**EXPLANATORY STATEMENT**

*Therapeutic Goods Act 1989*

*Therapeutic Goods (Standard for Menstrual Cups) Amendment Order 2023*

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 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. 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 applicable standards 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 Menstrual Cups) Order 2018* (“the Principal Order”) is an order made under section 10 of the Act for the purpose of establishing a ministerial standard for menstrual cups. The Principal Order specifies the minimum requirements for the quality and safety of menstrual cups, including the requirements in relation to information that must be supplied with the menstrual cup.

The purpose of the *Therapeutic Goods (Standard for Menstrual Cups) Amendment Order 2023* (“the Amendment Order”) is to amend the Principal Order to make minor updates, principally to increase the limit for the duration of use of menstrual cups, which must be stated on information supplied with a menstrual cup, from 8 hours to 12 hours.

**Background**

The Australian Government is responsible for regulating the quality, safety and efficacy of therapeutic goods. This is achieved in part by requiring compliance with the default standards under the Act and specifying ministerial standards under section 10 of the Act by reference to a range of matters including the manufacture of therapeutic goods.

The Principal Order applies to therapeutic goods that are menstrual cups and specifies requirements for all menstrual cups relating to the manufacture, design, packaging and labelling of these products. In addition, the Principal Order specifies certain information that must be supplied with menstrual cups, including instructions for use, warnings and limits to the duration of use.

In early 2023, industry identified a need to review the Australian recommended use time of menstrual cups, in order to be consistent with international best practice. Initially, the decision to limit the use of menstrual cups to 8 hours was primarily based on data pertaining to tampon use. However, as menstrual cups have now been in the market for an additional 5 years, richer data has been generated that reflects a use time of up to 12 hours. In particular, the research does not highlight an increased risk to users of menstrual cups when used for up to 12 hours. Importantly, advice from the Advisory Committee on Medical Devices (an advisory committee established under the *Therapeutic Goods Regulations 1990*) indicated that any risk to consumer safety incurred by a change in intended use from a period of up to 8 hours to a period of up to 12 hours was so slight that it was unquantifiable.

Furthermore, the regulation of these goods overseas supports a use time of up to 12 hours. As the Australian products are not markedly different to the international market, there are insufficient grounds to retain the 8-hour limit in Australia. In addition, aligning with regulation overseas will potentially increase supply (and the variety of menstrual cups available) in Australia.

The Amendment Order therefore amends the Principal Order to provide that the information leaflet that must be supplied with a menstrual cup must include a limit to the duration of use, not exceeding 12 hours.

The Amendment Order also makes another minor amendment to include a refence to “TGO 99” within the name of the instrument. As this instrument is commonly referred to as “TGO 99”, this will improve access to the instrument when searching for TGO 99.

**Consultation**

In July 2023, RegTech was informed of the proposed amendments and given the opportunity to provide feedback. RegTech is a forum of key industry bodies and associations that facilitates consultation between the TGA and the medical device industry. No specific feedback was received from RegTech.

The Office of Impact Analysis advised that the making of the Amendment Order is unlikely to have a more than minor regulatory impact so the preparation of an Impact Analysis is not required (OIA23-05256).

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 the day after registration on the Federal Register of Legislation.

**Attachment A**

**Details of the *Therapeutic Goods (Standard for Menstrual Cups) Amendment Order 2023***

**Section 1 – Name**

This section provides that the name of the instrument is the *Therapeutic Goods (Standard for Menstrual Cups) Amendment Order 2023* (“the Amendment Order”).

**Section 2 – Commencement**

This section provides that the Amendment Order commences on the day after registration 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*.

**Section 4 – Schedules**

This section provides that each instrument that is specified in Schedule 1 to the Amendment Order is amended as set out in the applicable items in that Schedule.

**Schedule 1—Amendments**

This Schedule amends the *Therapeutic Goods (Standard for Menstrual Cups) Order 2018* to update the name of the instrument, to include a reference to the order number (TGO 99), and to increase the limit for the duration of use of menstrual cups, which must be stated on information supplied with a menstrual cup, from 8 hours to 12 hours.

**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 Menstrual Cups) Amendment Order 2023***

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 Menstrual Cups) Amendment Order 2023* (“the Amendment Order”)is made by a delegate of the Minister under subsection 10(3A) of the *Therapeutic Goods Act 1989* (“the Act”).

The purpose of the Amendment Order is to amend the *Therapeutic Goods (Standard for Menstrual Cups) Order 2018* (“the Principal Order”) to make minor updates, principally to increase the limit for the duration of use of menstrual cups, which must be stated on information supplied with a menstrual cup, from 8 hours to 12 hours.

The Principal Order applies to therapeutic goods that are menstrual cups and specifies requirements for all menstrual cups relating to the manufacture, design, packaging and labelling of these products. In addition, the principal instrument specifies certain information that must be supplied with menstrual cups, including instructions for use, warnings and limits to the duration of use.

In early 2023, industry identified a need to review the Australian recommended use time of menstrual cups, in order to be consistent with international best practice. Initially, the decision to limit the use of menstrual cups to 8 hours was primarily based on data pertaining to tampon use. However, as menstrual cups have now been in the market for an additional 5 years, richer data has been generated that reflects a use time of up to 12 hours. In particular, the research does not highlight an increased risk to users of menstrual cups when used for up to 12 hours. Importantly, advice from the Advisory Committee on Medical Devices (an advisory committee established under the *Therapeutic Goods Regulations 1990*) indicated that any risk to consumer safety incurred by a change in intended use from a period of up to 8 hours to a period of up to 12 hours was so slight that it was unquantifiable.

Furthermore, the regulation of these goods overseas supports a use time of up to 12 hours. As the Australian products are not markedly different to the international market, there are insufficient grounds to retain the 8-hour limit in Australia. In addition, aligning with regulation overseas will potentially increase supply (and the variety of menstrual cups available) in Australia.

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**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 standards 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 maintains the right to health by helping to ensure the continued safety and quality of therapeutic goods that are menstrual cups. The Amendment Order amends the Principal Order to update the limit to the duration of use for menstrual cups. This ensures that the Principal Order continues to effectively provide for appropriate minimum standards that align with international standards, supporting the safe use of these products for women. The alignment with international regulatory standards will also potentially increase supply in Australia or increase the range of menstrual cups that may be available in Australia.

**Conclusion**

The Amendment Order 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.