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The International Comparative Legal Guide to:

Pharmaceutical Advertising 2018

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A practical cross-border insight into pharmaceutical advertising

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Country Question and Answer Chapters:

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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) ("the TG Act") and its subordinate legislation (principally, the Therapeutic Goods Regulations 1990 (Cth) ("the TG Regulations")). The TG Act is administered by the Therapeutic Goods Administration ("the 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 which regulate advertising generally, most notably, the Competition and Consumer Act 2010 (Cth) ("the 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 ("the ACCC").

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

- the Therapeutic Goods Advertising Code 2015 ("the TGAC"), promulgated by the Therapeutic Goods Advertising Code Council, which applies to all advertisements for therapeutic goods other than those directed at healthcare professionals or wholesalers of therapeutic goods. The TGAC is delegated legislation, made under the TG Act;
- the Medicines Australia Code of Conduct ("MACC") and supporting Guidelines, which relate to the promotion of prescription-only medicines. Edition 18 of this Code commenced on 16 May 2015 together with an updated version of the Guidelines. 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 Australian Self-Medication Industry ("ASMI") Code of Practice, which relates to the advertising of non-prescription consumer healthcare products. The ASMI Code of Practice was last revised in November 2016;
- the Medical Technology Industry Code of Practice ("MTIC") (administered by the Medical Technology Association of Australia ("MTAA")), ninth edition, effective from 1 January 2015, which relates to the behaviour of medical device and technology companies;
- IVD Australia's Code of Conduct applies to the behaviour of companies who market *in vitro* diagnostic products in Australia. The second edition of the IVD Australia Code of Conduct was published in October 2013. Edition 2.1, which contains cosmetic changes only, was released in September 2015; and
- the Complementary Medicines Australia ("CMA") Marketing & Supply Code of Practice for the Marketing of Complementary Medicines and Healthfood Products. The most recent version of this Code was published in November 2015.

1.2 How is "advertising" defined?

The TG Act defines "advertisement" to mean:

> "*...any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods*."

Under this definition, an advertisement is something that is published or broadcast that 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. The Complaints Resolution Panel established by the TG Regulations tends to apply the definition very broadly.

The question of whether a particular statement constitutes an advertisement is also commonly tested under the industry codes. For example, the MACC defines "promotion" in similar terms to "advertisement" 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 healthcare professionals, are regulated by the MACC. Sales representatives and those directly involved in the development, review and approval of promotional materials relating to prescription medicines are required to complete a training course in relation to the MACC and trade practices and privacy laws, to the extent that it is relevant to their role within a specified time of commencing employment, and on an ongoing basis, as needed.

There are otherwise no formal requirements for the types of internal approval process which companies must have in place (although there are certain types of advertisements which must be approved by appropriate regulatory authorities (see the answer to question 1.5)). 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 or code 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, most particularly the MACC (which applies to prescription medicines), has specific requirements for policies or guidelines for some promotional activities. For example, clause 9.7.2 of the MACC requires companies to develop clear guidelines for the provision of sponsorships to healthcare professionals, which must be publicly disclosed if required (see question 5.2 below).

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?

There are certain types of advertisement which must be approved before they can be used. Generally, an advertisement must be approved if:

- it relates to a non-prescription medicinal product;
- its intended audience is broader than healthcare professionals (including alternative health practitioners) or wholesalers of therapeutic goods;
- it contains more information than the name of the goods, the price of the goods, a picture of the goods and the name of a supplier; and
- it is intended for publication in newspapers or magazines, in the form of posters/billboards in public places, or broadcast on radio, television or film.

The power to approve advertisements is delegated to one of the industry peak bodies. Depending upon the nature of the medicinal product, or the type of advertisement, applications for approval are made to ASMI or CMA.

The approvers are allowed 60 days to approve advertisements, but usually try to complete their review within 10 days.

There is a fee for approval.

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 answer to this question depends on the nature of the advertisement.

In the case of advertisements which require approval, the TGA has the power to withdraw the approval of any advertisement, in effect stopping its further publication. In the case of advertisements to the general public which do not require approval, the TGA has 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 which is false or misleading.

In the case of advertisements which are the subject of a complaint to the Complaints Resolution Panel (discussed in question 1.7 below), the TGA has the power to order the withdrawal of an advertisement, and to order the publication of a correction or retraction. However, the TGA can only exercise these powers on a recommendation by the Complaints Resolution Panel.

The TGA does not have any specific powers in relation to advertisements for prescription products (which can only be directed at healthcare professionals). However, Medicines Australia, which hears complaints about such advertisements, is entitled by the MACC to order their withdrawal, and to order corrective advertising.

There is a right to an internal merits review of any decision of the TGA made pursuant to the powers listed 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 which conducts merits reviews of administrative decisions).

In addition to the powers which are directed specifically at therapeutic goods, the ACL empowers the ACCC to seek court orders for the withdrawal of advertisements, and for retractions or corrective advertising. It is possible that the ACCC would exercise its powers in relation to a therapeutic good in an appropriate case. Similar actions may also be brought by private citizens and competitors.

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

First, the TG Act and TG Regulations create a number of offences that can be breached in the rules 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$10,500,000 for corporations and AU$1,050,000 for individuals.

The TGA is responsible for enforcing these provisions.

(b) The Complaints Resolution Panel

The Complaints Resolution Panel ("CRP") is established by the TG Regulations. It can consider whether advertisements in newspapers or magazines, on public display (such as billboards), or on radio, television or film, breach the provisions of the TG Act, or the TG Regulations (including the criminal offence provisions), or the TGAC.

The CRP's procedure is complaints-driven. It will only examine an advertisement if a complaint is made to it. Any person has standing to make a complaint to the CRP.

The CRP has no power to impose sanctions. However, it can refer a matter to the TGA and recommend further action.

(c) Industry Bodies

Each of the codes mentioned above include a complaints resolution body.

The most commonly used is the Medicines Australia Code of Conduct Committee, which hears complaints relating to prescription-only medicines. The Committee can impose sanctions on Medicines Australia members, including fines of up to AU$300,000, corrective advertising and the suspension or expulsion of members.

(d) General Law

The ACL contains a number of provisions which 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.

(e) Practical Considerations

Generally speaking, it is the less formal measures which ensure compliance with the rules in relation to the advertising of medicinal products.

Prosecutions for breaches of the TG Act are extremely rare.

Complaints about advertising through the CRP, or through one of the industry bodies (most often Medicines Australia), are common and are often initiated by competitors or as a result of findings by the Monitoring Committee, which proactively assesses advertisements for compliance with the MACC. Although the sanctions available to these bodies are not, strictly speaking, enforceable, the risk of TGA scrutiny is usually enough to ensure that advertisers comply with their rulings.

Medicines Australia publishes regular quarterly reports of complaints considered by its Code of Conduct Committee. During the 12 months from 1 July 2015 to 30 June 2016 there were nine new complaints received by the Code of Conduct Committee. These include complaints initiated by competitors, by healthcare professionals and matters referred to the Code of Conduct Committee by Medicines Australia's own Monitoring Committee. There were no complaints initiated by members of the general public, although such complaints are permitted under the MACC.

Competitor-initiated court action in respect of advertisements is rare, although it does occur. A recent 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 has recently been subject to an AU$6 million 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 25 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 Code Committee in accordance with Section 20 of the MACC and to abide by the Code 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 directly handled by the CRP.

Generally speaking, the TGA allows complaints to be addressed through whichever one of these is the most appropriate mechanism. While the TGA can investigate breaches and impose criminal sanctions for some advertising breaches, such steps are, in our experience, rare.

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.

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 its breach.

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

The MACC provides that its complaints resolution procedure should not be used by pharmaceutical companies simply as a competitive tool (see Appendix 1 to the MACC). Nevertheless, competitors often bring complaints under the MACC on the basis of public interest in healthcare professionals 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 authorised (or, to use the Australian terminology, registered, listed or included on the Australian Register of Therapeutic Goods ("the ARTG")), there is a blanket prohibition 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 the discussion of the definition of "advertisement" under question 1.2 above).

Both the TG Act and the MACC treat each indication of a product as a separate product, so the prohibition on advertising unregistered products also applies to promoting registered products for uses outside of their approved indications.

The MACC contains provisions which set out what manufacturers and suppliers are allowed to say about unregistered prescription products (section 1.4 of the MACC). Company personnel from

the medical department, including field-based medical personnel, may provide information to healthcare professionals on unapproved products or subjects not covered by the Product Information (e.g. unapproved indication) upon receipt of an unsolicited request. Such information must be compiled and provided by medical department personnel and not sales team members.

The MACC allows companies to provide published literature, sponsor scientific meetings and supply or display educational material at meetings.

It also permits companies to provide information at international or Australasian congresses if a product or indication is approved or registered in a country from which a significant number of attendees originate, even if the indication is not approved in Australia. In this instance, educational and promotional material, along with Product Information, may be made available, provided it complies with section 9.6 (Trade Displays) of the MACC and is clearly identified as not being approved for that indication in Australia. Starter packs of products or information about an unapproved indication may be displayed, but not distributed.

Finally, it permits companies to make information about non-approved indications for a product available on Medical Information websites or applications, subject to certain limitations (including the fact that the website is password protected so as to only allow access by healthcare professionals).

In general, there are no specific prohibitions on persons other than manufacturers or suppliers making statements about unregistered products or indications, provided that those statements do not amount to "advertisements" – that is to say statements intended to promote the use or supply of the goods – and make it clear that the statement relates to unregistered products or indications.

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 above, this raises the question of whether there is an intention to promote the use or supply of the product. Educational information including medical literature may be permitted to be provided on request.

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. main stream public media) please specify.

There are no provisions in the TG Act which deal specifically with press releases.

However, the MACC does deal with press releases about prescription-only medicines. It says (section 13.4.1):

> "*Media releases must be educational and not include promotional statements or claims, or comparisons with other products. A product specific media release must be in language that reflects current community standards*."

Companies should not issue product-specific media releases to announce a new product, or major indication to the general public, until the product has been registered in Australia and reasonable steps have been taken to inform the medical and pharmacy professions of its availability.

These provisions do not prohibit a company listed on the Australian Securities Exchange from issuing a non-promotional product-specific media release in line with its continuous disclosure requirements.

No other product-specific media releases are permitted by the MACC. In addition, a company may respond to media enquiries, comment to the journalist or editor on published articles containing incorrect information and respond to inquiries from members of the general public in an educative and non-promotional manner.

Product-specific media releases about unapproved products or indications directed at health professionals are otherwise subject to section 1.4 of the MACC which prohibits the consolidated provision of information about unapproved products and indications to healthcare professionals.

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

Yes, but only in response to a specific request from the healthcare professional. Generally, it is acceptable to send healthcare professionals published, peer-reviewed articles or proceedings of scientific symposia, but not company-authored material which falls outside of this description. Information provided must be balanced and not promotional and should be distributed by a company's medical department.

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 answered a question which is related to the interaction between German national law and the EC Directive 2001/83. It is not part of Australian law.

Questions 2.1 to 2.4 describe the circumstances in which details about unapproved medicinal products may be made available to healthcare professionals or the general public.

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 dealing with the provision of information about unregistered products or indications in this context.

However, such information may constitute an advertisement, as that term is defined in the TG Act and, as a result, would (technically at least) breach the TG Act. That being said, providing it was clear that there was no intention to sell the product in question until it was approved, such conduct would be unlikely to attract censure or sanction.

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 provides (in sections 12.1 and 13.11) that the sole purpose of market research activities must be to collect data, and not as a means to promote to or reward healthcare professionals or the general public. Section 12.1 specifically provides that market research may be undertaken in respect of an unapproved indication, but must not be used as a means to promote an unapproved product or indication. There must be a genuine initiative to collect relevant and useful information to enhance the quality use of medicines. Market research studies must be clearly identified as such, when an initial approach is made to healthcare professionals.

The Australian Market and Social Research Society's Code of Professional Behaviour provides guidance to researchers in the practice of market research.

3 Advertisements to Healthcare Professionals

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

It depends upon the type of advertisement, the type of product and the length of time the product has been on the market. By way of example, for advertisements for prescription-only medicines published in periodicals, the MACC provides that the advertisement ("primary advertisement") for a product (or indication) which has been on the market for less than two years must contain:

- the product's brand name;
- the Australian-approved names of its active ingredients;
- the name of the supplier and its location;
- a form of product information (a statement in a specified form setting out information such as the approved indications, contraindications, clinically significant warnings, precautions for use and adverse events and interactions);
- all PBS listings, including any restrictions (the PBS, or Pharmaceutical Benefits Scheme, is the government scheme whereby the supply of many prescription-only medicines is subsidised by the Federal government); and
- a clear and unambiguous statement that prescribers should review the full product information before prescribing.

3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?

The precise requirements will vary from product to product. However, in the case of prescription medicines, the MACC contains detailed provisions explaining what information must be contained in an advertisement. Those requirements include a range of specific positive obligations, as well as some general prohibitions (for example, they must be "current, accurate, balanced and must not mislead either directly, by implication, or by omission", MACC, section 1.3).

In Australia, the document equivalent to the SmPC is the Product Information ("PI"). There is no prohibition on advertisements including references to studies which are not in the PI, although if such studies relate to indications which are not approved in Australia, that will give rise to a separate difficulty. However, the MACC requires that some kinds of advertisement (called Primary Advertisements) contain either the PI or an abridged version of the PI. It also requires that all written advertisements for a product be Primary Advertisements for 24 months after the first advertising of a new product or indication or 12 months after a change of clinical significance to the PI.

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

The MACC requires companies to obtain a healthcare professional's documented consent to include their name or photograph in any kind of promotional material. Whenever a healthcare professional's name is specified in any kind of promotional material, other than in citations of published references, the company should ensure the healthcare professional is aware of and provides documented approval for the use of his or her name in the context of the entire promotional material.

The MTIC also provides that the name or photograph of a healthcare professional 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.

Advertisements subject to the TGAC (that is, advertisements directed at the general public) must not contain or imply endorsement by individuals who are healthcare professionals by way of their representation in advertisements or academic qualifications, or who are likely to be known as healthcare professionals by the reasonable person.

Many healthcare professionals 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.

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 are made.

The MACC provides that any comparison must reflect the body of evidence and does not mislead by distortion, by undue influence or in some other way. Comparisons must be factual, fair, capable of substantiation, and referenced to its source, and must not be disparaging.

According to the provisions of the MACC, the accepted level of statistical significance is $p < 0.05$. If comparative data that are not statistically significant are used:

- the lack of significance must be stated explicitly; and
- the data must not be used to generalise or to indicate superiority or inferiority.

If there is no statement of the significance or lack of significance of particular comparative data, the lack of a p value must be explicitly stated.

An advertisement using such comparative data must also distinguish between mathematically determined statistical significance as compared with clinical significance.

The Guidelines to the MACC ("the Guidelines") state clearly that, "unequivocal supporting evidence", is required for comparative claims.

Therefore, considerable care must be taken in making comparative claims based on data from different studies. There have been several instances where such claims have been challenged on the basis that the studies are too different to permit an accurate comparison of the relevant data.

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. This means that special care must be taken in its use.

The MACC has a provision which deals specifically with comparative advertising (section 1.8). It provides:

> "*The intention of this provision is to prohibit unfair and unjustified comparisons with the products or activities of a competitor.*
>
> *Care must be taken to ensure that any comparison properly reflects the body of evidence and does not mislead by distortion, by undue emphasis or in any other way. Comparisons of products must be factual, fair, capable of substantiation, referenced to its source; and must not be disparaging. 'Hanging' comparatives – those that merely claim that a product is better, stronger or more widely prescribed, etc., must not be used.*
>
> *Claims of comparative efficacy or safety must not be based solely on a comparison of Product Information documents that does not reflect the general literature, as those documents are based on different databases and are not directly comparable. This applies to Australian as well as overseas Product Information documents. These claims must be substantiated with respect to all aspects of efficacy or safety. Where a comparative claim relates to a specific parameter, any claims must be clearly identified as pertaining to that parameter…*"

Section 1.8 also governs the use of comparative studies; see question 3.4 above.

There is no prohibition on making references to a competitor's product which has not yet been authorised in Australia 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, and the prohibitions against misleading or deceptive conduct.

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

Companies may supply to healthcare professionals, on request, literature about subjects not included in the Product Information for a particular prescription product, including unapproved indications (section 4.2.4 of the MACC).

The MACC provides that the general interpretation and conclusions of any reprints of journal articles, proceedings of educational events or summaries of literature used in promotion must be consistent with the product information for both the sponsor's products, and any competitor's products with which a comparison is being made.

Quotations relating to prescription products, taken from public broadcasts or private occasions, including medical conferences or symposia, should not be published without the speaker's consent. In addition, if a company sponsors the reporting of a congress or symposium, this activity must comply with the MACC.

3.7 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 which deal specifically with the use of "teaser" advertisements.

The MACC contains provisions which regulate, with great particularity, the form of advertisements for prescription-only medicines to healthcare professionals. For example, most advertisements must contain some form of product information. Subject to content and context, it is possible that a teaser advertisement would not comply with these requirements, and would therefore breach the MACC.

Nevertheless, there have been instances of teaser (or "disease state") advertisements directed at the general public which have survived regulatory scrutiny. These are now specifically regulated by section 13.8 of the MACC.

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 the MACC provides that distribution of samples (called "starter packs" in the MACC) must be carried out in a reasonable manner including compliance with the conditions of registration of a product on the ARTG.

The MACC provides that starter packs should only be supplied for one of four purposes:

- for immediate use in the surgery for relief of symptoms;
- for the use of alternative treatments, prior to a prescription being written;
- for after-hours use; or
- for gaining familiarisation with the product.

The MACC also contains specific rules regarding the size and quantity of samples which can be supplied, and the requirements to keep adequate records.

4.2 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 the giving or offering of gifts, benefits in kind and pecuniary advantages to healthcare professionals or administrative staff as an inducement to recommend, prescribe, dispense or administer a company's product(s). It also prohibits the provision of gifts or offers to healthcare professionals, subject only to certain specific exceptions, namely:

- company-branded pens and notepads provided at company-run or sponsored education events;
- medical educational material, including literature reprints;
- sponsorship to attend educational events. There are limitations on the extent of such sponsorship, which are discussed further in section 5 below; and
- hospitality at an educational event, which must be secondary to educational content. Again, the specific limits on hospitality are discussed in section 5 below.

Under the MTIC, a medical device company must ensure that sales of medical technology are made solely on the basis of efficacy, safety, quality, price and service and never on the basis of a healthcare professional receiving payments, gifts or hospitality.

Thus, a medical device company may provide a healthcare professional with an item that benefits patients or serves a genuine educational function provided that the item has a fair market value of less than AU$100, except in the case of medical textbooks or anatomical models. The MTIC does recognise that there is, within the medical technology industry, a legitimate practice of providing to healthcare professionals appropriate sample medical technologies for genuine training, education or medical technology evaluation purposes. However, no non-educational branded promotional item may be given to a healthcare professional, even if the item is of minimal value and is related to the healthcare professional's work or for the benefit of patients.

Under the MTIC, a medical device company may provide hospitality to healthcare professionals. The specific limits in relation to hospitality are discussed in section 5 below.

4.3 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.

There are no rules which prevent manufacturers or suppliers from giving gifts or donations to healthcare institutions or to donate equipment or fund the cost of certain types of services. Both the industry codes and also anti-bribery legislation in Australia provide important prohibitions against the giving of personal gifts.

The MACC contains general provisions which impose obligations on promoters of prescription-only medicines in their dealings with potential customers. For example, the sponsorship of any healthcare professional activity must be able to successfully withstand professional and public scrutiny, conform to professional and community standards of good taste and enhance the quality use of medicines.

The MACC also prohibits any sponsorship from being conditional upon an obligation to prescribe a particular product or to have any conditions which might interfere with a healthcare professional's prescribing or dispensing practices. It requires companies to develop clear guidelines for awarding sponsorship.

There are similar, although less detailed, provisions in the MTIC.

If a gift or donation is too closely aligned to a promotion or advertisement, it might breach some other rule or provision of the codes.

4.4 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?

Involvement in educational goods and services is prescribed in sections 4 and 9 of the MACC. Most importantly, section 4.1 of the MACC specifies that all items of an educational nature, whether for the education of healthcare professionals or to be used by a healthcare professional in consultation with a patient, must be dedicated to improving the quality use of medicines or assisting a patient in their understanding of a condition or disease. Materials supplied for medical education must include the name of the supplier and city, town or locality of the registered office. Materials supplied for medical education may include promotional claims or statements, but must comply with sections 1, 2 and 3 of the MACC. Such accompanying material should be clearly identified as promotional material.

4.5 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 which 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.

In addition, while the MACC does not have anything to say about volume-related discounts expressly, 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 (see question 4.2 above). Generally speaking, an arrangement for a volume-related discount which is made with the purchasing department of a healthcare institution will not raise issues, but an arrangement which delivers benefits directly to clinicians may.

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 which are on the PBS's F2 formulary (the formulary for products which have one or more generic competitors) to disclose to the government the "true" price at which they sell their products, by disclosing all "benefits" which are provided to purchasers in community pharmacy or private hospital settings. Those true prices are then used to calculate a reduced subsidy which the federal government will provide for the medicine in question.

4.6 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?

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. If so, then such an arrangement would be prohibited by relevant industry codes, including the MACC (see the discussion at question 4.3 above).

However, there are some circumstances where companies are able to offer to pay the cost of certain services associated with the use of their product, provided that there are sufficient safeguards which prevent that payment from influencing the ultimate decision about prescription. These are limited and apply only in specific circumstances. Whether an arrangement of the sort described could be safely created 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 which may arise is whether the arrangements amounted 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.

4.7 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 which 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 users rights under the ACL.

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

Yes, they can.

The MACC provides that pharmaceutical companies may sponsor "educational events" organised by a society, college, university or other healthcare professional organisation and the attendance of healthcare professionals at these events if:

- the primary objective of the meeting is to enhance medical knowledge and the quality use of medicines in Australia; and
- they conform with the rules relating to the sponsorship of healthcare professional activities (see question 4.3).

The company must ensure an appropriate balance between the duration of educational content and any hospitality provided to delegates.

4.9 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 which prohibit commercial bribery, there is no single anti-bribery/anti-corruption authority. Rather, such laws are investigated by state police forces (and in the case of Federal offences, the Australian Federal Police) and where necessary, referred to public prosecutors for enforcement.

In addition, some Australian states have commissions established specifically to investigate public corruption (for example, the Independent Commission Against Corruption in New South Wales). As such, 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 to healthcare professionals.

The most comprehensive rules are those in the MACC relating to the offering of hospitality by persons supplying prescription-only medicines, discussed below.

Under the MACC, if an Australian healthcare professional's attendance at an overseas event is sponsored by an Australian company, or if the hospitality is provided overseas in the context of the healthcare professional providing a service to an Australian company, then the MACC requirements will apply. Accordingly, any arrangements should be subject to approval by the Australian affiliate.

The MTAA Code of Practice does not expressly address the question of hospitality provided overseas, but we think the same approach should comply.

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?

The MACC permits prescription pharmaceutical companies to sponsor healthcare professionals to attend Australasian and international educational and scientific meetings, provided the meeting is directly related to the healthcare professional's area of expertise. Companies are required to have clear guidelines about the way in which they award such sponsorship and to ensure that there is a formal agreement or an exchange letter in place which records the terms of the sponsorship.

The MACC permits a company to pay for travel to and from a meeting, provided that for an Australasian event, travel must be by economy class only, but for international events, travel may be by economy or business class. The MACC also permits a company to pay for a healthcare professional's "reasonable" accommodation expenses, including an allowance for meals and beverages (provided that such allowance is not "excessive").

The MACC prohibits companies from paying for, or subsidising, the travel costs of a healthcare professional's guest, family or companion. It also prohibits delegates being paid for their time to attend a company educational event or international educational events.

The MACC also prohibits companies from providing "entertainment" for healthcare professionals.

Where a company provides hospitality in connection with a medical educational event it runs or sponsors a healthcare professional to attend, the MACC provides that within Australia the maximum cost of "a meal" including all food and beverages, but not including taxes and gratuities, must not exceed AU$120. The MACC also says that the maximum amount would only be appropriate in exceptional circumstances. Overseas the Australian maximum, or local guidelines, are to be used as a guide.

The MTIC permits medical device companies to sponsor the attendance of healthcare professionals at conferences primarily dedicated to promoting objective medical, scientific and educational activities and discourse, but requires that the conference organiser choose the recipient of the sponsorship and make all of the travel and accommodation arrangements. The payment in respect of the sponsorship must be made to the conference organiser.

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?

Relationships with healthcare professionals, including involvement in educational meetings, are regulated by section 9 of the MACC. Section 9.5.5 specifies that any hospitality provided at a sponsored educational event must be secondary to the educational purpose. Sections 9.4.5 and 9.7.6 specify that for educational meetings directly organised by companies, and that are the responsibility of companies, all accommodation must be of a reasonable level and be appropriate for the time and duration of the meeting and origin of the delegates. Meals provided at an educational meeting should be secondary to the educational content of the meeting and must not be excessive (stated in sections 9.4.3 and 9.7.7). No entertainment should be provided (sections 9.4.6 and 9.7.10).

Furthermore, as specified in sections 9.4.2 and 9.5.4, the venue and location must be conducive to education and learning and must not be chosen for its leisure, sporting or recreational facilities. A company must not subsidise or pay for the costs of family or companions of attendees at educational meetings.

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 which prohibits suppliers and manufacturers of medicinal products from retaining healthcare professionals for the purposes of providing expert services. It is common practice for Australian companies to retain panels of independent experts with whom they consult in relation to their products.

Section 9.9 of the MACC deals specifically with advisory boards and requires the need for the advisory board to be documented and genuine. It also requires that board meetings be held in Australia (except where being held in conjunction with an international symposium or an international advisory board meeting) and that records of service and minutes of meetings be kept by the company.

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

Yes, the MACC permits healthcare professionals to be paid for taking part in post-marketing surveillance studies, provided that the payment is commensurate with the work involved and is not based on the number of prescriptions written. The rules governing post-marketing surveillance studies are contained in section 10 of the MACC.

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

Yes, it is possible to pay healthcare professionals to take part in market research provided that the sole purpose of the market research is to collect data and not a means to promote or reward healthcare professionals.

The MACC provides that any payment to healthcare professionals "must be kept to a minimum and should not exceed a level commensurate with the time involved" (section 12.3). If a voucher is given instead of cash payment, it must be valid only to obtain an item directly relevant to the practice of medicine or pharmacy. A voucher for entertainment is not acceptable. A donation to a registered charity *in lieu* of cash payment may be acceptable if the value is commensurate with the work undertaken.

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 it is possible.

Advertisements for medicinal products which are to be published in newspapers or magazines, or in the form of posters or billboards, or broadcast on radio, television, or film, must be approved before they are used. See question 1.5 above.

All advertisements for medicinal products directed at the general public must comply with the provisions of the TG Act and the TG Regulations and also with the TGAC, as well as with the provisions in the ACL which relate to advertising generally.

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

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 construction and content of disease education campaigns are governed by section 13.8 of the MACC. The emphasis of these campaigns should be on the condition and its recognition as opposed to the treatment options. This does not prevent campaigns referring to the availability of different treatment options, so long as it is done without encouraging an individual to seek a prescription for a prescription-only product.

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

Section 13.8.7 requires the name of a pharmaceutical company to be identified in any disease education campaign, but that it should not be given prominence.

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 provides some guidelines for press releases to the lay media in relation to prescription-only medicines. A product-specific media release must be educational and may include a non-comparative description of the mechanism of action, price to the patient or date of product/indication availability. However, it must not include promotional statements or claims, comparisons with other products, quotes from experts, opinion leaders or patients that are promotional or comparative in nature or images of product packaging.

A product specific media release must contain all of the following in the main body of the release:

- the product's brand name;
- the Australian Approved Name of the active ingredients in the product;
- its approved indications;
- therapeutic class;
- PBS listings and restrictions, or a notation if the products are not listed on the PBS; and
- a summary of the side effect profile, product's precautions, adverse effects, warnings, contraindications and interactions consistent with the Minimum Product Information.

There were two decisions of the Medicines Australia Code of Conduct Committee in 2015, which make it clear that the Committee is applying these requirements increasingly strictly.

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.

The ASMI Code of Practice contains some general provisions relating to the advertising of non-prescription medicines. Any background information on products and research initiatives which are published in corporate brochures or annual reports, must comply with the ASMI Code of Practice.

The CMA Code of Practice permits such background information to be published in relation to complementary healthcare products, provided that it does not intend to promote the use or supply of the product.

Lastly, it is important to ensure that the representations being made in relation to the products or research initiatives of the company are not in breach of section 18 of the ACL.

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

MACC contains rules which apply to company involvement with patient support groups. They provide that companies must ensure that activities associated with the patient support groups are not considered as promotional, and that no incentives are provided to patients to participate in these programmes, other than material that will enhance positive health outcomes and compliance.

Section 14 of the MACC also contains rules for how companies interact with Health Consumer Organisations ("HCOs"). These relationships are permitted and recognised as beneficial for enhancing the quality use of medicines by the Australian community, and the interaction between these bodies is also quite strictly controlled. A set of guidelines, Working Together – A Guide to Relationships between Health Consumer Organisations and Pharmaceutical Companies, has been developed to govern relationships with HCOs.

A company may also undertake to sponsor a patient or HCO representative to attend a third-party scientific or medical conference, where that attendance is based solely on their specific interest in a particular therapeutic area. Clear guidelines must be developed to govern these relationships.

Furthermore, on 30 April 2014, companies were required to submit to Medicines Australia their first annual reports identifying the HCOs they support. Such information will be published on Medicines Australia's website.

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?

A prescription pharmaceutical company may provide items for the benefit of patients, provided that those items satisfy the requirements for a Patient Support Program set out in section 17 of the MACC. There are a number of specific requirements for a Patient Support Program, but section 17 summarises those requirements as follows:

> "*Patient Support Programs may only be offered to patients who have already been prescribed a prescription-only Product. The healthcare and wellbeing of patients must be the objective of a Patient Support Program. The obligation to be open and transparent about the conduct and management of a Patient Support Program is also central. This obligation is the basis for the requirement to communicate to patients about any payments that are made to a healthcare professional in association with a Patient Support Program*."

A company must develop a clinical rationale for each Patient Support Program.

There are no specific provisions about Patient Support Programs in the MTIC, but the MTIC does contain the following general statement about providing benefits to patients:

> "*MTAA recognises and supports relationships between Industry and Health Consumer Organisations, government bodies and other independent bodies having an interest in Consumer education in relation to Medical Technologies, which are used by Consumers for the sole purpose of facilitating education of Consumers and enhancing their quality use of those products*."

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?

There is no obligation on companies to disclose the details of clinical trials being conducted in Australia.

Australia does have a clinical trial registry (which also relates to New Zealand clinical trials), called the Australia New Zealand Clinical Trials Registry, which can be found online at anzctr.org.au. This registry is operated by an independent not-for-profit organisation. Registration of clinical trials is voluntary, but if a company chooses to register a clinical trial then the funding source for the trial must be disclosed.

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 see the answer to question 7.3.

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. Edition 18 of the MACC introduced a transparency regime for transfers of value to healthcare professionals by prescription pharmaceutical companies. The regime applies to all Medicines Australia members and in respect of activities that are "related to prescription medicines". This would include activities in respect of medicines not yet granted marketing authorisation. From 1 October 2015, companies were required to disclose on their website all transfers of value made to healthcare professionals (or to third parties at the request of a healthcare professional). The disclosure must include the identity of the healthcare professional and details about the circumstances of the transfer. The only exceptions are fees paid to conduct clinical trials and fees for market research, where the market research is conducted by a third party and the company itself is not aware of the identity of the healthcare professionals chosen to participate.

Such disclosure must be made twice a year.

There is no similar regime for medical device manufacturers.

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?

Section 41.3.2 of the MACC requires a company to obtain appropriate consents from a healthcare professional to the disclosure of transfers of value. If a company does not obtain those consents it is in a difficult position because it will be breaching Australian privacy law if it discloses the transfer of value, but will be breaching the MACC if it does not. The practical answer is that a company should not make a transfer of value to a healthcare professional who has not provided the appropriate consents.

8 The Internet

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

The legislation contains a few special rules governing internet advertising. 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. Those advertisements do not require prior approval, since the internet is exempt from the definition of "broadcast media" (regulation 5BA of the TG Regulations).

Websites available to the general public are often disease-centred, and do not provide product-specific information. A prescription pharmaceutical company may use the internet to provide to members of the public the following information:

- a brief non-promotional summary of the company's products available in Australia, in accordance with the current approved Product Information;
- 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 which the TG Regulations require companies to provide to consumers with each supply of a medicine.

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

The MACC contains further detailed rules dealing with the use of the internet and social media to provide information both to the general public and to healthcare professionals.

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

The MACC provides that any promotional information directed at healthcare professionals must be, "accessible only via a secure system that is designed to prevent access by members of the general public" (section 2.4.1).

8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? 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, the relationship between its publisher and the company, and the context in which the link is provided. However, as a matter of general principle, there will always be a risk that the content of a linked website will be attributed to a company.

The MACC provides (section 13.9.2) that when making a reference or linkage to another information source, the company's website should, by virtue of a clear screen, make the following statements:

- the information a reader is about to be referred to may not comply with the Australian regulatory environment and that readers should refer to the CMI for products to fully understand the terms of a product's registration in Australia;
- the intent of providing this material is informational and not as advice; and
- any information provided by this source should be discussed with the reader's healthcare professional and does not replace their advice.

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

Companies should take great care in placing information about their products on their website. Advertising of prescription products to the general public is prohibited, and the content of advertisements for other products is regulated. Given the broad definition of advertisement in the relevant legislation and codes, it is important to consider carefully whether a reference to a product on a website might amount to an advertisement.

However, it is common practice for Australian pharmaceutical companies to include on their website the names of their products and a brief description of their approved indications. As noted above in question 8.1, a pharmaceutical company may also include a copy of the product's CMI. Section 13.9 of the MACC provides specific guidance on the type of content that is permissible.

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

To a limited extent. Clause 13.10 of the MACC deals specifically with social media. It requires that information provided to the general public via social media comply with a number of other relevant provisions of the MACC. It also provides that:

- companies are responsible for all content on company-initiated or controlled social media sites;
- companies must have policies and procedures which govern their employees' interactions on social media so as to ensure compliance with the MACC; and
- companies must report all adverse events which they note during monitoring of social media sites.

Other codes contain references to social media, but no special obligations in relation to it. However, in November 2013 ASMI published guidelines for the use of social media by the self-medication industry.

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?

On 6 March 2018 the *Therapeutic Goods Amendment (2017 Measures No 1) Act 2018* (Cth) received Royal Assent. This bill has provided for enhanced enforcement powers in respect of breaches of the provisions in the TG Act which regulate advertising. The changes create a three-tiered structure of offences, so that:

- strict liability offences with no aggravating element attract a maximum penalty of AU$21,000;
- fault-based offences with no aggravating element attract a maximum penalty of AU$210,000 or 12 months imprisonment; and
- fault-based offences with an aggravating element attract a maximum penalty of AU$840,000 or five years' imprisonment.

In addition to these tiers of criminal offences, the amendments give the TGA more options in relation to civil penalties, including a new regime for infringement notices (which enable a person to discharge their liability by paying a fine which does not constitute an admission of guilt or liability), but also significantly increased maximum civil penalties (exceeding AU$10 million for some corporate offences).

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

The TGA has a programme to reform the regulation of advertising which began with the passage of the reforms outlined in question 9.1 above in March 2018.

We expect to see a revised Therapeutic Goods Advertising Code and a streamlined complaints process in July 2018. There has been a consultation process in relation to these changes. That process has recommended certain changes to the TGAC to make its requirements more objective and easier to enforce. It is also possible that the new Code will remove some of the restrictions on the advertisement of medicines that do not require a prescription but may only be supplied by pharmacists.

At the same time, it is proposed that for all advertisements for therapeutic goods directed at the general public, the various delegations of complaints handling functions to industry bodies will be withdrawn and the TGA will assume responsibility as a single body for all complaints related to advertising to the general public.

Finally, the *Therapeutic Goods Amendment (2017 Measures No 1) Act 2018* (Cth) contains provisions which will remove the requirement for pre-approval of certain advertisements, but which do not come into effect until 1 July 2020.

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

The Medicines Australia Monitoring Committee, which proactively reviews categories of promotional materials, is increasingly active, and has significantly increased its activities in recent years. In the last few years it has been responsible for instigating approximately 50% of all complaints.

Otherwise, the most significant recent development is the Full Federal Court's decision in *ACCC v Reckitt Benckiser*, discussed at question 1.7 above. The AU$6 million fine imposed in this case represents the largest fine ever imposed for a breach of the Federal Consumer protection laws and demonstrates that the consumer regulator will take action in relation to the therapeutic goods where it feels it is appropriate to do so.

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As an independent firm, we have relationships with leading firms around the world. That means our clients can be confident they have access to the best possible advice, wherever and whenever they need it.

Other titles in the ICLG series include:

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