Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Changes to the Permissible Indications Determination

Consultation paper

Version 1.0, June 2026

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Introduction

Listed medicines are considered low-risk medicines as they can only use low-risk ingredients and make low-level indications. These medicines are not individually evaluated by the Therapeutic Goods Administration (**TGA**) before they are released onto the market. Instead, they are automatically included in the Australian Register of Therapeutic Goods (**ARTG**) following completion of an online application and certification by the sponsor (product owner) that their product meets all applicable Australian legislative requirements in relation to safety, quality and efficacy. These medicines can be identified by an ARTG identification number starting with 'AUST L' on their medicine label.

Since listed medicines are not evaluated prior to being included in the ARTG, we use a variety of mechanisms to help ensure that they are safe for consumers. One such mechanism is they may only contain indications (health claims) covered by a list of permissible indications made by the Minister of Health and Ageing under section 26BF of the *Therapeutic Goods Act 1989* (**the Act**). These 'pre-approved' low-level indications and their requirements for use are set out in the Therapeutic Goods (Permissible Indications) Determination (currently (No. 1) 2025)[1] (**Permissible Indications Determination**) to ensure that only appropriate claims are made for low-risk medicines.

Permissible indications have been assessed against a set of criteria and determined to be appropriate for listed medicines. These criteria are intended to ensure that permissible indications will only cover (and listed medicines will be limited to making) indications relating to:

- health maintenance
- health enhancement
- prevention of dietary deficiency; or
- certain non-serious[2], self-limiting diseases, ailments, defects or injuries.

About this consultation

The TGA is seeking public comment on issues and proposed amendments to the Permissible Indications Determination.

The issues include:

1. Omission of the word *mild* from an indication referring to eczema.
2. Inconsistent/incorrect requirements for indications relating to the thyroid.
3. Lack of flexibility to use alternative label statements for an indication including the term *antipyretic*.
4. Missing label statement requirement for an indication referring to neural tube defects.
5. Missing label statement requirement for an indication referring to inducing sleep.

The proposed amendments to the affected permissible indications are provided in five groups, corresponding with the five issues listed above. Proposed amendments (deletion or addition) to indication and/or indication requirements are provided in red text.

The purpose of the consultation is to seek feedback from interested parties on the proposed amendments to the Permissible Indications Determination to address the identified issues. This information will be taken into consideration when making decisions to amend the Permissible Indications Determination.

TGA's implementation of the proposed changes and transition periods for existing products will be informed by consultation feedback and provided with the publication of the consultation outcomes.

[1] www.legislation.gov.au/F2025L00450/asmade/text

[2] Note that the term *serious* as used in this document and the Permissible Indications Determination has the same meaning as serious, in relation to a form of a disease, condition, ailment or defect in section 28 of the Therapeutic Goods Advertising Code.

We invite you to provide your feedback by answering the questions in this consultation paper in the consultation hub by 12 August 2026.

If you have any questions relating to this consultation, please email: nonprescriptionmedicines@health.gov.au.

Issues identified with the Permissible Indications Determination

Issue 1: Omission of the word *mild* from an indication referring to eczema

Background

Indications for listed medicines may only refer to non-serious forms of a disease, ailment, defect or injury. The target qualifier *mild* is used to qualify an indication to make it clear that the indication is only referring to a non-serious form of a disease, condition, ailment or defect, for example: *mild arthritis*, *mild eczema*. Where a permissible indication includes the term 'mild' this must also be included on the medicine's label.

The following indication is not qualified with the word *mild* which is inconsistent with the listed medicine framework and with other permissible indications referring to eczema:

> *Helps reduce occurrence of symptoms of eczema/dermatitis.*

Representations of eczema without a mild qualifier are inappropriate for a listed medicine as it can imply that the medicine is indicated for moderate to severe eczema. A sponsor using this indication for their listed medicine may be at risk of non-compliance.

Further, the above indication does not have the following requirement, which is inconsistent with other permissible indications referring to eczema:

> *Product presentation must only refer to mild eczema.*

Group 1 Proposed amendment: amend indication and add requirement to eczema indication

Current indication	Proposed amended indication	Proposed amended indication requirement
Helps reduce occurrence of symptoms of eczema/dermatitis	Helps reduce occurrence of symptoms of mild eczema/dermatitis	Label statement: If symptoms persist, talk to your health professional. Product presentation must only refer to mild eczema.

Potential impact for Group 1 Proposed amendment:

As of 15 June 2026, there are currently 67 medicines that include this indication in the medicine's ARTG entry.

However, inclusion of the indication in the medicine's ARTG entry does not necessarily mean that the indication is included on a medicine's label or other promotional material. Further, where the indication is included on a medicine label, it is unknown if the medicine's presentation would be considered to be

implying a serious disease. That is, the overall presentation of the medicine may clearly indicate that the medicine is not for the treatment of a serious condition.

Therefore, the impact of the proposal is unknown.

TGA's implementation of the proposed changes and transition periods for existing products will be informed by consultation feedback and provided with the publication of the consultation outcomes.

Group 1 Proposed amendment consultation questions

1. Do you agree with amending the indication and its requirement as proposed?
2. Will this change represent a regulatory burden for you? If so, please provide details.
3. Do you have any other comments or feedback on the issue or proposal?

Issue 2: Inconsistent/incorrect requirements for indications relating to the thyroid

Background

Indications for listed medicines may not refer to the treatment of a serious form of a disease, ailment, defect or injury, or refer to the prevention or cure of any disease, ailment, defect or injury[3].

There are currently seven permissible indications referring to the thyroid (five in Part 4 and two in Part 17 of the Permissible Indications Determination).

Inconsistency in requirements between thyroid indications

There is currently inconsistency in relation to the requirements for the seven indications referring to the thyroid indications:

- the two indications in Part 17 require a label statement: *If you have pre-existing thyroid conditions, seek advice from your medical practitioner before taking this medicine*; while
- the five indications in Part 4 do not have this requirement.

For consistency, and in the interest of consumer safety, it is proposed that all indications referring to the thyroid should have the same requirements. Accordingly, we are proposing to include the required label statement, *If you have pre-existing thyroid conditions, seek advice from your medical practitioner before taking this medicine*, to the five indications where the statement has been omitted.

Wording of indication requirement

We are also proposing an amendment to an apparent ambiguity in relation to another indication requirement. All seven permissible indications include the following presentation requirement:

> *Product presentation must not imply or refer to any thyroid related diseases*.

[3] As an exception to this criterion, the list of permissible indications includes certain indications covered by the prohibited and restricted representation exemptions on the basis of their public health importance, safe history of use and well-established evidence base.

The wording of this requirement may create ambiguity for sponsors regarding the inclusion of the required label statement, *If you have pre-existing thyroid conditions, seek advice from your medical practitioner before taking this medicine,* as the warning statement itself refers to a thyroid related disease.

As such, we are proposing to amend the wording in the current requirement to clarify that the medicine cannot refer to *the treatment, prevention or cure of* any thyroid related diseases.

Therefore, the TGA is proposing to include:

a) the following label statement for five indications where it is currently omitted:
If you have pre-existing thyroid conditions, seek advice from your medical practitioner before taking this medicine.
b) the following amendment to the indication requirement for all seven indications referring to the thyroid:
Product presentation must not imply or refer to ***the treatment, prevention or cure of*** *thyroid related diseases.*

Group 2 Proposed amendments: amend/add requirements for thyroid indications

Current indication	Current requirements	Proposed amended requirements
Aid/assist thyroid hormone production	Product presentation must not imply or refer to any thyroid related diseases.	Product presentation must not imply or refer to ~~any~~ the treatment, prevention or cure of thyroid related diseases. Label statement: If you have pre-existing thyroid conditions, seek advice from your medical practitioner before taking this medicine.
Maintain/support healthy thyroid gland function	Product presentation must not imply or refer to any thyroid related diseases.	Product presentation must not imply or refer to ~~any~~ the treatment, prevention or cure of thyroid related diseases. Label statement: If you have pre-existing thyroid conditions, seek advice from your medical practitioner before taking this medicine.
Maintain/support healthy thyroid hormones	Product presentation must not imply or refer to any thyroid related diseases.	Product presentation must not imply or refer to ~~any~~ the treatment, prevention or cure of thyroid related diseases. Label statement: If you have pre-existing thyroid conditions, seek advice from your medical practitioner before taking this medicine.
Maintain/support thyroid gland health	Product presentation must not imply or refer to any thyroid related diseases.	Product presentation must not imply or refer to ~~any~~ the treatment, prevention or cure of thyroid related diseases. Label statement: If you have pre-existing thyroid conditions, seek advice from your medical practitioner before taking this medicine.
Thyroid tonic	Product presentation must not imply or refer to any thyroid related diseases.	Product presentation must not imply or refer to ~~any~~ the treatment, prevention or cure of thyroid related diseases. Label statement: If you have pre-existing thyroid conditions, seek advice from your medical practitioner before taking this medicine.

Current indication	Current requirements	Proposed amended requirements
Aid/assist healthy thyroid hormone production for pregnancy	Indication can only be used for medicines that contain iodine as a mandatory component of one or more permitted active ingredients and the recommended daily dose of the medicine provides a minimum of 150 micrograms of iodine. Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester. Label statement: If you are concerned about the health of yourself or your baby, talk to your health practitioner. Label statement: If you have pre-existing thyroid conditions, seek advice from your medical practitioner before taking this medicine. Product presentation must not imply or refer to any thyroid related diseases.	Indication can only be used for medicines that contain iodine as a mandatory component of one or more permitted active ingredients and the recommended daily dose of the medicine provides a minimum of 150 micrograms of iodine. Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester. Label statement: If you are concerned about the health of yourself or your baby, talk to your health practitioner. Label statement: If you have pre-existing thyroid conditions, seek advice from your medical practitioner before taking this medicine. Product presentation must not imply or refer to ~~any~~ the treatment, prevention or cure of thyroid related diseases.
Maintain/support healthy thyroid gland function for pregnancy	Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester. Label statement: If you are concerned about the health of yourself or your baby, talk to your health practitioner. Label statement: If you have pre-existing thyroid conditions, seek advice from your medical practitioner before taking this medicine. Indication can only be used for medicines that contain iodine as a mandatory component of one or more permitted active ingredients and the recommended daily dose of the medicine provides a minimum of 150 micrograms of iodine. Product presentation must not imply or refer to any thyroid related diseases.	Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester. Label statement: If you are concerned about the health of yourself or your baby, talk to your health practitioner. Label statement: If you have pre-existing thyroid conditions, seek advice from your medical practitioner before taking this medicine. Indication can only be used for medicines that contain iodine as a mandatory component of one or more permitted active ingredients and the recommended daily dose of the medicine provides a minimum of 150 micrograms of iodine. Product presentation must not imply or refer to ~~any~~ the treatment, prevention or cure of thyroid related diseases.

Group 2 Proposed amendments potential impact

As of 15 June 2026, there are currently 413 medicines using at least one of the seven indications for the thyroid in the ARTG entry for their medicine. 379 of these medicines do not currently require the proposed label statement on their medicine labels. The requirement for an additional label statement is likely to impact sponsors as they will be required to include it on their medicine label.

TGA's implementation of the proposed changes and transition periods for existing products will be informed by consultation feedback and provided with the publication of the consultation outcomes.

Group 2 Proposed amendments consultation questions

4. Do you agree with the amendments to the requirements in relation to Issue 2?
5. Will this change represent a regulatory burden for you? If so, please provide details.
6. Do you have any other comments or feedback on the issue or proposal?

Issue 3: Lack of flexibility to use alternative label statements for an indication including the term *antipyretic*

Background

The permissible indication, *Antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling,* currently requires the label statement:

> *Not to be used in children under 5 years.*

Sponsors are not provided with the ability to use an alternative label statement (e.g. *Adults only*), that may better reflect the medicine's intended target population and supporting evidence.

While this label statement excludes use in children under 5 years, the requirement to use a specific age-based statement may create ambiguity when read alongside directions for use or dosing information on the label.

For example, a medicine intended for adolescent and adult use would still be required to state *Not to be used in children under 5 years.* When read together with other elements of the label, this may create uncertainty about the appropriate population for use and reduce the clarity and effectiveness of label statements in supporting safe and appropriate use.

Allowing greater flexibility in how age-related restrictions are expressed may maintain appropriate safety controls whilst supporting more consistent and easily understood labelling, including where sponsors wish to apply more restrictive statements such as *Adults only*, that better align with the product's intended use.

Group 3 Proposed amendment: amend requirement for antipyretic indication

Current indication	Current requirements	Amended requirements
Antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling	Label statement: If symptoms persist, talk to your health professional. Label statement: Not to be used in children under 5 years.	Label statement: If symptoms persist, talk to your health professional. Label statement: Not to be used in children under 5 years of age OR words that clearly exclude use of the medicine in children under 5 years of age such as 'Adults only'.

Group 3 Proposed amendment potential impact

As of 15 June 2026, there are currently 128 medicines using this indication in the ARTG entry for their medicine.

As it is unknown to the TGA which label statement/s is/are included on the medicine label and whether the medicine's presentation would be considered confusing for consumers.

Therefore, the impact of the proposal is unknown.

TGA's implementation of the proposed changes and transition periods for existing products will be informed by consultation feedback and provided with the publication of the consultation outcomes.

Group 3 Proposed amendment consultation questions

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7. Do you agree with the amendments to the requirements for this indication?
8. Will this change represent a regulatory burden for you? If so, please provide details.
9. Do you have any other comments or feedback on the issue or proposal?

Issue 4: Missing label statement requirement for an indication referring to neural tube defects

Background

Prior to the implementation of the Permissible Indications Determination, the coded indication, *Help to prevent neural tube defects such as spina bifida and/or anencephaly,* included the following label statement requirement:

> *Do not exceed the stated dose except on medical advice. If you have had a baby with a neural tube defect/spina bifida - seek medical advice (or words to that effect).*

This requirement was inadvertently omitted in the initial Permissible Indications Determination[4], and as such, important information is not being conveyed to consumers.

Group 4 Proposed amendment: add requirement for neural tube defect indication

Add/reinstate a required label statement to the indication *Help to prevent neural tube defects such as spina bifida and/or anencephaly.*

Proposed Amendment

Current indication	Current requirements	Amended requirements
Help to prevent neural tube defects such as spina bifida and/or anencephaly	Indication can only be used for medicines that contain folic acid as an active ingredient and the recommended daily dose of the medicine provides a minimum of 400 micrograms of folic acid. Product presentation referring to the prevention of neural tube defects must include at least one of the following label statements: when trying to conceive and during the first trimester of pregnancy, and/or when taken at least four weeks before conception and during the first trimester of pregnancy. If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.	Indication can only be used for medicines that contain folic acid as an active ingredient and the recommended daily dose of the medicine provides a minimum of 400 micrograms of folic acid. Product presentation referring to the prevention of neural tube defects must include at least one of the following label statements: when trying to conceive and during the first trimester of pregnancy, and/or when taken at least four weeks before conception and during the first trimester of pregnancy. If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester. Label statement: Do not exceed the stated dose except on medical advice. If you have had a baby with a neural tube defect/spina bifida - seek medical advice (or words to that effect).

Group 4 Proposed amendment potential impact

As of 15 June 2026, there are currently 84 medicines using these indications in the ARTG entry for their medicine.

The requirement for an additional label statement is likely to impact sponsors as they will be required to include it on their medicine label.

TGA's implementation of the proposed changes and transition periods for existing products will be informed by consultation feedback and provided with the publication of the consultation outcomes.

Group 4 Proposed amendment consultation questions

10. Do you agree with reinstating the requirement for the indication?

[4] www.legislation.gov.au/F2018L00215/asmade/text

11. Will this change represent a regulatory burden for you? If so, please provide details.
12. Do you have any other comments or feedback on the issue or proposal?

Issue 5: Missing label statement requirement for an indication referring to inducing sleep

Background

Currently, the indication *Decrease/Reduce/Relieve sleeplessness* has the following required label statement:

> *If symptoms persist, talk to your health professional.*

A similar indication, *Soporific/induces sleep*, does not have this label statement requirement.

Although this indication does not specifically refer to a symptom, it suggests that the medicine should be used if a person is experiencing sleeplessness; and as such, consumers should be advised that if this symptom persists, they should seek medical advice.

Group 5 Proposed amendment: add requirement for a sleep indication

Current indication	Current requirements	Proposed amended requirement
Soporific/induces sleep	NIL	Label statement: If symptoms persist, talk to your health professional.

Group 5 Proposed amendment potential impact

As of 15 June 2026, there are currently 246 medicines using these indications in the ARTG entry for their medicine.

However, it is likely that 238 of these medicines already include the label statement, *If symptoms persist, talk to your health professional,* due to the inclusion of other indications in the medicine's ARTG entry that also have this requirement.

While it is unknown which indications are included on the medicine label (and therefore necessitate the label statement), the impact of introducing the new requirement is likely to be minimal.

TGA's implementation of the proposed changes and transition periods for existing products will be informed by consultation feedback and provided with the publication of the consultation outcomes.

Group 5 Proposed amendment consultation questions

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13. Do you agree with adding the requirement to this indication?

14. Will this change represent a regulatory burden for you? If so, please provide details.
15. Do you have any other comments or feedback on the issue or proposal?

Version history

Version	Description of change	Author	Effective date
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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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