BOARD NOTICE 100 OF 2020

THE SOUTH AFRICAN PHARMACY COUNCIL

RULES RELATING TO GOOD PHARMACY PRACTICE

The South African Pharmacy Council intends to publish amendments to Annexure A of the *Rules relating to good pharmacy practice* which was published on 17 December 2004, Government Gazette No: 27112, Board Notice 129 of 2004, in terms of section 35A(b)(ii) of the Pharmacy Act, 53 of 1974.

Interested parties are invited to submit, within **60 days** of publication of this notice, substantiated comments on or representation regarding the amendments to the existing minimum standards and/or the additional minimum standards. Comments must be addressed to The Registrar, South African Pharmacy Council, Private Bag X40040, Arcadia, or fax (012) 326-1496 or email BN@sapc.za.org

SCHEDULE

Rules relating to what constitutes good pharmacy practice

1. In these rules "the Act" shall mean the Pharmacy Act, 53 of 1974, as amended, and any expression to which a meaning has been assigned in the Act shall bear such meaning.

2. The following rule to Annexure A of the *Rules relating to good pharmacy practice* is hereby amended –

   (a) Rule 2.32 Minimum Standard for the disposal and destruction of medicines and scheduled substances.

TA MASANGO
REGISTRAR

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Rule 2.32 MINIMUM STANDARD FOR THE DISPOSAL AND DESTRUCTION OF MEDICINES AND SCHEDULED SUBSTANCES

***Rule 2.32 is hereby repealed and replaced as follows*:**

2.32.1 Introduction

The disposal and destruction of medicines and scheduled substances may only take place in accordance with the Medicines and Related Substances Act, 101 of 1965 and other applicable legislation.

Regulation 44 of the *General Regulations* published under the Medicines and Related Substances Act, 101 of 1965 states that -

(1) a medicine or scheduled substance shall only be destroyed by a waste treatment facility authorised to destroy medicines or pharmaceutical waste in terms of the National Environmental Waste Management Act, 59 of 2008;

(2) no medicines or scheduled substances other than those as determined by the South African Health Products Regulatory Authority (SAHPRA) shall be disposed of into municipal sewerage systems; and

(3) the disposal and destruction of medicines or scheduled substances must be conducted in such a manner to ensure that the medicines or scheduled substances cannot be salvaged, and the medicine or scheduled substance has been denatured.

In addition, pharmacists and persons authorised to handle medicines in terms of the Medicines and Related Substances Act, 101 of 1965, should not dispose of medicines and scheduled substances in refuse that may be destined for landfill or municipal refuse sites.

2.32.2 Purpose

The purpose of this standard is to ensure that the disposal and destruction of medicines and scheduled substances within pharmacies, medicines rooms or Primary Health Care Clinic (PHC) dispensaries is undertaken safely and in accordance with the requirements of Regulation 44 of the *General Regulations* under the Medicines and Related Substances Act, 101 of 1965, relevant waste management legislation and with due regard to minimising the risk of such an activity causing harm to the environment or harm to the health of the population.

2.32.3 Definitions

(a) ***Authority*** in terms of these Rules shall mean the South African Health Products Regulatory Authority (SAHPRA).

(b) ***Disposal*** in terms of these Rules shall mean the removal of medicines and scheduled substances from the pharmacy, medicine room or PHC dispensary for

purposes of destruction by a waste treatment facility duly authorised by the National Environmental Waste Management Act, 59 of 2008.

(c) ***Destruction*** in terms of these Rules shall mean rendering the medicines and scheduled substances unusable or irretrievable for use or consumption, taking into consideration the environment and harm to the health of the population.

(d) ***Waste treatment facility*** means a site licensed in terms of the *National Environmental Waste Management Act 59 of 2008* that may be used to accumulate waste for the purpose of storage, recovery, treatment, reprocessing, recycling or sorting of that waste. N.B. *Council requires that the waste treatment facility be in possession of a certificate specifically to dispose of medical waste, in line with Section 51(1)(a)* of the *National Environmental Waste Management Act 59 of 2008.*

2.32.4 General considerations

Some of the elements in this standard are not statutory requirements but are good practice which pharmacists would be expected to follow whenever feasible.

(a) All destruction must take place in accordance with local municipal regulations regarding the disposal of chemical or medicinal waste. The person responsible for the destruction may be requested to prove that the method of destruction is in accordance with such regulations.

(b) All medicines and scheduled substances (including medicines and scheduled substances returned by patients) must be disposed in such a manner that does not allow recovery or retrieval.

(c) For the disposal and destruction of medicines or scheduled substances, refer to Regulation 44 (4-6) of the *General Regulations* (2017) published under the Medicines and Related Substances Act, 101 of 1965.

2.32.5 Minimum requirements for the disposal of medicines and scheduled substances

The disposal must be properly documented. All quantities removed must be recorded in a pharmacy stock management system. In the case of specified schedule 5 (where applicable) and schedule 6 medicines and scheduled substances, the quantities of medicines and scheduled substances to be disposed must be indicated in the relevant register and signed by the witnesses required in the procedure.

2.32.5.1 The following details should be recorded:

(a) name, quantity, strength, batch numbers (if applicable) and dosage form of the medicines and scheduled substances;
(b) date of expiry of the medicines and scheduled substances;
(c) in the event of the information detailed in Rule 2.32.5.1(a) and (b) not being available, the weight of the medicines and scheduled substances;
(d) name, position and signature of the person and the witness disposing the medicines and scheduled substances;
(e) reason for the disposal; and

(f) date of disposal.

2.32.5.2 Medicines and scheduled substances destined for destruction should be separated into six types and labelled accordingly as these follow different destruction rules:

(a) solid dosage forms;
(b) creams, ointments and powders;
(c) ampoules and liquids (contained in glass);
(d) aerosols;
(e) radioactive drugs; and
(f) cytostatic and cytotoxic medicines.

2.32.5.3 Collection and on-site transportation of medicines and scheduled substances destined for destruction must be collected on a regular basis to avoid accumulation of the waste.

2.32.6 Minimum requirements for the destruction of medicines and scheduled substances

Subsequent to the destruction detailed in Regulation 44(4) to (6) of the *General Regulations* under the Medicines and Related Substances Act, 101 of 1965, the waste treatment facility shall issue a certificate and maintain a record of the destruction. The certificate shall contain the following information:

(a) name of the medicine or scheduled substance (if known) or the schedule of the medicine or scheduled substance concerned;
(b) quantity destroyed;
(c) date of destruction of the medicine or scheduled substance;
(d) name and designation of a pharmacist (s) and other persons in line with Regulation 44(4) to (6) in whose presence such destruction took place; and
(e) other information as determined by the Authority.

The certificate and the record of the disposal and destruction for the pharmacy, medicine room or PHC dispensary must be kept onsite for 5 years.