Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission 2022

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

Dated 14 December 2022

Adjunct Professor John Skerritt
Deputy Secretary
Health Products Regulation Group
Department of Health and Aged Care

Contents

1 Name

This instrument is the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission 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	20 December 2022.	20 December 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Note: This table relates only to the provisions of this instrument as originally made.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) health practitioner;
(d) manufacture;
(e) Register;
(f) registered goods;
(g) sponsor;
(h) supply;
(i) therapeutic goods.

In this instrument:

Act means *Therapeutic Goods Act 1989*.

active ingredient has the same meaning as in the Regulations.

approved COVID-19 vaccination provider means a provider who is:

(a) a recognised vaccination provider within the meaning of the *Australian Immunisation Register Act 2015*; and

(b) approved or authorised under relevant state or territory legislation to administer relevant COVID-19 vaccines; and

(c) approved by the Department to participate in the National COVID-19 Vaccination Program.

Regulations means the *Therapeutic Goods Regulations 1990.*

relevant COVID-19 vaccines means registered goods containing a substance included in Schedule 4 to the current Poisons Standard for which an indication has been accepted in relation to the inclusion of the goods in the Register that relates to active immunisation for the prevention of the coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2.

Note: The expression ***registered goods*** is defined in section 3 of the Act to mean:

(a) therapeutic goods included in the part of the Register for goods known as registered goods; or

(b) therapeutic goods included in the part of the Register for goods known as provisionally registered goods.

relevant person means each of the following:

(a) the sponsor of the relevant COVID-19 vaccine;

(b) the manufacturer of the relevant COVID-19 vaccine.

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

Therapeutic Goods Administration has the same meaning as in the Regulations.

trade name has the same meaning as in the Regulations.

valuable consideration means any consideration of value but does not include tobacco or medicines (other than listed medicines).

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, an advertisement made in accordance with this instrument that references, expressly or by implication, that the therapeutic goods to which this instrument relates have been recommended or approved by the Therapeutic Goods Administration (within the Australian Government Department of Health and Aged Care), the Australian Government Department of Health and Aged Care or the Commonwealth Government is, by virtue of this instrument, also authorised for the purposes of subsections 42DL(9) and 42DLB(6) of the Act.

(3) 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) Permission 2019.*

Note 1: The *Therapeutic Goods (Restricted Representations—Government Health Campaigns) Permission 2019* deals with Commonwealth and state or territory health campaigns relating to vaccines.

Note 2: The *Therapeutic Goods (Restricted Representations—Government Health Campaigns) Permission 2019* 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: restricted representations

Note: See section 5.

Permitted use of restricted representations				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Restricted representation**	**Advertisement**	**Therapeutic goods**	**Conditions**
1	a representation relating to the therapeutic goods that promotes the use or supply of those goods	an advertisement about the therapeutic goods, other than: (a) an advertisement that is made by a relevant person; or (b) an advertisement that is: (i) on the label of the therapeutic goods; or (ii) on the package in which the therapeutic goods are contained; or (iii) on any material included with the package in which the therapeutic goods are contained	relevant COVID-19 vaccines	the advertisement must: (a) be consistent with Commonwealth health messaging in relation to the National COVID-19 Vaccination Program; and (b) not contain any reference to: (i) the name of the sponsor or the manufacturer of the therapeutic goods; or (ii) trade names, or active ingredients, of the therapeutic goods; unless the advertisement is made by an approved COVID-19 vaccination provider; and (c) not contain any statement comparing the therapeutic goods; and (d) not contain any statement to the effect that the therapeutic goods cannot cause harm or have no side effects; and (e) not contain any statement regarding the therapeutic goods that is false or misleading

Permitted use of restricted representations				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Restricted representation**	**Advertisement**	**Therapeutic goods**	**Conditions**
2	a representation to the effect that valuable consideration may be provided to a person who has been fully or partly vaccinated with the therapeutic goods in accordance with the National COVID-19 Vaccination Program	an advertisement about the therapeutic goods made in accordance with item 1	relevant COVID-19 vaccines	the advertisement must: (a) contain a statement to the effect that the vaccination must be undertaken on the advice of a health practitioner; and (b) not promote specific therapeutic goods within the class of therapeutic goods; and (c) not contain an offer of alcohol that: (i) encourages excessive or rapid consumption of alcohol; or (ii) has a strong or evident appeal to minors Note: The supply or service of alcohol must comply with Responsible Service of Alcohol requirements.
3	a representation relating to the therapeutic goods that promotes the use or supply of those goods	an advertisement made by a relevant person 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 are contained; or (c) on any material included with the package in which the therapeutic	relevant COVID-19 vaccines	all of the following: (a) the advertisement must: (i) be consistent with Commonwealth health messaging in relation to the National COVID-19 Vaccination Program; and (ii) not contain any statement comparing the therapeutic goods; and (iii) not contain any statement to the effect that the therapeutic goods

Permitted use of restricted representations				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Restricted representation**	**Advertisement**	**Therapeutic goods**	**Conditions**
		goods are contained		cannot cause harm or have no side effects; and (iv) not contain any statement regarding the therapeutic goods that is false or misleading (b) the advertisement must not contain any reference to: (i) the name of the sponsor or the manufacturer of the therapeutic goods, except where the name is used in a copyright notice; or (ii) trade names, or active ingredients, of the therapeutic goods; and (c) where the advertisement contains the name of the sponsor or the manufacturer in a copyright notice—the notice must not appear conspicuously in the advertisement Note: A copyright notice may be in the form '© company name 2022'

Schedule 2—Repeals

Note: See section 7.

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1 The whole of the instrument

Repeal the instrument.