

BOARD NOTICE 106 OF 2011**THE SOUTH AFRICAN PHARMACY COUNCIL****RULES RELATING TO GOOD PHARMACY PRACTICE**

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

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 sections of Annexure A of the *Rules relating to Good Pharmacy Practice* are to be amended—
 - (a) Section 1.2.2
 - (b) Section 2.29
 - (c) Section 1.2.11.5
3. The following section of Annexure A of the *Rules relating to Good Pharmacy Practice* is to be added –
 - (a) Section 1.2.14

Interested persons are invited to submit, within 60 days of publication of this notice, substantiated comments on or representations regarding the Minimum standards for pharmacy premises, facilities and equipment to the Registrar, The South African Pharmacy Council, Private Bag X40040, Arcadia, 0007, or Fax 086 5063010 or email: debbie.hoffmann@sapc.za.org (for the attention of the Senior Manager: Legal Services and Professional Conduct).



TA MASANGO
REGISTRAR/CEO

MINIMUM STANDARDS FOR PHARMACY PREMISES, FACILITIES AND EQUIPMENT

Section 1.2.2: Another business or practice in a pharmacy premises or a pharmacy in another business, is amended as follows:

Paragraph (b) which read as follows:

- (b) The pharmacy premises must be clearly demarcated and identified from the premises of any other business or practice.*

is deleted and replaced with subsections 1.2.2.1 and 1.2.2.2 below:

1.2.2.1 A PHARMACY IN ANOTHER BUSINESS

- (a) The pharmacy premises must be clearly demarcated and identified from the premises of any other business or practice;*
- (b) The demarcation must be permanent, solid and closed-off at all times, which demarcation may be inter alia, brick and mortar, aluminium, steel, glass, dry wall or wood partition;*
- (c) The demarcation must be from floor to the ceiling and must enclose all areas of the pharmacy, which includes but is not limited to the waiting area, the clinic, the semi-private area, the private area and/or clinic;*
- (d) The pharmacy must have a single point of entry and a single point of exit in compliance with the Occupational Health and Safety Act, 85 of 1993 (OHSA).*

1.2.2.2 ANOTHER BUSINESS OR PRACTICE IN A PHARMACY

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

- (a) the other business has obtained approval from their statutory council or registration authority (if applicable) and submit same with the application;*
- (b) the other business does not pose any conflicting interest either ethically or professionally to the practice of pharmacy:*
 - (i) added security risk to the keeping and supply of medicines;*
 - (ii) added risk to the patients;*
 - (iii) compromises the quality, efficacy and safety of the medicine;*
- (c) the premises of the other business must be clearly demarcated and identified from the pharmacy premises:*
 - (i) the demarcation must be permanent, solid, closed-off at all times, that is, brick and mortar, aluminium, steel, glass, dry wall or wood partition;*
 - (ii) the demarcation must be from floor to the ceiling height and must enclose all areas attached to the pharmacy, viz; the waiting area, the clinic, the semi-private area and/or the private area.*

Section 1.2.11.5: Reference Sources, is amended as follows:

Paragraph (a) which read as follows:

- (a) one of the last three (3) editions of Martindale.*

is deleted and replaced with paragraph (a) below:

- (a) one of the last five (5) editions of Martindale.*

The following new section is added:

1.2.14 PHARMACY TRANSACTIONS

*For a pharmacy that is within another business, the following transactions shall take place **within the pharmacy only**:*

- (a) *the prescription shall be handed (sic) in or submitted to the pharmacy;*
- (b) *the dispensing process (phase 1,2, and 3);*
- (c) *the recording of medicines and scheduled substances, which includes the recording of schedule 1 and 2 medicines in terms of Regulation 11 of the General Regulations to the Medicines and Related Substance Act, 101 of 1965;*
- (d) *the payment for all medicine and scheduled substances.*

Section 2.29: Products which may not be sold in a pharmacy, is amended as follows:

Paragraph (e) which read as follows:

- (e) *lotto tickets.*

is deleted and replaced with paragraph (e) below:

- (e) *gambling services and/or products.*



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