

DEPARTMENT OF HEALTH
MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965)
CONSOLIDATED SCHEDULES 01 AUGUST 2025

The Minister of Health has, in terms of section 22A(2) and 37A of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), on the recommendation of the South African Health Products Regulatory Authority (SAHPRA), made and updated the Schedules.

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 Authority, 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);
Annexure 1B:	Emergency Care Provider (Emergency Care Practitioner);
Annexure 1C:	Basic Ambulance Assistant;
Annexure 1D:	Ambulance Emergency Assistant;
Annexure 1E:	Emergency Care Technician;
Annexure 1F:	Emergency Care Assistant;
 - (ii) Annexure 2: Dental Therapist;
 - (iii) Annexure 3: Optometrist;
 - (iv) Annexure 4: Podiatrist;
 - (v) Annexure 5: Oral Hygienists.

Acetanilide and alkyl acetanilides.

Acetarsol, when intended for human vaginal use.

Acetylcysteine,

- a. when used as a mucolytic in acute respiratory conditions for a maximum treatment period of 14 days;
- b. **except** when intended for injection or for the management of paracetamol overdose. (S3)

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;

- a. in oral dosage forms in concentrations equivalent to 0,01 percent or less of arsenic trioxide; (S2)
- b. **except** when intended for injection. (S4)

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,

- a. preparations and mixtures 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)
- b. preparations containing more than 3 percent of benzydamine, but not exceeding 5 percent, when intended for application to the skin; (S3)
- c. **except** preparations and mixtures containing 3 percent or less of benzydamine, when intended for application to the skin; (S0) or
- d. **except** preparations and mixtures containing 3 milligrams or less of benzydamine per throat lozenge: Provided that the total dose swallowed does not exceed 36 milligrams of benzydamine per day and the pack size does not exceed 16 lozenges; (S0)
- e. **except** when indicated for human vaginal use. (S2)

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)

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)

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)

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)

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)

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)

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)

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)

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).

Cetirizine

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 200 µg of Chromium per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S0)

Ciclopirox.

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)

Dequalinium,

- a. when intended for oral topical use, as oral solutions or lozenges;
- b. **except** when intended for human vaginal use. (S2)

Diclofenac,

- a. when intended for application to the skin and containing more than 1 % m/m of diclofenac; (S3)
- b. **except** when intended for application to the skin and containing 1 % m/m or less of diclofenac subject to a maximum pack size of 50 grams; (S0)
- c. **except** when intended for the emergency treatment of acute gout attacks, subject to a maximum daily dose of 150 mg for a maximum treatment period of 3 days; (S2)
- d. **except** when intended for human use only in the treatment of fever or mild to moderate pain of inflammatory origin, or for the treatment of post-traumatic conditions, subject to a maximum daily dose of 75 mg for a maximum treatment period of 5 day; (S2)
- e. **except** when intended for veterinary use. (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),

- a. when intended for application to skin, eyes, ears and nares and containing 1 percent or less of ephedra alkaloids, and not intended for export; (S6)
- b. **except** oral preparations and mixtures, in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, containing not more than 30 milligrams of ephedrine per dose, with a maximum daily dose not exceeding 120 milligrams, subject to a maximum pack size of 360 milligrams and limited to one pack per customer. (S2)

Ephedrine,

- a. 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; (S6)
- b. **except** products registered in terms of the Act, not intended for export, and being oral preparations and mixtures, in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, containing not more than 30 milligrams of ephedrine per dose, with a maximum daily dose not exceeding 120 milligrams, subject to a maximum pack size of 360 milligrams and limited to one pack per customer. (S2)

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)

Fexofenadine.

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 not more than 0,25 milligrams of fluorine per dosage unit;
- b. **except** in toothpaste containing not more than 0,15 percent fluoride; (S0) and
- c. **except** in mouth rinses containing not more 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. **except** when intended for application to the skin and indicated for the symptomatic relief of localised pain and inflammation, 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 (S0)
- 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).

5-Hydroxy Tryptophan,

- a. in oral preparations with a maximum daily dose not exceeding 220 mg of 5-Hydroxy tryptophan, alone or in combination with other active pharmaceutical ingredients; (S5)
- b. **except** in oral preparation with a maximum daily dose not exceeding 220 mg of 5-Hydroxy alone or in combination with other active pharmaceutical ingredients, with general health claims as a health supplement. (S0)

Hyoscine butylbromide; substances, preparations and mixtures thereof-

- a. when intended for oral administration in pack sizes not exceeding 20 tablets of 10 mg strength or less, or 100 ml of oral liquid dosage of 0.1% mass/ volume or less; (S2)
- b. **except** transdermal preparations when intended for the prevention of the symptoms of motion sickness; (S2)
- c. **except** when intended for parenteral administration. (S3)

Icodextrin.

Ibuprofen,

- a. when contained in preparations intended for application to the skin, containing 5 % m/m or less of ibuprofen, and presented in a pack size exceeding 50 grams; (S0)
- b. when contained in transdermal patches containing 200mg of ibuprofen per patch or less, and indicated for use by patients aged 16 years and older;
- c. when contained in oral medicinal preparations, intended for human use only, 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).
- d. **except** when intended for the treatment of haemodynamically significant patent ductus arteriosus in infants less than 34 weeks of gestational age; (S4)
- e. **except** when intended for veterinary use. (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)

- c. **except** when intended for veterinary use. (S3)

Iodine,

- a. in oral preparations or mixtures containing more than 150 µg of Iodine per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S0)

Iron,

- a. in oral preparations or mixtures containing more than 24 mg of elemental 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)

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)

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)

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)

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)

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)

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)

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)

Lactococcus 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)

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)

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)

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)

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)

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)

Levocetirizine

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).

Loratadine.

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,

- a. in oral preparations containing more than the maximum daily dose of 210 mg of methionine alone or in combination with other active pharmaceutical ingredients. (S0)

. 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, intended for human use only 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)
- c. **except** when intended for veterinary use. (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. when registered as metered sprays containing not more than 1 mg per dose or less;
- 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

- a. when intended for oral dosage forms, nasal dosage forms, or ophthalmic dosage forms containing more than 0,2 percent; (S1)
- b. **except** ophthalmic preparations containing 0,2 percent or less; (S0)
- c. **except** when intended for injection. (S4)

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.

Racecadotril.

Pyridoxine – see Vitamin B6.

Riboflavin – see Vitamin B2.

Selenium,

- a. in oral preparations or mixtures containing more than 200 µg of Selenium per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)
- b. **except** in preparations thereof for injection when intended for veterinary use. (S4)

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

p-Synephrine,

- a. oral preparations and mixtures registered in terms of the Act and intended for the symptomatic relief of nasal and sinus congestion, where the recommended daily dose for adults is 50 milligrams or less and for children 6 to 12 years is 25 milligrams or less, with a maximum pack size of 5 days; (S6)
- b. **except** preparations and mixtures registered in terms of the Act and intended for application to the skin, ears and nares containing 1 percent or less of p-synephrine and containing 0,2 percent or less for application to the eyes; (S0)
- c. **except** oral preparations and mixtures registered in terms of the Act and intended for the symptomatic relief of nasal and sinus congestion, where the recommended daily dose for adults is more than 50 milligrams and for children 6 to 12 years is more than 25 milligrams. (S2)

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. in oral preparations with a maximum daily dose not exceeding 220 mg of L-tryptophan, alone or in combination with other active pharmaceutical ingredients; (S5)

- b. **except** in oral preparation with a maximum daily dose not exceeding 220 mg of L-tryptophan alone or in combination with other active pharmaceutical ingredients, with general health claims as a health supplement. (S0)

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

Vanadium,

- a. in oral preparations or mixtures containing more than 182 µg of Vanadium per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S0)

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 <i>only</i>)		
LOCAL ANAESTHETIC		
Substance	:	Lignocaine hydrochloride
Indication	:	Local Anaesthetic
Route of Administration	:	Topical application
WATER		
Substance	:	Water for injection
Indication	:	Diluent
Route of Administration	:	Parenteral
WATER		
Substance	:	Water for irrigation
Indication	:	Wound and dressing irrigation
Route of Administration	:	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)		
LOCAL ANAESTHETIC		
Substance	:	Lignocaine hydrochloride
Indication	:	Local Anaesthetic
Route of Administration	:	Topical application
WATER		
Substance	:	Water for injection
Indication	:	Diluent
Route of Administration	:	Parenteral
WATER		
Substance	:	Water for irrigation
Indication	:	Wound and dressing irrigation
Route of Administration	:	Solution

ANNEXURE 1C: BASIC AMBULANCE ASSISTANT

BASIC AMBULANCE ASSISTANT registered with Health Professions Council of South Africa	
WATER	
Substance	: Water for injection
Indication	: Diluent
Route of Administration	: Parenteral
WATER	
Substance	: Water for irrigation
Indication	: Wound and dressing irrigation
Route of Administration	: Solution

ANNEXURE 1D: AMBULANCE EMERGENCY ASSISTANT

AMBULANCE EMERGENCY ASSISTANT registered with Health Professions Council of South Africa	
WATER	
Substance	: Water for injection
Indication	: Diluent
Route of Administration	: Parenteral
WATER	
Substance	: Water for irrigation
Indication	: Wound and dressing irrigation
Route of Administration	: Solution

ANNEXURE 1E: EMERGENCY CARE TECHNICIAN

EMERGENCY CARE TECHNICIAN registered with Health Professions Council of South Africa	
WATER	
Substance	: Water for injection
Indication	: Diluent
Route of Administration	: Parenteral
WATER	
Substance	: Water for irrigation
Indication	: Wound and dressing irrigation
Route of Administration	: Solution

ANNEXURE 1F: EMERGENCY CARE ASSISTANT

EMERGENCY CARE ASSISTANT registered with Health Professions Council of South Africa	
WATER	
Substance	: Water for injection
Indication	: Diluent
Route of Administration	: Parenteral
WATER	
Substance	: Water for irrigation
Indication	: Wound and dressing irrigation
Route of Administration	: 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	:	Paracetamol
Indication	:	Dental pain
Route of Administration	:	Oral
SURFACE ANAESTHETIC		
Substance	:	Lidocaine / Lignocaine hydrochloride
Indication	:	Dental surface anaesthesia
Route of Administration	:	Topical/Jelly/Pump Spray
ANTI-VIRAL		
Substance	:	Acyclovir
Indication	:	Viral infection of lips
Route of Administration	:	Topical
ANTI-FUNGAL		
Substance	:	Ketoconazole
Indication	:	Treatment of fungal infections
Route of Administration	:	Cream/Gel
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.

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

OPTOMETRIST (Bachelors degree in Optometry – B OPTOM) with additional qualifications registered with the Health Professions Council of South Africa in terms of the Health Professions Act, 1974 (Act 56 of 1974) and recognised by the Health Professions Council of South Africa as an authorised prescriber.

ANALGESIC		
Substance	:	Paracetamol
Indication	:	Mild Pain
Route of Administration	:	Oral
ANALGESIC/ ANTI INFLAMMATORY		
Substance	:	Ibuprofen
Indication	:	Mild to Moderate Pain
Route of Administration	:	Oral
ANTI HISTAMINE/ VASOCONSTRICTOR/ MAST CELL STABILISER		
Substance	:	Loratadine
Indication	:	Atopic dermatitis involving the eyelids
Route of Administration	:	Oral
SYMPATHOMIMETIC		
Substance	:	Phenylephrine
Indication	:	Minor ocular irritation
Route of Administration	:	Topical (Drops)

ANNEXURE 4: PODIATRIST

PODIATRIST registered with the Health Professions Council of South Africa in terms of the Health Professions Act, 1974 (Act 56 of 1974)

PODIATRIST		
LOCAL ANAESTHETIC		
Substance	:	Amethocaine/ Tetracaine
Indication	:	Local Anaesthesia
Route of Administration	:	Topical (Cream)
LOCAL ANAESTHETIC		
Substance	:	Chloroethane (Ethyl Chloride)
Indication	:	Local Anaesthesia
Route of Administration	:	Topical (Spray)
LOCAL ANAESTHETIC		
Substance	:	Lignocaine/ Lidocaine
Indication	:	Local Anaesthesia
Route of Administration	:	Topical (Pump, Spray, Cream, Patch)

ANNEXURE 5: ORAL HYGIENIST

Oral hygienists registered with the Health Professions Council of South Africa (HPCSA) in terms of the Health Professions Act, 1974 (Act 56 of 1974)

ORAL HYGIENIST	
LOCAL ANAESTHETIC	
Substance	: Lignocaine/Lidocaine hydrochloride
Indication	: Dental surface anaesthesia (excluding injectables)
Route of Administration	: Topical
TOPICAL FLUORIDES	
Substance	: -
Indication	: Applicable to dentistry
Route of administration	: Topical
TOPICAL ANAESTHETIC	
Substance	: Ethyl chloride
Indication	: Dental surface anaesthesia
Route of Administration	: Topical

- END SCHEDULE 1 -

SCHEDULE 2

- (i) 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.
- (ii) 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.
- (iii) 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 Authority, 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);
Annexure 1B:	Emergency Care Provider (Emergency Care Practitioner);
Annexure 1C:	Basic Ambulance Assistant;
Annexure 1D:	Ambulance Emergency Assistant;
Annexure 1E:	Emergency Care Technician;
Annexure 1F:	Emergency Care Assistant;
 - (ii) Annexure 2: Dental Therapist;
 - (iii) Annexure 3: Optometrist;
 - (iv) Annexure 4: Podiatrist.

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)

Albendazole,

- a. when intended for the treatment of intestinal parasites, as a single oral dose; (S4)
- b. **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).

Alcaftadine.

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;

- a. **except** in oral dosage forms containing the equivalent of 0,01 percent or less of arsenic trioxide; (S1)
- b. **except** when intended for injection. (S4)

Aspirin (acetyl salicylic acid), when intended for:

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

Atovaquone,

- a. when co-formulated with proguanil and intended and labelled for the chemoprophylaxis of malaria in those weighing 11 kilograms or more. (S4)

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.

Benzydamine,

- a. when intended for human vaginal use; (S3)
- b. **except** preparations and mixtures containing 3 percent or less of benzydamine, when intended for application to the skin; (S0)
- c. **except** preparations containing more than 3 percent of benzydamine, but not exceeding 5 percent, when intended for application to the skin; (S1)
- d. **except** preparations and mixtures 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; (S1)
- e. **except** preparations and mixtures containing 3 milligrams or less of benzydamine per throat lozenge: Provided that the total dose swallowed does not exceed 36 milligrams of benzydamine per day and the pack size does not exceed 16 lozenges. (S0)

Bevonium methylsulphate.

Bilastine.

Bismuth, when intended for oral use.

Bromhexine.

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

Brompheniramine

Bucizine.

Budesonide,

a. when intended for the prophylaxis and treatment of seasonal and perennial allergic rhinitis in adults and children aged 12 years and older; (S3)

b. **except** when intended for inhalation and nasal administration, unless listed in another Schedule. (S4)

Butinoline.

Calabar bean alkaloids.

Camphorated Opium Tincture.

Camylofin.

Cantharidin.

Canthaxanthin

Carbinoxamine.

Carbocysteine.

Carbuterol, **except**

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

b. when intended for injection. (S4)

Carisoprodol.

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)

Chlorpheniramine.

Chlorprenaline.

Cholestyramine.

Chlorzoxazone.

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.

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

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)

Dequalinium

- a. when intended for human vaginal use;
- b. **except** when intended for oral topical use, as oral solutions or lozenges (S1)

Desloratadine.

Dexchlorpheniramine.

Dextromethorphan.

Diclofenac,

- a. when intended for the emergency treatment of acute gout attacks, subject to a maximum daily dose of 150 mg for a maximum treatment period of 3 days; (S3)
- b. when intended for human use only in the treatment of fever or mild to moderate pain of inflammatory origin, or for the treatment of post-traumatic conditions, subject to a maximum daily dose of 75 mg for a maximum treatment period of 5 days;
- c. **except** when intended for application to the skin and containing 1 % m/m or less of diclofenac subject to a maximum pack size of 50 grams; (S0)
- d. **except** when intended for application to the skin and containing more than 1 % m/m of diclofenac; (S1)
- e. **except** when intended for veterinary use. (S3)

Dicyclomine.

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

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

Dihydrocodeine,

- a. oral solid preparations, in combination with one or more therapeutically active substances, 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. (S4)

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, in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, containing not more than 30 milligrams of ephedra alkaloids per dose, with a maximum daily dose not exceeding 120 milligrams, subject to a maximum pack size of 360 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, in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, containing not more than 30 milligrams of ephedrine per dose, with a maximum daily dose not exceeding 120 milligrams, subject to a maximum pack size of 360 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.

Esomeprazole when indicated 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)

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)

Estriol,

- a. When intended for human vaginal use
- b. **except** when intended for oral contraception; (S3)
- c. **except** when intended for hormone replacement therapy; (S4)
- d. **except** when intended for veterinary use. (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)

Flavoxate.

Fluconazole, as a single dose of 150 mg when indicated for the following fungal infections in adults:

- a. Vaginal candidiasis, recurrent
- b. Candidial balanitis associated with vaginal candidiasis.

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 and indicated for the symptomatic relief of localised pain and inflammation, 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; (S0)
- 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.

Fusidic acid, when intended for topical application. (S4)

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 butylbromide; substances, preparations and mixtures thereof-

- a. when intended for oral administration in pack sizes exceeding 20 tablets or 100 ml, or strengths exceeding 10 mg per oral solid dosage form or 0.1% mass/ volume; (S1)
- b. transdermal preparations when intended for the prevention of the symptoms of motion sickness; (S3)
- c. **except** when intended for parenteral administration. (S3)

Ibuprofen,

- a. when contained in oral medicinal preparations, intended for human use only 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. when contained in oral medicinal preparations, intended for human use only 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 contained in preparations intended for application to the skin, containing 5 % m/m or less of ibuprofen; (S0, S1)
- e. **except** when contained in transdermal patches containing 200mg of ibuprofen per patch or less, and indicated for use by patients aged 16 years and older (S1);
- f. **except** 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; (S1)
- g. **except** when intended for the treatment of haemodynamically significant patent ductus arteriosus in infants less than 34 weeks of gestational age; (S4)
- h. **except** when intended for veterinary use. (S3)

Indometacin,

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

Influenza virus vaccine.

Ipratropium, **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.

Levodropropizine.

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.

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 human use only in 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)
- c. **except** when intended for veterinary use. (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, intended for human use only 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)
- d. **except** when intended for veterinary use. (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 oral solid dosage forms containing 2mg or less;
- c. when registered as inhalers containing 10mg or less per cartridge;
- d. 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;
- e. **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)
- f. **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 and including 21mg/ 24 hours or 25 mg/ 16 hours; (S1)
- g. **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).

Olopatidine.

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, when contained in preparations intended for use as a muscle relaxant. (S4)

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), 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 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 in combination with another pharmacologically active substance and intended for the symptomatic relief of nasal and sinus congestion, subject to a maximum pack size of 300 milligrams for adults and 150 milligrams for children, limited to one pack per customer. (S6)

Phenyltoloxamine.

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, for a maximum treatment period of 5 days;(S3)
- b. when intended for the treatment of mild to moderate pain or fever of inflammatory origin or for the treatment of post-traumatic conditions, for a maximum treatment period of 5 days; (S3)
- c. **except** when intended for veterinary use. (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 methysulphate.

Polio vaccine.

Potassium,

- a. in oral preparations or mixtures containing more than 20 millimoles (1500mg) of potassium per 24 hours;
- 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.

Proguanil,

- a. when co-formulated with atovaquone and intended and labelled for the chemoprophylaxis of malaria in those weighing 11 kilograms or more. (S4)

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. Immediate-release oral preparations and mixtures containing not more than 60 milligrams of pseudoephedrine per dose or controlled-release oral preparations and mixtures containing not more than 120 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)

Rizatriptan, when in oral solid dosage forms providing 5 mg or less and presented as packs of no more than 2 oral solid dosage forms, indicated for the acute relief of migraine attacks, with or without aura, in patients previously diagnosed by a medical practitioner and initiated on treatment with rizatriptan (S4)

Rotavirus, live attenuated.

Rubella vaccine.

Rupatadine.

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)

Sumatriptan, when in oral solid dosage forms providing 50 mg or less and presented as packs of no more than two oral solid dosage forms, indicated for the acute relief of migraine attacks, with or without aura, in patients previously diagnosed by a medical practitioner and initiated on treatment with sumatriptan. (S4)

p-Synephrine,

- a. oral preparations and mixtures registered in terms of the Act and intended for the symptomatic relief of nasal and sinus congestion, where the recommended daily dose for adults is more than 50 milligrams and for children 6 to 12 years is more than 25 milligrams; (S6)
- b. **except** preparations and mixtures registered in terms of the Act and intended for application to the skin, ears and nares containing 1 percent or less of p-synephrine and containing 0,2 percent or less for application to the eyes; (S0)
- c. **except** oral preparations and mixtures registered in terms of the Act and intended for the symptomatic relief of nasal and sinus congestion, where the recommended daily dose for adults is 50 milligrams or less and for children 6 to 12 years is 25 milligrams or less, with a maximum pack size of 5 days. (S1)

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

Tetanus toxoid,

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.

Tripolidine.

Trospium.

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

Typhoid vaccine.

Ulipristal.

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 *dl*-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
SELECTIVE β2 AGONISTS		
Substance	:	Salbutamol
Indication	:	Bronchodilator
Route of Administration	:	Aerosol
NON-STEROIDAL ANTI-INFLAMMATORY		
Substance	:	Ibuprofen
Indication	:	Analgesic/ Anti-inflammatory
Route of Administration	:	Oral
ANALGESIC		
Substance	:	Paracetamol
Indication	:	Analgesic/ Anti-pyrexia
Route of Administration	:	Oral

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
SELECTIVE β2 AGONISTS		
Substance	:	Salbutamol
Indication	:	Bronchodilator
Route of Administration	:	Aerosol

EMERGENCY CARE PRACTITIONER (B Tech: Emergency Medical Care)	
ANTI-SPASMODIC	
Substance	: Hyoscine butylbromide
Indication	: Anti-spasmodic
Route of Administration	: Oral
ANTI-PROPULSIVE	
Substance	: Loperamide
Indication	: Symptomatic management of diarrhoea in adults
Route of Administration	: Oral
NON-STEROIDAL ANTI-INFLAMMATORY	
Substance	: Ibuprofen
Indication	: Analgesic/ Anti-inflammatory
Route of Administration	: Oral
ANALGESIC	
Substance	: Paracetamol
Indication	: Analgesic/ Anti-pyrexia
Route of Administration	: Oral

ANNEXURE 1C: BASIC AMBULANCE ASSISTANT

BASIC AMBULANCE ASSISTANT registered with Health Professions Council of South Africa	
*ANTI-CHOLINERGIC	
Substance	: Ipratropium bromide
Indication	: Inhalant Bronchodilator (atropine derivative anti-cholinergic)
Route of Administration	: Respirator Solution
*SELECTIVE β_2 AGONISTS	
Substance	: Salbutamol
Indication	: Bronchodilator
Route of Administration	: Aerosol

ANNEXURE 1D: AMBULANCE EMERGENCY ASSISTANT

AMBULANCE EMERGENCY ASSISTANT registered with Health Professions Council of South Africa		
ANTI-CHOLINERGIC		
Substance	:	Ipratropium bromide
Indication	:	Inhalant Bronchodilator (atropine derivative anti-cholinergic)
Route of Administration	:	Respirator Solution
SELECTIVE β2 AGONISTS		
Substance	:	Salbutamol
Indication	:	Bronchodilator
Route of Administration	:	Aerosol

ANNEXURE 1E: EMERGENCY CARE TECHNICIAN

EMERGENCY CARE TECHNICIAN registered with Health Professions Council of South Africa		
ANTI-CHOLINERGIC		
Substance	:	Ipratropium bromide
Indication	:	Inhalant Bronchodilator (atropine derivative anti-cholinergic)
Route of Administration	:	Respirator Solution
SELECTIVE β2 AGONISTS		
Substance	:	Salbutamol
Indication	:	Bronchodilator
Route of Administration	:	Aerosol

ANNEXURE 1F: EMERGENCY CARE ASSISTANT

EMERGENCY CARE ASSISTANT registered with Health Professions Council of South Africa		
ANTI-CHOLINERGIC		
Substance	:	Ipratropium bromide
Indication	:	Inhalant Bronchodilator (atropine derivative anti-cholinergic)
Route of Administration	:	Respirator Solution
SELECTIVE β2 AGONISTS		
Substance	:	Salbutamol
Indication	:	Bronchodilator
Route of Administration	:	Aerosol

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
Substance	:	Diclofenac
Indication	:	Dental pain
Route of Administration	:	Oral
Substance	:	Indometacin
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
Substance	:	Miconazole
Indication:	:	Treatment of fungal infections
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 recognised by the Health Professions Council of South Africa as an authorised prescriber.

OPTOMETRIST		
ANTIBACTERIAL		
Substance	:	Mupirocin
Indication	:	Impetigo (Eyelids); External Hordeolum, Infected atopic dermatitis
Route of Administration	:	Topical application
ANTI HISTAMINE/ VASOCONSTRICTOR/ MAST CELL STABILISER		
Substance	:	Antazoline
Indication	:	Allergic and Atopic Conjunctivitis
Route of Administration	:	Topical application
ANTI HISTAMINE/ VASOCONSTRICTOR/ MAST CELL STABILISER		
Substance	:	Tetrazoline
Indication	:	Minor ocular irritation; Red eye
Route of Administration	:	Topical application
ANTI HISTAMINE/ VASOCONSTRICTOR/ MAST CELL STABILISER		
Substance	:	Oxymetazoline
Indication	:	Minor ocular irritation; Red eye
Route of Administration	:	Topical application
ANTI HISTAMINE/ VASOCONSTRICTOR/ MAST CELL STABILISER		
Substance	:	Cetirizine; Levocetirizine
Indication	:	Atopic dermatitis involving the eyelids
Route of Administration	:	Oral
ANTI HISTAMINE/ 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

ANNEXURE 4: PODIATRIST

PODIATRIST registered with the Health Professions Council of South Africa in terms of the Health Professions Act, 1974 (Act 56 of 1974)

PODIATRIST	
Anti-inflammatories	
Substance	: Diclofenac sodium and Ibuprofen
Indication	: Pain management
Route of Administration	: Oral

- 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 Authority 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;
 - (v) Annexure 4: Podiatrist.

Acamprosate.

Acebutolol.

Aceclofenac.

Acetazolamide.

Acetohexamide.

Acetylcholine, when intended for ophthalmic use.

Acetylcysteine,

- a. when intended for injection or for the management of paracetamol overdose;
- b. **except** when used as a mucolytic in acute respiratory conditions for a maximum treatment period of 14 days. (S1)

Acipimox.

Acidinium.

Adapalene.

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

Alclofenac.

Alendronic acid.

Aliskiren

Allopurinol.

Alogliptin.

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-

- a. containing 3 percent or less of benzydamine, when intended for application to the skin; (S0)
- b. containing more than 3 percent of benzydamine, but not exceeding 5 percent, when intended for application to the skin; (S1)
- c. 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; (S1)
- d. containing 3 milligrams or less of benzydamine per throat lozenge: Provided that the total dose swallowed does not exceed 36 milligrams of benzydamine per day and the pack size does not exceed 16 lozenges. (S0)
- e. intended for human vaginal use. (S2)

Bepidil.

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,

- a. when intended inhalation or nasal administration, unless listed in another Schedule. (S4)
- b. **except** when intended for the prophylaxis and treatment of seasonal and perennial allergic rhinitis in adults and children aged 12 years and older. (S2)

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)

Carbimazole

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, cyclopenthiazide, 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)

Clevidipine

Clofibrate.

Clonidine **except** when intended for the prevention of migraine. (S2)

Clopidogrel.

Codeine (methylmorphine),

- 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.

Dexketoprofen trometamol.

Dialysate preparations.

Dichlorphenamide.

Diclofenac,

- a. **except** when intended for application to the skin and containing 1 % m/m or less of diclofenac subject to a maximum pack size of 50 grams; (S0)
- b. **except** when intended for application to the skin and containing more than 1 % m/m of diclofenac; (S1)
- c. **except** when intended for the emergency treatment of acute gout attacks, subject to a maximum daily dose of 150 mg for a maximum treatment period of 3 days; (S2)
- d. **except** when intended for human use only in the treatment of fever or mild to moderate pain of inflammatory origin, or for the treatment of post-traumatic conditions subject to a maximum daily dose of 75 mg for a maximum treatment period of 5 days. (S2)

Dienogest.

Diffunisal.

Diflalone.

Digitalis, its glycosides and other active principles thereof, unless diluted below one unit (BP) in each 2,0 grams. (S0)

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.

(-)-6 epigallocatechin gallate

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)

Estriol,

a. when intended for oral contraception

b. **except** when intended for human vaginal use (S2);

c. **except** when intended for hormone replacement therapy. (S4)

d. **except** when intended for veterinary use (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 intended for the treatment of post-traumatic conditions, for a maximum period of 5 days;(S3)
- b. 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. **except** when intended for application to the skin and indicated for the symptomatic relief of localised pain and inflammation, 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. (S0)
- 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)

Folinic acid (leucovorin)

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).

Glutathione, when intended for intravenous infusion or for injection. (S0)

Glycopyrronium.

Guanabenz.

Guanethidine.

Guanfacine.

Guanoxan.

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

Homatropine; ophthalmic preparations thereof. (S2)

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

- a. when intended for oral contraception;
- b. **except** when intended for human vaginal use (S2), and
- c. **except** hormones when specifically intended for emergency postcoital contraception. (S2, S4, S5)

Hydralazine.

Hydrochlorothiazide.

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

Hydroxypropyl methylcellulose when intended for ophthalmic use (S0)

Hyoscine butylbromide; substances, preparations and mixtures thereof-

- a. **except** when intended for oral administration; (S1, S2) and
- b. **except** transdermal preparations when intended for the prevention of the symptoms of motion sickness. (S2)

Ibuprofen, **except**

- a. when contained in preparations intended for application to the skin, containing 5 % m/m or less of ibuprofen; (S0, S1)
- b. when contained in transdermal patches containing 200mg of ibuprofen per patch or less, and indicated for use by patients aged 16 years and older (S1)
- c. 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; (S1)
- d. when contained in oral medicinal preparations intended for human use only, 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)

- e. when contained in oral medicinal preparations, intended for human use only, 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; (S2)
- f. for the emergency treatment of acute gout attacks for a maximum treatment period of 5 days; (S2)
- g. 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.

Insulin glargine.

Insulin lispro

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 elemental 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).

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.

Levalbuterol

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 human use only in 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, intended for human use only 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; (S1)
- 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.

Olmesartan.

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.

Oxyprenolol.

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, **except:**

- a. when intended for the emergency treatment of acute gout attacks, for a maximum treatment period of 5 days; and
- b. when intended for the treatment of mild to moderate pain or fever of inflammatory origin or for the treatment of post-traumatic conditions, for a maximum treatment period of 5 days. (S2)

Pirprofen.

Potassium canrenoate.

Potassium,

- a. when intended for intravenous infusion or for injection;
- b. **except** when contained in oral rehydration preparations; (S0)
- c. **except** in oral preparations or mixtures containing more than 20 millimoles (1500mg) of potassium per 24 hours. (S2)

Practolol.

Prazosin.

Primidone.

Probenecid.

Probucol.

Procaterol, when contained in respirator solutions. (S2)

Proctofene.

Propacetamol.

Propiverine.

Propranolol.

Proquazone.

Proscillaridine.

Protamine.

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.

Sacubitril.

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

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

Saxagliptin.

Silimarin – see Silymarin.

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)

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.

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.

Trifarotene.

Trimethadione.

Tropicamide.

Tulobuterol, when contained in respirator solutions. (S2)

Umeclidinium.

Ursodeoxycholic acid.

V. cholera.

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 β_2 AGONISTS		
Substance	:	Salbutamol
Indication:	:	Bronchodilator
Route of Administration	:	Inhalant
SELECTIVE β_2 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
ANALGESIC		
Substance	:	Paracetamol
Indication	:	Analgesic/ Anti-pyrexia
Route of Administration	:	Parenteral
PLASMA SUBSTITUTES AND COLLOID SOLUTIONS		
Substance	:	Ringers Lactate
Indication	:	Plasma expanders
Route of Administration	:	Parenteral
PLASMA SUBSTITUTES AND COLLOID SOLUTIONS		
Substance	:	Polygeline
Indication	:	Plasma expanders
Route of Administration	:	Parenteral
PLASMA SUBSTITUTES AND COLLOID SOLUTIONS		
Substance	:	Sodium Bicarbonate 8,5 %
Indication	:	Metabolic acidosis
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 β_2 AGONISTS		
Substance	:	Salbutamol
Indication:	:	Bronchodilator
Route of Administration	:	Inhalant
SELECTIVE β_2 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
ANALGESIC		
Substance	:	Paracetamol
Indication	:	Analgesic/ Anti-pyrexia
Route of Administration	:	Parenteral
*ANTI-SPASMODIC		
Substance	:	Hyoscine butylbromide
Indication	:	Anti-spasmodic
Route of Administration	:	Parenteral
**ARTERIAL SMOOTH MUSCLE AGENT		
Substance	:	Hydralazine
Indication	:	Hypertension in pregnancy
Route of Administration	:	Oral
BETA BLOCKER		
Substance	:	Labetalol
Indication	:	Hypertension in pregnancy
Route of Administration	:	Parenteral

EMERGENCY CARE PRACTITIONER (B Tech: Emergency Medical Care)	
**CLASS III ANTI-ARRHYTHMIC	
Substance	: Sotalol
Indication	: Anti-arrhythmic
Route of Administration	: Oral/ Parenteral
PLASMA SUBSTITUTES AND COLLOID SOLUTIONS	
Substance	: Ringers Lactate
Indication	: Plasma expanders
Route of Administration	: Parenteral
PLASMA SUBSTITUTES AND COLLOID SOLUTIONS	
Substance	: Polygeline
Indication	: Plasma expanders
Route of Administration	: Parenteral
PLASMA SUBSTITUTES AND COLLOID SOLUTIONS	
Substance	: Sodium Bicarbonate 8,5 %
Indication	: Metabolic acidosis
Route of Administration	: Parenteral
**VASODILATOR	
Substance	: Isosorbide dinitrate
Indication	: Acute pulmonary syndrome/ Acute pulmonary oedema
Route of Administration	: Parenteral

ANNEXURE 1C: BASIC AMBULANCE ASSISTANT

BASIC AMBULANCE ASSISTANT registered with Health Professions Council of South Africa	
*SELECTIVE β_2 AGONISTS	
Substance	: Salbutamol
Indication:	: Bronchodilator
Route of Administration	: Inhalant

ANNEXURE 1D: AMBULANCE EMERGENCY ASSISTANT

AMBULANCE EMERGENCY ASSISTANT registered with Health Professions Council of South Africa		
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
PLASMA SUBSTITUTES AND COLLOID SOLUTIONS		
Substance	:	Ringers Lactate
Indication	:	Plasma expanders
Route of Administration	:	Parenteral
PLASMA SUBSTITUTES AND COLLOID SOLUTIONS		
Substance	:	Polygeline
Indication	:	Plasma expanders
Route of Administration	:	Parenteral
PLASMA SUBSTITUTES AND COLLOID SOLUTIONS		
Substance	:	Sodium Bicarbonate 8,5 %
Indication	:	Metabolic acidosis
Route of Administration	:	Parenteral
*CARBOHYDRATES		
Substance	:	Dextrose
Indication	:	Nutrition / Acute Symptomatic Hypoglycaemic Treatment in adults and paediatrics
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

*OTHER MINERAL SUPPLEMENTS		
Substance	:	Magnesium sulphate
Indication	:	Mineral supplement; prevention and control of seizures and hypertension in toxemia of pregnancy
Route of Administration	:	Parenteral
SELECTIVE β_2 AGONISTS		
Substance	:	Salbutamol
Indication:	:	Bronchodilator
Route of Administration	:	Inhalant

ANNEXURE 1E: EMERGENCY CARE TECHNICIAN

EMERGENCY CARE TECHNICIAN registered with Health Professions Council of South Africa		
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
PLASMA SUBSTITUTES AND COLLOID SOLUTIONS		
Substance	:	Ringers Lactate
Indication	:	Plasma expanders
Route of Administration	:	Parenteral

PLASMA SUBSTITUTES AND COLLOID SOLUTIONS		
Substance	:	Polygeline
Indication	:	Plasma expanders
Route of Administration	:	Parenteral
PLASMA SUBSTITUTES AND COLLOID SOLUTIONS		
Substance	:	Sodium Bicarbonate 8,5 %
Indication	:	Metabolic acidosis
Route of Administration	:	Parenteral
CARBOHYDRATES		
Substance	:	Dextrose
Indication	:	Nutrition / Acute Symptomatic Hypoglycaemic Treatment in adults and paediatrics
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
OTHER MINERAL SUPPLEMENTS		
Substance	:	Magnesium sulphate
Indication	:	Mineral supplement; prevention and control of seizures and hypertension in toxemia of pregnancy, Ventricular anti-arrhythmic
Route of Administration	:	Parenteral
ORGANIC NITRATES		
Substance	:	Glyceryl trinitrate
Indication	:	Vasodilator
Route of Administration	:	Oral
SELECTIVE β_2 AGONISTS		
Substance	:	Salbutamol
Indication:	:	Bronchodilator
Route of Administration	:	Inhalant

ANNEXURE 1F: EMERGENCY CARE ASSISTANT

EMERGENCY CARE ASSISTANT registered with Health Professions Council of South Africa	
PLASMA SUBSTITUTES AND COLLOID SOLUTIONS	
Substance	: Hydroxyethyl Starch
Indication	: Plasma expanders
Route of Administration	: Parenteral
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
PLASMA SUBSTITUTES AND COLLOID SOLUTIONS	
Substance	: Ringers Lactate
Indication	: Plasma expanders
Route of Administration	: Parenteral
PLASMA SUBSTITUTES AND COLLOID SOLUTIONS	
Substance	: Polygeline
Indication	: Plasma expanders
Route of Administration	: Parenteral
PLASMA SUBSTITUTES AND COLLOID SOLUTIONS	
Substance	: Sodium Bicarbonate 8,5 %
Indication	: Metabolic acidosis
Route of Administration	: Parenteral
CARBOHYDRATES	
Substance	: Dextrose
Indication	: Nutrition / Acute Symptomatic Hypoglycaemic Treatment in adults and paediatrics
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
OTHER MINERAL SUPPLEMENTS		
Substance	:	Magnesium sulphate
Indication	:	Mineral supplement; prevention and control of seizures and hypertension in toxemia of pregnancy
Route of Administration	:	Parenteral
SELECTIVE β_2 AGONISTS		
Substance	:	Salbutamol
Indication:	:	Bronchodilator
Route of Administration	:	Inhalant

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 recognised by the Health Professions Council of South Africa as an authorised prescriber.

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)
BETA-BLOCKER	
Substance	: Betaxolol
Indication	: Open-Angle Glaucoma in Adults
Route of Administration	: Topical Application (Drops)
SYMPATHOMIMETIC	
Substance	: Brimonidine
Indication	: Open-Angle Glaucoma in Adults
Route of Administration	: Topical Application (Drops)

OPTOMETRISTS	
BETA-BLOCKER	
Substance	: Levobunolol
Indication	: Open-Angle Glaucoma in Adults
Route of Administration	: Topical Application (Drops)

ANNEXURE 4: PODIATRIST

PODIATRIST registered with the Health Professions Council of South Africa in terms of the Health Professions Act, 1974 (Act 56 of 1974)

PODIATRIST		
SYMPATHOMIMETIC		
Substance	:	Adrenaline / Epinephrine
Indication	:	Sympathomimetic catecholamine for the management of shock
Route of Administration	:	Parenteral
LOCAL ANAESTHETIC		
Substance	:	Bupivacaine Hydrochloride 2 %
Indication	:	Local Anaesthesia
Route of Administration	:	Parenteral
LOCAL ANAESTHETIC		
Substance	:	Bupivacaine Hydrochloride 2 % with Adrenaline
Indication	:	Local Anaesthesia
Route of Administration	:	Parenteral
LOCAL ANAESTHETIC		
Substance	:	Levobupivacaine Hydrochloride with Adrenaline
Indication	:	Local Anaesthesia
Route of Administration	:	Parenteral
LOCAL ANAESTHETIC		
Substance	:	Lidocaine (Lignocaine) Hydrochloride
Indication	:	Local Anaesthesia
Route of Administration	:	Parenteral
LOCAL ANAESTHETIC		
Substance	:	Lidocaine (Lignocaine) Hydrochloride with Adrenaline
Indication	:	Local Anaesthesia
Route of Administration	:	Parenteral
LOCAL ANAESTHETIC		
Substance	:	Mepivacaine Hydrochloride
Indication	:	Local Anaesthesia
Route of Administration	:	Parenteral

– 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 Authority, 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);
Annexure 1B:	Emergency Care Provider (Emergency Care Practitioner);
Annexure 1C:	Basic Ambulance Assistant;
Annexure 1D:	Ambulance Emergency Assistant;
Annexure 1E:	Emergency Care Technician;
Annexure 1F:	Emergency Care Assistant;
 - (ii) Annexure 2: Dental Therapist;
 - (iii) Annexure 3: Optometrist;
 - (iv) Annexure 4: Podiatrist;
 - (v) Annexure 5: Oral Hygienist.

Abacavir.

Abatacept.

Abciximab.

Abemaciclib.

Abiraterone.

Acalabrutinib.

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.

Alginic 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.

Alatrofloxacin.

Albendazole,

- a. **except** when intended for the treatment of intestinal parasites, as a single oral dose; (S2)
- b. **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).

Albutrepenonacog alfa.

Alclometasone.

Alcuronium.

Aldesleukin.

Alectinib.

Alefacept.

Alemtuzumab.

Alfacalcidol.

Alfuzosin.

Alglucosidase alfa.

Alirocumab.

Alizapride.

Almitrine.

Alosetron.

Alpelisib.

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.

Amivantamab.

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-spore 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-spore 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-spore 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).

Apalutamide.

Apixaban.

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

Apraclonidine.

Apramycin.

Apremilast.

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).

Arsenamide, when intended for injection.

Arsenic;

a. when intended for injection;

b. **except** in oral dosage form. (S1, S2)

Artemether and its derivatives.

Artemisinin.

Artemotil.

Artesunate.

L-Asparaginase.

Asciminib.

Astemizole.

Atazanavir.

Atezolizumab.

Atipamizole.

Atorvastatin.

Atosiban.

Atovaquone, **except**

- a. when co-formulated with proguanil and intended and labelled for the chemoprophylaxis of malaria in those weighing 11 kilograms or more. (S2)

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).

Axitinib.

Azacitidine.

Azathioprine.

Azithromycin.

Azlocillin.

Aztreonam.

Bacampicillin.

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).

Baclofen.

Baloxavir.

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).

Baricitinib.

Barium sulfate.

Basiliximab.

Bazedoxifene.

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

Bedaquiline.

Bedinvetmab.

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

Belatacept.

Belimumab.

Bemegride.

Bemiparin.

Bendamustine.

Benethamine penicillin.

Benralizumab.

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.

Besifloxacin.

Betamethasone.

Bethanechol.

Betiatide.

Bevacizumab.

Bicalutamide.

Bictegravir.

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.

Blinatumomab.

Boceprevir.

Bortezomib.

Botulinum toxin.

Brentuximab.

Bretylium tosylate.

Brigatinib.

Brolucizumab.

Bromocriptine.

Budesonide,

a. **except** when intended for the prophylaxis and treatment of seasonal and perennial allergic rhinitis in adults and children aged 12 years and older; (S2)

b. **except** when intended for inhalation or nasal administration, unless listed in another Schedule. (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.

Cabotegravir.

Cabozantinib.

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.

Cannabidiol, **except**-

- a. in complementary medicines containing no more than 600 mg cannabidiol per sales pack, providing a maximum daily dose of 20 mg of cannabidiol, and making a general health enhancement, health maintenance or relief of minor symptoms (low -risk) claim; (S0) or
- b. processed products made from cannabis raw plant material intended for ingestion containing 0,0075 percent or less of cannabidiol where only the naturally occurring quantity of cannabinoids found in the source material are contained in the product. (S0)

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)

Carfilzomib.

Carglumic.

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).

Casirivimab.

Casopitant.

Caspofungin.

Catridecacog.

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.
Ceftolozane.
Ceftriaxone.
Cefuroxime.
Cefalotin.
Ceritinib.
Cerivastatin.
Certoparin.
Ceruletide.
Cetrorelix.
Cetuximab.
Chlorambucil.
Chlormadinone.
Chlormethine.
Clodantoin.
Chloroquine
Choriogonadotropin alfa.
Chloramphenicol.
Chlorquinaldol.

Chlortetracycline, **except** when listed elsewhere in the Schedules and **except** injections thereof intended 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).

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).

Cobicistat.

Cobimetinib.

Colfosceril.

Colistimethate.

Colistin,

- a. when presented as a finished pharmaceutical product; and
- b. **except** when compounded by a pharmacist in terms of Section 14(4) of the Act, by a veterinarian, or by a holder of a Section 22C(1)(a) licence, or presented as the raw material. (S6)

Contrast media, unless listed elsewhere in the Schedules.

Corifollitropin alfa.

Corticosteroids (natural or synthetic), unless listed elsewhere in the Schedules, **except** –

- a. triamcinolone when intended for application to oral lesions; (S2) and
- b. when contained in preparations intended for nasal administration. (S2, S3)

Co-tetroxazine.

Co-trifamole.

Co-trimoxazole.

Crisaborole.

Crisanlizumab.

Crizotinib.

Cyclofenil.

Cyclophosphamide and its derivatives, unless listed in another Schedule.

Cycloserine.

Cyprenorphine.

Cyproterone acetate.

Cytarabine.

Dabigatran

Dabrafenib.

Dacarbazine.

Dacliximab.

Daclizumab.

Dacomitinib.

Dactinomycin.

Dalteparin.

Danaparoid.

Danofloxacin.

Dantrolene.

Dapagliflozin.

Dapivirine.

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

Daptomycin.

Daratumumab.

Darbepoetin Alfa.

Darolutamide.

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.

Deferiprone.

Deferoxamine.

Degarelix.

Demecarium.

Demeclocycline.

Denosumab.

Deoxycholic acid.

Desirudin.

Deslorelin.

Desonide.

Desmopressin.

Desoximetasone.

Dexamethasone.

Dexlansoprazole.

Diatrizoic acid.

Diazoxide.

Dichlorophen,

- a. **except** in preparations and mixtures when intended for application to the skin; (S0)
- b. **except** in preparations containing 0,5 percent or less of dichlorophen when intended for use in terms of the provisions of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972);
- c. **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 fumarate.

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.

Doravirine.

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. (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).

Dronedarone.

Drospirenone,

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

Drotrecognin.

Dulaglutide.

Dupilumab.

Durvalumab.

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.

Efraloctocog alfa.

Eftrenonacog alfa (Human coagulation Factor IX).

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

Eletriptan.

Eltrombopag.

Elvitegravir.

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.

Entrectinib.

Enzalutamide.

Epicillin.

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

Epirizole.

Epirubicin (4-epidoxorubicin).

Eplerenone.

Epoetin beta, polyethylene glycol.

Eptacog alfa.

Eptifibatide.

Eptinezumab.

Erenumab.

Ergometrine maleate.

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

Eribulin.

Erlotinib.

Ertapenem.

Erythromycin.

Esomeprazole, **except** when indicated 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)

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.

Estriol,

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

Etamiyan.

Etanercept.

Etelcalcetide.

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.

Eto glucid.

Etoposide.

Etravirine.

Everolimus.

Evolocumab.

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.

Faricimab.

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.

Fidaxomicin.

Filgrastim.

Finasteride.

Fingolimod.

Flecainide.

Florfenicol.

Flosequinan.

Flucloxacillin.

Fluconazole, **except** as a single dose of 150 mg when indicated for the following fungal infections in adults

- a. Vaginal candidiasis, recurrent
- b. Candidial balanitis associated with vaginal candidiasis. (S2)

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 not more than 0,25 milligrams of fluorine per dosage unit; (S1)
- b. **except** in toothpaste containing not more than 0,15 percent fluoride; (S0) and
- c. **except** in mouth rinses containing not more than 0,15 percent fluoride. (S0)

Fluorometholone.

5-Fluorouracil.

Fluprednidene.

Flurbiprofen,

- a. when intended for ophthalmic use; (S4)
- 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. (S0)
- 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.

Follitropin delta.

Fondaparinux.

Formoterol.

Fosamprenavir.

Fosaprepitant.

Fosfomycin.

Fosphenytoin sodium.

Fostemsavir.

Fotemustine.

Framycetin.

Fremanezumab

Frovatriptan.

Frunevetmab.

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, **except** when intended for topical application. (S2)

Gadobutrol.

Gadodiamide.

Gadofosveset.

Gadoversetamide.

Galactose, when used as a contrast agent.

Galantamine.

Galcanezumab.

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.

Glofitamab.

Glucagon.

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

Golimumab.

Gonadorelin.

Goserelin.

Grapiprant.

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.

Guselkumab.

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 coagulation factors.

Human C1-esterase inhibitor

Human fibrinogen, when indicated for use as a haemostatic.

Human normal immunoglobulin.

Human Plasma.

Human Plasma Proteins.

Human thrombin, when indicated for use as a haemostatic.

Human von Willebrand Factor.

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).

Hycanthone.

Hydrocortisone and hydrocortisone acetate, **except** 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. (S2)

Hydroxycarbamide. (Hydroxyurea)

Hydroxychloroquine.

Ibandronic acid.

Ibuprofen,

- a. Ibuprofen, when intended for the treatment of a haemodynamically significant patent ductus arteriosus in infants less than 34 weeks of gestational age;
- b. **except** when contained in preparations intended for application to the skin; containing 5 % m/m or less of ibuprofen; (S0, S1)
- c. **except** when contained in transdermal patches containing 200mg of ibuprofen per patch or less, and indicated for use by patients aged 16 years and older (S1)
- d. **except** 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; (S1)
- e. **except** when contained in oral medicinal preparations intended for human use only, 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)
- f. **except** when contained in oral medicinal preparations, intended for human use only, 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; (S2)

g. **except** for the emergency treatment of acute gout attacks for a maximum treatment period of 5 days; (S2)

h. **except** when intended for veterinary use. (S3)

Ibutilide.

Ibritumomab.

Ibrutinib.

Icatibant.

Icosapent ethyl

Idarubicin.

Idarucizumab.

Idebenone.

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

Idursulfase.

Ifosfamide.

Iloprost.

Imatinib.

Imdevimab.

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.

Inclisiran.

Indacaterol.

Indinavir.

Indium chloride pentetreotide.

Infliximab.

Ingenol mebutate.

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)

Isoflupredone.

Isoniazid.

Isopirin.

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

Isoxsuprine.

Itopride.

Itraconazole.

Ixabepilone.

Ixazomib.

Ixekizumab.

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.

Latanoprostene

Ledipasvir.

Leflunomide.

Lenalidomide.

Lenograstim.

Lenvatinib.

Lepirudin.

Lesinurad.

Letermovir.

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.

Linagliptin.

Lincomycin.

Linezolid.

Lipegfilgrastim.

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).

Lokivetmab.

Lomefloxacin.

Lomustine.

Lopinavir.

Loracarbef.

Loteprednol.

Lovastatin.

Lubiprostone.

Lumefantrine.

Luprositol, when intended for veterinary use.

Lurasidone.

Lutropin alfa.

Lymecycline.

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

Macitentan.

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.

Meningococcal Group B vaccine.

Menotrophin.

Mepacrine.

Mephentermine.

Mepirizole.

Mepivacaine.

Mepolizumab.

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)

Metamizole (dipyrone).

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

Metergoline.

Methacholine.

Methampyrone (dipyrone).

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)

Midostaurin.

Mifamurtide.

Mifepristone.

Miglitol.

Miglustat.

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.

Molnupiravir.

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.

Mosunetuzumab

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.

Neratinib.

Netilmicin.

Netobimin.

Netupitant.

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.

Nintedanib.

Niraparib.

Niridazole.

Nirmatrelvir.

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.

Nitric oxide.

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).

Nivolumab.

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.

Noradrenaline (norepinephrine).

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)

Nonacog beta pegol.

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.

Obinutuzumab.

Oclacitinib.

Octocog alfa.

Ocrelizumab.

Ocriplasmin.

Octreotide.

Ofatumumab.

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).

Olaratumab.

Oleandomycin.

Olipudase alfa.

Olodaterol.

Oloparib.

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.

Orbifloxacin.

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

Ornipressin.

Orphenadrine, **except** when contained in preparations intended for use as a muscle relaxant. (S2)

Osaterone, when intended for veterinary use.

Oseltamivir.

Osimertinib.

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).

Oxytocin.

Paclitaxel.

Palbociclib.

Palivizumab.

Palonosetron.

Pamidronate disodium.

Pamidronic acid.

Pancuronium.

Panituzumab.

Panobinostat.

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.

Paromomycin.

Pasireotide.

Pazopanib.

Pegfilgrastim.

Peginterferon alpha.

Peginterferon beta 1a.

Pembrolizumab.

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.

Pertuzumab.

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.

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

Phenylephrine

- a. when intended for injection
- b. **except** ophthalmic preparations containing 0,2 percent or less. (S0)
- c. **except** for oral dosage forms, nasal dosage forms, or ophthalmic dosage forms containing more than 0,2 percent (S1)

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.

Pirfenidone.

Piribedil.

Pirlimycin.

Piromidic acid.

Pivampicillin.

Pivmecillinam.

Pixantrone.

Plerixafor.

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

Polatuzumab.

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.

Pomalidomide.

Ponesimod.

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.

Pralsetinib.

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.

Pretomanid.

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, **except**

- b. when co-formulated with atovaquone and intended and labelled for the chemoprophylaxis of malaria in those weighing 11 kilograms or more. (S2)

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).

Proylidone.

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 mixtures 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.

Ramucirumab.

Ranibizumab.

Ranolazine.

Rapacuronium.

Rasagiline.

Rasburicase.

Ravulizumab.

Recombinant human epidermal growth factor (rhEGF).

Regorafenib.

Remdesivir.

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).

Respiratory syncytial virus antigen (recombinant).

Retapamulin.

Revefanacin.

Ribavirin.

Ribociclib.

Rifabutin.

Rifampicin.

Rifapentine.

Rifaximin.

Rilpivirine.

Riluzole.

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

Riociguat.

Risdiplam.

Ritodrine.

Ritonavir.

Rituximab.

Rivaroxaban.

Rizatriptan, **except** when in oral solid dosage forms providing 5 mg or less and presented as packs of no more than 2 oral solid dosage forms, indicated for the acute relief of migraine attacks, with or without aura, in patients previously diagnosed by a medical practitioner and initiated on treatment with rizatriptan (S2)

Robenacoxib.

Rocuronium.

Roflumilast.

Rolitetracycline **except** when listed elsewhere in the Schedules and **except** injections thereof intended 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).

Romiplostim.

Ropinirole.

Ropivacaine.

Rosoxacin.

Rosuvastatin.

Rotigotine.

Roxadustat.

Roxithromycin.

Roxatidine.

Ruxolitinib.

Safinamide.

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

R-salbutamol, **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).

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.

Saroglitazar magnesium.

Sarolaner, **except** when intended and registered for the control of ticks and fleas in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Satralizumab

Secukinumab.

Selegiline.

Selenium,

- a. in preparations thereof for injection when intended for veterinary use;

- b. **except** in oral preparations or mixtures containing more than 200 µg of Selenium per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)

Selexipag.

Semaglutide.

Semuloparin.

Serelaxin.

Sermorelin.

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

Sertindole.

Sevelamer.

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine.

Sildenafil.

Silicone oil (polydimethylsiloxane) when intended for intraocular use.

Silodosin.

Siltuximab.

Simoctogog alfa.

Simvastatin.

Siponimod.

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.

Somapacitan.

Sparfloxacin.

Spectinomycin.

Stavudine.

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

Stiripentol

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, **except** when in oral solid dosage forms providing 50 mg or less and presented as packs of no more than two oral solid dosage forms, indicated for the acute relief of migraine attacks, with or without aura, in patients previously diagnosed by a medical practitioner and initiated on treatment with sumatriptan. (S2)

Sunitinib.

Suramin.

Surfactant associated proteins.

Suxamethonium.

Suxethonium.

Streptokinase.

Streptomycin.

Tacrine.

Tacrolimus.

Tadalafil.

Tafamidis.

Tafluprost.

Talampicillin.

Talazoparib.

Taliglucerase alfa.

Tamoxifen.

Tamsulosin.

Taurolidine.

Tasonermin.

Tazobactam.

Tegafur.

Tegaserod.

Teicoplanin.

Tedizolid.

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 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.

Tipiracil.

Tivozanib.

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.

Tilmicosin.

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.

Tofacitinib.

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.

Tozinameran.

Trabectedin.

Trametinib.

Tranexamic acid.

Trastuzumab.

Trastuzumab deruxtecan.

Trastuzumab emtansine.

Travoprost.

Tremelimumab.

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.

Tulathromycin.

Turoctocog Alpha.

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.

Upadacitinib.

Urapidil.

Urethane.

Urofollitropin.

Urokinase.

{Vaccines, see – Biologicals}

Ustekinumab.

Valaciclovir.

Valganciclovir

Valnemulin.

Vancomycin.

Vardenafil.

Varicella Zoster Virus glycoprotein E antigen.

Vasoactive intestinal polypeptide.

Vasopressin.

Vecuronium.

Vedolizumab.

Velaglucerase alfa.

Velpatasvir.

Vemurafenib.

Venetoclax.

Vericiguat.

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.

Zanubrutinib.

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.

Zofenopril.

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 β_2 AGONISTS		
Substance	:	Salbutamol
Indication:	:	Bronchodilator
Route of Administration	:	Parenteral
SELECTIVE β_2 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	:	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
*ANTI-FIBRINOLYTIC		
Substance	:	Tranexamic acid
Indication	:	Major haemorrhage in trauma
Route of Administration	:	Parenteral
**OXYTOCIN		
Substance	:	Oxytocin
Indication	:	Post-partum haemorrhage
Route of Administration	:	Parenteral
CORTICOSTEROID		
Substance	:	Prednisolone
Indication	:	Glucocorticoid/ Steroidal anti-inflammatory
Route of Administration	:	Oral
LOCAL ANAESTHETIC		
Substance	:	Lignocaine hydrochloride
Indication	:	Local anaesthesia
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)		
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 β_2 AGONISTS		
Substance	:	Salbutamol
Indication:	:	Bronchodilator
Route of Administration	:	Parenteral
SELECTIVE β_2 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	:	Parenteral
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
**CORTICOSTEROID	
Substance	: Betamethasone
Indication	: Pre-term birth
Route of Administration	: Parenteral
*ANTICHOLINESTERASE	
Substance	: Neostigmine
Indication	: Reversal of neuromuscular blockade
Route of Administration	: Parenteral
*CHOLINESTERASE INHIBITOR	
Substance	: Sugammadex
Indication	: Reversal of neuromuscular blockade
Route of Administration	: Parenteral
*SEROTONIN ANTAGONIST	
Substance	: Ondansetron
Indication	: Post-operative nausea and vomiting
Route of Administration	: Parenteral
*ANTI-FIBRINOLYTIC	
Substance	: Tranexamic acid
Indication	: Major haemorrhage in trauma
Route of Administration	: Parenteral
OXYTOCIN	
Substance	: Oxytocin
Indication	: Post-partum haemorrhage
Route of Administration	: Parenteral
CORTICOSTEROID	
Substance	: Prednisolone

EMERGENCY CARE PRACTITIONER (B Tech: Emergency Medical Care)	
Indication	: Glucocorticoid/ Steroidal anti-inflammatory
Route of Administration	: Oral
LOCAL ANAESTHETIC	
Substance	: Lignocaine hydrochloride
Indication	: Local anaesthesia
Route of Administration	: Parenteral

ANNEXURE 1C: BASIC AMBULANCE ASSISTANT

<u>BASIC AMBULANCE ASSISTANT</u> registered with Health Professions Council of South Africa	
*SELECTIVE β2 AGONISTS	
Substance	: Fenoterol
Indication	: Bronchodilator
Route of Administration	: Parenteral
OPIOID ANTAGONIST	
Substance	: Nitrous oxide
Indication	: Analgesic Gas
Route of Administration	: Inhalant (50:50 combination with Medical Oxygen)

ANNEXURE 1D: AMBULANCE EMERGENCY ASSISTANT

AMBULANCE EMERGENCY ASSISTANT registered with Health Professions Council of South Africa		
*ADRENERGIC		
Substance	:	Adrenaline / Epinephrine
Indication	:	Sympathomimetic catecholamine
Route of Administration	:	Parenteral
*CORTICOSTEROIDS		
Substance	:	Methylprednisolone
Indication	:	Glucocorticoid / Steroidal Anti-Inflammatory
Route of Administration	:	Parenteral
*CORTICOSTEROIDS		
Substance	:	Hydrocortisone
Indication	:	Glucocorticoid / Steroidal Anti-Inflammatory
Route of Administration	:	Parenteral
*HYPERGLYCAEMIC AGENT		
Substance	:	Glucagon
Indication	:	Hyperglycaemic agent
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)
SELECTIVE β_2 AGONISTS		
Substance	:	Fenoterol
Indication	:	Bronchodilator
Route of Administration	:	Parenteral
LOCAL ANAESTHETIC		
Substance	:	Lignocaine hydrochloride
Indication	:	Local anaesthesia
Route of Administration	:	Parenteral

ANNEXURE 1E: EMERGENCY CARE TECHNICIAN

EMERGENCY CARE TECHNICIAN registered with Health Professions Council of South Africa			
ADRENERGIC			
Substance	:	Adrenaline / Epinephrine	
Indication	:	Sympathomimetic catecholamine	
Route of Administration	:	Parenteral	
CORTICOSTEROIDS			
Substance	:	Methylprednisolone	
Indication	:	Glucocorticoid / Steroidal Anti-Inflammatory	
Route of Administration	:	Parenteral	
CORTICOSTEROIDS			
Substance	:	Hydrocortisone	
Indication	:	Glucocorticoid / Steroidal Anti-Inflammatory	
Route of Administration	:	Parenteral	
HYPERGLYCAEMIC AGENT			
Substance	:	Glucagon	
Indication	:	Hyperglycaemic agent	
Route of Administration	:	Parenteral	
ANTI-ARRHYTHMICS			
Substance	:	Amiodarone	
Indication	:	Class III Anti-arrhythmic / Atrial & Ventricular	
Route of Administration	:	Parenteral	
*ANTI-EMETIC			
Substance	:	Metoclopramide monohydrochloride	
Indication	:	Propulsive Anti-emetic / Dopamine Antagonist	
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	

ANTI-CHOLINERGIC		
Substance	:	Atropine
Indication	:	Competitive Anti-Cholinergic, Bradycardia, Anti-arrhythmic
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)
**OXYTOCIN		
Substance	:	Oxytocin
Indication	:	Post-partum haemorrhage
Route of Administration	:	Parenteral
CORTICOSTEROID		
Substance	:	Prednisolone
Indication	:	Glucocorticoid/ Steroidal anti-inflammatory
Route of Administration	:	Oral
LOCAL ANAESTHETIC		
Substance	:	Lignocaine hydrochloride
Indication	:	Local anaesthesia
Route of Administration	:	Parenteral

ANNEXURE 1F: EMERGENCY CARE ASSISTANT

EMERGENCY CARE ASSISTANT registered with Health Professions Council of South Africa		
*ADRENERGIC		
Substance	:	Adrenaline / Epinephrine
Indication	:	Sympathomimetic catecholamine
Route of Administration	:	Parenteral

CORTICOSTEROIDS		
Substance	:	Methylprednisolone
Indication	:	Glucocorticoid / Steroidal Anti-Inflammatory
Route of Administration	:	Parenteral
CORTICOSTEROIDS		
Substance	:	Hydrocortisone
Indication	:	Glucocorticoid / Steroidal Anti-Inflammatory
Route of Administration	:	Parenteral
HYPERGLYCAEMIC AGENT		
Substance	:	Glucagon
Indication	:	Hyperglycaemic agent
Route of Administration	:	Parenteral
ANTI-CHOLINERGIC		
Substance	:	Atropine
Indication	:	Competitive Anti-Cholinergic, Bradycardia, Anti-arrhythmic
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)
SELECTIVE β_2 AGONISTS		
Substance	:	Fenoterol
Indication	:	Bronchodilator
Route of Administration	:	Parenteral
LOCAL ANAESTHETIC		
Substance	:	Lignocaine hydrochloride
Indication	:	Local anaesthesia
Route of Administration	:	Parenteral
CORTICOSTEROID		
Substance	:	Prednisolone
Indication	:	Glucocorticoid/ Steroidal anti-inflammatory
Route of Administration	:	Oral

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
PENICILLINS AND BETA-LACTAMS COMBINATION		
Substance	:	Amoxicillin + clavulanic acid
Indication	:	Dental infections, abscesses
Route of Administration	:	Oral
MACROLIDES		
Substance	:	Erythromycin
Indication	:	For patients allergic to Penicillin
Route of Administration	:	Oral
ANTI-PROTOZOAL		
Substance	:	Metronidazole
Indication	:	Dental orofacial and odontogenic infections

DENTAL THERAPIST (Bachelors degree in Dental Therapy)		
(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 recognised by the Health Professions Council of South Africa as an authorised prescriber.

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)
ANTIBACTERIAL	
Substance	: Tetracycline
Indication	: Trachoma
Route of Administration	: Oral
ANTIBACTERIAL	
Substance	: Doxycycline
Indication	: Trachoma
Route of Administration	: Oral
ANTIBACTERIAL	
Substance	: Azithromycin

OPTOMETRISTS	
Indication	: Trachoma
Route of Administration	: Oral
ANTIBACTERIAL	
Substance	: Fuscidic acid
Indication	: For Blepharitis and sty
Route of Administration	: Topical drops or ointment
ANTIBACTERIAL	
Substance	: Neomycin
Indication	: For Blepharitis only
Route of Administration	: Topical drops or ointment
ANTIBACTERIAL	
Substance	: Bacitracin
Indication	: For Blepharitis only
Route of Administration	: Ointment
ANTIBACTERIAL	
Substance	: Polymyxin B
Indication	: For Blepharitis only
Route of Administration	: Ointment
PROSTAGLANDIN ANALOGUES (PGAs)	
Substance	: Latanoprost, Travoprost, Bimatoprost
Indication	: Glaucoma
Route of Administration	: Drops

ANNEXURE 5: ORAL HYGIENISTS

Oral hygienists registered with the Health Professions Council of South Africa (HPCSA) in terms of the Health Professions Act, 1974 (Act 56 of 1974)

ORAL HYGIENIST	
LOCAL ANAESTHETIC	
Substance	: Lignocaine/Lidocaine hydrochloride with or without Adrenaline or Noradrenaline
Indication	: Dental surface anaesthesia (local anaesthetic)
Route of Administration	: Local injection
LOCAL ANAESTHETIC	
Substance	: Mepivacaine with or without Adrenaline
Indication	: Dental surface anaesthesia (local anaesthetic)
Route of administration	: Local injection
LOCAL ANAESTHETIC	
Substance	: Articaine with Adrenaline
Indication	: Dental surface anaesthesia (local anaesthetic)
Route of administration	: Local injection
LOCAL ANAESTHETIC	
Substance	: Prilocaine with or without Adrenaline
Indication	: Dental surface anaesthesia (local anaesthetic)
Route of administration	: Local injection

–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.
- 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 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 Authority, 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);
 - Annexure 1B: Emergency Care Provider (Emergency Care Practitioner).
 - Annexure 1C: Basic Ambulance Assistant
 - Annexure 1D: Ambulance Emergency Assistant
 - Annexure 1E: Emergency Care Technician
 - Annexure 1F: Emergency Care Assistant
- 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.

Alfaxalone.

Alprazolam**.

Amisulpride.

Amitriptyline and its derivatives.

Amoxapine.

Anaesthetic preparations containing pregnanedione derivatives.

Androstanolone.

Androstenediol.

Aponal.

Apronalide.

Aripiprazole.

Armodafanil.

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.

Benzoctamine.

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.

Brexiprazole.

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.

Cariprazine.

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.

Esketamine

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**.

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).

5-Hydroxy Tryptophan,

- a. **except** in oral preparations with a maximum daily dose not exceeding 220 mg of 5-Hydroxy tryptophan, alone or in combination with other active pharmaceutical ingredients; (S1)
- b. **except** in oral preparation with a maximum daily dose not exceeding 220 mg of 5-Hydroxy tryptophan alone or in combination with other active pharmaceutical ingredients, with general health claims as a health supplement. (S0)

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**.

Lemborexant.

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

Lofepramine.

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.

Phenazepam.

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,

- a. **except** in oral preparations with a maximum daily dose not exceeding 220 mg of L-tryptophan, alone or in combination with other active pharmaceutical ingredients; (S1)
- b. **except** in oral preparation with a maximum daily dose not exceeding 220 mg of L-tryptophan alone or in combination with other active pharmaceutical ingredients, with general health claims as a health supplement;(S0)

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)	
ANALGESIC INHALANT	
Substance	: Methoxyflurane (Penthrox Inhaler)
Indication	: Analgesia
Route of Administration	: Inhalant
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
*INDUCTION AGENTS	
Substance	: Ketamine
Indication	: Analgesia
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)	
ANALGESIC INHALANT	
Substance	: Methoxyflurane (Penthrox Inhaler)
Indication	: Analgesia
Route of Administration	: Inhalant
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
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

ANNEXURE 1C: BASIC AMBULANCE ASSISTANT

BASIC AMBULANCE ASSISTANT registered with Health Professions Council of South Africa	
ANALGESIC INHALANT	
Substance	: Methoxyflurane (Penthrox Inhaler)
Indication	: Analgesia
Route of Administration	: Inhalant

ANNEXURE 1D: AMBULANCE EMERGENCY ASSISTANT

AMBULANCE EMERGENCY ASSISTANT registered with Health Professions Council of South Africa	
ANALGESIC INHALANT	
Substance	: Methoxyflurane (Penthrox Inhaler)
Indication	: Analgesia
Route of Administration	: Inhalant

ANNEXURE 1E: EMERGENCY CARE TECHNICIAN

EMERGENCY CARE TECHNICIAN registered with Health Professions Council of South Africa	
ANALGESIC INHALANT	
Substance	: Methoxyflurane (Penthrox Inhaler)
Indication	: Analgesia
Route of Administration	: Inhalant
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

EMERGENCY CARE TECHNICIAN registered with Health Professions Council of South Africa		
NON-SELECTIVE ANTIHISTAMINE		
Substance	:	Promethazine
Indication	:	Antihistamine
Route of Administration	:	Parenteral

ANNEXURE 1F: EMERGENCY CARE ASSISTANT

EMERGENCY CARE ASSISTANT registered with Health Professions Council of South Africa		
ANALGESIC INHALANT		
Substance	:	Methoxyflurane (Penthrox Inhaler)
Indication	:	Analgesia
Route of Administration	:	Inhalant
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

- 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 Authority, 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);
Annexure 1B: Emergency Care Provider (Emergency Care Practitioner).
Annexure 1E: Emergency Care Technician

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.

Carfentanil, when intended for veterinary use. (S7)

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. (S0)

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.

Colistin,

- a. when compounded by a pharmacist in terms of Section 14(4) of the Act, by a veterinarian, or by a holder of a Section 22C(1)(a) licence, or presented as the raw material; and
- b. **except** when presented as a finished pharmaceutical product. (S4)

Cyclobarbital.

Desomorphine.

Dexamfetamine (Dexamphetamine) in medicines registered in terms of the Act and intended for the treatment of Attention-Deficit Hyperactivity Disorder. (S7)

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)

Dextrophan.

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.

Diphenoxin (or diphenoxylie 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}

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, in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, containing not more than 30 milligrams of ephedra alkaloids per dose, with a maximum daily dose not exceeding 120 milligrams, subject to a maximum pack size of 360 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, in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, containing not more than 30 milligrams of ephedrine per dose, with a maximum daily dose not exceeding 120 milligrams, subject to a maximum pack size of 360 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)

Ethylmethylthiambutene.

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.

Ibogaïne.

Isomethadone.

Ketobemidone.

Levomoramide.

Levophenacymorphan.

Levorphanol.

Lisdexamfetamine (Lisdexamphetamine), in medicines registered in terms of the Act and intended for the treatment of Attention-Deficit Hyperactivity Disorder. (S7)

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.

Phenylbutazone and its derivatives.

Phenylpropanolamine (norephedrine),

- a. **except** products registered in terms of the Act, not intended for export and oral 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 in combination with another pharmacologically active substance and intended for the symptomatic relief of nasal and sinus congestion, subject to a maximum pack size of 300 milligrams for adults and 150 milligrams for children, limited to one pack per customer. (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 or controlled-release oral preparations and mixtures containing not more than 120 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.

Remifentanil.

Secobarbital.

Sufentanil.

p-Synephrine,

- a. **except** preparations and mixtures registered in terms of the Act and intended for application to the skin, ears and nares containing 1 percent or less of p-synephrine and containing 0,2 percent or less for application to the eyes; (S0)
- b. **except** oral preparations and mixtures registered in terms of the Act and intended for the symptomatic relief of nasal and sinus congestion, where the recommended daily dose for adults is 50 milligrams or less and for children 6 to 12 years is 25 milligrams or less, with a maximum pack size of 5 days; (S1)
- c. **except** oral preparations and mixtures registered in terms of the Act and intended for the symptomatic relief of nasal and sinus congestion, where the recommended daily dose for adults is more than 50 milligrams and for children 6 to 12 years is more than 25 milligrams. (S2)

Tapentadol.

Tetrahydrocannabinol, **except**

- a. in raw cannabis plant material cultivated and possessed in accordance with a permit issued in terms of the Plant Improvement Act (Act 11 of 2018) and processed products manufactured from such material, intended for agricultural or industrial purposes, including the manufacture of consumer items or products which have no pharmacological action or medicinal purpose, or

- b. when raw cannabis plant material is cultivated, possessed and consumed by an adult, in private for personal consumption.

Thebacon.

Thebaine.

Thiafentanyl.

Tilidine.

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

ANNEXURE 1E: EMERGENCY CARE TECHNICIAN

EMERGENCY CARE TECHNICIAN registered with Health Professions Council of South Africa		
*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 *)

5F – APINACA (5F AKB-48).

AB-CHMINACA.

AB-FUBINACA.

AB-PINACA.

ADB-CHMINACA (MAB-CHMINACA)

ADB-FUBINACA

AH-7921.

Alpha-PHP.

AM-2201.

5F-AMB-PINACA (5F-AMB, 5F-MMB-PINACA).

Acetylfentanyl.

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).

Brorphine.

Bufotenine (N, N-dimethylserotonin).

Butyrfentanyl.

Carfentanil, **except** when intended for veterinary use. (S6)

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

Cathinone ((-)-2-aminopropiophenone).

1-(4-chloro-2,5-dimethoxyphenyl)propan-2-amine (DOC).

Clonazepam

4-CMC (4-chloromethcathinone; clephedrone).

CUMYL-4CN-8INACA

CUMYL-PEGACLONE.

Dexamfetamine (Dexamphetamine) **except** in medicines registered in terms of the Act and intended for the treatment of Attention-Deficit Hyperactivity Disorder (S6)

Diclazepam

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).

Dipentylone.

Diphenidine.

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

N-ethylhexedrone.

N-Ethylnorpentylone (ephylone)

Ethylphenidate.

Etilamfetamine (N-ethylamphetamine).

Etizolam

Etryptamine.

Eutylone.

Fenetylline.

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

- (i) acetyl- α -methylfentanyl;
- (ii) α -methylfentanyl;
- (iii) α -methylfentanyl-acetanilide;
- (iv) α -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)
- (xii) 4-anilino-*N*-phenethylpiperidine (ANPP);
- (xiii) *N*-phenethyl-4-piperidone (NPP).
- (xiv) Acryloylfentanyl (acrylfentanyl).
- (xv) 4-fluoroisobutyrfentanyl (4-FIBF, pFIBF).
- (xvi) Furanylfentanyl
- (xvii) Tetrahydrofuranylfentanyl (THF-F).
- (xviii) Cyclopropylfentanyl. (N-Phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]cyclopropanecarboxamide)
- (xix) Methoxyacetyl fentanyl. (2-methoxy-*N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]acetamide)
- (xx) Ortho-fluorofentanyl. (*N*-(2-fluorophenyl)-*N*-[1-(2-phenylethyl)piperidin-4-yl]propanamide)
- (xxi) Parafluorobutyrfentanyl (*N*-(4-fluorophenyl)-*N*-[1-(2-phenylethyl)piperidin-4-yl]butanamide)
- (xxii) Crotonylfentanyl.
- (xxiii) Valeryl fentanyl.

Flualprazolam.

Flubromazolam.

4-fluoroamphetamine (4-FA).

2-Fluorodeschloroketamine.

FUB-AMB (MMB-FUBINACA, AMB-FUBINACA)

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).

Isotonitazene

Lefetamine *(SPA).

Lisdexamfetamine (Lisdexamphetamine), **except** in medicines registered in terms of the Act and intended for the treatment of Attention-Deficit Hyperactivity Disorder. (S6)

Lysergide (Lysergic acid diethylamide) *(LSD).

4F-MDMB-BINACA.

MDMB – CHMICA.

5F-MDMB-PICA (5F-MDMB-2201).

MDMB-4en-PINACA.

5F-MDMB-PINACA (5F-ADB).

4- MEC.

Methyl alpha-phenylacetoacetate (MAPA)

3-Methoxyphencyclidine.

MT-45.

Mephedrone.

Mescaline (3,4,5-trimethoxyphenethylamine).

Mesocarb.

Methamphetamine and methamphetamine racemate.

Methaqualone and any preparation containing methaqualone.

Methcathinone.

Methiopropamine (MPA).

Methoxetamine (MXE).

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-methylenedioxypyrovalerone (MDPV).

Methylone (beta-keto-MDMA).

Methypylon.

Metonitazene.

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

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

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

Nabilone. (S8)

Norfentanyl.

Ocfentanil.

Para-methoxymethylamphetamine (PMMA).

Para-methyl-4-methylaminorex (4,4-DMAR).

5F-PB-22.

Pentedrone. 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.

Pholocodine.

Psilocin (4-hydroxy-NN-dimethyltryptamine).

Psilocybine (4-phosphoryloxy-NN-dimethyltryptamine).

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

α -pyrrolidinovalerophenone (α -PVP).

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).

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

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

U47700.

UR-144.

XLR-11.

- 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)

Nabilone. (S7)

- END SCHEDULE 8 -