Therapeutic Goods (Restricted Representations—Modified-Release Paracetamol) Permission 2020

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

Dated 31 January 2020

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

Contents

1 Name

This instrument is the *Therapeutic Goods (Restricted Representations—Modified-Release Paracetamol) 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	The day after this instrument is made.	1 February 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Note: This table relates only to the provisions of this instrument as originally made.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) label;
(c) medicine;
(d) Register; and
(e) Secretary.

In this instrument:

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

Note: The *Therapeutic Goods (Standard for Tablets, Capsules and Pills) (TGO 101) Order 2019* may be accessed on the internet at www.legislation.gov.au.

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.

stated content has the same meaning as in the Therapeutic Goods (Standard for Tablets, Capsules and Pills) (TGO 101) Order 2019.

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 that is to the effect that the therapeutic goods can provide temporary relief of persistent pain associated with osteoarthritis	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	a registered medicine, other than a prescription medicine, that: (a) is a modified-release capsule or tablet; and (b) has a stated content of 665 mg of paracetamol or less; and (c) contains paracetamol as the only active ingredient; and (d) has an indication accepted in relation to its inclusion that relates to the relief of pain associated with osteoarthritis	