Therapeutic Goods (Restricted and Prohibited Representations—IVD Medical Devices) Permission (No. 2) 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

Contents

1 Name

This instrument is the *Therapeutic Goods (Restricted and Prohibited Representations—IVD Medical Devices) Permission (No. 2) 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Note: This table relates only to the provisions of this instrument as originally made.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) health practitioner;
(c) included in the Register;
(d) label;
(e) therapeutic goods;
(f) 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 2 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.

Class 4 IVD medical device has the same meaning as in the Medical Devices Regulations.

COVID-19 rapid antigen test kit 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.

IVD medical device, or in vitro diagnostic 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.

prohibited representation means a representation referred to in subsection 42DJ(1) of the Act.

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

Regulations means the *Therapeutic Goods Regulations 1990.*

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

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

specified goods means an IVD medical device, other than a COVID-19 rapid antigen test kit, that is:

(a) included in the Register; and

(b) classified under the Medical Devices Regulations as a Class 1 IVD medical device, Class 2 IVD medical device, Class 3 IVD medical device or Class 4 IVD medical device; and

(c) either:

(i) intended, by the person under whose name the goods are or are to be supplied, to be used in a medical testing laboratory by a trained laboratory professional; or

(ii) intended to be used in point of care testing by a health practitioner.

5 Permission

(1) 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 (to the extent that those representations are restricted representations) 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) For subsections 42DK(2) and (3) of the Act, in relation to each item mentioned in the table in Schedule 1, the representations specified in column 2 (to the extent that those representations are prohibited representations) 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 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 or territory health campaigns relating to COVID-19, and is published 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

Note: See section 5.

Permitted use of restricted and prohibited representations				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Representations**	**Advertisements**	**Therapeutic goods**	**Conditions**
1	a representation relating to the therapeutic goods that is necessary to describe the function of the goods and that refers, expressly or by implication, to: (a) a serious form of a disease, condition or ailment; or (b) a disease or virus mentioned in Item 10 of Part 1 of Schedule 2 to the Regulations	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	specified goods	an advertisement about the therapeutic goods that is not: (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; must be accompanied by a statement, which is prominently displayed or communicated, to the effect that the therapeutic goods cannot be purchased by the general public

Schedule 2—Repeals

Note: See section 7.

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1 The whole of the instrument

Repeal the instrument.