

Technical Alert

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

Dear member,

An updated version of the Therapeutic Goods (Permissible Ingredients) Determination has now been registered on the Federal Register of Legislation (FRL). The updated determination is titled the [Therapeutic Goods \(Permissible Ingredients\) Determination No. 1 of 2017](#). Determination No. 1 of 2017 revokes and replaces the Therapeutic Goods (Permissible Ingredients) Determination No. 2 of 2016 which commenced in October 2016.

The Determination makes a number of changes to the Previous Determination. These include, for example, correcting a number of unintended errors, making a number of requirements relating to the use of particular ingredients clearer, introducing 11 new ingredients for use in listed medicines for the first time and removing the availability of one ingredient from use in such medicines.

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

A combined copy of the 6 volume legislative instrument can be downloaded [here](#).

More information can be found at [26BB Legislative Instrument: Frequently asked questions](#).