DEPARTMENT OF HEALTH

NO. 2853 **8 December 2022**

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 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.

DR M.J PHAAHLA, MP
MINISTER OF HEALTH
DATE: 02/12/2022

SCHEDULE

Definitions

1. In these regulations, any word or expression to which a meaning has been assigned in the Act shall have the meaning so assigned, unless the context indicates otherwise: -

"Authority" means the South African Health Products Regulatory Authority established by section 2 of the Act;

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

"the Regulations" means the General Regulations as published under overnment 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 "compound" of the following definition:

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

(*a*) by a pharmacist practising in accordance with the Pharmacy Act, 1974;

(*b*) by a veterinarian practising in accordance with the Veterinary and Para-Veterinary Professions Act, 1982 (Act 19 of 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 —

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

"(1) A pharmacist—

(*a*) compounding a medicine for sale in the retail trade in terms of section 14(4)(*b*) of the Act must only compound a quantity that is related to a treatment regimen of a particular person or animal to be used by the person or for the animal for not more than 30 consecutive days from the date of sale;

(*b*) must indicate clearly on the label of a medicine compounded for sale in the retail trade in terms of section 14(4)(*b*) of the Act the—

(i) dates of compounding and sale; and

(ii) statement "Use within X days", where X relates to the number of days within which the medicine should be used; and

(*c*) may, in the case of medicine intended for the retail trade, based on the amount of medicine compounded previously for a particular period, compound such medicine in anticipation of supply thereof within such particular period."

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

"(3) No medicine may be compounded by a pharmacist, veterinarian or a person licensed in terms of section 22C(1)(*a*) of the Act to compound a medicine for sale- "

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

(*d*) 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;"

(*e*) by the deletion of paragraph (*f*) of sub-regulation (3)

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

Publication of guidelines

4. The Authority must Within six (6) months of the date of publication of this regulation in the *government gazette*, publish draft guidelines on good compounding practice for public comment.

Short title

5. These Regulations are called General Regulations made in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965): Amendment.