

BOARD NOTICE 35 OF 2012
THE SOUTH AFRICAN PHARMACY COUNCIL

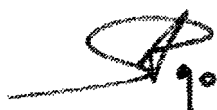
RULES RELATING TO GOOD PHARMACY PRACTICE

The South African Pharmacy Council herewith publishes amendments to minimum standards to Annexure A of the *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 amended—
 - (a) Section 1.2.2
 - (b) Section 1.2.11.5
 - (c) Section 2.29
3. The following section of Annexure A of the *Rules relating to Good Pharmacy Practice* is added –
 - (a) Section 1.2.14



TA MASANGO
REGISTRAR

MINIMUM STANDARDS FOR PHARMACY PREMISES, FACILITIES AND EQUIPMENT

Section 1.2.2: Another business or practice in a pharmacy 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 identified and demarcated 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 height and must enclose all areas attached to the pharmacy, viz; the waiting area, the clinic, the semi-private area and the private area.*
- (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).*
- (e) In order to comply with the requirement of accessibility to pharmaceutical services, a pharmacist must have an unfettered 24 hour access to the pharmacy.*

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 such as:*
 - (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 identified and demarcated from the pharmacy premises:*

- (i) *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;*
- (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 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 over or delivered to a designated pharmacy staff or submitted to the pharmacy directly, e.g. by electronic transmission, postal/courier delivery or deposited in a locked prescription receiving box which is only accessible to the pharmacist (as per GPP rules);*
- (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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