



Changes to advertising for medicines containing codeine

From 1 February 2018, all medicines containing codeine will become prescription medicines and will no longer be able to be advertised to the public.

In the interim, all advertisements to the public for medicines containing codeine must comply with the therapeutic goods advertising requirements.

Advertising to the public prior to 1 February 2018

Prior to 1 February 2018, pharmacy-only medicines containing codeine for the relief of coughs and colds can be advertised to the public, provided that the advertisements meet all applicable legislative requirements (including the need for pre-approval of advertisements appearing in certain media – see below). However, advertising to the public for pharmacist-only codeine containing medicines (e.g. those for pain relief) is prohibited.

Approval to advertise codeine products to the public in specified media

Medicine advertisements that are intended for [specified media](#) (such as television, radio, magazines and newspapers) require [pre-approval](#) under Regulation 5G of the Therapeutic Goods Regulations 1990 before they are broadcast or published. Unless withdrawn, approved advertisements are valid for two years from the date of issue.

Until 1 February 2018, advertisements in specified media for **pharmacy-only** medicines containing codeine will continue to require approval before being published or broadcast. **Pharmacist-only** medicines containing codeine cannot be advertised to consumers.

Advertising codeine medicines compliantly

Prior to 1 February 2018, advertisements to the public for medicines containing codeine must continue to comply with all legislative requirements, including the [Therapeutic Goods Advertising Code](#).

The TGA reminds all advertisers that section 4(2)(d) of the [Therapeutic Goods Advertising Code](#) prohibits the use of language that could cause fear and distress for consumers. Advertisements for medicines containing codeine that refer to the impending change in arrangements for scheduling of codeine could cause fear and distress for the public and encourage inappropriate stockpiling of these medicines.

It is an offence in Australia to advertise prescription medicines to the public.

Medicines containing codeine will be prescription medicines from 1 February 2018, so these medicines cannot be advertised to the public from this date.



Changes to advertising on 1 February 2018

From 1 February 2018, all medicines containing codeine will become prescription medicines and will no longer be able to be advertised to the public¹.

Advertisers should take appropriate steps well in advance of 31 January 2018 to ensure that advertisements for codeine containing medicines are not published or broadcast on their behalf after that date. This includes internet and social media advertising.

An existing approval under Regulation 5G for an advertisement for medicines containing codeine will no longer authorise the publishing or broadcasting of that advertisement from 1 February 2018, regardless of the date on which the approval was issued.

Approvals may include explicit notice of this.

Any applications to advertise medicines containing codeine to the public that have not been decided by 31 January 2018 will no longer be able to be approved after that date².

Please note that the therapeutic goods legislation does not provide for the refund or reimbursement of fees paid for advertising pre-approval.

Additional information for pharmacists

Pharmacists will need to make arrangements to remove any public advertising for medicines containing codeine in preparation for 1 February 2018, including product packaging, shelf, stand and floor advertising, dummy display products, website and social media material.

However, from 1 February 2018, pharmacies may continue to include codeine containing medicines in prescription price lists for consumers, provided that the price lists comply with the [Price Information Code of Practice](#).

Additional information for sponsors and manufacturers of codeine products

Sponsors and manufacturers will need to make arrangements to remove any public advertising (that they control) for medicines containing codeine in preparation for 1 February 2018. This includes website and social media material.

Additional information for broadcasters and publishers

Publishers and broadcasters should take steps to ensure that advertisements for medicines containing codeine are not published or broadcast through their media after 31 January 2018.

Advertising to health professionals

Medicines containing codeine can continue to be advertised to health professionals after 1 February 2018. However, advertisements will still need to comply with the *Therapeutic Goods Act 1989* and relevant industry codes of conduct.

Advertisers must ensure that, from 1 February 2018, advertisements for codeine-containing medicines are directed **exclusively to healthcare professionals**. Any advertisements that are also available to the public (including those directed to pharmacy assistants) may be considered illegal advertising of prescription medicines as outlined above for advertising to consumers.

1 The advertising of prescription medicines to the public is prohibited under section 42DL of the *Therapeutic Goods Act 1989*.

2 Due to the new scheduling arrangements, from 1 February 2018, medicines containing codeine will cease to be 'designated therapeutic goods' (as defined in the Therapeutic Goods Regulations 1990) and therefore will be ineligible for applications seeking advertising approval.

