



Therapeutic Goods (Restricted Representations— HHD Group Pty Limited) (AZ) Permission 2021

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

Dated 23 August 2021

Nicole McLay
Assistant Secretary
Health Products Regulation Group
Department of Health

Contents

1 Name.....	1
2 Commencement	1
3 Authority	1
4 Definitions	1
5 Permission.....	2

Schedule 1—Permission: restricted representations	3
--	----------

1 Name

This instrument is the *Therapeutic Goods (Restricted Representations—HHD Group Pty Limited) (AZ) 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.	24 August 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Note: This table relates only to the provisions of this instrument as originally made.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) Register;
- (d) registered goods;
- (e) registration number;
- (f) supply;
- (g) therapeutic goods.

In this instrument:

ABC Pronunciation Guide means the Pronunciation Guide published by the Australian Broadcasting Corporation, as in force or existing at the commencement of this instrument.

Note: The ABC Pronunciation Guide is available at www.pronounce.abc.net.au.

Act means *Therapeutic Goods Act 1989*.

COVID-19 means coronavirus disease (COVID-19) caused by SARS-CoV-2.

HHD Group Pty Limited means the Australian registered company, HHD Group Pty Limited (ACN 119920204).

other COVID-19 vaccines means registered goods 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 COVID-19, but does not include the specified goods.

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

specified goods means the registered goods with the trade name VAXZEVRIA, registration number 349072, that contain 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 COVID-19.

Note 1: The specified goods were previously known as COVID-19 Vaccine AstraZeneca.

Note 2: The specified goods are commonly known as AZ.

Therapeutic Goods Administration means the part of the Australian Government Department of the Health known as the Therapeutic Goods Administration.

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, the Australian Government Department of Health or the Commonwealth Government is, by virtue of this instrument, authorised for the purposes of subsections 42DL(9) and 42DLB(6) of the Act.
- (3) To avoid doubt, an advertisement made in accordance with this instrument is authorised for the purposes of subsections 42DL(10) and 42DLB(7) of the Act.
- (4) The permission given in subsection (1) applies for the period starting on the commencement of this instrument and ending on 31 December 2021.

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, expressly or by implication, the use or supply of those goods for COVID-19	an advertisement made by HHD Group Pty Limited about the therapeutic goods, other than an advertisement that is: <ul style="list-style-type: none"> (a) on the label of the goods; (b) on the package in which the goods are contained; (c) on any material included with the package in which the goods are contained 	specified goods	all of the following: <ul style="list-style-type: none"> (a) the advertisement must: <ul style="list-style-type: none"> (i) be consistent with the indication accepted in relation to the inclusion of the therapeutic goods in the Register; and (ii) be consistent with Commonwealth health messaging in relation to the national vaccination program for COVID-19; and (iii) not contain any comparisons with other COVID-19 vaccines; and (iv) not contain any statement to the effect that the therapeutic goods cannot cause harm or have no side effects; and (v) not contain any statement or fact that is inaccurate, false or misleading; and (vi) where the advertisement includes audio content—comply with the ABC Pronunciation Guide, including for the letter ‘z’; and (vii) with the exception of television and radio advertisements—include written content identifying the source of each claim relating

Permitted use of restricted representations

Column 1	Column 2	Column 3	Column 4	Column 5
Item	Restricted representation	Advertisement	Therapeutic goods	Conditions
				to adverse events or mortality rates; and (b) prior to the advertisement being published or broadcast, HHD Group Pty Limited must: (i) provide the source of each claim relating to adverse events or mortality rates to the Therapeutic Goods Administration for review; and (ii) obtain written agreement from the Therapeutic Goods Administration for the use of each claim in the advertisement Note: The therapeutic goods may be identified in an advertisement with reference to their registered trade name or common name (including the abbreviation, AZ).
