Technical Alert

Updated Permissible Indications Determination

Summary

A new permissible indications determination, *Therapeutic Goods (Permissible Indications) Determination (No.2) 2019*, commenced on 14 November.

This version repeals and replaces the previous version, Therapeutic Goods (Permissible Indications) Determination (No. 1) 2019.

Listed medicines already in the ARTG will be expected to be compliant with the new requirements by the end of the transition period for permitted indications on **6 March 2021**.

Eight new indications

This table contains those indications that are now available for selection, along with label and evidence requirements:

New Indications	Evidence requirement	Requirement
Decrease/reduce/relieve urinary urgency associated with medically diagnosed overactive bladder	Scientific or tradition of use	The product presentation must only refer to medically diagnosed overactive bladder. Label requirement: If symptoms persist or worsen talk to your medical practitioner
Decrease/reduce/relieve urinary incontinence associated with medically diagnosed overactive bladder	Scientific or tradition of use	The product presentation must only refer to medically diagnosed overactive bladder. Label requirement: If symptoms persist or worsen talk to your medical practitioner
Decrease/reduce duration of symptoms of haemorrhoids	Scientific or tradition of use	Label statement: If symptoms persist or worsen talk to your medical practitioner
Maintains/supports refreshing sleep	Scientific or tradition of use	

Helps reduce occurrence of mild migraines	Scientific or tradition of use	Product presentation must only refer to mild migraine. If symptoms persist, worsen, talk to your medical practitioner.
Helps reduce the occurrence of sore throat	Scientific or tradition of use	Label requirement: If symptoms persist, worsen or episodes become more frequent, talk to your medical practitioner
Helps reduce carbohydrate metabolism	Scientific	Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range. If product is indicated for weight loss, include the label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
Helps reduce the occurrence of symptoms of medically-diagnosed gluten-sensitivity caused by inadvertent gluten ingestion.	Scientific	Product presentation must not imply or refer to individuals with coeliac disease or dermatitis herpetiformis. Label statement: For use only in conjunction with a gluten-free diet. Label statement: If symptoms persist, worsen or episodes become more frequent talk to your medical practitioner.

More restrictive changes

More restrictive requirements - [NOTE CHANGES DUE BY 6 MARCH 2021]
If your medicine includes the indication: Shukrala/aphrodisiac/enhance sexual vitality
The indication has been updated to: Shukrala/spermatogenic/increase semen *(because Shukrala translates to spermatogenic/increase semen and is not synonymous with aphrodisiac and/or enhancing sexual vitality.)* **Always check the Determination to ensure compliance before making a product change.** **Refer to "how to use legislation" on the CMA webpage: http://www.cmaustralia.org.au/TGA-Timeline**
ARTG: Entries for existing listings will update automatically. However, CMA recommends sponsors check entries to ensure they are correctly updated.
Labels: All new listings must carry the revised label changes from 14 November 2019.
Labels: Existing listings have **until 6 March 2021** to update product labels

More restrictive requirements - [NOTE CHANGES DUE BY 6 MARCH 2021]
If your medicine includes the indications: 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. Decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections
The requirement has been updated to include: NEW WARNING STATEMENT: A*dults only OR Not to be used in children under two years of age without medical advice (or words to that effect)* has been added. **Always check the Determination to ensure compliance before making a product change.** **Refer to "how to use legislation" on the CMA webpage: http://www.cmaustralia.org.au/TGA-Timeline**
ARTG: Entries for existing listings will update automatically. **However CMA recommends sponsors check entries to ensure they are correctly updated.**
Labels: All new listings (from 14 November 2019) must include the new requirement.
Labels: Existing listings have **until 6 March 2021** to bring labels into compliance (or whatever the TGA words are).

More restrictive requirements - [NOTE CHANGES DUE BY 6 MARCH 2021]
If your medicine includes the indication: Decrease/reduce/relieve morning sickness

The requirement has been updated to include: NEW WARNING STATEMENT: If symptoms persist or worsen talk to your medical practitioner. PRESENTATION REQUIREMENT: Product presentation must not imply or refer to severe morning sickness such as hyperemesis gravidarum. **Always check the Determination to ensure compliance before making a product change.** **Refer to "how to use legislation" on the CMA webpage: http://www.cmaustralia.org.au/TGA-Timeline**
ARTG: No changes are required to ARTG listings by the TGA or sponsors.
Labels: All new listings (from 14 November 2019) must include the new requirement.
Labels: Existing listings have **until 6 March 2021** to bring labels into compliance

More restrictive requirements - [NOTE CHANGES DUE BY 6 MARCH 2021]
If your medicine includes the indications: Maintain/support joint cartilage health Maintain/support good/beneficial/friendly gut flora during antibiotic use Maintain/support foetal CNS/brain development
The indications have been updated to include: The word 'helps', in order to improve consistency with existing indications. The revised expression for theses indications is: Helps maintain/support joint cartilage health Helps maintain/support good/beneficial/friendly gut flora during antibiotic use Helps maintain/support foetal CNS/brain development **Always check the Determination to ensure compliance before making a product change.** **Refer to "how to use legislation" on the CMA webpage: http://www.cmaustralia.org.au/TGA-Timeline**
ARTG: Entries for existing listings will update automatically. **However, CMA recommends sponsors check entries to ensure they are correctly updated.**
Labels: All new listings (from 14 November 2019) must include the updated expression of the indications
Labels: Existing listings are NOT required to be updated as the revised indications have the same meaning and intent.

Less restrictive changes

Less restrictive requirements
If your medicine includes the indications: Maintain/support preconception health Helps enhance/promote preconception health
Then you should be aware that: The TGA have amended preconception indications so that the warning statement for pregnancy ONLY applies to product directed at women. PRESENTATION CHANGE: If you have products with this indications that are directed to men only, they will NO LONGER be required to carry the warning statement: 'Advise your doctor of any medicine you take during pregnancy, particularly in the first trimester'. **Always check the Determination to ensure compliance before making a product change.** **Refer to how to use legislation on the CMA webpage: http://www.cmaustralia.org.au/TGA-Timeline**
Labels: Although changes are not mandatory, sponsors that have preconception medicines directed towards men only are permitted to remove the warning statement from their label from 14 November 2019.
ARTG: No changes are required to ARTG listings by the TGA or sponsors

Less restrictive requirements
If your medicine includes the indications: 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 Maintain/support bone healing/repair Maintain/support bone health Maintain/support bone mass/density/integrity Maintain/support bone strength

Then you should be aware that: The TGA have corrected the requirements so that the product presentation CAN refer to osteoporosis when the indications referring to osteoporosis (specified in column 2 of Table of this instrument) are also made for the relevant medicine." PRESENTATION CHANGE: If you have products with these indications, the overall product presentation MAY refer to osteoporosis. **Always check the Determination to ensure compliance before making a product change.** **Refer to how to use legislation on the CMA webpage: http://www.cmaustralia.org.au/TGA-Timeline**
Labels: Although these changes are not mandatory, the presentation of medicines that carry these indications may refer to osteoporosis, from 14 November 2019.
ARTG: No changes are required to ARTG listings by the TGA or sponsors

Less restrictive requirements
If your medicine includes the indication: Hepatoprotectant/protect the liver.
Then you should be aware that: The TGA have broadened the evidence required to support the indication to both traditional and scientific sources. **Always check the Determination to ensure compliance before making a product change.** **Refer to how to use legislation on the CMA webpage: http://www.cmaustralia.org.au/TGA-Timeline**
Labels and ARTG: No action is required for ARTG listings, packaging or labelling.

Next Steps for affected companies

Companies should review the relevant product labels, packing and ARTG entries for compliance with the updated determination and schedule the required changes **before 6 March 2021**.

Resources

Permissible Indications Determination

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

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