Technical Alert

TGA Public Consultation: Advertising Complaints Handling
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Consultation on Adoption of EU Guidelines for ethanol for children & boron

TGA Public Consultation: Advertising Complaints Handling

The proposed new model for handling advertising complaints for therapeutic goods is open for consultation, available here on the TGA website.

From 1 July 2018, the TGA will be the single body handling advertising complaints, for the purposes of reducing complexity, more rapid timeframes, and greater consistency in decision-making. The TGA's first lines of action will include education, information and advice. They will have access to broader enforcement powers including sanctions and penalties to use where deemed necessary. The changes were in response to the Review of Medicines and Medical Devices and were introduced in the *Therapeutic Goods Amendment (2017 Measures No. 1) Act 2018* on 5 March 2018. With the changes now in place within the Therapeutic Goods Act, this consultation is in order to seek feedback and any required fine-tuning on the design and implementation of the new complaints-management process.

Below is a summary of the TGA's proposed approach to advertising compliance. Further details including education measures, sanctions and penalties are included in the consultation documents.

Table1: Our Approach to Compliance

Help and Support	Inform and Advise	Correct Behaviour	Enforce
Make compliance easy	Help to become and stay compliant	Deter by detection	Administrative, civil or criminal action

The TGA is seeking stakeholder views on the TGA's proposed new complaints handling model and the graduated responses to advertising non-compliance. Submissions are due by **Monday 4 June 2018**. Member input or comments outside of committee feedback may be provided to technical@cmaustralia.org.au

CMA Submission to 2018 Advertising Code and proposed Guidance

CMA's public submission to the 2018 Advertising Code can be found on our website here:

www.cmaustralia.org.au/Submissions

CMA's full submission is available to members only via member log-in to the CMA website here, alternatively, please request a copy at technical@cmaustralia.org.au

TGA guidance for new substance applications, including ARGCM Version 8.0

In line with recent legislative changes, the TGA has updated website materials and guidance for new complementary medicine substance applications, including the Australian Regulatory Guidelines for Complementary Medicines (ARGCM) Part C.

Guidance for New Substance Applications

The TGA have updated guidance and forms for completing an application to begin the processing of a request for the evaluation of a substance for use in listed complementary medicines. The changes include the following:

- Application Form for evaluation of a substance for use in listed complementary medicines;
- Guidance Version 1.1 for completing the application.

An overview of the changes to evaluation of substances for use in listed complementary medicines can be found here which is also linked to from the TGA's Complementary medicines reforms page.

ARGCM Part C Updates

The new Version 8.0 of the ARGCM can be found here on the TGA website, superseding Version 7.2 which has been archived here. Version 8.0 includes:

- An **overview** of the application process for new substance applications, including eligible substances; application categories; timeframes and fees; exclusive use of new ingredients.
- The **application phases** of a new substance application.
- The **types of Information and data** required for an application for a new substance evaluation.

Consultation on Adoption of EU Guidelines for ethanol for children & boron

The Therapeutic Goods Administration (TGA) commenced consultation on adoption of European Union (EU) guidelines. This consultation relates to registered medicines, including registered complementary medicines, and submissions close **22 May 2018**.

Among the EU guidelines proposed for adoption is the Updated Annex to the European Commission guideline on 'Excipients in the labelling and packaging leaflet of medicinal products for human use' (EMA/CHMP/302620/2017) which contains guidance on:

- Ethanol in medicines for children
- Boric acid (and Borates) in medicines for children less than 12 years, and pregnant women.

The guidelines are currently not proposed for adoption in the 26BB Permissible Ingredients Determination and therefore not likely to impact listed medicines at this time. However, they may be examined by TGA at a later date.

Members are encouraged to forward concerns or comments to technical@cmaustralia.org.au for attention by the Committee Secretariat.