**Technical Alert**

**Update to the Permissible Ingredients Determination**

A new [*Therapeutic Goods (Permissible Ingredients) Determination (No. 3) 2020*](https://www.legislation.gov.au/Series/F2020L01018) (the Determination), has commenced. This instrument is made under section 26BB of the *Therapeutic Goods Act 1989* ('the Act') and repeals the *Therapeutic Goods (Permissible Ingredients) Determination (No. 2) 2020*.

This Technical Alert contains a list of changes with a Checklist/Notes field for sponsors to use to assist in identifying the changes, as part of a table which includes:

* Each new or changed ingredient
* The original requirements
* New (amended) specific requirements.

For ingredients that have changed:

**Sponsors** should review affected products for changes to compliance requirements (this may include increased or decreased regulatory requirements). The change to this Determination mostly contains reduced regulatory requirements.

**Suppliers of proprietary ingredients** should also ensure that changes are checked and up to date and provide relevant information to sponsors of products. Sponsors are responsible for compliance of their products under the Act and should check with proprietary ingredient suppliers.

**Levodopa**

This Determination corrects the requirements for herbs containing levodopa as a herbal component in accordance with the Poisons Schedule, to clarify that the concentration of levodopa in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.

This is a reduced regulatory requirement than was previously identified for some ingredients in the Determination and may therefore represent a relaxation of requirements for some medicines.

**NOTE: *Fallopia multiflora* (Fo-Ti or He Shou Wu)**

Changes to *Fallopia multiflora* are not listed in the below changes. However, CMA are aware that the TGA are currently proposing regulatory (safety) actions in relation to all products containing *Fallopia multiflora*, and that this is likely to lead to changes to the 26BB Determination for this ingredient in the near future. If you are currently developing or intending to develop any products with *Fallopia multiflora* please contact CMA via [Lucy.Lang@cmaustralia.org.au](mailto:Lucy.Lang@cmaustralia.org.au) for more information.

**Summary of all changes**

A total of 10 changes have been made in the Determination. The changes include:

* the introduction of one new ingredient, ***ethyl phenylglycidate***, for use in listed and assessed listed medicines - Ethyl phenylglycidate must only be used in medicines in combination with other permitted ingredients as a fragrance proprietary excipient formulation; The concentration of ethyl phenylglycidate in a medicine must not be more than 0.0000024% w/w (equivalent to 24 parts per billion).
* Minor amendments in relation to three ingredients to ensure greater consistency with the Poisons Standard:
  + ***Euphorbia lathyris*;**
  + ***Mucuna pruriens*; and**
  + ***Vicia faba***;
* Reflecting the advice of the Complementary Medicines Evaluation Committee in relation to the correction of an inadvertent error in the applicable requirements for the ingredient ***Citrullus colocynthis***;
* The removal of requirements for
  + ***Carapichea ipecacuanha***, to avoid duplication for this ingredient with applicable requirements for medicines containing this ingredient that apply under the *Therapeutic Goods Order No. 95 - Child-resistant packaging requirements for medicines 2017* (TGO 95); and
  + ***Fraxinus excelsior*** and ***Perilla frutescens*** to reflect that the TGA no longer evaluates or allocates names for chemical constituents that can be used as therapeutic or quality markers in herbal ingredients;
* Updating the name of the ingredient ***Juniperus mexicana***to the amended Australian Approved Name ***Juniperus deppeana***; and
* The removal of the ingredient ‘**guaiacwood acetate’**, as it is a synonym of the existing ingredient ‘**guaiyl acetate’**.

Members are encouraged to forward any identified issues to [technical@cmaustralia.org.au](mailto:technical@cmaustralia.org.au)

| Ingredient name | Change type | Change reason | Prior purpose | New purpose | Prior requirements | New requirements | Sponsor notes |
| --- | --- | --- | --- | --- | --- | --- | --- |
| CARAPICHEA IPECACUANHA | Change | Clarification of requirements | A, H | A, H | ~~Emetine is a mandatory component of Carapichea ipecacuanha.~~  ~~The concentration of emetine in the medicine must be no more than 0.2%.~~  ~~Except when used in a medicine containing only homoeopathic preparations, a child resistant closure must be fitted onto the container.~~ | Emetine is a mandatory component of Carapichea ipecacuanha.  The concentration of emetine in the medicine must not be more than 0.2%. |  |
| CHANGE OF NAME FROM JUNIPERUS MEXICANA TO JUNIPERUS DEPPEANA | Change | Update to ingredient name | E | E | ~~Permitted for use only in combination with other permitted ingredients as a fragrance.~~  ~~If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.~~ | Permitted for use only in combination with other permitted ingredients as a fragrance.  If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |  |
| CITRULLUS COLOCYNTHIS | Change | Clarification of requirements | H | H | ~~Only for use as an active homoeopathic ingredient.~~  ~~When for oral use, the concentration of Citrullus colocynthis must be more than 4X (i.e. 1X 2X 3X).~~ | Citrullus colocynthis can only be included in medicines for oral use when the dilution of the mother tincture is 10,000 fold (4X) or more. |  |
| ETHYL PHENYLGLYCIDATE | Addition | Clarification of requirements |  | E | ~~N/A~~ | Ethyl phenylglycidate must only be used in medicines in combination with other permitted ingredients as a fragrance proprietary excipient formulation.  The concentration of ethyl phenylglycidate in a medicine must not be more than 0.0000024% w/w (equivalent to 24 parts per billion). |  |
| EUPHORBIA LATHYRIS | Change | Clarification of requirements | A, H | A | ~~Levodopa (of Euphorbia lathyris) is a mandatory component of Euphorbia lathyris.~~  ~~The concentration of Levodopa (of Euphorbia lathyris) in the medicine must be no more than 10mg/kg or 10mg/L or 0.001%.~~ | Levodopa is a mandatory component of Euphorbia lathyris.  The concentration of levodopa in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%. |  |
| FRAXINUS EXCELSIOR | Change | Clarification of requirements | A, H | A, H |  | The components Nuzhenide and secoiridoid glucoside GL3 are only available when the plant part is seed |  |
| GUAIACWOOD ACETATE | Removal | Removal of redundant ingredient name (synonym) | E |  | ~~Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.~~  ~~If used in a flavour the total flavour concentration in a medicine must be no more than 5%.~~  ~~If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.~~ |  |  |
| MUCUNA PRURIENS | Change | Clarification of requirements | A, H | A | ~~Levodopa (of Mucuna pruriens) is a mandatory component of Mucuna pruriens.~~  ~~The concentration of Levodopa (of Mucuna pruriens) in the medicine must be no more than 1mg/kg or 1mg/L or 0.1%.~~ | Levodopa is a mandatory component of Mucuna pruriens.  The concentration of levodopa in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%. |  |
| PERILLA FRUTESCENS | Change | Clarification of requirements | A, E, H | A, E, H | ~~Rosmarinic acid and vicenin-2 are only permitted for use if the plant part of Perilla frutescens is leaf.~~ |  |  |
| VICIA FABA | Change | Clarification of requirements | A, H | A,H | ~~Levodopa (of Vicia faba) is a mandatory component of Vicia faba.~~  ~~The concentration of Levodopa (of Vicia faba) from all ingredients in the medicine must be no more than 1mg/kg or 1mg/L or 0.1%~~ | Levodopa is a mandatory component of Vicia faba.  The concentration of levodopa in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%. |  |