

**BOARD NOTICE 194 OF 2016**  
**THE SOUTH AFRICAN PHARMACY COUNCIL**  
**RULES RELATING TO GOOD PHARMACY PRACTICE**

The South African Pharmacy Council intends to publish amendments and additional minimum standards to be added to Annexure A of the *Rules relating to good pharmacy practice* which was published on the 17 December 2004 Government Gazette No: 27112 in 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 90 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, the South African Pharmacy Council, Private Bag 40040, Arcadia, or fax (012)326-1496 or email [BN@sapc.za.org](mailto: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 minimum standard as published herewith shall constitute an additional standard to be added to Annexure A of the *Rules relating to good pharmacy practice* in accordance with section 35A(b)(ii) of the Act –
  - (a) Minimum standards for the selling of HIV screening test kits.



**TA MASANGO**  
**REGISTRAR**

## MINIMUM STANDARD FOR THE SELLING OF HIV SCREENING TEST KITS

### 1. Purpose

In April 2010, South Africa launched an HIV Counselling and Testing (HCT) campaign that, among other things, sought to increase the number of people who test, know their HIV status and receive treatment. This is in line with the goals laid out in the country's National Strategic Plan (NSP) for HIV, Sexually Transmitted Infections and Tuberculosis, which aims to significantly reduce the number of new infections and expand access to appropriate treatment, care and support to people diagnosed with HIV.

The minimum standard for the selling of HIV screening test kits aims to provide guidance on how the pertinent issues and concerns relating to HIV home testing should be addressed. These pertinent issues and concerns are the reliability of testing instrument, consent and counselling-related concerns.

### 2. General Considerations

Pharmacist must only sell HIV test kits for screening which have been approved by WHO or such suitable authority.

### 3. Pre-test Counselling

Buying a HIV home test kit is deemed to be consenting to testing. Individuals using the tests, however, may not have considered their options and the consequences of the result. Since the person will be performing the test him/herself, access to counselling shall be available to:

- (i) prepare the person for the result of the test;
- (ii) inform the patient that the self-test should not be taken as a conclusive diagnosis; and
- (iii) inform the patient that the diagnosis of HIV infection is dependent on a confirmatory test.

### 4. Knowledge

- (a) Pharmacists must ensure that they have adequate knowledge on all aspects of HIV screening kits as well as have the ability to demonstrate the use of the test kit to patients as the need arises;
- (b) the pharmacists must be able to provide the caregiver/patient with information on:
  - (i) how to conduct the test;
  - (ii) how to correctly interpret the test results; and
  - (iii) where to access follow-up and support services in the surrounding area.