



## Therapeutic Goods Advertising Code 2018 Update

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Following the TGA Report: “*Consultation: Therapeutic Goods Advertising Code - Proposed improvements including proposed framework for Schedule 3 medicine advertising*” (August 2017), the Therapeutic Goods Administration (TGA) released the updated draft *Therapeutic Goods Advertising Code 2018 (Draft New Code)* for consultation on 29 March 2018 and the consultation period closed on 27 April 2018.

The Code is a legislative instrument made under section 42BAA of the *Therapeutic Goods Act 1989 (Cth)* (the **Act**) by the Minister or their delegate. It is the key advertising compliance standard that sets out minimum requirements and underpins the regulatory framework for the advertising of therapeutic goods to the public.

The Act defines advertisement, in relation to therapeutic goods, as including; any statement, pictorial representation or design (however made) that is intended, whether directly or indirectly, to promote the use or supply of the goods.

This definition is very broad and captures therapeutic good advertisements that are published or broadcast in a number of media, including newspapers, magazines, television (including pay TV), radio, the Internet (including Facebook, Twitter and other social media) catalogues and point of sale material. It also captures the product label if it includes a statement, pictorial representation or design that is intended to promote the use or supply of a therapeutic good.

A useful comparison prepared by the TGA between the 2015 version (**Existing Code**) and the proposed 2018 version is available at: <https://www.tga.gov.au/sites/default/files/comparison-between-the-therapeutic-goods-advertising-code-2015-and-the-proposed-2018-code.pdf>

Some of the amendments are as follows:

- All guidance materials included in the Existing Code are now included in separate Code guidelines, including pre-approval guidance;
- Section 10 (**Effect**) of the Code has been amended to include some new requirements, including advertising for therapeutic goods must support the safe and proper use of therapeutic goods by presenting the goods in accordance with directions or instructions for use;
- Section 11(2)(d) (**What must advertisements contain – general rules**) of the Draft New Code is a new provision requiring Sponsors to alert the consumer of where they can obtain further important information about the medicine, including adverse reactions, precautions, contraindications and method of use;

- Section 20 (**Allergies**) is a new provision – stating that if therapeutic goods have a history of causing a serious allergic reaction in a particular patient group, advertising for those therapeutic goods must contain a warning applicable to that patient group, prominently displayed or communicated;
- Section 21 (**Consistency with public health campaigns**) is a new provision – If a relevant public health campaign is current at the time of advertising therapeutic goods, the promotion of the goods must not be inconsistent with the public health campaign and the other objects of the Code. Sponsors will therefore need to keep abreast of current public health campaigns, and compliance may have challenges if an advertising campaign is planned, booked and paid for well in advance;
- Section 23 (**Complementary medicines**): In relation to complementary medicines, the Draft New Code states that if an advertisement for a complementary medicine includes a claim based on evidence of a history of traditional use and paradigm, the reliance on this traditional use must be disclosed in the advertisement and the disclosure must be displayed or communicated in the advertisement. It may be unclear exactly what is a “traditional use” as compared to a non-traditional use; and
- Section 27 (**Sunscreens**) has a new provision relating to the advertising of sunscreens.

Once the TGA has considered feedback from this consultation and from the Therapeutic Goods Advertising Code Council (**TGACC**), final amendments will be made to the proposed draft Code and guidance document. At this stage it is anticipated that the new Code will come into effect from 1 July 2018.<sup>30</sup>



<sup>30</sup> <https://www.tga.gov.au/consultation/consultation-draft-therapeutic-goods-advertising-code-2018-and-associated-guidelines>