

DEPARTMENT OF HEALTH

NO. R. 3261

24 March 2023

**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.509 (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, Government Notice No. R586 (Medicines and Related Substances Act, 1965: Schedules) in Government Gazette 43347, 22 May 2020, Government Notice No. R1375 (Medicines and Related Substances Act 1965: Schedules) in Government Gazette 44019, 18 December 2020, Government Notice No. 893 (Medicines and Related Substances Act 1965: Schedules) in Government Gazette 45176, 17 September 2021 and Government Notice No. 2685 (Medicines and Related Substances Act 1965: Schedules) in Government Gazette 47373, 28 October 2022 using the following convention:

- 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.
- (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

Cetirizine

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).

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)

Levocetirizine

ANNEXURE 3: OPTOMETRIST

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

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

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

ANALGESIC	
Substance	: Paracetamol
Indication	: Mild Pain
Route of Administration	: Oral

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

ANNEXURE 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)

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

- END SCHEDULE 1 -

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

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).

[Cetirizine]

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)

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)

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)

[Levocetirizine]

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)

- END SCHEDULE 2 -

SCHEDULE 3

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

Carbimazole

Clevidipine

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)

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

Schedule 3

- 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).

Insulin Lispro

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)

Trifarotene

– END SCHEDULE 3 –

SCHEDULE 4

- a. All substances referred to in this Schedule are excluded when specifically packed, labelled, sold and used for –
- (i) industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose; and
 - (ii) analytical laboratory purposes.
- b. All preparations of substances or mixtures of such substances containing or purporting to contain any substance referred to in this Schedule and includes the following:
- (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);
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

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).

AmivantamabEptinezumab

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)

GlofitamabHuman C1-esterase inhibitorHuman von Willebrand FactorIbuprofen

- 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).

Icosapent ethyl

Latanoprostene

Mosunetuzumab

NirmatrelvirPonesimodRifapentineTremelimumabVasopressinVericiguatANNEXURE 5: ORAL HYGIENISTSOral hygienists registered with the Health Professions Council of South Africa (HPCSA)In terms of the Health Professions Act, 1974 (Act 56 of 1974)

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

ORAL HYGIENISTS**Substance** : Prilocaine with or without Adrenaline**Indication** : Dental surface anaesthesia (local anaesthetic)**Route of administration** : Local injection**- END SCHEDULE 4 -**

SCHEDULE 5 AND SPECIFIED SCHEDULE 5

- a. All preparations or mixtures of such substances containing or purporting to contain substances that is chemically related and incorporates a structural fragment into its structure that is similar to the structure of a listed substance and /or exhibits pharmacodynamic properties similar to the listed substance referred to in this Schedule include the following:
- (i) The salts and esters of such substances, where the existence of such salts and esters is possible; and
 - (ii) all preparations and mixtures of such substances where such preparations and mixtures are not expressly excluded.
 - (iii) all homologues of listed substances (being any chemically related substances that incorporate a structural fragment into their structures that is similar to the structure of a listed substance and/or exhibit pharmacodynamic properties similar to the listed substance in the schedules), unless listed separately in the Schedules.
- b. In terms of Section 22A(5)(f) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, may prescribe and apply, only within his/her scope of practice and subject to the indication for use of such substances and medicines and to the conditions determined by the 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 **

- END SCHEDULE 5 -

SCHEDULE 6

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

under his/her care, the Schedule 6 substances and medicines provided for in the Annexures to this Schedule published in the Gazette in terms of the Act.

- (i) Annexure 1A: Emergency Care Provider (Paramedic);
- (ii) Annexure 1B: Emergency Care Provider (Emergency Care Practitioner).

– END SCHEDULE 6 –

SCHEDULE 7

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

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

– END SCHEDULE 7 –

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



DR MJ PHAAHLA, MP
MINISTER OF HEALTH

DATE: 17/02/2023