



Comments on the Consultation Paper

'Improving advertising arrangements for therapeutic goods

27 August 2010

Background

The Pharmacy Guild of Australia (Guild) is pleased to be able to provide comment to the Therapeutic Goods Administration (TGA) on the 'Regulation of Therapeutic Goods Advertising'¹.

The Guild is an employers' organisation servicing the needs of independent community pharmacies. It strives to promote, maintain and support community pharmacies as the most appropriate primary providers of health care to the community through optimum therapeutic use of medicines, medicines management and related services.

Advertising Regulations

There are three general elements for advertising of therapeutic goods:

1. Direct-to-consumer advertising instigated by the product sponsor/manufacturer.
2. Direct-to-consumer advertising instigated by the intermediary retailer (e.g. a pharmacy).
3. Advertising to the intermediary retailer by the product sponsor/manufacturer (e.g. advertising to health care professionals).

These elements are managed under a co-regulatory system which is designed to protect the public and/or retailers from unscrupulous operators who may make exaggerated or misleading claims about product effectiveness and/or safety to increase product sales.

There are a number of regulatory implements providing a framework to regulate the advertising of therapeutic products and devices and the provision of price information when direct-to-consumer advertising is prohibited. These include:

- Trade Practices Act
- Therapeutic Goods Act
- Therapeutic Goods Regulations
- Therapeutic Goods Advertising Code 2007 (TGAC)
- Price Information Code
- Medicines Australia Code of Conduct
- Australian Self- Medication Industry (ASMI) Code of Conduct

¹ <http://www.tga.gov.au/regreform/cons-advertising.htm>

- Complementary Healthcare Council (CHC) Code of Practice

Pharmacy Self-Regulation

The Guild has a policy on the ‘advertising of medicines’, which was adopted in February 2005 and is available to all members. In this policy, the Guild supports the view that consumers have the right to make an informed choice about medicines and their health and that publicly available information about medicines must be current, accurate, based on sound evidence and should not promote excessive or inappropriate use.

Pharmacy is a unique retail environment consisting of a retail component combined with the professional service obligations of pharmacy practice. Unlike general retailers, pharmacists have ethical as well as legal responsibilities with regards to advertising activities, which are administered by the relevant registration authority. Advertising guidelines² are available for all registered health practitioners and a breach of the guidelines may constitute unprofessional conduct and/or professional misconduct. Such misconduct may be dealt with by the relevant Board through the disciplinary mechanisms available under the *Health Practitioner Regulation National Law 2009*.

Within community pharmacy, professional self-regulation is also managed through the Quality Care Pharmacy Program (QCPP) which has a standard³ for advertising and promotion that is subject to continual review. In summary, this standard requires pharmacy advertising or promotion to:

- comply with the *Therapeutic Goods Advertising Code 2007*
- ensure claims are supported by evidence
- be accurate and balanced
- not promote inappropriate or excessive use and
- ensure price lists comply with the Price Information Code.

Over 80% of community pharmacies are accredited under QCPP and are subject to audit every two years.

² <http://www.ahpra.gov.au/>

³ Standard 4: Advertising and Promotions; QCPP 2nd Edition; May 2006: Version 1.0

Comments

The Guild has provided responses to the questions of relevance within the consultation paper as well as some general commentary on other issues with the current advertising regulatory processes.

1. Overall awareness for advertising of therapeutic goods.

The Guild is supportive of the essential regulations for advertising as they are in the public interest and support Australia's National Medicines Policy⁴ and Quality Use of Medicines (QUM) Strategy⁵. However, the regulatory system for advertising is confusing and the majority of pharmacists and the public are often not aware of how advertising approval processes or the advertising complaints system works.

As part of the National Registration and Accreditation Scheme (NRAS)⁶ through the National Pharmacy Board of Australia (NPBA)⁷, pharmacists are expected to meet their professional responsibilities in line with:

- the Code of Conduct for registered health practitioners
- Professional practice standards developed by the Pharmaceutical Society of Australia (PSA) and
- Guidelines for advertising of regulated health services.

Whilst there is cross-reference within these publications with the TGA regulatory framework, it is imperative that all elements are integrated and that pharmacists understand the whole system.

The Guild also understands that the administration of some advertising complaints is managed under state or territory legislation rather than national. If so, we seek clarification on which aspects are managed under which system. Ideally, we believe that the legislation of all states and territories should reflect the national legislation or adopt it by reference. This would ensure consistency in the management of complaints and breaches and minimise the risk of serious, and potentially serial, offenders 'slipping through the gap'.

We agree that the system as a whole could be streamlined and that there is a need for greater clarity and awareness of pharmacy's obligations with respect to the regulations and which body is responsible for managing complaints and breaches. This is reflected by the recommendation⁸ from the Productivity Commission to 'streamline and clarify advertising rules' and 'address the need for a simplified system for complaints about national advertising'. This recommendation has been accepted in principle by the Australian Government⁹.

⁴ <http://www.health.gov.au/internet/main/publishing.nsf/Content/nmp-objectives-policy.htm>

⁵ <http://www.health.gov.au/internet/main/publishing.nsf/Content/national-medicines-policydoc~national-medicines-policy-5>

⁶ www.ahpra.gov.au

⁷ <http://www.pharmacyboard.gov.au/>

⁸ Response 4.4 (Pg 82): Annual Review of Regulatory Burdens on Business: Manufacturing and Distributive Trades (August 2008); www.pc.gov.au

⁹ <http://www.finance.gov.au/publications/response-to-the-pc-manufacturing-and-distributive-trades-review/index.html>

In addition, the Guild advocates for a promotional campaign to inform consumers of how the system is meant to work and their rights in making a complaint. We also advocate for the development of clear and concise guidelines, with a corresponding training campaign, for product sponsors and retailers to ensure they understand:

- their responsibilities
- how to ensure that any advertising or promotional materials are in line with relevant standards and codes and
- how the complaint process works, and which body is responsible for managing complaints and what the consequences may be.

The Co-regulatory model

The Guild is strongly supportive of the existing co-regulatory model of therapeutic goods promotion. The existing system fosters a strong open collaborative partnership between Government and industry organisations. This relationship is vital to ensuring advertisers receive clear guidance and communication in producing responsible advertising which complies with regulatory requirements.

The broad coverage of the TGAC and diverse nature of the therapeutic goods industry would make a self-regulatory model nearly impossible to implement successfully. However, co-regulation requires very clear direction to delineate responsibility and identify the arrangements and processes in place to minimise oversight or lapses.

2. The pre-approval process

a. Should the current pre-approval process for advertising be retained?

The Guild strongly supports retaining the pre-approval process. We believe the pre-approval process is essential for maintaining integrity in the promotion of therapeutic goods to consumers.

Whilst the Guild supports utilising the expertise of the three bodies responsible for the pre-approval of advertising materials (Medicines Australia, ASMI and CHC), we would like to see greater consistency in the approval process for all therapeutic products and greater transparency.

And reiterating a previous point, industry and retailers need to be clearly informed about the pre-approval process and what actions are necessary to obtain approval. Initiatives to encourage further uptake of the education seminars presented by the TGA and ASMI would be welcome.

b. If so, should all forms of advertising be considered in this process?

We are in principle supportive of extending the pre-approval process to apply to all forms of advertising, however the burden this would place on the approvals process would be prohibitive.

The Guild does not have a position regarding whether advertisements for therapeutic devices should be included in the pre-approval process. We note however that the Complaints Resolution Panel (CRP) experiences a high volume of complaints in relation to therapeutic devices.

We are aware that issues have been identified with some in-store promotional materials that are not subject to pre-approval processes, particularly for listed complementary medicines such as weight-loss products. The pre-approval process would be invaluable in promoting compliance with advertising regulations in such cases.

Pharmacists often publish direct-to-consumer advertising material and in doing so, generally carry the responsibility to ensure the materials meet all the relevant codes and standards. Requiring that only some advertising materials gain approval adds to the confusion and increases the risk of oversight by the pharmacist, leaving them vulnerable to disciplinary action for predominantly inadvertent omissions.

c. Challenges in implementation

The Guild supports the requirement for pre-approval prior to publication, but believes that this is unachievable due to the burden of volume and challenges in policing such as system.

- *The volume of material to be considered would cripple the pre-approvals process*
Materials currently not requiring pre-approval includes in-store promotional material, internet and other electronic material, medical devices, direct marketing material and catalogue advertising. These materials may be prepared by either the sponsor or the retailer. Particularly in the case of electronic media, the volume and complexity of advertisements means that under current arrangements, it is neither practical nor timely to require pre-approval. However, it does merit further consideration.
- *Cost of pre-approval*
The maintenance of the pre-approval system is borne by the advertiser. In-store promotion and electronic material often have a much smaller audience and smaller budgets than advertising placed in specified media. As such, the cost of pre-approval may form a substantial barrier to the advertiser. The Guild would be concerned if community pharmacies were asked to bear a financial cost in the pre-approval of website and in-store promotional material.
- *Quality assurance*
Arrangements are needed to ensure that the publicised advertisement is the same as that which was approved. We are aware of complaints in which the advertisement put to air varies from the approved copy.

3. Complaints mechanisms:

In its policy on the advertising of medicines, the Guild asserts that all advertisements for medicines should include a mandatory statement regarding the advertising code and how to make a complaint.

Pharmacists publish direct-to-consumer advertisements for therapeutic goods which may be the subject of a complaint. Generally complaints have been made to the pharmacist's registering authority and/or the Health Complaints Commission in the relevant state or territory. These different health complaints mechanisms are not

necessarily integrated with the national system for advertising complaints and have been further complicated by the NRAS which came into effect as of 1 July 2010.

Responsibility for managing complaints

The Guild is aware of the frustration from pharmacy owners of having complaints previously being made to the state/territory Pharmacy Board about dubious pharmacy advertising practices to be advised that it must be dealt with by the TGA, only to find that there has been little recourse or follow-through and that the practice continues. This not only disillusiones the pharmacists who abide by the various standards and codes, but there is no incentive for those pharmacies in breach to mend their ways. In observing poor advertising practices continue, there is a risk that other pharmacies may copy these poor practices which is of great concern to the pharmacy profession as a whole.

For individual pharmacists, professional complaints are directed to the NPBA for action, or in the case of New South Wales, to the NSW Healthcare Complaints Commission. As complaints may also be directed to the CRP for consideration, a pharmacy advertisement may be subject to two complaint processes with associated penalties or disciplinary action under federal and state regulations.

The Guild believes that the CRP is the appropriate forum for complaints regarding advertising of pharmacy products or services to be considered. The NPBA or the Healthcare Complaints Commission should only consider complaints about advertising where they demonstrate gross professional misconduct by a pharmacist or group of pharmacists.

Any refinement of the regulatory system for advertising should be considered in the context of these self-regulatory processes for the pharmacy profession and remove duplicative processes, with formal referral processes implemented where appropriate. It is important that professional pharmacy organisations such as the Guild continue to be involved in discussions for revising the regulatory system for advertising.

Buying groups/Banner groups

Another complexity for administering regulatory measures within community pharmacy is the fact that many community pharmacies are part of 'buying groups' or 'banner groups'. These groups usually include pharmacies from multiple states and territories and provide the pharmacies with advertising material as part of their agreements. There is no possibility for each individual pharmacist to have direct control over the content of this material. Under the TGA regulatory arrangements, the 'buying group' or 'banner group' as the entity responsible for such advertisements must adhere to regulatory codes and standards. However, the pharmacist owner/manager has the professional responsibility for the same advertisement under NRAS. This makes it very confusing for pharmacists and industry as well as the regulatory bodies and means there is potential for pharmacists to be unwittingly in breach of some of the professional codes or standards.

As mentioned earlier, the Guild believes that guidelines be developed for community pharmacy and industry which clearly and concisely delineates requirements, obligations and complaints processes with regards to the advertising of therapeutic goods. The Guild could then advise members to ensure that pharmacy agreements between pharmacy owners and 'buying groups' or 'banner groups' contained clauses

which ensured those groups had an obligation to comply with relevant codes. Pharmacy owners could also be made more aware of their obligations and responsibilities.

a. Should the TGA publish on its website information related to products removed from the Australian Register of Therapeutic Goods (ARTG)?

Yes, the Guild agrees that this information should be published on the ARTG. Furthermore, we support having greater transparency with the advertising process for therapeutic goods and associated complaints mechanisms. In fact, we believe that then the ARTG could be greatly improved and made more user-friendly for public use by improving the search capabilities and the information provided in the initial list of 'search results', such as:

- registration status and
- whether a product is 'Registered' or 'Listed'.

Improving the search capability by ingredient would also greatly enhance the functionality of the ARTG for public use, improving transparency relating to a product's registration status.

The Guild would welcome the opportunity to further discuss with the TGA ways in which the public search function could be enhanced to improve the effectiveness of the database and to facilitate transparency.

b. Should the CRP be reconstituted as an independent body?

It is essential that the CRP has the appropriate expertise in its membership, and that the membership is equitably distributed to ensure holistic representation and independence. The Guild believes the current model of the CRP works well, however we would be supportive of moves to review the quorum requirements of the panel.

Any pharmacy health professional representative on the CRP needs to be strongly familiar with not only pharmacy practice and regulations regarding advertising, but additionally professional practice standards, QCPP, codes of ethics, the regulation of medicines generally and professional programs. It is highly unlikely that a representative could be identified without nomination from professional organisations which represent the profession.

We would support a review of the quorum requirements to CRP to ensure greater representation of health care professionals in all meetings. Health care professionals are often under-represented in panel meetings, and a requirement for at least two health care professionals to be present may be appropriate.

The Guild is also concerned with the CRP having to deal with complaints relating to efficacy, or evidence of, which is often not within the scope of expertise for the CRP. The complexity of these complaints can significantly impact on their efficiency in managing the number of complaints they receive. We fully support having complaints relating to efficacy being referred to the TGA for consideration.

c. Should the CRP consider complaints about all forms of advertising?

The Guild strongly supports the proposal for the CRP to consider complaints relating to all forms of advertising for therapeutic products. This would not only streamline and fortify the complaints process, but also provide greater consistency.

There is concern that ‘below-the-line’ media which is not produced by ASMI or CHC members ‘falls between the cracks’ of advertising regulation. This would include in-store displays, direct mailings or catalogues.

The challenge of this recommendation is the increased volume the CRP may need to consider. Appropriate resourcing is required to ensure the CRP continues to make appropriate and considered determinations.

‘Trivial complaints’

There is a suggestion for trivial complaints to be managed separately to the CRP. Our concern with this is the subjectivity in classifying what complaints are ‘trivial’. Having separate arrangements to manage trivial complaints as compared to those that are more serious may increase the risk of problem advertisements ‘slipping through the gap’. This is particularly relevant as the CRP often identifies other matters in complaints which may initially be regarded as ‘trivial’.

Rather than having a completely separate mechanism for dealing with trivial matters, the CRP could implement a ‘filtering’ process so that trivial matters are dealt with perfunctorily and matters that are more serious or for which there is uncertainty can be dealt with more thoroughly by the CRP. Such a filtering process would need clear guidelines and appropriate risk-management strategies to be in place to ensure transparency in the process and to minimise lapses.

Managing complaints for therapeutic services

Complaints relating to advertising therapeutic services are not managed by the CRP and there is a risk that these may ‘fall through the cracks’. Such complaints should be dealt with by a formal referral process back to appropriate regulatory bodies, such as health care practitioner regulatory boards.

‘News’ Items

Currently, any content contained within news, current affairs or entertainment programming is exempt from the TGAC. The Guild is concerned that this exemption, intended to protect the reporting of ‘bona fide’ news, can be exploited by product sponsors. We are aware of many cases where programs have broadcast ‘news stories’ which appear little more than loosely veiled promotional activities for products with limited or questionable efficacy.

There are no regulatory controls for such activities, and it would seem there is greater concern regarding ‘Listed’ products. It is not uncommon for pharmacies to be inundated with requests for products that have been ‘discussed’ in current affairs programs. An example of this is the product ‘Cellasene^{®10}’, which featured heavily in current affairs programs in the late 1990s. This product was promoted as a natural treatment for cellulite and pharmacies and health food stores could

¹⁰ <http://www.mlmwatch.org/04C/RSI/rsi04.html>

not keep up with the demand. This product also had issues of misleading promotion and misrepresentation in the United States of America¹¹. There was also a flurry of ‘me-too’ products that quickly entered the market.

With such consumer demand, pharmacists had limited access to information regarding the product’s efficacy or safety, putting them in an awkward position in trying to balance their professional responsibility with the consumer’s desire to self-treat with the new ‘wonder product’.

The Guild believes judgements on what constitutes bona fide news and what constitutes advertorial should be made on the basis of their presentation rather than the program in which it is broadcast. Deleting the word ‘program’ from Section 3.1(c) of the TGAC may be one way of addressing this.

d. Should civil penalties apply for breaches of the regime?

The Guild supports stronger sanctions for those that breach advertising codes or standards, so long as a reasonable investment has been made into informing and training industry and retailers of the processes and their responsibilities.

Currently, unless a restricted representation is made, advertising breaches are unlikely to receive a penalty any stronger than a notice to withdraw the advertisement and to not repeat the misdemeanour. Even in the worst cases, the strongest penalty imposed is a 180 day retraction.

In many cases, by the time the CRP has made a determination, the run of the advertisement in specified media is complete. As such, a request to remove the representation and not repeat it within 12 months appears little disincentive to abide by the Therapeutic Goods Act and the TGAC.

Advertisements which make reference to prohibited representations should be subject to penalties in addition to retraction of an advertisement.

We would be supportive of stronger penalties for repeat breaches or publication of advertisements following a ‘refusal to approve’ being issued by an Advertising Services Manager. Repeat breaches should be considered not just in cases of an individual product, but to all brand extensions. One example of this could be the Ease-a-Cold[®] product range, for which the CRP has had to review multiple complaints of a similar nature for similar products with different Aust L numbers.

Although stronger penalties are needed to enhance compliance with advertising regulation, discretion should be used in cases where breaches are genuinely of an inadvertent nature. Pharmacists in particular need clear direction and access to information as they may be subject to penalties imposed under the profession’s self-regulatory process as well as federal or state civil penalties.

¹¹ <http://www.mlmwatch.org/04C/RSI/cellasesuit.html>

4. General comment

Therapeutic Goods Advertising Code Council

The Guild has some concerns regarding the structure and voting arrangements of the Therapeutic Goods Advertising Code Council (TGACC). We feel it is important to ensure the TGACC has an equitable distribution of professional to industry membership. Should one group be unduly weighted, it is natural that decisions would tend to favour those with the greater representation. We feel the TGACC appears heavily biased towards the advertising industry and those who represent medicine/device sponsors and would benefit from more health care professional involvement to provide some balance. We would support a review of the structure and terms of reference for the TGACC.

Assessing efficacy and therapeutic claims

As discussed earlier, the Guild agrees that it is more appropriate for the TGA to investigate matters relating to efficacy. The TGA has greater scope and expertise than either the CRP or the TGACC to investigate such matters. This would mean that complaints regarding efficacy should be referred by the CRP to the TGA for consideration. It is important however that this referral and response occur in a timely manner.

To further clarify our position, any assumption that therapeutic claims in relation to a 'Registered' product have already been considered by the TGA during the product registration process is dangerous. Issues of efficacy need to be considered specifically in relation to the claims which are made in advertising material, which may or may not relate to the evidence which supported the ARTG listing. Additionally there are many medicines which were grandfathered onto the ARTG when it was created and have hence not been tested for efficacy.

We also suggest that advertising guidelines could be improved to ensure greater clarity for reference by all parties involved in the advertising process. As an example, clarity should be given to distinguish advertising claims versus therapeutic claims. For clarification, an advertisement may claim '4 out of 5 people prefer Brand A' and have the data to support this statistic. This is an advertisement claim and should not be confused with therapeutic claims, such as '4 out of 5 people respond well to Brand A without any side-effects'.

Pharmacy Assistants

The TGAC applies to all advertisements for therapeutic goods, except under the exemptions listed in 3.1 of the code. This means that any material directed to pharmacy assistants which promotes the use of therapeutic goods needs to comply with the code.

While pharmacy assistants are not health care professionals, they are involved in the supply of therapeutic goods to consumers. Consideration on what constitutes appropriate education and product promotion of medicines to this group is important. Currently advertising material in media directed to pharmacy assistants must include the mandatory statements 'Use only as directed' and 'If symptoms persist, see your healthcare professional'. These warning statements are out of place in advertising designed to encourage supply rather than consumption of these products.

Pharmacy assistant training presents an additional challenge. A literal interpretation of the TGAC could find independent bona fide training material in breach of the code,

particularly in relation to restricted and prohibited representations. For example, training which discussed medicines and devices for chronic conditions, such as diabetes, asthma or blood pressure would likely be in breach of the code.

Registered Training Organisations (RTOs) who produce Certificate II, III and IV training for pharmacy assistants must comply with the Australian Quality Training Framework (AQTF), which requires materials to be accurate and impartial.

The Guild believes the following principles in promoting therapeutic goods to pharmacy assistants should apply:

- The activities of pharmacy assistants are regulated as they work under the supervision of a pharmacist who must comply with legal and professional obligations.
- Advertisements should be appropriately tailored, recognising the role of pharmacy assistants in supplying therapeutic goods.
- Bona fide training resources produced by RTOs should be exempt from the TGAC.

Price Lists

A recurring issue for pharmacists has been the dubious use of price lists to promote therapeutic goods. Even with the availability of the Price Information Code of Practice¹², we are often advised that price lists for various pharmacy groups continue to be circulated with phrases such as ‘lowest price guaranteed’. Concern has also been expressed that the price lists do not advise that for particular medicines also covered by the Pharmaceutical Benefits Scheme (PBS), dispensing at the ‘listed price’ might negate any of the ‘Safety Net’¹³ advantages associated with the PBS.

The issue of ‘price lists’ is also one for which we are often advised by members that there appears to be no clear or consistent manner in which complaints are dealt with. We believe the CRP should be given the jurisdiction to deal with such complaints with strong penalties for repeat offences.

Conclusion

The Guild congratulates the TGA in taking the initiative to undertake a review process of the regulatory processes associated with the advertising of therapeutic goods. The proposed amendments provide an opportunity to improve the current arrangements which are not only confusing, but have a number of inconsistencies.

Pharmacy is very much involved in the advertising of therapeutic goods, both in direct-to-consumer advertising and from sponsor-to-pharmacy and the Guild remains available for future collaboration with the TGA to resolve issues related to advertising to and from pharmacy.

¹² <http://www.tga.gov.au/advert/index.htm>

¹³ <http://www.medicareaustralia.gov.au/provider/pbs/pharmacists/safety-net.jsp>

Reference Sources:

References are available on request

- i. QCPP 2nd Edition; May 2006: Version 1.0
- ii. Pharmacy Guild of Australia Policy: Advertising of Medicines
- iii. TGA website
- iv. AHPRA website
- v. Australian Government Department of Health and Ageing website
- vi. Australian Government Productivity Commission website
- vii. Australian Government Department of Finance and Deregulation website

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