Submission in response to the
Advertising Therapeutic Goods in Australia Consultation Paper

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The Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

CHF welcomes the opportunity to comment on the *Advertising Therapeutic Goods in Australia Consultation Paper*, released by the Therapeutic Goods Administration (TGA) on 30 June 2010. The advertising of therapeutic goods to consumers has long been an area of concern for CHF, as advertising of therapeutic goods can be extremely persuasive. It is essential that there are strong regulatory arrangements in place to ensure that the information provided to consumers through advertisements is accurate and supported by evidence. CHF supports the Object of the Therapeutic Goods Advertising Code 2007:

> *…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.*

However, CHF considers that there are flaws in the current regulatory arrangements of therapeutic goods advertising in Australia that must be addressed if the Object of the Code is to be met.

This submission addresses the consultation questions provided in the Consultation Paper.

Overall awareness of the arrangements for advertising of therapeutic goods

Are the current arrangements for advertising of therapeutic goods in Australia known to you? Should these be better known or understood?

CHF is aware of the current arrangements for the advertising of therapeutic goods in Australia. However, the current arrangements are confusing and inconsistent, as outlined in our response to the next question. Some information on the multiple arrangements in place for complaints handling, including addresses for making complaints, is available on the TGA's website, but it is of concern that there does not appear to be a link to the Complaints Resolution Panel's website (www.tgacrp.com.au).

The general lack of public recognition of the TGA and its role and functions, including those relating to advertising of therapeutic goods, create challenges in building public awareness of the current arrangements. CHF recognises that the TGA currently lacks the resources for promotion, but argues that ***building public awareness of the current arrangements and complaints mechanisms is essential.***

CHF's members report unfamiliarity with the arrangements and may find that the inconsistencies and complexities of the current regulatory arrangements are difficult to understand, which is a factor in discouraging consumers from reporting concerns or making complaints. As one consumer commented,

> *The several complaint mechanisms and the different addresses for the agencies make it very difficult for consumers to lodge complaints. Consumers are, after all, busy people who are likely to have priorities other than complaining about advertisements, however justifiable and important the claim might be. A single point of contact would be a major help for the consumer who has a complaint – or even a question.*

Similarly, another consumer commented,

> *Unless a consumer was associated in some way with the therapeutic goods industry they would not know there were any controls, any regulations or any complaints processes; nor would they know how to access this information. Worse, few would question the advertised claims. Even if consumers did have access to the Advertising Code, they would not understand it! It is not consumer friendly.*

Arguably, current arrangements could be better promoted, including through the provision of more comprehensive information (including relevant links) on the TGA's website and the provision of information and links to complaints processes on other websites (for example, the NPS website). ***Funding for education of consumers and health professionals about the regulatory framework for therapeutic goods advertising, and how to make a complaint if consumers are concerned about an advertisement, would also demonstrate the stated commitment to reducing misleading and deceptive marketing and advertising of therapeutic goods.***

Do you have comments or complaints about the current advertising arrangements?

CHF has a number of concerns about the current regulatory arrangements for advertising of therapeutic goods.

- *Lack of consistency in requirements for different media*

  There is currently a lack of consistency in how advertisements are handled in different forms of media. As noted in the Consultation Paper, advertisements to be published in print media, radio and television for non-prescription medicines require pre-approval, but advertisements to be published on the internet or in-store do not require pre-approval, even if they are for the same products and include the same content. The reasoning behind this discrepancy is unclear. While CHF accepts that there is a resource implication for the TGA in policing the latter, this should not be the reason for the TGA to diminish its responsibility in ensuring that this form of advertising is socially responsible and that the TGA continues to perform its function as the responsible regulatory body. ***CHF believes that the TGA needs to reconsider the priority it assigns to its functions as the regulator of therapeutic goods advertising and administrator of the Therapeutic Goods Advertising Code, with greater emphasis placed on resourcing these functions, if the Government has a genuine commitment to meeting the Code objectives.***

  The multiple approval mechanisms in place may also create confusion and a lack of consistency, particularly for complementary medicines. Advertisements for complementary medicines in broadcast media or cinematograph films must be approved by the Australian Self-Medication Industry (ASMI), but advertisements in

other forms of media must be approved by the Complementary Healthcare Council (CHC). The same advertisement for a complementary medicine, presented in two different media, may therefore require separate approvals from two bodies, even if the content is identical.

- *Lack of consistency in complaints handling*

  There are also inconsistencies in how complaints about advertising of therapeutic goods are handled. Complaints about print media, radio, television and internet advertisements for non-prescription medicines and medical devices may be made to the TGA's Complaints Resolution Panel (CRP), but complaints about other advertisements (for example, in-store promotions) must be made to either the CHC (for complementary medicines) or to ASMI (for non-complementary over the counter medicines). As noted in the Consultation Paper, this means that a complaint about the same advertisement in two different media (for example, in a newspaper and and an in-store brochure) must be made to two different complaints bodies, 'even if the substance of the advertisement and the complaint is the same'. ***The separation of these functions creates confusion and inconsistency, and processes should be streamlined for the purposes of accountability, transparency and ease of use for the complainant.***

- *Adequacy of current complaints mechanisms*

  CHF has a number of concerns about the adequacy of current complaints mechanisms, including the deterrent effects of the current sanctions. These concerns are addressed in detail in response to questions under the *Complaints mechanisms* heading below.

- *Transparency*

  Some consumers have expressed concerns about transparency of complaints procedures, including outcomes of complaints once they are referred to the TGA by the CRP. Again, this is addressed under the *Complaints mechanisms* heading.

- *Applicability of the Code to all forms of direct-to-consumer advertising*

  Under current regulatory arrangements, direct-to-consumer advertising of prescription medicines, and most medicines which can only be obtained through a pharmacist, is banned. However, CHF has been contacted by consumers and health professionals raising concerns about a form of 'de facto' direct-to-consumer advertising, which involves advertisements that do not mention the name of a specific medicine, but encourage consumers to 'ask your doctor' about new treatment options or types of medications.

  One example from 2009 involved advertisements by Pfizer for a combination heart pill, advising consumers to talk to their doctor if they are taking multiple medications for their heart. Print versions of these advertisements including a tear-off section to be taken to the doctor, saying '*I'd like to discuss my treatment for high blood pressure or high cholesterol. Please advise me if a combination heart pill is suitable'*. Pfizer's brand and logo were prominently placed in the advertisement. The marketing to consumers was matched by advertisements for the medication in publications targeted at health professionals, advising doctors that '*patients will soon be asking about their suitability for combination heart medications'*.

A consumer group sought information from Medicines Australia and the TGA about whether these advertisements breached restrictions on direct-to-consumer advertising of prescription medicines. The Medicines Australia Code of Conduct Committee determined that these advertisements did not breach the code as they did not promote a specific product. No response was received from the TGA.[1]

This example is not unique, with 'unbranded' advertisements of this type also reported for HIV, osteoporosis and erectile dysfunction. ***It is essential that this kind of advertising to consumers is addressed by advertising regulations, and existing loopholes are closed.***

Using the Advertising Arrangements

Do you currently use the arrangements to place approved advertisements?

Not applicable.

Do you find advertisements of therapeutic goods helpful?

CHF recognises that there may be value to consumers in the advertisement of therapeutic goods, as advertising can inform consumers about availability of new products or changes or improvements to existing products. However, ***it is essential that advertising meets all requirements in sections 4, 5 and 6 of the Therapeutic Advertising Code 2007 to ensure that consumers have all relevant and credible information and are able to make informed decisions about these products.***

The pre-approval process

Should the current pre-approval process for advertising be retained? If so, should all forms of advertising be considered in this process?

Regardless of what process is in place for advertising approvals, there must be consistency across different forms of advertising. ***If the pre-approval process is to be retained, then it should apply to all forms of advertising, including those to which it currently does not apply, for example internet advertising and in-store promotions. Further, if a pre-approvals process is retained, it would arguably be more efficient if there was a single pre-approvals process, if not for all therapeutic goods than at least for each class of therapeutic goods.*** This would streamline the current arrangement whereby advertisements for complementary medicines in different media must be approved by two different bodies.

If the pre-approval process is not retained, then it must be replaced by a rigorous monitoring process which:

[1] Croakey 2009 'Where does the TGA stand on Pfizer campaign?', 13 October 2009, online at http://blogs.crikey.com.au/croakey/2009/10/13/where-does-the-tga-stand-on-pfizer-campaign/, accessed 20 August 2010; Croakey 2009 'When is an ad not an ad?', 8 June 2009, online at http://blogs.crikey.com.au/croakey/2009/06/08/when-is-an-ad-not-an-ad/, accessed 20 August 2010.

- is fully funded
- includes educational activities to inform consumers and health professionals of the requirements for therapeutic goods advertising
- is integrated with a process for managing breaches and complaints that has the power to impose sanctions that are sufficiently severe to have a genuine deterrent effect.

Given the difficulties that would be involved in monitoring advertising across all media, particularly internet advertising, CHF is inclined to recommend that some form of pre-approval process should be retained to ensure that advertising meets regulatory requirements. The pre-approval process should have a particular focus on the validity of claims made in the advertisements.

Complaints mechanism

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

CHF would welcome the publication of information on the TGA website about products that have been removed from the ARTG, as this would increase transparency of regulatory processes. This information should include information about why products have been removed, including if they have been removed by a sponsor.

To further increase regulatory transparency, ***the TGA should publish on its website the outcomes of all complaints referred to it by other complaints resolutions bodies.*** Currently, consumers are concerned that there is a lack of transparency about what occurs after a complaint has been referred to the TGA due to industry non-compliance with a decision by the CRP. In May 2010, CHF was advised by the Parliamentary Secretary for Health, the Hon Mark Butler MP, that he intended to ask the TGA to consider whether complaints outcomes should be included in materials to be published following recent amendments to the *Therapeutic Goods Act 1989*. CHF would strongly support publication of complaints outcomes by the TGA.

Should the CRP be reconstituted as an independent body?

CHF does not consider that the CRP needs to be reconstituted as an independent body, though we would welcome greater transparency about the arrangements that are currently in place to address any conflicts of interest that arise. Consumers have also identified that it is important that any complaints handling bodies, including the CRP, should include consumer representation going beyond a single 'token' consumer. It has been suggested that ***such bodies should include at least two consumer representatives, who are supported with appropriate briefings about the relevant legislation and regulations, as well as supported financially with payment of sitting fees and expenses.***

Should the CRP consider complaints about all forms of advertising?

CHF strongly believes that there should be a single body to consider complaints about all forms of advertising. Current procedures are inconsistent and inefficient, particularly when complaints about the same advertisement in different forms have to go through different complaints processes. This single body could be based on the existing CRP structure, or could be a new body. However, ***if the CRP (or another body) is to consider complaints about all forms of advertising, it should be appropriately resourced and have the power to impose enforceable sanctions that are sufficiently severe to deter breaches.***

Should civil penalties apply for breaches of the regime?

If regulatory arrangements for the advertising of therapeutic goods are to be effective, there must be more effective penalties in place for breaches of the regime. Civil penalties are likely to provide a more effective means of sanction than the current criminal penalties, which are rarely applied.

CHF would strongly support the introduction of sanctions and penalty arrangements that are enforceable and provide real deterrents against breaches and ensure that effective remedial action is taken when advertisements are found to breach the regime. A range of civil penalties including infringement notices and enforceable undertakings including fines, corrective advertising orders and delisting of products (combined with a refusal to list a product substantially similar to one that has been cancelled until relevant remedial action is taken) would be far more effective than the current sanctions, which have proven to be ineffective.

Recommendations

The TGA should reconsider the priority it assigns to its functions as the regulator of therapeutic goods advertising and administrator of the Therapeutic Goods Advertising Code, with greater emphasis placed on resourcing these functions, if the Government has a genuine commitment to meeting the Code objectives.

The TGA should receive sufficient resourcing to promote its role and functions and build public awareness of the current arrangements and complaints mechanisms for therapeutic goods advertising.

Funding should be provided to an appropriate body/bodies for the education of consumers and health professionals about the regulatory framework for therapeutic goods advertising and how to make a complaint.

Complaints handling processes should be streamlined for accountability, transparency and ease of use for complainants.

Advertising regulations must address existing loopholes that allow unbranded or 'Ask Your Doctor' advertisements to consumers to continue.

If a pre-approval process is to be retained, it must apply to all forms of advertising, and current arrangements should be streamlined through a single pre-approval process.

If the pre-approval process is not retained, then it must be replaced by a rigorous monitoring process which is fully funded; includes educational activities to inform consumers and health professionals of the requirements for therapeutic goods advertising; and is integrated with a process for managing breaches and complaints that has the power to impose sanctions that are sufficiently severe to have a genuine deterrent effect.

The TGA should publish on its website the outcomes of all complaints referred to it by other complaints resolutions bodies.

Complaints handling bodies should include at least two appropriately supported consumer representatives.

A single body, with appropriate resourcing and powers to impose enforceable sanctions, should consider complaints about all forms of advertising.

Sanctions and penalty arrangements should be enforceable and sufficiently severe to provide real deterrents against breaches and ensure that effective remedial action is taken when advertisements are found to breach the regime.

Conclusion

In this submission, CHF has raised a number of concerns about the current arrangements for the regulation of therapeutic goods advertising in Australia, including:

- inadequate information for consumers about current arrangements
- lack of consistency in requirements for different media
- lack of consistency in how complaints are handled
- inadequacy of current complaints mechanisms, including the deterrent effect of current sanctions
- lack of transparency
- inapplicability of the current arrangements to all forms of direct-to-consumer advertising.

CHF argues that, in order for the TGA to adequately meet the object of its own Advertising Code, it must place appropriate resourcing priority on performing its function as the body responsible for monitoring and regulating advertising of therapeutic goods to consumers.

CHF would strongly support the introduction of a single complaints process for therapeutic goods advertising, covering advertising in all media, combined with the introduction of genuine sanctions for breaches of the regulatory regime. In addition, there must be consumer education about how therapeutic goods can be advertised, and how consumers can raise concerns or make a complaint. Improvements to current arrangements are essential if consumers are to be confident that advertising of therapeutic goods promotes the quality use of therapeutic goods, is socially responsible and does not mislead or deceive the consumer.

Representing consumers on national health issues

Consumers Health Forum of Australia

The Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

CHF does this by:

1. advocating for appropriate and equitable healthcare
2. undertaking consumer-based research and developing a strong consumer knowledge base
3. identifying key issues in safety and quality of health services for consumers
4. raising the health literacy of consumers, health professionals and stakeholders
5. providing a strong national voice for health consumers and supporting consumer participation in health policy and program decision making

CHF values:

- our members' knowledge, experience and involvement
- development of an integrated healthcare system that values the consumer experience
- prevention and early intervention
- collaborative integrated healthcare
- working in partnership

CHF member organisations reach thousands of Australian health consumers across a wide range of health interests and health system experiences. CHF policy is developed through consultation with members, ensuring that CHF maintains a broad, representative, health consumer perspective.

CHF is committed to being an active advocate in the ongoing development of Australian health policy and practice.