

Technical Alert

Therapeutic Goods Permissible Ingredients (26BB) Determination No.2 of 2016

Dear member,

The new [Ingredients Determination No 2. of 2016](#) has been published and will include 205 amendments to ingredients for use in Listed complementary medicines.

In summary, these include:

- Adding 38 ingredients to the list;
- Amending 164 ingredients currently contained in the Determination, including:
 - clarifying some ingredient-specific requirements; for some ingredients this is to bring the Determination in line with the Poisons Standard;
 - correcting IT-system error for some ingredient purposes included in the previous Determination;
 - minor formatting changes and corrections.
- Removing 3 ingredients from the Determination
 - For two of these ingredients, this means removal of ingredient synonyms in the Determination as part of moving to internationally accepted terminology for ingredient naming. These ingredients will be included under different names.
 - Musk Ambrette will be removed from the Permissible Ingredients Determination to align the Determination with a recent medicines scheduling decision to include the substance in Schedule 10 of the Poisons Standard (*Standard for the Uniform Scheduling of Medicines* (SUSMP)). The decision to schedule the ingredient is available on the [TGA website](#). This ingredient is not currently used in any Listed complementary medicine on the ARTG.
- The Determination also removes the active and excipient purposes for the ingredient *Sanguinaria canadensis*. The effect of this change is that *Sanguinaria canadensis* is suitable for homoeopathic use more dilute than 4X only, on the basis of a recent ingredient safety evaluation.

Please note: The TGA website is anticipated to be update to reflect these changes today 03.08.16

Resources:

[Permissible Ingredients Determination No.2 of 2016 - Combined Volumes](#) (1-6)

[CMA member briefing - new ingredients approved for listed medicines](#) (July 2016)

Proposed approach to updating the 'Permissible Ingredients' determination

The TGA propose the following scheduled updates to be made to the Determinations list.

- April 2016, incorporating industry feedback received to mid-March 2016
- July 2016, incorporating amendments received up to 1 June 2016
- October 2016, incorporating amendments received up to 1 September 2016
- January 2017, incorporating amendments received up to 1 December 2016.

CMA will continue to monitor the adequacy of the proposed quarterly update cycle and will work with the TGA to evaluate this approach over the next 12 months. It is the intention of the TGA to reduce the interval between process cut-off and publication of the determination on the Federal Register of Legislation as the list of ingredients is refined.

When updating the determination the priority is to ensure the availability of new ingredients for use in listed medicines. Therefore, TGA anticipate some flexibility around the above dates to align with completion of new ingredient evaluations.

Reporting errors or omissions

Reporting of errors and or omissions identified with the Permitted Ingredients' Determination is welcomed and can be provided in writing to complementary.medicines@tga.gov.au. Where this feedback is provided in accordance with the timeframes outlined above, it will consider it in the course of making the next scheduled update.

ENDS