Technical Alert

Public consultation: Proposed improvements to the *Therapeutic Goods Advertising Code*, including proposed framework for Schedule 3 medicine advertising

Dear member,

The TGA has published its paper Consultation: Therapeutic Goods Advertising Code. It addresses a number of advertising recommendations from the Medicines and Medical Devices Regulation (MMDR) Review and follows on from the November 2016 Consultation: The regulatory framework for advertising therapeutic goods. CMA's submission to that consultation can be found here.

This consultation provides opportunity to stakeholders to provide a response to proposed changes to the Advertising Code. Following the consultation there will be a draft version of the Code that will be released for comment late this year / early 2018.

The consultation also covers a proposed framework to underpin advertising of S3 medicines to the public, following strong support for direct to consumer advertising from the April 2017 public consultation Scheduling Policy Framework and Advertising of Pharmacist-only medicines (Schedule 3 substances).

CMA encourages all members to read the paper and provide the TGA with a submission by this date. The consultation period is open for 6 weeks, with the closing date for submission to the TGA **13 October 2017**.

CMA will be providing a submission to Government. If you would like to share with CMA a copy of your company's response, please provide a copy to submissions@cmaustralia.org.au.

Examples of relevant items to CM sponsors

There are particular areas that may affect Complementary Medicines, including but not limited to:

- Item 4.1 relating to minimising subjectivity of the Code to support effective sanctions and enforcement of advertising requirements.
- Item 4.2 relating to core objectives for the new Code, such as:
    - Details of the scientific information relied upon in making advertising claims must be publicly accessible.
    - Application of public interest criteria against the provision of must not encourage, or be likely to encourage inappropriate or excessive use of the goods.

- Advertisements must contain all mandatory and applicable information (e.g. requirements to include contraindications and warning statements).
- Vitamins and weight loss or management products will be subject to specific warning information and other requirements that need to be prominently displayed or communicated in the advertisement.

- Item 4.3 relating to Council recommendations, such as:
  - New definitions of prohibited and restricted representations.
  - New restricted representations, examples including
    - reference in an advertisement for a therapeutic good to any procedure (or product requiring such a procedure for its intended purpose), that can only be performed by a suitably qualified healthcare professional;
    - reference to "obesity" either directly or indirectly.
- Item 4.4 relating to 2016 Consultation comments, such as:
  - development of a new Advertising Code to remove subjectivity, to unambiguously communicate requirements and include specific examples of compliant and non-compliant advertising, and to include accompanying guidelines.

ENDS