DEPARTMENT OF HEALTH

NO. R. 219 **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:

- 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);

(ii) Annexure 1B: Emergency Care Provider (Emergency Care Practitioner);

(iii) Annexure 2: Dental Therapist;

(iv) Annexure 3: Optometrist.

Schedule 1

Benzydamine, **[preparations and mixtures containing -]**

a. preparations and mixtures containing 3 percent or less of benzydamine, when intended for application to the skin (S3); or

b. 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)

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)

Hyoscine butylbromide; substances, preparations and mixtures thereof-

a. when intended for oral administration in pack sizes not exceeding 20 tablets of 10 mg strength or less, or 100 ml of oral liquid dosage of 0.1% mass/ volume or less; (S2)
b. except transdermal preparations when intended for the prevention of the symptoms of motion sickness; (S2)
c. except when intended for parenteral administration. (S3)

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 **[in possession of a Section 22A(15) permit as provided for by the Medicines and Related Substances Act, 1965 (Act 101 of 1965)[** recognised by the Health Professions Council of South Africa as an authorised prescriber.

– 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);

(ii) Annexure 1B: Emergency Care Provider (Emergency Care Practitioner);

(iii) Annexure 2: Dental Therapist;

(iv) Annexure 3: Optometrist.

Schedule 2

[Dulaglutide]

Hyoscine butylbromide; substances, preparations and mixtures thereof-

a. when intended for oral administration in pack sizes exceeding 20 tablets or 100 ml, or strengths exceeding 10 mg per oral solid dosage form or 0.1% mass/volume; (S1)
b. transdermal preparations when intended for the prevention of the symptoms of motion sickness; (S3)
c. except when intended for parenteral administration. (S3)

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 **[in possession of a Section 22A(15) permit as provided for by the Medicines and Related Substances Act, 1965 (Act 101 of 1965)[** recognised by the Health Professions Council of South Africa as an authorised prescriber.

– 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.

Benzydamine, except preparations and mixtures containing -

a. 3 percent or less of benzydamine when intended for application to the skin (S1);

b. 0,15 percent or less of benzydamine when intended for use as a mouthrinse 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)

c. 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)

Glutathione, when intended for intravenous infusion or for injection. (S0)

Hyoscine butylbromide; substances, preparations and mixtures thereof-

a. except when intended for oral administration; (S1, S2) and

b. except transdermal preparations when intended for the prevention of the symptoms of motion sickness. (S2)

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 [**in possession of a Section 22A(15) permit as provided for by the Medicines and Related Substances Act, 1965 (Act 101 of 1965)[** recognised by the Health Professions Council of South Africa as an authorised prescriber.

– 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);

(ii) Annexure 1B: Emergency Care Provider (Emergency Care Practitioner);

(iii) Annexure 2: Dental Therapist;

(iv) Annexure 3: Optometrist.

Brigatinib.

Dulaglutide.

Macitentan.

Miglustat.

Netupitant.

Ocrelizumab.

Olaratumab.

Pixantrone.

Sarolaner, except when intended and registered for the control of ticks and fleas in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Tedizolid.

Tilmicosin.

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 **[in possession of a Section 22A(15) permit as provided for by the Medicines and Related Substances Act, 1965 (Act 101 of 1965)[** recognised by the Health Professions Council of South Africa as an authorised prescriber.

– END SCHEDULE 4 –

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.

ADB-CHMINACA (MAB-CHMINACA)

ADB-FUBINACA

CUMYL-4CN-8INACA

N-Ethylnorpentylone (ephylone)

FUB-AMB (MMB-FUBINACA, AMB-FUBINACA)

Schedule 7

Fentanyl-analogues (unless listed in another Schedule) including:

xviii. Cyclopropylfentanyl. (N-Phenyl-N-[l-(2-phenylethyl)piperidin-4-yl]cyclopropanecarboxamide)

xix. Methoxyacetyl fentanyl. (2-methoxy-N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide)

xx. Ortho-fluorofentanyl. (N-(2-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide)

xxi. Parafluorobutyrlfentanyl (*N-(* 4-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]butanamide)

– END SCHEDULE 7 –

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

DR ZL MKHIZE, MP
MINISTER OF HEALTH
DATE: 13/02/2020