

Technical Alert

GMP Clearance Guidance Updated; Advertising Code Q&A; Curcuminoids naming update; SME Assist Workshop in Adelaide.

Updated GMP Clearance Guidance

The TGA have published updated GMP clearance on the TGA website, as [version 18.1](#), in response to feedback received via the TGA Industry Working Group (TIWGG). The updated guidance is greatly improved for usability and relevance. It includes:

- A table of fees for different application types.
- GMP, quality, technical agreements: additional guidance.
- Applications for extension: additional guidance.
- Introduction of two new sections “Keep up to date” and “Troubleshooting”.

A print version of guidance is located [here](#).

Questions regarding this guidance can be directed to GMPclearance@tga.gov.au or to the CMA as a member of the TIWGG working group at technical@cmaustralia.org.au

Advertising: Q&A on the Advertising Code

In late 2018, the TGA conducted webinars and seminars to introduce the Therapeutic Advertising Code (No.2) 2018. There were many questions taken on notice by the TGA at these seminars.

The TGA have begun to publish the responses, which will be added to over time. If there are pressing advertising questions, please advise CMA so we can advise the TGA Advertising unit of particular priorities.

These questions and responses are published [here](#).

The initial answers include:

1. Guidance around how to make scientific citations.
2. The difference between “endorsements” and “testimonials”.
3. Advice regarding advertising materials that are currently not ready, even though the Code has now been implemented:

‘Provided that your advertising is fully compliant with the 2015 Code and there are no concerns that the advertising will jeopardise public health and safety, the TGA may exercise enforcement discretion in handling any complaint about your advertising.’

Please also contact CMA if the enforcement of the new Code is applied and the issue is not safety related, particularly in the first half of 2019.

Curcuminoids naming update

Due to numerous complexities and implementation and technical issues regarding the issue of updating the ingredient name “Curcumin” (which currently reflects a mix of curcuminoids), to “Curcuminoids” (for the mix of curcuminoids) OR “Curcumin” (for singular curcumin), the TGA are not continuing to pursue this matter in the short term. Sponsors may continue to name products in accordance with existing arrangements.

The TGA are intending to provide a website update shortly to reflect this matter. Further updates will be shared when they become available.

SME Assist Workshop in Adelaide

The TGA SME assist section is partner with Flinders University and the Medical Device Partnering Program to present a workshop for small to medium enterprise (SME) including startups and researchers in meeting their legal obligations with respect to therapeutic goods regulation.

The workshop is aimed at those that are new to the regulatory framework and is designed to help entities understand their responsibilities at different stages of the regulation process.

When: Thursday 14 February 2019, 9:00am - 2.30pm

Where: Flinders University at Tonsley, Theatre 2, 1284 South Road, Tonsley SA 5042

RSVP: Register your interest by Friday **1 February 2019**.

Go [here](#) to register interest for this workshop.

Members are encouraged to forward any identified issues to technical@cmaustralia.org.au for attention by the Committee Secretariat.

ENDS