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Regulatory reform
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Dear Sir / Madam,

Advertising Therapeutic Goods in Australia: Consultation Paper

We write in relation to the above Consultation Paper, and would like to provide the comments below.

1. Preamble

Over the last two decades ASMI has developed an enviable reputation which is based on its ability to ensure responsible behaviour in the market through self-regulation. It is ASMI's position that a relevant, timely, cost-effective and responsible system for advertising therapeutic goods can (and should) be based on co-regulatory and self-regulatory principles.

We request that this consultation process be informed by the substantial quantity of work previously undertaken in relation to the advertising of therapeutic products under the trans-Tasman regulatory authority ("ANZTPA").

Although ANZTPA is no longer being pursued, it is ASMI's opinion that the multi-stakeholder collaboration previously undertaken produced a robust, consensus-based scheme, much of which is still relevant.

In particular we would like to draw attention to the following relevant documents:

- *Report of a review of Advertising therapeutic Products in Australia and New Zealand*, Toogoolawa Consulting Pty Ltd, November 2002 (the "Toogoolawa report")
- *Proposed Trans-Tasman Model for the Regulation of Advertising of Therapeutic Products*, Interim Advertising Council, October 2004 (the "IAC model")
- *Australia New Zealand Therapeutic Products Advertising Code*, Version 11, November 2004 (the "TPAC")
- *Australia New Zealand Therapeutic Products Regulatory Scheme (Advertising) Rule 2006* (the "Joint Scheme")

We further request that the reforms which proceed from this Consultation Paper be negotiated, developed, communicated and implemented in a timely, open and transparent manner. It is essential that any such reform process proceed on the basis of full consultation with all stakeholders.

2. Overview

Before addressing the specific questions asked in the Consultation Paper we would like to broadly outline the characteristics of what we believe to be an appropriate scheme.

2.1 Purpose

It is ASMI's opinion that reforms to the current system should (consistent with the IAC report of 2004):

- Effectively protect the public interest and public health and safety.
- Capture and retain existing self-regulatory processes where they are working well, within a co-regulatory framework.
- Improve the cost-effectiveness and timeliness of the system.
- Provide consumers with an appropriate education about the system including a well understood avenue for the submission of complaints.
- Achieve consistency of treatment and outcomes between industry sectors and advertisers.

2.2 Advertising Codes

It is ASMI's opinion that the advertising of all therapeutic goods in all media should be covered by effective and relevant codes of practice. Advertising to consumers should be covered by a single principles-based code. Advertising to Healthcare Professionals (HCP's) should be covered by a similar principles-based code that applies to all therapeutic goods. This HCP code would be supplemented with industry sector specific codes containing more detailed requirements.

2.3 Advertising Scheme

It is ASMI's opinion that an effective advertising scheme would have:

- Application to all advertisers regardless of membership of any industry association.
- Application to all advertising regardless of the medium employed.
- Timely, relevant and cost-effective pre-approval of designated types of advertising.
- Timely, relevant and cost-effective monitoring of advertising not subject to pre-approval.
- Timely, consistent and transparent complaints mechanisms for all advertising.
- Effective sanctions.
- Judicious use of self-regulatory, co-regulatory and non-regulatory approaches consistent with the COAG Principles of Best Practice Regulation.

Such a scheme has been summarised in the following table:

Proposed Advertising Scheme		
Item	**Co-regulatory component**	**Self-regulatory component**
Code of practice – Description	TGAC	Principles based code + Industry sector specific codes
Code of practice – Scope	Advertising to consumers	Advertising to HCP's
Complaints panel	CRP	Industry panels
Sanctions	Range of sanctions specified in the *Therapeutic Goods Act*, enforceable against all advertisers	Range of sanctions specified in the industry codes of practice, enforceable against all advertisers
Pre-approval of advertising	Applicable to certain, identified media based on assessment of risk and resources	
Monitoring of advertising	All other media not subject to pre-approval (with an appropriate range of sanctions)	

3. Specific Questions from the current Consultation Paper

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

The current arrangements for advertising are understood by ASMI and ASMI members.

However, knowledge and understanding can always be improved and it is suggested that the current TGACC seminars be supplemented with a range of education and training materials targeted to the various stakeholders.

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

ASMI members have a number of concerns in relation to the current system:

Non-association members

ASMI members are concerned at the lack of effective complaint mechanisms in relation to certain advertising generated by non-association members.

If a non-association member places consumer advertising in specified media, complaints may be lodged with the CRP (in relation the TGAC) who can then impose sanctions on the advertiser if the advertising is found to be in breach. However, if a non-association member places consumer advertising in other media (or directs advertising to healthcare professionals), then there is no complaints panel to which a complaint may be addressed. While the complainant may report the matter to the TGA, this course of action rarely results in a transparent outcome.

ASMI therefore suggests that reforms be adopted to introduce a more level playing field in this area, by way of:

- Making compliance with industry codes of practice in relation to HCP advertising a condition of registration, regardless of the advertiser's membership of an industry association.
- Revising the jurisdiction of the CRP so that it can hear complaints in relation to all consumer advertising, regardless of medium (the desired effect would be that the CRP is the single Panel to which all complaints in relation to consumer advertising is addressed).

Effective sanctions

ASMI members are concerned that CRP lacks the power to impose effective and relevant sanctions. ASMI suggests that the CRP's powers be extended to allow it to issue orders, impose fines and to accept enforceable undertakings.

Prompt Determinations

ASMI members are concerned at delays in the hearing of complaints. Because advertising will often remain in place until a determination is made, it is essential that decisions be made promptly. If advertising is found to be in breach it is important to minimise the consumers' exposure to such advertising. ASMI members question the effectiveness of all but the most severe sanctions when the determination is made after the advertising campaign has finished.

Appeals in relation to CRP Determinations

ASMI members are concerned that neither the complainant nor the advertiser has a right of appeal in relation to CRP determinations. However, any right of appeal should not interfere with the requirement for prompt corrective action when warranted.

Do you currently use the arrangements to place approved advertisements?

ASMI members use the pre-approval process.

Do you find advertisements of therapeutic goods helpful?

ASMI members find advertisements for therapeutic goods to be essential for maintaining a viable medicines industry (consistent with the National Medicines Policy).

ASMI members also consider advertising to be essential for creating consumer awareness and encouraging appropriate and responsible use of self-medication to treat and prevent illness.

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

ASMI considers that the current pre-approval process is timely and cost-effective.

It is ASMI's position that the current demarcation between the advertising which requires pre-approval, and the advertising which does not, is arbitrary and reflects a practical decision regarding resources rather than a decision based on protecting consumers.

It is ASMI's position that pre-approval provides valuable and objective insights to advertisers, protects consumers and is more effective at preventing inappropriate communication than increasing penalties.

Consistent with the above, ASMI propose the following:

- In principle, if pre-approval is to be applied, it should be applied all forms of advertising directed to consumers.
- In practice, pre-approval may need to be limited to certain forms of advertising directed to consumers and that any such demarcation would be based on practical considerations, such as the availability of resources and the potential risks to consumers.
- Should any change from the current arrangements be made (for example to include pre-approval of internet advertising) the timeliness and costs of approvals should not be adversely affected. Any such change would require a Regulation Impact Statement (RIS).
- All advertising not subject to pre-approval should be the subject of a timely, relevant and cost-effective monitoring program which includes appropriate sanctions and applies to all advertisers regardless of industry association membership.

Consideration should be given to the expansion of the delegated authority to approve advertising to include accredited persons and entities. It is suggested that appropriately trained and accountable persons could be used to pre-approve advertising (similar to the TAPS arrangements in New Zealand). Such a reform has the potential to reduce approval times.

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

See above.

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

Yes.

It is also ASMI's position that the process of removal of products from the ARTG should be as transparent as possible.

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

It is ASMI's position that the CRP is already an independent body.

The function, membership and processes of the CRP are defined in *Therapeutic Goods Regulations*.

The constitution of the CRP represents a wide range of stakeholders representing industry, consumers and healthcare professionals. It is ASMI's position that such a wide range of membership is necessary to ensure that the Panel has the expertise required to effectively meet its obligations.

It is ASMI's position that the nomination of the Panel Chairperson by the TGACC remains appropriate.

It is ASMI's position that the use by the Panel of majority vote to determine questions remains appropriate.

It is ASMI's position that it is not the independence of the CRP that is in issue, it is the speed with which determinations are made that is in issue. We suggest that delays experienced by the Panel could be addressed by either of the following:

- Increased resources which would allow the CRP to meet more frequently.
- Reduced need for the CRP to consider efficacy data would allow the CRP to determine individual complaints more quickly (discussed in more detail below).

ASMI suggests that the membership of the CRP be expanded to include a member with communication and advertising expertise.

Should the CRP consider complaints about all forms of advertising?

It is ASMI's position that the CRP should consider all forms of advertising directed to consumers (regardless of advertising medium).

Should civil penalties apply for breaches of the regime?

It is ASMI's position that sanctions should be enforceable and effective.

Sanctions in relation to consumer advertising should be applied by the CRP.

Sanctions in relation to HCP advertising should be applied by industry panels. A range of sanctions should be available with the severity to be commensurate with the risk to public health and safety.

In order to be effective and business impacting, penalties should also take into account the differences between industry sectors (in terms of budgets, types of products and typical advertising media):

- What constitutes a financial disincentive to a small advertiser may be no disincentive to a larger advertiser.
- Removal of a listable product from the ARTG may create less impact than removal of a registrable product
- Publication of a retraction statement on a web site may have less impact than publication in an industry journal.

Other matters

A range of other matters are discussed in the "Preamble" and "Overview" above.

Additionally, ASMI would like to comment on the issue of the CRP dealing with questions of efficacy. It is ASMI's position that the efficacy assessment of therapeutic goods is the responsibility of the Regulator. Neither the delegates responsible for pre-approval nor the CRP should be used in place of the Regulator for the assessment of the efficacy of therapeutic goods. An increase in the level of post-marketing review by the TGA would reduce the need for the delegates and the CRP to determine matters of efficacy. This is not to suggest that the CRP should be prevented from reviewing data in order to determine compliance with the TGAC. In fact, such a review is essential for determining compliance with sections 4(1)(b) and 4(2)(c) of the TGAC. It is ASMI's position that the CRP and the delegates responsible for pre-approval should be able to review data used as the basis for claims, but this is not the same as evaluating the efficacy of a product.

Contact Details

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Yours faithfully,

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