**Technical Alert**

# Therapeutic Goods (Permissible Ingredients) Determination No. 1 of 2018

## Update: Therapeutic Goods Regulations due

The *Therapeutic Goods (Permissible Ingredients) Determination No. 1 of 2018* has been registered on the Federal Register of Legislation. The Determination repeal and replaces the previous Determination – the *Therapeutic Goods (Permissible Ingredients) Determination No. 5 of 2017* that commenced in November 2017.

The full Determination and the Explanatory statement on the FRL can be located here.

CMA members are invited to download the 6 volumes as a combined volume from the CMA website, available here.

The determination provides for a number of changes and additions of ingredients, their names, content limits and required warning statements. Amendments include:

- Addition of new ingredients:
    - *Tinospora sinensis* as an active ingredient (however we note this appears to have been included in previous versions).
    - Chicken comb extract as an active ingredient (previously approved by the Delegate but not included in the Determination by error).
    - PEG/PPG-14/7 dimethyl ether as an excipient for topical medicines.
    - 2-hydroxyacetophenone as an excipient for topical medicines.

- Addition of curcuminoids as a new ingredient name (see more below).
- Removal of the (S) warning statement: 'If symptoms persist consult your healthcare practitioner', from the following herbal ingredients:
    - *Aloe ferox, Aloe perryi, Aloe vera, Aloes cape*
    - Cascara dry, Cascara powder
    - Cassia fistula
    - *Frangula purshiana*, Frangula bark dry, Frangula bark powder
    - *Rhamnus cathartica*, *Rhamnus frangula*
    - *Rheum officinale*, *Rheum palmatum*, *Rheum rhaponticum*, *Rheum tanguticum*
    - Rhubarb, Rhubarb root dry, Rhubarb root powder
    - *Senna alexandrina*, Senna fruit Alexandrian dry, Senna fruit Alexandrian powder
    - Senna fruit Tinnevelly dry, Senna fruit Tinnevelly powder

- Senna leaf dry, Senna leaf powder
- Senna occidentalis, Senna tora

- The PSYLL warning statement 'On medical advice' (or words to that effect)' for Plantago species will be limited to only the flower, seed or pollen, based on an evaluation conducted by the European Medicines Agency.
  - Plantago afra
  - Plantago arenaria
  - Plantago asiatica
  - Plantago major
  - Plantago ovata
  - Plantago lanceolata

- For *Plantago lanceolate* there is the addition of the CHILD 5 warning statement: 'Use in children under 3 years is not recommended', based on an evaluation conducted by the European Medicines Agency.
- For the ingredient 'tilactase', the reference to 'haemoglobin units' will be corrected to 'acid lactase units'.
- To align with the Poisons Standard, there is a change in the threshold limit of coumarin, in species containing coumarins. The new requirement will read "the concentration of coumarin in the medicine must be no more than 0.001%" and reference to the "maximum daily dose of the medicine" will be removed. Affected ingredients are:
  - *Anthoxanthum odoratum*
  - Cassia cinnamon bark dry
  - *Cinnamomum camphora*
  - *Cinnamomum cassia*
  - *Cinnamomum verum*
  - Cinnamon bark oil
  - Cinnamon dry
  - Cinnamon leaf oil
  - Cinnamon powder
  - *Dipteryx odorata*
  - *Galium odoratum*

- Correction of restrictions related to *Piper methysticum* to correctly align with the Poisons Standard. The restriction will now refer to use of dried or aqueous preparation or aqueous extract of the whole or peeled root or rhizome.

### Curcumin / Curcuminoids

The TGA have added 'curcuminoids' as an Australian Ingredient Name (AIN). The TGA intends that 'curcuminoids' will replace 'curcumin' for those products that include a mixture of curcuminoids as the ingredient in the medicine. The mixture is composed of curcumin, demethoxycurcumin and bis-demethoxycurcumin, as defined by the British Pharmacoepoeia (BP).

The ingredient name 'curcumin' will remain for any products that include only 'curcumin' which is defined by the BP as 1,7-bis(4-Hydroxy-3-methoxyphenyl)hepta-1,6- diene-3,5-dione (458-37-7).

The TGA will be providing industry with a minimum 18 months transition period. CMA is continuing to discuss some details with the TGA and will provide more information as it becomes available.

Members are encouraged to forward any identified issues to technical@cmaustralia.org.au for attention by the Committee Secretariat.

## Update: Therapeutic Goods Regulations due

The changes to the *Therapeutic Goods Regulations 1990* ('the Regulations') that supply the administrative arrangements for key reforms to complementary medicines, have been approved by the Government and will be registered on the Federal Register of Legislation early this week.

Key introduced reforms include the two year exclusivity for new complementary medicine ingredients, and the ability of sponsors to submit applications for the new pathway.

CMA will provide a technical alert when the updated Regulations and associated TGA guidance documentation becomes available on the TGA website this week.

**ENDS**