Therapeutic Goods (Restricted Representations—Melatonin) Permission 2021

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

Dated 27 May 2021

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

Contents

1 Name

This instrument is the *Therapeutic Goods (Restricted Representations—Melatonin) 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.	28 May 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Note: This table relates only to the provisions of this instrument as originally made.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 subsection 3(1) of the Act, including the following:

(a) advertise;
(b) indication;
(c) label;
(d) medicine;
(e) primary pack;
(f) Register;
(g) registered goods;
(h) therapeutic goods;
(i) Therapeutic Goods Advertising Code.

In this instrument:

Act means *Therapeutic Goods Act 1989*.

active ingredient has the same meaning as in the *Therapeutic Goods Regulations 1990*.

modified-release has the same meaning as in TGO 101.

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 that is referred to in section 42DD of the Act.

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

(a) is manufactured in the dosage form of a modified-release tablet; and
(b) contains melatonin as the only active ingredient; and
(c) has a stated content of 2mg or less of melatonin; and
(d) is in a primary pack that contains not more than 30 tablets; and
(e) has an indication accepted in relation to its inclusion that relates to the treatment of primary insomnia.

stated content has the same meaning as in TGO 101.

tablet has the same meaning as in TGO 101.

TGO 101 means the *Therapeutic Goods (Standard for Tablets, Capsules and Pills) (TGO 101) Order 2019.*

Note: TGO 101 is a legislative instrument published on the Federal Register of Legislation at www.legislation.gov.au.

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 representation**	**Advertisement**	**Therapeutic goods**	**Condition**
1	a representation to the effect that the therapeutic goods are for the short term treatment of primary insomnia, characterised by poor quality of sleep, in adults aged 55 years or over	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	an advertisement about the therapeutic goods that is not: (a) on the label of the therapeutic goods, or (b) on the package in which the therapeutic goods are contained; or (c) on any material included with the package in which the therapeutic goods are contained; must: (d) be accompanied by a statement, which is prominently displayed or communicated, to the effect that primary insomnia is insomnia without an underlying medical cause or any other clear cause; and (e) not promote the therapeutic goods as being compatible with, or able to be used concurrently with, other treatments for insomnia