

Technical Alert

Amended Therapeutic Goods Regulations 1990

No action required on Curcumin/Curcuminoids currently

Therapeutic Goods Regulations 1990

The *Therapeutic Goods Legislation Amendment (2018 Measures No. 1) Regulations 2018* has been registered on the Federal Register of Legislation (FRL), [here](#). While the legislation is now in effect, the *Therapeutic Goods Regulations 1990* incorporating this Amendment is not yet available on the FRL for download, and is expected to be available in several days.

This amendment:

- Introduces the new pathway for listed assessed medicines within the Regulations
- Outlines the new fee structure and timeframes for new ingredients and listed assessed medicines.
- Removes the requirement for pre-approval of advertisements from 1 July 2020.

Application forms and guidance material for *new ingredients* (updated) and the *listed assessed pathway* (new) are not yet available and are awaiting approval and publication onto the TGA website. CMA has a copy of Version 1 of the final Listed Assessed Evidence Guidelines. Interested members can email technical@cmaustralia.org.au

No action required on Curcumin/Curcuminoids currently

Yesterday's Technical Alert advised that the *Therapeutic Goods (Permissible Ingredients) Determination No. 1 of 2018* is now available, and that 'curcuminoids' has been added as an Australian Ingredient Name (AIN). 'Curcuminoids' will replace 'curcumin' for those products that include a mixture of curcuminoids as ingredient, with an 18 months transition period.

The TGA and CMA had previously agreed to hold off the Curcuminoids change until the June 2018 Determination to allow time to work through a number of issues for clarification. The TGA will now be removing the ingredient Curcuminoids from the Determination until June.

The updated Determination removing Curcuminoids is expected to be available in the next 1-2 weeks. TGA have not yet enabled the ingredient within the TBS/eBS Listed Medicines application system, so sponsors will not be able to see or use the ingredient.

Therefore, sponsors do not need to take any actions in relation to Curcumin / Curcuminoids at the current time.

Further clarification on the change to 'curcuminoids' will be provided as it becomes available.

ENDS