Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Advertising Therapeutic Goods in Australia: Consultation Paper

June 2010

Purpose

The objective of this paper is to consult interested parties on options for reform to the regulatory arrangements for advertising therapeutic goods. After consideration of comments on the attached questions, the Government will identify a preferred package of reforms.

Objectives

Most developed countries have a system of regulating the advertising of therapeutic goods as part of their wider system of regulating therapeutic goods. This is because the way in which therapeutic goods are advertised can have implications for the way in which they are used, and hence for their safety and efficacy.

The Government's objectives are to achieve a regulatory framework for advertising therapeutic goods that is more efficient, effective, transparent and consistent than the current system, that balances the risks and benefits, and that adopts a risk management approach complementary to that used for regulating therapeutic goods.

A system of advertising regulation for therapeutic goods should contribute to the quality use of medicines by ensuring that health care professionals and consumers receive accurate information about the quality, safety and efficacy of medicines. It is particularly important that consumers receive accurate information about the benefits and risks of those goods that they can safely access without the intervention of a health care professional.

Background

Current model

In Australia advertisements for therapeutic goods are generally subject to the requirements and limitations of the *Therapeutic Goods Act 1989* (the Act) and subordinate legislation made under the Act. Some advertisements for some goods are subject to "self-regulation" by industry bodies, and promotional material directed to health care professionals for prescription medicines is required under the Act to adhere to a particular industry code of conduct.

Direct-to-consumer advertising of medicines which require a prescription (Schedules 4 and 8) is banned, and so generally is such advertising for medicines which may only be obtained through a pharmacist (Schedule 3). Advertisements for these medicines to health professionals must comply with the Medicines Australia Code of Conduct. Advertisements for other medicines and devices must comply with the Therapeutic Goods Advertising Code made under the Act.

Complaints about some forms of advertisements for therapeutic goods may be directed to a Complaints Resolution Panel established under the Therapeutic Goods Regulations, while complaints about other types of advertisements may be made to industry associations or directly to the Therapeutic Goods Administration (TGA).

Address: PO Box 100 Woden ACT 2606 Website: www.tga.gov.au
Telephone: 02 6232 8444 Facsimile: 02 6232 8605 ABN 40 939 406 804

It is important to note that these arrangements do not apply to healthcare services or practices. Where the advertisement is not about a therapeutic good but rather a service, there are other more appropriate consumer protection arrangements such as the Australian Competition and Consumer Commission (ACCC).

Concerns have been raised by some opponents of the current advertising framework that the system is not working to protect consumers as well as it might.

There have also been claims that the current arrangements impose unnecessary regulatory burdens on some industry sectors.

These are not new issues. Developing a robust advertising regime that addressed weaknesses in the Australian regime and accommodated the New Zealand scheme was an important part of the Australia New Zealand Therapeutic Products Authority process.

More recently the Productivity Commission in its *Review of the Regulatory Burdens on Business: Manufacturing and Distributive Trades* (2008) expressed concerns over the plethora of interlocking and overlapping controls over marketing and advertising that include significant cross portfolio and inter- and intra-jurisdictional legislative requirements. The Commission recommended (4.4) that:

> **"**after further consideration of the most appropriate model, the Australian Government should streamline and clarify advertising rules and work with state and territory governments to ensure reforms also address the need for a simplified system for complaints about national advertising."

Government has accepted this recommendation in principle, agreed that it will consider changes to the advertising regulatory arrangements to streamline requirements and reduce regulatory burdens, and consult with interested parties on the proposed revised arrangements.

Optimising current arrangements

It has been suggested that some aspects of the current arrangements do not provide optimal arrangements for ensuring the public health objectives of the advertising framework are met.

First, there is perceived inconsistency in the approach to handling of advertisements in different media. Advertisements in print media, radio and television for non-prescription medicines require pre-approval, but the same advertisements on the internet or in-store promotional material do not. Complaints about print media, radio, television and internet advertisements for non-prescription medicines and medical devices may be made to the Complaints Resolution Panel (CRP), but complaints about other advertisements may not. A complaint about the same advertisement in a newspaper and in an in-store flyer must be directed to two different places, even if the substance of the advertisement and the complaint is the same.

Second, the complaints mechanism is facing significant increases in workload and spends much of its time dealing with evidence of efficacy issues which should be handled within the TGA as part of the regulatory process.

Third, there is a perception that the complaints handling process is not as transparent as it could be, and that the sanctions available to CRP and the TGA do not provide sufficient deterrence.

Some options

A number of potential options have been prepared to enhance the operation and effectiveness of the advertising arrangements. These include:

- The TGA could publish on its website information related to products removed from the ARTG for advertising offences.
- The Complaints Resolution Panel could refer directly to the TGA all matters related to efficacy of products.
- The Government could move to increase and broaden the level of penalties and sanctions associated with breaches of the advertising arrangements.
- The Government could reconstitute the membership of the Complaints Resolution Panel to ensure greater independence.

Next steps

Feedback is sought on the options proposed above and on the specific questions that follow.

Electronic submissions addressing these matters should be emailed to:

advertising.consultation@tga.gov.au

Hard copy submissions addressing these matters should be addressed to:

The Project Officer
Advertising Consultation
Regulatory Reform
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

All submissions will be published on the TGA Website. For submissions made by individuals, all personal details will be removed where possible from the submission before it is published**.**

Confidential material contained within a submission should be clearly marked. Reasons for a claim to confidentially must be included. Where possible, confidential material will be removed from material published on the TGA's website.

It would be helpful if your submission included:

- A contact name and full contact details including: address, telephone number and , if applicable, facsimile and email address

Enquiries should be directed via email to advertising.consultation@tga.gov.au, or to 02 6232 8560.

Interested parties should respond by close of business Friday 27 August 2010.

Consultation Questions

Overall awareness of the arrangements for advertising of therapeutic goods:

Questions for consideration:

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

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

Using the advertising arrangements:

Questions for consideration:

Do you currently use the arrangements to place approved advertisements?

OR

Do you find advertisements of therapeutic goods helpful?

The pre-approval process:

Questions for Consideration:

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

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

- Advertising of non-prescription medicines in print, radio and television do require pre-approval, but others do not eg internet, in-store promotion.

Complaints mechanisms:

Questions for consideration:

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

- In order to enhance the transparency of regulatory processes, it is proposed that the TGA will regularly publish on its website those products that have been removed from the ARTG as a result of a regulatory decision.

Should the Complaints Resolution Panel (CRP) be reconstituted as an independent body?

- Currently the CRP is made up of nominees from industry associations, professional organisations, peak consumer organisations and the TGA, and has an independent chair.
- Virtually all complaints considered by the CRP are related to members or potential members of the industry associations represented on the Panel.
- If an independent complaints resolution body is to be maintained, any perceptions of conflicts of interest could be addressed by requiring members to be independent of the therapeutic goods and advertising industries.

Should the CRP consider complaints about all forms of advertising?

- Some media for non-prescription medicines and medical devices are within scope of the CRP's oversight e.g. print, radio and television, but others are currently exempt e.g. in-store promotion.
- Many complaints handled by the CRP are essentially trivial and straightforward and may be better dealt with in another way.

Should civil penalties apply for breaches of the regime?

- More broadly, there are no provisions for seeking civil penalties or enforceable undertakings for breaches of the advertising provisions of the legislation.
- Any revised sanction and penalty arrangements need to provide a regime that is both a real deterrent against transgression, and ensures the effective remediation of advertisements that are found to be in breach.
- The sanctions regime under the legislation could be strengthened to include civil penalty contravention provisions and court-imposed remedial action for advertising breaches.
- The TGA could also be given the power to refuse to list a product that was substantially similar to one that had been cancelled unless and until the relevant remedial action had been taken.