Submission by Free TV Australia

Therapeutic Goods Administration

Consultation: Therapeutic Goods Advertising Code

13 October 2017

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1 Executive Summary

- Free TV represents Australia's commercial free-to-air television licensees. On behalf of our members, we welcome this opportunity to submit their views to the Therapeutic Goods Administration (**TGA**) in response to the consultation paper.[1]
- We support increasing the number of Schedule 3 over-the-counter (**OTC**) medicines that can be advertised directly to the public.
- We accept that there are some Schedule 3 medicines that will not be appropriate for direct advertising to consumers. However, we consider that the starting position should be that all other OTC medicines should be able to be advertised, unless a risk-based scientific process determines otherwise.
- Commercial free-to-air television is a heavily regulated platform with robust compliance processes that can be responsibly used to provide more information direct to consumers on the range of OTC medicines available and the right place to go to seek assistance.
- Under current arrangements, the Australian regulatory regime is out of step with international benchmarks, with other jurisdictions commonly permitting equivalent medicines to be advertised. Broadening the range of OTC medicines that can be advertised directly to the public will bring Australia closer into line with jurisdictions like the United Kingdom, where a similar model to the one proposed by the TGA is already successfully operating.
- Even in jurisdictions like New Zealand which, like the United States, allows prescription-only medication to be advertised directly to the public, data reveals a high level of public acceptance and strong compliance by advertisers.
- Responsible advertising of OTC medicines has a clear role to play in informing the public about available treatments and stimulates appropriate use of medicines for common and easily treated conditions. Informed, motivated, and involved patients can dramatically improve the quality of their own care and reduce the costs to the health system.
- This is supported by a study undertaken by the Centre for Health Economics Research and Evaluation that found that by responsibly providing information on treatment options for a hypothetical minor ailment, the potential for unnecessary GP visits would drop significantly.
- As such, what is being proposed by the TGA is a modest reform, but one that studies have shown will lead to better health outcomes and will expand upon the $10.4 billion a year savings that are already achieved through the existing self-care arrangements.
- We also support remaking the TGA Code to ensure its requirements are clear and unambiguous. This is particularly important in the context of the proposals to introduce enhanced compliance and enforcement powers and strict liability offences. Specific comments regarding the proposed TGA Code provisions are attached to this submission at Appendix A.
- Finally, we consider that the consultation paper proposes a sensible set of modest reforms that should be progressed. We thank the TGA for its work on these important issues.

[1] Therapeutic Goods Advertising Code: Proposed improvements including proposed framework for Schedule 3 medicine advertising (Consultation Paper).

2 Introduction

The value of commercial free-to-air television to the Australian public remains high. Free-to-air television delivers high-quality programming to 97 per cent of Australian households for free.

The commercial free-to-air sector already plays a role in delivering the Government's broadcast public policy objectives. Most commonly, people think about the sector's role in delivering Australian content and reinforcing our sense of national identity through the telling of Australian stories. Free-to-air broadcasters also contribute by delivering breaking news, emergency service warnings, community service announcements, and other timely information that can be critical for the wellbeing of the population.

It is less common to think about the role that TV plays in the achievement of a far broader set of Government policy objectives, such as the efficient delivery of quality healthcare. Yet this is what is possible if the Government reforms the current restrictions on the advertising of OTC medicines. As set out in this submission, this review process is an opportunity to increase the efficiency of the healthcare system.

Free TV Australia's role—Commercials Advice (CAD)

The Australian commercial free-to-air television sector is characterised by a strong compliance culture, with a mature and well understood self-regulatory framework. Anything that is broadcast on commercial television must comply with the Commercial Television Industry Code of Practice (the **Code**). The Code is registered with the Australian Communications and Media Authority who must assess whether it is in accordance with prevailing community standards.

Beyond our Code, the *Broadcasting Services Act 1992* (**BSA**) requires licensees not to use broadcasting services in the commission of an offence against another act or a law of a State or Territory. This is an incredibly broad requirement and one that establishes a heavy compliance burden on broadcasters.

Within Free TV there is a team that provides commercial advice for advertisers—CAD—that reviews and classifies television commercials (**TVCs**) according to our Code. This determines the times of day TVCs can be shown and during which programs. For example, there are strict limitations on when alcohol advertising can be shown.

In addition, CAD also checks for compliance with a range of legislative obligations. CAD produces a handbook that describes in detail the extensive checklist that TVCs are reviewed against. For example, CAD will review for compliance and check substantiation of claims in TVCs in relation to the:

- *Competition and Consumer Act 2010* (which includes the Australian Consumer Law)
- *NICNAS Cosmetic Guidelines 2007*
- *Therapeutic Goods Act 1989 and Regulations*
- *Therapeutic Goods Advertising Code.*

The current arrangements for therapeutic goods requires that scripts for TVCs must be pre-cleared by the Australian Self-Medication Industry (ASMI), prior to being submitted to Free TV or broadcasters. TVCs for therapeutic devices must still comply with the *Therapeutic Goods Act*, Regulations and TGA Code, but do not need pre-approval by ASMI.

As part of CAD's role in reviewing TVCs for therapeutic devices, Free TV requires that advertisers submit evidence that the device and its intended purpose are registered with the TGA. In addition, CAD also checks for substantiation of any claims and written statements in support of testimonials.

As set out in section 4 of our submission, this process has led to excellent compliance results, with an extremely low level of TVC complaints regarding therapeutic goods. The same strong

compliance framework would be brought to bear should the Government accept our recommendation to allow advertising of a broader range of OTC medicines.

3 Public interest benefit in expanding advertising of schedule 3 medicines

3.1 Partnership to support the quality use of medicines

Commercial free-to-air television has a role to play in supporting the quality use of medicines. In fact, the media is recognised as a partner in the National Medicines Policy.[2]

The National Medicines Policy notes that the optimum use of medicines is achieved by:

- consumers and health practitioners having timely access to accurate information and education about medicines and their use;
- public health and health education programs, and other programs relating to quality use of medicines (for example, development and implementation of guidelines, implementation of schemes for the disposal of unwanted medicines) being coordinated between the Commonwealth Government and State/Territory Governments as well as others in this partnership;
- industry and health practitioners contributing through appropriate information, education and promotion activities; and
- issues relating to use of medicines should be reported accurately and responsibly by the media.[3]

Allowing a broader range of OTC medication to be advertised to the public will directly assist in the timely provision of accurate, balanced information that is recognised in the National Medicines Policy.

Advertising of OTC medications helps to inform the public about available treatments and stimulates appropriate use of medicines for common and easily treated conditions. This in turn can encourage greater collaboration with professional pharmacists, reduce unnecessary visits to the GP and can arrest the progress of some conditions before they become more serious and require greater levels of more costly medical intervention.

Informed, motivated, and involved patients can dramatically improve the quality of their own care and reduce the costs to the health system. Responsible advertising of OTC medicines has a clear role to play in assisting with the quality use of medicines.

In conjunction with appropriate advice, advertisers can also supplement their campaigns with product information to health care providers. This contributes to the health literacy of the public as well as pharmacists and other health care professionals.

Consistent with the concept of the partnership that is required to achieve the optimum use of medicines and the delivery of an efficient health system, Free TV recognises the need for information provided through TVCs to be well-regulated, as discussed later in this submission.

3.2 Supporting health care professionals as primary source of advice

Free TV strongly supports responsible advertising of OTC medicines that reinforces the role of the health care professional in the consumer's decision as to whether a treatment is right for them.

The Pharmacy Guild of Australia has also indicated its qualified support for advertising of Schedule 3 OTC medicines. Together with noting a need for a transition and support period, the

[2] National Medicines Policy, Australian Government, pg. 1
[3] Ibid, pg 3

Pharmacy Guild considers that all advertisements should inform consumers that Schedule 3 OTC medicines are only available in consultation with a pharmacist and that all advertisements should include a direction to 'ask your pharmacist.'[4]

Free TV supports the Pharmacy Guild's position regarding the role that the pharmacist must play in the decision-making process. To that end, we support the principle of mandatory messages being included in TVCs that refer consumers to pharmacists for advice.

To become a pharmacist, an individual must undertake a minimum of 4 years of study, complete a minimum of 1,824 hours of supervised practice and pass a written and oral exam. All pharmacists must be registered with the Pharmacy Board of Australia. To maintain that registration Pharmacists must meet strict criteria and obligations including that they must:

- complete an approved program of study, internship and examination.
- meet national registration standards, codes and guidelines.
- renew registration every year and notify the Board of changes to principal place of practice, name or address within 30 days.
- maintain recency of practice.
- carry out and record continuing professional development (CPD).
- make mandatory notifications about 'notifiable conduct'.
- notify in writing within 7 days if charged with or convicted of an offence punishable by 12 months jail or more.
- comply with audits to check renewal declarations.[5]

We note this information to highlight the enormous training and development investment that is made by pharmacists and the greater role that they can responsibly perform in the delivery of an efficient health care system.

It is also worth considering the role of the internet in providing information on medicines. The internet has allowed pharmaceutical companies to provide detailed product information above and beyond the material normally packaged with the product.

At the same time, care must be taken to ensure consumers are receiving right information for their condition and are seeking professional advice. Television advertising has a significant role to play in providing regulated information in relation to certain therapeutic goods, as well as reinforcing the role of professional, trained health care providers, like pharmacists, in the decision-making process.

3.3 A more efficient health system

According to figures recently released by the Australian Institute of Health and Welfare, Australia spent a total of $170.4 billion on health in 2015/2016. Government spending accounted for two-thirds of this expenditure ($114.6 billion).[6] This includes the cost of servicing 145.1 million GP visits.[7] Australia now spends more than 10 per cent of its GDP on health.

[4] Pharmacy Guild of Australia, Policies & Position Statements, Advertising of Professional Pharmacy Products and Services
[5] http://www.pharmacyboard.gov.au/Registration.aspx
[6] Health Expenditure in Australia 2015-2016, Australian Institute of Health and Welfare, pg. 23
[7] http://www.health.gov.au/internet/main/publishing.nsf/Content/Annual-Medicare-Statistics

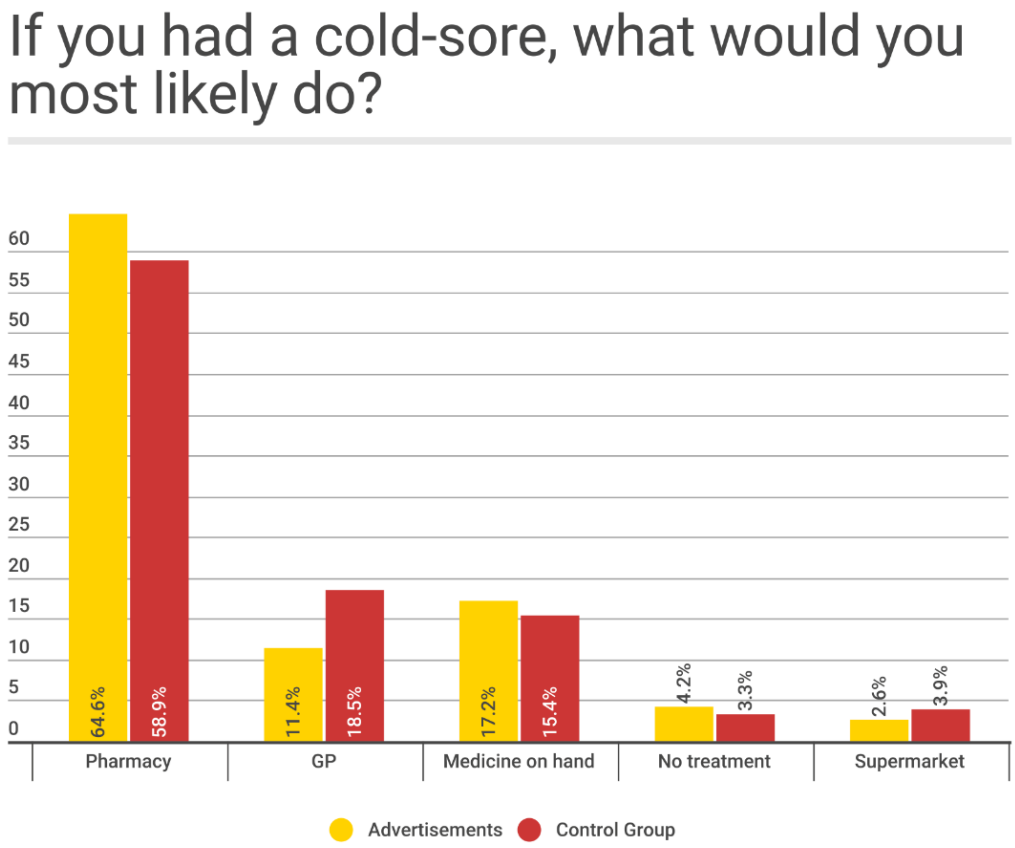
Against this backdrop it is important that policy makers use every available mechanism to improve the efficiency of the health care system.

As such, the role of OTC medicines in an efficient health care system should be closely examined. A study undertaken by Macquarie University in 2014 estimated that the current use of OTC medicines by Australian consumers saves the Australian economy $10.4 billion annually. This is made up of a savings associated with an estimated 58 million fewer GP visits and the associated direct and indirect costs.[8]

Building on these cost savings, the Centre for Health Economics Research and Evaluation, (University of Technology Sydney) has undertaken a detailed study on the potential impact of advertising Schedule 3 medicines on consumers and pharmacists. This work was commissioned by ASMI and was included in their May 2017 submission in relation to the Scheduling Policy Framework.

The study assessed 1295 consumers, 501 pharmacists and 500 pharmacy assistants to determine the change in their attitudes to treating a minor ailment after seeing a TVC for a hypothetical OTC treatment.

As the below graph demonstrates, the group shown the TVC was almost 40 per cent less likely to seek advice from a GP for the minor ailment. Conversely, there was 10 per cent increase in the number of people who said they would seek advice from a pharmacist.



Source: Centre for Health Economics Research and Evaluation, University of Technology Sydney

The results demonstrate that after viewing a responsible TVC, that meets many of the minimum criteria discussed in the consultation paper, consumers were much more likely to seek out the assistance of a professional pharmacist. After seeing the TVC, over 60 per cent of consumers agreed with the proposition that they would let the pharmacist determine whether the medication

[8] Macquarie University Centre for the Health Economy, The Value of OTC medicines in Australia, pg. 3

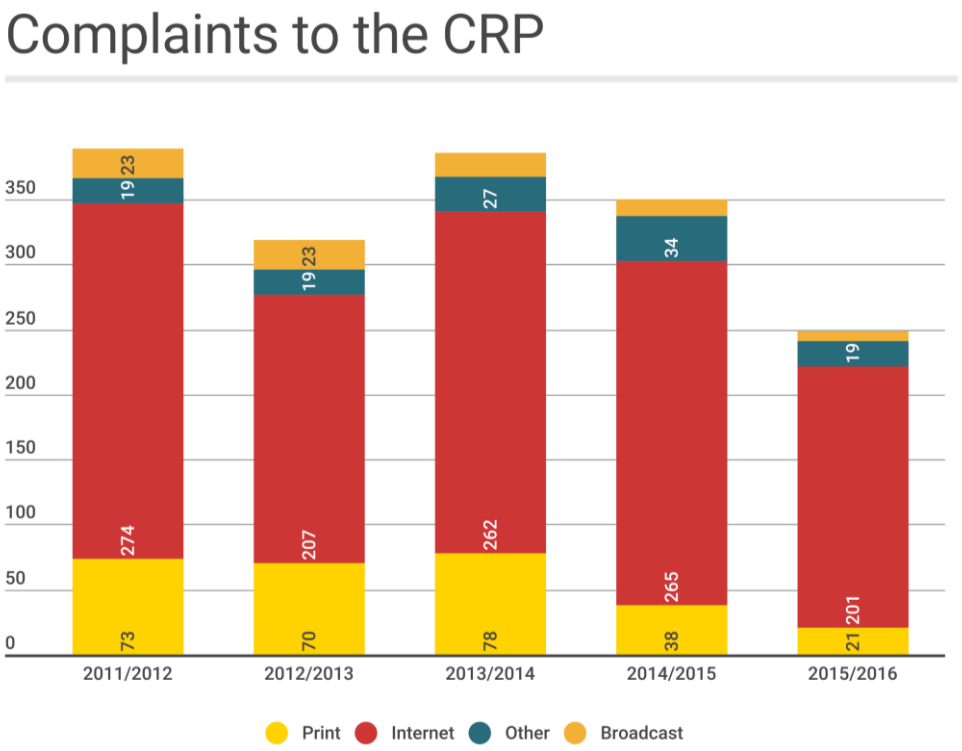
was appropriate for them. Again, this highlights how the commercial free-to-air TV platform can be coupled with sensible well-crafted regulations to enhance health outcomes.

Free TV recognises the need to ensure that the scripting of TVCs reinforces the health outcomes that we want as a community. For example, as was the case in this hypothetical TVC, the primacy of the healthcare professional in the decision-making process needs to be well understood and promoted.

4 Commercial TV has a strong compliance culture

The current model for regulating TVCs relating to therapeutic goods and devices is mature, well understood by all stakeholders and is achieving outstanding compliance results.

An independent TGA Complaints Resolution Panel (CRP) exists to receive complaints about all forms of advertising directed to consumers. The success of broadcasters' rigorous compliance checking process is borne out by the very low level of complaints received in relation to TVCs.



Source: http://www.tgacrp.com.au/wp-content/uploads/files/CRP_complaints_summary_1-Jul-2015_to_30-Jun-2016.pdf

As shown in the graph above, complaints relating to TGA goods and devices on commercial television have always been low and have actually been steadily declining. In 2015/2016, only seven complaints were made against TVCs regarding the TGA goods and devices. Four of these were upheld with the remainder either being referred to the TGA or being found not to be justified.

This provides policy makers with a high degree of confidence that even with the removal of the pre-approval process, commercial broadcasters have in place the appropriate checks and balances. This will ensure that should more Schedule 3 medicines be approved for advertising, they will be managed responsibly by our industry, consistent with our record to date.

5 International experience

In many countries similar to Australia, direct to consumer advertising of OTC medicines is allowed. Below we highlight two case studies—the UK and New Zealand—to demonstrate the community reaction to advertising.[9]

5.1 United Kingdom

A close analogy to the regulatory framework that is being considered by the TGA is that applying in the United Kingdom (UK).

Under their regime, any OTC medicine, including pharmacy medicines, can be advertised to the general public. It is illegal to advertise prescription-only medicines directly to the public.

For OTC medicines, the Proprietary Association of Great Britain (PAGB) reviews all of their members' advertising to the public against their codes of practice. The PAGB is the UK trade association for the consumer healthcare industry - which represents the manufacturers of branded OTC medicines, self-care medical devices and food supplements. As such, their role is similar to the current ASMI role in Australia.

TVCs must be submitted to pre-clearance centres to ensure compliance with the UK Code of Broadcast Advertising.[10]

Under this regime, in 2016/2017 there were just five complaints relating to PAGB member products published by either the Medicines and Healthcare products Regulatory Agency (MHRA) or the Advertising Standards Authority. Five complaints are equivalent to just 0.06% of the total number of advertisements submitted for clearance.[11]

> "The number of upheld cases each year in the OTC sector is usually small since the Proprietary Association of Great Britain (PAGB) reviews prior to issue all consumer advertising from their members."
>
> *Medicines and Healthcare products Regulatory Agency Association, 2016 Annual Report*

It is instructive to note the high degree of confidence that the UK regulator—the MHRA—has in this self-regulatory model, through its comments on the expected low numbers of complaints regarding the advertising of goods.

In the Australian context, as highlighted above, broadcasters have robust compliance systems and have similarly low levels of complaints for the products that can currently be advertised.

5.2 New Zealand

New Zealand, like the USA, allows direct to consumer advertising of prescription-only medication. Despite this key difference to Australia, there are still some useful conclusions that can be drawn from the operation of the New Zealand system.

Medsafe is the New Zealand Medicines and Medical Devices Safety Authority that is responsible for the regulation of medicines and medical devices in New Zealand. Medsafe has issued a Guideline on the Regulation of Therapeutic Products, Part 7 of which covers advertising. The general requirements of the Guideline cover very similar key objectives as proposed by the TGA in the consultation paper.[12]

Similar to the UK, there is strong evidence that the New Zealand self-regulatory system is delivering on the needs and expectations of the community. Data received from the Advertising Standards Authority of NZ (ASANZ) shows that during the period 1 January 2012 to 31 August

[9] ASMI Submission to TGA Scheduling Policy Framework, pg. 23
[10] https://www.gov.uk/guidance/advertise-your-medicines
[11] Consumer healthcare in a changing world, PAGB, Pg.13
[12] http://www.medsafe.govt.nz/regulatory/Guideline/GRTPNZ/Part7_Advertising_of_therapeutic_products.pdf

2017 there were a total of 29 complaints to the ASANZ against either an OTC medicine or Medical Device. Of these only 19 related to TVCs. This is less than 3% of the total complaints received by ASANZ.

6 A robust TGA advertising code

Free TV agrees with and supports the sentiments expressed in the Consultation Paper that a clear therapeutic goods advertising code (**TGA Code**) that contains objective and unambiguous requirements is mutually beneficial to advertisers and regulatory decision makers, and essential to compliance.

For commercial free-to-air television broadcasters, this is particularly important in the context of the changes introduced by the *Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017* (the **Bill**) that is currently before the Parliament. These changes to the regulatory framework increase the regulatory risks for broadcasters in relation to broadcasting of health-related content as a result of:

- the introduction of new penalties, offences and enhanced enforcement action by the Secretary of the Department of Health; and
- the abolition of the existing requirement for advertisements to be pre-approved by ASMI (proposed in Schedule 6, Part 2 of the Bill).

While Free TV supports the removal of the ASMI pre-approval process, there is likely to be increased uncertainty as to compliance and liability for advertising content. This will mean that broadcasters are taking on increased risk in relation to the advertising of health-related content in circumstances where they are not responsible for that content.

This is particularly the case as a result of new criminal offence provisions that will apply to broadcasters where the requisite 'intention' to advertise can be shown. Previous decisions by the TGA Complaints Resolution Panel have been unclear in relation to the point at which this intention arises. The risks increase further in circumstances such as integrated advertising where broadcasters may exert a degree of production control over an advertisement.

A degree of risk also remains for broadcasters in relation to the civil penalty provisions, as there remains lack of clarity around what would constitute 'reasonable steps' for the purposes of the exception in Schedule 6 at s 42MA. This arises if 'as a result of steps taken by the person, it was reasonable for the person to assume that the advertisement complied with the Therapeutic Goods Advertising Code.'

The risks associated with these provisions are amplified for broadcasters because of Part 1, clause 7(1)(h) of Schedule 2 of the BSA, which states:

> "*the licensee will not use broadcasting services in the commission of an offence against another Act or a law of a State or Territory.*"

The potential consequences for breach of broadcasters' licence conditions are serious and include suspension or cancellation of the relevant broadcasting licence, being pursued in relation to a civil penalty in the Federal Court or having the matter referred to the Director of Public Prosecutions.

In this context, it critically important that the TGA Code imposes clear and objective requirements in relation to advertising of health-related content. At the same time, there are some circumstances where flexibility is required to enable broadcasters to meet the requirements of the TGA Code in a manner that is practical in the circumstances. We set out our suggestions in relation to how this can be achieved below.

6.1 Exemption in relation news, public interest and entertainment programs

Currently, the TGA Code makes clear that it does not apply to bona fide news, public interest or entertainment programs. This is an important exemption that enables broadcasters to broadcast health-related stories that inform the public about public health issues, medicines and

products. It is critical in the context of the enhanced offence provisions, that this exemption is clear and unambiguous and facilitates the dissemination of health-related information via news and current affairs, public interest and entertainment programming.

There has been some confusion in relation to the scope of this provision as well as the scope of the definition of an Advertisement under the Act.[13] Previous decisions of the Complaints Resolution Panel have suggested that an assessment of whether material is advertising material requires a consideration of "whether the material, in the eyes of an ordinary and reasonable viewer, ought to be regarded as "intended… to promote the use or supply" of the product in question. This means that the subjective intention of the broadcaster has been disregarded, even in circumstances where there has been no commercial arrangement made between a broadcaster and a product manufacturer/supplier to promote or advertise a product and no other evidence of an intention to promote. Instead, the CRP has construed the definition to imply a test based on the 'objective' viewpoint of the ordinary and reasonable viewer, and whether they would reasonably perceive an intention to promote the use or supply of the product in question.

Under the proposed changes, the definition of Advertisement is to be repealed and replaced with a lengthier definition of "Advertise" which includes statements, pictorial representation or design on the label, package, or any material included with the package in which the goods are contained. For broadcasters, it is unclear whether the inclusion of a pack shot of a therapeutic good either alone, or in combination with bona fide news about the product or the associated health condition or ailment, will be considered advertising material and inadvertently contravene the Code.

In addition, the exemption in the Code for bona fide news, public interest or entertainment programs is not applied in the Act. At present, there is an exception for bona fide news in the definition of Generic Information in the Act, however, this does not exclude it from the definition of Advertisement. This inconsistency between the Advertising Code and the Act requires amendment. Once it can be determined that material relating to a therapeutic good is bona fide news, public interest or entertainment programming, it should not then also constitute an advertisement under the Act.

The following matters should be clarified to ensure it is robust and does not constrain the flow of information about health products to the public:

- When material is bona fide news, public interest or entertainment material, it cannot also be an 'advertisement' for the purposes of section 3 of the TGA. This has been the source of some confusion and it should be clarified that the definition of 'advertisement' excludes bona fide news, public interest and entertainment programs.
- Where it is unclear whether the material is or is not bona fide news, or a public interest or entertainment program, the intention of the broadcaster in broadcasting the relevant material and the fact that the broadcaster did not obtain any consideration for broadcasting the material (or the fact that the broadcaster had no commercial interest in the relevant business), should be taken into account in determining whether or not the material falls within the definition of 'advertisement'. This is consistent with the Commercial Television Industry Code of Practice. There may be circumstances where a news or entertainment program reports on a particular product however this should not of itself bring the program material within the definition of 'advertisement' for the purposes of s 3 of the TGA – otherwise the risk to broadcasters or running health-related stories will be too high despite their intrinsic value.

[13] Noting that the Department's proposal to repeal the definition of "Advertisement" and replace it with a definition of "advertise"

6.2 Clarification of the definition of 'therapeutic use'

It is currently an offence for advertisements to make claims about the therapeutic use of a product unless the product is included on the Australia Register of Therapeutic Goods (ARTG).[14]

A therapeutic use claim includes a claim in relation to the use of the good 'in or in connection with preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons, or influencing, inhibiting or modifying a physiological process in persons.'

Free TV's view is that it would assist to have guidance in relation to these definitions and in particular, in relation to what constitutes 'influencing, inhibiting or modifying physiological process.' For example, it would assist if the proposed guidelines to accompany the TGA Code included a non-exhaustive list of examples of terms or phrases (such as 'fighting wrinkles', 'nourishing skin', 'supporting nutrition', 'maintaining health' that are not considered to be therapeutic use claims).

In the UK, the MHRA provides guidance to advertisers for advertising medicines within the UK through the publication, the Blue Guide. The Blue Guide summarises the regulatory requirements for advertising medicines, provides background as to why the industry needs to be regulated and gives specific, practical examples of compliant and non-compliant advertising material to assist advertisers in complying with the relevant legislation. For example, whilst the definition of 'advertisement' in the UK *Medicines (Advertising) Regulations 1994* gives a non-exhaustive list of examples of activities that are classed as an advertisement, the Blue Guide provides a number of examples of what are not advertisements for the purposes of the Regulations. The guidance uses plain language, practical examples and often discourages advertisers from making claims that may offend advertising regulations.

The TGA once provided guidelines in relation to the cosmetic/therapeutic interface in respect of product claims. This document was issued by the National Coordinating Committee on Therapeutic Goods, following input from the Cosmetic, Toiletry and Fragrance Association of Australia. The guidelines, which have now been archived, provided guidance, in the form of practical examples of generally acceptable and unacceptable claims that cosmetics to make in order to comply with the Act and the TGA Code.

An updated guidance document in relation to therapeutic use claims, similar to the guidance provided by the MHRA in the UK and previously provided by the TGA would be useful for industry to understand the scope of the provisions of the Act.

6.3 Proposed Code Changes

Section 4 of the Consultation Paper sets out a number of other proposed changes to give effect to a more objective advertising code. Free TV notes that the revised TGA Code has not yet been provided and there is insufficient detail and clarity in relation to a number of the proposals. Free TV makes a number of initial recommendations in relation to the proposals contained in the Consultation Paper in Appendix A, however we note that further consultation will be required once the proposals are more fully formed and once a draft of the proposed changes is available.

[14] *Therapeutic Goods Act 1989*, Chapter 5.

7 Recommendations

7.1 Broaden the advertising allowed of Schedule 3 medicines

A strong public policy case has been made to allow advertising of a broader range of OTC medicines.

As demonstrated throughout this submission, the commercial free-to-air television sector has a strong compliance base from which to responsibly contribute to better health outcomes through the provision of information to the community. This should be supported by a clear and unambiguous TGA Code, as discussed in Section 6 and Appendix A.

The change is relatively modest and in-line with international practice and is supported by robust analysis that shows it can lead to more efficient health care system.

7.2 Presumption in favour of advertising for new OTC medicines

We recognise that there are some medicines that are not likely to be suitable for direct to consumer advertising.

However, the starting position should be that new and down-scheduled OTC medicines can be advertised, unless a risk-based scientific process determines otherwise. The Consultation Paper sets out a process under which this risk-based process could be undertaken by an expert working group and we would support this approach.

A transition period should be established to enable all medicines that *are not* listed on Appendix H to be advertised. This transition period should allow enough time for the expert working group to consider all medicines currently in Schedule 3 and determine their suitable for direct to consumer advertising. At the end of this period, Appendix H should switch to become a list of all Schedule 3 medicines that cannot be advertised. This would ensure that going forward there was a presumption in favour of new and down-scheduled medicines being able to be advertised, unless the delegate also determines to list them on Appendix H.

While this process would establish a different starting point, it is important to note that Free TV's proposal would still see the advertising of medicines strictly regulated under the therapeutic goods regulatory framework, consistent with the Governments response to recommendation 52.

7.3 The new TGA Code needs to be clear and unambiguous

Free TV agrees that a clear TGA Code that contains objective and unambiguous requirements is mutually beneficial to advertisers and regulatory decision makers, and essential to compliance.

To achieve this:

- the exemption in relation to bona fide news, public interest or entertainment programs must be strengthened; and
- Certain common terms and phrases should be recognised as not constituting therapeutic use claims and clarification of this should be provided in guidelines.

Free TV has also made a number of initial recommendations in relation to how to achieve more clarity and objectivity in the TGA Code at Appendix A. We note however that the revised TGA Code has not yet been provided and there is insufficient detail and clarity in relation to some proposals. In formulating this detail, care will need to be taken in balancing the benefits to the consumer of new regulatory requirements with imposing an unnecessary regulatory burden on advertisers. Free TV would like the opportunity to provide more detailed feedback on how to achieve clarity and objectivity in the TGA Code once the proposals are more fully formed or a draft of the proposed changes is available.

Appendix A – Detailed comments on core objectives of new TGA Code

Advertisements must be truthful, balanced and not misleading. Claims about therapeutic goods must be consistent with the entry of the goods in the ARTG.

The Consultation Paper suggests including the existing TGA Act requirement that claims regarding therapeutic goods must be consistent with their listing in the Australian Register of Therapeutic Goods (ARTG) in the TGA Code. While supporting this suggestion, Free TV notes that this should be included as a reference to the TGA Act rather than an overlapping TGA Code obligation.

The Consultation Paper also provides that 'Advertisements must contain all mandatory and applicable information to provide consumers relevant information that encourages responsible use and promotes safe use of the therapeutic good'. It is unclear how this will be incorporated and whether it is proposed that there will be additional requirements under the TGA Code. Free TV agrees that this information should be clearly set out, as is currently the case, however, Free TV seeks further clarity in relation to how it is proposed to include this requirement in the new TGA Code.

All claims used in advertisements for therapeutic goods must be substantiated

'Publicly accessible'

Section 4.3 of the Consultation Paper provides that 'Scientific information referred to in an advertisement must be presented accurately, be educationally appropriate and written in language that can be readily understood by the audience to whom it is directed. Details of the scientific information relied upon must be publicly accessible.' Free TV suggests a definition of 'scientific information' be included within the TGA Code as one does not currently exist. The proposed requirement for public accessibility of scientific information is new and the Consultation Paper does not provide any details of how this requirement would apply. Free TV notes that in most cases, scientific information in relation to a particular product will be commercial-in-confidence information and Free TV queries how the proposed requirement to have scientific information be available publicly would be of added benefit to the consumer. Any requirement in the TGA Code should balance the need for public accessibility with the importance of keeping commercially sensitive information confidential.

Identification of sponsors

The Consultation Paper also refers to a new requirement that the advertisement 'must identify the sponsor of the scientific study and must also detail if the sponsor of that study has or had any direct or indirect commercial interest in the therapeutic good or the ingredients being promoted in the advertisement'. This requirement that past as well as present, indirect as well as direct commercial interests be disclosed in relation to the good or any of its ingredients, in the advertisements is incredibly broad and in Free TV's view will lead to increased ambiguity rather than less. The current TGA Code requirement that the publication of research results must identify the researcher and financial sponsor of the research is sufficient and provides the consumer with adequate information. Any further requirements will cause unnecessary burden on advertisers and would be of very limited if any additional benefit to consumers.

Proposed requirement that comparative advertising not 'disparage'

The Consultation Paper refers to an additional requirement that comparative advertising of therapeutic goods must not be 'disparaging'. Free TV does not agree with this additional requirement. It is unclear what it adds over and above the existing requirements that advertising must be correct and must not be likely to mislead or deceive. A requirement that comparative advertising is not disparaging poses the risk of effectively outlawing comparative advertising and is ambiguous in meaning and scope.

Testimonials

The proposed new requirement that testimonials be 'current' is subjective and requires guidance. If such a requirement is included in the TGA Code, Free TV suggests inclusion of guidance on what this requirement means. Free TV recommends a period of 2 years.

In relation to the proposed new requirements that the person providing the testimonial must be accurately identified and that any valuable consideration provided for the testimonial must be acknowledged, Free TV recommends that any such requirements should form part of the existing documentation requirement. These obligations must be balanced against the practicality of including a long list of disclaimers in an advertisement. Free TV's view is that there should not be new or additional requirement to identify the person above the existing requirements that TVCs should not mislead or deceive.

Endorsements by health-related bodies or organisations

The existing requirement that advertisements must not contain or imply endorsement by health-related bodies is too broadly drafted and therefore ambiguous, causes confusion and should be clarified. It is possible that any relationship between a healthcare professional and a device may imply endorsement by the healthcare professional and ultimately this will depend on a subjective view of the relationship. In Free TV's view, this requirement would be much clearer and objective if the reference to 'imply' was removed.

Advertisements of therapeutic goods must give adequate and appropriate information on the risks, cautions and side effects as well as provide a balance between promoting responsible self-treatment and encouraging consumers to seek timely professional help

Mandatory statements, contraindications and warning statements

The Consultation Paper provides that consideration is being given to strengthening this part of the TGA Code, including by specifying the duration, (for broadcast media), font size (in print media) or relative prominence (e.g. in outdoor marketing) of mandatory statements, contraindications and warning statements.

Free TV's view is that the TGA Code currently provides for a sensible and practical approach to these messages. There is no demonstrated need for additional prescriptive measures relating to duration or font size of mandatory warning messages. This is one area where broadcasters require flexibility in the delivery of the messages, so long as they are clear to viewers. Free TV notes that its Operational Practice Standards 29 and 36 address these issues,[15] taking into account the limitations of certain file formats and implications that file formats have for font size. In addition, TVCs and infomercials vary in length (between 15 seconds for a short TVC and 30 minutes for an infomercial). Flexibility is required to enable inclusion of warning messages which are appropriate and achieve clarity in the context of the particular TVC.

Sponsorship advertisements

The Consultation Paper proposes to provide additional limitations on sponsorship announcements however the extent of the changes and how they would apply, what types of sponsorship announcements they would apply and how they would fit with existing section 4(6) of the TGA Code remains very unclear. Free TV seeks clarification on these issues.

[15] Free TV Australia Operational Practice OP-29, Quality Specifications for file Delivery of SDTV and HDTV Commercials; Free TV Australian OP 36, Quality Specifications for Delivery of SDTV and HDTV commercials on storage media.