

REPLACEMENT EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Medical Devices—Excluded Purposes) Amendment (COVID-19 Rapid Antigen IVD Medical Devices for Self-Testing) Specification 2021

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 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 Rapid Antigen IVD Medical Devices for Self-Testing) Specification 2021* (“the Amendment Specification”) amends the Principal Specification to provide that for Class 1 in vitro diagnostic (“IVD”) medical devices for self-testing, an excluded purpose is testing in relation to a serious disease, with the exception of testing for certain transmissible diseases, diagnosis of certain diseases or conditions and testing for the presence of SARS-CoV-2 antigens. The Amendment Specification also provides that for Class 3 and 4 IVD medical devices for self-testing, an exception to the excluded purpose of testing specimens from the human body is testing for the presence of SARS-CoV-2 antigens.

Background

The Principal Specification identifies excluded purposes for the purposes of section 41BEA of the Act. Previously, it did this only in relation to certain medical devices that are Class 2, Class 3 or Class 4 IVD medical devices for self-testing. The Amendment Specification amends the Principal Specification to specify excluded purposes in relation to Class 1 IVD medical devices for self-testing.

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 only intended by its manufacturer to be used for one 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 makes a number of amendments to the Principal Specification, principally to specify that the testing of specimens from the human body in relation to a serious disease is an excluded purpose for Class 1 IVD medical devices for self-testing, while also identifying a number of important exceptions to this:

- testing for the presence of, or exposure to, specified pathogenic organisms or transmissible agents including chlamydia, hepatitis B, hepatitis C, herpes, human immunodeficiency virus, seasonal influenza, gonorrhoea and syphilis;
- diagnosing, aiding in the diagnosis of, indicating the presence of, or testing for the presence of markers that are precursors to, diabetes, kidney disease or cardiovascular disease (other than by genetic testing); and
- for a Class 1 IVD medical device for self-testing that is for supply on or after 1 November 2021, testing for the presence of SARS-CoV-2 antigens.

The effect of these exceptions is that Class 1 IVD medical devices for self-testing that are intended by their manufacturer to be used exclusively for one or more of the purposes identified in these exceptions are not precluded from being the subject of an application for inclusion in the Register.

The Amendment Specification also amends the Principal Instrument to identify testing for the presence of SARS-CoV-2 antigens as an exception to the excluded purposes for Class 3 and 4 IVD medical devices. This similarly has the effect that Class 3 and Class 4 IVD medical devices for self-testing that are intended by their manufacturer to be used exclusively for testing for the presence of SARS-CoV-2 antigens and that are for supply on or after 1 November 2021, are not precluded from being the subject of an application for inclusion in the Register.

In providing the exception in relation to self-testing for the presence of SARS-CoV-2 antigens to the excluded purposes for Class 1, Class 3 and Class 4 IVD medical devices for self-testing, antigens, 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. This is an important step in supporting the National Plan to transition Australia's National COVID-19 Response and aligns with the timeframe where it is expected that approximately 70 % of Australians will be double vaccinated.

The 1 November 2021 date in relation to Class 1, Class 3 and Class 4 IVD medical devices that are for self-testing for to detect the presence of SARS-CoV-2 antigens is also designed to allow time for industry to establish appropriate systems in relation to the use of such products, to ensure their reliable use at home, including enabling any consumer who has a positive test using such a product to be able to be supported through access to a confirmatory polymerase chain reaction (“PCR”) test at a COVID-19 testing centre.

Consultation

The Prime Minister granted an exemption from the requirement to complete a regulatory impact analysis in the form of a Regulation Impact Statement for all Australian Government measures made in response to COVID-19. The Amendment Instrument is made in response to the public health emergency and relies on this exemption (Office of Best Practice Regulation ID: 26445).

The use of self-administered at home rapid antigen tests has been considered and discussed by the Australian Health Protection Principal Committee (AHPPC), the Department of Health's Strategy Evidence and Research Group, a number of Commonwealth departments and specific state government departments including Health and Education. In addition, the Department of Health's Rapid Antigen Testing Branch has been working with state and territory governments, their advisors and peak bodies on the potential technical and logistical considerations for implementation of a framework to support self-testing, for aged care and other industries, as well as the broader community for high risk settings and venues. The timing and subsequent decision by the Minister's delegate to allow the introduction of COVID-19 rapid antigen self-testing has been taken with consideration of achieving vaccination rates as outlined in the National Plan to Australia's COVID-19 response: www.pmc.gov.au/national-plan-transition-australias-national-covid-response.

Prior to the amendment of the Specification, and whilst a framework to support COVID-19 rapid antigen self-testing in Australia was being considered, the TGA was asked to progress work that could allow the provision of self-tests in the future. To facilitate this, on 6 September 2021 an invitation to register interest in supplying COVID-19 rapid antigen self-tests was released on the TGA website.

Sponsors that registered interest were invited to submit information to the TGA so that when it was determined by the Minister's delegate, with advice from the Government and other stakeholders that it was an appropriate time to permit the commercial provision of self-tests, this could be done without significant delays. Guidance on performance requirements and risk mitigation strategies for COVID-19 rapid antigen self-tests was published on the TGA website on 10 September 2021 to assist sponsors and manufacturers to understand the requirements and prepare their documentation for when applications for the inclusion of such products in the Register could be submitted.

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 on 1 October 2021.

Details of the *Therapeutic Goods (Medical Devices—Excluded Purposes) Amendment (COVID-19 Rapid Antigen IVD Medical Devices for Self-Testing) Specification 2021*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Medical Devices—Excluded Purposes) Amendment (COVID-19 Rapid Antigen IVD Medical Devices for Self-Testing) Specification 2021* (“the Amendment Specification”).

Section 2 – Commencement

This section provides that the Amendment Specification commences on 1 October 2021.

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 inserts 3 new definitions into section 4 of the Principal Specification, for ‘Class 1 IVD medical device’, ‘SARS-CoV-2’ and ‘serious disease’.

Item 1 provides that ‘Class 1 IVD medical device’ and ‘serious disease’ have the same meanings as in the *Therapeutic Goods (Medical Devices) Regulations 2002*, and that ‘SARS-CoV-2’, or severe acute respiratory syndrome coronavirus 2, means the virus that causes coronavirus disease (COVID-19).

Item 2 inserts section 4A into the Principal Specification. New section 4A applies in relation to medical devices that are Class 1 IVD medical devices for self-testing, other than those mentioned in paragraphs 4A(1)(c)-(e), and has the effect of making it clear that the purposes mentioned in Part 1A of Schedule 1 to the Principal Specification are specified for the purposes of paragraph 41FD(ia) and subsection 41FF(1A) of the Act (“excluded purposes”) in relation to such Class 1 IVD medical devices.

Item 3 inserts a new Part 1A into Schedule 1 to the Principal Specification. Item 1 of the table in new Part 1A of Schedule 1 specifies that testing specimens from the human body in relation to a serious disease, other than as provided for in paragraphs (a)-(c) of item 1, is an excluded purpose for Class 1 IVD medical devices for self-testing.

Paragraphs (a)-(c) list exceptions to this, in relation to:

- testing for the presence of, or exposure to, any of the pathogenic organisms or transmissible agents listed in subparagraph (i)-(viii);
- diagnosing, aiding in the diagnosis of, indicating the presence of, or testing for the presence of markers that are precursors to, diabetes, kidney disease or cardiovascular disease (other than by genetic testing); and
- for a Class 1 IVD medical device for self-testing that is for supply on or after 1 November 2021, testing for the presence of SARS-CoV-2 antigens.

The effect of these exceptions is that a Class 1 IVD medical device for self-testing that is intended by its manufacturer to be used exclusively for one of these uses will not be precluded from being the subject of an application for inclusion in the Register, allowing sponsors and manufacturers of such products to apply for marketing approval of their products in Australia.

Item 4 amends Part 2 of Schedule 1 to the Principal Specification to introduce new paragraph (c) to item 1 of Part 2 of Schedule 1. New paragraph (c) refers to testing for the presence of SARS-CoV-2 antigens, and has the effect that, similar to Class 1 IVDs for self-testing, Class 3 and Class 4 IVD medical devices for self-testing that are intended by their manufacturer to be used exclusively for the purpose of testing for the presence of SARS-CoV-2 antigens and that are for supply on or after 1 November 2021, are not precluded from being the subject of an application for inclusion in the Register.

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 Rapid Antigen IVD Medical Devices for Self-Testing) Specification 2021

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 Rapid Antigen Medical Devices for Self-Testing) Specification 2021* (“the 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 principle 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 instrument makes a number of amendments to the principal instrument, principally to specify that the testing of specimens from the human body in relation to a serious disease is an excluded purpose for Class 1 IVD medical devices for self-testing, while also identifying a number of important exceptions to this:

- testing for the presence of, or exposure to, specified pathogenic organisms or transmissible agents such as chlamydia, hepatitis B, hepatitis C, herpes, human immunodeficiency virus, seasonal influenza, gonorrhoea and syphilis;
- 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; and
- for a Class 1 IVD medical device for self-testing that is for supply on or after 1 November 2021, testing for the presence of SARS-CoV-2 antigens.

The effect of these exceptions is that Class 1 IVD medical devices for self-testing that are intended by their manufacturer to be used exclusively for one or more of the purposes

identified in these exceptions are not precluded from being the subject of an application for inclusion in the Register, allowing sponsors and manufacturers of such products to apply for marketing approval of their products in Australia.

The instrument also amends the principal instrument to identify testing for the presence of SARS-CoV-2 antigens as an exception to the excluded purposes for Class 3 and 4 IVD medical devices. This similarly has the effect that Class 3 and Class 4 IVD medical devices for self-testing that are intended by their manufacturer to be used exclusively for testing for the presence of SARS-CoV-2 antigens and that are for supply on or after 1 November 2021, are not precluded from being the subject of an application for inclusion in the Register.

In providing the exception in relation to self-testing for the presence of SARS-CoV-2 antigens to the excluded purposes for Class 1, Class 3 and Class 4 IVD medical devices for self-testing, antigens, 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. This is an important step in supporting the National Plan to transition Australia's National COVID-19 Response and aligns with the timeframe where it is expected that approximately 70 % of Australians will be double vaccinated.

The 1 November 2021 date in relation to Class 1, Class 3 and Class 4 IVD medical devices that are for self-testing for to detect the presence of SARS-CoV-2 antigens is also designed to allow time for appropriate systems to be put in place in relation to the use of such products, including by states and territories, to ensure their reliable use at home, including enabling any consumer who has a positive test using such a product to be able to be supported through access to a confirmatory polymerase chain reaction (“PCR”) test at a COVID-19 testing centre.

Human rights implications

The 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 instrument takes positive steps to support the right to health by prohibiting the supply of Class 1 IVD medical devices for self-testing in relation to a serious disease. Class 1 IVD medical devices that are used for self-testing for a serious disease are not generally considered appropriate without consulting a medical practitioner or other health professional or are considered to be beyond the ability of the average person to evaluate accurately or treat safely without supervision by a medical or other health professional.

Some Class 1 IVD medical devices for self-testing are not prohibited, such as those that test for certain sexually transmissible diseases, as there are greater benefits arising from the supply and availability of certain such 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, LGBTQI individuals and people in rural or remote areas, and in relation to reducing delays in testing and supporting earlier treatment.

The instrument takes further positive steps to support the right to health by providing an exception to the excluded purposes for Class 1, Class 3 and Class 4 IVD medical devices for self-testing, in relation to self-testing for the presence of SARS-CoV-2 antigens, for such devices that are for supply on or after 1 November 2021. 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 devices will provide faster results for users than other testing methods, with possible applications at state or territory borders, international airports, in workplaces and potentially in the context of large events.

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.