BOARD NOTICE 139 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

- 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 1.2.2 Minimum Standard for another business or practice in a pharmacy or a pharmacy in another business.

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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Rule 1.2.2 is hereby repealed and replaced as follows: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;
 - 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 in a pharmacy 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.
- (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; and
 - (v) pharmacy as a health establishment 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.