Technical Alert

Availability of new ingredients for use in listed medicines

Dear member,

Recently, you would have received the outcomes of the CMA member consultation on a range of new substances proposed for expedited evaluation. This body of work flows on from discussions CMA has held with the TGA in relation to leveraging off existing TGA work, as well as work of other regulators, to deliver streamlined approvals of ingredients.

In addition, 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 has identified ingredients with a low risk profile, and which are considered appropriate for a streamlined assessment to determine whether they could be made available for use in listed medicines without the need for an individual application and full evaluation.

CMA is pleased to inform members that 10 new ingredients have been assessed by the TGA as suitable for use in listed medicines and, where required, compositional guidelines have been developed.

It is intended that the required legislative instruments under subsection 9A(5) of the *Therapeutic Goods Act 1989,* required to permit the use of these ten ingredients as active ingredients in listed medicines, will be finalised in the coming weeks.

New ingredients:

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

Attachment 1 includes the list of ingredients and the conditions that will be included in the Listing Notices.
Attachment 2 includes the relevant compositional guidelines.

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Request for assistance to develop compositional guidelines

We are also pleased to inform members that an additional 10 ingredients have been assessed as suitable for use in listed medicines, subject to compositional guidelines being developed. These ingredients are mostly herbal and are seen to have a low risk profile.

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 to Emma.Burchell@cmaustralia.org.au

This project is viewed as an excellent case example of how leveraging existing evaluations minimises duplication of work, and delivers increased flexibility and reduced regulatory burden on industry. We are optimistic that further work of a similar nature may be identified through our ongoing engagement with the TGA and through the outcomes of the Review of Medicines and Medical Devices Regulation.

If you would like to discuss any of the above information, please contact Emma Burchell on 02 6260 4022 or Emma.Burchell@cmaustralia.org.au

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