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AN OUNCE OF PREVENTION OR A POUND OF CURE?

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The abolishment of the pre-approval process for the advertising of complementary medicines and harsher penalties for breaches of advertising regulations.

On 5 March 2018, the *Therapeutic Goods Amendment (2017 Measures No.1) Act 2018* (Amendment Act) received Royal Assent. The Amendment Act introduces a number of changes to the *Therapeutic Goods Act 1989* (Cth) (the Act) which remove regulatory red tape relating to the advertising of complementary medicines, and instead introduces stricter offences for breaching advertising regulations. The controversial changes will affect the way complementary medicines are marketed and advertised in Australia.

Among the most notable changes to the Act are:

- Those relating to the removal of a pre-approval process for medicine advertisements.
- More severe penalties for breaches of the Therapeutic Goods Administration (TGA)'s advertising code.
- The introduction of a permitted indications list, which seeks to limit the language used to advertise complementary medicines.

BACKGROUND

The Amendment Act saw the realisation of changes proposed in the Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017 and Therapeutic Goods (Charges) Amendment Bill 2017, which were introduced in order to implement a number of recommendations of the Expert Panel Review of Medicines and Medical Devices Regulation, and to provide clarity and consistency across the regulation of different kinds of therapeutic goods.

One of the most contentious amendments is the removal of the pre-approval process for advertisements for medicines (including homeopathic goods, vitamins and herbal products). Under the pre-approval system, the Australian Self Medication Industry and Complementary Medicines Australia assessed the claims of efficacy in potential advertisements to ensure advertisements were not misleading. The system drew criticism for not keeping up with technological advertising trends as it required pre-approval of for print, radio and TV, but not for internet ads.

The justification behind the removal of the pre-approval process is that the system would benefit from a more self-regulatory advertising regime, and that through increased scrutiny of products on the market and increased penalties for advertising violations, the Act could continue to protect consumers.

Reported concerns of the new system are that the errors regularly identified in the pre-approval process will now find their way to publication, and not until a review or complaint is made will any such misleading advertisements be rectified. Critics of the amendments have argued that prevention is better than the cure, and that the risk of harm of a misleading medicine advertisements is so great (especially in the context of social media and viral marketing) that pre-approval processes are more important than ever.

THE AMENDMENTS

Prior to the amendments, Division 2 of Part 5-1 of the Act dealt with therapeutic goods advertisements for which an approval was required, and created offences for failing to obtain approval or publishing an advertisement that differed in any respect from the advertisement which was approved. The Amendment Act repealed this entire division in order to allow for a more self-regulatory advertising regime, and removed the requirement for manufacturers to obtain approval before advertisements of their medicines are broadcast or published.

Foreshadowing a potential influx of noncompliant advertising under a self-regulatory regime, new sections have been inserted into the Act conferring powers upon the Department of Health to order for advertisements to be ceased, retracted, corrected or destroyed (s 42DV), and to create new offences for noncompliance with such orders (s 42DW). The TGA's powers of investigation and enforcement of the advertising regime have been also been broadened in an attempt to bring the TGA system into line with comparable Commonwealth regulators such as ASADA and the Office of Drug Control (Part 1 of Schedule 6, and Schedule 7 of the Act).

To further encourage compliance with the advertising regulations, a new tiered offence regime has been introduced to the general advertising offences under s 42DL of the Act. Previously, advertising contraventions resulted in a penalty of $12,600. Among the new maximum penalties include:

1. $21,000 for a strict liability offence (s 42DL(3)).
2. $210,000 or imprisonment for 12 months or both for an ordinary offence (s 42DL(2)).
3. $840,000 or imprisonment for 5 years, or both for a serious offence where the use of goods in reliance on the advertisement has, or would be likely to result in harm or injury to any person (s 42DL(1)).

Given the seriousness of the penalties, the TGA has created a "permitted indications" list, which is aimed at ensuring manufacturers are clear of the permitted indications and restrictions on advertising complementary medicines. For example, if a product advertises that it may "reduce hair loss", it must be supported by scientific or traditional evidence, and must contain the label statement: *"If symptoms persist, seek the advice of a healthcare professional. Product presentation must not imply or refer to serious conditions associated with alopecia e.g. autoimmune disease, chemotherapy."*

The permitted indications list has drawn stark criticism however. It provides over 1,000 indicators, but requires just 14% of these indicators to be supported by scientific evidence. For the rest, the manufacturer is able to rely on "traditional" evidence (i.e. over 75 years of use in traditional medicine, such as Chinese medicine, herbalism or homeopathy). Unsurprisingly, health professionals and consumer advocates have criticised this approach.

PRACTICAL IMPLICATIONS

The reduction of red tape will do nothing to slow down the notable increase in advertising for complementary medicines, in particular traditional medicines, for which there is now a clear framework for what can and cannot be indicated in advertisements.

Given the seriousness of the penalties for advertising breaches, and the lack of guidance previously afforded by the pre-approval system, manufacturers and distributors of medicines must take unprecedented levels of care in ensuring its advertising is not in breach of the regulations.

In recent years Australia has seen an increase in consumer class actions relating to misleading advertising of medicines. If manufacturers and distributors of medicines continue to take risks in relation to the advertising and marketing of their products, they are likely to now face serious repercussions on a number of fronts.

The long-term effects of the amendments, and the impact they will have on consumer protection are yet to be seen. Within two years, the Government will arrange for an independent review of the system, at which time the efficacy of the amendments will be examined.

Therapeutic Goods Amendment (2017 Measures No.1) Act 2018

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