Technical Alert

Permissible Ingredient Determination

Consultation on more proposed changes to the Determination

The TGA released a new consultation on 30 August 2019 proposing more amendments to the Permissible Ingredients Determination: Changes to permissible ingredients - Low-negligible risk. The proposed ingredient changes are categorised as low-negligible risk. These substances have been flagged for various reasons, such as on expert committee decisions and international regulation.

Ingredient	Proposed change
Boron	New required warning statements: (BORON2) 'Do not give to a child less than 2 years old as this medicine contains boron and may impair fertility in the future. (EXTRNL) 'For external use on unbroken skin only.' (label warning or directions for use)
Withania somnifora	New required warning statement: 'Consult a health care professional prior to use if you are pregnant or breastfeeding
Vitex Agnus-castus	New required warning statement: (VAC) 'Vitex agnus-castus can affect hormones in the body and may interact with prescription medicines such as oral contraceptives. Consult your health care professional before use.'
Hydroxyisohexyl-3-cyclohexene carboxaldehyde	Removal from the Determination
Isphaghula spp, *Plantago spp* and psyllium husk	When a dose for children is stated, the medicine requires the following warning statement on the medicine label: (PSYLL) '**Should only be used for children** on medical advice' (or words to that effect).
Cymbopogon spp	Addition of mandatory component: Aldehydes calculated as citral is a mandatory component of Cymbopogon flexuosus. The concentration of Aldehydes calculated as citral in the medicine must be no more than 5% for topical use.
Malus pumila	Removal from the Determination

Detailed reasoning for each substance, and the proposed new requirements, are included on the consultation page.

Timeframe for consultation

Instructions for making a submission are included on the consultation page, with all comments due by **11 October 2019.**

Stage	Scheduled timeframe	TGA Action
Review & risk assessment	Up to 29 August 2019	Review of existing ingredients issues and assessment of the risk category.
Proposal	Friday, 30 August 2019	List of proposed low-negligible risk changes published on the TGA website for public comment.
Consideration	Friday, 11 October 2019	Comment period closes and TGA commences review of consultation responses.
Notification	Monday, 2 December 2019	TGA publishes finalised list of upcoming changes and implementation timeframes.
Commencement	Monday, 2 March 2020	New Determination commences on the Federal Register of Legislation.
Finalisation	Monday, 2 March 2021	Transition period ends.

Update to the existing Permissible Ingredient Determination

As foreshadowed in the technical alert of 21 August 2019 the most recent changes to the Permissible Ingredient Determination were formalised with registration of the instrument Therapeutic Goods Amendment (Permissible Ingredients) Determination (No. 1) 2019 on 29 August 2019. Details of all the changes included in this amendment are included in the previous technical alert.

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

ENDS