Therapeutic Goods (Restricted Representations—Adrenaline Auto-Injectors and Pre-Filled Syringes) Permission 2021

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

Dated 30 August 2021

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

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1 Name

This instrument is the *Therapeutic Goods (Restricted Representations—Adrenaline Auto-Injectors and Pre-Filled Syringes) Permission 2021*.

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 made.	31 August 2021

Note: This table relates only to the provisions of this instrument as originally made.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) directions for use;
(c) health practitioner;
(d) indications;
(e) label;
(f) Register;
(g) therapeutic goods; and
(h) 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 means a representation referred to in section 42DD of the Act.

specified goods means a registered medicine, other than a prescription medicine, that:

(a) contains:

(i) 0.5mg/0.3mL adrenaline (epinephrine); or

(ii) 0.3 mg/0.3 mL adrenaline (epinephrine); or

(iii) 0.15 mg/0.3 mL adrenaline (epinephrine);

as the only active ingredient; and

(b) is in the form of an auto-injector, or pre-filled syringe, suitable for self-administration; and

(c) has an indication accepted in relation to its inclusion that relates to the emergency treatment of anaphylaxis.

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.

6 Repeals

Each instrument that is specified in Schedule 2 is repealed as set out in the applicable items in that Schedule.

Schedule 1—Permission: restricted representations

Note: See section 5.

Permitted use of restricted representations				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Restricted representations**	**Advertisements**	**Therapeutic goods**	**Conditions**
1	a representation that is to the effect, expressly or by implication, that the therapeutic goods are for the emergency treatment of anaphylaxis, and includes a representation that is contained within the name of the goods	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	specified goods	the representation must be: (a) consistent with the directions for use of the therapeutic goods; and (b) accompanied by advisory statements, which are prominently displayed or communicated, to the effect of the following: (i) adrenaline is not a substitute for subsequent emergency medical or hospital care; and (ii) call 000 immediately after administering adrenaline; and (iii) an additional dose may be needed while waiting for emergency medical services; and (iv) the medicine can be obtained from a pharmacy with a prescription; and (v) the medicine can be obtained from a pharmacy without a prescription where a pharmacist is satisfied that the

Permitted use of restricted representations				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Restricted representations**	**Advertisements**	**Therapeutic goods**	**Conditions**
				relevant person has been assessed by an appropriate health practitioner as needing to carry adrenaline and the health practitioner has provided that person with a formal action plan for anaphylaxis
2	a representation that refers, expressly or by implication, to anaphylaxis; and: (a) relates to the proper use of the therapeutic goods; or (b) is made in the context of providing accurate, balanced and contemporary information about the therapeutic goods and anaphylaxis	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	specified goods	the representation must be: (a) consistent with the directions for use of the therapeutic goods; and (b) accompanied by advisory statements, which are prominently displayed or communicated, to the effect of the following: (i) adrenaline is not a substitute for subsequent emergency medical or hospital care; and (ii) call 000 immediately after administering adrenaline; and (iii) an additional dose may be needed while waiting for emergency medical services; and (iv) the medicine can be obtained from

Permitted use of restricted representations				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Restricted representations**	**Advertisements**	**Therapeutic goods**	**Conditions**
				a pharmacy with a prescription; and (v) the medicine can be obtained from a pharmacy without a prescription where a pharmacist is satisfied that the relevant person has been assessed by an appropriate health practitioner as needing to carry adrenaline and the health practitioner has provided that person with a formal action plan for anaphylaxis

Note: The specified goods must comply with applicable requirements for pharmacist-only medicines in the Therapeutic Goods Advertising Code, which includes a requirement to prominently display or communicate certain statements in addition to those specified in column 5.

Schedule 2—Repeals

Note: See section 6.

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1 The whole of the instrument

Repeal the instrument.