DEPARTMENT OF HEALTH

NO. 6466 **1 August 2025**

MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT No. 101 OF 1965)

SCHEDULES

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

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 Act1 1965: Schedules) in Government Gazette 44019, 18 December 2020, Government Notice No. 883 (Medicines and Related Substances Act1 1965: Schedules) in Government Gazette 45176, 17 September 2021 and Government Notice No. 2685 (Medicines and Related Substances Act1 1965: Schedules) in Government Gazette 47373, 28 October 2022, Government Notice No. R3261 (Medicines and Related Substances Act1 1965: Schedules) in Government Gazette 48358, 24 March 2023 and Government Notice No.5181 (Medicines and Related Substances Act1 1965: Schedules) in Government Gazette 51171 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

Iron,

a. in oral preparations or mixtures containing more than 24 mg of elemental iron per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)

b. except in preparations thereof for injection; (S3)

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

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 an 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 or less; **[(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)

ANNEXURE 2: DENTAL THERAPIST

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

DENTAL THERAPIST (Bachelors degree in Dental Therapy)		
ANALGESIC, ANTIPYRETIC, ANTI INFLAMMATORY		
Substance	:	Paracetamol
Indication	:	Dental pain
Route of Administration	:	Oral
SURFACE ANAESTHETIC		
Substance	:	Lidocaine / Lignocaine hydrochloride
Indication	:	Dental surface anaesthesia
Route of Administration	:	Topical/Jelly/Pump Spray
ANTI-VIRAL		
Substance	:	Acyclovir
Indication	:	Viral infection of lips
Route of Administration	:	Topical
ANTI-FUNGAL		
Substance	:	Ketoconazole
Indication	:	Treatment of fungal infections
Route of Administration	:	Cream/Gel
VITAMINS AND MINERALS		
Substance	:	-
Indication	:	Applicable to Dentistry
Route of Administration	:	Oral

– 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

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

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

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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 21mg/ 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)

[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 millilitre dosage unit in the case of oral liquid preparations and mixtures. (S6)]

ANNEXURE 2: DENTAL THERAPIST

DENTAL THERAPIST (Bachelor's degree in Dental Therapy) registered with Health Professions Council of South Africa

DENTAL THERAPIST (Bachelors degree in Dental Therapy)		
ANALGESIC, ANTIPYRETIC, ANTI INFLAMMATORY		
Substance	:	Ibuprofen
Indication	:	Dental pain
Route of Administration	:	Oral
Substance	:	Diclofenac
Indication	:	Dental pain
Route of Administration	:	Oral
Substance	:	Indometacin
Indication	:	Dental pain
Route of Administration	:	Oral
ANALGESIC, ANTIPYRETIC, ANTI INFLAMMATORY		
Substance	:	Codeine
Indication	:	Dental pain
Route of Administration	:	Oral
ANTI-FUNGALS		
Substance	:	Nystatin
Indication:	:	Candidal infections of the oral cavity
Route of Administration	:	Oral
Substance	:	Miconazole
Indication:	:	Treatment of fungal infections
Route of Administration	:	Oral

– END SCHEDULE 2 –

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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

Iron,

a. in preparations thereof for injection; (S0)

b. except in oral preparations or mixtures containing more than 24 mg of elemental iron per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S1)

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

Nicotine,

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

– END SCHEDULE 3 –

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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

Albutrepenonacog alfa.

Chlormethine.

Deferiprone.

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

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

Frunevetmab.

Isoflupredone.

Lurasidone.

Metamizole (dipyrone).

Niraparib.

Nonacog beta pegol.

Olipudase alfa.

Ravulizumab.

Respiratory syncytial virus antigen (recombinant).

Somapacitan.

Talazoparib.

Trastuzumab deruxtecan.

Varicella Zoster Virus glycoprotein E antigen.

Zanubrutinib.

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ANNEXURE 2: DENTAL THERAPIST

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

DENTAL THERAPIST (Bachelors degree in Dental Therapy)		
LOCAL ANAESTHETIC		
Substance	:	Lignocaine / Lidocaine hydrochloride 2 percent with Vasoconstrictor (Adrenaline)
Indication	:	Dental local anaesthesia
Route of Administration	:	Parenteral
LOCAL ANAESTHETIC		
Substance	:	Lignocaine / Lidocaine hydrochloride 3 percent without a Vasoconstrictor (Adrenaline)
Indication	:	Dental local anaesthesia
Route of Administration	:	Parenteral
LOCAL ANAESTHETIC		
Substance	:	Mepivacaine hydrochloride 2 percent with a Vasoconstrictor (Adrenaline)
Indication	:	Dental local anaesthesia
Route of Administration	:	Parenteral
LOCAL ANAESTHETIC		
Substance	:	Mepivacaine hydrochloride 3 percent without a Vasoconstrictor (Adrenaline)
Indication	:	Dental local anaesthesia
Route of Administration	:	Parenteral
ANTI-MICROBIALS (Beta-Lactams)		
Substance	:	Penicillins
Indication	:	Dental orofacial and odontogenic infections (Non prophylactic)
Route of Administration	:	Oral
PENICILLINS AND BETA-LACTAMS COMBINATION		
Substance	:	Amoxicillin + clavulanic acid
Indication	:	Dental infections, abscesses
Route of Administration	:	Oral
MACROLIDES		
Substance	:	Erythromycin
Indication	:	For patients allergic to Penicllin
Route of Administration	:	Oral
ANTI-PROTOZOAL		
Substance	:	Metronidazole

DENTAL THERAPIST (Bachelors degree in Dental Therapy)		
Indication	:	Dental orofacial and odontogenic infections (Non prophylactic)
Route of Administration	:	Oral
AUTONOMIC SYMPATHOMIMETICS		
Substance	:	Adrenaline
Indication	:	Emergency medicine for drug related anaphylactic shock
Route of Administration	:	Parenteral

– 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

a. 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 **

[Fluocinolone.]

– 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)
Annexure 1B: Emergency Care Provider (Emergency Care Practitioner)
Annexure 1E: Emergency Care Technician

[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)]

– END SCHEDULE 6

SCHEDULE 7

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

(i) the isomers of such substances, where the existence of such isomers is possible within the chemical designation;

(ii) the esters and ethers of such substances and of the isomers referred to in (i), as well as the isomers of such esters and ethers, where the existence of isomers of such esters, or ethers is possible;

(iii) the salts of such substances and of the isomers referred to in (i), as well as the salts of the esters, ethers and isomers referred to in (ii), where the existence of such salts is possible;

(iv) the isomers of any of the salts referred to in (iii), where the existence of such isomers is possible;

(v) all preparations and mixtures of any of the above.

(vi) all homologues of listed substances (being any chemically related substances that incorporate a structural fragment into their structures that is similar to the structure of a listed substance and/or exhibit pharmacodynamic properties similar to the listed substance in the schedules), unless listed separately in the Schedules.

(Trivial or unofficial names are marked *)

Dipentylone.

Pholcodine.

2-Fluorodeschloroketamine.

– END SCHEDULE 7 –

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

DR PAKISHE AARON MOTSOALEDI, MP
MINISTER OF HEALTH
DATE: 28/6/2025