

HIV self-testing kits enjoy successful launch in Portugal

The sale of HIV self-testing kits in Portugal is proving effective, but counterfeit kits risk undermining successes. Gonçalo Figueiredo Augusto reports.



In July 2019, the Portuguese HIV Programme announced that, based on 2017 data, Portugal had already met the UNAIDS 90-90-90 targets 3 years ahead of the 2020 deadline. By the end of 2017, 92.2% of all people living with HIV had been diagnosed, while 90.2% of those diagnosed were receiving antiretroviral therapy and 93.0% of those receiving treatment were virally suppressed. These figures are impressive, especially since Portugal only fully implemented the WHO guidelines of treating all people living with HIV irrespective of their CD4 count or clinical stage in 2015.

In an attempt to reach under-served populations in Portugal and anyone else who remains undiagnosed, the sale of HIV self-testing kits across the country was introduced on Oct 1, 2019. The kits are for sale in community pharmacies costing around €25. A total of 387 HIV self-testing kits were sold in the first month only, according to the Portuguese Association of Pharmacies.

Isabel Aldir, infectious diseases specialist and director of the HIV programme, said these preliminary figures “seem to show people are welcoming self-testing but it is still too early to draw definitive conclusions”. HIV self-testing is an additional testing option for a group of the population who likes to get tested frequently but wishes to do so in absolute anonymity, away from clinics or other providers. Before the introduction of self-testing kits for sale in pharmacies, people were only able to buy self-testing kits online.

As new evidence supporting the provision of HIV self-testing emerged, in 2016 WHO recommended that HIV self-testing should be offered as an additional approach to HIV testing services. However, even though allowed in other European countries,

commercialisation of self-diagnostic HIV tests was not initially allowed in Portugal. The government lifted legal barriers to the commercialisation of self-testing kits in community pharmacies in October 2018. Yet it was not until September 2019 that a pharmaceutical company (Mylan) formally requested approval from the Portuguese Authority of Medicines and Health Products (INFARMED) to commercialise HIV self-testing kits.

The Portuguese HIV Programme was reformed in 2012 and is currently one of the priority health programmes of the Directorate-General of Health. In recent years, the programme has prioritised investment in expanding HIV testing through funding rapid HIV testing in community-based organisations/non-governmental organisations (CBOs/NGOs) and also in public primary health care units. As a result, between 2012 and 2018, the number of rapid HIV tests funded by the HIV programme has almost doubled, reaching 34 458 in 2018.

However, other public bodies are also funding CBOs/NGOs that deliver rapid testing not only for HIV, but also for other sexually transmitted and blood borne infections, including hepatitis B and C. Also, in primary health care units, physicians are increasing HIV testing for their patients. In 2018, 257 485 HIV tests were done in public primary care units in Portugal, around 22 000 more HIV tests than in 2012. With 8% of all people living with HIV still undiagnosed, the Portuguese HIV Programme hopes that HIV self-testing helps the country to reach the UNAIDS 95-95-95 targets well ahead of the 2030 deadline. “Any strategy aiming to facilitate HIV testing will contribute to reach the 95% targets”,

highlights Aldir. “But other actions remain equally important, namely combined prevention, as well as retention and relinkage to health care”, she adds.

Meanwhile, the Swedish Medical Products Agency has identified an HIV self-testing kit from a Chinese manufacturer which does not comply with the European directive on medical devices for in-vitro diagnostics. Although the commercialisation of this device in Portugal has not been reported, INFARMED has issued a general warning stating that this device is sold online and that there is free circulation in the European Economic Area, advising consumers “not to buy or use this device”. Since 2011, INFARMED has been warning consumers and retailers about the dangers of online buying of self-testing devices and the risks of counterfeit kits.

In the UK, regulators have advised the public to beware of counterfeit self-testing kits for HIV and other sexually transmitted infections. The UK Medicines and Healthcare Regulatory Authority (MHRA) says it has seized 12 000 such counterfeit kits between 2015 and 2019. The kits have been returning negative results for HIV when patients are in fact HIV positive. These infected people can then unknowingly infect others, believing themselves to be HIV-negative. The MHRA says that warning signs that devices for sexually transmitted infections are fake include instructions printed on a home printer, the absence of a European safety mark, and non-official looking packaging such as a sandwich bag.

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For more on **UNAIDS 90-90-90 targets for 2020** see <https://www.unaids.org/en/resources/909090>

For more on **UNAIDS 95-95-95 targets for 2030** see <https://www.unaids.org/en/resources/campaigns/World-AIDS-Day-Report-2014>