

AUSTRALIAN MEDICAL DEVICES GUIDELINES

Advertising Medical Devices

Guidance Document Number 8

Version 1.5

DISCLAIMER

This document is provided for guidance only. It should not be relied upon to address every aspect of relevant legislation. Please refer to the *Therapeutic Goods Act 1989* as amended by the *Therapeutic Goods Amendment (Medical Devices) Bill 2002* and the *Therapeutic Goods (Medical Devices) Regulations 2002* for legislative requirements.

FURTHER INFORMATION

The Medical Devices Information Unit of the Office of Devices, Blood and Tissues of the Therapeutic Goods Administration (TGA) can be contacted by:

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Facsimile: (02) 6232 8299

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AMENDMENT SCHEDULE

Version Number	Date of Amendment	Summary of Amendments

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INTRODUCTION

This guidance document is one of a series that has been produced to help explain the new regulatory system for medical devices in Australia that commenced on 5 October 2002. The new system has been established by the *Therapeutic Goods Act 1989* as amended by the *Therapeutic Goods Amendment (Medical Devices) Bill 2002* and the *Therapeutic Goods (Medical Devices) Regulations 2002*.

Many other guidance documents are available in this series. The series was developed to assist a wide-ranging audience and additional documents can be included if there is enough demand. A separate guidance document is available describing the series.

Although each guidance document has been developed to provide information about particular aspects of the new medical devices regulatory system in Australia, it is expected that a certain amount of cross-referencing to other documents in the series will be inevitable.

It should be noted that three terms “therapeutic goods”, “therapeutic devices” and “medical devices” are used in the legislation. The *Therapeutic Goods Act 1989* (the Act) is concerned with therapeutic goods which when it was first written described the regulation of medicines and therapeutic devices. At that time many other countries used the term “medical device” and not “therapeutic device”. When the Australian legislation was revised in late 2002 the term “medical device” was introduced. Therefore, for the next five years, the Act will regulate medicines, therapeutic devices and medical devices. The therapeutic devices are the registered or listed entries that were in the Australian Register of Therapeutic Goods (ARTG) before 4 October 2002, or which could entered during the 5 year transition period under certain conditions. Medical devices are those products that are entered in the ARTG after 4 October 2002 under the revised legislation. The medical devices in the ARTG will be known as medical devices included in the ARTG, or more colloquially known as “inclusions”.

Advertisements for therapeutic goods, including devices, directed to consumers are required to comply with the *Therapeutic Goods Act 1989* (the Act), Part 2 of the *Therapeutic Goods Regulations 1990* (the Regulations) and the Therapeutic Goods Advertising Code (TGAC).

The object of the TGAC is “to ensure that the marketing and advertising of therapeutic goods to consumers is conducted in a manner that promotes the quality use of therapeutic goods, is socially responsible and does not mislead or deceive the consumer”. The TGAC is based on a set of principles, and when interpreting the code, the total presentation and context of the advertisement is taken into consideration.

The TGAC is updated on a regular basis and therefore it is important to ensure that the current version is referred to. A copy of the code can be found on the Therapeutic Goods Advertising Code Council website, “www.tgacc.com.au”. Information about restricted representations and copies of the exemptions that have been granted are available on the TGA website, “www.tga.gov.au/docs/html/therad.htm”.

THE REGULATION OF ADVERTISING

The advertising of therapeutic goods, including medical devices, is regulated in Australia under a co-regulatory arrangement and involves the TGA, the therapeutic goods industry, health care professionals, consumers, the advertising industry, retailers, the Australian Competition & Consumer Commission (ACCC), Medsafe in New Zealand, and the media.

The Therapeutic Goods Advertising Code Council (the Code Council) consists of 12 members and 7 observers. The Code Council is the principal body responsible for considering the requirements for advertising and making recommendations to the Minister on advertising issues, including amendments to the advertising requirements in the legislation.

An advertisement is defined in the Act, as:

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

This includes product labels, pamphlets, and instructions for use, promotional samples, promotional seminars, demonstrations and displays.

Advertising is considered as part of the information provided with medical devices required by the essential principles (refer to Schedule 1, Part 2, 7 of *the Therapeutic Goods (Medical Devices) Regulations 2002*). Unlike medicines, advertisements for medical devices do not have to be approved prior to publication, however the advertisements must comply with:

- Section 22(5) of the Act that specifies advertising of a therapeutic good can only refer to the indications which are included in the Australian Register of Therapeutic Goods (ARTG) for that specific good.
- Part 2 of the Regulations and the TGAC.

SOME OF THE PRINCIPLES OF THE THERAPEUTIC GOODS ADVERTISING CODE

According to the TGAC, advertisements for therapeutic goods must:

- comply with the statute and common law of the Commonwealth, States and Territories, and
- contain correct and balanced statements only and claims, which the sponsor has already verified.

Advertisements for therapeutic goods must not:

- be likely to arouse unwarranted or unrealistic expectations of product effectiveness;
- be likely to lead to consumers self-diagnosing or inappropriately treating potentially serious diseases;
- 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 people to believe
 - that they are suffering from a serious ailment, or
 - that harmful consequences may result from the therapeutic good not being used.
- encourage inappropriate or excessive consumption;
- 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;
- 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; or
- be directed to minors, except... the following therapeutic goods or medical devices:
 - tampons,
 - condoms and personal lubricants,
 - bandages and dressings,
 - devices for management of chronic conditions under medical supervision.

OBTAINING AN EXEMPTION FOR A RESTRICTED REPRESENTATION

To obtain an exemption for a restricted representation in advertisements for medical devices, including labels, directed to consumers, the advertiser must make a submission to the TGACC and to the Director of the Office of Devices, Blood and Tissues (ODBT) of the TGA.

The request for an exemption should include an explanation as to why the exemption is required and where possible should address the Public Interest Criteria in Appendix 6 of the TGAC. The submission needs to include:

1. a copy of the proposed advertisement,
2. the ARTG entry for the therapeutic good or a letter on TGA letterhead identifying the product as an exempt good,
3. justification for using the restricted representation in an advertisement,
4. evidence validating the claims in the advertisement, and
5. responses to the relevant segments of the public interest criteria in Appendix 6 of the TGAC.

The Code Council will apply the public interest criteria and make a recommendation to the TGA that will be considered prior to making a decision to either grant or deny the request for an exemption.

CONSIDERATION OF COMPLAINTS

The Complaints Resolution Panel, established under the Regulations, considers complaints about therapeutic goods, including:

- consumer medicines and devices, and
- those that appear in:
 - newspapers,
 - magazines,
 - billboards,
 - outdoor posters,
 - cinema films,
 - radio, and
 - television.

The Panel, chaired by a trade practices lawyer, consists of 8 members representing industry, consumers, health care practitioners, with the TGA as an observer. An additional member is nominated from the Medical Industry Association of Australia (MIAA) when the Panel considers a complaint about a medical device. The panel does have the power to impose sanctions and refer unresolved matters to the TGA for further action.

If a complaint is upheld, the advertiser may be requested to withdraw the advertisement or publish corrective advertising. If the advertiser fails to comply with this request, the matter is referred to the TGA for further action. For medical devices, this referral is directed to the Office of Devices, Blood and Tissues (ODBT).

The Advertising Unit of the TGA considers complaints about other forms of medical device advertisements (such as labels, leaflets, flyers, promotional brochures or information on the Internet) and recommendations are made to ODBT.

WHERE CAN FURTHER INFORMATION BE OBTAINED?

For more information about the advertising provisions under the Act and Regulations, please contact:

The Advertising and Export Section
Non-Prescription Medicines Branch
Therapeutic Goods Administration

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