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Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance

AUSTRALIA

Australia

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Introduction

In Australia, the advertising of pharmaceutical products and medical devices to consumers and health professionals is administered via a co-regulatory system.

The Therapeutic Goods Administration ("TGA"), a division of the Federal Government Department of Health and Ageing, is the key authority regulating pharmaceutical products and medical devices in Australia, including their advertising and promotion.

The TGA is supported in its regulatory activities by a number of industry organizations which have implemented and enforce codes of conduct applicable to member countries.

The advertising and promotion of pharmaceutical products and medical devices is monitored fairly actively in Australia. In addition to review by regulators, it has been the subject of media coverage and commentary.

Regulatory Framework

The primary regulatory instrument is the Therapeutic Goods Act 1989 ("TG Act") and associated subordinate regulations which include the following:

- Therapeutic Goods Regulations 1990 ("Regulations")
- Therapeutic Goods (Medical Devices) Regulations 2002
- Therapeutic Goods Advertising Code 2007 ("TGA Code")

Compliance with the Regulations and the TGA Code is mandatory under the TG Act. The TGA Code regulates advertising to consumers (not to healthcare practitioners).

In Australia, voluntary industry codes govern the conduct of member pharmaceutical and medical technology companies, in particular interactions between sponsors and healthcare practitioners, including advertising and promotion. These industry codes include the following:

- Medicines Australia Code of Conduct ("MA Code")
- Medical Technology Association of Australia Code of Practice ("MTAA Code")
- Australian Self-Medication Industry ("ASMI") Code of Practice
- Complementary Health Council ("CHC") Code of Practice for the Marketing of Complementary Healthcare Products
- IVD Australia Code of Conduct

The codes are not legally binding, but operate as industry standards, and members of the relevant industry organizations may be subject to penalties if their conduct infringes a relevant code.

The promotion of pharmaceutical products and medical devices is also subject to general trade practices and consumer protection laws set out in the Australian Consumer Law (part of the Competition and Consumer Act 2011). Relevant provisions include the following:

- Section 18: a general prohibition on conduct by a corporation, in trade or commerce, which is misleading or deceptive or likely to mislead or deceive
- Sections 29 and 33: prohibit specific types of false representations, including false representations as to the standard, quality, value or grade of a product; as to sponsorship, approval, performance characteristics, uses or benefits; or the need for particular goods or services

The TG Act defines advertisement broadly as: "any statement, pictorial representation or design, however made, that is intended

whether directly or indirectly to promote the use or supply of therapeutic goods."

This definition is adopted in the Regulations, the TGA Code, and industry codes.

The TG Act and the TGA Code define health professionals to include: medical practitioners, psychologists, dentists, veterinary surgeons, pharmacists, physiotherapists, dieticians, scientists working in medical laboratories or nurses; wholesalers and purchasing officers of therapeutic goods; herbalists, homeopathic practitioners, chiropractors, naturopaths, nutritionists, traditional Chinese medicine practitioners, podiatrists or osteopaths.

For the purposes of industry codes, "healthcare practitioner" is defined slightly more broadly.

Permitted and Prohibited Practices

Advertising to Consumers

In Australia, all pharmaceutical products and medical devices must be included on the Australian Register of Therapeutic Goods ("ARTG"), unless exempt, before they can be supplied, promoted and advertised in Australia.

The TG Act provides that:

- unregistered goods must not be advertised in Australia to consumers or healthcare professionals; and
- pharmaceutical products and medical devices must not be advertised for any indication which has not been accepted and included on the ARTG in relation to that product or device.

The TG Act also provides that all advertisements must comply with the Regulations and the TGA Code. The object of the TGA Code is to ensure that the marketing and advertising of therapeutic goods to

consumers is conducted in a socially responsible manner that promotes the quality use of therapeutic goods and does not mislead or deceive consumers.

Significantly:

- advertising prescription-only and certain pharmacist-only medicines to the general public is prohibited; and
- advertising over-the-counter (OTC) medicines, complementary medicines and devices is generally permitted.

Advertising to consumers may take a range of forms, including:

- magazines or newspapers;
- television, radio or cinema;
- the internet;
- billboards or public transport;
- leaflets, flyers, brochures, catalogues, letterbox drops; and
- medical journals

Prior approval is required for advertisements to consumers in the form of broadcast media (television and radio), print media (newspapers and magazines, including inserts) and outdoor media (billboards, bus shelters, sides and interiors of buses, and taxi displays). The approval process has been delegated by the Federal Department of Health and Ageing to the ASMI and the CHC.

No prior approval is required for advertisements relating to medical devices.

The TGA Code includes a range of additional requirements and prohibitions in relation to advertising including the following:

- Minimum product information requirements - All advertisements (apart from limited point of sale material) must contain:
    - the trade name of the goods;
    - a reference to approved/permitted indications for the use of the goods
    - where applicable, a list of ingredients or a prominent "ALWAYS READ THE LABEL" statement; and
    - a prominent "USE ONLY AS DIRECTED" statement.

  Direct marketing and internet advertising must contain additional product information, as must pharmacist-only medicines and radio advertising where claims are made in relation to symptoms of diseases or conditions. Print advertisements must also include ARTG numbers.

- Prohibited representations, including as to the treatment of sexually transmitted diseases, HIV/AIDS or mental illness.
- Prior approval must be obtained to use certain restricted representations in relation to particular diseases (see TGA Code, Appendix 6).
- An advertisement for therapeutic goods must not:
    - be likely to arouse unwarranted and unrealistic expectations of product effectiveness;
    - be likely to lead to consumers self-diagnosing or inappropriately treating potentially serious diseases;
    - mislead, or be likely to mislead, directly or by implication or through emphasis, comparisons, contrasts or omissions;

- abuse the trust or exploit the lack of knowledge of consumers or contain language which could bring about fear or distress;
- contain any matter which is likely to lead persons to believe that they are suffering from serious ailment or that harmful consequences may result from the therapeutic good not being used;
- encourage, or be likely to encourage, inappropriate or excessive use;
- contain any claim, statement or implication that it is infallible, unfailing, magical, miraculous, or that it is a certain, guaranteed or sure cure;
- contain any claim, statement or implication that it is effective in all cases of a condition; or
- contain any claim, statement or implication that the goods are safe or that their use cannot cause harm or that they have no side-effects.

- Scientific information must be presented in a manner that is accurate, balanced and not misleading.
- Requirements in relation to comparative advertising.
- Endorsements are strictly regulated.
- Testimonials must be documented, genuine, not misleading and illustrate typical cases only.
- Samples must not be offered.
- Specific requirements in relation to the advertising of analgesics, vitamins and weight management.

The MA Code also regulates interactions with consumers in relation to pharmaceutical products and prescribes mandatory requirements in relation to:

- product media releases;
- educational materials;
- disease education activities; and
- patient support programs.

Finally, the Australian Consumer Law Act will apply to any and all promotional claims and advertising to consumers. As a general rule, companies should avoid claims which are unduly broad, vague, ambiguous or exaggerated. In order to meet any allegation of breach, companies should ensure that they are in a position to substantiate claims by reference to appropriate factual and scientific data.

Advertising to Healthcare Practitioners

Advertisements directed to healthcare practitioners are regulated by the MA Code (for pharmaceutical products) and the MTAA Code (for medical devices and technology).

Pharmaceutical Products

For prescription medicines, inclusion on the ARTG is subject to a condition that promotional material must comply with the MA Code. Non-prescription medicines, OTC and complementary medicines are also regulated by the ASMI and the CHC.

The MA Code sets out the following requirements for educational and promotional material directed to healthcare practitioners:

- All material must be current, balanced, accurate and fully supported by product information.
- Material must not mislead directly or by implication or omission.
- Materials must be in good taste.
- Unqualified superlatives are prohibited.

- A product may only be described as "new" for the first 12 months it is available in Australia.
- Comparative statements must properly reflect the body of evidence and not mislead, must be factual and fair, must be capable of substantiation and must not be disparaging.
- Materials must include product information and PBS information.
- There are mandatory type and size requirements for print media.
- Specific requirements apply to primary advertisements, secondary advertisements and short advertisements.
- Specific requirements apply to advertorials and company-commissioned articles.
- Mandatory information, type and font size requirements apply to leave-behinds, sales aids and leaflets.
- There are mandatory requirements for audiovisual material, restricted access television and advertising on the internet, including close circuit websites for healthcare professionals, social media and e-newsletters.

Medical Devices and Technology

The MTAA Code requires the following:

- Advertisements to health care practitioners must contain:
    - the brand name of the product;
    - the name and contact details of the product sponsor;
    - claims consistent with the intended purpose of the product; and

- all such other information required by law or as a condition of grant of a license.

- Advertisements must:
  - not be misleading or deceptive or likely to mislead;
  - reflect a high standard of social responsibility and conform to standards of good taste;
  - not claim that a device or technology has some special merit, quality or property unless the claim can be substantiated;
  - not use the term "safe" without appropriate qualification; and
  - not describe a product as "new" after 12 months without appropriate qualification.

- Member companies must be able to substantiate all claims in an advertisement by reliable technical, scientific or other support, and provide substantiation of claims upon any request by third parties.

- The name or photograph of a healthcare practitioner must not be used without his/her written permission, nor in any way that is contrary to ethical guidelines or likely to mislead, deceive or confuse.

- Advertisements must not unfairly denigrate a competitor's product. Comparative advertising must be based upon comparative testing of the relevant products, the outcomes must be reported in a fair and balanced manner, and each outcome must be referenced and consistent with the body of evidence.

Other Promotional Activities

Competitions

The MA Code regulates competitions directed to healthcare practitioners, requiring as follows:

- Competitions must be based upon medical knowledge.
- The prize must be relevant to the practice of medicine.
- Individual prizes must be of low monetary value or educational.
- Entry to the competition must not be dependent on prescribing, ordering or recommending a product.
- Competitions must be appropriately documented and comply with all relevant laws.

The MTAA Code includes provisions in relation to competitions directed to healthcare practitioners and consumers.

In relation to consumers, the MTAA Code provides that:

- a competition must not be directed to consumers in relation to any medical device which is used or intended to be used or administered by a medical practitioner; and
- entry to a competition must not, as a condition of entry, require a consumer to use or purchase a product.

The MTAA Code provides, in relation to healthcare practitioners, that:

- a competition must be based entirely on medical or other specialist healthcare knowledge or the acquisition of that knowledge;
- prizes must be directly relevant to the practice of medicine or field of the specialist healthcare and of minimal monetary value; and

- entry into a competition must not be dependent on ordering, recommending, using or prescribing a product.

Gifts

The MA Code only permits gifts to healthcare professionals which consist of brand name reminders, educational material, a competition prize or a sponsorship arrangement. Gifts must not be given to induce recommendations or prescriptions.

The MTAA Code permits companies to provide a gift of appreciation to a healthcare professional in very limited circumstances. The gift must be of minimal value (i.e., no more than AUD100) and serve a genuine educational function for the healthcare practitioner or a consumer. Medical textbooks, anatomical models and branded promotional items of limited value may also be provided.

The MTAA Code permits philanthropic gifts or donations to charitable or philanthropic organizations for educational or research purposes, provided that donations or philanthropic grants must not be made for the purpose of inducing a healthcare practitioner to purchase, lease, recommend or use particular products.

Sample Products

The MA Code permits the provision of "starter packs" which are one-third the size of retail or trade packs, bear compliant labeling and include relevant product information. Starter packs must be provided to healthcare professionals (not directly to patients), and companies must keep records.

The MTAA Code acknowledges the legitimate practice of providing healthcare practitioners with appropriate sample products for genuine training, educational or product evaluation purposes.

Entertainment

Both the MA Code and MTAA Code expressly provide that interactions with healthcare practitioners must not include

entertainment (including sporting events, musicals and other forms of entertainment).

Hospitality

Both the MA Code and MTAA Code regulate the provision of hospitality to healthcare practitioners.

Hospitality must only be provided in the context of an educational conference or meeting, in an environment which is conducive to enhancing education and learning. The venue must not be chosen for its leisure or recreational facilities.

The MTAA Code further provides that, where hospitality is provided at a third party educational conference (such as a conference hosted by a medical society), the hospitality must be available to all attendees or a specialty sub-group; be subordinate to the educational and technical purposes of the conference; and be appropriate in value.

Sponsorship for Training, Research, Employee Positions or Events

Both the MA Code and the MTAA Code permit certain types of sponsorship subject to specific requirements, as follows:

- Training, education and product demonstrations conducted by or on behalf of companies

  MA Code: There must be objective evidence as to the educational value of the event; the venue must be chosen for the provision of education, not for its leisure or recreational facilities; meals and beverages must not be excessive; travel must be in economy class; no entertainment may be provided; delegates must not be paid; and the attendance of partners or other family members must not be funded.

  MTAA Code: The program must be conducted in a clinical, educational, conference or other setting conducive to the effective transmission of knowledge; any hospitality must be modest in value and subordinate in time and focus to the

education/training; and the program must be recorded in a detailed agenda or written agreement.

- Sponsorship or grants for third party educational conferences

  MA Code: The primary objective of the conference must be the enhancement of medical knowledge and improving the quality use of medicine; the third party organizer must independently determine educational content, speakers and attendees; there must be no payment for entertainment, attendance or family members. The Code also permits companies to sponsor a particular healthcare practitioner to attend an educational event directly related to their area of expertise provided there are clear guidelines for the grant of such sponsorships, it is recorded in a formal agreement and the sponsorship is not linked to prescribing.

  MTAA Code: The conference must be primarily dedicated to promoting objective medical, scientific and educational activities; the sponsorship or grant must be proportionate to the overall cost of the conference; the conference sponsor must control the program, select the sponsorship recipient and make necessary payments; the sponsorship must not be conditional; and the sponsorship or grant must be recorded in a written agreement.

- Grants or donations for educational or research purposes (which may include, by way of example, a fellowship position)

  The types of organizations which may receive donations are those established to advance medical education, research with scientific merit or public education.

Contracts with Healthcare Professionals and Medical Institutions

The MA Code permits companies to legitimately seek the services of suitably qualified and experienced healthcare practitioners to provide

services, advice and guidance. These arrangements may include consulting agreements and appointments to advisory boards. There must be a written agreement between the company and healthcare practitioner and the remuneration paid to the healthcare practitioner must be commensurate with the services provided. MA Code provisions in relation to sponsorships, grants and financial support may also apply.

The MTAA Code also provides that companies may engage healthcare practitioners to provide valuable genuine consulting services provided that such an engagement may take place only where a legitimate need and purpose of the services is identified in advance and product promotion is not a purpose for the engagement. MTAA Code provisions relating to training, education and product demonstrations may also apply.

Both codes permit companies to enter into appropriate arrangements with medical practices, hospitals, medical institutions and health research organizations.

Consequences of Breach

Liability Under Civil and Criminal Law

The TG Act provides a range of offenses relating to failure to comply with the TGA Code and other misrepresentations in the context of advertising. The maximum penalty for each offense is currently AUD10,800,000 for corporations; though a misrepresentation regarding a medicine or device being listed on the ARTG may result in a maximum penalty of AUD9 million.

Whereas only the Secretary of the TGA may commence action on behalf of the Commonwealth Government for breach of the TG Act, any person may take civil action for breach of t the Australian Consumer Law, seeking remedies including declarations or injunctions.

Other available remedies for breach of the Australian Consumer Law also include corrective advertising, damages and related remedies. If

the regulator, which is the Australian Competition and Consumer Commission, takes action, a Court may also award fines.

Australia, like many other jurisdictions, also has anti-bribery legislation with local and potentially extraterritorial effect. The legislation is relevant to dealings with individuals who may be public officials (foreign or local), such as doctors or employees of government-owned hospitals.

Under the Australian Criminal Code Act 1995 (Cth), it is a criminal offense to bribe a foreign public official. Bribery is providing, causing, offering, or promising to provide a benefit to a foreign public official that is not legitimately due with the intention of influencing the foreign public official in order to obtain or retain business or a business advantage that is not legitimately due.

As the definition of "benefit" includes any advantage and is not limited to property, this means that the provision can apply to hospitality and entertainment, as well as to gifts.

Similar provisions apply at a state level in relation to local public officials.

Even where doctors or other individuals are not considered public officials, it can also be an offense to offer or give a corrupt commission, reward, or other undisclosed benefit to an agent as an inducement to act/not act or favor/disfavor any person in relation to the affairs or business of the agent's principal, whether or not a public official is involved. It also is a criminal offense for an agent (or related party) to receive or solicit such an undisclosed benefit.

Some Australian companies may also be subject to provisions of the UK Bribery Act 2010 if they carry on a business or part of a business in the UK. Similarly the United States Foreign Corrupt Practices Act ("FCPA") has a wide geographical reach and will apply, for example, to Australian subsidiaries of US companies.

The sanctions for breach of the MA Code include cessation of conduct and withdrawal, corrective action and monetary fines ranging from a minimum of AUD100,000 for a technical or minor breach to AUD250,000 for a severe and unremedied breach.

The sanctions for breach of the MTAA Code depend upon the severity of the breach and include recalls, retraction notices, fines (AUD50,000 for a moderate breach to AUD200,000 for a serial breach for a severe breach) and expulsion from the MTAA.

Recommendations

As indicated above, the advertising and promotion of pharmaceutical products and medical devices is monitored relatively actively in Australia. The advertising and promotion of products by sponsor companies to healthcare professionals has, in particular, been the subject of media coverage and commentary.

We recommend that manufacturers and sponsors put in place appropriate internal codes of conduct and associated guidelines in relation to the advertising and promotion of products in Australia, ensuring these are adapted to comply with local regulations.

We also recommend conducting regular training sessions for local company representatives (including sales teams) to ensure awareness and compliance with internal codes of conduct and regulatory requirements. This is critical in order to minimize any potential exposure, including, significantly, under anti-bribery legislation, including the FCPA. It is also a mandatory requirement for member organizations of local industry organizations, including Medicines Australia and the Medical Technology Association of Australia.

At a practical level, it is critical to distinguish between advertising and promotional materials which are directed to consumers (where permissible) and those which are directed to healthcare professionals. As outlined in this chapter, differing considerations will apply.

Finally, Australian regulators including the TGA and the Australian Consumer and Competition Commission (which administers the Australian Consumer Law) have wide-ranging investigation and enforcement powers. Companies should take care and seek advice in relation to their dealings with regulators, including as to representations made in response to any regulatory enquiries and the disclosure of commercially sensitive, confidential and potentially privileged material.

This third edition of "Promoting Medical Products Globally. Handbook of Pharma and MedTech Compliance" is intended to provide an overview of the applicable compliance laws governing the cooperation between the medical industry and physicians in Europe, North America, Latin America and the Asia Pacific region. It highlights the legal framework within which medical device and pharmaceutical companies cooperate with health care professionals. It deals with common sponsoring practices such as invitations, conferences and financial grants for research, personnel and equipment as well as other promotional activities such as the giving of gifts, samples and other items and services which are of interest to health professionals. We trust that the third edition is a useful resource for lawyers, compliance officers, managing directors and managers in marketing and medical departments of the medical industry to assess the legal impact on their promotion and marketing activities involving healthcare professionals or medical institutions.

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