

REGULATORY REFORM TO THE ADVERTISING OF MEDICINES AND MEDICAL DEVICES

23 December 2016 | Australia
Legal Briefings - By **Emma Iles** and **Helen Cousins**

The Australian Government has announced that the regulation of medicines and medical devices advertising is to be changed. Given recent examples of challenges faced by advertisers of these products in accurately conveying product characteristics and performance, the proposed regulatory reforms could leave sponsors and the industry exposed to increased risk of false or misleading advertising claims with potentially severe consequences. We outline the background of the reform, the implications to be aware of and tips for sponsors and other advertisers of medicines and medical devices.

BACKGROUND

In July 2015 an expert panel appointed to consider the regulatory framework for therapeutic goods recommended 58 changes. Those changes were largely accepted by the Australian Government and a roll out over two years has commenced. One significant area of regulatory reform contemplated is the move to the self-regulation of the advertising of medicines and medical devices to the public.

ADVERTISING REFORMS

While the prohibition on advertising prescription medicines and pharmacist only medicines to the public will remain in place, the Government has supported significant reform to the advertising of over-the-counter medicines (**OTCM**) and complementary medicines (**CM**). In particular:

- removing entirely the requirement of Government approval for advertisements of OTCM and CM to the public in favour of the self-regulation of advertising; and
- enhancing enforcement powers to deter inappropriate and misleading and deceptive conduct in the advertising of medicines and medical devices.

The removal of pre-publication approval means that the following regulatory inconsistencies existing under the current law will fall away:

- pre-publication approval for advertising of medical devices to the public is *not* required regardless of the risk classification of the device whereas pre-publication approval *is* required for advertising of OTCMs and CMs, depending on the media;
- pre-publication approval of advertisements in print media, radio and free-to-air TV *is* required whereas it is *not* required for advertisements on the internet, on pay-TV or in below the line materials (such as leaflets, flyers, catalogues, brochures, shelf talkers, letter box drop or at point of sale); and
- the industry association to which a sponsor must apply for advertising pre-approval varies depending on the advertising media chosen. So in the case of a multimedia campaign for the same product, a sponsor needs to seek pre-publication approval from more than one entity.

Of importance for sponsors and other advertisers of medicines and medical devices are the reforms directed to enhancing enforcement powers. The Government stressed that its acceptance of the expert panel's recommendation to abolish the whole process of vetting and pre-approval of the advertising was conditional on the implementation of various protections for consumers.

The Government has since proposed hefty new penalties for advertising offences and the introduction of new civil penalties (set out in the TGA consultation paper on the regulatory framework for advertising therapeutic goods released in November 2016). Maximum offence penalties of up to 5 years imprisonment and civil penalties for companies and individuals of up to A\$9 million and A\$900,000 respectively are contemplated.

IMPLICATIONS FOR SPONSORS AND OTHER ADVERTISERS OF MEDICINES AND MEDICAL DEVICES

The need for accurate advertising has not changed. But the increased enforcement powers and significant penalties contemplated by the proposed reforms, combined with the removal of advertising pre-approvals for some medicines, increases the risks for non-compliant sponsors and other advertisers of medicines and medical devices.

While the Government has committed to developing sponsor education programmes to assist with the understanding of and compliance with advertising obligations, the onus will solely be on sponsors to meet their legal obligations. There will be a greater need for robust internal risk assessment processes in addition to legal and regulatory review to ensure that proposed advertising does not breach relevant laws. Indeed, it is not uncommon for the ACCC to investigate advertising in the medical and pharmaceutical industries. Recent examples include:

- Reckitt Benckiser (Australia) Pty Ltd being held liable for engaging in misleading and deceptive conduct relating to representations made concerning its Nurofen specific pain products.
- Chemmart having to withdraw all promotional materials regarding the usefulness of Symbion Pty Ltd's 'myDNA' genetic test in identifying a person's response to certain drugs.
- Safe Breast Imaging Pty Ltd being held liable to pay a penalty of A\$200,000 for making false representations relating to breast imaging performed using its devices.
- Recent investigations by the ACCC into claims published by IVF clinics about success rates that resulted in several major clinics amending their websites.

TIPS FOR SPONSORS AND OTHER ADVERTISERS OF MEDICINES AND MEDICAL DEVICES

In general terms, care should always be taken to ensure that any statements made in advertising are clear and accurate, and if necessary legal advice sought, but some lessons that sponsors can take from these recent examples for the future are:

- Use technical terms with care – such terms may be generally understood by industry participants but can be misleading to consumers.
- Consider the impression created from any combination of words and images – the combination could be different to the impression created by either the text or image in isolation.
- Claims or representations made about the effectiveness of a medical treatment or product should be accurate and supported by adequate scientific evidence.
- Avoid making overly broad statements about products and consider whether statements should be qualified.
- Consider not just what is said or written, but also what is implied.

KEY CONTACTS

If you have any questions, or would like to know how this might affect your business, phone, or email these key contacts.



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