



Advertising of hearing devices and promotion of services

There has recently been a range of issues referred to the Australian Government Hearing Services Program (the program) for consideration about the advertising of hearing devices and the interactions between device suppliers, service providers, hearing practitioners and clients. These questions and answers aim to clarify the obligations and responsibilities of the key players in the hearing sector and the position of the Department of Health (the Department).

1. Clients

At the centre of the program is the client. The legislation which underpins the Voucher System and certain provisions in the Service Provider Contract act to support the integrity of the Program through protecting the interests of the client and maintaining their trust in the practitioner.

The *Hearing Service Rules of Conduct 2012*, made under the Act, require that services provided are based on the voucher holder's individual requirements and identified hearing impairment. The current Service Provider Contract emphasises the importance of client services that are ethical, safe, respectful and appropriate. The Hearing Rehabilitation Outcomes (which are a Standard under the Service Provider Contract) contain a range of provisions emphasizing the importance of client goals and expectations, and of optimising client outcomes.

In this context, the World Health Organisation (WHO) notes that

We need to re-establish the core value of health care, which is health and well-being of all people as the central goal. This entails a more holistic and people-centred approach to health care, and a balanced consideration of the rights and needs as well as the responsibilities and capacities of all health constituents and stakeholders. [People Centred Health Care – A Policy Framework, WHO 2007]

Consistent with the WHO Framework, service providers are expected to safeguard the rights of the client to make informed decisions about managing their hearing loss, including transparency of any commercial arrangements which may influence (or could be perceived as influencing) matters of clinical judgement.

2. Device Suppliers and Manufacturers

What are the obligations on hearing device suppliers when advertising their products?

The choices that clients make to manage their hearing loss can be influenced by advertisements for hearing devices.

Hearing aids are medical devices which are regulated for safety, quality and performance under the *Therapeutic Goods Act 1989* (the TG Act) and the *Therapeutic Goods (Medical Devices) Regulations 2002*. They are also subject to the advertising requirements set out in the TG Act, *Therapeutic Goods Regulations 1999* (the TG Regulations), and the *Therapeutic Goods Advertising Code* (the Code). This legislation is administered by the Therapeutic Goods Administration (TGA), which is a part of the Department of Health.

In considering whether any material is advertising, TGA applies the broad definition of ‘advertisement’, as set out in section 3 of the TG Act

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

Advertising of hearing aids to consumers is also covered by the *Competition and Consumer Act 2010*. In addition to the general requirement that advertisements are not misleading or deceptive, Schedule 2 of the *Competition and Consumer Act 2010* sets out the provisions for the Australian Consumer Law (ACL) including

- a national law guaranteeing consumer rights when buying goods and services
- a national product safety law and enforcement system
- a national law for unsolicited consumer agreements covering door-to-door sales and telephone sales and
- penalties, enforcement powers and consumer redress options.

The above provisions apply irrespective of whether an advertisement about hearing devices is directed to hearing practitioners supplying services (either privately or under the Voucher Scheme), or to the general public.

Does it make any difference whether the advertising is directed to consumers or whether it is directed to audiologists/audiometrists?

Advertising directed exclusively to “health professionals” is excluded from the requirements in Part 5-1 (Advertising and generic information) of the TG Act, which is designed to regulate advertising to the general public. The types of health professionals who are the subject of the exclusion are listed in section 42AA of the TG Act or are members of the bodies described in Schedule 1 of the TG Regulations. Audiologists and audiometrists are not explicitly referenced on this list and are not exempted under section 42AA of the TG Act when they are not members of a prescribed body for the purposes of this section (i.e. under Schedule 1 of the TG Regulations).

This means that advertisements directed to hearing practitioners must comply with the advertising requirements in Part 5-1 of the TG Act and the Code (i.e. in the same way as any advertising directed to the general public).

Section 4 (3) of the Code states that

An advertisement must not offer any personal incentive to a pharmacy assistant, or other non-healthcare professional sales person at retail, to recommend or supply therapeutic goods.

In the context of hearing services, this means that a personal incentive cannot be offered to a hearing practitioner to promote hearing devices to consumers (for example a gift for selling products above a certain value or competitions with prizes for selling particular hearing devices).

The Code also includes advertising requirements for: the presentation of scientific information; professional recommendations; comparative advertising and testimonials.

The TGA may take action against the party responsible for placing the advertising (i.e. making the offer), where it is satisfied that there has been a breach of the legislation.

Are there any other restrictions on advertising hearing aids?

In general, any hearing device advertised for supply in Australia must be entered in the Australian Register of Therapeutic Goods (ARTG), unless specifically exempt from this

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requirement (for example some custom made hearing aids). Hearing devices purchased overseas and imported for personal use do not need to be included in the ARTG – however, such products may not meet the required standards of quality, safety and performance for supply in Australia. Consumers are advised to consult with their hearing care or healthcare practitioner before considering such a purchase.

What are some of the more frequently noted requirements of the Therapeutic Goods Advertising Code which may be relevant to the advertising of hearing devices?

Section	The Code states that advertisements
4(1)(b)	must contain only correct and balanced statements which the product sponsor has verified [e.g. statements such as this hearing aid uses the most sophisticated technology on the market today cannot be made unless there is evidence that this statement is true]
4(2)(a)	must not be likely to arouse unrealistic or unwarranted expectations of product effectiveness [e.g. if you use this hearing aid your hearing will be restored – noting that the results and success with using any range of listening devices depend on a wide range of individual characteristics and trial, practice and training with the device.]
4(2)(c)	must not mislead or be likely to mislead. [e.g. the XYZ hearing aids will significantly improve your ability to hear an understand the spoken word in all environments]
4(2)(d)	must not exploit the lack of knowledge of consumers or abuse their trust. must not use language that causes fear or distress. [e.g. if you don't use this hearing aid your hearing loss will get worse]
4(2)(g)	must not claim that the advertised product is magical or infallible. [e.g. this hearing aid will cure your hearing loss]
4(2)(h)	must not claim that the advertised product is effective in all cases. [e.g. this hearing aid is suitable for anyone with a hearing loss]
4(5)	if making comparisons, must make only balanced and accurate comparisons. must not imply that the therapeutic products being compared are ineffective or harmful [e.g. you will achieve better results with this hearing aid than Brand X – such a statement is only acceptable if supported by information and qualified to explain what is meant by “better results”]
4(6)(b)	must not claim that the product advertised is endorsed by hospitals or any overseas or Australian government body, including the TGA [e.g. this hearing aid is approved by the program] if referring to sponsorship of a healthcare facility or government body, must not imply that the sponsorship is also an endorsement. must not claim the product advertised is endorsed by a healthcare professional [e.g. 8 out of 10 Ear, Nose and Throat specialists would recommend Brand X hearing aids].
4(6)(c)	if containing an endorsement by a healthcare professional association or healthcare body, must include the name of the endorser and acknowledge any payment or other valuable consideration [such as where a hearing loss consumer organisation recommends the brand of hearing aid].

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Is internal marketing material about hearing devices considered to be an advertisement for the purposes of the *Therapeutic Goods Act 1989*?

Material which is used by hearing practitioners to be given to clients during consultations where such material is designed to provide the person with clinical or technical information about hearing conditions or procedures is not considered to be advertising. Similarly information about hearing loss provided as part of a public health program would not meet the definition of advertising. However, advertising does include situations in which hearing practitioners provide information on particular hearing devices to clients.

Who do I complain to if I believe that there has been a breach of any of these requirements?

Complaints about advertisements for hearing devices appearing in radio, television, consumer magazines, newspapers, billboards, cinema or the Internet may be sent to

The Executive Officer
Complaints Resolution Panel
PO Box 764
North Sydney NSW 2059

Further information about lodging a complaint about the advertising of a therapeutic device is available on the website -

www.tga.gov.au/making-complaint-about-advertising-therapeutic-product#lodging

Any claims that a contracted service provider has breached a requirement of the Service Provider Contract should be referred to hearing@health.gov.au for investigation, together with any supporting evidence.

What are the penalties or sanctions for breaching the Therapeutic Goods Advertising Code?

The procedures of the Therapeutic Products Advertising Complaints - Complaints Resolution Panel, including the options available where an advertisement is found to be in breach of the Therapeutic Goods advertising Code, are available on the Complaints Resolution Panel website www.tgacrp.com.au.

3. Hearing Service Providers

Can action be taken against the device supplier or service provider if they offer a financial inducement to hearing practitioners to sell a particular hearing device?

In 2011, an industry led *Working Group on Promotion of Therapeutic Products* developed a high level statement of principles to be included by therapeutic goods industry associations in their codes of practice. Consistent with these self-regulatory principles, the Medical Technology Association of Australia (MTAA) Code of Conduct 8th edition – 2012 requires that a company must undertake and encourage ethical business practices and socially responsible Industry conduct and must not use any inappropriate inducement or offer any personal benefit or advantage in order to promote or encourage the use of its products. The MTAA Code also provides that where a healthcare professional owns an interest in a Medical Technology Company, they must disclose that interest to a Consumer where the healthcare professional recommends a product that is marketed by that company.

However, there is no requirement for a hearing service provider (whether they provide hearing services under the program or not) to be a member of the MTAA. The MTAA Code indicates that where a complaint is made against a non-member of MTAA, the company will be invited to participate in the complaints process.

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Complaints about financial inducements offered to hearing practitioners to make certain recommendations (which may not be in the best interest of the client) should be referred to MTAA or the relevant Professional Practitioner Body.

Are service providers able to offer financial incentives, commissions, bonuses, trips etc. to staff who reach a certain revenue threshold for selling hearing aids?

Clause 5.2 (c) of the Service Provider Contract requires that a service provider must ensure that it and its staff provide services to clients in accordance with professional standards and ethical practice.

While not currently explicit in the Contract, the Department is of the view that it is reasonable to judge ethics against the requirements of the PPB Codes of Conduct and the MTAA Code of Conduct. These Codes (explicitly or implicitly) support the disclosure of financial interests to clients, where these interests are, or may be perceived, as being in conflict with the exercising of professional judgment.

The manner in which this is done is a matter for each service provider. However, the Department expects that there will be standard processes in place to ensure that this obligation is met. This does not mean that a service provider is required to disclose the exact amount of any commission or additional benefit payable to the hearing practitioner on an individual basis to the client. A simple statement noting that the hearing practitioner is eligible to receive a commission or benefit for the sale of hearing aids for which the client is required to make a financial contribution (ie partially subsidised devices) is considered acceptable.

Are there any other restrictions on the advertising of hearing services more generally (for example, inducements to attract new clients)?

As audiology/audiometry is not a regulated health service, the only restrictions on advertising of the service are those imposed on contracted service providers in the Hearing Services Program or as imposed by the *Competition and Consumer Act 2010*.

While there is no legislative barrier to service providers using a discount, gift or other inducement to attract clients, it is expected that the offer must be truthful and the terms and conditions of that offer must be set out clearly in the advertisement. Service Providers who have entered into a contract under the Hearing Services Program are required to act in a way that does not bring the Program into disrepute. This requirement is interpreted as any action that a contracted service may take that significantly undermines the public's trust and confidence in the integrity of the Program but does not extend more broadly to matters across the hearing profession.

The TGA does not have a role in the regulation of service provision. The Department regulates the delivery of hearing services which are funded under the Hearing Services Program where compliance with specific requirements is expected under the legislation and the Service Provider Contract.

4 Hearing Practitioners

Are there any limits on hearing practitioners accepting gifts, trips, sponsored educational events, reimbursement etc. tied directly or indirectly to recommending certain brands of hearing aids?

There has been increasing public scrutiny of the relationships between healthcare practitioners and industry in general. While some members of the community have called for Government regulation of such relationships, the preference is for industry and practitioners to work towards strengthened self-regulation. It is generally accepted that in order to preserve the community's trust in the integrity of health practitioners, any interests that may influence the decision of all healthcare practitioners should be clear and transparent.

It is therefore the responsibility of the industry and hearing practitioners to decide how any conflicts of interest should be managed when entering into a financial arrangement that could be perceived to influence the decisions hearing practitioners make on behalf of their clients. It is general practice in the health sector that any arrangement with the medical industry that results in benefit financial or non-financial should be declared before any recommendations or decisions are made with respect to devices or technology on behalf of clients. Ultimately, this is an ethical matter for the Professional Practitioner Bodies and the industry.

Professional Practitioner Bodies

The Audiology Australia Code of Conduct prescribes that

- Members shall not enter into employment or business conditions that may compromise the independence of their clinical judgment.
- Members must act in good faith and for a proper purpose and shall disclose, and take reasonable steps to avoid, any actual, perceived or potential conflict of interest that could improperly influence members' duties and responsibilities.

The Hearing Aid Audiometrist Society of Australia Code of Ethics requires that: members shall not participate in activities that constitute a conflict of interest (Clause w).

One of the fundamental principles of the Code of Ethics of the Australasian College of Audiology is that members need to employ sound and ethical business practices that are open to scrutiny, by both clients and regulatory bodies.

Additionally, some states/territories have enacted a Code of Conduct for unregistered health practitioners in legislation (for example, Schedule 3 of the NSW *Public Health Regulation 2012* sets out such a code). While these codes do not prohibit the acceptance of financial considerations for prescribing certain devices, they usually include provisions to require that practitioners provide services in a safe and ethical manner, including prescribing devices that serve the needs of the client. A draft National Code of Conduct is being developed through the Australian Health Ministers' Advisory Conference which all states/territories are being encouraged to adopt into legislation.

Please note, these Q&As are provided for information purposes only and do not constitute legal advice and should not be used as such. Formal legal advice should be sought in particular matters.