Technical Alert

Open for comment:
New Substances for use in listed medicines

Dear CMA member,

As members would be aware, CMA has long advocated for a streamlining of new substance applications for use in listed medicines in Australia. We are active in working with the TGA in the review of business processes for complementary medicines, with the aim of gaining efficiencies within current legislation for new substance applications and registered complementary medicines.

In the CMA response to the Government's de-regulation agenda, we recommended the TGA streamline the evaluation of new substances for use as permitted ingredients for listed medicines. This may be achieved by information sharing with regulatory counterparts, for example the outcomes of evaluation reports produced by Health Canada.
We have been working to put forward a list of potential new substances that may be subject to an expedited evaluation or risk assessment, including potential substances approved by Health Canada or where substances have been subject to previous TGA review.

List of potential ingredients that may be subject to an expedited risk assessment

Call for comment: In anticipation of future work, CMA is seeking industry feedback on the draft list of ingredients, specifically any advice in relation to the prioritisation of these substances. Please see the list of potential substances at **Attachment A**.
Feedback can be sent to Emma Burchell at: Submissions@cmaustralia.org.au **by Friday, 20 February 2015.**

Note: The TGA advises that none of the substances included on the list are currently under review or are likely to begin active evaluation in the near future. Any evaluation or review undertaken by the TGA in 2015 will be subject to available resources.

Should an individual member of industry seek to ensure prioritisation of any of the ingredients on the list a formal application, including application fees, would be required to be submitted to the TGA. To assist members in this regard a copy of the TGA's draft *Potential Information Sources to Support New Substance Application*s can be read here.

Background
The list of potential substances has been compiled with reference to the following criteria (and noting the primary reason for the evaluation of a substance is to determine whether it is of appropriate quality and safety to be permitted for use in listed medicines):

- OCM scoping of likely industry need, particularly in comparative jurisdictions as determined by reviewing market trends;
- advice from CMA and other industry associations of likely market need;
- advice from regulators in comparative jurisdictions regarding recent monographs, for example Health Canada; and
- prior evaluation undertaken by comparable Australian regulatory authorities.

Note: in relation to evaluations undertaken by comparable Australian regulatory authorities, consideration was based off an existing list of 40 substances that were developed in the context of the original Australian-New- Zealand harmonisation project (PILS project). The TGA states that as this work is of an historical nature, it is unable to be relied upon without additional evaluation or risk assessment to ensure currency.

Evaluation and risk assessments completed

CMA provides, at attachment B, a list of evaluations and risk assessments completed by the TGA during 2014. As previously advised to members, *Garcinia Gummi-Gutta* was assessed by the TGA as an expedited risk assessment. This occurred on the basis of an evaluation report from Health Canada and this ingredient has now been approved for use in listed medicines.

Three additional ingredients have entered into a preliminary assessment phase: Acai, *Berberis aristata* and *Terminalia arjuna*. However, these substances have not yet been approved and no further assessment has been completed at this stage. These preliminary assessments were begun on the basis of existing evaluation work already undertaken by the TGA.
See **attachment B** for a list of new substance assessments initiated by the TGA during 2014.

Note: Evaluation reports provided to the TGA by partner agencies cannot be publically released as these documents are subject to confidentiality agreements.

ENDS