

## **EXPLANATORY STATEMENT**

### *Therapeutic Goods Act 1989*

#### *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021*

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 Australian Government Department of Health (“the Department”).

Part 5-1 of the Act provides the regulatory framework in relation to advertisements about therapeutic goods in the public domain. Relevantly, 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 Code”). The Code is designed to set out requirements for advertisements about therapeutic goods that are directed to the public, to protect the public from false or misleading therapeutic goods advertising and the consequent risks to public health. A person who advertises, or causes the advertising of, therapeutic goods that do not comply with the Code may be subject to offence and civil penalty provisions in sections 42DM and 42DMA of the Act.

The *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021* (“the Instrument”) is a legislative instrument made under section 42BAA of the Act. Schedule 1 to the Instrument constitutes the Code relating to advertisements about therapeutic goods for the purposes of section 42BAA of the Act (“the new Code”).

The new Code specifies a range of requirements in relation to advertisements about therapeutic goods. The requirements are intended to ensure that advertisements about therapeutic goods promote their safe and proper use, and that appropriate controls on advertisements about therapeutic goods are in place to protect the Australian public from the potential personal and public health risks associated with unethical, inaccurate, or misleading advertising practices.

### **Background**

The Code is a major compliance standard, which sets out the requirements for advertisements about therapeutic goods in the public domain. Advertising in the public domain is permitted for the majority of medical devices, as well as most medicines available for over-the-counter sale in Australia. The advertising of prescription-only and certain pharmacist only medicines to the public is prohibited; however, price information for these medicines can be advertised, with the Code setting out the conditions under which this may occur. The Code authorises the publication or dissemination of price information in relation to medicines that are registered goods and that contain a substance included in Schedule 3, 4 or 8 to the current Poisons Standard (but not a substance that is included in Appendix H of that Standard), that are otherwise prohibited from being advertised to the public.

The regulation of advertisements about therapeutic goods contributes to the safe and proper use of therapeutic goods by ensuring that the general public receives accurate and balanced information about the quality, safety and efficacy of those goods. It is essential that only credible information is presented in advertisements about therapeutic goods, so that consumers are able to make informed

decisions regarding the suitability of the goods for their particular health needs, and do not delay seeking advice or treatment from a health practitioner where appropriate.

Reflecting the significance of such concerns in relation to the advertising of therapeutic goods, the Act contains (in addition to the offence and civil penalty provisions in sections 42DM and 42DMA for advertisements that do not comply with the Code), requirements relating to compliance with the Code as a criterion or basis for the making of a number of significant regulatory decisions under the Act, including in particular decisions in relation to:

- the registration, listing or inclusion of therapeutic goods in the Australian Register of Therapeutic Goods (“the Register”);
- the suspension or cancellation of therapeutic goods from the Register; and
- the approval of the use of restricted representations in advertisements about therapeutic goods (a restricted representation is a representation in an advertisement about therapeutic goods that refers to a form of disease, condition, ailment or defect that the Code identifies as being a serious form of disease, condition, ailment or defect).

The *Therapeutic Goods Advertising Code (No.2) 2018* (“the former Code”), was made on 31 October 2018 and commenced on 1 January 2019. Since then, experience with the former Code has provided information on opportunities for improving some provisions and its general clarity. With the potential for serious consequences for non-compliance, it is important that the Code remains contemporary and clear.

Two initiatives in particular have informed the improvements that the new Code reflects in comparison with the former Code. In 2020, an independent review of the therapeutic goods advertising framework was conducted by Ms Rosemary Sinclair AM (“the Sinclair Review”), which recommended that the TGA increase the clarity and objectivity of the code by (among other steps) maintaining a log of code issues that stakeholders have identified as being unclear, inconsistent or difficult to work with. The TGA implemented this recommendation, and the log of issues compiled by the TGA informed public consultation on improvements to the former Code that was undertaken in 2021 (this consultation is outlined in more detail below). The Final Report relating to the Sinclair Review, titled *Review of the Therapeutic Goods Advertising Framework* and subtitled *Final Report on the impact of advertising reforms from the Expert Panel Review of Medicines and Medical Devices Regulation, and other initiatives*, dated June 2020, is available on the TGA’s website and is freely available.

In addition, in 2020 collaborative efforts to review aspects of the former Code were initiated following feedback from the Therapeutic Goods Advertising Consultative Committee (“the TGACC”), including that certain provisions were too complex, and in some cases, difficult to apply. The TGACC is a forum through which the TGA consults with industry, the media and publishing and broadcasting bodies involved in the advertising of therapeutic goods to the public. Its membership also includes representatives of Government bodies and consumer and health professional representative bodies. The TGACC established working groups in 2020 to identify and consider specific areas where the former Code could be improved and where new or updated guidance could also assist advertisers to better understand their obligations.

The improvements incorporated into the new Code reflect both these initiatives, as well as issues raised by stakeholder feedback since the commencement of the 2018 Code and public consultation undertaken between 7 May 2021 and 18 June 2021 on proposed improvements to the former Code.

In particular, the new Code reflects the following improvements in relation to the former Code:

- simplifying the language and structure of the Code to improve readability, reduce complexity and therefore increase overall compliance;
- revising and streamlining the mandatory statements required to be included in advertisements about therapeutic goods;
- clarifying the requirements relating to testimonials and endorsements about therapeutic goods, and resolving inconsistencies relating to such requirements; and
- expanding the types of therapeutic goods that may be offered as a sample.

The new Code will commence on 1 January 2022 and repeals the former Code.

To assist advertisers in preparing to comply with its requirements, the new Code provides that, despite the repeal of the former Code, the former Code continues to apply for the first six months following the commencement of the new Code. In effect, this means that advertisers will have the option of complying with the requirements for advertising therapeutic goods set out in either the new Code or the former Code for the duration of that six month transition period.

The six month transition period will end on 30 June 2022, with the effect that from 1 July 2022 advertisers must ensure that advertisements about therapeutic goods comply with the requirements set out in the new Code to avoid committing an offence under section 42DM of the Act or breaching the civil penalty provision in section 42DMA of the Act, or raising other issues of regulatory compliance under the Act in relation to which compliance with the Code is relevant.

## **Consultation**

Both the Sinclair Review and the collaborative work with members of the TGACC in 2020 informed a significant round of public consultation undertaken by TGA between 7 May 2021 and 18 June 2021 on options to improve the former Code.

A total of 67 submissions were received in response to the consultation, including from advertisers and media (such as Commercial Radio Australia), therapeutic goods sponsors and manufacturers (such as Ego Pharmaceuticals and Herbs of Gold), peak industry bodies and associations (such as Complementary Medicines Australia, Consumer Healthcare Products Australia and the National Retail Association), regulatory affairs firms, policy advocates and health professional and consumer organisations (such as the Australian Medical Association, the Royal Australian College of General Practitioners and the Consumers Health Forum of Australia).

There was broad support for simpler rules around the use of existing mandatory statements and health warnings in advertisements. In addition, many stakeholders advocated for the introduction of alternative mandatory statements in advertisements for typically ‘non-consumer’ therapeutic goods.

There was a greater divergence of views on proposals to strengthen the rules around the use of language and images in advertising that may invoke a sense of fear or distress in consumers. Stakeholder views about who should and should not be allowed to make product endorsements and testimonials for use in advertising were also widely divergent, and there was a range of views around the rules relating to advertising involving the offer or provision of free samples of therapeutic goods and the criteria that should apply when determining what types of goods should be exempted from any general restrictions on this practice.

This feedback, and other feedback received in the course of the public consultation, was incorporated into the new Code (including through striking an appropriate balance between some of the more divergent views mentioned above on particular aspects), which also reflects concerted efforts to ensure a document with a simplified structure and plain language. The new Code will also be supported in this regard by associated guidance that is also designed to be more accessible and user-friendly for all stakeholders and the public.

The TGA sought advice from the Office of Best Practice Regulation (“OBPR”) in relation to whether a Regulatory Impact Statement was required for the making of the new Code. OPBR advised that, as the changes were informed by stakeholder feedback and would be unlikely to have more than a minor regulatory impact, a Regulation Impact Statement was not required (OBPR ID 44204).

### **Incorporation by reference**

The new Code provides for a number of matters by reference to Commonwealth Acts and disallowable legislative instruments. These are the:

- *Therapeutic Goods Act 1989*;
- *Therapeutic Goods Regulations 1990*;
- *Therapeutic Goods (Medical Devices) Regulations 2002*;
- *National Health Act 1953*;
- *Veterans’ Entitlements Act 1986*;
- *Therapeutic Goods Order No. 91 – Standard for labels of prescription and related medicines*;
- *Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines*;
- *Therapeutic Goods (Medicines Advisory Statements) Specification 2021*;
- *Therapeutic Goods (Permissible Ingredients) Determination (No. 3) 2021*;
- *Therapeutic Goods (Permissible Indications) Determination (No. 1) 2021*.

For the avoidance of doubt, in accordance with section 14 of the *Legislation Act 2003* (“the Legislation Act”), these Acts and legislative instruments are incorporated as in force or existing from time to time, and so any changes subsequently made to these Acts or legislative instruments will be automatically incorporated. Each is freely available on the Federal Register of Legislation at [www.legislation.gov.au](http://www.legislation.gov.au).

The new Code specifies certain therapeutic goods by reference to matters contained in the current Poisons Standard. The current Poisons Standard is defined in the Act as the document last prepared by the Secretary under paragraph 52D(2)(b) of the Act. While the current Poisons Standard is a legislative instrument, it is not subject to disallowance under section 42 of the Legislation Act. However, subsection 42BAA(2) of the Act expressly allows for dynamic incorporation of documents in an instrument made under section 42BAA of the Act, despite subsection 14(2) of the Legislation

Act. Moreover, subsection 52F(1) expressly allows a legislative instrument made under the Act to make provision in relation to a matter by applying, adopting or incorporating any matter contained in the current Poisons Standard as in force or existing from time to time. The current Poisons Standard is incorporated in the new Code as in force or existing from time to time, in accordance with these provisions. The current Poisons Standard is freely available on the Federal Register of Legislation at [www.legislation.gov.au](http://www.legislation.gov.au).

The new Code does not apply to advertisements about therapeutic goods made in accordance with the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission (No. 4) 2021* (“the Permission”). The Permission is an administrative instrument made by a delegate of the Secretary under section 42DK of the Act, and commenced on 24 September 2021. The Permission is incorporated as in force or existing on a particular date, that being 24 September 2021. The Permission is published in accordance with the requirements under subsection 42DK(6) of the Act on the Department’s website. It is freely available at [www.tga.gov.au](http://www.tga.gov.au).

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

The Instrument is compatible with the 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 Instrument is a disallowable legislative instrument for the purposes of the *Legislation Act 2003*, and commences on 1 January 2022.

## **Details of the *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021***

### **Section 1 – Name**

This section provides that the name of the instrument is the *Therapeutic Good (Therapeutic Goods Advertising Code) Instrument 2021* (“the Instrument”).

### **Section 2 – Commencement**

This section provides that the Instrument will commence on 1 January 2022.

### **Section 3 – Authority**

This section provides that the legislative authority for making the 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 such instrument. This Instrument is made in accordance with that provision.

### **Section 4 – Therapeutic Goods Advertising Code**

This section provides that Schedule 1 constitutes the code relating to advertisements about therapeutic goods for the purposes of section 42BAA of the Act.

### **Section 5 - Transitional**

This section provides that between the commencement of the Instrument on 1 January 2022 and 30 June 2022 (“the transition period”), advertisements about therapeutic goods to which this Instrument applies may comply with the requirements set out in the *Therapeutic Goods Advertising Code (No.2) 2018* (“the former Code”), as an alternative to the requirements set out in Schedule 1 to this Instrument. In effect, despite the repeal of the former Code, advertisers will have the option of either relying on the requirements specified in this Instrument, or the requirements specified in the former Code when advertising therapeutic goods for the duration of the transition period.

### **Section 6 – Repeals**

This section repeals the *Therapeutic Goods Advertising Code (No.2) 2018*.

## **Schedule 1—Therapeutic Goods Advertising Code**

### **Part 1—Preliminary**

This Part provides for the name of the *Therapeutic Goods Advertising Code* (“the Code”), the objects of the Code, and sets out key terms used in the Code.

#### **Section 1 – Name**

This section provides that the name of the Code is the *Therapeutic Goods Advertising Code*.

#### **Section 2 – Objects of this Code**

This section provides that the objects of the Code are to specify the requirements for advertisements about therapeutic goods so that advertisements:

- promote the safe and proper use of the therapeutic goods by minimising misuse, overuse or underuse; and
- are ethical and do not mislead or deceive the consumer or create unrealistic expectations about the performance of the therapeutic goods; and
- support informed health care choices; and
- are not inconsistent with current public health campaigns.

#### **Section 3 – Simplified outline of this Code**

This section provides a simplified outline for the Code and each of its parts. It provides that this Code specifies requirements for advertisements about therapeutic goods.

Part 1 deals with preliminary matters, including the definitions of key terms.

Part 2 specifies the advertisements to which the Code does, and does not, apply.

Part 3 specifies general requirements for advertisements about therapeutic goods.

Part 4 deals with mandatory statements and other required information that must be included in advertisements about therapeutic goods.

Part 5 specifies additional requirements for advertisements about analgesics, sunscreens and therapeutic goods for weight management.

Part 6 deals with testimonials and endorsements used in advertisements about therapeutic goods.

Part 7 deals with samples and incentives offered in advertisements about therapeutic goods.

Part 8 defines ‘serious’ form of a disease, condition, ailment or defect, and specifies public interest criteria, for the purposes of restricted representations.

Part 9 deals with advertisements about therapeutic goods comprising price information.

#### **Section 4 – Definitions**

This section provides the definitions of key terms used in the Code, including ‘analgesic’, ‘health professional’, ‘health warning’, ‘intended purpose’, ‘other therapeutic goods’, ‘pharmacy marketing group’, ‘price information’, ‘prominently displayed or communicated’, ‘public health campaign’, and ‘short form advertisement’.

This section also notes that some expressions used in the Code, namely ‘advertise’, ‘current Poisons Standard’, ‘directions for use’, ‘health practitioner’ ‘included in the Register’, ‘indications’, ‘label’, ‘medical device’, ‘medicine’, ‘Register’, ‘registered goods’, and ‘supply’ have the same meaning as in subsection 3(1) of the Act.

#### **Part 2—Application of this Code**

##### **Sections 5 – Advertisements to which this Code applies**

Subsection 5(1) provides that the Code applies to advertisements about therapeutic goods, other than advertisements specified in section 6.

Subsection 5(2) provides that the Code applies in relation to a particular advertisement, by reference to its likely impact on a reasonable person to whom the advertisement is directed. The view of the likely impact of the advertisement is through the objective eyes of the reasonable person to whom an advertisement is directed; subjective reactions that may be peculiar to specific individual attitudes and sensitivities are put to one side.

Subsection 5(3) provides that in applying the Code to an advertisement, the total presentation and context in which the advertisement is used is considered. In assessing whether an advertisement about therapeutic goods is consistent with the Code, the words (whether written or spoken), images, advertising medium and general presentation of the advertisement will all be considered.

##### **Section 6 – Advertisements to which this Code does not apply**

This section provides the circumstances in which advertisements about therapeutic goods are excluded from the operation of the Code.

Subsection 6(1) provides that the Code does not apply to an advertisement that is directed exclusively to a person mentioned in section 42AA of the Act. This includes medical practitioners, psychologists, dentists, and pharmacists. Subsection 6(1) also provides that the Code does not apply to an advertisement that is part of, or otherwise comprises, a public health campaign or is made in accordance with the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission (No. 4) 2021* made under section 42DK of the Act, as in force or existing on 24 September 2021.

Subsection 6(2) provides that other than Part 9, the Code does not apply to an advertisement about therapeutic goods that only contains price information about medicines that are registered goods and



contain a substance included in schedule 3, 4, or 8 to the current Poisons Standard (but not a substance that is included in Appendix H of the current Poisons Standard).

The effect of this provision is that where the dissemination or publication of price information in relation to therapeutic goods mentioned in the subsection constitutes advertising, the dissemination or publication of such information is taken to be authorised, for the purposes of subsections 42DL(10) and 42DLB(7) of the Act, if it complies with Part 9 of this Code. This in turn will mean that the publication or dissemination of price information about prescription medicines or certain pharmacist-only medicines complying with Part 9 of this Code will not contravene the offence and civil penalty provisions in the Act.

Subsection 6(3) provides that the Code does not apply to genuine news that is broadcast or published in any medium by a broadcaster, datacaster, the SBS, or a person of a kind prescribed by the *Therapeutic Goods Regulations 1990* (“the Regulations”) for the purposes of paragraphs 42DLB(10)(a) or 42DMA(2)(a) of the Act. The notes to this subsection provide the definitions for the mentioned types of publisher.

### **Part 3—General**

#### **Section 7 – Simplified outline of this Part**

This section provides that Part 3 specifies the general requirements that apply to advertisements about therapeutic goods. The purpose of these provisions is to ensure advertisements about therapeutic goods are accurate, balanced and not misleading, promote the safe and proper use of the goods and are consistent with public health campaigns.

#### **Section 8 – Accuracy**

Subsection 8(1) provides that advertisements about therapeutic goods must be accurate, balanced and not misleading, or likely to be misleading, and that all information presented must have been substantiated prior to publication or dissemination.

Subsection 8(2) provides that advertisements about therapeutic goods included in the Register must not be inconsistent with the indication or intended purpose accepted in relation to the inclusion of the goods in the Register.

#### **Section 9 – Safe and proper use**

This section provides requirements for advertisements about therapeutic goods to support the safe and proper use of the goods.

Subsection 9(1) provides that an advertisement about therapeutic goods must not represent the goods to be safe, or without harm or side-effect, or effective in all cases, or a guaranteed cure, or infallible, unfailing, magical, or miraculous. The purpose of this provision is to ensure that a person is not likely to be influenced by an advertisement to use a medicine in preference to those that have been prescribed by their medical or health practitioner.

Subsection 9(2) provides that advertisement about therapeutic goods must not be likely to cause undue alarm, fear or distress, or contain a representation to the effect that harmful consequences may result from the therapeutic goods not being used, unless the representation is the subject of a permission made under section 42DK of the Act or an approval given under section 42DF of the Act.

Subsection 9(3) specifies the types of statements, pictorial representations or designs that are prohibited in advertisements about therapeutic goods. These include statements that are inconsistent with the relevant label, directions for use, consumer medicine information, instructions for use, or patient information leaflet of the goods. Similarly, this subsection prohibits statements that would, or would be likely to, delay or discourage persons seeking necessary medical attention or from undertaking treatment prescribed by a medical practitioner. This would include statements that would encourage people to self-medicate rather than to seek treatment from their medical practitioner.

Subsection 9(3) also prohibits statements, pictorial representations or designs that exaggerate, or are likely to exaggerate, the efficacy or performance of the goods. Similarly, the subsection prohibits advertisements about therapeutic goods encouraging inappropriate or excessive use of the goods. For example, an advertisement that suggests a medicine may be used by the general population (despite there being sub-populations, such as children, in which use of the medicine is not appropriate) would be seen as encouraging inappropriate use of the medicine. This subsection also prohibits statements containing comparisons about therapeutic goods, classes of therapeutic goods, or therapeutic services (“comparator goods or services”) where such a comparison suggests that the comparator goods or services are harmful or ineffectual.

## **Section 10 – Consistency with public health campaigns**

This section provides that an advertisement about therapeutic goods must not be inconsistent with current public health campaigns.

## **Section 11 – Scientific or clinical representations**

This section provides requirements in relation to scientific or clinical representations used in advertisements about therapeutic goods.

Subsection 11(1) provides that section 11 does not apply to consumer medicine information, labels of therapeutic goods, patient information leaflets or instructions for use.

Subsection 11(2) provides that any scientific or clinical representations used in advertisements about therapeutic goods must contain terminology that is clearly communicated and can be readily understood by the audience to whom the advertisement is directed. The scientific or clinical representations must also be consistent with the body of scientific or clinical evidence applicable to the therapeutic goods that are the subject of the advertisement. Taken together, these provisions generally prevent the use of scientific or clinical ‘jargon’ or highly specialised scientific or medical terminology in advertising about therapeutic goods.

Subsection 11(3) provides that if scientific or clinical research is explicitly or implicitly cited in the advertisement, the advertisement must identify the researcher, and identify the financial sponsor of the research where the advertiser knows, or ought reasonably to have known, that information. The research must be cited in a way that allows consumers to access the study. This provision does not

require an advertiser to provide consumers with a copy of the cited research. The provision does, however, prevent advertisers from citing research that is not available to the consumer for reasons of confidentiality.

## **Section 12 – Advertising to children**

This section provides requirements in relation to advertisements about therapeutic goods directed at children.

Subsection 12(1) provides that section 12 does apply to labels of therapeutic goods.

Subsection 12(2) provides that advertisements about therapeutic goods must not be directed to children under 12 years of age.

Subsection 12(3) provides that advertisements about therapeutic goods must not be directed to children 12 years of age and over, unless the goods are specified in column 2 of an item in Annexure 1, and advertised in accordance with the conditions (if any) specified in column 3 of the item. The goods must also not contain a substance included in Schedule 2, 3, 4 or 8 to the current Poisons Standard.

## **Part 4—Mandatory statements and other required information**

### **Division 1—Preliminary**

#### **Section 13 – Simplified outline of this Part**

This Part deals with mandatory statements and other required information that must be included in advertisements about therapeutic goods.

Division 1 specifies the advertisements to which this Part does not apply.

Division 2 specifies mandatory statements that must be included in advertisements about therapeutic goods that are only available from pharmacists (section 15), advertisements about therapeutic goods that are not available for supply to the general public (section 16), and short form advertisements about therapeutic goods (section 17).

Division 3 deals with other advertisements about medicines, medical devices, and other therapeutic goods. It identifies the circumstances in which health warnings and other required information must be included in an advertisement.

#### **Section 14 – Application of this Part**

This section provides that Part 4 does not apply to consumer medicine information, labels of therapeutic goods, instructions for use, and patient information leaflets. This Part does also not apply to advertisements that comprise one or more of the following:

- the name of the goods;
- a pictorial representation of the goods;

- the price of the goods;
- the point of sale of goods;

and does not refer, expressly or by implication, to a claim relating to therapeutic use.

## **Division 2—Mandatory statements for particular advertisements**

This Division is accompanied by a note that advertisements mentioned in this Division do not need to comply with Division 3.

### **Section 15 – Advertisements—therapeutic goods only available from a pharmacist**

This section applies to advertisements about therapeutic goods consisting of, or containing, a substance included in Schedule 3 to, and Appendix H of, the current Poisons Standard. Such advertisements must contain the statement ‘ASK YOUR PHARMACIST ABOUT THIS PRODUCT’. This statement must be prominently displayed or communicated.

### **Section 16 – Advertisements—therapeutic goods not available for purchase by general public**

This section applies to advertisements about therapeutic that are published or disseminated to the general public and are about goods that are only available for supply through a health professional. Such advertisements must contain the statement ‘THIS PRODUCT IS NOT AVAILABLE FOR PURCHASE BY THE GENERAL PUBLIC’. This statement must be prominently displayed or communicated.

### **Section 17 – Advertisements—short form**

This section applies to advertisements about therapeutic that are short form advertisements. Such advertisements must contain the statement ‘ALWAYS FOLLOW THE DIRECTIONS FOR USE’. This statement must be prominently displayed or communicated.

## **Division 3—Mandatory statements and other required information for other advertisements**

### **Section 18 – Application of this Division**

This Division does not apply to the advertisements mentioned in Division 2.

### **Section 19 – Advertisements—medicines**

This section provides requirements in relation to advertisements about medicines.

Subsection 19(1) provides general requirements in relation to advertisements about medicines. Such advertisements must contain the name of medicine within the meaning of *Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines* (“TGO 92”). These advertisements must also contain one or more accepted indications for the medicine and the statement ‘ALWAYS READ THE LABEL AND FOLLOW THE DIRECTIONS FOR USE’. This statement must be prominently displayed or communicated.

Subsection 19(2) provides requirements for advertisements about medicines that facilitate directly their purchase (or other supply), without the opportunity for the medicine to be physically inspected by the consumer prior to purchase. An example of such an advertisement would be one that is published on a website, social media, or a software application through which a transaction for the medicine may be conducted. In addition to the general requirements, these types of advertisements must also include:

- the name of the dosage form within the meaning of TGO 92; and
- the quantity of the medicine within the meaning of TGO 92; and
- each active ingredient; and
- if one or more health warnings apply in relation to the medicine—either a list of the health warnings or a link to the health warnings. Either need to be prominently displayed or communicated.

Subsection 19(3) provides clarity as to the meaning of ‘link to the health warnings’ mentioned in subsection 19(2). Such a link to health warnings in relation to a medicine must provide a consumer with direct access to the warnings or a document containing those warnings. An example of this would be a link that takes consumers to a webpage that lists the health warnings, or a webpage that houses a document containing the health warnings. Such webpages cannot contain documents related to other goods or lists of health warnings for other goods.

Subsection 19(4) provides the definitions for terms used in section 19. It provides that ‘accepted indication’ means:

- in relation to a medicine that is included in the Register—an indication that is accepted in relation to the inclusion of the medicine; or
- in relation to a medicine that is not included in the Register and is not prescribed for the purposes of subsections 42DL(12) and 42DLB(9) of the Act—an indication that is displayed on the label of the medicine.

It provides that ‘health warning’, in relation to a medicine (or an ingredient contained in the medicine), means a warning, contra-indication, precaution or restriction, that is:

- required under a relevant instrument to be included on the label of the medicine; and
- reasonably necessary to inform a decision of a consumer to purchase the medicine.

The reference to ‘reasonably necessary’ is in relation to the reasonable person; what such a person would consider reasonable in the circumstances as necessary to inform a decision by a potential consumer to purchase the medicine.

Subsection 19(4) also provides that in section 19, ‘relevant instrument’ means one or more of the following:

- an instrument made under subsection 3(5A) of the Act relating to medicine advisory statements;
- a determination made under section 26BB of the Act relating to permissible ingredients;
- a determination made under section 26BF of the Act relating to permissible indications;

- a condition of registration or listing imposed under the Act in relation to the medicine;
- TGO 92.

The notes to this definition provide examples of the instruments made under the mentioned provisions of the Act.

## **Section 20 – Advertisements—medical devices**

This section provides requirements in relation to advertisements about medical devices.

Subsection 20(1) provides general requirements in relation to advertisements about medical devices. Such advertisements must contain the trade name of a device, an accurate description of the device, and one or more of its accepted intended purposes. The advertisement must also contain either of the following statements ‘ALWAYS FOLLOW THE DIRECTIONS FOR USE’ or ‘ALWAYS READ THE LABEL AND FOLLOW THE DIRECTIONS FOR USE’. The statement must be prominently displayed or communicated.

Subsection 20(2) provides requirements for advertisements about medical devices that directly facilitate their purchase (or other supply), without the opportunity for the medical devices to be physically inspected by the consumer prior to purchase. An example of such an advertisement would be one that is published on a website, social media, or a software application through which a transaction for the medical device may be conducted. In addition to the general requirements, these types of advertisements must also include:

- each ingredient of the device that is a substance included in a schedule to the current Poisons Standard, where relevant; and
- if one or more health warnings apply in relation to the device—either a list of the health warnings or a link to the health warnings. Either needs to be prominently displayed or communicated.

Subsection 20(3) provides clarity as to the meaning of ‘link to the health warnings’ mentioned in subsection 20(2). Such a link to health warnings in relation to a medical device must provide a consumer with direct access to the warnings or a document containing those warnings. An example of this would be a link that takes consumers to a webpage that lists the health warnings, or a webpage that houses a document containing the health warnings. Such webpages cannot contain documents related to other goods or lists of health warnings for other goods.

Subsection 20(4) provides the definitions for terms used in section 20. It provides that ‘accepted intended purposes’ means:

- in relation to a medical device included in the Register—an intended purpose that is accepted in relation to the inclusion of the device; or
- in relation to a medical device that is not included in the Register and is not prescribed for the purposes of subsections 42DL(12) and 42DLB(9) of the Act—an intended purpose that is displayed on the label of the device, and otherwise communicated in the instructions for use for the device.

It provides that ‘health warning’, in relation to a medical device (or an ingredient contained in the device), means a warning, contra-indication, precaution or restriction, that is:

- required under a relevant instrument to be included on the label of the medical device, or in the instructions for use; and
- reasonably necessary to inform a decision of a consumer to purchase the device.

The reference to ‘reasonably necessary’ is in relation to the reasonable person; what such a person would consider reasonable in the circumstances as necessary to inform a decision by a potential consumer to purchase the device.

Subsection 20(4) also provides that in section 20, ‘relevant instrument’ means one or more of the following:

- the Medical Devices Regulations;
- a condition of inclusion imposed under the Act in relation to the device;
- the current Poisons Standard.

### **Section 21 – Advertisements—other therapeutic goods**

This section provides requirements in relation to advertisements about other therapeutic goods.

Subsection 21(1) provides general requirements in relation to advertisements about other therapeutic goods. Such advertisements must contain the trade name of the goods, an accurate description of the goods, and one or more of their accepted indications. Where a label is on or attached to such goods, the advertisement must contain the statement ‘ALWAYS READ THE LABEL AND FOLLOW THE DIRECTIONS FOR USE’. This statement must be prominently displayed or communicated. Where no label is on or attached to the other therapeutic goods, the advertisement must contain the statement ‘ALWAYS FOLLOW THE DIRECTIONS FOR USE’. This statement must be prominently displayed or communicated in the advertisement.

Subsection 21(2) provides requirements for advertisements about other therapeutic goods that directly facilitate their purchase (or other supply), without the opportunity for the other therapeutic goods to be physically inspected by the consumer prior to purchase. An example of such an advertisement would be one that is published on a website, social media, or a software application through which a transaction for the other therapeutic goods may be conducted. In addition to the general requirements, these types of advertisements must also include:

- each ingredient of the goods that is a substance included in a schedule to the current Poisons Standard, where relevant; and
- if one or more health warnings apply in relation to the device—either a list of the health warnings or a link to the health warnings. Either needs to be prominently displayed or communicated.

Subsection 21(3) provides clarity as to the meaning of ‘link to the health warnings’ mentioned in subsection 21(2). Such a link to health warnings in relation to other therapeutic goods must provide a consumer with direct access to the warnings or a document containing those warnings. An example of this would be a link that takes consumers to a webpage that lists the health warnings, or a webpage

that houses a document containing the health warnings. Such webpages cannot contain documents related to other goods or lists of health warnings for other goods.

Subsection 21(4) provides the definitions for terms used in section 20. It provides that ‘accepted indications’ means:

- in relation to other therapeutic goods included in the Register—an indication that is accepted in relation to the inclusion of the goods; or
- in relation to other therapeutic goods that are not included in the Register and are not prescribed for the purposes of subsections 42DL(12) and 42DLB(9) of the Act—an indication that is displayed on the label of the goods.

It provides that ‘health warning’, in relation to other therapeutic goods (or an ingredient contained in the goods), means a warning, contra-indication, precaution or restriction, that is:

- required under a relevant instrument to be included on the label of the goods, or in the instructions for use, of the goods; and
- reasonably necessary to inform a decision of a consumer to purchase the goods

The reference to ‘reasonably necessary’ is in relation to the reasonable person; what such a person would consider reasonable in the circumstances as necessary to inform a decision by a potential consumer to purchase the goods.

Subsection 21(4) also provides that in section 21, ‘relevant instrument’ means one or more of the following:

- a condition of listing imposed under the Act in relation to the goods;
- the current Poisons Standard.

## **Part 5—Additional requirements for advertisements about particular therapeutic goods**

This Part is accompanied by a note that provides that this Part deals with additional requirements for advertisements about analgesics, sunscreens and therapeutic goods for weight management. The requirements in Part 5 apply in addition to the requirements in Part 4 (as applicable).

### **Section 22 – Application of this Part**

This section provides that Part 5 does not apply to consumer medicine information, labels of therapeutic goods, instructions for use, and patient information leaflets.

### **Sections 23 – Additional requirements for particular therapeutic goods**

This section provides additional requirements in relation advertisements about particular therapeutic goods.



Subsection 23(1) provides that an advertisement about an analgesic must contain the statement, ‘INCORRECT USE COULD BE HARMFUL’. This statement must be prominently displayed or communicated:

Subsection 23(2) provides that if an advertisement about a complementary medicine includes one or more claims based on evidence of traditional use, then a statement about the reliance on the traditional use must be prominently displayed or communicated in the advertisement.

Subsection 23(3) provides requirements for advertisements about therapeutic goods that are, or contain, a sunscreen and that claims or implies that the sunscreen will prevent sunburn or skin cancer. Such advertisements must depict sunscreen as being only one component of sun protection as well as include qualifying statements or visual representations, that are prominently displayed or communicated. These statements are that prolonged high-risk sun exposure should be avoided and frequent use and re-application in accordance with directions is required for effective sun protection.

Subsection 23(4) provides requirements for advertisements about therapeutic goods that contain one or more claims relating to weight management. Such advertisements must include statements or visual representations, that are prominently displayed or communicated, which promote the need for a healthy energy-controlled diet and physical activity. The advertisements must not include any reference or depiction suggesting that the therapeutic goods will correct or reverse the effects of overeating or over consumption of food or drink. Such advertisements must also not contain visual representations, statistics or testimonials of individuals that are not consistent with the results that would be expected to be achieved on average by consumers of the goods.

Subsection 23(5) provides that in this section, the term ‘weight management’ includes weight loss, weight control, weight maintenance, measurement reduction, clothing size reduction and hunger suppression. The list cannot be exhaustive; whether a claim is about weight management is a function of the presentation within the advertisement.

## **Part 6—Testimonials and endorsements**

### **Section 24 – Testimonials and endorsements**

This section specifies requirements for testimonials and endorsements used in advertisements about therapeutic goods.

Subsection 24(1) provides that testimonials and endorsements used in an advertisement about therapeutic goods must comply with the requirements of this section, and all other applicable provisions of this Code.

Subsection 24(2) provides that a testimonial or endorsement about therapeutic goods must not be inconsistent with the label for the goods and their instructions for use or directions for use. In addition, a testimonial or endorsement must not be inconsistent with either of the following:

- in relation to goods that are included in the Register—an indication or intended purpose that is accepted in relation to the inclusion of the goods; or

- in relation to goods that are not included in the Register and are not prescribed for the purposes of subsections 42DL(12) and 42DLB(9) of the Act—an indication or intended purpose that is displayed on the label of the goods, and otherwise communicated in the directions for use or the instructions for use for the goods.

Subsection 24(3) provides that if a testimonial or endorsement states or implies a health benefit, then the health benefit must be typical of the benefit expected from the goods when used in accordance with the label, the instructions for use or directions for use and the entry in the Register for the goods.

Subsection 24(4) prohibits advertisements about therapeutic goods from containing testimonials made by specified persons or bodies. These specified persons or bodies are any of the following:

- a person who is engaged in the production, marketing or supply of the goods (“a relevant person”);
- a member of a relevant person’s immediate family, unless the advertisement discloses that the person who made the testimonial is an immediate family member of the relevant person;
- a person or organisation mentioned in paragraphs 24(6)(a) to (e);
- a corporation.

The note to subsection 24(4) provides that the relevant person referred to in that subsection includes influencers, direct sellers and other persons who have, or will receive, valuable consideration for making the testimonial.

Subsection 24(5) provides that an advertisement for therapeutic goods must not contain a testimonial, unless the advertiser has verified the content of, and identity of the person providing, the testimonial.

Subsection 24(6) prohibits endorsements about therapeutic goods being given, either expressly or by implication, by the following specified persons or bodies:

- a government or government authority, unless otherwise permitted by the Act or Regulations, or an employee or contractor of such a body;
- a hospital, or healthcare facility, other than a community pharmacy, or an employee or contractor of such a body;
- a current or former health practitioner, health professional or medical researcher;
- a person who represents themselves as being qualified or trained to diagnose, treat or prevent disease, ailment, defect or injury in persons;
- an organisation that represents the interests of healthcare consumers, or represents the interests of current or former health practitioners, health professionals or medical researchers, unless the advertisement discloses the name of the organisation and whether the organisation has received, or will receive, any valuable consideration for the endorsement.

Testimonials and endorsements are often effectively used in social media. These provisions assist consumers to weigh the value of the testimonial or endorsement in any decision to purchase the goods. The intention is to ensure that the person providing a testimonial discloses an ‘immediate family’ relationship with a relevant person involved in the production, marketing or supply of the goods. A person providing a testimonial is a member of a relevant person’s immediate family, if the

person is that other person's parent, grandparent, spouse, de facto spouse, child or ward, noting 'immediate family' is defined in the Code to have the same meaning as in the Regulations.

## **Part 7—Samples and incentives**

### **Section 25 – Samples**

This section provides the requirements relating to the offer of samples in advertisements about therapeutic goods.

Subsection 25(1) provides that an advertisement about therapeutic goods must not contain or consist of a sample, or an offer of a sample, unless:

- the goods are mentioned in an item in Annexure 2; and
- the conditions (if any) for that item are met; and
- the goods do not contain a substance included in Schedule 2, 3, 4 or 8 to the current Poisons Standard; and
- in relation to goods included in the Register—the goods are supplied in a pack accepted in relation to the inclusion of the goods.

Subsection 25(2) provides that, in section 25, sample means any therapeutic goods given for free.

### **Section 26 – Incentives**

This section provides that an advertisement must not offer any personal incentive or commission to a pharmacy assistant, or any retail sales person who is not a health professional, in exchange for recommending or supplying the goods.

## **Part 8—Restricted representations**

### **Section 27 – Simplified outline of this Part**

This Part deals with restricted representations for the purposes of section 42DD of the Act. It identifies the circumstances in which a disease, condition, ailment or defect is considered to be a serious form, and mentions the public interest criteria for deciding whether to approve or refuse the use of restricted representations under section 42DF of the Act.

### **Section 28 – Restricted representations—serious form of a disease, condition, ailment or defect**

This section provides that for the purposes of section 42DD of the Act, when a form of a disease, condition, ailment, or defect is a serious form. A form of disease, ailment or condition will be considered a serious form if it is medically accepted that the form requires diagnosis or treatment or supervision by a health practitioner who is suitably qualified, except where the form has been medically diagnosed and medically accepted as being suitable for self-treatment and management. This criterion is satisfied if any one of diagnosis, treatment or supervision can only be carried out by a suitably qualified healthcare practitioner; that is, a person with a recognised qualification in an appropriate medical discipline whether as a general practitioner or a specialist. A form of disease,

condition, ailment or defect is also considered a serious form if there is a diagnostic (including screening), preventative, monitoring, susceptibility or pre-disposition test available for the form (including a self-administered test), which requires medical interpretation or follow-up by a suitably qualified medical practitioner. These two categories do not include pregnancy, other than pregnancy with a medical, obstetric or surgical complication.

Section 42DD of the Act provides that a representation in an advertisement about therapeutic goods, which refers to a serious form of a disease, condition, ailment, or defect is a restricted representation. Section 42DF of the Act enables the Secretary to approve the use of a restricted representation, in response to an application, and to impose conditions on the approval. Section 42DK of the Act enables the Secretary to permit the use of specified restricted representations in specified advertisements about specified therapeutic goods.

### **Section 29 – Restricted representations—public interest criteria**

This section sets out the public interest criteria for the purposes of paragraph 42DF(4)(c) of the Act. These are criteria that the Secretary must take into account in determining whether or not to approve the use of a particular restricted representation. These criteria are:

- whether the representation would be likely to take advantage of the vulnerability of consumers, or particular groups of consumers, impacted by the disease, condition, ailment or defect; and
- whether the representation would be likely to result in consumers not seeking timely medical attention, where the attention is necessary to prevent negative health consequences, morbidity or mortality, or deterioration or progression of the disease, condition, ailment or defect; and
- whether the representation would be likely (alone, through repetition or together with other representations) to have a negative impact on public health; and
- such other aspects of the public interest as may appear to be appropriate to the Secretary.

### **Part 9—Price information**

This Part is accompanied by a note that, for the avoidance of doubt, provides that the publication or dissemination of price information made in accordance with this Part is authorised by the Department for the purposes of subsections of subsections 42DL(10) and 42DLB(7) of the Act.

### **Section 30 – Simplified outline of this Part**

Part 9 sets out the conditions under which information about the price of prescription medicines and certain pharmacist-only medicines, that are registered goods, may be provided to the general public.

### **Section 31 – Application of this Part**

This section provides that Part 9 applies to an advertisement about therapeutic goods that is, or comprises, price information:

- in relation to medicines that are registered goods and contain a substance included in Schedule 3, 4 or 8 to the current Poisons Standard (but not included in Appendix H of the current Poisons Standard); and

- published or disseminated to the general public.

### **Section 32 – Publication or dissemination of price information**

This section provides requirements relating to the publication or dissemination of price information.

Subsection 32(1) provides that price information may only be published or disseminated by a retail pharmacy, an agent acting on behalf of a retail pharmacy (including a pharmacy marketing group), or a medical practitioner approved under section 92 of the *National Health Act 1953*.

Subsection 32(2) provides that price information must not be published or disseminated in relation to a medicine listed in the pharmaceutical benefits scheme, and supplied through alternative arrangements under section 100 of the *National Health Act 1953*, other than dispensing fees for buprenorphine hydrochloride and methadone hydrochloride.

Subsection 32(3) provides the means by which price information may not be published or disseminated. This subsection prohibits the publication or dissemination of price information by radio or television transmission, including pay and streaming services as well as by digital or non-digital displays, including but not limited to displays in shopping malls outside individual pharmacies, in or on public transport or on billboards. The subsection also prohibits the publication or dissemination of price information by cinema advertising.

Subsection 32(4) provides that where price information for a medicine is published or disseminated through a search function included in an electronic sales system, the results of the search must only include:

- if the search is conducted using the name of the medicine or part thereof—a list of relevant medicines of that name; or
- if the search is conducted using an active ingredient or part thereof of the medicine—a list of relevant medicines in alphabetical order.

Subsection 32(5) disapplies the operation of specified provisions from price information published or disseminated in accordance with subsection (4). The specified provisions are paragraph 33(1)(a), subsections 33(2) and (3), paragraph 35(a) and section 36.

This section provides that price information may only be published or disseminated by retail pharmacies, agents acting on behalf of retail pharmacies including pharmacy marketing groups, or dispensing doctors. Manufacturers, distributors and sponsors of medicines and other health practitioners or health professionals are prohibited, by their omission from this section, from publishing or disseminating price information.

### **Section 33 – Presentation of price information**

This section provides the requirements for the presentation of price information in advertisements about therapeutic goods.

Subsection 33(1) provides that price information in relation to a medicine must be published or disseminated in a list containing not less than 25 medicines (“the price information list”) and accompanied by the name and contact details of the retail supplier from whom each medicine mentioned in the price information list may be purchased at the list price.

Subsection 33(2) provides that subject to subsection 33(3), the price information list must specify medicines in alphabetical order with reference to trade name or active ingredient.

Subsection 33(3) provides that medicines may be grouped in a price information list according to the schedule in the current Poisons Standard in which the medicines are included, provided that the price information list contains three or more medicines from each schedule in each grouping and persons in whose names the medicines are included in the Register.

These provisions operate to prevent consumers being directed to a particular medicine over and above any other medicines.

### **Section 34– Description of medicines**

This section provides the requirements for how medicines should be described when presenting price information.

Subsection 34(1) provides that a medicine in a price information list must be specified with reference to the name of the medicine within the meaning of *Therapeutic Goods Order No. 91 – Standard for labels of prescription and related medicines* (“TGO 91”) or TGO 92 as applicable.

Subsection 34(2) provides that a price information list must include, in relation to each medicine:

- if there is more than one strength of the medicine—the strength of each active ingredient as it appears on the label of the medicine; and
- the dosage form in which the medicine is presented; and
- the purchase price of the relevant number of units of the standard pack accepted in relation to the inclusion of the medicine in the Register (“standard pack”); and
- the quantity contained in the standard pack.

Subsection 34(3) provides that for the purposes of this section, where the pharmaceutical benefits scheme or Repatriation Benefits Scheme permits more than one unit of the standard pack to be prescribed, the ‘relevant number of units’ of a standard pack is the maximum number of units that may be prescribed under those schemes. This subsection provides that in any other case the ‘relevant number of units’ of a standard pack is one.

Subsection 34(4) provides that a price information list may include a reference to the requirement to obtain a prescription for a particular medicine.

### **Section 35 – General restrictions**

This section provides general restrictions on the presentation of price information lists. A price information list must not:

- present or describe a medicine in a way that directs consumers to a particular medicine over and above any other medicine, whether or not that particular medicine is mentioned in the price information list; or
- be accompanied by any promotional statement, pictorial representation or design; or
- include an adjective or phrase that qualifies the name, formulation or pack size of the medicine, a term indicating the predicted or recommended length of supply, or any embellishment; or
- promote the purchase of quantities or multiple pack sizes that are not accepted in relation to the inclusion of the goods in the Register, except as provided under section 34; or
- use a comparative adjective or term to qualify the purchase price of the medicine; or
- give any prominence to the text of the name, description or purchase price of a particular medicine compared to any other medicine in the price information list; or
- offer rewards or bonus points, or be associated with any other advertising that promotes rewards or bonus points; or
- limit or qualify the availability of the price, other than by including a statement of validity or expiration of the purchase price; or
- be accompanied by, or located in proximity to, information (including implications or references to other sources of information) regarding indications, diseases, conditions, ailments or defects, so that a reasonable person might infer that the medicine would cure or alleviate those diseases, conditions, ailments or defects.

### **Section 36 – Medicines listed in the pharmaceutical benefits scheme**

This section provides requirements in relation to presenting price information for medicines listed in the pharmaceutical benefits scheme.

Subsection 36(1) provides that if a pharmacy marketing group publishes or disseminates a price information list that includes price information for a medicine listed in the pharmaceutical benefits scheme (that is a brand premium or therapeutic group premium) and the price information list includes price information for the pharmacy marketing group's own generic medicine (that is listed in the pharmaceutical benefits scheme), then the price information list must also include price information for at least one other bench-mark price brand of that medicine, where such medicine exists.

Subsection 36(2) provides that a price information list that includes a medicine listed in the pharmaceutical benefits scheme must clearly indicate that the medicine is listed in the pharmaceutical benefits scheme. The total purchase price must also be clearly specified with reference to the general price or concessional price or both.

Subsection 36(3) provides that a price information list, which includes a medicine listed in the pharmaceutical benefits scheme, must indicate that the purchase price is subsidised by the Australian Government and only applies when the medicine is prescribed for the medical conditions listed in the pharmaceutical benefits scheme schedule for that medicine.

Subsection 36(4) provides that a price information list may include a statement that particular medicines are listed in the pharmaceutical benefits scheme only in relation to certain diseases, conditions, ailments or defects (without specifying those diseases, conditions, ailments or defects).

**Annexure 1—Advertising to children**

This annexure specifies the therapeutic goods that may be advertised to children who are 12 years of age or over for the purposes of section 12 of the Code.

**Annexure 2—Samples**

This annexure specifies the therapeutic goods that may offered as a sample for the purposes of section 25 of the Code.



## Statement of Compatibility with Human Rights

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

### *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021*

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 the legislative instruments

The *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021* (“the instrument”) is made under section 42BAA of the Act. The purpose of the instrument is to set out requirements for advertisements for therapeutic goods that are directed to the public, to protect the public from false or misleading therapeutic goods advertising and the consequent risks to public health.

Schedule 1 to the instrument constitutes the code relating to advertisements about therapeutic goods for the purposes of section 42BAA of the Act (“the code”).

The code specifies a range of requirements in relation to advertisements about therapeutic goods. The requirements are intended to ensure that advertisements about therapeutic goods promote their safe and proper use, and that appropriate controls on advertisements are in place to protect the Australian public from the potential personal and public health risks associated with unethical, inaccurate, or misleading advertising practices.

The regulation of advertisements about therapeutic goods contributes to the safe and proper use of therapeutic goods by ensuring that the general public receives accurate and balanced information about the quality, safety and efficacy of those goods. It is essential that only credible information is presented in advertisements about therapeutic goods, so that consumers are able to make informed decisions regarding the suitability of the goods for their particular health needs, and do not delay seeking advice or treatment from a health practitioner where appropriate.

Reflecting the significance of such concerns in relation to the advertising of therapeutic goods, the Act contains (in addition to the offence and civil penalty provisions in sections 42DM and 42DMA for advertisements that do not comply with the code), requirements relating to compliance with the code as a criterion or basis for the making of a number of significant regulatory decisions under the Act, including in particular decisions in relation to:

- the registration, listing or inclusion of therapeutic goods in the Australian Register of Therapeutic Goods (“the Register”);
- the suspension or cancellation of therapeutic goods from the Register; and
- the approval of the use of restricted representations in advertisements about therapeutic goods (a restricted representation is a representation in an advertisement about therapeutic goods

that refers to a form of disease, condition, ailment or defect that the code identifies as being a serious form of disease, condition, ailment or defect).

The *Therapeutic Goods Advertising Code (No.2) 2018* (“the former code”), was made on 31 October 2018 and commenced on 1 January 2019. Since then experience with the former code has provided information on opportunities for improving some provisions and its general clarity. With the potential for serious consequences for non-compliance, it is important that the code remains contemporary and clear.

The code repeals the former code to reflect the following improvements:

- simplifying the language and structure of the code to improve readability, reduce complexity and therefore increase overall compliance;
- revising and streamlining the mandatory statements required to be included in advertisements about therapeutic goods;
- clarifying the requirements relating to testimonials and endorsements about therapeutic goods, and resolving inconsistencies relating to such requirements; and
- expanding the lists of therapeutic goods that may be offered as a sample.

### **Human rights implications**

The instrument engages two human rights and freedoms recognised in the instruments listed in section of the *Human Rights (Parliamentary Scrutiny) Act 2011*, the right to freedom of opinion and expression, and the right to health.

#### *Right to freedom of opinion and expression*

In seeking to regulate the advertising of therapeutic goods to the Australian public, the instrument engages the right to freedom of opinion and expression in Article 19 of the International Convention on Civil and Political Rights (“ICCPR”). Article 19 provides at Clause 2 that everyone shall have the right to freedom of expressing, including the right to seek, receive and impart information orally or through a range of media. Clause 3 of Article 19 notes that the exercise of these rights may be subject to restrictions as are provided by law and are necessary for (among other things) the protection of public health. The Human Rights Committee of the United Nations has expressed the view that for a limitation to be ‘necessary’, there must a burden of justification on government agencies, to demonstrate that any restrictive measures are proportional (United Nations Human Rights Committee, *General Comment No. 34*, note 4, para 3, cited in Australian Human Rights Commission, *Background Paper: Human Rights in Cyberspace*, available at <https://www.humanrights.gov.au/publications/background-paper-human-rights-cyberspace/4-permissible-limitations-iccpr-right-freedom>).

The instrument seeks to regulate the content of advertisements for therapeutic goods in the interests of public health. The provisions of the instrument aim to ensure that such advertisements provide consumers with accurate information that is not misleading. It includes information that consumers need to make safe and informed choices about therapeutic goods in connection with their health, or with cautions about the need to seek further medical advice where appropriate. As such, any

limitations on the right to freedom falls within the exemption set out in Article 19(3) of the ICCPR, and are proportionate in the circumstances.

### *Right to health*

Additionally, 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 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 requiring advertisements for therapeutic goods to include important information relating to the safe and proper use of therapeutic goods and otherwise to not include information that is false or misleading. The instrument also takes positive steps to promote the right to health through the inclusion of measures designed to support public health and to prevent possible negative health outcomes arising from the misuse or inappropriate use of therapeutic goods. For instance, the instrument provides that advertisements about therapeutic goods must not cause, or be likely to cause, undue alarm, fear and distress. The instrument also provides that advertisements about therapeutic goods must not be directed to children under 12 years of age, and that advertisements about therapeutic goods contain mandatory statements to support their safe and proper use, such as “Always read the label” or “Always follow the directions for use”.

In so doing, the instrument contributes to the safe and proper use of therapeutic goods by ensuring that the general public receives accurate and balanced information about the quality, safety and efficacy of therapeutic goods. It is essential that only credible information is presented in advertisements for therapeutic goods, so that consumers are able to make informed decisions regarding the suitability of the goods for their particular health needs, and do not delay seeking advice or treatment from a health practitioner where appropriate.

### **Conclusion**

This instrument is compatible with human rights because it engages the right to freedom of opinion and expression, and falls within the exemption set out in Article 19(3) of the ICCPR, promotes the right to health in Article 12 of the ICESCR and otherwise does not raise any other human rights issues.