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DEPARTMENT OF HEALTH

NO. 4389

16 February 2024

ALLIED HEALTH PROFESSIONS ACT 63 OF 1982

REGULATIONS RELATING TO THE PROFESSION OF HOMEOPATHY

The Minister of Health intends, in terms of section 38(1)(i) and (I) of the Allied Health Professions Act, 1982 (Act No. 63 of 1982), after consultation with the Allied Health Professions Council, to make the regulations as set out in the Schedule.

Interested persons are invited to submit substantiated comments or representations in writing on the proposed amendments to the regulations, to the Director-General: Health, Private Bag X828, Pretoria, 0001 (for the attention of the Director: Public Entities Governance, Ms M Mushwana, <u>mihloti.mushwana@health.gov.za</u>) and Mr. Godfrey Tsebe, <u>Godfrey.tsebe@health.gov.za</u> within three months of the date of publication of this Notice.

RM.J. PHAAHLA, MP MINISTER OF HEALTH DATE: /4/12/2023

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SCHEDULE

Definitions

 In these regulations any expression defined in the Act bears that meaning and, unless the context otherwise indicates –

"allersodes" means homeopathic medicines or substances which include medicines or substances derived from antigens, toxins, ferments, precipitinogens, agglutinogens, opsonogens, lysogens, venins, agglutinins, complements, opsonins, amboceptors, precipitins and original proteins;

"compound" means the combining or mixing of substances or medicines to create a medicine used in the profession of homeopathy;

"dispense" means the issuing, interpretation and evaluation of a prescription, or the selection, manipulation, preparation, recording or compounding of a homeopathic medicine or substance used in homeopathy, the labelling and supplying of such medicine or substance in an appropriate container and the provision of information and instructions to ensure its safe and effective use by a patient;

"formulate" for the purpose of making a homeopathic medicine, whether used alone or in combination, means to calculate or determine medicines or substances and the quantities, dosage and strengths of such medicines or substances, including the process of preparing or combining such medicines or substances;

"homeopathic substance" means any substance or mixture of substances, preparation, compound, product or device which –

- (a) is compounded, formulated, manufactured, prepared, manipulated, altered or adjusted in accordance with homeopathic principles, techniques or philosophy; or
- (b) is modelled on homeopathic principles or philosophy or is termed a homeopathic medicine, remedy or substance;
- (c) is obtained by method of successive dilution, succussion and/or trituration whether achieved manually, mechanically, or electronically including radionically, or by whatever means or whatever scale of dilution;
- (d) consists mainly of, or contains a substance which, is generally regarded or accepted as being a homeopathic medicine, remedy or substance and includes

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but is not limited to starting substances, nosodes, allersodes, isodes and sarcodes;

"Homeopathy" means the system of medicine developed by Samuel Hahnemann, that involves the diagnosis and treatment of physical or mental defects, diseases, illness, deficiencies or abnormalities by assisting the body's self-healing and self-regulatory processes using homeopathic substances prepared in accordance with the philosophy, theory, principles and techniques recorded in the Organon of Medicine, or other council-accepted homeopathic *materia medica*, *vade mecums*, homeopathic pharmacopoeia or equivalent homeopathic standards;

"isode" means a homeopathic substance derived from a botanical, biological, chemical or synthetic substance or scheduled substance or any medicine, including an excipient or binder, which has been ingested or otherwise absorbed by the body and is believed to have produced a disease or disorder which interferes with homeostasis;

"materia medica" means any council-accepted publication in which the botanical or chemical properties or the physical character of substances, the natural history of the effect of substances on the body in health and disease, the collective symptoms obtained from experimental study of substances or the therapeutics relating to the application of substances in disease are described and which may include homeopathic substances;

"medicine" bears the meaning ascribed to it in section 1 of the Medicines and Related Substances Act No 101 of 1965;

"Medicines and Related Substances Act" means the Medicines and Related Substances Act, 1965 (Act No 101 of 1965) and includes the regulations made thereunder;

"nosode" means a homeopathic substance derived from organs or tissues in a pathological state or from disease-causing agents such as bacteria, fungi, parasitic ova, parasites, virus particles, yeast or disease products or excretions;

"Organon of Medicine" refers to any of the six editions of the Organon of Medicine written by the founder of homeopathy, Samuel Hahnemann in which the principles, philosophy and practice of homeopathy are described;

"prepare" means any act pertaining to the making or changing or adaptation or manipulation of a homeopathic medicine or various medicines, substances or 94 No. 50138

ingredients and the preparation of substances or medicines for the purposes of compounding, formulating or dispensing;

"scheduled substance" bears the meaning ascribed to it in section 1 of the Medicines and Related Substances Act No 101 of 1965;

"sarcodes" means homeopathic substances which are derived from organs or tissues of healthy animals;

"starting substance" is a basic or original substance from which a homeopathic substance is prepared or manufactured using homeopathic principles and techniques; "the Regulations of 2001" means the Regulations made under section 38 of the Allied Health Professions Act, 1982 (Act No. 63 of 1982), as published under Government Notice No. R. 127 of 12 February 2001 as corrected by Government Notice No. R266 of 26 March 2001;

"the Regulations of 1982" means the Regulations made under section 38 of the Allied Health Professions Act, 1982 (Act No. 63 of 1982), as published under Government Notice No. R. 2610 of 03 December 1982 and amended by: Government Notice No. R. 870 of 29 April 1983, Government Notice No. R. 1196 of 10 June 1983, Government Notice No. R. 870 of 29 April 1983, Government Notice No. R. 1196 of 10 June 1983, Government Notice No. R. 1745 of 12 August 1983, Government Notice No. R. 2322 of 26 October 1984, Government Notice No. R. 2712 of 14 December 1984, Government Notice No. R. 1083 of 17 May 1985, Government Notice No. R. 2394 of 21 November 1986, Government Notice No. R. 1622 of 31 July 1987, Government Notice No. R. 2366 of 23 October 1987, Government Notice No. R. 629 of 31 March 1988, Government Notice No. R. 2439 of 2 December 1988, Government Notice No. R. 2030 of 16 October 1992, Government Notice No. R. 203 of 4 February 1994, Government Notice No. R. 1700 of 25 October 1996; and as repealed (Chapters 1,2,3,4,5,6,7,9,10,12 and 15) by Government Notice No. R. 127 of 12 February 2001; and

"the Act" means the Allied Health Professions Act, 1982 (Act No.63 of 1982).

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Acts specifically pertaining to the profession of a homeopath

- 2. The following are acts specifically pertaining to the profession of a homeopath-
 - The physical and psychological examination of any person for the purpose of diagnosing any defect, illness, disease or deficiency in such person;
 - (b) The use or request of any medical diagnostic investigations which may include the withdrawal of intravenous blood;
 - (c) The treatment or prevention of any defect, illness, disease or deficiency in any person by means of:
 - any medicine or substance in accordance with and based on homeopathic principles or procedures;
 - (ii) any other medicine, substance or device permitted to any homeopath in terms of any applicable legislation;
 - (iii) health promotion and preventative interventions, including but not limited to dietary and lifestyle advice or interventions;
 - (d) Advising any person on his or her physical or mental health status; and
 - (e) Any other act or procedure specifically pertaining to the profession of Homeopathy based on the education and training of a homeopath, as approved by the council from time to time at the recommendation of the professional board and supported by the Organon of Medicine.

Prescription and possession of substances

- (1) Subject to the provisions of the Medicines and Related Substances Act, a practitioner registered as a homeopath may, for the purposes of his or her practice-
 - (a) Possess or have under his or her control -
 - (i) any homeopathic substance;
 - substances that are not scheduled or are scheduled under the Medicines Act and Related Substances Act, or substances listed in Annexure 1;

- (iii) starting substances and those scheduled substances, including any derivatives, such as salts or esters, used in the preparation, formulation, compounding and dispensing of homeopathic substances that are recorded in any council-accepted homeopathic *materia medica*, homeopathic pharmacopeia or in any other equivalent homeopathic or non-homeopathic standard, in quantities and concentrations not more than what is considered reasonably necessary for homeopathic purposes;
- (iv) allersodes, isodes, nosodes and sarcodes;
- (v) substances referred to in sub-paragraphs (i), (ii), (iii), (iv), and water in an injectable form.
- (2) Subject to the provisions of the Medicines and Related Substances Act, a practitioner registered as a homeopath may, for the purposes of his or her practice prescribe for, administer to, or dispense to, a patient -
- (a) any homeopathic substance, or preparation or mixture of substances, or medicines or substances containing homeopathic substances, in any homeopathic dose or potency;
- (b) starting substances and preparations and mixtures of homeopathic substances whether they include scheduled substances or substances not scheduled under the Medicines and Related Substances Act;
- (c) medicines, substances, preparations and mixtures of substances that are scheduled or unscheduled substances including
 - i. vitamins;
 - ii. minerals;
 - iii. animal extracts, products and derivatives;
 - iv. fats, oils and fatty acids;
 - v. carotenoids;
 - vi. polyphenols and bioflavonoids;
 - vii. amino-saccharides;
 - viii. saccharides (including prebiotics);
 - ix. probiotics;
 - x. gemmotherapy
 - xi. flower essences

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- xii. health supplements; and
- xiii. any other scheduled substance or medicine that may be prescribed for the purpose identified in the Schedule, including any substance listed in Annexure 1;
- xiv any registered complementary medicine combination product that contains a homeopathic substance; and
- xv substances referred to in sub-paragraphs (i), (ii), (iii), (iv), water, and saline, in an injectable form, where applicable.
- (3) Subject to the provisions of the Medicines and Related Substances Act, a practitioner registered as a homeopath may, for the purposes of his or her practice formulate, prepare, manipulate or compound and dispense-
- (a) any substance, preparations and mixtures of substances that are recorded in any council-accepted homeopathic materia medica or any homeopathic pharmacopoeia, or any unscheduled substance for the purpose of making a homeopathic medicine;
- (b) substances referred to in paragraph (a) in homeopathic form;
- (c) substances referred to in paragraph (b) in homeopathic form; and
- (d) any homeopathic substance, or a preparation or mixture of substances or medicines or substances containing a homeopathic substance, in any homeopathic dose or strength.

Repeal of laws

4. Regulation 28 of the Regulations made under section 38 of the Act as published under Government Notice No R127 of 12 February 2001 as corrected by Government Notice No R266 of 26 March 2001, and Regulation 47 of Regulations made under section 38 of the Act as published under Government Notice No R2610 of 03 December 1982 and amended by Government Notice No R870 of 29 April 1983, Government Notice No R1196 of 10 June 1983, Government Notice No R1745 of 12 August 1983, Government Notice No R2322 of 26 October 1984, Government Notice No R2712 of 14 December 1984, Government Notice No R1083 of 17 May 1985,

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Government Notice No R2394 of 21 November 1986, Government Notice No R1622 of 31 July 1987, Government Notice No R2366 of 23 October 1986, Government Notice No R1622 of 31 July 1987, Government Notice no R2366 of 23 October 1987, Government Notice No R629 of 31 March 1988, Government Notice No R2439 of 02 December 1988, Government Notice No R2855 of 07 December 1990, Government Notice No R3089 of 20 December 1991, Government Notice No R2900 of 16 October 1992, Government Notice No R203 of 04 February 1994, and Government Notice No R1700 of 25 October 1996;, are hereby repealed.

Short title

 These regulations are called the Regulations Relating to the Homeopathic Profession, 2023.