Technical Alert

Changes to the Permitted Indications Determination

Subject to approval by the minister, the TGA intends to update the Permissible Indications Determination to add 4 new indications and make minor changes/clarifications to 32 existing indications.

The TGA has indicated it will write to affected sponsors advising of the changes but will not be providing a list of each product that is likely to be affected.
A complete list of pending changes to the Permissible Indications Determination, along with implementation dates and actions for sponsors of affected medicines, is provided below.

New indications

New indication	Evidence requirement	Requirements
Decrease/reduce/relieve urinary urgency associated with medically diagnosed overactive bladder	Scientific	Must include 'medically diagnosed' in the indication. Label requirement: 'If symptoms persist seek the advice of a healthcare professional'
Decrease/reduce/relieve urinary incontinence associated with medically diagnosed overactive bladder	Scientific	Must include 'medically diagnosed' in the indication. Label requirement: 'If symptoms persist seek the advice of a healthcare professional'
Helps reduce occurrence of mild migraines	General	Product presentation must only refer to mild migraine.
Decrease/reduce duration of symptoms of haemorrhoids	General	Label statement: If symptoms persist, talk to your health professional.

Changed indications

1. Corrections to indication wording – same meaning and intent

Current indication	Amended indication	Reason
Maintain/support joint cartilage health	Helps maintain/support joint cartilage health	Addition of the word 'helps' for consistency with other similar indications.
Maintain/support good/beneficial/friendly gut flora during antibiotic use	Helps maintain/support good/beneficial/friendly gut flora during antibiotic use	Addition of the word 'helps' for consistency with other similar indications.
Maintain/support foetal CNS/brain development	Helps maintain/support foetal CNS/brain development	Addition of the word 'helps' for consistency with other similar indications.

The ARTG entries of these medicines will automatically update. It is not anticipated that label changes will be required as the revised indications have the same meaning and intent.

2. Correction to indication wording – change in meaning and intent

Current indication(s)	Amended indication(s)	Reason
Shukrala/aphrodisiac/enhance sexual vitality	Shukrala/spermatogenic/increase semen	Shukrala translates to spermatogenic/increase semen and is not synonymous with aphrodisiac and/or enhancing sexual vitality.

The ARTG entries of these medicines will automatically update. As the revised indication has a different meaning and intent, sponsors of affected medicines may need to:

- update their product labels (to remove reference to aphrodisiac and/or enhancing sexual vitality); or, alternatively
- add other permitted indications to their ARTG entry to be consistent with their current product labels (where they hold appropriate evidence).
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3. Correction to indication requirement - same meaning and intent

Current indication/s	Change in requirement	Reason
Maintain/support preconception health Helps enhance/promote preconception health	Addition of the wording '*If directed for women*': to the current label requirement: 'Advise your doctor of any medicine you take during pregnancy, particularly in the first trimester'.	Requirement not applicable to products directed to men only.
Aids/assists healthy bone development/growth/building Help maintain/support bone mineralisation Helps enhance/promote bone healing/repair Helps enhance/promote bone health Helps enhance/promote bone mass/density Helps enhance/promote bone mineralisation Helps enhance/promote bone strength Helps enhance/promote/increase metabolism of (state mineral) in bones Maintain/support (state mineral) absorption in bones	Addition of note (see below) to the current requirement 'Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis or osteoporosis'. *Note: this requirement is not intended to apply when the indications referring to osteoporosis (specified in column 2 of Table of this instrument) are also made for the relevant medicine*	The requirement has been amended to clarify that these indications may be used concurrently with indications referring to osteoporosis (that are allowed for certain calcium and vitamin D supplements).

Current indication/s	Change in requirement	Reason
Maintain/support bone healing/repair Maintain/support bone health Maintain/support bone mass/density/integrity Maintain/support bone strength		

The ARTG entries of these medicines will automatically update. No sponsor action is required.

4. Correction to indication requirement - addition of requirement

Current indication/s	Change in requirement	Reason
Decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections Relieve symptoms of mild upper respiratory tract infections Helps reduce occurrence of symptoms of upper respiratory tract infections Decongestant/relieve nasal congestion Decrease/reduce/relieve bronchial mucous congestion Decrease/reduce/relieve mild upper respiratory tract congestion Kasa hara/relieve cough Antitussive/cough suppressant Decrease/reduce/relieve mild bronchial cough Decrease/reduce/relieve cough Relieve dry unproductive cough Enhance/improve/promote/increase cough productivity	Label statement: *(COLD) – Adults only* OR *Not to be used in children under two years of age without medical advice* (or words to that effect) Listed medicines already on the ARTG will have until **March 2021** to comply with this requirement, by updating labels and packaging. Sponsors might also wish to update associated educational and marketing material. Any new listings from the date that the Determination is in force will need to comply with the new requirements immediately.	The warning statement (COLD) - Adults only. OR Not to be used in children under 2 years of age without medical advice' was previously required for cough and cold medicines but was not included in the first Determination. Statement reinstated as there may be serious consequences of inappropriately treating cold and flu in children without medical attention, e.g. a child may appear to have a cold but actually be suffering from a more serious illness.

Decrease/reduce/relieve morning sickness	Label statement: *If symptoms persist or worsen talk to your medical practitioner.* Product presentation must not imply or refer to severe morning sickness such as hyperemesis gravidarum.	The 'If symptoms persist…' label statement requirement was inadvertently not included in the first determination for this indication.

The ARTG entries of these medicines will automatically update. Sponsors of affected medicines will need to update their product labels to include the new label statements (as per the transition arrangements specified in the determination) if the medicine labels do not already include this statement.

Transition Dates and the Fee-free period

The fee – free period for making changes to indications on the ARTG ends soon on **6 September.** CMA requested an extension to this deadline which has not yet been granted, so sponsors are encouraged to be prepared for the existing deadline.

Date	Description
6 March 2018	The permitted indications reform comes into effect. The transition period for existing listed products commences.
6 September 2019	The 'fee-free' period for sponsors to transition existing listed products ends. An application fee will apply to transitioning products in accordance with the TGA's Schedule of fees and charges.
6 March 2021	The transition period for existing listed medicines ends. All listed medicines must only contain permitted indications. ARTG entries that have not transitioned to Permitted Indications will be cancelled.

Feedback from CMA members

Some CMA members have communicated that the rate and number of changes introduced by the TGA is impractical and unmanageable, imposing a high regulatory burden on business practices.

CMA is aware of this situation and is negotiating with the TGA regarding these matters. The TGA believes most issues arising from the consultation have now been addressed, and that further updates to the instrument are unlikely. However the TGA has asked that sponsors take action to update their labels as soon as possible.

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

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