

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Medical Devices—Excluded Purposes) Amendment (COVID-19 Self-Testing) Specification 2022

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 and Aged Care.

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 the 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 of the Act.

The *Therapeutic Goods (Medical Devices—Excluded Purposes) Specification 2020* (“the Principal 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 Principal Specification.

The *Therapeutic Goods (Medical Devices—Excluded Purposes) Amendment (COVID-19 Self-Testing) Specification 2022* (“the Amendment Specification”) amends the Principal Specification to provide that for Class 1 in vitro diagnostic (“IVD”) medical devices for self-testing, testing for the presence of SARS-CoV-2 nucleic acid is an *exception to* the excluded purpose of testing in relation to a serious disease. The Amendment Specification also provides that for Class 3 and 4 IVD medical devices for self-testing, testing for the presence of SARS-CoV-2 nucleic acid is an *exception to* the excluded purpose of testing specimens from the human body. In each instance, such testing is in addition to testing for SARS-CoV-2 antigens, which is currently included in the Principal Specification as an exception to these same excluded purposes.

Background

The Principal Specification identifies excluded purposes for the purposes of section 41BEA of the Act. Previously, for COVID-19 self-testing, it only identified antigen tests as an exception to the excluded purpose of self-testing for Class 1, 3 and 4 IVD medical devices. The Amendment Specification amends the Principal Specification to specify that SARS-CoV-2 nucleic acid tests are also an exception to the excluded purpose of self-testing for Class 1, 3 and 4 IVD medical devices.

An IVD medical device for self-testing is defined in the *Therapeutic Goods (Medical Devices) Regulations 2002* as an IVD medical device that is 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 where, if the 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 with formal training in a medical field or discipline to which the self-testing relates.

Section 41BEA of the Act, under which the Principal Specification is made, is not limited to IVD medical devices for self-testing, but the Principal 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.

The effect of identifying excluded purposes in the Principal Specification is that a kind of medical device that is intended by its manufacturer to only be used for one or more of the excluded purposes specified in the Principal 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.

The Amendment Specification amends the Principal Specification to identify an exception to the excluded purpose of the testing of specimens from the human body in relation to a serious disease, which applies to Class 1, 3 and 4 IVD medical devices for self-testing. Namely, it specifies that testing for SARS-CoV-2 nucleic acids is an exception, alongside the previously implemented exception for SARS-CoV-2 antigen tests.

The effect of these exceptions is that approved SARS-CoV-2 nucleic acid tests are no longer prohibited for supply in Australia. They are also not precluded from being the subject of an application for inclusion in the Register.

In enabling the supply of Class 1, 3 and 4 IVD medical devices for self-testing for the presence of SARS-CoV-2 nucleic acid, the Amendment Specification forms part of the measures to support the public health response to the COVID-19 pandemic, and in particular the management of COVID-19 transmission in the community.

Consultation

Extensive stakeholder consultation was undertaken at the time the Principal Specification was made in 2020. The stakeholder feedback received in relation to that consultation indicated support for the availability of self-tests for certain serious diseases, noting the availability of confirmatory testing services in the community.

As the principal effect of the Amendment Specification is to ensure that an application for marketing approval in Australia may be made for a Class 1, 3 or 4 IVD that is a SARS-CoV-2 nucleic acid self-test and that such products may be lawfully supplied once approved, this outcome is consistent with the feedback received in 2020. As such, separate consultation was not undertaken in relation to the making of the Amendment Specification.

In relation to regulatory impact analysis, the Amendment Specification is not outside the scope of the certification letter prepared at the time the Principal Specification was made and relies on this exemption (Office of Best Practice Regulation ID: 42800).

The Amendment 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 Amendment 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 Amendment Specification commences the day after registration on the Federal Register of Legislation.

Details of the *Therapeutic Goods (Medical Devices—Excluded Purposes) Amendment (COVID-19 Self-Testing) Specification 2022*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Medical Devices—Excluded Purposes) Amendment (COVID-19 Self-Testing) Specification 2022* (“the Amendment Specification”).

Section 2 – Commencement

This section provides that the Amendment Specification commences on the day after it is registered on the Federal Register of Legislation.

Section 3 – Authority

This section provides that the legislative authority for making the Amendment Specification 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. The Amendment Specification is also made in accordance with that provision.

Section 4 – Schedules

This section provides that each instrument that is specified in a Schedule to the Amendment Specification is amended or repealed as set out in the applicable items in the Schedule concerned, and that any other item in a Schedule to the Amendment Specification has effect according to its terms.

SCHEDULE 1 – AMENDMENTS

Schedule 1 amends the *Therapeutic Goods (Medical Devices—Excluded Purposes) Specification 2020* (“the Principal Specification”).

Item 1 amends table item 1, column 2, paragraph (c) of Part 1A of Schedule 1 to the Principal Specification, to include SARS-CoV-2 nucleic acid testing as an exception to the excluded purpose of testing specimens from the human body in relation to a serious disease for Class 1 IVD medical devices.

Item 2 amends table item 1, column 2, paragraph (c) of Part 2 of Schedule 1 to the Principal Specification, to include SARS-CoV-2 nucleic acid testing as an exception to the excluded purpose of testing specimens from the human body in relation to a serious disease for Class 3 and 4 IVD medical devices.

The purpose of these amendments is to allow for inclusion in the Register of Class 1, 3 or 4 IVD medical devices for self-testing to test for the presence of SARS-CoV-2 nucleic acid, facilitating the lawful supply and availability of such tests in Australia.

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) Amendment (COVID-19 Self-Testing) Specification 2022

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) Amendment (COVID-19 Self-Testing) Specification 2022* (“the amendment instrument”) is made under section 41BEA of the *Therapeutic Goods Act 1989* (“the Act”). This instrument amends the *Therapeutic Goods (Medical Devices—Excluded Purposes) Specification 2020* (“the principal instrument”).

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 the inclusion of a kind of medical device in the Australian Register of Therapeutic Goods (“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.

The principal instrument 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 that are intended to be used exclusively for one or more of the purposes specified in the principal instrument from being approved for marketing in Australia. A kind of medical device that is only intended by its manufacturer to be used for one or more of such excluded purposes 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.

The amendment instrument amends the principal instrument to identify an exception to the excluded purpose of the testing of specimens from the human body in relation to a serious disease, which applies to Class 1, 3 and 4 IVD medical devices for self-testing. Namely, it specifies that testing for SARS-CoV-2 nucleic acids is an exception, alongside the previously implemented exception for SARS-CoV-2 antigen tests.

The effect of these exceptions is that approved SARS-CoV-2 nucleic acid tests are no longer prohibited for supply in Australia. They are also not precluded from being the subject of an application for inclusion in the Register.

In enabling the supply of Class 1, 3 and 4 IVD medical devices for self-testing for the presence of SARS-CoV-2 nucleic acid, the amendment instrument forms part of the measures to support the public health response to the COVID-19 pandemic, and in particular the management of COVID-19 transmission in the community.

Human rights implications

The amendment instrument engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural Rights (“the 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 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 amendment instrument takes positive steps to support the right to health by providing an exception to the excluded purpose of self-testing for Class 1, Class 3 and Class 4 IVD medical devices, in relation to self-testing for the presence of SARS-CoV-2 nucleic acid. This is a particularly important measure to support the public health response to the COVID-19 pandemic and the management of COVID-19 transmission in the community, as such self-testing devices will provide fast results for users and more options when seeking to test for COVID-19. This exemption will allow nucleic acid tests to be lawfully supplied in Australia alongside the previously exempt antigen tests, ensuring access for consumers to these products and supporting effective management of the COVID-19 pandemic.

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.