**DEPARTMENT OF HEALTH**

**NO. 2685** **28 October 2022**

## 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 Noice 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 and Government Notice No. 883 (Medicines and Related Substances Act1 1965: Schedules) in Government Gazette 45176, 17 September 2021 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 |

Dequalinium

(a) when intended for oral topical use, as oral solutions or lozenges;

(b) except when intended for human vaginal use (S2)

Phenylephrine

a. when intended for oral dosage forms, nasal dosage forms, or ophthalmic dosage forms containing more than 0,2 percent (S1)

b. except ophthalmic preparations containing 0,2 percent or less. (S0)

c. except when intended for injection (S4)

**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)

| **ORAL HYGIENISTS** | | |
|---|---|---|
| LOCAL ANAESTHETIC | | |
| Substance | : | Lignocaine/Lidocaine hydrochloride |
| Indication | : | Dental surface anaesthesia (excluding injectables) |
| Route of Administration | : | Topical |
| TOPICAL FLUORIDES | | |
| Substance | : | - |
| Indication | : | Applicable to dentistry |
| 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 |

Dequalinium

(a) when intended for human vaginal use;

(b) except when intended for oral topical use, as oral solutions or lozenges (S1)

Estriol,

a. When intended for human vaginal use

b. except when intended for oral contraception; (S3)

c. except when intended for hormone replacement therapy. (S4)

d. except when intended for veterinary use (S4)

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

**ANNEXURE 4: PODIATRIST**

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

| **PODIATRIST** | |
|---|---|
| Anti-inflammatories | |
| Substance | : Diclofenac sodium and Ibuprofen |
| Indication | : Pain management |
| Route of Administration | : Oral |

**– 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

Estriol,

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

Folinic acid (leucovorin)

Levalbuterol

**– 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 4: | Podiatrist |

Alectinib

Alpelisib

Apalutamide

Asciminib

Bedinvetmab

Bictegravir

Cabotegravir

Cabozantinib

Casirivimab

Dacomitinib

Dapivirine

Darolutamide

**[Dequalinium]**

Entrectinib

Estriol,

a. when intended for hormone replacement therapy
b. when intended for veterinary use
c. except when intended for oral contraception; (S3)
d. except when intended for human vaginal use (S2);

Faricimab

Fremanezumab

Glucagon

Guselkumab

Icatibant

Idebenone

Imdevimab

Inclisiran

Itopride

Letermovir

Linagliptin

Molnupiravir

Neratinib

Noradrenaline (norepinephrine)

Oloparib

Phenylephrine

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

Polatuzumab

Pralsetinib

Pretomanid

Recombinant human epidermal growth factor (rhEGF)

Remdesivir

Revefanacin

Risdiplam

Rizatriptan, except when in oral solid dosage forms providing 5 mg or less and presented as packs of no more than 2 oral solid dosage forms, indicated for the acute relief of migraine attacks, with or without aura, in patients previously diagnosed by a medical practitioner and initiated on treatment with rizatriptan (S2)

Safinamide

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine

Satralizumab

Selexipag

Tafamidis

Tivozanib

Tozinameran

Turoctocog Alpha

Upadacitinib

Zofenopril

**ANNEXURE 3: OPTOMETRISTS**

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

| **OPTOMETRISTS** | | |
|---|---|---|
| ANTIBIOTICS | | |
| Substance | : | Fuscidic acid |
| Indication | : | For Blepharitis and stye |
| Route of Administration | : | Topical drops or ointment |

| **OPTOMETRISTS** | | |
|---|---|---|
| ANTIBIOTICS | | |
| Substance | : | Neomycin |
| Indication | : | For Blepharitis only |
| Route of Administration | : | Topical drops or ointment |
| ANTIBIOTICS | | |
| Substance | : | Bacitracin |
| Indication | : | For Blepharitis only |
| Route of Administration | : | Ointment |
| ANTIBIOTICS | | |
| Substance | : | Polymyxin B |
| Indication | : | For Blepharitis only |
| Route of Administration | : | Ointment |
| PROSTAGLANDIN ANALOGUES (PGAs) | | |
| Substance | : | Latanoprost, Travoprost, Bimatoprost |
| Indication | : | Glaucoma |
| Route of Administration | : | Drops |

**– 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 **

Esketamine

Lemborexant

**[Recombinant human epidermal growth factor (rhEGF)]**

**– END SCHEDULE 5 –**

**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.

Brorphine

Eutylone

Metonitazene

Norfentanyl

**– END SCHEDULE 7 –**

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

**DR M.J PHAAHLA, MP**
**MINISTER OF HEALTH**
**DATE:** 06/10/2022