



South African  
Pharmacy Council

## **SOUTH AFRICAN PHARMACY COUNCIL LIFTS THE BAN ON SALE OF HOME-USE HIV SCREENING TEST KITS BY PHARMACIES**

The South African Pharmacy Council, by way of Board Notice 193 of 2016, has amended the Rules Relating to Good Pharmacy Practice (GPP), specifically Rule 2.13.5.8, by deleting paragraph (h) which reads; “Pharmacists must not sell HIV tests for patients to perform at home”. This change to GPP removes the ban on pharmacists to sell home-use HIV tests kits to patients with effect from 23<sup>rd</sup> December 2016. It is important to note at this juncture that home-use HIV screening tests are designed specifically for self-testing and are **not** the same as the clinical screening test kits currently used by healthcare professionals, including pharmacists. Home-use test kits are designed explicitly for use by the general public. The kits have clear, detailed directions with illustrations for usage, are highly sensitive and are intended solely for the screening of HIV antibodies and not as a diagnosis of HIV infection. A positive result with a home-use kit needs to be followed up with a confirmatory test by a healthcare professional before an infection with HIV can be verified.

One of the original reasons for the prohibition on the sale of self-testing kits was the devastating implications a positive result could have on the public when testing at home with no support or counselling. 20 years ago a diagnosis of HIV infection was the equivalent of a death sentence and the negative stigma around HIV infection reinforced social inequalities based on gender, race, ethnicity, class, sexuality and culture. Thankfully the advent of effective treatment with new anti-retrovirals (ARVs) has dramatically changed patient outcomes and now a well-managed HIV positive person can expect to lead a relatively normal life.

Since the publishing of the GPP ban back in 2004 a number of significant changes in the health care arena have occurred. In April 2010, South Africa launched an HIV Counselling and Testing (HCT) campaign that, among other things, sought to massively increase the numbers of people who test, know their HIV status and

receive treatment. This was in line with the goals laid out in the country's National Strategic Plan (NSP) for HIV, Sexually Transmitted Infections and Tuberculosis, which aimed to significantly reduce the number of new infections and to expand access to appropriate treatment, care and support to people diagnosed with HIV. In 2014 UN member states endorsed a new Political Declaration called the '90 90 90' strategy. This strategy called for 90% of all people living with HIV to know their HIV status, 90% of all people diagnosed with HIV infection to receive sustained antiretroviral therapy and 90% of all people receiving antiretroviral therapy to have viral suppression, by 2020.

South Africa recently adopted this ambitious strategy aimed at bringing about an HIV free generation. In line with this strategic objective, and due to the fact that HIV testing kits are already being sold directly to the public by unqualified people, Council decided to review the outdated rule and to allow pharmacists to sell the kits.

The purchase of an HIV screening test kit from a pharmacy gives the public the option of screening themselves for HIV infection in the privacy of their own home with the reassurance that they are using a reliable kit and with the knowledge that there is professional counselling readily available to answer any questions, assist with the interpretation of results and help with referral to appropriate health facilities if necessary.

Council has also published Board Notice 194 of 2016 which proposes a new Minimum Standard for the Selling of HIV Screening Test Kits. Comment by interested parties should be forwarded to the Registrar by 23<sup>rd</sup> March 2017. The aim of this standard is to provide guidance on how the pertinent issues and concerns relating to HIV home testing should be dealt with by the pharmacist. These include the reliability of the testing instrument and how to deal with issues such as consent, counselling and information that needs to be available to the public when purchasing these kits.

Council would like to see pharmacies selling only WHO, or equivalent authority (i.e. bearing United States (FDA), Europe (CE) or Australia (TGA) mark) approved devices. The act of purchasing the kit will be seen as consenting to testing. Since the individual purchasing the test kit may not have considered all of his/her options and the consequences of a positive result, it is important that the public is made aware of the availability of counselling in the pharmacy to prepare the person for the result. The public must also be made aware that the HIV screening test kit is for screening purposes only and that a diagnosis of HIV infection is only made after a second confirmatory test at an approved health facility. Pharmacists should acquaint themselves with the location of these health facilities within their communities in order to be able to refer patients who require further testing.

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Lastly, we urge pharmacists to familiarise themselves with the updated Minimum Standards for the Performance of the HIV Tests (i.e. 2.13.5 with Rule 2.13.5.8(h) deleted), as well as the new Minimum Standard for the Selling of HIV Screening Test Kits for comment, as mentioned above.

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