



Therapeutic Goods (Restricted Representations—Medical Devices for Chronic Respiratory Diseases) Permission 2026

I, Michael Shum, as delegate of the Secretary of the Department of Health, Disability and Ageing, make the following permission.

Dated 19 June 2026

Michael Shum
Acting Assistant Secretary
Regulatory Compliance Branch
Health Products Regulation Group
Department of Health, Disability and Ageing

Contents

1 Name.....	1
2 Commencement	1
3 Authority	1
4 Definitions	1
5 Permission.....	2

Schedule 1—Permission	3
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1 Name

This instrument is the *Therapeutic Goods (Restricted Representations—Medical Devices for Chronic Respiratory Diseases) Permission 2026*.

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.	

Note: This table relates only to the provisions of this instrument as originally made.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 subsection 3(1) of the Act, including the following:

- (a) advertise;
- (b) included in the Register;
- (c) indications;
- (d) medical device;
- (e) medicine;
- (f) Register;
- (g) therapeutic goods;
- (h) Therapeutic Goods Advertising Code.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

chronic respiratory disease means a non-communicable disease that affects the airways or other structures of the lungs.

Note: Examples of chronic respiratory diseases include asthma and chronic obstructive pulmonary disease (COPD).

companion software application means a software application that is a medical device other than an IVD medical device, and that:

- (a) is included in the Register; and
- (b) has an intended purpose, certified under section 41FD of the Act and accepted in relation to the inclusion of the device in the Register, that relates to the use of the device as an accessory to a delivery device or monitoring device.

delivery device means a medical device that:

- (a) is included in the Register; and
- (b) has an intended purpose, certified under section 41FD of the Act and accepted in relation to the inclusion of the device in the Register, that relates to the use of the device:
 - (i) to administer or deliver medicine for inhalation; or
 - (ii) as an accessory to, or in combination with, a medical device that is used to administer or deliver medicine for inhalation; or
 - (iii) to monitor, or enhance the effectiveness of, a person's use of medicine for inhalation.

instructions for use has the same meaning as in the MD Regulations.

MD Regulations means the *Therapeutic Goods (Medical Devices) Regulations 2002*.

monitoring device means a medical device that:

- (a) is included in the Register; and
- (b) has an intended purpose, certified under section 41FD of the Act and accepted in relation to the inclusion of the device in the Register, that relates to the use of the device to monitor lung health or measure lung function.

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

restricted representation means a representation referred to in section 42DD of the Act.

5 Permission

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

Schedule 1—Permission

Note: See section 5.

Permitted use of restricted representations			
Column 1	Column 2	Column 3	Column 4
Item	Representation	Therapeutic goods	Conditions
1	<p>a representation relating to the therapeutic goods that refers to a chronic respiratory disease, where the representation is:</p> <p>(a) to the effect that the goods may assist in the management of the disease; or</p> <p>(b) to the effect that the goods are intended for use by persons that are diagnosed with the disease; or</p> <p>(c) necessary to describe the function of the goods</p>	<p>one or more of the following:</p> <p>(a) a delivery device, where the medicine for inhalation has an indication that relates to the chronic respiratory disease;</p> <p>(b) a monitoring device</p>	<p>all of the following:</p> <p>(a) the advertisement must not be inconsistent with the intended purpose of the therapeutic goods or any conditions relating to the inclusion of the goods in the Register;</p> <p>(b) the representation must be accompanied by advisory statements, prominently displayed or communicated, to the effect that:</p> <p>(i) persons using the therapeutic goods as part of a management plan for their chronic respiratory disease should seek support from their medical practitioner or other health professional; and</p> <p>(ii) if the therapeutic goods are intended for use in a particular age range—the intended age range;</p> <p>(c) the representation must not be inconsistent with:</p> <p>(i) the instructions for use of the therapeutic goods; or</p> <p>(ii) any instructions on the packaging of the therapeutic goods; or</p> <p>(iii) any instructions on the therapeutic goods</p>

Permitted use of restricted representations			
Column 1	Column 2	Column 3	Column 4
Item	Representation	Therapeutic goods	Conditions
2	a representation relating to the therapeutic goods that refers to a chronic respiratory disease, where the representation is to the effect that the goods may assist in the administration or delivery of medicine for the management of the disease	a delivery device, where the medicine for inhalation has an indication relating to the chronic respiratory disease	all of the following: (a) the advertisement must not be inconsistent with the intended purpose of the therapeutic goods or any conditions relating to the inclusion of the goods in the Register; (b) the representation must be accompanied by advisory statements, prominently displayed or communicated, to the effect that: (i) persons using the therapeutic goods as part of a management plan for their chronic respiratory disease should seek support from their medical practitioner or other health professional; and (ii) if the therapeutic goods are intended for use in a particular age range—the intended age range
3	a representation relating to the therapeutic goods that refers to a chronic respiratory disease, where the representation is to the effect that the goods may assist in monitoring or self-monitoring (including at home) the disease	a monitoring device	all of the following: (a) the advertisement must not be inconsistent with the intended purpose of the therapeutic goods or any conditions relating to the inclusion of the goods in the Register; (b) the advertisement must not state or imply that the therapeutic goods may be used for self-diagnosis of a chronic respiratory disease; (c) the representation must be accompanied by advisory statements,

Permitted use of restricted representations			
Column 1	Column 2	Column 3	Column 4
Item	Representation	Therapeutic goods	Conditions
			<p>prominently displayed or communicated, to the effect that:</p> <p>(i) persons using the therapeutic goods as part of a management plan for their chronic respiratory disease should seek support from their medical practitioner or other health professional; and</p> <p>(ii) if the therapeutic goods are intended for use in a particular age range—the intended age range</p>
4	<p>a representation relating to the therapeutic goods that refers to a chronic respiratory disease, where the representation is to the effect that:</p> <p>(a) the goods may assist in the management of the disease; or</p> <p>(b) the goods are intended for use by persons that are diagnosed with the disease; or</p> <p>(c) the goods are to be used with a delivery device or a monitoring device</p>	a companion software application	<p>all of the following:</p> <p>(a) the advertisement must not be inconsistent with the intended purpose of the therapeutic goods or any conditions relating to the inclusion of the goods in the Register;</p> <p>(b) the advertisement must not state or imply that the therapeutic goods may be used for self-diagnosis of a chronic respiratory disease;</p> <p>(c) the representation must be accompanied by advisory statements, prominently displayed or communicated, to the effect that:</p> <p>(i) persons using the therapeutic goods as part of a management plan for their chronic respiratory disease should seek support from their medical practitioner or other</p>

Permitted use of restricted representations			
Column 1	Column 2	Column 3	Column 4
Item	Representation	Therapeutic goods	Conditions
			<p>health professional; and</p> <p>(ii) if the therapeutic goods are intended for use in a particular age range—the intended age range;</p> <p>(d) where the therapeutic goods use artificial intelligence to support their intended purpose—the advertisement must contain advisory statements, prominently displayed or communicated, to the effect that:</p> <p>(i) the goods use artificial intelligence (AI) technology to support their intended purpose; and</p> <p>(ii) if the goods use generative artificial intelligence to support their intended purpose—there can be limitations with information generated using artificial intelligence (AI)</p>