Technical Alert

Amendments to the TGA *Advertising Code No. 2 of 2018*

The TGA have released a new version of the *TGA Advertising Code No.2 of 2018*, to make minor corrections and clarifications, which are described in the tables below. The legislative instrument that made the changes is available here, and the TGA update here. The compilation of the Advertising Code incorporating the amendments into a single document is expected to be available in the next few days on the Federal Register of Legislation.

The changes relax some of the restrictions that were causing impediments to advertisers.

The TGA update also clarifies advertisements in retail catalogues will generally require pre-approval.

Changes of most relevance to complementary medicines regulation

- ***Indication from the label that is required in advertising is now permitted to vary wording, with same meaning and intent***

  Advertisers can now vary the wording of the indications or intended purpose used in the advertisement from that included on the good's label or instructions for use – provided that it does not differ in meaning or intent (sections 12 and 13).

  Paragraph 13(2)(b) and Paragraph 12(3)(d)

  An advertisement for a medicine must contain the following:

  > at least one of the indications for the medicine, as the indication appears on the medicine's label, or as modified in a manner that does not change the meaning or intent of the indication as it appears on the medicine's label;

  (Previously: (b) one or more of the indications for the medicine, as they appear on the medicine's label)

  Also see changes to 12(4)(c) and 12(5)(c) for changes to 'other' therapeutic goods and devices.

- ***Single advisory statement for multiple medicines within one advertisement***

  The change allows advertisers, when promoting multiple medicines in one advertisement, to use a single statement to alert consumers to the need to read the label to establish if the medicines are right for them, instead of requiring two or more such statements, which could inadvertently detract from the prominence of mandatory information.

  Subsection 13(2A) - new

  (2A) If an advertisement relates to more than one medicine and:

  (a) the advertisement does not relate to one or more other therapeutic goods or medical devices; and

  (b) at least one of the medicines advertised includes an ingredient in Part 1 or Part 2 of Schedule 1 for which there is a health warning;

  then the following statement may be prominently displayed or communicated in the advertisement instead of the applicable statements mentioned in the table in paragraph (2)(c):

  THESE MEDICINES MAY NOT BE RIGHT FOR YOU. READ THE LABEL BEFORE PURCHASE.

- ***Pregnancy (uncomplicated) not a restricted representation***
  Change: Amended to make it clear that most statements in therapeutic goods advertisements relating to pregnancy, other than to a pregnancy that has a medical, obstetric or surgical complication, are not restricted representations.

  Due to a change in the way 'a serious form of a disease, condition, ailment or defect' is defined in the current Code, representations referring to 'pregnancy' were inadvertently captured. If pregnancy is a restricted representation, advertisers would be required to obtain approval from the TGA to make basic and well accepted claims that therapeutic goods could prevent pregnancy, provide nutritional support during pregnancy, and screen for or detect pregnancy. Such a requirement is an unnecessary regulatory burden and inconsistent with the objectives of the restricted representation requirements.

Section 28(2)(a) - new

(2) A serious form of a disease, condition, ailment or defect does not include:

(a) pregnancy, other than pregnancy with a medical, obstetric or surgical complication;

- ***Parts 3 and 4 of Schedule 1 are not health warnings***
  Clarification to section 13 that, the test for whether there is a health warning for a medicine is limited to the inclusion of an ingredient listed in Part 1 or Part 2 of Schedule 1 (i.e. Parts 3 and 4 are not relevant).

Paragraph 13(2)(c)

(c) subject to subsections (2A) and (5)—the requirements specified in the following table in relation to the type of medicine specified:

Type of medicine	Requirements
A medicine that does not include any ingredients in Part 1 or Part 2 of Schedule 1 for which there are health warnings *(Previously: A medicine for which there are no health warnings)*	The following statement, prominently displayed or communicated: *ALWAYS READ THE LABEL*
A medicine that includes an ingredient in Part 1 or 2 of Schedule 1 for which there are health warnings	Either: (a) the following statement, prominently displayed or communicated: *THIS MEDICINE MAY NOT BE RIGHT FOR YOU. READ THE LABEL BEFORE PURCHASE*; or (b) both of the following, prominently displayed or communicated: (i) the following statement: *ALWAYS READ THE LABEL*; and (ii) the health warnings.

- ***TGA-Assessed Claimer***
  This change ensures that advertisements for complementary medicines that are either registered or 'listed assessed' medicines, may use the TGA assessed claimer without breaching the Code, if the medicine is authorised or permitted to use the claimer.

  Further information on the claimer is on the TGA website here.

Paragraph 16(1)(b)

(1) This section does not apply to:…

(b) in relation to a medicine that is listed under section 26AE of the Act or a complementary medicine that is registered under section 25 of the Act—a statement, pictorial representation or design authorised or required by a government or government authority (not including a foreign government or foreign government authority) under paragraphs 42DL(9)(b) and 42DLB(6)(b) of the Act, or prescribed by the Regulations for the purposes of paragraphs 42DL(9)(c) and 42DLB(6)(c) of the Act.

- ***Code not applicable to public health campaigns***
  This amendment clarifies that the Code is not intended to apply to advertisements that are part of a public health campaign:

Subsection 6(2)

This instrument does not apply to an advertisement that:

(a) is directed exclusively to health professionals; or

(b) is part of, or otherwise comprises, a public health campaign.

Other changes

- Clarifications to the definition of 'health warnings' for medical devices and "other therapeutic goods" (tampons, menstrual cups and disinfectants that are not medical devices) (section 4). This is to ensure that the definition of 'health warning' for a medical device or "other therapeutic goods" is a statement required by law to be included on the label or instructions for use to the effect of various specified warnings, and ensures that this important information about the potential impact on a person's health from using or taking these goods will be available for consumers to inform their selection.
- Clarification that the section 11 mandatory statement applies to advertising of any therapeutic good that includes a Schedule 3 substance, when the advertising is permitted by inclusion of the substance in Appendix H of the Poisons Standard.
- The exemption for picture / price / point of sale from the requirements of section 13 has been amended so that representations other than therapeutic claims can still be used without affecting the exemption.
- Clarification that the Code (other than Schedule 4) does not apply to advertising that consists solely of the dissemination of price information where it relates to prescription and/or pharmacist-only medicines that are registered goods (and not to unapproved therapeutic goods).

ENDS