EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Amendment Order 2025

The *Therapeutic Goods Act 1989* ("the Act") provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy or performance, 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, Disability and Ageing ("the Department").

Subsection 10(1) of the Act 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. Subsection 10(2) of the Act provides that an order establishing a standard for therapeutic goods may be specified by reference to the quality of the goods, or the procedures to be carried out in the manufacture of the goods, among other matters. An order may also require that a matter relating to the standard be determined in accordance with a particular test, or require that goods be labelled or packaged in a manner, or kept in containers that comply with requirements, specified in the order.

Importantly, a person who imports, exports or supplies therapeutic goods that do not conform to an applicable standard may be subject to offence and civil penalty provisions in sections 14 and 14A of the Act. The Secretary may, however, give consent in writing in relation to the importation, exportation or supply of therapeutic goods that do not conform to an applicable standard, in accordance with those sections.

The *Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Order 2019* ("the Principal Order") is made under section 10 of the Act and establishes a ministerial standard for therapeutic goods that are disinfectants, sanitisers and sanitary fluids and powders. The Principal Order specifies minimum requirements for the quality and safety of such products.

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) (TGO 104) Amendment Order 2025* ("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 to incorporate the most recent version of the *TGA instructions for disinfectant testing* ("the Instructions"). The Amendment Order also amends the tests that hospital grade disinfectant wipes or sponges for single use must pass to meet minimum performance requirements in the Principal Order, to align with the most recent version of the Instructions.

Background

The Department is responsible for regulating the quality, safety and efficacy or performance 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, other than the therapeutic goods identified under subsection 6(2) (including, for example, antiseptics and skin disinfectants). The Principal Order specifies labelling requirements

designed specifically to address the risks that may be associated with the handling and use of such products, as well as packaging requirements, performance requirements and more general requirements relating to stability data, shelf life and toxicity data in relation to such products.

The performance requirements in the Principal Order relate in particular to compliance with specified microbiological tests, including tests set out in 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.

Relevantly, subsection 13(4) of the Principal Order provides that if a disinfectant wipe or sponge that is for single use is tested in accordance with the test conditions on the label (if any), the disinfectant must pass **two** tests, being:

- either:
    - the TGA Disinfectant Test under the conditions specified in Option A or B of that test; or
    - an appropriate test equivalent to the TGA Disinfectant Test as specified in Division 2 of Part 2 of the Instructions; and
- an appropriate test for single or multiple use as specified in Division 2 of Part 2 of the Instructions.

Purpose

The Amendment Order amends the Principal Order to:

- incorporate the most recent version of the Instructions (Version 4.0, August 2025), which is published on the TGA website; and
- amend subsection 13(4) to require only **one** of the specified three test options for hospital grade disinfectant wipes or sponges for single use be passed to meet minimum performance requirements.

The amendment to refer to the most recent version of the Instructions follow publication of an updated version of the Instructions which has updates to the required tests that hospital grade disinfectant wipes or sponges for single use must pass.

The Amendment Order consequently amends subsection 13(4) to align with the updated Instructions. It clarifies that only one of the following tests is required and is considered sufficient evidence of suitable disinfectant efficacy for hospital grade disinfectant wipes or sponges for single use:

- the TGA Disinfectant Test, meaning the test specified in Part 1 of the Instructions, under the conditions specified in Option A or Option B of that test;
- an appropriate test equivalent to the TGA Disinfectant Test as specified in Division 2 of Part 2 of the Instructions;
- an appropriate test for single or multiple use as specified in Division 2 of Part 2 of the Instructions.

Incorporation by reference

The Amendment Order incorporates the document *TGA instructions for disinfectant testing* (Version 4.0, August 2025), which is published by the TGA and specifies the testing requirements in relation to disinfectants and sanitary products for the purposes of the Principal Order. The most recent version of the Instructions, includes updates to the required tests that hospital grade disinfectant wipes

or sponges for single use must pass. This document is incorporated as it is in force or existing on 11 August 2025. This document is freely available from the TGA website (www.tga.gov.au).

Consultation

Between 22 July and 30 August 2024, the TGA undertook a public consultation to obtain stakeholder feedback on the proposed amendments to the Instructions. The TGA received 7 responses, including responses from key industry representatives, such as disinfectant product sponsors and manufacturers, and industry bodies. Overall, the feedback received was supportive of the proposed changes to the Instructions. The feedback also included requests for clarification of test requirements, alignment with updated international standards, and simplification of technical language in the Instructions.

All respondents to the consultation were notified of the overall outcomes of the consultation and were informed that consequential amendments will be made to the Principal Order. The TGA also publicly published the outcome of the consultation and noted that minor amendments will be made to the Principal Order.

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) (TGO 104) Amendment Order 2025*

Section 1 Name

This section provides that the name of the instrument is the *Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Amendment Order 2025* (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 – Section 4 (definition of *Instructions*)

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 4.0, August 2025), which is published on the TGA website. The revised definition specifies that it refers to the document as in force or existing at 11 August 2025.

Item 2 – Paragraphs 13(4)(a) and (b)

Item 2 repeals and replaces paragraphs 13(4)(a) and (b) with a new paragraph 13(4)(a), which effectively combines the tests in paragraphs 13(4)(a) and (b) and requires compliance with at least one.

Specifically, this amendment has the effect of requiring hospital grade disinfectants that are for single use only to pass one of the following three tests:

- the TGA Disinfectant Test under the conditions specified in Option A or Option B of that test;
- an appropriate test equivalent to the TGA Disinfectant Test as specified in Division 2 of Part 2 of the Instructions;
- an appropriate test for single or multiple use as specified in Division 2 of Part 2 of the Instructions.

This amendment ensures that the performance testing requirements for hospital grade disinfectant wipes or sponges for single use aligns with current testing practices. The amendment clarifies that the TGA Disinfectant Test (Option A or B), a test equivalent to the TGA Disinfectant Test, or an appropriate bactericidal carrier test are each, on their own, considered sufficient to provide evidence of suitable disinfectant efficacy for hospital grade disinfectant wipes or sponges for single use that pass one of these tests.

Item 3 – Paragraph 13(4)(c)

Item 3 renumbers paragraph 13(4)(c) as 13(4)(b) as a consequence of the amendments made by item 2 above to combine paragraphs (a) and (b) into a single paragraph (a).

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) (TGO 104) Amendment Order 2025

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

Subsection 10(1) of the Act 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. Subsection 10(2) of the Act provides that an order establishing a standard for therapeutic goods may be specified by reference to the quality of the goods, or the procedures to be carried out in the manufacture of the goods, among other matters. An order may also require that a matter relating to the standard be determined in accordance with a particular test, or require that goods be labelled or packaged in a manner, or kept in containers that comply with requirements, specified in the order.

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- the TGA Disinfectant Test, meaning the test specified in Part 1 of the Instructions, under the conditions specified in Option A or Option B of that test;
- an appropriate test equivalent to the TGA Disinfectant Test as specified in Division 2 of Part 2 of the Instructions;
- an appropriate test for single or multiple use as specified in Division 2 of Part 2 of the Instructions.

Human rights implications

The Amendment Order 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 Order supports the right to health by updating performance testing requirement set out in the Instructions to help ensure the safety, quality and efficacy of therapeutic goods that are disinfectants. The Amendment Order makes amendments to the Principal Order to ensure that the Principal Order is in line with the most recent Instructions and continues to effectively provide for minimum performance requirements for disinfectants so as to ensure their safe and effective use. The Amendment Order also reduces regulatory burden and supports the supply of hospital grade disinfectant wipes or sponges for single use by streamlining the tests that such products are required to pass.

Conclusion

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