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

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

Dated 23 June 2021

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

Contents

1 Name

This instrument is the *Therapeutic Goods (Restricted and Prohibited Representations—Nicotine) 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.	2 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Note: This table relates only to the provisions of this instrument as originally made.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 section 3 of the Act, including the following:

(a) advertise;
(b) current Poisons Standard;
(c) health practitioner;
(d) medical device;
(e) Register;
(f) supply;
(g) therapeutic goods;
(h) Therapeutic Goods Advertising Code.

In this instrument:

Act means the *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.

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, hookah pens, e-pens, e pipes and vape pens.

prohibited representation means a representation referred to in subsection 42DJ(1) of the Act.

relevant person means a retail pharmacy or a pharmacy marketing group.

Note: A reference to a retail 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.

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

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	a representation to the effect that the therapeutic goods are available for supply from a relevant person on prescription from a health practitioner to assist with smoking cessation, and may include information about the dosage form of the goods	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: (a) a website; (b) social media; (c) a p…er in, … ir…ediate p…imi…o, the …ises of the re… …on; (d) oth… …rint me… in…ding a catalogue	a nicotine vaping product, and any associated vaping device that … a medica… devi…sed exclusi… for the vaporis…n and …dmi…ration by inh… …n of the …cotin… v…ing pro…uct	the advert…ement mus… not: (a) be trans…ted by … or te… …ion inc…ing pay and …eaming services; or be pro…oted: (i) by social media influencers or brand ambassadors; or (ii) through social media platforms using paid promotion; or (iii) on billboards; or (iv) in cinema advertising; or (c) contain pictures of the therapeutic goods; or (d) contain trade names; or (e) contain references to flavours
2	a repres…tion to the effect that the …utic goods assist with smoking cessation	an advertisement about the therapeutic goods	an established nicotine replacement therapy	

Note: 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.