

# Therapeutic Goods Advertising Code Gets a Makeover

**Jaimie Wolbers, Simone Mitchell and Jonathan Kelp** (MinterEllison) discuss what the new Therapeutic Goods Advertising Code 2021 will mean for advertisers.

On 1 January 2022, the new *Therapeutic Goods Advertising Code 2021 (Cth)* (**Code**) came into effect. The Code sets out the requirements for the promotion of therapeutic goods (such as medicines and medical devices) in Australia with a view to ensuring that such advertising, promotes the quality use of products, is socially responsible and does not mislead or deceive consumers.

In Australia, the majority of medical devices, as well as most medicines available for over-the-counter sale, can be advertised to consumers. However, the promotion to the public of prescription medicines, and certain pharmacist only medicines, is prohibited. While Australia dealt with the Omicron COVID-19 wave over the summer months of 2021/22, significant changes were introduced to Australia's therapeutic goods advertising regime through the implementation of the new Code.

Despite coming into effect on 1 January 2022, the life sciences sector has been provided with a six month transition period during which they may choose to comply with either the 2018 or 2021 versions of the Code. However, from 1 July 2022, all therapeutic goods advertising directed to consumers will need to comply with the new Code. Advertisers who do not comply risk committing an offence under section 42DM of the *Therapeutic Goods Act 1989 (Cth)* (**Act**) or breaching the civil penalty provision in section 42DMA, each of which may attract significant penalties.

Key features of the new Code include changes to the mandatory statements that must be included in advertisements, an expanded list of products that may be provided as samples to the general public, and clarification that the use of influencers (ie individuals who are paid or otherwise incentivised) to promote therapeutic goods is not permitted. We set out a summary of these key features below.

## Updated mandatory statements

One of the notable additions to the new Code is a requirement to prominently display or communicate the following statement in advertisements for products that cannot be directly purchased by a consumer, and that are supplied through healthcare professionals:

*"This product is not available for purchase by the general public"*

We expect that the introduction of this mandatory statement is tied to one of the key objects of the Code (set out at section 2), which is to ensure that advertisements for therapeutic goods support informed healthcare choices. It also aligns with the existing requirements in the Code to ensure that any advertisement for a therapeutic good does not:

## Key Takeouts

- The changes to the Code will affect how therapeutic goods can be promoted to consumers in Australia. Changes include amendments to mandatory statements which must be included in advertising.
- The deadline for ensuring compliance with the new Code is 30 June 2022.
- Sponsors and advertisers should not delay in reviewing existing and future marketing campaigns for compliance with the new Code.

- delay or discourage persons from seeking necessary medical attention; or
- delay or discourage persons from undertaking treatment prescribed by a medical practitioner.

Advertisements for products that are not available for direct purchase by consumers are not required to comply with the more prescriptive requirements set out in Part 4, Division 3 of the Code. This is a similar situation for:

- advertisements for pharmacist only medicines (therapeutic goods consisting of or containing a substance included in Schedule 3 and Appendix H of the Poisons Standard) which must prominently display or communicate the statement:

*"Ask your pharmacist about this product"; and*

- short form advertisements (radio spots of ≤ 15 seconds or text only advertisements of ≤ 300 characters, where there is no reasonable capacity to include a picture, logo or other imagery as part of the advertisement) which must prominently display or communicate the statement:

*"Always follow the directions for use"*

Part 4, Division 3 sets out mandatory statements and required information that must be included in all other advertisements for medicines, medical devices and other therapeutic goods. There are additional requirements, including to prominently display and communicate any health warnings, in circumstances where the advertisement facilitates the direct purchase or supply of the therapeutic goods without the consumer having an opportunity to inspect the product (i.e. advertisements published on websites, social media pages or via a software application through which a transaction for the product may be conducted).

## Samples

The Code now includes an expanded list of therapeutic goods that offer samples by way of an advertisement. An advertisement about therapeutic goods may now include or offer the following therapeutic goods as samples (provided they are included on the Australian Register of Therapeutic Goods and do not include a substance included in Schedules 2, 3, 4 or 8 of the Poisons Standard):

- personal lubricants;
- COVID-19 rapid antigen tests for self-testing;
- disinfectants;
- face masks and gloves for preventing the transmission of disease in persons;
- hand sanitisers;
- lancets and blood glucose strips for use in connection with measuring blood glucose;
- nicotine replacement therapies administered by oromucosal or transdermal means, including sprays, patches, gums, lozenges, sachets and tablets;
- oral hygiene products, including toothpaste, mouthwash and interdental brushes;
- oral rehydration products;
- tampons and menstrual cups; and

- wound care dressings for superficial wounds, including first aid items and antiseptics.

This adds to the existing list which was previously limited to:

- condoms;
- goods that are / contain a sunscreen;
- stoma devices for self-management; and
- continence catheter devices for self-management.

## Testimonials & Endorsements – implications for influencers

Importantly, the new Code also consolidates the requirements regarding testimonials and endorsements into section 24. Although the requirements relating to testimonials and endorsements largely remain unchanged, the new Code clarifies that social media influencers who have received (or will receive) payment or valuable consideration in order to provide a testimonial are considered to be persons engaged in the marketing of therapeutic goods. The Code prohibits the use of testimonials from persons engaged in the marketing of therapeutic goods and, therefore, it is now clear that sponsors and advertisers of therapeutic goods must not engage or use influencers to provide testimonials promoting therapeutic goods. This should hopefully lead to a change in the way in which therapeutic goods are advertised on social media.

## Event Report: CAMLA Young Lawyers Music Law 301 Seminar

**Jess Millner** (MinterEllison, CAMLA Young Lawyers Committee representative)

On 11 April 2022 Marque Lawyers hosted the CAMLA Young Lawyers Music Law 301 Seminar. The 301 seminar was a fabulous way to round out the CAMLA Young Lawyers Music Seminar Series. **Michael Bradley** and **Emma Johnsen** of Marque Lawyers were joined by artist and producer **Jack River** (aka Holly Rankin) to discuss some of the current issues facing the music industry. It was an insightful discussion covering the impact of the pandemic on music touring and events, the ins and outs of record label deals, the rise of NFTs in the music industry and the “Beneath the Glass Ceiling” campaign.

The seminar was a unique opportunity for young lawyers to gain valuable industry insights.

Thank you very much to the panel for an engaging and open discussion. For those that missed it the seminar was recorded and it is available to CAMLA members on the CAMLA website – check it out!

