BOARD NOTICE 70 OF 2021

SOUTH AFRICAN PHARMACY COUNCIL

RULES RELATING TO GOOD PHARMACY PRACTICE

The South African Pharmacy Council herewith publishes amendments for implementation to the minimum standards as contained in Annexure A of the *Rules relating to good pharmacy practice* which was published on 17 December 2004 Government Gazette No: 27112, in Board Notice 129 of 2004 (as amended) in terms of Section 35A(b)(ii) of the Pharmacy Act, 53 of 1974.

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 rules to Annexure A of the *Rules relating to good pharmacy practice* are hereby amended –

   (a) Rule 1.2.2; and
   (b) Rule 2.32.

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MINIMUM STANDARDS FOR PHARMACY PREMISES, FACILITIES AND EQUIPMENT

Rule 1.2.2 Another business or practice in a pharmacy or a pharmacy in another business

Rule 1.2.2 is hereby repealed and replaced as follows:

1.2.2 Another business or practice in a pharmacy or a pharmacy in another business

(a) the owner and/or the responsible pharmacist of a pharmacy must obtain the approval of Council prior to allowing a person who is not registered with Council to conduct a separate business or practice in the pharmacy.

(b) the following will be considered another business or practice in a pharmacy; if the:

(i) business or practice derives income or profit from members of the public for the activities, services or products provided;
(ii) transactions arising from the activities, services or products provided do not form part of the pharmacy records;
(iii) customer records held by the other business or practice are separate from the pharmacy records;
(iv) health professional or person providing services in the business or practice is not employed by the pharmacy;
(v) business or practice providing services in the pharmacy has its own title, branding and/or is traditionally known by the public as such; and
(vi) business or practice operating within the pharmacy is owned by a third party.

1.2.2.1 Another business or practice in a pharmacy

The following will be applied by Council in considering applications for another business or practice in a pharmacy. The operation of another business or practice, within a pharmacy must be such that:

(a) the other business or practice does not pose any conflicting interest either ethically or professionally to the practice of pharmacy such as:

(i) compromise the pharmacy as a health establishment;
(ii) add any security risk to the acquisition, keeping and supply of medicines;
(iii) add risk to the patients, particularly in terms of patient confidentiality and the right to privacy;
(iv) compromise the quality, safety, and efficacy of the medicine; and/or
(v) compromise the image of the pharmacy and the profession in general.

(b) the activities of the other business or practice must not interfere or compromise the operations of the pharmacy;

(c) the area of the business or practice must be clearly identified, permanent and visibly demarcated within the pharmacy;

(d) the other business or practice shall not operate outside the operating hours of the pharmacy, if the other business or practice shares the same entrance as the pharmacy; and

(e) the other business or practice may not sell products that are prohibited from being sold in a pharmacy, as per rule 2.29.

1.2.2.2 A pharmacy in another business

Where a pharmacy is situated within another business which is not a hospital or other health establishment –

(a) The location of the pharmacy within another business shall take into consideration the:

(i) accessibility of pharmaceutical services;
(ii) security aspects relating to the acquisition, storing and supplying of medicines;
(iii) risk relating to patients, particularly in terms of patients' confidentiality and the rights to privacy;
(iv) quality, safety and efficacy of medicines is not compromised;
(v) pharmacy as a health establishment is not compromised; and
(vi) the pharmacy as a health establishment and the profession in general is not compromised.

(b) The pharmacy premises must be clearly identified, permanent and visibly demarcated from the premises of any other business;

(c) For the purpose of protecting access to medicines and patient confidentiality, such areas (dispensary and where medicines and patient records are kept) must be secured and closed off; and

(d) In order to comply with the requirement of accessibility to pharmaceutical services, a pharmacist must have 24-hour access to the pharmacy.

Rule 2.32 MINIMUM STANDARD FOR THE DESTRUCTION AND DISPOSAL 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, medicine 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 of 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 medicines and scheduled substances for disposal 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 of 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 of 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) radiopharmaceuticals; and
(f) cytostatic and cytotoxic medicines.

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