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DEPARTMENT OF HEALTH

NO. R. 2562 **30 September 2022**

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

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

The Minister of Health has, 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), made 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), within one month of the date of publication of this Notice.

DR M.J. PHAAHLA, MP
MINISTER OF HEALTH
DATE: 27/09/2022

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SCHEDULE

Definitions

1. In these Regulations any word or expression to which a meaning has been assigned in the Act, has the meaning so assigned, 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 by the substitution for the definition of "compounding" of the following definition:

" **"compound"** means the preparation, mixing, combining, packaging and labelling of a medicine—

(a) by a pharmacist, pharmacist intern or pharmacist's assistant practising in accordance with the Pharmacy Act, 1974 (Act No. 56 of 1974);

(b) by a veterinarian practising in accordance with the Veterinary and Para-Veterinary Professions Act, 1982; or

(c) by a person licensed in terms of section 22C(1)(a) of the Act and practising in accordance with their scope of practice;"

Amendment of regulation 3 of the Regulations

3. Regulation 3 of the Regulations is hereby amended —

(1) by the substitution for sub-regulation (1) of the following sub-regulation:

"(1A) A pharmacist compounding a medicine for sale in terms of section 14(4)(a) of the Act—

(a) must only compound a quantity that is intended to be used by a particular patient—

(i) for not more than 30 consecutive days from the date of compounding: Provided that the date of compounding and the statement "Use within 30 days" are clearly indicated on the label; or

(ii) in accordance with good compounding practice as determined by the Authority; and

(b) may, based on the amount of medicine compounded previously for a particular patient, compound such medicine in anticipation of supply thereof to such patient.

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(1B) A pharmacist compounding a medicine for sale in terms of section 14(4)(b) of the Act—

(a) must only compound a quantity that is intended for sale in the retail trade, or in accordance with a prescription for a particular person, animal, or group of animals—

(i) for not more than 30 consecutive days from the date of compounding: Provided that the date of compounding and the statement "Use within 30 days" are clearly indicated on the label; or

(ii) in accordance with good compounding practice as determined by the Authority;

(b) may, in the case of medicine intended for sale in the retail trade, based on the amount of such medicine compounded previously for a particular period, compound such medicine in anticipation of supply thereof within such period; and

(c) may, based on a history of receiving a prescription for a medicine for a particular person, animal, or group of animals, compound such medicine in anticipation of receipt of the required prescription and thereafter supply the medicine upon receipt of the prescription.

(1C) A veterinarian compounding a medicine for sale in terms of section 14(4)(a) of the Act—

(a) must only compound a quantity that is intended to be used for a particular animal or group of animals—

(i) for not more than 30 consecutive days from the date of compounding: Provided that the date of compounding and the statement "Use within 30 days" are clearly indicated on the label; or

(ii) in accordance with good compounding practice as determined by the Authority; and

(b) may, based on the amount of medicine compounded previously for a particular animal or group of animals, compound such medicine in anticipation of supply thereof to such animal or group of animals.

(1D) A person licensed in terms of section 22C(1)(a) of the Act to compound a medicine for sale in terms of section 14(4)(a) of the Act—

(a) must only compound a quantity that is intended to be used by a particular patient —

(i) for not more than 30 consecutive days from the date of compounding: Provided that the date of compounding and the statement "Use within 30 days" are clearly indicated on the label; or

(ii) in accordance with good compounding practice as determined by the Authority; and

(b) may, based on the amount of medicine compounded previously for a particular patient, compound such medicine in anticipation of supply thereof to such patient."

(2) by the deletion of paragraph of sub-regulation (3)(a).

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(3) by the substitution for paragraph (*b*) of sub-regulation (3) of the following paragraph:

"(b) which has been declared undesirable in terms of section 23 of the Act or prohibited in terms of section 36A of the Act in the case of a veterinary medicine;

(4) by the substitution for paragraph (*f*) of sub-regulation (3) of the following sub-paragraph:

"(f) for purpose of export, unless:

(i) authorised in terms of the Pharmacy Act, 1974; and

(ii) where applicable, is the holder of a permit issued in terms of section 22A(7)(a) and/or 22A(11)(a) of the Act; or"

(5) by the insertion in paragraph (*g*) after the expression "in accordance with good", of the word "compounding".

(6) by the insertion after sub-regulation (3) of the following sub-regulation:

"(4) The Authority must, within six months of promulgation of these Regulations publish draft guidelines on good compounding practice for public comment."

Short title

4. These Regulations are called Regulations Made in terms of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965: Amendment.

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