26 August 2010

The Project Officer
Advertising Consultation
Regulatory reform
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

Dear Sir / Madam,

Advertising Therapeutic Goods in Australia: Consultation Paper

This submission is presented by The Communications Council. We write in relation to the above Consultation Paper, and would like to provide the comments below.

Preamble & Credentials

The Communications Council is the peak body representing the marketing communications industry. The Healthcare Communications Council (HCC) is a key committee within the Communications Council which aims to encourage the highest professional standards among all member agencies while helping clients to better understand and appreciate the value of agency services.

The Communications Council welcomes the Commonwealth Government's desire to improve advertising arrangements for therapeutic goods. In particular its 'support of self-regulation of industry conduct', as flagged in the Parliamentary Secretary for Health's recent paper.

The Communications Council is in a unique position to put forward a point of view in respect of any proposed changes to the advertising code, by virtue of its sub-committee the Healthcare Communications Council (HCC), which includes almost all the Australian specialist healthcare communication companies, who work with the regulations on a daily basis.

Members of the HCC are those advertising agencies who have the necessary specialist skills and resources to prepare communication programmes for any class of therapeutic product and to understand the regulatory codes that affect these programmes.

The Communications Council has prepared a submission that approaches the regulatory issue from a practical perspective, in the expectation that the advertising industry via the Communications Council might play a more beneficial role in the design, implementation and on-going maintenance/refinement of the amended regulatory system.

Review of requirements

Overall Objective:

To 'streamline and clarify advertising rules and work with State and Territory government to ensure reforms also address the need for a simplified system for complaints about national advertising'.

In principle the CC endorses the objectives but questions the role of State and Territory Governments other than overall approval and commitment to a new improved system.

Areas of Concern

1.0 Inconsistency in approvals

2.0 Limitations of Complaints Resolution Panel in scope, workload, implementation/penalties and transparency.

3.0 Awareness (esp. Public awareness) of advertising regulation.

> The Communications Council agrees that all three of these issues need addressing and our recommendations are to be found in the answers to the specific questions below.

Questions

1.0 Overall awareness of the arrangements for the advertising of therapeutic goods.

1.1 Are the current arrangements for the advertising of therapeutic goods in Australia known to you?

> Yes, it is our business to know them, keep up to date with them and apply them to the communication programs we produce on behalf of our clients.

1.2 Should they be better known or understood?

> Yes we believe there is benefit to a wider understanding that the advertising of therapeutic goods is covered by a strictly policed co-regulatory code.
>
> This will require a government funded information programme similar to that which the mainstream advertising industry has been successfully running to publicise and invite comment/complaints to the Advertising Services Board (ASB).

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

> In reflecting on the current arrangements that are a mix of government regulation and self-regulation, there do not appear to have been any major problems that have affected Public health and safety.
>
> Undeniably there have been problems as a result of sponsors breaking or circumnavigating the regulations, but the system itself works well, except in the area of policing and enforcement. While there are complaints in the main these are from well-known activists with particular agendas and the ability to exploit media interest.

The Parliamentary Secretary has indicated that he is in favour of 'strengthening self-regulation.' Whether this leads to a totally self-regulated approach as is working in NZ, or the continuation of a co-regulatory system is for further discussion. We will assume for this discussion that there will still be Commonwealth Government involvement by way of underpinning legislation to allow self-regulation but at the same time legislate for more effective penalties and their more timely enforcement, to deter those who break the regulations (see below 4.0).

The Communications Council supports the concept of an industry framework for universal adherence to consistent industry-wide codes, based on a common set of high level principles. This was a key recommendation as spelt out in the final version of the Australia New Zealand Therapeutic Products Advertising Code (ANZTPAC). It would not be difficult for all the relevant industry bodies to amend their self-regulatory codes to both incorporate and reflect these principles.

The ANZTPAC essentially provides a workable blueprint for an overarching framework for the regulation of all therapeutic goods advertising together with detail as to how it could work by accommodating all industry self-regulatory codes.

The amendments it suggests cover all the code problems highlighted. It also includes the need for a government funded monitoring system to ensure regulations/codes are being observed in both above and below the line material. It also provides for an alternative 2-tiered governance system and a slightly revised complaints board composition.

Recommendation:

The Communications Council would recommend that consideration be given to the adoption in Australia of the proposed ANZTPAC code less its NZ components.

2.0 Using the current advertising arrangements.

2.1 Do you currently use the arrangements to place approved advertisements?

Yes it is the focus of part of our industry's business.

2.2 Do you find advertisements of therapeutic goods helpful?

As consumers we do find ads of therapeutic goods helpful. Without them the public would have little appreciation of what options are available to self-treat their minor ailments and symptoms without troubling their GP and therefore incurring a cost for Medicare.

As far as HCPs are concerned, advertising communication programs perform an important role in keeping them informed of new treatment options available to their patients.

3.0 The Pre-approval Process

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

Yes but it should be augmented (see below).

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

No (see below)

Towards an improved approval process

There is an implication that all advertisements from TV commercials to mailings on particular prescription drugs should go through an approval process irrespective of media. The current system has evolved because *consumers* have limited abilities to judge the benefit of therapeutic claims in an advertisement and so some form of pre-vetting of OTC advertising is required to ensure they are not going to be misled. Currently the main advertising campaigns require approval only if they are to appear in mainstream media ie print or broadcast (excluding digital). Not all advertising material, irrespective of whether or not it derives from the main advertising campaign, requires pre-approval, but is still required to observe the relevant code. Rather than provide more and costly resources for more pre-approvals, we recommend an effective monitoring system for consumer materials both above and below the line, rather than relying on complaints.

There is also the assumption that all ads are pre-approved at sponsor/company level by a suitably qualified executive. To facilitate this, it is for consideration that the Delegated Authority (DA) system from NZ is adopted that allows for suitably trained company executives or independent consultants to provide approval for all material in all media. A centralized approval process as exists now, subcontracted to ASMI & CHC would still approve new campaigns in mainstream media as recommended in ANZTPAC. They would also be available for those small sponsors without the necessary resources to employ a DA and to implement training courses for DAs.

MTAA (Devices) would be included in the above system.

Those sponsors not a part of any industry group who currently "escape/avoid" regulation would as a condition of listing/registration, have to nominate which industry code they agree to be regulated by.

Recommendation

The Communications Council recommends retention of the current system of approval for consumer ads provided that adequate monitoring and policing is in place backed by suitable and enforceable penalties. CC also recommends the NZ DA system be considered for adoption in Australia.

As far as the approval of prescription drug advertising materials is concerned the self-regulatory code does not require pre-approval. HCPs are judged to have knowledge in their relevant fields, and are able to discriminate between information of value and advertising hyperbole.

There have been concerns expressed in the Secretary's paper about HCPs decisions being based on incentives rather than sound clinical advice. The current relevant Code from Medicines Australia (MA) expressly forbids such behaviour and is empowered to deal effectively with any breaches that are brought to its attention.

There are also very strict rules for Medical education that those agencies accredited by the RACGP, strictly adhere to.

Recommendation

The Communications Council sees no reason for the inclusion of a pre-approval process into MA's code.

4.0 Complaints mechanisms

4.1 Should the TGA publish on its website, information related to products removed from the ARTG?

In the interests of transparency, the Communications Council would support this, but with the proviso that should the offending sponsor subsequently address the regulatory issue satisfactorily, their name should be removed and a note included that they had regained their listing.

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

With the exception of a small number of activists there appears to be no major dissatisfaction with the constitution of the current CRP. The current panel does however lack a member with hands-on advertising/communication experience.

Recommendation

The Communications Council recommends that the CRP remain as currently constituted with the inclusion of a member with communication and advertising experience. We would suggest that a retired healthcare advertising executive be considered for this role.

The CRP should also be granted greatly increased powers of implementation and penalties (see below*).*

4.3 Should the CRP consider complaints about all forms of (therapeutic goods) advertising?

Currently all industries have a complaints procedure and these, as opposed to the central CRP should handle below the line complaints about OTC products. With all sponsors having to declare which code they will observe at ARTG stage they should also be made aware they are also liable to its penalties.

As regards ads in different media, it is recommended that the CRP continues to handle complaints about all ads for OTC products placed in any form of paid for media; however it is recommended that trivial complaints such as lack of key numbers should be handled by CRP at desk-level.

Complaints about prescription products should continue to be handled by the MA Code complaints committee.

4.4 Should civil penalties apply for breaches of the regime?

Yes. This has been the key problem facing the CRP, which will require the underpinning of law to enforce it.

On the issue of transparency, the determinations of the CRP are already published in full on the TGACC website for any public scrutiny. All industry complaints bodies will be required to publish their determinations as a condition of being part of the new regulatory system.

On the issue of products similar to those cancelled by TGA for breaches of the code - we do not agree that they should be refused listing, unless the same company in order to try and circumvent the code that their previous product had breached, was launching the product.

5.0 Other

5.1 Labelling and brand names.

TGA should be empowered to refuse to list/register a product with a brand name that was or implied a therapeutic claim which could not be substantiated e.g. Fat-Blaster.

5.2 Governance

It is recommended that the 2-tiered governance arrangements as recommended for the administration of ANZTPAC be adopted.

SUMMARY

The ANZTPAC proposals of July 2005 address all the issues raised by the Secretary in his paper and answers all the questions raised by the TGA in its call for submissions.

These recommendations should be adopted as soon as possible including a major information programme to inform all stakeholders of its intent and scope.

We also believe the extra amendments in this submission further enhance the effectiveness of the new regulatory system.