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The International Comparative Legal Guide to: Pharmaceutical Advertising 2011

A practical cross-border insight
into pharmaceutical advertising

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Penny Smale

Managing Editor

Alan Falach

Deputy Publisher

George Archer

Publisher

Richard Firth

Published by

Global Legal Group Ltd.
59 Tanner Street
London SE1 3PL, UK
Tel: +44 20 7367 0720
Fax: +44 20 7407 5255
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■ Preface by Tom Spencer, Counsel, GlaxoSmithKline Plc.

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Australia



Colin Loveday



Greg Williams

Clayton Utz

1 General - Medicinal Products

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

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 medicinal products 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 old Trade Practices Act was renamed the CC Act, with effect from 1 January 2010, and the consumer protection provisions in the Trade Practices Act became part of the ACL. 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 2007 (“**the TGAC**”), promulgated by the Therapeutic Goods Advertising Code Council, which applies to all advertisements for therapeutic goods other than those directed at health professionals or wholesalers of therapeutic goods. The TGAC was last revised on 26 February 2007. It is given the force of legislation by the TG Regulations;
- the Medicines Australia Code of Conduct (“**MACC**”) and supporting Guidelines, which relate to the promotion of prescription-only medicines. Edition 16 of this Code and the Guidelines commenced on 1 January 2010. Most innovator companies in Australia are members of Medicines Australia and subject to the MACC as a condition of their membership. It is also a standard condition of marketing approval for prescription products that the sponsor comply with the provisions of the MACC. However, generic manufacturers who are not members of Medicines Australia will not necessarily be bound by its other provisions (for example the provisions dealing with relationships with health practitioners);
- the Australian Self-Medication Industry (“**ASMI**”) Code of Practice, which relates to the advertising of non-prescription consumer healthcare products. The June 2009 version was current at the time of writing, although changes made at ASMI’s 2010 Annual General Meeting are pending;

- the Medical Technology Association of Australia (“**MTAA**”)/Medical Technology Association of New Zealand (“**MTANZ**”) Code of Practice, 6th Edition, published 1 October 2010, which relates to the behaviour of medical devices and technology companies;
- IVD Australia’s Code of Conduct (the 1st Edition of which came into effect in October 2010) applies to the behaviour of companies who market *in vitro* diagnostic products in Australia; and
- the Complementary Healthcare Council of Australia (“**CHC**”) Code of Practice for the Marketing of Complementary Healthcare and Healthfood Products. The November 2005 version was current at the time of writing.

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, 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 Code 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? If so, what aspects should those SOP's cover?

There are no legal or code requirements for companies to have specific Standard Operating Procedures (“SOPs”) in relation to advertising activities. Advertising activities of companies are strictly controlled and directed by the TG Act, TG regulations and TG Advertising Code, along with the MACC and other industry codes.

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 health 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 “mainstream media” or in the form of posters or billboards 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 the CHC.

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 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 health professionals). However, Medicines Australia, which hears complaints about such advertisements, is entitled by its Code of Conduct 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 review 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.

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? To what extent may competitors take direct action through the courts?

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 for breaches of the rules relating to advertising. These are criminal offences. The penalties imposed for a breach of these rules are fines of up to AU\$6,600.

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 includes 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 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 is in identical terms

to the former section 52 of the Trade Practices Act), which prohibits a corporation from engaging in “misleading and deceptive conduct” in the course of “trade or commerce”. This provision has been widely used to challenge advertisements.

(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 Code. 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.

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.

Sections 21 and 22 of the MACC deal with complaints against non-members. Complaints concerning promotional activities of non-members will be forwarded to the non-member with an invitation to have the complaint adjudicated by the Code Committee and to abide by the Code Committee’s decision and 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 medical devices and non-prescription medicines 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 the 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 as a competitive tool. Nevertheless, competitors often bring complaints under the Code on the basis of the 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 health 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’s 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 Medicines Australia Code of Conduct 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 their approved indications.

The Medicines Australia Code of Conduct contains provisions which set out what manufacturers and suppliers are allowed to say about unregistered prescription products. These allow 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 the Code and is clearly identified as not being approved for that indication in Australia.

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 indicators.

2.2 May information on unauthorised medicines be published? If so, in what circumstances?

Yes, provided that the publication does not amount to an advertisement or promotion of the medicine in question. As noted above, this turns on 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 medicinal products which are not yet authorised? If so, what limitations apply?

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

However, the Medicines Australia Code of Conduct does deal with press releases about prescription-only medicines. It says:

- 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 press releases regarding products or indications which are not registered in Australia. However, this does not prevent companies from “responding” to key international developments such as landmark trials, but any such response must be current, accurate and balanced and must not be promotional. Its intent must be educational. In practice this leaves limited scope for pro-active press releases.

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

Yes, but only in response to a specific request from the health professional. Generally, it is acceptable to send health professionals published, peer-reviewed articles or proceedings of scientific symposia, but not company authored material which falls outside of this description.

2.5 May information 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.

2.6 Is it possible for companies to involve health professionals in market research exercises concerning possible launch materials for medicinal products 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 that the sole purpose of market research activities must be to collect data and not a means to promote to and/or reward healthcare professionals. They 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 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 Health Professionals

3.1 What information must appear in advertisements directed to health 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 Medicines Australia Code of Conduct provides that the advertisement for a product 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 (the PBS, or Pharmaceutical Benefits Scheme, is the government scheme whereby certain prescription-only products are made available to the public at little or no cost); 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 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. 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 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 (question 9.2). The MTAA Code of Practice 2009 also provides that the name or photograph of a health 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.

Many healthcare professionals are also subject to ethical requirements and codes of practice which provide guidance on suitable involvement with industry. Companies must 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 are 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. However, the Guidelines to the Medicines Australia Code of Conduct (“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 comparator 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 which had not yet been authorised in Australia?

There is no statutory prohibition on the use of comparative advertisements or the mention of competitor products in such advertisements.

However, there is case law about section 18 of the ACL which indicates that comparative advertising has a greater risk of misleading the reader and therefore requires special care on the part of the advertiser. This means that special care must be taken in its use.

The MACC has a provision which deals specifically with comparative advertising (section 1.7). It provides:

“In presenting a comparison, care must be taken to ensure that it properly reflects the body of evidence and does not mislead by distortion, by undue emphasis or in any other way. Comparison of products must be factual, fair and capable of substantiation and 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.”

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.

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

The MACC provides that the conclusions of any literature or proceedings of symposia 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. In addition, any reports from congresses, symposia or other medical meetings sponsored by a member of the pharmaceutical industry must be a balanced, true and accurate reflection of the findings of that meeting.

3.7 Are “teaser” advertisements permitted, which alert a reader to the fact that information on something new will follow (without specifying the nature of what will follow)?

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 health 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 Code of Conduct.

There have been some instances of teaser advertisements directed at the general public which appear to have survived regulatory scrutiny.

4 Gifts and Financial Incentives

4.1 It is possible to provide health professionals with samples of products? If so, what restrictions apply?

Yes. If the product is a prescription-only medicine then the MACC provides that samples (called “starter packs” in the Code) 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 quantity of samples which can be supplied.

4.2 Is it possible to give gifts or donations of money to medical practitioners? If so, what restrictions apply?

Yes. However, the MACC and the MTAA Code of Practice impose strict limitations on the type of gifts which can be supplied and the circumstances in which gifts can be supplied by manufacturers and suppliers of prescription-only medicines.

4.3 Is it possible to give gifts or donations of money to institutions 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?

There are no rules which prevent manufacturers or suppliers from giving gifts or donations to health institutions or to donate equipment or fund the cost of certain types of services. 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 MTAA Code of Practice.

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

- 4.4 Is it possible to provide medical or educational goods and services to doctors 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 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. 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 or even regulate the provision of volume-related discounts.

However, it would be necessary to ensure that any volume-related discounting arrangement was not such as to infringe Australian competition (anti-trust) law. Furthermore, 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 is phasing in requirements for pharmaceutical manufacturers to disclose to the government the “true” price at which they sell their products. The disclosure requirements have applied to some drugs since 1 August 2007 and from December 2010 apply to apply PBS-listed products which are on the PBS’s F2 formulary (the formulary for products which have one or more generic competitors).

- 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?**

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 in only specific circumstances.

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.

- 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.

- 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 meetings” organised by third parties and the attendance of healthcare professionals at these meetings 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).

5 Hospitality and Related Payments

- 5.1 What rules govern the offering of hospitality to health professionals? Does it make a difference if the hospitality offered to those health professionals will take place in another country?**

The industry codes contain rules governing the offering of hospitality to health professionals.

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

It does not matter where the event takes place.

- 5.2 Is it possible to pay for a doctor 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?**

Doctors may be “sponsored” to attend scientific meetings, provided that the primary purpose of the meeting is educational and the assistance and sponsorship will be used for purposes which fulfil that objective. Under the MACC doctors must be selected by reference to their interest in the subject matter of the meeting and their ability to communicate relevant information to Australian healthcare professionals. 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 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 the meeting is directly related to the doctor’s area of expertise. The Code also permits a company to pay for a

doctor's "reasonable" accommodation expenses, including an allowance for meals (provided that such allowance is not "extravagant").

The MACC prohibits companies from paying for or subsidising the travel costs of a doctor's family. 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 doctors.

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 doctors to attend?

Involvement in educational meetings is regulated by section 9 of the MACC. Section 9.5.5 specifies that any hospitality provided by companies either directly or by sponsorship or assistance to the organisers of educational meetings, 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 hospitality 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.

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 or recreational facilities. A company must not subsidise or pay for the costs of family or companies of attendees at educational meetings.

If a successful complaint is brought against a company, numerous penalties can be imposed including, for example, fines.

5.4 Is it possible to pay doctors to provide expert services (e.g. participating in focus groups)? If so, what restrictions apply?

Yes. There is nothing which prohibits suppliers and manufacturers of medicinal products from retaining doctors for the purposes of providing expert services. It is common practice for Australian companies to retain panels of independent experts whom they consult in relation to their products.

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

Yes, the MACC permits doctors to be paid for taking part in Post-Marketing Surveillance studies ("PMS Studies"), provided that the payment is commensurate with the work involved and is not based on the number of prescriptions written. The rules governing PMS studies are contained in section 10 of the MACC.

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

Yes, it is possible to pay doctors 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 doctors. The MACC

provides that any payment to doctors "must be kept to a minimum and should not exceed a level commensurate with the time involved" (section 11.3).

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 1.4 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 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 12.7 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 12.7.7 requires the name of a pharmaceutical company to be identified in any disease education campaign but also states 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?

Such press releases may breach the TG Act. However, they appear to be tacitly accepted by the regulatory authorities.

The MACC provides some guidelines for press releases to the lay media in relation to prescription-only medicines. It requires press releases to include information about a product's "precautions, adverse reactions, warnings, contraindications and interactions". It also provides that the intent of such releases must be educational and they must "not include promotional statements or claims, or comparisons with other products" or promote to the general public.

The Code also permits companies, subject to certain conditions, to issue a media release to the general media to announce a new product or a major indication approval, provided that the product

has been registered for use in Australia and the medical profession has been supplied with appropriate information.

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.

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 is published in corporate brochures or annual reports must comply with the ASMI Code of Practice.

The CHC 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 funding of patient support groups, including any transparency requirement as regards the recording of donations and other support in corporate reports?

The 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 no incentives are provided to patients to participate in these programmes, other than material that will enhance positive health outcomes and compliance.

Section 13 of the Code 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. Under the Code, where a company engages with a HCO they must make publicly available, preferably via the company website, a list of HCOs to which they provide financial support and/or significant direct/indirect non-financial support.

7 The Internet

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

There are few special rules governing internet advertising. Internet advertisements are subject to the same regulatory regime as other advertisements for medicinal products. As such, Internet advertising of prescription-only medicines direct to the public is prohibited.

However, although internet advertisements seem to fall within the definition of advertisements which must be approved before they can be published (because it is a “broadcast media”), as a matter of practice such advertisements are treated as “below the line” advertisements which do not require approval.

The MACC contains more detailed rules dealing with the use of the

internet to provide pharmaceutical information both to the general public and to health professionals.

The CHC Code of Practice also contains some specific guidelines dealing with the use of the internet to promote complementary healthcare products.

7.2 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 health professionals?

The MACC provides that any promotional information directed at health professionals must be “*accessible only via a secure system that is designed to prevent access by members of the general public*”.

7.3 What rules apply to the content of independent websites that may be accessed by 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.

7.4 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. Some Australian pharmaceutical companies also include a copy of the 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. Section 12.8 of the MACC provides specific guidance on the type of content that is permissible.

8 General - Medical Devices

8.1 What laws and codes of practice govern the advertising of medical devices in Australia?

Medical devices are subject to the same legislation as medicinal products - the TG Act and the TG Regulations. However, the rules which govern the advertising of medical devices are slightly different from those which govern the advertising of medicinal products. While advertisements for medical devices do not need to be pre-approved, the TG Regulations contain numerous provisions about what can or cannot be included in an advertisement.

Advertisements for medical devices directed at the general public are also subject to the TGAC.

The industry association which represents manufacturers of medical devices is the Medical Technology Association of Australia (“MTAA”). The MTAA Code of Practice provides guidance for member companies about the advertising of medical devices and technology and the relationships between companies and healthcare professionals.

In 2010 some members of the Australian *in vitro* diagnostics industry established their own industry body, IVD Australia which, as of October 2010 has its own Code of Conduct.

The ASMI Code of Practice does have some *de facto* application to manufacturers and suppliers of medical devices, particular if the device in question can be purchased directly by the public.

8.2 Are there any restrictions on payments or hospitality offered to doctors in connection with the promotion of a medical device?

Section 6.2(c) of the MTAA/MTANZ Code states that a medical device company may pay for reasonable travel and modest lodging costs incurred by attending healthcare professionals in relation to company-sponsored educational or technology demonstrations, however nothing is specifically mentioned in relation to other payments, such as remuneration. Section 6.5 also qualifies that any hospitality provided as a courtesy to healthcare professionals must be incidental to any commercial presentation of technology, must not include entertainment, must be modest in value and must have an educative element to the presentation.

In addition, where a healthcare professional is engaged as a consultant in relation to a specific technology product or products, any remuneration arrangement must be documented by way of an agreement and must reflect fair market value for the consultancy services provided.

The IVD Australia Code of Practice also contains provisions which are to broadly similar effect.

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?

There have been no major changes to the rules in the last year. However, the last year has seen consolidation of a number of changes to the rules made in the previous years. These changes have all been in the direction of strengthening the rules which govern pharmaceutical advertising and seeking greater transparency and accountability in relationships between companies and healthcare professionals.

More generally, the introduction of the Australian Consumer Law, while not creating any new advertising requirements, has increased the powers of the ACCC to enforce the existing standards.

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

The Commonwealth Government is currently conducting a consultation process with stakeholders across the prescription medicine, medical device, complementary medicine and over-the-counter industry groups about the prospect of introducing a single uniform code which would address the promotion of therapeutic goods. The consultation process was completed on 27 August 2010, but there has been no announcement of any outcome as yet.

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

An extensive review of Edition 15 of the Code was completed during 2009, resulting in the production of Edition 16 of the Code, which took effect from 1 January 2010. Edition 16 includes a number of significant changes to the previous edition, including a tightening of the rules for pharmaceutical advertising and the introduction of further measures which are said to be designed to lead to increased accountability and transparency of industry conduct. 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.

**Colin Loveday**

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

Tel: +61 2 9353 4193
Fax: +61 2 8220 6700
Email: cloveday@claytonutz.com
URL: www.claytonutz.com

As the national convenor of the Clayton Utz Product Liability Group, Colin Loveday is an experienced litigation lawyer specialising in the defence of product liability, class actions and toxic tort claims.

Colin has broad experience advising Australian and multinational pharmaceutical and medical device companies in relation to their dealings with the TGA, Pharmaceutical Benefits Scheme and Medicines Australia. His work in this area has included a full range of issues, including those associated with clinical trials, labelling, advertising and product promotion, pricing, product recalls and hazard alerts.

Over the past decade, Colin has also been intimately involved in the development of Australia's product liability laws and in the majority of class actions and mass tort cases in this area. His defence work includes IUD, pacemakers, diet pills and a variety of prescription products and medical devices. Colin is internationally recognised for his work in the field of drug and device litigation. He has worked extensively with in-house counsel and lawyers in the US and Europe developing international defence strategies and working with international expert witnesses.

Colin is a member of the International Association of Defense Counsel (IADC), the Defense Research Institute (DRI) and the Australian National Product Liability Association. Colin is Chair of the Product Law and Advertising Committee of the International Bar Association.

**Greg Williams**

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

Tel: +61 2 9353 4798
Fax: +61 2 8220 6700
Email: gwilliams@claytonutz.com
URL: www.claytonutz.com

Greg Williams is a partner in the Product Liability group. He acts primarily for the pharmaceutical and medical device industry. He advises his clients about regulatory issues, including issues relating to registration and listing, pricing, advertising and labelling, as well as product safety issues. He also acts in litigious product liability matters and has special expertise in class action litigation, both product liability and commercial. Greg has a Masters Degree in Biochemistry.

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