



Therapeutic Goods (Information Specification— Therapeutic Vaping Goods and Vaping Goods) Instrument 2024

I, Nick Henderson, as delegate of the Minister for Health and Aged Care, make the following specification instrument.

Dated 30 June 2024

Nick 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 (Information Specification—Therapeutic Vaping Goods and Vaping Goods) Instrument 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 5 to 11 of Schedule 1 to the <i>Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024</i> commences. 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Note: This table relates only to the provisions of this instrument as originally made.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 subsections 61(5AB), (5D), (7B) and (7D) 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) Commonwealth authority;
- (c) corresponding State law;
- (d) Secretary;
- (e) supply;
- (f) therapeutic goods;
- (g) vaping goods.

- (1) In this instrument:

Act means the *Therapeutic Goods Act 1989*.

authority means:

- (a) a Commonwealth authority; or
- (b) a department of State of the Commonwealth or a State; or
- (c) a department or administrative unit of the Public Service of a Territory; or
- (d) an authority of the Commonwealth, a State or Territory;

that has functions relating to vaping goods, therapeutic goods, health, revenue or law enforcement.

Note: Examples of authorities include the Department of Home Affairs (including the Australian Border Force), the Australian Criminal Intelligence Commission, the Australian Federal Police, the Australian Commission on Safety and Quality in Health Care, the Australian Taxation Office, the Queensland Police Service, the New South Wales Ministry of Health and HealthShare Victoria.

customs legislation means the *Customs Act 1901* and all regulations made under that Act.

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

relevant therapeutic vaping good means one or more of the following:

- (a) a therapeutic vaping good;
- (b) a therapeutic cannabis vaping good;
- (c) a therapeutic vaping kit;
- (d) goods in a therapeutic vaping pack.

sample has the same meaning as in the TG regulations.

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

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

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

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

TG Regulations means the *Therapeutic Goods Regulations 1990*.

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

- (2) 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 a corresponding State law; or
 - (b) under regulations made under the Act (including the TG Regulations and MD Regulations) or a corresponding State law; 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; or
 - (d) by, or at the request or on the instruction of, an officer of a State or Territory exercising a power or function under the Act, a corresponding State law or regulations made under the Act or a corresponding State law.

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- (3) A reference in this instrument to testing includes examination, analysis or testing conducted or otherwise carried out:
- (a) under the Act or a corresponding State law; or
 - (b) under regulations made under the Act (including the TG Regulations and MD Regulations) or a corresponding State law; 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; or
 - (d) by, or at the request or on the instruction of, an officer of a State or Territory exercising a power or function under the Act, a corresponding State law or regulations made under the Act or a corresponding State law.

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 column 2 of the table in Schedule 2 may be released to the public.

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

6 Release of vaping goods information

- (1) For the purpose of subsection 61(7A) of the Act, in relation to each item in the table in Schedule 3, the kinds of vaping 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(7A) 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(7B), specified kinds of vaping goods information for a specified purpose.

- (2) For the purpose of subsection 61(7C) of the Act, the kinds of vaping goods information specified in column 2 of the table in Schedule 4 may be released to the public.

Note: Kinds of vaping goods information specified under subsection 61(7C) of the Act may be released by the Secretary to the public under subsection 61(7D).

7 Repeals

Each instrument that is specified in Schedule 5 to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

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 (or kinds of persons, bodies or authorities)			
Column 1	Column 2	Column 3	Column 4
Item	Kinds of therapeutic goods information	Persons, bodies or authorities	Purposes
1	<p>information relating to one or more relevant therapeutic vaping goods, including (but not limited to) the following:</p> <p>(a) the particulars of the relevant therapeutic vaping good, including strength, formulation, composition, design specification or presentation;</p> <p>(b) the actual, attempted, suspected or proposed importation, exportation, manufacture, supply, possession or advertising of the relevant therapeutic vaping good, including information about the identity or conduct of:</p> <p>(i) the sponsor, wholesaler, supplier, advertiser or possessor of the good;</p> <p>(ii) persons involved, or apparently involved, in the actual, attempted, suspected or proposed importation, exportation, manufacture, supply, possession or advertising of the good;</p>	<p>the following persons, bodies or authorities:</p> <p>(a) an authority</p>	<p>to support cooperation, and otherwise to seek or provide assistance, in monitoring, compliance and enforcement activities under Commonwealth, State or Territory law relating to the importation, exportation, manufacture, supply, possession or advertising of relevant therapeutic vaping goods</p>

Therapeutic goods information that may be released to a person, body or authority (or kinds of persons, bodies or authorities)

Column 1	Column 2	Column 3	Column 4
Item	Kinds of therapeutic goods information	Persons, bodies or authorities	Purposes
	<p>(c) information about compliance with requirements under the Act and any instruments made under the Act, or any other Commonwealth, State or Territory law, including (but not limited to) information relating to the following:</p> <p>(i) any relevant exemption, consent, authority, approval, permit, permission, licence, determination or other authorisation (a relevant authorisation);</p> <p>(ii) any information held by the Department relating to a relevant authorisation or application for a relevant authorisation;</p> <p>(iii) compliance with customs legislation;</p> <p>(d) any decision or action taken under the Act and any instruments made under the Act, or any other Commonwealth, State or Territory law in relation to a relevant therapeutic vaping good;</p> <p>(e) monitoring, compliance or enforcement activity conducted, or proposed to be conducted, in relation to a relevant therapeutic vaping good,</p>		

Therapeutic goods information that may be released to a person, body or authority (or kinds of persons, bodies or authorities)

Column 1	Column 2	Column 3	Column 4
Item	Kinds of therapeutic goods information	Persons, bodies or authorities	Purposes
	including (but not limited to) the following: <ul style="list-style-type: none">(i) surveillance, search, seizure, forfeiture, destruction or recall of a relevant therapeutic vaping good;(ii) the commencement, progress or result of a civil penalty proceeding, a criminal prosecution or a proceeding seeking an injunction in relation to any act or omission related to a relevant therapeutic vaping good;(f) information relating to testing, and the results of testing, of a sample of a relevant therapeutic vaping good;(g) information relating to an ingredient, component, reagent, material or other article that is, is intended to be or is suspected of being, used in the manufacture of a relevant therapeutic vaping good		

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	<p>information relating to one or more relevant therapeutic vaping goods that are the subject of an exemption, consent, authority, approval, licence, determination or other authorisation (a <i>relevant authorisation</i>) under:</p> <ul style="list-style-type: none">(a) the Act and any instrument made under the Act; or(b) the customs legislation; <p>including (but not limited to) information relating to the following:</p> <ul style="list-style-type: none">(c) details of a relevant therapeutic vaping good, or a sample of a relevant therapeutic vaping good, including strength, formulation, composition, design specification or presentation;(d) details of the sponsor, supplier or advertiser of a relevant therapeutic vaping good;(e) the actual, attempted, suspected or proposed importation, exportation, manufacture or supply of a relevant therapeutic vaping good, or the withdrawal of a relevant therapeutic vaping good from supply in Australia;(f) any information held by the Department relating to an authorisation or application for a relevant authorisation;(g) compliance with requirements under the Act and any instruments made under the Act, including the details of any review undertaken by the Department in relation to the compliance of a relevant therapeutic vaping good with these requirements;(h) information relating to an adverse event which is, or may be associated with, the use of a relevant therapeutic vaping good;(i) information relating to testing, and the results of testing, of a relevant therapeutic vaping good, or a sample of a relevant therapeutic vaping good, including information relating to the quality, safety or efficacy of the good;(j) information relating to actions, or possible actions, that may be reasonable and appropriate to take in the interests of public health or safety, including safety alerts or recall actions about actual or potential dangers or health risks associated with the use of a relevant therapeutic vaping good;(k) the safe use of a relevant therapeutic vaping good;(l) information relating to the appropriate disposal of a relevant therapeutic vaping good;(m) information relating to an ingredient, component, reagent, material or other article that is, is intended to be or is suspected of being, used in the manufacture of a relevant therapeutic vaping good
2	<p>information relating to one or more relevant therapeutic vaping goods that are or have been, or are suspected of being or having been, imported into, exported from, manufactured or supplied in, Australia, including (but not limited to) the following:</p>

Therapeutic goods information that may be released to the public

Column 1 Column 2

Item	Kinds of therapeutic goods information
(a)	details about a relevant therapeutic vaping good, or a sample of a relevant therapeutic vaping good, including strength, formulation, composition, design specification or presentation;
(b)	details of the actual or apparent sponsor, supplier or advertiser of a relevant therapeutic vaping good;
(c)	the actual, attempted, suspected or proposed importation, exportation, manufacture or supply of a relevant therapeutic vaping good, including details about the location and premises where the relevant therapeutic vaping goods have been supplied, stored or otherwise dealt with;
(d)	information relating to an adverse event which is, or may be associated with, the use of a relevant therapeutic vaping good;
(e)	information relating to testing, and the results of testing, of a relevant therapeutic vaping good, or a sample of a relevant therapeutic vaping good, including information relating to the quality, safety or efficacy of the good;
(f)	information relating to actions, or possible actions, that may be reasonable and appropriate to take in the interests of public health or safety, or patient safety, including safety alerts or recall actions about actual or potential dangers or health risks associated with the use of a relevant therapeutic vaping good;
(g)	information relating to the appropriate disposal of a relevant therapeutic vaping good;
(h)	information relating to an ingredient, component, reagent, material or other article that is, is intended to be or is suspected of being, used in the manufacture of a relevant therapeutic vaping good

Schedule 3—Release of vaping goods information to a person, body or authority

Note: See subsection 6(1).

Vaping goods information that may be released to a person, body or authority (or kinds of persons, bodies or authorities)			
Column 1	Column 2	Column 3	Column 4
Item	Kinds of vaping goods information	Persons, bodies or authorities	Purposes
1	<p>information relating to one or more vaping goods, including (but not limited to) the following:</p> <p>(a) the particulars of the vaping good, including strength, formulation, composition, design specification or presentation;</p> <p>(b) the actual, attempted, suspected or proposed importation, exportation, manufacture, supply, possession or advertising of the vaping good, including information about the identity or conduct of:</p> <p>(i) the sponsor, wholesaler, supplier, advertiser or possessor of the good;</p> <p>(ii) persons involved, or apparently involved, in the actual, attempted, suspected or proposed importation, exportation, manufacture, supply, possession or advertising of the good;</p> <p>(c) information about compliance with requirements under the</p>	<p>the following persons, bodies or authorities:</p> <p>(a) an authority</p>	<p>to support cooperation, and otherwise to seek or provide assistance, in monitoring, compliance and enforcement activities under Commonwealth, State or Territory law relating to the importation, exportation, manufacture, supply, possession or advertising of vaping goods</p>

Vaping goods information that may be released to a person, body or authority (or kinds of persons, bodies or authorities)

Column 1	Column 2	Column 3	Column 4
Item	Kinds of vaping goods information	Persons, bodies or authorities	Purposes
	<p>Act and any instruments made under the Act, or any other Commonwealth, State or Territory law, including (but not limited to) information relating to the following:</p> <p>(i) any relevant exemption, consent, authority, approval, permit, permission, licence, determination or other authorisation (a relevant authorisation);</p> <p>(ii) any information held by the Department relating to a relevant authorisation or application for a relevant authorisation;</p> <p>(iii) compliance with customs legislation;</p> <p>(d) any decision or action taken under the Act and any instruments made under the Act, or any other Commonwealth, State or Territory law in relation to a vaping good;</p> <p>(e) monitoring, compliance or enforcement activity conducted, or proposed to be conducted, in relation to a vaping good, including (but not limited to) the following:</p> <p>(i) surveillance, search, seizure, forfeiture,</p>		

Vaping goods information that may be released to a person, body or authority (or kinds of persons, bodies or authorities)

Column 1	Column 2	Column 3	Column 4
Item	Kinds of vaping goods information	Persons, bodies or authorities	Purposes
	<p>destruction or recall of a vaping good;</p> <p>(ii) the commencement, progress or result of a civil penalty proceeding, a criminal prosecution or a proceeding seeking an injunction in relation to any act or omission related to a vaping good;</p> <p>(f) information relating to testing, and the results of testing, of a vaping good, or a sample of a vaping good;</p> <p>(g) information relating to an ingredient, component, reagent, material or other article that is, is intended to be or is suspected of being, used in the manufacture of a relevant vaping good</p>		

Schedule 4—Release of vaping goods information to the public

Note: See subsection 6(2).

Vaping goods information that may be released to the public	
Column 1	Column 2
Item	Kinds of vaping goods information
1	<p>information relating to one or more vaping goods that are the subject of an exemption, consent, authority, approval, licence, determination or other authorisation (a <i>relevant authorisation</i>) under:</p> <ul style="list-style-type: none">(a) the Act and any instrument made under the Act; or(b) the customs legislation; <p>including (but not limited to) information relating to the following:</p> <ul style="list-style-type: none">(c) details of a vaping good, or a sample of a relevant vaping good, including strength, formulation, composition, design specification or presentation;(d) details of the sponsor, supplier or advertiser of a vaping good;(e) the actual, attempted, suspected or proposed importation, exportation, manufacture or supply of a vaping good, or the withdrawal of a vaping good from supply in Australia;(f) any information held by the Department relating to an authorisation or application for a relevant authorisation;(g) compliance with requirements under the Act and any instruments made under the Act, including the details of any review undertaken by the Department in relation to the compliance of a vaping good with these requirements;(h) information relating to an adverse event which is, or may be associated with, the use of a vaping good;(i) information relating to testing, and the results of testing, of a vaping good, or a sample of a vaping good, including information relating to the quality, safety or efficacy of the good;(j) information relating to actions, or possible actions, that may be reasonable and appropriate to take in the interests of public health or safety, including safety alerts or recall actions about actual or potential dangers or health risks associated with the use of a vaping good;(k) the safe use of a vaping good;(l) information relating to the appropriate disposal of a vaping good;(m) information relating to an ingredient, component, reagent, material or other article that is, is intended to be or is suspected of being, used in the manufacture of a vaping good
2	<p>information relating to one or more relevant vaping goods that are or have been, or are suspected of being or having been, imported into, exported from, manufactured supplied or possessed in, Australia, including (but not limited to) the following:</p> <ul style="list-style-type: none">(a) details about a vaping good, or a sample of a vaping good, including strength, formulation, composition, design specification or presentation;

Vaping goods information that may be released to the public

Column 1 Column 2

Item	Kinds of vaping goods information
	<ul style="list-style-type: none">(b) details of the actual or apparent sponsor, supplier or advertiser of a vaping good;(c) the actual, attempted, suspected or proposed importation, exportation, manufacture or supply of a vaping good, including details about the location and premises where the vaping goods have been supplied, stored or otherwise dealt with;(d) information relating to an adverse event which is, or may be associated with, the use of a vaping good;(e) information relating to testing, and the results of testing, of a vaping good, or a sample of a relevant vaping good, including information relating to the quality, safety or efficacy of the good;(f) information relating to actions, or possible actions, that may be reasonable and appropriate to take in the interests of public health or safety, or patient safety, including safety alerts or recall actions about actual or potential dangers or health risks associated with the use of a vaping good;(g) information relating to the appropriate disposal of a vaping good;(h) information relating to an ingredient, component, reagent, material or other article that is, is intended to be or is suspected of being, used in the manufacture of a vaping good
3	information about decisions or actions taken under the Act and any instruments made under the Act, in relation to one or more relevant vaping goods

Schedule 5—Repeals

Note: See section 7.

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

1 The whole of the instrument

Repeal the instrument.