

## **EXPLANATORY STATEMENT**

### *Therapeutic Goods Act 1989*

#### *Therapeutic Goods (Medical Devices—Excluded Purposes) Specification 2020*

The *Therapeutic Goods Act 1989* (“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. The Act is administered by the Therapeutic Goods Administration (“the TGA”) within the Australian Government Department of Health.

Section 41BEA of the Act provides that the Secretary may, by legislative instrument, specify purposes for the purposes of paragraph 41FD(ia) and subsection 41FF(1A) of the Act. Paragraph 41FD(ia) requires a person who applies for the inclusion of a kind of medical device in the Australian Register of Therapeutic Goods (“the Register”) to certify that their kind of device is not to be used exclusively for one or more of the purposes specified under section 41BEA. Subsection 41FF(1A) provides that the Secretary must not include a kind of medical device in the Register if the Secretary is satisfied that the kind of device is to be used exclusively for one or more of the purposes specified under section 41BEA.

The *Therapeutic Goods (Medical Devices—Excluded Purposes) Specification 2020* (“the Specification”) is made under section 41BEA of the Act and specifies such purposes for paragraph 41FD(ia) and subsection 41FF(1A) of the Act, to preclude medical devices from being approved for marketing in Australia if they are intended to be used exclusively for one or more purposes specified in the Specification.

The Specification also repeals and replaces the *Therapeutic Goods (Excluded purposes) Specification 2010* (“the Former Specification”), which was due to sunset on 1 October 2020 under the sunset provisions of the *Legislation Act 2003*.

### **Background**

The Specification identifies excluded purposes for the purposes of section 41BEA of the Act, in relation to medical devices that are Class 2 in vitro diagnostic medical devices (“IVDs”) for self-testing, and medical devices that are Class 3 and Class 4 IVDs for self-testing. An IVD medical device for self-testing is defined in the *Therapeutic Goods (Medical Devices) Regulations 2002*.

Section 41BEA of the Act, under which the Specification is made, is not limited to IVD medical devices of IVDs for self-testing, but the Specification’s focus on such products reflects the particular potential risks that may be associated with using such products to test for serious diseases in such settings, without the involvement of an appropriately qualified health professional.

IVD medical devices that are intended by their manufacturer to be for self-testing or in-home use for serious diseases (e.g. notifiable infectious diseases, sexually transmitted diseases, cancer and genetic markers of disease) have been prohibited from supply in Australia since 1 July 2010 under the Former Specification. In 2014, the Former Specification was amended to allow for the legal supply of an IVD that is a human immunodeficiency virus test.

The Specification incorporates a number of changes in comparison with the Former Specification with changes, principally to allow the supply of Class 3 and Class 4 IVD medical devices that are self-tests for the presence of, or exposure to specified infectious diseases such as influenza, chlamydia, gonorrhoea, herpes, syphilis, hepatitis B and hepatitis

C, and that are self-tests (other than genetic tests) for the diagnosis or to indicate the presence of, or to detect the presence of markers that are precursors for, diabetes, kidney disease or cardiovascular disease. It is important to note that, while no longer excluded from marketing approval, such self-tests will still need to meet the applicable regulatory requirements for medical devices under the Act and the MD Regulations be included in the Register (unless otherwise exempt).

The Specification identifies the testing of specimens from the human body, other than for these uses, as an excluded purpose for Class 3 and Class 4 IVD medical devices for self-testing. The Specification also identifies testing for faecal occult blood as an excluded purpose for Class 2 IVD medical devices for self testing.

The effect of identifying these excluded purposes in the Specification is that a kind of medical device that is only intended by its manufacturer to be used for one of the excluded purposes specified in the Specification may not be included in the Register. As a result, it is unlawful to import, export, or supply or manufacture such a device, unless it is otherwise exempt under the one of the pathways in the Act for the supply etc. of unapproved therapeutic goods.

### **Consultation**

The Office of Best Practice Regulation advised that a regulation impact statement was not required in relation to the making of the Specification (OBRP ID42800).

A public consultation was conducted in late 2019 on whether there was considered to be a continuing need for this specification and which prohibitions, if any, should be maintained. There were 26 submissions received. Overall respondents were in favour of continuing to prohibit supply of certain self-testing IVDs for serious diseases such as cancer and genetic tests for diagnosis or prediction of serious diseases. However, there was support for a number of self-tests for some infectious diseases such as influenza, sexually transmitted diseases and hepatitis C, being made available in Australia. It was also outlined that the risks of direct-to-consumer genetic testing cannot be safely mitigated to ensure that potential harms are reduced to an acceptable level.

A number of teleconferences were held between March and July 2020 as a follow up to clarify some of the issues raised in the submissions to the public consultation. The teleconferences confirmed the view that self-tests for cancer and genetic self-testing should continue to be prohibited. It was considered that self-tests for serious infectious diseases should also continue to be prohibited except where there were greater benefits arising from supply of certain self-tests, and risk mitigations were in place. Those benefits were identified as increased access to testing in populations less likely to see a medical practitioner including intravenous drug users, LGBTQI individuals, and people in rural or remote areas; reduced delays in testing and potential for earlier treatment; and the supply of high quality self-tests that have been evaluated and approved by the TGA could minimise the risk of purchase of unapproved tests from overseas.

The Specification is a disallowable legislative instrument for the purposes of the *Legislation Act 2003*. Details of the Specification are set out in **Attachment A**.

The Specification is compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

The Specification commences on 1 October 2020.

**Details of the *Therapeutic Goods (Medical Devices—Excluded Purposes) Specification 2020***

**Section 1 – Name**

This section provides that the name of the instrument is the *Therapeutic Goods (Medical Devices—Excluded Purposes) Specification 2020*.

**Section 2 – Commencement**

This section provides that the instrument commences on 1 October 2020.

**Section 3 – Authority**

This section provides that the legislative authority for making the instrument is section 41BEA of the *Therapeutic Goods Act 1989* (“the Act”).

Subsection 33(3) of the *Acts Interpretation Act 1901* relevantly provides that, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character, the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument. This instrument is also made in accordance with that provision.

**Section 4 – Definitions**

This section provides the definition of terms used in the instrument. Terms such as ‘IVD medical device for self-testing’ and ‘Class 2 IVD medical device’ have the same meaning as in the *Therapeutic Goods (Medical Devices) Regulations 2002*.

This section also notes that some expressions used in the instrument, for example, ‘medical device’ and ‘State’, are defined in the Act and therefore have the same meaning as in the Act.

**Section 5 – Excluded purposes—Class 2 IVD medical devices**

This section provides that the purposes specified in Part 1 of Schedule 1 are specified for the purposes of paragraph 41FD(ia) and subsection 41FF(1A) of the Act (“excluded purposes”) in relation to certain Class 2 IVD medical devices.

This section only applies to a Class 2 IVD medical device that is an IVD medical device for self-testing. It also only applies where the medical device is not intended exclusively for export or is not intended to be used exclusively for testing as part of a government health screening program. Therefore, the prohibition on medical devices for the purposes specified in the instrument does not apply to an IVD medical device for self-testing if it is for use exclusively for export or for testing as part of a government health screening program.

**Section 6 – Excluded purposes—Class 3 and 4 IVD medical devices**

This section provides that the purposes specified in Part 2 of Schedule 1 are specified for the purposes of paragraph 41FD(ia) and subsection 41FF(1A) of the Act (“excluded purposes”) in relation to certain Class 3 and 4 IVD medical devices.

This section only applies to a Class 3 or 4 IVD medical device that is an IVD medical device for self-testing and is not intended to be used exclusively for testing to monitor a disease or condition that has been diagnosed by a suitably qualified health professional. Accordingly, self-tests for monitoring purposes only (i.e. not for diagnosis) will continue to be allowed.

It also only applies where the medical device is not intended exclusively for export or is not intended to be used exclusively for testing as part of a government health screening program. Therefore, the prohibition on medical devices for the purposes specified in the instrument does not apply to an IVD medical device for self-testing if it is for use exclusively for export or for testing as part of a government health screening program.

## **Section 7 – Repeals**

This section provides that the instrument specified in Schedule 2 is repealed as set out in the applicable items in that Schedule.

## **SCHEDULE 1 – EXCLUDED PURPOSES**

### **Part 1—Class 2 IVD medical devices**

The table in Part 1 of Schedule 1 specifies the excluded purpose for Class 2 IVD medical devices for self testing is testing for faecal occult blood. In effect, supply of Class 2 IVD self-tests will be allowed (as is currently the case) except for Class 2 IVD medical devices that are intended for self-testing for faecal occult blood unless they are for use as part of a government screening program.

### **Part 2—Class 3 and 4 IVD medical devices**

The table in Part 2 of Schedule 1 specifies the excluded purposes for Class 3 and Class 4 IVD medical devices for self-testing is testing specimens from the human body. There are, however, a couple of exceptions.

Firstly, supply of Class 3 and Class 4 IVD medical devices that are self-tests will not be allowed except for self-tests to test for human immunodeficiency virus, hepatitis B virus, hepatitis C Virus, seasonal influenza virus, neisseria gonorrhoea, chlamydia trachomatis, treponema pallidum (syphilis) and herpes simplex virus type 1 and 2. The effect of this is that IVD medical devices used exclusively for these transmissible agents can be included in the Register and is intended to increase detection of these transmissible agents by addressing access and acceptability issues (including cost, time and convenience of testing) and enabling greater access to tests that have been assessed for quality, safety and performance by the Therapeutic Goods Administration. Other pathogenic organisms or transmissible agents, including human papillomavirus, are still prohibited.

Secondly, supply of Class 3 and Class 4 IVD self-tests will not be allowed except for self-tests to diagnose, aid in the diagnosis of, indicate the presence of, or test for the presence of markers that are precursors to diabetes, kidney disease or cardiovascular disease, noting that genetic self-tests for these conditions will still be prohibited.

## **SCHEDULE 2 – REPEALS**

This Schedule specifies that the *Therapeutic Goods (Excluded purposes) Specification 2010* is repealed. The *Therapeutic Goods (Excluded purposes) Specification 2010* would otherwise sunset on 1 October 2020 pursuant to the *Legislation Act 2003*.

## Statement of Compatibility with Human Rights

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

### *Therapeutic Goods (Medical Devices—Excluded Purposes) Specification 2020*

This disallowable 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 legislative instrument

The *Therapeutic Goods (Medical Devices—Excluded Purposes) Specification 2020* (“the instrument”) is made under section 41BEA of the *Therapeutic Goods Act 1989* (“the Act”). This instrument repeals and replaces the *Therapeutic Goods (Excluded purposes) Specification 2010* (“the former instrument”), which is due to sunset on 1 October 2020 pursuant to the *Legislation Act 2003*.

Section 41BEA of the Act provides that the Secretary may, by legislative instrument, specify purposes for the purposes of paragraph 41FD(ia) and subsection 41FF(1A) of the Act. Paragraph 41FD(ia) requires an applicant for inclusion of a kind of medical device in the Register to certify that devices of that kind are not to be used exclusively for one or more of the purposes specified under section 41BEA. Subsection 41FF(1A) provides that the Secretary must not include a kind of device in the Register if the Secretary is satisfied that the kind of device is to be used exclusively for one or more of the purposes specified under section 41BEA.

Home-use or self-testing in vitro diagnostic medical devices (“IVDs”) for serious diseases (e.g. notifiable infectious diseases, sexually transmitted diseases, cancer and genetic markers of disease) have been prohibited from supply in Australia since 1 July 2010 under the former instrument. The former instrument was amended in 2014 to allow for the legal supply of human immunodeficiency virus test. The excluded purposes specified in the former instrument are those considered inappropriate for an IVD medical device for self-testing and, therefore, devices with an excluded purpose as its sole purpose cannot be included in the Register. As a result, it is unlawful to import, export, or supply or manufacture such a device (unless it is otherwise exempt under the Act).

The instrument replaces the former instrument with changes that would allow the supply of Class 3 and 4 IVD medical devices that are self-tests for some infectious diseases such as influenza, chlamydia, gonorrhoea, herpes, syphilis, hepatitis B and hepatitis C and self-tests (other than genetic tests) for diabetes, kidney disease or cardiovascular disease. Such self-tests would still need to meet applicable regulatory requirements under the Act and be included in the Register (unless otherwise exempt). The instrument also includes an excluded purpose for Class 2 IVD medical devices that are for the purpose of testing for faecal occult blood.

The excluded purposes specified in the instrument are considered inappropriate for an IVD medical device for self-testing (given the serious nature of the diseases that may be tested for and that such testing may occur without the involvement of a suitably qualified health professional) and, as such, where such a kind device has an excluded purpose as its sole purpose, it cannot be included in the Register.

As a result, it is unlawful to import, export, or supply or manufacture such a device (unless it is otherwise exempt under 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 direct supervision of a health professional who has formal training in a medical field or discipline to which the self-testing relates.

### **Human rights implications**

The instrument engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR). Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standards of physical and mental health.

In *General Comment No.14: The Right to the Highest Attainable Standard of Health (Art.12)* (2000), the United Nations Committee on Economic, Social and Cultural Rights states that health is a ‘fundamental human right indispensable for the exercise of other human rights’, and that the right to health is not to be understood as the right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

The instrument takes positive steps to support the right to health by prohibiting the supply of self-testing for certain conditions where it is not appropriate for individuals to self-test. For example, testing with Class 3 and Class 4 IVD medical devices are not generally considered appropriate without consulting a medical practitioner or other health professional or are beyond the ability of the average person to evaluate accurately or treat safely without supervision by a medical or other health professional.

Some IVD medical devices for self-testing are not prohibited, such as certain sexually transmissible disease, as there are greater benefits arising from supply of certain self-tests, and risk mitigations are in place, including in relation to supporting increased access to testing populations less likely to see a medical practitioner such as intravenous drug users, LGBTIQ individuals and people in rural or remote areas, and in relation to reducing delays in testing and supporting earlier treatment.

### **Conclusion**

The instrument is compatible with human rights because it maintains and supports the right to health in Article 12 of the ICESCR and otherwise does not raise any other human rights issues.