

Member Alert

Availability of new ingredients for use in listed medicines Listing Notice for 10 new ingredients

Dear member,

CMA is pleased to inform that 10 new ingredients have been assessed by the TGA as suitable for use in listed medicines. The relevant Listing Notice permitting their use is now registered on the Federal Register of Legislative Instruments (see www.comlaw.gov.au/Details/F2015L01421).

It is anticipated that the publication of the relevant compositional guidelines, along with the necessary updates to eBS, will be finalised by the TGA COB Tuesday 15 September.

New ingredients:

1. Ribose
2. Calcium and Magnesium pyruvate
3. Octanoic acid
4. *Terminalia arjuna*
5. *Berberis aristata*
6. Co-Methylcobalamin
7. Choline dihydrogen citrate
8. *Lepidium meyenii*
9. *Trachyspermum ammi*
10. Dimethylglycine hydrochloride

CMA has long advocated for the streamlining of new substance applications for use in listed medicines in Australia. We have been active in working with the regulator in relation to leveraging off existing TGA work, as well as the work of other regulators, to deliver streamlined approvals of ingredients.

Members would be aware of the large body of work undertaken on ingredients as part of the joint Australia New Zealand Therapeutic Products Agency (ANZTPA) phase 1 (2004-2007) to identify and evaluate ingredients to be included in a Permitted Ingredients List for "Class 1 Medicines". In considering the evaluation work completed at that time, and evaluation work undertaken by other international regulators, the TGA identified ingredients with a low risk profile, and which are considered appropriate for a streamlined assessment.

We are pleased to see the results of this work.

Next Steps

As outlined in the 5 August [Technical Alert](#), we are looking to assist the TGA to progress the approval of another set of 10 ingredients, including the development of their relevant compositional guidelines.



Ingredients subject to compositional guideline:

1. *Grifola frondosa* (Maitake mushroom)
2. *Kunzea ericoides* (Manuka oil) essential oil
3. *Euterpe oleracea* (Acai)
4. *Huperzia serrata*
5. Totarol (*Podocarpus totara* wood – supercritical fluid extract)
6. *Tinospora cordifolia* (whole plant)
7. *Gynostemma pentaphyllum*
8. *Macropiper excelsum*
9. *Aegle marmelos*
10. Ox bile and ox bile ethanol extract

Industry call for comment:

CMA would appreciate input (including relevant data) from prospective users of these new ingredients regarding their potential intended uses. We also invite interested members to contact CMA with regard to providing input into the development of associated compositional guidelines for TGA consideration.

Please use the template for compositional guidelines located on the TGA website for your feedback (a link is included [here](#)) and send feedback to Emma.Burchell@cmaustralia.org.au

We look forward to working with industry on this next development.

ENDS