

Regulation Gazette

No. 11213

Regulasiekoerant

Vol. 666

18

**December
Desember 2020**

No. 44019

Contents

<i>No.</i>	<i>Gazette No.</i>	<i>Page No.</i>
GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS		
Health, Department of/ Gesondheid, Departement van		
R. 1375 Medicines and Related Substances Act (101/1965): Schedules	44019	3

GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF HEALTH**NO. R. 1375****18 DECEMBER 2020****MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT No. 101 OF 1965)
SCHEDULES**

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

This Schedule amends the Schedules as inserted by Government Notice R.609 (Medicines and Related Substances Act, 1965: Schedules) in Government Gazette 24727, 10 April 2003; substituted by Government Notice R.935 (Medicines and Related Substances Act, 1965: Schedules) in Government Gazette 31387, 5 September 2008; and amended by Government Notice R.1230 (Medicines and Related Substances Act, 1965: Schedules) in Government Gazette 32838, 31 December 2009; Government Notice R.227 (Medicines and Related Substances Act: Schedules) in Government Gazette 35149, 15 March 2012; Government Notice R.674 (Medicines and Related Substances Act, 1965: Schedules) in Government Gazette 36827, 13 September 2013; Government Notice R.690 (Medicines and Related Substances Act, 1965: Schedules) in Government Gazette 36850, 20 September 2013; Government Notice R.104 (Medicines and Related Substances Act, 1965: Schedules) in Government Gazette 37318, 11 February 2014; Government Notice R.352 (Medicines and Related Substances Act, 1965: Schedules) in Government Gazette 37622, 8 May 2014; Government Notice R.234 (Medicines and Related Substances Act, 1965: Schedules) in Government Gazette 38586, 20 March 2015; Government Notice R.254 (Medicines and Related Substances Act, 1965: Schedules) in Government Gazette 39815, 15 March 2016; Government Notice R.254 (Medicines and Related Substances Act, 1965: Schedules) in Government Gazette 40041, 03 June 2016; Government Notice No.748 (Medicines and Related Substances Act, 1965: Schedules) in Government Gazette 41009, 28 July 2017; Government Notice No.1261 (Medicines and Related Substances Act, 1965: Schedules) in Government Gazette 41256, 17 November 2017; Government Notice No.1262 (Medicines and Related Substances Act, 1965: Schedules) in Government Gazette 42052, 23 November 2018 and Government Notice No.755 (Medicines and Related Substances Act, 1965: Schedules) in Government Gazette 42477, 23 May 2019; Government Notice No.R219 (Medicines and Related Substances Act, 1965: Schedules) in Government Gazette 430151, 28 February 2020 and Government Notice No.R586 (Medicines and Related Substances Act, 1965: Schedules) in Government Gazette 43347, 22 May 2020 using the following convention:

Schedule 1

- Words in bold and in square brackets (e.g. **[Gamma benzene hexachloride]** in Schedule 1), indicate omission from a Schedule
- Words underlined with a solid line (e.g. Gamma benzene hexachloride), indicate insertions in a Schedule.

SCHEDULE

In these Schedules, "the Act" means the Medicines and Related Substances Act, 1965 (Act No.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 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.

Schedule 1

- (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

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)

Benzylamine,

- a. preparations and mixtures containing **[0,15 percent or less of benzydamine, when]** intended for use as a mouth rinse or for topical application in the mouth and throat; provided that the total dose swallowed does not exceed 36 milligrams of benzydamine per day. (S3)
- b. except preparations and mixtures containing 3 percent or less of benzydamine, when intended for application to the skin (S0) [(S3)]; or
- c. 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)
- d. except when indicated for human vaginal use. (S2)

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)

Schedule 1

- 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)

ANNEXURE 1A: EMERGENCY CARE PROVIDER (PARAMEDIC)

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

PARAMEDIC (National Diploma in Emergency Medical Care graduates <i>only</i>)	
<u>WATER</u>	
Substance	: Water for injection
Indication	: Diluent
Route of Administration	: Parenteral
<u>WATER</u>	
Substance	: Water for irrigation
Indication	: Wound and dressing irrigation
Route of Administration	: Solution

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

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

EMERGENCY CARE PRACTITIONER (B Tech: Emergency Medical Care)	
<u>WATER</u>	
Substance	: Water for injection
Indication	: Diluent
Route of Administration	: Parenteral
<u>WATER</u>	
Substance	: Water for irrigation
Indication	: Wound and dressing irrigation
Route of Administration	: Solution

Schedule 1

ANNEXURE 1C: BASIC AMBULANCE ASSISTANT**BASIC AMBULANCE ASSISTANT** registered with Health Professions Council of South Africa

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

ANNEXURE 1D: AMBULANCE EMERGENCY ASSISTANT**AMBULANCE EMERGENCY ASSISTANT** registered with Health Professions Council of South Africa

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

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

<u>EMERGENCY CARE TECHNICIAN</u> registered with Health Professions Council of South Africa	
<u>WATER</u>	
<u>Substance</u>	<u>: Water for injection</u>
<u>Indication</u>	<u>: Diluent</u>
<u>Route of Administration</u>	<u>: Parenteral</u>
<u>WATER</u>	
<u>Substance</u>	<u>: Water for irrigation</u>

Schedule 1

EMERGENCY CARE TECHNICIAN registered with Health Professions Council of South AfricaIndication : Wound and dressing irrigationRoute of Administration : Solution**ANNEXURE 1F: EMERGENCY CARE ASSISTANT****EMERGENCY CARE ASSISTANT** registered with Health Professions Council of South Africa**EMERGENCY CARE ASSISTANT** registered with Health Professions Council of South AfricaWATERSubstance : Water for injectionIndication : DiluentRoute of Administration : ParenteralWATERSubstance : Water for irrigationIndication : Wound and dressing irrigationRoute of Administration : Solution**ANNEXURE 4: PODIATRIST**

PODIATRIST [(B.Tech degree in Podiatry)] registered with the Health Professions Council of South Africa in terms of the Health Professions Act, 1974 (Act 56 of 1974)

– END SCHEDULE 1 –

Schedule 2

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);
<u>Annexure 1C:</u>	<u>Basic Ambulance Assistant</u>
<u>Annexure 1D:</u>	<u>Ambulance Emergency Assistant</u>
<u>Annexure 1E:</u>	<u>Emergency Care Technician</u>
<u>Annexure 1F:</u>	<u>Emergency Care Assistant</u>
 - (ii) Annexure 2: Dental Therapist;
 - (iii) Annexure 3: Optometrist.
 - (iv) Annexure 4: Podiatrist

Arsenic;

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

Benzylamine,

- a. when intended for use human vaginal use: (S3)

Schedule 2

- b. except preparations and mixtures containing 3 percent or less of benzydamine, when intended for application to the skin; (S0)
- c. 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)
- 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)"

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

Doxycycline,

- a. when intended and labelled for the chemoprophylaxis of malaria in those aged 8 years and older **[for periods not exceeding 4 months of continuous use]**. (S4)

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 **[S1]** (S0)
- d. except when intended for ophthalmic use. (S4)

olopatidine.

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

PARAMEDIC (National Diploma in Emergency Medical Care graduates <i>only</i>)	
<u>SELECTIVE β_2 AGONISTS</u>	
Substance	: Salbutamol
Indication	: Bronchodilator
Route of Administration	: Aerosol
<u>NON-STEROIDAL ANTI-INFLAMMATORY</u>	
Substance	: Ibuprofen
Indication	: Analgesic/ Anti-inflammatory
Route of Administration	: Oral
<u>ANALGESIC</u>	
Substance	: Paracetamol
Indication	: Analgesic/ Anti-pyrexia
Route of Administration	: Oral

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

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

<u>EMERGENCY CARE PRACTITIONER</u> (B Tech: Emergency Medical Care)	
<u>SELECTIVE β_2 AGONISTS</u>	
Substance	: Salbutamol
Indication	: Bronchodilator
Route of Administration	: Aerosol
<u>ANTI-SPASMODIC</u>	
Substance	: Hyoscine butylbromide
Indication	: Anti-spasmodic
Route of Administration	: Oral
<u>ANTI-PROPULSIVE</u>	
Substance	: Loperamide
Indication	: Symptomatic management of diarrhoea in adults
Route of Administration	: Oral

Schedule 2

EMERGENCY CARE PRACTITIONER

(B Tech: Emergency Medical Care)

NON-STEROIDAL ANTI-INFLAMMATORY

Substance : Ibuprofen

Indication : Analgesic/ Anti-inflammatory

Route of Administration : Oral

ANALGESIC

Substance : Paracetamol

Indication : Analgesic/ Anti-pyrexia

Route of Administration : Oral

ANNEXURE 1C: BASIC AMBULANCE ASSISTANT**BASIC AMBULANCE ASSISTANT** registered with Health Professions Council of South Africa**BASIC AMBULANCE ASSISTANT** registered with Health Professions Council of South Africa***ANTI-CHOLINERGIC**

Substance : Ipratropium bromide

Indication : Inhalant Bronchodilator (atropine derivative anti-cholinergic)

Route of Administration : Respirator Solution

***SELECTIVE B2 AGONISTS**

Substance : Salbutamol

Indication : Bronchodilator

Route of Administration : Aerosol

ANNEXURE 1D: AMBULANCE EMERGENCY ASSISTANT**AMBULANCE EMERGENCY ASSISTANT** registered with Health Professions Council of South Africa**AMBULANCE EMERGENCY ASSISTANT** registered with Health Professions Council of South Africa**ANTI-CHOLINERGIC**

Substance : Ipratropium bromide

Indication : Inhalant Bronchodilator (atropine derivative anti-cholinergic)

Route of Administration : Respirator Solution

SELECTIVE B2 AGONISTS

Substance : Salbutamol

Indication : Bronchodilator

Route of Administration : Aerosol

Schedule 2

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

<u>EMERGENCY CARE TECHNICIAN</u> registered with Health Professions Council of South Africa	
<u>ANTI-CHOLINERGIC</u>	
Substance	Ipratropium bromide
Indication	Inhalant Bronchodilator (atropine derivative anti-cholinergic)
Route of Administration	Respirator Solution
<u>SELECTIVE β_2 AGONISTS</u>	
Substance	Salbutamol
Indication	Bronchodilator
Route of Administration	Aerosol

ANNEXURE 1F: EMERGENCY CARE ASSISTANT**EMERGENCY CARE ASSISTANT** registered with Health Professions Council of South Africa

<u>EMERGENCY CARE ASSISTANT</u> registered with Health Professions Council of South Africa	
<u>ANTI-CHOLINERGIC</u>	
Substance	Ipratropium bromide
Indication	Inhalant Bronchodilator (atropine derivative anti-cholinergic)
Route of Administration	Respirator Solution
<u>SELECTIVE β_2 AGONISTS</u>	
Substance	Salbutamol
Indication	Bronchodilator
Route of Administration	Aerosol

ANNEXURE 4: PODIATRIST

PODIATRIST [(B.Tech degree in Podiatry)] registered with the Health Professions Council of South Africa in terms of the Health Professions Act, 1974 (Act 56 of 1974)

– END SCHEDULE 2 –

Schedule 3

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

Benzydamine, except preparations and mixtures-

- a. containing 3 percent or less of benzydamine, when intended for application to the skin; ~~(S0)~~ [(S1)]
- b. ~~[containing 0,15 percent or less of benzydamine, when]~~ intended for use as a mouth rinse or for topical application in the mouth and throat; provided that the total dose swallowed does not exceed 36 milligrams of benzydamine per day; (S1)

Schedule 3

- c. 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)"
- d. intended for human vaginal use. (S2)

Clonidine except when intended for the ~~[treatment]~~ prevention of migraine. (S2)

Dexketoprofen trometamol.

(-)-6 epigallocatechin gallate

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. ~~[(S1)]~~ (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)

Nicardipine.

Umeclidinium.

ANNEXURE 1A: EMERGENCY CARE PROVIDER (PARAMEDIC)

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

<u>PARAMEDIC (National Diploma in Emergency Medical Care graduates <i>only</i>)</u>	
<u>ANALGESIC</u>	
Substance	: Paracetamol
Indication	: Analgesic/ Anti-pyrexia
Route of Administration	: Parenteral
<u>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</u>	
Substance	: Ringers Lactate
Indication	: Plasma expanders
Route of Administration	: Parenteral
<u>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</u>	
Substance	: Polygeline
Indication	: Plasma expanders
Route of Administration	: Parenteral
<u>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</u>	
Substance	: Balanced Salt Solution
Indication	: Plasma expanders
Route of Administration	: Parenteral
<u>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</u>	
Substance	: Sodium Bicarbonate 8.5 %
Indication	: Metabolic acidosis
Route of Administration	: Parenteral

Schedule 3

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

<u>EMERGENCY CARE PRACTITIONER(B Tech: Emergency Medical Care)</u>	
<u>ANALGESIC</u>	
Substance	: Paracetamol
Indication	: Analgesic/ Anti-pyrexia
Route of Administration	: Parenteral
<u>*ANTI-SPASMODIC</u>	
Substance	: Hyoscine butylbromide
Indication	: Anti-spasmodic
Route of Administration	: Parenteral
<u>**ARTERIAL SMOOTH MUSCLE AGENT</u>	
Substance	: Hydralazine
Indication	: Hypertension in pregnancy
Route of Administration	: Oral
<u>BETA BLOCKER</u>	
Substance	: Labetalol
Indication	: Hypertension in pregnancy
Route of Administration	: Parenteral
<u>*CALCIUM CHANNEL BLOCKER</u>	
Substance	: Nifedipine
Indication	: Hypertension in pregnancy
Route of Administration	: Parenteral
<u>**CLASS III ANTI-ARRHYTHMIC</u>	
Substance	: Sotalol
Indication	: Anti-arrhythmic
Route of Administration	: Oral/ Parenteral
<u>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</u>	
Substance	: Ringers Lactate
Indication	: Plasma expanders
Route of Administration	: Parenteral
<u>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</u>	
Substance	: Polygeline
Indication	: Plasma expanders
Route of Administration	: Parenteral

Schedule 3

EMERGENCY CARE PRACTITIONER(B Tech: Emergency Medical Care)	
PLASMA SUBSTITUTES AND COLLOID SOLUTIONS	
Substance	Balanced Salt Solution
Indication	Plasma expanders
Route of Administration	Parenteral
PLASMA SUBSTITUTES AND COLLOID SOLUTIONS	
Substance	Sodium Bicarbonate 8,5 %
Indication	Metabolic acidosis
Route of Administration	Parenteral
**VASODILATOR	
Substance	Isosorbide dinitrate
Indication	Acute pulmonary syndrome/ Acute pulmonary oedema
Route of Administration	Parenteral

ANNEXURE 1C: BASIC AMBULANCE ASSISTANT**BASIC AMBULANCE ASSISTANT** registered with Health Professions Council of South Africa

<u>BASIC AMBULANCE ASSISTANT</u> registered with Health Professions Council of South Africa	
*SELECTIVE B2 AGONISTS	
Substance	Salbutamol
Indication:	Bronchodilator
Route of Administration	Inhalant

ANNEXURE 1D: AMBULANCE EMERGENCY ASSISTANT**AMBULANCE EMERGENCY ASSISTANT** registered with Health Professions Council of South Africa

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

Schedule 3

<u>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</u>	
<u>Substance</u>	<u>Hydroxyethyl Starch</u>
<u>Indication</u>	<u>Plasma expanders</u>
<u>Route of Administration</u>	<u>Parenteral</u>
<u>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</u>	
<u>Substance</u>	<u>Sodium chloride</u>
<u>Indication</u>	<u>Plasma expanders</u>
<u>Route of Administration</u>	<u>Parenteral</u>
<u>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</u>	
<u>Substance</u>	<u>Ringers Lactate</u>
<u>Indication</u>	<u>Plasma expanders</u>
<u>Route of Administration</u>	<u>Parenteral</u>
<u>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</u>	
<u>Substance</u>	<u>Polygeline</u>
<u>Indication</u>	<u>Plasma expanders</u>
<u>Route of Administration</u>	<u>Parenteral</u>
<u>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</u>	
<u>Substance</u>	<u>Balanced Salt Solution</u>
<u>Indication</u>	<u>Plasma expanders</u>
<u>Route of Administration</u>	<u>Parenteral</u>
<u>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</u>	
<u>Substance</u>	<u>Sodium Bicarbonate 8,5 %</u>
<u>Indication</u>	<u>Metabolic acidosis</u>
<u>Route of Administration</u>	<u>Parenteral</u>
<u>*CARBOHYDRATES</u>	
<u>Substance</u>	<u>Dextrose</u>
<u>Indication</u>	<u>Nutrition / Acute Symptomatic Hypoglycaemic Treatment in adults and paediatrics</u>
<u>Route of Administration</u>	<u>Parenteral</u>
<u>*CO-ENZYME</u>	
<u>Substance</u>	<u>Thiamine (Vitamin B1)</u>
<u>Indication</u>	<u>Nutritional supplement/ Vitamin B (Emergency treatment of Wernicke's encephalopathy and Beriberi)</u>
<u>Route of Administration</u>	<u>Parenteral</u>
<u>*OTHER MINERAL SUPPLEMENTS</u>	
<u>Substance</u>	<u>Magnesium sulphate</u>
<u>Indication</u>	<u>Mineral supplement; prevention and control of seizures and hypertension in toxemia of pregnancy</u>
<u>Route of Administration</u>	<u>Parenteral</u>

Schedule 3

SELECTIVE β_2 AGONISTS

Substance : Salbutamol
 Indication : Bronchodilator
 Route of Administration : Inhalant

ANNEXURE 1E: EMERGENCY CARE TECHNICIAN**EMERGENCY CARE TECHNICIAN registered with Health Professions Council of South Africa****EMERGENCY CARE TECHNICIAN registered with Health Professions Council of South Africa****PLASMA SUBSTITUTES AND COLLOID SOLUTIONS**

Substance : Dextran
 Indication : Plasma expanders
 Route of Administration : Parenteral

PLASMA SUBSTITUTES AND COLLOID SOLUTIONS

Substance : Hydroxyethyl Starch
 Indication : Plasma expanders
 Route of Administration : Parenteral

PLASMA SUBSTITUTES AND COLLOID SOLUTIONS

Substance : Sodium chloride
 Indication : Plasma expanders
 Route of Administration : Parenteral

PLASMA SUBSTITUTES AND COLLOID SOLUTIONS

Substance : Ringers Lactate
 Indication : Plasma expanders
 Route of Administration : Parenteral

PLASMA SUBSTITUTES AND COLLOID SOLUTIONS

Substance : Polygeline
 Indication : Plasma expanders
 Route of Administration : Parenteral

Schedule 3

<u>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</u>	
Substance	Balanced Salt Solution
Indication	Plasma expanders
Route of Administration	Parenteral
<u>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</u>	
Substance	Sodium Bicarbonate 8.5 %
Indication	Metabolic acidosis
Route of Administration	Parenteral
<u>CARBOHYDRATES</u>	
Substance	Dextrose
Indication	Nutrition / Acute Symptomatic Hypoglycaemic Treatment in adults and paediatrics
Route of Administration	Parenteral
<u>*CO-ENZYME</u>	
Substance	Thiamine (Vitamin B1)
Indication	Nutritional supplement/ Vitamin B (Emergency treatment of Wernicke's encephalopathy and Beriberi)
Route of Administration	Parenteral
<u>OTHER MINERAL SUPPLEMENTS</u>	
Substance	Magnesium sulphate
Indication	Mineral supplement: prevention and control of seizures and hypertension in toxæmia of pregnancy. Ventricular anti-arrhythmic
Route of Administration	Parenteral
<u>ORGANIC NITRATES</u>	
Substance	Glyceryl trinitrate
Indication	Vasodilator
Route of Administration	Oral
<u>SELECTIVE B2 AGONISTS</u>	
Substance	Salbutamol
Indication	Bronchodilator
Route of Administration	Inhalant

ANNEXURE 1F: EMERGENCY CARE ASSISTANT**EMERGENCY CARE ASSISTANT registered with Health Professions Council of South Africa**

<u>EMERGENCY CARE ASSISTANT registered with Health Professions Council of South Africa</u>	
<u>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</u>	
<u>Substance</u>	<u>Dextran</u>
<u>Indication</u>	<u>Plasma expanders</u>
<u>Route of Administration</u>	<u>Parenteral</u>
<u>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</u>	
<u>Substance</u>	<u>Hydroxyethyl Starch</u>
<u>Indication</u>	<u>Plasma expanders</u>
<u>Route of Administration</u>	<u>Parenteral</u>
<u>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</u>	
<u>Substance</u>	<u>Sodium chloride</u>
<u>Indication</u>	<u>Plasma expanders</u>
<u>Route of Administration</u>	<u>Parenteral</u>
<u>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</u>	
<u>Substance</u>	<u>Ringers Lactate</u>
<u>Indication</u>	<u>Plasma expanders</u>
<u>Route of Administration</u>	<u>Parenteral</u>
<u>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</u>	
<u>Substance</u>	<u>Polygeline</u>
<u>Indication</u>	<u>Plasma expanders</u>
<u>Route of Administration</u>	<u>Parenteral</u>
<u>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</u>	
<u>Substance</u>	<u>Balanced Salt Solution</u>
<u>Indication</u>	<u>Plasma expanders</u>
<u>Route of Administration</u>	<u>Parenteral</u>
<u>PLASMA SUBSTITUTES AND COLLOID SOLUTIONS</u>	
<u>Substance</u>	<u>Sodium Bicarbonate 8.5 %</u>
<u>Indication</u>	<u>Metabolic acidosis</u>
<u>Route of Administration</u>	<u>Parenteral</u>

Schedule 3

<u>CARBOHYDRATES</u>	
<u>Substance</u>	<u>Dextrose</u>
<u>Indication</u>	<u>Nutrition / Acute Symptomatic Hypoglycaemic Treatment in adults and paediatrics</u>
<u>Route of Administration</u>	<u>Parenteral</u>
<u>*CO-ENZYME</u>	
<u>Substance</u>	<u>Thiamine (Vitamin B1)</u>
<u>Indication</u>	<u>Nutritional supplement/ Vitamin B (Emergency treatment of Wernicke's encephalopathy and Beriberi).</u>
<u>Route of Administration</u>	<u>Parenteral</u>
<u>OTHER MINERAL SUPPLEMENTS</u>	
<u>Substance</u>	<u>Magnesium sulphate</u>
<u>Indication</u>	<u>Mineral supplement, prevention and control of seizures and hypertension in toxemia of pregnancy</u>
<u>Route of Administration</u>	<u>Parenteral</u>
<u>SELECTIVE β_2 AGONISTS</u>	
<u>Substance</u>	<u>Salbutamol</u>
<u>Indication:</u>	<u>Bronchodilator</u>
<u>Route of Administration</u>	<u>Inhalant</u>

ANNEXURE 4: PODIATRIST

PODIATRIST [(B.Tech degree in Podiatry)] registered with the Health Professions Council of South Africa in terms of the Health Professions Act, 1974 (Act 56 of 1974)

– END SCHEDULE 3 –

Schedule 4

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.
- 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);
<u>Annexure 1C:</u>	<u>Basic Ambulance Assistant</u>
<u>Annexure 1D:</u>	<u>Ambulance Emergency Assistant</u>
<u>Annexure 1E:</u>	<u>Emergency Care Technician</u>
<u>Annexure 1F:</u>	<u>Emergency Care Assistant</u>
 - (ii) Annexure 2: Dental Therapist;
 - (iii) Annexure 3: Optometrist.
 - (iv) Annexure 4: Podiatrist

Abemaciclib.Acalabrutinib.Arsenic:

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

Schedule 4

Atezolizumab.

Baloxavir.

Baricitinib.

Benralizumab.

Besifloxacin.

Brolucizumab.

Carglumic.

Crisaborole.

Crisanlizumab.

Dimethyl fumarate.

Doxycycline, except

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

Doravirine.

Durvalumab.

Erenumab.

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. **[(S1)] (S0)**
- d. except when intended for the treatment of post-traumatic conditions, for a maximum period of 5 days; (S2)

Schedule 4

Follitropin delta.Frovatriptan.Galcanezumab.Human normal immunoglobulin.Lenvatinib.Lokivetmab.Ranolazine.Saroglitazar magnesium.Semaglutide.Simociclogo alfa.Siponimod.**ANNEXURE 1A: EMERGENCY CARE PROVIDER (PARAMEDIC)**

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

<u>PARAMEDIC (National Diploma in Emergency Medical Care graduates)</u>	
<u>*ANTI-FIBRINOLYTIC</u>	
<u>Substance</u>	: <u>Tranexamic acid</u>
<u>Indication</u>	: <u>Major haemorrhage in trauma</u>
<u>Route of Administration</u>	: <u>Parenteral</u>
<u>**OXYTOCIN</u>	
<u>Substance</u>	: <u>Oxytocin</u>
<u>Indication</u>	: <u>Post-partum haemorrhage</u>
<u>Route of Administration</u>	: <u>Parenteral</u>
<u>CORTICOSTEROID</u>	
<u>Substance</u>	: <u>Prednisolone</u>
<u>Indication</u>	: <u>Glucocorticoid/ Steroidal anti-inflammatory</u>
<u>Route of Administration</u>	: <u>Parenteral</u>
<u>LOCAL ANAESTHETIC</u>	
<u>Substance</u>	: <u>Lignocaine hydrochloride</u>
<u>Indication</u>	: <u>Local anaesthesia</u>
<u>Route of Administration</u>	: <u>Parenteral</u>

Schedule 4

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

<u>EMERGENCY CARE PRACTITIONER (B Tech: Emergency Medical Care)</u>	
<u>**CORTICOSTEROID</u>	
Substance	: Betamethasone
Indication	: Pre-term birth
Route of Administration	: Parenteral
<u>**CORTICOSTEROID</u>	
Substance	: Dexamethasone
Indication	: Pre-term birth
Route of Administration	: Parenteral
<u>**DIRECT THROMBIN INHIBITOR</u>	
Substance	: Bivalirudin
Indication	: Adjunct in percutaneous coronary angioplasty
Route of Administration	: Parenteral
<u>**DOPAMINERGIC</u>	
Substance	: Dopamine
Indication	: Haemodynamic support
Route of Administration	: Parenteral
<u>**ADRENERGIC</u>	
Substance	: Dobutamine
Indication	: Haemodynamic support
Route of Administration	: Parenteral
<u>*ANTICHOLINESTERASE</u>	
Substance	: Neostigmine
Indication	: Reversal of neuromuscular blockade
Route of Administration	: Parenteral
<u>*CHOLINESTERASE INHIBITOR</u>	
Substance	: Sugammadex
Indication	: Reversal of neuromuscular blockade
Route of Administration	: Parenteral
<u>*SEROTONIN ANTAGONIST</u>	
Substance	: Ondansetron
Indication	: Post-operative nausea and vomiting
Route of Administration	: Parenteral

Schedule 4

EMERGENCY CARE PRACTITIONER (B Tech: Emergency Medical Care)	
*ANTI-FIBRINOLYTIC	
Substance	: Tranexamic acid
Indication	: Major haemorrhage in trauma
Route of Administration	: Parenteral
OXYTOCIN	
Substance	: Oxytocin
Indication	: Post-partum haemorrhage
Route of Administration	: Parenteral
CORTICOSTEROID	
Substance	: Prednisolone
Indication	: Glucocorticoid/ Steroidal anti-inflammatory
Route of Administration	: Parenteral
LOCAL ANAESTHETIC	
Substance	: Lignocaine hydrochloride
Indication	: Local anaesthesia
Route of Administration	: Parenteral

ANNEXURE 1C: BASIC AMBULANCE ASSISTANT**BASIC AMBULANCE ASSISTANT** registered with Health Professions Council of South Africa

<u>BASIC AMBULANCE ASSISTANT</u> registered with Health Professions Council of South Africa	
*SELECTIVE β_2 AGONISTS	
Substance	: Fenoterol
Indication	: Bronchodilator
Route of Administration	: Parenteral

Schedule 4

ANNEXURE 1D: AMBULANCE EMERGENCY ASSISTANT**AMBULANCE EMERGENCY ASSISTANT registered with Health Professions Council of South Africa**

<u>AMBULANCE EMERGENCY ASSISTANT registered with Health Professions Council of South Africa</u>	
<u>*ADRENERGIC</u>	
Substance	: Adrenaline / Epinephrine
Indication	: Sympathomimetic catecholamine
Route of Administration	: Parenteral
<u>*CORTICOSTEROIDS</u>	
Substance	: Methylprednisolone
Indication	: Glucocorticoid / Steroidal Anti-Inflammatory
Route of Administration	: Oral
<u>*CORTICOSTEROIDS</u>	
Substance	: Hydrocortisone
Indication	: Glucocorticoid / Steroidal Anti-Inflammatory
Route of Administration	: Parenteral
<u>*HYPERGLYCAEMIC AGENT</u>	
Substance	: Glucagon
Indication	: Hyperglycaemic agent
Route of Administration	: Parenteral
<u>*OPIOID ANTAGONIST</u>	
Substance	: Naloxone hydrochloride
Indication	: Opioid Antagonist / Narcotic Antagonist
Route of Administration	: Parenteral
<u>OPIOID ANTAGONIST</u>	
Substance	: Nitrous oxide
Indication	: Analgesic Gas
Route of Administration	: Inhalant (50:50 combination with Medical Oxygen)
<u>SELECTIVE B2 AGONISTS</u>	
Substance	: Fenoterol
Indication	: Bronchodilator
Route of Administration	: Parenteral
<u>LOCAL ANAESTHETIC</u>	
Substance	: Lignocaine hydrochloride
Indication	: Local anaesthesia
Route of Administration	: Parenteral

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

EMERGENCY CARE TECHNICIAN registered with Health Professions Council of South Africa	
ADRENERGIC	
Substance	Adrenaline / Epinephrine
Indication	Sympathomimetic catecholamine
Route of Administration	Parenteral
CORTICOSTEROIDS	
Substance	Methylprednisolone
Indication	Glucocorticoid / Steroidal Anti-Inflammatory
Route of Administration	Oral
CORTICOSTEROIDS	
Substance	Hydrocortisone
Indication	Glucocorticoid / Steroidal Anti-Inflammatory
Route of Administration	Parenteral
HYPERGLYCAEMIC AGENT	
Substance	Glucagon
Indication	Hyperglycaemic agent
Route of Administration	Parenteral
ANTI-ARRHYTHMICS	
Substance	Amiodarone
Indication	Class III Anti-arrhythmic / Atrial & Ventricular
Route of Administration	Parenteral
*ANTI-EMETIC	
Substance	Metoclopramide monohydrochloride
Indication	Propulsive Anti-emetic / Dopamine Antagonist
Route of Administration	Parenteral
SELECTIVE B2 AGONISTS	
Substance	Salbutamol
Indication:	Bronchodilator
Route of Administration	Parenteral
SELECTIVE B2 AGONISTS	
Substance	Fenoterol
Indication	Bronchodilator
Route of Administration	Parenteral

Schedule 4

<u>ANTI-CHOLINERGIC</u>	
<u>Substance</u>	: Atropine
<u>Indication</u>	: Competitive Anti-Cholinergic, Bradycardia, Anti-arrhythmic
<u>Route of Administration</u>	: Parenteral
<u>OPIOID ANTAGONIST</u>	
<u>Substance</u>	: Naloxone hydrochloride
<u>Indication</u>	: Opioid Antagonist / Narcotic Antagonist
<u>Route of Administration</u>	: Parenteral
<u>OPIOID ANTAGONIST</u>	
<u>Substance</u>	: Nitrous oxide
<u>Indication</u>	: Analgesic Gas
<u>Route of Administration</u>	: Inhalant (50:50 combination with Medical Oxygen)
<u>**OXYTOCIN</u>	
<u>Substance</u>	: Oxytocin
<u>Indication</u>	: Post-partum haemorrhage
<u>Route of Administration</u>	: Parenteral
<u>CORTICOSTEROID</u>	
<u>Substance</u>	: Prednisolone
<u>Indication</u>	: Glucocorticoid/ Steroidal anti-inflammatory
<u>Route of Administration</u>	: Parenteral
<u>LOCAL ANAESTHETIC</u>	
<u>Substance</u>	: Lignocaine hydrochloride
<u>Indication</u>	: Local anaesthesia
<u>Route of Administration</u>	: Parenteral

ANNEXURE 1F: EMERGENCY CARE ASSISTANT**EMERGENCY CARE ASSISTANT registered with Health Professions Council of South Africa**

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

Schedule 4

<u>CORTICOSTEROIDS</u>	
Substance	Methylprednisolone
Indication	Glucocorticoid / Steroidal Anti-Inflammatory
Route of Administration	Oral
<u>CORTICOSTEROIDS</u>	
Substance	Hydrocortisone
Indication	Glucocorticoid / Steroidal Anti-Inflammatory
Route of Administration	Parenteral
<u>HYPERGLYCAEMIC AGENT</u>	
Substance	Glucagon
Indication	Hyperglycaemic agent
Route of Administration	Parenteral
<u>ANTI-CHOLINERGIC</u>	
Substance	Atropine
Indication	Competitive Anti-Cholinergic, Bradycardia, Anti-arrhythmic
Route of Administration	Parenteral
<u>OPIOID ANTAGONIST</u>	
Substance	Naloxone hydrochloride
Indication	Opioid Antagonist / Narcotic Antagonist
Route of Administration	Parenteral
<u>OPIOID ANTAGONIST</u>	
Substance	Nitrous oxide
Indication	Analgesic Gas
Route of Administration	Inhalant (50:50 combination with Medical Oxygen)
<u>SELECTIVE B2 AGONISTS</u>	
Substance	Fenoterol
Indication	Bronchodilator
Route of Administration	Parenteral

ANNEXURE 4: PODIATRIST

PODIATRIST [(B.Tech degree in Podiatry)] registered with the Health Professions Council of South Africa in terms of the Health Professions Act, 1974 (Act 56 of 1974)

– END SCHEDULE 4 –

Schedule 5

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 **

Armodafanil.

Recombinant human epidermal growth factor (rhEGF).

Schedule 5

ANNEXURE 1A: EMERGENCY CARE PROVIDER (PARAMEDIC)

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

PARAMEDIC (National Diploma in Emergency Medical Care graduates)	
*INDUCTION AGENTS	
Substance	: Ketamine
Indication	: Analgesia
Route of Administration	: Parenteral

ANNEXURE 1E: EMERGENCY CARE TECHNICIAN

EMERGENCY CARE TECHNICIAN registered with Health Professions Council of South Africa

EMERGENCY CARE TECHNICIAN registered with Health Professions Council of South Africa	
BENZODIAZEPINE DERIVATIVE	
Substance	: Diazepam
Indication	: Anti-convulsant/Sedative/Hypnotic
Route of Administration	: Parenteral
*BENZODIAZEPINE DERIVATIVE	
Substance	: Midazolam
Indication	: Antic-convulsant/Sedative/Hypnotic
Route of Administration	: Parenteral
*BENZODIAZEPINE DERIVATIVE	
Substance	: Lorazepam
Indication	: Anti-convulsant/Sedative/Hypnotic
Route of Administration	: Parenteral
BENZODIAZEPINE ANTAGONIST	
Substance	: Flumazenil
Indication	: Benzodiazepine Antagonist
Route of Administration	: Parenteral
NON-SELECTIVE ANTIHISTAMINE	
Substance	: Promethazine
Indication	: Antihistamine
Route of Administration	: Parenteral

Schedule 5

EMERGENCY CARE ASSISTANT registered with Health Professions Council of South Africa	
BENZODIAZEPINE DERIVATIVE	
Substance	Diazepam
Indication	Anti-convulsant/Sedative/Hypnotic
Route of Administration	Parenteral
*BENZODIAZEPINE DERIVATIVE	
Substance	Midazolam
Indication	Antic-convulsant/Sedative/Hypnotic
Route of Administration	Parenteral
*BENZODIAZEPINE DERIVATIVE	
Substance	Lorazepam
Indication	Anti-convulsant/Sedative/Hypnotic
Route of Administration	Parenteral
BENZODIAZEPINE ANTAGONIST	
Substance	Flumazenil
Indication	Benzodiazepine Antagonist
Route of Administration	Parenteral

– END SCHEDULE 5 –

Schedule 6

SCHEDULE 6

- a. All preparations or mixtures of such substances containing or purporting to contain substances that is chemically related and incorporates a structural fragment into its structure that is similar to the structure of a listed substance and /or exhibits pharmacodynamic properties similar to the listed substance referred to in this Schedule include the following (unless expressly excluded or unless listed in another Schedule):
- (i) the isomers of such substances, where the existence of such isomers is possible within the chemical designation;
 - (ii) the esters and ethers of such substances and of the isomers referred to in (i) as well as the isomers of such esters and ethers, where the existence of isomers of such esters or ethers is possible;
 - (iii) the salts of such substances and of the isomers referred to in (i), as well as the salts of the esters, ethers and isomers referred to in (ii), where the existence of such salts is possible;
 - (iv) the isomers of any of the salts referred to in (iii), where the existence of such isomers is possible;
 - (v) all preparations and mixtures of any of the above.
 - (vi) all homologues of listed substances (being any chemically related substances that incorporate a structural fragment into their structures that is similar to the structure of a listed substance and/or exhibit pharmacodynamic properties similar to the listed substance in the schedules), unless listed separately in the Schedules.
- b. In terms of Section 22A(5)(f) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, may prescribe and supply, only within his/her scope of practice and subject to the indication for use of such substances and medicines and to the conditions determined by the Authority, to patients under his/her care, the Schedule 6 substances and medicines provided for in the Annexures to this Schedule published in the *Gazette* in terms of the Act.
- (i) Annexure 1A: Emergency Care Provider (Paramedic);
Annexure 1B: Emergency Care Provider (Emergency Care Practitioner).
Annexure 1E: Emergency Care Technician

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

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

PARAMEDIC (National Diploma in Emergency Medical Care graduates)	
**ANALGESIC	
Substance	Fentanyl
Indication	Opioid/ Narcotic
Route of Administration	Parenteral

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

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

EMERGENCY CARE PRACTITIONER (Bachelor of Technology Degree in Emergency Medical Care) registered with the Health Professions Council of South Africa	
ANALGESIC	
Substance	Fentanyl
Indication	Opioid/ Narcotic/ Induction of Anaesthesia
Route of Administration	Parenteral

ANNEXURE 1E: EMERGENCY CARE TECHNICIAN

EMERGENCY CARE TECHNICIAN registered with Health Professions Council of South Africa

EMERGENCY CARE TECHNICIAN registered with Health Professions Council of South Africa	
*ANALGESICS	
Substance	Morphine sulphate
Indication	Opioid/Narcotic
Route of Administration	Parenteral

Schedule 7

SCHEDULE 7

All preparations or mixture of such substances containing or purporting to contain substances referred to in this Schedule include the following (unless expressly excluded or unless listed in another Schedule):

- (i) the isomers of such substances, where the existence of such isomers is possible within the chemical designation;
- (ii) the esters and ethers of such substances and of the isomers referred to in (i), as well as the isomers of such esters and ethers, where the existence of isomers of such esters, or ethers is possible;
- (iii) the salts of such substances and of the isomers referred to in (i), as well as the salts of the esters, ethers and isomers referred to in (ii), where the existence of such salts is possible;
- (iv) the isomers of any of the salts referred to in (iii), where the existence of such isomers is possible;
- (v) all preparations and mixtures of any of the above.
- (vi) all homologues of listed substances (being any chemically related substances that incorporate a structural fragment into their structures that is similar to the structure of a listed substance and/or exhibit pharmacodynamic properties similar to the listed substance in the schedules), unless listed separately in the Schedules.

Dexamfetamine (Dexamphetamine) except in medicines registered in terms of the Act and intended for the treatment of Attention-Deficit Hyperactivity Disorder (S6) [and its salts; preparations thereof. (S8)]

– END SCHEDULE 7 –

Schedule 8


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.

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

These Schedules as amended come into operation on the date of publication in the Government Gazette.



DR ZWELINI LAWRENCE MKHIZE, MP

MINISTER OF HEALTH

DATE: 23/11/2020