

(6 September 2024 – to date)

## MEDICINES AND RELATED SUBSTANCES ACT 101 OF 1965

(Gazette No. 1171, Notice No. 1002 dated 7 July 1965. Commencement date: 1 April 1966 [Proc. No. 94, Gazette No. 1413])

### SCHEDULES

Government Notice 935 in Government Gazette 31387 dated 5 September 2008. Commencement date:  
5 September 2008.

#### As amended by:

Government Notice R1230 in Government Gazette 32838 dated 31 December 2009. Commencement date:  
31 December 2009.

Government Notice R227 in Government Gazette 35149 dated 15 March 2012. Commencement date:  
15 March 2012.

Government Notice R674 in Government Gazette 36827 dated 13 September 2013. Commencement date:  
13 September 2013.

Government Notice R690 in Government Gazette 36850 dated 20 September 2013. Commencement date:  
20 September 2013.

Government Notice R104 in Government Gazette 37318 dated 11 February 2014. Commencement date:  
11 February 2014.

Government Notice R352 in Government Gazette 37622 dated 8 May 2014. Commencement date:  
8 May 2014.

Government Notice R234 in Government Gazette 38586 dated 20 March 2015. Commencement date:  
20 March 2015.

Government Notice 254 in Government Gazette 39815 dated 15 March 2016. Commencement date:  
15 March 2016.

Government Notice 620 in Government Gazette 40041 dated 3 June 2016. Commencement date:  
3 June 2016.

*Government Notice 748 in Government Gazette 41009 dated 28 July 2017. Commencement date: 28 July 2017.*

*Government Notice 1261 in Government Gazette 41256 dated 17 November 2017. Commencement date: 17 November 2017.*

*Government Notice R1098 in Government Gazette 41971 dated 12 October 2018. Commencement date: 12 October 2018.*

*Government Notice R1262 in Government Gazette 42052 dated 23 November 2018. Commencement date: 23 November 2018.*

*Government Notice R755 in Government Gazette 42477 dated 23 May 2019. Commencement date: 23 May 2019.*

*Government Notice R219 and Government Notice R220 in Government Gazette 43051 dated 28 February 2020. Commencement date: 28 February 2020.*

*Government Notice R586 in Government Gazette 43347 dated 22 May 2020. Commencement date: 22 May 2020.*

*Government Notice R1375 in Government Gazette 44019 dated 18 December 2020. Commencement date: 18 December 2020.*

*Government Notice 883 in Government Gazette 45176 dated 17 September 2021. Commencement date: 17 September 2021.*

*Government Notice R2412 in Government Gazette 46789 dated 26 August 2022. Commencement date: 26 August 2022.*

*Government Notice 2685 in Government Gazette 47373 dated 28 October 2022. Commencement date: 28 October 2022.*

*Government Notice R3261 in Government Gazette 48358 dated 24 March 2023. Commencement date: 24 March 2023.*

*Government Notice 5181 in Government Gazette 51171 dated 6 September 2024. Commencement date: 6 September 2024.*

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

## **SCHEDULE**

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

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

### **SCHEDULE 0**

- (a) All substances referred to in this Schedule are excluded when specifically packed, labelled, sold and used for -
  - (i) industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose, and which are intended to be ingested by man or animals as a food or applied to the body as a cosmetic, and which are approved for such use in terms of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972) or that are registered in terms of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947); and
  - (ii) analytical laboratory purposes.
- (b) This Schedule shall include all substances or mixtures of such substances containing or purporting to contain substances referred to, including the salts and esters of such substances, where the existence of such salts and esters is possible, except where such substances or mixtures of substances are expressly excluded.

This Schedule includes all substances or mixtures of substances subject to registration in terms of the Act and which are not listed in any of the other Schedules.

### **SCHEDULE 1**

- a. All substances referred to in this Schedule are excluded when specifically packed, labelled, sold and used for -
  - (i) industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose; and
  - (ii) analytical laboratory purposes.

- b. All preparations of substances or mixtures of such substances containing or purporting to contain any substance referred to in this Schedule and includes the following:
- (i) The salts and esters of such substances, where the existence of such salts and esters is possible; and
  - (ii) all preparations and mixtures of such substances where such preparations and mixtures are not expressly excluded.
- c. In terms of section 22A(4)(a)(v) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974 (Act No. 56 of 1974) other than a medical practitioner or dentist may prescribe and supply, only within his/her scope of practice and subject to the indication for use of such substances and medicines and to the conditions determined by the Authority, to patients under his/her care, the Schedule 1 substances and medicines provided for in the Annexures to this Schedule published in the *Gazette* in terms of the Act.
- (i)
 

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

**Acetanilide and alkyl acetanilides.**

**Acetarsol**, when intended for human vaginal use.

**Acetylcysteine,**

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

**Acyclovir**, when intended for application to the lips in the early treatment of recurrent herpes simplex virus infections. (S4)

**Ambroxol.**

**Amethocaine** - see Tetracaine

**Amorolfine.**

**Anethole trithione.**

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

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

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

- (a) preparations and mixtures when used as vasoconstrictors and decongestants in antihistamine-containing nose and eye preparations; and
- (b) appliances for inhalation in which the substance is adsorbed onto solid material but excluding cathine ((+)-norpseudoephedrine), ephedrine, etafedrine, N-methylephedrine, N-diethylaminoethylephedrine, phenylpropanolamine, prenylamine. (S2, S6, S7)

**Arsenic:**

- (a) in oral dosage forms in concentrations equivalent to 0.01 percent or less of arsenic trioxide. (S2)
- (b) except when intended for injection. (S4)

**Ascorbic Acid** -see Vitamin C.

**Azelaic acid.**

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

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

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

**Benzethonium chloride**, when intended for human vaginal use.

**Benzocaine**,

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

**Benzydamine**,

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

**Bifidobacterium adolescentis**,

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

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

- c. ....

**Bifidobacterium animalis subsp. Animalis,**

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

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

- c. ....

**Bifidobacterium animalis subsp. Lactis,**

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

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

- c. ...

**Bifidobacterium bifidum,**

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

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

**Bifidobacterium breve,**

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

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

**Bifidobacterium lactis,**

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

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

**Bifidobacterium longum *subsp.* Infantis,**

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

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

**Bifidobacterium longum *subsp.* Longum,**

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

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

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

**Bioallethrin.**

**Bitolterol.**

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



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

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

**Bunamidine**.

**Butoconazole**.

- (a) when intended for human vaginal use specifically for the treatment of recurrent vaginal candidiasis; (S4)  
or
- (b) when intended for application to the skin. (S4)

**Calcium**,

- a. in oral preparations or mixtures containing more than 1 300 mg of calcium per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)
- b. except in preparations thereof for injection; (S3)
- c. except when indicated for the treatment of hyperphosphataemia; (S4)
- d. except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

**Carbamoyl benzamide phenyl isoxazoline**, except when intended and registered as a stock remedy in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

**Cetirizine**

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

**Chloroform**, preparations and mixtures containing more than 0,5 percent and less than 20 percent of chloroform, except for industrial purposes including the manufacturing and compounding of products not intended for medicinal use. (S0, S5)

**Chromium**, in oral preparations or mixtures containing more than 200 µg of Chromium per recommended daily dose alone or in combination with other active pharmaceutical ingredients, (S0)

**Ciclopirox**.

**Clotrimazole,**

- (a) when intended for human vaginal use specifically for the treatment of recurrent vaginal candidiasis; (S4)  
and
- (b) when intended for application to the skin. (S4)

**Collagenase clotridiopeptidase**, when intended for application to the skin.

**Copper,**

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

**Cyanocobalamin** -see Vitamin B12.

**Deanol** and its derivatives, unless listed in another Schedule, when specifically packaged, labelled and used for industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose, which are intended to be ingested by man or animals as food or applied to the body as a cosmetic and which are approved for such use in terms of the Foodstuffs, Cosmetics and Disinfectants Act, 1972, (Act 54 of 1972) and for analytical laboratory purposes. (S5)

**Dequalinium**

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

**Diclofenac,**

- a. when intended for application to the skin and containing more than 1 % m/m of diclofenac; (S3)
- b. except when intended for application to the skin and containing 1 % m/m or less of diclofenac subject to a maximum pack size of 50 grams; (S0)
- c. except when intended for the emergency treatment of acute gout attacks, subject to a maximum daily dose of 150 mg for a maximum treatment period of 3 days; (S2)

- d. except when intended for human use only in the treatment of fever or mild to moderate pain of inflammatory origin, or for the treatment of post-traumatic conditions, subject to a maximum daily dose of 75 mg for a maximum treatment period of 5 day; (S2)
- e. except when intended for veterinary use (S3).

**Diosmine.**

**Dithiazanine.**

**Econazole,**

- (a) when intended for human vaginal use specifically for the treatment of recurrent vaginal candidiasis; (S4)  
or
- (b) when intended for application to the skin. (S4)

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

**Ephedra alkaloids (natural or synthetic),**

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

**Ephedrine,**

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

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

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

**Ethyl chloride**

**Ethylphenylephrine.**

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

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

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

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

**Fexofenadine.**

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

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

**Flurbiprofen,**

- (a) when in the form of lozenges, indicated for the relief of pain associated with sore throats, subject to:
  - (i) a maximum of 8,75 milligrams per lozenge.
  - (ii) a maximum treatment period of 3 days, and
  - (iii) a maximum pack size of 15 lozenges (S3)
- (b) except when intended for application to the skin and indicated for the symptomatic relief of localised pain and inflammation, provided that in the case of application by transdermal patch: :
  - (i) use is restricted to adults and children 12 years and older, and
  - (ii) the treatment period is limited to a maximum of 4 weeks (S0).
- (c) except when intended for the treatment of post-traumatic conditions, for a maximum period of 5 days; (S2)

- (d) except when intended for ophthalmic use. (S4)

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

**Fluorides,**

- a. in oral medicinal preparations or mixtures intended for ingestion containing not more than 0,25 milligrams of fluorine per dosage unit;
- b. except in toothpaste containing not more than 0,15 percent fluoride; (S0) and
- c. except in mouth rinses containing not more than 0,15 percent fluoride; (S0)
- d. except in oral medicinal preparations or mixtures intended for ingestion containing more than 0,25 milligrams of fluorine per dosage unit. (S4)

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

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

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

**O-(β-hydroxyethyl) rutosides.**

**Hyaluronic acid and its salts,**

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

**Hyoscine butylbromide;** substances, preparations and mixtures thereof-

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

**Icodextrin.**

**Ibuprofen**

- a. when contained in preparations intended for application to the skin, containing 5% m/m or less of ibuprofen, and presented in a pack size exceeding 50 grams; (S0)
- b. when contained in transdermal patches containing 200mg of ibuprofen per patch or less, and indicated for use by patients aged 16 years and older;
- c. when contained in oral medicinal preparations, intended for human use only, supplied in a solid dose form as divided doses contained in packs not exceeding 24 dosage units or divided doses and containing ibuprofen as the only active therapeutic substance, intended for the treatment of mild to moderate pain or fever of inflammatory origin or for the treatment of post-traumatic conditions in adults and children over 12 years of age where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children 12 years and older does not exceed 20 milligrams per kilogram of body weight. (S2, S3).
- d. except when intended for the treatment of haemodynamically significant patent ductus arteriosus in infants less than 34 weeks of gestational age; (S4)
- e. except when intended for veterinary use. (S3)

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

**Indanazoline.**

**Indometacin,**

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

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

**Iodine,**

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

**Iron,**

- (a) in oral preparations or mixtures containing more than 24 mg of Iron per recommended daily dose alone or in combination with other active pharmaceutical ingredients: (S0)
- (b) except in preparations thereof for injection: (S3)
- (c) except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

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

**Isoconazole,** when intended for

- (a) human vaginal use specifically for the treatment of recurrent vaginal candidiasis (S4); and
- (b) application to the skin. (S4)

**Ketoconazole,** when intended for

- (a) application to the skin,
- (b) except preparations and mixtures containing not more than 1,0 percent of ketoconazole, when intended for the prevention and treatment of dandruff. (S0, S4)

**Ketoprofen,**

- a. when intended for application to the skin; (S3)
- b. except when intended for the short term management of headache, toothache, muscular ache, backache, minor pain associated with arthritis, pain associated with menstrual cramps (dysmenorrhoea), minor aches and pains associated with the common cold and fever, at a maximum dose of 75 milligrams of ketoprofen in 24 hours; (S2)

- c. except when intended for the emergency treatment of acute gout attacks; (S2)
- d. except when intended for the treatment of post-traumatic conditions, subject to a maximum dose of 100 milligrams of ketoprofen per day, for a maximum treatment period of 5 days; (S2)
- e. except in the form of lozenges indicated and intended for the relief of pain associated with sore throats in patients 18 years and older subject to-
  - (i) a maximum of 12,5 milligrams per lozenge;
  - (ii) a maximum of 5 lozenges in any 24 hour period;
  - (iii) a maximum treatment period of 3 days; and
  - (iv) a maximum pack size of 15 lozenges. (S2)

**Lactobacillus acidophilus and Lactobacillus bitidus**, when intended for therapeutic purposes, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

**Lactobacillus acidophilus,**

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

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

**Lactobacillus brevis,**

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

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

**Lactobacillus caucasicus,**



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

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

**Lactobacillus casei,**

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

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

**Lactobacillus fermentum,**

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

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

**Lactobacillus gasseri,**

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

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

**Lactobacillus helveticus,**

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

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

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

**Lactobacillus johnsonii,**

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

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

**Lactobacillus paracasei,**

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

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

**Lactobacillus plantarum,**

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

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

**Lactobacillus reuteri,**

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

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

**Lactobacillus rhamnosus,**

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

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

**Lactobacillus salivarius,**

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

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

**Lactococcus lactis,**

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

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

**Levocetirizine**

**Lidocaine,**

- a. when intended for topical use
- b. in oral preparations containing 2% or less of lidocaine, per dosage unit;

- c. except when intended for ophthalmic or parenteral use; (S4)
- d. except when intended for the treatment of neuropathic pain associated with previous herpes zoster infection. (S4)

**Lignocaine**, - see Lidocaine

**Local anaesthetics**, except

- (a) when intended for ophthalmic or parental use; (S4)
- (b) oxybuprocaine, proxymetacaine and tetracaine, when contained in eye drops intended for emergency treatment of "arc eyes"; (S2) and
- (c) ophthalmic preparations registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

**Loratidine**.

**Lufenuron**, except when intended and registered as a systemic preparation against fleas in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

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

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

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

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

**Manganese**,

- a. in oral preparations or mixtures containing more than 4 mg of Manganese per recommended daily dose alone or in combination with other active pharmaceutical ingredients: (S0)
- b. in preparations thereof for injection when intended for veterinary use.

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

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

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

**Methionine**,

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

**Miconazole**,

- (a) when intended for human vaginal use specifically for the treatment of recurrent vaginal candidiasis; (S4) and
- (b) when intended for application to the skin. (S4)
- (c) except for topical treatment of fungal infections of the mouth. (S2)

**Microfibrillar collagen hydrochloride**.

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

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

**N-acetyl-aspartyl-glutamic acid**.

**Naphazoline**, when intended for nasal use. (S2)

**Naproxen**,

- a. when contained in preparations intended for application to the skin; (S2, S3)
- b. when contained in oral medicinal preparations, intended for human use only containing naproxen as the only active therapeutic substance intended for patients over 16 years of age, for the treatment of mild to moderate pain or fever of inflammatory origin at a maximum dose of 600 milligrams naproxen base (660 milligrams naproxen sodium) in a 24 hour period for a maximum treatment period of 5 days and

supplied in a solid dose form as divided doses contained in packs not exceeding the stated maximum treatment period; (S2, S3)

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

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

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

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

**Nicotine,**

- a. when intended for human medicinal use as an aid to smoking cessation, when registered and presented as nicotine transdermal patches for continuous application to the skin in strengths up to and including 21mg/ 24 hours or 25 mg/ 16 hours;
- b. except when registered for human medicinal use as an aid to smoking cessation and presented as nicotine gum or lozenges containing not more than 4 mg nicotine per piece; (S0)
- c. except when registered for human medicinal use as an aid to smoking cessation and presented as nicotine gum or lozenges containing more than 4 mg nicotine per piece; (S2)
- d. except when intended for human medicinal use as an aid to smoking cessation, when registered and presented as nicotine transdermal patches for continuous application to the skin in strengths containing more than 21mg/ 24 hours or 25 mg/ 16 hours; (S2)
- e. except when registered as metered sprays containing not more than 1 mg per dose; (S2)
- f. except when registered as oral solid dosage forms containing not more than 2 mg; (S2)
- g. except when registered as inhalers containing not more than 10 mg per cartridge; (S2)
- h. except when intended for human medicinal use as an aid to smoking cessation or as a substitute for a tobacco product (as defined in the Tobacco Products Control Act, 1993, as amended). (S3)

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

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

**Normal Saline** (Sodium chloride 0.9 % m/v) when intended for injection, in a dosage form not exceeding 20 millilitres in volume. (S0, S3)

**Nystatin**,

- (a) when intended for application to the skin, and
- (b) when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis, and
- (c) except when presented as oral drops containing not more than 100 000 I.U. per ml. (S2)
- (d) except when intended for systemic use or the initial treatment of vaginal candidiasis. (S4)
- (e) except when intended and registered as a stock remedy for pigeons in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act 1947 (Act 36 of 1947).

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

**Orthodichlorobenzene**, when intended for topical human medicinal use.

**Oxetacaine (Oxethazaine)**,

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

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

**Oxymetazoline**, when intended for nasal use. (S2)

**Pancreatin**.

**Pantothenic Acid** - see Vitamin B5.

**Paracetamol**, except -

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

- (i) a maximum of 12,5 grams of paracetamol per primary pack, and
- (ii) in the case of tablets or capsules, presented in blister strip packaging or in containers with child-resistant closures; and
- (iii) labelled with the following boxed warning, placed prominently on at least the main panel of the immediate container label and outer label (carton):

"CONTAINS PARACETAMOL - READ THE PACKAGE INSERT"; (S0)

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

- (i) a maximum of 100 millilitres per primary pack in the case of the liquid or syrup dosage form containing 120 milligrams or less of paracetamol per 5 millilitres;
- (ii) a maximum of 20 millilitres per primary pack in the case of the paediatric drops;
- (iii) labelled with the following boxed warning, placed prominently on at least the main panel of the immediate container label and outer label (carton):

"CONTAINS PARACETAMOL - READ THE PACKAGE INSERT"; (S0)

(c) when contained in rectal suppositories. (S2)

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

(e) when intended for injection. (S3)

**Paradichlorobenzene**, when intended for topical human medicinal use.

**Penciclovir**, when intended for application to the lips in the early treatment of recurrent herpes simplex virus infections. (S4)

**Pentosan polysulfate** sodium, except when intended for the treatment of interstitial cystitis. (S3)

**Phenylephrine**



- a. when intended for oral dosage forms, nasal dosage forms, or ophthalmic dosage forms containing more than 0,2 percent (S1)
- b. except ophthalmic preparations containing 0.2 percent or less. (S0)
- c. except when intended for injection (S4)

**Phospholipids**, when applied for therapeutic purposes.

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

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

**Pramoxine**

**Prilocaine**,

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

**Procaine**, when intended for oral administration.

**Propentofylline**, when intended for veterinary use. (S4)

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

**Proteolytic (fibrinolytic) enzymes**,

- (a) for oral use and
- (b) when intended for application to the skin, and
- (c) except when intended for soft contact lens cleaners; (S0) and
- (d) except when intended for injection. (S4)

**Pyrantel pamoate**, including veterinary use, except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947). Correct

**Pyridoxilate.**

**Pyridoxine** - see Vitamin B6.

**Racecadotril.**

**Riboflavin** - see Vitamin B2.

**Selenium,**

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

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

**p-Synephrine,**

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

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

**Tetracaine,**

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

**Tetrahydrozoline**, when intended for nasal use. (S2)

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

**Thiamine** -see Vitamin B1.

**Thiomersal**.

**Thiram**, except when intended and registered as a fungicide in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

**Ticlatone**, when intended for application to the skin.

**Tioconazole**.

- (a) when intended for human vaginal use specifically for the treatment of recurrent vaginal candidiasis; and
- (b) when intended for application to the skin. (S4)

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

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

**5-Hydroxy Tryptophan**,

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

**L-tryptophan**,

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

**Vanadium,**

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

**Vitamin B1 (Thiamine) and derivatives thereof,**

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

**Vitamin B2 (Riboflavin) and derivatives thereof,**

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

**Vitamin B5 (Pantothenic Acid) and derivatives thereof,**

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

**Vitamin B6 (Pyridoxine) and derivatives thereof,**

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

**Vitamin B12 (Cyanocobalamin) and derivatives thereof,**

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

**Vitamin C (Ascorbic Acid),**

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

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

**Vitamin K and derivatives thereof,**

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

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

**Xylometazoline**, when intended for nasal use. (S2)

**Zinc and derivatives thereof,**

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

**Zinc salts,**

- a. except when intended for oral ingestion, where the daily dose is less than 50 milligrams of elemental zinc; (S0),
- b. except when intended for topical use by humans; (S0),

- c. when intended for veterinary use as an injection;
- d. except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

## ANNEXURES TO SCHEDULE 1

### ANNEXURE 1A: EMERGENCY CARE PROVIDER (PARAMEDIC)

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

<b>PARAMEDIC</b> (National Diploma in Emergency Medical Care graduates <b>only</b> )	
<b>LOCAL ANAESTHETIC</b>	
Substance	Lignocaine Hydrochloride
Indication	Local Anaesthetic
Schedule	1
Route of Administration	Topical application
<b>WATER</b>	
Substance	Water for injection
Indication	Diluent
Route of Administration	Parenteral
<b>WATER</b>	
Substance	Water for irrigation
Indication	Wound and dressing irrigation
Route of Administration	Solution

*(Annexure 1A to Schedule 1 inserted by GNR 674 of 2013)*

*(Annexure A to Schedule 1 amended by GN 1375 dated 18 December 2020)*

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

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

<b>EMERGENCY CARE PRACTITIONER</b> (B Tech: Emergency Medical Care)	
<b>LOCAL ANAESTHETIC</b>	
Substance	Lignocaine Hydrochloride
Indication	Local Anaesthetic
Schedule	1
Route of Administration	Topical application
<b>WATER</b>	

Substance	Water for injection
Indication	Diluent
Route of Administration	Parenteral
<b>WATER</b>	
Substance	Water for irrigation
Indication	Wound and dressing irrigation
Route of Administration	Solution

*(Annexure 1B to Schedule 1 inserted by GNR 674 of 2013  
Annexure 1B to Schedule 1 amended by GN 1375 dated 18 December 2020)*

### **ANNEXURE 1C: BASIC AMBULANCE ASSISTANT**

**BASIC AMBULANCE ASSISTANT** registered with Health Professions Council of South Africa

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

*(Annexure 1C of Schedule 1 added by GN 1375 dated 18 December 2020)*

### **ANNEXURE 1D: AMBULANCE EMERGENCY ASSISTANT**

**AMBULANCE EMERGENCY ASSISTANT** registered with Health Professions Council of South Africa

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

*(Annexure 1D of Schedule 1 added by GN 1375 dated 18 December 2020)*

**ANNEXURE 1E: EMERGENCY CARE TECHNICIAN****EMERGENCY CARE TECHNICIAN** registered with Health Professions Council of South Africa

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

*(Annexure 1E of Schedule 1 added by GN 1375 dated 18 December 2020)***ANNEXURE 1F: EMERGENCY CARE ASSISTANT****EMERGENCY CARE ASSISTANT** registered with Health Professions Council of South Africa

<b>EMERGENCY CARE ASSISTANT</b> registered with Health Professions Council of South Africa	
<b>WATER</b>	
Substance	Water for injection
Indication	Diluent
Route of Administration	Parenteral
<b>WATER</b>	
Substance	Water for irrigation
Indication	Wound and dressing irrigation
Route of Administration	Solution

*(Annexure 1F of Schedule 1 added by GN 1375 dated 18 December 2020)***ANNEXURE 2: DENTAL THERAPIST****DENTAL THERAPIST** (Bachelors degree in Dental Therapy) registered with Health Professions Council of South Africa

<b>DENTAL THERAPIST</b> (Bachelors degree in Dental Therapy)	
<b>ANALGESIC, ANTIPYRETIC, ANTI INFLAMMATORY</b>	
Substance	Paracetamol
Indication	Dental pain
Schedule	1
Route of Administration	Oral
<b>SURFACE ANAESTHETIC</b>	
Substance	Lidocaine/ Lignocaine Hydrochloride
Indication	Dental surface anaesthesia



Schedule	1
Route of Administration	Topical
<b>ANTI-VIRAL</b>	
Substance	Acyclovir
Indication	Viral infection of lips
Schedule	1
Route of Administration	Topical
<b>VITAMINS AND MINERALS</b>	
Substance	-
Indication	Applicable to Dentistry
Schedule	1
Route of Administration	Oral
<b>MOUTH AND THROAT PREPARATIONS</b>	
Substance	-
Indication	Applicable to Dentistry
Schedule	1
Route of Administration	Oral

*(Annexure 2 of Schedule 1 added by GNR 674 dated 13 September 2013)*

### **ANNEXURE 3: OPTOMETRIST**

**OPTOMETRIST** (Bachelors degree in Optometry - B OPTOM) registered with the Health Professions Council of South Africa.

<b>OPTOMETRIST</b>		
<b>OPHTHALMIC PREPARATIONS</b>	:	OTHER
Substance	:	Fluorescein
Indication	:	For diagnostic purpose only i.e. In detecting corneal abrasions and foreign bodies in the eye, in applanation tonometry, in assessing the patency of the nasolacrimal duct and in contact lens fitting procedures
Route of Administration	:	Intra-ocular

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

<b>ANALGESIC</b>		
Substance	:	Paracetamol
Indication	:	Mild Pain
Route of Administration	:	Oral
<b>ANALGESIC/ANTI INFLAMMATORY</b>		

Prepared by:

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

*[Annexure 3 of Schedule 1 added by GNR 674 of 13 September 2013]*

*(Annexure 3 of Schedule 1 substituted by GN 620 of 3 June 2016)*

*(Annexure 3 of Schedule 1 amended by GN 748 of 28 July 2017)*

*(Annexure 3 of Schedule 1 amended by GNR 219 of 28 Feb 2020.)*

*(Annexure 3 of Schedule 1 amended by GNR 220 of 28 Feb 2020).*

*(Annexure 3 of Schedule 1 substituted by GNR 3261 dated 24 March 2023)*

#### **ANNEXURE 4: PODIATRIST**

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

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

*(Annexure 4 inserted by Government Notice R220 in Government Gazette 43051 dated 28 February 2020)*

*(Annexures 4 amended by Government Notice R1375 in Government Gazette 44019 dated 18 December 2020.)*

#### **ANNEXURE 5: ORAL HYGIENISTS**

Prepared by:

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

ORAL HYGIENISTS		
TOPICAL ANAESTHETIC		
Substance	:	Ethyl chloride
Indication	:	Dental surface anaesthesia
Route of Administration	:	Topical

*(Annexure 5 inserted by GN 2685 dated 28 October 2022)*

*(Annexure 5 of Schedule 1 substituted by GNR 3261 dated 24 March 2023)*

*(Annexure 3 substituted by Government Notice 620 in Government Gazette 40041 dated 3 June 2016)*

*(Annexure 3 amended by Government Notice 748 in Government Gazette 41009 dated 28 July 2017)*

*(Annexures 1A, 1B, 2 & 3 inserted by Government Notice R674 in Government Gazette 36827 dated 13 September 2013.)*

*(Annexure 3 amended by Government Notice R219 in Government Gazette 43051 dated 28 February 2020)*

*(Annexure 3 amended by Government Notice R220 in Government Gazette 43051 dated 28 February 2020)*

*(Annexures 1C, 1D, 1E & 1F inserted by Government Notice R1375 in Government Gazette 44019 dated 18 December 2020.)*

*(Annexures 1A & 1B amended by Government Notice R1375 in Government Gazette 44019 dated 18 December 2020.)*

#### **- END SCHEDULE 1 -**

*(Schedule 1 amended by Government Notice R1230 in Government Gazette 32838 dated 31 December 2009)*

*(Schedule 1 amended by Government Notice R227 in Government Gazette 35149 dated 15 March 2012)*

*(Schedule 1 amended by Government Notice R690 in Government Gazette 36850 dated 20 September 2013)*

*(Schedule 1 amended by Government Notice R104 in Government Gazette 37318 dated 11 February 2014. Commencement date: 11 February 2014)*

*(Schedule 1 amended by Government Notice R352 in Government Gazette 37622 dated 8 May 2014)*

*(Schedule 1 amended by Government Notice R234 in Government Gazette 38586 dated 20 March 2015)*

*(Schedule 1 amended by Government Notice 254 in Government Gazette 39815 dated 15 March 2016)*

*(Schedule 1 amended by Government Notice 620 in Government Gazette 40041 dated 3 June 2016)*

*(Schedule 1 amended by Government Notice 748 in Government Gazette 41009 dated 28 July 2017)*

*(Schedule 1 amended by Government Notice 1261 in Government Gazette 41256 dated 17 November 2017)*

*(Schedule 1 amended by Government Notice R1098 in Government Gazette 41971 dated 12 October 2018)*

*(Schedule 1 amended by Government Notice R1262 in Government Gazette 42052 dated 23 November 2018)*

*(Schedule 1 amended by Government Notice R755 in Government Gazette 42477 dated 23 May 2019)*

*(Schedule 1 amended by Government Notice R219 in Government Gazette 43051 dated 28 February 2020)*

*(Schedule 1 amended by Government Notice R220 in Government Gazette 43051 dated 28 February 2020)*

*(Schedule 1 amended by Government Notice R1375 in Government Gazette 44019 dated 18 December 2020)*

*(Schedule 1 amended by Government Notice 883 in Government Gazette 45176 dated 17 September 2021)*

*(Schedule 1 amended by GN 2685 dated 28 October 2022)*

*(Schedule 1 amended by GNR 3261 dated 24 March 2023)*

## **SCHEDULE 2**

- a. All substances referred to in this Schedule are excluded when specifically packed, labeled, sold and used for-
- (i) industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose; and
  - (ii) analytical laboratory purposes.
- b. All preparations of substances or mixtures of such substances containing or purporting to contain any substance referred to in this Schedule and includes the following:
- (i) The salts and esters of such substances, where the existence of such salts and esters is possible; and
  - (ii) all preparations and mixtures of such substances where such preparations and mixtures are not expressly excluded.
- c. In terms of section 22A(5)(f) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974 (Act 56 of 1974) other than a medical practitioner or dentist may prescribe and supply, only within their scope of practice and subject to the indication for use of such substances and medicines and to the conditions determined by the Authority, to patients under his/her care, the Schedule 2 substances and medicines provided for in the Annexures to this Schedule published in the *Gazette* in terms of the Act.
- (i) Annexure 1A: Emergency Care Provider (Paramedic);
  - Annexure 1B: Emergency Care Provider (Emergency Care Practitioner);
  - Annexure 1C: Basic Ambulance Assistant
  - Annexure 1D: Ambulance Emergency Assistant
  - Annexure 1E: Emergency Care Technician
  - Annexure 1F: Emergency Care Assistant

- (ii) Annexure 2: Dental Therapist;
- (iii) Annexure 3: Optometrist.
- (iv) Annexure 4: Podiatrist

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

**Acrivastine.**

**Adrenaline (epinephrine)**, except -

- (a) ophthalmic preparations when intended for glaucoma, and
- (b) preparations for injection. (S3, S4)

**Albendazole,**

- a. when intended for the treatment of intestinal parasites, as a single oral dose; (S4)
- b. except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

**Alcaftadine.**

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

**Alverin.**

**Amethocaine-** see Tetracaine

**Aminopentamide.**

**Amyl nitrite.**

**Antazoline.**

**Antihistamines**, except -

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

**Antimicrobial substances**, namely -

- (a) griseofulvin, mupirocin, natamycin when intended for application to the skin, nares and external ear; (S4)
- (b) nystatin preparations intended for application to the oral cavity, nares and external ear. (S1, S4)

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

**Aptocaine**.

**Arecoline**.

**Arsenic**;

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

**Aspirin (acetyl salicylic acid)**, when intended for:

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

**Atovaquone**,

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

**Atropine**, except

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

**Azatadine**

**Azelastine**.

**Bambuterol**.

Prepared by:

**Bamipine.**

**BCG vaccine** - see *Mycobacterium bovis*.

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

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

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

**Benproperine.**

**Benzydamine,**

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

**Bevonium methylsulphate.**

**Bilastine.**

**Bismuth**, when intended for oral use.

**Bromhexine.**

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

**Brompheniramine**

**Bucizine.**

**Budesonide,**

- a. when intended for the prophylaxis and treatment of seasonal and perennial allergic rhinitis in adults and children aged 12 years and older; (S3)
- b. except when intended for inhalation and nasal administration, unless listed in another Schedule. (S4)

**Butinoline.**

**Calabar bean alkaloids.**

**Camphorated Opium Tincture.**

**Camylofin.**

**Cantharidin.**

**Canthaxanthin**

**Carbinoxamine.**

**Carbocisteine.**

**Carbuterol**, except

- (a) when contained in respirator solutions; (S3) and
- (b) when intended for injection. (S4)

**Carisoprodol.**

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



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

**Chlorpheniramine.**

**Chlorprenaline.**

**Cholestyramine.**

**Chlorzoxazone.**

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

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

**Cinnarizine.**

**Clemastine.**

**Clemizole.**

**Clidinium bromide.**

**Codeine (methyldmorphine),**

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

- d. except liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, containing more than 10 milligrams of codeine (calculated as base) per 5 millilitre dosage unit; (S3)
- e. except single component codeine preparations. (S6)

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

**Cyclandelate.**

**Cyclizine.**

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

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

**Dequalinium**

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

**Desloratidine.**

**Dexchlorpheniramine**

**Dextromethorphan.**

**Diclofenac,**

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

- e. except when intended for veterinary use. (S3)

**Dicyclomine.**

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

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

**Dihydrocodeine,**

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

**Dimethindene.**

**Dimethothiazine.**

**Dimetindene.**

**Diphenhydramine.**

**Diphenylpyraline.**

**Diphtheria toxoid vaccine.**

**{D-norpseudoephedrine - see cathine (S6)}**

**Doxycycline,**

- a. when intended and labelled for the chemoprophylaxis of malaria in those aged 8 years and older; (S4)

**Doxylamine.**

**Dulaglutide.**

**Ebastine.**

**Emedastine.**

**Emepronium.**

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

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

- a. oral preparations and mixtures, in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, containing not more than 30 milligrams of ephedra alkaloids per dose, with a maximum daily dose not exceeding 120 milligrams, subject to a maximum pack size of 360 milligrams and limited to one pack per customer; (S6)
- b. except when intended for application to skin, eyes, ears and nares and containing 1 percent or less of ephedra alkaloids. (S1)

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

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

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

**Epinastine.**

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

**Ergotamine**

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

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

**Estradiol,**

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

**Estriol,**

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

**Ethylmorphine:**

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

**Etilefrine.**

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

**Exalamide.**

**Famotidine**, when intended for the short-term symptomatic relief of heartburn caused by excess acid, subject to -

- (a) a maximum dose of 10 milligrams;
- (b) a maximum daily dose (per 24 hours) of 20 milligrams;
- (c) a maximum treatment period of 2 weeks. (S4)

**Fedrilate.**

**Fenoprofen.**

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

**Fenoterol**, except

- (a) when contained in respirator solutions; (S3) and
- (b) when intended for injection or for the prevention or delay of labour. (S4)

**Flavoxate.**

**Flunarizine.**

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

- (a) a maximum dose of 50 micrograms per nostril and a maximum daily dose of 100 micrograms per nostril in the case of adults and children over 16 years of age;

- (b) a maximum dose of 25 micrograms per nostril and a maximum daily dose of 75 micrograms per nostril in children 12 to 16 years of age;
- (c) a maximum pack size of 240 doses. (S3, S4)

**Flurbiprofen,**

- a. when intended for the treatment of post-traumatic conditions, for a maximum period of 5 days; (S3)
- b. except when in the form of lozenges, indicated for the relief of pain associated with sore throats, subject to:
  - (i) a maximum of 8,75 milligrams per lozenge;
  - (ii) a maximum treatment period of 3 days; and
  - (iii) a maximum pack size of 15 lozenges. (S1)
- c. except when intended for application to the skin and indicated for the symptomatic relief of localised pain and inflammation, provided that in the case of application by transdermal patch:
  - (i) use is restricted to adults and children 12 years and older; and
  - (ii) the treatment period is limited to a maximum of 4 weeks. (S0)
- d. except when intended for ophthalmic use. (S4)

**Fluticasone furoate,**

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

**Fluticasone propionate,**

- a. when intended for nasal administration, as an aqueous spray, in the short-term (less than 6 months) prophylaxis and treatment of symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12 years of age, subject to-
  - (i) a maximum daily dose of 100 micrograms per nostril;
  - (ii) and a maximum pack size limit of 120 doses. (S3)
- b. except when intended for administration other than by inhalation or nasal administration. (S4)

**Fusafungine.**

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

**Gadopentetic acid.**

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

**Gelsemium alkaloids.**

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

**Haemophilus influenzae vaccine (Hib)**

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

**Hepatitis B vaccine**

**Hexametazine.**

**Hexoprenaline -**

- (a) except when contained in respirator solutions; (S3) and
- (b) except when intended for injection or for the prevention or delay of labour. (S4)

**Homatropine**; preparations and mixtures thereof, except ophthalmic preparations. (S3)

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



- (a) when intended for human vaginal use, and
- (b) when specifically intended for emergency postcoital contraception. (S3, S4, S5)

**Human papillomavirus vaccine.**

**Hyaluronic acid and its salts,**

- a. when intended for ophthalmic use in preparations (except injectables) containing more than 0,1 percent;
- b. except when intended for use with contact lens solutions or as an ophthalmic lubricant in concentrations of not more than 0,1 percent; (S0)
- c. except when intended for topical application to the skin; (S1)
- d. except when intended for parenteral use; (S4)
- e. except in preparations containing less than 2,5 percent when intended for topical use in terms of the provisions of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972).

**Hydrocortisone and hydrocortisone acetate,** when used in

- a maximum concentration of 1 percent in preparations intended for application to the skin, and
- b in a maximum concentration of 1 percent used in combination with miconazole for topical application in the treatment of athlete's foot. (S4)

**Hydroquinone;** preparations and mixtures containing 2 percent or less thereof, when intended for application to the skin. (S3)

**Hyoscine butylbromide;** substances, preparations and mixtures thereof-

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

**Ibuprofen,**

- a. when contained in oral medicinal preparations, intended for human use only in combination with one or more other active therapeutic substances and intended for the treatment of mild to moderate pain or fever of inflammatory origin for a maximum treatment period of 10 days where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight. (S3)
- b. when contained in oral medicinal preparations, intended for human use only as the only active therapeutic substance in oral liquid preparations in packs not exceeding 100 millilitres in volume or in oral solid preparations in packs exceeding 24 dosage units or divided doses, when intended for adults and children over the age of 1 year; for the treatment of mild to moderate pain of inflammatory origin for a maximum treatment period of 10 days, or for the treatment of fever of inflammatory origin or for the treatment of post-traumatic conditions where the recommended daily dose of ibuprofen for adults does not exceed 1,2 grams and for children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (S1, S3)
- c. for the emergency treatment of acute gout attacks for a maximum treatment period of 5 days; (S3)
- d. except when contained in preparations intended for application to the skin, containing 5 % m/m or less of ibuprofen; (S0, S1)
- e. except when contained in transdermal patches containing 200mg of ibuprofen per patch or less, and indicated for use by patients aged 16 years and older (S1);
- f. except when contained in oral medicinal preparations supplied in a solid dose form as divided doses contained in packs not exceeding 24 dosage units or divided doses and containing ibuprofen as the only active therapeutic substance, intended for the treatment of mild to moderate pain or fever of inflammatory origin or for the treatment of post-traumatic conditions in adults and children over 12 years of age where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children 12 years and older does not exceed 20 milligrams per kilogram of body weight; (S1)
- g. except when intended for the treatment of haemodynamically significant patent ductus arteriosus in infants less than 34 weeks of gestational age; (S4)
- h. except when intended for veterinary use. (S3)

**Indometacin,**

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

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

**Influenza vaccine.**

**Influenza virus vaccine.**

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

**Isoaminile**

**Isoprenaline (isoproterenol)**, except

- (a) when contained in respirator solutions; (S3) and
- (b) when intended for injection, (S4)

**Isopropamide.**

**Isothipendyl.**

**Ketoprofen,**

- a. when intended for the short term management of headache, toothache, muscular ache, backache, minor pain associated with arthritis, pain associated with menstrual cramps (dysmenorrhoea), minor aches and pains associated with the common cold and fever, at a maximum dose of 75 milligrams of ketoprofen in 24 hours;
- b. when intended for the emergency treatment of acute gout attacks or for the treatment of post-traumatic conditions, subject to a maximum dose of 100 milligrams of ketoprofen per day, for a maximum treatment period of 5 days;
- c. in the form of lozenges indicated and intended for the relief of pain associated with sore throats in patients 18 years and older subject to-
  - (i) a maximum of 12,5 milligrams per lozenge;
  - (ii) a maximum of 5 lozenges in any 24 hour period;
  - (iii) a maximum treatment period of 3 days; and
  - (iv) a maximum pack size of 15 lozenges. (S3)

- d. except when intended for application to the skin. (S1)

**Ketotifen**

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

- (a) maximum daily dose of 15 milligrams
- (b) maximum treatment period of 14 days. (S4)

**Levocabastine.**

**Levodropropizine.**

**Levonorgestrel,**

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

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

**Local anaesthetics,**

- (a) except when intended for ophthalmic and parental use; (S4)
- (b) oxybuprocaine, proxymetacaine and tetracaine, when contained in eye drops intended for emergency treatment of "arc eyes".

**Lobelia alkaloids.**

**Lodoxamide.**

**Loperamide.**

**Measles vaccine**

**Mebeverine.**

**Mebhydrolin.**

**Meclozine.**

**Mefenamic acid,**

- a. when intended for the treatment of post-traumatic conditions, for a maximum treatment period of 5 days; and
- b. preparations containing mefenamic acid as the only therapeutically active substance, when intended for human use only in the treatment of primary dysmenorrhoea, subject to a maximum daily dose of 500 milligrams 3 times a day and a maximum treatment period of 3 days; (S3)
- c. except when intended for veterinary use. (S3)

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

**Mepenzolate bromide.**

**Mephenesin.**

**Mepyramine.**

**Mequitazine.**

**Mercuric ammonium chloride.**

**Mercuric chloride.**

**Mercuric iodide.**

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

**Mercury organic compounds**

- (a) substances, preparations and mixtures in the form of aerosols, intended for application to the skin and mucous membranes and substances.
- (b) preparations and mixtures containing the equivalent of 0,6 percent or more of elemental mercury, intended for application to the skin and mucous membranes.

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

**Mesna**, except preparations intended for injection. (S4)

Metaproterenol (orciprenaline), except

- (a) when contained in respirator solutions; (S3) and
- (b) when intended for injection, (S4)
- (c) when intended for the prevention or delay of labour. (S4)

**Methixene**.

**Methocarbamol**.

**Metholilazine**.

**Methoxyphenamine**.

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

**Miconazole**, when intended for human use in preparations containing 2 percent or less of miconazole, for the topical treatment of fungal infections of the mouth (oral candidiasis). (S1, S4)

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

**Mizolastine**.

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

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

**Monoethanolamine**.

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

**Mumps vaccine.**

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

***Mycobacterium bovis* vaccine (BCG).**

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

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

**Naproxen,**

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

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

**Nedocromil.**

**Nicergoline.**

**Nicotine,**

- a. when registered for human medicinal use as an aid to smoking cessation and presented as nicotine gum or lozenges containing more than 4mg nicotine per piece;
- b. when registered as metered sprays containing 1mg per dose or less;

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

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

- (a) a maximum dose of 150 milligrams;
- (b) a maximum daily dose of 300 milligrams;
- (c) a maximum treatment period of two weeks. (S4)

**{(+)-norpseudoephedrine** - see cathine (S6)}

**Noscapine.**

**Nux vomica**; substances, preparations and mixtures thereof, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

**Nystatin,**

- (a) when presented as oral drops containing not more than 100 000 I.U. per ml, and
- (b) except when intended for application to the skin, (S1) and



- (c) except when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis, (S1) and
- (d) except when intended for systemic use or the initial treatment of vaginal candidiasis, (S4)
- (e) except when intended and registered as a stock remedy for pigeons in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

**Octatropine.**

**Oleoresin of aspidium (Filix Mas).**

**Olopatadine.**

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

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

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

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

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

**Otilonium bromide.**

**Oxatomide.**

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

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

**Oxyphencyclimine.**

**Oxyphenonium.**

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

- (a) maximum daily dose of 20 milligrams

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

**Papaverine**; substances, preparations and mixtures thereof.

**Paracetamol**,

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

**Pentoxifylline**.

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

**Pertussis toxoid vaccine**.

**Phenazone (antipyrone)**.

**Phenazopyridine**.

**Phenindamine**.

**Pheniramine**.

**Phenylpropanolamine (norephedrine)**, contained in products registered in terms of the Act, and not intended for export, unless listed separately in the Schedules,

- a. oral preparations and mixtures where the recommended daily dose for adults does not exceed 100 milligrams and for children 6 to 12 years does not exceed 50 milligrams, when in combination with another pharmacologically active substance and intended for the symptomatic relief of nasal and sinus congestion, subject to a maximum pack size of 300 milligrams for adults and 150 milligrams for children, limited to one pack per customer. (S6)

**Phenyltoloxamine**.

**Pholcodine**, when prepared, mixed or compounded

- a. containing 20 milligrams or less of pholcodine (calculated as base) per dosage unit; or
- b. containing 20 milligrams or less of pholcodine (calculated as base) per 5 millilitres dosage unit in the case of liquid oral preparations and mixtures. (S6)

**Pholedrine.**

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

**Pinaverium.**

**Pipenzolate.**

**Pipoxolan.**

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

**Piroxicam,**

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

**Pizotifen**; preparations and mixtures, when intended for prophylaxis of migraine. (S5)

**Pneumococcal vaccine**, conjugated.

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

**Poldine methysulphate.**

**Polio vaccine.**

**Potassium,**

- a. in oral preparations or mixtures containing more than 20 millimoles (1500mg) of potassium per 24 hours;
- b. except when intended for intravenous infusion or for injection; (S3)
- c. except when contained in oral rehydration preparations. (S0)

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

Prepared by:

**Prifinium bromide.**

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

**Procyclidine.**

**Proglumide.**

**Proguanil,**

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

**Promethazine,**

- (a) when intended for use as an antihistamine, and
- (b) when intended for application to the skin, and
- (c) when intended specifically for the treatment of travel sickness. (S5)

**Propantheline bromide.**

**Propyphenazone.**

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

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

- a. Immediate-release oral preparations and mixtures containing not more than 60 milligrams of pseudoephedrine per dose or controlled-release oral preparations and mixtures containing not more than 120 milligrams of pseudoephedrine per dose, and not more than 240 milligrams per day, when in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, subject to a maximum pack size of 720 milligrams and limited to one pack per customer. (S6)

**p-Synephrine,**

- a. oral preparations and mixtures registered in terms of the Act and intended for the symptomatic relief of nasal and sinus congestion, where the recommended daily dose for adults is more than 50 milligrams and for children 6 to 12 years is more than 25 milligrams; (S6)

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

**Pyrobutamine.**

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

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

- a. maximum daily dose of 10 milligrams,
- b. maximum treatment period of 14 days. (S4)

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

- (a) a maximum dose of 75 milligrams;
- (b) a maximum daily dose of 300 milligrams;
- (c) a maximum treatment period of two weeks, (S3)

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

**Rimiterol**, except

- (a) when contained in respirator solutions (S3) and
- (b) when intended for injection. (S4)

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

**Rotavirus**, live attenuated.

**Rubella vaccine.**

**Rupatidine.**

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

**Salbutamol,** except

- (a) when contained in respirator solutions; (S3) and
- (b) when intended for injection. (S4)

**Salmefamol,** except

- (a) when contained in respirator solutions; (S3) and
- (b) when intended for injection. (S4)

**Siccanin,** when intended for application to the skin. Sodium cromoglycate, except when intended for veterinary use. (S4)

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

**Sulfadiazine silver** when intended for application to the skin in the short-term treatment of minor burns, provided that the pack size is limited to a maximum of 50 grams. (S4)

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

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

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

**Tetanus toxoid.**

**Tetanus vaccine.**

**Tetracaine,**

- a. when contained in eye drops intended for the emergency treatment of “arc eyes”

- b. except when intended for topical use; (S1)
- c. except in oral preparations containing 2% or less of tetracaine, per dosage unit; (S1)
- d. except when intended for ophthalmic or parenteral use.(S4)

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

**Thenalidine**.

**Thenyldiamine**.

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

**Thiethylperazine**.

**Tiaprofenic acid**, when intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S3)

**Timepidium**.

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

**Trimebutine**.

**Trimeprazine (Alimemazine)**.

**Tripelennamine**.

**Triprolidine**.

**Trospium**.

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

**Typhoid vaccine**.

**Ulipristal**.

**Vitamin A and derivatives thereof** and including retinol, retinal, retinoic acids and beta-carotene (but excluding isotretinoin) and not listed elsewhere in the Schedules, contained in preparations or mixtures

containing more than 5 000 I.U (or 1 500 mg of the retinol equivalent or 3 000 mg of the beta-carotene equivalent) but not more than 10 000 I.U (or 3 000 mg of the retinol equivalent or 6 000 mg of the beta-carotene equivalent) of Vitamin A per recommended daily dose alone or in combination with other active pharmaceutical ingredients, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agriculture Remedies and Stock Remedies Act, 1947 (Act 36 of 1947). (S0, S3)

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

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

## ANNEXURES TO SCHEDULE 2

### ANNEXURE 1A: EMERGENCY CARE PROVIDER (PARAMEDIC)

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

<b>PARAMEDIC</b> (National Diploma in Emergency Medical Care graduates <b>only</b> )	
<b>ANTI-CHOLINERGIC</b>	
Substance	Ipratropium Bromide
Indication	Inhalant Bronchodilator (atropine derivative anticholinergic)
Schedule	2
Route of Administration	Respirator Solution
<b>SELECTIVE <math>\beta_2</math> AGONISTS</b>	
Substance	Salbutamol
Indication	Bronchodilator
Route of Administration	Aerosol
<b>NON-STEROIDAL ANTI-INFLAMMATORY</b>	
Substance	Ibuprofen
Indication	Analgesic/ Anti-inflammatory
Route of Administration	Oral
<b>ANALGESIC</b>	
Substance	Paracetamol
Indication	Analgesic/ Anti-pyrexia
Route of Administration	Oral

*(Annexure 1A of Schedule 2 inserted by GNR 674 of 2013)*

*(Annexure 1A of Schedule 2 amended by GN 1375 of 2020)*

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

Prepared by:



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

<b>EMERGENCY CARE PRACTITIONER (B Tech: Emergency Medical Care)</b>	
<b>ANTI-CHOLINERGIC</b>	
Substance	Ipratropium Bromide
Indication	Inhalant Bronchodilator (atropine derivative anti-cholinergic)
Schedule	2
Route of Administration	Respirator Solution
<b>SELECTIVE <math>\beta_2</math> AGONISTS</b>	
Substance	Salbutamol
Indication	Bronchodilator
Route of Administration	Aerosol
<b>ANTI-SPASMODIC</b>	
Substance	Hyoscine butylbromide
Indication	Anti-spasmodic
Route of Administration	Oral
<b>ANTI-PROPULSIVE</b>	
Substance	Loperamide
Indication	Symptomatic management of diarrhoea in adults
Route of Administration	Oral
<b>NON-STEROIDAL ANTI-INFLAMMATORY</b>	
Substance	Ibuprofen
Indication	Analgesic / Anti-inflammatory
Route of Administration	Oral
<b>ANALGESIC</b>	
Substance	Paracetamol
Indication	Analgesic / Anti-pyrexia
Route of Administration	Oral

*(Annexure 1B of Schedule 2 inserted by GNR 674 of 2013)*

*(Annexure 1B of Schedule 2 amended by GN 1375 of 2020)*

#### **ANNEXURE 1C: BASIC AMBULANCE ASSISTANT**

**BASIC AMBULANCE ASSISTANT** registered the Health Professions Council of South Africa

<b>BASIC AMBULANCE ASSISTANT</b> registered the Health Professions Council of South Africa	
<b>*ANTI-CHOLINERGIC</b>	
Substance	Ipratropium bromide
Indication	Inhalant Bronchodilator (atropine derivative anti-cholinergic)

Route of Administration	Respirator Solution
<b>SELECTIVE <math>\beta</math>2 AGONISTS</b>	
Substance	Salbutamol
Indication	Bronchodilator
Route of Administration	Aerosol

*(Annexure 1C of Schedule 2 added by GN 1375 of 2020)*

#### **ANNEXURE 1D: AMBULANCE EMERGENCY ASSISTANT**

**AMBULANCE EMERGENCY ASSISTANT** registered the Health Professions Council of South Africa

<b>AMBULANCE EMERGENCY ASSISTANT</b> registered the Health Professions Council of South Africa	
<b>ANTI-CHOLINERGIC</b>	
Substance	Ipratropium bromide
Indication	Inhalant Bronchodilator (atropine derivative anti-cholinergic)
Route of Administration	Respirator Solution
<b>SELECTIVE <math>\beta</math>2 AGONISTS</b>	
Substance	Salbutamol
Indication	Bronchodilator
Route of Administration	Aerosol

*(Annexure 1D of Schedule 2 added by GN 1375 of 2020)*

#### **ANNEXURE 1E: EMERGENCY CARE TECHNICIAN**

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

<b>EMERGENCY CARE TECHNICIAN</b> registered the Health Professions Council of South Africa	
<b>ANTI-CHOLINERGIC</b>	
Substance	Ipratropium bromide
Indication	Inhalant Bronchodilator (atropine derivative anti-cholinergic)
Route of Administration	Respirator Solution
<b>SELECTIVE <math>\beta</math>2 AGONISTS</b>	
Substance	Salbutamol
Indication	Bronchodilator
Route of Administration	Aerosol

*(Annexure 1E of Schedule 2 added by GN 1375 of 2020)*

#### **ANNEXURE 1F: EMERGENCY CARE ASSISTANT**

**EMERGENCY CARE ASSISTANT** registered with Health Professions Council of South Africa

<b>EMERGENCY CARE ASSISTANT</b> registered the Health Professions Council of South Africa	
<b>ANTI-CHOLINERGIC</b>	

Substance	Ipratropium bromide
Indication	Inhalant Bronchodilator (atropine derivative anti-cholinergic)
Route of Administration	Respirator Solution
<b>SELECTIVE <math>\beta_2</math> AGONISTS</b>	
Substance	Salbutamol
Indication	Bronchodilator
Route of Administration	Aerosol

*(Annexure 1F of Schedule 2 added by GN 1375 of 2020)*

## **ANNEXURE 2: DENTAL THERAPIST**

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

<b>DENTAL THERAPIST (Bachelors degree in Dental Therapy)</b>	
<b>ANALGESIC, ANTIPYRETIC, ANTI INFLAMMATORY</b>	
Substance	Ibuprofen
Indication	Dental pain
Schedule	2
Route of Administration	Oral
<b>ANALGESIC, ANTIPYRETIC, ANTI INFLAMMATORY</b>	
Substance	Codeine
Indication	Dental pain
Route of Administration	Oral
<b>ANTI-FUNGALS</b>	
Substance	Nystatin
Indication	Candidal infections of the oral cavity
Schedule	2
Route of Administration	Oral

*(Annexure 2 of Schedule 2 added by GNR 674 of 2013 and amended by GN 620 of 2016)*

## **ANNEXURE 3: OPTOMETRIST**

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

<b>OPTOMETRIST</b>	
<b>ANTIBACTERIAL</b>	
Substance	Mupirocin
Indication	Impetigo (Eyelids); External Hordeolum, infected atopic dermatitis
Route of Administration	Topical application

ANTIHISTAMINE / VASOCONSTRICTOR / MAST CELL STABILISER Substance Indication Route of Administration	   Antazoline Allergic and Atopic Conjunctivitis Topical application
ANTIHISTAMINE / VASOCONSTRICTOR / MAST CELL STABILISER Substance Indication Route of Administration	   Tetrazoline Minor ocular irritation; Red eye Topical application
ANTIHISTAMINE / VASOCONSTRICTOR / MAST CELL STABILISER Substance Indication Route of Administration	   Oxymetazoline Minor ocular irritation; Red eye Topical application
ANTIHISTAMINE/ VASOCONSTRICTOR / MAST CELL STABILISER Substance Indication Route of Administration	   Cetirizine; Loratidine; Levocetirizine Atopic dermatitis Involving the eyelids Oral
ANTIHISTAMINE / VASOCONSTRICTOR / MAST CELL STABILISER Substance Indication Route of Administration	   Sodium Cromoglycate Vernal Kerato conjunctivitis Topical application
STEROIDAL ANTI INFLAMMATORY Substance Indication Route of Administration	   Hydrocortisone Dermatitis, Ectopic or Seborrhoeic Eczema Topical application

*(Annexure 3 of Schedule 2 added by GN 620 of 2016, amended by GN 748 of 2017 and GNR 219 of 2020)*

#### **ANNEXURE 4: PODIATRIST**

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

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

*[Annexure 4 of Schedule 2 added by GN 1375 of 2020. No additional information given.]*

*(Annexure 4 substituted by GN 2685 dated 28 October 2022)*

*(Annexure 2 substituted by Government Notice 620 in Government Gazette 40041 dated 3 June 2016)*

*(Annexures 1A, 1B, & 2 inserted by Government Notice R674 in Government Gazette 36827 dated 13 September 2013.)*

*(Annexure 3 added by Government Notice 620 in Government Gazette 40041 dated 3 June 2016)*

*(Annexure 3 amended by Government Notice 748 in Government Gazette 41009 dated 28 July 2017)*

*(Annexure 3 amended by Government Notice R219 in Government Gazette 43051 dated 28 February 2020)*

*(Annexure 1A & 1B amended by Government Notice R1375 in Government Gazette 44019 dated 18 December 2020.)*

*(Annexure 1C, 1D, 1E & 1F inserted by Government Notice R1375 in Government Gazette 44019 dated 18 December 2020.)*

*(Annexure 4 inserted by Government Notice R1375 in Government Gazette 44019 dated 18 December 2020.)*

**- END SCHEDULE 2 -**

*(Schedule 2 amended by Government Notice R1230 in Government Gazette 32838 dated 31 December 2009)*

*(Schedule 2 amended by Government Notice R227 in Government Gazette 35149 dated 15 March 2012)*

*(Schedule 2 amended by Government Notice R690 in Government Gazette 36850 dated 20 September 2013)*

*(Schedule 2 amended by Government Notice R104 in Government Gazette 37318 dated 11 February 2014. Commencement date: 11 February 2014)*

*(Schedule 2 amended by Government Notice R352 in Government Gazette 37622 dated 8 May 2014)*

*(Schedule 2 amended by Government Notice R234 in Government Gazette 38586 dated 20 March 2015)*

*(Schedule 2 amended by Government Notice 254 in Government Gazette 39815 dated 15 March 2016)*

*(Schedule 2 amended by Government Notice 620 in Government Gazette 40041 dated 3 June 2016)*

*(Schedule 2 amended by Government Notice 748 in Government Gazette 41009 dated 28 July 2017)*

*(Schedule 2 amended by Government Notice 1261 in Government Gazette 41256 dated 17 November 2017)*

*(Schedule 2 amended by Government Notice R1098 in Government Gazette 41971 dated 12 October 2018)*

*(Schedule 2 amended by Government Notice R1262 in Government Gazette 42052 dated 23 November 2018)*

*(Schedule 2 amended by Government Notice R755 in Government Gazette 42477 dated 23 May 2019)*

*(Schedule 2 amended by Government Notice R219 in Government Gazette 43051 dated 28 February 2020)*

*(Schedule 2 amended by Government Notice R1375 in Government Gazette 44019 dated 18 December 2020.)*

*(Schedule 2 amended by Government Notice 883 in Government Gazette 45176 dated 17 September 2021.)*

*(Schedule 2 amended by Government Notice R2412 in Government Gazette 46789 dated 26 August 2022)*

*(Schedule 2 amended by GN 2685 dated 28 October 2022)*

*(Schedule 2 amended by GNR 3261 dated 24 March 2023)*

### **SCHEDULE 3**

- a. All substances referred to in this Schedule are excluded when specifically packed, labelled, sold and used for -
  - (i) industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose; and
  - (ii) analytical laboratory purposes.
- b. All preparations of substances or mixtures of such substances containing or purporting to contain any substance referred to in this Schedule and includes the following:
  - (i) The salts and esters of such substances, where the existence of such salts and esters is possible; and
  - (ii) all preparations and mixtures of such substances where such preparations and mixtures are not expressly excluded.
- c. In terms of section 22A(5)(f) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974 (Act 56 of 1974) other than a medical practitioner or dentist may prescribe and supply, only within his/her scope of practice and subject to the indication for use of such substances and medicines and to the conditions determined by the Authority, to patients under his/her care, the Schedule 3 substances and medicines provided for in the Annexures to this Schedule published in the *Gazette* in terms of the Act.
  - (i) Annexure 1A: Emergency Care Provider (Paramedic);
  - (ii) Annexure 1B: Emergency Care Provider (Emergency Care Practitioner);
  - (iii) Annexure 2: Dental Therapist;
  - (iv) Annexure 3: Optometrist.
  - (v) Annexure 4: Podiatrist

Acamprosate.

Acebutolol.

Aceclofenac.

Acetazolamide.

Acetohexamide.

Acetylcholine, when intended for ophthalmic use.

Acetylcysteine,

- a. when intended for injection or for the management of paracetamol overdose;
- b. except when used as a mucolytic in acute respiratory conditions for a maximum treatment period of 14 days. (S2)

**Acipimox.**

**Acridinium.**

**Adapalene.**

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

**Alclofenac.**

**Alendronic acid.**

**Aliskiren.**

**Allopurinol.**

**Alogliptin.**

**Alprenolol.**

**Amiloride.**

**Amlodipine.**

**Ancrod.**

**Anthiolimine, when intended for injection.**

**Arsanilic acid.**

**Ascorbic Acid -see Vitamin C.**

**Atenolol.**

**Atropine,**

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

**Azapropazone.**

**Balsalazide**

**Barnidipine.**

**Beclamide.**

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

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

**Benazepril.**

**Bendazac.**

**Benfluorex.**



**Benoxaprofen.**

**Benzbromarone.**

**Benzydamine**, except preparations and mixtures -

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

**Bepridil.**

**Beta-benzalbutyramide.**

**Beta-galactosidase**, when intended for therapeutic purposes.

**Betahistine.**

**Betaxolol.**

**Bethanidine.**

**Bevantolol.**

**Bezafibrate.**

**Bisoprolol.**

**Bopindolol.**

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

Prepared by:

**Brimonidine.**

**Brinzolamide.**

**Budesonide,**

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

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

**Buflomedil.**

**Buformin.**

**Bumetanide.**

**Butecosone,** when intended for Inhalation or nasal administration.

**Cadralazine.**

**Caffeine,** when intended for injection.

**Calcipotriol.**

**Calcium,**

- a. in preparations thereof for injection; (S0)
- b. except in oral preparations or mixtures containing more than 1300 mg of calcium per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S1)
- c. except when indicated for the treatment of hyperphosphataemia; (S4)
- d. except when registered in terms of the provisions of the Fertilizers. Farm Feeds. Agricultural Remedies and Stock Remedies Act. 1947 (Act 36 of 1947).

**Calcium carbimide.**

**Calcium disodium edetate**, when intended for injection.

**Calcium dobesilate**.

**Calcium salts**, preparations thereof, when intended for injection, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

**Candesartan**.

**Captopril**.

**Carazolol**.

**Carbachol**, ophthalmic preparations thereof when intended for glaucoma. (S4)

**Carbamazepine**.

**Carbenoxolone**, except when intended for application to the oral mucosa. (S0)

**Carbimazole**

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

**Carprofen**.

**Carteolol**.

**Carvedilol**.

**Celecoxib**.

**Celiprolol**.

**Chenodeoxycholic acid**.

**Chlorazaniol**.

**Chlorexolone**.

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

**Chlorpropamide.**

**Chlorthalidone.**

**Cholecalciferol - see Vitamin D.**

**Chromonar.**

**Ciclesonide**

**Cilazapril.**

**Cilomilast.**

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

**Clevidipine**

**Clofibrate.**

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

**Clopidogrel.**

**Codeine (methyldorphine),**

- a. oral solid preparations, in combination with one or more therapeutically active substances, containing more than 10 milligrams of codeine (calculated as base) per dosage unit, when contained in products registered in terms of the Act, and not intended for export;
- b. liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, containing more than 10 milligrams of codeine (calculated as base) per 5 millilitre dosage unit, when contained in products registered in terms of the Act, and not intended for export;
- c. except oral solid preparations, in combination with one or more therapeutically active substances, containing not more than 10 milligrams of codeine (calculated as base) per dosage unit, with a maximum

daily dose not exceeding 80 milligrams, and in packs containing sufficient dosage units for a maximum treatment period of 5 days and limited to one pack per customer, when contained in products registered in terms of the Act, and not intended for export; (S2)

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

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

**Colecalciferol** see Vitamin D

**Colestipol.**

**Copper,**

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

**Copper salts**, when intended for injection.

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

**Cyanocobalamin** -see Vitamin B12.

**Cyclandelate.**

**Cyclopentolate**; ophthalmic preparations thereof. (S2)

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

**Darifenacin.**

**Debrisoquine.**

**Delapril.**

**Dexketoprofen trometamol.**

**Dialysate preparations.**

**Dichlorphenamide.**

**Diclofenac,**

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

**Dienogest.**

**Diflunisal.**

**Diflalone.**

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

**Dihydrocodeine,**

- a. oral solid preparations, in combination with one or more therapeutically active substances, containing more than 10 milligrams of dihydrocodeine (calculated as base) per dosage unit, when contained in products registered in terms of the Act, and not intended for export;
- b. liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, containing more than 10 milligrams of dihydrocodeine (calculated as base) per 5 millilitre dosage unit, when contained in products registered in terms of the Act, and not intended for export;

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

**Dihydroergocristine.**

**Dilevalol.**

**Diltiazem.**

**Dimercaprol**, when intended for injection.

**Dipivefrin.**

**Dipyridamole.**

**Dipyrocetyl.**

**Disulfiram.**

**Dithranol.**

**Dornase alfa (rh DNase).**

**Dorzolamide.**

**Doxazosin.**

**Drospirenone,**

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

Prepared by:

**Eltenac.**

**Enalapril.**

**Endralazine.**

**(-)- 6 epigallocatechin gallate**

**Eprosartan.**

**Ergocalciferol** - see Vitamin D.

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

**Esculin**, when intended for oral use.

**Esmolol.**

**Estradiol,**

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

Estriol,

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

**Ethacrynic acid.**

**Ethosuximide.**



**Etisazol.**

**Etodolac.**

**Etodolic acid.**

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

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

**Etoricoxib.**

**Exenatide.**

**Felbamate.**

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

**Felodipine.**

**Fenbufen.**

**Fenclofenac.**

**Fendiline.**

**Fenofibrate.**

**Fenoprofen,**

- (a) except when intended for the emergency treatment of acute gout attacks, (S2) and
- (b) when intended for the treatment of post traumatic conditions, for a maximum treatment period of 5 days.  
(S2)

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

**Fentiazac.**

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

**Firocoxib.**

**Floctafenine.**

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

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

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

**Flunixin.**

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

**Flurbiprofen**, except

- a. when intended for the treatment of post-traumatic conditions, for a maximum period of 5 days; (S3)
- b. when in the form of lozenges, indicated for the relief of pain associated with sore throats, subject to:
  - (i). a maximum of 8,75 milligrams per lozenge;
  - (ii). a maximum treatment period of 3 days; and
  - (iii). a maximum pack size of 15 lozenges. (S1)
- b. except when intended for application to the skin and indicated for the symptomatic relief of localised pain and inflammation, provided that in the case of application by transdermal patch:
  - (i) use is restricted to adults and children 12 years and older; and
  - (ii) the treatment period is limited to a maximum of 4 weeks. (S0)

*(Numbering as given in the Gazette)*

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

**Fluticasone furoate,**

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

**Fluticasone propionate,**

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

**Flunixin.**

**Flurbiprofen, except -**

- a. when intended for the treatment of post-traumatic conditions, for a maximum period of 5 days; (S3)
- b. when in the form of lozenges, indicated for the relief of pain associated with sore throats, subject to:
  - (i) a maximum of 8,75 milligrams per lozenge;

- (ii) a maximum treatment period of 3 days; and
  - (iii) a maximum pack size of 15 lozenges. (S1)
- b. except when intended for application to the skin and indicated for the symptomatic relief of localised pain and inflammation, provided that in the case of application by transdermal patch:
  - (i) use is restricted to adults and children 12 years and older; and
  - (ii) the treatment period is limited to a maximum of 4 weeks. (S0)
- c. when intended for the treatment of post-traumatic conditions, for a maximum period of 5 days; (S2)
- d. when intended for ophthalmic use. (S4)

**Folinic acid** (leucovorin)

**Fosinopril.**

**Frusemide.**

**Gabapentin.**

**Gadoxetic acid.**

**Gelatine succinylated.**

**Gemfibrozil.**

**Gestodene.**

**Glafenine.**

**Glibenclamide.**

**Glibornuride.**

**Gliclazide.**

**Glimepiride.**

**Glimidine.**

**Glipizide.**

**Gliquidone.**

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

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

**Glycopyrronium.**

**Guanabenz.**

**Guanethidine.**

**Guanfacine.**

**Guanoxan.**

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

**Homatropine**; ophthalmic preparations thereof. (S2)

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

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

**Hydralazine.**

**Hydrochlorothiazide.**

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

**Hydroxypropyl methylcellulose** when intended for ophthalmic use (S0)

**Hyoscine butylbromide**; substances, preparations and mixtures thereof-

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

**Ibuprofen**, except

- a. when contained in preparations intended for application to the skin, containing 5 % m/m or less of ibuprofen; (S0, S1)
- b. when contained in transdermal patches containing 200mg of ibuprofen per patch or less, and indicated for use by patients aged 16 years and older (S1)
- c. when contained in oral medicinal preparations supplied in a solid dose form as divided doses contained in packs not exceeding 24 dosage units or divided doses and containing ibuprofen as the only active therapeutic substance, intended for the treatment of mild to moderate pain or fever of inflammatory origin or for the treatment of post-traumatic conditions in adults and children over 12 years of age where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children 12 years and older does not exceed 20 milligrams per kilogram of body weight; (S1)
- d. when contained in oral medicinal preparations intended for human use only, in combination with one or more other active therapeutic substances and intended for the treatment of mild to moderate pain or fever of inflammatory origin for a maximum treatment period of 10 days where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (S2)
- e. when contained in oral medicinal preparations, intended for human use only, as the only active therapeutic substance in oral liquid preparations in packs not exceeding 100 millilitres in volume or in oral solid preparations in packs exceeding 24 dosage units or divided doses, when intended for adults and children over the age of 1 year; for the treatment of mild to moderate pain of inflammatory origin for a maximum treatment period of 10 days, or for the treatment of fever of inflammatory origin or for the treatment of post-traumatic conditions where the recommended daily dose of ibuprofen for adults does not exceed 1,2 grams and for children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (S2)
- f. for the emergency treatment of acute gout attacks for a maximum treatment period of 5 days; (S2)

- g. when intended for the treatment of haemodynamically significant patent ductus arteriosus in infants less than 34 weeks of gestational age (S4).

**Imepitoin**, when intended for veterinary use.

**Imidapril**.

**Indacaterol**.

**Indapamide**.

**Indometacin**, except

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

**Indoprofen**.

**Indoramin**.

**Injections**, unless listed in another Schedule.

**Insulin**.

**Insulin aspart**.

**Insulin degludec**.

**Insulin Glargine**.

**Insulin Lispro**

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

**Irbesartan**.

**Iron**,

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

- b. except in oral preparations or mixtures containing more than 24 mg of Iron per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S1)
- c. except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

**Iron salts**, when intended for injection, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

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

**Isosorbide.**

**Isoxicam.**

**Isradipine.**

**Ivabradine.**

**Ivermectin**, except when intended and registered as an anthelmintic and/or ectoparasiticide in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

**Ketanserin.**

**Ketoprofen,**

- a. except when intended for application to the skin; (S1)
- b. except when intended for the short term management of headache, toothache, muscular ache, backache, minor pain associated with arthritis, pain associated with menstrual cramps (dysmenorrhoea), minor aches and pains associated with the common cold and fever, subject to a maximum dose of 75 milligrams of ketoprofen in 24 hours; (S2)
- c. except when intended for the emergency treatment of acute gout attacks or for the treatment of post-traumatic conditions, subject to a maximum dose of 75 milligrams of ketoprofen per day and a maximum treatment period of 5 days; (S2)
- d. except in the form of lozenges indicated and intended for the relief of pain associated with sore throats in patients 18 years and older subject to-
  - (v) a maximum of 12,5 milligrams per lozenge;



- (vi) a maximum of 5 lozenges in any 24 hour period;
- (vii) a maximum treatment period of 3 days; and
- (viii) a maximum pack size of 15 lozenges. (S2)

*(Note – Numbering as published in Gazette No. 38586)*

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

**Labetalol.**

**Lacidipine.**

**Lacosamide.**

**Lumiracoxib.**

**Lamotrigine.**

**Lercanidipine.**

**Levalbuterol**

**Levothyroxine.**

**Levetiracetam.**

**Levobunolol.**

**Levonorgestrel,**

- a. when intended for oral contraception
- b. except when intended for emergency post coital contraception; (S2)
- c. except when administered via an Intra[*sic*] Uterine System. (S4)

**Levosemendan.**

**Lidoflazine.**

**Linagliptin**

**Liothyronine sodium.**

**Lisinopril.**

**Lonazolac.**

**Lornoxicam.**

**Losartan.**

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

**Meclofenamic acid.**

**Mefenamic acid**, except -

- a. when intended for the treatment of post-traumatic conditions, for a maximum period of 5 days; and
- b. preparations containing mefenamic acid as the only therapeutic active substance, when intended for human use only in the treatment of primary dysmenorrhoea subject to a maximum daily dose of 500 milligrams mefenamic acid 3 times a day and a maximum treatment period of 3 days. (S2)

**Meloxicam. (S4)**

**Mepindolol.**

**Mesalazine (5-aminosalicylic acid),**

**Mesulphene.**

**Metaproterenol (orciprenaline)**, when contained in respirator solutions. (S2, S4)

**Metformin.**

**Methazolamide.**

**Methimazole.**

**Methsuximide.**

Prepared by:

**Methyldopa.**

**Metipranolol.**

**Metolazone.**

**Metoprolol.**

**Mibefradil.**

**Mirabegron.**

**Moexipril.**

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

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

**Montelukast.**

**Moxonidine.**

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

**Nadolol.**

**Naftidrofuryl.**

**Naproxen**, except

- a. when contained in preparations intended for application to the skin; (S1, S2)
- b. when contained in oral medicinal preparations, intended for human use only containing naproxen as the only active therapeutic substance intended for patients over 16 years of age, for the treatment of mild

to moderate pain or fever of inflammatory origin at a maximum dose of 600 milligrams naproxen base (660 milligrams naproxen sodium) in a 24 hour period for a maximum treatment period of 5 days and supplied in a solid dose form as divided doses contained in packs not exceeding the stated maximum treatment period. (S1, S2)

- c. when intended for the treatment of acute gout attacks, for a maximum treatment period of 5 days in patients over 16 years of age. (S1, S2)

**Nateglinide,**

**Nebivolol.**

**Nepafenac.**

**Nicardipine.**

**Nicotine,**

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

**Nifedipine.**

Prepared by:

**Niflumic acid.**

**Nimodipine.**

**Nisoldipine.**

**Nitrendipine.**

**Nitroglycerine**, when intended for medicinal use.

**Noradrenaline theophylline** - see Theodrenaline.

**Norelgestromin.**

**Norethisterone,**

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

**Norgestrel,**

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

**Normal Saline** (Sodium chloride 0.9 % m/v) when intended for injection, except when intended for injection in a dosage form not exceeding 20 millilitres in volume. (S0, S1)

**Olsalazine.**

**Omesartan.**

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

**Oxaprozin.**

**Oxcarbazepine.**

Prepared by:

**Oxitracetam.**

**Oxovinca.**

**Oxyprenolol.**

**Oxybutynin.**

**Pantothenic Acid** - see Vitamin B5.

**Parecoxib.**

**Para-aminosalicylic acid** and its esters.

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

**Parenteral Nutrition** formulations.

**Penbutolol.**

**Penicillinase**, when intended for injection.

**Pentaerythritol tetranitrate.**

**Pentolinium.**

**Pentosan polysulfate sodium**, when intended for the treatment of interstitial cystitis. (S1)

**Perindopril.**

**Phenformin.**

**Phenobarbital**, preparations and mixtures containing not more than 90 milligrams of phenobarbital per minimum recommended or prescribed dose when intended for continued use in epilepsy. (S5)

**Phenoxymethylpenicillin**, when intended for the prophylaxis of rheumatic fever, (S4)

**Phentolamine.**

**Phenytoin.**

**Physostigmine**; ophthalmic preparations thereof, when intended for glaucoma. (S4)

**Pilocarpine**; ophthalmic preparations thereof intended for glaucoma. (S4)

**Pindolol**.

**Pioglitazone**.

**Piracetam**.

**Pirbuterol**, when contained in respirator solutions. (S2)

**Piretanide**.

**Piroxicam**, except:

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

**Pirprofen**.

**Potassium canrenoate**.

**Potassium**,

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

**Practolol**.

**Prazosin**.

**Primidone**.

**Probenecid**.

Prepared by:

**Probucol**

**Procaterol**, when contained in respirator solutions. (S2)

**Proctofene.**

**Propacetamol.**

**Propiverine.**

**Propranolol.**

**Proquazone.**

**Proscillaridine.**

**Protamine.**

**Prothionamide**, when intended for oral use.

**Pygeum africanum** (lipido-sterolic complex extract thereof).

**Pyrazinamide**, when intended for oral use.

**Pyridoxine** - see Vitamin B6.

**Pyrimethamine.**

**Pyrithioxin.**

**Quinapril.**

**Racecadotril.**

**Raloxifene.**

**Ramipril.**

**Ranitidine**, except where administered orally for short-term symptomatic relief of heartburn and hyperacidity, subject to a maximum dose of 75 milligrams, a maximum daily dose of 300 milligrams and a maximum treatment period of two weeks. (S2)

Prepared by:



**Raubasine.**

**Rauwolfia alkaloids.**

**Repaglinide.**

**Reproterol**, when contained in respirator solutions. (S2)

**Reserpine** (natural or synthetic).

**Riboflavin** - see Vitamin B2.

**Rimiterol**, when contained in respirator solutions. (S2, S4)

**Risedronate.**

**Rofecoxib.**

**Rosiglitazone.**

**Roxarzone** (3-nitro-4-hydroxyphenylarsonic acid), when intended for veterinary use.

**Sacubitril.**

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

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

**Saxagliptin.**

**Sitagliptin phosphate.**

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

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

**Solcoseryl**; ophthalmic preparations thereof. (S0, S4)

**Solifenacin.**

Prepared by:

**Sotalol.**

**Spirapril.**

**Spironolactone.**

**Strontium**, except when contained in toothpaste. (S0)

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

**Sulindac.**

**Suloctjidil.**

**Sulphinpyrazone.**

**Sulthiame.**

**Suprofen.**

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

**Tasosartan.**

**Tazarotene.**

**Telmisartan.**

**Tenidap.**

**Tenoxicam.**

**Tepoxalin.**

**Terazosin.**

**Terbutaline**, when contained in respirator solutions. (S2)

**Terizidone.**

Prepared by:

**Terodiline.**

**Theodrenaline** - see Noradrenaline theophylline.

**Thiacetazone.**

**Thiamine** - see Vitamin B1.

**Thiocolchicoside.**

**Thyroid gland** and its active principles and derivatives, unless listed in another Schedule.

**Tiagabine.**

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

**Ticagrelor.**

**Ticlopidine.**

**Timolol.**

**Tiotropium.**

**Tolamolol.**

**Tolazamide.**

**Tolbutamide.**

**Tolfenamic acid.**

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

**Tolterodine.**

**Topiramate.**

**Torasemide.**

**Trandolapril.**

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

**Triamterene.**

**Tricaine.**

**Trifarotene**

**Trimethadione.**

**Tropicamide.**

**Tulobuterol**, when contained in respirator solutions. (S2)

**Umeclidinium.**

**Ursodeoxycholic acid.**

**V. cholera.**

**Valdecoxib.**

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

**Valsartan.**

**Vedaprofen.**

**Verapamil (iproveratril).**

**Veratrum alkaloids.**

**Vigabatrin.**

**Vildagliptin.**

**Vincamine.**

**Vinpocetine.**

Vitamin A and derivatives thereof and including retinol, retinal, retinoic acids and beta-carotene (but excluding isotretinoin) and not listed elsewhere in the Schedules, contained in preparations or mixtures containing more than 10 000 I.U (or 3 000 mg of the retinol equivalent or 6 000 mg of the beta-carotene equivalent) of Vitamin A per recommended daily dose alone or in combination with other active pharmaceutical ingredients, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agriculture Remedies and Stock Remedies Act, 1947 (Act 36 of 1947). (S0, S2)

**Vitamin B1 (Thiamine)** and derivatives thereof,

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

**Vitamin B2 (Riboflavin)** and derivatives thereof,

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

**Vitamin B3 - See Niacin.**

**Vitamin B5 (Pantothenic Acid)** and derivatives thereof,

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

**Vitamin B6 (Pyridoxine)** and derivatives thereof,

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

**Vitamin B12 (Cyanocobalamin)** and derivatives thereof,

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

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

**Vitamin C (Ascorbic Acid),**

- a. in preparations thereof for injection; (S0)
- b. except in oral preparations or mixtures containing more than 1000 mg of Vitamin C per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S1)

**Vitamin D (cholecalciferol),** preparations thereof for injection and oral preparations and mixtures thereof containing more than 1 000 I.U. per recommended daily dose, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947). (S0)

**Vitamin K and derivatives** thereof,

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

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

**Xamoterol.**

**Xipamide.**

**Zafirlukast.**

**Zinc salts,**

- (a) for oral ingestion, where the daily dose is more than 50 milligrams of elemental zinc; (S0).
- (b) except preparations thereof for injection, when intended for veterinary use; (S1) and
- (c) except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

**Zomepirac.**

**ANNEXURES TO SCHEDULE 3**

**ANNEXURE 1A: EMERGENCY CARE PROVIDER (PARAMEDIC)**

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

<b>PARAMEDIC</b> (National Diploma in Emergency Medical Care graduates <i>only</i> )	
<b>PLATELET AGGREGATION INHIBITOR</b> Substance Indication Schedule Route of Administration	Clopidogrel Platelet aggregation inhibitor 3 Oral
<b>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</b> Substance Indication Schedule Route of Administration	Dextran Plasma expanders 3 Parenteral
<b>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</b> Substance Indication Schedule Route of Administration	Hydroxyethyl Starch Plasma expanders <b>3</b> Parenteral
<b>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</b> Substance Indication Schedule Route of Administration	Sodium Chloride Plasma expanders <b>3</b> Parenteral
<b>SELECTIVE <math>\beta</math>2 AGONISTS</b> Substance Indication Schedule Route of Administration	Salbutamol Bronchodilator 3 Inhalant
<b>SELECTIVE <math>\beta</math>2 AGONISTS</b> Substance Indication Schedule Route of Administration	Fenoterol Bronchodilator 3 Inhalant
<b>MINERAL SUPPLEMENT/ ELECTROLYTE</b> Substance Indication	Calcium chloride Positive inotrope- peri-cardiac and cardiac arrest / Electrolyte / Mineral Supplement



Schedule	3
Route of Administration	Parenteral
<b>OTHER MINERAL SUPPLEMENT</b>	
Substance	Magnesium sulphate
Indication	Mineral supplement; prevention and control of seizures and hypertension in toxemia of pregnancy
Schedule	3
Route of Administration	Parenteral
<b>CARBOHYDRATES</b>	
Substance	Dextrose
Indication	Nutrition / Acute Symptomatic Hypoglycaemic Treatment
Schedule	3
Route of Administration	Parenteral
<b>HIGH CEILING LOOP DIURETIC</b>	
Substance	Furosemide
Indication	Diuretic
Schedule	3
Route of Administration	Parenteral
<b>ORGANIC NITRATES</b>	
Substance	Glyceryl Trinitrate
Indication	Vasodilator
Schedule	3
Route of Administration	Oral
<b>ANTI-EMETIC</b>	
Substance	Cyclizine
Indication	Antihistamine, anti-emetic
Schedule	3
Route of Administration	Parenteral
<b>CO-ENZYME</b>	
Substance	Thiamine (Vitamin B1)
Indication	Nutritional supplement / Vitamin B (Emergency treatment of Wernicke's encephalopathy and Beriberi)
Schedule	3
Route of Administration	Parenteral
<b>ANALGESIC</b>	
Substance	Paracetamol
Indication	Analgesic / Anti- pyrexia
Route of Administration	Parenteral

<b>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</b> Substance Indication Route of Administration	Ringers Lactate Plasma expanders Parenteral
<b>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</b> Substance Indication Route of Administration	Polygeiine Plasma expanders Parenteral
<b>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</b> Substance Indication Route of Administration	Sodium Bicarbonate 8,5 % Metabolic acidosis Parenteral

*(Annexure 1A of Schedule 3 added by GNR 674 of 2013, amended by GN 1375 of 2020 and GN 883 of 2021)*

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

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

<b>EMERGENCY CARE PRACTITIONER (B Tech: Emergency Medical Care)</b>	
<b>PLATELET AGGREGATION INHIBITOR</b> Substance Indication Schedule Route of Administration	Clopidogrel Platelet aggregation inhibitor 3 Oral
<b>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</b> Substance Indication Schedule Route of Administration	Dextran Plasma expanders 3 Parenteral
<b>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</b> Substance Indication Schedule Route of Administration	Hydroxyethyl Starch Plasma expanders 3 Parenteral

<b>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</b>	
Substance	Sodium Chloride
Indication	Plasma expanders
Schedule	3
Route of Administration	Parenteral
<b>SELECTIVE <math>\beta_2</math> AGONISTS</b>	
Substance	Salbutamol
Indication	Bronchodilator
Schedule	3
Route of Administration	Inhalant
<b>SELECTIVE <math>\beta_2</math> AGONISTS</b>	
Substance	Fenoterol
Indication	Bronchodilator
Schedule	3
Route of Administration	Inhalant
<b>MINERAL SUPPLEMENT/ ELECTROLYTE</b>	
Substance	Calcium Chloride
Indication	Positive inotrope- peri cardiac and cardiac arrest / Electrolyte / Mineral Supplement
Schedule	3
Route of Administration	Parenteral
<b>OTHER MINERAL SUPPLEMENTS</b>	
Substance	Magnesium sulphate
Indication	Mineral supplement; prevention and control of seizures and hypertension in toxemia of pregnancy
Schedule	3
Route of Administration	Parenteral
<b>CARBOHYDRATES</b>	
Substance	Dextrose
Indication	Nutrition / Acute Symptomatic Hypoglycaemic Treatment
Schedule	3
Route of Administration	Parenteral
<b>HIGH CEILING LOOP DIURETIC</b>	
Substance	Furosemide
Indication	Diuretic
Schedule	3
Route of Administration	Parenteral
<b>ORGANIC NITRATES</b>	
Substance	Glyceryl Trinitrate

Indication	Vasodilator
Schedule	3
Route of Administration	Oral
<b>ANALGESIC</b>	
Substance	Paracetamol
Indication	Analgesic / Anti-pyrexia
Route of Administration	Parenteral
<b>* ANTI-SPASMODIC</b>	
Substance	Hyoscine butylbromide
Indication	Anti-spasmodic
Route of Administration	Parenteral
<b>** ARTERIAL SMOOTH MUSCLE AGENT</b>	
Substance	Hydralazine
Indication	Hypertension.in pregnancy
Route of Administration	Oral
<b>BETA BLOCKER</b>	
Substance	Labetalol
Indication	Hypertension in pregnancy
Route of Administration	Parenteral
<b>** CLASS III ANTI-ARRHYTHMIC</b>	
Substance	Sotalol
Indication	Anti-arrhythmic
Route of Administration	Oral/ Parenteral
<b>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</b>	
Substance	Ringers Lactate
Indication	Plasma expanders
Route of Administration	Parenteral
<b>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</b>	
Substance	Polygeline
Indication	Plasma expanders
Route of Administration	Parenteral
<b>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</b>	
Substance	Sodium Bicarbonate 8,5 %
Indication	Metabolic acidosis
Route of Administration	Parenteral
<b>** VASODILATOR</b>	

Substance	Isosorbide dinitrate
Indication	Acute pulmonary Syndrome / Acute pulmonary oedema
Route of Administration	Parenteral
<b>ANTI-EMETIC</b>	
Substance	Cyclizine
Indication	Antihistamine, anti-emetic
Schedule	3
Route of Administration	Parenteral
<b>CO-ENZYME</b>	
Substance	Thiamine (Vitamin B1)
Indication	Nutritional supplement / Vitamin B (Emergency treatment of Wernicke's encephalopathy and Beriberi)
Schedule	3
Route of Administration	Parenteral

(Annexure 1B of Schedule 3 added by GNR 674 of 2013, amended by GN 1375 of 2020 and GN 883 of 2021)

#### **ANNEXURE 1C: BASIC AMBULANCE ASSISTANT**

**BASIC AMBULANCE ASSISTANT** registered with Health Professions Council of South Africa

<b>BASIC AMBULANCE ASSISTANT</b> registered with Health Professions Council of South Africa	
<b>SELECTIVE <math>\beta</math>2 AGONISTS</b>	
Substance	Salbutamol
Indication	Bronchodilator
Route of Administration	Inhalant

(Annexure 1C of Schedule 3 added by GN 1375 of 2020)

#### **ANNEXURE 1D: AMBULANCE EMERGENCY ASSISTANT**

**AMBULANCE EMERGENCY ASSISTANT** registered with Health Professions Council of South Africa

<b>AMBULANCE EMERGENCY ASSISTANT</b> registered with Health Professions Council of South Africa	
<b>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</b>	
Substance	Dextran
Indication	Plasma expanders
Route of Administration	Parenteral
<b>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</b>	
Substance	Hydroxyethyl Starch

Indication	Plasma expanders
Route of Administration	Parenteral
<b>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</b>	
Substance	Sodium chloride
Indication	Plasma expanders
Route of Administration	Parenteral
<b>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</b>	
Substance	Ringers Lactate
Indication	Plasma expanders
Route of Administration	Parenteral
<b>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</b>	
Substance	Polygeline
Indication	Plasma expanders
Route of Administration	Parenteral
<b>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</b>	
Substance	Sodium Bicarbonate 8,5%
Indication	Plasma expanders
Route of Administration	Parenteral
<b>* CARBOHYDRATES</b>	
Substance	Dextrose
Indication	Nutritional / acute symptomatic hypoglycaemic treatment in adults and paediatrics
Route of Administration	Parenteral
<b>* CO-ENZYME</b>	
Substance	Thiamine (Vitamin B1)
Indication	Nutritional supplement / Vitamin B (Emergency treatment of Wernicke's encephalopathy and Beriberi)
Route of Administration	Parenteral
<b>*OTHER MINERAL SUPPLEMENTS</b>	
Substance	Magnesium sulphate
Indication	Mineral supplement; prevention and control of seizures and hypertension in toxemia of pregnancy
Route of Administration	Parenteral
<b>SELECTIVE <math>\beta_2</math> AGONISTS</b>	
Substance	Salbutamol
Indication	Bronchodilator

Route of Administration	Inhalant
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*(Annexure 1D of Schedule 3 added by GN 1375 of 2020 and amended by GN 883 of 2021)*

### **ANNEXURE 1E: EMERGENCY CARE TECHNICIAN**

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

<b>EMERGENCY CARE TECHNICIAN</b> registered with Health Professions Council of South Africa	
<b>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</b> Substance Indication Route of Administration	Dextran Plasma expanders Parenteral
<b>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</b> Substance Indication Route of Administration	Hydroxyethyl Starch Plasma expanders Parenteral
<b>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</b> Substance Indication Route of Administration	Sodium chloride Plasma expanders Parenteral
<b>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</b> Substance Indication Route of Administration	Ringers Lactate Plasma expanders Parenteral
<b>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</b> Substance Indication Route of Administration	Polygeline Plasma expanders Parenteral
<b>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</b> Substance Indication Route of Administration	Sodium Bicarbonate 8,5% Plasma expanders Parenteral
<b>* CARBOHYDRATES</b> Substance Indication	Dextrose Nutritional / acute symptomatic hypoglycaemic treatment in adults and paediatrics

Route of Administration	Parenteral
<b>* CO-ENZYME</b>	
Substance	Thiamine (Vitamin B1)
Indication	Nutritional supplement / Vitamin B (Emergency treatment of Wernicke's encephalopathy and Beriberi)
Route of Administration	Parenteral
<b>*OTHER MINERAL SUPPLEMENTS</b>	
Substance	Magnesium sulphate
Indication	Mineral supplement; prevention and control of seizures and hypertension in toxemia of pregnancy. Ventricular anti-arrhythmic.
Route of Administration	Parenteral
<b>ORGANIC NITRATES</b>	
Substance	Glycerol trinitrate
Indication	Vasodilator
Route of Administration	Oral
<b>SELECTIVE <math>\beta_2</math> AGONISTS</b>	
Substance	Salbutamol
Indication	Bronchodilator
Route of Administration	Inhalant

*(Annexure 1E of Schedule 3 added by GN 1375 of 2020 and amended by GN 883 of 2021)*

### **ANNEXURE 1F: EMERGENCY CARE ASSISTANT**

**EMERGENCY CARE ASSISTANT** registered with Health Professions Council of South Africa

<b>EMERGENCY CARE ASSISTANT</b> registered with Health Professions Council of South Africa	
<b>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</b>	
Substance	Dextran
Indication	Plasma expanders
Route of Administration	Parenteral
<b>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</b>	
Substance	Hydroxyethyl Starch
Indication	Plasma expanders
Route of Administration	Parenteral
<b>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</b>	
Substance	Sodium chloride
Indication	Plasma expanders



Route of Administration	Parenteral
<b>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</b> Substance Indication Route of Administration	Ringers Lactate Plasma expanders Parenteral
<b>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</b> Substance Indication Route of Administration	Polygeline Plasma expanders Parenteral
<b>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</b> Substance Indication Route of Administration	Sodium Bicarbonate 8,5% Metabolic acidosis Parenteral
<b>* CARBOHYDRATES</b> Substance Indication Route of Administration	Dextrose Nutritional / acute symptomatic hypoglycaemic treatment in adults and paediatrics Parenteral
<b>* CO-ENZYME</b> Substance Indication Route of Administration	Thiamine (Vitamin B1) Nutritional supplement / Vitamin B (Emergency treatment of Wernicke's encephalopathy and Beriberi) Parenteral
<b>*OTHER MINERAL SUPPLEMENTS</b> Substance Indication Route of Administration	Magnesium sulphate Mineral supplement; prevention and control of seizures and hypertension in toxemia of pregnancy. Parenteral
<b>SELECTIVE <math>\beta_2</math> AGONISTS</b> Substance Indication Route of Administration	Salbutamol Bronchodilator Inhalant

*(Annexure 1F of Schedule 3 added by GN 1375 of 2020 and amended by GN 883 of 2021)*

### **ANNEXURE 3: OPTOMETRIST**

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

Prepared by:

<b>OPTOMETRIST</b>	
<b>CYCLOPLEGICS</b>	
Substance	Atropine
Indication	Cyclopegic refraction; Treatment of Uveitis
Route of Administration	Topical application (drops)
<b>MYDRIATICS / CYCLOPLEGICS</b>	
Substance	Tropicamide
Indication	Cyclopegic; Mydriatic
Route of Administration	Topical application (drops)
<b>MYDRIATICS / CYCLOPLEGICS</b>	
Substance	Cyclopentolate
Indication	Cyclopegic; Mydriatic
Route of Administration	Topical application (drops)
<b>MYDRIATICS / CYCLOPLEGICS</b>	
Substance	Homatropine
Indication	Cyclopegic; Mydriatic
Route of Administration	Topical application (drops)
<b>ANTI GLAUCOMA</b>	
Substance	Pilocarpine
Indication	Acute Glaucoma
Route of Administration	Topical application (drops)
<b>ANTI GLAUCOMA</b>	
Substance	Timolol
Indication	Acute Glaucoma
Route of Administration	Topical application (drops)
<b>BETA-BLOCKER</b>	
Substance	Betaxolol
Indication	Open-Angle Glaucoma in Adults
Route of Administration	Topical Application (Drops)
<b>SYMPATHOMIMETIC</b>	
Substance	Brimonidine
Indication	Open-Angle Glaucoma in Adults
Route of Administration	Topical Application (Drops)
<b>BETA-BLOCKER</b>	
Substance	Levobunolol
Indication	Open-Angle Glaucoma in Adults
Route of Administration	Topical Application (Drops)

*(Annexure 3 of Schedule 3 added by GN 620 of 2016 and amended by GN 748 of 2017, GNR 219 of 2020 and GNR 220 of 2020)*

#### **ANNEXURE 4: PODIATRIST**

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

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

*(Annexure 4 inserted by Government Notice R220 in Government Gazette 43051 dated 28 February 2020)*

*(Annexure 4 amended by Government Notice R1375 in Government Gazette 44019 dated 18 December 2020.)*

*(Annexures 1A & 1B inserted by Government Notice R674 in Government Gazette 36827 dated 13 September 2013.)*

*(Annexure 3 added by Government Notice 620 in Government Gazette 40041 dated 3 June 2016)*

*(Annexure 3 amended by Government Notice 748 in Government Gazette 41009 dated 28 July 2017)*

*(Annexure 3 amended by Government Notice R219 in Government Gazette 43051 dated 28 February 2020)*

Prepared by:

*(Annexure 3 amended by Government Notice R220 in Government Gazette 43051 dated 28 February 2020)*

*Annexures 1A, 1B & 4, amended by Government Notice R1375 in Government Gazette 44019 dated 18 December 2020.)*

*(Annexures 1C, 1D, 1E & 1F inserted by Government Notice R1375 in Government Gazette 44019 dated 18 December 2020.)*

*(Annexures 1A, 1B, 1D, 1E & 1F amended by Government Notice 883 in Government Gazette 45176 dated 17 September 2021.)*

Indication	:	Local Anaesthesia
Route of Administration	:	Parenteral

*(Annexure 4 inserted by Government Notice R220 in Government Gazette 43051 dated 28 February 2020)*

*(Annexure 4 amended by Government Notice R1375 in Government Gazette 44019 dated 18 December 2020.)*

### **- END SCHEDULE 3 -**

*(Schedule 3 amended by Government Notice R1230 in Government Gazette 32838 dated 31 December 2009)*

*(Schedule 3 amended by Government Notice R227 in Government Gazette 35149 dated 15 March 2012)*

*(Schedule 3 amended by Government Notice R690 in Government Gazette 36850 dated 20 September 2013)*

*(Schedule 3 amended by Government Notice R104 in Government Gazette 37318 dated 11 February 2014.  
Commencement date: 11 February 2014)*

*(Schedule 3 amended by Government Notice R352 in Government Gazette 37622 dated 8 May 2014)*

*(Schedule 3 amended by Government Notice R234 in Government Gazette 38586 dated 20 March 2015)*

*(Schedule 3 amended by Government Notice 254 in Government Gazette 39815 dated 15 March 2016)*

*(Schedule 3 amended by Government Notice 620 in Government Gazette 40041 dated 3 June 2016)*

*(Schedule 3 amended by Government Notice 748 in Government Gazette 41009 dated 28 July 2017)*

*(Schedule 3 amended by Government Notice 1261 in Government Gazette 41256 dated 17 November 2017)*

*(Schedule 3 amended by Government Notice R1098 in Government Gazette 41971 dated 12 October 2018)*

*(Schedule 3 amended by Government Notice R1262 in Government Gazette 42052 dated 23 November 2018)*

*(Schedule 3 amended by Government Notice R755 in Government Gazette 42477 dated 23 May 2019)*

*(Schedule 3 amended by Government Notice R219 in Government Gazette 43051 dated 28 February 2020)*

*(Schedule 3 amended by Government Notice R220 in Government Gazette 43051 dated 28 February 2020)*

*(Schedule 3 amended by Government Notice R1375 in Government Gazette 44019 dated 18 December 2020.)*

*(Schedule 3 amended by Government Notice 883 in Government Gazette 45176 dated 17 September 2021.)*

*(Schedule 3 amended by GN 2685 dated 28 October 2022)*

*(Schedule 3 amended by GNR 3261 dated 24 March 2023)*

**SCHEDULE 4**

- a. All substances referred to in this Schedule are excluded when specifically packed, labelled, sold and used for -
- (i) industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose; and
  - (ii) analytical laboratory purposes.
- b. All preparations of substances or mixtures of such substances containing or purporting to contain any substance referred to in this Schedule and includes the following:
- (ii) The salts and esters of such substances, where the existence of such salts and esters is possible; and
  - (iii) all preparations and mixtures of such substances where such preparations and mixtures are not expressly excluded.

*Note – Numbering as published in the Gazette*

- c. In terms of section 22A(5)(f) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974 (Act 56 of 1974) other than a medical practitioner or dentist may prescribe and supply, only within his/her scope of practice and subject to the indication for use of such substances and medicines and to the conditions determined by the Authority, to patients under his/her care, the Schedule 4 substances and medicines provided for in the Annexures to this Schedule published in the *Gazette* in terms of the Act.
- (i)
 

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

**Abacavir.**

Prepared by:

**Abatacept.**

**Abciximab.**

**Abemaciclib.**

**Abiraterone.**

**Acalabrutinib.**

**Acarbose.**

**Acediasulfone.**

**Acetarsone diethylamine salt**, when intended for injection.

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

**Adalimumab.**

**Adenosine.**

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

**Afatinib.**

**Agalsidase alfa.**

**Agalsidase beta.**

**Aglepristone.**

**Alatrofloxacin.**

**Albendazole,**

- a. except when intended for the treatment of intestinal parasites, as a single oral dose; (S2)
- b. except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

**Alclometasone.**

**Alcuronium.**

**Aldesleukin.**

**Alectinib**

**Alefacept.**

**Alemtuzumab.**

**Alfacalcidol.**

**Alfuzosin.**

**Alglucosidase alfa.**

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

**Alirocumab.**

**Alizapride.**

**Almitrine,**

**Alosetron.**

**Alpelisib**

**Alphachymotrypsin ( $\alpha$ -chymotrypsin)**, when intended for ophthalmic use.

**Alprostadil.**

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

**Altrenogest** for use in animals.

**Amantadine.**

Prepared by:

**Ambrisentan.**

**Amethocaine**, - see Tetracaine.

**Amifostine.**

**Amikacin.**

**Aminoacridine.**

**Aminogluthethimide.**

**Aminolevulinic.**

**Aminophenazone.**

**Aminopyrine (amidopyrine).**

**Aminosalicylic acid.**

**Amiodarone.**

**Amiphenazole.**

**Amivantamab**

**Amodiaquine.**

**Amoxicillin.**

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

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

**Amphotericin B**



**Amprenavir.**

**Amrinone.**

**Amsacrine.**

**Anagrelide.**

**Anastrozole.**

**Anecortave.**

**Anidulafungin.**

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

**Antihemophilic factor.**

**Antimalarials**, unless listed elsewhere in the Schedules.

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

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

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

(b) when intended for use as -

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

**Antisera**, unless listed elsewhere in the Schedules when intended for veterinary use, except antisera registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

**Apalutamide**

**Apixaban.**

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

**Apraclonidine.**

**Apramycin.**

**Apremilast.**

**Aprepitant.**

**Aprotinin.**

**A- $\beta$  arteether.**

**Arabinosylcytosine.**

**Arprinocid**, except when intended and registered as an anticoccidial preparation in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

**Arsenamide**, when intended for injection.

**Arsenic,**

- a. when intended for injection;
- b. except in oral dosage form. (S1, S2)

**Artemether and its derivatives.**

**Artemisinin.**

**Artemotil.**

**Artesunate.**

**Asciminib**

**L-Asparaginase.**

**Astemizole.**

**Atazanavir.**

**Atezolizumab.**

**Atipamizole.**

**Atorvastatin.**

**Atosiban.**

**Atovaquone, except**

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

**Atracurium besilate.**

**Atropine,**

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

Prepared by:

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

**Auranofin.**

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

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

**Axitinib.**

**Azacitidine.**

**Azathioprine.**

**Azithromycin.**

**Azlocillin.**

**Aztreonam.**

**Bacampicillin.**

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

**Baclofen.**

**Baloxavir.**

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

**Baricitinib.**

**Barium sulfate.**

**Basiliximab.**

**Bazedoxifene.**

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

**Bedaquiline.**

**Bedinvetmab**

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

**Belatacept.**

**Belimumab.**

**Bemegride.**

**Bemiparin.**

**Bendamustine.**

**Benethamine penicillin.**

**Benralizumab.**

**Benzathine benzylpenicillin.**

**Benzathine phenoxymethylpenicillin.**

**Benzocaine,**

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

**Benzylpenicillin.**

Prepared by:

**Besifloxacin.**

**Betamethasone.**

**Bethanechol.**

**Betiatide.**

**Bevacizumab.**

**Bicalutamide.**

**Bictegravir**

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

**Bimatoprost**

**Biolimus.**

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

- (a) except vaccines, when listed elsewhere in the Schedules and vaccines registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).
- (b) but specifically including the following -
  - (i) Equine anti-human thymocyte globulin;
  - (ii) Equine gamma globulin;
  - (iii) Human anti-D immunoglobulin;
  - (iv) Human anti-thymocyte rabbit immunoglobulin;
  - (v) Hepatitis A vaccine;
  - (vi) Hepatitis B immunoglobulin;

- (vii) Human normal immunoglobulin, possibly polyvalent or possibly including IgG, IgA, or IgM;
- (viii) Human plasma albumin;
- (ix) *Neisseria meningitides* vaccine;
- (x) Pneumococcal vaccine, polysaccharide;
- (xi) Rabies immunoglobulin;
- (xii) Rabies vaccine;
- (xiii) Recombinant cholera toxin B subunit;
- (xiv) rhDNase-dornase alfa;
- (xv) Tetanus immunoglobulin;
- (xvi) Varicella immunoglobulin;
- (xvii) Varicella-zoster virus vaccine;
- (xviii) Yellow Fever virus, attenuated.

**Biperiden.**

**Bleomycin.**

**Blinatumomab.**

**Boceprevir.**

**Bortezomib.**

**Botulinum toxin.**

**Brentuximab.**

**Bretylium tosilate.**

**Brigatinib.**

**Brolucizumab.**

**Bromocriptine.**

**Budesonide,**

- a. except when intended for the prophylaxis and treatment of seasonal and perennial allergic rhinitis in adults and children aged 12 years and older; (S2)
- b. except when intended inhalation or nasal administration, unless listed in another Schedule. (S3)

**Bufenoide.**

**Bumadizone.**

**Bupivacaine.**

**Buserelin.**

**Busulfan.**

**Butoconazole**, except -

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

**Cabazitaxel.**

**Cabergoline.**

**Cabotegravir**

**Cabozantinib**

**Calcitonin.**

**Calcitriol.**

**Calcium,**



- a. when indicated for the treatment of hyperphosphataemia; (S0)
- b. except in oral preparations or mixtures containing more than 1300 mg of calcium per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S1)
- c. except in preparations thereof for injection; (S3)
- d. except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

**Calcium acetate**, when indicated for treatment of hyperphosphataemia

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

**Canakinumab**.

**Candididin**.

**Cannabidiol**, except—

- a. in complementary medicines containing no more than 600 mg cannabidiol per sales pack, providing a maximum daily dose of 20 mg of cannabidiol, and making a general health enhancement, health maintenance or relief of minor symptoms (low-risk) claim; (S0) or
- b. processed products made from cannabis raw plant material intended for ingestion containing 0.0075 percent or less of cannabidiol where only the naturally occurring quantity of cannabinoids found in the source material are contained in the product. (S0)

**Capecitabine**.

**Capreomycin**.

**Capsaicin**, when intended for transdermal application.

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

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

**Carbenicillin.**

**Carbetocin.**

**Carbidopa.**

**Carboplatin.**

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

**Carfilzomib.**

**Carglumic.**

**Carmustine.**

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

**Capreomycin.**

**Casirivimab**

**Casopitant.**

**Caspofungin.**

**Catridecacog.**

**Cefaclor.**

**Cefadroxil.**

**Cefalexin.**

**Cefaloridine.**

**Cefalosporin.**

**Cefalotin.**

**Cefamandole.**

**Cefazolin.**

**Cefepime.**

**Cefquinome.**

**Cefixime.**

**Cefmetazole.**

**Cefodizime.**

**Cefonicid.**

**Cefoperazone.**

**Cefotaxime.**

**Cefotetan.**

**Cefovecin.**

**Cefoxitin,**

**Cefpirome.**

**Cefpodoxime.**

**Cefprozil.**

**Cefquinome**

**Cefradine.**

**Cefsulodin.**

**Ceftaroline.**

**Ceftazidime.**

**Ceftibuten.**

**Ceftiofur.**

**Ceftizoxime.**

**Ceftobiprole.**

**Ceftolozane.**

**Ceftriaxone.**

**Cefuroxime.**

**Cefalotin.**

**Ceritinib.**

**Cerivastatin.**

**Certoparin.**

**Ceruletide.**

**Cetrorelix.**

**Cetuximab.**

**Chlorambucil.**

**Chloramphenicol.**

**Chlorguinaldol.**

**Chlormadinone.**

**Chloroquine**

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

**Choriogonadotropin alfa.**

**Chorionic gonadotrophin.**

**Chymopapain**, when intended for injection.

**Ciclacillin.**

**Ciclosporin.**

**Cilastatin.**

**Cinacalcet.**

**Cinoxacin.**

**Ciplofloxacin.**

**Ciprofloxacin.**

**Cisapride.**

**Cisatracurium.**

**Cisplatin.**

**Cladribine.**

**Clanobutin.**

**Clarithromycin.**

**Clavulanic acid.**

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

**Clemizole penicillin.**

**Clenbuterol.**

**Clindamycin.**

Prepared by:

**Clioquinol.**

**Clobetasol.**

**Clobetasone.**

**Clodantoin.**

**Clofazimine.**

**Clomifene.**

**Cloprostenol**, when intended for veterinary use.

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

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

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

**Cobicistat.**

**Cobimetinib.**

**Colfosceril.**

**Colistimethate.**

**Colistin,**

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

**Contrast media**, unless listed elsewhere in the Schedules.

**Copper,**

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

**Corifollitropin alfa.**

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

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

**Co-tetroxazine.**

**Co-trifamole.**

**Co-trimoxazole.**

**Crisaborole.**

**Crisanlizumab.**

**Crizotinib.**

**Cyclofenil.**

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

**Cycloserine.**

**Ciclosporin.**

**Cyprenorphine.**

**Cyproterone acetate.**

**Cytarabine.**

**Dabigatran**

**Dabrafenib.**

**Dacarbazine.**

**Dacliximab.**

**Daclizumab.**

**Dacomitinib**

**Dactinomycin.**

**Dalteparin.**

**Danaparoid.**

**Danofloxacin.**

**Dantrolene.**

**Dapagliflozin.**

**Dapivirine**

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

**Daptomycin.**

**Daratumumab.**

**Darbepoetin Alfa.**

**Darolutamide**

**Darunavir.**

**Dasatinib.**



**Daunorubicin.**

**Decitabine.**

**Deconexent (DHA) 380**, when indicated for the treatment of hypertriglyceridaemia.

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

**Deferasirox.**

**Deferipone.**

**Deferoxamine.**

**Degarelix.**

**Demecarium.**

**Demeclocycline.**

**Denosumab**

**Deoxycholic acid.**

**Desirudin.**

**Deslorelin.**

**Desmopressin**

**Desonide.**

**Desoximetasone.**

**Dexamethasone.**

**Dexlansoprazole.**

**Diatrizoic acid.**

**Diazoxide.**

**Dichlorophen,**

- a. except in preparations and mixtures when intended for application to the skin; (S0)
- b. except in preparations containing 0,5 percent or less of dichlorophen when intended for use in terms of the provisions of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972);
- c. except when intended for use and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

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

**Diclodronic acid.**

**Dicloxacillin.**

**Didanosine.**

**Diethylcarbamazine.**

**Diflorasone.**

**Difloxacin.**

**Diffucortolone.**

**Dihydralazine.**

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

**Dihydrotachysterol.**

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

**Di-isopropyl fluorophosphate.**

**Dilazep.**

**Diloxanide furoate.**

**Dimethyl fumarate.**

**Dimethyl sulphoxide.**

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

**Diminazene**, except when intended and registered as an antibabesial in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

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

**Dinitrophenol.**

**Dinoprostone.**

**Diphemethoxidine.**

**Difenidol.**

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

**Disopyramide.**

**Distigmine.**

**Ditazole.**

**Dobutamine.**

**Docetaxel.**

**Dolasetron.**

**Dolutegravir.**

**Domperidone.**

**Dopa.**

**Dopamine.**

**Doravirine.**

**Doripenem**

**Doxapram.**

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

**Doxorubicin.**

**Doxycycline**, except

- a. when intended and labelled for the chemoprophylaxis of malaria in those aged 8 years and older (S2)
- b. in preparations thereof for the treatment of animals and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

**Dronedarone.**

**Drospirenone,**

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

**Drotrecognin.**

**Dulaglutide.**

**Dupilumab.**

**Durvalumab.**

**Dutasteride.**

**Dydrogesterone**

**Econazole**, except -

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

**Edoxudine.**

**Edrophonium.**

**Efalizumab.**

**Efavirenz.**

**Efraloctocog alfa.**

**Eftrenonacog alfa** (Human coagulation Factor IX).

**Eicosapent (EPA) 460**, when indicated for the treatment of hypertriglyceridaemia.

**Eletriptan.**

**Eltrombopag.**

**Elvitegravir.**

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

**Empagliflozin.**

**Emtricitabine**

**Encainide.**

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

Prepared by:

**Enoxacin.**

**Enoxaparin,**

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

**Enrofloxacin.**

**Entacapone.**

**Entecavir.**

**Entrectinib**

**Enzalutamide.**

**Epicillin.**

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

**Epirizole.**

**Epirubicin (4-epidoxorubicin).**

**Eplerenone.**

**Epoetin beta, polyethylene glycol.**

**Eptacog alfa.**

**Eptifibatide**

**Eptinezumab**

**Erenumab.**

**Ergometrine maleate**

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

**Eribulin**

**Erlotinib.**

**Ertapenem.**

**Erythromycin.**

**Esomeprazole**, except when indicated for the temporary, short-term relief of heartburn and hyperacidity, subject to:

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

**Estradiol,**

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

**Estriol,**

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

**Estramustine.**

**Etamiyan.**

**Etanercept.**

**Etelcalcetide.**

**Ethambutol.**

**Ethionamide.**

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

**Etidronic acid.**

**Etiproston.**

**Etofamide.**

**Etoglucid.**

**Etoposide.**

**Etravirine.**

**Everolimus.**

**Evolocumab.**

**Exemestane**

**Ezetimibe.**

**Famciclovir.**

**Famotidine**, except when intended for the short term symptomatic relief of heartburn caused by excess acid, where the maximum dose is 10 milligrams, the maximum daily dose (per 24 hours) is 20 milligrams and the maximum treatment period is 2 weeks. (S2)

**Fampridine.**

**Faricimab**

**Fazadinium.**



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

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

**Fenoldopam**.

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

**Fenticonazole**.

**Fertirelin**.

**Ferucarbitran**.

**Fidaxomicin**.

**Filgrastim**.

**Finasteride**.

**Fingolimod**

**Flecainide**.

**Florfenicol**.

**Flosequinan**.

**Flucloxacillin**.

**Fluconazole**.

**Flucytosine**.

**Fludarabine**.

**Fludrocortisone acetate**

**Flugestone**.

**Flumethasone.**

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

**Fluocinolone.**

**Fluocinonide.**

**Fluocortolone.**

**Fluorides,**

- a. except in oral medicinal preparations and mixtures intended for ingestion containing not more than 0,25 milligrams of fluorine per dosage unit; (S1)
- b. except in toothpaste containing not more than 0,15 percent fluoride; (S0) and
- c. except in mouth rinses containing not more than 0,15 percent fluoride. (S0)

**Fluorometholone.**

**5- Fluorouracil.**

**Fluprednidene.**

**Flurbiprofen,**

- a. when intended for ophthalmic use; (S4)
- b. except when in the form of lozenges, indicated for the relief of pain associated with sore throats, subject to:
  - (i) a maximum of 8,75 milligrams per lozenge;
  - (ii) a maximum treatment period of 3 days; and
  - (iii) a maximum pack size of 15 lozenges. (S1)
- c. except when intended for application to the skin, provided that in the case of application by transdermal patch:
  - (i) use is restricted to adults and children 12 years and older; and

(ii) the treatment period is limited to a maximum of 4 weeks. (S0)

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

**Flutamide.**

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

**Fluticasone furoate**, except -

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

(i) a maximum daily dose of 55 micrograms per nostril; and

(ii) a maximum pack size limit of 120 doses. (S2)

b. when intended for inhalation or nasal administration. (S3)

**Fluticasone propionate**, except -

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

(i) a maximum daily dose of 100 micrograms per nostril; and

(ii) a maximum pack size of 120 doses. (S2)

c. when intended for inhalation or nasal administration. (S3)

*(Note – Incorrect numbering as published in Gazette No. 38586)*

**Fluvastatin.**

**Follitropin alfa.**

**Follitropin delta.**

**Fondaparinux.**

Prepared by:

**Formoterol.**

**Fosamprenavir.**

**Fosaprepitant.**

**Fosfomycin.**

**Fosphenytoin sodium.**

**Fostemsavir.**

**Fotemustine.**

**Fremanezumab**

**Framycetin.**

**Frovatriptan.**

**Ftorafur.**

**Fulvestrant.**

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

**Furazolidone.**

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

**Gadobutrol.**

**Gadodiamide.**

**Gadofosveset.**

**Gadoversetamide.**

**Galactose**, when used as a contrast agent

**Galantamine.**

**Galcanezumab**

**Gallamine.**

**Gamithromycin.**

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

**Ganciclovir.**

**Ganirelix.**

**Gatifloxacin.**

**Gefitinib.**

**Gemcitabine.**

**Gemtuzumab.**

**Gemifloxacin.**

**Gentamicin.**

**Gestrinone.**

**Glatiramer.**

**Glofitamab**

**Glucagon**

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

**Golimumab.**

**Gonadorelin.**

Prepared by:

**Goserelin.**

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

**Granisetron.**

**Granulocyte Colony Stimulating Factor (G-CSF).**

**Grapiprant.**

**Grepafloxacin.**

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

**Guselkumab**

**Halcinonide.**

**Halofantrine.**

**Halofenate.**

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

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

**Halometasone.**

**Halquinol.**

**Hemin.**

**Heparin.**

**Heptaminol.**

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

**Histrelin.**

Prepared by:

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

- (a) when specifically intended for emergency postcoital contraception; (S2)
- (b) when intended for oral contraception; (S3)
- (c) insulin; (S3)
- (d) epinephrine; ( S2, S3, S4)
- (e) corticotrophin (adrenocorticotrophic hormone; ACTH); (S5)
- (f) Human growth hormone (human somatotropin) - all forms; (S5)
- (g) zeranol, natural estrogen, and progesterone, when intended and registered as a veterinary production improver in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).
- (h) BST (Bovine somatotropin), when intended and registered as a production improver in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

**Human coagulation factors.**

**Human C1-esterase inhibitor**

**Human fibrinogen**, when indicated for use as a haemostatic.

**Human normal immunoglobulin.**

**Human Plasma.**

**Human Plasma Proteins.**

**Human thrombin**, when indicated for use as a haemostatic.

**Human von Willebrand Factor**

**Hyaluronidase.**

**Hyaluronic acid and its salts,**

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

**Hycanthone.**

**Hydrocortisone and hydrocortisone acetate,** except when used in

- a. maximum concentration of 1 percent in preparations intended for application to the skin, and
- b. in a maximum concentration of 1 percent used in combination with miconazole for topical application in the treatment of athlete's foot. (S2)

**Hydroxycarbamide. (Hydroxyurea)**

**Hydroxychloroquine.**

**Ibandronic acid.**

**Ibrutinib.**

**Ibuprofen,**

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



- d. except when contained in oral medicinal preparations supplied in a solid dose form as divided doses contained in packs not exceeding 24 dosage units or divided doses and containing ibuprofen as the only active therapeutic substance, intended for the treatment of mild to moderate pain or fever of inflammatory origin or for the treatment of post-traumatic conditions in adults and children over 12 years of age where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children 12 years and older does not exceed 20 milligrams per kilogram of body weight; (S1)
- e. except when contained in oral medicinal preparations intended for human use only, in combination with one or more other active therapeutic substances and intended for the treatment of mild to moderate pain or fever of inflammatory origin for a maximum treatment period of 10 days where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (S2)
- f. except when contained in oral medicinal preparations, intended for human use only, as the only active therapeutic substance in oral liquid preparations in packs not exceeding 100 millilitres in volume or in oral solid preparations in packs exceeding 24 dosage units or divided doses, when intended for adults and children over the age of 1 year; for the treatment of mild to moderate pain of inflammatory origin for a maximum treatment period of 10 days, or for the treatment of fever of inflammatory origin or for the treatment of post-traumatic conditions where the recommended daily dose of ibuprofen for adults does not exceed 1,2 grams and for children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (S2)
- g. except for the emergency treatment of acute gout attacks for a maximum treatment period of 5 days; (S2)
- h. except when intended for veterinary use (S3).

**Ibutilide.**

**Ibritumomab.**

**Icatibant**

**Icosapent ethyl**

**Idarubicin.**

**Idarucizumab.**

**Idebenone**

Prepared by:

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

**Idursulfase.**

**Ifosfamide.**

**Iloprost.**

**Imatinib.**

**Imdevimab**

**Imidocarb**, except when intended and registered as an antibabesial for the treatment of babesiosis in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

**Imiglucerase.**

**Imiquimod.**

**Imipenem.**

**Inclisiran**

**Indacaterol.**

**Indinavir.**

**Indium chloride pentetreotide.**

**Infliximab.**

**Ingenol mebutate.**

**Inosine pranobex.**

**Interferon alpha.**

**Interferon beta.**

**Interferon gamma.**

**Intra-uterine devices.**

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

**Intrifiban.**

**Iobitridol.**

**Iocarmic acid.**

**Iodamide sodium.**

**Iodised oil**, when used as a contrast agent.

**Iodixanol.**

**Iofendylate.**

**Ioglicic acid.**

**Iohexol.**

**Iomeprol.**

**Iopamidol.**

**Iopanoic acid.**

**Iopromide.**

**Iotalamate sodium.**

**Iotrolan.**

**Ioversol.**

**Ioxitalamic acid.**

**Ioxoglate sodium.**

**Ipilimumab**

Prepared by:

**Irinotecan.**

**Isepamicin.**

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

**Isoniazid**

**Isopirin.**

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

**Isoxsuprine.**

**Itopride**

**Itraconazole.**

**Ixabepilone.**

**Ixazomib.**

**Ixekizumab.**

Josamycin.

**Kanamycin.**

**Ketoconazole**, except -

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

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

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

**Lamivudine.**

**Lanreotide.**

Prepared by:

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

- (a) a maximum daily dose of 15 milligrams (S2); and
- (b) a maximum treatment period of 14 days. (S2)

**Lanthanum.**

**Lapatinib.**

**Laronidase.**

**Laropiprant.**

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

**Latamoxef.**

**Latanoprost.**

**Latanoprostene**

**Ledipasvir.**

**Leflunomide.**

**Lenalidomide.**

**Lenograstim.**

**Lenvatinib**

**Lepirudin.**

**Lesinurad.**

**Letermovir**

**Letrozole.**

**Leuprolide acetate**

**Levallorphan.**

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

**Levobupivacaine.**

**Levodopa.**

**Levofloxacin.**

**Levonorgestrel,**

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

**Levosimendan.**

**Liarozole.**

**Lidocaine,**

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

**Lignocaine, see Lidocaine.**

**Linagliptin**

**Lincomycin.**

**Linezolid.**

**Lipegfilgrastim.**

**Liraglutide.**

**Lixisenatide.**

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

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

**Lokivetmab.**

**Lomefloxacin.**

**Lomustine.**

**Lopinavir.**

**Loracarbef.**

**Loteprednol.**

**Lovastatin.**

**Lubiprostone.**

**Lumefantrine.**

**Luprositol**, when intended for veterinary use.

**Lutropin alfa.**

**Lymecycline.**

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

Prepared by:

**Macitentan.**

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

**Mafenide.**

**Mangafodipir trisodium.**

**Mandelic acid.**

**Maraviroc.**

**Marbofloxacin.**

**Maropitant**, when intended for veterinary use.

**Mavacoxib**

**Mecamylamine.**

**Mecillinam.**

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

**Medroxyprogesterone.**

**Mefloquine.**

**Meglumine diatrizoate.**

**Meglumine gadobenate.**

**Meglumine gadoterate.**

**Meglumine iodipamide.**

**Meglumine ioglycamate.**



**Meglumine iotalamate.**

**Meglumine iotroxate.**

**Meglumine pentetate.**

**Melagatran.**

**Melarsoprol.**

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

**Melphalan and its derivatives**, unless listed in another Schedule,

**Memantine.**

**Meningococcal Group B vaccine.**

**Menotrophin**

**Mepacrine.**

**Mephentermine.**

**Mepirizole.**

**Mepivacaine.**

**Mepolizumab.**

**Meropenem.**

**6-Mercaptopurine and its derivatives**, unless listed in another Schedule.

**Mercury**, preparations and mixtures that contain mercury metal and that are intended for medicinal use, except preparations of mercuric oxides containing less than 3 percent of mercury. (S2)

**Mesna**, when intended for injection. (S2)

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

Prepared by:

**Metergoline.**

**Methacholine.**

**Methampyrone (dipyrone).**

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

**Methotrexate.**

**Methoxsalen.**

**Methyl-5-aminolevulinate.**

**Methylnaltrexone.**

**Methylprednisolone.**

**Methysergide.**

**Metoclopramide.**

**Metomidate.**

**Metrizoic acid.**

**Metronidazole,** except when-

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

**Mexiletine.**

**Mezlocillin.**

**Micafungin.**

**Miconazole,**

- (a) except when intended for application to the skin; (S1) and
- (b) except when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis; (S1) and
- (c) except when intended for human use in preparations containing 2 per cent or less of miconazole, when intended for the topical treatment of fungal infections of the mouth (oral candidiasis). (S2)

**Midostaurin.**

**Mifamurtide.**

**Mifepristone.**

**Miglitol.**

**Miglustat.**

**Milrinone.**

**Miltefosine.**

**Minocycline.**

**Minoxidil**, except when intended for application to the scalp in preparations containing not more than 2 percent (w/v) and which are registered in terms of the Act. (S2)

**Misoprostol.**

**Mitomycin C.**

**Mitoxantrone.**

**Mivacurium.**

**Mizolastine.**

**Mofebutazone.**

**Molgramostim.**

**Molnupiravir**

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

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

**Moracizine.**

**Morazone.**

**Morinamide promolate.**

**Morphethylbutyne.**

**Mosunetuzumab**

**Moxifloxacin.**

**Mucoglucuronan.**

**Muromonab.**

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

**Mycophenolic acid.**

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

**Nadroparin.**

**Nalidixic acid.**

**Nalorphine.**

**Naloxone.**

**Naltrexone.**

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

**Naratriptan.**

**Natalizumab.**

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

**Nelfinavir.**

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

**Nefopam**

**Neostigmine.**

**Neotizide.**

**Neratinib**

**Netilmicin.**

**Netobimin.**

**Netupitant.**

**Nevirapine.**

**Niacin** when intended for hypercholesterolaemia. (S0)

**Niacin (Nicotinic Acid)** and derivatives thereof,

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

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

**Nicorandil.**

**Nifuratel.**

**Nifuroxazide.**

**Nifurtinol.**

**Nikethamide.**

**Nilotinib**

**Nilutamide.**

**Nimesulide.**

**Nimorazole.**

**Nimotuzumab.**

**Nimustine.**

**Nintedanib.**

**Niridazole.**

**Nirmatrelvir**

**Nitric oxide.**

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

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

**Nitrofural**, except preparations thereof intended for application to the skin, (S1)

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

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

**Nitroxoline.**

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

**Nivolumab.**

**Nizatidine**, except when intended for oral administration for short-term symptomatic relief of heartburn and hyperacidity, where the maximum dose is 150 milligrams, the maximum daily dose is 300 milligrams and the maximum treatment period is two weeks. (S2)

**Nomegestrol.**

Noradrenaline (**norepinephrine**)

**Norethisterone,**

- a. when intended for parenteral use as a contraceptive;
- b. when intended for hormone replacement therapy;
- c. except when intended for oral contraception. (S3)

**Norfloxacin.**

**Norgestrel,**

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

**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 ml, (S2)
- (c) except when intended for application to the skin, (S1) and

- (d) except when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis. (S1)
- (e) except when intended and registered as a stock remedy for pigeons in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

**Obidoxime.**

**Obinutuzumab.**

**Oclacitinib.**

**Ocrelizumab.**

**Ocriplasmin.**

**Octogog alfa.**

**Octreotide.**

**Ofatumumab.**

**Ofloxacin.**

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

**Olaratumab.**

**Oleandomycin.**

**Olodaterol.**

**Oloparib**

**Omalizumab.**

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

- a. a maximum daily dose of 20mg



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

**Ondansetron.**

**Oprelvekin.**

**Orbifloxacin.**

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

**Ornipressin.**

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

**Osaterone**, when intended for veterinary use.

**Oseltamivir.**

**Osimertinib.**

**Oxamniquine.**

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

**Oxacillin.**

**Oxaliplatin.**

**Oxetacaine** (Oxethazaine),

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

**Oxolinic acid.**

**Oxybuprocaine,**

- a. when intended for ophthalmic or parenteral use.

- b. except when contained in eye drops intended for the emergency treatment of "arc eyes". (S2)

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

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

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

**Oxytocin.**

**Paclitaxel.**

**Palbociclib.**

**Palivizumab.**

**Palonosetron.**

**Pamidronate disodium.**

**Pamidronic acid.**

**Pancuronium.**

**Panituzumab.**

**Panobinostat.**

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

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

**Paricalcitol.**

**Paromomycin.**

**Pasireotide.**

**Pazopanib.**

**Pegfilgrastim.**

**Peginterferon alpha.**

**Peginterferon beta 1a.**

**Pembrolizumab.**

**Pemetrexed.**

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

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

**Penicillamine.**

**Pentamidine.**

**Pentostatin.**

**Perfluorooctane**, when intended for intraocular use. (S2)

**Pergolide.**

**Perhexiline.**

**Pertuzumab.**

**Phenacetin**, except preparations and mixtures intended for external use and containing not more than 0,1 percent phenacetin as stabilizer.

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

**Pheneticillin.**

**Phenindione.**

**Phenopyrazone.**

**Phenoxybenzamine.**

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

**Phenylephrine**

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

**Phospholipids** when intended for parenteral administration. (S0)

**Phthalylsulfathiazole.**

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

**Picrotoxin.**

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

**Pimecrolimus.**

**Pimobendan.**

**Pipemidic acid.**

**Piperacillin, anhydrous.**

**Pirenzepine.**

**Pirfenidone.**

**Piribedil.**

**Piriimycin.**

**Piromidic acid.**

**Pivampicillin.**

**Pivmecillinam.**

**Pixantrone.**

**Plerixafor.**

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

**Polatuzumab**

**Polydimethylsiloxane** - see Silicone oil.

**Polyethylene glycol - epoetin beta.**

**Polyglycerylene-dextran.**

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

**Polystyrene sulfonic acid** when intended for therapeutic purposes.

**Polynoxylin.**

**Pomalidomide.**

**Ponesimod**

**Poractant alpha.**

**Posaconazole.**

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

Prepared by:

**Pradofloxacin**, when intended for veterinary use.

**Pralidoxime**.

**Pralsetinib**

**Pramipexole**.

**Prasugrel**.

**Pravastatin**.

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

**Prednisolone**.

**Pretomanid**

**Prilocaine**.

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

**Primaquine**.

**Procainamide**.

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

**Procarbazine**.

**Progesterone**.

**Proguanil**, except

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

**Propafenone.**

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

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

**Protein C** (isolated from human plasma).

**Proylidone.**

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

**Protionamide.**

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

**Prucalopride.**

**Pyrazinamide.**

**Pyricarbate.**

**Pyridostigmine.**

**Pyrimethamine.**

**Quinagolide**

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

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

**Quinupristin.**

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

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

**Ractopamine.**

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

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



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

**Raltegravir.**

**Raltitrexid.**

**Ramucirumab.**

**Ranibizumab.**

**Ranolazine**

**Rapacuronium.**

**Rasagiline.**

**Rasburicase.**

**Recombinant human epidermal growth factor (rhEGF)**

**Regorafenib.**

**Remdesivir**

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

**Retapamulin.**

**Revefanacin**

**Ribavirin.**

**Ribociclib.**

**Rifabutin.**

**Rifampicin.**

**Rifapentine.**

**Rifaximin.**

**Rilpivirine.**

**Riluzole.**

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

**Riociguat.**

**Risdiplam**

**Ritodrine.**

**Ritonavir.**

**Rituximab.**

**Rivaroxaban.**

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

**Robenacoxib.**

**Rocuronium.**

**Roflumilast.**

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

**Romiplostim.**

**Ropinirole.**

**Ropivacaine.**

**Rosoxacin.**

**Rosuvastatin.**

**Rotigotine.**

**Roxithromycin.**

**Roxadustat.**

**Roxatidine.**

**Ruxolitinib.**

**R-salbutamol**, except when intended and registered as a stock remedy in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

**Safinamide**

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

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

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

**Salmeterol.**

**Saquinavir.**

**Saraftoxacin.**

**Saroglitazar magnesium.**

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

**Satralizumab**

**Secukinumab.**

**Selegiline.**

**Selenium,**

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

**Selexipag**

**Semaglutide.**

**Semuloparin.**

**Serelaxin.**

**Sermorelin.**

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

**Sertindole.**

**Sevelamer.**

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

**Sildenafil.**

**Silicone oil** (polydimethylsiloxane) when intended for intraocular use.

**Silodosin.**

**Siltuximab.**

**Simoctogog alfa.**

**Simvastatin.**

**Siponimod.**

**Sirolimus.**

**Sisomicin.**

Prepared by:

**Sodium aurothiomalate.**

**Sodium cromoglycate**, when intended for veterinary use. (S2)

**Sodium dihydroazapentacene polysulphonate.**

**Sodium fluoride**; except oral medicinal preparations and mixtures thereof containing 40 milligrams or more per daily dose. (S1)

**Sodium nitroprusside.**

**Sodium polystyrene sulphonic acid**, when indicated for therapeutic use.

**Sofosbuvir.**

**Solcoseryl**, except preparations intended for application to the skin, to the mucous membranes of the mouth and to the lips and except ophthalmic preparations thereof. (S0, S3)

**Sorafenib.**

**Sparfloxacin.**

**Spectinomycin.**

**Stavudine.**

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

**Stiripentol.**

**Streptokinase.**

**Strychnine**, except -

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

- (ii) subject to the State Veterinarian obtaining prior written approval for such use from the Director of the concerned provincial conservation institution or authority in his area of jurisdiction, a copy of such written approval being attached to the written prescription

**Styramate.**

**Sugammadex.**

**Sulbactam.**

**Sulfabenzamide.**

**Sulfacetamide.**

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

**Sulfadiazine silver**, except when intended for application to the skin in the short term treatment of minor burns, provided that the pack size is limited to a maximum of 50 grams; (S2)

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

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

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

**Sulfafurazole** (sulfisoxazole).

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

**Sulfamethizole.**

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

**Sulfametopyrazine.**

**Sulfamoxole.**

**Sulfanilamide.**

**Sulfasalazine.**

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

**Sulfisomidine.**

**Sulfamerazine.**

**Sulfapyridine.**

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

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

**Sultamicillin.**

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

**Sunitinib.**

**Suramin.**

**Surfactant associated proteins.**

**Suxamethonium.**

**Suxethonium.**

**Streptokinase.**

**Streptomycin.**

**Tacrine.**

Prepared by:

**Tacrolimus.**

**Tadalafil.**

**Tafamidis**

**Tafluprost.**

**Talampicillin.**

**Taliglucerase alfa.**

**Tamoxifen.**

**Tamsulosin.**

**Taurolidine.**

**Tasonermin.**

**Tazobactam.**

**Tedizolid.**

**Tegafur.**

**Tegaserod.**

**Teicoplanin.**

**Telaprevir.**

**Telbivudine.**

**Telithromycin.**

**Temozolomide.**

**Temsirolimus.**

**Tenecteplase.**

Prepared by:



**Teniposide.**

**Tenofovir.**

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

**Terconazole.**

**Terfenadine.**

**Teriflunomide.**

**Terizidone.**

**Teriparatide.**

**Tetanus toxoid.**

**Tetrabenazine.**

**Tetracaine,**

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

**Tetracosactrin (Tetracosactide).**

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

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

**Terlipressin.**

**Thalidomide.**

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

**Thiabendazole**, except -

- (a) when intended for application to the skin; (S1) and
- (b) when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

**Thiamphenicol.**

**Thioacetazone.**

**Thiostrepton.**

**Thiotepa**

**Thymopentin.**

**Thyrotropin alfa.**

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

**Tibolone.**

**Ticarcillin.**

**Tigecycline.**

**Tildipirosin** when intended for veterinary use.

**Tilmicosin.**

**Tiludronic acid.**

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

**Tinidazole.**

Prepared by:

**Tinzaparin.**

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

**Tioguanine.**

**Tiopronin.**

**Tipiracil.**

**Tipranavir.**

**Tirilazad.**

**Tivozanib**

**Tobramycin.**

**Tocainide.**

**Tocilizumab.**

**Tofacitinib.**

**Tolcapone.**

**Tolrestat.**

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

**Topotecan.**

**Toremifene.**

**Tozinameran**

**Trabectedin.**

**Trametinib.**

Prepared by:

**Tranexamic acid.**

**Trastuzumab.**

**Trastuzumab emtansine**

**Travoprost.**

**Tremelimumab**

**Treosulfan.**

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

**Triflusal.**

**Trifluridine.**

**Trimetaphan.**

**Trimethoprim**, except when specifically intended and registered in combination with sulphonamides for the treatment of gastro-enteritis and pneumonia in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

**Trimetrexate.**

**Trioxysalen.**

**Triptorelin.**

**Tromantadine.**

**Trometamol.**

**Tropisetron.**

**Tuberculin.**

**Tubocurarine.**

**Tulathromycin.**

**Turoctocog Alpha**

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

**Tyropanoic acid.**

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

**Unoprostone.**

**Upadacitinib**

**Urapidil.**

**Urethane.**

**Urofollitropin.**

**Urokinase.**

**Ustekinumab.**

**(Vaccines, see - Biologicals)**

**Valaciclovir.**

**Valganciclovir**

**Valnemulin.**

**Vancomycin.**

**Vardenafil.**

**Vasoactive intestinal polypeptide.**

**Vasopressin**

**Vecuronium.**

**Vedolizumab.**

**Velaglucerase alfa.**

**Velpatasvir.**

**Vemurafenib.**

**Venetoclax.**

**Vericiguat**

**Vernakalant.**

**Verteporfin.**

**Vidarabine.**

**Vilanterol.**

**Vinblastine.**

**Vincristine.**

**Vindesine.**

**Vinorelbine.**

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

**Vismodegib.**

**Voriconazole.**

**Vorinostat.**

**Vorozole.**

**Warfarin.**

**Zalcitabine.**

**Zanamivir.**

**Zofenopril**

**Zidovudine.**

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

**Ziv-aflibercept.**

**Zolmitriptan.**

**Zoledronic acid.**

**Zotarolimus.**

## **ANNEXURES TO SCHEDULE 4**

### **ANNEXURE 1A: EMERGENCY CARE PROVIDER (PARAMEDIC)**

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

<b>PARAMEDIC (National Diploma in Emergency Medical Care graduates)</b>	
<b>ANTI-ARRHYTHMICS</b>	
Substance	Adenosine
Indication	Endogenous Purine Nucleoside / Supraventricular Antiarrhythmic
Schedule	4
Route of Administration	Parenteral
<b>ANTI-ARRHYTHMICS</b>	
Substance	Amiodarone
Indication	Class III Anti-arrhythmic/ Atrial & Ventricular
Schedule	4
Route of Administration	Parenteral
<b>ANTI-ARRHYTHMICS</b>	

Substance	Lignocaine Hydrochloride (Systemic)
Indication	Class I B- Ventricular Anti-arrhythmic
Schedule	4
Route of Administration	Parenteral
<b>ADRENERGIC</b>	
Substance	Adrenaline / Epinephrine
Indication	Sympathomimetic catecholamine
Schedule	4
Route of Administration	Parenteral
<b>ANTI-CHOLINERGIC</b>	
Substance	Atropine
Indication	Competitive Anti-Cholinergic, Bradycardia, Anti-arrhythmic
Schedule	4
Route of Administration	Parenteral
<b>SELECTIVE <math>\beta_2</math> AGONISTS</b>	
Substance	Salbutamol
Indication	Bronchodilator
Schedule	4
Route of Administration	Parenteral
<b>SELECTIVE <math>\beta_2</math> AGONISTS</b>	
Substance	Fenoterol
Indication	Bronchodilator
Schedule	4
Route of Administration	Parenteral
<b>CORTICOSTEROIDS</b>	
Substance	Hydrocortisone
Indication	Glucocorticoid / Steroidal Anti-Inflammatory
Schedule	4
Route of Administration	Parenteral
<b>HYPERGLYCAEMIC AGENT</b>	
Substance	Glucagon
Indication	Hyperglycaemic agent
Schedule	4
Route of Administration	Parenteral
<b>CORTICOSTEROIDS</b>	
Substance	Methylprednisolone
Indication	Glucocorticoid / Steroidal Anti-Inflammatory
Schedule	4
Route of Administration	Parenteral
<b>ANTI-EMETIC</b>	



Substance	Metoclopramide Monohydrochloride
Indication	Propulsive Anti-emetic/ Dopamine Antagonist
Schedule	4
Route of Administration	Parenteral
<b>OPIOID ANTAGONIST</b>	
Substance	Naloxone Hydrochloride
Indication	Opioid Antagonist / Narcotic Antagonist
Schedule	4
Route of Administration	Parenteral
<b>OPIOID ANTAGONIST</b>	
Substance	Nitrous Oxide
Indication	Analgesic Gas
Schedule	4
Route of Administration	Inhalant
<b>*ANTI-FIBRINOLYTIC</b>	
Substance	Tranexamic acid
Indication	Major haemorrhage in trauma
Route of Administration	Parenteral
<b>**OXYTOCIN</b>	
Substance	Oxytocin
Indication	Post-partum haemorrhage
Route of Administration	Parenteral
<b>CORTICOSTEROID</b>	
Substance	Prednisolone
Indication	Glucocorticoid / Steroidal anti-inflammatory
Route of Administration	Oral
<b>LOCAL ANAESTHETIC</b>	
Substance	Lignocaine hydrochloride
Indication	Local anaesthesia
Route of Administration	Parenteral

*(Annexure 1A of Schedule 4 added by GNR 674 of 2013, amended by GN 1375 of 2020 and by GN 883 of 2021)*

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

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

<b>EMERGENCY CARE PRACTITIONER (B Tech: Emergency Medical Care)</b>	
<b>ANTI-ARRHYTHMICS</b>	
Substance	Adenosine
Indication	Endogenous Purine Nucleoside / Supraventricular Anti-arrhythmic

Prepared by:

Schedule	4
Route of Administration	Parenteral
<b>ANTI-ARRHYTHMICS</b>	
Substance	Amiodarone
Indication	Class III Anti-arrhythmic/ Atrial & Ventricular
Schedule	4
Route of Administration	Parenteral
<b>ANTI-ARRHYTHMICS</b>	
Substance	Lignocaine Hydrochloride (Systemic)
Indication	Class I B- Ventricular Anti-arrhythmic
Schedule	4
Route of Administration	Parenteral
<b>ADRENERGIC</b>	
Substance	Adrenaline/ Epinephrine
Indication	Sympathomimetic catecholamine
Schedule	4
Route of Administration	Parenteral
<b>ANTI-CHOLINERGIC</b>	
Substance	Atropine
Indication	Competitive Anti-Cholinergic, Bradycardia, Anti-arrhythmic
Schedule	4
Route of Administration	Parenteral
<b>SELECTIVE <math>\beta_2</math> AGONISTS</b>	
Substance	Salbutamol
Indication	Bronchodilator
Schedule	4
Route of Administration	Parenteral
<b>SELECTIVE <math>\beta_2</math> AGONISTS</b>	
Substance	Fenoterol
Indication	Bronchodilator
Schedule	4
Route of Administration	Parenteral
<b>CORTICOSTEROIDS</b>	
Substance	Hydrocortisone
Indication	Glucocorticoid / Steroidal Anti-Inflammatory
Schedule	4
Route of Administration	Parenteral
<b>CORTICOSTEROIDS</b>	
Substance	Methylprednisolone
Indication	Glucocorticoid / Steroidal Anti-Inflammatory

Schedule	4
Route of Administration	Parenteral
<b>HYPERGLYCAEMIC AGENT</b>	
Substance	Glucagon
Indication	Hyperglycaemic agent
Schedule	4
Route of Administration	Parenteral
<b>ANTI-EMETIC</b>	
Substance	Metoclopramide Monohydrochloride
Indication	Propulsive Anti-emetic/ Dopamine Antagonist
Schedule	4
Route of Administration	Parenteral
<b>OPIOID ANTAGONIST</b>	
Substance	Naloxone Hydrochloride
Indication	Opioid Antagonist/Narcotic Antagonist
Schedule	4
Route of Administration	Parenteral
<b>OPIOID ANTAGONIST</b>	
Substance	Nitrous Oxide
Indication	Analgesic Gas
Schedule	4
Route of Administration	Inhalant (50:50 combination with Medical Oxygen)
<b>THROMBOLYTIC AGENTS</b>	
Substance	Streptokinase
Indication	Enzymes
Schedule	4
Route of Administration	Parenteral
<b>THROMBOLYTIC AGENTS</b>	
Substance	Tenecteplase
Indication	Enzymes
Schedule	4
Route of Administration	Parenteral
<b>ANTITHROMBOTIC AGENTS</b>	
Substance	Heparin Sodium
Indication	Anticoagulant
Schedule	4
Route of Administration	Parenteral
<b>ANTITHROMBOTIC AGENT</b>	
Substance	Enoxaparin
Indication	Anticoagulant

Schedule	4
Route of Administration	Parenteral
<b>MUSCLE RELAXANTS (NEURO BLOCKING AGENTS)</b>	
Substance	Suxamethonium Chloride
Indication	Depolarizing Muscle Relaxant
Schedule	4
Route of Administration	Parenteral
<b>MUSCLE RELAXANTS (NEURO BLOCKING AGENTS)</b>	
Substance	Vecuronium
Indication	Competitive Muscle Relaxant
Schedule	4
Route of Administration	Parenteral
<b>MUSCLE RELAXANTS (NEURO BLOCKING AGENTS)</b>	
Substance	Rocuronium
Indication	Non-Depolarizing Muscle Relaxants
Schedule	4
Route of Administration	Parenteral
<b>**CORTICOSTEROID</b>	
Substance	Betamethasone
Indication	Pre-term birth
Route of Administration	Parenteral
<b>*ANTICHOLINESTERASE</b>	
Substance	Neostigmine
Indication	Reversal of neuromuscular blockade
Route of Administration	Parenteral
<b>* CHOLINESTERASE INHIBITOR</b>	
Substance	Sugammadex
Indication	Reversal of neuromuscular blockade
Route of Administration	Parenteral
<b>* SEROTONIN ANTAGONIST</b>	
Substance	Ondansetron
Indication	Post-operative nausea and vomiting
Route of Administration	Parenteral
<b>*ANTI-FIBRINOLYTIC</b>	
Substance	Tranexamic acid
Indication	Major haemorrhage in trauma
Route of Administration	Parenteral
<b>OXYTOCIN</b>	
Substance	Oxytocin
Indication	Post-partum haemorrhage

Route of Administration	Parenteral
<b>CORTICOSTEROID</b>	
Substance	Prednisolone
Indication	Glucocorticoid/ Steroidal anti-inflammatory
Route of Administration	Parenteral
<b>LOCAL ANAESTHETIC</b>	
Substance	Lignocaine hydrochloride
Indication	Local anaesthesia
Route of Administration	Parenteral

*(Annexure 1B of Schedule 4 added by GNR 674 of 2013, amended by GN 1375 of 2020 and by GN 883 of 2021)*

### **ANNEXURE 1C: BASIC AMBULANCE ASSISTANT**

**BASIC AMBULANCE ASSISTANT** registered with Health, Professions Council of South Africa

<b>BASIC AMBULANCE ASSISTANT</b> registered with Health, Professions Council of South Africa	
<b>SELECTIVE <math>\beta_2</math> AGONISTS</b>	
Substance	Fenoterol
Indication	Bronchodilator
Route of Administration	Parenteral
<b>OPIOID ANTAGONIST</b>	
Substance	Nitrous Oxide
Indication	Analgesic Gas
Route of Administration	Inhalant (50:50 combination with Medical Oxygen)

*(Annexure 1C of Schedule 4 added by GN 1375 of 2020 and amended by GN 883 of 2021)*

### **ANNEXURE 1D: AMBULANCE EMERGENCY ASSISTANT**

**AMBULANCE EMERGENCY ASSISTANT** registered with the Health Professions Council of South Africa

<b>AMBULANCE EMERGENCY ASSISTANT</b> registered with the Health Professions Council of South Africa	
<b>*ADRENERGIC</b>	
Substance	Adrenaline / Epinephrine
Indication	Sympathomimetic catecholamine
Route of Administration	Parenteral
<b>*CORTICOSTEROIDS</b>	
Substance	Methylprednisolone
Indication	Glucocorticoid / Steroidal Anti-Inflammatory
Route of Administration	Parenteral
<b>*CORTICOSTEROIDS</b>	
Substance	Hydrocortisone
Indication	Glucocorticoid / Steroidal Anti-inflammatory
Route of Administration	Parenteral

<b>HYPERGLYCAEMIC AGENT</b>	
Substance	Glucagon
Indication	Hyperglycaemic agent
Route of Administration	Parenteral
<b>*OPIOID ANTAGONIST</b>	
Substance	Naloxone hydrochloride
Indication	Opioid Antagonist / Narcotic Antagonist
Route of Administration	Parenteral
<b>*OPIOID ANTAGONIST</b>	
Substance	Nitrous Oxide
Indication	Analgesic Gas
Route of Administration	Inhalant (50:50 combination with Medical Oxygen)
<b>SELECTIVE <math>\beta_2</math> AGONISTS</b>	
Substance	Fenoterol
Indication	Bronchodilator
Route of Administration	Parenteral
<b>LOCAL ANAESTHETIC</b>	
Substance	Lignocaine hydrochloride
Indication	Local anaesthesia
Route of Administration	Parenteral

*(Annexure 1D of Schedule 4 added by GN 1375 of 2020 and amended by GN 883 of 2021)*

### **ANNEXURE 1E: EMERGENCY CARE TECHNICIAN**

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

<b>EMERGENCY CARE TECHNICIAN</b> registered with Health Professions Council of South Africa	
<b>ADRENERGIC</b>	
Substance	Adrenaline / Epinephrine
Indication	Sympathomimetic catecholamine
Route of Administration	Parenteral
<b>CORTICOSTEROIDS</b>	
Substance	Methylprednisolone
Indication	Glucocorticoid / Steroidal Anti-Inflammatory
Route of Administration	Parenteral
<b>CORTICOSTEROIDS</b>	
Substance	Hydrocortisone
Indication	Glucocorticoid / Steroidal Anti-Inflammatory
Route of Administration	Parenteral
<b>HYPERGLYCAEMIC AGENT</b>	
Substance	Glucagon
Indication	Hyperglycaemic agent

Prepared by:

Route of Administration	Parenteral
<b>ANTI-ARRHYTHMICS</b>	
Substance	Amiodarone
Indication	Class III Anti-arrhythmic / Atrial & Ventricular
Route of Administration	Parenteral
<b>*ANTI-EMETIC</b>	
Substance	Metoclopramide monohydrochloride
Indication	Propulsive Anti-emetic / Dopamine Antagonist
Route of Administration	Parenteral
<b>SELECTIVE <math>\beta_2</math> AGONISTS</b>	
Substance	Salbutamol
Indication	Bronchodilator
Route of Administration	Parenteral
<b>SELECTIVE <math>\beta_2</math> AGONISTS</b>	
Substance	Fenoterol
Indication	Bronchodilator
Route of Administration	Parenteral
<b>ANTI-CHOLINERGIC</b>	
Substance	Atropine
Indication	Competitive Anti-Cholinergic, Bradycardia, Anti-arrhythmic
Route of Administration	Parenteral
<b>OPIOID ANTAGONIST</b>	
Substance	Naloxone hydrochloride
Indication	Opioid Antagonist / Narcotic Antagonist
Route of Administration	Parenteral
<b>OPIOID ANTAGONIST</b>	
Substance	Nitrous Oxide
Indication	Analgesic Gas
Route of Administration	Inhalant (50:50 combination with Medical Oxygen)
<b>**OXYTOCIN</b>	
Substance	Oxytocin
Indication	Post-partum haemorrhage
Route of Administration	Parenteral
<b>CORTICOSTEROID</b>	
Substance	Prednisolone
Indication	Glucocorticoid / Steroidal Anti-inflammatory
Route of Administration	Oral
<b>LOCAL ANAESTHETIC</b>	
Substance	Lignocaine hydrochloride
Indication	Local anaesthesia

Route of Administration	Parenteral
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*(Annexure 1E of Schedule 4 added by GN 1375 of 2020 and amended by GN 883 of 2021)*

### **ANNEXURE 1F: EMERGENCY CARE ASSISTANT**

**EMERGENCY CARE ASSISTANT** registered with the Health Professions Council of South Africa

<b>EMERGENCY CARE ASSISTANT</b> registered with the Health Professions Council of South Africa	
<b>*ADRENERGIC</b>	
Substance	Adrenaline / Epinegrine
Indication	Sympathomimetic catecholamine
Route of Administration	Parenteral
<b>CORTICOSTEROIDS</b>	
Substance	Methyprednisolone
Indication	Glucocorticoid / Steroidal Anti-Inflammatory
Route of Administration	Parenteral
<b>CORTICOSTEROIDS</b>	
Substance	Hydrocortisone
Indication	Glucocorticoid / Steroidal Anti-Inflammatory
Route of Administration	Parenteral
<b>HYPERGLYCAEMIC AGENT</b>	
Substance	Glucagon
Indication	Hyperglycaemic agent
Route of Administration	Parenteral
<b>ANTI-CHOLINERGIC</b>	
Substance	Atropine
Indication	Competitive Anti-Cholinergic, Bradycardia, Anti-arrhythmic
Route of Administration	Parenteral
<b>OPIOID ANTAGONIST</b>	
Substance	Naloxone hydrochloride
Indication	Opioid Antagonist / Narcotic Antagonist
Route of Administration	Parenteral
<b>OPIOID ANTAGONIST</b>	
Substance	Nitrous Oxide
Indication	Analgesic Gas
Route of Administration	Inhalant (50:50 combination with Medical Oxygen)
<b>SELECTIVE <math>\beta_2</math> AGONISTS</b>	
Substance	Fenoterol
Indication	Bronchodilator
Route of Administration	Parenteral
<b>LOCAL ANAESTHETIC</b>	
Substance	Lignocaine hydrochloride



Indication	Local anaesthesia
Route of Administration	Parenteral
<b>CORTICOSTEROIDS</b>	
Substance	Prednisolone
Indication	Glucocorticoid / Steroidal Anti-Inflammatory
Route of Administration	Oral

*(Annexure 1F of Schedule 4 added by GN 1375 of 2020 and amended by GN 883 of 2021)*

## **ANNEXURE 2: DENTAL THERAPIST**

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

<b>DENTAL THERAPIST</b> (Bachelors degree in Dental Therapy)	
<b>LOCAL ANAESTHETIC</b>	
Substance	Lignocaine/ Lidocaine Hydrochloride 2% with Vasoconstrictor (Adrenaline)
Indication	Dental local anaesthesia
Schedule	4
Route of Administration	Parenteral
<b>LOCAL ANAESTHETIC</b>	
Substance	Lignocaine/ Lidocaine Hydrochloride 3% without a Vasoconstrictor (Adrenaline)
Indication	Dental local anaesthesia
Schedule	4
Route of Administration	Parenteral
<b>LOCAL ANAESTHETIC</b>	
Substance	Mepivacaine Hydrochloride 2% with a Vasoconstrictor (Adrenaline)
Indication	Dental local anaesthesia
Schedule	4
Route of Administration	Parenteral
<b>LOCAL ANAESTHETIC</b>	
Substance	Mepivacaine Hydrochloride 3% without a Vasoconstrictor (Adrenaline)
Indication	Dental local anaesthesia
Schedule	4
Route of Administration	Parenteral
<b>ANTI-MICROBIALS (Beta-Lactams)</b>	
Substance	Penicillins
Indication	Dental orofacial and odontogenic infections (Non prophylactic)
Schedule	4
Route of Administration	Oral
<b>ANTI-PROTOZOAL</b>	

Substance	Metronidazole
Indication	Dental orofacial and odontogenic infections (Non prophylactic)
Schedule	4
Route of Administration	Oral
<b>AUTONOMIC SYMPATHOMIMETICS</b>	
Substance	Adrenaline
Indication	Emergency medicine for drug related anaphylactic shock
Schedule	4
Route of Administration	Parenteral

*(Annexure 2 of Schedule 4 added by GN 674 of 2013)*

*(Annexures 1A, 1B, & 2 inserted by Government Notice R674 in Government Gazette 36827 dated 13 September 2013.)*

*(Annexure 1A & 1B amended by Government Notice R1375 in Government Gazette 44019 dated 18 December 2020.)*

*(Annexures 1C, 1D, 1E, & 1F inserted by Government Notice R1375 in Government Gazette 44019 dated 18 December 2020.)*

*(Schedule 1A, 1B, 1C, 1D, 1E & 1F amended by Government Notice 883 in Government Gazette 45176 dated 17 September 2021.)*

### **ANNEXURE 3: OPTOMETRIST**

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

<b>OPTOMETRISTS</b>	
<b>ANTIBACTERIAL</b>	
Substance	Chloramphenicol
Indication	Bacterial conjunctivitis; Anterior blepharitis; Posterior blepharitis
Route of Administration	Topical Application
<b>ANTIBACTERIAL</b>	
Substance	Tetracycline
Indication	Chlamydial conjunctivitis; Blepharitis
Route of Administration	Topical Application
<b>ANTIBACTERIAL</b>	
Substance	Erythromycin
Indication	Chlamydial conjunctivitis; Blepharitis; Impetigo (Not to be used as 1 <sup>st</sup> Line treatment)
Route of Administration	Topical Application
<b>ANTIBACTERIAL</b>	

Substance	Aciclovir
Indication	Conjunctivitis; Herpes simplex blepharitis; Epithelial Keratitis
Route of Administration	Topical Application
<b>LOCAL ANAESTHETIC</b>	
Substance	Tetracaine
Indication	Diagnostic Aide
Route of Administration	Topical Application (Drops)
<b>LOCAL ANAESTHETIC</b>	
Substance	Oxybuprocaine and other equivalent local anaesthetics
Indication	Diagnostic Aide
Route of Administration	Topical Application (Drops)
<b>ANTIBACTERIAL</b>	
Substance	Tetracycline
Indication	Trachoma
Route of Administration	Oral
<b>ANTIBACTERIAL</b>	
Substance	Doxycycline
Indication	Trachoma
Route of Administration	Oral
<b>ANTIBACTERIAL</b>	
Substance	Azithromycin
Indication	Trachoma
Route of Administration	Oral
<b>ANTIBIOTICS</b>	
Substance	Fusidic acid
Indication	For Blepharitis and sty
Route of Administration	Topical drops or ointment
<b>ANTIBIOTICS</b>	
Substance	Neomycin
Indication	For Blepharitis only
Route of Administration	Topical drops or ointment
<b>ANTIBIOTICS</b>	
Substance	Bacitracin
Indication	For Blepharitis only
Route of Administration	Ointment
<b>ANTIBIOTICS</b>	
Substance	Polymyxin B
Indication	For Blepharitis only
Route of Administration	Ointment
<b>PROSTAGLANDIN ANALOGUES (PGAs)</b>	

Substance	Latanoprost, Travoprost, Bimatoprost
Indication	Glaucoma
Route of Administration	Drops

*(Annexure 3 of Schedule 4 added by GN 620 of 2016, amended by GN 748 of 2017, GNR 219 of 2020 and GNR 220 of 2020)*

*(Annexure 3 added by Government Notice 620 in Government Gazette 40041 dated 3 June 2016)*

*(Annexure 3 amended by Government Notice 748 in Government Gazette 41009 dated 28 July 2017)*

*(Annexure 3 amended by Government Notice R219 in Government Gazette 43051 dated 28 February 2020)*

*(Annexure 3 amended by Government Notice R220 in Government Gazette 43051 dated 28 February 2020)*

*(Annexure 3 amended by GN 2685 dated 28 October 2022)*

#### **ANNEXURE 4: PODIATRIST**

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

*(Annexures 4 inserted by Government Notice R1375 in Government Gazette 44019 dated 18 December 2020. No further information given other than this heading)*

#### **ANNEXURE 5: ORAL HYGIENISTS**

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

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

Indication	:	Dental surface anaesthesia (local anaesthetic)
Route of administration	:	Local injection

*(Annexure 5 of Schedule 4 added by GNR 3261 dated 24 March 2023)*

**- END SCHEDULE 4 -**

*(Schedule 4 amended by Government Notice R1230 in Government Gazette 32838 dated 31 December 2009)*

*(Schedule 4 amended by Government Notice R227 in Government Gazette 35149 dated 15 March 2012)*

*(Schedule 4 amended by Government Notice R690 in Government Gazette 36850 dated 20 September 2013)*

*(Schedule 4 amended by Government Notice R104 in Government Gazette 37318 dated 11 February 2014. Commencement date: 11 February 2014)*

*(Schedule 4 amended by Government Notice R352 in Government Gazette 37622 dated 8 May 2014)*

*(Schedule 4 amended by Government Notice R234 in Government Gazette 38586 dated 20 March 2015)*

*(Schedule 4 amended by Government Notice 254 in Government Gazette 39815 dated 15 March 2016)*

*(Schedule 4 amended by Government Notice 620 in Government Gazette 40041 dated 3 June 2016)*

*(Schedule 4 amended by Government Notice 748 in Government Gazette 41009 dated 28 July 2017)*

*(Schedule 4 amended by Government Notice 1261 in Government Gazette 41256 dated 17 November 2017)*

*(Schedule 4 amended by Government Notice R1098 in Government Gazette 41971 dated 12 October 2018)*

*(Schedule 4 amended by Government Notice R1262 in Government Gazette 42052 dated 23 November 2018)*

*(Schedule 4 amended by Government Notice R755 in Government Gazette 42477 dated 23 May 2019)*

*(Schedule 4 amended by Government Notice R219 in Government Gazette 43051 dated 28 February 2020)*

*(Schedule 4 amended by Government Notice R220 in Government Gazette 43051 dated 28 February 2020)*

*(Schedule 4 amended by Government Notice R586 in Government Gazette 43347 dated 22 May 2020)*

*(Schedule 4 amended by Government Notice R1375 in Government Gazette 44019 dated 18 December 2020.)*

*(Schedule 4 amended by Government Notice 883 in Government Gazette 45176 dated 17 September 2021.)*

*(Schedule 4 amended by GN 2685 dated 28 October 2022)*

*(Schedule 4 amended by GNR 3261 dated 24 March 2023)*

**SCHEDULE 5 AND SPECIFIED SCHEDULE 5**

- a. All preparations or mixtures of such substances containing or purporting to contain substances that is chemically related and incorporates a structural fragment into its structure that is similar to the structure of a listed substance and/or exhibits pharmacodynamic properties similar to the listed substance referred to in this Schedule include the following:
  - (i) The salts and esters of such substances, where the existence of such salts and esters is possible; and

- (ii) all preparations and mixtures of such substances where such preparations and mixtures are not expressly excluded.
- (iii) all homologues of listed substances (being any chemically related substances that incorporate a structural fragment into their structures that is similar to the structure of a listed substance and/or exhibit pharmacodynamic properties similar to the listed substance in the schedules), unless listed separately in the Schedules.

b. In terms of Section 22A(5)(f) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, may prescribe and apply, only within his/her scope of practice and subject to the indication for use of such substances and medicines and to the conditions determined by the Medicines Control Council, to patients under his/her care, the Schedule 5 and Specified Schedule 5 substances and medicines provided for in the Annexures to this Schedule published in the *Gazette* in terms of the Act.

- (i) Annexure 1A: Emergency Care Provider (Paramedic);  
           Annexure 1B: Emergency Care Provider (Emergency Care Practitioner).  
           Annexure 1E: Emergency Care Technician

c. Specified Schedule 5 substances listed in this schedule are subject to additional control in terms of section 22A of the Act as required under the provisions of the 1971 Convention on Psychotropic Substances and are denoted by\*\*

**Acitretin.**

**Agomelatine.**

**Alfaxalone.**

**Alprazolam\*\*.**

**Amisulpride.**

**Amitriptyline and its derivatives.**

**Amoxapine.**

**Anaesthetic preparations** containing pregnanedione derivatives.

**Androstanolone.**

**Androstenediol.**

**Aponal.**

**Apronalide.**

**Aripiprazole.**

**Armodafanil.**

**Asenapine.**

**Atomoxetine.**

**Azacyclonol.**

**Barbituric acid\*\*** and its derivatives\*\*, unless listed in another Schedule, excluding- amobarbital, cyclobarbital, pentobarbital and secobarbital (S6), and preparations and mixtures containing not more than 90 milligrams of phenobarbital\*\* per minimum recommended or prescribed dose when intended for continued use in epilepsy. (S3)

**Benactyzine** and its derivatives unless listed in another Schedule.

**Benfluramate.**

**Benzoctamine.**

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

**Benzquinamide.**

**Beta-aminopropylbenzene and beta-aminoisopropylbenzene:**

- (a) any compound structurally derived from either of these substances by substitution in the side chain or by ring closure therein (or by both such substitution and such ring closure); and
- (b) any salt or substance falling under the above, and
- (c) except preparations and mixtures of the above when used as vasoconstrictors and decongestants in antihistamine nose and eye preparations; (S1) and
- (d) except when contained in appliances for inhalation in which the substance is absorbed onto solid material; (S1, S7) and

- (e) excluding cathine ((+)-norpseudoephedrine), ephedrine, etafedrine, N-methylephedrine, N-diethylaminoethylephedrine, phenylpropanolamine, prenylamine and preparations and mixtures thereof; and
- (f) except substances listed in Schedule 7. (S1, S2, S6)

**Bolandirol.**

**Bolasterone.**

**Boldenone.**

**Brexpiprazole.**

**Bromides;** preparations and mixtures thereof containing 80 milligrams or more of bromine as bromide per recommended daily dose, except when specifically packaged, labelled and used for industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose, which are intended to be ingested by man or animals as food or applied to the body as a cosmetic and which are approved for such use in terms of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 and for analytical laboratory purposes. (S2)

**Bromazepam\*\*.**

**Bromisovalum.**

**Brotizolam\*\*.**

**Bupropion.**

**Buspirone.**

**Butriptyline.**

**Butyrophenones.**

**Carbromal.**

**Cariprazine.**

**Chloral derivatives,** unless listed in another Schedule.



**Chlordiazepoxide\*\*.**

**Chlormethiazole.**

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

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

**Chlorpromazine.**

**Chlorprothixene.**

**Citalopram.**

**Clobazam\*\*.**

**Clomacran.**

**Clomipramine.**

**Clonazepam\*\*.**

**Clopenthixol.**

**Clorazepic acid\*\*.**

**Clotebol.**

**Clothiapine.**

**Clozapine.**

**Corticotrophin (adrenocorticotrophic hormone; ACTH).**

**Cyclobenzaprine.**

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

**Danazol.**

Prepared by:

**Dapoxetine.**

**Deanol** and its derivatives, unless listed in another Schedule, except when specifically packaged, labelled and used for industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose, which are intended to be ingested by man or animals as food or applied to the body as a cosmetic and which are approved for such use in terms of the Foodstuffs, Cosmetics and Disinfectants Act, 1972, and for analytical laboratory purposes, (S1)

**Dehydrochloromethyltestosterone.**

**Desflurane.**

**Desipramine.**

**Desvenlafaxine.**

**Detomidine.**

**Dexfenfluramine.**

**Dexmedetomidine.**

**Dextropropoxyphene**; preparations and mixtures for oral use containing not more than 135 milligrams of dextropropoxyphene, calculated as the base, per dosage unit or with a concentration of not more than 2,5 percent in undivided preparations. (S6)

**Diazepam\*\*.**

**Dibenzepin.**

**Diprenorphine.**

**Donepezil.**

**Dosulepin.**

**Dothiepin.**

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

**Droperidol.**

Prepared by:

**Drostanolone.**

**Duloxetine.**

**Ecothiopate.**

**Emylcamate.**

**Enflurane.**

**Epitiostanol.**

**Escitalopram.**

**Esketamine**

**Estazolam\*\*.**

**Ethchlorvynol\*\*.**

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

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

**Ethylestrenol.**

**Etifoxine.**

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

**Etomidate.**

**Etretinate.**

**Fencamfamine\*\*.**

**Fenfluramine.**

**Flumazenil\*\*.**

Prepared by:

**Fluocinolone.**

**Fluoxetine.**

**Fluoxymesterone.**

**Flupenthixol.**

**Fluphenazine.**

**Flurazepam\*\*.**

**Fluspirilene.**

**Fluvoxamine.**

**Formebolone.**

**Furazabol.**

**Haloperidol.**

**Halothane.**

**Hedonal** and its esters, except when specifically packaged, labelled and used for industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose, which are intended to be ingested by man or animals as food or applied to the body as a cosmetic and which are approved for such use in terms of the Foodstuffs, Cosmetics and Disinfectants Act, 1972, and for analytical laboratory purposes.

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

**5-Hydroxy Tryptophan,**

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

**Hydroxyzine.**

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

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

**Iproniazid.**

**Isoflurane.**

**Isotretinoin.**

**Ketamine.**

**Ketazolam\*\*.**

**Lemborexant**

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

**Lofepamine.**

**Loprazolam\*\***

**Lorazepam\*\*.**

**Lormetazepam\*\*.**

**Loxapine.**

**Maprotiline.**

**Mazindol\*\*.**

**Mebolazine.**

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

**Meclofenoxate.**

**Medazepam\*\*.**

**Medetomidine.**

**Melitracene.**

**Mephenoxalone.**

**Meprobamate\*\***

**Mesterolone.**

**Metandienone.**

**Metenolone.**

**Methandranone.**

**Methandriol.**

**Methoxyflurane.**

**Methyltestosterone.**

**Metrifonate.**

**Mianserin.**

**Mibolerone.**

**Midazolam\*\*.**

**Milnacipran.**

**Mirtazapine.**

**Mitrazapine.**

**Moclobemide.**

**Modafinil.**

**Molindone.**

**Nalbuphine.**

**Nandrolone.**

**Nefazodone.**

**Nitrazepam\*\*.**

**Nomifensine.**

**Norclostebol.**

**Norethandronlone.**

**Nortriptyline.**

**Olanzapine.**

**Oxabolone.**

**Oxandrolone.**

**Oxazepam\*\*.**

**Oxymesterone.**

**Oxymetholone.**

**Oxypertine.**

**Paliperidone.**

**Paliperidone.**

**Paraldehyde.**

**Pargyline.**

**Paroxetine.**

**Pemoline\*\*** and its complexes\*\*.

**Perampanel.**

**Phenazepam.**

**Phenethylhydrazine.**

**Phenothiazine and its derivatives.**

- (a) unless listed in another Schedule.
- (b) except preparations and mixtures containing promethazine or dimethothiazine or their salts when used solely as an antihistaminic; (S2) and
- (c) except preparations containing promethazine or its salts when intended specifically for the treatment of travel sickness or application to the skin; (S2) and
- (d) except phenothiazine when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

**Phentermine\*\*.**

**Pimethixene**, except preparations and mixtures thereof when used solely as an antihistaminic. (S2)

**Pimozide.**

**Pipradrol\*\***

**Pizotifen**, except preparations and mixtures thereof when used solely as an antihistaminic or when intended for the prophylaxis of migraine. (S2)

**Prasterone (Dehydroepiandrosterone, DHEA).**

**Prazepam\*\*.**

**Prochlorperazine maleate**

**Prolintane.**

**Pregabalin.**



**Propofol.**

**Protrirityline.**

**Quazepam\*\*.**

**Quetiapine.**

**Quinbolone.**

**Quinupramine.**

**Reboxetine.**

**Rimonabant.**

**Risperidone.**

**Rivastigmine.**

**Romifidine.**

**Sertindole**

**Sertraline.**

**Sevoflurane.**

**Sibutramine.**

**Stanozolol.**

**Stenbolone.**

**Sulphonmethane.**

**Sulpiride.**

**Temazepam\*\***

**Testolactone.**

**Testosterone**, except subcutaneous implants thereof when specifically intended and registered as a veterinary production improver in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

**Thioguanosine.**

**Thiopentone.**

**Thiothixene.**

**Tiapride.**

**Tiletamine.**

**Tizanidine.**

**Tramadol.**

**Tranlycypromine.**

**Trazodone.**

**Trenbolone**, except subcutaneous implants thereof when specifically intended and registered as a veterinary production improver in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Tretinoin, when intended for oral preparation. (S3)

**Triazolam\*\*.**

**Trifluoroperazine.**

**Trihexyphenidyl.**

**Trimipramine.**

**5-Hydroxy Tryptophan,**

- a. except in oral preparations with a maximum daily dose not exceeding 220 mg of 5-Hydroxy tryptophan, alone or in combination with other active pharmaceutical ingredients; (S1)

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

**L-tryptophan,**

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

**Varenicline.**

**Venlafaxine.**

**Viloxazine.**

**Vortioxetine.**

**Xylazine.**

**Zaleplon.**

**Zimelidine.**

**Ziprasidone.**

**Zolazepam.**

**Zolpidem\*\*.**

**Zopiclone.**

**Zotepine.**

**Zuclopenthixol.**

**ANNEXURES OF SCHEDULE 5**

**ANNEXURE 1A: EMERGENCY CARE PROVIDER (PARAMEDIC)**

Prepared by:

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

<b>PARAMEDIC</b> (National Diploma in Emergency Medical Care graduates)	
<b>BENZODIAZEPINE DERIVATIVE</b>	
Substance	Diazepam
Indication	Anti Convulsant/ Sedative/ Hypnotic
Schedule	5
Route of Administration	Parenteral
<b>BENZODIAZEPINE DERIVATIVE</b>	
Substance	Midazolam
Indication	Anti Convulsant/ Sedative/ Hypnotic
Schedule	5
Route of Administration	Parenteral
<b>BENZODIAZEPINE DERIVATIVE</b>	
Substance	Lorazepam
Indication	Anti Convulsant/ Sedative/ Hypnotic
Schedule	5
Route of Administration	Parenteral
<b>BENZODIAZEPINE ANTAGONIST</b>	
Substance	Flumazenil
Indication	Benzodiazepine Antagonist
Schedule	5
Route of Administration	Parenteral
<b>NON-SELECTIVE ANTIHISTAMINE</b>	
Substance	Promethazine
Indication	Antihistamine
Schedule	5
Route of Administration	Parenteral
<b>*INDUCTION AGENTS</b>	
Substance	Ketamine
Indication	Analgesia
Route of Administration	Parenteral
<b>ANALGESIC INHALANT</b>	
Substance	Methoxyflurane (Penthrox Inhaler)
Indication	Analgesia
Route of Administration	Inhalant

*(Annexure 1A of Schedule 5 inserted by Government Notice R674 in Government Gazette 36827 dated 13 September 2013.)*

(Annexures 1A of Schedule 5 amended by Government Notice R1375 in Government Gazette 44019 dated 18 December 2020.)

(Annexure 1A of Schedule 5 amended by Government Notice 883 in Government Gazette 45176 dated 17 September 2021.)

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

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

<b>EMERGENCY CARE PRACTITIONER (B Tech: Emergency Medical Care)</b>	
<b>BENZODIAZEPINE DERIVATIVE</b>	
Substance	Diazepam
Indication	Anti Convulsant/ Sedative/ Hypnotic
Schedule	5
Route of Administration	Parenteral
<b>BENZODIAZEPINE DERIVATIVE</b>	
Substance	Midazolam
Indication	Anti Convulsant/ Sedative/ Hypnotic
Schedule	5
Route of Administration	Parenteral
<b>BENZODIAZEPINE DERIVATIVE</b>	
Substance	Lorazepam
Indication	Anti Convulsant/ Sedative/ Hypnotic
Schedule	5
Route of Administration	Parenteral
<b>BENZODIAZEPINE ANTAGONIST</b>	
Substance	Flumazenil
Indication	Benzodiazepine Antagonist
Schedule	5
Route of Administration	Parenteral
<b>NON-SELECTIVE ANTIHISTAMINE</b>	
Substance	Promethazine
Indication	Antihistamine
Schedule	5
Route of Administration	Parenteral
<b>INDUCTION AGENTS</b>	
Substance	Ketamine
Indication	Dissociative Anaesthesia /Analgesic/Mild Bronchodilator
Schedule	5
Route of Administration	Parenteral
<b>INDUCTION AGENTS</b>	

Substance	Etomidate
Indication	Induction Agent
Schedule	5
Route of Administration	Parenteral
<b>ANALGESIC INHALANT</b>	
Substance	Methoxyflurane (Pentrox Inhaler)
Indication	Analgesia
Route of Administration	Inhalant

*(Annexure 1B of Schedule 5 inserted by Government Notice R674 in Government Gazette 36827 dated 13 September 2013.)*

*(Annexure 1B of Schedule 5 amended by Government Notice 883 in Government Gazette 45176 dated 17 September 2021.)*

### **ANNEXURE 1C: BASIC AMBULANCE ASSISTANT**

<b>BASIC AMBULANCE ASSISTANT</b> registered with the Health Professions Council of South Africa	
<b>ANALGESIC INHALANT</b>	
Substance	Methoxyflurane (Pentrox Inhaler)
Indication	Analgesia
Route of Administration	Inhalant

*(Annexure 1C amended by Government Notice 883 in Government Gazette 45176 dated 17 September 2021.)*

### **ANNEXURE 1D: AMBULANCE EMERGENCY ASSISTANT**

<b>AMBULANCE EMERGENCY ASSISTANT</b> registered with the Health Professions Council of South Africa	
<b>ANALGESIC INHALANT</b>	
Substance	Methoxyflurane (Pentrox Inhaler)
Indication	Analgesia
Route of Administration	Inhalant

*(Annexure 1D of Schedule 5 amended by Government Notice 883 in Government Gazette 45176 dated 17 September 2021.)*

### **ANNEXURE 1E: EMERGENCY CARE TECHNICIAN**

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

<b>EMERGENCY CARE TECHNICIAN</b> registered with Health Professions Council of South Africa	
<b>BENZODIAZEPINE DERIVATIVE</b>	
Substance	Diazepam
Indication	Anti Convulsant/ Sedative/ Hypnotic
Route of Administration	Parenteral
<b>BENZODIAZEPINE DERIVATIVE</b>	

Substance	Midazolam
Indication	Anti Convulsant/ Sedative/ Hypnotic
Route of Administration	Parenteral
<b>BENZODIAZEPINE DERIVATIVE</b>	
Substance	Lorazepam
Indication	Anti Convulsant/ Sedative/ Hypnotic
Route of Administration	Parenteral
<b>BENZODIAZEPINE ANTAGONIST</b>	
Substance	Flumazenil
Indication	Benzodiazepine Antagonist
Route of Administration	Parenteral
<b>NON-SELECTIVE ANTIHISTAMINE</b>	
Substance	Promethazine
Indication	Antihistamine
Route of Administration	Parenteral
<b>ANALGESIC INHALANT</b>	
Substance	Methoxyflurane (Penthrox Inhaler)
Indication	Analgesia
Route of Administration	Inhalant

*(Annexures 1E of Schedule 5 inserted by Government Notice R1375 in Government Gazette 44019 dated 18 December 2020.)*

*(Annexure 1E of Schedule 5 amended by Government Notice 883 in Government Gazette 45176 dated 17 September 2021.)*

#### **ANNEXURE 1F: EMERGENCY CARE ASSISTANT**

<b>EMERGENCY CARE ASSISTANT</b> registered with Health Professions Goyncil of South Africa	
<b>BENZODIAZEPINE DERIVATIVE</b>	
Substance	Diazepam
Indication	Anti Convulsant/ Sedative/ Hypnotic
Route of Administration	Parenteral
<b>BENZODIAZEPINE DERIVATIVE</b>	
Substance	Midazolam
Indication	Anti Convulsant/ Sedative/ Hypnotic
Route of Administration	Parenteral
<b>BENZODIAZEPINE DERIVATIVE</b>	
Substance	Lorazepam
Indication	Anti Convulsant/ Sedative/ Hypnotic
Route of Administration	Parenteral
<b>BENZODIAZEPINE ANTAGONIST</b>	
Substance	Flumazenil
Indication	Benzodiazepine Antagonist

Prepared by:

Route of Administration	Parenteral
<b>ANALGESIC INHALANT</b>	
Substance	Methoxyflurane (Penthrox Inhaler)
Indication	Analgesia
Route of Administration	Inhalant

*(Annexure 1F inserted by Government Notice R1375 in Government Gazette 44019 dated 18 December 2020.)*

*(Annexure 1F amended by Government Notice 883 in Government Gazette 45176 dated 17 September 2021.)*

**- END SCHEDULE 5 -**

*(Schedule 5 amended by Government Notice R1230 in Government Gazette 32838 dated 31 December 2009)*

*(Schedule 5 amended by Government Notice R227 in Government Gazette 35149 dated 15 March 2012)*

*(Schedule 5 and Specified Schedule 5 amended by Government Notice R690 in Government Gazette 36850 dated 20 September 2013)*

*(Schedule 5 amended by Government Notice R234 in Government Gazette 38586 dated 20 March 2015)*

*(Schedule 5 amended by Government Notice 254 in Government Gazette 39815 dated 15 March 2016)*

*(Schedule 5 amended by Government Notice 748 in Government Gazette 41009 dated 28 July 2017)*

*(Schedule 5 amended by Government Notice 1261 in Government Gazette 41256 dated 17 November 2017)*

*(Schedule 5 amended by Government Notice R1098 in Government Gazette 41971 dated 12 October 2018)*

*(Schedule 5 and Specified Schedule 5 amended by Government Notice R1262 in Government Gazette 42052 dated 23 November 2018)*

*(Schedule 5 and Specified Schedule 5 amended by Government Notice R1375 in Government Gazette 44019 dated 18 December 2020.)*

*(Schedule 5 amended by Government Notice 883 in Government Gazette 45176 dated 17 September 2021.)*

*(Schedule 5 and Specified Schedule 5 amended by GN 2685 dated 28 October 2022)*

*(Schedule 5 amended by GNR 3261 dated 24 March 2023)*

**SCHEDULE 6**

- a. All preparations or mixtures of such substances containing or purporting to contain substances that is chemically related and incorporates a structural fragment into its structure that is similar to the structure of a listed substance and /or exhibits pharmacodynamic properties similar to the listed substance referred to in this Schedule include the following (unless expressly excluded or unless listed in another Schedule):
  - (i) the isomers of such substances, where the existence of such isomers is possible within the chemical designation;



- (ii) the esters and ethers of such substances and of the isomers referred to in (i) as well as the isomers of such esters and ethers, where the existence of isomers of such esters or ethers is possible;
  - (iii) the salts of such substances and of the isomers referred to in (i), as well as the salts of the esters, ethers and isomers referred to in (ii), where the existence of such salts is possible;
  - (iv) the isomers of any of the salts referred to in (iii), where the existence of such isomers is possible;
  - (v) all preparations and mixtures of any of the above.
  - (vi) all homologues of listed substances (being any chemically related substances that incorporate a structural fragment into their structures that is similar to the structure of a listed substance and/or exhibit pharmacodynamic properties similar to the listed substance in the schedules), unless listed separately in the Schedules.
- b. In terms of Section 22A(5)(f) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, may prescribe and supply, only within his/her scope of practice and subject to the indication for use of such substances and medicines and to the conditions determined by the Medicines Control Council, to patients under his/her care, the Schedule 6 substances and medicines provided for in the Annexures to this Schedule published in the *Gazette* in terms of the Act.
- (i) Annexure 1A: Emergency Care Provider (Paramedic)
  - (ii) Annexure 1B: Emergency Care Provider (Emergency Care Practitioner)

**Acetorphine.**

**Acetyldihydrocodeine.**

**Acetylmethadol.**

**Alfentanil.**

**Allylprodine.**

**Alphacetylmethadol.**

**Alphameprodine.**

**Alphamethadol.**

Prepared by:

**Alphaprodine.**

**Amineptine.**

**Amobarbital.**

**Anileridine.**

**Benzethidine.**

**Benzphetamine.**

**Benzylmorphine.**

**Beta-aminopropylbenzene and beta-aminoisopropylbenzene derivatives**, being any compound structurally derived from either of these substances by substitution in the side chain or by ring closure therein (or by both such substitution and such ring closure):

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

**Betacetylmethadol.**

**Betameprodine.**

**Betamethadol.**

**Betaprodine.**

**Bezitramide.**

**Buprenorphine.**

Prepared by:

**Butalbital.**

**Butorphanol.**

**Carfentanil**, when intended for veterinary use. (S7)

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

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

**Chlorphentermine.**

**Clonitazene.**

**Coca leaf and any salt**, compound, derivative or preparation of coca leaf and any salt, compound, derivative or preparation thereof that is chemically equivalent or identical to any of these substances, whether obtained directly or indirectly by extraction from material or substances obtained from plants, or obtained independently by chemical synthesis, or by a combination of extraction and chemical synthesis, except decocainized coca leaf and extractions of coca leaf where such extractions contain no cocaine or ecgonine. (S0)

**Codeine (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; (S2, S3)
- c. except liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, in preparations not registered in terms of the Act, or when intended for export. (S2, S3)

**Codoxime.**

**Colistin,**

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

**Cyclobarbital.**

**Desomorphine.**

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

**Dextromoramide.**

**Dextropropoxyphene**, except preparations and mixtures for oral use containing 135 milligrams or less of dextropropoxyphene, calculated as the base, per dosage unit or with a concentration of not more than 2,5 percent in undivided preparations. (S5)

**Dextrorphan.**

**Diampromide.**

**Diethylpropion (amfepramone).**

**Diethylthiambutene.**

**Dihydrocodeine,**

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

**Dihydroetorphine.**

**Dihydromorphine.**

**Dimenoxadol.**

**Dimepheptanol.**

**Dimethylthiambutene.**

**Dioxaphethyl butyrate.**

**Difenoxin (or diphenoxyllic acid)**, except mixtures containing, per dosage unit, 0,5 milligrams or less of difenoxin, calculated as the base, and a quantity of atropine sulphate equal to at least 5 percent of such quantity of difenoxin, calculated as the base, as is present in the mixture. (S2)

**Diphenoxylate**, except preparations containing not more than 2,5 milligrams of diphenoxylate, calculated as the base, and not less than 25 micrograms of atropine sulphate per dosage unit. (S2)

**Dipipanone.**

**(D-norpseudoephedrine - see cathine)**

**Drotebanol.**

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

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

- a. except products registered in terms of the Act, not intended for export, and being oral preparations and mixtures, in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, containing not more than 30 milligrams of ephedra alkaloids per dose, with a maximum daily dose not exceeding 120 milligrams, subject to a maximum pack size of 360 milligrams and limited to one pack per customer; (S2)
- b. except when intended for application to skin, eyes, ears and nares and containing 1 percent or less of ephedra alkaloids. (S1)

**Ephedrine,**

- a. except products registered in terms of the Act, not intended for export, and being oral preparations and mixtures, in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, containing not more than 30 milligrams of ephedrine per dose, with a maximum daily dose not exceeding 120 milligrams, subject to a maximum pack size of 360 milligrams and limited to one pack per customer; (S2)
- b. except preparations and mixtures intended for application to the skin, eyes, ears and nares and containing 1 percent or less of ephedrine. (S1)

**Ethylmethylthiambutene.**

**Ethylmorphine,**

- (a) except oral solid preparations, in combination with one or more therapeutically active substances, and containing 20 milligrams or less of ethylmorphine (calculated as base) per dosage unit; (S2) and
- (b) except liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, and containing 20 milligrams or less of ethylmorphine (calculated as base) per 5 millilitre dosage unit. (S2).

**Etonitazene.**

**Etorphine and analogues.**

**Etoxadine.**

**Fenproporex.**

**Fentanyl**, when intended for therapeutic purposes. (S7)

**Flunitrazepam.**

**Furethidine.**

**Glutethimide.**

**Hydrocodone (dihydrocodeinone).**

**Hydromorphanol (14-hydroxydihydromorphine).**

**Hydromorphone (dihydromorphinone).**

**Hydroxy pethidine.**

**Ibogaine.**

**Isomethadone.**

**Ketobemidone.**

**Levomoramide.**

**Levophenacymorphan.**

**Levorphanol.**

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

**Mecloqualone.**

**Mefenorex.**

**Meptazinol.**

**Metazocine.**

**Methadone.**

**Methadone-intermediate.**

**Methorphan**, including levomethorphan and racemethorphan, but excluding dextromethorphan. (S2)

**Methyldesorphine.**

**Methyldihydromorphine.**

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

**Metopon.**

**Moramide-intermediate.**

**Morpheridine.**

**Morphine**, except preparations and mixtures of morphine containing 0,2 percent or less of morphine, calculated as anhydrous morphine. (S2).

**Morphine methobromide** and other pentavalent nitrogen morphine derivatives.

**Morphine-N-oxide and its derivatives.**

**Myrophine (myristylbenzylmorphine).**

**Nefopam.**

**Nicocodine.**

**Nicodicodine.**

**Nicomorphine.**

**Noracymethadol.**

**Norcodeine.**

**Norlevorphanol.**

**Normethadone.**

**Normorphine (demethylmorphine or N-demethylated morphine).**

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

**Norpipanone.**

**Opium and opiates and any salt**, compound, derivative or preparation of opium or opiates, whether obtained directly or indirectly by extraction from material or substances obtained from plants, or obtained independently by chemical synthesis, or by a combination of extraction and chemical synthesis, except mixtures containing 0,2 percent or less of morphine, calculated as anhydrous morphine. (S2)

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

**Oxycodone (14-hydroxydihydrocodeinone or dihydrohydroxycodeinone).**

**Oxymorphone (14-hydroxydihydromorphinone or dihydrohydroxymorphinone).**

**Pentazocine.**

**Pentobarbital.**

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

**Phenadoxone.**

**Phenampromide.**



**Phenazocine.**

**Phendimetrazine.**

**Phenomorphan.**

**Phenoperidine.**

**Phenylpropanolamine (norephedrine),**

- a. except products registered in terms of the Act, not intended for export and oral preparations and mixtures where the recommended daily dose for adults does not exceed 100 milligrams and for children 6 to 12 years does not exceed 50 milligrams, when in combination with another pharmacologically active substance and intended for the symptomatic relief of nasal and sinus congestion, subject to a maximum pack size of 300 milligrams for adults and 150 milligrams for children, limited to one pack per customer (S2)

**Pholcodine**, except when prepared, mixed or compounded

- a. containing 20 milligrams or less of pholcodine (calculated as base) per dosage unit; or
- b. containing 20 milligrams or less of pholcodine (calculated as base) per 5 millilitre dosage unit in the case of liquid oral preparations and mixtures. (S2)

**Piminodine.**

**Piritramide.**

**Proheptazine.**

**Properidine.**

**Propiram.**

**Pseudoephedrine**, except contained in products registered in terms of the Act, and not intended for export, being oral preparations and mixtures containing not more than 60 milligrams or controlled-release oral preparations and mixtures containing not more than 120 milligrams of pseudoephedrine per dose, and not more than 240 milligrams per day, when in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, subject to a maximum pack size of 720 milligrams and limited to one pack per customer. (S2)

**p-Synephrine,**

Prepared by:

- a. except preparations and mixtures registered in terms of the Act and intended for application to the skin, ears and nares containing 1 percent or less of *p*-synephrine and containing 0.2 percent or less for application to the eyes; (S0)
- b. except oral preparations and mixtures registered in terms of the Act and intended for the symptomatic relief of nasal and sinus congestion, where the recommended daily dose for adults is 50 milligrams or less and for children 6 to 12 years is 25 milligrams or less, with a maximum pack size of 5 days; (S1)
- c. except oral preparations and mixtures registered in terms of the Act and intended for the symptomatic relief of nasal and sinus congestion, where the recommended daily dose for adults is more than 50 milligrams and for children 6 to 12 years is more than 25 milligrams. (S2)

**Racemoramide.**

**Racemorphan.**

**Remifentanyl.**

**Secobarbital.**

**Sufentanyl.**

**Tapentadol.**

**Thebacon.**

**Thebaine.**

**Thiafentanyl.**

**Tilidine.**

**Tetrahydrocannabinol**, except:

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

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

**Trimeperidine.**

**Zipeprol.**

## **ANNEXURES TO SCHEDULE 6**

### **ANNEXURE 1A: EMERGENCY CARE PROVIDER (PARAMEDIC)**

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

<b>PARAMEDIC</b> (National Diploma in Emergency Medical Care graduates)	
<b>ANALGESICS</b>	
Substance	Morphine Sulphate
Indication	Opioid/Narcotic
Schedule	6
Route of Administration	Parenteral

*(Annexures 1A of Schedule 6 inserted by Government Notice R674 in Government Gazette 36827 dated 13 September 2013.)*

*(Annexures 1A of Schedule 6 amended by Government Notice R1375 in Government Gazette 44019 dated 18 December 2020.)*

*(Annexure 1A of Schedule 6 amended by Government Notice 883 in Government Gazette 45176 dated 17 September 2021.)*

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

#### **EMERGENCY CARE PRACTITIONER**

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

<b>EMERGENCY CARE PRACTITIONER</b> (Bachelor of Technology Degree in Emergency Medical Care) registered with the Health Professions Council of South Africa	
<b>ANALGESICS</b>	
Substance	Morphine Sulphate
Indication	Opioid/ Narcotic
Schedule	6
Route of Administration	Parenteral

*(Annexures 1B of Schedule 6 inserted by Government Notice R674 in Government Gazette 36827 dated 13 September 2013.)*

Prepared by:

*(Annexures 1B of Schedule 6 inserted by Government Notice R1375 in Government Gazette 44019 dated 18 December 2020.)*

*(Annexure 1B of Schedule 6 amended by Government Notice 883 in Government Gazette 45176 dated 17 September 2021.)*

### **ANNEXURE 1E. EMERGENCY CARE TECHNICIAN**

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

<b>EMERGENCY CARE TECHNICIAN</b> registered with Health Professions Council of South Africa	
<b>*ANALGESICS</b>	
Substance	Morphine Sulphate
Indication	Opioid/ Narcotic
Route of Administration	Parenteral

*(Annexures 1E of Schedule 6 inserted by Government Notice R1375 in Government Gazette 44019 dated 18 December 2020.)*

### **- END SCHEDULE 6 -**

*(Schedule 6 amended by Government Notice R1230 in Government Gazette 32838 dated 31 December 2009)*

*(Schedule 6 amended by Government Notice R227 in Government Gazette 35149 dated 15 March 2012)*

*(Schedule 6 amended by Government Notice R104 in Government Gazette 37318 dated 11 February 2014. Commencement date: 11 February 2014)*

*(Schedule 6 amended by Government Notice R352 in Government Gazette 37622 dated 8 May 2014)*

*(Schedule 6 amended by Government Notice R234 in Government Gazette 38586 dated 20 March 2015)*

*(Schedule 6 amended by Government Notice 254 in Government Gazette 39815 dated 15 March 2016)*

*(Schedule 6 amended by Government Notice 620 in Government Gazette 40041 dated 3 June 2016)*

*(Schedule 6 amended by Government Notice 748 in Government Gazette 41009 dated 28 July 2017)*

*(Schedule 6 amended by Government Notice 1261 in Government Gazette 41256 dated 17 November 2017)*

*(Schedule 6 amended by Government Notice R755 in Government Gazette 42477 dated 23 May 2019)*

*(Schedule 6 amended by Government Notice R586 in Government Gazette 43347 dated 22 May 2020)*

*(Schedule 6 amended by Government Notice R1375 in Government Gazette 44019 dated 18 December 2020.)*

*(Schedule 6 amended by Government Notice 883 in Government Gazette 45176 dated 17 September 2021.)*

*(Schedule 6 amended by GNR 3261 dated 24 March 2023)*

*(Schedule 6 amended by GN dated 6 September 2024)*

### **SCHEDULE 7**

All preparations or mixture of such substances containing or purporting to contain substances referred to in this Schedule include the following (unless expressly excluded or unless listed in another Schedule):

Prepared by:

- (i) the isomers of such substances, where the existence of such isomers is possible within the chemical designation;
- (ii) the esters and ethers of such substances and of the isomers referred to in (i), as well as the isomers of such esters and ethers, where the existence of isomers of such esters, or ethers is possible;
- (iii) the salts of such substances and of the isomers referred to in (i), as well as the salts of the esters, ethers and isomers referred to in (ii), where the existence of such salts is possible;
- (iv) the isomers of any of the salts referred to in (iii), where the existence of such isomers is possible;
- (v) all preparations and mixtures of any of the above.
- (vi) all homologues of listed substances (being any chemically related substances that incorporate a structural fragment into their structures that is similar to the structure of a listed substance and/or exhibit pharmacodynamic properties similar to the listed substance in the schedules), unless listed separately in the Schedules.

**(Trivial or unofficial names are marked \*)**

AB-CHMINACA.

AB-FUBINACA.

AB-PINACA.

5F – APINACA (5F AKB-48).

Acetylfentanyl.

ADB-CHMINACA (MAB-CHMINACA)

ADB-FUBINACA

AH-7921.

Alpha-PHP.

AM-2201.

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

Prepared by:

Aminorex.

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

1-Benzy|piperazine (BZP)

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

- (a) preparations and mixtures when used as vasoconstrictors and decongestants in antihistamine nose and eye preparations; (S1) and
- (b) appliances for inhalation in which the substance is absorbed onto solid material: (S1)
- (c) excluding cathine {(+)-norpseudoephedrine}, ephedrine, etafedrine, N-methylephedrine, N-diethylaminoethylephedrine, phenylpropanolamine, prepylamine: (S1, S2, S5)
- (d) except substances listed in S1, S2, S5, and S6.

Brolamfetamine {(+)-4-bromo-2,5-dimethoxy- $\alpha$ -methylphenethylamine} \*(DOB).

4-bromo-2,5-dimethoxyphenethylamine (2C-B) \*(Nexus).

Brorphine

Bufotenine (N,N-dimethylserotonin).

Butyrfentanyl.

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

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

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

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

4-CMC (4-chloromethcathinone; clephedrone).

Clonazepam

Prepared by:

CUMYL-4CN-8INACA

CUMYL-PEGACLONE.

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

Diclazepam

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

1,3 Dimethylamylamine also known as (1,3 DMAA/1,3 dimethylpentylamine/2-amino-4-methylhexane/2-hexanamine/4-methylhexane-2-amine/4-methyl-2-hexanamine/4-methyl-2-hexylamine/4-methyl-(9C1)/dimethylamylamine/geranamine/methylhexanamine/methylhexanamine)

(+)- 2,5-dimethoxy- $\alpha$ -methylphenethylamine \*(DMA).

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

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

3-(1,2-dimethylheptyl)-7,8,9,10-tetrahydro-6,6,9-trimethyl-6H-dibenzo[b,d]pyran-1-ol\*(DMHP).

(+)-N, $\alpha$ -dimethyl-3,4-(methylenedioxy) phenethylamine \*(MDMA).

Dimethyltryptamine [3-(2-(dimethylamino) ethyl) indole] \*(DMT).

Diphenidine.

(+)-4-ethyl-2,5-dimethoxy- $\alpha$ -phenethylamine \*(DOET).

N-ethylhexedrone.

Ethylone.

Ethylphenidate.

N-Ethylnorpentylone (ephylone)

Etilamfetamine (N-ethylamphetamine).

Etizolam

Etryptamine.

Eutylone

Fenetylline.

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

(i) acetyl-alpha-methylfentanyl;

(ii) alpha-methylfentanyl;

(iii) alpha-methylfentanyl-acetanilide;

(iv) alpha-methylthiofentanyl;

(v) benzyl-fentanyl;

(vi) beta-hydroxyfentanyl;

(vii) beta-hydroxy-3-methylfentanyl;

(viii) 3-methylfentanyl and its two isomeric forms:

cis-N-(3- methyl-1-(2-phenethyl)-4-piperidyl) propionanilide; and

trans-N-(3-methyl-1-(2-phenethyl)-4-piperidyl) propionanilide;

(ix) 3-methylthiofentanyl;

(x) para-fluorofentanyl; and

(xi) thiofentanyl. (S6)

(xii) 4-anilino-N-phenethylpiperidine (ANPP);

(xiii) N-phenethyl-4-piperidone (NPP).

(xiv) Acryloylfentanyl (acrylfentanyl).



- (xv) 4-fluoroisobutyrfentanyl (4-FIBF, pFIBF).
- (xvi) Furanylfentanyl
- (xvii) Tetrahydrofuranylfentanyl (THF-F).
- xviii. Cyclopropylfentanyl. (N-Phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]cyclopropanecarboxamide)
- xix. Methoxyacetyl fentanyl. (2-methoxy-N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide)
- xx. Ortho-fluorofentanyl. (N-(2-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide)
- xxi. Parafluorobutyrfentanyl (N-(4-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]butanamide)
- (xxii) Crotonylfentanyl.
- (xxiii) Valeryl fentanyl.

Flualprazolam

Flubromazolam

4-fluoroamphetamine (4-FA).

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

Gamma-hydroxybutyrate \*(GHB).

Harmaline (3,4-dihydroharmine).

Harmine (7-methoxy-1-methyl-9H-pyrido (3,4-b)-indole).

Heroin (diacetylmorphine).

3-hexyl-7,8,9,10-tetrahydro-6,6,0-trimethyl-6H-dibenzo [b,d]-pyran-1-ol \*(Parahexyl).

Isotonitazene

Lefetamine \*(SPA).

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

Prepared by:

Lysergide (Lysergic acid diethylamide) \*(LSD).

4F-MDMB-BINACA.

MDMB - CHMICA

MDMB-4en-PINACA.

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

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

4-MEC.

Mephedrone.

Mescaline (3,4,5-trimethoxyphenethylamine).

Mesocarb.

Methamphetamine and methamphetamine racemate.

Methaqualone and any preparation containing methaqualone.

Methcathinone.

Methiopropamine (MPA).

Methoxetamine (MXE).

2-methoxy- $\alpha$ -methyl-4,5-(methylenedioxy)phenethylamine \*(MMDA).

p-methoxy- $\alpha$ -methylphenethylamine \*(PMA).

3-Methoxyphencyclidine.

Methyl alpha-phenylacetoacetate (MAPA)

4 methylaminorex,

((Methylenedioxyamphetamine \*(MDA) and its analogues - see tenamphetamine).

3,4-methylenedoxypyrovalerone (MDPV).

Methylone (beta-keto-MDMA).

Methypylon,

Metonitazene

MT-45.

Nabilone. (S8)

Norfentanyl

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

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

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

Ocfentanil.

Para-methoxymethylamphetamine (PMMA)

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

5F-PB-22.

Pentedrone.

Pethidine-analogues, including:

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

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

Phencyclidine \*(PCP) and its congeners, including:

- (i) eticyclidine (N-ethyl-1-phenylcyclohexylamine) \*(PCE);
- (ii) rolycyclidine (1-(1-phenylcyclohexyl) pyrrolidine) \*(PHP or PCPY); and
- (iii) tenocyclidine (1-(1-(2-thienyl) cyclohexyl) piperidine) \*(TCP).

Phenmetrazine.

Psilocin (4-hydroxy-NN-dimethyltryptamine).

Psilocybine (4- phosphoryloxy-NN-dimethyltryptamine).

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

$\alpha$ -pyrrolidinovalerophenone ( $\alpha$ -PVP).

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

- cannabicyclohexanol;
- JWH-018;
- JWH-073;
- JWH-200;
- CP-47,497;
- CP47,497-C6;
- CP 47,497-C7;
- CP47,497-C8;
- CP 47,497-C9;
- HU-210

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

- (i) (+)-N-ethyl- $\alpha$ -methyl-3,4-(methylenedioxy) phenethylamine \*(N-ethyl MDA);
- (ii) (+)-N-( $\alpha$ -methyl-3,4-(methylenedioxy) phenethyl) hydroxylamine \*(N-hydroxy MDA).

1-(3-trifluoromethylphenyl) piperazine \*(TFMPP),

( $\pm$ )-3, 4, 5- trimethoxy- $\alpha$ -methylphenethylamine \*(TMA).

U47700.

UR-144.

XLR-11.

**- END SCHEDULE 7 -**

*(Schedule 7 amended by Government Notice R227 in Government Gazette 35149 dated 15 March 2012)*

*(Schedule 7 amended by Government Notice R690 in Government Gazette 36850 dated 20 September 2013)*

*(Schedule 7 amended by Government Notice R352 in Government Gazette 37622 dated 8 May 2014)*

*(Schedule 7 amended by Government Notice R234 in Government Gazette 38586 dated 20 March 2015)*

*(Schedule 7 amended by Government Notice 254 in Government Gazette 39815 dated 15 March 2016)*

*(Schedule 7 amended by Government Notice 748 in Government Gazette 41009 dated 28 July 2017)*

*(Schedule 7 amended by Government Notice 1261 in Government Gazette 41256 dated 17 November 2017)*

*(Schedule 7 amended by Government Notice R755 in Government Gazette 42477 dated 23 May 2019)*

*(Schedule 7 amended by Government Notice R219 in Government Gazette 43051 dated 28 February 2020)*

*(Schedule 7 amended by Government Notice R586 in Government Gazette 43347 dated 22 May 2020)*

*(Schedule 7 amended by Government Notice R1375 in Government Gazette 44019 dated 18 December 2020)*

*(Schedule 7 amended by Government Notice 883 in Government Gazette 45176 dated 17 September 2021.)*

*(Schedule 7 amended by GN 2685 dated 28 October 2022)*

*(Schedule 7 amended by GNR 3261 dated 24 March 2023)*

**SCHEDULE 8**

All preparations or mixture of such substances containing or purporting to contain substances referred to in this Schedule include the following (unless expressly excluded or unless listed in another Schedule):

- (i) the isomers of such substances, where the existence of such isomers is possible within the chemical designation;
- (ii) the esters and ethers of such substances and of the isomers referred to in (i), as well as the isomers of such esters and ethers, where the existence of such isomers of esters and ethers is possible;
- (iii) the salts of such substances and of the isomers referred to in (i), as well as the salts of the esters, ethers and isomers referred to in (ii), where the existence of such salts is possible;
- (iv) the isomers of any of the salts referred to in (iii), where the existence of such isomers is possible;
- (v) all preparations and mixtures of any of the above.

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

Nabilone. (S7)

**- END SCHEDULE 8 -**

*(Schedule 8 amended by Government Notice 254 in Government Gazette 39815 dated 15 March 2016)*

*(Schedule 8 amended by Government Notice 1261 in Government Gazette 41256 dated 17 November 2017)*

*(Schedule 8 amended by Government Notice R1375 in Government Gazette 44019 dated 18 December)*

These Schedules as amended come into operation on the date of publication in the *Government Gazette*.

(Signed)

**ME TSHABALALA-MSIMANG**

**Minister of Health**

**SCHEDULE 9**

*(Repealed by section 27 of Act 90 of 1997)*