

EXPLANATORY STATEMENT

Therapeutic Goods Advertising Code (No. 2) 2018

Section 42BAA, Therapeutic Goods Act 1989

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

The Act also provides a framework for regulating advertisements for therapeutic goods, including a number of provisions that require advertisements for therapeutic goods to the public to comply with the Therapeutic Goods Advertising Code (the Advertising Code). The Advertising Code, which sets out minimum requirements for advertisements about therapeutic goods directed to the public, is a legislative instrument made by the Minister or his or her delegate under section 42BAA of the Act. Appropriate controls on advertising are required to protect the public from false or misleading advertising of therapeutic goods and the consequent risks to public health.

The *Therapeutic Goods Amendment (2017 Measures No. 1) Act 2018*, which commenced on 6 March 2018, supported by the *Therapeutic Goods Legislation Amendment (2018 Measures No. 1) Regulations 2018*, which commenced on 20 March 2018, implement a number of key recommendations made by the Expert Panel Review of Medicines and Medical Devices Regulation and accepted by the Government, including reforms to improve and streamline the advertising of therapeutic goods to the public.

Enactment of the *Therapeutic Goods Amendment (2017 Measures No. 1) Act 2018* has provided the TGA with enhanced compliance and enforcement powers to protect the public from inappropriate or misleading advertising. These include graduated penalties (with both fault-based and strict liability offences) and corresponding civil penalties in some cases, such as sections 42DM and 42DMA respectively for dealing with therapeutic goods advertising that does not comply with the Advertising Code. The enhanced powers in the Act will provide flexibility allowing the Secretary or his or her delegate to respond appropriately to non-compliant advertising behaviours.

In June 2018, following a consultation period, the delegate of the Minister made the *Therapeutic Goods Advertising Code 2018* (the Advertising Code 2018) which was registered on the Federal Register of Legislative Instruments. The purpose of the Advertising Code 2018 was to remake the *Therapeutic Goods Advertising Code 2015* (the Advertising Code 2015) to support implementation of the Government-accepted recommendations of the Expert Panel Review of Medicines and Medical Devices Regulation:

- providing increased clarity and objectivity to support new and amended enforcement provisions in the Act to deal with breaches of advertising requirements; and
- improving consistency between the requirements for medicines and medical devices.

The Advertising Code 2018 also incorporated a number of amendments that:

- enhance and clarify previous provisions;
- address inconsistencies and issues that had been previously identified through public consultation and/or by the former Therapeutic Goods Advertising Code Council; or
- are of a minor and/or technical nature.

The Advertising Code 2018 had a commencement date of 1 January 2019.

Further to consultation on the proposed guidance material to accompany the Advertising Code 2018, and further targeted consultations on the Advertising Code 2018 (including with the recently-established Therapeutic Goods Advertising Consultative Committee) it was appropriate to clarify and refine the instrument. To implement these changes, the Advertising Code 2018 will be replaced with the *Therapeutic Goods Advertising Code (No. 2) 2018* (Advertising Code (No. 2) 2018).

The key changes made by the Advertising Code (No. 2) 2018 are intended to:

- clarify what is required by the obligation that a particular health warning or other statement is ‘prominently displayed or communicated’ in an advertisement for therapeutic goods. This term is defined, as applicable for both visual and spoken statements, by reference to the impact of the statement on the consumer; the requirement is that such an important statement is likely, in the case of a visual statement, to be easily read from a reasonable viewing distance and, for a spoken statement, able to be clearly heard and understood. For each advertising medium the statement must be repeated as often as is necessary to ensure that it is likely to be noticeable to a viewer or a listener.
- specify particular ‘health warnings’ that are to be included, in accordance with the requirements of the Code, in advertising for medicines which contain particular ingredients as listed in Schedule 1. This schedule reflects a set of the most serious warning statements that sponsors of (principally) registered over the counter medicines and listed (mostly complementary) medicines are or will be required to include on the labels of their products under a number of other requirements under the Act (for example, for listed medicines - the *Therapeutic Goods (Permissible Ingredients) Determination No.3 of 2018*, and for registered over the counter medicines - the *Medicines Advisory Statement Specification 2017* and for both categories of medicine –*Therapeutic Goods Order No.69 – General Requirements for Labels for Medicines 2017* and *Therapeutic Goods Order No.92 – Standard for labels of non-prescription medicines*). The statements in Schedule 1 have, where possible, been condensed, for suitability for inclusion in therapeutic goods advertisements, focussing on the most important health information for consumers to be aware of when considering buying a medicine, e.g. for Chlorhexidine, “Chlorhexidine can cause severe allergic reactions”, or for Ibuprofen “Do not use

if you have a stomach ulcer, impaired kidney function, heart failure, are allergic to anti-inflammatory medicines, or in the last 3 months of pregnancy”. The explanation under Schedule 1 gives more detail about the specific circumstances of their application. The health warning requirements for medical devices and other therapeutic goods are also clarified.

The Advertising Code (No. 2) 2018 will commence on 1 January 2019 and repeals the both the Advertising Code 2015 and the Advertising Code 2018, meaning that the Advertising Code 2018 will never take effect.

BACKGROUND

The Advertising Code (No. 2) 2018 is the major compliance standard which sets out the minimum advertising requirements and underpins the regulatory framework for the advertising of specified therapeutic goods to the public. It also provides the regulatory authorisation for the publication of price information for prescription and certain pharmacist-only medicines that cannot otherwise be advertised to the public. This will replace the *Price Information Code of Practice 2006*.

Compliance with the Advertising Code (No. 2) 2018 is a criterion or a basis for the making of the following decisions under the Act and the *Therapeutic Goods Regulations 1990* (Regulations):

- (a) pre-approval of specified advertisements for publication or broadcast as established under regulation 5G of the Regulations (until 1 July 2020);
- (b) the registration, inclusion or listing of therapeutic goods on the Australian Register of Therapeutic Goods (the Register);
- (c) suspension or cancellation of the entry of therapeutic goods from the Register;
- (d) approving “restricted representations”, to be used in advertisements for particular therapeutic goods under section 42DF of the Act. 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 Advertising Code identifies as a serious form of a disease, condition, ailment or defect;
- (e) the presence or absence of restricted or prohibited representations as one of the criteria for exemption from the requirements of Parts 3-2 or 3-2A of the Act for homoeopathic medicines; and
- (f) determining compliance or non-compliance with Code provisions for the purposes of sections 42DM and 42DMA of the Act.

Details of the Advertising Code (No. 2) 2018 are set out in Attachment 1.

CONSULTATION

There has been significant consultation on the development of the Advertising Code (No. 2) 2018, including those provisions that are similar or identical to those consulted upon during the development of the Advertising Code 2018, made in June 2018.

The policy proposals behind the Advertising Code (No. 2) 2018 were the subject of recommendations of the Review. The Review process involved extensive consultation with stakeholders from industry, consumer groups and the medical profession about the

regulation of therapeutic goods in Australia, including the advertising of therapeutic goods.

Noting the legislative history summarised above, consultation specifically relating to the Advertising Code (No. 2) 2018 included:

- an initial public consultation on broad proposals for development of a new Code during August to October 2017;
- five targeted consultation workshops with key sectors in relation to proposed Code provisions in February 2018;
- consultation with the former Therapeutic Goods Advertising Code Council (the Council) including consideration in March 2018 of a draft Code. The Council was a statutory body established under regulation 42A of the Regulations and comprised relevant stakeholders including the therapeutic goods industry, advertisers, health professionals and consumers. The Council's functions included considering requirements for the advertising of therapeutic goods and changes to the code, to accept submissions for this purpose and to advise the Minister accordingly;
- public consultation on a more mature draft code incorporating feedback from the Council, from 29 March to 27 April 2018;
- further consultation with the Council in May 2018 advising of proposed revisions to the consultation draft;
- consultation between August and October 2018 on draft guidance material, followed by consultation, including with the newly established Therapeutic Goods Administration Consultative Committee (comprised of industry and consumer representatives relevant to therapeutic goods) on further revisions to the Code made consequentially to that process and to improve the instrument's clarity.

These formal consultations were complemented by a significant number of meetings with individual stakeholders on drafts of the Code between March and October 2018.

Submissions made to the consultations and comments made at the stakeholder workshops and by the Committee have been taken into consideration in the drafting of the Advertising Code (No. 2) 2018.

STATEMENT OF COMPATIBILITY WITH HUMAN RIGHTS

The Advertising Code (No. 2) 2018 is compatible with human rights. The Advertising Code (No. 2) 2018 engages the right to freedom of opinion and expression, and falls within the exemption set out within Article 19(3) of the International Covenant on Civil and Political Rights, as the limitations on this right are made under law, are proportionate, and are consistent with the need to protect public health.

The Advertising Code (No. 2) 2018 promotes the right to health by requiring that health information provided to the public via advertising is accurate, appropriate for its intended audience, and consistent with public health messaging.

A Statement of Compatibility with Human Rights is at Attachment 2.

DETAILS OF THE *THERAPEUTIC GOODS ADVERTISING CODE (NO. 2) 2018*

Part 1 – Preliminary

This Part provides for the name of the instrument and its commencement; it sets out the definitions, the object of the Code and its application, for example it does not apply to genuine news that is broadcast or published by specified persons. It specifies how the Code should be applied, for example by reference to its likely impact on a reasonable person to whom the advertisement is directed and that consideration is given to the total presentation and context of the relevant advertisement. Part 1 provides for the repeal of the *Therapeutic Goods Advertising Code 2015* (Advertising Code 2015) and the *Therapeutic Goods Advertising Code 2018* (Advertising Code 2018) as specified in Schedule 5. Part 1 also makes clear that the Advertising Code 2015 applies to advertisements that have been approved under regulation 5G of the *Therapeutic Goods Regulations 1990* (Regulations) prior to the commencement of the *Therapeutic Goods Advertising Code (No. 2) 2018* (Advertising Code (No 2) 2018) on 1 January 2019.

Section 1

This section provides that the name of the instrument is the *Therapeutic Goods Advertising Code (No. 2) 2018*.

Section 2 - Commencement

This section provides that the Code will commence operation on 1 January 2019, other than Part 4 of Schedule 1 which will commence operation on 1 September 2020.

This reflects that Part 4 of Schedule 1 contains health warnings based on label warning statements that will not be mandatory for certain medicines until 1 September 2020, as a result of the end of the transitional arrangements under *Therapeutic Goods Order No.92 – Standard for labels of non-prescription medicines*. However, nothing precludes an advertiser from voluntarily including the health warnings in Part 4 of Schedule 1 in a relevant advertisement before that date, to assist consumers.

Section 3 – Authority

This section provides this instrument is made under subsection 42BAA(1) of the Act.

Section 4 - Definitions

This section sets out a number of important definitions used in the Code. A number of expressions used in the Code are defined in subsection 3(1) of the Act, including the definitions of ‘advertise’, ‘current Poisons Standard’, ‘health practitioner’ and ‘directions for use’.

Terms defined by section 4 of the Code include:

‘advertiser’, which is defined consistently with sections 42DL(1) and 42DLB(1) of the Act to mean a person who: (a) advertises, by any means, therapeutic goods; or (b) causes the advertising, by any means, of therapeutic goods;

‘analgesic’, means a medicine for internal use to relieve aches and pains, containing one or more of salicylic acid, non-steroidal anti-inflammatory drugs, or paracetamol, but does not include a medicine which is designed to treat a self-limiting condition, and in which these substances are combined with one or more other active ingredients and the other ingredients have been included in the medicine for indications other than the relief of aches and pains;

‘bench-mark price brand’ for a multi branded medicine means the lowest priced product within the group of medicines listed by the Pharmaceutical Benefits Scheme (PBS) as brands of the same medicine. These bioequivalent brands may also be referred to as ‘generic medicines’ in other contexts. For a medicine listed by the PBS there may be more than one bench-mark price brand for that medicine;

‘child’ means a person under the age of 18 years;

‘complementary medicine’ has the same meaning as in the Regulations;

‘dispensing doctor’ refers to a medical practitioner approved under section 92 of the *National Health Act 1953*;

‘health professional’ refers to a person engaged in one of the professions or activities mentioned in section 42AA of the Act. These include medical practitioners, dentists, optometrists, nurses, dental therapists, and persons engaged in the business of wholesaling therapeutic goods. Schedule 1 of the Regulations also prescribes the bodies for whose members Part 5-1 of the Act does not apply;

‘health warning’, for a medicine that contains an ingredient mentioned in column 1 of the table in Schedule 1, in the circumstances set out in column 2 of that table, means the statement mentioned in column 3 of the table in Schedule 1. For a medical device or other therapeutic goods, ‘health warning’ means a statement that is required under the Act, the Regulations or the Medical Devices Regulations to be included on the label or in instructions for use that warns that a person who takes or uses the device or good as intended may die, require hospitalisation or a longer period of hospitalisation required than if the person had not taken or used the device or goods, or require a medical practitioner to treat or prevent injury, disability, incapacity or physical impairment;

‘immediate family’ has the same meaning as in the Regulations. This term is defined in regulation 2 of those Regulations as including a person’s parent, grandparent, spouse, *de facto* spouse, child or ward;

‘ingredients’ includes both active ingredients and any other substances or groups of substances that are required to be on the label of the medicine under paragraph 8(1)(j) of the *Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines*;

‘Medical Devices Regulations’ means the *Therapeutic Goods (Medical Devices) Regulations 2002*;

‘other therapeutic goods’ means therapeutic goods that are not medicines, biologicals or medical devices;

‘patient information leaflet’ has the same meaning as in cl 13A.3 of Schedule 4 to the Medical Devices Regulations. A patient information leaflet is a leaflet that clauses 13A.1 and 13A.3 of Schedule 1 to the Medical Devices Regulations require must be provided in an implantable medical device or an active implantable medical device and that it is not a

suture, staple, dental filling, dental brace, tooth crown, screw, wedge, plate, wire, pin, clip or connector and that meets the specified requirements of clauses 13A.3 and 13A.4;

‘price information’, for prescription medicines and pharmacist-only medicines is information about the total purchase price of medicines to consumers, and for medicines subsidised under the Pharmaceutical Benefits Scheme or the Repatriation Pharmaceutical Benefits Scheme, the price paid by the consumer when the prescription is dispensed;

‘prominently displayed or communicated’ for a visual statement in an advertisement, means standing out so as to be easily read from a reasonable viewing distance for the particular media type in the context in which the advertisement is intended to be viewed, and repeated as often as is necessary to ensure that it is likely to be noticeable for a viewer. For a spoken statement in an advertisement, ‘prominently displayed or communicated’ means able to be clearly heard and understood, and repeated as often as is necessary to ensure that it is likely to be noticeable for a listener. Several sections of the Code, including sections 11, 12 and 13, require the inclusion of specified health warnings or other statements in an advertisement to be ‘prominently displayed or communicated’. This phrase is used consistently throughout the Code to ensure that the specified messages, that are critical to the consumer when selecting a product for self-treatment, are given prominence so that they are likely to be noticeable for consumers;

‘public health campaign’, is a campaign about a public health matter which is conducted, approved or funded by the Commonwealth government or a State or Territory Government or by a statutory authority;

‘Regulations’ means the *Therapeutic Goods Regulations 1990*;

‘specified media’ is defined by reference to section 42B of the Act – to mean mainstream media, broadcast media, cinematograph films or displays about goods including posters in shopping malls (except in an individual shop) and in or on public transport and on billboards;

‘total purchase price’, for therapeutic goods, means the total cost of the goods to a consumer, including the administration, handling and infrastructure fee, any mark-up payable to the pharmacist, or any dispensing fee, additional fee or allowable extra fee if charged by the pharmacist. In relation to prescriptions for therapeutic goods which are subsidised under the Pharmaceutical Benefits Scheme and Repatriation Pharmaceutical Benefits Scheme, the total purchase price includes any premium, such as a brand or therapeutic group premium, or special patient contribution, which must be paid by the consumer;

‘unscheduled’, for a good, means that it does not consist of, or contain, a substance which is included in a schedule to the current Poisons Standard.

Several definitions in the Code are defined by a reference to another legislative instrument. Under the *Legislation Act 2003*, these (and other references to other legislative instruments in the Code – e.g. subsection 12(3)) are taken to be references to the relevant legislative instrument as in force from time to time. The ‘current Poisons Standard’ is not a disallowable legislative instrument, but is defined in the Act to have the meaning given by section 52A of the Act. Section 52A provides that the term ‘current Poisons Standard’ means either the first Poisons Standard prepared under paragraph 52D(2)(b) of the Act, or the document last prepared under that paragraph (including as amended). The practical

effect of the section is that a reference to the current Poisons Standard is taken to be a reference to that Standard as amended from time to time, similarly giving that definition an ambulatory operation (this approach is permitted under subsection 42BAA(2) of the Act).

Section 5 – Object

The Object of this Code is to ensure that the advertising of therapeutic goods to consumers is conducted in a manner that:

- promotes the safe and proper use of therapeutic goods by minimising their misuse, overuse or underuse; and
- is ethical and does not mislead or deceive the consumer, or create unrealistic expectations about the performance of the goods; and
- supports consumers in making informed choices about their health care; and
- is not inconsistent with current public health campaigns.

Whilst the Quality Use of Medicines is not explicitly referenced in the objects of the new Code, ‘quality use’ principles are adequately reflected in the objects as specified.

Section 6 – Application

This section sets out the circumstances in which the Code applies and how it should be read. It clarifies the circumstances in which it does not apply; the Code applies to the advertising of therapeutic goods to the public; it is excluded from applying to advertisements directed exclusively to health professionals.

Subsection (3) provides for the application of the Code for a particular advertisement by considering its likely impact on the reasonable person to whom the advertisement is directed. The view of the likely impact of the advertisement is through the objective eyes of a person to whom an advertisement is directed; subjective reactions which may be peculiar to specific individual attitudes and sensitivities are put to one side.

Subsection (4) provides that in applying the Code, the total presentation and context of an advertisement will be considered. The words (whether written or spoken), images, advertising medium and general presentation of the advertisement will all be considered in determining whether the advertisement is consistent with the Code.

Subsection (5) applies the Code to any person who advertises therapeutic goods (by any means), or causes the advertising (by any means) of therapeutic goods. This will include not only the person or persons who commission and pay for the advertising, but also the broadcaster, datacaster, publisher or internet service provider who transmit or promulgate the advertising. Subsection (6), however, limits the scope of subsection (5) and excludes the application of the Code to genuine news that is broadcast or published in any medium by a broadcaster, a datacaster, the SBS, or a person prescribed by the Regulations.

Genuine news, in relation to therapeutic goods, is a report in relation to that good in any medium which is, by reference to all of the circumstances, an authentic information report, not intended to promote the use or supply of that good. That is, the news broadcast, datacast, publication or other information report in any medium must not be intended, whether directly or indirectly, to promote the use or supply of the relevant therapeutic goods.

Section 6A – Repeal

This section provides that the instruments specified in Schedule 5 are repealed.

Section 6B – Transitional arrangements

This section clarifies, for advertisements for therapeutic goods that were approved under Division 2 of Part 2 of the Regulations before the commencement of this Code (pre-approved advertisements), the version of the Code that applies.

Subsection (2) provides that, despite the repeal of the *Therapeutic Goods (Advertising Code) 2015* (the former Code) by section 6A (read with Schedule 5) of the Code, the former Code, as in force immediately before the commencement of this Code continues to apply until either:

- the day on which the approval number for the advertisement expires, in accordance with the Regulations; or
- for an advertisement for which approval is withdrawn in accordance with the Regulations, the day on which approval is withdrawn.

Section 7 - Price information

This section excludes the application of the Code, with the exception of Schedule 4, to advertising that only disseminates price information – for prescription medicines and pharmacist-only medicines that may not otherwise be advertised to the public. Schedule 4 of the Code incorporates provisions relating to price information, and replaces the former *Price Information Code of Practice 2006*.

Subsection (2) provides that for the purposes of subsection 42DL(10) and 42DLB(7) of the Act, if disseminating price information about goods mentioned in those subsections constitutes advertising, it is authorised provided that the price information complies with Schedule 4 of this Code. The effect of this provision is that dissemination of price information concerning prescription medicines and certain pharmacist-only medicines complying with Schedule 4 does not contravene the offence and civil penalty provisions in the Act.

Part 2 – General requirements for the advertising of therapeutic goods

Advertising therapeutic goods is unlike the advertising of other commodities as by definition they will influence the health status of the population to whom the advertising is directed. Further this advertising requires considered regulation due to the potentially emotive context of individual health management decisions, as much of the information relating to health requiring specialised and advanced educational qualifications to be properly understood and evaluated, and incorrect or inappropriate decisions may carry possible significant additional public and private health costs. This Code assists with ensuring that advertisements contain critical information needed by consumers to inform their decision to purchase and use a therapeutic good.

The purpose of this Part is to ensure that advertisements are consistent with and support the safe and effective use of therapeutic goods that are being advertised by requiring that an advertisement gives relevant consumers the minimum information including warnings necessary to achieve this purpose.

Accordingly, this Part sets out the general requirements for advertising therapeutic goods including for accuracy about the claims, presentations, representations and comparisons of the therapeutic goods that are being advertised and the effect of the use of those goods.

It is prescriptive about statements that are required to be included if a medicine or medical device or other therapeutic good has a health warning and, similarly, if it does not have a health warning. Different requirements are specified if the goods that are being advertised are not available for physical examination before purchase. For the advertisement of these goods, all the information that would normally be available to the consumer by way of the packaging and labelling would need to be made available through the advertisement.

The purpose of drawing consumers' attention to warnings is to assist consumers make informed health choices, in particular when making the decision to self-treat and select a product suitable for their individual needs. These requirements are for the statements to be 'prominently displayed or communicated'. It is important that certain critical public messages are noted and retained by consumers. Prior to the commencement of the Code, such statements have not been given the prominence that was required to enable consumers to purchase and use medicines appropriate for them.

This Part also sets out requirements that an advertisement include statements to follow the directions or instructions for use. If the advertisement includes a claim relating to a symptom or a disease, condition, ailment or defect, it must contain statements that, in certain circumstances, the consumer talk to a health professional. There are specific requirements for 'prominently displayed or communicated' statements in advertisements for pharmacist-only medicines.

Generally, these requirements do not apply to a label or consumer medicine information, a patient information leaflet, or to an advertisement displaying only the name or picture of therapeutic goods or their price or point of sale, or any combination of these, provided the advertisement does not contain or imply a claim relating to therapeutic use, or any other representation.

Scientific or clinical representations (specifically cited research studies and scientific or clinical claims), endorsements and testimonials carry their own disclosure requirements. If an advertisement includes a 'testimonial', a statement about a therapeutic good made by a person that claims to have used that good, the requirements relating to 'endorsements' in section 16 will not apply.

Prohibitions apply to incentives for pharmacy assistants or retail sales persons, advertising to children and the provision of samples except in the circumstances set out in the Code. Advertising contemporaneously with public health campaigns must not be inconsistent with a public health campaign, to the extent that that is known or ought reasonably to be known.

Section 8 – Approved advertisements

This section sets out the requirements for advertisements which have obtained pre-approval from the Secretary's delegate under Part 2 of the Regulations and which are published in mainstream media or in displays about goods (including posters in shopping malls, in or on public transport, and on billboards, pursuant to the requirements in paragraphs (a) and (d) of the definition of 'specified media' in section 42B of the Act).

This requirement applies only to non-prescription medicines that can be advertised to the public.

For these advertisements, the advertisement must include the approval number given to the advertisement (as set out in regulation 5J of the Regulations), and that approval number must stand alone, be legible, and must be situated in the bottom right hand corner of the advertisement.

This section will cease to have any practical application from 1 July 2020 consequential on the commencement of Part 2 of Schedule 6 of the *Therapeutic Goods Amendment (2017 Measures No.1) Act 2018* after which advertisements for therapeutic goods will no longer require pre-approval.

Section 9 – Accuracy

This section sets out the requirements for accuracy, truthfulness, appropriate comparisons and consistency with the entry for the goods on the Register in the advertising of therapeutic goods.

All claims made in therapeutic goods advertising must be both valid and accurate, and all information presented in an advertisement must have been substantiated prior to the advertising. Substantiating evidence could include clinical study reports, literature reviews, or an objective critical review of all data presented by a clinical expert. Claims that are not therapeutic claims, for example ‘Australia’s leading brand’ must also have been substantiated.

Therapeutic goods advertising must be truthful, balanced and not misleading or likely to mislead persons to whom the advertisement is directed. The requirement for balanced advertising is intended to prevent advertisers of therapeutic goods from making exaggerated claims as to the effectiveness of the goods.

If the advertising compares therapeutic goods, or classes of therapeutic goods, it must not disparage the compared goods or class of goods by claiming, either directly or indirectly, that the goods against which the advertised product is being compared could cause harm, or are unlikely to be effective.

Advertising of therapeutic goods entered on the Australian Register of Therapeutic Goods (the Register) must be consistent with the entry on the Register. For example, an advertisement for a good which is entered on the Register with an indication of reducing muscle soreness must be consistent with this indication.

Section 10 – Effect

This section requires advertising of therapeutic goods to support the safe and proper use of the goods by presenting the appropriate use of the goods (in accordance with the directions or instructions for use), and not exaggerating their efficacy or performance.

Therapeutic goods advertising must not be likely to lead to people delaying necessary medical attention, or delaying the use of or failing to use treatment prescribed by a medical practitioner; for example by encouraging people to self-medicate rather than to seek treatment from their medical practitioner.

Advertising of therapeutic goods also must not encourage inappropriate or excessive use of the goods. For example, an advertisement which suggests that a medicine should be used by the general population, and there are sub-populations, such as children, in which

use of the medicine is not appropriate may encourage inappropriate use of the medicine (which is inconsistent with the Quality Use of Medicines framework¹).

Advertisements for therapeutic goods must not contain any claim, statement, implication, or representation that the use of the goods is safe or their use cannot cause harm; or that such use has no side-effects; that the goods are effective in every case of a condition, or that using them will guarantee a cure. The purpose of this provision is to ensure that a patient may not be lead, by the advertisement, to use a medicine that may be advertised in preference to those that have been prescribed by their medical or health practitioner.

Advertisements must not claim, state, imply or represent that the therapeutic goods advertised are infallible, unailing, magical or miraculous; and they may not claim that a person may be harmed by not using the product – unless this claim, statement, implication or representation is permitted under section 42DK of the Act or approved under section 42DF of the Act.

Section 42DK of the Act enables the Secretary to permit the use of restricted representations in certain advertisements about specified therapeutic goods. A restricted representation is defined in section 42DD of the Act and by section 28 of this Code (see below). Section 42DF of the Act enables the Secretary to approve an application for the use of a restricted representation.

Section 11 – Pharmacist-only medicines (required statement)

Subsection (1) excludes the obligations imposed by this section on the content of advertisements from applying to a label, to consumer medicine information, or a patient information leaflet. The obligations imposed by the section also do not apply to an advertisement displaying only the name or picture of therapeutic goods or their price or point of sale, or any combination of these, provided the advertisement does not contain or imply a claim relating to therapeutic use, or any other representation.

This section applies to advertisements for medicines which can only be sold with the approval of a pharmacist (pharmacist-only medicines), that is, a medicine which consists of or contains a substance which is included in Schedule 3 of the current Poisons Standard and Appendix H of that Standard.

Subsection (2) mandates that an advertisement for such medicines must contain the following statement, prominently displayed or communicated: *ASK YOUR PHARMACIST—THEY MUST DECIDE IF THIS PRODUCT IS RIGHT FOR YOU.*

This required statement recognises the professional responsibility of pharmacists for providing access to such medicines.

Mandatory statements are not required to be capitalised, or in any particular font style, size or format, when included as visual statements in an advertisement, as long as they are ‘prominently displayed or communicated’ within the meaning of that term as defined in section 4. For example, font embellishments (including serifs, italicised, cursive, shadowed, calligraphic, poster) and other fancy or irregular fonts, may affect the extent to which the required statement stands out so as to be easily read for the purposes of that threshold.

¹ See <http://www.health.gov.au/internet/main/publishing.nsf/content/nmp-quality.htm>

Sections 12 and 13 operate subject to section 11; those sections apply to advertisements other than advertisements to which section 11 applies. Section 11 exclusively specifies the required statement for a pharmacist-only medicine.

Section 12 – What must advertisements contain – therapeutic goods that are not available for physical examination before purchase

This section applies to advertisements for therapeutic goods which are not physically available for examination by the consumer before or at the time of purchase. The section ensures that important information that would be available on the label for the good or within the instructions for use of the good, are reproduced within the advertisement and available to the consumer before any decision is made to purchase the good. These advertisements might appear in a mail order catalogue or on a website that both advertises and sells therapeutic goods. Section 12 does not apply to advertisements to which section 11 applies, being advertisements for pharmacist-only medicines.

Subsection (2) excludes this section from applying to a medicine label, to consumer medicine information, or to a patient information leaflet.

Subsection (3), in effect, sets out the minimum requirements for an advertisement for a medicine, by requiring that an advertisement for a medicine must contain:

- the name of the medicine as defined by *Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines*;
- the name of the dosage form of the medicine, within the meaning of *Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines*;
- the quantity of the medicine, within the meaning of *Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines*;
- one or more of the indications for the medicine, as they appear on the medicine's label;
- a list of the ingredients;
- if there are no health warnings for the medicine, a statement prominently displayed or communicated: *ALWAYS READ THE LABEL*; or if there are health warnings for the medicine, either a statement prominently displayed or communicated: *THIS MEDICINE MAY NOT BE RIGHT FOR YOU. READ THE WARNINGS BEFORE PURCHASE* followed immediately by information about where the health warnings can be found within the advertisement; or otherwise a statement prominently displayed or communicated: *ALWAYS READ THE LABEL* together with the health warnings themselves;
- the required statement mentioned in subsection 13(6) (as applicable), regarding following the directions or instructions for use, prominently displayed or communicated; and
- the required statement or statements mentioned in subsection 13(7) (as applicable), regarding changes to symptoms, prominently displayed or communicated.

The minimum requirements for an advertisement for a medical device, where the physical product is not available for examination, are set out in subsection (4) as follows:

- an accurate description of the device;
- if the trade name is available, a reference to it; otherwise a reference to another name for the device;
- the intended purpose of, or indications for the device, as they appear on the device's label or primary packaging, as appropriate to the device;
- a list of ingredients for the device, where relevant;
- if the device has no health warnings, *either* a statement prominently displayed or communicated *ALWAYS READ THE LABEL*, or *ALWAYS READ THE INSTRUCTIONS FOR USE*, as appropriate for the packaging of the device;
- if the device has health warnings, *either*:
 - a statement, prominently displayed or communicated, *THIS PRODUCT MAY NOT BE RIGHT FOR YOU. READ THE WARNINGS BEFORE PURCHASE*, immediately followed by information about where the health warnings may be found.

or

- a statement, prominently displayed or communicated, *ALWAYS READ THE LABEL*, or *ALWAYS READ THE INSTRUCTIONS FOR USE*, as appropriate for the packaging of the device, accompanied by the health warnings themselves.

This requirement is to ensure that health information that is critical to the consumer's decision to purchase the therapeutic good is brought to his or her attention before the good is purchased;

- the required statement mentioned in subsection 13(6) (as applicable), regarding following the directions or instructions for use, prominently displayed or communicated; and
- the required statement or statements mentioned in subsection 13(7) (as applicable), regarding changes to symptoms, prominently displayed or communicated.

Subsection (5) sets out the minimum requirements for information which must be included in an advertisement for other therapeutic goods (defined in section 4 of the Code as therapeutic goods which are not medicines, biologicals or medical devices):

- an accurate description of the goods;
- if the trade name is available a reference to it, otherwise, a reference to another name for the goods;
- the intended purpose of, or indications for, the goods as they appear on the label for the goods or its primary packaging, as appropriate to the goods;
- a list of ingredients for the goods, where relevant;
- where the other therapeutic goods have no health warnings:
 - a prominently displayed or communicated statement *either ALWAYS READ THE LABEL* or *ALWAYS READ THE INSTRUCTIONS FOR USE*

This requirement is to ensure that health information that is critical to the consumer's decision to purchase the good is brought to his or her attention before the good is purchased;

- where the other therapeutic goods have health warnings: *either*
 - a statement, prominently displayed or communicated, *THIS PRODUCT MAY NOT BE RIGHT FOR YOU. READ THE WARNINGS BEFORE PURCHASE* followed immediately by information about where the health warnings may be found.

or

- a statement, displayed or communicated *either ALWAYS READ THE LABEL or ALWAYS READ THE INSTRUCTIONS FOR USE* together with the health warnings, as appropriate for the packaging of the goods.

This requirement is to ensure that health information that is critical to the consumer's decision to purchase the good is brought to his or her attention before the opportunity to purchase the good;

- the required statement mentioned in subsection 13(6) (as applicable), regarding following the directions or instructions for use, prominently displayed or communicated; and
- the required statement or statements mentioned in subsection 13(7) (as applicable), regarding changes to symptoms, prominently displayed or communicated.

Mandatory statements are not required to be capitalised, or in any particular font style, size or format, when included as visual statements in an advertisement, as long as they are 'prominently displayed or communicated' within the meaning of that term as defined in section 4. For example, font embellishments (including serifs, italicised, cursive, shadowed, calligraphic, poster) and other fancy or irregular fonts, may affect the extent to which the required statement stands out so as to be easily read for the purposes of that threshold.

Section 13 – What must advertisements contain – general rules

This section sets out the information which advertisements for medicines, medical devices and other therapeutic goods must contain. The section does not apply to advertisements for pharmacist-only medicines to which section 11 applies. It also does not apply to advertisements of therapeutic goods to which section 12 applies; that is, advertisements where the goods are not available for physical examination before purchase. The section applies, for example, in advertisements to be used in retail outlets such as supermarkets or pharmacies where the medicines, medical devices, or other therapeutic goods, are physically available to be examined before purchase.

Subsection (1) also excludes the obligations imposed by this section on the content of advertisements from applying to a patient information leaflet. The obligations imposed by the section also do not apply to a label, to consumer medicine information, or to an advertisement displaying only the name or picture of therapeutic goods or their price or point of sale, or any combination of these, provided the advertisement does not contain or imply a claim relating to therapeutic use, or any other representation.

Minimum content requirements, including health warnings

Subsection (2) requires an advertisement for a medicine to contain the following:

- a reference to the name of the medicine as defined by the *Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines*;
- one or more of the indications for the medicine, as they appear on the medicine's label; and
- subject to subsection (5), if there are no health warnings for the medicine: a statement prominently displayed or communicated *ALWAYS READ THE LABEL*; or
- subject to subsection (5), if the medicine includes an ingredient in Part 1 or 2 of Schedule 1 for which there are health warnings, *either*
 - a prominently displayed or communicated statement: *THIS MEDICINE MAY NOT BE RIGHT FOR YOU. READ THE LABEL BEFORE PURCHASE*; or
 - both prominently displayed or communicated statements: *ALWAYS READ THE LABEL*; and the health warnings themselves.

This requirement is to ensure that health information that is critical to the consumer's decision to purchase the good is brought to the consumer's attention before purchase.

Subsection (3) requires an advertisement for a medical device must contain the following:

- an accurate description of the device;
- if a trade name is available a reference to it; or otherwise, a reference to another name for the device;
- a reference to the intended purpose of, or indications for the device;
- subject to subsection (5), if there are no health warnings for the device, a statement prominently displayed or communicated: *ALWAYS READ THE LABEL* or *ALWAYS READ THE INSTRUCTIONS FOR USE*, as appropriate for the packaging of the device;
- subject to subsection (5), if there are health warnings for the device, and the label of the device is visible on the primary pack, *either* prominently displayed or communicated a statement *THIS PRODUCT MAY NOT BE RIGHT FOR YOU. READ THE LABEL BEFORE PURCHASE*; or the statement (prominently displayed or communicated) *ALWAYS READ THE LABEL* together with the health warnings;
- subject to subsection (5), if there are health warnings for the device, and the device does not have a label visible on the primary pack, *either* a prominently displayed or communicated statement *THIS PRODUCT MAY NOT BE RIGHT FOR YOU. READ THE INSTRUCTIONS FOR USE BEFORE PURCHASE*; or a statement (prominently displayed or communicated) *ALWAYS READ THE INSTRUCTIONS FOR USE*, together with the health warnings.

This requirement is to ensure that health information that is critical to the consumer's decision to purchase the good is brought to the consumer's attention before purchase.

Subsection (4) requires an advertisement for other therapeutic goods (defined in section 4 of the Code as therapeutic goods which are not medicines, biologicals or medical devices), must at a minimum contain the following:

- an accurate description of the goods;
- if a trade name is available a reference to it, otherwise a reference to another name for the goods;
- a reference to the intended purpose of, or indications for the goods;
- subject to subsection (5), if there are no health warnings for the goods, *either* a statement prominently displayed or communicated *ALWAYS READ THE LABEL*, *or* a statement prominently displayed or communicated *ALWAYS READ THE INSTRUCTIONS FOR USE* as appropriate for the packaging of the goods;
- subject to subsection (5), if there are health warnings for the goods, and the label of the goods is visible on the primary pack, *either* a prominently displayed or communicated statement *THIS PRODUCT MAY NOT BE RIGHT FOR YOU. READ THE LABEL BEFORE PURCHASE*; *or* prominently displayed or communicated a statement *ALWAYS READ THE LABEL*, together with the health warnings;
- subject to subsection (5), if there are health warnings for the goods, and the goods do not have a label visible on the primary pack, *either* a prominently displayed or communicated statement *THIS PRODUCT MAY NOT BE RIGHT FOR YOU. READ THE INSTRUCTIONS FOR USE BEFORE PURCHASE*; *or* a prominently displayed or communicated statement: *ALWAYS READ THE INSTRUCTIONS FOR USE*, together with the health warnings.

This requirement is to ensure that health information that is critical to the consumer's decision to purchase the good is brought to the consumer's attention before purchase

For all of the above types of therapeutic goods, subsection (5) excludes the requirements to include required statements and/or health warnings from applying to radio advertisements that are 15 seconds or less in duration, or to text only advertisements that consist of 300 characters or less for which there is no reasonable capacity to include pictures, logos or other imagery as part of the advertisement. This has the effect that the requirements in section 13 do not apply to formats like Twitter and classified advertisements. It is not intended to provide a general exemption for all social media such as Facebook and Instagram, as these are capable of containing a greater number of words and to include pictures, logos or other imagery. Instagram has a limit of 2,200 characters or 300 words while Facebook post character limit is 63,206 characters or 8600 words and both make provision for the inclusion of pictures, logos or other imagery and, accordingly, advertisements on these mediums should not be subject to this exemption. Nor is the exemption intended to apply to television advertisements which may contain written text, pictures, logos, or other imagery, and so are capable of including the required statements and health warnings no matter the duration of the advertisement. The manner in which short duration television advertisements must comply with the obligations in the Code to

include mandatory statements is not prescribed and compliance may be achieved, for example, through the inclusion of either text or spoken word statements (or both).

Other required statements

Subsection (6) provides that advertisements must contain as appropriate either of the following statements prominently displayed or communicated: *FOLLOW THE DIRECTIONS FOR USE* or *FOLLOW THE INSTRUCTIONS FOR USE*.

Subsection (7) operates subject to subsection (7A), and requires that advertisements containing a claim relating to a symptom of a disease, condition, ailment or defect to contain a statement prominently displayed or communicated as appropriate to the duration or recurrence of the symptoms, being *either or both* of the following: *IF SYMPTOMS PERSIST, TALK TO YOUR HEALTH PROFESSIONAL*, or where symptoms are continuous (arthritis) or recurrent (asthma), *IF SYMPTOMS WORSEN OR CHANGE UNEXPECTEDLY, TALK TO YOUR HEALTHCARE PROFESSIONAL*.

Subsection (7A) clarifies that where the advertisement must contain both the statements in subsection (7), the statements may be shortened and combined into one statement, so as to avoid duplication.

The requirement in subsection (7), however, does not apply to radio advertisements 15 seconds or less in duration or to text only advertisements of 300 characters or less for which there is no reasonable capacity to include pictures, logos or other imagery as part of the advertisement. This has the effect that the requirements in section 13 do not apply to formats like Twitter and classified advertisements. As with subsection (5) which is in analogous terms, this provision is not intended to provide a general exemption for all social media such as Facebook and Instagram, as these are capable of containing a greater number of words and to include pictures, logos or other imagery. Nor is the exemption intended to apply to television advertisements which may contain written text, pictures, logos, or other imagery, and so are capable of including the required statements and health warnings no matter the duration of the advertisement.

Mandatory statements are not required to be capitalised, or in any particular font style, size or format, when included as visual statements in an advertisement, as long as they are ‘prominently displayed or communicated’ within the meaning of that term as defined in section 4. For example, font embellishments (including serifs, italicised, cursive, shadowed, calligraphic, poster) and other fancy or irregular fonts, may affect the extent to which the required statement stands out so as to be easily read for the purposes of that threshold.

Section 14 – Section 14 is intentionally not used

Section 14 of this instrument is intentionally not used, in order to preserve the current numbering of the provisions in the Code when compared to the Advertising Code 2018. This is because the Regulations will, from 1 January 2019, contain a number of references to specific provisions of the Code which, if section 14 were to be used and subsequent sections renumbered, would require consequential amendment (see for example, regulation 8 as amended by item 39 of Part 8 of the *Therapeutic Goods Legislation Amendment (2018 Measures No.3) Regulations 2018*).

Section 15 – Scientific or clinical representations

Subsection (1) of section 15 excludes the obligations imposed by this section on the content of advertisements from applying to a patient information leaflet and to a label or to consumer medicine information.

This section sets out the requirements where an advertisement makes a scientific or clinical representation or the advertisement contains an explicit or implied citation to scientific or clinical literature. All scientific or clinical language or terms must be appropriate, clearly communicated, and must be readily understood by the target audience for the advertisement. Scientific or clinical representations must be consistent with the body of scientific or clinical evidence applicable to the therapeutic goods which 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 of therapeutic goods.

If research results are explicitly or implicitly cited in the advertisement, the advertisement must identify the researcher and 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 citation of research that is not available to the consumer for reasons of confidentiality.

Section 16 – Endorsements

Testimonials may be viewed as a type of endorsement. However, this section does not apply to testimonials to which section 17 applies. The section also does not apply to a statement, pictorial representation or design (also known as a ‘claimer’) for a medicine listed in the Register under paragraph 26AE(3)(a) of the Act, which is prescribed in the Regulations for the purposes of paragraphs 42DL(9)(c) and 42DLB(6)(c) of the Act.

This section prohibits, in advertisements for therapeutic goods, any endorsement from or implication that the therapeutic goods are endorsed by a government authority, hospital or healthcare facility (other than a community pharmacy), or an employee or contractor of one of these bodies; a health practitioner, health professional, medical researcher or a group of any of these persons. Such endorsements are prohibited so as to avoid a consumer being unduly influenced to purchase a therapeutic good by the weight he or she may give to statements made by healthcare related persons or bodies.

Subsection (3) prohibits an advertisement for therapeutic goods from containing an endorsement from, or the implication that the therapeutic goods are endorsed by:

- an organisation representing the interests of healthcare consumers,
- an organisation representing the interests of health practitioners, health professionals, or medical researchers, or
- an organisation which conducts or funds research into any disease condition, ailment or defect, or
- an employee or contractor of any of these organisations (unless they otherwise fall within the terms of paragraph (2)(b) or (c)),

unless the advertisement names the organisation, and discloses the nature of the endorsement, and whether the organisation, employee or contractor has received or will receive valuable consideration for the endorsement. Note that an organisation may be either incorporated or unincorporated. This requirement ensures that consumers are aware whether such persons are remunerated for their endorsement.

It is intended that the section will extend to endorsements obtained or provided under a sponsorship arrangement to the extent that the endorsement is of a kind to which the section by its terms applies. For example, where an advertisement for therapeutic goods contains an endorsement from, or implies that the goods are endorsed by, a particular sponsor who is an organisation of a kind mentioned in paragraph (3)(a), or an employee or contractor of such an organisation, the advertisement must name the organisation and disclose the nature of the endorsement (that is, that it is being made under a sponsorship arrangement) and whether the organisation, or employee, has received, or will receive, any valuable consideration for the endorsement. Under sponsorship arrangements, such valuable consideration might typically be either a financial benefit or in-kind support including through the provision of goods. However, where a sponsorship arrangement is with an individual who gives a testimonial about a therapeutic good that the person claims to have used, the testimonial must comply with the requirements of section 17.

Section 17 – Testimonials

This section prescribes the requirements for testimonials if used in an advertisement for therapeutic goods. Subsection (1) defines a testimonial as a statement about a therapeutic good made by a person who claims to have used that good. Since only natural persons can actually use the therapeutic good, corporations are precluded from providing testimonials.

A testimonial used in an advertisement for therapeutic goods must be made by a person whose details have been verified prior to the advertisement occurring and who has used the goods for their intended purpose. Also, the person providing the testimonial must not be involved with the production, sale, supply or marketing of the goods; or an employee or officer of a corporation that is involved with the production, sale, supply, or marketing of the goods; or an employee or contractor of a government authority, hospital or healthcare facility (other than a community pharmacy); or a health practitioner, health professional, or medical researcher or a group of such persons.

The testimonial must be verified (prior to the advertisement occurring) as to the use of the goods and the claims made by the person, and must be typical of the results which can be expected from the use of the goods in accordance with the directions for use or intended purpose of the goods.

Subsection (3) requires that the testimonial disclose whether the person providing the testimonial has received, or will receive, any valuable consideration for the testimonial; that the testimonial disclose where another person takes the place of the person providing the testimonial in the advertisement; and must disclose where the person providing the testimonial is an immediate family member of an individual involved in the production, sale, supply or marketing of the goods.

Testimonials are often effectively used in audio/visual media. These provisions ensure that consumers are aware of important facts about the testimonials as presented in the advertising, which will assist them to weigh the importance of the testimonial in any decision to purchase the good. The intention is to ensure that the person providing a testimonial discloses an ‘immediate’ family relationship (with another person in the good’s supply chain). A person providing a testimonial is an immediate family member of an individual involved in the supply chain for the good, if he or she is that other person’s parent, grandparent, spouse, *de facto* spouse, child or ward of that person, noting ‘immediate family’ is defined in the Code to have the same meaning as in the Regulations.

Whether an unsolicited post or comment on the website, social media site, internet blog or other medium of an advertiser is a testimonial subject to the requirements of section 17 turns on whether it is ‘used’ in that advertisement. It is consistent with the ordinary principles of statutory interpretation to choose an interpretation that gives effect to the purpose of section 17, and more broadly, the Code, (see the Object in section 5). As noted above, section 17 is intended to ensure that consumers are aware of important facts about the testimonials as presented in the advertising, which will assist them to weigh the importance of the testimonial in any decision to purchase the good. The scope of section 17 is also informed by the Object that includes that the Code ensure that advertising is conducted in a manner that supports informed health care choices.

Applying the ordinary meaning of ‘use’ that includes ‘to avail oneself of; apply to one’s own purposes; to exploit (a person) for one’s own ends’ (see the Macquarie Dictionary online edn accessed on 28 October 2018) it is reasonable to take the view that such an unsolicited testimonial would fall to be regulated by section 17 where there is evidence that it is applied for the purposes of the advertisement; it is exploited for the advertisement’s own ends. This may be established in the negative; that there is no evidence that the advertiser had taken reasonable steps to block or to remove an unsolicited testimonial; the failure to take such steps has the effect that the testimonial is ‘used’ in the advertisement. This is consistent with the purpose of section 17 and with the Object in section 5.

That an unsolicited testimonial falls to be regulated by section 17 does not mean that its ‘use’ is prohibited; it may be used provided that it complies with the requirements in section 17, for example that the details of the person who made the testimonial are verified. Unsolicited testimonials are unlikely to raise the disclosure obligations in subsection 17(3) for valuable consideration.

It is also important to note that such an unsolicited testimonial is subject to the other obligations under the Code and the Act. It would, for example, be a contravention of subsection 22(5) of the Act if the testimonial purported to promote the use of the

therapeutic good for an indication for which the good is not accepted for inclusion in the Register.

Section 18 – Incentives

This section provides that an advertisement for therapeutic goods must not offer any personal incentives to a pharmacy assistant or another retail salesperson who is not a health professional to recommend or supply therapeutic goods. This is intended to recognise the pre-eminent responsibility of specified health professionals for the actions and conduct of their staff and prevents the intrusion of other commercial parties into that relationship.

Section 19 – Advertising to children

This section prohibits advertisements for therapeutic goods being primarily directed to children under the age of 12 years in any circumstances and from being primarily directed to children aged 12 years or over. The prohibition in relation to children aged 12 years or over does not apply to a limited list of therapeutic goods set out in Schedule 2 of this Code. Conditions may be placed on advertisements for therapeutic goods primarily directed at children aged 12 or over. This section does not apply to labels.

This provision is intended to recognise the importance of the child's parent, guardian or other adult carer in selecting therapeutic goods to be used by children. The provision read together with Schedule 2, allows advertising to be primarily directed to children aged 12 years or over for selected types of therapeutic goods, consistent with the 'health profile' of those goods and the increasing independence of children of this age.

Section 20 – Samples

This section prohibits advertisements for therapeutic goods, apart from therapeutic goods mentioned in Schedule 3 advertised in accordance with the specified conditions, from containing an offer of a sample. The objective of this provision is to ensure that samples will not be available by advertisement to influence a consumer to purchase a therapeutic good, that therapeutic goods are only selected and used for their indication or intended purpose when actually needed by the consumer for that indication or purpose.

The particular therapeutic goods for which samples may be offered in advertisements listed in Schedule 3, are: condoms; a therapeutic good that is or contains a sunscreen; stoma management devices for self-management; and continence catheter devices for self-management.

The provision in Schedule 3 of a therapeutic good that is or contains a sunscreen, to enable samples to be available by advertising, has an important public health benefit. Section 27 also applies to an 'advertisement of a therapeutic good that is or contains a sunscreen'; the discussion below about section 27 notes the scope of operation of each section.

The reference to 'self-management' in the context of stoma management and continence catheter devices, recognises that such goods are generally intended for in-home use by an individual or his or her carers. The inclusion of such goods in Schedule 3 reflects the important public health benefit that the inclusion of an offer of a sample can provide in advertisements for devices of that kind and is consistent with the public health objects of the Code in that it supports informed health care choices by individuals requiring these supports.

Section 20 has no application, however, to the provision of samples of therapeutic goods to schools or school children for the purposes of an education programme for public health purposes. Such action is not considered to be ‘advertising’ for the purposes of the application of the Act. This is because the intention of such programmes is not to promote the use or supply of the goods but rather for the purposes of education on a public health issue. Because there is no advertisement involved, section 20 has no application to those specified circumstances.

Section 21 – Consistency with public health campaigns and other objects

This section prohibits promotion of therapeutic goods from being inconsistent with a relevant public health campaign of which the advertiser knows, or ought reasonably to have known, is or will be current at the time of advertising.

The objective of this provision is to ensure that that advertising of therapeutic goods does not undermine or otherwise diminish the message contained in relevant government public health campaigns. The provision has the effect that an advertiser who is preparing an advertisement in advance would need to ensure that it is not inconsistent with a relevant public health campaign that they know, or ought reasonably to have known, will be taking place at the time of the advertisement. Whether a public health campaign is relevant for this purpose will vary depending upon the circumstances including the nature of the therapeutic goods in question.

Part 3 – Specific requirements for the advertising of particular therapeutic goods

This Part specifies requirements for advertising for identified therapeutic goods. The main purpose of this Part is to ensure that a consumer has all information relevant to the therapeutic good being advertised whilst he or she considers whether to purchase that identified good. To meet this objective for those identified goods, past experience dictates that the advertisement should include particular health and safety related statements specific to those goods.

The rules in this Part apply in addition to the rules in Part 2 in relation to advertisements for the particular therapeutic goods mentioned in each section.

Section 22 – Application

This section excludes the application of Part 3 of the Code to the labels of therapeutic goods, to consumer medicine information and to patient information leaflets.

Section 23 – Complementary medicines

This section requires that an advertisement for a complementary medicine, which incorporates a claim based on evidence of a history of traditional use and paradigm, must disclose that the claim is based on traditional use and prominently display or communicate this disclosure in the advertisement. The intention is to ensure that consumers are aware of all information relevant to the consumers’ consideration of whether to purchase a complementary medicine.

Section 24 – Analgesics

This section specifies additional requirements for advertisements for analgesics. Such advertisements must contain a warning statement which is prominently displayed or

communicated: *INCORRECT USE COULD BE HARMFUL*. Such advertisements are prohibited from implying that the consumption of analgesics is safe, or that analgesics have relaxing, tension-relieving, sedative or stimulating effects. This recognises the particular harms that use of ‘analgesics’ (as defined in section 4) have caused in the past.

As noted for the statements required by sections 11, 12 and 13, it is not intended that the mandatory statement required by this section requires capitalisation, or any particular font style, size or format, when included as a visual statement in an advertisement, as long as it is ‘prominently displayed or communicated’ within the meaning of that term as defined in section 4.

Section 25 – Vitamins and minerals

This section specifies additional requirements for advertisements for vitamins and minerals; they are prohibited from claiming or implying that such products are a substitute for good nutrition or a balanced diet, or that the supplements are better or more beneficial than the same nutrients obtained from dietary sources. The purpose of these requirements is to ensure that consumers assess the value of these medicines within the appropriate nutritional context when considering whether purchase the good.

Section 26 – Therapeutic goods that are for weight management

This section specifies additional requirements for advertisements for therapeutic goods which contain any claim relating to weight management. Weight management includes but is not limited to 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. Such advertisements must balance these claims with messages about the need for a healthy energy-controlled diet and physical activity. These advertisements must not include any reference or depiction suggesting that the therapeutic goods will correct or reverse the effects of overeating or overconsumption of any food or drink.

An advertisement for therapeutic goods with a claim relating to weight management may only feature individuals in images or visual representations or use individuals’ statistics or testimonials if the results obtained by those individuals from the use of the goods would be expected to be achieved on average by users of the good.

Section 27 – Sunscreens

This section sets out particular requirements for an advertisement of therapeutic goods that is or contains a sunscreen, which claims or implies that the good (the sunscreen) will prevent sunburn or skin cancer.

This provision is not intended to extend to those goods that are, or contain, a sunscreen referred to in item 5 of the table in Schedule 2 of the *Therapeutic Goods (Excluded Goods) Determination 2018*, when used, advertised or presented for supply in the particular way specified therein. The section therefore extends to both primary and secondary sunscreens (as they are sometimes commonly known) to the extent that they are not otherwise an ‘excluded good’ under that instrument.

In relation to such goods, if an advertisement claims or implies that the sunscreen will prevent sunburn or skin cancer, the advertisements must depict the sunscreen as being only one part of sun protection, rather than as a complete sun protection in itself; and must

include statements or visual representations, prominently displayed or communicated, to the effect that prolonged high risk sun exposure should be avoided, and that frequent re-application of sunscreens, or their use in accordance with directions, is required for effective sun protection.

Section 20, read with Schedule 3, also applies to the advertising of ‘therapeutic goods that are or contain a sunscreen’ and the scope of that phrase should be construed consistently across both provisions.

Australia has rates of skin cancer amongst the highest in the world. These requirements reinforce critical public health messages that are important for effective consumer use of sunscreens in the prevention of skin cancer.

Part 4 – Restricted representations and prohibited representation

Section 28 – Restricted representations – serious form of disease, condition, ailment or defect

This section provides the definition of the serious form of a disease, condition, ailment or defect for which section 42DD of the Act gives authority. There are two criteria, only one of which must be present for the ‘serious form’ requirement to be met:

- it is medically accepted that the form requires diagnosis or treatment or supervision by a suitably qualified healthcare professional (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 professional; that is, a person with an recognised qualification in an appropriate medical discipline whether general practice or specialist; or
- there is a diagnostic (including screening), preventative, monitoring, susceptibility or pre-disposition test available for the form (including a self-administered test), and which requires medical interpretation or follow-up. The effect of this provision is to ensure that diagnostic tests (in the widest consumer understanding of the term) are only advertised to consumers where they can understand the need for and the clinical importance of the test and are also capable of evaluating the outcome of that test and its role in guiding their subsequent use of any other therapeutic goods

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.

This section does not apply to diseases to which section 30 of this Code applies. These diseases would also meet the criteria for restricted representation unless excluded from the scope of this section.

Section 29 – Restricted representations – public interest criteria

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

- whether the reference would be likely to take advantage of the vulnerability of consumers, or particular groups of consumers, when faced with the disease, condition, ailment or defect;
- whether the reference would be likely to result in consumers not seeking timely professional medical advice where required (such as where that advice is important to prevent negative health consequences, morbidity or mortality, or deterioration or progression of the disease, condition, ailment or defect);
- whether the reference would be likely (alone, through repetition or together with other references) to have a negative impact on public health (or to have an effect on persons other than those to whom the advertisement is directed);
- such other aspects of the public interest as may appear to be appropriate to the Secretary.

Section 30 – Prohibited representations

This section prescribes representations which are prohibited, for the purpose of paragraph 6B(1)(b) of the Regulations. Sections 42DL and 42DLB of the Act make provision for offences and a civil penalty for using prohibited representations in advertising for therapeutic goods. Representations which are prohibited, unless permitted by the Secretary under section 42DK of the Act, are as follows:

- any representation regarding abortifacient action;
- any representation about the treatment, cure, prevention or diagnosis (including screening), monitoring or susceptibility of or pre-disposition to the following diseases:
 - neoplastic disease (cancer);
 - sexually transmitted diseases;
 - human immunodeficiency virus and acquired immune deficiency syndrome (HIV AIDS);
 - hepatitis C virus (HCV); and
 - mental illness.

These diseases and the representations regarding abortifacient action are recognised as being particularly emotive for consumers and accordingly reference to these in advertising may not be appropriately weighed by consumers.

Certain exceptions to this prohibition can be made on public health grounds by the Secretary under section 42DK of the Act.

Schedule 1 – Medicine ingredients with specific health warnings

Clause 1 of this Schedule includes a table of medicine ingredients, circumstances and statements for the purposes of paragraph (a) of the definition of ‘health warnings’ in

section 4. That paragraph provides that ‘health warning’, for a medicine that contains an ingredient mentioned in column 1 of the table in Schedule 1, in the circumstances set out in column 2 of that table, means the statement mentioned in column 3 of the table in Schedule 1.

The health warning statements listed in this Schedule 1 must be included in advertisements for a medicine containing an ingredient this schedule, in the circumstances required by sections 12(3)(f) and 13(2)(f) of the Code.

Parts 3 and 4 of Schedule 1 include health warnings for allergenic ingredients in registered or listed medicines. It is appropriate that advertisements for medicines containing these ingredients include the health warnings specified in those Parts of Schedule 1 when the medicine is not available for physical examination before purchase. Accordingly, only advertisements to which section 12 of the Code applies must, where relevant, include the health statements listed in Parts 3 and 4 of Schedule 1. In practical effect, the whole of Schedule 1 is potentially applicable to advertisements regulated by section 12.

However, it is not considered necessary to include the health warnings for medicines including allergenic ingredients in other advertisements where the consumer will be able to examine the goods before purchase and can read its label. The health warning statements for the allergenic ingredients listed in Parts 3 and 4 of Schedule 1 are therefore not required to be included in advertisements regulated by section 13 of the Code. Accordingly, only Parts 1 and 2 of Schedule 1 are potentially applicable to advertisements regulated by section 13.

This schedule reflects a set of the most serious warning statements that sponsors of principally registered over the counter medicines and listed (mostly complementary) medicines are or will be required to include on the labels of their products under a number of other requirements under the Act (for example, for listed medicines - the *Therapeutic Goods (Permissible Ingredients) Determination No.3 of 2018*, and for registered over the counter medicines - the *Medicines Advisory Statement Specification 2017* and for both categories of medicine –*Therapeutic Goods Order No.69 – General Requirements for Labels for Medicines 2017* and *Therapeutic Goods Order No.92 – Standard for labels of non-prescription medicines*). The statements in Schedule 1 have, where possible, been condensed, for suitability for inclusion in therapeutic goods advertisements, focussing on the most important health information for consumers to be aware of when considering buying a medicine, e.g. for Chlorhexidine, “Chlorhexidine can cause severe allergic reactions”, or for Ibuprofen “Do not use if you have a stomach ulcer, impaired kidney function, heart failure, are allergic to anti-inflammatory medicines, or in the last 3 months of pregnancy”.

Schedule 2 – Advertising to children

Clause 1 – Goods that may be advertised to children

For the purposes of section 19, this clause sets out therapeutic goods which may be primarily advertised to children aged 12 or over:

- (a) tampons;
- (b) acne preparations;
- (c) sunscreens SPF 15+;

- (d) condoms and personal lubricants;
- (e) bandages and dressings;
- (f) Class 1 medical devices for management of chronic conditions under medical supervision;
- (g) cold sore preparations;
- (h) lip balm;
- (i) unscheduled anti-dandruff preparations.

Schedule 3 – Samples

Clause 1 – Goods that may be offered as samples

This clause advises that for the purposes of section 20, samples of the following therapeutic goods may be offered as samples:

- (a) condoms
- (b) therapeutic goods that are or contain a sunscreen;
- (c) stoma devices for self-management;
- (d) continence catheter devices for self-management.

Section 20 prohibits advertisements for therapeutic goods from containing an offer of a sample, except where the goods are mentioned in this Schedule and advertised in accordance with any applicable conditions.

The discussion above in relation to section 20 includes further discussion of some of the goods listed in this schedule.

Schedule 4 – Price Information

This schedule of the Code replaces the former *Price Information Code of Practice 2006*. The benefits to consumers of providing for the inclusion of price information in advertisements are that they would have additional information to assist in their choice of what products to use. These benefits could be financial in that price advertising would allow them to select the ‘best buy’ and/or lead to greater competition amongst suppliers with associated price reductions. The benefits to consumers could also be in improved health outcomes if wider availability of product information led to safer, more effective use of medicines and where product advertising associated with public health campaigns led to better health outcomes for the community as a whole

Clause 1 – Purpose

This clause sets out the purpose of this schedule, which is to set out the conditions under which information about prices for prescription medicines and some pharmacist-only medicines may be provided to the general public.

Clause 2 – Application

This Schedule applies to price information directed to consumers for therapeutic goods which contain substances included in Schedules 3, 4 or 8 to the current Poisons Standard but not included in Schedule H to that Standard.

Price information may not be provided for medicines on the Pharmaceutical Benefits Scheme which are supplied through alternative arrangements under section 100 of the *National Health Act 1953*, except for dispensing fees for buprenorphine hydrochloride and methadone hydrochloride. Section 100 enables the Minister to make special arrangements for an adequate supply of pharmaceutical benefits for persons living in isolated areas, or for whose treatment pharmaceutical benefits are inadequate.

Clause 3 – Who may provide price information

This clause provides that price information may only be provided by retail pharmacists or their agents (including pharmacy marketing groups) or by dispensing doctors.

Manufacturers, distributors or sponsors of medicines may not provide price information, unless they are pharmacy marketing groups acting on behalf of retail pharmacists.

This also excludes by their omission from this clause, other medical practitioners and other health professionals from providing price information.

Clause 4 – Responsibility for compliance with this Schedule

This clause provides that the persons who publish, by any means, or who causes the publication, by any means, of price information have the responsibility to make sure that the price information complies with Schedule 4 of the Code.

Clause 5 – Methods for provision of price information

Price information to which this Schedule applies may be provided by any method except transmission using radio or television; displays, including posters, in shopping malls (except inside individual shops), in or on public transport, on billboards; or cinema advertising. Effectively, only methods may be used that provide a copy of the price information to the consumer, thus facilitating price comparison between retail suppliers.

Subclause (2) provides that where price information for the medicine is identified through a search function included in an electronic sales system, the results of the search must only include:

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

These provisions of this Schedule do not apply to price information identified in accordance with subclause (2):

- (a) subclause 6(1) and paragraph 6(3)(a);
- (b) clause 8; and
- (c) clause 9.

Clause 6 – General requirement restricting promotion

This clause sets out in some detail the general requirement restricting promotion of particular medicines within price information. Price information must not direct consumers to any medicine in preference to any other medicine. Price information must not:

- include or be presented with promotional statements, pictures or designs; or
- use adjectives or phrases that qualify the name of the medicine, the sponsor's pack size or the medicine's formula; or use terms indicating the length of supply which might be predicted or recommended;
- promote the purchase of particular quantities or multiple packs, except as provided under Clause 7 of this Schedule;
- use comparative adjectives or words to qualify the price to be paid for the medicine;
- give prominence to the text of the name, description or price of a medicine compared to the remainder of the text;
- offer rewards or bonus points, or be included together with any other advertising that promotes such rewards or bonus points;
- limit or qualify the availability of the price, other than by stating any limitations on the validity or time for expiry of the price;
- include any embellishment; or
- be accompanied by, or near to, information (including by implication or reference to other sources of information) regarding approved or unapproved indications, diseases, conditions, ailments or defects so that a reasonable person could infer that the medicine will cure or alleviate those diseases, conditions, ailments or defects.

Price information must include at least 25 medicines, and must be accompanied by the names and contact details of retail suppliers from whom the medicine may be obtained at that price. This last requirement does not apply to price information for medicines mentioned in clause 5(2) of this schedule, which are identified through a search function included in an electronic sales system.

These provisions ensure that price information is not used as a surrogate for advertising to consumers of prescription or certain pharmacist only medicines where in general, that advertising would attract either criminal offence (s42DL of the Act) or civil penalty (s42DLB of the Act).

Clause 7 – Description of medicines

Medicines must be described in price information using the name of the medicine as defined in *Therapeutic Goods Order No. 91 – Standard for labels of prescription and related medicines*, as in force from time to time, or *Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines* as in force from time to time. Both of these documents may be accessed at www.legislation.gov.au. Price information must include, for each medicine:

- (a) if there is more than one strength of a form of the medicine—the strength of each active ingredient as it appears on the label of the medicine; and
- (b) the form in which the medicine is presented; and
- (c) the price for the relevant number of units of the sponsor’s standard pack; and
- (d) the quantity contained in the sponsor’s standard pack.

For this section, the *relevant number of units* of the sponsor’s standard pack is - if the Pharmaceutical Benefits Scheme or Repatriation Benefits Scheme permit more than one unit of the sponsor’s pack to be prescribed, the maximum number of units that may be prescribed under those schemes; or otherwise, one.

Subclause (4) provides that the need for a prescription for a particular medicine may also be indicated.

Clause 8 – Presentation of price information

This clause sets out some requirements for the presentation of price information. In price information, medicines must be listed in alphabetical order by name, or by the names of active ingredients, unless they are grouped according to the Schedule of the Poisons Standard in which they are included, as set out in the following paragraph. This provision also supports the requirement that any one medicine should not receive prominence

Medicines may be grouped according to the schedule of the Poisons Standard (as in force at the time of making of the Code) in which they are included, as long as there are sufficient numbers of medicines from each Schedule in each grouping so that consumers are not directed to a particular medicine over and above any other medicines and there are medicines from three or more sponsors included. Alternatives are provided for the presentation of price information in ways that will assist consumers with price comparison between retail suppliers.

Clause 9 – Pharmaceutical Benefits Scheme subsidised medicines

If a pharmacy marketing group publishes price information which includes both a Pharmaceutical Benefits Scheme subsidised medicine with a brand premium or therapeutic group premium, and the group’s own generic medicine, that information must include at least one other bench-mark price brand of that medicine in addition to their own medicine (where such products exist). This provision helps ensure that ‘house brands’ sold by a retail supplier cannot be given prominence over other comparable brands.

Medicines subsidised under the Pharmaceutical Benefits Scheme must be identified and the total purchase price must be clearly identified as the general or concessional price. Both prices may be provided.

Price lists which include a Pharmaceutical Benefits Scheme subsidised medicine must include an indication that the price is subsidised by the Australian Government, and only applies when prescribed for the medical conditions listed in the Pharmaceutical Benefits Scheme Schedule for that medicine.

The price information may include a statement that specified medicines are subsidised under the Pharmaceutical Benefits Scheme only for a limited range of diseases, conditions, ailments or defects.

Schedule 5 – Repeals

Schedule 5 repeals the whole of the *Therapeutic Goods Advertising Code 2015* and the whole of the *Therapeutic Goods Advertising Code 2018*.

Statement of Compatibility with Human Rights

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

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

Overview of the Legislative Instrument

The *Therapeutic Goods Advertising Code (No. 2) 2018* (the Advertising Code (No. 2) 2018) is made by the Minister or delegate under subsection 42BAA(1) of the *Therapeutic Goods Act 1989* (the Act). The Act is administered by the Therapeutic Goods Administration (TGA), which is part of the Department of Health. The Advertising Code (No. 2) 2018 sets out a range of important requirements to support the integrity of the advertising of specified therapeutic goods to the public.

The object of the Advertising Code (No. 2) 2018 is to ensure that the marketing and advertising of therapeutic goods to consumers is conducted in a manner that promotes the quality use of therapeutic goods, is socially responsible and does not mislead or deceive the consumer.

Compliance of consumer advertisements for therapeutic goods with the Advertising Code (No. 2) 2018 is a criterion for the making of a number of administrative decisions under the Act and is also referred to in the Regulations, and in administrative and court-based sanctions (for example, the Secretary may cancel the marketing approval of a therapeutic good that is registered or listed in the Australian Register of Therapeutic Goods if there is a significant breach, involving the goods, of an applicable provision of the Code, and if, as a result, the presentation of the goods is significantly misleading (paragraph 30(1)(fb) of the Act refers).

The *Therapeutic Goods Amendment (2017 Measures No. 1) Act 2018*, which commenced on 6 March 2018, supported by the *Therapeutic Goods Legislation Amendment (2018 Measures No. 1) Regulations 2018*, which commenced on 20 March 2018, implement a number of key recommendations made by the Expert Panel Review of Medicines and Medical Devices Regulation and accepted by the Government, including reforms to improve and streamline the advertising of therapeutic goods to the public.

Enactment of the *Therapeutic Goods Amendment (2017 Measures No. 1) Act 2018* has provided the TGA with enhanced compliance and enforcement powers to protect the public from inappropriate or misleading advertising. These include graduated penalties (with both fault-based and strict liability offences) and corresponding civil penalties in some cases, such as sections 42DM and 42DMA respectively for dealing with therapeutic goods advertising that does not comply with the Advertising Code. The enhanced powers

in the Act will provide flexibility allowing the Secretary or his or her delegate to respond appropriately to non-compliant advertising behaviours.

In June 2018, following a consultation period, the delegate of the Minister made and registered on the Federal Register of Legislative Instruments, the *Therapeutic Goods Advertising Code 2018* (the Advertising Code 2018). The purpose of the Advertising Code 2018 was to remake the *Therapeutic Goods Advertising Code 2015* (the Advertising Code 2015) to support implementation of the Government-accepted recommendations of the Expert Panel Review of Medicines and Medical Devices Regulation:

- providing increased clarity and objectivity to support new and amended enforcement provisions in the Act to deal with breaches of advertising requirements; and
- improving consistency between the requirements for medicines and medical devices.

The Advertising Code 2018 also incorporated a number of amendments that:

- enhance and clarify previous provisions;
- address inconsistencies and issues that had been previously identified through public consultation and/or by the former Therapeutic Goods Advertising Code Council; or
- are of a minor and/or technical nature.

The Advertising Code 2018 had a commencement date of 1 January 2019.

Further to consultation on the proposed guidance material to accompany the Advertising Code 2018, and further targeted consultations on the Advertising Code 2018 (including with the recently-established Therapeutic Goods Advertising Consultative Committee) it was appropriate to clarify and refine the instrument. To implement these changes, the Advertising Code 2018 will be replaced with the *Therapeutic Goods Advertising Code (No. 2) 2018* (Advertising Code (No. 2) 2018).

The key changes made by the Advertising Code (No. 2) 2018 are intended to:

- clarify what is required by the obligation that a particular health warning or other statement is ‘prominently displayed or communicated’ in an advertisement for therapeutic goods. This term is defined, as applicable for both visual and spoken statements, by reference to the impact of the statement on the consumer; the requirement is that such an important statement is likely, in the case of a visual statement, to be easily read from a reasonable viewing distance and, for a spoken statement, able to be clearly heard and understood. For each advertising medium the statement must be repeated as often as is necessary to ensure that it is likely to be noticeable to a viewer or a listener.
- specify particular ‘health warnings’ that are to be included, in accordance with the requirements of the Code, in advertising for medicines which contain particular ingredients as listed in Schedule 1. This schedule reflects a set of the most serious warning statements that sponsors of (principally) registered over the counter medicines and listed (mostly complementary) medicines are or will be required to include on the labels of their products under a number of other requirements under the Act (for example, for listed medicines –the *Therapeutic Goods (Permissible*

Ingredients) Determination No.3 of 2018, and for registered over the counter medicines –the *Medicines Advisory Statement Specification 2017* and for both categories of medicine –*Therapeutic Goods Order No.69 – General Requirements for Labels for Medicines 2017* and *Therapeutic Goods Order No.92 – Standard for labels of non-prescription medicines*). The statements in Schedule 1 have, where possible, been condensed, for suitability for inclusion in therapeutic goods advertisements, focussing on the most important health information for consumers to be aware of when considering buying a medicine, e.g. for Chlorhexidine, “Chlorhexidine can cause severe allergic reactions”, or for Ibuprofen “Do not use if you have a stomach ulcer, impaired kidney function, heart failure, are allergic to anti-inflammatory medicines, or in the last 3 months of pregnancy”. The health warning requirements for medical devices and other therapeutic goods are also clarified.

The Advertising Code (No. 2) 2018 will commence on 1 January 2019 and repeals the both the Advertising Code 2015 and the Advertising Code 2018, meaning that the Advertising Code 2018 will never take effect.

Human rights implications

This legislative instrument engages two human rights prescribed in the instruments listed in section 3 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

The instrument, in seeking to regulate the advertising of therapeutic goods in Australia, engages Article 19 of the *International Covenant on Civil and Political Rights*. Article 19 provides at Clause 2 that everyone shall have the right to freedom of expression, including the right to seek, receive and impart information orally or through a range of media. Clause 3 of Article 19, however, notes that the exercise of these rights may subject to restrictions as are provided by law and are necessary for the protection of, *inter alia*, public health. The Human Rights Committee of the United Nations has expressed the view that for a limitation to be ‘necessary’ imposes a burden of justification on government agencies, to demonstrate that any restrictive measures are proportional.² Here, the restrictions on the content of advertisements for therapeutic goods are intended to protect the public from the harm to health which may ensue from inappropriate or incorrect use of therapeutic goods in reliance on inappropriate advertising for those goods. The safeguards established by the Code aim to give clear guidance to advertisers to ensure that advertising material is accurate, appropriate for the target audience, and gives guidance as to when consumers should contact pharmacists or doctors to seek further advice about the goods advertised, or about any deterioration in their condition.

The *Therapeutic Goods Advertising Code (No. 2) 2018* is a legislative instrument made by the Minister’s delegate pursuant to the authority granted to the Minister by section 42BAA of the *Therapeutic Goods Act 1989*.

² 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 URL: <https://www.humanrights.gov.au/publications/background-paper-human-rights-cyberspace/4-permissible-limitations-iccpr-right-freedom>

The Code seeks to regulate the content of advertisements for therapeutic goods in the interests of public health. The provisions of the Code aim to ensure that such advertisements provide consumers with the information they need to make safe and informed choices about medicines, medical devices and other therapeutic goods, or with cautions to ensure they seek further advice where appropriate.

The Code engages the right to freedom of opinion and expression, and falls within the exemption prescribed by clause 3 of Article 19 as the limitations it prescribes on freedom of expression are provided for by law, and are necessary for the protection of public health. These limitations are proportionate to the risk to public health posed by inaccurate or misleading advertising of therapeutic goods.

Right to health

The instrument also engages the right to health, set out in Article 12 of the ICESCR. The Office of the United Nations High Commissioner for Human Rights and the World Health Organisation have noted that the right to health does not merely include access to health care, but also to the underlying determinants of health, including health-related education and information³.

Clause 1 of Article 12 states that the States Parties recognise the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. In regulating advertising of therapeutic goods to the public, the *Therapeutic Goods Advertising Code (No. 2) 2018* 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. In particular, section 21 of the Code, which requires that advertising of therapeutic goods must be consistent with public health campaigns, seeks to ensure that health messages given to the public are not contradicted by advertisements sending a contrary message.

Conclusion

This legislative instrument is compatible with human rights in that it engages the right to freedom of opinion and expression in order to protect public health, and protects the right to health.

John Skerritt, delegate of the Minister for Health

³ Office of the United Nations High Commissioner for Human Rights/World Health Organisation, 2008, *Fact Sheet No. 31: The Right to Health*, available at URL: <http://www.ohchr.org/Documents/Publications/Factsheet31.pdf>