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Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance

AUSTRALIA

Australia

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Introduction

In Australia, 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 companies.

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 2018 ("**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 professionals).

In Australia, voluntary industry codes govern the conduct of member pharmaceutical and medical technology companies in their

interactions between sponsors and healthcare professionals, including advertising and promotion. These industry codes include the following:

- Medicines Australia Code of Conduct ("**MA Code**")
- Medical Technology Industry Code of Practice ("**MTAA Code**")
- Australian Self-Medication Industry ("**ASMI**") Code of Practice
- Complementary Medicines Australia ("**CMA**") Marketing & Supply Code of Practice: Complementary Medicines
- 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 2010). 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," in relation to therapeutic goods, broadly as: "any statement, pictorial representation or design that is

intended, whether directly or indirectly, to promote the use or supply of the goods, including where the statement, pictorial representation or design is on the label of the goods; or is on the package in which the goods are contained; or is on any material included with the package in which the goods are contained."

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

The TG Act defines "health professionals" to include: medical practitioners, psychologists, dentists, pharmacists, optometrists, chiropractors, physiotherapists, nurses, midwives, dental hygienists, dental prosthetists, dental therapists or osteopaths; wholesalers and purchasing officers of therapeutic goods; herbalists, homoeopathic practitioners, naturopaths, nutritionists, practitioners of traditional Chinese medicine or podiatrists registered under a law of a state or territory.

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

Permitted and Prohibited Practices

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.
- Pharmaceutical products and medical devices must not be advertised for any indication or purposes which has not been accepted and included on the ARTG in relation to that product or device.

Advertising to Consumers

The TG Act requires that all advertisements to consumers 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.
- 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, catalogs, letterbox drops

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 CMA.

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 exceptions) must contain:
    - the name of the goods
    - a reference to indications for the use of the goods
    - depending on the kind of goods and whether the goods come with health warnings or not, a prominent statement "ALWAYS READ THE LABEL" or "ALWAYS READ THE INSTRUCTIONS FOR USE" or "THIS MEDICINE/PRODUCT MAY NOT BE RIGHT FOR YOU. READ THE LABEL BEFORE PURCHASE" or "ALWAYS READ THE INSTRUCTIONS FOR USE."

  Where the goods are not available for physical examination before purchase, advertisements must contain additional product information, as must pharmacist-only medicines.

- Prohibited representations, including as to abortifacient action or the treatment, cure or prevention of neoplastic diseases, sexually transmitted diseases, HIV/AIDS, hepatitis C virus or mental illness.

- Restricted representations (as to serious forms of disease, condition, ailment or defect) can only be made if TGA approval is obtained.

- An advertisement for therapeutic goods must not:
    - offer any personal incentive to a pharmacy assistant or any retail sales person who is not a health professional to recommend or supply goods

- exaggerate 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
- contain any claim, statement, implication or representation that harmful consequences may result from the therapeutic good not being used (subject to exceptions)
- encourage inappropriate or excessive use
- contain any claim, statement, implication or representation that the goods are infallible, unfailing, magical, miraculous, or that it is a certain, guaranteed or sure cure
- contain any claim, statement, implication or representation that the goods are effective in all cases of a condition
- 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 representations must be presented in a manner that is appropriate, clearly communicated, able to be readily understood by the audience to whom it is directed and be consistent with the body of scientific evidence applicable to the advertised goods.
- Requirements in relation to comparative advertising.

- Endorsements by healthcare professionals, healthcare professional associations and government authorities are prohibited.
- Testimonials are strictly regulated.
- Samples must not be offered, apart from condoms and sunscreens.
- Specific requirements in relation to the advertising of complementary medicines, analgesics, vitamins and minerals, weight management and sunscreens.

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

- product media releases
- educational materials
- patient aids
- disease education activities
- use of the internet
- social media
- market research
- patient support programs

Finally, the Australian Consumer Law 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. 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 professionals are regulated by the MA Code (for prescription 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 CMA.

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

- 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 certain 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 reference manual advertising, 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 healthcare professionals 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
  - all such other information required by law or as a condition of grant of a license
- Advertisements must:
  - comply with the Code and relevant laws and regulations
  - not be misleading or deceptive or likely to mislead
  - reflect a high standard of social responsibility and conform to standards of good taste

- be readily recognizable by the target audience as an advertisement
- not claim that a device or technology is unique or has some special merit, quality or property unless the claim can be substantiated
- not use the term "safe" without appropriate qualification
- not imitate the branding, names, logos, get-up or graphic design, copy, slogans, or general layout adopted by a competitor in a way that is likely to mislead, deceive or confuse
- 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 data, and provide substantiation of claims upon any request by third parties within 10 working days.
- The name or photograph of a healthcare professional must not be used without his/her written permission, nor in any way that is contrary to the codes and ethical guidelines of that healthcare professional (if so informed by the healthcare professional).
- Advertisements must not denigrate a competitor's product. Comparative advertising must be based upon strong evidence supporting the claim and 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. Companies must ensure that claims are current, accurate and balanced and not mislead by implication or omission.

Other Promotional Activities

Competitions

The conduct of a competition must comply in all respects with all applicable laws and regulations.

The MA Code regulates competitions conducted by companies supplying prescription medicines that are directed to healthcare professionals, requiring as follows:

- Competitions for healthcare professionals that include the provision of a prize are not permitted.
- Companies may offer a quiz for health professionals at a trade display, but no prize may be offered.
- A quiz must be clearly separate from market research surveys and starter pack requests.

The MTAA Code includes provisions in relation to competitions directed to healthcare professionals 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 healthcare professional.

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

- A competition must be based entirely on medical or other specialist healthcare knowledge or the acquisition of that knowledge.
- Prizes must be modest in value (i.e., no more than AUD 100) and directly relevant to the practice of medicine or field of specialist healthcare or be an item of an educational nature.

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

Gifts

Under the MA Code, gifts to healthcare professionals are prohibited unless it is a company-branded item of stationery, educational material directed to healthcare professionals or patients, sponsorship to attend an educational event or hospitality at an educational event. Gifts must not be given to induce recommendations or prescriptions.

It is not acceptable for a company to provide a gift of flowers, confectionery or other gift unrelated to the practice of medicine or pharmacy to a health professional to mark or acknowledge an occasion such as a family bereavement or special occasion.

The MTAA Code generally prohibits companies from providing a gift to a healthcare professional. However, occasionally, companies may provide a healthcare professional with an item that benefits patients or serves a genuine educational function for the healthcare professional, provided that the item has a fair market value of less than AUD 100. Medical textbooks and anatomical models may also be provided.

The MTAA Code prohibits companies from giving a healthcare professional any type of non-educational branded promotional item, even if the item is of minimal value and related to the healthcare professional's work or for the benefit of patients. This restriction does not apply to medical devices marketed only to consumers.

The MA Code and MTAA Code permit 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 professional to purchase, lease, recommend, use or arrange for the purchase, or lease or use of the company's medical technology, among other conditions.

Sample Products

The MA Code permits the supply 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 of supply.

The MTAA Code acknowledges the legitimate practice of providing healthcare professionals 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 professionals 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 professionals.

Hospitality must be modest and 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, sporting or recreational facilities.

The MA 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 provided in a manner that does not interfere with attendance at conference functions; be subordinate to the educational and technical purposes of the conference; and be appropriate in value. The maximum cost of a meal (including beverages) provided by a company to a healthcare professional within Australia must not exceed AUD 120 (excluding GST and gratuities), and this maximum would only be appropriate in exceptional circumstances such as a dinner at a learned society

conference with substantial educational content – in the majority of circumstances, the cost of a meal (including beverages) should be well below this figure. For hospitality in association with overseas educational meetings, this maximum and/or local guidelines should be used as a guide.

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, sporting or recreational facilities; meals and beverages must not exceed the AUD 120 threshold; air travel with Australia and New Zealand must be in economy class; travel must be by the most practical and direct route to and from the educational event(s), without allowing for more time at the destination than is reasonably justified to enable the healthcare professional to participate in the educational meeting; 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; the company may pay for reasonable travel and modest lodging costs incurred by attending healthcare professionals; 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 guests or family members. The Code also permits companies to sponsor a particular healthcare professional 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 conditional upon any obligation of the recipient or offered or provided in a manner that would interfere with the independence or professional obligations of a healthcare professional.

  MTAA Code: the conference must be primarily dedicated to promoting objective medical, scientific and educational activities and discourse; 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 upon any obligation of the recipient or offered or provided in a manner that would interfere with the independence or professional obligations of a healthcare professional, be consistent with guidelines established by the conference organizer, not give rise to or facilitate any breach of the Code and 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 professionals 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 the healthcare professional and the remuneration paid to the healthcare professional 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 professionals to provide valuable genuine consulting services provided that such an engagement may take place only where a legitimate need and purpose for the services is identified in advance and product promotion is not a purpose of the engagement. Compensation paid to healthcare professionals must be consistent with the fair market value for the services provided. MTAA Code provisions relating to training, education and product demonstrations may also apply.

The MA Code and MTAA Code 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 advertising offenses, including for failure to comply with the TGA Code. There are criminal offenses (including strict liability offences) and civil offenses for breaches of advertising provisions under the TG Act. For example, the maximum

civil penalty for failure to comply with the TGA Code is currently AUD 10.5 million for corporations.

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 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 impose 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 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 federal and 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.

Professional Codes of Conduct

The sanctions for breach of the MA Code include cessation of conduct and withdrawal, corrective action and monetary fines ranging from a maximum of AUD 100,000 for a technical or minor breach to AUD 250,000 for a severe and/or repeated breach.

The sanctions for breach of the MTAA Code depend upon the severity of the breach and include recalls, retraction notices, fines (AUD 50,000 for a moderate breach to AUD 200,000 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 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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