

Article Information

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Therapeutic Goods Advertising Code 2021: a simplified approach

After an 18-month period of consultation with stakeholders, the Therapeutic Goods Administration (TGA) has recently announced the release of the Therapeutic Goods Advertising Code 2021. The new Code is more streamlined with a view to ease of application.

When does the new Code apply?

The Therapeutic Goods Advertising Code 2021 came into effect on 1 January 2022. However, advertisers have until 30 June 2022 to transition to the new Code. During this transition period, advertisers can follow either Code at their discretion.

What does the new Code have in common with the previous version?

The overall Australian regulatory context is the same, for example:

- many therapeutic goods cannot be advertised at all^[1]; and
- advertising may not refer to serious disease (i.e a disease which requires diagnosis, treatment or supervision by a health practitioner) without TGA approval; and
- the definition of an “advertisement” under the Therapeutic Goods Act covers any statement or pictorial representation (including on a website, product packaging and “point of sale” promotions) that is intended to promote the use or supply of therapeutic goods.

The Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021 (**Therapeutic Goods Advertising Code**), in common with the 2018 edition, requires advertisements of therapeutic goods:

- to promote safe and proper use of the goods,
- to not mislead or deceive consumers,
- to encourage informed health care choices; and
- to be consistent with current public health campaigns. .

What's changed?

Key changes in the Therapeutic Goods Advertising Code 2021 are as follows:

- The new Code reduces the number of mandatory statements required to accompany advertisements of therapeutic goods. For instance:
 - an advertisement about therapeutic goods only available from a pharmacist must contain the statement: **‘ask your pharmacist about this product’**;
 - advertisements for therapeutic goods only available through a health professional must include the statement: **‘this product is not available for purchase by the general public’**; and
 - a short form advertisement must contain the statement **‘always follow the directions for use’**;
- The new Code makes it easier to identify the specific requirements for advertising medicines, medical devices or other therapeutic goods;
- The new Code has been amended to distinguish between therapeutic goods that are available online versus those that can be physically viewed by consumers so as to ensure that relevant warnings (or links to the warnings) are

provided in the advertising of products which cannot be physically inspected;

- The Code clarifies that paid testimonials or testimonials based on incentives cannot be included in advertisements (whereas 2018 Code simply required the disclosure of incentives);
- Pursuant to the global COVID-19 pandemic, the Code now includes additional exceptions to the normal prohibition on offering samples in advertising, such as hand sanitisers, face masks and COVID-19 rapid antigen tests; however, the products offered as samples must be included in the Australian Register of Therapeutic Goods;
- The requirements that advertisements promote 'safe and proper use' of therapeutic goods in the Code have been expanded to also prohibit advertisements that cause undue alarm or distress.

What should advertisers do?

Overall, these changes aim to simplify the requirements of the Therapeutic Goods Advertising Code while continuing to promote accurate and balanced advertising. Advertisers should:

- review the new Code carefully, and note that some content (on "prohibited" and "restricted" representations) is now included in the Regulations instead of in the Code;
- consider your approach to testimonials given the restrictions on using paid testimonials.

While there is a transitional period to allow time for updating the specific elements of your advertising that are affected by the changes, the update is also an opportunity to sanity check that your advertising is balanced and accurate.

[\[1\]](#) Medicines classified as Schedule 3 (pharmacist only), Schedule 4 (prescription only) and Schedule 8 (controlled substances) unless specifically exempted; Biologicals