DEPARTMENT OF HEALTH

NO. 4349 **9 February 2024**

ALLIED HEALTH PROFESSIONS ACT 63 OF 1982

REGULATIONS RELATING TO THE PROFESSION OF PHYTOTHERAPY

The Minister of Health intends, in terms of section 38(1)(i) and (l) 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, Mihloti.mushwana@health.gov.za and Godfrey.tsebe@health.gov.za, within three months of the date of publication of this notice.

DR M.J PHAAHLA
MINISTER OF HEALTH
DATE: 11/12/2023

SCHEDULE

Definitions

1. In these Regulations, any word or expression to which a meaning has been assigned in the Act shall have the meaning so assigned and, unless the context otherwise indicates–

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

"phytotherapist" means a person who is a practitioner registered as such under the Act;

"phytotherapy" is the system of medicine that involves the diagnosis or treatment of a physical or mental defect, illness, disease, deficiency or abnormality in any person, or in the promotion and maintenance of health by the administration or prescription of a herbal medicine, substance or preparation which may be prepared, manipulated, formulated, or compounded and dispensed by a phytotherapist;

"substance" means anything which, whether used alone or in combination in either its original or natural state or in compounded, manipulated or prepared form, constitutes a herbal medicine or forms part of a herbal medicine or which is a basic substance; and

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

Acts Specifically Pertaining to the Profession of a Phytotherapist

2. The following acts are acts specially pertaining to the profession of a phytotherapist –

(a) 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:

(i) any medicine or substance in accordance with and based on phytotherapy principles or procedures;

(ii) any other medicine, substance or device permitted to any phytotherapist in terms of any applicable legislation; and

(iii) health promotion and preventative interventions, including but not limited to nutritional and lifestyle advice.

(d) Advising any person on his or her physical or mental health;

(e) Any other act or procedure specifically pertaining to the profession of phytotherapy based on the education and training of a phytotherapist as accepted by the Council from time to time at the recommendation of the professional board.

Remedies relating to Phytotherapy

3. (1) Subject to the provisions of the Medicines and Related Substances Act , a practitioner registered as a phytotherapist may, for the purposes of his or her practice–

(a) possess or have under his or her control –

(i) any herbal medicine, substance or preparation;

(ii) substances that are not scheduled or scheduled under the Medicines Act No. 101 of 1965, or substances listed in Annexure one;

(iii) substances, including scheduled substances, that are used as basic substances in the preparation, formulation, compounding and dispensing of herbal medicines, substances or preparations;

(iv) those scheduled substances which are recorded in a council-accepted herbal monograph, herbal *materia medica*, herbal pharmacopoeia or in any other equivalent herbal or non-herbal standard, in quantities and concentrations that do not exceed what is reasonably necessary for this purpose;

(v) such scheduled substances, other than those contemplated in subparagraph (iv), as are determined to be necessary for the practice of phytotherapy by the Council, at the recommendations of the professional board, and published in the *Gazette*;

(vi) ethanol, glycerol or other permitted solvents used in phytotherapy;

(vii) substances referred to in sub-paragraphs (i),(ii), (iii), (iv) and water in an injectable form, where applicable; and

(b) Prescribe for, administer to, or dispense to, a patient -

(i) any herbal substance, or preparation or mixture of substances, or medicines or substances containing herbal substances, in any phytotherapeutic dose;

(ii) basic substances and preparations or mixtures of herbal substances whether they include scheduled substances or substances not scheduled under the Medicines and Related Substances Act No. 101 of 1965;

(iii) medicines, substances, preparations and mixtures of substances that are scheduled or unscheduled substances including –

a. vitamins;

b. minerals;

c. animal extracts, products and derivatives;

d. fats, oils and fatty acids;

e. carotenoids;

f. polyphenols and bioflavonoids;

g. amino-saccharides;

h. saccharides (including prebiotics);

i. probiotics;

j. gemmotherapy

k. flower essences

l. health supplements;

m. any substance listed in Annexure one in any phytotherapeutic dose; and

n. any other scheduled substance or medicine that may be prescribed for the purpose identified in the Schedule.

(iv) substances referred to in sub-paragraphs (i),(ii) and (iii), water and saline, in an injectable form, where applicable; and

(c) formulate, prepare, manipulate or compound and dispense –

(i) any substance, preparations and mixtures of substances that are recorded in a council-accepted herbal monograph, *materia medica* or herbal pharmacopoeia or any unscheduled substance for the purpose of making a herbal medicine;

(ii) substances referred to in paragraph (a) (i) – (iv);

(iii) substances referred to in paragraph (b) (i), (ii) and (iii) j, k and m; and

(iv) any herbal substance or a preparation or mixture of substances or medicines or substances containing a herbal substance, in any phytotherapeutic dose or strength.

(2) For the purposes of this regulation:-

(a) **"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.

(b) **"basic substance"** in relation to phytotherapy means any substance obtained from plants or parts of plants from which or out of which a dilution or mixture is prepared or manufactured, or any stronger concentration of such substance.

(c) **"compound"** means the combining or mixing of substances or medicines to create a medicine used in the profession of phytotherapy.

(d) **"dispense"** means the issuing, interpretation and evaluation of a prescription, or the selection, manipulation, preparation, recording or compounding of a

herbal medicine or substance used in phytotherapy, 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.

(e) **"formulate"** for the purpose of making a herbal medicine, whether used alone or in combination, means to calculate or determine medicines or substances and the quantities and strengths of such medicines or substances, including the process of preparing or combining such medicines or substances, and the calculation or determination of the dosage of such herbal medicine.

(f) **"herbal medicine,** substance or preparation" means all or part of a plant, fungus, alga, seaweed or lichen, or other substance:

(i) that is obtained only by drying, crushing, distilling, freezing, fermentation, lyophilisation, extracting, expressing, comminuting, mixing with an inert diluent substance or another herbal substance or mixing with water, ethanol, glycerol, oil or aqueous ethanol; or other permitted solvents; with or without the addition of heat;
(ii) that is not subjected to any other treatment or process other than a treatment or process that is necessary for its presentation in a pharmaceutical dosage form;
(iii) where part of a plant, fungus, seaweed or lichen refers to a structure such as a root, root bark, rhizome, mycelium, fruiting body, bulb, corm, tuber, stem, inner or outer bark, wood, meristematic tissue, shoot, bud, thallus, resin, oleoresin, gum, natural exudate or secretion, gall, leaf, frond, flower (or its parts), inflorescence, pollen, fruit, seed, cone, spores or other whole plant part; and
(iv) may include any isolated plant constituent.

(g) **"herbal monograph"** means a council-accepted reference standard that is compiled in order to define identity, quality and safety criteria as well as therapeutic information on a particular herbal substance, preparation or medicine.

(h) **"prepare"** means any act pertaining to the making or changing or adaptation or manipulation of an herbal medicine or various medicines, substances or ingredients and the preparation of substances or medicines for the purposes of compounding, formulating or dispensing.

Repeal

4. Regulation 29 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 46 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, 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, Government Notice No R1700 of 25 October 1996; and as repealed (Chapters 1, 2, 3, 4, 5, 6, 7, 9, 10, 12, and 15) by Government Notice No R127 of 12 February 2001, are hereby repealed.

Short title

5. These regulations are called the Regulations Relating Specifically to the Profession of Phytotherapy, 2023.

Annexure 1

Scheduled substances that are obtained solely from plants or parts of plants:

i. Alkaloids and glycosides;

ii. all poisonous alkaloids and glycosides not specifically named in Schedule 1, 2, 3, 4, 5, 6 or 7 of the Medicines and Related Substances Control Act, 1965, containing not more than one part per thousand of such alkaloids or glycosides, excluding the following alkaloids and glycosides in the maximum strength as indicated below:

a. Aconite tincture (B.P.);
b. Belladonna tincture (B.P. 1980);
c. Cocaine: substances containing not more than one part per thousand of cocaine, calculated as cocaine alkaloid;
d. Gelsemium tincture (B.P.C. 1973);
e. Ipecacuanha tincture (B.P. 1980);
f. Sabadilla alkaloids (B.P.C. 1934);
g. Veratrum tincture (B.P.C. 1934);
h. Digitalis leaf (B.P. 1980);
i. Hyoscine: substances containing not more than one part per thousand thereof;
j. Nux vomica;
k. Opium tincture (Ph.Cx., 11th edition): substances containing not more than one part per thousand thereof;
l. Papaverine: substances containing not more than one part per thousand thereof;
m. Pilocarpine;
n. Pygeum africanum (lipido-sterolic complex extract thereof);
o. Radix valerianae and its extracts;
p. Rauwolfia serpentina (dry root), (Ph.Cx., 11th edition);
q. Strophanthus (B.P.);
r. Tubocurarine: substances containing not more than one part per thousand thereof; and
s. Vincamine.