GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF HEALTH

NO. 4251 **15 January 2024**

MEDICINES AND RELATED SUBSTANCES ACT, 1965

SCHEDULES

The Minister of Health intends, 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), to make and update the Schedules.

Interested persons are invited to submit any substantiated comments or representations on the proposed Update to the Schedule to the Director-General of Health, Private Bag X828, Pretoria, 0001 (for attention of the Director: Public Entities Governance; mihloti.mushwana@health.gov.za and paul.tsebe@health.gov.za), within two months of the date of publication of this notice.

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 Notice 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, Government Notice No. 883 (Medicines and Related Substances Act1 1965: Schedules) in Government Gazette 45176, 17 September 2021; Government Notice No. 2685 (Medicines and Related Substances Act1 1965: Schedules) in Government Gazette 47373, 28 October 2022 and Government Notice No. R3261 (Medicines and Related Substances Act1 1965: Schedules) in Government Gazette 48358, 24 March 2023 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 this schedule, **"the Act"** means the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965).

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)

Tetrahydrocannabinol **[(-)-transdelta-9-tetrahydrocannabinol)]**, except

a. in raw cannabis plant material cultivated and possessed in accordance with a permit issued in terms of the Plant Improvement Act (Act 11 of 2018) and processed products manufactured from such material, intended for agricultural or industrial purposes, **[and not for human or animal ingestion, containing 0,2 % percent or less of tetrahydrocannabinol;]** including the manufacture of consumer items or products which have no pharmacological action or medicinal purpose, or

b. **[processed products made from cannabis containing 0,001 percent or less of tetrahydrocannabinol; or]**

c. when raw cannabis plant material is cultivated, possessed, and consumed by an adult, in private for personal consumption.

DR M.J. PHAAHLA, MP
MINISTER OF HEALTH
DATE: 21/12/2023