EXPLANATORY STATEMENT

Therapeutic Goods (Excluded purposes) Amendment Specification 2014 (No.1)

Section 41BEA, Therapeutic Goods Act 1989

The Therapeutic Goods (Excluded purposes) Amendment Specification 2014 (No.1) is a specification made under section 41BEA of the *Therapeutic Goods Act 1989* (the Act). The purpose of the Specification is to amend the Therapeutic Goods (Excluded purposes) Specification 2010 (the Principal Specification) so that paragraph 4(2)(a) of the Principal Specification no longer applies to a kind of in-vitro diagnostic (IVD) medical device for self-testing that is used for the purpose of testing for the human immunodeficiency virus (HIV). The effect of this amendment is that IVD medical devices used exclusively for self-testing for HIV can be included in the Australian Register of Therapeutic Goods (the Register), subject to satisfying the applicable regulatory requirements.

This Specification commenced on the day after it was registered on the Federal Register of Legislative Instruments.

BACKGROUND

The Act provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in or exported from Australia. In relation to medical devices, the efficacy of therapeutic goods refers to the performance of the goods as the manufacturer intended. The Therapeutic Goods Administration (the TGA), which is part of the Department of Health, is responsible for administering the Act.

An IVD medical device for self-testing is defined in the Therapeutic Goods (Medical Devices) Regulations 2002 as an IVD medical device:

- intended to be used in the home or similar environment by a lay person, or
- in the collection of a sample by a lay person, and if that sample is tested by another person, the results are returned directly to the person from whom the sample was taken without the supervision of a health professional.

The Act prohibits the Secretary of the Department of Health from including IVD medical devices for self-testing in the Register if they are used exclusively for one or more of the purposes identified as "excluded purposes" in a specification made by the Secretary under section 41BEA of the Act. As a result, it is unlawful to import, export, supply or manufacture such a device unless it is otherwise exempt under the Act.

The Principal Specification sets out a number of excluded purposes. One of the excluded purposes (set out in paragraph 4(2)(a) of the Principal Specification) is the exclusive use of an IVD medical device for self-testing to test specimens from the human body for the presence of, or exposure to, pathogenic organisms or transmissible agents, including agents that cause notifiable diseases. This paragraph is applicable to transmissible infectious agents and covers testing for HIV. Thus the Secretary is prevented from including IVD medical devices for self-testing used exclusively for testing for HIV in the Register.

Although the Principal Specification prevents IVDs exclusively for self-testing for HIV from being included in the Register, individuals can import these devices for themselves or their family members under certain exemptions provided under the legislation for personal importation of medical devices. However, the quality, safety and performance of these imported devices have not been evaluated by the TGA or, in some cases, any regulator, and this presents a risk to individual and population health, where poor quality and unacceptable levels of test failure can have significant consequences.

The early diagnosis of HIV is of critical importance in treating those living with HIV and in preventing its spread. As at the end of 2012, approximately 25,700 people in Australia were known to be living with HIV infection. However, it is estimated that the total number of people living with HIV in Australia was between 28,000 and 34,000 at that time (see the Kirby Institute Annual Surveillance Report on HIV, viral hepatitis and sexually transmissible infections in Australia for 2013). This means that an important proportion of the HIV-infected individuals in Australia were undiagnosed.

Given the disproportionately high contribution to HIV transmission by people who do not know they are infected (see Wilson D, Hoare A, Regan D & Law M. Importance of promoting HIV testing for preventing secondary transmissions: modelling the Australian HIV epidemic among men who have sex with men. *Sexual Health,* 2009, 6, 19-33), efforts to improve testing and therefore diagnosis and linkage to treatment, care and support are crucial. Up to 35% of people living with HIV in Australia are diagnosed late, with an average of 3.4 years between infection and diagnosis, increasing potential transmission of HIV and delaying treatment. Increasing HIV testing is integral to reducing new transmissions of HIV and to maximising individual health outcomes by increasing rates of diagnoses and treatment uptake.

The introduction of rapid HIV tests used in non-laboratory settings is a significant development which has the potential to increase the rate of voluntary and appropriate testing among priority populations by overcoming common barriers to testing such as time, convenience and perceptions around accessing traditional tests. Some of these groups are known to have inadequate or nil uptake of HIV testing through more mainstream methods.

It is anticipated that introducing an additional method of HIV testing, through home self-testing, may increase testing, diagnosis and awareness of HIV status and, in turn, lead to a decrease in HIV transmission and an increase in treatment uptake in Australia.

Enabling IVD medical devices for HIV self-testing to be included on the Register is consistent with the Seventh National HIV Strategy (2014-2017). The strategy recognises that HIV testing models need to focus on simplifying the testing process for individuals and addressing access and acceptability issues, including cost, time and convenience.

The Specification amends paragraph 4(2)(a) of the Principal Specification so that it does not apply to self-testing IVDs exclusively used for the purpose of detecting HIV infection. The effect of this amendment is that a kind of IVD medical device that is exclusively for self-testing for HIV can, if it satisfies relevant regulatory requirements in Chapter 4 of the Act, be included in the Register and be lawfully supplied in Australia. The purpose of the amendment is to increase detection of HIV in the community by enabling greater access to tests that have been assessed for quality, safety and performance by the TGA.

The Secretary is able to impose conditions on the inclusion of a medical device in the Register, and to amend or impose additional conditions at any time after it has been so included. Any decision by the Secretary to include an IVD medical device for self-testing for HIV on the Register would involve consideration of whether specific conditions should be imposed to minimise the risks associated with the use of the medical device.

CONSULTATION

In April 2014, the TGA wrote to a number of stakeholders, including state and territory governments, patient and advocacy groups, hospitals, clinical colleges, industry groups and universities and research institutes, to seek feedback on the proposal to enable IVD medical devices used exclusively for self-testing for HIV to be included in the Register. Stakeholders were invited to comment, in particular, on:

- the risks and benefits of home-testing as a means to enable and promote timely HIV detection and increase testing rates overall, particularly amongst hard-to-reach population groups;
- the risks and benefits of allowing TGA to approve such devices for HIV self-testing that are of acceptable safety and quality and perform as intended to increase HIV detection rates in Australia; and
- any limitations or conditions that should be placed on the supply of HIV self-testing devices.

The TGA received 38 submissions. The great majority supported the proposal. A small number of submissions were opposed. Some submissions provided comments without expressing support or opposition. Copies of written submissions received as part of this consultation process are available on TGA's website (www.tga.gov.au).

The submissions identified a number of potential risks and potential benefits. The risks included the possibility of inaccurate results as a result of testing performed in the early stages of infection or incorrect use of the medical device. They also outlined that self-testing consumers would not have access to appropriate pre and post-test counselling and so may not receive appropriate counselling and the opportunity for testing and management of other sexually transmitted infections may be reduced. Most of the risks identified are of a kind that can be addressed as part of the approval process for the IVDs.

The benefits that were identified included increased access and frequency of testing, improvement in health outcomes through earlier diagnosis (and therefore earlier intervention, treatment and advice) and the opportunity for access to higher quality devices for home use (ie. that had been evaluated for quality, safety and performance by the TGA).

The Specification is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

In relation to compatibility with human rights, it is considered that the Specification is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*, and a Statement of Compatibility setting that out in further detail is below.

SUPPLEMENTARY MATERIAL - STATEMENT OF COMPATIBILITY FOR A LEGISLATIVE INSTRUMENT THAT DOES NOT RAISE ANY HUMAN RIGHTS ISSUES

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

This statement of compatibility is prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Therapeutic Goods (Excluded purposes) Amendment Specification 2014 (No.1)

This legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Legislative Instrument

This Specification amends paragraph 4(2)(a) of the Principal Specification so that the paragraph no longer applies to a kind of in-vitro diagnostic (IVD) medical device for self-testing that is used exclusively to test for the human immunodeficiency virus (HIV). The effect of this amendment is that using a self-testing IVD medical device exclusively to test for HIV is not an excluded purpose. As a result of this amendment, such a kind of IVD medical device can be included in the Australian Register of Therapeutic Goods and thus be lawfully supplied in Australia. The purpose of the amendment is to increase detection of HIV in the community by enabling greater access to tests that have been assessed for quality, safety and performance by the TGA.

Human rights implications

The Specification is not considered to engage any of the applicable rights or freedoms and does not raise any human rights issues.

Conclusion

This legislative instrument is compatible with human rights as it does not raise any human rights issues.

Professor Jane Halton PSM
Secretary of the Department of Health