Therapeutic Goods (Restricted Representations—COVID-19 Oral Treatments) Permission 2022

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

Dated 13 May 2022

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—COVID-19 Oral Treatments) Permission 2022*.

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.	14 May 2022

Note: This table relates only to the provisions of this instrument as originally made.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) current Poisons Standard;
(c) medicine;
(d) Register;
(e) registered goods;
(f) therapeutic goods;
(g) Therapeutic Goods Advertising Code.

In this instrument:

Act means *Therapeutic Goods Act 1989*.

Regulations means the *Therapeutic Goods Regulations 1990*.

relevant COVID-19 treatment means registered goods that are medicine, and that:

(a) contain a substance included in Schedule 4 to the current Poisons Standard; and
(b) have an indication accepted in relation to the inclusion of the goods in the Register that relates to the treatment of coronavirus disease (COVID-19); and
(c) are for oral administration.

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

trade name has the same meaning as in the Regulations.

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) To avoid doubt, a reference in an advertisement that is made in accordance with this instrument, relating to therapeutic goods containing a substance included in Schedule 4 to the current Poisons Standard, is by virtue of this instrument, authorised for the purposes of subsections 42DL(10) and 42DLB(7) of the Act.

Schedule 1—Permission: restricted representations

Note: See section 5.

Permitted use of restricted representations				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Restricted representations**	**Advertisements**	**Therapeutic goods**	**Conditions**
1	a representation that is to the effect that the therapeutic goods are available for supply on prescription from a particular pharmacy or other dispenser, for the treatment of COVID-19	an advertisement about the therapeutic goods, other than 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 relevant COVID-19 treatment	the advertisement must specify either or both of the following: (a) the trade name; (b) the International Non-proprietary Name (INN); of the therapeutic goods available at the particular pharmacy or other dispenser

Note: Advertisements mentioned in this table must comply with the Act and the Therapeutic Goods Advertising Code.