



## **Therapeutic Goods (Restricted and Prohibited Representations—Nicotine) Permission (No. 2) 2021**

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

Dated 17 August 2021

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

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## 1 Name

This instrument is the *Therapeutic Goods (Restricted and Prohibited Representations—Nicotine) Permission (No. 2) 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.	18 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Note: This table relates only to the provisions of this instrument as originally made.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) included in the Register;
- (d) medical device;
- (e) Register;
- (f) supply;
- (g) therapeutic goods;
- (h) Therapeutic Goods Advertising Code.

In this instrument:

*Act* means *Therapeutic Goods Act 1989*.

*established nicotine replacement therapy* means a therapeutic good that is included in the Register, other than a nicotine vaping product, that:

- (a) contains nicotine as the only active ingredient; and
- (b) has an indication accepted in relation to its inclusion that relates to assisting with smoking cessation.

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***nicotine vaping product*** has the same meaning as in TGO 110 and includes both a product that is, and a product that is not, included in the Register.

Note 1: ***Nicotine vaping product*** is defined in section 4 of TGO 110 to mean a medicine that contains nicotine in solution and that is:

- (a) a finished product; and
- (b) intended to be vaporised and administered by inhalation using a vaping device.

Note 2: Nicotine vaping products may also be described as nicotine vape liquids, or nicotine e-liquids.

Note 3: Examples of vaping devices include e-cigarettes, e-cigars, e-hookah pens, e-pens, e-pipes and vape pens.

Note 4: A nicotine vaping product that is not included in the Register has not been evaluated by the Secretary under section 25 of the Act for quality, safety and efficacy.

***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.

***relevant person*** means a community pharmacy or a pharmacy marketing group.

Note: A reference to a community pharmacy includes a reference to an online pharmacy.

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

***TGO 110*** means the *Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021*.

Note: TGO 110 is a legislative instrument published on the Federal Register of Legislation at [www.legislation.gov.au](http://www.legislation.gov.au).

***trade name*** has the same meaning as in the *Therapeutic Goods Regulations 1990*.

## 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 subsection 42DK(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.
- (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 3, 4 or 8 to the current Poisons Standard or therapeutic goods that are not included in the Register, is by virtue of this instrument also authorised by the

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Australian Government Department of Health for the purposes of subsections 42DL(10) and (12), and 42DLB(7) and (9), of the Act.

## **6 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	Representation	Advertisement	Therapeutic goods	Conditions
1	<p>a representation that is:</p> <p>(a) <i>[insert name of community pharmacy or community pharmacy brand]</i> can dispense nicotine prescriptions; or</p> <p>(b) prescription nicotine is available <i>[(here) or (at) (insert name of community pharmacy or community pharmacy brand)]</i>; or</p> <p>(c) nicotine prescribed for smoking cessation can be dispensed at <i>[insert name of community pharmacy or community pharmacy brand]</i>; but may be modified in accordance with one or more of the following:</p> <p>(d) the name of the community pharmacy mentioned in paragraph (a), (b) or (c) may include the location of that pharmacy;</p>	<p>an advertisement about the therapeutic goods made by the relevant person mentioned in column 2, through one or more of the following media under the direct control of that person:</p> <p>(a) a single tile on a website that is:</p> <p>(i) text only; and</p> <p>(ii) published using no more than three colours or shades in total;</p> <p>(b) a post on social media that is:</p> <p>(i) text only; and</p> <p>(ii) published using no more than three colours or shades in total;</p> <p>(c) a poster displayed inside, or immediately outside, the premises of a</p>	<p>a nicotine vaping product, and any associated vaping device that is a medical device used exclusively for the vaporisation and administration by inhalation of the nicotine vaping product</p>	<p>the advertisement must not:</p> <p>(a) be transmitted by radio or television, including pay and streaming services; or</p> <p>(b) be promoted:</p> <p>(i) by social media influencers or brand ambassadors; or</p> <p>(ii) through social media platforms using paid promotion; or</p> <p>(iii) on billboards; or</p> <p>(iv) in cinema advertising; or</p> <p>(c) contain pictures or images of the therapeutic goods; or</p> <p>(d) contain trade names, trademarks or logos relating to the therapeutic goods; or</p> <p>(e) contain references to flavours</p>

<b>Permitted use of restricted and prohibited representations</b>				
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>	<b>Column 5</b>
<b>Item</b>	<b>Representation</b>	<b>Advertisement</b>	<b>Therapeutic goods</b>	<b>Conditions</b>
	(e) the name of the community pharmacy brand mentioned in paragraph (a), (b) or (c) may be substituted with a reference to [ <i>select pharmacies</i> ] with or without a reference to the name of the community pharmacy brand;	community pharmacy that: (i) does not exceed 594 mm by 420 mm (A2 size); and (ii) is text only; and (iii) is published using no more than three		
	(f) the reference to the word nicotine in paragraph (a), (b) or (c) may be substituted with one or more of the following: (i) liquid nicotine; (ii) nicotine pods; (iii) nicotine e-cigarettes	(d) a single tile in other print media, including a catalogue that: (i) does not exceed 50 mm by 50 mm; and (ii) is text only; and (iii) is published using no more than three colours or shades in total;		
2	a representation to the effect that the therapeutic goods assist with smoking cessation	an advertisement about the therapeutic goods	an established nicotine replacement therapy	

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Note 1: The evidence relating to nicotine vaping products assisting with smoking cessation is mixed.

Note 2: The advertisements mentioned in items 1 and 2 of the table in Schedule 1 must comply with the Act and the Therapeutic Goods Advertising Code, including requirements relating to the accuracy of the advertisements and the use of mandatory warning statements.



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## **Schedule 2—Repeals**

Note: See section 6.

### ***Therapeutic Goods (Restricted and Prohibited Representations— Nicotine) Permission 2021***

#### **1 The whole of the instrument**

Repeal the instrument.