SUBMISSION BY COMMERCIAL RADIO AUSTRALIA

CONSULTATION: THERAPEUTIC GOODS ADVERTISING CODE

October 2017

Commercial Radio Australia (**CRA**) is the peak industry body representing the interests of commercial radio broadcasters throughout Australia. CRA has 260 member stations, comprising 99% of the Australian commercial radio industry.

CRA welcomes the opportunity to respond to the Department of Health's Consultation[1] (**Consultation**) regarding amendments to the *Therapeutic Goods Advertising Code 2015* (**TGA Code**).

We note that the Department plans to publish a draft amended TGA Code in late 2017/early 2018. We will make submissions regarding the detail at that stage.

In the meantime, we set out below a number of broad points, which we urge the Department to take into account when drafting the new Code.

1. Summary

- The TGA Code currently operates in conjunction with the ASMI approval system, which provides advertisers and broadcasters with a clear and robust means of achieving compliance under the *Therapeutic Goods Act 1989* (**TGA**).
- A detailed review of the TGA Code is difficult in the absence of further information regarding the surrounding framework of the therapeutic goods advertising regime, particularly the nature and extent of any specialist approval process.
- Our comments are based on the premise that advertisers will have access to some form of specialist approval mechanism, whether it is mandatory or not. Without such a mechanism, the detail contained in the TGA Code is likely to require further amendment.
- CRA maintains its opposition to any proposal that the pre-approval system be abolished and replaced by an entirely self-regulatory system.
- However, If the ASMI mandatory pre-approval system is removed, CRA is open to its replacement by a non-mandatory approval mechanism. This will enable a specialist approval body to continue to approve advertisements on a non-mandatory basis.

[1] Consultation: Therapeutic Goods Advertising Code (August 2017)

Although the scheme will be non-mandatory, we would seek legislative protection for broadcasters that broadcast an 'approved' advert. At a minimum, an approval should satisfy the 'reasonable steps' requirement in the broadcasters' exemption.

- CRA urges the Department to consider extending the exemptions currently available in the TGA Code. In particular, the exemptions available to radio advertisements of 15 seconds or less should be extended to radio advertisements of 30 seconds or less.
- CRA supports the proposal to permit direct to consumer advertising of an increased range of over the counter medicines.

2. Retention of the TGA Code

The commercial radio industry agrees that a TGA Code should be retained, as a means of setting out the key principles applicable to the advertising of therapeutic goods.

CRA broadly supports the proposals that:

- the Code should 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.[2]
- the advertising of therapeutic goods should continue to be regulated under a legislative framework that includes a Code[3];
- the Code should remove the inconsistencies between the treatment of medicines and medical devices where appropriate[4];
- the Code should provide for objective tests to determine breaches of the Code (on the basis that broadcasters generally will have a reduced level of liability under section 42DLB(10) of the *Therapeutic Goods Amendment (2017 Measures No 1) Bill 2017*) (**TGA Amendment Bill**)[5]; and
- the Code should permit direct to consumer advertising of a wider range of Schedule 3 substances.[6]

However, CRA maintains its resistance to Recommendation 55, namely that 'the whole process of vetting and pre-approval of the advertising of therapeutic products to the public is stopped in favour of a more self-regulatory regime'.

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[2] Page 4, Consultation.

[3] Recommendation 52 of the Expert Panel Review of Medicines and Medical Devices Regulation.

[4] Ibid. Recommendation 54.

[5] Page 4, Consultation.

[6] Page 5, Consultation

The TGA Code operates within the context of a more extensive regulatory regime, as prescribed under the TGA. Accordingly, the issue of whether there will be a mandatory or non-mandatory pre-approval mechanism must be resolved before the detail of the TGA Code can be finalised.

3. Concerns regarding abolition of pre-approval mechanism

CRA continues to resist the suggestion that the current pre-approval system for advertisements for medicines should be replaced with an entirely self-regulatory system.[7][8]

The pre-approval system works effectively and greatly assists broadcasters in complying with the TGA and associated rules around medicine advertising. It is effective in achieving:

- evidence based decisions from specialists;
- consistency; and
- consumer protection.

Specialist knowledge

The pre-approval process ensures that advertisements for medicines are assessed by individuals with appropriate technical and scientific expertise. The regulation of therapeutic good advertising is a highly specialised area and should only be undertaken by individuals with specific experience in the area.

A self-regulatory regime is likely to involve decisions from people without the level of specialisation of the pre-approval assessors. This may lead inadvertently to the publication of advertisements that contravene the TGA and associated regulations.

The impact of such advertisements on public health is potentially serious, and the damage may not be repaired by stronger civil or criminal penalties. In order properly to protect consumers, the focus must remain on preventing such advertisements from going to air, rather than on sanctions for infringement.

Consistency

The pre-approval process ensures consistency in application of the TGA. It ensures that the claims are considered in a consistent way, both in relation to the product and the TGA.

[7] Recommendation 55.

[8] Currently, advertisements for medicines must be approved by the Australian Self-Medication Industry (**ASMI**). This is also required as a licence condition under clause 6, Schedule 2, Part 2 of the *Broadcasting Services Act 1992*.

A self-regulatory system is likely to include more variance and inconsistency between permitted claims. This is uncertain for broadcasters, placing them at risk of infringement, and is confusing for consumers.

Protection for consumers

The pre-approval process carries important public health and safety benefits, by ensuring that the claims are TGA compliant and factually accurate.

A self-regulatory system, accompanied by increased sanctions, would not provide the same level of protection for consumers. The damage caused by an inaccurate claim may not be reparable, as it may involve damage to a consumer's health and wellbeing.

The key objective of any legislative framework must be to *prevent* breaches from occurring, rather than imposing penalties once the breach has occurred. Pre-approvals are the best means of achieving this level of protection for the community.

4. Non-mandatory pre-approval mechanism

CRA is concerned that the abolition of mandatory pre-approvals by ASMI will leave broadcasters without the requisite specialist knowledge to assess whether advertisements for therapeutic goods are compliant with the TGA Code. This could expose broadcasters to a new level of liability.

This is a particularly significant issue for commercial radio, given the nature of the industry.

CRA has 260 member stations, 220 of which are located in rural or regional Australia. These stations do not have in-house legal teams and would not be equipped to make decisions regarding the acceptability or otherwise of advertisements for therapeutic goods.

The commercial radio industry's view is that some form of specialist approval mechanism must be made available to advertisers if the pre-approval system is to be abolished.

CRA is open to considering an alternative non-mandatory mechanism, which would provide access to specialist assistance and pre-approval for therapeutic good advertisements. This could operate as part of a self-regulatory regime and so would be consistent with a deregulatory approach.

Areas of the TGA Code that are likely to require specialist scientific knowledge include:

- prohibition of particular promotional behaviours (e.g. off label use)[9];
- truthfulness of representations concerning indications (medicines) and intended purpose (medical devices)[10];
- scientific substantiation of claims[11]; and

[9] Section 4 'Proposed Code Changes' (4.2(1)) of the Consultation.

[10] Ibid, 4.2(2).

- information regarding medical risks[12].

CRA submits that approval for an advertisement under any non-mandatory scheme should provide broadcasters with protection from liability for advertising offences, as it would satisfy the requirement of 'reasonable steps' under section 42DLB(1) of the TGA Amendment Bill.

5. Broadcasters' liability

CRA is pleased to note that there is an exemption for broadcasters in relation to civil penalties under section 42DLB of the TGA Amendment Bill where:

> *as a result of steps taken by the person, it was reasonable for the person to assume that subsections (2) to (9) did not apply to the advertisement.*

The commercial radio industry would like this exemption to be reiterated in the TGA Code. This will make the scope of broadcasters' liability clear and will make the Code more user friendly, by removing the need to cross reference the Code with the implementing legislation.

CRA also urges the Department to include further detailed comment in the TGA Code on:

- what would constitute reasonable steps necessary to satisfy the exemption under section 42DLB; and
- confirmation that the criminal prosecutions will not be brought against broadcasters unless there are exceptional circumstances. In particular, broadcasters will not be prosecuted where they have simply broadcast the advertisement supplied to them by the advertiser, as no *mens rea* in relation to the crime will exist.

6. Expand on the existing exemptions in the TGA Code

The commercial radio industry urges the Department to expand on the exemptions in the existing TGA Code. This is in line with the deregulatory approach being taken by the Government.

The commercial radio industry supports the specific exemptions currently available to radio. These exemptions provide for less detailed information to be provided in radio advertisements of 15 seconds or less.

CRA urges the Department to consider extending the radio specific exemptions to advertisements of 30 seconds or less. Radio is unique in that it has one means – audio – of communicating a message. Unlike other media, analogue radio advertisements cannot include text that is visible alongside the substantive content.

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[11] Ibid, 4.2(3).

[12] Ibid, 4.2(4).

In radio, any spoken mandatory information takes over the entire audio for the time it takes to broadcast such detail. The required information takes up a significant portion of the broadcast advertisement, even when the advert lasts 30 seconds.

This places radio at a significant commercial disadvantage compared with other media.

Accordingly, CRA asks the Department to consider extending the exemptions available to radio, so that the existing exemptions are available for advertisements of 30 seconds or less.

At a minimum, CRA expects to see the existing TGA Code exemptions maintained. In particular:

- exemptions applicable to radio advertisements of 15 seconds or less[13];
- references to sponsorships of government agency, hospital or healthcare service facility should be permitted (subject to the endorsement prohibition provisions)[14];
- endorsements should be allowed in specific circumstances[15]; and
- testimonials should be permitted[16].

7. Extension of advertising to over the counter medicines

The commercial radio industry notes the Government's caveat to its acceptance of Recommendation 53, namely that the issue of advertising pharmacist only medicinal substances (Schedule 3) will be considered as part of a further review.[17]

The current *Guidelines for brand advertising of substances included in Schedule 3 of the Poisons Standard* have not been updated since 2000. It is not permissible to advertise Schedule 3 substances unless the substance is also listed in Appendix H of the *Therapeutic Goods Regulations*.

In making the decision whether to permit the advertisement of Schedule 3 substances, the Guidelines explain that the potential public health benefit will be considered. While CRA agrees that the public health benefit may be relevant, it submits that a wide interpretation of such a benefit should be applied.

The Department recognises that there appears to be a 'default view that Schedule 3 substances should not be advertised unless there are exceptional public health benefits in doing so'.[18]

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[13] TGA Code 2015, sections 6, 7.

[14] Ibid, 4(6)(a).

[15] Ibid, 4(6)(c).

[16] Ibid, 4(6)(7).

[17] Page 7, Consultation.

The Expert Panel Review of Medicines and Medical Devices Regulation referred to the advertising of pharmacist only medicines as effectively being banned in Australia, and therefore out of step with other comparable countries.[19]

CRA would support an expansion of substances for inclusion in Schedule H, to enable direct to consumer advertising of pharmacist only medicinal substances.

If the expansion of permitted substances is accompanied by additional mandatory information, we urge the Department to consider granting exemptions or shortened forms of wording for radio advertisements.

We would be pleased to discuss any of these issues in more detail should the Department wish to do so.

Please contact [redacted] for clarification on any aspect of this submission.

[18] Ibid, page 8.

[19] Ibid, page 8.