

Technical Alert

TGA Inaugural Annual GMP Industry Forum Call for items of interest

As an outcome from the TGA-Industry Working Group on GMP (TIWGG), a proposal for an annual TGA GMP Industry Forum was raised. Early discussions are scoping the possibility of a two day event to be scheduled for mid-March 2018, on either 15-16 or 22-23 March. In terms of location, the event may be hosted on a rotating basis in Canberra, Sydney or Melbourne.

In order to make these events a success, we are keen to scope member's interest and suggestions for content at a future GMP Industry Forum. Please provide your advice on the type of content and suggestions on arrangements and hosting of such an event, including preferred location, to CMA via submissions@cmaustralia.org.au by 14 July.

Review and Appeal Rights for Ingredient Applicants

The TGA has now amended the *Therapeutic Goods Act 1989* to provide review and appeal rights for applicants of new ingredients permitted for use in listed complementary medicines. These legislative changes, effective 1 July 2017, implement Recommendation 47 of the Medicines and Medical Devices Regulation (MMDR) review. The implementation of this recommendation will increase transparency of the TGA's administrative processes, improve procedural fairness and remove barriers to business.

Previously, review and appeal rights were not available in relation to TGA decisions about applications for new ingredients, such as where the TGA refused to approve the use of the ingredient in listed medicines.

From the 1 July, applicants who apply to have a new ingredient permitted for use in listed complementary medicines can appeal the TGA's decision about the application under section 60 of the Act. These rights are similar to those already available to the person who made the application and only in relation to decisions to refuse to permit the use of the ingredient in listed medicines. These changes do not change the application or evaluation processes for new ingredients.

For information about review and appeal rights under the Act, please refer to the [Guidance for requesting reconsideration of an initial decision](#). For information about the review and appeal rights for applications that have been lodged for assessment, please contact the TGA Complementary Medicines via ph. 1800 020 653 or via email at complementary.medicines@health.gov.au

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