Therapeutic Goods (Restricted Representations—Naloxone) Permission 2019

I, Nicole McLay, as delegate of the Secretary of the Department of Health, make the following permission.

Dated 20 December 2019

Nicole McLay
Assistant Secretary
Regulatory Education and Compliance Branch
Health Products Regulation Group
Department of Health

Contents

1 Name

This instrument is the *Therapeutic Goods (Restricted Representations—Naloxone) Permission 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	1 January 2020.	1 January 2020

Note: This table relates only to the provisions of this instrument as originally made.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 42DK of the *Therapeutic Goods Act 1989*.

4 Definitions

Note: A number of expressions used in this instrument are defined in section 3 of the Act, including the following:
(a) advertise;
(b) current Poisons Standard;
(c) indication;
(d) label;
(e) Register;
(f) therapeutic goods; and
(g) Therapeutic Goods Advertising Code.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

prominently displayed or communicated has the same meaning as in the Therapeutic Goods Advertising Code.

registered medicine means a medicine that is included in the part of the Register for goods known as registered goods.

restricted representation has the same meaning as in section 42DD of the Act.

serious form of a disease means a serious form of a disease within the meaning of section 28 of the Therapeutic Goods Advertising Code.

5 Permission

For subsection 42DK(1) of the Act, in relation to each item mentioned in the table in Schedule 1, the restricted representations specified in column 2 are permitted to be used in the advertisements specified in column 3, about the therapeutic goods specified in column 4, subject to the conditions (if any) specified in column 5.

Schedule 1—Permission: restricted representation

Note: See section 5.

Permitted use of restricted representation				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Restricted representation**	**Advertisement**	**Therapeutic goods**	**Conditions**
1	a representation that is to the effect that the therapeutic goods: (a) can assist in the emergency treatment of opioid overdoses; or (b) are intended to be used as part of the emergency treatment for known or suspected opioid overdoses where there is respiratory depression or central nervous system depression or both (*see note at end*); or (c) are for emergency use after known or suspected overdoses of opioids, including but not limited to: (i) buprenorphine, (ii) codeine; (iii) dihydrocodeine; (iv) fentanyl; (v) heroin; (vi) methadone; (vii) morphine; (viii) oxycodone; (ix) pethidine; (x) tapentadol; or (d) can temporarily reverse the effect of opioids	an advertisement about the therapeutic goods including, but not limited to, an advertisement that is: (a) on the label of the therapeutic goods; (b) on the package in which the therapeutic goods are contained; (c) on any material included with the package in which the therapeutic goods are contained	a registered medicine that contains naloxone and that: (a) has an indication accepted in relation to its inclusion that refers to the treatment of opioid overdose; and (b) is included in Schedule 3 to the current Poisons Standard	the representation must be accompanied by advisory statements, which are prominently displayed or communicated and to the effect of the following: (a) naloxone is not a substitute for emergency medical care; and (b) call 000 immediately before administering naloxone; and (c) both of the following: (i) additional doses may be required until emergency medical treatment arrives; and (ii) ask your pharmacist at the time of purchase

Permitted use of restricted representation				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Restricted representation**	**Advertisement**	**Therapeutic goods**	**Conditions**
2	a representation that: (a) refers, expressly or by implication, to "opioid overdose"; and (b) is made in the context of providing accurate, balanced and contemporary information for the purpose of informing consumers of the effect of naloxone on the human body	an advertisement about the therapeutic goods including, but not limited to, an advertisement that is: (a) on the label of the therapeutic goods; (b) on the package in which the therapeutic goods are contained; (c) on any material included with the package in which the therapeutic goods are contained	a registered medicine that contains naloxone and that: (a) has an indication accepted in relation to its inclusion that refers to the treatment of opioid overdose; and (b) is included in Schedule 3 to the current Poisons Standard	the representation must be accompanied by advisory statements, which are prominently displayed or communicated and to the effect of the following: (a) naloxone is not a substitute for emergency medical care; and (b) call 000 immediately before administering naloxone; and (c) both of the following: (i) additional doses may be required until emergency medical treatment arrives; and (ii) ask your pharmacist at the time of purchase

Note: Paragraph 15(2)(a) of the Therapeutic Goods Advertising Code provides that any scientific or clinical terminology in an advertisement must be appropriate, clearly communicated and able to be readily understood by the audience to whom it is directed.