Department of
Health, Social Services
and Public Safety
www.dhsspsni.gov.uk

CONSULTATION ON A PROPOSAL TO REMOVE THE BAN ON THE SALE OF HIV SELF-TESTING KITS TO THE PUBLIC IN NORTHERN IRELAND

OCTOBER 2014

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The Consultation

Introduction

1.1 The Department of Health, Social Services and Public Safety (the Department) invites your views on a proposed policy change to revoke the HIV Testing Kits and Services Regulations (NI) 1992 (the Regulations), thereby removing the ban on the sale of HIV self-testing kits directly to the public in Northern Ireland.

1.2 Currently, anyone wishing to test for HIV has to go to a health professional to do so, for example, to a GP or sexual health or genitourinary medicine (GUM) clinic. Some people are reluctant to use existing testing services, and many HIV infections are diagnosed late, meaning that treatment can be more difficult.

1.3 "Self-testing" is where an individual who wants to know his or her HIV status, collects a sample, performs a test and interprets the result in private, i.e. the individual does not need to go to a GP or clinic for a test, and the sample is not sent away to a laboratory for diagnosis and result. HIV self-testing kits are also known as home testing kits and are similar in approach to home pregnancy or diabetes monitoring tests.

1.4 The proposed change would enable an individual to buy a HIV self-testing kit in Northern Ireland to test him/herself for HIV and find out the results about their HIV status quickly and in private. HIV self-testing detects signs of an immune response but does not provide a definitive diagnosis. A reactive (positive) result of HIV from self-testing must be confirmed by a health professional in a clinical setting.

1.5 Removing the ban on HIV self-testing kits in Northern Ireland is intended to encourage earlier detection of HIV here. Early diagnosis and treatment of HIV improves an individual's prognosis (the course and outcome of the infection), and reduces the chance of onward HIV transmission. HIV self-testing provides an opportunity for people to test themselves; it may enable people who are not currently reached by existing HIV testing and counselling services to obtain information about their HIV status; and may provide an additional pathway to HIV prevention, care and treatment.

1.6 This consultative document sets out the background to the proposal and invites general comments and responses to the consultation questionnaire. We are particularly keen to hear from members of the public, health professionals, Health and Social Care organisations, voluntary organisations representing and supporting those who are most at risk of HIV, and any other interested parties.

Background

HIV

2.1 HIV stands for Human Immunodeficiency Virus. The virus attacks the immune system, and weakens an individual's ability to fight infections and disease. HIV is transmitted through sexual contact, blood-borne contact (by sharing needles and other injecting equipment contaminated with blood) and from infected mother to child.

2.2 Social contact such as living together, eating together, coughing, sneezing and using the same toilet will not transmit HIV. The HIV virus is present in very low concentrations in saliva – too low to be infectious, but with new technology, some HIV tests can detect HIV in saliva.

2.3 There is no cure for HIV, but there are treatments to enable most people with the virus to live a long and healthy life. In Northern Ireland, the specialist HIV clinic in the Royal Victoria Hospital provides people diagnosed as HIV positive with a network of support and access to a counsellor, social worker, dietician, dentist, pharmacist and specialist doctors.

2.4 AIDS is the final stage of HIV infection, when the body can no longer fight life-threatening infections. With early diagnosis and effective treatment, most people with HIV will not go on to develop AIDS. Further information on HIV and AIDS is available at http://www.nidirect.gov.uk/hiv-and-aids

2.5 The advertising and sale of HIV testing kits directly to the public was banned in 1992. This was primarily because of concerns over the performance of tests emerging on the market and the need for pre- and post- test counselling to be provided.

HIV in Northern Ireland

2.6 During 2012 there were 95 new HIV diagnoses made in Northern Ireland. Prevalence of HIV in Northern Ireland remains lower than in the rest of the UK. However, between 2000 and 2012, Northern Ireland had the highest percentage increase in annual new diagnoses of HIV, compared to the rest of the UK.

2.7 There were 639 people diagnosed with HIV and living in Northern Ireland receiving HIV-related care during 2012.

HIV Testing

2.8 It is generally recommended that an HIV test is carried out in a healthcare setting. In 2008 and 2010 the Department issued guidance to Health and Social Care (HSC) staff who deal with the management of HIV infection[1,2]. The guidance included recommended action to improve access to HIV testing so that people would be aware of their status sooner, and to enable effective

[1] http://www.dhsspsni.gov.uk/hss-md-34-2008.pdf
[2] http://www.dhsspsni.gov.uk/hss-md-23-2010.pdf

management of their condition and reduce the chances of onward transmission.

2.9 HIV testing is offered through a range of settings[3] including Genitourinary Medicine (GUM) Clinics or sexual health clinics, GP surgeries, antenatal clinics, community addiction teams or private clinics. Most HIV tests use a blood sample that is taken from a vein in the arm, and HIV diagnostic tests used as part of clinical services are extremely accurate. Testing of saliva is less reliable than testing of blood. However, a number of different testing techniques are available for use in different circumstances. There are population groups at particular risk of acquiring HIV, and health interventions may include targeted HIV testing services for different groups of the population.

2.10 Over 56,000 HIV tests are carried out annually in NI. Approximately 26,000 tests are carried out as part of the antenatal screening programme; and around 30,000 are performed outside of the antenatal screening programme.

2.11 The HSC works with voluntary organisations The Rainbow Project[4] and Positive Life[5], providing community-based HIV rapid testing services by trained staff. Rapid HIV testing can enable a higher proportion of people, tested in out-reach settings, to know their HIV status. A rapid HIV test is a screening test and additional testing carried out by a health professional in a clinical setting is necessary to confirm a preliminary reactive (positive) result.

Home sampling and self-testing

2.12 A home sampling HIV test is where an individual undertakes the test at home, sends the sample away, and receives the result later. Sometimes called a home screening test or postal test, a home sampling HIV kit involves an individual collecting a sample of blood (finger prick) or saliva (oral fluid) in their own home. The individual then posts the sample to a laboratory for analysis. Usually, a week or so later, the individual receives the result by telephone, text or on-line from the laboratory. A reactive (positive) result means that the laboratory cannot rule out that the individual has HIV, and the individual is strongly advised to get a blood test in a clinic to confirm the result (confirmatory blood test).

2.13 Self-testing is where an individual undertakes the HIV test and reads the result at home – there is no laboratory or health professional involved. A self-test for HIV is either blood-based or saliva-based. The test provides the result in less than 30 minutes and the individual interpreting the test results does not

[3] http://servicefinder.hscni.net/

[4] The Rainbow Project provides a range of information and support services to lesbian, gay, bisexual and/or transgender people, their families and friends, including counselling, health promotion advice and sexual health testing.
http://www.rainbow-project.org/

[5] Positive Life supports and promotes positive living for people affected by HIV. It provides a range of services for individuals and their families, including a confidential helpline 0800 137 437.
http://positivelifeni.com/

have to be medically trained. All reactive test results must be followed up with a confirmatory blood test by a health professional.

Window Period for Testing

2.14 The period of time between becoming infected with the HIV virus and the infection being detectable by a test is called the “window period”. Therefore, if a HIV test is performed during the window period, a negative result may not necessarily mean the absence of HIV infection and the result can be false. The individual may have tested too early, i.e. before the immune response (antibodies) can be detected by the test. Therefore, it is recommended that an individual who may have been recently infected with HIV should have a repeat test some weeks or months after the possible date of infection. Different tests have different window periods, which can be as long as three months.

False Negative and False Positive Test Results

2.15 A false negative result is one that fails to detect antibodies in an individual who is in fact HIV-infected (i.e. a result which incorrectly identifies an HIV-positive individual as HIV-negative). This is most likely to occur during the window period, and repeated testing over time may be necessary to determine the individual is not infected with HIV.

2.16 HIV tests have been developed to be especially sensitive and, sometimes, a positive result will be obtained even when there are no HIV antibodies in the blood. This is known as a “false positive”, and because of this, all positive results must be confirmed by another test method. A confirmed positive result from the second test method means that the individual is infected with HIV. Because of the risk that a positive result from a single test is, in fact, a false positive, many doctors prefer to talk about the result being 'reactive' rather than 'positive'.

2.17 Widespread HIV testing in low-risk populations is likely to produce a proportionally higher number of false positives.

Undiagnosed HIV and late diagnoses

2.18 It is estimated that one in five people with HIV in the UK remain unaware of their status. This means that those people are unable to benefit from treatment and risk unknowingly transmitting HIV to others. Reducing undiagnosed HIV remains a continuing challenge.

2.19 Another challenge is the need to reduce late diagnoses of HIV infection. While there has been a steady decline in the proportion of late diagnoses over the past ten years across the UK, it is estimated that almost one in two new HIV diagnoses (46%) are made at a late stage of infection (after the point at which HIV treatment is recommended).

The Legal Framework

3.1 The HIV Testing Kits and Services Regulations (Northern Ireland) 1992 make it illegal to advertise, sell or supply an HIV testing kit to a member of the public (as opposed to a business). The Regulations also require that a registered medical practitioner (i.e. a registered doctor) must provide, or supervise, all HIV testing services.

What is illegal under the Regulations?

3.2 The Regulations make it a criminal offence to:

- Sell or supply an HIV testing kit or component to a member of the public (Regulation 2)
- Sell or supply an HIV testing kit without an accompanying warning notice (Regulation 3)
- Provide HIV testing services which are not provided or directed by a registered medical practitioner (Regulation 4)

3.3 In addition, Regulation 5 places restrictions on the advertising of HIV kits, components and services.

3.4 Home sampling HIV testing services provided by or under the direction of a registered doctor are legal; whereas self-testing for HIV is illegal.

3.5 There is no legislation in place which prohibits the advertising or sale of any other (non-HIV) self-test kits directly to the public. All self-testing kits sold here must meet the requirements of the Medical Devices Regulations 2002[6], which transpose, i.e. put into law, the requirements set out in EU Directive 98/79/EC[7] on *in vitro* diagnostic medical devices (tests that are used to diagnose diseases and monitor the clinical status of patients using samples of blood, cells or other tissues obtained from a patient).

[6] http://www.legislation.gov.uk/uksi/2002/618/contents/made
[7] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:331:0001:0037:EN:PDF

What has changed to prompt the proposal to remove the ban on the sale of HIV self-testing kits to the public in Northern Ireland?

4.1 The 1992 Regulations pre-date the introduction of effective HIV treatment, when an HIV diagnosis was very much seen as an acute condition resulting in imminent death. HIV testing technology then was not as sophisticated and developed as it is today.

Treatment

4.2 The prognosis for someone diagnosed with HIV infection today is very different to what it was in 1992. If diagnosed early, people with HIV who receive treatment live full and normal lives and have a very low risk of onward transmission of the virus. HIV has become a manageable long-term condition for the vast majority of people.

Technology

4.3 Advances in HIV testing technology over recent years have resulted in the availability of rapid HIV testing and point-of-care kits for professional use. There is choice around the type of testing device available. Salivary testing and finger-prick blood tests, for the majority of users, will indicate if an individual does not have HIV infection, or if a follow-up confirmatory test is needed. These kits are regulated and have facilitated HIV testing services to be extended into primary care and in non-healthcare community settings, especially for groups at increased risk of HIV. These testing kits may be suitable for self-testing if manufacturers choose to develop them.

Illegal Online Self-testing HIV kits

4.4 There is evidence that unregulated self-testing is already happening. The UK Medicines and Healthcare Products Regulatory Agency (MHRA) is aware that HIV self-testing kits have been sold illegally online. These kits are not subject to any form of UK quality control; they may be of poor quality; are not intended for use without medical supervision; and do not include sufficient information.

Counselling

4.5 HIV counselling aims to assist people to make informed decisions, such as whether to have an HIV test; to help support those living with HIV (affected directly and indirectly) to cope better and lead more positive lives; and to prevent HIV transmission. However, some people do not take up voluntary counselling and testing.

4.6 There has been a shift away from in-depth pre-test counselling, with a focus on obtaining informed consent. Pre-test counselling was considered necessary when there was no effective treatment and an HIV diagnosis could lead to AIDS and death. Nowadays, due to advances in treatment, many people who are diagnosed early can expect a near-normal life expectancy. Also some people do not want pre-test counselling, which can be a barrier to them accessing HIV testing services.

4.7 Post-test counselling helps the individual understand and cope with the HIV test result. Counselling for those who have tested HIV-positive includes

discussion on ways to reduce HIV transmission and relevant referral services. Counselling for those who have a negative test result, but who may have had the test during the window period, or are at high risk of HIV infection, may include discussion on the need for a repeat HIV test and how to reduce the risk of acquiring HIV.

Advocacy/ Opposition

4.8 Some HIV organisations have called for a change in the law to permit the purchase and use of self-testing kits for HIV. They consider that a safe alternative to unregulated kits from the Internet should be available to those who want to self-test for HIV; and that lifting the ban would allow the government to ensure proper quality control to protect consumers from sub-standard kits.

4.9 The 2011 House of Lords Select Committee report on HIV recommended that the Regulations banning the sale of HIV testing kits to the public should be repealed. The UK Chief Medical Officers' Expert Advisory Group on AIDS also supports the removal of the ban to legalise the sale of HIV self-testing kits.

4.10 Others are against the sale of self-testing kits because there is a potential for individuals to perform their test or interpret their results incorrectly; there is a lack of post-test counselling; and there is no direct link to treatment options and care. Concerns have also been raised as to the potential for coercion into HIV testing against the individual's will.

HIV self-testing in other countries

4.11 Policy on HIV self-testing varies across countries. In some countries HIV testing is illegal; in many others there are no formal regulations or policies. Some countries support self-testing: HIV self-tests which are blood-based are available in Hong Kong and The Netherlands; in the United States, the regulatory authority approved[8] the first HIV self-testing (saliva) kit for sale in 2012. The US saliva-based HIV self-testing kit (Oraquick) is available on-line and over the counter at pharmacies and costs around $40 (£25 equivalent price).The website provides information including advice on HIV, risk and prevention, how to take the test, a customer support helpline, and where to find local services, including counselling and treatment services.

4.12 In April 2014, England, Scotland and Wales legalised the sale of HIV self-testing kits (by revoking their respective HIV Testing Kits and Services Regulations 1992).

4.13 France also approved over the counter sale of HIV self-test kits in 2014 and other countries are considering its introduction.

[8] http://www.fda.gov/forconsumers/consumerupdates/ucm310545.htm

Regulation of HIV testing kits

5.1 HIV testing kits are classified as *in vitro* diagnostic devices (IVDs) and all such devices sold in the UK must comply with the requirements of the *In Vitro* Diagnostic Medical Devices Directive (98/79/EC)[7] and Medical Devices Regulations 2002[6].

5.2 The Directive sets out a list of essential safety, quality and performance requirements which manufacturers of IVDs must meet before being placed on the EU market, as well as imposing various other regulatory requirements upon the manufacturer. Amongst other things this would include having a quality management and manufacturing system, clinical data to support claims and that instructions for use are provided that enable the device to be used safely taking in to account the knowledge of the user. For HIV test kits a Common Technical Specification (CTS) has been established for manufacturers to meet.

5.3 HIV testing kits are subject to the highest level of scrutiny which includes the manufacturer demonstrating compliance with the Directive to a Notified Body, - a Notified Body is an independent organisation designated and monitored by the Regulatory Authorities in member states (the Medicines and Healthcare products Regulatory Agency [MHRA] in the UK) as competent to undertake this function. For high risk devices such as this they would review the design and manufacturing processes before the device is placed on the market and ensure the CTS requirements mentioned above are met before issuing conformity assessment certification to the manufacturer. The ongoing audit process also includes batch-release testing to ensure the device continues to meet these requirements.

5.4 In addition, the Directive[7] sets out specific requirements for devices for self-testing. For a self-test kit a Notified Body is also required to examine the design to ensure their suitability for non-professional users. The design of the kit must ensure ease of use for the individual using it and reduce, as far as practicable, the risk of user error in handling the device and interpretation of results. The information provided with the kit must be easy to understand and accurate. The label must state clearly that it is for self-testing. The instructions for use must include how to interpret the result, along with advice on what action to take in the event of a positive, negative or indeterminate result and the possibility of false positive or false negative results. The information must include a statement clearly directing the user not to take any decision of medical relevance without first consulting with their doctor.

5.5 Having obtained certification from a Notified Body, the manufacturer applies the CE marking to the IVD which denotes that it is safe to use, meets the relevant regulatory requirements, and performs as intended. A medical device should not be marketed in the UK without carrying a legitimate CE Mark of Conformity. MHRA as the regulatory authority for devices in the UK has a post market surveillance and enforcement role and powers under the Consumer Protection Act to ensure that all devices being placed on the market are safe and fit for purpose.

The Options considered

6.1 The Department has considered the developments in HIV self-testing, and explored the following options:

Option 1: Continue as we are

6.2 Keeping the existing 1992 Regulations would mean that the sale of HIV self-testing kits remains illegal in Northern Ireland. At this present time (September 2014) there are not any HIV self-test kits that have been regulatory approved (CE marked) and can be placed on the UK or EU market. However, it is expected that CE marked HIV self-testing kits will be available later in 2014 or 2015.

6.3 People wishing to have an HIV test can consult a health professional for advice about testing, and be tested with high quality, accurate laboratory tests through existing HSC services, with a direct link to counselling, support, treatment and care. The multi-disciplinary team at the Regional Centre for HIV Care and Management based at the Royal Victoria Hospital, Belfast offers a range of services including advice, treatment and specialist support to patients diagnosed with HIV.

6.4 HIV testing is also available in community settings, through voluntary organisations, linking with the HSC services. Home sampling kits are also available, where a saliva or blood sample is taken and sent to a laboratory for testing.

6.5 However, for a variety of reasons, including a fear of HIV-related stigma, some people are deterred from using existing testing services. This unmet need must be addressed by reducing the barriers to HIV testing.

6.6 Although illegal, it is difficult to prevent sales of HIV self-testing kits over the Internet. Consumers who have purchased HIV test kits online would have done so in good faith, unaware that such kits are not subject to the quality control which applies to other legally available self-testing kits (i.e. CE marking), contain few or no instructions, provide misleading results and lack sufficient information for users.

Option 2: Remove the ban on the sale of HIV self-testing kits to the public in Northern Ireland

6.7 Removing the ban would make it lawful to sell and advertise the sale of HIV self-testing kits in Northern Ireland. Self-testing provides an additional safe choice of how to test for HIV, and may reach out to those people who do not access existing HSC HIV testing services. Increasing the options for safe and effective HIV testing, especially for those at increased risk, is very important in order to help reduce undiagnosed HIV and prevent onward transmission by people who do not know they have HIV.

6.8 Should the ban be lifted, any HIV self-testing kits sold here would have to comply with existing regulations which are applicable to kits used to test human samples such as blood or saliva. The regulatory framework of CE marking ensures that all test kits are safe to use and perform as intended by the manufacturer. People purchasing CE marked HIV self-testing kits could be confident that the kits are of good quality and fit for purpose.

6.9 Self-testing for HIV at home offers privacy and convenience, and is likely to encourage more people to test for HIV. However, there are concerns about untrained people interpreting self-testing results and coping with a reactive (positive) result outside of a healthcare setting. There would be no face-to-face counselling immediately provided along with a HIV self-test result. However, counselling would be available when people go for a confirmatory test, provided that they follow-up with this.

6.10 Concerns about the reliability and accuracy of HIV self-testing kits underlines the importance of having a reactive self-test result confirmed by HSC clinic-based tests. A false negative result from a HIV self-test could provide false reassurance that an individual does not have HIV infection, and post-test counselling provides the opportunity to discuss reducing risk-taking behaviour, the possibility of needing repeated tests over a period of time, and referral to other services, including tests for other sexually transmitted infections. There are also concerns about linkage to services, treatment and care.

6.11 If self-tests were to become available in Northern Ireland, there may be additional demands placed on GUM clinics due to an increase in the number of confirmatory tests. It is acknowledged that there are already significant pressures on sexual health services. Investment in sexual health can result in considerable cost savings to the health service. For example, treatment costs for those with HIV living in Northern Ireland total approximately £3.0 million each year and preventing a single individual from acquiring HIV would save the health service over £350,000 in lifetime treatment costs.

Proposal to remove the ban on the sale of HIV self-testing kits to the public in Northern Ireland

7.1 Having considered the options, the Department is proposing to remove the ban on HIV self-testing kits in Northern Ireland (Option 2). Should it be decided to proceed with this policy change, legislation would be required to revoke (in effect cancel) the HIV Testing Kits and Services Regulations (NI) 1992.

7.2 HIV self-testing would not replace clinic-based testing. However, self-testing kits for HIV could expand the reach of HIV testing due to their privacy and convenience. The acceptability and demand for self-testing medical devices generally has increased; and HIV self-testing kits are seen as a means to increase HIV testing among those who have never tested before and those who are at more risk of HIV.

7.3 There is a minimum legal requirement for the information to be included with testing kits, including instructions for use and what to do if the result gives a reactive result. However, advice and counselling through telephone helplines or web-based services could be made available.

7.4 Should the ban be lifted, it is the intention that anonymised information will be collated on the confirmed status of patients who have presented for further laboratory tests following a reactive self-test for HIV. Personal details would not be made available.

7.5 In summary, the Department is proposing to change the law to allow the sale of HIV self-testing kits in Northern Ireland. Increasing HIV testing would increase the likelihood that HIV infection would be diagnosed earlier. The costs of late diagnosis are substantial to both the individual and the health service. Late diagnosis means that the individual is likely to become ill more often, have complex health needs, and may require long-term social care and support services. People who are aware of their positive HIV status are more likely to seek follow-up care and reduce their risk behaviours. Early-diagnosed HIV is a manageable chronic condition and people who are diagnosed with HIV early and receive treatment are able to live long and healthy lives. Allowing the sale of HIV self-testing kits to the public in Northern Ireland will increase choice and options for HIV testing, with significant benefits for the individual, public health and health and social care services.

Consultation Questions

8.1 Views are invited on the following questions:

(i) Should the ban on the sale of HIV self-testing kits directly to the public in Northern Ireland be removed?

(ii) If yes, what are the issues that need to be taken into account in legalising self-testing for HIV?

(iii) If no, please let us know your reasons and how they might be addressed?

Equality consultation questions

8.2 Section 75 of the NI Act 1998 requires all public bodies in carrying out their functions relating to Northern Ireland, to have due regard to the need to promote equality of opportunity between persons of different religious belief, political opinion, racial group, age, marital status or sexual orientation; between men and women generally; between persons with a disability and persons without; and between persons with dependants and persons without. The Department is also required to "have regard" to the desirability of promoting good relations between persons of a different religious belief, political opinion or racial group.

8.3 In accordance with these statutory obligations and the guidance produced by the Equality Commission for Northern Ireland, the Department has carried out a preliminary screening of the proposed policy change and has concluded that an Equality Impact Assessment is not required. If you consider this decision is not correct please advise the Department by completing and returning the consultation questionnaire, including any supporting evidence you may have. The preliminary screening is available on the Department's website at http://www.dhsspsni.gov.uk/index/consultations/current_consultations.htm

(iv) Is the proposal likely to have an adverse impact on any of the nine equality groups identified under Section 75 of the Northern Ireland Act 1998? If yes, please state the group or groups and provide comment on how these adverse impacts could be reduced or alleviated.

(v) Are you aware of any indication or evidence – qualitative or quantitative – that the proposal set out in this consultation document may have an adverse impact on equality of opportunity or on good relations? If yes, please give details and comment on what you think should be added or removed to alleviate the adverse impact.

(vi) Is there an opportunity to better promote equality of opportunity or good relations? If yes, please give details as to how.

(vii) Are there any aspects of the proposal where potential human rights violations may occur?

How to respond to this Consultation

9.1 The consultation will run from 1 October to 31 December 2014. Your comments are invited on the proposal to remove the ban on the sale of HIV self-testing kits in Northern Ireland. It would be helpful if you would complete and return the response questionnaire available on the Department's website at:
http://www.dhsspsni.gov.uk/index/consultations/current_consultations.htm

9.2 You should send your completed consultation response questionnaire to:

Email: phdconsultation@dhsspsni.gov.uk

Post: Health Improvement Policy Branch
Department of Health, Social Services and Public Safety
Room C.4.22
Castle Buildings
Stormont Estate
BELFAST
BT4 3SQ

9.3 Completed consultation response questionnaires must be received by the Department by 3.00pm on 31 December 2014. Responses received after this date will only be considered with prior agreement from the Department.

9.4 If you have any queries regarding the consultation please telephone 028 9052 0526 or 028 90520772 or send an email with your query to email: phdadmin@dhsspsni.gov.uk.

9.5 Please note that responses to this consultation will be subject to the Freedom of Information Act 2000 which gives the right of access to information held by public authorities. For further information, please read Annex 1.

9.6 The Department will publish a summary of responses following completion of the consultation process.

Annex 1

FREEDOM OF INFORMATION

The Department will publish a summary of responses following completion of the consultation process. Your response, and all other responses to the consultation, may be disclosed on request. The Department can only refuse to disclose information in exceptional circumstances. **Before** you submit your response, please read the paragraphs below on the confidentiality of consultations and they will give you guidance on the legal position about any information given by you in response to this consultation.

The Freedom of Information Act 2000 gives the public a right of access to any information held by a public authority, namely, the Department in this case. This right of access to information includes information provided in response to a consultation. The Department cannot automatically consider as confidential, information supplied to it in response to a consultation.

However, it does have the responsibility to decide whether any information provided by you in response to this consultation, including information about your identity should be made public or be treated as confidential. If you do not wish information about your identity to be made public please indicate this in your response to the consultation.

This means that information provided by you in response to the consultation is unlikely to be treated as confidential, except in very particular circumstances. The Secretary of State for Constitutional Affairs' Code of Practice on the Freedom of Information Act provides that:

- The Department should only accept information from third parties in confidence if it is necessary to obtain that information in connection with the exercise of any of the Department's functions and it would not otherwise be provided;

- The Department should not agree to hold information received from third parties "in confidence" which is not confidential in nature; and

- Acceptance by the Department of confidentiality provisions must be for good reasons, capable of being justified to the Information Commissioner.

For further information about confidentiality of responses please contact the Information Commissioner's Office:

Tel: 028 9026 9380
Email: ni@ico.gsi.gov.uk
Website: http://www.informationcommissioner.gov.uk/

Annex 2

Screening and Impact Assessments

Human Rights and Equality Implications

Section 75 of the Northern Ireland Act 1998 requires Departments in carrying out their functions relating to Northern Ireland to have due regard to the need to promote equality of opportunity:

- between persons of different religious belief, political opinion, racial group, age, marital status or sexual orientation;
- between men and women generally;
- between person with a disability and persons without; and
- between persons with dependants and persons without.

In addition, without prejudice to the above obligation, Departments should also, in carrying out their functions relating to Northern Ireland, have due regard to the desirability of promoting good relations between persons of different religious belief, political opinion or racial group. Departments also have a statutory duty to ensure that their decisions and actions are compatible with the European Convention on Human Rights and to act in accordance with these rights.

Preliminary screening of the proposal has been undertaken and, at this stage, it is considered that the removal of the ban on the sale of HIV self-testing kits to the public in Northern Ireland would not have a negative impact on any of the S75 groups and an Equality Impact Assessment is not necessary.

Rural Proofing

It is considered that there would be no negative impact on the provision of services to the rural community should the ban on the sale of HIV self-testing kits to the public in Northern Ireland be removed.

Health Impact

It is considered that removing the ban on the sale of HIV self-testing kits to the public in Northern Ireland would have a positive impact on health outcomes, as increasing access to HIV testing would increase the likelihood that HIV infection would be diagnosed earlier. People who are aware of their positive HIV status are more likely to seek follow-up care and reduce their risk-taking behaviours.

Sustainable development

It is considered that should the ban on the sale of HIV self-testing kits to the public in Northern Ireland removed there would be no negative environmental impact. HIV is a chronic condition and due to a variety of reasons, including stigma and illness, some people may be unable to sustain employment. People may experience a lack of support, social isolation and face financial disadvantage which can deteriorate into poverty. The removal of the ban on the sale of HIV self-testing kits to the public may, in the longer term, provide social and economic benefits.

Regulatory Impact Assessment

Removing the ban would allow consumers who wish to purchase and use an HIV self-testing kit to do so. The Department does not consider that a Regulatory Impact Assessment is required as removing the ban on HIV self-testing kits would impose no costs (or savings) on business, charities, social economy enterprises or the voluntary sector. Manufacturers and retailers would be positively impacted by the removal of the ban on the sale of HIV self-testing kits to the public in Northern Ireland as it would permit the creation of a market for HIV self-testing kits.

Annex 3

Consultation Response Questionnaire on a Proposal to Remove the Ban on the sale of HIV self-testing kits to the public in Northern Ireland

The Department of Health, Social Services and Public Safety welcomes your views on a proposed policy change to revoke the HIV Testing Kits and Services Regulations (NI) 1992, thereby removing the ban on the sale of HIV self-testing kits directly to the public in Northern Ireland.

(Please tick a box)

I am responding: as an individual ☐ on behalf of an organisation ☐

Name: _____
Job Title: _____
Organisation: _____
Address: _____
_____
Postcode: _____
Email: _____

I do not wish information about my identity to be made public ☐

Views are invited on the following questions by 31 December 2014:

Q1 Should the ban on the sale of HIV self-testing kits directly to the public in Northern Ireland be removed? (Please tick a box)

Yes ☐ No ☐ Don't know/ no views ☐

Q2 If yes, what are the issues that need to be taken into account in legalising self-testing for HIV?

Comments

Q3 If no, please let us know your reasons and how they might be addressed?

Comments

Equality implications

Q4 Is the proposal to remove the ban on the sale of HIV self-testing kits to the public in Northern Ireland likely to have an adverse impact on any of the nine equality groups identified under Section 75 of the Northern Ireland Act 1998?

Yes ☐ **No** ☐

If yes, please state the group or groups and provide comment on how these adverse impacts could be reduced or alleviated in the proposal.

Q5 Are you aware of any indication or evidence – qualitative or quantitative – that the proposal to remove the ban on the sale of HIV self-testing kits to the public in Northern Ireland may have an adverse impact on equality of opportunity or on good relations?

Yes ☐ **No** ☐

If yes, please give details and comment on what you think should be added or removed to alleviate the adverse impact?

Q6. Is there an opportunity to better promote equality of opportunity or good relations?

Yes ☐ **No** ☐

If yes, please give details as to how.

Q7. Are there any aspects of the proposal to remove the ban on the sale of HIV self-testing kits to the public in Northern Ireland where potential human rights violations may occur?

Yes ☐ **No** ☐

If yes, please give details as to how.

Further Comments

Please use the box below to provide any further comments you would like to make in relation to the proposal to remove the ban on the sale of HIV self-testing kits directly to the public in Northern Ireland.

Thank you for your comments.

You should send your completed consultation response questionnaire to:

Email: phdconsultation@dhsspsni.gov.uk

Post: Health Improvement Policy Branch
Department of Health, Social Services and Public Safety
Room C.4.22
Castle Buildings
Stormont Estate
BELFAST
BT4 3SQ

Completed consultation response questionnaires must be received by the Department by 3.00pm on 31 December 2014. Responses received after this date will only be considered with prior agreement from the Department.

If you have any queries regarding the consultation please telephone 028 9052 0526 or 028 90 520772 or send an email with your query to email: phdadmin@dhsspsni.gov.uk.