In July 2012, the Food and Drug Administration (FDA) approved the OraQuick test (OraSure Technologies) as the first HIV self-testing kit in the USA.1 This over-the-counter test, retailing at approximately US$35 - 40 (R245 - 280), uses saliva from a mouth swab and provides a result within 20 - 40 mins. OraSure has established a consumer support centre that provides telephonic support and referrals.2 In a recent study of New York-based men who have sex with men (MSM) who were provided with the self-testing kit, few experienced problems performing the test.7 Studies by the Integration of TB in Education and Care for HIV/AIDS (iTEACH) in rural KwaZulu-Natal, South Africa (SA), are showing equally promising results (K Dong, personal communication). It would seem that, with appropriate support, self-testing is poised to revolutionise HIV-testing.

In a South African context, we consider the implications of the United States Food and Drug Administration’s recent approval of the OraQuick HIV self-testing kit. We argue that current law and policy inhibit the roll-out of accurate and well-regulated self-testing kits, and create a loophole for sale in supermarkets, but not pharmacies.

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FDA stamp of approval means that the public need not be concerned about the accuracy of OraQuick if it were to become available locally, this would not necessarily hold true for other HIV self-tests that are currently obtainable at community pharmacies, and are left unregulated. Although implementing an effective regulatory system for medical devices is challenging, unjustified restrictions such as those in the GPP could easily be addressed.

A recent Civil Society Consensus Statement on strategies to improve HIV testing and counselling highlighted these and other challenges of HIV-testing policies, paradigms and legal frameworks in SA.10 The Statement endorsed self-testing ‘if accompanied by the same essential components of any HIV testing service, including easy access to accurate information’ and linkages to care. These are indeed vital components of the goal to enable everyone in SA to test for HIV regularly, and to do so when and where they choose.

Useful websites:
- ‘The first in-home oral HIV test’: http://www.oraquick.com/home

References