Australian Government
Department of Health
Therapeutic Goods Administration

Guidance on the regulation of menstrual cups in Australia

Version 1.0, November 2018

TGA Health Safety Regulation

The purpose of this guidance is to help sponsors understand how the TGA interprets regulations, and thus indicate how a sponsor can comply.

This is a guide only, and sponsors are encouraged to familiarise themselves with the legislative and regulatory requirements in Australia. If necessary, seek professional advice as it is the responsibility of each sponsor to understand and comply with these requirements.

This document will evolve over time and updates and clarifications will be included as required. Feedback on the guidance is always welcome.

Contents

Introduction

Menstrual cups are therapeutic products which are exempt from inclusion on the Australian Register of Therapeutic Goods (ARTG).

Prior to 1 July 2018, menstrual cups were required to be listed on the ARTG. As a result of recent regulatory amendments, these products became exempt goods and therefore you are no longer required to have an ARTG entry for these products.

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

If you have a problem with a menstrual cup, please tell us about it at: Report a medical device adverse event (medical device user).

For sponsors and applicants

To reflect this regulatory amendment, 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. The TGA 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 no longer 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 (Single Therapeutic Goods) Order No.1 of 1991
- *Therapeutic Goods Order No.99 – Standards for Menstrual Cups*

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.

Manufacturer's details

The manufacturer or supplier of the menstrual cup must be able to be identified through their name or trademark, which should be permanently and legibly included on the packaging or on the Information Leaflet enclosed inside the pack.

Information leaflet

An information leaflet containing the following information must be included with your product:

- 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.

- 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	• Avoid using medical terms, or explain them if you must use them. • The information must appear in English. • 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.
Font	• Use a font style that is easy to read, avoiding fonts that look like handwriting. • Use lower case as much as possible, keeping upper case for headings and warnings only. • Choose the colour of your fonts and graphics carefully, and aim to maximise readability.
Graphic Aids	• As some people using your product may have limited language and literacy skills, support your information with graphics where possible. • Graphic representations should be simply line drawings or photos. • Limit graphic representations to the most important information. • Make sure graphics appear next to the text that describes what they are representing.

Note

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.

Note

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

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Devices Branch, Therapeutic Goods Administration	November 2018

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au

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