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.

Bamidipine.

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)

Colfoscenl.

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 rekatle 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.

MOhabalala

ME TSHABALALA-MSIMANG
MINISTER VAN GESONDHEID