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GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF HEALTH**NO. R. 586****22 MAY 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; Government Notice No.755 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 42477, 23 May 2019; Government Notice No.219 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 43051, 28 February 2020; and Government Notice No.220

(Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 43051, 28 February 2020 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 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.

Schedule 4

- | | | |
|-------|--------------|--|
| (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 |

Cannabidiol, except-

- a. in complementary medicines containing no more than 600 mg cannabidiol per sales pack, providing a maximum daily dose of 20 mg of cannabidiol, and making a general health enhancement, health maintenance or relief of minor symptoms (low-risk) claim; (S0) or
- b. processed products made from cannabis raw plant material intended for ingestion containing 0,0075 percent or less of cannabidiol where only the naturally occurring quantity of cannabinoids found in the source material are contained in the product. (S0)

- 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 Authority, 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).

[Dronabinol (I) (-)-transdelta-9-tetrahydrocannabinol), except: [when intended for therapeutic purposes. (S7)]

- a. in raw plant material and processed products manufactured from such material, intended for

Schedule 6

industrial purposes and not for human or animal ingestion, containing 0,2 % percent or less of tetrahydrocannabinol;

- b. processed products made from cannabis containing 0,001 percent or less of tetrahydrocannabinol; or
- c. when raw plant material is cultivated, possessed, and consumed by an adult, in private for personal consumption.

[{(-)-transdelta-9-tetrahydrocannabinol - see dronabinol}.]

– 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.

[Cannabis (dagga), the whole plant or any portion or product thereof, except:

- a. when separately specified in the Schedules; (S4;S6) or**
- b. processed hemp fibre containing 0,1 percent or less of tetrahydrocannabinol and products manufactured from such fibre, provided that the product does not contain whole cannabis seeds and is in a form not suitable for ingestion, smoking or inhaling purposes; or**
- c. processed product made from cannabis seeds containing not more than 10 milligrams per kilogram (0,001 percent) of tetrahydrocannabinol and does not contain whole cannabis seeds.**

["Processed" means treated by mechanical, chemical or other artificial means but does not include - (a) harvesting; or (b) the natural process of decay".]

[Dronabinol [(-)-transdelta-9-tetrahydrocannabinol]. (S6)]

[Tetrahydrocannabinol and their alkyl homologues, except:

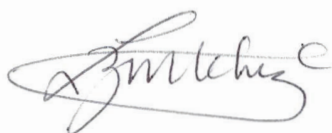
Schedule 7

- a. when separately specified in the Schedules;
- b. dronabinol ((-)-transdelta-9-tetrahydrocannabinol), when intended for therapeutic purposes; (S6)
- c. in hemp seed oil, containing 10 milligrams per kilogram or less of tetrahydrocannabinols, when labelled "Not to be taken" or "Not for internal human use"; or
- d. in products for purposes other than internal human use containing 10 milligrams per kilogram or less of tetrahydrocannabinols.

["Hemp seed oil" means the oil obtained by cold expression from the ripened fruits (seeds) of *Cannabis sativa*.]

– END SCHEDULE 7 –

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



DR Z.L MKHIZE, MP

MINISTER OF HEALTH

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