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# GOVERNMENT NOTICE

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## DEPARTMENT OF HEALTH

No. R. 716

15 September 2014

### 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 any substantiated comments in writing on the proposed amendments to the Director-General: Health, Private Bag X828, Pretoria, 0001 (for attention of the Acting Director: Complimentary Medicines) within three months from date of publication of this notice.

### SCHEDULE

#### Definitions

1. In these regulations "**the regulations**" means the General Regulations as published under Government Notice No. R. 510 in GG 24727 of 15 April 2005, as amended.

"**the Act**" means the Medicines and Related Substances Act, 1965 (Act 101 of 1965)

#### Amendment of Regulation 1

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

### **Amendment of Regulation 8**

3. Regulation 8 of the Regulations is hereby amended by the substitution for paragraph (z) in subregulation (1) of the following paragraphs:

- “(z) the category of medicine immediately preceding the registration or application number;
- (aa) the pharmacological classification of the medicine; and
  - (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.”.”.

### **Amendment of Regulation 9**

4. Regulation 9 of the Regulations is hereby amended by the substitution for paragraph (t) in subregulation (1) of the following paragraphs:

- “(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.”.”.

**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 any 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.”.”.

**Amendment of Regulation 25**

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

- (a) by the insertion of the following after the expression “30.3 Blood fractions” :-  
“30.4 Pre- and Probiotics  
30.5 Other”; and
- (b) by the addition 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.”.

**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) health supplements, and
- b) such disciplines as may be determined by the Council after consultation with the Allied Health Professions Council of South Africa.”.”.

**Amendment of Regulation 40**

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

“(q) in the case of a complementary medicine-

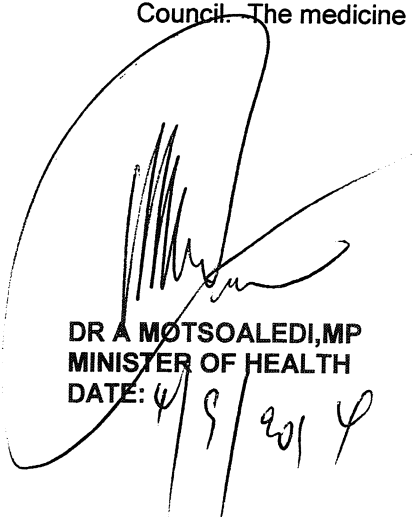
- (i) a statement identifying the discipline of the medicine where relevant; and
- (ii) if the medicine has not received registration with the Medicines Control Council the disclaimer “This medicine has not been evaluated by the Medicines Control Council. The medicine is not intended to diagnose, treat, cure or prevent any disease.”.”.

**Amendment of Regulation 48**

9. Regulation 48 of the Regulations is hereby amended by the substitution of paragraph (w) of subregulation (1) of the following paragraph:

“(w) 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. The medicine is not intended to diagnose, treat, cure or prevent any disease.”.”.



DR A MOTSOALEDI, MP  
MINISTER OF HEALTH  
DATE: 4/9/2014