Therapeutic Goods (Restricted Representations—COVID-19 Rapid Antigen Tests) Permission (No. 2) 2021

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

Dated 31 August 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—COVID-19 Rapid Antigen Tests) Permission (No. 2) 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.	1 December 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Note: This table relates only to the provisions of this instrument as originally made.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 to 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) health practitioner;
(c) included in the Register;
(d) label;
(e) Register;
(f) therapeutic goods;
(g) Therapeutic Goods Advertising Code.

In this instrument:

Act means *Therapeutic Goods Act 1989*.

Class 1 IVD medical device has the same meaning as in the Medical Devices Regulations.

Class 3 IVD medical device has the same meaning as in the Medical Devices Regulations.

infection with COVID-19 means infection with the virus SARS-CoV-2 that causes coronavirus disease (COVID-19).

IVD medical device has the same meaning as in the Medical Devices Regulations.

Medical Devices Regulations means the *Therapeutic Goods (Medical Devices) Regulations 2002.*

point of care testing has the same meaning as in the Medical Devices Regulations.

prominently displayed or communicated has the same meaning as in section 4 of the Therapeutic Goods Advertising Code.

relevant practitioner means:

(a) a health practitioner; or

(b) a person registered under a law of a state or territory to practice paramedicine.

Note: The term ***health practitioner*** is defined for subsection 3(1) of the Act to mean a person who is registered or licenced under a law of a state or territory to practice in certain health professions specified in the definition, including medicine.

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

specified goods means a COVID-19 rapid antigen test kit that is:

(a) included in the Register; and

(b) classified as a Class 3 IVD medical device; and

(c) intended for point of care testing by a relevant practitioner; and

may (or may not) be supplied for use in conjunction with an instrument or analyser that is a Class 1 IVD medical device.

5 Permission

For subsection 42DK(1) of the Act, in relation to each item mentioned in the table in Schedule 1, the representations specified in column 2 are permitted to be used in advertisements specified in column 3, about the therapeutic goods specified in column 4, subject to the conditions (if any) specified in column 5.

6 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 representation

Note: See section 5.

Permitted use of restricted representation

Column 1 Item	Column 2 Restricted representation	Column 3 Advertisement	Column 4 Therapeutic goods	Column 5 Conditions
1	a representation to the effect that the therapeutic goods may be used to detect possible infection with COVID-19	an advertisement about the therapeutic goods, other than an advertisement that is: (a) on the label of the therapeutic goods; or (b) on the package in which the therapeutic goods ar… conta…ed; or (c) on a… mater… …cluded …th th… …ckage whic… …e therape… …c goods … …ied	specified goods	all of the following (a) the advertisem… …t must be consistent with … …ernment healt… …ging … …lation to … …sting fo… …fection … …VID-1… (b) th… …d… …tisemen… …ust co… …statemen…, which …re pro… …y displayed …communicated, to the ef… …of the following: (i) the therapeutic goods must not be supplied for the purpose of self-testing; and (ii) the therapeutic goods must only be used by relevant practitioners, or persons under their supervision, who are trained in the correct use of the goods and the interpretation of the test results; and (iii) negative test results do not exclude infection with COVID-19 (so face masks, social distancing and good hygiene practice must be maintained); and (iv) positive test results or symptomatic persons require immediate confirmatory testing with a polymerase chain reaction (***PCR***) test; (c) the advertisement must **not**: (i) include a claim that the therapeutic goods are diagnostic; or

Permitted use of restricted representation				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Restricted representation**	**Advertisement**	**Therapeutic goods**	**Conditions**
				(ii) state or infer that PCR (or other laboratory) testing is not needed; or (iii) state that the therapeutic goods are capable of early detection; or (iv) include claims relating to the accuracy, specificity, sensitivity or limit of detection of the therapeutic goods; or (v) include comparisons with other therapeutic goods; or (vi) infer that the therapeutic goods are capable of determining whether or not a person is infectious, or the degree of their infectiousness; or (vii) include endorsements or testimonials Note: The advertisement may (but is not required to) include statements relating to one or more of the following: (a) sample (or specimen) type; (b) testing time; (c) cost

Note: The advertisements mentioned in the table must comply with the Act and the Therapeutic Goods Advertising Code, including requirements relating to the accuracy of the advertisements.

Schedule 2—Repeals

Note: See section 6.

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1 The whole of the instrument

Repeal the instrument.