



Therapeutic Goods (Restricted Representations— Influenza Vaccines) Permission 2022

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

Dated 11 May 2022

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

Contents

1 Name.....	1
2 Commencement	1
3 Authority	1
4 Definitions	1
5 Permission.....	2
6 Application	2
Schedule 1—Permission: restricted representations	3

1 Name

This instrument is the *Therapeutic Goods (Restricted Representations—Influenza 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	The day after this instrument is made.	12 May 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Note: This table relates only to the provisions of this instrument as originally made.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) Register;
- (e) registered goods;
- (f) supply;
- (g) Therapeutic Goods Advertising Code;
- (h) therapeutic goods.

In this instrument:

Act means *Therapeutic Goods Act 1989*.

approved influenza 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 influenza vaccines.

Regulations means the *Therapeutic Goods Regulations 1990*.

relevant business means a business that has established a workplace vaccination program in partnership with an approved influenza vaccination provider.

relevant influenza 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 influenza disease.

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

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, 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 also 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

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 representations	Advertisements	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 made by: <ul style="list-style-type: none"> (a) an approved influenza vaccination provider; or (b) a health practitioner; or (c) a relevant business 	relevant influenza vaccines	the advertisement must not: <ul style="list-style-type: none"> (a) be inconsistent with Commonwealth, State or Territory health messaging in relation to influenza vaccines; or (b) contain any reference to trade names of the therapeutic goods; or (c) contain any statement to the effect that the therapeutic goods are safe, cannot cause harm or have no side effects; or (d) contain any statement regarding the therapeutic goods that is false or misleading

Note: Advertisements mentioned in this table must comply with the Act and the Therapeutic Goods Advertising Code.