

## **EXPLANATORY STATEMENT**

### *Therapeutic Goods Act 1989*

#### *Therapeutic Goods (Standard for Tampons) (TGO 103) Amendment Order 2022*

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 and Aged Care.

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. Subsection 10(2) 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 the goods be labelled or packaged in a specified manner. 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.

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 Tampons) (TGO 103) Order 2019* (“the Principal Order”) is an order made under section 10 of the Act for the purpose of establishing a ministerial standard for therapeutic goods that are menstrual tampons. The Principal 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, principally by requiring that tampons supplied in Australia must comply with the Australian Standard AS 2869-2008 *Tampons-Menstrual* (“AS 2869-2008”).

The Australian Standard AS 2869-2008 was revised in 2022, to provide greater international harmonisation of absorbency ranges and test methods, and consequent labelling changes. The purpose of the *Therapeutic Goods (Standard for Tampons) (TGO 103) Amendment Order 2022* (“the Amendment Order”) is to amend the Principal Order to incorporate the revised version of the Australian Standard, AS 2869:2022 *Tampons-Menstrual* (“AS 2869:2022”).

The principal changes in the updated version of the Australian Standard AS 2869:2022 as compared with AS 2869-2008 are:

- harmonisation of the absorbency ranges with the Code of Practice of the European Disposables and Nonwoven Association (“EDANA”) for tampons in the European market;
- the addition of an increased absorbency range;

- revision of the primary absorbency labelling markings and the addition of optional secondary absorbency labelling markings;
- the listing of details to be included in the accompanying information leaflet;
- revision of microbial content test methods; and
- removal of the ether soluble substances test.

The product requirements under AS 2869:2022 have, for the most part, not been altered from those under AS 2869-2008. Rather, the existing requirements continue but with additional ways (principally in relation to testing and labelling) to demonstrate compliance, by allowing the use of overseas data and methods. There is an exception to this in relation to the introduction of an increase to the absorbency range of tampons, which will allow for the supply of tampons with higher absorbency levels than previously permitted in Australia.

### **Consultation**

The update of the Australian Standard from AS 2869-2008 to AS 2869:2022 was requested by industry and supported by the TGA.

In June 2022, the TGA consulted with the key industry associations that represent suppliers of tampons in Australia - Accord Australasia (“Accord”) and Consumer Healthcare Products Australia - in relation to updating the Principal Order to reflect the revised Australian Standard for tampons. While both bodies were in favour of the proposal, Accord requested a two year transition period in relation to the labelling elements of the changes under AS 2869:2022, to enable sufficient time for product labels to become compliant with the new requirements. Consequently, transitional arrangements reflecting this period have been included in the Amendment Order.

The Office of Impact Analysis advised that a Regulation Impact Statement is not required for the Amendment Order (OBPR ID: OBPR22-03013).

### **Incorporation by reference**

The Amendment Order adopts the Australian Standard AS 2869:2022 *Tampons – Menstrual*, published by or on behalf of Standards Australia, as in force or existing at 30 November 2022. This standard specifies a range of requirements for tampons, including in relation to materials, absorptive capacity, microbial content, withdrawal cord pull strength and water repellency, marking and packaging.

The Australian Standard AS 2869:2022 may be purchased from SAI Global at <https://infostore.saiglobal.com/en-au/Standards/>. 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. 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.

In addition, by prior written arrangement with the TGA, copies of both Australian Standard AS 2869-2008 and Australian Standard AS 2869:2022 may be made available for viewing, free of charge, at the TGA office in Fairbairn, ACT.

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.

**Details of the *Therapeutic Goods (Standard for Tampons) (TGO 103) Amendment Order 2022***

**Section 1 Name**

This section provides that the name of the instrument is the *Therapeutic Goods (Standard for Tampons) (TGO 103) Amendment Order 2022* (“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”). 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 the Schedule concerned, and that any other item in a Schedule to the Amendment Order has effect according to its terms.

**Schedule 1 – Amendments**

This Schedule amends the *Therapeutic Goods (Standard for Tampons) (TGO 103) Order 2019* (“the Principal Order”).

Item 1 repeals and substitutes the definition of ‘Australian Standard’ in section 4 of the Principal Order to provide that it means the updated version of the Australian Standard, being AS 2869:2022 *Tampons-Menstrual*, published by, or on behalf of, Standards Australia, as in force or existing at 30 November 2022.

Item 2 inserts new section 6A after section 6 of the Principal Order, to provide for certain transitional arrangements. This section provides that, despite the amendments made by the Amendment Order, the labelling requirements under the previous version of the Australian Standard, AS 2869-2008, may continue to be complied with as an alternative to the labelling requirements specified in AS 2869:2022 for the duration of the transitional period, which is from the commencement of the Amendment Order until 31 December 2024.

## **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) (TGO103) Amendment Order 2022***

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* (“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 menstrual tampons. The principal instrument 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, principally by requiring that tampons supplied in Australia must comply with the Australian Standard AS 2869-2008 *Tampons-Menstrual* (“AS 2869-2008”). The Australian Standard AS 2869-2008 was revised in 2022, to provide greater international harmonisation of absorbency ranges and test methods, and consequent labelling changes.

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 Tampons) (TGO 103) Amendment Order 2022* (“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 to incorporate the updated version of the Australian Standard, AS 2869:2022.

The principal changes in the updated version of the Australian Standard AS 2869:2022 as compared with AS 2869-2008 are:

- harmonisation of the absorbency ranges with the Code of Practice of the European Disposables and Nonwoven Association (“EDANA”) for tampons in the European market;
- the addition of an increased absorbency range;
- revision of the primary absorbency labelling markings and the addition of optional secondary absorbency labelling markings;
- the listing of details to be included in the accompanying information leaflet;
- revision of microbial content test methods;
- removal of the ether soluble substances test.

The product requirements under AS 2869:2022 have, for the most part, not been altered from those under AS 2869-2008. Rather, the existing requirements continue but with additional ways (in relation to testing and labelling) to demonstrate compliance, by allowing the use of overseas data and methods. There is an exception to this in relation to the introduction of an increase to the absorbency range of tampons, which will allow for the supply of tampons with higher absorbency levels than previously permitted in Australia.

## **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 continued safety and quality of therapeutic goods that are menstrual tampons. The amendment instrument amends the principal instrument to incorporate the revised version of the Australian Standard, so ensuring that the principal instrument continues to effectively provide for minimum performance and packaging requirements for tampons. By incorporating the revised Australian Standard in the principal instrument, the amendment instrument helps to ensure that important minimum requirements for the safe manufacture and design of tampons continue to be in place, and supports the safe use of these products for women.

## **Conclusion**

The amendment 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.