EXPLANATORY MEMORANDUM TO

THE HIV TESTING KITS AND SERVICES (REVOCATION) REGULATIONS (NORTHERN IRELAND) 2015

2015 No. 412

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Health, Social Services and Public Safety ("the Department") to accompany the Statutory Rule (details above) which is laid before the Northern Ireland Assembly.

1.2 The Statutory Rule is made under Article 12(1) of the Health and Medicines (Northern Ireland) Order 1988 and is subject to the negative resolution procedure.

2. Purpose

2.1 The HIV Testing Kits and Services (Revocation) Regulations (Northern Ireland) 2015 ("the 2015 Regulations") revoke the HIV Testing Kits and Services Regulations (Northern Ireland) 1992 (SR 1992 No. 293) ("the 1992 Regulations") which made it an offence, subject to certain exceptions, to advertise HIV testing kits, services or components, to sell or supply a 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.

2.2 The 2015 Regulations will permit the sale, supply and advertising of HIV self-testing kits, from 29 January 2016, which meet existing European quality standards set out in the *In Vitro Diagnostic Medical Devices Directive (98/79/EC).* Removal of the ban 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.

2.3 These Regulations apply only to Northern Ireland.

3. Background

3.1 Currently anyone wishing to test for HIV has to go to a health professional at a GP surgery or sexual health or Genitourinary Medicine (GUM) clinic. HIV is a stigmatised health issue which can deter some people from accessing existing HIV testing services. Legalising the sale of HIV self-testing kits will increase the options to test and will have an important role in reaching those who are not using existing services.

4. Consultation

4.1 The Department undertook a public consultation (1 October 2014 to 31 December 2014) on the proposal to remove the ban on the sale of HIV self-testing kits directly to

the public in Northern Ireland. A total of 22 responses were received, which included responses submitted on behalf of Health and Social Care organisations, voluntary organisations, professional bodies and unions; and responses from individuals working in Health and Social Care and from members of the public.

4.2 The majority of respondents to the consultation broadly welcomed the proposal but stressed the need for safe and regulated kits, with clear information for the kit user, including the instruction to follow up a reactive result with a health professional for confirmatory testing; and the provision of information on HIV and other sexual health matters.

4.3 At the time of the consultation, there was no approved (CE-marked) HIV self-testing kits available on the UK market. Since then a HIV self-testing kit has been approved for sale and the regulatory requirements (*In Vitro Diagnostic Medical Devices Directive (98/79/EC)* will address many of the issues raised by respondents to the consultation. The Department will work with the Public Health Agency to make available public information on HIV self-testing.

5. Equality Impact

5.1 An Equality Screening, Disability Duties and Human Rights Assessment on the implications of the policy change was carried out prior to consultation, and reconsidered taking account of the responses received. The 2015 Regulations are considered to be compliant with section 75 of the Northern Ireland Act 1998.

6. Regulatory Impact

6.1 The 2015 Regulations are deregulatory in nature and a Regulatory Impact Assessment is not considered necessary because they will not result in any costs or savings, or increased fees by predetermined formula such as the rate of inflation. It is not anticipated that there will be any adverse impact on business, charities, social economy or voluntary bodies.

7. Financial Implications

7.1 There are no financial implications of the 2015 Regulations in relation to public funds. There will be financial implications for an individual who chooses to purchase a HIV self-testing kit.

8. Section 24 of the Northern Ireland Act 1998

8.1 The 2015 Regulations revoke the 1992 Regulations which as they stand are considered to be in contravention of section 24(1)(b) of the Northern Ireland Act 1998 since an approved HIV self-testing kit became available on the UK market. The Department is satisfied that the 2015 Regulations are not incompatible with any of the Convention rights or community law, and do not discriminate against a person on the grounds of religious belief or political opinion.

9. EU Implications

9.1 The 2015 Regulations revoke the 1992 Regulations which are incompatible with the free movement of goods within the EU.

10. Parity or Replicatory measure

10.1 Separate but equivalent legislation to revoke their respective HIV Testing Kits and Services Regulations 1992 came into force in England, Wales and Scotland on the 6 April 2014 (prior to an approved HIV self-testing kit being available on the UK or EU market).

11. Additional Information

11.1 Not applicable.