Therapeutic Goods (Information Specification—Therapeutic Vaping Goods and Vaping Devices) Instrument 2023

I, Anthony Lawler, as delegate of the Minster for Health and Aged Care, make the following instrument.

Dated 15 December 2023

Professor Anthony Lawler
Deputy Secretary
Health Products Regulation Group
Department of Health and Aged Care

Contents

1 Name

This instrument is the *Therapeutic Goods (Information Specification—Therapeutic Vaping Goods and Vaping Devices) Instrument 2023*.

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 the commencement of the *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023*. However, this instrument does not commence at all if the *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023* 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Note: This table relates only to the provisions of this instrument as originally made.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 subsections 61(5AB) and (5D) 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) Commonwealth officer;
(b) presentation;
(c) Secretary;
(d) sponsor;
(e) therapeutic goods.

(1) In this instrument:

Act means the *Therapeutic Goods Act 1989*.

Australian Taxation Office means the part of the Treasury portfolio that administers the taxation regulatory framework.

Commonwealth authority means an authority of the Commonwealth that has functions relating to therapeutic goods, health or law enforcement.

Note: Examples of Commonwealth authorities include the Department of Home Affairs (including the Australian Border Force), the Australian Criminal Intelligence Commission and the Australian Federal Police.

Customs Regulations means the *Customs (Prohibited Imports) Regulations 1956*.

disposable therapeutic vape has the same meaning as in the TG Regulations.

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

sample has the same meaning as in the TG Regulations.

state or territory authority means an authority of a State or Territory that has functions relating to therapeutic goods, health or law enforcement.

TG Regulations means the *Therapeutic Goods Regulations 1990*.

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

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

Therapeutic Goods Administration, or ***TGA***, means the part of the Department known as the Therapeutic Goods Administration.

therapeutic goods information has the meaning given by subsection 61(1) of the Act.

therapeutic vaping device has the same meaning as in the MD Regulations.

therapeutic vaping device accessory has the same meaning as in the MD Regulations.

therapeutic vaping goods has the same meaning as in the TG Regulations.

therapeutic vaping kit has the same meaning as in the TG Regulations.

therapeutic vaping pack has the same meaning as in the TG Regulations.

therapeutic vaping substance has the same meaning as in the TG Regulations.

therapeutic vaping substance accessory has the same meaning as in the TG Regulations.

(2) For the avoidance of doubt, a reference in this instrument to a sample includes a sample (or part of a sample) taken, collected or otherwise obtained:
  (a) under the Act; or
  (b) under regulations made under the Act (including the *Therapeutic Goods Regulations 1990*); or

(c) by, or at the request or on the instruction of, a Commonwealth officer, including in the exercise of the executive power of the Commonwealth.

(3) For the avoidance of doubt, a reference in this instrument to examination or testing includes examination or testing conducted or otherwise carried out:

(a) under the Act; or

(b) under regulations made under the Act (including the *Therapeutic Goods Regulations 1990*); or

(c) by, or at the request or on the instruction of, a Commonwealth officer, including in the exercise of the executive power of the Commonwealth.

5 Release of therapeutic goods information

(1) For the purpose of subsection 61(5AA) of the Act, in relation to each item in the table in Schedule 1, the kinds of therapeutic goods information specified in column 2 may be released to a person, body or authority (or kinds of persons, bodies or authorities) specified in column 3, for the purposes specified in column 4.

Note: Under subsection 61(5AA) of the Act, the Secretary may release to a person, body or authority that is specified, or is of a kind specified, under subsection 61(5AB), specified kinds of therapeutic goods information for a specified purpose.

(2) For the purpose of subsection 61(5C) of the Act, the kinds of therapeutic goods information specified in the table in Schedule 2 may be released to the public.

Note: Kinds of therapeutic goods information specified under subsection 61(5D) of the Act may be released by the Secretary to the public under subsection 61(5C).

Schedule 1—Release of therapeutic goods information to a person, body or authority

Note: See subsection 5(1).

Therapeutic goods information that may be released to a person, body or authority			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Kinds of therapeutic goods information**	**Persons, bodies or authorities**	**Purposes**
1	information about one or more therapeutic vaping goods, therapeutic vaping kits and goods in a therapeutic vaping pack (the ***relevant goods***), including but not limited to the following: (a) details about the relevant goods, including formulation, composition, design specification or presentation; (b) information about the importation, manufacture or supply of the relevant goods; (c) information about the sponsor of the relevant goods; (d) information about other persons involved, or apparently involved, in the importation, manufacture or supply of the relevant goods; (e) a notice, or information about a notice, or the absence of a notice, that relates to the relevant goods under item 15 in Schedule 5A to the TG Regulations or 2.17 in Part 2 of Schedule 4 to the MD Regulations; (f) a determination, or information about a determination, by the Secretary under item 15	the following persons, bodies or authorities: (a) a Commonwealth authority; (b) a state or territory authority; (c) the Australian Taxation Office	to support compliance and enforcement activities relating to the importation, manufacture and supply of the relevant goods

Therapeutic goods information that may be released to a person, body or authority			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Kinds of therapeutic goods information**	**Persons, bodies or authorities**	**Purposes**
	in Schedule 5A to the TG Regulations or item 2.17 in Part 2 of Schedule 4 to the MD Regulations that relates to the relevant goods; (g) information about a compliance or enforcement activity conducted, or proposed to be conducted, in relation to the relevant goods, including but not limited to search, seizure, destruction, recall, the giving of an infringement notice, or the commencement of a civil penalty proceeding or criminal prosecution; (h) information or evidence provided by the sponsor to support statements made in a notice under item 15 of Schedule 5A to the TG Regulations or item 2.17 of Part 2 of Schedule 4 to the MD Regulations; (i) complaints, intelligence or any other information about the compliance of the relevant goods with requirements under the Act, including but not limited to the conditions of an applicable exemption; (j) complaints, intelligence or any other information about the compliance of persons involved, or apparently involved, in the importation, manufacture or supply of the relevant goods;		

Therapeutic goods information that may be released to a person, body or authority			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Kinds of therapeutic goods information**	**Persons, bodies or authorities**	**Purposes**
	(k) information about compliance with an applicable standard or the essential principles (as relevant); (l) a consent, or information about a consent, or the absence of a consent, that relates to the relevant goods under sections 14, 14A, 41MA or 41MAA of the Act; (m) an approval, or information about an approval, or the absence of an approval, that relates to the relevant goods under sections 19, 41HB or 41HC of the Act; (n) a permit, or information about a permit, or the absence of a permit, issued under regulation 5 or 5A of the Customs Regulations that relates to the relevant goods; (o) information relating to an investigation or finding about compliance of the relevant goods with regulations 5 or 5A of the Customs Regulations; (p) information relating to the examination or testing, and the results of the examination or testing, of a sample of the relevant goods		
2	information about a starting material that is an ingredient or component for use in the manufacture of a therapeutic vaping substance, therapeutic vaping substance accessory,	the following persons, bodies or authorities: (a) a Commonwealth authority; (b) a state or territory	to support compliance and enforcement activities relating to the importation, manufacture and supply

Therapeutic goods information that may be released to a person, body or authority			
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Item	**Kinds of therapeutic goods information**	**Persons, bodies or authorities**	**Purposes**
	including but not limited to: (a) details about the starting material, including formulation, composition or presentation; (b) information about the importation, manufacture or supply of the starting material; (b) information about the sponsor of the starting material; (c) information about other persons involved, or apparently involved, in the importation, manufacture or supply of the starting material; (d) a notice, or information about a notice, or the absence of a notice, that relates to the starting material under item 16 in Schedule 5A to the TG Regulations; (e) information about a compliance or enforcement activity conducted, or proposed to be conducted, in relation to the starting material, including but not limited to search, seizure, destruction, recall, the giving of an infringement notice, or the commencement of a civil penalty proceeding or criminal prosecution; (f) complaints, intelligence or any other information about the compliance of the starting material with requirements under the Act, including but not	authority; (c) the Australian Taxation Office	of the starting material

Therapeutic goods information that may be released to a person, body or authority			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Kinds of therapeutic goods information**	**Persons, bodies or authorities**	**Purposes**
	limited to compliance with the conditions of an applicable exemption; (g) complaints, intelligence or any other information about the compliance of persons involved, or apparently involved, in the importation, manufacture or supply of the starting material; (h) information about compliance of the starting material with an applicable standard (if any); (i) a consent, or information about a consent, or the absence of a consent of the Secretary under sections 14 or 14A of the Act that relates to the starting material (if any); (j) a permit, or information about a permit, or the absence of a permit, issued under regulations 5 or 5A of the Customs Regulations that relates to the starting material; (k) information relating to an investigation or finding about the compliance of the relevant goods with regulations 5 or 5A of the Customs Regulations; (l) information relating to the examination or testing, and the results of the examination or testing, of a sample of the starting material		
3	information about an article or component for use in the manufacture of a therapeutic	the following persons, bodies or authorities: (a) a Commonwealth	to support compliance and enforcement activities relating to the

Therapeutic goods information that may be released to a person, body or authority			
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	vaping device or therapeutic vaping device accessory, including but not limited to: (a) details about the article or component, including design specification or presentation; (b) information about the importation, manufacture or supply of the article or component; (c) information about the sponsor of the article or component; (d) information about other persons involved, or apparently involved, in the importation, manufacture or supply of the article or component; (e) a notice, or information about a notice, or the absence of a notice, that relates to the article or component under item 2.18 in Part 2 of Schedule 4 to the MD Regulations; (f) information about a compliance or enforcement activity conducted, or proposed to be conducted, in relation to the article or component, including but not limited to search, seizure, destruction, recall, the giving of an infringement notice, or the commencement of a civil penalty proceeding or criminal prosecution; (g) complaints, intelligence or any other information about the compliance of the article or component	authority; (b) a state or territory authority; (c) the Australian Taxation Office	importation, manufacture and supply of the article or component

Therapeutic goods information that may be released to a person, body or authority			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Kinds of therapeutic goods information**	**Persons, bodies or authorities**	**Purposes**
	with requirements under the Act, including but not limited to compliance with the conditions of an applicable exemption; (h) complaints, intelligence or any other information about the compliance of persons involved, or apparently involved, in the importation, manufacture or supply of the article or component; (i) information about compliance of the article or component with the essential principles (if relevant); (j) a consent, or information about a consent, or the absence of a consent, that relates to the article or component under sections 41MA or 41MAA of the Act (if relevant); (k) a permit, or information about a permit, or the absence of a permit, issued under regulation 5A of the Customs Regulations that relates to the article or component; (l) information relating to an investigation or finding about the compliance of the relevant goods with regulation 5A of the Customs Regulations; (m) information relating to the examination or testing, and the results of the examination or testing, of a sample of the article or component		

Therapeutic goods information that may be released to a person, body or authority			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Kinds of therapeutic goods information**	**Persons, bodies or authorities**	**Purposes**
4	information about a therapeutic cannabis vaping device or a therapeutic cannabis vaping device accessory (the ***relevant goods***), including but not limited to the following: (a) details about the relevant goods, including design specification or presentation; (b) information about the importation, manufacture or supply of the relevant goods; (c) information about the sponsor of the relevant goods; (d) information about other persons involved, or apparently involved, in the importation, manufacture or supply of the relevant goods; (e) a notice, or information about a notice, or the absence of a notice, that relates to the relevant goods under: (i) item 2.1 in Part 2 of Schedule 4 to the MD Regulations; or (ii) paragraph 5A(13)(a) of the Customs Regulations; (f) an approval, or information about an approval, or the absence of an approval, that relates to the relevant goods under sections 41HB or 41HC of the Act; (g) information about a	the following persons, bodies or authorities: (a) a Commonwealth authority; (b) a state or territory authority; (c) the Australian Taxation Office	to support compliance and enforcement activities relating to the importation, manufacture and supply of the relevant goods

Therapeutic goods information that may be released to a person, body or authority			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Kinds of therapeutic goods information**	**Persons, bodies or authorities**	**Purposes**
	compliance or enforcement activity conducted, or proposed to be conducted, in relation to the relevant goods; (h) complaints, intelligence or any other information about the compliance of the relevant goods with requirements under the Act, including but not limited to compliance with the conditions of an applicable exemption; (h) complaints, intelligence or any other information about the compliance of persons involved, or apparently involved, in the importation, manufacture or supply of the relevant goods; (i) information about compliance of the relevant goods with the essential principles; (j) a consent, or information about a consent, or the absence of a consent, that relates to relevant goods under sections 41MA or 41MAA of the Act; (k) a permit, or information about a permit, or the absence of a permit, issued under regulation 5A of the Customs Regulations that relates to the relevant goods; (l) information relating to an investigation or finding about the compliance of the relevant goods with regulation 5A of the Customs Regulations;		

Therapeutic goods information that may be released to a person, body or authority			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Kinds of therapeutic goods information**	**Persons, bodies or authorities**	**Purposes**
	(m) information relating to the examination or testing, and the results of the examination or testing, of a sample of the relevant goods		
5	information about a disposable therapeutic vape, including but not limited to: (a) details about the disposable therapeutic vape, including formulation, composition, design specification or presentation; (b) information about the importation, manufacture or supply of the disposable therapeutic vape; (c) information about the sponsor of the disposable therapeutic vape; (d) information about other persons involved, or apparently involved, in the importation, manufacture or supply of the disposable therapeutic vape; (e) information about a compliance or enforcement activity conducted, or proposed to be conducted, in relation to the disposable therapeutic vape, including but not limited to search, seizure, destruction, recall, the giving of an infringement notice, or the commencement of a civil penalty proceeding or criminal prosecution;	the following persons, bodies or authorities: (a) a Commonwealth authority; (b) a state or territory authority; (c) the Australian Taxation Office	to support compliance and enforcement activities relating to the importation, manufacture and supply of the disposable therapeutic vape

Therapeutic goods information that may be released to a person, body or authority			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Kinds of therapeutic goods information**	**Persons, bodies or authorities**	**Purposes**
	(d) complaints, intelligence or any other information about the compliance of the disposable therapeutic vape with requirements under the Act, including but not limited to compliance with the conditions of an applicable exemption; (h) complaints, intelligence or any other information about the compliance of persons involved, or apparently involved, in the importation, manufacture or supply of the disposable therapeutic vape; (e) a permit, or information about a permit, or the absence of a permit issued under regulations 5 or 5A of the Customs Regulations that relates to the disposable therapeutic vape; (f) information relating to an investigation or finding about the compliance of the disposable therapeutic vape with regulation 5 or 5A of the Customs Regulations; (g) information relating to the examination or testing, and the results of the examination or testing, of a sample of the disposable therapeutic vape		

Schedule 2—Release of therapeutic goods information to the public

Note: See subsection 5(2).

Therapeutic goods information that may be released to the public	
Column 1	**Column 2**
Item	**Kinds of therapeutic goods information**
1	the following information relating to one or more therapeutic vaping goods, therapeutic vaping kits or goods in a therapeutic vaping pack (the ***relevant goods***) that are the subject of a notice under item 15 in the table in Schedule 5A to the TG Regulations or item 2.17 in the table in Part 2 of Schedule 4 to the MD Regulations: (a) details of the relevant goods, including strength and presentation; (b) details of the sponsor of the relevant goods; (c) the date the relevant notice was given by the sponsor to the Secretary; (d) information relating to the compliance of the relevant goods with the applicable standards, essential principles, or any consent given in relation to the relevant goods under section 14, 14A, 41MA or 41MAA of the Act; (e) other information relating to compliance of the relevant goods with the conditions of the exemption under which the notice was given
2	the following information relating to one or more starting materials that are the subject of a notice under item 16 in the table in Schedule 5A to the TG Regulations, or one or more articles or components that are the subject of a notice under item 2.18 in the table in Part 2 of Schedule 4 to the MD Regulations: (a) details of the starting materials, articles or components; (b) details of the sponsor of the starting materials, articles or components; (c) the date the relevant notice was given by the sponsor to the Secretary; (d) information relating to compliance of the starting materials, articles or components with the conditions of the exemption under which the notice was given
3	the following information relating to one or more therapeutic vaping goods, therapeutic vaping kits or goods in a therapeutic vaping pack (the ***relevant goods***) that are the subject of a determination under item 15 in the table in Schedule 5A to the TG Regulations or item 2.17 in the table in Part 2 of Schedule 4 to the MD Regulations: (a) details of the relevant goods; (b) details of the sponsor of the relevant goods; (c) the date of the determination; (d) the reasons for the determination; (e) information relating to actions, or possible actions, that may be reasonable and appropriate to take under the Act in the interests of public health and safety
4	the following information relating to the therapeutic goods mentioned in items 1 or 2 that are not the subject of a notice mentioned in those items: (a) details of the goods; (b) details of the sponsor of the goods;

Therapeutic goods information that may be released to the public	
Column 1	**Column 2**
Item	**Kinds of therapeutic goods information**
	(c) information about the importation, manufacture and supply of the goods;
	(d) information relating to actions, or possible actions, that may be reasonable and appropriate to take under the Act in the interests of public health and safety