhydrous morphine. (S6)

Nabumetone, when intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S3)

Naproxen,

a) as the sodium salt, when intended for the short term management of headache, toothache, muscular ache, backache, minor pain associated with arthritis, pain associated with menstrual cramps (dysmenorrhoea), minor aches and pains associated with the common cold and fever, at a maximum dose of 600 milligrams naproxen (660 milligrams naproxen sodium) in 24 hours;

b) and when supplied by a pharmacist to a patient and intended for the emergency treatment of acute gout attacks or for the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S1, S3)

Nedocromil

Nicergoline

Nicotine when intended for human medicinal use, except-

(a) nicotine gum containing 4mg or less nicotine per piece where the pack size does not exceed 30 pieces per pack when these medicines are used for the relief of nicotine withdrawal symptoms as an aid to smoking cessation only (S0).

(b) nicotine transdermal patches for continuous application to the skin in strengths up to and including 15mg/16 hours when these medicines are used for the relief of nicotine withdrawal symptoms as an aid to smoking cessation only. (S1)

Nizatidine, when administered orally for short-term symptomatic relief of heartburn and hyperacidity, subject to-

(a) a maximum dose of 150 milligrams;

(b) a daily dose of 300 milligrams

(c) a maximum treatment period of two weeks. (S4)

Norcodeine; preparations and mixtures when compounded with one or more therapeutically active substances and containing 20 milligrams or less of norcodeine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of norcodeine (calculated as base) per 5 millilitre dosage unit. (S6)

Noscapine

Nux vomica; substances, preparations and mixtures thereof, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Octatropine methylbromide.

Oleoresin of aspidium (Filix Mas).

Olopatadine.

Opium; mixtures containing not more than 0,2 percent of morphine, calculated as anhydrous morphine. (S6)

Orphenadrine.

Otilonium bromide.

Oxybuprocaine, when contained in eye drops intended for emergency treatment of arc eyes. (S4)

Oxyphencyclimine.

Oxyphenonium.

Papaverine; substances, preparations and mixtures thereof.

Paracetamol, when contained in rectal suppositories. (S0, S1)

Pentoxyfylline

Phenazone (antipyrone)

Phenazopyridine

Phenylpropanolamine, preparations and mixtures where the recommended daily dose for adults does not exceed 100 milligrams and for children 6 to 12 years, does not exceed 50 milligrams, when intended for the symptomatic relief of nasal and sinus congestion.

Pholcodine; preparations and mixtures when compounded with one or more therapeutically active substances and containing 20 milligrams or less of pholcodeine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of pholcodeine (calculated as base) per 5 millilitre dosage unit. (S6)

Pholedrine

Pinaverium

Pipenzolate

Pipoxolan

Pirbuterol, except when contained in respirator solutions. (S3)

Piroxicam, when intended for the emergency treatment of acute gout attacks and when intended for the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S3)

Pizotifen; preparations and mixtures, when intended for prophylaxis of migraine (S5)

Podophyllum resin; preparations and mixtures containing 20 percent or less thereof. (S4)

Poldine methylsulphate.

Polyvalent snake antivenom.

Potassium chloride, where the recommended dose is more than 20 millimol of potassium (1500 milligrams of potassium chloride) per 24 hours or when intended for intravenous infusion or for injection, but except when contained in oral rehydration preparations. (S0)

Prifinium bromide.

Procaterol, except when contained in respirator solutions. (S3)

Procyclidine

Proglumide

Promethazine; preparations and mixtures when intended for use as an antihistamine, for application to the skin and when intended specifically for the treatment of travel sickness. (S5)

Propantheline bromide.

Propyphenazone

Proxymetacaine, when contained in eye drops intended for emergency treatment of arc eyes. (S4)

Quinine; preparations and mixtures containing more than 1,0 percent thereof.

Ranitidine, when administered orally for short-term symptomatic relief of heartburn and hyperacidity, subject to-

(a) a maximum dose of 75 milligrams;

(b) a daily dose of 300 milligrams

(c) a maximum treatment period of two weeks. (S3)

Reproterol, except when contained in respirator solutions. (S3)

Rimiterol, except when contained in respirator solutions (S3) and except when intended for injection. (S4)

Sabadilla alkaloids; substances, preparations and mixtures containing 1,0 per cent or more thereof.

Salbutamol, except when contained in respirator solutions (S3) and except when intended for injection. (S4)

Salmefamol, except when contained in respirator solutions (S3) and except when intended for injection. (S4)

Salmeterol.

Siccanin, when intended for application to the skin.

Silver sulphadiazine, when intended for application to the skin in the short-term treatment of minor burns, provided that the pack size is limited to a maximum of 50 grams. (S4)

Sodium cromoglycate, except when intended for veterinary use. (S4)

Strychnine; preparations and mixtures containing 0,2 percent or less thereof, except the substance. (S4)

Sulphonamides, when intended for application to the eyes, nares and vagina, (S4), except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947).

Terbutaline, except when contained in respirator solutions. (S3)

Tetracaine, when contained in eye drops intended for emergency treatment of arc eyes. (S4)

Theophylline and its derivatives, unless listed in another Schedule, except preparations for injection. (S4)

Tiaprofenic acid, when intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S3)

Timepidium.

Tiotropium.

Triamcinolone, when intended for application to oral lesions. (S4)

Trimebutine

Trospium.

Tuberculin, when intended for human use (S4)

Tulobuterol, except when contained in respirator solutions. (S3)

Vaccines, when intended for human use

- END SCHEDULE 2 -

Schedule 3

(*a*) All substances referred to in this Schedule are excluded when specifically packed, labelled and used for -

(i) industrial purposes including the manufacture or compounding of consumer items or products, which have no pharmacological action or medicinal purpose; and

(ii) analytical laboratory purposes.

(b) All substances referred to in this Schedule include the following:

(i) The salts and esters of such substances, where the existence of such salts and esters is possible; and

(ii) all preparations and mixtures of such substances where such preparations and mixtures are not expressly excluded.

(*c*) In terms of Section 22A(5)(f) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, may prescribe and supply to patients under their care, the Schedule 3 substances and medicines provided for in the Annexures, only within their scope of practice and subject to the conditions determined by the Medicines Control Council. The conditions and the Annexures will be published in the *Gazette.*

Acamprosate.

Acebutolol.

Aceclofenac.

Acetazolamide.

Acetohexamide.

Acetylcholine, when intended for ophthalmic use.

Acipimox.

Adapalene.

Adrenaline (epinephrine); ophthalmic preparations thereof, when intended for glaucoma. (S2, S4)

Alclofenac.

Alendronic acid.

Allopurinol.

Alprenolol.

Amiloride.

Amodipine.

Ancrod.

Anthiolimine, when intended for injection.

Arsanilic acid.

Atenolol.

Atropine; ophthalmic preparations thereof. (S2)

Azapropazone.

Balsalazide.

Barnidipine.

Beclamide.

Benazepril.

Bendazac.

Benfluorex.

Benoxaprofen.

Benzbromarone.

Benzydamine, except preparations and mixtures containing -

(a) 3 per cent or less of benzydamine when intended for application to the skin;

(b) 0,15 per cent or less of benzydamine when intended for use as a mouthrinse or for topical application in the mouth and throat: Provided that the total dose does not exceed 36 mg of benzydamine per day. (S1)

Bepridil.

Beta-benzalbutyramide.

Beta-galactosidase, when intended for therapeutic purposes.

Betahistine.

Betaxolol.

Bethanidine.

Bevantolol.

Bezafibrate.

Bisoprolol.

Bopindolol.

Brimonidine.

Brinzolamide.

Buflomedil.

Buformin.

Bumetanide.

Cadralazine.

Calcipotriol.

Calcium carbimide.

Calcium disodium edetate, when intended for injection.

Calcium dobesilate.

Candesartan.

Captopril.

Carazolol.

Carbachol; ophthalmic preparations thereof when intended for glaucoma. (S4)

Carbamazepine.

Carbenoxolone, except when intended for application to the oral mucosa.

Carbuterol, when contained in respirator solutions. (S2, S4)

Carprofen.

Carteolol.

Carvedilol.

Celecoxib.

Celiprolol.

Chenodeoxycholic acid.

Chlorazanil.

Chlorexolone.

Chlorothiazide and other derivatives of benzo-1,2,4-thiadiazine-7-sulphonamide-1,1-dioxide, whether hydrogenated or not, including hydrochlorothiazide, bendrofluazide, benzthiazide, cyclopenthiazide, hydroflumethiazide, metchlorothiazide and polythiazide.

Chlorpropamide.

Chlorthalidone.

Chromonar.

Cilazapril.

Cimetidine, except when intended for the short-term symptomatic relief of heartburn, dyspepsia and hyperacidity, where the maximum dose is 200 milligrams, the maximum daily dose (per 24 hours) is 800 milligrams and the maximum treatment period is 2 weeks. (S2)

Clofibrate.

Clonidine, except when intended for the treatment of migraine. (S2)

Clopidogrel.

Colchicine, except in cases of emergency. (S2)

Colestipol.

Copper salts, when intended for injection.

Corticosteroids (natural or synthetic), when contained in preparations intended for inhalation, except-

(a) beclomethasone dipropionate, when intended for nasal administration, other than by aerosol, indicated for the treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12, where the maximum dose per nostril is 100 micrograms, the maximum daily dose per nostril is 200 micrograms and the pack size is limited to 200 doses; and

(b) flunisolide, when intended for nasal administration, other than by aerosol, in a strength not exceeding 0,025 per cent (w/v), indicated for treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12, where in the case of adults and children over the age of 16 years, the maximum dose per nostril is 50 micrograms and the maximum daily dose per nostril is 100 micrograms and in the case of children 12 to 16 years, the maximum dose per nostril is 25 micrograms and the maximum daily dose per nostril is 75 micrograms and the pack size is limited to 240 doses and

(c) fluticasone propionate, when intended for nasal administration, other than by aerosol, in the short-term (less than 6 months) prophylaxis and treatment of symptoms of allergic rhinitis (hay fever) in adults and children over 12, where the maximum daily dose per nostril is 100 micrograms and the pack size is limited to 120 doses. (S2, S4)

Cyclandalate

Cyclopentolate; ophthalmic preparations thereof. (S2)

Debrisoquine.

Delapril.

Dichlorphenamide.

Diclofenac, except when intended for application to the skin, (S1) and except when intended for the emergency treatment of acute gout attacks and except when intended for the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S2)

Diflunisal.

Diftalone.

Digitalis; its glycosides and other active principles thereof, unless diluted below one unit (BP) in each 2,0 grams.

Dihydroergocristine.

Dilevalol.

Diltiazem.

Dimercaprol, when intended for injection.

Dipivefrin.

Dipyridamole.

Dipyrocetyl.

Disulfiram.

Dithranol.

Domase alfa (rh DNase).

Dorzolamide.

Doxazosin.

Eltenac.

Enalapril.

Endralazine.

Eprosartan.

Escin (aescin), except preparations and mixtures thereof intended for application to the skin and containing 1,0 percent or less of escin. (S1)

Esculin, when intended for oral use.

Esmolol.

Ethacrynic acid.

Ethambutol.

Ethionamide, when intended for oral use.

Ethosuximide.

Etisazol.

Etodolac.

Etodolic acid.

Felbamate.

Felodipine.

Fenbufen.

Fenclofenac.

Fendiline.

Fenofibrate.

Fenoprofen, except when intended for the emergency treatment of acute gout attacks and when intended for the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S2)

Fenoterol, when contained in respirator solutions. (S2, S4)

Fentiazac.

Floctafenine.

Flufenamic acid, except preparations and mixtures intended for application to the skin. (S1)

Flunixin.

Flurbiprofen, except -

(a) when intended for ophthalmic use; (S4)

(b) when intended for application to the skin, including application by transdermal patch, the indications are for use by adults and children 12 years and older and the treatment period is limited to 4 weeks; (S1)

(c) when supplied by a pharmacist to a patient and intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S2)

Fosinopril.

Furosemide.

Gabapentin.

Gemfibrozil.

Glafenine.

Glibenclamide.

Glibornuride.

Gliclazide.

Glimepiride.

Glimidine.

Glipizide.

Gliquidone.

Glucosamine, substances, preparations and mixtures when intended for the treatment of primary and secondary osteoarthritis, osteochondrosis and spondylosis.

Guanabenz.

Guanethidine.

Guanfacine.

Guanoxan.

Hexoprenaline, when contained in respirator solutions. (S2, S4)

Homatropine; ophthalmic preparations thereof. (S2)

Hormones (natural or synthetic, including recombinant forms), when intended for oral contraception, except oral contraceptives containing only progestogen and except hormones when specifically intended for emergency postcoital contraception. (S2, S4, S5)

Hydralazine.

Hydroquinone; preparations and mixtures thereof containing more than 2,0 percent hydroquinone. (S2)

Ibuprofen, when specifically intended for the treatment of inflammatory joint diseases. (S1, S2)

Indapamide.

Indomethacin, except when intended for application to the skin, and except when intended for the emergency treatment of acute gout attacks. (S1, S2)

Indoprofen.

Indoramin.

Insulin

Irbesartan.

Iron salts, when intended for injection, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Isoniazid and its derivatives, unless listed in another Schedule.

Isoprenaline (isoproterenol), when contained in respirator solutions. (S2, S4)

Isosorbide.

Isoxicam.

Isradipine.

Ivermectin, except when intended and registered as an anthelmintic and/or ectoparasiticide in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Ketanserin.

Ketoprofen, except -

(a) when intended for application to the skin; (S1)

(b) when intended for the short term management of headache, toothache, muscular ache, backache, minor pain associated with arthritis, pain associated with menstrual cramps (dysmenorrhoea), minor aches and pains associated with the common cold and fever, at a maximum dose of 75 milligrams of ketoprofen in 24 hours; (S2)

(c) when supplied by a pharmacist to a patient and intended for the emergency treatment of acute gout attacks or for the treatment of post-traumatic conditions such as pain, swelling and inflammation, at a maximum dose of 75mg of ketoprofen per day, for a maximum period of 5 days. (S2)

Ketorolac trometamol, when intended for ophthalmic use. (S4)

Labetalol.

Lacidipine.

Lamotrigine.

Lercanidipine.

Levetiracetam.

Levobunolol.

Levosemindan.

Lidoflazine.

Lisinopril.

Lonazolac.

Lomoxicam.

Losartan.

Meclofenamic acid.

Mefenamic acid, except when intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days; and except preparations containing mefenamic acid as the only therapeutic active substance, when intended for the treatment of primary dysmenorrhoea where the

maximum daily dose is 500 millligrams mefanamic acid 3 times a day and the maximum treatment period is 3 days. (S2)

Meloxicam.

Mepindolol.

Mesalazine (5-aminosalicylic acid).

Mesulphene.

Metaproterenol (orciprenaline), when contained in respirator solutions. (S2, S4)

Metformin.

Methazolamide.

Methimazole.

Methsuximide.

Methyldopa .

Metipranolol.

Metolazone.

Metoprolol.

Mibefradil.

Moexipril.

Montelukast.

Moxonidine.

Nabumetone, except when intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S2)

Nadolol.

Naftidrofuryl.

Naproxen, except -

(a) when intended for application to the skin; (S1)

(b) the sodium salt, when intended for the short term management of headache, toothache, muscular ache, backache, minor pain associated with arthritis, pain associated with menstrual cramps (dysmenorrhoea), minor aches and pains associated with the common cold and fever, at a maximum dose of 600 milligrams naproxen (660 milligrams naproxen sodium) in 24 hours; (S2)

(c) when supplied by a pharmacist to a patient and intended for the emergency treatment of acute gout attacks or for the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S2)

Nateglinide.

Nebivolol.

Nicardipine.

Nifedipine.

Niflumic acid.

Nimesulide.

Nimodipine.

Nisoldipine.

Nitrendipine.

Nitroglycerine, when intended for medicinal use.

Olsalazine.

Orlistat.

Oxaprozin.

Oxcarbazepine.

Oxitracetam.

Oxovinca.

Oxyprenolol.

Oxybutynin.

Parecoxib

Para-aminosalicylic acid and its esters.

Penbutolol.

Penicillinase, when intended for injection.

Pentaerythritol tetranitrate.

Pentolinium.

Pentosan polysulfate sodium, when intended for the treatment of interstitial cystitis. (S1)

Perindopril.

Phenformin.

Phenobarbital, preparations and mixtures containing not more than 90 milligrams of phenobarbital per minimum recommended or prescribed dose when intended for continued use in epilepsy. (S5)

Phenoxymethylpenicillin, when intended for the prophylaxis of rheumatic fever. (S4)

Phentolamine.

Phenytoin.

Physostigmine; ophthalmic preparations thereof, when intended for glaucoma. (S4)

Pilocarpine; ophthalmic preparations thereof intended for glaucoma. (S4)

Pindolol.

Pioglitazone.

Piracetam.

Pirbuterol, when contained in respirator solutions. (S2)

Piretanide.

Piroxicam, except when intended for the emergency treatment of acute gout attacks and when intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S2)

Pirprofen.

Potassium canrenoate.

Practolol.

Prazosin.

Primidone.

Probenecid.

Probucol.

Procaterol, when contained in respirator solutions. (S2)

Proctofene.

Propacetamol.

Propiverine.

Propranolol.

Proquazone.

Proscillaridine.

Prothionamide, when intended for oral use.

Pygeum africanum (lipido-sterolic complex extract thereof).

Pyrazinamide, when intended for oral use.

Pyrimethamine

Pyrithioxin.

Quinapril.

Racecadotril.

Raloxifene.

Ramipril.

Ranitidine, except where administered orally for short-term symptomatic relief of heartburn and hyperacidity, where the maximum dose is 75 milligrams, the

maximum daily dose is 300 milligrams and the maximum treatment period is two weeks. (S2)

Raubasine.

Rauwolfia alkaloids.

Repaglinide.

Reproterol, when contained in respirator solutions. (S2)

Reserpine (natural or synthetic).

Rimiterol, when contained in respirator solutions. (S2, S4)

Risedronate.

Rofecoxib.

Rosiglitazone.

Roxarzone (3-nitro-4-hydroxyphenylarsonic acid), when intended for veterinary use.

Salbutamol, when contained in respirator solutions. (S2, S4)

Salmefamol, when contained in respirator solutions. (S2, S4)

Solcoseryl; ophthalmic preparations thereof. (S0, S4)

Sotalol.

Spirapril.

Spironolactone.

Strophanthus; its glycosides and their hydrolysis products, and their derivatives, unless listed in another Schedule.

Sulindac.

Suloctidil.

Sulphinpyrazone.

Sulthiame.

Suprofen.

Sylimarin.

Tasosartan.

Tazarotene.

Telmisartan.

Tenidap.

Tenoxicam.

Terazosin.

Terbutaline, when contained in respirator solutions. (S2)

Terizidone.

Terodiline.

Thiacetazone.

Thyroid gland and its active principles and derivatives, unless listed in another Schedule.

Tiagabine.

Tiaprofenic acid, except when intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S2)

Ticlopidine.

Timolol.

Tolamolol.

Tolazamide.

Tolbutamide.

Tolfenamic acid.

Tolmetin, except when intended for application to the skin. (S1)

Tolterodine.

Topiramate.

Torasemide.

Trandolapril.

Tretinoin.

Triamterene.

Tricaine.

Trimethadione.

Tropicamide.

Tulobuterol, when contained in respirator solutions. (S2)

Ursodeoxycholic acid.

Valdecoxib.

Valproic acid and its derivatives, unless listed in another Schedule.

Valsartan.

Vedaprofen.

Verapamil (iproveratril).

Veratrum alkaloids.

Vigabatrin.

Vincamine.

Vinpocetine.

Vitamin A; preparations thereof for injection and oral preparations and mixtures thereof containing more than 10 000 I.U. per recommended daily dose, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Vitamin D; preparations thereof for injection and oral preparations and mixtures thereof containing more than 500 I.U. per recommended daily dose, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Xamoterol.

Xipamide.

Zafirlukast.

Zinc salts for oral ingestion where the daily dose is more than 50 milligrams of elemental zinc (S1), except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947).

Zomepirac.

- END SCHEDULE 3 -

Schedule 4

(a) All substances referred to in this Schedule are excluded when specifically packed, labelled and used for -

(i) industrial purposes including the manufacture or compounding of consumer items or products, which have no pharmacological action or medicinal purpose; and

(ii) analytical laboratory purposes.

(b) All substances referred to in this Schedule include the following:

(i) The salts and esters of such substances, where the existence of such salts and esters is possible; and

(iii) all preparations and mixtures of such substances where such preparations and mixtures are not expressly excluded.

(c) In terms of Section 22A(5)(f) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, may prescribe and supply to patients under their care, the Schedule 4 substances and medicines provided for in the Annexures, only within their scope of practice and subject to the conditions determined by the Medicines Control Council. The conditions and the Annexures will be published in the *Gazette*.

Abacavir.

Acarbose.

Acetarsone diethylamine salt, when intended for injection.

Acyclovir, except when intended for application to the lips in the early treatment of recurrent Herpes simplex virus infections. (S1)

Adenosine.

Adrenaline, when intended for injection. (S2, S3)

Albendazole, except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Alcuronium.

Aldesleukin.

Alfuzosin.

Alisapride.

Almitrine.

Alosetron.

Alphacalcidol, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Alphachymotrypsin, when intended for ophthalmic use.

Alprostadil.

Amantadine.

Amifostine.

Aminoglutethimide.

Aminopyrine (amidopyrine).

Amiodarone.

Amiphenazole.

Amprenavir.

Amrinone.

Amsacrine.

Anagrelide.

Anastrozole.

Anticoagulants, except preparations intended for application to the skin. (S1)

Antihemophilic factor.

Antimalarials, excluding chloroquine in combination with proguanil when intended specifically for malaria prophylaxis. (S1

Antimicrobial substances synthesised in nature or the laboratory, being substances used in the specific treatment of infections, except the following when intended for topical application to the epidermis, nares and external ear:

Bacitracin; (S1)

gramicidin; (S1)

griseofulvin; (S2)

mupirocin; (S2)

natamycin; (S2)

nystatin; (S1, S2)

polymyxin B; (S1)

tyrothricin; (S1)

and except when intended for use as germicides and antiseptics, and except nystatin oral drops (S1) and except nystatin when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis (S1), and except phenoxymethylpenicillin when intended for the prophylaxis of rheumatic fever (S3) and except when intended for use as indicated below and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947:

Ampicillin, cloxacillin, dihydrostreptomycin, penethamate hydriodide and procaine benzylpenicillin; intra-mammary preparations thereof, containing tracer dye(s) and intended for the treatment of mastitis in cattle;

amprolium, decoquinate, dinitolmide, ethopabate, lasalocid, maduramicin, monensin and narasin when intended as anti-coccidial preparations;

avilomycin, avoparcin, carbadox, flavophospholipol, monensin, nitrovin, olaquindox, virginiamycin and zinc bacitracin when intended to promote growth as a feed additive;

carnidazole, when intended for trichomonas in pigeons;

chlortetracycline, rolitetracycline and tetracycline; injections thereof, intended for the treatment of anaplasmosis, footrot, heartwater, navel ill and pneumonia in sheep and cattle;

chlortetracycline; capsules thereof, for use in pigeons;

chlortetracycline and tetracycline derivatives when intended for topical use in the management of wounds in animals;

dimetridazole, when intended for trichomonas in pigeons, as an anti-bacterial preparation for pigs and to promote growth;

doxycycline and oxytetracycline; preparations thereof, except preparations intended to be used as an additive to feed;

furaltadone, when intended as a single oral dosage for gastro-intestinal infections;

hygromycin, when intended as an anthelmintic for pigs;

salinomycin,when intended as an anti-coccidial preparation and to promote growth;

tylosin, when intended for addition to drinking water and feedstuff for administration to poultry and pigs.

Antisera, when intended for veterinary use, except antisera registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Apomorphine, when indicated for the treatment of erectile dysfunction. (S2)

Apraclonidine.

Aprotinin.

Arabinosylcytosine.

Arprinocid, except when intended and registered as an anticoccidial preparation in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Arsenamide, when intended for injection.

Artemether and its derivatives.

Artemotil.

L-asparaginase.

Astemizole.

Atipamezole.

Atorvastatin.

Atosiban.

Atovaquone.

Atracurium besilate.

Auranofin.

Azathioprine.

Baclofen.

Basiliximab.

Bee venom, except preparations intended for application to the skin.

Bemegride.

Bethanechol.

Bimatoprost.

Biologicals, injectable preparations thereof, when intended for human use, except tuberculin when intended for human use and except vaccines when intended for human use, and except polyvalent snake antivenom. (S2)

Biperiden.

Bleomycin.

Bretylium tosylate.

Bromocriptine.

Bufenoide.

Bumadizone.

Buserelin.

Busulphan.

Cabergoline.

Calcitonin.

Calcitriol.

Calcium polystyrene sulphonate, when intended for therapeutic purposes.

Cambendazole.

Capecitabine.

Carbachol, except ophthalmic preparations thereof, when intended for glaucoma. (S3)

Carbidopa.

Carboplatin.

Carbuterol, when intended for injection. (S2, S3)

Carmustine.

Cerivastatin.

Ceruletide.

Chlorambucil.

Chlordantoin, when intended for human vaginal use.

Chloroquine, when intended for antirheumatic use. (S1)

Chymopapain, when intended for injection.

Cisapride.

Cisatracurium.

Cisplatin.

Cladribine.

Clanobutin.

Clazuril, except when intended and registered as an anti-coccidial preparation in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Clenbuterol.

Clofazimine.

Clomiphene.

Closantel, except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Clotrimazole, except when intended for application to the skin and when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis. (S1)

Colfosceril.

Corticosteroids (natural or synthetic), unless listed in another Schedule, except -

(a) hydrocortisone and hydrocortisone acetate when used as a single active ingredient in a maximum concentration of 1,0 per cent in preparations intended for application to the skin; (S2)

(b) triamcinolone when intended for application to oral lesions; (S2) and

(c) when contained in preparations intended for inhalation. (S2, S3)

Cotetroxazine.

Co-trimoxazole.

Cyclofenil.

Cyclophosphamide and its derivatives, unless listed in another Schedule.

Cyclosporin.

Cyprenorphine.

Cyproterone acetate.

Cytarabine.

Dacarbazine.

Dacliximab.

Dactinomycin (actinomycin D).

Dantrolene.

Dapsone and its derivatives, unless listed in another Schedule.

Daunomycin (daunorubicin).

Deferoxamine.

Demecarium.

Desirudin.

Diazoxide.

Dichlorophen, except preparations and mixtures when intended for application to the skin and except when intended for use and registered as an anthelmintic in terms of

the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Diclazuril, except when intended registered as an anti-coccidial preparation in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Diclodronic acid.

Didanosine.

Diethylcarbamazine.

Dihydralazine.

Dihydrotachysterol.

Di-isopropyl fluorophosphate.

Dilazep.

Diloxanide furoate.

Dimethyl sulphoxide.

Diminazene, except when intended and registered as an antibabesial in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Dinitrophenol.

Dinoprostone.

Diphemethoxidine.

Diphenidol.

Diprenorphine.

Disodium pamidronate.

Disophenol, except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Disopyramide.

Distigmine.

Ditazole.

Dobutamine.

Docetaxol.

Dolasetron.

Dopa.

Dopamine.

Doxapram.

Doxepin, when intended for application to the skin. (S5)

Doxorubicin.

Drotecognin.

Econazole, except when intended for application to the skin and when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis. (S1)

Enilconazole, except when intended for application to the skin. (S1)

Edoxudine.

Edrophonium.

Efavirenz.

Eletriptan.

Emetine, except substances, preparations and mixtures containing less than 0,2 percent of alkaloids, calculated as emetine.

Encainide.

Enoxacin.

Enrofloxacine.

Entacapone.

Epirubicin. (4-epidoxorubicin)

Ergot alkaloids (natural or synthetic); except preparations and mixtures thereof when intended for the treatment of migraine. (S2)

Esomeprazole.

Estramustine.

Etidronate.

Etiproston.

Ethoglucid.

Etofamide.

Etoposide.

Famciclovir.

Famotidine, except when intended for the short term symptomatic relief of heartburn caused by excess acid, where the maximum dose is 10 milligrams, the maximum daily dose (per 24 hours) is 20 milligrams and the maximum treatment period is 2 weeks. (S2)

Fazadinium.

Febantel, except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Fenchlorphos.

Fenoterol, when intended for the prevention or delay of labour and preparations thereof for injection. (S2, S3)

Fenticonazole.

Fertirelin.

Filgrastim.

Finasteride.

Flecainide.

Flosequinan.

Fluconazole.

Flucytosine.

Fludarabine.

Flugestone.

Flunisolide.

Fluorides; except oral medicinal preparations and mixtures thereof containing 0,25 milligrams or more of fluorine as fluoride per recommended daily dose, unless listed in another Schedule. (S1)

5-fluorouracil.

Flurbiprofen, when intended for ophthalmic use. (S1, S2, S3)

Flutamide.

Fluvastatin.

Fondaparinux.

Fotemustine.

Ftorafur.

Furazolidone.

Galantamine.

Gallamine.

Ganciclovir.

Ganirelix.

Gemcitabine.

Gemtuzumab

Gestrinone.

Glatiramer.

Glycosaminoglycan polysulphate (previously mucopolysaccharide poly-sulphuric acid ester), except when intended for application to the skin. (S1)

Goserelin.

Granisetron.

Halofantrine.

Halofenate.

Halofuginone, except when intended and registered as an anti-coccidial preparation in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Halogenated hydroxyquinolines, except when intended for application to the skin (S2), and except di-iodohydroxyquinoline when intended and registered as an anti-coccidial preparation in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947).

Hemin.

Heptaminol.

Hexoprenaline, when intended for the prevention or delay of labour and preparations thereof for injection. (S2, S3)

Hormones (natural or synthetic, including recombinant forms), with either hormonal or anti-hormonal action, unless listed in another Schedule, except-

(a) when specifically intended for emergency postcoital contraception (S2);

(b) when intended for oral contraception (S2, S3);

(c) insulin (S3);

(d) adrenaline (epinephrine) (S2, S3, S4);

(e) corticotrophin (adrenocorticotrophichormone; ACTH) (S5);

(f) Human growth hormone (human somatotropin) -all forms (S5);

(g) zeranol, natural estrogen, and progesterone, when intended and registered as a veterinary production improver in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947;

(h) BST (Bovine somatotropin), when intended and registered as a stock remedy in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Hyaluronidase.

Hyaluronic acid and its derivatives.

Hycanthone.

Hydroxyurea.

Hylan.

Ibandronic Acid.

Ibutilide.

Idarubicin.

Idoxuridine, except when intended for application to the skin. (S1)

Iloprost.

Imatinib.

Imidocarb, except when intended and registered as an antibabesial for the treatment of babesiosis in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Imiglucerase.

Imiquimod.

Indinavir.

Infliximab.

Inosiplex (inosine pranobex).

Interferon alpha.

Interferon beta.

Interferon gamma.

Intra-uterine devices.

Intrifiban.

Irinotecan.

Isepamicin.

Isoconazole, except when intended for application to the skin and when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis. (S1)

Isopirin.

Isoprenaline (isoproterenol), when intended for injection. (S2, S3)

Isoxsuprine.

Itraconazole.

Ketoconazole, except preparations and mixtures containing not more than 1, 0 per cent of ketaconazole, when intended for the prevention and treatment of dandruff and except when intended for application to the skin. (S0, S1)

Ketorolac trometamol, except when intended for ophthalmic use. (S3)

Lamivudine.

Lansoprazole, except when intended for the temporary short-term relief of heartburn and hyperacidity, subject to –

a) a maximum daily dose of 15mg

b) a maximum treatment period of 14 days. (S2).

Latanoprost.

Leflunomide.

Letrozole.

Levallorphan.

Levamisole, except when intended and registered as an anthelmintic and an immunomodulator in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Levobupivacaine.

Liarozole.

Local anaesthetics, when intended for ophthalmic and parenteral use, except oxybuprocaine, proxymetacaine and tetracaine, when contained in eye drops intended for emergency treatment of arc eyes, and except lignocaine when contained in antimicrobial preparations for injection as well as in ophthalmic preparations registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Lomustine.

Lopinavir.

Lovastatin.

Lumefantrine.

Lysozyme, except preparations and mixtures when intended for application to the skin. (S1)

Mecamylamine.

Mefloquine.

Melarsoprol, when intended for injection.

Melphalan and its derivatives, unless listed in another Schedule.

Mephentermine.

Mepirizole.

2-mercaptopropionyl glycine.

6-mercaptopurine and its derivatives, unless listed in another Schedule.

Mercury; preparations and mixtures that contain mercury metal and that are intended for medicinal use.

Mesna, when intended for injection. (S2)

Metaproterenol (orciprenaline), when intended for the prevention or delay of labour, and preparations thereof for injection. (S2, S3)

Metergoline.

Methacholine.

Methampyrone.

Methotrexate.

Methoxsalen.

Methysergide.

Metoclopramide.

Metomidate.

Metronidazole.

Mexiletine.

Miconazole, except when intended for application to the skin and except when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis (S1), and except when intended for human use in preparations containing 2 per cent or less of miconazole, when intended for the topical treatment of fungal infections of the mouth (oral candidiasis) (S2).

Mifepristone.

Miglitol.

Milrinone.

Miltefosine.

Minoxidil, except when intended for application to the scalp. (S2)

Misoprostol.

Mitomycin C.

Mitoxantrone.

Mivacurium.

Mizolastine.

Mofebutazone.

Molgramostim.

Mometasone.

Moracizine.

Morazone.

Morphazinamide.

Morphethylbutyne.

Mucoglucuronan.

Muromonab.

Mycophenolic acid.

Nalidixic acid.

Nalorphine.

Naloxone.

Naltrexone.

Naratriptan.

Nefopam.

Nelfinavir.

Neostigmine.

Netobimin.

Nevirapine.

Nicarbazin, except when intended and registered as an anti-coccidial preparation in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Nifuratel.

Nikethamide.

Nilutamide.

Nimorazole.

Nimustine.

Niridazole.

Nitrofurantoin, except preparations thereof intended for application to the skin. (S1)

Nitrofurazone, except preparations thereof intended for application to the skin. (S1)

Nitrous oxide gas, alone or in combination with other gasses.

Nitroxoline.

Nitroxynil, except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Nizatidine, except when intended for oral administration for short-term symptomatic relief of heartburn and hyperacidity, where the maximum dose is 150 milligrams, the maximum daily dose is 300 milligrams and the maximum treatment period is two weeks. (S2)

Obidoxime.

Octreotide.

Omeprazole.

Ondansetron.

Oprelvekin.

Ornidazole, except when intended for application to the skin. (S1)

Oseltamivir.

Oxamniquine.

Oxfendazole, except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Oxolinic acid.

Oxybuprocaine, except when contained in eye drops intended for emergency treatment of arc eyes. (S2)

Oxyclosanide, except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Paclitaxel.

Palivizumab.

Paltitrexid.

Pamidronic acid.

Pancuronium.

Pantoprazole.

Paricalcitrol.

Penciclovir, except when intended for application to the lips in the early treatment of recurrent Herpes simplex virus infections. (S1)

Penicillamine.

Pentamidine isethionate.

Pentostatin.

Pergolide.

Perhexiline.

Phenacetin, except preparations and mixtures intended for external use and containing not more than 0,1 percent phenacetin as stabilizer.

Phenamidine, except when intended and registered as an antibabesial in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Phenopyrazone.

Phenoxybenzamine.

Phenylbutazone and its derivatives, unless listed in another Schedule.

Physostigmine, except ophthalmic preparations thereof when intended for glaucoma. (S3)

Picrotoxin.

Pilocarpine, except ophthalmic preparations thereof intended for glaucoma. (S3)

Pimecrolimus

Pipemidic acid.

Pirenzepine.

Piribedil.

Piromidic acid.

Podophyllum resin; preparations and mixtures containing more than 20 per cent of podophyllum resin. (S1)

Polyglycerylene-dextran.

Poractant alpha.

Potassium dichromate, except preparations and mixtures containing not more than 15 micrograms of potassium dichromate per dosage unit.

Pralidoxime.

Pramipexole.

Pravastatin.

Praziquantel, except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Procainamide.

Procarbazine.

Propafenone.

Propentofylline, except when intended for veterinary use. (S1)

Propylhexedrine, except when used as a vasoconstrictor and decongestant in nose preparations and inhalants. (S1)

Proteolytic (fibrinolytic) enzymes, when intended for injection. (S1)

Proxymetacaine, except when contained in eye drops intended for emergency treatment of arc eyes. (S2)

Pyridinolcarbamate.

Pyridostigmine.

Quinoronium sulphate, except when intended and registered as an antibabesial in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Rabeprazole.

Ractopamine, when used as a veterinary production improver.

Radio-active compounds, when used for diagnostic purposes.

Rafoxanide, except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Rapacuronium.

Rasburicase

Recombinant human tissue-type plasminogen activator (rt-PA).

Resorantel, except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Riluzole.

Rimiterol, when intended for injection. (S2, S3)

Ritodrine.

Ritonavir.

Rituximab.

Rizatriptan.

Rocuronium bromide.

Ropinirole.

Rosoxacin.

Rosuvastatin.

Roxatidine.

Salbutamol, when intended for injection. (S2, S3)

Salmefamol, when intended for injection. (S2, S3)

Saquinavir.

Selegiline.

Selenium salts, preparations thereof for injection, when intended for veterinary use.

Sermorelin.

Sertaconazole, except when intended for application to the skin (S1)

Sertindole.

Sildenafil.

Simvastatin.

Sirolimus.

Sodium aurothiomalate.

Sodium cromoglycate, when intended for veterinary use. (S2)

Sodium dihydroazapentacene polysulphonate.

Sodium fluoride; except oral medicinal preparations and mixtures thereof containing 40 milligrams or more per daily dose. (S1)

Sodium nitroprusside.

Solcoseryl, except preparations intended for application to the skin, to the mucous membranes of the mouth and to the lips and except ophthalmic preparations thereof. (S0, S3).

Stavudine.

Streptokinase

Strychnine, subject thereto that for the control of problem predatory mammals -

(a) it shall only be supplied on a written prescription issued by a State Veterinarian, for use in the particular State Veterinarians' area of jurisdiction, in a quantity not exceeding 5 grams; and

(b) the State Veterinarian shall obtain prior written approval for such use from the Director of the concerned provincial conservation institution or authority in his area of jurisdiction, a copy of which shall be attached to the written prescription; and except preparations and mixtures containing 0,2 per cent or less of strychnine when included in Schedule 2.

Styramate.

Sulphonamides, except -

(a) substances, preparations and mixtures intended for application to the eyes, nares and vagina; (S2)

(b) silver sulphadiazine, when intended for application to the skin in the short term treatment of minor burns, provided that the pack size is limited to a maximum of 50 grams; (S2)

(c) when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Sumatriptan.

Suramin.

Suxamethonium.

Suxethonium.

Tacrine.

Tacrolimus.

Tadalafil.

Tamoxifen.

Tamsulosin.

Tasonermin.

Tegafur.

Tegaserod.

Temozolomide.

Tenecteplase.

Teniposide.

Terbinafine, except when intended for application to the skin. (S1)

Terconazole.

Terfenadine.

Teriparatide.

Tetramisole, except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Theophylline and its derivatives, unless listed in another Schedule; preparations intended for injection. (S2)

Thiabendazole, except when intended for application to the skin (S1) and except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Thioguanine.

Thymopentin.

Tibolone.

Tiludronic Acid.

Tin fluoride, when intended for injection

Tinidazole.

Tioconazole, except when intended for application to the skin and when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis. (S1)

Tirilazad.

Tocainide.

Tolcapone.

Tolrestat.

Toltrazuril, except when intended and registered as an anti-coccidial preparation in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Topotecan.

Toremifene.

Tranexamic acid.

Trastuzumab.

Travoprost.

Treosulfan.

Triclabendazole, except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Triethylene thiophosphoramide.

Trifluorothymidine.

Trimetaphane.

Trimethoprim, except when specifically intended and registered for the treatment of gastro-enteritis and pneumonia in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Trimetrexate.

Trioxsalen.

Triptorelin.

Tromantadine.

Trometamol.

Tropisetron.

Tuberculin, when intended for veterinary use. (S2)

Tubocurarine.

Unoprostone.

Urapidil.

Urethane.

Urokinase.

Vaccines for veterinary use except vaccines registered in terms of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Valaciclovir.

Vanillic acid diethylamide.

Vardenafil.

Vasoactive intestinal polypeptide.

Vecuronium bromide.

Verteporfin.

Vidarabine.

Vinblastin.

Vincristin.

Vindesine.

Vinorelbine.

Voriconazole.

Vorozole.

Zalcitabine.

Zanamivir.

Zidovudine (AZT).

Zolmitriptan.

Zoledronic acid.

- END SCHEDULE 4 -

Schedule 5 and specified Schedule 5

(a) All substances referred to in this Schedule include the following:

(i) The salts and esters of such substances, where the existence of such salts and esters is possible; and

(ii) All preparations and mixtures of such substances where such preparations and mixtures are not expressly excluded.

(b) In terms of Section 22A(5)(f) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, may prescribe and supply to patients under their care, the Schedule 5 substances and medicines provided for in the Annexures, only within their scope of practice and subject to the conditions determined by the Medicines Control Council. The conditions and the Annexures will be published in the Government Gazette.

(c) Specified Schedule 5 substances listed in this schedule are subject to additional control in terms of section 22A of the Act as required under the provisions of the 1971 Convention on Psychotropic Substances and are denoted by "**".

Acitretin.

Amisulpride.

Amitryptyline and its derivatives, unless listed in another Schedule.

Amoxapine.

Anaesthetic preparations containing pregnanedione derivatives.

Androstanolone.

Androstenediol.

Aponal.

Apronalide.

Azacyclonol.

Barbituric acid** and its derivatives**, unless listed in another Schedule, excluding-

(a) amobarbital, cyclobarbital, pentobarbital and secobarbital (S6), and

(b) preparations and mixtures containing not more than 90 milligrams of phenobarbital** per minimum recommended or prescribed dose when intended for continued use in epilepsy. (S3)

Benactyzine and its derivatives, unless listed in another Schedule.

Benfluramate.

Benzoctamine.

Benzodiazepines** and their derivatives**, unless listed in another Schedule and except flunitrazepam. (S6)

Benzquinamide.

Beta-aminopropylbenzene and beta-aminoisopropylbenzene, any compound structurally derived from either of these substances by substitution in the side chain or by ring closure therein (or by both such substitution and such ring closure) and any salt or substance falling under the above, except preparations and mixtures of the above when used as vasoconstrictors and decongestants in antihistamine nose and eye preparations and except when contained in appliances for inhalation in which the substance is absorbed in solid material and excluding cathine ((+)-norpseudoephedrine), ephedrine, etafedrine, N-methylephedrine, N-diethylaminoethylephedrine, phenylpropanolamine, prenylamine and preparations and mixtures thereof except substances listed in Schedule 7. (S1, S2, S7)

Bolandiol.

Bolasterone.

Boldenone.

Bromides; preparations and mixtures thereof containing 80 milligrams or more of bromine as bromide per recommended daily dose, except when specifically packaged, labelled and used for industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose, which are intended to be ingested by man or animals as food or applied to the body as a cosmetic and which are approved for such use in terms of the Foodstuffs, Cosmetic and Disinfectants Act, 1972 and for anaytical laboratory purposes. (S2)

Bromisovalum.

Brotizolam**.

Bupropion.

Buspirone.

Butriptyline.

Butyrophenones.

Carbromal.

Chloral derivatives, unless listed in another Schedule.

Chlormezanone, except mixtures thereof where the maximum recommended or prescribed dose does not exceed 100 milligrams of chlormezanone. (S2)

Chlorprothixene.

Citalopram.

Clomacran.

Clomethiazole (previously listed as "heminevrin").

Clomipramine.

Clopenthixol.

Clostebol.

Clothiapine.

Clozapine.

Corticotrophin (adrenocorticotrophic hormone; ACTH).

Cyclobenzaprine.

Danazol.

Deanol and its derivatives, unless listed in another Schedule, except when specifically packaged, labelled and used for industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose, which are intended to be ingested by man or animals as food or applied to the body as a cosmetic and which are approved for such use in terms of the Foodstuffs, Cosmetic and Disinfectants Act, 1972, and for analytical laboratory purposes. (S1)

Dehydrochloromethyltestosterone

Desflurane.

Detomidine

Dexfenfluramine.

Dexmedetomidine.

Dextropropoxyphene; preparations and mixtures for oral use containing not more than 135 milligrams of dextropropoxyphene, calculated as the base, per dosage unit or with a concentration of not more than 2,5 percent in undivided preparations. (S6)

Diprenorphine.

Donepezil.

Dothiepin.

Doxepin, except when intended for application to the skin. (S4)

Droperidol.

Drostanolone.

Ecothiopate.

Emylcamate.

Enflurane.

Ephedrine (natural or synthetic), except when contained in products registered in terms of the Act. (S1, S2)

Epitiostanol.

Escitalopram.

Ethchlorvynol**.

Ether (diethyl ether); except substances, preparations and mixtures containing more than 20 per cent of ether. (S1)

Ethinamate** and its derivatives**, unless listed in another Schedule.

Ethylestrenol.

Etodroxizine, except preparations and mixtures thereof when used solely as an antihistamine. (S2)

Etomidate.

Etretinate.

Fencamfamine**.

Fenfluramine.

Flumazenil.

Fluoxetine.

Fluoxymesterone.

Flupenthixol.

Fluspirilene.

Fluvoxamine.

Formebolone.

Furazabol.

Haloperidol.

Halothane.

Hedonal and its esters, except when specifically packaged, labelled and used for industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose, which are intended to be ingested by man or animals as food or applied to the body as a cosmetic and which are approved for such use in terms of the Foodstuffs, Cosmetic and Disinfectants Act, 1972, and for anaytical laboratory purposes.

Human growth hormone (human somatotropin) -all forms.

Hydroxyzine.

Imipramine and its derivatives, unless listed in another Schedule.

Iproniazid.

Isoflurane.

Isotretinion.

Ketamine.

Lithium salts, when intended for medicinal use, except when intended for application to the skin. (S2)

Lofepramine.

Loxapine.

Maprotiline.

Mazindol**.

Mebolazine

Mechlorethamine and its derivatives, unless listed in another Schedule.

Meclofenoxate.

Medetomidine.

Melitracene.

Mephenoxalone.

Meprobamate**.

Mesterolone

Metandienone

Metenolone.

Methandranone.

Methandriol.

Methoxyflurane.

Methyltestosterone.

Metrifonate.

Mianserin.

Mibolerone.

Milnacipran.

Mirtazapine.

Moclobemide.

Molindone.

Nalbuphine.

Nandrolone.

Nefazodone.

Nomifensine.

Norclostebol.

Norethandronlone.

Olanzapine.

Oxabolone.

Oxandrolone.

Oxymesterone.

Oxymetholone.

Oxypertine.

Paraldehyde.

Pargyline.

Paroxetine.

Pemoline** and its complexes**.

Phenethylhydrazine.

Phenothiazine and its derivatives, unless listed in another Schedule, except preparations and mixtures containing promethazine or dimethothiazine or their salts when used solely as an antihistaminic (S2), and except preparations containing promethazine or its salts when intended specifically for the treatment of travel sickness or application to the skin, (S2), and except phenothiazine when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Phentermine**.

Pimethixene, except preparations and mixtures thereof when used solely as an antihistaminic. (S2)

Pimozide.

Pipradrol**.

Pizotifen, except preparations and mixtures thereof when used solely as an antihistaminic or when intended for the prophylaxis of migraine. (S2)

Prasterone (Dehydroepiandrosterone, DHEA).Prolintane.

Propofol.

Quetiapine.

Quinbolone.

Quinupramine.

Reboxetine.

Risperidone.

Rivastigmine.

Romifidine.

Sertraline.

Sevoflurane.

Sibutramine.

Stanozolol.

Stenbolone.

Sulphonmethane.

Sulpyride.

Testolactone.

Testosterone, except subcutaneous implants thereof when specifically intended and registered as a veterinary production improver in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Thioguanosine.

Thiothixene.

Tiapride.

Tiletamine.

Tizanidine.

Tramadol.

Tranylcypromine.

Trazodone.

Trenbolone, except subcutaneous implants thereof when specifically intended and registered as a veterinary production improver in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Trihexyphenidyl.

L-tryptophan, when intended for medicinal use, except when intended for medicinal use as supplementation for nutritional purposes. (S1)

Venlafaxine.

Viloxazine.

Xylazine.

Zaleplon.

Zimelidine.

Ziprasidone.

Zolazepam.

Zolpidem**.

Zopiclone.

Zotepine.

Zuclopenthixol.

- END SCHEDULE 5 -

Schedule 6

(a) All substances referred to in this Schedule include the following (unless expressly excluded or unless listed in another Schedule):

(i) the isomers of such substances, where the existence of such isomers is possible within the chemical designation;

(ii) the esters and ethers of such substances and of the isomers referred to in (i), as well as the isomers of such esters and ethers, where the existence of such esters, ethers and isomers is possible;

(iii) the salts of such substances and of the isomers referred to in (i), as well as the salts of the esters, ethers and isomers referred to in (ii), where the existence of such salts is possible;

(iv) the isomers of any of the salts referred to in (iii), where the existence of such isomers is possible;

(v) all preparations and mixtures of any of the above.

(b) In terms of Section 22A(5)(f) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, may prescribe and supply to patients under their care, the Schedule 6 substances and medicines provided for in the Annexures, only within their scope of practice and subject to the conditions determined by the Medicines Control Council. The conditions and the Annexures will be published in the *Gazette*.

Acetorphine.

Acetyldihydrocodeine, except preparations and mixtures when compounded with one or more therapeutically active substances and containing 20 milligrams or less of acetyldihydrocodeine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of acetyldihydrocodeine (calculated as base) per 5 millilitre dosage unit. (S2)

Acetylmethadol.

Alfentanil.

Allylprodine.

Alphacetylmethadol.

Alphameprodine.

Alphamethadol.

Alphaprodine.

Amobarbital.

Anileridine.

Benzethidine.

Benzphetamine.

Benzylmorphine.

Betacetylmethadol.

Betameprodine.

Betamethadol.

Betaprodine.

Bezitramide.

Buprenorphine.

Butalbital.

Butorphanol

Cathine ((+)-norpseudoephedrine), except preparations and mixtures containing 50 milligrams or less of cathine per dosage unit. (S2)

Chlorodyne (Chloroform and Morphine Tincture BP 1980) or any preparation or mixture thereof described as chlorodyne; except preparations and mixtures containing 5,0 percent or less of chlorodyne in combination with other active medicinal substances. (S2)

Chlorphentermine.

Clonitazene.

Coca leaf and any salt, compound, derivative or preparation of coca leaf and any salt, compound, derivative or preparation thereof that is chemically equivalent or identical to any of these substances, whether obtained directly or indirectly by extraction from material or substances obtained from plants, or obtained independently by chemical synthesis, or by a combination of extraction and chemical synthesis, except

decocainized coca leaf and extractions of coca leaf where such extractions contain no cocaine or ecgonine.

Codeine (methylmorphine); except preparations and mixtures when compounded with one or more therapeutically active substances and containing 20 milligrams or less of codeine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of codeine (calculated as base) per 5 millilitre dosage unit. (S2)

Codoxime.

Cyclobarbital.

Desomorphine.

Dextromoramide.

Dextropropoxyphene, except preparations and mixtures for oral use containing 135 milligrams or less of dextropropoxyphene, calculated as the base, per dosage unit or with a concentration of not more than 2,5 percent in undivided preparations. (S5)

Diampromide.

Diethylpropion (amfepramone).

Diethylthiambutene.

Difenoxin (or diphenoxylic acid), except mixtures containing, per dosage unit, 0,5 milligrams or less of difenoxin, calculated as the base, and a quantity of atropine sulphate equal to at least 5,0 per cent of such quantity of difenoxin, calculated as the base, as is present in the mixture. (S2)

Dihydrocodeine, except preparations and mixtures when compounded with one or more therapeutically active substances and containing 20 milligrams or less of dihydrocodeine (calculated as base) per dosage unit and except liquid oral preparations and mixtures containing 20 milligrams or less of dihydrocodeine (calculated as base) per 5 millilitre dosage unit. (S2)

Dihydroetorphine.

Dihydromorphine.

Dimenoxadol.

Dimepheptanol.

Dimethylthiambutene.

Dioxaphethyl butyrate.

Diphenoxylate, except preparations containing not more than 2,5 milligrams of diphenoxylate, calculated as the base, and not less than 25 micrograms of atropine sulphate per dosage unit.(S1)

Dipipanone.

Dronabinol [(-)-transdelta-9-tetrahydrocannabinol], when intended for therapeutic purposes. (S7)

Drotebanol.

Ecgonine, and the esters and derivatives thereof that are convertible to ecgonine and cocaine.

Ethylmethylthiambutene.

Ethylmorphine; except preparations and mixtures when compounded with one or more therapeutically active substances and containing 20 milligrams or less of ethylmorphine (calculated as base) per dosage unit and liquid,oral preparations and mixtures containing 20 milligrams or less of ethylmorphine (calculated as base) per 5 millilitre dosage unit. (S2)

Etonitazene.

Etorphine and analogues.

Etoxeridine.

Fenproporex.

Fentanyl, when intended for therapeutic purposes. (S7)

Flunirazepam.

Furethidine.

Glutethimide.

Hydrocodone (dihydrocodeinone).

Hydromorphinol (14-hydroxydihydromorphine).

Hydromorphone (dihydromorphinone).

Hydroxypethidine.

Isomethadone.

Ketobemidone.

Levomoramide.

Levophenacylmorphan.

Levorphanol.

Mecloqualone.

Mefenorex.

Meptazinol.

Metazocine.

Methadone.

Methadone-intermediate.

Methorphan, including levomethorphan and racemethorphan, but excluding dextromethorphan. (S2)

Methyldesorphine.

Methyldihydromorphine.

Methylphenidate and its derivatives, unless listed in another Schedule.

Metopon.

Moramide-intermediate.

Morpheridine.

Morphine, except preparations and mixtures of morphine containing 0,2 percent or less of morphine, calculated as anhydrous morphine. (S2)

Morphine methobromide and other pentavalent nitrogen morphine derivatives.

Morphine-N-oxide and its derivatives.

Myrophine (myristylbenzylmorphine).

Nicocodine.

Nicodicodine.

Nicomorphine.

Noracymethadol.

Norcodeine; except preparations and mixtures when compounded with one or more therapeutically active substances and containing 20 milligrams or less of norcodeine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of norcodeine (calculated as base) per 5 millilitre dosage unit. (S2)

Norlevorphanol.

Normethadone.

Normorphine (demethylmorphine or N-demethylated morphine).

Norpipanone.

Opium and opiates and any salt, compound, derivative or preparation of opium or opiates, whether obtained directly or indirectly by extraction from material or substances obtained from plants, or obtained independently by chemical synthesis,

or by a combination of extraction and chemical synthesis, except mixtures containing 0,2 per cent or less of morphine, calculated as anhydrous morphine.(S2)

Opium-poppy and poppy straw, whether obtained directly or indirectly by extraction from material or substances obtained from plants, or whether obtained independently by chemical synthesis, or by a combination of extraction and chemical synthesis.

Oxycodone (14-hydroxydihydrocodeinone or dihydrohydroxycodeinone).

Oxymorphone (14-hydroxydihydromorphinone or dihydrohydroxymorphinone).

Pentazocine.

Pentobarbital.

Pethidine, pethidine-intermediate A, pethidine-intermediate B and pethidine-intermediate C. (S8)

Phenadoxone.

Phenampromide.

Phenazocine.

Phendimetrazine.

Phenomorphan.

Phenoperidine.

Pholcodeine, except preparations and mixtures when compounded with one or more therapeutically active substances and containing 20 milligrams or less of pholcodeine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of pholcodeine (calculated as base) per 5 millilitre dosage unit. (S2)

Piminodine.

Piritramide.

Proheptazine.

Properidine.

Propiram.

Racemoramide.

Racemorphan.

Remifentanil.

Secobarbital.

Sufentanil.

Thebacon.

Thebaine.

Tilidine.

{(-)-transdelta-9-tetrahydrocannabinol - see dronabinol}

Trimeperidine.

Zipeprol.

- END SCHEDULE 6 -

Schedule 7

All substances referred to in this Schedule include the following (unless expressly excluded or unless listed in another Schedule):

(a) The isomers of such substances, where the existence of such isomers is possible within the chemical designation;

(b) The esters and ethers of such substances and of the isomers referred to in (a), as well as the isomers of such esters and ethers, where the existence of such esters, ethers and isomers is possible;

(c) The salts of such substances and of the isomers referred to in (a), as well as the salts of the esters, ethers and isomers referred to in (b), where the existence of such salts is possible;

(d) The isomers of any of the salts referred to in (c), where the existence of such isomers is possible;

(e) All preparations and mixtures of any of the above.

(Trivial or unofficial names are marked *)

Aminorex.

Amphetamine. (S8)

Brolamfetamine ((±)-4-bromo-2,5-dimethoxy-α-methylphenethylamine)*(DOB).

4-bromo-2,5-dimethoxyphenethylamine (2C-B) *(Nexus).

Bufotenine (N,N-dimethylserotonin).

Cannabis (dagga), the whole plant or any portion or product thereof, except:

(a) when separately specified in the Schedules; (S6) or

(b) processed hemp fibre containing 0.1 per cent or less of tetrahydrocannabinol and products manufactured from such fibre, provided that the product does not contain whole cannabis seeds and is in a form not suitable for ingestion, smoking or inhaling purposes; or

(c) processed product made from cannabis seeds containing not more than 10mg/kg (0.001 per cent) of tetrahydrocannabinol and does not contain whole cannabis seeds.

["Processed" means treated by mechanical, chemical or other artificial means but does not include- (a) harvesting; or (b) the natural process of decay"]

Cathinone ((-)-(S)-2-aminopropiophenone).

Dexamphetamine. (S8)

Diethyltryptamine [3-(2-(diethylamino) ethyl) indole] *(DET).

(+)-2,5-dimethoxy-α-methylphenethylamine *(DMA).

2,5-dimethoxy-α-4-dimethylphenethylamine *(DOM, STP) and its derivatives.

3-(1,2-dimethylheptyl)-7,8,9,10-tetrahydro-6,6,9-trimethyl-6H-dibenzo[b,d]pyran-1-ol *(DMHP).

(+)-N,α-dimethyl-3, 4-(methylenedioxy)phenethylamine * (MDMA).

Dimethyltryptamine [3-(2-(dimethylamino) ethyl) indole] *(DMT).

(+)-4-ethyl-2,5-dimethoxy-α-phenethylamine *(DOET).

Dronabinol [(-)-transdelta-9-tetrahydrocannabinol] (S6)

Etilamfetamine (N-ethylamphetamine).

Etryptamine.

Fenetylline.

Fentanyl-analogues (unless listed in another Schedule) including:

- acetyl-alpha-methylfentanyl;
- alpha-methylfentanyl;
- alpha-methylfentanyl-acetanilide;
- alpha-methylthiofentanyl;
- benzyl-fentanyl;
- beta-hydroxyfentanyl;
- beta-hydroxy-3-methylfentanyl;
- 3-methylfentanyl and its two isomeric forms:
  - cis-N-(3-methyl-1-(2-phenethyl)-4-piperidyl) propionanilide; and
  - trans-N-(3-methyl-1-(2-phenethyl)-4-piperidyl) propionanilide;
- 3-methylthiofentanyl;
- para-fluorofentanyl; and
- thiofentanyl. (S6)

Gamma-hydroxybutyrate (GHB).

Harmaline (3,4-dihydroharmine).

Harmine [7-methoxy-1-methyl-9H-pyrido (3,4-b)-indole].

Heroin (diacetylmorphine).

3-hexyl-7,8,9,10-tetrahydro-6,6,0-trimethyl-6H-dibenzo [b,d]-pyran-1-o1* (parahexyl).

Lefetamine *(SPA).

Lysergide (Lysergic acid diethylamide)*(LSD).

Mescaline (3,4,5-trimethoxyphenethylamine).

Mesocarb.

Methamphetamine and methamphetamine racemate.

Methaqualone and any preparation containing methaqualone.

Methcathinone.

2-methoxy-α-methyl-4,5-(methylenedioxy)phenethylamine *(MMDA).

p-methoxy-α-methylphenethylamine *(PMA).

4 methylaminorex.

{(Methylenedioxyamphetamine *(MDA) and its analogues - see tenamphetamine}

Methyprylon.

Nabilone.(S8)

Pethidine-analogues, including:

1-methyl-4-phenyl-4-propionoxy-piperidine *(MPPP);

1-methyl-4 phenyl-1,2,5,6-tetrahydropiperidine *(MPTP); and

1-phenylethyl-4-phenyl-4-acetyloxy-piperidine *(PEPAP).

Phencyclidine *(PCP) and its congeners, including :

eticyclidine (N-ethyl-1-phenylcyclohexylamine *(PCE));

rolycyclidine (1-(1-phenylcyclohexyl) pyrrolidine *(PHP or PCPY)); and

tenocyclidine (1-[1-(2-thienyl) cyclohexyl] piperidine *(TCP).

Phenmetrazine.

Psilocin (4-hydroxy-NN-dimethyltryptamine).

Psilocybine (4-phosphoryloxy-NN-dimethyltryptamine).

Pyrovalerone (4'-methyl-2-(1-pyrrolidinyl) valerophenone).

Tenamfetamine (methylenedioxyamphetamine *(MDA)) and its analogues:

(±)-N-ethyl-α-methyl-3,4-(methylenedioxy) phenethylamine *(N-ethyl MDA):

(±)-N-[α-methyl-3,4-(methylenedioxy) phenethyl] hydroxylamine *(N-hydroxy MDA).

Tetrahydrocannabinol and their alkyl homologues, except:

(a) when separately specified in the Schedules;

(b) dronabinol ((-)-transdelta-9-tetrahydrocannabinol), when intended for therapeutic purposes. (S6);

(c) in hemp seed oil, containing 10mg/kg or less of tetrahydrocannabinols, when labelled "Not to be taken"*(Not for internal human use - alternatively)*; or

(d) in products for purposes other than internal human use containing 10mg/kg or less of tetrahydrocannabinols.

["Hemp seed oil" means the oil obtained by cold expression from the ripened fruits (seeds) of *Cannabis sativa*.]

(±)-3, 4, 5-trimethoxy-α-methylphenethylamine *(TMA).

- END SCHEDULE 7 -

Schedule 8

All substances referred to in this Schedule include the following (unless expressly excluded or unless listed in another Schedule):

(a) the isomers of such substances, where the existence of such isomers is possible within the chemical designation;

(b) the esters and ethers of such substances and of the isomers referred to in (a), as well as the isomers of such esters and ethers, where the existence of such esters, ethers and isomers is possible;

(c) the salts of such substances and of the isomers referred to in (a), as well as the salts of the esters, ethers and isomers referred to in (b), where the existence of such salts is possible;

(d) the isomers of any of the salts referred to in (c), where the existence of such isomers is possible;

(e) all preparations and mixtures of any of the above.

Amphetamine and its salts; preparations thereof. (S7)
Dexamphetamine and it salts; preparations thereof. (S7)
Nabilone. (S7)

- END SCHEDULE 8 -

These Schedules come into operation on 2 May 2003.

MTshabalala

ME TSHABALALA-MSIMANG

MINISTER OF HEALTH

No. R. 509 **10 April 2003**

WET OP MEDISYNE EN VERWANTE STOWWE, 1965 (WET NO. 101 VAN 1965)

BYLAES

Die Minister van Gesondheid het kragtens artikel 22A(2) van die Wet op Medsiyne en Verwante Stowwe, 1965 (Wet No. 101 van 1965), op aanbeveling van die Medisynebeheerraad, die Bylaes in die Bylae voorgeskryf.

BYLAE

In hierdie Bylaes beteken "die Wet" die Wet op Medisyne en Verwante Stowwe, 1965 (Wet No. 101 van 1965).

BYLAES

BYLAE 0

(a) Alle stowwe bedoel in hierdie Bylae word uitgesluit wanneer spesifiek verpak, geëtiketteer en gebruik vir –

(i) nywerheidsdoeleindes, met inbegrip van die vervaardiging of opmaak van verbruikersitems of -produkte wat geen farmakologiese werking of gebruik as geneesmiddel het nie, wat bedoel is om deur die mens of diere as voedsel ingeneem te word of as kosmetiese middel aan die liggaam aangewend te word, en wat vir sodanige gebruik kragtens die Wet op Voedingsmiddels, Skoonheidsmiddels en Ontsmettingsmiddels, 1972 (Wet No. 54 van 1972), goedgekeur is of kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947 (Wet No. 36 van 1947), geregistreer is; en

(ii) analitiese laboratoriumdoeleindes.

(b) Alle stowwe bedoel in hierdie Bylae sluit die volgende in:

(i) Die soute en esters van sodanige stowwe, indien die bestaan van sodanige soute en esters moontlik is; en

(ii) alle preparate en mengsels van sodanige stowwe, waar sodanige preparate en mengsels nie uitdruklik uitgesluit word nie.

Hierdie Bylae sluit alle stowwe in wat aan registrasie ingevolge die Wet onderworpe is en nie in enige van die ander Bylaes gelys word nie.

BYLAE 1

(a) Alle stowwe bedoel in hierdie Bylae word uitgesluit wanneer spesifiek verpak, geëtiketteer en gebruik vir –

(i) nywerheidsdoeleindes, met inbegrip van die vervaardiging of opmaak van verbruikersitems of -produkte wat geen farmakologiese werking of gebruik as geneesmiddel het nie,
(ii) en analitiese laboratoriumdoeleindes.

(b) Alle stowwe bedoel in hierdie Bylae sluit die volgende in:

(i) Die soute en esters van sodanige stowwe, indien die bestaan van sodanige soute en esters moontlik is; en
(ii) alle preparate en mengsels van sodanige stowwe, waar sodanige preparate en mengsels nie uitdruklik uitgesluit word nie.

(c) Ingevolge artikel 22A(4)(a)(v) van die Wet mag 'n praktisyn, verpleegkundige of 'n persoon wat kragtens die Wet op Gesondheidsberoepe, 1974 (Wet No. 56 van 1974), geregistreer is, uitgesonderd 'n geneesheer of tandarts, die Bylae 1-stowwe en -medisyne waarvoor in die Aanhangsels voorsiening gemaak word, voorskryf en aan pasiënte onder sy of haar sorg verskaf slegs binne die bestek van sy of haar praktyk en behoudens die voorwaardes bepaal deur die Medisynebeheerraad. Die voorwaardes en Aanhangsels sal in die *Staatskoerant* gepubliseer word.

Anetooltritioon
Antimalariamiddels; chlorokien in samestelling met proguaniel, wanneer spesifiek bedoel vir die voorkoming van malaria. (B4)
Antimikorbiese stowwe, naamlik basitasien, gramisidien, polimiksien B en tirotrisien, wanneer bedoel vir aanwending aan die vel, neusholtes en buite-oor, soos uitgesluit van die voorwaardes in Bylae 4. (B2, B4)
Antimoonkaliumtartraat en antimoonnatriumtartraat; stowwe, preparate en mengsels wat 1,0 persent of meer daarvan bevat.
Antistolmiddels, wanneer bedoel vir aanwending aan die vel. (B4)
Arseen; stowwe, preparate en mengsels wat die ekwivalent van minder as 0,01 persent arseentrioksied bevat. (B2)
Aselaïensuur.
Asetanilied en alkielasetaniliede.
Asetarsol, wanneer bedoel vir menslike vaginale gebruik.
Asiklovir, wanneer bedoel vir aanwending aan die lippe tydens vroeë behandeling van herhalende Herpes-simpleksvirusinfeksies. (B4)
Belladonna-alkaloïede, wanneer spesifiek bedoel vir plaaslike aanwending. (B2)
Bensetoniumchloried, wanneer bedoel vir menslike vaginale gebruik.
Bensidamien; preparate en mengsels –

(a) wat 3 persent of minder besidamien bevat, wanneer bedoel vir aanwending aan die vel;
(b) wat hoogsten 0,15 persent besidamien bevat, wanneer bedoel vir gebruik as 'n mondspoelmiddel of vir plaaslike aanwending in die

mond of keel: Met dien verstande dat die totale dosis nie 36 mg besidamien per dag oorskry nie.

Beta-aminopropielbenseen en beta-aminoïsopropielbenseen, soos uitgesluit van die voorwaardes van Bylae 5. (B5)

Bifonasool, wanneer bedoel vir aanwending aan die vel.

Bioalletrien.

Bitolterol.

Bufeksamak, wanneer bedoel vir aanwending aan die vel.

Bunamidien.

Chloorheksidien, wanneer bedoel vir menslike vaginale gebruik.

Chloroform; preparate en mengsels wat minder as 20 persent chloroform bevat. (B5)

Dialisaatpreparate.

Diklofenak, wanneer bedoel vir aanwending aan die vel. (B2, B3)

Diosmien.

Ditiasanien.

Efedra-alkaloïede (natuurlik of sinteties), uitgesonderd efedrienpreparate en -mengsels wat bedoel is vir aanwending aan die vel, oë, ore en neusholtes en wat hoogstens 1,0 persent efedra-alkaloïede bevat, en ander preparate en mengsels wat hoogstens 30 milligram efedrien of efedra-alkaloïede per dosis bevat. (B2, B5)

Efedrien bevat in produkte geregistreer kragtens die Wet, preparate en mengsels bedoel vir aanwending aan die vel, oë, ore en neusholtes en wat hoogstens 1,0 persent efedrien bevat, en ander mondelike preparate en mengsels wat hoogstens 30 milligram efedrien per dosis bevat. (B2, B5)

Ekonasool, wanneer bedoel vir aanwending aan die vel en vir menslike vaginale gebruik, spesifiek vir die behandeling van herhalende vaginale kandidiase. (B4)

Enilkonasool, wanneer bedoel vir aanwending aan die vel. (B4)

Eskien; medisinale preparate en mengsels daarvan wat bedoel is vir aanwending aan die vel en wat hoogstens 1,0 persent eskien bevat. (B3)

Eter (diëtieleter); alle stowwe, preparate en mengsels wat minder as 20 persent eter bevat. (B5)

Etielfenielefrien.

Etofenamaat, wanneer bedoel vir aanwending aan die vel.

Felbinak, wanneer bedoel vir aanwending aan die vel.

Fenbendasool, uitgesonderd wanneer dit geregisteer is kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.

Fenielefrien, uitgesonderd oogpreparate wat hoogstens 0,2 persent fenielefrien bevat.

Fentikonasool, wanneer bedoel vir aanwending aan die vel.

Flubendasool, uitgesonderd wanneer bedoel en geregistreer as 'n wurmmiddel kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.

Flufenaamsuur, wanneer bedoel vir aanwending aan die vel.

Fluoriede; mondelike medisinale preparate en mengsels daarvan wat minstens 0,25 milligram fluoor as fluoried per aanbevole daaglikse dosis bevat, tensy in 'n ander Bylae gelys. (B4)

Flurbiprofeen, wanneer bedoel vir aanwending aan die vel, insluitende aanwending deur middel van 'n transdermale plakker, onderworpe daaraan dat in die geval van aanwending deur middel van 'n transdermale plakker indikasie beperk

word tot gebruik deur volwassenes en kinders van 12 jaar en ouer en die behandelingstydperk nie 4 weke oorskry nie. (B2, B3, B4)

Fosfolipiede, wanneer dit vir terapeutiese doeleindes aangewend word.

Gammabenseenheksachloried; medisinale preparate en mengsels vir menslike gebruik, wanneer bedoel vir aanwending aan die vel.

Glikosaminoglikaanpolisulfaat (voorheen mukopolisakkariedpoliswaelsuurester), wanneer bedoel vir aanwending aan die vel. (B4)

Ibuprofeen, wanneer bevat in preparate bedoel vir aanwending aan die vel. (B2, B3)

Idanasolien.

Idoksudirien, wanneer bedoel vir aanwending aan die vel. (B4)

Indometasien, wanneer bedoel vir aanwending aan die vel. (B2, B3)

Inspuitings, tensy in 'n ander Bylae gelys, behalwe wanneer geregistreer kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.

Irrigasievloeistowwe.

Isokonasool, wanneer bedoel vir aanwending aan die vel en vir menslike vaginale gebruik, spesifiek vir die behandeling van herhalende vaginale kandidiase. (B4)

Kalsiumsoute; preparate daarvan, wanneer bedoel vir inspuiting, uitgesonderd wanneer dit ingevolge die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947, geregistreer is.

Ketokonasool, wanneer bedoel vir aanwending aan die vel, uitgesonderd preparate en mengsels wat hoogstens 1,0 persent ketokonasool bevat en bedoel is vir die voorkoming en behandeling van skilfers. (B0, B4)

Ketoprofeen, wanneer bedoel vir aanwending aan die vel. (B2, B3)

Klotrimasool, wanneer bedoel vir aanwending aan die vel en vir menslike vaginale gebruik, spesifiek vir die behandeling van herhalende vaginale kandidiase. (B4)

Lactobacillus acidophilus en *L. bifidus*, wanneer bedoel vir terapeutiese doeleindes, uitgesonderd wanneer geregistreer kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.

Lisosiem, wanneer bedoel vir aanwending aan die vel. (B4)

L-triptofaan, wanneer bedoel vir medisinale gebruik as aanvulling vir voedingkundige doeleindes. (B5)

Luksabendasool, uitgesonderd wanneer bedoel en geregistreer as 'n wurmmiddel kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.

Malation, uitgesonderd wanneer bedoel en geregistreer as 'n eksoparasietdoder kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.

Mangaansoute, preparate daarvan vir inspuiting wanneer bedoel vir veterinêre gebruik.

Mebendasool, uitgesonderd wanneer bedoel en geregistreer as 'n wurmmiddel kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.

Metenamien (heksamien), uitgesonderd wanneer bedoel vir aanwending aan die vel, en uitgesonderd wanneer bedoel en geregistreer as 'n urinêre antiseptikum kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.

Metionien, wanneer bedoel as geneesmiddel.

Mikonasool, wanneer bedoel vir aanwending aan die vel en vir menslike vaginale gebruik, spesifiek vir die behandeling van herhalende vaginale kandidiase. (B2, B4)

Mikrofibillêre kollageenhidrochloried.

Morantelsitraat, uitgesonderd wanneer bedoel en geregistreer as 'n wurmmiddel kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.

Nafasolien, wanneer bedoel vir gebruik in die neus.

Naprokseen, wanneer bedoel vir aanwending aan die vel. (B2, B3)

N-asetielaspartielglutamiensuur.

Natriumfluoried; preparate en mengsels daarvan wat minstens 40 milligram per daaglikse dosis bevat. (B4)

Nikotien; wanneer gebruik as transdermale nikotienplakkers vir deurlopende aanwending aan die vel in sterktes tot en met 15 mg/16 uur, slegs wanneer hierdie medisyne gebruik word vir die verligting van nikotienonttrekkingsimptome as hulpmiddel by staking van die rookgewoonte (B2), uitgesonderd nikotienkougom wat hoogstens 4 mg nikotien per stukkie bevat en die pakketgrootte nie 30 stukkies per pakket te bowe gaan nie, slegs wanneer hierdie medisyne gebruik word vir die verligting van nikotienonttrekkingsimptome as hulpmiddel by staking van die rookgewoonte.

Nistatien, wanneer bedoel vir aanwending aan die vel en vir menslike vaginale gebruik, spesifiek vir die behandeling van herhalende vaginale kandidiase. (B4)

Nitrofurantoïen, wanneer bedoel vir aanwending aan die vel. (B4)

Nitrofurasoon, wanneer bedoel vir aanwending aan die vel. (B4)

O-(β--hidroksiëtiel)rutosiede.

Oksibendasool, uitgesonderd wanneer bedoel en geregistreer as 'n wurmmiddel kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.

Oksimetasolien, wanneer bedoel vir gebruik in die neus.

Ornidasool, wanneer bedoel vir aanwending aan die vel. (B4)

Ortodichloorbenseen, wanneer bedoel vir menslike plaaslike medisinale gebruik.

Paradichloorbenseen, wanneer bedoel vir menslike plaaslike medisinale gebruik.

Parasetamol –

(1) stowwe, preparate en mengsels, uitgesonderd –

(a) wanneer dit voorkom in tablette of kapsules wat elk hoogstens 500 milligram parasemtemol bevat en –

(i) dit in 'n primêre verpakking wat altesaam hoogsten 12,5 gram parasetamol in sodanige tablette of kapsules bevat, verpak is;

(ii) dit in stolpverpakking of in houers met kinderbestande deksels verpak is;

(iii) die primêre verpakking 'n etiket op het waarop onderstaande omraamde waarskuwing prominent op ten minste die hoofpaneel van die onmiddellike houer-etiket en buite-etiket (karton) gedruk is:

BEVAT PARASETAMOL – LEES DIE VOUBILJET;

(b) wanneer dit voorkom in enkelverpakte poeiers of sachets wat elk hoogsten 1 000 milligram parasemtemol bevat en –

(i) dit in 'n primêre verpakking wat altesaam hoogsten 12,5 gram parasetamol in sodanige tablette of kapsules bevat, verpak is;

(ii) die primêre verpakking 'n etiket op het waarop onderstaande omraamde waarskuwing prominent op ten minste die hoofpaneel van die onmiddellike houer-etiket en buite-etiket (karton) gedruk is:
BEVAT PARASETAMOL – LEES DIE VOUBILJET;

(c) wanneer die voorkom in vloeistof- of stroopvorm wat hoogstens 120 milligram parasetamol per 5 milliliter bevat, of in pediatriese doseervorm (druppels) wat hoogstens 120 milligram parasetamol per 1,2 milliliter bevat en –

(i) in die geval van die vloeistof- of stroopvorm wat hoogstens 120 milligram parasetamol per 5 milliliter bevat, dit in 'n primêre verpakking wat hoogstens 100 milliliter bevat, verpak is;

(ii) in die geval van die pediatriese doseervorm (druppels) wat hoogstens 120 milligram parasetamol per 1,2 milliliter bevat, dit in 'n primêre verpakking wat hoogstens 20 milliliter bevat, verpak is;

(iii) die primêre verpakking 'n etiket op het waarop onderstaande omraamde waarskuwing prominent op ten minste die hoofpaneel van die onmiddellike houer-etiket en buite-etiket (karton) gedruk is:
BEVAT PARASETAMOL – LEES DIE VOUBILJET;

(2) wanneer dit voorkom in rektale setpille. (B2)

Pensiklovir, wanneer bedoel vir aanwending aan die lippe tydens vroeë behandeling van herhalende Herpes-simpleksvirusinfeksies. (B4)

Pentosaanpolisulfaatnatrium, uitgesonderd wanneer bedoel vir die behandeling van interstisiële sistitis. (B3)

Pirantelpamoaat, wanneer bedoel vir veterinêre gebruik, uitgesonderd wanneer bedoel en geregistreer as 'n wurmmiddel kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.

Piridoksilaat.

Proguaniel, wanneer gebruik in samestelling met chlorokien, wanneer spesifiek bedoel vir die voorkoming van malaria. (B4)

Prokaïenhidrochloried, wanneer bedoel vir mondelike toediening.

Propentifillien, wanneer bedoel vir veterinêre gebruik. (B4)

Propielheksedrien, wanneer gebruik as 'n bloedvaatvernouer en ontstuwer in neuspreparate en inasemmiddels. (B4)

Proteolitiese (fibrinolitiese) ensieme vir mondelike gebruik en wanneer bedoel vir aanwending aan die vel, tensy in 'n ander Bylae gelys, en uitgesonderd wanneer bedoel vir sagtekontaklens-reinigers en uitgesonderd wanneer bedoel vir inspuiting. (B0, B4)

Sertakonasool, wanneer bedoel vir aanwending aan die vel. (B4)

Sinksoute, preparate daarvan vir inspuiting, wanneer bedoel vir veterinêre gebruik. (B3)

Terbinafien, wanneer bedoel vir aanwending aan die vel. (B4)

Tetrahidrosolien, wanneer bedoel vir gebruik in die neus.

Tiabendasool, wanneer bedoel vir aanwending aan die vel. (B4)

Tiklatoon, wanneer bedoel vir aanwending aan die vel.
Tiokonasool, wanneer bedoel vir aanwending aan die vel en vir menslike vaginale gebruik, spesifiek vir die behandeling van herhalende vaginale kandidiase. (B4)
Tiraam, uitgesonderd wanneer bedoel en geregistreer as 'n swamdoder kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.
Tolmetien, wanneer bedoel vir aanwending aan die vel. (B3)
Xilometasolien, wanneer bedoel vir gebruik in die neus.

– EINDE VAN BYLAE 1 –

BYLAE 2

(a) Alle stowwe bedoel in hierdie Bylae word uitgesluit wanneer spesifiek verpak, geëtiketteer en gebruik vir –

(i) nywerheidsdoeleindes, met inbegrip van die vervaardiging of opmaak van verbruikersitems of -produkte wat geen farmakologiese werking of gebruik as geneesmiddel het nie,
(ii) en analitiese laboratoriumdoeleindes.

(b) Alle stowwe bedoel in hierdie Bylae sluit die volgende in:

(i) Die soute en esters van sodanige stowwe, indien die bestaan van sodanige soute en esters moontlik is; en
(ii) alle preparate en mengsels van sodanige stowwe, waar sodanige preparate en mengsels nie uitdruklik uitgesluit word nie.

(c) Ingevolge artikel 22A(5)(f) van die Wet mag 'n praktisyn, verpleegkundige of 'n persoon wat kragtens die Wet op Gesondheidsberoepe, 1974 (Wet No. 56 van 1974), geregistreer is, uitgesonderd 'n geneesheer of tandarts, die Bylae 2-stowwe en -medisyne waarvoor in die Aanhangsels voorsiening gemaak word, voorskryf en aan pasiënte onder sy of haar sorg verskaf slegs binne die bestek van sy of haar praktyk en behoudens die voorwaardes bepaal deur die Medisynebeheerraad. Die voorwaardes en Aanhangsels sal in die *Staatskoerant* gepubliseer word.

Adrenalien (epinefrien), uitgesonderd oogpreparate wanneer bedoel vir gloukoom en uitegsonderdpreparate vir inspuiting.
Akonietalkaloïede; stowwe, preparate en mengsels wat 0,02 persent of meer daarvan bevat.
Akrivastien.
Alkaloïede en glikosiede; alle giftige alkaloïede en glikosiede, en die soute van sodanige giftige alkaloïede en glikosiede wat nie uitdruklik in ander Bylaes gelys word nie.
Alverien.
Amielnitriet.
Aminopentamied.
Amorolfien.

Antihistaminika, ongeag die indikasie of doseervorm, uitgesonderd –

(a) astemisool en terfenadien; (B4)

(b) wanneer afsonderlik in hierdie Bylaes gelys; (B2, B5) en

(c) uitgesonderd wanneer geregistreer kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947 (Wet No. 36 van 1947).

Antimikorbiese stowwe, naamlik griseofulvien, mupirosien, natamisien, wanneer bedoel vir aanwending aan die vel, neusholtes en buite-oor, asook nistatienpreparate bedoel vir aanwending in die mondholte, neusholtes en buite-oor, en uitgesonderd nistatien wanneer bedoel vir aanwending aan die vel en vir menslike vaginale gebruik, spesifiek vir die behandeling van herhalende vaginale kandidiase, soos uitgesluit van die voorwaardes in Bylae 4. (B1, B4)

Apomorfien; preparate en mengsels daarvan, uitgesonderd wanneer aangedui vir die behandeling van erektiele disfunksie. (B4)

Aptokaïen.

Arekolien.

Areseen; stowwe, preparate en mengsels wat die ekwivalent van 0,01 persent of meer arseentrioksied bevat. (B1)

Aselastien.

Asetieldihidrokodeïen; preparate en mengsels wanneer saamgestel met een of meer aktiewe medisinale en wat hoogstens 20 milligrambestanddeel asetieldihidrokodeïen (as basis) per dosiseenheid bevat, en vloeibare preparate en mengsels vir mondelike toediening wat hoogstens 20 milligram asetieldihidrokodeïen (as basis) per 5 milliliter dosiseenheid bevat. (B6)

Asetielsisteïen

Atropien; stowwe, preparate en mengsels daarvan, uitgesonderd oogpreparate. (B3)

Bambuterol.

Beklometasoondipropionaat, wanneer bedoel vir toediening in die neus (uitgesonderd toediening per aërosol)tydens die behandeling van die simptome van seisoenale allergiese rinitis (hooikoors) by volwassenes en kinders ouer as 12 jaar, onderworpe daaraan dat –

(a) die maksimum dosis per neusgat 100 mikrogram is;

(b) die maksimum daaglikse toediening per neusgat 200 mikrogram is;

(c) die verpakking tot 200 dosisse beperk is. (B3, B4)

Belladonna-alkaloïede; stowwe, preparate en mengsels daarvan, uitgesonderd wanneer bedoel vir plaaslike aanwending.

Benproperien.

Bevoniummetielsulfaat.

Biologiese middels, wanneer bedoel vir menslike gebruik, met inbegrip van polivalente slangbytteëgif en uitgesonderd ander inspuitbare preparate daarvan. (B4)

Bismut, wanneer bedoel vir mondelike gebruik.

Braakneut; stowwe, preparate en mengsels daarvan, uitgesonderd wanneer geregistreer kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.

Bromheksien.

Bromiede; preparate en mengsels daarvan wat minder as 80 milligram broom as bromied per aanbevole daaglikse dosis bevat. (B5)

Butinolien.

"Camphorated Opium Tincture BP".
Chloormesanoon; mengsels daarvan waar die maksimum aanbevole of voorgeskrewe dosis nie 100 milligram chloormesanoon te bowe gaan nie. (B5)
Chloorprenalien.
Chloorsoksasoon.
Chlorodien ("Camphorated Opium Tincture BP") of enige preparaat of mengsel daarvan beskryf as chlorodien; preparate en mengsels wat hoogstens 5,0 persent chlorodien in samestelling met ander aktiewe medisinale bestanddele bevat. (B6)
Cholestiramien.
Dekstrometorfaan.
Desloratidien.
Difenoksien (difenoksielsuur); preparate wat hoogstens 0,5 milligram difenoksien, as die basis bereken, per dosiseenheid bevat asook 'n hoeveelheid atropiensulfaat, gelyk aan minstens 5,0 persent van die hoeveelheid difenoksien, as die basis bereken, in die mengsel. (B6)
Difenoksilaat; preparate wat hoogsten 2,5 milligram difenoksilaat, as die basis bereken, en minstens 25 mikrogram atropiensulfaat per dosiseenheid bevat. (B6)
Dihidrokodeïen; preparate en mengsels, wanneer saamgestel met een of meer aktiewe medisinale bestanddele en wat hoogstens 20 milligram dihidrokodeïen (as basis) per dosiseenheid bevat en vloeibare preparate en mengsels vir mondelike toediening wat hoogstens 20 milligram dihidrokodeïen (as basis) per 5 milliliter dosiseenheid bevat. (B6)
Diklofenak, wanneer bedoel vir noodbehandeling van akute jigaanvalle en wanneer bedoel vir die behandeling van posttraumatiese toestande soos pyn, swelling en inflammasie, vir 'n maksimum tydperk van 5 dae. (B1, B3)
Disiklomien.
{D-norpseudoëfedrien – sien katien.}
Domperidoon.
Efedra-alkaloïede (natuurlik of sinteties); preparate en mengsels wat bedoel is vir aanwending aan die vel, oë, ore en neusholtes en wat hoogstens 1,0 persent efedra-alkaloïede bevat, en ander preparate en mengsels wat hoogstens 30 milligram efedrien of efedra-alkaloïede per dosis bevat. (B2)
Efedrien wat voorkom in produkte wat kragtens die Wet geregistreer is, uitgesonderd preparate en mengsels bedoel vir aanwending aan die vel, oë, ore en neusholtes en wat hoogstens 1,0 persent efedrien bevat, en ander orale preparate en mengsels wat hoogstens 30 milligram efedrien per dosis bevat. (B1, B5)
Eksalamied.
Emedastien.
Emepronium.
Ergotalkaloïede (natuurlik of sinteties), wanneer bedoel vir die behandeling van migraine. (B4)
Etielefrien.
Etielmorfien; preparate en mengsels wanneer saamgestel met een of meer aktiewe medisinale bestanddele en hoogstens 20 milligram etielmorfien (as basis) per dosiseenheid bevat en vloeibare preparate en mengsels vir mondelike toediening wat hoogstens 20 milligram etielmorfien (as basis) per 5 milliliter dosiseenheid bevat. (B6)

Famotidien, wanneer bedoel vir die korttermyn simptomatiese verligting van sooibrand, dispepsie en hiperasiditeit, onderworpe daaraan dat –

(a) die maksimum dosis 10 milligram is;

(b) die maksimum daaglikse dosis (per 24 uur) 20 milligram is;

(c) die maksimum tydperk van behandeling 2 weke is. (B4)

Fedrilaat.

Fenasoon (antipiroon).

Fenasopiridien.

Fenielpropanolamien; preparate en mengsels waar die aanbevole daaglikse dosis vir volwassenes nie 100 milligram oorskry nie en vir kinders 6 tot 12 jaar oud nie 50 milligram oorskry nie, wanneer bedoel vir die simptomatiese verligting van neus- en sinuskongestie.

Fenoprofeen, wanneer bedoel vir noodbehandeling van akute jigaanvalle en wanneer bedoel vir die behandeling van posttraumatiese toestande soos pyn, swelling en inflammasie, vir 'n maksimum tydperk van 5 dae. (B3)

Fenoterol, uitgesonderd wanneer dit voorkom in respiratoroplossings (B3) en uitgesonderd wanneer bedoel vir inspuiting of vir die voorkoming of vertraging van kraam. (B4)

Flavoksaat.

Flunisolied, wanneer bedoel vir toediening in die neus, uitgesonderd toediening per aërosol, in 'n sterkte van hoogsten 0,025 persent (G/v) en wat aangedui is vir behandeling van die simptome van seisoenale allergiese rinitis (hooikoors) by volwassenes en kinders ouer as 12 jaar, onderworpe daaraan dat –

(a) in die geval van volwassenes en kinders ouer as 16 jaar, die maksimum dosis per neusgat 50 mikrogram is en die maksimum daaglikse toediening per neusgat 100 mikrogram is;

(b) in die geval van kinders 12 tot 16 jaar oud, die maksimum dosis per neusgat 25 mikrogram is en die maksimum daaglikse toediening per neusgat 75 mikrogram is;

(c) die verpakking tot 240 dosisse beperk is. (B3, B4)

Flurbiprofeen, wanneer dit deur 'n apteker aan 'n pasiënt verskaf word en bedoel is vir die behandeling van posttraumatiese toestande soos pyn, swelling en inflammasie, vir 'n maksimum tydperk van 5 dae. (B1, B3, B4)

Flutikasoonpropionaat, wanneer bedoel vir toediening in die neus (uitgesonderd toediening deur middel van aërosol) oor die kort termyn (minder as 6 maande) vir die voorkoming en behandeling van simptome van allergiese rinitis (hooikoors) by volwassenes en kinders ouer as 12 jaar, onderworpe daaraan dat –

(a) die maksimum dosis 100 milligram is;

(b) die verpakking tot 120 dosisse beperk is. (B3)

Foledrien.

Folkodien; preparate en mengsels, wanneer saamgestel met een of meer aktiewe medisinale bestanddele en wat hoogstens 20 milligram folkodien (as basis) per dosiseenheid bevat, en vloeibare preparate en mengsels vir mondelike toediening wat hoogstens 20 milligram folkodien (as basis) per 5 milliliter dosiseenheid bevat. (B6)

Formoterol.

Fusafungien.

Gadopentetiensuur.

Gehalogeneerde hidroksikinoliene, wanneer bedoel vir aanwending aan die vel. (B4)

Gelsemiumalkaloïede; stowwe, preparate en mengsels daarvan.
Glikopirronium.
Heksametasien.
Heksoprenalien, uitgesonderd wanneer dit voorkom in respiratoroplossings (B3) en uitgesonderd wanneer bedoel vir inspuiting of vir die voorkoming of vertraging van kraam. (B4)
Hidrokinoon; preparate en mengsels wat hoogstens 2 persent daarvan bevat, wanneer bedoel vir aanwending aan die vel. (B3)
Hidrokortisoon en hidrokortisoonasetaat, wanneer gebruik in 'n maksimum konsentrasie van 0,1 persent in preparate bedoel vir aanwending aan die vel en hidrokortisoon in 'n maksimum konsentrasie van 1,0 persent wanneer gebruik in samestelling met mikonasool vir plaaslike aanwending in die behandeling van voetskimmel. (B4)
Hiossien; stowwe, preparate en mengsels daarvan, met inbegrip van transdrmale preparate wanneer bedoel vir die voorkoming van die simptome van reissiekte.
Homatropien; preparate en mengsels daarvan, uitgesonderd oogpreparate. (B3)
Hormone (natuurlik of sinteties, met inbegrip van rekombinante vorme), met óf hormonale óf antihormonale werking, wanneer bedoel vir menslike vaginale gebruik en mondelike voorbehoedmiddels wat slegs progestogeen bevat en hormone wanneer spesifiek bedoel vir nood postkoïtale kontrasepsie. (B3, B4, B5)
Ibuprofeen in mondelike medisinale preparate –

(a) waarvan die aanbevole daaglikse dosis vir volwassenes nie 1,2 gram oorskry nie en dié vir kinders tot en met 12 jaar nie 20 milligram per kilogram liggaamsmassa oorskry nie;
(b) wanneer bedoel vir die noodbehandeling van akute jigaanvalle;
(c) wanneer bedoel vir die behandeling van posttraumatiese toestande soos pyn, swelling en inflammasie, vir 'n maksimum tydperk van 5 dae,

uitgesonderd wanneer bedoel vir die behandeling van inflammatories gewrigsiektes. (B3)

Indometasien, wanneer bedoel vir noodbehandeling van akute jigaanvalle. (B1, B3)
Iopromied.
Ipratropiumbromied.
Isoaminiel.
Isoprenalien (isoproterenol), uitgesonderd wanneer dit voorkom in respiratoroplossings (B3) en uitgesonderd wanneer bedoel vir inspuiting. (B4)
Isopropamied.
Kalabarboontjie-alkaloïede; stowe, preparate en mengsels daarvan.
Kaliumchloried, waar die aanbevole dosis meer as 20 millimol kalium (1 500 milligram kaliumchloried) per 24 uur is, of wanneer bedoel vir intraveneuse infusie of vir inspuiting, maar uitgesonderd wanneer dit voorkom in mondelike rehidrasiepreparate.
Kamilofien.
Kantaridien.
Kantaxantin, wanneer bedoel as geneesmiddel.
Karbosisteïen.
Karbuterol, uitgesonderd wanneer dit voorkom in respiratoroplossings (B3) en uitgesonderd wanneer bedoel vir inspuiting. (B4)
Karisoprodol.

Katien ((+)-norpseudoëfedrien); preparate en mengsels wat hoogstens 50 milligram katien per dosiseenheid bevat. (B6)

Ketoprofeen –

(a) wanneer bedoel vir die korttermynbehandeling van hoofpyn, tandpyn, spierpyn, rugpyn, geringe pyn geassosieer met artritis, pyn geassosieer met menstruele krampe (dismenorree), geringe pyn en pyn geassosieer met gewone verkoue, en koors, met 'n maksimum daaglikse dosis van 75 milligram ketoprofeen in 24 uur;

(b) wanneer dit deur 'n apteker aan 'n pasiënt verskaf word en bedoel is vir die noodbehandeling van akute jigaanvalle of vir die behandeling van posttraumatiese toestande soos pyn, swelling en inflammasie, teen 'n maksimum dosis van 100 milligram ketoprofeen per dag, vir 'n maksimum tydperk van 5 dae. (B1, B3)

Kinien; preparate en mengsels wat meer as 1,0 persent daarvan bevat.

Klidiniumbromied.

Klonidien, wanneer bedoel vir die behandeling van migraine. (B3)

Kodeïen (metielmorfien); preparate en mengsels, wanneer saamgestel met een of meer aktiewe medisinale bestanddele en wat hoogstens 20 milligram kodeïen (as basis) per dosiseenheid bevat, en vloeibare preparate en mengsels vir modelike toediening wat hoogstens 20 milligram kodeïen (as basis) per 5 milliliter dosiseenheid bevat. (B7)

Kolgisein, in noodgevalle. (B3)

Kontrasmedia.

Kwik organiese verbindings; stowwe, preparate en mengsels wat die ekwivalent van 0,6 persent of meer elemental kwik bevat, en stowwe, preparate en mengsels wat in die vorm van aërosols is, en wat bedoel is vir aanwending aan die vel en slymvliese, uitgesonderd fenielmerkurinitraat uitgesonderd wanneer geregistreer kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.

Kwikammoniumchloried.

Kwikchloried.

Kwikjodiet.

Kwikoksiede; stowwe, preparate en mengsels daarvan, uitgesonderd dié wat minder as 3,0 persent kwik bevat.

Lansoprasool, wanneer bedoel vir die tydelike korttermynverligting van sooibrand en hiperasiditeit, onderworpe aan –

(a) 'n maksimum daaglikse dosis van 15 milligram;

(b) 'n maksimum behandelingstydperk van 14 dae. (B4)

Levosetirisien.

Litiumsoute, wanneer bedoel vir aanwending aan die vel. (B5)

Lobelia-alkaloïede; stowwe, preparate en mengsels daarvan.

Lodoksamied.

Loperamied.

Loratadien.

Mebeverien.

Mefenaamsuur, wanneer bedoel vir die behandeling van posttraumatiese toestande soos pyn, swelling en inflammasie, vir 'n maksimum tydperk van 5 dae; en preparate met mefenaamsuur as die enigste aktiewe medisinale bestanddeel, wanneer bedoel vir die behandeling van primêre dismenorree, waar die die

maksimum daaglikse dosis 500 milligram 3 maal per dag is en die maksimum tydperk van behandeling 3 dae is. (B3)

Mefenesien.

Mepensolaatbromied.

Mesna, uitgesonderd preparate bedoel vir inspuiting. (B4)

Metaproterenol (orsiprenalien), uitgesonderd wanneer dit voorkom in respiratoroplossings en uitgesonderd wanneer bedoel vir inspuiting of vir die voorkoming of vertraging van kraam. (B4)

Metikseen.

Metokarbamol, wanneer bedoel as geneesmiddel.

Metoksifenamien.

Mikonasool, wanneer bedoel vir menslike gebruik in preparate wat hoogstens 2 persent mikosanool bevat en bedoel is vir plaaslike behandeling van fungusinfeksies van die mond (orale kandidiase). (B4)

Minoksidiel, wanneer bedoel vir aanwending aan die kopvel. (B4)

Morfien;mengsels wat hoogstens 0,2 persent morfien, bereken as anhidrese morfien, bevat. (B6)

Nabumetoon, wanneer bedoel vir die behandeling van posttraumatiese toestande soos pyn, swelling en inflammasie, vir 'n maksimum tydperk van 5 dae. (B3)

Naprokseen –

(a) die natriumsout daarvan, wanneer bedoel die die korttermynbehandeling van hoofpyn, tandpyn, spierpyn, rugpyn, geringe pyn weens artritis, pyn weens menstruele krampe (dismenorree), geringe pyn geassosieer met verkoue en koors, in 'n maksimum dosis van 600 milligram naprokseen (660 milligram naprokseennatrium) in 24 uur;

(b) wanneer dit deur 'n apteker aan die pasiënt verskaf word en bedoel is vir die noodbehandeling van akute jigaanvalle of vir behandeling van posttraumatiese toestande soos pyn, swelling en inflammasie, vir 'n maksimum tydperk van 5 dae. (B1, B3)

Natriumkromoglikaat, uitgesonderd wanneer bedoel vir veterinêre gebruik. (B4)

Nedokromiel.

Nikotien, wanneer bedoel vir menslike medisinale gebruik, uitgesonderd –

(a) nikotienkougom wat hoogstens 4 mg nikotien per stukkie bevat en die pakketgrootte nie 30 stukkies per pakket te bowe gaan nie, slegs wanneer hierdie medisyne gebruik word vir die verligting van nikotienonttrekkingsimptome as hulpmiddel by staking van die rookgewoonte; (B0);

(b) transdermale nikotienplakkers vir deurlopende aanwending aan die vel in sterktes tot en met 15 mg/16 uur, slegs wanneer hierdie medisyne gebruik word vir die verligting van nikotienonttrekkingsimptome as hulpmiddel by staking van die rookgewoonte. (B2)

Nisatidien, wanneer mondeliks toegedien vir korttermyn simptomatiese verligting van sooibrand en hiperasiditeit, onderworpe daaraan dat –

(a) die maksimum dosis 150 milligram is;

(b) die maksimum daaglikse dosis 300 milligram is; en

(c) die maksimum tydperk van behandeling twee weke is. (B4)

Nisergolien.

Norkodeïen; preparate en mengsels, wanneer saamgestel met een of meer aktiewe medisinale bestanddele en wat hoogstens 20 milligram norkodeïen (as basis)

per dosiseenheid bevat, en vloeibare preparate en mengsels vir mondelike toediening wat hoogstens 20 milligram norkodeïen (as basis) per 5 milliliter dosiseenheid bevat. (B6)

Noskapien.

Oksibuprokaïen, wanneer dit voorkom in oogdruppels bedoel vir noodbehandeling van sweis-oë. (B4)

Oksifenonium.

Oktatropienmetielbromied.

Oliehars van aspidium (Filix Mas).

Olopatadien.

Opium; mengsels wat hoogstens 0,2 persent morfien, bereken as anhidriese morfien, bevat. (B6)

Orfenadrien.

Otiloniumbromied.

Papawerien; stowwe, preparate en mengsels daarvan.

Parasemtamol, wanneer dit voorkom in rektale setpille. (B0, B1)

Pentoksifillien.

Pinaverium.

Pipensolaat.

Pipoksolaan.

Pirbuterol, uitgesonderd wanneer dit voorkom in respiratoroplossings. (B3)

Piroksikaam, wanneer bedoel is vir die noodbehandeling van akute jigaanvalle of vir behandeling van posttraumatiese toestande soos pyn, swelling en inflammasie, vir 'n maksimum tydperk van 5 dae. (B3)

Pisotifeen; preparate en mengsels daarvan, wanneer bedoel vir die voorkoming van migraine. (B5)

Podofillumhars; preparate en mengsels wat hoogstens 20 persent daarvan bevat. (B4)

Poldienmetielsulfaat.

Polivalente slangbytteëgif.

Prifiniumbromied.

Proglumied.

Prokaterol, uitgesonderd wanneer dit voorkom in respiratoroplossings. (B3)

Proksimetakaïen, wanneer dit voorkom in oogdruppels bedoel vir die noodbehandeling van sweis-oë. (B4)

Prometasien; preparate en mengsels, wanneer bedoel vir gebruik as antihistaminika, vir aanwending aan die vel en wanneer spesifiek bedoel vir die behandeling van reissiekte. (B5)

Propantelienbromied.

Propifenasoon.

Prosiklidien.

Rantidien, wanneer mondeliks toegedien vir korttermyn simptomatiese verligting van sooibrand en hiperasiditeit, onderworpe daaraan dat –

(a) die maksimum dosis 75 milligram is;

(b) die maksimum daaglikse dosis 300 milligram is; en

(c) die maksimum tydperk van behandeling twee weke is. (B3)

Reproterol, uitgesonderd wanneer dit voorkom in respiratoroplossings. (B3)

Rimiterol, uitgesonderd wanneer dit voorkom in respiratoroplossings en uitgesonderd wanneer bedoel vir inspuiting. (B4)

Sabadilla-alkaloïede; stowwe, preparate en mengsels wat 1,0 persent of meer daarvan bevat.

Salbutamol, uitgesonderd wanneer dit voorkom in respiratoroplossings en uitgesonderd wanneer bedoel vir inspuiting. (B4)
Salmefamol, uitgesonderd wanneer dit voorkom in respiratoroplossings en uitgesonderd wanneer bedoel vir inspuiting. (B4)
Salmeterol.
Setirisien.
Sikkanien, wanneer bedoel vir aanwending aan die vel.
Siklandelaat.
Siklopentolaat, uitgesonderd oogpreparate daarvan. (B3)
Silwersulfadiasien, wanneer bedoel vir aanwending aan die vel vir die korttermynbehandelings van geringe brandwonde, onderworpe daaraan dat die verpakking beperk word tot hoogstens 50 gram.
Simetidien, wanneer bedoel vir die korttermyn simptomatiese verligting van sooibrand, dispepsie en hiperasiditeit, onderworpe daaraan dat –

(a) die maksimum dosis 200 milligram is;
(b) die maksimum daaglikse dosis (per 24 uur) 800 milligram is;
(c) die maksimum tydperk van behandeling 2 weke is. (B3)

Strignien; preparate en mengsels wat 0,2 persent of minder daarvan bevat, uitgesonderd die stof. (B4)
Sulfonamiede, wanneer bedoel vir aanwending aan die oë, neusholtes en vagina (B4), uitgesonderd wanneer geregistreer kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.
Teofillien en die derivate daarvan, tensy in ander Bylaes gelys, uitgesonderd preparate vir inspuiting. (B4)
Terbutalien, uitgesonderd wanneer dit voorkom in respiratoroplossings. (B3)
Tetrakaïen, wanneer dit voorkom in oogdruppels bedoel vir die noodbehandeling van sweis-oë. (B4)
Tiaprofeensuur, wanneer bedoel vir die behandeling van posttraumatiese toestande soos pyn, swelling en inflammasie, vir 'n maksimum tydperk van 5 dae. (B3)
Timepidium.
Tiotropium.
Triamsinoloon, wanneer bedoel vir aanwending aan mondletsels. (B4)
Trimebutien.
Trospium.
Tuberkulien, wanneer bedoel vir menslike gebruik. (B4)
Tulobuterol, uitgesonderd wanneer dit voorkom in respiratoroplossings. (B3)
Vaksiene, wanneer bedoel vir menslike gebruik.

– EINDE VAN BYLAE 2 –

BYLAE 3

(a) Alle stowwe bedoel in hierdie Bylae word uitgesluit wanneer spesifiek verpak, geëtiketteer en gebruik vir –

(i) nywerheidsdoeleindes, met inbegrip van die vervaardiging of opmaak van verbruikersitems of -produkte wat geen farmakologiese werking of gebruik as geneesmiddel het nie,

(ii) en analitiese laboratoriumdoeleindes.

(b) Alle stowwe bedoel in hierdie Bylae sluit die volgende in:

(i) Die soute en esters van sodanige stowwe, indien die bestaan van sodanige soute en esters moontlik is; en
(ii) alle preparate en mengsels van sodanige stowwe, waar sodanige preparate en mengsels nie uitdruklik uitgesluit word nie.

(c) Ingevolge artikel 22A(5)(f) van die Wet mag 'n praktisyn, verpleegkundige of 'n persoon wat kragtens die Wet op Gesondheidsberoepe, 1974 (Wet No. 56 van 1974), geregistreer is, uitgesonderd 'n geneesheer of tandarts, die Bylae 3-stowwe en -medisyne waarvoor in die Aanhangsels voorsiening gemaak word, voorskryf en aan pasiënte onder sy of haar sorg verskaf slegs binne die bestek van sy of haar praktyk en behoudens die voorwaardes bepaal deur die Medisynebeheerraad. Die voorwaardes en Aanhangsels sal in die *Staatskoerant* gepubliseer word.

Adapaleen.
Adrenalien (epinefrien); oogpreparate daarvan, wanneer bedoel vir gloukoom. (B2, B4)
Akamprosaat.
Alendroonsuur.
Alklofenak.
Allopurinol.
Alprenolol.
Amilodopien.
Amiloried.
Ankrod.
Antiolimien, wanneer bedoel vir inspuiting.
Arsanielsuur.
Asapropasoon.
Asebutolol.
Aseklofenak.
Asetasolamied.
Asetielcholien, wanneer bedoel vir oftalmiese gebruik.
Asetohekasmied.
Asipimoks.
Atenolol.
Atropien; oogpreparate daarvan. (B2)
Balsalasied.
Barnidipien.
Beklamied.
Benasepriel.
Bendasak.
Benfluoreks.
Benoksaprofeen.
Bensbromaroon.
Bensidamien, uitgesonderd preparate en mengsels wat –

(a) hoogstens 3 persent bensidamien bevat, wanneer bedoel vir aanwending aan die vel;

(b) wat hoogstens 0,15 persent bensidamien bevat, wanneer bedoel as 'n mondspoelmiddel of vir plaaslike aanwending in die mond en keel: Met dien verstande dat die totale dosis nie 36 milligram bensidamien per dag oorskry nie. (B1)

Bepridiel.
Besafibraat.
Betabensalbutiramied.
Betagalaktosidase, wanneer bedoel vir terapeutiese doeleindes.
Betahistein.
Betaksolol.
Betanidien.
Bevantolol.
Bisoprolol.Bopindolol.
Brimonidien.
Brinsoolamied.
Buflomediel.
Buformien.
Bumetanied.
Chenodeoksicholsuur.
Chloorasaniel.
Chlooreksoloon.
Chloorpropamied.
Chloortalidoon.
Chloortiasied en ander derivate van benso-1,2,4-tiadiasien-7sulfonamied-1,1-dioksied, hetsy gehidrogeneer al dan nie, met inbegrip van hidrochloortiasied, bendrofluasied, benstiasied, siklopentiasied, hidroflumetiasied, metchloortiasied en politiasied.
Chromonaar.
Debrisokien.
Delapriel.
Dichloorfenamied.
Diflunisal.
Diftaloon.
Digitalis; die glikosiede en ander aktiewe beginsels daarvan, tensy verdun tot minder as een eenheid (BP) in elke 2,0 gram.
Dihidroërgokristien.
Diklofenak, uitgesonderd wanneer bedoel vir aanwending aan die vel (B1), en uitgesonderd wanneer bedoel vir noodbehandeling van akute jigaanvalle en uitgesonderd wanneer bedoel vir die behandeling van posttraumatiese toestande soos pyn, swelling en inflammasie, vir 'n maksimum tydperk van 5 dae. (B2)
Dilevalol.
Diltiasem.
Dimerkaprol, wanneer bedoel vir inspuiting.
Dipiridamool.
Dipirosetiel.
Dipivefrien.
Disulfiraam.

Ditranol.
Doksasosien.
Dornase alfa (rhDNase).
Dorsolamied.
Eltenak.
Enalapriel.
Endralasien.
Eprosartaan.
Eskien, uitgesonderd preparate en mengsels daarvan wat bedoel is vir aanwending aan die vel en wat hoogstens 1,0 persent eskien bevat. (B1)
Eskulien, wanneer bedoel vir mondelike gebruik.
Esmolol.
Etakriensuur.
Etambutol.
Etionamied, wanneer bedoel vir mondelike gebruik.
Etisasool.
Etodolak.
Etodoliensuur.
Etosuksimied.
Felbamaat.
Felodipien.
Fenbufeen.
Fendilien.
Fenformien.
Fenitoïen.
Fenklofenak.
Fenobarbitaal; preparate en mengsels wat hoogstens 90 milligram fenobarbitaal per minimum aanbevole of voorgeskrewe dosis bevat wanneer bedoel vir voortgesette gebruik by epilepsie. (B5)
Fenofibraat.
Fenoksimetielpenisillien, wanneer bedoel vir die voorkoming van rumatiekkoors. (B4)
Fenoprofeen, uitgesonderd wanneer bedoel vir noodbehandeling van akute jigaanvalle en uitgesonderd wanneer bedoel vir die behandeling van posttraumatiese toestande soos pyn, swelling en inflammasie, vir 'n maksimum tydperk van 5 dae. (B2)
Fenoterol, wanneer dit voorkom in respiratoroplossings. (B2, B4)
Fentiasak.
Fentolamien.
Fisostigmien; oogpreparate daarvan, wanneer bedoel vir gloukoom. (B4)
Floktafenien.
Flufenaamsuur, uitgesonderd preparate en mengsels bedoel vir aanwending aan die vel. (B1)
Fluniksien.
Flurbiprofeen, uitgesonderd –

(a) wanneer bedoel vir oftalmiese gebruik; (B4)
(b) wanneer bedoel vir aanwending aan die vel, met inbegrip van aanwendings deur middel van 'n transdermale plakker, en die indikasies beperk word tot gebruik deur volwassenes en kinders van12 jaar en ouer, en die tydperk van behandeling hoogstens 4 weke is; (B1)

(c) wanneer dit deur 'n apteker aan 'n pasiënt verskaf word en bedoel is vir die behandeling van posttraumatiese toestande soos pyn, swelling en inflammasie, vir 'n maksimum tydperk van 5 dae. (B2)

Fosinopriel.
Furosemied.
Gabapentien.
Gemfibrosiel.
Glafenien.
Glibenklamied.
Glibornuried.
Glikasied.
Glikidoon.
Glimepiried.
Glimidien.
Glipisied.
Glukosamien; stowwe, preparate en mengsels, wanneer bedoel vir die behandeling van primêre en sekondêre osteo-artritis, osteochondose en spondilose.
Guanabens.
Guanetidine.
Guanfasien.
Guanoksaan.
Heksoprenalien, wanneer dit voorkom in respiratoroplossings. (B2, B4)
Hidralasien.
Hidrokinoon; prparate en mengsels daarvan wat meer as 2,0 persent hidrokinoon bevat. (B2)
Homatropien, oogpreparate daarvan. (B2)
Hormone (natuurlik of sinteties, met inbegrip van rekombinante vorme), wanneer bedoel as mondelike voorbehoedmiddels, uitgesonderd mondelike voorbehoedmiddels wat slegs progestogeen bevat en uitgesonderd hormone wanneer spesifiek bedoel vir nood postkoïtale kontrasepsie. (B2, B4, B5)
Ibuprofeen, wanneer spesifiek bedoel vir die behandeling van inflammatoriese gewrigsiektes. (B1, B2)
Indapamied.
Indometasien, uitgesonderd wanneer bedoel vir aanwending aan die vel en uitgesonderd wanneer bedoel vir noodbehandeling van akute jigaanvalle (B1, B2)
Indoprofeen.
Indoramien.Insulien.
Irbesartaan.
Isoksikaam.
Isoniasied en die derivate daarvan, tensy in 'n ander Bylae gelys.
Isoprenalien (isoproterenol), wanneer dit voorkom in respiratoroplossings. (B2, B4)
Isosorbied.
Isradipien.
Ivermektien, uitgesonderd wanneer bedoel en geregistreer as 'n wurmmiddel en/of 'n ektoparasietdoder kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.
Kadralasien.
Kaliumkanrenoaat.
Kalsipotriol.

Kalsiumdobesilaat.
Kalsiumkarbimied.
Kandesartaan.
Kaptopriel.
Karasolol.
Karbachol; oogpreparate daarvan, wanneer bedoel vir gloukoom. (B4)
Karbamasepien.
Karbenoksoloon, uitgesonderd wanneer bedoel vir aanwending aan die slymvlies van die mond.
Karbuterol, wanner dit voorkom in respiratoroplossings. (B2, B4)
Karprofeen.
Karteolol.
Karvedilol.
Ketanserien.
Ketoprofeen, uitgesonderd –

(a) wanneer bedoel vir aanwending aan die vel; (B1)
(b) wanneer bedoel vir die korttermynbehandeling van hoofpyn, tandpyn, spierpyn, rugpyn, geringe pyn geassosieer met artritis, pyn geassosieer met menstruele krampe (dismenorree), geringe pyn geassosieer met gewone verkoue en koors, met 'n maksimum daaglikse dosis van 75 milligram ketoprofeen in 24 uur; (B2)
(c) wanneer deur 'n apteker aan 'n pasiënt verskaf en bedoel vir noodbehandeling van akute jigaanvalle of vir die behandeling van posttraumatiese toestande soos pyn, swelling en inflammasie, met 'n maksimum daaglikse dosis van 75 milligram ketoprofeen per dag, vir 'n maksimum tydperk van 5 dae. (B2)

Ketorolaktrometamol, wanneer bedoel vir oftalmiese gebruik. (B4)
Kinapriel.
Klofibraat.
Klonidien, uitgesonderd wanneer bedoel vir die behandeling van migraine. (B2)
Klopidogrel.
Kolgisien.
Kopersoute, wanneer bedoel vir inspuiting.
Kortikosteroïede (natuurlik of sinteties), wanneer dit voorkom in preparate bedoel vir inhalasie, uitgesonderd –

(a) beklometasoondipropionaat, wanneer bedoel vir toediening in die neus, uitgesonderd toediening per aërosol, tydens die behandeling van die simptome van seisoenale allergiese rinitis (hooikoors) by volwassenes en kinders ouer as 12 jaar, waar die maksimum dosis per neusgat 100 mikrogram is, die maksimum daaglikse dosis per neusgat 200 mikrogram is en die verpakking tot 200 dosisse beperk is; en
(b) flunisolied, wanneer bedoel vir toediening in die neus, uitgesonderd toediening per aërosol, in 'n sterkte van hoogstens 0,25 persent (g/v) en aangedui is vir die behandeling van die simptome van seisoenale allergiese rinitis (hooikoors) by volwassenes en kinders ouer as 12 jaar, waar, in die geval van volwassenes en kinders ouer as 16 jaar, die maksimum dosis per neusgat 50 mikrogram is, die maksimum daaglikse dosis per neusgat 100 mikrogram is, en in die geval van kinders 12 tot 16 jaar, die maksimum dosis per neusgat 25 mikrogram

is en die maksimum daaglikse dosis per neusgat 75 mikrogram is en die verpakking tot 240 dosisse beperk is; en

(c) flutikasoonpropionaat, wanneer bedoel vir toediening in die neus, uitgesonderd toediening per aërosol, oor die kort termyn (minder as 6 maande) vir die voorkoming en behandeling van allergiese rinitis (hooikoors) by volwassenes en kinders ouer as 12 jaar, waar die maksimum daaglikse dosis per neusgat 200 mikrogram is en die verpakking tot 120 dosisse beperk is. (B2, B4)

Labetalol.
Lamotrigien.
Lasidipien.
Lerkanidipien.
Levetirasetaam.
Levobonulol.
Levosemindaan.
Lidoflasien.
Lisinopriel.
Lonasolak.
Lornoksikam.
Losartan.
Mefenaamsuur, uitgesonderd wanneer bedoel vir die behandeling van posttraumatiese toestande soos pyn, swelling en inflammasie, vir 'n maksimum tydperk van 5 dae,en uitgesonderd preparate met mefenaamsuur as die enigste aktiewe medisinale bestanddeel, wanneer bedoel vir die behandeling van primêre dismenorree, waar die maksimum daaglikse dosis 500 milligram mefenaamsuur 3 maal per dag is en die maksimum tydperk van behandeling 3 dae is. (B2)
Meklofenaamsuur.
Meloksikaam.
Mepindolol.
Mesalasien (5-aminosalisielsuur).
Mesulfeen.
Metaproterenol (orsiprenalien), wanneer dit voorkom in respiratoroplossings. (B2, B4)
Metasoolamied.
Metformien.
Metieldopa.
Metimasool.
Metipranolol.
Metolasoon.
Metopolol.
Metsuksimied.
Mibefradiel.
Moëksipriel.
Moksonidien.
Montelukast.
Nabumetoon, uitgesonderd wanneer bedoel vir die behandeling van posttraumatiese toestande soos pyn, swelling en inflammasie, vir 'n maksimum tydperk van 5 dae. (B2)
Nadolol.Naftidrofuriel.
Naprokseen, uitgesonderd –

(a) wanneer bedoel vir aanwending aan die vel; (B1)
(b) wanneer bedoel vir die korttermynbehandeling van hoofpyn, tandpyn, spierpyn, rugpyn, geringe pyn geassosieer met artritis, pyn geassosieer met menstruele krampe (dismenorree), geringe pyn geassosieer met gewone verkoue en koors, met 'n maksimum daaglikse dosis van 600 milligram naprokseen (660 milligram naprokseennatrium) in 24 uur; (B2)
(c) wanneer deur 'n apteker aan 'n pasiënt verskaf en bedoel vir noodbehandeling van akute jigaanvalle of vir die behandeling van posttraumatiese toestande soos pyn, swelling en inflammasie, vir 'n maksimum tydperk van 5 dae. (B2)

Nateglinied.
Nebivolol.
Nifumiensuur.Nimesulied.
Nikardipien.
Nimodipien.
Nisoldipien.
Nitrendipien.
Nitrogliserien, wanneer bedoel vir medisinale gebruik.
Oksaprosien.
Oksibutinien.
Oksiprenolol.
Oksirasetaam.
Okskarbasepien.
Oksovinka.
Olsalasien.
Orlistat.
Para-aminosalisielsuur en die esters daarvan.
Parekoksib.
Penbutolol.
Penisillinase, wanneer bedoel vir inspuiting.
Pentaëritritoltetranitraat.
Pentolinium.
Perindopriel.
Pindolol.
Pioglitasoon.
Pirasetaam.
Pirbuterol, wanneer dit voorkom in respiratoroplossings.
Piretanied.
Pirimetamien.
Piritioksien.
Piroksikaam, uitgesonderd wanneer bedoel vir noodbehandeling van akute jigaanvalle en uitgesonderd wanneer bedoel vir die behandeling van posttraumatiese toestande soos pyn, swelling en inflammasie, vir 'n maksimum tydperk van 5 dae. (B2)
Pirprofeen.
Praktolol.
Prasosien.
Primidoon.
Probenesied.

Probukol.
Prokasoon.
Prokaterol, wanneer dit voorkom in respiratoroplossings. (B2)
Proktofeen.
Propasetamol.
Propiverien.
Propranolol.
Proskillaridien.
Protionamied, wanneer bedoel vir mondelike gebruik.
Pygeum africanum (lipido-steroliesekompleks-ekstrak daarvan).
Raloxifeen.
Ramipriel.
Ranitidien, uitgesonderd wanneer mondeliks toegedien vir korttermyn simptomatiese verligting van sooibrand en hiperasiditeit, waar die maksimum dosis 75 milligram is, die maksimum daaglikse dosis 300 milligram is en die maksimum tydperk van behandeling 2 weke is. (B2)
Rapagl;inied.
Rasekadotriel.
Rauwolfia-alkaloïede.
Reproterol, wanneer dit voorkom in respiratoroplossings. (B2)
Reserpien (natuurlik en sinteties).
Rimiterol, wanneer dit voorkom in respiratoroplossings. (B2, B4)
Risedronaat.
Rofekoksib.
Roksarsoon (3-nitro-4-hidroksifenielaarsoonsuur) wanneer bedoel vir veterinêre gebruik.
Rosiglitasoon.
Roubasien.
Safirlukast.
Salbutamol, wanneer dit voorkom in respiratoroplossings. (B2, B4)
Salmefamol, wanneer dit voorkom in respiratoroplossings. (B2, B4)
Selekoksib.
Seliprolol.
Siklandelaat.
Siklopentolaat; oogpreparate daarvan. (B2)
Silasapriel.
Silimarien.
Simetidien, uitgesonderd wanneer bedoel vir die korttermyn simptomatiese verligting van sooibrand, dispepsie en hiperasiditeit, waar die maksimum dosis 200 milligram is, die maksimum daaglikse dosis (per 24 uur) 800 milligram is en die maksimum tydperk van behandeling 2 weke is. (B2)
Sinksoute vir mondelike inname waar die daaglikse dosis meer as 50 milligam elementale sink is, uitgesonderd wanneer geregistreer kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.
Skildklier en die aktiewe bestanddele en derivate daarvan, tensy in 'n ander Bylae gelys.
Solkoseriel; oogpreparate daarvan. (B0, B4)
Somepirak.
Sotalol.
Spirapriel.

Spironolaktoon.
Strofantus; die glikosiede daarvan en hulle hidoliseprodukte, en die derivate daarvan, tensy in 'n ander Bylae gelys.
Sulfienpirasoon.
Sulindak.
Suloktidiel.
Sultiaam.
Suprofeen.
Tasaroteen.
Tasosartaan.
Telmisartaan.
Tenidap.
Tenoksikaam.
Terabutalien, wanneer dit voorkom in respiratoroplossings. (B2)
Terasosien.
Terisidoon.
Terodilien.
Tiagabien.
Tiaprofeensuur, uitgesonderd wanneer bedoel vir die behandeling van posttraumatiese toestande soos pyn, swelling en inflammasie, vir 'n maksimum tydperk van 5 dae. (B2)
Tiasetasoon.
Tiklopedien.
Timolol.
Tolamolol.
Tolasamied.
Tolbutamied.
Tolfenaamsuur.
Tolmetien, uitgesonderd wanneer bedoel vir aanwending aan die vel.
Tolterodien.
Topiramaat.
Torasemied.
Trandolapriel.
Tretinoïen.
Triamtereen.
Trikaïen.
Trimetadioon.
Tulobuterol, wanneer dit voorkom in respiratoroplossings. (B2)
Ursodeoksicholsuur.
Valdekoksib.
Valproïensuur en die derivate daarvan, tensy in 'n ander Bylae gelys.
valsartaan.
Vedaprofeen.
Verapamiel (iproveratriel).
Veratrumalkaloïede.
Vigabatrien.
Vinkamien.
Vinposetien.
Vitamien A; preparate daarvan vir inspuiting en mondelike preparate en mengsels daarvan wat meer as 10 000 I.E per aanbevole daaglikse dosis bevat,

uitgesonderd wanneer geregistreer kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.

Vitamien D; preparate daarvan vir inspuiting en mondelike preparate en mengsels daarvan wat meer as 500 I.E per aanbevole daaglikse dosis bevat, uitgesonderd wanneer geregistreer kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.

Xamoterol.

Xipamied.

Ystersoute, wanneer bedoel vir inspuiting, uitgesonderd wanneer geregistreer kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.

– EINDE VAN BYLAE 3 –

BYLAE 4

(a) Alle stowwe bedoel in hierdie Bylae word uitgesluit wanneer spesifiek verpak, geëtiketteer en gebruik vir –

(i) nywerheidsdoeleindes, met inbegrip van die vervaardiging of opmaak van verbruikersitems of -produkte wat geen farmakologiese werking of gebruik as geneesmiddel het nie,

(ii) en analitiese laboratoriumdoeleindes.

(b) Alle stowwe bedoel in hierdie Bylae sluit die volgende in:

(i) Die soute en esters van sodanige stowwe, indien die bestaan van sodanige soute en esters moontlik is; en

(ii) alle preparate en mengsels van sodanige stowwe, waar sodanige preparate en mengsels nie uitdruklik uitgesluit word nie.

(c) Ingevolge artikel 22A(5)(f) van die Wet mag 'n praktisyn, verpleegkundige of 'n persoon wat kragtens die Wet op Gesondheidsberoepe, 1974 (Wet No. 56 van 1974), geregistreer is, uitgesonderd 'n geneesheer of tandarts, die Bylae 4-stowwe en -medisyne waarvoor in die Aanhangsels voorsiening gemaak word, voorskryf en aan pasiënte onder sy of haar sorg verskaf slegs binne die bestek van sy of haar praktyk en behoudens die voorwaardes bepaal deur die Medisynebeheerraad. Die voorwaardes en Aanhangsels sal in die *Staatskoerant* gepubliseer word.

2-merkaptopropionielglisien.

5-fluoorurasiel.

6-merkaptopurien en die derivate daarvan, tensy in 'n ander Bylae gelys.

Abasavir.

Adenosien.

Adrenalien, wanneer bedoel vir inspuiting. (B2, B3)

Akarbose.

Albendasool, uitgesonderd wanneer bedoel en geregistreer as 'n wurmmiddel kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.
Aldesleukien.
Alfachimotripsien, wanneer bedoel vir oftalmiese gebruik.
Alfakalsidol, uitgesonderd wanneer geregistreer kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.
Alfusosien.
Alisapried.
Alkuronium.
Almitrien.
Alosetroon.
Alprostadiel.
Amantadien.
Amifenasool.
Amifostien.
Aminoglutetimied.
Aminopirien (amidopirien).
Amiodaroon.
Amprenavir.
Amrinoon.
Amsakrien.
Anagrelied.
Anastrosool.
Antihemofiliese faktor.
Antimalariamiddels, uitgesonderd chlorokien in samestelling met proguaniel, wanneer spesifiek bedoel vir die voorkoming van malaria. (B1)
Antimikrobiese stowwe gesintetiseer in die natuur of in die laboratorium, synde stowwe wat gebruik word by die spesifieke behandeling van infeksie, uitgesonderd die volgende, wanneer bedoel vir plaaslike aanwending aan die epidermis, neusholtes en buite-oor:

basitrasien; (B1)
gramisidien; (B1)
griseofulvin; (B2)
mupirosien; (B2)
natamisien; (B2)
nistatien; (B2)
polimiksien B; (B1)
tirotrisien: (B1)

en uitgesonderd wanneer bedoel vir gebruik as kiemdoders en antiseptika, en uitgesonderd nistatien wanneer bedoel vir menslike vaginale gebruik, spesifiek vir die behandeling van herhalende vaginale kandidiase (B1), en uitgesonderd fenoksimetielpenisillien wanneer bedoel vir die voorkoming van rumatiekkoors (B3), en uitgesonderd wanneer bedoel vir gebruik soos hieronder aangedui en geregistreer kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947:

ampisillien, dihidrostreptomisien, kloksasillien, penetamaathidrojodied en prokaïenbesielpenisillien; intra-uierpreparate daarvan wanneer gekoppel aan merkerkleurstof, bedoel vir die behandeling van mastitis by beeste;

amprolium, dekokinaat, dinitolmied, etopabaat, lasalosied, maduramisien, monensien en narasien, wanneer bedoel as antikoksidiale middels;

avilamisien, avoparsien, flavofosfolipol, karbadoks, monensien, nitrovien, olkindiks, virginiamisien, en sinkbasitrasien, wanneer bedoel as groeistimulante; karnidasool, wanneer bedoel vir trichomonas by duiwe;

chloortetrasiklien, rolitetrasiklien, en tetrasiklien; inspuitings daarvan, bedoel vir behandeling van anaplasmose, hartwater, longontsteking, naelstringontsteking en vrotpootjie by skape en beeste;

chloortetrasiklien; kapsules daarvan, vir gebruik by duiwe;

chloortertasiklien- en trasiklienderivate, wanneer bedoel vir plaaslike aanwending in die bestuur van wonde by diere;

dimetridasool, wanneer bedoel vir trichomas by duiwe, as 'n antibakteriese middel by varke en as 'n groeistimulant; doksisiklien;

furaltadoon, wanneer bedoel as 'n enkel orale doseervorm vir die behandeling van gastro-intestinale infeksies;

higromisien, wanneer bedoel as 'n wurmmiddel by varke;

oksitetrasiklien;

salinomisien, wanneer bedoel as 'n antikoksidiale middel en as 'n groeistimulant;tilosien, wanneer bedoel vir byvoeging by drinkwater en voer vir toediening aan varke en hoenders.

Antisera vir veterinêre gebruik, uitgesonderd antisera geregistreer kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.

Antistolmiddels, uitgesonderd preparate bedoel vir aanwending aan die vel. (B1)

Apomorfien, wanneer aangedui vir die behandeling van erektiele disfunksie. (B2)

Apraklonidien.

Aprotinien.

Arabinosielsitosien.

Arprinosied, uitgesonderd wanneer bedoel en geregistreer as 'n antikoksidiale middel vir pluimvee kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.

Arseenamied, wanneer bedoel vir inspuiting.

Artemeter en die derivate daarvan.

Artemotil.

Asatriopien.

Asertarsoondiëtielamiensout, wanneer bedoel vir inspuiting.

Asiklovir, uitgesonderd wanneer bedoel vir aanwending aan die lippe in die vroeë behandeling van herhalende Herpes-simpleksvirusinfeksies. (B1)

Astemisool.

Atipamesool.

Atorvastatien.

Atosibaan.

Atovakwoon.

Atrakuriumbesilaat.

Baklofeen.

Basiliksimab.

Bemegried.

Betanechol.

Bimatoprost.

Biologiese middels, inspuitbare preparate daarvan, wanneer bedoel vir menslike gebruik, uitgesonderd tuberkulien wanneer bedoel vir menslike gebruik en uitgesonderd vaksiene wanneer bedoel vir menslike gebruik, en uitgesonderd polivalente slangbytteëgif. (B2)
Biperideen.
Bleomisien.
Bretiliumtosilaat.
Bromokriptien.
Bufenoïed.
Bumadisoon.
Buserelien.
Busulfaan.
Byegif, uitgesonderd preparate bedoel vir aanwending aan die vel.
Chimopapaïen, wanneer bedoel vir inspuiting.
Chloorambusiel.
Chloordantoïen, wanneer bedoel vir menslike vaginale gebruik.
Chlorokien, wanneer bedoel vir antirumatiese gebruik. (B1)
Dakarbasien.
Dakliksimab.
Daktinomisien (aktinomisien D).
Dantroleen.
Dapsoon en die derivate daarvan, tensy in 'n ander Bylae gelys.
Deferoksamien
Demekarium.
Desidurien.
Diasoksied.
Dichlorofeen, uitgesonderd preparate en mengsel bedoel vir aanwending aan die vel en uitgesonderd wanneer bedoel en geregistreer as 'n wurmmiddel kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.
Didanosien.
Diëtielkarbamasien.
Difemetoksidien.
Difenidol.
Dihidralasien.
Dihidrotagisterol.
Diïsopropielfluoorfosfaat.
Diklasuriel, uitgesonderd wanneer geregistreer as 'n antikosidiale preparaat kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.
Diklodroonsuur.
Dilasep.
Diloksaniedfuroaat.
Dimatielsulfoksied.
Diminaseen, uitgesonderd wanneer bedoel en geregistreer as 'n antibabesiale middel kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.
Dinatriumpamidronaat.
Dinitrofenol.
Dinoprostoon.
Diprenorfien.

Disofenol, uitgesonderd wanneer bedoel en geregistreer as 'n wurmmiddel kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.
Disopiramied.
Distigmien.
Ditasol.
Dobutamien.
Doksapraam.
Doksepin, wanneer bedoel vir aanwending aan die vel. (B5)
Doksorubisien.
Dolasetron.
Dopa.
Dopamien.
Dosetaksol.
Dounomisien (dounorubisien).
Drotekognien.
Edoksudien.
Edrofonium.
Efavirens.
Ekonasool, uitgesonderd wanneer bedoel vir aanwending aan die vel en wanneer bedoel vir menslike vaginale gebruik, spesifiek vir die behandeling van herhalende vaginale kandidiase. (S1)
Eletriptan.
Emetien, uitgesonderd stowwe, preparate en mengsels wat minder as 0,2 persent alkaloïede, berekn as emetien, bevat.
Enielkonasool, uitgesonderd wanneer bedoel vir aanwending aan die vel. (B1)
Enkaïnied.
Enoksasien.
Enrofloksasien.
Entakapoon.
Epirubisien (4-epidoksorubisien).
Ergotalkaloïede (natuurlik of sinteties), uitgesonderd peparate en mengsels daarvan wanneer bedoel vir die behandeling van migraine. (B2)
Esomeprasool.
Estramustien.
Etidronaat.
Etiprostoon.
Etofamied.
Etoglusied.
Etoposied.
Famotidien, uitgesonderd wanneer bedoel vir die korttermyn simptomatiese verligting van sooibrand veroorsaak deur oormaat suur, waar die maksimum dosis 10 milligram is, die maksimum daaglikse dosis (per 24 uur) 20 milligram is en die maksimum tydperk van behandeling 2 weke is. (B2)
Famsiklovir.
Fasadinium.
Febantel, uitgesonderd wanneer bedoel en geregistreer as 'n wurmmiddel kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.
Fenamidien, uitgesonderd wanneer bedoel en geregistreer as 'n antibabesiale middel kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.

Fenasetien, uitgesonderd preparate en mengsels wat vir uitwendige gebruik bedoel is en wat hoogstens 0,1 persent fenasetien as stabiliseerder bevat.
Fenchloorfos.
Fenielbutasoon en die derivate daarvan, tensy in 'n ander Bylae gelys.
Fenoksibesamien.
Fenopirasoon.
Fenoterol, wanneer bedoel vir die voorkoming of vertraging van kraam en preparate daarvan vir inspuiting. (B2, B3)
Fentikonasool.
Fertirelien.
Filgrastim.
Finasteried.
Fisostigmien, uitgesonderd oogpreparate daarvan wanneer ebdoel vir gloukoom. (B3)
Flekaïnied.
Flosekinaan.
Fludarabien.
Flugestoon.
Flukonasool.
Flunisolied.
Fluoriede; uitgesonderd mondelike medisinale preparate en mengsels daarvan wat 0,25 milligram of meer fluoor as fluoried per aanbevole daaglikse dosis bevat, tensy in 'n ander Bylae gelys. (B1)
Flurbiprofeen, wanneer bedoel vir oftalmiese gebruik. (B1, B2, B3)
Flusitosien.
Flutamied.
Fluvastatien.
Fondaparinuks.
Fotemustien.
Ftorafur.
Furasolidoon.
Galantamien.
Gallamien.
Ganireliks.
Gansiklovir.
Gehalogeneerde hidroksikinoliene, uitgesonderd wanneer bedoel vir aanwending aan die vel (B2), en uitgesonderd dijodiumhidroksikinolien wanneer bedoel en geregistreer geregistreer as 'n antikoksidiale preparaat kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.
Gemsitabien.
Gemtusumab.
Gestrinoon.
Glatiramer.
Glikosaminoglikaanpolisulfaat (voorheen mukopolisakkariedpoliswaelsuurester), uitgesonderd wanneer bedoel vir aanwending aan die vel. (B1)
Goserelien.
Granisetroon.
Halofantrien.
Halofenaat.

Halofuginoon, uitgesonderd wanneer bedoel en geregistreer as 'n antikoksidiale preparaat kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.
Heksoprenalien, wanneer bedoel vir voorkoming of vertraging van kraam, en preparate daarvan vir inspuiting. (B2, B3)
Hemien.
Heptaminol.
Hialironidase.
Hialironsuur en die derivate daarvan.
Hidroksi-ureum.
Hikantoon.
Hilaan.
Hormone (natuurlik of sinteties, met inbegrip van rekombinante vorme), met óf hormonale óf antihormonale werking, tensy in 'n ander Bylae gelys, uitgesonderd –

(a) wanneer spesifiek bedoel vir nood postkoïtale kontrasepsie; (B2)
(b) wanneer bedoel vir mondelike voorbehoedmiddels; (B2, B3)
(c) insulien; (B3)
(d) adrenalien (epinefrien); (B2, B3, B4)
(e) kortikotrofien (adrenokortikotropiese hormoon; AKTH); (B5)
(f) menslike groeihormoon (menslike somatotropien) – alle vorme ; (B5)
(g) seranol, estrogeen en progesteroon, wanneer bedoel en geregistreer as 'n veterinêre produksieverbeteringsmiddel kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947;
(h) BST (beessomatotropien), wanneer bedoel en geregistreer as 'n veemiddel kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.

Ibandroonsuur.
Ibutilied.
Idarubisien.
Idoksuridien, uitgesonderd wanneer bedoel vir aanwending aan die vel. (B1)
Iloprost.
Imatinib.
Imidokarb, uitgesonderd wanneer bedoel en geregistreer as 'n antibabesiale middel vir die behandeling van babesiose kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.
Imigluserase.
Imikimod.
Indinavir.
Infliksimab.
Inosipleks (inosienpranobeks)
Interferon alfa.
Interferon beta.
Interferon gamma.
Intra-uteriene toestelle.
Intrifibaan.
Irinotekaan.
Isepamisien.

Isokonasool, uitgesonderd wanneer bedoel vir aanwending aan die vel en wanneer bedoel vir menslike vaginale gebruik, spesifike vir die behandeling van herhalende vaginale kandidiase. (B1)
Isoksuprien.
Isopirien.
Isoprenalien (isoproterenol), wanneer bedoel vir inspuiting. (B2, B3)
Itrakonasool.
Kabergolien.
Kaliumdichromaat, uitgesonderd preparate en mengsels wat hoogstens 15 mikrogram kaliumdichromaat per dosiseenheid bevat.
Kalsitonien.
Kalsiumpolistireensulfonaat, wanneer bedoel vir terapeutiese doeleindes.
Kambendasool.
Kapesitabien.
Karbachol, uitgesonderd oogpreparate daarvan, wanneer bedoel vir gloukoom. (B3)
Karbidopa.
Karboplatien.
Karbuterol, wanneer bedoel vir inspuiting. (B2, B3)
Karmustien.
Ketokonasool, uitgesonderd preparate en mengsels wat hoogstens 1,0 persent ketakonasool bevat, wanneer bedoel vir die voorkoming en behandeling van skilfers, en uitgesonder wanneer bedoel vir aanwending aan die vel. (B0, B1)
Ketorolaktrometamol, uitgesonderd wanneer bedoel vir oftalmiese gebruik. (B3)
Kinoriumsulfaat, uitgesonderd wanneer bedoel en geregistreer as 'n antibabesiale middel kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.
Kladribien.
Klanobutien.
Klasuriel, uitgesonderd wanneer bedoel en geregistreer as 'n antikoksidiale preparaat kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.
Klenbuterol.
Klofasimien.
Klomifeen.
Klosantel, uitgesonderd wanneer bedoel en geregistreer as 'n wurmmiddel kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.
Klotrimasool, uitgesonderd wanneer bedoel vir aanwending aan die vel en wanneer bedoel vir menslike vaginale gebruik, spesifiek vir die behandeling van herhalende vaginale kandidiase. (B1)
Kolfoseriel.
Kortikosteroïede (natuurlik of sinteties), tensy in 'n ander Bylae gelys (B5), uitgesonderd –

(a) hidrokortisoon en hidrokortisoonasetaat wanneer gebruik as 'n ankele aktiewe bestanddeel met 'n maksimum konsentrasie van 1,0 persent in preparate bedoel aanwending aan die vel; (B2)
(b) triamsinoloon, wanneer bedoel vir aanwending aan mondletsels; (B2) en
(c) wanneer dit voorkom in preparate bedoel vir inaseming. (B2, B3)

Kotetroksasien.
Kotrimoksasool.

Kwik; preparate en mengsels wat kwikmetaal bevat en bedoel is vir medisinale gebruik.
Lamivudien.
Lansoprasool, uitgesonderd wanneer bedoel vir die tydelike korttermynverligting van sooibrand en hiperasiditeit, onderworpe aan –
(a) 'n maksimum daaglikse dosis van 15 milligram;
(b) 'n maksimum tydperk van behandeling van 14 dae. (B2)
L-asparaginase.
Latanoprost.
Leflunomied.
Letrosool.
Levallorfan.
Levamisool, uitgesonderd wanneer bedoel en geregistreer as 'n wurmmiddel en 'n immunomoduleerder kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.
Levobupivakaïen.
Liarosool.
Lisosiem, uitgesonderd preparate en mengsels wanneer bedoel vir aanwending aan die vel. (B1)
Lokale anestetika, wanneer bedoel vir oftalmiese neparenterale gebruik, uitgesonderd oksibuprokaïen, proksimetakaïen en tatrakaïen, wanneer dit voorkom in oogdruppels bedoel vir noodbehandeling van sweis-oë, en uitgesonderd lignokaïen wanneer dit voorkom in antimikrobiese preparate vir inspuiting asook in oogpreparate geregistreer kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.
Lopinavir.
Lovastatien.
Lumefantrien.
Lumostien.
Mefentermien.
Meflokien.
Mekamielamien.
Meksiletien.
Melarsoprol, wanneer bedoel vir inspuiting.
Melfalaan en die derivate daarvan, tensy in 'n ander Bylae gelys.
Mepirisool.
Mesna, wanneer bedoel vir inspuiting. (B2)
Metacholien.
Metampiroon.
Metaproterenol (orsiprenalien), wanneer bedoel vir die voorkoming of vertraging van kraam, en preparate daarvan vir inspuiting.(B2, B3)
Metergolien.
Metisergied.
Metoklopramied.
Metokssaleen.
Metomidaat.
Metotreksaat.
Metronidasool.
Mifepristoon.
Miglitol.

Mikonasool, uitgesonderd wanneer bedoel vir aanwending aan die vel en uitgesonderd wanneer bedoel vir menslike vaginale gebruik, spesifiek die behandeling van herhalende vaginale kandidiase, en uitgesonderd wanneer bedoel vir menslik gebruik in preparate wat hoogstens 2 persent mikonasool bevat en bedoel is vir die plaaslike behandeling van fungusinfeksies van die mond (orale kandidiase). (B2)
Milrinoon.
Miltefosien.
Minoksidiel, uitgesonderd wanneer bedoel vir aanwending aan die kopvel. (B2)
Misolastien.
Misoprostol.
Mitoksantroon.
Mitomisien C.
Mivakurium.
Mofebutasoon.
Molgramostim.
Mometasoon.
Morasisien.
Morasoon.
Morfasienamied.
Morfetielbutyn.
Mukoglukoronaan.
Muromonab.
Nalidiksiensuur.
Naloksoon.
Nalorfien.
Naltreksoon.
Naraptriptaan.
Natriumdihidroasapentaseenpolisulfonaat.
Natriumfloried; uitgesonderd mondelike medisinale preparate en mengsels daarvan wat 40 milligram of meer per daaglikse dosis bevat. (B1).
Natriumkromoglikaat, wanneer bedoel vir veterinêre gebruik. (B2)
Natriumnitroprussied.
Nefopaam.
Nelfinavir.
Neostigmien.
Netobimien.
Nevirapien.
Nifuratel.
Nikarbasien, uitgesonderd wanneer bedoel en geregistreer as 'n antikoksidiale preparaat kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.
Niketamied.
Nilutamied.
Nimorasool.
Nimustien.
Niridasool.
Nisatidien, uitgesonderd wanneer bedoel vir mondelike toediening vir die korttermyn simptomatiese verligting van sooibrand en hiperasisditeit, waar die maksimum

dosis 150 milligram is, die maksimum daaglikse dosis 300 milligram is en die maksimum tydperk van behandeling 2 weke is. (B2)

Nitrofuraantoïen, uitgesonderd preparate daarvan bedoel vir aanwending aan die vel. (B1)

Nitrofurasoon, uitgesonderd preparate daarvan bedoel vir aanwending aan die vel. (B1)

Nitroksiniel, uitgesonderd wanneer bedoel en geregistreer as 'n wurmmiddel kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.

Nitroksolien.

Obidoksiem.

Oksfendasool, uitgesonderd wanneer bedoel en geregistreer as 'n wurmmiddel kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.

Oksibuprokaïen, uitgesonderd wanneer dit voorkom in oogdruppels bedoel vir die noodbehandeling van sweis-oë. (B2)

Oksiklosanied, uitgesonderd wanneer bedoel en geregistreer as 'n wurmmiddel kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.

Oksoliensuur.

Oktreotied.

Omeprasool.

Ondansetroon.

Ouranofien.

Paklitaksel.

Palivisumab.

Paltitreksied.

Pamidroonsuur.

Pankuronium.

Pantoprasool.

Parikalsitrol.

Penisillamien.

Pensiklovir, uitgesonderd wanneer bedoel vir aanwending aan die lippe in die vroeë behandeling van hethalende Herpes-simpleksvirusinfeksies. (B1)

Pentamidienisetionaat.

Pentostatien.

Pergolied.

Perheksilien.

Pimekrolimus.

Pipemidiensuur.

Pirensepien.

Piribediel.

Piridinolkarbamaat.

Piridogstimien.

Piromidiensuur.

Podofillumhars; preparate en mengsels wat meer as 20 persent podofillumhars bevat. (B1)

Poligliserileendekstraan.

Poraktant alfa.

Pralidoksien.

Pramipeksool.

Prasikwantel, uitgesonderd wanneer bedoel en geregistreer as 'n wurmmiddel kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.
Pravastatien.
Prokaïenamied.
Prokarbasien.
Proksimetakaïen, uitgesonderd wanneer dit voorkom in oogdruppels bedoel vir die noodbehandeling van sweis-oë. (B2)
Propafenoon.
Propentofillien, uitgesonderd wanneer bedoel vir veterinêre gebruik.
Propielheksedrien, uitgesonderd wanneer gebruik as 'n bloedvaatvernouer en ontstuwer in neuspreparate en inasemmiddels. (B1)
Proteolitiese (fibrinolitiese) ensieme, wanneer bedoel vir inspuiting. (B1)
Rabeprasool.
Radioaktiewe verbindings, wanneer vir diagnostiese doeleindes gebruik word.
Rafoksanied, uitgesonderd wanneer bedoel en geregistreer as 'n wurmmiddel kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.
Raktopamien, wanneer gebruik as 'n veterinêre produksieverbeteringsmiddel.
Rapakuronium.
Rasburikase.
Rekombinante mensweefseltipe plasminogeenaktiveerder (rt-PA).
Resorantel, uitgesonderd wanneer bedoel en geregistreer as 'n wurmmiddel kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.
Rilusool.
Rimiterol, wanneer bedoel vir inspuiting. (B2, B3)
Risatriptaan.
Ritodrien.
Ritonavir.
Rituksimab.
Roksatidien.
Rokuroniumbromied.
Ropinirool.
Rosoksasien.
Rosuvastatien.
sakinavir.
Salbutamol, wanneer bedoel vir inspuiting. (B2, B3)
Salmefamol, wanneer bedoel vir inspuiting. (B2, B3)
Salsitabien.
Sanamivir.
Selegilien.
Seleniumsoute, preparate daarvan vir inspuiting, wanneer bedoel vir veterinêre gebruik.
Semorelien.
Serivastatien.
Sertakonasool, uitgesonderd wanneer bedoel vir aanwending aan die vel. (B1)
Sertindool.
Seruletied.
Sidovudien (AZT).
Siklofeniel.
Siklofosfamied en die derivate daarvan, tensy in 'n ander Bylae gelys.
Siklosporien.

Sildenafil.
Simvastatien.
Siprenorfien.
Siproteroonasetaat.
Sirolimus.
Sisapried.
Sisatrakurium.
Sisplatien.
Sitarabien.
Soledroonsuur.
Solkoseriel, uitgesonderd preparate bedoel vir aanwending aan die vel, aan die slymvliese van die mond en aan die lippe en uitgesonderd oogpreparate daarvan. (B0, B3)
Solmitriptaan.
Stavudien.
Stikstofoksiedgas, alleen of in kombinasie met ander gasse.
Stiramaat.
Streptokinase.
Strignien, onderworpe daaraan dat vir die bestryding van probleemroofdiere wat soogdiere is –

(a) dit verskaf word slegs op skriftelike voorskrif van 'n Staatsveearts vir gebruik in daardie Staatsveearts se regsgebied, tot 'n hoeveelheid van hoogstens 5 gram; en
(b) die Staatsveearts vooraf skriftelike goedkeuring vir sodanige gebruik verkry van die Direkteur van die betrokke provinsiale bewaringsinstansie of -owerheid in sy of haar regsgebied, waarvan 'n afskrif aan die skriftelike voorskrif geheg moet word;

en uitgesonderd preparate en mengsels daarvan wat hoogstens 0,2 persent strignien bevat wanneer by Bylae 2 ingesluit.
Suksamentonium.
Suksetonium.
Sulfoonamiede, uitgesonderd –

(a) stowwe, preparate en mengsels bedoel vir aanwending aan die oë, neusholtes en vagina; (B2)
(b) silwersulfadiasien, wanneer bedoel vir aanwending aan die vel, vir die korttermynbehandeling van geringe brandwonde, onderwopre daaraan dat die verpakking beperk word tot tot hoogstens 50 gram; (B2)
(c) uitgesonderd wanneer geregistreer kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.

Sumatriptan.
Suramien.
Tadalafiel.
Takrien.
Takrolimus.
Tamoksifeen.
Tamsulosien.
Tasonermin.
Tegafur.
Tegaserod.
Temosolomied.

Tenekteplaas.
Teniposied.
Teofillien en die derivate daarvan, tensy in 'n ander Bylae gelys; preparate bedoel vir inspuiting. (B2)
Terbinafien, uitgesonderd wanneer bedoel vir aanwending aan die vel. (B1)
Terfenadien.
Teriparatied.
Terkonasool.
Tetramisool, uitgesonderd wanneer bedoel en geregistreer as 'n wurmmiddel kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.
Tiabendasool, uitgesonderd wanneer bedoel vir aanwending aan die vel (B1) en uitgesonderd wanneer bedoel en geregistreer as 'n wurmmiddel kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.
Tiberkulien, wanneer bedoel vir veterinêre gebruik. (B2)
Tiboloon.
Tiludroonsuur.
Timopentien.
Tinfluoried, wanneer bedoel vir inspuiting.
Tinidasool.
Tioguanien.
Tiokonasool, uitgesonderd wanneer bedoel vir aanwending aan die vel en wanneer bedoel vir menslike vaginale gebruik, spesifiek vir die behandeling van herhalende vaginale kandidiase. (B1)
Tirilasad.
Tokaïnied.
Tolkapoon.
Tolrestaat.
Toltrasuriel, uitgesonderd wanneer bedoel en geregistreer as 'n antikoksidiale preparaat kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.
Topotekaan.
Torimefeen.
Traneksaamsuur.
Trastusumab.
Treosulfaan.
Triëtileentiofosforamied.
Trifluorotimidien.
Triklabedasool, uitgesonderd wanneer bedoel vir aanwending aan die vel (B1) en uitgesonderd wanneer bedoel en geregistreer as 'n wurmmiddel kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.
Trimetafaan.
Trimetopriem, uitgesonderd wanneer spesifiek bedoel en geregistreer vir die behandeling van gastro-enteritis en longontsteking kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.
Trimetreksaat.
Triokssaleen.
Triptorelien.
Tromantadien.
Trometamol.
Tropisetron.

Tubokurarien.
Unoprostoon.
Urapidiel.
Uretaan.
Urokinase.
Vaksiene vir veterinêre gebruik, uitgesonderd wanneer geregistreer kragtens die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947.
Valasiklovir.
Vanilliensuurdiëtielamied.
Vardenafiel.
Vasoaktiewe intestinale polipeptied.
Vekuroniumbromied.
Verteporfin.
Vidarabien.
Vinblastien.
Vindesien.
Vinkristien.
Vinorelbien.
Vorikonasool.

– EINDE VAN BYLAE 4 –

BYLAE 5 EN GESPESIFISEERDE BYLAE 5

(a) Alle stowwe bedoel in hierdie Bylae sluit die volgende in:

(i) Die soute en esters van sodanige stowwe, indien die bestaan van sodanige soute en esters moontlik is; en
(ii) alle preparate en mengsels van sodanige stowwe, waar sodanige preparate en mengsels nie uitdruklik uitgesluit word nie.

(b) Ingevolge artikel 22A(5)(f) van die Wet mag 'n praktisyn, verpleegkundige of 'n persoon wat kragtens die Wet op Gesondheidsberoepe, 1974 (Wet No. 56 van 1974), geregistreer is, uitgesonderd 'n geneesheer of tandarts, die Bylae 5-stowwe en -medisyne waarvoor in die Aanhangsels voorsiening gemaak word, voorskryf en aan pasiënte onder sy of haar sorg verskaf slegs binne die bestek van sy of haar praktyk en behoudens die voorwaardes bepaal deur die Medisynebeheerraad. Die voorwaardes en Aanhangsels sal in die *Staatskoerant* gepubliseer word.

(c) Gespesifiseerde Bylae 5-stowwe in hierdie bylae vermeld, is onderworpe aan bykomende beheer ingevolge artikel 22A van die Wet, soos vereis by die 1971-Konvensie oor Psigotropiese Stowwe, en word deur "**" aangedui.

Amisulpried.

Amitriptilien en die derivate daarvan, tensy in 'n ander Bylae gelys
Amoksapien.
Androstanoloon.
Androsteendiol.
Anestetiese preparate wat pregnaandioonderivate bevat.
Aponal.
Apronalied.
Asasiklonol.
Asitretien.
Barbituursuur** en die derivate** daarvan, tensy in 'n ander Bylae gelys, uitgesonderd –

(a) amobarbitaal, siklobarbitaal, pentobarbitaal en sekobarbitaal; (B6) en

(b) preparate en mengsels wat hoogstens 90 milligram fenobarbitaal** per minimum aanbevole of voorgeskrewe dosis bevat wanneer bedoel vir aanhoudende gebruik by epilepsie. (B3)

Benakstisien en die derivate daarvan, yensy in 'n ander Bylae gelys.
Benfluramaat.
Benskinamied.
Bensodiasepiene** en die derivate** daarvan, tensy in 'n ander Bylae gelys, en uitgesonderd flunitrasepaam. (B6)
Bensoktamien.
Beta-aminopropielbenseen en beta-aminoïsopropielbenseen, enige verbinding struktureel afkomstig van hierdie stowwe deur substitusie in die syketting of deur ringsluiting daarin (of deur substitusie as ringsluiting) en enige sout of stof wat hieronder val, uitgesonderd preparate en mengsels van bogenoemde wanneer dit gebruik word as bloedvaatvernouers en ontstuwers in antihistaminiese neus- en oogpreparate, en uitgesonderd wanneer dit voorkom in inasemtoestelle waarin die stof in soliede materiaal geabsorbeer is, en uitgesonderd katien((+)-norpseudoëfedrien), N-diëtielaminoëtielefedrien, efedrien, etafedrien, fenielpropanolamien, N-metielfedrien en prenielamien en preparate en mengsels daarvan, uitgesonderd stowwe gelys in Bylae 7. (B1, B2, B7)
Bolandiol.
Bolasteroon.
Boldenoon.
Bromiede; preparate en mengsels daarvan wat 80 milligram of meer broom as bromied per aanbevole daaglikse dosis bevat; uitgesonderd wanneer spesifiek verpak, geëtiketteer en gebruik vir nywerheidsdoeleindes, met inbegrip van die vervaardiging of opmaak van verbruikersitems of -produkte wat geen farmakologiese werking of gebruik as geneesmiddel het nie, wat bedoel is om deur die mens of diere as voedsel ingeneem te word of as kosmetiese middel aan die liggaam aangewend te word, en wat vir sodanige gebruik kragtens die Wet op Voedingsmiddels, Skoonheidsmiddels en Ontsmettingsmiddels, 1972 (Wet No. 54 van 1972), goedgekeur is, en vir analitiese doeleindes. (B2)
Broomisovalum.
Brotisolaam.**
Bupropioon.
Buspiroon.
Butirofenone.
Butriptilien.

Chlooprotikseen.
Chloormesanoon, uitgesonderd mengsels daarvan waar die maksimum aanbevole of voorgeskrewe dosis nie 100 milligram chloormesanoon oorskry nie. (B2)
Chloraalderivate, tensy in 'n ander Bylae gelys.
dansol.
Deanol en die derivate daarvan, tensy in 'n ander Bylae gelys, uitgesonderd wanneer spesifiek verpak, geëtiketteer en gebruik vir nywerheidsdoeleindes, met inbegrip van die vervaardiging of opmaak van verbruikersitems of -produkte wat geen farmakologiese werking of gebruik as geneesmiddel het nie, wat bedoel is om deur die mens of diere as voedsel ingeneem te word of as kosmetiese middel aan die liggaam aangewend te word, en wat vir sodanige gebruik kragtens die Wet op Voedingsmiddels, Skoonheidsmiddels en Ontsmettingsmiddels, 1972 (Wet No. 54 van 1972), goedgekeur is.
Dehidrochloormetieltestosteroon.
Deksfenfluramien.
Deksmedetomidien.
Dekstropropoksifeen; derivate en megsels daarvan vir mondelike gebruik wat hoogstens 135 milligram dekstropropoksifeen, as basis bereken, per dosiseenheid bevat of met 'n konsentrasie van hoogstens 2,5 persent in onverdeelde preparate. (B6)
Desfluraan.
Detomidien.
Diprenorfien.
Doksepien, uitgesonderd wanneer bedoel vir aanwending aan die vel. (B4)
Donepesil.
Dotiëpien.
Droperidol.
Drostanoloon.
Efedrien (natuurlik of sinteties), uitgesdonderd wanneer dit voorkom in produkte geregistreer kragtens die Wet. (B1, B2)
Ekotiofaat.
Emielkamaat.
Enfluraan.
Epitiostanol.
Essitalopraam.
Etchloorvinol.**
Eter (diëtieleter); uitgesonderd stowwe, preparate en mengsels wat meer as 20 persent eter bevat. (B1)
Etielestrenol.
Etinamaat** en derivate** daarvan, tensy in 'n ander Bylae gelys.
Etodroksisien, uitgesonderd preparate en mengsels daarvan wanneer dit uitsluitlik as 'n antihistamien gebruik word. (B2)
Etomidaat.
Etretinaat.
Fenetielhidrasien.
Fenfluramien.
Fenkamfamien.**
Fenotiasien en die derivate daarvan, tensy in 'n ander Bylae gelys, uitgesonderd preparate en mengsels wat prometasien of dimetotiasien of hulle soute bevat, wanneer dit uitsluitlik as 'n antihistamien (B2) gebruik word en uitgesonderd

preparate wat prometasien of die soute daarvan bevat, wanneer dit spesifiek bedoel is vir die behandeling van reissiekte of aanwending aan die vel (B2), en uitgesonderd fenotiasien, wanneer bedoel engeregistreer as 'n wurmmiddel kragtens die Wet op Misstowwe, Veevoer, Landboumiddels en Veemiddels, 1947 (Wet No. 36 van 1947).

Fentermien.**
Flumaseniel.
Fluoksetien.
Fluoksimesterron.
Flupentiksol.
Fluspirileen.
Fluvoksamien.
Formeboloon.
Furasabol.
Haloperidol.
Halotaan.
Hedonaal en die esters daarvan, uitgesonderd wanneer spesifiek verpak, geëtiketteer en gebruik vir nywerheidsdoeleindes, met inbegrip van die vervaardiging of opmaak van verbruikersitems of -produkte wat geen farmakologiese werking of gebruik as geneesmiddel het nie, wat bedoel is om deur die mens of diere as voedsel ingeneem te word of as kosmetiese middel aan die liggaam aangewend te word, en wat vir sodanige gebruik kragtens die Wet op Voedingsmiddels, Skoonheidsmiddels en Ontsmettingsmiddels, 1972 (Wet No. 54 van 1972), goedgekeur is.
Hidroksisien.
Imipramien en die derivate daarvan, tensy in 'n ander Bylae gelys.
Iproniasied.
Isofluraan.
Isotretinoïen.
Karbromaal.
Ketamien.
Klomakraan.
Klometiasool (voorheen bekend as "heminevrien").
Klomipramien.
Klopentiksol.
Klostebol.
Klotiapien.
Kortikotrofien (adrenokortikotropiese hormoon: AKTH)
Litiumsoute, wanneer bedoel vir medisinale gebruik, uitgesonderd wanneer bedoel vir aanwending aan die vel. (B2)
Lofepramien.
Loksapien.
L-triptofaan, wanneer bedoel vir medisinale gebruik, uitgesonderd wanneer bedoel vir medisinale gebruik as aanvulling vir voedingkundige doeleindes. (B1)
Maprotilien.
Masindol.**
Mebolasien.
Mechlooretamien en die derivate daarvan, tensy in 'n ander Bylae gelys.
Medetomedien.
Mefenoksaloon.

Meklofenoksaat.
Melitraseen.
Menslike groeihormoon (menslike somatotropien – alle vorme).
Meprobamaat.**
Mesteroloon.
Metandiënoon.
Metandranoon.
Metandriol.
Metenoloon.
Metieltestosteroon.
Metoksifluraan.
Metrifonaat.
Mianserien.
Miboleroon.
Milnasipran.
Mirtasapien.
Moklobemied.
Molindoon.
Nalbufien.
nandrollon.
Nefasodoon.
Nomifensien.
Noretandroloon.
Norklostebol.
Oksaboloon.
Oksandroloon.
Oksimesteroon.
Oksimetoloon.
Oksipertien.
Olansapien.
Paraldehied.
Pargilien.
Paroksetien.
Pemolien** en die komplekse** daarvan.
Pimetikseen, uitgesonderd preparate en mengsels daarvan wanneer uitsluitlik as 'n antihistamien gebruik. (B2)
Pimosied.
Pipradrol.**
Pisotifeen, uitgesonderd preparate en mengsels daarvan wanneer uitsluitlik as 'n antihistamien gebruik of wanneer bedoel vir die voorkoming van migraine. (B2)
Prasteroon (dihidroëpiandrosteroon, DHEA).
Prolintaan.
Propofol.
Reboksetien.
Risperidoon.
Rivastigmien.
Romifidien.
Saleplon.
Sertralien.

Sevofluraan.
Sibutramien.
Siklobensaprien.
Simelidien.
Siprasidoon.
Sitalopraam.
Solasepaam.
Solpidem.**
Sopikloon.
Sotepien.
Stanosolol.
Stenboloon.
Sulfoonmetaan.
Sulpiried.
Testolaktoon.
Testosteroon, uitgesonderd subkutane inplantings daarvan wat spesifiek bedoel is vir en geregistreer is as 'n veterinêre produksieverbeteringsmiddel kragtens die Wet op Misstowwe, Veevoer, Landboumiddels en Veemiddels, 1947.
Tiapried.
Tiletamien.
Tioguanosien.
Tiotikseen.
Tisanidien.
Tramadol.
Tranielsipromien.
Trasodoon.
Trenboloon, uitgesonderd subkutane inplantings daarvan wat spesifiek bedoel is vir en geregistreer is as 'n veterinêre produksieverbeteringsmiddel kragtens die Wet op Misstowwe, Veevoer, Landboumiddels en Veemiddels, 1947.
Triheksifenidiel.
Venlafaksien.
Viloksasien.
Xilasien.
Zuklopentiksol.

– EINDE VAN BYLAE 5 –

BYLAE 6

(a) Alle stowwe bedoel in hierdie Bylae sluit die volgende in (tensy uitdruklik uitgesluit of tensy in 'n ander Bylae gelys):

(i) Die isomere van sodanige stowwe, indien die bestaan van sodanige isomere binne die spesifieke chemiese benaming moontlik is;

(ii) die esters en eters van sodanige stowwe en van die isomere bedoel in (i), asook die isomere van sodanige esters en eters, indien die bestaan van sodanige esters, eters en isomere moontlik is;

(iii) die soute van sodanige stowwe en van die isomere bedoel in (i), asook die soute van die esters, eters en isomere bedoel in (ii), waar die bestaan van sodanige soute moontlik is;

(iv) die isomere van enige van die soute bedoel in (iii), waar die bestaan van sodanige isomere moontlik is;

(v) alle preparate en mengsels van enige van bogenoemde.

(b) Ingevolge artikel 22A(5)(f) van die Wet mag 'n praktisyn, verpleegkundige of 'n persoon wat kragtens die Wet op Gesondheidsberoepe, 1974 (Wet No. 56 van 1974), geregistreer is, uitgesonderd 'n geneesheer of tandarts, die Bylae 6-stowwe en -medisyne waarvoor in die Aanhangsels voorsiening gemaak word, voorskryf en aan pasiënte onder sy of haar sorg verskaf slegs binne die bestek van sy of haar praktyk en behoudens die voorwaardes bepaal deur die Medisynebeheerraad. Die voorwaardes en Aanhangsels sal in die *Staatskoerant* gepubliseer word.

{(-)-transdelta-9-tertrahidrokannabinol – sien dronabinol}
Alfametadol.
Alfaprodien.
Alfasetielmetadol.
Alfentaniel.
Allielprodien.
Amobarbitaal.
Anileridien.
Asetieldihidrokodeïen, uitgesonderd preparate en mengsels , wanneer opgemaak met een of meer aktiewe medisinale bestanddele en wat hoogstens 20 milligram asetieldihidrokodeïen (as basis) per dosiseenheid bevat, en uitgesonderd vloeibare preparate en mengsels vir mondelike toediening wat hoogstens 20 milligram asetieldihidrokodeïen (as basis) per 5 milliliter dosiseenheid bevat. (B2)
Asetilemetadol.
Asetorfien.
Bensetidien.
Bensfetamien.
Bensielmorfien.
Besitramied.
Betameprodien.
Betametadol.
Betaprodien.
Betasetielmetadol.
Buprenorfien.
Butalbitaal.
Butorfanol.

Chloorfentermien.
Chlorodien ("Chloroform and Morphine Tincture BP 1980") of enige preparaat of mengsel daarvan beskryf as chlorodien; uitgesonderd preparate en mengsels wat hoogstens 0,5 persent chlorodien in samestelling met ander aktiewe medisinale bestanddele bevat. (B2)
Dekstromoramied.
Dekstropropoksifeen, uitgesonderd preparate en mengsels vir mondelike gebruik wat hoogstens 135 milligram dekstropropoksifeen, as basis bereken, per dosiseenheid bevat of met 'n konsentrasie van hoogstens 2,5 persent in onverdeelde preparate. (B5)
Desomorfien.
Diampromied.
Diëtielpropioon (amfepramoon).
Diëtieltiambuteen.
Difenoksien (of difenoksielsuur), uitgesonderd mengsels wat per dosiseenheid hoogstens 0,5 milligram difenoksien, as basis bereken, bevat asook 'n hoeveelheid atropiensulfaat gelyk aan minstens 5,0 persent van sodanige hoeveelheid difenoksien, as basis bereken, as wat in die mengsel is. (B2)
Difenoksilaat, uitgesonderd preprate wat hoogstens 2,5 milligram difenoksilaat, as basis berekn, en minstens 25 mikrogram atropiensulfaat per dosiseenheid bevat. (B1)
Dihidroëtorfien.
Dihidrokodeïen, uitgesonderd preparate en mengsels wanneer opgemaak met een of meer aktiewe medisinale bestanddele en wat hoogstens 20 milligram dihidrokodeïen (as basis) per dosiseenheid bevat, en uitgesonderd vloeibare preprate en mengsels vir mondelike toediening wat hoogstens 20 milligram dihidrokodeïen (as basis) per 5 milliliter dosiseenheid bevat. (B2)
Dihidromorfien.
Dimefeptanol.
Dimenoksadol.
Dimetieltiambuteen.
Dioksafetielbutiraat.
Dipipanoon.
Dronabinol ((-)-transdelta-9-tertrahidrokannabinol), wanneer bedoel vir terapeutiese doeleindes.
Ekgonien, en die esters en derivate daarvan wat veranderbaar is in ekgonien en kokaïen.
Etielmorfien; uitgesonderd preparate en mengsels wanneer opgemaak met een of meer aktiewe medisinale bestanddele en wat hoogstens 20 milligram etielmorfien (as basis) per dosiseenheid bevat en uitgesonderd vloeibare preprate en mengsels vir mondelike toediening wat hoogstens 20 milligram etielmorfien (as basis) per 5 milliliter dosiseenheid bevat. (B2)
Etilemetieltiambuteen.
Etokseridien.
Etonitaseen.
Etorfien en analoë.
Fenadoksoon.
Fenampromied.
Fenasosien.
Fendimetrasien.

Fenomorfaan.
Fenoperidien.
Fenproporeks.
Fentaniel, wanneer bedoel vir terapeutiese doeleindes. (B7)
Flunitrasepaam.
Folkodien, uitgesonderd preparate en mengsels wanneer opgemaak met een of meer aktiewe medisinale bestanddele en wat hoogstens 20 milligram folkodien (as basis) per dosiseenheid bevat en uitgesonderd vloeibare preprate en mengsels vir mondelike toediening wat hoogstens 20 milligram folkodien (as basis) per 5 milliliter dosiseenheid bevat. (B2)
Furetidien.
Glutetimied.
Hidrokodoon (dihidrokodeïnoon).
Hidroksiepetidien.
Hidromorfinol (14hidroksidihidromorfien).
Hidromorfoon (dihidromorfinoon).
Isometadoon.
Katien ((+)-norpseudoëfedrien), uitgesonderd preparate en mengsels wat hoogstens 50 milligram katien per dosiseenhedi bevat. (B2)
Ketobemidoon.
Klonitaseen.
Kodeïen (metielmorfien); uitgesonderd preparate en mengsels wanneer opgemaak met een of meer aktiewe medisinale bestanddele en hoogstens 20 milligram kodeïen (as basis) per dosiseenheid en uitgesonderd vloeibare prparate en mengsels vir mondelike toediening wat hoogstens 20 milligram kodeïen (as basis) per 5 milliliter dosiseenheid bevat. (B2)
Kodoksiem.
Kokablare en enige sout, verbinding, derivaat of preparaat van kokablare, en enige sout, derivaat of prepraat daarvan wat chemies ekwivalent of identies is aan enige van hierdie stowwe, hetsy direk of indirek verkry deur ekstraksie uit materiaal of stowwe van plantaardige afkoms, of onafhanklik verkry deur middel van chemiese sintese, of deur 'n kombinasie van ekstraksie en chemiese sintese, uitgesonderd gedekokaïniseerde kokablare en ekstraksies van kokablare waar sodanige ekstraksies geen kokaïen of ekgonien bevat nie.
Levofarnol.
Levofenasielmorfaan.
Levomoramied.
Mefenoreks.
Meklokaloon.
Meptasinol.
Metadoon.
Metadoon-tussenstof.
Metasosien.
Metieldesorfien.
Metieldihidromorfien.
Metielfenidaat en die derivate daarvan, tensy in 'n ander Bylae gelys.
Metopoon.
Metorfaan, met inbegrip van levometorfaan en rasemtorfaan, maar uitgesonderd dekstrometorfaan. (B2)
Mirofien (miristielbensielmorfien).

Moramied-tussenstof.
Morferidien.
Morfien, uitgesonderd preparate en mengsels van morfien wat hoogstens 0,2 persent morfien, bereken as anhidriese morfien, bevat. (B2)
Morfienmetobromied en ander pentavalente stikstofmorfienderivate.
Morfien-N-oksied en die derivate daarvan.
Nikokodien.
Nikomorfien.
Norasimetadol.
Norkodeïen; uitgesonderd preparate en mengsels wanneer opgemaak met een of meer aktiewe medisinale bestanddele en wat hoogstens 20 milligram norkodeïen (as basis) per dosiseenheid bevat en uitgesonderd vloeibare preprate en mengsels vir mondelike toediening wat hoogstens 20 milligram norkodeïen (as basis) per 5 milliliter dosiseenheid bevat. (B2)
Norlevorfanol.
Normetadoon.
Normorfien (demetielmorfien of N-gedemetileerde morfien).
Norpipanoon.
Oksidoon (14-hidroksidihidrokodeïnoon of dihidrohidroksikodeïoon).
Oksimorfoon (14-hidroksidihidromorfinoon of dihidrohidroksimorfinoon).
Opium en opiate en enige sout, verbinding, derivaat of preparaat van opium of opiate, hetsy direk of indirek verkry deur ekstraksie uit materiaal of stowwe van plantaardige afkoms, of onafhanklik verkry deur middel van chemiese sintese, of deur 'n kombinasie van ekstraksie en chemiese sintese, uitgesonderd mengsels wat hoogstens 0,2 persent morfien, bereken as anhidriese morfien, bevat. (B2)
Opiumpapawer of papawerstrooi, hetsy direk of indirek verkry deur ekstraksie uit materiaal of stowwe van plantaardige afkoms, of onafhanklik verkry deur middel van chemiese sintese, of deur 'n kombinasie van ekstraksie en chemiese sintese.
Pentasosien.
Pentobarbitaal.
Petidien, petidien-tussenstof A, petidien-tussenstof B en petidien-tussenstof C. (B8)
Piminodien.
Piritramied.
Proheptasien.
Properidien.
Propiraam.
Rasemoramied.
Rasemorfaan.
Remifentaniel.
Sekobarbitaal.
Siklobarbitaal.
Sipeprol.
Sufentaniel.
Tebaïen.Tilidien.
Tebakon.
Trimeperidien.

– EINDE VAN BYLAE 6 –

BYLAE 7

Alle stowwe bedoel in hierdie Bylae sluit die volgende in (tensy uitdruklik uitgesluit of tensy in 'n ander Bylae gelys):

(a) Die isomere van sodanige stowwe, indien die bestaan van sodanige isomere binne die spesifieke chemiese benaming moontlik is;

(b) die esters en eters van sodanige stowwe en van die isomere bedoel in (a), asook die isomere van sodanige esters en eters, indien die bestaan van sodanige esters, eters en isomere moontlik is;

(c) die soute van sodanige stowwe en van die isomere bedoel in (a), asook die soute van die esters, eters en isomere bedoel in (b), waar die bestaan van sodanige soute moontlik is;

(d) die isomere van enige van die soute bedoel in (c), waar die bestaan van sodanige isomere moontlik is;

(e) alle preparate en mengsels van enige van bogenoemde.

(Triviaal- of gewone name of nieamptelike name word met "*" gemerk.)

(±)-2,5-dimetoksi-αmetielfenetielamien *(DMA).
(±)-3,4,5-trimetoksi-α-metielfenetielamien *(TMA)
(±)-4-etiel-2,5-dimetoksi-α-fenetielamien *(DOET).
(±)-N,α-dimetiel-3,4-(metileendioksi)fenetielamien *(MDMA).
2,5-dimetoksi-α-4-dimetielfenetielamien *(DOM, STP) en die derivate daarvan.
2-metoksi-α-metiel-4,5-(metieleendioksi)fenetielamien *(MMDA).
3-(1,2-dimetielheptiel)-7,8,9,10-tetrahidro-6,6,9,-trimetiel-6H-dibenso[b,d]piraan-1-ol *(DMHP).
3-heksiel-7,8,9,10-tetrahidro-6,6,0-trimetiel-6H-dibenso[b,d]-piraan-1-ol (paraheksiel).
4-bromo-2,5-dimetoksifenetielamien (2C-B) *(Nexus).
4-metielaminoreks.
Amfetamien.
Aminoreks.
Brolamfetamien ((±)-4-bromo-2,5-dimetoksi-α-metielfenetielamien)
Bufotenien (N,N-dimetielserotonien).
Cannabis (dagga), die hele plant of enige gedelte of produk daarvan, uitgesonderd –

(a) wanneer afsonderlik in die Bylaes gespesifiseer; (B6) of
(b) verwerkte hennepvesel wat hoogstens 0,1 persent tetrahidrokannabinol bevat en produkte vervaardig van sodanige vesel: Met dien verstande dat die produk nie heel *Cannabis*-sade bevat nie en nie in 'n vorm is wat ingeneem, gerook of ingeasem kan word nie; of
(c) verwerkte produkte gemaak van *Cannabis*-sade, wat hoogstens 10 milligram per kilogram (0,001 persent) tetrahidrokannabinol bevat en nie heel *Cannabis*-sade bevat nie.

["Verwerkte" beteken behandel op meganiese, chemiese of ander kunsmatige wyse, maar sluit nie (a) oes of (b) die natuurlike verrottingsproses in nie.]

Deksamfetamien. (B8)
Diëtieltriptamien. (3-(2-(diëtielamino)-etiel)-indool) *(DET).
Dimetieltriptamien (3-(2-(dimetielamino)etiel)indool) *(DMT).
Dronabinol ((-)-transdelta-9-tertrahidrokannabinol). B6
Etielamfetamien (N-etielamfetamien).
Etriptamien.
Fenetillien.
Fenmetrasien.
Fensiklidien en die verwante stowwe daarvan, met inbegrip van –
    etisiklidien (N-etiel-1-fenielsikloheksielamien *(PCE));
    rolisiklidien (1(1-fenielsikloheksiel)pirrolidien *(PHP of PCPY); en
    tenosiklidien (1-[1-(2-tiëniel)-sikloheksiel]piperidien *(TCP)
Fentaniel-analoë (tensy in 'n ander Bylae gelys), met inbegrip van –
    alfametielfentaniel;
    alfametielfentanielasetanilied;
    alfametieltiofentaniel;
    asetielalfametielfentaniel;
    bensielfentaniel;
    betahidroksi-3-metielfentaniel;
    betahidroksifentaniel;
    3-metielfentaniel en die twee isomere vorme daarvan:
        cis-N-(3-metiel-1-(2-fenetiel)-4-piperidiel)-propioonanilied; en
        trans-N-(3-metiel-1-(2-fenetiel)-4-piperidiel)-propioonanilied;
    3-metieltiofentaniel;
    parafluoorfentaniel; en
    tiofentaniel. (B6)
Gammahidroksibuteraat *(GHB).
Harmalien (3,4-dihidroharmien).
Harmien (7-metoksi-1-metiel-9H-pirido(3,4-b)-indool).
Heroïen (diasetielmorfien).
Katinoon ((-)-(S)-2-aminopropiofenoon).
Lefetamien *(SPA).
Lisergied (lisergiensuurdiëtielamied) *(LSD).
Meskalien (3,4,5-trimetoksifenetielamien).
mesokarb.
Metakoloon en enige preparaat wat metakaloon bevat.
Metamfetamien en metamfetamienrasemaat.
{Metieleendioksiamfetamien *(MDA) en die analoë daarvan – sien Tenamfetamien}
Metipriloon.
Metkatinoon.
Nabiloon. (B8)
Petidien-analoë, met inbegrip van –
    1-metiel-4-feniel-4-propioonoksipiperidien *(MPPP)
    1-metiel-4-feniel-1,2,5,6-tetrahidropiperidien *(MPTP); en
    1-fenieletiel-4-feniel-4asetieloksipiperidien *(PEPAP).
Pirovaleroon (4'-metiel2-(1-pirollidiniel)valerofenoon).
p-metoksi-α-metielfenetielamien *(PMA).
Psilosibien (4-fosforieloksi-NN- dimetieltriptamien).
Psilosien (4-hodroksi-NN-dimetieltriptamien).
Tenamfetamien (metieleendioksiamfetamien *MDA)) en die analoë daarvan:

(±)-N-etiel-α-metiel-3,4-(metieleendioksi)fenetielamien *(N-etiel-MDA);
(±)-N-[α-metiel-3,4-(metieleendioksi)fenetiel]hidroksilamien *(N-hidroksi-MDA).

Tetrahidrokannibol en die homoloë daarvan, uitgesonderd –

(a) wanneer afsonderlik in die Bylaes gespesifiseer;
(b) dronabinol ((-)-transdelta-9-tetrahidrokannibol) wanneer bedoel vir terapeutiese doeleindes; *B6)
(c) hennepsaadolie wat hoogstens 10 milligram per kilogram tetrahidrokannibole bevat, wanneer geëtiketteer "Moenie inneem nie" of alternatiewelik "Nie vir inwendige menslike gebruik nie"; of
(d) produkte vir ander doeleindes as inwendige menslike gebruik wat hoogstens 10 milligram per kilogram tetrahidrokannibole bevat.

["Hennepsaadolie" beteken die olie verkry deur koudpersing uit die ryp vrigte (sade) van *Cannabis sativa*.]

– EINDE VAN BYLAE 7 –

BYLAE 8

Alle stowwe bedoel in hierdie Bylae sluit die volgende in (tensy uitdruklik uitgesluit of tensy in 'n ander Bylae gelys):

(a) Die isomere van sodanige stowwe, indien die bestaan van sodanige isomere binne die spesifieke chemiese benaming moontlik is;

(b) die esters en eters van sodanige stowwe en van die isomere bedoel in (a), asook die isomere van sodanige esters en eters, indien die bestaan van sodanige esters, eters en isomere moontlik is;

(c) die soute van sodanige stowwe en van die isomere bedoel in (a), asook die soute van die esters, eters en isomere bedoel in (b), waar die bestaan van sodanige soute moontlik is;

(d) die isomere van enige van die soute bedoel in (c), waar die bestaan van sodanige isomere moontlik is;

(e) alle preparate en mengsels van enige van bogenoemde.

Amfetamien en die soute daarvan; preparate daarvan. (B7)
Deksamfetamien en die soute daarvan; preparate daarvan. (B7)
Nabillon. (B7)

Hierdie Bylaes tree op 2 Mei 2003 in werking.

MTshabalala

ME TSHABALALA-MSIMANG
MINISTER VAN GESONDHEID

No. R. 510 **10 April 2003**

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

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

GENERAL REGULATIONS

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

SCHEDULE

DEFINITIONS

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

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

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

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

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

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

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

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

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

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

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

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

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

"dispense"-

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

REQUIREMENTS FOR THERAPEUTIC EQUIVALENCE

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

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

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

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

THE MANNER AND CONDITIONS FOR ALLOWING INTERNATIONAL TENDERING

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

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

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

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

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

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

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

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

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

EXPEDITED REGISTRATION PROCESS FOR MEDICINES FOR HUMAN USE

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

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

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

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

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

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

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

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

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

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

PARTICULARS TO BE PUBLISHED IN THE GAZETTE

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

(a) The proprietary name of the medicine;

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

(c) the dosage form of the medicine;

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

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

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

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

IMPORTATION OF MEDICINES IN TERMS OF SECTION 15C

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

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

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

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

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

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

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

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

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

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

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

(e) documentary proof-

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

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

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

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

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

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

(3) The Minister-

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

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

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

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

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

(a) a certified copy of that permit;

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

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

(6) The council-

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

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

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

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

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

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

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

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

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

LABELLING OF MEDICINES INTENDED FOR ADMINISTRATION TO HUMANS

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

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

(b) the proprietary name of the medicine;

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

(d) the dosage form of the medicine;

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

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

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

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

(i) sugar contained in the medicine; or

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

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

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

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

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

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

(n) the lot number of the medicine;

(o) the expiry date of the medicine;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(v) date of dispensing; and

(vi) reference number.

PACKAGE INSERTS FOR MEDICINES FOR HUMAN USE

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

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

(b) Proprietary name and dosage form;

(c) Composition, i.e-

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

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

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

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

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

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

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

(f) Indications;

(g) Contra-indications;

(h) Warnings;

(i) Interactions;

(j) Pregnancy and lactation;

(k) Dosage and directions for use;

(l) Side effects and special precautions;

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

(n) Identification;

(o) Presentation;

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

(q) Registration number, i.e

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

PATIENT INFORMATION LEAFLET

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

(a) Scheduling status;

(b) proprietary name and dosage form;

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

(d) the approved indications and use;

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

(i) contra-indications;

(ii) precautions;

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

(iv) interactions;

(v) the following general statements:

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

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

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

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

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

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

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

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

"store all medicines out of reach of children."

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

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

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

(k) registration number of the medicine;

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

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

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

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

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

PRESCRIPTION BOOK

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

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

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

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

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

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

(f) prescription reference number.

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

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

(b) its name and quantity; and

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

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

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

(a) the date and transaction of every sale;

(b) the name of the medicine;

(c) the name and address of every purchaser;
(d) the quantities sold;

(e) the batch number; and

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

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

IMPORTATION OF MEDICINES INTO THE REPUBLIC

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

(a) Cape Town Airport or harbour;

(b) Port Elizabeth Airport or harbour;

(c) Durban Airport or harbour; and

(d) Johannesburg international airport

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

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

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

TRANSMISSION OF MEDICINES THROUGH THE REPUBLIC

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

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

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

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

PERMITS IN TERMS OF SECTION 22A OF THE ACT

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

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

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

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

(b) identification number of the applicant;

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

(d) qualifications of the applicant;

(e) telephone and facsimile numbers of applicant

(f) purpose for which the application is made;

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

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

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

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

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

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

(b) identification number of applicant;

(c) name and address of employer;

(d) qualifications of the applicant;

(e) telephone and facsimile numbers of applicant;

(f) particulars of the research project;

(g) address at which research will be undertaken;

(h) estimated duration of project;

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

(j) source of supply; and

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

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

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

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

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

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

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

(d) telephone and facsimile numbers of applicant;

(e) address at which manufacturing is to be undertaken; and

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

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

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

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

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

(b) identification number of the applicant;

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

(d) qualification of the applicant;

(e) telephone and facsimile numbers of applicant; and

(f) purpose for which the application is made.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(ii) local production of the raw material;

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

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

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

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

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

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

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

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

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

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

LICENCE TO DISPENSE OR COMPOUND AND DISPENSE MEDICINES

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

LICENCE TO MANUFACTURE, ACT AS A WHOLESALER OR DISTRIBUTE MEDICINES

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

(a) must prior to commencing business as such-

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

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

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

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

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

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

(ii)registration of the responsible pharmacist;

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

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

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

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

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

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

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

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

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

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

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

(4) If the Council is satisfied that:

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

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

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

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

(5) The registrar must:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) be accompanied by a prescribed fee; and

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

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

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

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

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

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

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

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

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

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

(6) The appeal committee -

(a) shall determine the procedure for its hearings;

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

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

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

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

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

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

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

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

(a) on which it was appointed; or,

(b) when the appeal hearing was completed,

whichever is the later.

APPLICATION FOR THE REGISTRATION OF A MEDICINE

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

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

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

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

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

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

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

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

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

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

(h) an application fee.

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

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

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

(i) Name

(ii) Business Address

(iii) Postal Address

(iv) Telephone Number

(v) Fax Number

(vi) e-mail address

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

(b) Particulars of a medicine:

(i) proprietary name

(ii) dosage form;

(iii) strength per dosage unit;

(iv) route of administration;

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

(vi) category and pharmacological classification;

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

(viii) approved name.

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

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

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

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

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

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

INFORMATION THAT MUST APPEAR IN THE REGISTER FOR MEDICINES

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

(a) the proprietary name of the medicine;

(b) the registration number allocated to the medicine;

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

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

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

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

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

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

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

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

APPLICATION FOR AN AMENDMENT TO THE MEDICINES REGISTER

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

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

(a) the registration number of the medicine;

(b) business address of the applicant;

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

(d) the details of the amendment applied for;

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

(f) the name of applicant.

CATEGORIES AND CLASSIFICATION OF MEDICINES

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

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

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

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

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

1. Central nervous system stimulants

1.1 Central analeptics

1.2 Psychoanaleptics (antidepressants)

1.3 Special antidepressant combinations

1.4 Respiratory stimulants

1.5 Hallucinogenic medicines and

1.6 Other central nervous system stimulants

2. Central nervous system depressants

2.1 Anaesthetics

2.2 Sedatives, hypnotics

2.3 Barbiturates

2.4 Non-barbiturates

2.5 Anticonvulsants, including anti-epileptics

2.6 Tranquillisers

2.6.1 Phenothiazines and their derivatives

2.6.2 Rauwolfia: Alkaloids and combinations

2.6.3 Diphenylmethane and its derivatives

2.6.4 Alkyl diols and their derivatives

2.6.5 Miscellaneous structures

2.7 Antipyretics or antipyretic and anti-inflammatory analgesics

2.8 Analgesic combinations

2.9 Other analgesics

2.10 Centrally acting muscle relaxants and

2.11 Other central nervous system depressants.

3. Connective Tissue Medicines

3.1 Antirheumatics (anti-inflammatory agents)

3.2 Non-hormonal preparations

3.3 Anti-gout preparations

3.4 Combinations with corticosteroids and

3.5 Others

4. Local anaesthetics

5. Medicines affecting autonomic function

5.1 Adrenomimetics (sympathomimetics)

5.2 Adrenolytics (sympatholytics)

5.3 Cholinomimetics (cholinergics)

5.4 Cholinolytics (anticholinergics)

5.4.1 Anti-Parkinsonism preparations

5.4.2 General

5.5 Ganglion blockers

5.6 Histamine

5.7 Antihistaminics, anti-emetics and antivertigo preparations

5.7.1 Antihistaminics

5.7.2 Anti-emetics and antivertigo preparations

5.8 Preparations for the common cold including nasal decongestants

5.9 Hydroxytryptamine (serotonin)

5.10 Serotonin antagonists and
5.11 Others

6. Cardiac medicines

6.1 Cardiac stimulants
6.2 Cardiac depressants

6.3 Cardiac glycosides and
6.4 Others

7. Vascular medicines

7.1 Vasodilators, hypotensive medicines

7.1.1 Rauwolfia and combinations

7.1.2 Rauwolfia: Diuretic combinations

7.1.3 Other hypotensives

7.1.4 Vasodilators - coronary and other medicines used in angina pectoris

7.1.5 Vasodilators - peripheral

7.2 Vasoconstrictors, pressor medicines

7.3 Migraine preparations

7.4 Lipotropic agents

7.5 Serum-cholesterol reducers and

7.6 Others

8. Medicines acting on blood and haemopoietic system

8.1 Coagulants, haemostatics

8.2 Anticoagulants

8.3 Erythropoietics (haematinics)

8.4 Plasma expanders and

8.5 Others

9. Medicines against alcoholism

10. Medicines acting on respiratory system

10.1 Antitussives and expectorants

10.2 Bronchodilators

10.2.1 Inhalants

11. Medicines acting on gastro-intestinal tract

11.1 Digestants

11.2 Gastro-intestinal antispasmodics and cholinolytics (anticholinergics)

11.3 Anorexigenics

11.4 Antacids

11.4.1 Acid neutralisers

11.4.2 Acid neutralisers with antispasmodics

11.4.3 Other

11.5 Laxatives

11.6 Lubricants and faecal softeners

11.7 Cholagogues

11.8 Suppositories and anal ointments

11.9 Antidiarrhoeals

11.9.1 Antidiarrhoeals in combination with anti-infective agents

11.9.2 Special combinations and

11.10 Others

12. Anthelmintics, bilharzia medicines, filaricides, etc.

13. Dermatological preparations

13.1 Antiseptics, disinfectants and cleansing agents

13.2 Antiscabies medicines

13.3 Surface anaesthetics

13.4 Antipruritics

13.4.1 Corticosteroids with or without anti-infective agents

13.4.2 Emollients and protectives

13.5 Rubefacients

13.6 Counterirritants

13.7 Keratolytics

13.8 Special combinations

13.8.1 Preparations for psoriasis

13.8.2 Fungicides

13.9 Radiation protectants

13.10 Melanin inhibitors and stimulants

13.11 Acne preparations and
13.12 Others

14. Preparations for treatment of wounds

14.1 Wound disinfectants
14.2 Wound dressings and
14.3 Others

15. Ophthalmic preparations

15.1 Ophthalmic preparations with antibiotics and/or sulphonamides

15.2 Ophthalmic preparations with corticosteroids

15.3 Combination antibiotics and
15.4 Others

16. Ear, nose and throat preparations

16.1 Nasal decongestants

16.2 Aural preparations

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

16.5 Others

17. Medicines acting on muscular system

17.1 Peripherally acting muscle relaxants

17.2 Muscle activators and

17.3 Others

18. Medicines acting on genito-urinary system

18.1 Diuretics

18.2 Antidiuretics

18.3 Ion-exchange preparations

18.4 Urolitholytics

18.5 Urinary tract antiseptics

18.6 Vaginal preparations

18.7 Contraceptive preparations

18.8 Ovulation controlling agents

18.9 Uterine antispasmodics and

18.10 Others

19. Oxytocics

20. Antimicrobial (chemotherapeutic) agents

20.1 Antibiotics and antibiotic combinations

20.1.1 Broad and medium spectrum antibiotics

20.1.2 Penicillins

20.1.3 Penicillin-streptomycin combinations

20.1.4 Antibiotic-sulphonamide combinations

20.1.5 Streptomycin and combinations

20.1.6 Topical antibiotics

20.1.7 Antifungal antibiotics

20.2 Other than antibiotics

20.2.1 Sulphonamides

20.2.2 Fungicides

20.2.3 Tuberculostatics

20.2.4 Leprostatics

20.2.5 Germicides

20.2.6 Medicines against protozoa

20.2.7 Spirochaeticides

20.2.8 Antiviral agents and

20.3 Others

21. Hormones, antihormones and oral hypoglycaemics

21.1 Insulin preparations

21.2 Oral hypoglycaemics

21.3 Thyroid preparations

21.4 Parathyroid preparations

21.5 Corticosteroids

21.5.1 Corticosteroids and analogues

21.5.2 Analgesic combinations

21.5.3 Anti-infective combinations

21.6 Anabolic steroids

21.7 Male sex hormones

21.8 Female sex hormones

21.8.1 Oestrogens

21.8.2 Progesterones with or without oestrogens
21.9 Androgen-oestrogen combinations

21.10 Trophic hormones

21.11 Hyperglycaemic hormones

21.12 Hormone inhibitors and
21.13 Others

22 Vitamins

22.1 Multivitamins and multivitamins with minerals

22.1.1 Vitamins for paediatric use

22.1.2 Vitamins for prenatal use

22.1.3 Vitamins for geriatric use

22.1.4 Vitamin B-complex with Vitamin C and

22.2 Others

23. Amino-acids

24. Mineral substitutes, electrolytes

25. Special foods

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

26. Cytostatic agents

27. Chelating agents (versenates) as heavy metal antidotes

28. Contrast media

29. Diagnostic agents

30. Biologicals

30.1 Antibodies

30.2 Antigens

30.3 Blood fractions

31. Enzymatic preparations

32. Other substances or agents

32.1 Tonics

32.2 Other

32.3 Slimming preparations

32.4 Water for injection

32.5 Artificial tear and contact lens solutions

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

32.7 Topical applications of delousing agents

32.8 Topical applications of insect repellents

32.9 Intra-uterine devices

32.10 Dental preparations

32.11 Solutions for haemo- or peritoneal dialysis

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

32.13 Preparations intended to promote hair growth

32.14 Sales packs containing two or more medicines with different indications

32.15 Radiopharmaceuticals and

32.16 Others

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

1. Central And Peripheral Nervous System

1.1 Central nervous system stimulants

1.1.1 Central analeptics

1.1.2 Respiratory Stimulants

1.2 Anaesthetics

1.2.1 Inhalation anaesthetics

1.2.2 Parenteral anaesthetics

1.2.3 Local anaesthetics

1.3 Narcotic analgesics

1.3.1 Opioid agonists

1.3.2 Opioid antagonists

1.4 Sedatives

1.4.1 Sedative hypnotics

1.4.2 Sedative analgesics

1.4.3 Sedative antagonists

1.5 Anticonvulsants including anti-epileptics

1.6 Tranquillisers

1.6.1 Phenothiazine derivatives

1.6.2 Butyrophenone derivatives

1.7 Neuroleptanalgesics

1.8 Analgesic antipyretics

1.9 Drugs used for euthanasia

2. Autonomic Nervous System

2.1 Sympathomimetics

2.2 Sympatholytics

2.3 Cholinergics

2.4 Antimuscarinics

3. Musculo-Skeletal System and Joints

3.1 Anti-inflammatory

3.1 .1 Steroidals

3.1.2 Non-steroidal anti-inflammatory drugs (NSAIDs)

3.1.2.1 Non selective COX2 inhibitors

3.1.2.2 Selective COX2 inhibitors

3.1.3 Topical agents

3.1.4 Combinations

3.1.5 Other

3.2 Analgesics

3.2.1 Opioids

3.2.2 NSAIDs

3.2.3 Topical agents

3.2.4 Combinations

3.3 Muscle relaxants

3.3.1 Centrally acting

3.3.2 Peripherally-acting

4. Autacoids

4.1 Histamine inhibitors

4.1.1 Antihistamines

4.1.2 Histamine release inhibitors

4.2 Serotonin antagonists

4.3 Others

5. Cardio-Vascular System

5.1 Positive inotropic agents

5.1.1 Cardiac glycosides

5.1.2 Methylxanthines

5.1.3 Others

5.2 Anti-arrhythmics

5.3 Vasodilators

5.3.1 Peripheral-acting vasodilators

5.3.2 Angiotensin inhibitors

5.3.3 Calcium channel inhibitors

6. Blood And Haemopoeitic System

6.1 Coagulants, haemostatics

6.2 Anticoagulants

6.3 Haematinics

6.4 Plasma expanders

7. Respiratory System

7.1 Antitussives and expectorants

7.2 Mucolytics

7.3 Bronchodilators

7.4 Combinations

8. Gastro-Intestinal System

8.1 Mouth washes

8.2 Emetics

8.3 Anti-emetics

8.4 Acid-reducers

8.4.1 Antacids and combinations

8.4.2 Histamine-2 receptor antagonists

8.4.3 Proton pump inhibitors

8.4.4 Cytoprotective agents

8.5 Motility enhancers

8.5.1 Lubricants and Faecal softeners

8.5.2 Laxatives and Purgatives

8.6 Antispasmotics

8.7 Antidiarrhoeals

8.7.1 Plain

8.7.2 With anti-microbial agents

8.7.3 Antimicrobial agents

8.7.4 Biologicals

8.8 Analgesics

8.9 Digestants

8.10 Preparations used in the rumen

8.10.1 Ruminotorics

8.10.2 Anti-bloat remedies

8.10.3 Others

9. Hepatic System

9.1 Cholagogues and cholerectics

9.2 Liver protectants and lipotropics

10. Urinary System

10.1 Diuretics

10.2 Urolitholytics and antispasmodics

10.3 Urinary tract antiseptics

10.4 pH modifiers

10.4.1 Urinary acidifiers

10.4.2 Urinary alkalinisers

10.5 Others

11. Reproductive System

11.1 Intravaginal and intra-uterine preparations

11.2 Sex hormones

11.2.1 Testosterone

11.2.2 Oestrogens

11.2.3 Progesterones & Progestogens

11.2.4 Combinations

11.3 Prostaglandins

11.4 Trophic hormones

11.5 Myometrial stimulants (Ecbolics)

11.6 Myometrial relaxants (Tocolytics)

11.7 Ovulation controlling agents

12. Endocrine System

12.1 Insulin preparations

12.2 Thyroid preparations

12.3 Corticosteroids

12.4 Growth Hormone

12.5 Anabolic steroids

13. Dermatologicals

13.1 Disinfectants and cleaning agents

13.2 Antiseptic and antimicrobial preparations

13.3 Antipuritics

13.3.1 Topical corticosteroids with or without anti-infective agents

13.3.2 Topical antihistamines with or without anti-infective agents

13.4 Emollients and protectives

13.5 Rubefacients and counter irritants

1 3.6 Keratolytics

13.7 Antifungals

13.8 Anti-parasitics

14. Ophthalmic And Aural Preparations

14.1 Anti-infectives

14.2 Corticosteroids

14.3 Combinations (anti-infective with corticosteroids)

14.4 Others

15. Wounds

15.1 Wound antiseptics

15.2 Wound dressings

15.3 Desloughing agents

16. Mammary Gland

16.1 Intra-mammary preparations

16.2 Preparations for the care of teats and udders

17. Antimicrobials

17.1 Antibacterials

17.1.1 Beta-lactams

17.1.1.1 Penicillins

17.1.1.2 Cephalosporins

17.1.2 Tetracyclines

17.1.3 Aminoglycosides

17.1.4 Macrolides and Lincosamides

17.1.5 Amphenicol

17.1.6 Quinolones

17.1.7 Sulphonamides and potentiators

17.1.8 Nitrofurans

17.1.9 Polypeptides

17.1.10 Other

17.1.11 Antibacterial combinations

17.2 Antifungals

17.3 Antivirals

17.4 Anti-protozoals

17.4.1 Anticoccidials

17.4.2 Antibabesials

17.4.3 Spirochaeticides

17.4.4 Others

18. Antiparasitic Agents

18.1 Endoparasiticides

18.1.1 Benzimidazoles and Probenzimidazoles

18.1.2 Macrocyclic lactones

18.1.3 Halogenated salicylanilides and Nitrophenols

18.1.4 Imidazoles

18.1.5 Tetrahydropyrimidines

18.1.6 Piperazines

18.1.7 Organophosphores

18.1.8 Others

18.1.9 Combinations

18.2 Endectocides

18.3 Ectoparasiticides

18.3.1 Organochlorines

18.3.2 Organophosphores

18.3.3 Pyrethrin and Pyrethroids

18.3.4 Formamidines

18.3.5 Nitroquanidines

18.3.6 Phenylpyrazoles

18.3.7 Insect growth hormones

18.3.8 Chitin inhibitors

18.3.9 Others

18.3.10 Combinations

19. Vitamins, Minerals And Geriatric Preparations

19.1 Vitamins only

19.2 Vitamin and mineral combinations

19.3 Minerals and electrolytes

19.4 Vitamins, electrolytes and aminoacid combinations

20. Cytostatic Agents

21. Immune Modulating Agents

22. Chelating Agents

23. Contrast Media

24. Biologicals

24.1 Dogs vaccines

24.2 Cats vaccines

24.3 Poultry vaccines

24.4 Other vaccines

24.5 Other biologicals

25 Production Enhancers

25.1 Antimicrobials

25.2 Hormones

25.2.1 Sex hormones

25.3 Beta agonists

25.4 Other

26. Fish Medicines

CERTIFICATE OF REGISTRATION

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

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

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

1. Proprietary name .....

2. Registration number .....

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

4. Dosage form .....

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

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

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

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

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

10. Conditions of registration.....

11. Date of registration .....

.....
Registrar of Medicines

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

DESTRUCTION OF MEDICINES

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

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

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

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

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

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

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

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

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

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

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

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

(e) the dosage form;

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

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

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

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

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

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

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

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

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

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

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

preceding calendar year;

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

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

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

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

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

(i) exportation; or

(ii) destruction thereof;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SEIZURE OF MEDICINES

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

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

(b) is suspected counterfeit;

(c) is misbranded;

(d) has expired

(e) is suspected stolen;

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

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

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

(i) is used in unauthorised clinical trial.

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

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

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

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

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

REPACKING OF MEDICINES INTO PATIENT READY PACKS

33. The repacking of medicines into patient ready packs-

(a) may only be carried out by-

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

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

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

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

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

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

CONDUCT OF CLINICAL TRIALS FOR HUMANS

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

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

(a) trial protocol;

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

(c) Curriculum Vitae of all investigators;

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

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

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

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

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

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

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

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

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

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

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

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

SKILLS OF MEMBERS OF THE COUNCIL AND ITS COMMITTEES

35. The Council shall include the following:

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

(b) an expert in clinical pharmacology;

(c) an expert in pharmaceutical chemistry;

(d) an expert in toxicology and drug safety;

(e) an expert in biotechnology;

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

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

(h) an expert in virology and microbiology;

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

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

(k) one person with knowledge of complementary medicines and

(l) a person with expertise in law.

CONTROL OF MEDICINES IN HOSPITALS

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

ADVERSE DRUG REACTION

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

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

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

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

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

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

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

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

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

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

PRICING COMMITTEE

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

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

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

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

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

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

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

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

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

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

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

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

INVESTIGATIONS

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

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

(b) adverse reaction is reported;

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

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

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

PACKAGE INSERTS FOR VETERINARY MEDICINES

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

at least one official language and in minimum legibility:

(a) the proprietary name;

(b) scheduling status;

(c) dosage form;

(d) composition, using generic or approved names;

(e) pharmacological classification;

(f) pharmacological action;

(g) pharmacokinetic properties and pharmacodynamic properties;

(h) contra-indications;

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

(j) side-effects and special precautions;

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

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

(m) storage instructions;

(n) registration number;

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

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

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

USE OF MEDICINES FOR THE PREVENTION OF MALARIA

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

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

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

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

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

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

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

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

OFFENCES AND PENALTIES

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

COMPLIANCE WITH REQUIREMENTS

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

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

BATCH RELEASE FOR BIOLOGICAL MEDICINES

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

ADVERTISING OF MEDICINES

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

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

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

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

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

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

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

(a) the proprietary name of such medicine;

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

(c) in the case -

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

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

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

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

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

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

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

RULES RELATING TO THE CONDUCT OF BUSINESS OF THE COUNCIL

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(c) reports of standing committees;

(d) motions

(e) correspondence;

(f) general.

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

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

(a) to add or insert certain words; or

(b) to omit certain words; or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

entitled to speak first.

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

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

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

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

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

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

meeting of the committee at which it has been given.

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

OBTAINING OF PETHIDINE OR PREPARATIONS THEREOF BY REGISTERED MIDWIVES

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

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

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

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

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

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

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

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

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

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

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

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

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

(iii) Strength; and

(iv) maximum supply.

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

(i) date of supply;

(ii) number of permit;

(iii) quantity of medicine supplied;

(iv) name and address of pharmacy; and

(v) the pharmacist's signature.

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

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

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

(i) date and time of administration;

(ii) name and address of patient;

(iii) quantity administered;

(iv) full signature;

(v) qualifications;

(vi) reason for administration; and

(vii) the balance on hand.

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

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

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

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

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

(11)The Director General shall:

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

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

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

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

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

(13) A permit shall contain the following information:

(a) permit number;

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

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

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

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

LABELLING FOR VETERINARY MEDICINE

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

(a) The words 'Veterinary Medicine';

(b) the proprietary name of such medicine;

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

(d) the dosage form of the medicine;

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

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

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

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

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

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

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

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

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

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

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

(m) the lot number of the medicine;

(n) the expiry date of the medicine;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

attached a label containing the following information:

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

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

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

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

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

(vi) date of dispensing;

REPEAL

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

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

COMMENCEMENT

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

ME TSHABALALA-MSIMANG
MINISTER OF HEALTH

No. R. 510 10 April 2003

ALGEMENE REGULASIES KRAGTENS DIE WET OP MEDISYNE EN VERWANTE STOWWE, 1965 (WET NO. 101 VAN 1965)

INHOUDSOPGAWE

Regulasieno.	Titel
1.	Woordomskrywing
2.	Vereistes vir terapeutiese ekwivalensie
3.	Die wyse en voorwaardes waarop internasionaal getender mag word
4.	Voorwaardes waarop 'n apteker medisyne vir verkoop in die kleinhandel mag aanmaak en die maksimum hoeveelheid daarvan
5.	Bespoedigde registrasieproses vir medisyne vir menslike gebruik
6.	Besonderhede wat in *Staatskoerant* gepubliseer moet word ten opsigte van 'n medisyne
7.	Invoer van medisyne kragtens artikel 15C
8.	Etikettering van medisyne bestem vir menslike gebruik
9.	Voubiljette vir medisyne vir menslike gebruik
10.	Pasiëntinligtingsblaadjie
11.	Voorskrifboek
12.	Invoer van medisyne in die land
13.	Vervoer deur die Republiek van medisyne
14.	Permitte kragtens artikel 22A van die Wet
15.	Invoer of uitvoer van gespesifiseerde Bylae 5-, of Bylae 6-, Bylae 7- of Bylae 8-medisyne of –stowwe
16.	Besit van gespesifiseerde hoeveelhede gelyste stowwe vir persoonlike medisinale gebruik deur persone wat die Republiek binnekom of verlaat
17.	Inligting wat jaarliks aan Direkteur-generaal verstrek moet word deur houer van permit om Bylae 6- en Bylae 7-stowwe in of uit te voer
18.	Lisensie om medisyne op te maak en toe te berei
19.	Lisensie om medisyne te vervaardig, of om op te tree as groothandelaar daarvan of dit te versprei
20.	Geldigheidsduur van 'n lisensie uitgereik kragtens regulasies 18 en 19 en hernuwing van lisensies
21.	Appèl teen beslissing van Direkteur-generaal of Raad
22.	Aansoek om registrasie van medisyne
23.	Inligting wat in medisyneregister moet verskyn
24.	Aansoek om wysiging van inskrywing in medisyneregister

25. Kategorieë en klassifikasie van medisyne
26. Registrasiesertifikaat
27. Vernietiging van medisyne
28. Besonderhede wat op voorskrif of bestelling vir medisyne moet verskyn
29. Opgawes wat verstrek moet word ten opsigte van gespesifiseerde Bylae 5-, en Bylae 6-, Bylae 7- en Bylae 8- en stowwe
30. Register van Bylae 5- en Bylae 6-medisyne
31. Metode van monsterneming tydens ondersoeke, die sertifikaat wat uitgereik moet word en verslagdoening oor ontledingsresultate
32. Beslaglegging op medisyne
33. Herverpakking van van medisyne in pasiëntgerede verpakkings
34. Doen van kliniese proewe vir mense
35. Kundigheid van lede van Raad en sy komitees
36. Beheer oor medisyne in hospitale
37. Ongunstige geneesmiddelreaksies
38. Pryskomitee
39. Ondersoeke
40. Voubiljette vir veterinêre medisyne
41. Gebruik van medisyne ter voorkoming van malaria
42. Misdrywe en strawwe
43. Voldoening aan regulasies
44. Lotvrystelling vir biologiese medisyne
45. Advertering van medisyne
46. Reëls met betrekking tot die voer van verrigtinge van Raad
47. Verkryging van petidien of preparate of mengsels daarvan deur geregistreerde vroedvroue
48. Etikettering van veterinêre medisyne
49. Herroeping

WET OP MEDISYNE EN VERWANTE STOWWE, 1965 (WET NO. 101 VAN 1965)

ALGEMENE REGULASIES

Die Minister van Gesondheid het, kragtens artikel 35 van die Wet op Medisyne en Verwante Stowwe, 1965 (Wet No. 101 van 1965), in oorleg met die Medisynebeheerraad, die regulasies in die Bylae uitgevaardig.

BYLAE

WOORDOMSKRYWING

1. In hierdie regulasies het enige woord of uitdrukking wat in die Wet omskryf is en nie hierin omskryf is nie, dieselfde betekenis as in die Wet, en, tensy uit die samehang anders blyk, beteken –

"aansoeker" 'n persoon wat 'n aansoek doen om die registrasie van 'n medisyne, of die bywerking of wysiging van 'n bestaande registrasie;

"bioëkwivalensie" die afwesigheid van 'n beduidende verskil in die biobeskikbaarheid tussen twee farmaseuties ekwivalente produkte in soortgelyke omstandighede in 'n behoorlik ontwerpte studie;

"die Wet" die Wet op Medisyne en Verwante Stowwe, 1965 (Wet No. 101 van 1965);

"doeanepakhuis" 'n doeane- en aksynspakhuis gelisensieer ingevolge artikel 19 van die Doeane- en Aksynswet, 1964 (Wet No. 91 van 1964);

"gemagtigde voorskrywer" 'n persoon by die Wet gemagtig om medisyne voor te skryf;

"groothandelaar" 'n handelaar wat medisyne van 'n vervaadiger koop en dit aan 'n kleinhandelaar, insluitende 'n groothandelsapteek, verkoop;

"handelsmerk" 'n handelsmerk soos omskryf in artikel 2 van die Wet op Handelsmerke, 1993 (Wet No. 194 van 1993);

"handelsnaam " of **"eiendomsnaam"** die naam wat uniek aan 'n bepaalde medisyne is en waardeur die medisyne gewoonlik geïdentifiseer word, en in die geval van 'n geregistreerde medisyne, die naam wat ingevolge artikel 15(5) van die Wet goedgekeur is;

"houer van 'n registrasiesertifikaat" 'n persoon op wie se naam 'n registrasiesertifikaat uitgereik is en wat verantwoordelik is vir alle aspekte van die medisyne, met inbegrip van gehalte en veiligheid en nakoming van registrasievoorwaardes;

"**kliniese proef**" 'n ondersoek betreffende 'n medisyne vir menslike gebruik waarby mense betrokke is en ten doel het om die kliniese, farmakologiese of farmakodinamiese uitwerking van die medisyne vas te stel of te verifieer, om enige ongunstige gebeurtenisse te identifiseer, om die opname, verspreiding, metabolisme en uitskeiding van die medisyne te bestudeer of die veiligheid of doeltreffendheid daarvan vas te stel;

"**lot**", met betrekking tot 'n medisyne, 'n omskrewe hoeveelheid van 'n medisyne wat in 'n enkele vervaardigingsiklus vervaardig is en homogene eienskappe het;

"**lotnommer**" 'n unieke nommer of kombinasie van nommers of syfers wat die vervaardiger aan 'n lot toegeken het;

"**minimum leesbaarheid**" drukwerk in 6-punt-Helvetica-lettertipe met swart ink op wit patroonpapier of die ekwivalent daarvan;

"**nagemaakte medisyne**" 'n medisyne ten opsigte waarvan 'n valse voorstelling oor die inhoud, identiteit of bron daarvan op enige wyse, met inbegrip van etikettering en verpakking, gemaak is;

"**ongunstige geneesmiddelreaksie**" 'n reaksie by 'n mens of 'n dier op 'n medisyne wat skadelik en onbedoeld is en voorkom by enige dosis, en ook kan voortspruit uit 'n gebrek aan doeltreffendheid van 'n medisyne, nie-etiketgebruik van 'n medisyne, oordosering, wangebruik of misbruik van 'n medisyne;

"**opmaak**" om 'n medisyne voor te berei, te meng, saam te stel, te verpak en te etiketteer vir toebereiding as gevolg van 'n voorskrif vir 'n individuele pasiënt deur 'n apteker of 'n persoon gemagtig kragtens die Wet;

"**parallelle invoer**" die invoer in die Republiek van 'n medisyne wat by patent beskerm word en/of in die Republiek geregistreer is, en wat buite die Republiek op die mark geplaas is deur of met toestemming van die betrokke patenthouer;

"**parallelle invoerder**" 'n persoon wat 'n medisyne deur parallelle invoer in die Republiek invoer op gesag van 'n permit uitgereik kragtens regulasie 7(3);

"**perseelmeesterlêer**" 'n dokument opgestel deur 'n vervaardiger waarin spesifieke en feitelike inligting oor goeie vervaardigingspraktyk vervat is rakende die produksiewerksaamhede en/of beheer oor farmaseutiese vervaardigingswerksaamhede verrig op 'n bepaalde perseel en enige nou-geïntegreerde werksaamhede in aangrensende of nabygeleë geboue;

"**persoon**" sowel 'n natuurlike as 'n regspersoon;

"**soos bepaal deur die Raad**" soos bepaal deur die Raad in die riglyne van tyd tot tyd in die *Staatskoerant* gepubliseer;

"toeberei" –

(a) in die geval van 'n apteker, toeberei soos omskryf in die Regulasies met betrekking tot die Aptekerspraktyk uitgevaardig kragtens die Wet op Aptekers, 1974 (Wet No. 53 van 1974);

(b) in die geval van 'n geneesheer, tandarts, praktisyn, verpleegkundige of enige gemagtigde voorskrywer–

(i) die vertolking en evaluering van 'n voorskrif;

(ii) die selektering, hersamestelling, verdunning, etikettering, aantekening en verskaffing van die medisyne in 'n gepaste houer; of

(iii) die verskaffing van inligting en instruksies om die veilige en doeltreffende gebruik van medisyne deur 'n pasiënt te verseker;

"verantwoordelike apteker" 'n verantwoordelike apteker soos omskryf in die Wet op Aptekers, 1974;

"vervaardig" alle werksaamhede, met inbegrip van die aankoop van materiaal, verwerking, produsering, verpakking, vrystelling en versending van medisyne en verwante stowwe, ooreenkomstig gehalteversekerings- en verwante beheermaatreëls;

"vervaardiger" 'n persoon wat 'n medisyne vervaardig, met inbegrip van 'n vervaardigende apteek;

"vervaldatum" die datum tot wanneer 'n medisyne die sterkte en ander eienskappe sal behou wat op die etiket vermeld word, welke sterkte en ander eienskappe ná verloop van tyd kan verander, en waarna die medisyne nie aan die publiek verkoop of gebruik mag word nie.

VEREISTES VIR TERAPEUTIESE EKWIVALENSIE

2.(1) 'n Medisyne word geag terapeuties ekwivalent aan 'n ander medisyne te wees indien albei medisynes –

(a) farmaseuties ekwivalent is, dit wil sê dieselfde hoeveelheid aktiewe bestanddele in dieselfde doseervorm het, aan dieselfde of vergelykbare standaarde voldoen en bedoel is om langs dieselfde roete toegedien te word; en

(b) ná toedieing in dieselfde molêre dosis, wesenlik dieselfde effek met betrekking tot sowel doeltreffendheid as veiligheid het.

(2) Terapeutiese ekwivalensie word bepaal op grond van vergelykende biobeskikbaarheids-, farmakodinamiese, kliniese of *in vitro*-studies wat voldoen aan die vereistes en aanvaarde kriteria vir bioëkwivalensie, soos bepaal deur die Raad.

DIE WYSE EN VOORWAARDES WAAROP INTERNASIONAAL GETENDER MAG WORD

3.(1) Die Staat mag internasionaal vir 'n medisyne tender indien daardie medisyne –

(a) buite die Republiek teen 'n laer prys bekom kan word; of

(b) na die mening van die Minister, noodsaaklik vir die nasionale gesondheid is.

(2) 'n Medisyne bedoel in subregulasie (1) wat nie geregistreer is wanneer tenders gevra word nie, kan aan 'nbespoedigde registrasieproses kragtens regulasies 5 onderwerp word.

(3) 'n Medisyne mag nie deur internasionale tender verkry word nie, tensy daardie medisyne ingevolge die Wet registreer is.

VOORWAARDES WAAROP 'N APTEKER MEDISYNE VIR VERKOOP IN DIE KLEINHANDEL MAG AANMAAK EN DIE MAKSIMUM HOEVEELHEID DAARVAN

4. 'n Apteker wat 'n medisyne vir verkoop in die kleinhandel kragtens artikel 14(4)(b) van die Wet aanmaak, moet slegs 'n hoeveelheid aanmaak wat –

(a) verband hou met die behandelingsregimen van 'n bepaalde pasiënt; en

(b) deur die pasiënt gebruik moet word vir hoogstens 30 agtereenvolgende dae vanaf die datum van toebereiding.

BESPOEDIGDE REGISTRASIEPROSES VIR MEDISYNE VIR MENSLIKE GEBRUIK

5.(1) Die bespoedigde registrasieproses vir medisyne vir menslike gebruik is soos volg:

(a) 'n Aansoek om medisyne wat op die "Essential Drugs List" verskyn, moet vergesel gaan van 'n verklaring deur die aansoeker dat daardie medisyne op daardie lys verskyn; en

(b) in die geval van medisyne wat nuwe chemiese entiteite bevat en as noodsaaklik vir die nasionale gesondheid geag word maar nie op die "Essential Drug List" verskyn nie, moet 'n skriftelike kennisgewing te dien effekte deur die Minister saam met die aansoek ingedien word.

(2) Aansoeke ten opsigte medisyne bedoel in subregulasie (1)(b) moet vergesel gaan van 'n Beknopte Basis vir Aansoek om Registrasie (BBAR), wat sodanige inligting moet bevat as wat die Raad bepaal.

(3) Die opsomming beoog in subregulasie (2) en die besonderhede wat daarin vervat moet word, moet wees soos die Raad bepaal.

(4) Die Raad kan sekere aansoeke met betrekking tot medisyne wat nuwe chemiese entiteite bevat, aan sodanige verkorte medisyne-oorwegingsproses onderwerp as wat die Raad bepaal, indien registrasie verleen is deur ander regulerende owerhede vir medisyne wat deur die Raad erken word vir die doel waarom aansoek gedoen word.

(5) Die aansoeker moet, binne 30 dae na ontvangs van die aansoek, deur die Raad in kennis gestel word of die aansoek aan 'n bespoedigde registrasieproses onderwerp gaan word al dan nie.

(6) Die Raad kan met betrekking tot 'n aansoek wat oorweeg word, enige inligting aanvra en sodanige inligting moet deur die aansoeker verstrek word binne die tydperk genoem deur die Raad, by gebreke waarvan die Raad die aansoek kan weier.

(7) Die Raad moet binne nege maande vanaf die datum van ontvangs van die aansoek deur die Registrateur 'n besluit met betrekking tot dieaansoek neem en die aansoeker van daardie besluit in kennis stel.

(8) Ondanks die bepalings van hierdie regulasie moet 'n aansoek om 'n bespoedigde registrasieproses steeds aan regulasie 22 voldoen.

BESONDERHEDE WAT IN *STAATSKOERANT* GEPUBLISEER MOET WORD

6. Die volgende besonderhede met betrekking tot aansoeke om registrasie bedoel in artikel 15(11) van die Wet, word in die *Staatskoerant* gepubliseer:

(a) Die handelsnaam van die medisyne;
(b) die goedgekeurde naam en hoeveeldheid van elke aktiewe bestanddeel van die medisyne;
(c) die doseervorm van die medisyne;
(d) die naam van die applikant wat dieaansoek om registrasie ingedien het;
(e) die nommer daaraan toegeken ingevolge artikel 15 van die Wet;
(f) die naam en adres van die vervaardiger en vervaardigingsfasiliteit; en
(g) die naam van die finale produkvrystellingsbeheer.

INVOER VAN MEDISYNE KRAGTENS ARTIKEL 15C

7.(1) 'n Medisyne beoog in artikel 15C(b) van die Wet mag verkoop word indien –

(a) die medisyne met toestemming van die houer van die patent op die medisyne buite die Republiek verkoop word;
(b) die medisyne ingevoer word van 'n persoon gelisensieer deur 'n regulerende owerheid wat deur die Raad erken word;

(c) die persoon wat die medisyne wil invoer, in besit is van 'n permit uitgereik deur die Minister; en

(d) die medisyne ingevolge die Wet geregistreer is.

(2) 'n Persoon wat medisyne bedoel in subregulasie (1) wil invoer, moet aan die Minister voorlê –

(a) 'n behoorlik ingevulde aansoek op 'n vorm goedgekeur en verskaf deur die Minister;

(b) 'n gewaarmerkte afskrif van sy of haar identiteitsdokument of, in die geval van 'n regspersoon, 'n sertifikaat van registrasie as sodanig in die Republiek;

(c) 'n gewaarmerkte afskrif van sy of haar registrasie ingevolge die Wet op Aptekers, 1974, waar van toepassing;

(d) 'n gewaarmerkte afskrif van die lisensie ten opsigte van die perseel ingevolge –

(i) artikel 19 van die Doeane- en Aksynswet, 1964 (Wet No. 91 van 1964); en

(ii) artikel 22 van die Wet op Aptekers, 1974;

(e) dokumentêre bewys –

(i) dat daar 'n patent op die medisyne in die Republiek is;

(ii) dat die medisyne in die land waarvandaan dit uitgevoer word, geregistreer is deur 'n regulerende owerheid wat deur die Raad erken word;

(iii) van die laagste prys waarteen die medisyne in die Republiek verkoop word;

(iv) van die prys waarteen die medisyne in die Republiek verkoop sal word; en

(v) hy of sy kan voldoen aan die goeievervaardigings- en verspreidingspraktyke deur die Raad vasgestel; en

(f) 'n onderneming dat hy of sy die voortgesette veiligheid, doeltreffendheid en gehalte van die medisyne sal verseker.

(3) Die Minister –

(a) kan die aansoek bedoel in subregulasie (2) met of sonder voorwaardes goedkeur;

(b) moet, indien hy of sy die aansoek goedkeur, 'n permit aan die aansoeker uitreik wat vir 'n tydperk van twee jaar geldig is;

(c) kan die permit rojeer indien die houer daarvan in gebreke bly om aan die voorwaardes van die permit te voldoen, of by aanvoering van enige ander gegronde redes.

(4) Die permit uitgereik ingevolge subartikel (3) mag slegs met goedkeuring van die Minister oorgedra word.

(5) 'n Persoon aan wie 'n permit ingevolge subregulasie (3) uitgereik is, moet by die Raad aansoek doen om die registrasie van die medisyne gespesifiseer in die permit deur by die Registrateur in te dien –

(a) 'n gewaarmerkte afskrif van daardie permit;

(b) 'n behoorlik ingevulde aansoek op 'n vorm goedgekeur en verskaf deur die Raad; en

(c) aansoekgelde soos bepaal deur die Raad.

(6) Die Raad –

(a) moet, indien hy oortuig is dat die aansoek bedoel in subregulasie (5) voldoen aan die vereistes van die Wet en hierdie regulasies, asook dié van die Raad met betrekking tot die veiligheid, doeltreffendheid en gehalte van die medisyne, en dat die registrasie daarvan in die openbare belang is, die aansoek met of sonder voorwaardes goedkeur; en

(b) kan aan die persoon bedoel in subregulasie (5) 'n registrasiesertifikaat uitreik ten opsigte van sodanige medisyne onder die naam wat die Raad goedkeur;

(7) Die registrasiesertifikaat bedoel in subregulasies (6) mag slegs met goedkeuring van die Minister oorgedra word.

(8) 'n Persoon wat 'n medisyne kragtens hierdie regulasies invoer, moet –

(a) die Minister skriftelik in kennis stel van enige verandering in die feite met betrekking tot die aansoek om 'n permit uitgereik kragtens subartikel (5) of in die voorwaardes waarop die permit uitgereik is;

(b) die Raad skriftelik in kennis stel van enige wysigings aan die aansoek om die registrasie van medisyne of die voorwaardes vir die registrasie van daardie medisyne;

(c) die houer van 'n registrasiesertifikaat in die Republiek skriftelik in kennis stel van die registrasie van die medisyne ingevolge hierdie regulasie.

(9) 'n Medisyne geregistreer ingevolge hierdie regulasie mag slegs verkoop word aan die Staat of 'n persoon wat ingevolge die Wet of enige ander wetgewing gemagtig is om medisyne te verkoop.

ETIKETTERING VAN MEDISYNE BESTEM VIR MENSLIKE GEBRUIK

8.(1) Behoudens die bepalings van subregulasies (2), (3) en (4) moet die onmiddellike houer van elke pakket waarin medisyne verkoop word wat vir

toediening aan mense bedoel is, 'n etiket aanhê waarop slegs die volgende besonderhede in duidelik leesbare, onuitwisbare letters in Engels en minstens een ander amptelike taal vermeld word:

(a) In die geval van 'n medisyne gelys in 'n bylae by die Wet, die letter "B", gevolg deur die nommer van die betrokke bylae, in 'n prominente lettergrootte en -tipe en voorsien van 'n vierkantige raam, onmiddellik voor die handelsnaam van die medisyne;

(b) die handelsnaam van die medisyne;

(c) die registrasienommer van die medisyne toegewys ingevolge artikel 15(6) van die Wet;

(d) die doseervorm van die medisyne;

(e) die goedgekeurde naam van elke aktiewe bestanddeel van die medisyne en die hoeveelheid daarvan in elke dosiseenheid, of per geskikte massa of volume of eenheid, beginnende by 'n aktiewe bestanddeel met 'n hoë bylaenommer, in letters met minimum leesbaarheid;

(f) die naam en persentasie van enige bakteriostatiese of bakteriedodende middel wat as preserveermiddel by die medisyne gevoeg is;

(h) in die geval van medisyne vir mondelinge of parenterale toediening, die hoeveelheid –

(i) suiker wat die medisyne bevat; of
(ii) etielakohol wat die medisyne bevat, uitgedruk as 'n persentasie van die totale volume van die medisyne, indien daardie hoeveelheid twee persent volgens volume oorskry;

(i) die inhoud van die medisynepakket uitgedruk in die gepaste eenheid of volume van die medisyne;

(j) waar prakties moontlik, die goedgekeurde indikasies vir die gebruik van die medisyne;

(k) waar prakties moontlik, die aanbevole dosis van die medisyne;

(l) waar van toepassing, die instruksie "Skud die bottel voor gebruik";

(m) in die geval van medisyne bedoel vir inspuiting by wyse van slegs 'n bepaalde roete van toediening, daardie roete van toediening by wyse van gepaste woorde of afkortings;

(n) die lotnommer van die medisyne;

(o) die vervaldatum van die medisyne;

(p) die naam van die houer van die registrasiesertifikaat van die medisyne;

(q) die vereistes betreffende die waarop die medisyne geberg moet word, met spesifieke vermelding van die toepaslike bergingstemperatuur en ander voorsorgmaatreëls wat vir die behoud van die medisyne vereis word;

(r) waar van toepassing, die stelling "Slegs vir uitwendige gebruik";

(s) die waarskuwing "Hou buite bereik van kinders";

(t) in die geval van 'n medisyne wat aspirien of parasetamol bevat, die waarskuwing "Moenie langer as 10 dae gebruik sonder om u geneesheer te raadpleeg nie";

(u) in die geval van medisyne wat vir mondelinge toediening bedoel is en fluoriede bevat, die waarskuwing "Bevat fluoried";

(v) in die geval van 'n medisyne wat vir mondelinge bedoel is en antihistamien bevat, die waarskuwings "Hierdie medisyne kan tot lomerigheid en verswakte konsentrasie lei, wat deur die gelyktydige inname van alkohol of ander sentraalsenustelsel-depressante vererger kan word";

(w) in die geval van oogdruppels of kunstraanoplossings ten opsigte waarvan bewyse rakende die selfsteriliseringsvermoë van die medisyne nie deur die Raad goedgekeur is nie, die waarskuwing "Moenie langer as 30 dae nadat dit oopgemaak is, gebruik nie";

(x) enige gespesifiseerde waarskuwing wat ingevolge artikel 15(7) van die Wet op die etiket van die medisyne verstrek moet word as 'n voorwaarde vir die registrasie daarvan;

(y) in die geval van 'n medisyne wat tartrasien bevat, die waarskuwing "Bevat TARTRASIEN".

(2) Indien die medisynepakket sowel 'n onmiddellike houeretiket as 'n buite-etiket aanhet, is die vereistes van subartikel (1) ook op die buite-etiket van toepassing: Met dien verstande dat dit voldoende is om op die onmiddellike houeretiket aan te gee –

(i) in die geval van medisyne wat bedoel is vir toediening by wyse van inspuiting en 'n totale volume van hoogstens 5 milliliter het, die besonderhede voorgeskryf by paragrawe (b), (e), (m), (n), (o) en (p) van subregulasie (1);

(ii) in die geval van 'n salf, room, jel of poeier met 'n netto massa van hoogstens 10 gram, die besonderhede voorgeskryf by paragrawe (b), (c), (e), (f), (n), (o), (p) en (x) van subregulasie (1);

(iii) in die geval van 'n vloeistof, oplossing of suspensie met 'n totale volume van meer as 1 milliliter maar hoogstens 15 milliliter, die

besonderhede voorgeskryf by paragrawe (b), (c), (d), (e), (n), (w), (o), (p) en (x) van subregulasie (1);

(iv) in die geval van 'n vloeistof, oplossing of suspensie met 'n totale volume van hoogstens 1 milliliter, die besonderhede voorgeskryf by paragrawe (b) en (n) van subregulasie (1);

(v) in die geval van medisyne wat in 'n stolpverpakking of soortgelyke verpakking verpak is, die besonderhede voorgeskryf by paragrawe (b), (n), (o) en (p) van subregulasie (1), wat so dikwels as wat prakties moontlik is, herhaal moet word.

(3) Die Raad kan magtiging verleen dat enige spesiale inligting wat nie by hierdie regulasie vereis word nie, op die etiket van die medisyne ingesluit word.

(4) Die vereistes van subregulasie (1) is nie van toepassing nie op –

(a) enige medisyne wat ooreenkomstig artikel 14(4) van die Wet verkoop word;

(b) enige medisyne verkoop deur 'n persoon wat kragtens artikel 22C gemagtig is om toebereiding te doen of 'n apteker in die loop van sy of haar professionele bedrywighede by die behandeling van 'n bepaalde pasiënt; of

(c) enige medisyne verkoop deur 'n apteker, deur 'n persoon gemagtig om medisyne op te maak en toe te berei, of in 'n hospitaalapteek volgens 'n voorskrif uitgereik deur 'n geneesheer of tandarts vir die behandeling van 'n bepaalde pasiënt: Met dien verstande dat sodanige medisyne verkoop word in 'n pakket wat 'n etiket aanhet waarop die volgende inligting verstrek word:

(i) die handelsnaam, goedgekeurde naam of die naam van elke aktiewe bestanddeel van die medisyne, waar van toepassing, of samestellende medisyne;
(ii) die naam van die persoon vir wie se behandeling daardie medisyne verkoop word;
(iii) die aanwysings vir die gebruik van die medisyne;
(iv) die naam ensakeadres van die persoon wat gemagtig is om daardie medisyne te verkoop;
(v) die datum van toebereiding; en
(vi) die verwysingnommer.

VOUBILJETTE VIR MEDISYNE VIR MENSLIKE GEBRUIK

9.(1) Behoudens die bepalings van subregulasies (2) en (3) moet elke pakket van 'n medisyne vergesel gaan van 'n voubiljet, as 'n afsonderlike entiteit of as 'n integrerende deel van die pakket, waarop onderstaande besonderhede in Engels en minstens een ander amptelike taal gedruk is in letters met 'n minimum leesbaarheid en onder die opskrifte en in die formaat gespesifiseer in hierdie regulasie:

(a) Die skeduleringstatus, dit wil sê die skeduleringstatus soos van tyd tot tyd deur die Minister bepaal;

(b) handelsnaam en doseervorm;

(c) samestelling, dit wil sê –

(i) die goedgekeurde naam van elke aktiewe bestanddeel en die hoeveelheid daarvan in 'n doseereenheid of per geskikte massa of volume of eenheid van die medisyne;
(ii) die goedgekeurde naam en hoeveelheid van enige bakteriostatiese of bakteriedodende middel wat in die medisyne aanwesig is as preserveermiddel, uitgedruk as 'n persentasie;
(iii) die hoeveelheid etielalkohol aanwesig in 'n preparaat vir mondelinge of parenterale toediening, indien daardie hoeveelheid twee persent volgens volume te bowe gaan;
(iv) die woorde "Bevat TARTRASIEN", indien die medisyne daardie bestanddeel bevat; en
(v) in die geval van 'n medisyne bedoel vir mondelinge toediening wat suiker bevat, al dan nie, die waarskuwing "Bevat suiker" of "Suikervry", na gelang van die geval;

(d) farmakologiese klassifikasie, dit wil sê die kategorie, die nommer en die beskrywing van die klassifikasie soos vermeld in regulasie 25;

(e) farmakologiese werking, dit wil sê 'n beskrywing van die farmakologiese werking van die medisyne, en, waar van toepassing, onder die subopskrif "Farmakokinetika": Farmakodinamika, Opsomomg van kliniese studies;

(f) indikasies;

(g) kontra-indikasies;

(h) waarskuwings;

(i) interaksies;

(j) swangerskap en laktasie;

(k) dosis en gebruiksaanwysings;

(l) newe-effekte en spesiale voorsorgmaatreëls;

(m) bekende simptome van oordosering en besonderhede van die behandeling daarvan;

(n) identifikasie;

(o) aanbieding;

(p) bergingsinstruksies wat prakties geformuleer is en bergingstemperature aandui;

(q) registrasienommer, dit wil sê –

(i) die nommer toegewys ingevolge artikel 15(6) van die Wet; of
(ii) in die geval van medisyne ten opsigte waarvan om registrasie aansoek gedoen is, die verwysingsnommer toegewys aan daardie aansoek, gevolg deur die uitdrukking "Wet 101/1965";

(r) die naam en sakeadres van die houer van die registrasiesertifikaat, of in die geval van 'n parallel ingevoerde medisyne, die naam en sakeadres van die houer van die parallellinvoerderspermit;

(s) datum van publikasie van die voubiljet:

Met dien verstande dat –

(i) indien die Raad beslis dat daar geen toepaslike inligting onder 'n bepaalde opskrif verstrek moet word nie, daardie opskrif met goedkeuring van die Raad weggelaat mag word;
(ii) die Raad, indien daarom aansoek gedoen word, 'n afwyking van die formaat en inhoud van 'n voubiljet kan magtig as 'n voorwaarde vir registrasie van 'n medisyne;
(iii) die Raad, indien daarom aansoek gedoen word, die insluiting op 'n voubiljet van enige gespesifiseerde inligting waarvan sodanige insluiting nie by hierdie regulasie vereis word nie, kan magtig; en
(iv) die Raad, indien daarom aansoek gedoen word, die inligting onder 'n bepaalde opskrif kan bepaal wat verstrek moet word ten opsigte van 'n vervangbare multibronmedisyne.

(2) Die vereistes van subregulasie (1) is nie van toepassing nie in die geval van medisyne wat die Minister kragtens artikel 36 van die Wet van die toepassing van die Wet uitgesluit het.

(3) Die vereistes van subregulasie (1) is nie van toepassing nie op –

(a) enige medisyne wat ooreenkomstig die bepalings van artikel 14(4) verkoop word;

(b) enige medisyne wat deur 'n geneesheer, tandarts, apteker of ander persoon wat gemagtig is om medisyne toe te berei, in die loop van sy of haar professionele bedrywighede vir die behandeling van 'n bepaalde pasiënt opgemaak en/of verkoop word;

(c) enige medisyne wat deur 'n apteker of 'n hospitaalapteek verkoop word ooreenkomstig 'n voorskrif deur 'n geneesheer of tandarts uitgereik vir die behandeling van 'n bepaalde pasiënt.

(4) Geen bepaling van subregulasies (2) en (3) word so uitgelê dat dit die insluiting van 'n voubiljet by die medisyne verbied nie.

(5) Die Raad kan enige indikasie intrek as hy van mening is dat die risiko- en voordeelprofiel van die medisyne vir die goedgekeurde indikasies waarvoor dit geregistree is, nie in die openbare belang is nie.

PASIËNTINLIGTINGSBLAADJIE

10.(1) Elke pakket medisyne moet 'n pasiëntinligtingsblaadjie hê wat die volgende inligting met betrekking tot die medisyne in Engels en minstens een ander amptelike taal bevat:

(a) Skeduleringstatus;

(b) handelsnaam en doseervorm;

(c) samestelling van die medisyne, dit wil sê die inligting bedoel in regulasie 9(1)(c);

(d) die goedgekeurde indikasies en gebruik;

(e) instruksies voordat die medisyne gebruik word, wat insluit –

(i) kontra-indikasies;
(ii) voorsorgmaatreëls;
(iii) waarskuwings, byvoorbeeld met betrekking tot die sedatiewe eienskappe van die medisyne of risiko's verbonde aan die skielike onttrekking van die medisyne;
(iv) interaksies;
(v) die volgende algemene stellings:
"Indien u medisyne op 'n gereelde grondslag gebruik, kan die gelyktydige gebruik daarvan saam met ander medisyne ongewenste interaksies veroorsaak. Raadpleeg asseblief u dokter, apteker of ander gesondheidsorgkundige."; en
"Indien u swanger is of u baba borsvoed terwyl u hierdie medisyne gebruik, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgkundige.";

(f) aanwysings oor hoe om die medisyne te gebruik, wat die volgende stellings moet insluit:
"Moenie medisyne wat vir u voorgeskryf is, met enigiemand anders deel nie. "; en "In die geval van oordosering, raadpleeg u dokter of apteker. Indien geeneen beskikbaar is nie, skakel die naaste hospitaal of gifhulpsentrum.";

(b) die lughawe of hawe van Port Elizabeth;

(c) die lughawe of hawe van Durban; of

(d) die Johannesburgse Internasionale Lughawe.

(2) 'n Persoon mag 'n medisyne of gelyste stof invoer slegs as hy of sy –

(a) ingevolge die Wet gelisensieer is om medisyne in te voer;

(b) in die geval van ongeregistreerde medisyne, deur die Raad gemagtig is om sodanige medisyne in te voer.

VERVOER DEUR DIE REPUBLIEK VAN MEDISYNE

13.(1) Medisyne, gelyste stowwe en mengsels wat gelyste stowwe bevat, wat deur die Republiek vervoer word –

(a) moet, terwyl dit in die Republiek is, geberg word in 'n doeanepakhuis wat by die Raad geregistreer is; en

(b) mag nie gehanteer word terwyl dit in die doeanepakhuis is nie, tensy dit deur die Raad gemagtig is.

(2) 'n Doeanepakhuis bedoel in subregulasies (1) moet voldoen aan die voorwaardes vir goeie berging wat die Raad bepaal.

PERMITTE KRAGTENS ARTIKEL 22A VAN DIE WET

14.(1) 'n Geneesheer of veearts wat 'n Bylae 8-stof wil bekom vir die behandeling of voorkoming van 'n mediese toestand by 'n bepaalde pasiënt, moet by die Direkteur-generaal aansoek doen om 'n permit om daardie stof of medisyne te gebruik.

(2) 'n Aansoek beoog in subregulasie (1) moet minstens die volgende inligting bevat:

(a) die naam en adres (sowel fisiese as posadres) van die aansoeker;

(b) die identiteitsnommer van die aansoeker;

(c) die registrasienommer van die aansoeker by die betrokke statutêre raad;

(d) die kwalifikasies van die aansoeker;

(e) die telefoon- en die faksnommer van die aansoeker;

(f) die doel waarvoor die aansoek gedoen word;

(g) in die geval van 'n geneesheer, die naam en adres van die pasiënt, die diagnose, die dosis en die behandelingstydperk; en

(h) in die geval van 'n veearts, die naam en adres van die dier se eienaar, die diagnose, die dosis en die behandelingstydperk;

(3) 'n Permit beoog in subregulasie (1) mag nie uitgereik word nie indien die Direkteur-generaal van mening is dat die aansoeker nie in staat is om die stof op sodanige wyse te hou of te berg dat verlies daarvan voorkom word nie.

(4) 'n Ontleder of navorser wat 'n Bylae 6- of 'n Bylae 7-stof vir opvoedkundige doeleindes, ontleding of navorsing wil bekom, moet by die Direkteur-generaal aan soek doen om 'n permit om daardie stof aldus te gebruik.

(5) 'n Aansoek beoog in subregulasies (4) moet minstens die volgende inligting bevat:

(a) die naam en adres (sowel fisiese as posadres) van die aansoeker;

(b) die identiteitsnommer van die aansoeker;

(c) die naam en adres van sy of haar werkgewer;

(d) die kwalifikasies van die aansoeker;

(e) die telefoon- en die faksnommer van die aansoeker;

(f) besonderhede van die navorsingsprojek;

(g) die adres waar dienavorsing gedoen gaan word;

(h) die beraamde duur van die projek;

(i) die totale hoeveelheid gelyste stowwe wat per jaar in voorraad gehou gaan word;

(j) die bron van die voorraad; en

(k) die plek waar en manier waarop die gelyste stowwe veilig geberg gaan word.

(6) Die Direkteur-generaal kan enige aansoek in subregulasie (4) beoog, toestaan of weier.

(7) Enige persoon wat 'n Bylae 6-stof wil vervaardig, moet by die Direkteur-generaal aansoek doen om 'n permit om sodanige stof te vervaardig.

(8) 'n Aansoek beoog in subregulasie (7), moet minstens die volgende inligting bevat:

(a) Die naam en adres (sowel fisiese as posadres) van die aansoeker;

(b) die registrasienommer van die aansoeker by die Suid-Afrikaanse Aptekersraad;

(c) 'n gewaarmerkte afskrif van die vervaardigingslisensie uitgereik deur die Raad;

(d) die telefoon- en faksnommer van die aansoeker;

(e) die adres waar die vervaardiging onderneem gaan word; en

(f) die beraamde hoeveelheid Bylae 6-stof wat vervaardig gaan word.

(9) Enige persoon wat 'n Bylae 5- of 'n Bylae 6-stof wil vervaardig vir ander doeleindes as medisinale doeleindes, moet by die Direkteur-generaal aansoek doen om 'n permit om sodanige stof te vervaardig.

(10) 'n Aansoek beoog in subregulasie (9) moet minstens die volgende inligting bevat:

(a) die naam en adres (sowel fisiese as posadres) van die aansoeker;

(b) die identiteitsnommer van die aansoeker;

(c) die registrasienommer van die aansoeker by die betrokke statutêre raad;

(d) die kwalifikasies van die aansoeker;

(e) die telefoon- en die faksnommer van die aansoeker;

(f) die doel waarvoor die aansoek gedoen word.

(11) 'n Geneesheer of veearts mag nie 'n gelyste stof of medisyne vir ander doeleindes as medisinale doeleindes buite 'n hospitaal toedien ter bevrediging of verligting van 'n gewoonte of drang nie, tensy hy of sy voldoen aan die voorwaardes gestel deur die Direkteur-generaal.

(12) Die Direkteur-generaal mag 'n permit beoog in subregulasie (9) uitreik slegs ná oorleg met die Dwelmadviesraad en die Raad.

(13) Die geneesheer of veearts bedoel in hierdie regulasies is onderworpe aan gereelde inspeksies kragtens die Wet.

(14) Die permit kan deur die Direkteur-generaal ingetrek, herroep of opgeskort word indien die persoon aan wie dit uitgereik is, versuim om aan die voorwaardes of vereistes van die permit te voldoen.

INVOER OF UITVOER VAN GESPESIFISEERDE BYLAE 5-, OF BYLAE 6-, BYLAE 7- OF BYLAE 8-STOWWE

15.(1) 'n Persoon wat gespesifiseerde Bylae 5- of Bylae 6-, Bylae 7- of Bylae 8-stowwe wil invoer of uitvoer, moet by die Direkteur-generaal aansoek doen om 'n permit om sodanige stowwe in te voer of uit te voer.

(2) 'n Aansoek beoog in subregulasie (1) moet minstens die inligting vereis by regulasie 14(2) bevat.

(3) Die aansoeker moet tesame met die aansoek 'n gewaarmerkte afskrif van die invoerpermit uitgereik deur die land waarheen die stof of medisyne uitgevoer gaan word, indien.

(4) 'n Permit uitgereik soos bedoel in subregulasie (1), is geldig vir 'n tydperk van ses maande.

BESIT VAN GESPESIFISEERDE HOVEELHEDE GELYSTE STOWWE VIR PERSOONLIKE MEDISINALE GEBRUIK DEUR PERSONE WAT DIE REPUBLIEK BINNEKOM OF VERLAAT

16.(1) Ondanks regulasie 12 en behoudens subregulasie (3) mag enige persoon wat die Republiek binnekom of verlaat, vir persoonlike medisinale gebruik in besit wees van 'n hoeveelheid Bylae 3-, Bylae 4-, Bylae 5- of Bylae 6-stof of -medisyne, wat nie die hoeveelheid wat nodig is vir gebruik vir 'n tydperk van een maand, te bowe mag gaan nie.

(2) 'n Persoon bedoel in subregulasie (1) moet –

(a) in besit wees van 'n geldige voorskrif vir sodanige gelyste stof of medisyne; of

(b) in besit wees van 'n sertifikaat deur 'n gemagtigde voorskrywer of deur 'n persoon wat sodanige gelyste stof of medisyne toeberei, ten effekte dat die betrokke gelyste stof of medisyne en die hoeveelheid daarvan vir die betrokke persoon voorgeskryf is, en die sertifikaat moet die naam en adres van die gemagtigde voorskrywer vermeld; en

(c) in die geval van 'n persoon wat die Republiek binnekom, sy of haar verblyfbesonderhede in die Republiek laat aanteken by die toegangspoort.

INLIGTING WAT JAARLIKS AAN DIREKTEUR-GENERAAL VERSTREK MOET WORD DEUR HOUER VAN PERMIT

17.(1) 'n Persoon aan wie 'n permit soos beoog in regulasie 15 uitgereik is, moet die volgende inligting met betrekking tot die stowwe bedoel in daardie regulasie aan die Direkteur-generaal verstrek:

(a) Die hoeveelheid van die stof, as grondstof of soos in 'n preparaat bevat, wat in voorraad was op 1 Januarie die voorafgaande jaar;

(b) die hoeveelheid van die stof wat gedurende die voorafgaande jaar verkry is deur –

(i) invoer van die stof, as grondstof of soos in 'n preparaat bevat;
(ii) plaaslike produksie van die grondstof;
(iii) plaaslike aankope van die grondstof, in welke geval die naam van die verskaffer ook verstrek moet word;

(c) die hoeveelheid van sodanige stof, as grondstof of soos in 'n preparaat bevat, waaroor gedurende die voorafgaande jaar beskik is deur uitvoer of op 'n ander wyse;

(d) die hoeveelheid van sodanige stof wat gedurende die voorafgaande kalenderjaar gebruik is in die produksie van enige ander Bylae 6- of Bylae 7-stof of 'n gespesifiseerde stof bedoel in artikel 22A(12)(a)(ii) en (iii) van die wet;

(e) die hoeveelheid van sodanige stowwe en preparate wat sodanige stowwe bevat, wat op 31 Desember van die voorafgaande jaar nog in voorraad was.

(2) Die inligting bedoel in subregulasie (1) moet aan die volgende vereistes voldoen:

(a) Hoeveelhede moet in metrieke eenhede uitgedruk word of as 'n persentasie van die betrokke stof;

(b) in die geval van opium en enige preparate wat opium bevat, moet hoeveelhede uitgedruk word as opium wat 10 persent anhidirese morfien bevat;

(c) preparate wat nie regstreeks van opium verkry word nie maar van 'n mengsel van opiumalkaloïede, moet uitgedruk word as morfien;

(d) hoeveelhede kokablare word uitgedruk as kokablare wat 0,5 persent kokaïen bevat; en

(e) indien voorraad gehou word of vervaardiging onderneem is namens 'n ander persoon, moet daardie feit vermeld word.

LISENSIE OM MEDISYNE OP TE MAAK EN TOE TE BEREI

18.(1) 'n Geneesheer, tandarts, praktisyn, verpleegkundige of enige ander persoon geregistreer kragtens die Wet op Gesondheidsberoepe, 1974 (Wet No. 56 van 1974), wat medisyne wil toeberei of opmaak en toeberei, moet by die

Direkteur-generaal aansoek doen om 'n lisensie om medisyne toe te berei of op te maak, soos beoog in artikel 22C(1) van die Wet.

(2) 'n Aansoek bedoel in subregulasie (1) moet vergesel gaan van die aansoekgelde wat die Direkteur-generaal bepaal.

(3) Die aansoek bedoel in subregulasie (1) moet minstens die volgende inligting bevat:

(a) Die naam, woonadres en sakeadres (sowel die fisiese as die posadres) van die aansoeker;

(b) die presiese ligging van die perseel waar die opmaak en/of toebereiding gaan geskied;

(c) bewys van voltooiing van 'n aanvullende kursus soos vereis by artikel 2C(2) van die Wet;

(d) die telefoon- en die faksnommer van die aansoeker, indien beskikbaar;

(e) bewys van registrasie by die toepaslike statutêre raad;

(f) bewys van die publikasie van die kennisgewing bedoel in subregulasie (5);

(g) motivering van die behoefte aan 'n lisensie in 'n bepaalde gebied;

(h) enige ander inligting wat die Direkteur-generaal vereis; en

(i) bewys van die vermoë om 'n pasiëntinligtingsblaadjie te verskaf.

(4) By die oorweging van 'n aansoek bedoel in subregulasie (1) moet die Direkteur-generaal die volgende in ag neem:

(a) Die bestaan van ander gelisensieerde gesondheidsfasiliteite in die omgewing van die perseel waar beoog word om medisyne op te maak en toe te berei;

(b) vertoë, as daar is, deur ander belanghebbende partye met betrekking tot die uitreiking, al dan nie, van 'n lisensie;

(c) die geografiese gebied wat deur die aansoeker bedien gaan word;

(d) die beraamde aantal gesondheidsorggebruikers in die geografiese gebied bedoel in paragraaf (a);

(e) demografiese oorwegings, met inbegrip van siektepatrone by en die gesondheidstatus van die gebruikers wat bedien gaan word; en

(f) enige ander inligting wat hy of sy nodig ag.

(5) Wanneer 'n aansoek bedoel in subregulasie (1) gedoen word, moet die aansoeker terselfdertyd kennis gee van sy of haar voorneme om aansoek te doen om 'n lisensie deur 'n kennisgewing te dien effekte te laat publiseer in 'n nuusblad wat versprei word in die gebied waar die aansoeker beoog om sy of haar praktyk te beoefen.

(6) Enige persoon kan 'n aansoek bedoel in subregulasie (1) steun of teenstaan deur vertoë aan die Direkteur-generaal te rig binne 30 dae na die publikasie van die kennisgewing bedoel in subregulasie (5).

(7) 'n Persoon bedoel in subregulasie (1) aan wie 'n lisensie uitgereik is –

(a) moet verkoopsrekords, in harde kopie of elektronies, met betrekking tot die medisyne wat opgemaak en toeberei is, behou vir 'n tydperk van vyf jaar na die verkoopsdatum;

(b) moet verseker dat die resepteergebied en enige perseel waar medisyne gehou word, geskik is vir die toebereiding of opmaak en toebereiding van medisyne ooreenkomstig goeie farmasiepraktyk;

(c) moet die medisyne bewaar in die vervaardiger se aanbevole bergingstoestande soos gespesifiseer op die medisyne-etiket en/of die voubiljet;

(d) mag nie medisyne op die perseel vooraf verpak nie, tensy daartoe gemagtig deur die Direkteur-generaal en ingevolge regulasie 33(a)(ii);

(e) moet medisyne behoorlik etiketteer met die naam van die pasiënt en 'n verwysingsnommer wat die pasiënt verbind met 'n pasiëntrekord;

(f) mag nie medisyne vir pasiënte opmaak en toeberei nie, tensy die verkoop voorafgegaan word deur 'n behoorlike diagnose en voorskrywing vir 'n bepaalde pasiënt deur die lisensiehouer;

(g) mag nie medisyne wat verval het, op die perseel hou nie, behalwe in 'n afgebakende gebied in 'n verseëlde houer wat duidelik gemerk is "VERVALDE MEDISYNE", en sodanige vervalde medisyne moet ooreenkomstig regulasie 27 vernietig word;

(h) moet die perseel waar die opmaak en toebereiding van medisyne geskied, beveilig wanneer hy of sy nie fisies op daardie perseel teenwoordig is nie;

(i) moet, wanneer 'n medisyne ingetrek word, daardie medisyne verwyder;

(j) moet die lisensie opvallend op die perseel bedoel in paragraaf (b) vertoon;

(k) moet aan die voorwaardes van sy of haar lisensie voldoen;

(8) Vir doeleindes van hierdie regulasie het "opmaak en toeberei" nie betrekking op 'n medisyne wat voorbereiding verg vir 'n eenmalige toediening aan 'n pasiënt tydens konsultasie nie.

LISENSIE OM MEDISYNE TE VERVAARDIG, OF OM OP TE TREE AS GROOTHANDELAAR DAARVAN OF DIT TE VERSPREI

19.(1) 'n Persoon bedoel in artikel 22C(1)(b) van die Wet –

(a) moet, voordat hy of sy as sodanig begin sake doen –

(i) by die Raad aansoek doen om 'n lisensie om medisyne, gelyste stowwe of mediese toestelle te vervaardig, as groothandelaar daarvan op te tree of dit te versprei;

(ii) 'n apteker as sodanig aanstel en aanwys om die vervaardiging of verspreiding van medisyne, gelyste stowwe of mediese toestelle te beheer;

(iii) 'n natuurlike persoon wat in die Republiek woonagtig is, aanstel en aanwys om teenoor die Raad verantwoordelik te wees vir nakoming van die Wet;

(b) moet by die Registrateur, op 'n vorm goedgekeur en verskaf deur die Raad, 'n aansoek indien om lisensie soos bedoel in paragraaf (a)(i);

(c) moet, as deel van die aansoek bedoel in paragraaf (b), aanvaarbare dokumentêre bewys lewer van –

(i) die besonderhede van die eienaar van die besigheid;

(ii) die registrasie van die verantwoordelike apteker;

(iii) die kwalifikasies van die werknemers om medisyne, gelyste stowwe of mediese toestelle ingevolge die Wet te vervaardig, te berg, te versprei en te verkoop;

(iv) die vermoë om te voldoen aan die goeie vervaardigings- of verpreidingspraktyke wat die Raad bepaal, wat die volgende moet insluit:

(aa) 'n Afskrif van 'n plaaslike gebiedsplan van die ligging van die sakeperseel waarop al die aangrensende eiendomme en die aard van die besigheid wat daarop gedryf word, aangedui is;

(bb) 'n vloerplan van die gebou waarin die sakeperseel geleë is;

(cc) 'n plan van die werklike inkleding van die sakeperseel;

(dd) 'n inventaris van die toerusting wat gebruik gaan word in die dryf van die besigheid;

(ee) 'n prosedure- en praktykshandleiding wat gevolg moet word om die veiligheid, doeltreffendheid en gehalte te verseker van die medisyne, gelyste stowwe of mediese toestelle watvervaardig of versprei en verkoop gaan word;

(d) moet die medisyne, gelyste stowwe of mediese toestelle spesifiseer wat vervaardig of versprei en verkoop gaan word;

(e) moet die aansoek- en inspeksiegelde bepaal deur die Raad, betaal.

(2) Die Registrateur kan aan die persoon bedoel in subregulasie (1) skriftelik kennis gee om, binne redelike tyd, wat in die kennisgewing vermeld moet word, sodanige bykomende dokumente of inligting aan die Raad te verstrek as wat die Raad vereis.

(3) Die Raad moet die sakeperseel gespesifiseer in die aansoek, inspekteer.

(4) Indien die Raad oortuig is dat –

(a) die persoon bedoel in subregulasie (1) aan die voorgeskrewe vereistes voldoen;

(b) die aansoek om 'n lisensie om medisyne, gelyste stowwe of mediese toestelle te vervaardig, op te tree as groothandelaar daarvan of om dit te versprei, voldoen aan die voorgeskrewe vereistes;

(c) die aansoeker daartoe in staat is om aan goeie vervaardigings- of verspreidingspraktyke te voldoen,

moet die Raad, met of sonder voorwaardes, die aansoek goedkeur en 'n lisensie aan die betrokke persoon uitreik.

(5) Die Registrateur moet –

(a) 'n aparte register hou van elke kategorie lisensiehouer soos beoog in subregulasie (1)(a)(i); en

(b) die lisensienommer, die naam van die lisensiehouer en sy of haar fisiese en posadres, in sodanige register aanteken.

(6) Ondanks die geldigheidsduur van die lisensie moet die lisensiehouer die jaargeld vir voortgesette registrasie, soos bepaal deur die Raad, betaal.

(7) 'n Lisensiehouer moet die Registrateur skriftelik in kennis stel van enige verandering in die besonderhede verstrek op die aansoek of aangeteken in die register, wat ná die uitreiking van die lisensie intree.

(8) Indien daar tot tevredenheid van die Raad bewys word dat 'n inskrywing in die register per abuis gedoen is of weens wanvoorstelling of in omstandighede wat nie by die Wet gemagtig is nie, mag daardie inskrywing uit die register geskrap word.

(9) 'n Persoon ten opsigte van wie se inskrywing 'n skrapping soos bedoel in subregulasie (8) gedoen is, moet kennis van daardie skrapping gegee word en enige sertifikaat uitgereik ten opsigte van die betrokke registrasie word geag gerojeer te wees vanaf die datum waarop kennis aldus gegee is.

(10) Die Raad kan die Registrateur gelas om uit die register te skrap die naam van 'n lisensiehouer –

(a) wat nie aan die Wet of aan die voorwaardes van sy of haar lisensie voldoen nie;

(b) indien die verantwoordelike apteker versuim om die vervaardiging of verspreiding van die medisyne, gelyste stowwe of mediese toestelle te beheer,

indien die lisensiehouer in gebreke bly om, binne 21 dae ná die datum waarop kennis gegee is van die Raad se voorneme om die naam van die lisensiehouer uit die betrokke register te skrap en die besigheid te sluit, skriftelike redes te verstrek waarom die lisensiehouer se naam nie uit die register geskrap of die besigheid nie gesluit moet word nie: Met dien verstande dat indien die Raad van mening is dat dit in die openbare belang is, hy kan afsien van die vereiste kennisgewing.

GELDIGHEIDSDUUR VAN 'N LISENSIE UITGEREIK KRAGTENS REGULASIES 18 EN 19 EN HERNUWING VAN LISENSIES

20.(1) 'n Lisensie uitgereik kragtens regulasie 18 is geldig vir 'n tydperk van drie jaar, en 'n lisensie uitgereik kragtens regulasie 19 is geldig vir 'n tydperk van vyf jaar vanaf die datum van uitreiking.

(2) 'n Lisensie bedoel in subregulasie (1) wat verstryk het, kan hernu word deur aansoek daarom te doen by die Direkteur-generaal of die Raad, na gelang van die geval.

(3) 'n Aansoek bedoel in subregulasie (2) moet –

(a) minstens die inligting of dokumente bevat wat in regulasie 18(3) of regulasie 19(1)(c), na gelang van die geval, genoem word;

(b) vergesel gaan van die voorgeskryf gelde; en

(c) 90 dae voor die verstryking van die bestaande lisensie gedoen word.

APPÈL TEEN BESLISSING VAN DIREKTEUR-GENERAAL OF RAAD

21.(1) 'n Appèl aangeteken of vertoë gerig kragtens artikel 24 van die Wet, moet aangeteken of gerig word binne 30 dae vanaf die datum waarop die besluit waarteen geappelleer of ten opsigte waarvan vertoë gerig word, aan die appellant of die persoon wat die vertoë rig, bekendgemaak is.

(2) By die aanteken van die appèl of die rig van die vertoë moet die appellant of persoon wat die vertoë rig, 'n kennisgewing per geregistreerde pos aan die Minister of aan die Direkteur-generaal en –

(a) in die geval van 'n beslissing van die Raad, aan die Registrateur van Medisyne, Medisynebeheerraad, Privaat Sak X828, Pretoria, 0001; of

(b) in die geval van 'n beslissing van die Direkteur-generaal, aan die Direkteur-generaal, Departement van Gesondheid, Privaat Sak X828, Pretoria, 0001,

stuur waarin die beslissing waarteen geappelleer word, vermeld word.

(3) Die kennisgewing bedoel in subregulasie (2) moet die gronde vir die appèl of vertoë duidelik en bondig uiteensit.

(4) Die Minister moet binne 30 dae na ontvangs van die kennisgewing van appèl 'n appèlkomitee aanstel om die appèl te beslis.

(5) Die Direkteur-generaal moet binne 15 dae na ontvangs van die kennisgewing bedoel in subregulasie (2) daardie kennisgewing aan die Minister voorlê en die Minister moet 'n beslissing oor die beslissing van die Direkteur-generaal gee binne 30 vanaf die datum waarop –

(a) die kennisgewing ontvang is; of
(b) die oorweging van die vertoë afgehandel is,

wat ook al die laatste is.

(6) Die appèlkomitee –

(a) moet die prosedure vir die aanhoor van appèlle bepaal;

(b) kan, as hy dit nodig ag, mondelinge getuienis of betoog aanvra of enige persoon wat –

(i) na die komitee se mening inligting kan verskaf oor die onderwerp van die appèl; of

(ii) die komitee meen 'n dokumente in sy of haar besit of onder sy of haar beheer het wat betrekking op die onderwerp van die appèl het,

dagvaar om voor hom te verskyn op die tyd en plek in die dagvaarding vermeld, ten einde vrae te beantwoord of 'n dokument voor te lê; en

(c) moet, as hy mondelinge getuienis of betoog aanvra –

(i) die datum, tyd en plek van die appèl bepaal en dit skriftelik aan die appellant en die Raad bekend maak;

(ii) 'n eed of plegtige verklaring afneem van enige persoon wat as getuie tydens die appèl geroep word.

(7) Persone wat voor die appèlkomitee verskyn, mag deur 'n regspraktisyn verteenwoordig word.

(8) Die appèlkomitee moet die appèl oorweeg en 'n beslissing in verband daarmee maak binne 'n tydperk van 30 dae vanaf die datum –

(a) waarop hy aangestel is; of

(b) waarop die appèl afgehandel is,

wat ook al die laatste is.

AANSOEK OM REGISTRASIE VAN MEDISYNE

22.(1) Enige persoon wat in die Republiek woonagtig is en sake doen, kan aansoek doen om doe registrasie van 'n medisyne.

(2) Die aansoek bedoel in subregulasie (1) moet die besonderhede insluit van die persoon wat toepaslike kennis van alle aspekte van die medisyne het en verantwoordelik sal wees vir kommunikasie met die Raad.

(3) 'n Aansoek bedoel in sybregulasie (1) word gedoen op die toepaslike vorm, wat by die Registrateur verkrygbaar is, en moet vergesel gaan van –

(a) 'n behoorlik ingevulde siftingsvorm, wat by die Registrateur verkrygbaar is;

(b) 'n voorgestelde etiket vir gebruik op die medisyne;

(c) waar van toepassing, 'n afskrif van die vervaardigingslisensie tesame met die huidige sertifikaat van goeie vervaardigingspraktyk uitgereik deur die regulerende owerheid van die land van oorsprong van die medisyne;

(d) in die geval van gespesifiseerde Bylae 5- en van Bylae 6-, Bylae 7- en Bylae 8-stowwe, 'n gewaarmerkte afskrif van die permit om sodanige stowwe te vervaardig;

(e) sodanige data oor die veiligheid, doeltreffendheid en gehalte van die medisyne, hetsy positief of negatief, as wat die Raad bepaal;

(f) bewys van die bestaan van 'n vervaardigingsperseel, dit wil sê 'n perseelmeesterlêer;

(g) enige ander inligting wat die Raad bepaal; en

(h) die aansoekgeld.

(4) Die inligting bedoel in subregulasie (3) moet in Engels en minstens een ander amptelike taal verstrek word.

(5) Die aansoekvorm bedoel in subregulasie (3) moet minstens die volgende inligting bevat:

(a) Besonderhede van die aansoeker en die beoogde houer van die registrasiesertifikaat:

(i) Naam;
(ii) sakeadres;
(iii) posadres;
(iv) telefoonnommer;
(v) faksnommer;
(vi) e-posadres;
(vii) in die geval van 'n regspersoon, kontakbesonderhede van die persoon bedoel in subregulasie (2);

(b) besonderhede van die medisyne:

(i) Handelsnaam;
(ii) doseervorm;
(iii) sterkte per dosiseenheid;
(iv) roete van toediening;
(v) land van oorsprong en registrasiestatus buite die Republiek;
(vi) kategorie en farmakologiese klassifikasie;
(vii) naam van die vervaardiger(s); en
(viii) goedgekeurde naam.

(6) 'n Medisyne ten opsigte waarvan aansoek om registrasie gedoen word, moet aan die tegniese vereistes voldoen wat die Raad bepaal.

(7) 'n Aansoek moet ten opsigte van elke individuele doseervorm en sterkte van 'n medisyne gedoen word.

(8) In 'n geval waar 'n medisyne ten opsigte waarvan aansoek gedoen word, by 'n regulerende owerheid buite die Republiek geregistreer is of was, moet die aansoek vergesel gaan van volgende inligting ten opsigte van daardie medisyne:

(a) 'n Afskrif van die registrasiesertifikaat;

(b) 'n voubiljet;

(c) die registrasievoorwaardes; en

(d) enige ander inligting wat die Raad bepaal.

(9) Die bepalings van hierdie regulasie is, met die nodige aanpassings, van toepassing op 'n aansoek om die registrasie van veterinêre medisyne.

INLIGTING WAT IN MEDISYNEREGISTER MOET VERSKYN

23. Die medisyneregister moet, ten opsigte van enige geregistreerde medisyne, die volgende inligting bevat:

(a) Handelsnaam;

(b) registrasienommer toegeken aan die medisyne;

(c) die goedgekeurde naam van elke aktiewe bestanddeel van die medisyne en die hoeveelheid daarvan in 'n dosiseenheid of per geskikte massa of volume of eenheid van die medisyne;

(d) die doseervorm van die medisyne, waar van toepassing;

(e) die naam van die houer van die registrasiesertifikaat;

(f) die naam en adres van die vervaardiger(s) en die vervaardigingsfasiliteit;

(g) die naam van die eindprodukvrystellingsbeheer;

(h) die naam van die eindprodukvrystellingsverantwoordelikheid;

(i) die datum van registrasie van die medisyne; en

(j) die registrasievoorwaardes van die medisyne bepaal ingevolge artikel 15(7) van die Wet.

AANSOEK OM WYSIGING VAN INSKRYWING IN MEDISYNEREGISTER

24.(1) 'n Houer van 'n registrasiesertifikaat kan, op die vorm wat die Raad bepaal, by die Registrateur aansoek doen om 'n inskrywing in die medisyneregister met betrekking tot 'n bepaalde medisyne te wysig.

(2) Die aansoek beoog in subregulasie (1) moet vergesel gaan van die voorgeskryf geld en moet die die volgende inligting bevat:

(a) Die registrasienommer van die medisyne;

(b) die sakeadres van die aansoeker;

(c) 'n verklaring deur die aansoeker dat die inligting wat verstrek word, volledig en korrek is;

(d) die besonderhede van die wysiging waarom aansoek gedoen word;

(e) sodanige ander inligting as wat die Raad bepaal; en

(f) die naam van die aansoeker.

KATEGORIEË EN KLASSIFIKASIE VAN MEDISYNE

25.(1) Die volgende is die basiese kategorieë van medisyne:

(a) Kategorie A – Medisyne wat vir menslike gebruik bestem is en wat sonder verdere verwerking gereed is vir toediening, met inbegrip van verpakte preparate waar slegs 'n draer by die effektiewe medisyne gevoeg word.

(b) Kategorie B – Medisyne wat normaalweg nie sonder verdere verwerking toegedien kan word nie.

(c) Kategorie C – Medisyne wat vir veterinêre gebruik bestem is en wat sonder verdere verwerking gereed is vir toedieing, met inbegrip van verpakte preparate waar slegs 'n draer by die effektiewe medisyne gevoeg word.

(2) Medisyne in Kategorie A word in die volgende klassifikasies ingedeel:

1. Stimulante van die sentrale senustelsel

1.1 Sentrale analeptika
1.2 Psigo-analeptika (antidepressante)
1.3 Spesiale antidepressantsamestellings
1.4 Asemhaalstimulante
1.5 Hallusinogene middels
1.6 Ander stimulante van die sentrale senustelsel

2. Depressante van die sentrale senustelsel

- 2.1 Anestetika
- 2.2 Kalmeermiddels, slaapmiddels
- 2.3 Barbiturate
- 2.4 Niebarbiturate
- 2.5 Stuipweermiddels, met inbegrip van epilepsieweermiddels
- 2.6 Bedaarmiddels
  - 2.6.1 Fenotiasiene en derivate daarvan
  - 2.6.2 Rauwolfia: alkaloïede en samestellings daarvan
  - 2.6.3 Difenielmetaan en derivate daarvan
  - 2.6.4 Alkieldiole en derivate daarvan
  - 2.6.5 Diverse strukture
- 2.7 Antipiretiese of antipiretiese en antiïnflammatoriese analgetika
- 2.8 Analgetiese samestellings
- 2.9 Ander analgetika
- 2.10 Sentraalwerkende spierverslappers
- 2.11 Ander depressante van die sentrale senustelsel

3. Bindweefselmiddels

- 3.1 Rumatiekmiddels (antiïnflammatoriese middels)
- 3.2 Hormoonvry preparate
- 3.3 Jigpreparate
- 3.4 Samestellings met kortikosteroïede
- 3.5 Ander

4. Lokaalanestetika

5. Middels met uitwerking outonomiese funksies

- 5.1 Adrenomimetika (simpatomimetika)
- 5.2 Adrenolitika (simpatolitika)
- 5.3 Cholinomimetika (cholinergiese middels)
- 5.4 Cholinolitika (anticholinergiese middels)
  - 5.4.1 Parkinsonismepreparate
  - 5.4.2 Algemeen
- 5.5 Ganglionblokkeerders
- 5.6 Histamien
- 5.7 Antihistaminika, antiëmetika en antivertigopreparate
  - 5.7.1 Antihistaminika
  - 5.7.2 Antiëmetika en antivertigopreparate
- 5.8 Verkouepreparate, met inbegrip van neusontstuwers
- 5.9 Hidroksitriptamien (serotonien)
- 5.10 Serotonienantagoniste
- 5.11 Ander

6. Hartmiddels

6.1 Hartstimulante
6.2 Hartdepressante
6.3 Hartglikosiede
6.4 Ander

7. Vaskulêre middels

7.1 Vasodilators, hipotensiemiddels
  7.1.1 Rauwolfia en samestellings
  7.1.2 Rauwolfia: diuretiese samestellings
  7.1.3 Ander hipotensiemiddels
  7.1.4 Vasodilators – koronêre en ander middels gebruik in angina pectoris
  7.1.5 Perifere vasodilators
7.2 Vasokonstriktors, pressormiddels
7.3 Migrainepreparate
7.4 Lipotropiese middels
7.5 Serumcholesterolverlagers
7.6 Ander

8. Middels met uitwerking op bloed en hemopoiëtiese stelsel

8.1 Bloedstolmiddels (koagulante), bloedstelpmiddels (hemostatika)
8.2 Antistolmiddels (antikoagulante)
8.3 Eritropoiëtika (hematinika)
8.4 Plasma-aanvullers
8.5 Ander

9. Anti-alkoholismemiddels

10. Middels met uitwerking op asemhalingstelsel

10.1 Hoesmiddels en ekspektorante
10.2 Brongodilators
  10.2.1 Inasemmiddels

11. Middels met uitwerking op maagdermkanaal

11.1 Spysverteringsmiddels
11.2 Maagdermkanaal-antispasmodika en -cholinolitika
11.3 Eetlusdempers

11.4 Teensuurmiddels
11.4.1 Suurneutraliseerders
11.4.2 Suurneutraliseerders met antispasmodika
11.4.3 Ander
11.5 Lakseermiddels
11.6 Smeermiddels en ontlastingversagters
11.7 Galdrywers
11.8 Setpille en anale salwe
11.9 Diarreemiddels
11.9.1 Diarreemiddels met infeksiewerende middels
11.9.2 Spesiale samestellings
11.10 Ander

12. Wurm- en bilharziamiddels, filarisiede, ens.

13. Velpreparate

13.1 Antiseptika, ontsmetmiddels en reinigingsmiddels
13.2 Jeuksiektemiddels
13.3 Oppervlakanestetika
13.4 Jeukweermiddels (antipruritika)
13.4.1 Kortikosteroïede met of sonder infeksiewerende middels
13.4.2 Versag- en beskermmiddels
13.5 Rubefasiënte middels (hiperemieveroorsakende middels)
13.6 Teenprikkelmiddels
13.7 Keratolitika
13.8 Spesiale samestellings
13.8.1 Preparate teen psoriasie
13.8.2 Swamdoders
13.9 Stralingsbeskermmiddels
13.10 Melanieninhibeerders en -stimulante
13.11 Akneepreparate
13.12 Ander

14. Wondbehandelingsmiddels

14.1 Wondontsmetmiddels
14.2 Wonddekkings
14.3 Ander

15. Oogpreparate (Oftalmiese preparate)

15.1 Oogpreparate met antibiotika en/of sulfoonamiede
15.2 Oogpreparate met kortikosteroïede
15.3 Samestellings van antibiotika
15.4 Ander

16. Oor-, neus- en keelpreparate

16.1 Neusontstuwers
16.2 Oorpreparate
16.3 Oppervlakanestetika
16.4 Neus-keel- en mond-keel-antiseptika
16.5 Ander

17. Middels met uitwerking op spierstelsel

17.1 Spierverslappers met perifere werking
17.2 Spieraktiveerders
17.3 Ander

18. Middels met uitwerking op urogenitale stelsel

18.1 Diuretika
18.2 Antidiuretika
18.3 Ioonuitruilingspreparate
18.4 Urolitolitika
18.5 Urienweg-antiseptika
18.6 Vaginale preparate
18.7 Voorbehoedpreparate
18.8 Ovulasiebeheermiddels
18.9 Uterusspasmolitika
18.10 Ander

19. Oksitosika

20. Antimikrobiese (chemoterapeutiese) middels

20.1 Antibiotika en antibiotiese samestellings
- 20.1.1 Breë- en mediumspektrumantibiotika
- 20.1.2 Penisilliene
- 20.1.3 Penisillien-streptomisien-samestellings
- 20.1.4 Antibiotikum-sulfoonamied-samestellings
- 20.1.5 Streptomisien en samestellings daarvan
- 20.1.6 Plaaslik aanwendbare antibiotika
- 20.1.7 Swambestrydende antibiotika

20.2 Nie-antibiotiese middels
- 20.2.1 Sulfoonamiede
- 20.2.2 Swamdoders
- 20.2.3 Tuberkulostatika
- 20.2.4 Leprostatika

20.2.5 Kiemdoders
20.2.6 Middels teen protosoë
20.2.7 Spirocheetdoders
20.2.8 Virusteenmiddels
20.3 Ander

21. Hormone, antihormone en hipoglukemieslukmiddels

21.1 Insulienpreparate
21.2 Hipoglukemieslukmiddels
21.3 Tiroïedpreparate
21.4 Paratiroïedpreparate
21.5 Kortikosteroïede
21.5.1 Kortikosteroïede en analoga
21.5.2 Analgetiese samestellings
21.5.3 Infeksiewerende samestellings
21.6 Anaboliese steroïede
21.7 Manlike geslagshormone
21.8 Vroulike geslagshormone
21.8.1 Estrogene
21.8.2 Progesterone met of sonder estrogene
21.9 Androgeen-estrogeen-samestellings
21.10 Trofiese hormone
21.11 Hiperglukemiehormoon
21.12 Hormooninhibeerders
21.13 Ander

22. Vitamiene

22.1 Multivitamiene en multivitamiene met minerale
22.1.1 Vitamiene vir pediatriese gebruik
22.1.2 Vitamiene vir voorgeboortegebruik
22.1.3 Vitamiene vir geriatriese gebruik
22.1.4 Vitamien B-kompleks met vitamien C
22.2 Ander

23. Aminosure

24. Mineraalvervangers, elektroliete

25. Spesiale voedsel

25.1 Babavoedsel en ander samestellings, uitgesonderd voedingsmiddels wat slegs as vervangers van moedersmelk dien

26. Sitostatika

27. Cheleermiddels (versenate) as teenmiddels teen swaarmetaalvergiftiging

28. Kontrasmedia

29. Diagnostiese middels

30. Biologiese middels

30.1 Teenliggaampies
30.2 Antigene
30.3 Bloedfraksies

31. Ensiempreparate

32. Ander stowwe of middels

32.1 Tonikums
32.2 Ander
32.3 Verslankpreparate
32.4 Water vir inspuiting
32.5 Kunstraan- en kontaklensoplossings
32.6 Preparate van boorsuur, boraks en sink, stysel en boorpoeier
32.7 Plaaslik aanwendbare ontluisingsmiddels
32.8 Plaaslik aanwendbare insekweerders
32.9 Intraüteriene toestelle
32.10 Tandheelhundige preparate
32.11 Oplossings vir hemo- en peritoneale dialise
32.12 Preparate waarby die uitdrukkings "medisinale" of "vir geneeskundige gebruik" of uitdrukkings met soortgelyke betekenis gebruik word
32.13 Preparate wat bedoel is om haargroei te bevorder
32.14 Verkoopspakkette wat twee of meer middels met verskillende indikasies bevat
32.15 Radiofarmaseutika
32.16 Ander

1.4 Kalmeermiddels
- 1.4.1 Sedatiewe hipnotika
- 1.4.2 Sedatiewe analgetike
- 1.4.3 Sedatiewe antagoniste

1.5 Stuipweermiddels, met inbegrip van epilepsieweermiddels

1.6 Bedaarmiddels
- 1.6.1 Fenotiasienderivate
- 1.6.2 Butirofenoonderivate

1.7 Neuroleptanalgetika

1.8 Analgetiese antipiretika

1.9 Middels gebruik vir eutanasie

2. Outonome senustelsel

2.1 Simpatomimetika

2.2 Simpatolitika

2.3 Cholinergiese middels

2.4 Antimuskariniese middels

3. Muskuloskeletale stelsel en gewrigte

3.1 Antiïnflammatoriese middels
- 3.1.1 Steroïedale middels
- 3.1.2 Niesteroïedale antiïnflammatoriese middels ("NSAIDs")
  - 3.1.2.1 Nieselektiewe COX2-inhibeerders
  - 3.1.2.2 Selektiewe COX2-inhibeerders
- 3.1.3 Plaaslik aanwendbare middels
- 3.1.4 Samestellings
- 3.1.5 Ander

3.2 Analgetika
- 3.2.1 Opioïede middels
- 3.2.2 Niesteroïedale antiïnflammatoriese middels
- 3.2.3 Plaaslik aanwendbare middels
- 3.2.4 Samestellings

3.3 Spierverslappers
- 3.3.1 Sentraalwerkend
- 3.3.2 Perifeerwerkend

4. Outakoïede middels

4.1 Histamieninhibeerders
- 4.1.1 Antihistamiene
- 4.1.2 Histamienvrystellingsinhibeerders

4.2 Serotonienantangoniste

4.3 Ander

5. Kardiovaskulêre stelsel

5.1 Positiewe inotropiese middels
- 5.1.1 Hartglikosiede

5.1.2 Metielxantiene
5.1.3 Ander
5.2 Anti-aritmiemiddels
5.3 Vasodilators
5.3.1 Perifeerwerkende vasodilators
5.3.2 Angiotensieninhibeerders
5.3.3 Kalsiumkanaalinhibeerders

6. Bloed- en hematopoiëtiese stelsel

6.1 Bloedstolmiddels (koagulante), bloedstelpmiddels (hemostatika)
6.2 Antistolmiddels (antikoagulante)
6.3 Eritropoiëtika (hematinika)
6.4 Plasma-aanvullers

7. Asemhalingstelsel

7.1 Hoesonderdrukkers en ekspektorante
7.2 Mukolitika
7.3 Brongodilators
7.4 Samestellings

8. Maagdermkanaal

8.1 Mondspoelmiddels
8.2 Emetika
8.3 Antiëmetika
8.4 Suurverminderaars
8.4.1 Teensuurmiddels en samestellings
8.4.2 Histamien 2-reseptorantagoniste
8.4.3 Protonpompinhibeerders
8.4.4 Sitobeskermingsmiddels
8.5 Motiliteitsbevorderingsmiddels
8.6 Antispasmodika
8.7 Diarreemiddels
8.7.1 Gewoon
8.7.2 Met antimikrobiese middels
8.7.3 Antimikorobiese middels
8.7.4 Biologiese middels
8.8 Analgetika
8.9 Spysverteringsmiddels
8.10 Middels gebruik in die grootpens
8.10.1 Ruminotorika (rumenstimulante)
8.10.2 Teenopblaasmiddels
8.10.3 Ander

9. Lewerstelsel

9.1 Galdrywers en choleretika
9.2 Lewerbeskermers en lipotropika

10. Urinêre stelsel

10.1 Diuretika
10.2 Urolitolitika en antispasmodika
10.3 Unrienwegantiseptika
10.4 pH-modifiseerders
10.4.1 Urinêre suurmiddels
10.4.2 Urinêre alkaliniseerders
10.5 Ander

11. Voortplantingstelsel

11.1 Intravaginale en intraüteriene preparate
11.2 Geslagshormone
11.2.1 Testosteroon
11.2.2 Estrogene
11.2.3 Progesterone en progestogene
11.2.4 Samestellings
11.3 Prostaglandiene
11.4 Trofiese hormone
11.5 Miometriumstimulante (ekbolika)
11.6 Miometriumverslappers (tokolitika)
11.7 Ovulasiebeheermiddels

12. Endokriene stelsel

12.1 Insulienpreparate
12.2 Tiroïedpreparate
12.3 Kortikosteroïede
12.4 Groeihormone
12.5 Anaboliese steroïede

13. Velmiddels

13.1 Ontsmet- en reinigingsmiddels
13.2 Antiseptiese en antimikrobiese preparate
13.3 Jeukweermiddels (antipruritika)
13.3.1 Plaaslik aanwendbare kortikosteroïede, met of sonder infeksiewerende middels
13.3.2 Plaaslik aanwendbare antihistamiene, met of sonder infeksiewerende middels
13.4 Versag- en beskermmiddels
13.5 Rubefasiënte middels en teenprikkelmiddels
13.6 Keratolitika
13.7 Swambestryders
13.8 Antiparasitika

14. Oog- en oorpreparate

14.1 Infeksiewerende middels

14.2 Kortikosteroïede
14.3 Samestellings (infeksiewerende middels met kortikosteroïede)
14.4 Ander

15. Wonde

15.1 Wondantiseptika
15.2 Wonddekkings
15.3 Middels vir die verwyderings van dooie weefsel

16. Melkklier

16.1 Intramammêre preparate (binne-uierpreparate)
16.2 Preparate vir die behandeling van spene en uiers

17. Antimikrobiese middels

17.1 Antibakteriese middels
- 17.1.1 Betalaktame
  - 17.1.1.1 Penisilliene
  - 17.1.1.2 Sefalosporiene
- 17.1.2 Tetrasikliene
- 17.1.3 Aminoglikosiede
- 17.1.4 Makroliede en linkosamiede
- 17.1.5 Amfenikol
- 17.1.6 Kinolone
- 17.1.7 Sulfoonamiede en versterkers
- 17.1.8 Nitrofurane
- 17.1.9 Polipeptiede
- 17.1.10 Ander
- 17.1.11 Antibakteriese samestellings

17.2 Swambestryders
17.3 Virusteenmiddels
17.4 Middels teen protosoë
17.4.1 Antikoksidiemiddels
17.4.2 Antibabesiamiddels
17.4.3 Spirocheetdoders
17.4.4 Ander

18. Antiparasitika

18.1 Endoparasietdoders
- 18.1.1 Bensimidasole en probensimidasole
- 18.1.2 Makrosikliese laktone
- 18.1.3 Gehalogeneerde salisielaniliede en nitrofenole
- 18.1.4 Imidasole
- 18.1.5 Tetrahidropirimidiene
- 18.1.6 Piperasiene
- 18.1.7 Organofosfors
- 18.1.8 Ander

18.1.9 Samestellings
18.2 Endektosiede
18.3 Ektoparasietdoders
18.3.1 Organochloormiddels
18.3.2 Organofosfors
18.3.3 Piretrien en piretroïede
18.3.4 Formamidiene
18.3.5 Nitrokwanadiene
18.3.6 Fenielpirasole
18.3.7 Insekgroeihormone
18.3.8 Chitieninhibeerders
18.3.9 Ander
18.3.10 Samestellings

19. Vitamiene minerale en geriatriese preparate

19.1 Slegs vitamiene
19.2 Vitamien- en mineraalsamestellings
19.3 Minerale en elektroliete
19.4 Vitamien-, elektroliet- en aminosuursamestellings

20. Sitostatika

21. Immuunmoduleringsmiddels

22. Cheleermiddels

23. Kontrasmedia

24. Biologiese middels

24.1 Entstowwe vir honde
24.2 Entstowwe vir katte
24.3 Entstowwe vir pluimvee
24.4 Ander entstowwe
24.5 Ander biologiese middels

25. Produksiebevorderingsmiddels

25.1 Antimikrobiese middels
25.2 Hormone
25.2.1 Geslagshormone
25.3 Beta-agoniste
25.4 Ander

26. Vismedisyne

REGISTRASIESERTIFIKAAT

26. 'n Registrasiesertifikaat wesenlik in die vorm hieronder uiteengesit, moet deur die Registrateur ingevolge artikel uitgereik word nadat 'n medisyne geregistreer is.

WET OP MEDISYNE EN VERWANTE STOWWE, 1965
(WET NO. 101 VAN 1965)

REGISTRASIESERTIFIKAAT VAN 'N MEDISYNE

Hierby word gesertifiseer dat die registrasie van die medisyne hieronder beskryf, kragtens artikel 15(3) van die Wet op Medisyne en Verwante Stowwe, 1965 (Wet No. 101 van 1965), en onderworpe aan die voorwaardes hieronder vermeld, deur die Medisynebeheerraad goedgekeur is.

1. Handelsnaam: .....

2. Registrasienommer: .....

3. Goedgekeurde naam van elke aktiewe bestanddeel en die hoeveelheid daarvan per dosiseenheid of per geskikte massa of volume of eenheid van die medisyne: .....

4. Doseervorm: .....

5. Voorwaardes waarop die medisyne geregistreer is: .....

6. Geregistreer op naam van (houer van registrasiesertifikaat): .....

7. Naam en adres van vervaardiger en die vervaardigingsfasiliteit: .....

8. Naam van eindprodukvrystrellingsbeheer: .....

9. Naam van eindprodukvrystellingsverantwoordelikheid: .....

10. Voorwaardes van registrasie: .....

11. Datum van registrasie: .....

.....
Registrateur van Medisyne

Uitgereik te ..... op ..... 20 ..... .

VERNIETIGING VAN MEDISYNE

27.(1) 'n Medisyne of gelyste stof, moet op die volgende wyse vernietig moet word:

(a) 'n Medisyne wat 'n Bylae 5-, Bylae 6-, Bylae 7- of Bylae 8-stof bevat, mag slegs in teenwoordigheid van 'n inspekteur, 'n beampte van die Suid-Afrikaanse Polisiediens of enige ander persoon deur die Direkteur-generaal gemagtig, vernietig word. Sodanige inspekteur, polisiebeampte of persoon, na gelang van die geval, moet 'n sertifikaat uitreik wat die vernietiging van die medisyne bevestig, en in die geval van 'n polisiebeampte moet die saaknommer in die register aangeteken word.

(b) Ondanks paragraaf (a) kan die Raad die vernietiging van 'n Bylae 5- of 'n Bylae 6-stof deur 'n vervaardiger van die stof magtig sonder dat 'n inspekteur teenwoordig is.

(c) In die geval van 'n Bylae 1-, Bylae 2-, Bylae 3- of Bylae 4-stof of -medisyne mag 'n apteker of 'n gemagtigde persoon in beheer van 'n plek waar medisyne of stowwe gehou word, so 'n stof of medisyne vernietig. Die betrokke apteker of gemagtigde persoon moet sodanige vernietiging sertifiseer.

(2) Daar mag oor geen medisyne beskik word deur dit in 'n munisipale rioolstelsel te stort nie.

(3) Die vernietiging van of beskikking oor medisyne of gelyste stowwe moet op sodanige wyse geskied as wat die Raad bepaal en as wat sal verseker dat dit nie herwin kan word nie.

BESONDERHEDE WAT OP VOORSKRIF OF BESTELLING VIR MEDISYNE MOET VERSKYN

28.(1) Elke voorskrif of bestelling vir medisyne moet in leesbare skrif geskryf, getik of deur middel van 'n rekenaar gedruk word en moet eiehandig deur 'n geneesheer, tandarts, veearts of gemagtigde voorskrywer of, in die geval van 'n bestelling, 'n gemagtigde persoon geteken word, en moet minstens die volgende vermeld:

(a) Die naam, kwalifikasie, praktyknommer en adres van die voorskrywer of die gemagtigde persoon wat die bestelling plaas.

(b) die naam en adres van die pasiënt, in die geval van 'n voorskrif, of die naam en adres van die persoon aan wie die medisyne gelewer gaan word, in die geval van 'n voorskrif deur 'n veearts;

(c) die datum waarop die die voorskrif gegee of die bestalling geplaas is;

(d) die goedgekeurde naam of die handelsnaam van die medisyne;

(e) die doseervorm;

(f) die sterkte van die doseervorm en die hoeveelheid van die medisyne wat voorsien moet word;

(g) in die geval van 'n voorskrif, instruksies vir die toediening van die dosis, die frekwensie van toediening en, in die geval van veterinêre medisyne vir voedselproduserende diere, die onttrekkingstydperk;

(h) die ouderdom en geslag van die pasiënt en, in die geval van veterinêre medisyne, die dierspesie; en

(i) die aantal kere dat die voorskrif herhaal kan word.

(2) In die geval van voorskrif of bestelling wat gefaks, ge-e-pos, deurgebel of andersins elektronies versend word, moet die apteker die egtheid van die voorskrif verifieer.

(3) 'n Permanente afskrif van die voorskrif of bestelling wat gefaks, ge-e-pos, deurgebel of andersins elektronies versend is soos bedoel in subregulasie (2), moet vir rekorddoeleindes gemaak word.

(4) Die voorskrif of bestelling wat gefaks, ge-e-pos, deurgebel of andersins elektronies versend is, moet binne sewe werksdae gevolg word deur die oorspronklike voorskrif of bestelling.

(5) Die voorskrywer moet aantekening hou van die diagnose wat op die voorskrif betrekking het, en, indien die pasiënt instem, die diagnose op die voorskrif aandui.

OPGAWES WAT VERSTREK MOET WORD TEN OPSIGTE VAN GESPESIFISEERDE BYLAE 5-, EN VAN BYLAE 6-, BYLAE 7- EN BYLAE 8-STOWWE

29.(1) Geen persoon mag 'n stof bedoel in artikel 22A(12) van die Wet invoer, uitvoer, in die groothandel verkoop, produseer, vervaardig of in die vervaardiging van enige medisyne of stof gebruik nie, tensy die Raad voor of op 28 Februarie elke jaar van 'n opgawe voorsien word waarin die volgende inligting verstrek word:

(a) Die hoeveelheid van die betrokke stof wat, as grondstof of soos in 'n preparaat bevat, op 1 Januarie die voorafgaande kalenderjaar in voorraad was.

(b) die hoeveelheid van die betrokke stof wat gedurende die voorafgaande kalenderjaar verkry is deur –

(i) invoer, as grondstof of soos in 'n preparaat bevat;
(ii) produksie van die grondstof in die Republiek;
(iii) die aankoop van die grondstof in die Republiek, en die naam van die verskaffer moet verstrek word;

(c) die hoeveelheid van die betrokke stof, as grondstof of soos in 'n preparaat bevat, waaroor gedurende die voorafgaande kalenderjaar beskik is deur –

(i) uitvoer; of
(ii) vernietiging;

(d) die hoeveelheid van die betrokke stof wat gedurende die voorafgaande kalenderjaar gebruik is in –

(i) die produksie van enige ander Bylae 6- of Bylae 7-stof of 'n gespesifiseerde stof bedoel in artikel 22A(12) van die Wet; en
(ii) die produksie van enige ander chemiese stof wat nie onder Bylae 6 of Bylae 7 ressorteer of by artikel 22A(12)(a) of (b) van die Wet gespesifiseer word nie;

(e) die hoeveelheid van die betrokke stof en preparate wat daardie stof bevat, wat op 31 Desember van die voorafgaande jaar nog in voorraad was.

(2) Ondanks subregulasie (1) kan die Raad 'n invoerder of uitvoerder van die indiening van 'n opgawe vrystel indien daardie bepaalde opgawe nie nodig is om vas te stel wat die verbruik van enige van die stowwe daarin vervat, is nie.

(3) Die opgawe beoog in subregulasie (1) moet aan die volgende vereistes voldoen:

(a) Alle hoeveelhede moet in metrieke eenhede uitgedruk word as 'n persentasiebasis van die betrokke stof;

(b) in die geval van opium en enige preparate wat opium bevat, moet hoeveelhede uitgedruk word as opium wat 10% anhidriese morfien bevat;

(c) preparate wat nie regstreeks van opium self verkry word nie, maar deur opiumalkloïede te meng, moet uitgedruk word as morfien;

(d) in die geval van preparate van kokablare moet die hoeveelhede kokablare uitgedruk word as kokablare wat 0,5 persent kokaïen bevat; en

(e) indien voorraad gehou word of vervaardiging onderneem is namens 'n ander persoon, moet daardie feit vermeld word.

REGISTER VAN GESPESIFISEERDE BYLAE 5- OF VAN BYLAE 5- OF BYLAE 6-MEDISYNE OF -STOWWE

30.(1) 'n Persoon wat gespesifiseerde Bylae 5- of Bylae 5- of Bylae 6-medisyne of stowwe invoer, uitvoer, vervaardig of verkoop, moet 'n register van sodanige medisyne of stowwe hou.

(2) Die register bedoel in subregulasie (1) moet die hoeveelheid van elke sodanige medisyne of stof meld wat op die laaste dag van Maart, Junie, September en Desember elke jaar in voorraad is, en moet ook die volgende inligting bevat:

(a) Die datum waarop die medisyne of stof ontvang of verskaf is;

(b) die naam en sakeadres van die persoon van wie die medisyne of stof ontvangs of wat dit versend het en, in die geval van ingevoerde 'n medisyne of stof, die invoerpermitnommer;

(c) die naam en adres van die persoon wat die medisyne of stof aangekoop het;

(d) die hoeveelheid, in woorde en syfers, van die medisyne of stof aangedui per dosiseenheid, massa of volume;

(e) in die geval van die verskaffing van die medisyne of stof op voorskrif, die naam en adres van die gemagtigde voorskrywer, tensy sodanige voorskrif by 'n hospitaal gegee is, in welke geval die naam van die gemagtigde voorskrywer aangeteken moet word;

(f) die hoeveelheid van die medisyne of stof vervaardig of gebruik in die vervaardigingsproses; en

(g) sodanige ander inligting as wat die Raad bepaal.

(3) Die register bedoel in subregulasie (1) moet vir 'n tydperk van vyf jaar na die datum van die laaste inskrywing daarin behou word.

(4) Indien die register op rekenaar gehou word, moet 'n rekenaardrukstuk elke maand gemaak word wat geteken, gedateer en geliasseer moet word.

(5) Rekords moet op 'n ordelike wyse geberg word sodat dit geredelik toeganklik is.

METODE VAN MONSTERNEMING TYDENS ONDERSOEKE, DIE SERTIFIKAAT WAT UITGEREIK MOET WORD EN VERSLAGDOENING OOR ONTLEDINGSRESULTATE

31.(1) 'n Inspekteur kan 'n monster of enige aantal monsters neem vir die doel van 'n toets, ondersoek of ontleding ingevolge die Wet deur 'n persoon gemagtig as 'n ontleder, farmakoloog of patoloog.

(2) Die monster of monsters bedoel in subregulasie (1) moet –

(a) geneem word in teenwoordigheid van die persoon wat in beheer van sodanige medisyne of stof is of, by afwesigheid van sodanige persoon, in teenwoordigheid van enige getuie daar teenwoordig;

(b) geneem en geberg word op sodanige wyse as wat die integriteit daarvan sal bewaar gedurende die hele ondersoekproses met betrekking tot die monster;

(c) verpak en verseël en gepas geëtiketteer of gemerk word op sodanige wyse as wat die aard daarvan toelaat, en moet op 'n geskikte manier aan 'n ontleder, farmakoloog of patoloog besorg word, tesame met die sertifikaat geteken deur die inspekteur, en die inspekteur moet ook by die vroegste moontlike geleentheid 'n afskrif van die sertifikaat aan die persoon bedoel in paragraaf (a) uitreik.

(3) Die ontleder, farmakoloog of patoloog bedoel in subregulasie (1) moet so gou moontlik na ontvangs van die monster dit toets, ondersoek of ontleed en verslag oor die resulate daarvan lewer.

(4) 'n Inspekteur bedoel in subregulasie (1) kan 'n monster gedurende 'n roetine-inspeksie by 'n vervaardiger, groothandelaar of kleinhandelaar neem vir die doel van 'n toets, ondersoek of ontleding ingevolge hierdie regulasies.

(5) Ondanks subregulasie (1) kan die Raad van 'n houer van 'n registrasiesertifikaat vereis om die Raad van 'n monster van 'n bepaalde medisyne of stof te voorsien ten einde dit te toets, te ondersoek of te ontleed.

(6) Sertifikate of verslae uitgereik ingevolge hierdie regulasie moet binne sewe dae vanaf die datum van uitreiking aan die Registrateur voorgelê word.

BESLAGLEGGING OP MEDISYNE

32.(1) Daar mag op 'n medisyne beslag gelê word indien dit –

(a) ongeregistreer is en in stryd met die Wet verkoop word;

(b) vermoedelik nagemaak is;

(c) 'n foutiewe handelsmerk dra;

(d) verval het;

(e) vermoedelik gesteel is;

(f) gelys is en in die besit is van 'n ongemagtigde persoon of van 'n gemagtigde persoon maar in ongemagtigde hoeveelhede;

(g) kragtens die Wet ongewens verklaar is;

(h) aan die Staat behoort en in die besit van 'n ongemagtigde persoon gevind word; of

(i) in 'n ongemagtigde kliniese proef gebruik word.

(2) 'n Inspekteur wat ingevolge artikel 28(1)(c) van die Wet op 'n item beslag lê,, moet so gou moontlik en op die toneel van die beslaglegging, 'n skriftelike inventaris opstel, wat die volgende moet insluit:

(a) Die datum, plek en tyd van die beslaglegging;

(b) die naam en persoonlike besonderhede van die persoon by wie dieitems in beslag geneem is;

(c) die naam en hoeveelheid van elke item waarop beslag gelê is; en

(d) die naam van die inspekteur wat die beslaglegging uitvoer.

(3) 'n Item bedoel in artikel 28(1)(c) van die Wet kan as getuienis gebruik word in enige strafregtelike verrigtinge uit hoofde van die Wet.

(4) 'n Inspekteur wat kragtens artikel 28(1)(d) 'n monster neem, moet van alle monsters wat geneem word, 'n skriftelike inventaris opstel, wat die volgende moet insluit:

(a) Die datum en die tyd waarop en die plek waar die monster geneem is;

(b) 'n beskrywing van die aard en grootte van elke monster wat geneem is;

(c) die persoonlike besonderhede van die persoon in wie se teenwoordigheid die monsters geneem is; en

(d) die naam van die inspekteur wat die monster geneem het.

HERVERPAKKING VAN VAN MEDISYNE IN PASIËNTGEREDE VERPAKKINGS

33. Die herverpakking van medisyne in pasiëntgerede verpakkings –

(a) mag slegs gedoen word –

(i) deur 'n apteker of onder toesig van 'n apteker; of
(ii) deur enige ander persoon ingevolge artikel 29(4) van die Wet op Aptekers, 1974;

(b) moet van 'n lotnommerstelsel gebruik maak wat al die inligting bevat met betrekking tot die bestanddele en prosedures gebruik in die gereedmaak van die pasiëntgerede verpakking;

(c) moet by die vereiste toestande met betrekking tot temperatuur en humiditeit gedoen word;

(d) moet gedoen word in 'n area van die perseel wat spesifiek en uitsluitlik vir herverpakking gebruik word; en

(e) moet gedoen word ooreenkomstig goeie verwaardigings –of verspruidingspraktyke.

DOEN VAN KLINIESE PROEWE VIR MENSE

34.(1) 'n Persoon wat 'n kliniese proef wil begin of wil doen ten opsigte van 'n ongeregistreerde medisyne of van 'n nuwe indikasie of 'n nuwe doseerregimen van 'n geregistreerde medisyne of stof, moet, op die vorm wat die Raad bepaal, by die Raad aansoek doen om magtiging om sodanige kliniese proef te doen.

(2) 'n Aansoek bedoel in subregulasie (1) moet vergesel gaan van die aansoek geld en moet minstens die volgende inligting bevat:

(a) 'n Proefprotokol;

(b) die ondersoekersbrosjure wat al die toepaslike chemiese, farmaseutiese, prekliniese, farmakologiese en toksikologiese data en, waar van toepassing, menslike farmakologiese en kliniese data bevat ten opsigte van die betrokke stof;

(c) *curricula vitae* van al die ondersoekers;

(d) 'n getekende verklaring deur die aansoeker en al die ondersoekers dat hulle vertroud is met die protokol en dit verstaan en dat hulle in die uitvoering van die proef sal voldoen aan goeie kliniese praktyk;

(e) die dokument vir ingeligte toestemming en die goedkeuring van enige etiekkomitee wat deur die Raad erken word.

(3) Die klinieseproefprotokol bedoel in subregulasie (2)(a) moet minstens die volgende inligting bevat:

(a) Die aantal menslike subjekte betrokke by die proef;

(b) die naam van die ondersoeker, wat 'n paslik gekwalifiseerde en bevoegde persoon moet wees wat deur die Raad goedgekeur en in die Republiek woonagtig is, wat in beheer sal wees van die perseel waar die proewe gedoen word; en

(c) sodanige ander inligting as wat die Raad bepaal.

(4) Kliniese proewe moet gedoen word ooreenkomstig die riglyne vir goeie kliniese praktyk wat van tyd tot tyd deur die Raad bepaal word.

(5) Geen persoon mag kliniese proewe soos bedoel in subregulasie (1) sonder die magtiging van die Raad doen nie.

(6) Die persoon wat die kliniese proef doen, moet elke ses maande vanaf die datum waarop die kliniese proef begin is, vorderingsverslae aan die Raad voorlê, asook 30 dae na die voltooiing of beëidiging van die kliniese proef.

(7) Die Raad kan bykomende inligting aanvra, 'n kliniese proef ondersoek of magtiging om 'n kliniese proef te doen, intrek indien hy van mening is dat die veiligheid van die subjekte van die proef in gevaar gestel word of dat die wetenskaplike redes vir die uitvoering van die proef verander het.

(8) 'n Medisyne bedoel in subregulasie (1) moet behoorlik geëtiketteer word en die pakket moet voldoende identifikasie verstrek van –

(a) die kliniese proef wat uitgevoer staan te word;

(b) die medisyne wat gebryuik gaan word;

(c) die persone aan wie die medisyne toegedien gaan word; en

(d) die naam en adres van die perseel waar die kliniese proef uitgevoer gaan word.

KUNDIGHEID VAN LEDE VAN RAAD EN SY KOMITEES

35. Die lede van die Raad moet die volgende insluit:

(a) Ten minste drie persone wat geneeshere is, van wie een 'n pediater, een 'n internis en een 'n spesialis in openbare gesondheid moet wees;

(b) 'n deskundige op die gebied van kliniese farmakologie;

(c) 'n deskundige op die gebied van farmaseutiese chemie;

(d) 'n deskundige op die gebied van toksikologie en geneesmiddelveiligheid;

(e) 'n deskundige op die gebied van biotegnologie;

(f) 'n apteker wat 'n deskundige op die gebied van farmaseutika is;

(g) 'n persoon met kennis op die studieterrein van ongunstige geneesmiddelreaksies;

(h) 'n deskundige op die gebied van virologie en mikrobiologie;

(i) 'n persoon met spesialiskennis van veterinêre kliniese farmakologie;

(j) 'n veearts aangewys deur die Minister van Landbou;

(k) 'n persoon met kennis van komplementêre medisyne; en

(l) 'n persoon met deskundigheid op die gebied van die regte.

BEHEER OOR MEDISYNE IN HOSPITALE

36. Die verantwoordelike apteker of enige ander persoon gelisensieer kragtens artikel 22C(1)(a) van die Wet moet oor die veiligheid, sekuriteit, aankoop, berging en toebereiding van medisyne in 'n hospitaal toesig hou.

ONGUNSTIGE GENEESMIDDELREAKSIES

37.(1) Die aansoeker om of houer van 'n registrasiesertifikaat ten opsigte van 'n medisyne of gelyste stof moet, op die wyse en binne die tydperk wat die Raad bepaal, die Raad in kennis stel van vermeende ongunstige geneesmiddelreaksies wat by hom of haar aangemeld word as gevolg van die gebruik van daardie medisyne of gelyste stof.

(2) Subregulasie (1) geld ook in die geval van ongeregistreerde medisyne wat kragtens artikel 14(4), 15C of 21 van die Wet gebruik word.

(3) Die houer van 'n sertifikaat bedoel in subregulasie (1) of die aansoeker ten opsigte van medisyne bedoel in subregulasie (2), na gelang van die geval, moet –

(a) binne die tydperk deur die Raad bepaal ná ontvangs van die aanmelding bedoel in subregulasie (1), die Raad in kennis stel van die stappe wat beoog word met betrekking tot die ongunstige geneesmiddelreaksies;

(b) wanneer die Raad dit ook al versoek, 'n bondige kritiese ontleding uitvoer van die veiligheids- en doeltreffendheidsprofiel van die betrokke medisyne en die resultate daarvan binne 'n gespesifiseerde tydperk aan die Raad voorlê; en

(c) indien die Raad, ná ontvangs van die resultate bedoel in paragraaf (b), bepaal dat die medisyne moontlik nie veilig vir gebruik is nie, en indien deur die Raad daartoe versoek, aan die Raad voorlê –

(i) gevalleverslae van alle vermeende ongunstige geneesmiddelreaksies met betrekking tot die medisyne; en

(ii) ander farmakowaaksaamheidsdata, soos geneesmiddelgebruiksyfers, periodieke veiligheidsbywerkingsverslae, farmakowaaksaamheidsverslae en dergelike;

(d) rekords van alle data oor ongunstige reaksies met betrekking tot sy of haar medisyne hou en in stand hou of toegang daartoe hê.

(4) Niks in hierdie regulasie word so uitgelê dat dit enige persoon belet om enige ongunstige geneesmiddelreaksie by die Raad aan te meld nie.

PRYSKOMITEE

38.(1) Die pryskomitee beoog in artikel 22G van die Wet bestaan uit hoogstens agttien lede, wat moet insluit –

(a) een persoon benoem deur die Minister van Finansies;

(b) een persson benoem deur die Minister van Handel en Nywerheid;

(c) een of meer persone wat die Departement van Gesondheid verteenwoordig;

(d) minstens een persoon met 'n agtergrond in farmakologie;

(e) minstens een persoon met 'n agtergrond in die regte;

(f) minstens een persoon met 'n agtergrond in akademiese mediese navorsing;

(g) minstens twee persone met 'n agtergrond in die ekonomie, van wie een 'n gesondheidsekonoom moet wees; en

(h) minstens een persoon wat onafhanklike pasiënt- of verbruikersgroepe verteenwoordig.

(2) Die komitee moet die prosedure vir die verrigting van sy sake bepaal.

(3) Die komitee kan, onderworpe aan die goedkeuring van die Minister, die subkomitees aanstel wat hy nodig ag, om enige aangeleentheid wat binne die bestek van die komitee se werksaamhede ingevolge die Wet val, te ondersoek en daaroor verslag te doen.

(4) Die Direkteur-generaal kan werknemers van die Departement aanwys om as die sekretariaat van die komitee te dien.

ONDERSOEKE

39. Die Raad kan 'n ondersoek met betrekking tot 'n medisyne doen indien –

(a) daardie medisyne in Suid-Afrika of enige ander land ingetrek word;

(b) ongunstige reaksie aangemeld word;

(c) vermoed of bevind word dat die medisyne nie aan die vereistes van die Wet voldoen nie;

(d) 'n internasionale waarskuwing met betrekking tot die medisyne uitgereik word; of

(e) hy dit om enige ander rede gepas ag om 'n ondersoek na die medisyne te doen.

VOUBILJETTE VIR VETERINÊRE MEDISYNE

40.(1) Die onmiddellike houer van 'n veterinêre medisyne wat verkoop word, moet die onderstaande inligting met betrekking tot die medisyne in minstens een amptelike taal en letters met 'n minimum leesbaarheid verstrek:

(a) Die handelsnaam;

(b) die skeduleringstatus;

(c) die doseervorm;

(d) die samestelling, gegee in generiese of goedgekeurde name

(e) die farmakologiese klassifikasie;

(f) die farmakologiese werking;

(g) die farmakokinetiese en die farmakodinamiese eienskappe;

(h) kontra-indikasies;

(i) waarskuwings of onttrekkingstydperk in die geval van voedselproduserende diere;

(j) newe-effekte en spesiale voorsorgmaatreëls;

(k) bekende tekens van oordosering en besonderhede van die behandeling daarvan;

(l) die hoeveelheid en sterkte van die aktiewe bestanddele per dosiseenheid;

(m) die bergingsinstruksies;

(n) die registrasienommer;

(o) die naam en sakeadres van die houer van die registrasiesertifikaat; en

(p) enige ander inligting wat die Raad van tyd tot tyd bepaal.

(2) Die Raad kan, indien daarom aansoek gedoen word, 'n afwyking van subregulasie (1) magtig.

GEBRUIK VAN MEDISYNE TER VOORKOMING VAN MALARIA

41.(1) Enige persoon wat in diens is van die departement van omgewingsbewaring van enige provinsiale regering mag die medisyne beoog in subregulasie (4) verkry, aanhou en gebruik vir doeleindes van die voorkoming van malaria.

(2) By die plek waar sodanige medisyne aangehou en gebruik word, moet 'n voorraad pamflette wat deur die Raad goedgekeur is en oor die gebruik van sodanige medisyne handel, moet vryelik beskikbaar wees.

(3) Elke werkgewer bedoel in subregulasie (1) wat die bepalings van hierdie regulasie toepas, moet –

(a) voor die einde van Maart elke jaar die Raad voorsien van 'n staat met die naam en ligging van elke plek waar sodanige medisyne aangehou en gebruik word; en

(b) 'n inspekteur wat behoorlik kragtens die Wet gemagtig is, toelaat om so 'n plek te inspekteer.

(4) Die medisyne in hierdie regulasie bedoel, is –

(a) tablette en vloeistowwe wat chlorokiensulfaat, pirimetamien en dapsoon of samestellings daarvan bevat in houers van hoogstens 20 tablette of 50 milliliter wanneer in vloeistofvorm, of tablette wat proguanielhidrochloried bevat in houers van hoogstens 100 tablette; of

(b) enige ander malariateenmiddel wees in die hoeveelhede wat die Direkteur-generaal van tyd tot tyd bepaal.

MISDRYWE EN STRAWWE

42. Enige persoon wat versuim om te voldoen aan die vereistes van, of die bepalings oortree van, of opsetlik foutiewe inligting verstrek in verband met –

(a) regulasie 7(1)(c) of (d) met betrekking tot die parallelle invoer van medisyne;

(b) regulasie 8 met betrekking tot die etikettering van medisyne bestem vir menslike gebruik;

(c) regulasie 9 met betrekking tot voubiljette;

(d) regulasie 10 met betrekking tot die pasiëntinligtingsblaadjie;

(e) regulasie 11 met betrekking tot die voorskrifboek;

(f) regulasie 12 of 13 met betrekking tot die invoer of vervoer van medisyne;

(g) regulasie 14 met betrekking tot permitte kragtens artikel 22A(9) van die Wet;

(h) regulasie 15 met betrekking tot die invoer of uitvoer van gespesifiseerde Bylae 5- en van Bylae 6-, Bylae 7- of Bylae 8-stowwe;

(i) regulasie 16 met betrekking tot die besit van gespesifiseerde hoeveelhede gelyste stowee vir persoonlike medisinale gebruik deur persone wat die Republiek binnekom of verlaat;

(j) regulasie 17 met betrekking tot inligting wat jaarliks aan die Direkteur-generaal verstrek moet word deur die houer van 'n permit om Bylae 6- en Bylae 7-stowwe in of uit te voer;

(k) regulasie 18 met betrekking tot 'n lisensie om medisyne op te maak of toe te berei;

(l) regulasie 19 met betrekking tot 'n lisensie om medisyne te vervaardig, of om op te tree as groothandelaar daarvan of dit te versprei;

(m) regulasie 27 met betrekking tot die vernietiging van medisyne;

(n) regulasie 28 met betrekking tot die besonderhede wat op 'n voorskrif of bestelling vir medisyne moet verskyn;

(o) regulasie 29 met betrekking tot opgawes wat verstrek moet word ten opsigte van gespesifiseerde Bylae 5-, en Bylae 6-, Bylae 7- en Bylae 8-medisyne en gespesifiseerde stowwe;

(p) regulasie 30 met betrekking tot die register van Bylae 5- en Bylae 6-medisyne;

(q) regulasie 34 met betrekking tot die doen van kliniese proewe;

(r) regulasie 40 met betrekking tot die voubiljette vir veterinêre medisyne;

(s) regulasie 45 met betrekking tot die advertering van medisyne; of

(t) regulasie 48 met betrekking tot die etikette vir veterinêre medisyne;

of wat 'n medisyne verkoop wat verval het, begaan 'n misdryf en is by skuldigbevinding strafbaar met 'n boete of met gevangenisstraf van hoogstens tien jaar.

VOLDOENING AAN REGULASIES

43.(1) Elke medisyne moet voldoen aan die standaarde en spesifikasies wat aan die Raad verstrek is op die vorm voorgeskryf by regulasie 22 en wat deur die Raad met betrekking tot daardie medisyne aanvaar is.

(2) Enige voorgestelde afwyking van die aanvaarde standaarde en spesifikasies bedoel in subregulasie (1) moet aan die Raad voorgelê word vir goedkeuring vooraf, en sodanige afwyking mag nie ingevoer word voordat sodanige goedkeuring verleen is nie.

LOTVRYSTELLING VIR BIOLOGIESE MEDISYNE

44. Die Raad kan met betrekking tot die registrasie van biologiese medisyne kragtens artikel 15(7) van die Wet vereis dat ses monsters van elke lot, tesame met ses afskrifte van die protokols van die toets van die massalot en die vullot en ses afskrifte van die vrystellingsertifikaat uitgereik deur die bevoegde owerheid in die land waarin die produk vervaardig is, aan hom voorgelê word as 'n voorwaarde vir lotvrystelling.

ADVERTERING VAN MEDISYNE

45.(1) Onderstaande vereistes geld vir enige advertensie van 'n medisyne.

(2) (a) Medisyne wat nie 'n gelyste stof bevat nie en medisyne wat 'n stof bevat wat in Bylae 0 of Bylae 1 gelys word, mag aan die publiek geadverteer word.

(b) Medisyne wat 'n stof bevat wat in Bylae 2, Bylae 3, Bylae 4, Bylae 5 of Bylae 6 gelys word, mag slegs vir die inligting van geneeshere, tandartse, veeartse, aptekers en ander persone wat gemagtig is om voor te skryf, of in 'n publikasie wat gewoonlik of slegs beskikbaar gestel word aan persone in hierdie regulasie vermeld, geadverteer word.

(c) Paragraaf (b) word nie so uitgelê dat dit 'n verbod daarop plaas dat die publiek ingelig word oor die pryse, name, pakketgrootte en sterkte van medisyne wat 'n stof bevat wat in Bylae 2, Bylae 3, Bylae 4, Bylae 5 of Bylae 6 gelys word nie.

(3) Geen advertensie van 'n advertensie mag 'n stelling bevat wat afwyk van, in stryd is met of verder gaan as die getuienis wat in die aansoek om registrasie van daardie medisyne met betrekking tot die veiligheid, gehalte of doeltreffendheid daarvan voorgelê is nie, indien sodanige getuienis deur die Raad ten opsigte van daardie medisyne aanvaar is en by die goedgekeurde voubiljet van daardie medisyne ingesluit is.

(4) 'n Skriftelike advertensie van 'n medisyne moet die volgende bevat:

(a) Die handelsnaam van die medisyne;

(b) die goedgekeurde naam en hoeveelheid van elke aktiewe bestanddeel van die medisyne in letters met 'n minimum leesbaarheid: Met dien verstande dat, in die geval van 'n medisyne wat slegs een aktiewe bestanddeel bevat, sodanige letters minstens die helfte van die grootte van die grootste letter moet wees wat vir genoemde handelsnaam gebruik word; en

(c) in die geval van –

(i) 'n geregistreerde medisyne, die registrasienommer daaraan toegewys ingevolge artikel 15(6) van die Wet;

(ii) 'n medisyne ten opsigte waarvan 'n aansoek om registrasie ooreenkomstig artikel 14 van die Wet ingedien is, die verwysingsnommer deur die Registrateur aan die aansoek toegewys, gevolg deur die uitdrukking "(Wet 101/1965)";

(d) in elke geval waar 'n ander naam as die handelsnaam ook gebruik word, sodanige ander naam in letters van die helfte van die grootte van die grootste lettergroote waarin die handelsnaam in die advertensie verskyn;

(e) in die geval van 'n veterinêre medisyne, 'n aanduiding dat die medisyne vir veterinêre gebruik is; en

(f) in die geval van 'n homeopatiese medisyne, 'n aanduiding dat die medisyne ooreenkomstig homeopatiese beginsels gebruik moet word.

(5) In die geval van 'n advertensie vir 'n medisyne wat meer as een aktiewe bestanddeel bevat, mag geen spesifieke melding gemaak word van die bepaalde eienskappe van enige individuele aktiewe bestanddeel nie, tensy 'n vermelding van hierdie aard deur die Raad vir insluiting by die voubiljet van daardie medisyne goedgekeur is.

(6) Wanneer 'n medisyne vir die eerste maal mondeling geadverteer word by persone bedoel in subregulasie (2)(b), moet skriftelike inligting wat minstens die gegewens vermeld in regulasie 9 of regulasie 40 insluit, terselfdertyd gegee word aan die persone aan wie die mondelinge advertensie gerig is, en wanneer

die medisyne by daaropvolgende geleenthede mondeling geadverteer word, moet daardie inligting op versoek beskikbaar wees.

REËLS MET BETREKKING TOT DIE VOER VAN VERRIGTING VAN RAAD

46. Benewens die bepalings met betrekking tot die voer van die verrigtinge van die Raad voorgeskryf by die Wet, geld die volgende reëls:

(1) kennisgewiings van gewone en buitengewone vergaderings van die Raad moet deur die Registrateur onderteken wees en moet die sake vermeld wat op die vergadering behandel moet word. In die geval van gewone vergaderings moet die kennisgewings per pos of per hand aan elke lid gestuur word en moet minstens tien dae voor die bepaalde datum van die vergadering uitgereik word. Vir buitengewone vergaderings geskied sodanige kennisgewing as wat die Voorsitter voldoende ag, en indien nodig, kan kennisgewing per telegram of per telefoon geskied. Indien alle lede toestem, kan 'n spesifieke vergadering op korter kennisgewing of sonder skriftelike kennisgewing belê word.

(2) Geen ander sake as dié in die betrokke kennisgewing genoem, mag op 'n vergadering behandel word nie, behalwe sake wat die Raad besluit om as dringende sake te behandel.

(3) Die Raad kan 'n vergadering tot enige dag of uur verdaag, maar op 'n voortsettingsvergadering mag geen ander sake behandel word as dié uiteengesit in die kennisgewing van die vergadering waarvan dit 'n voortsetting is nie, behalwe sake wat die Raad besluit om as dringende sake te behandel.

(4) Die Registrateur moet 'n presensielys hou van al die lede wat 'n vergadering bywoon.

(5) 'n Lid wat 'n saak aan die Raad wil voorlê, moet minstens 30 dae voor die datum waarvoor 'n vergadering belê moet word, 'n skriftelike kennisgewing van sy of haar mosie aan die Registrateur stuur, en die kennisgewing van sy of haar mosie moet vermeld word in die kennisgewing van die vergadering. Die mosie moet saam met die ander sake wat aan die Raad voorgelê moet word, in die aangeduide volgorde oorweeg word.

(6) Geen saak mag behandel word sonder behoorlike kennisgewing ooreenkomstig reël (5) nie, tensy die vergadering verlof verleen dat die saak as 'n mosie ingedoen kan word. As daar geen sekondany vir die mosie is nie, word dit nie verder behandel nie.

(7) Die kworum vir 'n komitee aangestel kragtens artikel 9(1)(b) van die Wet is 'n meerderheid van die lede van daardie komitee.

(8) As die Raad nie sit nie, moet die Registrateur sover moontlik alle sake binne die opdrag van 'n komitee na daardie komitee verwys en die komitee moet, indien moontlik, aan die volgende vergadering van die Raad daaroor verslag

doen. Hierdie reël is nie van toepassing op gewone roetineaangeleenthede of op sake waarvan die beginsel reeds by regulasie of besluit van die Raad nie vasgestel is nie.

(9) Die prosedurereëls soos hierin bepaal vir die hou van gewone of buitengewone vergaderings van die Raad is van toepassing op komiteevergaderings.

(10) Afskrifte van komiteeverslae moet, waar moontlik, aan elke lid van die Raad gestuur word saam met die kennisgewing van die vergadering waarop die verslae oorweeg moet word.

(11) Die verrigtings van elke vergadering van die Raad word aangeteken in die vorm van getikte notule, wat op die volgende vergadering, ná goedkeuring, deur die Voorsitter met sy handtekening bekragtig moet word.

(12) (a) Die notule van elke vergadering van die Raad en die Uitvoerende Komitee moet 'n opsomming bevat van die sake wat behandel is en van die mosies en amendemente wat voorgestel en aanvaar of verwerp is, met vermelding van die name van die voorsteller en sekondant, maar kommentaar of opmerkings deur die lede word nie vermeld nie.

(b) Die notule van alle vergaderings van komitees van die Raad aangestel kragtens artikel 9(1)(b) van die Wet moet 'n opsomming bevat van die sake wat behandel en die besluit wat geneem is, maar kommentaar of opmerkings van lede word nie vermeld nie.

(13) Die Registrateur moet so spoedig as wat redelik moontlik is na afloop van 'n vergadering van die Raad of van 'n komitee, 'n afskrif van die notule aan al die lede van die Raad stuur.

(14) Die notule kan as gelees beskou word: Met dien verstande dat enige lid kan voorstel dat 'n sekere notule gelees word sodat sodanige verbetering of toevoeging aangebring kan word as wat nodig blyk te wees.

(15) By die opening van elke afsonderlike sessie van die Raad moet geleentheid aan lede van die Raad gegee word om vrae te stel aangaande die werksaamhede van die Raad, en dié vrae moet dan, indien moontlik, onmiddellik, of so nie op die volgende vergadering, beantwoord word deur die Voorsitter of sodanige ampsdraer of amptenaar as wat die Voorsitter gelas. Geen bespreking word daaroor toegelaat nie.

(16) Die agenda vir elke vergadering van die Raad of 'n komitee van die Raad moet deur die Registrateur in oorleg met die Voorsitter opgestel word en moet die volgende insluit:

(a) Goedkeuring van die notule van die vorige vergadering;

(b) sake voortspruitende uit die notule van die vorige vergadering;

(c) verslae van vaste komitees;

(d) mosies;

(e) korrespondensie;

(f) algemeen.

'n Lid van die Raad mag egter op 'n bepaalde vergadering voorstel dat 'n item op die agenda van daardie bepaalde vergadering van die Raad voor ander items op die agenda behandel word.

(17) Alle mosies en amendemente moet, tensy anders deur die Voorsitter toegelaat, skriftelik en deur die voorsteller onderteken wees, en voordat ander lede daaroor praat, moet hulle deur die Voorsitter, of deur die Registrateur met die toestemming van die Voorsitter, voorgelees word en dan gesekondeer word. Alle formele amendemente moet so geformuleer word dat hulle as selfstandige mosies voorgelees kan word.

'n Amendement moet betrekking hê op die mosie wat dit bestem is om te wysig en moet die oorspronklike mosie nie op so 'n manier wysig dat dit in werklikheid 'n nuwe mosie word nie. Die amendement moet so geformuleer word dat –

(a) sekere woorde by- of ingevoeg word; of

(b) sekere woorde weggelaat word; of

(c) dat sekere woorde weggelaat en ander woorde by- of ingevoeg word.

(18) Tensy die Raad toestem, mag geen mosie of amendement teruggetrek word nadat dit deur of met toestemming van die Voorsitter voorgelees is nie.

(19) Die sekondant van 'n mosie of amendement kan sy spreekbeurt voorbehou tot enige stadium van die bespreking.

(20) As 'n amendement voorgestel word, kan ander amendemente daarop volg en dan kom die laaste amendement eerste onder bespreking.

(21) As elke amendement verwerp word, moet die oorspronklike mosie tot stemming gebring word.

(22) As 'n amendement aangeneem word, word dit as 'n selfstandige mosie beskou en met betrekking tot verdere amendemente in alle ander opsigte as 'n oorspronklike mosie behandel.

(23) Wanneer 'n mosie onder bespreking is, word geen ander voorstel toegelaat nie, behalwe een van die volgende:

(a) 'n Amendement, naamlik "dat die mosie soos volg gewysig word: ... ";

(b) die uitstel van die saak, naamlik "dat die vergadering oorgaan tot die volgende item op die agenda";

(c) die beëidiging van die bespreking, naamlik "dat die saak nou tot stemming gebring word";

(d) die verdaging van die bespreking, naamlik "dat die bespreking van die mosie verdaag word";

(e) die verdaging van die Raad, naamlik "dat die Raad nou verdaag word".

(24) Wanneer 'n amendement onder bespreking is, word geen ander voorstel toegelaat nie, behalwe een van die volgende:

(a) 'n Amendement, naamlik "dat die mosie soos volg gewysig word: ... ";

(b) die beëidiging van die bespreking, naamlik "dat die saak nou tot stemming gebring word";

(c) die verdaging van die bespreking, naamlik "dat die bespreking van die mosie verdaag word";

(d) die verdaging van die Raad, naamlik "dat die Raad nou verdaag word".

(25) 'n Voorstel om die saak uit te stel (waarin 'n datum vir die verdere oorweging van die saak vermeld kan word) moet ingedien en gesekondeer word sonder bespreking, en kan te eniger tyd ingedien word, selfs gedurende die bespreking van 'n amendement. As die voorstel aangeneem word, moet die saak oorstaan. As die voorstel nie aangeneem word nie, duur die bespreking voort.

(26) 'n Voorstel om die bespreking te beëindig moet sonder bespreking ingedien en gesekondeer word en moet onmiddellik tot stemming gebring word. As die voorstel aangeneem word, moet die Raad dadelik oor die mosie of amendement onder bespreking stem.

(27) As 'n voorstel vir die verdaging van die vergadering aangeneem word, moet die Raad tot die volgende item op die agenda oorgaan en moet die bespreking hervat word op die eersvolgende gewone vergadering van die Raad. Die voorsteller van die verdaging het dan by hervatting van die bespreking die reg om eerste te praat.

(28) As 'n voorstel vir die verdaging van die Raad ingedien en gesekondeer is, kan die Voorsitter, voordat hy of sy die saak tot stemming bring, die Raad vra of die Raad voor die sluiting van die vergadering tot die behandeling van onbestrede sake wil oorgaan.

(29) 'n Mosie om 'n besluit geneem op 'n vorige vergadering te herroep, word slegs oorweeg indien kennis daarvan gegee is ooreenkomstig reël (6). Dit word met 'n meerderheid van stemme aangeneem. 'n Mosie om 'n besluit geneem tydens 'n sessie van die Raad te herroep, kan egter ondanks bostaande bepaling

tydens dieselfde sessie van die Raad oorweeg word, mits skriftelik kennis gegee word dat die aangeleentheid op die daaropvolgende dag van daardie sessie oorweeg sal word. Dit word slegs aangeneem indien twee derdes van van die stemme ten gunste daarvan is.

(30) Die Registrateur moet in die notule enige beslissing van die Voorsitter betreffende die vertolking van hierdie reëls opneem as 'n lid, wanneer die beslissing gegee word, daarom vra.

(31) Kennis kan gegee word van 'n mosie om 'n beslissing van die Voorsitter betreffende die vertolking van hierdie reëls te hersien as 'n lid, wanneer die beslissing gegee word, daarom vra.

(32) Kennis kan gegee word van 'n mosie om 'n beslissing van die Voorsitter in hersiening te neem, en die gee daarvan word geag 'n opdrag aan die Uitvoerende Komitee te wees om die betrokke beslissing te oorweeg en daaroor aan die Raad verslag te doen, en sodanige kennisgewing moet op die agenda geplaas word.

(33) Die beslissing van die voorsitter van enige komitee oor 'n punt van orde kan op versoek van enige twee lede van die komitee wat aanwesig was op die vergadering waarop die beslissing gegee is, in hersiening geneem word deur die Uitvoerende Komitee, wat as hy dit goedvind, kan gelas dat die betrokke beslissing herroep of gewysig word, en die beslissing van die Uitvoerende Komitee moet nagekom word deur die voorsitter van die komitee wie se beslissing betwis is, tensy en totdat dit deur die Raad herroep word. As enige beslissing van die Voorsitter van die Uitvoerende Komitee betwis word, moet die Voorsitter die voorsitterstoel ontruim terwyl die saak bespreek word: Met dien verstande dat geen beslissing bespreek of hersien mag word op die vergadering van die komitee waarop dit gegee is nie.

(34) Indien enige lid nie met die meerderheid saamstem nie en hy of sy sy of haar meningsverskil wil laat notuleer, moet hy of sy dit dadelik vermeld, en sodanige meningsverskil moet dan in die notule opgeneem word.

VERKRYGING VAN PETIDIEN OF PREPARATE DAARVAN DEUR GEREGISTREERDE VROEDVROUE

47.(1) 'n Persoon wat kragtens die Wet op Verpleging, 1978 (Wet No. 50 van 1978), as 'n vroedvrou geregistreer is en die gelyste stowwe vermeld in 'n lys deur die Raad in die *Staatskoerant* gepubliseer, vir toediening in 'n verloskundige geval wil koop, verkry of aanhou, moet skriftelik by die Direkteur-generaal om 'n permit aansoek doen.

(2) 'n Aansoek beoog in subregulasie (1) moet die volgende inligting bevat:

(a) Die tipe verloskundige diens waarvoor die gelyste stowwe benodig word;

(b) die volle naam van die aansoeker, tesame met bewys van geldende registrasie by die Suid-Afrikaanse Raad op Verpleging;

(c) die gerigistreerde naam en adres van die apteek waar die aansoek voornemens is om die gelyste stowwe te bekom;

(d) die naam, sterkte en hoeveelheid van elke gelyste stof wat benodig word;

(e) die presiese hoeveelhede van die maksimum voorraad van alle gelyste stowwe waarvoor die permit aangevra word;

(f) die fisiese adres van die perseel waar beoog word om die verloskundige te lewer.

(3) Die Direkteur-generaal kan, by ontvangs van die betrokke aansoek en nadat hy of sy sodanige navrae gedoen het as wat hy of sy nodig ag, 'n permit uitreik wat die aansoeker magtig om die verlangde gelyste stowwe te koop en te verkry om dit aan te hou of toe te dien.

(4) Die permit word uitgereik in die vorm wat die Direkteur-generaal bepaal en in drievoud, waarvan die oorspronklike aan die bedoelde apteek en die duplikaat aan die aansoeker (die geregistreerde vroedvrou) gaan en die derde eksemplaar deur die Direkteur-generaal behou word.

(5) 'n Permit bedoel in subregulasie (3) word onderworpe aan die volgende voorwaardes uitgereik:

(a) Die aansoeker moet 'n register van gelyste stowwe hou in die vorm wat die Raad bepaal, waarin die volgende besonderhede aangeteken moet word met betrekking tot die gelyste stowwe bedoel in Deel (a):

(i) Die bylaenommer;
(ii) die naam van die stof;
(iii) die sterkte daarvan; en
(iv) die maksimum voorraad.

(b) Die apteker wat die gelyste stowwe verskaf, moet die volgende besonderhede in Deel (b) van die vroedvrou se register van gelyste stowwe aanteken:

(i) Die datum van verskaffing;
(ii) die permitnommer;
(iii) die hoeveelheid medisyne verskaf;
(iv) die naam en adres van die apteek; en
(v) die apteker se handtekening.

(c) Die vroedvrou moet in teenwoordigheid van die apteker vir ontvangs van die gelyste stowwe in die register van gelyste stowwe teken.

(d) Die geregistreerde vroedvrou moet ná toediening van die gelyste stowwe die volgende besonderhede in Deel (c) van die register van gelyste stowwe aanteken:

(i) Die datum en tyd van toedieing;
(ii) die naam en adres van die pasiënt;
(iii) die hoeveelheid toegedien;
(iv) sy of haar volle handtekening;
(v) sy of haar kwalifikasies;
(vi) die rede vir toedieing; en
(vii) die balans voorhande.

(6) Die aansoeker is persoonlik daarvoor verantwoordelik om alle gelyste stowwe wat hy of sy kragtens 'n permit koop of verkry, in veilige bewaring te hou.

(7) Die houer van 'n permit moet te alle tye, op versoek van iemand behoorlik daartoe gemagtig deur die Direkteur-generaal, vir doeleindes van inspeksie die bedoelde permit, register van gelyste stowwe en hoeveelhede gelyste stowwe in sy of haar besit toon.

(8) Die Direkteur-generaal kan te eniger tyd, by kennisgewing aan die aansoeker, die permit kanselleer of intrek.

(9) By ontvangs van 'n kennisgewing van kansellasie of intrekking moet die aansoeker persoonlik die permit en sy of haar register van gelyste stowwe, tesame met enige gelsyte stowwe wat steed in sy of haar besit is, aan die Direkteur-generaal oorhandig vir beskikking.

(10) Indien die aansoeker om die een of ander rede nie daartoe in staat is om die items bedoel in subregulasie (9) persoonlik te oorhandig nie, kan dit deur die Direkteur-generaal of 'n behoorlik gemagtigde verteenwoordiger van die Direkteur-generaal by die aansoeker afgehaal word.

(11) Die Direkteur-generaal moet –

(a) 'n register hou van alle permitte uitgereik aan vroedvroue;

(b) die Registrateur van die Suid-Afrikaanse Raad op Verpleging –

(i) voor die einde van Februarie elke jaar in kennis stel van die volle name en adresse van alle persone aan wie permitte uitgereik is;
(ii) in kennis stel van die volle naam en adres van elke vroedvrou wie se permit gekanselleer of ingetrek is, asook die redes vir vir daardie handeling.

(12) 'n Permit uitgereik kragtens hierdie regulasie is geldig vir 'n tydperk van twee jaar en is hernieubaar.

(13) 'n Permit moet die volgende inligting bevat:

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