Technical Alert

T.G Advertising Code updates: Dates and preliminary consultation outcomes

The TGA has been assessing submissions to the consultation on the draft 2018 Therapeutic Goods Advertising Code and making changes accordingly, including many that are in accordance with the submissions from Complementary Medicines Australia and member companies.

Preliminary feedback about these changes is as follows. Note this provides is not necessarily comprehensive of all changes that will occur, which are subject to ongoing TGA and legislative drafter processes.

- There will be a **transition period** for industry between July 2018 and January 2019.
- On **1 July 2018**:
    - The new 2018 Code will be legislatively made, however advertisements will not be legally obliged to comply until **1 January 2019**.
    - The existing 2015 Code will be amended to include warning statements for Schedule 3 products, to allow the advertising changes for S3 products continue.
    - Between **1 July 2018 and 1 January 2019**, advertisements may comply with either Code.
- **Public consultation on the Advertising guidance document** will open late June and close in August.
- **Prohibited and restricted representations.** These have been simplified even further, however, have been kept consistent with the need to comply with medical device regulations. Reference to **self-diagnosis** and **self-management** of conditions are being included to further clarify conditions that are not prohibited or restricted.
- **Allergies**. The requirements for an allergy warning statement is being removed. The Code will continue to require any health warnings that could have a serious risk to consumer health and safety.
- "If symptoms persist, worsen or change unexpectedly, see your healthcare professional" will not be included, it will revert to the existing symptom statement.
- **Internet / Direct Marketing definition**. The TGA are proposing to remove the proposed definition and replaced with a provision that only applied the requirements for providing all relevant information only at the **point of sale** of a product where that point of sale does not have the physical goods present (therefore consumer is unable to read label). This allays the concern that large amounts of information were going to be required for online or direct marketing advertisements that were not at the point of sale.
- **Advertising for children**. This will be clarified to ensure the provision is only capturing advertisements that are **primarily directed** at children, not advertising for children's products that are primarily advertised to adults.

- **Traditional paradigms of evidence.** There will be further clarification of requirements, to allay concerns about how to identify and communicate a paradigm where there are multiple indications and multiple paradigms.
- **Scientific representations**. This will be modified to better differentiate which types of information do and do not need to be published.
- **Prominently displayed and communicated** requirements will be reserved for critical health messages.
- **Samples**. Provisions regarding samples are being re-instated in the Code due to feedback regarding WHO codes.
- **Testimonials**. Relatives will now be allowed to provide testimonials.

The TGA Presentation from May 2018 on Advertising Reforms is now available for viewing on the TGA website here.

Permitted Indications Update: New eBS ELF functionality to link 'Condition' indications to 'Symptom' indications

On June 8 the TGA launched new functionality to ELF for permitted indications, which allows sponsors the option to link individual 'symptom' indications to a parent indication of a (non-serious) disease or condition. For example:

Parent indication: 'Helps decrease/reduce/relieve symptoms of hayfever'
- Linked indication: 'Helps decrease/reduce/relieve watery eyes'
- Linked indication: 'Helps decrease/reduce/relieve runny nose'

The *Listed medicines application and submission user guide* has been updated to provide guidance on linking indications in the online listing form. Pages 22-27 of the updated June 2018 version include information on adding and removing linked indications, available here.

Rationale

The TGA have stated that enabling sponsors to link specific symptoms to a disease or condition will increase the flexibility and usability of the list and allow sponsors to align the indication with the evidence they hold. In addition, providing sponsors with the ability to link symptoms to a disease or a condition will make the intended use of their product clear in the ARTG entry.

The TGA have provided that linking indications in this way is optional: A symptom indication can be included in the ARTG as a standalone indication; & it is not mandatory to link symptom indications to a parent indication. CMA is seeking further clarification if there are compliance expectations for linking indications for sponsors in relationship to evidence held.

ENDS