GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. 935 **5 September 2008**

Schedule 0

MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965)

SCHEDULES

The Minister of Health has, in terms of section 22A (2) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), on the recommendation of the Medicines Control Council, made and updated the Schedules in the Schedule

SCHEDULE

In these Schedules, "the Act" means the Medicines and Related Substances Act, 1965 (Act 101 of 1965)

Note: Where an alternative schedule(s) is included in natural parentheses at any point of an inscription, this is provided to indicate one or more alternative scheduling designation/s. This is for information only and shall not be used in the interpretation of such inscription.

SCHEDULE 0

a. All substances referred to in this Schedule are excluded when specifically packed, labelled, sold 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 which are intended to be ingested by man or animals as a 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 54 of 1972) or that are registered in terms of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947); and

   (ii) analytical laboratory purposes.

b. This Schedule shall include all substances or mixtures of such substances containing or purporting to contain substances referred to, including the salts and esters of such substances, where the existence of such salts and esters is possible, except where such substances or mixtures of substances are expressly excluded.

This Schedule includes all substances or mixtures of 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, labelled, sold 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 preparations of substances or mixtures of such substances containing or purporting to contain any substance 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(4)(a)(v) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974 (Act 56 of 1974) other than a medical practitioner or dentist may prescribe and supply, only within his/her scope of practice and subject to the indication for use of such substances and medicines and to the conditions determined by the Medicines Control Council, to patients under his/her care, the Schedule 1 substances and medicines provided for in the Annexures to this Schedule published in the *Gazette* in terms of the Act.

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)

Antimony potassium tartrate and antimony sodium tartrate; in concentrations of 1 percent or more. (S0)

Any compound structurally derived from either beta-aminopropylbenzene or beta-aminoisopropylbenzene by substitution in the side chain or by ring closure therein (or by both such substitution and such ring closure); and presented as:

Schedule 1

a. preparations and mixtures when used as vasoconstrictors and decongestants in antihistamine-containing nose and eye preparations; and

b. appliances for inhalation in which the substance is adsorbed onto solid material but excluding cathine ((+)-norpseudoephedrine), ephedrine, etafedrine, N-methylephedrine, N-diethylaminoethylephedrine, phenylpropanolamine, prenylamine. (S2, S6, S7)

Arsenic; in concentrations equivalent to 0,01 percent or less of arsenic trioxide. (S2)

Azelaic acid.

Bacitracin, when intended for topical application to the epidermis, nares and external ear. (S4)

Bee venom, preparations intended for application to the skin. (S4)

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

Benzethonium chloride, when intended for human vaginal use.

Benzydamine; preparations and mixtures containing –

a. 3 percent or less of benzydamine, when intended for application to the skin (S3); or

b. 0,15 percent 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 dose swallowed does not exceed 36 milligrams of benzydamine per day. (S3)

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

Bioallethrin.

Bitolterol.

Blood collection bags, when intended for the collection and preservation of blood for subsequent use.

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

Bunamidine.

Butoconazole,

a. when intended for human vaginal use specifically for the treatment of recurrent vaginal candidiasis; (S4) or

b. when intended for application to the skin. (S4)

Chlorhexidine, when intended for human vaginal use. (S0)

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

Clotrimazole,

a. when intended for human vaginal use specifically for the treatment of recurrent vaginal candidiasis; (S4) and

b. when intended for application to the skin. (S4)

Schedule 1

Deanol and its derivatives, unless listed in another Schedule, 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, Cosmetics and Disinfectants Act, 1972, (Act 54 of 1972) and for analytical laboratory purposes. (S5)

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

Diosmine.

Dithiazanine.

Econazole,

a. when intended for human vaginal use specifically for the treatment of recurrent vaginal candidiasis; (S4) or

b. when intended for application to the skin. (S4)

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

Ephedra alkaloids (natural or synthetic), unless listed separately in the Schedules, intended for application to skin, eyes, ears and nares and containing 1 percent or less of ephedra alkaloids, and not intended for export. (S2, S6)

Ephedrine, preparations and mixtures intended for application to the skin, eyes, ears and nares and containing 1 percent or less of ephedrine, and not intended for export. (S2, S6)

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

Ether (diethyl ether); in concentrations of less than 20 percent. (S5)

Ethylphenylephrine.

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

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

Fenbendazole, except when registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

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

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 (Act 36 of 1947).

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

Flurbiprofen,

a. in the form of lozenges, indicated for the relief of pain associated with sore throats, subject to:

(i) a maximum of 8,75 milligrams per lozenge,

(ii) a maximum treatment period of 3 days, and

(iii) a maximum pack size of 15 lozenges (S2, S3, S4)

b. when intended for application to the skin, provided that in the case of application by transdermal patch –

(i) use is restricted to adults and children 12 years and older, and

(ii) the treatment period is limited to a maximum of 4 weeks. (S2, S3, S4)

Fluorescein, when intended for ophthalmic use by the topical route only. (S3)

Fluorides,

a. oral medicinal preparations or mixtures intended for ingestion containing 0,25 milligrams or less of fluorine per dosage unit; (S0, S4)

b. excluding toothpaste containing less than 0,15 percent fluoride; (S0) and

c. excluding mouth rinses containing less than 0,15 percent fluoride. (S0)

Gamma benzene hexachloride, when intended for application to the skin.

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

Gramicidin, when intended for topical application to the epidermis, nares and external ear. (S4)

O-(β-hydroxyethyl) rutosides.

Hyaluronic acid and its salts, when contained in preparations containing 2,5 percent or more intended for topical application to the skin, except preparations containing less than 0,25 percent when intended for topical use in terms of the provisions of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972). (S0, S2, S4)

Icodextrin.

Ibuprofen, when contained in preparations intended for application to the skin. (S2, S3, S4)

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

Indanazoline.

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

Irrigation fluids, being sterile fluids intended for irrigation of wounds or hollow visci.

Isoconazole, when intended for

a. human vaginal use specifically for the treatment of recurrent vaginal candidiasis (S4); and

b. application to the skin. (S4)

Ketoconazole, when intended for

a. application to the skin,

b. except preparations and mixtures containing not more than 1,0 percent of ketoconazole, 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 (Act 36 of 1947).

Local anaesthetics, except

a. when intended for ophthalmic or parental use; (S4)

b. oxybuprocaine, proxymetacaine and tetracaine, when contained in eye drops intended for emergency treatment of "arc eyes"; (S2) and

c. ophthalmic preparations registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

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 (Act 36 of 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 (Act 36 of 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 (Act 36 of 1947).

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

Mebendazole, except when registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Methenamine (hexamine), when intended for application to the skin, (S4)

Methionine.

Miconazole,

a. when intended for human vaginal use specifically for the treatment of recurrent vaginal candidiasis; (S4) and

b. when intended for application to the skin. (S4)

c. except for topical treatment of fungal infections of the mouth. (S2)

Microfibrillar collagen hydrochloride.

Morantel except when registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Schedule 1

N-acetyl-aspartyl-glutamic acid.

Naphazoline, when intended for nasal use. (S2)

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

Nicotine, when intended for human medicinal use, except when used for the relief of nicotine withdrawal symptoms as an aid to smoking cessation and presented in the following formulations -

a. nicotine gum pieces,

   (i) containing less than 4 milligrams nicotine per piece, and

   (ii) in packs containing not more than 30 pieces per pack; (S0), and

b. nicotine transdermal patches, intended for continuous application to the skin in strengths up to and including 15 milligrams/16 hours. (S2)

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

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

Normal Saline (Sodium chloride 0,9 % m/v) for injection in a dosage form not exceeding 20 milliliters in volume. (S3)

Nystatin,

a. when intended for application to the skin, and

b. when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis, and

c. except when presented as oral drops containing not more than 100 000 I.U. per ml. (S2)

d. except when intended for systemic use or the initial treatment of 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 (Act 36 of 1947).

Oxymetazoline, when intended for nasal use. (S2)

Pancreatin.

Paracetamol, except -

a. immediate release tablets or capsules each containing 500 milligrams or less of paracetamol, or in individually wrapped powders or in sachets containing 1 000 milligrams or less of paracetamol, subject to -

   (i) a maximum of 12,5 grams of paracetamol per primary pack, and

   (ii) in the case of tablets or capsules, presented in blister strip packaging or in containers with child-resistant closures; and

(iii) 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"; (S0)

b. in liquid or syrup dosage form containing 120 milligrams or less of paracetamol per 5 millilitres or in paediatric drops containing 120 milligrams or less of paracetamol per 1,2 millilitres, subject to -

(i) a maximum of 100 millilitres per primary pack in the case of the liquid or syrup dosage form containing 120 milligrams or less of paracetamol per 5 millilitres;

(ii) a maximum of 20 millilitres per primary pack in the case of the paediatric drops;

(iii) 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"; (S0)

c. when contained in rectal suppositories. (S2)

d. when contained in modified release formulations. (S2)

e. when intended for injection. (S3)

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 percent or less. (S0)

Phospholipids, when applied for therapeutic purposes.

Polymixin B, when intended for topical application to the epidermis, nares or external ear. (S4)

Procaine, when intended for oral administration.

Propentofylline, when intended for veterinary use. (S4)

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

Proteolytic (fibrinolytic) enzymes,

a. for oral use and

b. when intended for application to the skin, and

c. except when intended for soft contact lens cleaners; (S0) and

d. except when intended for injection. (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 (Act 36 of 1947). Correct

Pyridoxilate.

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

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

Tetrahydrozoline, when intended for nasal use. (S2)

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 (Act 36 of 1947).

Ticlatone, when intended for application to the skin.

Tioconazole,

a. when intended for human vaginal use specifically for the treatment of recurrent vaginal candidiasis; and

b. when intended for application to the skin. (S4)

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

Tyrothricin when intended for topical application to the epidermis, nares and external ear. (S4)

L-tryptophan,

a. when intended for medicinal use in dosages of less than 5mg/kg/day or

b. intended as supplementation for nutritional purposes. (S5)

Water for Injection in a dosage form not exceeding 20 milliliters in volume. (S3)

Xylometazoline, when intended for nasal use. (S2)

Zinc salts, when intended for veterinary use as an injection, except

a. when intended for oral ingestion or topical use by humans; (S0), or

b. when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

- END SCHEDULE 1 -

SCHEDULE 2

a. All substances referred to in this Schedule are excluded when specifically packed, labelled, sold 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 preparations of substances or mixtures of such substances containing or purporting to contain any substance 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 (Act 56 of 1974) other than a medical practitioner or dentist may prescribe and supply, only within their scope of practice and subject to the indication for use of such substances and medicines and to the conditions determined by the Medicines Control Council, to patients under his/her care, the Schedule 2 substances and medicines provided for in the Annexures to this Schedule published in the *Gazette* in terms of the Act.

Acetylcysteine, except when intended for injection. (S3)

Acetyldihydrocodeine:

a. oral solid preparations, in combination with one or more therapeutically active substances, and containing 20 milligrams or less of acetyldihydrocodiene (calculated as base) per dosage unit; and

b. liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, and containing 20 milligrams or less of acetyldihydrocodeine (calculated as base) per 5 millilitre dosage unit. (S6)

Aconite alkaloids, preparations containing 0,02 percent or more. (S0)

Acrivastine.

Adrenaline (epinephrine), except -

a. ophthalmic preparations when intended for glaucoma, and

b. preparations for injection. (S3, S4)

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

Alverin.

Aminopentamide.

Amorolfine.

Amyl nitrite.

Antihistamines, except -

a. astemizole and terfenadine; (S4)

b. when listed separately in these Schedules. (S5)

Schedule 2

Antimicrobial substances, namely

a. griseofulvin, mupirocin, natamycin when intended for application to the skin, nares and external ear; (S4)

b. nystatin preparations intended for application to the oral cavity, nares and external ear. (S1, S4)

Apomorphine; except when indicated for the treatment of erectile dysfunction. (S4)

Aptocaine.

Arecoline.

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

Atropine; except ophthalmic preparations and injections. (S3, S4)

Azatadine

Azelastine.

Bambuterol.

Bamipine.

Beclomethasone, 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 maximum dose equivalent to 100 micrograms of beclomethasone diproprionate per nostril, a maximum daily dose equivalent to 200 micrograms of beclomethasone diproprionate per nostril and a maximum of 200 doses per pack. (S3, S4)

Belladonna alkaloids, except when intended for topical application. (S1)

Benproperine.

Bevonium methylsulphate.

Bismuth.

Bromhexine.

Bromides, preparations containing less than 80 milligrams of bromine per recommended daily dose. (S5)

Brompheniramine

Buclizine.

Butinoline.

Calabar bean alkaloids.

Camphorated Opium Tincture.

Camylofin.

Cantharidin.

Canthaxanthin

Schedule 2

Carbinoxamine.

Carbocisteine.

Carbuterol, except

a. when contained in respirator solutions; (S3) and

b. when intended for injection. (S4)

Carisoprodol.

Cetirizine.

Chlormezanone; preparations containing not more than 100 milligrams per recommended dose. (S5)

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

Chloroquine, when used in combination with proguanil and when intended specifically for malaria prophylaxis. (S4)

Chlorpheniramine.

Chlorprenaline.

Cholestyramine.

Chlorzoxazone.

Clonidine when intended for the treatment of migraine. (S3)

Cimetidine, when intended for the short-term symptomatic relief of heartburn, dyspepsia and hyperacidity, subject to a maximum unit dose of 200 milligrams, a maximum daily dose of 800 milligrams and a maximum treatment period of 2 weeks. (S3)

Cinnarizine.

Clemastine.

Clemizole.

Clidinium bromide.

Codeine (methylmorphine),

a. oral solid preparations, in combination with one or more therapeutically active substances, and containing 20 milligrams or less of codeine (calculated as base) per dosage unit; or

b. liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, and containing 20 milligrams or less of codeine (calculated as base) per 5 millilitre dosage unit. (S6)

Colchicine, when intended for the emergency treatment of acute gout, subject to a maximum total treatment course of 6 milligrams. (S3)

Schedule 2

Cyclandelate.

Cyclizine.

Cyclopentolate, except when intended for ophthalmic administration. (S3)

Cyproheptadine, when indicated for allergic rhinitis or antipruritic use. (S5)

Desloratidine.

Dexchlorpheniramine.

Dextromethorphan.

Diclofenac, for a maximum period of 5 days when intended for

a. the emergency treatment of acute gout attacks, or

b. the treatment of post traumatic conditions. (S1, S3)

Dicyclomine.

Diphenoxin (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 percent of such quantity of difenoxin, calculated as the base, as is present in the mixture. (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)

Dihydrocodeine,

a. oral solid preparations, in combination with one or more therapeutically active substances, and containing 20 milligrams or less of dihydrocodeine (calculated as base) per dosage unit; (S6) or

b. liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, and containing 20 milligrams or less of dihydrocodeine (calculated as base) per 5 milliliters dosage unit. (S6)

Dimethindene.

Dimethothiazine.

Dimetindene.

Diphenhydramine.

Diphenylpyraline.

{D-norpseudoephedrine - see cathine (S6)}

Doxylamine.

Ebastine.

Emedastine.

Schedule 2

Emepronium.

Emetine, substances, preparations and mixtures containing less than 0,2 percent of alkaloids, calculated as emetine. (S4)

Ephedra alkaloids (natural or synthetic), contained in products registered in terms of the Act, and not intended for export, unless listed separately in the Schedules:

a. oral preparations and mixtures containing not more than 30 milligrams of ephedra alkaloids per dose, when in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, subject to a maximum pack size of 720 milligrams and limited to one pack per customer; (S6)

b. except when intended for application to skin, eyes, ears and nares and containing 1 percent or less of ephedra alkaloids. (S1)

Ephedrine, contained in products registered in terms of the Act, and not intended for export,

a. oral preparations and mixtures containing not more than 30 milligrams of ephedrine per dose, when in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, subject to a maximum pack size of 720 milligrams and limited to one pack per customer; (S6)

b. except preparations and mixtures intended for application to the skin, eyes, ears and nares and containing 1 percent or less of ephedrine. (S1)

Epinastine.

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

Ethylmorphine:

a. oral solid preparations, in combination with one or more therapeutically active substances, and containing 20 milligrams or less of ethylmorphine (calculated as base) per dosage unit; (S6) and

b. liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, and containing 20 milligrams or less of ethylmorphine (calculated as base) per 5 milliliters dosage unit. (S6)

Etilefrine.

Etodroxizine, preparations and mixtures when used solely as an antihistamine. (S5)

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)

Schedule 2

Fedrilate.

Fenoprofen,

a. when intended for the emergency treatment of acute gout attacks, and

b. when intended for the treatment of post-traumatic conditions, for a maximum treatment period of 5 days. (S3)

Fenoterol, except

a. when contained in respirator solutions; (S3) and

b. when intended for injection or for the prevention or delay of labour. (S4)

Fexofenadine.

Flavoxate.

Flunarizine.

Flunisolide, when intended for nasal administration, other than by aerosol in a strength not exceeding 0,025 percent (m/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 intended for the treatment of post-traumatic conditions, 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 maximum daily dose of 100 micrograms per nostril and a maximum pack size limit of 120 doses. (S3)

Fusafungine.

Gadopentetic acid.

Gelsemium alkaloids.

Glycopyrronium.

Griseofulvin, when intended for application to the skin, nares and external ear. (S4)

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

Hexametazine.

Schedule 2

Hexoprenaline -

a. except when contained in respirator solutions; (S3) and

b. 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, prohormonal or anti-hormonal action unless listed elsewhere in the Schedules,

a. when intended for human vaginal use, and

b. when specifically intended for emergency postcoital contraception. (S3, S4, S5)

Hyaluronic acid and its salts when intended for ophthalmic use in preparations (except injectables) containing 0,1 percent or less; (S0, S1, S4)

Hydrocortisone and hydrocortisone acetate, when used in

a. maximum concentration of 1 percent in preparations intended for application to the skin, and

b. in a maximum concentration of 1 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. when intended for the treatment of post-traumatic conditions for a maximum treatment period of 5 days, where the recommended daily dose for adults does not exceed 1,2 g and the dose for children up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (S3)

b. for the emergency treatment of acute gout attacks; (S3)

c. except when intended for the treatment of a haemodynamically significant patent ductus arterious in infants less than 34 weeks of gestational age. (S4)

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

Influenza vaccine.

Iopromide.

Ipratropium, when contained in respirator solutions. (S3)

Isoaminile.

Isoprenaline (isoproterenol), except

a. when contained in respirator solutions; (S3) and

Schedule 2

b. when intended for injection. (S4)

Isopropamide.

Isothipendyl.

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 intended for the emergency treatment of acute gout attacks;

c. when intended for the treatment of post-traumatic conditions, subject to a maximum dose of 100 milligrams of ketoprofen per day, for a maximum treatment period of 5 days. (S1, S3)

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

a. maximum daily dose of 15 milligrams

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

Levocabastine.

Levocetirizine.

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

Local anaesthetics,

a. except when intended for ophthalmic and parental use; (S4)

b. oxybuprocaine, proxymetacaine and tetracaine, when contained in eye drops intended for emergency treatment of "arc eyes".

Lobelia alkaloids.

Lodoxamide.

Loperamide.

Loratadine.

Measles vaccine

Mebeverine.

Mebhydrolin.

Meclozine.

Mefenamic acid,

Schedule 2

a. when intended for the treatment of post-traumatic conditions, for a maximum treatment period of 5 days; and

b. preparations containing mefenamic acid as the only therapeutically active substance, when intended for the treatment of primary dysmenorrhoea, subject to a maximum daily dose of 500 millligrams 3 times a day and a maximum treatment period of 3 days. (S3)

Mepenzolate bromide.

Mephenesin.

Mepyramine.

Mequitazine.

Mercuric ammonium chloride.

Mercuric chloride.

Mercuric iodide.

Mercuric oxides, substances, preparations and mixtures thereof, containing less than 3 per cent of mercury. (S4)

Mercury organic compounds

a. substances, preparations and mixtures in the form of aerosols, intended for application to the skin and mucous membranes and substances,

b. preparations and mixtures containing the equivalent of 0,6 percent or more of elemental mercury, intended for application to the skin and mucous membranes,

c. except phenylmercuric nitrate when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Mesna, except preparations intended for injection. (S4)

Metaproterenol (orciprenaline), except

a. when contained in respirator solutions; (S3) and

b. when intended for injection. (S4)

c. when intended for the prevention or delay of labour, (S4)

Methixene.

Methocarbamol.

Metholilazine.

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)

Schedule 2

Minoxidil, when intended for application to the scalp in preparations containing not more than 2 percent (m/v) and which are registered in terms of the Act. (S4)

Mizolastine.

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

Mumps vaccine.

Mupirocin, when intended for application to the skin, nares and external ear. (S4)

Nabumetone, when intended for the treatment of post-traumatic conditions, for a maximum treatment period of 5 days. (S3)

Naphazoline, except when intended for nasal use. (S1)

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; and

b. when intended for the emergency treatment of acute gout attacks; and

c. when intended for the treatment of post-traumatic conditions, for a maximum treatment period of 5 days. (S1, S3)

Natamycin, when intended for application to the skin, nares and external ear. (S4)

Nedocromil.

Nicergoline.

Nicotine when intended for human medicinal use, except -

a. nicotine gum containing 4 milligrams 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 15 milligrams/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 maximum daily dose of 300 milligrams;

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

Norcodeine,

a. oral solid preparations, in combination with one or more therapeutically active substances, and containing 20 milligrams or less of norcodeine (calculated as base) per dosage unit; (S6) or

b. liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, and containing 20 milligrams or less of norcodeine (calculated as base) per 5 millilitre dosage unit. (S6)

{(+)-norpseudoephedrine - see cathine (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 (Act 36 of 1947).

Nystatin,

a. when presented as oral drops containing not more than100 000 I.U. per ml, and

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

c. except when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis, (S1) and

d. except when intended for systemic use or the initial treatment of vaginal candidiasis. (S4)

Octatropine.

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.

Oxatomide.

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

Oxymetazoline,except when intended for nasal use (S1).

Oxyphencyclimine.

Oxyphenonium.

Papaverine; substances, preparations and mixtures thereof.

Paracetamol,

a. when contained in rectal suppositories, or

b. when contained in modified release formulations. (S0, S1, S3)

Pentoxyfylline.

Schedule 2

Phenazone (antipyrone).

Phenazopyridine.

Phenindamine.

Pheniramine.

Phenylpropanolamine (norephedrine), 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.

Phenyltoloxamine.

Pholcodine,

a. oral solid preparations, in combination with one or more therapeutically active substances, and containing 20 milligrams or less of pholcodine (calculated as base) per dosage unit; (S6) or

b. liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, and containing 20 milligrams or less of pholcodine (calculated as base) per 5 milliliters dosage unit. (S6)

Pholedrine.

Pimethixene, preparations and mixtures thereof when used solely as an antihistaminic. (S5)

Pinaverium.

Pipenzolate.

Pipoxolan.

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

Piroxicam,

a. when intended for the emergency treatment of acute gout attacks, and

b. when intended for the treatment of post-traumatic conditions, for a maximum treatment 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.

Polio vaccine.

Potassium chloride,

a. where the recommended dose is more than 20 millimol of potassium (1 500 milligrams of potassium chloride) per 24 hours, (S0)

b. except when intended for intravenous infusion or for injection; (S3) and

c. except when contained in oral rehydration preparations. (S0)

Povidone iodine when intended for application to the vagina. (S0)

Prifinium bromide.

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

Procyclidine.

Proglumide.

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

Promethazine,

a. when intended for use as an antihistamine, and

b. when intended for application to the skin, and

c. when intended specifically for the treatment of travel sickness. (S5)

Propantheline bromide.

Propyphenazone.

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

Pseudoephedrine, contained in products registered in terms of the Act, and not intended for export,

a. oral preparations and mixtures containing not more than 60 milligrams of pseudoephedrine per dose, and not more than 240 milligrams per day, when in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, subject to a maximum pack size of 720 milligrams and limited to one pack per customer. (S6)

Pyrobutamine.

Quinine, preparations and mixtures containing not more than 1 percent thereof. (S4)

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

a. a maximum dose of 75 milligrams;

b. a maximum daily dose of 300 milligrams;

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

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

Rimiterol, except

a. when contained in respirator solutions (S3) and

b. when intended for injection. (S4)

Rubella vaccine.

Schedule 2

Sabadilla alkaloids; substances, preparations and mixtures containing 1 percent or more thereof.

Salbutamol, except

a. when contained in respirator solutions; (S3) and

b. when intended for injection. (S4)

Salmefamol, except

a. when contained in respirator solutions; (S3) and

b. when intended for injection. (S4)

Siccanin, when intended for application to the skin.

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

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

Sulphadiazine silver 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)

Sulphonamides when intended for application to the eyes, nares and vagina; (S4)

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

Tetanus vaccine.

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

Tetrahydrozoline, except when intended for nasal use. (S1)

Thenalidine.

Thenyldiamine.

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

Thiethylperazine.

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.

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

Trimebutine.

Trimeprazine (Alimemazine).

Tripelennamine.

Triprolidine.

Trospium.

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

Typhoid vaccine.

Xylometazoline, except when intended for nasal use. (S1)

- END SCHEDULE 2

SCHEDULE 3

a. All substances referred to in this Schedule are excluded when specifically packed, labelled, sold 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 preparations of substances or mixtures of such substances containing or purporting to contain any substance 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 (Act 56 of 1974) other than a medical practitioner or dentist may prescribe and supply, only within his/her scope of practice and subject to the indication for use of such substances and medicines and to the conditions determined by the Medicines Control Council, to patients under his/her care, the Schedule 3 substances and medicines provided for in the Annexures to this Schedule published in the *Gazette* in terms of the Act.

Acamprosate.

Acebutolol.

Aceclofenac.

Acetazolamide.

Acetohexamide.

Acetylcholine, when intended for ophthalmic use.

Acetylcysteine, when intended for injection. (S2)

Acipimox.

Schedule 3

Adapalene.

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

Alclofenac.

Alendronic acid.

Aliskiren

Allopurinol.

Alprenolol.

Amiloride.

Amlodipine.

Ancrod.

Anthiolimine, when intended for injection.

Arsanilic acid.

Atenolol.

Atropine; ophthalmic preparations. (S2, S4)

Azapropazone.

Balsalazide.

Barnidipine.

Beclamide.

Benazepril.

Bendazac.

Benfluorex.

Benoxaprofen.

Benzbromarone.

Benzydamine, except preparations and mixtures containing -

a. 3 percent or less of benzydamine when intended for application to the skin (S1);

b. 0,15 percent 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 swallowed does not exceeds 36 milligrams of benzydamine per day. (S1)

Bepridil.

Beta-benzalbutyramide.

Beta-galactosidase, when intended for therapeutic purposes.

Schedule 3

Betahistine.

Betaxolol.

Bethanidine.

Bevantolol.

Bezafibrate.

Bisoprolol.

Bopindolol.

Brimonidine.

Brinzolamide.

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

Buflomedil.

Buformin.

Bumetanide.

Cadralazine.

Calcipotriol.

Calcium carbimide.

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 (Act 36 of 1947).

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. (S0)

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

Carprofen.

Carteolol.

Carvedilol.

Schedule 3

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.

Ciclesonide

Cilazapril.

Cilomilast.

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

Clofibrate.

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

Clopidogrel.

Colchicine, except when intended for the emergency treatment of acute gout, subject to a maximum total treatment course of 6 milligrams. (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, subject to a maximum dose per nostril of 100 micrograms, a maximum daily dose per nostril of 200 micrograms and a pack size 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, subject to, in the case of adults and children over the age of 16 years, a maximum dose per nostril is 50 micrograms and a maximum daily dose per nostril of 100 micrograms,

and in the case of children 12 to 16 years, a maximum dose per nostril of 25 micrograms and a maximum daily dose per nostril of 75 micrograms and a pack size 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, subject to a maximum daily dose per nostril of 100 micrograms and a pack size limited to 120 doses. (S2, S4)

Cyclandalate.

Cyclopentolate; ophthalmic preparations thereof. (S2)

Darifenacin.

Debrisoquine.

Delapril.

Dialysate preparations.

Dichlorphenamide.

Diclofenac,

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

b. except when intended for the emergency treatment of acute gout attacks; (S2) and

c. except when intended for the treatment of post traumatic conditions, for a maximum treatment 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.

Dornase alfa (rh DNase).

Schedule 3

Dorzolamide.

Doxazosin.

Eltenac.

Enalapril.

Endralazine.

Eprosartan.

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

Esculin, when intended for oral use.

Esmolol.

Ethacrynic acid.

Ethambutol.

Ethionamide.

Ethosuximide.

Etisazol.

Etodolac.

Etodolic acid.

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

Etoricoxib.

Exenatide

Felbamate.

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

Felodipine.

Fenbufen.

Fenclofenac.

Fendiline.

Fenofibrate.

Fenoprofen,

a. except when intended for the emergency treatment of acute gout attacks, (S2) and

Schedule 3

b. when intended for the treatment of post traumatic conditions, for a maximum treatment period of 5 days. (S2)

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

Fentiazac.

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

Firocoxib.

Floctafenine.

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

Fluorescein, except when intended for ophthalmic use by the topical route only. (S1)

Flunixin.

Flurbiprofen, except -

a. when intended for ophthalmic use; (S4)

b. when intended for application to the skin in adults and children 12 years and older only, including application by transdermal patch, subject to a maximum treatment period of 4 weeks; (S1)

c. when intended for the treatment of post-traumatic conditions, for a maximum treatment period of 5 days. (S2)

d. in the form of lozenges, indicated for the relief of pain associated with sore throats, subject to:

(i) a maximum treatment period of 3 days, and

(ii) a maximum of 8,75 milligrams per lozenge,

(iii) a maximum pack size of 15 lozenges (S1)

Fluticasone

Fosinopril.

Frusemide.

Gabapentin.

Gadoxetic acid.

Gemfibrozil.

Glafenine.

Glibenclamide.

Glibornuride.

Gliclazide.

Glimepiride.

Schedule 3

Glimidine.

Glipizide.

Gliquidone.

Glucosamine, substances, preparations and mixtures when intended for the treatment of primary and secondary osteoarthritis, osteochondrosis and spondylosis, except when registered as a feed supplement in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Guanabenz.

Guanethidine.

Guanfacine.

Guanoxan.

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

Homatropine; ophthalmic preparations thereof. (S2)

Hormones (natural or synthetic, including recombinant forms), with either hormonal, prohormonal or anti-hormonal action, unless listed elsewhere in the schedules;

a. when intended for oral contraception;

b. except when intended for human vaginal use (S2), and

c. 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, except when used in oral medicinal preparations –

a. for the treatment of post-traumatic conditions for a maximum treatment period of 5 days, where the recommended daily dose for adults does not exceed 1,2 g and the dose for children up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (S2)

b. for the emergency treatment of acute gout attacks; (S2)

c. for the treatment of a haemodynamically significant patent ductus arterious in infants less than 34 weeks of gestational age. (S4)

Indapamide.

Indometacin, except

a. for application to the skin (S1), and

b. for the emergency treatment of acute gout attacks (S2).

Indoprofen.

Schedule 3

Indoramin.

Injections, unless listed in another Schedule.

Insulin.

Ipratropium, except when contained in respirator solutions. (S2)

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 (Act 36 of 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 (Act 36 of 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, subject to a maximum dose of 75 milligrams of ketoprofen in 24 hours; (S2)

c. when intended for the emergency treatment of acute gout attacks or for the treatment of post-traumatic conditions, subject to a maximum dose of 75milligrams of ketoprofen per day and a maximum treatment period of 5 days. (S2)

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

Labetalol.

Lacidipine.

Lumiracoxib.

Lamotrigine.

Lercanidipine.

Levothyroxine.

Schedule 3

Levetiracetam.

Levobunolol.

Levosemindan.

Lidoflazine.

Lisinopril.

Lonazolac.

Lornoxicam.

Losartan.

Meclofenamic acid.

Mefenamic acid, except -

a. when intended for the treatment of post-traumatic conditions, for a maximum period of 5 days; and

b. preparations containing mefenamic acid as the only therapeutic active substance, when intended for the treatment of primary dysmenorrhoea subject to a maximum daily dose of 500 millligrams mefenamic acid 3 times a day and a maximum treatment period of 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.

Schedule 3

Nabumetone, except when intended for the treatment of post-traumatic conditions, for a maximum treatment 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, subject to a maximum dose of 600 milligrams naproxen (660 milligrams naproxen sodium) in 24 hours; (S2)

c. when intended for the emergency treatment of acute gout attacks; (S2)

d. when intended for the treatment of post traumatic conditions, for a maximum treatment period of 5 days. (S2)

Nateglinide.

Nebivolol.

Nicardipine.

Nifedipine.

Niflumic acid.

Nimesulide.

Nimodipine.

Nisoldipine.

Nitrendipine.

Nitroglycerine, when intended for medicinal use.

Normal Saline (Sodium chloride 0,9 % m/v) except for injection in a dosage form not exceeding 20 milliliters in volume. (S1)

Olsalazine.

Omesartan.

Orlistat.

Oxaprozin.

Oxcarbazepine.

Oxitracetam.

Oxovinca.

Schedule 3

Oxyprenolol.

Oxybutynin.

Parecoxib.

Para-aminosalicylic acid and its esters.

Paracetamol, when intended for injection. (S0, S1, S2)

Parenteral Nutrition formulations.

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,

a. except when intended for the emergency treatment of acute gout attacks, (S2) or

b. when intended for the treatment of post-traumatic conditions, for a maximum treatment period of 5 days. (S2)

Pirprofen.

Potassium canrenoate.

Schedule 3

Potassium chloride, where the recommended dose is more than 20 millimol of potassium (1 500 milligrams of potassium chloride) per 24 hours (S2) or when intended for intravenous infusion or for injection, but except when contained in oral rehydration preparations. (S0)

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, subject to a maximum dose of 75 milligrams, a maximum daily dose of 300 milligrams and a maximum treatment period of two weeks. (S2)

Raubasine.

Rauwolfia alkaloids.

Repaglinide.

Reproterol, when contained in respirator solutions. (S2)

Schedule 3

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)

Solifenacin.

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.

Tepoxalin.

Terazosin.

Terbutaline, when contained in respirator solutions. (S2)

Terizidone.

Schedule 3

Terodiline.

Thiacetazone.

Thiocolchicoside.

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, for a maximum treatment period of 5 days. (S2)

Ticlopidine.

Timolol.

Tiotropium

Tolamolol.

Tolazamide.

Tolbutamide.

Tolfenamic acid.

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

Tolterodine.

Topiramate.

Torasemide.

Trandolapril.

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

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.

Schedule 3

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 (Act 36 of 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 (Act 36 of 1947).

Water for injection except in a dosage form not exceeding 20milliliters in volume. (S1)

Xamoterol.

Xipamide.

Zafirlukast.

Zinc salts,

a. for oral ingestion, where the daily dose is more than 50 milligrams of elemental zinc; (S0),

b. except preparations thereof for injection, when intended for veterinary use; (S1) and

c. except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Zomepirac.

- END SCHEDULE 3 -

SCHEDULE 4

a. All substances referred to in this Schedule are excluded when specifically packed, labelled, sold 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.

Schedule 4

b. All preparations of substances or mixtures of such substances containing or purporting to contain any substance 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 (Act 56 of 1974) other than a medical practitioner or dentist may prescribe and supply, only within his/her scope of practice and subject to the indication for use of such substances and medicines and to the conditions determined by the Medicines Control Council, to patients under his/her care, the Schedule 4 substances and medicines provided for in the Annexures to this Schedule published in the *Gazette* in terms of the Act.

Abacavir.

Abatacept

Acarbose.

Acediasulfone.

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)

Adalimumab.

Adenosine.

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

Aglepristone.

Alatrofloxacin.

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 (Act 36 of 1947).

Alclometasone.

Alcuronium.

Aldesleukin.

Alefacept.

Alemtuzumab.

Alfuzosin.

Alizapride.