

EXPLANATORY STATEMENT

Therapeutic Goods (Articles that are Medical Devices) Specification 2014

Subsection 41BD(2B), Therapeutic Goods Act 1989

The *Therapeutic Goods (Articles that are Medical Devices) Specification 2014* is a specification made under subsection 41BD(2B) of the *Therapeutic Goods Act 1989* (the Act). The primary purpose of the Specification is to ensure that pathology tests and related instrumentation, that are used for the purpose of predicting the susceptibility or predisposition of persons to a disease or ailment, are medical devices.

The effect of this Specification is that such pathology tests and related instrumentation can be included in the Australian Register of Therapeutic Goods (the Register) as medical devices and thus be imported, exported, manufactured or supplied in Australia. The requirements under the Act for goods to be included in the Register as medical devices include compliance with essential principles and the application of an appropriate conformity procedure to the goods. The Specification also corrects a drafting oversight by specifying that pathology tests and related instrumentation, that are used to test for pregnancy in persons, are medical devices.

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.

Section 41BD of the Act contains a definition of medical device. Paragraph 41BD(1)(a) of the Act provides that any instrument, apparatus, appliance, material or other article that is intended to be used for the purpose of certain identified therapeutic uses, and that does not achieve its principal intended action by pharmacological, immunological or metabolic means (although it may be assisted in its function by such means), is a medical device. The therapeutic uses set out in paragraph 41BD(1)(a) include the purposes of diagnosis, prevention, monitoring, treatment or alleviation of a disease or the investigation of a physiological process. However, there is no reference to instruments, apparatus, appliances, material or other articles that are intended to be used for the purpose of predicting the susceptibility or predisposition of persons to a disease or ailment, or for the purpose of testing for pregnancy in persons.

In recent years, technological advances have resulted in an increased availability of pathology tests and instrumentation that can be used for predictive purposes. These can provide an indication of a person's susceptibility or predisposition to a particular disease or condition in order to predict their future health status.

Predictive testing is used to determine the likelihood of a person developing a specific disease or ailment at some time in the future. For example, specific inherited mutations in the BRCA1 gene or the BRCA2 gene greatly increase a person's risk of developing certain cancers, particularly female breast and ovarian cancers. The outcome of such testing can influence future management decisions such as, for example, enhanced screening or prophylactic (risk-reducing) surgery.

Another type of predictive testing is carrier testing. Carrier testing is used to determine whether or not a person carries a genetic mutation that does not generally affect the person's health but may increase his or her chance of having children with the condition in question. For example, cystic fibrosis can only occur when both parents of a child are carriers of the genetic mutations that cause the disease. Carriers usually display no symptoms of the disease and it is only when two carriers conceive a child together that there is a 25 per cent risk of that child having the disease. The outcome of such testing can therefore influence future reproductive decisions.

The importance of tests that can be used to predict a person's susceptibility or predisposition to a disease or ailment in patient management decisions requires that these tests undergo an appropriate level of regulatory oversight. As paragraph 41BD(1)(a) of the Act does not expressly refer to instruments, apparatus, appliances, material or other articles that are intended to be used in testing for the purpose of predicting susceptibility or predisposition to a disease or ailment, there may be some uncertainty as to whether pathology tests and related instrumentation that are intended for this purpose are medical devices for the purposes of the Act.

Even if not medical devices, such instruments, apparatus, appliances material or other articles would nevertheless be regulated as therapeutic devices under Part 3-2 of the Act. This is because, under the definition of therapeutic goods and therapeutic use in subsection 3(1) of the Act, a good that is used in connection with testing the susceptibility of persons to a disease or ailment is a therapeutic good, even if it is not a medical device. However, it is appropriate that these types of goods be regulated under Chapter 4 of the Act as medical devices, rather than under Part 3-2 of the Act, as this allows regulatory requirements and pre-market scrutiny, of a level consistent with other IVD medical devices with a comparative level of risk, to be applied.

Pathology tests and instrumentation for testing persons for pregnancy have, ever since the IVD regulatory regime came into operation on 1 July 2010, been considered by the TGA and sponsors to be in IVD medical devices. There are a number of IVD medical devices for testing for pregnancy in persons currently included in the Register under Chapter 4. However, paragraph 41BD(1)(a), in defining what constitutes a medical device, does not expressly refer to testing for pregnancy in persons. This omission is the result of a drafting oversight. Testing for pregnancy is included in the definition of therapeutic use in subsection 3(1) of the Act and pregnancy tests, if they are not medical devices, would nevertheless be regulated as therapeutic devices under Part 3-2 of the Act. It is appropriate that the status of pregnancy tests as IVDs and regulated under Chapter 4 of the Act be confirmed.

Subsection 41BD(2B) of the Act provides that the Secretary may, by legislative instrument, specify a class of instrument, apparatus, appliance, material or other article for the purposes of the definition of medical device. Under paragraph 41BD(1)(ab), any instrument,

apparatus, appliance, material or other article included in a class specified under subsection 41BD(2B) is a medical device.

This Specification specifies that instruments, apparatus, appliances, materials or other articles (whether used alone or in combination, and including the software for their proper application) intended to be used for the examination of a specimen derived from a human body for the purpose of predicting a person's susceptibility or predisposition to a disease or ailment, for instance through genetic testing, are medical devices for the purposes of the Act, unless they achieve their principal intended action by pharmacological, immunological or metabolic means. This is intended to put beyond doubt that such goods are medical devices and to ensure that these goods can be regulated as IVD medical devices, consistent with other medical devices of comparable risk.

This Specification also specifies that instruments, apparatus, appliances, materials or other articles (whether used alone or in combination, and including the software for their proper application) intended for the examination of a specimen derived from a human body for the purpose of testing pregnancy in persons are medical devices for the purposes of the Act, unless they achieve their principal intended action by pharmacological, immunological or metabolic means. This corrects a drafting oversight and ensures that pregnancy tests can continue to be regulated as IVD medical devices.

CONSULTATION

A public consultation paper was released by the TGA in May 2013 to address a number of issues identified by stakeholders during the transition period for the IVD medical devices regulatory framework. One of the issues addressed in the consultation paper was the regulation of IVDs used for testing for susceptibility or predisposition to a disease or ailment.

The consultation process was extensive and enabled input from industry, healthcare providers and the community. Further discussions were held with key stakeholder groups, peak industry bodies and individual sponsors and manufacturers.

Thirty-four submissions were received and those that were not marked as confidential are available on the TGA website at <http://tga-test.launchpad.agileware.com.au/submissions-received-proposed-amendments-new-regulatory-framework-vitro-diagnostic-medical-devices-ivds>.

The majority of those consulted were supportive of the proposal to ensure that tests for susceptibility or predisposition to a disease or ailment are treated as medical devices and considered that it was in the interest of both consumers and providers for these products to be regulated in a manner that reflects the level of risk they represent. In support of this, it was noted that molecular genetic tests can have a significant impact on individuals and therefore these tests should be regulated in the same manner as other IVDs. It was also noted that any test use for the purpose of predicting disease susceptibility or predisposition should be treated as a medical device, irrespective of the specific technology used for the test.

On 17 October 2014 a regulation impact statement (RIS) was finalised and published on TGA's website at <https://www.tga.gov.au/publication/regulation-impact-statement-amendments-new-regulatory-framework-vitro-diagnostic-medical-devices-ivds>. The RIS recommended amendments to ensure that IVDs used to test for susceptibility or predisposition to a disease or ailment are adequately captured under the definition of medical device.

The consultation paper and RIS did not specifically address the issue of the regulatory status of therapeutic goods used for testing for pregnancy. The omission of reference to pregnancy tests in paragraph 41BD(1)(a) was identified in the course of considering the issues raised through the consultation process as a matter that should be clarified. As pathology tests and instrumentation for testing persons for pregnancy have been treated as IVD medical devices since July 2010, the Specification will not alter existing arrangements and is of a machinery nature.

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 (Articles that are Medical Devices) Specification 2014

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.

Overview of the Legislative Instrument

The *Therapeutic Goods (Articles that are Medical Devices) Specification 2014* is a specification made under subsection 41BD(2B) of the *Therapeutic Goods Act 1989* (the Act). Subsection 41BD(2B) of the Act provides that the Secretary may, by legislative instrument, specify a class of instrument, apparatus, appliance, material or other article for the purposes of the definition of medical device. Under paragraph 41BD(1)(ab), any instrument, apparatus, appliance, material or other article included in a class specified in a specification under subsection 41BD(2B) is a medical device.

The purpose of the Specification is to ensure that pathology tests and related instrumentation that are used for the purpose of predicting the susceptibility or predisposition of persons to a disease or ailment are medical devices. This will ensure that these types of goods can be regulated under Chapter 4 of the Act as medical devices and that the level of regulatory requirements and pre-market scrutiny that is applied is of a level consistent other IVD medical devices with a comparative level of risk.

The Specification also corrects a drafting oversight in the definition of medical device in paragraph 41BD(1)(a) of the Act by specifying that pathology tests and related

instrumentation that are used to test pregnancy in persons are medical devices. Pathology tests and related instrumentation that are used to test for pregnancy in persons have been understood to be, and treated as, in vitro diagnostic (IVD) medical devices by the TGA and industry since July 2010. The inclusion of such tests and related instrumentation in the Specification therefore supports existing arrangements.

The effect of this Specification is that such pathology tests and related instrumentation can be included in the Australian Register of Therapeutic Goods (the Register) as medical devices in order to be imported, exported, manufactured or supplied in Australia. The requirements under the Act for goods to be included in the Register as medical devices include compliance with essential principles and the application of an appropriate conformity procedure to the goods.

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.

Dr John Skerrett

Delegate of the Secretary of the Department of Health