



Therapeutic Goods (Restricted Representations— COVID-19 Oral Treatments) Permission (No. 3) 2022

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

Dated 4 August 2022

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

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1 Name

This instrument is the *Therapeutic Goods (Restricted Representations—COVID-19 Oral Treatments) Permission (No. 3) 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.	5 August 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Note: This table relates only to the provisions of this instrument as originally made.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 oral treatment means registered goods that are medicine, and that:

- (a) contain a substance included in Schedule 4 to the current Poisons Standard; and

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- (b) have an indication accepted in relation to the inclusion of the goods in the Register that relates to the treatment of coronavirus disease 2019 (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.

6 Application

This instrument does not apply to an advertisement made in accordance with the *Therapeutic Goods (Restricted Representations—Government Health Campaigns) (COVID-19) Permission 2022*.

Note: The *Therapeutic Goods (Restricted Representations—Government Health Campaigns) (COVID-19) Permission 2022* deals with Commonwealth and State and Territory health campaigns related to COVID-19, and may be accessed at www.tga.gov.au.

7 Repeals

Each instrument that is specified in Schedule 2 is repealed as set out in the applicable items in that Schedule.

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 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 oral 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.

Schedule 2—Repeals

Note: See section 7.

Therapeutic Goods (Restricted Representations—COVID-19 Oral Treatments) Permission (No. 2) 2022

1 The whole of the instrument

Repeal the instrument.