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GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF HEALTH

NO. 858 **25 JULY 2016**

MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965)

GENERAL REGULATIONS MADE IN TERMS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965): AMENDMENT

The Minister of Health intends, in terms of section 35 of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), and in consultation with the Medicines Control Council, to make the regulations in the Schedule.

Interested persons are invited to submit, within **1 (one) month** of publication of this notice, comments on the proposed regulations to the Director-General: Health, Private Bag X828, Pretoria, 0001, for the attention of the Registrar of Medicines.

SCHEDULE

Definitions

1. In these regulations **"the regulations"** means the General Regulations as published under Government Notice No. R. 510 in GG 24727 of 10 April 2003, as amended.

"the Act" means the Medicines and Related Substances Act, 1965 (Act No.101 of 1965).

Amendment of Regulation 1

2. Regulation 1 of the Regulations is hereby amended by—

(a) replacing the following definition after the definition of **"clinical trial"**:

"complementary medicine" means any substance or mixture of substances that—-

(a) originates from plants, fungi, algae, seaweeds, lichens, minerals, animals or other substance as determined by Council, and

(b) is used or purporting to be suitable for use or manufactured or sold for use –

(i) in maintaining, complementing, or assisting the innate healing power or physical or mental state, or

(ii) to diagnose, treat, mitigate, modify, alleviate or prevent disease or illness or the symptoms or signs thereof or abnormal physical or mental state ,

of a human being or animal, and

(c) is used-

(i) as a health supplement, or

(ii) in accordance with those disciplines as determined by Council, or

(d) is declared by the Minister, on recommendation by the Council, by notice in the Gazette to be a complementary medicine;

(b) the addition of the following definition after **"expiry date"**:

"health supplement" means any substance, extract or mixture of substances that—

a) may—

i) supplement the diet;

ii) have a nutritional physiological effect, or

iii) include pre- and probiotics classified as schedule 0, and

b) are sold in pharmaceutical dosage forms not usually associated with a foodstuff and excludes injectables or substances in schedule 1 or higher.

Amendment of Regulation 8

3. Regulation 8 of the Regulations is hereby amended by—

(a) the substitution for sub-paragraph (h)(i) in subregulation (1) of the following sub-paragraph:

"(h) in the case of a medicine for oral or parenteral administration, the quantity of—

(i) sugar or artificial sweetener contained in the medicine and the statement: 'Contains Sugar' or 'Contains Artificial Sweetener'; or";

(b) the substitution for paragraph (bb) in subregulation (1) of the following paragraph:

"(bb) in the case of a complementary medicine—

(i) a statement identifying the discipline of the medicine where relevant; **[and]**

(ii) if the medicine has not received registration with the Medicines Control Council the disclaimer "This medicine has not been evaluated by the Medicines Control Council. This medicine is not intended to diagnose, treat, cure or prevent any disease.";

(iii) in the case of health supplements, upon registration, the disclaimer "Health supplements are intended only to complement health or supplement the diet"; and

(iv) containing genetically modified organisms, compliance with labelling as specified by the Consumer Protection Act, 2008 (Act No. 68 of 2008), in respect of genetically modified organisms.".

Amendment of Regulation 9

4. Regulation 9 of the Regulations is hereby amended by—

(a) the substitution for paragraph (c) in subregulation (1) of the following paragraphs:

"(c) Composition, i.e -

(i) the approved name of each active ingredient and the quantity thereof contained in a dosage unit or per suitable mass or volume or unit of the medicine;

(ii) the approved name and quantity of any bactericidal or bacteriostatic agent included in the medicine as a preservative, expressed as a percentage;

(iii) the quantity of ethyl alcohol included in a preparation for oral or parenteral administration, if such quantity exceeds two per cent by volume;

(iv) the words "contains TARTRAZINE" should the medicine contain such ingredient; **[and]**

(v) in the case of a medicine, for oral administration, which contains or does not contain sugar, the warning: "contains sugar" or "sugar free", whichever is applicable; and

(vi) in the case of a medicine, for oral administration, which contains artificial sweetener, the warning: "contains artificial sweetener".; and

(b) the substitution for paragraph (t) in subregulation (1) of the following paragraph:

"(t) in the case of a complementary medicine-

(i) a statement identifying the discipline of the medicine where relevant; **[and]**

(ii) if the medicine has not received registration with the Medicines Control Council the disclaimer "This medicine has not been evaluated by the Medicines Control Council. This medicine is not intended to diagnose, treat, cure or prevent any disease; and

(iii) in the case of health supplements, upon registration, the disclaimer "Health supplements are intended only to complement health or supplement the diet".".

Amendment of Regulation 10

5. Regulation 10 of the Regulations is hereby amended by the substitution for paragraph (n) in subregulation (1) of the following paragraph:

"(n) in the case of a complementary medicine-

(i) a statement identifying the discipline of the medicine where relevant; **[and]**

(ii) if the medicine has not received registration with the Medicines Control Council the disclaimer "This medicine has not been evaluated by the Medicines Control Council. This medicine is not intended to diagnose, treat, cure or prevent any disease; and

(iii) in the case of health supplements, upon registration, the disclaimer "Health supplements are intended only to complement health or supplement the diet".".

Amendment of Regulation 25

6. Regulation 25 of the Regulations is hereby amended by—

(a) the insertion of the following after the expression "30.3 Blood fractions":

"30.4 Probiotics

30.5 Other"; and

(b) the insertion of the following after the expression "32.16 Others":

"33. Minerals

34. Animal Extracts, Products and Derivatives

35. Fats, Oils and Fatty Acids

36. Carotenoids

37 Bioflavonoids

38. Aminosaccharides

39. Saccharides (including prebiotics)

40. Complementary medicine not otherwise specified

40.1 Discipline Specific Traditional Claim

40.2 Health Supplement - Multiple Substance Formulation".

Amendment of Regulation 25A

7. Regulation 25A of the Regulations is hereby substituted for the following:

"DISCIPLINES OF COMPLEMENTARY MEDICINE

25A. Medicines in category D are subdivided into—

a) such disciplines as may be determined by the Council after consultation with the Allied Health Professions Council of South Africa; and

b) health supplements.".

Amendment of Regulation 40

8. Regulation 40 of the Regulations is hereby amended by the substitution for subregulation (1) paragraph (q)(i) of the following paragraph:

"(q) in the case of a complementary medicine—

(i) a statement identifying the discipline of the medicine where relevant; and"

Amendment of Regulation 45

9. Regulation 45 of the Regulations is hereby amended by—

(a) the substitution for sub-regulation (4) of the following sub-regulation:

"(4) An **[written]** advertisement for a medicine shall contain:"; and

(b) substitution for sub-regulation (4)(c)(v) of the following sub-regulation:

"(v) of a complementary medicine—

(aa) a statement identifying the discipline of the medicine where relevant;

(bb) an indication that the medicine must be used in accordance with the applicable complementary discipline and principles where relevant;

(cc) if the medicine has not received registration with the council the disclaimer: "This medicine has not been evaluated by the council. The medicine is not intended to diagnose, treat, cure or prevent any disease"; and

(dd) in the case of health supplements, upon registration, the disclaimer "Health supplements are intended only to complement health or supplement the diet".

Amendment of Regulation 48

10. Regulation 48 of the Regulations is hereby amended by the substitution of sub-regulation (1) paragraph (w)(i) of the following paragraph:

"(w) in the case of a complementary medicine—

(i) a statement identifying the discipline of the medicine where relevant; and"

Short title

11. These regulations are called the General Regulations made in terms of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965); Amendment.

DR A MOTSOALEDI
MINISTER OF HEALTH
DATE: 11/7/2016

WARNING!!!

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