

REPLACEMENT EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Order 2019

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 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. Offence and civil penalties may apply if therapeutic goods (other than medical devices) that do not comply with an applicable standard are imported, exported or supplied. The Secretary may, however, consent in writing to the import, supply or export of such goods notwithstanding their non-compliance (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 Order”) is an order made by a delegate of the Minister for Health under section 10 of the Act. The purpose of the Order is to establish a ministerial standard for therapeutic goods that are disinfectants, sanitisers and sanitary fluids and powders. The Order specifies the minimum requirements for the safety and quality of these therapeutic goods, other than those that are identified as not being subject to the Order (for example, antiseptics and skin disinfectants).

The Order also repeals and replaces the existing Therapeutic Goods Order No. 54 – Standard for Disinfectants and Sterilants (“the former Order”), which was due to sunset on 1 April 2019 under the sunset provisions of the *Legislation Act 2003*.

Background

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

The Order applies to therapeutic goods that are disinfectants, sanitisers and sanitary fluids and powders. It will contribute to the quality, safety and efficacy of these goods by specifying labelling requirements designed specifically to address the risks that may be associated with the handling and use of the goods, and by requiring that disinfectants comply with packaging

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

The performance testing requirements specified in the Order for disinfectants apply depending on whether a disinfectant is a hospital grade disinfectant or a household grade disinfectant – in each case, as defined in the *Therapeutic Goods Regulations 1990* (“the Regulations”). In relation to household grade disinfectants, it is important to note that the Order applies to such goods whether they are marketed and labelled as being for household and/or commercial use.

If disinfectants do not perform as claimed by a sponsor on the labelling and packaging of the goods, for example, in relation to whether the disinfectants have virucidal, sporicidal, tuberculocidal, or fungicidal properties against such organisms, there may be a threat to public health and safety associated with their use, particularly in relation to hospital grade disinfectants.

The Order principally addresses these risks by specifying minimum performance testing requirements for different types of hospital grade and household grade disinfectants, including those that are for general purpose use on surfaces, those that are surface spray disinfectants and disinfectant wipes and sponges (for single or multiple use). These requirements include that where a claim is made for a disinfectant that it has a sporicidal, fungicidal, tuberculocidal, virucidal or other biocidal use, the Order specifies that these claims must be supported by specific tests in relation to each such claim (the testing requirements themselves are set out in the TGA document *TGA Instructions for Disinfectant Testing*, March 2019).

The Order also addresses the safe use and handling of disinfectants, sanitisers and sanitary fluids and powders by requiring that the stability of disinfectants and their safety in relation to toxicity must be established through data that meets specified requirements, and by requiring the labels of disinfectants, sanitisers and sanitary fluids and powders to include a range of important information. This information includes, for example, the approved name of the goods, the quantity or proportion of each active ingredient, expiry date, and clear and adequate instructions for each of the manufacturer’s intended uses of the goods including the method of use and clear warnings in relation to any dangers that may exist if an incorrect method of use is employed. Disinfectants that are for use on hard surfaces are also required to be labelled with the words “Hard surface disinfectant only” and “Not to be used on skin”.

In comparison with the former Order, the Order in particular does not constitute a standard for sterilants (these are defined in the Regulations as chemical agents that kill microbes with the result that sterility assurance level of a microbial survivor is less than 10^{-6}). This reflects that when the former Order was made in 1996, the Act regulated such goods as registered or listed therapeutic goods whereas now, following amendments to the Act by the *Therapeutic Goods Amendment (Medical Devices) Act 2002*, such goods are regulated as medical devices, under Chapter 4 of the Act.

Also, in comparison with the former Order, the Order does not include any reference to Therapeutic Goods Order No.37 General Requirements for Labels for Therapeutic Devices (“TGO 37”), but rather sets out, in one place, the applicable labelling requirements for disinfectants, sanitisers and sanitary fluids and powders (section 16 of the Order refers). This

reflects that TGO 37 was repealed under the sunset provisions of the *Legislation Act 2003* on 1 October 2018.

Consultation

On 18 December 2018, a draft of the Order and associated guidance documents were released for public consultation, with submissions invited until 12 February 2019. Twenty one submissions were received, including from the Australian Self Medication Industry, Accord, the Aerosol Association of Australia and the Australian Food and Grocery Council, as well as one State Health Department. Most respondents expressed support for the draft Order and the guidance documents. A number of respondents suggested improvements, many of which were incorporated into the final version of the Order. Some of the suggested improvements will be further considered for future incorporation.

In addition, the Office of Best Practice Regulation advised that a regulation impact statement was not considered to be required in relation to the Order (Office of Best Practice Regulation reference ID 23300).

Incorporation by reference

The Order adopts the document *TGA Instructions for Disinfectant Testing* (March 2019), which is published by the TGA and specifies certain testing requirements in relation to disinfectants and sanitary products for the purposes of the Order. The Order incorporates that document as it is in force or existing immediately before the commencement of the Order. This document is available for free from the TGA's website, www.tga.gov.au.

The Order also refers to the Australian Approved Names List, as defined in the Regulations. Subregulation 2(1) of the Regulations defines this term as the document entitled 'Australian Approved Names List for Therapeutic Substances', published by the TGA, as in force from time to time. In so doing, the intention in relation to the reference to this document in the Order is to refer to the Australian Approved Names List as in force from time to time (consistent with its meaning in the Regulations), an approach authorised by subsection 10(4) of the Act. This document is available for free from the TGA website, www.tga.gov.au.

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

The 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 Order is a disallowable legislative instrument, and commences on 31 March 2019.

Details of the *Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Order 2019*

Part 1 Preliminary

This Part provides for the name of the Order, its commencement, authority and application, and a small number of other matters including, for example, setting out definitions for key terms used in the Order.

Section 1 Name

This section provides that the name of this Order is the *Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Order 2019*, and that it may also be cited as TGO 104.

Section 2 Commencement

This section provides that this Order commences on 31 March 2019.

Section 3 Authority

This section provides that the legislative authority for making the Order is section 10 of the *Therapeutic Goods Act 1989* (“the Act”).

Section 4 Definitions

This section provides definitions for a number of terms used in the Order. In particular, these include ‘approved name’, ‘disinfectant wipe or sponge’, ‘Instructions’, ‘sanitary fluid’ and ‘sanitary powder’. A number of terms have the same meaning as in the *Therapeutic Goods Regulations 1990*, for example ‘disinfectant’, ‘hospital grade disinfectant’ and ‘household grade disinfectant’.

The note to this section also makes it clear that a number of expressions used in the Order have the same meaning as in the Act, for example ‘batch’ and ‘current Poisons Standard’.

Section 5 Standard

This section provides that the Order constitutes a standard for disinfectants, sanitisers and sanitary fluids and powders.

Section 6 Application

This section provides that the Order applies to therapeutic goods that are disinfectants, sanitisers, sanitary fluids and sanitary powders. However, this section also makes it clear that the Order does not apply to the therapeutic goods identified in paragraphs 6(2)(a) – (h) including, for example, sterilants, antiseptics and skin disinfectants, and contact lens care products.

Section 7 Requirements

This section provides that the requirements that apply to disinfectants under the Order are those requirements specified in Parts 2 and 3 of the Order.

This section also provides that the requirements that apply to sanitisers and sanitary fluids and powders are those requirements specified in Part 3 of the Order.

Section 8 Repeals

This section provides that each instrument that is specified in Schedule 2 to the Order is repealed as set out in that Schedule.

Part 2 Requirements for disinfectants

This Part provides for general requirements in relation to disinfectants, including those in relation to approved names for disinfectant ingredients, stability data, shelf life and toxicity data. It also provides for specific performance requirements and packaging requirements in relation to disinfectants.

Division 1 General requirements

Section 9 Approved names for ingredients etc

This section provides that a disinfectant may only be comprised of ingredients with an approved name (this term is defined in section 4 as meaning the name of an ingredient as included in the Australian Approved Names List).

This section also provides that the physical form of a disinfectant must be appropriate for its intended use.

Section 10 Stability data

This section provides that the physical and chemical stability, and microbial efficacy, of a disinfectant must be established, in accordance with the requirements set out in the TGA document *TGA Instructions for Disinfectant Testing* (March 2019), using the final form of the disinfectant when stored in its proposed container and packaging material for supply (except in the circumstances identified in subsections 10(2) and (3)).

Section 11 Shelf life

This section provides that a disinfectant must not have a shelf life of more than 5 years.

Section 12 Toxicity data

This section provides that the safety of a disinfectant in relation to its toxicity must be established, and that toxicity data for the disinfectant must include the matters identified in paragraphs 12(a) – (e) including, for example, potential hazards to the user through accidental body contact, and acute oral toxicity in concentrations equivalent to those likely to be encountered in use.

Division 2 Performance requirements

Section 13 Performance requirements for hospital grade disinfectants

This section provides that a hospital grade disinfectant must comply with the minimum performance requirements specified in this section for each claim made in relation to the use of the disinfectant on the label, when tested at the highest dilution recommended on the label for that use, and at the end of the shelf life for that use.

This section also sets out a number of performance testing requirements for specified kinds of hospital grade disinfectants (e.g. hospital grade disinfectants that are for general purpose use on surfaces), when tested in accordance with the test conditions specified on the label of the disinfectant (if any).

Section 14 Performance requirements for household grade disinfectants

This section provides that a household grade disinfectant must comply with the minimum performance requirements specified in this section for each claim made in relation to the use of the disinfectant on the label, when tested at the highest dilution recommended on the label for that use, and at the end of the shelf life for that use.

This section also sets out a number of performance testing requirements for specified kinds of household grade disinfectants (e.g. household grade disinfectants that are for general purpose use on surfaces), when tested in accordance with the test conditions specified on the label of the disinfectant (if any).

Division 3 Packaging requirements

Section 15 Packaging of disinfectants

This section provides that a disinfectant must be enclosed in a container that is suitably designed to ensure that the disinfectant is adequately protected and contained. For a disinfectant that is, or contains a substance that is, included in a Schedule to the Poisons Standard, the container must also comply with any applicable requirements in relation to such a container specified in the Poisons Standard.

Part 3 Requirements for disinfectants, sanitisers, sanitary fluids and sanitary powders

This Part provides for labelling requirements in relation to disinfectants, sanitisers and sanitary fluids and powders.

Section 16 Labelling requirements

This section provides that the label of a disinfectant, sanitiser or sanitary fluid or powder that is, or contains a substance that is, included in a Schedule to the Poisons Standard must comply with any applicable requirements in relation to such a label specified in the Poisons Standard.

This section also provides that (subject to subsections 16(3) and (4)), the container and any primary pack of a disinfectant, sanitiser and sanitary fluid or powder must be labelled with the information specified in paragraphs 2(a) to (i), and provides for a number of other matters

related to the labelling of these goods including, for example, that a household grade disinfectant must not be labelled as “hospital grade disinfectant”.

Schedule 1 Acceptable common names

This Schedule sets out acceptable common names for the purposes of the definition of ‘common name’ in section 4 of the Order.

Schedule 2 Repeals

This Schedule repeals the *Therapeutic Goods Order No. 54 – Standard for Disinfectants and Sterilants*.

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) Order 2019

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* is made by a delegate of the Minister under section 10 of the *Therapeutic Goods Act 1989* (“the Act”).

The purpose of the instrument is to establish a ministerial standard for therapeutic goods that are disinfectants, sanitisers and sanitary fluids and powders. The instrument specifies the minimum requirements for the safety and quality of these therapeutic goods, other than those that are identified as not being subject to the instrument (for example, antiseptics and skin disinfectants).

The instrument also repeals and replaces the existing *Therapeutic Goods Order No.54 – Standard for Disinfectants and Sterilants* (“the former instrument”), which was due to sunset on 1 April 2019 under the sunset provisions of the *Legislation Act 2003*.

The instrument applies to therapeutic goods that are disinfectants, sanitisers and sanitary fluids and powders, and is designed to ensure the quality, safety and efficacy of these goods by specifying labelling requirements designed specifically to address the risks associated with their use, and by requiring that disinfectants comply with specific performance tests and requirements relating to stability data, shelf life and toxicity data, as well as packaging requirements.

The performance testing requirements specified in the instrument for disinfectants apply depending on whether a disinfectant is a hospital grade disinfectant or a household grade disinfectant – in each case, as defined in the *Therapeutic Goods Regulations 1990* (“the Regulations”). In relation to household grade disinfectants, it is important to note that the instrument applies to such goods whether they are marketed and labelled as being for household and/or commercial use.

If disinfectants do not perform as claimed by a sponsor on the labelling and packaging of the goods, for example, in relation to whether the disinfectants have virucidal, sporicidal, tuberculocidal, or fungicidal properties against such organisms, there may be a threat to public health and safety associated with their use, particularly in relation to hospital grade disinfectants.

The instrument principally addresses these risks by specifying minimum performance testing requirements for different types of hospital grade and household grade disinfectants,

including those that are for general purpose use on surfaces, surface spray disinfectants and disinfectant wipes and sponges (for single or multiple use).

These requirements include that where a claim is made for a disinfectant that it has a sporicidal, fungicidal, tuberculocidal, virucidal or other biocidal use, the instrument specifies that these claims must be supported by specific tests in relation to each such claim. The testing requirements themselves are set out in the document *TGA Instructions for Disinfectant Testing* (March 2019), which is published by the TGA and available on the TGA website.

The instrument also addresses the safe use and handling of disinfectants, sanitisers and sanitary fluids and powders by requiring that the stability of disinfectants and their safety in relation to toxicity must be established through data that meets specified requirements, and by requiring the labels of disinfectants, sanitisers and sanitary fluids and powders to include a range of important information. This information includes, for example, the approved name of the goods, the quantity or proportion of each active ingredient, expiry date, and clear and adequate instructions for each of the manufacturer's intended uses of the goods, including the method of use and clear warnings in relation to any dangers that may exist if an incorrect method of use is employed. Disinfectants that are for use on hard surfaces are also required to be labelled with the words "Hard surface disinfectant only" and "Not to be used on skin".

In comparison with the former instrument, the instrument in particular does not constitute a standard for sterilants (these are defined in the Regulations as chemical agents that kill microbes with the result that sterility assurance level of a microbial survivor is less than 10^{-6}). This reflects that when the former instrument was made in 1996, the Act regulated such goods as registered or listed therapeutic goods whereas now, following amendments to the Act by the *Therapeutic Goods Amendment (Medical Devices) Act 2002*, such goods are regulated as medical devices, under Chapter 4 of the Act.

Also, in comparison with the former instrument, the instrument does not include any reference to Therapeutic Goods Order No. 37 General Requirements for Labels for Therapeutic Devices ("TGO 37"), but rather sets out, in one place, the applicable labelling requirements for disinfectants, sanitisers and sanitary fluids and powders. This reflects that TGO 37 was repealed under the sunset provisions of the *Legislation Act 2003* on 1 October 2018.

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 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 instrument takes positive steps to promote the right to health by ensuring the safety, quality and efficacy of therapeutic goods that are disinfectants, sanitisers and sanitary fluids

and powders, through mandating 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 use.

In so doing, the instrument addresses the element of the right to health that relates to the right to healthy natural and workplace environments (particularly, for example, in relation to ensuring the efficacy of hospital grade disinfectants for which claims of virucidal, sporicidal, tuberculocidal, or fungicidal properties are made), and the creation of conditions which would assure to all medical service and medical attention in the event of sickness, in relation to ensuring the safety and quality of essential disinfectants and sanitary products.

The requirements of the instrument are further bolstered in this regard by the criminal, civil and regulatory sanctions that may apply under the Act for persons who import, supply or export therapeutic goods that do not comply with applicable standards.

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.

Miranda Lauman, delegate of the Minister for Health