

Clarification on changes to requirements to the Permissible Indications

The first *Therapeutic Goods (Permissible Indications) Determination No.1 of 2018* was registered on the Federal Register of Legislation in March 2018. Sponsors were given 3 years to transition ARTG entries to permitted indications.

Subsequently, new Permissible Indications Determinations have been released, which have added more restrictive requirements pertaining to those permitted indications. For example, the “COLD” warning statement has been added to a number of indications after the introduction of the initial Determination. Sponsors of affected medicines were advised that product labels will need to be updated to include the new label statements. HOWEVER, a specific transition period has not been provided for those additional requirements within the subsequent versions of the Determination.

This means, that if you had transitioned your ARTG entry and labels to permitted indications, and a new requirement was later added to a version of the Determination without a transition period for that requirement, then the medicine has technically become “ineligible for listing”. CMA have worked to clarify this issue with the TGA and have confirmed the following key points:

- Enforcement discretion applies in the above situation until **6 March 2021**. Regulatory actions (such as a proposal to Cancel for this specific issue) won't apply if your medicine is missing a requirement that was added to that indication AFTER your medicine transitioned to permitted indications.
- For these medicines, the TGA may still send an “Obligations notice”, which raise the issue as an obligation or reminder for the 6 March 2021 date. However the TGA will not publish the issue as a non-compliance issue, if it is detected prior to 6 March 2021.
- From 6 March 2021, all medicines are expected to be compliant with all permitted indication requirements, including any new requirements that were added after the first Determination.
- CMA has requested that if any more additional requirements are to be added to indications from 2020 onwards, that a specific transition period is provided for within the Determination.

Resources:

- Changes to Permissible Indications [in February 2019](#) [Determination No 1. of 2019] and CMA [Technical Alert](#)
- Changes to Permissible Indications [in November 2019](#) [Determination No 2. of 2019] and CMA [Technical Alert](#)
- Determination on Federal Register of Legislation ([Determination & amendments](#))
- CMA [TGA-Timelines page](#) reminders for members

For further questions, please contact us at: technical@cmaustralia.org.au

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