Comparison between Therapeutic Goods Advertising Code 2015 and the proposed 2018 Code

Part 1—Preliminary

Proposed TGAC 2018	Existing TGAC 2015
Part 1—Preliminary	
1 Name This instrument is the *Therapeutic Goods Advertising Code 2018*.	Sections 1,2 & 3 of the draft new Code are equivalent to the cover page of the existing Code (2015)
2 Commencement This instrument commences on 1 July 2018.	
3 Repeal of previous Advertising Code The *Therapeutic Goods Advertising Code 2015* is repealed.	
4 Definitions Note: A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following: (a) advertise; (b) complementary medicine; (c) directions for use; (d) health practitioner; (e) included in the Register; (f) indications; (g) label; (h) listed; (i) medical device; (j) medicine; (k) presentation; (l) Register; (n) sponsor; (o) State; (p) State law; (q) supply; (r) therapeutic goods; (s) therapeutic use. In this instrument: ***Act*** means the *Therapeutic Goods Act 1989*. ***analgesic*** means a medicine for internal use, containing one or more of the following substances intended for the relief of aches and pains: (a) salicylic acid, its salts, its derivatives (including aspirin) and their salts; (b) other non-steroidal anti-inflammatory drugs; (c) paracetamol;	Draft new Code lists examples of terms used in the instrument that are defined in section 3(1) of the *Therapeutic Goods Act 1989*. The existing Code also referred readers to section 3(1) of the Act for some definitions. A number of additional terms have been added to the examples list. These are • advertise instead of advertising –Definition under section 6(1) of draft new Code • complementary medicine; • directions for use; • health practitioner; • included in the Register; • indications; • listed; • medical device • medicine • presentation • Register • State • State law; and • supply The definitions listed under the note will be incorporated in the Code guidelines. Further, all guidance material included in the existing Code (2015) has been included in the Code guidelines. This includes pre-approval guidance (apart from the requirement to include approval number) and references to the Complaints Resolution Panel (CRP) & the Therapeutic Goods Advertising Code Council (TGACC). The following definitions are no longer required and have not been included in the new Code: • Broadcast media • Complaints Resolution Panel • Designated therapeutic goods • Mainstream media • Price Information Code of Practice • Specified media • Therapeutic Goods Advertising Code Council; also • Typical – which has been defined within the relevant provision ***analgesic*** has been moved from section 7(1)(a) of the existing

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not including such a medicine where: (d) the condition for which it is designed is a self-limiting condition; and (e) the substances mentioned in paragraphs (a)-(c) are combined with one or more other active ingredients; and (f) the other ingredients have been included in the medicine for indications other than the relief of aches and pains. ***bench-mark price brand***, in relation to a generic medicine, means the lowest priced product within the group of medicines that are listed by the Pharmaceutical Benefits Scheme as bioequivalent products of the generic medicine. ***child*** means an individual under the age of 18. ***dispensing doctor*** means a medical practitioner approved under section 92 of the *National Health Act 1953*. ***displayed or communicated***, in relation to a statement in an advertisement, means: (a) in the case of a visual statement—standing out so as to be easily read from a reasonable viewing distance; and (b) in the case of a spoken statement—able to be clearly heard and understood. ***health professional*** means a person mentioned in section 42AA of the Act. ***Medical Devices Regulations*** means the *Therapeutic Goods (Medical Devices) Regulations 2002*. ***Poisons Standard*** means the Standard in force under section 52D of the Act at the commencement of this Code ***price information*** means information about: (a) the total purchase price of medicines that is to be paid by consumers of those medicines; and (b) in relation to medicines that are subsidised under the Pharmaceutical Benefits Scheme (or Repatriation Pharmaceutical Benefits Scheme), the price paid by the consumer when the prescription is filled. ***prominently displayed or communicated***, in relation to a statement in an advertisement, means: (a) forming part of the main message of the advertisement for the audience to whom it is directed; and (b) in the case of a visual statement—standing out so as to be easily read from a reasonable viewing distance; and (c) in the case of a spoken statement—able to be clearly heard and understood; and (d) in the case of a visual advertisement not designed to be viewed all at once (for example, a printed brochure or a webpage that will be scrolled through)—repeated as often as is necessary to ensure that is likely to be seen by a viewer. ***public health campaign*** means a campaign about a public health matter that is conducted, approved or funded by the Commonwealth or a State or Territory.	Code Additional definitions in the draft new Code include: • Child – section 19/20 & Schedule 2 – advertising to children • Health professional – sections 6(2), 16(1)(c) &(2)(a)(ii) • displayed or communicated sections 11(2)(c)(i), 11(3)(d), 12(1)(d), 12(1)(f), 12(1)(g), 12(2)(d), 12(2)(f), 12(2)(g), 13(2), 13(3) & 23 • Medical Devices Regulations – section 12(2)(e) • prominently displayed or communicated – sections 12(1)(e), 12(1)(h), 12(2)(e), 12(2)(h), 13(4), 14, 20, 24 & 27 • public health campaign – sections 5(d) & 21 • unscheduled - Schedule 2 New definitions that relate to the Price Information -Schedule 1 – include: • bench-mark price brand • dispensing doctor • price information • total purchase price

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Regulations means the *Therapeutic Goods Regulations 1990*. ***total purchase price***, in relation to therapeutic goods, means the total cost of the goods to a consumer, including: (a) any pharmacy mark-up, additional fee or allowable extra fee if applied by the pharmacist; and (b) in relation to Pharmaceutical Benefits Scheme and Repatriation Pharmaceutical Benefits Scheme prescriptions—any premium (such as a brand or therapeutic group premium or special patient contribution) that must be paid by the consumer. ***unscheduled***, in relation to a medicine, means not consisting of, or containing, a substance included in a schedule to the Poisons Standard.	
5 Object The Object of this Code is to ensure that the marketing and advertising of therapeutic goods to consumers is conducted in a manner that: (a) promotes the safe and proper use of therapeutic goods by minimising misuse, overuse or underuse of the goods; and (b) is ethical and does not mislead or deceive the consumer or create unrealistic expectations about product performance; and (c) supports informed health care choices; and (d) is consistent with current public health campaigns.	Combines the existing Code 2015 objective and section 4(2)(a). Socially responsible has been replaced by "ethical". Section 5(c) & (d) of the draft new Code are new provisions. The requirements for section 5(d) are set out under section 21 of the new draft Code. Reference to the quality use of therapeutic goods is included in the Code guidelines and relevant aspects incorporated into the Object as well as requirements set out in section 10 of the draft new Code. Section (1)(2) of the existing Code (consistency with *WHO Ethical Criteria for Medicinal Drug Promotion 1988*) no longer appears as it is medicine centric and the current provision is not an enforceable requirement. However, the WHO criteria have been referenced in the Code guidelines.
6 Application of the Code	Section (3)(1) of the existing Code (advertisements for therapeutic goods are subject to the Act, the Regulations, the Australian Consumer Law under the *Competition and Consumer Act 2010* and other relevant laws). Removed as redundant – This aspect has been covered in Code guidelines.
(1) Subject to subsection (2), this Code applies to the advertising of therapeutic goods. Note: In subsection 3(1) of the Act, ***advertise*** is defined as follows: ***advertise***, in relation to therapeutic goods, includes make any statement, pictorial representation or design that is intended, whether directly or indirectly, to promote the use or supply of the goods, including where the statement, pictorial representation or design: (a) is on the label of the goods; or (b) is on the package in which the goods are contained; or (c) is on any material included with the package in which the goods are contained.	Section 6(1) of draft new Code is equivalent to section 3(1)(a) of the existing Code
(2) This Code does not apply to advertisements directed exclusively to health professionals.	Section 6(2) of draft new Code is equivalent to section 3(1)(b) of the existing Code
(3) This Code is to be applied, in relation to a particular advertisement, by reference to its likely impact on a reasonable person to whom the advertisement is directed.	Section 6(3) of draft new Code is equivalent to section 3(2) of the existing Code
(4) In applying this Code to an advertisement, the total presentation and context of the advertisement is to be taken into account.	Section 6(4) of draft new Code is equivalent to section 1(3) of the existing Code. Both provisions (sections 3(2) & 1(3)) have been collocated so that they can be read together.
(5) This Code applies to any person who:	New provision for clarity

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(a) advertises, by any means, therapeutic goods; or (b) causes the advertising, by any means, of therapeutic goods.	
(6) However, this Code does not apply to genuine news that is broadcast or published in print by a person mentioned in subsection (7), or material published online that is a replication of such news. (7) For subsection (6), the persons are a broadcaster, a datacaster, the SBS or a person of a kind prescribed by the Regulations for the purposes of paragraphs 42DLB(10)(a) or 42DMA(2)(a) of the Act. Note1: In subsections 42DLB(11) and 42MA(3), broadcaster, datacaster and SBS are defined as follows: **broadcaster** has the meaning given by clause 3 of Schedule 2 to the Broadcasting Services Act 1992. **datacaster** means a person who holds a datacasting licence (within the meaning of the Broadcasting Services Act 1992). **SBS** has the same meaning as in the Special Broadcasting Service Act 1991. Note 2: For the purposes of paragraphs 42DLB(10)(a) or 42DMA(2)(a) of the Act, the Regulations prescribe a publisher of a print edition of a newspaper or magazine that is or was available to the public by way of purchase in Australia.	Section 3(1)(c) of the existing Code has been revised to remove reference to public interest or entertainment as recommended by the CRP. Exemption for bona fide news has been retained.
	Section 3(3) of existing Code is no longer required. Pre-approval notes are included in the Code guidelines as they stem from the provisions in the Act, in particular – Part 5-1, Division 2—*Therapeutic goods advertisements for which an approval is required*, including section 42 offence provisions and the Regulations – Part 2, Division 2—*Advertisements for which approval is needed* Section 3(3)(a) of the existing Code is also not required. It too has been included in the Code guidelines – section 5C(2) of Regulations exempts picture/price/place from pre-approval requirements
7 Price information (1) This Code, other than Schedule 1, does not apply to advertising that consists solely of the dissemination of price information. (2) For the purposes of subsections 42DL(10) and 42DLB(7) of the Act, to the extent that the dissemination of price information in relation to therapeutic goods mentioned in those subsections constitutes advertising, the dissemination is authorised if it complies with Schedule 1.	Section 7 of draft new Code is equivalent to section 3(3)(b) of the existing Code. The existing Price Information Code of Practice (PICOP) has been incorporated (with amendments) in Schedule 1 of draft new Code.
	Section 3(4) of existing Code regarding appeals and complaints is guidance material which has been moved to the Code guidelines.

Part 2—Requirements for advertising therapeutic goods—general

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8 Approved advertisements (1) This section applies only to advertisements:	Section 8 of draft new Code is equivalent to section 6(4) of the existing Code

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(a) to which Part 2 of the Regulations applies; and (b) that are published in media referred to in paragraph (a) or (d) of the definition of ***specified media*** in section 42B of the Act. (2) The advertisement must include the approval number allocated to the advertisement under the Regulations. (3) The approval number must: (a) stand alone; and (b) be legible; and (c) be located in the bottom right hand corner of the advertisement.	
	Section 4(1)(a) of existing Code is unnecessary as required under law. Moved to Code guidelines.
9 Accuracy Advertising for therapeutic goods must satisfy the following: (a) any claims made in the advertising are valid, and all information presented can be substantiated; and (b) it is truthful, balanced and not misleading or likely to mislead, including in its claims, presentations, representations and comparisons; and (c) if the goods are included in the Register— it is consistent with the entry for the therapeutic goods in relation to that inclusion.	Section 9(a) of draft new Code is equivalent to section 4(1)(b) of the existing Code Section 9(b) of draft new Code is equivalent to section 4(2)(c) of the existing Code Section 9(c) of draft new Code is a new provisions and is consistent with existing sections 22(5) & 41ML of the Act
10 Effect Advertising for therapeutic goods must: (a) support the safe and proper use of therapeutic goods by: (i) presenting the goods in accordance with directions or instructions for use; and (ii) not exaggerating product efficacy or performance; and (b) 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; and (c) not encourage inappropriate or excessive use of the therapeutic goods; and (d) not contain any claim, statement, implication or representation that: (i) the therapeutic goods are safe or that their use cannot cause harm, or that they have no side-effects; or (ii) the therapeutic goods are effective in all cases of a condition or that the outcome from their use is a guaranteed or sure cure; or (iii) the therapeutic goods are infallible, unfailing, magical or miraculous; or (iv) harmful consequences may result from the therapeutic goods not being used — unless the claim, statement, implication or representation is permitted under	Section 10(a)(i) of draft new Code is a new provision Section 10(a)(ii) of draft new Code replaces section 4(2)(a) of the existing Code Section 10(b) of draft new Code is a new provision similar to "inappropriately treating potentially serious diseases" aspect of section 4(2)(b) of the existing Code Section 10(c) of draft new Code is equivalent to section 4(2)(f) of the existing Code s10(d)(i) of draft new Code is equivalent to section 4(2)(i) of the existing Code Section 10(d)(ii) of draft new Code is equivalent to section 4(2)(h) and part of 4(2)(g) of the existing Code Section 10(d)(iii) of draft new Code is equivalent to the remaining part of section 4(2)(g) of existing Code Section 10(d)(iv) of draft new Code is equivalent to section 4(2)(e) of the existing Code

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section 42DK of the Act or approved under section 42DF of the Act.	
	Section 4(2)(b) of the existing Code is covered by the restricted representation provisions (section 28) and section 10(b) of draft new Code - Serious diseases/ailments are restricted representations. Section 4(2)(d) of the existing Code is covered by other provisions such as section10(a) or (b) of draft new Code.
11 What must advertisements contain—general rules (1) This section does not apply to: (a) a label or consumer medicine information; or (b) an advertisement displaying only the name or picture of therapeutic goods and/or their price or point of sale, provided the advertisement does not contain a claim relating to therapeutic use; or (c) an advertisement for a medicine that is covered by section 14; or (d) direct marketing or internet marketing. (2) An advertisement for a medicine must contain the following: (a) a reference to the name of the medicine, within the meaning of other therapeutic goods legislation; (b) a reference to the intended purpose of the medicine; (c) subject to subsection (4)—either: (i) the following statement, displayed or communicated: *ALWAYS READ THE LABEL*; or (ii) a list of the ingredients; (d) information about where further information about the medicine, including adverse reactions, precautions, contraindications and method of use, can be found or obtained. (3) An advertisement for medical devices or therapeutic goods that are not medicines, medical devices or biologicals must contain the following: (a) an accurate description of the goods; (b) a reference to the trade name of the goods, if applicable; (c) a reference to the intended purpose of the goods; (d) subject to subsection (4), for goods that are intended to be used by the consumer—the following statement, displayed or communicated: *ALWAYS READ THE LABEL*; (e) information about where further information about the goods, including adverse reactions, precautions, contraindications and method of use, can be found or obtained. (4) Paragraphs (2)(c) and (3)(d) do not apply to radio	Section 11(1) of draft new Code is equivalent to sections 6(1) & (2) of the existing Code Section 11(2) of draft new Code is for medicines and equivalent to section 6(3) of the existing Code Section 11(2)(d) of draft new Code is a new provision alerting the consumer of where they can obtain further important information about the medicine Section 11(3) of draft new Code is equivalent to section 6(3) of the existing Code for medical devices & other therapeutic goods Section 11(4) of draft new Code is equivalent to sections 6(3)(c)(ii) of the existing Code providing an exemption from the requirements under paragraphs 2(c) and 3(d) for short form advertisements

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commercials that are 15 seconds or less in duration or to written advertisements that consist of 256 characters or less.	
12 What must advertisements contain—direct marketing and internet marketing (1) A direct marketing or internet marketing advertisement for a medicine must contain the following: (a) the name of the medicine, within the meaning of other therapeutic goods legislation; (b) the intended purpose of the medicine; (c) a list of the ingredients; (d) the following statement, displayed or communicated: *ALWAYS READ THE LABEL*; (e) as applicable, the required statements mentioned in subsection 13(4) and sections 14, 24 and 27, prominently displayed or communicated on each page that features the medicine; (f) as applicable, the required statements mentioned in subsections 13(2) and 13(3), displayed or communicated on each page that features the medicine; (g) any mandatory warning statements that are required for the medicine under other therapeutic goods legislation, displayed or communicated on each page that features the medicine; (h) if the medicine, when used according to its directions for use: (i) has known serious adverse effects (in terms of severity and clinical importance); or (ii) is contraindicated for a known group of people because it could cause serious adverse effects which are required by other therapeutic goods legislation to be mentioned on the label; an appropriate warning of those effects, prominently displayed or communicated on each page that features the medicine. (2) A direct marketing or internet marketing advertisement for a medical device must contain the following: (a) an accurate description of the device; (b) the trade name of the device, if applicable; (c) the intended purpose of the device; (d) the following statement, displayed or communicated: *ALWAYS READ THE LABEL*; (e) the required statements mentioned in subsection 13(4), prominently displayed or communicated on each page that features the device; (f) the required statements mentioned in subsections 13(2) and 13(3), displayed or communicated on each page that features the device;	Section 12(1) of draft new Code is equivalent to section (6)(3)(c)(i) of the existing Code as it applies to medicines Sections12(2) & (3) of draft new Code are the equivalent provisions for medical devices Section12(4) of draft new Code is the equivalent provision for other therapeutic goods

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(g) any information of a kind mentioned in subsection (3) that must, under clause 13.3 of the Schedule 1 to the Medical Devices Regulations, be provided with the device, displayed or communicated on each page that features the device; (h) if the device, when used according to its intended purpose has known serious adverse effects (in terms of severity and clinical importance)— an appropriate warning of those effects, prominently displayed or communicated on each page that features the device. (3) For the purposes of paragraph (2)(g), the information is any warnings, restrictions, or precautions that should be taken, in relation to use of the device. (4) A direct marketing or internet marketing advertisement for therapeutic goods that are not medicines, medical devices or biologicals must contain the following: (a) an accurate description of the goods; (b) the trade name of the goods, if applicable; (c) the intended purpose of the goods; (d) information about where further information about the goods, including adverse reactions, precautions, contraindications and method of use, can be found or obtained.	
13 Required statements (1) This section does not apply to: (a) a label or consumer medicine information; or (b) an advertisement displaying only the name or picture of therapeutic goods and/or their price or point of sale, provided the advertisement does not contain a claim relating to therapeutic use; or (c) an advertisement for a medicine that is covered by section 14; or (d) direct marketing or internet marketing. (2) An advertisement for a medicine must contain the following statement, displayed or communicated: *FOLLOW THE DIRECTIONS FOR USE.* (3) An advertisement for a medical device, or for therapeutic goods other than a medicine or medical device, must contain the following statement, displayed or communicated: *FOLLOW THE INSTRUCTIONS FOR USE.* (4) If an advertisement contains a claim relating to a symptom of a disease, condition, ailment or defect, the advertisement must contain the following statement, prominently displayed or communicated: *IF SYMPTOMS PERSIST, WORSEN OR CHANGE UNEXPECTEDLY, TALK TO YOUR HEALTHCARE PROFESSIONAL*. (5) Paragraph (4) does not apply to radio commercials that are 15 seconds or less in duration or to written advertisements that consist of 256 characters or less.	Section 13(1) of draft new Code is equivalent to sections 6(1) & (2) of the existing Code Section 13(2) of draft new Code is equivalent to section (6)(3)(d) of the existing Code for medicines Sections 13(3) of draft new Code is equivalent to section 6(3)(d) of the existing Code for medical devices & other therapeutic goods Section 13(4) of draft new Code is also equivalent to section 6(3)(d) of the existing Code where the advertisements includes claims relating to symptoms of diseases or conditions Section 13(5) of draft new Code is also equivalent to section sections 6(3)(c)(ii) of the existing Code providing an exemption from the requirements under paragraphs 13(4) for short form advertisements

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14 Required statement—pharmacist-only medicines An advertisement for a medicine consisting of, or containing, a substance included in Schedule 3 of the Poisons Standard and Appendix H of that Standard, must contain the following statement, prominently displayed or communicated: *ASK YOUR PHARMACIST—THEY MUST DECIDE IF THIS PRODUCT IS RIGHT FOR YOU*	Section 14 of draft new Code is equivalent to section (6)(3)(e) of the existing Code.
	Section (6)(3)(f) of the existing Code has been removed as it is redundant.
15 Scientific representations Where an advertisement makes a scientific or clinical claim: (a) any scientific terminology must be appropriate, clearly communicated and able to be readily understood by the audience to whom it is directed; and (b) any research results must identify the researcher and financial sponsor of the research; and (c) if a specific research study is cited—the study must be sufficiently identified to enable consumers to access it; and (d) any scientific representation must be consistent with the body of scientific evidence applicable to the advertised therapeutic goods.	Section 15 of draft new Code is equivalent to section 4(4) of the existing Code. The first requirement of existing section 4(4) is covered under section 9(b) of draft new Code
16 Endorsements (1) An advertisement for therapeutic goods must not contain an endorsement from, or imply that the therapeutic goods are endorsed by: (a) a government agency, hospital or healthcare facility; or (b) an employee or contractor of a government agency, hospital or healthcare facility; or (c) a health practitioner, health professional, medical researcher or a group of such persons; or (d) a contractor of a person or a group mentioned in paragraph (c). (2) An advertisement for therapeutic goods must not contain an endorsement from, or imply that the therapeutic goods are endorsed by: (a) an organisation that: (i) represents the interests of healthcare consumers; or (ii) represents the interests of health practitioners, health professionals or medical researchers; or (iii) conducts or funds research into any disease, condition, ailment or defect; or (b) an employee of an organisation mentioned in paragraph (a), other than an individual mentioned in subsection (1); unless the advertisement: (c) names the organisation; and (d) discloses:	Section 4(6)(a) of the existing Code has been removed. However, advertisements that reference *sponsorship of any government agency, hospital or other facility providing healthcare services* would be considered an endorsement and covered by the section 17 of draft new Code. Section 16(1) of draft new Code is equivalent to 4(6)(b) of the existing Code Section 16(2) of draft new Code is equivalent to 4(6)(c) of the existing Code

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(i) the nature of the endorsement; and (ii) whether the organisation, or employee, has received, or will receive, any valuable consideration for the endorsement.	
17 Testimonials (1) A testimonial used in an advertisement for therapeutic goods must be: (a) made by a person: (i) whose details are verifiable; and (ii) who has used the goods for their intended purpose; and (iii) who is not: (A) involved with the production, sale, supply or marketing of the goods; or (B) an individual who is a relative or associate of an individual who is involved with the production, sale, supply or marketing of the goods; or (C) an employee or officer of a corporation that is involved with the production, sale, supply or marketing of the goods; and (b) verifiable as to the use of the goods and the claims made by the person; and (c) typical of the results to be expected from the use of the goods in accordance with the directions for use, or purpose, of the goods. (2) A testimonial must: (a) disclose where any valuable consideration has been given to the person providing the testimonial; and (b) disclose where another person is taking the place in the advertisement of the person providing the testimonial; and (c) indicate where the original testimonial has been truncated, altered or paraphrased in the advertisement.	Section 17 of draft new Code is equivalent to s4(7) of the existing Code but with improved clarity
18 Incentives An advertisement must not offer any personal incentive to a pharmacy assistant, or any retail sales person who is not a healthcare professional, to recommend or supply therapeutic goods.	Section 18 of draft new Code is equivalent to section 4(3) of the existing Code
	Section 4(5) of the existing Code (Comparative advertising) has been removed as these requirements are covered under other provisions in the draft new Code. Comparative advertising is discussed in the Code guidelines
	Section 4(8) of the existing Code (samples) has been removed. This provision does not prevent the supply of a sample. It prohibits advertising the offer of a sample. Supply of therapeutic good samples is a matter for states and territories.
19 Advertising to children (1) Advertising must not be directed to children under the age of 12 in any circumstances.	Section 19 of draft new Code is equivalent to section 4(2)(j) of the existing Code

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(2) Advertising, other than advertising of therapeutic goods mentioned in Schedule 2, must not be directed to children aged 12 or over.	
20 Allergies If therapeutic goods have a history of causing a serious allergic reaction in a particular patient group, advertising for those therapeutic goods must contain a warning applicable to that patient group, prominently displayed or communicated.	Section 20 of draft new Code is a new provision – consistent with labelling requirements and important from a public health and safety perspective for potential buyers of the product to be aware where the product may cause a serious allergic reaction.
21 Consistency with public health campaigns If a relevant public health campaign is current at the time of advertising therapeutic goods, the promotion of the goods must not be inconsistent with the public health campaign and the other objects of this Code.	Section 21 of draft new Code is a new provision to ensure that TG advertisements do not undermine public health campaigns– also see Objective of new draft Code – section 5(d)

Part 3—Rules relating to particular therapeutic goods

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Part 3—Rules relating to particular therapeutic goods Note: The rules in this Part apply, in relation to the goods mentioned in each section, in addition to Part 2.	
22 Application This Part does not apply to labels.	
23 Complementary medicines If an advertisement for a complementary medicine includes a claim based on evidence of a history of traditional use and paradigm, the reliance on this traditional use must be disclosed in the advertisement and the disclosure must be displayed or communicated in the advertisement.	Section 23 of draft new Code is a new provision committed to in the Department of Health's submission to the Senate Community Affairs Legislation Committee
24 Analgesics (1) An advertisement for an analgesic must contain the following warning statement, prominently displayed or communicated: *INCORRECT USE COULD BE HARMFUL.* (2) An advertisement for an analgesic must not imply that: (a) analgesic consumption is safe; or (b) analgesics will relax, relieve tension, sedate or stimulate.	Section 24(1) of draft new Code is a simplified version but equivalent to section 7(1)(c) of the existing Code The term a*nalgesic* (section 7(1)(a) including the exclusion under s7(1)(b) of the existing Code) is defined under section 4 of draft new Code Section 24(2) of draft new Code is equivalent to section 7(1)(e) of the existing Code. All of the mandatory statements under sections 7(1)(c) & (d) of the existing Code are no longer required to be specified here as they are covered by other sections (apart from the statement *incorrect use could be harmful*)
25 Vitamins and minerals (1) An advertisement for vitamin or mineral supplements must not claim or imply that the supplements: (a) are a substitute for good nutrition or a balanced diet; or (b) are in any way superior to or more beneficial than dietary nutrients.	Section 25(1)(a) of draft new Code and section 7(2)(a) of the existing Code are equivalent Section 25(1)(b) of draft new Code to 7(2)(b) of the existing Code are equivalent
26 Weight Management (1) An advertisement for therapeutic goods containing any claim relating to weight management must balance the	Section 26 of draft new Code section is equivalent to section 7(3) of the existing Code with improved clarity.

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claims with the need for a healthy energy-controlled diet and physical activity. (2) Advertising of therapeutic goods containing any claim relating to weight management must not include any reference or depiction suggesting that the therapeutic goods will correct or reverse the effects of overeating or over-consumption of any food or drink. (3) An advertisement for therapeutic goods containing any claim relating to weight management must not: (a) feature individuals in images or visual representations; or (b) use individuals' statistics or testimonials; unless the results expected to be achieved by those individuals from the use of the goods are typical of the results achieved by users of the goods. (4) In this section: ***weight management*** includes the following: (a) weight loss; (b) weight control; (c) weight maintenance; (d) measurement reduction; (e) clothing size reduction; (d) hunger suppression.	
27 Sunscreens Advertising of sunscreens must: (a) depict sunscreens as being only one part of sun protection; and (b) include statements or visual representations, prominently displayed or communicated, to the effect that: (i) prolonged high-risk sun exposure should be avoided; and (ii) frequent re-application or use in accordance with directions is required for effective sun protection.	Section 27 of draft new Code is a new provision which underlines the important public health message that underpins the use of sunscreens

Part 4—Restricted representations and prohibited representations

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Part 4—Restricted representations and prohibited representations	
28 Restricted representations—serious form of disease, condition, ailment or defect For the purposes of section 42DD of the Act, a form of a disease, condition, ailment or defect is a serious form if: (a) it is medically accepted that the form requires diagnosis and treatment or supervision by a suitably qualified healthcare professional; or (b) it is a form that is likely to significantly impair a person's physical or mental health; or	Section 28 of draft new Code takes into account TGACC recommended changes including removal of Part 2, Appendix 6 of the existing Code.

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(c) there is a diagnostic test available for the form (including a self-administered test), but the results of the test are not appropriate for self-interpretation. Note 1: Section 42DD of the Act provides that a representation that refers to a serious form of a disease, condition, ailment or defect is a restricted representation. Note 2: Sections 42DF and 42DK of the Act provide for the Secretary to approve or permit the use of a restricted representation in certain circumstances. Note 3: See sections 42DL and 42DLB of the Act for offences and a civil penalty for advertising therapeutic goods, where the advertisement contains a restricted representation.	
29 Restricted representations—public interest criteria For the purposes of paragraph 42DF(4)(c) of the Act, the public interest criteria are as follows: (a) 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; (b) 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); (c) 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); (d) such other aspects of the public interest as may appear to be appropriate to the Secretary.	Section 29 of draft new Code is equivalent to Appendix 6, Part 2 – 'public interest criteria to be applied' - of the existing Code
30 Prohibited representations For the purposes of paragraph 6B(1)(b) of the Regulations, the following representations are prohibited representations: (a) any representation regarding abortifacient action; (b) any representation regarding the treatment, cure, prevention or diagnosis of the following diseases: (i) neoplastic disease; (ii) sexually transmitted diseases; (iii) human immunodeficiency virus and acquired immune deficiency syndrome (HIV AIDS); (iv) hepatitis C virus (HCV); (v) mental illness. Note 1: Subsection 42DJ(1) of the Act provides that representations of a kind specified in regulations made for the purposes of that subsection are prohibited representations about therapeutic goods of a kind specified in those regulations. Subregulation 6B(1) of the Regulations provides that the representations mentioned in this Code are prohibited representations. Note 2: Section 42DK of the Act provides for the Secretary to permit the use of a prohibited representation in certain circumstances. Note 3: See sections 42DL and 42DLB of the Act for offences and a civil	Section 30 of draft new Code is equivalent to existing Part 1, Appendix 6 of the existing Code apart from the exception. This exception power resides in the amended Act under subsection 42DK which empowers the Secretary, by writing, to permit the use of specified prohibited representations in specified advertisements about particular therapeutic goods where it is in the interests of public health.

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penalty for advertising therapeutic goods, where the advertisement contains a prohibited representation.	
Schedule 1—Price Information Note: See section 7	Schedule 1 of draft new Code is a new schedule that incorporates the existing Price Information Code of Practice
Schedule 2—Advertising to children Note: See section 19. 1 Goods that may be advertised to children For the purposes of section 19, the following therapeutic goods may be 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) devices for management of chronic conditions under medical supervision; (g) cold sore preparations; (h) lip balm; (i) unscheduled anti-dandruff preparations.	Schedule 2 of draft new Code is equivalent to Appendix 5 of the existing Code. Existing pre-amble moved to Code guidelines
	Appendix 1of the existing Code removed. Reference to the WHO criteria included in the Code guidelines
	Appendix 2 of the existing Code is blank
	Appendix 3 of the existing Code (approval of mainstream advertisements) has been moved to the Code guidelines
	Appendix 4 of the existing Code (appeals and complaints mechanisms) has been moved to the Code guidelines