Therapeutic Goods Amendment (Therapeutic Goods Advertising Code) Instrument 2019

I, Gillian Mitchell, as delegate of the Minister for Health, make the following instrument.

Dated 26 July 2019

Gillian Mitchell
First Assistant Secretary
Regulatory Practice and Support Division
Health Products Regulation Group
Department of Health

Contents

1 Name

This instrument is the *Therapeutic Goods Amendment (Therapeutic Goods Advertising Code) Instrument 2019*.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	**Column 2**	**Column 3**
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	The day after this instrument is registered.	

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under section 42BAA of the *Therapeutic Goods Act 1989*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Therapeutic Goods Advertising Code (No.2) 2018

1 Section 3

Omit "Act", substitute "*Therapeutic Goods Act 1989*".

2 Section 4 (definition of *health warning*)

Repeal the definition, substitute:

health warning means:

(a) in relation to a medicine that contains an ingredient mentioned in column 1 of an item in a table in Schedule 1, in the circumstances set out in column 2 of that item—the statement mentioned in column 3 of that item;

(b) in relation to a medical device or other therapeutic goods—a statement that is required under the Act, Regulations or Medical Devices Regulations to be included on the label, or in the instructions for use, of the device or goods, and is to the effect that:

(i) a person who takes, or uses, the device or goods as intended may:

(A) die; or

(B) require hospitalisation or a longer period of hospitalisation than would be required if the person had not taken, or used, the device or goods; or

(C) require a medical practitioner to treat or prevent an injury, disability, incapacity, or impairment (the latter in relation to a bodily function, organ or structure), as a consequence of taking, or using, the device or goods; or

(ii) the device or goods should not be taken, or used, in certain circumstances, which are described by reference to one or more of the following:

(A) a serious form, within the meaning of subsection 28(1), of a disease, condition, ailment or defect;

(B) an implantable device;

(C) a specific class of persons;

(D) pregnancy.

Note: A statement referred to in subparagraph (b)(ii) may be in the form of "DO NOT USE IF" followed by a reference to one of the matters mentioned in sub-subparagraphs (b)(ii)(A) to (D).

3 Subsection 6(2)

Repeal the subsection, substitute:

(2) This instrument does not apply to an advertisement that:

(a) is directed exclusively to health professionals; or

(b) is part of, or otherwise comprises, a public health campaign.

4 Subsection 7(1)

After "information", insert "for medicines that are registered goods".

5 Section 11 (heading)

Repeal the heading, substitute:

11 Therapeutic goods containing a Schedule 3 substance (required statement)

6 Subsection 11(2)

Omit "a medicine", substitute "therapeutic goods".

7 Paragraph 12(3)(d)

Repeal the paragraph, substitute:

(d) at least one of the indications of the medicine, as the indication appears on the medicine's label, or as modified in a manner that does not change the meaning or intent of the indication as it appears on the medicine's label;

8 Paragraph 12(3)(h)

After "(as applicable),", insert "prominently".

9 Paragraph 12(4)(c)

Repeal the paragraph, substitute:

(c) at least one of the intended purposes of, or indications for, the device, as the intended purpose or indication appears on the label or primary packaging of the device, or as modified in a manner that does not change the meaning or intent of the intended purpose or indication as it appears on the label or primary packaging of the device;

10 Paragraph 12(5)(c)

Repeal the paragraph, substitute:

(c) at least one of the intended purposes of, or indications for, the goods, as the intended purpose or indication appears on the label or primary packaging of the goods, or as modified in a manner that does not change the meaning or intent of the intended purpose or indication as it appears on the label or primary packaging of the goods;

11 Paragraph 13(1)(c)

Repeal the paragraph, substitute:

(c) an advertisement that:
  (i) displays only the name or picture of therapeutic goods or their price or point of sale, or any combination of these things; and
  (ii) does not contain or imply a claim relating to therapeutic use; or

12 Paragraph 13(2)(b)

Repeal the paragraph, substitute:

(b) at least one of the indications for the medicine, as the indication appears on the medicine's label, or as modified in a manner that does not change the meaning or intent of the indication as it appears on the medicine's label;

13 Paragraph 13(2)(c)

Omit "subject to subsection (5)", substitute "subject to subsections (2A) and (5)".

14 Paragraph 13(2)(c) (cell at table item dealing with a medicine for which there are no health warnings, column headed "Type of medicine")

Repeal the cell, substitute:

A medicine that does not include any ingredients in Part 1 or Part 2 of Schedule 1 for which there are health warnings

15 After subsection 13(2)

Insert:

(2A) If an advertisement relates to more than one medicine and:

(a) the advertisement does not relate to one or more other therapeutic goods or medical devices; and

(b) at least one of the medicines advertised includes an ingredient in Part 1 or Part 2 of Schedule 1 for which there is a health warning;

then the following statement may be prominently displayed or communicated in the advertisement instead of the applicable statements mentioned in the table in paragraph (2)(c):

(c) *THESE MEDICINES MAY NOT BE RIGHT FOR YOU. READ THE LABEL BEFORE PURCHASE*.

16 Paragraph 13(3)(c)

Repeal the paragraph, substitute:

(c) at least one of the intended purposes of, or indications for, the device, as the intended purpose or indication appears on the label or primary packaging of the device, or as modified in a manner that does not change the meaning or intent of the intended purpose or indication as it appears on the label or primary packaging of the device;

17 Paragraph 13(4)(c)

Repeal the paragraph, substitute:

(c) at least one of the intended purposes of, or indications for, the goods, as the intended purpose or indication appears on the label or primary packaging of the goods, or as modified in a manner that does not change the meaning or intent of the intended purpose or indication as it appears on the label or primary packaging of the goods;

18 Paragraph 16(1)(b)

Repeal the paragraph, substitute:

(b) in relation to a medicine that is listed under section 26AE of the Act or a complementary medicine that is registered under section 25 of the Act—a statement, pictorial representation or design authorised or required by a government or government authority (not including a foreign government or foreign government authority) under paragraphs 42DL(9)(b) and 42DLB(6)(b) of the Act, or prescribed by the Regulations for the purposes of paragraphs 42DL(9)(c) and 42DLB(6)(c) of the Act.

19 Section 28

Repeal the section, substitute:

(1) Subject to subsection (2), 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 or treatment or supervision by a suitably qualified health professional, except where the form has been medically diagnosed and medically accepted as being suitable for self-treatment and management; or

(b) there is a diagnostic (including screening), preventative, monitoring, susceptibility or pre-disposition test available for the form (including a self-administered test), which requires medical interpretation or follow-up.

(2) A serious form of a disease, condition, ailment or defect does not include:

(a) pregnancy, other than pregnancy with a medical, obstetric or surgical complication; or

(b) any of the diseases mentioned in section 30.

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.

20 Schedule 1 (table, Part 1, item dealing with Aspirin, column 3)

Omit " heart failure,".

21 Clause 1 of Schedule 4

After "certain pharmacist-only medicines", insert ", that are registered goods,".

22 Application of amendments

The amendments made by this instrument apply in relation to:

(a) an advertisement occurring after the commencement of this instrument to which Division 2 of Part 2 of the *Therapeutic Goods Regulations 1990* does not apply; and

(b) an advertisement occurring after the commencement of this instrument to which Division 2 of Part 2 of the *Therapeutic Goods Regulations 1990* applies, unless the advertisement is the subject of an approval given prior to the commencement of this instrument and that approval remains in force at the time of the advertisement.