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# GOVERNMENT NOTICE

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## DEPARTMENT OF HEALTH

No. R. 870

15 November 2013

### 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 has, in consultation with the Medicines Control Council, in terms of section 35 of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), made the regulations in the Schedule.

#### 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 the insertion of the following definition after the definition of "**bonded warehouse**":  
"**clinical trial**" means an investigation in respect of a medicine for use in humans and animals that involves human subjects or animals and that is intended to discover or verify the clinical, pharmacological or pharmacodynamic effects of the medicine, identify any adverse events, study the absorption, distribution, metabolism and excretion of the medicine or ascertain its safety or efficacy;  
  
"**complementary medicine**" means any substance or mixture of substances that-
  - (a) originates from plants, minerals or animals;
  - (b) is used or intended to be used for, or manufactured or sold for use in assisting the innate healing power of a human being or animal to mitigate, modify, alleviate or prevent illness or the symptoms thereof or abnormal physical or mental state; and
  - (c) is used in accordance with the practice of the professions regulated under the Allied Health Professions Act, 1982 (Act No. 63 of 1982);".

**Amendment of Regulation 2**

3. Regulation 2(1) of the Regulations is hereby amended by the substitution for paragraph (a) of the following paragraph:

“(a) (i) are pharmaceutically equivalent, i.e, contain the same amount of active substances in the same dosage form, meet the same or comparable standards and are intended to be administered by the same route; or

(ii) are pharmaceutical alternatives, i.e, contain the same active moiety but differ either in chemical form of that moiety or in the dosage form or strength; and”.

**Amendment of Regulation 6**

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

(a) the substitution for paragraph (b) of the following paragraph:

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

(b) the addition of the following paragraphs:

“(h) name of the final product release responsibility;

(i) date of registration; and

(j) conditions of registration, if any.”.

**Amendment of Regulation 8**

5. Regulation 8 of the regulations is hereby amended by-

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

“(c) the registration number of the medicine allocated in terms of section 15(6) of the Act or the application number allocated by Council in terms of the Act followed by the expression Act 101/1965;”

(b) the addition of the following paragraphs in subregulation (1):

“(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; 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.”;

(c) the substitution for subregulation (2) of the following subregulation:

“(2) If the medicine package bears both an immediate container label and an outer label, the requirements of sub-regulation (1) shall apply to the outer label as well: Provided that it shall be sufficient to provide on the immediate container label-

- (i) in the case of medicines intended for administration by injection and having a total volume not exceeding 5 ml, the details prescribed in paragraphs (b), (e), (m), (n), (o), (p) and (bb) of sub-regulation (1);
- (ii) in the case of an ointment, cream, gel or powder having a net mass not exceeding 10 grams, the details prescribed in paragraphs (b), (c), (e), (f), (n), (o), (p), (x) and (bb) of sub-regulation (1);
- (iii) in the case of liquid, solution or suspension having a total volume of more than 1 ml, but not exceeding 15 ml, the details prescribed in paragraphs (b), (c), (d), (e), (n), (w), (o), (p), (x) and (bb) of sub-regulation (1);
- (iv) in the case of a liquid, solution or suspension having a total volume not exceeding 1 ml, the details prescribed in paragraphs (b), (n) and (bb) of sub regulation (1);
- (v) in the case of a medicine packed in blister or similar packaging, the details prescribed in paragraphs (b), (n), (o), (p) and (bb) of sub-regulation (1), repeated as frequently as is practicable.”; and

(d) the addition in subregulation (4)(c) of the following item:

- “(vii) a statement identifying the discipline of the medicine, if falling under category D

**Amendment of Regulation 9**

6. Regulation 9 of the Regulations is hereby amended by

(a) the substitution for paragraphs (h) and (l) in subregulation (1) of the following paragraphs:

“(h) Warnings and special precautions

(l) Side effects;” and

(b) addition in subregulation (1) of the following paragraphs:

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

(i) a statement identifying the discipline of the medicine; 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**

7. Regulation 10 of the Regulations is hereby amended by-

(a) the substitution for item (ii) in subregulation (1) of the following item:

“(ii) precautions and warnings;”;

(b) the substitution for item (v) in subregulation (1) of the following item:

“(v) the following general statement:

Always tell your health care professional if you are taking any other medicine.

If you are pregnant or breast feeding your baby please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.”;

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

“(g) side effects, including the following general statement:

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice;”;

(d) the addition of the following paragraphs in subregulation (1)

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

- (i) a statement identifying the discipline of the medicine; 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 11**

8. Regulation 11 of the Regulations is hereby amended by the substitution for subregulation (4) of the following subregulation:

"(4) The manufacturer or wholesaler shall keep a record at the business address, of Schedule 2, 3, 4 and 5 medicines and substances in the form of invoices that will reflect."

#### **Amendment of Regulation 12**

9. Regulation 12 of the Regulations is hereby amended by the substitution for paragraphs (c) and (d) in subsection (1) of the following paragraphs:

- "(c) King Shaka International Airport or Durban harbour;
- (d) OR Tambo International Airport."

#### **Amendment of Regulation 16**

10. Regulation 16 of the Regulations is hereby amended by the substitution for subregulation (1) of the following subregulation:

"(1) Notwithstanding regulation 12 and subject to subregulation (3) any person entering the Republic may be in possession, for personal medicinal use, of a quantity of a Schedule, 3, 4, 5 or 6 substance, which shall not exceed a quantity required for use for a period of three months."

#### **Amendment of Regulation 18**

11. Regulation 18 of the Regulations is hereby amended by-

- (a) the substitution for subregulation (1) of the following subregulation:

“ (1) As contemplated in section 22C(1) of the Act, a medical practitioner, dentist or any other person registered in terms of the Health Professions Act, 1974 (Act No. 56 of 1974), practitioner or nurse desiring to dispense or compound and dispense medicines shall apply to the Director-General for a licence to dispense or compound and dispense medicines within his or her scope of practice.”; and

(b) the addition in subregulation (3) of the following paragraph:

“ (j) the scope of practice of the applicant applying for the licence.”.

#### **Amendment of regulation 22**

12. Regulation 22 of the Regulations is hereby amended by the substitution in subregulation (5)(b) for item (vi) of the following item:

“ (vi) category, pharmacological classification, and a statement identifying the discipline if falling under category D;”.

#### **Amendment of Regulation 23**

13. Regulation 23 of the Regulations is hereby amended by the addition of the following paragraphs:

- “(k) category of the medicine;
- (l) pharmacological classification of the medicine; and
- (m) a statement identifying the discipline of the medicine, if falling under category D.”.

#### **Amendment of Regulation 25**

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

(a) the addition in subregulation (1) of the following paragraph:

“ (d) Category D = Complementary medicines intended for use in humans and animals which are, without further manipulation, ready for administration, including packaged preparations where only a vehicle is added to the effective medicine.”;

(b) the substitution for the first sentence of subsection (2) of the following sentence:



“(2) Medicines in categories A and D (human complementary medicines) are subdivided into the following pharmacological classifications:”; and

(c) the substitution for subregulation (3) of the following subregulation:

“(3) Medicines in categories C and D (veterinary complementary medicines) are subdivided into the following pharmacological classifications.”.

#### **Insertion of Regulation 25A**

15. The following heading and regulation are inserted after regulation 25:

#### **“ DISCIPLINES OF COMPLEMENTARY MEDICINES**

**25A.** Medicines in category D are subdivided into such disciplines as may be determined by the Council after consultation with the Allied Health Professions Council of South Africa.”.

#### **Amendment of Regulation 26**

16. The following regulations is hereby substituted for regulation 26 of the regulations:

“26. A certificate of registration substantially in the form shown below shall be issued by the Council in terms of section 15(3) after a medicine has been registered:

#### **MEDICINES AND RELATED SUBSTANCES ACT 1965, (ACT 101 OF 1965): MEDICINE REGISTRATION CERTIFICATE**

It is hereby certified that registration of the medicine described below has been approved by the Council in terms of Section 15(3)(a) of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), subject to the conditions indicated.

1. Proprietary name.....

2. Registration number .....

3. Approved name of every active ingredient and quantities thereof per dosage unit or per suitable mass or volume or unit of the medicine.....

- 4. Dosage form .....
- 5. Conditions under which the medicine is registered .....
- 6. Name of holder of certificate of registration.....
- 7. Name and address of the manufacturer and the manufacturing facility... ..
- 8. Name of the final product release control .....
- 9. Name of the final product release responsibility .....
- 10. Date of registration .....
- 11. Category of medicine.....
- 12. Pharmacological classification.....
- 13. Discipline of medicine, if falling under Category D.....

Registrar

Issued at ..... on.. ..... 20.....”

**Amendment of Regulation 28**

17. Regulation 28 of the Regulations is hereby amended by the substitution in subregulation (1) for paragraph (f) of the following paragraph:

“(f) the strength of the dosage form and the quantity of the medicine to be supplied: Provided that in the case of Schedule 6 substances the quantity to be supplied shall be expressed in figures as well as in words: Provided further that where the prescriber has failed to express the quantity in figures as well as in words, the medical practitioner, dentist, veterinarian or pharmacist dispensing the medicine may, after obtaining confirmation from the prescriber, insert the words or figures that have been omitted;”.

**Amendment of Regulation 30**

18. Regulation 30 of the Regulations is hereby amended by-

(a) the substitution for the heading of the following heading:

**“REGISTER OF SPECIFIED SCHEDULE 5 OR 6 MEDICINES”**; and

(b) the substitution for subregulation (1) of the following subregulation:

“ (1) A person importing, exporting, manufacturing or selling specified Schedule 5 or Schedule 6 medicines or substances shall keep a register of such medicines or substances.”.

**Amendment of Regulation 32**

19. Regulation 32 of the Regulations is hereby amended by the substitution for paragraph (c) in subsection (1) of the following paragraph:

(c) is misbranded or adulterated;”.

**Amendment of Regulation 34**

20. Regulation 34 of the Regulations is hereby amended by the substitution for the title of the Regulation with the following title:

**“CONDUCT OF CLINICAL TRIALS FOR HUMANS AND ANIMALS”**.

**Amendment of Regulation 37**

21. Regulation 37 of the Regulations is hereby amended by the substitution for subregulation (2) of the following subregulation:

“Subregulation (1) also applies in the case of unregistered medicine used in terms of section 14(4), 15C, 21 and 36 of the Act.”.

**Amendment of Regulation 40**

22. Regulation 40 of the Regulations is hereby amended by the addition in subregulation (1) of the following paragraph:

- “(q) in the case of a complementary medicine-
  - (i) a statement identifying the discipline of the medicine; 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 48**

23. Regulation 48 of the Regulations is hereby amended by-

(a) the addition in subregulation (1) of the following paragraphs:

- “(u) the category of medicine;
- (v) the pharmacological classification of medicine; and
- (w) in the case of a complementary medicine-
  - (i) a statement identifying the discipline of the medicine; 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.”;

(b) the substitution for subregulation (2) of the following subregulation:

“(2) If the medicine package bears both an immediate container label and an outer label, the requirements of subregulation (1) shall apply to the outer label as well: Provided that it shall be sufficient to give on the immediate container label-

- (i) in the case of medicines intended for administration by injection and having a total volume not exceeding 5 ml, the details prescribed in paragraphs (a), (b), (e), (k), (l), (m), (n) and (w) of subregulation (1);

(ii) in the case of an ointment, cream, gel or powder having a nett mass not exceeding 10 grams, the details prescribed in paragraphs (a), (b), (c), (e), (m), (n), (o), and (w) of subregulation (1);

(iii). in the case of a liquid, solution or suspension having a total volume more than 1 ml but not exceeding 15 ml, the details prescribed in paragraphs (a), (b), (c), (d), (e), (l), (m), (n), (o), and (w) of subregulation (1);

(iv) in the case of a liquid, solution or suspension having a total volume not exceeding 1 ml, the details prescribed in paragraphs (a), (b), (o), and (w) of subregulation (1);

(v) in the case of a medicine packed in blister or similar packaging, the details prescribed in paragraphs (a), (b), (m), (n), (o), and (w) of subregulation (1), repeated as frequently as is practicable.”; and

(c) by the addition in subsection (4)(c) of the following subparagraph:

“(vii) a statement identifying the discipline of the medicine, if falling in category D.”.

#### **Insertion of Regulations 48A, 48B and 48C**

24. The following headings and regulations are inserted after regulation 48:

#### **“ACQUISITION AND USE OF MEDICINES BY EMERGENCY SERVICES, MASTERS OF SHIPS AND OFFICERS IN CHARGE OF ANY AIRCRAFT**

**48A.** An official in charge of health services at a local government or a medical practitioner designated by such official may, notwithstanding these regulations, on the written request of a person in charge of emergency services, the master of the ship or the officer in charge of an aircraft, authorise the purchase, acquisition, keeping or use of a Schedule 0, Schedule 1, Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6 substance: Provided that the quantity shall be reasonable and on condition that such medicine is intended for emergency medicinal use only.

#### **USE OF MEDICINES FOR EXHIBITION PURPOSES**

**48B.** A manufacturer, importer, wholesaler, distributor or a person marketing medicines may use a medicine or scheduled substance sample for exhibition purposes

or to introduce such medicine or scheduled substance to healthcare providers or the public: Provided that such samples:

(a) are only meant for such exhibition or the launch of such medicine or scheduled substance; and

(b) may not be handed out or given to any healthcare provider or member of the public.”.

## IMPLEMENTATION

**48C.** (1) Amendments addressing complementary medicines as per Regulation 8 Labelling of medicines intended for administration to humans, Regulation 9 Package inserts for medicines for human use, Regulation 10 Patients information leaflet, Regulation 40 Package insert for Veterinary medicines, Regulation 48 Labelling of veterinary medicines shall come into operation three months from the date of publication of this amendment.

(2) With effect from the date of publication of this notice, the Medicines Control Council has by virtue of powers vested in it by section 14(2) of the Act, by resolution approved by the Minister of Health, determined that-

(a) (i) complementary medicines falling in Category D and in the pharmacological classification 20.2.8 (Antiviral agents), 21.2 (Oral hypoglycaemics), 6 (Cardiac medicines), 26 (Cytostatic agents) are subjected to registration and shall relate to medicines that are available for sale in the Republic on the date on which this notice comes into operation and shall relate also to medicines that become available after the said date.

(ii) applications for registration of such medicines as per sub regulation 2(a)(i) that are available for sale in the Republic on the date on which it comes into operation shall be submitted to the Medicines Control Council within six (6) months of the date of this publication.

(b) (i) complementary medicines falling in Category D and in the pharmacological classification 32.3 (Slimming preparations) and pharmacological classifications 7.1, 21.7 (Male sex hormones), pharmacological classification 21.8 (Female sex hormones) and pharmacological classification 21.9 (androgen-oestrogen combinations) claiming sexual stimulation and sexual dysfunction available for

sale in the Republic on the date on which it comes into operation shall be subjected to registration within 24 months of the date of this publication.

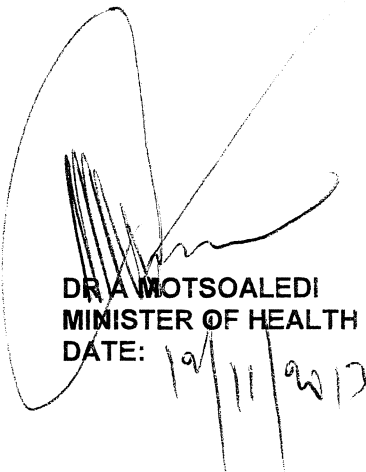
(ii) medicines as per sub regulation 2(b)(i) that become available after the said date shall be subjected to registration in terms of the Act.

(c) (i) complementary medicines falling in Category D and in the pharmacological classification 32.16 (Other) and claiming immune stimulation or expressions of similar connection and medicines falling in pharmacological classification 17 (Medicines acting on muscular system) and pharmacological classification 22 (Vitamins) claiming to be sport supplements and exceeding the upper limit of vitamins and minerals as published by Council that become available after the said date are subjected to registration.

(ii) applications for registration of such medicines as per sub regulation 2(c)(i) that are available for sale in the Republic on the date on which this notice comes into operation shall be submitted to the Medicines Control Council within 30 months of the date of this publication.

(d) (i) complementary medicines falling in category D and in all the remaining pharmacological classifications as per Regulation 25(2) and (3) that are available for sale in the Republic on the date of this notice shall come in operation on the date on which it is published which will not be later than December 2019.

(ii) complementary medicines falling in category D and in the pharmacological classifications as per Regulation 25(2) and (3) that become available after the date of publication of this notice shall be subjected to registration as per the provisions of the Act.



**DR A MOTSOALEDI**  
**MINISTER OF HEALTH**  
DATE: 19/11/2013

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