EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Standard for Disinfectants and Sanitary Products) Amendment Order 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.

Subsection 10(1) of the Act relevantly provides that the Minister may, by legislative instrument, make an order determining that matters specified in the order constitute a standard for therapeutic goods or a class of therapeutic goods identified in the order. Criminal offences and civil penalties may apply if therapeutic goods (other than medical devices) that do not conform with an applicable standard are imported into, exported from, or supplied in Australia. The Secretary may, however, consent in writing to the import, supply or export of goods that do not conform with an applicable standard (sections 14 and 14A of the Act refer).

Without limiting the generality of subsection 10(1), subsection 10(2) relevantly provides that an order establishing a standard for therapeutic goods may be specified by reference to a variety of matters including the quality of the goods and the procedures to be undertaken in the manufacture of those goods. In addition, an order may require matters relating to the standard to be determined in accordance with a particular test.

The *Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Order 2019* ("the Principal Order") is an order made under section 10 of the Act and establishes a ministerial standard specifying minimum safety and quality requirements for therapeutic goods that are disinfectants, sanitisers and sanitary fluids and powders. The Principal Order does not apply in relation to therapeutic goods identified under subsection 6(2) of that Order including, for example, antiseptics and skin disinfectants.

Subsection 10(3A) of the Act provides that the Minister may, by legislative instrument, vary or revoke an order made under subsection 10(1) of the Act. The *Therapeutic Goods (Standard for Disinfectants and Sanitary Products) Amendment Order 2020* ("the Amendment Order") is made by a delegate of the Minister under that subsection.

The purpose of the Amendment Order is to amend the Principal Order, principally to incorporate the most recent version of the *TGA instructions for disinfectant testing* ("the Instructions") and to better target a label warning requirement in relation to disinfectants that contain chlorhexidine. The Amendment Order also makes a small number of clarifications and corrections to the Principal Order.

Background

The Australian Government Department of Health is responsible for regulating the quality, safety and efficacy of therapeutic goods. This is achieved in part by specifying ministerial standards for therapeutic goods which may relate to a range of matters including, for example, the manufacture, testing, labelling and packaging of the goods, and by otherwise applying default standards that are constituted by statements in the international pharmacopoeias defined in the Act.

The Principal Order applies to therapeutic goods that are disinfectants, sanitisers and sanitary fluids and powders, and specifies labelling requirements designed specifically to address the risks that may be associated with the handling and use of the goods. The Principal Order also specifies packaging

requirements, specific performance tests and more general requirements relating to stability data, shelf life and toxicity data.

The Principal Order specifies a number of important performance requirements, which principally require that disinfectants comply with specified microbiological tests, such as those prescribed in the document, TGA Instructions for Disinfectant Testing (March 2019) ("the Instructions"). Additional testing is required where a claim is made for a disinfectant in relation to sporicidal, fungicidal, tuberculocidal, virucidal or other biocidal use. The performance testing requirements specified in the Principal Order for disinfectants apply depending on whether a disinfectant is a hospital grade disinfectant or a household grade disinfectant.

Specifically, the Amendment Order amends the Principal Order to:

- incorporate the most recent version of the Instructions (Version 2.1, March 2020), which has been published on the TGA website. This updated version includes two additional organisms (*E. coli* and *S. aureus*) for hospital grade disinfectants in Table 1 of Part 1 of the Instructions, which deals with the selection of test parameters for disinfectants using the TGA Disinfectant Test. These organisms were inadvertently omitted from this table in the first version of the Instructions published in March 2019. This version has also been updated in relation to virucidal testing requirements relating to the SARS-CoV-2 (COVID-19 virus);
- amend a number of headings in section 13 of the Principal Order to clarify that those provisions relate to performance requirements for hospital grade disinfectants;
- amend a number of headings in section 14 of the Principal Order to clarify that those provisions relate to performance requirements for household grade disinfectants;
- amend section 14 to correct two inadvertent errors;
- make minor amendments to section 16 of the Principal Order, which deals with labelling requirements, to clarify the interaction between subsections 16(2), (3), (4) and (7);
- amend paragraph 16(2)(i) of the Principal Order to better target the labelling requirement specified in subparagraph 16(2)(i)(vii). Pursuant to this amendment, only the labels of disinfectants that contain chlorhexidine as an active ingredient are required to include the words "not to be used on skin", rather than all disinfectants intended to be used on hard surfaces; and
- amend item 2 and item 8 of Schedule 1 to the Principal Order to add some further acceptable common names in relation to disinfectant wipes and sponges, and surface spray disinfectants, for the purposes of the definition of 'common name' in section 4 of the Principal Order. These additional common names are consistent with the common names currently specified in that Schedule.

Consultation

Since the commencement of the Principal Order, the TGA has received ongoing feedback from peak bodies, including Accord and Consumer Health Products Australia, in relation to matters that required correction or clarification. The changes proposed by the Amendment Order give effect to that feedback. In addition, the TGA conducted targeted stakeholder consultation in November 2019 in relation to the proposed labelling requirements for hard surface disinfectants containing chlorhexidine. Stakeholders supported the proposal.

The Office of Best Practice Regulation ("OBPR") has advised that the preparation of a regulation impact statement is not required in relation to the changes proposed by the Amendment Determination, because those changes are unlikely to have more than minor regulatory impact (OBPR ID: 43397).

Incorporation by reference

The Amendment Order incorporates the document *TGA instructions for disinfectant testing* (Version 2.1, March 2020), which is published by the TGA and specifies certain testing requirements in

relation to disinfectants and sanitary products for the purposes of the Principal Order. This document is incorporated as it was in force or existing on 31 March 2020. This document is available for free from the TGA website at www.tga.gov.au.

Details of the Amendment Order are set out in **Attachment A**.

The Amendment Order 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 Order is a disallowable legislative instrument, and commences on the day after it is registered on the Federal Register of Legislation.

Attachment A

Details of the *Therapeutic Goods (Standard for Disinfectants and Sanitary Products) Amendment Order 2020*

Section 1 Name

This section provides that the name of the instrument is the *Therapeutic Goods (Standard for Disinfectants and Sanitary Products) Amendment Order 2020* ("the Amendment Order").

Section 2 Commencement

This section provides that the Amendment Order 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 Order is section 10 of the *Therapeutic Goods Act 1989* ("the Act"). Specifically, subsection 10(3A) of the Act provides that the Minister may, by legislative instrument, vary or revoke an order made under subsection 10(1) of the Act.

Section 4 Schedules

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

Schedule 1 Amendments

Schedule 1 to the Amendment Order amends the *Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Order 2019* ("the Principal Order").

Item 1 of Schedule 1 amends section 4 of the Principal Order to introduce a revised definition of 'Instructions'. The revised definition incorporates the most recent version of the *TGA instructions for disinfectant testing* (Version 2.1, March 2020), which is published on the TGA website. Version 2.1 of the Instructions includes two additional organisms (*E. coli* and *S. aureus*) for hospital grade disinfectants in Table 1: *Selection of test parameters for disinfectants using the TGA Disinfectant Test* in Part 1 of the Instructions. These organisms were inadvertently omitted from this table in the first version of the Instructions published in March 2019. This version has also been updated in relation to virucidal testing requirements relating to the SARS-CoV-2 (COVID-19 virus).

Items 2 to 5 of Schedule 1 amend the headings of subsections 13(4) to (7) of the Principal Order to make it clear that these provisions are concerned with hospital grade disinfectant wipes or sponges.

Item 6 of Schedule 1 makes a correction to clarify that a disinfectant that is for general purpose use on surfaces is only required to pass one of the tests specified in subparagraphs 14(2)(a)(i) to (iii), when tested in accordance with the test conditions specified on the label.

Item 7 of Schedule 1 corrects the heading of subsection 14(3) to make it clear that this subsection is concerned with household grade disinfectants.

Items 8, 10, 11 and 12 of Schedule 1 amend the headings of subsections 14(4) to (7) to make it clear that these provisions are concerned with household grade disinfectant wipes and sponges.

Item 9 of Schedule 1 corrects an error in subparagraph 14(4)(a)(i) of the Principal Order. This item substitutes the TGA Disinfectant Test specified in Part 1 of the Instructions under the conditions specified in Option C of that test, instead of Option A or Option B.

Item 13 of Schedule 1 amends subsection 16(2) of the Principal Order to clarify that subsection 16(7), in addition to subsections 16(3) and (4), contains requirements that apply in relation to information that is the subject of the labelling requirements set out in subsection 16(2).

Item 14 of Schedule 1 amends subparagraph 16(2)(i)(vii) of the Principal Order to better target the labelling requirement specified in that subparagraph. Under this amendment, only the label of disinfectants that contain chlorhexidine as an active ingredient are required to include the words "not to be used on skin", rather than all disinfectants intended to be used on hard surfaces.

Item 15 of Schedule 1 amends subsection 16(4) of the Principal Order to clarify that the batch number and expiry date of the goods do not need to be set out on the main label if they are engraved or embossed on, or on a label attached to, the container or primary pack of the goods.

Item 16 of Schedule 1 repeals and replaces item 2 of Schedule 1 to the Principal Order, to add three further acceptable common names for a disinfectant wipe or sponge. These additional names are 'commercial grade – disinfectant wipe or disinfectant sponge', 'hospital grade – disinfectant wipe or disinfectant sponge' and 'household grade – disinfectant wipe or disinfectant sponge' and are consistent with the other current common names for a disinfectant wipe or sponge.

Item 17 of Schedule 1 repeals and replaces item 8 of Schedule 1 to the Principal Order, to add two further acceptable common names for a surface spray disinfectant. These additional names are 'commercial grade – surface spray disinfectant' and 'household grade – surface spray disinfectant', and are consistent with the other current common names for a surface spray disinfectant.

Attachment B

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Standard for Disinfectants and Sanitary Products) Amendment Order 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 the Legislative Instrument

The *Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Order 2019* ("the principal instrument") is an order made under section 10 of the *Therapeutic Goods Act 1989* ("the Act") for the purpose of establishing a ministerial standard for therapeutic goods that are disinfectants, sanitisers and sanitary fluids and powders. The principal instrument specifies the minimum requirements for the safety and quality of these therapeutic goods, other than those goods that are identified as not being subject to the order (for example, antiseptics and skin disinfectants).

Subsection 10(3A) of the Act provides that the Minister may, by legislative instrument, vary or revoke an order made under subsection 10(1) of the Act. The *Therapeutic Goods (Standard for Disinfectants and Sanitary Products) Amendment Order 2020* ("the amendment instrument") is made by a delegate of the Minister under that subsection.

The purpose of the amendment instrument is to amend the principal instrument, principally to incorporate the most recent version of the *TGA instructions for disinfectant testing* ("the Instructions") and to better target a label warning requirement in relation to disinfectants that contain chlorhexidine. The amendment instrument also makes a small number of clarifications and corrections to the principal instrument.

Specifically, the instrument amends the principal instrument to:

- incorporate the most recent version of the Instructions, which was published on the TGA website in March 2020. This updated version includes two additional organisms (*E. coli* and *S. aureus*) for hospital grade disinfectants in Table 1 of Part 1 of the Instructions, which deals with the selection of test parameters for disinfectants using the TGA Disinfectant Test. These organisms were inadvertently omitted from this table in the first version of the Instructions published in March 2019. This version has also been updated in relation to virucidal testing requirements relating to the SARS-CoV-2 (COVID-19 virus);
- amend a number of headings in section 13 to clarify that those provisions relate to performance requirements for hospital grade disinfectants;
- amend a number of headings in section 14 to clarify that those provisions relate to performance requirements for household grade disinfectants;
- amend section 14 to correct two inadvertent errors;
- make minor amendments to section 16 , which deals with labelling requirements, to clarify the interaction between subsections 16(2), (3), (4) and (7);
- amend paragraph 16(2)(i) to better target the labelling requirement specified in subparagraph 16(2)(i)(vii). Pursuant to this amendment, only the labels of disinfectants that contain chlorhexidine as an active ingredient are required to include the words "not to be used on skin", rather than all disinfectants intended to be used on hard surfaces; and
- amend item 2 and item 8 of Schedule 1 to add some further acceptable common names in relation to disinfectant wipes and sponges, and surface spray disinfectants, for the purposes of

the definition of 'common name' in section 4 of the principal instrument. These additional common names are consistent with the common names currently specified in that Schedule.

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 standard of physical and mental health, and includes an obligation to take reasonable measures within available resources to progressively secure broader enjoyment of the right.

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 instrument takes positive steps to promote the right to health by helping to ensure the safety, quality and efficacy of therapeutic goods that are disinfectants, sanitisers and sanitary fluids and powders. The amendment instrument makes amendments to the principal instrument to ensure that the principal instrument continues to effectively provide for minimum performance and packaging requirements for disinfectants and minimum benchmarks for the labelling of disinfectants, sanitisers and sanitary fluids and powders so as to ensure safe and effective use.

In so doing, the amendment instrument addresses elements of the right to health that relate to improving all aspects of environmental and industrial hygiene, controlling the spread of diseases, and creating conditions that improve medical service and medical attention in the event of sickness.

Conclusion

This instrument is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR as outlined above, and otherwise does not raise any human rights issues.