DEPARTMENT OF HEALTH

NO. R. 2412 26 August 2022

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

Schedule 2

(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., <u>Gamma benzene hexachloride</u>), 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 2

- 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);

Schedule 2

(ii) Annexure 1B: Emergency Care Provider (Emergency Care Practitioner). (iii) Annexure 2: Dental Therapist. (iv) Optometrist. Annexure 3:

Podiatrist

[Chloroquine, when used in combination with proguanil and when intended specifically for malaria prophylaxis. (\$4)]

- END SCHEDULE 2 -

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

(v)

Annexure 4:

DR M.J. PHAAHLA, MP
MINISTER OF HEALTH
DATE: 29/04/2027