

# **Therapeutic Goods (Restricted Representations— COVID-19 Testing Advice) Permission 2021**

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

Dated 20 September 2021

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

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### 1 Name

This instrument is the *Therapeutic Goods (Restricted Representations—COVID-19 Testing Advice) 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.

Column 1	Column 2	Column 3	
Provisions	Commencement	Date/Details	
1. The whole of this instrument	The day after this instrument is made.	21 September 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Note: This table relates only to the provisions of this instrument as originally made.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) current Poisons Standard;
  - (c) label;
  - (d) Register;
  - (e) therapeutic goods;
  - (f) Therapeutic Goods Advertising Code.

In this instrument:

Act means Therapeutic Goods Act 1989.

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

*specified goods* means therapeutic goods that are included in the Register, other than goods containing a substance included in Schedule 3, 4 or 8 to the current Poisons Standard (but not a substance that is specified in Appendix H of the current Poisons Standard).

## 5 Permission—restricted representations

- (1) 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 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) The permission given in subsection (1) applies for the period starting on the commencement of this instrument and ending on 31 December 2022.

# Schedule 1—Permission: restricted representations

Note: See section 5.

Column 1	Column 2	Column 3	Column 4	Column 5
Item	Restricted representations	Advertisements	Therapeutic goods	Conditions
1	a representation to the effect that if you have symptoms relating to COVID-19, seek health advice about getting tested	<ul> <li>an advertisement about the therapeutic goods including, but not limited to, an advertisement that is:</li> <li>(a) on the label of the therapeutic goods; or</li> <li>(b) on the package in which the therapeutic goods are contained; or</li> </ul>	specified goods	
		<ul><li>(c) on any material included with the package in which the therapeutic goods are contained</li></ul>		
2 a representation to the effect that if you have symptoms relating to COVID-19 such as [ <i>inse</i> <i>symptoms</i> ], seek health advice about getting tested	effect that if you have symptoms relating to COVID-19 such as [ <i>insert</i> <i>symptoms</i> ], seek health advice about getting	<ul> <li>an advertisement about the therapeutic goods including, but not limited to, an advertisement that is:</li> <li>(a) on the label of the therapeutic goods; or</li> <li>(b) on the package in which the therapeutic goods are contained; or</li> </ul>	specified goods	
		<ul> <li>(c) on any material included with the package in which the therapeutic goods are contained</li> </ul>		

Note 1: Symptoms of COVID-19 may include fever, respiratory symptoms (such as coughing, sore throat or shortness of breath), runny nose, congestion, headache, muscle or joint pains, nausea, diarrhoea, vomiting, loss of sense of smell, altered sense of taste, loss of appetite and fatigue.

Note 2: Advertisements for therapeutic goods that are directed to the public must comply with the Therapeutic Goods Advertising Code, including the requirement that advertisements must not be inconsistent with a public health campaign. The use of a permitted restricted representation mentioned in item 1 or 2 of the table in an advertisement that otherwise conflicts with the public health messaging about SARS-CoV-2 or COVID-19 (e.g. staying home when unwell) would be unlikely to comply with this requirement.