Therapeutic Goods (Restricted Representations—COVID-19 Rapid Antigen Tests) Permission (No. 3) 2021

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

Dated 13 October 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. 3) 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.	5 October 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Note: This table relates only to the provisions of this instrument as originally made.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.

instructions for use has the same meaning as in the Medical Devices Regulations.

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

IVD medical device for self-testing 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 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 in 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.

SARS-CoV-2 (COVID-19) means the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) that causes the disease COVID-19.

serious form, in relation to a disease, condition or ailment, has the same meaning as in the Therapeutic Goods Advertising Code.

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

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

Note: The specified goods may be an IVD medical device for self-testing, or an IVD medical device for point of care testing by a relevant practitioner, or both.

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 the 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	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Restricted representation**	**Advertisement**	**Therapeutic goods**	**Conditions**
1	a representation to the effect, expressly or by implication, that the therapeutic goods may be used to detect possible infection with SARS-CoV-2 (COVID-19), including a representation that is contained within the name of the goods	an advertisement about the therapeutic goods including, but not limited to, an advertisement that is: (a) on the label of the therapeutic goods; or (b) on the package in which the therapeutic goods are contained; or (c) on any material included with the package in which the therapeutic goods are contained, including instructions for use	specified goods	all of the following (a) the advertisement must be consistent with government health messaging regulation to testing for infection SARS-CoV-2 (COVID-19); (b) the advertisement must not be inconsistent with the intended use of the therapeutic goods accepted in relation to the inclusion of the goods in the Register, and any conditions of inclusion relating to the goods; (c) the advertisement must contain statements, which are prominently displayed or communicated, to the effect of the following: (i) if the therapeutic goods are included in the Register for self-testing—the goods may be supplied for self-testing in the home or other environment; and (ii) if the therapeutic goods are included in the Register for point of care testing only—the therapeutic goods must 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 SARS-CoV-2 (COVID-19); and

Permitted use of restricted representation				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Restricted representation**	**Advertisement**	**Therapeutic goods**	**Conditions**
				(iv) positive test results or symptomatic persons require immediate confirmatory testing with a polymerase chain reaction (***PCR***) test; (d) the advertisement must **not**: (i) include a claim that therapeutic goods are diagnostic; or (ii) state or infer that PCR (or another 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 (except where such claims are included solely in instructions for use relating to the 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;

Permitted use of restricted representation				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Restricted representation**	**Advertisement**	**Therapeutic goods**	**Conditions**
				(b) testing time; (c) cost
2	a representation that refers, expressly or by implication, to a serious form of disease, condition or ailment, where the reference is necessary to provide information about the proper use of the therapeutic goods	an advertisement made in accordance with item 1 that includes instructions for use relating to the therapeutic goods (including but not limited to instructions in written, graphical, pictorial or video form)	specified goods	

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 advertisement.

Schedule 2—Repeals

Note: See section 6.

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

1 The whole of the instrument

Repeal the instrument.