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AIDS HELPLINE: 0800-0123-22 Prevention is the cure

Contents

DEPARTMENT OF HEALTH

NO. R. 755 **23 MAY 2019**

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 Regulatory Authority (SAHPRA), made and updated the Schedules in the Schedule.

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; and Government Notice No.1261 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 41256, 17 November 2017 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 Medicines Control Council, 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.

Fexofenadine.

– 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 Medicines Control Council, 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.

Budesonide,

a. when intended for the prophylaxis and treatment of seasonal and perennial allergic rhinitis in adults and children aged 12 years and older; (S3)

b. except when intended for inhalation and nasal administration, unless listed in another Schedule. (S4)

Schedule 2

[**Fexofenadine**.]

Fusidic acid, when intended for topical application. (S4)

[Loratidine].

– 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 Medicines Control Council, 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.

Budesonide,

a. when intended inhalation or nasal administration, unless listed in another Schedule. (S4)

b. except when intended for the prophylaxis and treatment of seasonal and perennial allergic rhinitis in adults and children aged 12 years and older. (S2)

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 Medicines Control Council, 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.

Baricitinib.

Belimumab.

Budesonide,

a. except when intended for the prophylaxis and treatment of seasonal and perennial allergic rhinitis in adults and children aged 12 years and older; (S2)

b. except when intended inhalation or nasal administration, unless listed in another Schedule. (S3)

Cannabidiol, **[when intended for therapeutic purposes (S7)]**

Cobimetinib.

Cobicistat.

Elvitegravir.

Fusidic acid, except when intended for topical application. (S2)

Idarucizumab.

Ledipasvir.

Nintedanib.

Panobinostat.

Velpatasvir.

Venetoclax.

– END SCHEDULE 4 –

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).

Schedule 6

Carfentanil, when intended for veterinary use. (S7)

– 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.

AB-CHMINACA.

AB-PINACA.

[Cannabidiol, except when intended for therapeutic purposes (S4)]

Carfentanil, except when intended for veterinary use. (S6)

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

(xiv) Acryloylfentanyl (acrylfentanyl).

(xv) 4-fluoroisobutyrfentanyl (4-FIBF, pFIBF).

(xvi) Furanylfentanyl

Schedule 7

(xvii) Tetrahydrofuranylfentanyl (THF-F).

4-fluoroamphetamine (4-FA).

5F-MDMB-PINACA (5F-ADB).

5F-PB-22.

Ocfentanil.

UR-144.

– END SCHEDULE 7 –

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

DR A MOTSOALEDI, MP
MINISTER OF HEALTH
DATE: 23/8/2018

DEPARTMENT OF HEALTH

NO. R. 756 **23 MAY 2019**

EXCLUSION OF CERTAIN PREPARATIONS CONTAINING CANNABIDIOL (CBD) FROM OPERATION OF CERTAIN PROVISIONS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965)

I, Dr Aaron Motsoaledi, Minister of Health, in terms of section 36(1) of Medicines and Related Substances Act, 1965 (Act No.101 of 1965) and on the recommendation of the South African Health Products Regulatory Authority (the Authority), hereby exclude from the operation of the Schedules to the Act published in terms of section 22A(2) of the Medicines and Related Substances Act, 1965, preparations containing cannabidiol (CBD) that-

a) contain a maximum daily dose of 20 mg cannabidiol (CBD) with an accepted low risk claim or health claim which only refer to:

   i. General health enhancement without any reference to specific diseases;
   ii. Health maintenance; or
   iii. Relief of minor symptoms (not related to a disease or disorder); or

b) Consist of processed products made from cannabis raw plant material and processed products, where only the naturally occurring quantity of cannabinoids found in the source material are contained in the product, and which contain not more than 0,001 % of tetrahydrocannabinol (THC) and not more than 0,0075 % total cannabidiol (CBD).

This exemption is effective immediately for a period not exceeding twelve (12) months from the date of signature of this Notice.

DR A MOTSOALEDI, MP
MINISTER OF HEALTH
DATE: 15/5/2019

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Anna-Marie du Toit (012) 748-6292 (Anna-Marie.DuToit@gpw.gov.za) and

Siraj Rizvi (012) 748-6380 (Siraj.Rizvi@gpw.gov.za)

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