

Technical Alert

New Permitted Indications Determination No. 1 of 2019; Outcomes of the Consultation on Permissible Indications

The list of indications has updated with a new instrument, [Therapeutic Goods \(Permissible Indications\) Determination \(No. 1\) of 2019](#) [the 'Second Determination (2019)']. The first Determination, the Permitted Indications Determination No. 1 of 2018, was made in March 2018.

Changes to the Second Determination (2019)

Changes made in the new instrument are organised into tables on the [TGA website](#). Particular changes of interest are included below in this technical alert, but please note that the TGA webpage has 8 tables of items, each relating to certain types of changes as summarised:

1. New Indications
2. Removed indications (Ayurvedic and TCM)
3. Changes to wording of requirements - same meaning and same intent
4. Correction to indication and wording - same meaning and same intent
5. Correction to indication and wording - change in meaning and change intent
6. Correction of evidence requirements
7. Additional Requirements to specific indications
8. Change in wording to requirements for specific indications

➤ RE-ADDED or CHANGES to Label Warning Statements ([Item 7](#) and [Item 3](#))

- **(COLD) – Adults only OR Not to be used in children under 2 years of age without medical advice**

The TGA have reinstated this statement for cold indications due to the possibility of serious consequences of inappropriately treating colds and flus in children without medical attention, e.g. a child may appear to have a cold but actually be suffering from a more serious illness.

- **'If symptoms persist, talk to your health professional'**

This has been added to an additional 8 permissible indications.

- **Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.**

This statement has been added to the Determination for 4 indications, if the medicines are for supplementation. It will replace the requirement currently in the Therapeutic Goods Regulations.

- **“Talk to” (healthcare professional etc) instead of “consult your”**

For consistency, warning statements for listed medicine labels have been updated to use the terminology that is consistent with the Advertising Code No. 2 of 2018 wording “talk to”, which will ultimately make the requirements more streamlined and straightforward for sponsors. Note that

labels should be updated when possible, however as the change in terminology has no real impact on consumers, this is particularly an item for enforcement discretion.

➤ NEW Indications ([Item 1](#))

The TGA have added a number of new indications from stakeholder feedback, many in response to CMA's request developed with regulatory working group members. These indications can be added to ARTG entries for free even if the entries have already been updated to permitted indications, until **8 September 2019**.

- Maintain/support energy production - *Scientific or Traditional*
- Helps decrease/reduce/relieve cartilage loss/wear/tear/damage - *Scientific*
- Maintain/support joint cartilage health - *Scientific*
- Helps enhance/improve/promote joint mobility - *Scientific or Traditional*
- Maintain/support good/beneficial/friendly gut flora during antibiotic use - *Scientific*
- Help restore good/beneficial/friendly gut flora after antibiotic use - *Scientific*
- Enhance promote stomach health - *Scientific or Traditional*
- Decrease/reduce/relieve symptoms of menstruation - *Scientific or Traditional*
- Helps maintain/support skin pH balance - *Scientific*
- Helps decrease/reduce/relieve symptoms of minor skin wounds (cuts, scratches and abrasions) - *Scientific or Traditional*
- Female tonic - *Traditional*
- Decrease/reduce oily skin - *Scientific or Traditional*
- Maintain/support foetal CNS/brain development - *Scientific*
- Helps decrease/reduce/relieve symptoms of mild mastitis while lactating/breastfeeding - *Scientific or Traditional*
- Helps reduce occurrence of symptoms of mild mastitis while lactating/breastfeeding - *Scientific or Traditional*

➤ REMOVED Traditional Indications ([Item 2](#))

Ayurvedic indications determined by TGA as not appropriate to be supported by evidence of traditional use:

- Medohara/helps dissipation of fats and liquids
- Meha hara/helps maintain blood sugar health
- Pandu hara/helps improve dietary iron

TCM indications recommended for removal by TCM expert:

- Stabilise mind
- Open body orifices

TCM Indications duplicated:

- Unblock/open/relax channels
- Strengthen/enrich/restore kidney Jing

➤ Other Changes

[Item 4](#), [Item 6](#) and [Item 8](#) include a variety of corrections and clarifications to particular indications and requirements. [Item 5](#) includes corrections to sunscreen indications.

Transition & Compliance Arrangements for New Requirements

Now: New listings will need to comply with the 2019 Determination as soon as it comes into force.

8 September 2019: ARTG entries can be updated fee-free to change to permitted indications (providing that other changes - such as a new product name - are not triggering a Grouping fee.)

8 March 2021: All medicines are expected to be compliant with the new requirements in the Second Determination (2019). Until this date, for *existing* medicines, the TGA are offering an 'enforcement discretion' approach. For example issues such as required label statements, will attract a reminder of requirements and no regulatory action.

Medicines supplied before the Second Determination (2019)

Please note that labelled medicines that were released for supply *before* the launch of the Second Determination (2019), and were compliant with the requirements of the first Determination, were in compliance at the time that the medicines were supplied, and should not be called or counted as a compliance issue. If your medicine is subject to a post market 'Listing Compliance Review' (following a Request for Information under Section 31 of the Act), it may help to note details regarding dates in your response.

Outcomes of Consultation on Permissible Indications

The TGA have updated the [webpage](#) describing the outcomes of the Public Consultation on permissible indications, particularly under "Issue 13 – Indications proposed by industry during the 2017 public comment". The TGA has provided that this is the finalisation of the consultation.

Sponsors can still apply for indications that are not on the list, including indications that are included in the "[Indications proposed by industry during the 2017 public comment](#)" Excel spreadsheet for reconsideration by the TGA. However the TGA have provided that a detailed justification for the context of an indication's use should be provided, preferably including why the indication is suitable for listed medicines (for example, is not a restricted representation, if this may be in question.) Please contact CMA if there are questions about possible applications.

The application form for a new permitted indication is the '**Indication and Qualifier application**' form via the TGA Business Services website, and attracts a fee, currently \$1,020. Information about the application process is available in the [Permitted indications for listed medicines](#) guidance document.

Members are encouraged to forward any identified issues to technical@cmaustralia.org.au for attention by the Committee Secretariat.

ENDS