



Therapeutic Goods (Restricted Representations—Salbutamol) Permission 2020

I, Sasha Barclay, as delegate of the Secretary of the Department of Health, make the following permission.

Dated 3 January 2020

Sasha Barclay
Acting Assistant Secretary
Regulatory Education and Compliance Branch
Health Products Regulation Group
Department of Health

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1 Name

This instrument is the *Therapeutic Goods (Restricted Representations—Salbutamol) 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/Details
1. The whole of this instrument	3 January 2020.	3 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Note: This table relates only to the provisions of this instrument as originally made.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) indications;
- (d) medicine;
- (e) Register;
- (f) registered goods;
- (g) therapeutic goods; and
- (h) Therapeutic Goods Advertising Code.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

Commonwealth health campaign means a campaign about a public health matter that is conducted, approved or funded by the Commonwealth.

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.

State health campaign means a campaign about a public health matter that is conducted, approved or funded by a State.

Note: State is defined in section 3 of the Act as including the Australian Capital Territory and the Northern Territory.

5 Permission

- (1) 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.
- (2) The permission given in subsection (1) applies for the period starting on the commencement of this instrument and ending on 30 April 2020.

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	<p>a representation that is to the effect that:</p> <p>(a) persons with asthma or chronic obstructive pulmonary disease ensure, where possible, that those persons take the therapeutic goods mentioned in column 4 in their possession with them in the event of an evacuation;</p> <p>(b) persons with asthma or chronic obstructive pulmonary disease ensure, where possible, that those persons take scripts in their possession for the therapeutic goods mentioned in column 4 with them in the event of an evacuation; or</p> <p>(c) persons with asthma or chronic obstructive pulmonary disease may obtain the therapeutic goods mentioned in column 4 from a particular named pharmacy; or</p> <p>(d) persons with asthma or chronic obstructive pulmonary disease may obtain the</p>	<p>an advertisement that is or forms part of:</p> <p>(a) a Commonwealth health campaign; or</p> <p>(b) a State health campaign; or</p> <p>(c) a Commonwealth emergency activity; or</p> <p>(d) a State emergency activity; or</p> <p>(e) an advertisement from a pharmacy</p>	<p>therapeutic goods that are registered medicines containing the active ingredient salbutamol, in relation to which the following two paragraphs apply:</p> <p>(a) the registered medicine has an indication accepted in relation to its inclusion in the Register that refers to the treatment of asthma or chronic obstructive pulmonary disease; and</p> <p>(b) the active ingredient salbutamol, which is contained in the registered medicine, complies with the entry for salbutamol included in Schedule 3 to the current Poisons Standard</p>	
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Permitted use of restricted representation				
Column 1	Column 2	Column 3	Column 4	Column 5
Item	Restricted representation	Advertisement	Therapeutic goods	Conditions
	therapeutic goods mentioned in column 4 from pharmacies with or without prescription if necessary			

- Note 1: Asthma and chronic obstructive pulmonary disease are serious forms of a disease, condition, ailment or defect within the meaning of section 28 of the Therapeutic Goods Advertising Code.
- Note 2: The use of any representation of the kinds mentioned above in advertising must comply with Part 5-1 of the Act and the Therapeutic Goods Advertising Code.
- Note 3: The permission given in this instrument is to enable the provision of information to the public about the availability of therapeutic goods that are registered medicines containing the active ingredient salbutamol during and following the bushfires in Australia in January 2020.