



Therapeutic Goods (Vaping Goods— Advertising) Authorisation 2024

I, Nicholas Henderson, as delegate of the Secretary of the Department of Health and Aged Care, make the following authorisation.

Dated 30 June 2024

Nicholas Henderson
Acting Deputy Secretary
Health Products Regulation Group
Department of Health and Aged Care

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1 Name

This instrument is the *Therapeutic Goods (Vaping Goods—Advertising) Authorisation 2024*.

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	At the same time as Parts 1 to 3 of Schedule 1 to the <i>Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024</i> commence. However, this instrument does not commence at all if the <i>Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024</i> does not commence.	

Note: This table relates only to the provisions of this instrument as originally made.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 42DZC 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) essential principles;
- (c) indications;
- (d) label;
- (e) medical practitioner;
- (f) nurse practitioner;
- (g) pharmacist;
- (h) sponsor;
- (i) State;
- (j) therapeutic goods;
- (k) Therapeutic Goods Advertising Code;
- (l) vaping goods;

-
- (l) vaping substance.

In this instrument:

Act means the *Therapeutic Goods Act*.

intended purpose has the same meaning as in the MD Regulations.

Commonwealth health campaign means a campaign about a public health matter that is conducted, approved or funded by the Commonwealth.

medicinal cannabis product has the same meaning as in the Regulations.

medicinal cannabis vaping goods means one or more of the following:

- (a) a therapeutic cannabis vaping good;
- (b) a vaping substance that is a medicinal cannabis product or a medicine that contains synthetic cannabis.

MD Regulations means the *Therapeutic Goods (Medical Devices) Regulations 2002*.

MDSO means the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023*.

Note: The MDSO is a legislative instrument published on the Federal Register of Legislation at www.legislation.gov.au.

notification ID number means the number given to the sponsor by the TGA in relation to a sponsor notice.

notified vaping goods means one or more vaping goods that are:

- (a) exempt under:
 - (i) item 15 in the table in Schedule 5A to the TG Regulations, in relation to which the sponsor has given a sponsor notice; or
 - (ii) item 2.17 in the table of Part 2 in Schedule 4 to the MD Regulations, in relation to which the sponsor has given a sponsor notice; and
- (b) not the subject of a determination by the Secretary, published on the Department's website, that the supply of the goods be stopped or should cease because the Secretary is satisfied that the supply of the goods compromises public health and safety or the goods do not comply with a standard applicable to the goods.

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

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

sponsor notice means a notice given to the Secretary in compliance with:

- (a) item 15 in the table in Schedule 5A to TG Regulations; or
- (b) item 2.17 in the table in Part 2 of Schedule 4 to the MD Regulations.

State health campaign means a campaign about a public health matter that is conducted, approved, or funded by a State.

Note: State is defined in subsection 3(1) of the Act as including the Australian Capital Territory and the Northern Territory.

TGO 93 means the *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017*.

Note: TGO93 is a legislative instrument published on the Federal Register of Legislation at www.legislation.gov.au.

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

Note: TGO 110 is a legislative instrument published on the Federal Register of Legislation at www.legislation.gov.au.

therapeutic cannabis vaping good has the same meaning as in the MD Regulations.

Therapeutic Goods Administration, or **TGA** has the same meaning as in the TG Regulations.

TG Regulations means the *Therapeutic Goods Regulations 1990*.

5 Authorisation

For section 42DZC of the Act, in relation to each item in the tables in Parts 1 and 2 of Schedule 1, the advertising, or class of advertising, specified in column 2, of the vaping goods specified in column 3, is authorised, subject to the conditions (if any) specified in column 4.

Schedule 1—Authorisation

Note: See section 5.

Part 1—Notified vaping goods

Authorised advertising			
Column 1	Column 2	Column 3	Column 4
Item	Advertising	Vaping goods	Conditions
1	advertising that is: (a) on the label of the vaping goods; or (b) on the package in which the vaping goods are contained; or (c) on any material included with the package in which the vaping goods are contained	notified vaping goods	the advertising must: (a) comply with the requirements specified in all of the following, as applicable to the vaping goods: (i) TGO 110; (ii) the MDSO; (iii) the essential principles; and (b) comply with the requirements for therapeutic goods specified in Part 3 of the Therapeutic Goods Advertising Code as if that Part applied to the vaping goods; and (c) not contain a prohibited representation or a restricted representation, as if one or more of those representations applied to the vaping goods
2	advertising that is directed exclusively to one or more of the following persons: (a) a medical practitioner; (b) a nurse practitioner; (c) a pharmacist; (d) a practice manager or purchasing officer for a person mentioned in paragraphs (a) to (c)	notified vaping goods	the advertising must: (a) only contain representations or information relating to all of the following: (i) the availability and price of the vaping goods; (ii) information necessary for the safe and effective use of the vaping goods; (iii) information about the vaping goods, including the indications or intended purposes, ingredients, formulation, composition, design specification or presentation; and (b) comply with the requirements for therapeutic goods specified in Part 3 of the Therapeutic Goods Advertising Code, as if that Part applied to the vaping goods; and

Authorised advertising			
Column 1	Column 2	Column 3	Column 4
Item	Advertising	Vaping goods	Conditions
			<ul style="list-style-type: none"> (c) contain the notification ID number and the indications or intended purposes; and (d) not be inconsistent with the information provided in the sponsor notice for the vaping goods; and (e) not be promoted at educational, scientific, trade or social events; and (f) not offer any personal payments, gifts, price discounts, incentives, or commissions, in exchange for recommending or supplying the vaping goods; and (g) not contain or consist of samples, or an offer of samples, of the vaping goods that are intended to be provided to a patient; and (h) not contain testimonials or endorsements about the vaping goods; and (i) not contain a prohibited representation or a restricted representation, as if one or more of those representations applied to the vaping goods
3	<p>advertising directed exclusively to and between persons who are engaged in the business of wholesale supply and retail supply of the vaping goods in accordance with:</p> <ul style="list-style-type: none"> (a) paragraph (h) of item 15 of Schedule 5A to the TG Regulations; or (b) paragraph (g) of item 2.17 of Part 2 of Schedule 4 to the MD Regulations 	notified vaping goods	<p>the advertising must:</p> <ul style="list-style-type: none"> (a) only contain representations or information relating to all of the following: <ul style="list-style-type: none"> (i) the availability and price of the vaping goods; (ii) information necessary for the safe and effective use of the vaping goods; (iii) information about the vaping goods, including the indications or intended purposes, ingredients, formulation, composition, design specification or presentation; and (b) comply with the requirements for therapeutic goods specified in

Authorised advertising			
Column 1	Column 2	Column 3	Column 4
Item	Advertising	Vaping goods	Conditions
			<p>Part 3 of the Therapeutic Goods Advertising Code, as if that Part applied to the vaping goods; and</p> <p>(c) contain the notification number and the indications or intended purposes; and</p> <p>(d) not be inconsistent with the information provided in the sponsor notice for the vaping goods; and</p> <p>(e) not be promoted at educational, scientific, trade or social events; and</p> <p>(f) not offer any personal payments, gifts, price discounts, incentives, or commissions, in exchange for recommending or supplying the vaping goods; and</p> <p>(g) not contain or consist of samples, or an offer of samples, of the vaping goods that are intended to be provided to a patient; and</p> <p>(h) not contain testimonials or endorsements about the vaping goods; and</p> <p>(i) not contain a prohibited representation or a restricted representation, as if one or more of those representations applied to the vaping goods</p>
4	<p>advertising that is advice or information given directly to a patient by one or more of the following persons, in the course of the treatment of that patient for smoking cessation or the management of nicotine dependence:</p> <p>(a) a medical practitioner;</p> <p>(b) a nurse practitioner;</p> <p>(c) a pharmacist</p>	notified vaping goods	<p>the advertising must:</p> <p>(a) only contain representations or information relating to one or more of the following:</p> <p>(i) the availability and price of the vaping goods;</p> <p>(ii) information necessary for the safe and effective use of the vaping goods;</p> <p>(iii) information about the vaping goods, including the indications or intended purposes, ingredients, formulation, composition, design specification or presentation; and</p>

Authorised advertising			
Column 1	Column 2	Column 3	Column 4
Item	Advertising	Vaping goods	Conditions
			<ul style="list-style-type: none"> (b) comply with the requirements for therapeutic goods specified in Part 3 of the Therapeutic Goods Advertising Code, as if that Part applied to the vaping goods; and (c) contain the indications or intended purposes; and (d) not contain testimonials or endorsements about the vaping goods; and (e) not contain a prohibited representation or a restricted representation, as if one or more of those representations applied to the vaping goods
5	advertising that is, or forms part of one or more of the following: <ul style="list-style-type: none"> (a) a Commonwealth health campaign; (b) a State health campaign 	vaping goods	

Part 2—Medicinal cannabis vaping goods

Authorised advertising			
Column 1	Column 2	Column 3	Column 4
Item	Advertising	Vaping goods	Conditions
1	advertising that is: <ul style="list-style-type: none"> (a) on the label of the vaping goods; or (b) on the package in which the vaping goods are contained; or (c) on any material included with the package in which the vaping goods are contained 	medicinal cannabis vaping goods	the advertising must: <ul style="list-style-type: none"> (a) comply with the requirements specified in TGO 93 as applicable to the vaping goods; and (b) comply with the requirements for therapeutic goods specified in Part 3 of the Therapeutic Goods Advertising Code, as if that Part applied to the vaping goods; and (c) not contain a prohibited representation or a restricted representation, as if those representations applied to the vaping goods
2	advertising that is directed exclusively to one or more persons mentioned in subsections 42AA(1) or (2) of the Act	medicinal cannabis vaping goods	
3	advertising that is advice or information given directly to a patient by a person mentioned in paragraphs 42AA(1)(a), (aa) or subsection 42AA(2) of the Act in the course of treatment of that patient	medicinal cannabis vaping goods	