

DEPARTMENT OF HEALTH

NO. R. 220

28 FEBRUARY 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.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 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, 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(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);
 - (ii) Annexure 1B: Emergency Care Provider (Emergency Care Practitioner);
 - (iii) Annexure 2: Dental Therapist;
 - (iv) Annexure 3: Optometrist;
 - (v) Annexure 4: Podiatrist

Schedule 1

ANNEXURE 3: OPTOMETRIST

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

<u>OPTOMETRIST</u>	
<u>SYMPATHOMIMETIC</u>	
Substance	: Phenylephrine
Indication	: Minor ocular irritation
Route of Administration	: Topical (Drops)

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)

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

– END SCHEDULE 1 –

SCHEDULE 3

- 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 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

Schedule 3

ANNEXURE 3: OPTOMETRIST

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

<u>OPTOMETRISTS</u>	
<u>BETA-BLOCKER</u>	
Substance	: Betaxolol
Indication	: Open-Angle Glaucoma in Adults
Route of Administration	: Topical Application (Drops)
<u>SYMPATHOMIMETIC</u>	
Substance	: Brimonidine
Indication	: Open-Angle Glaucoma in Adults
Route of Administration	: Topical Application (Drops)
<u>BETA-BLOCKER</u>	
Substance	: Levobunolol
Indication	: Open-Angle Glaucoma in Adults
Route of Administration	: Topical Application (Drops)

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)

<u>PODIATRIST</u>	
<u>SYMPATHOMIMETIC</u>	
Substance	: Adrenaline / Epinephrine
Indication	: Sympathomimetic catecholamine for the management of shock
Route of Administration	: Parenteral
<u>LOCAL ANAESTHETIC</u>	
Substance	: Bupivacaine Hydrochloride 2 %
Indication	: Local Anaesthesia
Route of Administration	: Parenteral
<u>LOCAL ANAESTHETIC</u>	
Substance	: Bupivacaine Hydrochloride 2 % with Adrenaline
Indication	: Local Anaesthesia
Route of Administration	: Parenteral

Schedule 3

PODIATRIST	
LOCAL ANAESTHETIC	
Substance	: Levobupivacaine Hydrochloride with Adrenaline
Indication	: Local Anaesthesia
Route of Administration	: Parenteral
LOCAL ANAESTHETIC	
Substance	: Lidocaine (Lignocaine) Hydrochloride
Indication	: Local Anaesthesia
Route of Administration	: Parenteral
LOCAL ANAESTHETIC	
Substance	: Lidocaine (Lignocaine) Hydrochloride with Adrenaline
Indication	: Local Anaesthesia
Route of Administration	: Parenteral
LOCAL ANAESTHETIC	
Substance	: Mepivacaine Hydrochloride
Indication	: Local Anaesthesia
Route of Administration	: Parenteral

– END SCHEDULE 3 –

Schedule 4

SCHEDULE 4

- 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:
- (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);
 - (ii) Annexure 1B: Emergency Care Provider (Emergency Care Practitioner);
 - (iii) Annexure 2: Dental Therapist;
 - (iv) Annexure 3: Optometrist;
 - (v) Annexure 4: Podiatrist

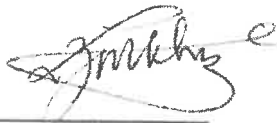
ANNEXURE 3: OPTOMETRIST

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<u>OPTOMETRISTS</u>	
<u>ANTIBACTERIAL</u>	
Substance	: Tetracycline
Indication	: Trachoma
Route of Administration	: Oral
<u>ANTIBACTERIAL</u>	
Substance	: Doxycycline
Indication	: Trachoma
Route of Administration	: Oral
<u>ANTIBACTERIAL</u>	
Substance	: Azithromycin
Indication	: Trachoma
Route of Administration	: Oral

– END SCHEDULE 4 –

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



DR Z.L MKHIZE, MP

MINISTER OF HEALTH

DATE: 20/01/2020