

POLICY NOTE

THE HIV TESTING KITS AND SERVICES REVOCATION (SCOTLAND) REGULATIONS 2014

SSI 2014/42

1. The above instrument is made in exercise of the powers conferred by section 23 of the Health and Medicines Act 1988. The instrument is subject to negative procedure.

Purpose of the instrument

2. This instrument revokes the HIV Testing Kits and Services Regulations 1992 (S.I. 1992/460) (the “**1992 Regulations**”) in Scotland, which made it an offence, subject to certain exceptions, to advertise HIV testing kits, services or components, to sell or supply an HIV testing kit or component to a member of the public, to sell or supply an HIV testing kit without an accompanying warning notice and to provide HIV testing services which are not provided or directed by a registered medical practitioner.

Policy Objectives

3. The revocation of the 1992 Regulations will permit the sale or supply of HIV self-testing kits, from 6 April 2014, which meet existing European quality standards set out in the *In Vitro Diagnostic Medical Devices Directive (98/79/EC)* (the “**IVD Directive**”).
4. The 1992 Regulations made it illegal to advertise, sell or supply an HIV testing kit to a member of the public. They also required that a registered doctor must provide, or supervise, all HIV testing services. In 1992 there was no effective treatment for HIV and while testing was becoming easier there were serious concerns around people getting tested without any pre-test counselling, under duress or without consent. There were also concerns that test results could be misinterpreted or not confirmed since they would not be supervised by a qualified healthcare professional. In 1992 the outlook for people diagnosed with HIV was very different to today. Before the introduction of effective treatment (known as antiretroviral therapy) an HIV diagnosis for most people would have led to AIDS, and death within months or a few years. For many people an HIV diagnosis would have had a significant psychological impact due to HIV being a stigmatised life limiting illness for which there was no treatment as well as the likelihood of discrimination with respect to employment, housing and other services. HIV professional and voluntary sector organisations, including the Terrence Higgins Trust, supported the 1992 Regulations.
5. Effective treatment for HIV became widely available through the NHS from 1996/97 and it has dramatically transformed the outlook for people diagnosed

with HIV. Today, diagnosed early and with access to treatment most people with HIV can expect a near normal life expectancy.

6. Removal of the 1992 Regulations will support the policy objective of increasing HIV testing to reduce undiagnosed and late diagnosis of HIV by increasing the choices available to individuals on how they test for HIV. Health Protection Scotland estimate that there are currently 4572 people diagnosed with HIV living in Scotland and a further 22% of people are estimated to remain undiagnosed. This means they are unable to benefit from highly effective HIV treatment and risk transmitting HIV to uninfected partners. There were 349 new diagnoses of HIV in 2013 in Scotland. In 2012, 42% of those newly diagnosed were at a late stage of infection, that is after the point at which treatment is recommended. Men who have sex with men (MSM) remain most at risk of HIV infection in Scotland followed by people originating from sub-Saharan Africa, many of whom acquire their infection abroad.
7. Although their sale has been illegal since 1992, there is evidence that HIV testing kits have been sold illegally through the internet, mostly from suppliers outside the UK or European Union. There is evidence that such kits have been of poor quality, are not intended for use without medical supervision and have included insufficient information about confirmatory testing. Removing the current ban will subject legal self-testing kits to existing regulatory Europe-wide quality standards. HIV testing kits placed on the European market will need to meet the requirements of the IVD Directive and Medical Devices Regulations 2002. The IVD Directive sets out specific requirements for self-testing devices including instructions for use by a lay user.
8. We anticipate that, following the removal of the ban, NHS Scotland will continue to provide the vast majority of HIV tests. However, legalising the sale of HIV self-testing kits will mean that individuals concerned about their HIV status, yet reluctant to use existing confidential HIV testing services, will be able to purchase a safe self-testing kit as an alternative. It is anticipated that self-testing kits will use a saliva sample. A positive test result from a self-test will always require a follow-up confirmatory blood test in a clinical setting and information on this will be included as part of the kit. Manufacturers of self-testing HIV kits are required, under the IVD Directive, to state the performance claims for sensitivity (the risk of false negatives) and specificity (the risk of false positives) in the labelling of the kit.
9. HIV self-testing kits differ from HIV sampling kits which have been available for some time and are legal. Home sampling kits involve the collection of a sample of saliva or blood which the individual sends to a registered laboratory for analysis which then send the result to the individual. HIV remains a stigmatised health condition which can deter some people from using testing services offered by the NHS or HIV community organisations. Legalising the sale of self-testing kits provides another safe means of testing. A survey by Terrence Higgins Trust in 2011 of 657 people in Britain indicated that 78% of gay men who had not tested or had last tested negative were in favour of legalising HIV self-testing. Sixty five per cent of all respondents (both HIV

positive and negative) supported legal HIV self-testing with 65% of gay men reporting that they would consider using a self-test kit. In 2012, the United States Food and Drug Administration approved the first over-the-counter HIV self-testing kit for home use which uses a saliva sample.

Other administrations

10. These Regulations apply in relation to Scotland only and will come into force on 6 April 2014. Parallel regulations are being made for England, and separately for Wales, and these are also due to come into force on 6 April 2014.

Consultation

11. The Scottish Government has not carried out a formal consultation given the support for the removal of the 1992 Regulations from HIV charities and others. However in 2013, over a period of four weeks, the Department of Health (DH) sought views from the leading HIV charities - the Terrence Higgins Trust and National AIDS Trust - and the two national HIV and sexual health professional organisations (the British HIV Association and the British Association for Sexual Health and HIV). DH also discussed the legalisation of HIV self-testing kits with Public Health England and the Expert Advisory Group on AIDS (EAGA), (a Departmental Expert Committee which provides advice to the UK health departments' Chief Medical Officers on matters relating to HIV). All supported legalisation to increase options and choices for HIV testing.
12. In late 2013 HIV Scotland held a seminar for key Scottish stakeholders (including patient representatives, the third sector and NHS Boards) to discuss self-testing kits. The feedback from the seminar was that there is largely support for the legalisation of self-test kits within Scotland.
13. The House of Lords HIV Select Committee in their 2011 report *No Vaccine, no cure: HIV and AIDS in the United Kingdom* (Cm 8190) also recommended removing the ban on the sale of HIV self-testing kits to help reduce undiagnosed and late diagnosed HIV. The Scottish Government responded to the House of Lords report in September 2011 supporting this recommendation and a review of the legislation which banned the sale of HIV self-testing kits.

Impact Assessments

14. An equality impact assessment has not been carried out. Removing this offence will have a positive equalities impact as it will make access to testing for HIV – which continues to be a highly stigmatised condition – more accessible to those who do not wish to access existing testing services. It extends choice and, for example, means that individuals in remote and rural communities can access testing more easily. It is expected to support

improvements in the diagnosis of people who are infected by HIV but currently unaware, leading to an improvement in their health and wellbeing.

Financial Effects

15. Removal of the 1992 Regulations will have a positive impact on businesses who will be able to manufacture and market HIV self-testing kits which meet existing Europe-wide quality controls. It will also have a positive impact on those HIV charities who provide testing services by expanding the range of tests they can offer.
16. Some Third Sector or NHS organisations will wish to make use of the tests, and there will be a cost associated with this for those organisations. However use of these tests will be entirely voluntary, and other, free of charge, testing routes will remain in place.
17. We expect the impact on HIV testing services provided by the NHS in Scotland to be negligible given that we anticipate that the vast majority of HIV tests will continue to take place, free of charge, in self-referral sexual health clinics where they are often done alongside other tests for sexually transmitted infections. If a person receives a positive indication of HIV infection from a self-test kit they will require a further confirmatory test in a clinical setting before the start of any treatment.
18. Increasing the choices available on how people get tested for HIV should lead to a reduction in the proportion of new HIV diagnoses currently diagnosed late (42%) and enable access to earlier NHS treatment. This benefits both the individual with diagnosed HIV and the NHS since HIV treatment costs increase the later HIV is diagnosed.

**Scottish Government
Public Health and CMO Directorate**

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