Therapeutic Goods (Restricted Representations—Sleep Apnoea Software) Permission 2025

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

Dated 4 June 2025

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

Contents

1 Name

This instrument is the *Therapeutic Goods (Restricted Representations—Sleep Apnoea Software) Permission 2025*.

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.	5 June 2025

Note: This table relates only to the provisions of this instrument as originally made.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) medical practitioner;
(d) Register;
(e) Therapeutic Goods Advertising Code.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

Class IIa medical device has the same meaning as in the MD Regulations.

intended purpose has the same meaning as in the MD Regulations.

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

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.

specified goods means a medical device that:

(a) is included in the Register; and

(b) is classified as a Class IIa medical device; and

(c) is a software-only mobile medical application, or a non-invasive medical device that incorporates software; and

(d) 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 identifying, and notifying users of the device of, patterns of breathing disturbances that are suggestive of sleep apnoea.

5 Permission

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

Schedule 1—Permission

Note: See section 5.

Column 1	Column 2	Column 3
Item	**Restricted representations**	**Conditions**
1	a representation to the effect that the specified goods may identify patterns of breathing disturbances that are suggestive of sleep apnoea	all of the following: (a) the advertisement must not: (i) be inconsistent with the intended purpose of the specified goods that is accepted in relation to the inclusion of the goods in the Register; and (ii) be inconsistent with any conditions relating to the inclusion of the specified goods in the Register; (b) the representation must be accompanied by advisory statements, which are prominently displayed or communicated, to the effect of the following: (i) the specified goods are not intended for use in the screening, diagnosis, treatment or management of sleep apnoea; (ii) if a pattern of breathing disturbances is identified by the specified goods, consult a medical practitioner; (iii) if the user has symptoms of sleep apnoea, or any other breathing disturbance, consult a medical practitioner; (iv) the absence of a notification does not exclude the presence sleep apnoea
2	a representation that comprises accurate, balanced and contemporary evidence-based information relating to sleep apnoea, including its prevalence in Australia	all of the following: (a) the advertisement must not: (i) be inconsistent with the intended purpose of the specified goods that is accepted in relation to the inclusion of the goods in the Register; and (ii) be inconsistent with any conditions relating to the inclusion of the specified goods in the Register; (b) the representation must be accompanied by advisory statements, which are prominently displayed or communicated, to the effect of the following: (i) the specified goods are not intended for use in the screening, diagnosis,

Column 1	Column 2	Column 3
Item	**Restricted representations**	**Conditions**
		treatment or management of sleep apnoea; (ii) if a pattern of breathing disturbances is identified by the specified goods, consult a medical practitioner; (iii) if the user has symptoms of sleep apnoea, or any other breathing conditions, consult a medical practitioner; (iv) the absence of a notification does not exclude the presence of sleep apnoea; (c) if the advertisement contains a representation relating to the prevalence of sleep apnoea—the representation must relate to the prevalence of sleep apnoea in Australia only