Australian Government
Department of Health
Therapeutic Goods Administration

Consultation: Therapeutic Goods Advertising Code

Proposed improvements including proposed framework for Schedule 3 medicine advertising

August 2017

TGA Health Safety Regulation

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1. Introduction

The Therapeutic Goods Administration (TGA) is responsible for regulating the supply, import, export, manufacturing and advertising of therapeutic goods. It does not regulate healthcare practitioners, their services or practices. These activities are regulated for certain practitioners through the National Registration and Accreditation Scheme, which is implemented by the Australian Health Practitioner Regulation Agency in partnership with 14 National Health Practitioner Boards.

The regulatory requirements for the advertising of therapeutic goods to the public are set out in the *Therapeutic Goods Act 1989* (the Act), the *Therapeutic Goods Regulations 1990* (the Regulations) and the *Therapeutic Goods Advertising Code 2015* (the Code). These requirements also apply to advertisements for health services directed to the public that also promote a therapeutic good associated with that service.

The Act defines *advertisement*, in relation to therapeutic goods, as including;

> *any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods*.

This definition is very broad and captures therapeutic good advertisements that are published or broadcast in a number of media, including newspapers, magazines, television (including pay TV), radio, the Internet (including Facebook, Twitter and other social media) catalogues and point of sale material. It also captures the product label if it includes a statement, pictorial representation or design that is intended to promote the use or supply of a therapeutic good.

The Code is a legislative instrument made under section 42BAA of the Act by the Minister or their delegate. It is the core compliance standard underpinning the legislative framework regulating the advertising of therapeutic goods to the public. A person commits an offence under the Act if they publish or broadcast an advertisement or generic information about therapeutic goods that does not comply with the Code.

The object of the Code is to 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.

Direct-to-consumer advertising of medicines which require a prescription from a registered healthcare practitioner (Schedules 4 and 8 of the *Poisons Standard*) is banned as is the advertising to the public of certain pharmacist-only (Schedule 3) medicines. Only non-prescription medicines (over-the-counter and complementary medicines) and medical devices can be advertised directly to the public. These advertisements must comply with the Code and other advertising requirements set out in the Act and Regulations.

As foreshadowed in the 2016 advertising consultation (*Consultation: The Regulatory Framework for Advertising Therapeutic Goods - November 2016)*, the Code will be redrafted to:

- provide for more objective tests to determine breaches of the Code, given the anticipated introduction of strict liability offences (Recommendation 58 of the Expert Panel Review of Medicines and Medical Devices Regulation)
- address the inconsistencies between medicines and medical devices (where appropriate) in accordance with Review Recommendation 54; and
- incorporate other amendments that have been discussed with stakeholders in recent years but have been on hold while the advertising framework was under review.

The Code also contains provisions for the advertising of medicines containing Schedule 3 substances, when included in Appendix H of the Standard for the Uniform Scheduling of Medicines and Poisons (the Poisons Standard). Following public consultation in April 2017 on the *Scheduling Policy Framework and Advertising of Pharmacist-only medicines (Schedule 3 substances)*, there was strong support for permitting the direct to consumer advertising of a wider range of Schedule 3 substances, provided there were certain additional controls. A proposed framework, including specific provisions proposed to be included in the Code to underpin advertising of S3 medicines to the public, is included in this paper.

2. Review recommendations and the Government's response

The Review advertising recommendations and the Government's response are relevant to the redrafting of the Code:

1. Recommendation Fifty Two

The Panel recommends that advertising of therapeutic products to the public continues to be regulated by the [TGA] under a legislative framework which includes an advertising code.

The Australian Government, in accepting Review Recommendation Fifty-Two, noted that stakeholders strongly supported continuing to regulate advertising of therapeutic goods to the public within the therapeutic goods regulatory framework.

2. Recommendation Fifty Four

The Panel recommends that the future requirements for advertising therapeutic products to the public are made consistent for all medicines and medical devices.

The Australian Government, in accepting Review Recommendation Fifty-Four, noted that increasing the consistency of approach could help reduce complexity for advertisers. It also noted that the difference between medicines and medical devices means that consistency may not be appropriate in particular circumstances.

3. Recommendation Fifty-Five

The Panel recommends 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.

The Australian Government, in accepting Review Recommendation Fifty-Five, noted that the acceptance of Recommendations Fifty-Seven (enforcement powers) and Fifty-Eight (sponsor education) is critical for managing potential concerns by consumers and healthcare professionals in accepting this recommendation. Removal of pre-approval requirements could help reduce unnecessary complexity for sponsors and advertisers, and is consistent with the Government's commitment to minimising unnecessary regulatory burden.

4. Recommendation Fifty-Six

The Panel recommends that current mechanisms for managing complaints are disbanded and a new mechanism is established consistent with best practice principles for complaint handling. In establishing the new complaints management mechanism, a single agency should be responsible to receive and manage complaints on the advertising of therapeutic products to the public. The Government should consider the following options:

A. establishing the function within the NRA [.e. the Therapeutic Goods Administration]or other existing Commonwealth agency and ensuring appropriate resourcing for the function; or

B. calling for tenders from external organisations to undertake the function.

The Australian Government, in accepting Review Recommendation Fifty-Six, noted that a single agency approach to complaints management has the potential to reduce complexity and encourage greater consistency in decision-making, benefiting consumers. To progress this recommendation, the Department of Health will consult with stakeholders on the appropriate design of the new complaints-management process.

Following the 2016 advertising consultation, the Government decided to make the TGA the single body responsible for handling of complaints about the advertising of therapeutic goods to the public.

5. Recommendation Fifty Seven

The Panel recommends that, further to Recommendation Twenty Eight regarding a review of the Act, consideration be given as to whether the current range of investigation and enforcement powers should be broadened.

The Australian Government, in accepting Review Recommendation Fifty-Seven, noted that broadening enforcement powers will benefit consumers by appropriate compliance with advertising regulatory requirements, and deter inappropriate and misleading advertising of products.

6. Recommendation Fifty Eight

The Panel recommends that the National Regulatory Authority facilitates the development of a formal sponsor education programme to provide industry and industry associations with appropriate information and tools to assist them in achieving compliance with advertising requirements under the regulatory framework.

The Australian Government, in accepting Recommendation Fifty-Eight, noted that developing sponsor education programmes to assist sponsors and advertisers in understanding their obligations will be particularly important once the reforms to the advertising regulatory framework are in place (particularly implementation of Recommendation Fifty-Five).

In addition the Review made two recommendations regarding the advertising of Schedule 3 substances (Pharmacist-only medicines).

7. Recommendation Twelve

The Panel recommends that the Schedule 3 Advertising Guidelines be reviewed, in consultation with State and Territory Governments, and in concert with the review of the Scheduling Policy Framework, to:

1. Provide for the development and adoption of a formal risk-benefit methodology for the assessment of Schedule 3 substances for inclusion on Appendix H of the Poisons Standard; and
2. Identify synergies between application requirements for re-scheduling and for inclusion of a Schedule 3 substance on Appendix H, so as to streamline these processes and reduce duplication.

The Australian Government, in accepting Recommendations Eleven and Twelve, noted that the Australian Health Ministers Advisory Council (AHMAC) has overall policy responsibility for the *Scheduling Policy Framework*, and therefore would need to consider any proposed changes.

8. Recommendation Fifty Three

The Panel recommends that advertising to the public continues to be prohibited for Schedule 4 and 8 prescription medicines, and the advertising of medicines in Schedule 3 of the Poisons Standard continues to be prohibited except those products containing ingredients set out in Appendix H (Recommendation Twelve refers).

The Australian Government, in accepting Recommendation Fifty-Three, noted that the issue of advertising of Schedule 3 (Pharmacist only) medicinal substances will be considered as part of a review of the *Scheduling Policy Framework* (Recommendations Eleven and Twelve).

See the complete Review recommendations and the Government response for further details.

3. Background

3.1. The Advertising Code

The last major update of the Code was completed in 2007. The Code was last remade and registered in the Federal Register of Legislation on 13 November 2015, to ensure its continued operation while the Review was ongoing[1]. For this reason, the Code was remade with minimal changes necessary to correct inaccuracies and/or out of date information as well as ensuring consistency of the Code with the Act and Regulations at that time.

Since 2007 there has been significant **broadening of the types of therapeutic goods** being promoted and sold directly to the public. These have included:

- genetic tests for diseases and for prediction of patient metabolism of /responses to medicines,
- the range and presentation of complementary medicines,
- point of sale in-vitro diagnostic devices (IVDs), and
- certain types of surgically implantable devices for a range of uses.

Similarly, the **methods and media used for promotion have expanded** beyond the traditional mainstream media to include:

- social media;
- embedded advertising in a variety of entertainment streaming media and platforms;
- product and sponsor websites;
- mobile platforms that can deliver personalised advertising; and
- "viewer aware" electronic bill boards and in store advertising.

The updated Code proposed for consultation subsequent to our receipt of feedback on this paper will need to remain relevant in this highly dynamic environment (in particular evolving online media platforms), while at the same time holding all types of therapeutic goods advertising to the public to the same standards.

[1] The Therapeutic Goods Advertising Code 2007 would have stopped operating (sunset under the *Legislative Instruments Act 2003*) on 1 April 2017 if no action was taken.

Changes to the Code are also required to improve clarity and objectivity of provisions due to **proposed changes to the advertising sanctions and penalties regime** (Review Recommendation 57), and in relation to Review Recommendation 54 to improve consistency between medicines and medical devices. Subject to the Government decision on its preferred option, a range of potential changes to the Code will be considered in relation to the advertising of pharmacist-only (Schedule 3) medicines to the public.

The Code will also be required to be **consistent with the proposed complementary medicine reforms that may impact on advertising** such as the permitted indications list (Review recommendation 38) and the new "Assessed Listed Medicine" pathway (Review recommendation 39) for sponsors of Listed medicines who can substantiate higher level product claims than those on the permitted indications list, and provide such evidence of product efficacy to the TGA for pre-market review. Required revisions to the Code may also include changes consequent to allowing certain complementary (and potentially OTC) medicine products to include a "claimer" of efficacy on their labels and promotional materials, consistent with the Government's acceptance of recommendation 45 of the MMDR.

Further, the Therapeutic Goods Advertising Code Council (the Council)[2] has reviewed various aspects of the Therapeutic Goods Advertising Code 2007 and made a number of recommendations to enhance and clarify several provisions. These proposed changes were kept on hold until the Government's responses to the Review recommendations became available. We have also become aware of other inconsistencies and regulatory issues with the Code over this same period.

3.2. Schedule 3 Advertising guidelines

The *Guidelines for brand advertising of substances included in Schedule 3 of the Poisons Standard* were written in 2000 and have not been updated since that time. For example, the document includes references to multiple committees and processes that no longer exist.

Furthermore, the consideration of substances for inclusion in Appendix H of the Poisons Standard appears to build on a default view that Schedule 3 substances should not be advertised unless there are exceptional public health benefits in doing so. In their discussion in the MMDR Report, the Expert Panel referred to the advertising of pharmacist-only medicines as [effectively] being banned in Australia, and that this was out of step with other comparable countries.

Feedback from the *Consultation: The scheduling policy framework and advertising of pharmacist-only medicines (Schedule 3 substances)*, showed that there was **support from a significant majority of stakeholders for broadening the direct-to-consumer (DTC) advertising of these substances**. In most cases, this support was conditional on the expectation that there would be specific requirements for these advertisements to ensure that consumers were aware that pharmacist advice and instructions on use of the medicine were required, and that certain Schedule 3 substances would not be appropriate for DTC advertising.

One proposed approach for consultation (see Section 6) captures these expectations, while utilising a mechanism that currently exists for Schedule 3 substances to allow for a smooth reform transition. It is anticipated that the general advertising requirements as set out in the Code will continue to apply to advertisements for Schedule 3 medicines, but with additional specific requirements to inform consumers, to manage the higher risks around these substances, but at the same time to recognise that they have been determined suitable for access without a prescription.

[2] A statutory committee established under Regulation 42A to advise the Minister on matters relating to the advertising of therapeutic goods (See Regulation 42B).

4. Proposed Code changes

4.1. Changes to support effective sanctions and enforcement of advertising requirements

It would be of mutual benefit to advertisers and regulatory decision makers to have clearer and more detailed objective requirements applying to advertisements about therapeutic goods directed to the public at large. The proposed enhanced enforcement and sanctions regime applying to advertising will provide a foundation to encourage compliance. This will only be effective if the provisions that set out requirements and details regarding non-compliance under the Code are clear and that any subjectivity in their interpretation is minimised. It is therefore proposed that changes be made to the Code include removing, or minimising subjectivity in the interpretation and implementation of the specific advertising provisions set out in the Code.

The proposed Code changes are of particular importance given the Government's acceptance of Review recommendations:

- Fifty-Five - "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"; and
- Fifty-Eight – "…developing sponsor education programmes to assist sponsors and advertisers in understanding their obligations…".

Introduction of enhanced compliance and enforcement powers for non- compliant advertising in conjunction with a more objective Code and centralisation of the management of advertising complaints with the TGA are part of a wider system measures being rolled out to improve compliance with the therapeutic goods advertising legislation. These measures also include a formal advertising compliance education program for sponsors and advertisers to provide them with a range of information and tools to assist them to remain compliant with the advertising requirements.

Do stakeholders support minimising subjectivity in the interpretation of provisions in the new Code?

4.2. Core objectives for the new Code

A new Code would be required to satisfy four core objectives:

1. **Advertisements must comply with the *Therapeutic Goods Act 1989*, regulations made under this Act, and the *Therapeutic Goods Advertising Code***

Part 5.1 of the *Therapeutic Goods Act 1989* and the *Therapeutic Goods Regulations 1990* specify requirements and prohibitions applying to advertisements to the public about therapeutic goods that must be complied with by advertisers and sponsors of therapeutic goods. Other sections in the Act also **prohibit particular promotional behaviours** by any person (e.g. use of indications or purposes for products not included on the ARTG). Similarly, the Code specifies requirements in relation to the content, statements, claims and representations about therapeutic goods.

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

Any representation (any written, pictorial or other descriptive matter) or claim (whether therapeutic or not) in the advertisement about therapeutic goods must be **truthful, balanced, valid and must be consistent with the indications (medicine) or intended purpose** (medical device) accepted in relation to the ARTG.

The intended purpose in a medical device inclusion can be very broad, as it may cover a range of medical devices in a grouped inclusion ('kind of medical device'). However, any representation made for a medical device must still be consistent with the intended purpose accepted in relation to the particular medical device's inclusion in the ARTG, and as detailed in its labelling and instructions for use. The Code may need to differentiate between medicines and medical devices in setting out these requirements.

Specifically advertisements **must not** directly or by implication, omission, ambiguity, exaggerated claim or comparison, **mislead or deceive, or be likely to mislead or deceive,** or abuse the trust or exploit the lack of knowledge, or exploit the superstitious or, without justifiable reason, play on fear or cause distress.

Advertisements must not contain any matter that is likely to **lead a person to believe that they are suffering from a serious ailment or that harmful consequences** may result from a therapeutic good **not** being used.

In addition, an advertisement (including a product label) **must not contain any claim, statement or implication that:**

- the therapeutic good is safe or that its use cannot cause harm; or
- that it has no side effect/s or risks associated with its use; or
- that the good is effective in all cases or conditions; or
- the product is infallible, unfailing, magical or miraculous, or that it is a certain, guaranteed or sure cure; or
- it is effective for specific demographic groups of patient (particularly where this may be a vulnerable group) without detailing the supporting evidence.

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. Mandatory information, (e.g. requirements to include contraindications and warning statements) will be listed in the new Code. In addition, some advertisements for medicines must contain additional statements based on the scheduling classification of the substance/s in the medicine under the current Poisons Standard.

As provided for under the current (2015) Code, certain categories of therapeutic goods such as analgesics, vitamins and weight loss or management products will be subject to **specific warning information** and other requirements that need to be prominently displayed or communicated in the advertisement including the product label. Depending of the decision of government around possible changes to the advertising of Schedule 3 medicines, these provisions may need to be extended to include certain categories of Schedule 3 medicines.

3. All claims used in advertisements for therapeutic goods must be substantiated

Scientific information referred to in advertisements **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.

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 also covers comparative advertising of therapeutic goods. The advertising of therapeutic goods must not be disparaging, must be factual, fair, and already substantiated. It must refer to the source of any scientific information and must be reflective of the body of available scientific evidence.

In relation to **testimonials**, the advertisement must be authenticated, genuine, current and typical and acknowledge any valuable consideration provided for the testimonial. The person providing the testimonial must be accurately identified and must not be an employee or related to the sponsor or the advertiser.

Certain **endorsements by health related bodies or organisations** would still be allowed, but subject to requirements to ensure they are not misleading and clearly disclose the relationship with the advertiser and basis for the endorsement.

4. 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

Promotion of therapeutic goods must be consistent with current social expectations for public media and presentation of claims and content in advertisements must also be consistent with any relevant public health or safety campaigns of the Commonwealth, State or Territory governments.

An advertisement about therapeutic goods **must not encourage, or be likely to encourage inappropriate or excessive use of the goods.** An advertisement must also not unduly glamorise products or prey on the vulnerability of particular consumers. In assessing compliance of an advertisement under this particular requirement, the following public interest criteria are to be applied:

- the advertisement must not impair the ability of a member of its audience to choose an appropriate therapeutic product to treat, manage or avoid a disease, condition, ailment or defect because of the vulnerability of the member of the audience;
- an advertisement for a medicine must be consistent with Quality use of Medicines (QUM) objectives and in relation to non-prescription medicines, that the advertisement must be for a condition that is suitable for self-diagnosis or self-management and must not impair the ability of a member of its likely audience to self-diagnose and/or self-manage that condition;
- the advertisement should not encourage or result in consumers or members of the public refraining from seeking timely and appropriate professional advice about the disease or the condition as it is important to prevent negative health consequences, deterioration or progression of disease;
- the advertisement is not likely to create a false expectation in its likely audience that the product will deliver health benefits or improvements to their quality of life;
- the advertisement is not likely (alone or through repetition or together with other references) to have a negative impact on public health or on persons to whom the advertisement is not directed); and

- in relation to medical devices:
  - the content of the advertisement is balanced and adequately sets out warnings, precautions and risks that make a particular treatment or procedure inadvisable;
  - the advertisement clearly identifies the important role of an appropriate healthcare professional and the advice that he or she provides; and
  - that the advertisement could not be construed to claim or imply that the use of the device or procedure is suitable in all cases.

Subject to the Government's final position on the advertising of pharmacist-only medicines to the public, consideration will need to be given to strengthening this section of the Code.

Advertisements must also **not discourage consumers** from taking medicines prescribed by a healthcare professional. Subject to the media of publication or broadcast of the advertisement, mandatory statements, contraindications and warning statements must be included in advertisements such as "if symptoms persist consult your healthcare professional" or the warnings included in legislative instruments made under the Act for this purpose. (e.g. in the *Medicines Advisory Statements Specification 2016*). The nature of such statements, and their duration (for broadcast media), font size (in print media) or relative prominence (e.g. in outdoor marketing) may also be specified.

In relation to **sponsorship advertisements**, it is proposed that a sponsorship advertisement must:

- clearly and primarily promote the team, individual, competition, event or activity being sponsored; and
- not contain a direct or implied claim or a sales message including any brand tag-line for a therapeutic product, other than product name, or in the case of a medical device, a purpose for use; and
- not imitate or use any part of a therapeutic product advertisement from any medium, or refer or link the advertisement from any medium.

It is also proposed that any disease awareness campaigns by sponsors of therapeutic goods, healthcare professionals, associations and other groups (e.g. Heart Foundation, Cancer Council) require that the campaign must be factual and balanced and support consumers in making informed health choices. Such campaigns must not identify a specific therapeutic good or sponsor either expressly or by implication.

Advertisements **must not offer any personal incentives** including product based contests, to pharmacy assistants, or other sales personnel employed by healthcare practitioners to recommend or supply therapeutic goods.

Similarly, any sponsorship advertisements promoting a team, individual, competition, event or activity will be subject to the advertising requirements.

The requirements proposed above are not exhaustive, and will be further specified in a draft of the Code legislative instrument that will be consulted upon publicly in the coming months.

Further, the assessment of conformity of an advertisement under the new Code should remain in terms of the probable impact upon a reasonable person to whom the advertisement is directed.

There are no proposed changes to the requirements in relation to professional recommendations.

We wish to obtain feedback to support the development of a new Code that is proposed to contain clearer and more specific details of what is and is not permitted in respect of advertisements about therapeutic goods.

The TGA seeks the views of stakeholders on the proposed requirements under the new Code as described above, and any other details or requirements that stakeholders believe should be clearly specified under the new Code.

Additionally, some stakeholders have called for guidelines to be available for advertisers (see Section 4.4 below).

Do you agree with guidelines to the new Code being developed? How should this guidance be made available to stakeholders?

4.3. The Council recommendations

As identified in the 2016 advertising consultation, the Council has made a number of recommendations to improve the operation of the Code.

These proposed changes include:

New definitions of prohibited and restricted representation

- The current definitions of "prohibited" and "restricted" representation, particularly in the light of new diagnostic techniques (such as those involving direct-to-consumer genetic testing), the advertising of diagnostic tests and the plan to allow enhanced efficacy claims for certain complementary medicines (Recommendation 39 of the Review refers) may be inadequate. The current restriction of prohibited claims to "treatment, cure and prevention" should be broadened to include all references to prohibited claims unless otherwise allowed in the Code.

New restricted representations

- Reference in an advertisement for a therapeutic good to any procedure (or product requiring such a procedure for its intended purpose), that can only be performed by a suitably qualified healthcare professional to become a restricted representation.
- Reference to "obesity" either directly or indirectly to become a restricted representation within the meaning of the *Therapeutic Goods Act 1989* (the Act).
- Clarifying that the representation "prevention of skin cancer" in respect of certain sunscreens is permitted as a restricted representation.
- Clarifying that the representations "devices that are used in contraception" or "in the prevention of disease transmission" are restricted representations.
- Amending the provisions dealing with "scientific information" to ensure that:
  - references to a specific research study in an advertisement must sufficiently identify the study as to allow consumers to access it;
  - it is educationally appropriate in language which is readily understood by the audience to whom it is directed; and
  - it continues to identify funding source, commissioning body for the study and any relationship to the sponsor or advertiser.

Testimonials and free samples

- Testimonials in advertisements to be subject to clearer more objective conditions.
- Prohibiting offers of free samples of therapeutic goods as part of an advertisement. Exceptions would be sunscreens and class I medical devices (including for example condoms and dressings where the intended purpose does not require intervention by an appropriately qualified healthcare professional) but excluding IVDs.

While an option would be to make changes to the Code to address all of the Council's recommendations, this would also need to take into consideration comments received from stakeholders in response to the 2016 advertising consultation and the current consultation regarding proposals to redraft the Code.

4.4. Consultation comments

A number of comments were received in response to the 2016 advertising consultation regarding the proposal to redraft the Code. These comments included:

1. Support for the **development of a new Code** to remove subjectivity by revising the interpretative provisions, particularly in light of the proposed enhanced sanctions and penalties, and consideration that it is important that any 'simplification' of the process for advertising regulation is not compromised by increased uncertainty around the implementation of the Code itself;
2. The Code should **clearly and unambiguously communicate requirements and include specific examples of compliant and non-compliant advertising**, and that the requirements should be consistently interpreted and applied, as well as being updated on a regular basis; and
3. There should be accompanying **guidelines** to assist with understanding of the requirements to enable compliance to the Code.

Are stakeholders supportive of including the recommendations in section 4.3 proposed by the Council for incorporation in a new Code?

Do stakeholders support the Code changes proposed in section 4.4 (1 to 3) in the 2016 advertising consultation comments?

5. Price Information Code of Practice (PICOP)

Pricing is a key element of a consumer's decision to purchase. The TGA recognises the need for a mechanism to permit the price of therapeutic goods to be communicated to consumers even where the goods themselves cannot lawfully be promoted directly to consumers.

The current Code supports the communication of "price information" to consumers where that information is consistent with the "*Price Information Code of Practice - September 2006*" (PICOP). This is permitted as set out in the PICOP even where the therapeutic good cannot otherwise be promoted directly to the public (e.g. for prescription medicines). **Better underpinning of the PICOP i**s proposed in developing the new Code.

The current arrangements set out in the PICOP apply to a limited range of goods and may only be accessed by particular specified practitioners. We will be considering the mechanism for

assisting with price communication and whether the PICOP is appropriate for this purpose and the detailed requirements currently set out in the PICOP.

Do you consider that the PICOP should:

- remain in the new Code, or
- be established as a separate legislative instrument under the *Therapeutic Goods Act* 1989, or
- are there other mechanisms for managing compliance with the PICOP?

6. An option for an Advertising Framework for Schedule 3 (pharmacist only) medicines

6.1. Overview

As outlined in Section 3.2 above, feedback from the *Consultation: The scheduling policy framework and advertising of pharmacist-only medicines (Schedule 3 substances)*, showed that there was support from a significant majority of stakeholders for broadening the direct-to-consumer (DTC) advertising of medicines containing these substances. In most cases, this support was conditional on the expectation that there would be specific requirements for these advertisements to ensure that consumers were aware that pharmacist advice and instructions on use of the medicine were required, and that certain Schedule 3 substances would not be appropriate for DTC advertising.

Based on feedback from this consultation, a proposed approach could be that Schedule 3 medicines can be advertised directly to consumers unless the Delegate determines that advertising is not appropriate for medicines containing a particular substance (or class of substances).

Existing Schedule 3 substances could be considered by a working group of jurisdictions, medical practitioners, pharmacists, consumer and industry representatives on a case-by-case basis, and advice sought as required from the Advisory Committee on Medicines Scheduling. The substances would then be included (or not included) in Appendix H following a decision by a delegate of the Secretary.

To ensure enforceability for substances that are permitted to be advertised, it is proposed to retain the current Appendix H mechanism of the Poisons Standard to specify those substances that *may* be advertised to the public (i.e., remains a "positive" list).

It would remain an offence to advertise any Schedule 3 medicine that is not included in Appendix H. directly to consumers.

The current Scheduling Policy Framework specifies that in making a decision on whether or not a substance should be included in Schedule 3 of the Poisons Standard, the Delegate may consider the following matters:

- The potential public health benefit;
- The likelihood of advertising of the substance leading to inappropriate patterns of medication use;

- The provisions of the Code and any prohibited and restricted representations relevant to the substance;
- Whether the application may result in advertising of goods for an indication other than those included in the Australian Register of Therapeutic Goods;
- The responsibility of pharmacists to be actively involved in the supply of [these] substance(s);
- Available Consumer Medicine Information;
- Available Risk Management Plan and application to the substance in an S3 environment;
- The level of patient education necessary to ensure safe and effective use;
- The desire of consumers to manage their own medication;
- Any other information that is relevant to the decision making.

It is not proposed that these requirements be altered.

6.2. Product advertising requirements

Advertisements for Schedule 3 substances included in Appendix H will be subject to all general requirements as set out in the Code and the Act.

The following additional requirements are proposed for advertisements for medicines containing Schedule 3 substances:

> "**Your pharmacist *must decide* if this product is suitable for you**."

The above statement is to be included prominently in the advertisement. For print advertisement this statement should appear at the top of the advertisement, for broadcast media this should be the leading statement.

> **"Ask your pharmacist about side effects relevant to you"**

The above statement is to be included prominently in the advertisement. For print advertisement this statement should appear at the bottom of the advertisement, for broadcast media this should be the ending statement.

It is proposed that a single standard phrase is to be included at the top/beginning and bottom/end of an advertisement to facilitate consumer education and standardisation of messaging. More specific requirements around statements will be consulted upon at the time of public consultation on the draft advertising code.

6.3. Substances unsuitable for inclusion in Appendix H

For some substances, it is acknowledged that direct-to-consumer (DTC) advertising would not be appropriate. It is a proposed that a working group, inclusive of a wide range of stakeholders would assess the existing list of substances included in Schedule 3. As a guide, the following categories may not be appropriate for DTC advertising:

- Injectable
- Substance for use in emergency situations
- Where safer analogues or therapeutically equivalent medicines are available
- Where there is potential for inappropriate use, abuse or diversion

- Where the substances form part of surgical procedure
- Medicine for treatment of chronic condition that requires a doctor as part of the treatment

6.4. Process for adding a substance to Appendix H

It is proposed that a similar process to re-scheduling, including public consultation, will be followed for consideration of Appendix H inclusion, and in parallel with the scheduling consideration.

This process is consistent with the Scheduling Policy Framework, as an addition to Appendix H is an amendment to the Poisons Standard, however referral to the ACMS would be at the Delegate's discretion. Public consultation supports natural justice for applicants and also provides a mechanism to identify any potential diversion, misuse, or broader public concerns.

It is also anticipated, consistent with scheduling decisions, there will be an implementation date set so as to allow pharmacists time to undertake education and preparedness activities.

Stakeholders are asked to provide feedback on the proposed option for advertising of Pharmacist-only medicines containing Schedule 3 substances and inclusion in Appendix H.

In particular, we would appreciate feedback on

- the specific requirements for advertisements containing Schedule 3 substances
- factors to be considered by the delegate
- restrictions on inclusion in Appendix H
- the proposed process

7. Next steps

Following review of submissions received in response to this consultation and as foreshadowed in the 2016 advertising consultation, revision of the Code will proceed in consultation with the current Council.

A further round of public consultation on the new draft Code is planned for late 2017/ early 2018. The new Code is expected to be in force before (or at the same time as) other proposed changes to the advertising framework come into effect.

The TGA proposes that further revisions to the Code will be consulted publically in accordance with the established processes for developing and amending legislative instruments.

Version history

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