

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Amendment (Therapeutic Goods Advertising Code) Instrument 2019

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 Act is administered by the Therapeutic Goods Administration (“the TGA”) within the Department of Health.

Section 42BAA of the Act provides that the Minister may, by legislative instrument, make a code relating to advertisements about therapeutic goods (known as the ‘Therapeutic Goods Advertising Code’).

The *Therapeutic Goods Advertising Code (No.2) 2018* (“the Code”) is made under section 42BAA and commenced on 1 January 2019 (except for Part 4 of Schedule 1 which commences on 1 September 2020). The Code sets out a range of requirements relating to the advertising of therapeutic goods in Australia.

The *Therapeutic Goods Amendment (Therapeutic Goods Advertising Code) Instrument 2019* (“the Amendment Instrument”) amends the Code, principally to correct a small number of errors, clarify the status of statements in advertisements for therapeutic goods in relation to pregnancy, and ensure that advertisers of medicines who are authorised to include information in their promotional materials highlighting that the medicine has been assessed by the TGA in relation to its efficacy, can do so without breaching the Code. There are also a number of changes to provide advertisers with more flexibility in how they include mandatory information in their advertisements.

Background

The Code sets out minimum requirements for the advertising of therapeutic goods in order to support informed and safe use of therapeutic goods by consumers. In particular, the Code underpins the regulatory framework for the advertising of therapeutic goods to the public. It also provides for the regulatory authorisation of advertisements that consist only of specified information about prescription and certain pharmacist-only medicines (principally in relation to the price of such products) that are otherwise prohibited from being advertised to the public.

Compliance with the Code is also an important criterion for the making of a number of key regulatory decisions under the Act. This includes, for example, the pre-approval of specified kinds of advertisements for therapeutic goods under regulation 5G of the *Therapeutic Goods Regulations 1990*, the registration, listing or inclusion of therapeutic goods in the Australian Register of Therapeutic Goods (“the Register”) and the suspension or cancellation of goods from the Register.

The Amendment Instrument amends the Code, principally to correct a small number of inadvertent errors and to:

- ensure that the definition of ‘health warning’ for a medical device or other therapeutic goods (principally, “other therapeutic goods” are tampons, menstrual cups and those disinfectants that are not medical devices) is a statement required by law to be included on the label or instructions for use *to the effect* of various specified warnings and to ensure that the definition does not, for a medical device or other therapeutic goods, inadvertently exclude certain types of statements about the taking or use of a medical device or ‘other therapeutic goods’. The purpose of these clarifications is to ensure that this important information about the potential impact on a person’s health from using or taking these kinds of goods will be available for consumers to inform their selection of these goods;

- clarify that the Code is not intended to apply to advertisements that are part of, or comprise, a public health campaign;
- clarify that the Code (other than Schedule 4) does not apply to advertising that consists solely of the dissemination of price information where it relates to prescription and/or pharmacist-only medicines that are registered goods (and not to unapproved therapeutic goods);
- clarify that, in complying with the requirement that an advertisement for a medicine, medical device or other therapeutic goods must contain one or more of the good's indications (these are statements that relate to the therapeutic use of a product), or intended purposes (where applicable), advertisers may either use such an indication or intended purpose as it is set out on the good's label or primary packaging, or modify the indication or intended purpose in a manner that does not change the meaning or intent of the indication or intended purpose, as it appears on the label or packaging;
- allow advertisers, when promoting multiple medicines in one advertisement, to use a single statement to alert consumers to the need to read the label to establish if the medicines are right for them, instead of requiring two or more such statements (which could inadvertently detract from the prominence of mandatory information);
- make it clear that most statements in therapeutic goods advertisements relating to pregnancy, other than to a pregnancy that has a medical, obstetric or surgical complication, are not restricted representations. Under the previous Code (the *Therapeutic Goods Advertising Code 2015*), pregnancy was not listed in Appendix 6 to that Code so was not captured as 'a serious form of a disease, condition, ailment or defect'. Due to a change in the way 'a serious form of a disease, condition, ailment or defect' is defined in the current Code, representations referring to 'pregnancy' were inadvertently captured. If pregnancy is a restricted representation, advertisers would be required to obtain approval from the TGA to make basic and well accepted claims that therapeutic goods could prevent pregnancy, provide nutritional support during pregnancy, and screen for or detect pregnancy. Such a requirement is an unnecessary regulatory burden and inconsistent with the objectives of the restricted representation requirements.

In addition, the Code is amended to ensure that advertisements for listed medicines that have been assessed by the Secretary for their efficacy claims, or registered complementary medicines, may use the TGA assessed claimer without breaching the Code if the medicine is authorised or permitted to use the claimer.

The introduction of the TGA claimer relates to the implementation of two of the recommendations of the Expert Panel Review of Medicines and Medical Devices Regulation ("the Review"), in relation to establishing a new pathway for marketing approval for listable medicines that are evaluated by the TGA in relation to the claims made about their efficacy (Review recommendation 39), and allowing sponsors of medicines that are approved for marketing under this new pathway to indicate on the promotional materials for their products that the medicine has been assessed by the TGA for that purpose (Review recommendation 45).

A claimer for sponsors of these medicines for this purpose has been developed ("TGA assessed claimer"), through extensive consultation with stakeholders, and is expected to be authorised soon for use in connection with medicines that are listed in the Register under the new pathway (section 26AE of the Act refers) or that are complementary medicines registered under section 25 of the Act.

There are two main ways in which the use of the TGA assessed claimer may be authorised or permitted under the Act. These are through an authorisation under paragraphs 42DL(9)(b) and 42DLB(6)(b) of the Act, or by an amendment to regulations for the purposes of paragraphs 42DL(9)(c) and 42DLB(6)(c) of the Act.

However, section 16 of the Code, which prohibits the use of government endorsements in therapeutic goods advertisements, only refers to statements, pictorial representations or designs that are prescribed in the regulations for this purpose.

As such, an amendment is needed to the Code to ensure that advertisements that are authorised to use the new TGA claimer under paragraphs 42DL(9)(b) and 42DLB(6)(b) of the Act are also excluded from the prohibition in section 16 of the Code.

Consultation

The amendments to the Code that are being made by the Amendment Instrument were consulted on with stakeholders at a meeting of the Therapeutic Goods Advertising Consultative Committee (“the Committee”) on 13 June 2019. This meeting included representatives of industry bodies (including in particular the Australian Self Medication Industry, Complementary Medicines Australia and the Medical Technology Association of Australia), representatives of advertisers (including The Communications Council and Free TV Australia), as well as consumer representatives (including the Consumers Health Forum of Australia and the National Rural Health Alliance) and representatives of other important stakeholders such as the Australian Competition and Consumer Commission, the Pharmacy Guild of Australia and the Royal Australian College of General Practitioners.

Stakeholders at the Committee meeting were supportive of the proposed amendments, and did not object to them or to the making of the Amendment Instrument. Subsequent submissions received from stakeholders at the Committee meeting highlighted a number of proposals for improving the clarity of some of the proposed amendments, and these proposals have been reflected in the Amendment Instrument.

The Office of Best Practice Regulation (OBPR) also advised that a regulation impact statement was not required in relation to the Amendment Instrument (OBPR reference: 23382).

Details of the Amendment Instrument are set out in **Attachment A**.

The Amendment Instrument is compatible with human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

The Amendment Instrument is a disallowable legislative instrument for the purposes of the *Legislation Act 2003* and commences on the day after registration on the Federal Register of Legislation.

Details of the *Therapeutic Goods Amendment (Therapeutic Goods Advertising Code) Instrument 2019*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods Amendment (Therapeutic Goods Advertising Code) Instrument 2019* (“the Amendment Instrument”).

Section 2 – Commencement

This section provides that the Amendment Instrument commences on the day after it is registered on the Federal Register of Legislation.

Section 3 – Authority

This section provides that the legislative authority for making the Amendment Instrument is section 42BAA of the *Therapeutic Goods Act 1989* (“the Act”).

Subsection 33(3) of the *Acts Interpretation Act 1901* relevantly provides that, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character, the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument. This instrument is made in accordance with that provision.

Section 4 – Schedules

This section provides that each instrument that is specified in a Schedule to the Amendment Instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and that any other item in a Schedule to the Amendment Instrument has effect according to its terms.

Schedule 1—Amendments

Schedule 1 amends the *Therapeutic Goods Advertising Code (No.2) 2018* (“the Code”).

Item 1 of Schedule 1 clarifies that the term “Act” in section 3 of the Code is the *Therapeutic Goods Act 1989*.

Item 2 of Schedule 1 amends section 4 of the Code to introduce a revised definition of ‘health warning’. The revised definition incorporates a small number of editorial amendments, first, with the inclusion of ‘is to the effect that’ at the end of paragraph (b) to ensure that, for a medical device or other therapeutic goods, health warning is not limited to the precise terms of the statements set out in paragraph (b) of the definition. It is statements *to this effect*. The revised definition also clarifies that it *does* embrace statements that the goods should not be used or taken in the circumstances described by reference to the itemised examples. Examples of such health warnings would include ‘*DO NOT USE IF YOU HAVE A DEEP VEIN THROMBOSIS*’ or ‘*DO NOT USE IF YOU HAVE A PACEMAKER*’. The purpose of these clarifications is to ensure that consumers will have the necessary information about the potential impact on their health from using or taking these kinds of goods. These clarifications also align the requirements for medical devices and ‘other therapeutic goods’, as far as possible, with the intent of the requirements for medicines, as specified in Schedule 1 of the Code. Among other things, the existence of a health warning for a medical device or for ‘other therapeutic goods’ serves to identify, for devices and other therapeutic goods, the specified requirements an advertisement must contain (see sections 12 and 13 of the Code). One option to comply with this obligation is for the advertisement to include the health warning itself.

Item 3 of Schedule 1 amends section 6 of the Code to insert a new subsection 6(2), principally to make it clear that the Code does not apply to an advertisement that is part of, or that otherwise comprises, a Government public health campaign.

Item 4 of Schedule 1 amends subsection 7(1) of the Code to make it clear that the Code (other than Schedule 4) does not apply to advertisements that consist solely of the dissemination of price information for medicines that are registered goods. This amendment clarifies that unapproved medicines are not covered by this exemption.

Items 5 and 6 of Schedule 1 amend section 11 of the Code to clarify that it applies to all therapeutic goods that contain a substance included in Schedule 3 of the Poisons Standard (and not only to medicines).

Item 7 of Schedule 1 inserts a new paragraph 12(3)(d) of the Code to provide more flexibility for advertisers and clarify that, for advertisements to which section 12 of the Code applies, an advertisement for a medicine must contain one or more of the medicine's indications (these are statements that relate to the therapeutic use of a product), as set out on the medicine's label, or as modified in a manner that does not change the meaning or intent of the indication as it appears on the label.

Item 8 of Schedule 1 amends paragraph 12(3)(h) of the Code to correct an inadvertent error in this paragraph.

Item 9 of Schedule 1 amends paragraph 12(4)(c) of the Code to provide more flexibility for advertisers and clarify that, for advertisements to which section 12 of the Code applies, an advertisement for a medical device must contain one or more of the device's intended purposes or indications, as set out on the device's label or primary packaging, or as modified in a manner that does not change the meaning or intent of the intended purpose or indication as it appears on the label or primary packaging.

Item 10 of Schedule 1 amends paragraph 12(5)(c) of the Code to provide more flexibility for advertisers and clarify that, for advertisements to which section 12 of the Code applies, an advertisement for other therapeutic goods must contain one or more of the good's intended purposes or indications, as set out on the good's label or primary packaging, or as modified in a manner that does not change the meaning or intent of the intended purpose or indication as it appears on the label of primary packaging.

Item 11 of Schedule 1 amends paragraph 13(1)(c) of the Code to make it clear that the requirements in section 13 of the Code do not apply to an advertisement that only displays the name or picture of therapeutic goods, their price or point of sale (i.e. the location where they may be purchased), or any combination of these, provided the advertisement does not contain or imply a claim relating to therapeutic use.

Item 12 of Schedule 1 amends paragraph 13(2)(b) of the Code to provide more flexibility for advertisers and clarify that, for advertisements to which section 13 of the Code applies, an advertisement for a medicine must contain one or more of the medicine's indications as set out on the medicine's label, or as modified in a manner that does not change the meaning or intent of the indication as it appears on the label.

Item 13 of Schedule 1 makes a consequential amendment to paragraph 13(2)(c) as a result of the amendment made to section 13 by item 15. The replacement of 'subject to subsection (5)' with 'subject to subsections (2A) and (5)' has the effect that the obligations imposed by paragraph 13(2)(c) are appropriately 'modified' by new subsection (2A).

Item 14 of Schedule 1 amends the first column of the first item in the table in paragraph 13(2)(c) to ensure consistency with the second item, and to ensure that it will apply to a medicine that includes

an ingredient in Part 3 for which there is a health warning (but not in Part 1 or 2) of Schedule 1 to the Code.

Item 15 of Schedule 1 inserts new subsection (2A) into section 13 of the Code to allow the use of a single specified statement in an advertisement promoting multiple medicines, rather than the statements specified in the table in paragraph 13(2)(c).

Item 16 of Schedule 1 amends paragraph 13(3)(c) of the Code to provide more flexibility for advertisers and clarify that, for advertisements to which section 13 of the Code applies, an advertisement for a medical device must contain one or more of the device's intended purposes or indications, as set out on the device's label or primary packaging, or as modified in a manner that does not change the meaning or intent of the intended purpose or indication as it appears on the label or primary packaging.

Item 17 of Schedule 1 amends paragraph 13(4)(c) of the Code to provide more flexibility for advertisers and clarify that, for advertisements to which section 13 of the Code applies, an advertisement for other therapeutic goods must contain one or more of the goods' intended purposes or indications, as set out on the goods' label or primary packaging, or as modified in a manner that does not change the meaning or intent of the intended purpose or indication as it appears on the label of primary packaging.

Item 18 of Schedule 1 inserts a new paragraph 16(1)(b) to ensure that advertisements for medicines listed under section 26AE of the Act that have been assessed by the Secretary for their efficacy claims, or for complementary medicines registered under section 25, and for which the use of the 'TGA assessed claim' is authorised under paragraphs 42DL(9)(b) and 42DLB(6)(b) of the Act, may use the 'TGA assessed claim' without breaching paragraph 16(2)(a) of the Code. Paragraph 16(2)(a) prohibits an advertisement for therapeutic goods to contain any endorsement from, or implication that the goods are endorsed by, among other things, a government authority.

Item 19 of Schedule 1 inserts a new section 28 to correct an inadvertent error and make it clear that statements in therapeutic goods advertisements relating to pregnancy, other than pregnancy with a medical, obstetric or surgical complication, are not restricted representations.

Item 20 of Schedule 1 makes an amendment to Schedule 1 to the Code to correct an inadvertent error.

Item 21 of Schedule 1 makes a minor, consequential amendment to Schedule 4 to the Code as a result of the amendment made to subsection 7(1) of the Code by item 4.

Item 22 sets out the arrangements for how the amendments made by the Amendment Instrument are to be applied. The amendments will apply in relation to the following:

- advertisements occurring after the commencement of the Amendment Instrument to which Division 2 of Part 2 of the *Therapeutic Goods Regulations 1990* ("the Regulations") does not apply (Division 2 of Part 2 of the Regulations deals with advertisements for which approval is needed); and
- advertisements occurring after the commencement of the Amendment Instrument to which Division 2 of Part 2 of the Regulations applies, unless the advertisement is the subject of an approval given prior to the commencement of the Amendment Instrument, and that approval remains in force at the time of the advertisement.

Statement of Compatibility with Human Rights

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

Therapeutic Goods Amendment (Therapeutic Goods Advertising Code) Instrument 2019

This disallowable 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 legislative instrument

The *Therapeutic Goods Amendment (Therapeutic Goods Advertising Code) Instrument 2019* (“the instrument”) is made under section 42BAA of the *Therapeutic Goods Act 1989* (“the Act”). The purpose of the instrument is to amend the *Therapeutic Goods Advertising Code (No.2) 2018* (“the Code”), principally to correct a small number of inadvertent errors, clarify the status of statements in advertisements for therapeutic goods in relation to pregnancy, and ensure that advertisers of medicines who are authorised to include information in their promotional materials highlighting that the medicine has been assessed by the TGA in relation to its efficacy, can do so without breaching the Code. There are also a number of changes to provide advertisers with more flexibility in how they include mandatory information in their advertisements.

The Code sets out minimum requirements for the advertising of therapeutic goods in order to support informed and safe use of therapeutic goods by consumers. In particular, the Code underpins the regulatory framework for the advertising of therapeutic goods to the public. It also provides for the regulatory authorisation of advertisements that consist only of specified information about prescription and certain pharmacist-only medicines (principally in relation to the price of such products) that are otherwise prohibited from being advertised to the public.

Compliance with the Code is also an important criteria for the making of a number of key regulatory decisions under the Act including, for example, the pre-approval of specified kinds of advertisements for therapeutic goods under regulation 5G of the *Therapeutic Goods Regulations 1990*, the registration, listing or inclusion of therapeutic goods in the Australian Register of Therapeutic Goods (“the Register”), and the suspension or cancellation of goods from the Register.

The instrument amends the Code, principally to correct a small number of inadvertent errors and:

- ensure that the definition of ‘health warning’ for a medical device or other therapeutic goods (principally, “other therapeutic goods” are tampons, menstrual cups and those disinfectants that are not medical devices), is a statement required by law to be included on the label or instructions for use *to the effect* of various specified warnings and to ensure that the definition does not, for a medical device or other therapeutic goods, inadvertently exclude certain types of statements about the taking or use of a medical device or ‘other therapeutic goods’. The purpose of these clarifications is to ensure that this important information about the potential impact on a person’s health from using or taking these kinds of goods will be available for consumers to inform their selection of these goods;
- clarify that the Code is not intended to apply to advertisements that are part of, or comprise, a public health campaign;
- clarify that the Code (other than Schedule 4) does not apply to advertising that consists solely of the dissemination of price information where it relates to prescription and/or pharmacist-only medicines that are registered goods (and not to unapproved therapeutic goods);
- clarify that, in complying with the requirement that an advertisement for a medicine, medical device or other therapeutic goods, must contain one or more of the intended purposes or

indications (these are statements that relate to the therapeutic use of a product) of the goods, advertisers may either use such an intended purpose or indication as it is set out on the good's label or primary packaging, or modify the intended purpose or indication in a manner that does not change the meaning or intent of the intended purpose or indication as it appears on the label or packaging;

- allow advertisers, when promoting multiple medicines in one advertisement, to use a single statement to alert consumers to the need to read the label to establish if the medicines are right for them, instead of requiring two or more statements (which could inadvertently detract from the prominence of mandatory information);
- ensure that advertisements for listed medicines that have been assessed by the Secretary for their efficacy claims, or for complementary medicines that are registered goods, may use the TGA assessed claimer without breaching the Code if the medicine is authorised or permitted to use the claimer under the Act;
- make it clear that most statements in therapeutic goods advertisements relating to pregnancy, other than pregnancy with a medical, obstetric or surgical complication, are not restricted representations. Under the previous Code (the *Therapeutic Goods Advertising Code 2015*), pregnancy was not listed in Appendix 6 to that Code and so was not captured as a 'serious form of a disease, condition, ailment or defect'. Due to a change in the way 'a serious form of a disease, condition, ailment or defect' is defined in the current Code, representations referring to 'pregnancy' were inadvertently captured. If pregnancy is a restricted representation, advertisers would be required to obtain approval from the TGA to make basic and well accepted claims that therapeutic goods could prevent pregnancy, provide nutritional support during pregnancy, and screen for or detect pregnancy. Such a requirement is an unnecessary regulatory burden and inconsistent with the objectives of the restricted representation requirements.

Human rights implications

The instrument engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural rights ("ICESCR").

Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standards of physical and mental health. In *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12)* (2000), the United Nations Committee on Economic, Social and Cultural Rights states that health is a 'fundamental human right indispensable for the exercise of other human rights', and that the right to health is not to be understood as the right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

The instrument takes positive steps to promote the right to health by helping to ensure the safe and proper use of therapeutic goods. The Code seeks to protect and promote the health of all Australians, and to prevent possible negative health outcomes from the misuse or inappropriate use of therapeutic goods. The instrument makes amendments to the Code to ensure that the Code continues to effectively regulate the advertising of therapeutic goods and that the benefits, uses and effects of therapeutic goods are accurately promoted.

Conclusion

This legislative instrument is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR and does not raise any other human rights issues.

Gillian Mitchell, delegate of the Minister for Health