



Therapeutic Goods (Restricted Representations— COVID-19 Vaccines) Permission 2021

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

Dated 4 June 2021

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

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Repealed

1 Name

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

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 June 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Note: This table relates only to the provisions of this instrument as originally made.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) health practitioner;
- (d) Register;
- (e) registered goods;
- (f) supply;
- (g) therapeutic goods;
- (h) Therapeutic Goods Advertising Code.

In this instrument:

Act means *Therapeutic Goods Act 1989*.

active ingredients has the same meaning as in the Regulations.

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 the 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.

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

trade name has the same meaning as in the Regulations.

valuable consideration means any consideration of value but does not include alcohol, 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.

Note: To avoid doubt, an advertisement made in accordance with this instrument that states, 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), the Australian Government Department of Health or the Commonwealth Government is, by virtue of this instrument, also authorised for the purposes of subsections 42DL(9), 42DL(10), 42DLB(6) and 42DLB(7) of the Act.

- (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.

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 an advertisement that is: <ul style="list-style-type: none"> (a) on the label of the therapeutic goods; (b) on the package in which the therapeutic goods are contained; (c) on any material included with the package in which the therapeutic goods are contained 	relevant COVID-19 vaccines	the advertisement must: <ul style="list-style-type: none"> (a) be consistent with Commonwealth health messaging in relation to the national vaccination program for COVID-19; and (b) not contain any reference to trade names, or active ingredients, of the therapeutic goods; 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
2	a representation to the effect that valuable consideration may be provided to a person who has been fully vaccinated with the therapeutic goods in accordance with the national vaccination program for COVID-	an advertisement about the therapeutic goods mentioned in item 1 that contains the representation specified in column 2 of this item	relevant COVID-19 vaccines	the advertisement must: <ul style="list-style-type: none"> (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

Permitted use of restricted representations

Column 1	Column 2	Column 3	Column 4	Column 5
Item	Restricted representation	Advertisement	Therapeutic goods	Conditions
	19, where the offer of valuable consideration is not conditional on vaccination occurring after that offer is made			

Repealed