**Technical Alert**

# Therapeutic Goods (Permissible Ingredients) Determination No. 1 of 2016

Dear member,

The Therapeutic Goods (Permissible Ingredients) Determination No. 1 of 2016 has now been published to the Federal Register of Legislation. Consequently determination No. 1 of 2015 has been repealed.

Determination No. 1 of 2016 includes 265 changes.
In summary, these include:

- adding 30 ingredients to the list
- correcting a range of minor errors, inconsistencies and omissions
- clarifying specific requirements for 24 ingredients
- clarifying the purposes for which several ingredients may be used in a listed medicine
- making a range of changes as a result of the International Harmonisation of Ingredient Names project.

Please note, 30 additional ingredients appear on the list of permissible ingredients for the first time, however these are not newly evaluated substances. For example, pine needle oil terpeneless is included and permitted for use if in combination with other permitted ingredients as a flavour or fragrance and subject to certain total flavour or fragrance concentration limitations, and petitgrain mandarin oil has been included and permitted for use if in combination with other permitted ingredients as a flavour and subject to a certain total flavour concentration limitation.

Changes are also included in relation to the requirements for Black cohosh (in powder or dry form), to replace an outdated warning statement that was inadvertently included in the previous Determination, and for thujone, to specify that it is a mandatory component of a number of 'Artemisia' ingredients, but that the concentration of thujone in listed medicines



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containing those ingredients must be no more than 4 per cent. In both of these cases, the effect of the changes will be to bring the Determination into line with the requirements that applied to such ingredients before the making of the previous Determination.

In relation to corrections and clarifications, these have primarily been made to bring the determination into line with the requirements that applied to such ingredients before the making of Determination No. 1 of 2015. A summary table of all changes will be made available on request to CMA.

Given the large number of changes, Determination No. 1 of 2016 has been made as a new determination under section 26BB of the Act. As the list becomes more refined and a smaller number of changes are required, it is anticipated that future updates to the instrument will be made by varying the existing determination under section(s) 26 BC and/or 26BD of the Act.

**Repeal of Listing Notices**

Prior to the commencement of Determination No. 1 of 2015, ingredients were authorised for use through the list of ingredients in (the now amended) Schedule 4 to the *Therapeutic Goods Regulations 1990*, or through notices made by the Minister under subsection 9A(5) of the Act (Listing Notices).

The permissible ingredients determination has now replaced the need for Listing Notices. For this reason, prior to the scheduled July update, all current Listing Notices will be repealed and removed from the TGA website. It appears that the listing notices will remain visible on the ComLaw website but will be marked as 'no longer in force' or words to that effect. This will not impact any current listed medicines. All goods that comply with current regulatory requirements set out in the determination will remain eligible for listing.

**Resources:** Therapeutic Goods (Permissible Ingredients) Determination No. 1 of 2016 Volumes 1-6 combined.



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