



Australian Government

Department of Health and Aged Care  
Therapeutic Goods Administration

---

# Regulation of menstrual cups in Australia

## Guidance

Version 2.0, February 2024

## Copyright

© Commonwealth of Australia 2024

This work is copyright. You may reproduce the whole or part of this work in unaltered form for your own personal use or, if you are part of an organisation, for internal use within your organisation, but only if you or your organisation do not use the reproduction for any commercial purpose and retain this copyright notice and all disclaimer notices as part of that reproduction. Apart from rights to use as permitted by the *Copyright Act 1968* or allowed by this copyright notice, all other rights are reserved and you are not allowed to reproduce the whole or any part of this work in any way (electronic or otherwise) without first being given specific written permission from the Commonwealth to do so. Requests and inquiries concerning reproduction and rights are to be sent to the TGA Copyright Officer, Therapeutic Goods Administration, PO Box 100, Woden ACT 2606 or emailed to <[tga.copyright@tga.gov.au](mailto:tga.copyright@tga.gov.au)>.

---

## Contents

|                                                   |          |
|---------------------------------------------------|----------|
| <b>Introduction</b>                               | <b>4</b> |
| <b>For sponsors and applicants</b>                | <b>4</b> |
| Existing ARTG entries                             | 4        |
| Current applications                              | 4        |
| Related guidance and legislation                  | 4        |
| <b>Regulatory requirements</b>                    | <b>4</b> |
| Permissible raw materials                         | 5        |
| Design requirements                               | 5        |
| Packaging                                         | 5        |
| Labelling requirements                            | 5        |
| Information to be provided with the menstrual cup | 5        |
| <b>Post market – Ongoing responsibilities</b>     | <b>6</b> |

## Introduction

Menstrual cups are therapeutic products which are [exempt](#) from inclusion on the [Australian Register of Therapeutic Goods \(ARTG\)](#). Note – these were required to be listed on the ARTG prior to 1 July 2018. Prior to 1 July 2018, menstrual cups were required to be listed on the ARTG

Menstrual cups are required to comply with [Therapeutic Goods Order No.99 – Standards for Menstrual Cups 2018](#) before they can be supplied in Australia.

## For sponsors and applicants

To comply with regulatory requirements, you may need to do the following:

### Existing ARTG entries

Sponsors with existing ARTG entries for tampons and/or menstrual cups can contact the TGA and request cancellation of their listed ARTG entries for these products. We will notify you when your ARTG entry is cancelled.

If you decide to maintain ARTG listing for these products, you will continue be responsible for paying all respective future [annual charges](#).

### Current applications

You do not require ARTG listing for menstrual cups, and therefore you may decide to withdraw your application. If you choose to do so, you will be free from paying any future fees or charges. You should know, however, that there is no provision for us to refund the fees you have already paid.

If you decide to continue with your application, the TGA will follow the normal assessment process, and you will be obliged to pay all respective fees and charges (as applicable).

## Related guidance and legislation

Menstrual cups must adhere to the requirements as set out in the:

[Therapeutic Goods Act 1989](#)

[Therapeutic Goods Regulations 1990](#)

[Therapeutic Goods Advertising Code 2015](#)

[Therapeutic Goods \(Standard for Menstrual Cups\) \(TGO 99\) Order 2018](#)

## Regulatory requirements

Each section below gives a brief outline of the regulatory requirements stated in Therapeutic Goods Order No.99 – Standards for Menstrual Cups.

## Permissible raw materials

Menstrual cups should be manufactured from material suitable for their intended purpose. None of the ingredients contained in the menstrual cup should appear in a sufficient concentration to cause an irritant or toxic reaction when the product is used as directed. The manufacturer/supplier should hold sufficient evidence to demonstrate that materials used for this purpose are in compliance with pharmacopoeia or other relevant standards.

## Design requirements

Your menstrual cup should be smooth and designed to minimise trauma to the end consumer.

## Packaging

Packaging materials and processes such as assembly and sealing should be validated under the requirements of relevant standards.

## Labelling requirements

Menstrual cups must include the following labelling on the packaging of the product:

- The name of your product.
- The name and address of the manufacturer or the sponsor.
- The batch number or serial number for the product contained within the pack.
- If the package contains two or more menstrual cups, the name of all the goods within the package and the quantity of each of the goods.
- If your product comes in multiple sizes, the size of the unit contained in the pack.
- The following warning in letters having a height of not less than 1 mm.

**IMPORTANT:** Menstrual cups have been associated with Toxic Shock Syndrome (TSS).

TSS is a rare but serious disease that may cause death. Read and keep the enclosed information.

## Information to be provided with the menstrual cup

The following information must be supplied with your product:

- Information to identify the manufacturer or supplier of the product. The name or trademark should be permanently and legibly included on the packaging or material enclosed inside the pack.
- An information leaflet that contains:
  - Detailed instructions for use, including warnings emphasising the need for hygiene and care during insertion, as well as how the product should be cleaned prior to, and in between, uses.
  - A limit to the duration of use, not exceeding 12 hours.
  - Information about Toxic Shock Syndrome (TSS), noting that while TSS is rarely associated with the use of menstrual cups, still occurs.
  - Notification that your menstrual cup is not supplied sterile. Although AS 2869:2008 Tampons – Menstrual is written for tampons, it contains an example of wording that can be used in the

information leaflet for the menstrual cup. Generally, the leaflet should be written in plain English and a simple style that will be easy for younger women, and women for whom English is a second language, to understand. Other factors you might like to consider in the preparation of your information leaflet are:

| Factor to consider | Description                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|--------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Content            | <ul style="list-style-type: none"> <li>• Avoid using medical terms or explain them if you must use them.</li> <li>• The information must appear in English.</li> <li>• You may elect to include the information in another language, but the translation of the information is your responsibility and will not be assessed or reviewed by us.</li> </ul>                                                                                             |
| Font               | <ul style="list-style-type: none"> <li>• Use a font style that is easy to read, avoiding fonts that look like handwriting.</li> <li>• Use lower case as much as possible, keeping upper case for headings and warnings only.</li> <li>• Choose the colour of your fonts and graphics carefully, and aim to maximise readability</li> </ul>                                                                                                            |
| Graphics           | <ul style="list-style-type: none"> <li>• As some people using your product may have limited language and literacy skills, support your information with graphics where possible.</li> <li>• Graphic representations should be simply line drawings or photos.</li> <li>• Limit graphic representations to the most important information.</li> <li>• Make sure graphics appear next to the text that describes what they are representing.</li> </ul> |



An example of the information you might include is contained in Appendix E of AS 2869:2008 Tampons – Menstrual

## Post market – Ongoing responsibilities

Your menstrual cup must continue to meet all regulatory, safety and performance requirements and standards while it continues to be supplied within Australia. Reporting adverse events associated with your product is a mandatory requirement.



Adverse events relating to your product can be reported at: Report a medical device adverse event (sponsor/manufacture)

## Version history

| Version | Description of change                 | Author                         | Effective date |
|---------|---------------------------------------|--------------------------------|----------------|
| V1.0    | Original publication                  | Medical Devices Branch,<br>TGA | November 2019  |
| V2.0    | New template, minor amendment to text | Medical Devices Branch,<br>TGA | February 2024  |

## **Therapeutic Goods Administration**

PO Box 100 Woden ACT 2606 Australia

Email: [info@tga.gov.au](mailto:info@tga.gov.au) Phone: 1800 020 653 Fax: 02 6203 1605

Web: [tga.gov.au](http://tga.gov.au)