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.
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Introduction

Tampons are therapeutic products which are regulated as 'Other Therapeutic Goods'. Before they can be supplied in Australia, they must be listed on the Australian Register of Therapeutic Goods (ARTG).

Tampons supplied in Australia must comply with *Therapeutic Goods Order No.82 – Standard for Tampons – Menstrual*. This order states that the Australian Standard “*AS 2869:2008 Tampons – Menstrual*” is currently the applicable standard for menstrual tampons in Australia.

*AS 2869:2008* aims to ensure that tampons are manufactured in a manner that will minimise recognised risks to health associated with the use of these products. The standard covers a range of factors including, but not limited to:

- Packaging
- Labelling
- Performance requirements
- Specific absorptive capacity
- Microbial content
- Withdrawal cord pull strength
- Water repellence

You can obtain a copy of *AS 2869:2008 Tampons – Menstrual* from SAI Global.

If you have a problem with a tampon, please tell us about it using the Report a medical device adverse event (medical device user) form.

Note

Tampons must meet *AS 2869:2008 Tampons – Menstrual*.

It is an offence to import and/or supply the therapeutic goods in Australia that do not conform with a standard applicable to the goods (refer sections 14 and 14A of the *Therapeutic Goods Act 1989*).

Related guidance and legislation

Tampons must also adhere to the requirements as set out in the:

- *Therapeutic Goods Act 1989*
- *Therapeutic Goods Regulations 1990*
- *Therapeutic Goods Order No. 82 - Standard for Tampons - Menstrual*
- *Therapeutic Goods Advertising Code 2015*
- *Therapeutic Goods (Single Therapeutic Goods) Order No.1 of 1991*
 Regulatory requirements

Your product must meet the requirements under AS 2869:2008 Tampons – Menstrual. Each section below gives a brief outline of the regulatory requirements stated in the Standard.

Components

The following is an extract from AS 2869:2008 Tampons – Menstrual:

5 MATERIALS

5.1 Permissible materials

Tampons should be manufactured from cellulosic materials (such as cotton and viscose rayon), or synthetic textile polymers, either singly or in combination, provided that adequate testing does not demonstrate a hazard. Polyester foam shall not be used. Carboxymethylcellulose (CMC) shall not be added to tampons.

   NOTE: Although in-vitro studies have indicated that polyester foam and not CMC may be responsible for enhancing the production of TSST-1 toxin under certain test conditions, high absorbency per se has been implicated in some epidemiological studies. It was therefore decided to prohibit the use of polyester foam, and to prohibit the addition of CMC to tampons. This requirement is in recognition of the fact that, although naturally occurring low background levels may be present, CMC is not added to tampons as there are consumer concerns about this substance. Concern has also been expressed about acrylate modified rayons. Where such materials are used, evidence is required that no demonstratable hazard exists.

5.2 Freedom from toxic and irritant effect

Tampons shall not contain ingredients in sufficient concentration to cause a toxic or irritant reaction when used as directed.

   NOTE: A suitable method is given in AS ISO 10993.10

5.3 Freedom from impurities

No foreign matter shall be evident when the material is visually inspected.

Design requirements

Withdrawal cord

Your product must contain a withdrawal cord. When the cord is hanging free from the tampon the length of the cord should be no less than 80mm long. The withdrawal cord must also meet minimum standards for water repellence and pull strength of the cord at its attachment point as set out in AS 2869:2008 Tampons – Menstrual.

Applicators

If your product includes an applicator the product should be smooth and designed so as to minimise trauma to the end consumer.
Packaging

There are four main elements to the packaging of tampons:

- **Unit Pack**
- **Primary Pack**
- **Supply Pack**
- **Transport Pack**

**Unit Pack**
Each individual tampon (and applicator, where provided) must be enclosed in a closed unit pack capable of maintaining the quality of the product until it is opened by the consumer. Unit packs should then be contained within a Primary Pack.

**Primary Pack**
A Primary Pack contains one or more Unit Packs and is designed to protect the Unit Packs during normal transport and storage. Primary Packs must be marked with the following information:

- The batch or lot number which must be identified with the words “Batch No.” or “Lot No.” or by words and/or symbols that have the same meaning.
- Labelling identifying the absorbency range of the product as follows:

<table>
<thead>
<tr>
<th>Absorbency range</th>
<th>Label</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 6g</td>
<td>As tampons with an absorbency of less than 6g are not widely available, no label is given</td>
</tr>
<tr>
<td>6 - 9g</td>
<td>Approximately 8g of absorbency Suitable for light flow</td>
</tr>
<tr>
<td>Greater than 9 - 12g</td>
<td>Approximately 11g absorbency Suitable for medium flow</td>
</tr>
<tr>
<td>Greater than 12 - 15g</td>
<td>Approximately 14g absorbency Suitable for heavy flow</td>
</tr>
</tbody>
</table>

- The following warning in words with a height not less than one millimetre:

> IMPORTANT: Tampon use has been associated with Toxic Shock Syndrome (TSS). TSS is a rare but serious disease that may cause death. Read and keep the enclosed information.
Note

While you are required to label your primary pack with the wording shown in the table above, this does not preclude you from using other words to identify the absorbency of your product as a part of your brand. Words such as "mini", "regular" and "super" may also be used.

You must use the specific label for the tampons contained within the Primary Pack on the front of your packaging. If you choose to display a table or labelling showing the absorbency of other tampons in your product range, this information should be on the back of the Primary Pack along with information again identifying the absorbency of the tampons contained within the Primary Pack.

Supply Pack

The Supply Pack is the form that the entire product takes when procured by the consumer. This may be the Primary Pack, but may also be the over-wrapping or sealing over the Primary Pack. The Supply Pack must be permanently and legibly marked with the following so it is visible at the time of purchase or procurement, or the Supply Pack must allow this information to be visible on the Primary Pack:

- Description of the contents, including the number of Unit Packs and the absorbency range label as outlined above.
- A list of the components that form the body of the tampon
- The following warning in words with a height not less than one millimetre:

  IMPORTANT: Tampon use has been associated with Toxic Shock Syndrome (TSS). TSS is a rare but serious disease that may cause death. Read and keep the enclosed information.

Transport Pack

The Transport Pack is the form a retailer or supplier will receive the product in. The Transport Pack must be marked with a date code or the same batch numbers as those on the enclosed Primary Packs.

Note

Transport Packs are only required when sending your product to retailers or suppliers. If you are selling your product directly to consumers, you are not required to adhere to the Transport Pack requirements.

Manufacturer’s details

The Manufacturer or Supplier of the tampons must be able to be identified through their name or trademark, which should be permanently and legibly included on the Supply Pack or on the Information Leaflet enclosed in the Primary Pack.
**Information leaflet**

An information leaflet containing the following information must be included with each Primary Pack:

- Detailed instructions for use including warnings emphasising the need for hygiene and care during insertion.

- Information about Toxic Shock Syndrome (an example of the information you might include is contained in *AS 2869:2008 Tampons – Menstrual*).

- Notification that tampons are not supplied sterile and that while tampons contain small amounts of bacteria normally present in the air, they have not been shown to carry the bacteria that cause Toxic Shock Syndrome (TSS).

*AS 2869:2008 Tampons – Menstrual* contains an example of wording that can be used in the information leaflet. 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:

<table>
<thead>
<tr>
<th>Factor to consider</th>
<th>Description</th>
</tr>
</thead>
</table>
| **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. |
Other labelling requirements

In addition to the above requirements, you must also include the following on the Supply Pack or on the Primary Pack (but visible through the Supply Pack):

- The name of your product
- The name and address of the manufacturer or the sponsor
- The quantity of tampons within the pack.

Kits containing tampons

If you are producing a kit that contains tampons bundled with other consumables, your product may meet the definition of a therapeutic kit.

Tampons that are included in a kit must meet AS 2869:2008 Tampons – Menstrual, and be included on the ARTG before the kit can be supplied to consumers. This means that the tampons contained in the kit must be supplied in a way that satisfies the packaging requirements as outlined above, there must be an information leaflet included in the Primary Pack, and the Supply Pack must be sufficient to preserve the tampons from any damage that may be caused by other products in the kit.

Note

Therapeutic kits must have their own, separate, listing on the ARTG.

If you intend to supply a therapeutic kit you will need to submit an application for listing of “Other Therapeutic Good – Listed other” through TGA's Business Services.

Test reports

The requirements for test reports for tampons are comprehensively outlined in AS 2869:2008 Tampons – Menstrual. These reports and their associated certificates must be signed and dated by the analyst, be less than 2 years old, and be from an acceptable test laboratory.

Laboratories undertaking testing to establish compliance with the requirements must have certification in the form of:

- NATA/NATA MRA partner or equivalent accreditation; or
- certification from a recognised authority to ISO 13485 - Medical Devices - Quality Management Systems; or
Absorptive capacity

Your test report will need to reference Appendix A of *AS 2869:2008 Tampons – Menstrual* and contain the following information:

- The number of tampons tested
- The highest and lowest absorptive capacity results in grams of water per tampon.
- The absorbency range, into which 90% of the estimated population falls.

Withdrawal cord strength

Your test report will need to reference Appendix B of *AS 2869:2008 Tampons – Menstrual* and contain the following information:

- For the dry state, the results of 10 individual tests and the mean force of those 10 tests.
- For the wet state, the results of 10 individual tests and the mean force of those 10 tests.

Withdrawal cord water repellence

Your test report will need to reference Appendix C of *AS 2869:2008 Tampons – Menstrual*, and state whether any of the samples sank completely beneath the water surface.

Total aerobic microbial count

Your test report will need to reference Appendix D of *AS 2869:2008 Tampons – Menstrual* and state the total aerobic microbial count per gram of each tampon and each applicator (if they are included with your product).

Making an application

Applications for multiple products

Many sponsors have a range of tampons in different sizes, or may sell differently branded versions of the same product. Generally these products are considered to be separate and distinct therapeutic goods under section 16 of the Act and therefore require individual listing on the ARTG.

Tampons are able to be treated as a single therapeutic good if they have the following common characteristics:

- the sponsor
- the principal manufacturer
- classification in the same Australian Device Group, and
- supply in the same state of sterility, whether sterile or non-sterile.

If your tampons meet these requirements, you can apply for listing of these goods with one application.

For further information refer the *Therapeutic Goods (Single Therapeutic Goods) Order No.1 of 1991*.
If you wish to enter additional goods that come within the requirement of the Single Goods Order onto an existing ARTG entry, you can request a variation of the listing of your therapeutic goods. This can be done by submitting a Device Change Request, which will be considered by the Delegate of the Secretary under section 9D of the Act.

**Note**

One DCR can be submitted for additional products providing the products share common characteristics as defined in the *Therapeutic Goods (Single Therapeutic Goods) Order No.1 of 1991*, and the only variation is in size of the goods and/or packaging/branding.

If the composition of the goods has changed (i.e. you are now manufacturing/supplying tampons that are made from different components/material), this is not a variation and you will need to submit an application for a separate listing of these goods on the ARTG.

**Information to accompany your application**

You may wish to provide the following information to support your application at the time of your submission:

- Labels
- Packaging
- Information Leaflet
- Test Certificates
- If your product includes an applicator – pictures and graphic representations of the applicator.

If you do not supply this information at the time you submit your application, we will request it from you at a later date. Evaluation of your application will be delayed until we receive and assess this information.

**Note**

If you elect to submit this information at the time that you make your application, you must ensure that the labels, packaging and information leaflet are versions you anticipate will be supplied with the products.

Additional information can be attached with your application for listing of Other Therapeutic Goods in TBS.
How to supply your information to us

Preferred method
Attach electronic copies of this information to your application in the TBS system. See Attaching supporting documents in this guidance.

Alternative methods

- If less than 15 pages, clearly state the application ID and the applicant name in the subject line and email the information to devices@tga.gov.au

- If more than 15 pages, you can send us an electronic copy in the form of a CD or DVD clearly identifying the application ID and the applicant name on the CD or DVD or

- A single hard copy of the information (two-sided print is acceptable)
  - Standard A4 paper should be used where possible with the margin sufficiently large that the information is not obscured by binding.
  - The information must be supplied in loose-leaf binders. Avoid plastic sleeves and staples.
  - Section the information for ease of reference and provide a table of contents for each binder.

CDs, DVDs and hard copies can be sent to:

Devices Applications and Verification
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
Submitting your application

To submit your application for your tampons to be listed on the ARTG, you will need access to the TGA's Business Services system (TBS).

You need to login into your TBS account to access the application forms. If you don't have an account/access, follow the instructions at TGA Business services: getting started with the TGA.

Step 1 - Login to TGA Business Services

Enter your user name and password.

Step 2 - Select the relevant application type

From the Applications menu, under the Medical Device list, select Device/OTG Application.
Step 3 – Complete the application form and attach all relevant documents

You’ll be taken to Page 1 of the application form to complete/confirm the required details. To begin, select *Other Therapeutic Good – Listed other* from the list in the *Application for* field.

Complete the required details for Page 1, remembering to add a Sponsor’s own reference before continuing. Select the *Next* button to continue.

Page 2 requires the relevant manufacturer’s details.

To search for your manufacturer, select the *Search* button under *Manufacturer name* which opens the search window.

Enter your search term and select the *Search* button. This will display a list of possible manufacturers which match (or closely match) your search term.

Once you have selected the correct manufacturer, select the *Add to Application* button.
To select the correct GMDN code for your application, select the **Search** button under the **GMDN code and description** field which will open the **GMDN search** window.

You can search by the GMDN code, or text in the GMDN description. Once you have found the correct GMDN, select it from the search results, and press **OK** to add the details to your application. Once you have completed Page 2, select **Next** to continue.

The final page has a:

- summary of the application information for you to review
- section to electronically attach supporting information
- declaration you need to agree to before you can submit your application.
**Attaching supporting documents**

To attach supporting information, select the *Add* button in the *Function to Attach/Add Supporting Information* field which will open the *File Upload* window.

Select the Document type from the dropdown list. You should attach all relevant documents from your computer. Select the Browse button and then select the relevant file from your computer to attach. Select the Add button to attach this file to your application.

**Note:** Follow this process for each file you need to attach.

Each attachment will be listed under the *Function to Attach/Add Supporting Information* field.

If you need to delete any attachments, select *Remove* next to the attachment you want to delete.
Before you can submit your application, you must agree to the declaration:

![Declaration]

When the form has been completed, select **Validate**. This will ensure that the form has all the required information to allow your form to be submitted.

**Note**

Validation of your form is only confirming that you have filled out all required fields in the application. Validation is not an approval of your application or a guarantee that all the required information has been submitted to the TGA.

If there are any issues with the form, they will be identified with blue writing near the top of the page that will link you to the incomplete information when you select it.

If you filled in all required fields in the application form, you will be able to submit your application.

**Fees and charges**

**Application fee**

The current application fee for tampons can be found in our [Schedule of fees and charges](#) under: Other listed and registered therapeutic goods (OTGs). The application fee is specifically stated under "Listed OTG fees".

**Evaluation fee**

If you provide sufficient evidence that your goods meet the requirements of *AS 2869:2008*, your application is unlikely to require further evaluation, and you will therefore not be required to pay an evaluation fee.
Where additional evaluation is required

If you do not have sufficient information to clearly demonstrate that your goods meet the standard, or if there are concerns regarding the safety of your product, further evaluation may be required. In this case you will be required to pay an evaluation fee.

The current fee for evaluating the safety of tampons can be found under “Other listed and registered therapeutic goods (OTGs)” on our Schedule of fees and charges page. The fee is specifically stated under “Listed OTG fees” as a “Fee for evaluating documents and information relating to the safety of listed therapeutic goods”.

Note

Application and evaluation fees are not refundable. For further information refer to the refunds webpage.

Annual charges

Once your product is listed on the ARTG, annual charges for maintaining your listing will apply. The current annual charge for tampons can be found in our Schedule of fees and charges page under “Other listed and registered therapeutic goods (OTGs)”. The fee is specifically stated under Annual charges as “Listed goods: tampons and disinfectants”.

Post market – ongoing responsibilities

Once a tampon has been listed on the ARTG, it must continue to meet all the regulatory, safety and performance requirements and standards that were required for the approval.

There are mandatory requirements for all sponsors of tampons, including:

- telling us about any changes to the composition of your product
- reporting adverse events; and
- ensuring the information on your ARTG listing remains current.

Note

Adverse events relating to your product can be reported using the Report a medical device adverse event (sponsor/manufacturer) form.
## Version history

<table>
<thead>
<tr>
<th>Version</th>
<th>Description of change</th>
<th>Author</th>
<th>Effective date</th>
</tr>
</thead>
<tbody>
<tr>
<td>V1.0</td>
<td>Original publication</td>
<td>Medical Devices Branch, TGA</td>
<td>18/08/2017</td>
</tr>
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</table>