BOARD NOTICE 184 OF 2017

South African Pharmacy Council
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BOARD NOTICE

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) Minimum standard for the sale of HIV self-screening test kits

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MINIMUM STANDARD FOR THE SALE OF HIV SELF-SCREENING TEST KITS

1. Definition

(a) HIV self-screening testing - is a process in which a person collects their own specimen (biological fluid) and then performs a test and interprets the result, often in a private setting, either alone or with a person they trust.

(b) HIV self-screening test kit - is a kit approved by an authority as defined in paragraph 3 for the purposes of self- screening for HIV infection.

2. 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 was followed in 2016 when the National Department of Health adopted the UNAIDS 90-90-90 targets. These initiatives are an attempt to get the HIV epidemic under control and are based on the principle of universal testing and treating. The intention is that by 2020, 90% of people who are HIV infected will be diagnosed, 90% of people who are diagnosed will be on antiretroviral treatment and 90% of those who receive antiretroviral will be virally suppressed. These principles support the goals laid out in the country's National Strategic Plan (NSP) 2017-2022, for HIV, Sexually Transmitted Infections and Tuberculosis, which inter alia, aims to significantly reduce the number of new infections and expand access to appropriate treatment, care and support to people diagnosed with HIV.

In order for this to succeed, HIV testing needs to be taken out of the clinics and into the community, and requires new and innovative ways to get people tested for HIV infection. HIV self-screening test kits could increase the numbers of people that get tested and know their status. The pharmacist is ideally placed to deal with the sale of HIV self-screening test kits, given the sensitivity and the professionalism required in dealing with the condition and as such Council supports the responsible sale of self-testing kits by pharmacists.

The minimum standard for the sale of HIV self-screening test kits aims to provide guidance on how pertinent issues and concerns relating to HIV self-screening should be addressed. The pertinent issues and concerns include:

(a) the reliability and ease of use of the testing instrument;

(b) patient consent;

(c) patient confidentiality and anonymity;

(d) ready access to confirmation of diagnosis and treatment should the test be reactive; and

(e) ready access to information, support, assistance and counselling as required.

3. Specific considerations

Pharmacists must only sell HIV self-screening test kits approved by suitable authorities such as:

(a) South African Health Products Regulatory Authority (SAHPRA); or

(b) World Health Organisation; or

(c) Other regulatory health authorities that SAHPRA aligns itself with such as FDA and EMEA.

4. Accessibility of HIV self-screening test kits

(a) the HIV self-screening test kits may be sold to persons from the age of 12 years and above.

5. The sale of HIV self-screening test kits

A pharmacist must ensure that the person buying this kit has access to the following information:

(a) instructions for use (IFU) leaflet included in the kit and should be followed when self-testing;

(b) screening test should not be taken as a conclusive diagnosis;

(c) diagnosis of HIV infection is dependent on a confirmatory test;

(d) there are three possible outcomes of the HIV self-screening test:

(i) "Reactive" or "Positive" - HIV antibodies have been detected indicating that the client **may** be HIV positive, and there is a need to perform a confirmatory test to validate the outcome;

(ii) "Non-Reactive" or "Negative" - no HIV antibodies have been detected. No further testing is required. The client should take steps to remain negative and may retest in minimum 6 weeks in cases of possible recent exposure (to exclude the window period); and

(iii) "Invalid" or "No Result" - the test has failed and the client should purchase another test kit and repeat the process.

(e) assistance, information and support if required before, during and after the test is available.

6. Knowledge

Pharmacists and/or pharmacy support personnel must ensure that they have adequate knowledge of relevant aspects of HIV and HIV self-screening test kits as well as the ability to demonstrate the use of the test kit to any person as the need arises.

***7.* Support information to be provided**

The following information must be accessible to person(s) purchasing or requesting assistance with HIV self-screening test kit:

(a) referral centres for confirmatory testing and counselling in the case of a reactive or positive result;

(b) information on HIV including how HIV is transmitted;

(c) information and referral on:

(i) Post-Exposure Prophylaxis (PEP) in the case of unintended exposure within 72 hours;

(ii) Pre-Exposure Prophylaxis (PrEP) in the case of ongoing risk to infection; and

(iii) Prevention of Mother to Child Transmission (PMTCT) in the case of exposure during pregnancy, child birth and/or breast-feeding.

This standard must be read together with other relevant standards.