Technical Alert

- **Therapeutic Goods Permissible Ingredients Determination No.3 of 2017**
- **Registration for SME Assist Workshop closing tomorrow**

Therapeutic Goods Permissible Ingredients (26BB) Determination No.3 of 2017

An updated version of the Therapeutic Goods (Permissible Ingredients) Determination under subsection 26BB(1) of the Therapeutic Goods Act has now been registered on the Federal Register of Legislation (FRL). The updated determination is titled the Therapeutic Goods (Permissible Ingredients) Determination No. 3 of 2017. This Determination revokes and replaces the Therapeutic Goods (Permissible Ingredients) Determination No. 2 of 2017 which commenced in April 2017.

The Determination makes a number of changes to the Previous Determination. These include introducing three new active ingredients plus one new excipient for use in listed medicines, removing the availability of eight ingredients from use in such medicines for safety related reasons, correcting unintended errors, and making a number of requirements relating to particular ingredients clearer.

The new Determination includes a total of **67 changes** to ingredients available for use in listed medicines which are summarised on the TGA update page. These include:

- The **addition of 4 new ingredients**
- The **removal of 8 herbal ingredients** due to safety related issues, and which were determined to be no longer suitable for use in listed medicines.
- **Changes to 55 existing ingredient entries**, including*:
    - Clarification of information for 12 ingredients.
    - Alignment of 23 ingredients with the requirements of RASML (Required Advisory Statements for Medicine Labels) and/or the Poisons Standard (Standard for the Uniform Scheduling of Medicines and Poisons).
    - Making requirements for 7 ingredients less restrictive, such as broadening the use to allow oral use when previously only for topical use.
    - Making requirements for 5 ingredients more restrictive, such as the inclusion of additional warning messages.
    - Correction of errors for 2 ingredients.
    - Name changes for 6 herbal ingredients.
    - Purpose restriction of 2 herbal ingredients, which are no longer included for use in homeopathics.

    * *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.

Registration for SME Assist Workshop closing tomorrow

Expressions of interest **close tomorrow** for the TGA's SME Assist workshop – Meeting your Obligations for Medicines.

The workshop is part of a program to assist small and medium enterprises and new or upcoming sponsors of medicines to understand their regulatory obligations. It is designed for those with a beginner level of understanding of therapeutic goods regulation in Australia and will cover regulation basics, including the responsibilities of sponsors at different stages.

To express interest in registering for the workshop, please fill out the registration form available here **before close of business Friday 4th August**.

More information about the TGA's SME Assist program generally is available here.