

## Technical Alert

### New Therapeutic Goods Advertising Code 2018 & transition arrangements.

#### TGA Seeking Professionals with Scientific or Consumer Expertise for Vacancies on Statutory Committees

### New Therapeutic Goods Advertising Code 2018 & transition arrangements.

The Therapeutic Goods Advertising Code 2018 has been entered onto the Federal Register of Legislation on 29 June 2018, available [here](#). The TGA has provided 6 months for advertisers to become familiar with the new Code and bring existing material into compliance (except pre-approved advertisements, which remain valid until their expiry date).

- The 2018 Code commences on **1 January 2019**. At this time 2015 Code will be repealed.
- From 1 January 2019, advertisements must comply with the 2018 Code;  
**EXCEPT** advertisements pre-approved to the 2015 Code, which may continue to be advertised until the expiry date of that approval.
- Pre-approvals continue until **1 July 2020**. Applications for pre-approvals will be assessed:
  - against the new 2018 Code after **1 January 2019**;
  - against the minimum requirements of the 2015 Code until **31 December 2018**.
- Complaints after 1 January:
  - Complaints for advertisements that are actively being advertised will be assessed against the new 2018 Code (unless there is an un-expired 2015 Code pre-approval).
  - Complaints about ads that were advertised before 1 January and are no longer being advertised will be assessed against the 2015 Code.

### Advertising Web Hub for Consumers and Advertisers

The TGA have launched an online [Advertising web hub](#) to bring together information for both consumers and advertisers about advertising related matters, including:

- The range of [sanctions, penalties, and compliance/enforcement tools](#);
- Basics and [general information page](#), including:
  - A [Decision Tree](#): Can I advertise this therapeutic good to the public?
  - Guidance on [advertising probiotic products](#), and other cosmetic or food interfaces.
- [Complaints handling](#), including an [online complaints form](#) and the TGA target timeframes;
- Initial [guidance for advertisers](#); including [pre-approvals](#); (further Consultation this month);
- An [education and training](#) page with the first e-module '[Introduction to the regulation of therapeutic goods advertising](#)';
- Advertising [decisions and announcements](#), including some enforcement actions taken (direction letters and public warning notices) against non-compliant goods.
- A stakeholder engagement information [page](#).

## Update to the T.G. Advertising Code 2015 for S3, Appendix H medicines.

The 2015 Code has been [amended](#) to include the option for advertisers of Schedule 3, Appendix H medicines (for complementary medicines, applicable to Pharmacist Only Vitamin D) to use the new warning statement that will be mandatory version in the new 2018 Code from 1 January 2018:

ASK YOUR PHARMACIST – THEY MUST DECIDE IF THIS PRODUCT IS RIGHT FOR YOU.

### ‘Health Warnings’ Requirement

As per CMA and other stakeholder request during consultation, the requirement to include allergen declarations is not included in the 2018 Code. A requirement for products that have ‘health warnings’ has been included (See below). The definition in the new 2018 Code for ‘health warnings’ captures some, but not all, advisory statements required for complementary medicines.

**Paragraph (2)(c) of Section 11** of the 2018 Code (*note: does not apply to radio commercials that are 15 seconds or less in duration or to written advertisements that consist of 300 characters or less.*)

| Type of medicine                                  | Requirements   |
|---|--|
| A medicine for which there are no health warnings | The following statement, displayed or communicated:<br><i>ALWAYS READ THE LABEL</i>  |
| A medicine for which there are health warnings    | Either:<br>(a) the following statement, prominently displayed or communicated:<br><i>THIS MEDICINE MAY NOT BE RIGHT FOR YOU. READ THE LABEL BEFORE PURCHASE;</i> or<br>(b) both of the following, displayed or communicated:<br>(i) the following statement:<br><i>ALWAYS READ THE LABEL;</i> and<br>(ii) the health warnings. |

**health warning**, in relation to therapeutic goods, means a statement that is required on the label or instructions for use that warns that a person who takes or uses the goods may:

- (a) die; or
- (b) require hospitalisation or a longer period of hospitalisation than would be required if the person had not taken or used the goods; or
- (c) require a medical practitioner to treat or prevent any of the following as a consequence of taking or using the goods:
  - (i) injury;
  - (ii) disability;
  - (iii) incapacity;
  - (iv) impairment of any bodily function, organ or structure.

For transparency of expectations around this new part, CMA will consult members with view to requesting further clarity from the TGA on which statements fall within the definition.



## TGA Seeking Professionals with Clinical or Consumer Expertise for Vacancies on Statutory Committees

The TGA are seeking expressions of interest from professionals with expertise in relevant **clinical** or **scientific** fields or **appropriate consumer health issues** to support the TGA functions as a best practice regulator.

Committee members contribute significantly towards the TGA's regulatory functions by providing independent expert advice on specific technical matters.

Committees with relevance to the field of complementary medicines include:

### **Advisory Committee on Complementary Medicines (ACCM)**

The ACCM advises and makes recommendations regarding the entry of complementary medicines on the ARTG

### **Advisory Committee on Medicines Scheduling (ACMS)**

The ACMS advises and makes recommendations about how medicines will be made available to the public

Expressions of interest must be received by cob **Tuesday, 31 July 2018**. Further information [here](#).

Expressions of interest must include:

- a cover letter stating the relevance of your expertise
- a nomination for one or multiple committees
- a current curriculum vitae
- a fully completed and signed 'Declaration of interest in support of application for membership of a TGA expert advisory committee'
- contact details of two referees
- your phone, email and postal contact details.

Enquiries can be made by email to [committee.vacancies@health.gov.au](mailto:committee.vacancies@health.gov.au)

**ENDS**