# EXPLANATORY STATEMENT

*Therapeutic Goods Act 1989*

*Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Amendment (Residual Activity) Order 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.

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, specifying minimum requirements for the quality and safety of such products. 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) (TGO 104) Amendment (Residual Activity) Order 2021* ("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 introduce requirements in relation to claims concerning the residual activity of a disinfectant. The Amendment Order also amends the Principal Order to incorporate the most recent version of the *TGA instructions for disinfectant testing* ("the Instructions"), and to make a small number of minor clarifications and updates 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 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.

The Amendment Order amends the Principal Order to:

- incorporate the most recent version of the Instructions (Version 3.0, December 2021), which is published on the TGA website;
- introduce a definition for 'residual activity' in section 4 of the Principal Order;
- amend subsections 13(2) and 14(2) to omit the word 'test' from each subsection, which had been incorrectly included;
- insert new section 14A into the Principal Order, which provides that, a claim of residual activity made in relation to a disinfectant must only relate to bacteria, yeast or viruses, and be based on residual activity that is established in accordance with the requirements in Division 2 of Part 2 of the Instructions (new section 14A applies to both hospital grade disinfectants and household grade disinfectants); and
- insert a new Part 4 into the Principal Order, which provides transitional arrangements to delay the application of new section 14A until 1 July 2022, for disinfectants included in the Australian Register of Therapeutic Goods ("the Register") before 1 January 2022 or included on the basis of an application for listing under section 26 of the Act that was made before 1 January 2022.

**Consultation**

An initial targeted consultation was conducted in October 2020 with ACCORD, followed by a public consultation in March 2021, to seek feedback on proposals to provide clarity in relation to residual activity claims, including defining residual activity, reviewing acceptance criteria and whether the claims should be restricted. Stakeholders were supportive of the proposed amendments.

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 Order, 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 3.0, December 2021), 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 is in force or existing on 1 January 2022. This document is freely available from the TGA website (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 1 January 2022.

**Attachment A**

**Details of the *Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Amendment (Residual Activity) Order 2021***

**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 (Residual Activity) Order 2021* ("the Amendment Order").

**Section 2 Commencement**

This section provides that the Amendment Order commences on 1 January 2022.

**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").

Items 1 and 2 of Schedule 1 amend section 4 of the Principal Order to introduce a revised definition of 'Instructions' and a new definition of 'residual activity'. The revised definition incorporates the most recent version of the *TGA instructions for disinfectant testing* (Version 3.0, December 2021), which is published on the TGA website. The revised definition specifies that it refers to the document as in force or existing at 1 January 2022. The new definition of 'residual activity' provides that residual activity means 'the capability of a disinfectant to continue to reduce the number of viable cells of relevant test organisms on a surface, when the disinfectant is used in accordance with the information provided on the label of the disinfectant'.

Items 3 and 4 make a minor correction to subsections 13(2) and 14(2) to remove the word 'test'.

Item 5 inserts new section 14A, which introduces requirements that apply when a claim of residual activity is made about a disinfectant. Specifically, new section 14A requires that residual activity claims must only be made in relation to bacteria, yeast or viruses, and must be based on residual activity established in accordance with the requirements in Division 2 of Part 2 of the Instructions. The Instructions provide, relevantly, that residual activity must be established in accordance with the methodology outlined in specified standards and substantiated by test data that meets specified acceptance criteria, that test methods must be justified with regards to the intended use of the disinfectants and that a residual activity claim must be for no more than 30 days.

Item 6 adds new Part 4 to the Principal Order to provide transitional arrangements in relation to the new residual activity requirements added to the Principal Order by the Amendment Order. Section 17

of Part 4 provides that the amendments relating to residual activity in the Amendment Order (specifically, items 2 and 5 of Schedule 1 to the Amendment Order) apply to disinfectants from 1 July 2022 for a disinfectant that was included in the Register before 1 January 2022, or included in the Register on or after 1 January 2022 on the basis of an application for listing under section 26 of the Act made before 1 January 2022.

**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 (Residual Activity) Order 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 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) (TGO 104) Amendment (Residual Activity) Order 2021* ("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 introduce requirements in relation to claims concerning the residual activity of a disinfectant. The amendment instrument also amends the principal instrument to incorporate the most recent version of the *TGA instructions for disinfectant testing* ("the Instructions") and makes a small number of clarifications and updates to the principal instrument.

Specifically, the instrument amends the principal instrument to:

- incorporate the most recent version of the Instructions (Version 3.0, December 2021), which is published on the TGA website;
- introduce a definition for 'residual activity' in section 4 of the Principal Order;
- amend subsections 13(2) and 14(2) to omit the word 'test' from each subsection, which had been incorrectly included;
- insert new section 14A into the Principal Order, which provides that, a claim of residual activity made in relation to a disinfectant must only relate to bacteria, yeast or viruses, and be based on residual activity that is established in accordance with the requirements in Division 2 of Part 2 of the Instructions (new section 14A applies to both hospital grade disinfectants and household grade disinfectants); and
- insert a new Part 4 into the Principal Order, which provides transitional arrangements to delay the application of new section 14A until 1 July 2022, for disinfectants included in the Australian Register of Therapeutic Goods ("the Register") before 1 January 2022 or included on the basis of an application for listing under section 26 of the Act that was made before 1 January 2022.

**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 their safe and effective use. In particular, the amendment instrument addresses claims of residual activity which, if made in relation to a disinfectant, must be appropriately established and substantiated by test data, so such claims are not misleading or misused.

**Conclusion**

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