

No. R. 587

22 July 2011

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, 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), intends to make the regulations in the Schedule.

Interested persons are invited to submit, within three months of publication of this notice, comments on the proposed regulations to the Director-General: Health, Private Bag X828, Pretoria 0001.

SCHEDULE

Amendment of Regulation 1

1. Regulation 1 of the Regulations is hereby amended by the insertion of the following definition after the definition of "clinical trials":

"complementary medicine" means a medicine that is used-

- (a) or intended to be used for, or manufactured or sold for use in assisting the innate healing power of a human being or animal; and
- (b) 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

2. 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, ie contain the same active moiety but differ either in chemical form of that moiety or in the dosage form or strength, administered by the same route but are otherwise not pharmaceutically equivalent; and"

Amendment of Regulation 6

3. 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;"

(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

4. 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) the discipline of the medicine; and
- (ii) the words: "use according to the principles of the discipline".

(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."

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

- "(vii) the discipline of the medicine, if falling under category D

Amendment of Regulation 9

5. Regulation 9 of the Regulations is hereby amended by the addition in subregulation (1) of the following paragraphs:

- " (t) in the case of a complementary medicine-
 - (i) the discipline of the medicine; and
 - (ii) the words: "use according to the principles of the discipline".

Amendment of Regulation 10

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

(a) the substitution in subregulation (1) for subparagraph (e)(v) of the following subparagraph:

" (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."

(b) 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; "

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

- " (n) in the case of a complementary medicine-
 - (i) the discipline of the medicine; and
 - (ii) the words: "use according to the principles of the discipline".

Amendment of Regulation 11

7. 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

8. 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

9. 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 or departing from 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

10. 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) or a 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."

(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

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

“(vi) category, pharmacological classification, and discipline if falling under category D.”

Amendment of Regulation 23

12. 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;
- (m) discipline of the medicine, if falling under category D.”

Amendment of Regulation 25

13. 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 subsection (2) of the following subsection:

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

(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

14. 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

15. 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. Conditions of registration
- 11. Date of registration
- 12. Category of medicine.....
- 13. Pharmacological classification medicine.....
- 14. Discipline of medicine, if falling under Category D.....

.....
Registrar

Issued at on..... 20"

Amendment of Regulation 28

16. 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

17. 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"

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

" (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

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

(c) is misbranded or adulterated."

Amendment of Regulation 40

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

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

- (i) the discipline of the medicine; and
- (ii) the words: "use according to the principles of the discipline"."

Amendment of Regulation 48

20. 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) the discipline of the medicine; and
 - (ii) the words: "use according to the principles of the discipline"."

(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."

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

"(vii) the discipline of the medicine, if falling in category D

Insertion of Regulations 48A and 48B

21. 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

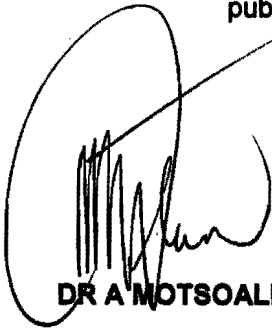
Schedule 6 substance: Provided that the quantity shall be reasonable and on condition that such medicine is intended for emergency medicinal use only.

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."



DR A MOTSOLEDI
MINISTER OF HEALTH