EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Excluded Goods) Amendment (Borderline Products—COVID-19) Determination 2021

Therapeutic Goods (Medical Devices—Specified Articles) Amendment (Borderline Products—COVID-19) Instrument 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 Department of Health.

Subsection 3(1) of the Act defines 'therapeutic goods' as goods that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be for therapeutic use, and includes biologicals and medical devices. Sections 7, 7AA, 32A and 41BD of the Act provide mechanisms to determine or clarify whether particular goods are or are not therapeutic goods, biologicals or medical devices, and therefore subject to the national system of controls established by the Act, including the requirement for those goods to be included in the Australian Register of Therapeutic Goods ("the Register").

Relevantly, section 7AA of the Act provides that the Minister may determine that specified goods (other than goods declared to be therapeutic goods under an order in force under section 7 of the Act) are excluded goods for the purposes of the Act, or are excluded goods for the purposes of the Act when used, advertised or presented for supply in a specified manner. Before making a determination under section 7AA, the Minister must have regard to certain matters specified in subsection 7AA(3) of the Act, and any other matter the Minister considers relevant in accordance with subsection 7AA(4) of the Act.

The matters that the Minister must have regard to before making a determination under subsection 7AA(3) of the Act are:

(a) whether it is likely that the specified goods might harm the health of members of the public if not regulated under the Act;

(b) whether it is appropriate in all the circumstances to apply the national system of controls established by the Act to regulate the specified goods; and

(c) whether the kinds of risks that members of the public might be exposed to from the specified goods could be more appropriately dealt with under another regulatory scheme.

Section 41BD of the Act provides the definition of medical device. Relevantly, paragraph 41BD(1)(a) of the Act provides that a medical device is any instrument, apparatus, appliance, software, implant, reagent, material or other article that is intended, by the person under whose name it is or is to be supplied, to be used for human beings for one or more of the purposes in subparagraphs 41BD(1)(a)(i) to (v), including for example, the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease.

Paragraph 41BD(1)(ab) of the Act provides that an instrument, apparatus, appliance, software, implant, reagent, material or other article that is included in a class of instruments, apparatus, appliances, software, implants, reagents, materials or other articles specified under subsection 41BD(2B), is also a medical device.

Instruments made under section 7AA and subsection 41BD(2B) of the Act are disallowable legislative instruments within the meaning of subsection 8(4) of the *Legislation Act 2003* ("the Legislation Act").

Purpose of amendments

The *Therapeutic Goods (Excluded Goods) Determination 2018* ("the Principal Determination") is made under section 7AA of the Act. The Principal Determination determines specified goods, including specified goods when used, advertised or presented for supply in a specified manner, to be excluded goods for the purposes of the Act.

The *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020* ("the Principal Instrument") is made under subsection 41BD(2B) of the Act. The Principal Instrument specifies that particular classes of instruments, apparatus, appliances, materials or other articles are medical devices for the purposes of the Act.

The *Therapeutic Goods (Excluded Goods) Amendment (Borderline Products—COVID-19) Determination 2021* ("the Amendment Determination") is made under section 7AA of the Act and amends the Principal Determination. The *Therapeutic Goods (Medical Devices—Specified Articles) Amendment (Borderline Products—COVID-19) Instrument 2021* ("the Amendment Instrument") is made under subsection 41BD(2B) of the Act and amends the Principal Instrument.

The Amendment Determination and Amendment Instrument are made in the context of the ongoing public health emergency caused by the coronavirus disease 2019 ("COVID-19"). In this context, the TGA has observed a significant increase in the number of enquiries from potential sponsors and manufacturers of certain products that may be described as borderline products at the interface of consumer goods and therapeutic goods; particularly in relation to whether COVID-19 claims are permitted to be made in relation to these products under the therapeutic goods legislation and whether such claims would result in these products needing to be listed or included in the Register. The principal purpose of these instruments is to provide greater clarity with respect to the regulation of borderline products. By making clear what is, and what is not, a medical device by way of deliberate inclusion or exclusion under the Act, the instruments provide greater certainty as to how borderline products are regulated in Australia.

Specifically, the Amendment Instrument inserts a new item in Schedule 1 to the Principal Instrument in relation to articles made principally of fabric that are used primarily on, or in close contact with, the human body and are represented expressly to be effective against the virus that causes COVID-19. The effect of this amendment is that articles such as bedsheets, clothes and towels that make COVID-19 claims will be regulated as medical devices. The new item does not include mattresses, household furnishings, furniture, non-sterile personal protective equipment or safety apparel used for the prevention of transmission of disease between persons (noting that the latter two articles are already regulated as medical devices in accordance with item 1 of Schedule 1 to the Principal Instrument and the former three articles are considered to be excluded goods pursuant to item 12 of Schedule 1 to the Principal Determination).

The Amendment Instrument also formally clarifies that substances designed to clean medical devices by way of disinfection or physical action, and substances intended specifically for disinfecting, cleaning, rinsing or hydrating contact lenses, are medical devices consistent with present regulatory arrangements.

Similarly, the Amendment Determination clarifies the status of certain cleaning products. It amends the Principal Determination by inserting a new item 3A in Schedule 1. This item excludes from the operation of the Act detergents and soaps made principally for general cleaning that do not fall within the definition of disinfectants provided by the *Therapeutic Goods Regulations 1990* ("the Regulations").

Item 2 of the Amendment Determination repeals and replaces item 12 of Schedule 1 to the Principal Determination to provide greater clarity as to the terms of the exclusion. It confirms that the exclusion applies in relation to films and coatings. For further clarification, it also provides that the articles specified in item 3 of Schedule 1 to the Principal Instrument do not fall within the terms of the exclusion. The effect is to ensure that the exclusion does not apply in relation to articles within the scope of item 3 of Schedule 1 to the Principal Instrument, such as bedsheets with COVID-19 claims.

Background

Generally, the intended purpose and claims made in relation to a product will determine its classification and regulatory requirements. However, as result of increased demand for COVID-19 related products, the characterisation of emerging borderline products can be difficult to discern. Examples include bed sheets that are treated with antiviral substances, surface modifying coatings that can be applied to household surfaces with COVID-19 claims, and laundry disinfectants with COVID-19 claims.

COVID-19 represents a severe and immediate threat to public health, both in Australia and globally, placing significant pressure on health care systems and causing economic disruption. In responding to the public health emergency effectively, it is essential for the TGA to maintain a clear regulatory framework for therapeutic goods. In maintaining that framework, it is appropriate to identify low risk products that are more appropriately regulated under other regulatory schemes, including under the Australian Consumer Law. Similarly, it is appropriate to identify products that require regulation as therapeutic goods. Clarifying the regulatory boundaries for borderline products enables government resources to be more appropriately utilised and promotes enhanced regulation of the quality, safety and efficacy of therapeutic goods available to the Australian public.

It also assists industry in understanding their regulatory requirements and responsibilities including, where relevant, the need for inclusion of certain products in the Register. Such inclusion provides consumers with a degree of assurance as to the effectiveness of such products. A clear regulatory framework for therapeutic goods also ensures appropriate regulatory oversight and allows for the advertising of borderline products under that framework, which is particularly important to address aggressive marketing behaviour that has been observed towards consumers during the pandemic.

Consultation

The Amendment Instrument and Amendment Determination have been made in light of a considerable increase in the number of enquiries, and applications for inclusion, made to the TGA in relation to borderline products. These inquiries prompted internal discussion within the TGA to provide greater clarity to existing regulatory arrangements. The Amendment Instrument and Amendment Determination do not alter these arrangements but simply provide certainty and clarification of the regulatory scheme.

In the circumstances, it was not considered necessary to conduct public consultation. A Regulation Impact Statement was not required as the measures are unlikely to have more than minor regulatory impact (OBPR ID 44220).

Details of the Amendment Determination and Amendment Instrument are set out in **Attachment A** and **Attachment B,** respectively.

The Amendment Determination and Amendment Instrument are compatible with 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 C.**

The Amendment Determination and Amendment Instrument are disallowable legislative instruments for the purposes of the Legislation Act and commence on the day after the Amendment Instrument is registered on the Federal Register of Legislation.

This explanatory statement has been prepared in relation to the Amendment Determination and Amendment Instrument in accordance with subsection 15J(4) of the Legislation Act.

Attachment A

Details of the *Therapeutic Goods (Excluded Goods) Amendment (Borderline Products—COVID-19) Determination 2021*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Excluded Goods) Amendment (Borderline Products—COVID-19) Determination 2021* ("the Amendment Determination").

Section 2 – Commencement

This section provides that the Amendment Determination commences at the same time as the *Therapeutic Goods (Medical Devices—Specified Articles) Amendment (Borderline Products—COVID-19) Instrument 2021* ("the Amendment Instrument") commences.

However, this instrument will not commence at all if the Amendment Instrument does not commence.

Section 3 – Authority

This section provides that the legislative authority for making the Amendment Determination is section 7AA 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 made in accordance with that provision.

Section 4 – Schedules

This section provides that each instrument that is specified in a Schedule to the Amendment Determination 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 instrument has effect according to its terms.

Schedule 1 – Amendments

This Schedule amends the *Therapeutic Goods (Excluded Goods) Determination 2018* ("the Principal Determination").

Item 1 adds a new item 3A after table item 3 in Schedule 1 to the Principal Determination to exclude from the operation of the Act detergents and soaps for laundering or general cleaning use, other than detergents and soaps that are disinfectants within the meaning of the *Therapeutic Goods Regulations 1990*.

Item 2 repeals and replaces table item 12 in Schedule 1 to the Principal Determination to exclude from the operation of the Act sanitation, environmental control and environmental detoxification equipment (including films and coatings), other than articles specified in item 3 of Schedule 1 to the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020.*

Attachment B

Details of the *Therapeutic Goods (Medical Devices—Specified Articles) Amendment (Borderline Products—COVID-19) Instrument 2021*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Medical Devices—Specified Articles) Amendment (Borderline Products—COVID-19) Instrument 2021* ("the Amendment Instrument").

Section 2 – Commencement

This section provides that the Amendment Instrument 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 Instrument is subsection 41BD(2B) 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 made in accordance with that provision.

Section 4 – Schedules

This section provides that each instrument that is specified in a Schedule to the Amendment Instrument 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 instrument has effect according to its terms.

Schedule 1 – Amendments

This Schedule amends the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020* ("the Principal Instrument").

Item 1 makes a minor consequential amendment to section 5 of the Principal Instrument by adding the words 'software, implants and reagents'. This reflects recent amendments made to section 41BD of the Act by the *Therapeutic Goods Amendment (2020 Measures No. 1) Act 2020*.

Item 2 adds four new items (items 3 to 6) to the end of the table in Schedule 1 to the Principal Instrument. The first of these items specifies bedding, clothing, towels and other articles made principally of fabric that are intended to be used primarily on, or in close contact with, the human body and are represented expressly to be effective against the virus that causes coronavirus disease (COVID-19) to be medical devices. However, this item does not include articles that are mattresses, household furnishings, furniture or articles that are personal protective equipment or safety apparel that are intended to be used to prevent the transmission of disease between persons. The latter are already regulated as medical devices, whether or not those devices make claims in relation to COVID-19, in accordance with item 1 of the Principal Instrument.

The other items added to the table in Schedule 1 to the Principal Instrument clarify that substances intended to be used to disinfect or clean medical devices, and disinfect, clean, rinse or hydrate contact lenses, are also medical devices, consistent with existing regulatory arrangements.

Attachment C

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Excluded Goods) Amendment (Borderline Products—COVID-19) Determination 2021

Therapeutic Goods (Medical Devices—Specified Articles) Amendment (Borderline Products—COVID-19) Instrument 2021

These disallowable legislative instruments are 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 instruments

The *Therapeutic Goods (Excluded Goods) Amendment (Borderline Products—COVID-19) Determination 2021* ("the amendment determination") and the *Therapeutic Goods (Medical Devices—Specified Articles) Amendment (Borderline Products—COVID-19) Instrument 2021* ("the amendment instrument"), are made under section 7AA and subsection 41BD(2B) of the *Therapeutic Goods Act 1989* ("the Act").

Section 7AA of the Act provides that the Minister may determine that specified goods (other than goods declared to be therapeutic goods under an order in force under section 7 of the Act) are excluded goods for the purposes of the Act, or are excluded goods for the purposes of the Act when used, advertised or presented for supply in a specified manner. Before making a determination under section 7AA, the Minister must have regard to certain matters specified in subsection 7AA(3) of the Act, and any other matter the Minister considers relevant in accordance with subsection 7AA(4) of the Act.

Section 41BD of the Act provides the definition of medical device. Relevantly, paragraph 41BD(1)(a) of the Act provides that a medical device is any instrument, apparatus, appliance, software, implant, reagent, material or other article that is intended, by the person under whose name it is or is to be supplied, to be used for human beings for one or more of the purposes in subparagraphs 41BD(1)(a)(i)–(v), including for example, the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease.

Paragraph 41BD(1)(ab) of the Act provides that an instrument, apparatus, appliance, software, implant, reagent, material or other article that is included in a class of instruments, apparatus, appliances, software, implants, reagents, materials or other articles specified under subsection 41BD(2B), is also a medical device.

Purpose

The amendment determination and amendment instrument are made under section 7AA and subsection 41BD(2B) of the Act, respectively. The amendment determination amends the *Therapeutic Goods (Excluded Goods) Determination 2018*, and the amendment instrument amends the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020*.

The amendment determination and amendment instrument are made in the context of the ongoing public health emergency caused by the coronavirus disease 2019 ("COVID-19"). In this context, the TGA has observed a significant increase in the number of enquiries from potential sponsors and manufacturers of certain products that may be described as borderline products at the interface of consumer goods and therapeutic goods, particularly in relation to whether COVID-19 claims are

permitted to be made in relation to these products under the therapeutic goods legislation and whether such claims would result in these products needing to be listed or included in the Australian Register of Therapeutic Goods ("the Register"). The principal purpose of these instruments is to provide greater clarity with respect to the regulatory status of borderline products.

Human rights implications

The amendment determination and amendment instrument engage 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 amendment determination and amendment instrument promote and support the right to health by reducing uncertainty for industry and consumers, in relation to the regulation of borderline products under the therapeutic goods framework. The regulation of these products has become increasingly important due to the public health emergency caused by COVID-19, which has placed significant pressure on health care systems and caused economic disruption.

By making clear what is, and what is not, a medical device by way of deliberate inclusion or exclusion, the instruments provide greater certainty as to how borderline products are regulated in Australia. The instruments identify products that are low risk and more appropriately regulated under other regulatory schemes, including under the Australian Consumer Law. Similarly, the instruments expressly specify those products that require regulation as therapeutic goods. Clarifying the regulatory boundaries for borderline products enables government resources to be more appropriately utilised and promotes enhanced regulation of the quality, safety and efficacy of therapeutic goods available to the Australian public.

It also assists industry in understanding their regulatory requirements and responsibilities including, where relevant, the need for inclusion of products in the Register. Such inclusion provides consumers with a degree of assurance as to the effectiveness of such products. A clear regulatory framework for therapeutic goods also ensures appropriate regulatory oversight and allows for the advertising of borderline products under that framework, which is particularly important to address aggressive marketing behaviour that has been observed towards consumers during the pandemic.

Conclusion

The amendment determination and amendment instrument are compatible with human rights because they promote the right to health in Article 12 of the ICESCR and otherwise do not raise any other human rights issues.