Legal summary for writing scripts

Feb 2020

MEDICAL ADVERTISING

Please Note: The information below is designed as a general outline only. It is not legal advice and you should not rely on it as such.

Summary

The advertising of prescription drugs is prohibited under the Therapeutic Goods Act 1989 (TGA). Non prescription medicines may be advertised but must comply with the 'therapeutic goods' regime.

Advertisers must also comply with the Therapeutic Goods Advertising Code (No 2) 2018. This took effect on 1 January 2019.

The regulatory regime for medicines is administered by the Therapeutic Goods Administration (TGA) and you can find more information about advertising medicines on the TGA's website - www.tga.gov.au.

Clause 6, Part 2 Special Conditions of the BSA stipulates that a broadcaster must not broadcast an advertisement relating to therapeutic goods that is required to be approved by the TGA without the relevant text first being approved. This is a broadcasting licence condition, so it is important that you comply with it.

Some goods are specifically excluded from being classed as 'therapeutic goods' under the *Therapeutic Goods (Excluded Goods) Determination 2018* (such as dental whiteners, ear candles, hair dyes, nail hardening solutions, foundations that contain sunscreen).

Pre-Approval

Advertisements for medicines require pre-approval before they can appear in specified media (defined to include radio broadcasters). This includes being assessed for compliance eith the Therapeutic Goods Advertising Code (No 2) 2018. **As a result of changes to the *Therapeutic Goods Act 1989*, this will no longer be required after 30 June 2020**.

Under section 42C of the TGA, it is an offence to broadcast an advertisement for therapeutic goods without pre-approval until 1 July 2020.

Restricted Representations

Restricted representations - reference to a serious disease, condition, ailment or defect - must be approved by the TGA before being used in any kind of advertising. This approval will still be required after 1 July 2020.

What Is A Non-Prescription Medicine?

A non-prescription medicine is one that will produce a specific medical outcome but which does not require a prescription. They are also known as "over the counter" medicines. Examples would include nurofen, paracetamol, cold and flu remedies, antiseptic products. Details are available on the TGA website. Click here

Non-prescription medicines are included on the Australian Register of Therapeutic Goods (ARTG) as they are considered to be therapeutic goods.

Therapeutic goods are ones which are represented for use in diagnosing, alleviating, preventing or curing a disease or ailment, or influencing a physiological process. They include conception and pregnancy testing products (section 3 *Therapeutic Goods Act 1989*).

Advertising Non-Prescription Medicines

- No therapeutic claims may be made unless the product is registered on ARTG and the advertisement has any necessary approval. This includes complimentary medicines (see below).
- Advertisements must also comply with the Therapeutic Goods Advertising Code.
- The Therapeutic Goods Advertising Code contains provisions regarding the content of advertisements for goods containing therapeutic claims. These include:
    - claims about certain diseases, such as HIV/AIDS, mental illness, sexually transmitted diseases, --skin diseases;
    - language that may cause fear or distress;
    - comparative advertising;

- professional recommendations;
- incentives; and
- scientific information.

Complementary Medicines

Complementary medicines (also known as 'traditional' or 'alternative' medicines) include vitamin, mineral, herbal, aromatherapy, and homoeopathic products. They also include traditional medicines, such as Chinese medicines.

Complementary medicines are regulated as medicines under the Therapeutic Goods Act 1989.

For advertising purposes, the regulatory regime is the same as for non-prescription medicines.

Complementary medicines may be either listed or registered on the ARTG, depending on their ingredients and the claims made. Low risk medicines will be listed rather than registered.

The advertisement must comply with the Therapeutic Goods Advertising Code.

Medical Devices

A “medical device” is a device (as opposed to a medicine) that is used for a specific therapeutic purpose, such as artificial hips, breast implants, blood pressure monitors, lubricating eye drops, orthodontics.

There is no approval process in relation to advertisements for medical devices. However, such advertisements must also comply with the Therapeutic Goods Advertising Code.

The Australian Regulatory Guidelines for Medical Devices (Part 2, section 12 at page 206) outlines the advertising requirements for medical devices. These include:

- medical devices must be included on the ARTG;
- compliance with the Therapeutic Goods Advertising Code (note the above comments regarding restrictions in the Code).

Prohibited Claims

Prohibited representations include any representation relating to the following:

- neoplastic disease (for example, cancer, tumours, malignancies);
- Sexually Transmitted Diseases (STD);
- HIV AIDS and/or HCV; and
- mental illness.

There is no provision to apply for exemptions in relation to the above prohibited claims. The only exceptions are claims about:

- the prevention of skin cancer through the use of sunscreens; and
- devices used in contraception or in the prevention of transmission of disease between persons.

In relation to these exceptions, an exemption must be granted prior to using the representation in an advertisement to consumers.

Foods Or Cosmetic Products

Advertisements for food or cosmetic products cannot generally include a health or therapeutic claim unless the product is also a therapeutic good within the TGA's jurisdiction.

Food

Some products make claims about the health effects they are intended to have on your body. This does not necessarily mean that they are therapeutic goods. They could be either food or medicines (i.e. therapeutic goods).

For some of these products it may be unclear whether they are a medicine or food, and therefore how they are regulated. Such products are described as being at the Food Medicine Interface.

Medicines and other types of therapeutic goods are regulated under the Therapeutic Goods Act. Foods are regulated by State and Territory food regulatory bodies by reference to the Australia New Zealand Food Standards Code.

A product may be presented to consumers in a variety of ways - this may be important in determining whether it is a food or medicine but is only one of the factors relevant to that determination. For example, minced garlic in a bottle is likely to be a food as there is a tradition of the use of food in that form in Australia. However, if chemicals in the garlic are extracted and marketed in a capsule with claims that the product can 'relieve flu symptoms' it might be considered a medicine.

Cosmetics

One of the main factors in determining whether a product is a cosmetic or medicine (or medical device) are the claims made about the product. For example, moisturisers incorporating sunscreen with a stated therapeutic purpose (e.g. helps prevent skin from the aging effects of UV) are medicines.