



## **Repealed Therapeutic Goods (Restricted Representations—Adrenaline Auto-Injectors and Pre-Filled Syringes) Permission 2020**

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

Dated 29 July 2020

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

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Repealed

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## 1 Name

This instrument is the *Therapeutic Goods (Restricted Representations—Adrenaline Auto-Injectors and Pre-Filled Syringes) Permission 2020*.

## 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 (day)
1. The whole of this instrument	The day after this instrument is made.	20 July 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Note: This table relates only to the provisions of this instrument as originally made.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 to this instrument.

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

## 3 Authority

This instrument is made under section 22DK of the *Therapeutic Goods Act 1989*.

## 4 Definitions

Notwithstanding any other definition of the words used in this instrument are defined in section 3 of the Act, including the following:

- (a) advise;
- (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 *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.

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**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) 0.3 mg/0.3 mL adrenaline (epinephrine); or
  - (ii) 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 the inclusion of which 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.

## 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 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: <ol style="list-style-type: none"> <li>on the label of the therapeutic goods;</li> <li>on the package in which the therapeutic goods are contained;</li> <li>on any material included with the package in which the therapeutic goods are contained</li> </ol>	specified goods	the representation must be: <ol style="list-style-type: none"> <li>consistent with the directions for use of the therapeutic goods; and</li> <li>accompanied by advisory statements, which are prominently displayed or communicated, to the effect of the following:               <ol style="list-style-type: none"> <li>adrenaline is not a substitute for subsequent emergency medical or hospital care; and</li> <li>call 000 immediately after administering adrenaline; and</li> <li>an additional dose may be needed while waiting for emergency medical services; and</li> <li>the medicine can be obtained from a pharmacy with a prescription; and</li> <li>the medicine can be obtained from a pharmacy without a prescription where a pharmacist is satisfied that the</li> </ol> </li> </ol>

Permitted use of restricted representation				
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 provided that person with a formal opinion relating to 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, up-to-date and contemporary information about the therapeutic goods and anaphylaxis	an advertisement about the therapeutic goods including, but not limited to, the advertisement that is: (a) on the label of the therapeutic goods; (b) on the packaging in which the therapeutic goods are contained; (c) on any material included with the package in which the therapeutic goods are contained	therapeutic 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

Permitted use of restricted representation				
Column 1	Column 2	Column 3	Column 4	Column 5
Item	Restricted representations	Advertisements	Therapeutic goods	Conditions
				(v) the medicine can be obtained from a pharmacy without prescription where pharmacist is notified by the relevant person has been assessed by an appropriate health practitioner carrying 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 the following statements in addition to those specified in column 5.