Therapeutic Goods (Vaping Goods—Other Indications) Determination 2024

I, Nicholas Henderson, as delegate of the Minster for Health and Aged Care, make the following determination.

Dated 29 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—Other Indications) Determination 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 *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024* commence. However, this instrument does not commence at all if the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024* 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Note: This table relates only to the provisions of this instrument as originally made.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 41RA 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) included in the Register;
(b) indications;
(c) medical device;
(d) medical practitioner;
(e) medicine;
(f) Register;
(g) registered goods;
(h) therapeutic goods;
(i) vaping device;
(j) vaping goods;
(k) vaping substance.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

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

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

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

Regulations means the *Therapeutic Goods Regulations 1990*.

5 Other indications for which vaping goods may be used

For the purposes of paragraph 41QB(11)(a) of the Act, in relation to each item of the table in Schedule 1, the indications in column 3 are determined to be indications (other than smoking cessation or management of nicotine dependence) for which the vaping goods in column 2 may be used.

Schedule 1—Other indications for which vaping goods may be used

Note: See section 5.

Other indications for which vaping goods may be used		
Column 1	**Column 2**	**Column 3**
Item	**Vaping goods**	**Indications**
1	a vaping good	the following: (a) for goods approved under paragraph 19(1)(b) of the Act—one or more indications specified in the approval; (b) for a medical device approved under paragraph 41HB(1)(e) of the Act—one or more intended purposes specified in the approval; (c) for goods exempt under item 3 of Schedule 5A to the Regulations—one or more indications set out in the notice that is given in accordance with that item; (d) for medical devices exempt under item 2.3 in Part 2 of Schedule 4 to the MD Regulations—the intended purpose set out in the notice that is given in accordance with that item
2	a medicinal cannabis vaping good	the following: (a) for a medical device included in the Register—one or more intended purposes accepted in relation to the inclusion of the medical device in the Register; (b) for a medical device approved under subsection 41HB(1)(d) of the Act—one or more intended purposes specified in the approval; (c) for a medical device authorised for supply under subsection 41HC(1) of the Act—one or more intended purposes specified in the authorisation; (d) for a medical device authorised for supply under rules made under subsection 41HC(6) of the Act—one or more purposes specified in the rules; (e) for medical devices exempt under regulation 7.2 of the MD Regulations, in relation to a person who is a Category A patient within the meaning of subregulation 7.2(2)—the use of the device in relation to the treatment of the person's condition, as set out in the statement referred to in subparagraph 7.2(1)(b)(ii) of the MD Regulations
3	a vaping substance that is: (a) a medicinal cannabis product; or	the following: (a) for registered goods—one or more indications that are accepted in relation to the inclusion of the goods in the Register;

Other indications for which vaping goods may be used		
Column 1	**Column 2**	**Column 3**
Item	**Vaping goods**	**Indications**
	(b) a medicine that contains synthetic cannabis	(b) for goods approved under subsection 19(1)(a) of the Act—one or more indications specified in the approval; (c) for goods authorised for supply under subsection 19(5) of the Act—one or more indications specified in the authorisation; (d) for goods authorised for supply under rules made under subsection 19(7A) of the Act—one or more indications specified in the rules; (e) for goods exempt under regulation 12A of the Regulations, in relation to a person who is a Category A patient within the meaning of subregulation 12A(5)—the use of the good in relation to the treatment of the person's condition, as set out in the statement referred to in subparagraph 12A(2)(a)(iii) of the Regulations