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Trends and Developments
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Trends and Developments

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Australia is seeing a significant change in the way in which advertising of therapeutic goods (the general term used to refer to medicines and medical devices) is regulated, resulting from increased levels of enforcement activity and significant changes to the expectations imposed on companies. These changes will require companies to think about their promotional activities in different and more sophisticated ways, if they are to take full advantage of the communication opportunities arising from the digital revolution.

For many years now, the advertising of therapeutic goods has been regulated through two parallel systems. First, the Australian government regulates the advertising of therapeutic goods through the Therapeutic Goods Act 1989 (Cth) (TG Act), the same legislation which establishes the system for the granting of marketing approval for therapeutic goods in Australia. Second, the industry regulates itself through Codes of Conduct published by peak industry bodies across a number of different sectors of the industry.

In general terms, the government's regulatory regime is focused on regulating advertising to the general public, while the industry codes focus on advertisements directed at healthcare professionals. However, the demarcation between the two spheres is not absolute and recent experience suggests that the lines have the potential to become more blurred.

Government Regulation

The TG Act establishes certain minimum standards for the advertising of therapeutic goods in Australia. "Advertising" is broadly defined to mean "any statement, pictorial representation or design that is intended, whether directly or indirectly, to promote the use or supply of the goods".

The TG Act is administered by the Therapeutic Goods Administration (TGA). The TGA publishes a code known as a Therapeutic Goods Advertising Code (TGAC), which deals with advertising directed at the general public.

For many years, the provisions of the TGAC were administered by a Complaints Resolution Panel. This process was widely thought to be ineffective because it depended on complaints and also because the Panel did not have the power to enforce its decisions directly. A review conducted in 2015 recommended the streamlining of enforcement and the introduction of new enforcement and penalty provisions.

As a result, from 1 July 2018 the Panel was abolished and the TGA took sole responsibility for the regulation of advertising under the TG Act. At the same time, the TGA received new enforcement powers, including the power to compel a person to cease an advertisement or to make a retraction or correction of an advertisement. The penalties for advertising breaches were also increased.

In October 2018, a new TGAC came into effect and the TGA published guidance as to its approach to advertising regulation and enforcement, the Australian Regulatory Guidelines for Advertising Therapeutic Goods (ARGATG).

The two and half years since the regulatory changes came into effect have seen a marked increase in the level of regulatory activity. This has included a June 2019 AUD10 million fine imposed by the Federal Court in civil penalty proceedings commenced by the TGA for the promotion of peptides and, more recently, the September 2020 conviction of the former owner of a sports supplements company for advertising unregistered supplements (including some which were prescription-only medicines).

The TGA's enforcement approach is very much a mix of carrot and stick. It seeks proactively to educate industry about compliance obligations. It will also select matters for further investigation, having regard to its state enforcement priorities, the risk involved in the behaviour and the compliance history of the advertiser. Similarly, its enforcement approach will be adapted to fit the particular circumstances of the breach, ranging from education and guidance, all the way up to criminal prosecution or civil penalty proceedings.

An interesting example of the TGA's enforcement activities concerned steps it took in late 2018 and early 2019 relation to a disease state-awareness campaign run by GlaxoSmithKline (GSK) in relation to meningococcal vaccines. While recognising the importance of disease state-awareness campaigns, the TGA took the view that GSK's campaign had overstepped the mark, because it linked meningococcal disease with meningococcal vaccines (although it did not mention any vaccine by name), making the campaign an advertisement for a prescription medicine, further exac-

erbated by the reference to a serious form of disease (a restricted representation, requiring approval under the TG Act and the TGAC).

However, consistent with its flexible and tiered approach to enforcement, the TGA did not immediately commence enforcement action, but instead notified GSK of its concerns. GSK ceased the campaign and the TGA regarded the matter as closed.

Although this outcome was achieved without controversy, it does indicate a willingness on the part of the TGA to step into an area - activities related to prescription medicines - which it has traditionally left to industry self-regulation in all but the most serious cases.

Although the new regime for the regulation of advertising had been in place for just two years, it was the subject of a review in 2020. The review found that the changes had been largely successful, but made 22 recommendations to build upon the reforms and the work undertaken by the TGA to implement them. Those recommendations included:

- the development and publication of Compliance Priorities and Education Priorities;
- the development of information-sharing protocols to facilitate information-sharing with relevant regulators;
- the development of clear guidance on the use of the TGA's broadened powers, particularly the more punitive measures; and
- focusing on improved compliance outcomes.

The TGA has already started to implement the review's recommendations, including by the publication of advertising compliance priorities which will guide its decisions as to the application of resources. Unsurprisingly at present, its Priority 1 is therapeutic goods associated with COVID-19. At Priority 2 are a range of products, including stem cell products, medicinal cannabis, therapeutic goods used in the cosmetic and beauty industry and weight-loss products, demonstrating the diversity of the TGA's concerns.

Industry Regulation

For many years now, the Australian government has permitted the therapeutic goods industry largely to regulate its own dealings with healthcare professionals, provided that the industry has established and operated an effective enforcement regime.

This has resulted in a number of industry peak bodies, or trade associations, publishing codes for their members, which include complaints-resolution mechanisms. Examples include the Medical Technology Association of Australia Code of Practice, which applies to medical device companies, and the Pathology Technology Australia Industry Code, which applies to suppliers of in vitro diagnostic devices. However, far and away the best known, most well-established and most sophisticated example is the Medicines Australia Code of Conduct (the MA Code), which applies to the innovative prescription pharmaceutical industry.

The MA Code is in its 19th edition. It includes provisions which deal with:

- the form and content of advertising material;
- appropriate interactions with healthcare professionals, including support for educational events and hospitality;
- the manner in which companies may interact with consumer organisations and the general public (including, for example, disease state-awareness campaigns).

In addition to Medicines Australia requiring compliance with the MA Code as a condition of membership, the TGA generally makes compliance with the MA Code a condition of market authorisation of prescription medicines.

The MA Code establishes a complaints-handling committee to deal with appeals from complaints outcomes and a monitoring committee responsible for monitoring company promotional activities, where appropriate referring them to the complaints committee for consideration of potential breaches of the MA Code.

Finally, it includes a transparency regime, requiring members to report on transfers of value to healthcare professionals. These reports are collated by Medicines Australia into a consolidated report published on the Medicines Australia website every six months.

The MA Code has struggled for relevance in recent years. Complaint levels have been generally low for the last decade (including a couple of years in which there were no complaints which made it to the Committee), making the MA Code susceptible to criticism that the complaints process (which often depends on complaints brought by competitors) is ineffective in flushing out instances of non-compliance.

Furthermore, the increased TGA enforcement activity in the consumer space since 2018 and the increased enforcement options available to the TGA raise questions as to whether the AUD300,000 maximum fine available under the MA Code is sufficient.

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The better view is that the low levels of complaints are a product of the fact that the MA Code is an example of successful industry self-regulation developed over 60 years, with most Medicines Australia members making a considerable investment in internal processes to achieve compliance with the MA Code. The low levels of complaints can be explained by the fact that the Australian prescription pharmaceutical industry has achieved high levels of compliance in its promotional activities.

However, the MA Code does face challenges arising from the rapid evolution of communications technologies and the shift from face to face to remote interaction between companies and prescribers (a trend which is, of course, accelerated by the COVID-19 pandemic). The Code has traditionally been a prescriptive document, which dealt with a range of specific and common interactions between companies and healthcare professionals, prescribing in detail what companies could and could not do when engaging in those activities. As new forms of interaction were added, successive editions of the MA Code were ever bulkier.

Edition 19, which came into effect on 30 March 2020, fundamentally changes the nature of the Code. The introduction to Edition 19 says, "The Code of Conduct provides a principles-based framework for appropriate and ethical decision-making by Companies when promoting prescription products and interacting with healthcare professionals". Many of the detailed provisions from previous editions have been removed or contain a reduced level of detail. In their place are more generalised principles, which must be adhered to by members. Indeed, Part A of Edition 19 sets out ten "Overarching Principles" which Companies "must ensure… are reflected in all activities covered by this Code". The ten Overarching Principles include:

- a statement that all activities undertaken by companies must have the purpose of supporting quality use of medicines;
- a commitment to transparency in interactions with healthcare professionals;
- commitments to the provision of current, accurate, balanced and scientifically valid information and to the support of the proper assessment of the risks and benefits of medicines;
- a prohibition on the offering or providing of anything that would have an inappropriate influence on prescribing;
- a requirement that company-initiated or sponsored events uphold the integrity and reputation of the industry.

Edition 19 does not entirely do away with specific obligations. Some traditional areas of interaction with healthcare professionals (for example Trade Displays and hospitality) remain subject to very specific requirements). Furthermore, the Code is supported by a number of documents (described by Medicines Australia as the "Toolkit") which provide companies with templates and guidance for many common activities.

However, there is no doubt that considerable flexibility has been incorporated in the Code, largely to give companies greater freedom to incorporate new technologies and methods of communication into their promotional activities.

Of course, with greater flexibility come new challenges and greater risk for companies, who may find that the clearly demarcated boundaries of permissible activities have disappeared. The temptation may be to conclude that those boundaries no longer exist. That is clearly not the case. Indeed, one suspects that in the short to medium term many of the specific rules from previous editions of the MA Code will continue to provide guidance as to what is appropriate. However, Edition 19 will ultimately require a different approach to compliance-one which requires the exercise of judgement and the ability to be objective about a company's promotional activities.

To the extent that one can read anything into the recent decisions of the Code of Conduct Committee in complaints it has considered, those decisions suggest that, if anything, the Committee is to hold members to a higher standard than has been the case historically. The Committee appears to be more willing to scrutinise claims closely and to find gaps between the claims which have been made and data relied on to support them or even, in some cases, to find that the way in which results are presented in a promotional piece is misleading, even if the results themselves are not.

Clayton Utz is recognised as a leading life sciences law firm. With 17 partners and over 25 qualified lawyers across its Sydney, Melbourne, Brisbane and Perth offices, the firm continues to build a reputation for innovative and incisive advice. The team has a unique combination of scientific, regulatory and legal expertise in prescription pharmaceuticals, OTC and complementary medicines and medical devices and is consistently the legal firm of choice for many Australian and global pharmaceutical and medical device companies. The firm advises on all aspects of the product life cycle, including the protection of IP, clinical trials, marketing approval, product labelling, reimbursement, approval and registration processes, promotion and distribution, product risk, product liability and product recall. Clayton Utz counts both established global pharmaceutical companies and agile start-ups among its clients. It has advised Medicines Australia (the prescription pharmaceutical industry body) about significant policy initiatives in the pharmaceutical space.

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Greg Williams is head of the life sciences department and is internationally recognised as a leading life sciences expert with sought-after expertise in the full life cycle of regulatory matters and complex litigation, including class actions and product liability litigation. In the regulatory sphere, he provides advice across the whole product life cycle, including product registration, reimbursement, advertising disputes, and product safety and recalls. He has particular expertise in providing strategic advice in relation to pricing and reimbursement issues and has assisted a number of clients in navigating difficult and contentious Australian reimbursement applications. Greg is a member of the International Association of Defence Council and Defence Research Institute.

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