Principles for a Regulatory Scheme for the Advertising of Therapeutic Products

February 2007

Purpose

This document highlights some of the key issues for consumers about the advertising of therapeutic products. It will assist consumer representatives and members provide input to the Australia New Zealand Therapeutic Products Authority (ANZTPA) on the draft *Australia New Zealand Therapeutic Products Regulatory Scheme (Advertising) Rule 2006*.

The document draws on the work of the Consumers' Health Forum of Australia (CHF) on Quality Use of Medicines over many years, including community engagement and Consumer Representatives' meetings. It presents some principles, with rationale, on which a sound regulatory scheme for the advertising of therapeutic products should be based.

Policy principles

To promote public health and safety and restrict misleading advertising of therapeutic products, CHF encourages a regulatory scheme that reflects the following key principles:

Policy Principle 1 – Objectives reflect public health and safety

The prime objective of the scheme to regulate the advertising of therapeutic products should be the protection and enhancement of public health and safety through the prevention of misleading or inappropriate advertising.

That objective must not be reduced or compromised by consideration of industry or other interests.

Policy Principle 2 – Decisions are transparent, accountable & clearly communicated

There should be transparency and accountability of all regulatory agency decision making in relation to the advertising of therapeutic products.

Regulatory agency decision making processes and decisions must be communicated clearly and be easily accessible.

Policy Principle 3 – Consumers must participate in decisions about advertising

Decisions made in relation to the advertising of therapeutic products should be made in partnership with consumers.

Policy Principle 4 – No direct to consumer advertising

Direct to consumer advertising of prescription medicines should remain prohibited in Australia, and harmonisation with New Zealand should not lower existing standards.

Policy Principle 5 – Advertising must be approved

Advertisements for therapeutic goods should be pre-approved by a competent and appropriately resourced body.

Advertisements that make any therapeutic claims for a product should be approved and the claims need to be supported by reliable data.

Any advertisement for a therapeutic product in any form of contemporary or emerging media should be subject to the proposed regulatory scheme.

Policy Principle 6 – Effective system of complaints

The system of complaints handling should be simple, easy to understand and accessible by consumers through a single point of contact.

The system should be adequately resourced to ensure it is efficient and effective and that complaints are heard within reasonable timeframes.

The regulatory scheme should provide for the protection of public health and safety through monitoring of compliance with the scheme, by taking timely action when complaints are received, and by ensuring penalties provide a meaningful disincentive to publishing misleading advertising.

Policy Principle 7 – Transitional arrangements maintain high standards

Any transitional arrangements should not, for the sake of administrative ease or convenience or any other reason, diminish the primacy of the public health and safety objectives of the legislative scheme.

Introduction

Australia New Zealand Therapeutic Products Authority

On 10 December 2003 the Australian and New Zealand governments signed an agreement to establish a joint scheme for the regulation of therapeutic products in the two countries. The Australia New Zealand Therapeutic Products Authority (ANZTPA) will replace the Australian Therapeutic Goods Administration (TGA) and the New Zealand Medicines and Medical Devices Safety Authority (Medsafe) and be accountable to both the Australian and New Zealand governments for the protection of public health and safety through the regulation of therapeutic products (medicines, medical devices, and complementary medicines/dietary supplements that have therapeutic uses).

As part of their 'Phase 2' consultations, ANZTPA released a draft Advertising Rule and a plain English guide to the rule.

Purpose of this Document

This document highlights some of the key issues for consumers about the advertising of therapeutic products. It will assist consumer representatives participating in consultations with the Australia New Zealand Therapeutic Products Authority (ANZTPA) on the draft *Australia New Zealand Therapeutic Products Regulatory Scheme (Advertising) Rule 2006*.

The document draws on past submissions prepared by the Consumers' Health Forum of Australia (CHF), as well as previous and more recent consultations with consumers. It presents some principles on which a sound regulatory scheme for the advertising of therapeutic products should be based and briefly explains the rationale behind each principle.

Policy Principles

Policy Principle 1 – Objectives reflect public health and safety

> The prime objective of the scheme to regulate the advertising of therapeutic products should be the protection and enhancement of public health and safety through the prevention of misleading or inappropriate advertising.
>
> That objective must not be reduced or compromised by consideration of industry or other interests.

The protection and enhancement of public health and safety through the prevention of misleading or otherwise inappropriate advertising of therapeutic goods must be the primary objective of the scheme which regulates the advertising of therapeutic goods. This is the fundamental reason for regulating therapeutic goods advertising.

If this clarity of purpose is lacking or is diluted by other objectives that may compete with or even contradict the public health and safety objective, then the public cannot be confident that the regulator, or other body(ies) with responsibility for implementing aspects of the scheme, is acting entirely in the interest of public health.

Policy Principle 2 – Decisions are transparent, accountable & clearly communicated

There should be transparency and accountability of all regulatory agency decision making in relation to the advertising of therapeutic products.

Regulatory agency decision making processes and decisions must be communicated clearly and be easily accessible.

Any organisation dealing with public health and safety and making decisions involving degrees of risk must be open and transparent to the community it serves and have strong accountability mechanisms in place. The current government policy of full cost recovery from industry for the regulatory processes emphasises the need for transparency and accountability. This will help maintain public confidence that industry is not able to use its funding to apply inappropriate pressure to the regulatory processes.

In addition, many of the regulatory agencies need to put more resources into communicating their processes and decisions, this is particularly so for complaints processes around the advertising of therapeutic products. Agencies generally do not report clearly and through sources which are accessible to consumers.

Policy Principle 3 – Consumers must participate in decisions about advertising

Decisions made in relation to the advertising of therapeutic products should be made in partnership with consumers.

For processes around the advertising of therapeutic products to be trusted by consumers, the processes need to be open to input by consumers and incorporate community and consumer values in decision making.

Consumers play a very important role in defining the nature and level of acceptable risk in relation to whether an advertisement for a therapeutic product is approved or whether a complaint in relation to an advertisement is upheld. The test contained in the current Australian *Therapeutic Goods Advertising Code 2006*, that '[t]he conformity of an advertisement with this Code should be assessed in terms of its probable impact upon the *reasonable person* to whom the advertisement is directed' [emphasis added], demonstrates the nature of decision making in relation to the advertising of therapeutic goods and the requirement that processes should be undertaken in partnership with consumers.

Policy Principle 4 – No Direct to Consumer Advertising

Direct to consumer advertising of prescription medicines should remain prohibited in Australia, and harmonisation with New Zealand should not lower existing standards.

CHF has consistently taken the position that regulatory harmonisation with New Zealand should not lower existing standards in Australia. It is understood that the proposal under the ANZTPA scheme is to proceed with the existing arrangements of different policies in respect of direct-to-consumer advertising in Australia and New Zealand, although this is not explicitly explained in the supporting material to the draft Advertising Rule.

Australia and the European Union (EU) currently prohibit the advertising of prescription medicines direct to consumers. New Zealand and the United States of America (USA) currently do not restrict advertising of prescription medicines. Research on this type of advertising in the USA and New Zealand cites a range of responses in relation to advertising of prescription medicines:

- increased risk behaviour due to perceptions that an illness was easily treated
- increased numbers of consumers requesting a medicine by name regardless of whether it was the most effective medicine for an illness
- increased prescription medicines cost
- lack of impartial and objective information, including when medicines had been withdrawn from sale due to patient deaths
- pharmaceutical companies with the most money to spend on marketing end up with the highest medicine sales, and
- increased promotion of medicines as an alternative to 'common sense' approaches to health, including dietary changes and exercise.[1]

These research findings are consistent with the concerns of CHF members that there are no real benefits to consumers in direct-to-consumer advertising, and that concerns about the risks of misleading information, extension of the market, and treatment safety are indeed real.

Policy Principle 5 – Advertising must be approved

Advertisements for therapeutic goods should be pre-approved by a competent and appropriately resourced body.

Advertisements that make any therapeutic claims for a product should be approved and the claims need to be supported by reliable data.

Any advertisement for a therapeutic product in any form of contemporary or emerging media should be subject to the proposed regulatory scheme.

Confusion sometimes arises as to whether an advertisement is for a therapeutic product, a cosmetic or a food. Advertisers, either inadvertently or otherwise, sometimes make therapeutic claims in advertisements for cosmetics or food. Any advertisement which makes a therapeutic claim should be considered an advertisement subject to the Advertising Rule. This is a simple way of ensuring manufacturers uphold the regulatory scheme.

A modern regulatory scheme for the advertising of therapeutic products should recognise that advertising is no longer restricted to television, radio and print-media, but incorporates other forms including short-message-service (SMS), internet advertising, multi-media messaging (MMS) and electronic mail, and should have flexibility to incorporate emerging media.

The regulatory scheme should also be constructed to ensure only bona fide 'before and after' comparisons are used in advertisements for therapeutic goods. 'Before and after' comparisons in advertisements are often misleading and encourage unrealistic expectations by consumers. Advertisers are suspected of using photographic tricks and other enhancements to present a better 'after' image (or worse 'before' image) to demonstrate the alleged effectiveness of their product.

Testimonials by health professionals should not be permitted in any advertising of therapeutic products.

The regulatory scheme should ensure proactive vetting of advertisements to ensure they are not misleading or otherwise contrary to the Advertising Rule. It is not sufficient that advertisements in breach of the Advertising Rule are identified through complaints as there will be a delay in having the advertisement withdrawn and the company may have already achieved its mass communication marketing aims.

Policy Principle 6 – Effective system of complaints

> The system of complaints handling should be simple, easy to understand and accessible by consumers through a single point of contact.
>
> The system should be adequately resourced to ensure it is efficient and effective and that complaints are heard within reasonable timeframes.
>
> The regulatory scheme should provide for the protection of public health and safety through monitoring of compliance with the scheme, by taking timely action when complaints are received, and by ensuring penalties provide a meaningful disincentive to publishing misleading advertising.

In Australia, complaints about inappropriate advertising to consumers are directed to relevant industry bodies initially, depending on the media in which the advertisement appears. Complaints about advertisements in media such as newspapers, television and radio are directed to the *Complaints Resolution Panel* of the *Therapeutic Goods Advertising Code Council*. There are two consumer representatives on the Panel, one from each of CHF and the Australian Consumers' Association (now CHOICE).

There are some criticisms of the current arrangements in Australia, including a lack of consumer awareness of the complaints process and that the system is cumbersome and untimely.

In New Zealand there are separate processes for complaints from consumers and for those made by competing pharmaceutical companies. There is a perception that the New Zealand model is efficient and effective, however, recent research found that information about risks was absent, incomplete or illegible in a range of direct-to-consumer advertisements[2].

On balance, Australia should work to improve awareness of complaints and advertising among consumers and ensure that consumer involvement is strengthened and not diminished in any future arrangements with New Zealand.

Simplicity and Accessibility

Consumers may need to access the complaints handling system for a variety of reasons – including to make complaints, to find information and to understand the regulations under which products are advertised. A consumer focused regulatory scheme for the advertising of therapeutic products must be accessible by consumers. It must be easy to understand and be able to be accessed wherever a consumer is geographically. At the moment consumers are not able to access the system easily because of its complexity, and because of the low profile of the bodies which administer the current scheme (for example, the *Therapeutic Goods*

Advertising Code Council). The administrative arrangements around the regulatory scheme should ensure that consumers understand who the agencies are and their roles and powers.

There should also be simple, easy to use points of access to the complaints system available to consumers. For example, a single telephone service, with a single access number, should be available through which consumers can be directed to the appropriate agency or body to make a complaint, be that complaint in relation to therapeutic good advertising, or other advertising for food or other consumer products.

Timeliness

There is currently a back-log of complaints to be heard by the *Complaints Resolution Panel* of the *Therapeutic Goods Advertising Code Council*. The large number of complaints lodged by one pharmaceutical company complaining against another is one reason for this, the under-resourcing of the agency tasked with administering the complaints processes is another. Delays in the hearing of complaints can mean that the advertiser has gained the benefit from the advertising before any complaint is heard. Also, any retraction or correction which might be required will not appear as a timely response to the advertisement itself, and may be meaningless to the consumer reading it.

Powers and Penalties

The market for non-prescription medicines in Australia is enormous and highly competitive. Manufacturers advertising their products are seeking a share of this market. Where they have done so by publishing misleading advertisements, they should be penalised appropriately. Penalties must provide a meaningful disincentive to publishing misleading advertising.

Where retractions or corrections are required, these should be published in the same publication as the original advertisement, and be of a similar size and prominence.

Policy Principle 7 – Transitional Arrangements

Any transitional arrangements should not, for the sake of administrative ease or convenience, diminish the primacy of the public health and safety objectives of the legislative scheme.

The regulatory scheme, for advertising and in other areas, being proposed under ANZTPA will require some restructuring of administrative and other arrangements in both Australia and New Zealand. The primary purpose of the regulatory scheme (that is, the protection of public health and safety) should not be diminished while these new arrangements are being put in place.

Further Reading

Consumers' Health Forum of Australia. Submission – A Proposal for a Trans Tasman Agency to Regulate Therapeutic Products, Discussion Paper. Canberra: CHF, 2002. Available at http://www.chf.org.au/publications/all_search3.asp?id=341.

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[1] Health Action International. Direct-to-Consumer Prescription Drug Advertising – The European Commission's Proposals for Legislative Change. Amsterdam: HAI-Europe, 2001. Viewed on 15 February 2007, http://www.haiweb.org/campaign/DTCA/BMintzes_en.pdf.

[2] Pratt 2000 in Health Action International. Direct-to-Consumer Prescription Drug Advertising – The European Commission's Proposals for Legislative Change. Amsterdam: HAI-Europe, 2001. Viewed on 15 February 2007, http://www.haiweb.org/campaign/DTCA/BMintzes_en.pdf.

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