

GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF HEALTH

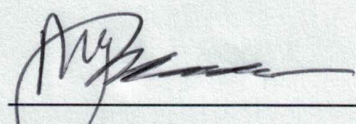
NO. R. 3258

24 March 2023

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 South African Health Products Regulatory Authority (SAHPRA), to make the regulations in the Schedule.

Interested persons are invited to submit any substantiated comments or representations on the proposed regulations to the Director-General of Health, Private Bag X828, Pretoria, 0001 (for the attention of the Director: Public Entities and Relations Management, mihloti.mushwana@health.gov.za and paul.tsebe@health.gov.za) within one month from the date of publication of this Notice.

**DR M.J. PHAAHLA, MP****MINISTER OF HEALTH****DATE:**

06/03/2023

SCHEDULE

Definitions

1. In these Regulations any expression defined in the Act bears that meaning and, unless the context otherwise indicates –
"the Act" means the Medicines and Related Substances Act, 1965 (Act 101 of 1965); and
"the Regulations" means the General Regulations as published under Government Notice 859 in *Government Gazette* 41064 of 25 August 2017.

Amendment of regulation 1 of the Regulations

2. Regulation 1 of the Regulations is hereby amended –
 - (a) by the substitution of the definition of "complementary medicine" for the following definition:
" **"complementary medicine"** means a Category D medicine;"
 - (b) by the insertion after the definition of "counterfeit medicine" of the following definition:
" **discipline-specific medicine** means a Category D medicine contemplated in regulation 9(2)(a) that is intended for use in humans;"
 - (c) by the substitution of the definition of "health supplement" for the following definition:
" **health supplement** means a Category D medicine contemplated in regulation 9(2)(b) that is intended for use in humans;" and
 - (d) by the insertion after the definition of "the Act" of the following definitions:
" **veterinary discipline-specific medicine** means a Category D medicine contemplated in regulation 9(2)(a) that is intended for use in animals;
 - (e) by the insertion after the definition of "the Act" of the following definitions:
" **veterinary health supplement** means a Category D medicine contemplated in regulation 9(2)(b) that is intended for use in animals;"

Amendment of regulation 9 of the Regulations**3. Regulation 9 of the Regulations is hereby amended —**

- (a) by the substitution in sub-regulation (1) for paragraph (d) of the following paragraph:
 - “(d) Category D = Medicines as classified in sub-regulation (2), intended for use in humans or animals which are, without further manipulation, ready for administration, including packaged preparations where only a vehicle is added to the effective medicine.”
- (b) by the substitution in sub-regulation (2) for paragraphs (a) and (b) of the following paragraphs:
 - “(a) medicines identified in class 33 of Annexure 1 and class 28 of Annexure 2; and
 - (b) medicines identified in class 34 of Annexure 1 and class 29 of Annexure 2, excluding medicines or substances listed as Schedule 1 or higher in the Act.”
- (c) by the substitution for sub-regulation (3) of the following sub-regulation:
 - “(3) Medicines in Categories A and D intended for use in humans are subdivided into classes as per Annexure 1”; and
- (d) by the substitution for sub-regulation (4) of the following sub-regulation:
 - “(4) Medicines in Categories C and D intended for use in animals are subdivided into classes as per Annexure 2.”

Amendment of regulation 10 of the Regulations

4. Regulation 10 of the Regulations is hereby amended by the substitution in sub-regulation (1)(cc) for the words “in the case of complementary medicine” of the words “in the case of a Category D medicine”.

Amendment of regulation 11 of the Regulations

5. Regulation 11 of the Regulations is hereby amended —

- (a) by the substitution in sub-regulation (2)(f) for the words “in the case of a complementary medicine” of the words “in the case of a Category D medicine”; and
- (b) by the addition in sub-regulation (2)(t)(ii) after the word “discipline” of the words “of the medicine”.

Amendment of regulation 12 of the Regulations

6. Regulation 12 of the Regulations is hereby amended —

- (a) by the substitution in sub-regulation (2)(n) for the words “in the case of a complementary medicine” of the words “in the case of a Category D medicine”; and
- (b) by the addition in sub-regulation (2)(n)(ii) after the word “discipline” of the words “of the medicine”.

Amendment of regulation 13 of the Regulations

7. Regulation 13 of the Regulations is hereby amended —

- (a) by the substitution in sub-regulation (1)(x) for the words “in the case of a complementary medicine” of the words “in the case of a Category D medicine”;
- (b) by the substitution for in sub-regulation (1)(x)(i) of the following sub-paragraph:
“(i) a statement identifying the discipline of the medicine, or the wording “Veterinary Health Supplement”, as the case may be;”
- (c) by the insertion in sub-regulation (1)(x)(ii) of the word “; and” after the words ““This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.””; and
- (d) by the insertion after sub-regulation (1)(x)(ii) of the following sub-paragraph:
“(iii) the words “Complementary Medicine”.”

Amendment of regulation 14 of the Regulations

8. Regulation 14 of the Regulations is hereby amended —

- (a) by the substitution in sub-regulation (2)(q) for the words “in the case of a complementary medicine” of the words “in the case of a Category D medicine”;

- (b) by the substitution for in sub-regulation (2)(q)(i) of the following sub-paragraph:
“(i) a statement identifying the discipline of the medicine, or the wording “Veterinary Health Supplement”, as the case may be;”
- (c) by the insertion in sub-regulation (2)(q)(ii) of the word “; and” after the words
““This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.””; and
- (d) by the insertion after sub-regulation (2)(q)(ii) of the following sub-paragraph:
“(iii) the words “Complementary Medicine”.”

Amendment of regulation 42 of the Regulations

9. Regulation 42 of the Regulations is hereby amended —

- (a) by the substitution in sub-regulation (5)(c)(ii) for the words “complementary medicine” of the words “Category D medicine”; and
- (b) by the substitution in sub-regulation (5)(c)(ii)(bb) for the word “complementary” of the words “Category D”.

Amendment of Annexure 1 of the Regulations

10. Annexure 1 of the Regulations is hereby amended —

- (a) by the substitution in the heading of Annexure 1 for the words “CLASSES OF MEDICINES IN CATEGORIES A AND D (HUMAN COMPLEMENTARY MEDICINE)” of the words “CLASSES OF MEDICINES IN CATEGORIES A AND D INTENDED FOR USE IN HUMANS”;
- (b) by the substitution in class 33 for the words “Complementary Medicines: Discipline-Specific Traditional Claims” of the words “Discipline-Specific Medicines”; and
- (c) by the substitution in class 34 for the words “Complementary Medicines: Health Supplements” of the words “Health Supplements”.

Amendment of Annexure 2 of the Regulations

11. Annexure 2 of the Regulations is hereby amended —

- (a) by the substitution in the heading of Annexure 2 for the words “CLASSES OF MEDICINES IN CATEGORIES C AND D (VETERINARY COMPLEMENTARY MEDICINES)” of the words “CLASSES OF MEDICINES IN CATEGORIES C AND D INTENDED FOR USE IN ANIMALS”;
- (b) by the substitution in class 28 for the words “Veterinary Complementary Medicines: Discipline-Specific Traditional Claims” of the words “Veterinary Discipline-Specific Medicines”; and
- (c) by the substitution in class 29 for the words “Veterinary Complementary Medicines: Supplements” of the words “Veterinary Supplements”.

Short title

- 12.** These Regulations are called General Regulations Made in Terms of the Medicines and Related Substances Act, 1965 (Act No. 101 Of 1965): Amendment