

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Standard for Tampons) (TGO 103) 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 Therapeutic Goods Administration (“the TGA”), which is part of the Department of Health, is responsible for administering the Act.

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 Tampons) (TGO 103) Order 2019* (“the Order”) is 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 menstrual tampons. The Order specifies the minimum requirements for the safety and quality of tampons.

The Order also repeals and replaces the Therapeutic Goods Order No. 82 – *Standard for Tampons – Menstrual* (“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 manufacture of those products, and otherwise applying default standards specified in international pharmacopoeias.

The Order applies to therapeutic goods that are menstrual tampons, a feminine hygiene product designed to absorb menstrual flow. The Order will contribute to the quality, safety and efficacy of these products by ensuring that these products are manufactured uniformly according to a quality standard. The Order specifies important safety and quality related requirements for all tampons in the interests of consumer safety, including in relation to the safe labelling and packaging of these products.

The Order requires that tampons supplied in Australia must comply with the Australian Standard for Tampons, AS 2869-2008 *Tampons - Menstrual* (“the Australian Standard”), as well as with a small number of labelling requirements.

The Australian Standard addresses, in particular, the risk of Toxic Shock Syndrome (“TSS”) associated with the use of tampons by menstruating women. Although the incidence of TSS in Australia and New Zealand is low, and investigations have shown that unopened tampons have not been contaminated by *Staphylococcus aureus* (the microorganism associated with TSS), the Australian Standard is designed to ensure that this position does not change by reducing the risk of TSS occurring, and to promote the health and comfort of users of these products.

The Australian Standard aims to ensure that tampons are manufactured in a manner that minimises the recognised health risks to consumers associated with the use of these products, by requiring that precautions are taken during the manufacture of the tampon and in the design of its packaging to ensure that contamination of the tampon does not occur. The Australian Standard also aims to ensure that tampons are of appropriate quality and performance when supplied to consumers.

To this end, the Australian Standard specifies a range of requirements for tampons, including those related to absorptive capacity, microbial content, withdrawal cord pull strength and water repellency, marking and packaging. Information to be included in an accompanying leaflet is also described.

The Order is largely consistent with the former Order it replaces, as the former Order also required compliance with the Australian Standard. The main difference between the two instruments is that the new Order requires that the name and address of the manufacturer or sponsor be included on the label of all tampons. This requirement is important in relation to identifying products, particularly in the event of a recall, or in relation to the reporting of adverse events by consumers or health practitioners.

Until recently, this labelling requirement was in place under a separate order (made under subsection 15(1) of the *Therapeutic Goods Act 1966*) – *Therapeutic Goods Order No.37 General Requirements for Labels for Therapeutic Devices* (“TGO 37”). TGO 37 required the inclusion of this information on the label of therapeutic devices as defined in that order. It was repealed under the sunset provisions of the *Legislation Act 2003* on 1 October 2018.

Consultation

In March 2019, the TGA consulted on the proposed making of the Order with the key industry associations that represent tampons sponsors in Australia – namely, Accord Australasia and the Australian Self Medication Industry Association, as well as with the Royal Australian and New Zealand College of Obstetricians and Gynaecologists and the Australian Food and Grocery Council. These stakeholders advised that they had no concerns with the proposed new Order.

The Office of Best Practice Regulation (“OBPR”) advised that a Regulation Impact Statement was not required for the making of the Order (OBPR ref: 23300).

Incorporation by reference

The Order adopts the Australian Standard (AS 2869-2008 *Tampons – Menstrual*), published by or on behalf of Standards Australia, as in force or existing immediately before the commencement of the instrument on 31 March 2019. This standard specifies a range of requirements for tampons related to materials, absorptive capacity, microbial content, withdrawal cord pull strength and water repellency, marking and packaging.

The Australian Standard may be purchased from https://infostore.saiglobal.com/en-au/Standards/AS-2869-2008-123618_SAIG_AS_AS_275693/. Unfortunately Standards Australia does not make its publications available for free, as the publications are subject to copyright (a range of prices may apply depending on whether a person wishes to obtain a hard copy or pdf). However, a preview of the Australian Standard may be viewed for free using the same link.

As an important benchmark for the safety and quality of tampons, it would be infeasible for sponsors and manufacturers not to adopt the Australian Standard on the basis that it is not available for free by Standards Australia. Further, it is expected that those most affected by the requirement to comply with the Australian Standard (sponsors and manufacturers of tampons) would have access to that publication and be familiar with its terms.

It should also be noted that the National Library's Trove online system (<https://trove.nla.gov.au/>) allows users to identify libraries in Australia that are open to the public where publications such as Australian Standards may be viewed. For example, a copy of this Australian Standard is available at the library of the Queensland University of Technology, which is open to the public.

Members of the public may also approach any library that participates in inter-library loans to request an inter-library loan with such university libraries, or to obtain a photocopy of a particular part or monograph for personal study or research (but not for commercial purposes), at a usual cost of \$16.50 per request (enquiries should be made with local libraries, State libraries and the National Library).

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 Tampons) (TGO 103) Order 2019*

Section 1 Name

This section provides that the name of the Order is the *Therapeutic Goods (Standard for Tampons) (TGO 103) Order 2019*. It may also be cited as TGO 103.

Section 2 Commencement

This section provides that the 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 sets out definitions for a number of terms used in the Order. In particular, these include ‘Australian Standard’ (as the document Australian Standard AS 2869-2008 *Tampons-Menstrual*, published by or on behalf of Standards Australia, as in force or existing immediately before the commencement of the Order on 31 March 2019) and ‘tampons’ (as therapeutic goods that are menstrual tampons).

This section also makes it clear that a number of terms have the same meaning as given in the Act, for example, ‘label’, ‘sponsor’ and ‘therapeutic goods’.

Section 5 Standard

This section provides that the Order constitutes a standard for tampons.

Section 6 Requirements

This section has the effect that tampons must comply with the requirements specified in the Australian Standard, and with the requirement that the label of the tampons must include the name and address of either the manufacturer or the sponsor of the tampons.

Section 7 Repeals

This section provides that the instruments specified in Schedule 1 are repealed.

Schedule 1 Repeals

This Schedule repeals Therapeutic Goods Order No. 82 – *Standard for Tampons – Menstrual*.

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Standard for Tampons) (TGO 103) 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 Tampons) (TGO 103) Order 2019* is an order made by the delegate of the Minister for Health under section 10 of the *Therapeutic Goods Act 1989* (“the Act”).

The matters specified in the instrument constitute a standard for therapeutic goods that are menstrual tampons. The purpose of the instrument is to specify the minimum requirements for the safety, efficacy and quality of tampons. The instrument also repeals and replaces the Therapeutic Goods Order No. 82 – *Standard for Tampons – Menstrual* (“the former Order”), which was due to sunset on 1 April 2019 under the sunset provisions of the *Legislation Act 2003*. The instrument commences on 31 March 2019.

The instrument principally requires that tampons supplied in Australia must comply with the Australian Standard AS 2869-2008 *Tampons – Menstrual* (“the Australian Standard”). The Australian Standard addresses, in particular, the risk of Toxic Shock Syndrome (“TSS”) associated with the use of tampons by menstruating women. Although the incidence of TSS in Australia and New Zealand is low, and investigations have shown that unopened tampons have not been contaminated by *Staphylococcus aureus* (the microorganism associated with TSS), the Australian Standard is designed to ensure that this position does not change by reducing the risk of TSS occurring, and to promote the health and comfort of users of these products.

The Australian Standard aims to ensure that tampons are manufactured in a manner that minimises the recognised health risks to consumers associated with the use of these products, by requiring that precautions are taken during the manufacture of the tampon and in the design of its packaging to ensure that contamination of the tampon does not occur. The Australian Standard also aims to ensure that tampons are of appropriate quality and performance when supplied to consumers.

To this end, the Australian Standard specifies a range of requirements for tampons, including in relation to absorptive capacity, microbial content, withdrawal cord pull strength and water repellency, marking and packaging. Information to be included in an accompanying leaflet is also described.

The instrument is largely consistent with the former Order it replaces, which also required compliance with the Australian Standard. The main difference between the two instruments is that the new instrument requires that the name and address of the manufacturer or sponsor be included on the label of all tampons. This requirement is important in relation to identifying

products, particularly in the event of a recall, or in relation to the reporting of adverse events by consumers or health practitioners.

Until recently this requirement was in place under a separate order (made under subsection 15(1) of the *Therapeutic Goods Act 1966*) – *Therapeutic Goods Order No.37 General Requirements for Labels for Therapeutic Devices* (“TGO 37”). TGO 37 required the inclusion of this information on the label of therapeutic devices as defined in that order. It 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 quality, safety and efficacy of menstrual tampons by requiring tampons to be manufactured uniformly according to a quality standard. By adopting the Australian Standard, the instrument supports the safe use of these products for women and ensures that important minimum safety and quality-related requirements for the manufacture and design of tampons are in place, particularly in relation to:

- alerting users about the risk of TSS and requiring that tampons be manufactured from materials that are non-toxic and suitable for use in such products;
- requiring that tampons be designed in such a manner so as to minimise trauma and are comfortable to use; and
- specifying requirements in relation to the safe labelling and packaging of these products.

In so doing, the instrument addresses the element of the right to health that relates to the quality of goods that are used for health, including in particular that they are scientifically and medically appropriate, and of good quality.

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