EXPLANATORY STATEMENT

Therapeutic Goods Advertising Code 2015 Amendment No.1 of 2018

Section 42BAA, Therapeutic Goods Act 1989

The *Therapeutic Goods Act 1989* (the Act) provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in or exported from Australia. The Therapeutic Goods Administration (the TGA), which is part of the Department of Health, is responsible for administering the Act.

The Act includes provisions regulating advertisements for therapeutic goods, including a number of provisions that require advertisements for therapeutic goods to the public to comply with the Therapeutic Goods Advertising Code. The code currently in force is the *Therapeutic Goods Advertising Code 2015* (the Advertising Code). The Advertising Code, which sets out minimum requirements for advertisements about therapeutic goods directed to consumers, is a legislative instrument made by the Minister under section 42BAA of the Act.

The purpose of the *Therapeutic Goods Advertising Code 2015 Amendment No.1 of 2018* (the Code Amendment) is to make a minor amendment to the Advertising Code in relation to the information required to be included in an advertisement for therapeutic goods that are included in Schedule 3, and Appendix H, of the current Poisons Standard, to provide advertisers with some additional flexibility in relation to the statement that is required to be contained in advertisements for such products.

The affected medicines are those that contain substances which require the pharmacist's professional advice for safe use and authorisation of supply, but which are recommended under the Poisons Standard to be made available to the public without a prescription, and which are permitted to be advertised to the public (subsection 42DL(10) of the Act prescribes the related offence).

The Code Amendment commenced on the day after it was registered on the Federal Register of Legislation.

BACKGROUND

The Advertising Code provides a standard within the advertising framework in the Act, setting out the requirements for the advertising of specified therapeutic goods to the public, and is an essential component of the regulatory framework for the advertising of those goods. It provides the core compliance standard underpinning the legislative framework regulating the advertising of specified therapeutic goods to the public.

Compliance with the Advertising Code is a criterion or a basis for the making of the following decisions under the Act and the Regulations:

(a) pre-approval of specified advertisements prior to publication or broadcast in specified media as established under regulation 5G of the Regulations;

(b) assessment of advertising complaints;

(c) the registration, inclusion or listing of therapeutic goods on the Australian Register of Therapeutic Goods (the Register);

(d) suspension or cancellation of the entry of therapeutic goods from the Register; and

(e) approving "restricted representations", to be used in advertisements for particular therapeutic goods under section 42DF of the Act. A restricted representation is identified in a part of the Advertising Code as a serious form of a disease, condition, ailment or defect.

A person commits an offence if a person advertises therapeutic goods by any means, or causes the advertising of therapeutic goods by any means, and the advertisement does not comply with the Advertising Code (section 42DM of the Act refers).

The *Therapeutic Goods Amendment (2017 Measures No.1) Act 2018*, which commenced, in most part, on 6 March 2018 (amendments to reflect the removal of pre-approval of certain therapeutic goods advertisements will commence from 1 July 2020), implemented a number of key recommendations made by the Expert Panel Review of Medicines and Medical Devices Regulation, including reforms to improve and streamline the advertising of therapeutic goods to the public.

Enactment of the *Therapeutic Goods Amendment (2017 Measures No. 1) Act 2018* has provided the TGA with enhanced compliance and enforcement powers to protect the public from inappropriate or misleading advertising, including in relation to the introduction of graduated penalties (with both fault-based and strict liability offences) and corresponding civil penalties in some cases, including in relation to advertising that does not comply with the Advertising Code. The enhanced powers in the Act are designed to provide greater scope for the Secretary to be able to respond appropriately to non-compliant advertising behaviours. In conjunction with these reforms, a new Therapeutic Goods Advertising Code has been prepared, and has been the subject of extensive consultation. This new Code, the *Therapeutic Goods Advertising Code 2018* (the New Code), will commence from 1 January 2019.

One of the measures in the New Code relates to information that must be included in an advertisement for medicines for which a pharmacist's advice is required for safe use and authority to supply, and for which advertising to the public is permitted (i.e. medicines that contain substances that are mentioned in both Schedule 3 and Appendix H of the current Poisons Standard) – examples of such products include fluconazole (an antifungal agent), and ulipristal (emergency contraception).

Currently under paragraph 6(e) of the Advertising Code, an advertisement (other than an advertisement for unbranded therapeutic goods, labels and retail advertisements that only display the name or picture of the goods, its price or point of sale) for such medicines must contain words to the effect of:

"YOUR PHARMACIST'S ADVICE IS REQUIRED".

Under section 14 of the New Code, however, this requirement would be strengthened to require the following wording instead for these medicines:

"ASK YOUR PHARMACIST – THEY MUST DECIDE IF THIS PRODUCT IS RIGHT FOR YOU".

The change in wording in relation to this requirement recognises the professional responsibility of pharmacist for providing consumer access to these kinds of medicines, by providing a more direct, assertive and action-oriented signal for consumers, rather than the current more passive statement in the Advertising Code.

This change is also designed to remind consumers of the important role pharmacist have in the supply of such medicines ahead of the new statement ahead of any possible expansion of the number of medicines that are included in Schedule 3 of the current Poisons Standard that will be able to be advertised to consumers through being included in Appendix H of the current Poisons Standard.

Currently only 19 of the 85 substances included in Schedule 3 of the current Poisons Standard are listed in Appendix H, meaning that medicines containing the other 66 Schedule 3 substances may not be advertised to the public (this is the effect of the criminal offence in subsection 42DL(10) of the Act, which prohibits the advertising of a therapeutic good that is included in Schedule 3, but not Appendix H, of the current Poisons Standard). The TGA is currently consulting on a proposal to allow additional medicines containing Schedule 3 substances to be advertised directly to consumers, except where specific substances are unsuitable for this due to safety concerns.

The effect of the Code Amendment is to provide advertisers with the early flexibility to use either the current statement in the Advertising Code (i.e. "Your Pharmacist's Advice is Required") or the new statement ("Ask Your Pharmacist – They Must Decide if This Product is Right For You"), from 1 July 2018, until the New Code commences on 1 January 2019. Under the New Code, advertisers will only have the option of the new statement.

Providing advertisers with the choice of the two statements allows this important benefit to be provided for consumers early where advertisers are able to accommodate it, but also acknowledges that some advertisers (including those whose advertisements were approved before 1 July 2018, or who at that point had a pending application for approval for an advertisement that includes the current statement) may need time to move to the new statement.

CONSULTATION

The new statement was developed in consultation with a working group of affected stakeholders comprising of health professionals, consumers, the advertising and the therapeutic goods industries. The proposed amendment to the Advertising Code to allow the option of the two statements for relevant S3 medicines was contained in the consultation draft of the New Code (consulted on during April 2018) and also outlined at the meeting of the Council on 25 May 2018, and was also one of the topics included in public webinars on the New Code that were operated from the TGA's website (www.tga.gov.au), after that date. . No objections were made to the proposal.

STATEMENT OF COMPATIBILITY WITH HUMAN RIGHTS

In relation to compatibility with human rights, it is considered that the Advertising Code 2015 is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*, and a Statement of Compatibility setting that out in further detail is below.

SUPPLEMENTARY MATERIAL - STATEMENT OF COMPATIBILITY WITH HUMAN RIGHTS FOR A LEGISLATIVE INSTRUMENT THAT DOES NOT RAISE ANY HUMAN RIGHTS ISSUES

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Therapeutic Goods Advertising Code 2015 Amendment No.1 of 2018

This legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Legislative Instrument

The *Therapeutic Goods Advertising Code 2015 Amendment No.1 of 2018* (the Code Amendment) is made under section 42BAA of the *Therapeutic Goods Act 1989*, and amends the *Therapeutic Goods Advertising Code 2015* (the Advertising Code), to allow advertisers of medicines containing substances included in Schedule 3, and Appendix H, of the current Poisons Standard to choose between one of two specified statements alerting consumers to the need to seek their pharmacist's advice about the medicine before selecting it.

These are medicines which require the professional advice of a pharmacist for safe use but which are recommended by the Poisons Standard to be made available to the public without a prescription, and which are permitted to be advertised to the public – e.g. Ibuprofen (a non-steroidal anti-inflammatory drug used for pain relief and reducing fever), and Dimenhydrinate for the prevention and relief of motion sickness (under subsection 42DL(10) of the Act, if these pharmacist-only medicines are included in Schedule 3, but not Appendix H, of the current Poisons Standard, it is an offence to advertise them to the public).

The *Therapeutic Goods Amendment (2017 Measures No. 1) Act 2018* amended the *Therapeutic Goods Act 1989* to introduce a number of advertising reforms, and in conjunction with these measures a new Code (the Therapeutic Goods Advertising Code 2018 (the New Code)) has been prepared, and will commence on 1 January 2019 (replacing the Advertising Code).

Under the current Advertising Code, an advertisement for these medicines must contain words to the effect of:

"YOUR PHARMACIST'S ADVICE IS REQUIRED".

Under the New Code, however, this requirement would be replaced with a requirement to include the following wording in such advertisements:

"ASK YOUR PHARMACIST – THEY MUST DECIDE IF THIS PRODUCT IS RIGHT FOR YOU".

The effect of the Code Amendment is to provide advertisers with the flexibility to use either statement in their advertisements, from 1 July 2018 until the New Code commences on 1 January 2019.

The new statement is principally designed to better alert consumers to the importance of seeking their pharmacist's advice in relation to these kinds of medicines, by providing a more direct signal for consumers, rather than the current more passive statement in the current Advertising Code. The new statement is also intended to be more helpful to a wider range of consumers, in order to reflect the expected expansion of the number of medicines in Schedule 3 of the current Poisons Standard that will be able to be advertised to consumers through being added to Appendix H of that instrument.

Providing advertisers with the choice of the two statements allows this important benefit to be provided for consumers early where advertisers are able to accommodate it, but also acknowledges that some advertisers (including those whose advertisements were approved before 1 July 2018, or who at that point had a pending application for approval for an advertisement that includes the current statement) may need time to move to the new statement.

Human rights implications

This legislative instrument does not engage any of the applicable rights or freedoms.

Conclusion

This legislative instrument is compatible with human rights as it does not raise any human rights issues.

Adj Professor John Skerritt, delegate of the Minister for Health