

Technical Alert

Therapeutic Goods Permissible Ingredients (26BB) Determination No.1 of 2017

Dear member,

The Therapeutic Goods Administration (TGA) has approved the new Therapeutic Goods (Permissible Ingredients) Determination No. 1 of 2017 under Section 26BB of the *Therapeutic Goods Act 1989*. TGA anticipates that the updated Determination will be published and available on the Federal Register of Legislation (FRL) after 30 January 2017. CMA has also requested that TGA publish a forward plan for quarterly updates to the Ingredients Determination for 2017 to assist industry with business planning.

The new Determination includes a total of **293 changes** to ingredients available for use in listed medicines (see [attached file](#)). These include:

- The **addition of 11 new ingredients**
- The **removal of one ingredient** which previously had limited availability as a homeopathic ingredient. This ingredient is not currently used in any medicines listed on the Australian Register of Therapeutic Goods (ARTG).
- **Changes to 281 existing ingredient entries**, including*:
 - Clarification of information for 45 ingredients;
 - Making requirements for 11 ingredients less restrictive;
 - Alignment of 59 ingredients with requirements for these substances included in the Poisons Standard (Standard for the Uniform Scheduling of Medicines and Poisons);
 - Name changes for 128 ingredients due to hyphen removal to better align with international standard for approved ingredient names
 - Changes to the 'purpose of ingredient' for 16 ingredients;
 - Addition of specific safety based requirements for 3 ingredients;
 - Changes to the monograph reference for 29 ingredients; and
 - Making requirements for 8 ingredients more restrictive.

* *Note:* TGA has informed that some ingredients required more than one type of change.

Once the Determination has been published on FRL, the [TGA website](#) will also be updated with a complete list of the 293 amendments.

Please find the [list of affected ingredients attached](#).

ENDS