Explanatory Memorandum to the HIV Testing Kits and Services Regulations 1992 (Revocation) (Wales) Regulations 2014

This Explanatory Memorandum has been prepared by the Department for Health and Social Services and is laid before the National Assembly for Wales in conjunction with the above subordinate legislation and in accordance with Standing Order 27.1.

Minister's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of the revocation of the HIV Testing Kits and Services Regulations 1992

Mark Drakeford

Minister for Health and Social Services, one of the Welsh Ministers

10 February 2014

1. Description

1.1 This Statutory Instrument revokes the HIV Testing Kits and Services Regulations 1992. Removal of these Regulations will legalise the sale of HIV self-testing kits, from 7 April 2014, which meet existing European quality standards set out in the *In Vitro Diagnostic (IVD) Medical Devices Directive (98/79/EC)* (IVD).

2. Matters of special interest to the Constitutional and Legislative Affairs Committee

2.1 None.

3. Legislative background

3.1 The Department of Health ("DoH") has confirmed that the Regulations in relation to England will be repealed using subordinate legislation.

3.2 The HIV Testing Kits and Services Regulations 1992 were made under section 23 of the Health and Medicines Act 1988.

3.3 The functions of the Secretary of State to make regulations in relation to HIV testing kits and services under section 23 of the Health and Medicines Act 1988 were transferred to the National Assembly for Wales by Article 2 and Schedule 1 of the National Assembly for Wales (Transfer of Functions) Order 1999 (SI.1999/672). These functions were subsequently transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (2006 c.32).

3.4 The Welsh Ministers have the power to create and remove regulations relating to HIV testing and services. The repeal of the 1992 Regulations will require a statutory instrument in Wales as the regulation making power is within the legislative competence of the National Assembly for Wales.

3.5 This instrument will follow the negative resolution procedure. This means that it will be made and laid before the Assembly but should not be brought into force until at least 21 (calendar) days from the date of laying. Subordinate legislation subject to the negative procedure comes into force on the date specified in the instrument, but there is a period during which the National Assembly for Wales can resolve to annul such instruments after they have been made. Standing Orders provide that this must be done within 40 calendar days from the date of laying – not including days whether the Assembly is dissolved or in recess for more than four days. Unless an annulment motion is tabled, there shall be no debate of this instrument in Plenary.

4. Purpose & intended effect of the legislation

4.1 The 1992 Regulations make it illegal to advertise, sell or supply an HIV testing kit to a member of the public. They also require that a registered medical practitioner (i.e. registered doctor) must provide, or supervise, all HIV testing services.

4.2 The Regulations were justified at the time they were made by concerns over the quality of HIV testing kits on the market (HIV was a new disease, testing kits for home use were unreliable and could be misleading). There were also concerns that individuals could be coerced by sexual partners, employers and others into testing, without any pre-test counselling, for a serious sexually transmitted infection, for which there was no effective

treatment available. Even if an individual voluntarily took the test, there could be substantial psychological costs due to a positive result being akin to a death sentence. In addition, there was significant imperfect information about HIV on the consumer side, and the Government retained some role in acting as a quality guardian.

4.3 However, since 1992, there has been progress on both these fronts. Highly effective treatment became widely available in 1996, so that well controlled HIV is no longer a "death sentence", and HIV testing technology has improved considerably.

4.4 Removal of these 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 get tested for HIV. Public Health England estimate that around 100,000 people are living with HIV in the UK of which almost a quarter are unaware they are infected. This means they are unable to benefit from highly effective HIV treatment and risk transmitting HIV to uninfected partners. There were 6,000 new diagnoses of HIV in 2011 and almost half of these were diagnosed late, that is after the point at which treatment is recommended. Gay and bisexual men remain the group most at risk of HIV infection in the UK followed by black African communities who acquired their infection abroad.

4.5 Removal of the current Regulations would mean that from April 2014, any HIV self-testing kit (also referred to as a home testing kit), which satisfies existing Europe-wide quality assurance standards (set out in the *IVD Medical Devices Directive (98/79/EC)*) could legally, be placed on the UK market.

4.6 The NHS undertakes over a million free HIV tests a year, with the majority taking place in confidential sexual health clinics where same-day HIV testing is also widely available. We anticipate the NHS will continue to provide the vast majority of HIV tests. However, legalising the sale of HIV self-testing kits would mean that individuals concerned about their HIV status, yet reluctant to use existing confidential NHS HIV testing services, could purchase a safe self-testing kit as an alternative. It is anticipated that self-test kits will use a saliva sample. A positive test result from a self-test would always require a follow-up confirmatory full blood test in a clinical setting and information on this would be included in the information included in a self-test kit.

4.7 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 must meet the requirements of the *IVD Medical Devices Directive (98/79/EC)* and Medical Devices Regulations 2002. The IVD Directive sets out specific requirements for self-testing devices including instructions for use by a lay user.

4.8 In 2012, the United States Food and Drug Administration approved the first over-the-counter self-testing HIV kit for home use which uses a saliva sample. 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.

4.9 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 would provide another safe means of testing. A survey by the Terrence Higgins Trust in 2011 of 657 people indicated that seventy eight per cent 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 (i.e. both HIV positive and negative) supported legal HIV self-testing with sixty five per cent of gay men reporting that they would consider using a self-test kit.

5. Consultation

5.1 There has been no formal consultation. The UK Government sought views from the Terrence Higgins Trust and National AIDS Trust, the British HIV Association, the British Association for Sexual Health and HIV, Public Health England and the Expert Advisory Group on AIDS. WG officials have also approached Public Health Wales for their views on the impact in Wales. All supported legalisation to increase options for HIV testing. One organisation raised a concern about the quality of patient information included in self-test kits since this 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. Removal of the current ban was also a recommendation of the House of Lords HIV Select Committee in their 2011 Report (*'No vaccine, no cure: HIV and AIDS in the United Kingdom*', Chapter 6, para 214).

5.2 The Department of Health did undertake a limited consultation with the aforementioned organisations to firm up estimates of the costs and benefits of the removal of these Regulations in line with the requirements of the Regulatory Policy Committee. The Validation Stage Impact Assessment takes account of stakeholders' comments on the methodology used to estimate the costs and benefits to business of removing these Regulations.

6. Regulatory Impact Assessment (RIA)

6.1 Removal of these Regulations will have a positive impact on businesses that will be able to manufacture and market HIV self-testing kits which meet existing Europe-wide quality controls. It would also have a positive impact on those HIV charities that provide testing services by expanding the range of tests they can offer.

6.2 The impact on the NHS is negligible given that we anticipate the NHS will remain the main provider of HIV testing.

6.3 Businesses will be positively impacted by the removal of the ban through repeal of the Regulations, as it permits the creation of a market for HIV testing kits. Although HIV infection rates may fall over time, the severity of the disease and the widespread education relating to it will ensure that testing kits will have a viable market for many years to come. There remains a barrier to entry in that any kits introduced to the market must adhere to appropriate levels of quality. This is typical for all over-the-counter medical products and is put in place to ensure patient safety.