EXPLANATORY MEMORANDUM TO

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

2014 No. 451

1. This explanatory memorandum has been prepared by the Department of Health (DH) and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 This instrument revokes the HIV Testing Kits and Services Regulations 1992 (S.I. 1992/460) (the "**1992 Regulations**") in England, 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.

3. Matters of special interest to the Joint Committee on Statutory Instruments

None.

4. Legislative Context

4.1 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**").

4.2 The enabling provision for this instrument is section 23 of the Health and Medicines Act 1988. This section provides that regulations may be made, subject to the negative resolution procedure, to provide the offences described in paragraph 2.1 above and to make other incidental or supplemental provisions as appropriate. Section 14 of the Interpretation Act 1978, implies a power, exercisable in the same manner and subject to the same parliamentary procedure, to revoke any instrument made under the enabling power.

5. Territorial Extent and Application

5.1 This instrument applies to England only. We understand that the devolved administrations for Scotland and for Wales aim to revoke the SI as it applies to Scotland and Wales from the same date.

5.2 The enabling provision for this instrument applies to England, Wales and Scotland. This function of the Secretary of State, in respect to Wales, was

transferred to the Welsh Ministers and, in respect to Scotland, was transferred to the Scottish Ministers.

6. European Convention on Human Rights

As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

7.1 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 would lead to AIDS and death within months or a few years. For most people an HIV diagnosis would have had a significant psychological impact linked to a stigmatised life limiting illness for which there was no treatment as well as discrimination with respect to employment, housing and other services. HIV professional and voluntary sector organisations, including the Terrence Higgins Trust, supported the 1992 Regulations.

7.2 Effective treatment for HIV became widely available through the NHS in England from 1996/97 and it has dramatically transformed the outlook for people with diagnosed HIV. Today, diagnosed early and with access to treatment most people with HIV can expect a near normal life expectancy.

7.3 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. Public Health England estimate that at the end of 2012 there were an estimated 91,500 people are living with HIV in England of whom approximately a fifth (22%) were unaware of their infection. This means they are unable to benefit from highly effective HIV treatment and risk transmitting HIV to uninfected partners. There were 5,846 new diagnoses of HIV in 2012 in England and almost half of these were diagnosed late, that is after the point at which treatment is recommended. Men who have sex with men remain the group most at risk of HIV infection in England followed by black African communities who acquired their infection abroad.

7.4 The NHS in England undertakes over one and a half million free HIV tests a year in sexual health and antenatal services. Nearly a million tests take place in self-referral sexual health clinics where same-day HIV testing is also widely available where test results are available within a few hours or less. We anticipate the NHS in England 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 in 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.

7.5 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.

7.6 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.

8. Consultation outcome

8.1 The Department of Health has not done 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 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 (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. One organisation raised a concern about the quality of patient information included in self-test kits which would need to be clear about seeking medical advice and a follow-up test in a clinical setting, if a self-test gave a positive indication of HIV infection. However this concern is mitigated by the requirement of the IVD Directive on patient information including on seeking medical advice.

8.2 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 Government responded to the House of Lords report in September 2011 supporting this recommendation and reported that the Department of Health would review the policy which banned the sale of HIV self-testing kits.

8.3 The Department of Health did a limited consultation with the aforementioned organisations and others to firm up estimates of the costs and benefits of the removal of the 1992 Regulations. The impact assessment takes account of stakeholders' comments on the methodology used to estimate the costs and benefits to business of removing the 1992 Regulations.

9. Guidance

9.1 There are no plans to issue guidance given the impact of removing the 1992 Regulations falls primarily on businesses which choose to develop and market an HIV self-test kit.

10. Impact

10.1 Removal of the 1992 Regulations will have a positive impact on businesses which 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.

10.2 As mentioned (paragraph 7.4) we expect the impact on HIV testing services provided by the NHS in England 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 test 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. From April 2013, local authorities in England commission HIV prevention services. Over time it is possible that local authorities might purchase HIV self-testing kits and make them available free-of-charge to groups at increased risk of HIV, as part of local targeted HIV prevention programmes.

10.3 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 (47%) 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.

10.4 The Reducing Regulation Committee (RPC) has confirmed that removal of the 1992 Regulations is deregulatory in nature and is eligible for fast-track status under the Government-wide Red Tape Challenge and the One-In-Two-Out initiatives. A draft Validation Impact Assessment is attached to this memorandum. The impact assessment has not been validated by the Regulatory Policy Committee but represents the Department's current best estimate of the size of the market. Work is on-going to finalise the estimates in the impact assessment and seek RPC validation.

11. Regulating small business

11.1 The legislation applies to small businesses and will enable them to advertise and sell quality-assured HIV self-testing kits to the public.

12. Monitoring and review

12.1 When quality-assured HIV self-testing kits become routinely available for sale, after 6 April 2014, the Department of Health will work with Public Health England, and others to consider the contribution of HIV self-testing kits to HIV testing rates more generally.

13. Contact

Kay Orton Department of Health Tel 020 7210 6214
kay.orton@dh.gsi.gov.uk can answer any queries regarding the instrument.