

# **GOVERNMENT GAZETTE**

# **OF THE**

# REPUBLIC OF NAMIBIA

N\$43.80 WINDHOEK - 31 October 2018 No. 6749 **CONTENTS** Page **GOVERNMENT NOTICE** Classification of Medicines and their Substances as Scheduled Substance: Medicines and Related No. 278 Substance Control Act, 2003 **Government Notice** 

### MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 278 2018

CLASSIFICATION OF MEDICINES AND OTHER SUBSTANCES AS SCHEDULED SUBSTANCES: MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

Under section 29(1) of the Medicines and Related Substances Control Act, 2003 (Act No.13 of 2003), I-

- classify, on the recommendation of the Namibia Medicines Regulatory Council, the (a) medicines and substances set out in the Schedule as Schedule 0, Schedule 1, Schedule 2, Schedule 3, Schedule 4 and Schedule 5 medicines and substances; and
- repeal Government Notice No. 180 of 25 July 2008. (b)

DR. B. HAUFIKU MINISTER OF HEALTH AND SOCIAL SERVICES

Windhoek, 15 October 2018

### **SCHEDULE**

#### **Definitions**

- 1. (1) In this notice, a word or expression to which a meaning has been assigned in the Act bears that meaning, and unless the context otherwise indicates -
  - (a) "dosage unit" means -
    - (i) a tablet;
    - (ii) a capsule; or
    - (iii) 5 millilitres in the case of liquid oral preparations and mixtures;
  - (b) "Schedule" means Schedule 0, Schedule 1, Schedule 2, Schedule 3, Schedule 4 or Schedule 5;
  - (c) "the Act" means the Medicines and Related Substances Control Act, 2003 (Act No. 13 of 2003); and
- (2) In any Schedule, a reference to "NS" with a number next to it in brackets, means that the medicine or other substance in the description concerned also occur in the Schedule to which the abbreviation refers.

# **General provision**

- **2.** Unless expressly excluded or unless listed in another Schedule, all substances referred to in any Schedule include the following -
  - (a) the isomers of such substances, if the existence of such isomers is possible within the specific chemical designation;
  - (b) the esters and ethers of such substances and of the isomers referred to in paragraph (a), as well as the isomers of such esters and ethers, if the existence of such esters, ethers and isomers is possible;
  - (c) the salts of such substances and of the isomers referred to in paragraph (a), as well as the salts of the esters and isomers referred to in paragraph (b), if the existence of such salts is possible;
  - (d) the isomers of any of the salts referred to in paragraph (c), if the existence of such isomers is possible; and
  - (e) all preparations and mixtures of any of the substances referred to in paragraphs (a),(b),(c) and (d).

#### **SCHEDULE 0**

2-4-dichloro-benzyl Alcohol

Abamectin

Acetic acid when intended for topical veterinary use

Acetyl-Isovaleryl-Tylosin tartrate

Activated Charcoal for medicinal use

Adenosine triphosphate (ATP) tetrasodium dihydrate salt

Afoxolaner

Albendazole, when intended for veterinary use (NS2)

Allyl trenbolone (Altrenogest)

Alphamethrin

Amitraz

Ammonium bicarbonate

Ammonium chloride

Ampicillin when intended as intra-mammary treatment for mastitis in veterinary use (NS2)

Amprolium when intended as an anti-coccidial preparation for veterinary use (NS2)

Amylmetacresol

Anhydrous Lanolin (wool fat)

Aspirin (acetyl salicylic acid)

Substances, preparations and mixtures except when intended for

- a. the prophylaxis of cardiovascular disease in adults; and
- b. the treatment of children or adolescents (NS1)

Avilamycin when intended as a feed additive for veterinary use (NS2)

Benzalkonium chloride

Benzoxonium Chloride

Benzoyl peroxide for medicinal use

Bisacodyl

Substances, preparations and mixtures except if:

- 1. containing more than 10 milligrams of Bisacodyl (NS1),
- 2. packed in a primary pack containing more than an aggregate of 100 milligrams of Bisacodyl (NS1)

Benzyl-Penicillin when intended as intra-mammary treatment for mastitis in veterinary use (NS2)

Boric acid

Caffeine, when intended for injection (NS2)

Calcium, when intended for veterinary use (NS1)

Camphor

Carbaryl

Cetylpiridinium

Chitosan when intended for veterinary use

Chlorfenvinfos

Chlorhexidine when intended for veterinary topical use (NS1)

Chloroform (Trichloromethane) when intended for veterinary topical use (NS1, NS3)

Chlorpyrifos

Chlortetracycline, when intended for veterinary use (NS2)

Choline Salicylate

Chondroitin sulphate when intended for veterinary use

Chromium, when intended for veterinary use (NS1, NS2)

Cinchona

Citric acid, single agent or in combination with other substances in oral rehydration salt or antacids

Clorsulon
Closantel
Cloxacillin when intended as intra-mammary treatment for mastitis in veterinary use (NS2)
Cobalt, when intended for veterinary use
Copper, when intended for veterinary use (NS1, NS2)
Cyfluthrin
Cyhalothrin
Cymiazole
Cypermethrin
Cyromazine
Decoquinate
Deltamethrin
Derquantel
Dextrose, in combination with other substances in oral rehydration salt except when intended for infusion (NS2)
Diazinon
Dichlorophen
Diclazuril
Diclorvos
Diflubenzuron
Diflubenzuron
Dihydrostreptomycin Sulphate when intended as intra-mammary treatment for mastitis in veterinary use (NS2)
Diminazene when intended as an antibabesial for veterinary use (NS2)
Dimitrazole
Dinitolmide when intended as an anti-coccidial preparation for veterinary use (NS2)
Doramectin
Doxycycline when intended as a feed additive in veterinary use (NS2)
Emodepside
Enilconazole
Eprinomectin
Esfenvalerate
Ethopabate when intended as an anti-coccidial preparation for veterinary use (NS2)
Febantel
Fenbendazole
Fenitrothion
Fenthion-methyl
Fenvalerate
Fipronil
Fluaruzon
Flumethrin
Fluralaner
Glucosamine when intended for veterinary use (NS2)
Gluteraldehydrate
Glycerin 5% in 2% colloidal oatmeal shampoo base when intended for veterinary topical use
Glycerine when intended for veterinary topical use
Guaifenesin
Imidacloprid

Imidazolidinyl Urea when intended for veterinary topical use

**Imidicloprid** 

Imidocarb when intended as an antibabesial for veterinary use (NS2)

Indoxacarb

Iodoform

Iron

Isometamidium chloride hydrochloride when intended as a trypanocydal agent for veterinary use

Ispaghula husk

Ivermectin

Kaolin, as a single active ingredient, except when in combination with Pectin (NS1)

Ketanserin tartrate

Lactic acid

Lactulose

Lasalocid Sodium when intended as an anti-coccidial preparation for veterinary use

Levamisole, if intended as an anthelmintic and an immunomodulator for veterinary use (NS2)

Levomenthol

Light Liquid Paraffin

Lufenuron

Maduramicin Ammonium when intended as an anti-coccidial preparation for veterinary use (NS2)

Magnesium, when intended for veterinary use

Manganese, when intended for veterinary use (NS1)

Mebendazole, when intended for veterinary use (NS1)

Metaflumizone

Methoprene

Methyl Salicylate

Milbemycin oxime

Monensin when intended as an anti-coccidial preparation and feed additive for growth promotion in veterinary use (NS2)

Moxidectin

Narasin when intended as an anti-coccidial preparation and feed additive for growth promotion in veterinary use (NS2)

Nicarbizin when intended as an anti-coccidial preparation and feed additive for growth promotion in veterinary use (NS2)

Niclosamide

Nitenpyram

Nitroxynil

Nux vomica, when intended for veterinary use (NS1)

Oleic Acid

Oxantel Pamoate

Oxfendazole

Oxifendazole

Oxyclozanide

Oxytetracycline, when intended for veterinary use (NS2)

# Paracetamol -

- 1) Substances, preparations and mixtures
  - a) in tablets or capsules containing less or equal to 500 milligrams of Paracetamol, if
    - packed in a primary pack containing not more than an aggregate of 12.5 grams of Paracetamol in such tablets or capsules;
    - ii) packed in blister strip packaging or in containers with child-resistant closures;
  - b) individual wrapped powders or in sachets containing 100 milligrams or less of Paracetamol, if packed in in a primary pack containing not more than aggregate of 12.5 grams of Paracetamol in such powders or sachets;

- c) in liquid or syrup dosage form containing 120 milligrams or less of paracetamol per 5 millilitres, if
  - packed in a primary pack containing not more than 100 millilitres in the case of the liquid or syrup dosage form containing 120 milligrams or less of Paracetamol per 5 millilitres;
  - ii) packed in a primary pack containing not more than 20 ml in the case of the paediatric dosage form (drops) containing 120 mg or less of Paracetamol per 1.2 ml
- 2) If contained in rectal suppositories. (NS1).

Pectin, as a single active ingredient, except when in combination with Kaolin (NS1)

Permethrin

Phenamidine isethionate

Phenazone when intended for veterinary use (NS1)

Phosphorous

Piperazine, when intended for veterinary use (NS3)

Piperonyl Butoxide

Plantago Ovata

Poly (hexamethylene biguanide) Hydrochloride when intended for topical veterinary use

Poly Dimethyl Ammonium Chloride when intended for topical veterinary use

Polyethylene glycol, when intended for veterinary use (NS2)

Polyguanidine

Polymethylol Urea Derivates

Potassium

Povidone iodine, except if intended for human vaginal use (NS1)

Praziquantel, if intended for veterinary use (NS2)

Propetamphos

Propoxur

Pyrantel embonate

Pyrantel Pamoate, if intended for veterinary use (NS1)

Rafoxanide

Resorantel

Ricobendazole

Robenidine when intended as an anti-coccidial for veterinary use

Saccharomyces cerevisiae

Salicylic acid

Salinomycin Sodium when intended as an anti-coccidial for veterinary use (NS2)

Selamectin

Selenium, if intended for veterinary use (NS1, NS2)

Senna alkaloids; Sennosides

Silymarin, providing not more than 600 mg of Silymarin per day (calculated as silibinin/silybin). (NS2)

Sodium, if intended for veterinary use

Sodium Alginate

Sodium Salicylate

Sodium Thiosulphate

Sorbimacrogol Laurate, when used as a cough syrup

Spinosad

Sucralfate

Sulphonamides when intended for veterinary use (NS1, NS2)

Sulphur, if intended for veterinary use

TEA Lauryl Sulphate when intended for veterinary topical use

Terpineol

### Tetrachlorvinphos

Tetramisole

Thiabendazole, except

- a. when intended for application to the skin; (NS1) and
- b. when intended for oral human use (NS2)

Toltrazuril

Triazophos

Trichlorfon

Triclabendazole

Triclandazole

Triflumuron

Trimethoprim, when specifically intended and registered in combination with sulphonamides for the treatment of gastro enteritis and pneumonia in veterinary use (NS2)

Turpentine gum

Tylosin when intended for addition to drinking water and feedstuff for administering to pigs and poultry

Undecenoate Acid

Urea

Vitamin A, when intended for veterinary use (NS1, NS2)

Vitamin B1, when intended for veterinary use (NS1, NS2)

Vitamin B12, when intended for veterinary use (NS1, NS2)

Vitamin B2, when intended for veterinary use (NS1, NS2)

Vitamin B3 (Nicotinamide), when intended for veterinary use (NS1, NS2)

Vitamin B5, when intended for veterinary use (NS1, NS2)

Vitamin B6, when intended for veterinary use (NS1, NS2)

Vitamin D, when intended for veterinary use (NS2)

Vitamin E, when intended for veterinary use (NS1)

Vitamin K, when intended for veterinary use (NS1, NS2)

White Soft Paraffin

Zinc, except

1) for oral ingestion, where the daily dose is more than 50 milligrams of elemental zinc (NS2)

#### **SCHEDULE 1**

Acetanilide and alkyl acetanilides.

Acetarsol, including preparations intended for human vaginal use.

Acetylcysteine, except when intended for injection or for the management of

paracetamol overdosage. (NS2)

Acetyldihydrocodeine, preparations and mixtures if compounded with one or more therapeutically active substances and containing 20 milligrams or less of acetyldihydrocodeine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of acetyldihydrocodeine (calculated as base) per 5 millilitre dosage unit. (NS4).

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

Acrivastine.

Acyclovir, if intended for application to the lips in the early treatment of recurrent Herpes simplex virus infections. (NS2)

Adrenaline (epinephrine), preparations not intended for injection and ophthalmic preparations not intended for glaucoma. (NS2)

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

Alverine.

Amethocaine - see Tetracaine.

Aminopentamide.

Amorolfine.

Ambroxol.

Amorolfine.

Amyl nitrate.

Anethole trithione.

Antazoline.

Anticoagulants, if intended for application to the skin. (NS2)

Antihistamines, irrespective of indication or dosage form, except -

- (a) Astemizole and Terfenadine (NS2);
- (b) if listed separately in Schedules 2 and 3; and
- (c) for veterinary use (NS0).

Antimalarials, preparations containing substances in the 4-aminoquinoline, 8-aminoquinoline, diguanide and diaminopyrimidine groups of compounds, if intended specifically for malaria prophylaxis. (NS2)

Antimicrobial substances, namely

- (a) griseofulvin, mupirocin, natamycin when intended for application to the skin, nares and external ear; (NS2)
- (b) nystatin preparations intended for application to the oral cavity, nares and external ear. (NS2)

Antimony potassium tartrate and antimony sodium tartrate; substances, preparations and mixtures containing 1.0 per cent or more thereof.

Antipyrine (phenazone), including preparations and mixtures, if intended for application to the skin. (NS0)

Apomorphine; preparations and mixtures thereof except if indicated for the treatment of erectile dysfunction. (NS2)

Aptocaine.

Arecoline.

Arsenic: preparations containing the equivalent of 0,01 percent or more of arsenic trioxide.

Aspirin (acetyl salicylic acid), when intended for:

- (a) the treatment of children or adolescents; and
- (b) the prophylaxis of cardiovascular disease in adults (NS0)

Atropine, except

- (a) when intended for use in ophthalmic preparations; (NS2)
- (b) when intended for use in injections. (NS2)

Azatadine

Azelaic acid.

Azelastine.

Bacitracin, when intended for topical application to the epidermis, nares and external ear. (NS2)

Bambuterol.

Bamipine.

BCG vaccine - see Mycobacterium bovis.

Beclomethasone propionate (See corticosteroids).

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. (NS2)

Bee venom, if intended for application to the skin. (NS2)

Belladonna alkaloids, except when intended for topical application.

Benproperine.

Benzethonium chloride, including preparations 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. (NS2)

Benzydamine, preparations and mixtures containing -

- (a) 3 per cent or less of benzydamine, if intended for application to the skin; and
- (b) 0.15 per cent or less of benzydamine if intended for use as a mouth rinse or for topical application in the mouth and throat, but the total daily dose may not exceed 36 milligrams of benzydamine. (NS2)

Beta-aminopropylbenzene and beta-aminoisopropylbenzene, as excluded from the conditions of Schedule 3. (NS3)

Bevonium methylsulphate.

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

#### Bifidobacterium lactis,

- (a) in pharmaceutical preparations and mixtures with medicinal claim(s);
- (b) except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10<sup>9</sup> 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";
- (c) except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1 x 10<sup>8</sup> cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Bifidobacterium longum subsp. Infantis,

- (a) in pharmaceutical preparations and mixtures with medicinal claim(s);
- (b) except in pharmaceutical preparations and mixtures for one or more strains containing  $\geq 1 \times 10^9$  cfu per dosage unit with the general health claim: "When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut";

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

Bifidobacterium longum subsp. Longum,

- (a) in pharmaceutical preparations and mixtures with medicinal claim(s);
- (b) except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10<sup>9</sup> 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";
- (c) except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1 x 10<sup>8</sup> cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Bifonazole, including preparations intended for application to the skin.

#### Bioallethrin.

#### Biologicals,

- (a) if intended for human medicinal use including injectable antivenoms,
- (b) except other injectable preparations thereof. (NS2)
- (c) except when listed in other schedules

Bismuth, including prerations intended for oral issue.

### 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.

#### Bromhevine

Bromides, preparations and mixtures thereof containing less than 80 milligrams of bromine as bromide per recommended daily dose. (NS3)

Brompheniramine

Buclizine.

Bufexamac, including preparations intended for application to the skin.

Bunamidine.

# Butinoline.

#### Butoconazole,

- (a) when intended for human vaginal use specifically for the treatment of recurrent vaginal candidiasis; (NS2) or
- (b) when intended for application to the skin. (NS2)

Calabar bean alkaloids; substances, preparations and mixtures thereof.

#### 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;
- (b) except in preparations thereof for injection; (NS2)
- (c) except when intended for veterinary use (NS0)

Camphorated Opium Tincture BP.

Camylofin.

Cantharidin.

Canthaxanthin, if intended for medicinal purposes.

Carbamoyl benzamide phenyl isoxazoline, except if intended for veterinary use (NS0).

Carbinoxamine.

Carbocisteine.

Carbuterol, if not contained in respirator solutions and if not intended for injection. (NS2)

Carisoprodol.

Cetirizine

Chlorhexidine, if intended for human vaginal use.

Chlormezanone, mixtures thereof if the maximum recommended or prescribed dose does not exceed 100 milligrams of chlormezanone. (NS2)

Chlorodyne (Chloroform and Morphine Tincture BP 1980) or any preparation or mixture thereof described as chlorodyne, preparations and mixtures containing 5,0% or less of chlorodyne in combination with other active medicinal ingredients. (NS4)

Chloroform, substances, preparations and mixtures containing less than 20% of chloroform. (NS3)

Chloroquine, when used in combination with proguanil and when intended specifically for malaria prophylaxis. (NS2)

Chlorpheniramine.

Chlorprenaline.

Chlorzoxazone.

Cholestyramine

Chromium, in oral preparations or mixtures containing more than 50  $\mu$ g of Chromium per recommended daily dose alone or in combination with other active pharmaceutical ingredients.

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

- (a) a maximum dose of 200 milligrams;
- (b) a maximum daily dose (per 24 hours) of 800 milligrams; and
- (c) a maximum treatment period of 2 weeks. (NS2).

Cinnarizine.

Clemastine.

Clemizole

Clidinium bromide.

Clonidine, if intended for the treatment of migraine. (NS2)

Clotrimazole, if intended for application to the skin and if intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis. (NS2)

Colchicine, when intended for the emergency treatment of acute gout, subject to a maximum total treatment course of 6 milligrams. (NS2)

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;
- (b) except in preparations thereof for injection. (NS2)
- (c) except if intended for veterinary use (NS0).

Corticosteroids (natural or synthetic) if contained in preparations intended for inhalation -

- (1) Beclomethasone dipropionate, if intended for nasal administration (other than by aerosol), in the treatment of the symptoms of seasonal allergic rhinitis (hayfever) in adults and children over the age of 12 years, subject to -
  - (a) a maximum dose of 100 micrograms per nostril;
  - (b) a maximum daily dose of 200 micrograms per nostril;
  - (c) a pack size limit of 200 doses (NS2).
- (2) Flunisolide, if intended for nasal administration, other than aerosol, in a strength not exceeding 0.025 per cent (w/w) indicated for the treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over the age of 12 years, if in the case of adults and children over the age of 16 years, the maximum dose per nostril in 50 micrograms and the maximum daily dose per nostril is 100 micrograms and in the case of children 12 to 16 years, the maximum dose per nostril is 25 micrograms and the maximum daily dose per nostril is 75 micrograms and the pack size is limited to 240 doses.
- (3) Fluticasone propionate, if intended for nasal administration, other than by aerosol, in the short-term treatment (less than 6 months) prophylaxis and treatment of symptoms of allergic rhinitis (hay fever) in adults and children over the age of 12 years, if the maximum daily dose per nostril in 100 micrograms and the pack size is limited to 120 doses. (NS2).

Cyclopentolate, but not ophthalmic preparations thereof. (NS2)

Cyanocobalamin - see Vitamin B12.

Cyproheptadine, when indicated for allergic rhinitis or antipruritic use. (NS3)

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.

Desloratidine.

Dexchlorpheniramine.

Dextromethorphan.

Dialysate preparations.

Dichlorophen, preparations and mixtures intended for application to the skin (NS2), except if intended for veterinary use (NS0).

Diclofenac, if intended for application to the skin, for emergency treatment of acute gout attacks and for the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (NS2)

Dicyclomine.

Difenoxin (or diphenoxylic acid), mixtures containing, per dosage unit, 0,5 milligrams or less of difenoxin, calculated as the base, and a quantity of atropine sulphate equal to at least 5,0% of such quantity of difenoxin, calculated as the base, as is present in the mixture. (NS4)

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. (NS4)

Dimethindene.

Dimethothiazine.

Dimetindene.

Diosmine.

Diphenhydramine.

Diphenylpyraline.

Diphtheria toxoid vaccine.

Diphenoxylate, preparations containing not more than 2,5 milligrams of diphenoxylate, calculated as the base, and not more than 25 micrograms of atropine sulphate per dosage unit. (NS4)

D-norpseudoephedrine (See Cathine)

Dithiazanine.

Doxylamine

Econazole, if intended for application to the skin and for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis. (NS2)

Emedastine.

Emepronium.

Emetine, substances, preparations and mixtures containing less than 0,2 percent of alkaloids, calculated as emetine. (NS2)

Enilconazole if intended for application to the skin. (NS2)

Ephedrine, oral preparations and mixtures containing not more than 30 milligrams of ephedrine per dose, when in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, subject to a maximum pack size of 720 milligrams and limited to one pack per customer; (NS4)

Epinastine.

Ergot alkaloids (natural or synthetic), if intended for the treatment of migraine. (NS2)

Ergotamine.

Escin (aescin), medicinal preparations and mixtures thereof intended for application to the skin and containing 1,0% or less of escin. (NS2)

Estradiol.

- (a) when intended for human vaginal use;
- (b) except when intended for oral contraception; (NS2)
- (c) except when intended for hormone replacement therapy. (NS2)

(d) except if intended for veterinary use (NS2)

Ethacridine.

Ether (diethyl ether), all substances, preparations and mixtures containing less than 20% of ether. (NS3)

Ethyl chloride.

Ethylmorphine, preparations and mixtures if compounded with one or more therapeutically active substances and containing 20 milligrams or less of ethylmorphine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of ethylmorphine (calculated as base) per 5 millilitre dosage unit. (NS4)

Ethylphenylephrine.

Etofenamate, including preparations intended for application to the skin. (NS2).

**Etilefrine** 

Etodroxizine, except preparations and mixtures thereof if used solely as an antihistamine. (NS3)

Exalamide.

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

- (a) a maximum dose of 10 milligrams;
- (b) a maximum daily dose (per 24 hours) of 20 milligrams; and
- (c) a maximum treatment period of 2 weeks. (NS2).

Fedrilate.

Felbinac, including preparations intended for application to the skin.

Fenbendazole, except if intended for veterinary use (NS0).

Fenoprofen, if intended for the emergency treatment of acute gout attacks and for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (NS2)

Fenoterol, if not contained in respirator solutions (NS2) and if not intended for injection or for the prevention or delay of labour. (NS2)

Fenticonazole, including preparations intended for application to the skin.

Fexofenadine.

Flubendazole, except if intended for veterinary use (NS0).

Flucytosine, if intended for application to the skin. (NS2)

Flufenamic acid, if intended for application to the skin. (NS2)

Flunarizine.

Flunisolide, (See corticosteroids)

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. (NS2)

Fluorescein, if intended for ophthalmic use. (NS2)

Fluorides, oral medicinal preparations and mixtures thereof containing 0.25 milligrams or more of fluorine as fluoride per recommended daily dose, unless listed in another schedule. (NS2)

Flurbiprofen -

- (1) if intended for application to the skin, including by transdermal patch, provided that in the case of application by transdermal patch indications are for use by adults and children of the age of 12 years and older and the treatment period is limited to 4 weeks (NS2);
- (2) if intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (NS2)

Fluticasone propionate, (See corticosteroids).

#### 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. (NS2)
  - (b) except when intended for administration other than by inhalation or nasal administration.

#### 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; and
  - (ii) a maximum pack size limit of 120 doses. (NS2)
  - (b) except when intended for administration other than by inhalation or nasal administration. (NS2)

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. (NS0)

Formoterol.

Fusafungine.

Gadopentetic acid.

Gelsemium alkaloids substances, preparations and mixtures thereof.

Glycopyrronium.

Glycosaminoglycan polysulphate (previously mucopolysaccharide poly-sulphuric acid ester) if intended for application to the skin. (NS2)

Gramicidin, when intended for topical application to the epidermis, nares and external ear. (NS2)

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

Haemophilus influenzae vaccine (Hib).

Hepatitis B vaccine.

Halogenated hydroxyquinolines, if intended for application to the skin. (NS2)

Hexametazine.

Hexoprenaline, if not contained in respirator solutions (NS2) and if not intended for injection or for the prevention or delay of labour. (NS2)

Homatropine, preparations and mixtures thereof, but not ophthalmic preparations. (NS2)

Hormones (natural or synthetic, including recombinant forms), with either hormonal or anti-hormonal action, -

- (1) if intended for
  - (a) human vaginal use;
  - (b) specific emergency post coital contraception;
- (2) except
  - (a) contraceptions; (NS2)
  - (b) natural estrogen, and progestrogen, if intended for veterinary use (NS2); and
  - (c) BST (Bovine somatropin) if intended for veterinary use. (NS2)

Human pappillomavirus vaccine.

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; (NS0)
- (c) except when intended for ophthalmic use in preparations (except injectables) containing more than 0,1 percent;
- (d) except when intended for parenteral use; (NS2)
- (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, except

(a) if used as a single active ingredient in a maximum concentration of 1,0% in preparations intended for application to the skin, and hydrocortisone in a maximum concentration of 1.0 per cent used in combination with miconazole for topical application in the treatment of athlete's foot. (NS2)

#### (b) if intended for veterinary use (NS2)

Hydroquinone; preparations and mixtures containing 2 per cent or less thereof, if intended for application to the skin. (NS2)

O- $(\beta$ -hydroxyethyl) rutosides.

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

Icodextrin.

Ibuprofen when contained in oral medicinal preparations

- (a) containing ibuprofen in combination with one or more other active therapeutic substances and intended for the treatment of mild to moderate pain or fever of inflammatory origin for a maximum treatment period of 10 days where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight. (NS2)
- (b) containing ibuprofen as the only active therapeutic substance in oral liquid preparations in packs not exceeding 100 millilitres in volume or in oral solid preparations in packs exceeding 24 dosage units or divided doses, when intended for adults and children over the age of 1 year; for the treatment of mild to moderate pain of inflammatory origin for a maximum treatment period of 10 days, or for the treatment of fever of inflammatory origin or for the treatment of post-traumatic conditions where the recommended daily dose of ibuprofen for adults does not exceed 1,2 grams and for children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (NS2)
- (c) for the emergency treatment of acute gout attacks for a maximum treatment period of 5 days; (NS3)
- (d) except when intended for the treatment of haemodynamically significant patent ductus arteriosus in infants less than 34 weeks of gestational age. (NS2).

Idoxuridine, if intended for application to the skin. (NS2)

Indanazoline. (NS2)

Indomethacin,

- (a) when intended for the emergency treatment of acute gout attacks; (NS2)
- (b) except when intended for application to the skin. (NS2)

Influenza virus vaccine.

Insulin, in cases of emergency. (NS2)

Iopromide

Ipecacuanha alkaloids, substances, preparations and mixtures thereof containing less than 0,2% alkaloids, calculated as emetine. (Also see Schedule 2 under "Emetine".)

Irrigation fluids.

Iron,

- (a) in oral preparations or mixtures containing more than 24 mg of Iron per recommended daily dose alone or in combination with other active pharmaceutical ingredients;
- (b) except in preparations thereof for injection; (NS2)
- (c) except when intended for veterinary use (NS0).

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

Isoaminile.

Isoconazole, if intended for application to the skin and for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis. (NS2)

Isoprenaline (isoproterenol), if not contained in respirator solutions and if not intended for injection. (NS2)

Isopropamide.

Isoconazole, when intended for

- (a) human vaginal use specifically for the treatment of recurrent vaginal candidiasis (NS4); and
- (b) application to the skin. (NS2)

Isosorbide, in cases of emergency. (NS2)

Isothipendyl.

Ketoconazole, if intended for application to the skin except preparations and mixtures containing not more than 1.0 per cent ketoconazole if intended for the prevention and treatment of dandruff. (NS2)

#### 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. (NS2)
- (d) except when intended for application to the skin. (NS2)
- (e) except when intended for veterinary use (NS2)

### Ketotifen.

#### 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 ≥1 x 10° 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"; (NS0)
- (c) except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1 x 10<sup>8</sup> cfu probiotics per daily serving, provided no medicinal or general health claim is made.

#### Lactobacillus brevis,

- (a) in pharmaceutical preparations and mixtures with medicinal claim(s);
- (b) except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10° 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"; (NS0)
- (c) except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1 x 10<sup>8</sup> cfu probiotics per daily serving, provided no medicinal or general health claim is made.

#### Lactobacillus caucasicus,

- (a) in pharmaceutical preparations and mixtures with medicinal claim(s);
- (b) except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10° 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"; (NS0)
- (c) except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1 x 10<sup>8</sup> cfu probiotics per daily serving, provided no medicinal or general health claim is made.

# Lactobacillus casei,

- (a) in pharmaceutical preparations and mixtures with medicinal claim(s);
- (b) except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10° 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"; (NS0)
- (c) except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1 x 10<sup>8</sup> cfu probiotics per daily serving, provided no medicinal or general health claim is made.

#### Lactobacillus fermentum,

- (a) in pharmaceutical preparations and mixtures with medicinal claim(s);
- (b) except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 109 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"; (NS0)

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

#### Lactobacillus gasseri,

- (a) in pharmaceutical preparations and mixtures with medicinal claim(s);
- (b) except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10<sup>9</sup> 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"; (NS0)
- (c) except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1 x 10<sup>8</sup> cfu probiotics per daily serving, provided no medicinal or general health claim is made.

### Lactobacillus helveticus,

- (a) in pharmaceutical preparations and mixtures with medicinal claim(s);
- (b) except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10<sup>9</sup> 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"; (NS0)
- (c) except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1 x 10<sup>8</sup> cfu probiotics per daily serving, provided no medicinal or general health claim is made

# Lactobacillus johnsonii,

- (a) in pharmaceutical preparations and mixtures with medicinal claim(s);
- (b) except in pharmaceutical preparations and mixtures for one or more strains containing  $\geq 1 \times 10^9$  cfu per dosage unit with the general health claim: "When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut"; (NS0)
- (c) except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1 x 10<sup>8</sup> cfu probiotics per daily serving, provided no medicinal or general health claim is made

# Lactobacillus lactis,

- (a) in pharmaceutical preparations and mixtures with medicinal claim(s);
- (b) except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10<sup>9</sup> 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"; (NS0)
- (c) except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1 x 10<sup>8</sup> cfu probiotics per daily serving, provided no medicinal or general health claim is made.

#### Lactobacillus paracasei,

- (a) in pharmaceutical preparations and mixtures with medicinal claim(s);
- (b) except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10<sup>9</sup> 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"; (NS0)
- (c) except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1 x 10<sup>8</sup> cfu probiotics per daily serving, provided no medicinal or general health claim is made.

### Lactobacillus reuteri,

- (a) in pharmaceutical preparations and mixtures with medicinal claim(s);
- (b) except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10<sup>9</sup> 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"; (NS0)
- (c) except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1 x 10<sup>8</sup> cfu probiotics per daily serving, provided no medicinal or general health claim is made.

#### Lactobacillus rhamnosus,

- (a) in pharmaceutical preparations and mixtures with medicinal claim(s);
- (b) except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10<sup>9</sup> 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"; (NS0)
- (c) except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1 x 10<sup>8</sup> cfu probiotics per daily serving, provided no medicinal or general health claim is made.

# Lactobacillus salivarius,

- (a) in pharmaceutical preparations and mixtures with medicinal claim(s);
- (b) except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10<sup>9</sup> 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"; (NS0)
- (c) except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act 54 of 1972) containing no less than 1 x 10<sup>8</sup> cfu probiotics per daily serving, provided no medicinal or general health claim is made.

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

- (a) a maximum daily dose of 15mg;
- (b) a maximum treatment period of 14 days. (NS2)

Lead acetate, when intended for veterinary use (NS0).

Lead plaster and its combinations.

Levocabastine.

#### Levocetirizine

#### Levonorgestrel,

- (a) when intended for emergency post coital contraception;
- (b) except when intended for oral contraception; (NS2)
- (c) except when administered via an Intra Uterine System. (NS2)

#### 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; (NS2)
- (d) except when intended for the treatment of neuropathic pain associated with previous herpes zoster infection. (NS2)
- (e) except when intended for veterinary use (NS2)

Lignocaine - see Lidocaine.

Lithium salts, if intended for application to the skin. (NS2)

Lobelia alkaloids; substances, preparations and mixtures thereof except if intended for ophthalmic use and parenteral use.

### Local anaesthetics, except

- (a) when intended for ophthalmic or parental use; (NS2)
- (b) oxybuprocaine, proxymetacaine and tetracaine, when contained in eye drops intended for emergency treatment of "arc eyes"; (NS2) and
- (c) ophthalmic preparations for veterinary use (NS0)

Lobelia alkaloids.

Lodoxamide.

Loperamide.

Loratadine.

Lufenuron, except if intended as a systemic preparation against fleas for veterinary use (NS0).

Luxabendazole, except if intended as an anthelmintic for sheep, goats and cattle (NS0).

Lysozyme, if intended for application to the skin. (NS2)

# Magnesium,

(a) 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. (NS0)

(b) except when intended for veterinary use (NS0)

Macrogolethers, if intended for human vaginal use, but not if intended for spermicidally lubricated condoms.

Malathion, if not intended as an ectoparasiticide for veterinary use (NS0).

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; (NS0)
- (b) in preparations thereof for injection when intended for veterinary use (NS0).

Measles vaccine.

Mebendazole, except if intended and registered as an anthelmintic for veterinary use (NS0).

Mebeverine.

Mebhydrolin.

Meclozine.

Mefenamic acid, if intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days, and preparations containing mefenamic acid as the only therapeutically active substance, if intended for the treatment of primary dysmenorrhoea, if the maximum daily dose is 500 milligrams 3 times a day and the maximum treatment period is 3 days. (NS2)

Melatonin, when used for the treatment of desyncronosis (jet-lag) in doses not exceeding 6 milligrams daily. (NS2).

Monoethanolamine.

Mepenzolate bromide.

Mephenesin.

Mepyramine.

Mequitazine.

Mercuric ammonium chloride.

Mercuric chloride.

Mercuric iodide.

Mercuric oxides, substances, preparations and mixtures thereof, but not those containing less than 3,0% of mercury.

Mercury organic compounds, substances, preparations and mixtures in the form of aerosols intended for application to the skin and mucous membranes and substances, preparations and mixtures containing the equivalent of 0,6 percent or more of elemental mercury, intended for application to the skin and mucous membranes except phenylmercuric nitrate if intended for veterinary use (NS0).

Metacresol sulphonic acid formaldehyde, includining preparations intended for human vaginal use.

Metaproterenol (orciprenaline), if not contained in respirator solutions (NS2) and if not intended for injection or for the prevention or delay of labour. (NS2)

Methenamine (hexamine),

- (a) if intended for application to the skin; (NS2)
- (b) except if intended as a urinary tract antiseptic for veterinary use (NS2).

Methionine, if intended for medicinal purposes.

Methixene.

Methocarbamol; if intended for medicinal purposes.

Methoxyphenamine.

Metronidazole, except

- (a) when intended for human vaginal use, specifically for the treatment of recurrent bacterial vaginosis (NS2)
- (b) when intended and registered for use in pigeons for veterinary use (NS0)

Miconazole,

- (a) when intended for human vaginal use specifically for the treatment of recurrent vaginal candidiasis; (NS2) and
- (b) when intended for application to the skin. (NS2)
- (c) except for topical treatment of fungal infections of the mouth. (NS2)

Microfibrillar collagen hydrochloride.

Molybdenum and derivatives thereof in oral preparations or mixtures containing more than 230  $\mu$ g of Molybdenum per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (NS0)

Morantel except when registered as an anthelmintic for veterinary use (NS0).

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. (NS2)

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. (NS2)

Mizolastine.

Morphine, mixtures containing 0,2% or less of morphine, calculated as anhydrous morphine. (NS4)

Mumps vaccine.

Mupirocin, when intended for application to the skin, nares and external ear. (NS4)

Mycobacterium bovis vaccine (BCG)

N-acetyl-aspartyl-glutamic acid.

Nabumetone, if intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (NS2)

Naphazoline, except when intended for nasal use.

#### Naproxen

- (a) when contained in preparations intended for application to the skin; (NS2)
- (b) when contained in oral medicinal preparations containing naproxen as the only active therapeutic substance intended for patients over 16 years of age, for the treatment of mild to moderate pain or fever of inflammatory origin at a maximum dose of 600 milligrams naproxen base (660 milligrams naproxen sodium) in a 24 hour period for a maximum treatment period of 5 days and supplied in a solid dose form as divided doses contained in packs not exceeding the stated maximum treatment period. (NS2)

Natamycin, when intended for application to the skin, nares and external ear. (NS2)

Nedocromil.

Nicergoline.

Niacin (Nicotinic Acid, Vitamin B3),

- (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;
- (b) except when intended for hypercholesterolaemia and for the management of dyslipidaemias.
- (c) except when intended for veterinary use. (NS0, NS2)

Nicotinamide, 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, except when intended for veterinary use (NS0)

### Nicotine,

- (a) when registered for human medicinal use as an aid to smoking cessation and presented as nicotine gum or lozenges containing more than 4mg nicotine per piece;
- (b) when registered as metered sprays containing 1mg per dose or less;
- (c) when registered as oral solid dosage forms containing 2mg or less;
- (d) when registered as inhalers containing 10mg or less per cartridge;
- (e) when intended for human medicinal use as an aid to smoking cessation, when registered and presented as nicotine transdermal patches for continuous application to the skin in strengths containing more than 21mg/24 hours or 25 mg/16 hours;
- (f) except when registered for human medicinal use as an aid to smoking cessation and presented as nicotine gum or lozenges containing not more than 4mg nicotine per piece; (NS0)
- (g) except when intended for human medicinal use as an aid to smoking cessation, when registered and presented as nicotine transdermal patches for continuous application to the skin in strengths up to an including 21mg/24 hours or 25 mg/16 hours;

(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). (NS2)

Nitrofurantoin, if intended for application to the skin. (NS2)

Nitrofurazone, if intended for application to the skin. (NS2)

Nitroglycerine, if intended for medicinal use in cases of emergency.(NS2)

Nitroscanate.

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

- (a) a maximum dose of 150 milligrams;
- (b) a daily dose of 300 milligrams;
- (c) a maximum treatment period of two weeks. (NS2)

Norcodeine, preparations and mixtures if compounded with one or more therapeutically active substances and containing 20 milligrams or less of norcodeine (calculated as base) per dosage unit and liquid preparations and mixtures containing 20 milligrams or less of norcodeine (calculated as base) per 5 millilitre dosage unit (NS4)

Normal Saline (Sodium chloride 0,9 percent m/v) when intended for injection, in a dosage form not exceeding 20 millilitres in volume. (NS2)

Noscapine.

Nux vomica; substances, preparations and mixtures thereof, except when intended for veterinary use (NS0).

#### 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, (NS2)
- (d) except when intended for systemic use or the initial treatment of vaginal candidiasis, (NS2)
- (e) except when intended and registered as a stock remedy for pigeons for veterinary use (NS0) and when presented as oral drops containing not more than 100 000 I.U. per millilitre for veterinary use (NS2)

Octatropine methylbromide.

Oleoresin of aspidium (Filix Mas.)

Olopatadine

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

- (a) a maximum daily dose of 20 milligrams
- (b) a maximum treatment period of 14 days. (NS2)
- (c) except when intended for veterinary use (NS2)

Opium, mixtures containing not more than 0,2% of morphine, calculated as anhydrous morphine. (NS4)

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. (NS2)

Ornidazole, if intended for application to the skin. (NS2)

Orphenadrine.

Orthodichlorobenzene, if intended for topical human medicinal use.

Otilonium bromide.

Oxetacaine (Oxethazaine),

- (a) in oral preparations containing an antacid;
- (b) except when intended for ophthalmic or parenteral use. (NS2)

Oxibendazole, except if intended and registered as an anthelmintic for veterinary use (NS0).

Oxybuprocaine, if contained in eye drops intended for emergency treatment of arc eyes. (NS2)

Oxymetazoline

Oxyphencyclimine.

Oxyphenonium.

Pancreatin.

Pancrelipase.

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. (NS2)

Papaverine, substances, preparations and mixtures thereof.

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"; (NS0)
- (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"; (NS0)
- (c) when contained in rectal suppositories.
- (d) when contained in modified release formulations.
- (e) when intended for injection. (NS2)

### Paradichlorobenzene

Penciclovir, if intended for application to the lips in the early treatment of recurrent Herpes simplex virus infections. (NS2)

Pentaerythritol tetranitrate, in cases of emergency. (NS2)

Pentosan polysulfate sodium except if intended for the treatment of interstitial cystitis. (NS2)

Pentoxifylline.

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

Pertussis toxoid vaccine.

Phenazone (antipyrone). (NS0)

Phenazopyridine.

Phenindamine.

Pheniramine

Phenylephrine, but not ophthalmic preparations containing 0,2% or less of phenylephrine. (NS0)

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

Phenyltoloxamine.

Pholedrine.

Pholcodine, preparations and mixtures if compounded with one or more therapeutically active substances containing 20 milligrams or less of pholcodine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of pholcodine (calculated as base) per 5 millitre dosage unit. (NS4)

Pholedrine.

Phospholipids, if 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.

- (a) if less than 250mg per recommededed daily dose and
- (b) if intended for veterinary use (NS0)

Pimethixene, preparations and mixtures thereof when used solely as an antihistaminic. (NS3)

Pinaverium.

Pipenzolate.

Piperonyl butoxide, if not intended and registered as an ectoparasiticide for veterinary use (NS0).

#### Pipoxolan.

Pirbuterol, if not contained in respirator solutions. (NS2)

Piroxicam, if intended for the emergency treatment of acute gout attacks and for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (NS2)

Pizotifen, preparations and mixtures, if intended for prophylaxis of migraine. (NS3)

Podophyllum resin, preparations and mixtures containing 20% or less thereof. (NS2)

Poldine methylsulphate.

Polymixin B, when intended for topical application to the epidermis, nares or external ear. (NS2)

Polio vaccine.

#### Potassium.

- (a) in oral preparations or mixtures containing more than 20 millimoles (1500mg) of potassium per 24 hours; (NS0)
- (b) except when intended for intravenous infusion or for injection; (NS2)

Povidone iodine, if intended for human vaginal use.

Pramoxine.

Prifinium bromide.

#### Prilocaine.

- (a) in topical preparations containing 10 percent or less of prilocaine;
- (b) except when intended for ophthalmic or parenteral use. (NS2)

Procaine hydrochloride, when intended for oral administration.

Procaterol, if not contained in respirator solutions.(NS2)

Procyclidine.

Proglumide.

Proguanil; if used in combination with chloroquine if intended specifically for malarial prophylaxis (NS2).

Promethazine; preparations and mixtures if intended for use as an antihistamine, for application to the skin and if intended specifically for the treatment of travel sickness. (NS3)

Propantheline bromide.

Propentofylline, if intended for veterinary use. (NS2)

Propylhexedrine, if used as a vasoconstrictor and decongestant in nose preparations and inhalants. (NS2)

Propyphenazone.

Proteolytic (fibrinolytic) enzymes for oral use and if intended for application to the skin, unless listed in another Schedule, but not if intended for injection and if intended for soft contact lens cleaners. (NS2)

Proxymetacaine, if contained in eye drops intended for emergency treatment of arc eyes. (NS2)

Pseudoephedrine,

oral preparations and mixtures containing not more than 60 milligrams of pseudoephedrine per dose, and not more than 240 milligrams per day, when in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, subject to a maximum pack size of 720 milligrams and limited to one pack per customer. (NS4)

Pyrantel pamoate, except when intended and registered as an anthelmintic for veterinary use (NS0)

Pyridoxilate.

Pyrobutamine.

Pyridoxine - see Vitamin B6.

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

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. (NS2)

Riboflavin - see Vitamin B2.

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

- (a) a maximum dose of 75 milligrams;
- (b) a daily dose of 300 milligrams;
- (c) maximum treatment period of 14 days. (NS2)

Reproterol, if not contained in respirator solutions. (NS2)

Rimiterol, if not contained in respirator solutions and if not intended for injection. (NS2)

Rotavirus, live attenuated

Rubella vaccine.

Rupatidine.

Sabadilla alkaloids; substances, preparations and mixtures containing 1.0 per cent or more thereof.

Salbutamol, if not contained in respirator solutions and if not intended for injection. (NS2)

Salmefamol, if not contained in respirator solutions and if not intended for injection. (NS2)

Salmeterol.

Selenium,

- (a) in oral preparations or mixtures containing more than 60 μg of Selenium per recommended daily dose alone or in combination with other active pharmaceutical ingredients;
- (b) except in preparations thereof for injection when intended for veterinary use. (NS0)

Sertaconazole, if intended for application to the skin. (NS2)

Siccanin, if intended for application to the skin.

Silver sulphadiazine, if 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. (NS2)

Sodium cromoglycate, if not intended for veterinary use. (NS2)

Sodium fluoride; preparations and mixtures thereof containing 40 milligrams or more per daily dose. (NS2)

Sodium pentosan polysulphate.

Solcoseryl, preparations thereof intended for application to the skin, to the mucous membranes of the mouth and to the lips. (NS2)

Strychnine, preparations and mixtures containing 0,2 percent or less thereof. (NS2)

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. (NS2)

Sulphonamides, if intended for application to the eyes, nares, and vagina. (NS2), except if intended for veterinary use (NS0)

Terbinafine, if intended for application to the skin. (NS2)

Terbutaline, if not contained in respirator solutions. (NS2)

Tetanus vaccine, except for veterinary use (NS0).

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"; (NS2)
- (d) except when intended for ophthalmic or parenteral use. (NS2)

Tetrahydrozoline, except when intended for nasal use.

Thenalidine.

Thenyldiamine.

Theophylline, unless listed in another Schedule, if not intended for injection. (NS2)

Thiabendazole, if intended for application to the skin. (NS2)

Thiethylperazine.

Thiomersal.

Thiram, if not intended and registered as a fungicide for veterinary use (NS0).

Tiaprofenic acid, if intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (NS2)

Ticlatone; if intended for application to the skin.

Timepidium.

Tioconazole, if intended for application to the skin and for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis. (NS2)

Tiotropium

Tolmetin, if intended for application to the skin. (NS2)

Triamcinolone, if intended for application to oral lesions. (NS2)

Trimebutine.

Trimeprazine (Alimemazine)

Tripelennamine.

Triprolidine

Trospium.

L-tryptophan,

- (a) when intended for medicinal use in dosages of less than 5 milligrams/kg/day or
- (b) intended as supplementation for nutritional purposes. (NS3)

Tuberculin, if intended for human use. (NS2)

Tulobuterol, if not contained in respirator solutions. (NS2)

Typhoid vaccine.

Tyrothricin when intended for topical application to the epidermis, nares and external ear. (NS2)

Vaccines, except for veterinary use (NS0, NS2)

Vitamin A excluding isotretinoin, 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 intended for veterinary use. (NS2, NS0)

Vitamin B1 (Thiamine),

- (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;
- (b) except in preparations thereof for injection.
- (c) except when intended for veterinary use (NS0, NS2)

Vitamin B2 (Riboflavin),

- (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;
- (b) except in preparations thereof for injection.
- (c) except when intended for veterinary use (NS0, NS2)

Vitamin B5 (Pantothenic Acid),

- 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;
- (b) except in preparations thereof for injection.
- (c) except when intended for veterinary use (NS0, NS2)

Vitamin B6 (Pyridoxine),

- (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;
- (b) except in preparations thereof for injection.
- (c) except when intended for veterinary use (NS0, NS2)

Vitamin B12 (Cyanocobalamin),

- (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;
- (b) except in preparations thereof for injection.
- (c) except when intended for veterinary use. (NS0, NS2)

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;
- (b) except in preparations thereof for injection.
- (c) except when intended for veterinary use (NS0, NS2)

Vitamin E, contained in preparations or mixtures containing more than 400 I.U. of Vitamin E per recommended daily dose, except when intended for veterinary use. (NS0)

Vitamin H (Biotin),

- 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.
- (b) except when intended for veterinary use (NS0)

Vitamin K (Phytomenadione),

- (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;
- (b) except in injection preparations;
- (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).
- (d) except when intended for veterinary use. (NS0, NS2)

Water for Injection in a dosage form not exceeding 20 milliliters in volume. (NS2)

Xylometazoline, when intended for nasal use. (NS2)

# **SCHEDULE 2**

4-aminosalicylic acid (para-aminosalicylic acid).
Abacavir.
Abatacept
Abciximab.
Abiraterone
Acamprosate.
Acarbose.
Acebutolol.
Aceclofenac.
Acediasulfone.
Acertarsone diethylamine salt, including preparations intended for injection.
Acetazolamide.
Acetohexamide.
Acetylcholine, including preparations intended for ophthalmic use.
Acetylcysteine, when intended for injection or for the management of paracetamol overdosage. (NS1)
Acipimox.
Acyclovir, if not intended for application to the lips in the early treatment of recurrent Herpes simplex virus infections. $(NS1)$
Adalimumab.
Adapalene.
Adenosine.
Adrenaline, when intended for injection.
Afatinib.
Agalsidase Alfa.
Agalsidase beta.
Aglepristone.
Alatrofloxacin
Albendazole, except when intended and registered as an anthelmintic for veterinary use (NS0)
Alclofenac.
Alclometasone.
Alcuronium.
Aldesleukin.
Alefacept.
Alendronic acid.
Alemtuzumab.
Alfacalcidol.
Alfuzosin.
Alendronic acid.
Alginic Acid, 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. (NS0)
Alglucosidase alfa.
Alisapride.
Aliskiren
Allopurinol.
Almitrine.
Alosetron
Alpha-chymotrypsin, including preparations intended for ophthalmic use.

Alphacalcidol, except if intended for veterinary use (NS0). Alprenolol. Alprostadil. Alteplase (recombinant human tissue-type plasminogen activator) (r-tPA). Altrenogest for veterinary use. Amantadine. Ambrisentan. Amethocaine - see Tetracaine. Amifostine Amikacin. Amiloride. Aminoacridine. Aminoglutethimide. Aminolevulinic. Aminopyrine (amidopyrine). Amiodarone. Amiphenazole. Aminophenazone. Amlodipine Amprenavir. Amrinone. Amsacrine. Anagrelide. Anastrozole. Ancrod. Anthiolimine, including preparations intended for injection. Anticoagulants, preparations not intended for application to the skin. (NS1) Antihaemophilic factor. Anti-malarials, excluding the 4-aminoquinoline, 8-aminoquinoline, diguanide and diaminopyrimidine groups of compounds and preparations thereof intended specifically for malaria prophylaxis. (NS1) Antimicrobial substances (chemotherapeutic substances) synthesised in nature or the laboratory, being substances used in the specific treatment of infections, but not the following if intended for topical application to the skin, nares and external ear bacitracin (NS1); (i) (ii) gramicidin (NS1); (iii) griseofulvin (NS1); (iv) mupirocin (NS1); (v) natamycin (NS1);

- (vi)
- nystatin (NS1);
- polymyxin B (NS1); (vii)
- (viii) tyrothricin (NS1)
- when intended for use as -(b)
  - (i) disinfectants, being topical agents or preparations used to treat inanimate objects, materials or surfaces, and that destroys or inhibits the growth of pathogenic micro-organisms so treated in the non-sporing or vegetative state, rendering them harmful to neither health nor the quality of perishable goods; (NS0)
  - (ii) antiseptics, being topical agents or preparations used on skin and other living tissues, and that destroys or inhibits the growth of pathogenic micro-organisms so treated in the non-sporing or vegetative state, protecting health and preventing infection; (NS0) and
  - 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 microorganisms so treated in the non-sporing or vegetative state, thereby protecting health, the quality of perishable goods, and preventing infection. (NS0)

(c) except if intended for veterinary use as indicated below (NS0)

ampicillin, cloxacillin, dihydrostreptomycin, penethamate hydriodide and procaine benzylpenicillin; intramammary preparations thereof, containing tracer dye(s) and intended for the tratment of mastitis in cattle;

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

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

carnidazole, if intended for trichomonas in pigeons;

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

chlortetracycline; capsules thereof, for use in pigeons;

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

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

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

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

hygromycin, if intended as an anthelmintic for pigs;

oxytetracycline;

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

tylosin, if intended for addition to drinking water and feedstuff for administering to poultry and pigs.

Antisera, unless listed elsewhere in the Schedules when intended for veterinary use, except antisera intended for veterinary use (NS0)

Apixaban.

Apomorphine, if indicated for the treatment of erectile dysfunction. (NS1)

Apraclonidine.

Apramycin.

Aprepitant.

Aprotinin.

A-β arteether.

Arabinosylcytosine.

Arprinocid, except if intended and registered as an anticoccidial preparation for poultry (NS0)

Arsanilic acid.

Arsenamide, including preparations intended for injection.

Artemether.

Artemisinin.

Artemotil.

Artesunate.

Ascorbic Acid – also see Vitamin C,

- (a) in preparations thereof for injection;
- (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. (NS1)
- (c) except in oral preparations or mixtures containing less than 1000 mg of Vitamin C per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (NS0)L-Asparaginase.

Astemizole.

Atazanavir.

Atenolol.

Atipamezole.

Atorvastatin.

Atosiban.

#### Atovaquone.

Atracurium besilate.

#### Atropine,

- (a) when intended for use in injections.
- (b) except when intended for use in ophthalmic preparations. (NS1)
- (c) except when intended for veterinary use (NS1)

#### Auranofin.

Avilamycin, except when listed elsewhere in the Schedules and except when intended and registered to promote growth as a feed additive for veterinary use (NS0)

Avoparcin, except when listed elsewhere in the Schedules and except when intended and registered to promote growth as a feed additive for veterinary use (NS0)

Azacitidine.

Azapropazone.

Azathioprine.

Azithromycin.

Azlocillin.

Aztreonam

Bacitracin, except when intended for topical application to the epidermis, nares and external ear. (NS1) and except when intended for veterinary use (NS0)

Baclofen.

Balsalazide.

Bambermycin, except when listed elsewhere in the Schedules and except when intended and registered to promote growth as a feed additive for veterinary use (NS0)

Barium sulfate.

Barnidipine.

Basiliximab.

Bacampicillin.

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. (NS1)

Bedaquiline.

Belatacep.

Bemegride.

Bemiparin.

Benazepril.

Bendamustine.

Bendazac.

Benethamine penicillin

Benfluorex.

Benoxaprofen.

Benzathine phenoxymethylpenicillin

Benzbromarone.

# Benzocaine,

- (a) when intended for ophthalmic or parenteral use;
- (b) except in lozenges containing 30 milligrams or less of benzocaine, per dosage unit; (NS1)
- (c) except when intended for topical use; (NS1)
- (d) except in preparations containing 2 percent or less of benzocaine. (NS1)

6749 Government Gazette 31 October 2018 31 Benzydamine, but not preparations and mixtures containing -3% or less of benzydamine, if intended for application to the skin and 0,15 percent or less of benzydamine when intended for use as a mouthrinse or for topical application (b) in the mouth and throat: Provided that the total dose swallowed does not exceeds 36 milligrams of benzydamine per day. (NS1) Benzylpenicillin. Bepridil. Beta-benzalbutyramide. Beta-galactosidase, if intended for therapeutic purposes. Betahistine. Betamethasone. Betaxolol. Bethanechol. Bethanidine. Betiatide. Bevacizumab. Bevantolol. Bezafibrate. Bicalutamide. Bifonazole, except when intended for application to the skin. (NS1) Bimatoprost. Biolimus. Biologicals, injectable preparations thereof. (b) except when intended for human medicinal use including injectable antivenoms; (NS1) except when listed in other schedules (c) Biperiden. Bisoprolol. Bleomycin. Boceprevir. Bopindolol. Bortezomib. Botulinum toxin. 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. (NS0) Brentuximab Bretylium tosylate. Brimonidine. Brinzolamide. Bromocriptine. Budesonide. Bufenoide. Bufexamac, except when intended for application to the skin. (NS1) Buflomedil. Buformin.

Bumadizone.
Bumetanide.
Bupivicaine.
Buserelin.
Busulphan.

Butecosone, when intended for inhalation or nasal administration.

Butoconazole, except -

- (a) when intended for application to the skin; (NS1) and
- (b) when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis.(NS1)

Cabazitaxel.

Cabergoline.

Cadralazine.

Caffeine, when intended for injection

Cefepime hydrochloride

Calcipotriol

Calcitonin.

Calcitriol.

Calcium carbimide.

Calcium,

- (a) in preparations thereof for injection;
- (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; (NS1)
- (c) except when intended for veterinary use (NS0)

Calcium disodium edetate, if intended for injection.

Calcium dobesilate.

Calcium polystyrene sulphonate, if intended for therapeutic purposes.

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). for veterinary use (NS0)

Canakinumab.

Candesartan.

Candicidin.

Capecitabine.

Capsaicin, when intended for transdermal application.

Capecitabine.

Capreomycin.

Captopril.

Carazolol.

Carbachol.

Carbadox, except when listed elsewhere in the Schedules and except when intended and registered to promote growth as a feed additive for veterinary use (NS0)

Carbamazepine.

Carbenicillin.

Carbenoxolone, except when intended for application to the oral mucosa. (NS0)

Carbetocin.

Carbidopa.

Carboplatin.

Carbuterol, if contained in respirator solutions and if intended for injection. (NS1)

Carbuterol, when contained in respirator solutions. (NS1)

Carmustine.

Carnidazole, except when listed elsewhere in the Schedules and except injections thereof intended for use in pigeons (NS0)

Carprofen.

Carteolol.

Carvedilol.
Casopitant.
Caspofungin
Cefaclor.
Cefadroxil.
Cefalexin.
Cefaloridine.
Cefalosporin.
Cefalotin.
Cefamandole.
Cefazolin.
Cefepime.
Cefixime.
Cefmetazole.
Cefodizime.
Cefonicid.
Cefoperazone.
Cefotaxime.
Cefotetan.
Cefovecin.
Cefoxitin.
Cefpirome.
Cefpodoxime.
Cefprozil.
Cefquinome.
Cefradine.
Cefsulodin.
Ceftaroline.
Ceftazidime.
Ceftibuten.
Ceftiofur.
Ceftizoxime
Ceftobiprole.
Ceftriaxone.
Cefuroxime.
Cefalotin
Celecoxib.
Celiprolol.
Cerivastatin.
Certoparin.
Ceruletide.
Cetrorelix.
Cetuximab.
Chenodeoxycholic acid.
Chlorambucil.
Chloramphenicol, not to be used in food producing animals.
Chlorazanil.
Chlordantoin, including preparations intended for human vaginal use.

Clopidogrel.

Cloprostenol, when intended for veterinary use.

Chlorexolone.
Choriogonadotropin alfa.
Chlormadinone.
Chloroquine
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.
Chlorquinaldol.
Chlorthalidone.
Cholestyramine resin.
Chorionic gonadotrophin
Chromonar.
Chymopapain, including preparations intended for injection.
Ciclacillin.
Ciclesonide
Ciclosporin.
Cilastatin.
Cilazapril.
Cinacalcet.
Cinoxacin.
Cilomilast.
Cimetidine, but not if intended for the short-term symptomatic relief of heart-burn, dyspepsia and hyperacidity, subject to -  (a) a maximum dose of 200 milligrams;  (b) a maximum daily dose (per 24 hours) of 800 milligrams; and  (c) a maximum treatment period of 14 days. (NS1)
Ciprofloxacin
Cisapride.
Cisatracurium.
Cisplatin. Cladribine.
Clanobutin.
Clarithromycin. Clavulanic acid.
Clazuril, except if intended and registered as an anticoccidial preparation for poultry (NS0)
Clerk to a l
Clenbuterol.
Clioquinol.
Clindamycin
Clobetasol.
Clobetasone
Clodantoin.
Clofazimine.
Clofibrate.
Clomiphene.
Clonidine, if intended for any other treatment than migraine. (NS1)

Closantel, except if intended as an anthelmintic for sheep and cattle (NS0)

Clotrimazole, if not intended for application to the skin and not intended for human vaginal use specifically for the treatment of recurrent vaginal candidiasis. (NS1)

Codeine (methylmorphine),

- (a) oral solid preparations, in combination with one or more therapeutically active substances, when contained in products;
- (b) liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, when contained in products;
- (c) except single component codeine preparations. (NS4)

Co-tetroxazine.

Co-trifamole

Co-trimoxazole.

Colchicine, except when intended for the emergency treatment of acute gout, subject to a maximum total treatment course of 6 milligrams. (NS1)

Colestipol.

Colfosceril.

Colistin.

Contrast media, unless listed elsewhere in the Schedules

#### Copper,

- (a) in preparations thereof for injection;
- (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. (NS1)
- (c) except when intended for veterinary use (NS0)

Corifollitropin alfa.

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

- (a) hydrocortisone and hydrocortisone acetate when used as a single active ingredient in a maximum concentration of 1,0 per cent in preparations intended for application to the skin; (NS1)
- (b) triamcinolone when intended for application to oral lesions; (NS1)

Cotetroxazine.

Cyclofenil.

Cyclandalate.

Cyclofenil

Cyclopentolate, ophthalmic preparations thereof. (NS1)

Cyclophosphamide, unless listed in another Schedule.

Cycloserine.

Cyclosporin.

Cyphenothrin (Pyrethroid), except when intended for veterinary use (NS0)

Cyprenorphine.

Cyproterone acetate.

Cytarabine.

Dabigatran

Dacarbazine.

Dacliximab.

Daclizumab.

Dactinomycin (actinomycin D).

Dalteparin.

Danaparoid.

Danofloxacin.

Dantrolene.

Dapagliflozin.

Dapsone, unless listed elsewhere in the Schedules.

Diftalone.

01/5
Daptomycin.
Darbepoetin Alfa
Darifenacin.
Darunavir.
Dasatinib.
Daunomycin (Daunorubicin).
Debrisoquine.
Decitabine.
Deconexent (DHA) 380, when indicated for the treatment of hypertriglyceride levels
Decoquinate, except when listed elsewhere in the Schedules and except when intended and registered as an anti-coccidial preparation for veterinary use (NS0)
Deferasirox.
Deferipone.
Deferoxamine.
Degarelix.
Delamanid
Delapril.
Demecarium.
Demeclocycline.
Denosumab
Deoxycholic acid
Desirudin.
Desogestrel and Ethnylestradiol
Desonide.
Desmopressin.
Desoximetasone.
Dexamethasone.
Dialysate preparations.
Diatrizoic acid.
Diazoxide.
Dichlorophen, but not preparations and mixtures intended for application to the skin (NS1) and not if intended as an anthelmintic for veterinary use (NS0)
Diclazuril, except if intended as an anticoccidial preparation for poultry (NS0)
Diclodronic acid.
Diclofenac, if not intended for application to the skin, not intended for emergency treatment of acute gout attacks and not intended for the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (NS1)
Dicloxacillin.
Dichlorphenamide.
Didanosine.
Dienogest.
Diethylcarbamazine.
Diflorasone.
Difloxacin.
Diflucortolone.
Diflunisal.
D:0.1

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

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Dihydralazine.	
Dihydroergocristine.	
Dihydrocodeine,	
<ul> <li>(a) oral solid preparations, in combination with one or more therapeutically contained in products registered in terms of the Act, and not intended for e</li> <li>(b) liquid oral preparations and mixtures, in combination with one or me substances, when contained in products registered in terms of the Act, and</li> <li>(c) except single component dihydrocodeine preparations. (NS4)</li> </ul>	export; ore therapeutically active
Dihydroergocristine.	
Dihydralazine.	
Dihydrotachysterol.	
Diiodohydroxyquinoline, except when intended as an anti-coccidial preparation for	or veterinary use (NS0)
Di-isopropyl fluorophosphate.	•
Dilazep.	
Dilevalol.	
Diloxanide furoate.	
Diltiazem.	
Dimercaprol, including preparations intended for injection.	
N,N-Dimethylformamide (DMF)	
Dimethyl sulphoxide.	
Diminazene, except when intended as an antibabesial for veterinary use (NS0).	
Dinitolmide, except when listed elsewhere in the Schedules and except when int preparation for veterinary use (NS0)	tended as an anti-coccidial
Dinitrophenol.	
Dinoprostone.	
Diphemethoxidine.	
Diphenidol.	
Dipivefrin.	
Diprenorphine.	
Dipyridamole.	
Dipyrocetyl.	
Disodium pamidronate.	
Disophenol, except if intended as an anthelmintic for sheep and goats (NS0)	
Disopyramide.	
Distigmine.	
Disulfiram.	
Ditazole.	
Dithranol.	
Dobutamine.	
Docetaxol.	
Dolasetron.	
Dolutegravir.	

Domperidone.

Dorzolamide. Doxapram.

Dornase alfa (rhDNase).

Dopa. Dopamine. Doripenem. Doxazosin.

Doxepin, if intended for application to the skin (NS3)

Doxorubicin.

Doxycycline,

- (a) except when intended and labelled for the chemoprophylaxis of malaria in those aged 8 years and older, for periods not exceeding 4 months of continuous use; (NS1)
- (b) except when intended for administration in animal feed (NS0);
- (c) when intended for veterinary use

Dronedarone.

Drospirenone,

- (a) when intended for oral contraception;
- (b) except when intended for hormone replacement therapy. (NS4)

Drotrecogin

Dutasteride.

Dydrogesterone.

Econazole, if not intended for application to the skin and for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis.(NS1)

Edoxudine.

Edrophonium.

Efavirenz.

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

Eletriptan.

Eltenac.

Eltrombopag.

Emetine, but not substances, preparations and mixtures containing less than 0,2% of alkaloids, calculated as emetine. (See ipecacuanha NS1).

Empagliflozin.

Emtricitabine

Enalapril.

Encainide.

Endralazine.

Enilconazole, except if intended for application to the skin. (NS1)

Enoxacin.

Enoxaparin.

Enramycin, except when intended to promote growth as a feed additive in veterinary use (NS0)

Enrofloxacine.

Entacapone.

Enzalutamide.

Epicillin.

Epinephrine, when intended for injection.

Epirizole.

Epirubicin (4-epidoxorubicin).

Eplerenone.

Epoetin beta, polyethylene glycol

Eprosartan.

Eptacog alfa.

Eptifibatide.

Ergometrine maleate.

Ergot alkaloids (natural or synthetic), preparations and mixtures thereof not intended for the treatment of migraine. (NS1)

6749 Government Gazette 31 October 2018 Eribulin. Erlotinib. Ertapenem. Etravirine. Erythromycin. Escin (aescin), but not preparations and mixtures thereof intended for application to the skin and containing 1,0% or less of escin. (NS1) Esculin, including preparations intended for oral use. Esmolol. Esomeprazole. Estradiol, when intended for oral contraception; (a) when intended for hormone replacement therapy (b) (c) except when intended for human vaginal use; (NS1) (d) when intended for veterinary use Estramustine. Etamiyan. Etanercept. Ethacrynic acid. Ethambutol. Ethionamide, including preparations intended for oral use. Ethopabate, except when listed elsewhere in the Schedules and except when intended as an anti-coccidial preparation for veterinary use (NS0) Ethoglucid. Ethosuximide. Etidronate. Etidronic acid. Etiproston. Etisazol. Etodolac. Etodolic acid. Etofamide. Etofenamate, except if intended for application to the skin. (NS1)

Etofenprox (Pyrethroid), except when intended for veterinary use (NS0)

Etoposide.

Everolimus.

Etoricoxib.

Exemestane.

Exenatide

Ezetimibe.

Famciclovir.

Famotidine, but not if intended for the short-term symptomatic relief of heartburn, dyspepsia and hyperacidity, subject to -

- a maximum dose of 10 milligrams; (a)
- a maximum daily dose (per 24 hours) of 20 milligrams; and (b)
- a maximum treatment period of 14 days. (NS1) (c)

Fampridine.

Fazadinium.

Febantel, except if intended as an anthelmintic for sheep, goats and cattle (NS0)

Felbamate.

Felbinac, except when intended for application to the skin. (NS1)

Felodipine.

Fenbufen.

Fenchlorphos, except when intended for veterinary use (NS0)

Fenclofenac.

Fendiline

Fenofibrate.

Fenoldopam.

Fenoprofen, if not intended for emergency treatment of acute gout attacks and not intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (NS1).

Fenoterol, if contained in respirator solutions and if intended for the prevention or delay of labour and preparations thereof for injection. (NS1)

Fentiazac.

Fenticonazole.

Fertirelin.

Ferucarbitran.

Ferric carboxymaltose

Ferric Hydroxide in Sucrose

Filgrastim.

Finasteride.

Fingolimod.

Flecainide.

Floctafenine.

Florfenicol.

Flosequinan.

Flucloxacillin.

Fluconazole.

Flucytosine, preparations and mixtures not intended for application to the skin. (NS1) (See corticosteroids)

Fludarabine.

Fludrocortisone acetate

Flufenamic acid, preparations and mixtures not intended for application to the skin. (NS1)

Flugestone.

Flumethasone.

Flunisolide, except when intended for inhalation or nasal administration. (NS1).

Fluocinolone.

Fluocinonide.

Fluocortolone.

Fluorides,

(a) except in oral medicinal preparations or mixtures intended for ingestion containing 0,25 milligrams or less of fluorine per dosage unit; (NS1) 5-Fluorouracil.

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 strenghth 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. (NS1)

Flunixin.

Fluorescein, except when intended for ophthalmic use by the topical route only. (NS1)

Fluorides; except oral medicinal preparations and mixtures thereof containing 0.25 milligrams or more of fluorine as fluoride per recommended daily dose, unless listed in another schedule (NS1).

## Fluprednidene.

# Flurbiprofen, except

- (a) when in the form of lozenges, indicated for the relief of pain associated with sore throats, subject to:
  - (i) a maximum of 8,75 milligrams per lozenge;
  - (ii) a maximum treatment period of 3 days; and
  - (iii) a maximum pack size of 15 lozenges. (NS1)
- (b) when intended for application to the skin, provided that in the case of application by transdermal patch:
  - (i) use is restricted to adults and children 12 years and older; and
  - (ii) the treatment period is limited to a maximum of 4 weeks. (NS1)
- (c) when intended for the treatment of post-traumatic conditions, for a maximum period of 5 days; (NS1)
- (d) when intended for ophthalmic use;

### Flutamide.

#### 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. (NS1)

# 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. (NS1)

## Fluvastatin.

Follitropin alfa.

Fondaparinux.

Formoterol.

Fosamprenavir.

Fosaprepitant.

Fosfomycin

Fosinopril.

Fosphenytoin sodium

Fotemustine.

Framycetin.

Ftorafur.

Fulvestrant.

Furaltadone, except when listed elsewhere in the Schedules and except when intended as a single oral dosage for gastro-intestinal infections and veterinary use (NS0)

Furazolidone

Furosemide.

Fusidic acid.

Gadobutrol.

Gadodiamide.

Gadofosveset

Gadoversetamide.

Gadoxetic acid.

Galactose, when used as a contrast agent
Galantamine.
Gelatine succinylated.
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. (NS1)
Ganciclovir.
Ganirelix.
Gatifloxacin.
Gefitinib
Gemcitabine.
Gemfibrozil.
Gemtuzumab.
Gemifloxacin.
Gentamicin
Gestodene.
Gestrinone.
Glafenine.
Glatiramer.
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 intended for veterinary use (NS0).
Glycosaminoglycan polysulphate (previously mucopolysaccharide poly-sulphuric acid ester), if not intended for application to the skin. (NS1)
Golimumab.
Gonadorelin
Goserelin.
Gramicidin except when intended for topical application to the epidermis, nares and external ear. (NS1)
Granisetron.
Granulocyte Colony Stimulating Factor (G-CSF).
Griseofulvin except when intended for topical application to the epidermis, nares and external ear. (NS1)
Grepafloxacin
Guanabenz.
Guanethidine.
Guanfacine.
Guanoxan.
Halcinonide.
Halofantrine.
Halofenate.
Halofunginone, but not if intended and registered as an anti-coccidial preparation for poultry (NS0)

Halogenated hydroxyquinolines, if not intended for application to the skin (S1).and except di iodohydroxyquinoline if intended and registered as an anticoccidial preparation for veterinary use (NS0)

Halometasone.

Halquinol

Hemin.

Heparin.

Heptaminol.

Hexoprenaline, when contained in respirator solutions. (NS1)

Homatropine, ophthalmic preparations thereof. (NS1)

#### Histrelin

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

- (a) contraceptions;
- (b) natural estrogen, and progestrogen, if intended for veterinary use; and
- (c) BST (Bovine somatropin) if intended for veterinary use.
- (d) except when specifically intended for emergency postcoital contraception; (NS1)
- (e) except insulin; (NS1)
- (f) except epinephrine; (NS1)
- (g) except corticotrophin (adrenocorticotrophic hormone; ACTH); (NS3)
- (h) except Human growth hormone (human somatotropin) all forms; (NS3)

Human fibrinogen, when indicated for use as a haemostatic.

Human Plasma.

Human thrombin, when indicated for use as a haemostatic

### Hyaluronidase.

Hyaluronic acid,

- (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.

Hydralazine.

Hydrochlorothiazide

Hydroquinone; preparations and mixtures thereof containing less than 2.0 per cent hydroquinone. (NS1).

Hydroxypropyl methylcellulose when intended for opthalmic use (NS0)

Hydroxycarbamide. (Hydroxyurea)

Hydroxychloroquine.

Hylan.

Ibandronic acid.

Ibuprofen,

when intended for the treatment of haemodynamically significant patent ductus arteriosus in infants less than 34 weeks of gestational age except when used in oral medicinal preparations

- (a) containing ibuprofen in combination with one or more other active therapeutic substances and intended for the treatment of mild to moderate pain or fever of inflammatory origin for a maximum treatment period of 10 days where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (NS1)
- (b) supplied in a solid dose form as divided doses contained in packs not exceeding 24 dosage units or divided doses and containing ibuprofen as the only active therapeutic substance, intended for the treatment of mild to moderate pain or fever of inflammatory origin or for the treatment of post-traumatic conditions in adults and children over 12 years of age where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children 12 years and older does not exceed 20 milligrams per kilogram of body weight; (NS1)

- (c) containing ibuprofen as the only active therapeutic substance in oral liquid preparations in packs not exceeding 100 millilitres in volume or in oral solid preparations in packs exceeding 24 dosage units or divided doses, when intended for adults and children over the age of 1 year; for the treatment of mild to moderate pain of inflammatory origin for a maximum treatment period of 10 days; or for the treatment of fever of inflammatory origin or for the treatment of post-traumatic conditions, where the recommended daily dose of ibuprofen for adults does not exceed 1,2 grams and for children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (NS1)
- (d) for the emergency treatment of acute gout attacks for a maximum treatment period of 5 days; (NS1)

Ibutilide.

Ibritumomab.

Idarubicin.

Idoxuridine, if not intended for application to the skin. (NS1)

Idursulfase.

Ifosfamide.

Iloprost.

Imatinib.

Imepitoin, when intended for veterinary use.

Imidapril.

Imidocarb, except if intended as an antibabesial for the treatment of babesiosis in veterinary use (NS0)

Imiglucerase.

Imiquimod.

Imipenem.

Indacaterol.

Indapamide.

Indinavir.

Indium chloride pentetreotide.

Indomethacin, if not intended for application to the skin and if not intended for the emergency treatment of acute gout attacks. (NS1)

Indoprofen.

Indoramin.

Infliximab.

Injections, unless listed in another Schedule.

Inosiplex (inosine pranobex).

Insulin, but not in cases of emergency. (NS1)

Insulin aspart.

Insulin degludec.

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.

Ipratropium, when contained in respirator solutions. (NS1)

Irbesartan.

Irinotecan

Iron,

- (a) in preparations thereof for injection;
- (b) except in oral preparations or mixtures containing more than 24 mg of Iron per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (NS1)
- (c) except when intended for veterinary use (NS0)

Isepamicin.

Isoconazole, if not intended for application to the skin and not intended for human vaginal use, specifically for the treatment of recurrent vaginal candidasis. (NS1)

Isoniazid.

Isopirin.

Isoprenaline (isoproterenol), if contained in respirator solutions and if intended for injection. (NS1)

Isosorbide.

Isoxicam.

Isoxsurprine.

Isradipine.

Itraconazole.

Ivabradine.

Ixabepilone.

Ivermectin, except if intended as an anthelmintic and or ectoparasiticide for veterinary use (NS0)

Josamycin.

Ketanserin.

Ketoconazole, if not intended for application to the skin and if not preparations and mixtures containing not more than 1.0 per cent of ketoconazole if intended for the prevention and treatment of dandruff. (NS1)

Ketoprofen, for veterinary use and if not -

- (a) intended for application to the skin (NS1);
- (b) 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 asspociated with the common cold and fever, at a maximum dose of 75 milligrams of ketoprofen in 24 hours. (NS1);
- (c) intended for the emergency treatment of acute gout attacks and if not intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, at a maximum dose of 75 milligrams, for a maximum period of 5 days. (NS1)
- (d) 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. (NS1)

Ketorolac, when intended for ophthalmic use.

L-Asparaginase.

L-tryptophan, if intended for medicinal use, but not if intended for medicinal use as supplementation for nutritional purposes. (NS1)

Labetalol.

Lacidipine.

Lacosamide.

Lumiracoxib.

Lamivudine.

Lamotrigine.

Lanreotide.

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

- (a) a maximum daily dose of 15 mg;
- (b) a maximum treatment period of 14 days.(NS1)

Lanthanum.

Lapatinib.

Laronidase.

Laropiprant.

Lasalocid, except when listed elsewhere in the Schedules and except when intended as an anti-coccidial preparation for veterinary use (NS0)

Latamoxef.

Latanoprost.

Leflunomide.

Lenalidomide.

Lenograstim.

Lepirudin.

Lercanidipine.

Letrozole.

Leuprolide acetate.

Levetiracetam.

Levallorphan.

Levamisole, except if intended as an anthelmintic and an immunomodulator for veterinary use (NS0)

Levobunolol.

Levobupivacaine.

Levodopa.

Levofloxacin.

Levonorgestrel,

- (a) when intended for oral contraception
- (b) when administered via an Inta-Uterine System.
- (c) except when intended for emergency post coital contraception; (NS1)

Levosemindan.

Levothyroxine

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) when intended for veterinary use
- (d) except when intended for topical use; (NS1)
- (e) except in oral preparations containing 2 percent or less of lidocaine per dosage form. (NS1)

Lidoflazine.

Lignocaine, see Lidocaine.

Linagliptin

Lincomycin.

Linezolid

Liothyronine sodium.

Liraglutide.

Lisinopril.

Lixisenatide.

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

- (a) when intended for topical use; (NS1)
- (b) oxybuprocaine, proxymetacaine and tetracaine when contained in eye drops intended for emergency treatment of "arc eyes"; (NS1).

Lomefloxacin.

Lomustine.

Lonazolac.

Lopinavir.

Loracarbef.

Lornoxicam.

Losartan.

Loteprednol.

Lovastatin

Loxapine.

Lovastatin.

Lumefantrine.

Luprositol, when intended for veterinary use.

Lutropin alfa

Lymecycline.

Lysozyme, preparations and mixtures thereof not intended for application to the skin. (NS1)

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, (NSO).

Maduramicin, except when listed elsewhere in the Schedules and except when intended as an anti-coccidial preparation for veterinary use (NS0)

Mafenide.

Mangafodipir trisodium.

Mandelic acid.

Maraviroc.

Marbofloxacin

Maropitant, when intended for veterinary use.

Mavacoxib.

Mecamylamine.

Mecillinam.

Meclofenamic acid.

Medical gases, when used in combination with nitrous oxide, but excluding such medical gasses when used alone or in combinations that exclude nitrous oxide. (NS0)

Medroxyprogesterone.

Mefenamic acid, if not intended for the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days, but not preparations containing mefenamic acid as the only therapeutically active substance if intended for the treatment of primary dysmenorrhoea, if the maximum daily dose is 500 milligrams of mefenamic acid 3 times a day and the maximum treatment period is 3 days. (NS1)

Methysergide.

Mefloquine.
Meglumine diatrizoate sodium or Meglumine amidotrizoate sodium
Meglumine gadobenate.
Meglumine gadoterate.
Meglumine iodipamide.
Meglumine ioglycamate.
Meglumine iotalamate.
Meglumine iotroxate.
Meglumine pentetate
Melagatran.
Melatonin, except when used for the treatment of desyncronosis (jet-lag) in doses not exceeding 6 milligrams daily. (NS1).
Melarsoprol
Melitracene.
Meloxicam.
Melphalan.
Memantine.
Menotrophin
Mepacrine.
Mephentermine.
Mepindolol.
Mepirizole.
Mepivicaine.
Meropenem
2-mercaptopurine glycine.
6-mercaptopurine.
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. (NS1)
Mesalazine (5-aminosalicylic acid).
Mesna
Mesulphene.
Metaproterenol (orciprenaline), when contained in respirator solutions.
Metergoline.
Methacholine.
Metformin.
Methampyrone (dipyrone).
Methazolamide.
Methenamine (hexamine),
(a) if not intended for application to the skin; (NS1)
(b) if intended as a urinary tract antiseptic for veterinary use
Methimazole.
Methotrexate.
Methoxsalen.
Methyl-5-aminolevulinate.
Methsuximide.
Methyldopa
Methylnaltrexone.
Methylprednisolone.

6749 Metipranolol. Metoclopramide. Metolazone. Metomidate. Metoprolol. Metrizoic acid. Metronidazole, except when intended for use in pigeons (NS0) intended for human vaginal use, specifically for the treatment of recurrent bacterial vaginosis. (NS1) (b) Mexiletine. Mezlocillin. Mibefradil. Micafungin. Miconazole, if not intended for application to the skin, if not intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis and if not intended for human use in preparations containing 2% or less of miconazole, if intended for the topical treatment of fungal infections of the mouth (oral candidiasis). (NS1) Mifepristone. Miglitol. Milrinone. Miltefosine. Minocycline. Minoxidil, except when intended for application to the scalp in preparations containing not more than 2 percent (m/v) (NS1) Mitomycin C. Mitoxantrone. Mivacurium. Mizolastine. Moexipril Mofebutazone. Molgramostim. 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; a maximum pack size of 200 doses. (NS1) Monensin except when listed elsewhere in the Schedules and except when intended as an anti-coccidial preparation and as a feed additive for growth promotion in veterinary use (NS0) Montelukast. Moracizine. Morazone. Morinamide promolate. Morphazinamide. Morphethylbutyne.

Moxifloxacin.

Moxonidine.

Mucoglucuronan.

Muromonab.

Mupirocin, except when intended for topical application to the epidermis, nares and external ear. (NS1)

Mycophenolate Mofetil

Mycophenolic acid.

Mycoplasma gallisepticum (Strain F) vaccine, except when intended for veterinary use (NS0)

Nabumetone, if not intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (NS1)

Nadolol.

Nadroparin.

Naftidrofuryl.

Nalidixic acid.

Nalorphine.

Naloxone.

Naltrexone.

Naproxen, except

- (a) when contained in preparations intended for application to the skin; (NS1)
- (b) when contained in oral medicinal preparations containing naproxen as the only active therapeutic substance intended for patients over 16 years of age, for the treatment of mild to moderate pain or fever of inflammatory origin at a maximum dose of 600 milligrams naproxen base (660 milligrams naproxen sodium) in a 24 hour period for a maximum treatment period of 5 days and supplied in a solid dose form as divided doses contained in packs not exceeding the stated maximum treatment period. (NS1)
- (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. (NS1)

Narasin except when listed elsewhere in the Schedules and except when intended as an anti-coccidial preparation for veterinary use (NS0)

Naratriptan.

Natalizumab.

Natamycin, except when intended for topical application to the epidermis, nares and external ear. (NS1)

Nateglinide.

Nebivolol.

Nefopam.

Nelfinavir.

Neomycin

Neostigmine.

Neotizide.

Nepafenac.

Netilmicin.

Netobimin.

Nevirapine.

Nicarbizin, except if intended as an anticoccidial preparation for veterinary use (NS0)

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; (NS0)
- (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; (NS1)
- (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; (NS1)
- (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; (NS1)

- (f) except when registered as metered sprays containing not more than 1 mg per dose; (NS1)
- (g) except when registered as oral solid dosage forms containing not more than 2 mg; (NS1)
- (h) except when registered as inhalers containing not more than 10 mg per cartridge. (NS1)

Nicorandil.

Nifedipine.

Niflumic acid.

Nifuratel.

Nifuroxazide.

Nifurtoinol

Nikethamide.

Nilotinib.

Nilutamide.

Nimesulide.

Nimodipine.

Nimorazole.

Nimotuzumab.

Nimustine.

Niridazole.

Nisoldipine.

Nitrendipine.

Nitrofurantoin, preparations thereof not intended for application to the skin. (NS1)

Nitrofurazone, preparations thereof not intended for applications to the skin. (NS1)

Nitrofural, except preparations thereof intended for application to the skin. (NS1)

Nitroglycerine, if intended for medicinal use but not in cases of emergency. (NS1)

Nitrous Oxide Gas, alone or in combination with other gases.

Nitrovin, except when listed elsewhere in the Schedules and except when intended to promote growth as a feed additive in veterinay use (NS0)

Nitroxoline.

Nitroxynil, except if intended as an anthelmintic for sheep, goats and cattle (NS0)

Nizatidine; except if intended for oral administration for short-term symptomatic relief of heartburn and hyperacidity, if the maximum dose is 150 milligrams, the maximum daily dose is 300 milligrams and the treatment period is two weeks.(NS1)

Nomegestrol.

Noradrenaline theophylline – see Theodrenaline.

Norelgestromin.

Norethisterone,

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

Norgestrel,

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

Norfloxacin.

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. (NS1)

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, (NS1)
- (c) except when intended for application to the skin, (NS1) and
- (d) except when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis, (NS1)
- (e) except when intended for pigeons (NS0)

52 Government Gazette 31 October 2018 Obidoxime. Octocog alfa. Ocriplasmin. Octreotide. Ofloxacin. Olaquindox, except when listed elsewhere in the Schedules and except when intended to promote growth as a feed additive in veterinary use (NS0) Oleandomycin Olsalazine. Omalizumab. Omeprazole, including when intended for veterinary use except when intended for the temporary, short-term relief of heartburn and hyperacidity, subject to: a maximum daily dose of 20 milligrams and (b) a maximum treatment period of 14 days. (NS1) Omesartan Ondansetron. Oprelvekin. 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. (NS1) Ondansetron. Oprelvekin. Ornidazole, except when intended for application to the skin. (NS1) Ornipressin. Osaterone, when intended for veterinary use. Oseltamivir. Oxaliplatin. Oxamniquine. Oxaprozin. Oxcarbazepine. Oxetacaine (Oxethazaine), when intended for ophthalmic or parenteral use; (a) except in oral preparations containing an antacid. (NS1) (b) Oxfendazole, except if intended as an anthelmintic for sheep, goats and cattle (NS0) Oxiracetam. Oxolinic acid. Oxovinca. Oxprenolol. Oxybuprocaine, when intended for ophthalmic or parenteral use; (a) except when contained in eye drops intended for the emergency treatment of "arc eyes". (NS1) (b) Oxybutynin. Oxyclosanide, except if intended as an anthelmintic for sheep, goats and cattle (NS0) Oxyphenbutazone, except when intended for the synchronization of oestrus in veterinary use (NS0) Oxytocin. Paclitaxel.

Palivizumab. Palonosetron. Paltitrexid.

Pamidronate disodium. Pamidronic acid.

Pancuronium.

Panituzumab.

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

- (a) a maximum daily dose of 20 milligrams (NS1); and
- (b) a maximum treatment period of 14 days. (NS1)

Para-aminosalicylic acid

Paracetamol, when intended for injection. (NS0, NS1)

Parecoxib.

Parenteral Nutrition formulations.

Paricalcitrol

Pazopanib.

Peginterferon alpha.

Peginterferon beta 1a.

Pemetrexed

Penbutolol.

Penciclovir, except if intended for application to the lips in the early treatment of recurrent Herpes simplex virus. (NS1)

Penicillamine.

Penicillinase, including preparations intended for injection.

Pentaerythritol tetranitrate.

Pentamidine isethionate.

Pentolinium.

Pentosan polysulfate if intended for the treatment of intersititial cystitis.

Pentostatin.

Perfluorooctane, when intended for intraocular use. (NS1)

Pergolide.

Perhexiline.

Perindopril.

Phenacetin, but not preparations and mixtures intended for external use and containing not more than 0,1% phenacetin as stabiliser.

Phenamidine, except if intended as a babesiacide for veterinary use (NS0)

Pheneticillin.

Phenformin.

Phenindione.

Phenobarbital, preparations and mixtures containing not more than 90 milligrams of Phenobarbital per minimum recommended or prescribed dose if intended for continued use in epilepsy (NS3)

Phenopyrazone.

Phenoxybenzamine.

Phenoxymethylpenicillin.

Phentolamine.

Phenylephrine, ophthalmic preparations containing more than 0,2 per cent of phenylephrine.

Phenylbutazone, prohibited for veterinary use.

Phenytoin.

Phospholipids when intended for parenteral administration. (NS0)

Phthalylsulfathiazole.

Physostigmine; ophthalmic preparations thereof, when intended for glaucoma.

Picrotoxin.

Pilocarpine, except ophthalmic preparations thereof intended for glaucoma.

Primidone.
Probenecid.
Probucol.

Pimecrolimus. Pimobendan. Pindolol. Pioglitazone. Pipemidic acid. Piperacillin, anhydrous Piracetam. Pirbuterol, if contained in respirator solutions. (NS1) Pirenzepine. Piretanide. Piribedil. Pirlimycin. Piromidic acid. Piroxicam, if not intended for the emergency treatment of acute gout attacks and if not intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (NS1) Pirprofen. Pivampicillin. Pivmecillinam Plerixafor. Podophyllum resin, preparations and mixtures containing more than 20% thereof. (NS1) Polydimethylsiloxane see Silicone oil. Polyglycerylene-dextran. Polymixin B, except when intended for topical application to the epidermis, nares and external ear. (NS1) Polynoxylin. Polysterene sulfonic acid when intended for therapeutic purposes Poractant alpha. Posaconazole. Potassium canrenoate. Potassium chloride, where the recommended dose is more than 20 millimol of potassium (1 500 milligrams of potassium chloride) per 24 hours or when intended for intravenous infusion or for injection. Potassium dichromate, but not preparations and mixtures containing not more than 15 micrograms of potassium dichromate per dosage unit. Practolol. Pradofloxacin, when intended for veterinary use. Pralidoxime. Pramipexole. Prasugrel. Pravastatin. Praziquantel, except if intended as an anthelmintic for veterinary use (NS0) Prazosin. Prednisolone. Prilocaine, when intended for ophthalmic or parenteral use; except in topical preparations containing 10 percent or less of prilocaine. (NS1) Primaquine.

Procainamide.

Procarbazine.

Procaterol, if contained in respirator solutions. (NS1)

Proctofene.

Progesterone.

Proguanil.

Propacetamol.

Propafenone.

Propentofylline, except if intended for veterinary use (NS1)

Propiverine.

Propylhexedrine, if not used as a vasoconstrictor and decongestant in nose preparations and inhalants. (NS1)

Propranolol.

Proquazone.

Proscillaridine.

Protein C (isolated from human plasma).

Proteolytic (fibrinolytic) enzymes, if intended for injection. (NS1)

Prothionamide, including preparations intended for oral use.

Protionamide

Proxymetacaine, except if contained in eye drops intended for emergency treatment of arc eyes (NS1)

Proyliodone.

Prucalopride.

Pygeum africanum (lipido-sterolic complex extract thereof).

Pyrazinamide, including preparations intended for oral use.

Pyricarbate.

Pyridinolcarbamate.

Pyridostigmine.

Pyrimethamine.

Pyrithioxin.

Quinagolide.

Quinapril.

Quinine, except preparations and mixures containing not more than 1 percent. (NS1)

Quinoronium sulphate, except if intended as a babesiacide for veterinary use (NS0)

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. (NS1)

Racecadotril.

Radio-active compounds, if used for diagnostic purposes.

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) 18F Fludeoxyglucose (2 deoxy 2 [18F] 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;
(xii) Technetium-99; (xiii) Thallium-201;
(xiv) Xenon-133;
(xv) Yttrium-90;
(xvi) Gold – 198.
Rafoxanide, except if intended as an anthelmintic for sheep and cattle (NS0)
Raloxifene.
Raltegravir.
Raltitrexid.
Ramipril.
Ranibizumab.
Ranitidine, except if administered orally for short-term relief of symptoms of heartburn and hyperacidity, it
the maximum dose is 75 milligrams, the maximum daily dose is 300 milligrams and the maximum treatment
period is 14 days. (NS1).
Rapacuronium.
Rasagiline.
Rasburicase.
Raubasine.
Rauwolfia alkaloids.
Recombinant human tissue-type plasminogen activator (re-PA).
Regorafenib
Repaglinide.
Reproterol, if contained in respirator solutions. (NS1)
Reserpine (natural or synthetic).
Resorantel. except if intended as an anthelmintic for sheep, goats and cattle (NS0)
Retapamulin.
Rifabutin.
Rifampicin.
Rifaximin.
Rilpivirine
Riluzole.
Rimiterol, when intended for injection. (NS1)
Riociguat.
Risedronate
Ritodrine.
Ritonavir.
Rituximab.
Rivaroxaban.
Rizatriptan.
Robenacoxib.
Rocuronium bromide.
Rofecoxib.
Roflumilast.
Romiplostim.
Ropinirole.
Ropivacaine.
Rosiglitazone.
Rosoxacin.

Spirapril.
Spironolactone.
Stavudine.

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

Rosuvastatin. Rotigotine. Roxarzone (3-nitro-4-hydroxyphenylarsonic acid), including if intended for veterinary use. Roxatidine. Roxithromycin. Ruxolitinib. Salbutamol, when intended for injection. (NS1) Salmefamol, when contained in respirator solutions. (NS1) Salmeterol. Saquinavir. Saxagliptin. Sarafloxacin. Selegiline. Serelaxin. Sermorelin. Sertaconazole, except if intended for application to the skin. (NS1) Sertindole. Sevelamer. Sildenafil. Silicone oil (polydimethylsiloxane) when intended for intraocular use. Silodosin Silymarin, except when providing not more than 600 mg of Silymarin per day (calculated as silibinin/ silybin). (NS0) Simvastatin. Sirolimus. Sisomicin. Sitagliptin phosphate Sodium aurothiomalate. Sodium cromoglycate, if intended for veterinary use. (NS1) Sodium dihydroazapentacene polysulphonate. Sodium fluoride, except oral medicinal preparations and mixtures thereof containing 40 milligrams or more per daily dose.(NS1) Sodium nitroprusside. Sodium phosphate, in preparations intended for the management of faecal impaction or for bowel cleansing prior to surgical and diagnostic procedures. (NS0) Sodium picosulphate, in preparations intended for the management of faecal impaction or for bowel cleansing prior to surgical and diagnostic procedures. (NS0) Sodium polystyrine sulphonic acid when indicated for therapeutic use. Solcoseryl; ophthalmic preparations thereof. (NS0) Solifenacin. Sorafenib. Sotalol. Sparfloxacin. Spectinomycin

Streptokinase.

Streptomycin.

Strontium, except when contained in toothpaste. (NS0)

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

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

- (a) it shall be supplied on a written prescription issued by a state veterinarian for use in the particular area where the veterinarian has jurisdiction in a quantity not exceeding 5 grams; and
- (b) the state veterinarian must obtain prior written approval for such use from the Minister responsible for environment and wildlife, a copy of which shall be attached to the written prescription, but not preparations and mixtures containing 0.2 per cent or less thereof. (NS1)

Styramate.

Sugammadex.

Sulbactam.

Sulfabenzamide.

Sulfacetamide.

Sulfadiazine, except when intended for veterinary use (NS0)

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; (NS1)

Sulfadimidine (sulfadimethoxine) except when intended for veterinary use (NS0)

Sulfamethazine except when intended for veterinary use (NS0)

Sulfadoxine except when intended for veterinary use (NS0)

Sulfafurazole (sulfisoxazole).

Sulfaguanidine except when intended for veterinary use (NS0)

Sulfamethizole.

Sulfamethoxazole except when intended for veterinary use (NS0)

Sulfametopyrazine.

Sulfamoxole.

Sulfanilamide.

Sulfathiazole, except when intended for veterinary use (NS0)

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 intended for veterinary use (NS0)

Sulindac.

Suloctidil.

Sulphinpyrazone.

Sultamicillin.

Sulthiame.

Sumatriptan.

Sunitinib.

Suprofen.

Suramin.

Surfactant associated proteins.

Suxamethonium.

Suxethonium.

Tacrine

Tacrolimus.		
Tadalafil.		
Tafluprost.		
Talampicillin		
Tamoxifen.		
Tamsulosin.		
Tasosartan.		
Tamsulosin.		
Tasonermin.		
Taurolidine.		
Tazarotene.		
Tazobactam.		
Tegafur.		
Teicoplanin.		
Tegaserod.		
Telaprevir.		
Telbivudine.		
Telithromycin		
Telmisartan.		
Temozolomide.		
Temsirolimus.		
Tenecteplase.		
Tenidap.		
Teniposide.		
Tenofovir.		
Tenoxicam.		
Tepoxalin.		
Terazosin.		
Terbinafine, if not intended for application to the skin. (NS1)		
Terbutaline, if contained in respirator solutions. (NS1)		
Terfenadine,		
Terconazole.		
Teriflunomide.		
Teriparatide.		
Terizidone.		
Terlipressin.		
Terodiline.		
Tetrabenazine.		
Tetracaine,		
(a) when intended for ophthalmic or parenteral use;		
(b) except when intended for topical use; (NS1)		
<ul> <li>(c) except in oral preparations containing 2 percent or less of Tetracaine; (NS1)</li> <li>(d) except when contained in eye drops intended for the emergency treatment of "arc eyes". (NS1)</li> </ul>		
Tetracosactrin (Tetracosactide).		
Tetramisole, except if intended as an anthelmintic for veterinary use (NS0)		
Thalidomide		
Theodrenaline – see Noradrenaline theophylline		
Theophylline unless listed in another Schedule, preparations intended for injection (NS1)		

Toremifene.

Thiabendazole, except
<ul><li>a. when intended for application to the skin; (NS1) and</li><li>b. when intended as an anthelmintic for veterinary use (NS0)</li></ul>
Thiacetazone.
Thiamphenicol.
Thioacetazone.
Thiocolchicoside.
Thioguanine.
Thiostrepton.
Thymopentin.
Thyroid gland and its active principles and derivatives, unless listed in another Schedule.
Thyrotropin alfa.
Tiagabine
Tiamulin, except when intended for veterinary use (NS0)
Tiaprofenic acid, if not intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (NS1)
Tibolone.
Ticagrelor.
Ticarcillin.
Ticlopidine.
Tigecycline.
Tildipirosin, when intended for veterinary use.
Tiludronic acid.
Timolol.
Tin fluoride, including preparations intended for injection.
Tinidazole.
Tioconazole, if not intended for application to the skin and not intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis. (NS1)
Tioguanine.
Tiopronin.
Tiotropium
Tipranavir.
Tirilazad.
Tobramycin.
Tocainide.
Tocilizumab.
Tolamolol.
Tolazamide.
Tollowanide.
Tolcapone. Tolfenamic acid.
Tolmetin, if not intended for application to the skin. (NS1)  Tolrestat.
Tolterodine.
Toltrazuril, except if intended as an anticoccidial preparation for poultry (NS0)
Topiramate.
Topotecan.
Torasemide.
1 Ottooringe.

Trabectedin. Trandolapril. Tranexamic acid. Trastuzumab. Travoprost. Treosulfan. Tretinoin, when intended for application to the skin. (NS3) Triamterene. Tricaine. Triclabendazole, except if intended as an anthelmintic for sheep, goats and cattle (NS0) Thiotepa. Triethylene thiophosphoramide. Trifluridine. Trifluorothymidine. Trimetaphane. Trimethadione. Trimethoprim, except when specifically intended in combination with sulphonamides for the treatment of gastro-enteritis and pneumonia in veterinary use (NS0) Trimetrexate. Trioxsalen. Triptorelin. Tromantadine. Trometamol. Tropicamide. Tropisetron. Tuberculin, if intended for veterinary use. (NS1) Tubocurarine. Tulobuterol, if contained in respirator solutions. (NS1) 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. (NS0) Tyropanoic acid. Tyrothricin, except when intended for topical application to the epidermis, nares and external ear. (NS1) Unoprostone. Urapidil. Urethane. Urofollitropin. Urokinase. Ursodeoxycholic acid. Ustekinumab. Vaccines, Vaccines for use in canines and felines; (a) (b) Vaccines against foot and mouth disease (FMD), contagious bovine pleurapneumonia (CBPP), avian influenza (AI), but FMD, CBPP and AI vaccines are restricted for use only by the Chief Veterinary Officer of the Directorate of Veterinary Services in the Ministry responsible for agriculture. Except all other vaccines (NS0) (c) Valaciclovir.

Valdecoxib,

Valganciclovir

Valnemulin.

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

Valsartan.
Vanillic acid diethylamide.
Vardenafil.
Vasoactive intestinal polypeptide.
Vecuronium bromide.
Vedaprofen.
Vemurafenib.
Verteporfin.
Verapamil (iproveratril).
Veratrum alkaloids.
Vernakalant.
Verteporfin.
Vidarabine.
Vigabatrin.
Vilanterol.
Vinblastine.
Vincamine.
Vincristine.
Vindesine.
Vinorelbine
Vinpocetine.
Veratrum alkaloids
Vigabatrin.
Vildagliptin.
Vincamine.

Vitamin A, preparations thereof for injection and oral preparations and mixtures thereof containing more than 10 000 I.U. per recommended daily dose, except when intended for veterinary use (NS0, NS1)

# Vitamin B1 (Thiamine),

Vinpocetine Vismodegib.

- (a) in preparations thereof for injection;
- (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.
- (c) except when intended for veterinary use (NS0, NS1)

# Vitamin B2 (Riboflavin),

- (a) in preparations thereof for injection;
- (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.
- (c) except when intended for veterinary use (NS0, NS1)

# Vitamin B3 (Niacin)

- (a) when intended for hypercholesterolaemia and for the management of dyslipidaemias;
- (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.
- (c) except when intended for veterinary use. (NS0, NS1)

# Vitamin B5 (Pantothenic Acid),

- (a) in preparations thereof for injection;
- (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.
- (c) except when intended for veterinary use. (NS0, NS1)

### Vitamin B6 (Pyridoxine),

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

except when intended for veterinary use. (NS0, NS1) (c)

Vitamin B12 (Cyanocobalamin),

- (a) in preparations thereof for injection;
- except in oral preparations or mixtures containing more than 100 µg of Vitamin B12 per recommended (b) daily dose alone or in combination with other active pharmaceutical ingredients. (NS0, NS1)
- except when intended for veterinary use (NS0) (c)

Vitamin C (Ascorbic Acid),

Zoledronic acid. Zomepirac. Zotarolimus.

- in preparations thereof for injection; (a)
- except in oral preparations or mixtures containing more than 1000 mg of Vitamin C per recommended (b) daily dose alone or in combination with other active pharmaceutical ingredients.
- except when intended for veterinary use. (NS0, NS1) (c)

Vitamin D (cholecalciferol or ergocalciferol), preparations thereof for injection and oral preparations and mixtures thereof containing more than 1 000 LU per recommended daily dose, except when intended for

mixtures thereof containing more than 1 000 1.U. per recommended daily dose, except when intended for veterinary use (NS0)		
Vitan	nin K (Phytomenadione),	
(a) in	injection preparations;	
(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,	
(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).	
(d)	except when intended for veterinary use. (NS0, NS1)	
Voric	onazole.	
Vorin	nostat.	
Voroz	zole.	
Warfa	arin.	
Water	r for injection except in a dosage form not exceeding 20 milliliters in volume. (NS1)	
Xamo	oterol.	
Xipar	mide.	
Zafirl	ukast.	
Zalcit	tabine.	
Zanar	mivir.	
Zidov	vudine. (AZT).	
Zinc,	where the daily dose is more than 50 milligrams of elemental zinc	
Ziv-a	flibercept.	
Zolm	itriptan.	

### **SCHEDULE 3**

Specified Schedule 3 substances listed in this schedule are subject to additional controls in terms of section 29 of the Act as required under the provisions of the 1971 Convention on Psychotropic Substances and are denoted by \*\*

Acitretin.
Agomelatine.
Alprazolam\*\*.
Amisulpride.
Amitryptyline, unless listed in another Schedule.
Amoxapine.
Anaesthetic preparations containing pregnanedione derivatives.

Androstanolone.

Androstenediol.

Aponal.

Apronalide.

Aripriprazole.

Asenapine.

Atomoxetine

Azacyclonol.

Barbituric acid\*\*, unless listed in another Schedule, but not amobarbital, cyclobarbital, pentobarbital and Secobarbital (NS2) and not preparations and mixtures containing more than 90 milligrams of phenobarbital per minimum recommended or prescribed dose if intended for continued use in epilepsy. (NS2)

Benactyzine, unless listed in another Schedule.

Benfluramate.

Benzoctamine.

Benzodiazepines\*\*, unless listed in another Schedule and except flunitrazepam. (S4).

Benzquinamide.

Beta-aminopropylbenzene and beta-aminoisopropylbenzene, any compound structurally derived from either of these substances by substitution in the side chain or by ring closure therein (or by both substitution and ring closure), and any salt or substances falling under the above, but not preparations and mixtures of the above if used as vasoconstrictors and decongestants in antihistamine nose and eye preparation and not if contained in appliances for inhalant in which the substance is absorbed in solid material and excluding cathine ((+)-norpseudoephedrine), ephedrine, etafedrine, N-methylephedrine, N-diethylaminoethylephedine, phenylpropanolamine, prenylamine and preparations and mixtures thereof, but not substances listed in Schedule 5. (NS1)

Bolandiol.

Bolasterone.

Boldenone.

Bromides, preparations and mixtures thereof containing 80 milligrams or more of bromine as bromide per recommended daily dose, but not if specifically packaged, labelled and used for industrial and non-medicinal laboratory purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose, which are intended to be ingested by man or animals as food or applied to the body as a cosmetic and which are approved for such use in terms of the Foodstuffs, Cosmetic and Disinfectant Act, 1972. (NS1)

Bromazepam\*\*.

Bromisovalum.

Brotizolam.

Bupropion.

Buspirone.

Butriptyline.

Butyrophenones.

Carbromal.

Chlordiazepoxide\*\*

Chloral derivatives, unless listed in another Schedule.

Chloroform, preparations and mixtures containing more than 20 per cent of chloroform. (NS1)

Chlormethiazole.

Chlormezanone, except mixtures thereof if the maximum recommended or prescribed dose does not exceed 100 milligrams of chlormezanone.(NS1)

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. (NS0, NS1)

Chlorpromazine.

Chlorprothixene.

Citalopram.

Clobazam\*\*.

Clomacran.

Clomethiazole (previously listed as 'heminevrin').

Clomipramine.

Clonazepam\*\*.

Clopenthixol.

Clostebol.

Clothiapine.

Clozapine\*\*.

Clorazepic acid\*\*.

Clostebol.

Clothiapine.

Clozapine.

Corticotrophin (Adrenocortocotrophic hormone: ACTH).

Cyclobenzaprine.

Cyproheptadine, except when indicated for allergic rhinitis or antipruritic use. (NS1)

Danazol.

Dapoxetine.

Deanol and its derivatives, unless listed in another Schedule, but not if specifically packaged, labelled and used for industrial and non-medicinal laboratory purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose, which are intended to be ingested by man or animals as food or applied to the body as a cosmetic and which are approved for such use in terms of the Foodstuffs, Cosmetic and Disinfectants Act,. 1972, and for analytical laboratory purposes. (NS1)

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% in undivided preparations. (NS4)

Diazepam**.
Dibenzepin.
Diprenorphine.
Donepezil.
Dosulepin.
Dothiepin.
Doxepin, except if intended for application to the skin. (NS2)
Droperidol.
Drostanolone.
Duloxetine.
Ecothiopate.
Emylcamate.
Enflurane.
Ephedrine (natural or synthetic) except if contained in products. (NS1)
Epitiostanol.
Escitalopram.
Estazolam**.
Ethchorvynol.
Ether (diethyl ether); all substances, preparations and mixtures containing more than 20 percent of ether
(NS1), 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, but not preparations and mixtures thereof if used solely as an antihistamine. (NS1)
Etomidate.
Etretinate.
Fencamfamine.
Fenfluramine.
Flumazenil.
Fluocinolone.
Fluoxetine.
Fluoxymesterone.
Flupenthixol.
Fluphenazine.
Flurazepam**.
Fluspirilene.
Fluvoxamine.
Formebolone.
Furazabol.
Gabapentin.
Haloperidol.
Halothane.
Hedonal and its esters, but not if specifically packaged, labelled and used for industrial and non-medicina

Hedonal and its esters, but not if specifically packaged, labelled and used for industrial and non-medicinal laboratory 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.

Human growth hormone (human somatotropin) - all forms, whether natural or synthetic, including recombinant forms, with either hormonal, prohormonal or anti-hormonal action). Hydroxyzine. Hygromycin B, except when listed elsewhere in the Schedules and except when intended as an anthelmintic for pigs (NS0) Imipramine, and its derivatives, unless listed in another Schedule. Iproniazid. Isoflurane. Isotretinion. Ketamine. Ketazolam\*\*. Lithium salts, if intended for medicinal use, except if intended for application to the skin. (NS1) Lofepramine. Loxapine. Lofepramine. Loprazolam\*\*. Lorazepam\*\*. Lormetazepam\*\*. Loxapine. Maprotiline. Mazindol. Mebolazine. Mechlorethamine, and its derivatives, unless listed in another Schedule. Meclofenoxate. Medazepam\*\* Medetomidine. Melitracene. Mephenoxalone. Meprobamate. Mesterolone. Metandienone. Metenolone. Methandranone. Methandriol. Methoxyflurane. Methyltestosterone. Metrifonate. Mianserin. Mibolerone. Midazolam\*\*. Milnacipran. Mirtazapine. Moclobemide. Modafinil. Molindone. Nalbuphine. Nandrolone. Nefazodone.

Nitrazepam**.
Nomifensine.
Norclostebol.
Norethandrolone.
Nortriptyline.
Olanzapine.
Oxabolone.
Oxandrolone.
Oxazepam**.
Oxymesterone.
Oxymetholone.
Oxypertine.
Paliperidone.
Paraldehyde.
Pargyline.
Paroxetine.
Pemoline, and its complexes.
Perampanel.
Phenethylhydrazine.
Phenothiazine and its derivatives, unless listed in another Schedule, except preparations and mixtures
containing promethazine or dimethothiazine or their salts if used solely as an antihistamine (S1) and except
preparations containing promethazine or its salts if intended specifically for the treatment of travel sickness
or application to the skin (NS1), and except phenothiazine if intended as an anthelmintic for veterinary use
(NS0)
Phentermine.
Pimethixene, except preparations and mixtures thereof of used solely as an antihistamine. (NS1)
Pimozide.
Piperazine (BZP)
Pipradrol.
Pizotifen, except preparations and mixtures thereof if used solely as an antihistamine or if intended for the prophylaxis of migraine. (NS1)
Prasterone (Dehydroepiandrosterone, DHEA).
Prazepam**.
Pregabalin.
Prochlorperazine maleate
Prolintane.
Propofol.
Protriptyline.
Quazepam**.
Quetiapine.
Quinbolone.
Quinupramine.
Reboxetine.
Risperidone.
Rivastigmine.
Romifidine.
Sertindole
Sertraline.
Sevoflurane.

Sibutramine.
Stanozolol.
Stenbolone.
Sulphonmethane.
Sulpiride.
Temazepam**.
Testolactone.
Testosterone, except when intended as veterinary production improver. (NS5)
Thioguanosine.
Thiopentone.
Thiothixene.
Tiapride.
Tiletamine.
Tizanidine.
Tramadol.
Tranyleypromine.
Trazodone.
Trenbolone, except when intended as veterinary production improver. (NS5)
Trihexyphenidyl.
Tretinoin, when intended for oral preparation. (NS2)
Triazolam**.
Trifluoroperazine.
Trihexyphenidyl.
Trimipramine
L-tryptophan, if intended for medicinal use, except if intended for medicinal use as supplementation for nutritional purposes (NS1)
Varenicline.
Venlafaxine.
Viloxazine.
Xylazine.
Zaleplon.
Zimelidine.
Ziprasidone.
Zolazepam.
Zolpidem**.
Zopiclone**.
Zotepine.
Zuclopenthixol.

### **SCHEDULE 4**

# Acetorphine.

Acetyldihydrocodeine, but not preparations and mixtures if compounded with one or more therapeutically active substances and containing 20 milligrams or less of acetyldihydrocodeine (calculated as base) per dosage unit and not liquid oral preparations and mixtures containing 20 milligrams or less of acetyldihydrochodeine (calculated as base) per 5 millilitre dosage unit. (NS1)

Acetylmethadol.

Alfentanil.

Allylprodine.

Alphacetylmethadol.

Alphameprodine.

Alphamethadol.

Alphaprodine.

Amineptine.

Amobarbital.

1 11110 0 411 0 1441

Anileridine.

Benzethidine.

Benzphetamine.

Benzylmorphine.

Betacetylmethadol.

Betameprodine.

Betamethadol.

Beta-aminopropylbenzene and beta-aminoisopropylbenzene, any compound structurally derived from either of these substances by substitution in the side chain or by ring closure therein (or by both substitution and ring closure), and any salt or substances falling under the above, but not preparations and mixtures of the above if used as vasoconstrictors and decongestants in antihistamine nose and eye preparation and not if contained in appliances for inhalant in which the substance is absorbed in solid material and excluding cathine ((+)-norpseudoephedrine), ephedrine, etafedrine, N-methylephedrine, N-diethylaminoethylephedine, phenylpropanolamine, prenylamine and preparations and mixtures thereof, but not substances listed in Schedule 5. (NS1)

Betacetylmethadol.

Betaprodine.

Betamethadol.

Betaprodine.

Bezitramide.

Buprenorphine.

Butalbital

Butorphanol

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

Chlorodyne (Chloroform and Morphine Tincture BP 1980) or any preparation or

mixture thereof described as chlorodyne

Chlorphentermine.

Clonitazene.

Coca leaf and any salt, compound derivative or preparation of coca leaf and any salt, compound, derivative or preparation thereof that is chemically equivalent or identical to any of these substances, whether obtained directly or indirectly by extraction from material or substances obtained from plants, or obtained independently by chemical synthesis, or by a combination of extraction and chemical synthesis, but not decocainised coca leaf and extractions of coca leaf if such extractions contain no cocaine or ecgonine.

Codeine (methylmorphine),

- (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; (NS2)

(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. (NS2)

Codoxime.

Cyclobarbital.

Desomorphine.

Dextromoramide.

Dextropropoxyphene, but not 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 per cent in undivided preparations. (NS3)

Dextrorphan.

Diampromide.

Diethylpropion (amfepramone).

Diethylthiambutene.

Difenoxin (or diphenoxylic acid), except mixtures containing, per dosage unit, 0,5 milligrams or less of difenoxin, calculated as the base, and a quantity of atropine sulphate equal to more than 5,0per cent of such quantity of difenoxin, calculated as the base, as is present in the mixture. (NS1)

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; (NS1, NS2)
- (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. (NS2)

Dihydroetorphine.

Dihydromorphine.

Dimenoxadol.

Dimepheptanol.

Dimethylthiambutene.

Dioxaphethyl butyrate.

Diphenoxylate, but not 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. (NS1)

Dipipanone.

{D-norpseudoephedrine - see cathine}

Dronabinol [(-)-transdelta-9-tetrahydrocannabinol], if intended for therapeutic purposes. (NS5)

Drotebanol.

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

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

- (a) except products registered in terms of the Act, not intended for export, and being oral preparations and mixtures containing not more than 30 milligrams of ephedra alkaloids per dose, when in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, subject to a maximum pack size of 720 milligrams and limited to one pack per customer; (NS1)
- (b) except when intended for application to skin, eyes, ears and nares and containing 1 percent or less of ephedra alkaloids. (NS1)

Ephedrine,

- (a) except oral preparations and mixtures containing not more than 30 milligrams of ephedrine per dose, when in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, subject to a maximum pack size of 720 milligrams and limited to one pack per customer; (NS1)
- (b) except preparations and mixtures intended for application to the skin, eyes, ears and nares and containing 1 percent or less of ephedrine. (NS1)

Ethylmethylthiambutene.

Ethylmorphine, except preparations and mixtures if compounded with one or more therapeutically active substances and containing 20 milligrams or less of ethylmorphine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of ethylmorphine (calculated as base) per 5 millilitre dosage unit. (NS1)

Etonitazene. Etoxeridine. Fenproporex. Fentanyl if intended for human therapeutic purposes. (NS5) Flunitrazepam. Furethidine. Glutethimide. Hydrocodone (dihydrocodeinone). Hydromorphinol (14-hydroxydihydromorphine). Hydromorphone (dihydromorphinone). Hydroxypethidine. Ibogaine. Isomethadone. Ketobemidone. Levomoramide. Levophenacylmorphan. Levorphanol. Mecloqualone. Mefenorex. Meptazinol. Metazocine. Methadone-intermediate. Methadone. Methorphan, including levomethorphan and racemethorphan, but excluding dextromethorphan. (NS1) Methyldesorphine. Methyldihydromorphine. Methylphenidate and its derivatives, unless listed in another Schedule. Metopon. Misoprostol. Moramide-intermediate. Morpheridine. Morphine methobromide and other pentavalent nitrogen morphine derivatives. Morphine, except preparations and mixtures of morphine containing 0,2 percent or less of morphine, calculated as anhydrous morphine. (NS1). Morphine-N-oxide and its derivatives. Myrophine (myristylbenzylmorphine). Nefopam. Nicocodine. Nicodicodine. Nicomorphine. Noracymethadol. Norcodeine.

Norlevorphanol.

Normethadone.

Normorphine (demethylmorphine or N-demethylated morphine).

Norpipanone.

Opium and opiates and any salt, compound, derivative or preparation of opium or opiates whether obtained directly or indirectly by extraction from material or substances obtained from plants, or obtained independently by chemical synthesis, or by a combination of extraction and chemical synthesis, but not mixtures containing 0,2% or less of morphine, calculated as anhydrous morphine. (NS1)

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

Oxycodone (14-hydroxydihydrocodeinone or dihydrohydroxycodeinone).

Oxymorphone (14-hydroxydihydromorphinone or dihydrohydroxymorphinone).

Pentazocine.

Pentobarbital.

Pethidine, pethidine-intermediate A, pethidine-intermediate B, and pethidine-intermediate C. (NS5)

Phenadoxone.

Phenampromide.

Phenazocine.

Phendimetrazine.

Phenomorphan.

Phenoperidine.

Pholcodine, except preparations and mixtures if compounded with one or more therapeutically active substances containing 20 milligrams or less of pholcodine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of pholcodine (calculated as base) per 5 millilitre dosage unit.(NS1).

Piminodine.

Piritramide.

Proheptazine.

Properidine.

Propiram.

Pseudoephedrine, except oral preparations and mixtures containing not more than 60 milligrams of pseudoephedrine per dose, and not more than 240 milligrams per day, when in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, subject to a maximum pack size of 720 milligrams and limited to one pack per customer.(NS1)

Racemoramide.

Racemorphan.

Remifentanil.

Secobarbital.

Sufentanil.

Tapentadol.

Thebacon.

Thebaine.

Thiafentanyl.

Tilidine.

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

Trimeperidine.

Zipeprol.