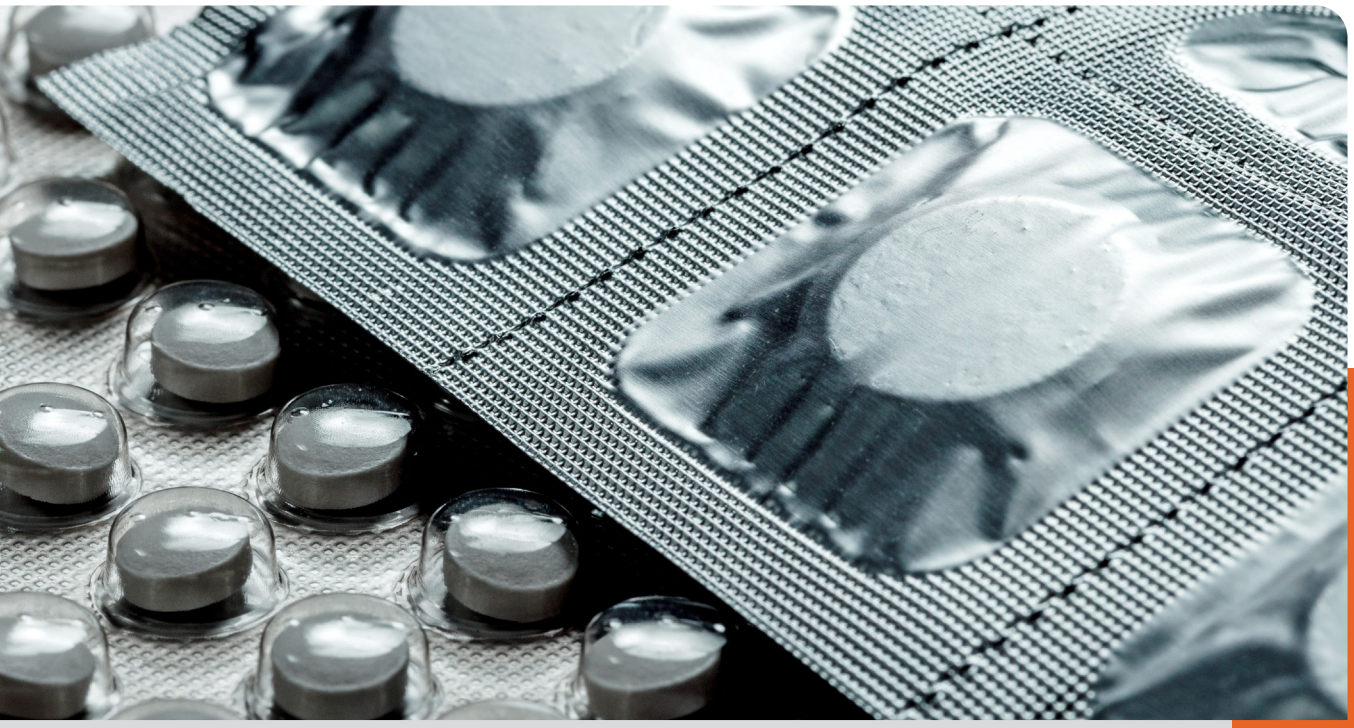
International
Comparative
Legal Guides



Pharmaceutical Advertising

2024

21st Edition

Contributing Editors:
Ian Dodds-Smith & Adela Williams
Arnold & Porter

glg Global Legal Group

Expert Analysis Chapters

Q&A Chapters

Australia

Clayton Utz


Greg Williams


Sheena McKie

1 General – Medicinal Products

1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

In Australia, the advertising of medicinal products is governed by the *Therapeutic Goods Act 1989* (Cth) (**TG Act**) and its subordinate legislation (principally, the *Therapeutic Goods Regulations 1990* (Cth) (**TG Regulations**)). The TG Act is administered by the Therapeutic Goods Administration (**TGA**). 'Therapeutic goods' is the phrase used in Australia to describe medicines and medical devices.

The advertising of therapeutic goods is also subject to the same laws that regulate advertising generally, most notably, the *Competition and Consumer Act 2010* (Cth) (**CC Act**), and the Australian Consumer Law (**ACL**), which is Schedule 2 to the CC Act. The CC Act is administered by the Australian Competition and Consumer Commission (**ACCC**).

There are also a number of Codes of Practice that contain provisions relating to the advertising of therapeutic goods. The most relevant to the advertising of medicinal products are:

- the *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021* (**TGAC**), which applies to all advertisements for therapeutic goods other than those directed at healthcare professionals (**HCPs**) or wholesalers of therapeutic goods. The TGAC came into effect on 1 January 2022 and replaces the *Therapeutic Goods Advertising Code (No 2) 2018* (**TGAC 2018**). The TGAC is delegated legislation, made under the TG Act;
- the Medicines Australia Code of Conduct (**MACC**), which relates to the promotion of prescription-only medicines. The MACC is described as a principles-based framework for appropriate and ethical decision-making by companies when promoting prescription products and interacting with HCPs, health consumer organisations and the general public. The 19th edition came into effect on 30 March 2020 (with an amendment adopted on 3 November 2022) along with an online Code of Conduct Resource Tool Kit. Most innovator companies in Australia are members of Medicines Australia, and are subject to the MACC as a condition of their membership. Furthermore, the listing of prescription medicines by the TGA is generally subject to a condition that promotional material for the medicine must comply with the MACC;
- the Generic and Biosimilar Medicines Association (**GBMA**) Code of Practice, the fifth edition of which came into effect in June 2021;
- the Medical Technology Industry Code of Practice (**MTIC**) (administered by the Medical Technology Association of Australia (**MTAA**)), 13th edition effective 1 January 2023, which relates to the behaviour of medical device and technology companies; and
- Pathology Technology, Australia's Industry Code of Conduct, which applies to the behaviour of companies who market *in vitro* diagnostic products in Australia. The fourth edition of the Code of Conduct was published in October 2020.

1.2 How is "advertising" defined?

The TG Act defines 'advertise' *in relation to therapeutic goods* as: '*any statement, pictorial representation or design that is intended, whether directly or indirectly, to promote the use or supply of the goods, including where the statement, pictorial representation or design*:

(a) is on the label of the goods;

(b) is on the package in which the goods are contained; or

(c) is on any material included with the package in which the goods are contained'.

Under this definition, whether or not something is an advertisement depends on whether it is 'intended' to promote the use or supply of goods. We are not aware of any case law that determines how this test of intention is to be applied, but in practice it is applied broadly.

The question of whether a particular statement constitutes an advertisement is also commonly tested under the industry codes. For example, the MACC defines 'advertisement' in near identical terms to 'advertise' under the TG Act.

1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

Advertisements for prescription medicines, which can only be directed to HCPs, are regulated by the MACC. Sales representatives are required to complete a Medicines Australia endorsed education programme in relation to the MACC, the pharmaceutical and healthcare industry, anatomy, product information (**PI**), clinical evidence and pharmacology within six months of commencing employment and on an ongoing basis. Any other person directly involved in the development, review and approval of promotional materials relating to prescription medicines must complete the MACC component of the programme within 12 months of commencing employment.

There are otherwise no formal requirements for the types of internal approval process that companies must have in place (although there are certain types of advertisements that must be approved by appropriate regulatory authorities (see question 1.5 below)). It is rather a matter of risk management.

1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

There are no legal requirements for companies to have specific standard operating procedures (**SOPs**) in relation to advertising or to employ personnel with a specific role in relation to advertising. The advertising activities of companies are strictly controlled and directed by the TG Act, TG Regulations and TGAC, along with the MACC and other industry codes. However, some codes have specific procedural requirements for certain promotional activities. For example:

- section 15.2 of the MACC requires companies to report on all sponsorships of independent educational meetings and symposia directed to HCPs;
- section 2.5 of the MACC requires companies to implement policies and procedures describing the roles and responsibilities of its employees when interacting in the social media space to ensure compliance with the MACC; and
- section 7 of the MACC requires companies to keep records of delivery, including the quantity and nature of medicines provided at no cost (whether as a starter or other sized pack), for a minimum of two years.

1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

The requirement that stipulated that advertisements in certain types of media must be approved was removed on 1 July 2020.

However, certain types of representations, called 'restricted representations', must be approved before they can be used in advertisements to the general public. A 'restricted representation' is an express or implied reference to a serious form of a disease, condition, ailment or defect, of a type specified in the TGAC.

Persons who wish to use restricted representations in advertisements can complete an 'application for approval to use a restricted representation in advertising'.

1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?

The TGA has a wide range of powers in respect of advertisements directed at the general public, including:

- the power to issue a notice prohibiting a person from publishing a particular advertisement if the TGA forms the view that the advertisement contains a representation that is false or misleading;
- the power to issue a substantiation notice to a person apparently responsible for advertising therapeutic goods, which requires that person to provide information to substantiate claims made in the advertisement, and, finally, issue a public warning notice;
- the power to require a person who advertises in breach of the relevant legislation to cease the advertisement, make a retraction or correction, recover and destroy copies of the advertisement or cease making a particular claim or representation; and
- in certain cases, the power to issue a public warning notice in respect of an advertisement.

There is a right to an internal merits review of some, but not all, of the TGA's powers outlined above. If a company is not satisfied by the internal merits review, then it may seek a further merits review from the Administrative Appeals Tribunal (a tribunal that conducts merits reviews of administrative decisions).

The TGA does not have any specific powers in relation to advertisements for prescription products (which can only be directed at HCPs). However, Medicines Australia, which hears complaints about breaches of the MACC, including non-compliant advertisements, may require the company to take immediate action to discontinue or modify the advertisement, and may require retraction statements, including corrective letters and advertising, to be issued by the company. Any corrective action required by the MACC Committee must be completed within 30 days of receipt of the decision and reasons. Medicines Australia may publish any failure to take corrective action and/or forward the complaint to the TGA or the ACCC. A company may appeal any decision of the MACC Committee or of the imposition of any fine.

1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases, please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?

There are a number of ways in which an advertiser might be subject to sanction:

a) Criminal Offences: The TG Act and TG Regulations create a number of offences relating to advertising. These include both criminal offences and civil penalty provisions. The penalties imposed for a breach of these rules are fines of up to AU$15,650,000 for corporations and AU$1,565,000 for individuals. The TGA is responsible for enforcing these provisions. Prosecutions or civil penalty proceedings for breaches of the TG Act are rare; however, the TGA has been increasingly active in issuing infringement notices and fines to pharmaceutical companies in relation to unlawful importation and advertising of unapproved therapeutic goods. Other sanctions the TGA may impose include suspension or cancellation of a product from the Australian Register of Therapeutic Goods (**ARTG**), the issuance of a public warning notice, an infringement notice or entering into an enforceable undertaking with the breaching company.

b) Industry Bodies: Each of the codes mentioned above include a complaints resolution body. Historically, the most commonly used was the MACC Committee, which hears complaints between members relating to prescription-only medicines. The Committee can impose sanctions

on Medicines Australia members, including fines of up to AU$250,000 and cumulative fines, corrective action and the withdrawal of offending material. Medicines Australia regularly publishes information about recent complaints considered by the Code and Appeals Committee, as well as annual reports of complaints processed in the past. Overall, complaint levels remain low. A review of the reported decisions in the past five years, up to and including March 2024, reveals that the same number of complaints were heard and determined within 2023 as between the years 2019 to 2022, demonstrating a higher level of inter-company complaints. The 2023 complaints focused on a range of communications to patients, healthcare professionals and the general public. This serves as a warning for companies to be vigilant in ensuring they take care in any comparative claims (whether express or implied), and that they have data to substantiate the claims they wish to make for their products that is of sufficient quality and consistent with the approved PI (refer to sections 1 and 1.1 of the MACC).

c) General Law: The ACL contains a number of provisions that impact on advertising, including the advertising of medicinal products. The most important is section 18 of the ACL, which prohibits a corporation from engaging in 'misleading or deceptive conduct' in the course of 'trade or commerce'. This provision has been widely used to challenge advertisements and promotional conduct. Competitor-initiated court action in respect of advertisements is rare, although it does occur. One example is *Novartis Pharmaceuticals Australia v Bayer Australia* (2015) 22 ALR 621, which concerned an unsuccessful claim by Novartis that Bayer's marketing of Eylea was misleading. Furthermore, Reckitt Benckiser was subject to an AU$6,000,000 civil penalty in respect of the promotion of Nurofen (ibuprofen). The proceedings were brought by the ACCC in respect of the promotion of different products to treat specific types of pain in circumstances where the formulation of each product was the same (*ACCC v Reckitt Benckiser* (2016) 340 ALR 25).

1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?

Complaints relating to promotional material for prescription medicines are directed to Medicines Australia. If such complaints are directed to the TGA, it will forward these complaints to Medicines Australia.

Section 16.3 of the MACC deals with complaints against non-members. Complaints concerning the conduct of non-members will be forwarded to the non-member with an invitation to have the complaint adjudicated by the MACC Committee in accordance with the MACC, and to abide by the MACC Committee's decision and any sanctions imposed. If the non-member declines the invitation, Medicines Australia has the right, but not the obligation, to forward the complaint to the TGA or the ACCC.

Complaints relating to the promotion of medical devices and non-prescription medicines to the general public are handled by the TGA.

1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?

The chief recourse for Australian companies who believe that their competitors are using advertising to gain an unfair competitive advantage is section 18 of the ACL, which prohibits misleading or deceptive conduct. There are relatively few restrictions on persons who may take action under section 18; it may be used, for example, by public interest groups. The ACCC may also commence proceedings for breach of section 18, in which case the court may impose fines for such breach.

It is also reasonably common for companies to make complaints to either the TGA or Medicines Australia about allegedly misleading or unfair advertisements.

Section 16.4 of the MACC provides that its complaints resolution procedure should not be abused, and that any complaints made by a complainant company against one or more companies within a therapeutic class considered frivolous or vexatious may amount to a breach of the MACC. Nevertheless, competitors often bring complaints under the MACC on the basis of public interest in HCPs receiving balanced, accurate and correct information about prescription products.

2 Providing Information Prior to Authorisation of Medicinal Product

2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?

Until a product is registered, listed or included on the ARTG, there is a blanket prohibition in the TG Act on the publication of any advertisement for therapeutic goods. There is also a blanket prohibition on making claims that a person can arrange the supply of unregistered therapeutic goods. However, not all references to a product will necessarily be 'advertisements' (see question 1.2 above).

Each indication of a product is treated as a separate product, so the prohibition on advertising unregistered products also applies to promoting registered products for uses outside of their approved indications.

However, these prohibitions do not apply to advertisements directed exclusively to: (1) health professionals; and (2) persons who are: engaged in the business of wholesaling therapeutic goods; purchasing officers in hospitals; purchasing therapeutic goods on behalf of a government or government authority; or purchasing officers or practice managers for health practitioners. Such advertisements are governed by applicable industry Codes of Practice.

The MACC provides that only company medical department personnel may provide information to HCPs on unapproved products or subjects not covered by the PI (e.g. unapproved indications/'off-label' uses), provided the exchange is non-promotional in intent, content and nature, any information relating to unapproved products or uses are clearly identified as such, and that the requirements of the MACC have been complied with.

Information on unapproved products and uses can be provided to HCPs on (password-protected) digital medical platforms only where the information is viewable when the HCP executes a search that includes specific search terms relating to the unapproved product or use.

So long as they are consistent with the MACC, companies can initiate or manage educational events. Companies should ensure that HCPs speaking at company-sponsored educational events in Australia are aware of the obligation to not promote unapproved products or indications. The MACC permits companies to provide or display educational and promotional material, along with the PI, regarding an unapproved product or indication at international or Australasian congresses hosted in Australia, provided any material used clearly identifies that it refers to an unapproved product or indication, and that the product or indication (as appropriate) is approved overseas.

Generally, there are no prohibitions on persons other than manufacturers or suppliers making factual statements about unregistered products or indications, provided that those statements do not amount to 'advertisements' as defined.

2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?

The publication of information about unauthorised medicines that amounts to an advertisement or promotion of the medicine in question including off-label information is prohibited. As noted at question 1.2 above, this raises the question of whether there is an intention to promote the use or supply of the product.

2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. mainstream public media), please specify.

There are no provisions in the TG Act or the MACC that deal specifically with press releases. As such, press releases are subject to the general prohibitions on the promotion of unapproved medicines, including unapproved indications. That is, anything that is promotional is prohibited.

Particular care should be taken when considering the publication of statements on company websites or in media releases, which may be directed to or otherwise accessed by the general public. These have recently been the subject of consideration by the MACC Committee in November 2023, and a member company fined AU$120,000.

2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?

Yes to both questions. The MACC considers it reasonable where HCPs are seeking clarity and/or additional information on unapproved products or uses for companies to provide such information. However, only company medical department personnel may engage in this exchange and the information provided must be clearly labelled as relating to an unapproved product or use.

2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?

The ECJ judgment in the *Ludwigs* case, which answered a question that is related to the interaction between German national law and EC Directive 2001/83, is not part of Australian law. Questions 2.1 to 2.4 above describe the circumstances in which details about unapproved medicinal products may be made available to HCPs.

2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?

There are no specific provisions or guidelines restricting the provision of information about unregistered products or indications for this purpose. However, the provision of such information may constitute a breach of the TG Act if it meets the definition of an 'advertisement'.

2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?

The TG Act prohibits the promotion of any therapeutic good that has not received regulatory approval. The MACC further provides that market research must be an initiative to collect relevant information to enhance the quality use of medicines and must not be used as a means to promote to research participants.

3 Advertisements to Healthcare Professionals

3.1 What information must appear in advertisements directed to healthcare professionals?

Sections 2.1 and 2.2 of the MACC provide that promotional material in any form directed to HCPs must include:

- the brand name of the product;
- the Australian approved name of the active ingredients next to the most prominent presentation of the brand name;
- information regarding the product by either including the Minimum PI (**MPI**) (approved indications, contraindications, clinically significant precautions and interactions, common adverse effects, dosage and method of use, any boxed warnings or black triangle TGA warnings and a statement directing HCPs to review the PI before prescribing), including a hyperlink to the PI for electronic materials, a direction to where the MPI or PI is in the same print publication, or a direction available from a trade display;
- a statement indicating the Pharmaceutical Benefits Scheme (**PBS**), Medicare Benefits Scheme (**MBS**), National Blood Authority (**NBA**), National Immunisation Program (**NIP**) or the Life Saving Drugs Program (**LSDP**) status of the product, with or without details of listing, or a direction to where the relevant information is available;
- the name of the supplier and the city, town or locality of the registered office; and

- the date that the material was prepared or last revised.

Promotional material should be presented in such a way that visible information is accurate and consistent with the MACC when read in isolation.

3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to: (a) studies not mentioned in the SmPC; or (b) studies which have not been published either in peer-reviewed journals or at all ("data on file")?

There are no specific prohibitions in the MACC on the information that may be included in advertisements to HCPs, provided that all information and claims are current, accurate, balanced, consistent with the approved PI, and do not mislead directly, by implication, or by omission. These general principles apply to the inclusion of studies in promotional material.

The Australian equivalent to the SmPC is the PI. There is no specific prohibition on advertisements including references to studies that are not in the PI, although if such studies relate to indications that are not approved in Australia, that will give rise to a separate difficulty.

There is no prohibition on referencing studies that have not been published or peer reviewed. However, the MACC places the obligation on companies to ensure that all promotional claims are referenced and that cited references provide the appropriate level of evidence for the claim being made, reflect the body of evidence and allow HCPs to independently evaluate the validity of the claims made.

'Data on file' may be relied on as substantiation for an advertising claim; however, such references must be available to be supplied on request and provide the appropriate level of evidence to support the claim. 'Data on file' can be used as sole substantiation for a claim regarding prescribing frequency or cumulative patient exposure; however, it should not be used as sole substantiation for a safety or efficacy claim (section 1.1 of the MACC).

3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?

Advertisements subject to the TGAC (that is, advertisements for therapeutic goods directed at the general public) must not contain or imply endorsements by HCPs, former HCPs, those who represent themselves as being qualified or trained to diagnose and treat diseases and injuries, or those who are likely to be known as HCPs by a reasonable person (Part 6, section 24(6)(d)). However, endorsements by an organisation that represents the interests of HCPs are permitted, provided that the advertisement names the organisation and whether the organisation has or will receive valuable consideration for the endorsement (Part 6, section 24(6)(f)).

Insofar as advertisements directed solely to healthcare professionals are concerned, the MACC does not prohibit endorsements by HCPs for advertisements of medicines, provided that the general principles set out in question 3.2 and others in the MACC are complied with. The company must also obtain an HCP's documented approval wherever their name, image or a direct quotation from their presentation or unpublished communication is used in any promotional material.

The MTIC provides in section 8.3(b) that the name or photograph of an HCP must not be used without the written permission of the professional, and must not be contrary to the ethical guidelines of the professional association of the professional, or be likely to mislead, deceive or confuse.

HCPs are also subject to ethical requirements and Codes of Practice, which provide guidance on suitable involvement with industry. Companies should be aware of those obligations when approaching HCPs for endorsements.

3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?

There is no specific requirement that there be data from any, or a particular number of, 'head to head' clinical trials before comparative claims may be made.

Section 1.1 of the MACC provides general guidance on the use of comparisons in substantiating data in promotional material:

- Statistical comparative claims must include sufficient detail to enable the reader to understand the statistical significance of the data (the accepted level of statistical significance is $p < 0.05$).
- If the results are not statistically significant, a qualifying statement must be included stating, in full, that the results are 'not statistically significant'.
- If the results do not include a statement of the significance or lack of significance, a qualifying statement must be included stating that the p value is not available.

Comparative claims based on studies reporting clinically important differences must include sufficient detail to enable the reader to understand the clinical significance of the data. Further general principles applicable to comparative claims are set out in question 3.5 below.

3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?

There is no statutory prohibition on the use of comparative advertisements, or the mention of competitor products in such advertisements. However, there have been many instances where the courts have held that comparative advertising has been misleading or deceptive under the ACL. This means that special care must be taken in its use.

The MACC provides a number of general principles in relation to the use of comparative claims in advertising. As an overarching principle, promotional claims must be consistent with the PI, including claims about competitor products. Companies should consider the appropriateness of superlatives, ensuring that any use of superlatives is substantiated by the appropriate level of evidence. 'Hanging' comparative claims (that a product is better, stronger, or more widely prescribed) should not be used. Further requirements are set out in question 3.4 above.

There is no prohibition on making references to a competitor's unapproved product in comparator advertisements. However, in making such claims, it is important to bear in mind the general prohibition against advertising for unapproved indications in Australia, the general principles explained above, and the prohibitions against misleading or deceptive conduct.

3.6 What rules apply to environmental "green" claims made in relation to specific products in promotional material?

The TG Act and TG Regulations do not impose specific obligations relating to 'green' claims; rather, the general prohibitions against misleading or deceptive conduct, and false or misleading representations, under the ACL, the therapeutic

goods legislation and the relevant industry codes will apply. 'Green' claims are now becoming an area of increased focus for the consumer regulator, the ACCC, and we expect to see increased regulatory action in this area in the near future.

3.7 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?

Scientific exchange between appropriate company personnel and HCPs is generally encouraged, provided it complies with the MACC. For the provision of scientific information around unapproved products or indications, see question 2.1.

Images and quotations of HCPs taken from any congress presentations should only be provided with their documented approval. In addition, if a company initiates or sponsors educational meetings and symposia, reporting must comply with section 15.2 of the MACC.

3.8 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?

There are no statutory provisions that deal specifically with the use of 'teaser' advertisements. The MACC's general principles with respect to promotional claims directed at HCPs will apply. That is, promotional material must not advertise an unapproved therapeutic good or indication, all promotional claims must be referenced and cited references must provide the appropriate level of evidence. Companies must ensure all promotional claims comply with these general principles and the prohibitions against misleading or deceptive conduct.

There have been instances of teaser advertisements directed at the general public that have survived regulatory scrutiny; however, each advertisement must be considered on its face.

3.9 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?

To the best of our knowledge, this problem has not previously arisen in Australia. However, reading the MACC and the TG Act strictly, the promotion of Product B for the use in question would be a breach of both and a variation of the PI for Product B would be required before any advertising could be undertaken that referred to the use of Product B for the indication in question.

4 Gifts and Financial Incentives

4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?

Yes. If the product is a prescription-only medicine, then sections 6 and 7 of the MACC provide that distribution of samples ('starter packs' in the MACC) must only be provided at the request of an HCP (signed, including the name and address of the person supplied and the name, strength and quantity of the starter packs) and must be:

- only for the purpose of enhancing patient access or enabling prescribers to gain experience with the product to improve patient care;
- only supplied by representatives employed by the holder of a manufacturer's licence or wholesale dealer's licence or by authorised company representatives;
- compliant with the labelling requirements under Therapeutic Goods Order 91 (Standard for labels of prescription and related medicines); and
- carried out in a reasonable manner, including compliance with the conditions of registration of a product on the ARTG.

Companies should keep a record of the delivery (nature and quantity) of the starter packs for a minimum of two years.

Generally, any programme for the supply of samples must be reasonable and withstand public scrutiny with regard to the amount of stock, the duration of the programme and any other relevant aspects.

Companies should also consider whether there are any state/territory requirements that may apply to the storage or handling of starter packs.

4.2 Are there any restrictions on the value of payments or benefits that may be provided to healthcare professionals or healthcare organisations for consultancy services? Is it necessary to obtain advance approval from the authorities for the arrangements?

There is no specific maximum dollar value placed on remuneration payable to HCPs in exchange for consultancy services. However, the MACC requires that all transfers of value (including benefits) are 'reasonable, appropriate and balanced when considered in context'. Any transfer of value for services rendered should not exceed that which is commensurate to the services provided (see question 4.3 for requirements of reporting transfers of value). Financial or in-kind support must not be conditional on the use of a specific product (excluding clinical research). There is no requirement to obtain advance approval from authorities prior to engaging an HCP for consultancy services. The MACC does require that a legitimate need for the services be clearly identified prior to approaching any prospective consultants and records of the agenda, services provided and contractual arrangements be maintained by the company.

4.3 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.

The MACC prohibits payments (including donations) to an HCP as an incentive or in return for their attendance at an educational event or trade stand or that are conditional on the use of a specific product. However, sponsorship to enable attendance at an educational event may be provided. A payment to an individual HCP may create the impression that the purpose is not related to the quality use of medicines, education, research or improving patient outcomes. Any financial support should be paid to a medical practice or health-related organisation, rather than directly to an individual HCP (see question 4.4).

Reports on transfers of value to Australian HCPs engaged in patient care or as sponsorship of a third-party organisation to

conduct educational activities for Australian HCPs engaged in patient care activities must be reported by Medicines Australia members to Medicines Australia and those reports must be published in accordance with the Reporting Schedule in the MACC.

Section 26 of the TGAC also stipulates that advertisements for therapeutic goods must not offer any personal incentive or commission to a pharmacy assistant, or any retail salesperson who is not a health professional, in exchange for recommending or supplying the goods.

4.4 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.

Donations of money or financial support for services are permitted but must not be provided to underwrite a commercial business or to generate income for the practice or institution. Companies must develop clear guidelines around the provision of grants and financial support of this nature. Companies must not pay for an employee's salary in part or in full. Companies may also temporarily loan a piece of equipment to a practice or organisation, provided it facilitates the quality use of medicines and the company may retrieve it (section 5.2 of the MACC).

4.5 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?

Provision of medical or educational material to HCPs is governed by section 3 of the MACC. It specifically provides that companies may provide medical literature, reprints and proceedings of educational events, but no part of the material should be specifically highlighted to draw the attention of the HCP, so as to induce their provision of the provider's products or services. Company-branded educational material is permitted (provided it complies with the above).

4.6 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?

Other than the general provisions set out above, there are no specific provisions that prohibit the provision of volume-related discounts. However, it would be necessary to ensure that any volume-related discounting arrangement does not infringe Australian competition (anti-trust) law.

Section 6 of the MACC provides some guidance in relation to trade packs of registered medicines: programmes for the provision of medicines at a reduced cost must be only for the purpose of enhancing patient access or enabling prescribers to gain experience with the product to improve patient care. Generally, however, it is important to ensure that a volume-related discount does not infringe the general prohibition in offering pecuniary benefits as an inducement to prescribe.

Finally, if a prescription product is listed on the PBS, certain aspects of its pricing are regulated and, depending on the particular product, this might limit the way in which volume-related discounts can be applied. The PBS scheme requires sponsors of PBS-listed products that are on the PBS's F2 formulary (the formulary for products that have one or more generic competitors) to disclose to the Government the 'true' price at which they sell their products, by disclosing all 'benefits' that are provided to purchasers in community pharmacy or private hospital settings. Those true prices are then used to calculate a reduced subsidy that the Federal Government will provide for the medicine in question.

4.7 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable? If so, what rules apply?

Most offers to provide or pay for additional services or equipment contingent upon the purchase of medical products would amount to an inducement to prescribe the particular product. Such an arrangement would be prohibited by the MACC, which requires companies, as an overarching principle, to offer nothing with conditions that would have an inappropriate influence on the approval, recommendation, prescribing, and/or use of a product.

Whether an arrangement of the sort described could be created in compliance with the MACC would depend on a more detailed analysis of the facts, in particular the relative value of the administration and training and its degree of connection to the product in question.

Assuming that such safeguards can be put in place, there is an additional restriction. The *Health Insurance Act 1973* (Cth) prohibits any person from making a 'contract of insurance' in respect of medical services funded by Medicare, Australia's universal healthcare system. In certain circumstances, an offer to pay for the provision of medical or technical services may breach this prohibition.

A final difficulty that may arise is whether the 'package deal' arrangements amount to a misuse of market power in breach of competition law. This would, again, depend on an analysis of specific facts and, in particular, whether the company could be said to have power in the relevant market. As an illustration, in *ACCC v Baxter Healthcare Pty Ltd* [2008] FCAFC 141, the Full Court of the FCA found that Baxter, the sole supplier of sterile fluids, had misused its market power by bundling the supply of their products with peritoneal dialysis products used by people with renal failure, an arrangement that was effectively designed to prevent competitors from being competitive in the supply of peritoneal dialysis products in contravention of section 46 of the CCA.

4.8 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?

There is nothing that prevents a supplier or manufacturer offering a refund scheme if a product does not work. Indeed, if a

pharmaceutical product proves to be defective, then the supplier is probably obliged by law to refund the purchase price of the product. However, if the product is a prescription-only medicine, then it may not be possible to promote such a scheme effectively. The advertising of prescription-only medicines direct to consumers is prohibited, and advertisement is defined extremely broadly. A widely publicised refund scheme might well be seen as an inducement to consumers.

Furthermore, where a supplier of goods offers a warranty or guarantee of performance to users of a product, the ACL requires that certain standard wording be included as part of the warranty or guarantee. The effect of this language is that the warranty or guarantee is in addition to, and not instead of, the user's rights under the ACL.

4.9 Are more complex patient access schemes or managed access agreements, whereby pharmaceutical companies offer special financial terms for supply of medicinal products (e.g. rebates, dose or cost caps, risk share arrangements, outcomes-based schemes), permitted in your country? If so, what rules apply?

In Australia, cost-effective access to prescription pharmaceuticals is provided though the PBS. Rebates, cost caps and managed access agreements are methods that are used from time to time to reach an agreement for the listing of pharmaceuticals between the Commonwealth, which is the sole payer in this scheme, and the pharmaceutical company.

Companies are also permitted to provide additional benefits to a patient though a Patient Support Program (**PSP**), provided the programme complies with the requirements set out in section 14 of the MACC (see question 6.8 below).

4.10 Is it acceptable for one or more pharmaceutical companies to work together with the National Health System in your country, pooling skills, experience and/or resources for the joint development and implementation of specific projects? If so, what rules apply?

Most public health services in Australia are provided by state and territory governments. These sorts of arrangements with state and territory health authorities are permissible, subject to general law prohibitions; for example, those relating to bribery and competition law.

4.11 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?

Section 4.4 of the MACC permits companies to sponsor an HCP to attend an educational event, which extends to their own continuing medical education, provided the support is publicly disclosed. Companies must develop their own sponsorship guidelines.

4.12 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?

While there are laws in each state and territory of Australia that prohibit commercial bribery, there is no single anti-bribery/anti-corruption authority. Rather, any breaches of the laws are investigated by state and territory police forces and, where necessary, referred to public prosecutors for enforcement. In addition, some states and territories have commissions established specifically to investigate public corruption (for example, the Independent Commission Against Corruption in New South Wales and the Independent Commissioner Against Corruption in Northern Territory).

There are also federal laws that prohibit commercial bribery. Breaches of these laws are investigated by the Australian Federal Police and referred to federal prosecutors for enforcement if necessary. The National Anti-Corruption Commission has recently been established to investigate and report on allegations of serious or systemic corrupt conduct within the Commonwealth public sector.

Whether at the federal or state and territory level, there is no formal relationship between the enforcement of advertising rules and anti-bribery laws, and dual enforcement is theoretically possible. So far as we are aware, pharmaceutical companies have yet to be subject to investigation for breaches of anti-bribery laws in Australia.

5 Hospitality and Related Payments

5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?

The industry codes contain rules governing the offering of hospitality (defined as provision of food and beverages) to HCPs. The MACC permits provision of hospitality to HCPs, provided that the hospitality does not compromise the independence of HCPs and upholds the integrity and reputation of the industry. Section 4.5 of the MACC sets out principles relating to the offering of hospitality to HCPs. Hospitality is limited to the HCP and not to any guests or relatives. Companies may provide food and beverages if it is secondary to the purpose of the activity and must not provide entertainment. Hospitality for food and beverages only is not reportable. Food and beverage provided in another country must comply with the monetary limit set by the industry association in that country (and if none exists, Australian standards apply). The threshold on hospitality must be 'moderate and reasonable' as judged by local standards where the service is provided. In Australia, this is a maximum of AU$140 per person per meal (excluding GST and gratuities).

5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?

Section 4.5 of the MACC also sets out principles relating to the offering of travel and accommodation to HCPs in connection

with events. Companies may provide accommodation, provided it is reasonable and appropriate to the duration of the event and usual residence of the HCP. Companies may sponsor the HCP's travel only in direct association with education events or consulting services. Such travel may be sponsored internationally in economy or business class, and domestically, or to New Zealand in economy class only. Entertainment must not be provided. The provision of travel, accommodation and attendance is limited to the HCP and does not include any guests or relatives, as this would be considered an inducement.

If the scientific meeting constitutes an educational event under the MACC, sponsorship for the individual to attend may be provided as long as it is directly related to the individual's area of expertise. Companies are responsible for developing their own guidelines in relation to sponsorship for HCPs to attend scientific educational events, which must be publicly disclosed.

5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?

Where a company provides the contents of and hospitality arrangements for scientific meetings it sponsors or organises, it is responsible for ensuring that they comply with the MACC requirements (see questions 5.1 and 5.2 above). Companies must ensure facilities chosen for the events are chosen for their appropriateness for the activity and not for their leisure, sporting or recreational facilities. Companies are held accountable by way of the reporting mechanism in the MACC.

5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?

Yes. There is nothing that prohibits suppliers and manufacturers of medicinal products from retaining HCPs for the purpose of providing expert services. General principles governing the remuneration of HCPs in section 5.1 of the MACC apply. These include: companies ensuring that all transfers of value are reasonable, appropriate and balanced when considered in context; any remuneration should not exceed that which is commensurate with the services; and all transfers should be reported in accordance with the MACC.

5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?

While the MACC does not specifically regulate payments to HCPs for their participation in post-marketing surveillance studies, the general principles governing remuneration of HCPs in section 5.1 of the MACC apply (see question 5.4 above).

Medicines Australia, together with the TGA, has also produced guidelines for the conduct of company-sponsored post-marketing surveillance studies, guideline 6 of which provides that any payment offered to the medical professional must be commensurate with the work involved.

5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?

Yes, provided that the sole purpose of the market research is to collect data to enhance the quality use of medicines and is not a means to promote products or reward HCPs. Such payment must be reported if the identities of the participants are known.

6 Advertising to the General Public

6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?

Yes. All advertisements for medicinal products directed at the general public must comply with the TG Act, the TG Regulations and the TGAC, as well as the ACL, which regulates advertising generally.

6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?

No. The TG Act prohibits the advertising of prescription-only medicines to the general public.

6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?

The purpose of such campaigns should be educational and encourage patients to seek further information from the appropriate HCP, and their emphasis should be on the condition and its recognition, as opposed to the treatment options. The content of any disease awareness campaigns is set out in section 13.2 of the MACC, which specifies:

- information may include descriptions of the therapeutic category but not any reference to a specific product;
- information should be presented in a comprehensive, balanced and fair manner without emphasising any particular option or the need for treatment; and
- the tone must not unnecessarily cause alarm nor stimulate demand for a particular product.

Additionally, disease education activities must not include any reference to a specific prescription product, or this would breach the prohibition on direct-to-consumer advertising of prescription medicines.

6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?

The MACC only provides that companies may engage with HCP-only media for promotional purposes, including issuing media releases and developing advertorial content, and does not contain any provisions relating to media releases to lay media. Any press releases directed to non-scientific journals must not constitute an advertisement and/or promote an unapproved product or indication.

6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?

Background information relating to prescription-only medicines or research initiatives for prescription-only medicines are permitted under the TG Act, TG Regulations and the TGAC, provided that the information is not intended to promote the use or supply of those products. Information may also be included in disclosures to the Australian Securities Exchange, where required. Representations made in relation to products or research initiatives must also not be misleading or deceptive.

6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?

The MACC refers to patient organisations as 'Health consumer organisations'. The MACC permits communications with health consumer organisations and patient advocacy groups, provided that discourse is limited to information that may assist the stakeholder in their role, and the proposal of any funding or sponsorship is capable of withstanding professional and public scrutiny.

Any engagement with these groups must be reported pursuant to clause 15.3 of the MACC. In their reports, companies should include the name of the organisation, a description of the support sufficient to enable an average reader to understand the nature of the support, and the value of any financial support. Companies should also clearly describe any significant non-financial support provided. Medicines Australia publishes this information on its website; therefore, the company is responsible for informing the organisation that the support will be publicly disclosed.

6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?

Prescription pharmaceutical companies have limited scope to provide items for the benefit of patients within the framework for PSPs (see answer to question 6.8 below). Clause 13 of the MACC further provides that 'product-specific programs, product information and patient aids are to be provided only to patients already prescribed the product'. They must not be promotional and, if they are items likely to be used outside the home and therefore visible to the general public, may be branded with the company name and logo only.

6.8 What are the rules governing company funding of patient support programmes?

A member of Medicines Australia may conduct programmes that aim to increase patient compliance with, and positive patient health outcomes from, a prescribed medical treatment. Such programmes must satisfy the requirements for a PSP set out in section 14 of the MACC, which provides that:

- PSPs must be for a legitimate need. The clinical rationale for the PSP must be documented;
- communications with PSP patients should identify the company and materials or calls the patient receives;
- the company may include information about a PSP into a product package, which extends to an enrolment form for a PSP that need not be TGA-approved but must not be promotion, should otherwise comply with the MACC and TGA legislation, and should state: 'the Patient Support Program is not authorised or approved by the Australian regulator of medicines, the TGA';
- provided appropriate patient consents have been provided and the data de-identified, a company may use patient data to report on whether the PSP provides an improvement in compliance, for safety monitoring or to otherwise increase positive health outcomes;
- data from a PSP should never be used for promotional purposes; and
- adverse drug reactions must be reported to the TGA.

7 Transparency and Disclosure

7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?

The 2023 National Statement on Ethical Conduct in Human Research (**National Statement**) notes that research can generate findings or results of significance to participants and others, and that the approach taken to communicating findings and results should reflect principles of good science and adhere to ethical principles of justice, respect and beneficence. The National Statement acknowledges that communicating findings or results may be required or optional, appropriate or inappropriate, and/or intentional or unintentional depending on the nature of the research and other circumstances. It also acknowledges that some researchers may consider it a moral obligation for companies to disclose the outputs and outcomes of clinical trials publicly (Chapter 3.1, Element 5), and that it is consistent with the ethical principles of respect, beneficence and justice to make the outputs or outcomes of research publicly available (Chapter 3.1, Element 6). Common mechanisms to disseminate outputs or outcomes include publication in peer-reviewed journals or books, conference presentations, commissioned reviews for public bodies or other forms of media.

The National Statement has the force of law by reference to section 12AD of the TG Regulations (for medicines) and regulations 7.3(2)(a), 7.5(3) and 8.4 of the Therapeutic Goods (Medical Devices) Regulations 2002 (Cth) (for medical devices). The National Statement (Chapter 3.1, Element 6) considers that publication of outcomes should not be withheld on the basis that they are negative or inconclusive.

7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?

There is no legislative requirement, but there are code requirements (see question 7.3 below).

7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?

Yes. The MACC commits its members to transparency in their interactions with HCPs and other stakeholders, to maintain trust and confidence in the industry. Member companies must ensure that all transfers of value are reasonable, appropriate and balanced when considered in context, and must report all transfers of value in accordance with the MACC. Reports of certain transfers of value to HCPs related to prescription medicines must: be published in accordance with the Reporting Schedule (section 15.4) using reporting templates in the Resource Tool Kit; be available on the company's website; comply with Australian privacy legislation regarding the reporting of individual HCP data; and remain publicly available for three years from publication. Within seven days of publishing the report, a company representative will provide Medicines Australia with a declaration that the report includes all transfers of value required by the MACC to be reported.

Reportable transfers of value to HCPs include:

- fees paid to the HCP in return for speaking at an education event;
- consultancy or advisory services or any fees associated with those services;
- any remuneration or sponsorship described in the MACC (except for payments to consultants for research and development work); and
- fees paid to HCPs, where their identity is known to the company for market research.

The reports must include the date and a description of the event or provisions of service, the HCP's name, profession and practice address, whether the payment was to an HCP or a third party, and the total amount of the transfer subdivided into registration fees, service fees, and any travel and accommodation.

7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?

Companies that disclose any transfers of value without providing the proper disclosure to the HCP about the disclosure of their personal information may be in breach of Australian privacy legislation; however, failing to disclose any transfers of value would result in their breach of the MACC. To avoid this predicament, section 15.1 of the MACC provides that companies must not make a transfer of value unless they have taken appropriate steps to give notice of the MACC's disclosure obligation to HCPs, which practically should involve a dialogue through which the company can obtain their consent to disclosure.

8 Digital Advertising and Social Media

8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?

Internet advertisements are subject to the same regulatory regime as other advertisements for medicinal products (see question 1.1). As such, Internet advertising of prescription-only medicines direct to the public is prohibited.

Internet advertising direct to consumers is possible for non-prescription medicines (except for certain pharmacist-only goods), and for medical devices.

For prescription medicines, a company may use the Internet to provide members of the public with the following information:

- a brief non-promotional summary of the company's products available in Australia, in accordance with the current approved PI;
- in company 'disease state' websites there should not be a focus on the company's products, although the company may choose to list all available treatment options (without making comparisons). Such a website should always include a statement to the effect that 'for further information, speak to your doctor'; and
- a copy of each product's Consumer Medicine Information (**CMI**), a leaflet containing basic information about the use of a product, its contraindications and risks that the TG Regulations require companies to provide to consumers with each supply of a medicine.

Where a website includes information directed to HCPs, this information should not be accessible to the general public (see question 8.2).

8.2 What, if any, level of security is required to ensure that members of the general public do not have access to websites or digital platforms intended for healthcare professionals?

A mechanism such as password protection for system entry is consistent with ensuring online promotional content is only available to HCPs.

8.3 What rules apply to the content of independent websites or digital platforms that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent sites to a company's website or platform? Will the company be held responsible for the content of the independent site in either case?

It will depend upon the nature of the independent website or digital platform, the relationship between its publisher and the company, and the context in which the link is provided. As general guidance, the MACC provides that where company-sponsored websites link to other Internet sites, the company is accountable for ensuring that these information sources and Internet sites are appropriate and will enhance appropriate prescribing, disease state understanding, dispensing, and usage of products in Australia. Users should be advised when navigating to an independent website via a link from the company's website of the following:

> *'The information a reader is about to be referred to may not comply with the Australian regulatory requirements. Further information relevant to the Australian environment is available from the Company or via the Product Information.'*

8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?

Online content that may be accessed by the general public must not advertise or include promotional claims for prescription medicines. Given the broad definition of advertisement in

the relevant legislation and codes (see question 1.2 above), it is important to consider carefully whether a reference to a product on a website might amount to an advertisement. Companies may provide non-promotional sources of information on their website, such as the CMI, risk management materials and the PI, provided they are accurate, complete and are not displayed in a promotional manner.

8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?

The TG Act and the TGAC apply to digital communications, such as social media platforms, where they are used to promote therapeutic goods. The TGA has published a sample social media acceptable use policy as guidance for companies promoting goods via social media and recently published a specific social media advertising guide in relation to therapeutic goods (available at https://www.tga.gov.au/tga-social-media-advertising-guide). Social media posts, including a hashtag, that promote the use or supply of therapeutic goods are advertisements and must therefore comply with the TG Act and the TGAC.

Company owners are responsible for the content on any of the social media pages the company controls and this responsibility extends to user-generated content such as comments posted on platforms controlled by the company. 'Influencers' are also subject to the advertising requirements for therapeutic goods. Several of the industry codes also regulate the use of social media. The TGAC also prohibits advertisements about therapeutic goods from containing a testimonial if the testimonial is made by persons including those engaged in the production, marketing or supply of the goods (including any influencers who have received or will receive valuable consideration in exchange for their testimonial; section 24(4) of the TGAC).

For the purpose of the MACC, all promotional activities on social media (defined broadly) are considered in the same way as more traditional media activities. Generally:

- content viewable by the general public should not promote a prescription product;
- companies are responsible for the content on their platforms;
- content that does not conform to community standards of ethics or good taste, or that relates to an unapproved product or indication, should be promptly removed; and
- companies should create policies and procedures for social media usage to ensure compliance with the MACC.

Companies subject to the MTIC must have policies and procedures in place describing the roles and responsibilities of company representatives when interacting with HCPs via social media, and must comply with the requirements of the MTIC relating to more traditional advertising and other relevant laws.

Companies subject to the GBMA Code of Practice using social media channels have a responsibility to ensure content on the pages owned or operated by complying members is accurate.

8.6 Are there any restrictions on social media activity by company employees using their personal accounts, including interactions with third parties through "likes", "applauds", etc.?

There are no specific restrictions of this sort. However, if company employees engage in conduct that could constitute advertising, they will be subject to the TG Act, TG Regulations and TGAC in relation to that conduct.

Clause 2.5 of the MACC, which deals with social media, acknowledges that company employees may engage with social media campaigns and provides that:

- it is appropriate for companies to create content that enables their employees to appropriately engage in company social media campaigns; and
- companies should have policies and procedures that describe the roles and responsibility of its employees and contractors when interacting in the social media space to ensure compliance with the Code of Conduct.

8.7 Are there specific rules governing advertising and promotional activity conducted virtually, including online interactions with healthcare professionals, virtual meetings and participation in virtual congresses and symposia?

The MACC contains provisions that deal with content hosted online and the use of social media in promotional activities (and which are discussed elsewhere in this chapter). However, there are no specific provisions in the MACC or elsewhere dealing with virtual meetings.

In 2020, Medicines Australia published a two-page briefing document on the conduct of virtual meetings, which includes the following guidance:

- the MACC applies to meetings regardless of their method of delivery;
- it is appropriate when hosting an educational event online to provide hospitality in the form of a delivered meal to HCPs at their workplace and in the (virtual) presence of company staff. It is not appropriate to provide such hospitality at an HCP's own home, regardless of context; and
- companies may host educational conferences, symposia and so on fully online, but in doing so, should ensure that video conferencing tools can be locked to ensure that only verified HCPs are present. Further special caution needs to be given to ensure that products are not promoted in a location where they are not approved.

9 Developments in Pharmaceutical Advertising

9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

The TGA's import, advertising and supply compliance priorities for 2023 and 2024 are to:

- detect, deter and disrupt the unlawful import, advertising and supply of nicotine vaping products;
- deter and disrupt unlawful advertising of medicinal cannabis, psilocybin and MDMA;
- detect and disrupt unlawful advertising of unapproved and high-risk medicines and medical devices used in the wellness and beauty industries, including those intended to alter the body's performance and appearance;
- detect, deter and disrupt the unlawful import of substandard and falsified therapeutic goods with a particular focus on those products that declare, or otherwise are suspected to contain, higher risk substances that pose a risk to human health and/or safety; and
- detect, deter and resolve the unlawful import, advertising and supply of medicines and medical devices advertised as traditional or alternative treatments, particularly those that contain substances that pose a risk to human health and/or safety.

Health technology assessments underpin and inform decisions of the Australian Government to fund and subsidise health technologies, including innovative and generic medicines, vaccines, medical services and life-saving drugs for rare diseases, through subsidy schemes and funding programmes including:

- the Pharmaceutical Benefits Scheme;
- the Medicare Benefits Schedule;
- the National Immunisation Program; and
- the Life Saving Drugs Program.

The Health Technology Assessment Policy and Methods Review (**HTA Review**) is currently ongoing. The HTA Review was initiated as part of a commitment agreed between Medicines Australia and the Commonwealth in the 2022–27 Strategic Agreement. The HTA Review seeks to identify features of health technology assessment that:

- are working effectively;
- may act as current or future barriers to earliest possible access;
- may act as current or future barriers to equitable access;
- detract from person-centredness; and
- may be creating perverse incentives.

A first public consultation (Consultation 1) closed on 6 June 2023 and a report was published on 10 November 2023. A second round of consultations, supported by an Options Paper (Consultation 2), opened for submissions on 22 January 2024 with online and in-person workshops taking place throughout February 2024. The reference committee is considering all evidence and input it received in Consultation 2 and throughout the review as it develops its final report and recommendations to the Australian Government. The review was due to be completed by 15 April 2024. The conduct of the HTA Review has been the subject of widespread commentary in the industry press, and we anticipate that the publication of its outcomes and recommendations will be highly controversial.

9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

The TGA prohibited the importation of disposable vapes into Australia from 1 January 2024. This ban applies to disposable vapes irrespective of nicotine content or therapeutic claims. The prohibition extended to include importation of all non-therapeutic vapes from 1 March 2024. In parallel with this ban, a new Special Access Scheme pathway to prescribe vapes commenced on 1 January 2024, which facilitated improved access to therapeutic vapes, permitting medical practitioners and nurse practitioners to prescribe the use of vapes where clinically appropriate. From 1 March 2024, further changes commenced, including:

- the requirement for therapeutic vape importers and manufacturers to notify the TGA of their product's compliance with the relevant product standards; and
- the requirement for importers to obtain a licence and permit from the Australian Government's Office of Drug Control before the products are imported.

During 2024, product standards for therapeutic vapes will also be strengthened, including to limit flavours, reduce permissible nicotine concentrations and require pharmaceutical packaging. A transition period will be allowed for businesses to comply with the new requirements.

The Government will introduce legislation in 2024 to prevent domestic manufacture, advertisement, supply and commercial possession of non-therapeutic and disposable single-use vapes to ensure comprehensive controls on vapes across all levels of the supply chain.

As outlined above, the TGA is also significantly strengthening the regulation of medical devices, including:

- detecting and disrupting unlawful advertising of unapproved and high-risk medicines and medical devices used in the wellness and beauty industries, including those intended to alter the body's performance and appearance;
- improving the regime for new medical devices to the Australian market and making changes to mutual recognition arrangements and acceptance of comparator regulatory approvals;
- strengthening the monitoring and follow-up for medical devices already in use;
- providing more information to patients about their devices; and
- introducing requirements for hospitals to report medical device adverse events (which will commence in March 2025).

9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

Consistent with its published priorities, we anticipate that the TGA will continue to be highly active in identifying, investigating and prosecuting non-compliance with therapeutic goods advertising laws, especially in respect of unapproved therapeutic goods.

In recent years since the TGA took control of advertising, we have seen higher levels of enforcement action, some substantial fines and penalties, but also increased sophistication in regulatory approach – for example, the extensive use of warning letters without follow-up regulatory action to educate advertisers about their obligations under the TG Act.

We also observe a secondary trend in the activities of the MACC Committee. During the course of 2023, complaint levels increased substantially in comparison to previous years (see question 1.7 above). In a heightened competitive market, companies need to be cautious to ensure not only that they have data to support the claims they wish to make for their products, but that the data are of sufficient quality and are consistent with the PI broader evidence available. If this is not the case, the Committee is increasingly willing to make findings of breach.

Greg Williams is a Partner in the Clayton Utz product liability group and the practice group leader for the firm's Commercial Litigation group. Greg advises and conducts litigation for clients operating in the pharmaceutical and medical devices industries. Greg's experience ranges from acting in large-scale product liability class actions and commercial litigation, to advising on regulatory issues, advertising and labelling requirements, and product safety issues.

Greg has acted for and advised clients in relation to class actions or grouped proceedings and other complex litigation in the High Court of Australia, the Federal Court of Australia and the Supreme Courts of New South Wales and Victoria.

In the regulatory sphere, Greg advises numerous Australian and overseas pharmaceutical and medical device clients on all aspects of the product life cycle, including regulatory and contractual arrangements for clinical trials, privacy, product registration and reimbursement, advertising disputes, and product safety and recalls. Greg has a Master's Degree in Biochemistry.

Clayton Utz
Level 15, 1 Bligh Street
Sydney NSW 2000
Australia

Tel: +61 2 9353 4798
Email: gwilliams@claytonutz.com
LinkedIn: www.linkedin.com/in/gregwilliamsculaw

Sheena McKie is a Special Counsel in the Clayton Utz product liability group and has been part of some of Australia's most high-profile, large-scale class actions, commercial and product liability litigation. This currently includes three medical device class actions and a large remediation program. Sheena regularly provides advice to Australian and overseas clients about the complex regulatory and legislative regimes applying to pharmaceutical (consumer and animal health) and medical technology products supplied or marketed in Australia. This includes PBS pricing, product classification, marketing and promotion, and clinical trial agreements. Sheena also advises clients in a range of industries (life sciences as well as food, cosmetics, and other consumer products) about product liability, product safety and recall issues and the ACL.

Clayton Utz
Level 15, 1 Bligh Street
Sydney NSW 2000
Australia

Tel: +61 2 9353 5732
Email: smckie@claytonutz.com
LinkedIn: www.linkedin.com/in/sheena-mckie-72881545

International Comparative Legal Guides

The **International Comparative Legal Guide** (ICLG) series brings key cross-border insights to legal practitioners worldwide, covering 58 practice areas.

Pharmaceutical Advertising 2024 features two expert analysis chapters and 23 Q&A jurisdiction chapters covering key issues, including:

- Providing Information Prior to Authorisation of Medicinal Product
- Advertisements to Healthcare Professionals
- Gifts and Financial Incentives
- Hospitality and Related Payments
- Advertising to the General Public
- Transparency and Disclosure
- Digital Advertising and Social Media
- Developments in Pharmaceutical Advertising

The International Comparative Legal Guides are published by: glg Global Legal Group