

GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

NO. R Submitted during 2008, 2009, 2011, 2012, 2013,
2014, 2015, 2016

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 and includes 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.
- (i) Annexure 1A: Emergency Care Provider (Paramedic);
 - (ii) Annexure 1B: Emergency Care Provider (Emergency Care Practitioner);
 - (iii) Annexure 2: Dental Therapist;
 - (iv) Annexure 3: Optometrist.

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)

Ambroxol.

Amethocaine - see Tetracaine.

Amorolfine.

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:

- 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)

Ascorbic Acid –see Vitamin C.

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.

Benzocaine,

- a. when intended for topical use;
- b. in oral preparations containing 2 percent or less of benzocaine;
- c. in lozenges containing 30 milligrams or less of benzocaine, per dosage unit;
- d. except when intended for ophthalmic or parenteral use. (S4)

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)

Bifidobacterium adolescentis,

- a. in pharmaceutical preparations and mixtures with medicinal claim(s);
- b. except in pharmaceutical preparations and mixtures for one or more strains containing $\geq 1 \times 10^9$ cfu per dosage unit with the general health claim:

“When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut”; (S0)

- c. except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1×10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Bifidobacterium animalis subsp. Animalis,

- a. in pharmaceutical preparations and mixtures with medicinal claim(s);
- b. except in pharmaceutical preparations and mixtures for one or more strains containing $\geq 1 \times 10^9$ cfu per dosage unit with the general health claim:

“When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut”; (S0)

- c. except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1×10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Bifidobacterium animalis subsp. Lactis,

- a. in pharmaceutical preparations and mixtures with medicinal claim(s);
- b. except in pharmaceutical preparations and mixtures for one or more strains containing $\geq 1 \times 10^9$ cfu per dosage unit with the general health claim:

“When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut”; (S0)

- c. except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1×10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Bifidobacterium bifidum,

- a. in pharmaceutical preparations and mixtures with medicinal claim(s);
- b. except in pharmaceutical preparations and mixtures for one or more strains containing $\geq 1 \times 10^9$ cfu per dosage unit with the general health claim:

“When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut”; (S0)

- c. except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1×10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Bifidobacterium breve,

- a. in pharmaceutical preparations and mixtures with medicinal claim(s);
- b. except in pharmaceutical preparations and mixtures for one or more strains containing $\geq 1 \times 10^9$ cfu per dosage unit with the general health claim:

“When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut”; (S0)
- c. except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1×10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Bifidobacterium lactis,

- a. in pharmaceutical preparations and mixtures with medicinal claim(s);
- b. except in pharmaceutical preparations and mixtures for one or more strains containing $\geq 1 \times 10^9$ cfu per dosage unit with the general health claim:

“When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut”; (S0)
- c. except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1×10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Bifidobacterium longum subsp. Infantis,

- a. in pharmaceutical preparations and mixtures with medicinal claim(s);
- b. except in pharmaceutical preparations and mixtures for one or more strains containing $\geq 1 \times 10^9$ cfu per dosage unit with the general health claim:

“When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut”; (S0)
- c. except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1×10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Bifidobacterium longum subsp. Longum,

- a. in pharmaceutical preparations and mixtures with medicinal claim(s);
- b. except in pharmaceutical preparations and mixtures for one or more strains containing $\geq 1 \times 10^9$ cfu per dosage unit with the general health claim:

“When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut”; (S0)

- c. except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1×10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

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

Bioallethrin.

Bitolterol.

Boron, in oral preparations or mixtures containing more than 3 mg of Boron per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S0)

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)

Calcium,

- a. in oral preparations or mixtures containing more than 1300 mg of calcium per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)
- b. except in preparations thereof for injection; (S3)
- c. except when indicated for the treatment of hyperphosphataemia; (S4)
- d. except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Carbamoyl benzamide phenyl isoxazoline, except 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 (Act 36 of 1947).

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

Chloroform, preparations and mixtures containing more than 0,5 percent and less than 20 percent of chloroform. (S0, S5)

Chromium, in oral preparations or mixtures containing more than 50 µg of Chromium per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S0)

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)

Collagenase clotridiopeptidase, when intended for application to the skin.

Copper,

- a. in oral preparations or mixtures containing more than 4 mg of Copper per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)
- b. except in preparations thereof for injection. (S3)

Cyanocobalamin –see Vitamin B12.

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)

Ethyl chloride.

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)

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

Fluorides,

- a. in oral medicinal preparations or mixtures intended for ingestion containing 0,25 milligrams or less of fluorine per dosage unit;
- b. except in toothpaste containing less than 0,15 percent fluoride; (S0) and
- c. except in mouth rinses containing less than 0,15 percent fluoride; (S0)
- d. except in oral medicinal preparations or mixtures intended for ingestion containing more than 0,25 milligrams of fluorine per dosage unit. (S4)

Flurbiprofen,

- a. when 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.(S3)
- 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.
- c. except when intended for the treatment of post-traumatic conditions, for a maximum period of 5 days; (S2)
- d. except when intended for ophthalmic use. (S4)

Folic Acid, in oral preparations or mixtures containing more than 500 µg of Folic Acid per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S0)

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,

- a. when intended for topical application to the skin;
- b. except when intended for use with contact lens solutions or as an ophthalmic lubricant in concentrations of not more than 0,1 percent; (S0)
- c. except when intended for ophthalmic use in preparations (except injectables) containing more than 0,1 percent; (S2)
- d. except when intended for parenteral use; (S4)
- e. except in preparations containing less than 2,5 percent when intended for topical use in terms of the provisions of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972),

Icodextrin.

Ibuprofen

- a. when contained in preparations intended for application to the skin; (S2, S3, S4).
- b. when contained in oral medicinal preparations supplied in a solid dose form as divided doses contained in packs not exceeding 24 dosage units or divided doses and containing ibuprofen as the only active therapeutic substance, intended for the treatment of mild to moderate pain or fever of inflammatory origin or for the treatment of post-traumatic conditions in adults and children over 12 years of age where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children 12 years and older does not exceed 20 milligrams per kilogram of body weight. (S2, S3).

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

Indanazoline.

Indometacin,

- a. when intended for application to the skin; (S3)
- b. except when intended for the emergency treatment of acute gout attacks; (S2)

Iron,

- a. in oral preparations or mixtures containing more than 24 mg of Iron per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)
- b. except in preparations thereof for injection; (S3)
- 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).

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,

- a. when intended for application to the skin; (S3)
- b. **except** 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. **except** when intended for the emergency treatment of acute gout attacks; (S2)
- d. **except** 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; (S2)
- e. **except** in the form of lozenges indicated and intended for the relief of pain associated with sore throats in patients 18 years and older subject to-
 - (i) a maximum of 12,5 milligrams per lozenge;
 - (ii) a maximum of 5 lozenges in any 24 hour period;
 - (iii) a maximum treatment period of 3 days; and
 - (iv) a maximum pack size of 15 lozenges. (S2)

Lactobacillus acidophilus,

- a. in pharmaceutical preparations and mixtures with medicinal claim(s);
- b. except in pharmaceutical preparations and mixtures for one or more strains containing $\geq 1 \times 10^9$ cfu per dosage unit with the general health claim:

“When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut”; (S0)

- c. except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1×10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Lactobacillus brevis,

- a. in pharmaceutical preparations and mixtures with medicinal claim(s);
- b. except in pharmaceutical preparations and mixtures for one or more strains containing $\geq 1 \times 10^9$ cfu per dosage unit with the general health claim:

“When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut”; (S0)

- c. except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1×10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Lactobacillus caucasicus,

- a. in pharmaceutical preparations and mixtures with medicinal claim(s);
- b. except in pharmaceutical preparations and mixtures for one or more strains containing $\geq 1 \times 10^9$ cfu per dosage unit with the general health claim:

“When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut”; (S0)

- c. except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1×10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Lactobacillus casei,

- a. in pharmaceutical preparations and mixtures with medicinal claim(s);
- b. except in pharmaceutical preparations and mixtures for one or more strains containing $\geq 1 \times 10^9$ cfu per dosage unit with the general health claim:

“When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut”; (S0)

- c. except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1×10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Lactobacillus fermentum,

- a. in pharmaceutical preparations and mixtures with medicinal claim(s);

- b. except in pharmaceutical preparations and mixtures for one or more strains containing $\geq 1 \times 10^9$ cfu per dosage unit with the general health claim:

"When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut"; (S0)

- c. except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1×10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Lactobacillus gasseri,

- a. in pharmaceutical preparations and mixtures with medicinal claim(s);

- b. except in pharmaceutical preparations and mixtures for one or more strains containing $\geq 1 \times 10^9$ cfu per dosage unit with the general health claim:

"When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut"; (S0)

- c. except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1×10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Lactobacillus helveticus,

- a. in pharmaceutical preparations and mixtures with medicinal claim(s);

- b. except in pharmaceutical preparations and mixtures for one or more strains containing $\geq 1 \times 10^9$ cfu per dosage unit with the general health claim:

"When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut"; (S0)

- c. except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1×10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Lactobacillus johnsonii,

- a. in pharmaceutical preparations and mixtures with medicinal claim(s);

- b. except in pharmaceutical preparations and mixtures for one or more strains containing $\geq 1 \times 10^9$ cfu per dosage unit with the general health claim:

"When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut"; (S0)

- c. except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1×10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Lactobacillus lactis,

- a. in pharmaceutical preparations and mixtures with medicinal claim(s);
- b. except in pharmaceutical preparations and mixtures for one or more strains containing $\geq 1 \times 10^9$ cfu per dosage unit with the general health claim:

“When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut”; (S0)

- c. except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1×10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Lactobacillus paracasei,

- a. in pharmaceutical preparations and mixtures with medicinal claim(s);
- b. except in pharmaceutical preparations and mixtures for one or more strains containing $\geq 1 \times 10^9$ cfu per dosage unit with the general health claim:

“When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut”; (S0)

- c. except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1×10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Lactobacillus plantarum,

- a. in pharmaceutical preparations and mixtures with medicinal claim(s);
- b. except in pharmaceutical preparations and mixtures for one or more strains containing $\geq 1 \times 10^9$ cfu per dosage unit with the general health claim:

“When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut”; (S0)

- c. except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1×10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Lactobacillus reuteri,

- a. in pharmaceutical preparations and mixtures with medicinal claim(s);

- b. except in pharmaceutical preparations and mixtures for one or more strains containing $\geq 1 \times 10^9$ cfu per dosage unit with the general health claim:

“When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut”; (S0)

- c. except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1×10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Lactobacillus rhamnosus,

- a. in pharmaceutical preparations and mixtures with medicinal claim(s);
- b. except in pharmaceutical preparations and mixtures for one or more strains containing $\geq 1 \times 10^9$ cfu per dosage unit with the general health claim:

“When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut”; (S0)

- c. except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1×10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Lactobacillus salivarius,

- a. in pharmaceutical preparations and mixtures with medicinal claim(s);
- b. except in pharmaceutical preparations and mixtures for one or more strains containing $\geq 1 \times 10^9$ cfu per dosage unit with the general health claim:

“When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut”; (S0)

- c. except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1×10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Lidocaine,

- a. when intended for topical use;
- b. in oral preparations containing 2 percent or less of lidocaine, per dosage unit;
- c. except when intended for ophthalmic or parenteral use; (S4)
- d. except when intended for the treatment of neuropathic pain associated with previous herpes zoster infection. (S4)

Lignocaine - see Lidocaine.

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).

Loratidine,

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)

Magnesium, in oral preparations or mixtures containing more than 250 mg of Magnesium per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S0)

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,

- a. in oral preparations or mixtures containing more than 4 mg of Manganese per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)
- b. in 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.

Molybdenum and derivatives thereof in oral preparations or mixtures containing more than 230 µg of Molybdenum per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S0)

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).

N-acetyl-aspartyl-glutamic acid.

Naphazoline, when intended for nasal use. (S2)

Naproxen

- a. when contained in preparations intended for application to the skin; (S2, S3)
- b. when contained in oral medicinal preparations containing naproxen as the only active therapeutic substance intended for patients over 16 years of age, for the treatment of mild to moderate pain or fever of inflammatory origin at a maximum dose of 600 milligrams naproxen base (660 milligrams naproxen sodium) in a 24 hour period for a maximum treatment period of 5 days and supplied in a solid dose form as divided doses contained in packs not exceeding the stated maximum treatment period. (S2, S3)

Niacin (Nicotinic Acid, Vitamin B3) and derivatives thereof,

- a. in oral preparations or mixtures containing more than 35 mg of Niacin per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)
- b. except when intended for hypercholesterolaemia and for the management of dyslipidaemias. (S4)

Nicotinamide and derivatives thereof, in oral preparations or mixtures containing more than 500 mg of Nicotinamide per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S0)

Nicotine,

- a. when intended for human medicinal use as an aid to smoking cessation, when registered and presented as nicotine transdermal patches for continuous application to the skin in strengths up to and including 21mg/ 24 hours or 25 mg/ 16 hours;
- b. except when registered for human medicinal use as an aid to smoking cessation and presented as nicotine gum or lozenges containing not more than 4 mg nicotine per piece; (S0)
- c. except when registered for human medicinal use as an aid to smoking cessation and presented as nicotine gum or lozenges containing more than 4 mg nicotine per piece; (S2)
- d. except when intended for human medicinal use as an aid to smoking cessation, when registered and presented as nicotine transdermal patches for continuous application to the skin in strengths containing more than 21mg/ 24 hours or 25 mg/ 16 hours; (S2)
- e. except when registered as metered sprays containing not more than 1 mg per dose; (S2)

- f. except when registered as oral solid dosage forms containing not more than 2 mg; (S2)
- g. except when registered as inhalers containing not more than 10 mg per cartridge; (S2)
- h. except when intended for human medicinal use as an aid to smoking cessation or as a substitute for a tobacco product (as defined in the Tobacco Products Control Act, 1993, as amended). (S3)

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

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

Normal Saline (Sodium chloride 0,9 percent *m/v*) when intended for injection, in a dosage form not exceeding 20 millilitres in volume. (S0, 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 millilitre, (S2)
- d. except when intended for systemic use or the initial treatment of vaginal candidiasis, (S4)
- e. except when intended and registered as a stock remedy for pigeons in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

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

Orthodichlorobenzene, when intended for topical human medicinal use.

Oxetacaine (Oxethazaine),

- a. in oral preparations containing an antacid;
- b. except when intended for ophthalmic or parenteral use. (S4)

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.

Pantothenic Acid –see Vitamin B5.

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.

Phosphorus, in oral preparations or mixtures containing more than 250 mg of Phosphorus per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S0)

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

Pramoxine.

Prilocaine,

- a. in topical preparations containing 10 percent or less of prilocaine;
- b. except when intended for ophthalmic or parenteral use. (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.

Pyridoxine –see Vitamin B6.

Riboflavin –see Vitamin B2.

Selenium,

- a. in oral preparations or mixtures containing more than 60 µg of Selenium per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)
- b. in preparations thereof for injection when intended for veterinary use.

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

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

Tetracaine,

- a. when intended for topical use;
- b. in oral preparations containing 2 percent or less of tetracaine, per dosage unit;
- c. except when contained in eye drops intended for the emergency treatment of “arc eyes”; (S2)
- d. except when intended for ophthalmic or parenteral use. (S4)

Tetrahydrozoline, when intended for nasal use. (S2)

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

Thiamine –see Vitamin B1.

Thiomersal.

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)

L-tryptophan,

- a. when intended for medicinal use in dosages of less than 5 milligrams/kg/day or
- b. intended as supplementation for nutritional purposes. (S5)

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

Vitamin B1 (Thiamine) and derivatives thereof,

- a. in oral preparations or mixtures containing more than 100 mg of Vitamin B1 per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)
- b. except in preparations thereof for injection. (S3)

Vitamin B2 (Riboflavin) and derivatives thereof,

- a. in oral preparations or mixtures containing more than 100 mg of Vitamin B2 per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)
- b. except in preparations thereof for injection. (S3)

Vitamin B5 (Pantothenic Acid) and derivatives thereof,

- a. in oral preparations or mixtures containing more than 200 mg of Vitamin B5 per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)
- b. except in preparations thereof for injection. (S3)

Vitamin B6 (Pyridoxine) and derivatives thereof,

- a. in oral preparations or mixtures containing more than 100 mg of Vitamin B6 per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)
- b. except in preparations thereof for injection. (S3)

Vitamin B12 (Cyanocobalamin) and derivatives thereof,

- a. in oral preparations or mixtures containing more than 100 µg of Vitamin B12 per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)
- b. except in preparations thereof for injection. (S3)

Vitamin C (Ascorbic Acid),

- a. in oral preparations or mixtures containing more than 1000 mg of Vitamin C per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)
- b. except in preparations thereof for injection. (S3)

Vitamin H (Biotin) and derivatives thereof, in oral preparations or mixtures containing more than 500 µg of Vitamin H per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S0)

Vitamin K and derivatives thereof,

- a. in oral preparations or mixtures containing more than 120 µg of Vitamin K per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)
- b. except in injection preparations; (S3)
- c. except when used in infant milk feeds or formulae in terms of the provisions of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972).

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

Xylometazoline, when intended for nasal use. (S2)

Zinc and derivatives thereof,

- a. in injection preparations when intended for veterinary use; (S3)
- b. except in oral preparations or mixtures containing not more than 25 mg of Zinc per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0,)
- c. except when intended for topical use; (S0)
- d. except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

ANNEXURE 1A: EMERGENCY CARE PROVIDER (PARAMEDIC)

PARAMEDIC (National Diploma in Emergency Medical Care graduates **only**) registered with Health Professions Council of South Africa

PARAMEDIC (National Diploma in Emergency Medical Care graduates only)		
LOCAL ANAESTHETIC		
Substance	:	Lignocaine hydrochloride
Indication	:	Local Anaesthetic
Route of Administration	:	Topical application

ANNEXURE 1B: EMERGENCY CARE PROVIDER (EMERGENCY CARE PRACTITIONER)

EMERGENCY CARE PRACTITIONER (Bachelor of Technology Degree in Emergency Medical Care) registered with Health Professions Council of South Africa

EMERGENCY CARE PRACTITIONER (B Tech: Emergency Medical Care)		
LOCAL ANAESTHETIC		
Substance	:	Lignocaine hydrochloride
Indication	:	Local Anaesthetic
Route of Administration	:	Topical application

ANNEXURE 2: DENTAL THERAPIST

DENTAL THERAPIST(Bachelors degree in Dental Therapy) registered with Health Professions Council of South Africa

DENTAL THERAPIST (Bachelors degree in Dental Therapy)		
ANALGESIC, ANTIPYRETIC, ANTI INFLAMMATORY		
Substance	:	Paracetamol
Indication	:	Dental pain
Route of Administration	:	Oral
SURFACE ANAESTHETIC		
Substance	:	Lidocaine / Lignocaine hydrochloride
Indication	:	Dental surface anaesthesia
Route of Administration	:	Topical
ANTI-VIRAL		
Substance	:	Acyclovir
Indication	:	Viral infection of lips
Route of Administration	:	Topical
VITAMINS AND MINERALS		
Substance	:	-
Indication	:	Applicable to Dentistry
Route of Administration	:	Oral
MOUTH AND THROAT PREPARATIONS		
Substance	:	-
Indication	:	Applicable to Dentistry
Route of Administration	:	Oral

ANNEXURE 3: OPTOMETRIST

OPTOMETRIST (Bachelors degree in Optometry – B OPTOM) registered with the Health Professions Council of South Africa in terms of the Health Professions Act, 1974 (Act 56 of 1974) and in possession of a Section 22A(15) permit as provided for by the Medicines and Related Substances Act, 1965 (Act 101 of 1965)

OPTOMETRIST	
OPHTHALMIC PREPARATIONS: OTHER	
Substance	: Fluorescein
Indication	: For diagnostic purpose only i.e. In detecting corneal abrasions and foreign bodies in the eye, in applanation tonometry, in assessing the patency of the nasolacrimal duct and in contact lens fitting procedures
Route of Administration	: Intra-ocular
ANALGESIC	
Substance	: Paracetamol
Indication	: Mild Pain
Route of Administration	: Oral
ANALGESIC/ ANTI INFLAMMATORY	
Substance	: Ibuprofen
Indication	: Mild to Moderate Pain
Route of Administration	: Oral

- 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 and includes 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.
- (i) Annexure 1A: Emergency Care Provider (Paramedic);
 - (ii) Annexure 1B: Emergency Care Provider (Emergency Care Practitioner);
 - (iii) Annexure 2: Dental Therapist.
 - (iv) Annexure 3: Optometrist.

Acetylcysteine, except when intended for injection or for the management of paracetamol overdose. (S3)

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.

Amethocaine- see Tetracaine.

Aminopentamide.

Amyl nitrite.

Antazoline.

Antihistamines, except -

- a. astemizole and terfenadine; (S4)
- b. when listed separately in these Schedules. (S5)

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)

Aspirin (acetyl salicylic acid), when intended for:

- a. the treatment of children or adolescents; and
- b. the prophylaxis of cardiovascular disease in adults (S0)

Atropine, except

- a. when intended for use in ophthalmic preparations; (S3)
- b. when intended for use in injections. (S4)

Azatadine

Azelastine.

Bambuterol.

Bamipine.

BCG vaccine – see *Mycobacterium bovis*.

Beclomethasone dipropionate, when intended for nasal administration as an aqueous spray, other than by pressurised aerosol, and indicated for the treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12 years of age, subject to

- a. a maximum dose of 100 micrograms per nostril and a maximum daily dose of 200 micrograms of per nostril and
- b. a maximum pack size of 200 doses. (S3, S4)

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

Benproperine.

Bevonium methylsulphate.

Bismuth, when intended for oral use.

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

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 (methylnorphine),

- a. oral solid preparations, in combination with one or more therapeutically active substances, containing not more than 10 milligrams of codeine (calculated as base) per dosage unit, with a maximum daily dose not exceeding 80 milligrams, and in packs containing sufficient dosage units for a maximum treatment period of 5 days, and limited to one pack per customer, when contained in products registered in terms of the Act, and not intended for export;
- b. liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, containing not more than 10 milligrams of codeine (calculated as base) per 5 millilitre dosage unit, with a maximum daily dose not exceeding 80 milligrams, and with a pack size not exceeding 100 millilitres, when contained in products registered in terms of the Act, and not intended for export;
- c. **except** oral solid preparations, in combination with one or more therapeutically active substances, containing more than 10 milligrams of codeine (calculated as base) per dosage unit; (S3)
- d. **except** liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, containing more than 10 milligrams of codeine (calculated as base) per 5 millilitre dosage unit ; (S3)
- e. **except** single component codeine preparations. (S6)

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

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.

Difenoxin (or diphenoxylate), 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, containing not more than 10 milligrams of dihydrocodeine (calculated as base) per dosage unit, with a maximum daily dose not exceeding 80 milligrams, and in packs containing sufficient dosage units for a maximum treatment period of 5 days, when contained in products registered in terms of the Act, and not intended for export;
- b. liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, containing not more than 10 milligrams of dihydrocodeine (calculated as base) per 5 millilitre dosage unit, with a maximum daily dose not exceeding 80 milligrams, and with a pack size not exceeding 100 millilitres, when contained in products registered in terms of the Act, and not intended for export;
- c. **except** oral solid preparations, in combination with one or more therapeutically active substances, containing more than 10 milligrams of dihydrocodeine (calculated as base) per dosage unit; (S3)
- d. **except** liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, containing more than 10 milligrams of dihydrocodeine (calculated as base) per 5 millilitre dosage unit; (S3)
- e. **except** single component dihydrocodeine preparations. (S6)

Dimethindene.

Dimethothiazine.

Dimetindene.

Diphenhydramine.

Diphenylpyraline.

Diphtheria toxoid vaccine.

{D-norpseudoephedrine - see cathine (S6)}

Doxycycline,

- a. when intended and labelled for the chemoprophylaxis of malaria in those aged 8 years and older, for periods not exceeding 4 months of continuous use; (S4)
- b. except in preparations thereof for the treatment of animals and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947), excluding when intended for administration in animal feed.

Doxylamine.

Ebastine.

Emedastine.

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)

Ergotamine.

Estradiol,

- a. when intended for human vaginal use;
- b. except when intended for oral contraception; (S3)
- c. except when intended for hormone replacement therapy. (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 milliliter 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)

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 as an aqueous spray, other than by pressurised aerosol, in a strength not exceeding 0,025 percent (*m/v*), and indicated for treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12 years of age, 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 16 years of age;
- b. a maximum dose of 25 micrograms per nostril and a maximum daily dose of 75 micrograms in children 12 to 16 years of age;
- c. a maximum pack size of 240 doses. (S3, S4)

Flurbiprofen,

- a. when intended for the treatment of post-traumatic conditions, for a maximum period of 5 days; (S3)
- b. except when 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. (S1)
- c. except 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. (S1)
- d. except when intended for ophthalmic use; (S4)

Fluticasone furoate,

- a. when intended for nasal administration, as an aqueous spray, in the short-term (less than 6 months) prophylaxis and treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12 years of age, subject to-
 - (i) a maximum daily dose of 55 micrograms per nostril; and
 - (ii) a maximum pack size limit of 120 doses. (S3)
- b. **except** when intended for administration other than by inhalation or nasal administration. (S4)

Fluticasone propionate,

- a. when intended for nasal administration, as an aqueous spray, in the short-term (less than 6 months) prophylaxis and treatment of symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12 years of age, subject to-
 - (i) a maximum daily dose of 100 micrograms per nostril;

(ii) and a maximum pack size limit of 120 doses. (S3)

b. **except** when intended for administration other than by inhalation or nasal administration. (S4)

Fusafungine.

Gadopentetic acid.

Gamma benzene hexachloride when intended to be used for the second line treatment of lice in a pack size not exceeding 60 millilitres. (S4)

Gelsemium alkaloids.

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

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

Haemophilus influenzae vaccine (Hib).

Hepatitis B vaccine.

Hexametazine.

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)

Human papillomavirus vaccine.

Hyaluronic acid and its salts,

a. when intended for ophthalmic use in preparations (except injectables) containing more than 0,1 percent;

b. except when intended for use with contact lens solutions or as an ophthalmic lubricant in concentrations of not more than 0,1 percent; (S0)

c. except when intended for topical application to the skin; (S1)

d. except when intended for parenteral use; (S4)

e. except in preparations containing less than 2,5 percent when intended for topical use in terms of the provisions of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972).

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 contained in oral medicinal preparations

- a. containing ibuprofen in combination with one or more other active therapeutic substances and intended for the treatment of mild to moderate pain or fever of inflammatory origin for a maximum treatment period of 10 days where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight. (S3)
- b. containing ibuprofen as the only active therapeutic substance in oral liquid preparations in packs not exceeding 100 millilitres in volume or in oral solid preparations in packs exceeding 24 dosage units or divided doses, when intended for adults and children over the age of 1 year; for the treatment of mild to moderate pain of inflammatory origin for a maximum treatment period of 10 days, or for the treatment of fever of inflammatory origin or for the treatment of post-traumatic conditions where the recommended daily dose of ibuprofen for adults does not exceed 1,2 grams and for children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (S1, S3)
- c. for the emergency treatment of acute gout attacks for a maximum treatment period of 5 days; (S3)
- d. except when intended for the treatment of haemodynamically significant patent ductus arteriosus in infants less than 34 weeks of gestational age. (S4).

Indometacin,

- a. when intended for the emergency treatment of acute gout attacks; (S3)
- b. except when intended for application to the skin. (S1)

Influenza virus vaccine.

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

Isoaminile.

Isoprenaline (isoproterenol), except

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

- 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 or 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;
- c. in the form of lozenges indicated and intended for the relief of pain associated with sore throats in patients 18 years and older subject to-
 - (i) a maximum of 12,5 milligrams per lozenge;
 - (ii) a maximum of 5 lozenges in any 24 hour period;
 - (iii) a maximum treatment period of 3 days; and
 - (iv) a maximum pack size of 15 lozenges. (S3)
- d. **except** when intended for application to the skin. (S1)

Ketotifen.

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.

Levonorgestrel,

- a. when intended for emergency post coital contraception;
- b. except when intended for oral contraception; (S3)
- c. except when administered via an Intra Uterine System. (S4)

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,

- 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 milligrams 3 times a day and a maximum treatment period of 3 days. (S3)

Melatonin, when used for the treatment of desynchronosis (jet-lag) in doses not exceeding 6 milligrams daily. (S4).

Mometasone furoate, when intended for nasal administration as an aqueous spray, other than by pressurized aerosol, and indicated for the treatment of the symptoms of seasonal or perennial allergic rhinitis (hay fever) in adults and children between the age of 2 and 11 years of age, subject to

- a. a maximum dose of 200 micrograms per nostril in adults and 50 micrograms per nostril in children; and
- b. a maximum pack size of 200 doses. (S3, S4)

Monoethanolamine.

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.

Metronidazole, when intended for human vaginal use, specifically for the treatment of recurrent bacterial vaginosis and except when intended and registered for use in pigeons in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947). (S4)

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 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)

Mycobacterium bovis vaccine (BCG).

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. when intended for the treatment of acute gout attacks, for a maximum treatment period of 5 days in patients over 16 years of age; (S3)
- b. except when contained in preparations intended for application to the skin;(S1) and
- c. except when contained in oral medicinal preparations containing naproxen as the only active therapeutic substance intended for patients over 16 years of age, for the treatment of mild to moderate pain or fever of inflammatory origin at a maximum dose of 600 milligrams naproxen base (660 milligrams naproxen sodium) in a 24 hour period for a maximum treatment period of 5 days and supplied in a solid dose form as divided doses contained in packs not exceeding the stated maximum treatment period. (S1, S3)

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

Nedocromil.

Nicergoline.

Nicotine,

- a. when registered for human medicinal use as an aid to smoking cessation and presented as nicotine gum or lozenges containing more than 4mg nicotine per piece;
- b. when registered as metered sprays containing 1mg per dose or less;
- c. when registered as oral solid dosage forms containing 2mg or less;
- d. when registered as inhalers containing 10mg or less per cartridge;
- e. when intended for human medicinal use as an aid to smoking cessation, when registered and presented as nicotine transdermal patches for continuous application to the skin in strengths containing more than 21mg/ 24 hours or 25 mg/ 16 hours;
- f. **except** when registered for human medicinal use as an aid to smoking cessation and presented as nicotine gum or lozenges containing not more than 4mg nicotine per piece; (S0)
- g. **except** when intended for human medicinal use as an aid to smoking cessation, when registered and presented as nicotine transdermal patches for continuous application to the skin in strengths up to an including 21mg/ 24 hours or 25 mg/ 16 hours; (S1)
- h. **except** when intended for human medicinal use as an aid to smoking cessation or as a substitute for a tobacco product (as defined in the Tobacco Products Control Act, 1993, as amended). (S3)

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)

{{(+)-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 than 100 000 I.U. per millilitre, 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)
- e. except when intended and registered as a stock remedy for pigeons in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Octatropine.

Oleoresin of aspidium (Felix Mas).

Olopatadine.

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

- a. a maximum daily dose of 20 milligrams
- b. a maximum treatment period of 14 days. (S4)

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

Orlistat, when used in a dose not exceeding 60 milligrams per main meal and not exceeding a maximum dose of 180 milligrams per 24-hour period. (S3)

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.

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

- a. maximum daily dose of 20 milligrams
- b. maximum treatment period of 14 days. (S4)

Papaverine; substances, preparations and mixtures thereof.

Paracetamol,

- a. when contained in rectal suppositories, or
- b. when contained in modified release formulations. (S0, S1, S3)

Pentoxifylline.

Perfluorooctane, except when intended for intraocular use.(S4)

Pertussis toxoid vaccine.

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

Pneumococcal vaccine, conjugated.

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

Poldine methylsulphate.

Polio vaccine.

Potassium,

- a. in oral preparations or mixtures containing more than 20 millimoles (1500mg) of potassium 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.

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)

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

- a. maximum daily dose of 10 milligrams;
- b. maximum treatment period of 14 days. (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)

Rotavirus, live attenuated.

Rubella vaccine.

Rupatidine,

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)

Sulfadiazine 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,

- a. when contained in eye drops intended for the emergency treatment of “arc eyes”
- b. except when intended for topical use; (S1)
- c. except in oral preparations containing 2 percent or less of tetracaine, per dosage unit; (S1)
- d. except when intended for ophthalmic or parenteral use.(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.

Vitamin A and derivatives thereof and including retinol, retinal, retinoic acids and beta-carotene (but excluding isotretinoin) and not listed elsewhere in the Schedules, contained in preparations or mixtures containing more than 5 000 I.U (or 1 500 milligrams of the retinol equivalent or 3 000 milligrams of the beta-carotene equivalent) but not more than 10 000 I.U (or 3 000 milligrams of the retinol equivalent or 6 000 milligrams of the beta-carotene equivalent) of Vitamin A per recommended daily dose alone or in combination with other active pharmaceutical ingredients, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agriculture Remedies and Stock Remedies Act, 1947 (Act 36 of 1947). (S0, S3)

Vitamin E and derivatives thereof, including *d*-alpha-tocopherol and not listed elsewhere in the Schedules, contained in preparations or mixtures containing more than 400 I.U. of Vitamin E per recommended daily dose.(S0)

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

ANNEXURE 1A: EMERGENCY CARE PROVIDER (PARAMEDIC)

PARAMEDIC (National Diploma in Emergency Medical Care graduates **only**) registered with Health Professions Council of South Africa

PARAMEDIC (National Diploma in Emergency Medical Care graduates <i>only</i>)		
ANTI-CHOLINERGIC		
Substance	:	Ipratropium bromide
Indication	:	Inhalant Bronchodilator (atropine derivative anti-cholinergic)
Route of Administration	:	Respirator Solution

ANNEXURE 1B: EMERGENCY CARE PROVIDER (EMERGENCY CARE PRACTITIONER)**EMERGENCY CARE PRACTITIONER**

(Bachelor of Technology Degree in Emergency Medical Care) registered with Health Professions Council of South Africa

EMERGENCY CARE PRACTITIONER (B Tech: Emergency Medical Care)		
ANTI-CHOLINERGIC		
Substance	:	Ipratropium bromide
Indication	:	Inhalant Bronchodilator (atropine derivative anti-cholinergic)
Route of Administration	:	Respirator Solution

ANNEXURE 2: DENTAL THERAPIST

DENTAL THERAPIST (Bachelors degree in Dental Therapy) registered with Health Professions Council of South Africa

DENTAL THERAPIST (Bachelors degree in Dental Therapy)		
ANALGESIC, ANTIPYRETIC, ANTI INFLAMMATORY		
Substance	:	Ibuprofen
Indication	:	Dental pain
Route of Administration	:	Oral
ANALGESIC, ANTIPYRETIC, ANTI INFLAMMATORY		
Substance	:	Codeine
Indication	:	Dental pain
Route of Administration	:	Oral
ANTI-FUNGALS		
Substance	:	Nystatin
Indication:	:	Candidal infections of the oral cavity
Route of Administration	:	Oral

ANNEXURE 3: OPTOMETRIST

OPTOMETRIST (Bachelors degree in Optometry – B OPTOM) registered with the Health Professions Council of South Africa in terms of the Health Professions Act, 1974 (Act 56 of 1974) and in possession of a Section 22A(15) permit as provided for by the Medicines and Related Substances Act, 1965 (Act 101 of 1965)

OPTOMETRIST		
ANTIBACTERIAL		
Substance	:	Mupirocin
Indication	:	Impetigo (Eyelids); External Hordeolum, Infected atopic dermatitis
Route of Administration	:	Topical application
ANTIHISTAMINE/ VASOCONSTRICTOR/ MAST CELL STABILISER		
Substance	:	Antazoline
Indication	:	Allergic and Atopic Conjunctivitis
Route of Administration	:	Topical application
ANTIHISTAMINE/ VASOCONSTRICTOR/ MAST CELL STABILISER		
Substance	:	Tetrazoline
Indication	:	Minor ocular irritation; Red eye
Route of Administration	:	Topical application
ANTIHISTAMINE/ VASOCONSTRICTOR/ MAST CELL STABILISER		
Substance	:	Oxymetazoline
Indication	:	Minor ocular irritation; Red eye
Route of Administration	:	Topical application
ANTIHISTAMINE/ VASOCONSTRICTOR/ MAST CELL STABILISER		
Substance	:	Cetirizine; Loratidine; Levocetirizine
Indication	:	Atopic dermatitis involving the eyelids
Route of Administration	:	Oral
ANTIHISTAMINE/ VASOCONSTRICTOR/ MAST CELL STABILISER		
Substance	:	Sodium Cromoglycate
Indication	:	Vernal Kerato conjunctivitis
Route of Administration	:	Topical application
STEROIDAL ANTI INFLAMMATORY		
Substance	:	Hydrocortisone
Indication	:	Dermatitis, Ectopic or Seborrhoeic Eczema
Route of Administration	:	Topical application

- 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 and includes 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.
- (i) Annexure 1A: Emergency Care Provider (Paramedic);
 - (ii) Annexure 1B: Emergency Care Provider (Emergency Care Practitioner);
 - (iii) Annexure 2: Dental Therapist;
 - (iv) Annexure 3: Optometrist.

Acamprosate.

Acebutolol.

Aceclofenac.

Acetazolamide.

Acetohexamide.

Acetylcholine, when intended for ophthalmic use.

Acetylcysteine, when intended for injection or for the management of paracetamol overdose. (S2)

Acipimox.

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.

Ascorbic Acid –see Vitamin C.

Atenolol.

Atropine,

- a. when intended for use in ophthalmic preparations; (S2)
- b. except when intended for use in injections. (S4)

Azapropazone.

Balsalazide.

Barnidipine.

Beclamide.

Beclomethasone dipropionate, when intended for inhalation or nasal administration, except when intended for nasal administration as an aqueous spray, other than by pressurised aerosol, and indicated for the treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12 years of age, subject to

- a. a maximum dose of 100 micrograms per nostril and a maximum daily dose of 200 micrograms of per nostril and
- b. a maximum pack size of 200 doses. (S2, S4)

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)

Bepiridil.

Beta-benzalbutyramide.

Beta-galactosidase, when intended for therapeutic purposes.

Betahistine.

Betaxolol.

Bethanidine.

Bevantolol.

Bezafibrate.

Bisoprolol.

Bopindolol.

Bowel cleansers, preparations intended for the management of faecal impaction, or for the purpose of bowel cleansing prior to surgical or diagnostic procedures, unless listed elsewhere in the Schedules. (S0)

Brimonidine.

Brinzolamide.

Budesonide, when intended for inhalation or nasal administration. (S4)

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

Buflomedil.

Buformin.

Bumetanide.

Butecosone, when intended for inhalation or nasal administration.

Cadralazine.

Caffeine, when intended for injection.

Calcipotriol.

Calcium carbimide.

Calcium,

- a. in preparations thereof for injection; (S0)
- b. except in oral preparations or mixtures containing more than 1300 mg of calcium per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S1)
- c. except when indicated for the treatment of hyperphosphataemia; (S4)
- d. 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.

Celecoxib.

Celiprolol.

Chenodeoxycholic acid.

Chlorazaniol.

Chlorexolone.

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

Chlorpropamide.

Chlorthalidone.

Cholecalciferol,- see Vitamin D.

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.

Codeine (methyldorphine),

- a. oral solid preparations, in combination with one or more therapeutically active substances, containing more than 10 milligrams of codeine (calculated as base) per dosage unit, when contained in products registered in terms of the Act, and not intended for export;
- b. liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, containing more than 10 milligrams of codeine (calculated as base) per 5 millilitre dosage unit, when contained in products registered in terms of the Act, and not intended for export;
- c. except oral solid preparations, in combination with one or more therapeutically active substances, containing not more than 10 milligrams of codeine (calculated as base) per dosage unit, with a maximum daily dose not exceeding 80 milligrams, and in packs containing sufficient dosage units for a maximum treatment period of 5 days and limited to one pack per customer, when contained in products registered in terms of the Act, and not intended for export; (S2)
- d. except liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, containing not more than 10 milligrams of codeine (calculated as base) per 5 millilitre dosage unit, with a maximum daily dose not exceeding 80 milligrams, and with a pack size not exceeding 100 millilitres and limited to one pack per customer, when contained in products registered in terms of the Act, and not intended for export; (S2)
- e. except single component codeine preparations. (S6)

Colchicine, except when intended for the emergency treatment of acute gout, subject to a maximum total treatment course of 6 milligrams. (S2)

Colestipol.

Copper,

- a. in preparations thereof for injection; (S0)
- b. **except** in oral preparations or mixtures containing more than 4 mg of Copper per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S1)

Corticosteroids (natural or synthetic), except when listed separately in the Schedules, when contained in preparations intended for inhalation or nasal administration (S4)

Cyanocobalamin –see Vitamin B12.

Cyclandelate.

Cyclopentolate; ophthalmic preparations thereof. (S2)

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

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)

Dienogest.

Diflunisal.

Diflalone.

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

Dihydrocodeine,

- a. oral solid preparations, in combination with one or more therapeutically active substances, containing more than 10 milligrams of dihydrocodeine (calculated as base) per dosage unit, when contained in products registered in terms of the Act, and not intended for export;

- b. liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, containing more than 10 milligrams of dihydrocodeine (calculated as base) per 5 millilitre dosage unit, when contained in products registered in terms of the Act, and not intended for export;
- c. except oral solid preparations, in combination with one or more therapeutically active substances, containing not more than 10 milligrams of dihydrocodeine (calculated as base) per dosage unit, with a maximum daily dose not exceeding 80 milligrams, and in packs containing sufficient dosage units for a maximum treatment period of 5 days; (S2)
- d. except liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, containing not more than 10 milligrams of dihydrocodeine (calculated as base) per 5 millilitre dosage unit, with a maximum daily dose not exceeding 80 milligrams, and with a pack size not exceeding 100 millilitres; (S2)
- e. except single component dihydrocodeine preparations. (S6)

Dihydroergocristine.

Dilevalol.

Diltiazem.

Dimercaprol, when intended for injection.

Dipivefrin.

Dipyridamole.

Dipyrocetyl.

Disulfiram.

Dithranol.

Dornase alfa (rh DNase).

Dorzolamide.

Doxazosin.

Drospirenone,

- a. when intended for oral contraception;
- b. except when intended for hormone replacement therapy. (S4)

Eltenac.

Enalapril.

Endralazine.

Eprosartan.

Ergocalciferol – see Vitamin D.

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.

Estradiol,

- a. when intended for oral contraception;
- b. except when intended for human vaginal use; (S2)
- c. except when intended for hormone replacement therapy. (S4)

Ethacrynic acid.

Ethosuximide.

Etisazol.

Etodolac.

Etodolic acid.

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

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

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
- 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)

Flunisolide, when intended for inhalation or nasal administration, except when intended for nasal administration as an aqueous spray, other than by pressurised aerosol, in a strength not exceeding 0,025 percent (*m/v*), and indicated for the treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12 years of age, subject to

- a. a maximum dose of 50 micrograms per nostril and a maximum daily dose of 100 micrograms of per nostril in the case of adults and children over 16 years of age;
- b. a maximum dose of 25 micrograms per nostril and a maximum dose of 75 micrograms in children 12 to 16 years of age
- c. a maximum pack size of 2400 doses. (S2, S4)

Flunixin.

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

Flurbiprofen, except

- a. when 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. (S1)
- 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. (S1)
- c. when intended for the treatment of post-traumatic conditions, for a maximum period of 5 days; (S2)
- d. when intended for ophthalmic use; (S4)

Fluticasone furoate,

- a. when intended for inhalation or nasal administration;

- b. **except** when intended for nasal administration, as an aqueous spray in the short-term (less than 6 months) prophylaxis and treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12 years of age, subject to-
 - (i) a maximum daily dose of 55 micrograms per nostril; and
 - (ii) a maximum pack size limit of 120 doses. (S2)
- c. **except** when intended for administration other than by inhalation or nasal administration. (S4)

Fluticasone propionate,

- a. when intended for inhalation or nasal administration;
- b. **except** when intended for nasal administration as an aqueous spray in the short-term (less than 6 months) prophylaxis and treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12 years of age, subject to-
 - (i) a maximum daily dose of 100 micrograms per nostril; and
 - (ii) a maximum pack size of 120 doses. (S2)
- c. **except** when intended for administration other than by inhalation or nasal administration. (S4)

Frusemide.

Gabapentin.

Gadoxetic acid.

Gelatine succinylated.

Gemfibrozil.

Gestodene.

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, 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.

Glycopyrronium.

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.

Hydrochlorothiazide.

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

Hydroxypropyl methylcellulose when intended for ophthalmic use (S0)

Ibuprofen, except when used in oral medicinal preparations

- a. containing ibuprofen in combination with one or more other active therapeutic substances and intended for the treatment of mild to moderate pain or fever of inflammatory origin for a maximum treatment period of 10 days where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (S2)
- b. supplied in a solid dose form as divided doses contained in packs not exceeding 24 dosage units or divided doses and containing ibuprofen as the only active therapeutic substance, intended for the treatment of mild to moderate pain or fever of inflammatory origin or for the treatment of post-traumatic conditions in adults and children over 12 years of age where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children 12 years and older does not exceed 20 milligrams per kilogram of body weight; (S1, S2, S3)
- c. containing ibuprofen as the only active therapeutic substance in oral liquid preparations in packs not exceeding 100 millilitres in volume or in oral solid preparations in packs exceeding 24 dosage units or divided doses, when intended for adults and children over the age of 1 year; for the treatment of mild to

moderate pain of inflammatory origin for a maximum treatment period of 10 days; or for the treatment of fever of inflammatory origin or for the treatment of post-traumatic conditions, where the recommended daily dose of ibuprofen for adults does not exceed 1,2 grams and for children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (S1, S2)

- d. for the emergency treatment of acute gout attacks for a maximum treatment period of 5 days; (S2)
- e. when intended for the treatment of haemodynamically significant patent ductus arteriosus in infants less than 34 weeks of gestational age. (S4)

Imepitoin, when intended for veterinary use.

Imidapril.

Indacaterol.

Indapamide.

Indometacin, except

- a. for application to the skin (S1), and
- b. for the emergency treatment of acute gout attacks (S2).

Indoprofen.

Indoramin.

Injections, unless listed in another Schedule.

Insulin.

Insulin aspart.

Insulin degludec.

Ipratropium, when contained in respirator solutions. (S2)

Irbesartan.

Iron,

- a. in preparations thereof for injection; (S0)
- b. except in oral preparations or mixtures containing more than 24 mg of Iron per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S1)
- 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).

Isoniazid and its derivatives, unless listed in another Schedule.

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

Isosorbide.

Isoxicam.

Isradipine.

Ivabradine.

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).

Ketanserlin.

Ketoprofen,

- a. **except** when intended for application to the skin; (S1)
- b. **except** 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. **except** when intended for the emergency treatment of acute gout attacks or for the treatment of post-traumatic conditions, subject to a maximum dose of 75 milligrams of ketoprofen per day and a maximum treatment period of 5 days; (S2)
- d. **except** in the form of lozenges indicated and intended for the relief of pain associated with sore throats in patients 18 years and older subject to-
 - (i) a maximum of 12,5 milligrams per lozenge;
 - (ii) a maximum of 5 lozenges in any 24 hour period;
 - (iii) a maximum treatment period of 3 days; and
 - (iv) a maximum pack size of 15 lozenges. (S2)

Ketorolac, when intended for ophthalmic use. (S4)

Labetalol.

Lacosamide.

Lacidipine.

Lumiracoxib.

Lamotrigine.

Lercanidipine.

Levonorgestrel,

- a. when intended for oral contraception

b. except when intended for emergency post coital contraception; (S2)

c. except when administered via an Intra-Uterine System. (S4)

Levothyroxine.

Levetiracetam.

Levobunolol.

Levosemidan.

Lidoflazine.

Linagliptin.

Liothyronine sodium.

Lisinopril.

Lonazolac.

Lornoxicam.

Losartan.

Macrogol (polyethylene glycol), when used for faecal impaction, or for the purposes of bowel cleansing prior to surgery or diagnostic procedures, except when intended for the treatment of constipation, (S0).

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 milligrams 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.

Mirabegron.

Moexipril.

Mometasone furoate, when intended for inhalation or nasal administration, except when intended for nasal administration as an aqueous spray, other than by pressurized aerosol, and indicated for the treatment of the symptoms of seasonal or perennial allergic rhinitis (hay fever) in adults and children between the age of 2 and 11 years of age, subject to

- a. a maximum dose of 200 micrograms per nostril in adults and 50 micrograms per nostril in children; and
- b. a maximum pack size of 200 doses. (S2, S4)

Montelukast.

Moxonidine.

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 contained in preparations intended for application to the skin; (S1, S2)
- b. when contained in oral medicinal preparations containing naproxen as the only active therapeutic substance intended for patients over 16 years of age, for the treatment of mild to moderate pain or fever of inflammatory origin at a maximum dose of 600 milligrams naproxen base (660 milligrams naproxen sodium) in a 24 hour period for a maximum treatment period of 5 days and supplied in a solid dose form as divided doses contained in packs not exceeding the stated maximum treatment period. (S1, S2)
- c. when intended for the treatment of acute gout attacks, for a maximum treatment period of 5 days in patients over 16 years of age. (S1, S2)

Nateglinide.

Nebivolol.

Nepafenac.

Nicardipine.

Nicotine,

- a. when intended for human medicinal use as an aid to smoking cessation or as a substitute for a tobacco product (as defined in the Tobacco Products Control Act, 1993, as amended);
- b. except when registered for human medicinal use as an aid to smoking cessation and presented as nicotine gum or lozenges containing not more than 4 mg nicotine per piece; (S0)
- c. except when intended for human medicinal use as an aid to smoking cessation, when registered and presented as nicotine transdermal patches for continuous application to the skin in strengths up to an including 21mg/ 24 hours or 25 mg/ 16 hours; (S1)
- d. except when intended for human medicinal use as an aid to smoking cessation, when registered and presented as nicotine transdermal patches for continuous application to the skin in strengths containing more than 21mg/ 24 hours or 25 mg/ 16 hours; (S2)
- e. except when registered for human medicinal use as an aid to smoking cessation and presented as nicotine gum or lozenges containing more than 4 mg nicotine per piece; (S2)
- f. except when registered as metered sprays containing not more than 1 mg per dose; (S2)
- g. except when registered as oral solid dosage forms containing not more than 2 mg; (S2)
- h. except when registered as inhalers containing not more than 10 mg per cartridge. (S2)

Nifedipine.

Niflumic acid.

Nimodipine.

Nisoldipine.

Nitrendipine.

Nitroglycerine, when intended for medicinal use.

Noradrenaline theophylline – see Theodrenaline.

Norelgestromin.

Norethisterone,

- a. when intended for oral contraception;
- b. except when intended for parenteral use as a contraceptive; (S4)
- c. except when intended for hormone replacement therapy. (S4)

Norgestrel,

- a. when intended for oral contraception;
- b. except when intended for hormone replacement therapy. (S4)

Normal Saline (Sodium chloride 0,9 percent *m/v*) when intended for injection, except when intended for injection in a dosage form not exceeding 20 millilitres in volume. (S0, S1)

Olsalazine.

Omesartan.

Orlistat, except when used in a dose not exceeding 60 milligrams per main meal and not exceeding a maximum dose of 180 milligrams per 24-hour period. (S2)

Oxaprozin.

Oxcarbazepine.

Oxitracetam.

Oxovinca.

Oxyphenolol.

Oxybutynin.

Pantothenic Acid –see Vitamin B5.

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.

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.

Probutol.

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.

Pyridoxine –see Vitamin B6.

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)

Reserpine (natural or synthetic).

Riboflavin –see Vitamin B2.

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)

Saxagliptin.

Silimarin – see Silymarin.

Silymarin.

Sitagliptin phosphate.

Sodium phosphate, in preparations intended for the management of faecal impaction or for bowel cleansing prior to surgical and diagnostic procedures. (S0)

Sodium picosulphate, in preparations intended for the management of faecal impaction or for bowel cleansing prior to surgical and diagnostic procedures. (S0)

Solcoseryl; ophthalmic preparations thereof. (S0, S4)

Solifenacin.

Sotalol.

Spirapril.

Spironolactone.

Strontium, except when contained in toothpaste. (S0)

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

Sulindac.

Suloctidil.

Sulphinpyrazone.

Sulthiame.

Suprofen.

Silymarin, except when present in a complementary medicine with an accepted low risk claim or health claim, providing not more than 600 mg of Silymarin per day (calculated as silibinin/silybin). (S0)

Tasosartan.

Tazarotene.

Telmisartan.

Tenidap.

Tenoxicam.

Tepoxalin.

Terazosin.

Terbutaline, when contained in respirator solutions. (S2)

Terizidone.

Terodiline.

Theodrenaline – see Noradrenaline theophylline.

Thiacetazone.

Thiamine –see Vitamin B1.

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)

Ticagrelor.

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.

Verapamil (iproveratril).

Veratrum alkaloids.

Vigabatrin.

Vildagliptin.

Vincamine.

Vinpocetine.

Vitamin B1 (Thiamine) and derivatives thereof,

- a. in preparations thereof for injection; (S0)
- b. except in oral preparations or mixtures containing more than 100 mg of Vitamin B1 per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S1)

Vitamin B2 (Riboflavin) and derivatives thereof,

- a. in preparations thereof for injection; (S0)
- b. except in oral preparations or mixtures containing more than 100 mg of Vitamin B2 per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S1)

Vitamin B3 – See Niacin.

Vitamin B5 (Pantothenic Acid) and derivatives thereof,

- a. in preparations thereof for injection; (S0)
- b. in oral preparations or mixtures containing more than 200 mg of Vitamin B5 per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S1)

Vitamin B6 (Pyridoxine) and derivatives thereof,

- a. in preparations thereof for injection; (S0)
- b. except in oral preparations or mixtures containing more than 100 mg of Vitamin B6 per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S1)

Vitamin B12 (Cyanocobalamin) and derivatives thereof,

- a. in preparations thereof for injection; (S0)
- b. except in oral preparations or mixtures containing more than 100 µg of Vitamin B12 per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S1)

Vitamin C (Ascorbic Acid),

- a. in preparations thereof for injection; (S0)

- b. except in oral preparations or mixtures containing more than 1000 mg of Vitamin C per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S1)

Vitamin D (cholecalciferol), preparations thereof for injection and oral preparations and mixtures thereof containing more than 1 000 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). (S0)

Vitamin K and derivatives thereof,

- a. in injection preparations; (S0)
- b. except in oral preparations or mixtures containing more than 120 µg of Vitamin K per recommended daily dose alone or in combination with other active pharmaceutical ingredients, (S1)
- c. except when used in infant milk feeds or formulae in terms of the provisions of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972).

Water for injection except in a dosage form not exceeding 20 milliliters 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.

ANNEXURE 1A: EMERGENCY CARE PROVIDER (PARAMEDIC)

PARAMEDIC (National Diploma in Emergency Medical Care graduates **only**) registered with Health Professions Council of South Africa

PARAMEDIC (National Diploma in Emergency Medical Care graduates only)	
PLATELET AGGREGATION INHIBITOR	
Substance	: Clopidogrel
Indication	: Platelet aggregation inhibitor
Route of Administration	: Oral
PLASMA SUBSTITUTES AND COLLOID SOLUTIONS	
Substance	: Dextran
Indication	: Plasma expanders
Route of Administration	: Parenteral
PLASMA SUBSTITUTES AND COLLOID SOLUTIONS	
Substance	: Hydroxyethyl Starch
Indication	: Plasma expanders
Route of Administration	: Parenteral
PLASMA SUBSTITUTES AND COLLOID SOLUTIONS	
Substance	: Sodium chloride
Indication	: Plasma expanders
Route of Administration	: Parenteral
SELECTIVE β2 AGONISTS	
Substance	: Salbutamol
Indication:	: Bronchodilator
Route of Administration	: Inhalant
SELECTIVE β2 AGONISTS	
Substance	: Fenoterol
Indication	: Bronchodilator
Route of Administration	: Inhalant
MINERAL SUPPLEMENT/ ELECTROLYTE	
Substance	: Calcium chloride
Indication	: Positive inotrope- peri-cardiac and cardiac arrest / Electrolyte / Mineral Supplement
Route of Administration	: Parenteral
OTHER MINERAL SUPPLEMENT	
Substance	: Magnesium sulphate
Indication	: Mineral supplement; prevention and control of seizures and hypertension in toxemia of pregnancy
Route of Administration	: Parenteral

PARAMEDIC (National Diploma in Emergency Medical Care graduates <i>only</i>)		
CARBOHYDRATES		
Substance	:	Dextrose
Indication	:	Nutrition / Acute Symptomatic Hypoglycaemic Treatment
Route of Administration	:	Parenteral
HIGH CEILING LOOP DIURETIC		
Substance	:	Furosemide
Indication	:	Diuretic
Route of Administration	:	Parenteral
ORGANIC NITRATES		
Substance	:	Glyceryl trinitrate
Indication	:	Vasodilator
Route of Administration	:	Oral
ANTI-EMETIC		
Substance	:	Cyclizine
Indication	:	Antihistamine, anti-emetic
Route of Administration	:	Parenteral
CO-ENZYME		
Substance	:	Thiamine (Vitamin B1)
Indication	:	Nutritional supplement/ Vitamin B (Emergency treatment of Wernicke's encephalopathy and Beriberi)
Route of Administration	:	Parenteral

ANNEXURE 1B: EMERGENCY CARE PROVIDER (EMERGENCY CARE PRACTITIONER)**EMERGENCY CARE PRACTITIONER**

(Bachelor of Technology Degree in Emergency Medical Care) registered with Health Professions Council of South Africa

EMERGENCY CARE PRACTITIONER(B Tech: Emergency Medical Care)	
PLATELET AGGREGATION INHIBITOR	
Substance	: Clopidogrel
Indication	: Platelet aggregation inhibitor
Route of Administration	: Oral
PLASMA SUBSTITUTES AND COLLOID SOLUTIONS	
Substance	: Dextran
Indication	: Plasma expanders
Route of Administration	: Parenteral
PLASMA SUBSTITUTES AND COLLOID SOLUTIONS	
Substance	: Hydroxyethyl Starch
Indication	: Plasma expanders
Route of Administration	: Parenteral
PLASMA SUBSTITUTES AND COLLOID SOLUTIONS	
Substance	: Sodium chloride
Indication	: Plasma expanders
Route of Administration	: Parenteral
SELECTIVE β2 AGONISTS	
Substance	: Salbutamol
Indication:	: Bronchodilator
Route of Administration	: Inhalant
SELECTIVE β2 AGONISTS	
Substance	: Fenoterol
Indication	: Bronchodilator
Route of Administration	: Inhalant
MINERAL SUPPLEMENT/ ELECTROLYTE	
Substance	: Calcium chloride
Indication	: Positive inotrope- peri cardiac and cardiac arrest / Electrolyte / Mineral Supplement
Route of Administration	: Parenteral
OTHER MINERAL SUPPLEMENTS	
Substance	: Magnesium sulphate
Indication	: Mineral supplement; prevention and control of seizures and hypertension in toxemia of pregnancy
Route of Administration	: Parenteral

EMERGENCY CARE PRACTITIONER(B Tech: Emergency Medical Care)		
CARBOHYDRATES		
Substance	:	Dextrose
Indication	:	Nutrition / Acute Symptomatic Hypoglycaemic Treatment
Route of Administration	:	Parenteral
HIGH CEILING LOOP DIURETIC		
Substance	:	Furosemide
Indication	:	Diuretic
Route of Administration	:	Parenteral
ORGANIC NITRATES		
Substance	:	Glyceryl trinitrate
Indication	:	Vasodilator
Route of Administration	:	Oral
ANTI-EMETIC		
Substance	:	Cyclizine
Indication	:	Antihistamine, anti-emetic
Route of Administration	:	Parenteral
CO-ENZYME		
Substance	:	Thiamine (Vitamin B1)
Indication	:	Nutritional supplement / Vitamin B (Emergency treatment of Wernicke's encephalopathy and Beriberi)
Route of Administration	:	Parenteral

ANNEXURE 3: OPTOMETRIST

OPTOMETRIST (Bachelors degree in Optometry – B OPTOM) registered with the Health Professions Council of South Africa in terms of the Health Professions Act, 1974 (Act 56 of 1974) and in possession of a Section 22A(15) permit as provided for by the Medicines and Related Substances Act, 1965 (Act 101 of 1965)

OPTOMETRISTS	
CYCLOPLEGICS	
Substance	: Atropine
Indication	: Cyclopegic refraction; Treatment of Uveitis
Route of Administration	: Topical Application (Drops)
MYDRIATICS/ CYCLOPLEGICS	
Substance	: Tropicamide
Indication	: Cyclopegic; Mydriatic
Route of Administration	: Topical Application (Drops)
MYDRIATICS/ CYCLOPLEGICS	
Substance	: Cyclopentolate
Indication	: Cyclopegic; Mydriatic
Route of Administration	: Topical Application (Drops)
MYDRIATICS/ CYCLOPLEGICS	
Substance	: Homatropine
Indication	: Cyclopegic; Mydriatic
Route of Administration	: Topical Application (Drops)
ANTI GLAUCOMA	
Substance	: Pilocarpine
Indication	: Acute Glaucoma
Route of Administration	: Topical Application (Drops)
ANTI GLAUCOMA	
Substance	: Timolol
Indication	: Acute Glaucoma
Route of Administration	: Topical Application (Drops)

- 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.
- b. All preparations of substances or mixtures of such substances containing or purporting to contain any substance referred to in this Schedule and includes 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.
- (i) Annexure 1A: Emergency Care Provider (Paramedic);
 - (ii) Annexure 1B: Emergency Care Provider (Emergency Care Practitioner);
 - (iii) Annexure 2: Dental Therapist;
 - (iv) Annexure 3: Optometrist.

Abacavir.

Abatacept

Abciximab.

Abiraterone.

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)

Afatinib.

Agalsidase Alfa.

Agalsidase beta.

Alginate Acid, its salts and complexes thereof, when intended for use in gastric regurgitation, gastro-oesophageal reflux and reflux associated with hiatus hernia in infants and young children under the age of 6 years. (S0)

Aglepristone.

Atrofloxacin.

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.

Alfacalcidol.

Alfuzosin.

Alglucosidase alfa.

Alizapride.

Almitrine.

Alosetron.

Alphachymotrypsin (α -chymotrypsin), when intended for ophthalmic use.

Alprostadil.

Alteplase (recombinant human tissue-type plasminogen activator) (r-tPA).

Altrenogest for use in animals.

Amantadine.

Ambrisentan.

Amethocaine- see Tetracaine.

Amifostine.

Amikacin.

Aminoacridine.

Aminoglutethimide.

Aminolevulinic.

Aminophenazone.

Aminopyrine (amidopyrine).

Aminosalicylic acid.

Amiodarone.

Amiphenazole.

Amodiaquine.

Amoxicillin.

Ampicillin except when listed elsewhere in the Schedules and except intra-mammary preparations thereof, containing tracer dye(s) and intended for the treatment of mastitis in cattle and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947. (Act 36 of 1947)

Amprolium, except when listed elsewhere in the Schedules and 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. (Act 36 of 1947)

Amphotericin B

Amprenavir.

Amrinone.

Amsacrine.

Anagrelide.

Anastrozole.

Anecortave.

Anidulafungin.

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

Antihemophilic factor.

Antimalarials, unless listed elsewhere in the Schedules.

Antimicrobial substances, natural or synthetic including substances purporting to be suitable for the treatment of microbial infections unless listed elsewhere in the Schedules, and except –

a. the following substances when intended for topical application to the epidermis, nares and external ear:

- (i) bacitracin; (S1)
- (ii) gramicidin; (S1)
- (iii) griseofulvin; (S2)
- (iv) mupirocin; (S2)
- (v) natamycin; (S2)
- (vi) polymyxin B; (S1)
- (vii) tyrothricin; (S1)

b. when intended for use as -

- (i) disinfectants, being topical agents or preparations used to treat inanimate objects, materials or surfaces, and that destroys or inhibits the growth of pathogenic micro-organisms so treated in the non-sporing or vegetative state, rendering them harmful to neither health nor the quality of perishable goods; (S0)
- (ii) antiseptics, being topical agents or preparations used on skin and other living tissues, and that destroys or inhibits the growth of pathogenic micro-organisms so treated in the non-sporing or vegetative state, protecting health and preventing infection; (S0) and
- (iii) germicides, being topical agents or preparations used to treat inanimate objects, materials or surfaces and/or on skin and other living tissues, destroying or killing pathogenic micro-organisms so treated in the non-sporing or vegetative state, thereby protecting health, the quality of perishable goods, and preventing infection. (S0)

Antisera, unless listed elsewhere in the Schedules 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 (Act 36 of 1947).

Apixaban.

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

Apraclonidine.

Apramycin.

Aprotinin.

Aprepitant.

A- β arteether.

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 (Act 36 of 1947).

Arsenamides, when intended for injection.

Artemether and its derivatives.

Artemisinin.

Artemotil.

Artesunate.

L-Asparaginase.

Astemizole.

Atazanavir.

Atipamizole.

Atorvastatin.

Atosiban.

Atovaquone.

Atracurium besilate.

Atropine,

a. when intended for use in injections. (S2)

b. except when intended for use in ophthalmic preparations. (S3)

Auranofin.

Avilamycin, except when listed elsewhere in the Schedules and except when intended and registered to promote growth as a feed additive in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947(Act 36 of 1947).

Avoparcin, except when listed elsewhere in the Schedules and except when intended and registered to promote growth as a feed additive in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947(Act 36 of 1947).

Azacitidine.

Azathioprine.

Azithromycin.

Azlocillin.

Aztreonam.

Baclofen.

Bacitracin, except when intended for topical application to the epidermis, nares and external ear. (S1) and except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Bambermycin, except when listed elsewhere in the Schedules and except when intended and registered to promote growth as a feed additive in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Barium sulfate.

Basiliximab.

Bacampicillin.

Beclomethasone dipropionate, except when intended for inhalation or nasal administration. (S3)

Bedaquiline.

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

Belatacept.

Bemegride.

Bemiparin.

Bendamustine.

Benethamine penicillin.

Benzathine benzylpenicillin.

Benzathine phenoxymethylpenicillin.

Benzocaine,

- a. when intended for ophthalmic or parenteral use;
- b. except in lozenges containing 30 milligrams or less of benzocaine, per dosage unit; (S1)
- c. except when intended for topical use; (S1)
- d. except in preparations containing 2 percent or less of benzocaine. (S1)

Benzylpenicillin.

Betamethasone.

Bethanechol.

Betiatide.

Bevacizumab.

Bicalutamide.

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

Bimatoprost.

Biolimus.

Biological medicines, injectable preparations thereof, when intended for human use and unless listed elsewhere in the Schedules,

- a. except vaccines, when listed elsewhere in the Schedules and vaccines registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).
- b. but specifically including the following -
 - (i) Equine anti-human thymocyte globulin;
 - (ii) Equine gamma globulin;
 - (iii) Human anti-D immunoglobulin;
 - (iv) Human anti-thymocyte rabbit immunoglobulin;
 - (v) Hepatitis A vaccine;
 - (vi) Hepatitis B immunoglobulin;
 - (vii) Human normal immunoglobulin, possibly polyvalent or possibly including IgG, IgA, or IgM;
 - (viii) Human plasmaalbumin;
 - (ix) *Neisseria meningitides* vaccine;
 - (x) Pneumococcal vaccine, polysaccharide;
 - (xi) Rabies immunoglobulin;
 - (xii) Rabies vaccine;
 - (xiii) Recombinant cholera toxin B subunit;
 - (xiv) rhDNase-dornase alfa;
 - (xv) Snake antivenom;
 - (xvi) Tetanus immunoglobulin;

- (xvii) Varicella immunoglobulin;
- (xviii) Varicella-zoster virus vaccine;
- (xix) Yellow Fever virus, attenuated.

Biperiden.

Bleomycin.

Boceprevir.

Bortezomib.

Botulinum toxin.

Brentuximab.

Bretylium tosilate.

Bromocriptine.

Budesonide, except when intended for inhalation or nasal administration. (S3)

Bufenoide.

Bumadizone.

Bupivacaine.

Buserelin.

Busulfan.

Butoconazole, except -

- a. when intended for application to the skin; (S1) and
- b. when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis.
(S1)

Cabergoline.

Cabazitaxel.

Calcitonin.

Calcitriol.

Calcium,

- a. when indicated for the treatment of hyperphosphataemia; (S0)
- b. except in oral preparations or mixtures containing more than 1300 mg of calcium per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S1)
- c. except in preparations thereof for injection; (S3)

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

Cambendazole, 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).

Canakinumab.

Candicidin.

Capsaicin, when intended for transdermal application.

Capecitabine.

Capreomycin.

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

Carbadox, except when listed elsewhere in the Schedules and except when intended and registered to promote growth as a feed additive in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Carbenicillin.

Carbetocin.

Carbidopa.

Carboplatin.

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

Carmustine.

Carnidazole, except when listed elsewhere in the Schedules and except injections thereof intended for use in pigeons and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Casopitant.

Caspofungin.

Cefaclor.

Cefadroxil.

Cefalexin.

Cefaloridine.

Cefalosporin.

Cefalotin.

Cefamandole.

Cefazolin.

Cefepime.

Cefixime.

Cefmetazole.

Cefodizime.

Cefonicid.

Cefoperazone.

Cefotaxime.

Cefotetan.

Cefovecin.

Cefoxitin.

Cefpirome.

Cefpodoxime.

Cefprozil.

Cefquinome.

Cefradine.

Cefsulodin.

Ceftaroline.

Ceftazidime.

Ceftibuten.

Ceftiofur.

Ceftizoxime.

Ceftobiprole.

Ceftriaxone.

Cefuroxime.

Cefalotin.

Cerivastatin.

Certoparin.

Ceruletide.

Cetrorelix.

Cetuximab.

Chlorambucil.

Chlormadinone.

Clodantoin.

Chloroquine

Choriogonadotropin alfa.

Chloramphenicol.

Chlorquinaldol.

Chlortetracycline except when listed elsewhere in the Schedules and except injections thereof intended for the treatment of anaplasmosis, footrot, heartwater, navel ill and pneumonia in sheep and cattle and capsules thereof intended for the use in pigeons and derivatives when intended for topical use in the management of wounds in animals and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Chorionic gonadotrophin.

Chymopapain, when intended for injection.

Ciclacillin.

Ciclosporin.

Cilastatin.

Cinacalcet.

Cinoxacin.

Ciprofloxacin.

Ciprofloxacin.

Cisapride.

Cisatracurium.

Cisplatin.

Cladribine.

Clanobutin.

Clarithromycin.

Clavulanic acid.

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 (Act 36 of 1947).

Clemizole penicillin.

Clenbuterol.

Clioquinol.

Clindamycin.

Clobetasol.

Clobetasone.

Clofazimine.

Clomifene.

Cloprostenol, when intended for veterinary use.

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 (Act 36 of 1947).

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

Cloxacillin, except when listed elsewhere in the Schedules and except intra-mammary preparations thereof, containing tracer dye(s) and intended for the treatment of mastitis in cattle and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Colfosceril.

Colistin.

Contrast media, unless listed elsewhere in the Schedules.

Corifollitropin alfa.

Corticosteroids (natural or synthetic), unless listed elsewhere in the Schedules, 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 nasal administration. (S2, S3)

Co-tetroxazine.

Co-trifamole.

Co-trimoxazole.

Crizotinib.

Cyclofenil.

Cyclophosphamide and its derivatives, unless listed in another Schedule.

Cycloserine.

Cyprenorphine.

Cyproterone acetate.

Cytarabine.

Dabigatran

Dacarbazine.

Dacliximab.

Daclizumab.

Dactinomycin.

Dalteparin.

Danaparoid.

Danofloxacin.

Dantrolene.

Dapagliflozin.

Dapsone and its derivatives, unless listed elsewhere in the Schedules.

Daptomycin.

Darbepoetin Alfa

Darunavir.

Dasatinib.

Daunorubicin.

Decitabine.

Deconexent (DHA) 380, when indicated for the treatment of hypertriglyceride levels.

Decoquate, except when listed elsewhere in the Schedules and 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 (Act 36 of 1947).

Deferasirox.

Deferipone.

Deferoxamine.

Degarelix.

Demecarium.

Demeclocycline.

Denosumab.

Desirudin.

Desonide.

Desmopressin.

Desoximetasone.

Dexamethasone.

Diatrizoic acid.

Diazoxide.

Dichlorophen, except -

- a. preparations and mixtures when intended for application to the skin; (S0) and
- b. 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 (Act 36 of 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 (Act 36 of 1947).

Diclodronic acid.

Dicloxacillin.

Didanosine.

Diethylcarbamazine.

Diflorasone.

Difloxacin.

Difluocortolone.

Dihydralazine.

Dihydrostreptomycin except when listed elsewhere in the Schedules and except intra-mammary preparations thereof, containing tracer dye(s) and intended for the treatment of mastitis in cattle and registered in terms of

the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Dihydrotachysterol.

Diiodohydroxyquinoline, 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 (Act 36 of 1947).

Di-isopropyl fluorophosphate.

Dilazep.

Diloxanide furoate.

Dimethyl sulphoxide.

Dimetridazole, except when listed elsewhere in the Schedules and except when intended for use in pigeons, as an anti-spirochaete preparation for pigs and to promote growth in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

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.

Dinitolmide, except when listed elsewhere in the Schedules and 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 (Act 36 of 1947).

Dinitrophenol.

Dinoprostone.

Diphemethoxidine.

Difenidol.

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 (Act 36 of 1947).

Disopyramide.

Distigmine.

Ditazole.

Dobutamine.

Docetaxel.

Dolasetron.

Dolutegravir.

Domperidone.

Dopa.

Dopamine.

Doripenem.

Doxapram.

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

Doxorubicin.

Doxycycline, except

- a. when intended and labelled for the chemoprophylaxis of malaria in those aged 8 years and older, for periods not exceeding 4 months of continuous use; (S2)
- b. in preparations thereof for the treatment of animals and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947), excluding when intended for administration in animal feed.

Dronedarone.

Drospirenone,

- a. when intended for hormone replacement therapy;
- b. except when intended for oral contraception. (S3)

Drotrecognin.

Dutasteride.

Dydrogesterone.

Econazole, except -

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

Edoxudine.

Edrophonium.

Efalizumab.

Efavirenz.

Eicosapent (EPA) 460, when indicated for the treatment of hypertriglyceride levels.

Eletriptan.

Eltrombopag.

Emetine, except substances, preparations and mixtures containing less than 0,2 percent of alkaloids, calculated as emetine. (S2)

Empagliflozin.

Emtricitabine

Encainide.

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

Enoxacin.

Enoxaparin.

Enramycin, except when intended and registered to promote growth as a feed additive in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Enrofloxacin.

Entacapone.

Entecavir.

Enzalutamide.

Epicillin.

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

Epirizole.

Epirubicin (4-epidoxorubicin).

Eplerenone.

Epoetin beta, polyethylene glycol.

Eptacog alfa.

Eptifibatide.

Ergometrine maleate.

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

Eribulin.

Erlotinib.

Ertapenem.

Etravirine.

Erythromycin.

Esomeprazole.

Estradiol,

- a. when intended for hormone replacement therapy;
- b. except when intended for human vaginal use; (S2)
- c. except when intended for oral contraception. (S3)

Estramustine.

Etamiyan.

Etanercept.

Etidronic acid.

Etiproston.

Ethopabate, except when listed elsewhere in the Schedules and 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 (Act 36 of 1947).

Ethambutol.

Ethionamide.

Etofamide.

Etoglucid.

Etoposide.

Everolimus.

Exemestane.

Ezetimibe.

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)

Fampridine.

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 (Act 36 of 1947).

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

Fenoldopam.

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

Fenticonazole.

Fertirelin.

Ferucarbitran.

Filgrastim.

Finasteride.

Fingolimod.

Flecainide.

Florfenicol.

Flosequinan.

Flucloxacillin.

Fluconazole.

Flucytosine.

Fludarabine.

Fludrocortisone acetate.

Flugestone.

Flumethasone.

Flunisolide, except when intended for inhalation or nasal administration. (S2, S3).

Fluocinolone.

Fluocinonide.

Fluocortolone.

Fluorides,

- a. except in oral medicinal preparations or mixtures intended for ingestion containing 0,25 milligrams or less of fluorine per dosage unit; (S1)
- b. except in toothpaste containing less than 0,15 percent fluoride; (S0) and
- c. except in mouth rinses containing less than 0,15 percent fluoride. (S0)

Fluorometholone.

5-Fluorouracil.

Fluprednidene.

Flurbiprofen,

- a. when intended for ophthalmic use; (S3)
- b. except when 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. (S1)
- c. except 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. (S1)
- d. except when intended for the treatment of post-traumatic conditions, for a maximum period of 5 days; (S2).

Flutamide.

Fluticasone furoate, **except -**

- a. when intended for nasal administration, as an aqueous spray, in the short-term (less than 6 months) prophylaxis and treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12 years of age, subject to-
 - (i) a maximum daily dose of 55 micrograms per nostril; and
 - (ii) a maximum pack size limit of 120 doses. (S2)
- b. when intended for inhalation or nasal administration. (S3)

Fluticasone propionate, **except -**

- a. when intended for nasal administration as an aqueous spray, in the short-term (less than 6 months) prophylaxis and treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12 years of age, subject to-
 - (i) a maximum daily dose of 100 micrograms per nostril; and
 - (ii) a maximum pack size of 120 doses. (S2)
- b. when intended for inhalation or nasal administration. (S3)

Fluvastatin.

Follitropin alfa.

Fondaparinux.

Formoterol.

Fosamprenavir.

Fosaprepitant.

Fosfomycin.

Fosphenytoin sodium.

Fotemustine.

Framycetin.

Ftorafur.

Fulvestrant.

Furaltadone, except when listed elsewhere in the Schedules and except when intended as a single oral dosage for gastro-intestinal infections and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Furazolidone.

Fusidic acid.

Gadobutrol.

Gadodiamide.

Gadofosveset.

Gadoversetamide.

Galactose, when used as a contrast agent.

Galantamine.

Gallamine.

Gamithromycin.

Gamma benzene hexachloride, except when intended to be used for the second line treatment of lice in a pack size not exceeding 60 millilitres. (S2)

Ganciclovir.

Ganirelix.

Gatifloxacin.

Gefitinib.

Gemcitabine.

Gemtuzumab.

Gemifloxacin.

Gentamicin.

Gestrinone.

Glatiramer.

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

Golimumab.

Gonadorelin.

Goserelin.

Gramicidin except when intended for topical application to the epidermis, nares and external ear. (S1)

Granisetron.

Granulocyte Colony Stimulating Factor (G-CSF).

Griseofulvin except when intended for topical application to the epidermis, nares and external ear. (S2)

Grepafloxacin.

Halcinonide.

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 (Act 36 of 1947).

Halogenated hydroxyquinolines, except when intended for application to the skin. (S2)

Halometasone.

Halquinol.

Hemin.

Heparin.

Heptaminol.

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

Histrelin

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

- a. when specifically intended for emergency postcoital contraception; (S2)
- b. when intended for oral contraception; (S3)
- c. insulin; (S3)
- d. epinephrine; (S2, S3, S4)
- e. corticotrophin (adrenocorticotrophic hormone; 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 (Act 36 of 1947).
- h. BST (Bovine somatotropin), when intended and registered as a production improver in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Human fibrinogen, when indicated for use as a haemostatic.

Human Plasma.

Human thrombin, when indicated for use as a haemostatic.

Hyaluronidase.

Hyaluronic acid and its salts,

- a. when intended for parenteral use;
- b. except when intended for use with contact lens solutions or as an ophthalmic lubricant in concentrations of not more than 0,1 percent; (S0)
- c. except when intended for topical application to the skin; (S1)
- d. except when intended for ophthalmic use in preparations (except injectables) containing more than 0,1 percent;(S2)
- e. except in preparations containing less than 2,5 percent when intended for topical use in terms of the provisions of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972).

Hycanthon.

Hydroxycarbamide. (Hydroxyurea)

Hydroxychloroquine.

Ibandronic acid.

Ibuprofen, when intended for the treatment of a haemodynamically significant patent ductus arteriosus in infants less than 34 weeks of gestational age. (S1, S2, S3)

Ibutilide.

Ibritumomab.

Idarubicin.

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

Idursulfase.

Ifosfamide.

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 (Act 36 of 1947).

Imiglucerase.

Imiquimod.

Imipenem.

Indacaterol.

Indinavir.

Indium chloride pentetreotide.

Infliximab.

Inosine pranobex.

Interferon alpha.

Interferon beta.

Interferon gamma.

Intra-uterine devices.

Intra-uterine systems, drug eluting, unless listed elsewhere in the Schedules.

Intrifiban.

Iobitridol.

Iocarmic acid.

Iodamide sodium.

Iodised oil, when used as a contrast agent.

Iodixanol.

Iofendylate.

Ioglicic acid.

Iohexol.

Iomeprol.

Iopamidol.

Iopanoic acid.

Iopromide.

Iotalamate sodium.

Iotrolan.

Ioversol.

Ioxitalamic acid.

Ioxoglate sodium.

Ipilimumab.

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)

Isoniazid

Isopirin.

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

Isoxsuprine.

Itraconazole.

Ixabepilone.

Josamycin.

Kanamycin.

Ketoconazole, except –

- a. preparations and mixtures containing not more than 1,0 per cent of ketoconazole when intended for the prevention and treatment of dandruff; (S0) or

b. when intended for application to the skin. (S0, S1)

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

Lamivudine.

Lanreotide.

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

a. a maximum daily dose of 15 milligrams (S2); and

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

Lanthanum.

Lapatinib.

Laronidase.

Laropiprant.

Lasalocid, except when listed elsewhere in the Schedules and 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 (Act 36 of 1947).

Latamoxef.

Latanoprost.

Leflunomide.

Lenalidomide.

Lenograstim.

Lepirudin.

Letrozole.

Leuprolide acetate.

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 (Act 36 of 1947).

Levobupivacaine.

Levodopa.

Levofloxacin.

Levonorgestrel,

- a. when administered via an Intra Uterine System;
- b. except when intended for oral contraception; (S3)
- c. except when intended for emergency post coital contraception. (S2)

Levosimendan.

Liarozole.

Lidocaine,

- a. when intended for ophthalmic or parenteral use;
- b. when intended for the treatment of neuropathic pain associated with previous herpes zoster infection;
- c. except when intended for topical use; (S1)
- d. except in oral preparations containing 2 percent or less of lidocaine per dosage form. (S1)

Lignocaine, see Lidocaine.

Lincomycin.

Linezolid.

Liraglutide.

Lixisenatide.

Local anaesthetics, when intended for ophthalmic or parenteral use except -

- a. when intended for topical use; (S1)
- b. oxybuprocaine, proxymetacaine and tetracaine when contained in eye drops intended for emergency treatment of "arc eyes"; (S2).

Lomefloxacin.

Lomustine.

Lopinavir.

Loracarbef.

Loteprednol.

Lovastatin.

Lumefantrine.

Luprositol, when intended for veterinary use.

Lutropin alfa.

Lymecycline.

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

Maduramicin, except when listed elsewhere in the Schedules and 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 (Act 36 of 1947).

Mafenide.

Mangafodipir trisodium.

Mandelic acid.

Maraviroc.

Marbofloxacin.

Maropitant, when intended for veterinary use.

Mavacoxib.

Mecamylamine.

Mecillinam.

Medical gases, when used in combination with nitrous oxide, but excluding such medical gasses when used alone or in combinations that exclude nitrous oxide. (S0)

Medroxyprogesterone.

Mefloquine.

Meglumine diatrizoate.

Meglumine gadobenate.

Meglumine gadoterate.

Meglumine iodipamide.

Meglumine ioglycamate.

Meglumine iotalamate.

Meglumine iotroxate.

Meglumine pentetate.

Melagatran.

Melarsoprol.

Melatonin, except when used for the treatment of desynchronosis (jet-lag) in doses not exceeding 6 milligrams daily. (S2).

Melphalan and its derivatives, unless listed in another Schedule.

Memantine.

Menotrophin

Mepacrine.

Mephentermine.

Mepirizole.

Mepivacaine.

Meropenem.

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, except preparations of mercuric oxides containing less than 3 percent of mercury. (S2)

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 (dipyron).

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

Methotrexate.

Methoxsalen.

Methyl-5-aminolevulinate.

Methylnaltrexone.

Methylprednisolone.

Methysergide.

Metoclopramide.

Metomidate.

Metrizoic acid.

Metronidazole, except when

- a. intended and registered for use in pigeons in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947) and
- b. intended for human vaginal use, specifically for the treatment of recurrent bacterial vaginosis. (S2)

Mexiletine.

Mezlocillin.

Micafungin.

Miconazole,

- a. except when intended for application to the skin; (S1) and
- b. except when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis; (S1) and
- c. 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.

Minocycline.

Minoxidil, except 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. (S2)

Misoprostol.

Mitomycin C.

Mitoxantrone.

Mivacurium.

Mizolastine.

Mofebutazone.

Molgramostim.

Mometasone furoate, except when intended for inhalation or nasal administration. (S2, S3)

Monensin except when listed elsewhere in the Schedules and except when intended and registered as an anti-coccidial preparation and as a feed additive for growth promotion in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Moracizine.

Morazone.

Morinamide promolate.

Morphethylbutyne.

Moxifloxacin.

Mucoglucuronan.

Muromonab.

Mupirocin, except when intended for topical application to the epidermis, nares and external ear. (S2)

Mycophenolic acid.

Mycoplasma gallisepticum (Strain F) vaccine, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Nadroparin.

Nalidixic acid.

Nalorphine.

Naloxone.

Naltrexone.

Narasin except when listed elsewhere in the Schedules and 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 (Act 36 of 1947).

Naratriptan.

Natalizumab.

Natamycin, except when intended for topical application to the epidermis, nares and external ear. (S2)

Nefopam.

Nelfinavir.

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

Neostigmine.

Neotizide.

Netilmicin.

Netobimin.

Nevirapine.

Niacin (Nicotinic Acid) and derivatives thereof,

- a. when intended for hypercholesterolaemia and for the management of dyslipidaemias; (S0)
- b. except in oral preparations or mixtures containing more than 35 mg of Niacin per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S1)

Nicarbazin, except when intended and registered as an anti-coccidian preparation in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Nicorandil.

Nifuratel.

Nifuroxazide.

Nifurtoinol.

Nikethamide.

Nilotinib.

Nilutamide.

Nimesulide.

Nimorazole.

Nimotuzumab.

Nimustine.

Niridazole.

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

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

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

Nitrous oxide, alone or in combination with other medical gases.

Nitrovin, except when listed elsewhere in the Schedules and except when intended and registered to promote growth as a feed additive in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

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 (Act 36 of 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)

Nomegestrol.

Norethisterone,

- a. when intended for parenteral use as a contraceptive;
- b. when intended for hormone replacement therapy;

- c. except when intended for oral contraception. (S3)

Norfloxacin.

Norgestrel,

- a. when intended for hormone replacement therapy;
- b. except when intended for oral contraception. (S3)

Novobiocin.

Nystatin,

- a. when intended for systemic use or the initial treatment of vaginal candidiasis;
- b. except when presented as oral drops containing not more than 100 000 I.U. per millilitre, (S2)
- c. except when intended for application to the skin, (S1) and
- d. except when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis, (S1)
- e. except when intended and registered as a stock remedy for pigeons in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Obidoxime.

Octocog alfa.

Ocriplasmin.

Octreotide.

Ofloxacin.

Olaquinox, except when listed elsewhere in the Schedules and except when intended and registered to promote growth as a feed additive in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Oleandomycin.

Omalizumab.

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

- a. a maximum daily dose of 20 milligrams
- b. a maximum treatment period of 14 days. (S2)

Ondansetron.

Oprelvekin.

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

Ornipressin.

Osaterone, when intended for veterinary use.

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 (Act 36 of 1947).

Oxacillin.

Oxaliplatin.

Oxetacaine (Oxethazaine),

- a. when intended for ophthalmic or parenteral use;
- b. except in oral preparations containing an antacid. (S1)

Oxolinic acid.

Oxybuprocaine,

- a. when intended for ophthalmic or parenteral use;
- b. except when contained in eye drops intended for the emergency treatment of "arc eyes". (S2)

Oxyclozanide, 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).

Oxyphenbutazone, except when intended and registered for the synchronization of oestrus in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947)

Oxytetracycline, except when listed elsewhere in the Schedules and except preparations thereof for the treatment of animals and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947) excluding when intended for administration in animal feed.

Oxytocin.

Paclitaxel.

Palivizumab.

Palonosetron.

Pamidronate disodium.

Pamidronic acid.

Pancuronium.

Panituzumab.

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

- a. a maximum daily dose of 20 milligrams (S2); and
- b. a maximum treatment period of 14 days. (S2)

Paricalcitol.

Pazopanib.

Pegfilgrastim.

Peginterferon alpha.

Peginterferon beta 1a.

Pemetrexed.

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

Penethamate hydriodide, except when listed elsewhere in the Schedules and except intra-mammary preparations thereof, containing tracer dye(s) and intended for the treatment of mastitis in cattle and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Penicillamine.

Pentamidine.

Pentostatin.

Perfluorooctane, when intended for intraocular use. (S2)

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 (Act 36 of 1947).

Pheneticillin.

Phenindione.

Phenopyrazone.

Phenoxybenzamine.

Phenoxyethylpenicillin, except when intended for the prophylaxis of rheumatic fever. (S3)

Phospholipids when intended for parenteral administration. (S0)

Phthalylsulfathiazole.

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

Picrotoxin.

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

Pimecrolimus.

Pimobendan.

Pipemidic acid.

Piperacillin, anhydrous.

Pirenzepine.

Piribedil.

Pirlimycin.

Piromidic acid.

Pivampicillin.

Pivmecillinam.

Plerixafor.

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

Polydimethylsiloxane see Silicone oil.

Polyglycerylene-dextran.

Polymixin B, except when intended for topical application to the epidermis, nares and external ear. (S1)

Polynoxylin.

Polystyrene sulfonic acid when intended for therapeutic purposes.

Poractant alpha.

Posaconazole.

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

Pradofloxacin, when intended for veterinary use.

Pralidoxime.

Pramipexole.

Prasugrel.

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 (Act 36 of 1947).

Prednisolone.

Prilocaine,

- a. when intended for ophthalmic or parenteral use; (S4)
- b. except in topical preparations containing 10 percent or less of prilocaine. (S1)

Primaquine.

Procainamide.

Procaine benzylpenicillin, except when listed elsewhere in the Schedules and except intra-mammary preparations thereof, containing tracer dye(s) and intended for the treatment of mastitis in cattle and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Procarbazine.

Progesterone.

Proguanil.

Propafenone.

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

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

Protein C (isolated from human plasma).

Proyliodone.

Proteolytic (fibrinolytic) enzymes, when intended for injection, and unless listed elsewhere in the Schedules. (S1)

Protionamide.

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

Prucalopride.

Pyrazinamide.

Pyricarbate.

Pyridostigmine.

Pyrimethamine.

Quinagolide.

Quinine, except preparations and mixures containing not more than 1 percent. (S2)

Quinoronium, 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 (Act 36 of 1947).

Quinupristin.

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

- a. maximum daily dose of 10 milligrams;
- b. maximum treatment period of 14 days. (S2)

Ractopamine.

Radiopharmaceuticals, being radioactive compounds and radio-active labelled compounds when used for diagnostic or therapeutic purposes, unless listed elsewhere in the Schedules, and including the following radioisotopes:

- (i) Chromium-51;
- (ii) ^{14}C – Urea;
- (iii) ^{18}F – Fludeoxyglucose (2 - deoxy – 2 - [^{18}F] fluoro- D- glucose
- (iv) Gallium-67;
- (v) Indium-111;
- (vi) Iodine-123;
- (vii) Iodine-125;
- (viii) Iodine-131;
- (ix) Phosphorous-32;
- (x) Radium – 223;
- (xi) Strontium-89;
- (xii) Technetium-99;
- (xiii) Thallium-201;
- (xiv) Xenon-133;
- (xv) Yttrium-90;
- (xvi) Gold – 198.

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 (Act 36 of 1947).

Raltegravir.

Raltitrexid.

Ranibizumab.

Rapacuronium.

Rasagiline.

Rasburicase.

Regorafenib.

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 (Act 36 of 1947).

Retapamulin.

Ribavirin.

Rifabutin.

Rifampicin.

Rifaximin.

Rilpivirine.

Riluzole.

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

Riociguat.

Ritodrine.

Ritonavir.

Rituximab.

Rivaroxaban.

Rizatriptan.

Robenacoxib.

Rocuronium.

Roflumilast.

Rolitetracycline except when listed elsewhere in the Schedules and except injections thereof intended for the treatment of anaplasmosis, footrot, heartwater, navel ill and pneumonia in sheep and cattle and registered in

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

Romiplostim.

Ropinirole.

Ropivacaine.

Rosoxacin.

Rosuvastatin.

Rotigotine.

Roxithromycin.

Roxatidine.

Ruxolitinib.

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

Salinomycin, except when listed elsewhere in the Schedules and except when intended as an anti-coccidial preparation and to promote growth and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

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

Salmeterol.

Saquinavir.

Sarafloxacin.

Selegiline.

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

Serelaxin.

Sermorelin.

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

Sertindole.

Sevelamer.

Sildenafil.

Silicone oil (polydimethylsiloxane) when intended for intraocular use.

Silodosin.

Simvastatin.

Sirolimus.

Sisomicin.

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.

Sodium polystyrene sulphonic acid when indicated for therapeutic use.

Sofosbuvir.

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)

Sorafenib.

Sparfloxacin.

Spectinomycin.

Stavudine.

Stents, Drug Eluting, unless listed elsewhere in the Schedules.

Streptokinase.

Strychnine, except –

- a. preparations and mixtures containing 0,2 per cent or less of strychnine; (S2) and
- b. subject thereto that it shall only be supplied for the control of problem predatory mammals -
 - (i) on a written prescription issued by a State Veterinarian, for use in the particular State Veterinarian's area of jurisdiction, and in a quantity not exceeding 5 grams; and
 - (ii) subject to the State Veterinarian obtaining 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 such written approval being attached to the written prescription

Styramate.

Sugammadex.

Sulbactam.

Sulfabenzamide.

Sulfacetamide.

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

Sulfadiazine silver, except 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)

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

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

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

Sulfafurazole (sulfisoxazole).

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

Sulfamethizole.

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

Sulfametopyrazine.

Sulfamoxole.

Sulfanilamide.

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

Sulfisomidine.

Sulfamerazine.

Sulfapyridine.

Sulfasalazine.

Sulfonamides, unless listed elsewhere in the Schedules, and except -

- a. substances, preparations and mixtures intended for application to the eyes, nares and vagina; (S2) and
- b. when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Sultamicillin.

Sumatriptan.

Sunitinib.

Suramin

Surfactant associated proteins.

Suxamethonium.

Suxethonium.

Streptokinase.

Streptomycin.

Tacrine.

Tacrolimus.

Tadalafil.

Taf luprost.

Talampicillin.

Tamoxifen.

Tamsulosin.

Taurolidine.

Tasonermin.

Tazobactam.

Tegafur.

Tegaserod.

Teicoplanin.

Telaprevir.

Telbivudine.

Telithromycin.

Temozolomide.

Temsirolimus.

Tenecteplase.

Teniposide.

Tenofovir.

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

Terconazole.

Terfenadine.

Teriflunomide.

Terizidone.

Teriparatide.

Terlipressin.

Tetrabenazine.

Tetracaine,

- a. when intended for ophthalmic or parenteral use;
- b. except when intended for topical use; (S1)
- c. except in oral preparations containing 2 percent or less of Tetracaine; (S1)
- d. except when contained in eye drops intended for the emergency treatment of "arc eyes". (S2)

Tetracosactrin (Tetracosactide).

Tetracycline, except when listed elsewhere in the Schedules and except injections thereof intended for the treatment of anaplasmosis, footrot, heartwater, navel ill and pneumonia in sheep and cattle and derivatives when intended for topical use in the management of wounds in animals and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

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 (Act 36 of 1947).

Thalidomide.

Theophylline and its derivatives, unless listed elsewhere in the Schedules, and preparations intended for injection. (S2)

Thiamphenicol.

Thioacetazone.

Thiabendazole, except -

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

Tioguanine.

Thiostrepton.

Thymopentin.

Thyrotropin alfa.

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

Tibolone.

Ticarcillin.

Tigecycline.

Tildipirosin, when intended for veterinary use.

Tiludronic acid.

Tin fluoride (stannous fluoride), when intended for injection.

Tinidazole.

Tinzaparin.

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)

Tiopronin.

Tipranavir.

Tirilazad.

Tobramycin.

Tocainide.

Tocilizumab.

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 (Act 36 of 1947).

Topotecan.

Toremifene.

Trabectedin.

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 (Act 36 of 1947).

Thiotepa.

Trifluridine.

Trimetaphan.

Trimethoprim, except when specifically intended and registered in combination with sulphonamides 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 (Act 36 of 1947).

Trimetrexate.

Trioxysalen.

Triptorelin.

Tromantadine.

Trometamol.

Tropisetron.

Tuberculin.

Tubocurarine.

Tylosin, except when listed elsewhere in the Schedules and except when intended for addition to drinking water and feedstuff for administration to poultry and pigs and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Tyropanoic acid.

Tyrothricin, except when intended for topical application to the epidermis, nares and external ear. (S1)

Unoprostone.

Urapidil.

Urethane.

Urofollitropin.

Urokinase.

{Vaccines, see – Biologicals}

Ustekinumab.

Valaciclovir.

Valganciclovir

Valnemulin.

Vancomycin.

Vardenafil.

Vasoactive intestinal polypeptide.

Vecuronium.

Vemurafenib.

Vernakalant.

Verteporfin.

Vidarabine.

Vilanterol.

Vinblastine.

Vincristine.

Vindesine.

Vinorelbine.

Virginiamycin, except when listed elsewhere in the Schedules and except when intended and registered to promote growth as a feed additive in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Vismodegib.

Voriconazole.

Vorinostat.

Vorozole.

Warfarin.

Zalcitabine.

Zanamivir.

Zidovudine.

Zinc bacitracin, except when listed elsewhere in the Schedules and except when intended and registered to promote growth as a feed additive in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Ziv-aflibercept.

Zolmitriptan.

Zoledronic acid.

Zotarolimus.

ANNEXURE 1A: EMERGENCY CARE PROVIDER (PARAMEDIC)

PARAMEDIC (National Diploma in Emergency Medical Care graduates **only**) registered with the Health Professions Council of South Africa

PARAMEDIC (National Diploma in Emergency Medical Care graduates)		
ANTI-ARRHYTHMICS		
Substance	:	Adenosine
Indication	:	Endogenous Purine Nucleoside / Supraventricular Anti-arrhythmic
Route of Administration	:	Parenteral
ANTI-ARRHYTHMICS		
Substance	:	Amiodarone
Indication	:	Class III Anti-arrhythmic / Atrial & Ventricular
Route of Administration	:	Parenteral
ANTI-ARRHYTHMICS		
Substance	:	Lignocaine hydrochloride (Systemic)
Indication	:	Class I B- Ventricular Anti-arrhythmic
Route of Administration	:	Parenteral
ADRENERGIC		
Substance	:	Adrenaline / Epinephrine
Indication	:	Sympathomimetic catecholamine
Route of Administration	:	Parenteral
ANTI-CHOLINERGIC		
Substance	:	Atropine
Indication	:	Competitive Anti-Cholinergic, Bradycardia, Anti-arrhythmic
Route of Administration	:	Parenteral
SELECTIVE β2 AGONISTS		
Substance	:	Salbutamol
Indication:	:	Bronchodilator
Route of Administration	:	Parenteral
SELECTIVE β2 AGONISTS		
Substance	:	Fenoterol
Indication	:	Bronchodilator
Route of Administration	:	Parenteral
CORTICOSTEROIDS		
Substance	:	Hydrocortisone
Indication	:	Glucocorticoid / Steroidal Anti-Inflammatory
Route of Administration	:	Parenteral

PARAMEDIC (National Diploma in Emergency Medical Care graduates)		
HYPERGLYCAEMIC AGENT		
Substance	:	Glucagon
Indication	:	Hyperglycaemic agent
Route of Administration	:	Parenteral
CORTICOSTEROIDS		
Substance	:	Methylprednisolone
Indication	:	Glucocorticoid / Steroidal Anti-Inflammatory
Route of Administration	:	Oral
ANTI-EMETIC		
Substance	:	Metoclopramide monohydrochloride
Indication	:	Propulsive Anti-emetic / Dopamine Antagonist
Route of Administration	:	Parenteral
OPIOID ANTAGONIST		
Substance	:	Naloxone hydrochloride
Indication	:	Opioid Antagonist / Narcotic Antagonist
Route of Administration	:	Parenteral
OPIOID ANTAGONIST		
Substance	:	Nitrous oxide
Indication	:	Analgesic Gas
Route of Administration	:	Inhalant

ANNEXURE 1B: EMERGENCY CARE PROVIDER (EMERGENCY CARE PRACTITIONER)**EMERGENCY CARE PRACTITIONER**

(Bachelor of Technology Degree in Emergency Medical Care) registered with the Health Professions Council of South Africa

EMERGENCY CARE PRACTITIONER(B Tech: Emergency Medical Care)		
ANTI-ARRHYTHMICS		
Substance	:	Adenosine
Indication	:	Endogenous Purine Nucleoside / Supraventricular Anti-arrhythmic
Route of Administration	:	Parenteral
ANTI-ARRHYTHMICS		
Substance	:	Amiodarone
Indication	:	Class III Anti-arrhythmic / Atrial & Ventricular
Route of Administration	:	Parenteral
ANTI-ARRHYTHMICS		
Substance	:	Lignocaine hydrochloride (Systemic)
Indication	:	Class I B- Ventricular Anti-arrhythmic
Route of Administration	:	Parenteral
ADRENERGIC		
Substance	:	Adrenaline / Epinephrine
Indication	:	Sympathomimetic catecholamine
Route of Administration	:	Parenteral
ANTI-CHOLINERGIC		
Substance	:	Atropine
Indication	:	Competitive Anti-Cholinergic, Bradycardia, Anti-arrhythmic
Route of Administration	:	Parenteral
SELECTIVE β2 AGONISTS		
Substance	:	Salbutamol
Indication:	:	Bronchodilator
Route of Administration	:	Parenteral
SELECTIVE β2 AGONISTS		
Substance	:	Fenoterol
Indication	:	Bronchodilator
Route of Administration	:	Parenteral
CORTICOSTEROIDS		
Substance	:	Hydrocortisone
Indication	:	Glucocorticoid / Steroidal Anti-Inflammatory
Route of Administration	:	Parenteral

EMERGENCY CARE PRACTITIONER(B Tech: Emergency Medical Care)		
CORTICOSTEROIDS		
Substance	:	Methylprednisolone
Indication	:	Glucocorticoid / Steroidal Anti-Inflammatory
Route of Administration	:	Oral
HYPERGLYCAEMIC AGENT		
Substance	:	Glucagon
Indication	:	Hyperglycaemic agent
Route of Administration	:	Parenteral
ANTI-EMETIC		
Substance	:	Metoclopramide monohydrochloride
Indication	:	Propulsive Anti-emetic / Dopamine Antagonist
Route of Administration	:	Parenteral
OPIOID ANTAGONIST		
Substance	:	Naloxone hydrochloride
Indication	:	Opioid Antagonist / Narcotic Antagonist
Route of Administration	:	Parenteral
OPIOID ANTAGONIST		
Substance	:	Nitrous oxide
Indication	:	Analgesic Gas
Route of Administration	:	Inhalant (50:50 combination with Medical Oxygen)
THROMBOLYTIC AGENTS		
Substance	:	Streptokinase
Indication	:	Enzymes
Route of Administration	:	Parenteral
THROMBOLYTIC AGENTS		
Substance	:	Tenecteplase
Indication	:	Enzymes
Route of Administration	:	Parenteral
ANTITHROMBOTIC AGENTS		
Substance	:	Heparin sodium
Indication	:	Anticoagulant
Route of Administration	:	Parenteral
ANTITHROMBOTIC AGENT		
Substance	:	Enoxaparin
Indication	:	Anticoagulant
Route of Administration	:	Parenteral

EMERGENCY CARE PRACTITIONER(B Tech: Emergency Medical Care)		
MUSCLE RELAXANTS (NEURO BLOCKING AGENTS)		
Substance	:	Suxamethonium chloride
Indication	:	Depolarizing Muscle Relaxant
Route of Administration	:	Parenteral
MUSCLE RELAXANTS (NEURO BLOCKING AGENTS)		
Substance	:	Vecuronium
Indication	:	Competitive Muscle Relaxant
Route of Administration	:	Parenteral
MUSCLE RELAXANTS (NEURO BLOCKING AGENTS)		
Substance	:	Rocuronium
Indication	:	Non-Depolarizing Muscle Relaxants
Route of Administration	:	Parenteral

ANNEXURE 2: DENTAL THERAPIST

DENTAL THERAPIST (Bachelors degree in Dental Therapy) registered with Health Professions Council of South Africa

DENTAL THERAPIST (Bachelors degree in Dental Therapy)		
LOCAL ANAESTHETIC		
Substance	:	Lignocaine / Lidocaine hydrochloride 2 percent with Vasoconstrictor (Adrenaline)
Indication	:	Dental local anaesthesia
Route of Administration	:	Parenteral
LOCAL ANAESTHETIC		
Substance	:	Lignocaine / Lidocaine hydrochloride 3 percent without a Vasoconstrictor (Adrenaline)
Indication	:	Dental local anaesthesia
Route of Administration	:	Parenteral
LOCAL ANAESTHETIC		
Substance	:	Mepivacaine hydrochloride 2 percent with a Vasoconstrictor (Adrenaline)
Indication	:	Dental local anaesthesia
Route of Administration	:	Parenteral
LOCAL ANAESTHETIC		
Substance	:	Mepivacaine hydrochloride 3 percent without a Vasoconstrictor (Adrenaline)
Indication	:	Dental local anaesthesia
Route of Administration	:	Parenteral
ANTI-MICROBIALS (Beta-Lactams)		
Substance	:	Penicillins
Indication	:	Dental orofacial and odontogenic infections (Non prophylactic)
Route of Administration	:	Oral
ANTI-PROTOZOAL		
Substance	:	Metronidazole
Indication	:	Dental orofacial and odontogenic infections (Non prophylactic)
Route of Administration	:	Oral
AUTONOMIC SYMPATHOMIMETICS		
Substance	:	Adrenaline
Indication	:	Emergency medicine for drug related anaphylactic shock
Route of Administration	:	Parenteral

ANNEXURE 3: OPTOMETRIST

OPTOMETRIST (Bachelors degree in Optometry – B OPTOM) registered with the Health Professions Council of South Africa in terms of the Health Professions Act, 1974 (Act 56 of 1974) and in possession of a Section 22A(15) permit as provided for by the Medicines and Related Substances Act, 1965 (Act 101 of 1965)

OPTOMETRISTS	
ANTIBACTERIAL	
Substance	: Chloramphenicol
Indication	: Bacterial conjunctivitis; Anterior blepharitis; Posterior blepharitis
Route of Administration	: Topical Application
ANTIBACTERIAL	
Substance	: Tetracycline
Indication	: Chlamydial conjunctivitis; Blepharitis
Route of Administration	: Topical Application
ANTIBACTERIAL	
Substance	: Erythromycin
Indication	: Chlamydial conjunctivitis; Blepharitis; Impetigo (Not to be used as 1 st Line Treatment)
Route of Administration	: Topical Application
ANTIBACTERIAL	
Substance	: Aciclovir
Indication	: Conjunctivitis; Herpes simplex blepharitis; Epithelial keratitis
Route of Administration	: Topical Application
LOCAL ANAESTHETIC	
Substance	: Tetracaine
Indication	: Diagnostic Aide
Route of Administration	: Topical Application (Drops)
LOCAL ANAESTHETIC	
Substance	: Oxybuprocaine and other equivalent local anaesthetics
Indication	: Diagnostic Aide
Route of Administration	: Topical Application (Drops)

-END SCHEDULE 4 -

SCHEDULE 5 AND SPECIFIED SCHEDULE 5

- a. All preparations or mixtures of such substances containing or purporting to contain substances that is chemically related and incorporates a structural fragment into its structure that is similar to the structure of a listed substance and /or exhibits pharmacodynamic properties similar to the listed 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.
 - (iii) all homologues of listed substances (being any chemically related substances that incorporate a structural fragment into their structures that is similar to the structure of a listed substance and/or exhibit pharmacodynamic properties similar to the listed substance in the schedules), unless listed separately in the Schedules.
- 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 apply, 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 5 and Specified Schedule 5 substances and medicines provided for in the Annexures to this Schedule published in the *Gazette* in terms of the Act.
- (i) Annexure 1A: Emergency Care Provider (Paramedic);
 - (ii) Annexure 1B: Emergency Care Provider (Emergency Care Practitioner).
- 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.

Agomelatine.

Alprazolam**.

Amisulpride.

Amitriptyline and its derivatives.

Amoxapine.

Anaesthetic preparations containing pregnanedione derivatives.

Androstanolone.

Androstenediol.

Aponal.

Apronalide.

Aripiprazole.

Asenapine.

Atomoxetine.

Azacyclonol.

Barbituric acid** and its derivatives**, unless listed in another Schedule, excluding- amobarbital, cyclobarbital, pentobarbital and secobarbital (S6), and 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.

Benzocetamine.

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

Benzquinamide.

Beta-aminopropylbenzene and beta-aminoisopropylbenzene:

- a. 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
- b. any salt or substance falling under the above, and
- c. except preparations and mixtures of the above when used as vasoconstrictors and decongestants in antihistamine nose and eye preparations; (S1) and
- d. except when contained in appliances for inhalation in which the substance is absorbed onto solid material; (S1, S7) and
- e. excluding cathine ((+)-norpseudoephedrine), ephedrine, etafedrine, N-methylephedrine, N-diethylaminoethylephedrine, phenylpropanolamine, prenylamine and preparations and mixtures thereof; and
- f. except substances listed in Schedule 7. (S1, S2, S6)

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, Cosmetics and Disinfectants Act, 1972 and for analytical laboratory purposes. (S2)

Bromazepam**.

Bromisovalum.

Brotizolam**.

Bupropion.

Buspirone.

Butriptyline.

Butyrophenones.

Carbromal.

Chloral derivatives, unless listed in another Schedule.

Chlordiazepoxide**.

Chlormethiazole.

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

Chloroform, all substances, preparations and mixtures containing more than 20 percent of chloroform. (S1), except for industrial purposes including the manufacturing and compounding of products not intended for medicinal use. (S0, S1)

Chlorpromazine.

Chlorprothixene.

Citalopram.

Clobazam**.

Clomacran.

Clomipramine.

Clonazepam**.

Clopenthixol.

Clorazepic acid**.

Clostebol.

Clothiapine.

Clozapine.

Corticotrophin (adrenocorticotrophic hormone; ACTH).

Cyclobenzaprine.

Cyproheptadine, except when indicated for allergic rhinitis or antipruritic use. (S2)

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, Cosmetics and Disinfectants Act, 1972, and for analytical laboratory purposes. (S1)

Dapoxetine.

Dehydrochloromethyltestosterone.

Desflurane.

Desipramine.

Desvenlafaxine.

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)

Diazepam**.

Dibenzepin.

Diprenorphine.

Donepezil.

Dosulepin.

Dothiepin.

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

Droperidol.

Drostanolone.

Duloxetine.

Ecothiopate.

Emylcamate.

Enflurane.

Epitiostanol.

Escitalopram.

Estazolam**.

Ethchlorvynol**.

Ether (diethyl ether); all substances, preparations and mixtures containing more than 20 percent of ether, (S1), except for industrial purposes including the manufacturing and compounding of products not intended for medicinal use.

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

Ethylestrenol.

Etifoxine.

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

Etomidate.

Etretinate.

Fencamfamine**.

Fenfluramine.

Flumazenil**.

Fluocinolone.

Fluoxetine.

Fluoxymesterone.

Flupenthixol.

Fluphenazine.

Flurazepam**.

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, Cosmetics and Disinfectants Act, 1972, and for analytical laboratory purposes.

Human growth hormone (human somatotropin) - all forms, whether natural or synthetic, including recombinant forms, with either hormonal, prohormonal or anti-hormonal action).

Hydroxyzine.

Hygromycin B, except when listed elsewhere in the Schedules and except when intended as an anthelmintic for pigs and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947)

Imipramine and its derivatives, unless listed elsewhere in the Schedules.

Iproniazid.

Isoflurane.

Isotretinoin.

Ketamine.

Ketazolam**.

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

Lofepamine.

Loprazolam**.

Lorazepam**.

Lormetazepam**.

Loxapine.

Maprotiline.

Mazindol**.

Mebolazine.

Mechlorethamine and its derivatives, unless listed elsewhere in the Schedules.

Meclofenoxate.

Medazepam**.

Medetomidine.

Melitracene.

Mephenoqualone.

Meprobamate**.

Mesterolone.

Metandienone.

Metenolone.

Methandranone.

Methandriol.

Methoxyflurane.

Methyltestosterone.

Metrifonate.

Mianserin.

Mibolerone.

Midazolam**.

Milnacipran.

Mirtazapine.

Moclobemide.

Modafinil.

Molindone.

Nalbuphine.

Nandrolone.

Nefazodone.

Nitrazepam**.

Nomifensine.

Norclostebol.

Norethandronlone.

Nortriptyline.

Olanzapine.

Oxabolone.

Oxandrolone.

Oxazepam**.

Oxymesterone.

Oxymetholone.

Oxypertine.

Paliperidone.

Paraldehyde.

Pargyline.

Paroxetine.

Pemoline** and its complexes**.

Perampanel.

Phenethylhydrazine.

Phenothiazine and its derivatives,

- a. unless listed in another Schedule,
- b. except preparations and mixtures containing promethazine or dimethothiazine or their salts when used solely as an antihistaminic; (S2) and
- c. except preparations containing promethazine or its salts when intended specifically for the treatment of travel sickness or application to the skin; (S2) and
- d. 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 (Act 36 of 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).

Prochlorperazine maleate.

Prazepam**.

Prolintane.

Pregabalin.

Propofol.

Protriptyline.

Quazepam**.

Quetiapine.

Quinbolone.

Quinupramine.

Reboxetine.

Rimonabant.

Risperidone.

Rivastigmine.

Romifidine.

Sertindole

Sertraline.

Sevoflurane.

Sibutramine.

Stanozolol.

Stenbolone.

Sulphonmethane.

Sulpiride.

Temazepam**.

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 (Act 36 of 1947).

Thioguanosine.

Thiopentone.

Thiothixene.

Tiapride.

Tiletamine.

Tizanidine.

Tramadol.

Tranlycypromine.

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 (Act 36 of 1947).

Tretinoin, when intended for oral preparation. (S3)

Triazolam**.

Trifluoroperazine.

Trihexyphenidyl.

Trimipramine.

L-tryptophan, except when intended for medicinal use in dosages of less than 5 milligrams/kg/day or intended as supplementation for nutritional purposes. (S1)

Varenicline.

Venlafaxine.

Viloxazine.

Vortioxetine.

Xylazine.

Zaleplon.

Zimelidine.

Ziprasidone.

Zolazepam.

Zolpidem**.

Zopiclone.

Zotepine.

Zuclopenthixol.

ANNEXURE 1A: EMERGENCY CARE PROVIDER (PARAMEDIC)

PARAMEDIC (National Diploma in Emergency Medical Care graduates *only*) registered with the Health Professions Council of South Africa

PARAMEDIC (National Diploma in Emergency Medical Care graduates)		
BENZODIAZEPINE DERIVATIVE		
Substance	:	Diazepam
Indication	:	Anti-convulsant/Sedative/Hypnotic
Route of Administration	:	Parenteral
BENZODIAZEPINE DERIVATIVE		
Substance	:	Midazolam
Indication	:	Anti-convulsant/Sedative/Hypnotic
Route of Administration	:	Parenteral
BENZODIAZEPINE DERIVATIVE		
Substance	:	Lorazepam
Indication	:	Anti-convulsant/Sedative/Hypnotic
Route of Administration	:	Parenteral
BENZODIAZEPINE ANTAGONIST		
Substance	:	Flumazenil
Indication	:	Benzodiazepine Antagonist
Route of Administration	:	Parenteral
NON-SELECTIVE ANTIHISTAMINE		
Substance	:	Promethazine
Indication	:	Antihistamine
Route of Administration	:	Parenteral

ANNEXURE 1B: EMERGENCY CARE PROVIDER (EMERGENCY CARE PRACTITIONER)**EMERGENCY CARE PRACTITIONER**

(Bachelor of Technology Degree in Emergency Medical Care) registered with the Health Professions Council of South Africa

EMERGENCY CARE PRACTITIONER(B Tech: Emergency Medical Care)		
BENZODIAZEPINE DERIVATIVE		
Substance	:	Diazepam
Indication	:	Anti-convulsant/Sedative/Hypnotic
Route of Administration	:	Parenteral
BENZODIAZEPINE DERIVATIVE		
Substance	:	Midazolam
Indication	:	Antic-convulsant/Sedative/Hypnotic
Route of Administration	:	Parenteral
BENZODIAZEPINE DERIVATIVE		
Substance	:	Lorazepam
Indication	:	Anti-convulsant/Sedative/Hypnotic
Route of Administration	:	Parenteral
BENZODIAZEPINE ANTAGONIST		
Substance	:	Flumazenil
Indication	:	Benzodiazepine Antagonist
Route of Administration	:	Parenteral
NON-SELECTIVE ANTIHISTAMINE		
Substance	:	Promethazine
Indication	:	Antihistamine
Route of Administration	:	Parenteral
INDUCTION AGENTS		
Substance	:	Ketamine
Indication	:	Dissociative Anaesthesia/Analgesic/Mild Bronchodilator
Route of Administration	:	Parenteral
INDUCTION AGENTS		
Substance	:	Etomidate
Indication	:	Induction Agent
Route of Administration	:	Parenteral

- END SCHEDULE 5 -

SCHEDULE 6

- a. All preparations or mixtures of such substances containing or purporting to contain substances that is chemically related and incorporates a structural fragment into its structure that is similar to the structure of a listed substance and /or exhibits pharmacodynamic properties similar to the listed substance 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 isomers of such esters or ethers 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.
 - (vi) all homologues of listed substances (being any chemically related substances that incorporate a structural fragment into their structures that is similar to the structure of a listed substance and/or exhibit pharmacodynamic properties similar to the listed substance in the schedules), unless listed separately in the Schedules.
- 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, 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 6 substances and medicines provided for in the Annexures to this Schedule published in the *Gazette* in terms of the Act.
- (i) Annexure 1A: Emergency Care Provider (Paramedic);
 - (ii) Annexure 1B: Emergency Care Provider (Emergency Care Practitioner).

Acetorphine.

Acetyldihydrocodeine;

Acetylmethadol.

Alfentanil.

Allylprodine.

Alphacetylmethadol.

Alphameprodine.

Alphamethadol.

Alphaprodine.

Amineptine.

Amobarbital.

Anileridine.

Benzethidine.

Benzphetamine.

Benzylmorphine.

Beta-aminopropylbenzene and beta-aminoisopropylbenzene derivatives, being 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);

- a. except preparations and mixtures of the above when used as vasoconstrictors and decongestants in antihistamine nose and eye preparations; (S1) and
- b. except when contained in appliances for inhalation in which the substance is absorbed in solid material; (S1) and
- c. excluding cathine ((+)-norpseudoephedrine), ephedrine, etafedrine, N-methylephedrine, N-diethylaminoethylephedrine, phenylpropanolamine, prenylamine and preparations and mixtures thereof; (S1, S2, S5) and
- d. except substances listed in Schedule 7. (S1, S2, S5)

Betacetylmethadol.

Betameprodine.

Betamethadol.

Betaprodine.

Bezitramide.

Buprenorphine.

Butalbital.

Butorphanol.

Cathine ((+)-norpseudoephedrine / D-norpseudoephedrine).

Chlorodyne (Chloroform and Morphine Tincture BP 1980) or any preparation or mixture thereof described as chlorodyne.

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 (methyilmorphine),

- a. single component codeine preparations;
- b. oral solid preparations, in combination with one or more therapeutically active substances, in preparations not registered in terms of the Act, or when intended for export; (S2, S3)
- c. liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, in preparations not registered in terms of the Act, or when intended for export. (S2, S3)

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)

Dextrorphan.

Diampromide.

Diethylpropion (amfepramone).

Diethylthiambutene.

Dihydrocodeine,

- a. single component dihydrocodeine preparations;
- b. oral solid preparations, in combination with one or more therapeutically active substances, in preparations not registered in terms of the Act, or when intended for export; (S2, S3)
- c. liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, in preparations not registered in terms of the Act, or when intended for export. (S2, S3)

Dihydroetorphine.

Dihydromorphine.

Dimenoxadol.

Dimepheptanol.

Dimethylthiambutene.

Dioxaphethyl butyrate.

Difenoxin (or difenoxyllic 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 percent of such quantity of difenoxin, calculated as the base, as is present in the mixture. (S2)

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. (S2)

Dipipanone.

{D-norpseudoephedrine - see cathine}

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.

Ephedra alkaloids (natural or synthetic), unless listed separately in the Schedules,

- a. except products registered in terms of the Act, not intended for export, and being 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; (S2)
- b. except when intended for application to skin, eyes, ears and nares and containing 1 percent or less of ephedra alkaloids. (S1)

Ephedrine,

- a. except products registered in terms of the Act, not intended for export, and being 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; (S2)

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

Ethylmethythiambutene.

Ethylmorphine,

- a. except 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; (S2) and
- b. except 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 millilitre dosage unit. (S2).

Etonitazene.

Etorphine and analogues.

Etoxadine.

Fenproporex.

Fentanyl, when intended for therapeutic purposes. (S7)

Flunitrazepam.

Furethidine.

Glutethimide.

Hydrocodone (dihydrocodeinone).

Hydromorphanol (14-hydroxydihydromorphine).

Hydromorphone (dihydromorphinone).

Hydroxypethidine.

Ibogaine.

Isomethadone.

Ketobemidone.

Levomoramide.

Levophenacymorphan.

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).

Nefopam.

Nicocodine.

Nicodicodine.

Nicomorphine.

Noracymethadol.

Norcodeine.

Norlevorphanol.

Normethadone.

Normorphine (demethylmorphine or N-demethylated morphine).

{{(+)-Norpseudoephedrine see D-norpseudoephedrine / Cathine}.

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 percent 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 dihydrohydroxycodone).

Oxymorphone (14-hydroxydihydromorphinone or dihydrohydroxymorphinone).

Pentazocine.

Pentobarbital.

Pethidine, pethidine-intermediate A, pethidine-intermediate B and pethidine-intermediate C. (S7)

Phenadoxone.

Phenampromide.

Phenazocine.

Phendimetrazine.

Phenomorphan.

Phenoperidine.

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

Piminodine.

Piritramide.

Proheptazine.

Properidine.

Propiram.

Pseudoephedrine, except contained in products registered in terms of the Act, and not intended for export, being 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.(S2)

Racemoramide.

Racemorphan.

Remifentanyl.

Secobarbital.

Sufentanyl.

Tapentadol.

Thebacon.

Thebaine.

Thiafentanyl.

Tilidine.

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

Trimeperidine.

Zipeprol.

ANNEXURE 1A: EMERGENCY CARE PROVIDER (PARAMEDIC)

PARAMEDIC (National Diploma in Emergency Medical Care graduates *only*) registered with the Health Professions Council of South Africa

PARAMEDIC (National Diploma in Emergency Medical Care graduates)		
ANALGESICS		
Substance	:	Morphine sulphate
Indication	:	Opioid/Narcotic
Route of Administration	:	Parenteral

ANNEXURE 1B: EMERGENCY CARE PROVIDER (EMERGENCY CARE PRACTITIONER)**EMERGENCY CARE PRACTITIONER**

(Bachelor of Technology Degree in Emergency Medical Care) registered with the Health Professions Council of South Africa

EMERGENCY CARE PRACTITIONER (B Tech: Emergency Medical Care)		
ANALGESICS		
Substance	:	Morphine sulphate
Indication	:	Opioid/Narcotic
Route of Administration	:	Parenteral

- END SCHEDULE 6 -

SCHEDULE 7

All preparations or mixture of such substances containing or purporting to contain 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 isomers of such esters, or ethers 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.
- (vi) all homologues of listed substances (being any chemically related substances that incorporate a structural fragment into their structures that is similar to the structure of a listed substance and/or exhibit pharmacodynamic properties similar to the listed substance in the schedules), unless listed separately in the Schedules.

(Trivial or unofficial names are marked *)

AH-7921.

AM-2201.

Aminorex.

Amfetamine (Amphetamine) and its salts; preparatioans thereof. (S8)

1-Benzylpiperazine (BZP)

Beta-aminopropylbenzene and beta-aminoisopropylbenzene, except 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:

- a. preparations and mixtures when used as vasoconstrictors and decongestants in antihistamine nose and eye preparations; (S1) and
- b. appliances for inhalation in which the substance is absorbed onto solid material; (S1)
- c. excluding cathine ((+)-norpseudoephedrine), ephedrine, etafedrine, N-methylephedrine, N-diethylaminoethylephedrine, phenylpropanolamine, prenylamine; (S1, S2, S5)

d. except substances listed in S1, S2, S5, and S6.

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 percent 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 10 milligram per kilogram (0,001 percent) 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"].

Catha edulis ("khat"), the whole plant or any portion or product thereof.

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

Dexamfetamine (Dexamphetamine) and its salts; preparations thereof. (S8)

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

1,3 Dimethylamylamine *also known as* (1,3 DMAA/ 1,3 dimethylpentylamine/ 2-amino-4-methylhexane/ 2-hexanamine/ 4-methylhexane-2-amine/ 4-methyl-2-hexanamine/ 4-methyl-2-hexylamine/ 4-methyl-(9CI)/ dimethylamylamine/ geranamine/ methylhexaneamine/ methylhexaneamine)
(+)-2,5-dimethoxy- α -methylphenethylamine *(DMA).

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

2,5-dimethoxy-4-(n)-propylthiophenethylamine (2C-T-7)

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:

- (i) acetyl-alpha-methylfentanyl;
- (ii) alpha-methylfentanyl;
- (iii) alpha-methylfentanyl-acetanilide;
- (iv) alpha-methylthiofentanyl;
- (v) benzyl-fentanyl;
- (vi) beta-hydroxyfentanyl;
- (vii) beta-hydroxy-3-methylfentanyl;
- (viii) 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;
- (ix) 3-methylthiofentanyl;
- (x) para-fluorofentanyl; and
- (xi) 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-ol *(Parahexyl).

Lefetamine *(SPA).

Lisdexamfetamine (Lisdexamphetamine). (S8)

Lysergide (Lysergic acid diethylamide) *(LSD).

Mephedrone.

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)}.

3,4-methylenedoxypropylvalerone (MDPV).

Methylone (beta-keto-MDMA).

Methyprylon.

25B-NBOMe (2C-B-NBOMe).

25C-NBOMe (2C-C-NBOMe).

25I-NBOMe (2C-I-NBOMe).

Nabilone. (S8)

Pethidine-analogues, including:

- (i) 1-methyl-4-phenyl-4-propionoxy-piperidine *(MPPP);
- (ii) 1-methyl-4 phenyl-1,2,5,6-tetrahydropiperidine *(MPTP); and
- (iii) 1-phenylethyl-4-phenyl-4-acetyloxy-piperidine *(PEPAP).

except pethidine-intermediate A, pethidine-intermediate B and pethidine-intermediate C. (S6)

Phencyclidine *(PCP) and its congeners, including:

- (i) eticyclidine (N-ethyl-1-phenylcyclohexylamine) *(PCE);
- (ii) rolycyclidine (1-(1-phenylcyclohexyl) pyrrolidine) *(PHP or PCPY); and
- (iii) 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).

Synthetic cannabinoids(synthetic substances with cannabis-like effects), including but not limited to:

- cannabicyclohexanol;
- JWH-018;
- JWH-073;
- JWH-200;
- CP-47,497;

- CP 47,497-C6;
- CP 47,497-C7;
- CP 47,497-C8;
- CP 47,497-C9;
- HU-210

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

- (i) (+)-N-ethyl- α -methyl-3,4-(methylenedioxy) phenethylamine *(N-ethyl MDA);
- (ii) (+)-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 10 milligram per kilogram or less of tetrahydrocannabinols, when labelled "Not to be taken" or "Not for internal human use"; or
- d. in products for purposes other than internal human use containing 10 milligram per kilogram or less of tetrahydrocannabinols.

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

1-(3-trifluoromethylphenyl) piperazine *(TFMPP).

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

- END SCHEDULE 7 -

SCHEDULE 8

All preparations or mixture of such substances containing or purporting to contain 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 isomers of esters and ethers 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.

Amfetamine (Amphetamine) and its salts; preparations thereof. (S7)

Dexamfetamine (Dexamphetamine) and its salts; preparations thereof. (S7)

Lisdexamfetamine (Lisdexamphetamine). (S7)

Nabilone. (S7)

- END SCHEDULE 8 -